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.

Demo: eCAP capsule

Demo: eCAP delivery device

Demo: eCAP smartphone application

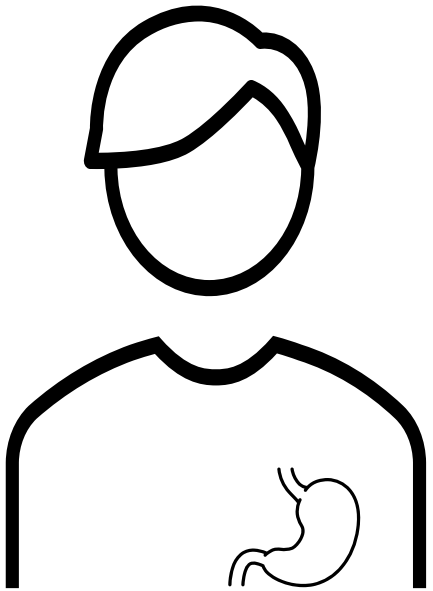
Current status

- A fully integrated capsule featuring pH, temperature and inertial sensing has been developed
- Bluetooth transmission demonstrated
- Multi sensing including pH demonstrated
- Successful preclinical test completed
- Currently preparing for clinical trials in France, Ukraine and Kenya Q 2 to Q 4 2026
- Planning to create start up in late 2026

Gastrointestinal disease

24 – 40% population incidence worldwide

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



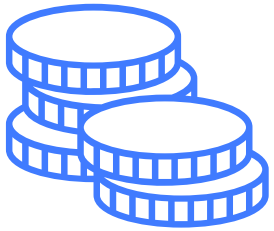
Soper, N.J., Swanström, L.L. and Eubanks, S. eds., 2014.

Use case

Gastroesophageal reflux disease: GERD

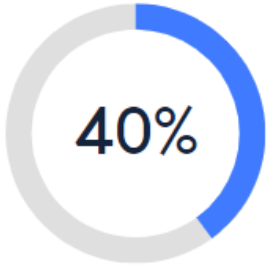
1.2 billion people globally

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

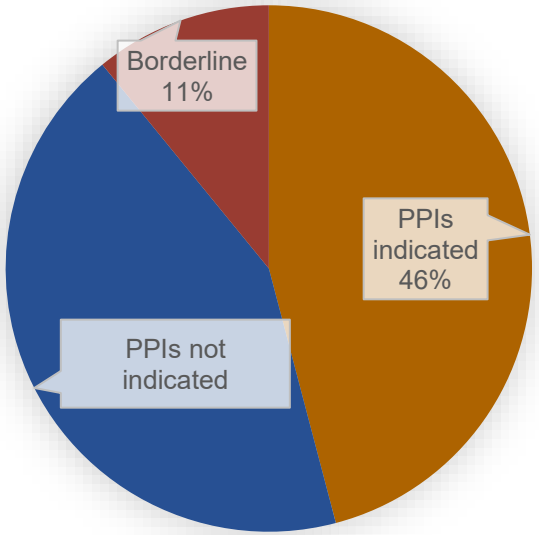


Treatment failures

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

Difficulties in diagnosis

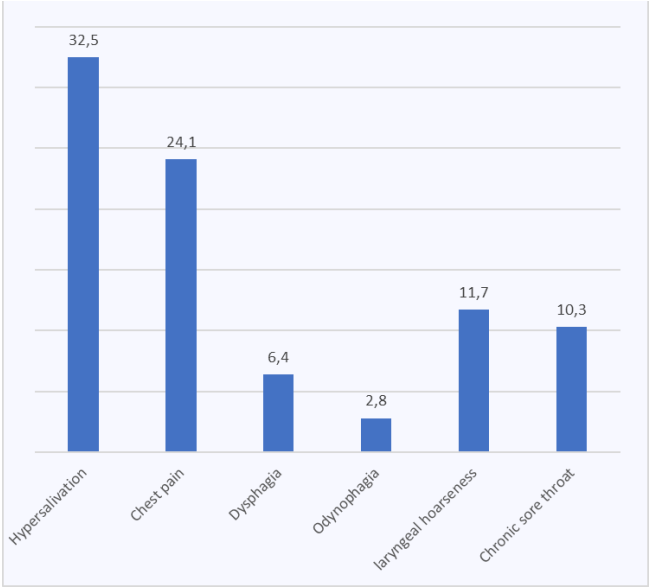
- Multitude of symptoms, severity subjective.
- Less than **2% of eligible patients** currently receive the correct diagnostic test.



