RRI IMPLEMENTATION
IN BIOSCIENCE ORGANISATIONS

GUIDELINES FROM THE  STARBIOS2 PROJECT

Andrea Declich with the STARBIOS2 partners

STARBIOS2 project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 709517.

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- University System of Maryland – UMB
- Fundacao Oswaldo Cruz – FIOCRUZ
- Uppsala University, Centre for Research Ethics & Bioethics – UUCRB

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FOREWORD

A model and some practical guidance for initiating change

These Guidelines are dedicated to promoting the practice of Responsible Research and Innovation (RRI) and a related structural change within research organisations of the biosciences sector. They represent one of the outputs of the project "**Structural Transformation to Attain Responsible BIOSciences – STARBIOS2**". RRI has been defined by the European Commission (EC) as:

> *"An approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation.*
>
> *Responsible Research and Innovation (RRI) implies that societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society".*

To encourage the reading of these Guidelines, it is useful to clarify the reasons why RRI and the related structural change should be an interesting and relevant objective for the intended readers, i.e., researchers, professionals and managers within research organisations in the biosciences. We can do this by presenting the **main assumption** at the basis of this work: **science, including the biosciences, and society co-evolve**. As some scholars stated (Bijker, 2018), "we live in a technological culture". Consequently, "we cannot hope to understand society and culture without understanding the role of science and technology" and, conversely, "to apply science and to design technologies without understanding their embeddedness in society and culture".

Such an assumption can be **further specified**. The relationship between science and society is becoming "much more intense and

complex. While, in the context of industrial society, science and society had few relations, being limited by social and institutional mechanisms (it is not by chance that universities were viewed as "ivory towers"), today, in the context of post-industrial society, they continuously interact at different levels, producing widespread phenomena of overlapping and hybridization, but also conflicts and mutual rejection. Pursuing a harmonious science-society co-evolution, therefore, becomes particularly difficult, even though increasingly necessary, since science more and more needs society and society, to develop, more and more needs science" (Bijker & d'Andrea, 2009).

This strong connection has many consequences, including that an increasing part of the working life of – at least some – (bio)scientists is devoted to dealing with the social relationships implied by the implementation of scientific research. Indeed, bioscientists' work is not strictly limited to laboratories. Researchers normally try to address the urgent challenges that are being faced by organisations and people in the biosciences. For example, they are variedly involved in other important tasks, going from presenting results to other scientific communities, to industry, to policy makers and, increasingly, to the public and civil society's representatives. Bioscientists do this also because they know that trust towards science has to be continuously reinvigorated. Furthermore, many bioscientists are actively engaged in efforts to improve the overall research systems. Some of them are engaged in the promotion of the best use of the human capital to its full potential, including the promotion of the condition of women in science.

Through the results of their research, **scientists have a role to play in society and in managing relations with society's other sectors**. In a changing context – science and society are undergoing dramatic and interconnected changes – this implies that the actors within science – also as responsible citizens – have at least part of the fate of the science-and-society relations in their hands. They actually play such a role in a number of ways. Unfortunately, they rarely play it systematically, and oftentimes without a full awareness and in

unfavourable organisational settings. For this reason, these Guidelines present jointly RRI and structural change within research organisations: the idea is that the practice of RRI in the biosciences should be supported also through changes that permeate research organisations in a durable way. The initiative of individuals or of groups of people, in order to be durable, should be reflected also in the organisations' structure and functioning.

How to play that role? How could scientific research organisations and the related activities change to improve the co-evolution of science and society? **RRI and structural change** in research organisations in the biosciences **concern these issues**.

These Guidelines outline some ideas and messages on RRI practice and structural change so to contribute to reflection and action. After a brief introduction, there is a section dedicated to a Model on the practice of RRI in bioscience research organisations; the following section contains some guidance on how to practice such a model and then a section describing the structural change process in practice and, particularly, some critical aspects of the implementation of RRI through dedicated Action Plans. The Guidelines are provided with one Appendix and one Annex that contain some brief texts (called, respectively Box and Note) that deal with some particular issues that emerge as relevant for the reading of the Guidelines and, in general, for the practice of RRI and structural change.

1. INTRODUCTION

These Guidelines are a tool to promote, within biosciences research organisations, a **structural change** (i.e., a durable transformation of a research organisation) that facilitates the practice of **Responsible Research and Innovation (RRI)**. They are one of the outputs of the project "Structural Transformation to Attain Responsible BIOSciences – STARBIOS2", funded by the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 709517.

The Guidelines arise from the **practical experience of implementing Action Plans** carried out by the research organisations involved in the STARBIOS2 project, from the **mutual learning** activity among the STARBIOS2 partners, also supported by a study and update of RRI issues (for a brief description of the Action Plans, see Appendix **Box #1**).

The Guidelines aim to help readers to **formalize and trigger structural change** aimed at introducing RRI-related practices that are appropriate to their own organisations. The Guidelines are not a series of prescriptions, but an **itinerary of reflection and self-interpretation** that is **addressed to different actors** within the biosciences, such as: researchers, research organisations managers and technical staff members, professionals within research-funding organisations, students and others. Although these Guidelines are not designed for their specific needs, they could be useful to science policy-makers as well. In very general terms, the Guidelines' readers are people who intend to promote RRI or to emphasize responsibility within the research activities in which they are engaged, or who are trying to collect resources for designing and implementing activities with this end (see Appendix, **Box #2**).

To support this itinerary of reflection and self-interpretation, the document provides:

- A description of a general **RRI Model** for research organisations within the biosciences, that is a set of ideas, premises and "principles of action" that define the practice of RRI in bioscience research organisations.

- Some practical **guidance for designing interventions** to promote RRI in research organisations in the biosciences, putting into practice the RRI Model.
- A set of **useful practices** in implementing the structural change process.

Information on particular **STARBIOS2 cases and experiences**, as well as **materials, tools and sources**, are also provided in the Appendix and in the Annex.

THE STARBIOS2 PROJECT IN BRIEF

The STARBIOS2 project (https://starbios2.eu) aims to contribute to the advancement of the RRI strategy underpinning Horizon 2020. The specific objectives of the project are to attain RRI structural change – i.e., a change that we assume is comprehensive, inclusive, contextualized and irreversible – in 6 European institutions (in Bulgaria, Germany, Italy, Slovenia, Poland, and the United Kingdom) through the implementation of Action Plans (APs) and to develop APs for 3 non-European institutions active in the field of biosciences (in Brazil, South Africa and the United States); to use the implementation of APs as a learning process to developing a set of guidelines on the implementation of RRI; and to develop a sustainable model for RRI in biosciences. The STARBIOS2 project has been designed and is currently being carried out by 9 institutions developing & implementing APs in partnership with further 3 institutions from Denmark, Italy, and Sweden, charged with internal evaluation, technical assistance for the APs implementing research organisations, and communication and dissemination. The project is coordinated by the University of Rome Tor Vergata.

2. AN RRI MODEL FOR RESEARCH ORGANISATIONS IN THE BIOSCIENCES

2.1 Crisis in the relationship between science and technology, and society

Science's autonomy is increasingly constrained by an overall change, in the way science is shaped and managed, affecting its structures, norms, values and practices. Such a transition is somehow similar to that affecting other social sectors, from politics, policy-making, and religion, to family and public administration: the shift towards the so-called "knowledge society" or "post-modern society". In this framework, scientific research and the related innovation activities face increasing difficulties.

Co-evolution science–society

Science and society **co-evolve**, but this relationship is changing. In this framework, today, there are many **critical issues**, involving also the biosciences.

Some trends in scientific activities

The ways in which scientific activities are carried out are changing continuously. Some **trends** could be highlighted, to be considered both as **risks and opportunities** (Bijker & d'Andrea, 2009):

- The diffusion of cooperative practices in scientific production
- The increasingly "context driven" character of research that is more and more governed by problem solving and opportunity exploitation concerns, and not primarily by traditional disciplines of knowledge
- The increasing diversity of the sites where research is carried out
- The increasing relevance of transdisciplinarity in research activities
- The increasing importance for the control of the research quality of actors beyond peers

- The increasing need for making science accountable towards a wide range of actors
- The increasing expectation that scientific results have economic impacts
- The orientation of policy-makers towards leading and steering the research process
- The bureaucratization of research (increasing burden of regulation and standardization)
- The increasing importance of the relationship between universities, governments and industries
- The access to public funds for research is increasingly competitive.

Problems for science

This situation brings about some **strong problems for science** that are not limited only to inadequate funding (especially for basic research).

Young and women researchers

Other critical issues concern the **people** working within the scientific sector, e.g.: researchers are, in many cases, actors who endure difficult conditions, especially the **young** ones who face the need of career mobility and the precariousness of positions (in the literature and in the public debate there is a growing concerns for the issue of precarious conditions also among researchers with a higher seniority level[1]); **women** too are suffering discrimination in scientific settings, more related to their progressively difficult access to top positions than to the very access to scientific careers (this also gauges forms of hidden discrimination).

Cost of publications and open access

Costs of publication are also a real issue since the evaluation of a scientist is more and more based on the number of publications. However, **open access is not so easy** considering that research data may

[1] See, for example: Stephan, P. (2013); Alberts, B. et al. (2014); Musselin, C. (2007); Herschberg, J. et al. (2018).

generate profit and there are growing difficulties in guaranteeing the quality of research.

Fragmentation of science

In this framework we note a de-standardization and fragmentation of the scientific world's **internal mechanisms**, a lack of internal **unity and consistency**, a weakening of the internal and external **boundaries**, and the fact that **research results** are sometimes unsatisfying or below expectations from an economic point of view (a picture of the critical areas of the life of scientists is provided in Appendix, **Box #3**).

The knowledge society

Society itself, as a whole, **is continuously changing**. We have moved from an industrial society (characterized by strong and well-defined structures and rules, hierarchical relationships, State's centrality, clear boundaries between sectors, groups, disciplines and competences) to a more fragmented, globalised, dynamic and disordered **knowledge** (or "post-modern") **society**, where science and technology are acquiring a social and economic weight they never had before (Bijker & d'Andrea, 2009). These phenomena are characterizing, indeed, the entire social life and concerns sectors such as politics and policy making, religion, family and so on (Bijker & d'Andrea, 2009; d'Andrea et al., 2017).

This implies that the ways in which **relations between Science & Technology (S&T) and society** have been regulated in the past are **no longer appropriate**. Various difficulties emerge, for example[2]: the decreasing authority of scientists and an increasing lack of consensus toward them; the diffusion of anti-scientific attitudes; a wider demand for an open research process to a closer public scrutiny; the diffusion and consolidations of stereotypes about science and technology; the increased resistance of scientists to engage more with society[3].

New difficulties for science, in terms of authority, consensus, etc.

The resulting picture seems to be that of **an overall transition** of the scientific world. The old way of managing the relation between science and society, based on a clear **distinction between basic research** (self-regulated and not "disturbed" by outside steering), and **applied research** (which is subject to immediate questions about relevance and external steering) is no longer valid and increasingly contested.

Basic and applied research

[2] Some items of the list emerged during the implementation of the APs foreseen by the STARBIOS2 project. For other criticalities see, for example: d'Andrea, L. et al. (2017); Bijker, W., & d'Andrea, L. (2009); Mezzana, D. et al. (2011).

[3] Various authors have pointed the presence of cultural and cognitive resistances towards public engagement and its embedment in academic institutions, for example: Watermeyer, R. (2015); Royal Society (2006); Burchell, K. (2015); Burns, D., Squires, H., (2011).

Fig. 1 — A schematic representation of relationship between Science and Society

The itinerary proposed in point 2.1 can be summarised through the pictures to the right.

The Model for RRI in bioscience research organisations has to do with the complex relationship between science and society. We could think that science, formed by different and variously related scientific communities, could be represented by an area within society as a whole (Fig. 1a).

The first step in the itinerary of the model is dedicated to the relations between these two areas (Fig. 1b). The focus is on the continuous exchanges between them, represented by double tipped arrows: input from science should be embraced by society and vice-versa. The point is that such exchanges have to be managed. The occurrence of a transition from an older way to manage this relationship, represented in Fig. B and a new one, is evident in Fig. 1c where the set of double-tipped arrows in the new situation is different from the past (more arrows in Fig. 1c than in Fig. 1b; the longer arrows represent the main institutional channels for science and society relations, and the shorter ones the new and less established exchanges).

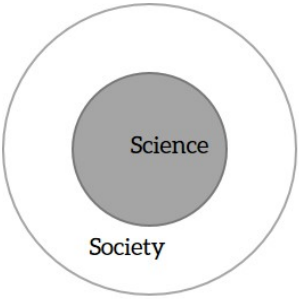


Fig. 1a

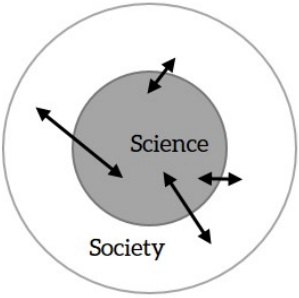


Fig. 1b

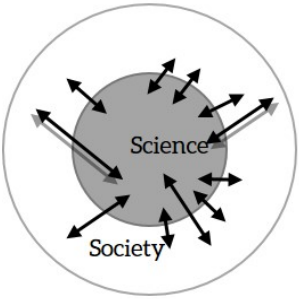


Fig. 1c

2.2 RRI as a possible way to face crisis

The RRI approach, launched by the EC, is a possible way to face the crisis in this transition phase. S&T has clear social impacts to be managed. Inherent in the RRI approach is the assumption that scientists engaged in research and innovation activities – together with other societal actors – try to evaluate the possible impacts and implications of their work, and anticipate the social expectations this work generates.

Talking about **RRI** could be **a way to face the critical** situation caused by the increased importance of S&T to society. Some **policies** have been devised to cope with this transition. In this regard, the European Commission (EC) launched the concept of RRI in 2011 and later put it at the centre of the Horizon 2020 Framework Research Programme (2013-2020). One of the most recent definitions of RRI provided by EC is the following:

Definition of RRI according to the EC

> *"Responsible research and innovation is an approach that anticipates and assess potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation.*
>
> ***Responsible Research and Innovation** (RRI) implies that societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society.*

5+1 RRI keys

*In practice, RRI is implemented as a package that includes multi-actor and **public engagement** in research and innovation, enabling **easier access** to scientific results, the take up of **gender** and **ethics** in the research and innovation content and process, and formal and informal **science education**[4]".*

An additional key: Governance

Another definition states that the RRI "package" includes an additional element (each element is defined as a "key"): **governance**, to "develop harmonious models for Responsible Research and Innovation that integrate public engagement, gender equality, science education, open access and ethics".

Other definitions of RRI – not necessarily inconsistent with the EC's one – do exist. One of the most accepted, proposed by Stilgoe et al. (2013), states that "responsible innovation means taking care of the future through collective stewardship of science and innovation in the present"[5]. In order to do so, those in the research and innovation sector are asked to act in the framework of 4 dimensions:

Dimensions of RRI action

- **Anticipation** – considering the possible research developments, the related risks and opportunities as well as the possible actors concerned
- **Inclusion** – involving, in this reflection, the actors who can contribute to a better understanding of the research developments and their consequences
- **Reflexivity** – analysing the meaning of the results of this reflection for the various actors involved

[4] http://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation (accessed on: 05/09/2019).

[5] Other relevant definitions have been proposed in literature over the years, but those described above are among the most influential. Comprehensive literature reviews have been provided, among others, by the GREAT and FIT4RRI projects (d'Andrea, L. et al., 2017).

- **Responsiveness** – applying consequent measures to research and innovation practices.

Social responsibility

An important challenge of RRI is that the full assumption of **social responsibility by research actors** can contribute to **solving many of the critical issues** emerging in the relations between S&T and society, **without betraying the basic mission of research and innovation:** producing new knowledge and make it available for new economic and social practices. This aspect is important since being responsible towards society beyond normal professional duties could be seen by scientists as a further burden for all those within the S&T sector who are already dealing with difficult situations.

We can consider the **RRI keys** as areas of the life of scientific communities in which the **criticalities, or most crucial aspects**, of the science-society relations are more evident.

Public engagement

1. **Public Engagement** is when the scientific community openly deals with other social and economic actors. Here the scientific communities justify and express the reasons for requesting resources and funds. If the S&T sector has missed the strong legitimacy that it had in the past, public engagement becomes an area in which it finds many difficulties.

Gender

2. **Gender** increasingly affects the life of the Scientific Community. Gender issues – due to the growing recognition of the relevance of women in society and of their presence in the public life, working environment and scientific community – challenge the current (and biased) ways in which human resources are recruited and managed, as well as the interpretive models that are strongly based on the exclusion of gender as a key variable in research programmes.

Open access

3. **Open access** is the "practice of providing on-line access to scientific information that is free of charge to the reader".

It concerns the circulation and evaluation of research results; the ways in which that takes place, including the limitations connected to the existing business models in the publishing sector; all are of the utmost importance to researchers' work and careers.

4. **Ethical issues** are related to the ways in which scientific advancements are critically scrutinized in terms of the possible harms they can produce, or in terms of compliance of research practices with the existing normative systems. Such assessment is becoming the context in which the scientific community risks conflict with other social actors. The ethical issues are connected also to the ways in which the S&T makes information about its own research procedures available (e.g., the correct way to conduct animal tests or inform patients).

Ethical issues

5. **Education** is another important area where S&T and society interact. Scientific education, beyond producing new generations of scientists (that are aware of RRI), has to aim also at creating a public that knows and acknowledges the characteristics of the scientific enterprise and its positive impacts on technology, economy and society.

Education

6. **Governance** is related to the ways in which the scientific community participates in the policy making process. This is a very important aspect of the S&T sector's existence since research and innovation are closely connected (regulation of scientific research, research funding, innovation policies for translating new findings, etc.).

Governance

It is by intervening in these areas – the RRI keys – that one can deal with critical science and society relations and show that RRI can be achieved.

Fig. 2 — RRI as a possible way to manage science-society relationship

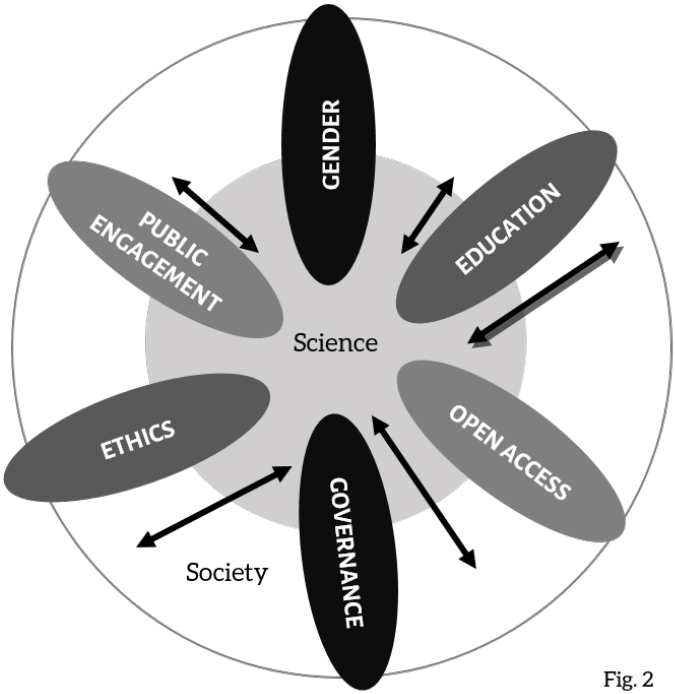


Fig. 2

RRI could be represented as one of the ways in which such an exchange with society is managed, particularly as focused on areas of the life of the scientific communities in which the relations with society are particularly critical. It is represented by the 6 areas of Fig. 2, each representing one of the RRI keys. We can imagine that such kinds of exchanges are managed according to specific rules (e.g., the so called RRI dimensions). Managing in this way the relations between science and society could help to make the situation described in Fig. 1c more harmonious.

2.3 What does RRI mean for the biosciences?

RRI should be contextualized within the sector where it is to be practiced. In the case of the Bioscience sector, the awareness of RRI "sector specificity" could imply an open consideration of the critical developments occurring, and the challenges faced, also in view of sustainability issues. Taking these factors into account could lead to better (bio)science, that is more able to address potential knowledge gaps related to societal concerns (ranging from economic impacts to ethical issues).

RRI is a process that entails dialogue between the societal actors throughout the research and innovation process, including in the **biosciences**.

Bioscience sector

The "**bioscience sector**" refers here to all the organisations of a different nature (academic and non-academic, public and private, for-profit and non-profit) that carry out research activities, or that support research and innovation, in the biosciences disciplines that include biomedicine, biology, systems biology, biochemistry, nature conservation, and biotechnological sciences. This definition encompasses disciplines that deal with **living organisms** and with life processes using specific **concepts**, within a strong **interdisciplinary context** (see Appendix, **Box #4**). Organisations in the biosciences face similar or analogous issues of scientific, epistemological, methodological, economic, organisational or ethical nature (on the relation between biosciences and RRI, see Appendix, **Box #5**).

RRI is sector specific

RRI is strongly "**sector specific**", i.e., depending on the **main actors** and how they are organized, the relevant scientific **themes** and **challenges**, the

research **heuristics** and **methodologies**; the potential social, economic and cultural **impacts** of research and innovation, and the related open **ethical issues**. How professional, health and safety **standards** are set also changes based on the sector. **"Non-scientific" actors** (companies, NGOs, etc.) are also different depending on the sector, and so are the dynamics that characterize their activities (on the complexity of relations within the biosciences see Appendix, **Box #6**). All this affects also the contribution that biosciences can make to the **sustainability of research and innovation**.

Sustainability of research

Like S&T in general, the bioscience sector is under pressure because of the "**biological revolution**" that began in the last decades of the 20th century, triggered by recombinant DNA technology, and amplified by a tidal wave of big data from genomics, proteomics and other high-throughput analytic approaches[6].

The bioscience sector is under pressure

For example, in the pharmaceutical industry, research infrastructures and learning networks, rather than individual organisations, are becoming more and more important, the phenomenon of "mega-centres" arises, and new business models emerge. In this framework, issues connected to **societal engagement** and dialogue with the diverse stakeholders beyond those within Academia becomes particularly relevant (see Annex, **Note #2** on "RRI for biodiversity conservation" and the **Note #9** on "Providing information to society on plants and biotechnology"). The growing set of **diverse stakeholders** concerned

Diversity of stakeholders

[6] See ESFRI European Strategy Forum on Research Infrastructures (2006); the Biotechnology and Biological Sciences Research Council (BBSRC) of the UK defined this century as the "age of the biosciences".

with the development of the biosciences makes it particularly relevant to promote a wider access to the results of scientific research.

Ethical challenges

Biosciences raise a number of **ethical challenges** connected to specific research fields, especially those connected to the study of life processes (for example, organismal cloning or, in the past decades, test tube babies).

The biosciences are also a sector of scientific research in which there are **more women** compared to other sectors within STEM (see Annex, **Box #8** on gender in the bioscience). However, this does not imply an absence of gender **discrimination**. **Gender issues** are very relevant for the biosciences, not only because of considerations based on justice and fairness, but also because **sexual variables** are of the utmost importance in research even if this fact has not yet fully impacted the scientific practice, (see Annex, **Note #3** on gender and publishing).

Gender issues

Emerging challenges for education...

Further challenges for the Biosciences emerge, considering the remaining RRI keys. The **education** of the scientists that will face these challenges in the (near) future has become more and more important. Also, the relevant stakeholders should be trained so that they are able to understand the social and economic impacts of the main achievements produced within the Biosciences (see Annex, **Note #5** on "Science education as a trigger for RRI structural change").

Open access...

The wide diversity of actors in the biosciences is makes **Open Access** more and more critical[7]. While

[7] The general provisions of the EC on the practice of Open Access in the European Research can be found herehttp://ec.europa.eu/research/openscience/index.cfm?pg=openaccess (accessed on:

the need for enlarging the circulation of scientific results remains unchanged, other challenges emerges, for example the protection of the Intellectual Property of such results given their potential economic value. The orientation to Open Access included data sharing (see Annex, **Note #8** on "ZIKA in Brazil Real Time Analysis: an RRI experience"). This orientation is particularly critical for the biosciences since it has to do also with what is considered the problem of reproducibility of research results that is particularly relevant in the biosciences (see Von Schomberg, 2019).

...and governance

Furthermore, **governance** issues emerge connected to the need to manage research organisations that are able to cope with the complexity of the sector (see Annex, **Note #10** on "RRI and governance of complex research organisation").

Globalization and...

Globalization impacts Bioscience sector in a very peculiar way too when we consider issues such as the use of **indigenous knowledge** for research on new active principles to be used in the pharmaceutical field, or the management of new, un-expected, or "resurgent" **epidemics** (one of the challenges being faced by the biosciences). Furthermore, different national research and innovation systems work differently but, nevertheless, **mutual exchanges**

24/07/2019). The effort is currently focused to enlarging this orientation towards Open Science in the Member States. It is the so called "Plan S", promoted by Science Europe, a group of heads of national research funding organisations, and Robert-Jan Smits, Senior Advisor on Open Access within the European Political Strategy Centre at the European Commission, https://www.scienceeurope.org/wp-content/uploads/2018/07/Plan_S_Communication_110718.pdf (accessed on: 24/07/2019). The EC has endorsed the "Plan S" and so did also the European Research Council https://ec.europa.eu/commission/commissioners/2014-019/moedas/announcements/plan-s-and-coalition-s-accelerating-transition-full-and-immediate-open-access-scientific_en (accessed on: 24/07/2019).

have increased, for example, African universities exchanges with Western universities are increasing which raises the issue of standardization of academic titles and curricula (see Annex, **Note #6** on the issue of RRI for Africa); among the other things, this raises the issues of the multiplicity of ethical approaches in different cultures (see Annex, **Note #7** on the "African ethics of Ubuntu"). At the same time, various local systems create even more intense contacts amongst themselves without losing their local peculiarities (glocalization).

...glocalization

All this means that the scientific sector affects the **social and professional networks to which** research **organisations belong**, the **public** and **research policies** that are relevant to them, the **scientific** communication (a broad definition of scientific communication is provided in the Appendix, **Box #7**; on scientific dissemination see also Annex, **Note #11** on "Achieving impact: some arguments for designing a communications strategy") and the "**mediation functions**" required to maintain relations amongst all the relevant actors.

Relations amongst relevant actors

Fig. 3 — RRI and the bioscience

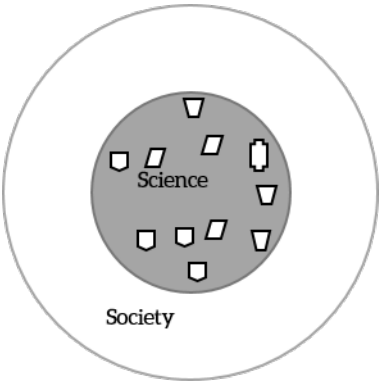


Fig. 3a

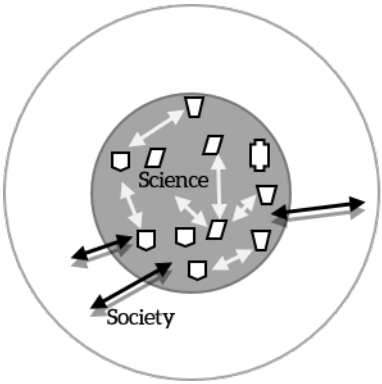


Fig. 3b

The model is based on the acknowledgement that the scientific world is not an undifferentiated area of social life. On the contrary within it there are a lot of differences and such diversity is organized by various institutional settings. Diversity consists also in differences between disciplines and sub-disciplines. Particularly, there are a number of different actors within the scientific communities. Such a differentiation of actors within science is represented as small geometric figures of various shapes (Fig. 3a). Various ways for describing diversity could be imagined. In particular, the biosciences sector could be understood as a sub-set of within the science area. Diversity has to do also with the ways in which RRI is (or can be) practiced (RRI is sector specific). Actors, within science and within biosciences, have various types of relations (Fig. 3b) among themselves and with the external world (e.g., each of them could have more or less relations of different type and there could be forms of coordination among actors of the same type).

2.4 Some principles of action

RRI makes sense only if it is useful for carrying out better research and innovation and for providing solutions to the problems of the professional life of the various actors within a given research organisation. To foster RRI-related structural change implies, among other things, that a vision of scientific activities is defined, the stages of the research process are reframed, the main characteristics of the research organisation (culture, agency, action, and identity) are affected by the promoted change.

RRI structural change

A set of "**Principles of action**" can be identified to put RRI into practice **within individual research organisations** and promote structural change accordingly. They should help each organisation in the biosciences (or groups within such organisations), to **define their own consistent set of practices** aimed at pursuing RRI. Each organisation defines **its own approach** to the practice of RRI based on an **interpretation** of its own characteristics and of the **context** in which it operates.

The "principles of action" are related to:

- The **assumptions** to be made to practice RRI within organisations
- The necessary definition of a **vision** of research
- The **stages** of the research process in which such a practice should enter
- The **aspects of the structure of an organisation** that have to be affected in order to make the RRI-oriented change structural.

