



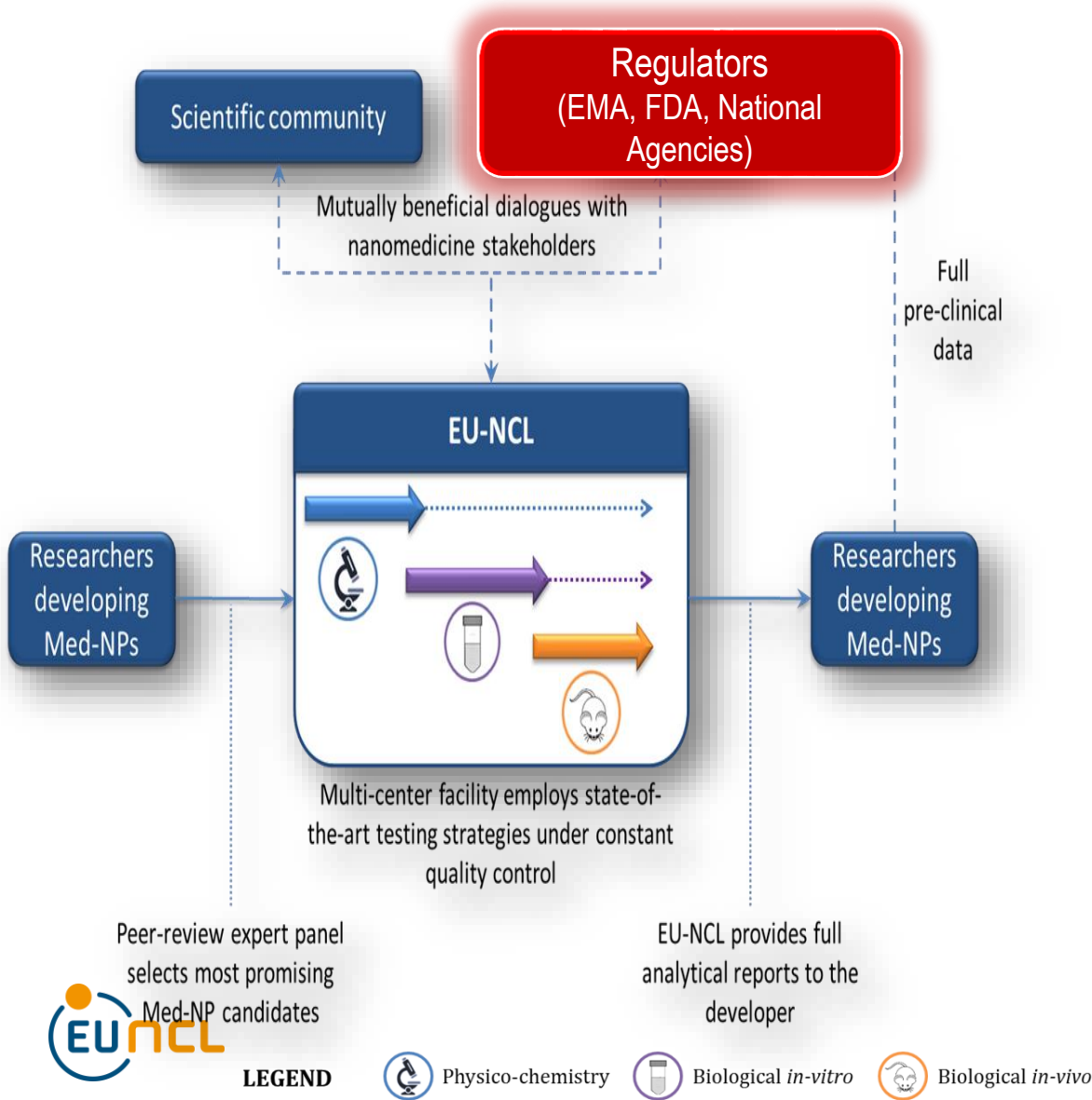
Anticipation of regulatory needs for nanomedicines

1st EU-NCL survey with regulators

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Interaction with the European Nanomedicine Characterisation Laboratory



- to ensure the relevance of EU-NCL methods for decision making in particular for regulatory needs
- a series of questionnaires addressed to regulatory working groups experienced

