Nano to Clinic – Synergies for Clinical Translation of Nanotechnology in Cancer Therapies

Date: March 3rd, 2023

Venue: Školska knjiga dd (Great Hall), Masarykova 28, Zagreb, Croatia

Nanotechnologies fundamentally change the current therapies and enable development of novel treatments and diagnostic approaches. The improvements in medical therapies and diagnostic achieved through innovative medical nanoproducts has a great and direct clinical importance and provide benefits for the patients. Hence, best practices in design and development of such nanoproducts will contribute to societal prosperity and welfare, by providing access to better and safer treatments.

This meeting aims to strengthen relations between industry, R&D&I sector, regulatory agencies, clinics, and patients with the ultimate goal of fostering the clinical translation of nanomedicine from bench to bedside. By promoting scientific exchanges, technological implementation and innovative solutions, the meeting will enable dialogue for rationalizing and focusing research efforts at the EU level in dealing with the grand challenge of nanomedicine translation for cancer therapies.

The meeting will focus on several factors that need to be discussed and considered in order to achieve the best societal impact:

1) *Safety aspects*: by discussing the best practices for the application of the Safe-by-Design concept during early stages of development and production of novel medical nanoproducts.
2) *Regulatory aspects*: by discussing necessary steps for regulatory acceptance of novel nanoproducts.
3) *Training and education aspects for a solid skilled workforce and patients*: by facilitating and expanding cross-disciplinary training for researchers, medical care providers, public health professionals working in industry, government, and academia, as well as for patients.

Organizer:
NANO2CLINIC: *Cost Action* CA17140 - Cancer nanomedicine - from the bench to the bedside

Nano2Clinic
Cancer Nanomedicine - from the bench to the bedside

cost
EUROPEAN COOPERATION IN SCIENCE & TECHNOLOGY

Supported by:
PHOENIX-OITB: Pharmaceutical Open Innovation Test Bed for Enabling Nano-pharmaceutical Innovative Products

Phoenix

SENDER: Safe-by-Design Approach for Development of Nano-Enabled-Delivery Systems to Target the Brain

SENDER

Local organizer:
Institute for Medical Research and Occupational Health, Zagreb, Croatia

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Funded by the European Union

The PHOENIX-OITB project receives funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 953110. COST Action CA 17140 "Cancer Nanomedicine from the Bench to the Bedside" is supported by COST (European Cooperation in Science and Technology). SENDER Safe-by-Design Approach for Development of Nano-Enabled-Delivery Systems to Target the Brain is a project financed within the "Research Cooperability" Program of the Croatian Science Foundation funded from the European Social Fund.

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P R O G R A M M E

Time	Title	Presenter
9:00-9:30	*Registration*	
9:30 - 9:50	**Welcome and introduction**	**Ivana Vinković Vrček** (CA17140 WG2 leader, Phoenix WP5 leader, SENDER coordinator) **Irena Brčić Karačonji**, Vice Director of the Institute for Medical Research and Occupational Health (IMI) **Ivica Malnar**, Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
9:50 - 10:30	**Cost Action CA17140 Nano2Clinic achievements**	**Sabrina Pricl**, CA17140 Chair
10:30 - 11:10	**PHOENIX-OITB project presentation**	**Nazende Günday-Türeli**, Phoenix Scientific Coordinator
11:10 - 11:50	*Coffee break*	
11:50 - 12:30	**Best practice: clinical translation of orphan nanodrug**	**Elisabet Gonzales,** Smart4Fabry Scientific Manager
12:30 - 13:10	**Best practice: nanotool for cancer diagnostic**	**Marija Plodinec,** ARTIDIS AG
13:10 - 14:00	*Lunch break*	

