An Agenda for Responsible Research and Innovation in ERA CoBioTech

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March 2019

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For more information please visit: www.cobiotech.eu

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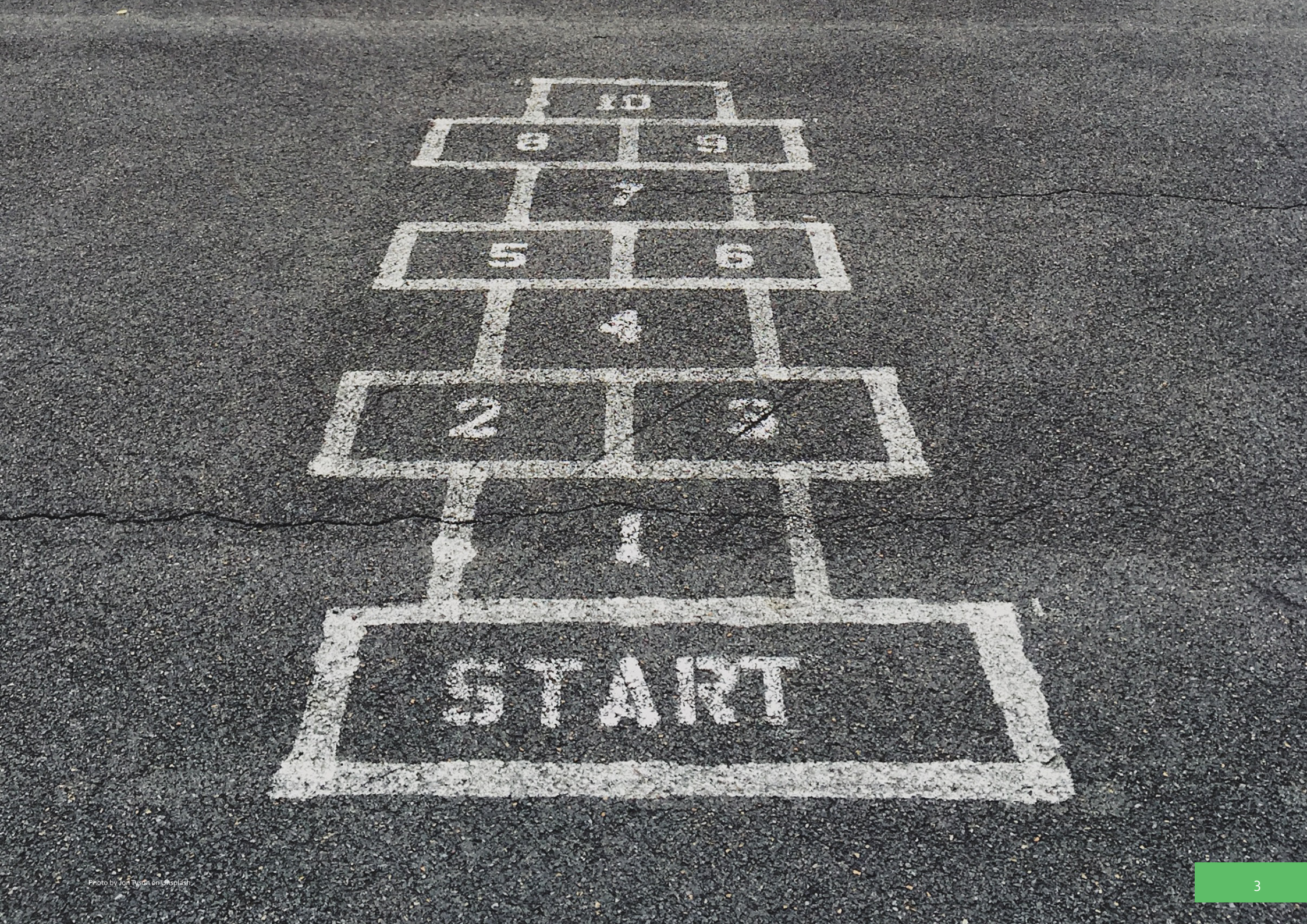
ERA CoBioTech

European Commission

Table of contents

List of Acronyms

ARRI	Agenda for Responsible Research and Innovation in ERA CoBioTech
BBSRC	Biotechnology and Biological Sciences Research Council, UK
CFC	Chlorofluorocarbon
EC	European Commission
EPSRC	Engineering and Physical Sciences Research Council, UK
ERA CoBioTech	ERA-NET Cofund on Biotechnologies
EU	European Union
FP	EC Framework Programme
GE^{3}LS	Genome Canada / Genome British Columbia Genomics and its Ethical, Environmental, Economic, Legal and Social Aspects Programme
IP	Intellectual Property
JUELICH	Forschungszentrum Jülich GmbH, Germany
MTA	Material Transfer Agreement
MRC	Medical Research Council, UK
RCN	The Research Council of Norway
RRI	Responsible Research and Innovation
TRL	Technology Readiness Level
VIRI	Virtual Institute for Responsible Innovation
WP	Work package



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Executive Summary

Strategic Priorities within Europe

ERA-NET Cofund on Biotechnologies (ERA CoBioTech), funded by the European Commission under the Horizon 2020 Programme, aims to maximise synergies between current mechanisms of biotechnology research funding in Europe, to discuss and demonstrate the benefits of a bio-based economy for society, and to maintain and strengthen Europe's position in biotechnology.

Each ERA-NET has a set of administrative work packages. This document forms part of Work Package 6, *Developing a Strategic Agenda for ERA CoBioTech*, which is led by staff at the Biotechnology and Biological Sciences Research Council, UK. WP6 includes the development of a Work Programme on Responsible Research and Innovation (RRI), with three goals:

1. Ensure the strategic vision of ERA CoBioTech is responsive to ethical, economic, legal, social, technological and political aspects so that decisions about investments are made with a rich understanding of the implications for different actors.
2. Ensure that the ERA CoBioTech research community is supported to consider responsible innovation in a way that works in their specific contexts and creates public value.
3. Embed and share the lessons of trialling a new approach to responsible innovation.

Responsible Research and Innovation

To date there have been many calls for Responsible Research and Innovation (RRI) but little opportunity to learn from existing programmes to develop best practice approaches. Therefore, this document introduces the theoretical background to RRI and presents the results of an analysis of extant RRI programmes and qualitative interviews with key stakeholders in the governance of biotechnology with experience of the implementation of RRI. The insights from this analysis are presented in the form of four key lessons for research funders and researchers wishing to embed RRI into their programmes. The lessons are:

1. **Commit to and value Responsible Research and Innovation:** Recent analyses have drawn attention to system-wide challenges that provide space for RRI. It is therefore important that funders actively incentivise, make visible and value the time and effort for critical thinking about science-society relationships.
2. **Support tailored approaches:** The most successful approaches to RRI appear to be highly tailored to the projects rather than using an externally imposed framework.
3. **Find an appropriate form of integration:** To date RRI has prioritised highly interdisciplinary modes of working. These are valuable but will not be suitable for all contexts.
4. **Go beyond projects:** Research into RRI will be more valuable if it can find ways to account for – and integrate with – governance spaces beyond the project level.

Operationalising RRI in ERA CoBioTech

The final part of the document uses these lessons to create a series of recommendations and translates these recommendations into the context of ERA CoBioTech. The Agenda for Responsible Research and Innovation that the document develops is tailored to the context of an ERA-NET, which is not just a mechanism to foster scientific collaboration but also a means to encourage national and regional funding agencies to exchange skills and expertise by developing and managing joint research programmes. For this reason, the Agenda cuts across a broad range of activities within the programme. In particular, it identifies and outlines the practical content of four key tasks that ERA CoBioTech will embark upon over the course of its lifespan:

- Developing a Strategic Vision
- Building Research Consortia
- Capacity Building Between Consortia
- Funding Evaluation and Measurement

1 Introduction and context to the report

ERA-NET Cofund on Biotechnologies (ERA CoBioTech), funded by the European Commission under the Horizon 2020 Programme, aims to maximise synergies between current mechanisms of biotechnology research funding in Europe to discuss and demonstrate the benefits of a bio-based economy for society, and to maintain and strengthen Europe's position in biotechnology.