The "principles of action" are hinged on an **operational definition of RRI** based on those presented above. Particularly, by the term **RRI** we

mean here the **activities/initiatives** carried out by a research organisation explicitly inspired by the EC's definition of RRI as well as activities that could be considered as "de-facto" RRI (even if not labelled as such), i.e. activities that in practice are **focused on one or more of the RRI keys** (Public engagement, Gender, Open access, Education, Ethics and Governance). More generally, by RRI here we mean **research and innovation practices** that consider the RRI keys and/or that are carried out according to an approach that **anticipates and reflects** about impacts, **includes** the **relevant actors** (within and outside the research organisations), and is **responsive** to them.

Explicit and "de facto" RRI actions

The role of the actors

Adopting some assumptions for the practice of RRI

RRI should be practiced as a **tool for carrying out better research and innovation** (see Appendix, **Box #9**) and for providing **solutions** to the problems of the **professional lives** of the various actors within research organisations. RRI practice, therefore, is able to address some of the most urgent challenges of research organisation (see Annex, **Note #1** reporting an experience conducted by one of the STARBIOS2 partners on the ways in which RRI addresses some of the challenges felt by individual organisations in the biosciences).

RRI for better research and innovation

This practice should take into consideration that RRI:

1. Is practiced for the benefit of **complex organisations**, which generally have **complex missions**
2. Is to be practiced not only by researchers but **also by other professionals** involved in research organisations or in research endeavours

3. Should entail the definition of **new roles** within a research organisation
4. Should not conflict with the main systems of incentives at work (see **Box #9** in the Appendix)
5. Should be **in line with the specific mission** of the research organisation.

A central aspect of research organisations' mission is the **production of new knowledge**. Therefore, **the practice of RRI should not divert the attention and efforts of researchers from their main goals**, rather it means conducting research while being aware of the relation between S&T and society. The practice of RRI and structural change consists also in **initiating a process that does not produce results instantaneously and that is going to continue over time**. There could be accelerations and stops, phases in which change is much focused, and others in which it has a wider scope.

Defining a research vision

RRI in research strategy and vision

Putting RRI at the centre of the research process begins at the moment a **research strategy** is defined. It includes also the **vision** a certain research group has of its scientific activities.

In very general terms, a "research vision" (see Appendix, **Box #10** "Research Vision: A definition and Its connection with RRI") means a specific way to approach research on certain topics and specific scientific questions and challenges to be addressed. It includes a set of scientific hypotheses and assumptions that are relevant within a broader research field. Oftentimes, a research vision includes some ideas concerning the possible applications and technical utilizations of the results

being pursued. In this sense, this vision is part of the agency of a specific research group. A vision is important for a research group because it is the basis for driving its overall activities.

When a research group, or an organisational unit, wants to define its own research vision, and its implementation strategy, **RRI issues could be raised**, e.g. concerning the ways in which sexual variables are managed, or whether the underlying assumptions address the policy-makers' or other stakeholders' priorities. The vision and the related strategies themselves are aimed at anticipating possible impacts of research (an example of how RRI could affect the definition of a research is provided in the Appendix, **Box #11**).

When a research group, or an organisational unit, tries to define its own research vision, and the related research strategy, it should **pay attention to its wider organisational setting** (e.g., the department for a research group or the university for a department). Some "**vectors**" of RRI should be singled out, understood as themes and objectives through which large organisations as a whole define the ways in which they pursue their mission(s), and could be stated in the overall mission of the organisation, or in broader strategic plans, etc. Each "vector" could imply the definition of strategies through which research and innovation could be consistently carried out by smaller units according to their disciplinary character. For example, the theme of **sustainability** has been chosen by one STARBIOS2 partner's university as pivotal to its policies; this could imply that RRI in biosciences is led by strategic themes such as nutrition, vaccination and infectious disease,

The vectors of RRI

nanotechnologies, etc. that could be understood also as the ways in which the biosciences contribute to the university orientation to sustainability.

Identifying the stages of research and innovation process relevant for RRI practice

RRI practice in the biosciences implies the adoption of an RRI orientation through the entire **research and innovation process**, which could co-evolve. There are various **stages** of the R&I process that could be reframed, for example: the search for **funds** and definition of **research projects**; the definition of **research protocols**; the **experiments** and their results; the definition of the **prototype**; the identification of **possible users** of the research output (see Appendix, **Box #12**).

RRI and the moments of research and innovation

Identifying the main aspects for RRI structural change within the research organisation

The practice of RRI suggested above does not consist of isolated initiatives and that practicing RRI in the framework of just one research project could be difficult. It could be easier if this practice **permeates an entire research organisation**.

RRI is easier if it permeates the entire research organisation

The **structural changes** needed to put RRI into practice as outlined above are **different for each organisation**. Some **structural aspects** of the **change** needed to practice RRI within an organisation concern, for example, the identification of **new roles** within the research organisation connected to various forms of societal dialogue, the redefinition of **research and innovation procedures** that involve the entire organisation, the redefinition of the

organisation's **mission and strategies**, and the definition of procedures to **control** this process.

A collective actor – in this case **a research organisation within the biosciences** – is a bearer of various internal characteristics that coexist and that bring about its dynamics. Such a perspective is based on a double assumption: each actor has a "**cognitive**" dimension[8] and an "**operational**" one[9], and its efforts are both aimed at the **self-construction** and at **modifying external reality**.

According to these assumptions, the examples of the **changes oriented to RRI** could be various but, in general, they must be **framed within four aspects** of an organisation.

RRI has to comply with:

1. The **culture** of the organisation, i.e., its overall worldview (e.g., as represented in documents such as vision statements, "strategic view" and so on), its values, the disciplinary background of their members, etc. — Culture
2. The **orientation to change**, or **agency**. The agency could be connected to the **scientific challenges of the sector** to which it belongs, say the biosciences; more generally, it could be related to pursuing a specific research programme. — Agency
3. The **action** of the organisation. This term refers to the actual implementation of activities connected to the organisational mission and core business. — Action
4. The **identity** of the organisation, that is the capacity of an organisation to implement its own objectives and programmes through its **internal structures**, i.e., how the staff is organized, how staff members interact with each other, how they establish relationships with external players; the endowment of human resources and skills; the ability to perform particular research routines, the available infrastructures. — Identity

[8] This dimension includes knowledge, ideas, representations of reality, feelings, etc.
[9] Within such dimension the actor takes action and becomes object of the action of others.

This scheme is useful for understanding **the actual practice of RRI – no matter if pervasive or still confined to small initial activities**. Should a strong hiatus emerge in the cognitive dimension (i.e., RRI not being an element of the organisation's culture or of its orientation to act) or in the operational dimension (i.e., where RRI is not translated into action, or the structure of the organisation is not able to support such an action), we could expect that RRI practice is going to be at best a temporary phenomenon, or that dissent concerning the opportunity to keep practicing it could emerge among the organisation's members. A similar outcome (see Appendix, **Box #20**) can be expected if the organisation is oriented to RRI for what concerns internal dynamics (e.g., including it in its regulation) without impacting external dynamics (e.g., RRI is not included in scientific and/or teaching activities).

THE MODEL: KEY MESSAGES

The Model that has been presented can be used for reflecting on the ways in which RRI can be practiced within research organisations in the biosciences sector. The key messages contained in the Model could be summarized by the following.

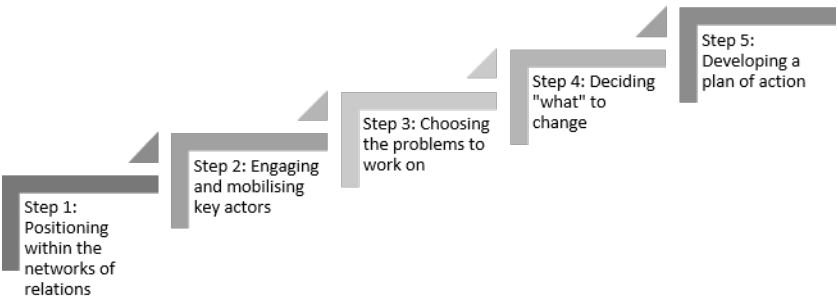
- In order to practice RRI it is necessary to consider that the relations between science and society are changing. This can be defined as a transition that impacts the professional life of scientists. The scientific community must face these issues.
- The practice of RRI is a possible response to the need for addressing systematically the science and society relationship. The RRI 5+1 keys represent areas in the life of scientific communities where the problems of relations between science and society emerge.
- The practice of RRI is "Sector specific" because it has to be contextualized in the different scientific sectors. Each scientific sector, indeed, receives several specific inputs and requests of a societal nature and research results represent important elements for the innovation of social and economic life.
- RRI sector specificity should imply an open consideration of the critical developments this research sector is taking, and the challenges that it faces.
- The way in which RRI is contextualized depends on the specific characteristics that the biosciences sector takes in different countries or regions. There is no unique interpretation of how RRI is influenced by various scientific sectors.
- The "Principles of action" contained in the model are aimed at making possible the practice of RRI within specific research organisations. They are tools that can be used so that each organisation defines its own approach to the practice of RRI based on an interpretation of its own characteristics and of the context in which it operates.

3. PRACTICAL GUIDANCE FOR USING THE MODEL TO PROMOTE RRI IN RESEARCH ORGANISATIONS IN THE BIOSCIENCES

The self-reflection process

The **second phase of the itinerary** proposes some suggestions for a **self-reflexive exercise** aimed at **contextualizing** the contents of the model and its practical meaning for the reader. The focus is on some of the issues that have to be addressed with the aim of designing an intervention for RRI oriented structural change within bioscience research organisations. The process can be summarized by the following figure.

Fig 4. Scheme of the self-reflection process



3.1 Positioning within the networks of relations

It is important that a research organisation formalizes its own position within the bioscience sector. Such an effort could be carried out by mapping the actors of the sector with which relations are maintained, and defining the position of each organisation concerning the main challenges being faced within the sector.

Self-positioning: 3 passages

A research organisation or a group within it has to be able to understand its own **position in the bioscience sector** or – more practically – the position within the part of the sector that is relevant for them. **Three passages** are needed.

A. Mapping the actors

The **first step** is individuating, or **mapping**, the most relevant "**external**" actors[10], those with which there are most similarities or differences from many angles (scientific, organisational, operational, etc.). Such actors could be research partners, including enterprises, research equipment suppliers and research services suppliers; funding agencies, donors and providers of research funds, including those in the private sectors that act as clients of research services. They could be also stakeholders of research activities that do not produce either scientific knowledge or innovation[11] such as representatives of research users; civil society organisations interested in the territorial impacts of research organisation activities; policy makers and regulators, both at the national and the local levels; professional organisations and so on (a possible list of types of

[10] Meant as actors not belonging to a given research organisation.
[11] Therefore, that are not strictly part of the sector but that are nevertheless affected by the research results.

actors in the biosciences is provided in the Appendix, **Box #13**). The relations with these actors can be very different in nature, ranging from representation activities, advocacy for common causes, customer-provider relationships, to cooperation for the achievement of common ends or for research activities. The management of relations with such a diverse set of actors is a complex task that requires **resources**, some form of **specialization**, and a strong **commitment**.

The mapping of relations with external actors can be made on the basis of various categories whose choice is, to a certain extent, arbitrary. As a matter of fact, there is not a set of categories that is a-priori correct, since they should help to define with as much detail as possible and on the basis of the actually available information (see Appendix, **Box #14**), the particular context in which each organisation operates. The choice of these categories is an attempt to contextualize the presence of an actor within the biosciences, and requires the **first important exercise of "self-interpretation"** (see Appendix, **Box #15**).

The biosciences are also characterised by some **specific challenges**, e.g.:

1. Policy challenges (the problems that are being addressed by International, Regional, national and local decision-makers and relevant for a given research organisation)
2. Scientific challenges (the particular knowledge gaps considered relevant within the scientific communities)
3. Innovation challenges (the demands coming from the industries concerning products and services that could be improved thanks to scientific research)

4. Ethical challenges (the ethical issues connected to new fields of research and innovation in which a given organisation is involved).

Having a **position about these challenges** serves to develop one's own vision, and this is the **second step**. Individuating the challenges does not mean defining them in absolute terms, but in terms that are relevant for a specific organisation (an example is proposed in the Annex, **Note #4** on "Technology transfer as a form of RRI").

The previous two steps are the necessary basis for the **third one** that is a critical analysis aimed at defining the **state of relations with other actors** and the possible critical aspects of these relationships.

C. Interpreting relations

3.2 Engaging and mobilising key "internal" actors

It is important to single out the "key" actors within organisations as a precondition for their mobilization. The first move is the identification and involvement of actors that already carry out RRI related activities.

There are different ways to mobilise the key actors

The process of change within research organisations depends on the **mobilization of the existing internal actors** (researchers, technical and administrative staff, librarians, etc. – both individuals and organized groups – see Appendix, **Box #16**) and on their possible orientation to change. The first move in this direction is the identification and involvement of actors that already carry out RRI-related activities. This implies also a **critical analysis** of their past experiences and of the **impacts** related to these activities (consensus obtained, conflicts raised, results obtained, etc.).

The actors within an organisation **can be spontaneously oriented to change and strongly motivated**. These actors can be identified and mobilized right away, for example through the establishment of a "core group" of people that promote change initiatives (see Appendix, **Box #17**). Other actors may be less interested (at least in an initial phase), or may be interested only in some aspects of the initiatives (e.g., being available to take action only on one of the RRI keys).

3.3 Choosing the problems to address

The promotion of RRI can be triggered by a clear identification of the problems to address and by an analysis of the current state of these problems. The consultation of internal actors is essential.

Using RRI keys to decide the problems to address

Based on the previous steps of the itinerary (i.e., the definition of the position within the biosciences including a vision about scientific activities, the identification of the internal actors oriented to practice in some form RRI) it **is possible to decide which problems should be addressed**. To do that, it could be helpful to use **the RRI keys** as analytical tools, since it could be decided to look at problems in the realm of the relationship with societal actors (public engagement), or at gender issues and so forth. Other choices, not driven by the use of the RRI keys, are possible and depend, indeed, on the results of the reflection process described previously.

The decision concerning the problems to address is an important step of the mobilization and change process. It involves the **consultation of the internal actors** within the research organisation.

3.4 Deciding what to change

The approach proposed here is based on the use of "Principles of action". Some domains of the organisation life could be the object of the action for change such as elements of organisational rules, roles and routines, aspects of the organisation's mission or groups' research visions, etc. Finally, the changes have to consistently impact the organisation's action, identity, culture and agency.

Another important moment is to **identify the things to be changed**.

Refer to the "Principles of action"

It may be useful to use the aforementioned "**Principles of action**". This implies, for example: taking into due consideration some "assumptions" connected to the practice of RRI; consider the complexity of organisations and the existence within them of various types of professionals; understand the need to activate new roles; respect the mission of the organisation. Furthermore, these actions of change must be consistent with the research "vision" of the groups called to practice it, and must be able to fit into the research process that constitutes the "engine" of organisations.

Considering some specific domains of action

In relation to the problems that have been identified, what can be changed concerns **the single organisation** (on the definition of these boundaries, see Appendix, **Box #18**), while other possible interventions, even if desirable, are beyond the scope of these Guidelines. By virtue of this, we must consider some **domains of the life of an organisation** in which it is possible to intervene, including: the formal and informal rules that determine the organisation's functioning, behaviour routines and some roles; non-research activities

(scientific communication, relations with civil society, etc.); the (re)definition of the organisation' mission, "vision statement" and objectives; the management of interactions between internal and external actors; negotiations to define the changes to be introduced; managing consent and possible conflicts related to these changes (negotiation is, indeed, a relevant aspect of change process as long as it has to do with actors interaction; see Appendix, **Box #19**).

Acting on these domains implies producing impacts on the **four aspects that shape organisations** (culture, agency, action and identity). In order to make changes that are "structural" and, in this framework, irreversible, these aspects of the organisation must be addressed in a coherent manner. For example, a new practice concerning gender in science once introduced thanks to a specific initiative, will take root if it is accepted within the organisation's culture, if it has to do with the agency of the internal actors, if it impacts the organisation's modus operandi (action) and if the organisation changes its structures so that such a practice can be reproduced (identity). The idea is that for rooting a change initiative – no matter its scope – a process should be triggered that impacts several aspects of the organisation life and, also for this reason, can be assumed as being gradual.

3.5 Developing a plan of action

Action Plans (APs) activate complex and non-linear processes. The scheme and specific steps of this process are presented here. APs are a tool for triggering the change, and a tool for managing the resulting complexity.

Ideally, the reflection path ends with the definition of an Action Plan (AP) aimed at the practice of RRI. It consists not only in describing a set of activities to be implemented over time with given resources, but also in activating a process of structural change. It is a **complex and non-linear process**, characterized by stops and starts, sudden progress and setbacks, unplanned solutions and deviations from the original plan (see Appendix, **Box #21**). The implementation of RRI initiatives requires pro-activity, flexibility and capacity to react rapidly to unexpected situations. An **Action Plan can be worked out in different ways** (a template for the design of the Action Plans is provided in the Annex, **Note #14**). You can start after an intense but brief design phase and then, in the implementation phase, make the necessary adjustments. Or, you can give precedence to an extensive and in-depth consultation, to start the actions in the most shared way possible. The choice between these two approaches depends on the context in which one operates, and obviously it is possible to identify intermediate solutions between them (on the two approaches, see the Appendix, **Box #22**).

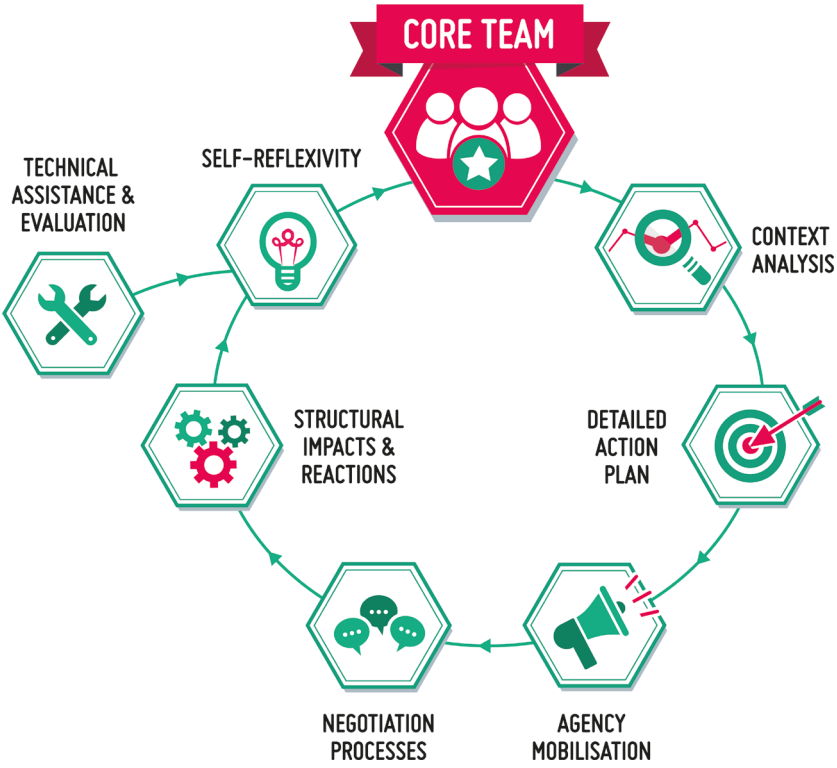
An Action Plan can be worked out in different ways

From a practical point of view, the Action Plans can be aimed at activating RRI-oriented changes through a process based on the following **steps**:

Action Plans: 7 steps to activate RRI-oriented changes

1. Activation of a **Core Team and Extended Team** to promote and implement the AP
2. Implementation of a **context analysis** of the AP setting
3. Definition of a **detailed AP**
4. **Mobilization of actors** for change towards RRI
5. **Negotiation processes** aimed at implementing the APs and addressing the emerging problems, conflicts and issues
6. Production of **structural impacts** and reaction
7. A **Self-reflective** exercise on the results being obtained and on the possible changes in the initially foreseen actions.

Fig 5. Scheme of the structural change process through the APs



PRACTICAL GUIDANCE: KEY MESSAGES

The Guidelines provide inspiration for a self-reflection aimed at contextualizing RRI and make it relevant for the needs of a research organisation in the biosciences. Particularly, from the Guidelines emerge the following key messages.

- In order to position an organisation within a network of relations it is necessary that an organisation reflects on its own relations and on the role it has in the biosciences sector, also in light of the most important challenges that the sector is facing; the results of such a reflection could be a basis of the definition of vision.
- The mobilization towards RRI of internal actors should be based on the assessment of their orientation to change. To this end, it is necessary to check if initiatives related to RRI have been already implemented in each organisation.
- The objectives to be reached for making possible the RRI practice and structural change have to be defined through the consultation of internal actors. The 5+1 RRI keys represent a possible guide for this consultation (i.e., the actors are consulted on themes related to one or more of such keys).
- The action oriented to RRI and structural change has to be within the scope of what can be done by an individual research organisation. Particularly, the action and the changes to implement should be chosen on the basis of this criterion and by implementing the "Principles of action".
- The definition of an Action Plan (AP) implies not only the consultation of the internal actors, but also the identification of the ways in which the changes generated have to be managed during the implementation of the AP.

4. THE STRUCTURAL CHANGE PROCESS IN PRACTICE

Action Plans (APs) activate complex and non-linear processes. The scheme and specific steps of this process are presented here. APs are a tool for triggering the change, and a tool for managing the resulting complexity.

The elaboration of an Action Plan implies the existence of a group of people willing to **promote and implement it**. Nevertheless, other **conditions** must also be fulfilled, such as people interested to support the promoters, the availability of resources and a permission or a mandate to operate (for example, the resolution of a governing body, the success in a call for tenders, etc.). If these conditions are fulfilled, the focus of attention shifts to the **implementation** of the planned actions.

The last part of the guidelines contains a presentation of some aspects of the actual experience of promoting RRI and structural change within research organisations in the biosciences through APs. This part is **mainly based on the relevant information collected on the implementation of APs** within STARBIOS2 (see Annex, **Note #12** and **Note #13**); some information is taken also from other sources (see the Appendix, **Box #23**). Particularly, the focus is on some "**Critical areas of implementation**", including several "**typical issues**" to be faced in order to trigger effectively a change process and promote RRI. For each area, **some practices are presented** that proved useful during the implementation of the APs or that emerged as such from the literature.

Critical areas of implementation, typical issues, and useful practices

The "critical areas of implementation" and the related "**useful practices**" are described in the paragraphs below.

4.1 Core Team establishment and maintenance

The first thing to do is the establishment of a *Core Team* whose leading function has to be maintained for the entire duration of an AP. The critical issues are: ensuring the **continuity and stability** of the Core Team composition; the acquisition of a wide set of **knowledge** and **competences**; **conciliating research activity and Core Team membership** (including the possible "time conflicts").

How to establish and maintain a Core Team for APs

Useful Practices

On the basis of the STARBIOS2 experience and of the literature a set of useful practices related to Core Team establishment and maintenance have been identified.

1. Setting up a multidisciplinary team

Some of the RRI keys are narrowly linked with specific disciplinary approaches, mostly belonging to social science and humanities, e.g., philosophy (ethics), communication science (societal engagement), sociology and psychology (gender), education science (education), data management science (open access). Moreover, the different phases of the AP may need specific competences that are not common for bioscientists such as those of social statistics (context analysis), political studies (implementation through negotiation), etc. Involving permanently in the Core Team people of these (and other) disciplines has been proven very useful for improving the effectiveness of the AP. Such process is facilitated if the institution where the AP is taking place is part of a university, in which inter-departmental or inter-faculty collaboration may be easier. Another possibility is hiring or involving in the Core Team experts from outside. It could be useful to create, around the Core Team, an Extended Team formed of people

that, even without a strong dedication, provide an enduring participation to the Core Team activities, particularly by providing specific expertise that could lack among the Core Team members.

Case from practical experience

The core group of one of the STARBIOS2 Action Plans was composed by the combination of two different bodies: the university and the university hospital. This approach allowed since the beginning the involvement of people with different disciplinary competences and expertise, ranging from social to medical sciences. Since Core Team members have been selected from different branches and organisations it was possible to have inside the Core Team an expert for each RRI key.

2. Including managerial skills in the team

An AP requires a set of management competencies that are not the same that are needed for doing research and are not necessarily available among research groups. Strategic management of resources, coordination of people with diverse professional and training backgrounds, the promotion of activities not directly connected to research work and related to RRI keys, the ability to set organisational objectives over time that are controllable and measurable, the ability to delegate others diverse task are all capacities that are needed for driving the AP along its different stages. For this reason, it is of pivotal importance to include managerial skills in the Core Team. This could be done in different ways: inserting in the team a professional research manager belonging to the institute where the AP is taking place, hiring or involving a manager from outside, or relying in non-professional people that have such skills even if they are not in their professional curricula.

3. Organising regular Core Team meetings for internal control and decision making

In order to guarantee continuity to the AP the set up of regular meetings with all the Core Team members is of pivotal importance for controlling the activities carried out and making decisions on the ongoing actions. Such meetings have proven useful even if they are brief. The presence of all team members fosters synergy among the different actions and sustains the sharing of the same vision among the team members. Moreover, through participating in regular meetings everybody in the Core Team is updated and knows what is going on in the different parts of the AP, whatever is its role or task. This allows mutual back-up inside the team and guarantees the continuity of action.

Case from practical experience

One of the STARBIOS2 APs had a Core Team composed of about 10 people. Since the beginning of the AP, the team decided to meet once in two weeks for updates and make decisions on the ongoing activities. At the beginning the meeting was causing problems to Core Team members since it was used as a space for in depth discussion, and its duration was uncontrolled. The team decided on a time limit for the meeting of 1 hour, so as to have a fast check of all the different actions and aspects ongoing in the Action Plan, and use small ad hoc meetings for in depth discussions. This approach saved time for Core Team members and made establishing regular meetings sustainable.

4. Designating a person dedicated to the AP

A practice that has proven valuable for implementation and impact is to designate a person prevalently dedicated to the AP. Such a person is not encumbered by other responsibilities, for example those connected to being a research group leader or carrying out the lab work. The person charged with the responsibility of the AP will be excluded from scientific, administrative and institutional duties and free from the stress that such responsibility brings about. In order to

be effective, the action of such a designated person should be trusted and backed by the Core Team leader and by the other Core Team members (in order to avoid that this function become peripheral). Under such conditions, the presence of a person dedicated to the AP facilitates continuity in time to the AP and a higher degree of coordination among the different actions.

4.2 Context Analysis and Detailed design

The success or failure of an Action Plan depends also on contextual factors. Therefore, critical aspects concern the **analysis of both external factors** (national policies and regulations, culture, etc.), and **internal factors** (organisational culture and values, leadership's attitudes, previous experiences within the organisation and the entire set of relations with external stakeholders). These are critical aspects of AP design, which should foresee the possibility to tackle the **problems and opportunities** for RRI and structural change that emerge during the implementation of the actions.

Analysing external and internal factors to design APs

Useful Practices

A set of practices for context analysis and detailed design identified in the STARBIOS2 and in other projects are reported below.

5. Adopting of a participatory design approach

A very practical way of analysing the internal context and increasing the relevance of the AP, is involving other actors in the design of the actions to be carried out for changing the organisation. Obviously, this can be done in different ways. In some cases informal meetings and in-depth discussions may be the privileged method of engaging other actors. In other cases, more formal approaches may be practiced such as ad hoc discussions and semi-public meetings for designing the AP, consultation through in depth interviews, or co-design workshops. These practices help to ensure that AP design makes the most of the information over the organisational context and that the viewpoints of various stakeholders enter in the definition of the actions to be undertaken. Furthermore, such an approach contributes to producing

a sense of ownership toward the AP that can help to face adverse contingencies, also of an external nature, that could occur during the project implementation.

6. Scouting previous RRI experiences present in the organisation

Another important practice is scouting and singling out the past experiences of the organisation in RRI and/or with RRI related initiatives can be singled out and considered. As a matter of fact, sometimes, especially at the beginning of the design phase, some of the past experiences are not widely known and acknowledged within the organisations (especially the largest ones). Leveraging what it has already been done is a way of using knowledge and resources that have been already activated for RRI or its related keys and also to get in touch with key people and network inside the organisation.

Case from practical experience

One of the STARBIOS2 Action Plans – operating in a University – carried out an extensive survey inside the organisation for identifying the initiatives related to the RRI keys and already ongoing. Interestingly, the visibility of many past experiences at the university level was very low at the beginning of the project. Through an internal analysis a set of interesting initiatives have been identified on the issues of gender equality, public engagement, science education, and open access. In order to do that the Core Team adopted different approaches ranging from analysing the University website, past and current research projects, conducting interviews and running a questionnaire, networking and meetings with important key players.

7. Identifying supporters and opponents

A useful practice of context analysis is the individuation of the possible internal supporters and opponents of RRI (or to some RRI keys). Such a "mapping" exercise can be carried out through consultation in the design phase of APs and entails both formal and

informal initiatives and discussions (as happened in STARBIOS2 and in other RRI projects). The identification of possible alliances is useful also in the following AP phases, since changes in the orientation of actors could emerge thanks to the very implementation that make the meaning of RRI clearer to them. The participatory and informal character of this activity has to be stressed, since the actual orientation of the actors (especially opposition) does not necessarily emerge openly and in formal contexts. Mapping could be considered, at least in part, as a by-product of the aforementioned consideration of the past experiences of RRI. These activities, normally, lead to the individuation also of actors that are available for cooperation with the AP. From this point of view, mapping exercise is a precondition of actors' mobilization effort, and implies various forms of negotiation.

