Regulatory Science For Innovation

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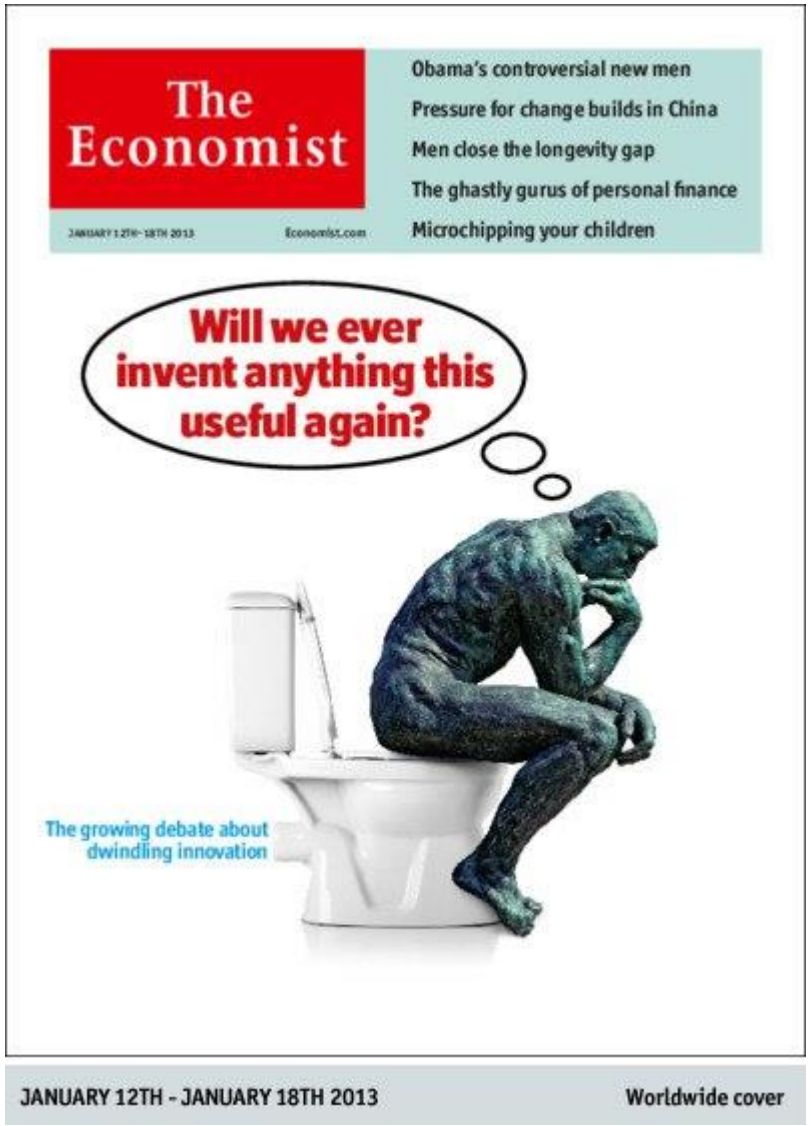
The Future of (Bio)pharmaceutical Manufacturing
28 February 2017

