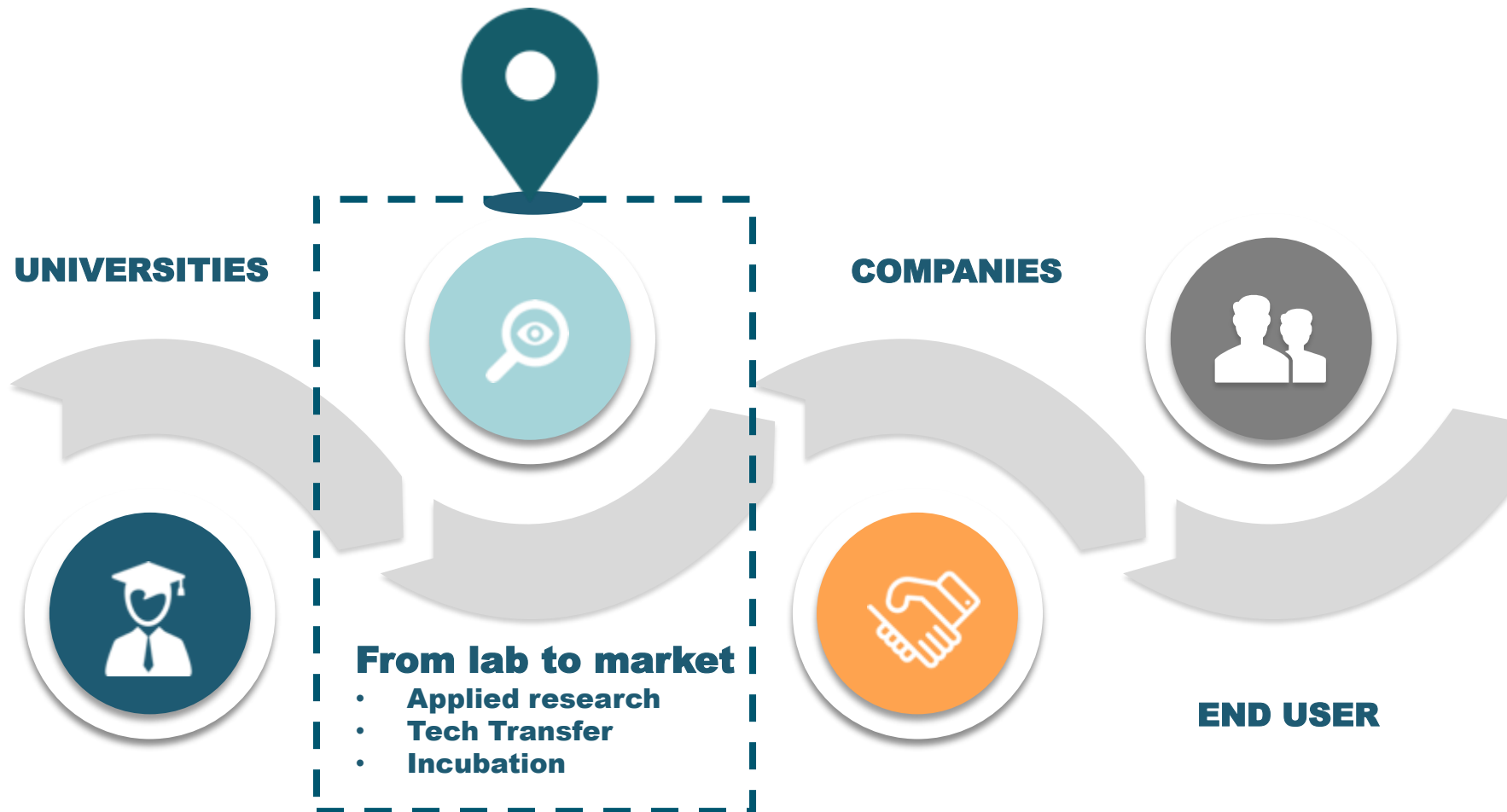
The image shows the exterior of a modern building, the Instituto Pedro Nunes, at dusk. The building features a prominent concrete structure with large glass windows and doors. The interior is brightly lit, revealing multiple levels and a modern design. The sky is dark, and the building's lights create a strong contrast. The text "Instituto Pedro Nunes" is overlaid in the top right corner in a large, bold, blue font. Below it, the text "LAS – Laboratory for Automation and Systems" is also in blue but smaller. The building's architecture is characterized by clean lines and a mix of materials, including concrete and glass.

