BIO RIMA

BIOmaterial RIsk MAnagement

In light of increasing regulatory demands on the use of medical devices (MD) and advanced therapeutic medicinal products (ATMP), the EU-funded BIORIMA project is taking a lead in developing an integrated risk management framework for the safe handling of nanobiomaterials (NBM) used in medical applications.

Here we highlight project outcomes in BIORIMA'S final year.

BIORIMA Project Overview

BIORIMA is developing:

- New tools and methods to assess human and environmental risks that may be associated with nano-structured biomaterials along their life cycle and for particular product value chains, including their production and use in different medical applications, possible release routes to the environment up to their final disposal.

- A web-based integrated risk management (IRM) framework to guide potential end-users (industries and regulators) to select and use the most appropriate tool or method to estimate the hazard of and exposure to NBM, and resulting risks associated with their production and use in medical applications, to meet new regulatory requirements and customer needs.

Integrated Risk Management Framework and DSS

The BIORIMA Integrated Risk Management Framework (IRMF) and web-based Decision Support System (DSS) have been further refined.

These major project outcomes offer various strategies for end-users, including regulators, manufacturers and users of NBM in medical devices (MD) and advanced medicinal therapeutic products (AMTP), to assess human health and environmental risks along their life cycle, in addition to clinical trials on their efficiency and side effects[1].

[1]Giubilato et al. 2020, Risk Management Framework for Nano-Biomaterials Used in Medical Devices and Advanced Therapy Medicinal Products, DOI:10.3390/ma13204532).

NBM Characterisation and Testing Data

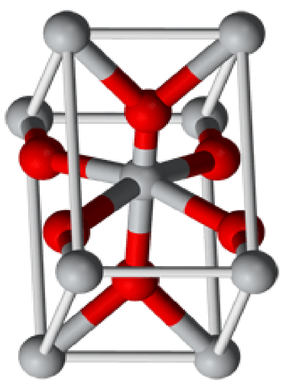
BIORIMA's multidisciplinary research team continues to update and improve the collection and curation of data and SOPs generated on the characterization and testing of NBMs.

Meanwhile, the ongoing comprehensive characterization campaign includes a large set of industrial and lab-scale NBMs to support exposure, fate and risk assessment, and the development of Safer by Design (SbD) tools: two major goals of BIORIMA. For this, we have followed up the properties and biotransformation of NBMs in relevant media, including different cell culture media, artificial gastrointestinal fluids, osteoarthritic synovial fluids, synthetic sweat, and artificial fresh and marine waters.

Safer by Design

The BIORIMA SbD approach was tested in three different case studies, including:

(1) Ag doped fibres for wound dressings;
(2) TiO2 based nanomaterials for sunscreen creams; and
(3) Fe-based NPs for theranostic applications, as representative test materials.



A specific case carried out by our Hong Kong University partner developed protective layers designed and synthesized for NBM to reduce their toxicities.

These material devices included porous silica dioxide and biocompatible amorphous carbon to coat AgNPs. In addition, an alternative green support was prepared for drug delivery from the inter-crosslinking of two biocompatible polymers.

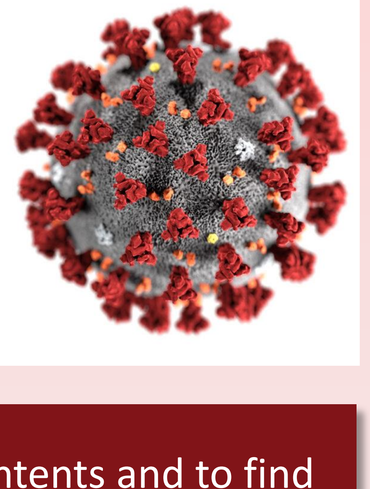
Human and Environmental Exposure

Studies on the development of human and environmental exposure assessment tools, devices and probabilistic models have been finalised, as has a simulation of a massive release of NBM. Leeds University succeeded in developing novel methods to assess the release of NBMs from the fracture/fatigue/tear of medical implants into the body. Based on these methods ISO and CEN standards for implants have been developed.

New results have been published on the assessment of human health (WU) and environmental effects (UAVR) of NBMs using *in vitro* (cell culture) and *in vivo* (animal) studies. As part of this research, the role of the bio-corona formation on NBM toxicity has been further investigated and suitable methods developed to study the composition of the protein corona and its interaction with NBMs.

The COVID-19 Task Force

In response to the EU call to participate in the global effort to combat the COVID-19 pandemic, BIORIMA has formed a COVID-19 task force and has already published a peer-reviewed paper on the use of nanomedicine against the SARS-COV-2 virus, showing the great potential of results produced to contribute to the control of the pandemic.



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