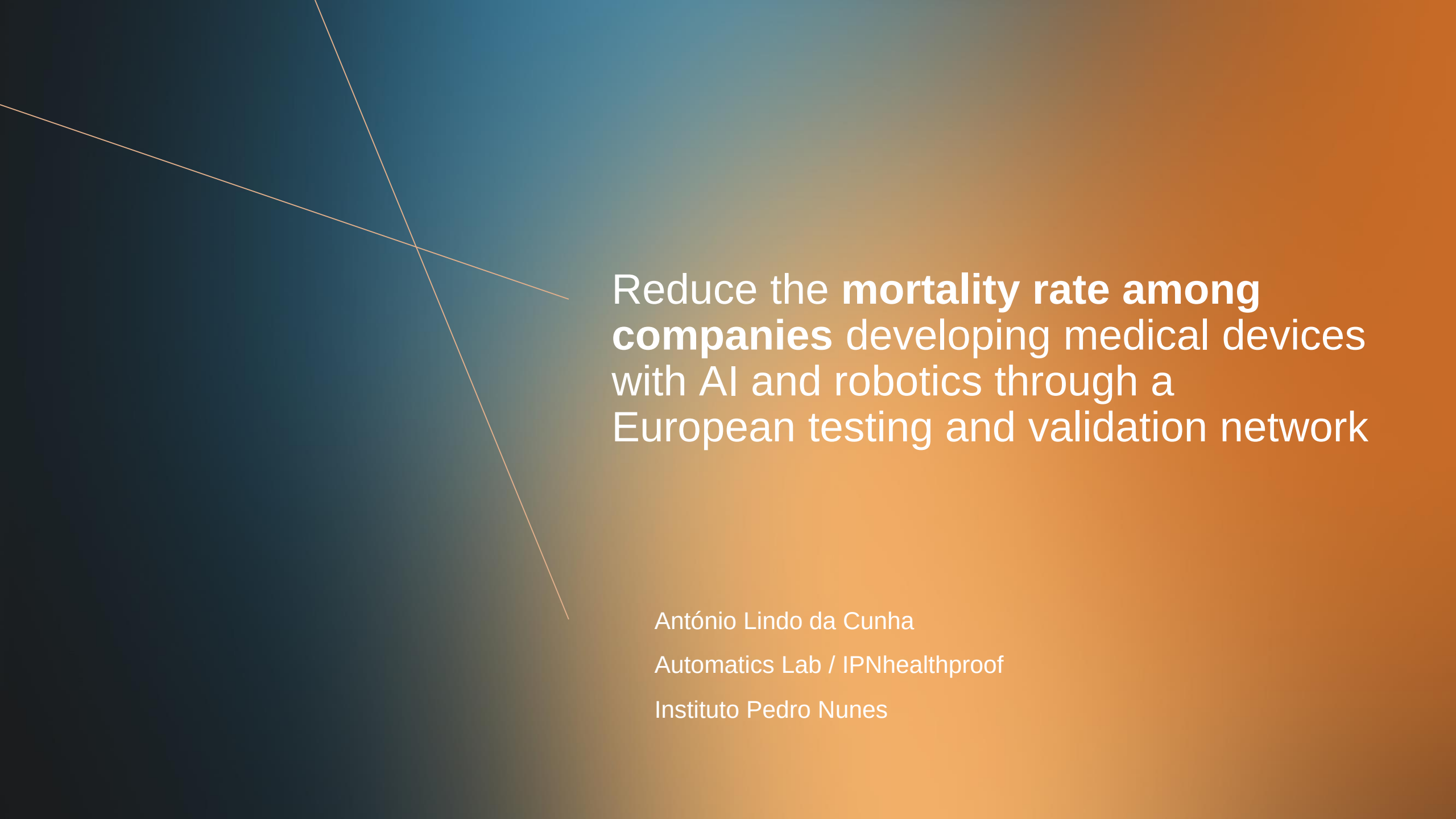




Reduce the **mortality rate among companies** developing medical devices with AI and robotics through a European testing and validation network

