



DELIVERABLE REPORT

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Project acronym: LUCA

Project title: Laser and Ultrasound Co-Analyzer for thyroid nodules

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Name, title and organisation of partner: Katharina Krischak, EIBIR Gemeinnützige GmbH zur Förderung der Erforschung der biomedizinischen Bildgebung (EIBIR)

Project website address: www.luca-project.eu



Content

1) Objectives	3
2) The presentation (slides in annex)	3
3) Conclusions.....	4
4) Annex.....	4



1) Objectives

The project presentation on Laser and Ultrasound Co-Analyzer for thyroid nodules (LUCA) aims to provide an overview of the project's background, the vision and mission shared by the project partners, as well as an introduction to the project work plan and the consortium.

2) The presentation (slides in annex)

To start with, the motivation behind the undertaking of the project is explained and graphically presented (slide 2). Thyroid cancer is a major and growing health challenge, however, current methods do not provide sufficient evidence and support to surgeons in their decision on the appropriate course of action. The large number of non-diagnostic and false positive results in thyroid nodule screening leads to many unnecessary surgeries. The LUCA project therefore aims to develop a new, non-invasive low-cost device that will provide doctors with enhanced information required to provide better and more specific results and enable better diagnosis. Once successful, LUCA will have an important socio-economic impact, diminishing the number of unnecessary surgeries and the associated comorbidities as well as improving the quality of life of patients.

The presentation also introduces the LUCA vision (slide 3), which starts at the present clinical practice in thyroid screening and the current state of research in the field and is followed by the proposed innovations during the LUCA period. The objectives after the LUCA project are the entrance of the LUCA device in clinical trials and, in the long run, its successful application in clinical practice. It is shown that the goal of LUCA is to start at a technology readiness level (TRL) of TRL 5 and advance to TRL 7.

The project's main objectives are given (slide 4), which include:

- the development of a novel, low-cost tool for the screening of thyroid nodules for malignant cancers;
- the development of an innovative probe that combines diffuse optics and clinical ultrasound for simultaneous multi-parametric ultrasound imaging and optical measurement of tissue hemodynamics and composition of the thyroid nodules;
- the development of a multi-modal, point-of-care device which integrates with the probe developed and a portable, low-cost ultrasound system;
- the establishment of the clinical usability of the LUCA device.

The consortium partners expect the project to have a major impact in the field of thyroid cancer screening (slide 5). An improvement in the specificity of the screening process in comparison to the conventional ultrasound-based workflow is anticipated and thus earlier and faster diagnosis for an effective treatment and management as well as a reduction in the number of unnecessary surgeries will be achieved. The LUCA device also has the potential to represent a very innovative tool for other types of cancer diagnosis, screening and therapy monitoring in areas of the body accessible to both ultrasound and near-infrared diffuse optical technologies. Therefore, LUCA is expected to have a significant impact on the field of thyroid cancer but also additional areas of cancer screening and a wide-market introduction of the LUCA technology is foreseen.

The presentation also introduces the LUCA consortium (slide 6-7), which includes renowned organisations and industry partners from all over Europe: ICFO – The Institute for Photonic Sciences, ES (Scientific Coordinator); Politecnico di Milano, IT; Consorci Institut d'Investigacions Biomediques August PI I Sunyer, ES; Hemophotonics SL, ES; Vermon SA, FR; ECM – Echo Control Medical, FR; University of Birmingham, UK; European Institute for Biomedical Imaging Research, AT. It also provides a brief overview of the expertise each partner organisation brings to the project.



The three phases of the project are presented (slide 8). During the first 18 months, the partners will work on the development and construction of the device components, while phase II (M12-M36) will focus on the testing of the developed components and the validation of the device in laboratory settings. Finally, phase III (M30-M48) is dedicated to the demonstration of the LUCA device in real-settings, the implementation of feedback received, as well as the performance of updates and final tests.