Research and Innovation

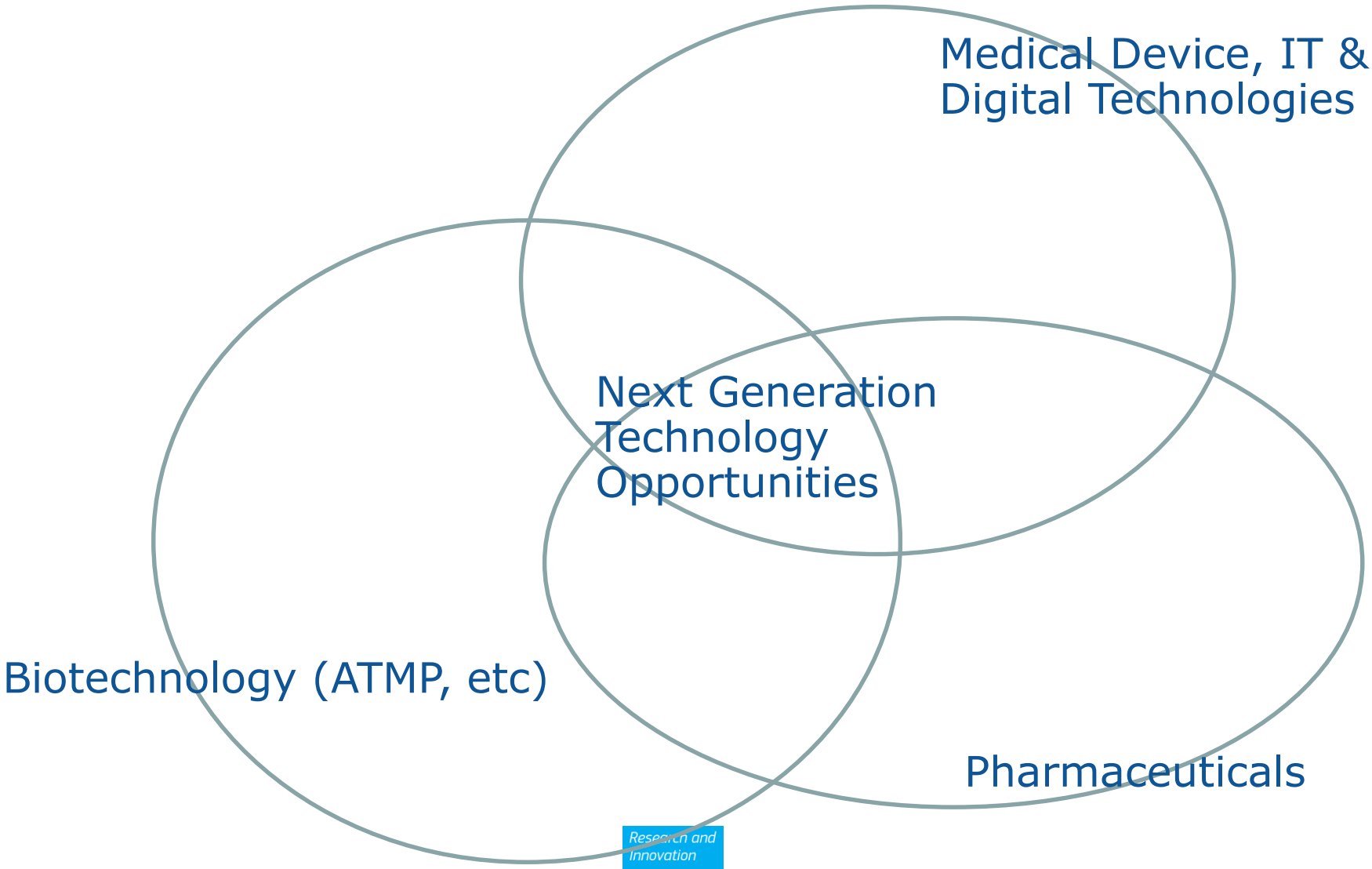
Paradigm shifts in Healthcare

- from acute medical interventions towards preventive strategies
- from the use of blockbuster “one-size-fits-all” towards the personalised approach
- from supportive treatments aiming towards a complete cure
- increased patient empowerment



