

Welcome to the pitching session on: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Presentation order	First Name	Last Name	Job position	Organization	Country
1	Oscar	Franco	Director of Department, Professor of Public Health	University Medical Center Utrecht - Julius Center for Health Sciences and Primary Care	Netherlands
2	Alessandra	Renieri	Full Professor, Director of Medical Genetics Unit, University of Siena	University of Siena	Italy
3	Jan	Baumbach	Professor	University of Hamburg	Germany
4	Svitlana	Surodina	CEO	Skein	United Kingdom
5	Oliver	Schmidt	Innovation Owner Clinical Condition Liver Cancer	Siemens Healthineers	Germany
6	Ana	Solana Sanchez	Lead MR scientist	GE Healthcare	Germany
7	Donato	Bonifazi	CEO	CVBF-EPTRI	Italy
8	Nadine	Nottrodt	Project manager	Fraunhofer ILT	Germany
9	Thomas	Hendel	Science Manager	Helmholtz Munich	Germany
10	Rachel	Steeg	EBiSC Project Manager	European Bank for induced Pluripotent Stem Cells	Germany
11	Anthi	Dzouveilidou		Collaborate Healthcare IKE	Greece
12	Arne-Christian	Faisst	CEO	4D Lifetec AG	Switzerland
13	Miroslav	Konecny	Project manager	GLYCANOSTICS, s.r.o.	Slovakia
14	Jan	Zuidema	CBO	Vivomicx	Netherlands
15	Marco	de Boer	CEO	Predica Diagnostics BV	Netherlands
16	Dominik	Geller	Founder & CEO	Hygiaso Ltd	Switzerland
17	Norberta	Balaisyte	Business developer	UniWeb BV	Belgium
18	Ana	Blanco Sanchez	Grants and Innovation Coordinator	Quibim SL	Spain
19	Malhar	Patel	Head of Clinical Engagement	Rhino Health, LTD	Israel

If you want to interact with other participants please use the chat function on the top right corner

Chat

How to contact the presenters?

Home Call days Agenda ▾ Organisations Participants Marketplace Project offers ▾ Pitchers - Call 3 Sessions



14:30 - 15:30	Matchmaking time - Topic: Strengthening the Advanced Therapy Medicinal Products (ATMP) therapeutic modalities for rare diseases
15:30 - 16:30	Pitching Session - Topic: Strengthening the Advanced Therapy Medicinal Products (ATMP) therapeutic modalities for rare diseases
Wednesday, December 14, 2022	
09:30 - 11:00	Info Session - Topic: Screening platform and prevention of diseases of unmet public health
11:00 - 11:30	Matchmaking time - Topic: Screening platform and prevention of diseases of unmet public health
11:30 - 13:00	Pitching Session - Topic: Screening platform and prevention of diseases of unmet public health
13:30 - 15:00	Info Session - Topic: Patient input and patient outcomes, support decision innovation
15:00 - 16:00	Matchmaking time - Topic: Patient input and evidence to improve patient outcomes, support decision innovation
16:00 - 17:00	Pitching Session - Topic: Patient input and evidence to improve patient outcomes, support decision innovation

Pitching Session Room 3
620 participants signed up for this session

DESCRIPTION:

Presentation order	Presentation title	First Name	Last Name	Job position	Organisation	Country
1	Global Research Initiative for Patient screening on NASH - (GRIP on NASH)	Oscar	Franco	Director of Department, Professor of Public Health	University Medical Center Utrecht - Julius Center for Health Sciences and Primary Care	Netherlands
2	Molecular biomarkers and clinical assessment of rare and common disorders	Alessandra	Renieri	Full Professor, Director of Medical Genetics Unit, University of Siena	University of Siena	Italy
3	Privacy-preserving AI for medical mechanotyping	Jan	Baumbach	Professor	University of Hamburg	Germany
4	Distributed data valuation technology and decision support system	Svitlana	Surodina	CEO	Skain	United Kingdom
5	ENGAGE - The challenge of liver cancer screening and outcome prediction	Oliver	Schmidt	Innovation Owner Clinical Condition Liver Cancer	Siemens Healthineers	Germany
6	PREDICTOM - Prediction of Neurodegenerative Disease using an AI driven Screening Platform	Ana	Solana Sanchez	Lead MR scientist	GE Healthcare	Germany
7	Biomarkers for diseases of public health interest - EPTRI Thematic Research Platform on Paediatric Biomarkers & Biosamples	Donato	Bonifazi	CEO	CVBF-EPTRI	Italy
8	Highspeed RAGE - Analytical platform for Highspeed cohort screening using Raman enhanced cell analysis	Nadine	Notrodt	Project manager	Fraunhofer ILT	Germany
9	NAKO - German National Cohort - a resource for health data and biosamples	Thomas	Hendel	Science Manager	Heimholtz Munich	Germany
10	European Bank for iPSCs	Rachel	Steag	EBISC Project Manager	European Bank for induced Pluripotent Stem Cells	Germany
11	Health, Clinical and Multi-omics Data Integration & Interpretation for precision health - prevention and management of chronic diseases	Antni	Douvididou	Special Projects Officer	Collaborate Healthcare IKE	Greece
12	High Sensitivity in Early Cancer Screening	Arne-Christan	Faist	CEO	4D Lifetec AG	Switzerland
13	Mind the Gap - Manufacturing of Immunoassay & Development of The Glycan Analysis Protocol	Miroslav	Konecny	Project manager	GLYCANOSTICS, s.r.o.	Slovakia
14	Last resort for hard to treat lung tumors	Jan	Zuidema	CBO	Vivomic	Netherlands
15	Novel 'targeted RNA sequencing technology' - oRNAseq	Marco	de Boer	CEO	Predica Diagnostics BV	Netherlands
16	Early Lung Cancer Screening	Dominik	Geller	Founder & CEO	Hyglass Ltd	Switzerland
17	Eforo - physical reserve monitoring a digital biomarker of frailty	Norberta	Balaisyte	Business developer	UniWeb BV	Belgium
18	Quibim: Transforming imaging data into actionable predictions	Ana	Bianco Sanchez	Grants and Innovation Coordinator	Quibim SL	Spain
19	Privacy-Preserving Data - Collaborations across Life Sciences	Malhar	Patel	Head of Clinical Engagement	Rhino Health, LTD	Israel

SPEAKERS:

- Norberta Balaisyte**
Business developer at UniWeb BV
- Jan Baumbach**
Professor at University of Hamburg
- Ana Blanco Sanchez**
Grants and Innovation Coordinator at Quibim SL



Thursday, December 15, 2022

IHI Call Days | Call 3

- **Global Research Initiative for Patient screening on NASH (GRIP on NASH)**

Contact person name: Prof Dr Oscar H Franco, MD, PhD

Organisation: University Medical Center Utrecht

E-mail: O.H.Franco@umcutrecht.nl

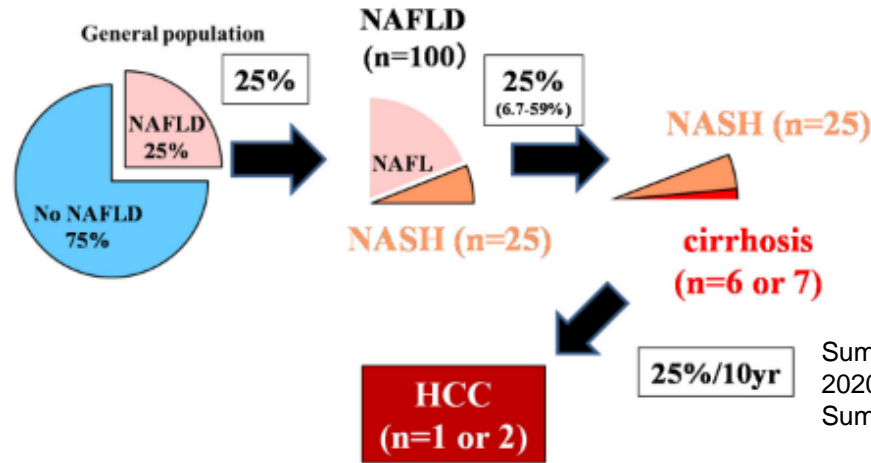
Link to:

- <https://nl.linkedin.com/in/oscar-h-franco-23992b10>
- www.umcutrecht.nl



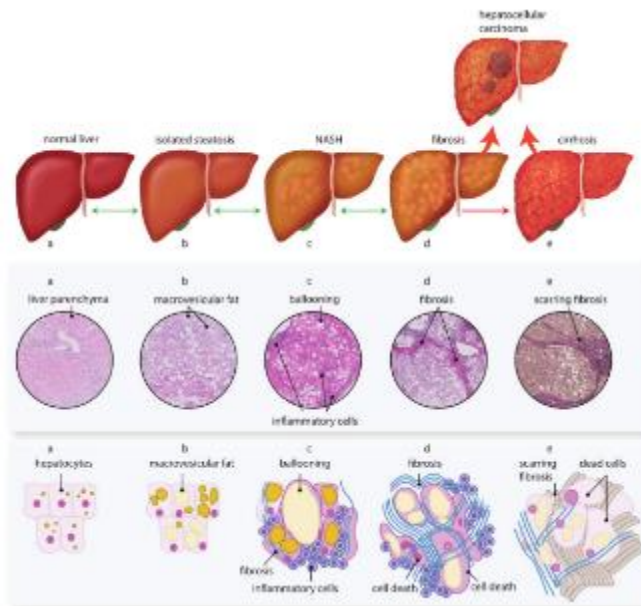
Challenges and needs

- NAFLD is a worldwide, rapidly increasing problem, linked to obesity and T2DM
- More research is needed to establish prevalence of NAFLD/NASH in different conditions
- Non-invasive tests are helpful tools for the diagnosis of NAFLD
- *Fibroscan* plays a central role in identifying patients at risk
- Multidisciplinary patient care pathways will improve identification of progressive patients, *but are not yet implemented*
- While drug development programs are promising, lifestyle intervention with body weight reduction remains the cornerstone



Sumida et al. Interv Obes Diabetes 2020; 3: 287
Sumida et al. Diagnostics 2020; 10: 579

Figure 1. The 25% rule in nonalcoholic fatty liver disease (NAFLD) [10].



Objectives

- A standardized patient care pathway improves diagnosis and management in clinical practice
-
- GRIP on NASH brings together PCP's and clinicians to help them implement a patient care pathway
 - GRIP on NASH will provide detailed information on prevalence and severity of the disease in different European countries
 - GRIP on NASH will identify novel targets for diagnosis and therapies by a multi-omics approach
 - GRIP on NASH will evaluate on a large scale the effects of lifestyle intervention in NAFLD/NASH

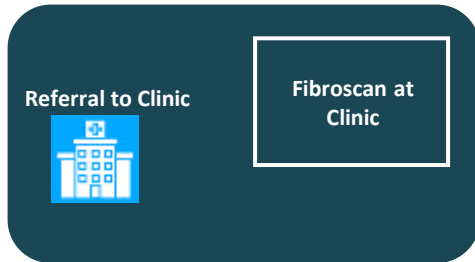


Main activities

1. Screen 10.000 high risk patients - 1000/country
2. Apply FIB-4 and FibroScan in each subject
3. Blood and liver samples to be sent to central lab (Amsterdam UMC, NL)
4. Start awareness campaign for professionals and patients
5. Educational programs

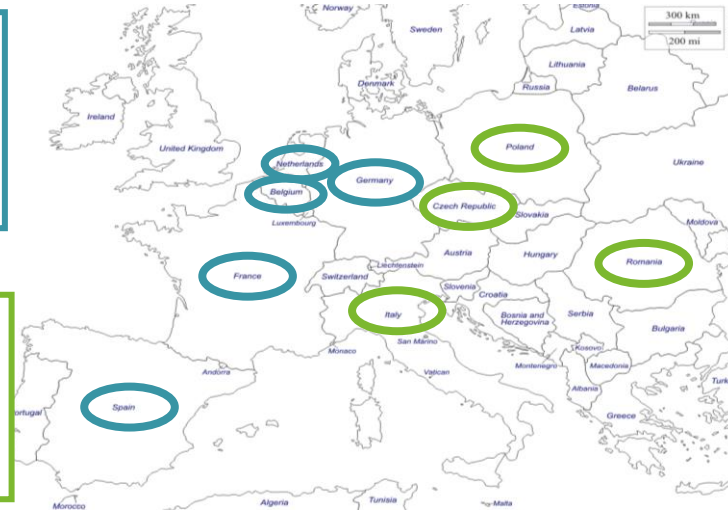
- GP / Primary Care Providers
- Patient awareness campaign
- Data Mining/apply AI
- Digital prescreening activity and telescreening

- high risk patients identified:
- Diabetes Melitus,
 - Hypertension,
 - Metabolic Syndrome,
 - Overweight/obesity



- > Start
1. Spain
 2. The Netherlands
 3. Germany
 4. Belgium
 5. France

- > Next tiers
1. Poland
 2. Czech Republic
 3. Italy
 4. Portugal
 5. Romania



F4: refer to clinic for further analysis and detailed Follow up

F2/F3: patients are referred back to PCP for Lifestyle intervention

After 3 months Lifestyle intervention patients are referred to Clinic for Fibroscan re-test

F0/F1: patients return to PCP to be followed there for their original condition

Repeat Fibroscan measurement after 3 years



Expertise and resources offered

- Scientific Steering Committee
 - Prof. Dr. D.E. Grobbee, UMC Utrecht, NL
 - Prof Dr. O.H. Franco, UMC Utrecht, NL
 - Prof. Dr. M Castro Cabezas, Erasmus MC, Franciscus Gasthuis&Vlietland Rotterdam, NL
 - Prof. S. Francque, University Hospital Antwerp, Belgium
 - Dr. A.G. Holleboom, Amsterdam UMC, NL
 - Prof. J.W.M. Muris, Maastricht UMC, NL
 - Prof. J. Schattenberg, University Medical Center Mainz, Germany
 - Dr. M.E. Tushuizen, Leiden UMC, NL
 - Prof. H. Cortez-Pinto, University of Lisbon, Portugal
 - Prof. C. Moreno, CUB Hôpital Erasme, Belgium
 - Prof. M. Romero-Gómez, University of Seville, Spain
 - Prof. L. Serfaty, Hautepierre Hospital, University of Strasbourg, France
- Independent Advisory Board
 - Prof. M.R. Taskinen, University of Helsinki, Finland
 - J Willemse, MSc, Director Dutch Liver Patients Association and Treasurer Liver Patients International
 - Prof. Marco Alings, Amphia Hospital, Breda, NL



Expertise requested

- Big pharma
- Medtech
- Big data companies
- Biomarker developers



IHI Call Days | Call 3

- Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Molecular biomarkers and clinical assessment of rare and common disorders

Contact person name: Alessandra Renieri

Organisation: University of Siena

E-mail: alessandra.renieri@unisi.it

Link to:

- Participant profile <https://en.unisi.it/ugov/person/10793>

Challenges and objectives

- prediction and prevention of human disorders
 - Many large biobanks have poor clinical description and patient re-contact not available
 - The project is suitable for IHI since require the collaboration between Academies and Companies
 - The newly post-Mendelian model developed for COVID-19 can be applied to any common disorders for prediction and prevention (about 80 % accuracy already)

Main activities

- Re-finement of the newly post-Mendelian model developed for COVID-19
- Application of the model to other common disorders
- Use of local biobank and registry (with re-contact of patients available) for testing the model

Expertise and resources offered

- Clinical and molecular expertise in rare and common disease ranging from nephropathy, muscular disorders, neurodegenerative and neurodevelopmental disorders, oncological diseases and acute and Long COVID.
- Vast biobank of biological specimens of rare disorders: 37.400 samples.
- 26.100 EHR of families with hereditary and sporadic disorders (consented for re-contacting)
- 7.500 Exome sequencing data of different disorders
- 5.000 Exome sequencing data of COVID-19

