Anticipation of regulatory needs for nanomedicines

1st EU-NCL survey with regulators

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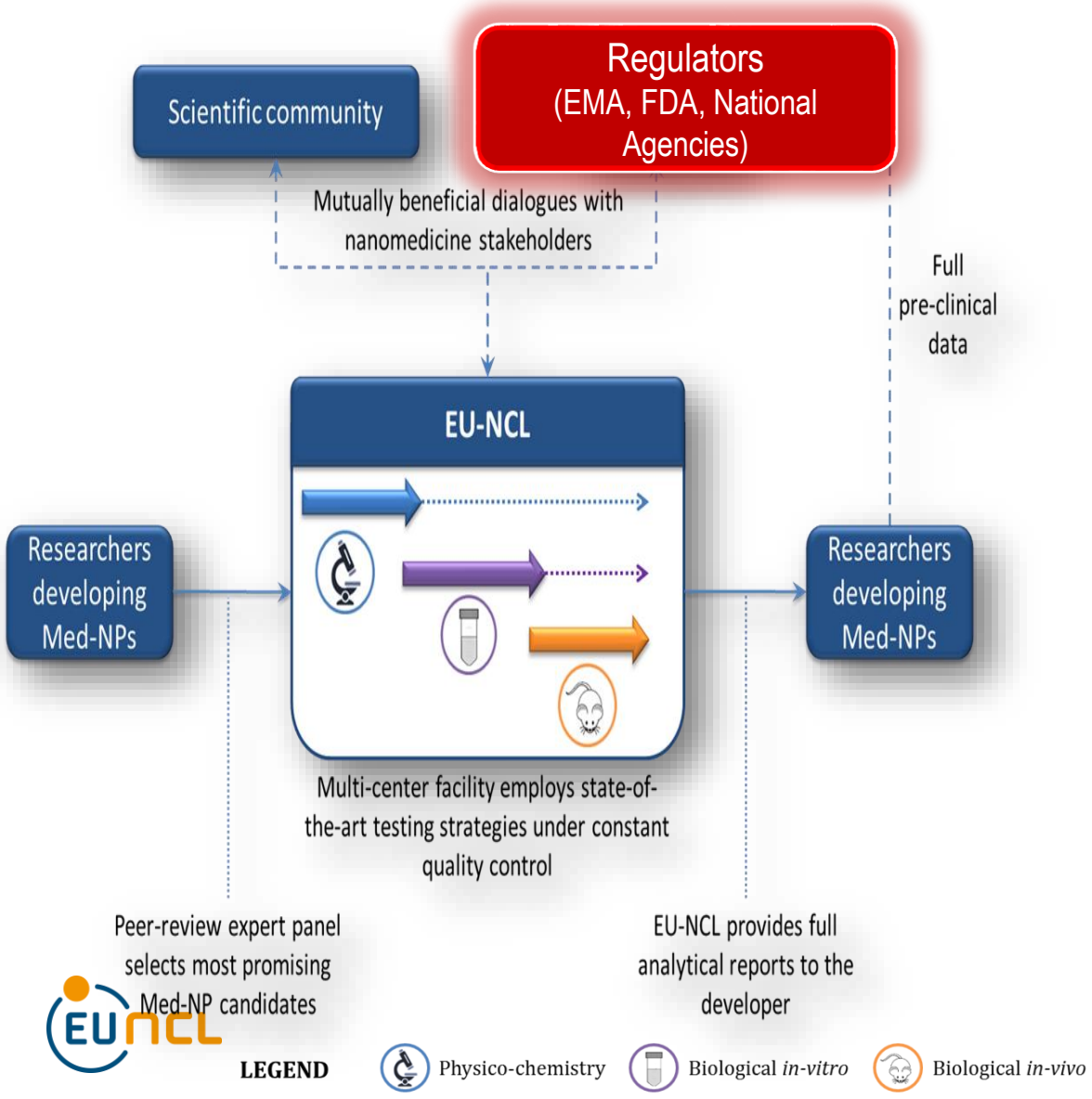
Interaction with the European Nanomedicine Characterisation Laboratory



