



# eHealth CAPsule for digestive disease diagnostics and therapy



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# Objective



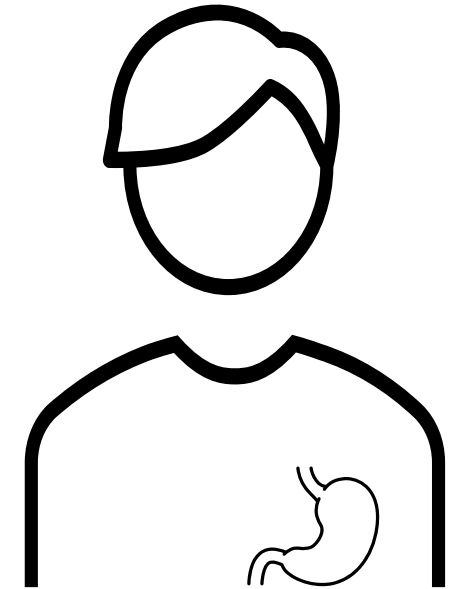
Develop a **smart multi-sensing capsule** combined with a **digital health platform** allowing an interactive patient interface for more precise diagnosis and monitoring of gastrointestinal conditions.



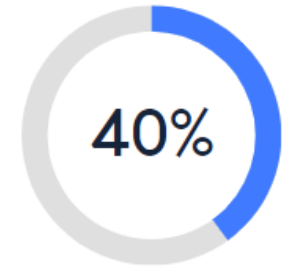
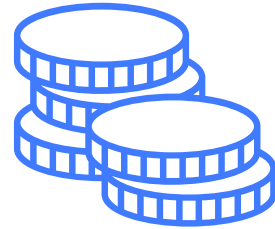
# Gastrointestinal disease

**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.

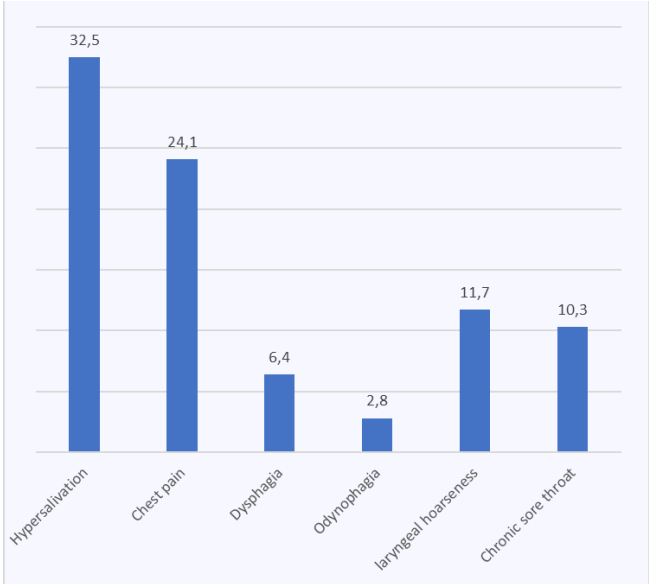
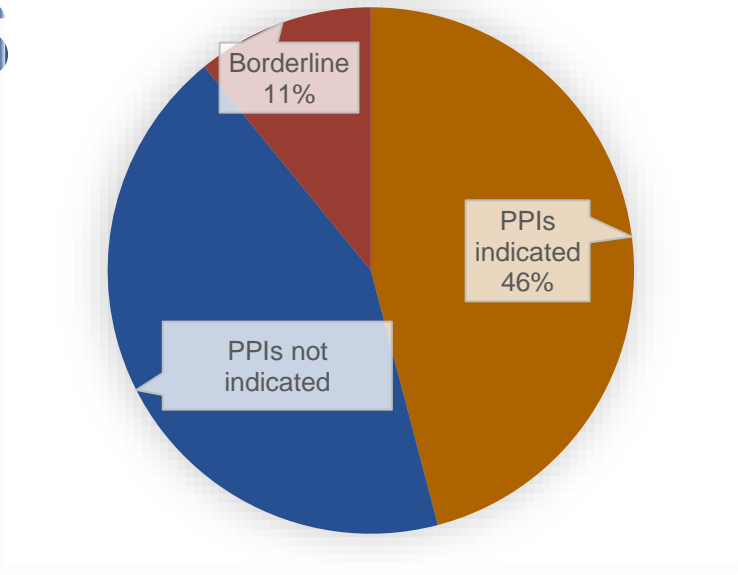
# Difficulties in diagnosis

