“ Translate or perish”

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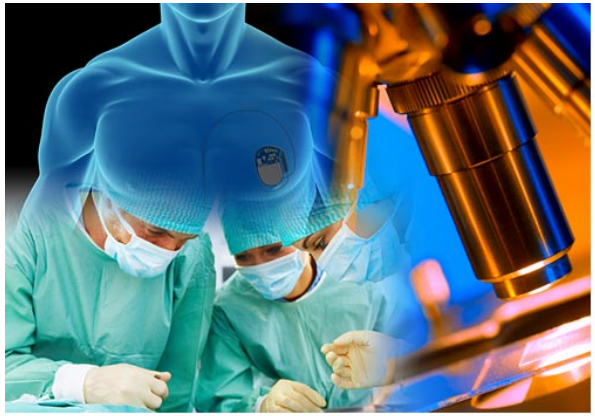
Med Tech in EU

- The market size is estimated at roughly € 100 billion(3)
- Around 8% of sales revenue is ploughed back into research and development
- There are almost 25,000 medical technology companies in Europe(2)
- 95% of MedTech companies are SMEs, the majority of which are small and micro-sized companies(2)
- 500 000 medical technologies
- Innovation cycle is 18-24 months
- New patent every 50 minutes



Source : Eucomed

Big deals in nanomed in 2013 > 1 Bn US$

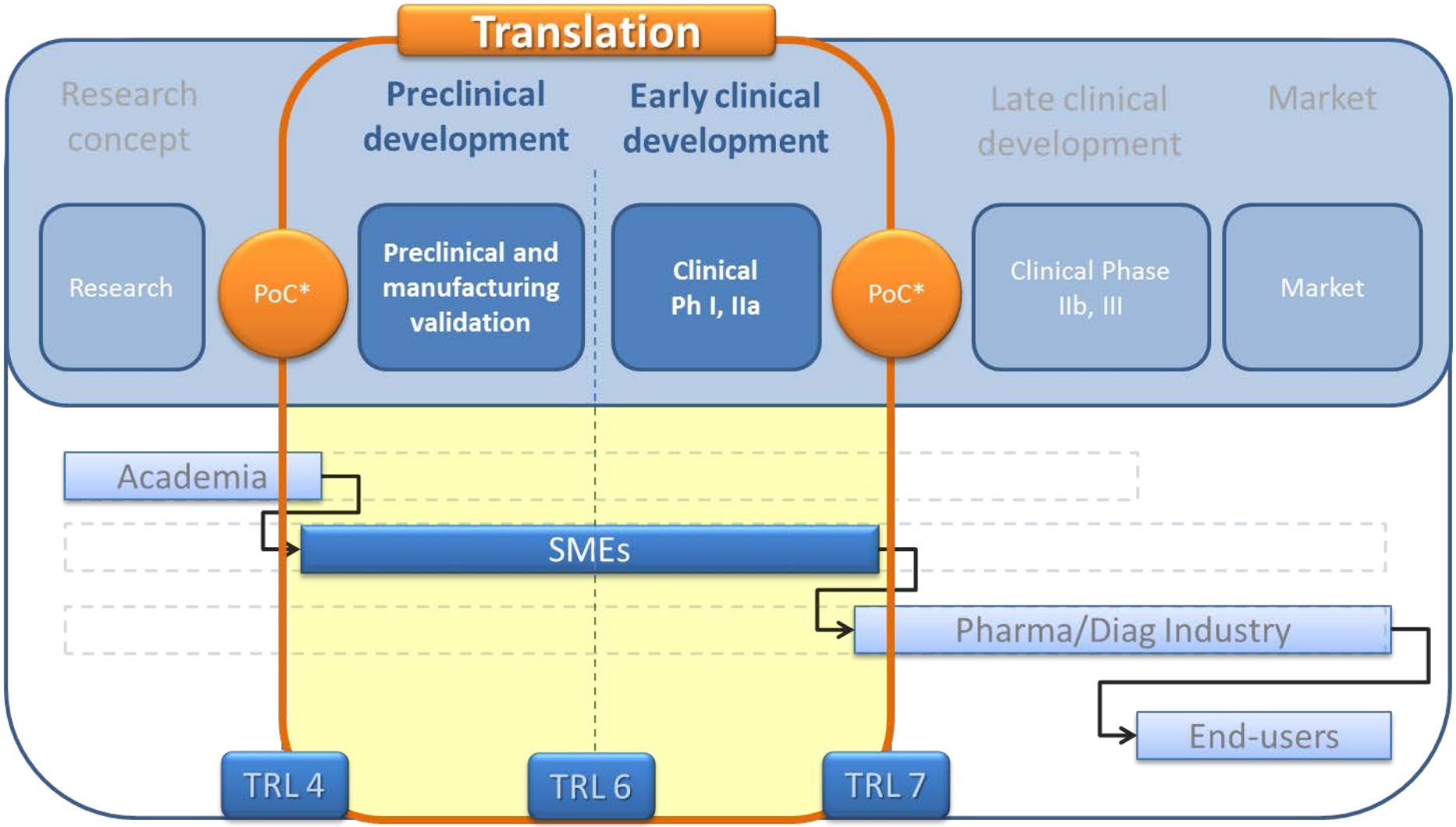
Why not in Europe?

