Regulatory Research Roadmap NanoSafety Cluster

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Regulator Research Roadmap Team

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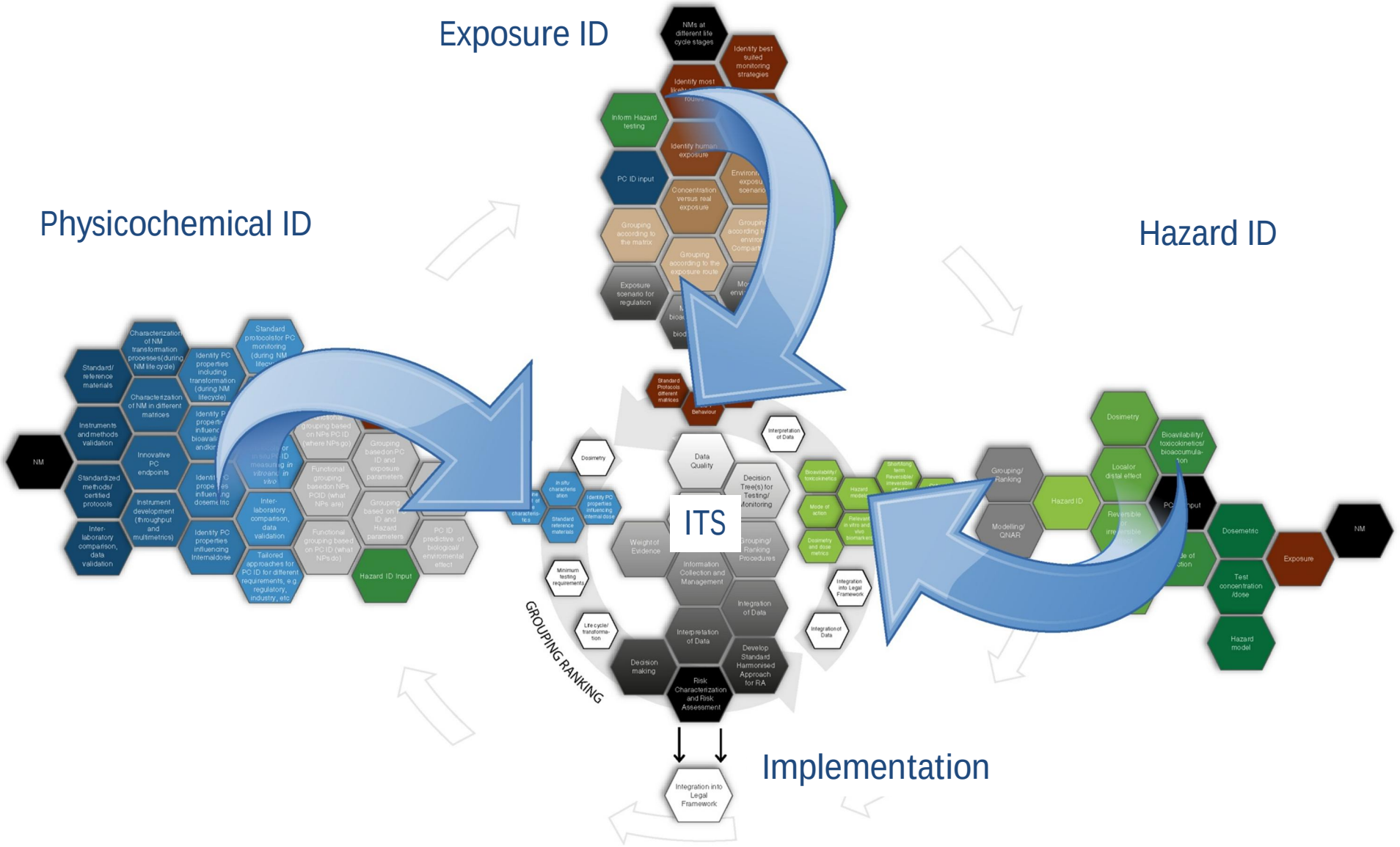
Regulatory Research Roadmap Purpose

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

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 (?)