# Instituto Pedro Nunes

LAS – Laboratory for Automation and Systems

# VALUE CHAIN



# From concept to solution

Step-up the development of solutions for companies



## Projects

## Services

### Idea

- Needs screening & KOL validation powered by needs-led innovation method
- Ideation of potential solutions to address the unmet need by codesign approaches
- Technology innovation pathway support
- Fundraising and business support

### Prototyping

- Development of proof of concept and MVP, including systems design, architecture and application development using cutting-edge domains of:
  - Embedded AI
  - IoT
  - Robotics
- "Works Like, Looks Like, Made Like" prototypes

### Proof of Feasibility and Value

- Technical feasibility assessment
- Usability tests, focusing on user experience and functionality feedback
- Field testing in clinical settings
- Early-stage health technology assessment

### Regulation for Medical Devices

- Global regulatory requirements (CE marking, ANVISA, FDA and UK processes)
- Support in the UDI process and registration in the EUDAMED platform
- Implementation of the new European Regulation EU 2017/745 and EU 2017/746
- Risk and Quality Management systems
- Specialised professional training
- Gap analysis (cybersecurity, requirements, design and development process and risk management)

# Regulatory Support Services



## Global regulatory requirements

- CE Marking;
- USA FDA Market Access;
- UKCA Marking;
- ANVISA Registration;
- UDI (Unique Device Identification) process;
- Global Regulatory Strategy Advice;
- Gap analysis for:
  - Design and development process, including electromedical and medical software;
  - Requirements, including electromedical and medical software;
  - Cybersecurity, including electromedical and medical software.

## MDR | IVDR | ISO

- Implementation of the new European Regulation requirements for:
  - Regulation UE 2017/745;
  - Regulation UE 2017/746.
- Including,
  - Product and Software compliance & security;
  - Implementation / update of the ISO 13485;
  - Risk management and risk management gap analysis;
  - Technical Documentation compilation;
  - EUDAMED registration;
  - UDI (Unique Device Identification) assignation;
  - Process submission to a notified body.

## Other Services

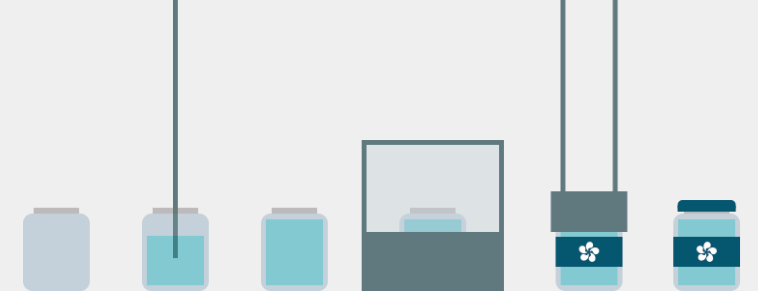
- Biological Evaluation Report, BER ;
- Clinical Evaluation and Clinical Evaluation Report, CER;
- PRRC, Person Responsible for Regulatory Compliance;
- Post market surveillance system (PMSRs and PSURs);
- Internal audits of the system and/or the product;
- Specialised professional training;
- Usability testing.



# R&D PROJECTS



# ROSE - Robot Sensing Tele-Ecography



**Tele ultrasound system** (from central hospitals to any remote location).

Compatible with any **Radiology Information System**.