Furthermore, the work packages and their respective main objective are listed (slide 9-11):

- Work Package 1, dedicated to project management, aims to achieve excellence in project management in technical and administrative terms.
- Work Package 2, focusing on the development of components and sub-systems, will utilize innovative components for new sub-systems and to develop an innovative, multi-modal probe that combines diffuse optics and clinical ultrasound.
- Work Package 3 will develop a low-cost, portable, point-of-care, robust LUCA demonstrator that integrates with the probe developed in WP2 and with a portable, low-cost ultrasound system.
- Work Package 4 will deal with ex vivo, phantom validation and standardization.
- Validation in real-settings to evaluate the clinical usability is the main objective of Work Package 5.
- Work Package 6 deals with the dissemination of the project results and aims to communicate them broadly and to the general public as well as directly to stakeholders and end-users.
- Finally, Work Package 7 is dedicated to the exploitation of the project results at all levels from know-how and intellectual property generation to business plan development in order to commercialize the probe and the LUCA device.

Moreover, the presentation briefly introduces the governance structure of the LUCA project (slide 12-13). The consortium bodies include: the Consortium General Assembly (CGA), which is the overall decision-making body, which decides on legal, contractual, ethical, and financial issues; the Steering Committee (SC), the executive operational body, which monitors the effective and efficient implementation of the project and is responsible for the proper execution and implementation of the decision of the CGA. Additionally, there is a Medical Advisory Board (MAB) made up of external members who advise the consortium on the performance and progress of the project as well as the appropriate resolution of potential conflicts and deviations. The body responsible for the monitoring of the strategic and commercial gains as well as the overall impact of the project is the Innovation and Exploitation Committee.

Finally, the project presentation also includes the key facts about the project such as start and end date, the maximum grant amount and the project website (slide 14). The LUCA website is currently under construction and will be available as of April 30, 2016.

3) Conclusions

The enclosed presentation as well as this publishable report is intended for public use to distribute key facts and information about the LUCA project to draw attention to the project among stakeholders as well as the general public.

4) Annex



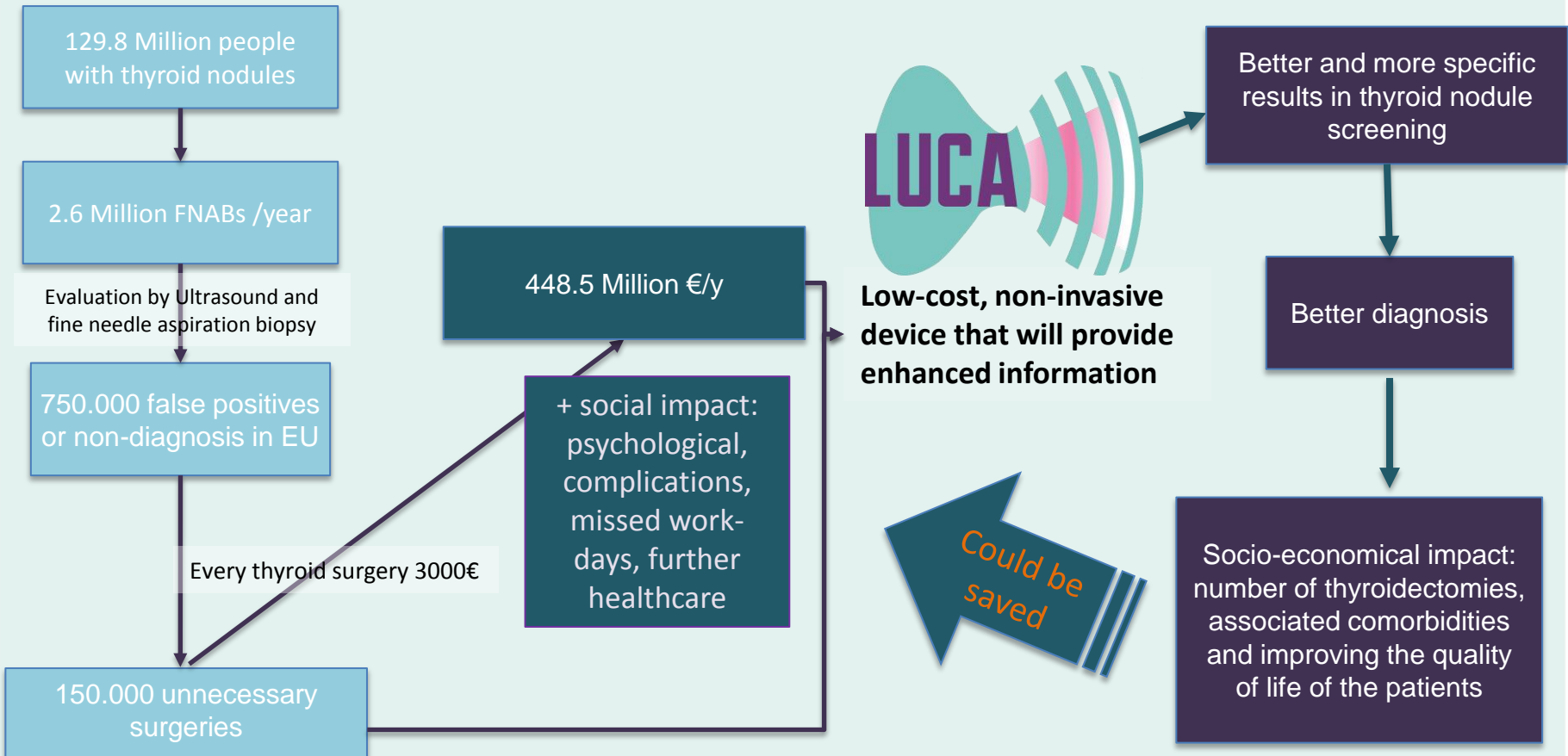
Laser and Ultrasound Co-Analyzer for thyroid nodules (LUCA)