Case from practical experience

One of the STARBIOS2 Action Plans was carried out in an organisation in which many people have difficulties to be involved in activities beyond the current academic duties. In the starting phase of the Action Plan it was very important for the Core Team to carry out a series of informal meetings with some key informants in order to identify which kind of alliances for promoting change should be established and on what issues. In practice, this activity identified the actors willing to participate in the Action Plan and those who, for diverse reasons, were reluctant.

8. Scanning of external opportunities and obstacles for development of APs

Contextualization of the AP has to do also with external actors and the environment in which the organisation operates. It is in this framework that it becomes relevant how the organisation is "positioned" within the biosciences, what are the external stakeholders with whom it keeps relations and their critical assessment (e.g., by considering strength and weaknesses of such a presence within the sector; the kind of cooperation and the possible

ways in which it could change). It is also in this framework that the current policies affecting the biosciences should be considered. The scanning of external opportunities and obstacles can be done in many different ways: participating at seminars, public meetings or conferences on the current trends and foreseen changes in scientific research at different levels (national, European, etc.); connecting with network or experts on RRI specific fields; establishing partnerships at national or international level; simply surveying the internet for collecting the needed information. It is worth stressing that the adoption of a participatory approach helps in carrying out this kind of assessment, since the internal actors participating in the exercise contribute to enrich the assessment of the relevant set of relations with external actors and, in general, of the actual position of the organisation within the biosciences.

Case from practical experience

The open access issue is new for some research institutes. One of the STARBIOS2 Action Plans started to work in this field through exploring the state of the art of this key issue at the national level. This analysis was proven to be very useful for the detailed design of the AP. In fact it identified and created connections with national contact points responsible for open access, network of experts, and similar projects carried out in other university and research institute of the same country. In this way the AP benefitted from a wide array of information, knowledge and resources for its design and implementation rather than starting from scratch.

9. Adopting of strategy-oriented design tools

Contextualization effort, to be effective, has to be translated consistently in the AP design. Particularly, the design of APs was carried out by maintaining a strategic attention to the changes that enable directly the practice of RRI within each organisation. In order to do this, in the STARBIOS2 experience, it was useful to propose as

the units of the AP design the so called "Stream of Actions" (SoAs), i.e., a set of coordinated actions aimed at achieving a change that is significant and feasible within the organisation context (each SoA was based on describing objectives and the context), inclusive (each SoA specified which actors to mobilise) and sustainable (each SoA was aimed at obtaining a specific change that may last beyond the end of the project).

10. Carrying out a periodical revision of the APs

Contextualization has to inform the entire duration of an AP. To this end, in the STARBIOS2 project, it proved useful to carry out a periodical revision of the APs (on an annual basis). It consisted in modifications ranging from small adjustments to major changes on the basis of an assessment of the many factors that lead to the success or difficulties of the actions undertaken (obstacles not initially foreseen; opposition by diverse actors, degree of support, etc.) and of the opportunities emerged for new initiatives.

4.3 The mobilisation of actors

The **mobilization of the internal social actors** – beyond the Core Team – is also crucial. The critical issues are: a possible **diffidence** toward RRI among bioscientists[12]; a **low priority** acknowledged to RRI related institutional changes[13]; participating in the AP and in the RRI activities **deviates from the main objectives and daily needs** of researchers[14].

Mobilizing internal actors is a critical effort

Useful Practices

A set of practices useful for mobilising actors have been identified both in the actual STARBIOS2 experience and through the initiatives surveyed in the literature.

11. Involve pro-RRI actors

Oftentimes inside research organisations there are actors that, in more or less developed ways, carry out RRI-related initiatives. While RRI is a relatively new approach, each of its 5 keys often has a tradition of practice, knowledge, network, etc. Nevertheless, sometimes people

[12] On this regards some authors stress that researchers tend not to consider themselves as non-responsible actors (Eden, G., Jirotka, M., & Stahl, B., 2013). These issues are relevant for the governance of research systems (Ruggiu, D., 2015). Some scholars underline that un-responsible outcomes of research could be the results of perfectly ethical individual behavior (Spruit, S.L., Hoople, G. D., & Rolfe, D.A. 2016).

[13] Becoming accountable beyond an actor own personal reach is not something immediately recognized as relevant by all the researchers. On the contrary, the sense of urgency for change of research organisations emerges as a relevant issue, including in the literature not immediately connected to RRI. This is the case of orientation towards entrepreneurial (and responsive to societal changes) universities, that would emerge when there is a crisis or the awareness that a certain problem has to be faced and solved (Kwiek, M., 2015), or the perception of internal and external challenges (Pinheiro, R., & Stensaker, B., 2014).

[14] Some authors observe that contemporary academia produces "structural forces" (individualization of researchers) that makes it difficult to reflect on responsibility related issues (Felt, U., Fochler, M., & Sigl, L., 2017). This has to do with the issue of incentives within research organisations and the practice of RRI that has been dealt with above.

active on these issues are not able to give continuity to their work. Involving people and groups active in the past on the different RRI keys is a good way of involving already interested people, of transmitting competences, and take over already developed actions instead of starting from scratch.

12. Involvement of Academic Leader in the AP

Involving organisations' leaders and the groups they belong to for the promotion of RRI and structural change is an important aspect of the actors' mobilization process. According to some studies on RRI, these actors should be those that are in charge of leading their organisation, managing the operations, defining policies, mediating between levels of the innovation system[15]. Other type of actors could be added, especially in Bioscience organisations, such as research (or laboratory) groups. The centrality of leaders and of their capacity to attract qualified staff for the promotion of structural change is noticed also in the literature covering issues close to RRI, such as that on the entrepreneurial university[16]. In general, such authors note that leadership is exercised through a strong vision (concerning also a wider role for the university in society). These elements emerge also from our direct experience, according to which the involvement of scientific leaders in the promotion of RRI seems beneficial, especially in a context in which the duties of researchers are in expansion and in which the time for research is getting short. Involving leaders is a good approach to getting the attention of researchers, and to mobilize them for promoting changes toward RRI.

Case from practical experience

One of the STARBIOS2 Action Plans involved in the "Extended Team" the dean of the faculty where the Action Plan is taking place. Through

[15] Kuhlmann, S. et al. (2016).
[16] Gibb, A.A., & Hannon, P. (2006).

a direct involvement in the compilation of the Action Plan it has been secured that the planned actions contribute to the mission of the faculty. This approach produced a strategic commitment toward the Action Plan and support for the Core Team in all the initiatives carried out.

13. Involvement of managerial, administrative and technical staff

The experience of implementing APs within research organisations in the biosciences indicates clearly that, beyond scientific leaders it is important to involve the other types of actors that are active within research organisations. Indeed, RRI practice implies the inclusion in the activities of administrative and technical staff, librarians and other people working in centralized structures.

14. Involving people on the basis of specific RRI issues

What proved beneficial for the implementation of some of the STARBIO2 APs was approaching actors within organisations starting on specific issues and not necessarily on the general RRI concept and all the 5+1 keys. Such a precaution – that could consist in handling one RRI key at a time – was taken to address the problem that RRI meaning is still not clear for many researchers in the biosciences. In order to do so, it is important to ascertain if they have a feeling of urgency to intervene on issues related to RRI. Sometimes, such groups and leaders have their own point of view on overall fate of their organisation that could be related to RRI. In this case, it is important to control what kinds of issues are raised by these actors as urgent and what kind of connection among these issues could be established. The emergence of an engagement toward specific aspects of RRI of the various actors and leaders within organisations can be promoted by the Core Team through sensitization activities targeted – as resulting from some interviews – to those internal groups and agents that have some kind of engagement on RRI related issues, or to those actors who, because

of their institutional functions and roles – mid and top management – can promote an orientation to RRI.

Case from practical experience

In one of the Action Plans of the project, the key players active in the 5 RRI key fields have been systematically involved in the implementation of the activities. The "Extended Team" was organised in a five point star-shaped structure: at the centre there was the Core Team, while for each point of the star there was an expert (or a group) of each of the different RRI keys already active in the organisation. This allowed the Core Team to leverage on the already existing experiences and to create new connections among different sectors and activities.

15. Involvement through sharing responsibility

A further arrangement that proved useful in the practice of RRI was the involvement of actors by sharing responsibility concerning the implementation of the foreseen actions. In fact, rather than asking for passive involvement, it proved more effective involving other stakeholders by including them in operational teams, and by assigning them special roles and tasks.

16. Mobilising actors on the basis of concrete initiatives

Rather than involving people on the implementation of the AP as a whole, sometimes it can be more effective to involve people through individual events or activity. This allows the other actors to know the team and the project through concrete actions and not only by starting from principles and ideas that are on paper.

17. Mobilising actors by creating incentives related to RRI

The mobilization of actors for RRI is facilitated if the current structure of incentives is taken into account. What proved useful, in this regard,

was the promotion of education initiatives that entered the system of assignment of credits to students. Also the assignment of doctoral thesis that included the RRI approach revealed a good way for motivating internal actors. A similar approach is the promotion of research proposals based also on the use of RRI keys and the related ideas. In general, it is important that the Core Team members and the other actors involved in the APs make clear that motivations for the RRI practice are consistent with the overall organisations' missions (mainly focused on research).

18. Including one-to-one approaches in the communication strategy

From the STARBIOS2 experience it emerged that mobilizing people through collective calls (e.g., in public meeting, during department meeting, etc.) sometimes has the effect of stressing the differences between the Core Team and the rest of the people in the department/faculty. Adopting a one-to-one communication instead has been so far a good way of creating new links and relations between the Core Team and other players active in the research institution.

19. Acknowledging time pressure and adopting time saving strategies

The experience carried out tells us that, in order to mobilize actors on RRI within research organisations it is important to acknowledge the time pressure that researchers normally feel in the implementation of their daily activities. If it was true for the Core Teams' members, it is even more so for other actors within organisations. What proved useful was to adopt methods aimed at saving time such as the organisation of very structured meetings, fixing up a time constraint for the meeting, the deployment of informal meetings, etc.

20. Keeping the attention on the AP high

RRI practice in research organisations implies that people are involved in their normal tasks and duties, connected to laboratory work and research and the implementation of "softer" activities connected to the 5+1 keys.

Such a diversification of tasks could also imply that RRI activities are sometimes implemented intermittently. Therefore, people interested in RRI may lose contact with the Core Team for a long time. The risk is that mobilization actions have to start from scratch several times. In order to keep the different actors involved in the AP, it is important to keep high their attention. This has been done in several ways such as keeping involved people informed via e-mails, websites or newsletters; organizing periodic short face-to-face meetings; presenting findings and results of the project on a regular basis and keeping them clear and short.

Case from practical experience

In one of the STARBIOS2 Action Plans a lot of significant key players outside the Core Team have been involved since the beginning of the plan. At the beginning, their involvement foresees the participation in periodical meetings and other initiatives. After a first period, it was clear that a direct involvement in too many meetings risked losing interest about the project. The team recognized the problem, but at the same time wanted to avoid losing contact with the persons involved. For these reasons the team involved the key players by person only when really needed, and set up a communication system at a distance to keep them updated on the Action Plan.

4.4 Negotiating change for the promotion of RRI and structural change

Negotiation is a type of interaction necessary for the realization of many activities foreseen by an AP. The critical aspect is that negotiation is a **complex activity** related to interactions of an interpretive, symbolic, institutional or operational nature (e.g., the operational implementation of the activities, the creation of consensus among the actors, the reduction or elimination of conflicts, etc.); its centrality in projects is often **underestimated**, also because it is mainly "invisible"; often takes place in highly **informal contexts**.

Negotiating change involves different aspects

Useful practices

Several examples of what the practice of negotiation would actually mean can be taken from the STARBIOS2 experience (and also from the literature). In the following, such examples are presented. Other relevant aspects of negotiation process are also presented through relevant examples.

21. Recourse to external experts and scientists for legitimating RRI issues

Negotiation has not to do with just operational aspects of RRI implementation, but also with more "intangible" aspects related to the meaning of RRI for those who are called to practice it. Oftentimes RRI, or one of its constituting keys, has to be legitimised in front of various actors, internal and external to the research organisations. For example, in some cases such a legitimation occurred through activities aimed at the presentation to the faculty members of themes such as gender in science, also involving external scientists. Initiatives of this type could look like isolated events, destined not to be replicated.

Nevertheless, they have an important meaning because they create familiarity and facilitate consensus about issues related to RRI. This activity represents mainly an interpretative negotiation, even if it has some symbolic elements.

Case from practical experience

In one of the STARBIOS2 Action Plans, gender equality in science was a new issue for the institute where the Action Plan was taking place and this issue was not acknowledged as a priority inside the research institute. The lack of a common ground upon which building the gender equality activities was an obstacle for the implementation of the plan. To overcome this obstacle a set of meetings with women scientists for sharing their experiences have been organized also with help of the responsible Ministry (policy maker). Furthermore the AP established connections with other similar initiatives active in the country. The presence of external experts and witnesses was an important element of legitimisation of the promoted gender equality action.

22. Promoting the scientific recognition of the team and the AP

In the AP implementation process it is important that the Core Team manages to engage other actors and makes them cooperate and sometimes there is no agreement about the importance of the issues raised with RRI. In order to do this it is useful to promote the scientific recognition of the team and of the AP. As results from the literature[17] on gender related structural change, such an action was needed because the novelty represented by the (focused on gender) Action Plans was contested in term of scientific legitimacy. This negotiation is of the interpretative type.

[17] Declich, G. & d'Andrea, L., (2018).

23. Providing evidence for the need to change

A further important aspect of negotiation is that consensus and legitimation of RRI is produced by proposing data that support the need to launch and practice RRI. In the framework of STARBIOS2, for example, in many cases data have been collected concerning the current practice connected to the RRI keys. Such data have also been used, successively, for supporting the action in favour of structural change. Such an approach is common in various projects for structural changes through the promotion of APs. The point to stress is not so much the need to collect such data: this is, indeed, what has to be normally done during the design of an AP (see above the part on contextualization). Rather, the issue is that of demonstrating the need of a change through the use of empirical evidence emerging from the collected data. The issue, therefore, is strengthening, through the available data, a certain interpretation of the reality, so that it becomes a relevant argument in favour of RRI promotion. This negotiation is mainly of the interpretative type.

Case from practical experience

One of the Action Plans of the project was developed in a context where a wide set of gender equality measures and activities have been already implemented. In such an advanced context it was difficult for the Core Team to raise attention for the need to change with respect to gender equality. In order to deal with that, the Action Plan was focused on collecting evidence of more subtle forms of inequality that had not been addressed before. In particular, the unequal access of women and men to publication was investigated and measured through a comprehensive analysis of the research papers funded by the organisation. The results were used to represent the inequality already existing and to urge concrete changes in publication policies.

24. Inserting RRI in already existing practices

A form of operational negotiation that proved useful was resorting to "organisation tools" that already exist within research organisations for promoting issues and debates such as those on RRI. Examples are the presentation of RRI in routine faculty seminars, or in already organized events at the university level concerning issues connected to RRI. Such an approach permits one to present RRI, or the AP activities, as something that can enter the organisation's life. The fact that sometimes it is not possible to label an initiative or activity as exclusively connected to the AP is offset by the possibility to access immediately already existing audiences.

25. Mainstreaming RRI in research activities

In the case of the STARBIOS2 project, some activities have been launched for increasingly characterizing Research and Innovation activities according to an RRI approach. These activities needed negotiations aimed at demonstrating the ways the organisations' scientific practices could be changed using such an approach. This implied the use of RRI related ideas in the design and implementation of scientific activities (scientific workshops, teaching, and application for funds). Several initiatives have been promoted concerning application for funds on research projects that entailed an RRI approach that *de facto* implied the creation of new scientific connections and networks using also RRI related arguments. The doctoral thesis assigned and/or completed on the basis of an RRI approach are also a way to demonstrate how scientific practice could change accordingly. In this field, it is to be mentioned that some STARBIOS2 partners have promoted a reflection on the connection between epigenetics, exposome and RRI, producing new scientific initiatives, both in the form of scientific/cultural exchanges (i.e., participation in International Conferences) and of the creation of new scientific cooperation. In all these cases, new ideas on scientific practice and RRI became objects of discussion and brought about some

changes on how research is carried out according to the RRI principle. This negotiation is of the operational type.

Case from practical experience

This approach was used by one of the Starbios2 Action Plans. The institute where the Action Plan is taking place organised each year an intensive activity of informal education for young European students and researchers in biosciences. Since the beginning of the Action Plan, the Core Team planned to focus on RRI issues. This plan was implemented, and the "RRI edition" of the informal education initiative was a success. To support this experiment, the Core Team has started negotiations to dedicate a corner of the informal education initiative to RRI, in all the subsequent editions. If successful, this negotiation will set up a permanent space for reflecting on the societal aspects of scientific research for young scientists participating in the initiative.

26. Making visible RRI key issues

Negotiation activities sometimes were aimed at making "physically visible" some initiatives connected to the RRI practice that means attributing meanings connected to RRI to specific objects or places; this happened when a procedure was launched for establishing a service infrastructure – a "family/parenting room" – near the entrance to the faculty where one of the STARBIOS2 AP was being implemented. In choosing this location, importance was given to the work-life balance issue by representing the effort underway to tackle the issue for almost all the regular visitors and users of the university premises. This negotiation is mainly of the symbolic type even in the example it implies forms of operational negotiation.

27. Underlining the scientific dimension of RRI

In one STARBIOS2 AP, some presentations to the Academic body have been carried out explaining the impact of an RRI-related approach on the results achieved in the past within the immunology discipline. The participation at a Biotechnology Summer School in Gdansk is another example, since it gave the attending students a proof of the relevance of RRI within their discipline. Symbolically, the impact of such negotiation was to raise the academic status of RRI related issues. Of course, this negotiation implied also interpretative negotiations.

28. Anchoring RRI to the institutional mission

Another example of negotiating RRI is inserting it in the university or faculty mission statement. In this respect the negotiation will be carried out involving the formal leadership at the various relevant levels. Sometimes, this insertion does not imply rules that have relevant operational consequences. Therefore, this negotiation is concentrated on promoting RRI mainly at the symbolic level and may be sustained through connecting RRI to the ways in which a university's mission is articulated (e.g., the so called three missions).

29. Creating permanent space of negotiation

Many of the key issues of RRI are felt as important by many researchers. Notwithstanding that, sometimes such issues do not emerge in the life of a research institution because of a lack of space where they may be understood, discussed and negotiated. One of the solutions proposed by a Core Team for overcoming this problem is the creation of permanent negotiation spaces inside the institution. Such spaces may be of different types: committees, observatories, annual seminars, etc. For this reason, negotiating such changes can be seen mainly as a form of institutional negotiation.

Case from practical experience

One of the STARBIOS2 Action Plans was focused on opening a dialogue with society on biotechnology issues after a long period in which this theme has been considered taboo. In this respect, since the beginning of the project it was assessed that this dialogue needed time, and different stages of interactions. For this long time perspective it was needed to carry out this dialogue beyond the end of the project, in other words to be sustainable. For this reason a new office within the research organisation was established with the aim of dialoguing with society. The Action Plan was useful for establishing practices, work routines, tools, relationships and resources so that this new space of dialogue with society may be permanently established. It was shown also that for such a new development to become a focal point of science-society dialogue, efforts are needed to convince the researchers too, that such a mediator is important to transfer their ideas and achievements to layman society.

30. Combining formal and informal approaches

A further aspect of negotiation that emerges from experience consists in the use of both formal and informal approaches to negotiation. Some actors are willing to discuss the AP activities and the possible cooperation only in a formal context (i.e., only in the framework of the duties defined by the regulation and by the hierarchical structure). In other cases, it proved useful and necessary to begin with informal exchanges, e.g., bilateral meeting without exercising decisional functions and not in the framework of specific internally regulated procedures. From the literature it emerges that sometimes, in the framework of the formal decision process, informal meetings with relevant internal actors for discussing the AP outputs also took place. The choice of the degree of formality of negotiation depends on specific circumstances and from the experience it results that it is useful to be open to various forms of dialogue. From some expert interviews, for example, it emerges that – especially at the beginning

of an AP – informal relations make it possible to clarify the basic RRI concepts to actors who could be in opposition. In general, we could say that informal relations have been widely practiced also in the APs of the STARBIOS2 project.

31. Combining top-down and bottom-up approaches

A further important aspect of negotiation consists in the fact that it can be carried out through both top-down and bottom-up approaches. As it emerges from the literature and projects on RRI related issues, the involvement of the organisations' leaders is generally a necessary element of a successful negotiation (dean, directors, etc.). In this sense, from some STARBIOS2 experiences emerges also that research group leaders should be considered as part of the organisation leadership. Nevertheless, it is to stress the importance of consulting, discussing and negotiating solutions with people with different and lower academic status (from PhD students to researchers). In many cases, indeed, they are the people who are called to implement RRI activities. As stated above, such a consultation and negotiation could happen in different ways, both formally (by establishing a consultation group in the framework of the AP) or informally. Furthermore, negotiation activities have to be aimed at the creation of consensus among the relevant constituencies (i.e., not just some specific actors, such as the top management, but all the members of a certain department) about the initiatives to be undertaken. For example, it can be useful – as happened in various cases – to involve the possible beneficiaries in the discussion over the ways in which a certain service for women researchers or other services can be carried out. Through such discussion moments, therefore, different points of view are compared and, thanks to this dialogue, a common interpretation can be reached about the problems to be addressed and solved.

Case from practical experience

One of the STARBIOS2 Action Plan provides a good example of this negotiation practice. The plan worked for promoting changes with two complementary approaches. Firstly, working in a bottom-up approach with students, doctoral students and postdoctoral researchers; secondly working in a top-down approach directly with high level representatives at the faculty level and at the university level, including the institutional bodies. From the bottom-up perspective, the plan was focused on developing and implementing educational activities on RRI and on RRI keys; from the top-down perspective, the plan was focused on committing academic leaders in inserting RRI in the decision making formal acts and statements.

32. Adopting a flexible approach

An aspect of negotiation process that is important for defining the related strategies is that it is "time consuming" and, because of its very nature, it is open and does not allow one to make exact previsions about outcome and implementation time. In some cases, in the framework of the STARBIOS2 project, the acknowledgment of these characteristics of negotiation resulted in changing the very approach to the implementation of actions. This issue emerged also from the other consulted sources as a typical aspect of implementation of initiatives of structural change towards RRI. Delays due to the just-mentioned characteristics of negotiation are also reported in the literature.

4.5 Self-reflection on the change process and the APs

The practice of self-reflexivity

The positive outcomes of the Self-reflection process cannot be taken for granted. Some critical aspects are: the need to understand **the emerging factors that hinder and facilitate** the practice of RRI (it also requires a learning process in order to cope with the novelty produced by the implementation of the AP); the **unexpected effects** of an AP must be brought under control through procedures that are not usual for researchers in the field of Bioscience; the need to develop the **ability to interpret** what happens with an AP.

Useful practices

The STARBIOS2 project has faced such criticalities through various activities aimed at providing the Core Teams with a wide set of information and tools for promoting self-reflection. In general, such practices aimed at promoting self-reflection have been facilitated by the Technical Assistance and evaluation. During the implementation of the APs, the following arrangements have been practiced.

33. Carrying out periodic monitoring sessions

Various forms of monitoring have been practiced for the implementation of the actions foreseen by the APs. Some Core Teams developed different internal forms of control of the various deadlines of the actions of their APs. On the other hand, Technical Assistance team interacted systematically with the Core Teams by reviewing the state of the art of the implementation of the individual APs. These activities represented a fundamental way through which the Core Teams acquired control over the implementation process and its

various, often unexpected, aspects. The information obtained in this way was an important basis of the overall self-reflection exercise.

Case from practical experience

In almost all the STARBIOS2 Action Plans there has been an organisation of the team based on the RRI keys. Each key has a person in charge of carrying out and following the activities. All the team developed some internal procedure aimed at monitoring the activities, based on exchange of information among the people in charge of the different RRI keys. In one AP such meetings have been organised every two weeks. The meetings have been very open and dynamic so to allow a real and quick exchange of information among the participants. The meetings were organised around a giant print of the Action Plan GANTT chart, so that actions, deadlines and persons in charge were visible for all the participants.

34. Using external evaluation as a source of self-reflection

Self-reflection has to be based on information inputs that are needed also for a possible redesign of the AP activities. Such input could be of different types and be the result of activities originated for various reasons, for example external evaluation (typically foreseen by various funding schemes of different funding agencies). The STARBIOS2 project foresaw also an external evaluation, carried out by one of the partners that were committed to this specific task. It was based on a scheme agreed among the partners and then carried out periodically through specific information collection activities. It was also foreseen that the Core Teams had to self-evaluate their work.

35. Reporting on activities as an occasion of self-reflection

Another possible occasion of self-reflection is the production of reports concerning the AP addressed to relevant actors. The STARBIOS2 project foresaw also reporting activities aimed at describing to external actors (e.g., the evaluators) the progress and results being obtained. Such activities implied a further effort for providing an analysis and representation of the activities being carried out, of the possible difficulties in the implementation and of the results being achieved. Reporting activity was a valuable occasion of self-reflection, at least for what concerns the operational aspects of the APs.

36. Participating in seminars and conferences on RRI

Core Teams' members during the implementation of the APs participated in various public debate initiatives aimed at dealing with RRI related issues at various levels. Such activities made it possible to improve Core Teams' interpretation ability and represented a useful tool for promoting, in general, the self-reflection exercise. Seminars and conferences were of very different types, going from international initiatives to more local ones, aimed at creating contacts and exchanges between actors in same regions or country.

37. Making the most interdisciplinary interaction within the Core Teams

In order to address the need to carry out self-reflection on RRI practice it proved useful to practice an interdisciplinary interaction within the Core Teams (that sometimes included also social scientists). Particularly, the continual and informal interaction within the Core Team, as it is also suggested in the literature[18], made it possible that very diverse approaches produced new visions and interpretations of the implementation of RRI and structural changes that otherwise

[18] Flipse et al. (2014)

would not have been possible. Such choice was particularly useful for approaching gender issues as well as societal engagement activities.

38. Reframing the APs

Self-reflection activities imply not just an analytical attitude aimed at collecting information on the activities and changes induced by the AP, but also a pro-active orientation aimed at reframing, in case of need, the AP activities on the basis of the interpretation of the new situation. As it was stressed, the Core Teams adjusted periodically their APs on the basis of a critical assessment of the results being achieved. It was a characteristic of the STARBIOS2 project since the beginning and turned out to be a very useful management tool. The fact that it was explicitly foreseen – and not considered a symptom of failure or bad design – facilitated a systematic self-reflective approach. The periodic revisions of the APs required a big effort of the Core Team that consisted of systematic critical assessment of the results being obtained from the collection of data, qualitative discussions, comparison of the results with the expectations, etc. Monitoring and evaluation activities, and the related reporting, provided very useful input for the periodic revision. The revision includes the improvement of the ways in which the AP is implemented and, to a certain extent, also a creative attitude aimed at designing new and different actions for the attainment of the AP's objectives.

Case from practical experience

One of the Action Plans at the beginning planned to carry out a huge amount of actions in each of the 5 RRI keys. At the end of the first year, it was clear that some of these actions were not so relevant, while others were very promising. At the same time it was clear that the great number of actions initially foreseen exceeded the Core Team implementation capacity. The periodic revision of the Action Plan proved to be a useful tool for reflecting on what was going on, what was really important for the team and consequently for re-structuring the plan.

39. Involving various actors in the self-reflexive exercise

The provision of an external point of view is indeed very helpful for the self-reflective exercise. In the framework of the STARBIOS2 project, the self-reflexive exercise has included diverse actors beyond the Core Team. It was foreseen, for example, a Technical Assistance (TA) – provided by a dedicated team not belonging to the organisations implementing the APs – through which some problems were addressed, discussed and possible solutions identified. Beyond the "services" provided, TA made it possible for the Core Teams' members to have the possibility to create a "space" of self-reflection with people who brought an expert but external point of view on RRI, structural change and other issues related to the AP implementation. TA included both bilateral and multilateral exchanges with other Core Teams. Such exchanges created the occasion for producing a more holistic vision of the promotion of RRI and structural change, facilitated by the comparison with similar experiences. Self-reflection was helped also through the acquisition of an appropriate language on RRI and structural change related issues, particularly focused on its practice in the biosciences. This effect was particularly valuable and could not have been taken for granted, since the members of the Core Teams mostly had a disciplinary background far from social and political sciences, Science and Technology Studies, management and organisational studies. TA promoted exchanges helped also to develop a more realistic orientation to RRI, based on the awareness that RRI-related change is a process that implies that not all that is desirable can be implemented immediately.

40. Implementing mutual learning sessions

Another part of the self-reflexivity was the implementation of mutual-learning sessions through which the various Core Teams discussed their experience with certain RRI keys and other relevant and specific problems that arose during the APs. This helped each Core Team to re-design some part of their APs and introduce possible changes or new ideas in the implementations practice. Such initiatives took place both through bilateral and multilateral dedicated exchanges among the Core Teams and the TA Team.

APPENDIX

BOX #1

The STARBIOS2 six Action Plans in brief

Here below the STARBIOS2 Action Plans are summarized in tables. Since the Action Plans are not concluded at the moment of the publication of these guidelines, they are presented as they were at midterm of the project (April 2018). Other activities that have been developing since then are not included in the tables below. The final list of activities carried out by each Action Plan will be part of the final reports to be delivered in April 2020.