**Remote ultrasound scans performed by robots are now a reality**

# ANIA

Advanced Natural Interaction Assistant



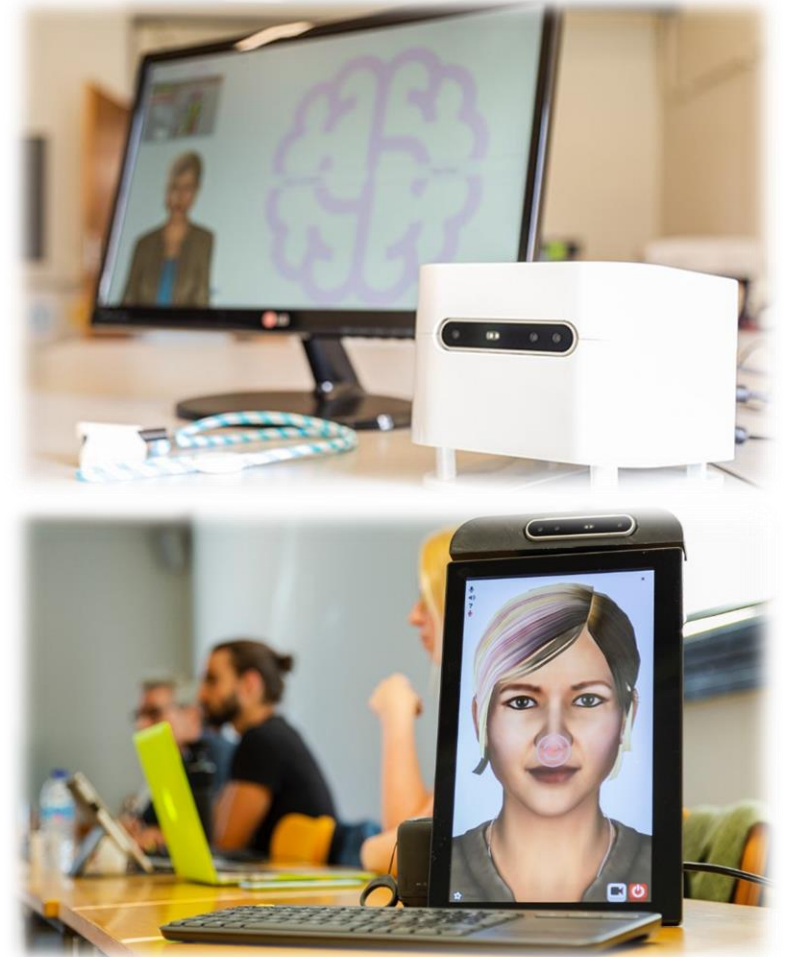
Is a ICT-based solution to support cognitive and physical vitality training at home.

Case study:

It provides 100+ games grouped by their respective cognitive domain. Allows remote training programs that includes physical training in the patient's living environment.

Main features:

- Virtual interactive assistant
- Smart device with supporting sensors
- Dual-task training exercises
- Web-based cognitive exercises



#DedicatedNetwork #DualTaskTraining #TeleRehabilitation

# Horizon Europe - Calls



## HEALTH CLUSTER - DESTINATION 1. STAYING HEALTHY IN A RAPIDLY CHANGING SOCIETY

HORIZON-HLTH-2024-STAYHLTH-01-02-two-stage: Towards a holistic support to children and adolescents' health and care provisions in an increasingly digital society

HORIZON-HLTH-2024-STAYHLTH-01-05-two-stage: Personalised prevention of non-communicable diseases - addressing areas of unmet needs using multiple data sources

## HEALTH CLUSTER - DESTINATION 2. LIVING AND WORKING IN A HEALTH-PROMOTING ENVIRONMENT

HORIZON-HLTH-2024-ENVHLTH-02-06-two-stage: The role of environmental pollution in non-communicable diseases: air, noise and light and hazardous waste pollution

## HEALTH CLUSTER - DESTINATION 3. TACKLING DISEASES AND REDUCING DISEASE BURDEN

HORIZON-HLTH-2024-DISEASE-03-08-two-stage: Comparative effectiveness research for healthcare interventions in areas of high public health need

HORIZON-HLTH-2024-DISEASE-03-14-two-stage: Tackling high-burden for patients, under-researched medical conditions