Survey with regulatory agencies

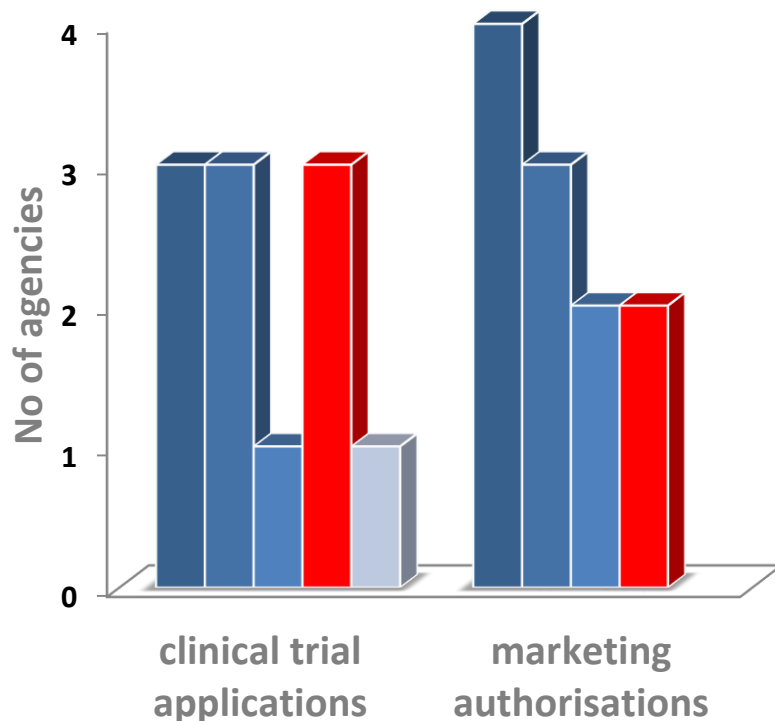
The objectives of the survey

- to get an overview on the experiences of regulators with nanomedicines in the various regions
- To anticipate information needs
- To identify future priorities to support the translation of nanomedicines towards clinical applications

No	Governmental organisation
1	Health Canada (market health products), Canada
2	European Medicines Agency
3	Swiss Agency for Therapeutic Products (Switzerland)
4	Health Canada (health products and food branch), Canada
5	United States Food and Drug Administration, USA
6	Pharmaceuticals and Medical Devices Agency, Office of New Drug II; Japan
7	Brazilian Health Surveillance Agency, Brazil
8	Ministry of Food and Drug Administration, Korea
9	Center for Drug Evaluation, Taiwan
10	National Institute for Public Health and the Environment, Netherlands
11	Federal Institute for Drugs and Medical devices, Germany
12	The Medicines and Healthcare products Regulatory Agency, United Kingdom
13	National Health laboratory, Luxembourg
14	Spanish Medicines Agency, Spain
15	Ministry of Health, labour and welfare, Japan
16	Australian Government, department of Health therapeutic goods administration, Australia
17	National Agency for food and drug administration and control, Lagos
18	Health Science Authority, Singapore

Overview on the number of nanomedicines requesting regulatory approval

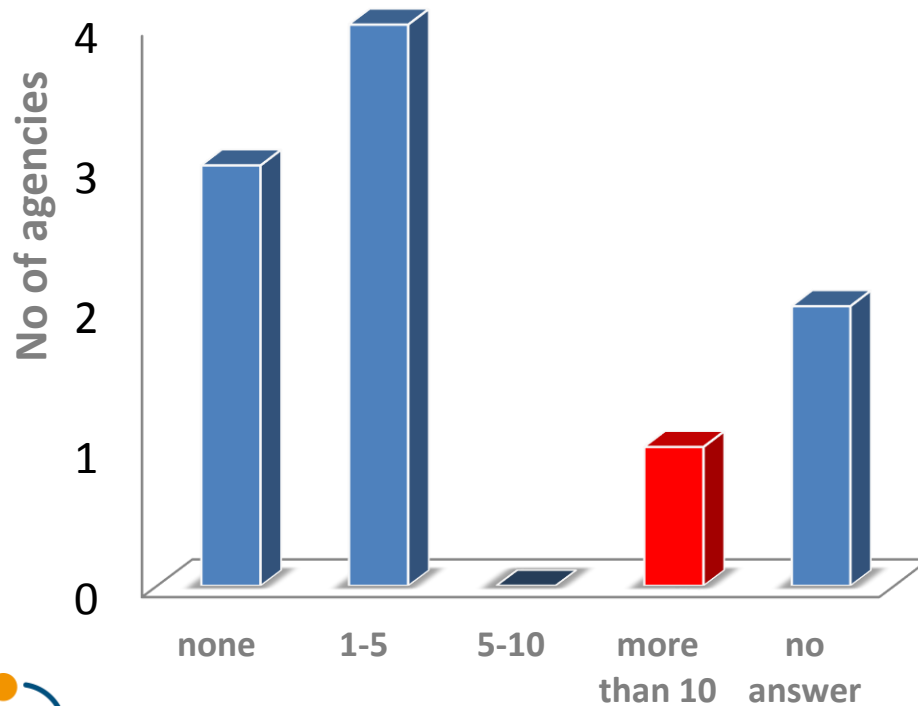
Applications for regulatory approval



- Regional differences of nanomedicine applications for the approval of clinical trials and market authorisation
- Knowledge sharing of regulatory bodies with more experiences required in order to prepare regions with less nanomedicine applications