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).

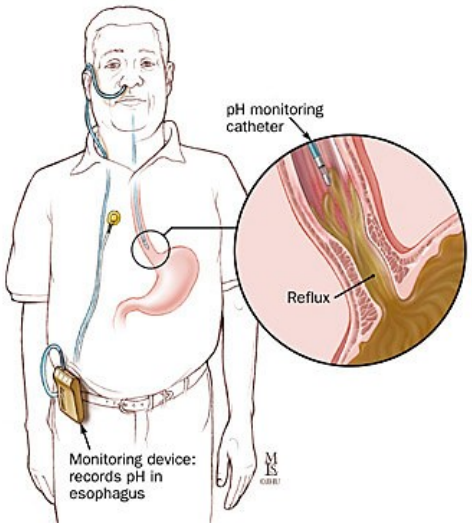
24-hour pH-metry

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

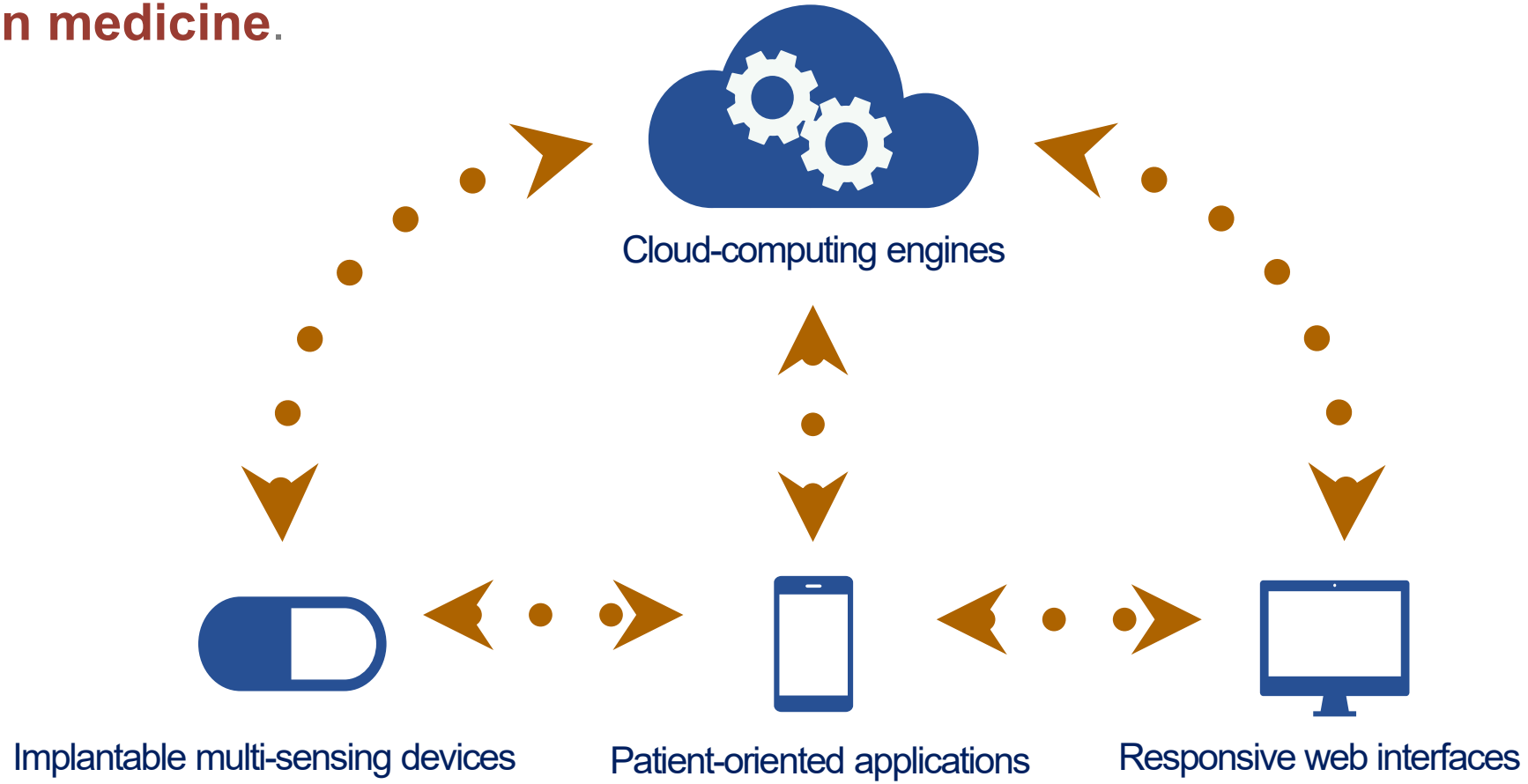
DeMeester score
Normal < 14,72



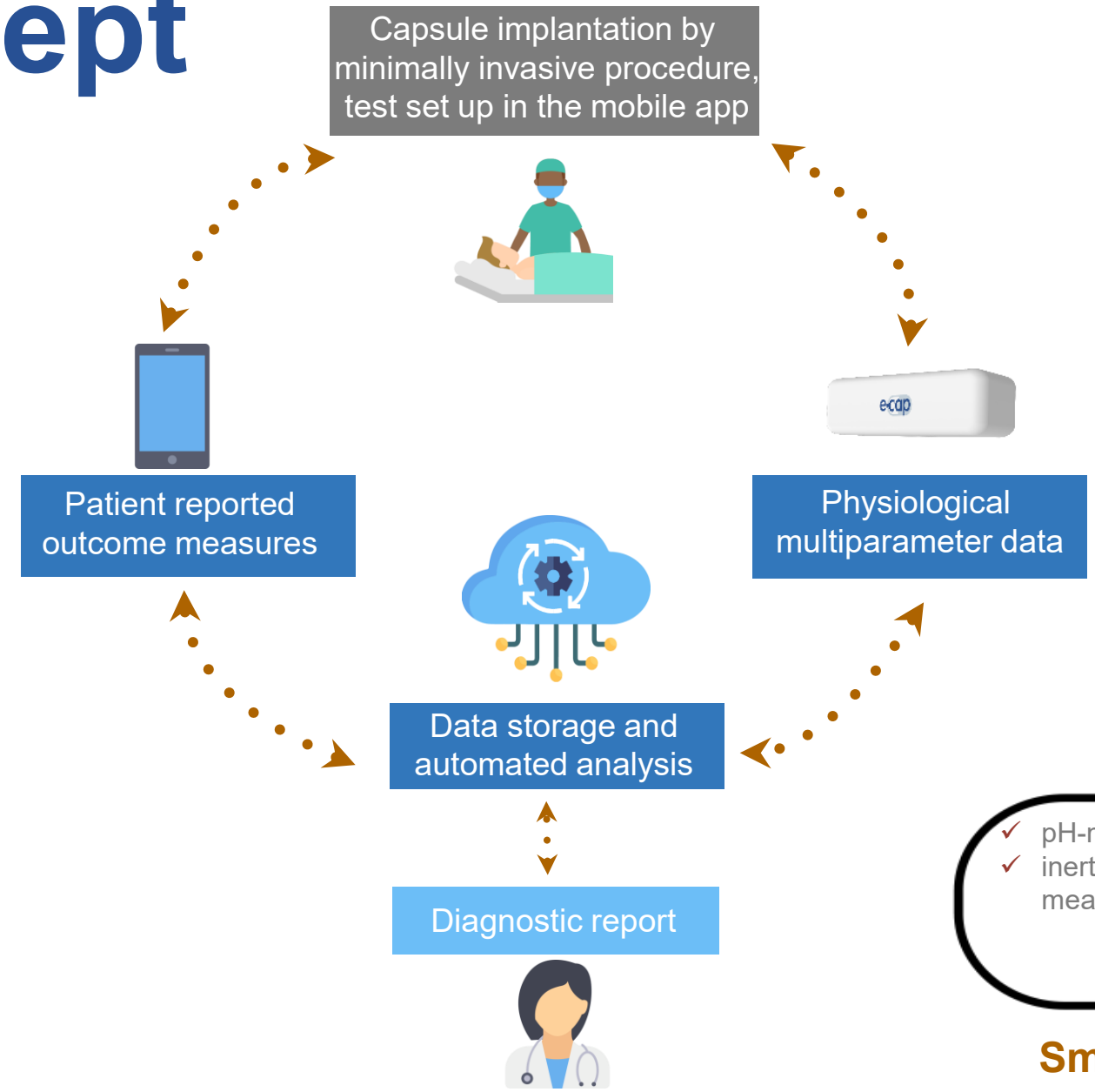
Johnson, L.F. & Demeester, T.R., 1974.

