EUPHORIA

Welcome to the EUPHORIA Project's Winter 2020 Newsletter!

The EUPHORIA Project – The Story so Far

The EUPHORIA team at the project kick-off, Munich 2019

Inflammatory bowel disease (IBD) is a group of chronic conditions, such as Crohn's disease (CD) and ulcerative colitis (UC), that affects more than 2.5 million people in Europe, posing a significant burden to patients and healthcare systems. The total economic burden of IBD, including unemployment, sick leave and work disability costs, is estimated at €4.5-5.6 billion each year in Europe alone. Treatments exist to reduce disease symptoms and prevent severe complications, but a better way is needed to monitor IBD inflammation during treatment. Endoscopy is currently the best method for diagnosis and monitoring, but it is invasive and expensive, and cannot be used frequently. What is needed, is a non-invasive alternative to improve patient care and yield substantial healthcare savings.

EUPHORIA will meet this need by establishing Multispectral Optoacoustic Tomography (MSOT) as a widespread routine clinical tool for non-invasive monitoring of IBD. MSOT technology illuminates the tissue of interest with laser light in the near-infrared and extended-infrared range whose wavelengths best penetrate deep beneath the skin. The absorption of photons results in the photoacoustic effect, i.e. the generation of thermoelastic expansion and ultrasound pressure waves. The MSOT system then generates ultrasound (US) and optoacoustic (OA) images that enable assessment of inflammation in IBD.

In the first eighteen months of the project, the improvements to the MSOT technology and preparations for the EUPHORIA study have successfully laid the foundations needed for us to deliver on our goals and achieve desired impacts. A large clinical study in IBD patients is about to begin using the enhanced MSOT system in order to generate evidence to support CE marking for the new device, validate the clinical utility of the technology to clinicians and healthcare payors and demonstrate benefit for IBD patients.

Dr Philipp Bell, EUPHORIA Coordinator

Dr Philipp Bell, EUPHORIA Coordinator based at **iThera Medical GmbH:** *"The enhanced MSOT technology developed during EUPHORIA promises to greatly benefit patients and health care systems. If the study is successful, those with IBD can benefit from reduced risk of complications and improved quality of life - through better and more convenient diagnosis, monitoring and care management. Physicians and hospitals could benefit from the availability of an in-office diagnostic tool with a sensitivity for detecting inflammation comparable to that of the gold standard, which is less expensive and suitable for frequent follow-up. Payors and healthcare systems could benefit from saving costs in terms of a reduction in the number of costly endoscopies, stopping ineffective treatments earlier, enabling more efficient use of clinical expertise and facilities, and improving patient outcomes. Apart from our great EUPHORIA partners we're grateful to the European Commission for supporting ground-breaking research that promises to have real impact on patients' lives and society as a whole."*

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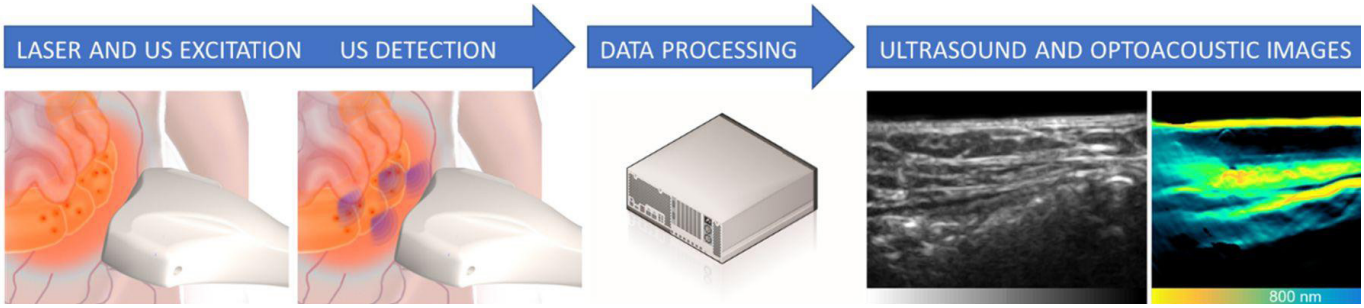
The EUPHORIA Clinical Study

On October 22, 2020, EUPHORIA Coordinator, iThera Medical, announced regulatory approval for a pivotal multi-center study in patients with inflammatory bowel disease (IBD). The EUPHORIA (Enhancing Ultrasound & Photoacoustics for Recognition of Intestinal Abnormalities) clinical study will commence at four investigational sites across Germany and Italy using iThera Medical's proprietary optoacoustic imaging technology, MSOT (multispectral optoacoustic tomography). A pilot study for the same indication using the same technology has shown that MSOT has the potential to non-invasively distinguish active inflammation from remission.

