

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



Vicki Stone<sup>1</sup>, Eric Bleeker<sup>2</sup>, Susan Dekkers<sup>2</sup>, Teresa Fernandes<sup>1</sup>, Judith Friesl<sup>3</sup>, Stefania Gottardo<sup>4</sup>, Andrea Haase<sup>5</sup>, Danail Hristozov<sup>6</sup>, Neil Hunt<sup>3</sup>, Nina Jeliaskova<sup>5</sup>, Helinor Johnston<sup>1</sup>, Frank von der Kammer<sup>7</sup>, Agnes Oomen<sup>2</sup>, Hubert Rauscher<sup>4</sup>, Dave Spurgeon<sup>8</sup>, Stella Stoycheva<sup>3</sup>, Claus Svendsen<sup>8</sup>, Soccoro Vazquez-Campos<sup>9</sup>, Alejandro Vilchez<sup>9</sup>, Wendel Wohlleben<sup>10</sup>

<sup>1</sup>Heriot-Watt University, Edinburgh, UK; <sup>2</sup>RIVM, Bilthoven, The Netherlands; <sup>3</sup>Yordas Group, Lancaster, UK; <sup>4</sup>JRC, Ispra, Italy; <sup>5</sup>German Federal Institute for Risk Assessment, Berlin, Germany; <sup>6</sup>GreenDecision, Venice, Italy; <sup>7</sup>Ideaconsult Ltd Sofia, Bulgaria; <sup>8</sup>University of Vienna, Vienna, Austria; <sup>9</sup>NERC, Wallingford, UK; <sup>10</sup>Leitat, Barcelona, Spain; <sup>11</sup>BASF, Ludwigshafen am Rhein, Germany

## 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.

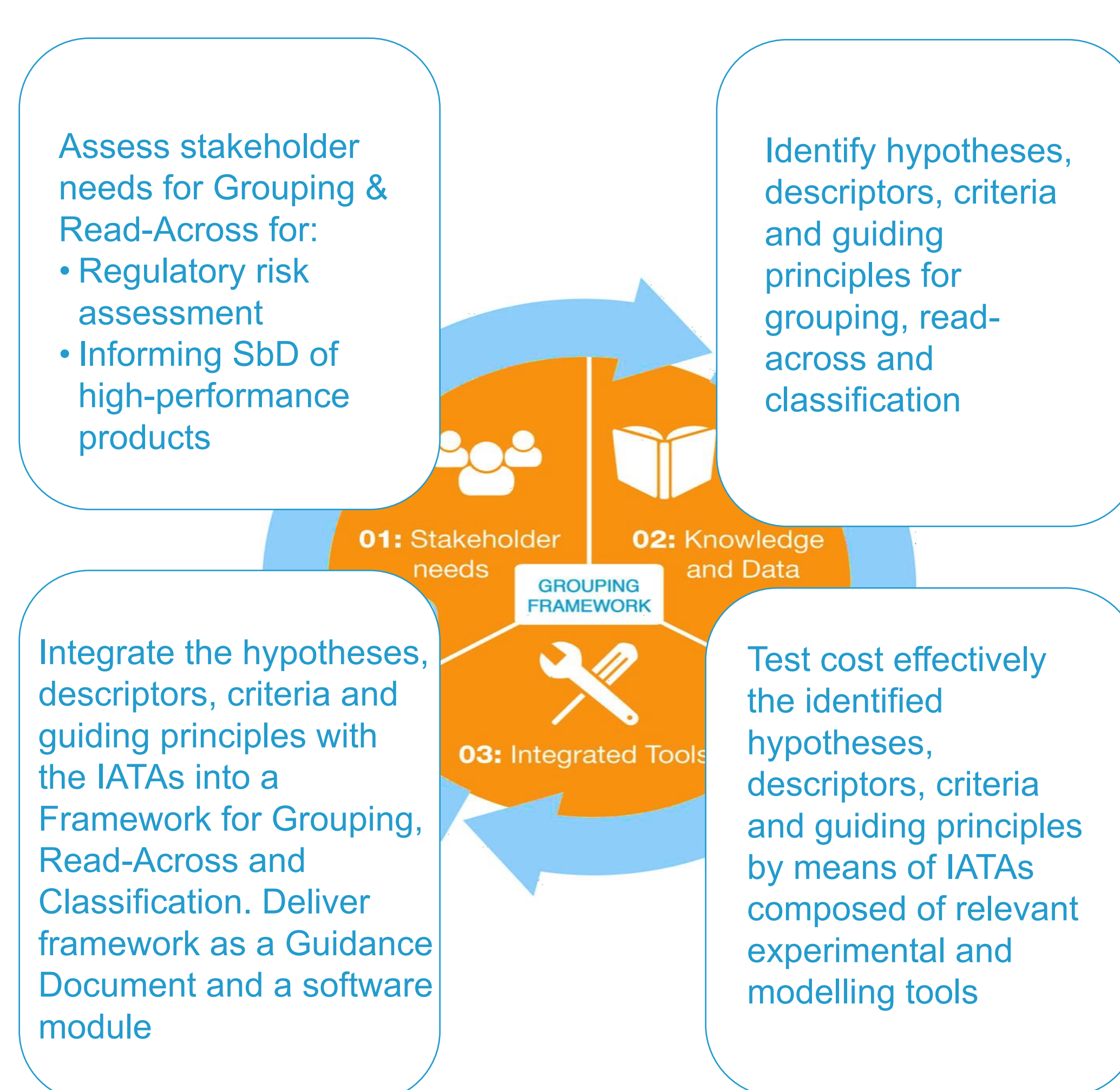
**GRACIOUS is developing a Framework to logically group NFs. The framework will allow use of (existing) data from similar NMs/NFs to extrapolate between (read-across) NFs, materials and substances, thereby reducing the need to assess exposure and toxicity on a case-by-case basis.**