- 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

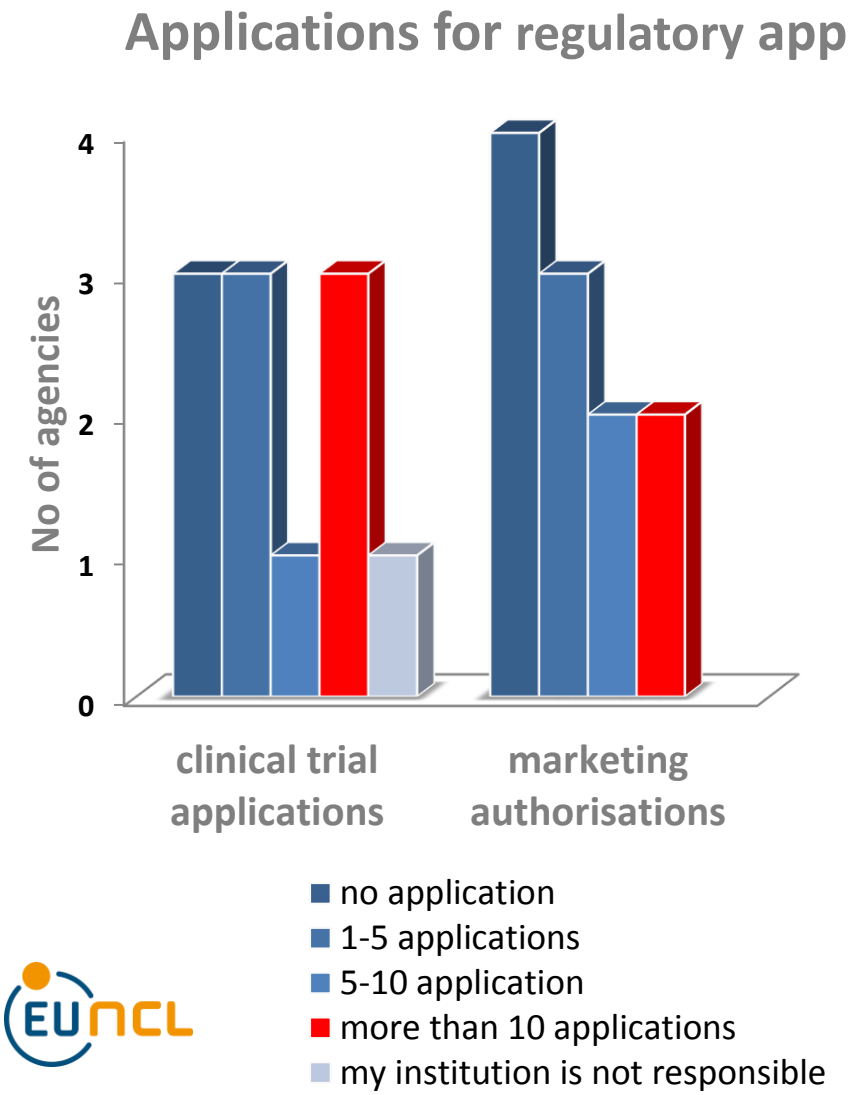
Survey with regulatory agencies

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

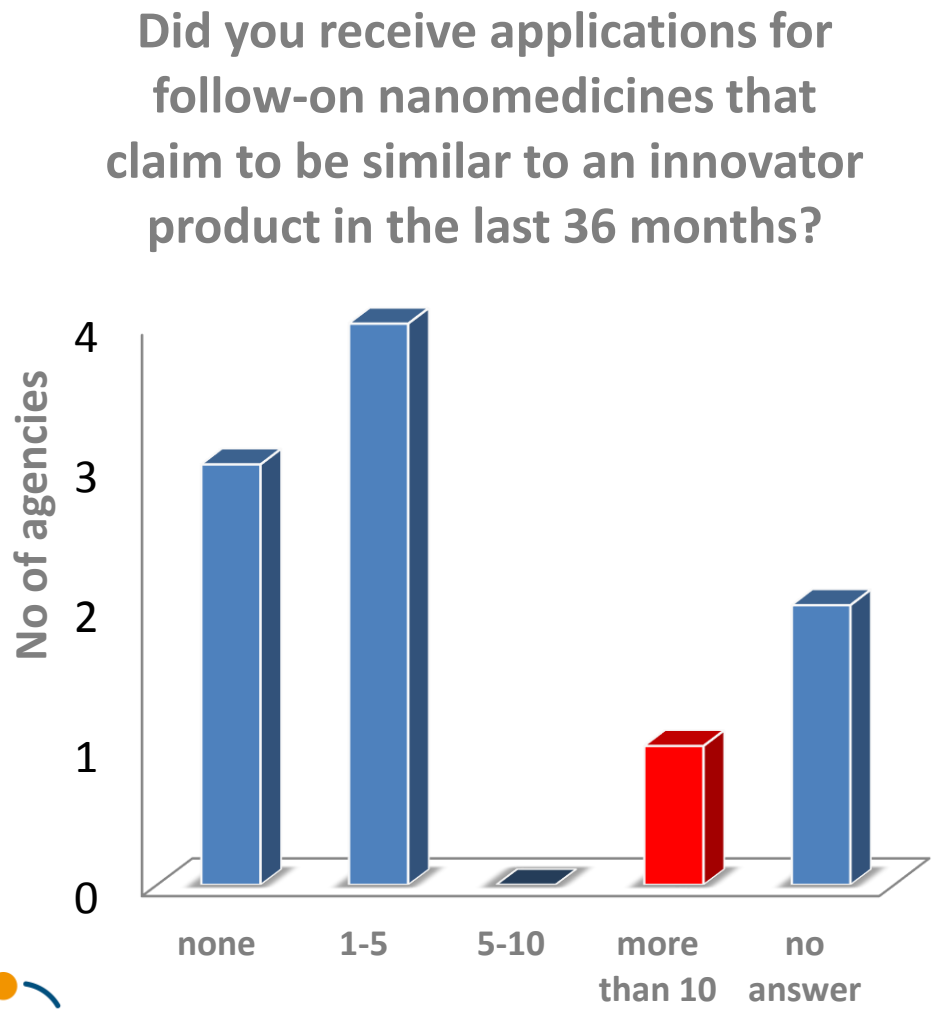
No	Governmental organisation
1	Health Canada (market health products), Canada
2	European Medicines Agency
3	Swiss Agency for Therapeutic Products (Switzerland)
4	Health Canada (health products and food branch), Canada
5	United States Food and Drug Administration, USA
6	Pharmaceuticals and Medical Devices 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