A fantastic environment

- We have scientists and entrepreneurs
  - 1500+ academic partners
  - 500+ SMEs
  - 280+ SMEs in EU projects

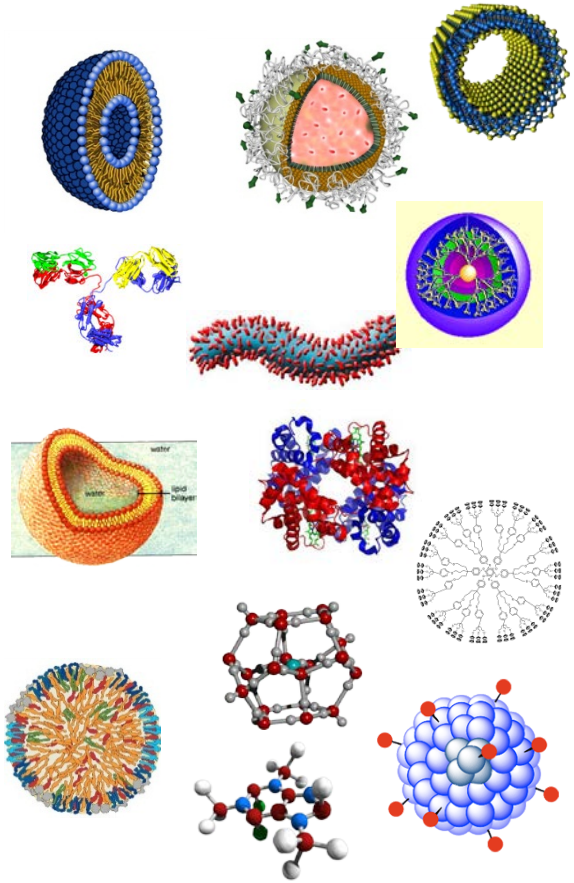
- Research money is there
  - 600 M€ invested by the European Commission under FP7
  - More than 160 research projects
  - 400+ companies

But we miss translation



* PoC = Proof of Concept

What is translation in nanomedicine?



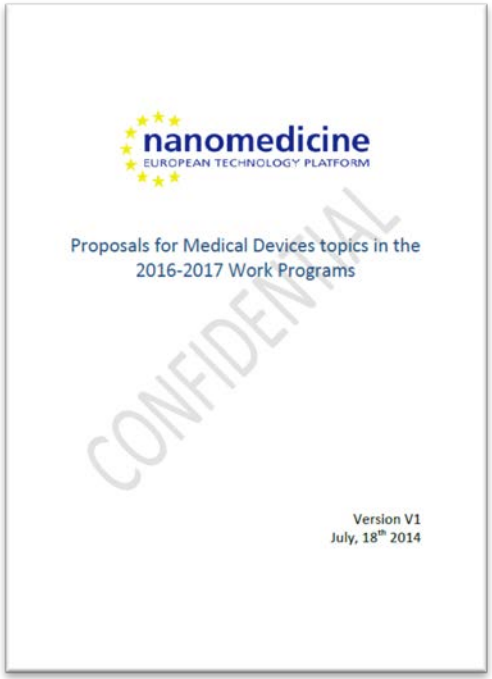
Molecules
(Academia)

Proof of concept

Products
(Industry)

Set up of a Working Group (June 2014)