António Lindo da Cunha

Automatics Lab / IPNhealthproof

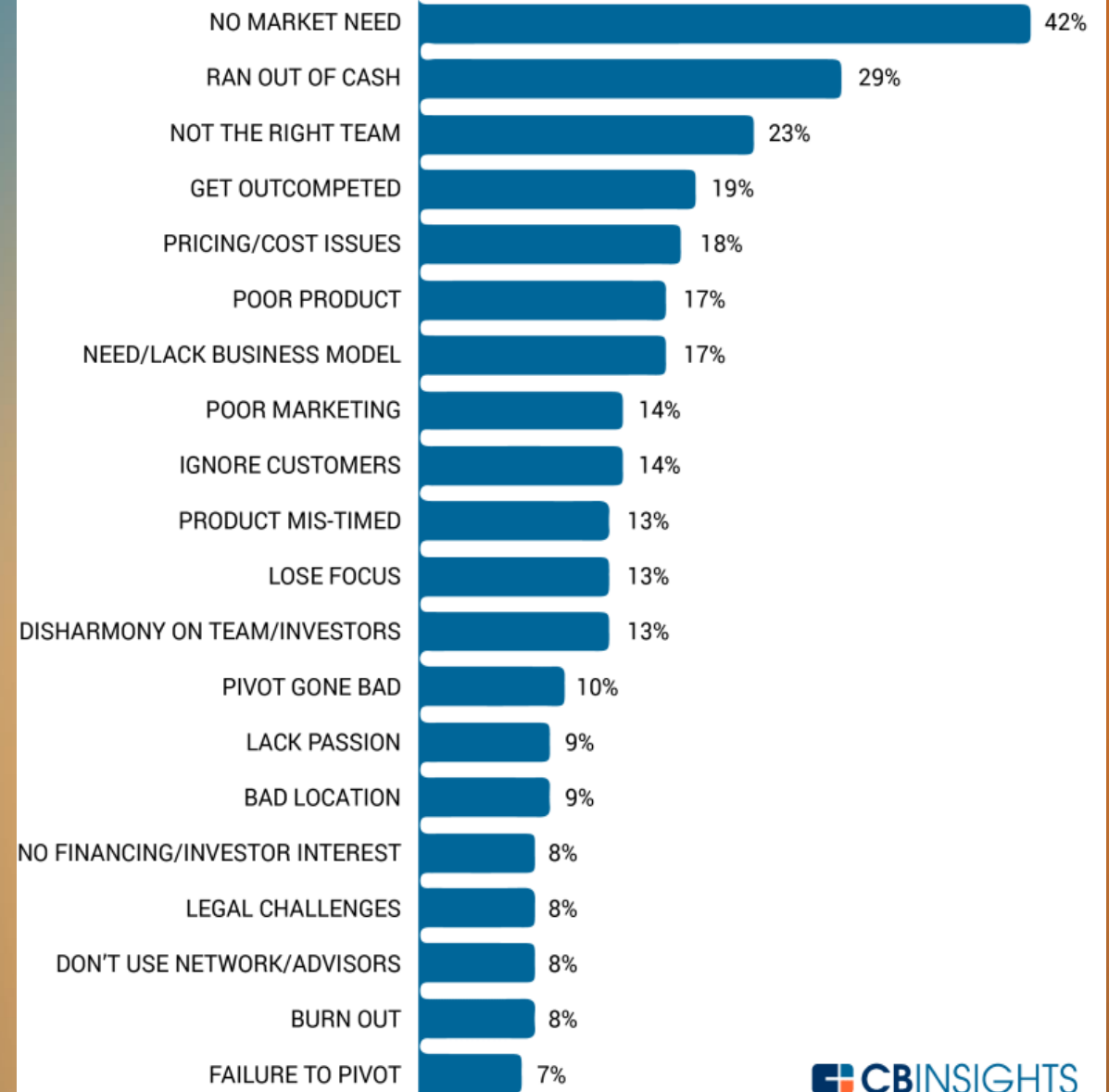
Instituto Pedro Nunes

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?

THE TOP 20 REASONS STARTUPS FAIL

Based on an Analysis of 101 Startup Post-Mortems



Medtech in Europe

The European MedTech sector has around **27.000 companies**
95% of which are SMEs

They need to demonstrate not only **safety and performance**, but
also **tangible benefits for the patients and the healthcare**
system (market need).

“More than 300,000 health applications exist with more than 200 added daily. “

“However, an evaluation of 280 diabetes mobile applications found only 5 associated with clinically meaningful improvement and none were of high methodological quality.”

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10799285/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6232741/>

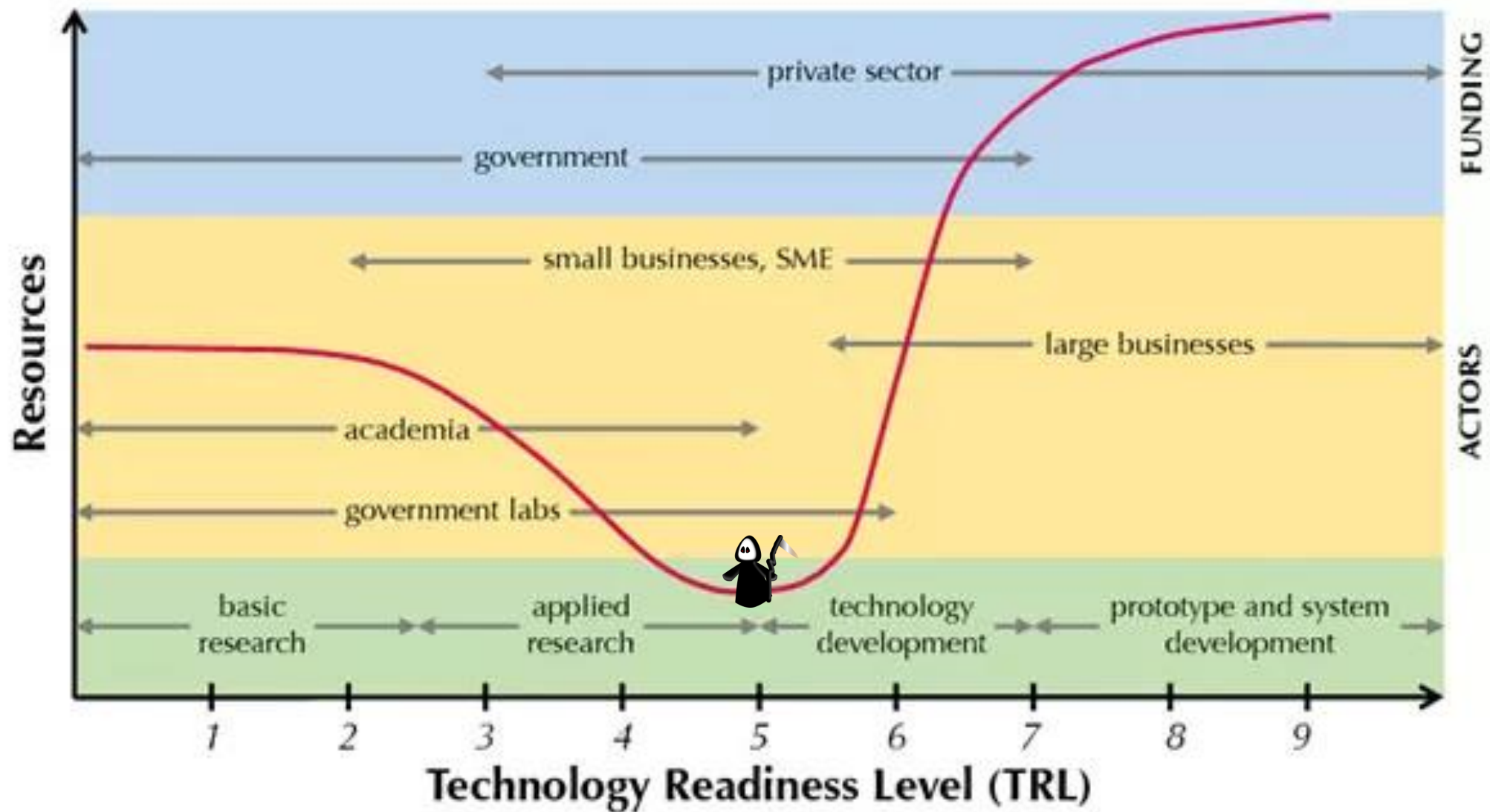
“Innovation is the market introduction of a technical or organisational novelty, not just its **invention.**”

