

# **Infrastructure for Responsible Research and Innovation**

An appraisal of the EuroNanoMed III portfolio

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**Abigail King & Robert Smith**



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# Overview

Responsible Research and Innovation (RRI) has been incorporated as an integral dimension of scientific research programmes to facilitate the consideration of social, political and economic influences of research, as well as ensure that public spending is allocated to research with commensurate public benefit. ENM introduced RRI Guidelines and considerations to their 2017 call for proposals, encouraging research teams to engage with the broader social issues related to their specific projects. This report presents the findings from an analysis of ENM documents between 2017 and 2021 that has sought to understand how ENM and research teams engage with RRI and how further RRI capacity may be built for the future.

Our key findings are as follows:

- Researchers understand RRI in multiple and various ways. We identified a total of 18 issues and over 150 activities that funded researchers associated with RRI in their projects.
- Despite this variation, there is a core of five issues that researchers most commonly refer to in their applications – **openness, animal experimentation and use, gender, safety and regulation** and **public and stakeholder engagement**. In their RRI sections, researchers devote particular attention to **animal experimentation and use**.
- In highlighting this common core, our claim is not that these issues are objectively the most important ones to engage with in the field of nanomedicine. Issues such as **socio-economic impact** and **access to treatments** are vital to producing a socially responsible research and innovation system, yet receive relatively less attention. Rather, the five core issues may be the more tangible ways for researchers to ‘give meaning’ to RRI.
- Most projects respond to at least one RRI prompt in the reporting process but researchers appear to devote little attention to the process, often copying and pasting text from one year to the next. Reporting is treated primarily as an accountability and compliance mechanism.
- It is unclear whether the limited attention to RRI in reporting is representative of the attention dedicated to it within projects; there is likely to be a degree of heterogeneity. For instance, across the portfolio are various examples of responsiveness – instances in which modifications to project design have been made in response to RRI considerations.
- A higher proportion of evaluators engaged with RRI in 2020 and 2021 than in 2017, showing the value of ENM’s RRI guidelines to reviewers. However, evaluators in all years appear to engage tangentially with RRI. Most frequently, evaluators referred to the concept in a brief sentence that took a form similar to “RRI issues were addressed”, suggesting RRI is interpreted as something ‘to be taken care of’ by researchers, rather than something equivalent to other parts of the research process, which received far greater attention from reviewers.

All findings are caveated by our reliance on statements in documentary sources, which do not give a comprehensive picture of the thought processes behind them. In-person qualitative research, either as a parallel study to a new programme or retrospectively as a form of ex post evaluation, would be needed to validate these findings and understand the reasons for them. However, this preliminary study does allow us to develop insights as to how programme managers might build capacity for RRI in the future, particularly when viewed in light of learning from other ERA-NET programmes.

Our key recommendations are:

1. To collectively identify a distinct set of goals, methods and frameworks that circumscribe RRI.
2. To offer a comprehensive and curated list of resources for teams to consider and engage with in the proposal stage and throughout the programme.
3. To include reviewers with a background in RRI and provide all reviewers with comprehensive RRI guidelines to reinforce engagement in the evaluation stage.
4. To offer teams space for reflection and engagement with RRI: both within programme documents, i.e., proposal and monitoring forms, as well as in the forms of iterative workshops.

# Introduction

Responsible Research and Innovation (RRI) arises from an understanding that scientific research has consequences that are profoundly social, with implications that reach far beyond a particular field. This understanding has formed particularly in the context of research funding which involves multiple competing considerations around the responsible use of public funds. RRI offers a way to address questions around the social and economic sustainability of research. It encourages reflection around funding priorities for different scientific fields and varying research outcomes, such as epistemic knowledge, translational potential and clinical benefit. Underlying RRI are principles such as equality, ethics, public participation, attention to and inclusion of stakeholder values and experiences, openness in data sharing and dissemination of findings, environmental safety, legal and regulatory issues, interdisciplinarity, and prospects for translation of findings to practice.

To address these debates in research funding prioritisation, funding programmes have developed policy frameworks for RRI that call for the responsible and sustainable application of research that reflects both scientific and social priorities. Programmes also frequently codify their priorities in guidelines, which make expectations concrete and direct both proposers and evaluators toward embedding RRI considerations in the research process. In 2017, EuroNanoMed III (ENM) introduced an initial set of RRI guidelines for applicants and modified the call text to include reference to RRI. The motivation behind these interventions was to help research teams frame their projects using RRI considerations and engage with the social context of their work. This introduction of RRI has been continued through to ENM's closing call.