ACTION PLAN OF THE UNIVERSITY OF ROME TOR VERGATA (ROME, IT)	
RRI Key	**Stream Of Action**[19]
Societal Engagement	Assessment and improvement of UNESCO Chair of interdisciplinary Biotechnology
	Set up of an integrated system for exchange with society
	Piloting new methodology of interaction with stakeholders
	Developing a strategy to exploit responsibly IP
Gender Equality	Raising awareness on how gender models affect research activity supporting women's careers
	Make transparent gender biases and inequalities
	Introduction and strengthening of the use of gender and sex as key variables in the research programmes
Education	Awareness raising on RRI Capacities improvement on RRI-related issues
	Transfer of RRI related issues to students
	Biotechnology transfer in developing countries
Open Access	Introduction of an open access policy plan
Ethics	Ethical aspects of research projects

[19] With the term "Stream of Action" we mean the building block of an APs, see Annex, Note 15.

ACTION PLAN OF THE UNIVERSITY OF OXFORD (OXFORD, UK)	
RRI Key	**Stream Of Action**
Societal Engagement	Review of the effectiveness of societal engagement (SE) in biomedical research and innovation
	Engaging with technology transfer within the NIHR Oxford BRC
Gender Equality	Development of new metrics to assess markers of achievement for women in translational medicine settings
	Qualitative study of women within the NIHR Oxford BRC
	Retrospective analyses of NIHR Oxford BRC metrics
	Scoping and encouraging the use of gender and sex as key variables in the research programmes
Education	Evaluating opportunities for lectures, seminars or workshops on RRI and disseminating RRI in Oxford
Open Access	Evaluating open access at the University of Oxford and developing a framework for comparison
Ethics	Ethics at the Edge of Consent: capacity, consent and vulnerability
	Ethics, Big Data and Research Data Governance
	Ethics, Health Research and Commercial Interests
ACTION PLAN OF THE UNIVERSITY OF PRIMORSKA (KOPER, SL)	
RRI Key	**Stream Of Action**
Societal Engagement	Cooperation with office for public relation
	Promotion of project activities in national events and at the UP
	Survey for the public task interest
	Organisation of Societal Engagement events
	Preparation of database of past project
Gender Equality	Statistical analysis of employment records
	Statistical analysis of gender structure in the projects and lectures
	Workshop organisations
	Meeting and collaboration with Ministry for labour, family social affairs and equal opportunities

	Meeting and negotiation with University stakeholders
	Merging with EU project
	On-line gender survey
Education	The update of three syllabuses
	Organisation of Education events and workshops
	Collaboration and negotiation with other Slovenian Universities
	Optional course in Environmental Ethics
Open Access	Analysis of past open access publications
	Investigation of OA possibilities at UP
	Organisation of Open Access Workshop
Ethics	Preparation of Code and Conduct for biology
	Survey regards bioethics and public perception
	Promotion of PhD thesis on Ethics
ACTION PLAN OF THE UNIVERSITY OF BREMEN (BREMEN, DE)	
RRI Key	**Stream Of Action**
Societal Engagement	Setting up criteria for successful societal engagement and technology transfer
	Promoting societal engagement through socio-scientific contextualization
Gender Equality	Raising awareness of gender issues
Education	Education to raise the awareness of RRI Keys
	Making a RRI Mission Statement at faculty level possible
Open Access	Promotion of open access
Ethics	Raising awareness of ethical issues
ACTION PLAN OF AGRIBIO INSTITUTE (SOFIA, BG)	
RRI Key	**Stream Of Action**
Societal Engagement	Establishment and sustainable maintenance of Plant biotechnology

	information centre of ABI
	Promoting socially oriented plant science
Gender Equality	Evaluation of the potential of gender as a key variable in ABI research
Education	Attracting young people to plant science
	Raising the awareness on RRI
Open Access	Analysis of Open Access related costs, opportunities, and researchers needs
Ethics	Raise public awareness on the ethics in plant research
ACTION PLAN OF THE UNIVERSITY OF GDANSK (GDANSK, PL)	
RRI Key	**Stream Of Action**
Societal Engagement	Rising Awareness and Providing Information on Bioscience Research
	Efficient Technology Transfer at UG for Marketable Innovations
	Aspects of Risk Management in BIOSciences
Gender Equality	Conducting a state-of-the-art analysis
	Designing tools for career development of women researchers
	Organisation of leadership workshop
Education	Raising Awareness on RRI
	RRI for Students& Young Researchers
	RRI Biotechnology Summer School
Open Access	State of the art analysis of Open Access at IFB
	Identification of obstacles of open access publishing through dialogues
	Development of Open Access Policy Plan
Ethics	State-of-the-art analysis on Ethics
	Development of Ethics Procedures

BOX #2

Mobilising resources for promoting RRI-oriented structural change

The implementation of RRI and structural change **requires the mobilization of people** within research organisations who are willing to dedicate part of their time, as well as financial resources, to this end. The quantity of these resources, obviously, must be appropriate to the programme of actions planned.

While people mobilization can be facilitated by the availability of **financial resources**, funds cannot be considered the "engine" that moves the machine of RRI promotion. This is, on the other hand, what the literature and also the STARBIOS2 project experience teaches: there is a "**de-facto RRI**" and things also move spontaneously.

In this framework, to start promoting RRI and structural change, a **strong motivation** and commitment by the promoters of the initiative is a necessary first condition. They must take the first steps towards identifying a plan of activities. **These first steps also include finding resources and recruiting people**. Planning the action must involve people able to collaborate in the realization of ambitious activities. RRI in a bioscience research organisation, in fact, should include first and foremost the bioscientists who work within it, but action is also required to share knowledge, including tacit knowledge, and negotiation with other actors (internally and externally). Therefore, the promotion of RRI requires a type of **interdisciplinary effort**. The involvement of teams of social scientists providing support for the RRI-related activities is highly desirable. It can be successful only if the programme of action is sound, credible and sensible, if it foresees convincing objectives, a good working environment in addition to adequate financial resources.

Furthermore, an **Action Plan** for RRI and structural change is an **ongoing process**, which starts with initiatives that could be also **limited in scope and that then increase in size** and relevance over time. It should be seen as an incremental process also with regards to the issue of human resources and finance.

BOX #3

Some critical areas of the life of a scientist

TRENDS	DESCRIPTION
1. Hypercompetition	Science as a hypercompetitive environment where the traditional process cycle has collapsed due to time constraints and equilibrium is impossible to sustain.
2. Acceleration of the research process	Working faster seen as a requirement for high quality research; changes in the organisation of academic life and in the researchers' lifestyle; researchers under condition of stress and pressure.
3. Shrinking of funds	Scientists and research organisation working in an increasingly competitive environment, especially in accessing to funds and publishing; decline in the success rate for grant applicants, with an increasing waste of time.
4. Task diversification	Market-oriented organisation of the research process, in which research is required to engage with a wider range of different types of activities (participation in extended research networks, direct involvement in innovation and technology transfer, activities related to accountability, transparency and public scrutiny, administrative work, etc.). This is leading to a decrease in the time devoted to scientific work.
5. Increased staffing	Increased numbers of contingent staff (PhD students and Postdocs), due to the need for cost containment; increased use of soft money to pay the contingent staff: fewer opportunities for young researchers to access permanent positions; increased pressure on young researchers to make more in less time, creating hardships especially for women scientists.

6. Increased segmentation	Segmentation of staff based on age and contractual status, producing impacts such as: • Decrease in productivity among young researchers • Increased control over academic tasks • Overtraining (tendency to retain PhD students and Postdocs longer than necessary) • Decrease in teaching quality (increasingly done by ever cheaper teaching staff) • Changes in internal labour relationships (research organisations no longer as a "community of peers" but merely as employers) • Individualisation (researchers increasingly acting as individual professionals and not as part of a staff) • Attitude of self-promotion among scientists Stratification and polarisation of academic staff (academic staff split between those benefit from change and those who are damaged by it).
7. Increased mobility	Mobility as a factor promoting an increase in scientific performance but having possible critical impacts on the lives of researchers, such as: delays in accessing permanent positions; difficulties in returning to one's home country; problems in managing family life, especially for women scientists; loss of social ties.
8. Increasing pressure on research assessment systems	Traditional research assessment procedures are no longer able to manage the hyperproduction of scientific knowledge; systematic problems and errors in peer review, lessening its reliability; problematic tendency to use quantitative indicators to assess researchers, research institutions and scientific journals, with distorting effects on science quality.

9. Governance shift	Tendency to adopt entrepreneurial models for managing research organisations, requiring a balance of different steering mechanisms; high variability in types of research organisations; differentiation in terms of national contexts; strong resistance to change; need for highly participatory approaches.
10. Increasing openness to external actors	Rising complexity in managing research organisations due to growing need to interact with external actors (political authorities, civil society, industry, etc.) for different reasons (innovation, providing expertise, public engagement, policy issues, societal engagement, science communication, etc.); need to find the right openness level; institutional undervaluation of openness-related initiatives; conceptual ambiguities and interpretive mismatches about openness; resistance and barriers to openness; decreasing trust in science.
11. Critical dynamics affecting the quality of research products	Impact of changes on the quality of research, such as: • Tendency of researchers to adopt safe and low-risk research strategies (favouring conservative and short-term thinking and penalising more creative and unorthodox approaches) • Tendency to produce irrelevant science (producing publications for career advancement rather than producing advances in science) • Tendency to produce redundant papers (publishing the same data or papers) • Tendency to work on research project that ensure short-term achievements and profitable results • Increasing malpractice • Decreasing reproducibility of scientific data • Undesirable impacts of commercial interests on research quality.

Source: d'Andrea et al., 2017

BOX #4

RRI, the biosciences and interdisciplinarity

The Bioscience sector is complex because, by its very nature and definition, it encompasses a wide array of disciplines and sub-disciplines. In a certain sense, it seems a **real field of relations** that implies cooperation or, in any case, the interaction of scientists that work in related areas and that, therefore, share similar aspects of their professional lives (lab practices, specific sets of knowledge and skills, etc.). Within the biosciences, the interdisciplinary interaction, more or less strong or explicit, is a basic aspect of the research activity.

Interdisciplinarity is a constitutive character of the biosciences also because of the **common focus on living organisms and various aspects of life processes** (whose definition anyhow change according to the disciplines). In this framework, once the core issues of RRI are recognized as relevant – i.e., how to promote a responsible approach to research that is aware of all the various social, ethical, cultural implications of dealing with life-related issues – **the need for cooperation among bioscientists with different disciplinary backgrounds** becomes more compelling. First of all, they could face similar problems and challenges (e.g., on ethical issues). Furthermore, interdisciplinarity is based on a problem-solving orientation (that is more and more relevant for research) implying that the research agenda is dictated also by policy agendas – that are focused on problems – and not only by scientific curiosity. This means that bioscientists have to find ways to cooperate amongst themselves and compare different approaches to similar problems, or analyse implications of their research that are not always evident when working within strictly-defined disciplinary boundaries. Different epistemologies can be compared – e.g., clinical research vs. genetics/molecular biology paradigm (Gittelman, 2016). Being involved in addressing similar

challenges, bioscientists are asked to work together to develop new approaches, coordinate methods and compare results (this is typical of new strongly interdisciplinary fields of research, such as epigenetics). A strong interdisciplinary approach to research implies changing several working routines and overcoming organisational barriers. Practicing RRI in the biosciences therefore can be seen as a great interdisciplinary challenge.

Interdisciplinarity should not be limited to strong cooperation within academia, between scientists with different disciplinary backgrounds, but also between people, regardless of their disciplinary background, that work in various organisational and institutional settings, for example university departments and the private sectors. Interdisciplinary cooperation should be understood as cooperation between different epistemic communities that, *de facto*, practice diverse approaches to scientific and technological research.

BOX #5

Biosciences and RRI

Biosciences are a sector particularly affected by social and ethical dynamics. For this reason an approach to research based on RRI and its Keys is highly relevant. In this regard, the focus on life processes that characterizes the biosciences has important consequences. Indeed, according to the Former President of the European Research Council and one of its founding members, Helga Nowotny: "Nature is no longer only what is 'out there', but we are intervening in and manipulating the Nature inside us – our cells and gene sequences, our immune system and perhaps even our germline – in an unprecedented way". Also according to Nowotny, "to know life, is to remake life", since it is already on the molecular level, no intervention is possible without altering "natural processes". For this reason, the biosciences are intrinsically characterized by the strong relevance of social dynamics.

This aspect of biosciences has become particularly evident in recent years thanks to a succession of great scientific advances that have strongly accentuated the social impacts of discoveries taking place in the sector (Clarke & Kitney, 2016). Moreover, the biosciences have an intrinsically social aspect because they have to do with sex and gender variables, with nutrition and health and, increasingly, with the productive activities, in addition to the traditional ones, connected to the food chain or the textile industry (see the topic of bioeconomy and the connection with synthetic biology, Clarke & Kitney, 2016 and the "Strategic Agenda – A vision for biotechnology in Europe", ERA CoBioTech, 2018). Other emerging issues, relevant for the medical field, are the growing opposition to vaccination, the spread of antibiotic-resistant pathogens, the recognition of the relevance of epigenetics and, in general, of the environmental impacts on health and gene

expression. Finally, biosciences are becoming more and more important also in relation to ecological issues, especially in the case of conservation and biodiversity as well as the study of systems for reducing GHG emissions related to human activities.

There are a number of examples of public debates in which the connection between research in biosciences and social dynamics is central. Von Schomberg (2019) recalls the story of BSE (Bovine Spongiform Encephalopathy) and of GMOs that have highlighted the strong link between research in biosciences and society, in particular in connection with risk management related to innovation. Furthermore, Von Schomberg stresses that market dynamics tremendously impact the trajectory of research on relevant health issues such as Malaria.

Recently, a strategic agenda was published by the ERA CoBioTech program entitled "A vision for biotechnology in Europe" (ERA CoBioTech, 2018) that puts 3 topics at the centre of the progress of European Biotechnology: "Research and Technology to address sustainability in Europe and beyond; Streamlined and purpose-oriented funding across Europe; Engaging the scientific community and beyond". RRI is indicated as one of the themes at the centre of the activities promoted by the CoBioTech ERA Program and has become an element of its Agenda (Smith et al., 2019).

Debates on these and other similar issues have been the basis of the very development of the RRI concept; for example, the awareness of the importance of the strong link between science and society has accompanied the development of biotechnologies and the so-called synthetic biology. In the UK, the Roadmaps of 2012 and 2016 for the development of synthetic biology have included the theme of RRI as a qualifying element (Clarke & Kitney, 2016). The European Union has also promoted a reflection between RRI and synthetic biology. In addition to the Agenda mentioned above, a further example is the SYNENERGENE project (https://www.synenergene.eu/).

BOX #6

Biosciences are an area of complex interaction among different actors

The bioscience sector consists of different actors in complex interaction.

The term "biosciences" does not imply an exclusive reference to **Academic research organisations** (and, consequently, to the disciplinary areas that compose such organisations). It includes organisations that are not academic in nature. Research in the biosciences, indeed, can be carried out both as part of **industry activities** and, anyhow, beyond the typical context and missions of academia (see the Magna Charta Universitatum[20]). In general, non-academic organisations do not have education as a priority mission.

The complexity within the biosciences implies various forms of division of labour. The path from research to innovation, from basic research to goods and services, can be composed in many ways. The **interaction between actors involved in each segment of these processes is not linear**, neither is it trivial. Input for basic research could come from interaction with those who develop technologies. In the last decades, this process characterizes the biosciences, and the entire field of S&T[21]. For this reason, it is appropriate to consider also the organisations that promote research and/or innovation as an important part of the bioscience sector. This is consistent with the orientation of the EC, which beyond the **Research Performing Organisations** (RPO's) also sees potential in involving in RRI the **Research Funding Organisations** (RFO's).

[20] http://www.magna-charta.org/magna-charta-universitatum/read-the-magna-charta/the-magna-charta (accessed on: 26/11/2018).
[21] See the concept of the Mode 2 knowledge production proposed by Nowotny, H., Scott, P., Gibbons, M., & Scott, P.B. (2001). See also Bijker, W., & d'Andrea, L. (2009).

These two types of organisations, on the other hand, have always had broad missions. The RFO's must contribute to research policies and the provision of funds; the RPO's must implement such policies and make the research results arrive "downstream". It is worth considering that at the companies that innovate by using research results there are always researchers and scientists, perhaps trained at the local University, that use research organisations' outputs. In many cases, the final results of innovation stem from the interaction between researchers that work in organisations of diverse nature.

BOX #7

Scientific communication: a broad definition

Scientific communication should not be understood only as a mere dissemination of research results but as an exchange with various social actors that, for different reasons, are interested in the scientific products (d'Andrea & Declich, 2005; d'Andrea, Quaranta & Quinti, 2005). According to this approach, scientific communication should foresee first a "representation" of the actors that communicate its results (its characteristics and activities); secondly, the vision concerning the scientific activities and results being communicated (therefore presenting possible risks, potential and actual utility and so forth) should be made clear. The actors with whom such a communication should take place are of a different type and, for each of them, communication assumes different forms and approaches.

There are different kinds of communication:

- Intra-epistemic, aimed at the member of the disciplinary community of the actors, the actors' peers
- Trans-epistemic, aimed at the members of disciplinary communities different from those of the actors promoting communication
- Social, that is aimed at different stakeholders and Civil society organisations
- Political, concerning policy makers and the so called "political society"
- Network, dealing with all the actors that are, in one way or another, involved in the implementation of the research activities being communicated (this is especially true when participatory research approaches are practiced)
- General, aimed at informing the general public.

BOX #8

Gender and gender issues in biosciences

Gender is an RRI key that, within the biosciences, assumes particular characteristics. In very general and introductory terms, it concerns both the participation of women in the bioscience sector and the integration of gender variables in, or genderization of, bioscientific research.

"She Figures 2015" (EC, 2016) is a report on the situation of women in research in Europe. It defines (EC, 2016, 28, note 9) **Horizontal segregation** as "the concentration of women and men in different sectors (sectoral segregation) and occupations (occupational segregation). In education, it is used to describe the over- or under-representation of one sex in particular subjects".

Horizontal segregation is very relevant. The EC report states that "despite progress, the under-representations of women continues to be a problem in all narrow fields of science and engineering, except life science". (EC, 2016, 20). The She Figure Report states that "When looking at the fields of science in which women and men conduct research within the higher education sector [HES], there still appear to be differences by sex. In 2012, women researchers in the HES were, in most countries, mostly concentrated in the social sciences or the medical sciences" (EC 2016, 61). The relatively higher presence of women in medical sciences is also evident in the private enterprise research sector (EC, 2016, 61); in general, discrimination against women is even less evident in the governmental research sector (EC, 2016, 61).

As for the attainment of education levels, in 2012 women obtaining an ISCED6[22] level degree were the majority only in the

[22] In the She Figure 2015 is stated: "Level 6 (also referred to as ISCED 6) covers: 'The second stage, which leads to the award of an advanced research qualification (e.g. PhD, non-PhD programmes with an advanced research component)" (EC, 2016, 19).

Life sciences (58%) but not in the other areas of natural sciences and engineering (in Europe, the percentage of women in these "narrow fields of studies" were ranging, in 2012, between 21% in computing and 38% in Architecture and Building; see Table 2.4, EC, 2016).

A similar trend in horizontal segregation is present in the U.S., where a higher proportion of degrees is obtained by women than men in the bioscience sector: "The combined consequence of these trends is that the share of biological science degrees awarded to women has increased from 40 to 60 percent over the last 30 years". (Mann & Di Prete, 2013); see also the statistics provided by Stanford University[23]).

Another important aspect of the segregation of women is "**vertical segregation**" defined as "(under-) representation of women in the highest grades/posts of research and as heads of academic institutions" (EC, 2016, 18). The She Figure 2015 report provides data on the position of women in biosciences related to the academic sector, particularly the "Grade A" level.

Despite the relatively high number of women bioscientists, there are obstacles to their pursuit of academic careers. In Natural Sciences and Engineering in Europe (28 countries), only 13% of top positions were held by women in 2013. This is the result of the presence of women continuously decreasing along the various academic career steps (EC, 2016, 126.). Unfortunately, these data are not precise, since "Natural Sciences and Engineering" is a wide field that includes sub-fields in which women are strongly underrepresented (such as engineering and technology), and fields where women are more present (life sciences). It is worth stressing that the general situation of women in the Higher Education Sector is changing: the She Figures 2015 Report indicates that there is an improvement of the overall position of women in Europe compared to the previous measurement, since women at Grade A level

[23] https://genderedinnovations.stanford.edu/institutions/disparities.html (accessed on: 31/10/2018).

position were 19.5% in all the fields of study in 2010 and then 20.9 in 2013 (EC, 2016, Figure 6.3).

A strong change of approaches within the bioscience disciplines will be needed to encourage the use of sex variables in research. This new perspective is gaining favour within the biosciences and attention to it is growing[24]. Nevertheless, such a perspective requires that the current efforts are maintained, for example by paying due attention to gender variables in clinical trials and animal studies when assessing and funding research. Also, the professional and scientific education of new cohorts of bioscientists should include the importance of determining whether new discoveries are equally applicable to different genders. For these reasons, gender issues represent an actual challenge for the biosciences that RRI should address.

[24] A list of pilot initiatives has been proposed. It can be found at the following links, all accessed on 2/11/2018.
UNIVERSITY OF PISA – ITALY; Testing innovative research tools (Medicine & Engineering); triggerproject.eu/wp-content/uploads/2014/05/Newsletter-3-_def.pdf; BIRKBECK COLLEGE, LONDON – UNITED KINGDOM; Testing new research procedures (Cognitive Sciences); triggerproject.eu/wp-content/uploads/2014/05/Trigger-newsletter_DEF.pdf; GENDERED INNOVATIONS – UNITED STATES; Rethinking the research process and Some case studies (Biomedical research); ec.europa.eu/research/swafs/gendered-innovations/index_en.cfm; genderedinnovations.stanford.edu/; UNIVERSITAT AUTÒNOMA DE BARCELONA – SPAIN; Mapping and assessing gender research (All fields); ec.europa.eu/research/swafs/pdf/pub_gender_equality/prages-guidelines_en.pdf; UNIVERSITAT AUTÒNOMA DE BARCELONA – SPAIN; Promotion of a gender perspective in teaching and research (All fields); www.uab.cat/doc/igualt_en

BOX #9

Better research and systems of incentives

One of the main ideas underlying these Guidelines is that the practice of RRI should improve research and help solve the problems of the professional lives of researchers. In the RRI-community such an idea was placed at the centre of the discussion (see some of the results of the NUCLEUS Project, http://www.nucleus-project.eu/, particularly, Gerber 2018; and of the RRI-Practice Project, https://www.rri-practice.eu/, particularly Owen et al 2019). The theme of research excellence connected to the practice of RRI was also indicated in the "Rome Declaration on Responsible Research and Innovation in Europe" as early as 2014[25]. Naturally, the issue of research excellence has been connected to the issue of incentives, which should not create a conflict between the search for scientific excellence and the practice of RRI (Owen et al., 2019). Incentives are of particular relevance in light of the theme of structural change in research organisations: they constitute a set of rules and accepted behaviours that favour the practice of RRI within organisations; in particular, one cannot think of promoting RRI when the existing internal rules actually discourage its practice (for example, by not recognizing the practice of RRI criteria in the evaluation of researchers).

In these Guidelines, a basic agreement is expressed with this approach according to which – in general – it is desirable that research excellence criteria are restated so they include RRI and, consequently, the related incentives should include provisions that favour its practice. Nevertheless, the assumption – stated in the model – that the practice of RRI "should not conflict with the main

[25] https://ec.europa.eu/research/swafs/pdf/rome_declaration_RRI_final_21_November.pdf (accessed on: 30/09/2019).

systems of incentives at work" could appear in contrast with the orientation that emerged in the RRI-community on this matter.

It should be noted that the focus of these Guidelines is RRI and structural change within individual organisations. In this framework, the Guidelines suggest a further possible strategy for the promotion of RRI with direct impacts. It consists of the idea that RRI should affect the way in which research groups formulate their "**research visions**", encompassing the research questions they seek to answer through their scientific activity. In this perspective, excellent research is that which effectively answers important scientific questions and, therefore, obtains recognition from the scientific community through the current system of incentives and rewards. In this framework and under certain conditions, **RRI is presented as an approach that associates the promotion of scientific quality and the pursuit of broader social aims**.

BOX #10

Research vision: a definition and its connection with RRI

In very general terms, a "research vision" means a specific way of approaching research on certain topics and specific scientific questions and challenges to be addressed. It includes a set of scientific hypotheses and assumptions that are relevant within a broader research field. Such hypotheses need further corroboration and are based on promising research results not yet fully accepted within the scientific community. Oftentimes, a research vision includes some ideas concerning the possible applications and technical utilizations of the results being pursued. In this sense, this vision is part of the agency of a specific research group. A vision is important for a research group because it is the basis for driving its overall activities.

It could be helpful to think of a research vision explicitly in relation to RRI issues. For example, when defining the vision of a research group, and the related implementation strategy, questions could be raised concerning the ways in which sexual variables are adequately considered, or whether the underlying assumptions address the policy-makers' or other stakeholders' priorities. The vision and the related strategy themselves are aimed at anticipating possible impacts of research. Do they foresee moments for discussing such impacts and/or for verifying the results obtained? Are the relevant actors and stakeholders consulted or considered within the vision and in the definition of the strategy?

BOX #11

Infections, nutrition, epigenetics and the exposome — RRI as an approach for designing research in biosciences

RRI is an approach that can help promote better research. This statement is particularly appropriate in biosciences that are particularly affected by social and ethical dynamics. One example concerns the study of infections, nutrition, and the related epigenetic responses. Infections and Nutrition are areas of the biosciences that transcend boundaries between disciplines and concern diverse stakeholders globally. Important instances are recent viral epidemics that demonstrated the importance of DNA sequencing and big data analysis for molecular epidemiology and vaccine development, and issues related to nutrition that comprise environmental factors which affect health and can even alter human gene expression. Stakeholders are faced with raising public awareness of epidemics and vaccines, improving nutrition globally, and fostering open access to big data.

In order to understand epigenetic in infections and nutrition some RRI-related strategies could be useful that help to cross boundaries between disciplines and regions, as well as scientific and non-scientific communities.

To this end, the STARBIOS2 partners have initiated various forms of scientific cooperation. In one of these initiatives – the organisation of a session in the American Advanced Science Society Meeting 2019 in Washington DC –, research activities were presented in which aspects of the RRI keys were relevant: a) recent viral epidemics (Ebola, Lassa and Zika) that demonstrated the importance of diagnostic tools, DNA sequencing and big data analysis for molecular epidemiology and vaccine development; b) nutrition, as all that an organism ingests comprises the exposome, and that impacts its gene expression.

The exposome, in particular, is an issue for which an RRI related approach is appropriate. Modern nutrition can include unconventional micronutrients such as non-coding genetic materials (small RNAs, microRNAs, degradome elements) present in vegetarian diets that can beneficially alter the human transcriptome. This could be important also in the framework of migration studies considering that, for example, the Exposome of Africa and Brazil differ from that of populations that work indoors and both environments strongly impact human gene expression.

BOX #12

Framing research process considering RRI

The stages **of the research and innovation process** could be reframed so that they can consider the definition of RRI and the assumptions listed in the main text. Such stages, based on the definition of a research vision, could be those briefly outlined below.

- **Search for research funds and definition of research projects**; research funds are looked for on the basis of the priorities set through the definition of the research vision and strategy (this implies also paying attention to funding organisation policies; existence of private funds for research, etc.); research proposals respond to the resulting strategies and research programmes.
- **Definition of research protocol**; the scientific questions emerging from the relations with the funding agencies are translated into a specific research protocol; research activities will be designed on the basis of the priorities decided when grants and funds were requested.
- **Experiments**; the protocol is put into practice; scientific questions and hypotheses are tested to check if they are corroborated and if the research programmes are challenged and have to be adjusted; new scientific questions could emerge and inputs could be given to adjust and update the research vision.
- **Definition of the prototype**; in the applied research, various prototypes could be tested in cooperation with various actors that could contribute to their development.
- Identification of **possible users of the research output**; the results that are being shaped or that are actually available are presented to possible users and discussed.

Examples of how research process could be interpreted according to the RRI keys and the assumptions are the following. The search for funds could be guided by a vision, which could be inclusive of an RRI concern. Funding agencies could be found with which there is "consonance" with the research vision. When defining the research proposal, questions could be raised concerning the governance of the project that is being submitted, if it is appropriate

to the needs and characteristics of the research organisations (e.g., are exchanges between international teams or for interdisciplinary reflections foreseen? Is the complex organisation of the project consistent with the characteristics of the Department?). Other questions could concern gender issues and if they are adequately approached; what are the Open Access requirements that should be inserted into the proposal being submitted; how and if the project being proposed affects teaching activities; if is it useful to consult stakeholders in order to check their points of view on the implementation of research activities being proposed; and so forth.

It should be stressed that this work is equivalent to a **strong critical approach** to the practice of research. As a matter of fact, it consists in providing an interpretation concerning how research and innovation activities should be changed thanks to the practice of RRI in each specific context (e.g., in each specific organisation that is part of a more general national research system).