ERA CoBioTech was established in December 2016, will run for five years, and aims to combine fields of industrial biotechnology, synthetic biology and systems biology. It builds on a string of programmes around biotechnology that existed in FP6 and FP7, most directly ERA-NET Industrial Biotechnology 2, ERA-NET for Applied Systems Biology, and ERA-NET Synthetic Biology.

Each ERA-NET has a set of administrative work packages. This document forms part of Work Package 6, *Developing a Strategic Agenda for ERA CoBioTech*, which is led by staff at the Biotechnology and Biological Sciences Research Council, UK. WP6 includes the development of a Work Programme on Responsible Research and Innovation (RRI), with three goals:

1. Ensure the strategic vision of ERA CoBioTech is responsive to ethical, economic, legal, social, technological and political aspects so that decisions about investments made with a rich understanding of the implications for different actors.
2. Ensure that the ERA CoBioTech research community is supported to consider responsible innovation in a way that works in their context and creates public value.
3. Embed and share the lessons of trialling a new approach to responsible innovation.

The purpose of this document is to contribute to the development of the RRI work programme, explaining how ERA CoBioTech partners and consortia will take collective responsibility to ensure that the new knowledge, technology and innovation produced has public value and is more democratic, more environmentally sustainable and addresses more meaningful societal demands than may otherwise be the case. To this end, the report has five components:

1. First it will define the problem space, namely the relationship between science, technology and innovation and the creation of public value.
2. It will then outline the concept and current practice of Responsible Research and Innovation.
3. Next, it will present the results of qualitative interviews and desk research that analysed the implementation of flagship RRI programmes to date. The results of this work take the form of a series of 'lessons'.
4. The lessons will be transposed into actionable recommendations for those wishing to institutionalise RRI within a funding programme.
5. Finally, the report will translate these lessons and recommendations into a programme of work for ERA CoBioTech.

2 The problem space: Science and public value

The most common justification for directing public funds towards research into science and technology is that doing so will produce benefits for societies. However, accurately predicting the benefits of research is incredibly difficult for the following three interconnected reasons[1-10]:

1. Contingencies.

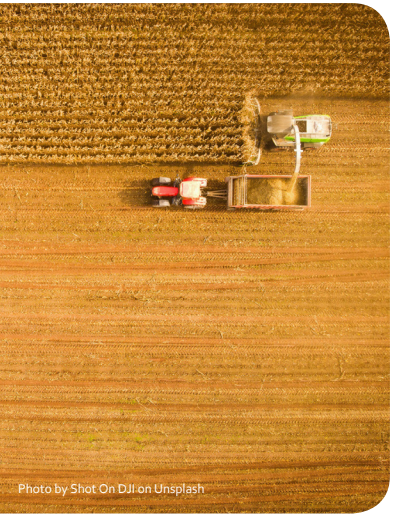
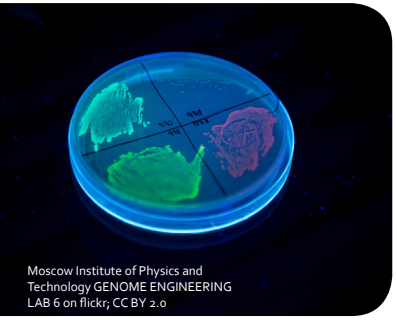


Photo by Shot On DJI on Unsplash

Science, technology and innovation do not develop in a linear manner with outcomes directly corresponding to the amount of money invested. Instead, development and distribution of benefits amongst social groups depends upon a wide range of social and situational factors such as who is involved, where the work is conducted, the kinds of oversight provided, and the types of intellectual property restrictions and other ownership arrangements in place.

These contingencies mean that two seemingly similar technologies can have vastly different social and political consequences. For instance, two different litres of biofuels could be produced in very different ways: One using sugar cane in Brazil and blended at a large scale into European petroleum, another using waste biomass in a European country and consumed locally. These two biofuels would use different supply chains would have vastly different social, political and likely ecological consequences[11,12].

2. Time lags.



Moscow Institute of Physics and Technology GENOME ENGINEERING LAB 6 on flickr; CC BY 2.0

The time between initial funding (when potential benefits are envisaged) and when impacts can be identified is unpredictable and often of significant duration. Taken with contingency, this has two consequences. First, suggestions of future benefits usually occur in periods of hype and can be made in only generalised terms, which do not account for the multiple factors that will determine who benefits and how[13-15]. Second, it is challenging to retrospectively trace pathways from inception to impact in a comprehensive manner[16,17].

Genome Editing is a case in point here: despite offering a step change in scientific techniques, making predictable genetic modifications is still extremely challenging, which in turn limits the ability to know which of the vaunted applications may be viable and how the value they create will be distributed[18-21].

3. Lock-in.

A final but important feature is that socio-technical change is hard to reverse or correct retrospectively. This is because of 'lock-in': new social behaviours become habitual, positions in a debate become entrenched, significant financial or material resources will have been invested, and new infrastructure may have been built (consider dependence on cars as the dominant mode of transport[22]). This means that it becomes harder – but not impossible (e.g. global use of CFCs) – to change the relationships between science and society as time passes.

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The challenge for policy makers: innovation governance

The above features hint at how science, technology and society 'co-evolve' amongst networks (e.g. people and organisations). Co-evolution implies a number of questions for policy makers responsible for investing resources into scientific and technological development:

- **A question of choice:** Where should finite resources (people, money, infrastructure etc.) be allocated and where not?
- **A question of control:** How should scientists, industrialists, policy makers, stakeholders and citizens foster science, technology and innovation so that they are beneficial for people and the environment?
- **A question of representation:** Under what conditions should decision making power be devolved to relatively small groups and under what conditions would they be improved by opening them up to broad groups of citizens, stakeholders and experts?

A wide range of governance mechanisms* help to shape the co-evolution of science, technology and society. What is needed, then, are more proactive forms of governing – and perhaps even talking and thinking about – the shared trajectories of science, technology and society†. These new modes of governing should account for contingency and look beyond prediction[45]. The 2007 European Commission report "Taking European Knowledge Seriously" makes a similar call, recommending that the EU move from risk-governance to innovation-governance, i.e. from narrowly-construed concerns with safety to governing for broader societal goals[1]. Because they are inherently upstream, research funding programmes are one key point at which this should happen.

In the context of ERA CoBioTech, answering these questions means engaging with a broader debate about the kind of Knowledge-Based Bio-Economy that programme partners and consortia are aiming to foster, and deciding who should be involved in the discussions that influence decision making and research. But what would innovation governance look like in practice? The objective of this review is to develop a set of recommendations for best practice within a research funding programme to help address this question.

* E.g. compliance with ethics and biosafety procedures, intellectual property regimes (material transfer agreements and patents), environmental risk assessment and product-specific regulation, certification and labelling, as well as market dynamics.

† For some examples of this mode of governance see Callon, Lascoumbes & Barthe (2009)[39], Whatmore and Landström (2011)[40] Stilgoe, Owen & Machnaghten[41] Smith et al (2017)[42], BBSRC & EPSRC (2010)[43] and Smith et al (Forthcoming)[44].

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3 Responsible Research and Innovation

Responsible Research and Innovation (RRI) is an innovation governance process that addresses current gaps in the established approaches described above. The concept was first articulated (as Responsible Innovation) by Richard Owen and partners at the EPSRC as an attempt to move beyond risk-based regulation in the field of nanoscience[46,47]. This was later embellished with cases of solar radiation management, also in the context of EPSRC-funded research[48,49]. It has subsequently been expanded to sit across the breadth of EPSRC's doctoral training funding mechanism.

