Decision support tools to boost the regulatory approval of safer and innovative nano and biomaterials used in the medical sector

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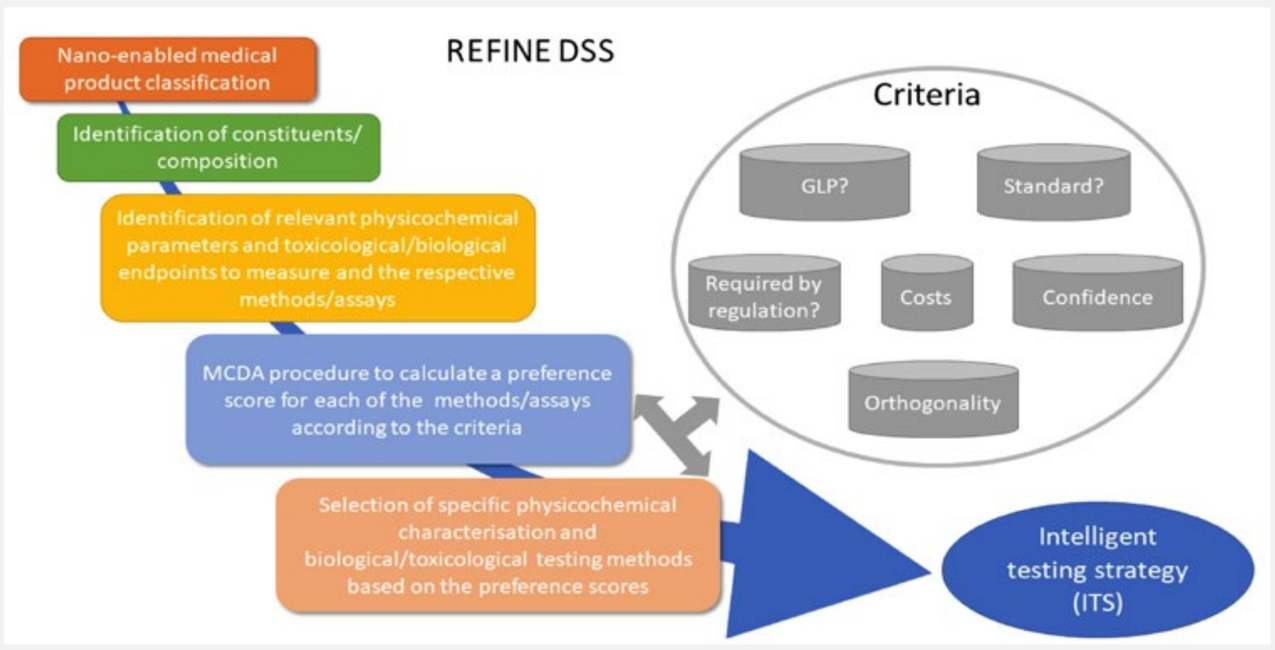
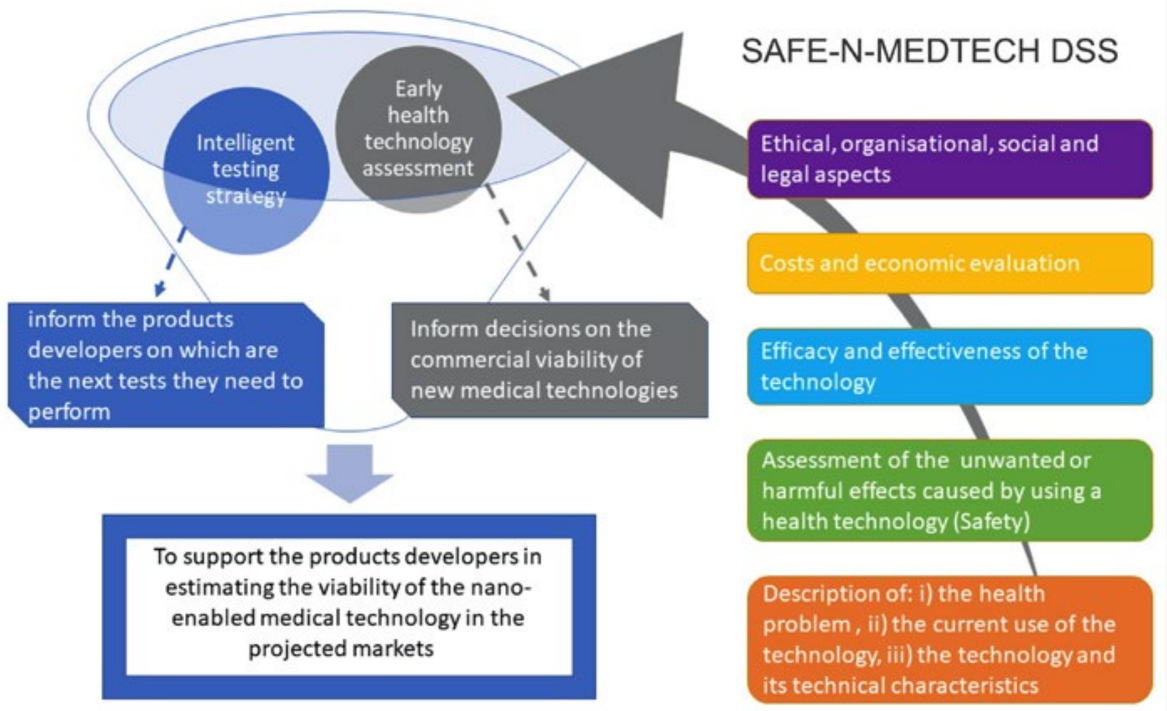
Introduction

Novel nano(bio)materials are being developed for use in a variety of medical applications such as nanopharmaceuticals, medical devices and tools for in vitro diagnostics. These novel medical technologies have demonstrated a strong potential for increasing the efficacy and safety of therapies, devices and diagnostic procedures to address a wide range of diseases. However, the successful translation of these technologies from their inception (proof-of-concept) to clinical practice has been challenged by substantial gaps in the scientific and technical capacity of R&D companies, especially SMEs, to address the ever evolving regulatory requirements in the emerging area of nanomedicine. To address these challenges, the EU Horizon 2020 projects REFINE and SAFE-N-MEDTECH are developing essential knowledge and tools to support the nanomedical industry in bringing their products faster to the market.



The REFINE Decision Support System (DSS) encompasses the information needed to implement an Intelligent Testing Strategy (ITS) (on the left side) and the criteria (in the gray circle) used by a Multicriteria Decision Analysis methodology to prioritize the available physicochemical and toxicological characterization methods for developing the ITS.

The SAFE-N-MEDTECH DSS implements two specific functionalities: the simplified Health Technology Assessment and the optimal ITS to cost-efficiently generate the data needed for assessing the safety of the medical technologies at each stage of the innovation process in order to successfully bring them to the market.



Conclusions

The REFINE DSS implements an intelligent testing strategy which provides a comprehensive set of preclinical characterization assays (physical, chemical, in-vitro and in-vivo etc.) to exhaustively characterize the nano-biomaterials to be assessed. The SAFE-N-MEDTECH DSS will implement a methodology for Early Health Technology Assessment of nano-enabled Medical Technologies. The two tools can be applied synergistically to inform go/no go business decisions at different stages of the product development based on considerations about safety, efficacy, quality, costs and socioeconomic criteria. Their implementation has the potential to substantially optimise R&D costs, while reducing the time of novel medical technologies to reach the market.

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