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Time	Title	Presenter
14:00-14:40	**International regulatory advances for Nanomedicines and their follow-ons.** The rise of bio- and nano-technologies has accelerated the development of complex medicines, and at the same time it has revealed new hurdles in regulatory science and is accelerating patient access to new and follow-on therapies. The diverse nature of complex medicines, including nanomedicine, poses challenges for the development of regulatory guidelines. This presentation will focus on the international regulatory advances made in this field and will highlight some of the differences between the regulatory frameworks and what it means for those developing complex drugs and their follow-on products.	**Jon de Vlieger**, Strategy Director Foundation Lygature
14:40-15:20	**The importance of having the right policies and regulations in place to ensure Patient safety – the case for nanomedicines.** The EU Nanomedicines Regulatory Coalition, believes that the EU needs a specific regulatory framework for nanomedicines and their off-patent follow-on copy products nanosimilars, to ensure patient safety. Currently, nanomedicines in the EU can be assessed under four different types of procedure: the national procedure, the decentralised procedure, mutual recognition, and the centralised procedure. This has led to strong regional differences in the regulation of nanomedicines and allows for the marketing of many different brand names, which in turn makes pharmacovigilance linkage difficult and thus compromises patient safety. The coalition has called on the EU to establish a framework whereby all nanomedicines and nanosimilars are assessed through an EMA centralised regulatory procedure. The presentation will discuss the advocacy campaign that is aiming to achieve this.	**Mike Isles**, Executive Director of the European Alliance for Access to Safe Medicines (EAASM)

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Time	Title	Presenter
15:20-16:00	**Novel Approaches to Theranostic Nanomedicine Design.** Nanomedicine represents one of the fastest growing fields of research in recent years, encompassing both therapeutics and diagnostics. All advances in nanomedicine are driven by material development on the nanoscale, with many applications established through fundamental research and design of novel nanomaterials. Theranostics, the combination of therapeutic and diagnostic nanomedicne, offers a platform towards personalised, precision medicine through the design of composite materials which act as drug carriers as well as diagnostic imaging probes.	**Marco Giardiello,** University of Liverpool, British Society for Nanomedicine
16:00-16:30	*Coffee break*	

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16:30-17:10	**Target efficacy vs. off-target risk of nanodrugs - lessons learned from individualization of chemotherapies using co-clinical organoid test system.** Discovery of lead candidates for the development of new therapies accounts for one of the earliest stages in drug development. Although - compared to clinical programs – the overall financial burden in this phase is rather low, in later stages of the development program can hardly corrected suboptimal decision-making and often leads to study termination. The main goal of our work is to utilize *in vitro* technologies as companion diagnostics to guide the selection of clinical guideline treatment options for systemic therapy of our patients in adjuvant/ palliative care setting. Given the clinical predictive value, alongside the opportunity to interrogate clinical follow up data of the original donor and associated molecular data, we believe our in vitro adversity scoring drug-testing pipeline has values for early stage assessment of nanomedicine interventions, particular those aiming to tackle resistance of cancer to standard of care therapy. Aspects on methods reporting-stringency and quality control to ensure functional stability of subjected biological test matrix to minimize heterogeneity of results in confirmatory assays, will also be discussed.	**Ulf Kahlert**, Otto-von-Guericke-Universität Magdeburg Medizinische Fakultät
17:10 - 17:50	**Regulatory aspects of clinical translation of nano-enabled products.** Nanomedicines have demonstrated clear advantages over their standard counterparts, raising significant attention from funding bodies and regulatory agencies alike. Yet those promising results have not achieved clinical translation at a similar pace. This presentation will focus on regulatory barriers and challenges hampering their potential in clinical practice and will look into current activities envisaged to bridge the gap between lab research and industrial manufacturing.	**Blanca Suarez Merino,** Regulatory Affairs Director from the Nanotechnology Industries Association (NIA)

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Time	Title	Presenter
17:50 - 18:20	**Risk Assessment in Nanomedicine**	**Maria Dusinska**, RiskGone Project Coordinator
18:20 - 18:40	Round table discussion	All
18:40 - 19:10	*Closing ceremony*	
19:10 - …	Dinner	Local organizer

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