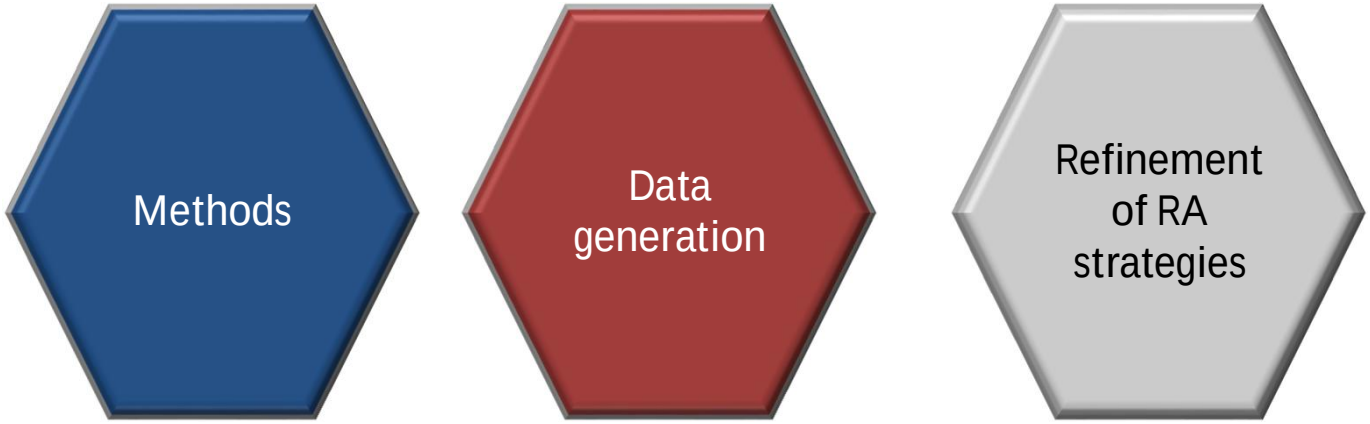
ITS-NANO Research Prioritisation



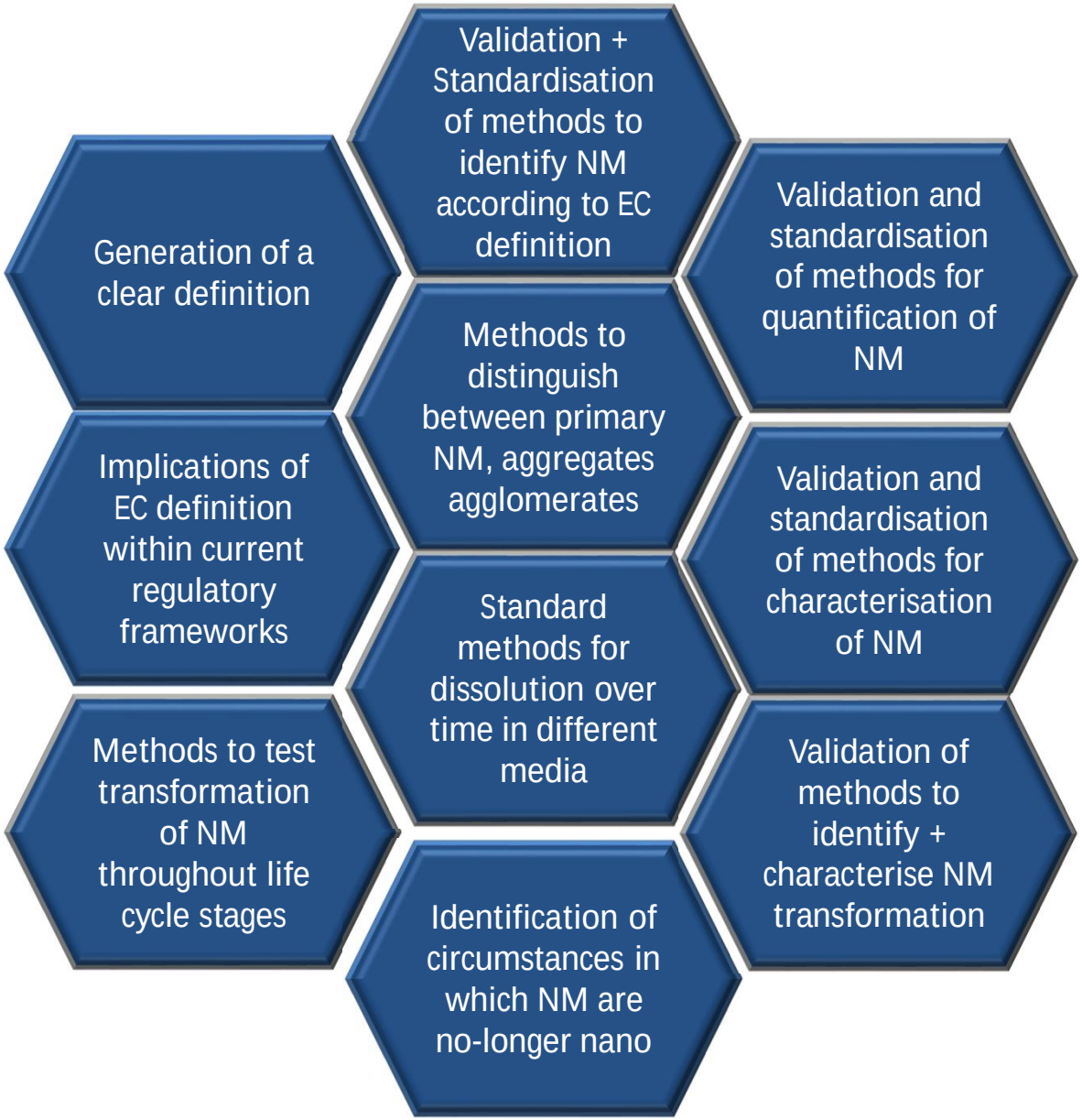
The Plan

- 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.

