



Regulatory Research Roadmap NanoSafety Cluster

April 2015 Helsinki

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Regulator Research Roadmap Team

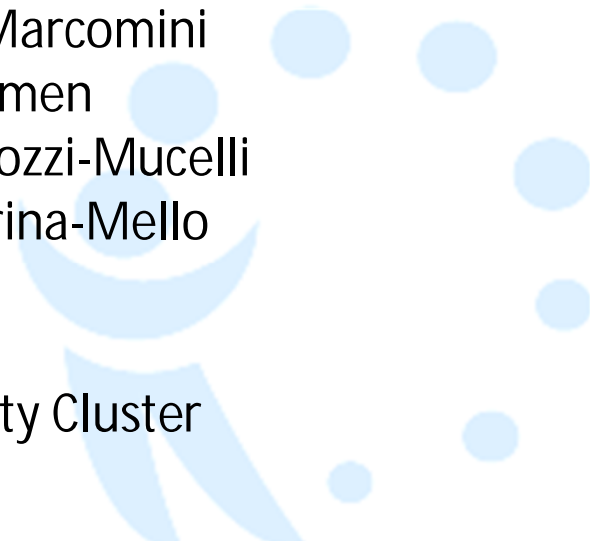
Input from:

Vicki Stone
Jacques-Aurelien Sergent
Enrico Bergamaschi
Susan Dekkers
Wilson Engelman
Serli Önlü
Juan Riego-Sintes
Janeck Scott-Fordsmand
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Potential input from:

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Wim de Coen
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Danail Hristzov
Andrej Kobe
Igor Linkov
Antonio Marcomini
Agnes Oomen
Stefano Pozzi-Mucelli
Adriale Prina-Mello
ECHA
ECVAM
NanoSafety Cluster

NanoSafety Cluster



Regulatory Research Roadmap Purpose

- To identify and structure the research required to deliver effective regulation of nanomaterial safety
- Including
 - Consumer
 - Occupational
 - Sector specific issues
- Excluding
 - Nanomedicine

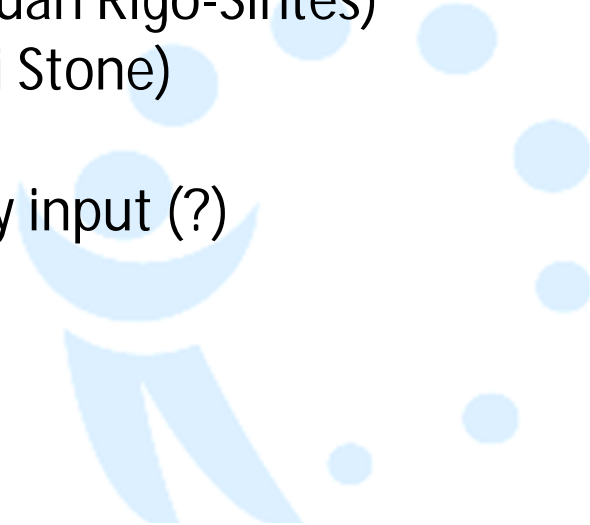
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Stage 1 – Identifying activities relevant to the RRR

- ITS-NANO hexagon diagrams to illustrate research prioritisation (Vicki Stone)
- NANoREG gap analysis (Susan Dekkers)
- US research and regulatory development (Phil Sayes EPA)
- MARINA tiered approach for RA (Agnes Oomen)
- Nanonext.nl (Adrienne Sips)
 - Dutch nanotechnology development programme
 - Risk Analysis and Technology Assessment (RATA)
- NANoREG questions relevant for regulators (Juan Rigo-Sintes)
- Safety-by-Design – SUN and NanoGuide (Vicki Stone)
- REACH (Juan Rigo-Sintes, Wim De Coen)
- EU occupational and safety at work regulatory input (?)
- Educational framework (?)