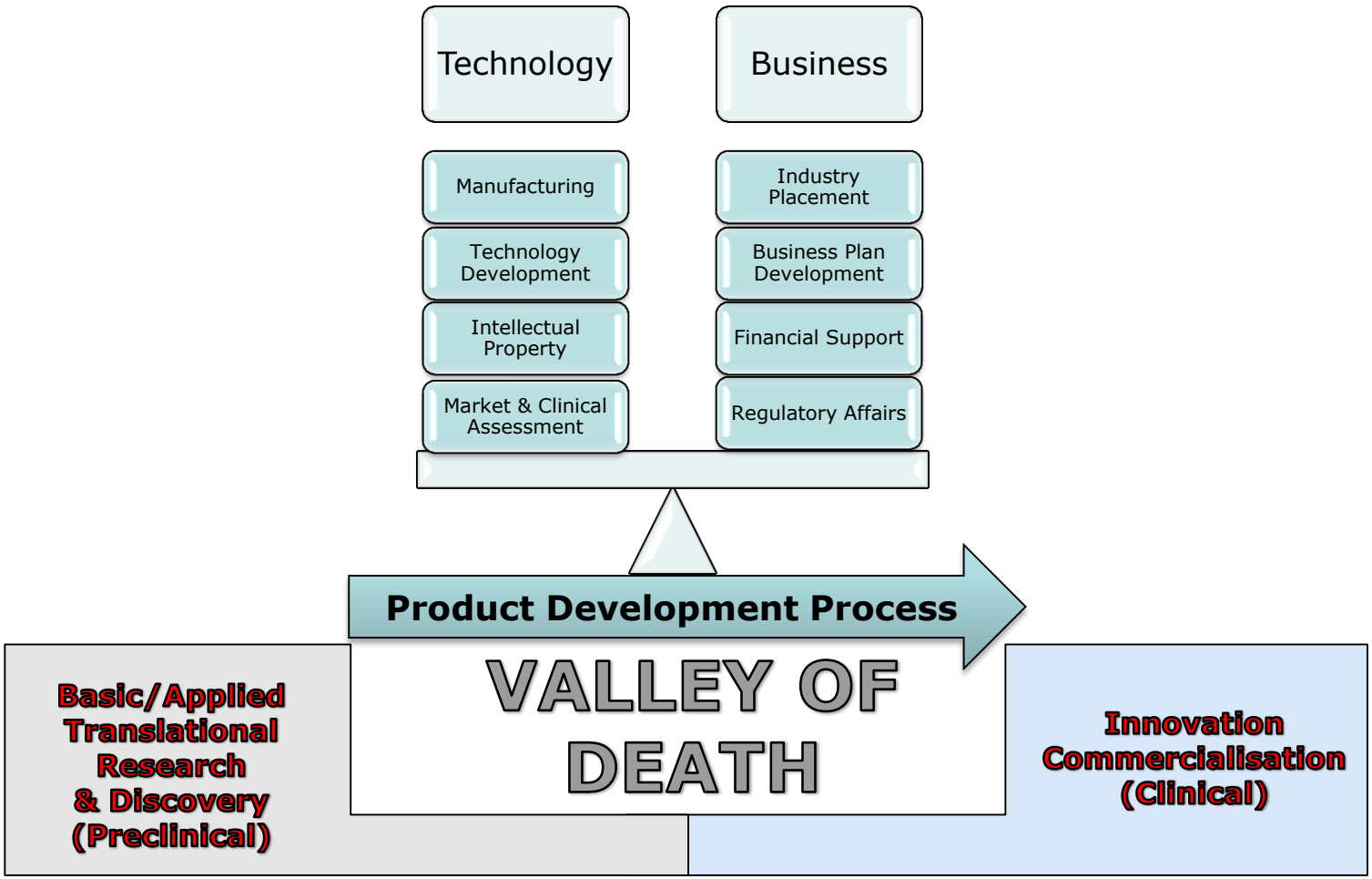
Innovation challenges :

- **Co-development with an existing therapy**
- **Improved delivery of an existing therapy**


Medical Device, IT &
Digital Technologies
Next Generation
Technology
Opportunities
Biotechnology (ATMP, etc)
Pharmaceuticals