- Mission : To propose Research and Innovation priorities
  - to speed up the development of medical devices in Europe
  - to facilitate the translation from laboratory proofs of concepts to clinically validated products ready for entering the certification process



- 15 Members from 9 organisations

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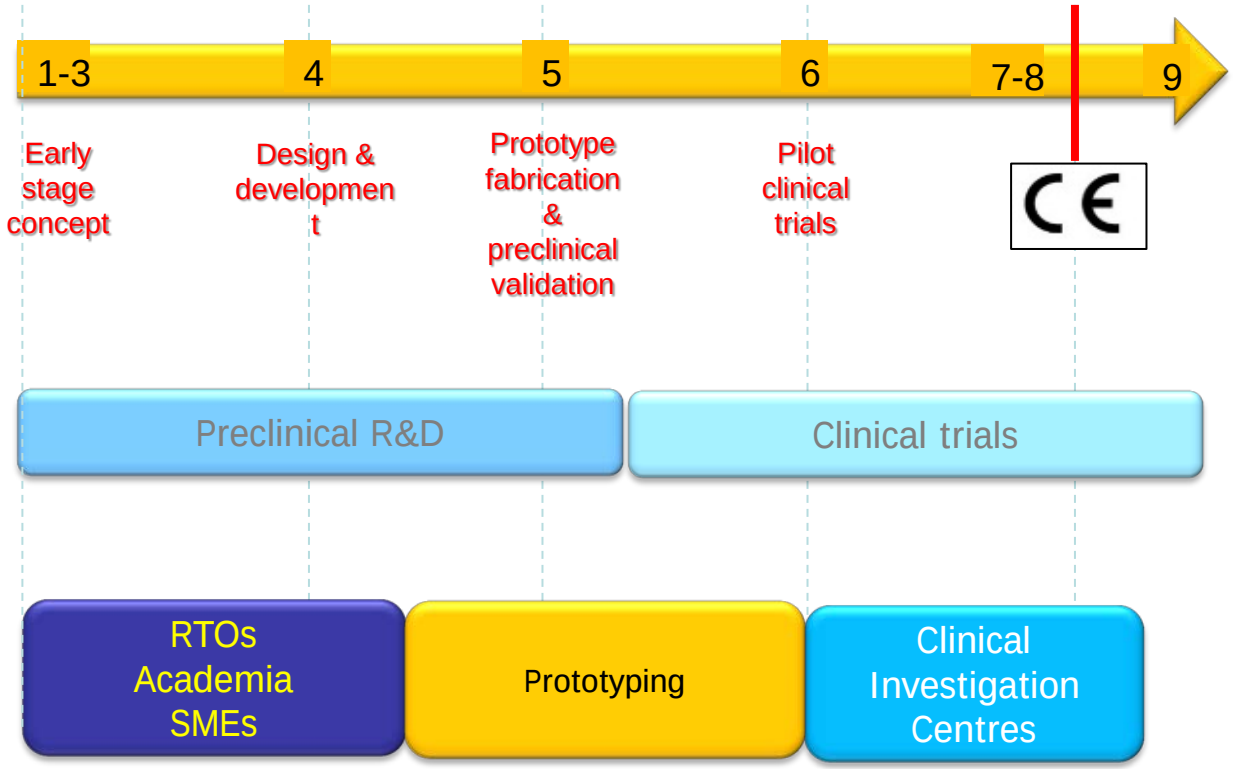
YOLE Développement SORIN GROUP AT THE HEART OF MEDICAL TECHNOLOGY Tyndall National Institute

