EUNCL
Nanomedicine
Characterisation
Laboratory

Cupido

European Infrastructure to improve translation in nanomedicine

Cupido workshop, Chilly-Mazarin

www.euncl.eu

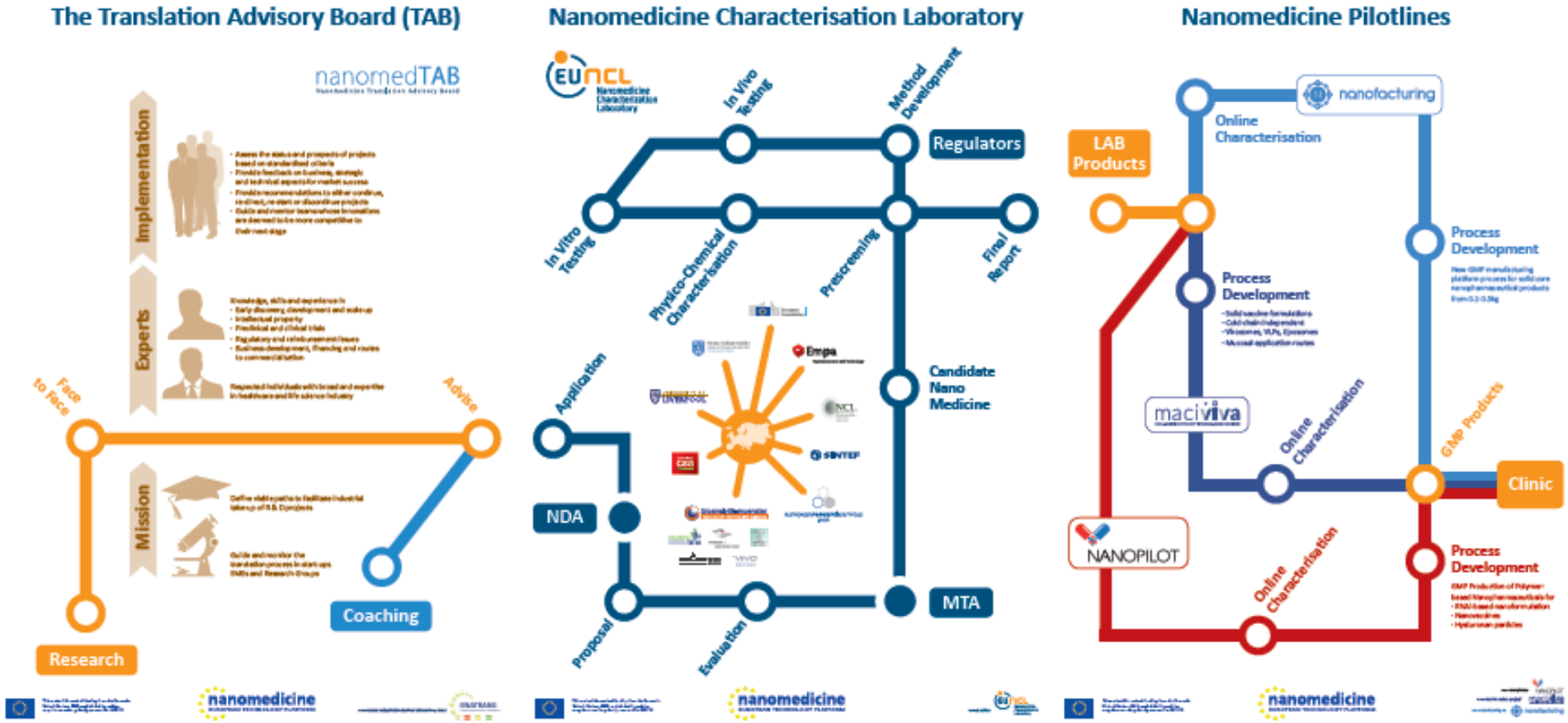
Outline

- What is EUNCL
- How does it work
- Where does it stands

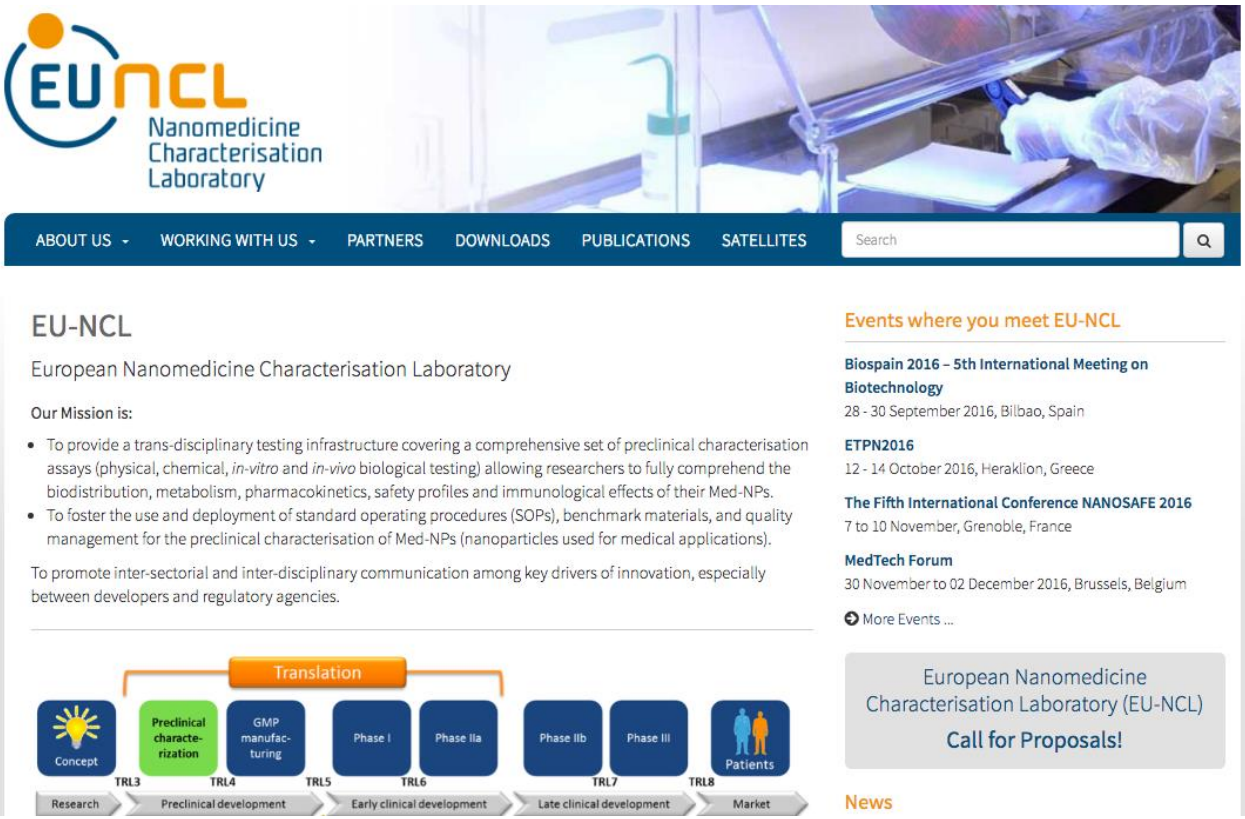
ID

- Research Infrastructure funded under H2020
  - *« Starting community »*
- Grant agreement
  - #654190
- Funding period
  - May 2015-April 2019
- EC Grant
  - € 4,995,181.00
- 8 partners