BOX #13

Possible types of actors in the biosciences sector

Actors within the biosciences could be divided into two large groups (Mezzana, 2018): "Actors of the process", that are directly involved in the research and innovation that are typical of the bioscience sector, and "actors of the context", those that can affect the first type of actors in different ways.

Within the biosciences, the "actors of the process" could be considered a variety of organisations, more or less involved with research. Such actors are characterized by many characteristics. For example they could be:

- Academic or non-academic
- Public or private
- Non-profit or for-profit
- Research funding or performing organisation.

Sectoral professional associations, innovation promotion organisations, etc. should also be considered. They are, then, "the actors of the context", such as, for example:

- Stakeholders (users associations, trade unions, consumers associations, professional associations, etc.)
- Policy makers and regulators
- Civil society/citizens organisations.

When mapping (or making an inventory of) the actors relevant to each organisation, it is useful to collect information about the relationships between the actors. For each actor singled out it could be useful to know, among other elements:

- The functions performed (research implementation; research funding; brokerage; innovation promotion, etc.)
- The services provided (e.g., hospitals)
- The business model (how resources are collected and used)
- Competition in accessing existing resources.

BOX #14

Data on the sector as a whole

In order to make the most of mapping the most important relations of a research organisation, it is important **to outline a picture of the sector as a whole**, at the local or broader levels, depending on the need. In order to do this, in relation to the research issues of each group or organisation, it is important to answer questions such as: How many Universities are working on certain issues? What is the dimension of the market relevant for a certain innovation? How many companies are working in a particular market?

Data and information on the biosciences sector are not always available in a complete way, especially in relation to the actors mentioned in the main text (see this chapter). In some cases there are studies and analyses of the sector and/or of its sub-sectors, related just to the academic actors. In other cases there are studies and data concerning the companies that are active in the economic sectors that produce goods and services that are based on knowledge produced from bioscientific research. The companies included in such analysis do not necessarily carry out research (also applied) in the biosciences. In other occasions, the data available are those connected to particular industrial clusters, including those focused on the use of knowledge and innovations produced within the bioscience sector. In this last case, the analysis could include actors of a very diverse nature (companies, research centres, associations, training institutions, etc.) connected by cooperative relationships.

Probably, the picture resulting from this information collection effort is not as precise as needed. Nevertheless, it is useful to proceed with the existing data and updating the information collected. Such an effort enables the interpretation of the position of individual research organisations in their closest operational

context. In this framework, it can help to identify the information about individual actors that could need to be further collected.

BOX #15

The bioscience sector and RRI: How a self-reflective excersise could work

RRI could be seen as a way a biosciences organisation reflects over its own position and role in the sector and in the world.

A given **organisation** or, more realistically, a **group** within it that is willing to promote RRI, can ask itself who are the possible actors and stakeholders within the biosciences that are most relevant for its own activities. In a RRI context, for example, one could ask itself who are the actors with which it is possible, or advisable, to start scientific exchanges concerning one or more of the 5+1 keys.

Raising such a question entails also a **critical analysis of the state of the relations with these actors** within the biosciences. Furthermore, this entails defining which relations to activate and the strategies needed for doing so. A question to raise could be, for example, what the possible mutual advantages are coming from a potential exchange.

Such a reflection, of course, does not happen in a void, but in relation to some practical aspects of the life of a research organisation. The external actors one would like to contact, for example, could be those related to specific scientific themes or policies. The case of the **nutrition** issues is an example, this being a typical policy issue that involves the bioscience sector. Dealing with this issue could require the consultation of **policy makers** in order to understand the contribution that a given bioscience organisation (or a group within it) could provide (e.g., in education, through the involvement within industrial clusters in the food value chain and so forth).

Obviously, research organisations within the biosciences have to produce new knowledge as a core mission. Beginning relations with actors within the sector, or with stakeholders and policy makers implies that some possible **knowledge demands** or **innovation**

needs have been identified. In this framework, especially where relations and dialogue are activated with actors that are relatively far from scientific research, issues concerning the **ethics of research** could emerge.

BOX #16

Diverse actors

Research organisations are **complex collective actors** that include several types of actors (mainly groups but sometimes the presence of influential individuals should be considered, especially if we consider individual cultural, scientific, political, or union leaders). Within research organisations, for example, there are **various research groups,** endowed with resources and with some kind of autonomy from several points of view (administrative, financial, etc.), that have their own formal and informal hierarchies, routines, etc. Furthermore, as research groups that bear a specific knowledge and expertise, they oftentimes play an external role in their respective **disciplinary communities**, in producing and diffusing knowledge, collecting funds, promoting cultural and academic relations, and so on. They are to some degree autonomous entities and, nevertheless, they have a specific place in the formal structure and hierarchy since they are subordinate in many respects and have to play a defined role within the research organisation. The relation between these subgroups and the overall organisation is, therefore, **an important aspect of the structure of each research organisations**.

A further distinction should be considered between **academic and non-academic researchers**. Academic researchers are those who are mainly involved in university organisations; consequently, they are mostly committed to universities' missions and their careers depend on the types of incentives produced within this institutional context (e.g., those connected to publishing). Even if innovation is becoming more and more relevant also within academia, it is to be stressed that university research activities and results are tightly connected to higher education, while researchers outside academia, for example in the industrial sector, are less committed to this type of mission. Research results themselves are

more valued within academia if they are published, while this outcome is relatively less relevant within industry than creating formal intellectual property.

Researchers and research groups are particularly relevant, but certainly they **are not the only types of actors** that operate within research organisations. Other actors contribute significantly to the pursuit of the organisations' missions, such as **technicians, administrative assistants, clerks and librarians**. In some cases such actors provide direct support to scientific research, as in the case of lab or ICT technicians, and they provide indirect support by facilitating access and use of resources and by promoting the organisations' efficiency in general as well as access to research products, as in the case of librarians.

Students are another important type of actor. They participate in academic life not only as learners and universities' service users, but also actively, as apprentices in research activities and by feeding the organisation's generational change. In this way, they contribute to the fate of the research organisations also through the role they play in the economy once they finish their educational path. This is particularly true in the case PhD students, whose research activities are important elements of the research policies of academic research organisations.

All the non-researchers working within research organisations **act both as individuals, and as collective actors**, depending on the cases and contexts. Students, for example, in many cases elect their representatives in the governing bodies of Universities and the same can happen to technicians, clerks and librarians. In many cases, these actors organize themselves so that they can represent diverse opinions or orientations existing within their respective constituencies. We have mentioned these non-researcher actors because they compose the overall picture of actor diversity within research organisations.

The practice of RRI does not necessarily imply the involvement of all the internal actors within an organisation (and, of course, not all the external ones). Nevertheless, it is necessary to be aware that RRI oriented actions **require the mobilization of various actors that, therefore, must be singled out and taken appropriately into consideration**.

BOX #17

Singling out actors for triggering the change process

At the centre of the change process oriented to RRI within bioscience organisations – especially in that particular form of change represented by the Action Plans (APs) – there is the **mobilization** of some actors, the launch of **actions connected to RRI** and the **increasing involvement of other internal actors**.

A central issue of these guidelines is that of **how the change process can be instigated**. The issue is connected to that of agency that – as stressed in the main text (see Para. 2.4.) – is a central aspect of the life of organisations, including research organisations. Agency is meant here as based on the concept of "**orientation to the future**". According to the approach of these guidelines, the issue of institutional and organisational change can be presented as strongly related to **the activation of specific actors/groups that bear an orientation to change**. We could imagine that, within an organisation, everything begins with the mobilization of a first group – a "**Core group**" – that, because of its action, triggers the entire change process. In implementing change action, such actors involve other actors and new operational and behavioural models, or new values, catch on.

Actors' mobilization has to be interpreted as a process and should not be imagined just as a foreseeable succession of action to undertake and with outcomes that can be taken for granted. An exchange between diverse actors implies the exchange of diverse orientation and the creation, or renovation, of the relations between them. In this framework, some issues are important such as **consensus**, **alliance** building between groups or possible **contrast between their different views**, **conflicts**, the promotion and management of **negotiation**. The various roles that have to be carried out by the actors in the structural change process of research organisations, therefore, also imply the implementation of

these relational aspects. From what has been said so far, this is an **open process**. Such an openness becomes evident at the beginning of Action Plans' implementation process when there is a stringent need to come to a shared point of view on the practice of RRI. But this openness is also clear in the subsequent phases, focused on the implementation of the activities for promoting RRI that imply a change in the relations between the involved actors and the emergence of new actors whose orientation to RRI develops also as a reaction to the actions being undertaken. The outcomes of the process of mobilization of the actors, therefore, cannot be taken for granted and are often unexpected, recursive, etc.

The process of self-interpretation to which these guidelines wish to contribute should therefore include the **individuation of those actors** who, within the individual research organisations, express some agreement with RRI related issues and themes. This is a preparatory moment to their mobilization. From a practical point of view, a first move consists in the identification of those groups that **already carry out activities that can be connected to RRI**. Then, other actors who are interested in RRI could be searched for. The identification of the actors who have a record of activities related to RRI implies also a **critical analysis** of their past experiences and of the **relational aspects** related to these activities (consensus obtained, conflicts raised, results obtained, etc.).

BOX #18

Institutions and the definition of the boundaries of organisations

In order to practice RRI and to promote structural change that favours such a practice, it is useful:

a) To **distinguish between institutions and organisations** in the specific context in which we are operating and
b) To **define the boundaries of the organisations** on which we are focusing our attention.

According to widely accepted definitions, **institutions** can be defined here, in an operational way, as the "rules of the game" (Alsop et al., 2006; Lawrence et al., 2011; Quaranta, 1985), and include the points of view of the actors on how such rules, and the related practices, have to be understood. The "rules of the game" have to be understood also as organisational practices (in this sense, the rules can also be "implicit" and informal and not only formal). On the other hand, **organisations** are "groups of individuals bound by a common purpose, subject to a defined set of authority relations, and dedicated to achieving objectives within particular rules of the game" (Alsop et al., 2006). This definition would imply that organisational change concerns not only the change of the formal rules (e.g., the internal regulation), but also the creation of a consensus among the concerned actors about such a change.

This distinction between organisations and institutions is important because, oftentimes, the two concepts overlap. Furthermore, the structural change these guidelines are about is referred to specific organisations. For this reason, the **"boundaries" of such organisations have to be clearly identifiable** (e.g., a University, a department, a research company).

The constitutive rules of organisations, according to the operational definition just provided, are the rules that regulate their

life and action. In general, such rules are rooted beyond the boundaries of individual organisations. Each organisation, indeed, has its own charter and internal regulations, but the set of norms that regulate their life, especially research organisations, depend on national and sectoral laws which the organisational rules must obey. This observation holds not only for written and formal norms. The academic sector, for example, is inspired by social and ethical norms that affect the behaviour of the individuals regardless their affiliation. This holds also for researchers outside academia, as in the case of integrity in scientific activities that is based on some unquestionable (and continuously evolving) principles that all research organisations put into practice.

In general, the rules (and the patterns of conduct) that define the actual behaviour of individual organisations and of their members are of a complex nature. For this reason, **structural change within an organisation has a complex nature too that depends on its institutional aspects** (cf. Kalpazidou Schmidt & Cacace, 2018). Such complexity emerges by carefully considering the relations existing between a research organisation and its surrounding (social, economic, juridical) environment. In summary, **each individual organisation is part of a larger institutional context.**

BOX #19

Actors interaction, negotiation, consensus and conflict

An aspect of organisational life that is particularly relevant for the implementation of RRI and for structural change is connected to the relations between actors, both internal and external to the organisation. We have specified above the importance of actors' diversity (in terms of discipline, functions, skills, etc.). What has to be stressed here is that the management of the relations among these actors are activities that imply a significant effort and that affect the outcomes of organisational activities in many fields. Attention should be paid to these relation-management activities, because they take place, normally, at an **informal level**.

Furthermore, maintaining relations with internal and external actors implies **negotiation**, which can be defined as an interaction process involving two or more people or groups in order to solve possible **conflicts** or to reach an **agreement** on "something", such as courses of action, collective or individual interests or organisational aims and outcomes. Negotiation could be of diverse types, depending on its objects. It can be interpretative, related to the interpretation of the situation within the organisation about the RRI related issues (e.g., the 5+1 keys); symbolic, concerning the visibility and recognition of RRI and its components; institutional, pertaining to the actual modification of the organisational structures, such as rules, procedures, institutional arrangements, etc.; operational, concerning the translation of decisions into new organisational practice and new ways of doing things. Also negotiations take place both in formal and in informal ways.

The management of relations with internal and external actors and negotiation are fundamental and interrelated aspects of organisational activities that can be strongly impacted by the practice of RRI.

BOX #20

Producing a change towards RRI that is structural

These Guidelines are focused on structural change, therefore on RRI-relevant changes that we assume should be, **comprehensive**, **inclusive, contextualized** and **irreversible** (Colizzi et al., 2018).

As for **comprehensiveness**, we mean that RRI oriented changes have to impact **several aspects of the life of an organisation** and the ways in which they are structured; in this framework it was stressed that it has to have also an "institutional character". For **inclusiveness** we mean that **all the relevant actors** within an organisation have to be involved in RRI-oriented changes since each of them contributes to the organisation's (complex) mission. **Contextualization** of RRI oriented actions is needed because of the complexity of research organisations, including those in the biosciences; particularly, contextualization means that changes have to be suited to the particular organisation story and operational environment.

Irreversibility concerns the following question: are the changes being introduced today through a given RRI oriented action going to last in the future? Since the future, as such, cannot be observed, the issue is to understand what are the characteristics of an organisation that can be detected today and that indicate what is likely to happen tomorrow.

In order to answer this question, we can resort to the four aspects of the shape of an organisation, culture, agency, action, and identity (see the Para 2.4. of the main text). Essentially, a given **change becomes structural if it affects consistently the four aspects of the life of an organisation** (culture, agency, action and identity). In order to understand this assumption an "***a contrario* mental experiment**" could be proposed in which we assume that one or more of the four aspects of the life of an organisation diverge when compared with a given RRI practice. Let's think, for example, of a

change connected to the promotion of a dialogue with stakeholders, particularly with enterprises. If the values shared by the organisation members are, on average, against these kinds of exchanges – typically, the profit motives of companies is considered as opposite to the disinterestedness of researchers – the initiatives of this type, probably will not last, also after an initial effort (the one, for example, made possible by a RRI oriented project). In the same way, if an organisation lacks groups or individuals oriented to cultivate relationships with industry – i.e., even without opposition in principle, there are no people willing to stop their lab work for this purpose – such dialogue initiatives are not likely to last. But, when the culture and orientation of the internal actors within an organisation are in favour of these exchanges, if for some reason no action is taken to promote and cultivate relationships with industry after an initial effort (e.g., sensitization, discussion, etc.), the change will remain potential but not actual. Finally, it is worth stressing that if the organisation does not create, or adapt, its internal structures and rules to the management of relations with industry – therefore its identity is not adapted to this end – it is less probable that such exchange initiatives will be carried out again in the future.

Such a complex process should be assumed as being gradual. Indeed, we cannot take for granted that these aspects of organisation shape are impacted simultaneously even if they are coherent. For example, the rules of an organisation (identity) can change more quickly than the culture of the participants, which requires greater graduality.

BOX #21

Structural change, complexity and its time dimension

The implementation of structural change through an AP – since it impacts on several aspects of an organisation – should be understood not as a mere execution of established plans, but rather as a **non-linear process**. Such kind of change, according to some authors, is often the result of the very way in which organisations react to the challenges coming from their own environment (March et al., 1993); other authors stress it is the consequence of the continuing repetition of behaviours that eventually are internalized by all the members of a given group and become routines (Berger & Luckmann, 1969). In general, structural change within an organisation through an AP proceeds according to a time frame that is not easy to foresee and does not depend only on how the AP has been designed, but also on the very dynamics of change. More in particular, the following reasons could be specified.

i. Structural change is **a process that implies the involvement of various actors**. The ways in which such an activation occurs affect the entire process and the results that will be obtained at the end of it. The involvement of actors for structural change, in particular, implies deliberative activities over the actions to be undertaken and, therefore, of negotiated initiatives. The results depend also on the number of actors involved that, in turn, cannot be exactly identified since the beginning and is, anyhow, also changing during (and thanks to) the process itself. This is an important reason why it is difficult to foresee the time a change will take and, therefore, to make an ex-ante esteem of it.

i. Change, for being defined as structural, has to affect – among other things – the **culture** of an organisation, therefore also the (prevalent) opinions and beliefs of the involved actors on issues concerning the organisation's life. It is acknowledged that such changes take a long time to happen (this is particularly true in academic milieus, see for example Clark, B.R., 1998). Any cultural change, furthermore, does not depend only on what happens within the concerned organisation – hence on the activities undertaken to change it – but also on external

factors. This is a second reason why structural change times are generally long and difficult to foresee.

i. The changes of operational routines of an organisation, by their very definition, are a consequence of the habits of the involved people, oftentimes through **formal and informal** processes that require **trial and error** and, eventually, the so-called **habituation**. Also this aspect of the structural change implies that it is slow. This, on the other hand, emerges clearly from various projects on institutional and structural change within organisations through APs (on the experience related to gender see Declich & d'Andrea, 2018).

Such considerations **could impact also the ways in which change could be measured**. If it takes a long and unforeseeable time, it would be a problem to measure it in terms of just the results achieved. Maybe, such results could be beyond the reach of an individual AP. A better strategy for measuring the change could be reading the signs that a process of change is in action, for example that the actors are oriented to pursue change and that there is consensus over the direction of change.

In this framework, it can be held that an AP is a tool that – more than for bringing about change in a deterministic way – is to be used to **concentrate actors' energies for triggering a change process** and for the – inevitably partial – management and steering of the time and direction of such a change.

BOX #22

Two different approaches to the APs

The two different interpretations of the APs share the same approach that could be defined "**knowing through the action**" (see Kalpazidou Schmidt & Cacace, 2018). The idea is that the points of view and orientations of the actors – those that matter for producing organisational change – can be actually known only through the deliberative approach and their real mobilization.

Immediate action is more emphasized in the first approach where, since the very beginning, the effort is aimed at implementing real change, and therefore through the activation of a complex dynamic that elicits criticalities, obstacles and facilitating factors, opponents and allies to change. The information and knowledge produced by such a type of action are then used in the iterative process or (re)design (and re-calibration) of the AP. An example of the first approach is the APs of STARBIOS2 project. They have been structured starting from the RRI keys and foresaw the definition of various "Streams of Actions" (SoAs), a set of activities for the pursuit of one or more objectives connected to each Key (e.g., a set of activities aimed at promoting forms of Public Engagement within a Department). Each AP was complemented by a set of information about the structure of the related organisation; this information was aimed at motivating the choice of actions, objectives, etc. The APs, from this point of view, resulted useful tools for organizing the activities aimed at structural change of the research organisations.

In the **second approach, more emphasis is given to the deliberation component** and, therefore, the actors are all involved since the beginning of the process and, particularly, those who have a stronger voice in the hierarchical structure. The AP could be seen as the **result of a phase of a relatively longer reflection** aimed at the inclusion before the beginning of the diverse actors (at the

various levels of management) for discovering the problems existing within each organisation, the actual needs and the orientation of individuals and groups that operate within them. In this framework, some pilot activities could be carried out in order to define a definitive AP. The second approach helps to put under control the consensus, although it could be more difficult to see the contrasts and criticalities that an effective change could trigger, since they emerge clearly only in the practice of change (once deliberation is over). Some EU funded projects for the promotion of RRI adopted such an approach, paying particular attention to the involvement of the high-level management of the research organisations. An example of the second approach, within the STARBIOS2 project, is also represented by the activities aimed at defining an AP by international partners.

The **possible choice between the two approaches** could depend on the actual operational context. In a situation in which the involvement of the hierarchy of the organisation can be achieved without big problems, it could be useful to begin with the second approach. In the cases in which the organisation is wide and very horizontal the involvement of hierarchies does not guarantee a diffuse involvement at the lower levels of the organisation, hence an effective triggering of the change process. In this case, it could be advisable to practice the first approach that is more focused on an immediate action and on the progressive involvement of various actors. The idea is that in these cases, direct action can be a more effective approach for mobilizing the various members of the organisation and of its hierarchies than the exercise of the authority in a dialogue.

BOX #23

How did we produce the Guidelines?

The Guidelines are based on the STARBIOS2 learning process and, particularly, on the use of three sources of information.

The observation of STARBIOS2 partners' experience from implementing APs constitutes the first source of information. Throughout the process of AP implementation, the Technical Assistance and Monitoring and Assessment teams collected the experience of STARBIOS2 partners (as explained in the Annex, Note #12 and #13). Through the technical assistance team, it was also possible to maintain close contacts with AP implementing partners.

The second source of information was recent literature and documentation (including grey literature) on RRI implementation initiatives, especially within the biosciences. The documentation and literature was collected through scientific literature databases with a semantic and qualitative research approach. A quantitative approach (keyword search) would have yielded a limited data set, as we focused on the implementation of RRI, a fairly recent phenomenon, in the specific sector of bioscience.

Based on the findings of the literature and documentation analysis, a set of living sources were identified and interviews were conducted with 8 people with direct experience of promoting RRI initiatives (mostly researchers involved in implementing RRI promotion projects). The international STARBIOS2 partners were interviewed on their experience in implementing activities of RRI nature. Additionally, contacts and exchanges were established and maintained with organisations involved in the implementation of RRI (or RRI-related) projects and initiatives. More information on "real life experiences" came from the participation in seminars and conferences dedicated to RRI and from informal talks held with RRI practitioners. For this purpose, the Biotechnology Summer School

organized in Gdansk by the Polish partner in September 2018 was particularly important.

In general, in all formal meetings of the STARBIOS2 consortium, issues related to RRI implementation were debated, in some cases involving the members of the International Scientific Advisory Committee (ISAC) of the STARBIOS2 project. In these occasions, discussions have been held also on how to define the Model and draft the Guidelines. On this basis, a first version of the Guidelines has been drafted and the Consortium partners provided their points of view. Furthermore, the Model has been discussed in a dedicated workshop held in Paris on 19 of March of 2019 (the model was described in a discussion document). An updated version of the Guidelines has been drafted and then discussed at distance with experts in biosciences and RRI. On overall point of view was requested, and particularly, concerning the fact that the text was Comprehensible by people that are new to the issue of RRI and structural change, comprehensive, (i.e. if it contains the issues that is necessary to deal with in order to promote the RRI practice), usable by the possible readers and relevant to the main problems and challenges that are being faced by research organisations within the biosciences. 20 people provided their point of view.

ANNEX

NOTES ON EXAMPLES OF DYNAMIC RRI IMPLEMENTATION TO ACHIEVE STRUCTURAL CHANGE IN BIOSCIENCES

NOTE #1

The UNESCO Interdisciplinary Chair in Biotechnology and Bioethics (2000-2009). An example of Responsible Research and Innovation between Europe and Africa

By Carla Montesano and Vittorio Colizzi

The "**Interdisciplinary Chair in Biotechnology and Bioethics**" of the University of Rome Tor Vergata is the first Italian UNESCO chair. It was founded in 1998 at the Biology Department, initially with the name "Interdisciplinary Chair in Biotechnology".

The general objectives of the UNESCO Chair are the promotion of interdisciplinary research and education in immunology and biotechnology, the collection of information and documentation in the field of biotechnology as well as the facilitation of the co-operation between the group of researchers of the University of Tor Vergata with other national and international institutions, **particularly in Africa**.

A distinctive characteristic of the UNESCO Chair has been the idea of carrying out research for solving urgent problems – for example the epidemics of HIV and Ebola virus – and for training professionals to implement the emergency interventions promoted by the Chair and the research activities needed to cope, in the long run, with such emergencies.

The UNESCO Chair, therefore, can be understood as an example of Responsible Research and Innovation aimed at coping with some of the most important health and societal challenges of the contemporary world. All the programmes carried out by the UNESCO Chair have had as their object one or more of the 5 RRI keys, such as Education, Ethics, Social Engagement, Open Access and Gender. For example, gender has been crucial for programmes concerning public health and the infections caused by HIV: the targets of the Chair's interventions have been mothers and

children, who are exposed to the vertical transmission of the HIV. Furthermore, education and gender are also at the centre of the current programmes supporting the reconstruction of the Somali National University and the development of higher education in Cameroon, in which a particular attention is paid to gender equity in professional university training. It could be stressed that all the activities involve various stakeholders beyond those strictly connected to the academic institutions and the research communities. **The promotion and the coordination of the STARBIOS2 project by the Department of Biology that hosts the UNESCO Chair is an expression of this orientation towards RRI**.

In general, the main programmes carried out by the UNESCO Chair were always an **inextricable mix of technical-scientific and social challenges**. A clear example of this connection concerns the fight against AIDS and other epidemics that have characterized most of the activities of the UNESCO Chair in West Africa. At the basis of this approach there was a **specific and innovative vision** that, at the time, was not common amongst the disciplinary community of immunologists. The idea was that in Africa, or in other regions with huge forests, important evolutionary processes were impacting the microbial world. In such geographic areas the evolution of virus such as HIV, Zika, or Ebola were impacted by human encroachment. Therefore the choice was to study the relations between hosts and microbes in the impacted locations so as to witness also the societal process driving change. It was just like fighting the war along the battle line. This vision represented not only a fresh immunologic perspective, but also a wider angle in which societal factors were important and played a pivotal role in bringing about the health and disease challenges taken on by the UNESCO Chair.

Below are presented the main programmes carried out by the UNESCO Chair, with a specific reference to the operational objectives and to the connected scientific challenges.

1. Programme to support Capacity Building and the treatment of HIV/AIDS infection in the Benghazi Centre for Infectious Diseases and Immunology (BCIDI) in Benghazi, Libya (2000-2006, EU funds).

The programme consisted of technological transfer initiatives and in training activities for the health professionals involved in the clinical follow up of HIV/AIDS infected children at the **BCIDI of Benghazi (Libya)**.

In 1998, at the paediatric hospital in Benghazi, over 400 children were accidentally infected with a single strain of HIV. This single virus impacted differently the clinical course of HIV infection in each child by inducing early and severe or mild and long diseases; from the point of view of biomedical research, such information was crucial because has highlighted one of the pathogenetic mechanism of HIV infection (see de Oliveira T., 2006).

The work of the UNESCO chair was aimed at strengthening the BCIDI laboratory and strengthening the level of treatment of HIV-infected patients up to international standards in synergy with other partners.

But this nosocomial outbreak was actually an immense social and cultural challenge that was undertaken not only for the activity in favour of the children of Benghazi.

In fact, through the work done it was also scientifically demonstrated, through the DNA sequencing of HIV (see de Oliveira T. 2006), that 6 Bulgarian nurses who stand accused and sentenced of death of transmitting the HIV strain to the children were innocent; such results supported the existence of nosocomial transmission scenario suggesting that paediatric hospital had a long-standing infection-control problem[26].

[26] The story of the diplomatic initiative for freeing the 6 nurses was carried out primarily by the European Union. It is described in the book (Pierini, M., 2008) written by one of the protagonists, the Head of the Delegation of the European Commission in Libya Marc Pierini. The book mentions the scientific works done also by researchers belonging to the UNESCO Chair. See also Ahuja et al. (2006) and Colizzi et al. (2007).

2. UNESCO Programme "Family First Africa" for scientific research and the fight against mother-child transmission of HIV/AIDS in Burkina Faso, Ivory Coast and Cameroon (2003-2005, UNESCO Funds)

The UNESCO Programme, funded through funds of the Italian Government and called "Family First Africa", consisted of technology transfer, training of health professionals as well as of HIV-infected mothers with the aim of limiting vertical infection in three countries of West and Central Africa (Cote d'Ivoire, Burkina Faso and Cameroon). In all these African countries, the programme created research and health organisations for the treatment of HIV-infected people that are still working today and are perfectly integrated into local health systems.

The scientific questions on which we focussed concerned the mother-child transmission mechanisms of HIV infection. In RRI terms we can say that we decided to investigate a problem under a gendered/sexual perspective. The relevance of this question was largely social: mother-child interactions contributed to the transmission of HIV, creating more danger and suffering. Thanks to this programme, 56 African professionals were trained, and some of them have gone on to obtain a formal PhD.

3. Capacity building and scientific research programme at the International Reference Centre "Chantal Biya", CIRCB, of Yaoundé (2006-2009, Funds from the Italian Ministry of Foreign Affairs and International Cooperation MAECI)

The foundation and launch of the new International Reference Centre for the fight against AIDS in Cameroon (International Reference Centre "Chantal Biya", CIRCB) was made possible by this programme through diverse initiatives aimed at technological transfer, training of health professionals, supporting the Health Ministry of Cameroon to identify the best prognostic and follow-up strategies as well as to reduce genetic resistance against antiretroviral drugs.

Particularly, the CIRCB greatly supports the study of **HIV-1 variability among antiretroviral-treated adolescents**, as this set

of children receives **low attention and poor therapeutic options** in resource-limited settings. As many HIV-infected children are now reaching adulthood, researchers and clinicians have established guidelines for **successful transition from paediatric to adult anti-retroviral regimen** in countries like Cameroon. The CIRCB is equipped and trained for the complete analysis of the HIV genome to reveal the viral mutations responsible for genetic resistance to anti-retroviral drug treatment.

The centre is currently composed of 5 physicians, 10 nurses and 20 researchers, mainly biologists, and it is the national reference centre for the fight against AIDS in Cameroon.