Challenge: Regulation of „Nanosimilars“

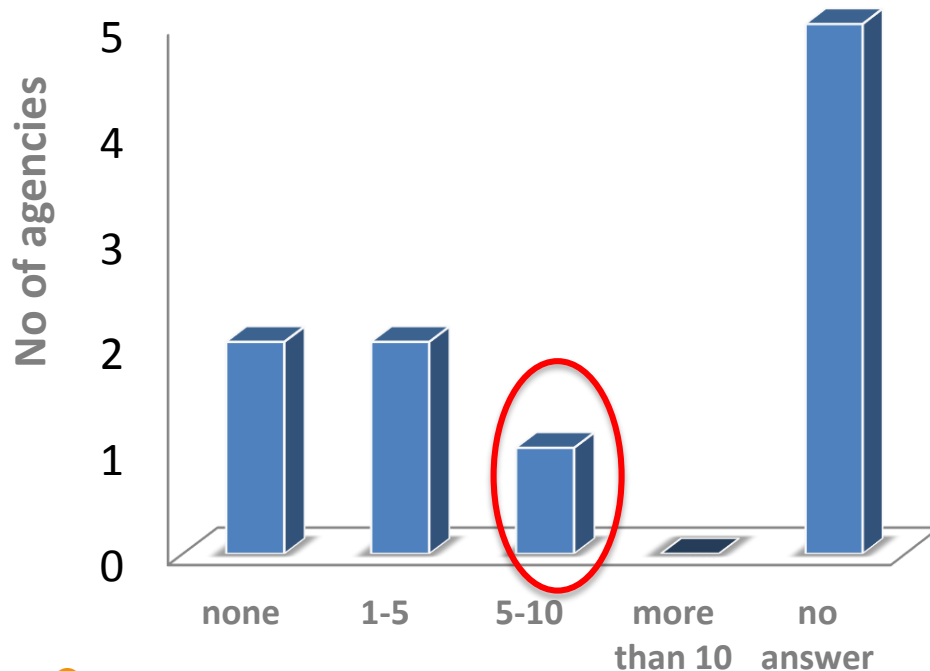
Did you receive applications for follow-on nanomedicines that claim to be similar to an innovator product in the last 36 months?



Regional differences demonstrating that follow-on products might be an upcoming challenge also for the European regulatory bodies

Challenge: Identification of the Regulatory Path

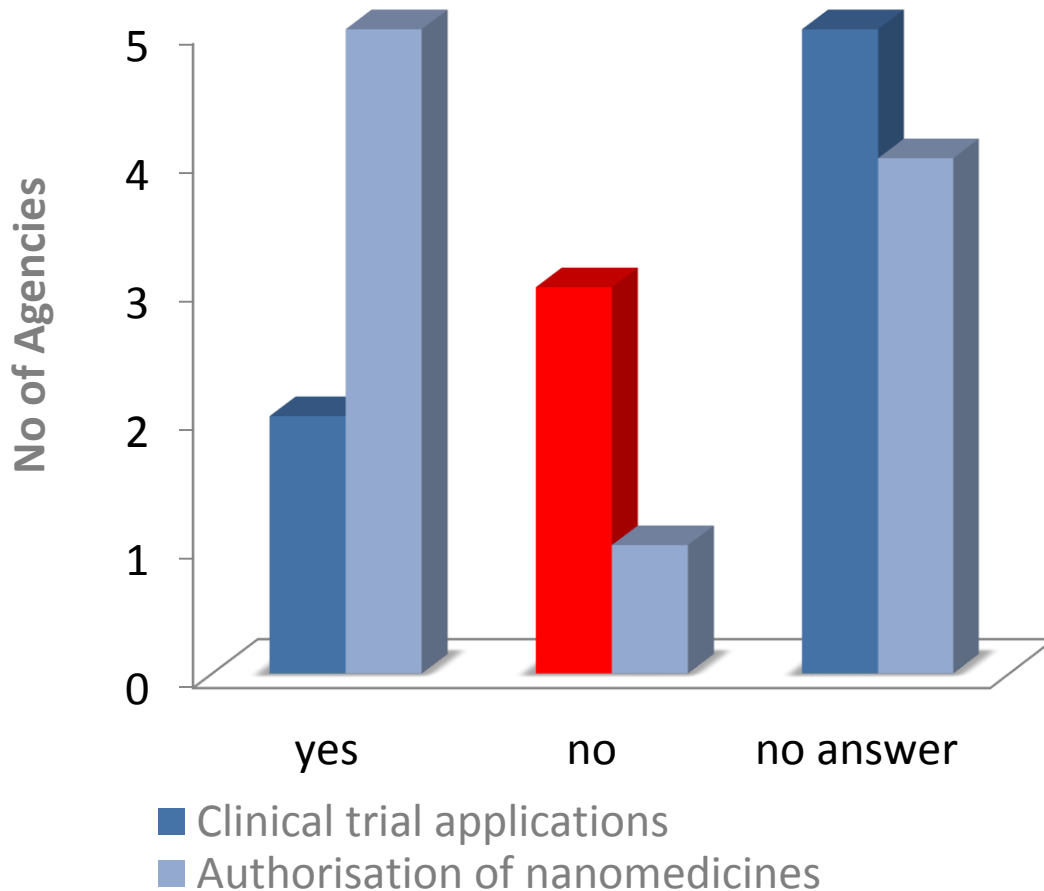
Did you regulate or were involved in discussions related to products containing nanomaterial that raises challenges regarding the regulatory pathway e.g. combination or borderline products?



