Pitching Session

Call 7 – Topic 3: Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Emma	BRODRICK	Technical Director	Existing	Rapid Biomarker Analysis at POC
2	Luiz	CORREA	Managing Director	Diagnostic Data Hub	Digital Transformation of Patient Consent (DigiConsent): Enhancing Efficiency in Healthcare Through E-Consent
3	Caroline	DESVERGNE	European programme manager	CEA Leti	Point-of-care devices and robust wearables to improve the clinical use of biomarkers (cellular, molecular, physiological)
4	Francesco	FASCETTI-LEON	Professor in Pediatric surgery	Pediatric Surgery Unit, Women's and childrens' health Department, Padova University	Non-invasivE multimodal monitoring tools for NeCrotizing enterocolitis in preterm infants: A piLot MulticEnteR sTudy (NEC-ALERT)
5	Kevser	FÜNFGELD	Digital Health Program Manager	Luxembourg Institute of Health	Development and implementation of virtual patient avatars derived from standardised, minimally and non-invasive biomarkers for enhanced clinical trials
6	Alexandra	GEORGESCU	Director of Science	thymia	Validation of multimodal biomarkers of mental health
7	Juan Ignacio	IMBAUD	COO	PROTEIN ALTERNATIVES SL	SEC6 signature: genomic biomarkers for recurrence prediction and treatment guidance in early-stage Colorectal Cancer patients
8	Georgi	KADREV	Co-founder & CEO	Kelvin Health	Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response
9	Elma	KERZ	Co-Founder and CEO of Exaia Technologies	Exaia Technologies	Trustworthy & Explainable AI for Mental Health Assessment: Harnessing NLP and ML/DL for the Detection, Timely Treatment and Remote Monitoring of Neurodegenerative and Psychiatric Disorders
10	Nicola	KIELLAND	project manager preaward	IDIAP Jordi Gol	Primary Care, a real-world environment
11	Irakli	LEZHAVA	CEO & Co-founder	Ensofy	Vocal Biomarkers for Mental Health Management
12	Shima	MAHMOUDI	Assistant professor	Silesian University of Technology	Advancing Tuberculosis Research: Unraveling Biomarkers for Enhanced Diagnostics, Prognostics, and Treatment Monitoring
13	Monika	MATUSIAK	MD	Institute of Physiology and Pathology of Hear	Molecular biomarkers of neuroplasticity after congenital deafness treatment by cochlear implantation - is serum level of MMP-9 a one?
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17	Anouk	POST	Postdoc	VU University	Advanced endoscopic imaging to visualize fluorescently-labelled molecules in vivo
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20	Ines	VALLEDOR	Sequencing Manager	Certest Biotec	Certest's NGS Comprehensive Adaptive Platform to Address Unmet Medical Needs

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IHI Call Days | Call 7

Call 7, topic 3: Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Rapid Biomarker Analysis at POC

Contact person name: Dr Emma Brodrick

Organisation: IMSPEX Diagnostics

E-mail: emma@imspex.com

Link to:

- Marketplace opportunity: https://ihi-call-days.ihi.b2match.io/participations/204213/opportunities
- Participant profile: https://ihi-call-days.ihi.b2match.io/participations/204213

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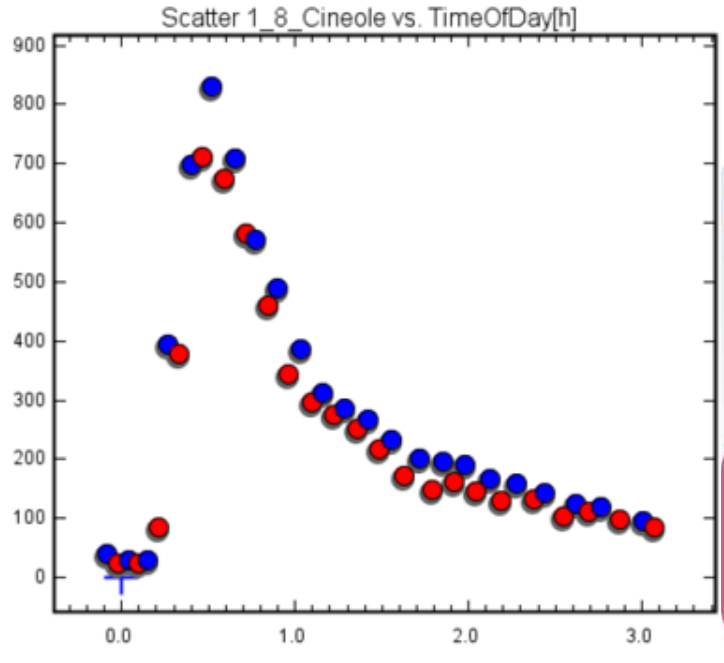
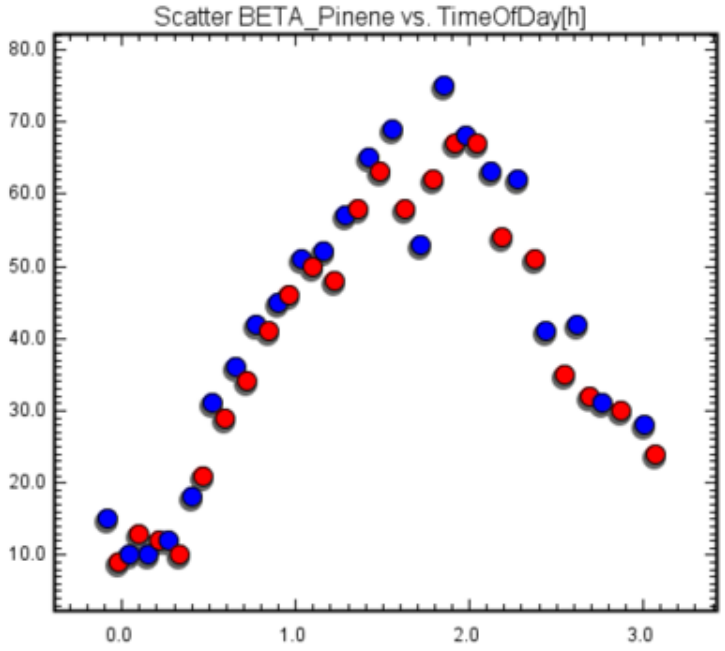
Challenges and objectives

- The main challenge is to rapidly validate biomarkers for clinical use
- Platform technology allows us to focus on multiple disease and patient application
- See rapid changes in biomarkers over short period of time at point of care





Our main objective within the project is to commercialise our GC-IMS technology:

- As a linked technology for precise and effective diagnosis
- For diagnosis-to-treatment pathways
- To create better treatment path selection

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Main activities

The main activities within the project is to use GC-IMS technology:

The **Breathspec** or the **Flavourspec**

Development of Technology for a specific disease and patient applications

Use GC-IMS technology for **clinical and analytical validation** in all call areas: diagnosing disease, early treatment path selection, monitoring disease progression, and treatment response assessment

Able to identify new volatile organic compound (VOCs) candidate biomarkers can be combined with existing biomarkers

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Expertise and resources offered

- We offer our analytical services and devices into any consortium
- Biomarkers and disease groups in the following areas:
  - Dementia
  - RTI, Asthma and COVID
  - UTIs and Women Health in pregnancy
  - IBD, Crohn's and Colitis
- IMSPEX has a QMS compliant to ISO13485, and had developed the Breathspec under IVDR with associated CE mark for use in COVID testing
- We are **not** bringing in-kind contributions

References:
1) Ruszkiewicz DM, et al. 2020. Diagnosis of COVID-19 by analysis of breath with gas chromatography-ion mobility spectrometry - a feasibility study. EClinicalMedicine, The Lancet. DOI:https://doi.org/10.1016/j.eclinm.2020 .100609
2) Lewis JM, et al. 2017 Dec 18;12(12):e0188879. doi: 10.1371/journal.pone.0188879.
3) Tiele A, et al 2020. Breath-based non-invasive diagnosis of Alzheimer's disease: a pilot study. J. Breath Res. 14 026003
4) Tiele A, et al. 2019. Simultaneous Assessment of Urinary and Fecal Volatile Organic Compound Analysis in De Novo Pediatric IBD. Sensors (Basel). doi: 10.3390/s19204496.

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Expertise requested

- We are looking for consortiums who are interested in

Partnering:

- for biomarker validation using VOCs
- for device use at POC
- for system development under the IVDR

Using:

- biomarkers to track pharmacokinetics and patient response
- GC-IMS for rapid throughput of trial subjects
- rapid analysis and identification of biomarkers at POC
- biomarkers for early trial end point
- big data for interrogation

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IHI Call Days | Call 7

User-centric technologies and optimised hospital workflows for a sustainable healthcare workforce

Digital Transformation of Patient Consent (DigiConsent): Enhancing Efficiency in Healthcare Through E-Consent

Luiz Correa

DxD Hub

lggcorrea@dxd-hub.com

https://ihi-call-days.ihi.b2match.io/participations/324438/opportunities

https://ihi-call-days.ihi.b2match.io/participations/324438

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Challenges and objectives

Multiple consent manually signed every year

Digitalization necessary – extra step

Multiple interactions necessary

Time consuming and demanding

- DigiConsent aims to address the administrative burden of paper-based patient consent in European healthcare by streamline the patient consent process, ensuring GDPR compliance, dynamic consent management, and efficient clinical trial engagement.
- More importantly, this will free important time from workforce that can focus on other activities, reduce the onus of data streamline incorporation of innovation and reduce economic burden of health system.

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Main activities

- Develop a user-friendly digital consent platform that can be integrated to multiple clinical/hospital settings/needs.
- Integrate dynamic consent capabilities for real-time updates.
- Ensure GDPR compliance and secure data availability.
- Pilot test with oncologists and cancer patients for clinical trials.

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Expertise and resources offered

- We bring expertise on data experience in developing user-friendly digital healthcare applications, patient engagement tools, data digitalization and integration into existing healthcare workflows.
- With a network of hospital and labs, we bring the understanding of the gaps and needs for the consent and its burden for the routine interaction with patients.
- We are connected to previous initiatives in the EU that have developed a framework for consent and engaging with other IHI consortia for exploring synergies.

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Expertise requested

Pharma – patient recruitment and needs of consent, especially oncology and clinical insights

Advocacy – patient perspective, needs and requirements

Payor – incorporation and interoperability of data and costs

Legal experts – regulation, policies, GDPR

Hospital/clinics – implementation and piloting

Networks and other consortia – past experiences and synergies

$ **Private Members – in-kind contributions**

- Stakeholders that would like to participate in the implementation phase for using in clinical trials

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IHI Call Days | Call 7

- Topic 3: Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Point-of-care devices and robust wearables to improve the clinical use of biomarkers (cellular, molecular, physiological)

Contact person name: **Caroline DESVERGNE**, European Programme Manager

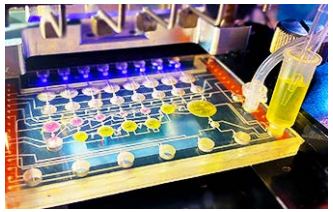
Organisation: **CEA Leti (FR)** – **Health Department**

E-mail: caroline.desvergne@cea.fr

Link to:

- Marketplace opportunity: click here for our detailed offer
- Participant profile: click here

Challenges and objectives



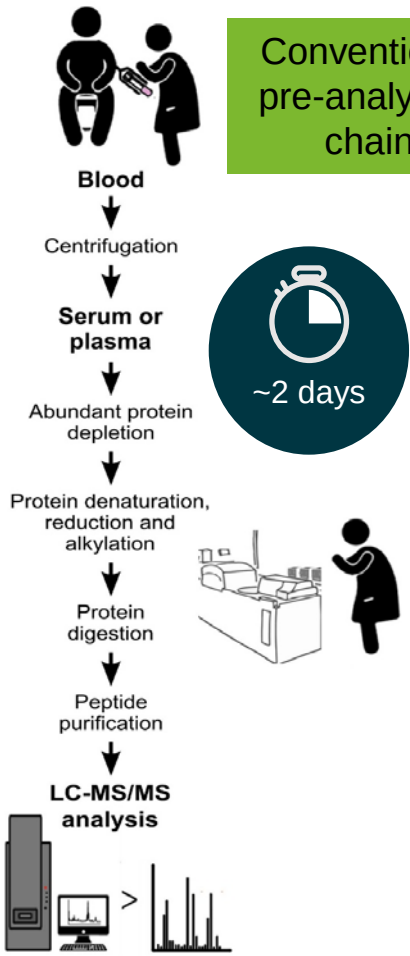
Main objective: Enhance the clinical use of biomarkers by solving key technological bottlenecks of current point-of-care and wearable devices

	Point-of-care devices for cellular and molecular biomarkers	Medical wearable devices for physiological and biochemical biomarkers
Key challenges	✓ Complete automated and miniaturized analyses on low volumes (few µL) ✓ Complex sample preparation (MRD, omics) ✓ Highly reproducible and fast (hours vs days) ✓ High sensitivity (µM) ✓ Multiplexed assays	✓ Comfortable and medical-grade devices ✓ Multimodality for biomarker panels (HR, spO_2, pCO_2, ECG, stress, cerebral activity…) ✓ Minimally-invasive sampling for biochemical biomarkers (microneedles) ✓ Personalized approaches (physiology, AI…)
	1 detailed example slide 3	1 detailed example slide 4

Targeted diseases: our technologies are developed for various pathological areas among which cancer, sepsis, mental health (major depressive and bipolar disorders), respiratory diseases, or cardiology (*see our pitch for topic 1 - Françoise Charbit*).

Main activities (1/2): fast and highly reproducible sample preparation for proteomic analyses

One documented factor for the clinical use of proteomic biomarkers is the **difficulty in achieving assay reproducibility** due to variations in analytical workflows.



~2 days

Conventional pre-analytical chain

PePs: fully automated sample preparation for proteomics by microfluidics from blood

Cartridge

~2 hours

Instrument

PATENTS 8 PATENTS

Improved clinical use:
- Fast analysis
- No trained staff
- High reproducibility
- Favor multiplex analyses

This solution can be adapted to:
- Complex sample preparation for trace biomarkers : cfDNA, proteins, EVs..
- Miniaturized biomolecular analyses: ELISA-on-chip, Immuno/Apta-Lamp,
- Other matrices: BAL, biopsies..

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PepS: An innovative Microfluidic device for Bedside Whole Blood Processing before Plasma Proteomics Analyses, Anal. Chem. 2021, 93, 683-690

Main activities (2/2): Minimally-invasive and wearable monitoring of biomarkers in interstitial fluid

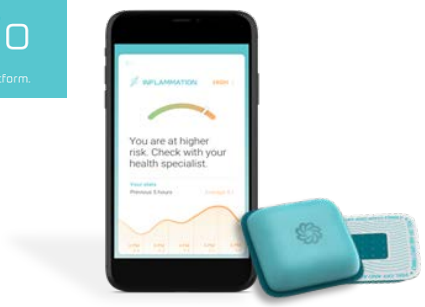
Interstitial fluid is an alternative to blood for biomarker analyses **to reduce the invasiveness of patient care** and **to obtain real-time dynamic profiles of biomarkers**.

Clinical need (Pr. Benjamin Besse, thoracic oncology, Gustave Roussy)

Early detection of high-risk treatment complications (radiotherapies or immunotherapies) with inflammation biomarkers or specific proteins (pH, lactate, CRP, cytokines, cortisol, specific proteins..)

Wearable solution combining two advanced technologies for the dynamic evaluation of key biomarkers

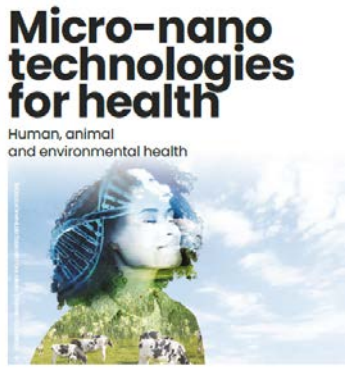
Painless polymer-based biocompatible microneedles (resorbable, high resolution, scalable, patch integration)



Xsensio (SME) Lab-on-skin™ proprietary platform (sensors for biomarker detection and real-time data collection)

Enhanced use of biomarkers :
- Lower burden for patients
- Lower workload for medical staff
- Better personalised follow-up
- Early warnings for severe complications

Expertise and resources offered



Explore our novel report on Micro- and Nano-Technologies for Health here

Assets for IHI

Expertise of collaborations with industry:

- ✓ 300 industrial partners, +75 start-ups
- ✓ Pre-industrial design and fabrication processes, MDR compliance, eco-innovation approaches
- ✓ Modular and versatile technologies (TRL 4-6)

Expertise of clinical collaborations:

- ✓ Pre-clinical and clinical facilities
- ✓ On-going clinical studies and support of clinicians to assess our technologies

Expertise of European projects:

- ✓ +100 projects
- ✓ We can lead a WP dedicated to advanced technologies

Our partners, also on the IHI platform:

- Clinicians in breast and lung cancer: Institut Gustave Roussy (FR)
- Clinicians in psychiatry, pneumology (FR): CHU Montpellier, CHU Grenoble
- Clinicians in cardiology: see the pitch from Françoise Charbit in topic 1
- INSERM Transfert (FR)
- Academic partners in cardio-cerebro-vascular-inflammatory-metabolic diseases biomarkers: Luxembourg Institute of Health (LU) (Yvan Devaux)
- Partnering SMEs:
  - Let it Care (FR) - Digital biomarkers for chronic diseases monitoring
  - Xsensio (CH) – Lab-on-skin analyses

Thank you for your attention!

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Non-invasivE multimodal monitoring tools for NeCrotizing enterocolitis in preterm infants: A piLot MulticEnteR sTudy (NEC-ALERT)

Contact person name: Prof. Francesco Fascetti-Leon

Organisation: Pediatric Surgery Unit, Department of Women and Children's Health, University of Padova, Italy

E-mail: ducimiriam@gmail.com/ francesco.fascettileon@unipd.it

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Challenges and objectives

This project aims to address Necrotizing Enterocolitis (NEC).

Necrotizing enterocolitis (NEC) is recognized as the most severe gastrointestinal neonatal emergency that primarily affects preterm infants with high morbidity and mortality despite advances in neonatal intensive care. Discovering non-invasive tools to predict NEC onset and severity is imperative to reduce mortality and to alleviate the enlarging burden for families and society due to NEC sequelae.

It is suitable for IHI because its primary objective revolves around identifying biomarkers for timely diagnosis, monitoring the progression of NEC, and assessing treatment responses.

Potential result: providing a prompt and accessible multimodal analysis tool to predict the risk and severity of NEC in preterm babies. This approach integrates antenatal findings, clinical data, inflammatory biomarkers, near-infrared spectroscopy, imaging data, and omic-analysis of plasma and faecal sample in premature infants.

Expected impact: This integrated multimodal tool can assist clinicians in identifying infants at increased risk for NEC, potentially leading to earlier diagnosis and prompt surgical intervention, improving also the prognosis and the survival rate of these patients. In addition, It will enable to develop personalized preventive strategies and therapies related to NEC onset and its course.

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Main activities

- Retrospectively analyze the existing large cohort of preterm babies < 32 weeks of gestation, within ERNICA network (European Reference Network on Rare and Inherited Congenital Anomalies) to identify classes of risk of NEC onset based on antenatal and post-natal findings.

- Longitudinal analyses of microbiome/metabolome from fecal and plasma samples of mother and infants within large scale pan-Europe cohort of preterm babies < 32 weeks of gestation to identify classes of risk.

- Collect antenatal data and prospectively monitor clinical data, blood exams and imaging data including near-infrared spectroscopy, at pre-set times points

- Develop a robust Artificial intelligence (AI) tools- multimodal deep learning approach- to assess personalized risk integrating clinical and multi-omics data

- Create a biobank of samples

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Expertise and resources offered

- PARTNERS:

- ERNICA partners, already involved in the Horizon-HLTH-2024-Stayhlth-01-two stages: Prevention of early and late non-communicable disease and promotion of a healthy life after preterm birth. '3PR' - awaiting reply

- Padova University EXPERTISE :

- Research institute with expertise in microbiome/ metabolomic analysis
- Bioinformatics experts with a background in computational genomics
- Abdominal Near-infrared spectroscopy tool

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Expertise requested

- Other referral hospitals with large cohort of preterm infants
- AI developers
- Companies with interest in converting AI-tools into a predictive App for clinicians
- Companies with interest in development of personalized faecal Array based on multi-omics analysis

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8	Georgi	KADREV	Co-founder & CEO	Kelvin Health	Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response
9	Elma	KERZ	Co-Founder and CEO of Exaia Technologies	Exaia Technologies	Trustworthy & Explainable AI for Mental Health Assessment: Harnessing NLP and ML/DL for the Detection, Timely Treatment and Remote Monitoring of Neurodegenerative and Psychiatric Disorders
10	Nicola	KIELLAND	project manager preaward	IDIAP Jordi Gol	Primary Care, a real-world environment
11	Irakli	LEZHAVA	CEO & Co-founder	Ensofy	Vocal Biomarkers for Mental Health Management
12	Shima	MAHMOUDI	Assistant professor	Silesian University of Technology	Advancing Tuberculosis Research: Unraveling Biomarkers for Enhanced Diagnostics, Prognostics, and Treatment Monitoring
13	Monika	MATUSIAK	MD	Institute of Physiology and Pathology of Hear	Molecular biomarkers of neuroplasticity after congenital deafness treatment by cochlear implantation - is serum level of MMP-9 a one?
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20	Ines	VALLEDOR	Sequencing Manager	Certest Biotec	Certest's NGS Comprehensive Adaptive Platform to Address Unmet Medical Needs

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IHI Call Days | Call 7

Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Development and implementation of virtual patient avatars derived from standardised, minimally and non-invasive biomarkers for enhanced clinical trials

Contact person name: **Dr. Kevser Fünfgeld** / PI: **Dr. Guy Fagherazzi**

Organisation: **Luxembourg Institute of Health**

E-mail: kevser.fuenfgeld@lih.lu / guy.fagherazzi@lih.lu

Link to:

- Opportunity: click here
- Profile: https://ihi-call-days.ihi.b2match.io/my

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Objectives

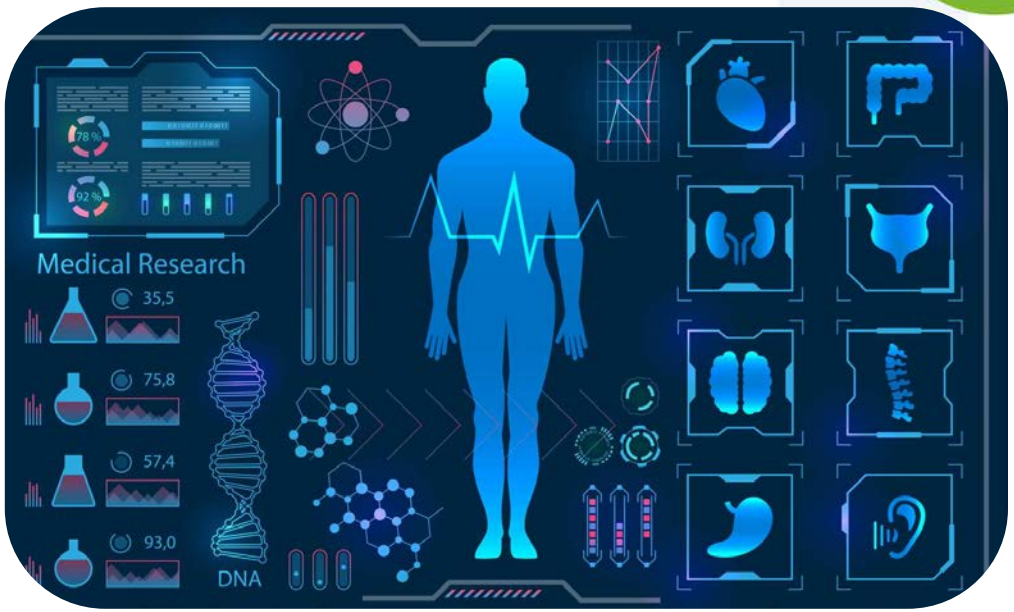
We want to develop **virtual avatars of people with diabetes** enrolled in clinical trials and implement a minimal, **standardised battery of assessments** combining clinical information, PROs with minimally invasive and non-invasive, digital biomarkers.

This will enable more **decentralized, patient-centric, cost-effective clinical trials** with at the same time, a **better, more comprehensive, high-granularity understanding** of the benefits of the new drugs, medical devices and therapies/interventions.

Within the IHI consortium, we want to

- **develop this battery of assessments,**
- **validate the included biomarkers**
- **integrate these virtual avatars into international guidelines,**
- **Implement it and demonstrate its superiority in comparison to standard study protocols in a pilot/feasibility trial.**

We aim to **co-design** this approach with **industrial partners, SMEs, patient associations, regulatory bodies** to ensure its feasibility and acceptability to accelerate the approval of new innovations.



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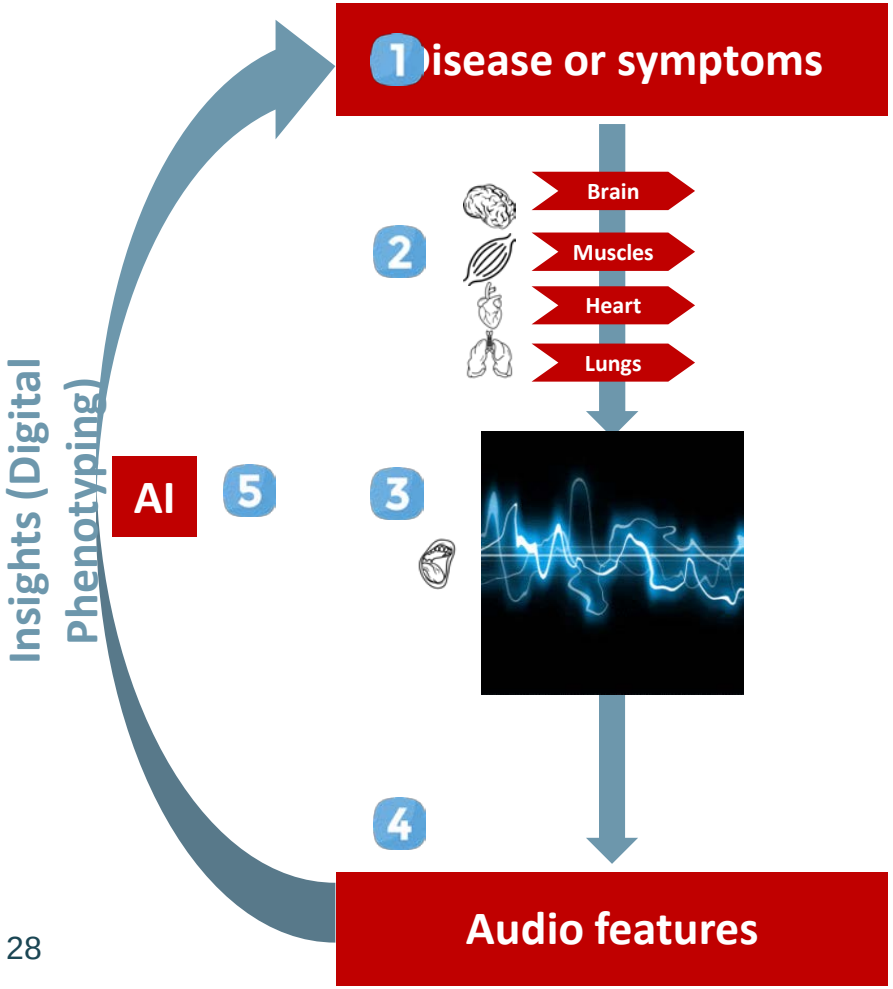
Our main expertise: digital & vocal biomarkers / “Voice is the new blood”



- Disease physiology alters acoustic, temporal and linguistic features from voice
- Using AI, these signatures from the voice can be identified and correlated to certain health outcomes (vocal biomarker)
- A vocal biomarker can be used to **monitor patients**, **diagnose a condition**, or **grade the severity or the stages of a disease** or for **drug development**.
- Vocal biomarkers are **non-invasive**, **economical, scalable**, and hold great potential for improving patient monitoring in clinical trials.

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Other expertise and resources offered

We are interested in leading a consortium to develop virtual avatars, combining classical and digital biomarkers, clinical and patient-reported outcomes to develop modern, decentralized, patient-centric clinical trials on diabetes.