4. Emergency programme in Sierra Leone during the Ebola epidemics (2015-2016, Funding from the Italian Episcopal Conference and Italian Ministry of Foreign Affairs - International cooperation - MAECI)

The Programme consisted of setting up a Laboratory of Molecular Biology and Immunology for the diagnosis of infection caused by the Ebola virus at the Holy Spirit Hospital of Makeni in Bombali District, Sierra Leone.

The Laboratory has facilitated the re-opening of the Holy Spirit Hospital (Makeni, Bombali District) allowing the diagnosis of Ebola infection and the follow-up of Ebola survivors. The Laboratory has been set up with molecular and cellular technologies to identify Ebola-positive individuals and it was also feasible for diagnosis and follow-up of infectious diseases as HIV, hepatitis B and hepatitis C and other sexually transmitted diseases.

The Laboratory at Holy Spirit Hospital was able to identify person exposed to Ebola infection (contacts) and survivors. Together with Public Health England, a non-invasive technology based on the detection of antibodies specific against Ebola in saliva has been developed. The training activity addressed to health care workers and university students has been one of the main objectives of this Programme, and still now (2019) personnel of the University of Rome Tor Vergata are teaching at the Public Health

School of the University of Makeni. Forty students and professionals were trained through this initiative, and the Programme is still supporting the School of Public Health of the University of Makeni, led by a Cameroonian PhD scientist trained by the UNESCO Chair at the University of Rome Tor Vergata".

5. Programme for supporting the reconstruction of the Somali National University (2015-2020)

The Programme that is composed of various projects involving various Italian universities is aimed at re-organizing the administration, renovating the infrastructure and training the teaching personnel of the Somali National University (UNS) both in Italy and in Somalia.

In the context of a bilateral Agreement between Italy and Somalia, the UNESCO Chair of Biotechnology and Bioethics supports a specific project (financially supported by the MAECI) to activate an e-learning Centre at UNS, by providing informatics equipment and teaching materials. Clinical fellow and PhD programmes are also in progress to form the future teaching personnel of the UNS.

6. Programme for supporting the universities of Cameroon (Funds from the University of Tor Vergata and the Conference of Rectors of the Italian Universities, 2015-2020)

The Programme has been launched with the aim of developing some sectors of teaching in the Cameroon Universities that are particularly weak, such as biomedical engineering, physiotherapy and biotechnology. The UNESCO Chair has acted as the main promoter of the initiative.

"During a visit of the President of Cameroon, S.H. Paul Biya, in Italy in 2016, a specific agreement was signed by the President of the Italian Conference of Rectors and all the Rectors of the eight public Cameroonian universities. Some innovative teaching programmes have been developed with the University of Dschang, Ngaudere, and Yaoundé under the supervision of the Ministry of

Higher Education of Cameroon. Moreover, the Evangelic University of Cameroon has activated, together with the University of Rome Tor Vergata, the Faculty of Science and Technology with the aim to experimentally pilot academic courses in Global Health, Medical Engineering, Physiotherapy, Oncology and Advanced Medical School that – after the approval by the Ministry of Higher Education of Cameroon - will be expanded to include other Cameroonian universities."

7. Programme support for the Centers for Diseases Control (CDC) and Prevention of the African Union through the Journal of Public Health in Africa (Funds from University of TorVergata-PagePress, 2016-2018)

This Programme disseminates best practices of Public Health in Africa through the Journal of Public Health in Africa. It is an open-access journal created by PagePress in Pavia and the holder of the UNESCO Chair has been for the last 3 years the Editor of the Journal. A specific agreement between PagePress and the Africa Centers for Diseases Control (a technical institution of the African Union) has been signed in December 2018 and initiated on 1 of January 2019 as the official Journal of the Africa-CDC. A new editorial strategy has been implemented to increase the impact of the Journal of Public Health in Africa within the continent.

8. Organisation of a session of the Conference of the American Association for the Advancement of Sciences (AAAS) in February 2019 on "Epigenetics in Infection, Diets and Environment: Responsible Research and Innovation"

Within the STARBIOS2 project, the UNESCO Chair has promoted new ideas concerning new fields of research in the immunology sector. Such an activity is seen as a consequence of the increasing awareness of RRI. In this framework, on February 2019, STARBIOS2 sponsored a session of the AAAS annual meeting. Particularly, we established that infections and nutrition both contribute to the "Exposome" of the human organism, and collecting "big data" on the response of the organism requires RRI-related strategies to cross boundaries between geographical regions,

scientific disciplines, as well as scientific and non-scientific communities. The orientation towards dealing with the concept of Exposome is seen by as a way to further investigate the development of immunological responses arising from the interaction between hosts, microbes, diets, and other environmental elements. The results of this research are deeply dependent on a wide set of factors – including social ones – that bring about the juxtaposition of hosts and environments.

NOTE #2

Responsible research and innovation for the conservation of biodiversity

By Elena Buzan

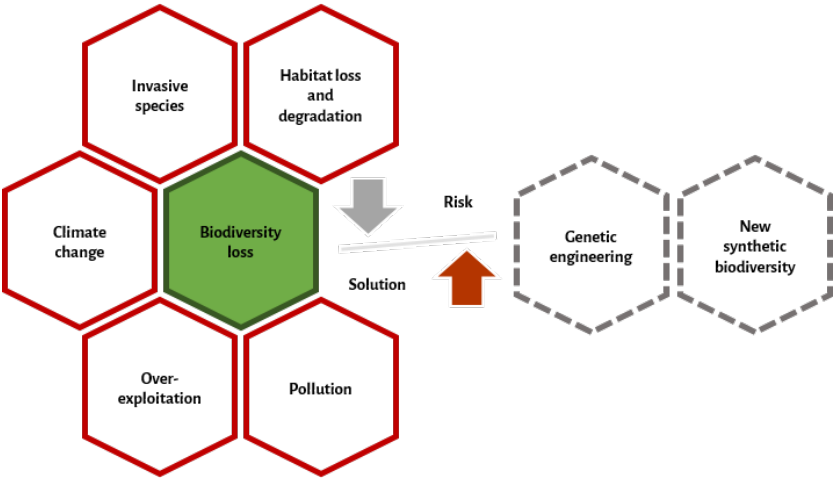
Biodiversity, the basis of the ability of ecosystems to provide services to humanity, has dramatically declined in past decades. The gravity of ongoing biodiversity loss is exemplified by the Earth's sixth mass extinction. Biodiversity loss is closely linked to human activities and has severe effects on growth and economic development.

Progress is being made in the research and development of environmental engineering and synthetic biology, with a growing number of advances in robotic manufacture, pharmacy, medicine, biotechnology, chemical engineering, agricultural and energy sectors. Also, these developments may provide solutions to many environmental challenges, such as climate change, scarcity of clean water and soil and biodiversity loss etc. Synthetic biology is a good example of how research and innovation could play a central role in growth and economic development. Although synthetic biology is beneficial for society, there are many scientific uncertainties surrounding the development of synthetic life, cells and genomes, especially in terms of their impact on the environment. Introduction of novel, synthetic organisms may pose a high risk for natural ecosystems and biodiversity (Figure 1). Therefore, risks and benefits of innovation for biodiversity are subject to debate, both in the field of research as well as in civil society.

Responsible Research and Innovation (RRI) is a rapidly evolving concept, with emphasis on motivation, theoretical conceptualization and translation into practice. RRI has lately included environmental sustainability as a key area for the social desirability of research and innovation. We believe that it is

essential to implement RRI in conservation biology, a discipline in crisis, protecting nature in all its complexity.

Figure 1. Major factors influencing biodiversity



It is crucial for society and its citizens to participate in the processes of RRI in biodiversity conservation. To ensure everyone's involvement, the public needs to be sufficiently literate about how science works. They need to be able to understand the benefits and risks of innovation in technology in order to participate in debates, evolve ethical thinking and make informed choices. Particular attention should be given to fostering new skills and knowledge by the education system; primary/ secondary schools and universities alike, centred on the use of science education with environmental ethics and bioethics. The education should develop many skills of scientific thinking, so that students are able to interpret evidence, evaluate innovation and technologies, make informed judgements, and argue their perspectives. By increasing awareness for the need for gender equity and for using sex as a key variable in research, one is teaching important scientific skills that are relevant in RRI.

By transforming the education system, the RRI culture of safeguarding biodiversity eventually spreads to influence both academic and non-academic groups.

In our work, five key principles (science education, public engagement, open access, gender equality and ethics) were used to design a framework (Figure 2a) for an impact assessment of RRI in biodiversity conservation. Our first step was to provide quantitative factors for promoting and monitoring RRI at a faculty (university) level, which is involved in the education of biodiversity conservation.

The second step was to assess the impact first on university employees and students and then on broader socio-economic indicators to ensure the durability of internationally sustainable nature conservation. Selected target groups were organised to explore five issues: professional development, policy change, open publications and data, gender in society and ethics of biological experiments and their environmental impacts (Figure 2b).

Figure 2. Framework to include RRI within conservation of nature's biodiversity

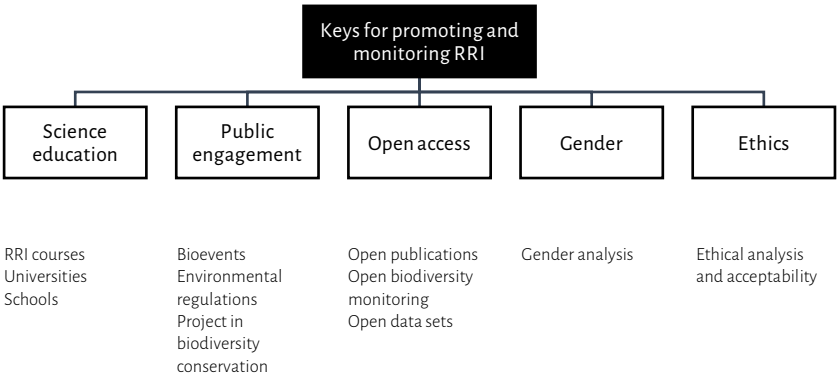


Figure 2a

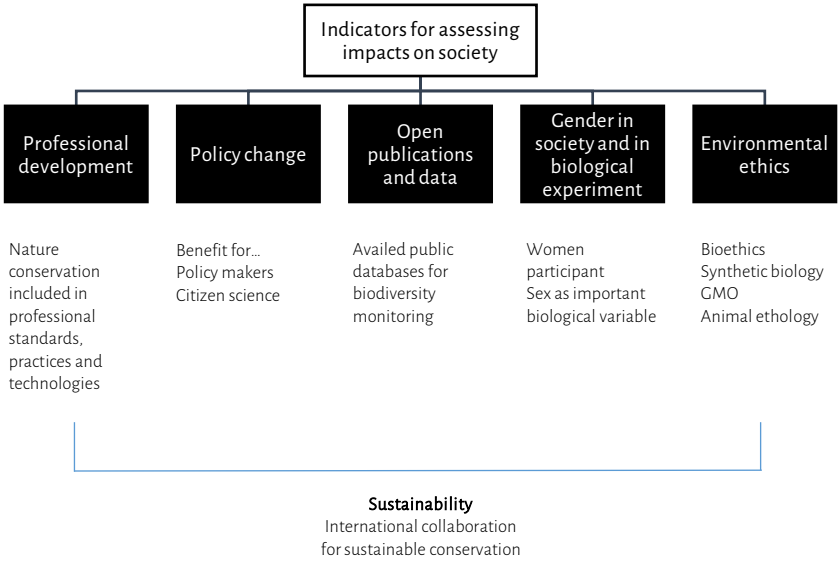


Figure 2b

Biodiversity data are highly heterogeneous due to the diversity of observed taxonomic groups, the methods used and different types of data produced. Ensuring data interoperability is vital to validate professional standards, practices and technologies. There is also an urgent need for data standardization for policy-makers and citizens. The standardization and data aggregation has to be prepared so that it is both human- and machine-readable. Universities and other education organisations should develop knowledge of inheritance using arguments pro and contra (example genetic modification of organism), and weighing up the benefits and risks that apply science to make a decision.

Citizen science is a form of public participation in scientific research which has gained significant momentum in recent years. This is particularly evident in biodiversity conservation and environmental sciences where input from citizen scientists has

greatly increased the number of publicly-available observations. Data collection starts with designing data forms, developing observation portals, communication of data collection methods and storing data by research institutions or government agencies, which allows an easy data presentation for different stakeholders. The partnership among academics, researchers, scientists, lecturers and society includes schools, students and families and is vital for opening up more opportunities for open education in environmental and biodiversity conservation. Promoting RRI can also enhance teachers' professional development by bridging formal and informal learning about innovation in synthetic biology and biotechnology while incorporating environmental ethics. Involving community through citizen science is vital for evidence-based pedagogical changes supported by knowledge, skills and a culture of RRI that involves all members of society in technological innovation and nature conservation.

NOTE #3

An analysis of gender equity in scientific authorships: a case study of the National Institute for Health Research Oxford Biomedical Research Centre

By Rinita Dam, Syed Ghulam Sarwar Shah, Pavel Ovseiko, Lorna Henderson, Vasiliki Kiparoglou and Alastair Buchan

Women are under-represented in academic medicine [1-2] including the authorship of scientific publications [3-5]. Funding requirements for the National Institute for Health Research (NIHR) Biomedical Research Centres (BRCs) have resulted in many improvements for women via the Athena SWAN Charter on gender equality [6]. However, there are still areas which need addressing. The number of women and their achievements are not tracked routinely by the NIHR BRCs and little is known about how much women contribute to research and innovation in the BRCs. It is therefore imperative to inform the acceleration of women's advancement and leadership in translational research not only in line with the stated objectives of the NIHR within the UK but also from the Responsible Research and Innovation (RRI) perspective within the wider European Research Area through the collection of gender-disaggregated bibliometric data and gender analysis of scientific authorships.

Aim: To undertake retrospective bibliometric analyses of authorship by gender using the NIHR Oxford BRC publications for the period from April 2012 to March 2017.

Methods: The authorship of NIHR Oxford BRC's research publications (n=2409) was analysed for gender of the first author, joint first authors, first corresponding author, joint corresponding authors, the last author and joint last authors. The gender of author(s) was used as a binomial variable: male and female. The gender of the authors was identified from the names of authors through a rigorous methodology. When the authors' names were difficult to associate

with the appropriate gender, further information was sought, such as their institutional affiliations, or social networks e.g. LinkedIn and ResearchGate. Gender API (gender-api.com) was also used when it was not possible to ascertain the gender of the authors via their institutional affiliations or via the social networks. In addition, some authors were contacted directly to ascertain their gender.

Data analysis: Data were analysed using frequencies and descriptive statistics in the SPSS (version 25 for windows). Publications with 'missing data', 'unable to determine gender of authors' and authors reported as 'trial groups' were not included in the analysis. In terms of calculating the proportion of female and male authorships, only authors with defined gender were included in the analysis. Chi-Square tests and *p* value less than 0.05 were used for identifying statistically significant differences in various types of authorship between male and female authors.

Results: The gender of the first author was mostly male (59%, n=1430) compared to female (41%, n= 994). 458 publications included joint first authors (authors that were named as equal contributors in publications), which included both male and female (57%, n=262), male (28%, n=127) and female (15%, n=69). The first corresponding authors were mostly male (65%; n=1565) compared to female (33.5%, n=806). 169 publications reported joint corresponding authorship which involved mostly male (63%, n=107) than female (29%, n=49) and both male and female (8%, n=13). Senior authors were mostly male (77%, n=1853) compared to female (23%, n=553). Joint senior authors reported in 229 publications were mostly male (47%, n=108) followed by both male and female (43%, n=98) and only 10% were female (n=23). Chi-square goodness-of-fit tests showed that the proportion of female authors was statistically significantly lower than the proportion of male authors in all categories of authorships in our sample.

Impact: STARBIOS2 has acted as a catalyst of structural change as these findings prompted the NIHR Oxford BRC to routinely record gender in scientific authorships and measure gender equity in research reporting.

NOTE #4

Technology transfer as a form of Responsible Research and Innovation (RRI)

By Maria Salvato

On 18 February 2019 the STARBIOS2 Consortium held a workshop on "Technology Transfer as a form of Responsible Research and Innovation" to showcase RRI efforts at the University of Maryland, Baltimore, Maryland, USA. The following is a brief presentation of this theme and, particularly, of the difficulties encountered and the solutions attempted in the implementation of Technology Transfer.

The University sees its mission as creating knowledge for the benefit of society, with Technology Transfer as the transmission of that knowledge to the public. To begin with, the university makes great efforts to educate the public about its discoveries and to assist its faculty in patenting and licensing their inventions. Technology transfer takes many forms, but three concrete examples of Technology Transfer are given here: 1) the transfer of a cholera vaccine to a company that could market it to the public; 2) the engagement of local people with AIDS by University sociologists and medics to help them manage their diseases; and 3) the transfer of technology from wealthy countries to resource-poor countries half-way around the globe. These examples illustrate both obstacles and solutions.

Infrastructures created to assist in technology transfer

To promote technology transfer, the university created infrastructures such as an Office of Public Engagement, an Office of Technology Transfer (OTT), and an Institute of Clinical Translation and Research (ICTR).

For public engagement, the University produces a number of newsletters and brochures describing faculty discoveries in

lay language. It holds educational seminars open to the public and has specific programs to educate school children about research (The CURE Project, Internships, and Summer Medical School). An area that needs improvement is the involvement of more faculties in STEM education; so more salary and promotion incentives are needed to insure faculty participation.

The OTT helps faculty members patent and license their inventions. Unfortunately most faculties do not want to take time outside their research laboratories to file provisional patents and to interface with marketing officers. A solution would be for universities to compensate faculty to file provisional patents, and to arrange for faculty to share in more of the income from licensing arrangements. The OTT sponsors classes in Entrepreneurship for ~12 graduate students a year. This educational effort is extremely valuable and could be expanded to educate more students, post-docs and faculty. The ICTR is another element of the University's infrastructure that promotes technology transfer by giving grant money to faculty for pilot studies that could lead to translation of research. The ICTR also creates core laboratory facilities that help develop research projects so they are more easily transferred to Contract Research Organisations. The University President's office has expanded its marketing of University inventions to the Biotech industry that is growing in Maryland. As public funding wanes and private funding increases, more faculties will look towards industry collaborations to fund their research.

Technology Transfer of a cholera vaccine

In the 1980's, Dr. James Kaper at the University of Maryland made genetic modifications to virulent ***Vibrio cholera*** in order to create a live-attenuated vaccine against cholera (Herzog, 2016). A single oral dose could confer 90% protection from severe cholera diarrhoea that annually afflicts as many as 4 million people around the world. With the help of a senior colleague who had industry connections, Dr. Michael Levine, the vaccine was marketed to a Swiss company.

Unfortunately, some of the biggest markets for such a vaccine, Europe and Australia, passed laws against the sale of "genetically modified organisms" (GMOs) and the market for this cholera vaccine shrank. For a time, the vaccine was only given away ***gratis*** by the World Health Organisation, and by 2004 it was no longer economically feasible to produce. The vaccine sat for years in cold storage, but cholera outbreaks in war-torn regions of the world caused the demand for this vaccine to resurge. In 2009 it was licensed to PaxVax in San Diego and in 2016 it was issued an FDA license. The lessons from this story are: 1) laboratory inventions do not go anywhere without marketing; 2) the resistance of popular beliefs (like anti-GMO sentiments) must be overcome by educating the public; 3) one must be patient and persistent to bring a vaccine to the people.

Health care delivery to the neighbourhood adjacent to the University

The University of Maryland School of Medicine sits next to a neighbourhood gripped by poverty, crime, and disease: 12 % of the adult population is HIV+, and 80% of the HIV+ people are Hepatitis C positive; the average annual income is $17,000 per family; 34% of the people believe AIDS was manufactured in a laboratory, and most of the population prefers to use "alternative medicine" (mysticism and herbs) (Temoshok & Wald, 2008). The University has created programs of job assistance, childcare, healthcare delivery, and spaces for public engagement, but it faces enormous obstacles. For example, although an estimated 30,000 individuals in a city of 600,000 people are HIV+, only 5,000 have agreed to medical treatment. The University tries to reach people through their churches, to promote HIV testing and treatment, and to create mental health and social programs. All these programs are small in comparison to the immense need but they do serve as beacons of hope.

Technology transfer from affluent to resource-poor countries

The University has many global programs in surveillance and health care delivery. Professor Claire Fraser, Director of the University's Institute of Genome Science and new President elect of the AAAS, provided a vaccine to Kenya for a disease that was decimating cattle. The funding obstacle was overcome by obtaining small private funding that later attracted World Bank funding. A similar effort to bring a Lassa vaccine to Nigeria was described by Professor Salvato, a member of the STARBIOS2consortium. The Nigerians want their own people trained in vaccine production, and they have money available for building an institute and paying teachers, but they still need more clinics to screen for disease, train technicians, medics and project managers, biosafety committees, animal care facilities, human subjects monitoring, and a better system for data storage and sharing. Such an effort will resemble the Argentinian effort to manufacture their Argentine Haemorrhagic fever vaccine. With a seed stock from the US Army and some US technical training the people of Argentina were able to achieve independent vaccine production in approximately 5 years (Ambrosio et al., 2018).

Professor Vittorio Colizzi, Director of the University of Rome and Principal organizer of the STARBIOS2 consortium spoke of epigenetic studies in Italy and Africa to monitor the effects of specific plant diets on miRNA expression and disease resistance. He described the difficulty of convincing subjects to volunteer for his studies. He also mentioned problems of ethically handling private information, and problems with making big data openly accessible. A core issue of technology transfer to Africa is the lack of academic infrastructure and trained personnel. All the members of the STARBIOS2consortium have training programs that recruit young medics and scientists from Africa. The developing countries problems in technology transfer are complex, but those with vision must be empowered to lead the political and scientific actors in a mutually agreeable strategy.

NOTE #5

Science education as a trigger for RRI structural change

By Doris Elster, Tanja Barendziak, Julia Birkholz

In this section, approaches and experiences at the University of Bremen illustrate how effective structural change processes can be triggered by science education. The RRI implementation and its associated structural change process pose a major challenge for research institutions. Future researchers and university students should acquire knowledge and skills to work responsibly during their academic experiences and training. Critical awareness and social responsibility are not additional skills to be casually patched onto research and innovation processes but should be a general attitude of researchers (Colizzi et al., 2019). To put RRI issues into practice in the Bremen context RRI should be fostered and developed through science education in a whole institution approach.

The University of Bremen is a relatively young university in Germany with 12 faculties and about 20,000 students. Faculty2 Biology and Chemistry is a partner in the STARBIOS2 project with the goal of developing a tailored Action Plan for the negotiation of a RRI mission statement. A Core Team with science educators as central agents is set up and the important stakeholders of the faculty (dean, vice dean, and members of the quality management) as well as representatives of students, doctoral students and researchers are involved in this process (Elster, 2016).

In the Horizon 2020 framework RRI is built on the following key dimensions: *Societal Engagement* and *technology transfer* focus on the promotion of the engagement of all societal actors in the R&I process; *Gender* aims at favouring gender equality within research institutions as well as in the R&I content; *Science Education* aims to provide future researchers with news capacities for attracting children and youth to science and technology; *Open Access* focuses

on making research and innovation transparent and accessible through making Open Access a reality; and ***Ethics*** aims to ensure high quality research results and ethical standards (Von Schomberg & Von Schomberg, 2013). The RRI mission statement of Faculty2 should refer to these key issues acknowledging the need for RRI to be critical, transformative within its environment, anticipative of future needs, inclusive and gender sensitive, reflexive about its actions, and responsive to trying new approaches and knowledge. For the implementation of these goals a complex roadmap (Figure 1) comprising four stages is set up (Elster et al., 2016).

In stage 1, we perform a comprehensive state-of-the-art analysis. It includes an analysis of literature and RRI research programmes. Based on this, we derive a theoretical model for the analysis of research projects and develop interview guidelines. We conduct the interviews with representatives of the focus groups of students, doctoral students and researchers. The results form the basis for a questionnaire survey. Based on the results of the interview and questionnaire surveys, we derive a list of criteria for the implementation of the RRI issues. It forms the basis for the first recommendations for the development of a RRI mission statement for the department.

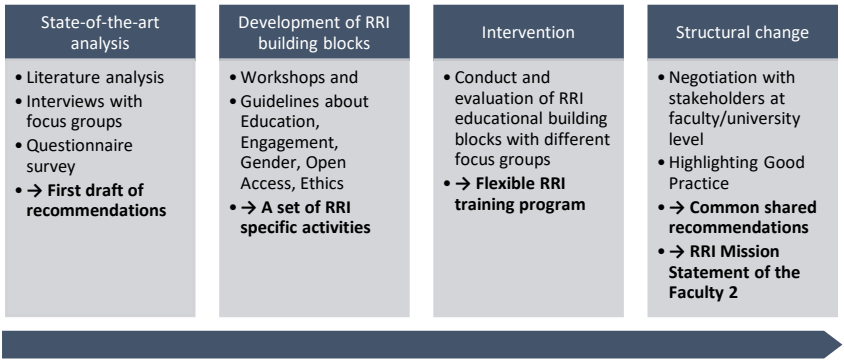
In stage 2, we develop different RRI educational building blocks and activities. They are based on a communication model and a theoretical model to promote RRI literacy. The RRI educational building blocks comprise reflective activities as well as RRI modules and workshops.

In stage 3, the RRI educational building blocks are tested and evaluated by the representatives of the different focus groups of students, doctoral students and researchers. They evaluation findings form the basis for a broad-based and flexible educational training program.

In stage 4, the evaluation of the RRI training programs as well as the results of the initial analyses lead to the derivation of RRI Key specific recommendations for the Faculty2. They are summarized

in the Booklet of Recommendations and form the basis for an in-depth negotiation process. The aim here is the RRI mission statement of the Faculty2.

Figure 1. Roadmap for structural change at the University of Bremen (Elster et al., 2016).



Educational concepts to promote RRI

Science education has an important role to educate the future scientists and university students. What scientists do, how they work, innovate and make decisions are important subjects for contemporary science education. While science and technology develop, science education needs to renew itself and work along with the developments in science and technology. New developments and technologies are very often controversially discussed in society. Therefore, a useful model for the processes of **communication between researchers and the public** is needed. It forms the basis of educational and didactical interventions.

In the case of the University Bremen new educational models should trigger the raising of awareness of RRI issues and an inspiring and fruitful structural change regarding RRI issues. As a consequence, within the Starbios2 project new educational concepts are developed at the level of students' individual training

by **RRI reflective activities**, **RRI modules** as inspiring practices, and **RRI in the curricula of academic programmes**. In addition, further events and outreach initiatives programmes are reported.

A communication model between researchers and the public

Our communication model is based on the Common Ground Theory based on Bromme (2000) and the Model for Communication about Biotechnology based on Ben France and John K. Gilbert (2006). In everyday communication, interaction partners encounter different perspectives. The question of how mutual comprehension arises in the case of different perspectives or knowledge especially in the expert and layman communication. The Common Ground Theory postulates that every act of communication presumes a common cognitive frame of reference between the partners of interaction called the common ground. All contributions to the process of mutual understanding serve to establish or ascertain and continually maintain this common ground (Bromme, 2000). "Two people´s common ground is, in effect, the sum of their mutual, common, or joint knowledge, beliefs, and suppositions" (Clark, 1996: 3).

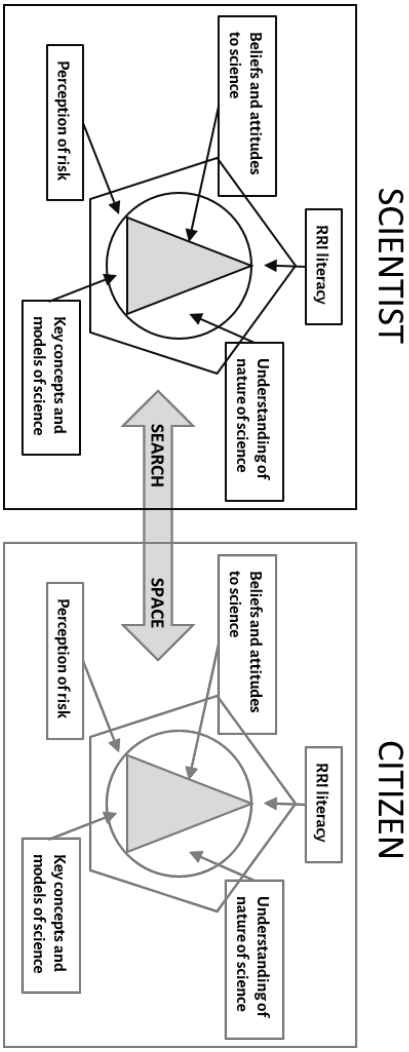
Researchers in the field of biosciences face the challenge to persuade "the public" of the rightness of their case, whilst "the public" is trying to argue a sceptical, or even contrary case. A model that might be of use in any field where technological controversy takes place was set up by France and Gilbert (2006). They took the idea of a communicating community, defined as relatively coherent social group engaging in communication with itself. The authors differ the biotechnology communities and the public communities. Each of the communities has a certain "view" on biotechnology that is made up of four "dimensions": their understanding of the nature of science and biotechnology; understanding of the key concepts and models used in biotechnology; perceptions of the nature of risk; and beliefs and attitudes about biotechnology.