A diverse set of programmes and projects are collected under the term 'Responsible Research and Innovation' and distinct but intertwined policy developments have resulted in at least two dominant frameworks. The work between Owen, Stilgoe, Macnaghten and the EPSRC resulted in the 'Anticipation, Inclusion, Reflexivity, Responsiveness' (AIRR) framework, articulated in a policy statement by the research council. The AIRR framework explicitly builds on the networked nature of science, technology and innovation: such processes are often distributed over extended timescales, across multiple spaces and between different actors, which poses challenges when allocating responsibility. A key goal of the AIRR framework is to act as a social innovation that instils a collective 'care for the future' across science, technology and innovation networks, asking those involved to:

1. consider the future directions of their work and its potential plausible consequences (Anticipate);
2. open up and seek out a broad range of voices, be they citizens or experts in decision making (Inclusion);
3. reflect on the significance of those directions and consider alternative approaches (Reflexivity); and
4. integrate the outcomes of this process into their own practices (Responsiveness).

Crucially, this conception of RRI requires redistributions of responsibility and potentially new roles and new institutions. For instance, one recent report by the British Academy and Royal Society examined 'Data Management and Use' in relation to the concept of Responsible Research and Innovation, and recommended the creation of a new 'Stewardship Body' to oversee the development of new data-intensive technologies [50]. Similarly, discussions about Gene Drive technologies, which are able to propagate naturally unfavourable traits through populations of organisms, has led to calls from research funders for the design of new governance mechanisms, such as 'Funder Forums'[51]. In this vein, one commonly identified and key issue is that of agenda setting and research programme design[52-54].

In parallel to these developments, policy makers in the European Commission have given political currency to the discourse of responsibility[55]. Over a roughly three-year period, an EC programme of Responsible Research and Innovation was developed, articulated in policy documents[56] and built into the EC's flagship Research and Innovation Agenda, Horizon 2020. The European Commission framework differs to EPSRC's and articulates RRI in terms of five 'keys': societal engagement, gender equality, open access, science education, and ethics compliance.

H2020's version of RRI operates at a scale beyond AIRR, in part because it is a complete replacement of a wide-ranging Science in Society Research Programme. The 'keys' can be viewed as a means to achieve this scale and function by adding momentum to pre-existing governance activities. However, in doing so they are likely to trade-off some of the socially transformative capacity that EPSRC aims at. While in practice these are distinct policy frameworks, some have suggested that the five keys can provide a useful entry point for those new to the idea of responsible innovation in science and technology – a place to begin discussion that can then move on to grappling with deeper system change and social learning that AIRR implies[57].

Plurality and RRI

In practice H2020's approach to RRI has resulted in a multitude of projects all attempting to articulate a concept of responsible innovation that is trans-national and suited to many different contexts[58]. However, these projects come from different national contexts and different disciplinary positions, meaning that the approaches that each RRI programme or project takes are often nationally sensitive, having evolved with the respective research cultures[48,55,59]. For instance, the AIRR framework has also been adopted by the Norwegian Research Council in its Biotek2010, Nano2021 and IKTPLUSS programmes*. In the United States, centres developed around the notion of Anticipatory Governance and Real Time Technology Assessment as part of the National Science Foundation National Nanotechnology Initiative[60]. RRI work in the UK is rooted in nanoscale science, geoengineering and synthetic biology, building on concepts such as 'Upstream Engagement'.

* See https://digitallifenorway.org/gb/responsibility (accessed 23/07/2018)

And programmes such as The Netherlands' Responsible Innovation Research Programme (NWO-MVI)†, mobilises a community that draws on concepts such as Constructive Technology Assessment and Value Sensitive Design[61].

An analysis of all these approaches reveals three common but often implicit tensions surrounding the implementation of RRI[62]:

1. **Should the approach be bottom-up or top-down?**
   Is RRI conceptualised as a process of (site-specific) mutual learning and capacity building or as something to be implemented top-down and evaluated through common indicators and metrics[49,58]?
2. **What is the most appropriate site to focus on?**
   Are scientific processes and technology development seen as sites for RRI or are they protected spaces, leaving RRI-related work to focus solely on the downstream implications of knowledge and technologies? If science and innovation are to be shaped, then how should this happen and who should be involved? For example, should it involve work in the laboratory, in the design of a research agenda, or in the commercialisation process, by expert representatives or through direct citizen participation?
3. **Is it best to work with existing innovation systems or foster alternative ones?**
   The goal of Responsible Research and Innovation is to foster public value from science, technology and innovation. However, some question the feasibility of such a goal within existing dominant regimes of economics and intellectual property ownership. Instead they suggest that alternative models of innovation developed with different economic frameworks, such as frugal innovation or grassroots innovation, may be better means to the same goal[63-66].

Implications for ERA CoBioTech

Drawing attention to diversity of approaches to RRI and the implicit tensions in policy and practice is significant for ERA CoBioTech in two key ways.

First, there is no one single 'right' approach to RRI; rather there are many national traditions and a plurality of methods that allow questions to be asked about the relationship between science, technology and public value. However, all the approaches outlined above commonly focus on the following shared goals[55,62,67]:

1. Engagement with users and/or publics;
2. Attention to the social context of the scientific research and its proposed uses;
3. Acknowledging the political dimensions of choices around science and technology, and seeking to establish processes to increase transparency and accountability for decisions;
4. Incorporating these analyses and activities in 'real time', while they are still able to have an influence, rather than after research and commercialisation; and
5. A desire to operate across multiple spaces within an innovation system, i.e. beyond the level of individual scientific projects.

Thus, the approach to RRI outlined in the final section takes these five goals as points of departure and seeks to mobilise, rather than impose on, pre-existing work and expertise. In practice this means not requiring that ERA CoBioTech commits to one specific version of RRI. Instead, institutions should be aware of the substantive differences in potential approaches and build on the lessons for best practice described in the following section.


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Second, ERA-NETs are not just a mechanism for collaboration amongst scientists; they are equally intended to encourage national and regional funding agencies to exchange skills and expertise by developing and managing joint research programmes. ERA CoBioTech incorporates 22 funding partners from 19 countries‡. Past reviews of the ERA-NET schemes have emphasised the heterogeneity of funders and their respective legislators. There are relevant distinctions to be made between respective funding sizes, preferred funding styles, administrative organisation and even the funder's relationship to H2020⁜. In the context of ERA CoBioTech's Agenda for Responsible Research and Innovation, it is therefore important to be aware that knowledge exchange between research funders matters almost as much as between funded researchers and to keep in sight the complexities involved in managing and administering an ERA-NET. The next section provides a series of lessons and recommendations for how best to achieve this.

† See https://www.nwo.nl/en/research-and-results/programmes/responsible+innovation (accessed 23/07/2018)
‡ Argentina, Belgium, Estonia, France, Germany, Holland, Israel, Italy, Latvia, Norway, Poland, Portugal, Romania, Russia, Slovenia, Spain, Switzerland, Turkey, and the UK. Although note not every funder takes part in all funding calls.
⁜ https://www.kowi.de/Portaldata/2/Resources/fp/Report-ERA-NET-FP6-H2020.pdf (Accessed 23/07/2018)

4 Learning from past experience with RRI

Despite an increase in the number of RRI programmes in the last few years, there has been little systemic learning with implementable policy recommendations. This section develops a series of cross-cutting lessons for the ERA CoBioTech programme from experiences within a range of flagship RRI programmes (see table one).

Targeted specifically towards research funders and programme managers, these lessons are based on telephone interviews, analysis of accompanying grey literature, and a series of published articles on researchers' experiences in the field. More methodological detail is provided in Annex 1.