GA No: 688303



Motivation:

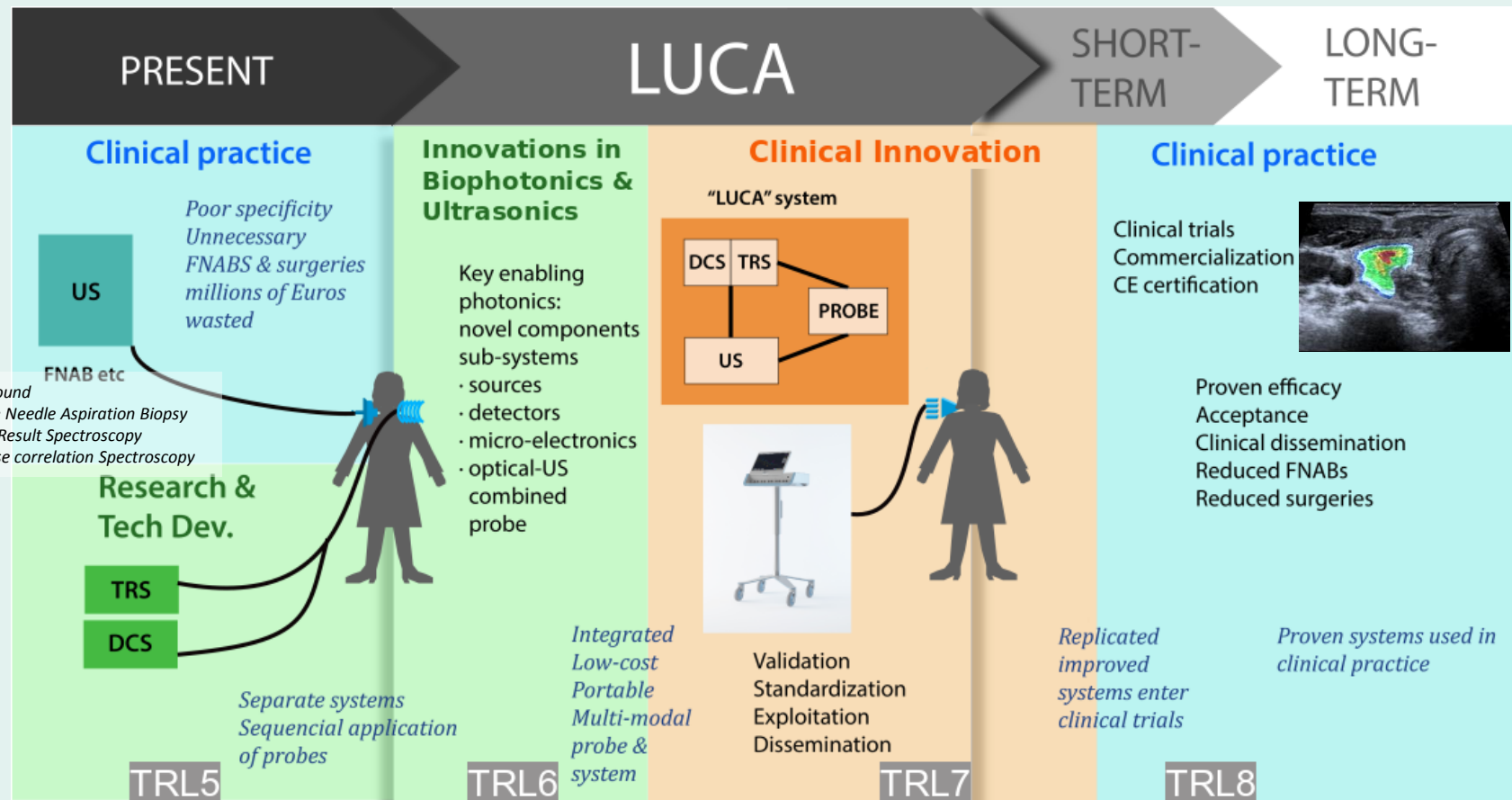
Thyroid cancer is a major and growing health challenge. Chances of survival and full recovery heavily depend on an early and fast diagnosis and an effective treatment.





