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

Dr. Nazende Günday-Türeli

Nano2Clinic – Synergies for Clinical Translation of
Nanotechnology in Cancer Therapies

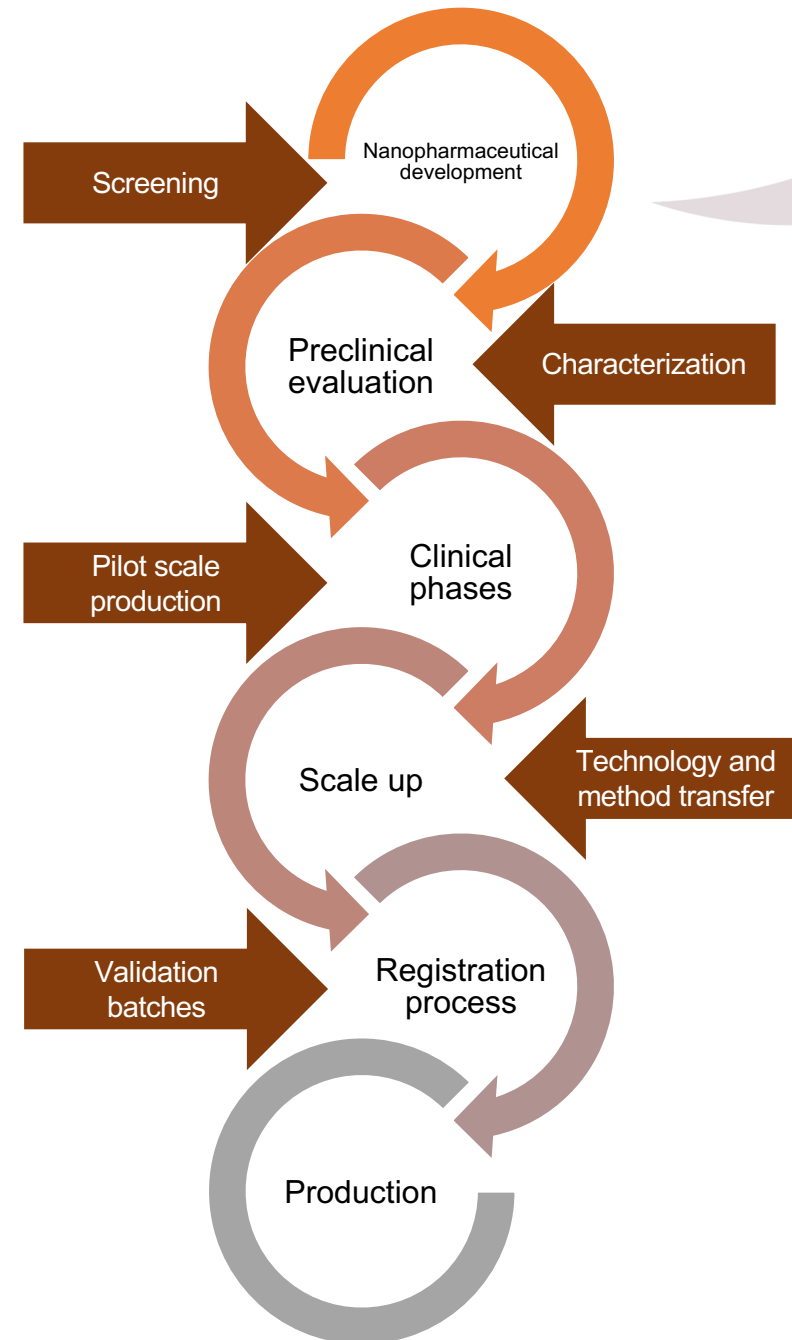
03.03.2023



Specific Challenges

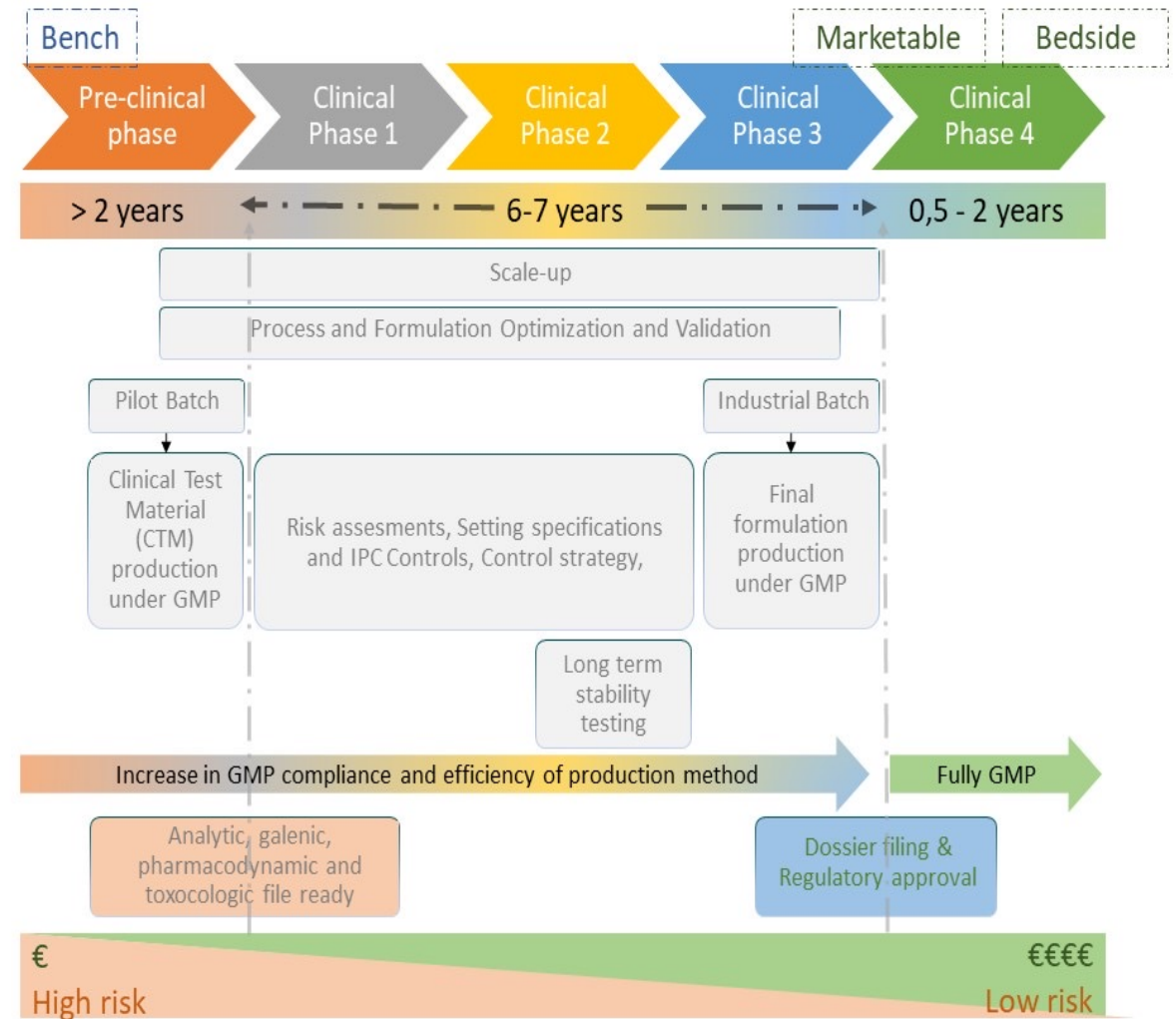
DT-NMBP-06-2020: Open Innovation Test Beds for nano-pharmaceuticals production (IA)

- **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

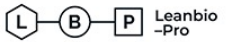


Nazende Günday-Türeli, Akif Emre Türeli, "Upscaling and GMP Production of Nanopharmaceuticals Drug Delivery Systems" in *Drug Delivery Trends: Volume 3: Expectations and Realities of Multifunctional Drug Delivery Systems*, edited by Ranjita Shegokar, Elsevier, 2020, p215-23



PHOENIX Consortium

- **12 partners** across Europe
- Coming together for **48 months** (01.03.2021 – 28.02.2025)
- Sharing project budget of **€14.45 million** and a requested **EU contribution of €11.1 million**
- Providing their own **resources and services** to boost the first implementation phase and **PHOENIX-OITB service generation** from M1
- 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