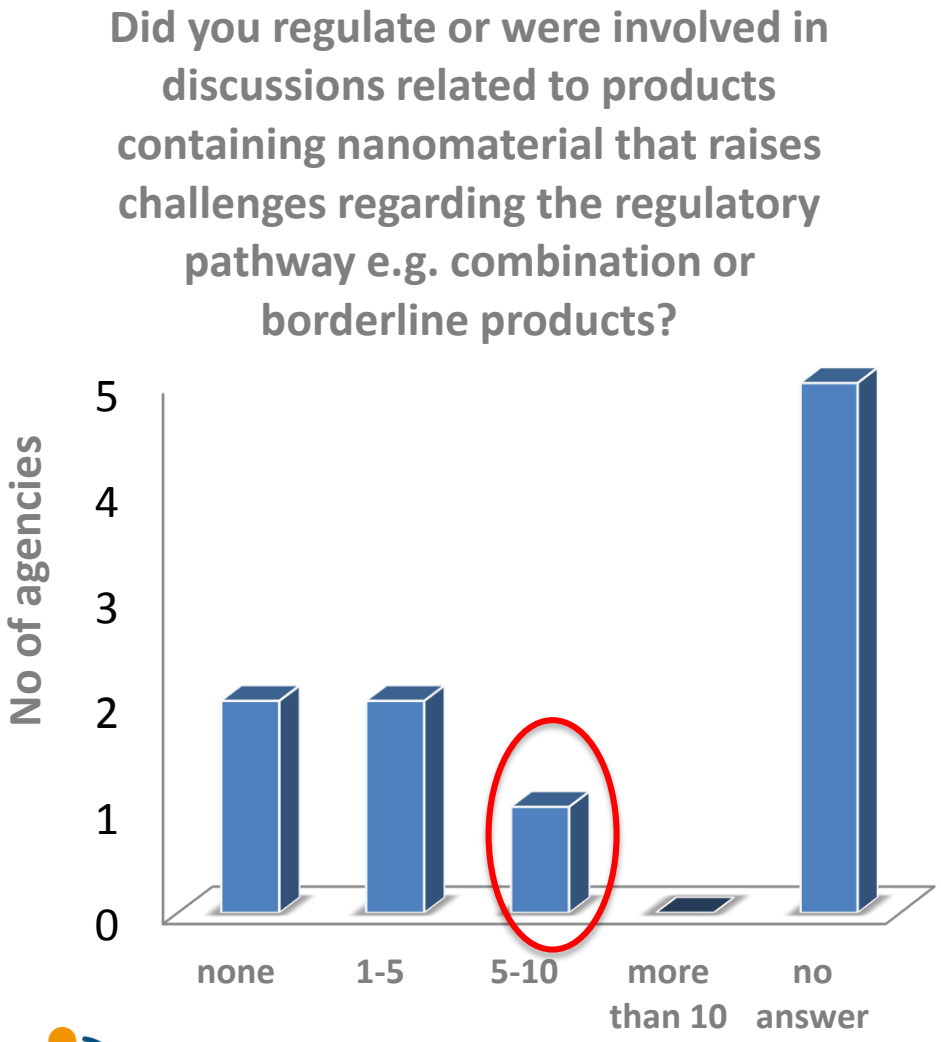
- Regional differences of nanomedicine applications for the approval of clinical trials and market authorisation
- Knowledge sharing of regulatory bodies with more experiences required in order to prepare regions with less nanomedicine applications

Challenge: Regulation of „Nanosimilars“



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

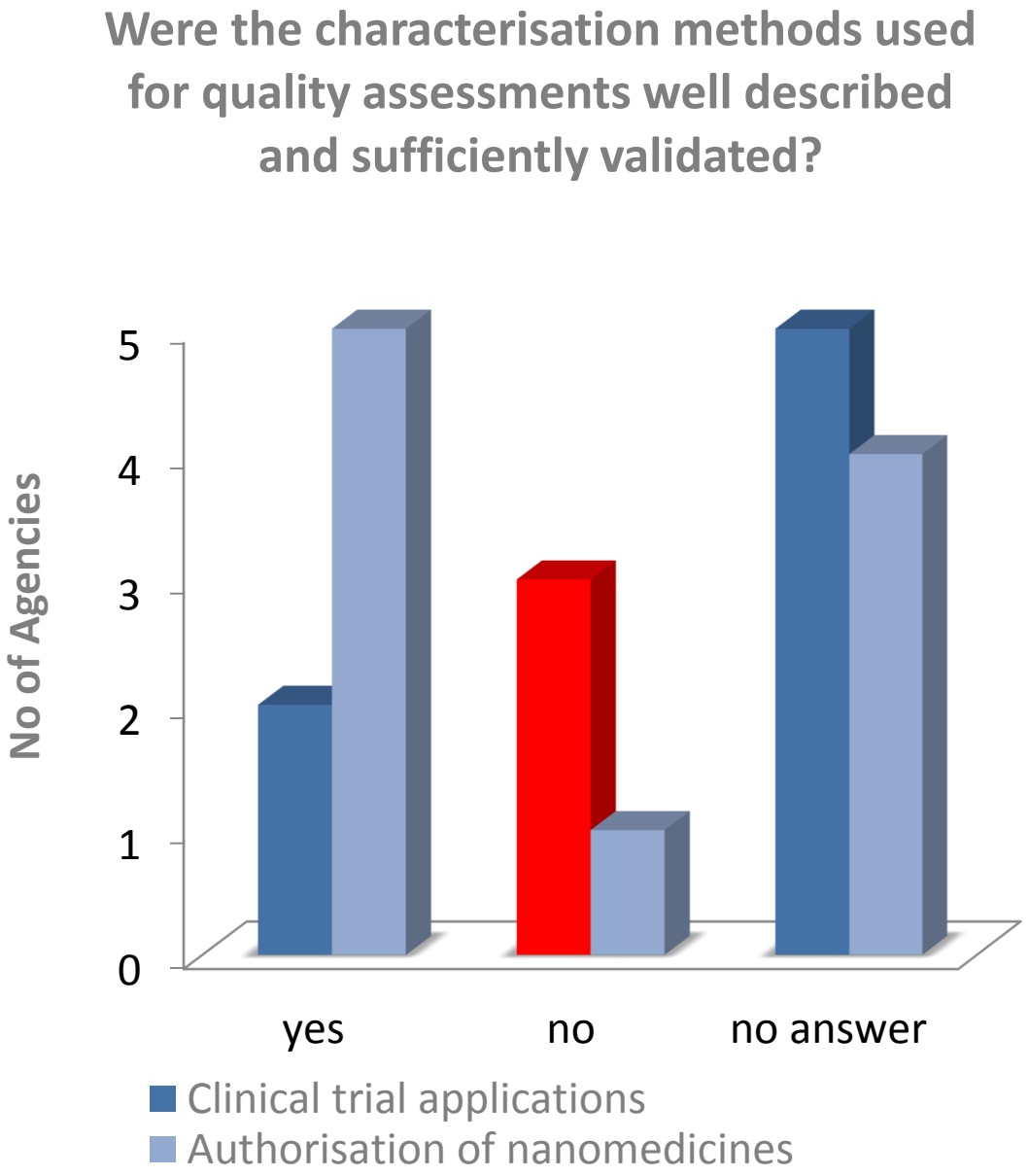
Challenge: Identification of the Regulatory Path