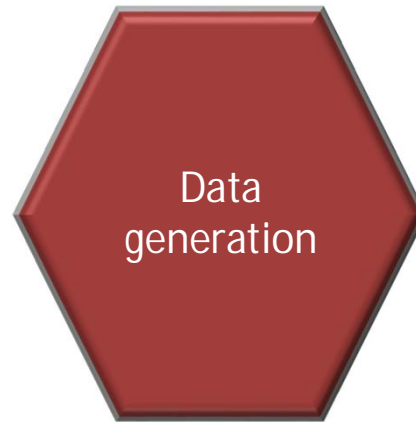
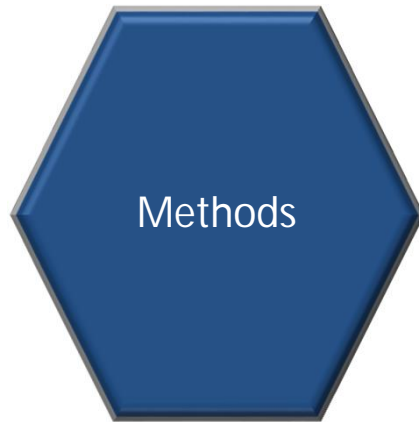
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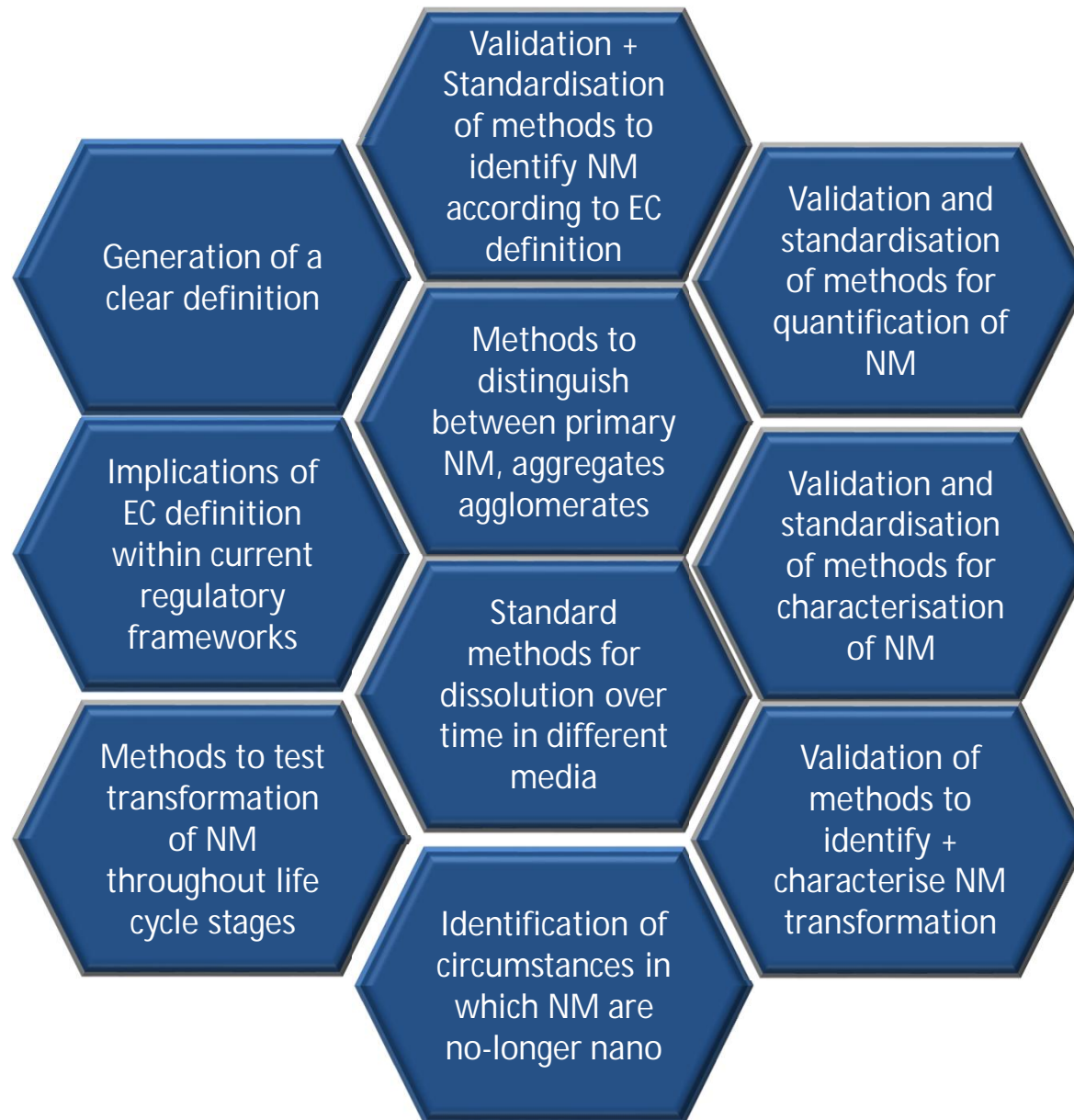
The Plan

