nanomedicine
EUROPEAN TECHNOLOGY PLATFORM

Nanomedicine Regulation Ecosystem

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Deutsche Plattform NanoBioMedizin

bioanalytik-muenster
TECHNOLOGY FOR THE LIFE SCIENCES

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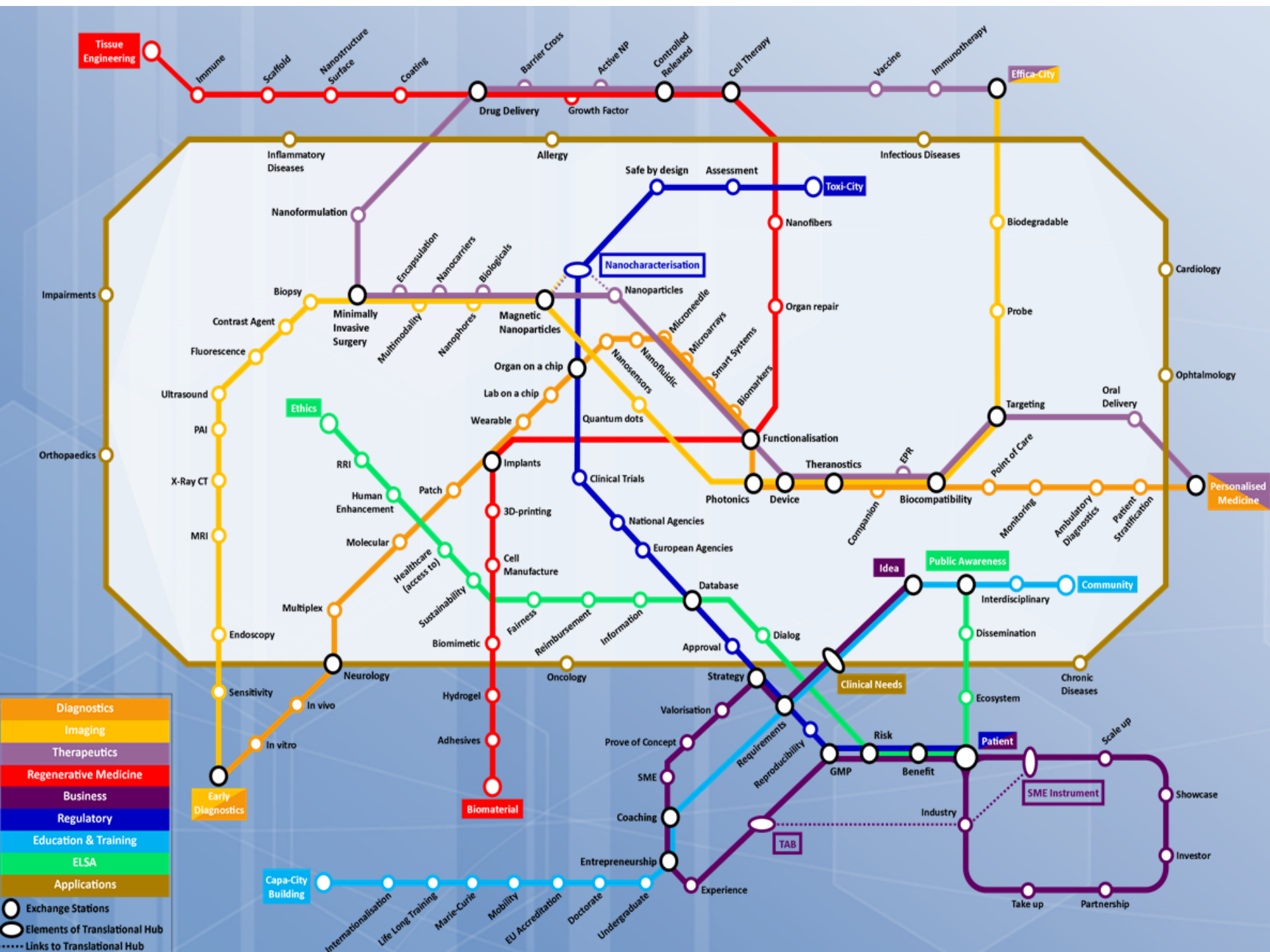

Tissue Engineering
Immune
Scaffold
Nanostructure Surface
Coating
Drug Delivery
Barrier Cross
Growth Factor
Active NP
Controlled Released
Cell Therapy
Vaccine
Immunotherapy
Effica-City
Inflammatory Diseases
Allergy
Infectious Diseases
Safe by design
Assessment
Toxi-City
Nanoformulation
Nanofibers
Biodegradable
Encapsulation
Nanocarriers
Biologicals
Nanocharacterisation
Cardiology
Impairments
Biopsy
Nanoparticles
Organ repair
Probe
Contrast Agent
Minimally Invasive Surgery
Multimodality
Nanophores
Magnetic Nanoparticles
Microneedle
Microarrays
Smart Systems
Biomarkers
Fluorescence
Nanosensors
Nanofluidic
Organ on a chip
Ophtalmology
Ultrasound
Lab on a chip
Ethics
Wearable
Quantum dots
Targeting
Oral Delivery
PAI
Functionalisation
Orthopaedics
RRI
Implants
Theranostics
EPR
Point of Care
Clinical Trials
X-Ray CT
Patch
Human Enhancement
Photonics
Device
Companion
Biocompatibility
Monitoring
Ambulatory Diagnostics
Patient Stratification
Personalised Medicine
3D-printing
National Agencies
MRI
Molecular
European Agencies
Healthcare (access to)
Cell Manufacture
Idea
Public Awareness
Community
Database
Interdisciplinary
Multiplex
Sustainability
Fairness
Reimbursement
Information
Dialog
Dissemination
Endoscopy
Biomimetic
Approval
Neurology
Oncology
Strategy
Clinical Needs
Chronic Diseases
Sensitivity
Hydrogel
Ecosystem
In vivo
Valorisation
Risk
Patient
Scale up
In vitro
Adhesives
Prove of Concept
Requirements
Reproducibility
GMP
Benefit
SME
SME Instrument
Showcase
Early Diagnostics
Biomaterial
Coaching
Industry
TAB
Investor
Entrepreneurship
Capa-City Building
Experience
Take up
Partnership
Internationalisation
Life Long Training
Marie-Curie
Mobility
EU Accreditation
Doctorate
Undergraduate
Diagnostics
Imaging
Therapeutics
Regenerative Medicine
Business
Regulatory
Education & Training
ELSA
Applications
Exchange Stations
Elements of Translational Hub
Links to Translational Hub

