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# Presentation of PHOENIX-OITB and its Open Call



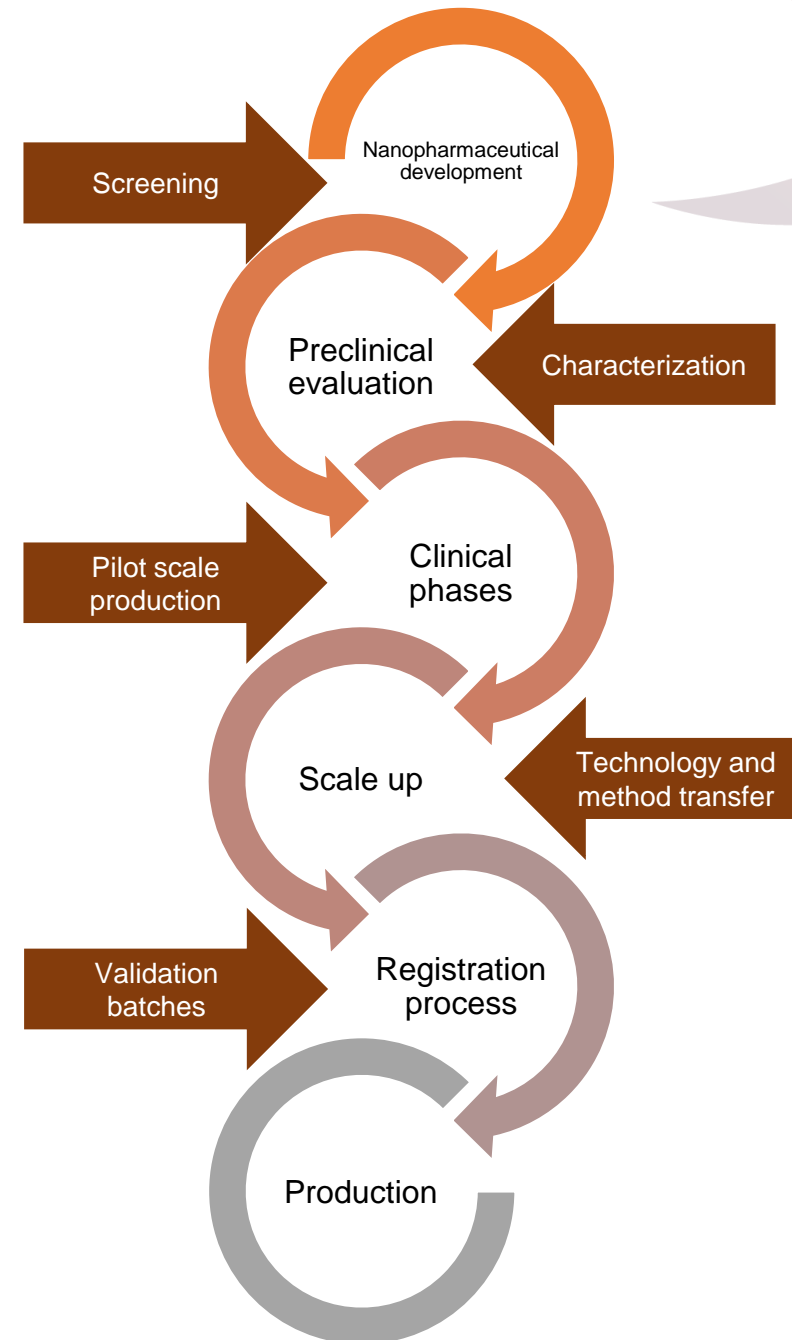
# **Pharmaceutical Open Innovation Test Bed for Enabling Nano-pharmaceutical Innovative Products**