- Post-Mendelian model developed by ML methods using both common and rare variants *ref: Common, low-frequency, rare and ultra-rare coding variants contribute to COVID-19 severity Fallerini C., et al. Hum Genet 2021 Dec 10;1-27.*

Expertise requested

- List profiles for desired partners, by category
 - SME or large companies who want place the post-Mendelian model in the market for using in prediction and prevention of human disorders

IHI Call Days | Call 3

- Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Privacy-preserving AI for medical mechanotyping

Contact person name: **Prof. Dr. Jan Baumbach**

Organisation: **University of Hamburg**, <https://cosy.bio>

E-mail: jan.baumbach@uni-hamburg.de

Link to:

- Marketplace opportunity: <https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGIjaXBhdGlvbk9wcG9ydHVuaXR5OjUzMzE1>
- Participant profile: <https://ihi-call-days.ihi.b2match.io/components/25061?query=Baumbach>

Challenges and objectives

- **Main objective:**

Internationalize screening platforms by making population screening programs **big-data and AI-ready**

- **Major challenge:**

Preservation of patients' **privacy rights** → Collaborative, **federated approach** involving industry, academia and medical stakeholders

Challenges and objectives

- **Our approach:**

Modular **federated AI platform** based on H2020 FeatureCloud

- **Relation to topic's impact/outcomes:**

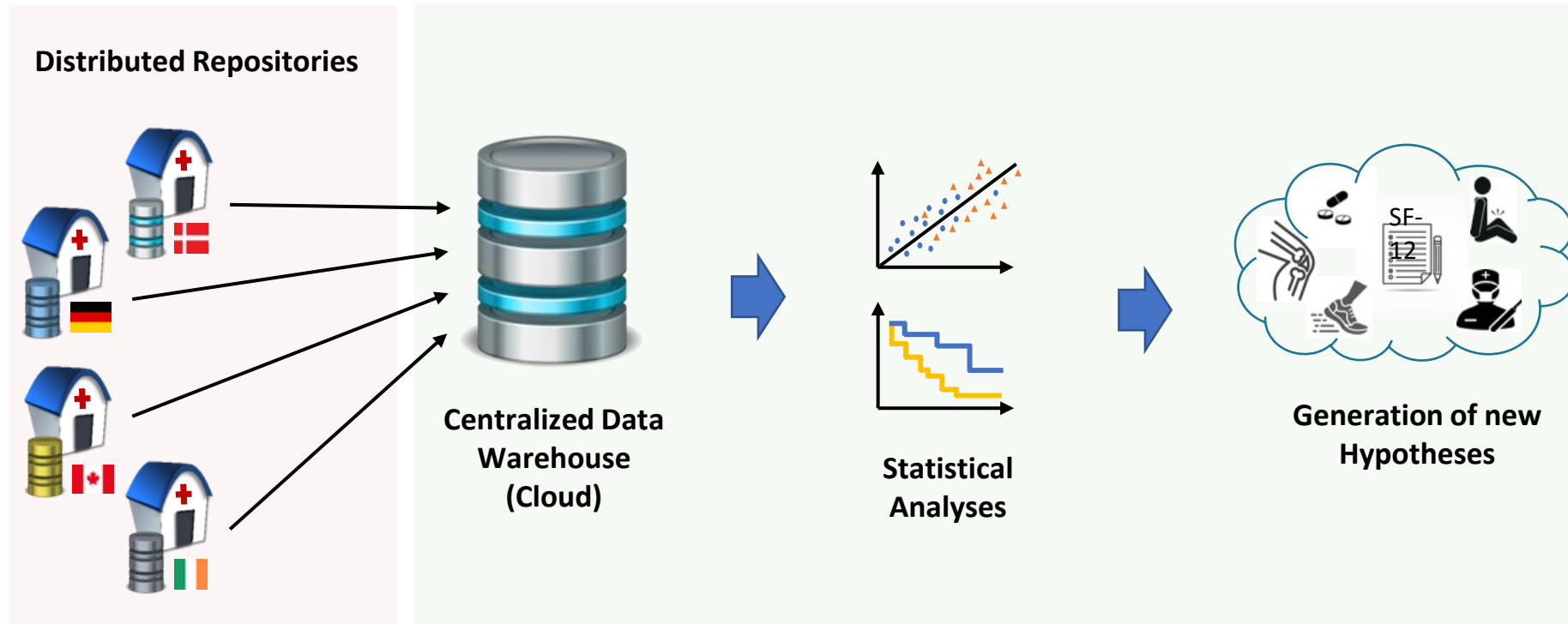
Improved patient risk stratification based on **mechanistic biomarkers**

- **Expected results:**

AI models and **AI store**/platform for risk/companion marker identification for screening platforms with **privacy-preserving, interoperable AI apps**

Main activities

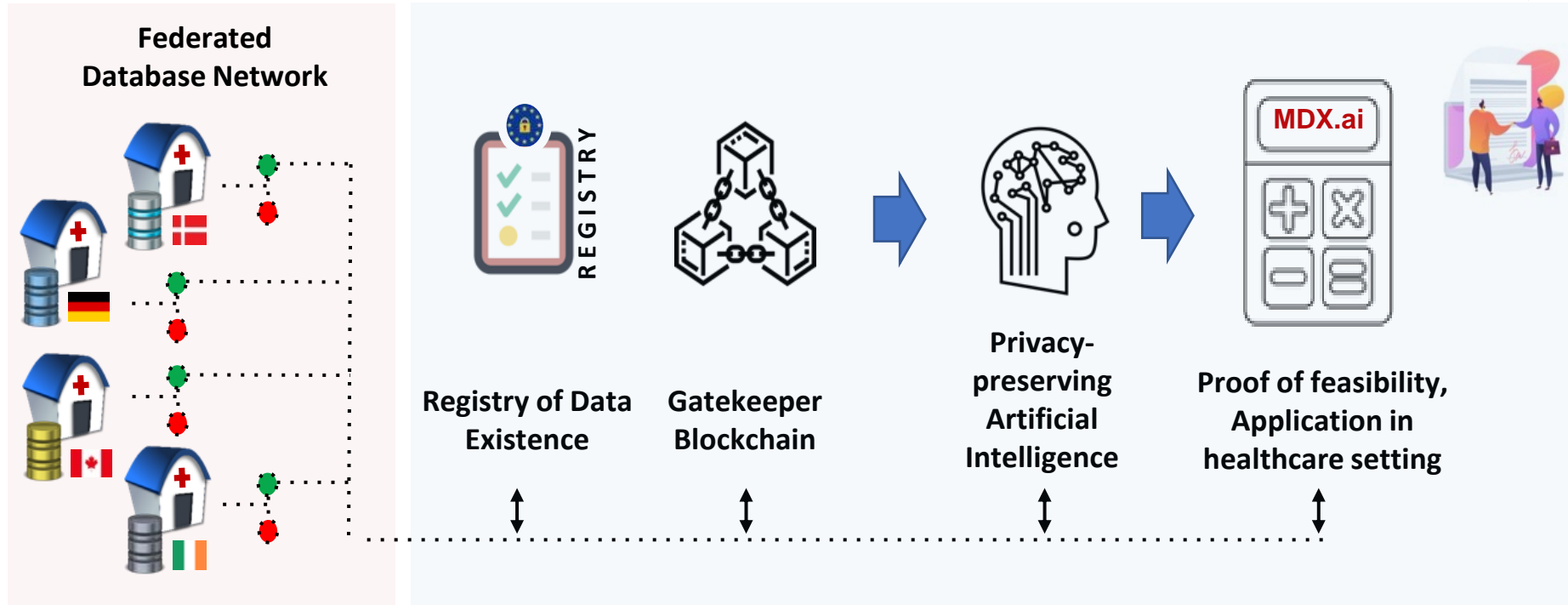
State of the art – Not privacy-preserving and not AI-driven



General population screening is not big-data-ready.

Main activities

Privacy-preserving AI-enhanced Network & Systems Medicine Approach



Federated database network and AI store to make population screening big-data-ready.

Expertise and resources offered

FeatureCloud

AI Store Help

REVOLUTIONISING
Privacy-Aware AI for Healthcare

Build machine learning models without programming knowledge and collaborate with other institutions without sharing your datasets.

AI Store Sign up

Privacy-Preserving AI
Federated Learning, Differential Privacy and Homomorphic Encryption enable a privacy-preserving analysis of your data. Across institutions.

Project Management
Create or join projects and collaborate with other institutions. Easily build workflows and run machine learning models with your collaborators.

AI Store
Our AI Store collects various AI models or whole analysis pipelines that can directly be used in your analysis.

↑ Top

The FeatureCloud consortium **experts:**

- AI/ML
- Omics
- Biomarkers
- Privacy
- Cyber security
- Ethics

Expertise and resources offered

The screenshot displays the FeatureCloud AI Store interface. At the top, there is a navigation bar with the FeatureCloud logo, 'AI Store', and 'Help' options. Below the navigation bar, a search bar and a filter sidebar are visible. The main content area shows a grid of application cards, each representing a different tool. The cards include:

- COX PH**: CoX PH Model (Survival Analysis (Regression))
- ADA BOOST**: Ada Boost (Classification)
- KM-ESTIMATOR**: Kaplan-Meier Estimator (Survival Analysis (Survival Curves))
- LOGISTIC REGRESSION**: Logistic Regression (Classification)
- LINEAR REGRESSION**: Linear Regression (Regression)
- GWAS**: GWAS - Chi-squared (Chi-Squared Test)
- NA-ESTIMATOR**: Nelson-Aalen Estimator (Survival Analysis (Survival Curves))
- EVALUATION**: Evaluation (Regr.) (Regression)
- CROSS-VALIDATION**: Cross Validation (Preprocessing)
- EVALUATION**: Evaluation (Classif.) (Classification)

Each card displays a star rating, a 'Federated computation' badge, and a list of supported features or methods.

> 60 apps

- 11 publications
- Apps for biomarkers
- Tested in hackathons
- Privacy certification
- Example: CRC screening

Expertise requested

- **Clinical partners**
 - Screening platforms / data providers
- **Large companies**
 - Pharma industry for companion & intervention marker discovery
- **SMEs**
 - Companies for lifestyle data / wearables
 - Legal & privacy certification
 - PREM & PROMs

IHI Call Days | Call 3

- Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Distributed data valuation technology and decision support system

Svitlana Surodina

Skein

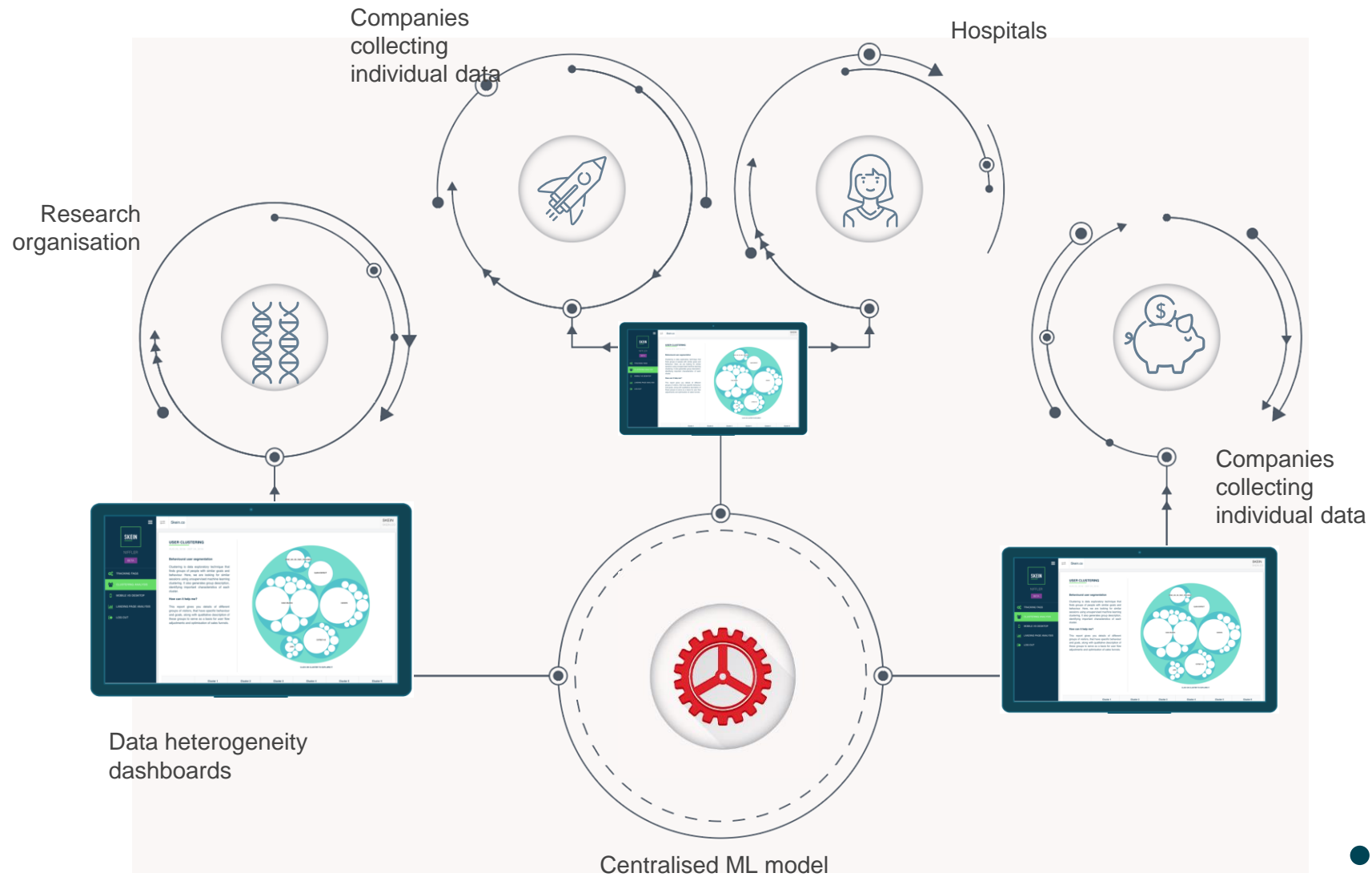
s@skein.co

- [Marketplace opportunity](#) 191938/opportunities
- [Participant profile](#) 191938



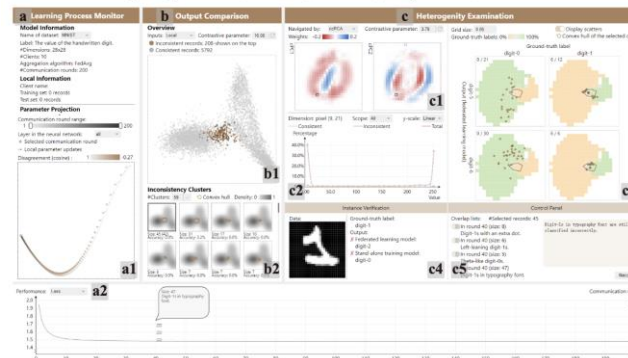
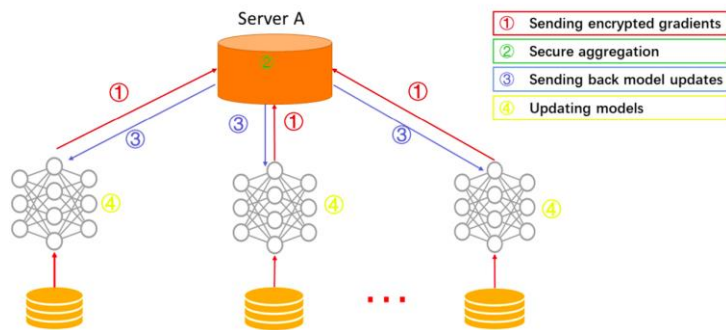
Challenges and objectives

- Ensuring ethical compliance of algorithms and data quality in AI-assisted decision making in the settings with limited data distributed across organisational silos:
 - Assess bias inherent in data, quantify and report ethical risks
 - Technology essential for most AI-supported medical diagnostic projects
 - The compliance dashboard is easily integrated into clinical research and operation workflows, saving millions on current and future compliance risks



Main activities

- Implementation and evaluation of existing technology
- Onboarding organisations - data holders
- R&D of visualisation modules, improving privacy
- Working with regulators on defining reporting formats and metrics



Expertise and resources offered

- Federated Learning-based data valuation technology
- Expertise in ethical AI, including methodologies, reporting and governance
- Ongoing research in visual decision support systems
- Capabilities in AI development and software R&D
- Experience with EU-funded projects, including EIT Health, two current Horizon Europe / 2020 grants
- Existing partners:



State of the Art Safety Standards in RA
THE EUROPEAN SOCIETY OF REGIONAL
ANAESTHESIA & PAIN THERAPY

Expertise requested

- We are looking for an industry or academic partner with access and need to collect personal data from distributed organisations, for example hospitals, to train prediction models, select patients for clinical trials and similar contexts.

