

Abstract: BIOPRAXIS faces drug development for rare cancers, including glioma and pancreatic cancer, using nanotechnology and biological molecules like proteins and peptides. Moreover, is also working in controlled release systems through nanoparticles (Solid Lipid Nanoparticles, Magnetic Nanoparticles, Lipid Nanovesicles), which improve therapeutic action of APIS and allow protection of biological molecules and targeting, imaging and future theragnostic of different diseases including cancer. BIOPRAXIS and some European Entities have worked previously in this area in projects as THERAGLIO project (Contract n FP-602923), MULTIFUN a finished FP7 project and HEATDELIVER: Heat and Drug Delivery nanosystem with active tumortargeting features (Eurotransbio project).

Based on the knowledge obtained, project NoCanTher (H2020-685795) aims at translating one of these nanoformulations to early clinical development for pancreatic cancer. The therapy is based on the functionalization of iron oxide nanoparticles using a targeting peptide and anti-cancer drugs, together with the effect of hyperthermia generated by an external alternate magnetic field. To successfully reach this objective, we will concentrate our efforts in two main group of activities:

- Nanomedicine up-scaling under GMP conditions: NoCanTher will scale up the manufacturing of the proposed nanoformulation from milligram-scale laboratory synthesis up to multigram-scale production to generate sufficient material for clinical and regulatory assays. To this aim, a GMP production line will be optimised and the relevant quality control will be conducted at the different stages of the up-scaling process.
- Clinical trial: NoCanTher will include late preclinical parameter testing to raise a clinical treatment protocol, regulatory assays, as well as the design of the clinical trial and the preparation of the Investigational Medicinal Product Dossier (IMPD). This strategy will allow us to apply for

Clinical Trial Authorisation (CTA) then, we will carry out a Phase I clinical trial. NoCanTher involves the participation of institutions from three different sectors (academia, industry, clinical) and from five different countries (Ireland, France, Germany, Spain and the UK).

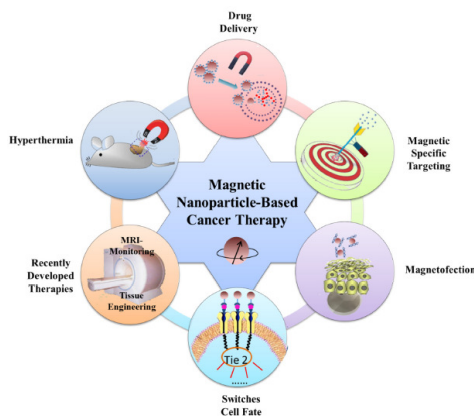


Figure 1: Figure illustrating the process.

References:

- [1] Multifunctionalized iron oxide nanoparticles for selective drug delivery to CD44-positive cancer cells, IOP Journal, Nanotechnology 27 (2016) 065103 (10pp)
- [2] Efficient treatment of breast cancer xenografts with multifunctionalized iron oxide nanoparticles combining magnetic hyperthermia and anti-cancer drug delivery, Breast Cancer Research, Kossatz et al. Breast Cancer Research (2015) 17:66.