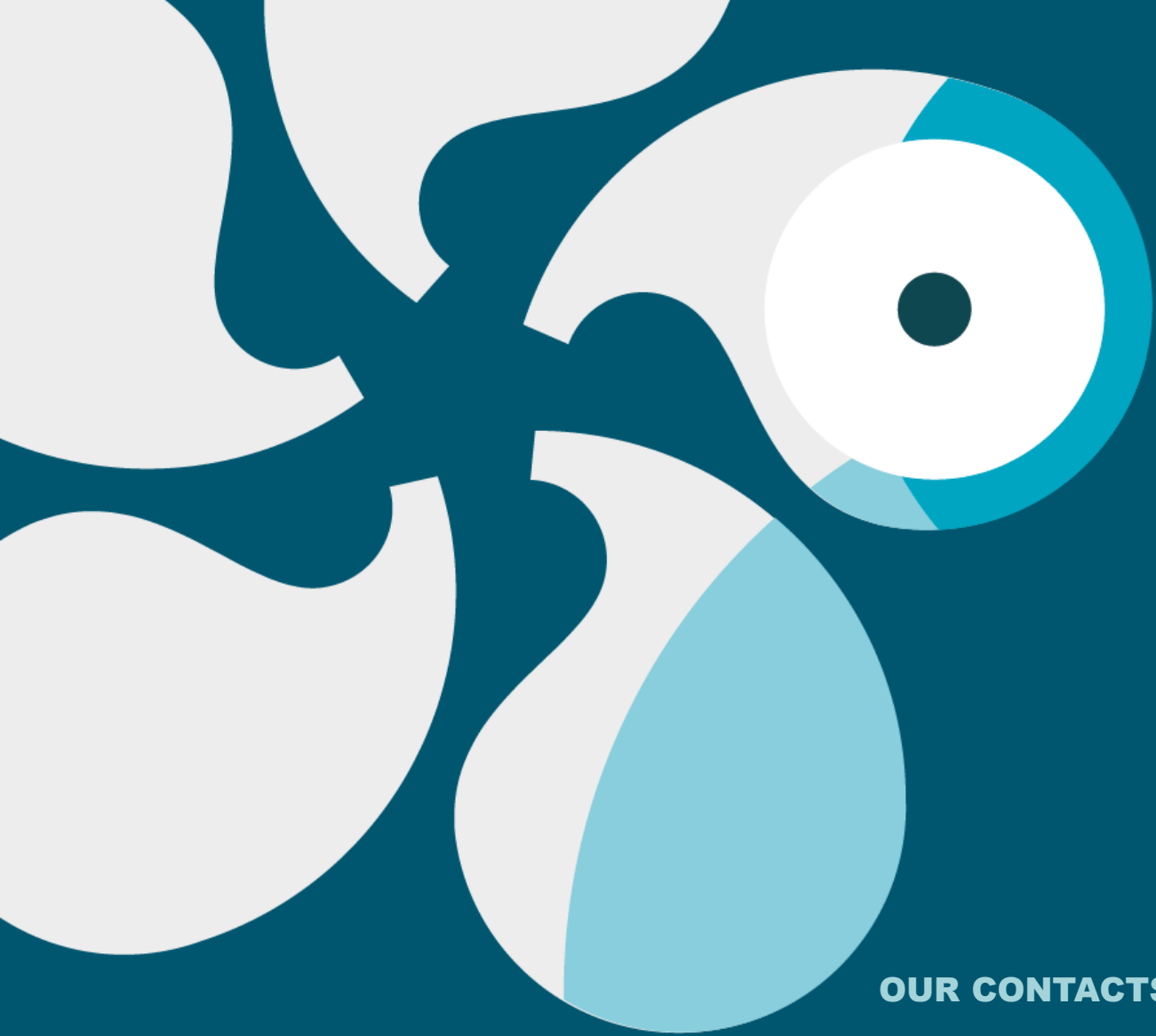
## HEALTH CLUSTER - DESTINATION 4. ENSURING ACCESS TO INNOVATIVE, SUSTAINABLE AND HIGH-QUALITY HEALTH CARE

HORIZON-HLTH-2024-CARE-04-04-two-stage: Access to health and care services for people in vulnerable situations

## CLUSTER 2 - DESTINATION : INNOVATIVE RESEARCH ON SOCIAL AND ECONOMICS TRANSFORMATIONS

HORIZON-CL2-2024-TRANSFORMATIONS-01-09 : The role of social economy in addressing social exclusion, providing quality jobs and greater sustainability





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<https://www.ipn.pt/laboratorio/LAS>