- Convert NANoREG Regulation Research Gap analysis into a hexagon diagram.
- Colour code the hexagons by identifying which research priorities are relevant or common to both road maps.
- Interrogate the diagram using the Regulatory Questions from NANoREG and edit as appropriate. (JRC)
- Interrogate the diagram in relation to current EU regulations (in particular REACH) and edit as appropriate. (ECHA)
- Compare and contrast the hexagon diagram generated with US activities and edit as appropriate.
- Generate one paragraph of text to outline each hexagon/priority and link to the relevant references, reports and projects.
- Put together the final text that introduces the roadmap, provides the roadmap diagram, the short description for each hexagon/priority with references, and the final conclusions.

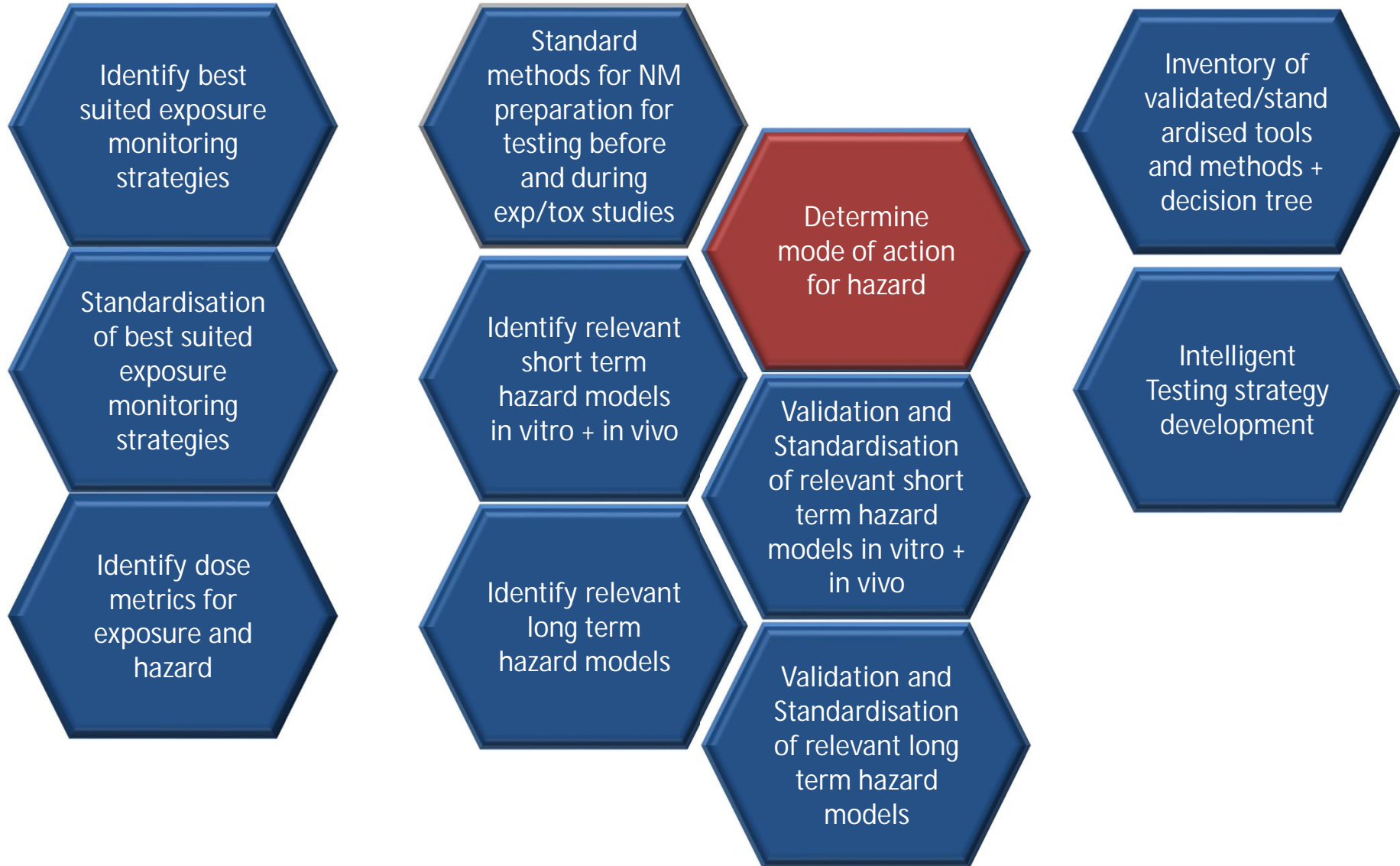
