

Between ethics and uncertainty -  
(self-) reflections on RRI in  
Nanomedicine (highlights from the  
EAB RRI summary):

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# Introductory question:

In your opinion, what is the most important resource in research in general, and in nanomedicine in particular ?

# Tentative answers:

- Brain power?
- Curiosity/Innovative ideas?
- Funding?
- Technically robust research facilities?
- Interdisciplinarity?
- Patients?

An additional answer:

TRUST!

# Summary of RRI-considerations from the External Advisory Board:

- Public engagement,
- Involvement of partners and participants throughout the project period,
- Reflection on the choice of research methods and goals,
- The need to address environmental impacts,
- Focus on production safety and efficiency,
- Ensure that the medicine or device is safe,
- Benefit sharing,
- Equitable access to nanomedicine.

# 1) Public engagement: Involvement of relevant stakeholders, 1:

- clinicians,
- patient interest groups,
- others (e.g. investors or advisors in business and strategy development)

# 1) Public engagement: Involvement of relevant stakeholders, 2:

## Core questions to address:

- How to involve stakeholders?
- How to identify which stakeholders to involve in a project?
  - How to involve them as early as possible?
- Opportunities and challenges of such and involvement?
  - How to ensure gender equity and observe gender dimensions when making these decisions?
- How else might you involve stakeholders in other aspects of your projects?

# 1) Public engagement: Involvement of relevant stakeholders, 3:

- Involving different stakeholders at the earliest possible stage implies coping not only with scientific illiteracy, but also with the challenge of *uncertainty*. Risk is a form of uncertainty where it is possible to identify in advance possible outcomes and statistically estimate the size of each possible outcome. Such assessments requires expert knowledge, including statistical knowledge. The two other uncertainty dimensions, stakeholders need to cope with, i.e. *qualitative uncertainty* and *ignorance*, are forms of uncertainty that are beyond the reach of expert knowledge to handle.
- Faced with such uncertainties experts and lay people are on equal footing; i.e. the only teacher with regard to such challenges is life's experience in the broadest sense of the word. These facts strongly favors the involvement of different stakeholders at the earliest possible stage of nanomedicine research and development.

## 2) Involvement of partners and participants throughout the project period, 1:

### Core questions to address:

- What project structures might be modified to allow for ongoing RRI consideration?
- What issues might be important to anticipate and reflect on throughout the project:
  - Processes
  - Content
  - Expected outcomes
  - Potential implications

## 2) Involvement of partners and participants throughout the project period, 2:

The RRI approach includes four interconnected and non-sequential key points:

- The processes of mutual exchange in setting and re-driving research and innovation direction (“Diverse & Inclusive”);
- Socially desirable science and innovation (“Anticipatory”);
- Participatory and accessible methodologies experimented in the research agenda and the dissemination of its outcomes (“Open and Transparent”); and
- Flexible, reflexive and socially responsible (“Responsive and Adaptive to Change”) governance of the process.

### 3) Reflection on the choice of research methods and goals, 1:

#### **Core questions to address:**

- How do you create work environments that allow for reflection about project methods and goals?
  - What pressures make this difficult? What supports could make this easier?
- With whom and how might you re-consider or adapt your methodological choices?
- With whom and how might you re-consider or adapt your goals?
  - How might success or failure be determined in relation to these goals?

### 3) Reflection on the choice of research methods and goals, 2:

- Abide by H2020 funding rules;
- Nanomedicines are attractive educational subjects although hype should be avoided.
- Be very careful with extrapolations based on stakeholders feedbacks;
- A critical evaluation of several options can lead to a re-driving of the project that will need to be re-evaluated (by RRI tools) in a second stage.

## 4) Address environmental impacts and sustainable solutions, 1:

### Core questions to address:

- What methods are available or needed to consider in advance; throughout; and after projects?
- How might broader impacts be considered, not just on the environment but also related to human health and lifestyles?
- How will you consider the distribution of impacts associated with resourcing, producing, and disposal of products associated with your work (if this is relevant)?
  - Reflect on the burden of undesirable impacts *and on* the benefits of desirable impacts.