Funder	Programme	Description
EPSRC, BBSRC & MRC	Synthetic Biology Research Centres	A series of large scale centres funded through the UK Research Councils' 'Synthetic Biology for Growth' strategic investment. A pre-requisite for funding was that each centre contained substantive Responsible Innovation components.
European Commission	Horizon 2020 Framework Programmes	One of the largest 'ethics, legal and social' programmes in terms of financial investment. A shift in conceptualisation from 'science in society' to 'responsible research and innovation' occurred at the start of the H2020 funding round in 2014.
Genome Canada & Genome British Columbia	Genomics and its Ethical, Environmental, Economic, Legal and Social Aspects (GE^3LS) Programme	Two not-for-profit catalyst organisations intended to produce genomic-based applications. The GE3LS programme runs in parallel to funded scientific and translational research.
NSF & Department of Energy	Synthetic Biology Engineering Research Centre (Synberc) and Joint Genome Institute (JGI)	Large research centres in the United States. Synberc had significant social science and ethics components. JGI introduced social and ethical review for scientific proposals.
iGEM Foundation	International Genetically Engineered Machine Competition (iGEM)	An annual synthetic biology competition, inaugurated in 2003. The foundation places an emphasis on 'Human Practices' being integrated into the scientific projects.
Research Council of Norway	Digital Life Programme and BIOTEK2021	Two large flagship biotechnology investments, each of which required responsible innovation components as pre-requisites for funding.
University of Tokyo	Science Interpreter Training Programme	An emerging Japanese programme, seeking to build capacity for novel 'ELSI methods' in genomics.

TABLE 1: PROGRAMMES REVIEWED AS PART OF THIS AGENDA

Four lessons for best-practice RRI

Lesson 1: Commit to and value responsible research and innovation

A core aspect of RRI is enabling scientists and engineers to ask questions about the social and political dimensions of their work and integrate the answers into their broader research trajectories. Many interviewees strongly argued that this is significantly influenced by the value that research funders confer on such processes. For instance, while the iGEM competition* locks entrants into quite a narrow definition of 'problem' (something 'out there' in the world) and 'solution' (synthetic biology technology), it has fostered and supported 'Human Practices' as a valuable approach by integrating it into the award structure of the competition. A team cannot achieve a gold medal award without showing effective and meaningful work in Human Practices[68]. The corollary of this point is that there is an onus on research funders to incentivise, make visible, and value the time and effort for critical thinking about science-society relationships.

Lesson 2: Support tailored approaches

An overarching lesson from both literature and interviews is that, if successful, the responsible innovation components of projects can provide rich explorations of the core complexities and uncertainties of a project and allow project researchers to reflect on the desirability of its goals. This means that project team members are likely to derive the most value from responsible innovation research if it is tightly interwoven with the natural science/engineering research so it can address substantive issues that this research raises. Thus, rather than RRI components being imposed uniformly by an external RRI Framework or checklist, project teams should be able to take an active role in identifying questions that they consider relevant to their project. External frameworks, such as the EC's Keys and EPSRC's approach, have value because they can provide useful entry points for broad concerns, but ideally collaborative project teams should be able to identify the specific research questions and approaches that fit with their project's national, organisational, and disciplinary context.

Lesson 3: Find an appropriate form of integration

Ideally, Responsible Research and Innovation projects should investigate relevant ethical, social, political and environmental dimensions in real-time rather than analysing impacts post-facto, and as a core part of the project's activities rather than as an add-on. An effective way to do this is through collaborative, interdisciplinary modes of working across the natural and social sciences and humanities†. It is important to note that while interdisciplinary modes of working can be fruitful, they can also come with increasingly well-documented ambivalences[69,70]. For instance, collaborative modes of working may take a disproportionate amount of effort to initiate, can be professionally precarious for early career researchers, and can come with high emotional burdens, especially when power and the ability to define roles rests with a single principal investigator (PI). Including interdisciplinary aspects as an after-thought to a grant may exacerbate such problems. While successful RRI research likely requires collaboration across natural and social sciences and humanities, the form of this collaboration should be determined by all the collaborators involved.

Lesson 4: Go beyond projects

The literature developing Responsible Research and Innovation approaches consistently argues that system-wide dynamics should be taken into account. Prominent scholars have argued that the failure to take such a multi-scalar perspective has resulted in biases and significant gaps in analyses of emerging science and technologies[71,72]. This means that individual scientific projects and technological objects are not the sole site of inquiry for RRI research. That said, the vast majority of funding devoted to responsible innovation practices is allocated through time-limited and discrete funding at the project level, and it is understandably daunting to address systemic issues – such as national and international funding priorities or intellectual property regimes – within an individual project. ERA CoBioTech funders can be champions for best-practice by helping to connect work across projects and enabling RRI research beyond the lab.

* The iGEM competition is an annual competition in synthetic biology in which approximately 300 undergraduate and postgraduate teams compete to design, construct and characterise new synthetic biology 'parts'. The annual 'jamboree' is one of the largest synthetic biology conferences in the world.
† Such an approach is represented by terms such as 'adjacency', 'parallel research', 'experimental collaboration', or 'intervention'.

5 Recommendations for best practice RRI

How would these lessons play out in practice? Here, we translate them into actionable recommendations, applicable to the context of ERA CoBioTech. The fourteen recommendations, overviewed in table two, are structured according to five key activities and three key groups of actors.

Recommendation	Activity	Audience
Treat Responsible Research and Innovation components as research.	Overarching recommendation	All
Communicate the commitment to RRI early in the funding cycle and provide pre-application support to understand its goals.	Developing funding calls	Funders
Ensure any RRI components are context-specific and detailed. **Try to build a 'conception to grave' work package.** **Researcher Equivalence.** **Resource accordingly.**	Building consortia applications and conducting research	Project consortia
Review RRI components thoroughly and appropriately. **Assess RRI as more than an indicator of 'impact'.** **Allow for emergent approaches to investigation.** **Don't be overly prescriptive.**	Evaluating funding applications	Grant reviewers/Funders
Help make connections. **Provide resources to connect RRI work across projects.** **Support research into sites beyond the lab.**	Capacity building	Funders Project consortia
Develop effective evaluation methods.	Grant monitoring and programme evaluation	Funders

TABLE 2: RECOMMENDATIONS INFORMING ERA COBIOTECH'S AGENDA FOR RRI WITH ASSOCIATED ACTIVITIES AND AUDIENCES

Overarching recommendation: Treat RRI components as research


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There are contrasting opinions about the status of RRI components within research projects. Many of the EC RRI projects are funded as 'support actions' rather than 'research', despite the fact that social scientists and other RRI practitioners are often professional researchers. Not treating RRI as 'research' can create confusion about the roles that component leaders are meant to take and can produce superficial work.

We recommend that ERA CoBioTech treats any RRI component as an engaged form of research. While there will likely be cross-over between this component, communication and outreach, and impact, such an approach will ensure that the RRI work is substantive. This means that RRI components require personnel with appropriate expertise and are not primarily about demonstrating a project's benefits for stakeholders. Ideally RRI components and the wider project will work towards an important issue of shared interest.

Recommendations for the development of funding calls

Communicate the commitment to RRI early in the funding cycle and provide pre-application support to understand its goals.


Photo by Neil Thomas on Unsplash

Our analysis points to the importance of close alignment between the natural and social science and humanities components of funded projects. In order to facilitate this, the requirements for RRI components should be articulated to ERA CoBioTech applicants as early as possible whilst acknowledging that such a requirement may be novel for many applicants. The commitment should therefore be accompanied by support materials such as the briefs produced as part of this contract. Additional support through workshops, online courses, etc. is welcomed.