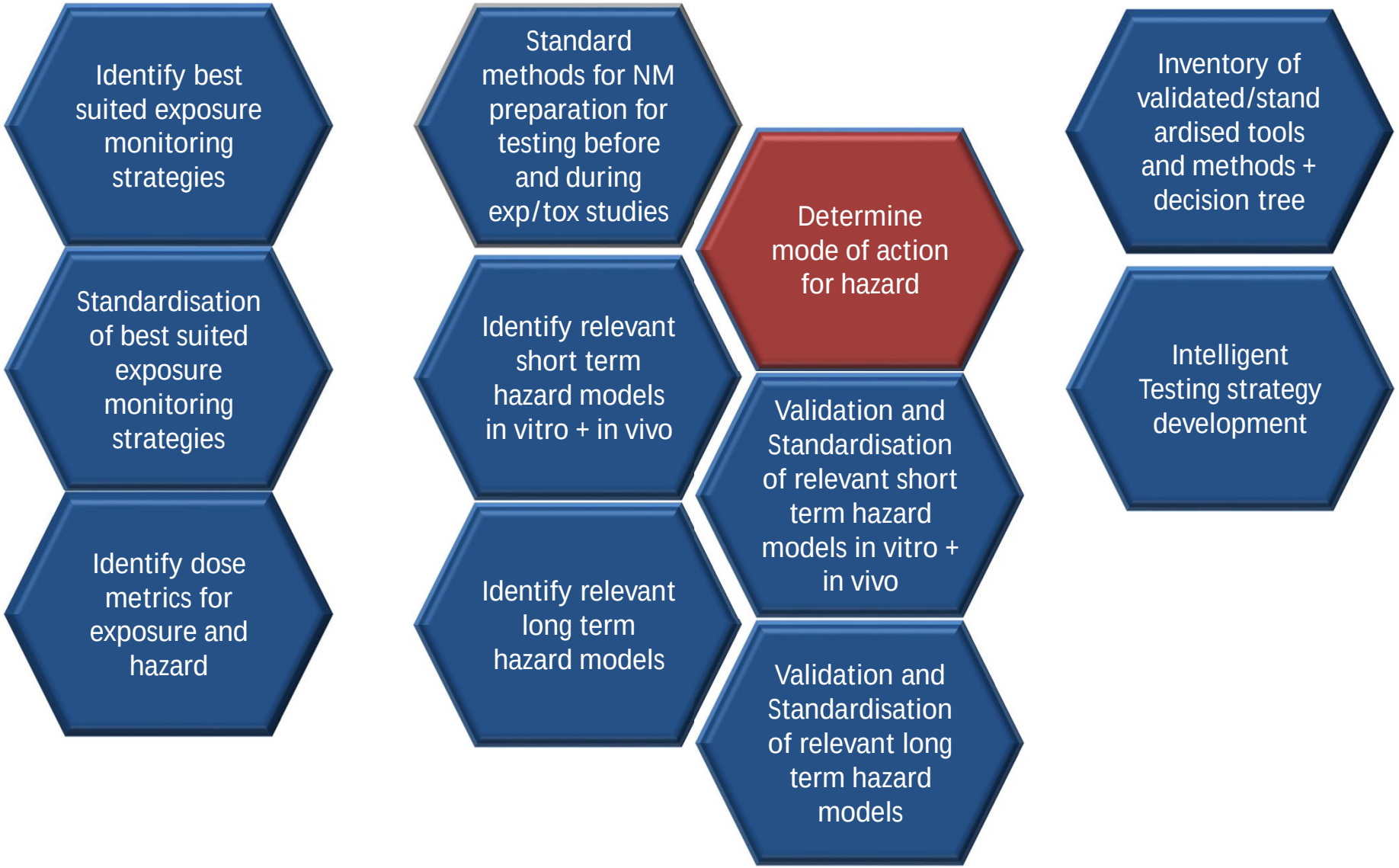
Regulatory Research Roadmap Priorities



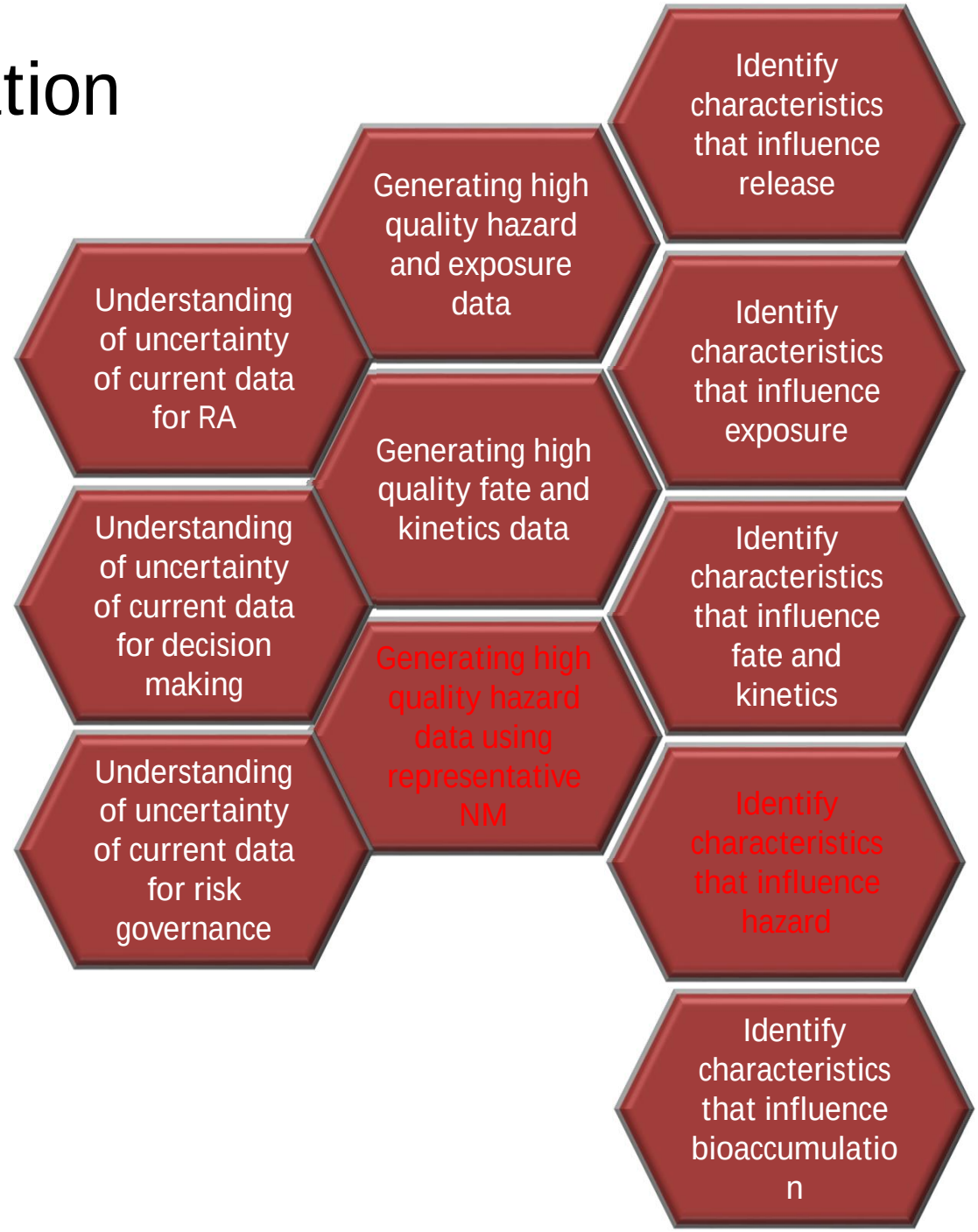
Methods – NM identification



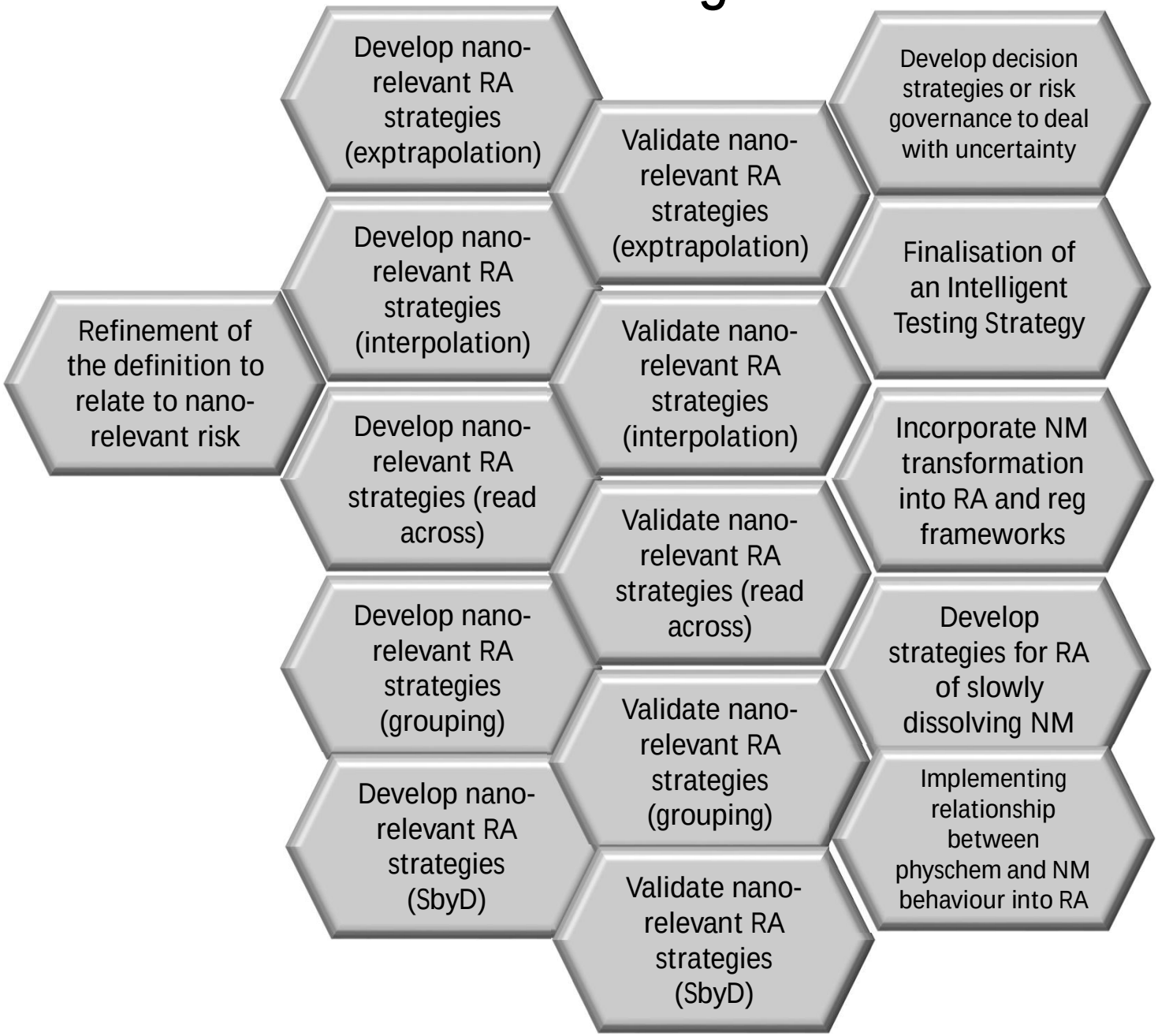
Methods – Exposure, Hazard and Beyond

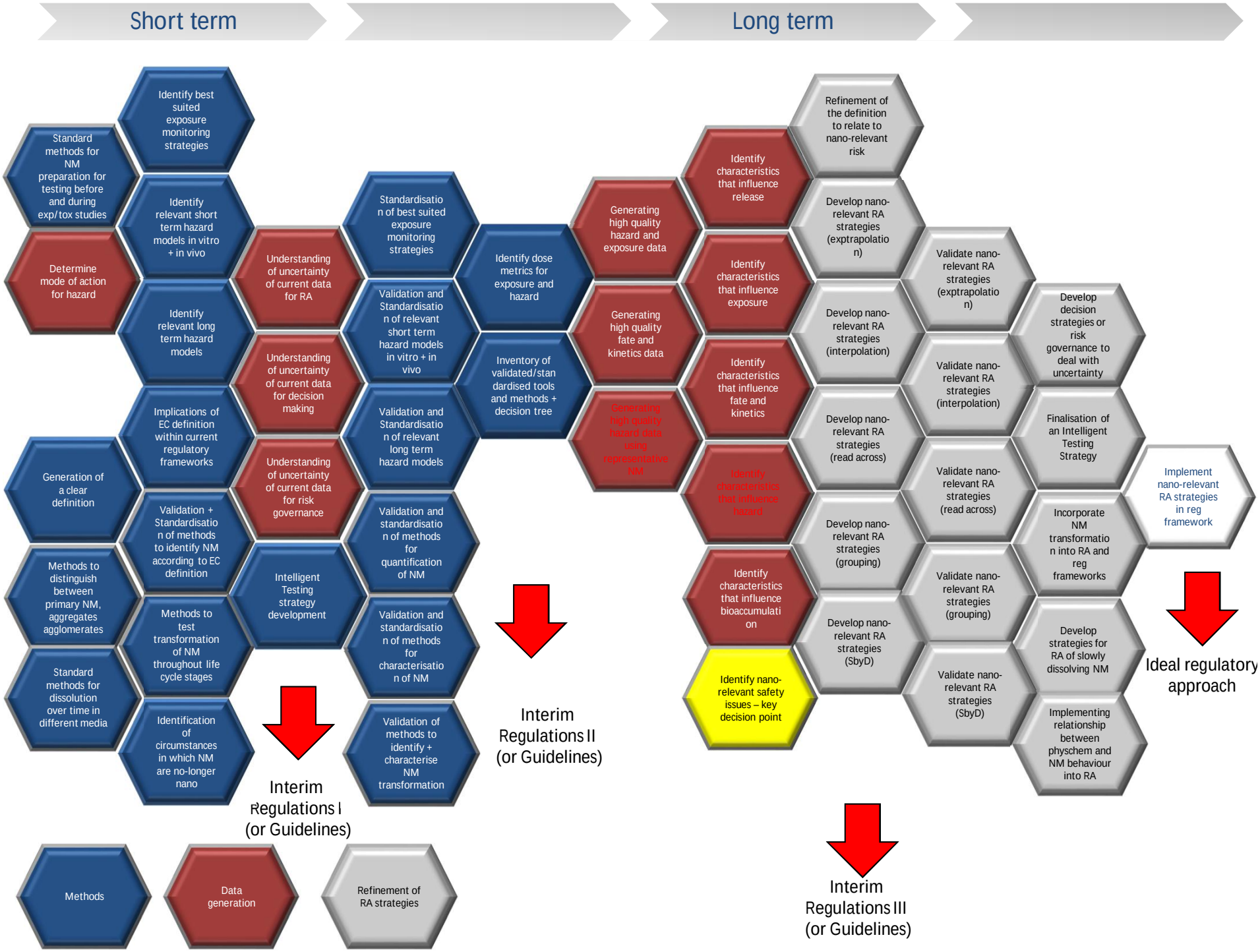


Data Generation



Refinement of RA strategies

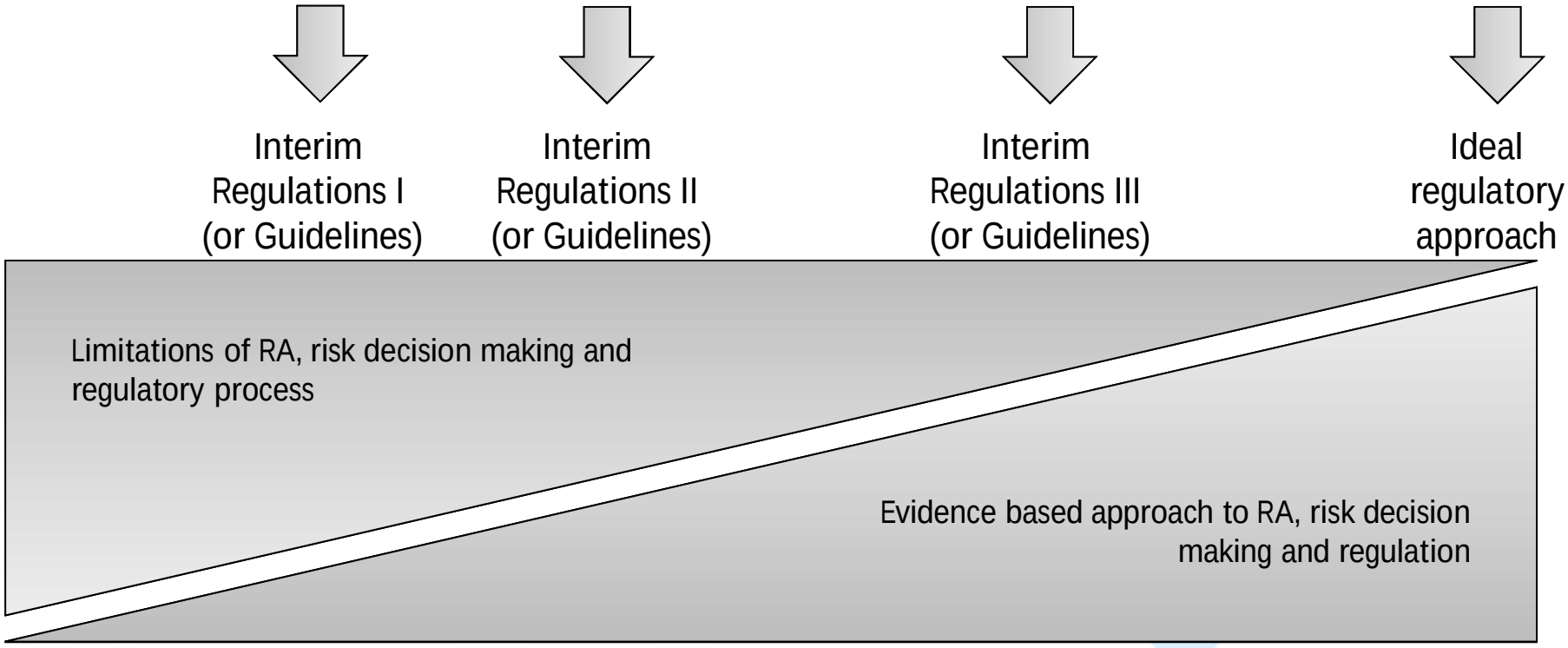



Short term
Long term
Identify best suited exposure monitoring strategies
Standard methods for NM preparation for testing before and during exp/tox studies
Identify relevant short term hazard models in vitro + in vivo
Determine mode of action for hazard
Identify relevant long term hazard models