“A inovação é a introdução no mercado de uma novidade técnica ou organizacional, e não apenas a sua invenção.”

TRL vs CIMIT

- + TRL1 Define basic properties
 - + TRL2 Analytical study
 - + TRL3 Proof of concept
 - + TRL4 Pre-prototype
 - + TRL5 Pre-prototype tested in lab
 - + TRL6 Prototype tested in relevant environment
 - + TRL7 Approved prototype
 - + TRL8 Pre-serial manufacturing
 - + TRL9 Product on market
- Innovation**





Source: Hensen, Jan & Loonen, Roel & Archontiki, Maria & Kanellis, Michalis. (2015). Using building simulation for moving innovations across the "Valley of Death". REHVA Journal, 52, 58-62.

Europe's strong regulatory framework





“

The AI Act is an historic milestone and largely reflects the risk-based approach we called for. We have our concerns, especially on the regulatory burden for SMEs. Now, for Europe to win the global AI race we need to work together to support our innovators.

CECILIA BONEFELD-DAHL

DIRECTOR-GENERAL, DIGITALEUROPE

DIGITALEUROPE

DIGITALEUROPE



TEF Health

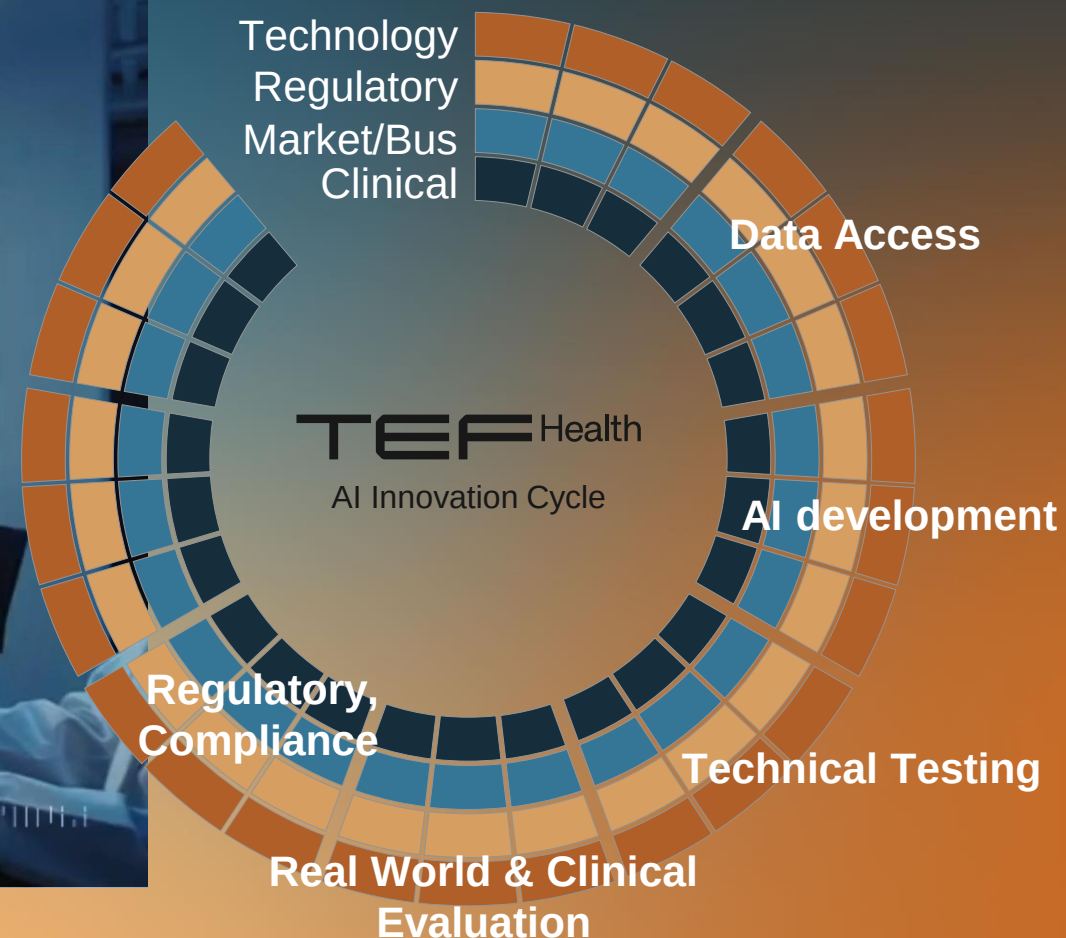
- €60 Mill for 5 years
- To continue past 2027