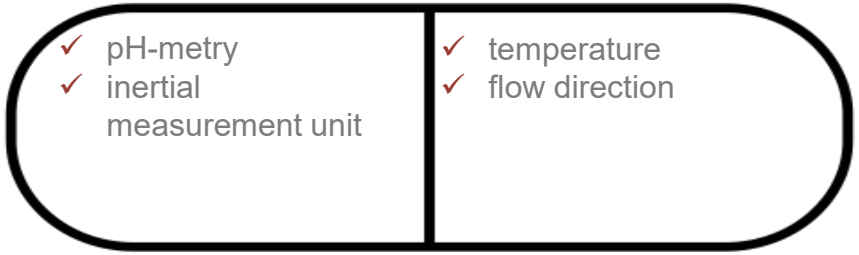
Aim of eCAP project

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



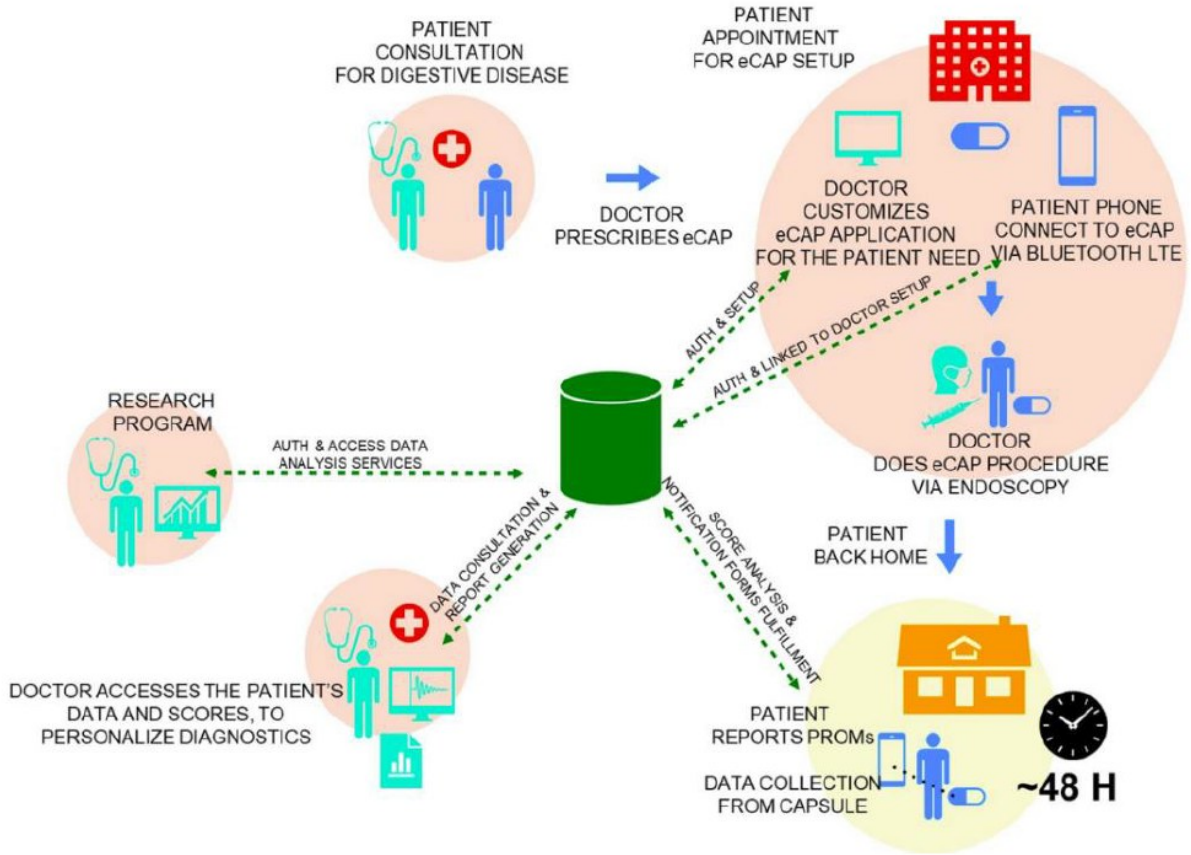
Concept



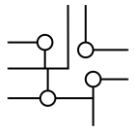


Smart multi-sensing capsule

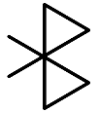
eCAP e-health platform organisation and work flow