- Clinical research
- Clinical epidemiology
- Diabetes research
- Digital biomarkers and novel clinical endpoints
- Project drafting and management
- Access to cohorts
- AI for health research

- **IKOP by LIH possible**

* IKOP - in-kind contributions to operational activities

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Expertise requested

We are looking for partners with whom we can start and lead a consortium on virtual avatars

- Partners with **validated or candidate minimally invasive biomarkers**
- Partners with **candidate non-invasive digital biomarkers**
- Healthcare professionals (**diabetologists**, …)
- **Methodologists** and **biostatisticians**
- **Data scientists** and AI experts
- Academic or private partners with access to patients for data analysis in **existing trials or cohorts** or capable of **new data and sample collection**
- **Pharma or medtech companies** willing to adopt a multimodal approach combining to develop more modern clinical trials to test their innovations
- Stakeholders (**regulatory agencies**, **patient associations, academic societies…**)

Interested? Contact us

Dr. Guy Fagherazzi
Principal Investigator
guy.fagherazzi@lih.lu

Dr. Kevser Fünfgeld
Project Manager
kevser.funfgeld@lih.lu

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Pitching Session

Today 25 January 2024, 10:00 – 12:30 **Brussels time**

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2	Luiz	CORREA	Managing Director	Diagnostic Data Hub	Digital Transformation of Patient Consent (DigiConsent): Enhancing Efficiency in Healthcare Through E-Consent
3	Caroline	DESVERGNE	European programme manager	CEA Leti	Point-of-care devices and robust wearables to improve the clinical use of biomarkers (cellular, molecular, physiological)
4	Francesco	FASCETTI-LEON	Professor in Pediatric surgery	Pediatric Surgery Unit, Women's and childrens' health Department, Padova University	Non-invasivE multimodal monitoring tools for NeCrotizing enterocolitis in preterm infants: A piLot MulticEnteR sTudy (NEC-ALERT)
5	Kevser	FÜNFGELD	Digital Health Program Manager	Luxembourg Institute of Health	Development and implementation of virtual patient avatars derived from standardised, minimally and non-invasive biomarkers for enhanced clinical trials
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IHI Call Days | Call 7

Biomarker Validation

Validation of multimodal biomarkers of mental health

Dr. Alexandra Georgescu
Director of Science @ thymia (SME)
Email: alexandra@thymia.ai

- Participant profile
- Marketplace 1 - biomarker validation for depression
- Marketplace 2 - AI for health & speech processing partner

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Challenges and objectives

- **Challenges in Depression:**
  - Untreated depression rates as high as 77%[1]
  - substantial costs (e.g. UK economy >£56 billion annually)
  - Problems: Highly heterogeneous profile & self-report
  - → Need: An objective and reliable biomarker to measure depression symptoms that can help clinicians assessing patients & adjusting treatments
  - **BUT**: AI Models trained on such biomarkers do not generalize well[2]

- **Objectives:**
  - **Evaluating a predictive AI model trained on multimodal biomarkers** (speech, facial movement and behaviour)[3] in a novel **clinical sample against established diagnostic standards**
  - Deliver **two high-impact peer-reviewed publications**

[1] Strawbridge R, et al. European Psychiatry.2022;65(1):e36
[2] Botelho C, et al. INTERSPEECH 2022
[3] Fara S., et al. INTERSPEECH 2023 (thymia publication)

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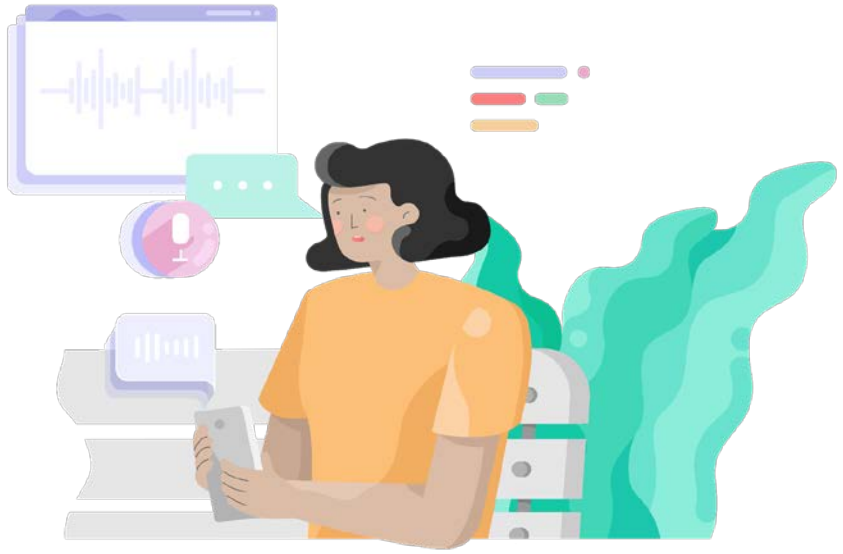
Main activities



Planning Stage

- Aim: To validate multimodal biomarkers for depression diagnosis and tracking of its symptoms

- Duration: 18 months

- Methods: diagnostic accuracy study:
  - 15 min, once a week, 7 activities for (including speech-eliciting activities) for 6 months
  - in 1130 depressed and control individuals
  - Evaluation will be done by comparing the model's output with the established diagnostic standard, the Structured Clinical Interview for DSM Disorders (SCID)

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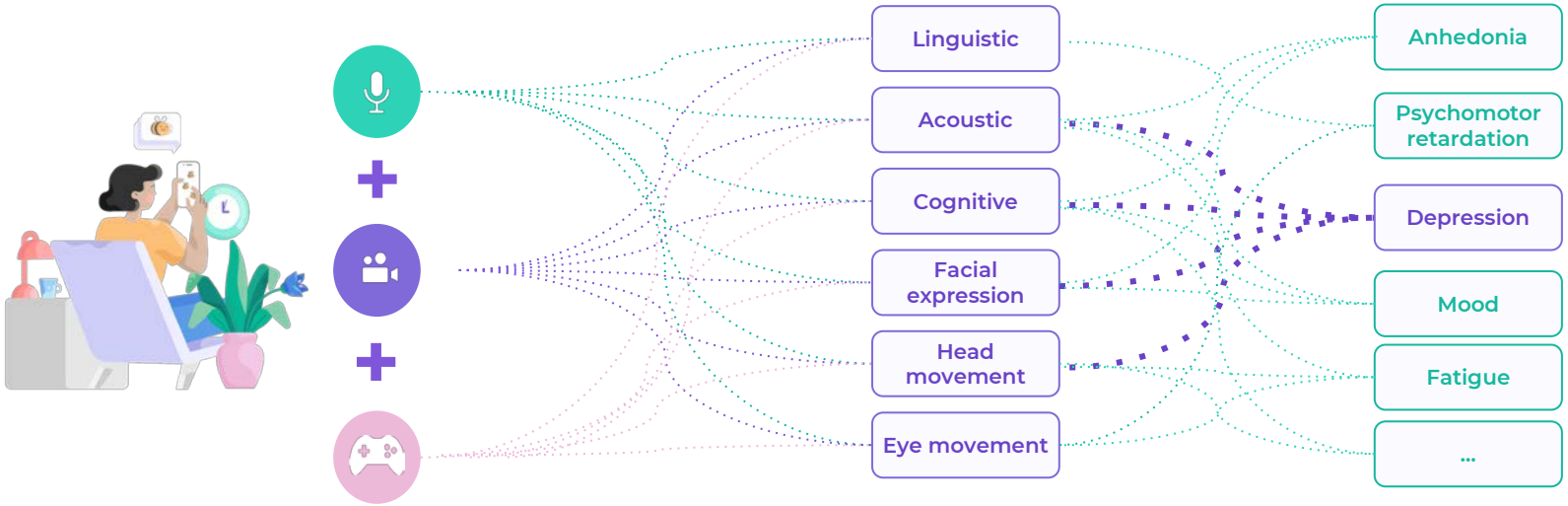
Expertise and resources offered

- AI/machine learning expertise (speech and multimodal signal data collection and analysis)
- Access to our proprietary datasets and models for collaboration with research institutes and individual academics. We ensure compliance with privacy standards by only sharing non-identifying data with collaborators, with participant consent for use in collaborative research.



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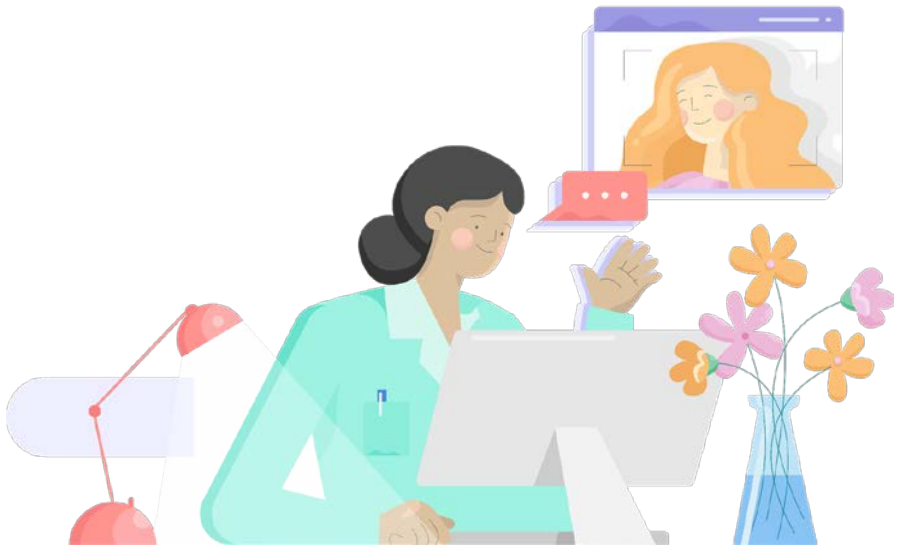
Expertise requested



We are eager to partner up with **clinical partners** and **research institutions** who share our commitment to advancing the field of mental health through innovative technology and research.

- Necessary: partners would bring access to clinical sites and/or patients (mental health, general practitioners or obstetrics/gynecology for perinatal depression);
- Desired: experience with IHI calls

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IHI Call Days | Call 7, Topic 3

Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

SEC6 signature: genomic biomarkers for recurrence prediction and treatment guidance in early-stage Colorectal Cancer patients

Organisation: **PROTEIN ALTERNATIVES SL (Madrid, Spain)**

Contact person name: Dr Juan Ignacio Imbaud (COO)

E-mail: jimbaud@proteinalternatives.com

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Challenges and objectives

Partner seeking for a consortium / coordinator

- Objective in IHI call:

  Clinical validation of colorectal cancer (CRC) genomic biomarkers for prediction of recurrence and response to chemotherapy.

- The challenge: stratification of early-stage CRC patients and treatment guidance

  > CRC is a heterogeneous disease with different outcomes according to the molecular subtypes.

  > **Differential epigenetic and genetic events** as microsatellite and chromosomal instability, CpG island methylator phenotype, P53, KRAS and BRAF mutations lead to **different pathogenesis** and **sensitivity to drugs**.

  > Current CRC classification is based **pathological features** (stage and differentiation grade) and **molecular features** (subtypes by CMS and CRIS classifiers).

  > Standard of care → stage III: surgery + adjuvant chemotherapy (recommended).

  → stage II: surgery + ¿Chemo? (only recommended for high-risk patients).

- Our solution:

  SEC6 (6-gene-based signature and algorithm). Six (6) novel genetic biomarkers and a simple predictive risk-score algorithm that facilitates patient stratification and clinical decision-making.

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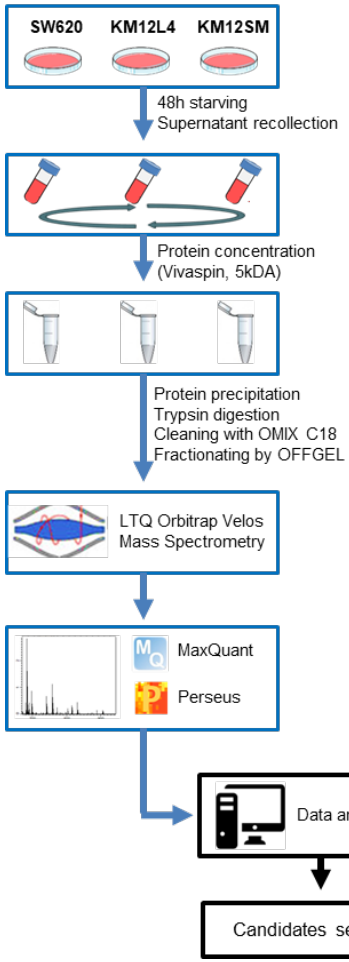
Robles et al., J Pathol Clin Res 2022 https://doi.org/10.1002/cjp2.294

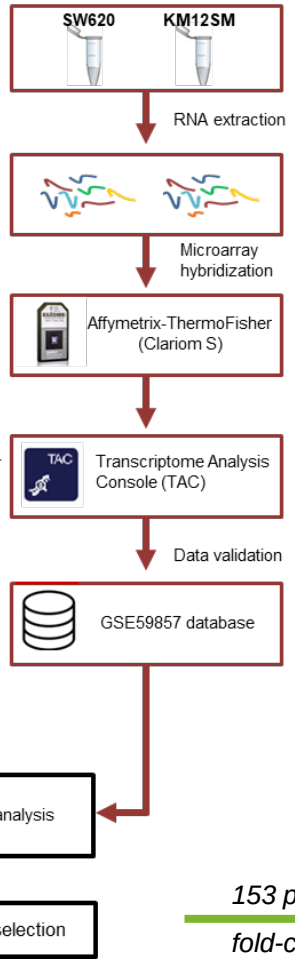
SEC6 technology development status

- **Completed work-flow**: CRC genetic biomarkers discovery, selection and validation

Proteomics

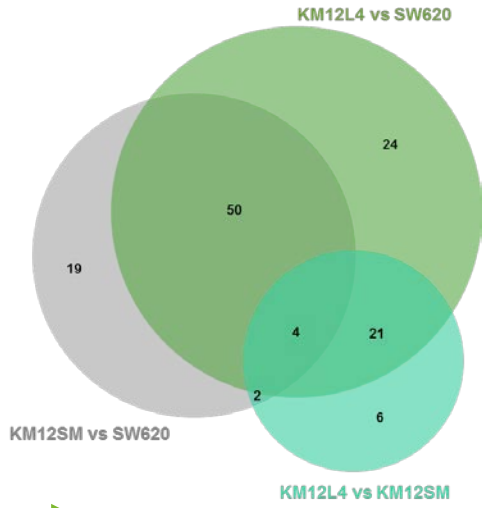


Transcriptomics



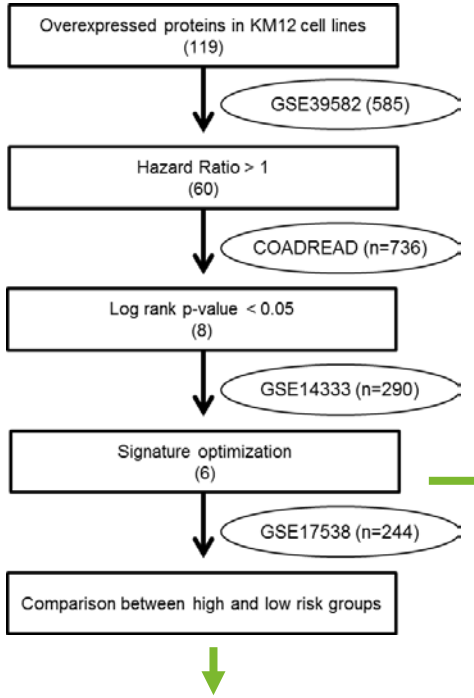
119 proteins upregulated

Differentially expressed metastasis-related proteins



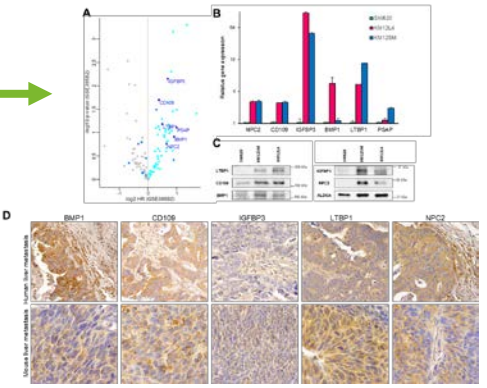
153 proteins fold-change >5

Bioinformatics (sequential selection in different datasets)



Training and validation in four different cohorts

Biomarkers validation



6-gene signature (SEC6) + *Risk score* algorithm

Stratification of stage II and stage III CRC patients

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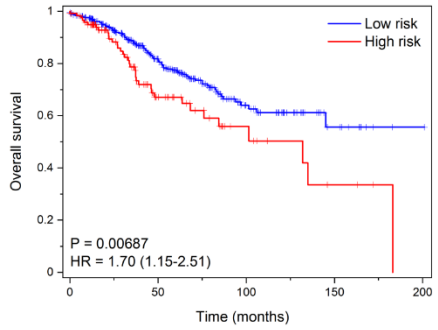
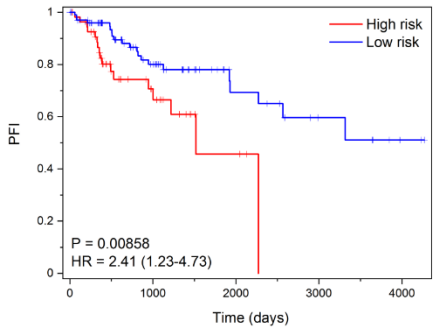
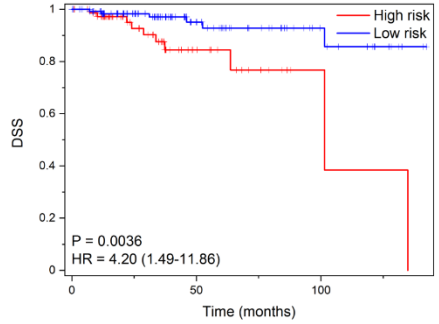
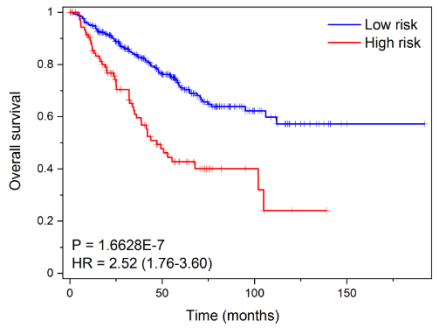
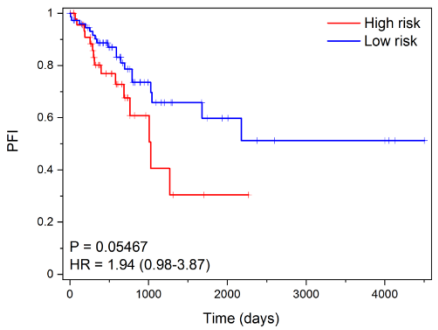
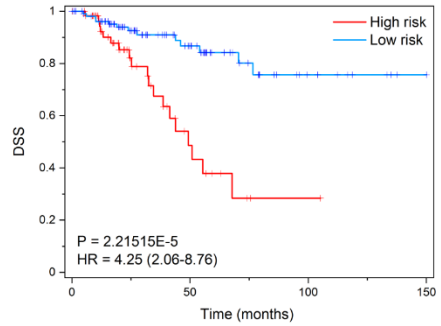
Robles et al., J Pathol Clin Res 2022 https://doi.org/10.1002/cjp2.294

SEC6 signature validaton in patients datasets

- **Recurrence prediction:** SEC6 expression is associated with poor prognosis

Colorectal cancer

	Overall survival	**Progression free interval**	**Disease specific survival**
	GSE17538, TCGA COADREAD, GSE39582	TCGA COADREAD	GSE17538, TCGA COADREAD ← *patients datasets*
Stage II			
Stage III			

Kaplan-Meier analysis of prognosis of II and III AJCC stages patients in the GSE17538, TCGA COADREAD and GSE39582 cohorts

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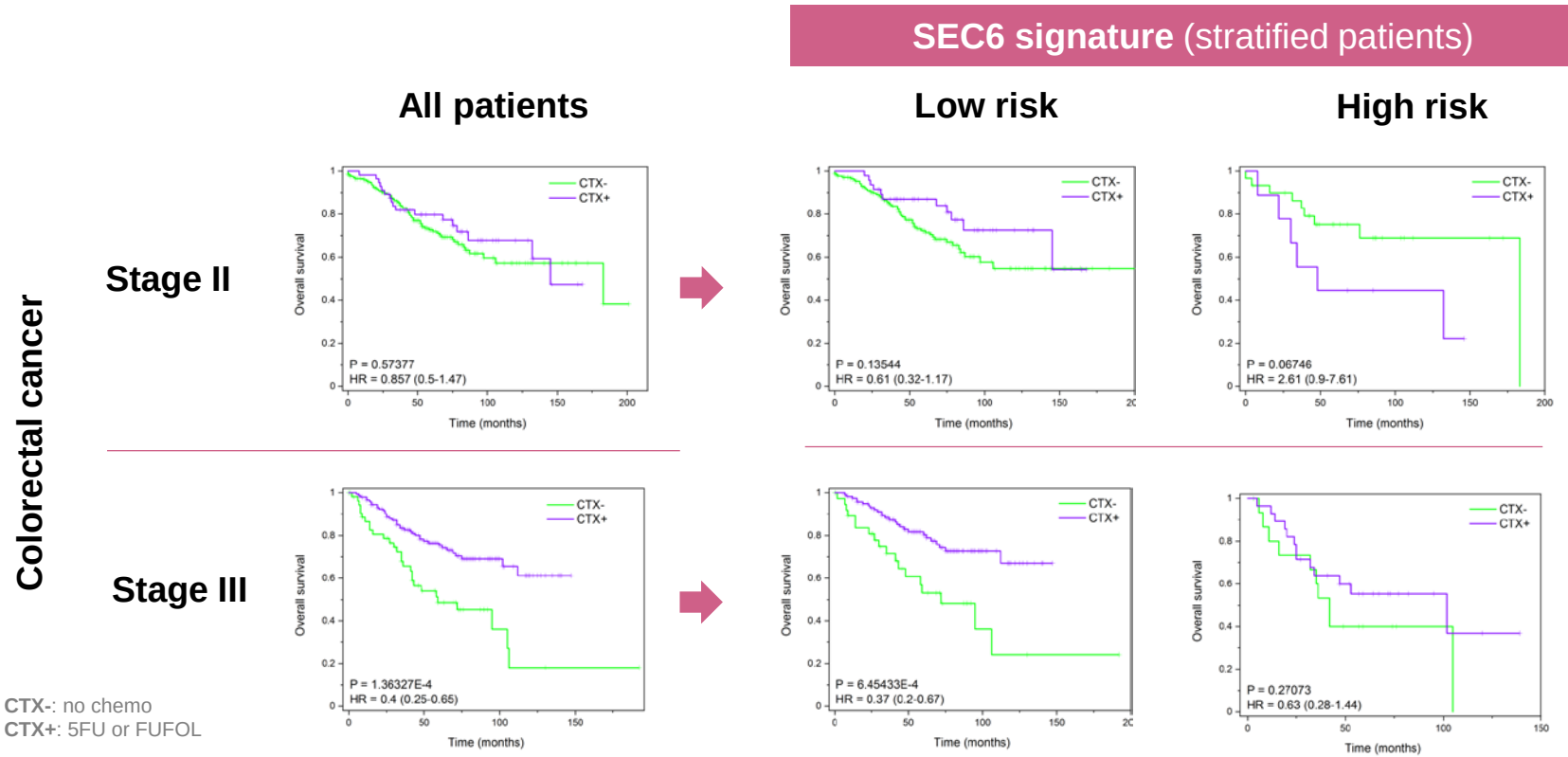
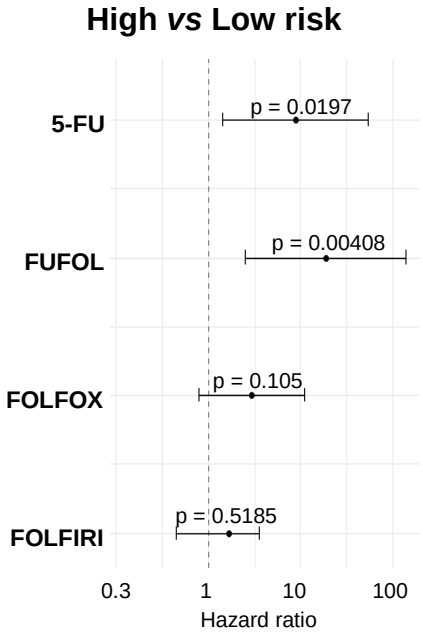
Robles et al., J Pathol Clin Res 2022 https://doi.org/10.1002/cjp2.294

SEC6 signature validaton in patients datasets

- **Treatment guidance:** SEC6 expression is associated with response to chemotherapy

SEC6 signature (stratified patients)





CTX-: no chemo
CTX+: 5FU or FUFOL

5-FU: 5-Fluorouracil
FUFOL: 5FU + Folinic Acid
FOLFOX: 5FU + Folinic Acid + Oxaliplatin
FOLFIRI: : 5FU + Folinic Acid + Irinotecan

High-risk early-stage CRC patients need more aggressive therapies to improve survival.

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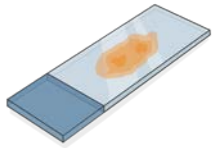
Activities proposed for IHI call

- **Present and future of SEC6**

  > **Ongoing Proof-of-concept (POC) study**: method set-up, SEC6 signature validation in a 'real environment' (create own datasets prior to clinical validation)

Cohort of CRC patients (n=300)
Hospital Clinico San Carlos



(FFPE)

Formalin-Fixed, Paraffin Embedded tumor samples

mRNA extraction

Quantification by qPCR
SEC6 + reference genes

- Risk-score algorithm optimization and threshold establishment (n=100)
- POC initial validation (n=200)

Final goal in IHI call: to conduct a multicentric and international clinical validation and regulatory process

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Expertise and resources offered

- Resources for the consortium:

  6-gene signature for the prognosis of colorectal cancer (Patent **PCT/EP2023/071178**)
- Expertise:

  Biomarkers discovery, selection and validation in cancer
- Access to our local partners network:

  Research Centers (CSIC-CIBMS) and Hospitals (Ramón y Cajal)
- Experience as a partner / coordinator in other similar projects:

  Eurostars (2020-2023); SME Instrument (2015-2018)
- In-kind contributions (Cash or in-kind contributions for Contributing Partners)

  No

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Expertise requested

Partner seeking for a consortium / coordinator

- Desired partners:
  - > Large Dx companies
  - > SMEs
  - > Hospitals
  - > Research institutes
- Desired technologies:
  - > mRNA extraction validated and robust technologies (from Formalin-Fixed, Paraffin Embedded samples)
  - > qPCR technologies and expertise (multiplexing)
  - > mRNA sequencing (alternatively).

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Thanks!!!

PROTEIN ALTERNATIVES SL (Madrid, Spain)

www.proteinalternatives.com

Contact person: Dr Juan Ignacio Imbaud (COO)

E-mail: jimbaud@proteinalternatives.com

Link to:

- Marketplace opportunity: https://ihi-call-days.ihi.b2match.io/participations/200664/opportunities
- Participant profile: https://ihi-call-days.ihi.b2match.io/participations/200664

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Topic 3: Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Kelvin Health Expertise Offer

Contact person name: **Georgi Kadrev**

Organisation: **Kelvin Health** (Bulgaria)

E-mail: georgi.kadrev@kelvin.health

Link to:

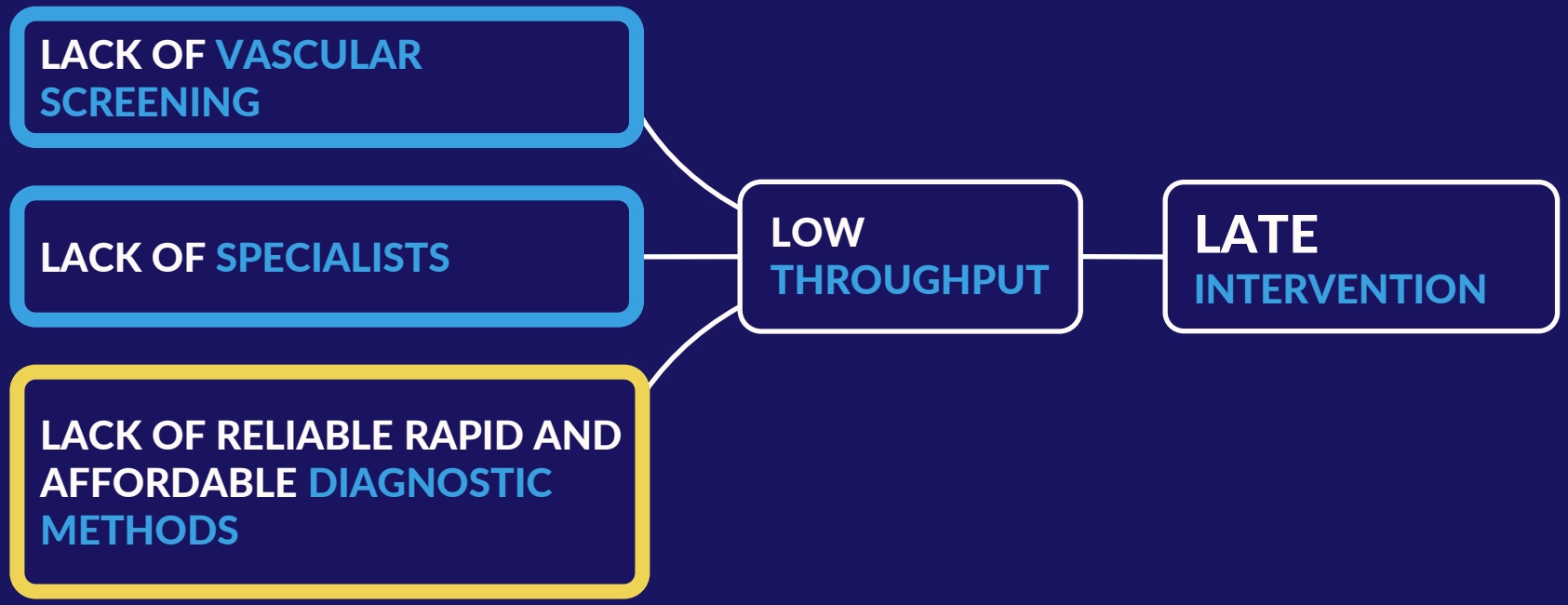
- Marketplace opportunity
- Participant profile

Expertise offered

- **Kelvin Health** is an intelligent solution for detection and monitoring of abnormalities and inflammation processes in different stages and conditions, using AI analysis applied to mobile-based digital thermal imaging.