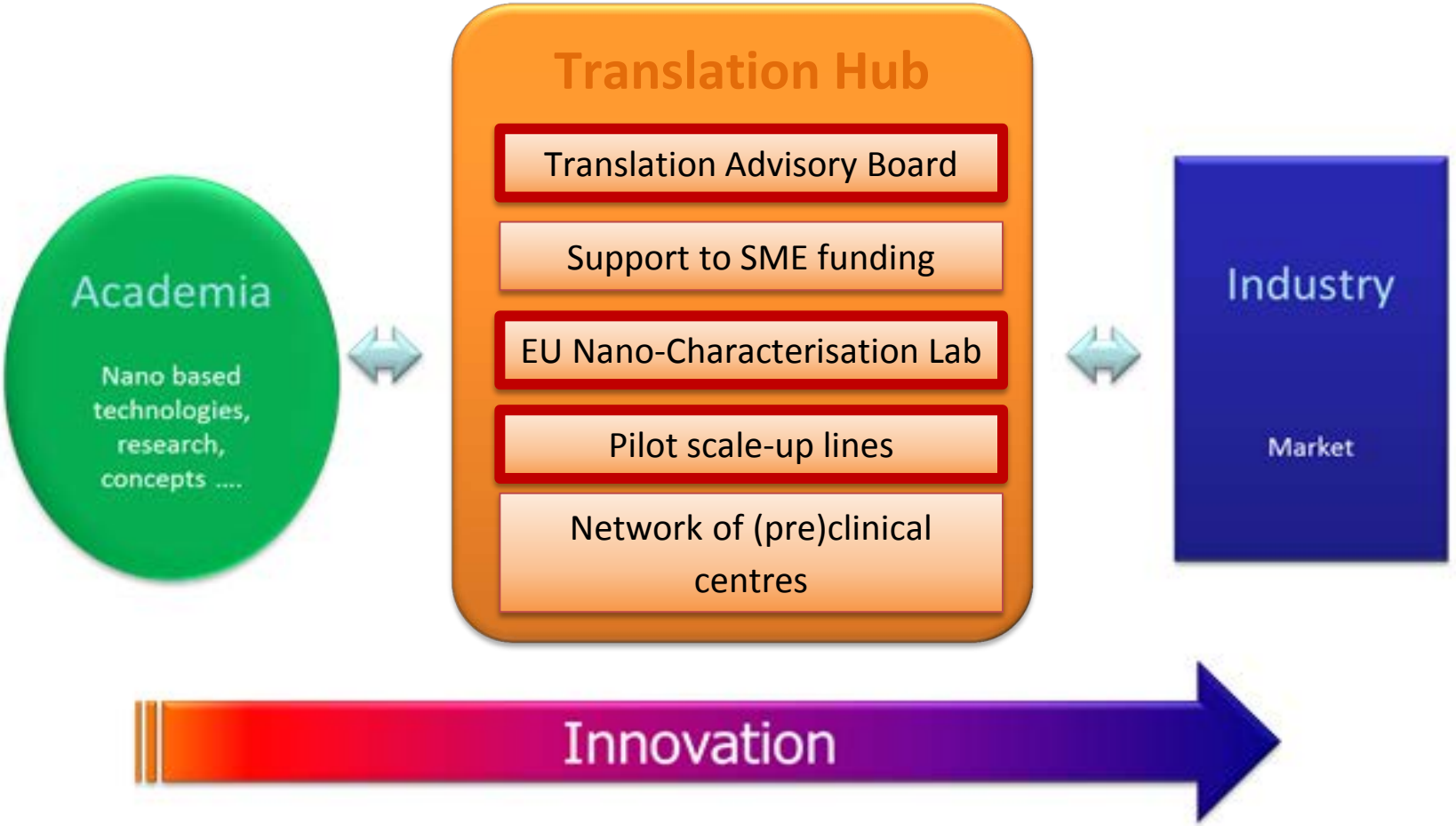
11 proposed topics

- Research & Innovation
  - “Flight simulator” for MedDev
  - Smart prosthetics
  - Smart super patches
  - Organ-on-a-chip
  - Energy autonomy
  - Multiscale integration/biohybridization
  - Prototyping & manufacturing
  - Clinical translation
- Coordination & Support
  - Translation by design
  - Boosting innovation

