



eHealth CAPsule for digestive disease diagnostics and therapy



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Objective

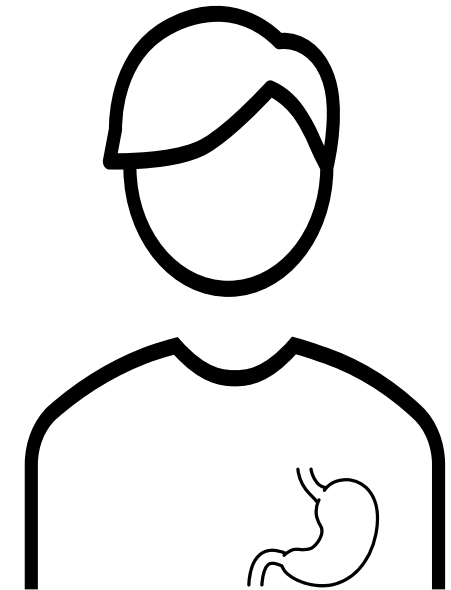


Develop a **smart multi-sensing capsule** combined with a **digital health platform** allowing an interactive patient interface for more precise diagnosis and monitoring of gastrointestinal conditions.

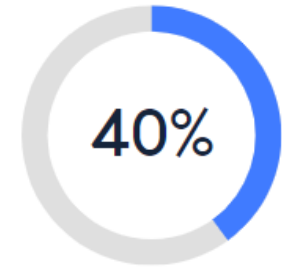
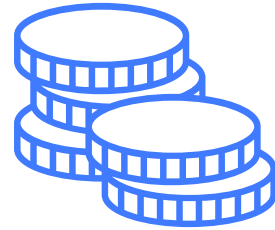
Gastrointestinal disease

24 – 40% population incidence worldwide

- Nausea/vomiting
- Bleeding
- **Gastroesophageal reflux**
- Inflammatory bowel disease
- Irritable Colon
- Constipation
- and others



Gastroesophageal reflux disease: GERD



1.2 billion people globally

are affected by GERD, with prevalence growing in all regions of the world

€30 billion/year

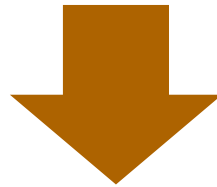
\$12,000 - annual cost per patient diagnosed in western world

Treatment failures

Insights, F.M., (2020).
 Soper, N.J., Swanström, L.L. and Eubanks, S. eds., 2014.

Difficulties in diagnosis

- Multitude of symptoms, severity subjective.
- Less than **2% of eligible patients** currently receive the correct diagnostic test.

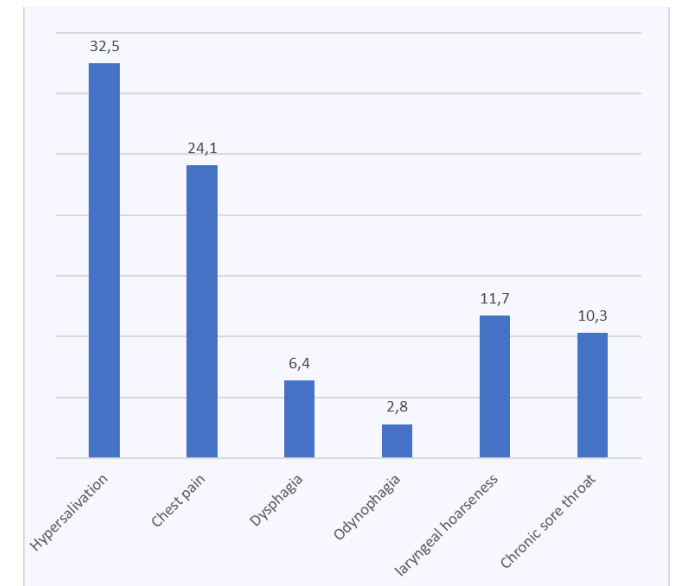
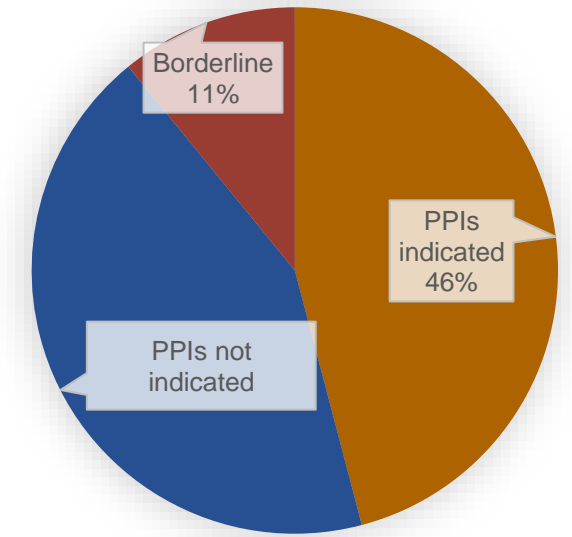