Regulatory Research Roadmap Priorities



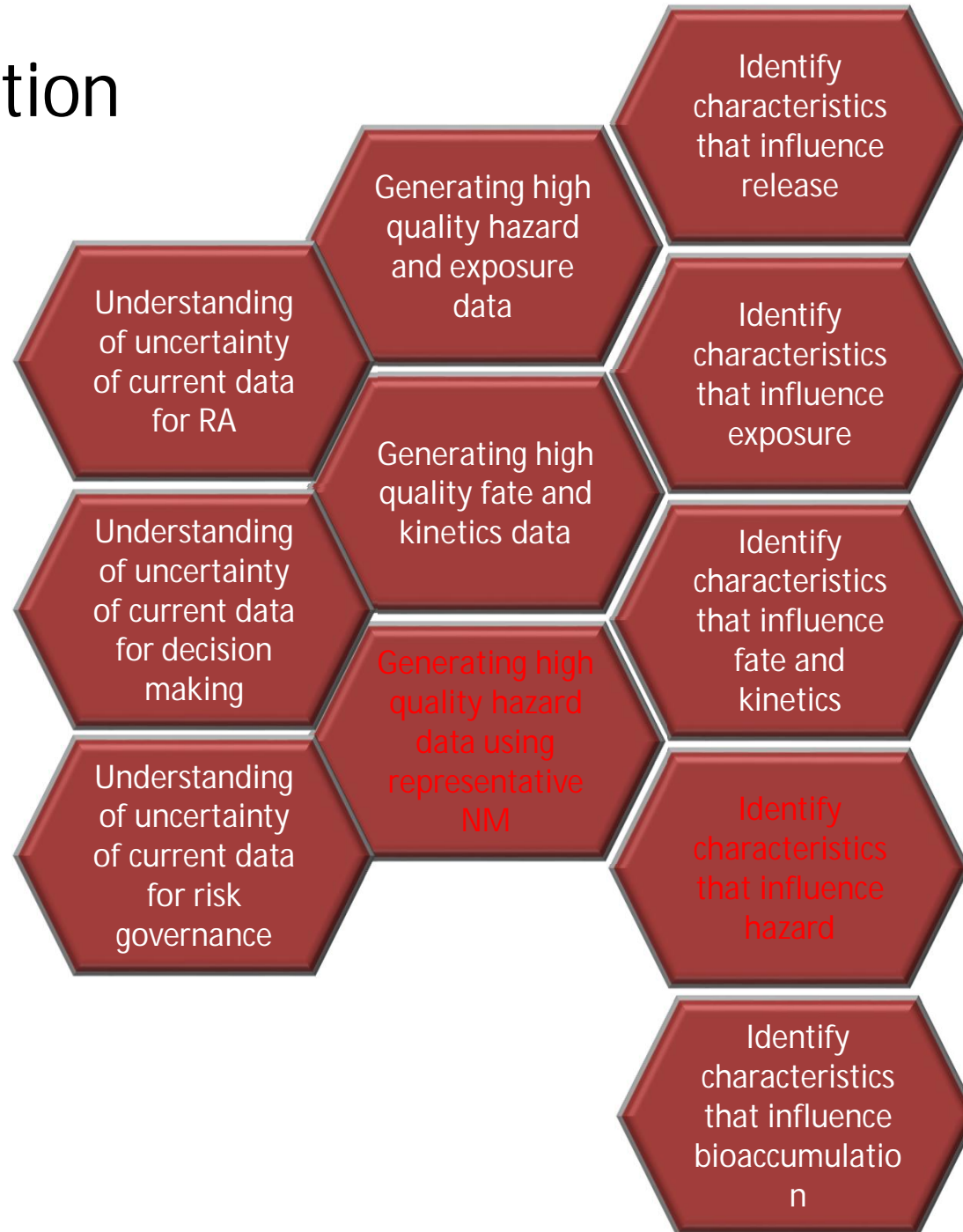
Methods – NM identification



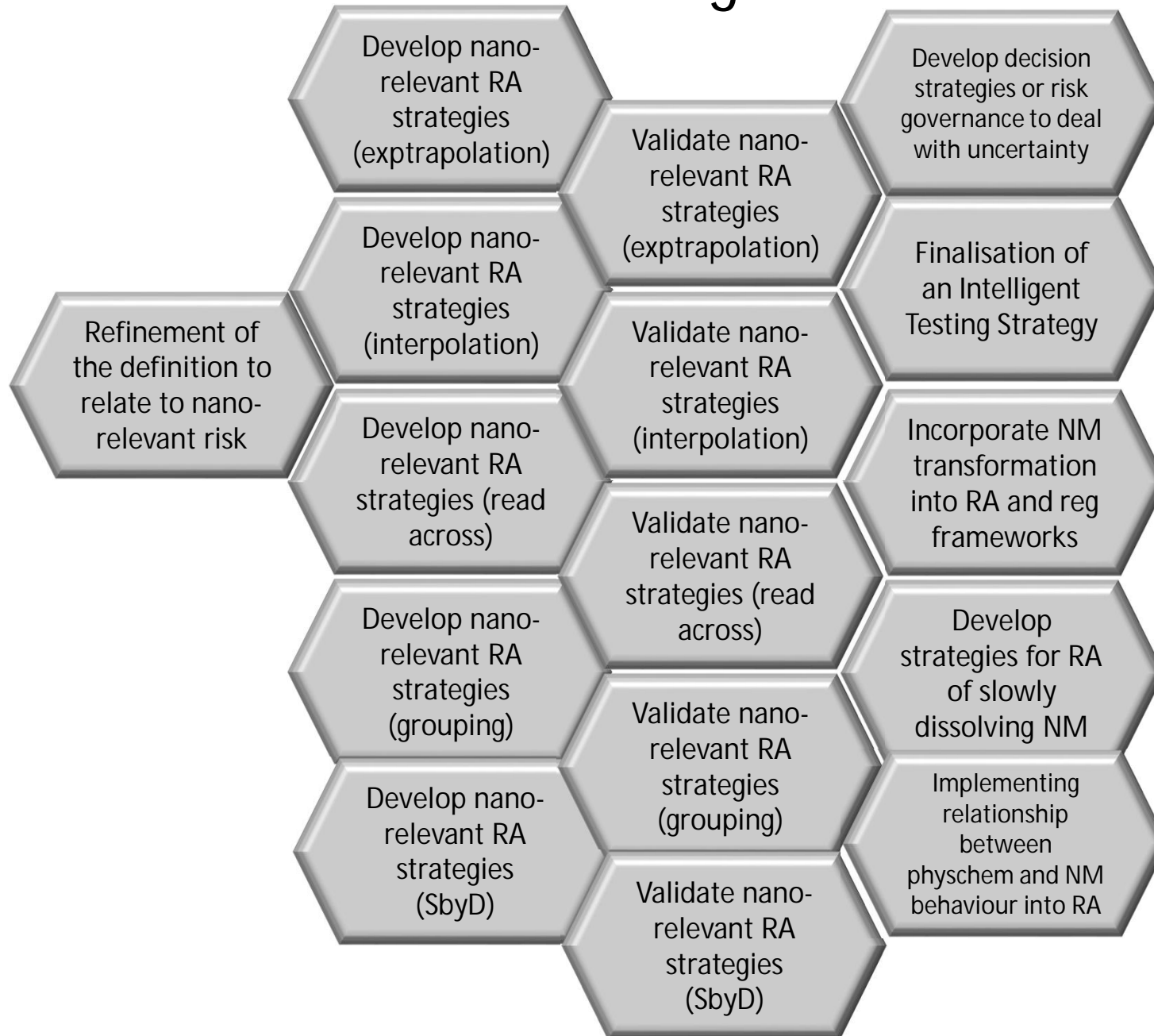
Methods – Exposure, Hazard and Beyond



Data Generation

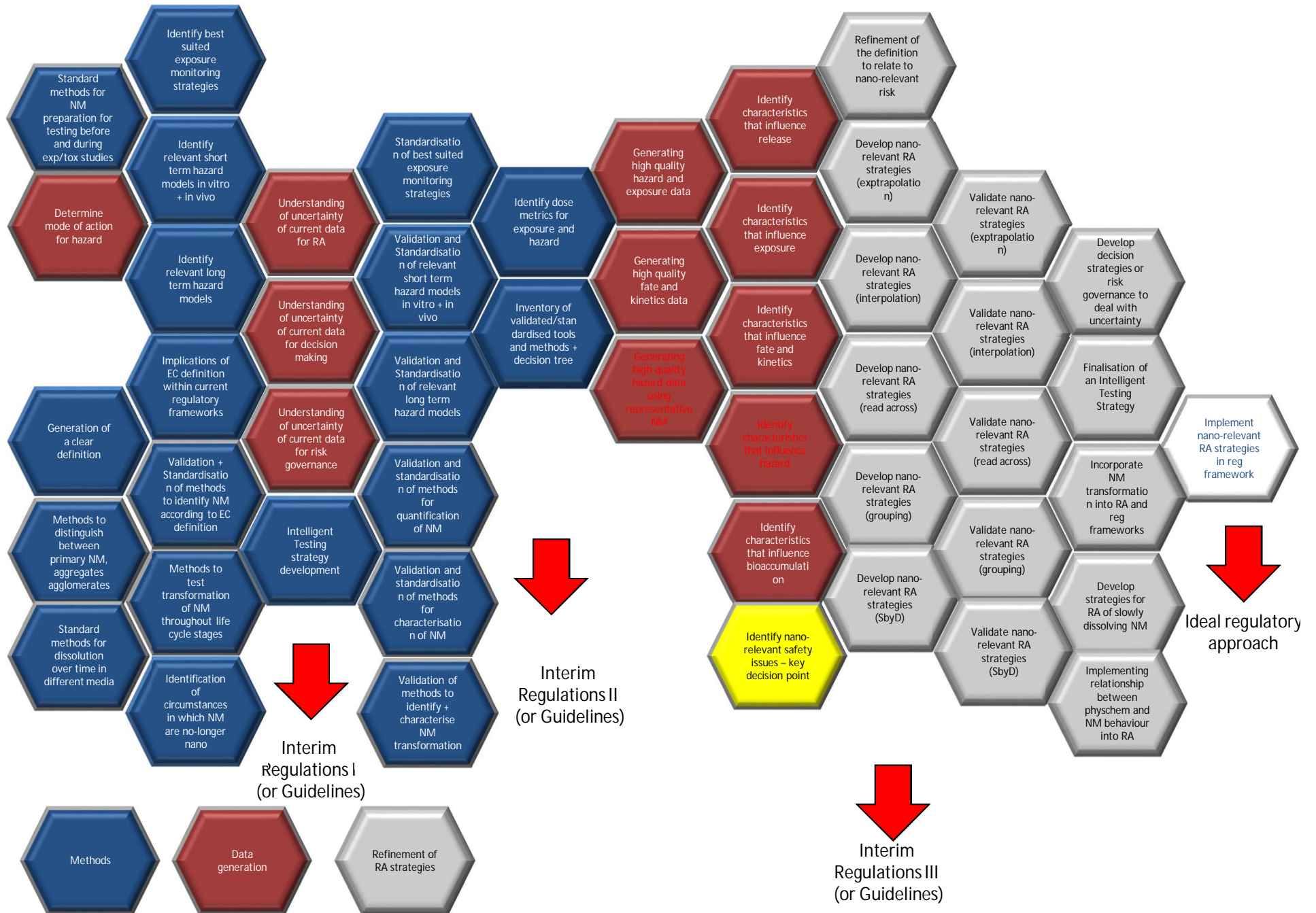


Refinement of RA strategies



Short term

Long term

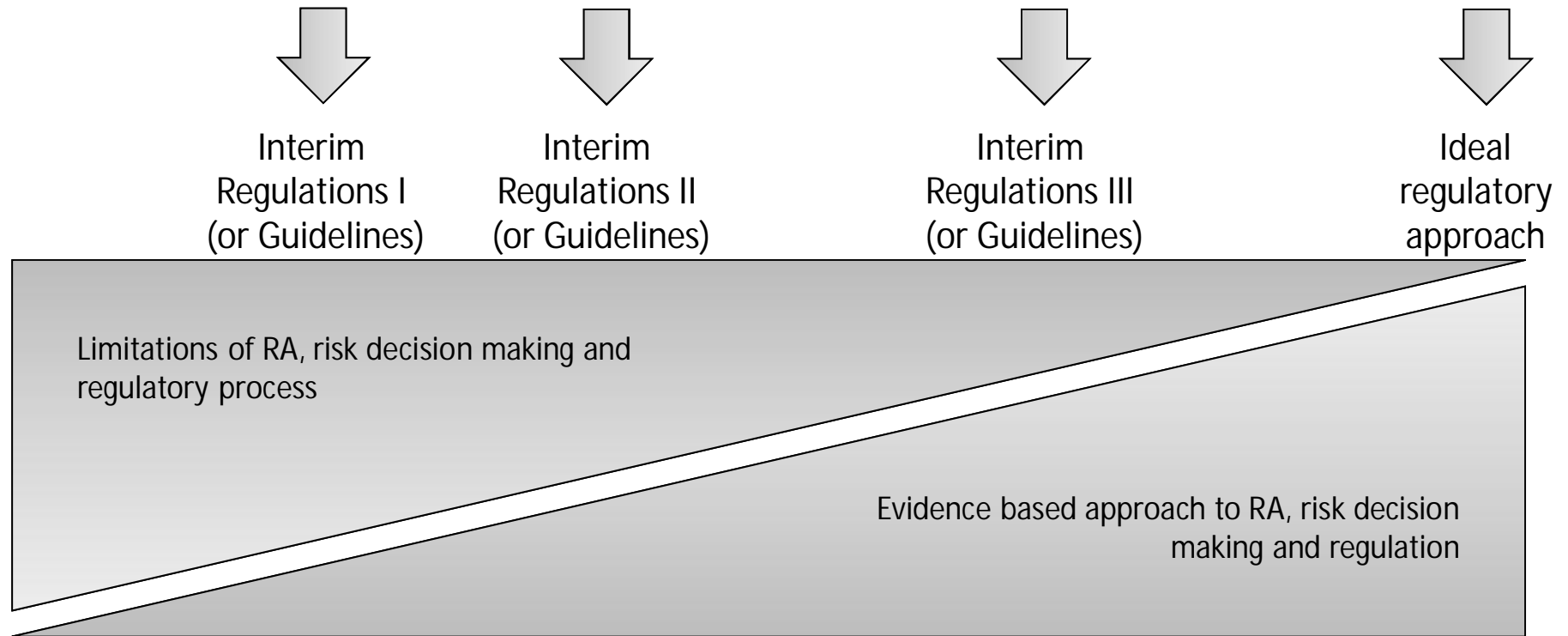


RRR diagram so far

- 48 (50) Research priority hexagons identified
- 20 methods
- 10 (11) data generation
- 16 Refinement of RA strategies
- 1 Identify nano-relevant safety issues – key decision point
- 1 implement nano-relevant RA strategies in regulatory frameworks
- 3 interim regulations/guidelines generated over time lead to a final fourth 'ideal regulatory approach'



We can't wait 15 years before identifying and acting upon nano-relevant regulation needs.....