### Objectives:

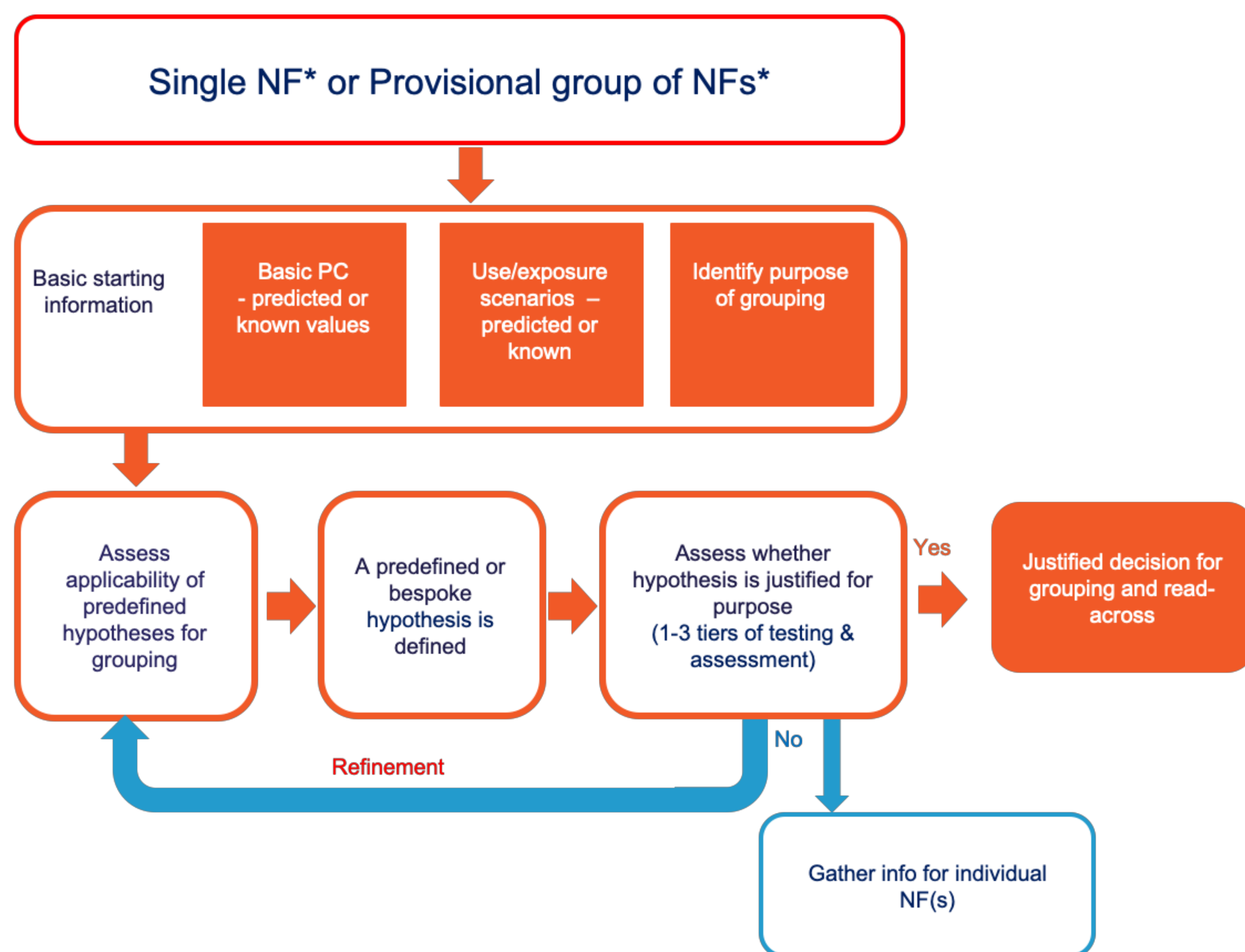
**O1:** Integrate key stakeholder needs with state-of-the-art thinking on grouping and read-across of NMs/NFs in order to design, develop and refine a sustainable Framework.

**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.



## Simple Framework Overview



\* If the purpose is to fill data gaps in regulatory REACH dossiers, then the same terminology applies as in the REACH Annexes 2.4: „NF“ stands for a single manufacturing output, or a „set of similar NFs“, if defined.

- Framework builds on state-of-the-art grouping concepts developed by industry (DF4NanoGrouping, Arts *et al.*) and regulators (ECHA 2017), along with extensive feedback provided by stakeholders.
- A basic suite of physical and chemical parameters is required to generate the basic grouping hypothesis.
- The basic hypothesis may be well-defined (e.g. quickly dissolving NFs) or user-defined.
- The hypothesis triggers tailored Integrated Approaches to Testing and Assessment (IATAs) that identifies the most relevant information, models and tests required.
- The IATAs span information on 'what they are', 'where they go', 'what they do' and 'life cycle'.
- The IATAs are comprised of tiers of increasing specificity to acquire the data needed to justify grouping and read-across.
- Early tiers include contain physicochemical, *in vitro* and *in silico* tests, whereas later tiers may contain regulated *in vivo* studies as a last resort.
- The Framework is an iterative process, where the hypothesis is refined and further studies are identified until a grouping decision has been scientifically justified.
- A read-across justification may be developed.

## 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 Framework and its grouping hypotheses will be tested using 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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[info@h2020gracious.eu](mailto:info@h2020gracious.eu)



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