Many patients are under or over treated

→ **Undertreated:** suffering, risk of cancer

→ **Overtreated:** tremendous cost & waste, delay in diagnosis

Kahrilas, P., Yadlapati, R., and Roman, S., (2017).



24-hour pH-metry

24-hour pH test +/- impedance is the gold standard for diagnosing GERD.

Percentage of total time pH < 4

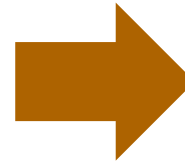
Percentage of upright time pH < 4

Percentage of supine time pH < 4

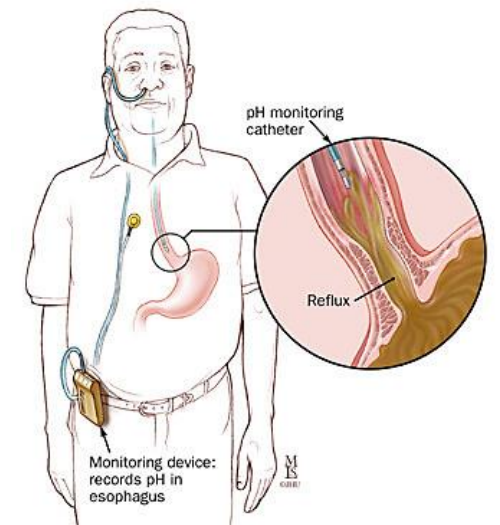
Number of reflux episodes

Number of reflux episodes lasting > 5 min

Longest reflux episode



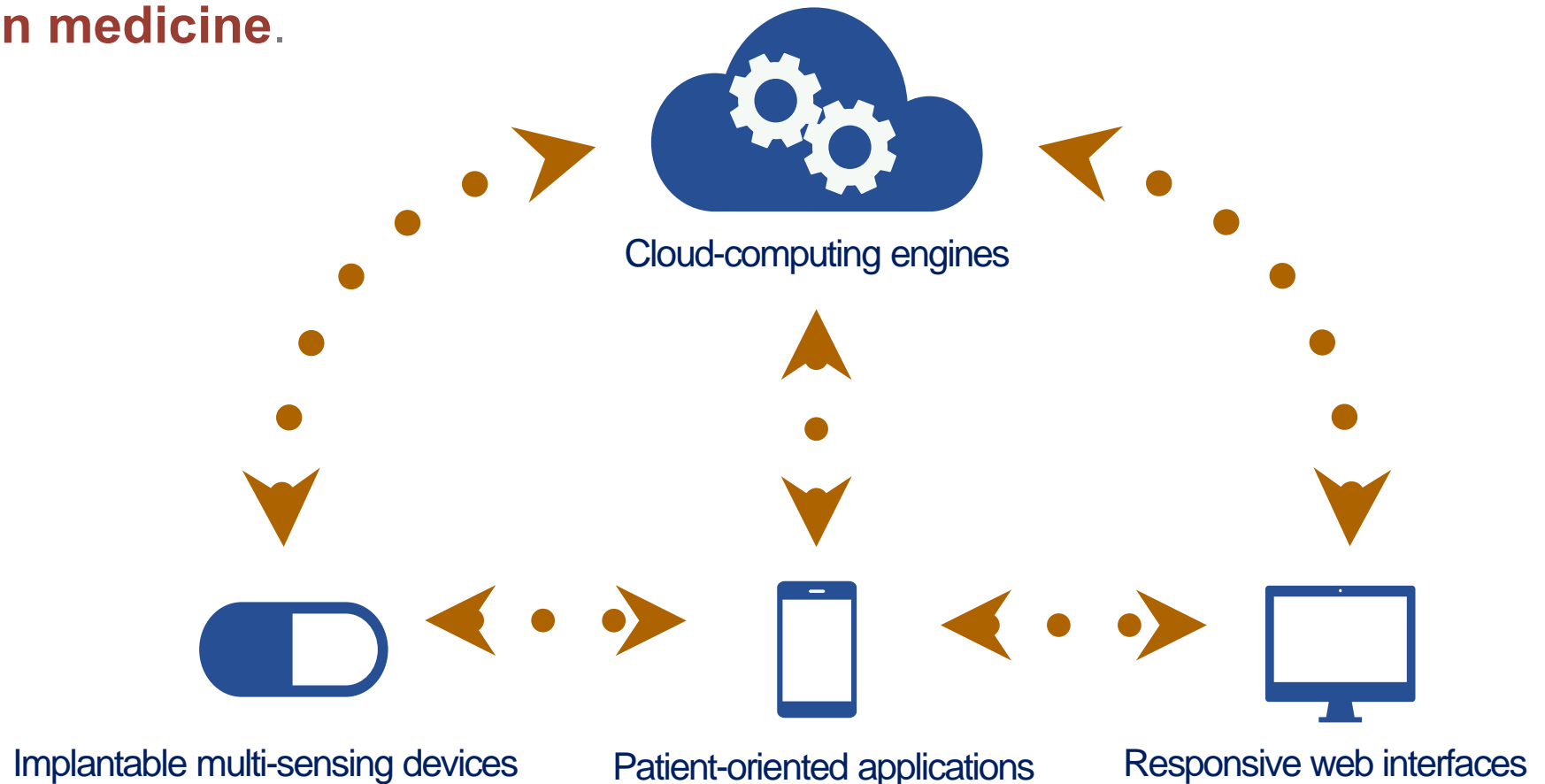
DeMeester score
Normal < 14,72



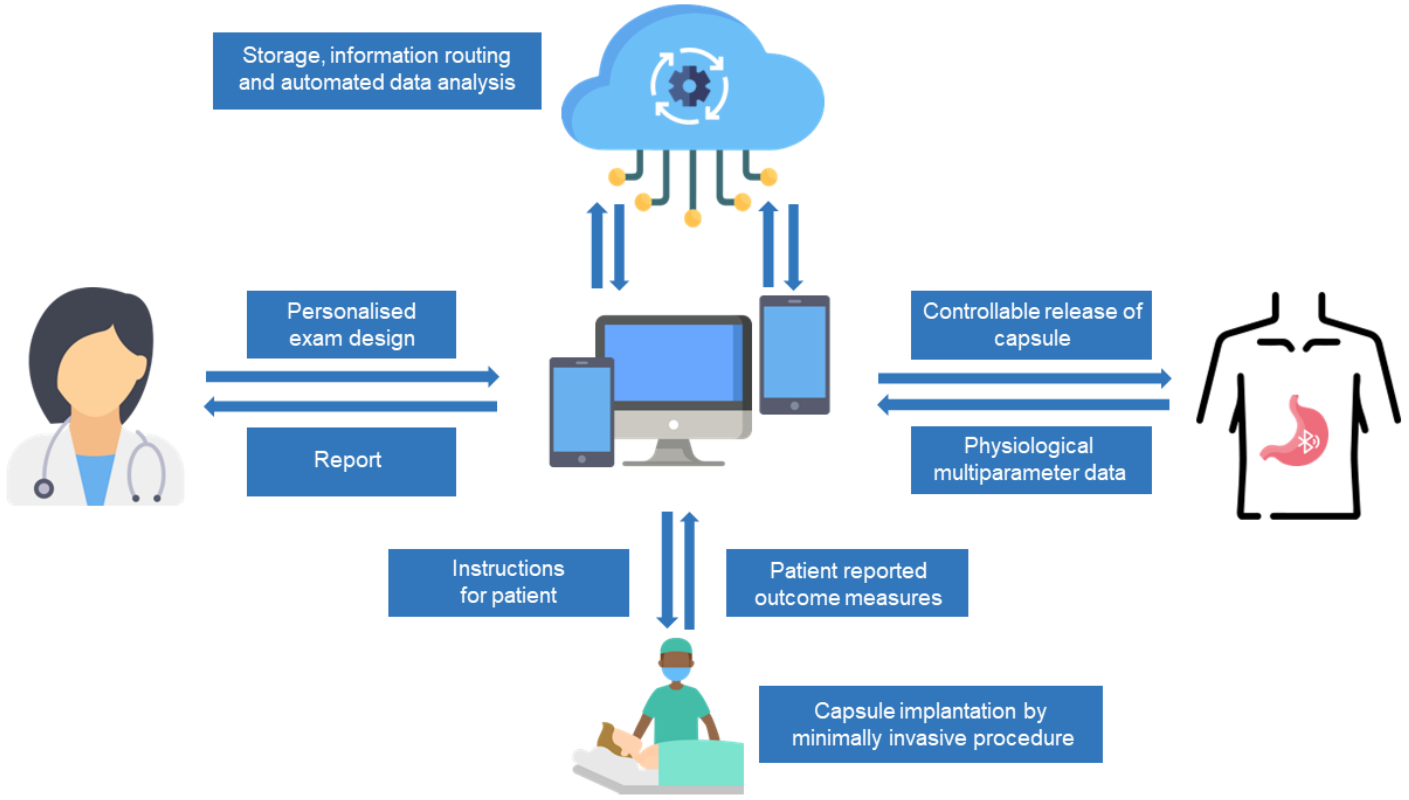
Johnson, L.F. & Demeester, T.R., 1974.