Recommendations for building consortia applications and conducting research

Ensure any RRI components are context-specific and detailed.

For RRI-related research to be substantive, it must be tailored to the project. We strongly recommend that RRI components be developed in association with the core project proposal, rather than on the periphery. As discussed below, this does not mean that all applications must detail the full specificities of the RRI research, but it does mean that applications must demonstrate a plan for developing this agenda. For example, if a project contains a discrete WP on RRI, the minimum requirement is that appropriate experts (e.g. social scientists) are identified.

Try to build a 'conception to grave' work package.

To ensure close alignment between the natural and social science and humanities components of funded projects, the RRI components should be discussed and set by project members early on in the process and continue through the life cycle of the project. For projects with extended timeframes, the precise nature of the work package will likely vary over time.

Researcher equivalence.

While the RRI components will often represent a smaller than average portion of an overall ERA CoBioTech project, it is crucial that the RRI-related staff are not considered subordinate or wholly at the service of other project elements. RRI should be a context specific and collaborative process, and in order to achieve this it is vital all collaborators have continuous input into the life of the project as a whole. Project teams should consider including RRI expertise in advisory boards and, where appropriate, RRI lead researchers as co-PIs. Such actions are indications that these components are taken seriously.


Photo by Christian Joudrey on Unsplash

Resource accordingly.

Research funders (ERA CoBioTech partners) should set appropriate baselines for financial resources dedicated to RRI activities and research. This could be either as a set amount for types of activity or as percentage of the overall budget and will help to ensure not only sufficient resources for RRI-related research, but also provide flexibility for the RRI programmes of work to change over time. Advocating for investigative flexibility implies a need for budgetary flexibility to ensure the ability to respond to changes in the life of the project and to collaborations that may arise over the course of the programme. Arguably, this is also the case for the natural and physical science components of projects[42].

Recommendations for the evaluation of funding applications

Review RRI components thoroughly and appropriately.

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If funders and applicants are to take seriously the commitment to examining the social, ethical, political, and environmental dimensions of projects, and if related RRI work packages are expected to contain substantive work with budgetary commitments, then they must be reviewed effectively. At a minimum, this means that grant reviewers must be capable of reviewing the social sciences and humanities aspects of grants. This likely means that two social scientists and/or humanities scholars will be required to sit on the review panel, with the power to request changes to relevant portions of applications.

Assess RRI as more than an indicator of 'impact'.

Interviewees explained that grants were significantly better when the RRI-related components of applications were reviewed in the same manner as the scientific components. In practice, RRI is currently assessed as part of the "impact" of a project. We recommend that RRI form part of a broad understanding of excellence and implementation that encompasses societal engagement and inclusion, enabling different kinds of innovation. This means that comprehensive RRI components should be visible in other aspects of an application's evaluation. Similarly the panel should use evaluation criteria for 'excellence' (see Annex 2) that are broad enough to not penalise placing RRI at the heart of the project.

Allow for emergent approaches to investigation.

Funders asking for projects to include RRI components should be open to unexpected outcomes, both from the RRI-related research and the project as a whole. A successful application may not identify what specific issues will be addressed in its RRI components, but rather detail the process through which such issues will be identified. However, if such an approach is taken, it is vital that the application outlines the appropriate methods, provides appropriate resources, and explains how emergent issues will be identified and explored as part of the project.

Don't be overly prescriptive.

In practice, allowing for bottom-up RRI practices and research means that there can be no hard and fast rules about the precise nature of RRI at a programme level. This is particularly the case for the ERA CoBioTech programme, which encourages involvement beyond the EU-15, thus involving a wide range of social, environmental, political, and economic contexts, and attendant concerns and questions. Unlike the Dissemination and Communication component of ERA CoBioTech projects, there is not a specific template for RRI-components. Subjecting the spaces created for science–society interactions to a tight framing undermines the creativity and value of such settings. Building in such flexibility is not an argument for vagueness; specificity regarding the methodological approaches and general research questions are arguably as – if not more – important. Many of the concerns that tight prescription seeks to allay can be tempered by the overarching recommendation, above, and by requiring procedural rigour.

Recommendations for capacity building across the ERA CoBioTech programme

Help make connections.

Interviewees stressed the importance of funders taking an active role in making connections between social and natural scientists. For example, the ERA CoBioTech funders could host "match-making" workshops at which natural scientists could meet social scientists whose interests align with theirs. Establishing such relationships before or in the process of developing a grant application, rather than writing the grant and then looking for RRI experts to add on, makes it more likely that RRI components of the grant can shape the overall research vision.

Photos: Anthony Cleveland

Provide resources to connect RRI work across projects.

ERA CoBioTech will fund a variety of projects across Europe and beyond. If many (if not all) of these projects have associated RRI work, this represents an opportunity for unique learning. We recommend that funders help coordinate networking across the projects and knowledge exchange between the experts involved in RRI work. This represents an opportunity for not only identifying and sharing best practices, but also conducting research.

Support research into sites beyond the lab.

The primary site of inquiry for RRI research needn't be restricted to the research project. Sites at different levels, such as funders, regulators, and international governance fora, may well be relevant to the questions and concerns related to a project. Indeed, there are many relevant system-wide insights in research management that are traditionally excluded from RRI practices but included in other national approaches, such as anticipatory governance or upstream engagement[73-77].

Recommendations for grant monitoring and programme evaluation

Develop effective evaluation methods.

RRI should be more than just an initial hurdle to gain access to research funds; when considered as substantive in its own right it must also be considered as part of evaluating a project's success. Adequate evaluation frameworks do not yet seem to exist. We therefore recommend that ERA CoBioTech take steps to develop such an approach, based on key principles derived from our interviews and literature, and likely combining qualitative and quantitative approaches. For instance, a prominent European Science Foundation report recommends a framework with the following features: qualitative analysis and broad quantitative indicators; a focus on process rather than output; and a commitment to a period of experimentation before finalising the approach taken[3]. Developing an evaluation framework would demonstrate ERA CoBioTech's commitment to engaging with questions of social value.

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6 Outlining ERA CoBioTech's approach to Responsible Research and Innovation

This report has introduced the context of ERA CoBioTech, the theoretical underpinnings of Responsible Research and Innovation and articulated a set of cross cutting lessons from previous science, technology and innovation programmes. In this part of the report we apply these insights to the ERA CoBioTech programme's Agenda for Responsible Research and Innovation (ARRI).

As discussed, there is no single right way to 'do' RRI. Instead, there is a broad range of RRI-related research and engagement activities able to explore the political, economic, environmental and social dimensions of science and technology and to provide relevant, diverse knowledge and perspectives to inform research and innovation. This pluralistic approach to RRI is important because ERA CoBioTech spans several Technology Readiness Levels (TRLs). In the context of a lower TRL, RRI may mean providing a substantial role for citizens in setting a research agenda but it might also mean seeking the input of experts outside a normal area of technical expertise by including social scientists, sociologists and/or economists to project advisory boards[44,78]. These approaches would be relevant for higher TRLs, but so would more formal and discrete approaches to examine and analyse the impacts of a technology.

Thus, ARRI aims to provide ERA CoBioTech with a framework that defines a broad arena for RRI's meaning within the programme, rather than narrowly dictating what RRI research and engagement should look like. Given the complexities of the ERA-NET programme within H2020 and the range of national funders, we have designed an ARRI for ERA CoBioTech that focuses on four key tasks spanning the breadth of the programme, i.e. that focus both on the project level and the operational work of ERA CoBioTech:

1. Developing a Research Agenda
2. Research Consortia
3. Capacity Building Between Consortia
4. Funding Evaluation and Measurement

The limits of this approach

The boundaries of ERA CoBioTech's approach to Responsible Research and Innovation deserve attention. Addressing questions of value in relation to science, technology and innovation is necessarily a collective endeavour and requires the input of many different actors in many different sites. ERA CoBioTech funders, the scientists and the partners that they support represent one small portion of the actors involved in the creation of value.

