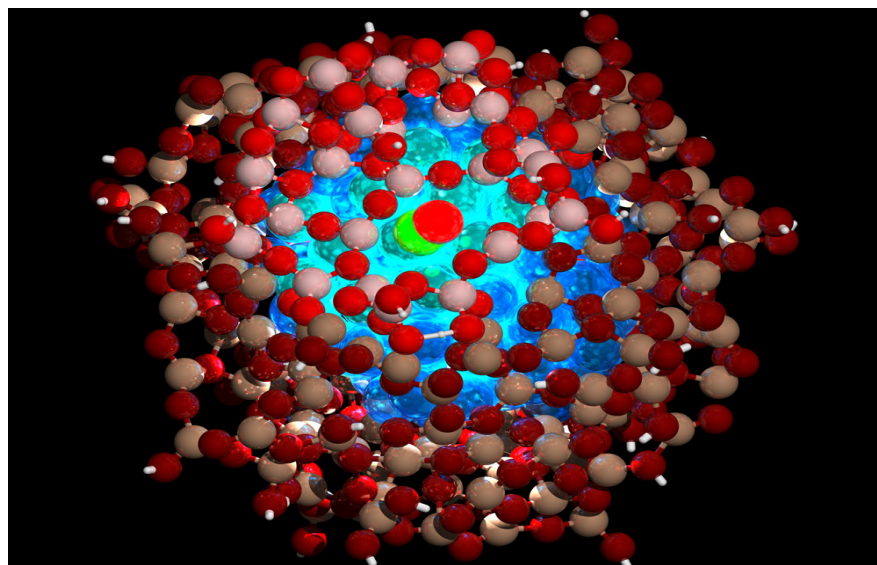




NoCanTher "Nanomedicine upscaling for early clinical phases of multimodal cancer therapy"

H2020-NMP-2015-two-stage GA 685795

NoCanTher: Nanomedicine Upscaling for Early Clinical Phases of Cancer Therapy



Ing. Oihane Ibarrola
Scientific Responsible for Process Technologies
Research & Development Division

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Outline

- Who we are
- Why is it necessary? → Pancreatic cancer
- Project description
 - Concept
 - Objectives
 - Stage of development
- Perspective





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Organización Sanitas Internacional: Healthcare Services

OSI is a healthcare specialized group of companies that comprises several healthcare providers and a network of hospitals and health centers.

OSI also includes educational institutions and societal-oriented companies that complement our health services in the market.

OSI has its own network of third and fourth level hospitals and Comprehensive medical centers for outpatient care with:

- ✓ Dental clinics
- ✓ Diagnostics centers
- ✓ Ophthalmological surgery
- ✓ Diagnostic imaging units
- ✓ Network of clinical laboratories
- ✓ Optical stores and pharmacies



All streamlined for a comprehensive, personalized and multidisciplinary approach.

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New Developments in other geographical areas and the establishment of R&D&i

GLOBAL PRESENCE



 Where we are  Where we head to

OSI by the numbers

- ✓ 14.000 employees
- ✓ 3.5 M users
- ✓ 941 cities
- ✓ 7 Hospitals
- ✓ 60 *medical centers*
- ✓ 57 Laboratories
- ✓ 1 University (UNISANITAS)
- ✓ 2 Foundations



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PRAXIS PHARMACEUTICAL

Services and Key Expertise



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PRAXIS PHARMACEUTICAL

Services and Key Expertise



Full formulation development, including:

- Biologics, peptides
- Micro and nano-encapsulation to enhance stability and for controlled release formulations



Analytical method development and validation



Process development and scale-up



cGMP manufacturing, release and stability studies for:

- Clinical trial material
- Small commercial scale (Orphan drugs)
- Cell Therapies

Full service from formulation development to clinical batches and commercial manufacturing