- 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

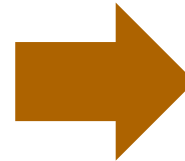
Percentage of upright time pH < 4

Percentage of supine time pH < 4

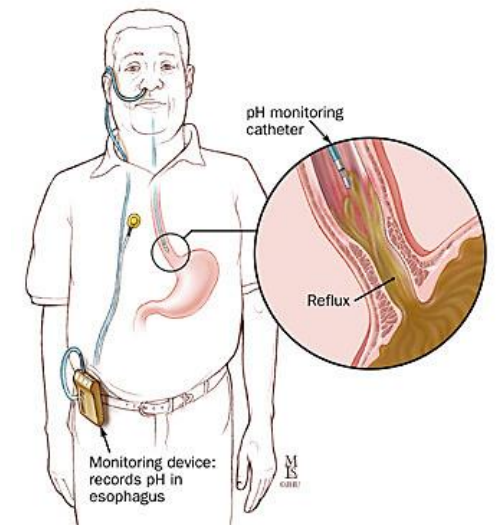
## Number of reflux episodes

Number of reflux episodes lasting > 5 min

Longest reflux episode



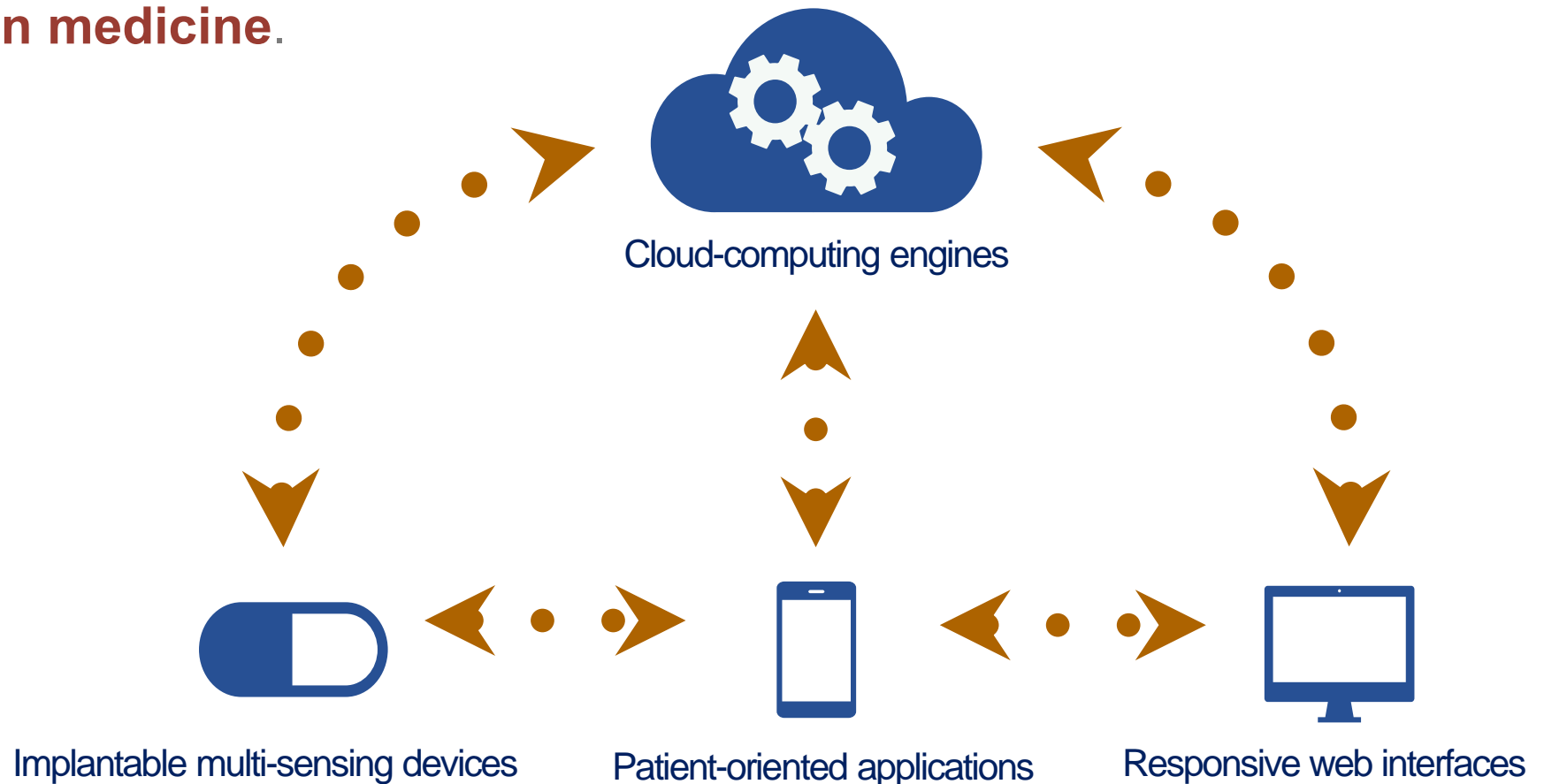
DeMeester score  
Normal < 14,72