People with the chronic condition IBD undergo recurring phases of inflammation and remission of the gastrointestinal tract. In treatment management of IBD, it is necessary to closely monitor inflammatory activity of the bowel because therapy failure occurs in 30-50% of patients. Persistent inflammatory activity is related to higher complication rates, hospitalization, and cancer – all of which may be avoided by early adaptive treatment changes through improved disease monitoring.

In current care, endoscopy is the gold standard in IBD diagnosis. However, this procedure poses a significant burden and complication risk on patients due to the need for bowel preparation and the invasiveness of the procedure. On the other hand, non-invasive procedures such as clinical examination and ultrasound imaging show high variability and diagnostic inaccuracy.

MSOT imaging is a new non-invasive diagnostic method based on the so-called photoacoustic effect – the conversion of light energy into sound waves. This technique combines pulsed laser excitation of tissue with ultrasound (US) detection. Tissue – in this case the colon wall – absorbs the laser light energy and emits ultrasound signals. The signal amplitude correlates with the blood concentration in the colon wall, a biomarker of inflammation.



Principle of MSOT imaging

The goal of the EUPHORIA clinical study is to assess the ability of MSOT as a tool to measure disease activity in the bowel wall of people with Crohn's disease (CD) and ulcerative colitis (UC). The diagnostic performance of the MSOT Acuity Echo investigational device will be compared to endoscopy and to other commonly used diagnostic procedures, such as MRI and ultrasound imaging as well as blood and fecal lab analyses. Lead Investigator Prof. Maximilian Waldner from the University Hospital Erlangen comments: 'We are extremely excited to bring MSOT closer to clinical routine for IBD patients by validating the findings from our initial pilot study.'

For the EUPHORIA study a total of approximately 540 subjects are expected to be enrolled, about half of which will be patients with CD and half with UC. The study will be divided into two phases. The first phase will determine the optimal device settings to identify active disease from remission. The second phase will make use of the optimal settings from the first phase and will confirm the accuracy of the device. The study sites in Germany are the University Hospital Erlangen and University Hospital Jena. The German sites will open for recruitment in Autumn 2020, with plans for two additional Italian sites to open in early 2021.

For further information on the study see the EUPHORIA website and watch our news page for updates: https://euphoria2020.eu/news/. The study has also been registered on https://clinicaltrials.gov/ (see https://clinicaltrials.gov/ct2/show/study/NCT04456400).

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The EUPHORIA Partners

EUPHORIA involves 5 partners from 4 European countries. The Coordinator of EUPHORIA is **iThera Medical**, owner of the core 'Acuity' MSOT technology. **IMASONIC** are leading on upgrading the transducer used in the MSOT device. Enhancement of the imaging, analysis and interpretation software is led by **RayFos**, while iThera Medical and **University Hospital Erlangen** are delivering the clinical validation of the MSOT system in the EUPHORIA clinical study. Project dissemination and administrative support is provided by **Pintail Limited**.

SME Partner RayFos in the Spotlight

Headquartered in Basingstoke in the south of England with eight employees, RayFos Limited is active in the optical engineering and real-time processing systems domain. This innovative scientific software firm specializes in advanced signal processing system integration for a variety of measurement applications.

Established in 2012, RayFos provides state-of-the-art solutions tailored to the needs and business requirements of their demanding high tech clients. To do this, RayFos works in close collaboration with its clients in a systematic yet flexible manner to deliver tailored, high impact innovation in scientific applications. The team is comprised of a group of career professionals with a wide range of scientific software expertise, professional certification and special skill sets in a variety of related engineering fields. The company is well-known for its development of alpha prototypes which can transform innovations to applied technologies and eventually functional products. The company has been involved in 8 EU-funded research projects.