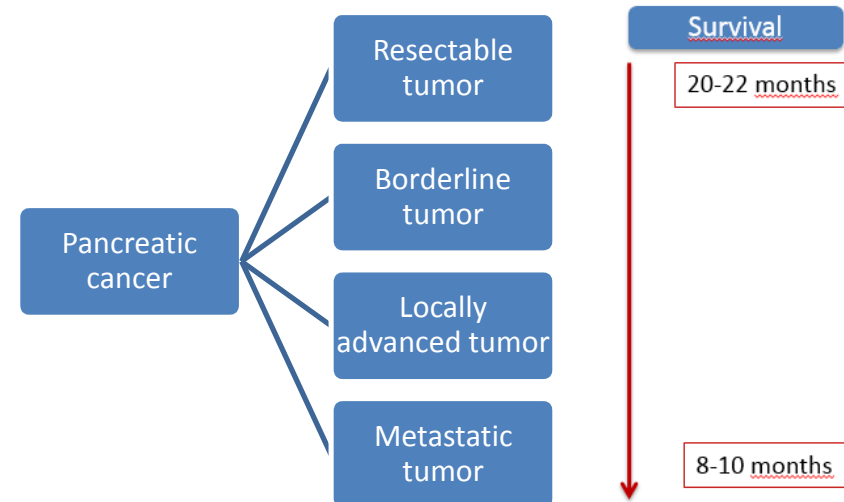
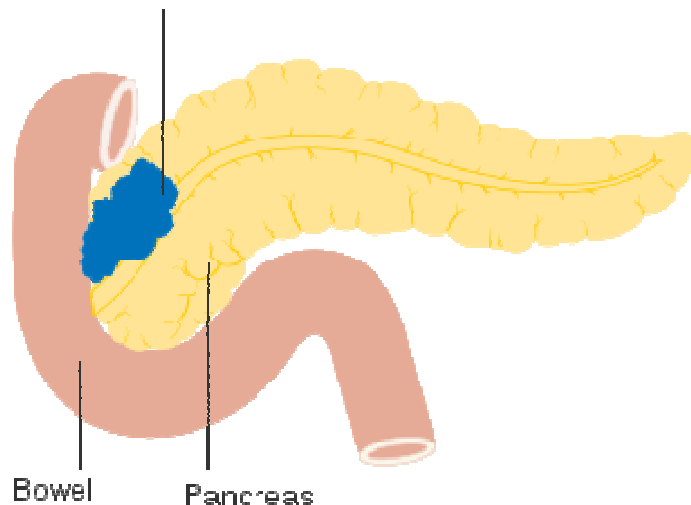
Our integrated services cover every step for a successful market launch and execution of clinical trials.

Why is it necessary? → Pancreatic Cancer

With **103,000 new cases in 2014** in Europe, pancreatic cancer is the 6th cause of death by cancer

In fact, it is expected that, **by 2030, pancreatic cancer becomes the first cause of death** above lung, colon or liver cancer