Testing and Experimentation Facility for Health AI and Robotics

TEF Health



TEF-Health offers 360+ Testing & Validation Services



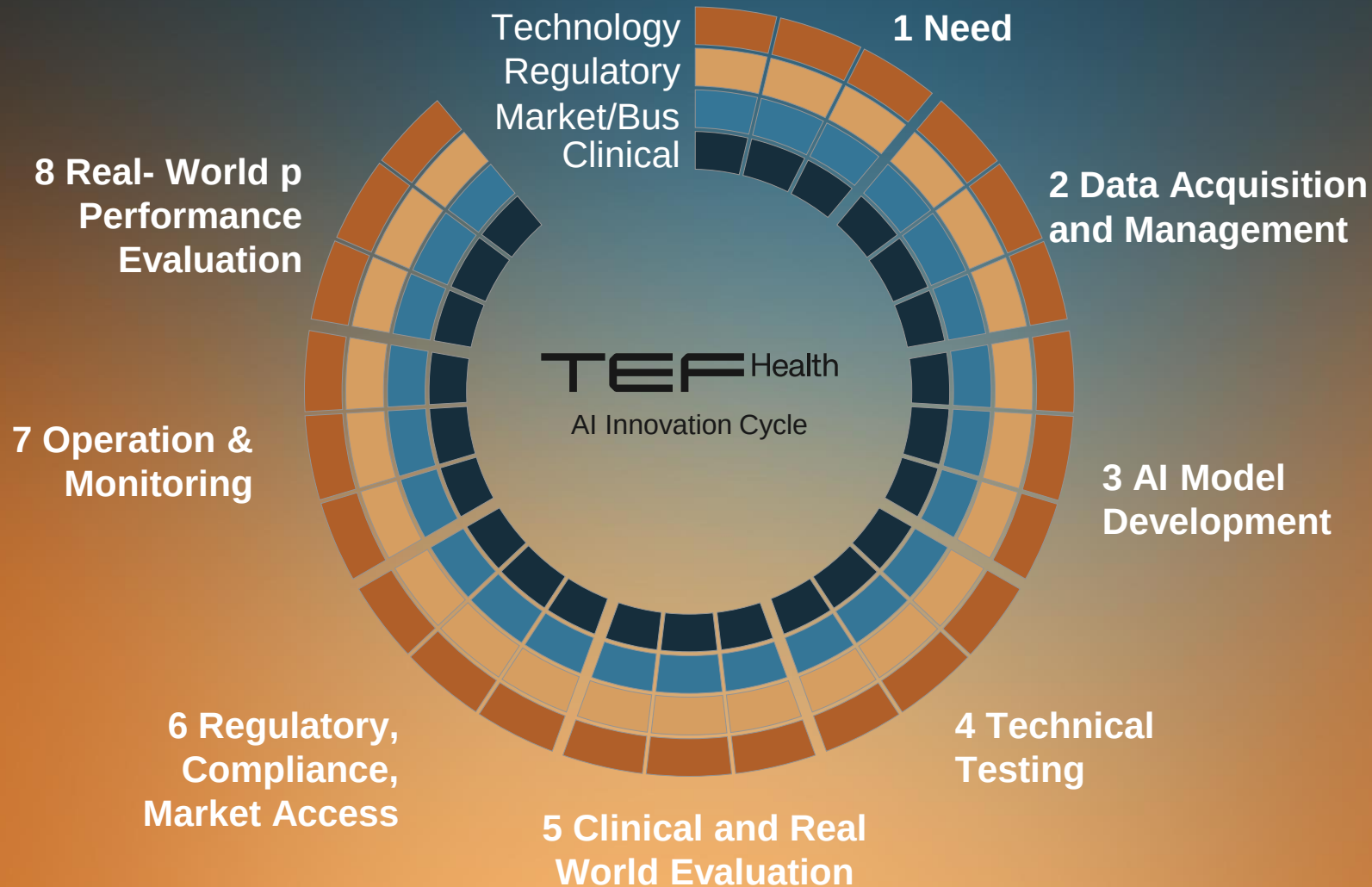


TEF Health



European Interface for Health AI Lifecycle Maturity

Testing and Experimentation Facility
for Health AI and Robotics



One Market Place

366 Service Offerings

32 Service Providers

8 Member States

TEF Health