Role of the Regulator

- To safeguard the public
- To facilitate innovation

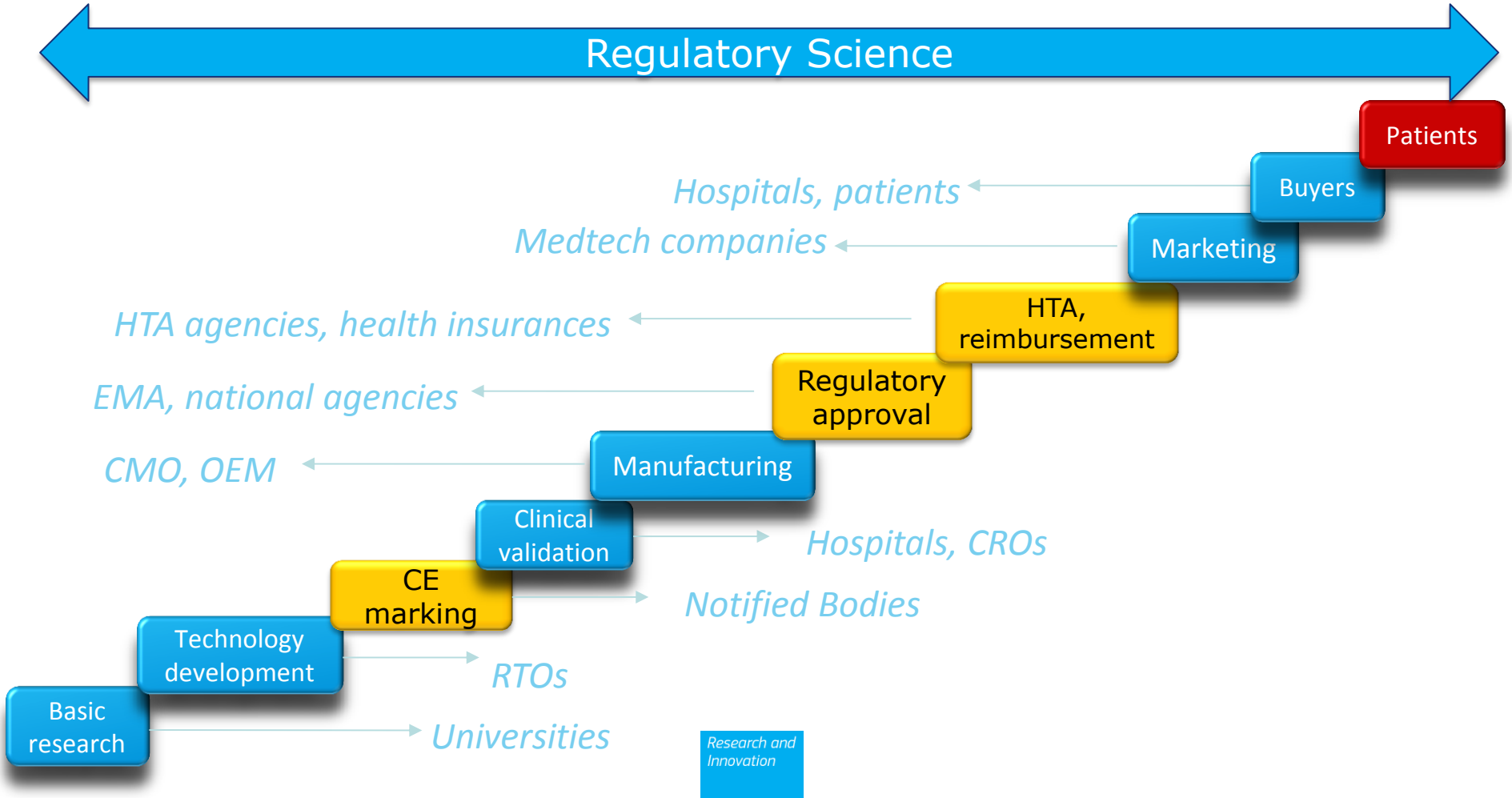

Technology
Business
Manufacturing
Technology Development
Intellectual Property
Market & Clinical Assessment
Industry Placement
Business Plan Development
Financial Support
Regulatory Affairs
Product Development Process
Basic/Applied Translational Research & Discovery (Preclinical)
VALLEY OF DEATH
Innovation Commercialisation (Clinical)