The cancer has grown into the tissues outside the pancreas

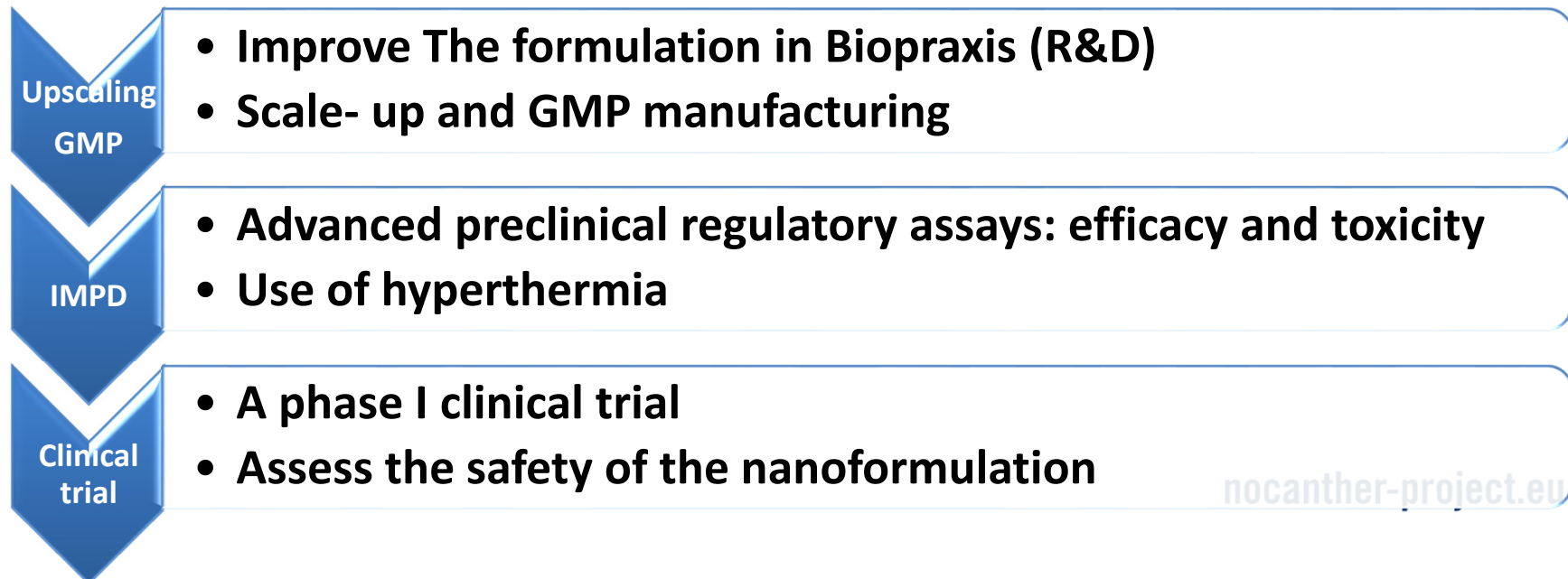




Project Description



Main goal → to translate the nanomedicine developed in the project to a Phase I clinical trial.



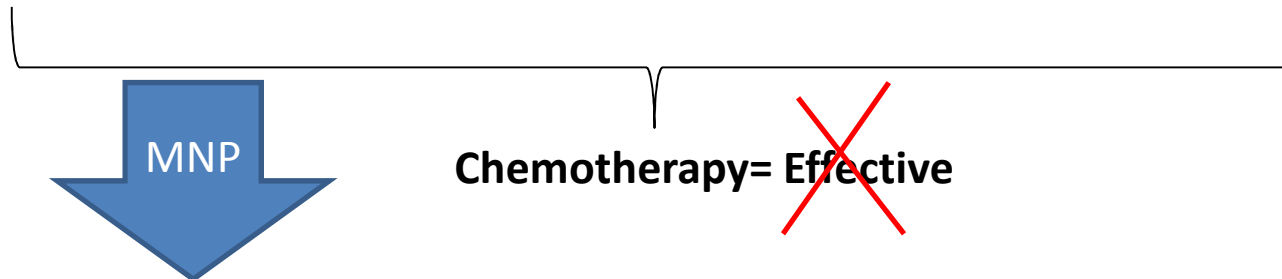


Project description → Objectives



•Pancreatic ductal carcinoma:

- Orphan disease
- Late diagnostic for lack of early symptoms → Advanced phase
- Survival rate < 5%
- Different from other cancers → Desmoplastic tissue (BARRIER)



Major advantages:

- Reduce side effects** → Intratumorally, targeting molecule, magnetic hyperthermia, metabolism.
- Versatile therapeutic approach** → adapted to the treatment of other malignancies.



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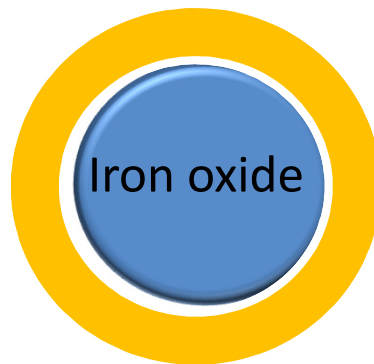
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Project Description

From preclinical...