The LUCA Vision

Overview of the LUCA vision, starting at the present clinical practice in thyroid screening and our current research, followed by the proposed innovations during the LUCA period and the short- and long-term impact of LUCA after the end of the project. The goal of LUCA is to start at a technology readiness level (TRL) of TRL 5 and move to TRL 7.



US: Ultrasound
FNAB: Fine Needle Aspiration Biopsy
TRS: Time Result Spectroscopy
DCS: Diffuse correlation Spectroscopy



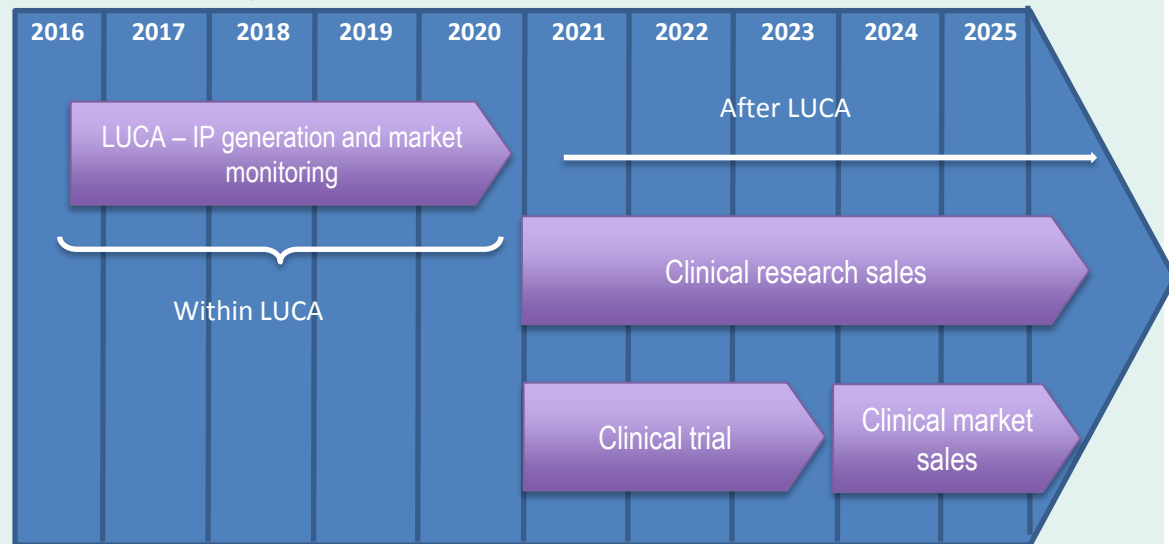
Objectives

- » To develop a **novel low-cost tool** for the **screening of thyroid nodules** for malignant cancers
- » To develop an **innovative probe** that combines diffuse optics and clinical ultrasound for simultaneous multi-parametric ultrasound imaging and optical measurement of tissue hemodynamics and composition of the thyroid nodules
- » To develop a **multi-modal, point-of care device** which integrates with the probe developed and a portable, low-cost ultrasound system
- » To establish the **clinical usability** of the LUCA device



