

Guidelines for Responsible Research and Innovation (RRI) in proposals to EuroNanoMed III

This RRI guideline is to give a short introduction to RRI as concept and provide sources for more information. It also presents *one possible way* of thinking about RRI and introducing these reflections and RRI measures into a project proposal in nanomedicine.

Two key objectives for the ERA-NET for nanomedicine (EuroNanoMed III) are to:

1. Encourage the nanomedicine community to adopt RRI, HSE and ensure alignment with current regulatory requirements.
2. Train funded researchers on:
 - Translation processes ([NOBEL-PROJECT](#) might be helpful here)
 - Responsible Research and Innovation (RRI), including co-creation, co-design and co-production
 - Regulatory aspects

What is RRI?

In a nutshell RRI is:

- Involving societal actors in science and innovation throughout R&I processes to better-align their orientation with the values of society.
- In Horizon 2020, RRI is described as a broad umbrella connecting different aspects of the relationship between R&I and society: public engagement, open access, gender equality, science education, ethics, and governance.

In the EU Programme for Research and Innovation 2014-2020, Horizon2020, **RRI is a cross-cutting issue**, actions are also promoted via 'Science with and for Society'. Here is the [H2020 definition](#) of RRI, including [public engagement](#), [open access](#), [gender](#), [ethics](#), [science education](#).

More recently, RRI has been articulated as **co-creation, co-design and co-production**: methodologies in which projects are structured to include stakeholders from the outside (e.g. users or interest groups) with the expertise of the social sciences and humanities (SSH). This [RRI Movie](#) by RRI Tools describes the idea well also includes a broad RRI-toolbox.

ENM's Joint Transnational Call 2020 call text says the following:

"Projects are required to discuss and respond to [Responsible Research and Innovation \(RRI\) aspects](#), **including co-creating, co-design and co-production**. Projects are required to include a plan to **disseminate results/outcomes** and how to achieve higher levels of technological readiness."

How can you include RRI in your proposal?

ENMIII's philosophy is to have *RRI as an integrated part of the project* involving all project participants. This means that the approach taken should be specific to the project. While RRI may focus on broadly recognised issues, they should not be approached in a generic way.

Developing a *shared understanding of the project's RRI aspects* as early as possible is really important. This will mean having conversations about their importance, action that is agreed upon, and what learning and adoption can occur throughout the project.

How this RRI content is adopted (e.g. who will be responsible for what work) in the proposal is project dependent. For example, RRI can be organised a cross-cutting part of the project or a separate work package. RRI in the project needs to be *coordinated*.

Please be aware that these guidelines and reflections neither represent the only RRI approach nor a complete list of examples of measures when implementing RRI in nanomedicine proposals. If you are aware of other tools or infrastructures relevant for RRI implementation in research and innovation projects in nanomedicine, please inform cam[at]rcn.no.

The following list provides examples of different RRI perspectives applicable for nanomedicine research projects (including ethical and safety issues). Choose those points relevant for your project.

1. Involve **stakeholders** of relevance to the project (e.g. clinicians, patient interest groups) at the earliest possible stage, to **pursue co-creation, co-design and co-production methodologies**.
 - a. Co-design methodologies are important to generate trust but these stakeholders may also have knowledge about the social, environmental or commercial problem you are trying to address in your project.
 - b. Think also about the appropriate **timing** of different stakeholders' inclusion: certain kinds of knowledge may be more useful than others at different points of your project. (e.g. Doctors, physicians and patient groups early in the process with industry and investors at a later stage.)
 - c. Think about **how** the involvement of these stakeholders and their knowledge can be formalised within your project. This may include a specific point in the middle of your project for reflection to occur, which may require your project to briefly pause, integrate this knowledge and potentially change course.
 - d. It will likely be valuable (but not obligatory) to include **expertise beyond the natural and physical sciences** – such as social scientists, anthropologists or philosophers. They will be able to provide methodologies to address key challenges, such as the risk of hype and expectations of patients wanting treatment.
2. Involve all partners and participants **in ongoing consideration of RRI throughout the project period**. Remember to **disseminate results/outcomes** and publish via **open science channels** if possible. Involve RRI experts in project implementation, if appropriate.
3. Reflect on/consider adapting **your choice of research methods** regarding, for example:
 - ethical issues,
 - *in vivo/in vitro* experiments,
 - use of new approaches such as “Safer by Design”.
 - Are there ways that your project can advance common practices on these issues?

4. Address **environmental impacts and sustainable solutions** by including, for example:
 - lifecycle analysis,
 - ecotoxicology studies,
 - nanocharacterisation at the European Nanomedicine Characterisation Laboratory ([EU-NCL](#)).

5. Show how the project (and product) **satisfy requirements for production safety and efficiency** by, for example:
 - addressing health, safety and environment (HSE) issues;
 - using the competence achieved by the [BIORIMA](#) project that aims to develop an Integrated Risk Management (IRM) framework for (nano)biomaterials (NBM) used in Advanced therapy medicinal products (ATMP) and Medical device (MD);
 - using the [EU NanoSafety Cluster](#)
 - using the resources and knowledge from former pilot lines in your project, when relevant:
 - [NanoPilot](#) – A pilot plant for the production of polymer-based nanopharmaceuticals in compliance with good manufacturing practice (GMP) (finished);
 - [Nanofactoring](#) – A multiple-scale, manufacturing platform to support the extensive pipeline of nanopharmaceutical products being developed in Europe (finished);

6. Ensure that the medicine or device in the body is a **safe product with clear benefits for the patient** by, for example
 - listening to/satisfying user needs and safety concerns,
 - involving [regulatory affairs](#) professionals (toxicity tests, etc.),
 - communicating with regulatory entities (the [Food and Drug Administration](#) (FDA) or the [European Medicines Agency](#) (pharmaceuticals and medical devices), etc.

7. **Consider who will benefit and how these benefits can be delivered**
 - Does your project address a specific problem or need?
 - Does your framing of the problem fit with other people's understanding of it? Can you gain access to these alternative framings?
 - In addition to societal benefits, also consider benefits to the research community through the generation of knowledge, access to infrastructure, the creation of networks and funding.
 - Consider the appropriate form of intellectual property in your project. Is it possible to adopt looser property rights than normal to broaden access? (See, e.g. the Open MTA.)
 - Could commercial or non-commercial organisations benefit from your research? How?
 - Consider also the risks and ways that these can be ameliorated. For instance, what are the risks of potential risks of data being released? How can you take care to ensure these data are interpreted appropriately?

Do these reflections and include measures as early as possible to design the project as relevant (for society) as possible. This can avoid the project to end in a blind road or having to start over again almost from scratch.

All these points can also be relevant to discuss in the light of the [UN Sustainable Development Goals \(SDG\)](#).