- Borderline and combination products will require special regulatory awareness in the future
- Flagged as a priority in EMAs strategy document 2020[1]

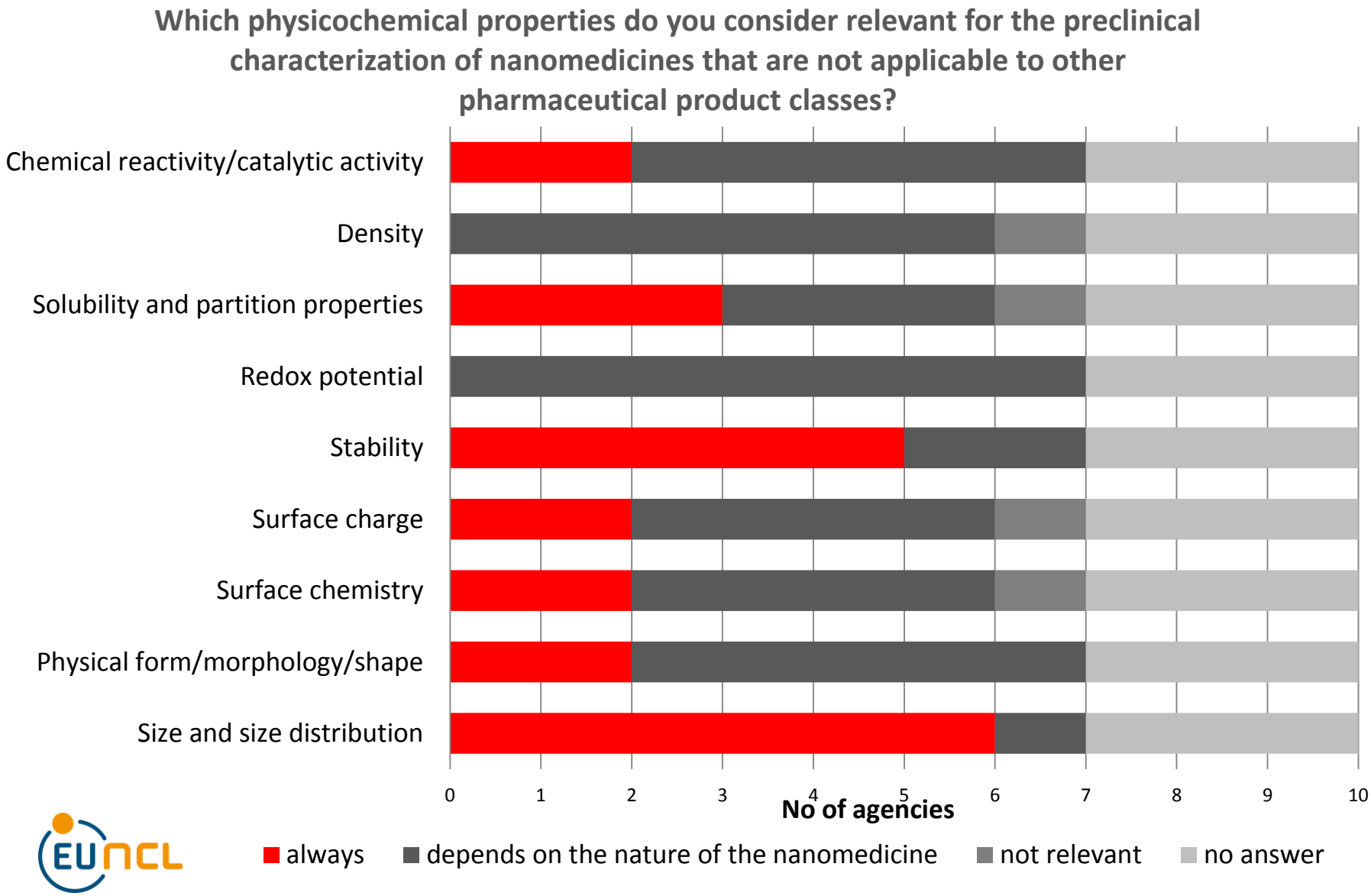
[1] http://www.ema.europa.eu/docs/en_GB/document_library/Oth