Expected Impact

- » Improvement in the **specificity** of the thyroid screening process compared to the conventional ultrasound-based workflow
- » **Earlier and faster diagnosis** for an effective treatment and management and reduction of the number of surgeries
- » **Potential application** of the LUCA device in other types of cancer diagnosis, screening and therapy monitoring (in areas of the body accessible to both techniques)
- » Reduction of **socio-economic cost** related to thyroid cancer
- » **Wide-market introduction** of the LUCA technology





Consortium

Optics, opto-electronics & Biophotonics



The Institute of Photonic Sciences



POLITECNICO MILANO 1863



Politecnico di Milano

UNIVERSITY OF BIRMINGHAM



University of Birmingham

Industrial: product developer



Vernon S.A.



Hemophotonics S.A.



Echo Control Medical

End-users Researcher & Clinics



EUROPEAN INSTITUTE FOR BIOMEDICAL IMAGING RESEARCH



European Institute for Biomedical Imaging Research

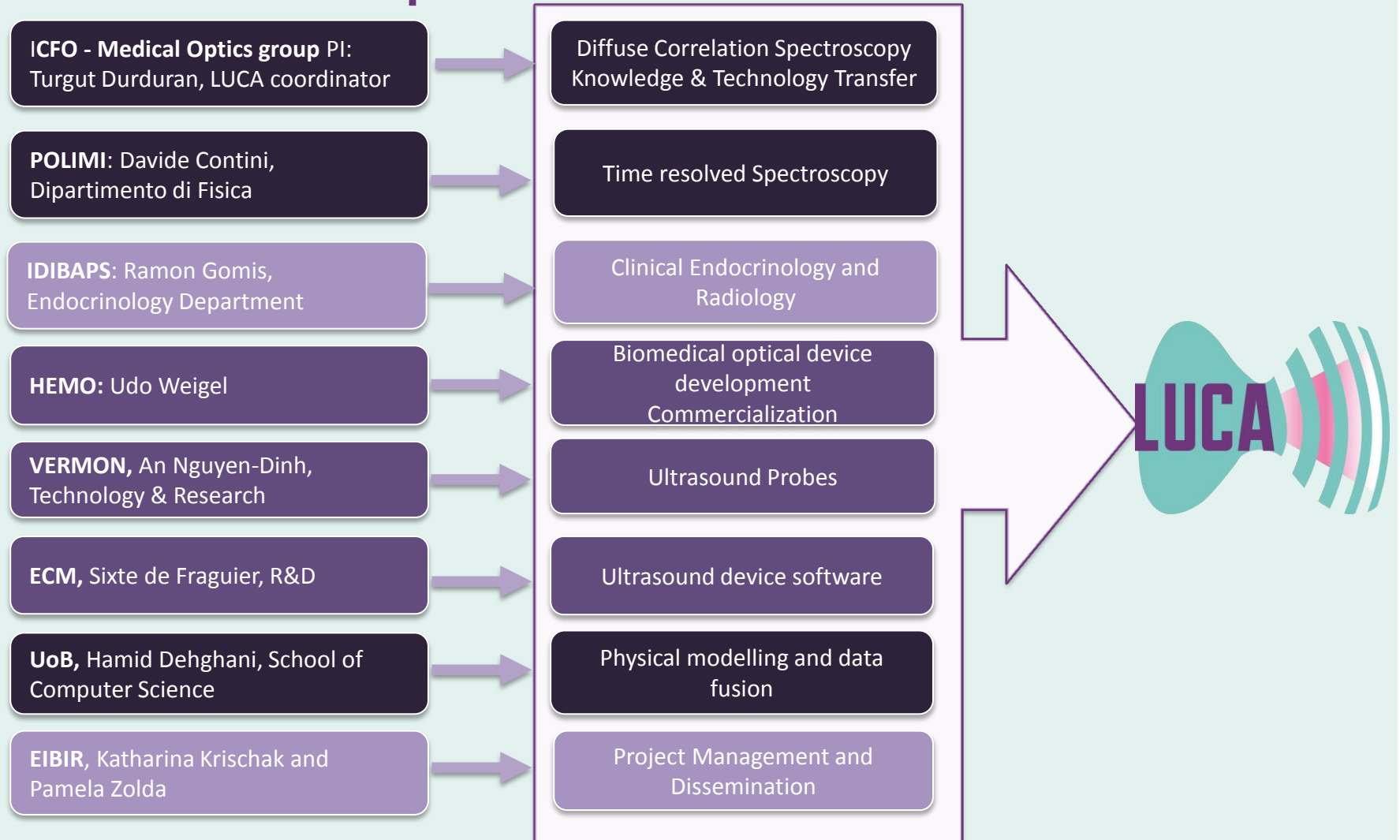


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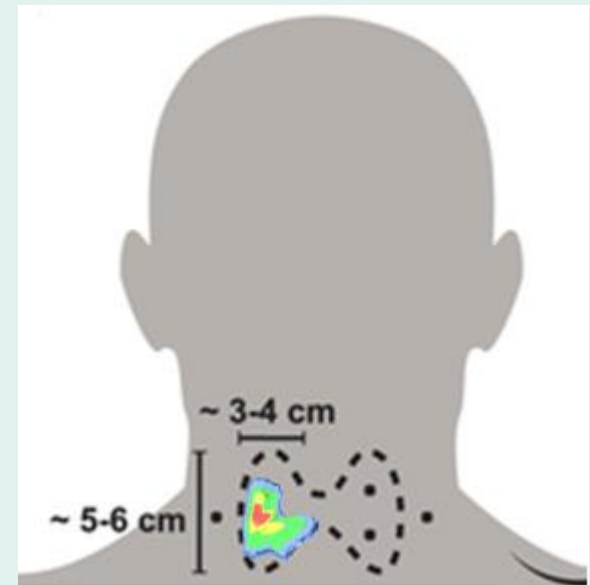