Aim of eCAP project

- 1) Bringing GERD diagnosis and treatment into the **digital medicine** era.
- 2) Leveraging **precision medicine**.



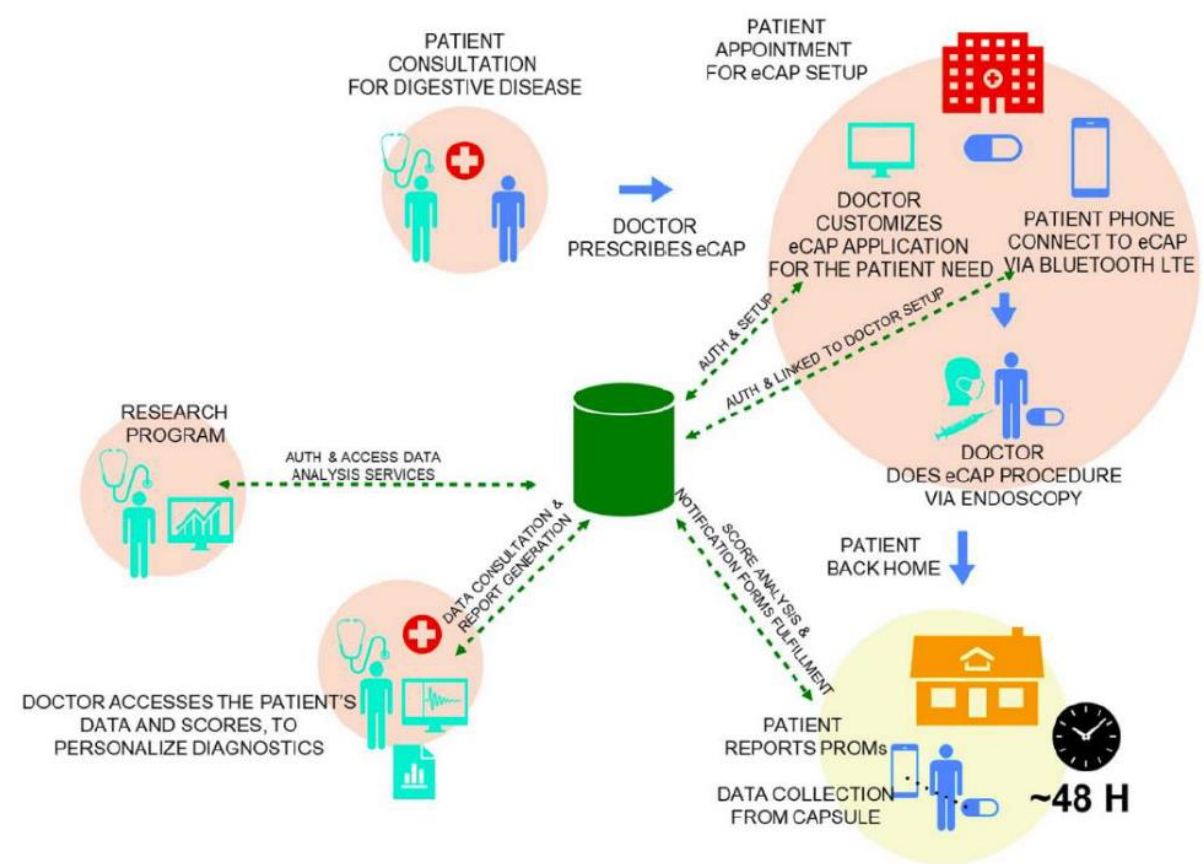
Vision of eCAP



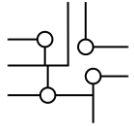
Smart multi-sensing capsule

- ✓ pH-metry
- ✓ inertial measurement unit
- ✓ temperature
- ✓ flow direction
- ✓ blood & bile detection
- ✓ pressure monitoring
- ✓ molecular sensor for inflammatory markers

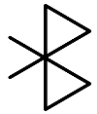
eCAP e-health platform organisation and work flow



Technology Brief



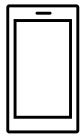
eHealth CAPsule design for digestive sensing & diagnostics



Bluetooth connectivity for smart phone interface



Cloud-base computation



User-friendly app for patients and doctors

First generation – eCAP1

Specifications

- Bluetooth LTE connection
- Power supply > 48 hours
- Robust attachment allowing remote release.

Multi-sensing technology

- pH detection for gastric reflux
- Inertial measurement of patient orientation
- Patient Temperature
- Reflux Flow direction (retrograde or antegrade movement of GI fluids).



Second generation – eCAP2

Specifications

- Similar attachment & Bluetooth connectivity as eCAP1
- Higher power supply: 72 hours to 1 week

Augmented sensor technology

- Blood and bile detection by photonics
- Pressure monitoring (Esophageal manometry)
 - Gauges esophagus contractions during stomach food movements
- Molecular sensor for an inflammatory marker