Many public debates about biotechnology directly question the dominant forms of intellectual property regimes and ownership[79,80] and in arenas outside ERA CoBioTech, important experiments are on-going to explore alternative models*. This Agenda for RRI does not mandate or even recommend particular forms of intellectual property (e.g. patent pooling, open MTA) or data sharing. Due to the complexity of national priorities, this is not a matter for ERA CoBioTech to determine. Of course, research consortia may choose to work on alternative IP as part of the RRI components of their projects and they may do so collectively. Indeed, possible indicators of success for the implementation of this Agenda would be that future calls are able to respond to the changing needs of the relevant communities over time, and that a series of shared issues and methods are addressed collaboratively over the course of the programme.

* See the BBSRC-funded 'OpenPlant Synthetic Biology Research Centre', which aims to develop open models of innovation. https://www.openplant.org (Accessed 23/07/2018).

Task one: Developing a strategic vision

Developing new ways to strengthen the connections between research and innovation agendas and citizens has long been suggested as instrumental in the creation of public value[7,81-84]. For instance, recent analyses have demonstrated mismatches in the priorities of members of the public and technologists in relation to agriculture and health[73†]. In arenas outside ERA CoBioTech, experiments are on-going to explore alternative modes of priority setting[‡]. Further, widespread public participation has been called for when determining the 'missions' of the European Commission's forthcoming 'Mission Oriented' Framework Programme[85⁜]. However, to date there have been relatively few documented attempts to open up agenda setting in biotechnology research programmes[86].

In practice: Trialling a new approach to agenda setting in ERA CoBioTech

Incorporating the present RRI subproject into ERA CoBioTech's Strategic Vision work package is in itself a commitment to ensure that RRI shapes the research agenda. However, in practice the programme will also trial an approach to developing a Strategic Vision that integrates RRI. In particular:

1. It will draw upon a rapid stakeholder mapping approach, previously developed with BBSRC staff and deploy it to identify relevant participants in a 'strategic vision' workshop.

2. Social scientists will co-design workshop tasks, focused around:
   a. identifying present and missing stakeholders;
   b. mapping important funding programmes and technological developments;
   c. reflecting on the key questions and purposes driving ERA CoBioTech;
   d. interrogating gaps and assumptions in the above dimensions and considering broad notions of success.

3. WP6's 'Strategic Vision' will be informed by the workshop and developed in partnership with social scientists.

† Specifically for health in terms of global disease burden vs. biomedical research priorities. For an introduction see https://www.theguardian.com/science/political-science/2018/mar/16/who-benefits-from-biomedical-science, https://www.natureindex.com/news-blog/drug-research-priorities-at-odds-with-global-disease-toll and https://observatoriosociallacaixa.org/en/-/responde-la-investigacion-a-las-necesidades-de-salud (Accessed, 23/07/2018).

‡ See e.g. Nesta, 'Everyone Makes Innovation Policy' Project, which has funded five experimental approaches to research agenda setting. https://www.nesta.org.uk/blog/announcing-the-everyone-makes-innovation-policy-programme-grantees/ (Accessed, 23/07/2018).

⁜ https://ec.europa.eu/info/node/71880 (Accessed, 23/07/2018)

Task two: Consortia-led research

ERA CoBioTech will facilitate the development of interdisciplinary consortia that develop research plans with a clear societal need. This research is highly specialised, meaning that consortia may be best-placed to understand and address issues as they emerge. Thus, each call in ERA CoBioTech contains a requirement that consortia build-in and appropriately resource on-going research and consideration of the ethical, social, environmental or political (etc.) dimensions of their work. Such an approach — that includes disciplines with expertise to address questions that 'go beyond the technical' — is a well-established approach to Responsible Research and Innovation. The research funded through ERA CoBioTech is diverse. There is not, therefore, a one-size-fits-all approach. ERA CoBioTech will adopt a broad understanding of what an appropriate topic for Responsible Research and Innovation is and what the appropriate methods are. Clear guidance on both the process and how it is to be evaluated will be provided with each funding call.

In practice: Integrating and assessing Responsible Research and Innovation within funding calls.

In practice, this task must be led by consortia members. However, ERA CoBioTech funders will provide support in the following ways:

1. Clear guidance explaining the expectations and assessment of Responsible Research and Innovation within ERA CoBioTech funding calls, including the forms of financial support available from each national funder (These are provided in Annex 2).

2. Clear guidance regarding the evaluation of Responsible Research and Innovation within the application review process.

3. Specific expertise relating to Responsible Research and Innovation will be represented in the Grant Evaluation Panel.

Task three: Capacity building between consortia

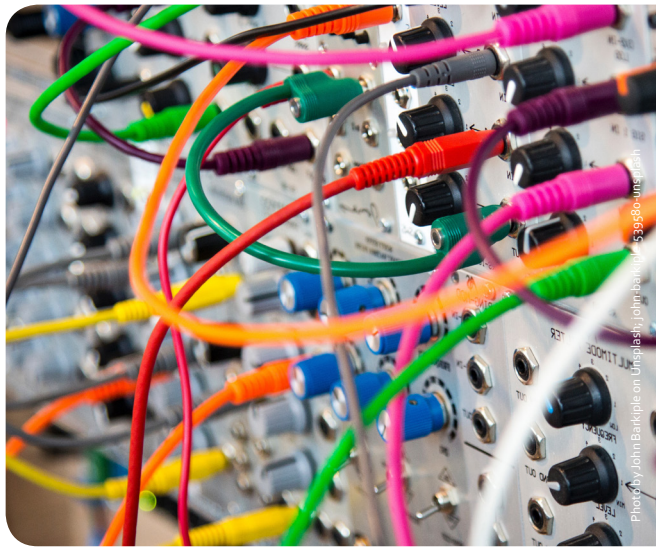

Photo by John Barkiple on Unsplash, john-barkiple-539380-unsplash

It is now common for funders to require Responsible Research and Innovation components in research proposals. However, the interdisciplinary collaborations that facilitate successful research in this area are fragile and the nature of project funding (e.g. time-limited, tightly-allocated) can make it challenging to take the experience generated in one project and transfer it to another.

Delivering ERA CoBioTech funding in tranches, and to consortia that are expressly built to collaborate across Europe, presents an opportunity to build reflective and methodological capacity across the programme. ERA CoBioTech funds diverse project consortia but there are similarities in the goals they aim to achieve, the methods they employ, the topics they address and the issues that members encounter. To begin to foster learning across the programme, ERA CoBioTech funders will provide activities and resources explicitly intended to build shared learning across the ERA CoBioTech programme.

In practice: Programme-wide workshops

A first step to building capacity will be to convene workshops specific to Responsible Research and Innovation over the life of the programme. These will be developed and implemented by external facilitators in collaboration with consortia members to address shared topics of interest or develop cross-cutting methods for RRI.

The workshops will be held as side-events to pre-existing cross-consortia meetings, namely the kick-off meeting for each funding cohort and project update meetings (mid-term and final seminars). Projects must therefore build attendance costs for two participants into their budgets.

In addition to these actions, future calls may specify particular areas of focus based on past experience within the ERA CoBioTech portfolio.

Task four: Developing appropriate measures of success

The final task that this agenda prioritises is research funder decision-making. We have already discussed funding calls, but one further activity relates to grant evaluation and portfolio analysis — activities that are used to analyse and evidence whether a programme has been successful. These evaluative processes are extremely important in shaping research because they indicate to scientists what outcomes are valued, such as IP, collaborative papers, grant income, and/or knowledge.