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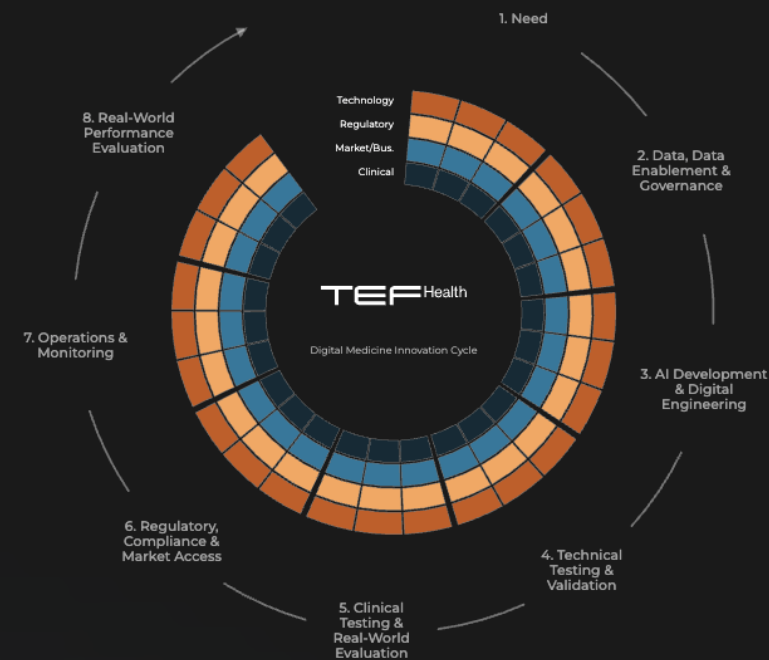
Bring trustworthy healthcare AI to Europe.

Testing, compliance, validation, infrastructure,
and regulatory guidance in one intelligent
ecosystem.

[Start Your Journey](#)

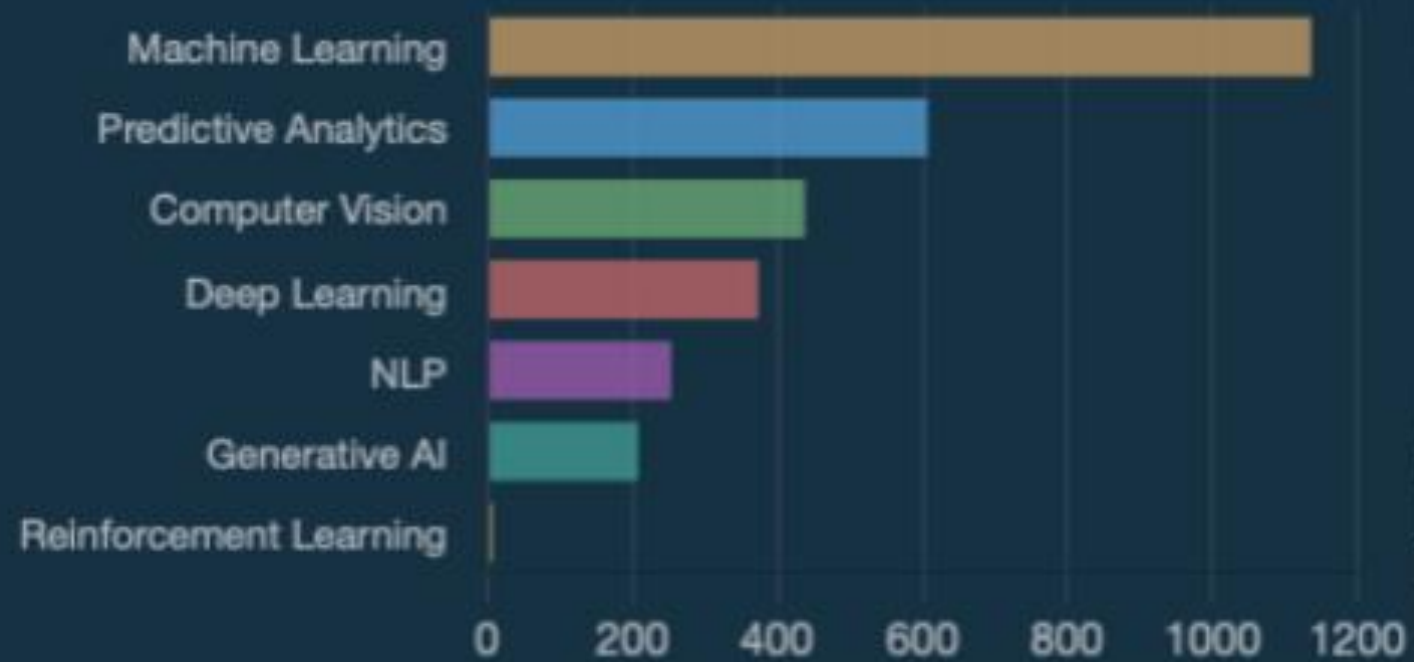
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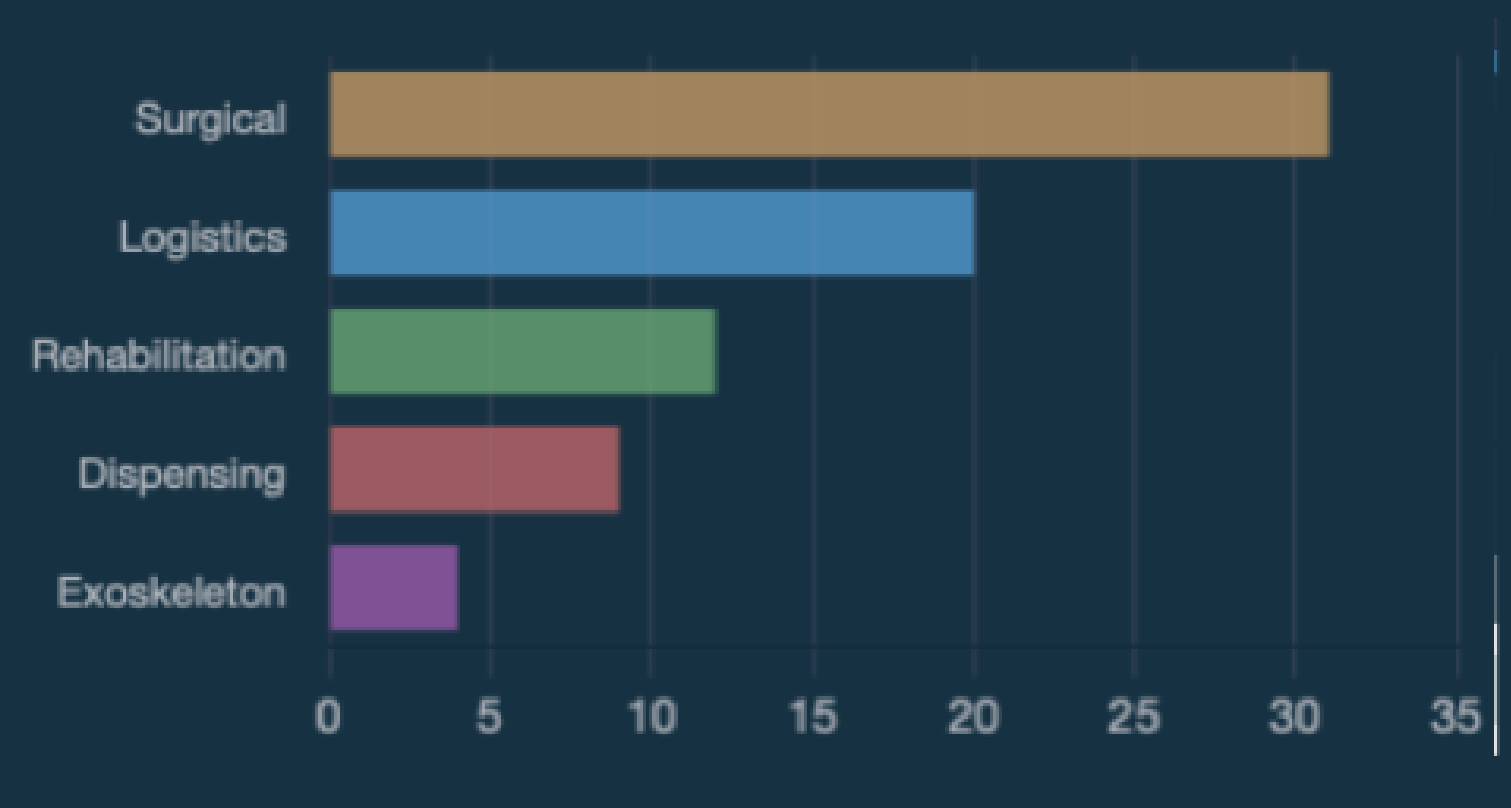
Filter by: **AI System Type**