As ENM ends and new programmes begin to develop their own approaches to RRI, it is useful to interrogate the ways in which project teams have responded to these guidelines, by engaging with the underlying tenets of RRI in their research processes over the past 5 years. This will help us to identify best RRI practices and encourage further reflection. To do this, we have formulated three guiding research questions, which structure the report:

1. How do researchers understand and implement RRI?
2. How do evaluators employ RRI considerations in their proposal evaluations?
3. How can we continue to build capacity for RRI in the future?

To answer these questions, we have analysed three of ENM's five calls (2017, 2020 and 2021), focusing on proposals and reviewer evaluations. We also analysed any available monitoring documents from projects in the years 2017 to 2021. As a concept within the literature on research and innovation governance, RRI is polymorphous and contested (Ribeiro et al., 2017; Owen and Pansera, 2019). We therefore understand the ENM call process as a space in which funders, applicants, and evaluators engage with RRI to 'give meaning' to the concept. We are interested in the different ways people engage with RRI and the resources they use to do so.

Our analysis emphasises the importance of infrastructure for RRI. Traditionally, infrastructure is understood as large, material objects that support networks, connections and flows of other materials, for example train tracks, roads, electricity systems and water ways. But infrastructure can also be thought of as immaterial systems that support and direct particular behaviours, relations and social practices (Meckin, 2020). Examples of these immaterial systems include common law, organisational cultures and regulatory frameworks. Infrastructure can also refer to the systematic provision of financial resources, knowledge or incentives. Certain practices only become possible with infrastructure.

Different forms of infrastructure enable people to engage with RRI at various points in a project's lifecycle.

- At the application stage, infrastructure impacts proposals in two primary forms: the specific ENM RRI Guidelines and broader external frameworks that guide RRI in scientific practice more generally.
- The ways in which reviewers engage with RRI in project evaluations offer another infrastructure that could support RRI activities.
- Finally, the follow up reporting documents structure and guide the ways in which project teams understand the evolution of RRI during the lifespan of their project.

As we detail in our conclusion, ‘thinking with’ these forms of infrastructure can help to understand how and where teams engage with RRI issues, and allow us to consider the ways engagement can be improved.

## Method

This research was conducted in Spring 2022. Using documents, we focused on the way that RRI was engaged with by the 38 funded projects in EuroNanonMed III’s 2017, 2020 and 2021 cohorts. For each project, documents included: (1) the project proposal; (2) reviewer evaluations, applicant rebuttals and the review panel’s consensus statement; and (3) responses to programme monitoring questionnaires. We also reviewed responses to programme monitoring questionnaire for the 2018 and 2019 cohorts. In total this amounted to an analysis of 160 documents.

Broadly, our approach draws on portfolio analysis (Wallace and Rafols, 2016), which seeks to identify trends across a funder’s portfolio, and discourse analysis, which examines how people mobilise text to create particular meanings (Alvesson and Kärreman, 2000). To structure our analysis we deployed a coding scheme from a prior analysis of RRI in ERA CoBioTech, another ERA-NET programme (Smith et al., 2021). Our analysis of projects had a twofold focus:

- **Issues** → What ethical, social, environmental or political issues do researchers explicitly state or implicitly suggest are relevant to their projects?
- **Enactments** → How do researchers’ concerns map to practices in their projects?

We thus extracted all references to *issues* and *enactments* from the documents. Like many other funding programmes, ENM includes dedicated ‘RRI sections’ in its documents. However the boundary between RRI and scientific practice is porous. Much of the academic literature on responsible innovation emphasises that there should not be a clear separation between ‘science’ and ‘RRI’, instead seeing such boundaries as strategically drawn to separate science from scrutiny (Burchell, 2007; Levidow and Carr, 1997). Consequently, for ideas relating to RRI, we cannot look solely at previously demarcated spaces for RRI but instead look for explicit and implicit references to the ideas behind RRI at multiple points in a document, e.g. in the lay and technical summaries, statements of goals, descriptions of work, description of project organisation, summaries of collaborative activities and summaries of major achievements provided in the monitoring process. Thus, in addition to explicit reference to RRI, we extracted references to issues salient to RRI such as public engagement and participation, intellectual property and societal impact. A similar approach was adopted to analyse proposal evaluations and project reporting.

In mapping out the two dimensions of RRI within ENM – issues and enactments – we aimed to understand which issues teams and reviewers thought were relevant and how these concerns were operationalised within the projects. We also paid attention to where these concerns lead. For instance, do they nurture

Call Year	Proposals funded
2017	17
2020	10
2021	11

Table 1. Number of funded proposals for each call year.

further considerations of RRI, do they consider the evolution of RRI throughout the project? Or, do they primarily seek to comply with certain external guidelines?