## **Presentation of the OITB and ist Open Call**

# Specific Challenges

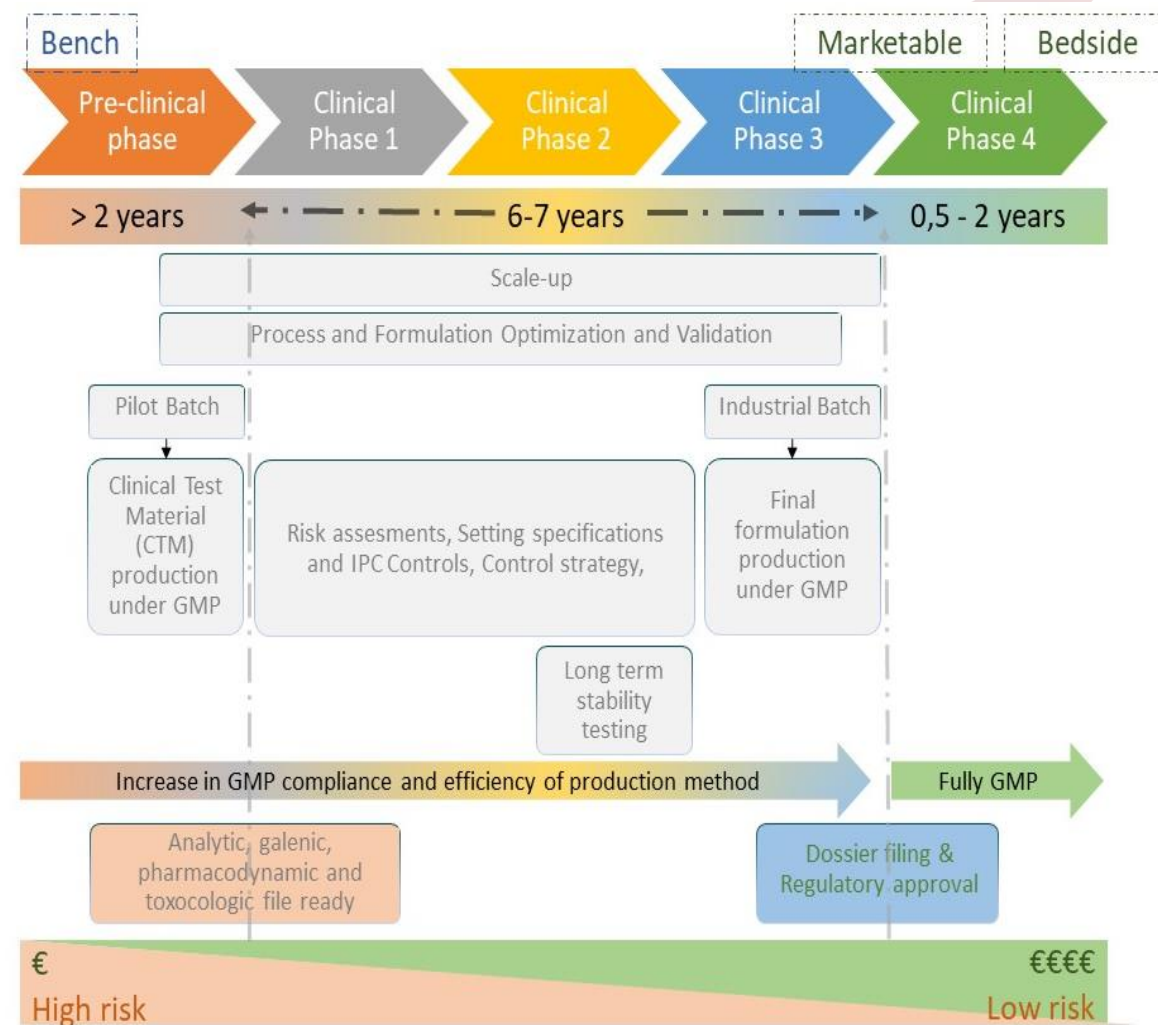
## DT-NMBP-06-2020: Open Innovation Test Beds for nano-pharmaceuticals production (IA)

- **Many novel promising lab PoC nano-pharmaceuticals across Europe and the world.**
  - Strong potential for providing more effective and safer therapies and diagnostic procedures for a wide range of diseases.
- **Major challenge to produce the novel nano-pharmaceuticals to GMP quality in sufficient quantity for late pre-clinical and clinical testing**



# Specific Challenges

- Main prerequisites for successful implementation: Affordable and advanced testing, manufacturing facilities and services for novel nano-pharmaceuticals
- Difficulties in industrial-scale production in terms of the product quantity and quality required for them entering clinical trials