EUNCL in the Nanomed Translation Hub



European Nanomedicine Characterization Laboratory

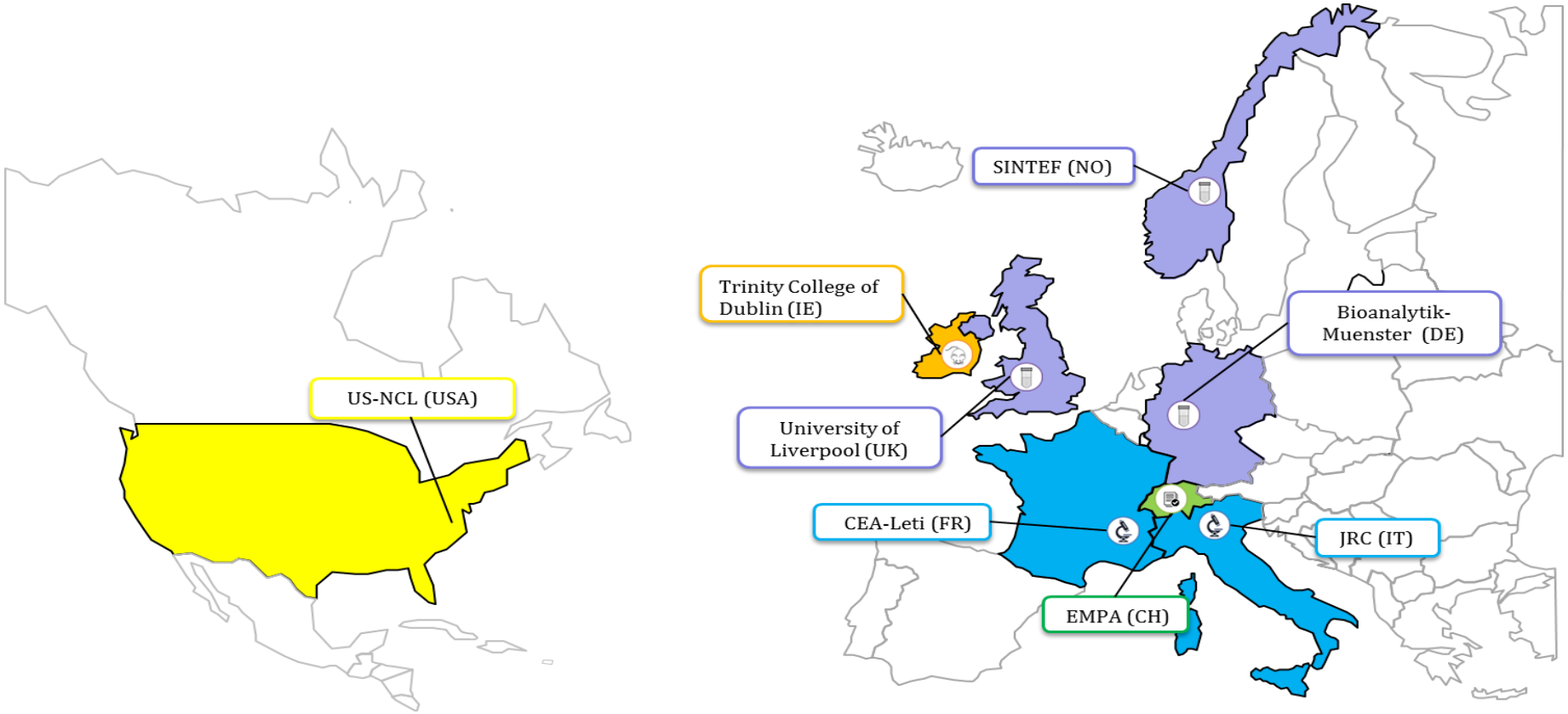


European Commission

Our missions

- To perform and standardize the pre-clinical characterization of nanomedicines
- To identify and characterize critical parameter related to nanomaterial interaction with biological systems
- To develop improved analytical methods to answer regulators' needs

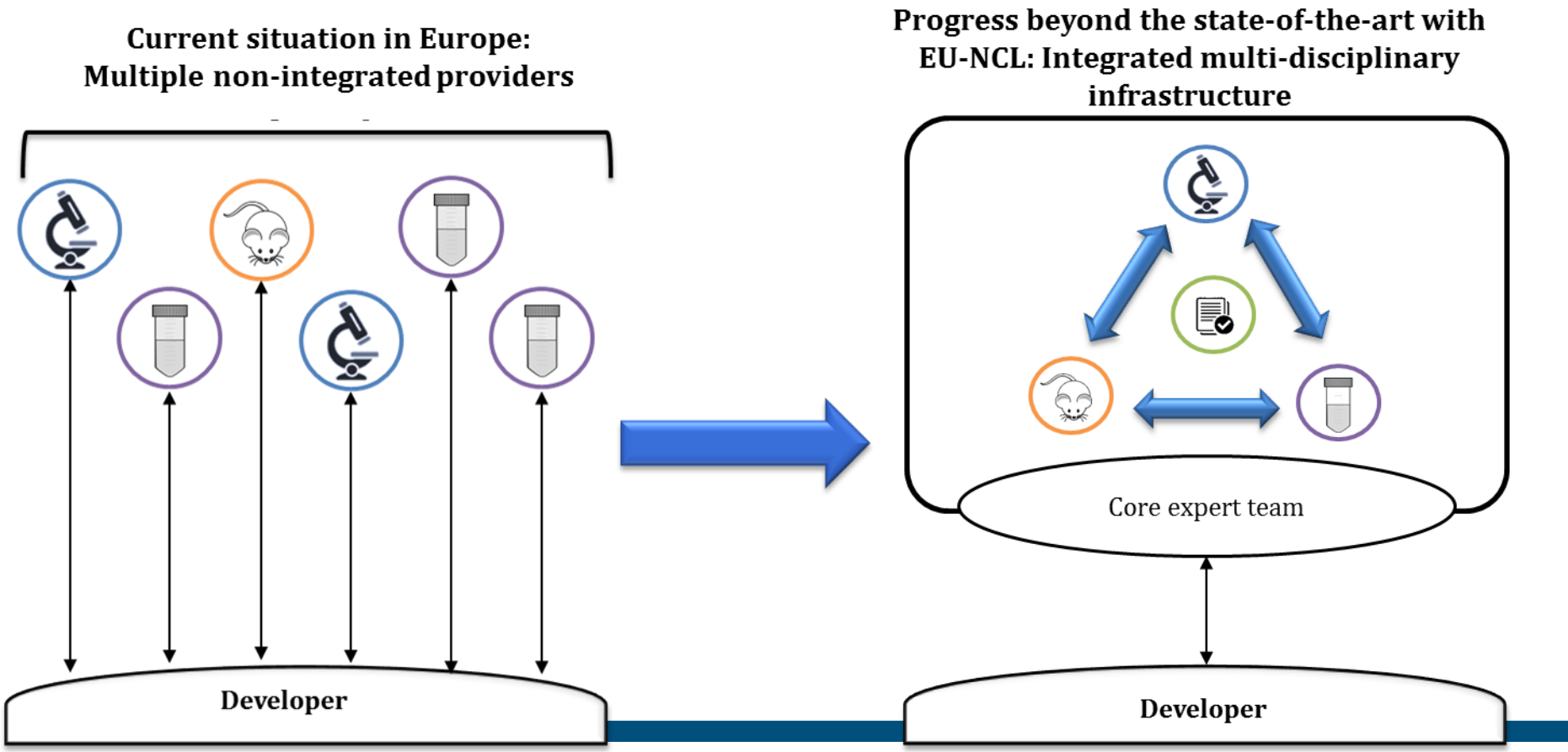
Who are the Core Members?