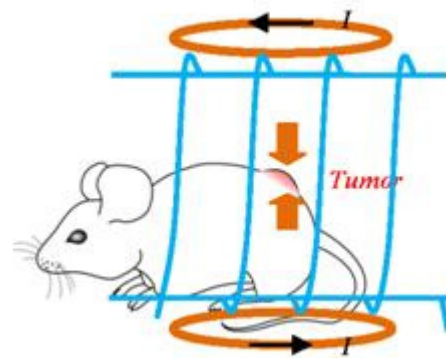


Coated and functionalized MNP



Intratumoral

Alternating Magnetic Field (AMF)



Tumoral cells death





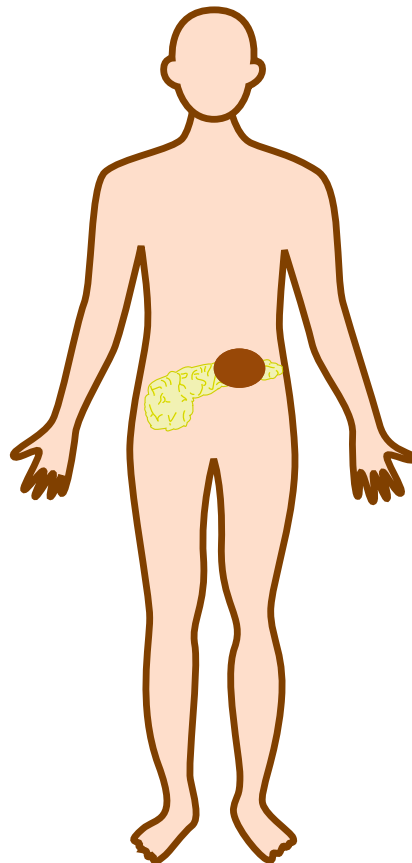
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H20