Similar to Bromme´s definition of a "common ground" (Bromme, 2000) France and Gilbert (2006) define a "search room" as a virtual

arena where the "views" of the communities of scientists and the public communities are exchanged. "Where there are elements of the views that are in common to the two, communication is possible. Where there is no commonality, the degrees of understanding reached must be used to construct a mutual understanding that may evolve into an agreement exchange" (France & Gilbert, 2006: 2).

Within our Starbios2 project in Bremen we have to expand this model in respect to the RRI issues. Firstly, we defined a *RRI literate researcher* is a person who 1) perceives sensibly to detect questions related to RRI issues related to societal engagement and technology transfer, gender, ethics, open access publications and science education; 2) who is willing to apply its knowledge of RRI issues; 3) who actively acts to disseminate RRI issues in the context of research and the research institution. Secondly, we expanded France and Gilbert´s four "dimensions" by a fifth dimension, the RRI literacy. And thirdly, we extended the model which specifically focused on biotechnology to a more comprehensive view on biosciences. Our inclusive communication model is summarized in Figure 2.

Figure 2. The inclusive communication model for biosciences



Promotion by RRI reflective activities

The promotion of critical thinking is considered one of the key issues of good scientific RRI education. Students and researchers should be encouraged to critically question what is good and conscientious practice within their scientific domain. They should be aware of societal needs and that research is not oblivious towards societal values.

Reflexive capacities are crucial for understanding the role and responsibilities of research. Therefore, students and researchers should be aware of the interrelationship of their own research with other areas of science. The goal is to open the view to collaborate and coproduce knowledge with researchers as well as professionals outside their own fields and with interested citizens.

Within the Starbios2 project a series of reflective activities in respect to the societal engagement, contextualization of research, publication open access, gender in research, diversity team management, ethics in science communication are developed, tested and evaluated. They are summarized in the RRI toolbox at the local website[27]

RRI modules as inspiring practices

In the context of Starbios2 at University of Bremen the concept of raising awareness of RRI issues through RRI educational building blocks is based on the Citizen-SIP educational model. The model is based on Problem-based Learning (PBL) in socio-scientific contexts (SSC) and Inquiry-based Science Education (IBSE) with a specific focus on Citizenship Education (CE). Problem-based learning stands for self-determined and discovering learning, action-oriented teaching, interdisciplinary learning and self-evaluation. Participants learn to analyse a topic or question, to find and use suitable sources of information, and finally to compare, select

[27] (https://blogs.uni-bremen.de/starbiosbremenenglish/).

and implement solutions. Socio-scientific issues (SSI) are open-ended, multifaceted social issues with conceptual links to science (Sadler, 2011). PBL in socio-scientific contexts in authentic research projects as "real-world scenarios" offers powerful opportunities to develop critical thinking on the nature of science and its implications (Lederman et al., 2014). IBSE is an appropriate educational instrument to acquire process skills and an adequate view of the Nature of Science (Capps & Crawford, 2013) as well as a meaningful understanding in a societal context. Citizen Education takes into account the moral and social function of education at a socio-political level.

RRI in science education requires that students have creative thinking and problem solving skills. RRI deals with dilemmas and uncertain situations where students' arguments are as important as the scientific facts. Examples of RRI modules developed at the University of Bremen are "Promotion of Risk Literacy in Regard to Nanotechnology", "Wake up – Sensitisation of adolescents for the stem cell donation for leukaemia patients", and "Biodiversity loss and climate change in the Wadden Sea". These modules are developed in doctoral and master studies in cooperation of scientists, science educators and teacher candidates. The modules are evaluated in in-service trainings, pre-service education and schools.

RRI in curricula of the bachelor's and master's programmes

University students as nascent researchers should acquire knowledge and skills needed to work responsibly during their academic experiences. In their academic development, ideas and concepts of RRI should be fostered and developed throughout the formative process of education. Traditional academic hierarchies should be modified to enhance the voluntary participation and debate among the students. In an atmosphere of openness and trust, students should be encouraged to draw their own conclusions and provide valuable contributions to the debate.

The integration of research and teaching can provide valuable ways of enhancing student learning experiences. Nevertheless, the linking can be challenging and the understanding of a "research-based education" and "research-informed teaching" within and between disciplines is diverse. The "nexus" of research and teaching is influenced by the departmental structural arrangements for organising research and teaching activities, and a potential gap in making connections between staff research outputs and students´ learning when this research is too far ahead of the undergraduate curriculum to be accessible to students (Jenkins, 2004). Graffiths (2004) and Healey (2005) distinguish five "Research-informed teaching" approaches:

- Research-led (RL): Students learning "about" the research of others.
- Research-oriented (RO): Students learning about research processes.
- Research-based (RB): Students learning as researchers.
- Research-tutored (RT): Students learning through critiquing research.
- Scholarship of teaching and learning (STL): Enquiring and reflecting on teaching and learning.

In the bachelor's Biology programme and in the different master's programmes at the Faculty2 all five approaches of research-informed teaching are offered. They provide different avenues for RRI learning. Whereas during the bachelor's programme different concepts, ideas, relevance and aims of research and RRI are discussed (RL and/or RO), the integration in research groups and writing of the bachelor theses offers the possibility of students learning as researcher (RB). That allows them to relate RRI processes in the own field and the role of responsibility in these processes. Especially within the associated modules "interdisciplinary key qualifications" students learn about criteria for good research and ethical issues in scientific writing.

In the master's programmes of biosciences students focus on the specific topics of their fields of research and research-tutored (RT) learning may be at the core. Science chats and master seminars

allow doing and experiencing dialogical reflection on research and innovation (STL) and a perspective with the wider society.

RRI in the curricula of PhD programmes

Most of the reflective activities developed in Starbios2 projects are targeted to PhD students and young researchers. When doing more or less self-reliant research the application of RRI issues is important. The assessment of possible societal impacts of one´s own concrete research activities as well ethical issues of research receive increased importance. The goal is to propose adoptions to better align a research project with societal needs, values and expectations.

A good practice example at the University of Bremen is the Graduate School Nano Competence – Research, Mediation, and Design. This interdisciplinary graduate school combines the expertise of natural sciences and humanities, aiming a ten lightening society about the applied aspects of nanotechnology (https://www.nano.uni-bremen.de/).

Especially in the doctoral programme of Science Education RRI is reflected and RRI issues like socio-scientific issues and contexts, how to deal with gender and diversity as well as ethical questions are fields of investigation in doctoral studies.

Further outreach events

There are different possibilities to bring scientists and/or scientific questions in direct connection with the societal needs. One example is the citizen science project "My Ocean Sampling Day (MyOSD)" of the Max Planck Institute of Bremen. It is a global scientific campaign to analyse marine microbial biodiversity and function, taking place during the solstice on June 21st. The goal of the MyOSD citizen initiative is to involve citizens, school classes, and teachers in the research process. Supported by scientists and equipped with the MyOSD Sampling Kit and a Smartphone APP which they can use to collect marine microbes and important environmental data, they help lead scientists to get a better understanding of the world's oceans and their microbial biodiversity.

One fruitful example is the Open Campus Day in Bremen. According to the motto "Science for You and Me", the Starbios2 Core Team presents and discusses topics of genetic engineering and its future. Participating children are offered hands-on activities, such as DNA isolation from strawberries and construction of DNA models with pearls. In addition, a reflection activity on future topics of genetic engineering is offered such as "Should mammoths be brought to life?" or "Green genetic engineering as a solution to global hunger?".

From the Booklet of RRI Recommendations to the RRI Mission statement

Responsible Research and Innovation (RRI) represents a contemporary view of the connection between science and society. The goal is to create a shared understanding of the appropriate roles of those who have a stake in the processes and products of science and technology, scientists as well as educators and the general public. It is estimated that a shared understanding and mutual trust will lead to safe and effective systems, processes and products of innovation (Sutcliffe, 2011).

To reach these goals at the Faculty2 of University of Bremen a complex road map (Figure 1) has been developed with science education as core elements. Educational building blocks, reflective activities, RRI modules, and curricula enrichment for bachelor´s, master´s and doctoral programmes have been reflected and further developed. A non-line RRI toolbox tailored for Faculty2 needs was set up. Based on formative evaluation of RRI activities, a broad literature analysis, interviews and a faculty-wide questionnaire survey the Booklet of Recommendations "Towards a Sustainable and Open Science – Enhancing Responsible Research and Innovation in the biosciences at the University of Bremen" (Elster, Barendziak & Birkholz, 2019). It will now be discussed and negotiated. Together with the on-line RRI toolbox it will form the sustainable outcome of the four-year-long process of RRI structural change and development of a RRI mission statement tailored to the Faculty2.

NOTE #6

RRI in Africa

By Carla Montesano and Vittorio Colizzi

The integration of university and research systems, and of these with civil society, is one of the open issues concerning the bioscience sector in the context of increasing globalization. This type of integration is not new in Europe (being among the aims of the European research framework programmes, which are also aimed at developing the so-called ERA - European Research Area) and has a long tradition within highly industrialized countries (for example between European countries and the USA). It constitutes a field of innovation in the case of cooperation with emerging and developing countries and, in particular, with the African continent. In the last two centuries this continent has often been the subject of passive transfer of European technologies and "values". However, in the last decades, African governments and research actors have been developing and implementing their own policies and action strategies in this field. For European and African people, developing together the responsibility for research, especially in the field of biosciences, is an opportunity that must go hand in hand with technological transfer and innovation, to which Africa is now making impressive qualitative and quantitative progress.

In this framework, the promotion of a shared orientation between European and African partners on the subject of research and responsible innovation can be a way to proceed. This theme was one of the objects of the Action Plan of the University of Tor Vergata.

On this matter, a workshop titled "RRI in Africa: challenges and perspectives" was held in October 2018. It was focused on RRI implementation in biosciences in Africa. The experiences of

STARBIOS2 members in the cooperation between African and European research organisations were discussed. Among the approximately 80 participants were professors and PhD students in Europe and Africa, STARBIOS2 members, rectors of the Somali National University and Evangelic University of Cameroon, representatives of Italian universities (Camerino, Modena, Rome La Sapienza, Rome Tor Vergata, Padua, Parma, Pavia and others) and research institutions (CNR), and UNESCO. Focusing on RRI implementation in biosciences, some topics of discussion were the RRI approach, problems specific to RRI in Africa, experiences from higher education in Cameroon and Italy, student mobility, and scientific projects of Africa PhD students enrolled in Italian universities. The discussions resulted in some ideas on how to best develop a plan for RRI implementation in African research institutions, and the conclusion that there may be a need to re-think the European strategy for RRI in the African context. In this framework, a promising approach for improving the exchanges between African and Italian universities was singled out in the promotion and further development of the "dual degrees" experience.

NOTE #7

Consider your Culture: African Ethics of Ubuntu

By Martha Wium and Luiz Fernando Zerbini

Ubuntu is very difficult to render into a Western language. It speaks of the very essence of being human ... you are generous, you are hospitable, you are friendly and caring and compassionate. You share what you have. It is to say, 'My humanity is inextricably bound up in yours.' We belong in a bundle of life.

Desmond Tutu

Bioethics aims to ensure that the way in which research is conducted is morally justifiable and socially acceptable. This can however not be a "one-size-fits-all" solution because of cultural differences among populations. Africa alone has 54 countries with more than 3000 ethnic groups that speak more than 2000 languages (Bamgbose, 2011), emphasizing the need to be culturally conscious/mindful. Although the impact of cultural differences on bioethics is widely recognised, it remains Western-dominated (Andoh, 2011; Barugahare, 2018). In bioethics, the *"African voice is not sufficiently included in the development of the international guidelines"* (Pan-African Bioethics Initiative, 2003) in other words it lacks 'Africanity'/'Africanness'. In general, Africa cultural morals and beliefs are grounded in a natural sociality of human beings that embodies a social/communitarian ethics in contrast to the individual ethic (Eze, 2008; Msoroka & Amundsen, 2018). African bioethics should embody the Spirit of Ubuntu.

In the words of Nelson Mandela (President of South Africa from 1994 to 1999), *"In Africa there is a concept known as 'ubuntu' – the profound sense that we are human only through the humanity of*

others; that if we are to accomplish anything in this world it will in equal measure be due to the work and achievement of others".

The Nguniword, Ubuntu, referred to as the foundation of African ethics, can be defined as "the moral-quality of a human being", "I am because we are" or "generosity, respect for man irrespective of position" (Lutz, 2009; Gade, 2012). Examples of how the principle of Ubuntu can be applied to conflicting ethical problems in public health and medicine in Africa can be found in Cooper et al. 2019.

Ubuntu shifts the meaning of bioethics to the everyday values of the African people; it embraces the core value that individuals should act in the best interest of the community without causing disadvantages to him/herself.

NOTE #8

ZIKA in Brazil Real Time Analysis (ZiBRA-2): an RRI experience

By Marta Giovanetti, Fernanda Khouri, Luiz Alcantara

Advances in DNA sequencing technology have ushered in a new era of pan-genomics and genomic surveillance, in which traditional molecular diagnostics and genotyping methods are being enhanced and even replaced by genomics-based methods to aid epidemiologic investigations of communicable diseases (Gardy et al., 2018). The ability to compare and analyse entire pathogen's genomes has allowed unprecedented resolution into how and why infectious diseases spread. The rapid development of these technologies has made sequencing of viral genomes possible and even routine (Shendure et al., 2008).

There are currently two major ways in which high-throughput sequencing technologies are used in public health and diagnostic applications, (i) to track outbreaks and epidemics in order to call for public health responses and (ii) to characterize individual infections to tailor treatment decisions (Theze et al., 2018; Faria et al., 2017). Focusing on these aims, genome sequencing has been successfully used to describe unique and detailed insights into the transmission, biology, and epidemiology of many health care-associated viral pathogens.

Considering the improvements on portability and quality of sequencing, and the acceleration and standardization of analytical pipelines, the applicable routine of genome sequencing may soon become the common *de facto* method for infectious disease control. In the context of virus investigations, pan-genomics and bioinformatics in general face great challenges. Rapid extraction of genomic features with an evolutionary signal facilitates

evolutionary analyses ranging from the reconstruction of species phylogenies to tracing epidemic outbreaks.

In February 2016, the World Health Organisation declared a Public Health Emergency of International Concern in response to the transmission of ZIKV in the Americas. In that context, the ZiBRA-2 project was launched as a multicentre collaboration between the University of Oxford, University of Birmingham, Evandro Chagas Institute, University of São Paulo and Oswaldo Cruz Foundation employing a promising approach to generating a substantial number of complete genome sequences for Zika virus (ZIKV) through MinION in a mobile laboratory trip.

The ZiBRA-2 project is based on principles of ethics, social engagement and open access to the information obtained. We consider that it is necessary to present the ZIKV results to other scientific communities and try to increase the participation of the public and civil society in bioscience research. Thus, during the project all the sequences and information generated are published in real-time on the ZiBRA-2 websites (http://www.zibraproject.org; https://www.zibra2project.org), and the final results are made available to society through scientific publications in open access journals.

Based on a previous genomic surveillance trip during the Ebola outbreak in Guinea in 2014-2015, the ZiBRA-2 project aimed to generate a large number of ZIKV complete genome sequences from the Northeast of Brazil covering a broad geographical region including historical samples, and from patients with a range of clinical presentations. The method consisted of genome-tiling PCR to enrich ZIKV material in clinical samples followed by library preparation prior to MinION loading (Faria et al., 2016; Quick et al., 2017).

The ZiBRA-2 team working together with the Central Laboratory of Public Health (LACEN) personnel, tested 1349 clinical samples for ZIKV RNA across Rio Grande do Norte, Paraíba, Recife, Maceió, and Bahia states and captured 850 mosquitoes from urban

and peri-urban fields in each place along the trip. The project also involved capacity building as each local team was trained to perform the whole protocol on subsequent trips. It is important to note that the team is composed of men and women who participate from the design of the study until the final publication and are trained at all stages, to reduce the gender discrimination. (Faria et al., 2016).

After the original trip that took place in June 2016, the ZiBRA-2 project has been extended and up to now trained teams to track not only ZIKV, but also other arboviruses circulating in Brazil including emerging and re-emerging strains. The team was also employed to investigate the dispersion of the CHIKV - East-Central South African genotype spreading in North Brazil (Naveca et al., 2019) as well as to characterize the largest Yellow Fever outbreak registered in Southeast Brazil in December 2016. By analysing 64 new yellow fever virus genomes the virus transmission pattern was revealed to originate in non-human primates, rejecting the hypothesis of urban transmissions.

As the mobile trips occur, more people are being trained to continue performing genomic surveillance throughout the country and also in some places in Africa like Angola and Cabo Verde (Hill et al., 2019). Also, the productivity of these trips is increasing each time, with generation of around 60 complete genome sequences in five days. Besides that, the development of faster protocols and more than 12 barcodes per run suggests this number will increase soon. A single flow cell used in MinION can run up to 96 genomes and produces reads up to 200 Kb in length, with a throughput of 1.5 Gb, and more than 100,000 reads at a single run. Ongoing improvements to the launched barcoding kits in the nanopore sequencing technology had the potential to increase the number of generated genomes per sequencing run from 12 to 96, which could also increase the number of genome sequences derived from affected regions and allow more detailed investigations of the

association between pathogen mutations and environmental context with less costs.

The participation of ZiBRA-2 in STARBIOS2 provides an ideal environment to showcase these research projects, and highlights the practice of Responsible Research and Innovation (RRI) in the context of this unique bioscience endeavour.

NOTE #9

Providing information to society on plants and biotechnology

By Daniela Moyankova and Dimitar Djilianov

Within the framework of Social Engagement, the Agrobioinstitute (ABI) Core Team focused its efforts on performing a structural change inside the institute with the idea to reach out to society.

ABI was established in 1985 to be a leading unit of plant biotechnology in Bulgaria. This aim was achieved and maintained in the first 20 years of the institute by strategic management and vision.

There was enormous progress in biology and especially in genetic engineering at the beginning of the 21 century. However, it was met, quite unexpectedly by controversial or even, negative public reaction in Europe. In this respect, Bulgaria's entrance into European Union in 2007 challenged its plant biotech politics, which resulted in a drastic U-turn and a total ban on plant genetic engineering. Facing this difficult situation, ABI realized that along with the broadening of its scientific topics, it should start to talk to society on controversial hot topics. In the years before the STARBIOS2 project, these efforts however, were more or less sporadic and often, not very successful, primarily due to the absence of a dedicated conduit for information and public communication.

Accordingly, the first step for the ABI Core Team was to propose a structural change in the institute aimed at establishing an independent unit focused on public information and dissemination of scientific findings and hot topics. The fact that the newly established Plant Biotech Information Centre (PBIC) includes STARBIOS2 Core Team members only is a specific characteristic that needs more elaboration. We decided that it would be easier, faster and more responsible, for the Core Team to take this action

upon itself, as scientists with solid backgrounds, known by the lay society and well-respected by the scientific community. This enabled the unit to critically assess the new information and to transfer directly the project's main ideas for implementing RRI practices.

For 2.5 years, PBIC has already made significant progress in its activities – both vertically and horizontally. Working with various administrations (vertical), the Centre provided updated information and scientific opinions to improve decision-making by the administration. With regards to the horizontal activities – contacts with NGOs, other scientific units and with the educational system – even more important and successful progress was made! This, obviously, appears to be the right way to promote science to society and to provide a platform for open and honest discussion on the more controversial issues of contemporary biological science. Participating in public events and scientific conferences, providing lectures and open science areas for students – these are among the main activities that produced demonstrable positive results. The most popular and successful events were National essay contests for young people, and they will be maintained by ABI.

From the very establishment of PBIC and its web page, our main task was to make this structural change sustainable and long-lasting! In this respect, being already in the second part of the project, it appears that the Centre is not only an information hub, but also an impartial and responsible platform to exchange new ideas and to discuss controversial issues. We feel we have created a well-recognized conduit for exchange with society and established its future post-STARBIOS2 role.

NOTE #10

RRI and governance of complex research organisation

By Krzysztof Bielawski, Marta Dziedzic, Izabela Raszczyk

The University of Gdańsk (UG) is a complex organisation – the largest university in the Pomorskie Region (Poland) with more than 30,000 undergraduate, post-graduate and PhD students trained at 11 faculties and employing approximately 3,200 staff. It as a dynamically developing institution that combines respect for tradition with a commitment to new directions. The University of Gdańsk has experience in the implementation of national and international projects focusing on research, teaching, networking, and development; it cooperates with higher education institutions and other entities in most European countries as well as outside Europe. The ultra-modern facilities on the University's Baltic Campus contribute to the high potential for providing innovative teaching and conducting excellent research.

STARBIOS2 activities focused on RRI were planned as pilot activities in one of the faculties: the Intercollegiate Faculty of Biotechnology of the University of Gdańsk and the Medical University of Gdańsk. From the beginning, the governance structure in the form of a "Core Team" has involved actors from the Faculty and the University authorities in order to keep the activities strictly in line with the institutional strategies and objectives. For implementation of activities 'facilitators' from other units have been involved in order to have a broad perspective that increases the chances for sustainability (e.g., Library, Office for Science).

In addition, the **current reform of the system of the Higher Education sector in Poland brought a synergistic effect**. University authorities recognize more and more the importance of RRI and their efforts will be "rewarded" as the so-called 'third

mission' of the universities has been included in the periodic national evaluation of institutions by the Ministry. The effects of this evaluation have a concrete impact on the funding that institutions receive.

Following the concept of establishing RRI practices in research organisations, it rapidly became obvious that such a complex organisation as a university requires structural modifications on various levels in order to achieve changes in the five areas of RRI. A process of institutional change requires adapting governance frameworks so that implementing good practices effectively becomes possible. STARBIOS2 actions have spread around the university.

One of the steps taken in the direction of providing institutional change at UG was signing the *Declaration of Social Responsibility (CSR)* in November 2017 in Warsaw during the conference *Social Responsibility of Science – challenges for academic and business environment* at the Polish Ministry of Development. At that time, 23 Polish higher education institutions signed a CSR Declaration. The declaration includes twelve points stipulating the principles related to CSR in higher education. On behalf of the University of Gdansk the document was signed by **Prof. Krzysztof Bielawski**, UG Vice-Rector for Development and Cooperation with Business and Industry, leader of the STARBIOS2 project at UG. Being a signatory of such a Declaration emphasizes the university's engagement in a dialogue with society. Such engagement is in accord with the principles of responsible research and innovation which have increased insignificance in the EU in recent years.

Representatives of the University of Gdansk: **prof. Krzysztof Bielawski, Izabela Raszczyk and prof. Barbara Pawłowska** have also become members of the working group on Social Responsibility of Academia founded by the Ministry of Investment and Economic Development of Poland. The group gathers on a regular basis to work on a comprehensive review of defining a socially-responsible academia and developing a collection of the best practices of responsible research implemented in the institutions of higher

education in Poland. The group plans **further dissemination and educational activities on a national level** to mobilise non-participating universities to join the initiative and adopt the *Declaration*.

Furthermore, the University of Gdańsk has also become part of the **Forum of the Engaged Universities**, consisting of 7 Polish universities that came together as a bottom-up initiative. This initiative also focuses on the issue of societally-engaged research and showcases those engaged research practices improving the societal impact on research. Meetings at the Ministry for Science and Higher Education have already taken place in order to make this initiative **visible to the decision-makers in the HEI sector.**

As the pilot edition of the STARBIOS2 project has focused on promoting and implementing RRI practices in the biosciences area, the Action Plan activities have been applied at the Intercollegiate Faculty of Biotechnology of University of Gdańsk and Medical University of Gdańsk (IFB). However, in some cases, it was also possible to affect university-wide regulations, such that the effects of implemented actions touched other UG faculties. Therefore, within the framework of the university-wide PRO UG programme, that was funded as a large project from external sources, a unified programme for undergraduate studies now includes an obligatory RRI course for all undergraduates, not just those in the biosciences. Promoting integration of RRI aspects into science education raises awareness of RRI in both teachers and students. A course "How to become an RRI-oriented scientist?" has been included in the syllabus for MA students at IFB starting from the academic year 2019/2020. Thus, the **structural change initiated by our efforts to raise awareness** resulted in an increased interest in the field, and have put our programme on **another level of receiving additional funding from another funding instrument** for implementation. This appears to be an approach that will achieve sustainability beyond the STARBIOS2 project.

To sum up, structural change in complex organisations requires involvement of institutional authorities and a broad involvement of actors. It is beneficial to use any upcoming external synergies. A critical mass of interested and active actors on a national level also facilitates the effort. Last but not least, a transfer of ideas into new funding is a good sign for long-term sustainability.

NOTE #11

Achieving impact: some arguments for designing a communications strategy

By Josepine Fernow

Practicing RRI implies that we make an effort to communicate beyond our peers, opening up research organisations and extending our reach to public policy makers and researchers in other fields. To achieve impact, researchers need to find new ways of interacting with actors outside their own fields. Ideally also doing it well, without wasting time, while maintaining public trust, and without contributing to misconceptions about what science can deliver.

Is this not what we do already? Yes and no. Academic research is driven by dissemination of results: aiming to reach peers by presenting and discussing results at the conferences they attend, and publishing in the journals they read. How do we move from sharing results to having a real impact on the structures we want to change? The biosciences depend on public trust: To receive public funding for research, to recruit research participants, and to gain acceptance for the outputs. And if that trust is lost along the way, it will be difficult to regain (Caulfield, 2005). As if this is not enough: Transferring technology from the academic domain into clinical or commercial applications requires trust from both the public *and* policy makers (Bubela, Hagen & Einsiedel, 2012). Is this a problem? Well, maybe…

If scientists frame technological advances in new ways, they might be able to capture the imagination of investors, politicians and funding agencies. This matters in a democratic society, where members of the public can influence their representatives, who in turn make decisions on both research funding and regulation, which is a very good argument for maintaining public trust (Bubela,

2006). Funding agencies are increasingly asking researchers to show how their work will have an impact. This requires new skills from scientists, who need to be able to think about what their contribution to society will be and design strategies to achieve impact.

Why does this matter to me? Bioscience can bring benefits for both individuals and society in the form of new treatments, resilient plants, or new foods. It has been claimed that scientists themselves have a professional responsibility to communicate their knowledge, along with their views on potential applications (Reydon, Kampourakis & Patrinos, 2012). However, if scientists over-promise, it can erode trust, and bad communication can lead to the *research hype paradox*. This means that if the public buys the hype, it could become more difficult to do research (Caulfield, 2005). Because of the huge potential benefits, research hype is a real threat for bioscience. As members of the public, we are all in a sense future patients, future consumers and future beneficiaries of all that science brings, the good and the bad. This means we all have a stake in research. Your project's communication strategy becomes important with the realization that media is part of a filter that science has to pass through before reaching the public. Although there is no linear relationship between how media portrays science and public opinion about it, the public only has access to information in the public domain (Caulfield, 2005).

Is this a problem? Perhaps, depending on how you view the public. Scientists tend to think that the public lacks knowledge about scientific issues, and that this lack of knowledge shapes public opinion on risks, policies and decisions. Scientists also tend to view the public as homogenous: either as one uniform group of non-experts, or as a range of distinct (but homogenous) groups of 'lay people' (Besley & Nisbet, 2013). In reality, however, the public is actually a heterogeneous and abstract collective (Condit, 2001) that consists of *everyone* in society (Burns et al., 2003). In other words, you need to figure out who you really want to talk to, and develop a strategy to achieve your goals. Designing communication or

public engagement activities requires dividing this collective into a series of overlapping publics that also includes scientists, mediators and decision makers (Burns et al., 2003).

How do I translate that into a communication strategy? First, we have to remember that communication is not just for the lay public. Your strategy should also include measures to do cross-disciplinary and cross-professional communication. Bioethicists need to understand the science behind the ethical, legal and social issues they research, and clinicians need to understand the biology behind the test results they give to patients. In an ideal world, dissemination and communication activities would foster buy-in to your results, followed by a readiness to implement them. However, **how** to do this requires some thinking. First, it is important to decide **what** it is you want to achieve, by describing **why** there is a need to communicate. The next question to answer is **who** you want to reach, followed by **how** to do that, and **when** would be a good time to talk to them.

A scientific dissemination strategy can help support impact by making outputs **discoverable and findable**. Taking some time to identify how and where your audiences would look for information about your work can be helpful when you design your publication strategy. Picking the 'right' journal for your publication, and ensuring open access (not forgetting that you can do self-archiving once the journal embargo ends), also helps ensure it is **available**. Adding communication tools, like editorial text, press activities and social media can amplify the dissemination of results and help make outputs **visible** for a larger group of people. This kind of complementary communication tools can help make the results **relevant** for other audiences. You can reach other stakeholders if you re-frame and adapt your results. Communication activities can also help make the outputs **understandable**. Either by translating your text to another language, or by adapting the message to other audiences, ranging from high-school children, to people with PhD's in social science, humanities, or physics.

Where do I start? To develop a strategy for communicating about this very guideline, STARBIOS2 started with a simple post-it brainstorming SWOT analysis exercise to identify the project's strengths and weaknesses, the opportunities we have to communicate about them, and potential threats to our communications. This is a good starting point to build a set of tools and tactics, which in essence is a list of different ways to exploit the opportunities, followed by a list of ways to mitigate the threats. An opportunity can be attending a conference to present results, the tactic to submit an abstract for a presentation, and the tool the presentation itself. A threat could be a competing initiative coming out with results at the same time, the tactic to mitigate that risk to approach that project and see if there are any avenues of collaboration, and the tool a joint publication or workshop.