There are always multiple ways of cutting data, all involving trade-offs, and several caveats are therefore important to mention. Here, the primary decision was how to balance depth of each funding call versus the longitudinal analysis of the programme, and of each project. The highly competitive nature of a funding programme means that an analysis that examines both funded and unfunded proposals will arguably tell us more about the way researchers are engaging with RRI than one focusing only on funded data. Similarly, an analysis that goes into too much detail per call will have fewer resources to develop longitudinal insights over time.

To balance the breadth-depth trade-off we analysed documents from three calls, focusing only on funded projects. This choice limits what we understand about the connection between project scores and meaningful RRI engagement but it provides more depth per project, as it grants access to the programme's monitoring documents for the early calls, allowing us to trace the evolution of RRI activities longitudinally from proposal through years 1 and 2 of a project. Of course, this means we did not examine proposals from years before RRI was included in the call text but phrases such as Ethical, Legal and Social Aspects (ELSA) were, meaning we do not understand the ways in which RRI might have been included in proposals in indirect and implicit ways prior to this inclusion, and the way in which its inclusion may have influenced representation of these issues.

A second significant choice is our reliance on 'proxies' to understand engagement with RRI (Strathern, 2004). For example, in the year 1 and 2 follow-ups, we drew on what teams reported as RRI activities but do not know the extent or substance of these activities and how these connect directly to understandings of RRI. In the evaluations, we drew on what evaluators commented in regard to RRI, however we do not have insight into how evaluators themselves understood RRI or the processes through which they evaluated proposed RRI engagement. In proposals, we observed how teams approached RRI in the ways they proposed to engage with various considerations. Consequently we do not have a full understanding of the ways in which teams grappled with RRI is and why they felt it is important, or not; we only have sporadic explanations from proposals where teams offered reflections on why RRI considerations and specific engagements were crucial for the project. Often, teams used a large part of an application's RRI section to provide information on ethical experimentation with animals, while leaving out other points that could be considered as RRI. We do not know if teams did this because they understood RRI mostly as being concern with the ethical use of animals, or for instance, if they were not sure where else to include these ethical details.



# Understandings of RRI in ENM proposals

To understand how researchers initially engaged with ENM's request to integrate RRI into projects we examined the RRI sections of all funded proposals for 2017, 2020, and 2021 call years. We paid particular attention to the RRI issues that project teams raised and the ways they proposed to engage with those issues.

Turning first to examine the issues raised by teams (table 2), we see a relatively diverse list of 20 issues, that coalesces around five issues over the three years: **openness**, **animal experimentation and use**, **gender**, **safety and regulation** and **public and stakeholder engagement**. There is a significant amount of variation with other issues, and several are raised by one or two teams per year – **socio-economic impact**, **data security**, **ethnicity**, **environmental sustainability and impact**, **protection and exploitation of results**, and **access to treatment**. This common core should not be seen as an objective assessment of the most important issues to engage with in the field of nanomedicine but likely represents issues that researchers view as accessible to translate into practice.

We also see variation across the years. For example, **transition and translation to market** was considered in most applications in 2017 but only one application in 2020 and 2021. Public and stakeholder engagement appeared in nearly all 2017 applications but the proportion falls to roughly half of proposals in subsequent years. Similar dynamics are visible with **informed consent**, and **early career researchers**. There are multiple potential reasons for these findings, and interviews with project teams would help to understand them.

Higher proportions of project teams in 2017 engaged with RRI issues in more substantive ways than in 2020 and 2021. Through careful examination of the application forms across all three years, we noted that project teams in 2017 introduced RRI issues earlier on in their applications as important aspects of the research. Project teams in 2017 wove RRI through their applications, mentioning it in multiple sections of the application form (within 3.1 Description of Proposed Work as well as in Work Package descriptions in 3.6).

These differences may be due to changes in the application form. The 2017 form included six prompts in section 3.1 to guide teams filling out the section. The final prompt was for project teams to address RRI, and nearly all project teams explained their project's approach to RRI in this section. This final prompt was removed in the 2020 and 2021 application forms, which coincided with applicants solely using the 'RRI section' to detail their activities, rather than weaving them throughout the whole proposal. Although we can only point to correlations rather than outline causal pathways, this suggests that ENM may have garner more engagement with RRI if they included this final prompt in the 3.1 section, as it seemed to incentivise project teams to weave RRI throughout their application. At a minimum, future programme administrators should pay close attention to continuously encouraging teams to engage with RRI across an application form.

Within the RRI sections of proposals, we traced 'enactments' as a way to understand how teams proposed to engage with RRI in practice (Table 3). Enactments include various methods, practices, activities and regulatory compliance. The diverse ways that teams propose to engage with RRI in practices is striking; we identified a total of 157 unique strategies and have provided examples of these in the respective table.