## 4) Address environmental impacts and sustainable solutions, 2:

- Show how the project (and product) satisfy requirements for production safety and efficiency by;
- The security and efficacy of the process should be considered already in the early stages of the project;
- Involve an industrial external consultant in the assessment of the technology.
- Get the consumer perspective on the real need for the product.

## 5) Requirements for production safety and efficiency:

### **Core questions to address:**

- Do you think there could be any trade-offs between safety and efficiency?
- How do you address potential safety and efficiency concerns?
- How might these decisions be made transparently and responsibly?

## 6) Ensure that the medicine or device is a safe product with clear benefits, 1:

### Core questions to address:

- What gaps in current practice are you trying to address?
  - How were these gaps understood and included in the project?
  - What advantages over current practice are you seeking to develop?
- How do you ensure research benefits are shared with as many aspects of society as possible and, if relevant, with the international community?
- How might advances in nanomedicine benefit developing / low-income countries in particular? What could be a fair and equitable way for sharing benefits with these partner countries?

## 6) Ensure that the medicine or device is a safe product with clear benefits, 2:

- Define clearly the medical need (with a robust health economy analysis);
- analyse the comparative advantage of your solutions compared to the gold standard, and
- define your product's Unique Selling Proposition.
- Create a circular discussion between physicians, industrial developers and regulators.

## 7) Benefit sharing - the international dimension, 1:

Article 15 of the Universal Declaration on bioethics and human rights (*Sharing of benefits*) states: “Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries”.

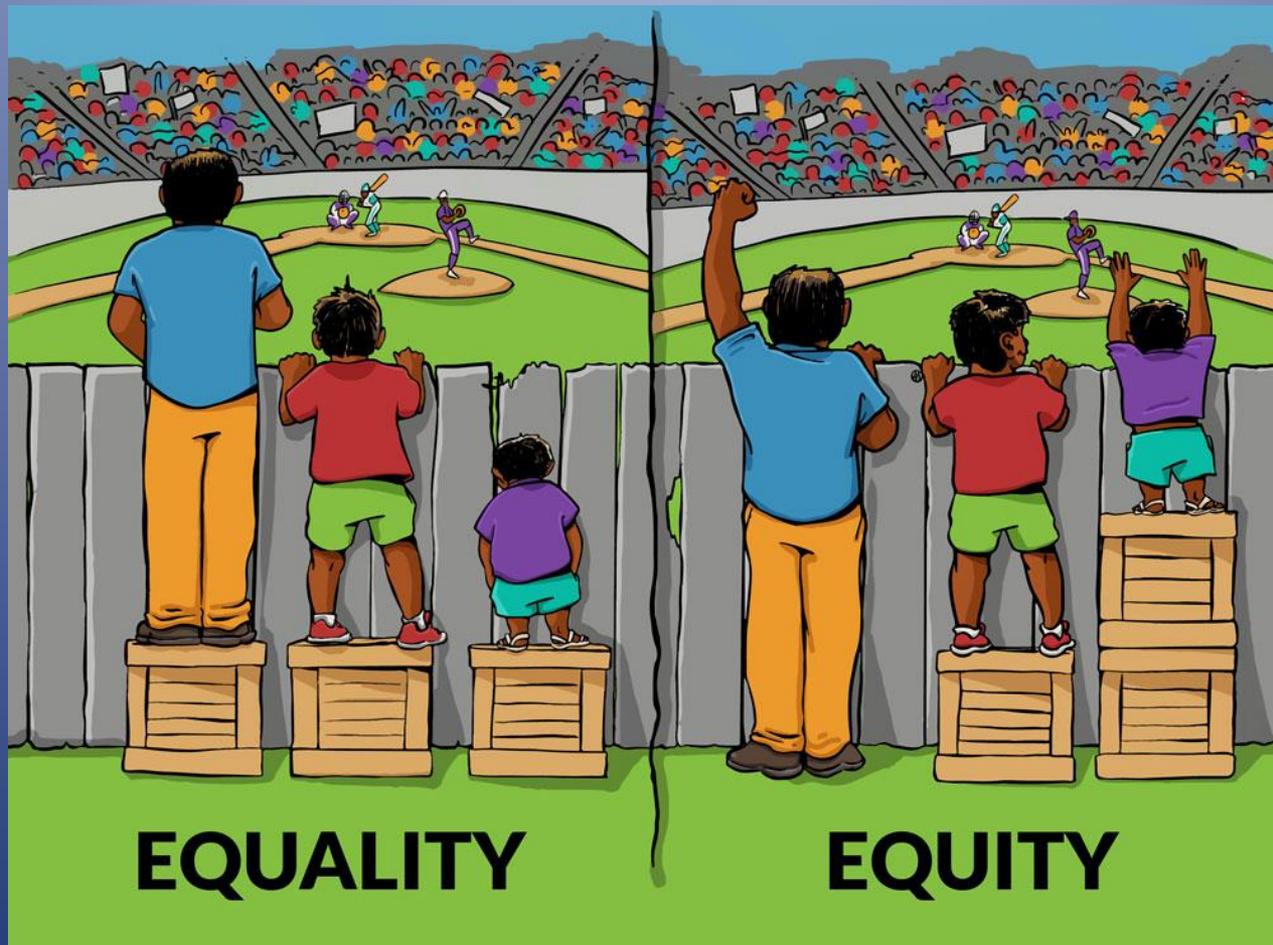
## 7) Benefit sharing - the international dimension, 2:

- For a sustainable ethics of benefit sharing to become true it is not sufficient to develop a global medical science policy and research strategy that takes into account the particular research for health needs of poor and low-income countries.
- What is needed in addition is the development of national research policies in the richer part of the world that include sustainable plans for *how* the benefits resulting from these research programs can be shared in an equitable way with poor and low-income countries.

## 7) Benefit sharing - the international dimension, 3:

This would imply creating “ways of involving low-income countries in the development of a fair and sustainable global policy on benefit sharing in nanomedicine.

# 8) Equitable access to nanomedicine, 1:



## 8) Equitable access to nanomedicine, 2:

- This requires first a focus on barriers hampering such access: financial barriers, scientific illiteracy, geographical barriers, language and cultural barriers, discrimination, racism, gender bias, social exclusion and unrest.
- Second, it would require a focus on Social determinants of health: income and social status, education, physical environment, employment and working conditions, social support networks, culture, genetics, personal behavior and coping skills, health services – access and use, and gender.

## 8) Equitable access to nanomedicine, 3:

If justice requires providing equitable access to the benefits of nanomedicine, then these barriers and determinants must be addressed as a matter of justice. This raises two questions:

- How could nanomedicine benefit poor and low-income countries?
- What could be a fair and equitable model to distribute the benefits among them?
- In addition it would be necessary to address the following questions:
  - What does benefit here mean?
  - Who has to define it?
  - Who has to define the reach of it?
  - Who decides what is good for whom?

## 8) Equitable access to nanomedicine, 4:

Some of the most important factors that affect the health of communities in low-income countries are: maternal mortality, child mortality, infectious diseases, malnutrition and chronic illnesses. Taking those factors into account the first question should NOT be:

How can nanomedicine be made able to help in a sustainable way the development and health of populations in low-income countries?

## 8) Equitable access to nanomedicine, 5:

Rather (in order of priority) the questions should be:

- What are the most frequent causes of death and disease in this country or region?
- What are the prevalent illnesses?
- How are they related to social determinants of health?
- What are the basic health needs of this community, and what are the cheapest and most sustainable ways of satisfying them, and to fight against the disease?
- *Finally, if nanomedicine is into the list of answers, the next question should be: will people have access to this technology in an equitable way?*

## 9) Any missing RRI point/perspective?

### Core questions to address:

- How do you integrate broader considerations about changes to overall quality of life that might be affected by the (medical) project being pursued?
- Have you thought about whether your work will make cultural, ethnic, gender, or physical-ability, socio-economic or related inequalities worse or better?
- How might you deal with controversial topics if they come up during the project?