Implications of EC definition within current regulatory frameworks
Generation of a clear definition
Validation + Standardisation of methods to identify NM according to EC definition
Methods to distinguish between primary NM, aggregates agglomerates
Methods to test transformation of NM throughout life cycle stages
Standard methods for dissolution over time in different media
Identification of circumstances in which NM are no-longer nano
Understanding of uncertainty of current data for RA
Understanding of uncertainty of current data for decision making
Understanding of uncertainty of current data for risk governance
Intelligent Testing strategy development
Standardisation of best suited exposure monitoring strategies
Validation and Standardisation of relevant short term hazard models in vitro + in vivo
Validation and Standardisation of relevant long term hazard models
Validation and standardisation of methods for quantification of NM
Validation and standardisation of methods for characterisation of NM
Validation of methods to identify + characterise NM transformation
Identify dose metrics for exposure and hazard
Inventory of validated/standardised tools and methods + decision tree
Generating high quality hazard and exposure data
Generating high quality fate and kinetics data
Generating high quality hazard data using representative NM
Interim Regulations I (or Guidelines)
Interim Regulations II (or Guidelines)
Interim Regulations III (or Guidelines)
Identify characteristics that influence release
Identify characteristics that influence exposure
Identify characteristics that influence fate and kinetics
Identify characteristics that influence hazard
Identify characteristics that influence bioaccumulation
Identify nano-relevant safety issues – key decision point
Refinement of the definition to relate to nano-relevant risk
Develop nano-relevant RA strategies (exptrapolation)
Develop nano-relevant RA strategies (interpolation)
Develop nano-relevant RA strategies (read across)
Develop nano-relevant RA strategies (grouping)
Develop nano-relevant RA strategies (SbyD)
Validate nano-relevant RA strategies (exptrapolation)
Validate nano-relevant RA strategies (interpolation)
Validate nano-relevant RA strategies (read across)
Validate nano-relevant RA strategies (grouping)
Validate nano-relevant RA strategies (SbyD)
Develop decision strategies or risk governance to deal with uncertainty
Finalisation of an Intelligent Testing Strategy
Incorporate NM transformation into RA and reg frameworks
Develop strategies for RA of slowly dissolving NM
Implementing relationship between physchem and NM behaviour into RA
Implement nano-relevant RA strategies in reg framework
Ideal regulatory approach
Methods
Data generation
Refinement of RA strategies