	Count of proposals			
	2017	2020	2021	Total
Proposals Funded	17	10	11	38
<b>Issues</b>				
Openness	16	8	9	33
Animal Experimentation and Use	14	9	9	32
Gender	14	5	7	26
Safety and Regulation	11	7	7	25
Public and Stakeholder Engagement	16	5	4	25
Use of Humans and Human Samples	12	3	2	17
Informed Consent	12	0	2	14
Early Career Researchers	6	2	5	13
Translation and Transition to Market	11	1	1	13
Patient/end-user needs, problems and expectations	4	3	4	11
Interdisciplinary expertise	6	0	1	7
Protection and exploitations of results (IP)	5	0	1	6
Gender in experimentation	1	2	3	6
Environmental Sustainability and Impact	4	1	1	6
Socio-economic impact	3	1	2	6
Data security	0	2	2	4
Ethncity	0	0	1	1
Access to Treatment	0	0	1	1

Table 2. Number of proposals across 2017, 2020, and 2021 that identified each RRI issue. Yellow highlighted cells show issues that were common to more than 50% of the respective cohort.

Tracing issues and enactments highlights some of the tensions in trying to formally-define and partition RRI. There was overspill between the ‘RRI section’ and other parts of the proposal, such as the IP, international collaborations or dissemination section. Issues that some teams identified as relevant to RRI, were addressed by others elsewhere, but not labelled as being relevant to RRI. Additionally, we noted that many research teams used a large part of the RRI section to discuss specific protocols around the ethical use of animals in scientific experimentation. In this way, there was often a conflation between RRI and research ethics. These findings draw attention to the heterogeneity of issues and enactments that research teams associate with RRI, and give some insight into teams’ different priorities. They show that RRI means many different things for ENM and its research teams, mirroring findings in the broader literature (Ribeiro et al., 2017; Hartley et al., 2017).

An initial recommendation for ENM and future programmes is therefore to collectively determine how they plan to ‘give meaning’ to RRI and to consider how RRI is distinct from other aspects of research. Ideally, this decision making process would be a collective one that incorporates as broad a range of stakeholders as possible within the programme’s remit. The distinctions would then be communicated in RRI guidelines and reflected through the application form. It is also important for ENM to consider what the value of RRI might be to research teams as they think through the social contexts of their work.

Issue	Distinct Enactments	Enactment examples
Patient/end-user needs, problems and expectations	5	Patient consultations; involvement of doctors; connections with patient associations; researcher studying psycho-social impact of nanomedicines.
Informed Consent	6	Protocol following Helsinki Declaration and Institutional Ethics Committee; compliance w/ national legislation; participant information sheets; answer patient questions.
Animal Experimentation and Use	15	Ethical compliance; limit number of experimental animals; follow NIH animal care guidelines; partners certified and trained to conduct animal studies; institutions w/ appropriate animal facilities and licenses.
Safety and Regulation	17	Conduct safety studies; use FDA approved materials; scientists trained to handle nanomaterials; create regulatory procedures w/ specialists; conduct risk assessments; follow human waste disposal regulations.
Protection and exploitation of results (IP)	5	Establish IP board; consortium IP agreement; identify key exploitable results; seek protection for new inventions.
Openness	19	Develop dissemination plan; update dissemination plan throughout project; publish in open access journals; share results in public forums; organise meetings w/ patients and families; deposit data in public repositories.
Early Career Researchers	9	Promote career development; include early career researchers as PIs on project team; link project with masters degree programme; workshops for young researchers.
Gender	10	Gender balance in consortium; consider gender in hiring process; include perspectives of male and female patients and specialists; Institutional equal opportunities policies.
Gender in experimentation	2	Consider gender balance and sex differences when designing experiments; conduct total population analyses.
Environmental Sustainability and Impact	5	Protocols for safe handling and disposal of materials; evaluate safety and environmental issues; radioactive waste stored appropriately, ensuring none is emitted into the environment.
Public and Stakeholder Engagement	14	Engage with policy makers, citizens, and educators; create public project website; involve patient groups and medical doctors; “co-creation, co-design, and co-production” methods; scientific advisory board.
Ethnicity	1	Consider ethnicity in hiring process.
Translation and Transition to Market	21	Establish exploitation committee; identify regulatory pathways; create business plan; comply with Good Manufacturing Practice; involve industrial partners; analyse materials and production costs for scale-up.
Data security	5	Adhere to cybersecurity regulations; data management training; store data according to FAIR principles; deposit and share data according to national legislation.
Use of Humans and Human Samples	9	Apply ethical standards and guidelines; obtain informed consent; data protection; anonymise donors; set safety and quality standards for donation, procurement, testing and processing.
Socio-economic impact	10	Improve quality of life and health; improve treatment efficacy, safety and patient compliance; reduce economic burden of disease for patients, healthcare costs, side effects, and recurrence of treatment .
Interdisciplinary expertise	3	Cooperation w/ diverse academic and industry groups; Establish EU trans-disciplinary collaboration; Ensure partners in complementary fields contribute to dissemination of results.
Access to Treatment	1	Adopt agreement that broadens access.
Total	157	

Table 3. Number and examples of unique enactments across 2017, 2020, and 2021 for each RRI issue.