IHI Call Days | Call 3

- Topic 1: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

ENGAGE

The challenge of liver cancer screening and outcome prediction

Contact person name: Oliver Schmidt

Organisation: Siemens Healthineers

E-mail: schmidt.oliver@siemens-healthineers.com

Link to:

- Marketplace opportunity: <https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGljaXBhdGlvbk9wcG9ydHVuaXR5OjU0NDcy>
- Participant profile: <https://ihi-call-days.ihi.b2match.io/participations/192295>

ENGAGE – Why Primary Liver Cancer?

#3 in mortality

> **830.000** Liver Cancer deaths per year, ~2.300 deaths per day

<16% survival rates

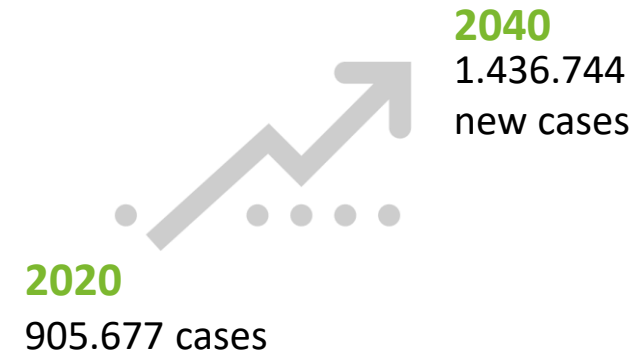
Consistently low average 5-year survival rates for last decades

Omnipresent risk factors



Asymptomatic occurrence

Incidence



high unmet public health need!!

ENGAGE - Objectives

Overcome the presentation of patient w NALFD cirrhosis and HCC in Europe

Select

Characterization of patients at risk for NASH cirrhosis and HCC through personalized screening strategies



Prevention

Detect

Early detection of pre-cirrhosis and HCC by multiparametric diagnostic/prognostic biomarkers



Therapy Selection

Navigate

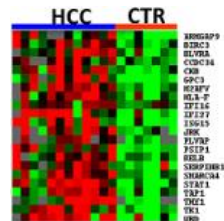
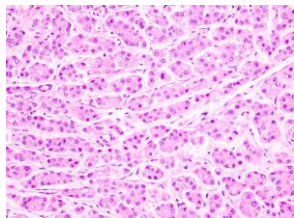
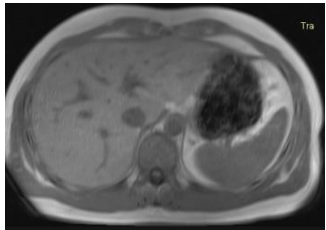
Tumor assessment and outcome prediction for available therapy options



Therapy Response

Main activities

- Clinical study with 3 arms to collect blood, stool and imaging data from patients at risk of liver cancer (NASH, Cirrhosis & HCC cohorts)
- Develop and test novel biomarker panels based on methylation and proteomic panels, MR/US imaging and elastography, and AI-driven combinations thereof
- Implement a patient engagement platform and data warehouse which consolidates results, provides educational material and invites participants to follow-ups



Expertise and resources offered

- Leading Clinics for Liver Cancer in Europe: Barcelona Clinic and AP-HP Beaujon providing clinical expertise, trial management and patient access
- Innovative Biotech: UniversalDX providing technology to detect cancer's signal in blood (in-kind contribution)
- Imaging Experts: Siemens Healthineers providing imaging and serum tests to risk stratify patients, detect and characterize cancer (IKOP & IKAA)



* IKOP - in-kind contributions to operational activities

** IKAA - in-kind contribution to additional activities

Expertise requested

- Large Companies that help to **increase in-kind contributions**
 - Pharma and MedTech companies interested in biomarker research for NASH and HCC and longitudinal disease management
 - IT companies interested in establishing data warehouses, AI frameworks and patient engagement platforms
 - Insurance companies interested in developing population health programs in metabolic disease and cancer prevention
- Research institutes and SMEs helping with health-economical modelling and AI research



IHI Call Days | Call 3



Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

PREDICTOM

Prediction of Neurodegenerative Disease using an AI driven Screening Platform

Contact person name: Ana Beatriz Solana, Timo Schirmer, Matthias Müllenborn

Organisation: GE Healthcare (ABS, TS); NovoNordisk (MM)

E-mail: anabea.solana@ge.com

Link to Marketplace:

- <https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGljaXBhdGlvbk9wcG9ydHVuaXR5OjU0NDY1>

PREDICTOM: Challenges and Objective

Onset of Neurodegenerative disease (NDD) precede first symptoms by many years

Consequences:

- Intervention in clinical trials might be too late with suboptimal success
- Poor disease management leading to huge societal burden

Opportunities:

- Early detection biomarkers, blood-based & imaging & other biomarkers for comprehensive personalized patient management
- AI engines & platforms

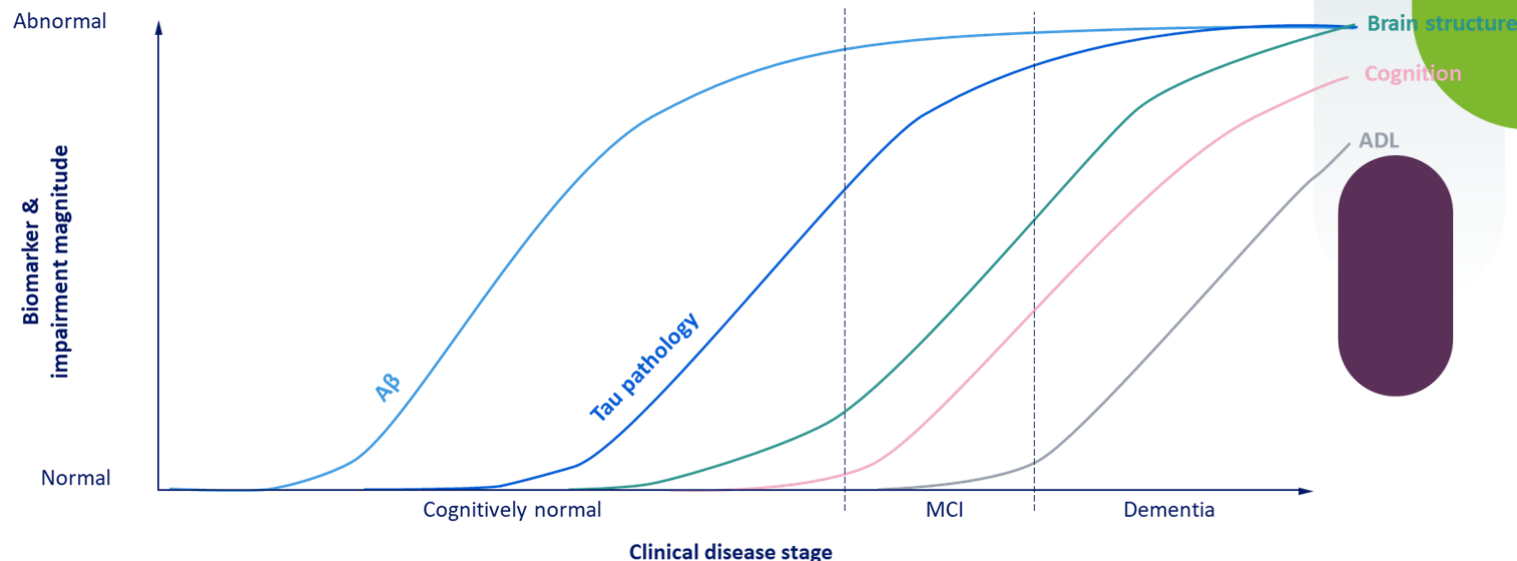
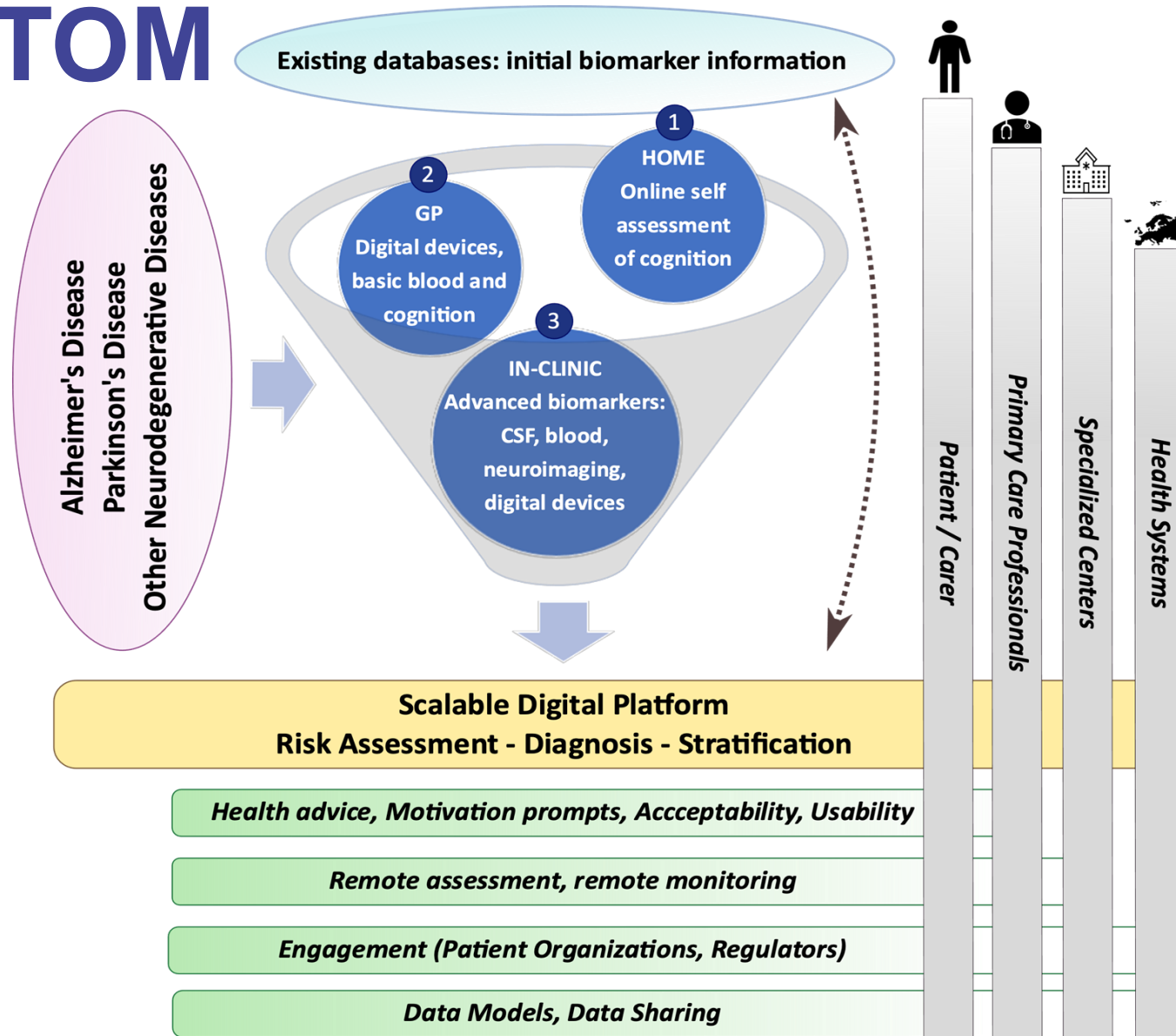


Figure adapted from Aisen PS et al, 2017¹ Courtesy of Novo Nordisk
Aβ, amyloid beta; AD, Alzheimer's disease; ADL, activities of daily living; MCI, mild cognitive impairment
1. Aisen PS et al. Alzheimers Res Ther 2017;9:60; 3. Alzheimer's Association Report. Alzheimers Dement 2020;16:391-460

PREDICTOM Objective: Develop an AI driven biomarker screening platform for NDD early diagnosis

PREDICTOM

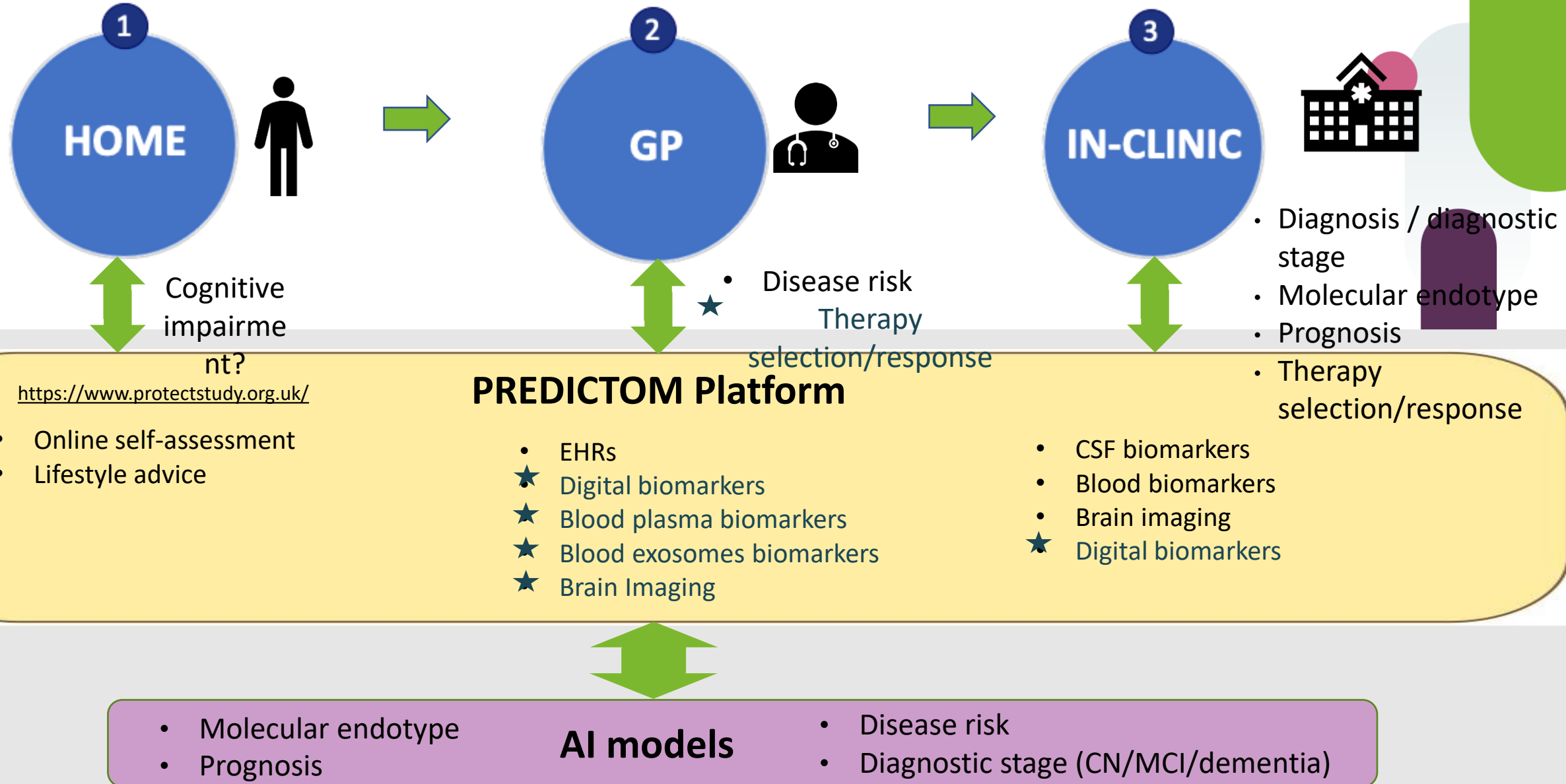


Cohort Screening Study aiming at general population, spreading across Europe.