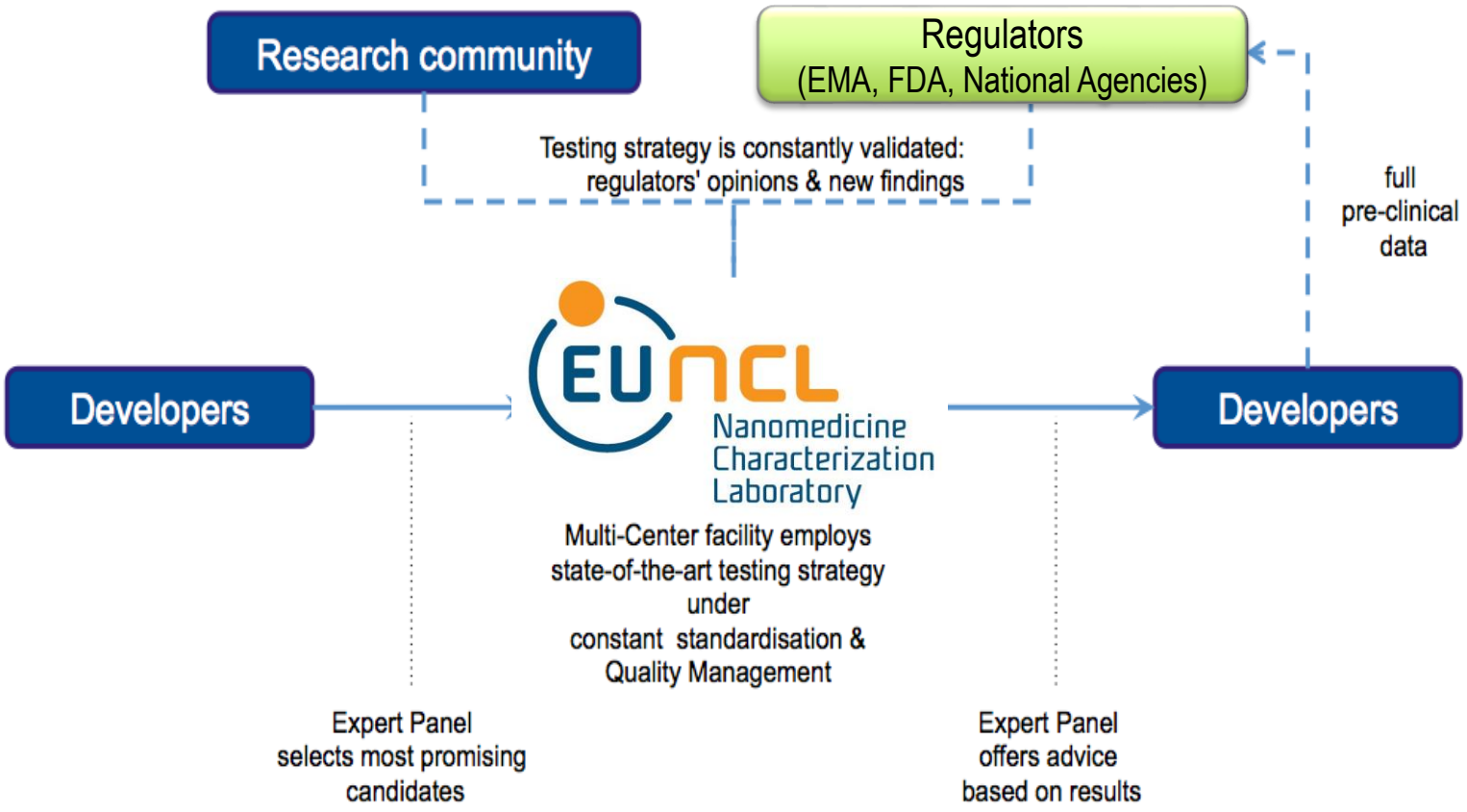
Who are the Satellite labs?