Issue	Years used	Examples of infrastructure
Openness	All	National Repositories; Open Access channels following the "gold route" as per European Commission recommendations; Scientific Journals; Researchgate Scientific Networks; Twitter
Animal Experimentation and Use	All	Institutional Ethical Approval; 3R Principles; Guide for the Use and Care of Laboratory Animals; National laws around animal use; EU directive on the protection of animals used for scientific purposes (2010/63/EU); NIH Guide for the care and use of laboratory animals; FELASA Guidelines and Recommendations; Health Products Regulatory Authority; Association for Assessment and Accreditation of Laboratory Animal Care; National Ministries of Agriculture
Gender	2017, 2021	Institutional Equal Opportunities Policies; European Commission Code of Conduct for the Recruitment of Researchers; EU rights to work-life balance; European Commission Gender Equality Strategy
Safety and Regulation	All	Food and Drug Administration; European Directive 98/24/EC; European Medicines Agency; Nuclear Safety Authority; European Commission's "Code of Conduct for Responsible Nanosciences and Nanotechnologies Research"; European Group on Ethics in Science and New Technologies; WHO Regulatory Framework for Health-care Waste
Public and Stakeholder Engagement	All	Scientific Regulatory Boards; Patient Associations; Institutional Press Offices; Social Media
Use of Humans and Human Samples	All	Institutional Ethical Approval; National Ministries of Health; International Legislation for the Transfer of Patient Material; EU Directive 2004/23/EC; EU Charter of Fundamental Rights and Directives; Declaration of Helsinki; Universal Declaration on the human genome and human rights adopted by UNESCO; WHO Regulatory Framework for Health-care Waste
Informed Consent	All	Declaration of Helsinki; Institutional Ethical Approval; National Ministries of Health; National Legislations on Public Health; UNESCO Universal Declaration of Human Rights
Early Career Researchers	2017, 2021	European Commission Good Scientific Practice; Erasmus Mundus NanoFar
Translation and Transition to Market	2017	Regulatory Preclinical Studies; Good Manufacturing Practice Compliance; SWOT (Strength, Weaknesses, Opportunities, and Threats) Analysis
Patient/end-user needs, problems and expectations	2017, 2020	European Medicines Agency; Ethical and Regulatory Advisory Boards
Interdisciplinary expertise	Never	N/A
Protection and exploitations of results (IP)	Never	N/A (however there may be infrastructure outlined in IP sections)
Gender in experimentation	Never	N/A
Environmental Sustainability and Impact	2021	EMAS (EU Eco Management and Advisory Scheme)
Socio-economic impact	Never	N/A
Data security	All	"Cybersecurity Requirements"; FAIR Principles; National Data Protection Authorities; European Commission Data Protection Legislation; EU Directive 2016/680
Ethnicity	Never	N/A
Access to Treatment	Never	N/A

Table 4. Whether proposals in each year used extant infrastructure as an enactment for RRI issues, as well as examples of extant frameworks used.

We can use proposal data to begin to ask where interpretations of RRI come from, in effect what resources they use to ‘give meaning’ to RRI. Across the three call years, teams drew primarily from two types of source – the internal ENM guidelines, and extant external frameworks.

There were many similarities between the RRI issues teams brought up and the list of RRI examples in the ENM RRI guidelines. In these guidelines, RRI issues included: (i) involvement of stakeholders, (ii) dissemination of results in open science channels, (iii) research methods (including ethical issues, considerations of animal use in research), (iv) environmental issues, (v) safety requirements, (vi) patient benefit and the ways through which benefits will be delivered. As table 2 shows, many of these are reflected in the issues teams included in their proposals. Further, teams often extracted specific wording from ENM’s RRI guidelines and reproduced it in their own proposals. Here, examples include “co-production/design/creation” and “RRI is integrated part of project including all participants”. The key words defining RRI in the guidelines were also frequently used as headings for issues that teams introduced in the RRI section of their application.