Validation status of characterisation methods



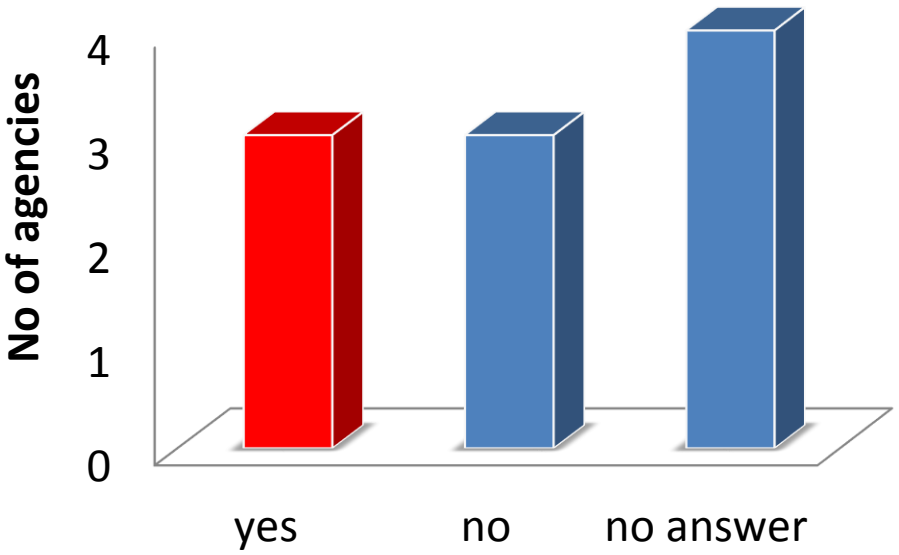
- only very few standards specifically addressing the application of nanotechnology in the health sector are available

Regulatory needs



Additional needs for toxicity testing

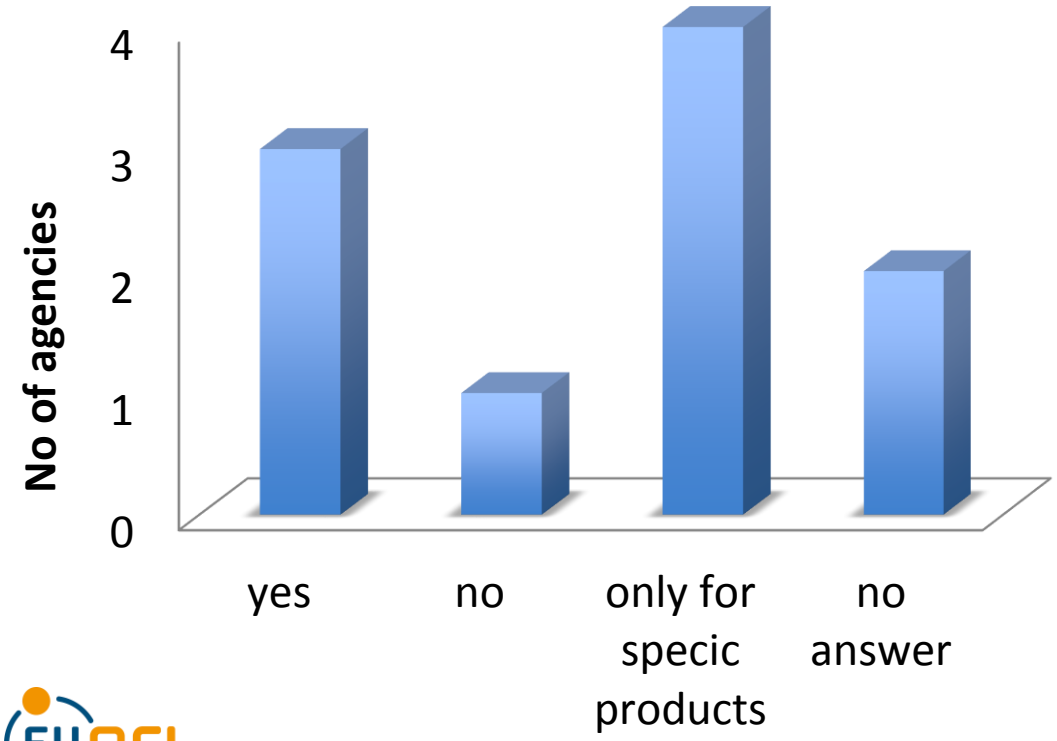
Did a specific property of the nanomedicine trigger any additional testing in vivo/in vitro in applications that you have reviewed?



- 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 experimens

Additional needs for toxicity testing

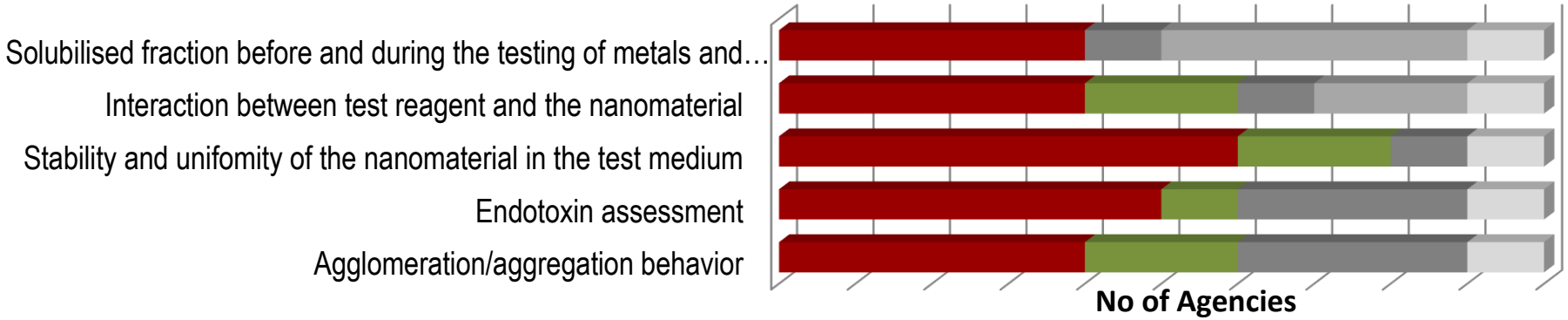
Is there a need to develop additional testing methods to assess the environmental effects of medicinal nanoparticles (ecotoxicology)?