- Our mission is to make preventable deaths and suffering from conditions like critical limb ischemia, carotid hypoperfusion, and breast cancer a thing of the past.

Hard access & inefficient diagnostics of PAD



ABI & DOPPLER ULTRASOUND

15+ MIN / SPECIALIST DEPENDANT
IMPRECISE FOR PATIENTS WITH DIABETES

X-RAY ANGIOGRAPHY

3 HOURS / $4,000+
INVASIVE / RADIATION

"It's crucial to **catch the disease early. Frequent follow-up** is also very important, but **barely achievable** with the existing examination methods."

*— **Prof. Ivo Petrov***
Chief Medical Officer, Kelvin Health

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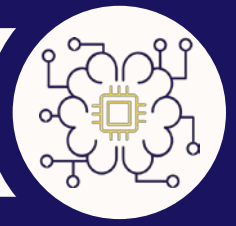
Diagnostics as simple as taking a **thermal image**

kelvin® health

1. **Mobile Thermocamera**

2. **Thermal Segmentation**

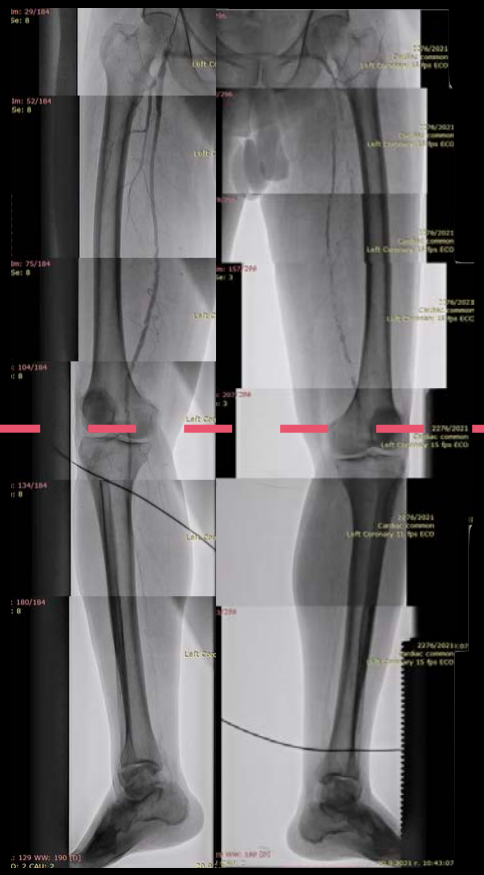
3. **Automated AI Analysis**

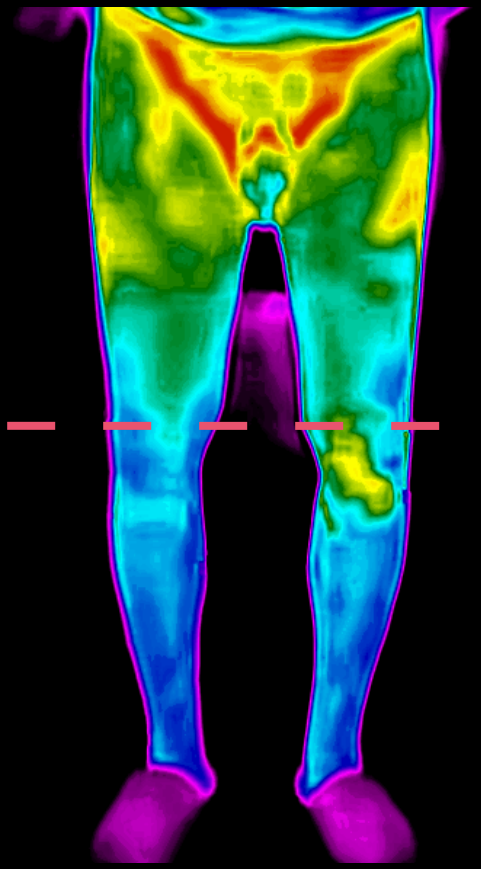


4. **Notifying the Specialist**

Kelvin Health's **precise rapid non-invasive Critical Limb Ischemia detection**

BLOOD FLOW BLOCKED AT THE KNEE LINE





"Kelvin Health reflects very well the CLI condition of the patient and its localities, confirmed with angiography."

*— **Prof. Ivo Petrov***
Head of Cardiology & Angiology, Acibadem "City Clinic" Cardio

X-RAY ANGIOGRAPHY

3 HOURS / $4,000+
INVASIVE / RADIATION

kelvin health

3 MINUTES / $50
NON-INVASIVE / NO RADIATION

1 100+ patients and 100% PAD sensitivity already

HIPAA & GDPR compliant software system

- iOS Application
- Data collection & annotation platform
- **86%** precise AI for Angiosome Segmentation
- **95%** accurate AI for Quality Control of the input data

Clinical data of PAD & CLI patients

- **1 100 +** Patients
- **8 000 +** Thermal Images
- **100%*** Sensitivity
- **96%*** Specificity

R&D partners and prospects

- **20 HCPs**
  Switzerland, Italy, Spain, Poland, UK, US, India, Slovenia, Greece, Bulgaria

ACIBADEM CITYCLINIC · ATHENS MEDICAL GROUP · UKC MARIBOR

- **Pharma patient enrollment**

novo nordisk · Roche

WINNER OF

- NOVARTIS — Oncology Global Innovation Challenge ’21; CVD Global Innovation Challenge ‘21
- Roche — Screening & Early Diagnostics Challenge ‘22
- MED-TECH WORLD — Health Tech Innovation of the Year ’22; Best Med-Tech Company to Work for in Year ’23
- EXTREME TECH CHALLENGE — Finalist XTC at CES ’23

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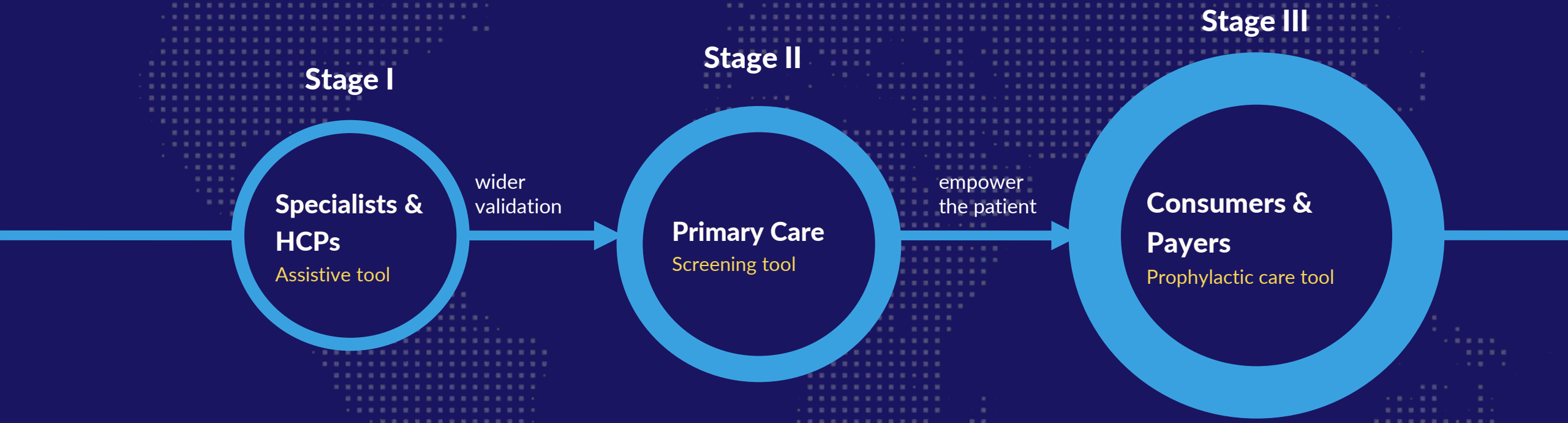
* based on a ML model trained on a dataset of 313 medically and technically annotated angiosomes of 42 patients

Gradual three-stage **healthcare system penetration**



Kelvin Health is a Member of the American Heart Association's Innovators' Network

American Heart Association.
Center for Health Technology & Innovation

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Potential contribution to your consortium

- **Kelvin Health** can contribute on the following Call's impacts:

➢ *New clinically-validated biomarker-driven approaches are available that lead, as relevant, to more precise and effective diagnosis, leaner diagnosis-to-treatment pathways, better treatment path selection, or improved follow-up and treatment response assessment and monitoring.*

➢ *A significant reduction in the diagnostic or therapeutic burden for patients (and caregivers) for example by favouring non- or minimally-invasive approaches.*

➢ *Validated tools and approaches supporting evidence-based health and care decisions addressing both the needs of patients and of healthcare systems*

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Topic 3: Clinical Validation of Biomarkers for Diagnosis, Monitoring Disease Progression and Treatment Response

Trustworthy & Explainable AI for Mental Health Assessment: Harnessing NLP and ML/DL for the Detection, Timely Treatment and Remote Monitoring of Neurodegenerative and Psychiatric Disorders

Contact person name: **PD Dr Elma Kerz**

Organisation: **Exaia Technologies**

E-mail: **e.kerz@exaia-tech.com**

Link to:

- Marketplace opportunity: https://ihi-call-days.ihi.b2match.io/participations/325573/opportunities
- Participant profile: https://www.linkedin.com/in/elma-kerz-14a658b5/?originalSubdomain=de

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Why Mental Health?

The Rising Prevalence of Dementia & Mental Health Disorders and their Far-Reaching Economic & Societal Consequences [1] [2] [3] [4]

55 *Million*

Individuals face Alzheimer's disease and related dementias worldwide in 2023, expected prevalence 150 million by 2050.

970 *Million*

Individuals affected globally in 2019 by psychiatric disorders, with a 25% surge in anxiety and depression in 2020.

$2.8 *Trillion*

Global economic cost in 2019 for ADRDs. Projected economic burden in 2050 is 16.9 trillion.

$1 *Trillion*

Annual cost of depression and anxiety for the global economy.

Sources:
1 OECD and EU 2018
2 The Lancet Global Health 2020
3 Nandi, A., Counts, N., Chen, S., Seligman, B., Tortorice, D., Vigo, D., & Bloom, D. E. (2022). Global and regional projections of the economic burden of Alzheimer's disease and related dementias from 2019 to 2050: A value of statistical life approach. EClinicalMedicine, 51.
4 Eehm J, Shield KD. Global burden of disease and the impact of mental and addictive disorders. Curr Psychiatry Rep. (2019) 21:1–7. doi: 10.1007/s11920-019-0997-0

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Why Mental Health?

Several Pressing Challenges in Today's Approaches to the Assessment and Screening of Neurodegenerative and Psychiatric Disorders

- Lack of Early Detection
- Intrusiveness and High Costs
- Limited Scalability

- Subjectivity and Memory Reliance
- Social Stigma and Accessibility
- Episodic Nature and Comorbidity Challenges
- Limited Scalability

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Objectives

Development of Science-Driven AI-Approaches for Precise, Scalable, Cost-Effective, Non-Intrusive Assessment of Neurodegenerative and Psychiatric Disorders

Advance Scientifically-Driven AI Methodologies: Pioneer AI approaches deeply rooted in scientific rigor, dedicated to facilitating trustworthy assessments.

Ensure Precision, Scalability, and Transparency: Develop AI solutions characterized by precision and scalability, emphasizing transparency to enhance understanding of assessment processes for diverse neurodegenerative and psychiatric conditions.

Design Cost-Efficient AI Solutions: Formulate approaches that uphold cost-effectiveness, promoting accessibility and affordability.

Promote Non-Intrusive and Explainable AI: Advocate for the creation of AI methodologies that are non-intrusive and incorporate human-centric and explainable AI principles.

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Main activities

- **Clinical Validation:**
  - Facilitate the translation of digital biomarkers into clinical settings.
  - Collaborate with healthcare professionals for stringent clinical validation.
  - Ensure the accuracy and effectiveness of digital biomarkers in real-world scenarios.
- **System Development:**
  - Contribute to the development of clinical decision support systems.
  - Integrate digital biomarkers into systems for early detection and monitoring.
  - Ensure interoperability with existing healthcare infrastructure.
- **Ecosystem Engagement:**
  - Collaborate with stakeholders in the mental healthcare ecosystem.
  - Engage with healthcare providers, researchers, and relevant organizations.
  - Seek feedback and input to enhance the practical applicability of the developed solutions.
- **Ethical Considerations:**
  - Implement and adhere to ethical guidelines in AI application, especially in mental health.
  - Ensure responsible and trustworthy use of AI technology.
  - Address privacy concerns and incorporate privacy-preserving measures.

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Main activities

- **Communication and Dissemination:**
  - Regularly communicate progress and findings within the consortium.
  - Participate in consortium meetings, workshops, and knowledge-sharing sessions.
  - Disseminate research outcomes through publications and presentations.
- **Continuous Improvement:**
  - Iterate on models and algorithms based on feedback and new insights.
  - Stay updated on advancements in NLP, ML/DL, and mental health research.
  - Incorporate improvements and refinements to enhance the efficacy of the developed solutions.
- **Impact Assessment:**
  - Assess the real-world impact of the developed clinical decision support systems.
  - Evaluate the effectiveness of early detection and continuous monitoring in improving patient outcomes.
  - Collect and analyze feedback from healthcare practitioners and end-users.

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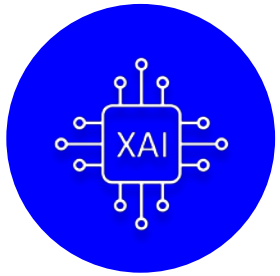
Exaia’s Unique AI Approach



Advanced Model Architectures

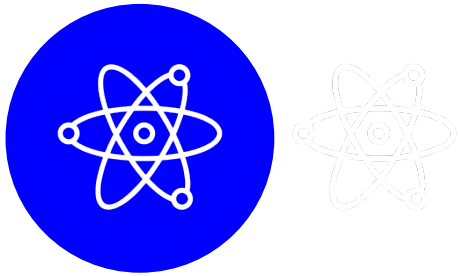
Our state-of-the-art ML/DL architectures integrate NLP-derived biomarkers, BiLSTM models, hybrid & ensemble models with large language models and multitask fusion models

Trained on Diverse Datasets

Our models undergo training across diverse datasets, ranging from extensive big data collections to specialized clinical sets. This diversity significantly enhances our AI systems to accurately understand various contexts while maintaining robustness and generalizability.

Comprehensive Insights

We provide more than mere risk level estimations for specific mental health conditions and provide a ranking of feature importance. This ranking pertains to NLP-derived language and speech biomarkers.



Academically Validated

Our ML/DL models have undergone rigorous validation in peer-reviewed research papers, demonstrating exceptional performance across various benchmark datasets in the field of mental health assessment.

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Expertise requested

List profiles for desired partners, by category (SME, large companies, research institutes, other)

Large Companies:
Siemens Healthineers, Philips, Roche, Bayer

SME & Research Institutes:
We are open to collaborating with SMEs and Research Institutions that are actively engaged in harnessing biomarkers for the assessment of neurodegenerative and psychiatric disorders. Our goal is to accelerate the transition to precision medicine and advance healthcare 4.0 in the field of mental health.

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IHI Call Days | Call 7

Topic 3: Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Primary Care, a real-world environment

Contact person name: Nicola Kielland

Organisation: IDIAP Jordi Gol

E-mail: nkielland@idiapjgol.org

Link to:

- Healthcare system: Primary Care resilience and chronic disease
- Participant profile IDIAP Jordi Gol

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A REAL-WORLD EVIDENCE

Salut/ Institut Català de la Salut

IDIAP JORDI GOL

51.922 professionals
↑9,5% augment repecte de l'any passat

8 hospitals

332 centres d'atenció primària
617 consultoris locals

289 equips d'atenció primària

82,2% de la població de Catalunya està assignada l'atenció primària de l'ICS

CAP **50.894.317** visites d'atenció primària

36 RESEARCH TEAMS

Data from ICS reports

This real environment is **PRIMARY CARE** where **ALL citizens** have access as the **FIRST STEP TO THE HEALTH SYSTEM** and where a large part of the diseases with the greatest impact (chronic diseases for example) are managed

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Main activities

- Prevention
- Risk
- IA decision making
- Ictus
- Kidney disease

Cardiovascular

Mental Health

- Prevention
- Burnout
- Depression
- other

Studies with drugs

- Drugs use
- Pharmacovigilance
- Adherence
- During pregnancy: HTA, preeclampsia
- Vaccines
- Infectious: use of antibiotics

Prevention and management of chronic health problems

... also

- childhood obesity
- fibromyalgia
- Odontology
- Vertigo

Social

- Gender perspective
- RRI
- Sexual&reproductive Health
- Social Impact
- Equity of access to health
- LGTBI

Cancer

- Cancer RWE
- Prevention

SIDIAP

The Information System for Research in Primary Care (SIDIAP)

8 millons persons since 2006

5.8 millon currently (2021)

WEBSITE: https://www.sidiap.org/index.php/es/

Real World Evidence

- Cáncer
- Metabolic síndrome
- Health/environment relationship
- environmental pollutants
- Drugs
- Immigrant population risk map
- Diabetes
- Cardiovascular
- health recommendations

Digital Health

- Artificial Intelligence
- Telemedicine
- TIC, Apps
- Immigration and Vaccines
- Pandemic prediction

Previous experience

- IHI/IMI:

(As partners)

- CHAFEA/EU4Health

(as coordinators)

- CERV-EQUAL (as coordinators)

- Horizon EU/H2020 (as partners):

- EMA: (as data partners)

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Ensofy

Vocal Biomarkers for Mental Health Management

Irakli Lezhava
CEO & Co-founder

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01 Challenge

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Ensofy 73

Patients with mental health issues often don’t talk about it

…making diagnosis and treatment of mental health disorders challenging

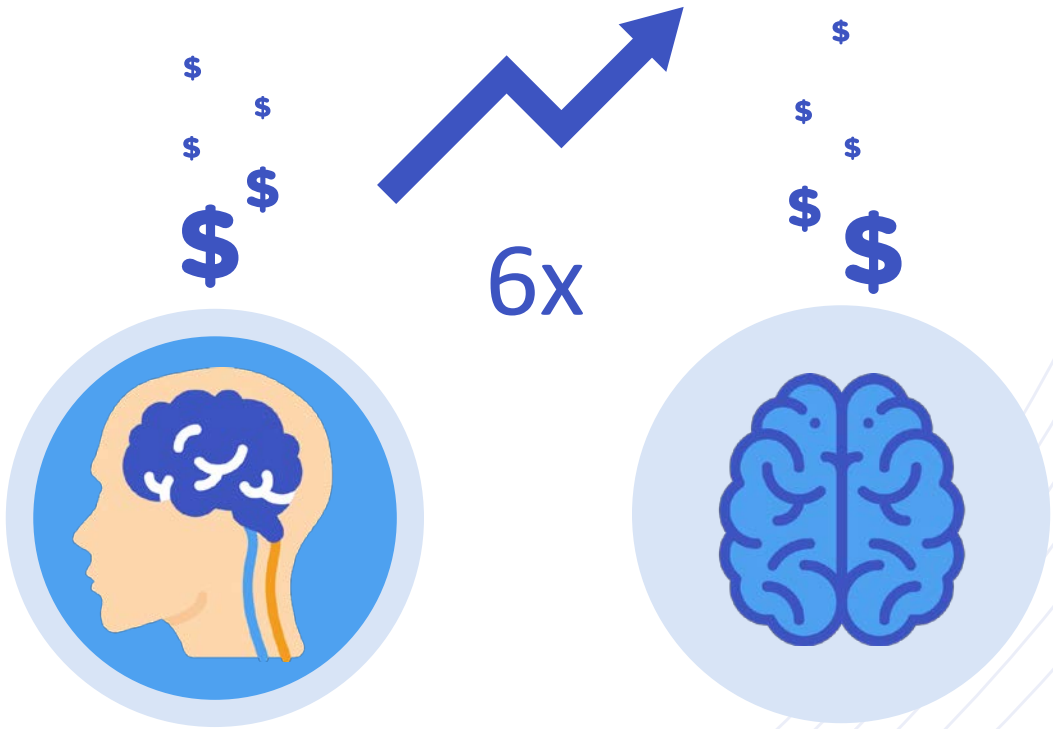
Mental Health Disorders are Under-diagnosed & Under-treated

Chronic patients have comorbid mental health conditions

Up to 80%

Only 1/3

Caregivers actively monitor patients' mental health



Leading to Excessive Treatment Costs & Poor Patient Health Outcomes

02

Solution

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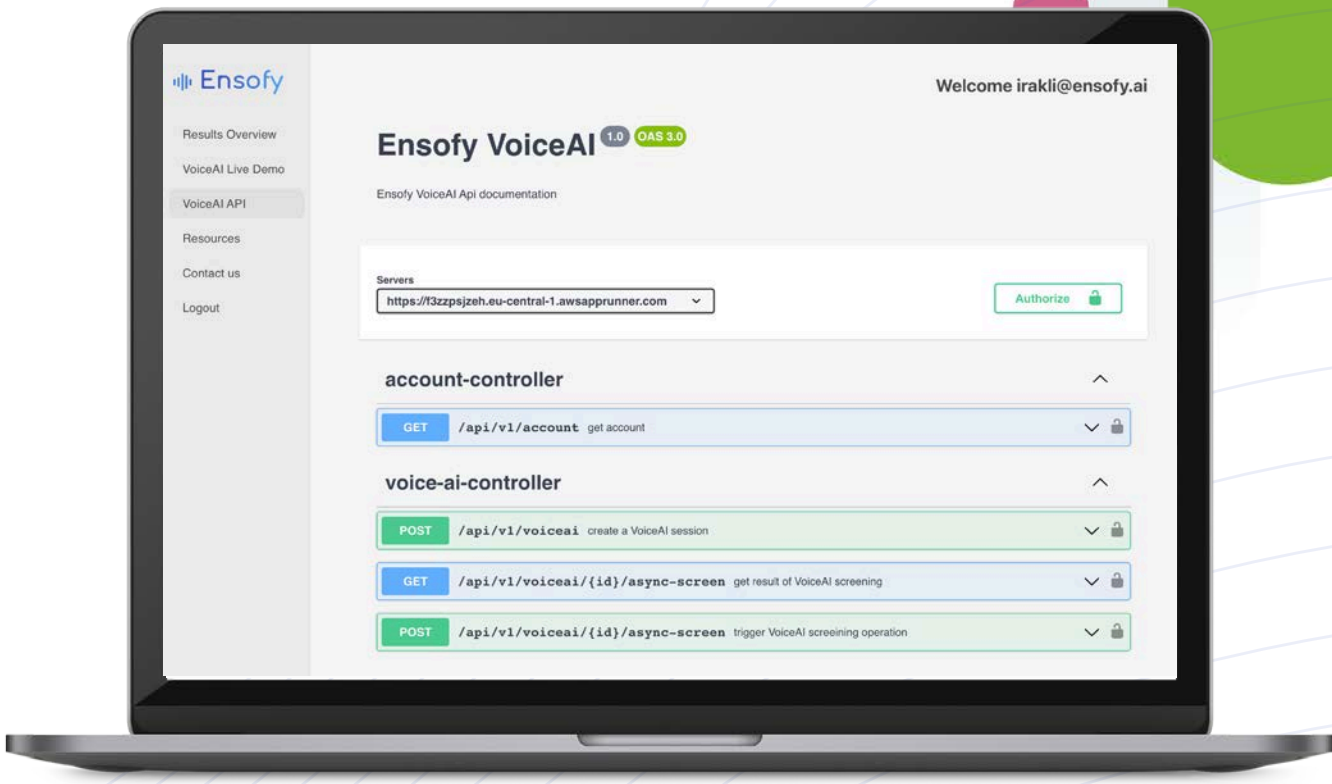
Ensofy 77

Manage Patient Mental Health using Vocal Biomarkers

- Enable early detection of mental health conditions & timely interventions.
- Empower caregivers to improve patient care and health outcomes.

Personalized for the Individual Careflows

- Customized AI solution for the target patient population and use-case.
- Identification and validation of vocal biomarkers, using raw audio records and patient data.



VoiceAI Platform >

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Ensofy

Clinical Validation of Vocal Biomarkers

- Seeking partnerships for the development and clinical validation of VoiceAI platform.
- Ideally, consortia should have access to relevant patient population.

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Ensofy

Founders

Irakli Lezhava

CEO & Co-founder

8+ years in Diagnostics, MedTech & Digital Health

Iveri Prangishvili

CTO & Co-founder

8+ years in AI, Software Engineering & Cloud

Looking for private-public partners for the clinical validation of vocal biomarkers platform in mental health

Email: irakli@ensofy.ai

Phone: +49 152 0592 4211

HOSMARTAI
AI for the smart hospital of the future

XLerateHealth

NVIDIA INCEPTION PROGRAM

aws activate

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 101016834.

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Ensofy

Pitching Session

Today 25 January 2024, 10:00 – 12:30 **Brussels time**

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Emma	BRODRICK	Technical Director	Existing	Rapid Biomarker Analysis at POC
2	Luiz	CORREA	Managing Director	Diagnostic Data Hub	Digital Transformation of Patient Consent (DigiConsent): Enhancing Efficiency in Healthcare Through E-Consent
3	Caroline	DESVERGNE	European programme manager	CEA Leti	Point-of-care devices and robust wearables to improve the clinical use of biomarkers (cellular, molecular, physiological)
4	Francesco	FASCETTI-LEON	Professor in Pediatric surgery	Pediatric Surgery Unit, Women's and childrens' health Department, Padova University	Non-invasivE multimodal monitoring tools for NeCrotizing enterocolitis in preterm infants: A piLot MulticEnteR sTudy (NEC-ALERT)
5	Kevser	FÜNFGELD	Digital Health Program Manager	Luxembourg Institute of Health	Development and implementation of virtual patient avatars derived from standardised, minimally and non-invasive biomarkers for enhanced clinical trials
6	Alexandra	GEORGESCU	Director of Science	thymia	Validation of multimodal biomarkers of mental health
7	Juan Ignacio	IMBAUD	COO	PROTEIN ALTERNATIVES SL	SEC6 signature: genomic biomarkers for recurrence prediction and treatment guidance in early-stage Colorectal Cancer patients
8	Georgi	KADREV	Co-founder & CEO	Kelvin Health	Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response
9	Elma	KERZ	Co-Founder and CEO of Exaia Technologies	Exaia Technologies	Trustworthy & Explainable AI for Mental Health Assessment: Harnessing NLP and ML/DL for the Detection, Timely Treatment and Remote Monitoring of Neurodegenerative and Psychiatric Disorders
10	Nicola	KIELLAND	project manager preaward	IDIAP Jordi Gol	Primary Care, a real-world environment
11	Irakli	LEZHAVA	CEO & Co-founder	Ensofy	Vocal Biomarkers for Mental Health Management
12	Shima	MAHMOUDI	Assistant professor	Silesian University of Technology	Advancing Tuberculosis Research: Unraveling Biomarkers for Enhanced Diagnostics, Prognostics, and Treatment Monitoring
13	Monika	MATUSIAK	MD	Institute of Physiology and Pathology of Hear	Molecular biomarkers of neuroplasticity after congenital deafness treatment by cochlear implantation - is serum level of MMP-9 a one?
14	Margaret	MC GEE	Associate Professor	University College Dublin	Clinical translation of Extracellular Vesicles as liquid biopsy for disease detection and monitoring
15	Avidan	NEUMANN	Professor, Head, Environmental Bioinformatics Group	Institute of Environmental Medicine @ Helmholtz Munich	Biomarker for early prediction of COVID-19 disease progression
16	Johannes	ÖSTERBERG	Supply Chain Manager	Sooma Medical	Biomarkers for novel depression treatment
17	Anouk	POST	Postdoc	VU University	Advanced endoscopic imaging to visualize fluorescently-labelled molecules in vivo
18	Lauri	RANNASTE	Research scientist	VTT Technical Research Centre of Finland Ltd	Development and production of diagnostic devices for point-of-care testing
19	Christoph	SACHSENMAIER	Business Development Consultant	Epimune Diagnostics	Clinical Validation of Epigenetic Immune Cell Quantification for Early Diagnosis and Management of Patients with Disorders of the Immune System
20	Ines	VALLEDOR	Sequencing Manager	Certest Biotec	Certest's NGS Comprehensive Adaptive Platform to Address Unmet Medical Needs

innovative health initiative

IHI Call Days | Call 7

Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Advancing Tuberculosis Research: Unraveling Biomarkers for Enhanced Diagnostics, Prognostics, and Treatment Monitoring

Contact person name: Shima Mahmoudi

Organisation: Silesian University of Technology, Gliwice, Poland

E-mail: shima.mahmoudi@polsl.pl

Link to:

- Marketplace opportunity https://ihi-call-days.ihi.b2match.io/participations/325905/opportunities
- Participant profile https://ihi-call-days.ihi.b2match.io/my

innovative health initiative

Challenges and objectives

- The project aims to address the lack of precise and sensitive tests for TB diagnosis, particularly for identifying different phases of TB infection and predicting disease progression. The current diagnostic methods have limitations in discriminating between phases of TB infection, leading to challenges in implementing effective public health policies and understanding immune responses during infection.