Clinical translation



The *Med Tech* Translation Hub



Conclusions

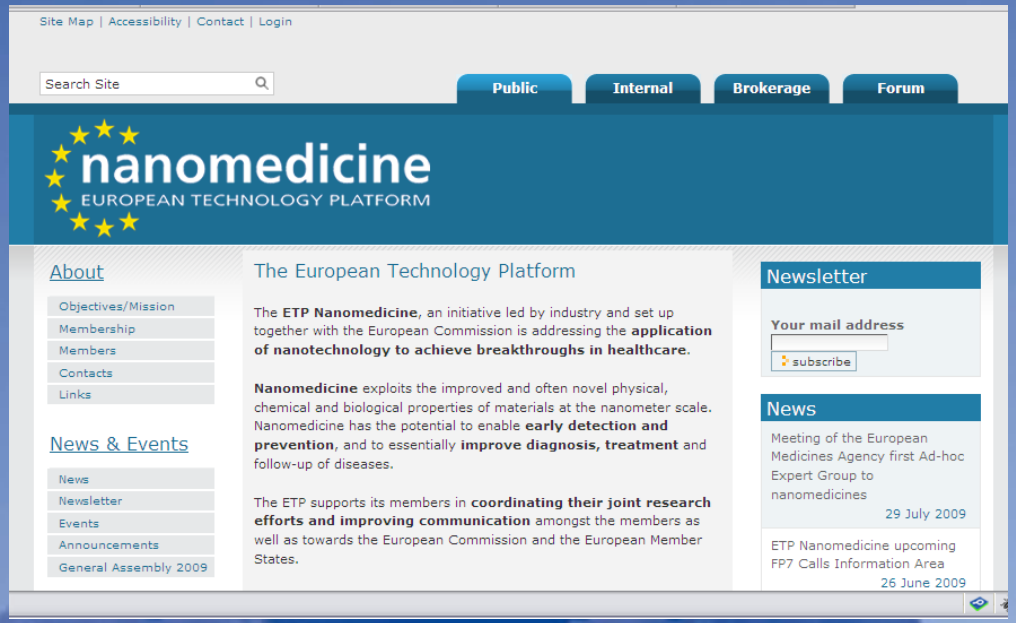
- Economic and social need to improve the success rate of medtech translation
- Moving from “solutions looking for problems" to « unmet medical needs looking for solutions »
- Embrace more of the ABC ecosystem (Academic, Business and Clinical)
- Bridging the gap from TRL4-5 to TRL7-8

Are you ready to cross the Valley of Death?

nanomedicine
EUROPEAN TECHNOLOGY PLATFORM

Consult www.etp-nanomedicine.eu to

- Download reports and documents
- Find further information
- Become a member
- …



For more information, contact:
secretariat@etp-nanomedicine.eu

Back up Slides

1 - “Flight Simulator”-like system for surgical mission rehearsal to prevent avoidable medical errors

ICT

Scope

ICT and nano-enabled solutions to facilitate the development and evaluation of new medical devices.

Optical, electrochemical, magnetic sensing platforms to be redesigned for integration onto minimally invasive surgical tools, onto the clinicians, and around the clinical environment.

Combined data sets from this sensing ecosystem to allow the interrogation of:

- the interactions between the surgical tools with the various tissues,
- the clinician’s movements and emotions,
- the interactions with the rest of the clinical team and infrastructure

Proposed Action: Research and Innovation Action

TRL: from 3 or 4 to 6

2 - Smart prosthetics

ICT

Scope:

Development of a range of sensors and feedback stimulation to be incorporated into prosthetics:

- Tactility
- Proprioception
- Touch sensations

For example, embedded tactility sensors into the cosmetic silicone coating of prostheses can provide a solution for restoration of the sensation of touch.

Flexibility, freedom of movement and comfort demand unobtrusive, highly miniaturised, ultra-low power (ULP) sensing capabilities.

Proposed Action: Research and Innovation Action

TRL: from 3 to 5

3 - Wearable and minimally invasive devices combining biochemical monitoring and drug delivery

ICT, NMP

Scope:

- Developing the new generation of wearable and/or minimally invasive devices
- Combining drug delivery and therapy control.
- Overcoming bottlenecks including
  - monitoring of physical (pulse, ECG) and biological parameters,
  - data fusion,
  - scoring approaches (statistic, heuristic, big data) for closed loop monitoring and treatment,
  - drug delivery systems,
  - adapted energy supply.
  - consumer behaviour, wearability and usage, clinical and medical operability, data security

The projects can include pre-clinical and clinical validation.