Platform to identify people at risk at the very early stages.

Simplified, cost-efficient technology access enabling frequent clinical & research use.

PREDICTOM: Data Flow



PREDICTOM

Preliminary Partners

COCIR

- GE Healthcare*
- Siemens Healthineers*

EFPIA

- NovoNordisk*
- Pfizer*

SME

- Lygature

Research Institutes

- CERTH
- Erasmus MC
- Fraunhofer
- ICM
- JOANNEUM RESEARCH, Digital
- KCL
- LMU

Other

- NICE
- Alzheimer Research

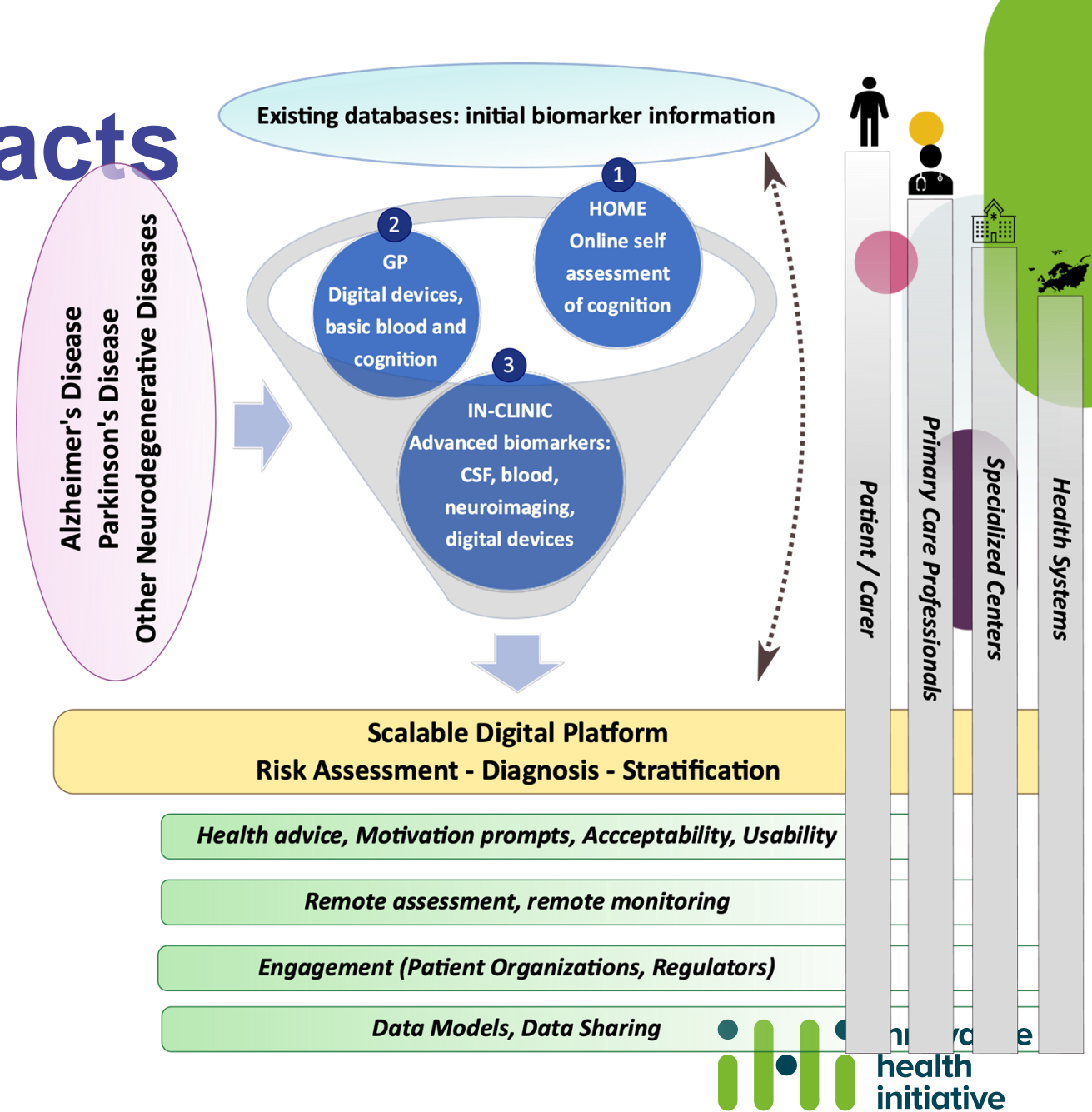
Potential Partners

- Biomarker analysis experts
- Regulatory experts
- Clinical study/drug development designers
- IT/software developers
- Healthcare system stakeholders & Healthcare training experts
- Novel biomarker measurement providers

* = in-kind contributors

PREDICTOM : Contacts

- Matthias Müllenborn, PhD (Novo Nordisk), zmul@novonordisk.com
- Timo Schirmer, PhD (GE Healthcare), timo.schirmer@med.ge.com
- Ana Beatriz Solana, PhD (GE Healthcare), anabea.solana@ge.com



IHI Call Days | Call 3

● Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Biomarkers for diseases of public health interest –
EPTRI Thematic Research Platform on Paediatric Biomarkers &
Biosamples

Contact person name: Donato Bonifazi

Organisation: European Paediatric Translational Research Infrastructure

E-mail: dbonifazi@eptri.eu

Link to:

- Marketplace opportunity: <https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGljaXBhdGlvbk9wcG9ydHVuaXR5OjU0MTg4>
- Participant profile: <https://ihi-call-days.ihi.b2match.io/participations/192138, www.eptri.eu>

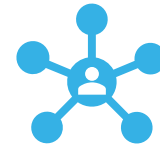
Challenges and objectives: biomarkers in paediatrics

- **The paediatric population represents an important group affected by unmet public health needs, as they show vulnerabilities that are unique to childhood.**

E.g. Antibiotic resistance, obesity, diabetes, neurodevelopmental disorders (mental health), asthma and respiratory diseases, allergy, gastrointestinal diseases and refractory childhood cancers.
- Whilst the use of extrapolation approaches to establish efficacy in children based on treatment response in adults may be applicable in some cases, there are many conditions in which **the availability of biomarkers could contribute to the faster characterisation of efficacy and safety in this population.**
- However, the identification and adoption of biomarkers to be used in paediatric subsets is a challenging field:
 - access to paediatric samples is necessary to ensure adequate evaluation of the predictive and prognostic performance of biomarkers in children. To date there is limited standards to ensure collection of biomarkers along with all relevant metadata (including treatment and patient characteristics)
 - current efforts are often limited to -omics/phenotypical aspects, ignoring how age-related changes interfere or modulate pathways and disease (i.e., ontogeny-related differences)
 - there are no integrated repositories or federated databases that would enable data mining and integration of data on biomarker, disease and intervention (e.g. PK, PD, safety and efficacy), which are well organised and in line with ethical and quality standards
 - paediatric diseases are rarer than adult diseases with small and diverse patient population making less attractive investments in paediatric research

Challenges and objectives: the EPTRI perspective in EU

- EPTRI is a pan-European initiative involving more than one hundred research units gathered together **to boost the paediatric research ecosystem** and provide services for the development of medicines for children.
- It acts as is a **distributed Research Infrastructure** organised with a Central Hub and several Spokes, represented by several research units grouped both within Thematic Research Platforms – TRPs (according to their field of expertise) and National Nodes (according to their location).



Centralised services
managed and delivered directly at Central Management Office level



Integrated services
provided through the five TRPs
according to their specific
research area of expertise

- EPTRI would like therefore to actively **collaborate with consortia** on the implementation of research activities to demonstrate the value of biomarkers as a tool for prognostic purposes, for predictors of efficacy and safety, with particular interest in areas where evidence generation based on controlled clinical trials in children is not easily feasible or practical.
- Through the creation of a curated environment, EPTRI expects to demonstrate how biomarkers can be used for early disorders detection and to support the development of novel medicines for children, including personalized medicines.

Challenges and objectives: the EPTRI role

Integrated services are provided through the five TRPs according to their specific research area of expertise



**Paediatric Medicines
Discovery**



**Paediatric
Biomarkers and
Biosamples**



**Developmental
Pharmacology**



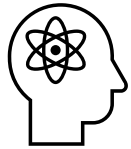
**Paediatric Medicines
Formulations**



**Paediatric
Medical Devices**

Expertise and resources offered

EPTRI includes a Thematic Research Platform (TRP) on Paediatric Biomarkers & Biosamples that can support activities related to biomarkers identification and validation. The TRP includes around 30 Research Units from 14 Eu/non-Eu countries, working in different therapeutic areas.



Science & methodology

- Identification and characterisation of biomarkers (transcriptomics, proteomics, metabolomics) in paediatric samples
- **Access to deposit of annotated paediatric biological samples**
- Bioinformatics
- Large-scale cohort screening study including neonates, infants, children and adolescents with the support of large paediatric clinical centres



Networking

- Using **biomarkers in conjunction with PKPD modelling and simulation** to support study design optimisation (e.g. enriched designs), dosing algorithms (i.e., personalised regimens),
- **Digital technologies and evaluation of biomarkers using advanced statistical and computational tools**
- Delivery of novel point-of-care testing (POCT) aimed at early identification and classification of patients who are candidate to receive biologic treatment..



Bioinformatics & data curation

- **Use of biomarkers for diagnostic/prognostic purposes and as basis for prediction of treatment response for the optimization of paediatric clinical trials and dose personalization.**
- Systematic review of clinically relevant differences between adult and paediatric conditions, through the use of innovative computational tools



Regulatory & writing

- Monitoring changes of markers of oxidative stress levels by using wearable devices, for the direct and non-invasive detection in biological fluids (e.g., **sweat, saliva** and exhaled breath condensate)
- **Regulatory qualification process of paediatric biomarkers**
- Contacts with patients' associations/YPAG for age tailored training/empowerment approaches starting from early childhood

References

- ID-EPTRI Deliverable 2.9 “Final Conceptual Design Report”.
- Catchpoole DR, Carpentieri D, Vercauteren S, Wadhwa L, Schleif W, Zhou L, Zhou J, Labib RM, Smits E, Conradie EH. Pediatric Biobanking: Kids Are Not Just Little Adults. Biopreserv Biobank. 2020 Aug;18(4):258-265. doi: 10.1089/bio.2020.29071.djc. Epub 2020 Jul 20. PMID: 32706974.
- Goldman J, Becker ML, Jones B, Clements M, Leeder JS. Development of biomarkers to optimize pediatric patient management: what makes children different? Biomark Med. 2011 Dec;5(6):781-94. doi: 10.2217/bmm.11.96.
- Shores DR, Everett AD. Children as Biomarker Orphans: Progress in the Field of Pediatric Biomarkers. J Pediatr. 2018 Feb;193:14-20.e31. doi: 10.1016/j.jpeds.2017.08.077.
- EFGCP-EFPIA joint report on paediatric unmet medical needs <https://www.efpia.eu/media/413577/efgcp-efpia-joint-report-on-paediatric-unmet-medical-needs.pdf>

IHI Call Days | Call 3

- Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need
Highspeed RACE - Analytical platform for Highspeed cohort screening using Raman enhanced cell analysis

Contact person name: Dr. Nadine Nottrodt

Organisation: Fraunhofer Institute for Lasertechnology ILT

E-mail: Nadine.Nottrodt@ilt.Fraunhofer.de

Link to:

- [Marketplace opportunity](#)
- [Participant profile](#)

Challenges and objectives

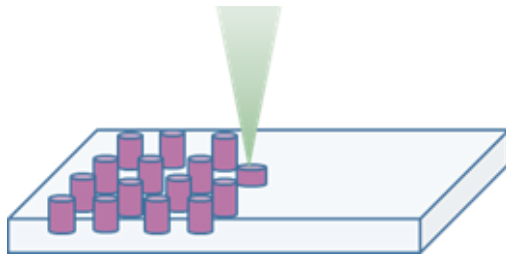
Enable **individually tailored therapies**.

- The basis is the search for **new biomarkers** that will help to better assess individual prognosis and likely therapy response.
- Miniaturisation of **screening** technology to detect biomarkers from large cohorts of patient samples base on a platform technology
 - **Problem:** Handling and analysis of **large cohorts** of patient samples to identify new biomarkers
 - **Solution:**
 - Reduction of sample volume, providing new chip designs
 - Automation of preparation, handling and analysis of samples using AI
 - Using new biomarkers to develop Organ-on-chip models for therapy development
 - Plattform allows for standardization and broad application

Main activities

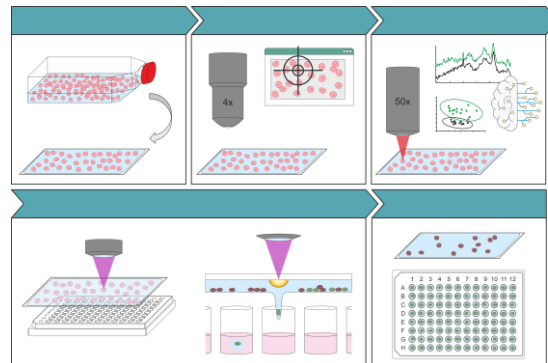
Assay development

- Parallelization
- Chip design
- Miniaturisation
- μm scale
- Laser based free-form



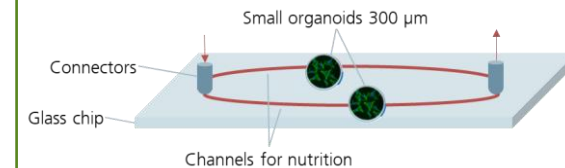
Process automation

- New machine concept
- Laser based sample isolation
- Raman analysis
- Fluorescence detection



Model development

- Collect analytical data
- Use deep learning algorithms
- Develop new disease models on chip
- Evaluation of new therapies



Expertise and resources offered

- **Fraunhofer institute for laser technology ILT (research institute)**
 - Expertise in Laser base Cell sorting processes
 - Process automation and machine concepts
 - Micro- and nanostructuring of Glass and other materials
 - Experts for optical analytics
- **LPKF (large company)**
 - Tailored high-quality, high-resolution nano-wells in glass
 - Process and machine development
- **NMI Natural and Medical science Institute (research institute)**
 - Development for assays for parallelized analysis of biomarkers
 - Miniaturization and automation of immunoassays
 - High content protein profiling
 - Development of disease models to study disease progression
 - Asses treatment option
 - Investigation of dys regulation of biochemical and metabolic processes

Expertise requested...