What does this mean in practice? The point of the STARBIOS2 project is having impact in the organisations that implement Action Plans. To achieve change, it has been essential to identify the right messages, the right people, and the best arguments to make them want to contribute. Impactful change is a process of co-creation, between different agents and organisational structures. We can use the voices of these agents to advocate for structural change. Using dissemination, communication and advocacy to extend this project's impact to other organisations. Moreover, we can use these tools to share our results and contribute to developing research about RRI.

This very guideline was developed to create organisational change in the *biosciences*. Our stakeholders consist of individual *bioscientists*, in different fields, as well as structures in universities and other research-performing organisations, that do not constitute a homogeneous audience. Our stakeholders extend to the EU and national research policy makers and research funding organisations. Before we speak, we need to know what to say, who to say it to, and why we address them.

NOTE #12

The complexity of monitoring and assessing RRI structural change implementation and impact in research organisations within biosciences

By Evanthia Kalpazidou Schmidt

This section comprises a presentation of some key aspects of the monitoring and evaluation of the actual experience of promoting RRI structural change within research organisations in the STARBIOS2 project. The focus is on the role of monitoring and assessment in the design, implementation and impact of the actions and in particular on some critical issues in promoting RRI and triggering effective structural change processes.

In the last decades, evaluation of research and innovation has become a valuable instrument in policy-making within varied contexts as a means to use scientific knowledge to support decision making (Dahler-Larsen, 2006; Kalpazidou Schmidt, 2009). In the framework of the STARBIOS2project, RRI evaluation has been perceived as a wide-ranging concept and has been employed as an efficient instrument in not only monitoring and assessing the implementation and impact of actions but has also been utilized as a continuous learning tool for the involved actors. As a learning instrument, it has been used for design and strategy-development, process assessment (opening the black box of the implementation process and providing feedback to address emerging issues and redesign actions) to assure the maintenance of high quality levels in the implementation of the tailor-made Action Plans throughout the duration of the project. Hence, a formative, developmental dimension, providing basis for adjustment and formative learning along the process, has been incorporated in the monitoring and assessment efforts. Similarly, a summative evaluation of outputs,

outcomes and impacts has been carried out to assess the degree to which the actions achieved their objectives or created the crucial conditions for RRI structural change to occur.

The main objectives of the monitoring and assessment activities have been: (i) to examine and assess the process and progress towards the objectives of the actions, (ii) to provide input as to the quality of the activities during the implementation process (in a learning and formative perspective), and (iii) to assess the achievement of planned objectives and expected impacts, in a summative perspective. The monitoring and assessment activities contributed also to RRI knowledge exchange and mutual learning. The activities in the specific context of the STARBIOS2project have thus been:

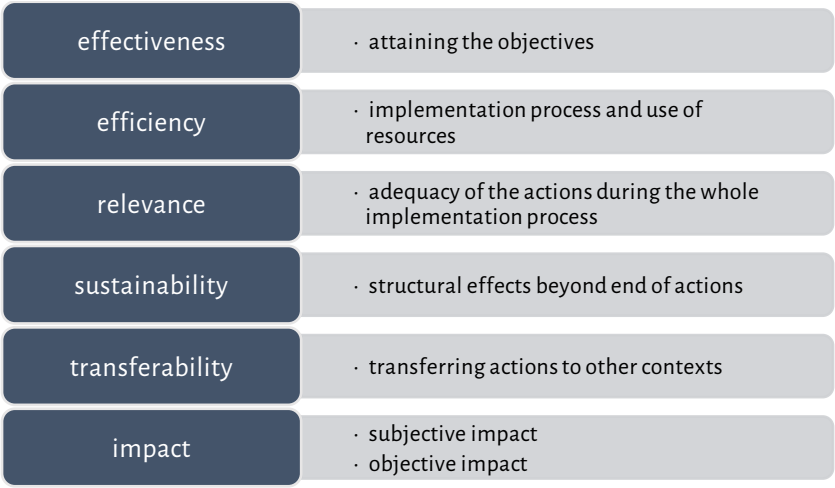
- Transversal: co-operation with all partners and facilitation of knowledge exchange.
- Communicative: identification of good practices, needs and potential benefits, encouraging critical self-reflection on the change process and the sustainability of the actions.
- Balancing an internal/external role and functioning as a critical partner, overseeing the flow of the Action Plans, mapping progress and enabling timely intervention.
- Accounting for the specificity of the project nature with distinct epistemic cultures and disciplines.
- Acknowledging the non-linearity of the transformation process.
- Considering the contextual conditions in complex, dynamic and adaptive systems.
- Adjusting evaluation design throughout the project to include emerging issues.

The internal role of the evaluators as embedded in the project provided the advantage of becoming acquainted with all actions in a high level of detail, aimed at utilizing this knowledge for the benefit of the implementation process, and allowed emerging issues to be addressed. This insight and understanding minimized the risk of an overly ethnocentric perspective with limited ability to capture the complex context-sensitive aspects of the implementation process in each Action

Plan in its cultural, institutional and national setting (Kalpazidou Schmidt & Cacace, 2017 and 2018). At the same time, innate in the evaluative task lay also an imperative to take on a more distanced perspective in order to allow for an independent assessment of the sufficiency of the project's development and progress. The monitoring and assessment standpoint mimicked an outside view and thus avoided "going native" (Lindlof, 1995) but functioned in a deeply committed participatory way.

In performing the monitoring and assessment of the RRI structural change actions, the criteria of *effectiveness* (attaining the objectives), *efficiency* (the implementation process, use of resources, managerial capacity), *relevance* (adequacy of the initiatives during the whole implementation process), *sustainability* (structural effects beyond the end of Action Plans), *transferability* (transferring actions to another context) and *impact*(short-, medium- and long-term impact)have been adopted (Kalpazidou Schmidt, 2016). Impact has been articulated in terms of *subjective* impact and *objective* impact (Figure 1).

Figure 1. Monitoring and assessment criteria



Subjective impact addressed the degree of approval among the beneficiaries of the various activities in the Action Plans, as well as the capacity to promote consensus about the activities among actors internal to the institutions, such as the staff and leadership, but also externally, reaching stakeholders from the local and/or national community. *Objective impact* referred to the effects obtained in terms of actual change within the implementing institutions, which may be expressed in numerical terms, but may also have a cultural, organisational or policy character, expressed in qualitative terms. Such impact may involve improved open access practices, increased share of women in senior and decision-making positions, change in the programmes, policies or work procedures of the institutions, adoption of the Action Plans processes and results by other R&I organisations or by subdivisions of the research institutions not initially involved in RRI activities. Objective impact may also comprise the creation of conditions that enable activation of further change processes.

As a first step in the assessment process, the strategic scope of the actions was scrutinized by examining the specific set of issues addressed and understanding them in relation to the particular contextual conditions and the objectives pursued by each RRI implementing organisation. The types of expected impacts were: (i) in the short-term, improvement of the uptake of RRI in the implementing research institutions; (ii) in the medium-term, production of tangible and measurable results in terms of organisational processes and structures, and making institutional change scalable to other institutions in the ERA; and (iii) in the long-term, increasing the ability of research institutions to generate innovation that reflects societal needs.

The monitoring and assessment activities have been performed on the basis of information derived from documents, information and data provided by the implementing teams and other stakeholders (such as other actors and beneficiaries); periodic bilateral monitoring sessions; various reporting activities and

information collected through monitoring schemes; mutual learning sessions; steering committee meetings; a range of bilateral *ad hoc* communication activities (such as support in developing survey questionnaires, evaluation templates, etc.); sessions with the coordinator and the technical-assistant partner; and on-site visits to the implementing institutions.

RRI structural change assessment in context

Besides the formative and summative elements, the monitoring and assessment activities aimed at, in a learning perspective, opening the black box of the space between the initiation of the actions and the impact by closely following the process of implementation to understand "what works better for whom in what circumstances, and why" (Pawson & Tilly, 1997).

Assessment of RRI implementation involves a range of challenges since RRI actions, themselves being complex, are carried out in complex environments. Such challenges comprise *attribution* problems (the effects of which are directly linked to the implementation of actions and how change has occurred), *measurement* problems (understanding the dynamics in complex contexts, availability of data and information, comparability of results, etc.), and *timing* problems (time lag from implementation until the generation of outputs and outcomes so that impact can be assessed).

Establishing a causal link between the RRI actions and the observed impacts requires the attribution of the observed change to the actions. However, in reality, implementations of complex concepts, such as RRI, in complex contexts, such as research institutions, make such pursuits challenging (cf. Cartwright & Hardie, 2012; Dahler-Larsen, 2012). The ability of RRI actions to foster the right conditions for change is therefore central in implementations in complex contexts (Reale et al., 2014), and impact assessment has to consider whether sufficient "conditions for impact" are created (Kalpazidou Schmidt & Cacace, 2017; Kalpazidou Schmidt et al., 2019). Thus, the following features have to be taken into account in complex system evaluations:

- RRI structural change actions are implemented at multiple levels in contexts that are complex, dynamic and adaptive.
- Complex systems involve multiple variables interacting in non-linear ways to produce outcomes and impacts.
- RRI is itself a complex concept implemented in complex systems.
- Establishing causal links between RRI actions and their effects pose a range of theoretical and methodological challenges.
- Complex systems respond to changes in the environment and adapt to new conditions – structures and cultures are resistant to change.
- The increased probability of change is part of the desirable effect of complex interventions (Kalpazidou Schmidt & Cacace, 2017).

A range of hybrid approaches seeks to address the above-mentioned challenges. One way to mitigate the risks connected to evaluation of RRI implementation is to use theory-based evaluations. Theory-driven evaluations focus on the questions: in which way and under which conditions a policy intervention causes the documented intended and unintended effects (Döring & Bortz, 2016). Theory-based approaches imply that the assessed variables are selected according to a theory that formulates implicit or explicit assumptions about interventions and their expected impact (Chen, 2012). Key elements in theory-based evaluations are (i) the design of an intervention theory and the theory of change of a particular intervention and (ii) the empirical investigation of the intervention theory. Such evaluations explore "not only whether the intervention works, but also how, for whom and in which context" (Van Belle et al, 2010). Understanding the contextual conditions not only enriches the assessment but may also support replication and generalizability of the outcomes of implementations (Rog, 2012).

Overall, to address the challenges related to monitoring and assessment of RRI structural change implementations some concrete lines of action are proposed: (i) adoption of a holistic approach that considers the constantly emerging needs; (ii) creation of a highly tailor-made monitoring and assessment design

involving all the stakeholders; (iii) incorporation of RRI action monitoring and assessment from the beginning in the process; (iv) the ability of RRI actions to foster the right conditions for change has to be central in dealing with the complexity of the systems; and finally (v) a theory-based evaluation approach may help mitigate the risks related to monitoring and assessing RRI implementation and support replication.

NOTE #13

Technical Assistance in the STARBIOS2 project

By Giovanni Caiati and Claudia Colonnello

In the STARBIOS2 project, Technical Assistance (TA) has been a service provided by the STARBIOS2 Consortium as a whole to help the Core Teams in carrying out their individual Action Plans (APs). TA has been implemented by a dedicated team of people external to the individual Core Teams composed of social researchers with experience in RRI, in project management, and in structural change initiatives.

More specifically, the support provided by TA has been aimed at **helping the Core Teams to drive the APs successfully** from the detailed design phase to completion. The **specific objectives** of the TA were to:

- **Support the implementation** of the activities and overcome emerging problems and issues
- **Reflect upon the AP activities**, results and reactions, and on this basis provide advice for developing a strategic approach in order to orient such activities toward the goal of structural change
- **Promote mutual learning** from other similar experiences inside the Consortium, in Europe and worldwide and, in general, improve the quality of their actions.

The TA activity is, by its nature, a reflexive and participatory exercise. In the STARBIOS2 project, it began with a reflection on the TA Team contribution to the life of the AP. Such reflection was presented and discussed with the AP Core Teams and, once their feedback was collected, was adopted as a general framework within which the TA played its role. TA started by considering three methodological lines.

a) **TA team as a "liminal" agent** – between outsider and insider. In fact, the TA team was an "outsider" since it was not part of the organisations where each AP was taking place. At the same time the Technical Assistance was part of the STARBIOS2 project and this made the TA team an "insider". This situation informed all the work of the TA team, which was not directly implied in and kept abreast of all the dynamics (resistances, drivers, institutional mechanisms) that characterized the research organisation implementing the APs. On the other hand, because it shared the same goals of the Core Teams, the TA team was in the position of providing advice, suggestions and observations, free from the biases deriving from being an insider of the research institution where the AP was taking place. This particular position helped the TA team in being accepted as an "assistant" by the AP Core Teams.

b) **TA as a bridge between the AP and other experiences** (inside and outside the project). The TA team was composed of social scientists, researchers and experts in RRI, Structural Change, Gender in science, Education and socialization of scientific research. Nevertheless, it was impossible to cover all the expertise related to the implementation of the APs that are wide in scope (the 5+1 keys of RRI) and whit diverse national background; for this reason, the TA acted not only on the basis of its own expertise but also as a bridge with expertise developed in all the APs (and those existing within their institutions), with the international partners (covering the experiences from outside Europe), and with other experiences and projects (on RRI or on each of the 5+1 keys) present in Europe. This was particularly useful for the implementation of APs within bioscience organisations in which, obviously, an internal expertise and specialization in RRI and social science was not prevalent (indeed, various AP Core Teams included also social scientists with experience in RRI; but nevertheless, they were composed mainly by bioscientists operating within bioscience research organisations).

c) **TA as a "non-invasive" action.** TA activities had to deal with the time constraints that the APs were facing since they were very ambitious in terms of tasks and activities to be carried out. In this framework, it is to be considered that the Core Teams were composed of researchers, professors, PhD students, etc. that have many research, institutional and teaching-related duties beyond the implementation of the APs. In order to cope with this situation, from the beginning the TA approach has stressed the quality of AP Core Teams time spent interacting with the AP Core Teams, over the quantity of interactions. This has meant a careful preparation of the meetings, their scheduling in advance (as far as possible), recording of what was said in feedback sheets, and having a dedicated space and time for the team without other interruptions.

In practice, the main areas in which the assistance to the APs took place are described below.

- Area 1: support the **APs design and reporting activities**. In this area fall all the activities that are related to designing and revising the AP, as well as the reporting activities foreseen in the project. The effort of the TA in these actions was at two levels. At a first level, TA supported the AP Teams to deliver the plans or the reports in time and in good shape. At the second level TA facilitated the use of these occasions as opportunities for reflection and for ensuring a strategic use of the AP. All the plans and reports delivered by the 6 AP teams followed an itinerary of discussion, reflection, review and suggestion in interaction with the Technical Assistance team.
- Area 2: support the **APs implementation**. Under this area fall all the activities connected with the everyday work of the AP teams. The effort of the TA in this area was trying to sustain the AP Teams in order to help them to achieve the goals they had established and to make their action more effective and efficient. Under this area lie activities such as: the periodic overview of the activities carried out in the APs (and related suggestions), the development of "joint activities" (between the AP and the TA teams); the supply of "on demand" support actions, sharing and presenting useful material for the development of the APs (toolkit, questionnaire models,

examples of similar actions, etc.), the identification of useful contacts for the implementation of the APs, etc.

- Area 3: activation and coordination of **mutual learning among the APs**. In this area fall the activities related to the learning across the different APs of the project. In this respect annual mutual learning meetings among the APs were organised. Moreover, the mutual learning was favoured through many different means by the TA team such as: suggestions, exchange of information, exchange of documents and tools, etc. Finally TA activated a cycle of remote Multilateral Sessions at a distance each one dedicated to sharing experiences inside the Consortium on one of the five RRI keys (Societal Engagement, Gender, Education, Open Access and Ethics). The mutual learning activities were oriented toward two goals: sustaining the implementation of the AP – even if indirectly; fuelling the general learning process in each AP team and in the project as a whole.

These three areas of action are obviously overlapping to certain extent. Nevertheless they catch very well the territory where the Technical Assistance operated for supporting the 6 APs.

The TA activities related to the three areas described above were implemented through a set of tools that were made available by the project, and namely:

- Assistance sessions at a distance
- Periodic on-site visits
- Mutual learning meetings
- On-demand support actions.

NOTE #14

Action Plan design tools — the Action Plan template

By Giovanni Caiati and Claudia Colonnello

Organizing and designing an Action Plan within a project like STARBIOS2 is a difficult task. One of the main difficulties is that the 5 RRI keys, albeit related to a single framework, are also very different from each other in terms of objectives and activities. To assist the Action Plan in the design phase in this section a set of tools were suggested during the implementation of the project. Such tools – that as a whole constitute a detailed design template for the Action Plans – are described below.

The template is a tool that also serves to make the contents of the Action Plan intersubjective between the members of the Core Team. For this reason, it facilitates the control of the implementation of the envisaged actions through the identification of deadlines. The Template, obviously, is not a guide to the identification of the problems on which to intervene, the actions to implement and the subjects with which to implement them.

1. Streams of Action (SoA) Sheet

In order to draft the detailed Action Plan it is important to single out the **main thematic elements** which should constitute its "building blocks". These elements may be called "**Streams of Actions**" (SoA). The planning process should result in a description of each Stream of Actions, in which the following components should be included: a premise (based on the needs of the individual institution/research organisation); a specific function within the project; and a set of expected outcomes in terms of structural change.

As the term itself implies, each SoA is made up of a mutually coordinated set of actions aimed to a specific purpose. Focusing on

the Stream of Actions limits the risk of working on many individual and mutually disconnected actions that could be ineffective, unable to continue after the project lifespan and to produce the expected long-term effects in terms of structural change. In some way, each SoA could be understood as a separate micro-project, with its own assumptions, objectives, actions and expected impacts somehow independent from other SoAs (albeit resonant with them).

Each Stream of Actions may be composed of the following items.

- **Code**: Attribute a code to the SoA using an upper-case letter (A, B, C, etc.).
- **Title**: Give a title to the SoA.
- **Area**: Specify one of the five RRI keys or the "transversal area"[28] the SoA refers to.
- **Context**: Provide a short description of the organisation's needs. This may be useful in order to frame the goal of the SoA in the specific context of the Action Plan.
- **Aim**: Describe the main aim of the SoA.
- **Target groups**: Specify the group of people, the institution/s or the organisation/s involved with or beneficiary of the SoA.
- **Duration**: Specify the duration of the SoA. SoAs may not last throughout the entire project lifespan.
- **Actions**: Provide a simple list of the planned actions included in the SoA. To better follow the Model of Structural Change, three different types of action can be distinguished.
    - **Detailed design of the action/s**: It could be necessary to focus the initial activities of the SoA to collect some additional information on the very specific issues connected with the concerned activity, also including literature or documentary reviews, internal consultations and other participative inquiries. This would also contribute in starting disseminating the initiative and collecting different points of view on its practical implementation. A set of activities should be scheduled in which the Core Team discusses and shapes

[28] This area focuses on those SoA pertaining to the Action Plan as a whole, such as the management, the periodic revision of the Action Plan, or any cross-cutting action affecting more than one RRI key.

each SoA. These activities, indeed, beyond their obvious practical aim, may represent the first step for creating a basis for consensus and involvement of internal and external stakeholders. Forms of participation and discussion could therefore be incorporated in the planning, from the Core Team to more extended groups of stakeholders, first of all including internal groups and offices active on RRI issues, when relevant.

    - **Implementation action/s**: these are the main components of the SoA, which are of course different for the various types of measures, including the preparation of training sessions, the organisation of public events, negotiation processes, publishing activities, etc.
    - **Reporting and follow/up actions**: It is convenient to foresee follow-up activities in which internal or external communication of results, as well as reporting activities and deliverable preparation can be envisaged. Furthermore, activities oriented to sustainability arrangements for the institutionalization of successful actions need to be foreseen, when possible.
- **Agency Mobilisation**: Indicate people, groups or institutions within the university that may be involved in the implementation of the activities and in their design. It is particularly useful to establish if and how the leadership of the organisation can be involved.
- **Coordination mechanisms**: Indicate the interactions of the SoA with other SoAs included in the Action Plan, other activities or initiatives already in place in the research institution or other actions developed within the STARBIOS2 project.
- **Sustainability / Structural impact**: Indicate how the stream of actions could have an impact beyond the project lifespan (it is an approximate description of the expected or desirable impacts as they can be established at the design stage).

A template and an example of SoA Sheet are given in the **Tool 1.** The example is drawn from the DoA/WP2 and therefore from the Tor Vergata Action Plan. The example below, however, is purely indicative and does not correspond to the real activities proposed by this partner.

The **number of Streams of Action** in each Action Plan may largely vary. In the STARBIOS2 project the SoAs of the Action Plans **ranged from 11 to 20**. These figures, like all other indications, are not binding but only indicative of the type of work required by an Action Plan.

2. Summary tables

Summary tables are a second important programming tool proposed during the STARBIOS2 project. They are useful to check the workload required by the AP as a whole (both in general and in any phase of the project). In addition, the summary tables can help understand the possible interactions between the different parts of the Action Plan so as to better assess its effectiveness. Two tables are suggested:

- The **Action Plan Summary Chart** (**Tool 2**), that brings together all the SoAs and, within them, the individual actions, without showing when actions are planned.
- The **Action Plan GANTT Chart** (**Tool 3**), that allows to view all the planned activities over time and to identify any work overload situation in any given period.

The detailed design of the Action Plan has been revised on an annual basis during the STARBIOS2 project.

TOOL #1

STREAM OF ACTIONS SHEET (TEMPLATE)

L (code letter of the SoA)
Title of the Stream of Actions (SoA)

Code	**Attribute a code to the SoA using an upper-case letter (A, B, C, etc.)**	**#**
Title	Give a title to the SoA	
Area	Specify one of the five RRI keys or the "transversal area" (AP management, AP communication tools, AP periodic revision, sustainability plan, etc.) the SoA refers to.	
Context	Provide a short description of the organisation's needs. This may be useful in order to frame the goal of the SoA in the specific context of the Action Plan.	
Aim	Describe the main aim of the SoA.	
Target groups	Specify the group of people, the institution/s or the organisation/s involved with or beneficiary of the SoA.	
Length of time	Specify the duration of the SoA. SoAs may not last throughout the entire project lifespan.	
Detailed design	A (very) short description of detailed design actions. All the actions are coded with the upper-case letter of the SoA and progressive numbers	L.1
Detailed design	''	L.2

Detailed design	*'' (rows can be freely deleted or added)*	L.3
Implementation	A (very) short description of the main implementation actions	L.4
Implementation	''	L.5
Implementation	*'' (rows can be freely deleted or added)*	L.6
Reporting Follow-up	A (very) short description of the Reporting / Follow-up actions	L.7
Reporting Follow-up	''	L.8
Reporting Follow-up	*'' (rows can be freely deleted or added)*	L.9
Agency Mobilisation	Indicate people, groups or institutions within the university that may be involved in the implementation of the activities and in their design. It is particularly useful to establish if and how the leadership of the organisation can be involved.	
Coordination mechanism	Indicate the interactions of the SoA with other SoAs included in the Action Plan, other activities or initiatives already in place in the research institution or other actions developed within the STARBIOS2 project.	
Sustainability / Structural impact	Indicate how the stream of actions could have an impact beyond the project lifespan (it is an approximate description of the expected or desirable impacts as they can be established at the design stage).	

TOOL #2

STREAM OF ACTIONS SHEET (FICTIONAL EXAMPLE)

F
Strengthening of the use of gender and sex as key variables of research

Code	**F**	**#**
Title	Introduction and strengthening of the use of gender and sex as key variables in the research programmes	
Area	Gender	
Context	Sex as a key variable in research is often underestimated. The Department of XXX is engaged in many gender sensitive research fields (list of gender sensitive research fields may be included). At the moment, this issue is not addressed at the department level and a shortage of knowledge about the use of these variables in the past and current research programmes can be also noticed. Moreover, there is little awareness of the innovation potential of inserting gender as a key research variable.	
Aim	Making the department aware of the relevance of gender as key variable in research programmes and inserting gender as a key variable in one or more ongoing or new research programmes	
Target group	Mainly researchers and research teams in the Department	
Length of time	M8-M44	
Detailed design	Analysis of past research programmes using gender as a key variable (M8-12).	**F.1**
Detailed design	On the basis of the previous analysis the Core Team will draft a note containing a set of new possible gender sensitive research programmes (i.e., considering the role of gender in pathology	**F.2**

	and therapy and the effects of drugs during pregnancy) (M13-14)	
Detailed design	Presentation of the note in an internal Workshop at the Department level. During the workshop the results of the previous actions would be openly discussed with the leadership of the Department, research team leaders, and researchers. The workshop may be organised as a participatory design activity allowing to contextualise and review the next steps of the SoA (M16).	**F.3**
Implementation	Singling out, amongst the ongoing or new research programmes, two programmes in which gender as a key research variable may be tested. These two research programmes will be implemented during a two-year testing period (M20 – M44).	**F.4**
Implementation	Along with gendered research programmes, the team will contact the professors of the Department in order to negotiate with them the yearly assignment of a number of degree and PhD thesis on gender-related research issues (M20-M44).	**F.5**
Reporting Follow-up	A final Seminar on Gendered Research in Bioscience may be carried out. The approaches and the results of the two pilots as well as other experiences from STARBIOS2 project or other projects should be presented. External experts may be also involved. Other research team leaders may be invited as attendees or as speakers to amplify the effect of the ongoing action. The public dimension of this seminar may increase the prestige of the initiative and raise attention on the issue. Such a seminar may be a catalyst for the other activities in the SoA in order to increase their visibility and to share their contents (M28, M40).	**F.6**
Reporting Follow-up	Taking into account the work done in STARBIOS2 as a whole, in the last months of the project the Core Team could work along with the professors involved in the thesis programme to insert in the teaching programmes a module on gender as a key variable for bioscience research. (M40-M48)	**F.7**

Reporting Follow-up	On the basis of the two-year research testing period, new applications for gendered research funds will be developed in the last months of the project.(M40-M48)	**F.8**
Agency Mobilisation	This SoA may benefit from the contribution of research team leader and single researchers, but also professors, PhDs and students. To connect this SoA with the University at large, the Parity Committee should be involved too. At the same time, the leadership of the Department should play a role in favouring participation and especially in ensuring the appropriate visibility to the final seminar.	
Coordination mechanism	a) An analysis of past research programmes is also planned in SoA=B; the two analyses should be coordinated with each other. b) The seminar may be organised during the steering committee meeting so as to allow the representatives of the other Action Plans to participate as speakers. c) The knowledge generated through the STARBIOS2 project (the model) can be used for the follow-up activities: gendered research proposal submission (F.8) and insertion of a training module on gender as key variable in the university courses (F.7)	
Sustainability and Structural impact	F.7 and F.8 activities should have two structural effects both on research and teaching in the department. Structural effects may be also seen at the level of the scientific culture of the department.	

TOOL #3

ACTION PLAN SUMMARY CHART (rows to be added or deleted as needed)

AREAS OF INTERVENTION	STREAMS OF ACTIONS	ACTIONS
1. SE	SoA A *(title)*	A.1
		A.n. *(rows can be freely deleted or added)*
	SoA B *(title)*	B.1.
		B.n.
	SoA C … *(rows can be freely deleted or added)*	…
		…
2. GE	SoA D *(title)*	D.1.
		D.n. … *(rows can be freely deleted or added)*
	SoA E … *(rows can be freely deleted or added)*	E.1.
		E.n. …
3. ED	SoA G *(title)*	G.1.
		G.n. …
	SoA H *(title)*	H.1.
		H.n. …
	SoA I … *(rows can be freely deleted or added)*	…
		…

4. OA	SoA J *(title)*	J.1.
		J.n. …
	SoA K … *(rows can be freely deleted or added)*	K.1.
		K.n. …
5. ET	SoA M *(title)*	M.1.
		M.n. …
	SoA N … *(rows can be freely deleted or added)*	N.1.
		N.n. …
6. TR	SoA P *(title)*	P.1.
		P.n. …
	SoA Q … *(rows can be freely deleted or added)*	Q.1.
		Q.n. …

TOOL #4

ACTION PLAN GANTT CHART

Phasing and scheduling (M1=May 2016) (lines to be added or deleted as needed)

	07	08	09	10	11	12	13	14	15	16	17
	First Year of Planning										
a – Title of SoA											
a.1 Title of action											
a.2 Title of action											
…											
b – Title of SoA											
b.1 Title of action											
b.2 Title of action											
…											
c – Title of SoA											
c.1 Title of action											
c.2 Title of action											
d – Title of SoA											
d.1 Title of action											
d.2 Title of action											
…											

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ABOUT THE STARBIOS2 GUIDELINES

This guideline aims to help readers formalize and trigger structural change aimed at introducing appropriate RRI-related practices to their own organisations. This is not a series of prescriptions, but an itinerary of reflection and self-interpretation addressed to different actors within the biosciences. To support this itinerary of reflection and self-interpretation, the document provides...

- a description of a general RRI Model for research organisations within the biosciences, that is a set of ideas, premises and "principles of action" that define the practice of RRI in bioscience research organisations,
- some practical guidance for designing interventions to promote RRI in research organisations in the Biosciences, putting into practice the RRI Model,
- a set of useful practices in implementing the structural change process,
- and information on particular STARBIOS2 cases and experiences, as well as materials, tools and sources, are also provided in the Appendix and in the Annex.