The Nanomedicine Translation HUB

TAB

Translation Advisory Board

Dedicated grants for SMEs

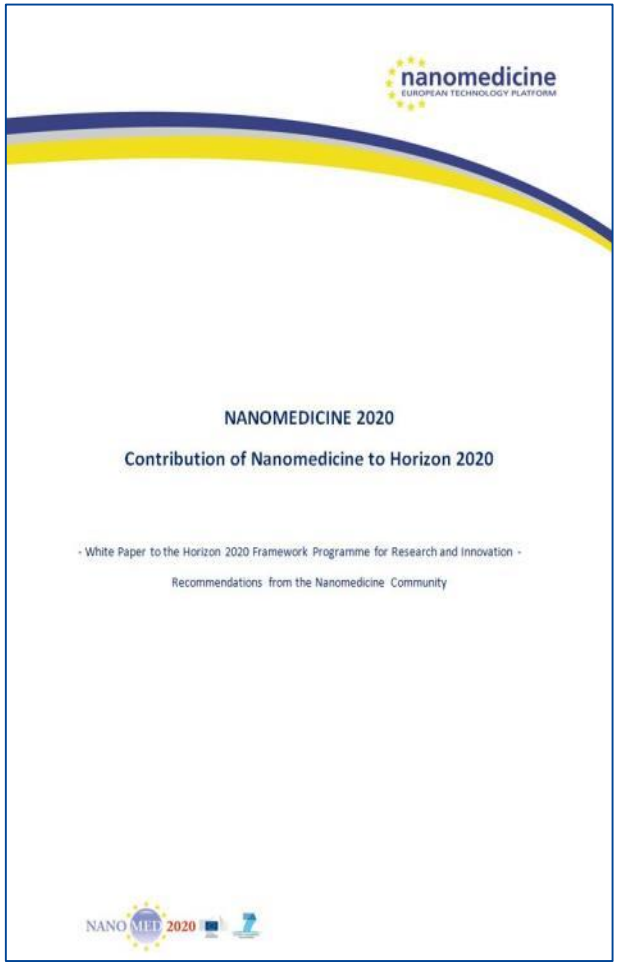
SME Instrument

EUNCL

EU Nanomedicine Characterisation Lab

Scale up of GMP manufacturing

GMP Pilot lines



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NANOMEDICINE 2020

Contribution of Nanomedicine to Horizon 2020

- White Paper to the Horizon 2020 Framework Programme for Research and Innovation -

Recommendations from the Nanomedicine Community

NANO MED 2020

ENATRANS
Enabling NAnomedicine TRANSlation

ENATRANS
Enabling Nanomedicine Translation

HORIZON 2020

Information Center

- Ecosystem's requirements, incl. from clinics and investors
- **Focus on regulation and reimbursement, access to clinics as major hurdles for translation**
- Compiled and synthesized information
  - **ENATRANS Website**
  - **Compendium**
  - **Webinars on**
    - **Regulatroy Ecosystem**
    - **Translation HUB**
    - **Translation Advisory Board**

Ecosystem of Nanomedicine

The translation of any new medical invention into a final product is a highly regulated and complex process. This section gives an overview of the broader nanomedicine ecosystem and issues to be aware of such as regulation, pricing and reimbursement systems by providing all data about these steps in place in Europe, at the EU, and Member States level.

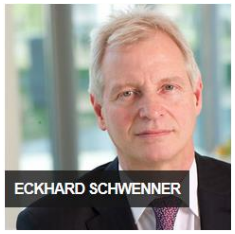
To bring a new medical product or device on the market it has to go through a long and complex process involving many authorities at regional, national and international level. To successfully manage this process it is mandatory to study and understand the different parts of the process in detail. The following sections will provide information, links and downloads to serve as a guide about what is required in which order and who can help at the different steps of the process.

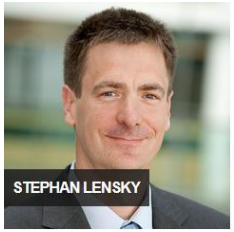
The process can be roughly devided into a market authorisation part - governed by regulation agencies such as the European Medicines Agency (EMA) or National Agencies -, a clinical trials part and, in continuation, the pricing and reimbursement systems mainly handled by national or regional authorities. To receive details about these three fields please follow the links below:

- Regulatory Process for Nanomedicine
- Clinical trials
- Pricing and Reimbursement of Nanomedicine

Translation Advisory Board

ENATRANS
Enabling NAnomedicine TRANSlation





„The TAB-in Session powered ideas into real projects and I couln't be more proud of having this experience"
Ana Cadete, University of Santiago de Compostella

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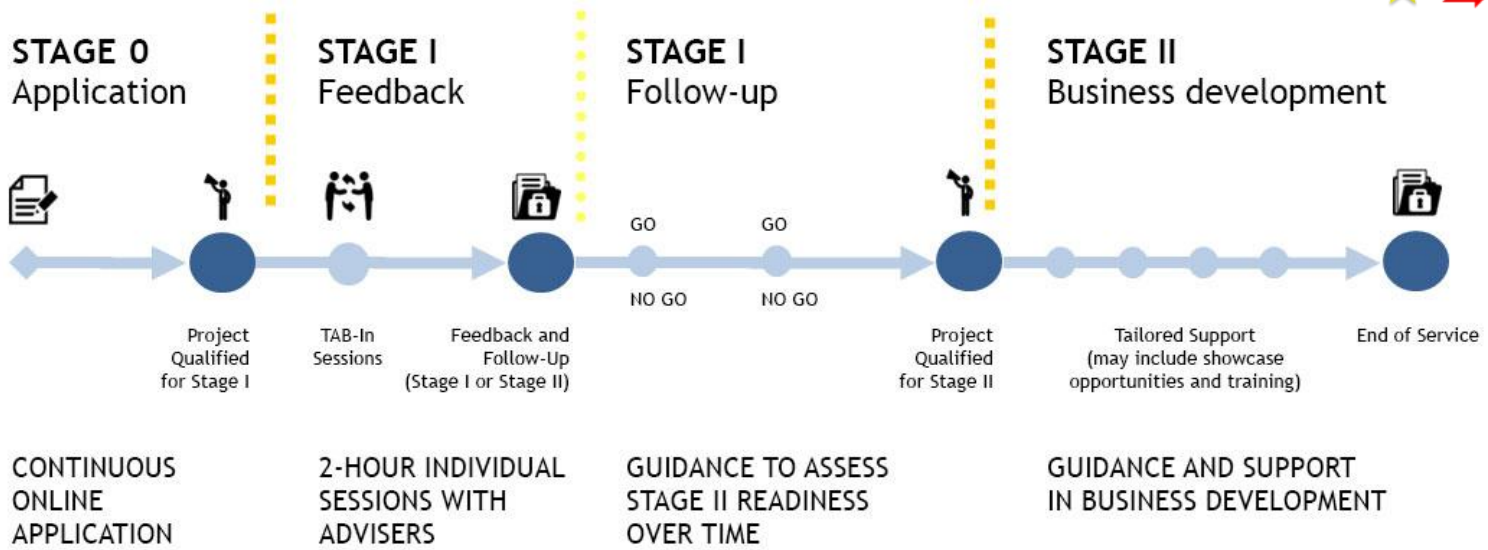
nanomedTAB
Nanomedicine Translation Advisory Board