Project Description

... to clinical



Locally advanced non-resectable tumors

Around 21 Patients

2 Hospitals



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H20



Praxis

Biopraxis Research

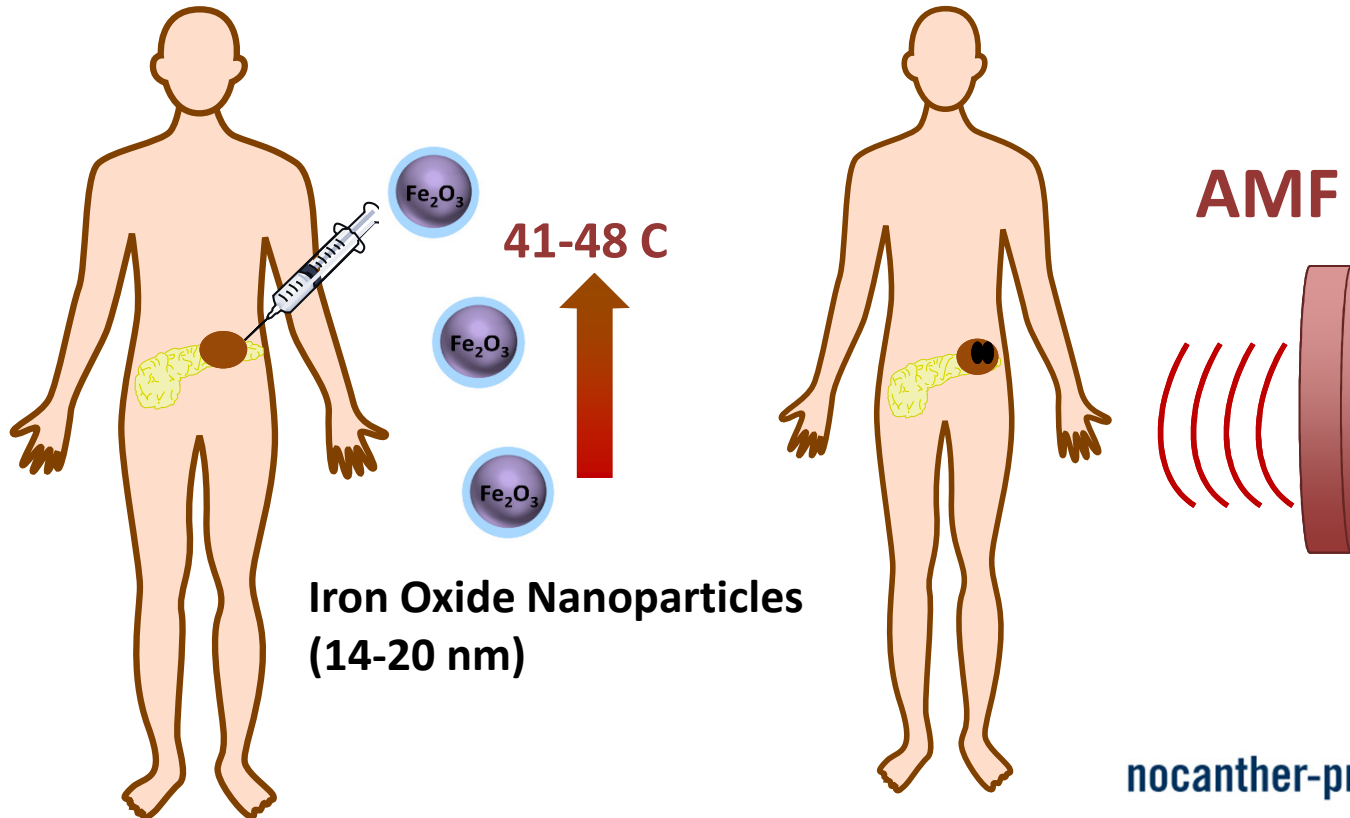
Project Description

Magnetic Hyperthermia



Magnetic
Hyperthermia
device

Portable!!



Iron Oxide Nanoparticles
(14-20 nm)

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Project description → Stage of development



RESONANT CIRCUITS
LIMITED

MACH (Magnetic Alternating Current Hyperthermia)

Portability - MACH system is mobile / transportable.

Scalability - Design focussed on core PCBs that can be run in parallel to increase field power.

Power supply requirements - Mains driven 240 VAC (standard wall socket)

Location requirements - Shielded room not required. Can operate within range of other patient monitoring systems i.e. Pulse oximeter, blood pressure monitor, ultrasound...