- ... for biomarker identification (clinician, research institutes)
- ... for digital analysis (SME)
- ... assay development (SME, large companies)
- ... regulation (SME, large companies or regulatory body)
- ... provision of patient samples (research institute, clinicians from all over Europe)

IHI Call Days | Call 3

- Topic 1 - Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

NAKO - German National Cohort - a resource for health data and biosamples

Thomas Hendel

HELMHOLTZ MUNICH →

thomas.hendel@Helmholtz-munich.de

Marketplace opportunity: <https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGljaXBhdGlvbk9wcG9ydHVu aXR5OjUzNDA3>

Participant profile: <https://ihi-call-days.ihi.b2match.io/participations/192454>

Challenges and objectives

- Biomarker identification or validation requires high quality data and biosamples.
- Both can be provided by *NAKO – German National Cohort*
 - Research infrastructure - “Biobank”
 - Longitudinal epidemiological study
 - Phenotype Data Collection, incl. Questionnaires, Exams, Record linkage with Electronic Health Records, more.
 - Biosamples: Serum, Plasma, Buffy coat, DNA, RNA, Saliva, Stool, Urine
 - (Multi-)Omics data pending - analyses to be done within IHI e.g.: Whole genome sequencing, Metabolomics, RNA sequencing, Proteomics, other relevant analytics.
 - 200,000 participants from german general population aged 20-69 yrs at baseline.
 - Carried out by academic network of 27 partner institutions
 - Funded by German Federal Ministry of Science and Education, Participating Member States and Helmholtz-Foundation.

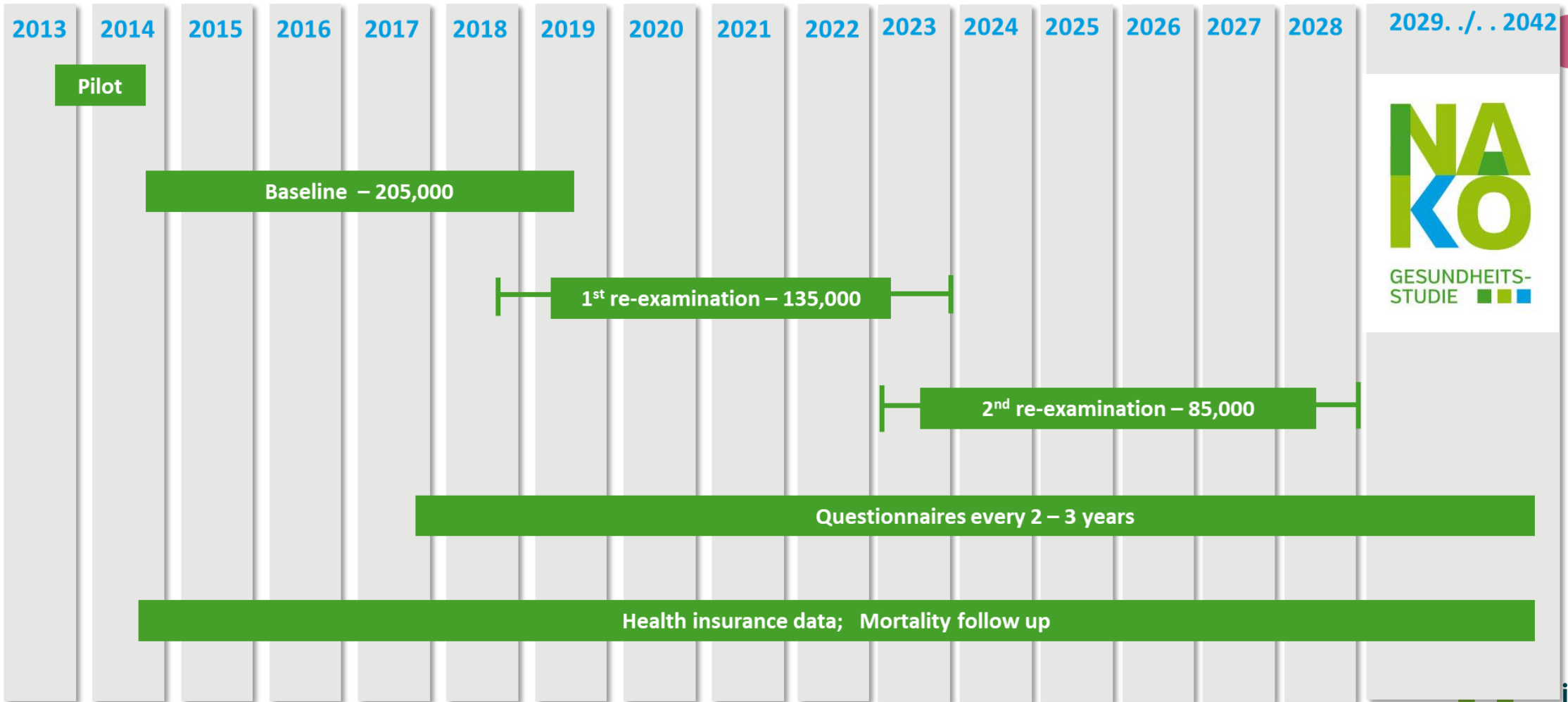
NAKO at a glance



HELMHOLTZ MUNICH



NAKO at a glance



NAKO at a glance



ROBERT KOCH INSTITUT



Deutsches Institut für Ernährungsforschung
Potsdam - Rehbrücke



MEDIZINISCHE FAKULTÄT

Institut für Sozialmedizin und Gesundheitsökonomie



Medizinische Fakultät
der Martin-Luther-Universität
Halle-Wittenberg



LEIBNIZ-INSTITUT
FÜR UMWELT-
MEDIZINISCHE
FORSCHUNG



UniversitätsKlinikum Heidelberg



EBERHARD KARLS
UNIVERSITÄT
TÜBINGEN



SAARLAND



UNIVERSITÄT'S
KLINIKUM
FREIBURG



Universität Regensburg

HELMHOLTZ
MÜNCHEN



NAKO at a glance



**Largest
Health study
in Germany**

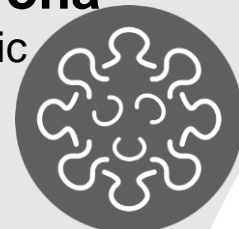
205,000
men and women
aged 20-69



Repeated deep
phenotyping



Study data
available before,
during and after
the **Corona**
pandemic



Repeated
imaging



**Record
linkage**
with secondary data
sources



Comprehensive
high-quality
biosample
collection



Repeated
written health
follow-up



Main activities

- Selection of suitable participants, data and biosamples
- Provision of quality assured data and
- Provision of biosamples for Omics Analyses within IHI project
- Potentially other R&D activities, feasible within NAKOs academic network, incl. omics-analyses

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**NA
KO**
GESUNDHEITS-
STUDIE

ihi innovative
health
initiative



Expertise and resources offered

- Resources:
 - Phenotype Data Collection, incl. Questionnaires, Exams, Record linkage with Electronic Health Records, more.
 - Biosamples: Serum, Plasma, Buffy coat, DNA, RNA, Saliva, Stool, Urine
- Expertise:
 - Academic network of 27 partner institutions with expertise many disease areas and

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**NA
KO**
GESUNDHEITS-
STUDIE

ihi innovative
health
initiative

Expertise requested

- Partners with interest in (Multi-)Omics analyses:
 - Whole genome sequencing,
 - Metabolomics,
 - RNA sequencing,
 - Proteomics,
 - potentially other relevant analytics.
- For Biomarker identification or validation

IHI Call Days | Call 3

- Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

European Bank for iPSCs

Contact person name: Dr. Rachel Steeg

Organisation: Fraunhofer-IBMT

E-mail: Rachel.Steeg@Fraunhofer.co.uk

Additional contacts: Julia.Neubauer@ibmt.fraunhofer.de; Sabine.Mueller@ibmt.fraunhofer.de;

Link to:

- <https://ihi-call-days.ihi.b2match.io/participations/198886/opportunities>
- <https://ihi-call-days.ihi.b2match.io/participations/198886>

- The European Bank for induced Pluripotent Stem Cells (EBiSC) is a centralised, non-profit iPSC repository.
- EBiSC is a research partner looking for consortia.

Challenges for projects using iPSCs:

- It can take **extensive time** to generate novel lines
- Undetected quality issues lead to **wasted investment** of time and money
- Transfer of minimally qualified iPSCs leads to **poor reproducibility**
- iPSC stocks can be damaged or lost through **poor cryostorage, nomenclature and labelling**
- Downstream applications such as differentiation can be **resource consumptive**
- Access to iPSCs from a third party can require **extensive negotiations**
- **Poor traceability** of iPSC line provenance

Expertise and resources offered

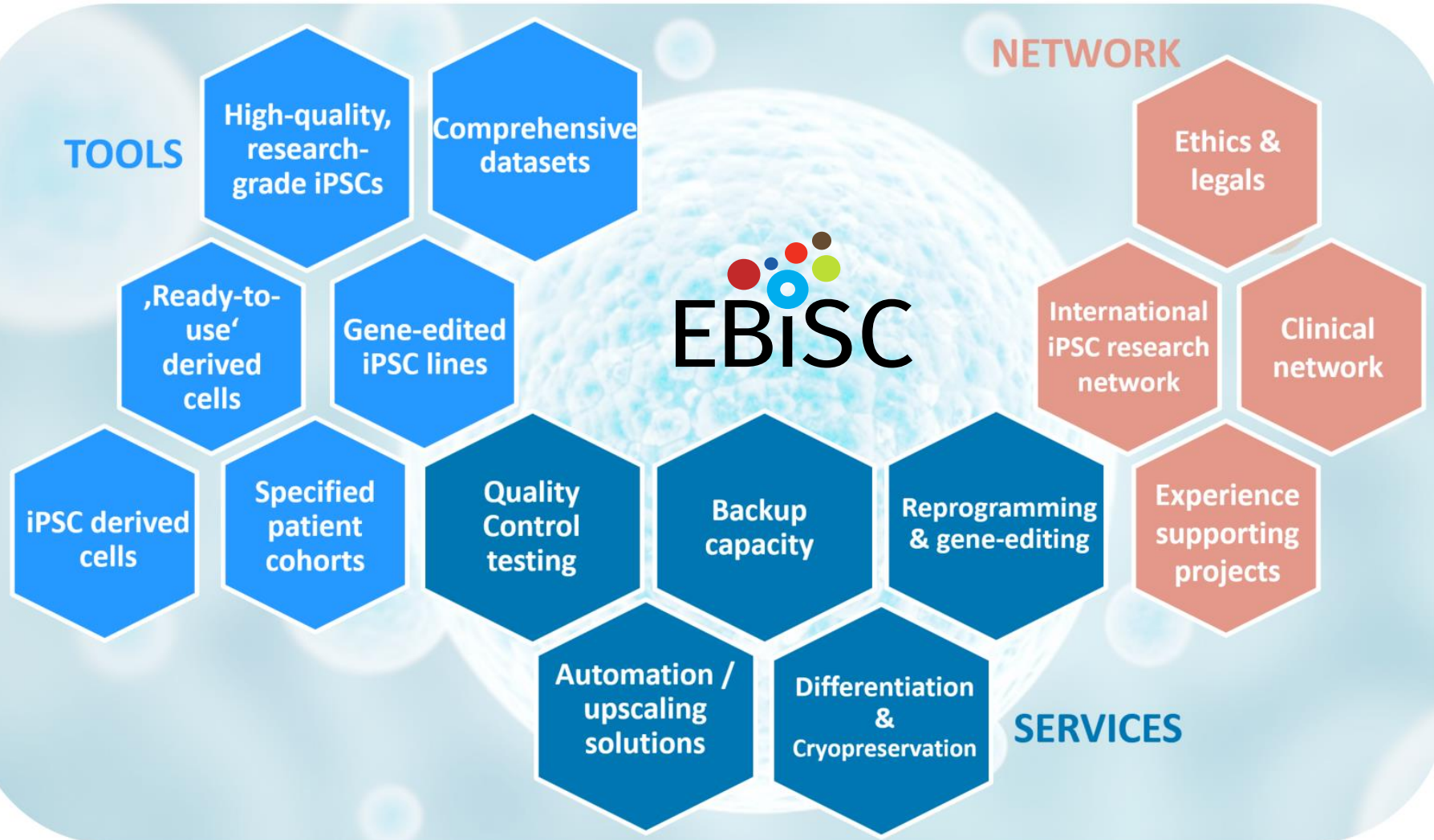
- **Resources:**

- Access to ~900 iPSC lines across ~35 different diseases
- Protocols for upscaling, differentiation and cryopreservation across multiple lineages
- Infrastructure for cross-site storage and rapid distribution
- Frameworks for ethical & legal governance and data management

- **Expertise:**

- Supporting international research projects using iPSCs
- Safeguarding iPSC tools, data and resources
- Accelerating progress in iPSC research projects
- Improving and standardising the quality of iPSC lines and tools
- Advising on ethical and legal aspects which can impact distribution even between consortia partners.
- Performing iPSC services for research projects, so they can focus on core scientific research.

Main activities



www.EBiSC.org

Contact@EBiSC.org

[@EBiSC_cells](https://twitter.com/EBiSC_cells)

www.linkedin.com/company/EBiSC

Rachel.Steeg@Fraunhofer.co.uk



Note: EBiSC is open to discussing multiple call topics.



IHI Call Days | Call 3

Health, Clinical and Multi-omics Data Integration & Interpretation
for precision health - prevention and management of chronic
diseases