The second common source that research teams drew on to reinforce and give meaning to RRI in their proposals was external infrastructure. As indicated in table 4, external infrastructure includes institutional, national and EU-level regulation and legislation, open access channels, academic programmes, data repositories, and social media. Most frequently, research teams listed compliance with these forms of infrastructure as an enactment of RRI in its own right and, while less often, some research teams offered specific plans of engagement with and beyond these supportive structures.

## Accounts of RRI in project progress reports

To begin to understand the extent of RRI engagement throughout the lifespan of funded projects, we examined the progress reports that projects provide to the programme at the end of their first and second year. To maximise the information available to us, we examined both reports for the 2017–19 calls, and the first-year reports from the 2020 call. The 2021 reports were not yet available.

These progress reports contain a number of distinct sections, including one on RRI which asks participants to:

- document any participation in RRI-related training activities;
- identify whether any approaches in the project have been modified to account for safety or efficiency considerations;
- document participation in events relating to ethics and research integrity;
- list deliverables, milestones or methodologies from the project that address ethical issues;
- consider whether members of the research project have engaged with governance issues, for instance through engagement with policy makers or contributing to standard setting;
- identify whether the project addresses the needs of disadvantaged social groups.

Our first observation is that this list of requests was designed to ask researchers about different predetermined RRI-dimensions and draws a boundary around RRI as a distinct part of the scientific project. However, as was the case with proposals, issues that projects deem relevant to RRI are also addressed in other parts of the progress report template. There are, for instance, entire sections in the report regarding international cooperation, dissemination, and potential impact. One question (no. 5) asks teams to report

the presence and percentage of young scientists in research consortium groups. As with the proposal templates, these sections distinguish these particular aspects as distinct from RRI, despite them appearing in the ENM RRI guidelines and being raised as salient by researchers. These overspills point to the flexibility in understanding what counts as ‘an RRI issue’ and where it fits within a research project. They raise challenges for a system of RRI reporting that begins with a set of predefined criteria that are developed independently of the issues researchers map to RRI in their proposals.

Turning now to examine what teams reported, we found that the majority of project teams from all years responded to at least one question within the RRI monitoring section (Table 5). The approaches to RRI that teams report are diverse. For instance, across the portfolio are 13 examples of ‘reflexive research design’ – instances in which teams report modifications to project design in response to RRI considerations. At first glance, this form of enactment is indicative that a team has been engaging substantively with RRI issues.

However, many of the responses were extremely short (“respecting ethical guidelines” or “obtained ethical clearance”), superficial, and were often copied and pasted between follow up documents from years 1 and 2. Several teams only reported activities around ethics in experimentation with animals, reflecting an understanding of RRI as being primarily concerned with animal ethics that we observed in the proposals. The superficial way that project teams engaged with these monitoring questions suggests they are not inspired to engage and reflect on how RRI is evolving throughout their project, but rather are approaching the follow up questions as an accountability exercise.

While accountability is an important aspect of monitoring and oversight, this should not come at the expense of opportunities for formative evaluation that allow teams to reflect, learn and make strategic decisions. As we detail in our concluding section, future programmes might seek to create explicit opportunities for these more reflective and responsive aspects of monitoring.

## Engagement with RRI in the evaluation panel

To begin to understand how evaluators engage with RRI, we examined feedback forms and rebuttals. Here we also see heterogeneity in individual approaches as well as standardisation as we move from 2017 to 2021.

In 2017, only four of the 21 experts involved in the peer review process incorporated RRI in their evaluations. Further, two of these reviewers evaluated RRI measures within Criterion 2: Impact, while the other two evaluated RRI within Criterion 3: Quality and efficiency of the implementation. In 2020 and 2021, higher proportions of expert reviewers mentioned RRI at least once in their evaluations: 11 out of 25 experts in 2020, and 20 out of 28 experts in 2021. There was also more consistency in where experts included their evaluation of RRI activities. In 2020, all but one expert who mentioned RRI did so within Criterion 2: Impact. In 2021, all experts who mentioned RRI did so within Criterion 2.

These findings demonstrate that in 2017, most reviewers did not explicitly prioritise RRI in the evaluation process, despite it being a requirement in the call text. They also highlight the different ways of appraising RRI within a research project, even amongst the small group who did incorporate RRI into their reviewing in 2017. The changes from 2017 to 2020 and 2021 suggest that (1) increasingly, expert reviewers are paying attention to RRI aspects within project evaluations as time goes on, and (2) expert reviewers

Call year	Follow-Up	Yes	No
2017	Year 1	13	3
	Year 2	14	2
2018	Year 1	10	2
	Year 2	9	3
2019	Year 1	10	3
	Year 2	10	3
2020	Year 1	6	2
	Year 2	N/A	N/A

Table 5. Number of project teams for calls 2017 – 2020 who responded at least one question within the RRI monitoring section of year 1 and 2 follow ups.

have increasingly consistent understandings of how RRI should be evaluated within the ENM scoring system.