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

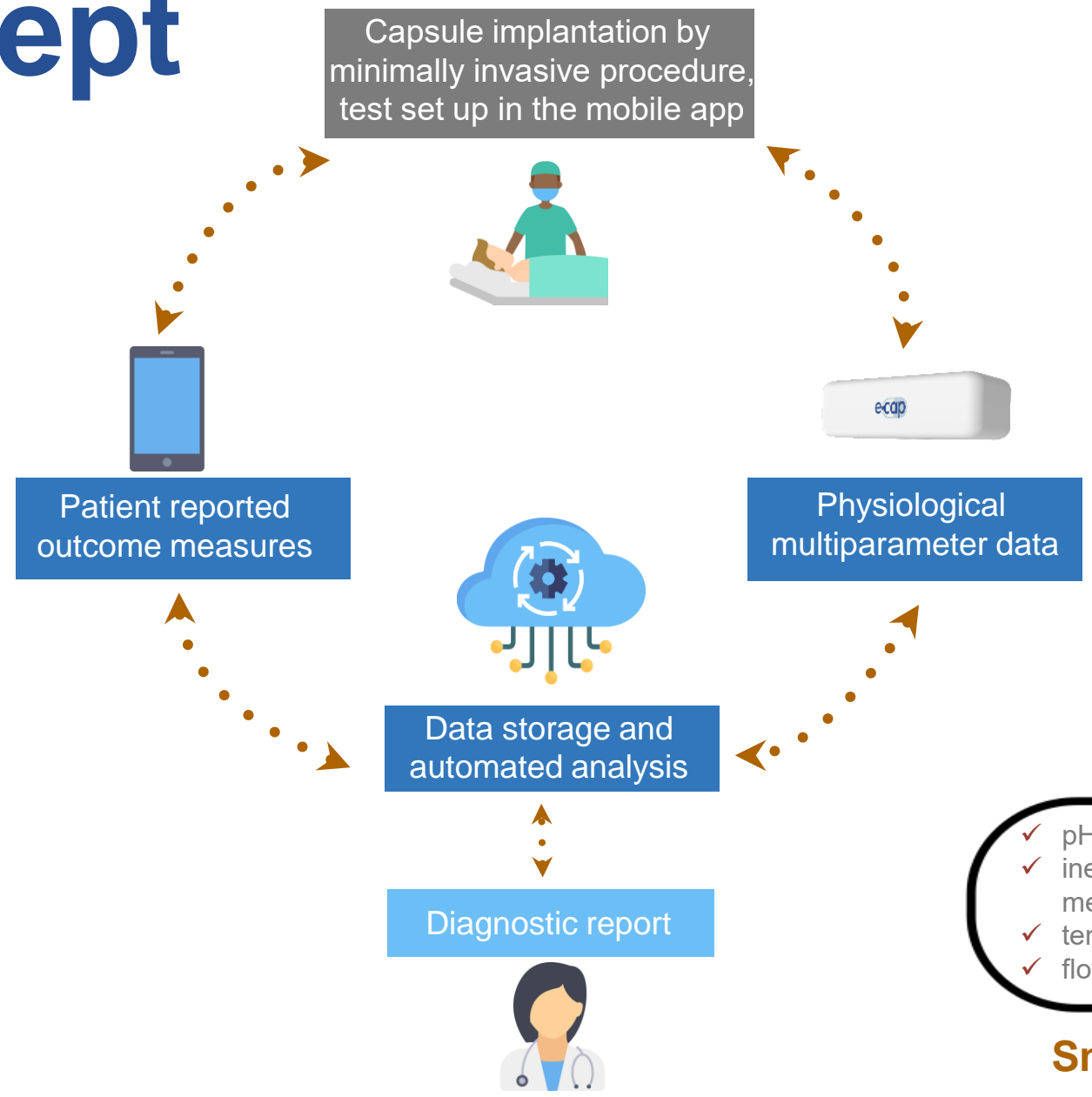
# Aim of eCAP project

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





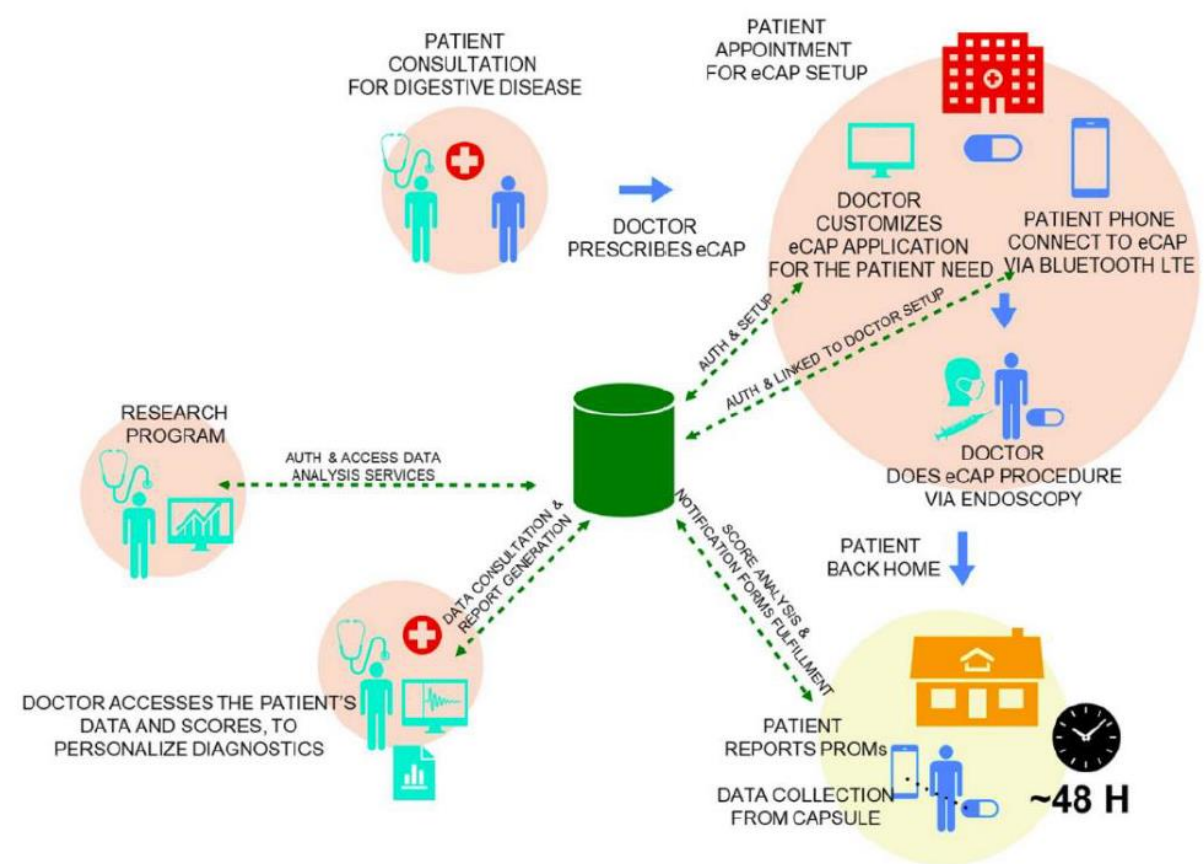
# Concept



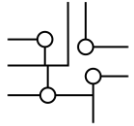
- |   |  |
|---|--|
| <ul style="list-style-type: none"><li>✓ pH-metry</li><li>✓ inertial measurement unit</li><li>✓ temperature</li><li>✓ flow direction</li></ul> | <ul style="list-style-type: none"><li>✓ blood &amp; bile detection</li><li>✓ pressure monitoring</li><li>✓ molecular sensor for inflammatory markers</li></ul> |
|---|--|

## Smart multi-sensing capsule

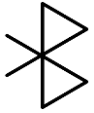
# eCAP e-health platform organisation and work flow



# Technology Brief



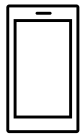
eHealth CAPsule design for digestive sensing & diagnostics



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

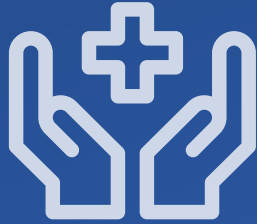
Keywords: smart capsule, bluetooth, GERD, GI, endoscopy

-  **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.

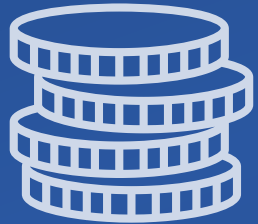
# eCAP impact



**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

Sentron



betthera



oly.med.