Proposed Action: Research and Innovation Action

TRL: from 2 to 6

4 - “Organ-on-a-Chip” – accelerating clinical trials of new drugs and cell therapies with smart devices

ICT, Health

Scope:

- Advances and combination of micro/nano-fluidics and in bioinformatics for use in the clinical testing of drug to monitor the response of artificial organs.
- Projects to develop models close to reality:
  - 1st phase: demonstrate the PoC in the use of such technologies to provide pre-clinical data comparable with results from traditional trials.
  - 2nd phase: integration of such devices to gain an overall picture and conduct clinical trials on-a-chip
- The clinical trial-on-a-chip could be applied to the assessment of new drugs or primary cells and stem cell differentiation (e.g therapeutic effect, toxicity) thanks to innovative approaches mimicking the in-vivo micro-environmental specificities (e.g. 3D cell culture), based on new materials, encapsulation strategies, nano-bio characterisation, micro-nanofluidics, biopolymers. Such devices must be reproducible and manufacturable to guarantee the reproduction of the biological interactions.

Proposed Action: Research and Innovation Action

TRL: from 2 to 5

5 - Human body condition monitoring

ICT

Scope:

- Novel sensor design and manufacturing of prototypes, consideration of nanomaterial surface coatings permitting small yet biocompatible sensors, packaging, power management including energy storage and energy harvesting, communication and read-out, as well as miniaturised actuators (for e.g. pressure release or drug infusion) when required.
- Sensor-to-surface communication as well as energy/power may be addressed in an appropriate manner depending on the application (wired communication and power for short term implantation may be sufficient, while wireless communication and power in the case of long term implantation should be pursued).
- In all cases, projects should result in a complete sensor system including read-out, and at least pre-clinical testing of the sensor system should be implemented.

Proposed Action: Research and Innovation Action

TRL: from 2 to 5

6 - Towards energy-autonomous smart medical devices

ICT

Scope:

The projects should develop innovative power supply and integration solutions for implantable Smart medical devices exploiting in-situ production of energy.

Primary objectives would be the development of materials and devices for:

- Body motion based low frequency energy harvesting device for implants applications
- Glucose Biofuel cells
- Solid state High density rechargeable batteries or
- ultra capacitors coupled to efficient energy scavengers
- Reliability and robustness study of the energy scavenger
- Biocompatible packaging for very small active MD in harsh environment

Proposed Action: Research and Innovation Action

TRL: from 3 to 6

7 - Multiscale integration at the biointerface

ICT

Scope:

The proposals may address:

- nano-enabled device or device concept where the multilevel integration (nano-bio-micro-mini) is required.
- Process chains permitting efficient manufacturing of such devices
- application to one or more specific demonstrator devices.

Advanced characterization methods should be an integral part of the proposals in order to allow for detailed analysis of the biological components, nanomaterials and microsystems throughout the integration chain.

Proposed Action: Research and Innovation Action

TRL: from 3 to 6

8 - Beyond laboratory proofs of concept:

Prototyping and manufacturing of small series of medical devices for pre- or clinical validation

ICT

Scope:

The proposed projects should focus on increasing the maturity of the existing technological platforms in Europe to address the specificities of the medical technology market and accompany industrial companies on the most delicate steps of the innovation chain.

The objective is to offer a single entry point to innovative prototyping services able to manufacture the first prototypes ready for pre-clinical and clinical validation.

This new offer should include:

- the questions of usage (end-users appropriation, clinical operability),
- the regulatory requirements for clinical trials and manufacturing quality (e.g. ISO13485),
- the set-up, for each class of medical devices, of a consolidated supply chain in EU.

Proposed Action: Innovation Action

TRL: from 4 to 6-7

Ideally it should fund a large and structuring project of 15-20M€, including demonstrators

9 - Medical translation centres for an accelerated and safer translation of innovative medical devices

Health, INFRA

- Accelerating clinical validation of innovative technologies in connection with the industrial medtech area
- Need for dedicated connected centres integrating multimodal and multidisciplinary investigations inside “cognitive” trials (association of clinical, multimodal imaging, interventional physical, electrophysiology and poly-omics investigations ...)
- International renewing of the biomedical strategy need to validate the first proof of concept in the medtech field in strong relationship with the new emerging methodology
- Strong multimodal assessment of tissue biodistribution is mandatory in the vectorisation field.

Proposed Action: Research & Innovation Action

TRL: from 4 to 6-7

10 - Translate by design: integrating users' requirements in designing smart Medical Devices

ICT

Scope:

The proposed CSAs should survey and coordinate the consideration of societal issues and users' requirements across the projects related to Smart Medical devices development.

It should provide support, guidance, training and methods to developers to engage with end-users, identify their needs and requirements and integrate them in the design of future products.