We met up with Vassilis Sarantos, the Chief Executive Officer at RayFos Limited to ask a few questions. First, we asked Vassilis to introduce himself.

I am an Electrical and Computer Engineer working for more than 25 years in software and hardware development for numerous product development projects for the global market. My main research interests include real-time image/video processing, embedded system development, software development, medical imaging, and metrology system development. I am the founder of RayFos and I am passionate about transforming scientific research lab prototypes to commercial devices.

You have worked with iThera Medical on previous projects. Can you tell us the history of this successful working relationship?

I got involved in MSOT development back in 2009 when neither iThera nor RayFos had yet been officially founded. iThera was looking for a team that could help mostly with the software development and data acquisition tasks of the preclinical MSOT system. For the first year or so it was just me, but soon we started growing as a team in order to cover the multiple aspects of the project needs. Hand-held detectors and requirements for clinical use called for serious real-time processing and imaging capabilities of the system. Since the beginning of the project, we are working closely with iThera on upcoming features of the product and we always try to engage early on the development cycle of those new features so as to provide feedback, while at the same time prepare the software architecture for these changes. This process builds mutual trust and prepares the two companies for the next round of innovation. I believe we have already had a few cycles of that and I hope we will see more in the years to come.

Read the entire interview with RayFos CEO Vassilis Sarantos on the EUPHORIA website: https://euphoria2020.eu/2020/09/rayfos-in-the-euphoria-spotlight/

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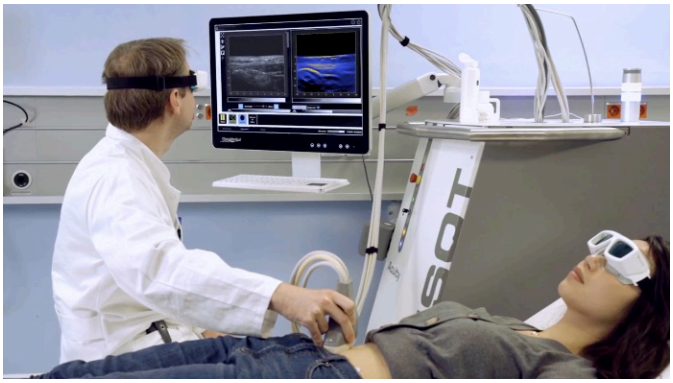
Dissemination Highlights

Our website, www.euphoria2020.eu is available in 4 languages: English, German, French and now Italian!

iThera exhibited EUPHORIA at the 2020 ECCO meeting. ECCO, the European Crohn's and Colitis Organisation held its 2020 meeting February 12-15th. Pre-meeting, iThera ran an email campaign to tell 7,000 clinicians, researchers and IBD patient advocacy groups about EUPHORIA and to invite them to the exhibition at ECCO.

The EUPHORIA Video – A Better Way to Monitor Inflammatory Bowel Disease (IBD) This was launched on March 10, 2020. Watch it! https://youtu.be/dk8ioq9oG6I



EUPHORIA-acknowledged publication in Nature Medicine *'Detection of collagens by multispectral optoacoustic tomography as an imaging biomarker for Duchenne muscular dystrophy'* was published in Nature Medicine, December 2, 2019.

IBD Twitter Chat organised by New Deal (https://newdeal-project.eu/) On April 27, 2020, clinical PI Prof Dr Max Waldner linked with Horizon 2020 project New Deal and Rachel Sawyer, an IBD patient advocate aka @bottomline on Twitter for a live chat to discuss new research and what the future of #IBD might look like! Read the recap here https://euphoria2020.eu/2020/04/euphoria-joins-eu-funded-new-deal-for-live-twitter-chat-to-explore-the-future-of-ibd-treatment/ #makeIBDwork

May 19th is World IBD Day. We ran a series of multi-lingual Tweets to shine a spotlight on our partners and their work within EUPHORIA. #WorldIBDDay2020

Join the conversation on
Twitter @euphoriaH2020 and
Facebook @EUPHORIAH2020

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