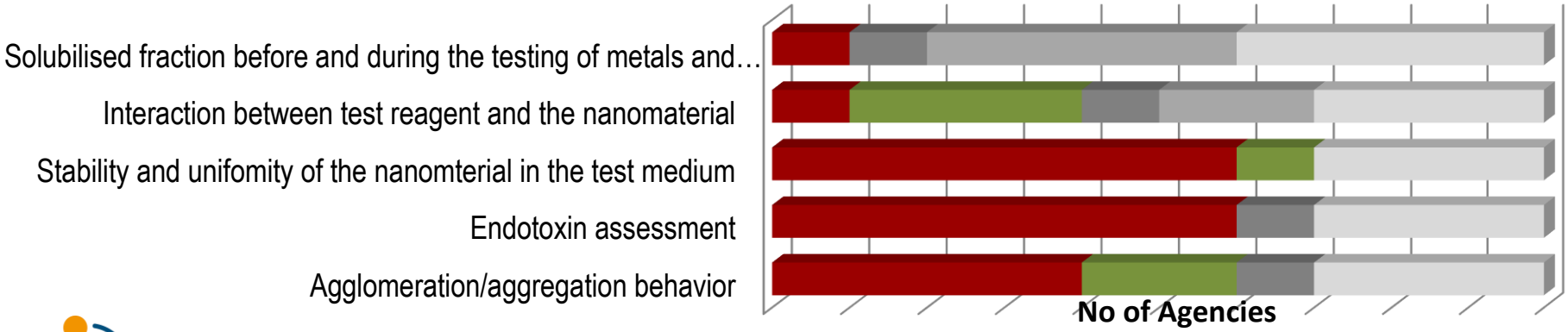
- some product classes might need to demonstrate the safety for the environment
- better understanding what kind of environmental tests have to be developed

Pitfalls for toxicity testing

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

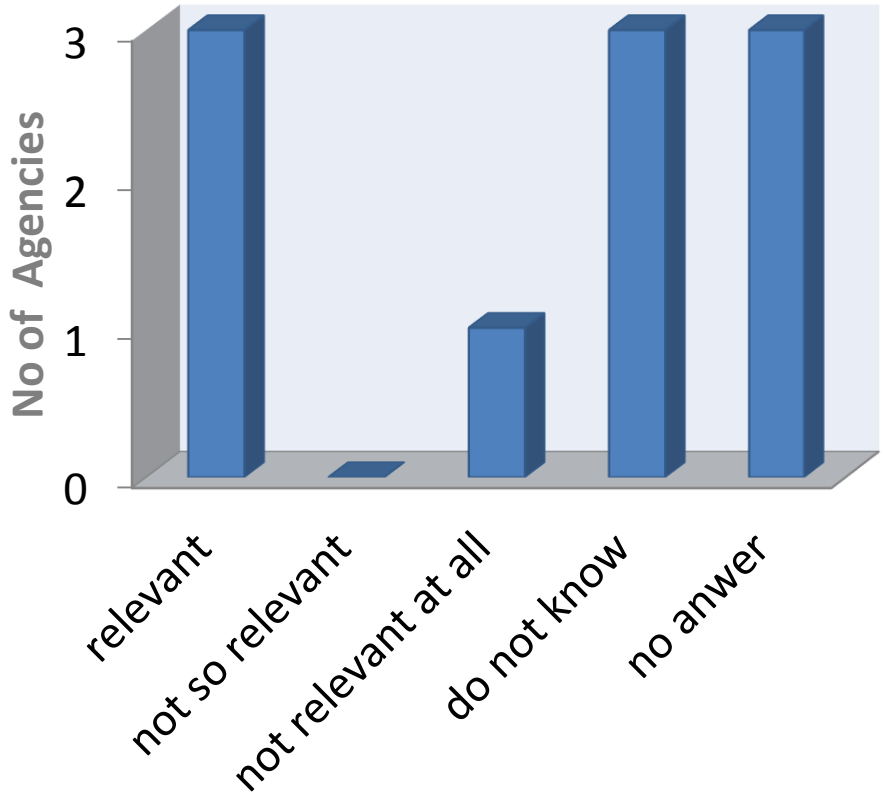


How do you value potential pitfalls for toxicity testing (in vitro/in vivo) in <u>clinical trial applications?</u>

