

Grouping, Read-Across and Classification framework for regulatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products

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Project Overview and Objectives

Due to the ever increasing array of nanomaterials (NMs)/nanoforms (NFs) on the market and under development, streamlining the information gathering for their risk assessment is needed.

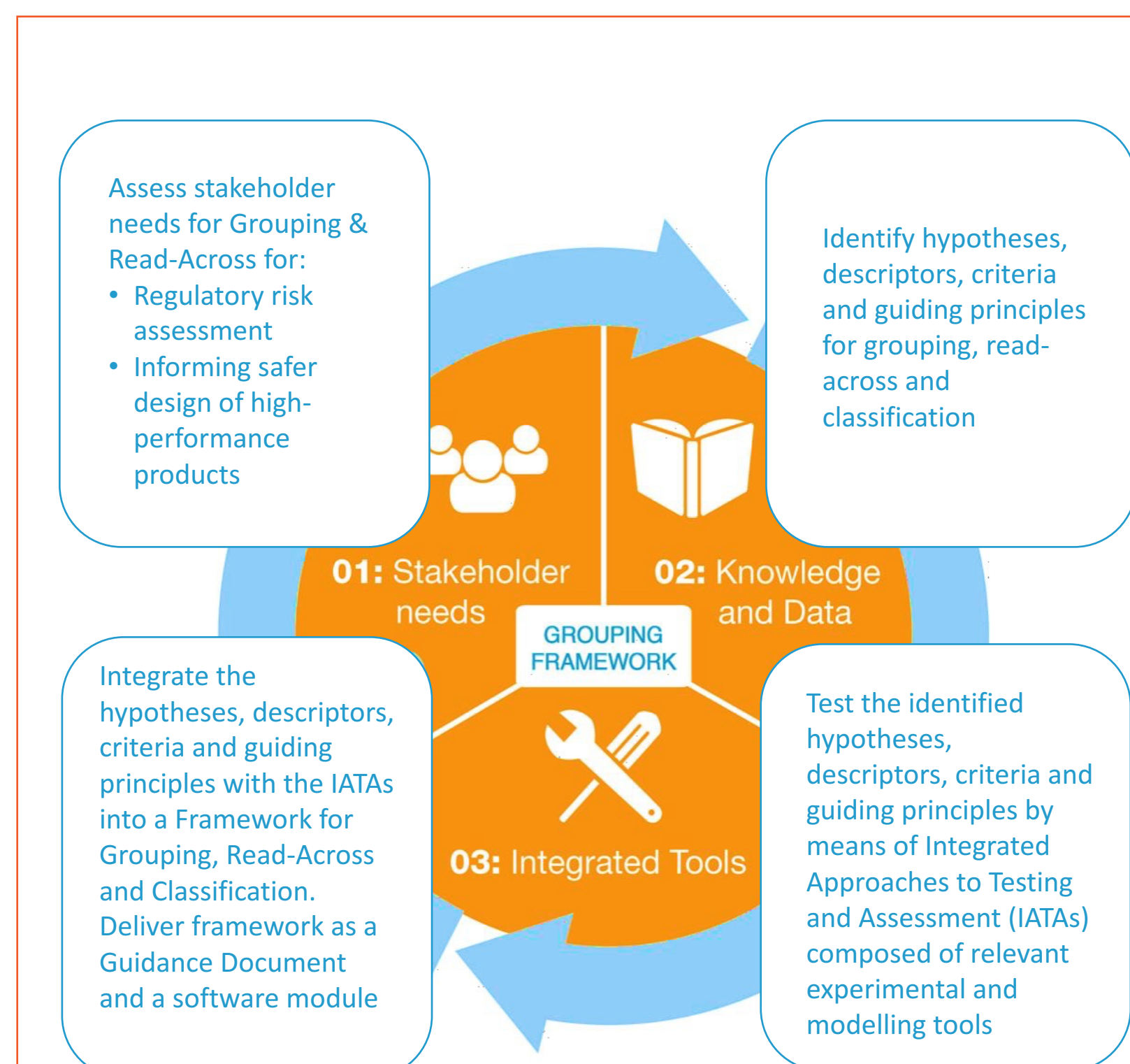
GRACIOUS is developing a Framework to logically grouping NFs, thereby allowing use of (existing) data from similar NMs/NFs extrapolation between (read-across) NFs, materials and substances, and reducing the need to assess exposure and toxicity on a case-by-case basis.

Objectives:

O1: Integrate key stakeholder needs with state-of-the-art thinking on grouping and read-across of NMs/NFs in order to design, develop and refine a sustainable Framework.