- Borderline and combination products will require special regulatory awareness in the future
- Flagged as a priority in EMAs strategy document 2020¹

Validation status of characterisation methods

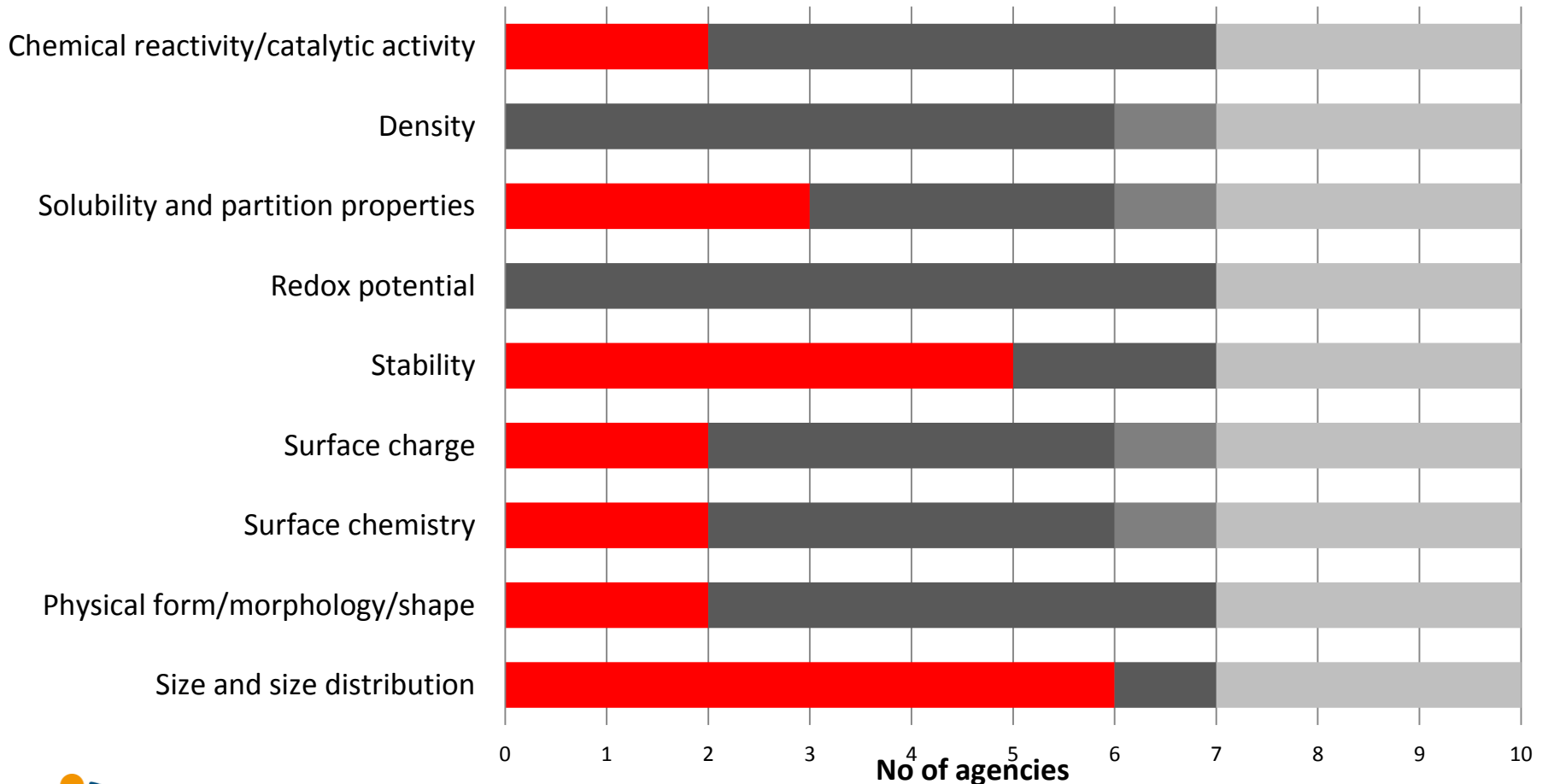
Were the characterisation methods used for quality assessments well described and sufficiently validated?



- only very few standards specifically addressing the application of nanotechnology in the health sector are available

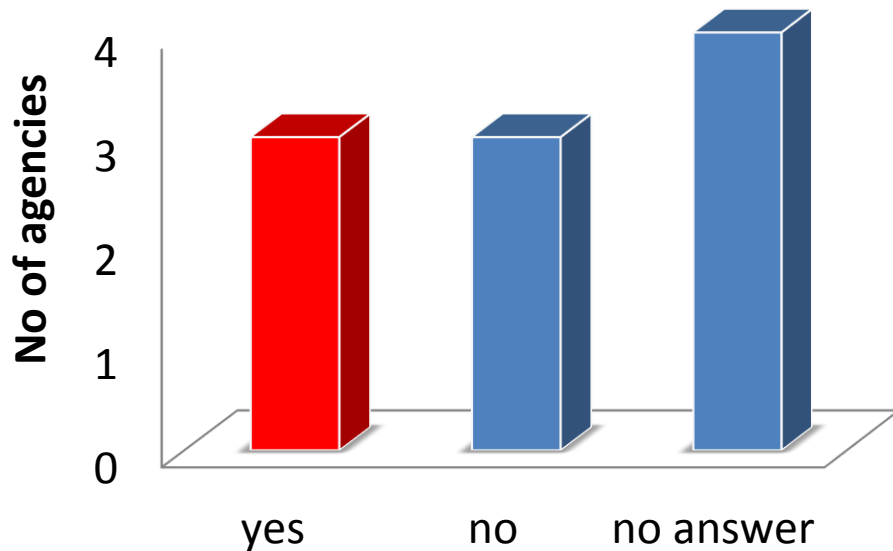
Regulatory needs

Which physicochemical properties do you consider relevant for the preclinical characterization of nanomedicines that are not applicable to other pharmaceutical product classes?