- CyberNano, Nates, FR
- FORTH Heraklion, GR
- INL, Braga, PT

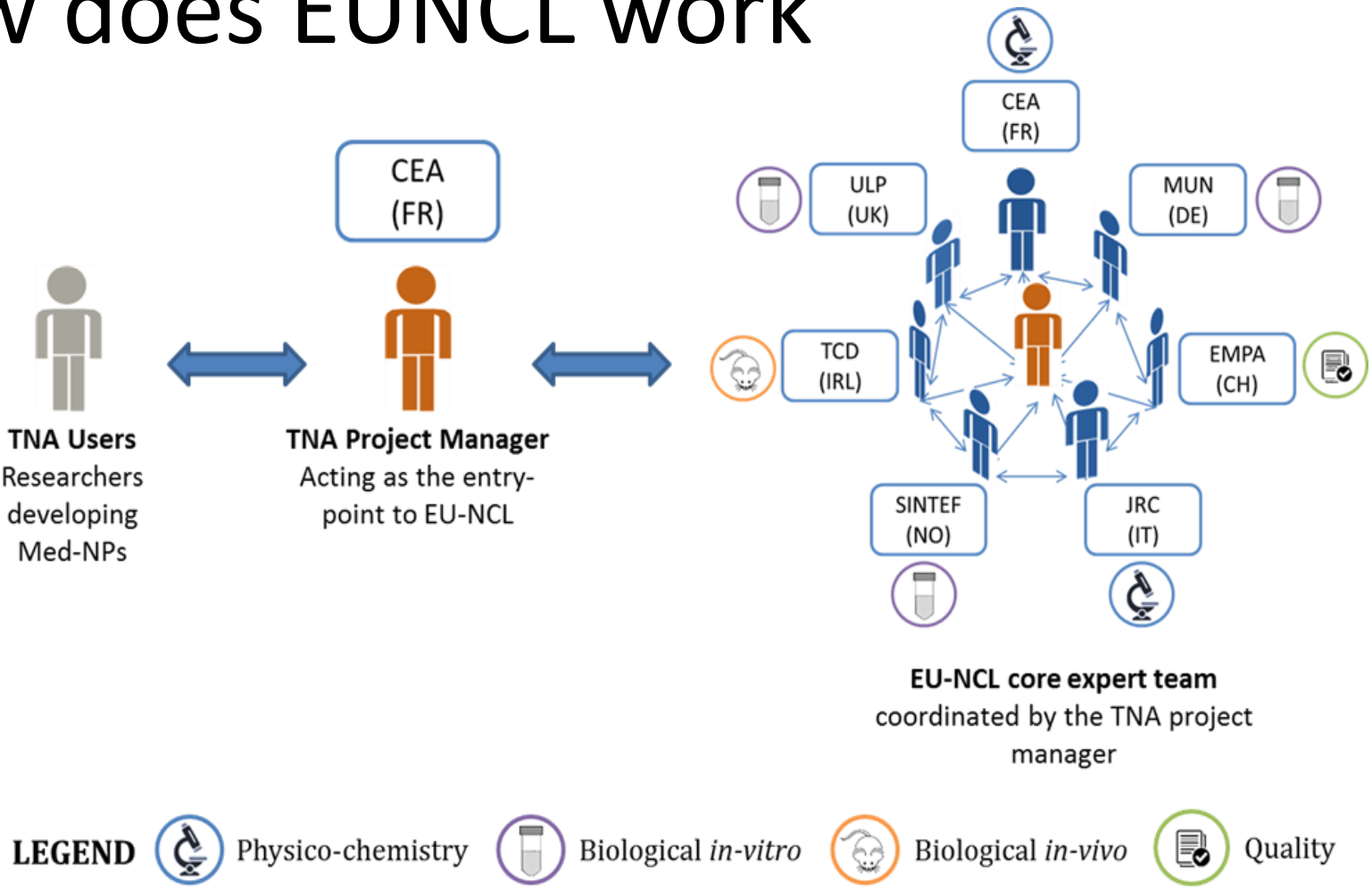
Why EUNCL?


Current situation in Europe:
Multiple non-integrated providers
Developer
Progress beyond the state-of-the-art with
EU-NCL: Integrated multi-disciplinary
infrastructure
Core expert team
Developer

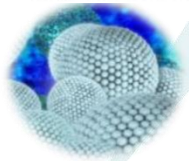
EUNCL Concept



How does EUNCL work



EUNCL offer

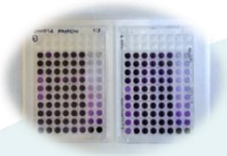


Candidate nanomedicine

PCC

- Size
- Surface potential
- Purity
- Surface morphology
- Composition

….



In vitro

Haematology/ Immunology/ Cytotoxicity

- Oxidative stress,
- Membrane permeability
- Mitochondrial dysfunction
- Complement Activation
- Coagulation properties
- Hemolytic properties