However, there remains considerable uncertainty regarding the most appropriate ways to capture the outcomes and added value of ERA-NET programmes, including how to evaluate Responsible Research and Innovation. ERA CoBioTech funders will therefore develop an approach that effectively captures and prioritises broad forms of value-generation across the portfolio.

ERA CoBioTech is uniquely placed to pioneer this kind of work for several reasons. The programme is in its first stages of operation, and the indicators for evaluation of the first round of funded projects are still under construction. It is also a multi-national, multidisciplinary programme with an explicit commitment to include RRI in the project specifications and its remit is to fund new and emerging scientific research that moves from one TRL level to another, focused on producing outcomes with potentially high impact on society.

In practice: piloting a novel form of programme evaluation

ERA CoBioTech is currently developing a series of evaluation criteria for the programme. In collaboration with the appropriate work package leaders, social scientists will develop and pilot a novel evaluative methodology. This will be based on recent advances at the intersection of Science and Technology Studies and Innovation Studies. In practice it will involve the commissioning of a review of evaluative methods in line with the principles of RRI followed by a collaboration with the FCT in Portugal, the current work package leaders for the development of indicators for ERA CoBioTech.

In 2014, the European Commission commissioned an expert group to advise on options for RRI indicators. The report (EC 2015) recommends the use of a limited set of indicators that are highly contextual, tailored to the needs and goals of the particular programme/project to ensure that they are both relevant and manageable. The expert group conclude that it was not possible for them to provide a general list of indicators for RRI, and that national and regional actors (including universities, research centres and funding agencies) need to design their own processes tailoring the indicators proposed in the report as well as adding their own where relevant[87].

Building on this advice, ERA CoBioTech will take the opportunity to pioneer the development of indicators that fuse evaluation of RRI with other forms of evaluation and measurement of the respective projects. The purpose of this would be to broaden the way programmes are measured to include measurements of the success of projects working in a mode consistent with the agenda outlined above. There is an opportunity for ERA CoBioTech to take the lead in developing indicators for the programme in line with its RRI agenda, and to begin to ask questions about how best to evaluate the programme in line with the principles of RRI outlined above. The key difference between this kind of approach to developing indicators and the approach suggested by the European Commission expert group's report is to develop a method of evaluation that does not evaluate RRI as separate component, but as integral to the programme itself[87].

Annex 1: Methodology for desk-review

To develop useable guidance for the implementation of responsible innovation in the context of the ERA CoBioTech Programme we used a mix of qualitative document analysis and qualitative interviewing. The first stage of research aimed to consolidate existing empirical work around Responsible Research and Innovation. We therefore reviewed existing policy approaches to Responsible Research and Innovation at the programme level, including complementary approaches for aligning social and scientific trajectories such as public value mapping or emerging portfolio analysis techniques.

Documentary analysis of published accounts working in Responsible Research and Innovation and interdisciplinary settings [69,70, 88-93], and two rounds of interviews (conducted by phone or Skype) followed the desk review. The first round of interviews was conducted with social scientists with experience implementing RRI at programme level. The purpose of these interviews was to derive cross cutting lessons from their experiences of implementing RRI in a range of flagship RRI programmes. This kind of synthesis of cross-programme experience did not to our knowledge exist in the published literature. We conducted a total of 6 interviews with social scientists who had been involved in 7 different programmes. These interviews were supplemented by a series of 20 similar interviews conducted by Smith and collaborators at GenØk, Tromsø (Dr Michael Bernstein) and the Institute for Advanced Sustainability Studies, Potsdam (Dr Stefan Schäfer), funded by the Virtual Institute for Responsible Innovation. The lessons derived from these interviews together with analysis of accompanying grey literature were delivered to ERA CoBioTech funders for comment and then subsequently integrated into the present document. They also form the basis of our recommendations presented in this document.

The second round of interviews was conducted with representatives of the funding bodies who are involved in ERA CoBioTech. We felt strongly that it was important to hear the views and experiences of funding agencies of the ERA CoBioTech for two reasons. First, there are significant differences amongst funders within ERA CoBioTech, in aspects such as organisational remits, national agenda setting processes, academic communities, policies regarding intellectual property, and mechanisms for public engagement. One of the goals for these interviews was therefore to learn more about how the different agencies were organised, how they operate and how they sit within their respective national landscapes, in order to develop an approach to RRI that accommodates the diversity of different national funders and contexts. The best way to gain this understanding was to speak directly to those who represent the various funding agencies for ERA CoBioTech. Second, it was important to include representatives of the various funding agencies to ensure our recommendations accommodated this diversity, and to function as cross-cutting recommendations. One goal of the ERA-NETs is to share expertise across national funding bodies and to develop shared processes for multinational collaboration. In our view, building this kind of bottom-up recommendations for a jointly funded programme, would not be possible without considering the views of the representatives for the programme from the different funding agencies.
In addition to policy review and qualitative interviewing, we conducted a portfolio analysis of the first ERA CoBioTech call. The purpose of this analysis was twofold: First to examine the framing and content of Responsible Research and Innovation within the first round of projects; second to investigate potential complementarity for future capacity building activities.

The findings of the research underpinning this agenda were presented and reviewed in May 2018 as part of an ERA CoBioTech consortium meeting at the French National Research Agency (ANR), Paris.

Annex 2: Supporting documents for ERA CoBioTech calls

Call pre-announcement

In the pre-call announcement, the high-level description contains reference to RRI, e.g.:

- As with previous funding calls, all projects will be expected to include aspects relating to 'Responsible Research & Innovation', communication and public engagement, and data management. Further information to support this process is available from the relevant national parties.

Call announcement and information for evaluators

In addition to these significant portions of text, it is also important to note slight variations in wording that are in line with best-practice RRI, including:

- Demonstrate and discuss the implications of a developing bioeconomy, rather than 'highlight': the benefits are neither clear nor evenly distributed.
- Emphasising that 'non-commercial' partners (and therefore multiple models of innovation) are also possible:
  - "Partnerships between academic researchers, and commercial (e.g. industrial) and non-academic partners"

Scope of the joint call

Contains reference to RRI:

> "ERA CoBioTech has made a commitment to ensure that the programme is in line with the concept of 'Responsible Research & Innovation'. This is to ensure that the programme develops in ways that address meaningful societal demands and foster environmental sustainability and social justice. As part of this commitment, projects must 'build-in' investigation of the social, environmental, philosophical or political dimensions of their research. This may include, but is not limited to, collaborative work with partners outside the natural sciences and engineering."

Amends reference to communication to be in line with RRI and allow for participants to include RRI components within this part of the project:

> "Each full proposal must include a two-page Dissemination and Communication plan, detailing how two-way dialogue with different public and stakeholder groups will be pursued. For more information see ANNEX 4: Dissemination and communication)."

Evaluation procedure

We have streamlined and clarified the evaluation criteria, removing separate references to LCA, RRI and ELSA and integrating them into RRI. Note that RRI should also be included under quality and efficiency of the implementation.

Full proposal evaluation

Full proposals that are submitted correctly and within the deadline will be checked for eligibility. The eligibility check will focus on the "General Eligibility criteria" (see page 9) and "National or regional regulations, national of regional eligibility criteria" (see ANNEX 2: National or regional regulations, National or regional eligibility criteria"). Non-eligible proposals will result in rejection of the entire project.

The eligible proposals will be peer-review evaluated by an international panel of experts with relevant expertise in the scientific fields concerned. Each expert is independent of any funding organisation involved in this call and no Conflict of Interest will exist in relation to the proposals evaluated. Each proposal will be reviewed by at least three external reviewers/experts. The composition of the international evaluation panel is decided by the ERA CoBioTech Call Steering Committee.