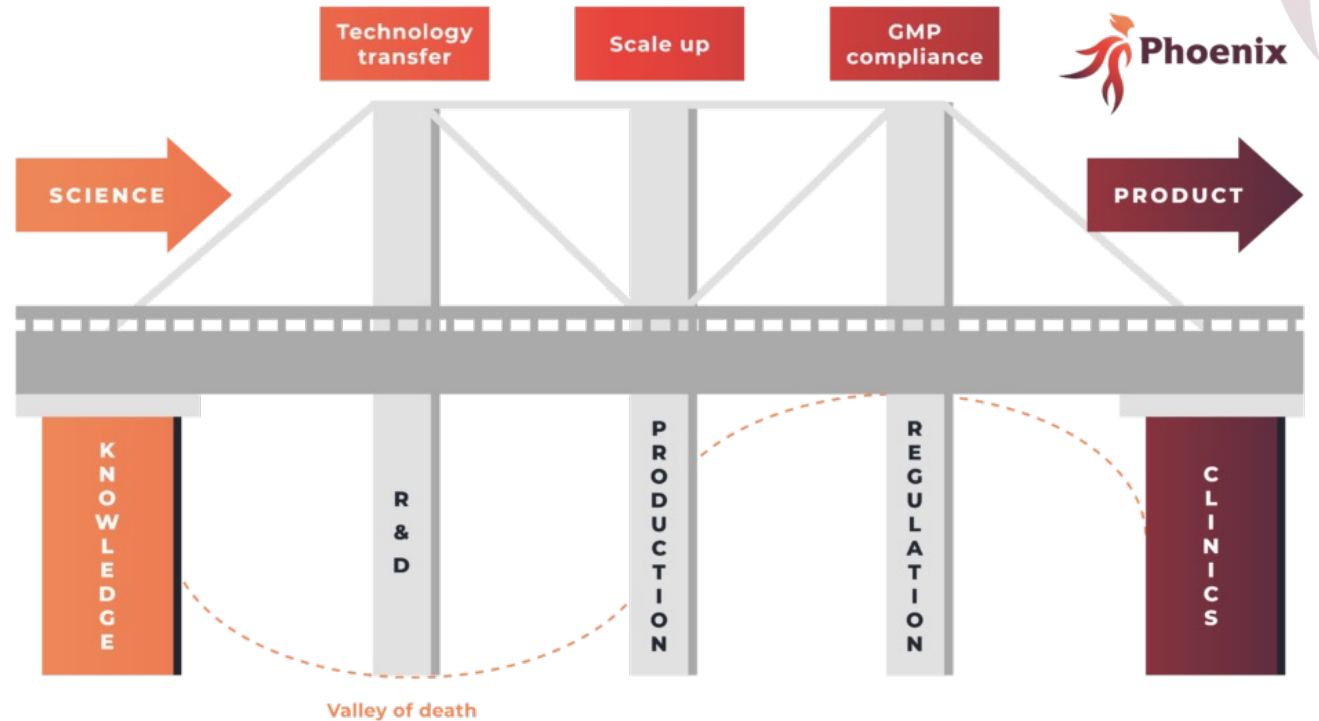
PARTNERS



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 Concept & Service Strategies

A non-profit, self-sustained, independent legal entity

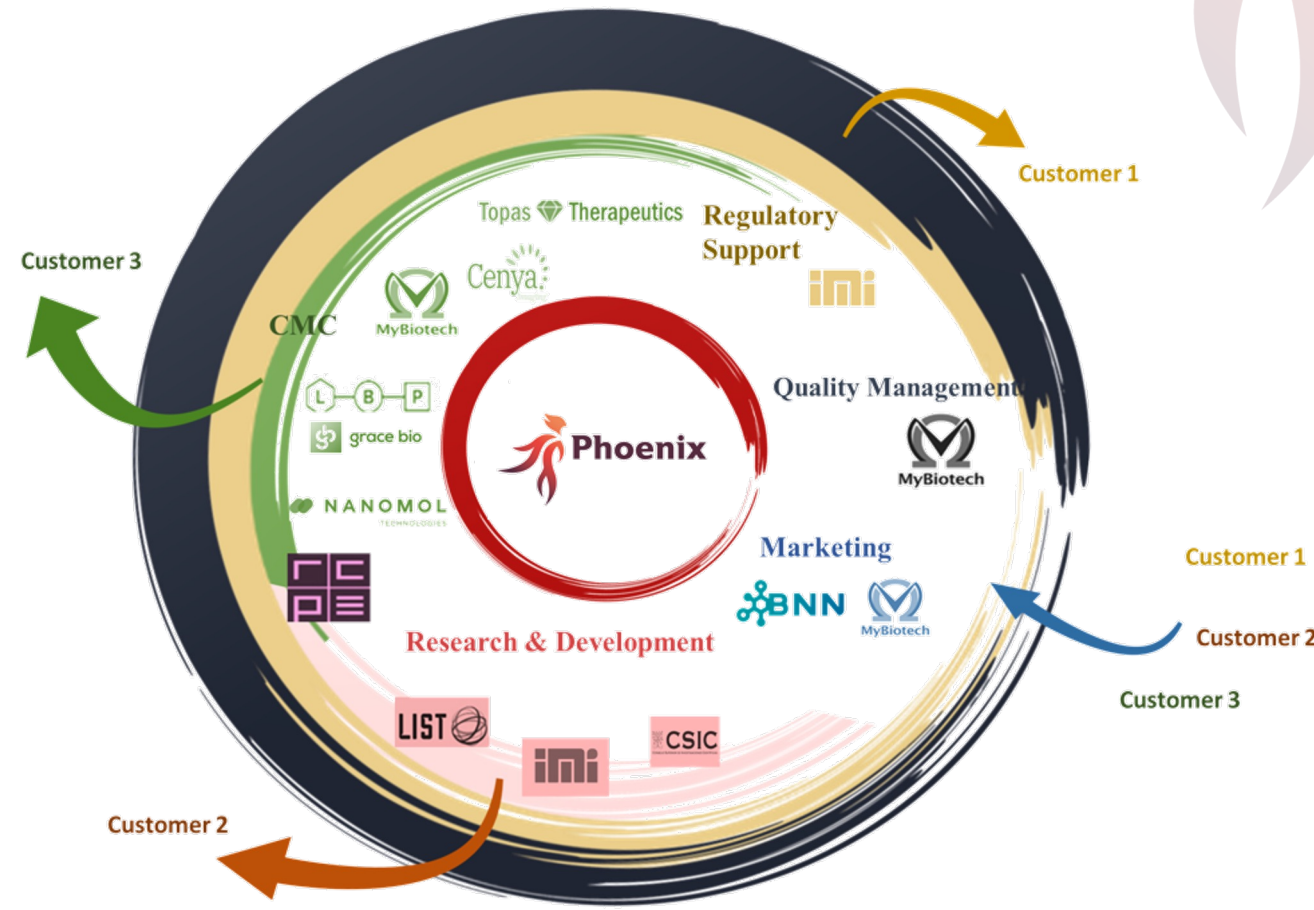
- enabling a smooth transfer from lab scale to GMP grade product covering all necessary QES, regulatory, and upscaling aspect
- creating an eco-system in the nanomedicine field to foster a thriving economy