Regulatory approaches could increase in sophistication with time as the knowledge base increases - 'something is better than nothing'

RRR text so far (33 pages)

021014

Methods, Data generation, Assessment of health effects, Identify best suited exposure monitoring strategies

The colour coding groups hexagons (research priorities) in order to simplify understanding

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1.1 Generation of a clear definition

Generation of a clear definition

A clear definition of nanomaterial should be scientifically or exhibit a well-defined scope and it should be possible to find. The definition should be as uniform as possible across different global locations, in order to prevent that a material is in one framework and not in another.

The European Commission (EC) published a recommendation of nanomaterials (2011/696/EU): http://ec.europa.eu/research/industrial_technologies/pdf/policy_recommendation-on-the-definition-of-nanomaterial-18102011_en.pdf

The European Parliament and the Council, European Parliament 2013 on a new agenda for European Consumer Policy (IP): <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//2013-0229+0-DO+0+0+0+0/EN/eng/leg-EN>

Most probably the most distinguishing aspect of the EC recommendation is the use of particle size distributions based on the numbers of particles or mass or volume of the particles, as the main classification.

More recently (March 2014) Joint Research Centre Institute for Protection published a review of the EC definition recommendation of the EC Recommendation for a definition of the term 'nanomaterial'. Completion of information concerning the experience with it: <http://publications.jrc.ec.europa.eu/repository/bitstream/11111/11111/1/11111.pdf>

Lately (August 2014) Joint Research Centre Institute for Reference and Measurements published the second review report (namely, EC Recommendation for a definition of the term 'nanomaterial' collected information concerning the experience with the definition): <http://publications.jrc.ec.europa.eu/repository/bitstream/11111/11111/1/11111.pdf>

Based on the feedback received regarding the current definition report of the series, and its assessment, presented in this report, now working on a set of indications on how the definition could be clarified, effectiveness and implementability. These recommendations

1.6 Standard methods for NM preparation for testing exposure/toxicology studies

* susceptibility/sensitivity according to species, age, status or genetic variation).