    - The project aligns with the goals of the "End TB Strategy" by focusing on TB diagnosis and prevention. The development of a specific diagnostic tool aligns with the objectives of the Innovative Health Initiative (IHI) by proposing innovative solutions for infectious disease diagnostics.

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Main objectives

1. **Develop a Novel IGRA Test:** Design and validate a new Interferon-Gamma Release Assay (IGRA) test using novel groups of antigens to accurately diagnose different phases of Tuberculosis (TB) infection.

2. **Identify Biomarkers for Disease Progression:** Investigate microorganisms and immune responses to identify biomarkers that can predict the progression from latent TB infection (LTBI) to active TB disease.

3. **Translate Knowledge to Clinical Application:** Transfer expertise in immune-based and molecular approaches to develop a clinically useful application of biomarkers using an enzyme-linked immunosorbent assay (ELISA) platform.

4. **Establish a TB Prevention Toolkit:** Lay the groundwork for the development of a specific diagnostic tool (TB prevention toolkit) capable of predicting which individuals with TB infection will progress to active disease.

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Main activities

- Perform laboratory experiments to validate the effectiveness and specificity of the novel test.
- Investigate the host immune responses to identify potential biomarkers that can accurately predict the progression from latent TB infection to active TB disease.
- Seek collaboration with reputable research institutions, clinical partners, and experts in the field of TB immunology.
- Collaborate with clinical partners who have access to well-characterized patient cohorts, including those with LTBI and active TB. Access to diverse clinical samples is crucial for a comprehensive validation study.

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Expertise and resources offered

- Integration of Technologies
  - Integration of Molecular Biology and Immunology
- Translational Research
  - Knowledge Translation: Ability to bridge the gap between laboratory discoveries and practical applications, translating research findings into clinically relevant diagnostic tools.
- Immunoassay Knowledge

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Expertise requested

- List profiles for desired partners, by category (SME, large companies, research institutes, other)
- Collaborating with a mix of partners will contribute to the credibility and applicability of the clinical validation outcomes.
- Tuberculosis Research Institutes
- Academic Medical Centers with Infectious Disease Departments
- Public Health Institutions
- TB Treatment Centers
- TB Reference Laboratories

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WORLD HEARING CENTER
OF THE INSTITUTE OF PHYSIOLOGY AND PATHOLOGY OF HEARING
Kajetany/Warsaw, Poland

Monika Matusiak, Dominika Oziębło, Monika Ołdak, Emilia Rejmak, Leszek Kaczmarek, Henryk Skarżyński

Molecular biomarkers of neuroplasticity after congenital deafness treatment by cochlear implantation - is serum level of MMP-9 a one?

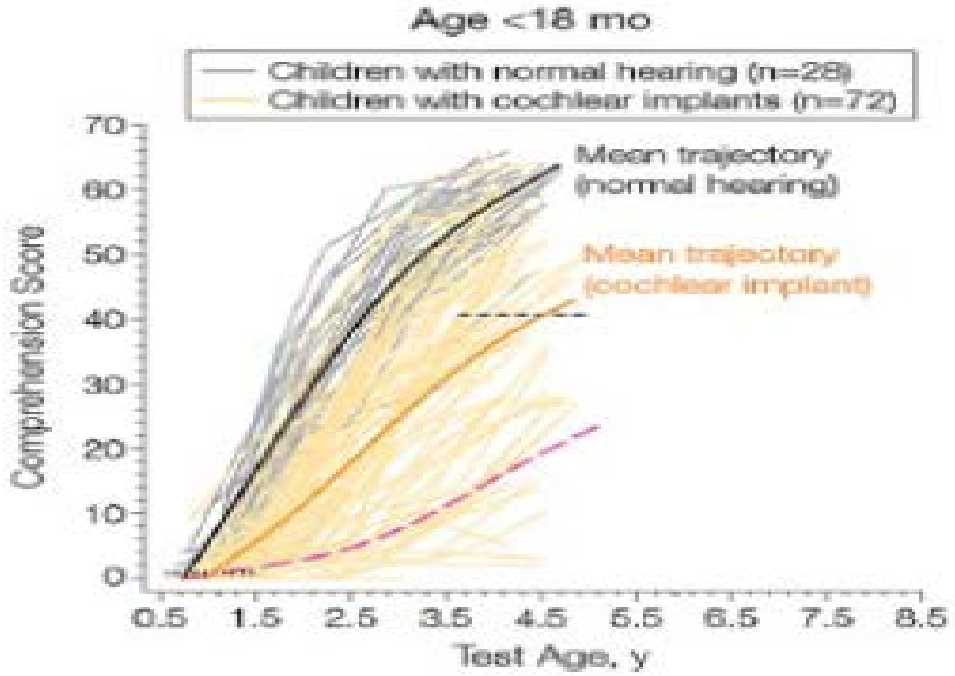
1. Institute of Physiology and Patholoy of Hearing, Warsaw
2. Nencki Institute of Experimental Biology, Warsaw

ESPCI, Rotterdam, 2023

- hughe variety of outcomes

- critical factors for CI outcome:

  - age at implantation
  - comorbidities
  - etiology
  - other



Niparko et al., Spoken language development in children following cochlear implantation, JAMA, 2010

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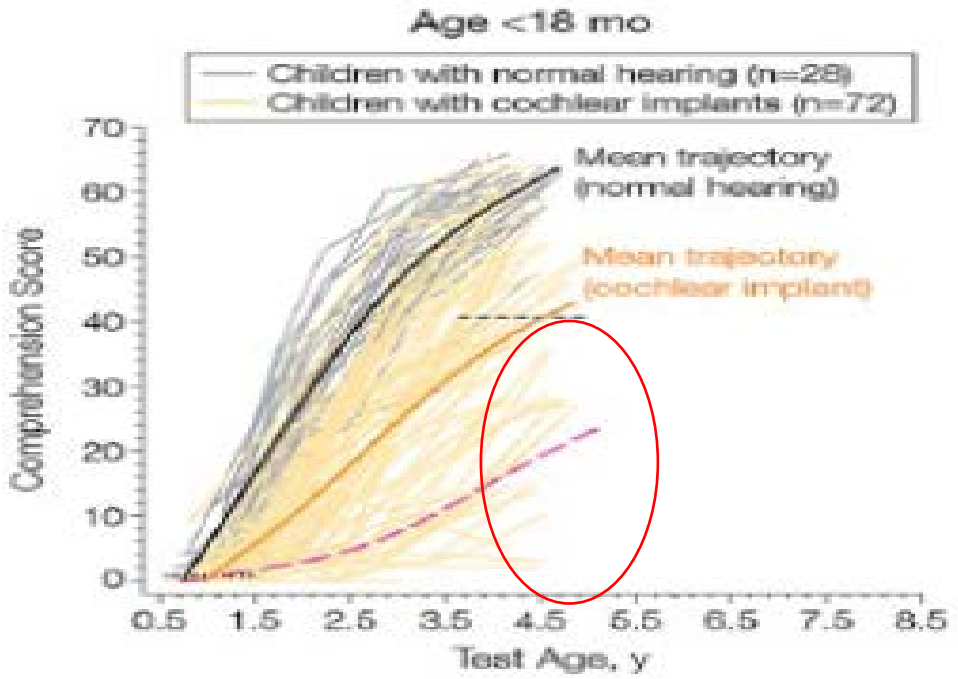

Niparko et al., Spoken language development in children following cochlear implantation, JAMA, 2010

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We need a biomarker

Personalisation of deafness treatment ?

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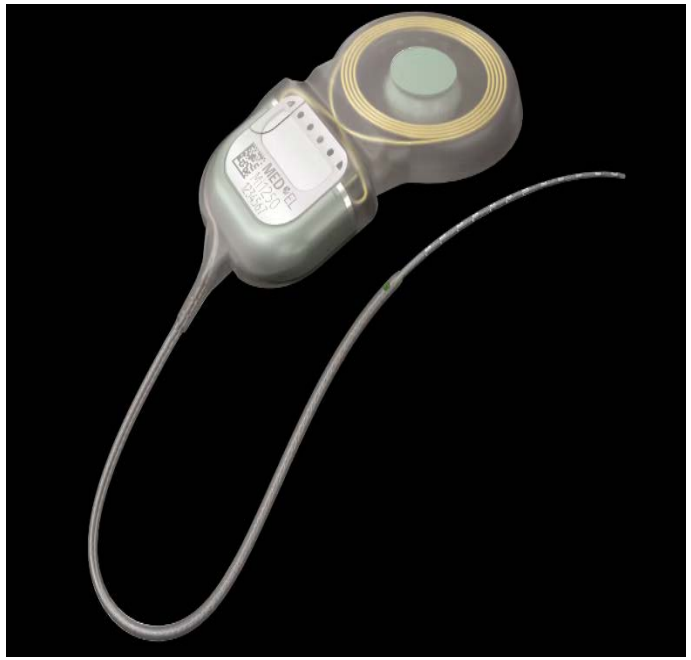
HARDWARE
SOFTWARE



INTERPLAY

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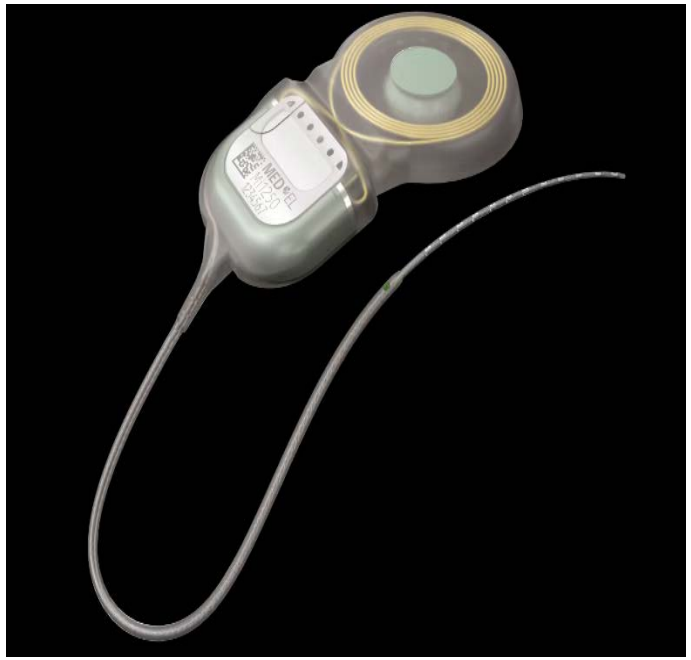
HARDWARE
SOFTWARE



INTERPLAY

WETWARE

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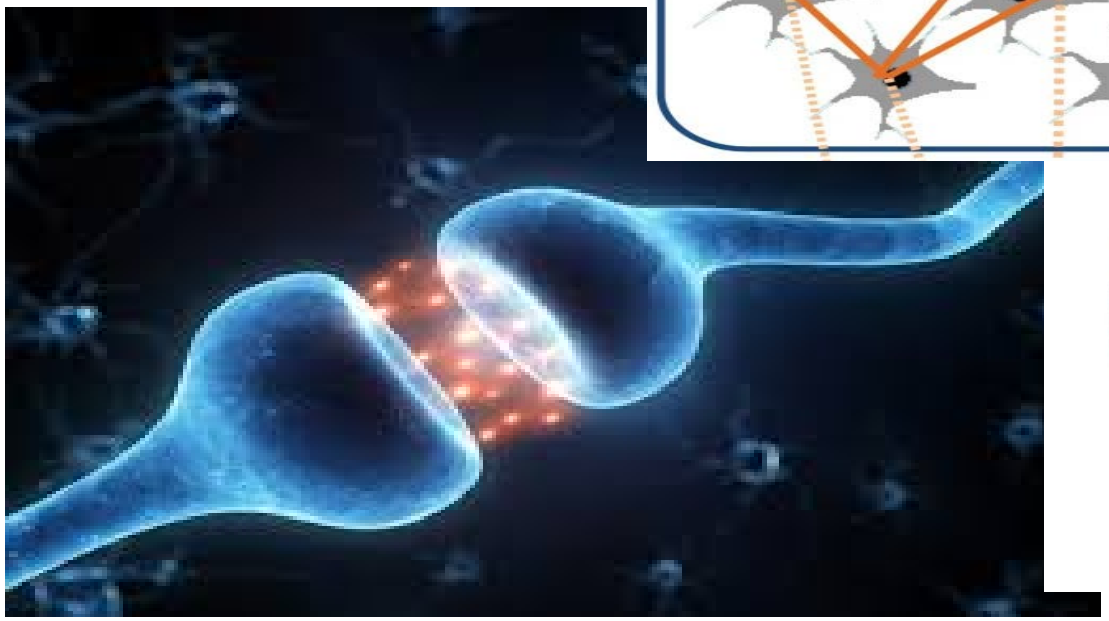
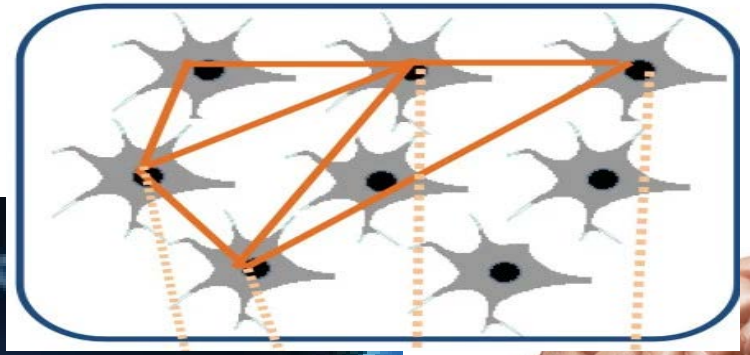
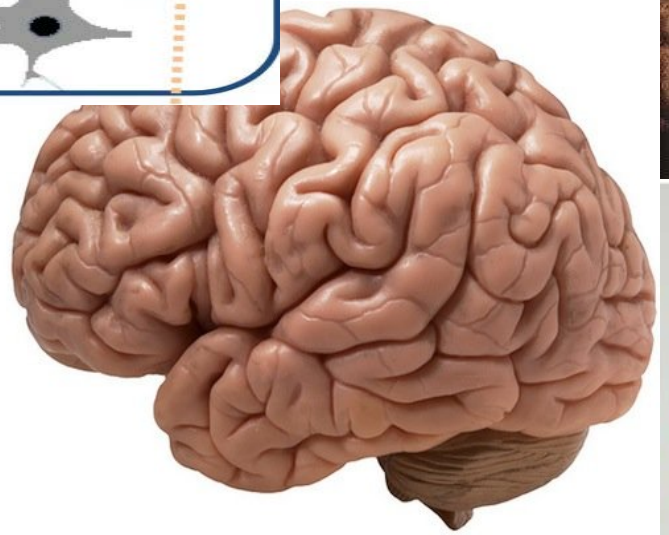
ENGRAM = MEMORY TRACE ➡ LANGUAGE FORMATION

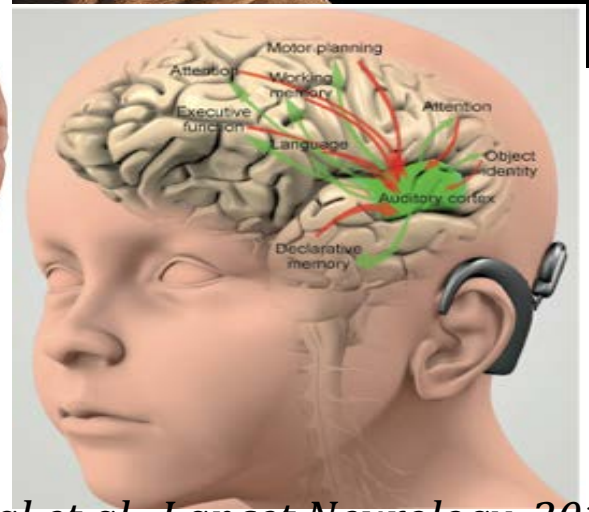
neural tract on which stimulation is passed on in the brain cortex

After :Konopka, Schutz and Kaczamrek, Neroscientist, 2011









Kral et al., Lancet Neurology, 2016

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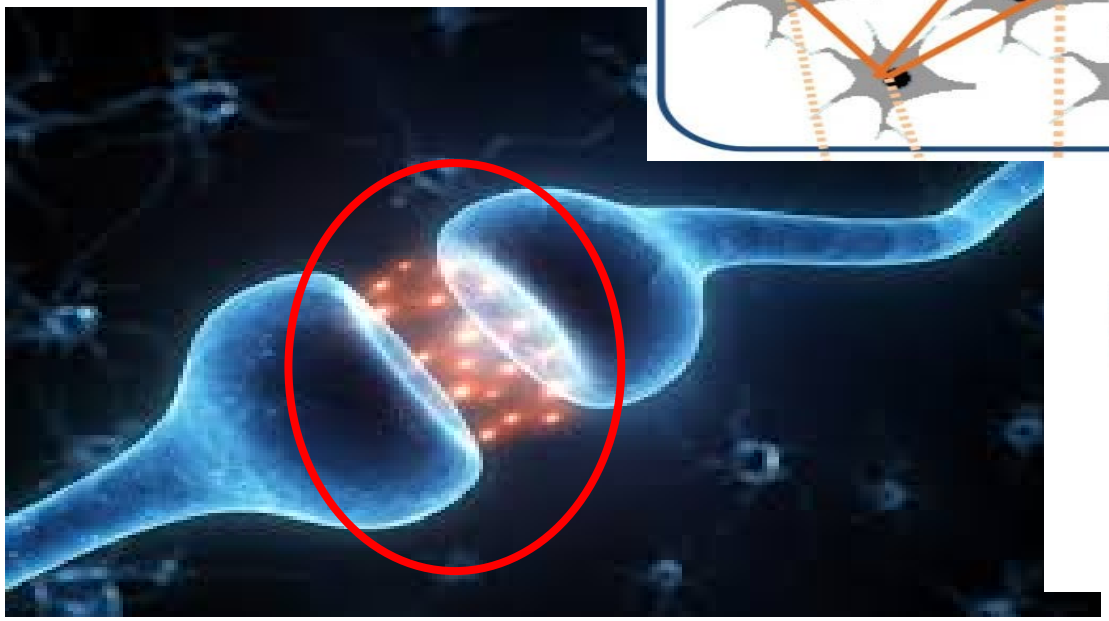

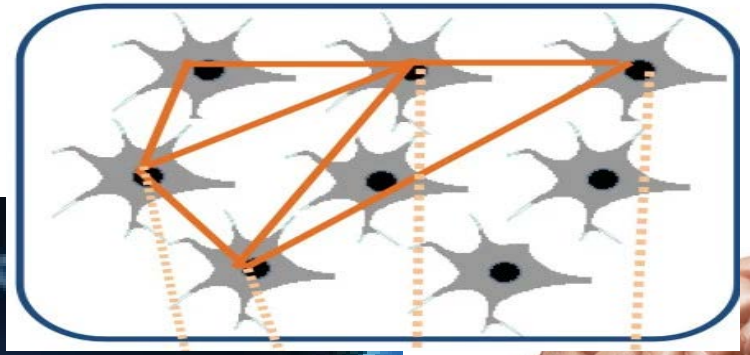

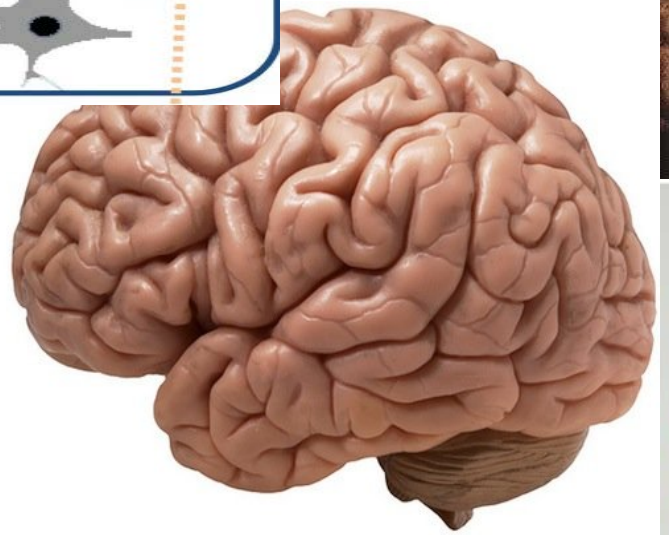

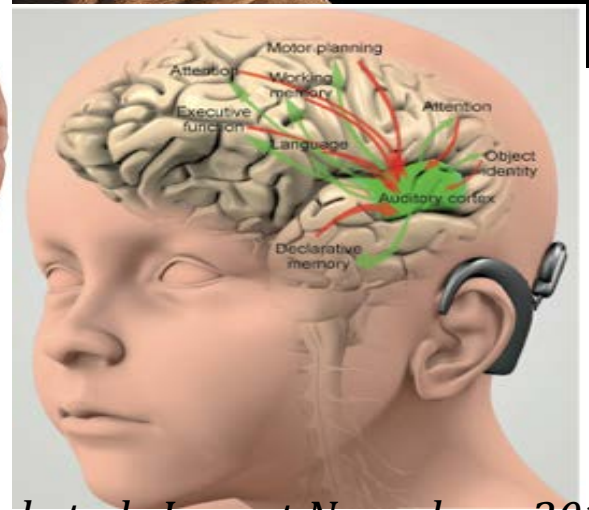

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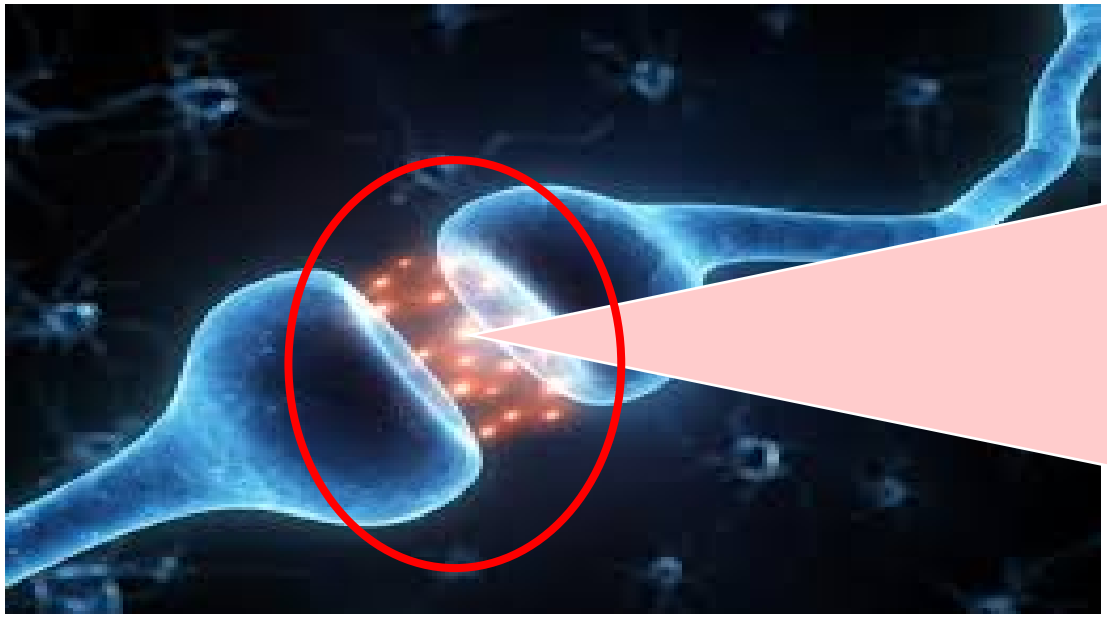

GLUTAMATE
GABA
MMP-9
ARC
MAPK
NMDAR
AMPAR
BDNF
NFKB
TAU
VEGF
RUNX2
……

ENGRAM = MEMORY TRACE ➡ LANGUAGE FORMATION

neural tract on which stimulation is passed on in the brain cortex

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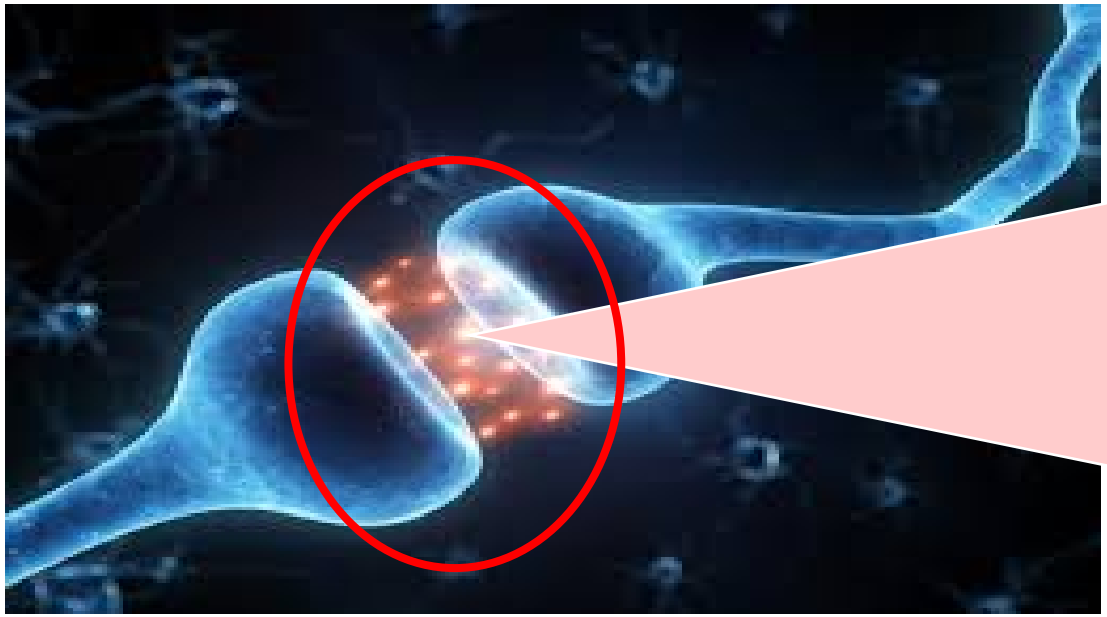

GLUTAMATE
GABA
MMP-9
ARC
MAPK
NMDAR
AMPAR
BDNF
NFKB
TAU
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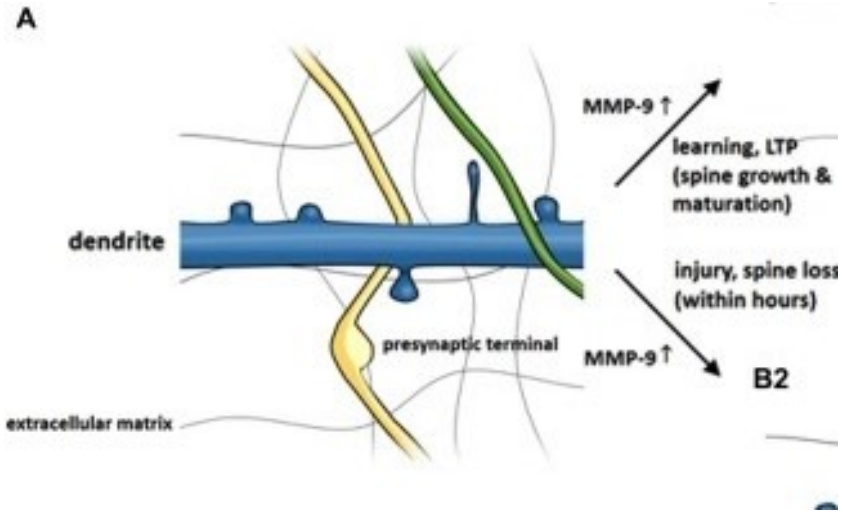
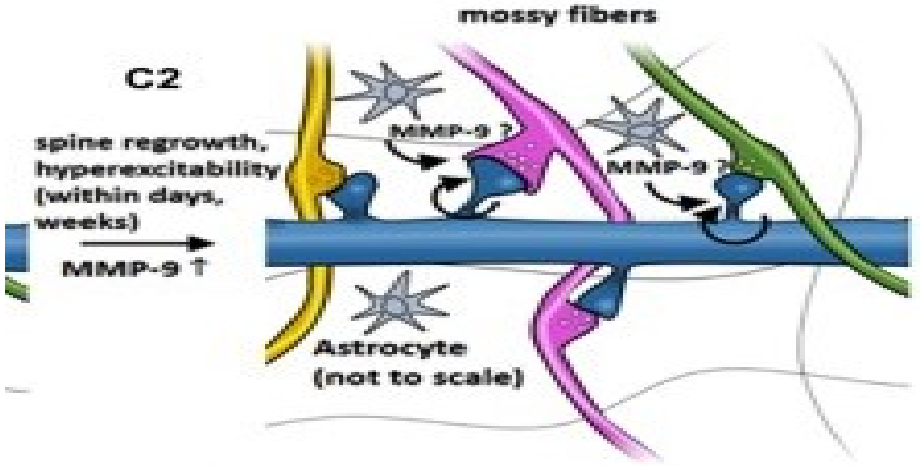
RUNX2
……

Matrix metalloproteinase 9 (MMP-9)

molecular level

- cleaves Extra Cellular Matrix (ECM)- facilitating neuronal contacts
- promotes maturation of dentritic spines





- cleaves pro-BDNF to BDNF

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MMP-9

clinical level

- a documented role in physiological and aberrant form of neural plasticity, like
  - schisophrenia,
  - epilepsy
  - addictions

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Brain-Derived Neurotrophic Factor (BDNF)

neurotrophine of a recognised role in neuroplasticity

- **molecular and synaptic level**
  critical factor for Long Term Potentiation,
  increases neuronal growth

- **clinical level**
  cognition, mood disorders, depression

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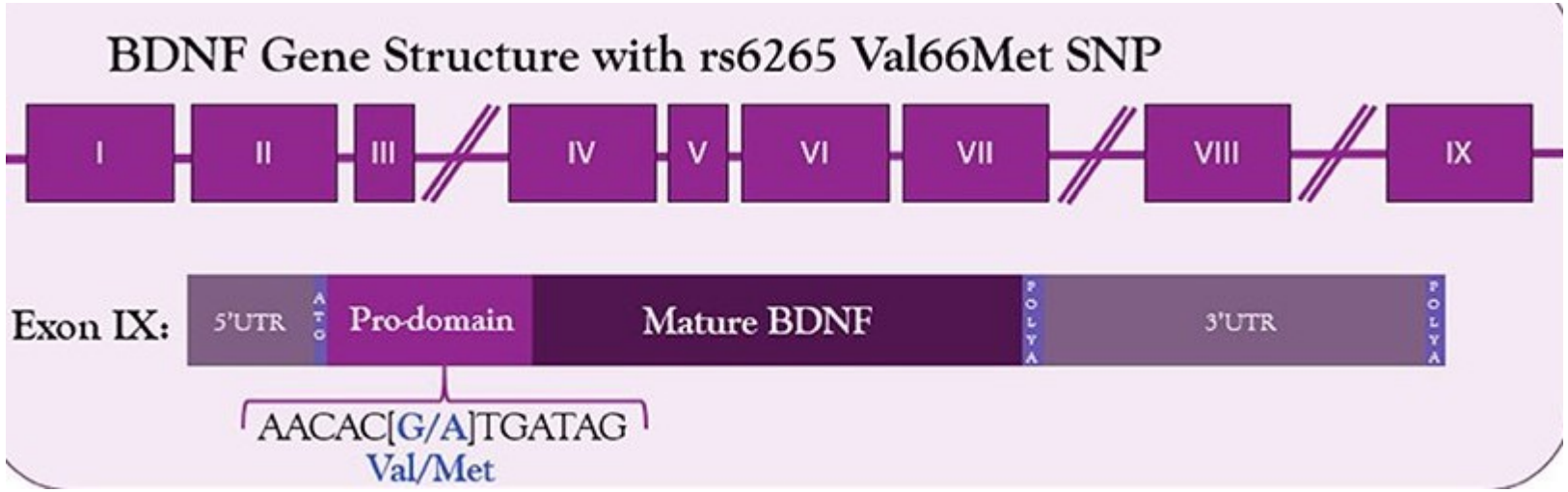
MMP9, BDNF functional variants

- SNP- single nucleotide polymorphism -
  substitution of one nucleotide affects the protein synthesis and function

- for example: rs3918242 of *MMP9* -1562C/T – promotor region, which affects the protein translation
  rs 6265 of *BDNF* Val66Met



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Hypothesis

carrying of functional variants of *MMP9* and *BDNF* and protein plasma levels of MMP-9, BDNF and pro-BDNF/BDNF ratio measured at cochlear implantation can serve as a prognostic factors for functional outcome of deafness treatment by means of cochlear implantation in deaf born, otherwise healthy, children.

