Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices

REFINE proposes a Regulatory Science Framework for the risk-benefit assessment of medical products and medical devices that are based on nanobiomaterials (NBMs).
Based on the identification of the most pressing regulatory challenges REFINE will identify the most suitable tiered decision and associated characterization methods where to then develop scientific knowledge associated to the adoption of NBMs.

The objectives of REFINE are:

- Identification of the most pressing regulatory and scientific challenges for nano(bio)material-based medicinal products and medical devices
- Development of a Decision Support System for the regulatory assessment of product
- Development and validation of new analytical or experimental methods
- Addressing harmonization needs
- Bridging involved communities and synergies across the sectors

Timeline: 1 December 2017- 30 November 2021

13 partners

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http://refine-nanomed.com/

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