Proposals will be evaluated according to the evaluation criteria given below:

Excellence

- Clarity and pertinence of the objectives
- Soundness of the concept
- Credibility of the proposed methodology
- Quality and expertise of the consortium as a whole

Impact

Extent to which the outputs of the project will contribute to:

- Technological and economic development, by describing an envisioned plan to achieve a higher TRL of the processes and technologies (please refer to Annex X of this document)
- Non-academic and commercial partners, for instance through technological innovation and expanding exploitation capabilities of industrial partners, or involving users.
- Future sustainability of biotechnology research and its outcomes, supported by a data management (DM) plan (please refer to Call annex, below of this document)
- ERA CoBioTech's commitment to Responsible Research and Innovation, for instance through investigation and consideration of:
  - The environmental aspects of transformation to a bio-based economy (e.g. through Life Cycle Assessment); and / or,
  - Interdisciplinary collaboration with social sciences and/or humanities researchers; and/or,
  - Other innovative approaches to responsible innovation within the CoBioTech Programme (please refer to Annex X of this document).
- Engagement with diverse public and stakeholder groups, through an efficient Dissemination and Communication plan (please refer to Annex X of this document)

Quality and efficiency of the implementation

- Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables,
- Appropriateness of the management structures and procedures, including risk and innovation management,
- Complementarity of the participants and extent to which the consortium as a whole brings together the necessary expertise,
- Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role
- the project budget is appropriate to the planned work and allows the achievement of the project goals.

National Guidelines

Should provide clear indication of national/regional funder abilities to support different forms of RRI.

Proposal Template

Now contains clear reference to RRI through consolidation of ELSA, LCA and RRI, and delineation of 'Ethics' from 'RRI'.

> **RESPONSIBLE RESEARCH & INNOVATION**
>
> *Projects must demonstrate a commitment to investigating and addressing social, ethical, political, environmental or cultural dimensions of the proposed research. This may include (but is not limited to) collaboration with social sciences, environmental sciences or humanities scholars, and/or the adoption of assessment methodologies such as life cycle assessment, technology assessment, integrated assessment or sustainability assessment.*
>
> Please explain the approach you will take, how it is tailored to your project and how it will resourced appropriately.Comments: (max. 2,000 characters incl. space)

Call Annex (Reviewer and applicants): Responsible Research and Innovation

The successful technologies and innovations that ERA CoBioTech aims to produce will need to be more than just technical: they will be successfully embedded into social, environmental and political worlds. This means that they will have to be a part of social change. There is much evidence to suggest that it is challenging to predict exactly how such change comes about. Instead of attempting to address these questions after a technology is rolled out, it is sensible to try to 'design-in' consideration of the social, environmental, economic, political and cultural dimensions to technologies as they are being conceived, designed and tested.

If this process of 'innovation governance' is done well, ERA CoBioTech can help to produce new scientific knowledge, new technologies and innovations that are more democratic, more environmentally sustainable and that address more meaningful societal demands than may otherwise be the case. If such technologies and innovations actively design-in the insights and knowledge of public and stakeholder groups, they are more likely to be 'socially robust' because they will accommodate questions that may arise later in their development.

There are many forms of 'innovation governance' but the most prominent, and arguably best-developed, is 'Responsible Research and Innovation'. There are many national and transnational frameworks for Responsible Research and Innovation, but it is these broad goals of producing more useful, more thoughtful and more democratic innovations that are most important to follow.

Implementing Responsible Research and Innovation requires a multi-level approach that is attentive to different sites of innovation governance – universities, companies, policy arenas. This means that responsibility must be a collective one; researchers are not the only ones responsible for developing innovations. ERA CoBioTech acknowledges this and is working to develop programme-level mechanisms for Responsible Research and Innovation.

At the project level this call supports a wide range of methodologies that will investigate the social, environmental, political, regulatory, historical, ethical or cultural dimensions of such research. ERA CoBioTech is conscious of the fact that technologies and innovation are products of social processes, meaning that attention may be best directed towards the laboratory, project or institutional cultures that produce them. Consortia should develop an approach that is best-suited to their topic and available expertise. The following approaches may be particularly appropriate to this call.

Interdisciplinary collaboration.

Social sciences and humanities scholars may be interested in collaborating with you. Researchers in Science and Technology Studies, Sociology, Anthropology, Geography, Socio-legal studies, History, Environmental Studies, and others may each bring new insights and expertise to the questions raised by your project. Their research may focus on the social and political dimensions of the project. These may include, but are not limited to, questions about translational pathways, dual-use, interdisciplinarity, biosafety, biosecurity, intellectual property or changing cultures of work in the life sciences. Some of the most innovative and productive research in this space has attempted to build collaborative research endeavours that value the contributions of both the social and natural sciences, for instance by creating spaces for reflection and discussion informed by data from each discipline.

Life Cycle Assessment (LCA)

LCA is an internationally standardised methodology (ISO 14040: 2006) that helps to quantify the environmental pressures related to goods and services (products). By attempting to account for the full life-cycle of the product, LCA helps to identify the trade-offs and potential areas for improvement . The applicants in this ERA CoBioTech call may use and are encouraged to seek to advance the development of LCA or another robust methodology to assess the environmental implications of products, processes and technologies that may be developed or improved within the project.

Other forms of assessment

Environmental aspects are only one dimension of products, processes and technologies in development; other aspects can be assessed through tools beyond LCA. There are many well-established methodologies, including but not limited to: foresight studies; real time technology assessment; value sensitive design; user-driven design; critical design; techno-moral vignettes; citizen forums; co-production research; integrated assessment; alternatives assessment; multi-criteria mapping; socio-technical integration research; and a wide range of approaches within History and Philosophy of Science and Technology, Innovation Studies, Science and Technology Studies, Sustainability Science or Empirical Bioethics.

Questions to consider when developing your consortia proposal

The following questions may be helpful to consider when developing your proposal.

Core questions and assumptions

- What is the central idea of your project?
- Are there any assumptions that underpin it and that would affect its success?
- Are there any kinds of knowledge that would help address those assumptions?
- Does your university or organisation have researchers working on the social, political, ethical or environmental dimensions of the life sciences?

Integration

- Is it possible to develop a set of shared research questions for all your collaborators at the outset?
- Does the most important question revolve around research in the lab or some other site (such as the pathways for translation, regulation, or the environment)?
- Are there particular points in time or sites where input and exchange would be particularly valuable?
- Is it valuable for the RRI component to extend over the life of your project?
- Is it possible for insights from the social, environmental, or legal research to inform the outcomes of your project? Can you demonstrate this?

Support & flexibility

- Can you demonstrate that the RRI research is resourced appropriately?
- Are there any extra resources, such as travel and networking, that you require from the ERA CoBioTech programme to support your RRI project?
- Is it possible for your consortia proposal to adapt to changing developments within the project over time?

Call pre-announcement

In the pre-call announcement, the high-level description contains reference to RRI, e.g.:

- Check the call scope and project topic areas
- Build a consortium (ERA CoBioTech partnering tool: www.submission-cobiotech.eu)
- Think about what each partner would offer, and discuss what each wants to offer.
- Ensure that you have appropriate expertise for the different features of the call, including Responsible Research & Innovation.
- Check carefully:
- the general eligibility criteria and principles of the ERA CoBioTech call
- The National Regulations of all consortium partners
- Develop an appropriate plan for dissemination of the results and discussion with relevant public, stakeholder or expert groups in accordance to the guidelines of ERA CoBioTech (Annex 4 of the Call Announcement)
- Select an appropriate DM approach and create a data management plan according to the requirements of ERA CoBioTech (See Call Documents)
- Create a plan how to achieve a higher TRL (TRL Plan) including , when relevant, exploitation and commercialisation of the project results
- Complete your full proposal according to the requirements in call text.
- The project description should not exceed max. 20 pages
- Submit your proposal via CoBioTech submission system: www.submission-cobiotech.eu before the deadline
- it is possible to submit your proposal several times – old version will be replaced by new version

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