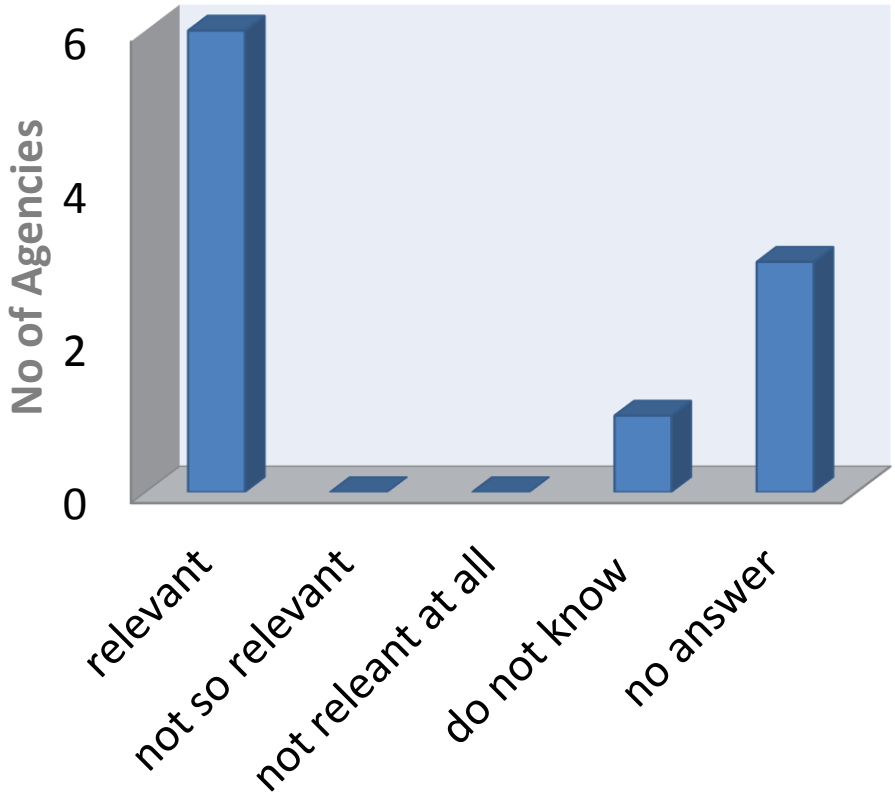


Harmonisation needs

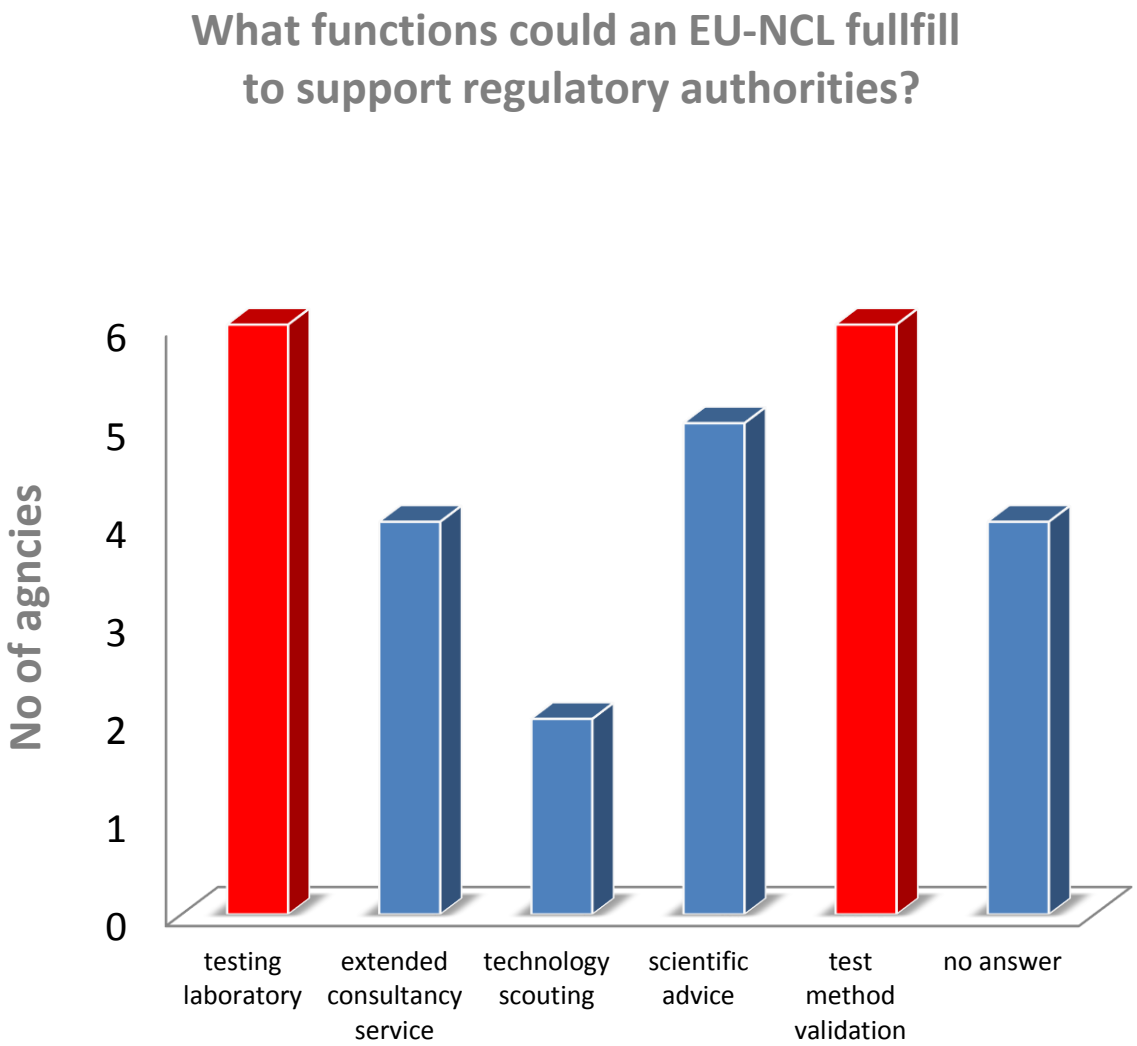
Do we need to harmonise the characterisation of nanomaterials used in medical devices (free nanomaterial administered to the patient) and medicinal products?