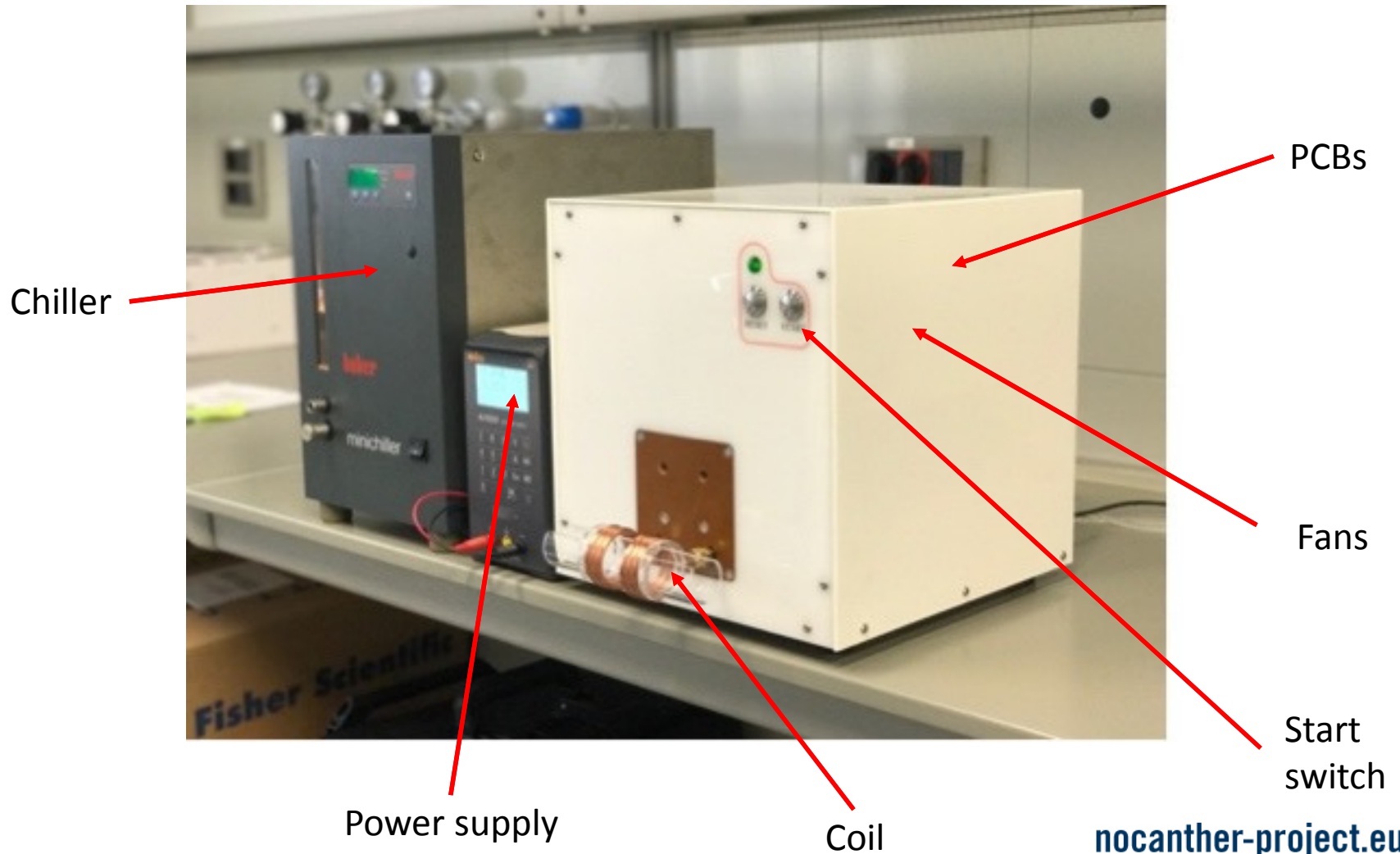
MACH
system



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PRE-CLINICAL MACH SYSTEM





Project description → Stage of development



to validate their efficacy and compliance...

GMPs

- Adaptable facilities
- Reproducibility
- Stability
- Sterility
- Purity
- Safety and nanosafety aspects





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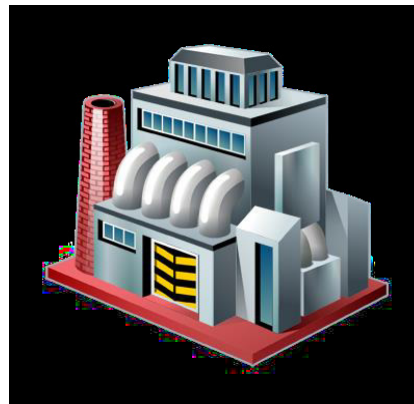
Perspective

Praxis Group:

Biopraxis (R+D)



**Praxis Pharmaceutical
(Manufacturing Division)**



Praxis Group



- Praxis → Explotation
- Partners → 5% Royalties

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Perspective

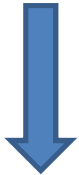
1. Define the final industrial process, characterise the final formulation → **Up-scale**
2. Final preclinical Assessment for **IMPD** submission
3. Register the MNP as a **medical device**
4. Enter a **Clinical Trial**



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Thanks for your
attention



And remember



SMALL CHANGES
CAN MAKE A
BIG
DIFFERENCE





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Discussion



oibarrola@praxisph.com

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