Additional needs for toxicity testing

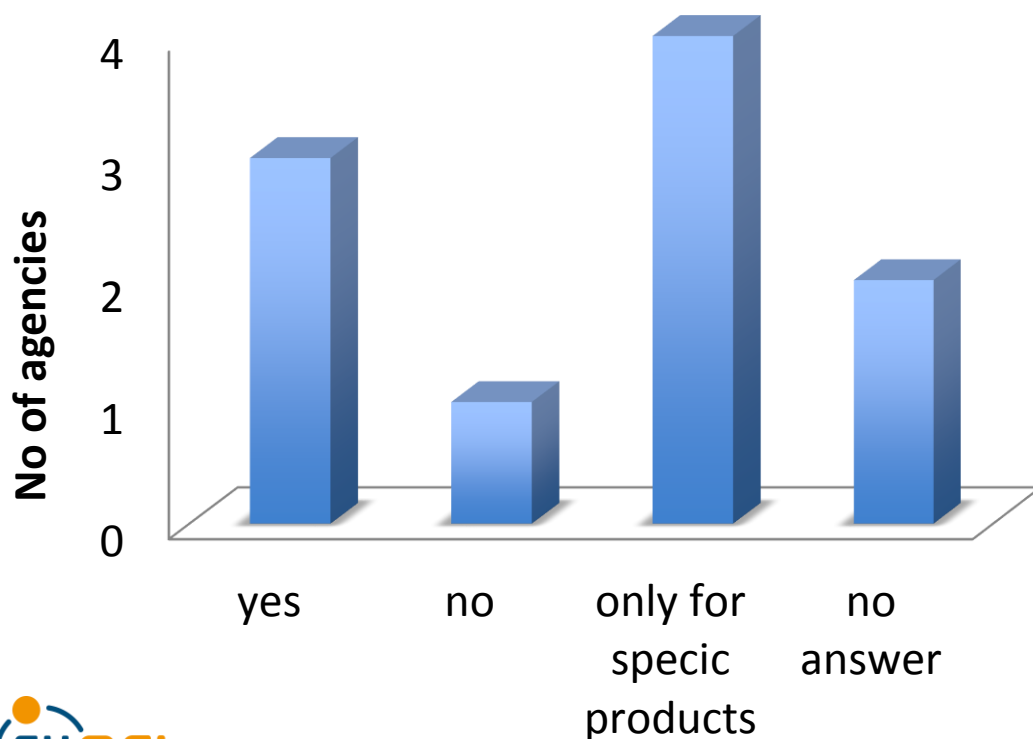
Did a specific property of the nanomedicine trigger any additional testing in vivo/in vitro in applications that you have reviewed?



- specific properties of nanomedicines can trigger additional in vitro and in vivo testing
- understanding if what kind of information is needed in order
- to make tailor made in vitro tests available before introducing additional laborious and expensive animal experiments

Additional needs for toxicity testing

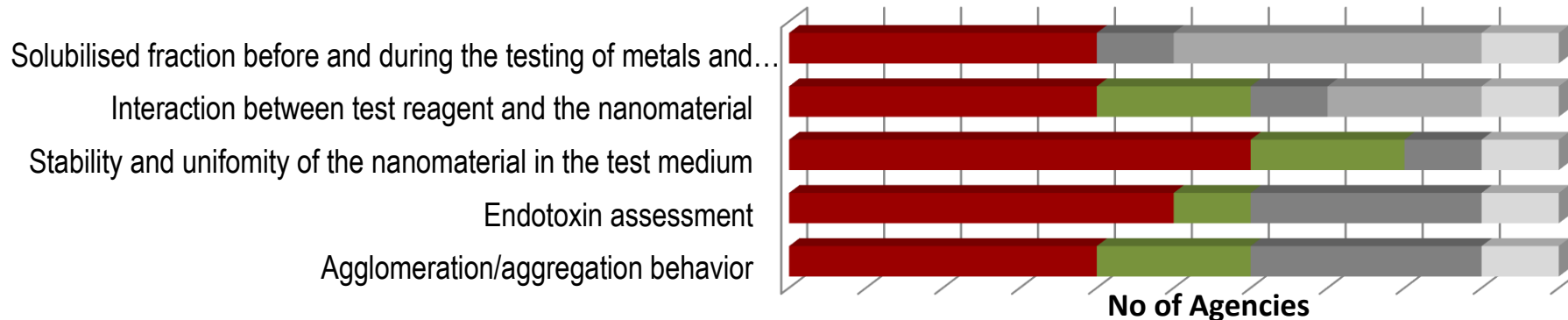
Is there a need to develop additional testing methods to assess the environmental effects of medicinal nanoparticles (ecotoxicology)?



