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

The ERA-NET for nanomedicine EuroNanoMed III has important objectives in
-Encouraging the community to adopt RRI, HSE and current regulatory requirements
-Training funded researchers on

- Translatability (ENATRANS might be helpful here)
- Responsible Research and Innovation (RRI)
- Regulatory aspects

What is RRI?
In a nutshell RRI is:

- Involving society in science and innovation 'very upstream' in the processes of R&I to align its outcomes with the values of society.
- A wide umbrella connecting different aspects of the relationship between R&I and society: public engagement, open access, gender equality, science education, ethics, and governance.

This RRI Movie by RRI Tools describes it well and here is also a general RRI-toolbox in broad sense.

This webpage is to give a short introduction to RRI as concept and sources for more information. It also presents *a possible way* of reflecting around RRI and introducing these reflections and RRI measures to a project proposal in nanomedicine.
The philosophy is to visualise *RRI as an integrated part of the project* involving all participants and not as an add-on in a separate work package.

The Joint Transnational Call 2019 call text says the following:
"Projects are required to discuss and respond to **Responsible Research and Innovation (RRI) aspects**. Projects are also required to include a plan to **disseminate results/outcomes** and how to achieve higher levels of technological readiness."

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'. The H2020 definition of RRI is:

- public engagement,
- open access,
- gender,
- ethics,
- science education

Please be aware of that these guidelines and reflections (next page) do 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.

Below, different RRI perspectives applicable for nanomedicine research projects (including ethical and safety issues) are described. 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.

2. Involve all partners and participants **in ongoing consideration of RRI throughout the project period**. Remember to **disseminate results/outcomes** and publish via **open access channels** if possible. Involve RRI experts in project implementation, if appropriate.

3. Reflect on/consider adapting **your choice of research methods** with regard to, for example:

- ethical issues,
- *in vivo*/*in vitro* experiments,
- use of new approaches such as "Safe by Design".

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 EU NanoSafety Cluster: http://www.nanosafetycluster.eu/
- using the resources and knowledge at one of the following 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);
  - Nanofacturing – A multiple-scale, manufacturing platform to support the extensive pipeline of nanopharmaceutical products being developed in Europe;
  - Maciviva – Large-scale thermostable nanopharmaceuticals products for therapeutic and prophylactic vaccines and other potential applications for direct application by non-invasive routes.

  These nanomedicine pilots are funded by the EU, and cost price reductions may be sought in connection with the use of these facilities.

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.

Do these reflections and include measures as early as possible to avoid ending in a blind road or having to start over again almost from scratch.