ITS-NANO
Phil Bayne
Ulila Vogel
Viola Stone

There is a need for more clarity regarding the best methods for human and environmental hazard testing. This is true for both tests and environmental exposure-modes. Such tests are costly and monitor, making it difficult to interpret the results. The need to improve understanding of dispersion characteristics and environmentally relevant media. This will enable better but at the same time there is a need to link to the final state of dispersion in the environment, in relation to the fate and effects.

The above text suggests that development of a single method however, is unlikely due to the variations in NM physical matrices and exposure scenarios/routes. In the future, a mix of dispersion options will be required to guide researchers toward most appropriate protocols. Protocols may not necessarily mono-dispersed suspensions. In many situations, they may be realistic situations with aggregated or agglomerated particles.

Which projects have or are currently developing protocols for NM? (e.g. NanoTox, NanoREG...?)

ITS-NANO
Phil Bayne
Ulila Vogel

1.8 Identify best suited exposure monitoring strategies

Exposure monitoring can be done for a variety of risk assessment, epidemiology, compliance testing, and testing measures (e.g. local exhaust ventilation systems, enclosures). The nature of the monitoring strategy will heavily depend on the use of personal monitoring approaches. Exposure monitoring for NMs is complicated as:

- 1) There is a lack of standard approaches and metrics (area, or other) that can be used for risk assessment;
- 2) The majority of direct reading instruments for NMs are not specific to engineered nanomaterials.

Arbeitsplatzbeurteilung-von-Schutzmaßnahmen-Index-2.doc

Van Boekel et al. (2012) Exposure Limits for Nanoparticles: Report of an International Workshop on Occupational Health and Safety. Am. J. Ind. Hyg. Vol. 73, No. 5, pp. 519-524. Available at: <http://erj.oxfordjournals.org/content/50/5/519.full.pdf.html>

Combine with 1.6

Validate nano-specific RA strategies (Boyd)

What is required to validate?

Combine with 1.8?

Develop decision strategies or risk governance to deal with uncertainty

Finalisation of an Intelligent Testing Strategy

Viola Stone

Incorporate NM transformation into RA and regulatory frameworks

Develop strategies for RA of slowly dissolving NM

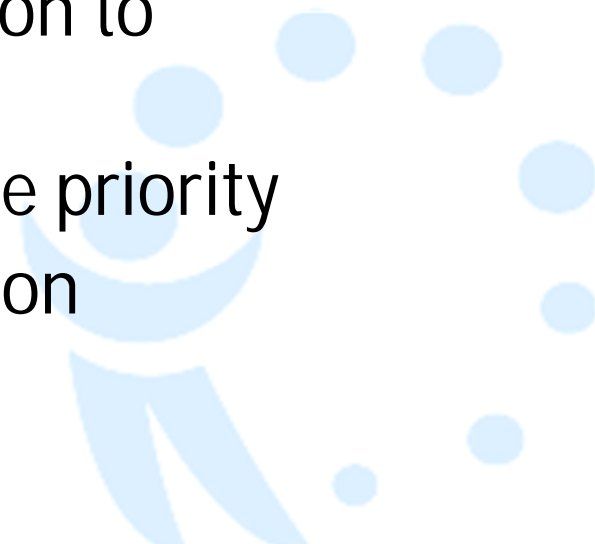
Implement relationships between physicochemical and NM behaviour into RA

Implement nano-specific RA strategies into regulatory frameworks

Markup Area

Latest update

- Latest version distributed to authors and potential targeted authors 14/04/15
- Feedback requested by end of April
- Each section should contain
 - An explanation of the issue/research priority
 - Outline of current status in relation to issue/priority
 - Recommendations relevant to the priority
 - Provide links to further information



Next steps

- Finish first draft of report Early May 2015
 - ECHA/REACH
 - Regulatory Questions NANoREG
- Circulate to cluster members Mid May 2015
- Feedback deadline Early June
- Second draft End June
- Checking by authors
- Final draft End July

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