AI System Type



Filter by: **Robotics Type**

Robotics Type

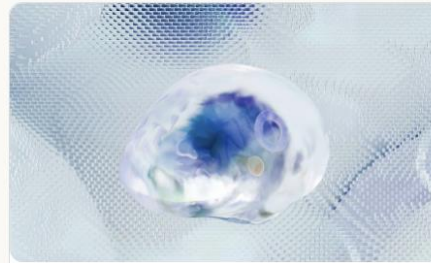


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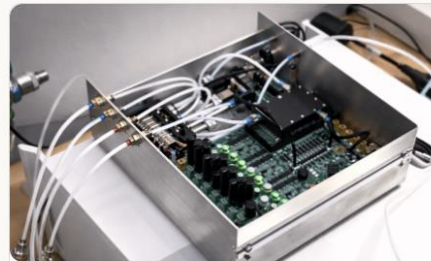
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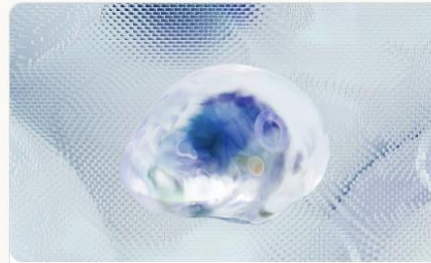
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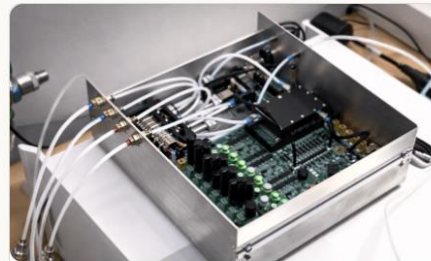
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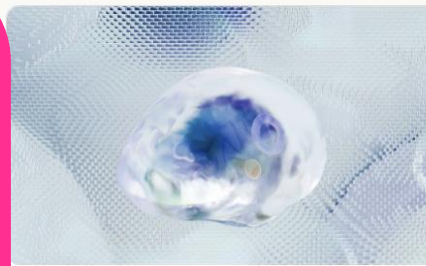
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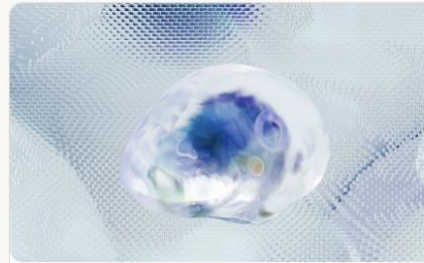
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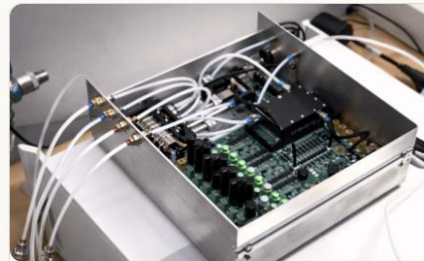
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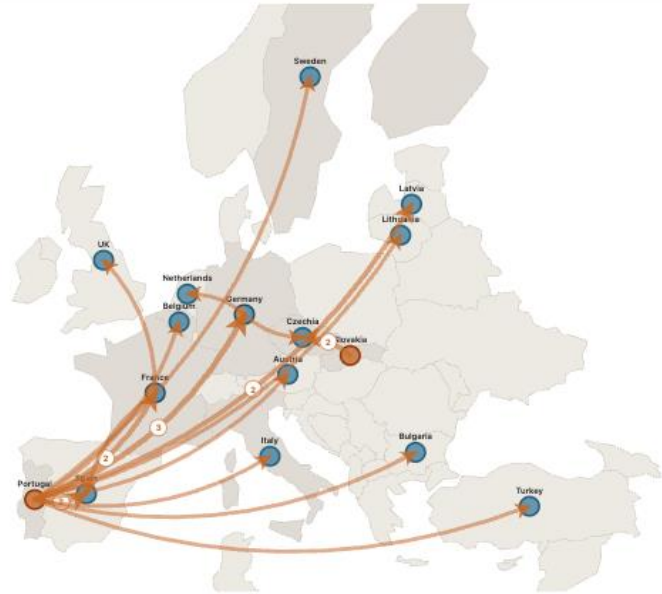
Geographic Distribution