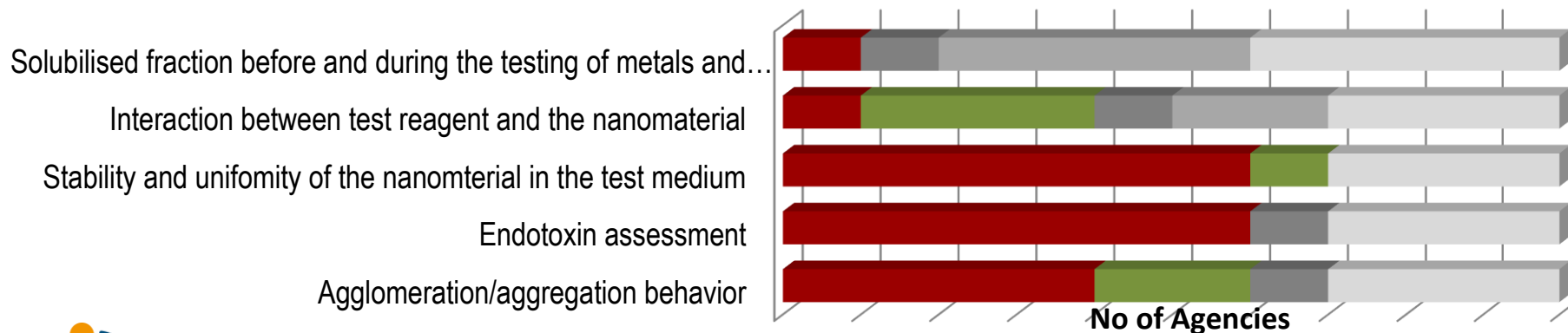
- some product classes might need to demonstrate the safety for the environment
- better understanding what kind of environmental tests have to be developed

Pitfalls for toxicity testing

How do you value potential pitfalls for toxicity testing (in vitro/in vivo) in market authorisations?

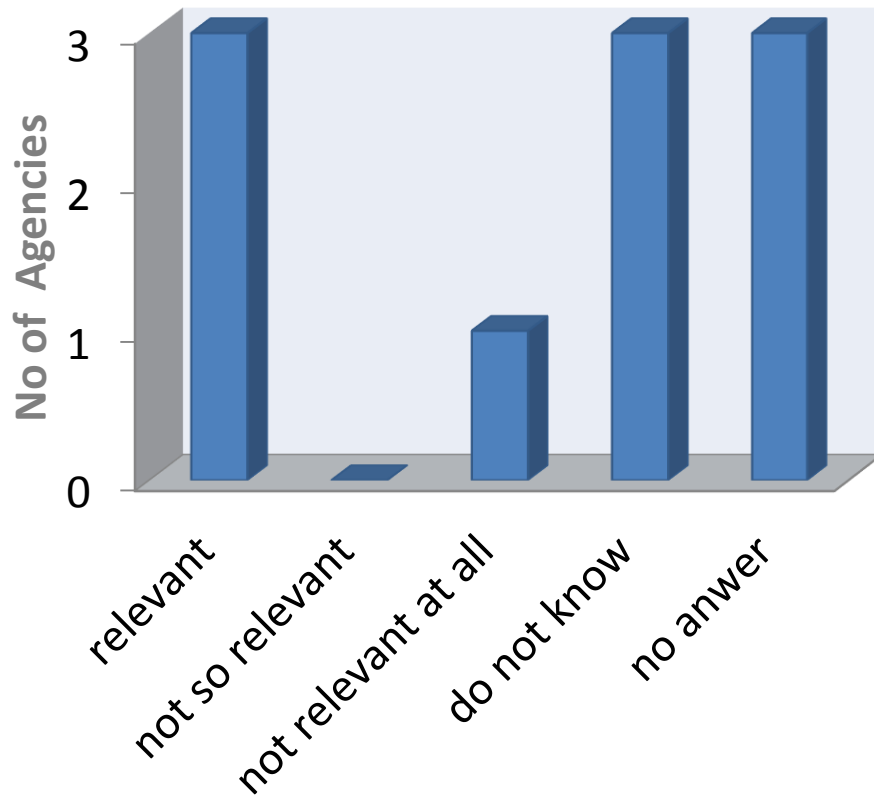


How do you value potential pitfalls for toxicity testing (in vitro/in vivo) in clinical trial applications?