Consortium's Expertise

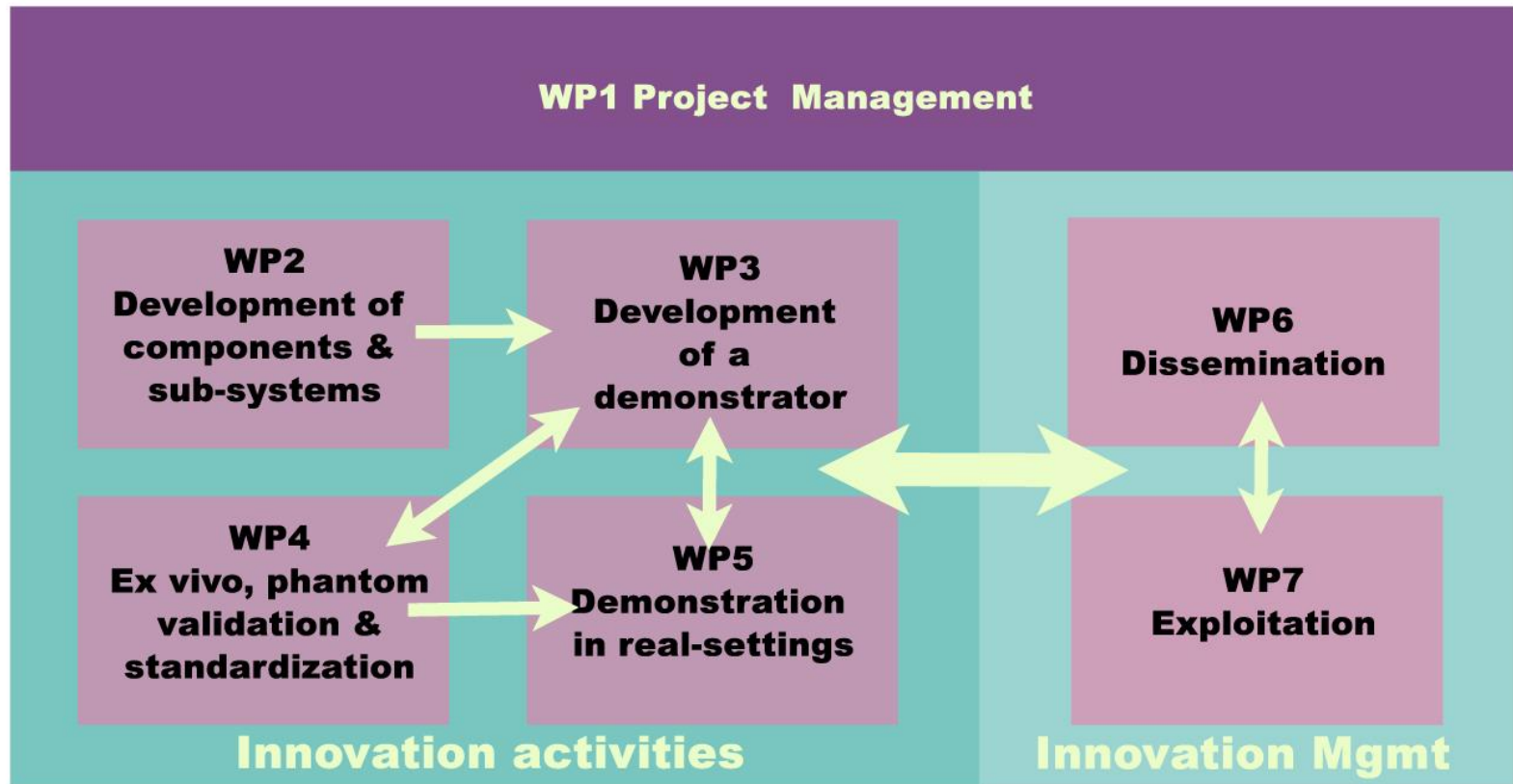


Work Plan

- » **Phase I** (M1-M18): Development and construction of device components
- » **Phase II** (M12-M36): Testing of components and validation of device in laboratory settings
- » **Phase III** (M30-M48): Demonstration in real-settings, feedback, upgrades and final tests



Work Packages





Work Packages: Objectives

- » WP1 Project Management
 - To achieve excellence in project management in technical and administrative terms
- » WP2 Development of components and sub-systems
 - To utilize innovative components for new sub-systems and to develop an innovative, multi-modal probe that combines diffuse optics and clinical ultrasound
- » WP3 Development of a demonstrator
 - To develop a low-cost, portable, point-of-care, robust LUCA demonstrator that integrates with the probe developed in WP2 and with a portable, low-cost ultrasound system
- » WP4 Ex vivo, phantom validation and standardization
 - To develop ex vivo phantoms and standards for validation and quality control