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Observational prospective cohort study

- 2016 - 2020 Institute of Physiology and Pathology of Hearing, Warsaw

Inclusion criteria

- bilateral congenital sensory-neural hearing loss, ABR > 80 dB
- CI activation before 2nd birthday

Exclusion criteria

- co-existing risk factors for hearing loss or language acquisition both during pregnancy and after birth
- presence of any acute inflammation confirmed by CRP level measurements

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Study design

- Cochlear implantation with same type of device- Med-EL Synchrony, operated by the same experienced surgeon, fitted by the same experienced team, received the same rehabilitation protocol
- 3 follow-up intervals: at cochlear implantation, at 8th and 18th month after CI activation with LittlEARs Questionnaire (LEAQ) score measurements

LEAQ
MMP9, *BDNF* SNPs
MMP-9, BDNF, pro-BDNF plasma levels
CRP plasma level

LEAQ

LEAQ

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Method

- *MMP9* SNPs – rs3918242, rs20455, rs2234681,
- *BDNF* SNP- rs6265

- MMP-9, BDNF, pro-BDNF plasma levels measurements– ELISA

- LittlEARs Parental Questionnaire (LEAQ) (0-35 points)

- Testing of DFNB1 locus- *GJB2*, *GJB6*

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Material

- 70 children enrolled, unilaterally implanted, regular CI users,
- 9 children excluded (withdrawal from the study, elevated CRP level, Autism Spectrum Disorder diagnosed during follow up)
- 61 children final study group
- 40 children diagnosed with DFNB1 related-deafness
    - 18 CI activation up to 1st birthday
    - 22 CI activation after 1st birthday

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Results

Plasma level at cochlear implantation	LEAQ 0	LEAQ 8	LEAQ 18
MMP-9 0	P=0.5, rho=0.07	P=0.3, rho=-0.1	**P=0.04, rho=-0.2**
BDNF 0	P=0.4, rho =-0.09	P-0.3, rho=-0.1	P=0.4, rho=-0.09
Pro-BDNF 0	P-0.4, rho=-0.1	P=0.4, rho=-0.09	P=0.8, rho =-0.03
Pro-BDNF 0/BDNF 0 ratio	P-0.5, rho=-0.08	P=0.4, rho=-0.09	P=0.6, rho=-0.05

Study group, N=61

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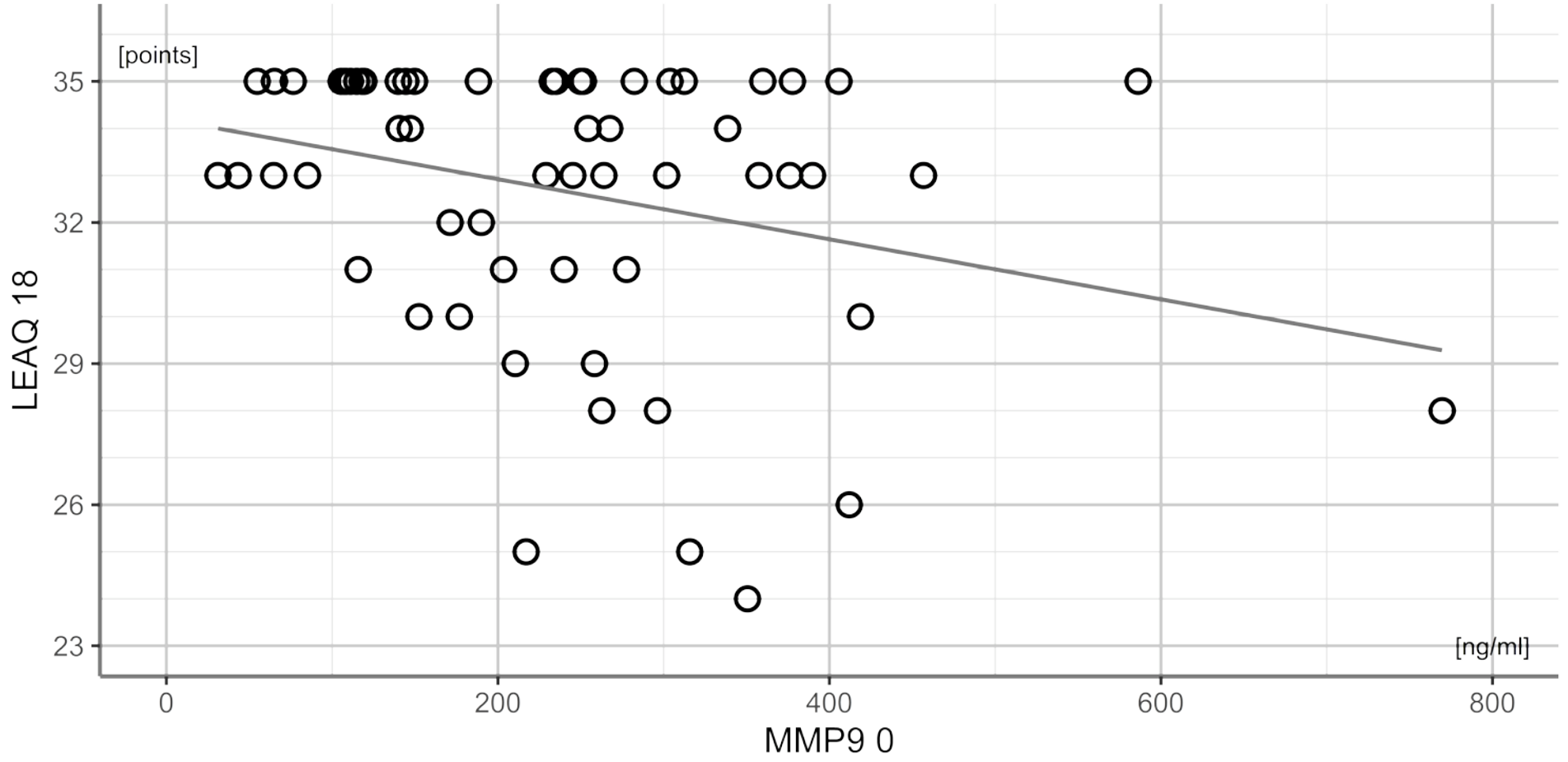

P=0.04, rho=-0.2

Study group, N=61

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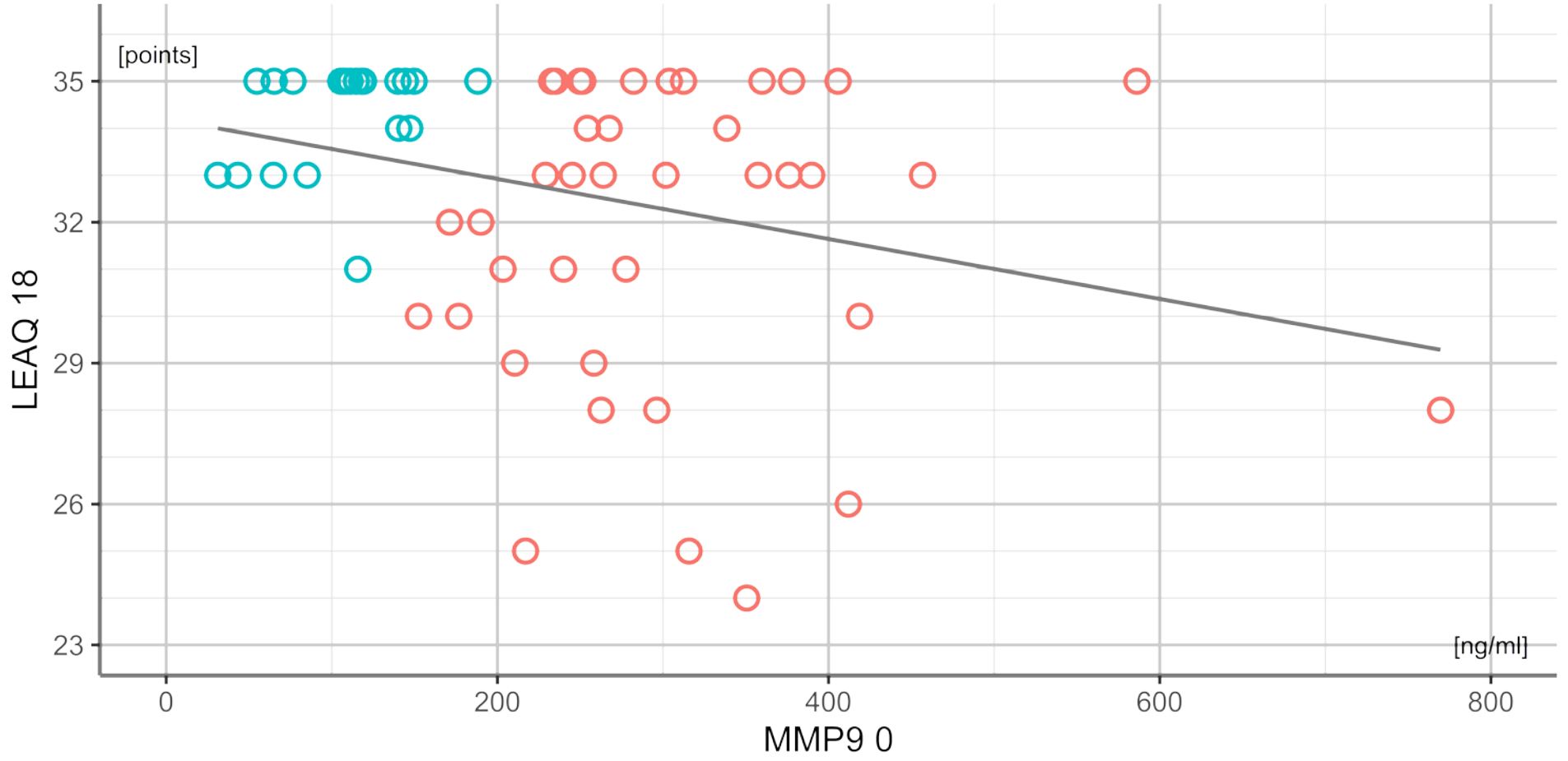

Study group, N=61, clustering

P=0.04, rho=-0.2

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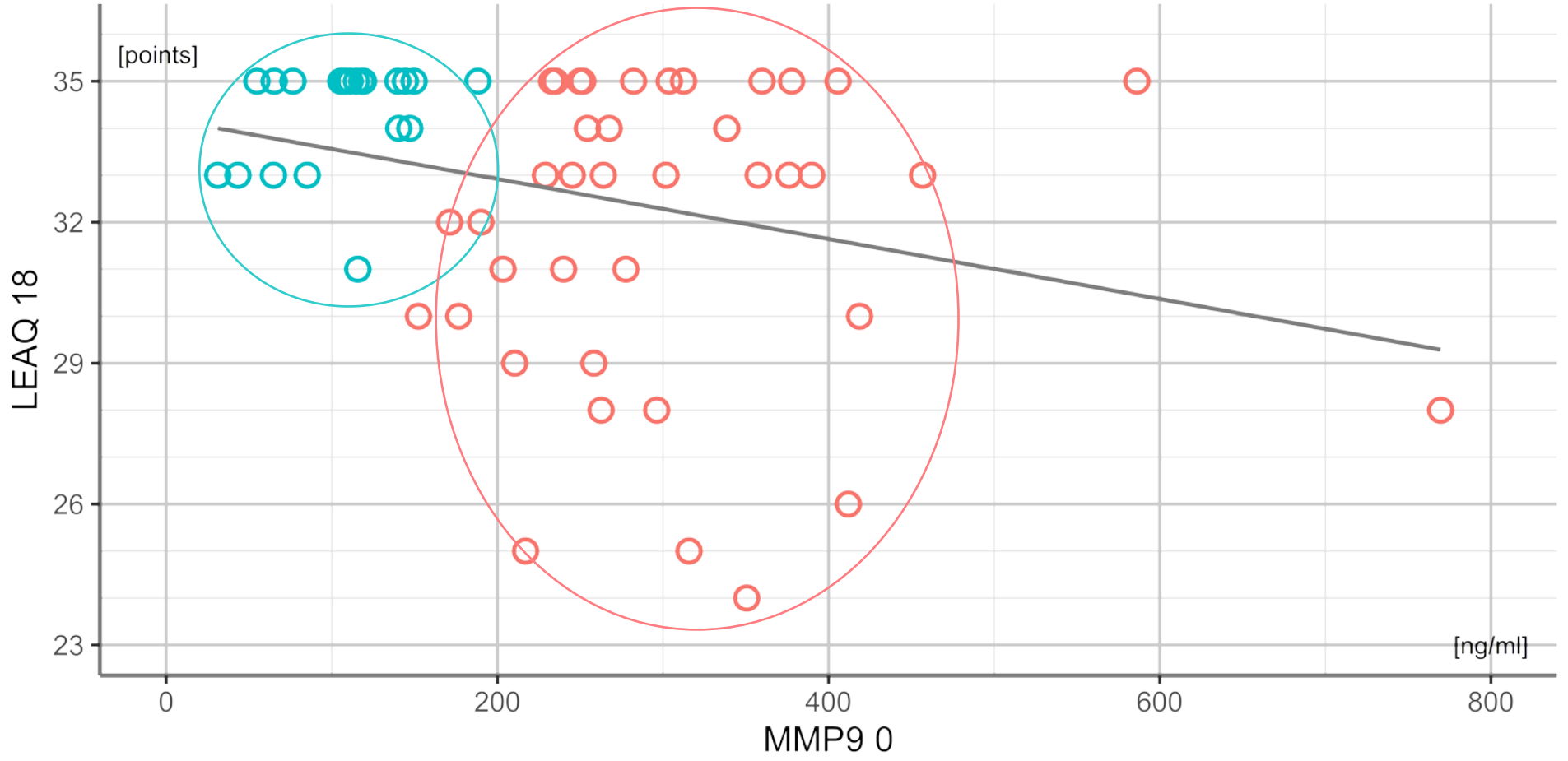

Study group, N=61, clustering

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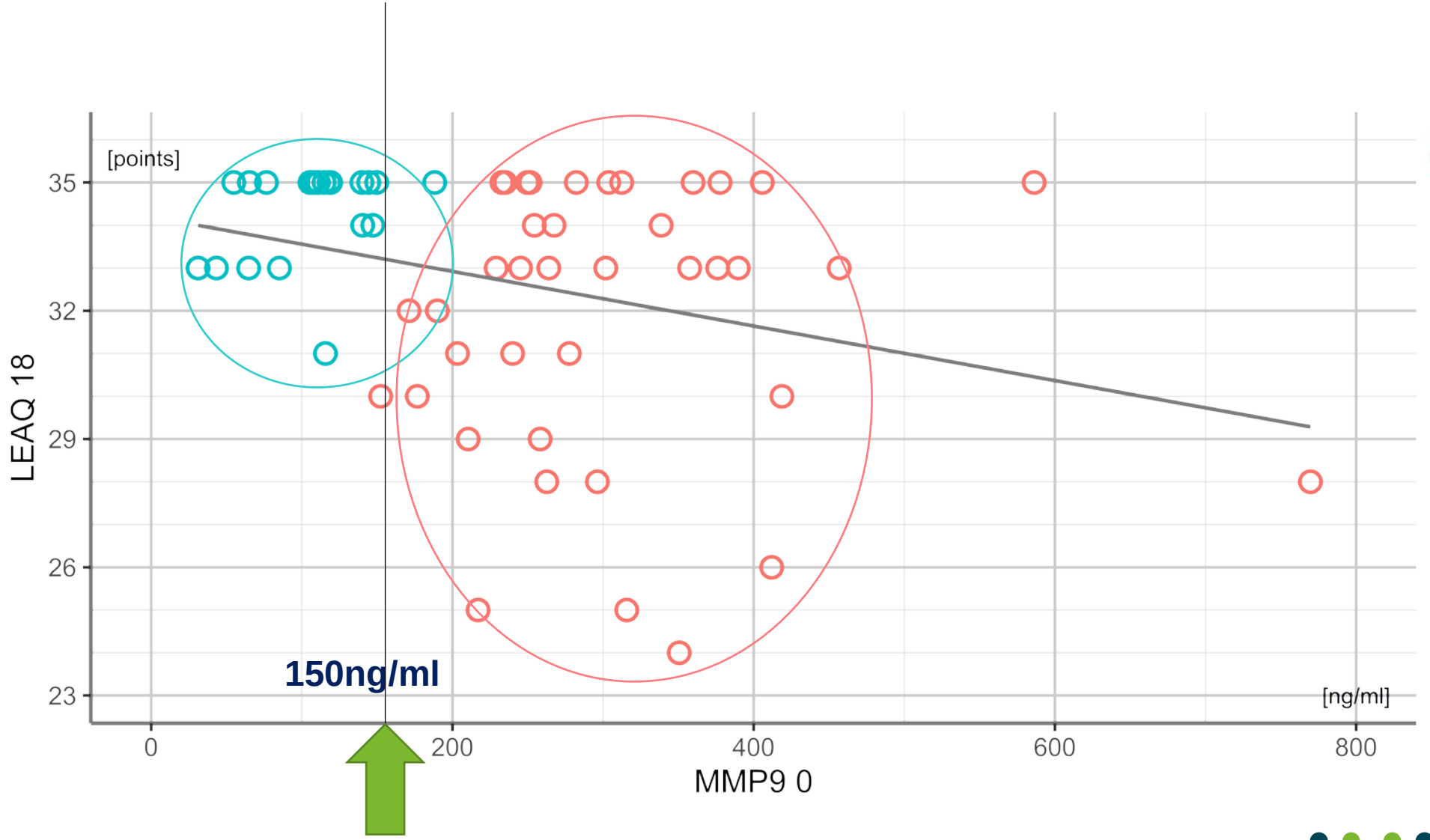

Study group, N=61, clustering

P=0.04, rho=-0.2

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Plasma level at cochlear implantation	LEAQ 0	LEAQ 8	LEAQ 18
MMP-9 0	p-=0.9, rho=-0.0003	P=0.07, rho=-0.2	**P=0.005, rho=-0.4**
BDNF 0	P=0.7, rho=-0.06	p=0.3, rho=-0.1	P=0.9, rho =-0.01
Pro-BDNF 0	P=0.1, rho=-0.2	p=0.3, rho=-0.03	P=0.1, rho=-0.2
Pro-BDNF 0/BDNF 0 ratio	P=0.1, rho=-0.2	P=0.1, rho=-0.2	P=0.1, rho=-0.2

DFNB1-related deafness subgroup, N=40

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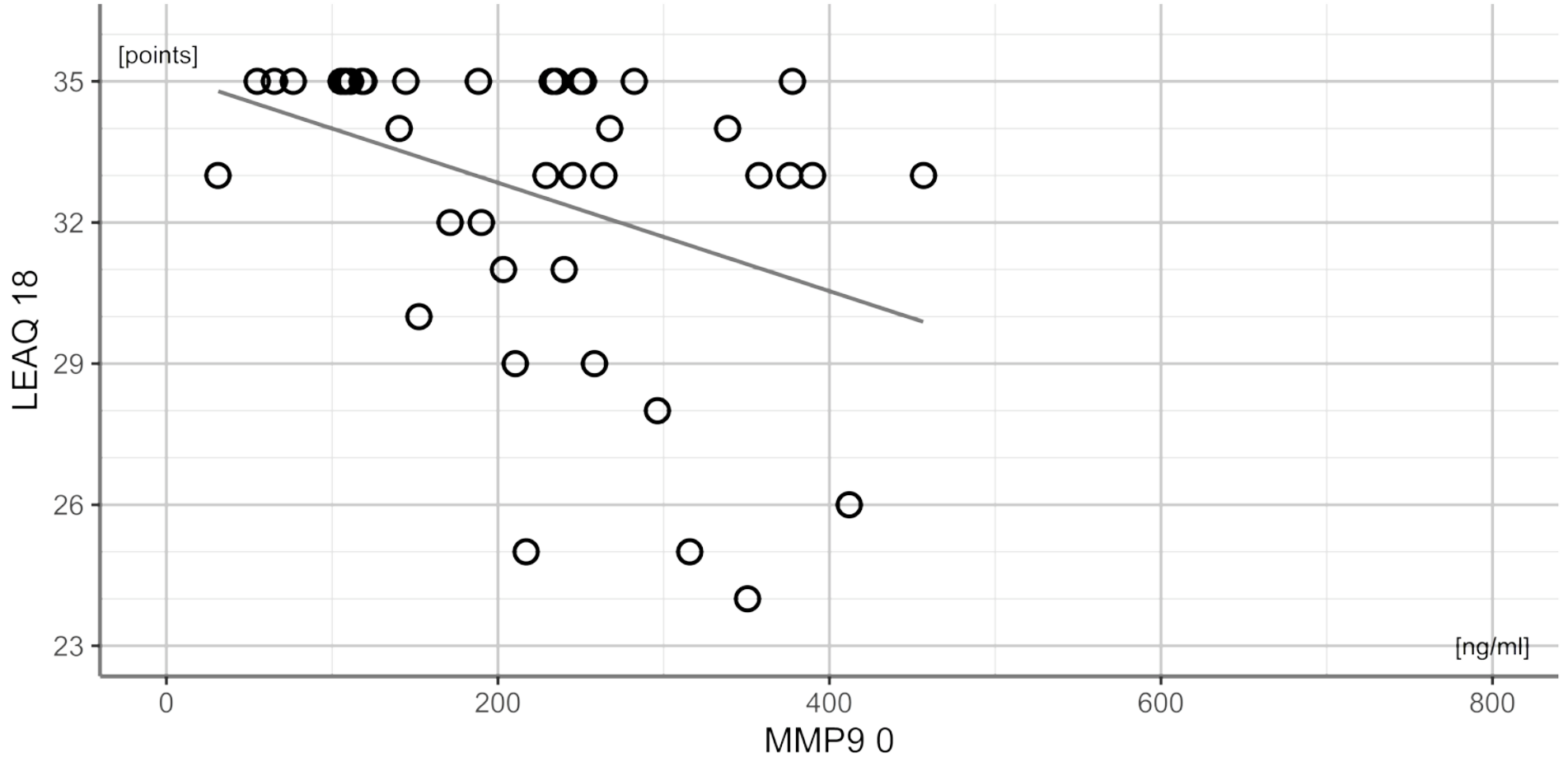

P=0.005, rho=-0.4

DFNB1-related deafness subgroup, N=40

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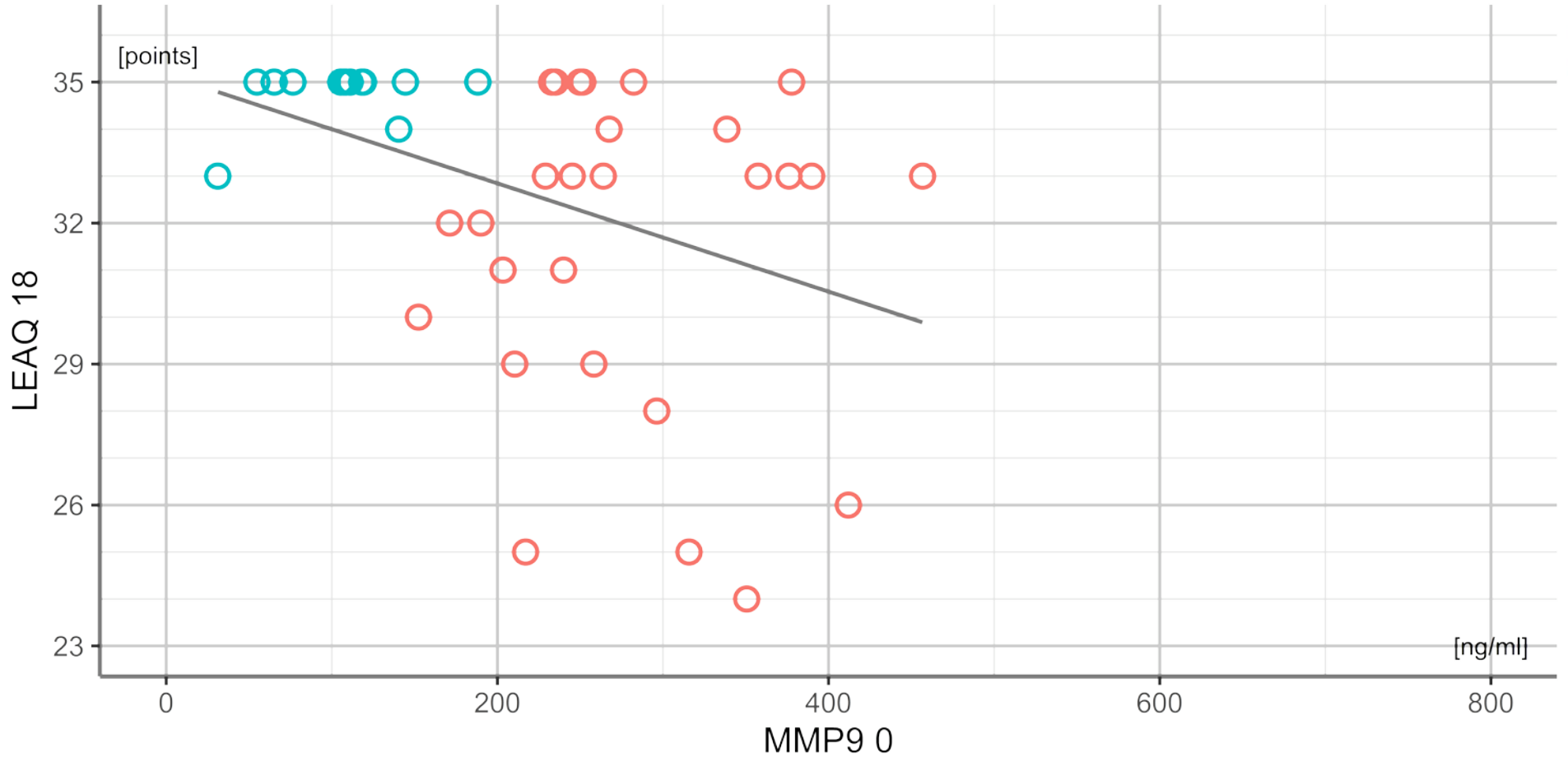