Project coordination and management



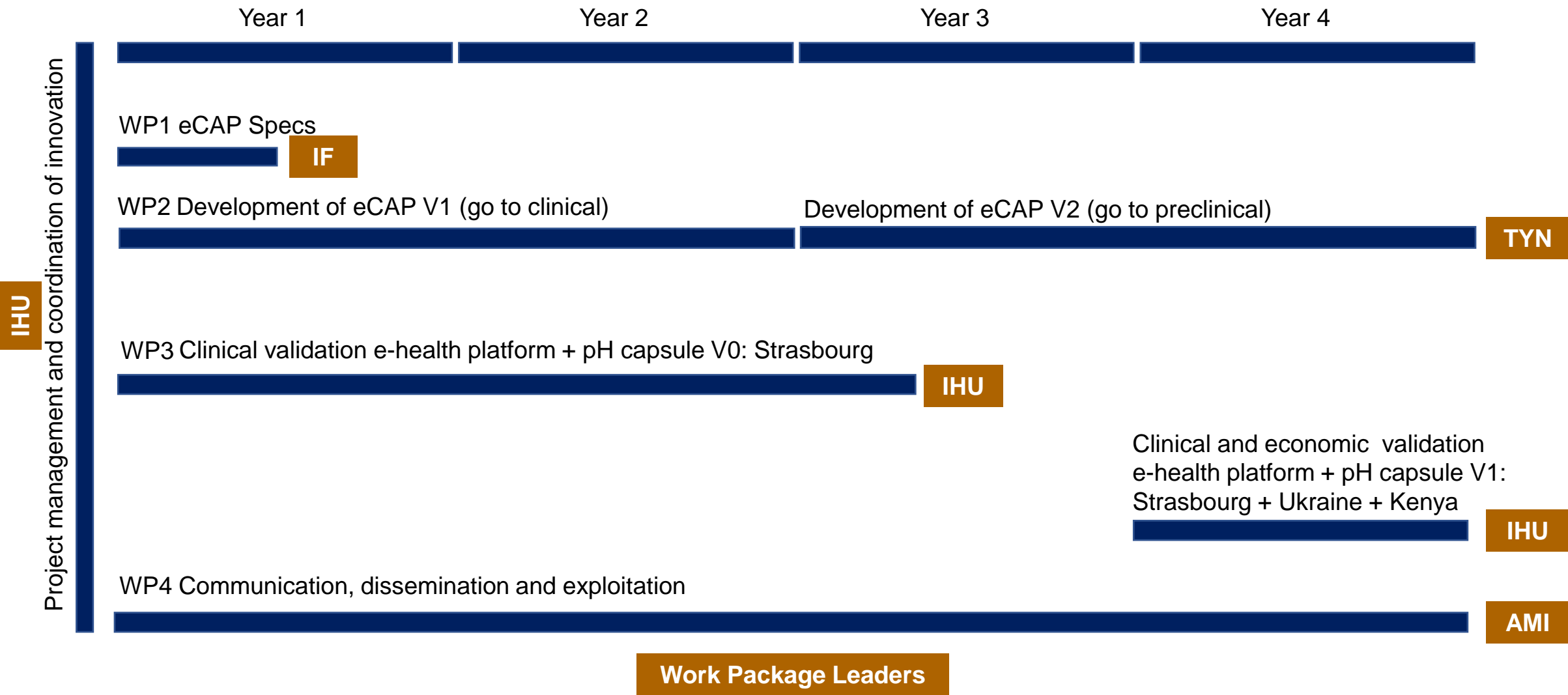


# World-class expertise

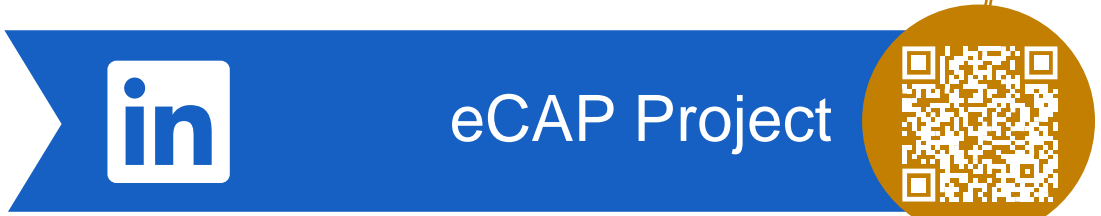
Partner	Role and expertise
The Institute of Image-Guided Surgery of Strasbourg	Coordinator Pre-clinical and clinical lead
Tyndall National Institute	Technical R&D: electronic and photonic design, fabrication, integration, testing
Sentron Europe BV	Microsensor technology: chip manufacturing, assembly and encapsulation for microsensors
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

A blue ribbon banner with a white laptop icon containing a globe on the left. To the right of the icon is the URL <https://ehealth-cap.eu/>. On the far right is a QR code inside a brown circle with a thin gold line extending from the top right.A blue ribbon banner with the LinkedIn 'in' logo on the left. To the right is the text 'eCAP Project'. On the far right is a QR code inside a brown circle with a thin gold line extending from the top right.A blue ribbon banner with the Twitter bird logo on the left. To the right is the text '@eCAP\_project'. On the far right is a QR code inside a brown circle with a thin gold line extending from the bottom right.

# 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.

Kahrilas, P., Yadlapati, R. and Roman, S., (2017). 'Emerging dilemmas in the diagnosis and management of gastroesophageal reflux disease. ' *F1000 Research*, 25(6), pp 1748-1758.

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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