TAB in Practice

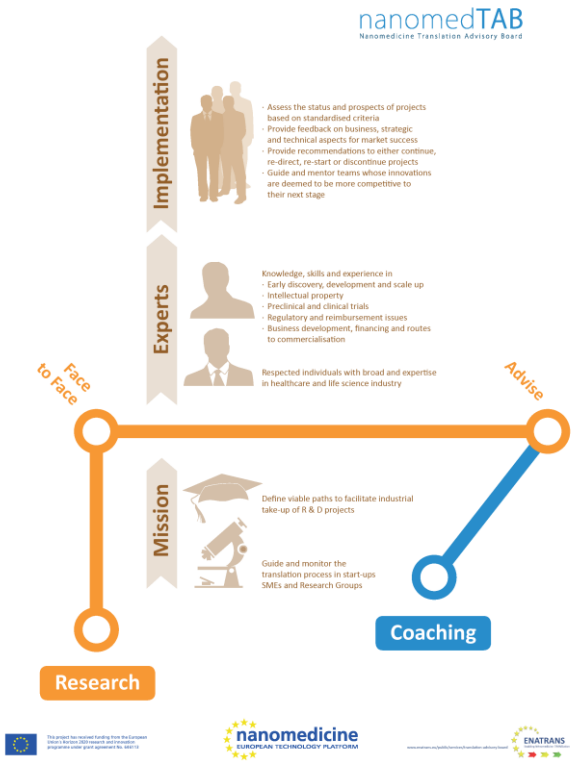


1st session Dublin – Oct 15	3rd session Heraklion – Oct 16	2nd session Basel – June 16
23 applications 10 F2F meetings	10 applications 8 F2F meetings	19 applications 9 F2F meetings

WWW.NANOMEDTAB.EU

Nanomed Translation Hub

The Translation Advisory Board (TAB)



HORIZON 2020

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NOBEL Organisation – 5 Work Packages

Translation Advisory Board
Start'Up Accelerator

Tec Minho
Interface da Universidade do Minho

Innovate & Accelerate

WP4

Knowledge management & Dissemination

WP2

Ecosystem Buiding

WP3

cea

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Communication,
Web media, Events,
Newsletters,

HealthTech Network

MedTech Europe
from diagnosis to cure

Tyndall National Institute
Institiúid Náisiúnta
Industry

Fondazione Don Carlo Gnocchi Onlus
Clinic

Roadmapping

WP5

bioanalytik-muenster
TECHNOLOGY FOR THE LIFE SCIENCES

Strategic R&I Agendas
Socio-Economic Impact
Life Cycle and Recyclability

General Management

WP1

VDI | VDE | IT

The Translation HUB

Academia

Translation Advisory Board

SME Funding Instrument

EU Nanomed Charac' Lab

Scale up Pilot Lines

Clinical Trials Centres

Industry

EUNCL
Nanomedicine
Characterisation
Laboratory

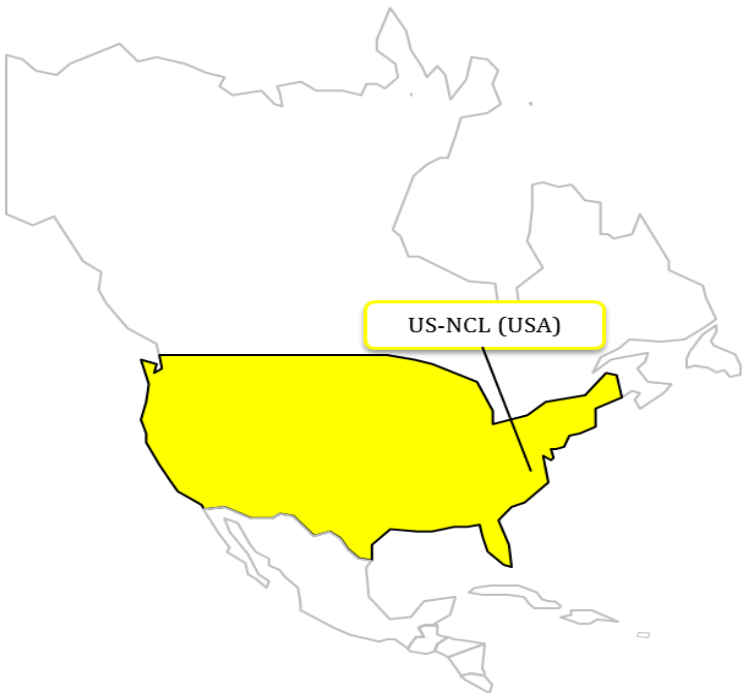
EUNCL

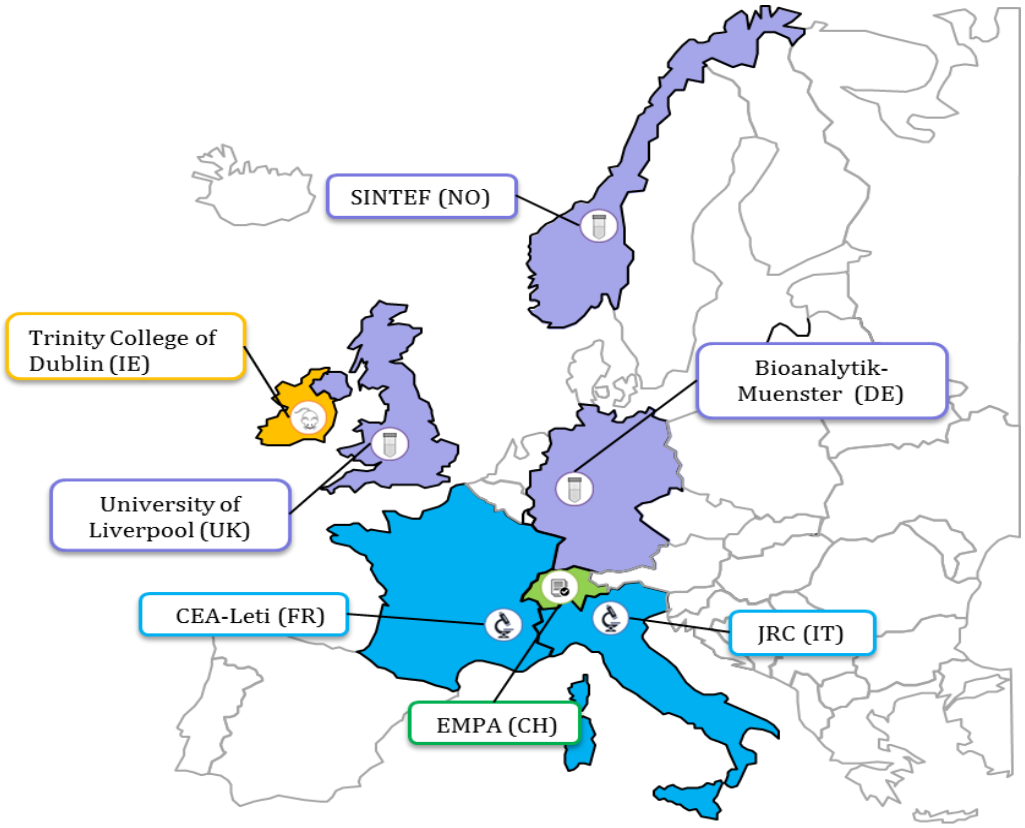
European **N**anomedicine **C**haracterisation **L**aboratory