P=0.005, rho=-0.4

DFNB1-related deafness subgroup, N=40, clustering

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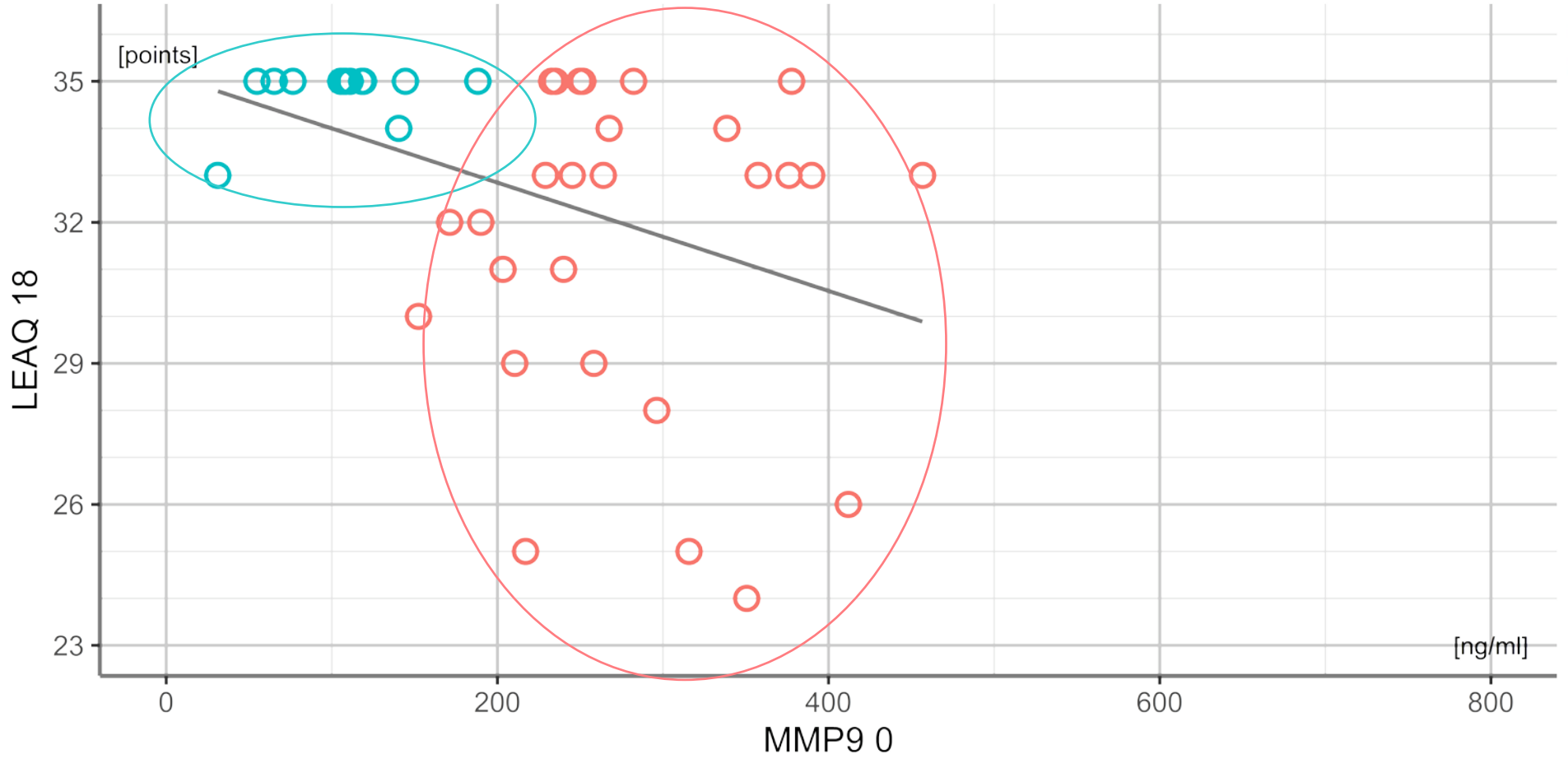

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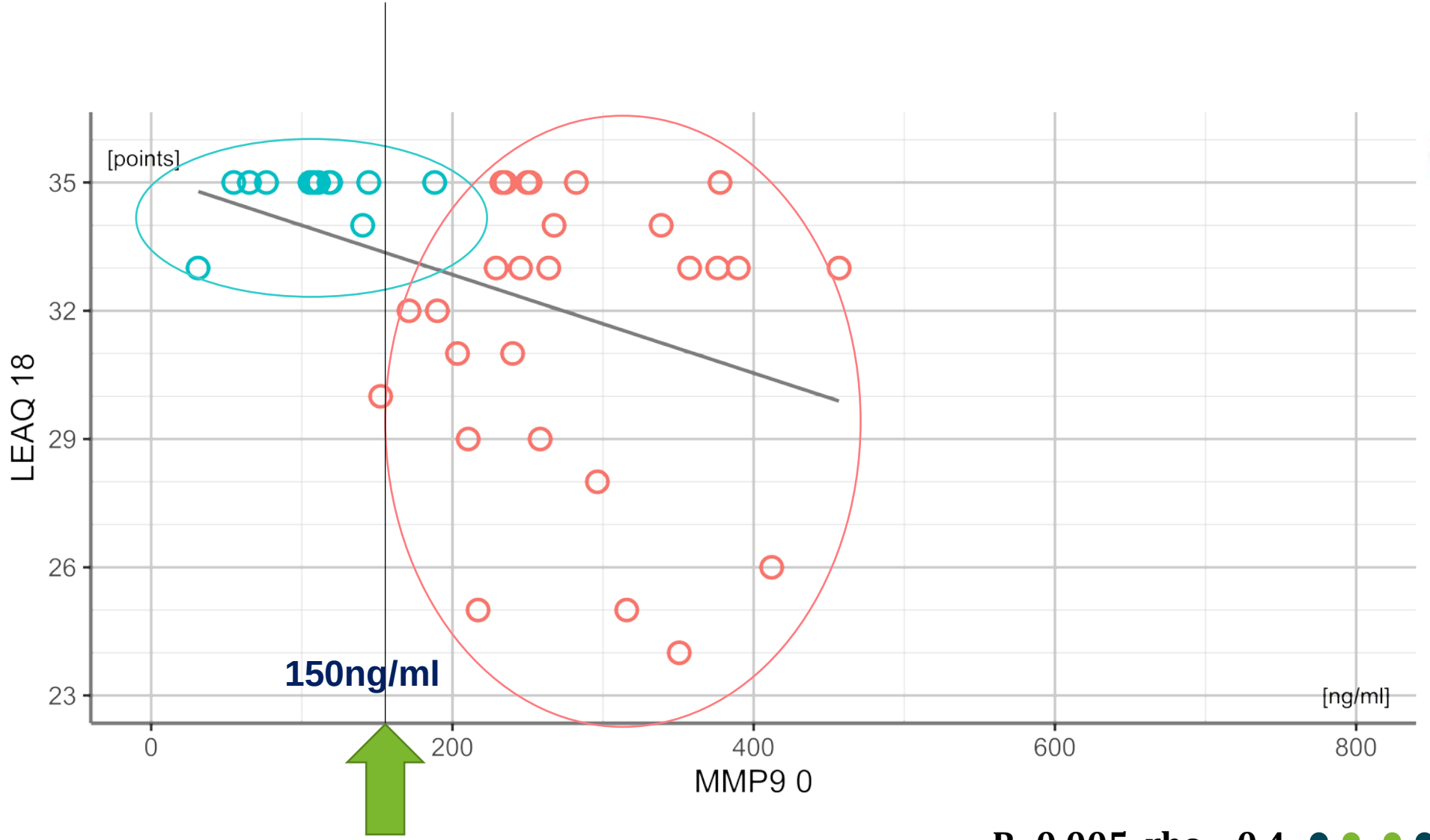

P=0.005, rho=-0.4

DFNB1-related deafness subgroup, N=40, clustering

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	Follow-up interval	Mean LEAQ score	P-value
MMP9 rs1839242			
C/C C/T	0	6.5(7.1)/2.5(3.9)	0.06
C/C C/T	8	27.8(4.6)/25.3(8.3)	0.5
C/C C/T	18	33.2(2.7)/30.6(3.9)	**0.03**

2.6 points

For *MMP9 rs2234681*, *MMP9 rs20544*, *BDNF* rs6265 – no statistically significant assiciations between functional variants and LEAQ 0, LEAQ 8, LEAQ 18

DFNB1-related deafness subgroup, N=40

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Plasma level at cochlear implantation	LEAQ 0	LEAQ 8	LEAQ 18
DFNB1-related deafness, CI activation up to 1, N=18			
MMP-9 0	P=0.2, rho=-0.2	P=0.3, rho=-0.2	P=0.1, rho=-0.3
BDNF 0	P=0.3, rho =0.2	P-0.9, rho=-0.009	P=0.9, rho=-0.02
Pro-BDNF 0	P-0.9, rho=-0.2	P=0.06, rho=-0.4	P=0.6, rho =-0.01
Pro-BDNF 0/BDNF ratio 0	P-0.5, rho=-0.01	P=0.09, rho=-0.4	P=0.9, rho=-0.02
DFNB1-related deafness subgroup, CI activation after 1, N=22			
MMP-9 0	p-=0.6, rho=-0.1	P=0.1, rho=-0.3	**P=0.01, rho=-0.5**
BDNF 0	**P=0.03, rho=0.4**	p=0.2, rho=-0.2	P=0.4, rho =-0.01
Pro-BDNF 0	P=0.06, rho=-0.4	p=0.4, rho=-0.01	P=0.07, rho=-0.3
Pro-BDNF 0/BDNF 0 ratio	**P=0.01, rho=-0.5**	P=0.4, rho=-0.1	P=0.2, rho=-0.2

Take home messages

- a child candidate, who has less than 150ng/ml plasma level of MMP-9 measured pre-impant have very high odds to score very well after 18 months of CI use

- peripheral blood is easily accessible, ELISA is fast and cheap

- molecular regulation of neuroplasticity after auditory deprivation longer than 1 year may involve different mechanisms, than in children with shorter duration of deafness.

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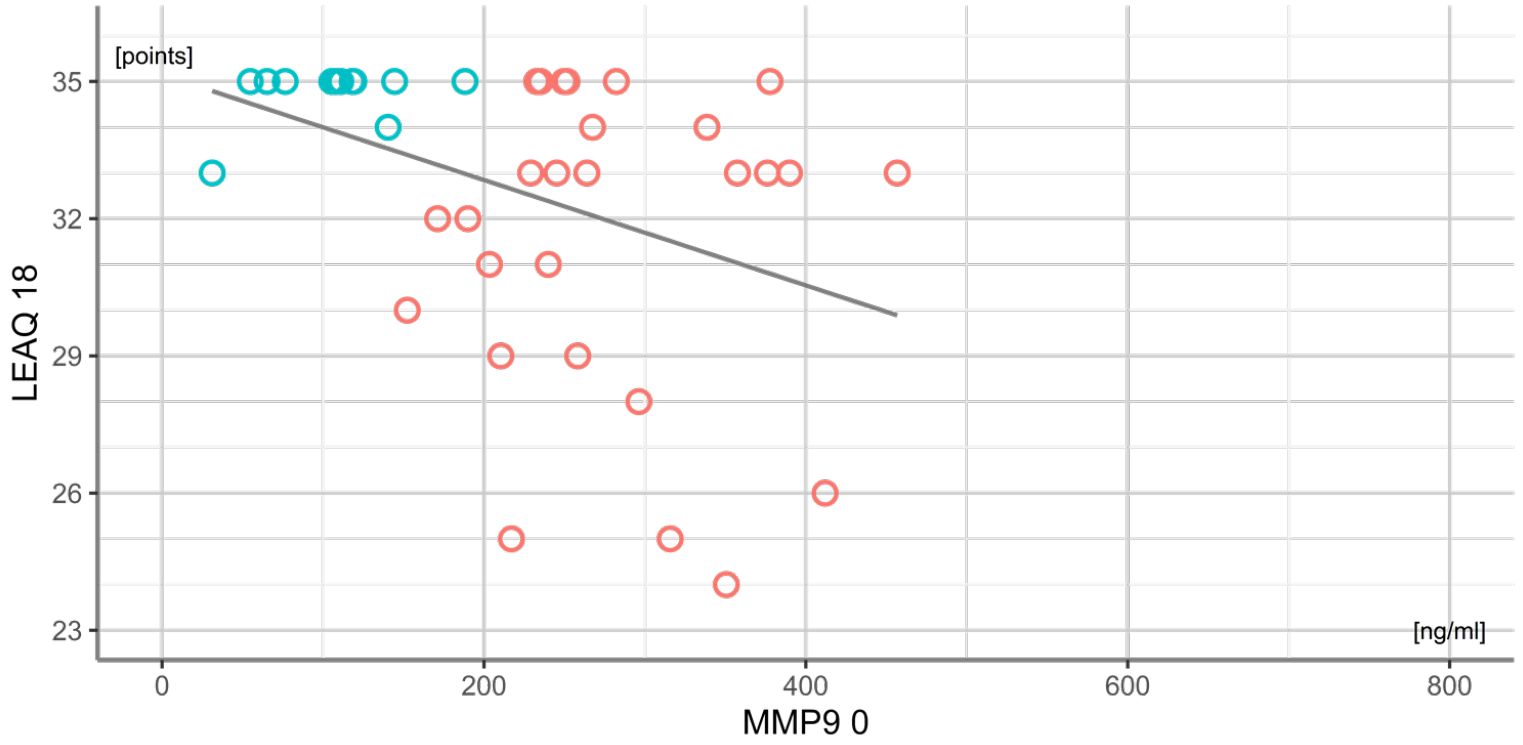
Perspective?

possible clinical application
- selective MMP-9 inhibitors?



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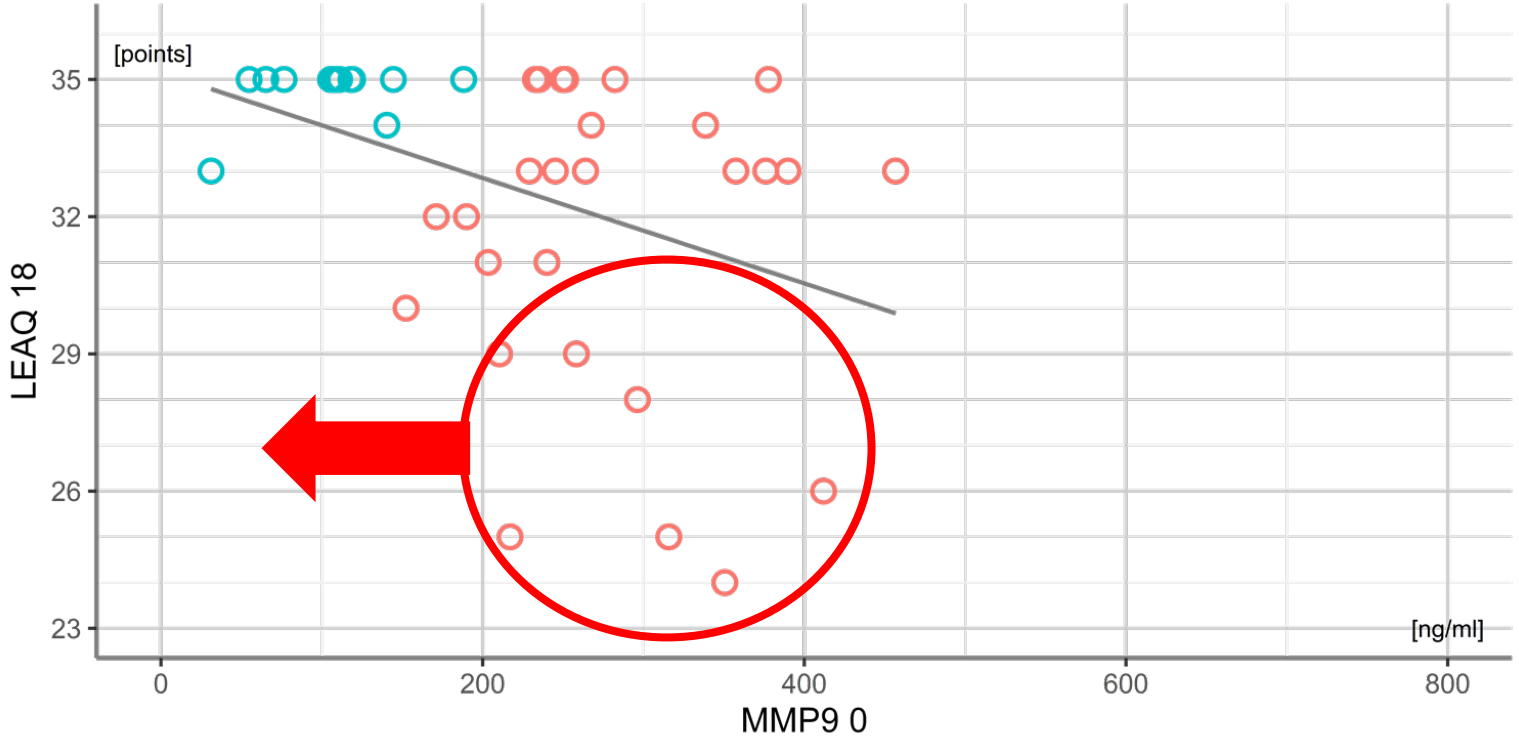

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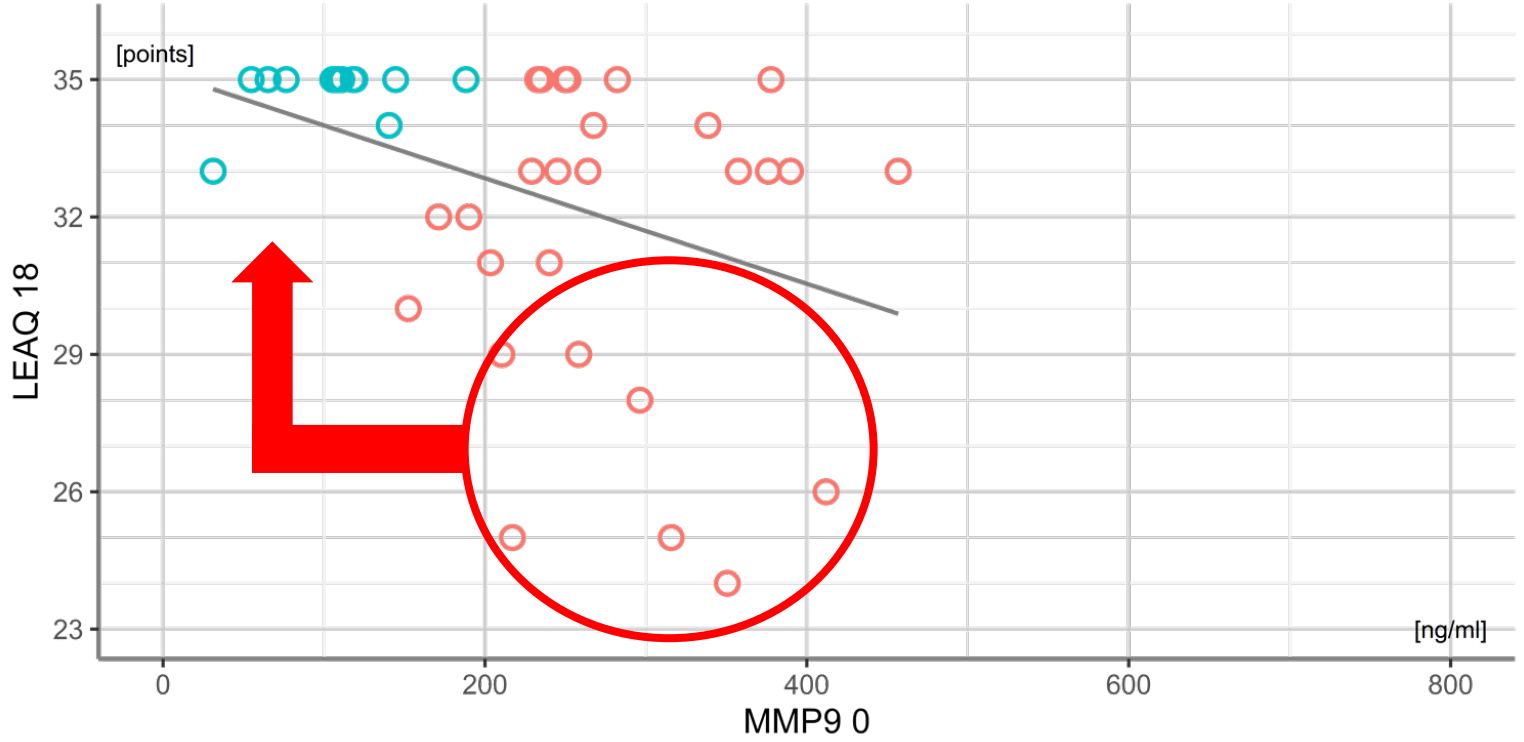

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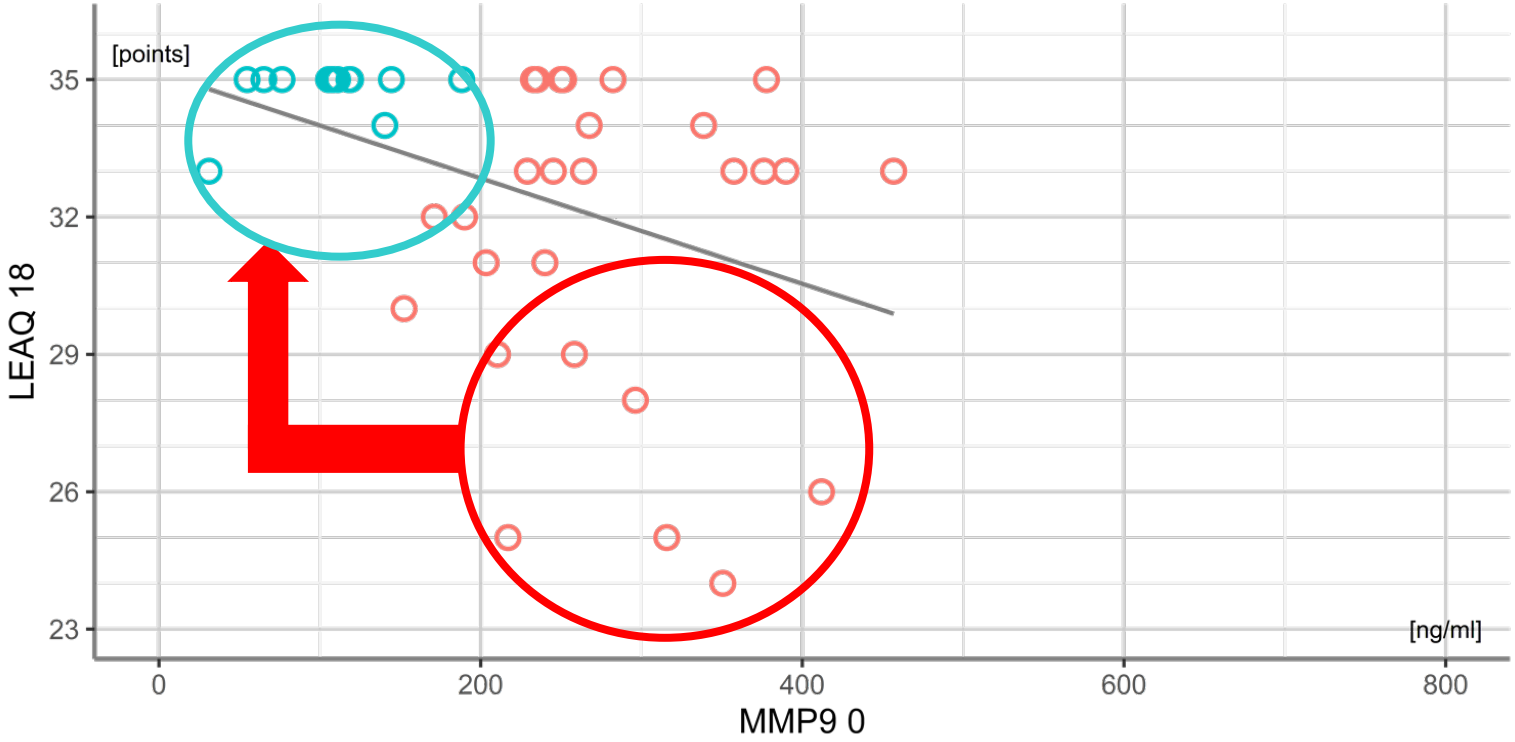

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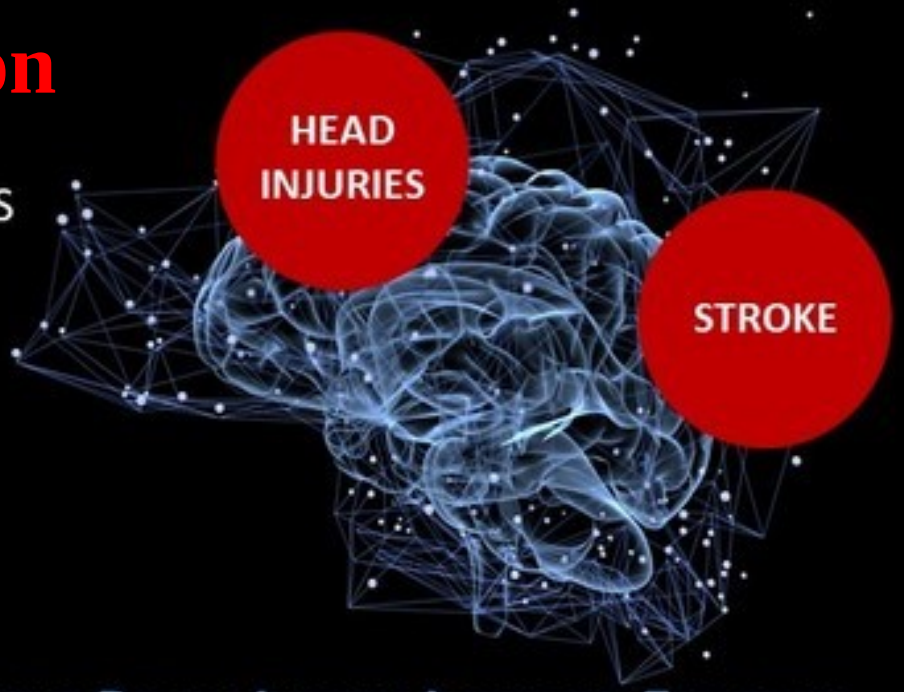
Post-traumatic epilepsy prevention

- Brain Injuries: 2.3 mln annually in EU & US
- Stroke: 1.9 mln annually in EU & US
- Up to 30% of patients develop epilepsy
- Severe effect on patient quality of life
- Average annual cost of symptomatic epilepsy treatment: € 5-15 K / patient



EpiFix – First Therapy To Prevent Brain Injury Induced Epilepsy

- Small molecule, MMP-9 inhibitor PKL-021
- Demonstrated efficacy in animal *in vivo* models
- Clinical candidate selected by drug repurposing strategy
- One week treatment duration to prevent epilepsy development

Utilization of a matrix metalloprotease inhibitor to develop an innovative therapeutic method that prevents the development of post-traumatic and post-stroke epilepsy - POIR.01.01.01-00-0235/20-00 project by Pikralida and Nencki Institute of Experimental Biology implemented under the Smart Growth Operational Program 2014 – 2020.