Two domains should be particularly addressed: Smart miniaturised implants and in-vitro diagnostic devices.

Proposed Action: Coordination & Support Action

TRL: from 2 to 7

11 - Fostering innovation in the smart medical devices sector, by networking, advising, training and coaching

ICT, Health, Marie-Curie

Scope:

A coordinated and targeted support is required on different levels to enable SMEs and academia with successful translation.

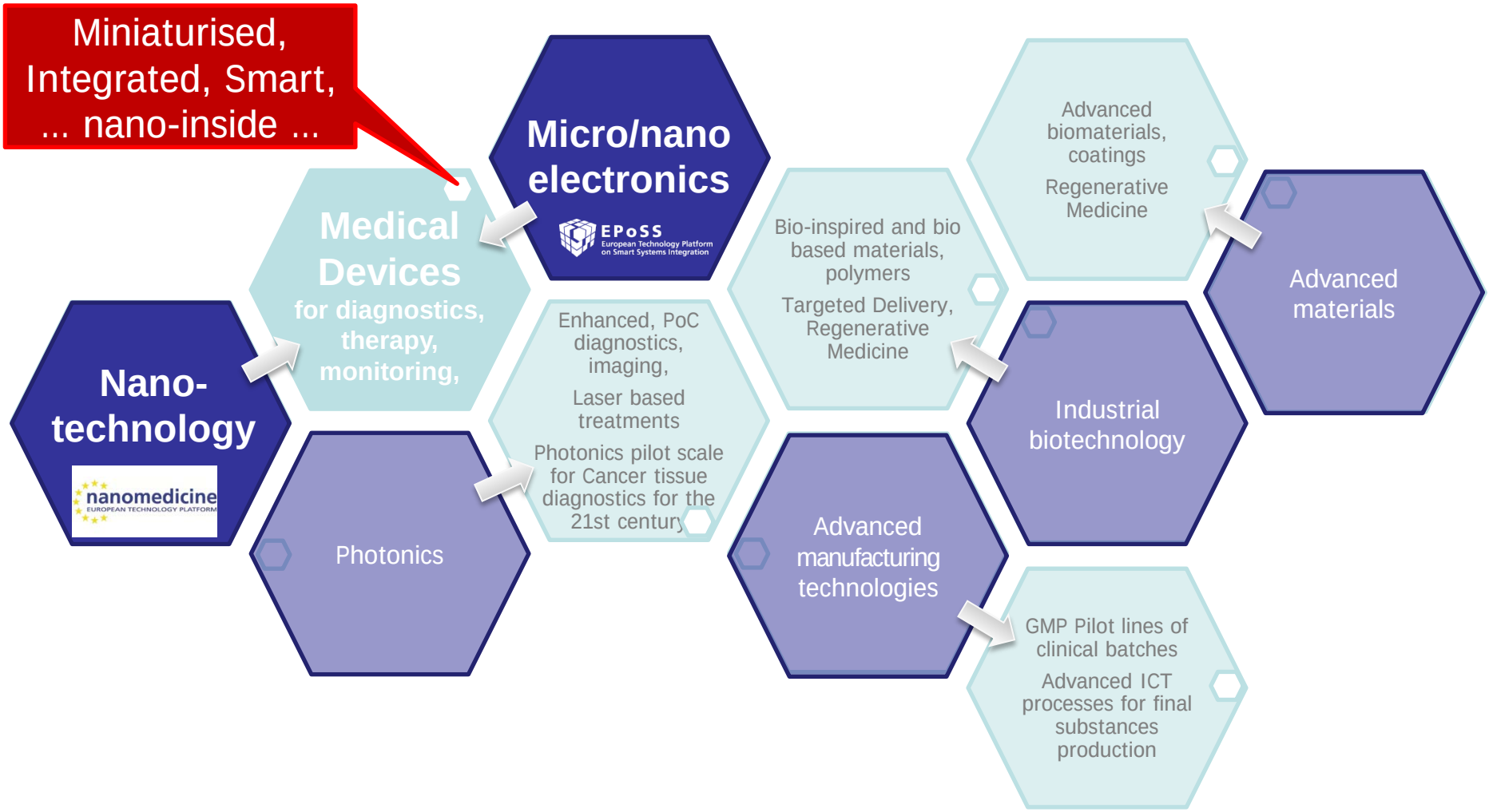
Proposals shall provide advice and follow-up at all stages of the R&D&I and provide examples of best practices to European R&D teams in the Smart Medical Devices sector. It shall provide business-oriented and technological assessment of technologies and business advice before engaging efforts to cope with regulation or to scale-up manufacturing.