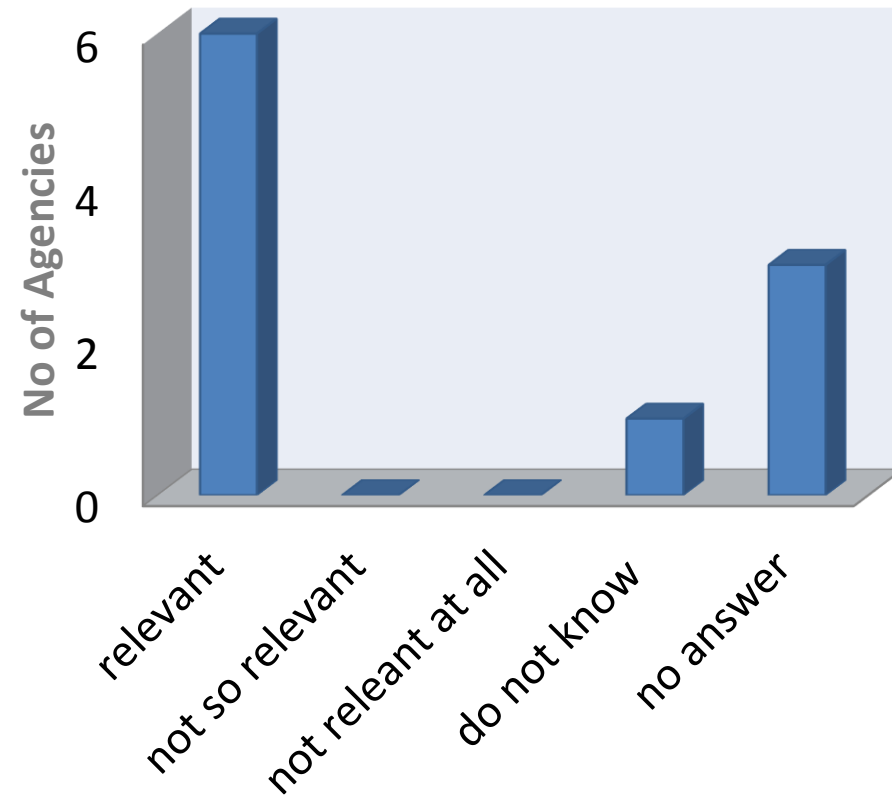


Harmonisation needs

Do we need to harmonise the characterisation of nanomaterials used in medical devices (free nanomaterial administered to the patient) and medicinal products?

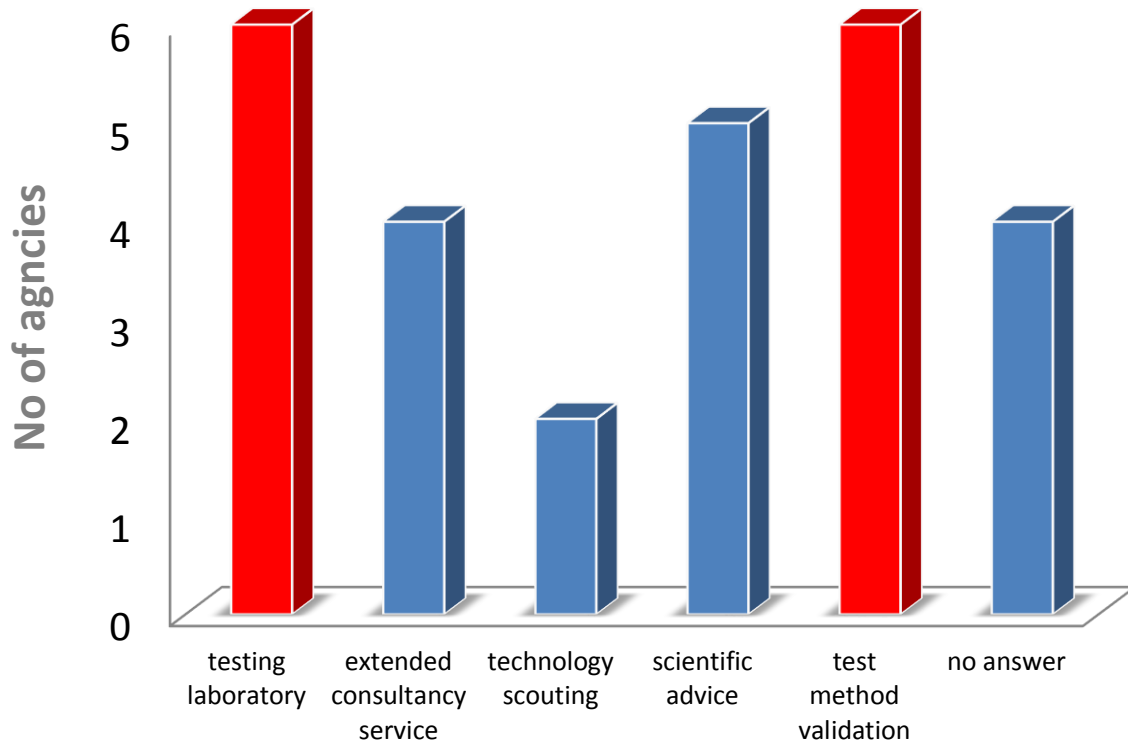


Is it relevant to harmonise testing requirements of medicinal products and medical devices for nanomedicines in the various regions?



Functions of the EU-NCL

What functions could an EU-NCL fulfill to support regulatory authorities?



The strategic partnership of the EU-NCL and the NCI-NCL can support regulatory by

- Providing expertise on information needs
- the development and validation of new test methods
- Supporting the harmonisation of methods

Conclusion

- Survey confirmed the regional differences
- Upcoming challenges might be „nanosimilars“ as well as borderline and combination products
- Additional toxicity tests might be required
- Currently only few standards for nanomedicine testing are available but consensus finding on future standardisation needs is ongoing
- Harmonisation of information requirements
- Alliance of EU-NCL and NCI-NCL can support the evaluation of



Next steps



- Publication of 1st EU-NCL survey in the format of a JRC technical report
- 2nd questionnaire with the EU Innovation Network
- Focus on requested information of European Agencies related to quality and safety of products in clinical trials

Stay in touch!