Funding:
Grant SONATA UMO 2013/14/D/NZ5/03337 National Science Centre

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4	Francesco	FASCETTI-LEON	Professor in Pediatric surgery	Pediatric Surgery Unit, Women's and childrens' health Department, Padova University	Non-invasivE multimodal monitoring tools for NeCrotizing enterocolitis in preterm infants: A piLot MulticEnteR sTudy (NEC-ALERT)
5	Kevser	FÜNFGELD	Digital Health Program Manager	Luxembourg Institute of Health	Development and implementation of virtual patient avatars derived from standardised, minimally and non-invasive biomarkers for enhanced clinical trials
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8	Georgi	KADREV	Co-founder & CEO	Kelvin Health	Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response
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11	Irakli	LEZHAVA	CEO & Co-founder	Ensofy	Vocal Biomarkers for Mental Health Management
12	Shima	MAHMOUDI	Assistant professor	Silesian University of Technology	Advancing Tuberculosis Research: Unraveling Biomarkers for Enhanced Diagnostics, Prognostics, and Treatment Monitoring
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IHI Call Days | Call 7

Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment responseTopic name

Clinical translation of Extracellular Vesicles as liquid biopsy for disease detection and monitoring

Contact person name: Margaret Mc Gee
Organisation: University College Dublin
E-mail: Margaret.mcgee@ucd.ie
Link to:
https://ihi-call-days.ihi.b2match.io/participations/200749/opportunities
https://people.ucd.ie/margaret.mcgee/about
https://www.twinflagproject.com/

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Challenges and objectives

- Our project objective is the development of new approaches to advance the implementation of Extracellular Vesicle - based liquid biopsy for disease detection and monitoring from human biofluids.
- We aim to develop technology for the detection of cancer specific EVs directly in human plasma, without the need for ultracentrifugation or size exclusion chromatography.
- We aim sort cancer specific EVs for comprehensive multi-omic profiling

Potential results include

- Development of a clinically applicable approach for translation of EVs as liquid biopsy
- Discovery of new cancer biomarkers and therapeutic targets.
- Development of a liquid-biopsy technology that is transferrable to many other diseases

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Main activities

- Development of nanoflow cytometry approaches for EV detection and characterization directly from human plasma
- Multi-omic EV profiling including proteomics, transcriptomics and metabolomics
- AI-assisted approaches for biomarker discovery
- Biomarker validation studies

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Expertise and resources offered

- Partners include researchers, clinicans, computational biologists, data analysts and industry.
- Expertise in cancer EV biology and multi-omic profiling including primary cancer blood and bone marrow EVs and EVs from other inflammatory disorders including arthritis and neurodegenerative diseases

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IHI Call Days | Call 7 – Topic 3

Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Biomarker for early prediction of COVID-19 disease progression

Contact person name: **Prof. Avidan Neumann**

Organisation: **Institute of Environmental Medicine (IEM),**

Helmholtz Munich & University Hospital Augsburg, Germany

E-mail: avidan.neumann@uni-a.de

Link to:

Participant profile: https://ihi-call-days.ihi.b2match.io/participations/325234

Marketplace opportunity: https://ihi-call-days.ihi.b2match.io/participations/325234/opportunities

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Challenges and objectives

- SARS-CoV-2 has become endemic,
  but still a considerable COVID-19 mortality (217,000 worldwide in 2023).
- Anti-viral and immune-modulating therapy for COVID-19 is available,
  but treatment required to start as early as 5 days post symptoms onset.
- **No biomarker validated to predict COVID-19 disease progression**,
  risk of hospitalization and/or symptomatic vs asymptomatic disease,
  at early time of SARS-CoV-2 positive diagnosis (~ 1-7 DPSO).
- **Biomarker for early prediction of COVID-19 disease progression**,
  that is **simple and feasible to measure at point-of-testing**,
  → **allow personalized treatment and reduce COVID-19 mortality**.

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Main activity

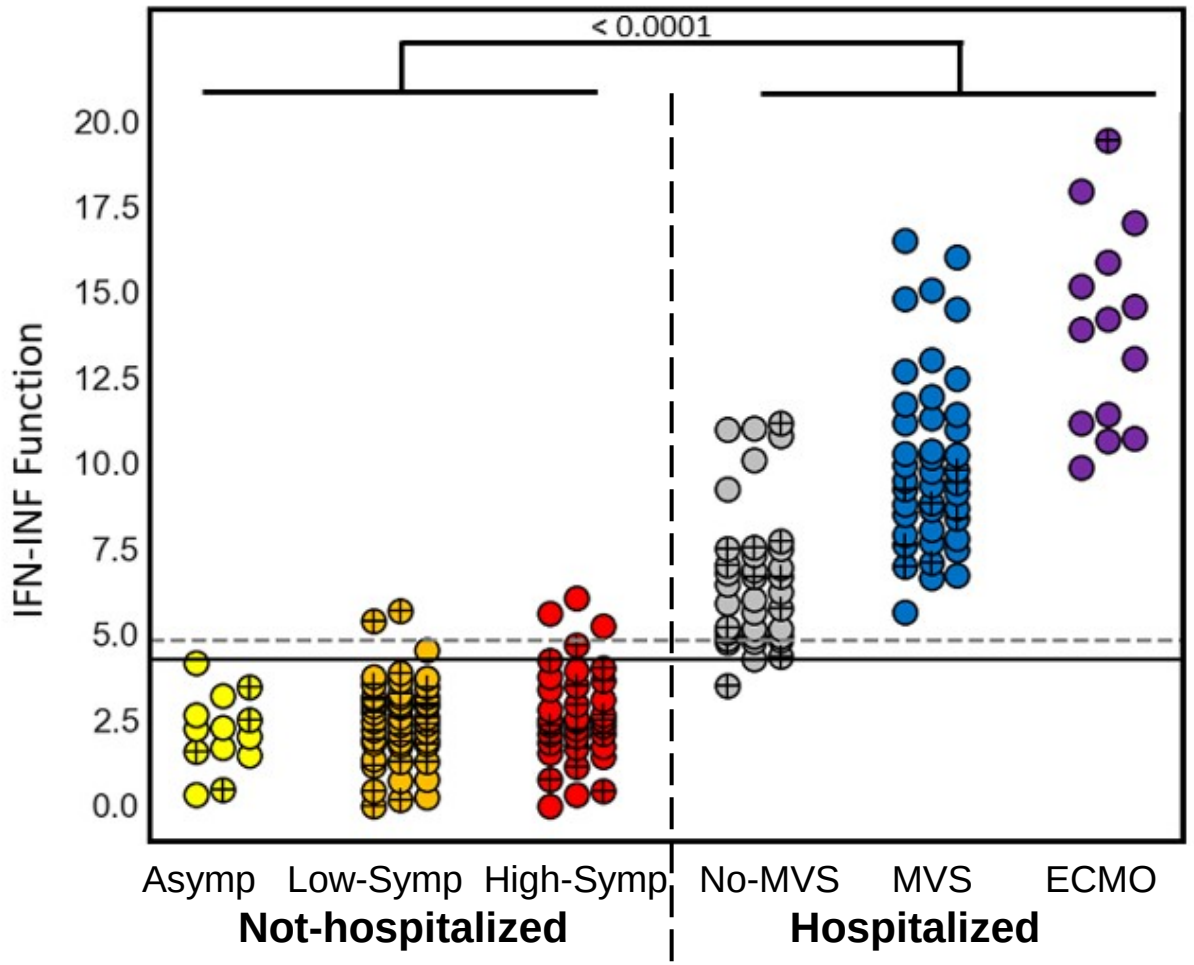
- Our published results: combination of cytokines predicting COVID-19 severity in hospitalized patients (Dorgham et al, ***JACI***, 2021; Neumann et al, ***Lancet***, 2021).

- Our preliminary results:

  simple to measure biomarkers combinations, measured as early as the day of the first PCR, that **accurately (97%) predict:**

  - COVID-19 hospitalization risk

  - Symptomatic vs asymptomatic disease course



We seek to:

- **Validate these biomarker combinations**
- **Develop instrument for measurement at point-of-test**
- **Validate and regulate instrument + biomarker for clinical use**
- **Clinical trials for early personalized treatment based on prediction**

⊕ Sample taken at day of 1st positive PCR (DPSO≤5)

(N=360 SARS-CoV-2 positive, manuscript in preparation)

Expertise and resources offered

- **Large potential cohort of patients with primary respiratory symptoms:** Established contacts with primary caregivers to allow the recruitment and sampling of up to 24,000 individuals with primary respiratory symptoms per year.
- **High throughput robotic lab platform for protein biomarkers and genomic measurements** (Perform project, EC funding).
- **App for symptoms diary**: We have developed, tested and validated diary app that allows online collection of patients' symptoms and clinical information.
- **COVID-19 clinic and outpatient clinic** at University Hospital Augsburg.
- **Bioinformatic expertise in biomarker discovery,** modeling viral dynamics and immune dynamics, microbiome analysis, immune repertoire analysis.

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Expertise requested

- **Consortium interested in validating biomarkers for COVID-19**
- **… Epidemiological expertise in validation studies**
  (research institute, CRO company)
- **… Regulatory expertise in biomarkers for disease progression**
  (SME, large company or regulatory body)
- **… Biotech company for development of instrument for point-of-test multiplex measurement of protein biomarkers**
  (SME or large biotech company)
- **… Pharma company with COVID-19 drug pipeline for clinical trials of early personalized therapy**
  (large biopharma company)

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Topic 3: Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Biomarkers for novel depression treatment

Contact person name: Johannes Österberg

Organisation: Sooma Medical

E-mail: Johannes@soomamedical.com

Link to:

- Marketplace opportunity
- Participant profile

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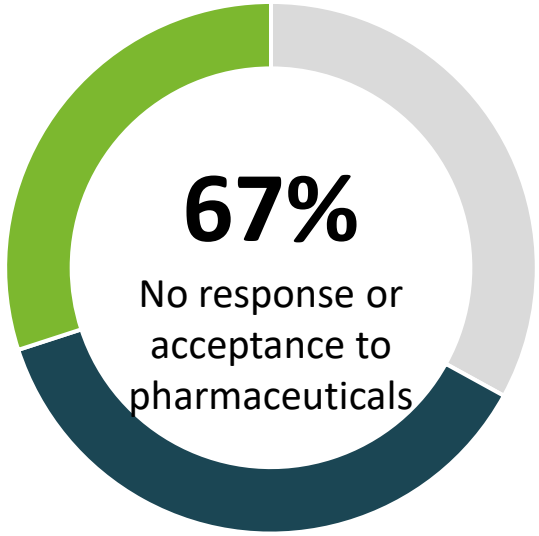
Challenges

300M
patients globally

>300M people suffer from depression globally
In 2020, due to COVID19 increased by 28%



Diagnosis and monitoring challenges:
-subjectivity of questionnaires
-Patient has delay in noticing treatment response
-clinician made assessments not scalable for the size of the challenge

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Objective

Multi-modal, scalable, non-invasive biomarkers for personalized treatment of depression

Diagnosis

- Scalable, precise and effective non-invasive biomarker

Treatment Response

- Early identification of positive treatment response or need for new treatment path selection
- Improved follow-up and monitoring

Remission Relapse

- Detection of remission
- Detection of relapse

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Main activities

- Develop technology for measuring, collecting and analysing data for non-invasive, physical, visual, vocal or other potential biomarker for depression that is used with Sooma tDCS treatment platform
- Verify and clinically validate the biomarker to improve treatment selection and access to personalized care
- Regulatory strategy for medical device certification and reimbursement of enhanced treatment model with biomarkers

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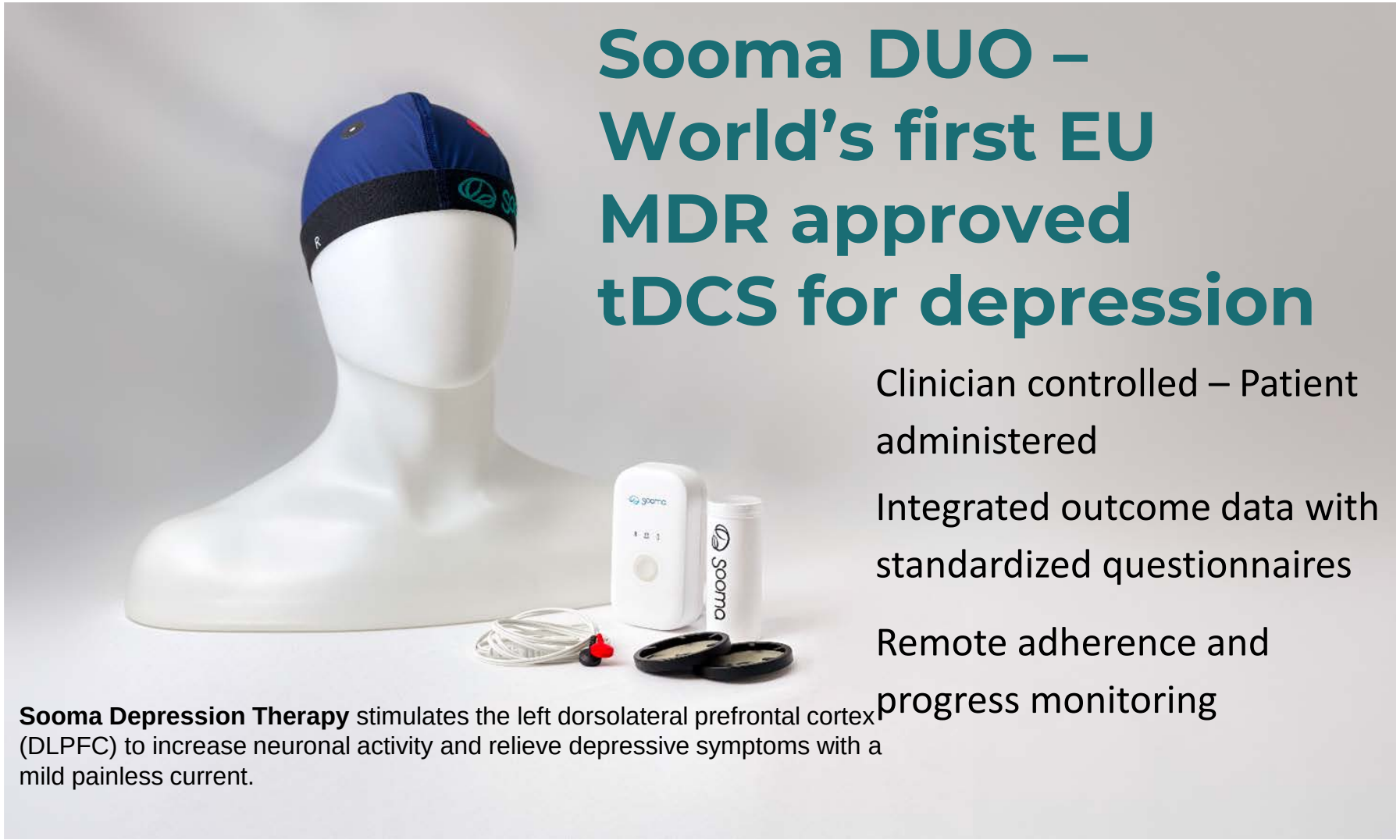
Expertise and resources offered



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Expertise requested

- Technology research institutes and partners:
  - Technology development
  - Technologies for collecting novel biomarkers for depression:
    - HRV frequency and time domains
    - Potential visual and AI backed technologies
    - Other potential candidates
- Clinical Research Institutes
  - Clinical validation of biomarkers with Sooma tDCS system
- Regulatory Partners
  - Strategy and preparation for approval and reimbursement

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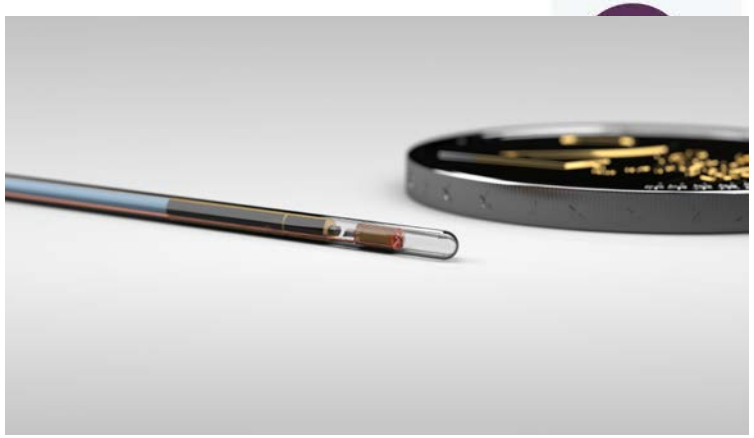
Advanced endoscopic imaging

to visualize
fluorescently-labelled molecules
in *vivo*

Contact: Anouk Post at a.l.post@vu.nl

What is it?

- Our endoscope provides imaging similar to PET-CT by combining molecular and structural imaging of tissue
- With a high resolution (~0.02 mm) up to 2 mm in depth
- It can be used to create high-resolution images of hollow organs (e.g. lungs, oesophagus, …)
- It uses two advanced imaging techniques: Targeted Fluorescence (molecular) and Optical Coherence Tomography (structural)



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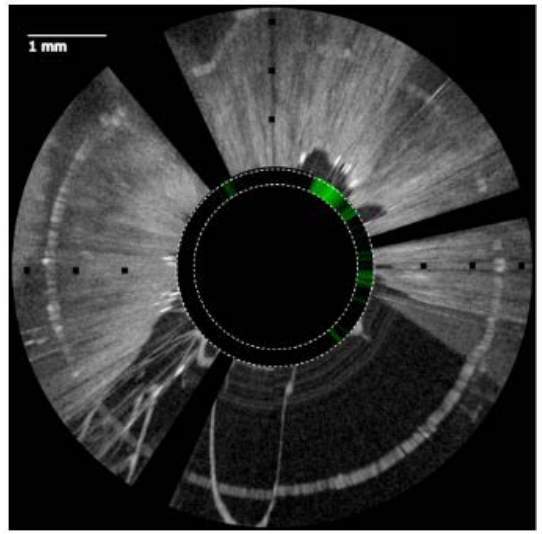
Contact: Anouk Post at a.l.post@vu.nl

How does it work?

- A fluorescent label can be attached to a molecule of interest that will light up when you illuminate it with our endoscope

- OCT provides an image of the tissue structure with a micrometer resolution



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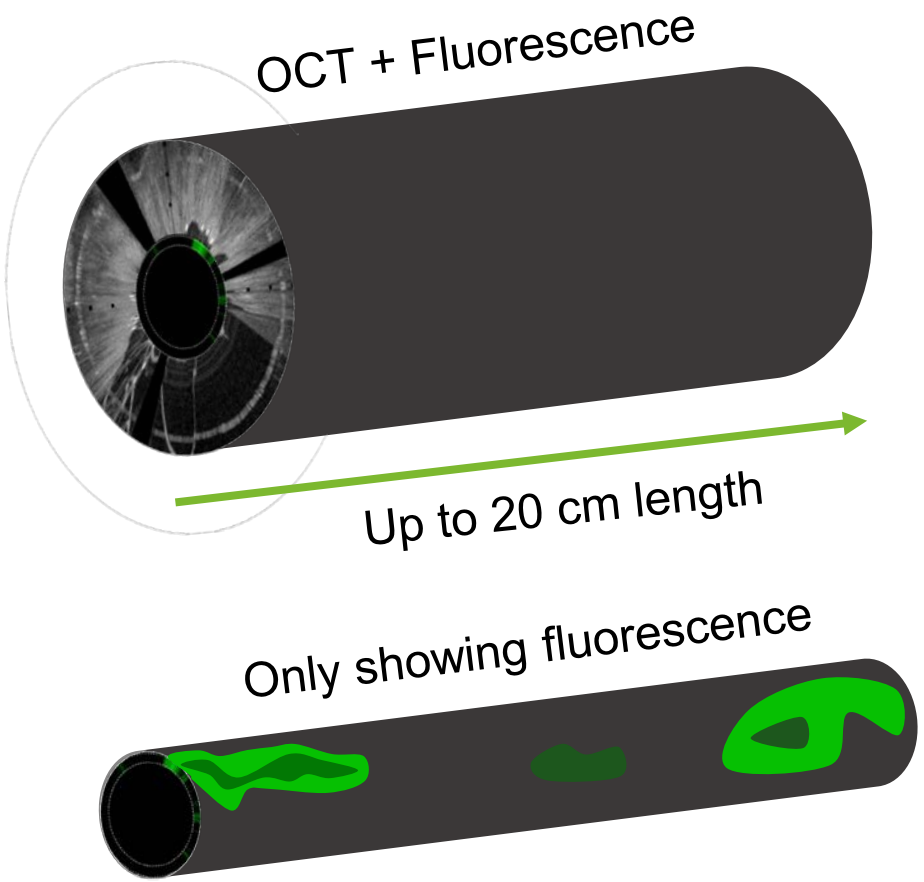
What can it do?



- Provide molecular information in structural context, similar to PET-CT
- Drug development: identify drug distribution in vivo by fluorescently-labelling a drug
- Disease diagnosis: by fluorescently-labelling biomarkers (e.g. a monoclonal antibody to detect cancer)

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Contact: Anouk Post at a.l.post@vu.nl

Who are we?

- Vrije Universiteit & VU Medical Center Amsterdam, the Netherlands
  Prof. Johannes de Boer, Professor of Biophotonics
- Physics group: development of novel imaging devices and data analysis methods
- Optical workshop: fabrication of new prototypes
- Tracer lab VUmc: development of new fluorescent tracers
- Hospital VUmc: execution of clinical studies

VU

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Contact: Anouk Post at a.l.post@vu.nl

What can we offer?

- Infrastructure to facilitate in vivo molecular imaging at unprecedented resolution
- Two prototype systems + endoscopes
  - 2 mm diameter for e.g. lungs
  - 1 cm diameter for e.g. oesophagus
- Development of prototypes more tailored to specific need
- Analysis of acquired data to relate to your application

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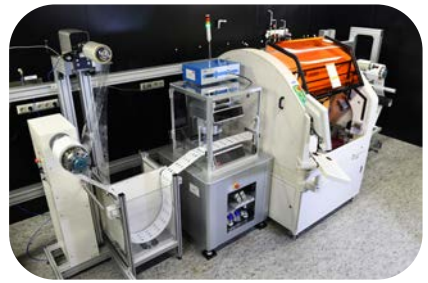
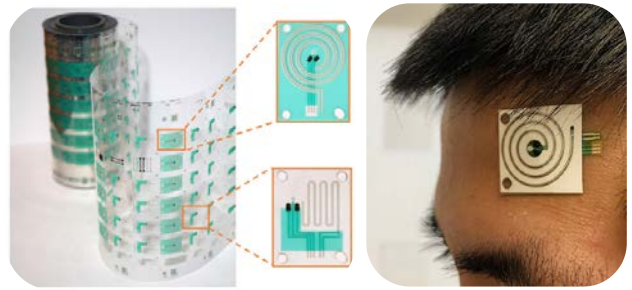
Topic 3. Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Development and production of diagnostic devices for point-of-care testing

Rannaste Lauri
Research Scientist
VTT Technical Research Centre of Finland Ltd
lauri.rannaste@vtt.fi

https://www.vttresearch.com/en
https://ihi-call-days.ihi.b2match.io/participations/207884
https://ihi-call-days.ihi.b2match.io/participations/207884/opportunities





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VTT

IHI participant ID: 207884

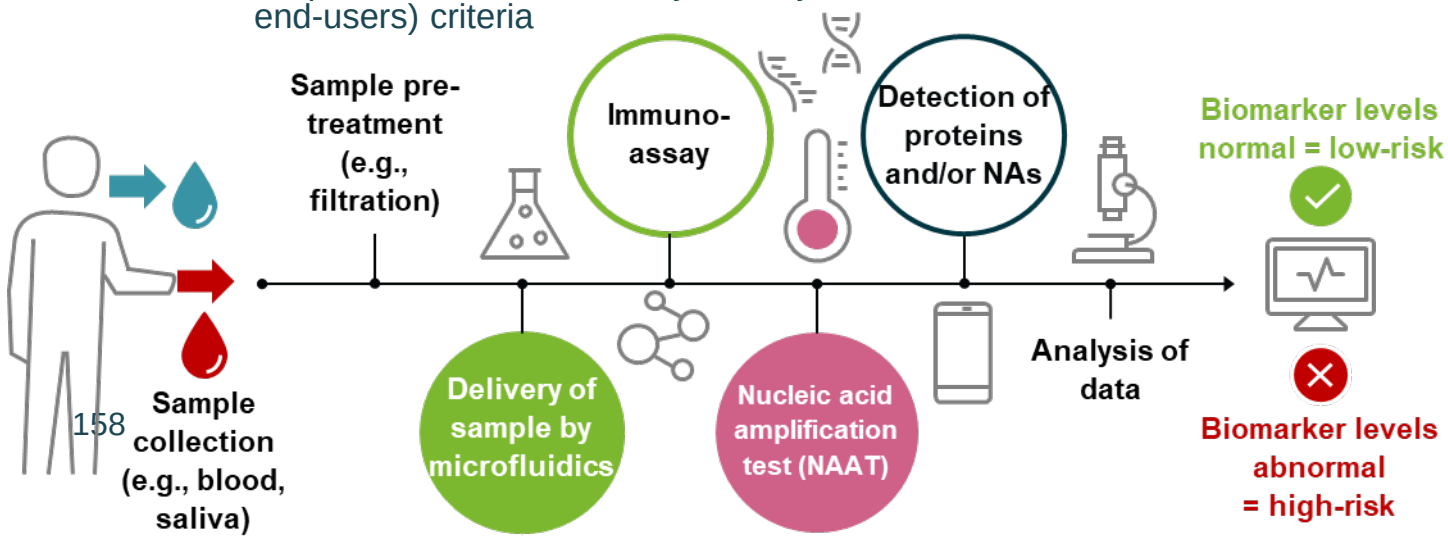
Challenges and objectives

Challenges: detecting multiple biomarkers with inexpensive and reliable diagnostic platform

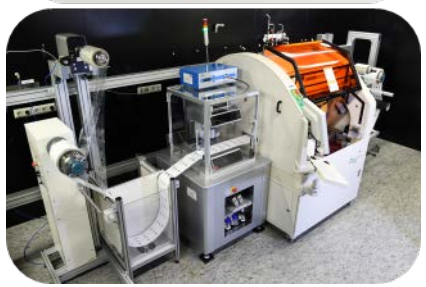
- Different technologies answer to different needs and all require different type of prototype development
- Scaling up prototypes require manufacturing capability with repeatability and reproducibility before they can be used in clinical validation
- Integration of different technologies as a single platform requires multidisciplinary expertise
- **REASSURED** (**R**eal-time connectivity, **E**ase of sample collection, **A**ffordable, **S**ensitive, **S**pecific, **U**ser-friendly, **R**apid and robust, **E**quipment-free or simple and **E**nvironmentally-friendly, **D**eliverable to end-users) criteria

Objectives: A biomarker or a panel of biomarkers can be adopted simultaneously to different levels

- Self-test for biomarker monitoring by the patient
- Rapid multiplexed point-of-care platform for healthcare professionals for personalized patient monitoring and rapid decision making
- Clinical diagnostic assay for conventional monitoring
- **Diagnostic platform that fulfills REASSURED** criteria



Mass-manufacturable PoC device for rapid diagnostics



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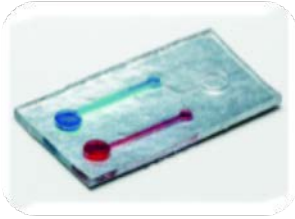
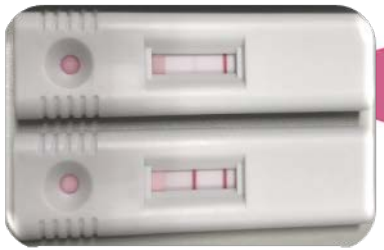
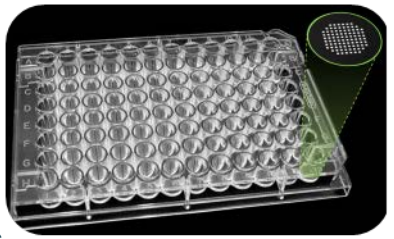
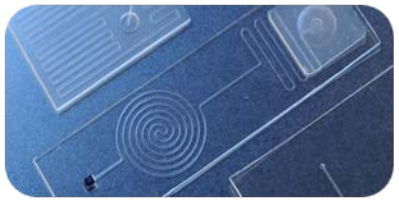
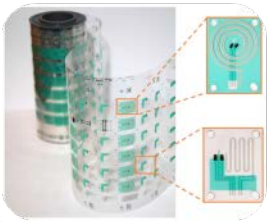
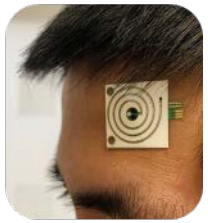
Main activities

VTT Technical Research Centre of Finland can provide comprehensive pipeline for diagnostics applications for the clinic and point-of-care (PoC)

- **Antibody discovery**
  - Conventional (protein antigens)
  - Proprietary technology for non-conventional targets (drugs, toxins, hormones)
- **Assay platforms development and manufacturing**
  - Conventional immunoassays, homogenous/single step immunocomplex assays
  - Lateral flow assays, microfluidics, multiplexed protein & antibody microarrays or nucleic acid tests
- **Detection methodologies and their development**
  - Colorimetric, luminescence, fluorescence, FRET, SPR, electrochemical
- **Manufacturing solutions and integration**
  - Recombinant proteins
  - Integrated microfluidics, lateral flow assays
  - Diagnostics platforms and wearables



