



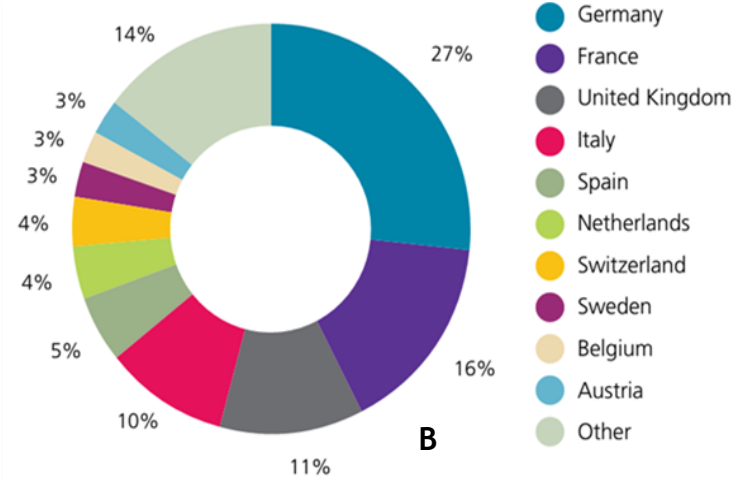
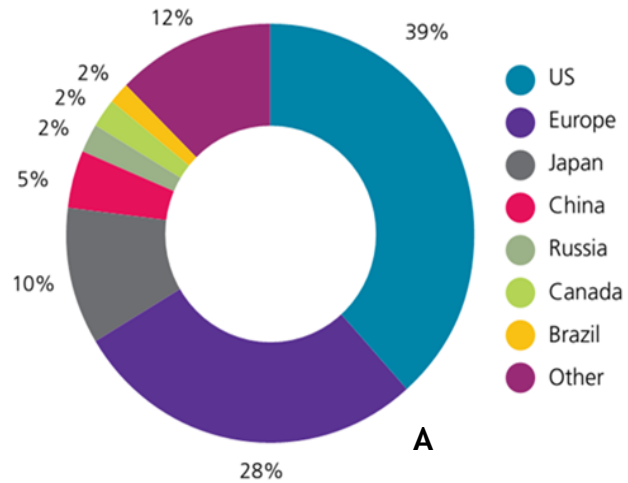
www.nortexcel2020.eu

Analysis of Dynamite methodology and definition of roadmap for its implementation and operationalization

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Knowledge Intensive Services, Lda

December 2017

MEDICAL DEVICES



World and European medical devices market by country

Adapted from Judite Neves, *Medical Device's Regulatory story*, INFARMED, March 2015

World medical devices value

\$400 billion
2017



\$522 billion
2022

CE-marking: Regulatory context in Portugal

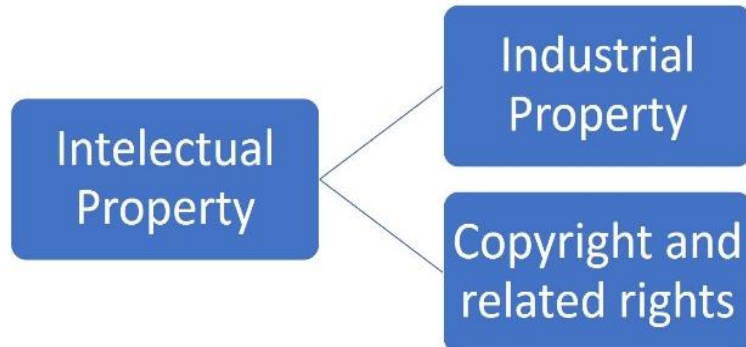
- ▶ **Decree-Law 273/95** - Rules governing the manufacture, marketing and entry into service of the medical devices and its accessories
- ▶ **Decree-Law 30/2003** - Transposes Directives 98/79/EC, 2000/70/EC and 2001/104/EC (Repealed by Decree-Law no. 145/2009, of 17 of June)
- ▶ **Decree-Law 76/2006** - Transfers to the National Institute of Pharmacy and Medicine the authority in the field of active implantable medical devices (Revoked by the Decree-Law no. 145/2009, of 17 of June)
- ▶ **Ordinance 136/96** - Technical standards for the manufacture, marketing and entry into service of DM and accessories
- ▶ **Decree-Law 145/2009** - Defines the rules to be followed in the investigation, manufacture, marketing, entry into service, surveillance and advertising of medical devices and transposes into national law the Directive 2007/47/EC. This is the currently the fundamental legislation on medical devices in Portugal
- ▶ **Decree-Law 189/2000** - Defines the rules governing the manufacture, marketing and use of the In vitro diagnosis medical devices (IVDD) and its accessories