Contact person name: **Anthi Dzouveleidou**

Organisation: **Collaborate Health Care**

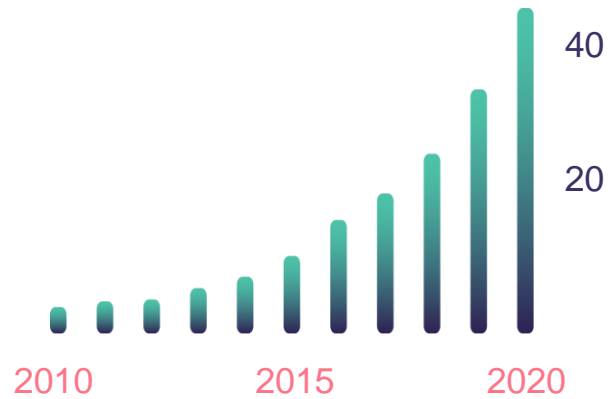
E-mail: **info@collaborate247.com**

Website: **www.collaborate247.com**



THE PROBLEM

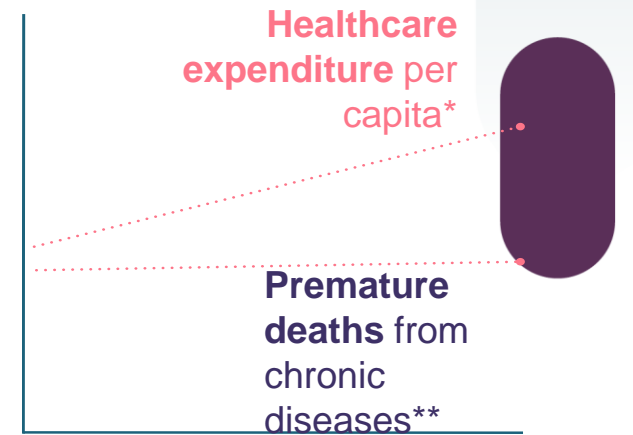
Health data has not been leveraged yet



50X Growth in Health Data



350.000 Digital Health Apps

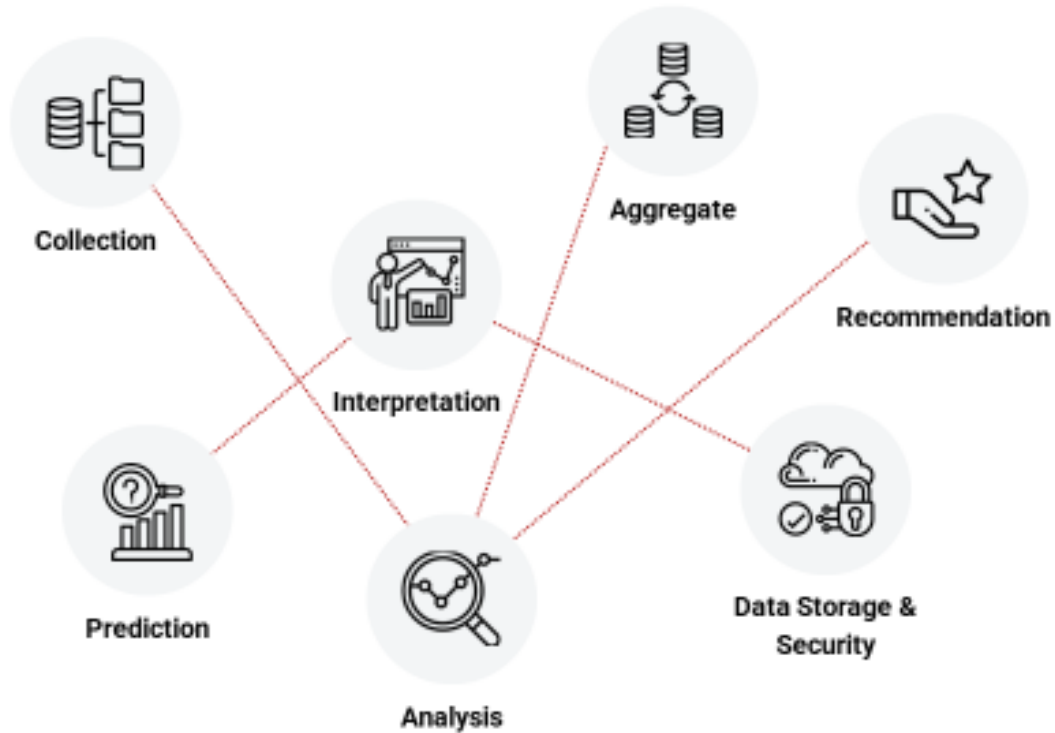


* OECD - Health at a Glance 2021

** WHO - Fact sheet on Noncommunicable diseases

Currently Fragmented & Inefficient

No alignment, scalability, coordination, of health data



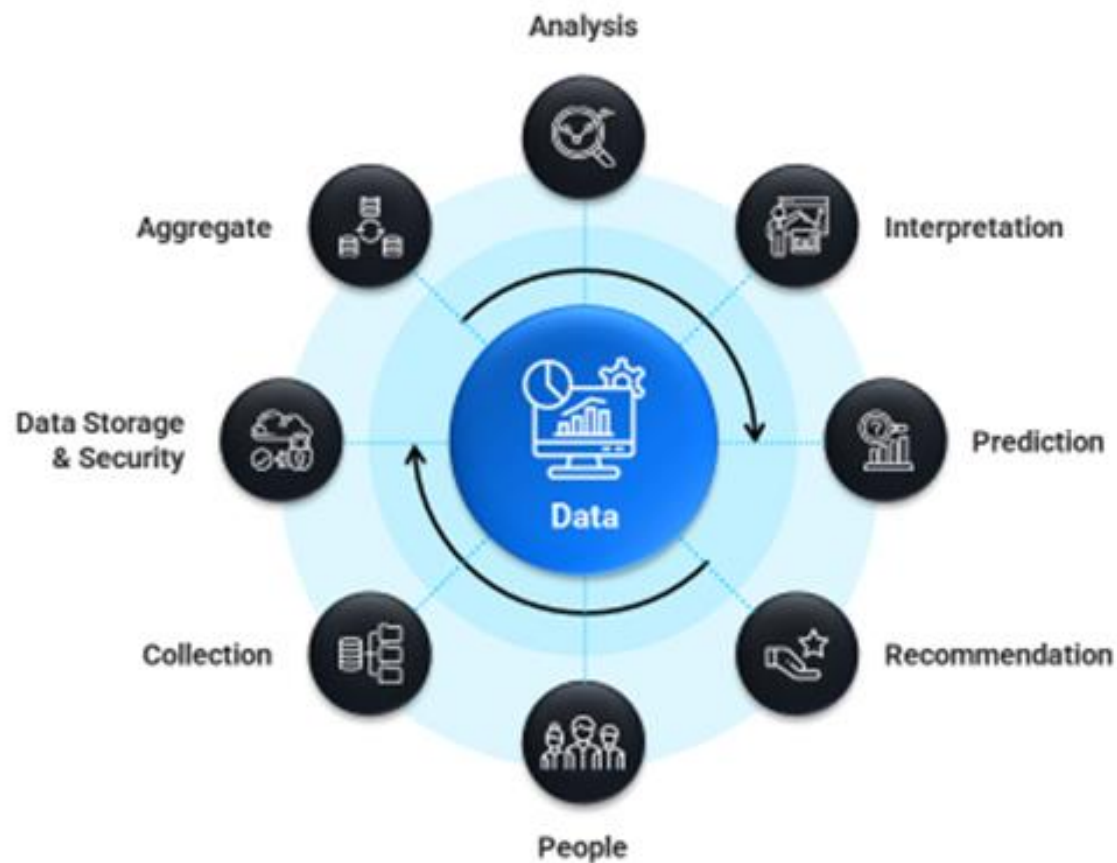
Correlations and Recommendations

- Take too long to develop
- Have limited impact



The Solution

AI-powered end-to-end data solutions and health analytics.



- **Clinical**
 - **Health**
 - **Multi-omics**
- Data Collection**

✓ Precision Health

✓ Holistic approach

Prevention & Management



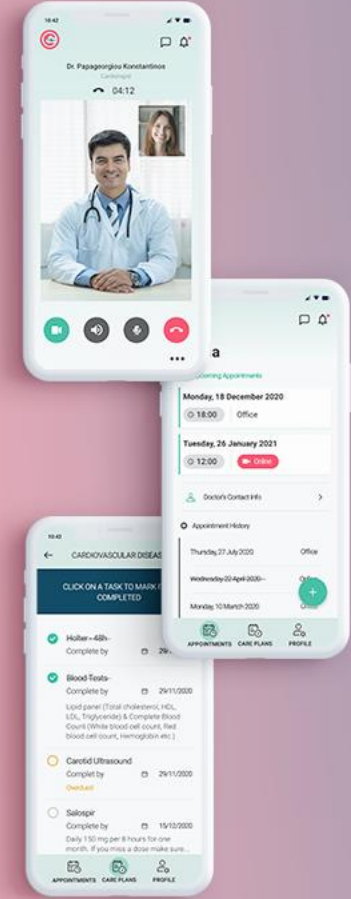
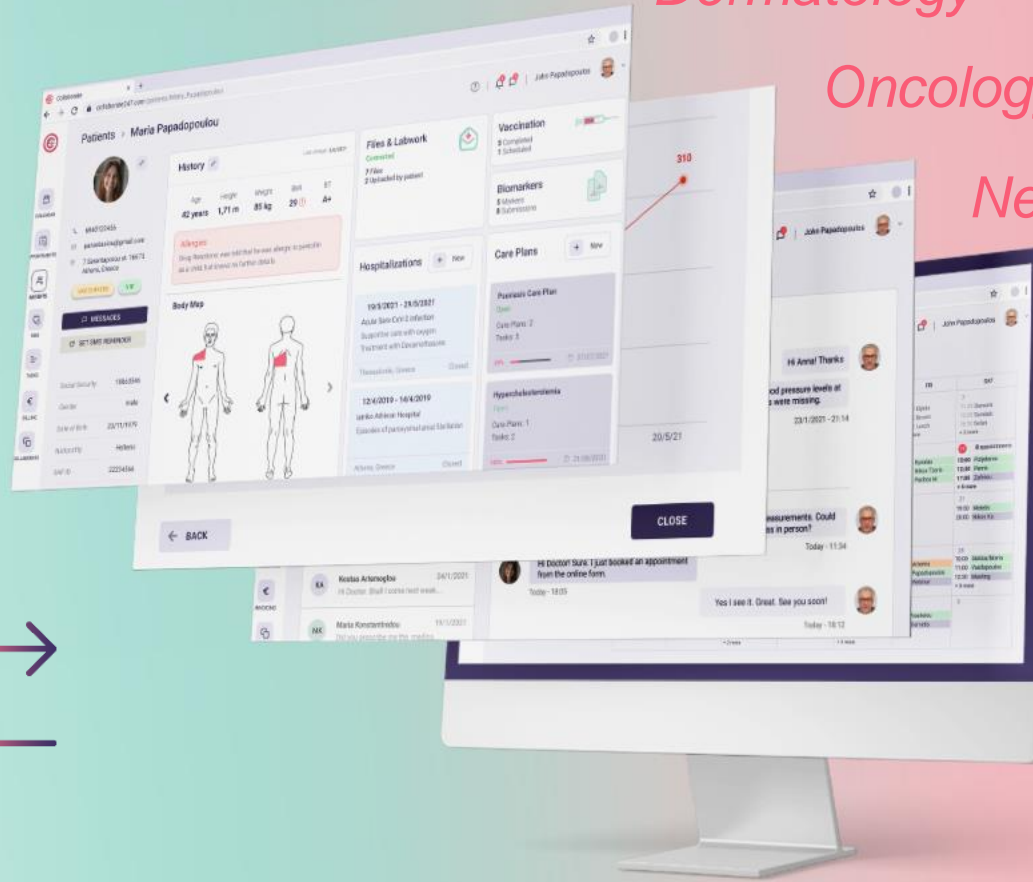
A Specialized Clinical Application & Analytics platform for Holistic Patient Care in prevention, management and treatment of patients with Chronic Conditions.

Dermatology

Oncology

Neurology

Cardiology



● Hospital EHR

● Specialty Clinic

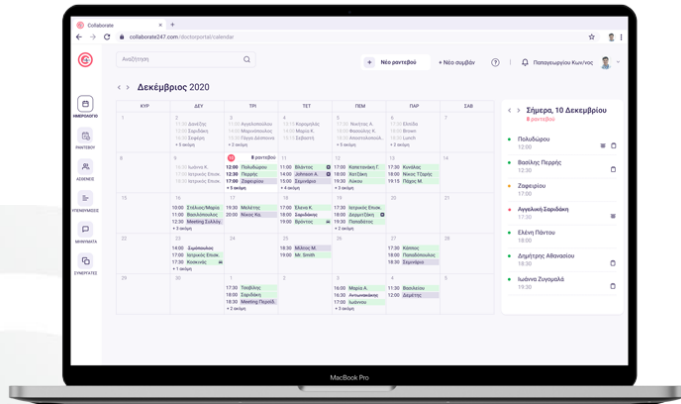
● Patients

● Non Patients

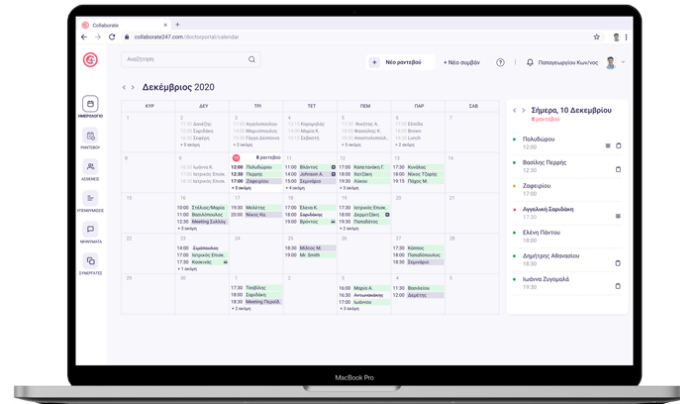
An intuitive patient management & risk stratification tool

- Patient records have been re-designed from scratch to display **clinical information** in a way that decreases the cognitive burden and distraction and **highlights** key data to ensure it is not overlooked

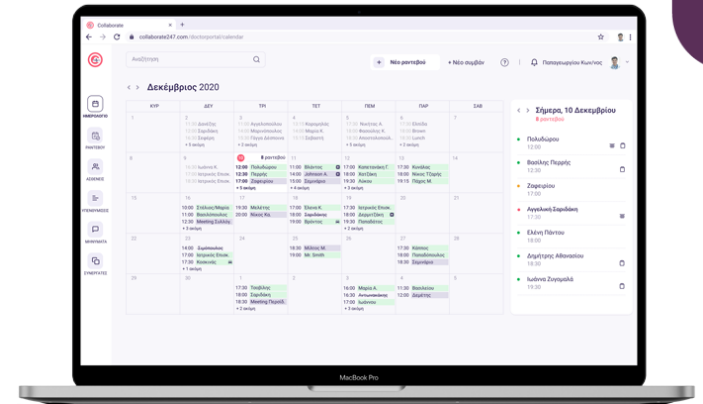
- **Chronic Disease Risk estimation** is easily calculated using widely recognized tools such as the **HEARTSCORE**



Intuitive Patient Records



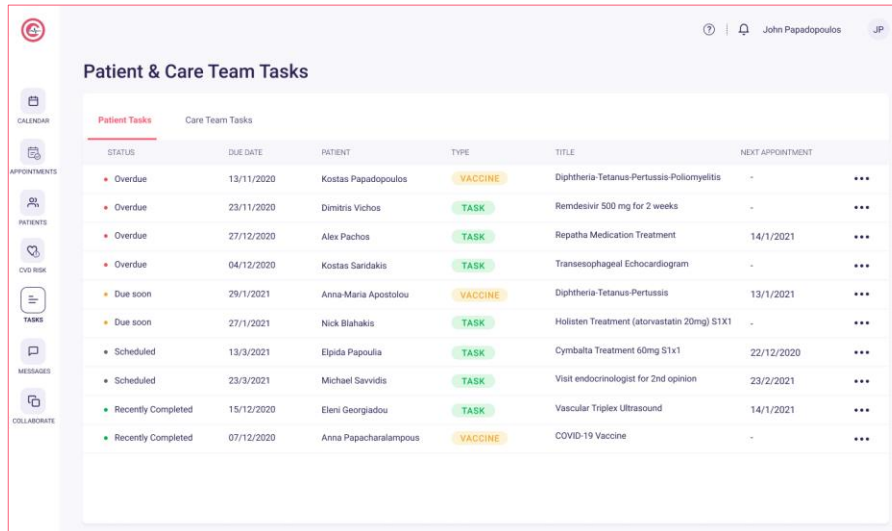
Patient CV Risk Stratification



HEARTSCORE integration

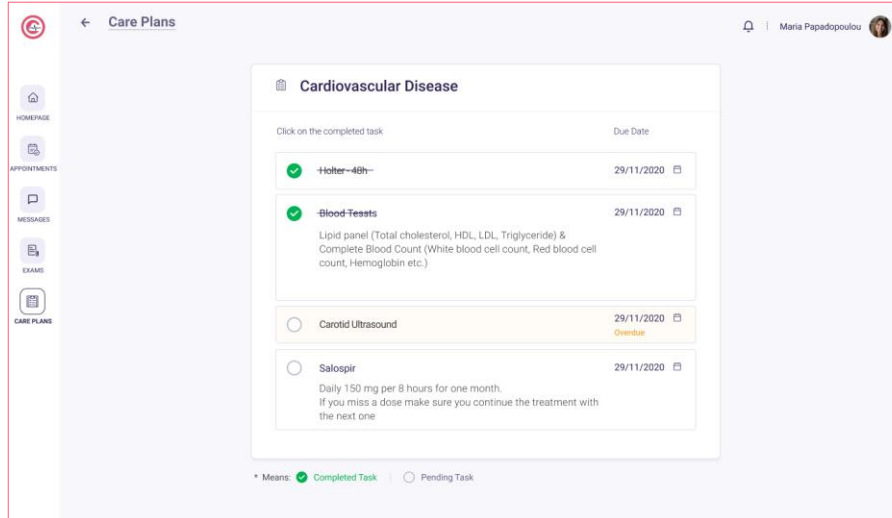
A care plan task management tool

- Designed to streamline patient follow-up & care team coordination during rehabilitation
- Ideal for the facilitation of clinical research and of decentralized clinical trials