📍 Clients
📍 Providers
≡ Cross-border



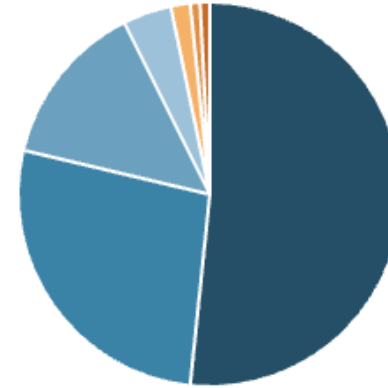
Geographic Distribution

📍 Clients
📍 Providers
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Service Provisions by Provider Member State

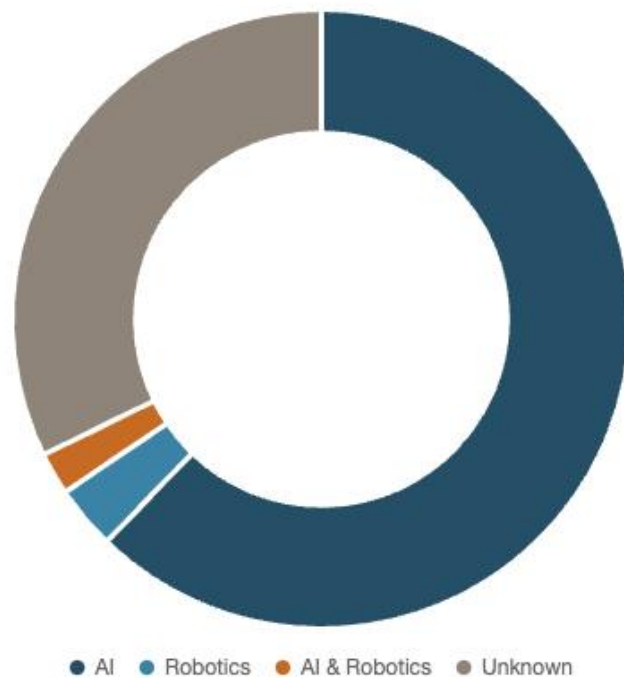
122 across 7 states



PT Portugal	63 (52%)
FR France	33 (27%)
DE Germany	17 (14%)
SK Slovakia	5 (4%)
BE Belgium	2 (2%)
SE Sweden	1 (1%)
IT Italy	1 (1%)

Products & Technology ?