-…

In vivo

-PK Biodistribution

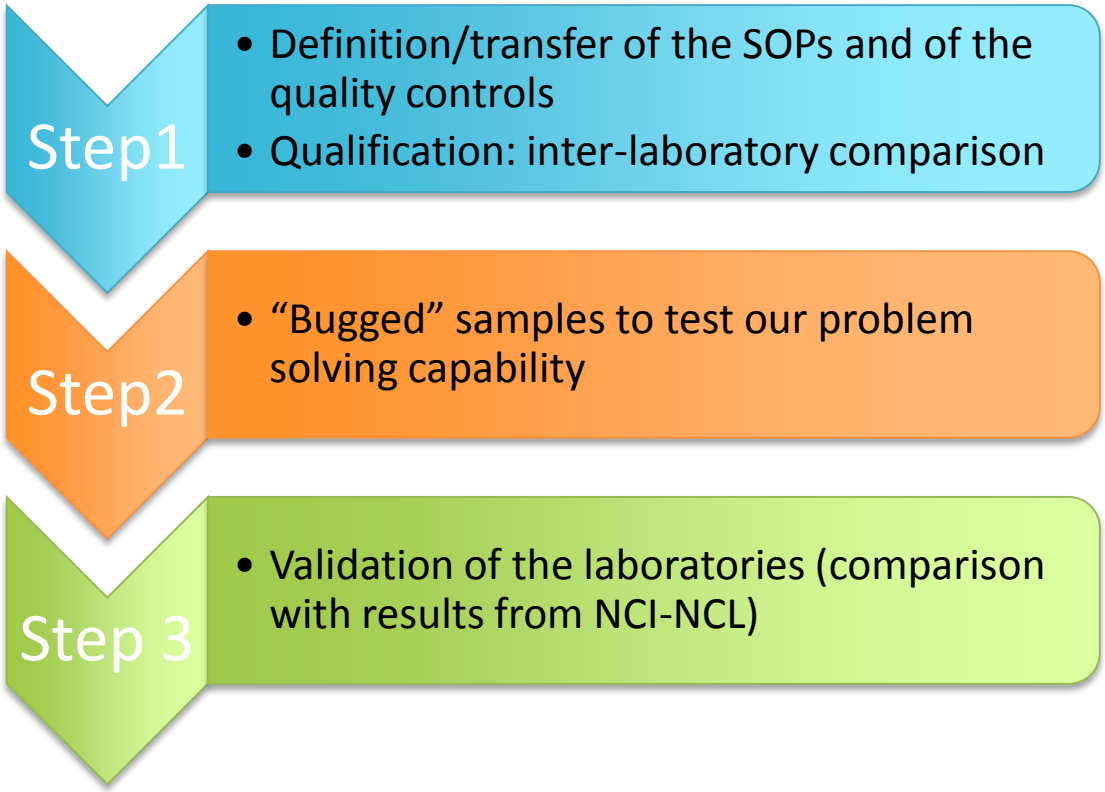
-Immunogenicity Toxicity

-Pharmakokinetic

…

Final report

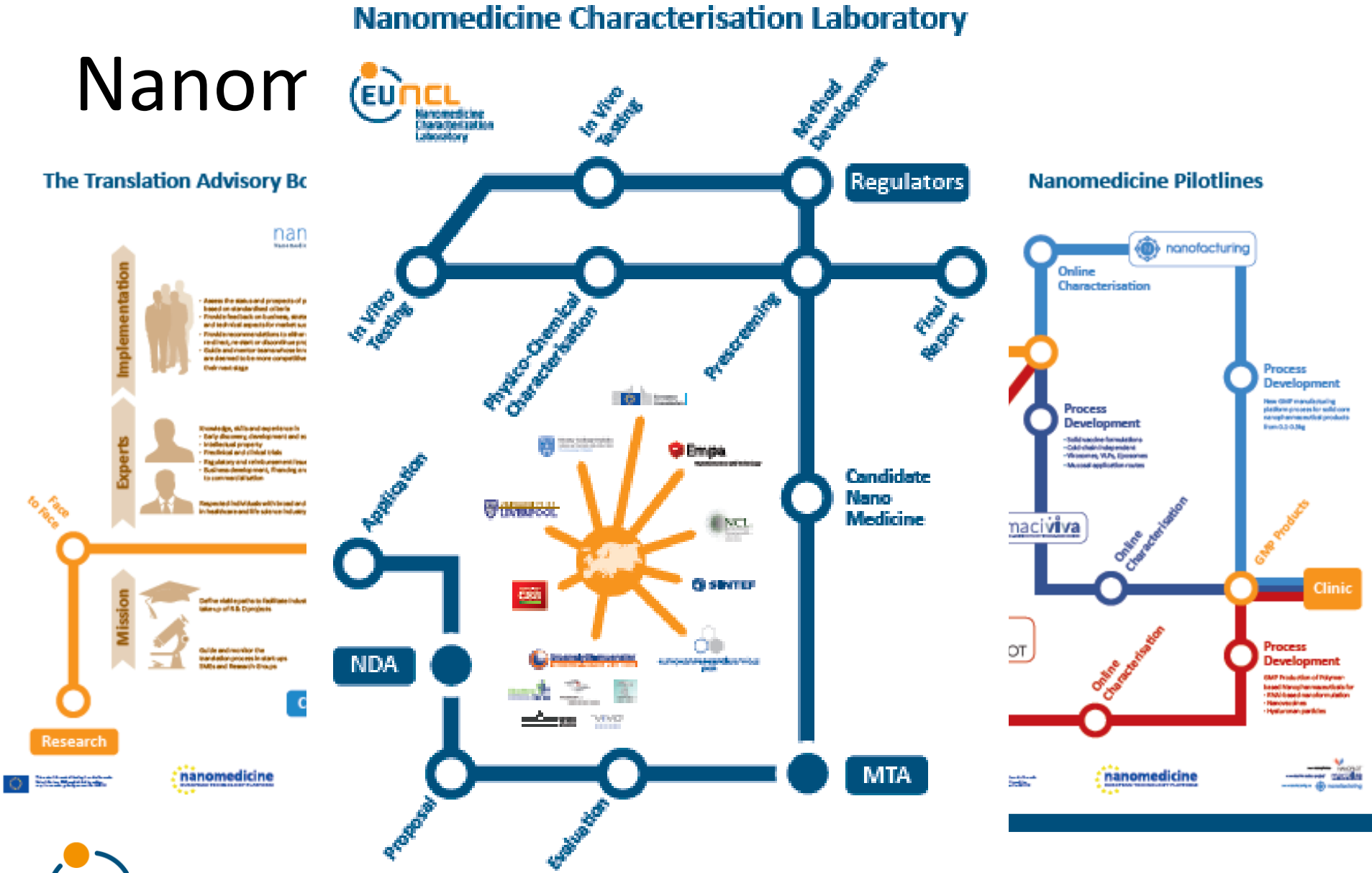
Standardized and validated SOP



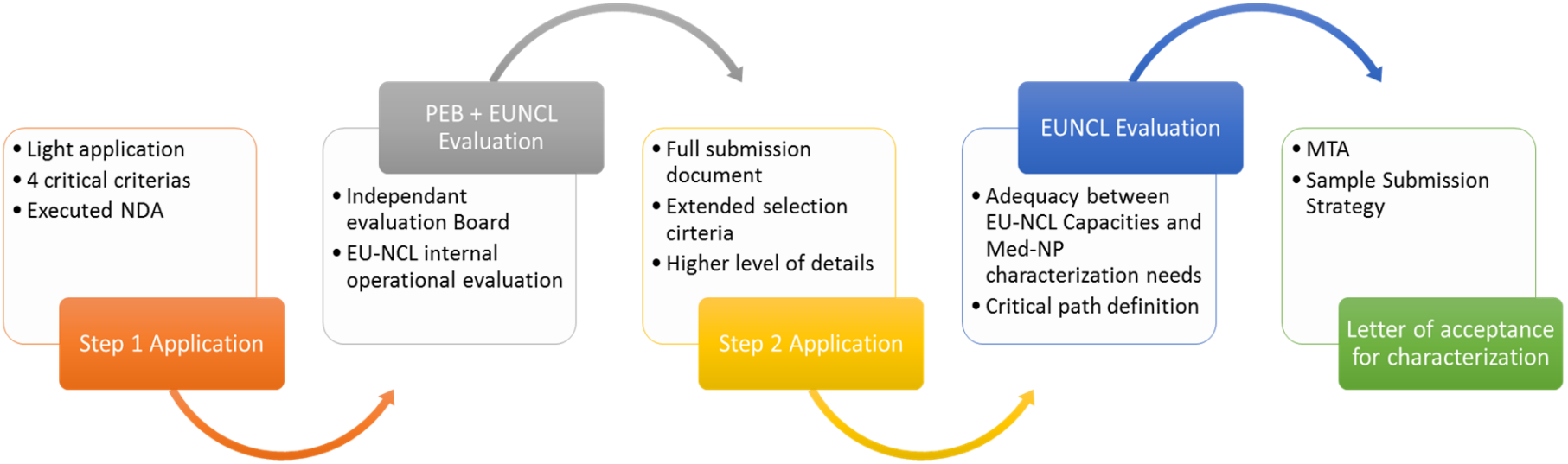
The Standard Operating Procedures (SOPs) have been qualified and validated in all the laboratories of the EU-NCL consortium..

Quality controls are defined according to the ISO 17025

Nanom


Nanomedicine Characterisation Laboratory
EUNCL
Nanomedicine Characterisation Laboratory
In Vivo Testing
Method Development
Regulators
In Vitro Testing
Physico-Chemical Characterisation
Prescreening
Final Report
Application
Candidate Nano Medicine
NDA
MTA
Proposal
Evaluation
The Translation Advisory Bc
Implementation
Experts
Mission
Face to Face
Research
nanomedicine
Nanomedicine Pilotlines
nanofacturing
Online Characterisation
Process Development
Process Development
Online Characterisation
GMP Products
Clinic
Online Characterisation
Process Development
nanomedicine

Application process



Who can apply?