PHOENIX Concept & Service Strategies

One-stop Shop

- “SEP” for any end-user with all level of R&D&I activities from lab to market
- Access to R&D&I and manufacturing facilities and services across Europe at fair conditions through SEP
- Reduced costs for production and regulatory compliance
- Harmonized conditions of PQMS for testing, QES characterization, scale-up and GMP production
- Accelerated development stages, thus market entry
- Paving the way for commercial and industrial implementation.

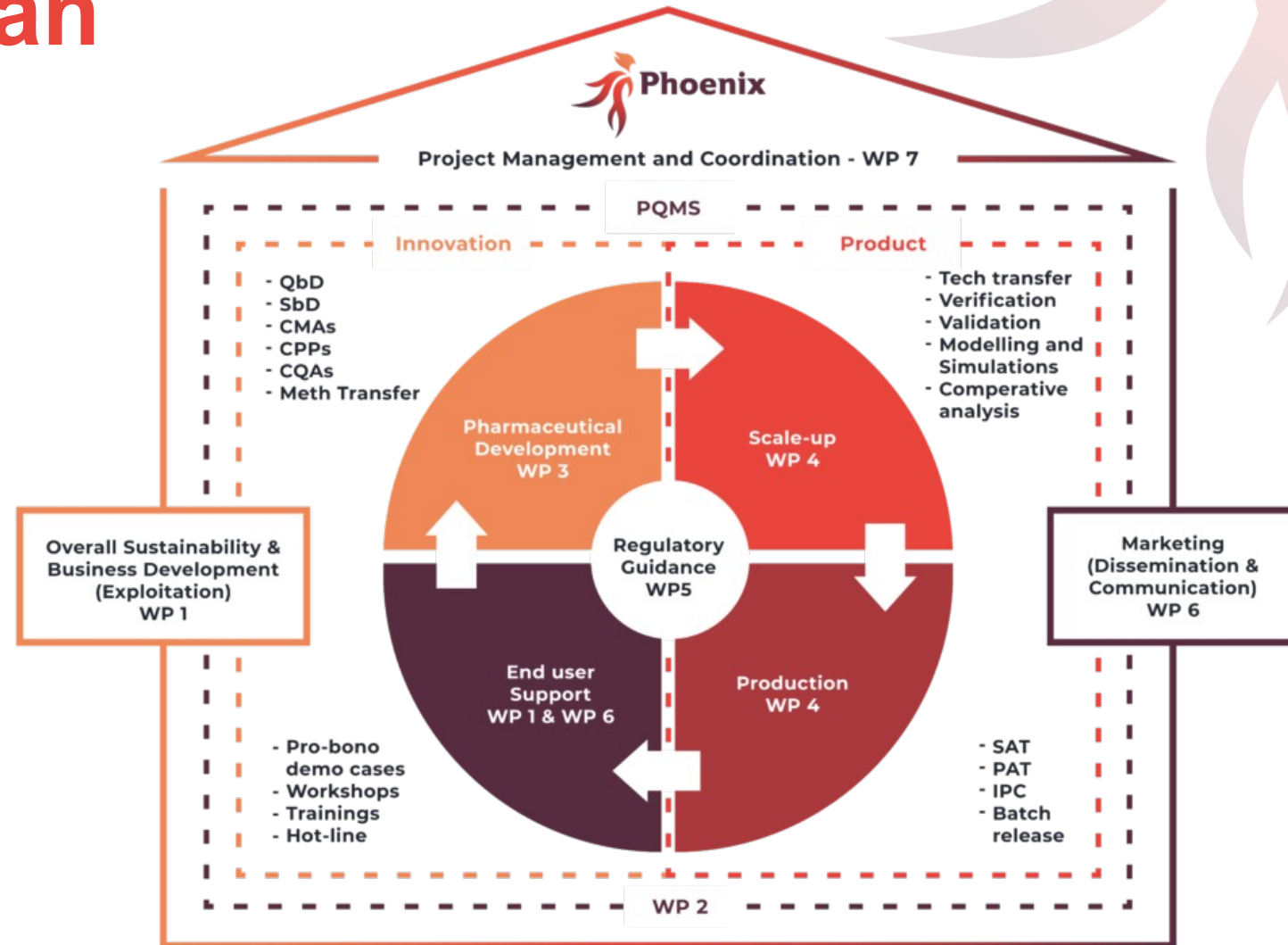


PHOENIX Work Plan

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

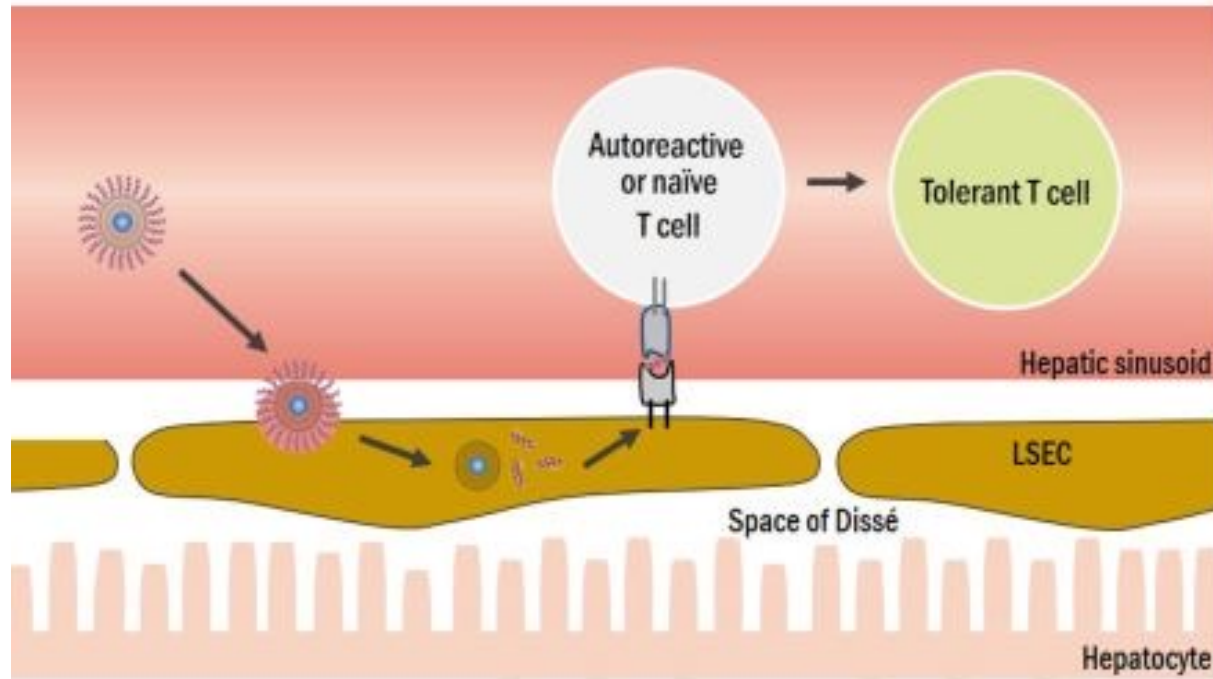




— DEMO CASE

Polymer-based diagnostic agent





2

— DEMO CASE

Polymeric particle conjugates loaded with small peptides



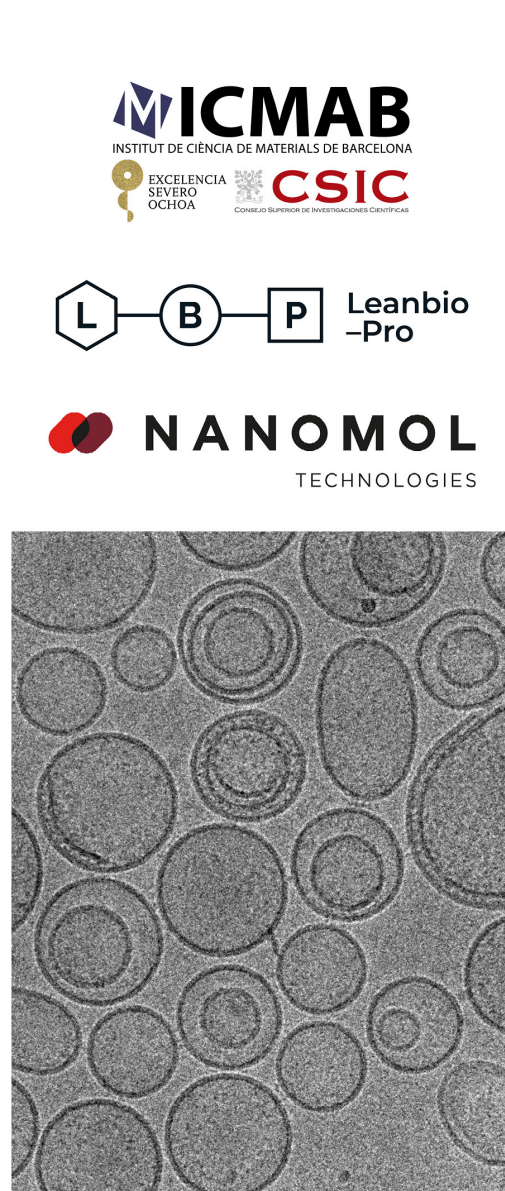
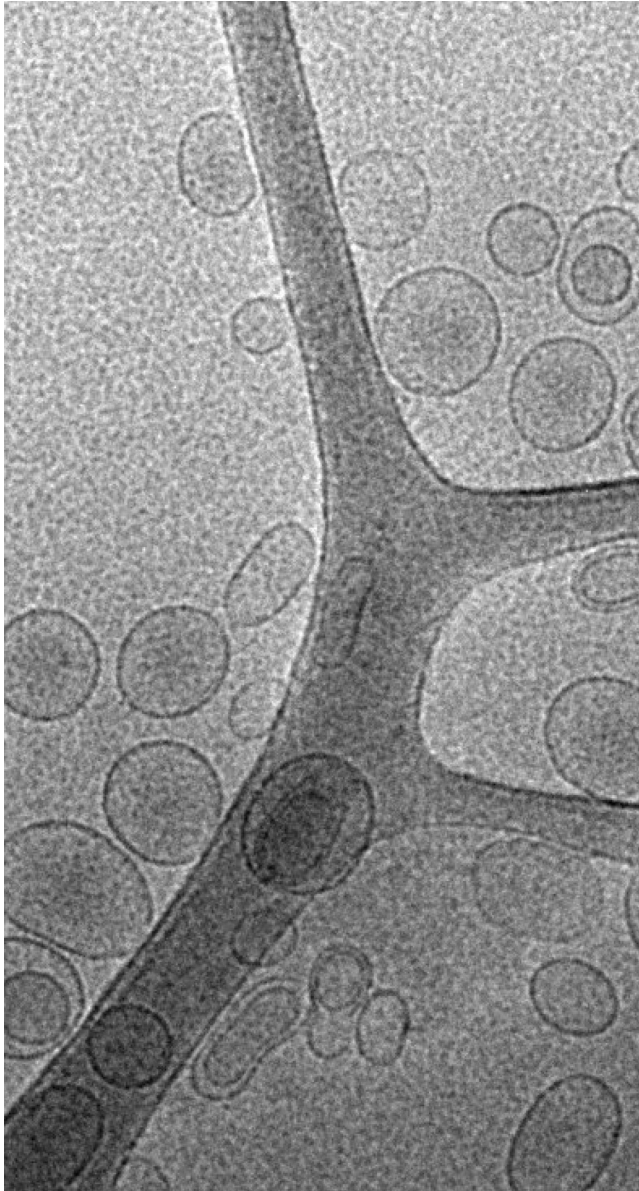