HORIZON 2020

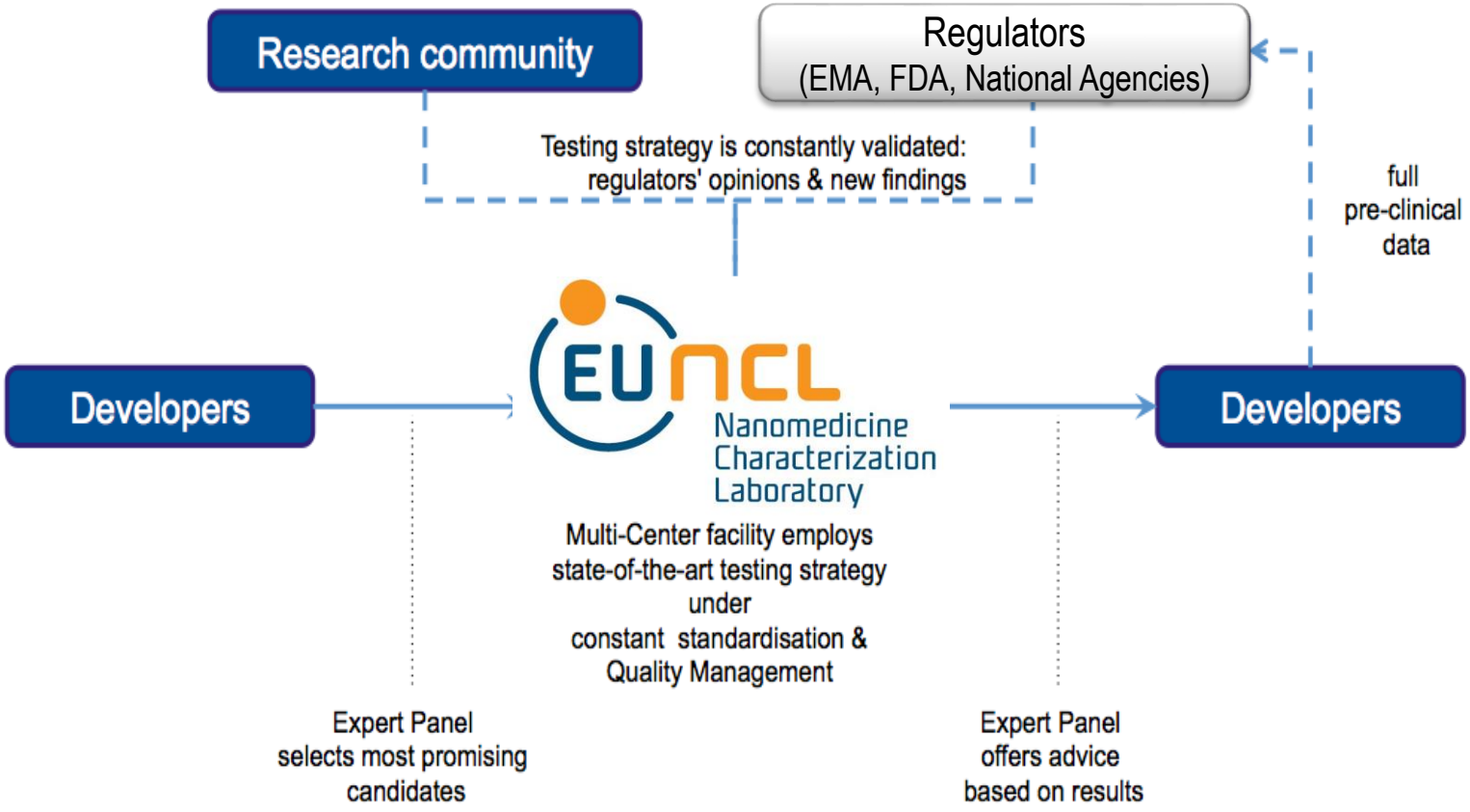
Core Members

EUNCL Nanomedicine Characterisation Laboratory

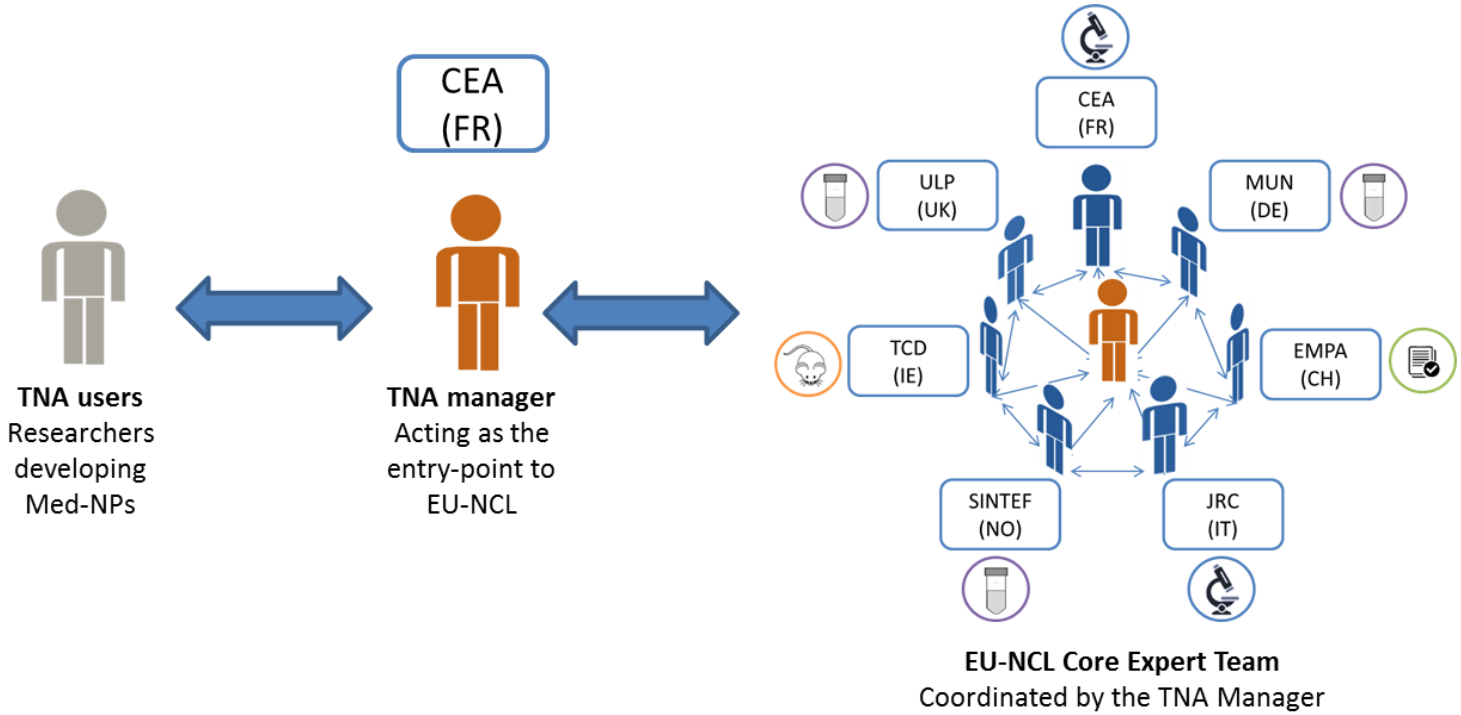




Concept


Research community
Regulators
(EMA, FDA, National Agencies)
Testing strategy is constantly validated:
regulators' opinions & new findings
full
pre-clinical
data
Developers
EUNCL
Nanomedicine
Characterization
Laboratory
Developers
Multi-Center facility employs
state-of-the-art testing strategy
under
constant standardisation &
Quality Management
Expert Panel
selects most promising
candidates
Expert Panel
offers advice
based on results