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Expertise and resources offered

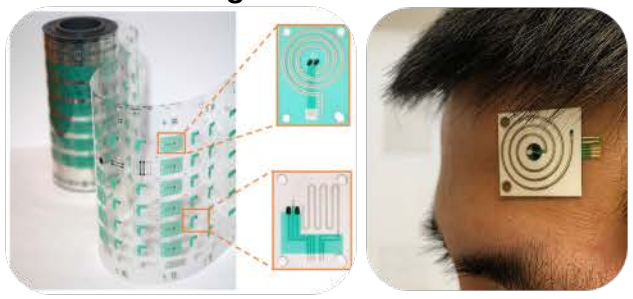
VTT Technical Research Centre of Finland can provide multidisciplinary experts/expertise and reach out our networks

- VTT is **an RTO** interested in partnering at any stage of our pipeline
- **ISO9001:2015 framework**
- Multidisciplinary research organization with focus on customer and partner success
- Proprietary and cutting edge technologies, experience in integration and manufacturing
- VTT biosensors is part of:
  - **MedPhab** (https://medphab.eu/) and **PrintoCent** (https://www.printocent.net/) consortiums, network of +50 companies from start-ups to SMEs, larger companies and research institutes

Heterologous protein manufacturing

Device and sensor technology

Sensor platform development with integrated microfluidics



Roll-to-roll / mass-Manufacturing and integration

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IHI Call Days | Call 7

Clinical Validation of Epigenetic Immune Cell Quantification for Early Diagnosis and Management of Patients with Disorders of the Immune System

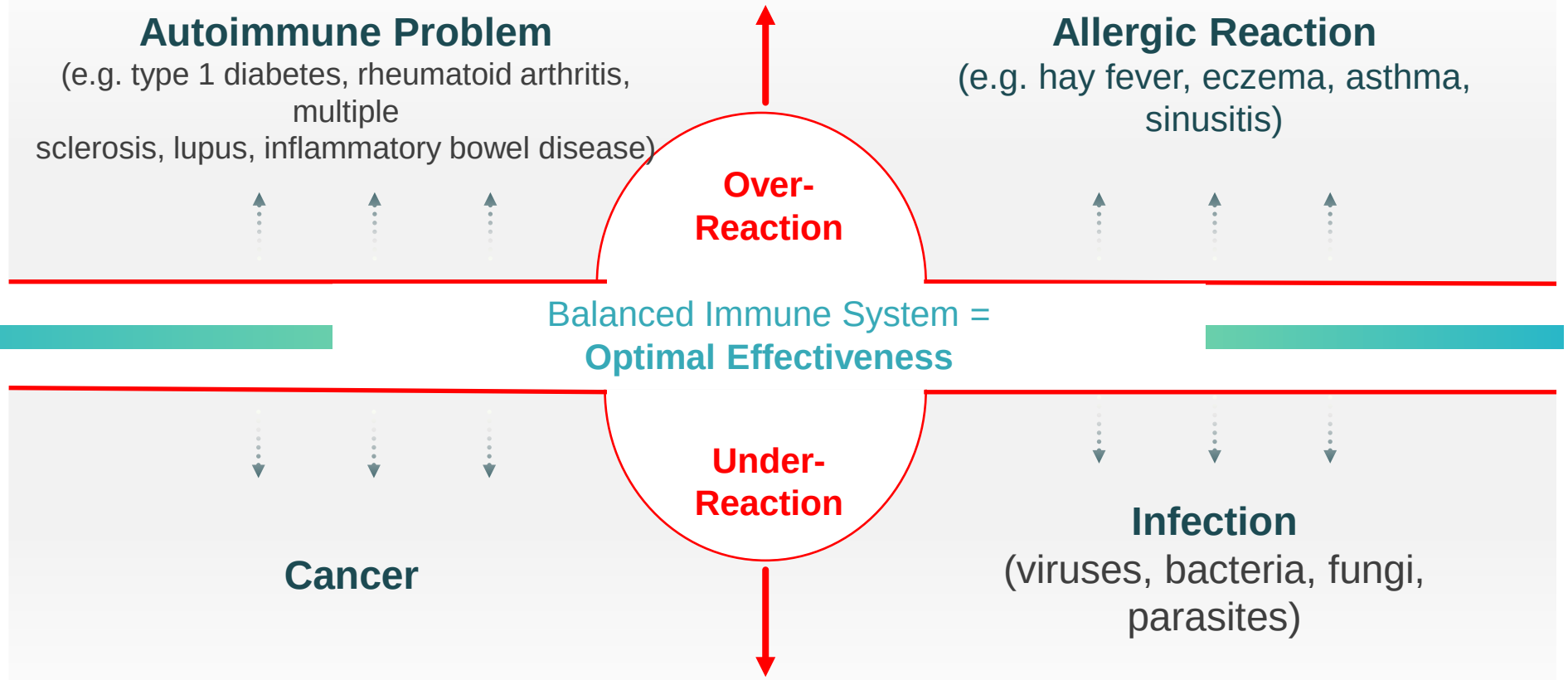
Christoph Sachsenmaier, PhD

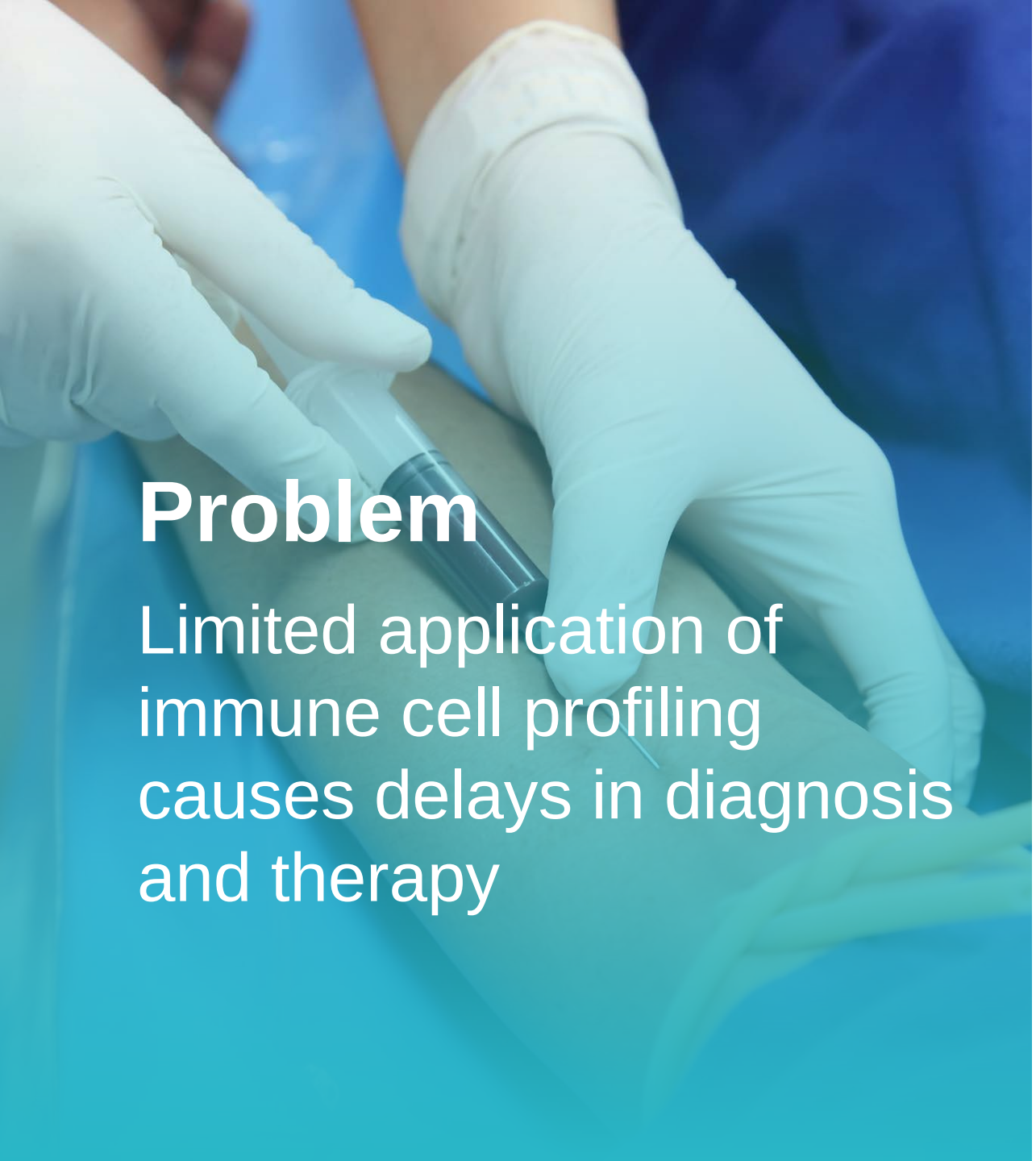
Epimune Diagnostics (Berlin, Germany)

E-mail: c.sachsenmaier@gmail.com

- Marketplace opportunity
- Participant profile

A Balanced Immune System is Essential for Health and Wellbeing





Problem

Limited application of immune cell profiling causes delays in diagnosis and therapy

EPIMUNE™ DIAGNOSTICS

Current Standard of Care – Flow Cytometry:

- Not part of routine blood check-up (CBC/Diff)
- Requires fresh blood to be analyzed within 24 hours
- Need trained personnel, high capital investment

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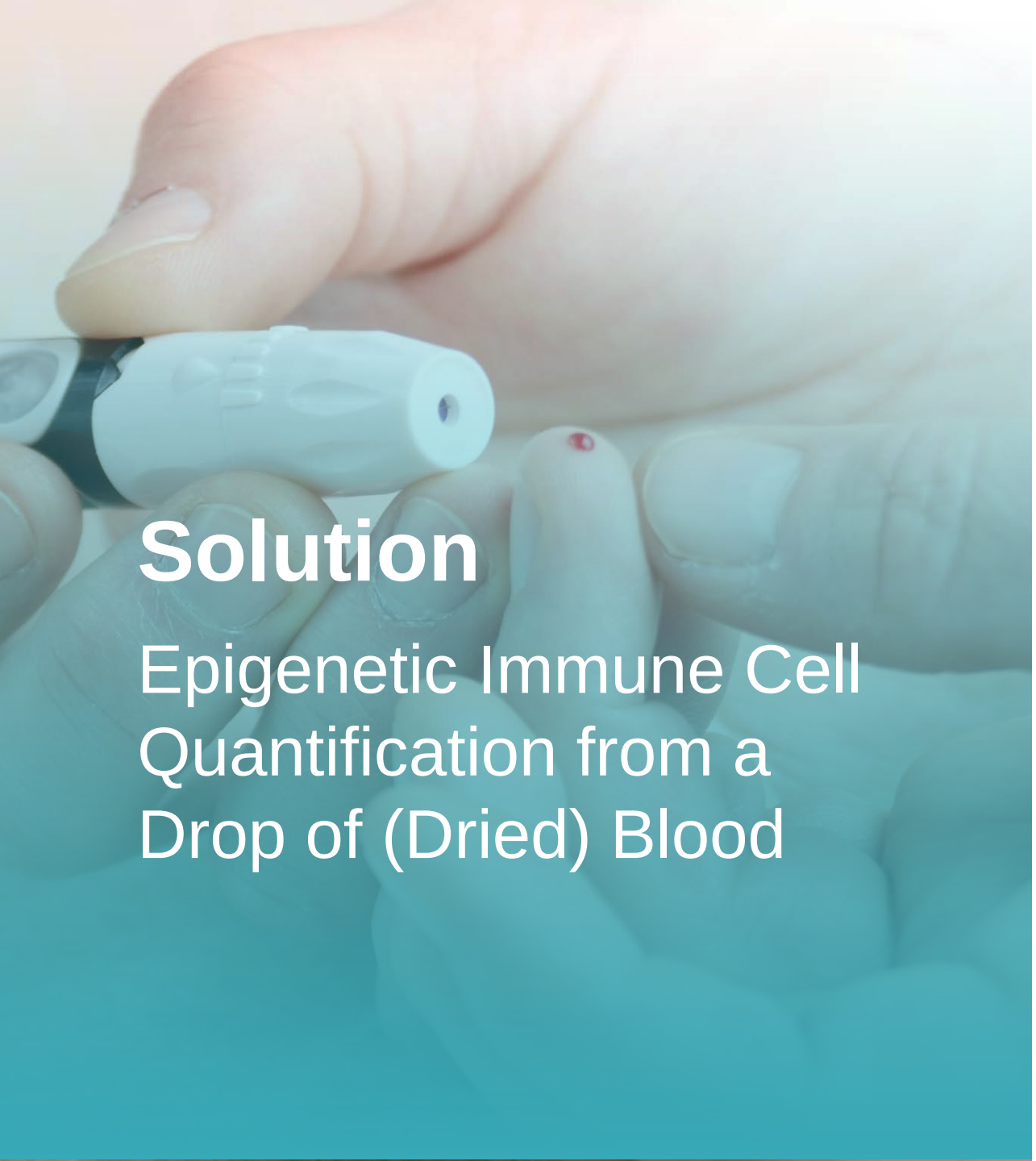

Solution

Epigenetic Immune Cell Quantification from a Drop of (Dried) Blood

i.Mune®

EPIMUNE™ DIAGNOSTICS

- Real-time PCR based
- Works on dried blood spots (DBS)
- Allows self-sampling

➢ **Early detection of immune disorders in patients with unspecific symptoms**

➢ **Newborn screening for Inborn Errors of Immunity**

➢ **Patient management (self-sampling)**

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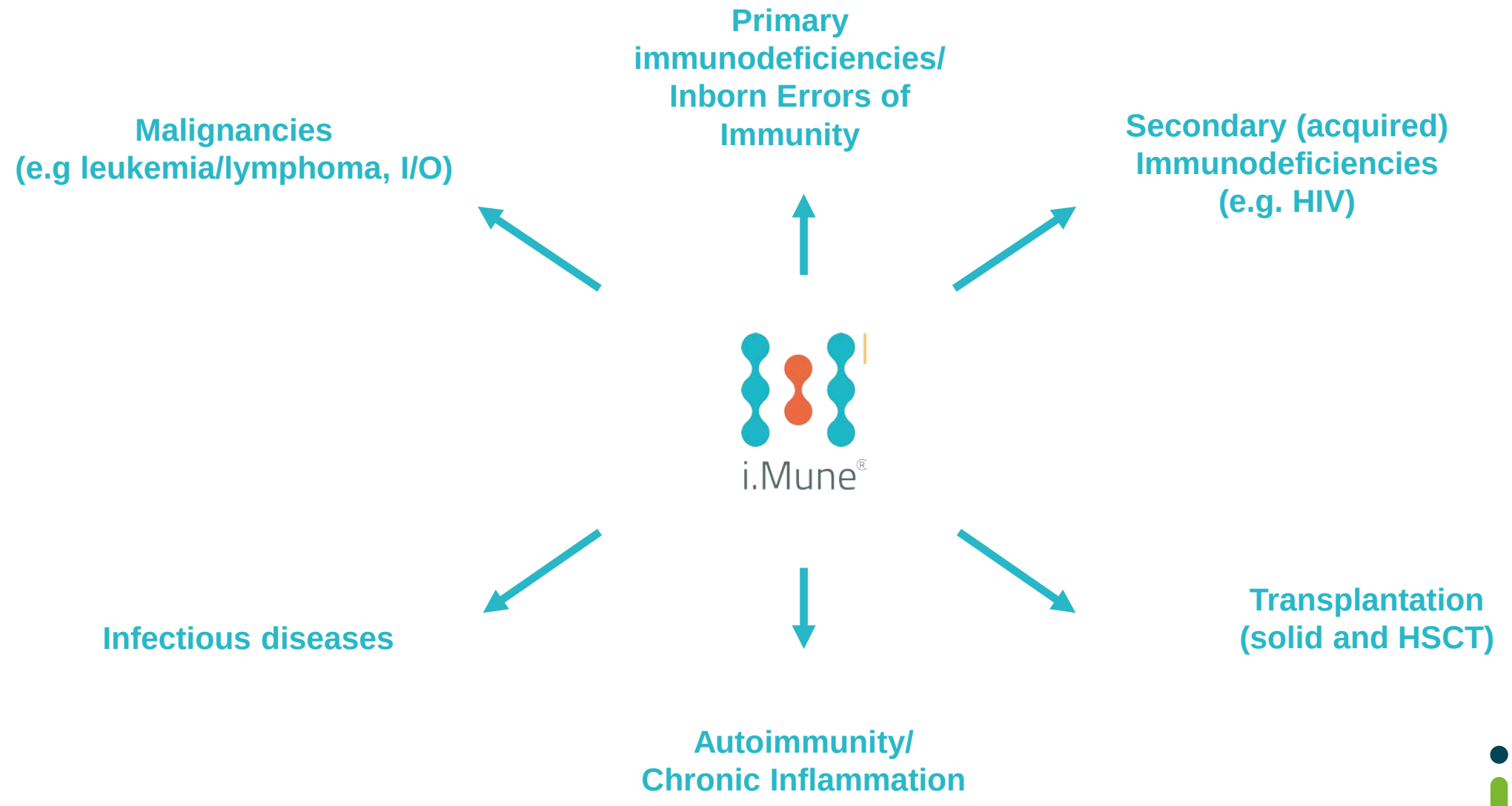
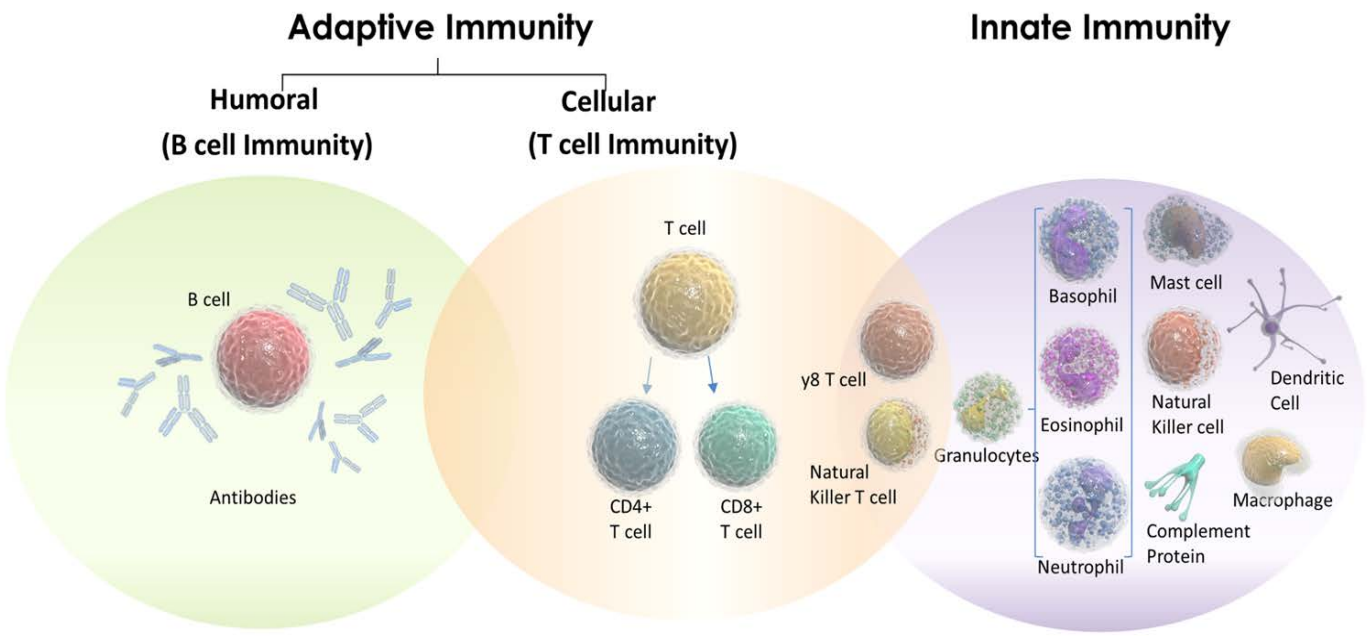
Clinical Applications



Epigenetic Immune Cell Quantification Platform



See: https://www.epimune-dx.com/english/services/ for available assays and applications

- CD19+ B cells
- Memory B-cells

- CD4+ T cells
- CD8+ T cells
- Overall T cells (CD3+)
- Naive CD8+ T cells
- Regulatory T cells (Treg)
- Th17 cells
- Tfh cells
- Memory CD4+ T cells

- NK cells (CD56 dim)
- Neutrophil granulocytes
- Basophil granulocytes
- Eosinophil granulocytes
- Monocytes
- Non-classical monocytes

- CXCR3+ cells
- CCR6+ cells
- PD1+ cells
- MDSC (myeloid derived suppressor cells)
- Plasmacytoid dendritic cells (pDC)
- Granulysin+ cells

Opportunity

Goal:

Clinical validation of epigenetic immune cell quantification in relevant indications

- CD4 cell quantification in HIV patients
- DBS-based monitoring of IEI patients
- Newborn screening
- …

Assets:

- Fully validated real-time PCR based epigentic immune cell quantification assays
- 3 (4) CE-IVD kits
- IVD development & manufacturing capabilities
- Testing laboratory (R&D)

Seeking:

- Clinical partners w/ suitable patient cohorts (retrosective/prospective)
- Patient organizations
- CRO (IVDR)

Potential:

- Game changer in managing patients with direct and indirect involvement of the immune system

Contact

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12489 Berlin, Germany

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Web: www.epimune-dx.com

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Topic 3. Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Certest's NGS Comprehensive Adaptive Platform to Address Unmet Medical Needs

Contact person name: Ines Valledor, Belén García-Manrique

Organisation: CERTEST BIOTEC

E-mail: innovacion@certest.es

Link to:

- Marketplace opportunity
- Participant profile

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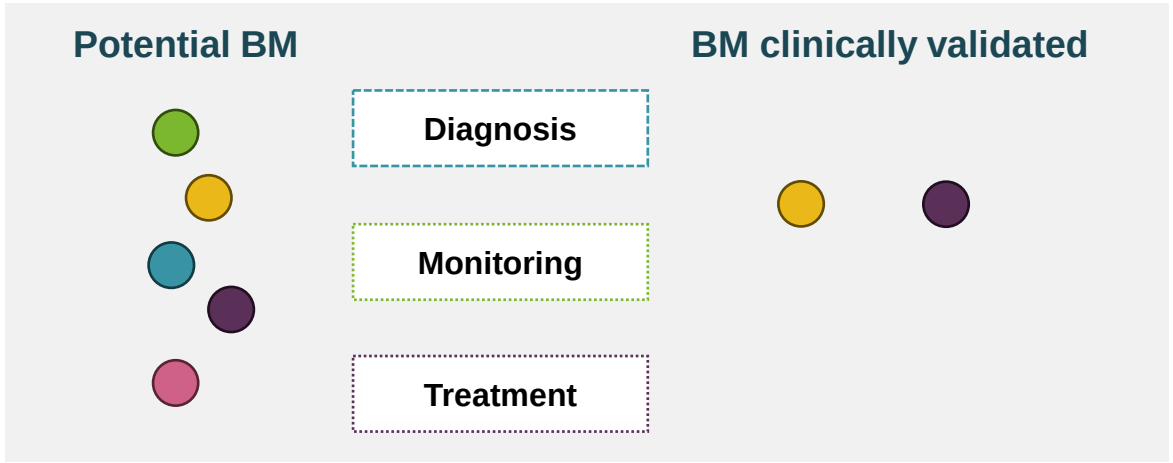
Challenges and objectives

Challenges



3.6% of EU children had unmet medical needs in 2021

3.2 % of EU people aged 65 years or over had **unmet medical needs** in 2022

Who are we?

- Spanish biotech company of IVD sector
- User-centric solutions for **biomarker detection**
- Immunodiagnostics and **molecular diagnostics**
- Applicable in various environments:
  - Hospitals, clinics, and laboratories

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Challenges and objectives

Our objective

- We aim to make an **impact in the healthcare sector** by providing **end-to-end**, **flexible**, **simple**, **user-friendly**, and **cost-effective solutions**.

certest

R&D → Clinical validation → Certification → Manufacturing → Market

EU-IVDR 2017/746

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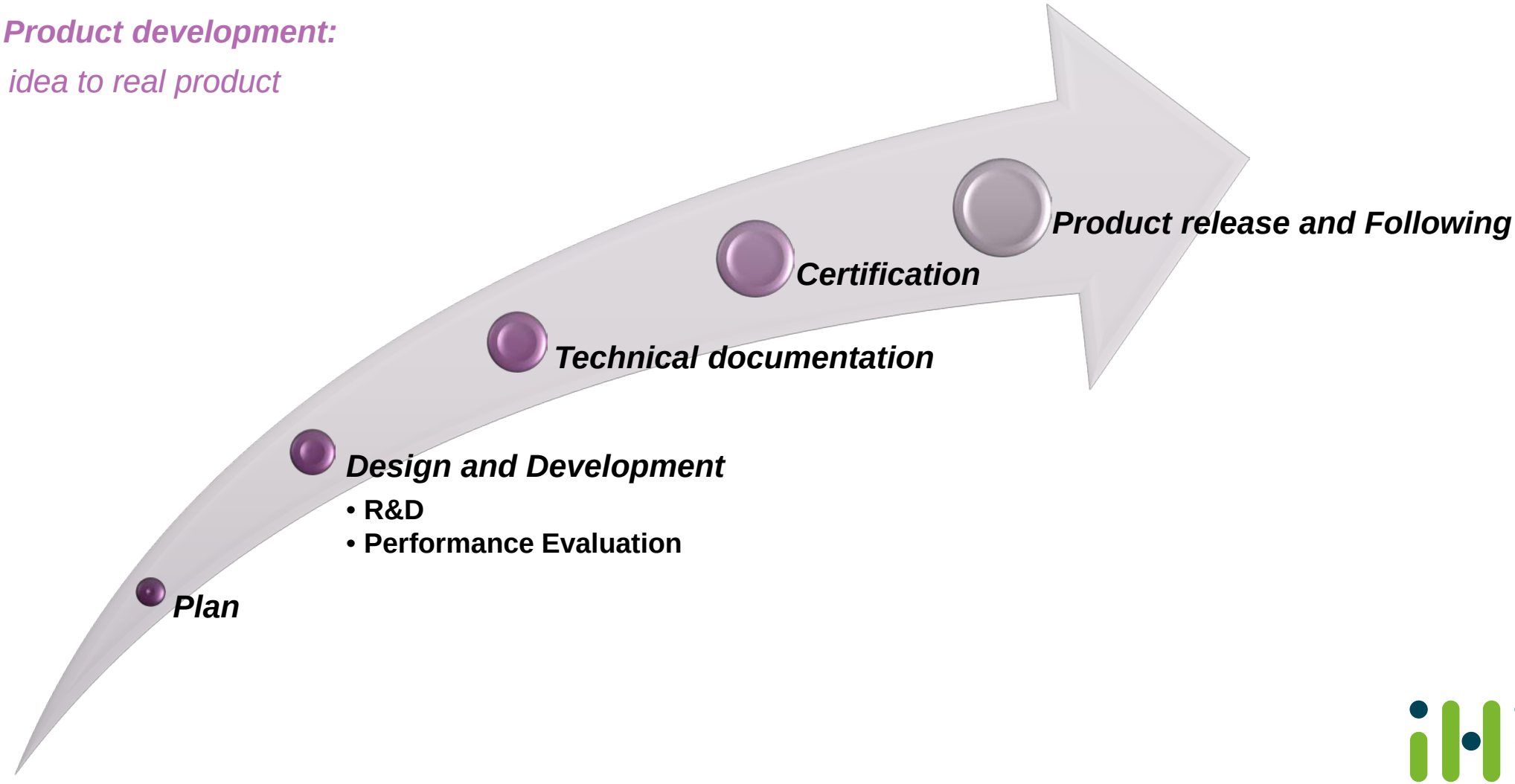
Main activities

What do we offer?

NGS Product development:

From idea to real product



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Main activities

What do we offer?

NGS Product development:

From idea to real product

R&D → **Scientific validity análisis** → **Establishment of initial requirements** → **Optimization** → **Design packaging** → **Software pipeline**

- **Panel design**
- **Optimization of library preparation**
- **Reagent synthesis**
- **Lyophilization**

- **Software development planning**
- **Software requirement analysis**
- **System design, implementation and software unit verification**
- **Software system testing**

Performance Evaluation → **Evaluation plan** → **Analytical performance** → **Clinical performance** → **Stability** → **Usability**

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Main activities

What do we offer?

NGS complete platform:

Everything needed from sample to result

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Expertise and resources offered

- **Experience developing In Vitro Diagnostic solutions**.
- **Experience developing and synthetizing raw materials** such as enzymes and oligonucleotides (primers, probes).
- **Experience complying with IVDR Regulation**. We perform extensive in-house analytical validation and always multi-centre clinical validation.
- **Partnerships and collaborations.** We seek to establish links with various institutions worldwide: public or private research centres, universities, hospitals or private diagnostic laboratories.

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Collaborations

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Thanks for your attention

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- Link to:

- Marketplace opportunity
- Participant profile