Academics

Inventors

Startups

SMEs

Acceptance criteria:

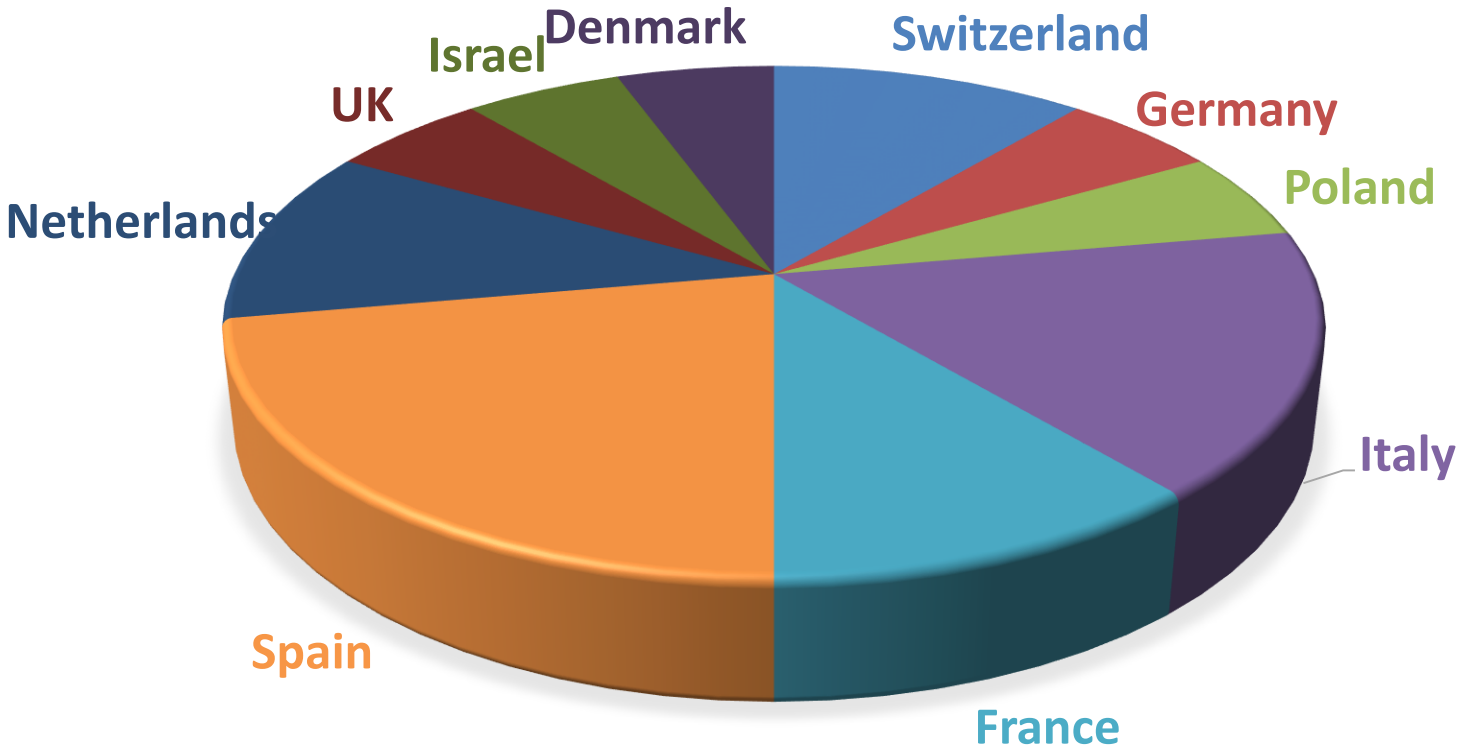
- Demonstrate the efficacy of the Med-NP in biological systems
- Ability to produce two independent batches (reproducibility)
- Provide a detailed production plan and its scaling up plan
- Propose a clear strategy to transfer the technology to the clinical environment

TNA numbers

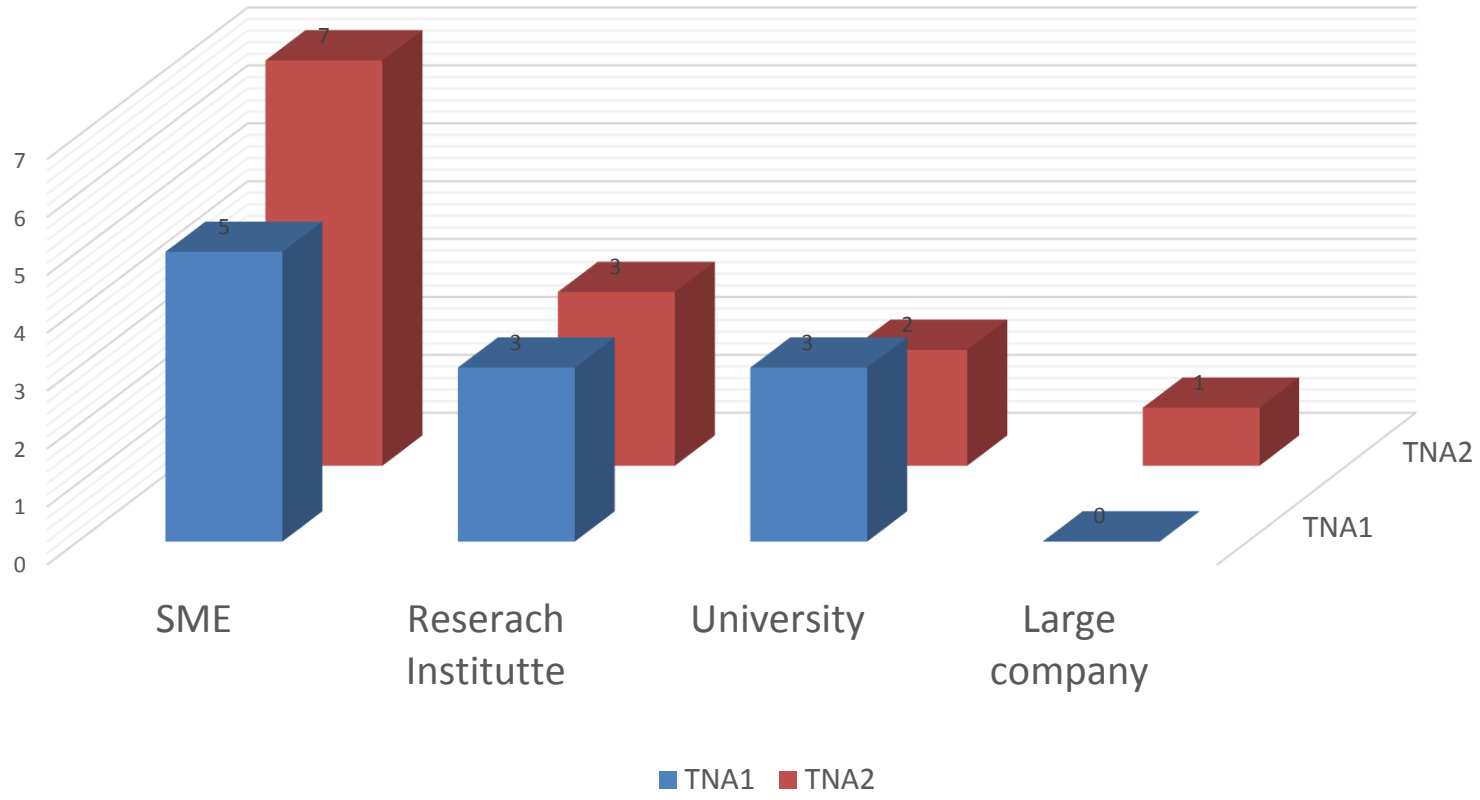
- After 2 TNA campaigns
- 23 applications so far
  - 15 accepted to step 2
  - 8 entered characterisation