Application to EUNCL

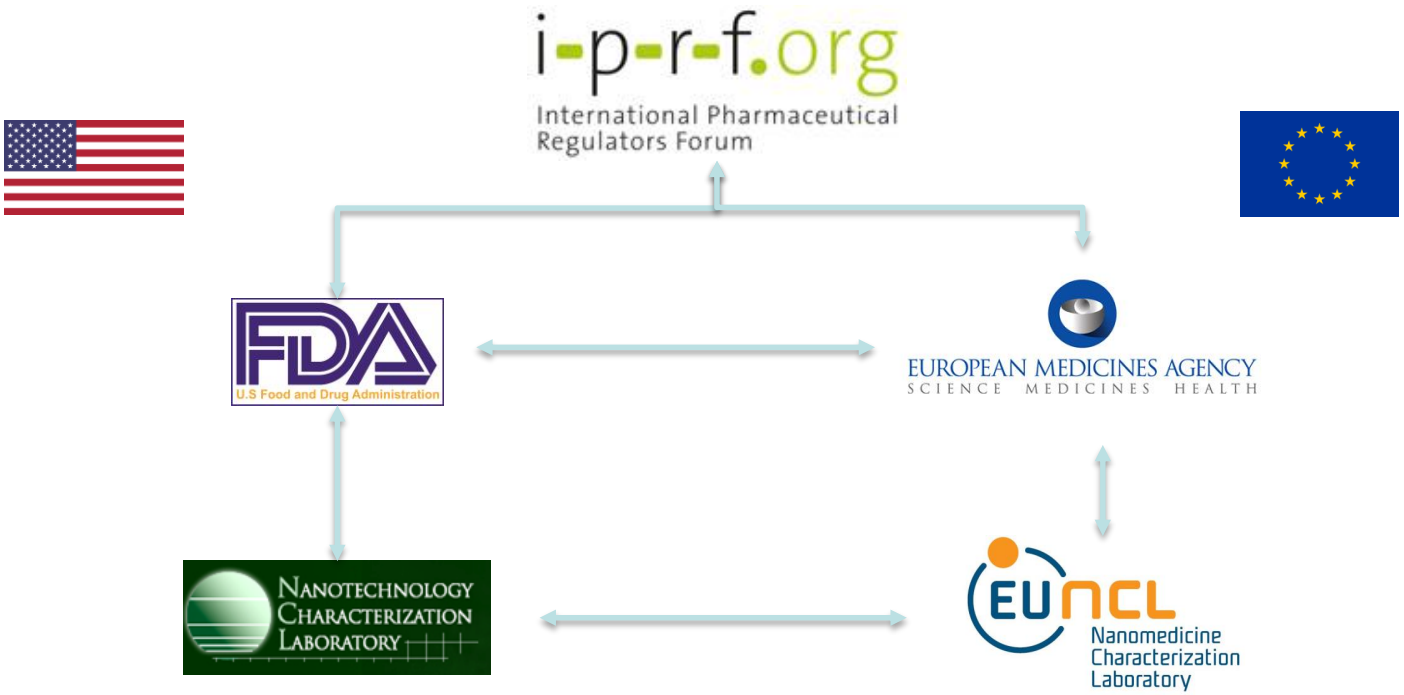


LEGEND Physico-chemistry Biological *in-vitro* Biological *in-vivo* Quality

Infrastructures for global support

EUNCL Nanomedicine Characterisation Laboratory

Interface with regulators



TNA1 (2016)

10 Applications

7 STEP2

4 Characterisation

2 on going

1 completed

TNA2 (2017)

11 Applications

9 STEP2

7 Characterisation

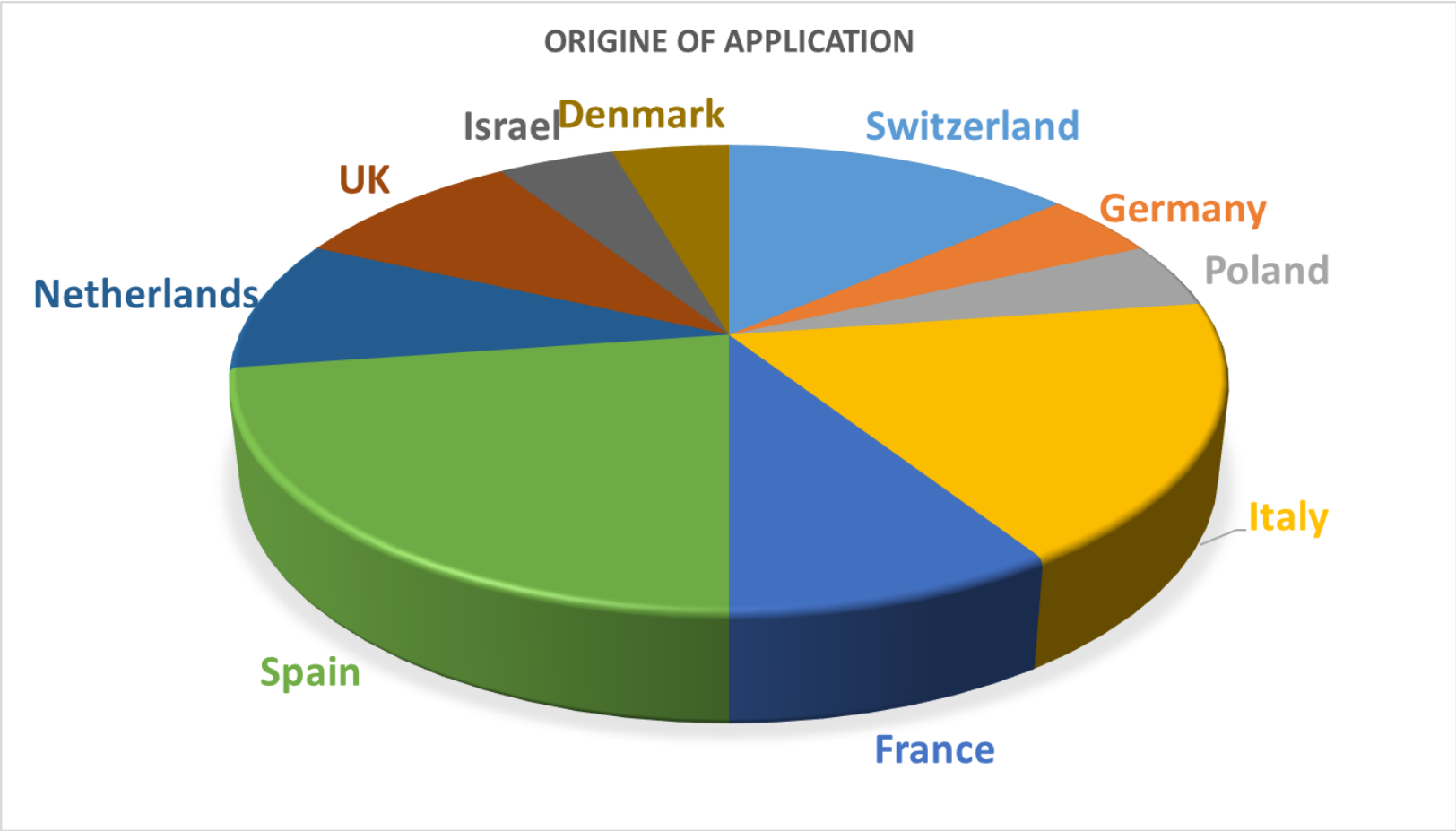
1 on going

TNA3 (05/2018)