3

— DEMO CASE

Nanocrystals for oral drug delivery



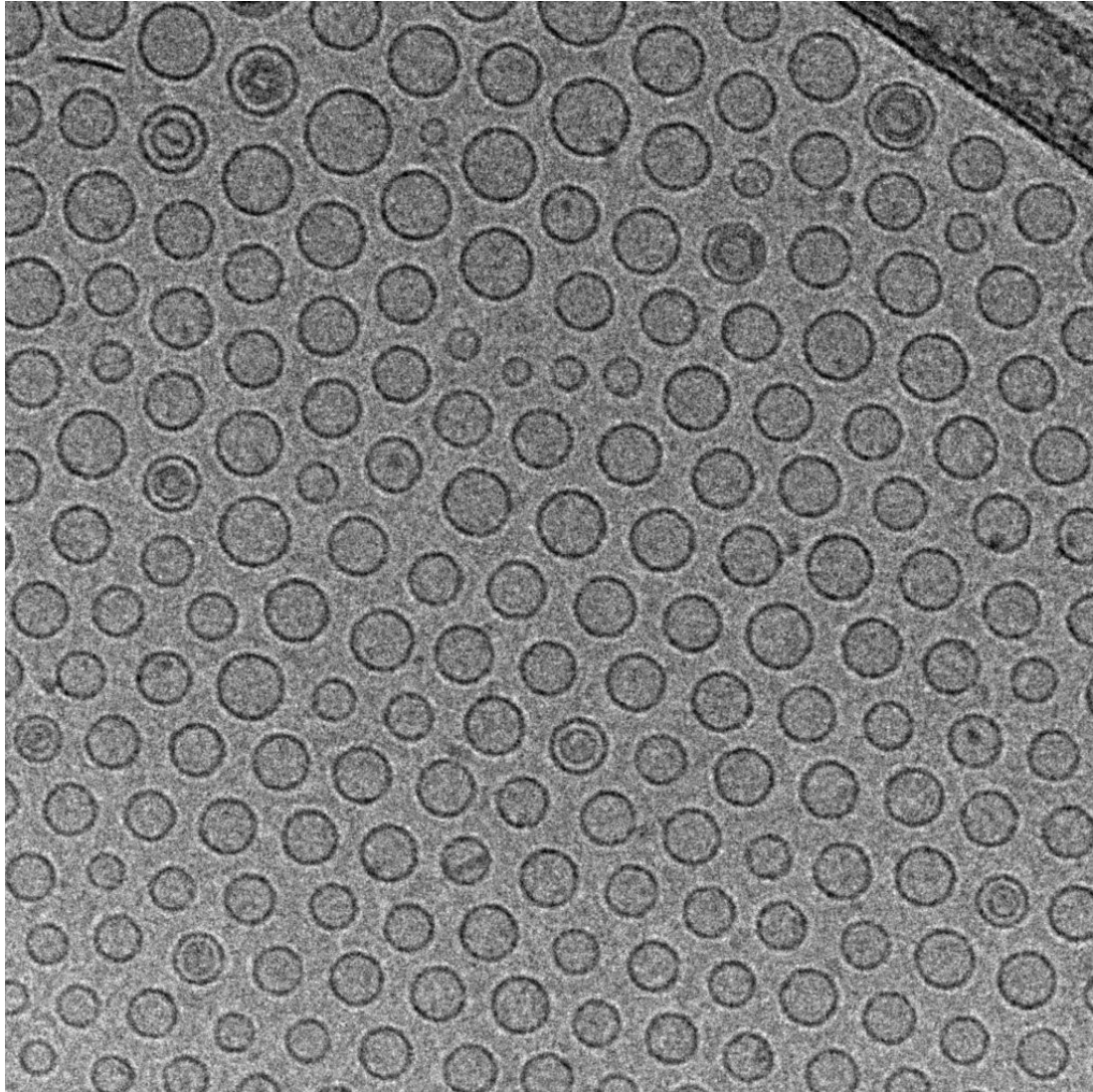


4

— DEMO CASE

Nanoliposomes loaded with an enzyme for intravenous administration





 **NANOMOL**
TECHNOLOGIES

5

 **MICMAB**
INSTITUT DE CIÈNCIA DE MATERIALS DE BARCELONA
 **EXCELENCIA SEVERO OCHOA**  **CSIC**
CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS

— **DEMO CASE**

Antimicrobial nanovesicles for topical administration



PHOENIX Work Plan

Service portfolio establishment:

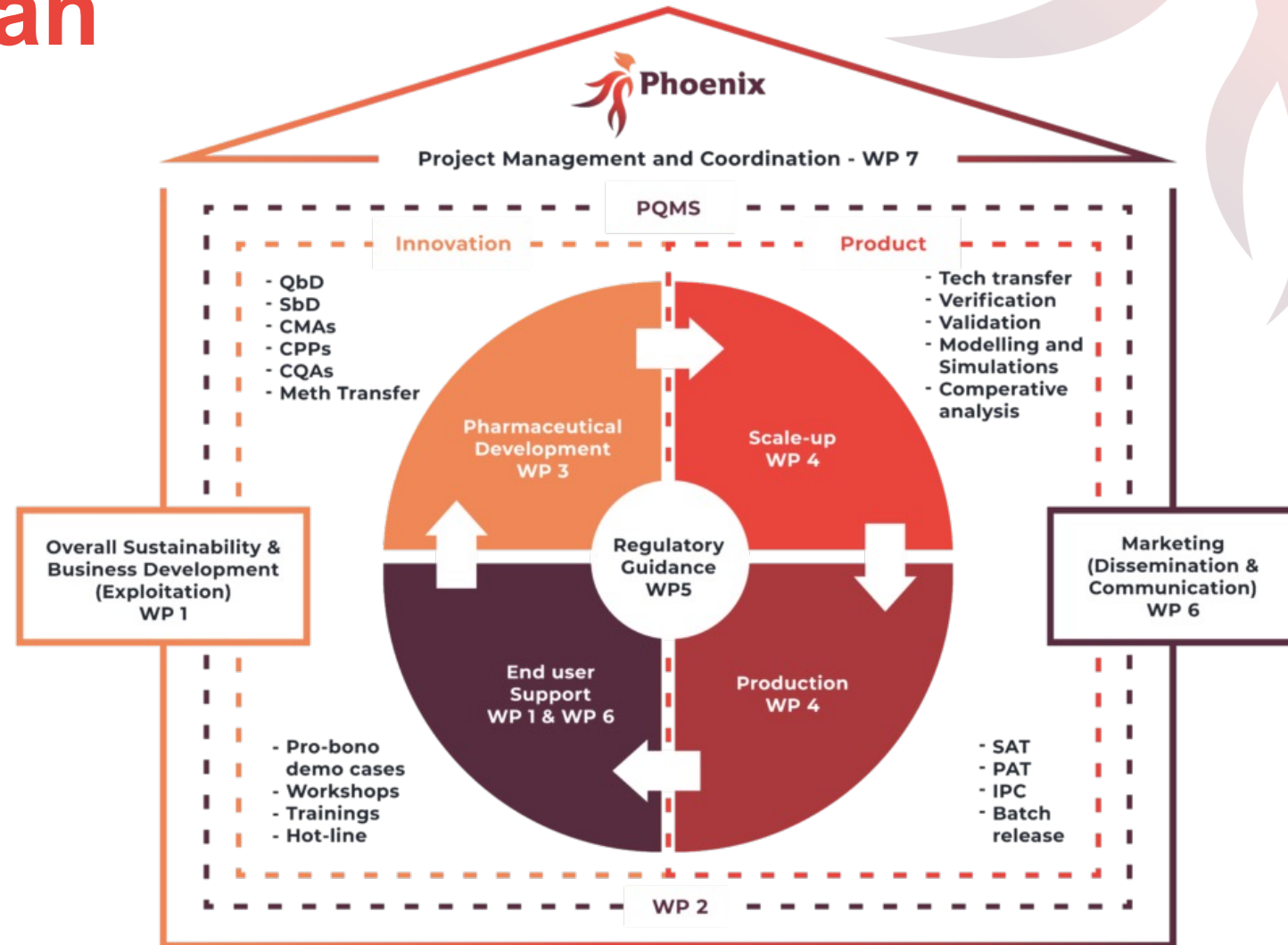
5 demo cases covering:

- **3 delivery routes**
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 - + 1 diagnostic agent
- **4 nano-pharmaceutical types**
 - nanocrystals, lipid vesicles, particle conjugates
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Service portfolio validation:

2 pro-bono demo cases covering:

- open call
- any end-user for any service
- all costs covered by PHOENIX project



PHOENIX Open Call

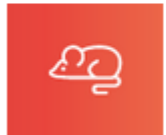
Offering funded services in 4 areas:



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 28 Feb 2023
- Notice given by 31 Mar 2023
- 2nd stage application due 30 June 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

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.

STATUS

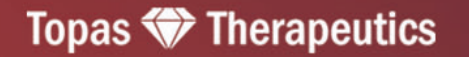
- 10 applicants
 - 4 countries (FR, ES, IT, UK)
 - 6 SMEs



Phoenix-OITB

- improve the European infrastructure and competence in nano-pharmaceutical process development, characterisation, quality control and production
- increase of the attractiveness of Europe as a location-of-choice to carry out advanced medical and nano-pharmaceutical research and product development
- improve nano-pharmaceuticals supply capacity and availability of a rich eco-system of related suppliers of products and services





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