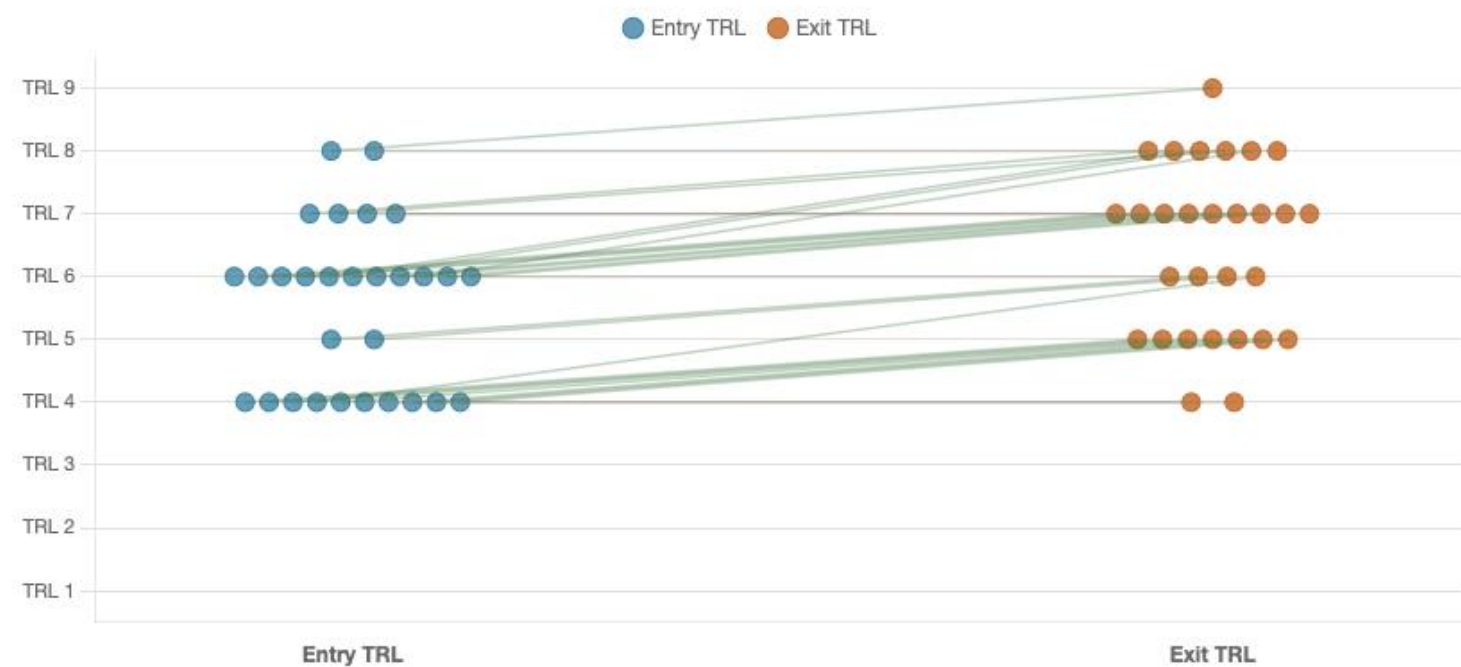
Product Categories



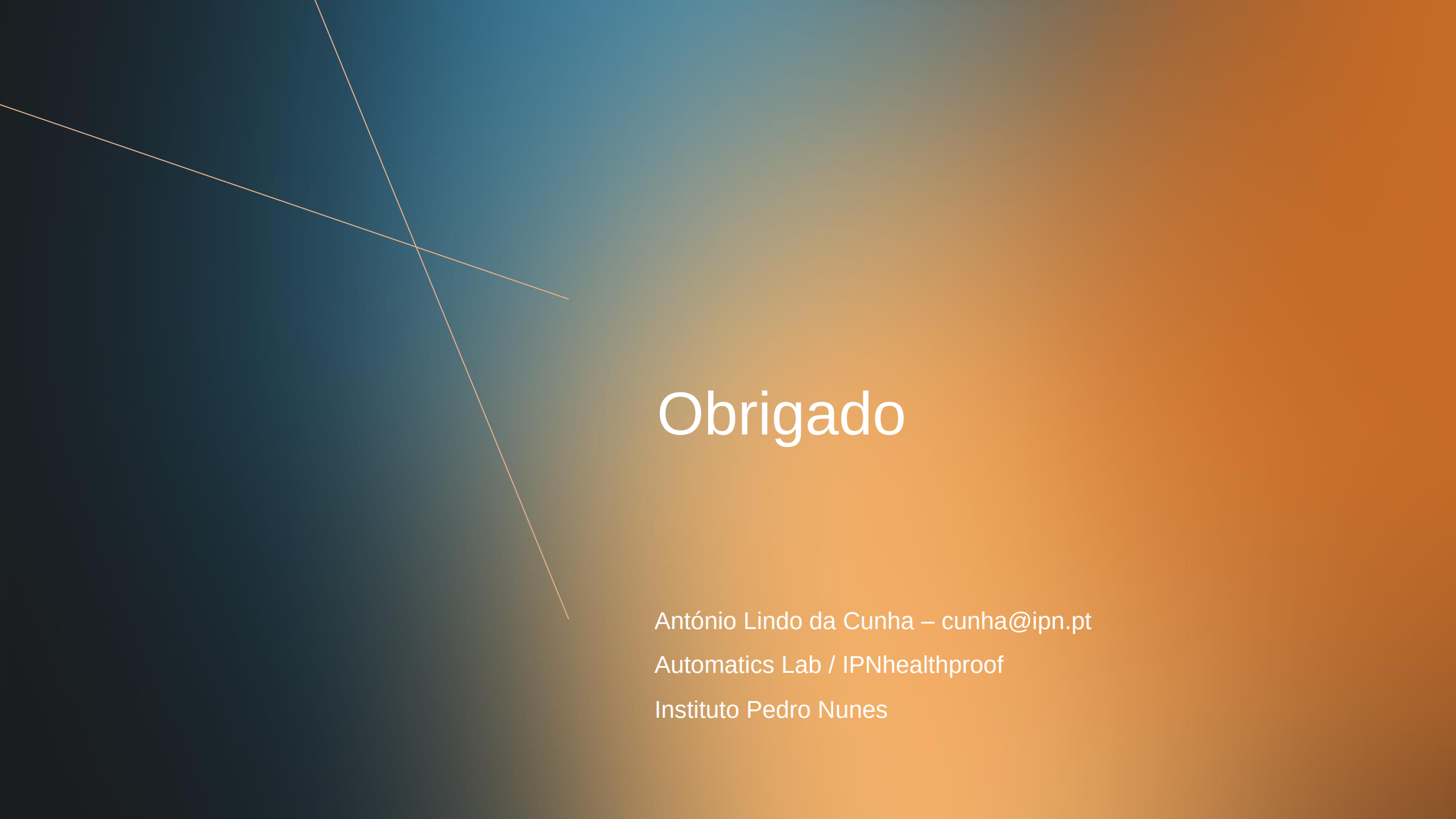
TRL Progression (Completed)

Avg Δ +0.9

≥ 1 TRL 79%







Obrigado

António Lindo da Cunha – cunha@ipn.pt

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