- More and more applications comes from industry (SMEs and Large)
- 90% cancer focus in TNA1, 67% in TNA2

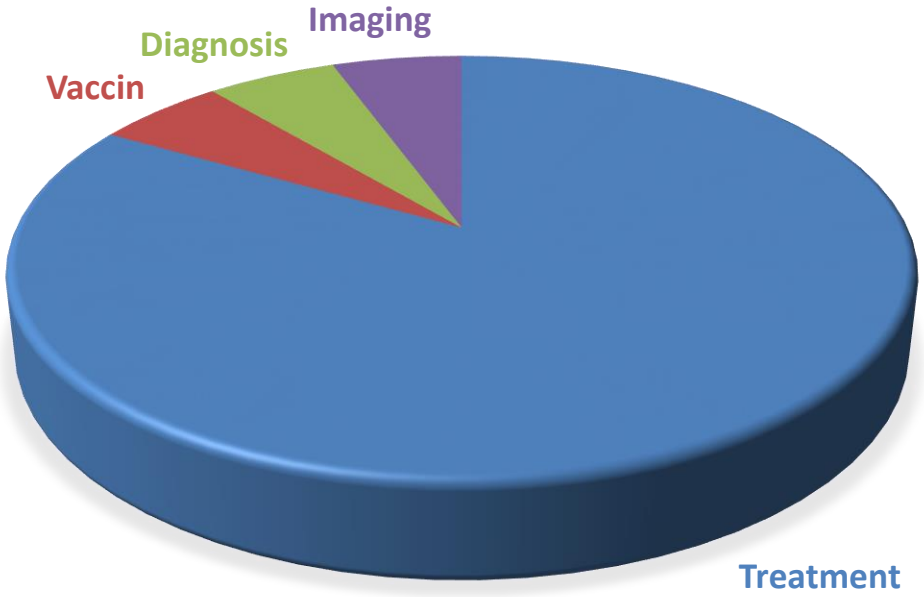
Applications' origine

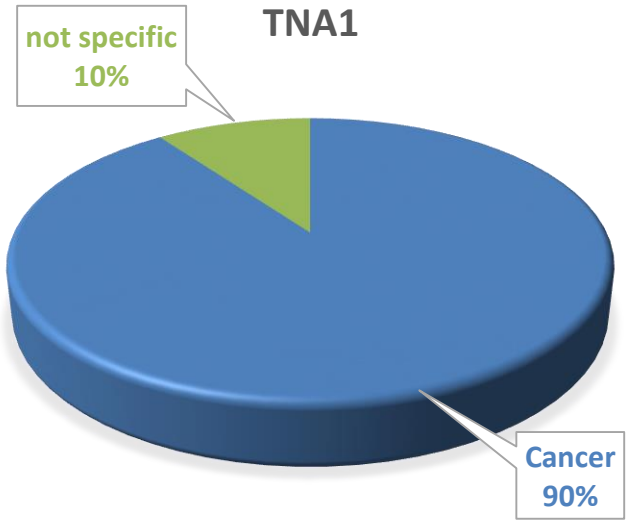


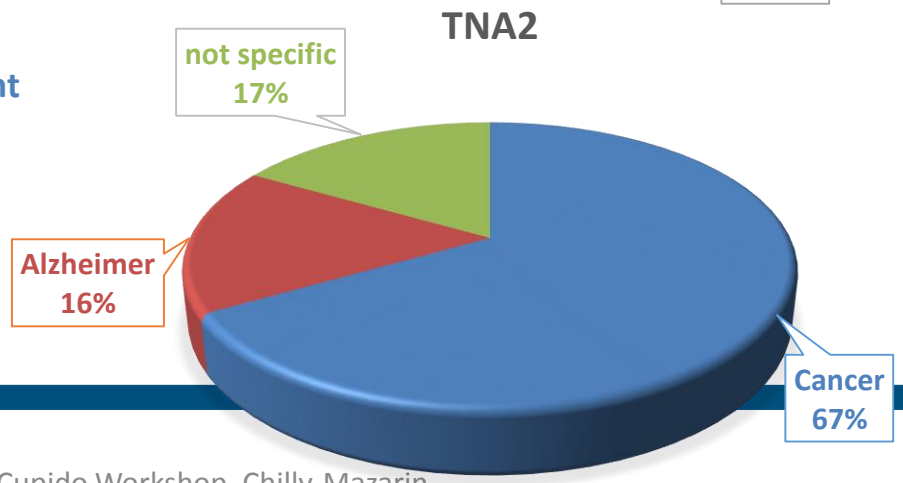
Applicants' profile



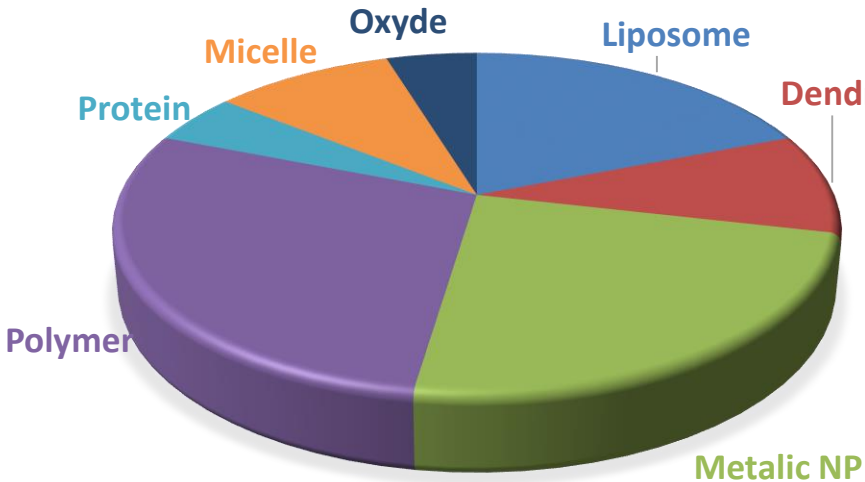
Applications





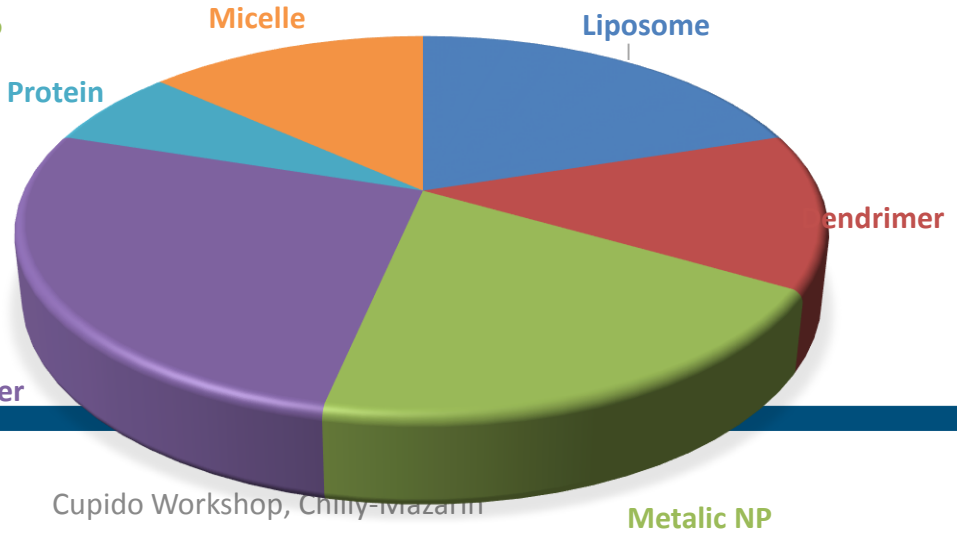


Type of nanomaterials



STEP1

STEP2



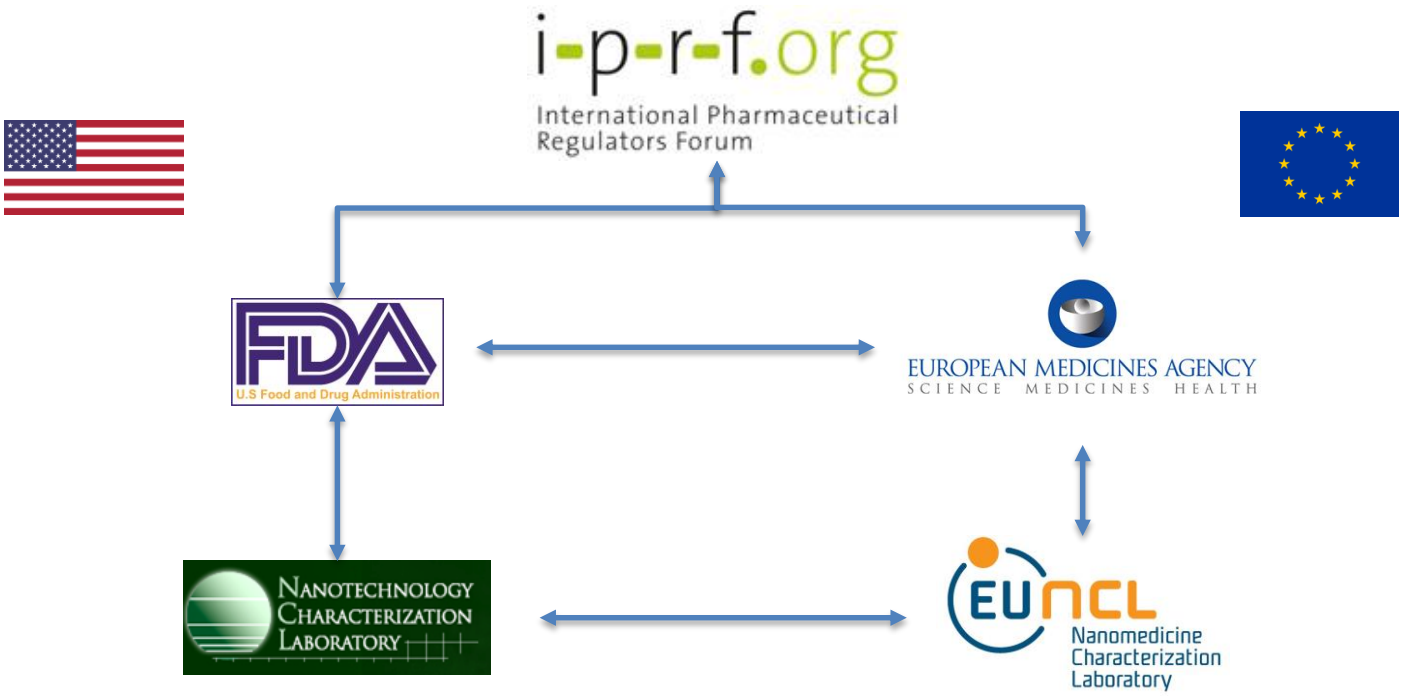
Lessons learned

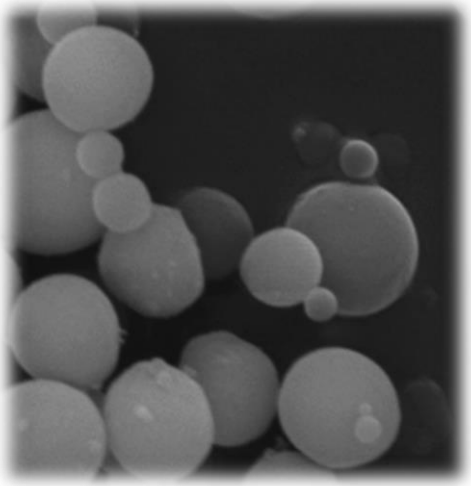
- Role of EUNCL evolves
  - Toward advice and support
  - Help prepare better application

- Maturity of projects
  - Advanced vs. Early stage
  - Difficulties in delivering GMP-like batches

- Main application drawback
  - Material quality & quantity
  - Key data missing

Regulatory environment





Source: www.cupidoproject.eu

- Looking forward Cupido's application

Thank You

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