 - Biomarkers to diagnose inflammatory gastrointestinal conditions
 - Used in combination with Endoscopy to gauge tissue damage.

eCAP project

Project duration: 01/05/2022 - 30/04/2026

EU contribution: €4.75 M

Topic: HORIZON-HLTH-2021-TOOL-06-01

Smart medical devices and their surgical implantation for use in resource-constrained settings

Keywords: smart capsule, bluetooth, GERD, GI, endoscopy



Objective 1: Create a novel smart GI capsule that contains multiple sensors to detect a variety of biochemical and physiologic events associated with GI disorders.



Objective 2: Integrate the capsule with an e-health platform that will facilitate result interpretation.



Objective 3: Validate the eCAP technology in patients suffering from gastroesophageal reflux disease.

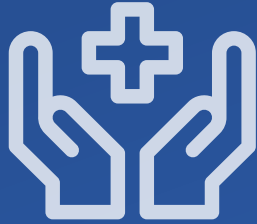


Objective 4: Transfer the eCAP technology in different clinical settings (Ukraine and Kenya) for clinical evaluation with GERD patients and assess the economic impact via cost-effective analysis.

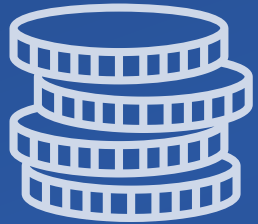
eCAP impact



Improved patient outcomes
achieved through timely and accurate diagnosis



Enhanced access to digestive disease diagnostics and care
enabled by decreased cost of equipment and expertise required from the physician for data interpretation



Decreased care costs
on the patient and system level



Patient empowerment
supported by user-friendly medical devices and inclusion of patient-reported symptoms in diagnosis

eCAP consortium



Sentron



betthera



olymed.