Training and coaching services should be provided to Management teams of healthcare SMEs to structure their processes according to the needs of their specific activity, and develop the strategies that optimize the chances of success.

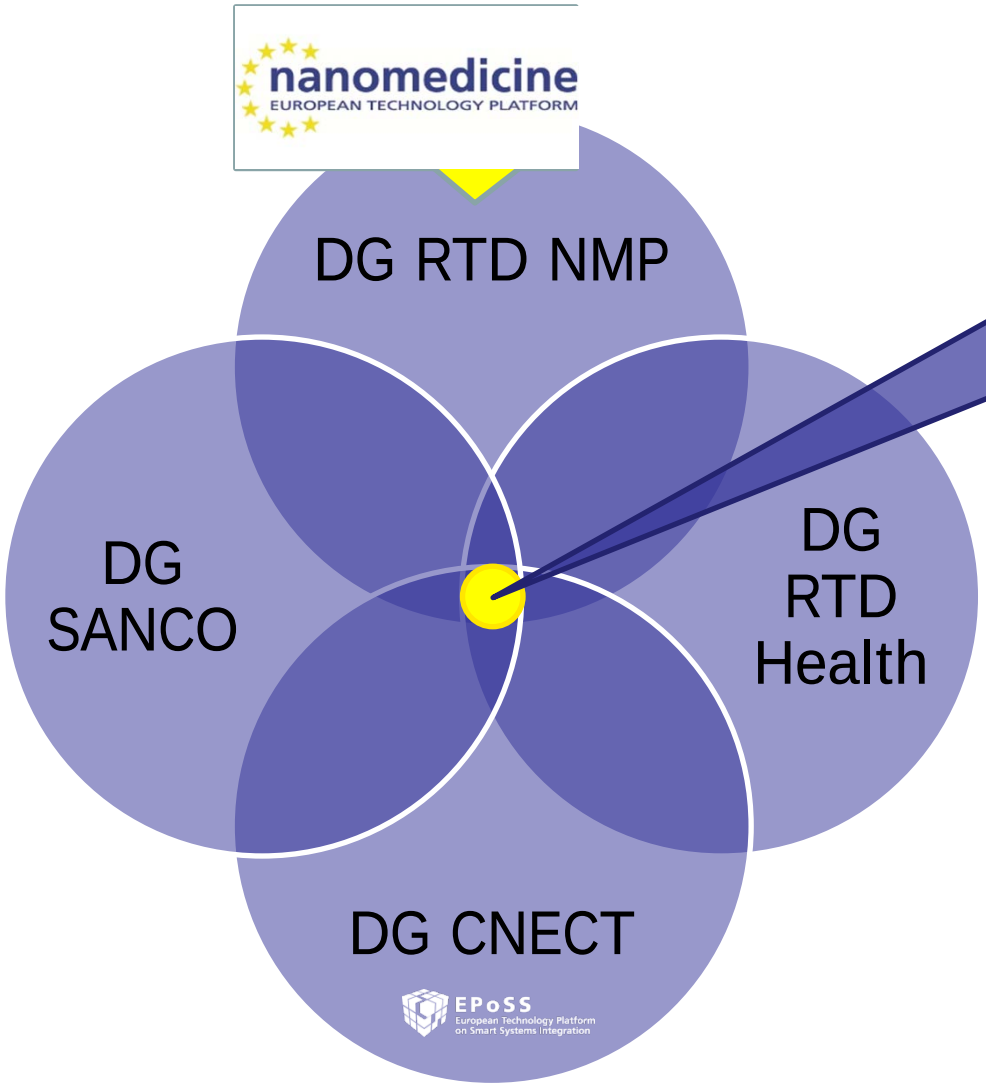
Proposed Action: Coordination & Support Action

TRL: from 2 to 7

Starting point: Multi-KETs approach of Medical Devices



Multi-sources in the EC for support of medical devices R&I



Innovative medical technologies to answer the societal challenge on Health, Demographic Change and Well-being

Need for an effective translation process of (nano-enabled) Medical Devices