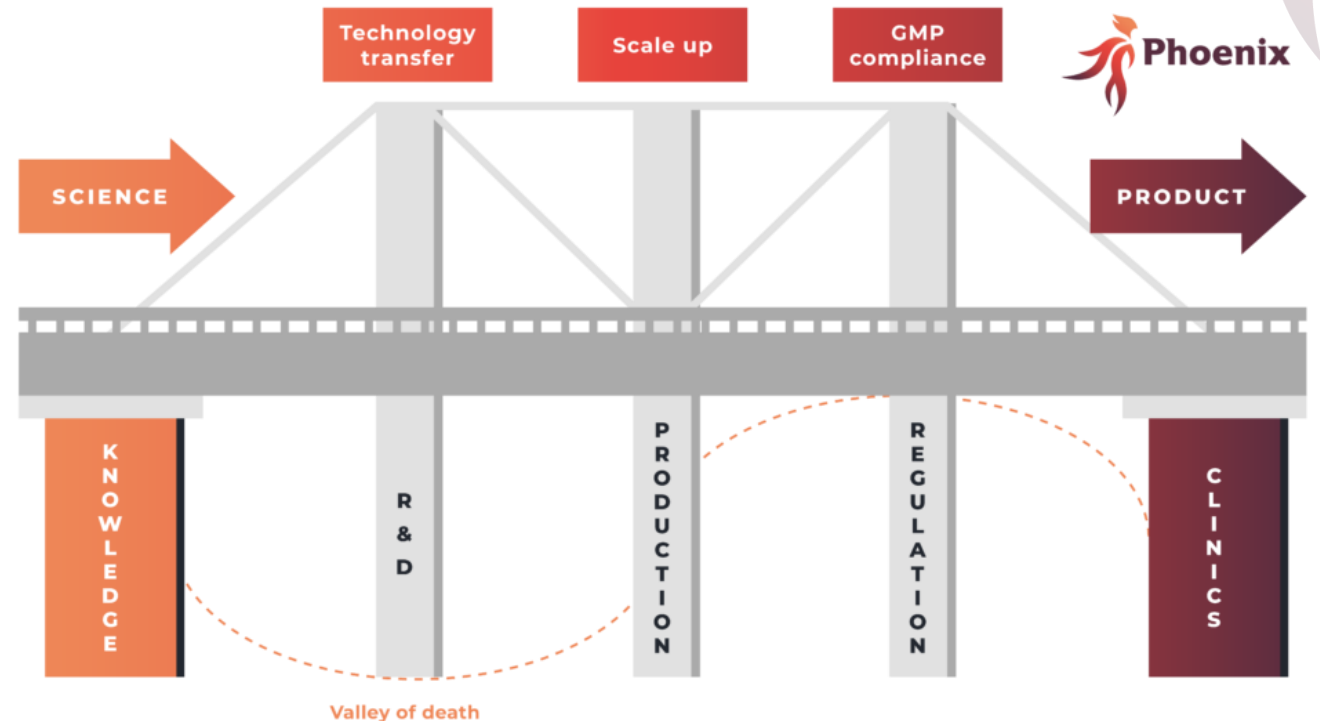
Nazende Günday-Türel, Akif Emre Türel, "Upscaling and GMP Production of Nanopharmaceuticals Drug Delivery Systems" in *Drug Delivery Trends: Volume 3: Expectations and Realities of Multifunctional Drug Delivery Systems*, edited by Ranjita Shegokar, Elsevier, 2020, p215-23



# Our Objective: Enabling Nano-pharmaceutical Innovative Products

**PHOENIX** bridging the innovation valley of death between science and nano-pharmaceutical product

...to enable the **seamless, timely and cost-friendly** transfer of **nano-pharmaceuticals** from **lab bench** to **clinical trials** by providing the necessary **advanced, affordable and easily accessible** PHOENIX-OITB.

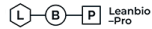


# PHOENIX Consortium

LIVERPOOL  
INSTITUTE OF SCIENCE  
AND TECHNOLOGY



NANOMOL  
TECHNOLOGIES



- 1 LIST
- 2 MyB
- 3 NT
- 4 LB
- 5 BNN
- 6 CSIC
- 7 IMROH
- 8 RCPE
- 9 CENYA
- 10 TT
- 11 GB
- 12 RECENDT



CSIC  
CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS



Topas Therapeutics



12 partners across Europe came together for responding to the current and future needs and challenges in bringing the newly developed nano-pharmaceuticals from the bench to the bed side.