European Commission

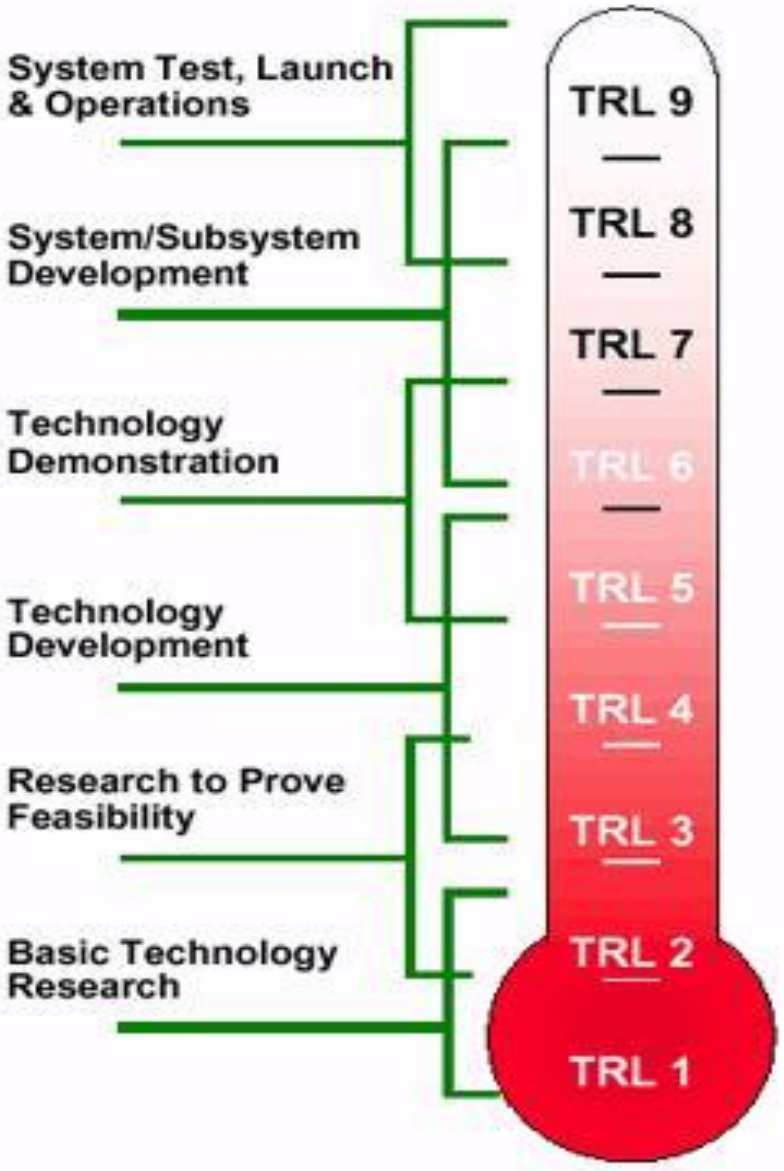
Regulatory Science

The acquisition and combination of scientific, technical and socio-economic data in a way to enable appropriate decision-taking regarding the marketing and use of innovative and cost-effective healthcare interventions by patients.

Stakeholders along the Innovation Chain



Research and Innovation



I. Technology Readiness Levels – Value-added milestones

TRL for Healthcare

Level	Definition	Explanation
1	Basic Principles Observed and Reported in the Context of a Capability Shortfall	Potential scientific application to defined problems is articulated.
2	Technology Concept and/or Application Formulated	Hypothesis(es) generated. Research plans and/or protocols developed, peer reviewed, and approved.
3	Analytical and Experimental Critical Function and/or Characteristic Proof of Concept	Basic research, data collection, and analysis. First hypotheses tested, alternative concepts explored. Initial characterisation of candidates in preclinical studies.
4	Component and/or Breadboard Validation in Laboratory/Field Environment	Non GxP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design
5	Component and/or Breadboard Validation in a Relevant (Operating) Environment	Intense period of nonclinical and pre-clinical GxP research studies involving parametric data collection and analysis in well-defined systems.
6	System/Sub-System Model or Prototype Demonstration in a Realistic (Operating) Environment or Context	Clinical Performance Studies to demonstrate safety in a small number of human subjects under strictly controlled conditions
7	System Prototype Demonstration in an Operational Environment or Context (e.g., Exercise)	Clinical Performance Studies to demonstrate effectiveness and safety with a fully operational prototype in an operational environment
8	Actual System Completed and Qualified through Test and Demonstration	Clinical Performance Studies to evaluate effectiveness and safety to evaluate overall risk-benefit ratio of the device and provide adequate basis for product labelling
9	Actual System Operationally Proven through Successful Mission Operations	Post Marketing Studies

II. Education and Training

- **Interdisciplinarity : science along with ethics, business administration, law etc.**
- **Mutual recognition of degrees, diplomas**
- **Practical hands-on training schemes in industrial settings**

III.Regulatory Incentives

- **Data certification**
- **Advice for SMEs**