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



Functions of the EU-NCL



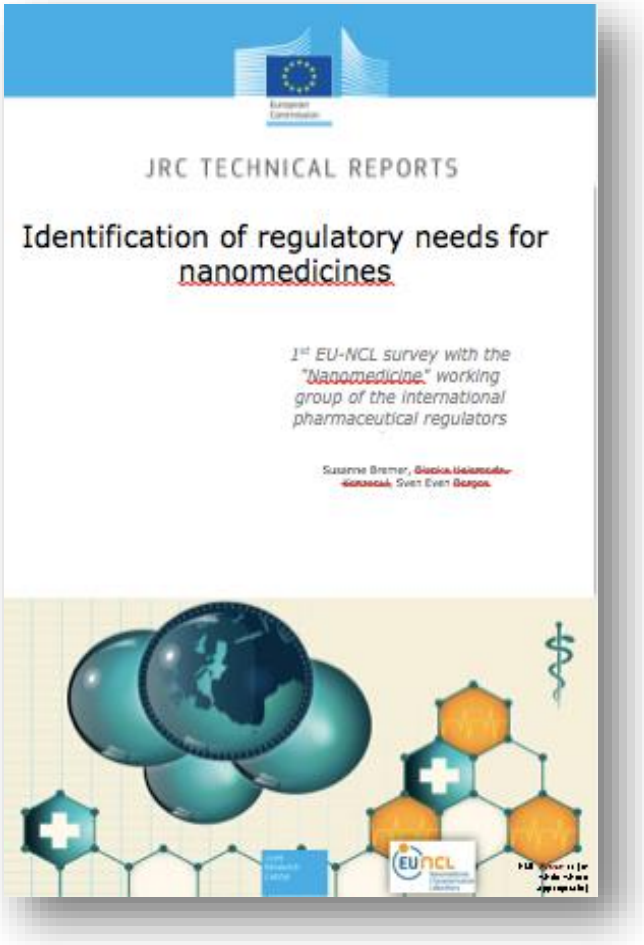
The strategic partnership of the EU-NCL and the NCI-NCL can support regulatory by

- 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 methods

Next steps



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

EU-NCL is funded by the European Union's Horizon 2020 Framework Programme, under grant agreement no. 65419

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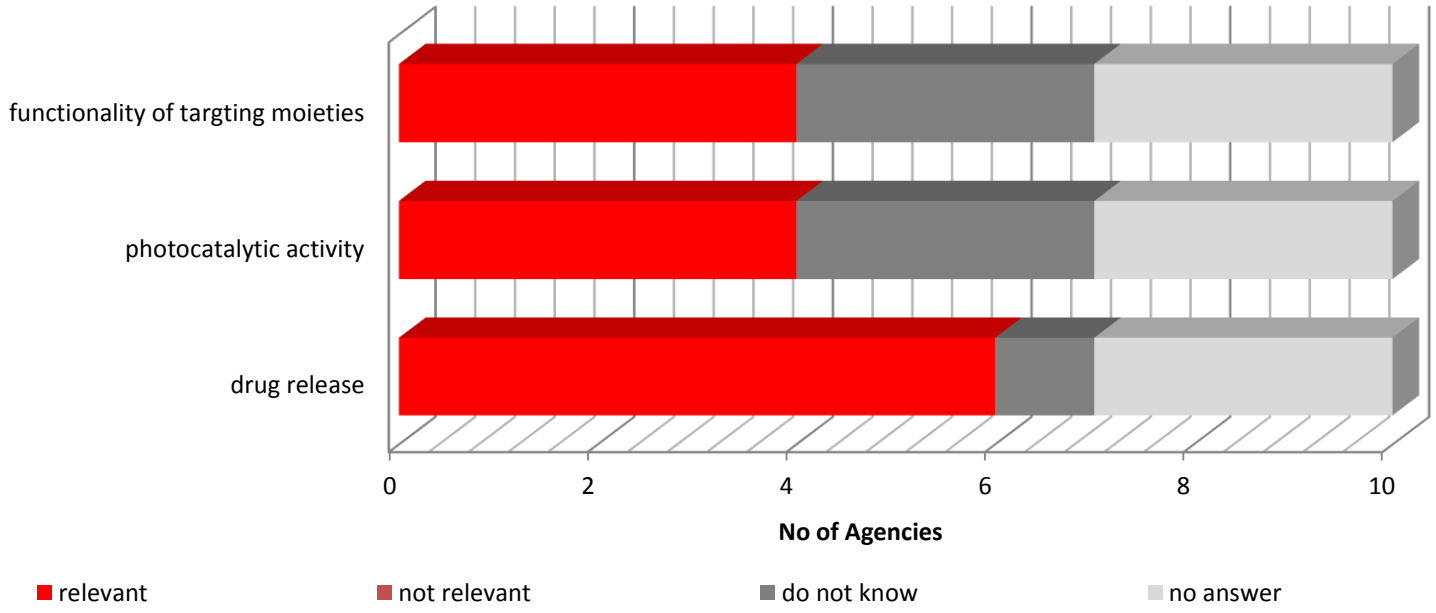
Thank you for your attention

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?



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