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Call for Proposals

The EUNCL provides critical **infrastructure** and characterisation services to qualify the selected nanoparticles' physical and chemical attributes, their in vitro biological properties, and their in vivo compatibility using animal models. The EU-NCL objective is to support and facilitate the regulatory review of your nanotechnologies that are intended for innovative therapies and diagnostics.

The EUNCL offers a comprehensive **assay cascade** aimed at evaluating the **quality and safety** of your nanomaterial. Moreover, the EUNCL will supply sponsors with a complete and detailed characterisation data set that enables researchers in academia, industry, and government to facilitate further development and translation of their nanotechnology strategies towards clinical applications.

The EUNCL characterisation platform aims to assess all categories of nanomedicines developed in EU.

EU-NCL call for access will accept continuous application with bi-annual review campaign in April and October each year.

This second review period of the 1st year call will accept organic as well as inorganic Med-NPs with putative application in cancer and infectious diseases treatment and/or diagnosis via injection and oral formulation.

If a project is selected, the EUNCL's services will be provided at no cost to the submitting sponsor.

[Guide for Applicants \(PDF, 0.2 MB\)](#)

[Non Disclosure Agreement \(PDF, 0.2 MB\)](#)



Events where you meet EU-NCL

The Fifth International Conference NANOSAFE 2016

7 to 10 November, Grenoble, France

nanoBio & Med 2016

22 - 24 November 2016, Barcelona, Spain

MedTech Forum

30 November to 02 December 2016, Brussels, Belgium

More Events ...

European Nanomedicine Characterisation Laboratory (EU-NCL)

Call for Proposals!

News

EU-NCL at CLINAM

In the previous eight years, the CLINAM Summit grew



<http://euncl.eu>

Thank you for your attention

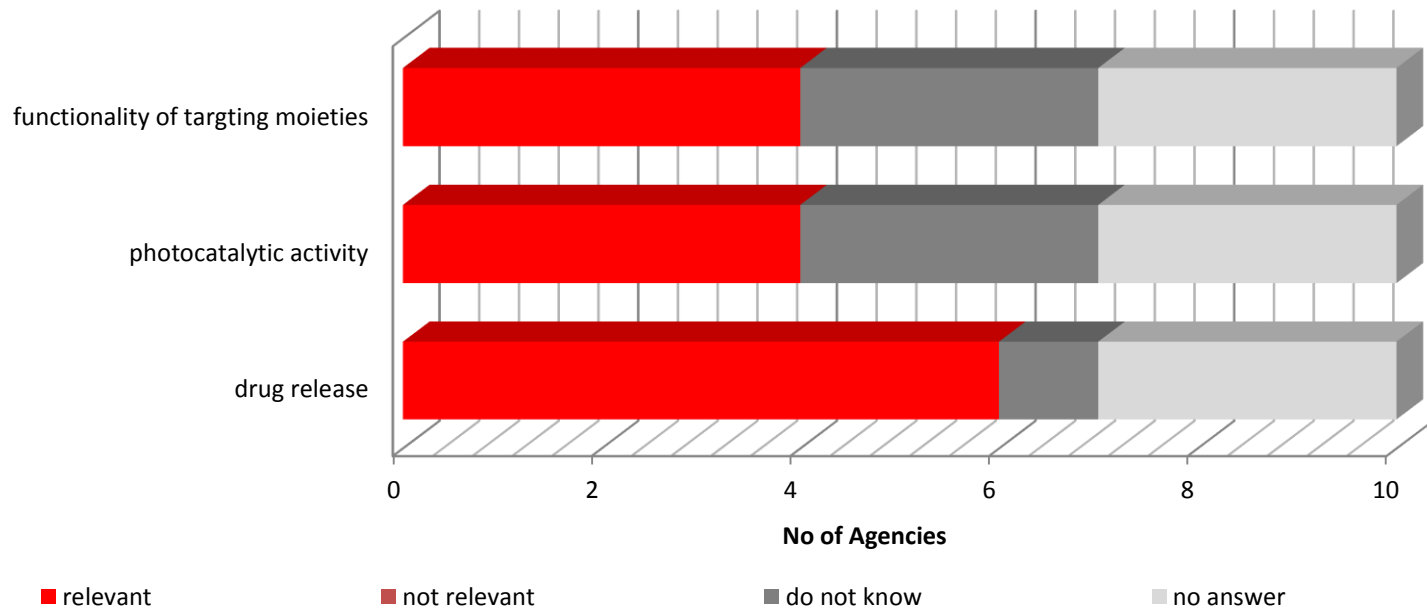
1st survey with the Nanomedicine Working Group of the international pharmaceutical regulators forum



- **Objectives:**
- Non-confidential information and work sharing, regulatory harmonization or convergence focused on nanomedicines / nanomaterial in drug products, borderline and combination products.
- Promotion of potential consensus finding on standards

- **JRC contribution**
- Compilation, mapping and discussion on terminology and definitions with focus on the classification of nanomedicines / nanotechnology in drug products
- Exchange and mapping of general Critical Quality Attributes for nanomedicines / nanotechnology in drug products
- **Survey with regulatory agencies**

**Which physicochemical properties
do you consider relevant for the preclinical characterization of nanomedicines?**



What will be the reference for comparison of nanoparticle-delivered drugs from a....