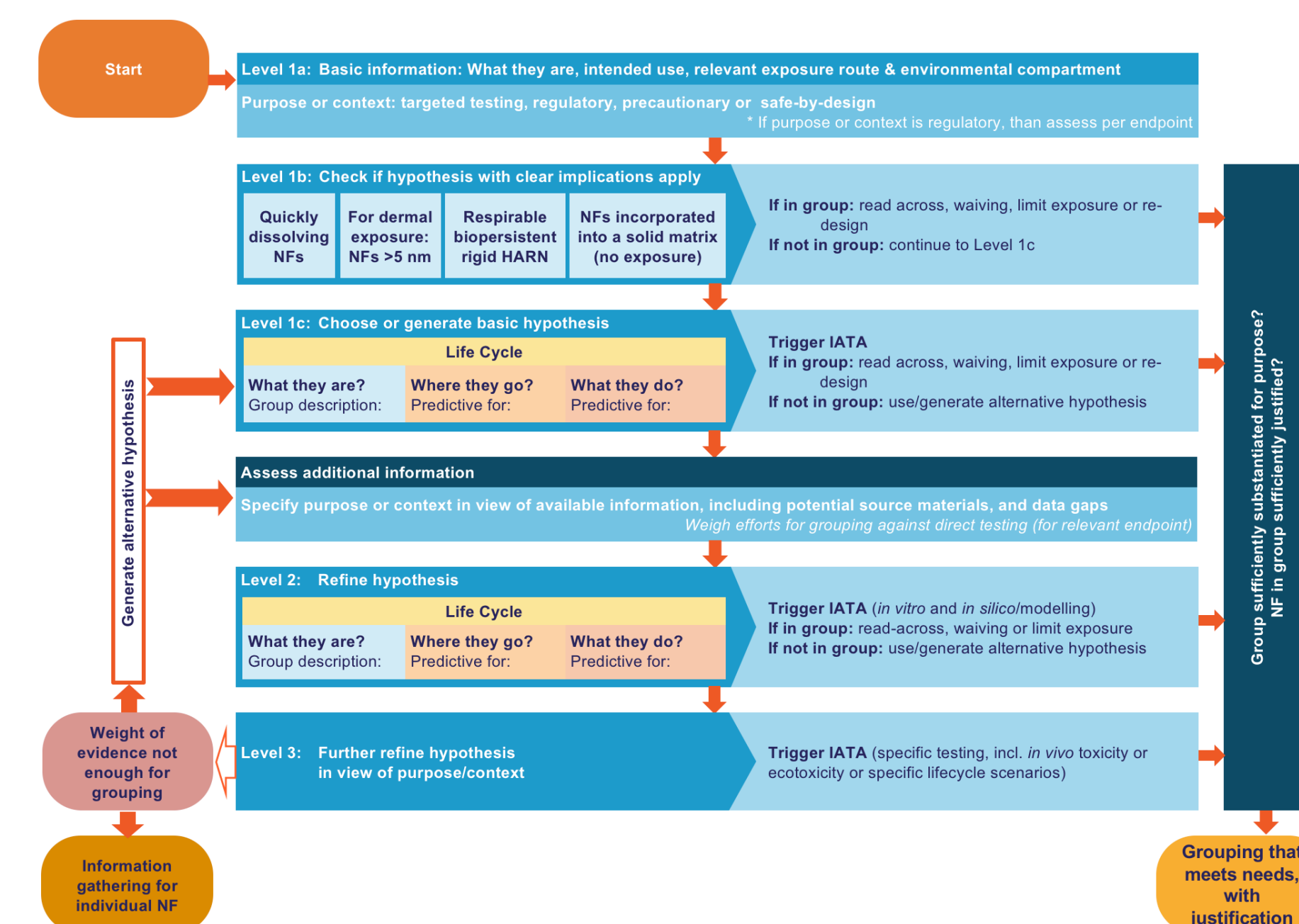
O2: Develop knowledge and generate data as the basis to derive **hypotheses**, criteria and guiding principles for grouping and read-across, as building blocks for the GRACIOUS Framework.

O3: Refine and integrate tools to build the GRACIOUS Framework, Guidance Document and software module.



Framework Design

- The GRACIOUS Framework builds on state-of-the-art grouping concepts developed by industry (DF4NanoGrouping, Arts *et al.*) and regulators (ECHA 2017).
- A basic suite of physical and chemical parameters is required to generate the basic grouping hypothesis.
- The basic hypothesis may be predefined (e.g. quickly dissolving NFs) or bespoke.
- The hypothesis triggers a tailored IATA that identifies the most relevant information, models and tests required.
- The Framework is an iterative process, where the hypothesis is refined and further studies are identified until a group description has been scientifically justified.
- A read-across justification may be developed.
- The Level 1 and 2 IATAs contain physicochemical, *in vitro* and *in silico* tests, whereas the Level 3 IATAs may contain regulated *in vivo* studies as a last resort.
- The Framework encompasses information on 'what they are', 'where they go', 'what they do' and 'life cycle'.



Expected Results

The Framework and its IATAs will be delivered as:

- An online software module fit-for-purpose for various key stakeholders (regulatory and industrial)
- A Guiding Background Document

Both the online module and the guiding background document will be designed for practical application to:

- Help industries and regulators assess environmental and human health risks of NMs/NFs cost-effectively
- Facilitate business decisions concerned with developing new nano-enabled products
- To inform Safety-by-Design practices

The GRACIOUS Framework and its grouping hypotheses will be tested to a set of case studies.

About the GRACIOUS Project

GRACIOUS develops a highly innovative science-based Framework to enable practical application of grouping, leading to read-across and classification of nanomaterials and nanoforms.



References

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No. 760840

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