# PHOENIX Consortium

Project budget of €14.45M and a requested EU contribution of €11.1M.  
12 partners

- providing their own resources and services to boost the first implementation phase and Phoenix-OITB service generation already at M1
- responding to the current and future needs and challenges in bringing the newly developed nano-pharmaceuticals from the bench to the bed side

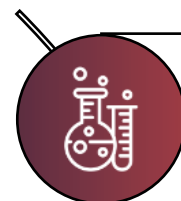


12 partners across Europe came together for responding to the current and future needs and challenges in bringing the newly developed nano-pharmaceuticals from the bench to the bed side.





# PHOENIX Concept & Service Strategies



## Physico-Chemical Characterisation

Services to perform an accurate physicochemical characterization, including techniques to characterize not only nanoparticles but also small and large molecules (synthetic or biological ones) as well as the characterization of the conjugated.



## In vitro Characterisation

Services that permit an extensive *in vitro* characterisation of the nanomedicine under development, allowing specific and critical questions to be answered related to its toxicity, like cytotoxicity, cell viability, sensitization & irritation, etc.



## In vivo Characterisation

Services that allow to cover part of the pre-clinical *in vivo* characterisation of the nanomedicine under study. Most of the assays available follow OECD/ICH test guidelines.



## Manufacturing

Services needed for the scale-up until the GMP manufacturing of a nanopharmaceutical.



## Innovation

Services that help the customer reach its goals. Transversal and complementary services to the ones in the other categories, equally necessary when developing novel nanopharmaceuticals.





# PHOENIX Work Plan

## Service portfolio establishment:

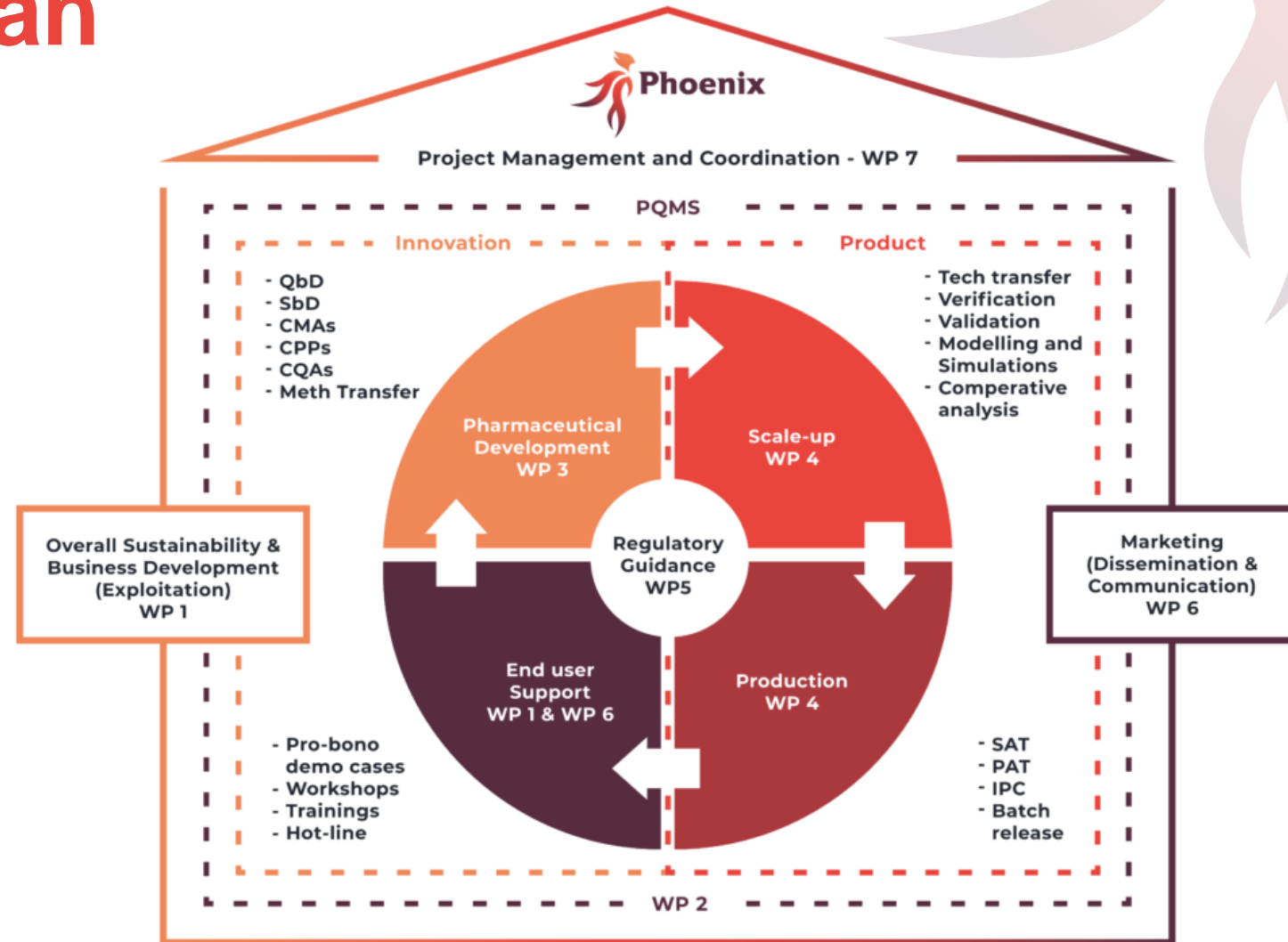
### 5 demo cases covering:

- **3 delivery routes**
  - i.v., oral, skin
  - + 1 diagnostic agent
- **4 nano-pharmaceutical types**
  - nanocrystals, lipid vesicles, particle conjugates
  - + polymeric diagnostic agent

## Service portfolio validation:

### 2 pro-bono demo cases covering:

- open call
- any end-user for any service
- up to 100% of costs covered by PHOENIX project



# PHOENIX Open Call

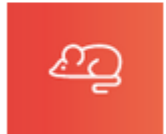
## Offering funded services in 4 areas:



Physico-Chemical Characterisation



in vitro Characterisation



in vivo Characterisation



Manufacturing

## Who can apply?

- Any legal entity (SME, start up or RTO) and research group, based in the European Union or associate countries of H2020

## Timeline

- Apply by 31<sup>st</sup> January 2023
- Notice given by 1<sup>st</sup> March 2023
- 2<sup>nd</sup> stage application due 31<sup>st</sup> March 2023

All info: <https://www.phoenix-oitb.eu/open-call/>



# PHOENIX Open Call

Offering funded services in 4 areas:



## Physico-Chemical Characterisation

- Surface Properties
- Moisture/Dry, Mass
- Size & Distribution
- Structure
- Morphology
- Composition
- Chemical Stability
- Particle concentration
- Drug (API) release kinetics
- Free/Encapsuled API Sterility



## in vitro Characterisation

- Composition
- Bioactivity
- Immunocompatibility
- Immunoresponse
- Extraction of targeted cells
- (A)cellular reactivity & cytotoxicity
- Cell viability
- Cel. struct.,
- Uptake & localisation,
- Inflammatory response
- Endocytosis/Exocytosis
- Sensitization & Irritation
- Cytotoxicity
- Genotoxicity
- Nanomechanical prop. of cells & tissues
- Dose metrics
- Microbial evaluation
- Transcriptomics
- Metabolomics
- Proteomics
- Gene expression



# PHOENIX Open Call

Apply by 31 Jan 2023!  
[www.phoenix-oitb.eu/open-call/](http://www.phoenix-oitb.eu/open-call/)

## Offering funded services in 4 areas:



### in vivo Characterisation

- Biodistribution
- Hemocompatibility
- Pharmacokinetics
- Pharmacodynamics
- Acute, Sub-acute & Repeated Dose systemic toxicity
- Reproductivity toxicity



### Manufacturing

- Manufacturing of liquid, semi-solid, solid nanoparticle formulations with a special focus on extended release parenterals
- lipid based formulations and nanovesicles
- Liposomes
- solid lipid nanoparticles
- crystalline nanoparticles, polymeric nanoparticles
- inorganic nanoparticles
- On-site lyophilization and fill and finish capabilities.

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Medicine  
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**THANK YOU FOR YOUR  
ATTENTION!**