Technology Brief

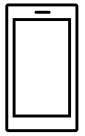


eHealth CAPsule design for digestive sensing & diagnostics



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

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).

HORIZON Europe Innovation Action

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.

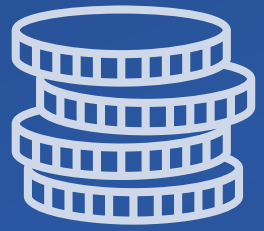
Objective 3: Validate the eCAP technology in patients suffering from gastroesophageal reflux disease.

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

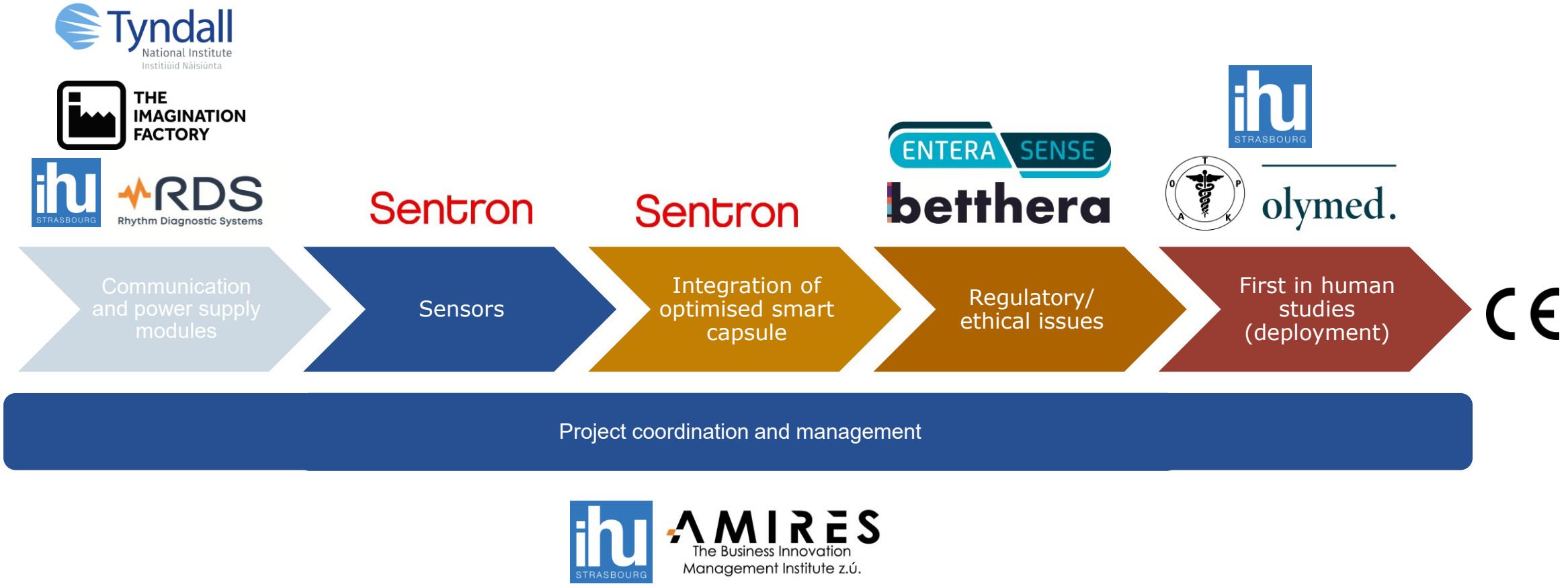
Enhanced access to digestive disease diagnostics and care
enabled by decreased cost of equipment and expertise required from the physician for data interpretation



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



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

Contact us

https://ehealth-cap.eu/

eCAP Project

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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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