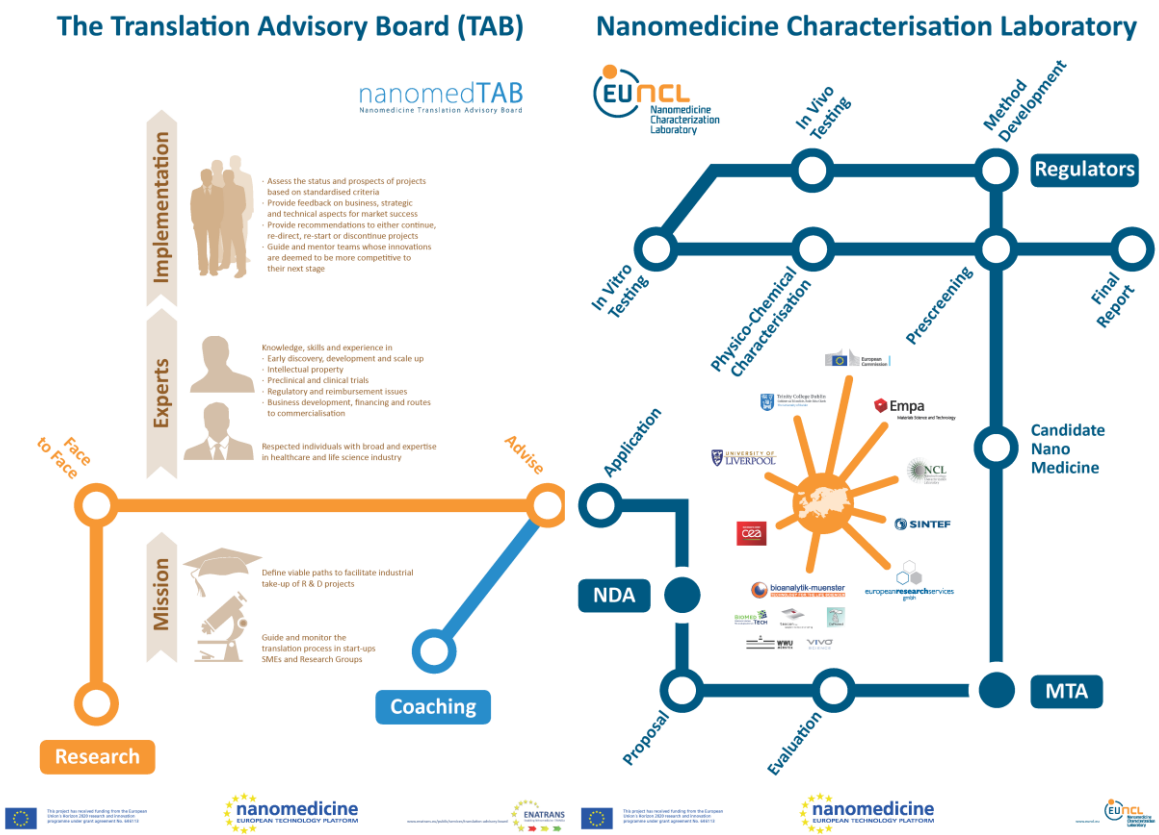
3 Applications

2 STEP2

Applications' origine



Nanomed Translation Hub



GMP Pilot Lines

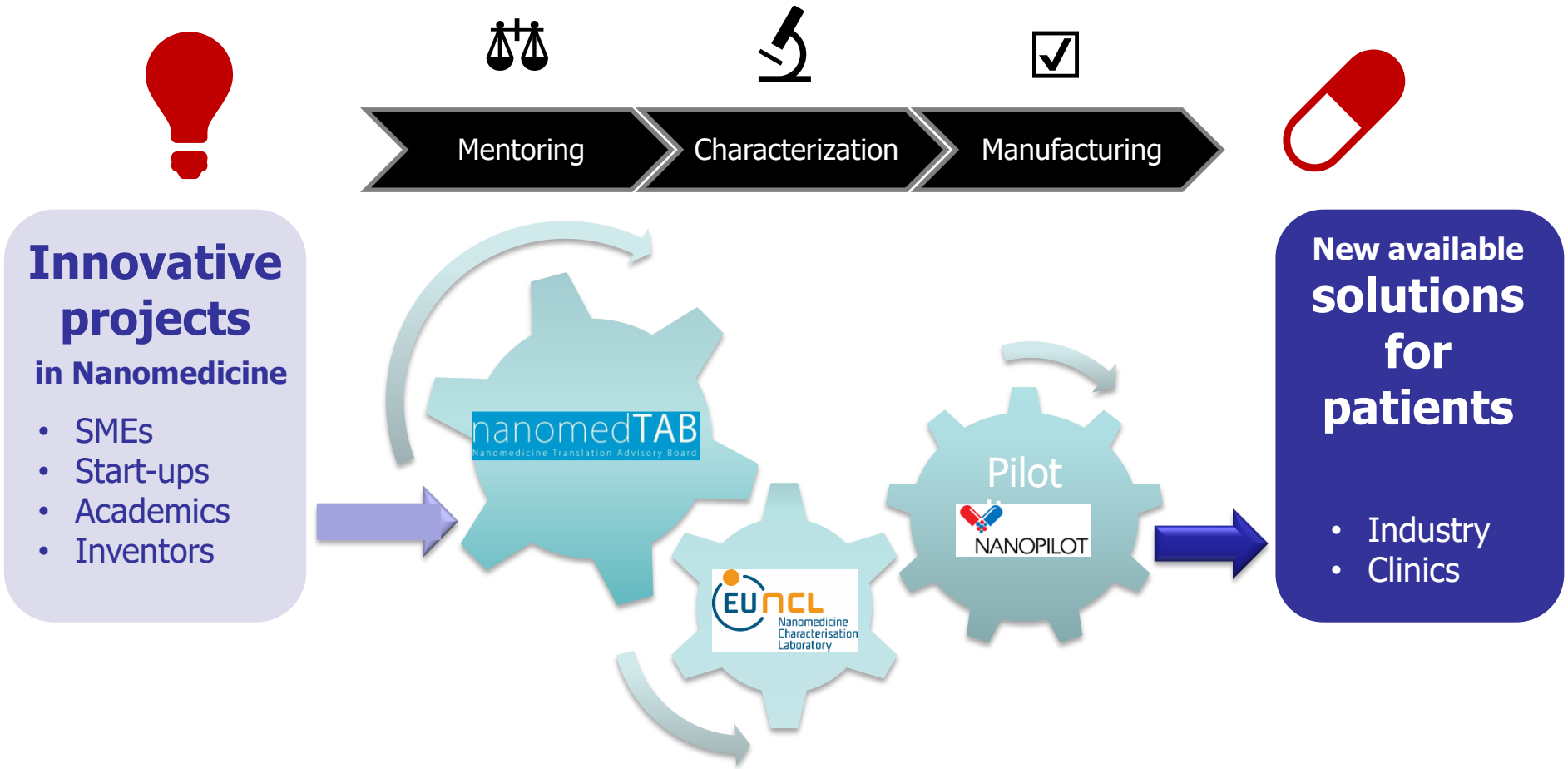
- From mL to L of active medical nanomaterial
- Scale up process for delivering clinical batches
- 3 pilot lines selected by EC in 2014