Patient & Care Team Tasks

STATUS	DUE DATE	PATIENT	TYPE	TITLE	NEXT APPOINTMENT
Overdue	13/11/2020	Kostas Papadopoulos	VACCINE	Diphtheria-Tetanus-Pertussis-Poliomyelitis	-
Overdue	23/11/2020	Dimitris Vichos	TASK	Remdesivir 500 mg for 2 weeks	-
Overdue	27/12/2020	Alex Pachos	TASK	Repatha Medication Treatment	14/1/2021
Overdue	04/12/2020	Kostas Saridakis	TASK	Transesophageal Echocardiogram	-
Due soon	29/1/2021	Anna-Maria Apostolou	VACCINE	Diphtheria-Tetanus-Pertussis	13/1/2021
Due soon	27/1/2021	Nick Blahakis	TASK	Holisten Treatment (atorvastatin 20mg) S1X1	-
Scheduled	13/3/2021	Elpida Papoula	TASK	Cymbalta Treatment 60mg S1x1	22/12/2020
Scheduled	23/3/2021	Michael Savvidis	TASK	Visit endocrinologist for 2nd opinion	23/2/2021
Recently Completed	15/12/2020	Eleni Georgiadiou	TASK	Vascular Triplex Ultrasound	14/1/2021
Recently Completed	07/12/2020	Anna Papacharalampous	VACCINE	COVID-19 Vaccine	-



Care Plans

Cardiovascular Disease

Click on the completed task

Task	Due Date
<input checked="" type="checkbox"/> Holter-48h	29/11/2020
<input checked="" type="checkbox"/> Blood Tests Lipid panel (Total cholesterol, HDL, LDL, Triglyceride) & Complete Blood Count (White blood cell count, Red blood cell count, Hemoglobin etc.)	29/11/2020
<input type="checkbox"/> Carotid Ultrasound	29/11/2020 Overdue
<input type="checkbox"/> Salospir Daily 150 mg per 8 hours for one month. If you miss a dose make sure you continue the treatment with the next one	29/11/2020

* Means: Completed Task | Pending Task

Healthcare Provider View

- Doctor's view of all patient prescribed tasks & care team tasks ordered by status (i.e. overdue, due soon etc.)

Patient View

- Patient's view of his/her prescribed rehabilitation tasks with detailed instructions, due date, reminders and action to mark a task as completed

A patient - provider communication tool

Guidance & Support:

- Virtual Appointments
- Chat
- Resource Center

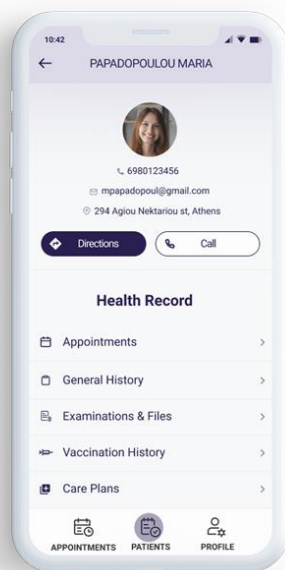
Monitoring:

- Detailed care plans as to-do lists
- E-logs (i.e. blood glucose logs)
- Patient Reported Outcomes

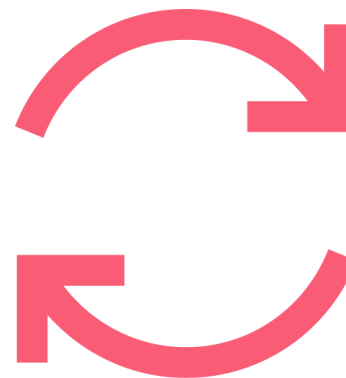
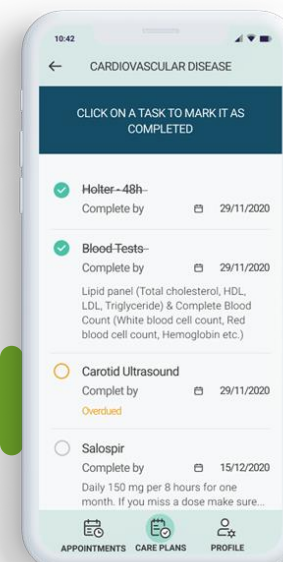
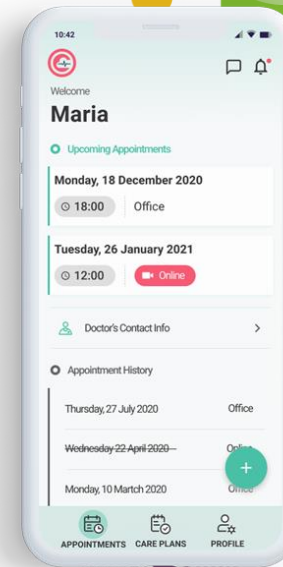
Follow-up:

- Appointment management
- Reminders & notifications
- Patient Reported Outcomes

Doctor Application



Patient App



A care team collaboration tool

- Physicians/Health Care providers can easily invite care team members or colleagues, seamlessly manage referrals and make more informed decisions through collaborative clinical reasoning directly on the patient's record.

The screenshot displays the 'Colaborate' interface for a patient's case details. The page is titled 'Collaboration > Case Details' and shows the user 'John Papadopoulos'. The patient's name is 'Post Myocardial Infarction Rehabilitation', and the patient is 'Male, 46 years old'. The interface includes a sidebar with navigation options: CALENDAR, APPOINTMENTS, PATIENTS, CVD RISK, TASKS, MESSAGES, and COLLABORATE. The main content area is divided into 'Care Plans' and 'Examination' tabs. Under 'Examination', there are sections for 'Case Background', 'Symptoms', 'Clinical Examination', and 'Attachments'. A 'Diagnosis' section contains the text: 'Looks like breast cancer. To be validated with 2nd opinion and CT exam'. To the right, a 'Care Team Collaboration' chat window is open, showing a conversation between Michael Kontos and Emma Jones. Michael asks for blood test uploads, and Emma agrees to order a vascular triplex ultrasound.

Remote team-based clinical reasoning

Scientific Research/ Clinical trials

Multomics
Specialized exams
DNA
PROs

- ⊙ Biomarkers acquisition, aggregation, analysis and processing
- ⊙ AI-driven risk stratification
- ⊙ Patient feedback

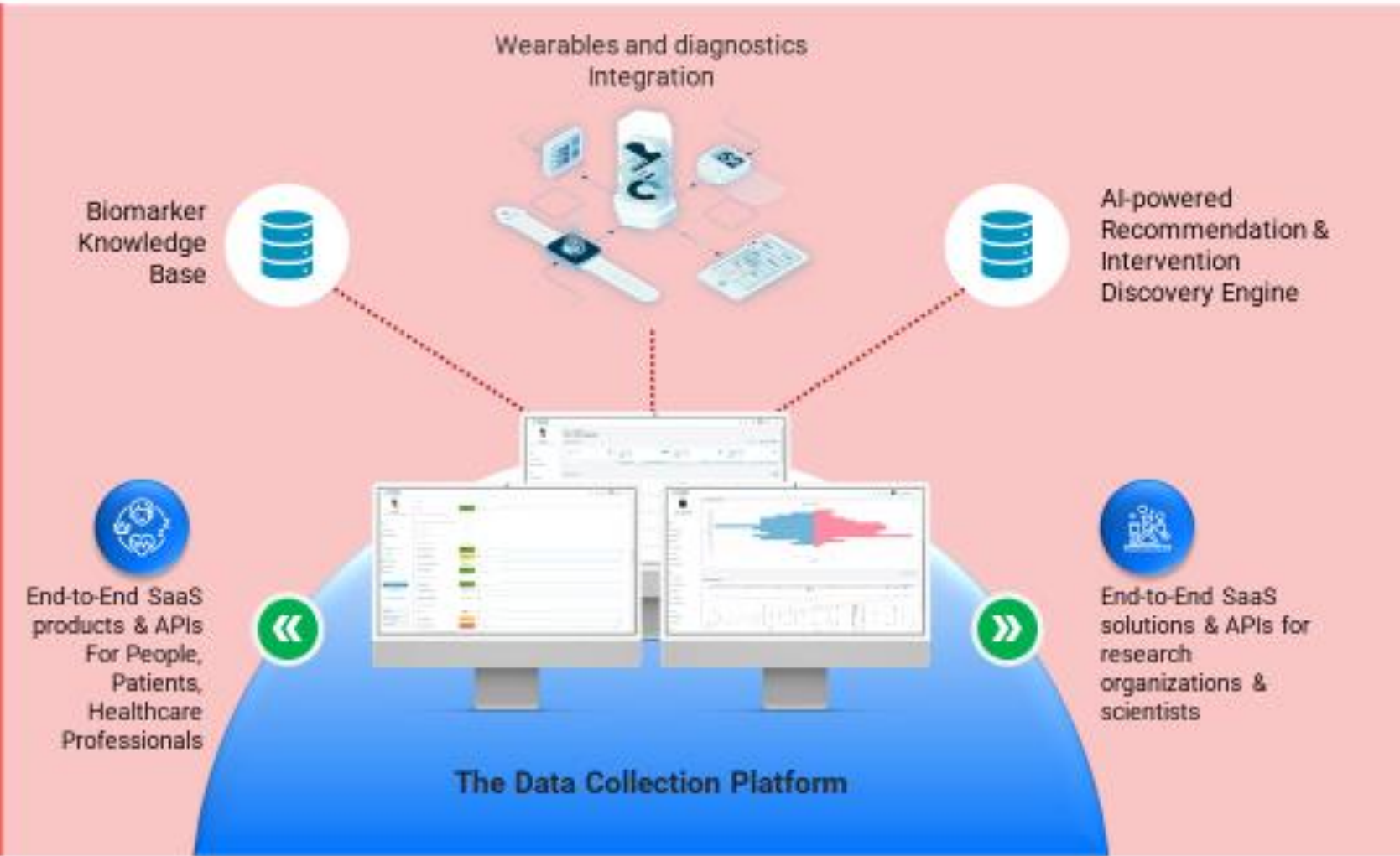


The Product – Looking Forward

The New Unified Health Platform

We are currently working on a **unified platform** focused on:

- knowledge base
- clinical trial mgt
- recommendation engine for precision health
- an AI-driven **intervention discovery engine**



Partners requested to work together in:

- Health data collection (clinical, lifestyle, nutrition,...)
- Multiomics
- Longevity biomarkers
- Chronic diseases biomarkers
- AI-based recommendations
- Wearables and specialized diagnostics

IHI Call Days | Call 3

- Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

High Sensitivity in Early Cancer Screening

Contact person name: Arne Faisst

Organisation: [4D Lifetec IHI Profile](#), www.4dlifetec.com

E-mail: arne.faisst@4dlifetec.com , +41794341049

Link to:

[High sensitivity in early cancer screening](#)

Improve early diagnosis of cancer

Cancer Burden (e.g Lung)

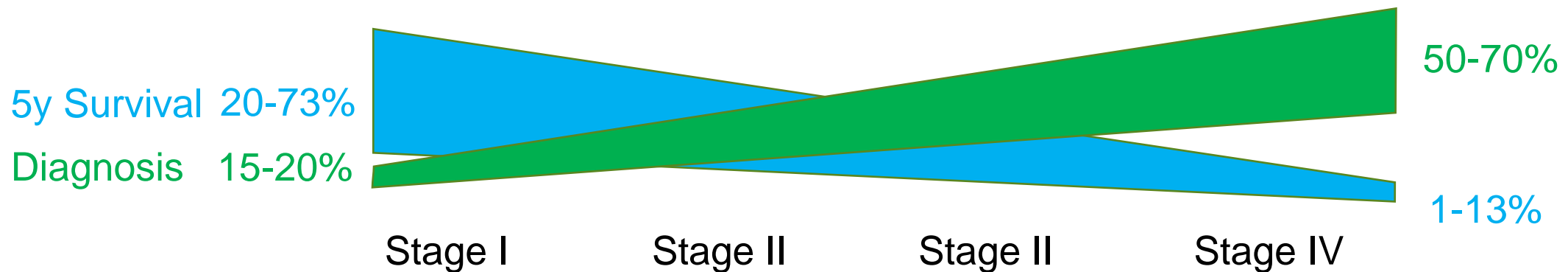
- **Leading cause of cancer deaths**
(400k deaths pa in EU)
- **Late diagnosis = poor prognosis**

Diagnosis

- **Highly invasive**
- **Low sensitivity and specificity in early stages cancer**
- **Burdensome confirmation**
(CT, biopsy, long ambiguity, repeat procedures)

Health Budget

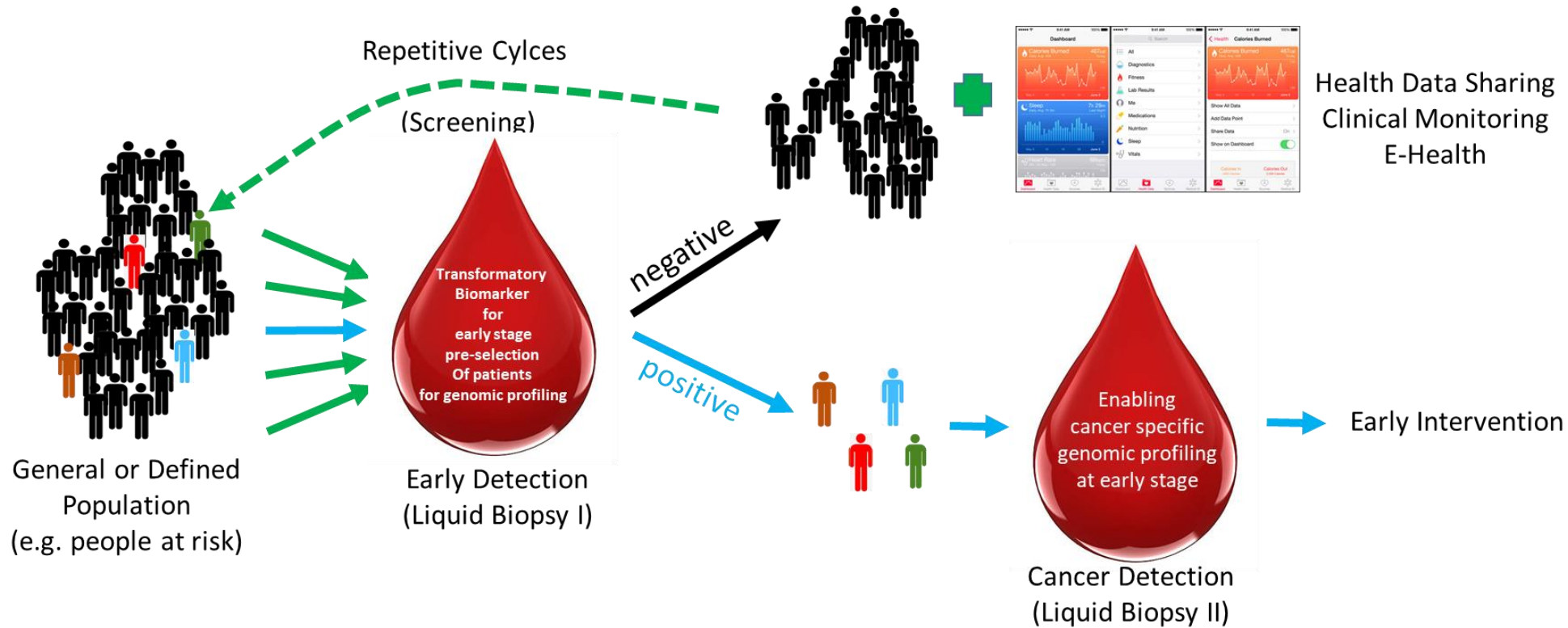
- **Emerging screenings are too costly**
- **Compromise on eligibility criteria**
- **Substantial budget spent on confirmed negatives**



Current frequencies of diagnosis and survival: [Lung Cancer in the EU](#), BMS, 2015 and [Lung cancer screening in Europe: where are we in 2021? - van Meerbeeck- Translational Lung Cancer Research \(amegroups.com\)](#)

Develop complementary early cancer diagnosis

Enabling cancer screening with a cost-efficient, easy to apply and fast liquid biopsy assay and targeting the right individuals to be further checked using cancer type specific Liquid Biopsies or other diagnostics



- Innovative and complementary tests
- Complementary markers (transformatory and genomic)
- Health data sharing
- Early interventions

- Evaluate screening tools and channels (study)
- Better characterised early LC patients
- Evidence and platform to make these tools and data available

- ↑ Outcomes
- ↓ Patient burden
- ↑ Health budget efficiency

Expertise and resources offered*



- Early stage transformational biomarker
- CE IVD marked for lung, prostate, breast and colon cancer
- Highly sensitive and specific solid tumor test, complementing genomic tests in particular for early stage tumors
- Subject consenting and permitted data linking
- Channel to digitally exchange with patients, consumer testing and DCT and RWD sourcing
- IDHERA participant. Subject-controlled access cancer population

... and further tools test, activity or exposure analysis, which could brought-in by additional partners

* 4D Lifetec and Hygiaso are Swiss Start-Ups and their consortium contribution will therefore not absorb any EU funding (associated partners from 3rd country).