However, the amount of attention devoted to RRI appears not to have increased. In 2017, one of the reviewers engaged with RRI far more comprehensively than the others. In general, this reviewer included one or two sentences about RRI in their evaluations, and listed what applicants had thought through well and what aspects of RRI they were missing. The other three reviewers did not incorporate detail, writing only short snippets such as “RRI guidelines are followed”, “RRI is partially followed”, or “RRI is lacking”. This pattern of concise statements continued in 2020 and 2021, with most reviewers offering a few words. Here, representative examples of RRI evaluations include “RRI is properly addressed”, “sufficient details on RRI issues”, “all RRI topics addressed”, “shows awareness of RRI issues”, “proposed dissemination and RRI appear adequate”, “RRI requirements presented in satisfactory manner”, “RRI issues have been presented thoroughly” and “RRI topics are minimally addressed”.

While most of these assessments are positive and could suggest that project teams are engaging comprehensively with RRI issues, their brevity, coupled with the counter examples of more substantive appraisals is more likely to highlight that most reviewers engaged superficially with RRI, treating it as a tick box exercise in the evaluation process. The scarcity of data here means that it is difficult to offer a rich analysis of the social dynamics shaping the evaluators’ engagement with RRI in ENM. There are likely systemic reasons – most reviews are conducted quickly and need to pay attention to many different dimensions. However, for funders seeking to improve the review process it raises questions about reviewers’ understanding of RRI, what they look for in terms of RRI while evaluating proposals, and the potential value of including expert RRI reviewers in an evaluation panel. Moving forward, including reviewers with a background in RRI could be a way to improve engagement between reviewers and project teams in the evaluation stage.

## How can administrators build capacity for RRI in the future?

Having briefly presented our analysis of RRI in ENM’s portfolio, we now turn to our final question by providing recommendations for administrators in future funding programmes.

When funders ask researchers and evaluators to engage with ideas like responsible research and innovation, they are asking them to do the challenging work of not just illuminating the social, political, ethical or environmental context of science, but also devising ways to ensure this context is brought into the research and innovation process. This is a meaning-making process: researchers and evaluators need to work out how to tether broad ideas about responsibility in science to their own immediate context. Importantly, this does not happen from a 'blank slate' but amongst a patchwork of existing ways of thinking about, talking about and practising responsibility in science. To make decisions about how to respond to requirements to 'do' RRI, people draw on their experiences, use their relationships and are conditioned by the broader incentive structures (e.g. which activities are likely to lead to promotion) of the cultures they work in.

An important part of this patchwork are external frameworks to manage the ethical, social, environmental and legal aspects of science, which exist independently of ENM and have developed over time. These include animal experimentation frameworks, such as the 3Rs – Replacement, Reduction, Refinement – and the European Commission's 'Five Keys' for Responsible Research and Innovation. A second important feature are the internal resources provided by ENM, such as the RRI guidelines – unsurprisingly, teams closely mirrored ENM's definition of RRI and the issues raised. We can understand these resources as a kind of infrastructure that conditions the way researchers think about and enact RRI. Our analysis therefore highlights that by asking researchers and evaluators to engage with RRI, the EuroNanoMed III programme has already begun to intervene in the research and innovation landscape by providing infrastructure for RRI, a valuable first step in building capacity for RRI. Future programmes could intervene here to offer a more comprehensive and collectively curated list of resources for teams to consider and engage with in upcoming funding cycles.

However, it is also important to examine how people in the programme interact with this infrastructure. Here, both researchers and evaluators appear to be engaging with RRI with a logic of compliance. While teams often drew on external sources to outline RRI activities, engagement often stopped there: teams frequently mobilised these infrastructures – ethical review, for instance – as the primary, or even sole, way to engage with RRI issues. We know from past research that existing frameworks for animal experimentation, for example, engage only partially with the complexities of this ethical issue (Davies, 2012; McLeod and Hartley, 2018).

As a previous study of ERA CoBioTech identified (Smith et al., 2021), a gap for future programmes is to shift the mindset that people approach RRI with from one of compliance to one of active engagement. Ideally, for instance, researchers would mobilise both ENM examples of RRI and external frameworks to assemble their own conceptualisations of, and plans for, RRI. The mandate for RRI would encourage teams to address aspects of important issues that external frameworks do not address. This 'active engagement' would lead to new case studies for teams to draw on and the evolution of internal and external governance frameworks. To be useful infrastructure must be maintained and upgraded.