Project coordination and management

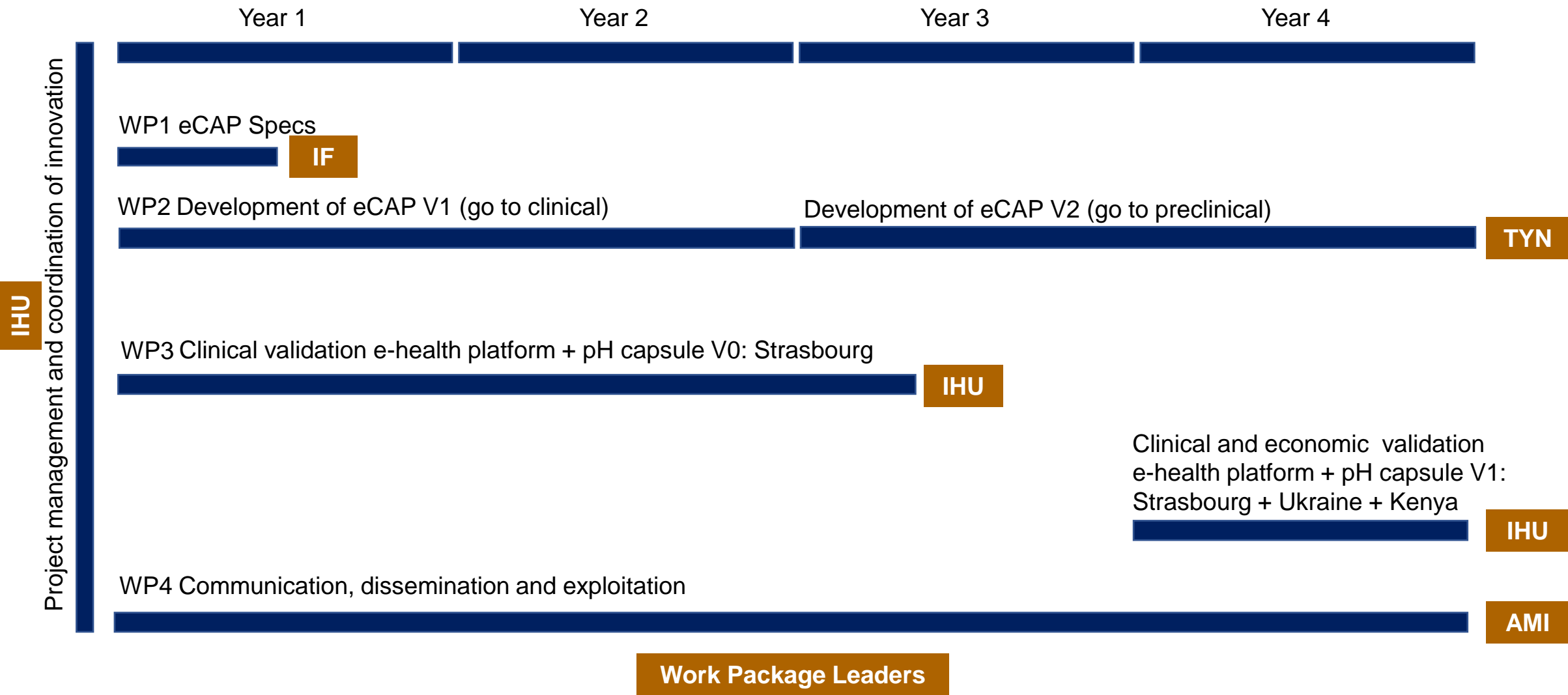


World-class expertise

Partner	Role and expertise
The Institute of Image-Guided Surgery of Strasbourg	Coordinator Pre-clinical and clinical lead
Tyndall National Institute	Technical R&D: electronic and photonic design, fabrication, integration, testing
Sentron Europe BV	Microsensor technology: chip manufacturing, assembly and encapsulation for microsensors
Integer	Manufacturing/Integration: battery design and manufacturing
Enterasense	Integration and commercialization
Operating Theatre Practitioners Association of Kenya	Dissemination & clinical studies in Kenya
Olymed	Dissemination & clinical studies in Ukraine
Imagination Factory	Design thinking, cultural integration Mechanical design for medical devices
Betthera	Health Economics
AMIRES, The Business Innovation Management Institute	Management Dissemination and communication
RDS (Rhythm Diagnostic Systems)	Development of the e-health platform



Implementation



Contact us



<https://ehealth-cap.eu/>



eCAP Project



@eCAP_project



References

Insights, F.M. (2020) 'Global Esophageal pH Monitoring Devices Market: Global Industry Analysis 2015 – 2019 and Opportunity Assessment, 2020 – 2030.' London.

Johnson, L.F. and Demeester, T.R., (1974) 'Twenty-four-hour pH monitoring of the distal esophagus.' *American Journal of Gastroenterology*, 62(4), pp. 325-332.

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Swanström L.L., Soper, N.J. and Leonard, M. 2014. 'Chapter 9.' in *Mastery of endoscopic and Laparoscopic Surgery*. 4th edn. Philadelphia: Lippincott Williams and Wilkins.

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