NANOPILOT

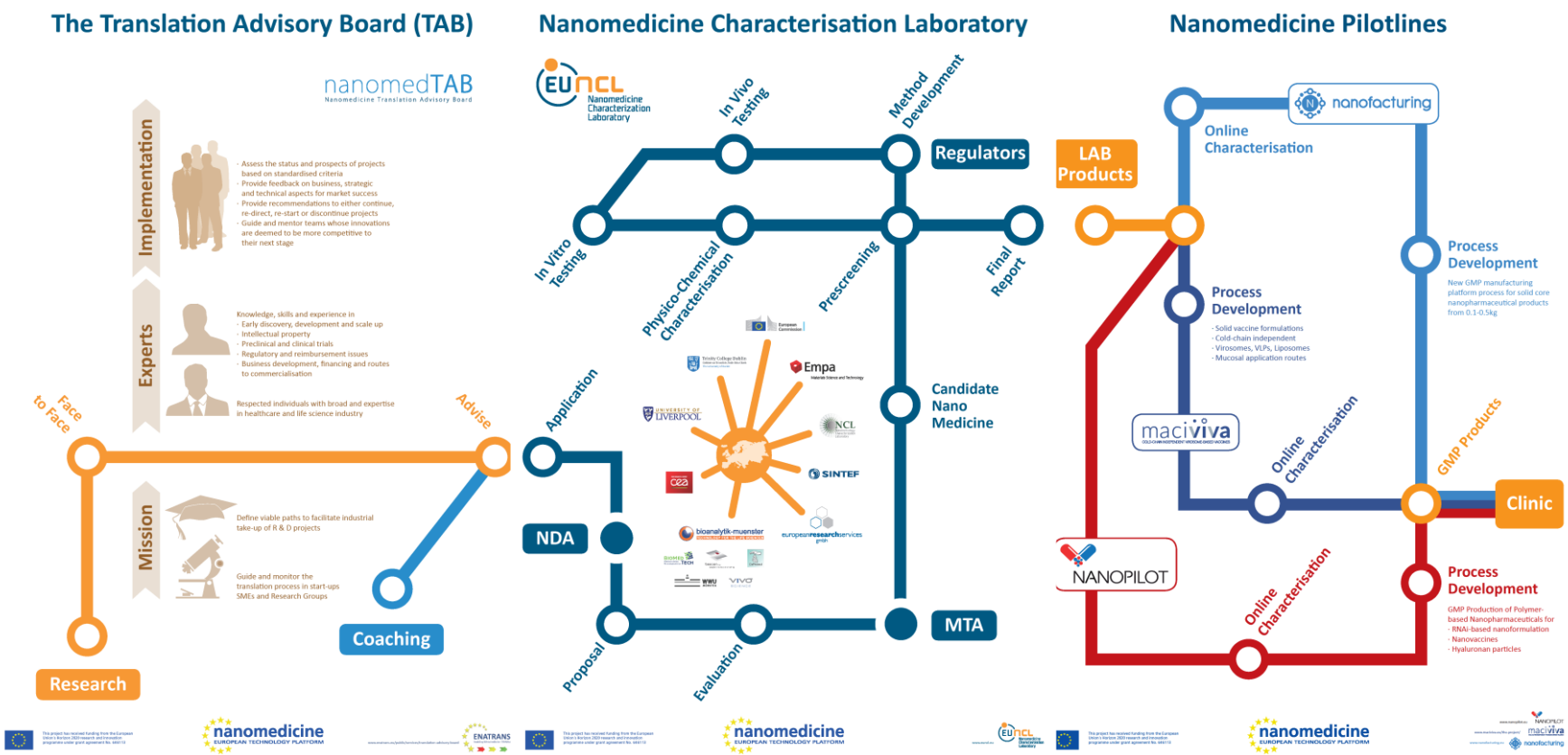
maciviva
COLD-CHAIN INDEPENDENT VIROSOME-BASED VACCINES

nanofacturing

EU Nanomedicine Translation HUB Process



Nanomed Translation Hub



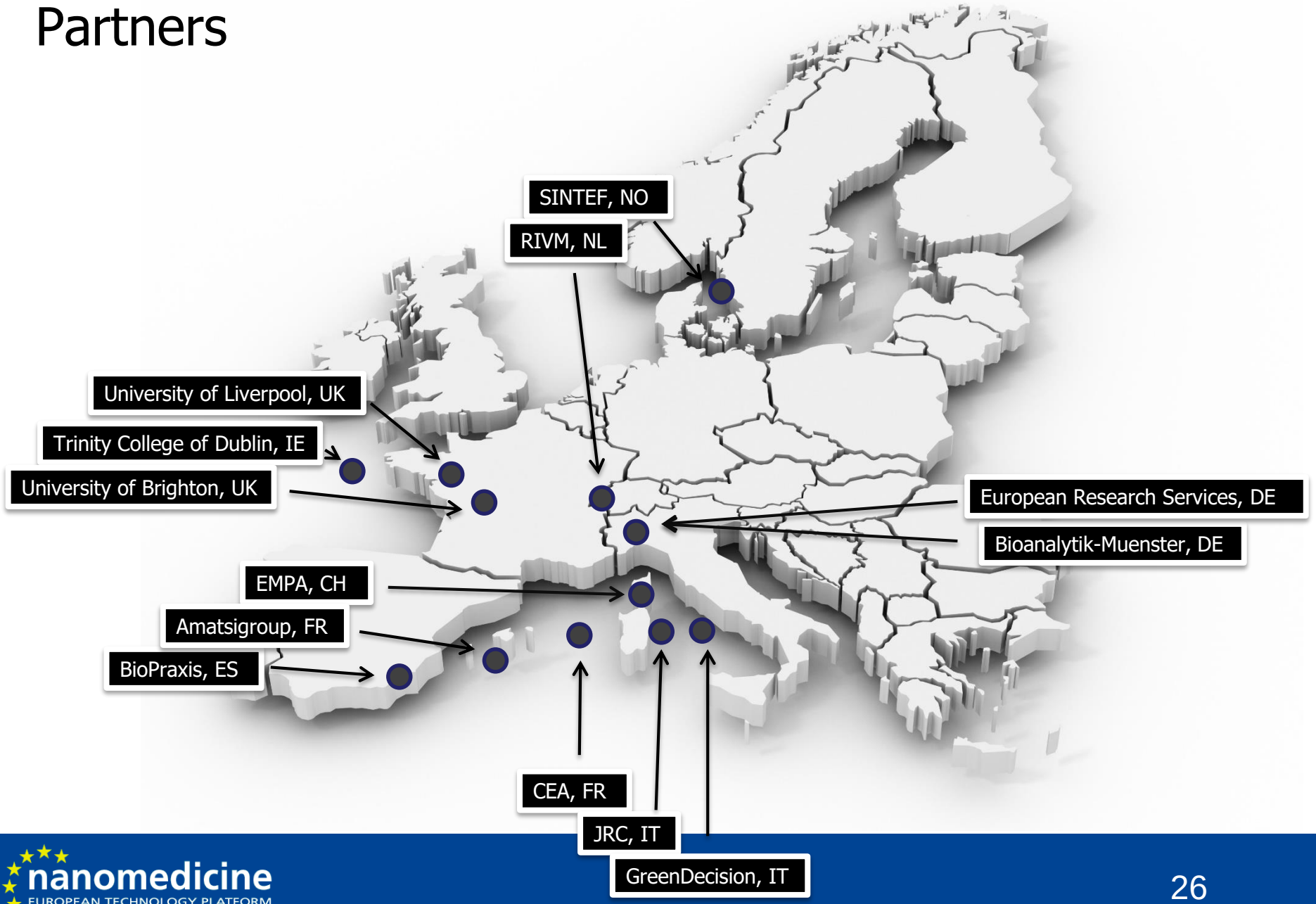
Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices

Objective

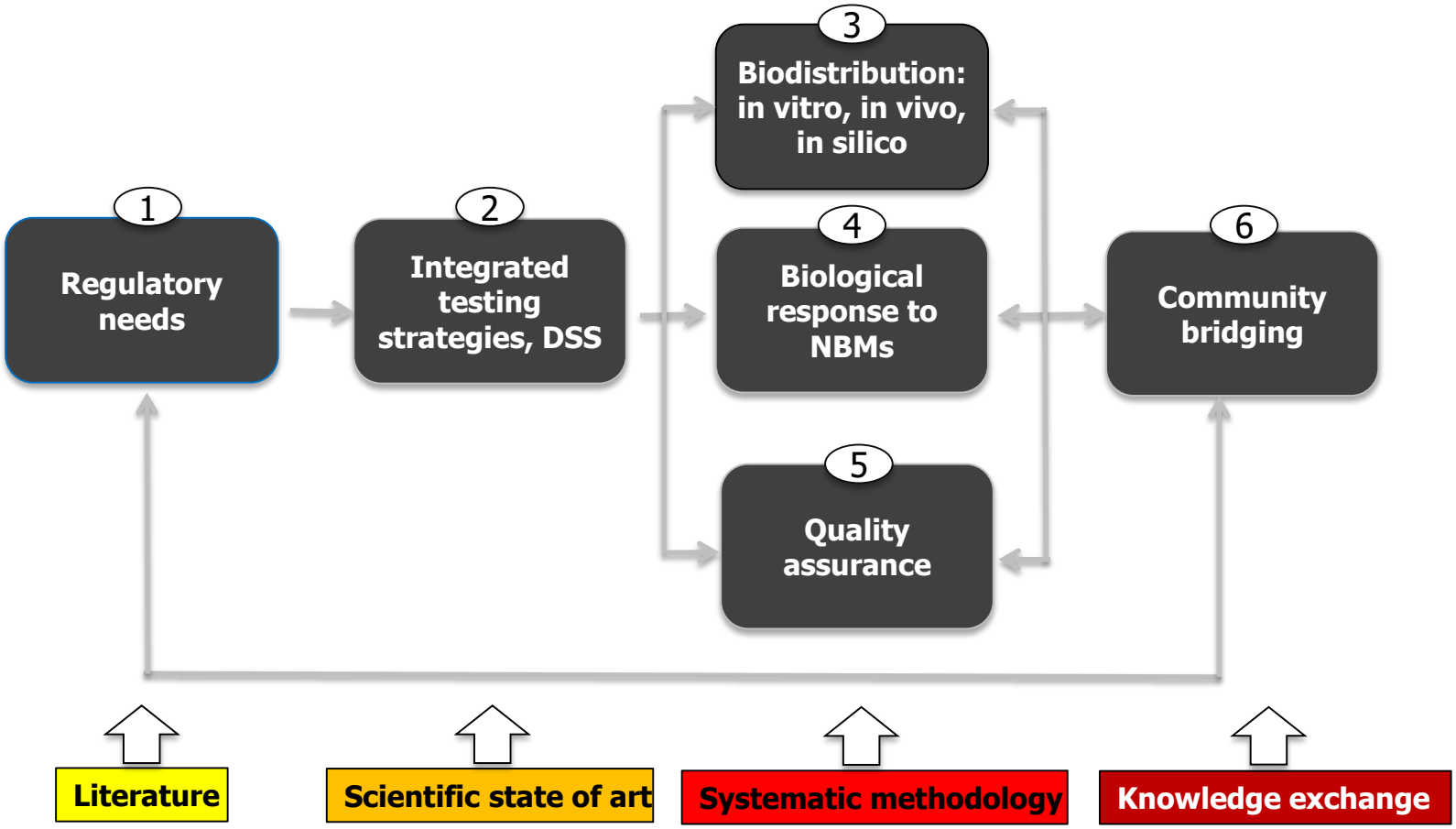
- Regulatory Science Framework for the risk-benefit assessment of NBM-based medicinal products and medical devices

1. Liaise with regulators, identify regulatory concerns
2. Match regulatory concerns with intelligent testing strategies
3. Rationalise testing
4. Refine testing methods to answer to the current most pressing regulatory concerns
5. Assure quality standards for development & testing
6. Bridge communities

Partners


SINTEF, NO
RIVM, NL
University of Liverpool, UK
Trinity College of Dublin, IE
University of Brighton, UK
European Research Services, DE
Bioanalytik-Muenster, DE
EMPA, CH
Amatsigroup, FR
BioPraxis, ES
CEA, FR
JRC, IT
GreenDecision, IT

Structure


1
Regulatory needs
2
Integrated testing strategies, DSS
3
Biodistribution: in vitro, in vivo, in silico
4
Biological response to NBMs
5
Quality assurance
6
Community bridging
Literature
Scientific state of art
Systematic methodology
Knowledge exchange

Aims

- Addressing the most pressing regulatory challenges:
  - borderline products, nanosimilars, products combining several functionalities.
- Identification of the regulatory challenges with Regulation Authorities from Europe and abroad,
- Design methods for tiered decision tree,
- Study/Predict physiological distribution of nanomedicines
- Development of a Decision Support System
- Develop and validate new analytical or experimental methods and assays requested by the regulators
- Improve the PBPK model for three nanoparticles

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Thank you for your attention!

Consult

www.euncl.eu

www.enatrans.eu

www.refine-nanomedicine.com

www.etp-nanomedicine.eu

to

- Download reports and documents
- Find further information