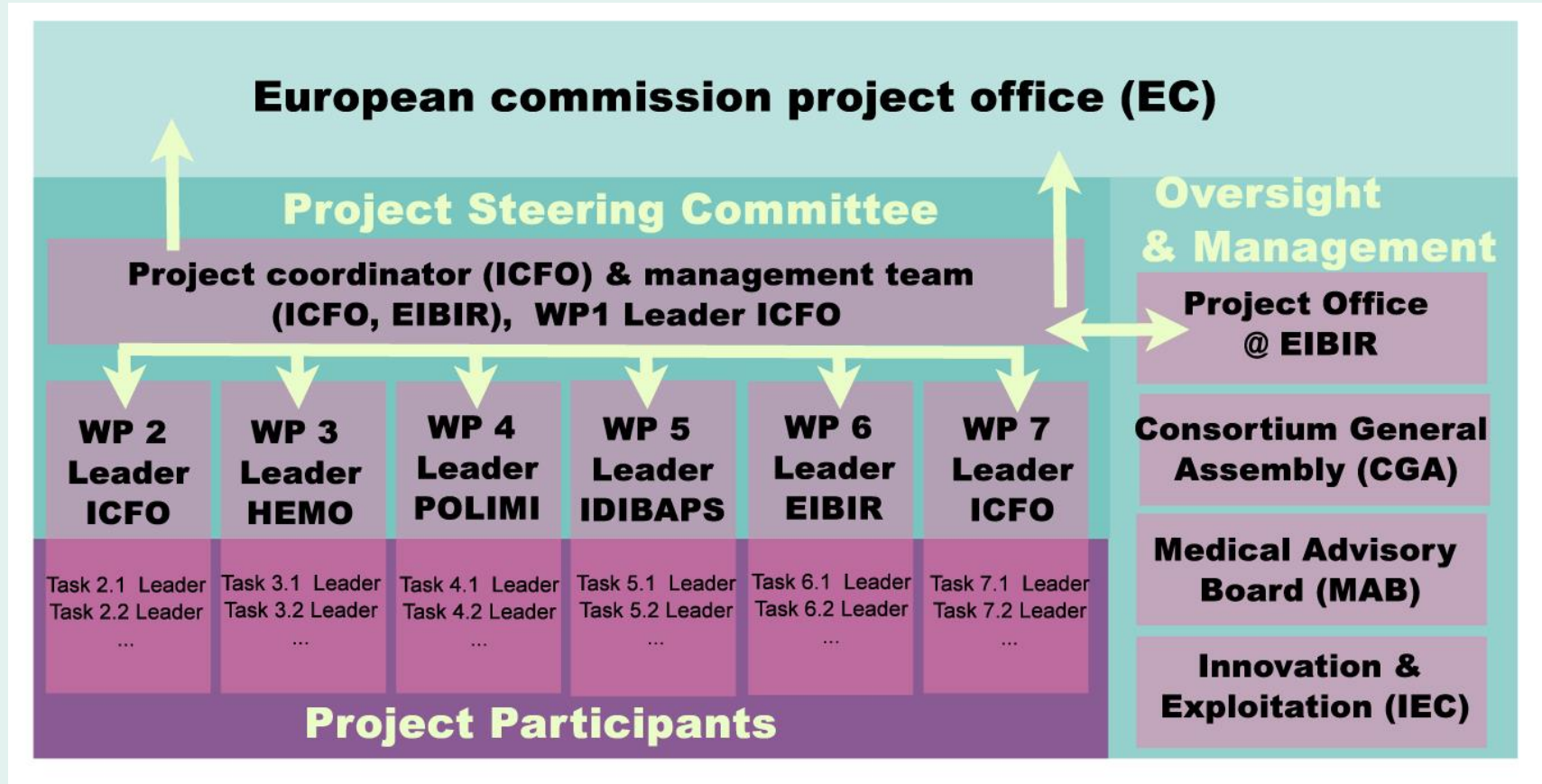


Work Packages: Objectives

- » WP5 Validation in real-settings
 - To evaluate the clinical usability and validate the system in real-settings
- » WP6 Dissemination
 - To disseminate project results broadly as well as directly to stakeholders and end-users
- » WP7 Exploitation
 - To exploit the project results at all levels from know-how and intellectual property generation to business plan development in order to commercialize the probe and the LUCA device



Governance Structure





Governance Structure: Consortium Bodies

- » Consortium General Assembly (CGA)
 - Overall decision-making body
 - Decides on legal, contractual, ethical and financial issues
- » Steering Committee (SC)
 - Executive operational body
 - Monitors the effective and efficient implementation of the project and is responsible for the proper execution and implementation of the decisions of the CGA
- » Medical Advisory Board (MAB)
 - External MAB members advise the consortium on the performance and progress of the project as well as the appropriate resolution of potential conflicts and deviations
- » Innovation and Exploitation Committee (IEC)
 - Monitors the strategic and commercial gains as well as the overall impact of the project



Key Information

- » LUCA runs from **February 1st 2016 to January 31st 2020**
- » Grant amount: **EUR 3,628,845.75**
- » www.luca-project.eu