Class	Sub-class	Risk	Examples	Observations
I	Basic	Low	Reusable surgical instruments, nonsterile gloves	<ul style="list-style-type: none"> - Low risk to patient - Non-invasive
	Sterile	Low	Sterile dressing, sterile gloves	
	Measurement function	Low	Volumetric urine bag	
II	IIa	Medium	Surgical blades, suction equipment	<ul style="list-style-type: none"> - Medium risk to patients - Invasive to human body, but only via natural body orifices - Also includes therapeutic diagnostics and devices for wound management
	IIb	High	Orthopedic Implants, radiotherapy equipment	<ul style="list-style-type: none"> - High risk to patients - Partially or totally implantable - May modify the biological or chemical composition of fluids
III	III	High	Prosthetic joints, coronary stent	<ul style="list-style-type: none"> - High risk to patients - Affect the functioning of vital organs and/or life-supporting systems

Intellectual Property

Benefits of IP

- ▶ Protecting innovation and creating new products and services
- ▶ Obtaining licenses to exploit products or processes patented by other companies
- ▶ Granting operating licenses on their own patents
- ▶ Using innovation or incorporating techniques protected by patents and utility models that have expired and are in the public domain
- ▶ Using the technological information present in patents to evaluate the innovation of the competition and sector its degree of protection
- ▶ Using the technological information to search for collaborators, partners and allies



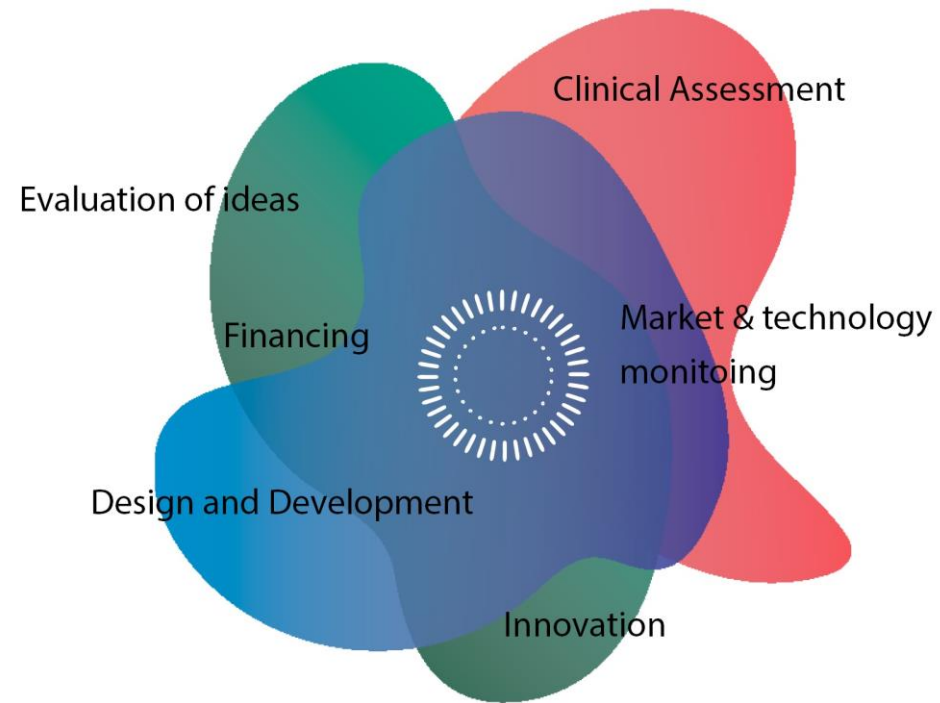
Depenning India

Dynamite Methodology

Network of medicine, health sciences,
medical technology, business and law
directed to SMEs and researchers via a web
platform as a one-stop shop on their way to
established medical products.



Promoting innovation, technology transfer
and networking in South-Eastern Austria





Innovation Support

- ▶ Online innovation support platforms
 - ▶ Online marketplaces for technologies
 - ▶ Project management and new product development - e.g. Hype Enterprise, Neptune Project
 - ▶ InnovationsLOTSE - Germany
- ▶ Disadvantages
 - ▶ Do not support the complete innovation value-chain
 - ▶ Do not aim the specificities of medical devices
 - ▶ Do not provide personalized feedback regarding specific doubts or problems

Adaptation of Dynamite by NXCEL

Platform to support companies and researchers to innovate in the industry of medical devices, from development to commercialization. It covers the following stages:

- ▶ Anamnesis
- ▶ Evaluation of the project
- ▶ Implementation phases
- ▶ Enterprise characteristics
- ▶ Market assessment
- ▶ Financing needs
- ▶ Innovation sustainability

Use Case #1

SME

- ✓ New Technology
- ✓ Market
- ✓ Business Model
- ✗ CE Certification

NXCEL Platform:

NORTEXCEL

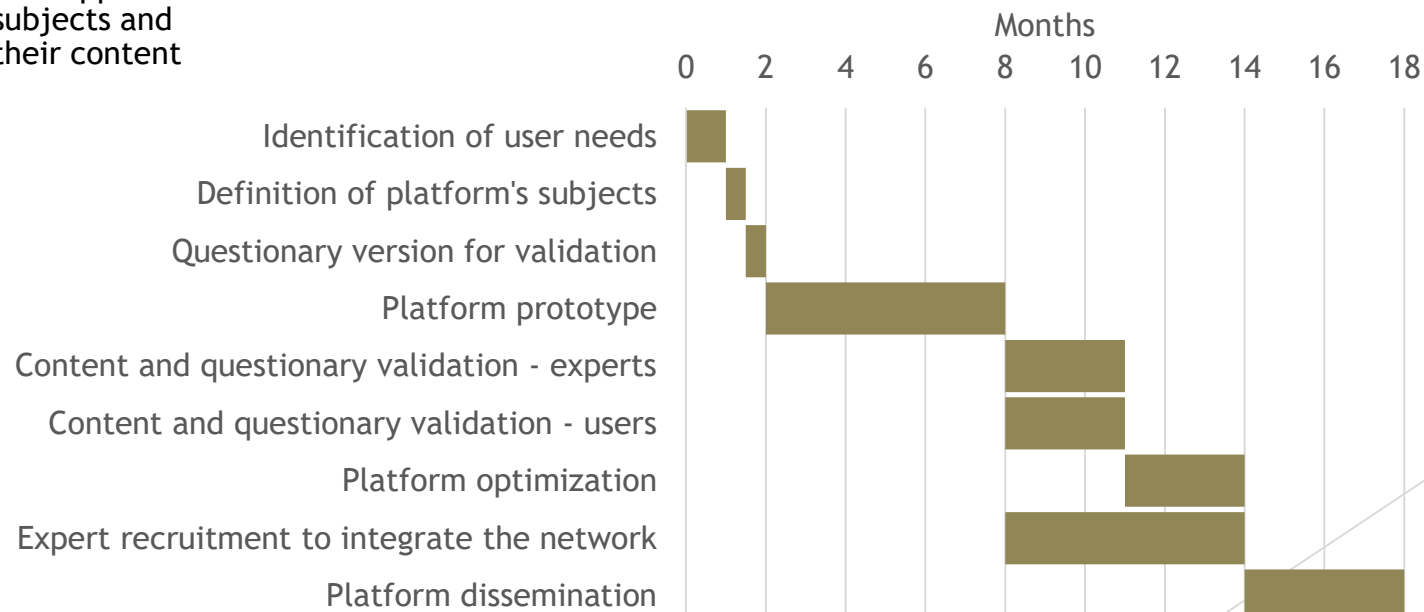
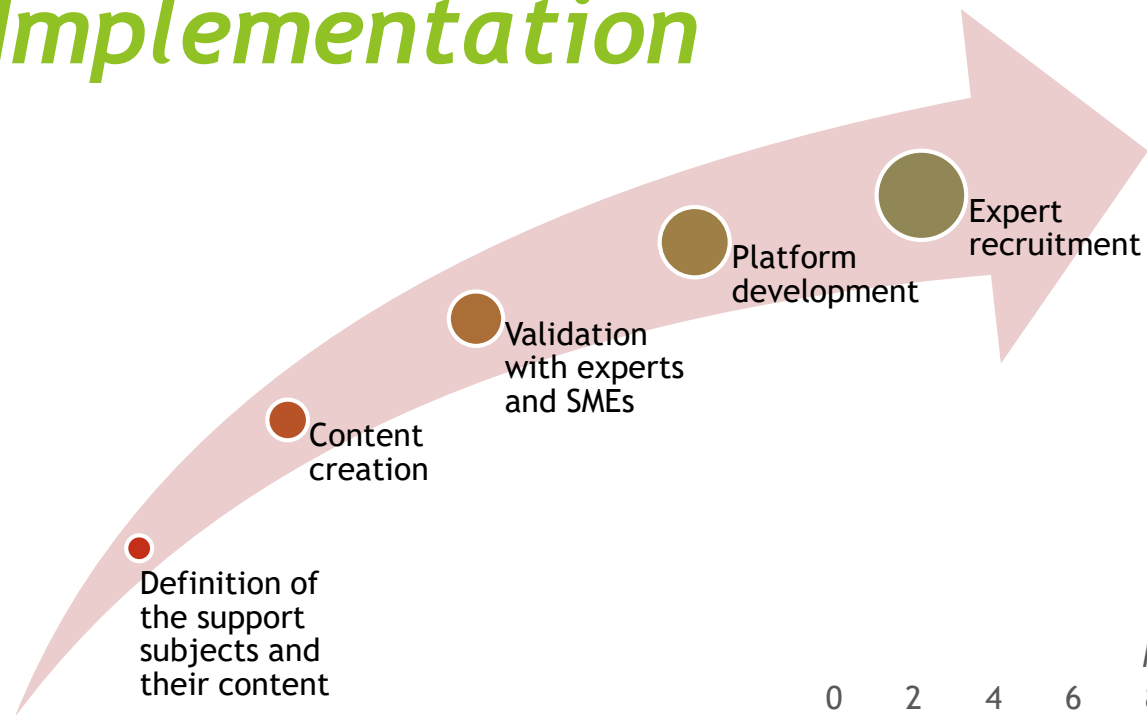
- Create new account
- Questionary to characterize the technology and to identify needs
- Direct contact for further clarifications



NORTEXCEL

Ask the Expert!

Implementation



N R T E X C E L

Centro de Excelência em Tecnologias Médicas