In practice, our overarching recommendation is for funding organisations and programme managers to 'think infrastructurally', seeing themselves as an active, coordinating, part of a research and innovation system with the capacity to shape the way different groups develop an understanding of RRI and put the idea into practice. Moving forwards, we can identify several points of infrastructure for funders to focus on, each responding to our key findings.

## **Collectively identifying the goals of RRI**

ENM's researchers do not share a single, comprehensive understanding of RRI. Despite having shared aims, large multilateral funding programmes such as EuroNanoMed III will always incorporate research



occurring a range of contexts, from different fields and to different ends. What social responsibility looks like in these contexts – what kind of issues are relevant, what methods are useful and what resources are available to teams to act on these issues – will always vary. The diversity of approaches in ENM's portfolio represents both a resource to learn from and draw upon and a challenge for those seeking to learn about what RRI is or could be in a particular context.

The first form of infrastructure that future funding programmes can provide is the opportunity to build a shared understanding of RRI within the funding programme, which balance tensions between diversity and cohesion in a programme. As other ERA-NET programmes have recently concluded (Smith et al., 2022), a first step towards strengthening RRI in the future would be to collectively identify a more limited set of goals, methods and frameworks that teams could work towards in a programme. Ideally this form of 'mission-oriented RRI' would be developed at the outset of a funding programme and iterated at key points onwards, for example by tailoring it to each funding call.

## **Using proposal review as a capacity building opportunity**

A higher proportion of evaluators engaged with RRI in 2020 and 2021 than in 2017, showing the value of ENM's RRI guidelines to reviewers. However, evaluators in all years appear to engage minimally with RRI. Most frequently, evaluators referred to the concept in a brief sentence that took a form similar to "RRI issues were addressed". This suggests RRI is interpreted as something 'to be taken care of' by researchers, rather than something equivalent to other parts of the research process, which received far greater attention from reviewers.

ENM could reformulate other forms of infrastructure in order to build capacity in RRI and to engage with its fluidity. This includes the proposal and follow up forms, which currently isolate RRI into one section. Instead, these forms could aim to weave RRI throughout the application and monitoring processes, as well as offer opportunities for reflection on the evolution of RRI across a research programme.

For proposal evaluation processes, ENM could also offer more space for iteration of feedback between reviewers and researchers as well as more support for reviewers around expectations of RRI. For example, reviewers could be encouraged to pay attention to research teams' understandings of the significance underlying and potential implications of each RRI concern, rather than the dichotomous 'RRI considerations are present' or 'absent' distinction observed in many reviewer remarks. Reviewers could further attend to whether RRI considerations have been carried throughout a proposal: is there room for RRI considerations to evolve over the lifespan of the project? Are there opportunities for team members to gain further perspective on and capacity around RRI? This form of engagement may encourage reviewers to examine more deeply the ways in which RRI is embedded within proposals; further, it may open a dialogue between reviewers and researchers.

## **Rethinking monitoring**

Finally, and as shown in our analyses above, reporting is treated by teams primarily as an accountability and compliance mechanism. This is common to many funding programmes, and is likely sustained by the approach taken by ENM. Monitoring and evaluation processes thus act as another form of infrastructure within scientific environment. However, the goals behind RRI, as well as other forms of research and innovation governance, such as transformative innovation policy offers an opportunity to advance evaluation practices.

New ways are needed to monitor RRI work to encourage more substantive engagement and better foreground the work that is already occurring. For example, teams could be encouraged to understand RRI as

a process that involves on-going reflection and experimentation. Questions in the follow up report could be altered to inspire this type of reflexivity. A similar suggestion emerged from a working group tasked with thinking about how to build capabilities for RRI in ERA CoBioTech (Smith et al., 2022). They suggested that instead of tick-box questions, researchers could be asked to provide a narrative about the people they had engaged with, the potential impacts of their research and to situate their scientific goals within a broader context. These ideas also raise questions about the dialogue between project teams and the funding programme's approach to RRI monitoring. There may, for instance, be opportunities to create workshops over the course of project timelines that facilitate reflection and shared learning around RRI that shift the logic from one of accountability to reflection, iteration and learning (see, e.g. Molas-Gallart et al., 2021).

There are also opportunities to explicitly connect monitoring processes to our earlier recommendations. Monitoring processes would be strengthened by identifying programme-wide understandings of RRI, weaving these understandings throughout the progress report form, and encouraging teams to reflect on the significance underlying RRI issues. For example, if the involvement of early career researchers is incorporated in a programme's overarching definition of RRI, the space to report early career engagement could encourage teams to reflect on the specific significance and meaning underlying this engagement, and the influence it has on the wider project—alongside the existing reporting metrics.

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