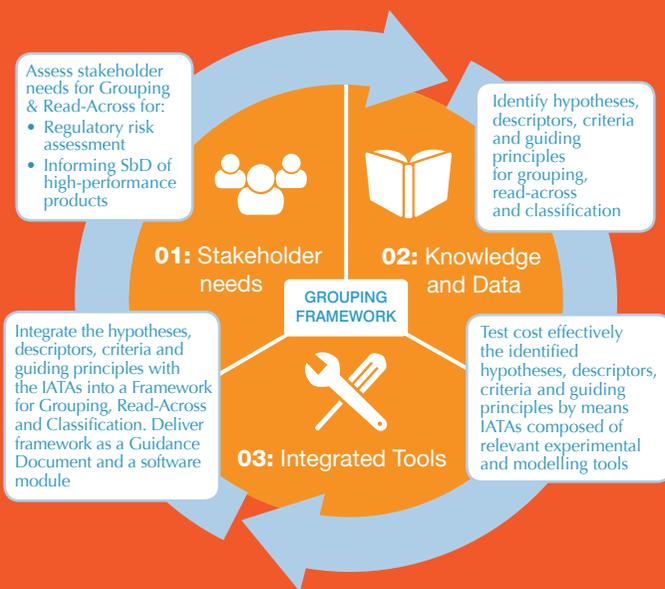


OBJECTIVES

- Integrate key stakeholder needs with state-of-the-art thinking on grouping and read-across of nanomaterials/nanoforms in order to design, develop and refine a sustainable Framework.
- Develop knowledge and generate data as the basis to derive hypotheses, criteria and guiding principles for grouping, leading to classification and read-across, as building blocks for the GRACIOUS Framework.
- Refine and integrate tools to build the GRACIOUS Framework, Guidance Document and software module.



PROJECT

GRACIOUS is a three and a half year EU project that runs from 2018 to 2021. It has a budget of about 7.1 million.

CONSORTIUM

GRACIOUS brings together 23 partners spanning Europe and the USA, including representatives from academia, industry, policy makers and regulators.



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

www.h2020gracious.eu



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

PROJECT OVERVIEW

The GRACIOUS project will develop a highly innovative science-based framework that supports the assessment of risk posed by the ever increasing array of nanomaterials on the market and under development. The framework will streamline the process for assessing their risk by logically grouping nanomaterials thereby allowing extrapolation between (read-across) nanomaterials and reducing the need to assess exposure to and toxicity on a case-by-case basis.

CONCEPT & STRUCTURE

WP1 will design and coordinate construction of the Framework, which will then be built by defining the descriptors and endpoints relevant to hypotheses generation for grouping and read-across (WP2-5).

To generate the knowledge and data needed to identify and test these hypotheses Integrated Approaches to Testing and Assessment (IATAs) will be developed to cover all domains of relevance for risk assessment:

1. Lifecycle environmental release and human exposure
2. What they are: physicochemical identity
3. Where they go: environmental fate, uptake and toxicokinetics
4. What they do: human and environmental toxicity

These descriptors and endpoints will define the tools needed to accept, reject or refine the hypotheses, which will then be built into a series of IATA s before integration into a Framework (WP6).

The IATAs will reduce, refine and replace (where possible) the need for animal testing by promoting the use of modelling (e.g. *in silico*, fate, exposure), *in vitro* and cell-free tests.

| WP1 Framework design and coordination of construction | | | |
|---|--|---|---|
| Lifecycle: Human exposure & environmental release WP2 Define release and exposure descriptions key to grouping | What they are WP3 Define descriptors of intrinsic physicochemical characteristics key to grouping | Where they go WP4 Characterise fate, uptake and toxicokinetics relevant to grouping | Where they go WP5 Identify relevant hazard outcomes relevant for grouping |
| Tools for defining release • Refine those that exist • Generate those that are missing | Tools for descriptors • Refine those that exist • Generate those that are missing | Tools for fate, uptake, toxicokinetics • Refine those that exist • Generate those that are missing | Tools for hazard outcomes • Refine those that exist • Generate those that are missing |
| IATA for tiered characterisation of release | IATA for tiered descriptor identification | IATA for tiered characterisation of fate, uptake and toxicokinetics | IATA for tiered hazard identification |
| WP6 • Integration of data/info to allow hypothesis generation • Integration of IATA for hypothesis testing | | WP6 • Data curation for new data during tool development • Data curation from which tools can draw data | |
| Stakeholder engagement, dissemination and exploitation WP7 | | Project coordination and management WP8 | |

EXPECTED RESULTS

The Framework and its Integrated Approaches to Testing and Assessment 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 existing NMs/NFs cost-effectively
- Facilitate business decisions concerned with developing new NEPs
- To inform Safety-by-Design practices