RRR diagram so far

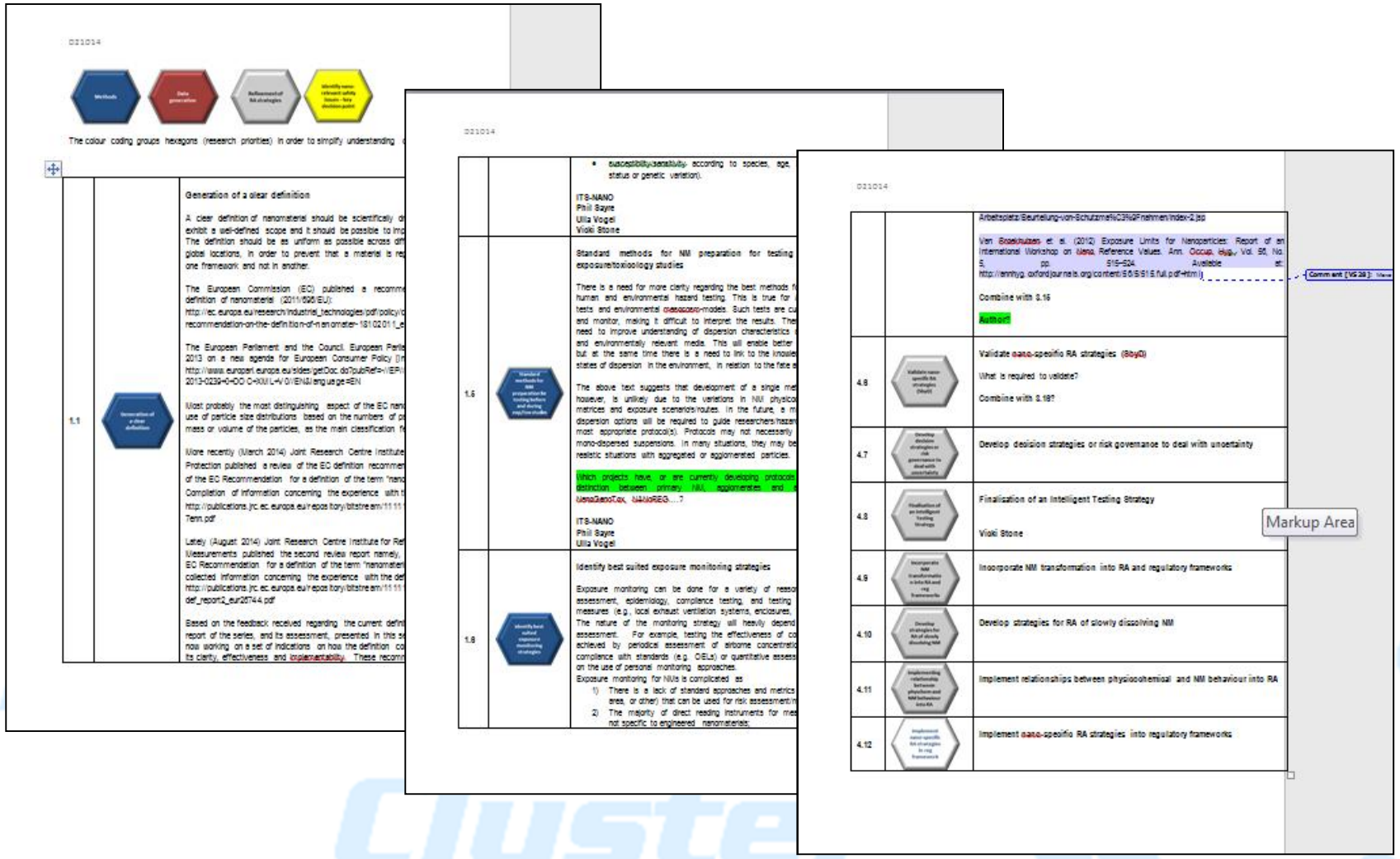
- 48 (50) Research priority hexagons identified
- 20 methods
- 10 (11) data generation
- 16 Refinement of RA strategies
- 1 Identify nano-relevant safety issues – key decision point
- 1 implement nano-relevant RA strategies in regulatory frameworks
- 3 interim regulations/guidelines generated over time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



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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