Expertise requested: Call For Partners Vested in (Lung) Cancer

Pharma
Diagnostics
MedTech
CROs
HC Provider
Research
Payer

Shared interest to
identify patients
earlier

Industry Consortium Lead

- Coordinator
- Industry, academic contributions (genomic LB tests, lab, study design/mgmt, HTA, data, finance)

Option to include:

- Further cancer types or linked diseases
- Additional diagnostic modalities or devices
- Early interventions/prevention (e.g. behavioural/medical)

Leveraging IMI/IHI initiatives and partners, data and tools
(e.g. H2O, IDERHA (IHI Call 1), EHDEN, OPTIMA, ...), **compounding their effect**

IHI Call Days | Call 3

- Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

**MIND
THE
GAP**

**Manufacturing of Immunoassay
& Development of The Glycan Analysis Protocol**

Contact person name: Miroslav Konecny
Organisation: Glycanostics
E-mail: miroslav.konecny@glycanostics.com
Link to:
- [Marketplace opportunity](#)
- [Glycanostics profile](#)

Challenges and objectives

GLYCANOSTICS® has invented, is developing and clinically validating a novel affordable, non-invasive next-generation liquid biopsy cancer diagnostic test with a final accuracy of up to 90%.

- The approach for analysis of glycans as cancer biomarkers is unique from a worldwide perspective since we are the only company focusing on the use of glycans as cancer biomarkers:
 - prostate, breast, lung, pancreatic, colorectal, bladder, thyroid, ovarian, testicular, liver and stomach
- The IHI project MIND THE GAP will advance early screening of some of the most cancer indications thanks to combination with other serum biomarkers.

Main activities

In the IHI project "MIND THE GAP" we aim to:

- Advance the breast cancer screening method in combination with other serum biomarkers (of different origin i.e., proteins, DNA/RNA, etc.)
- Develop a massive screening/ diagnostic test for pancreatic and lung cancer indications
- Identification of novel biomarkers (preferably tissue-specific) for other cancer indications, suitable for massive cancer screening/ diagnostics.

Expertise and resources offered

Glycanostics brings to a consortium:

- Proprietary IP technology and know-how
- Strong scientific background in the area of biomarker discovery and assay development
- State of the art R&D infrastructure in Bratislava (SK)
- Project coordination and management skills, incl. project writing
- Extensive experience in R&D projects
(incl. implemented ERC grant and Horizon Europe EIC Accelerator)
- Business drive

Expertise requested

MIND THE GAP additional partnerships sought:

- Protein / RNA(DNA) biomarkers for indications presented above
- Clinical institutions for clinical validations of the biomarkers
- Clinical institutions to launch of the diagnostic tests across EU
- Magnetic (nano)particles synthesis
- Protein labelling protocols

Academia / Research, SME, Industry, Non-Governmental Organization or Agency, Public Administration (EU / Non-EU), Patient Organization, Regulatory Authority



- Personalized Diagnostics for Oncology(PDO)

Last resort for hard to treat lung tumors

Contact person name: Jan Zuidema, CBO

Organisation: Vivomicx BV

E-mail: j.zuidema@vivomicx.eu

Link to: [Marketplace opportunity](#) & [Participant profile](#)

Challenges in untreatable lung cancers and PDO objectives

- aim: provide clinicians with a decision support system to determine treatment options for patients with hard-to-treat lung tumors e.g. non responders to immune therapy (IT).
- This fits into the IHI call, Screening platform and biomarkers for prediction and prevention.
 - Current
 - low survival
 - no rational system to determine best treatment
 - Treatment
 - No improvement
 - highly negative impact on quality of living


Patient Urgency IT
Durable response rate 15-20%
World market \$ 16 billion (2020)
80% of which is wasted, \$ 12,8 billion
Source: Hopkins Medical 2022

We expect PDO to lead to personalised treatment recommendations based on integrated analysis of multi-omics tumor data, clinical data and literature. This will lead to better quality of life, expansion of life span and potentially recovery

Main activities

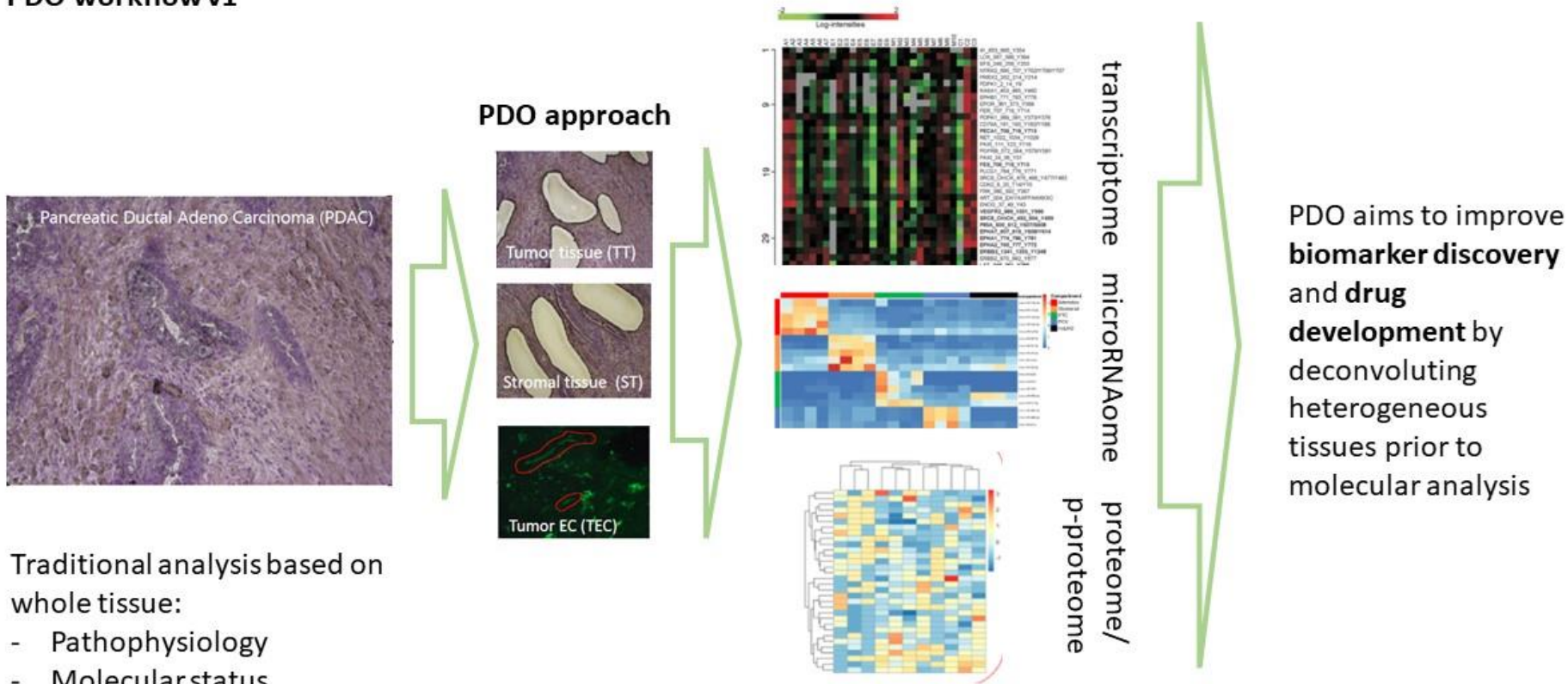
- Clarify molecular signature of complex tumors of patients, which do not respond to therapy
 - multi-omics analysis
 - using bio-informatics & AI
- determine the active pathway in a tumor
- testing traditionally chosen drugs on patient material
- treatment option.

Once a validated workflow has been established and a clinical test carried out, this technology approach can be applied to oncology indications where a patient biopsy can be obtained.

 = basic workflow in place

Main activities

PDO workflow v1



Traditional analysis based on whole tissue:

- Pathophysiology
- Molecular status

Expertise and resources offered

- Clinical expertise in the field of lung oncology – University Medical Center Groningen (NL)
- Vivomicx(NL) expert in LaserMicroDissection, selecting subsets of cells in tissue
- Technical University of Denmark (DK) generate proteomics datasets
- TAmiRNA (AU) generates datasets on transcriptomics and mRNA & miRNA
- Biogenity (DK) is an omics expert and performs the multi-omics data integration.
- Biostrand/IPA (B) is expert in data-integration and NLP (natural language processing).
- Potential drug candidates for treatment are identified
- & tested out on patient cells, best candidates selected
- the physician receives a treatment recommendation

Expertise requested

- Corporates with strong clinical oncology product background for expertise regarding commercial clinical setting and funding
- Patient organizations for the patients view on PDO and possible funding
- Other supporters and visionaries

IHI Call Days | Call 3

Topic 1: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Novel "targeted RNA sequencing technology" - ciRNAseq

Contact person name: Marco de Boer, PhD MBA
Organisation: Predica Diagnostics BV
E-mail: marco.deboer@predicadx.com



Link to:

- [Marketplace opportunity](#)
- [Participant profile](#)

Unmet medical need

21 %

Cancer survival rate when diagnosed **LATE**

89 %

Cancer survival rate when diagnosed **EARLY**

40 billion \$ spent on
cancer drugs

Large groups of cancer patients receive
wrong treatment due to lack of reliable CDx

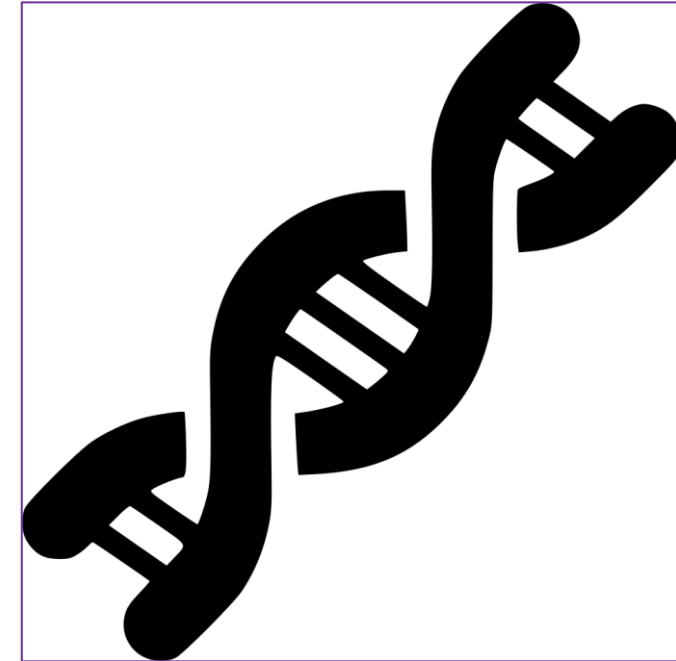
Early detection is KEY for prevention of cancer
Personalized diagnostics is KEY for treatment of cancer

Genome analysis can be complemented with Phenotyping



Patient

Pathology/disease



Genome

Genotype

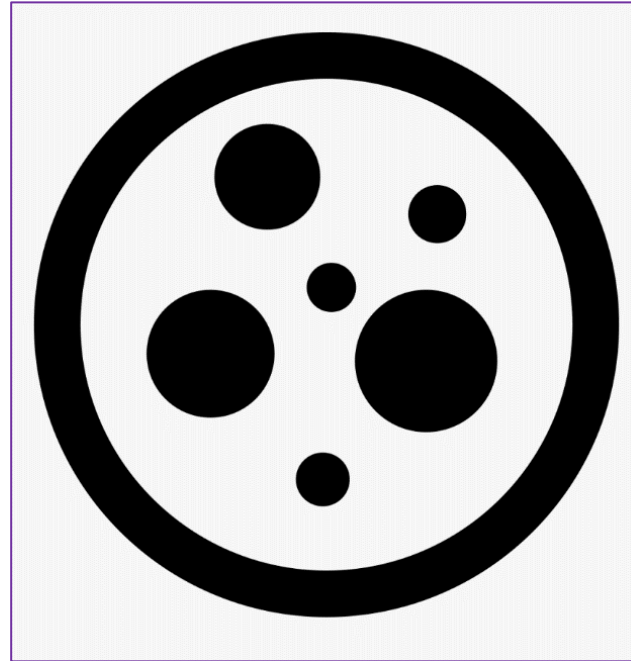
Genome analysis can be complemented with Phenotyping

from Genomics to Phenomics



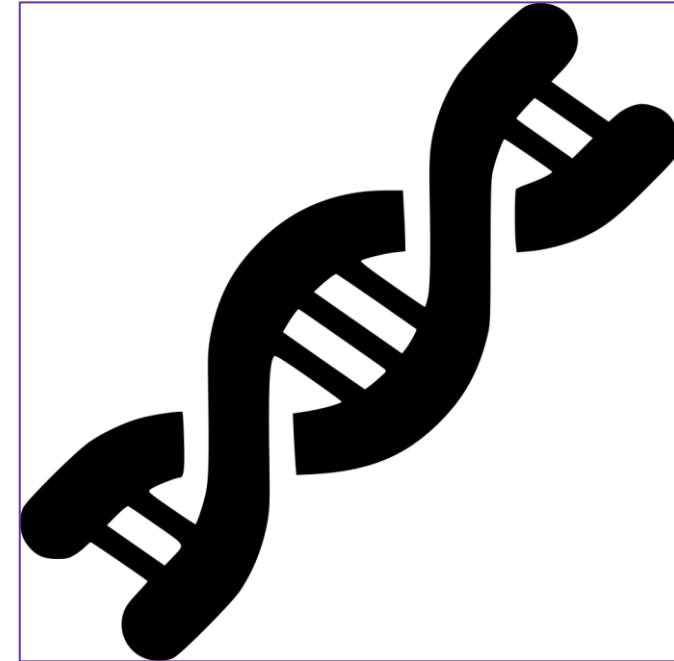
Patient

Pathology/disease



Signaling Pathways

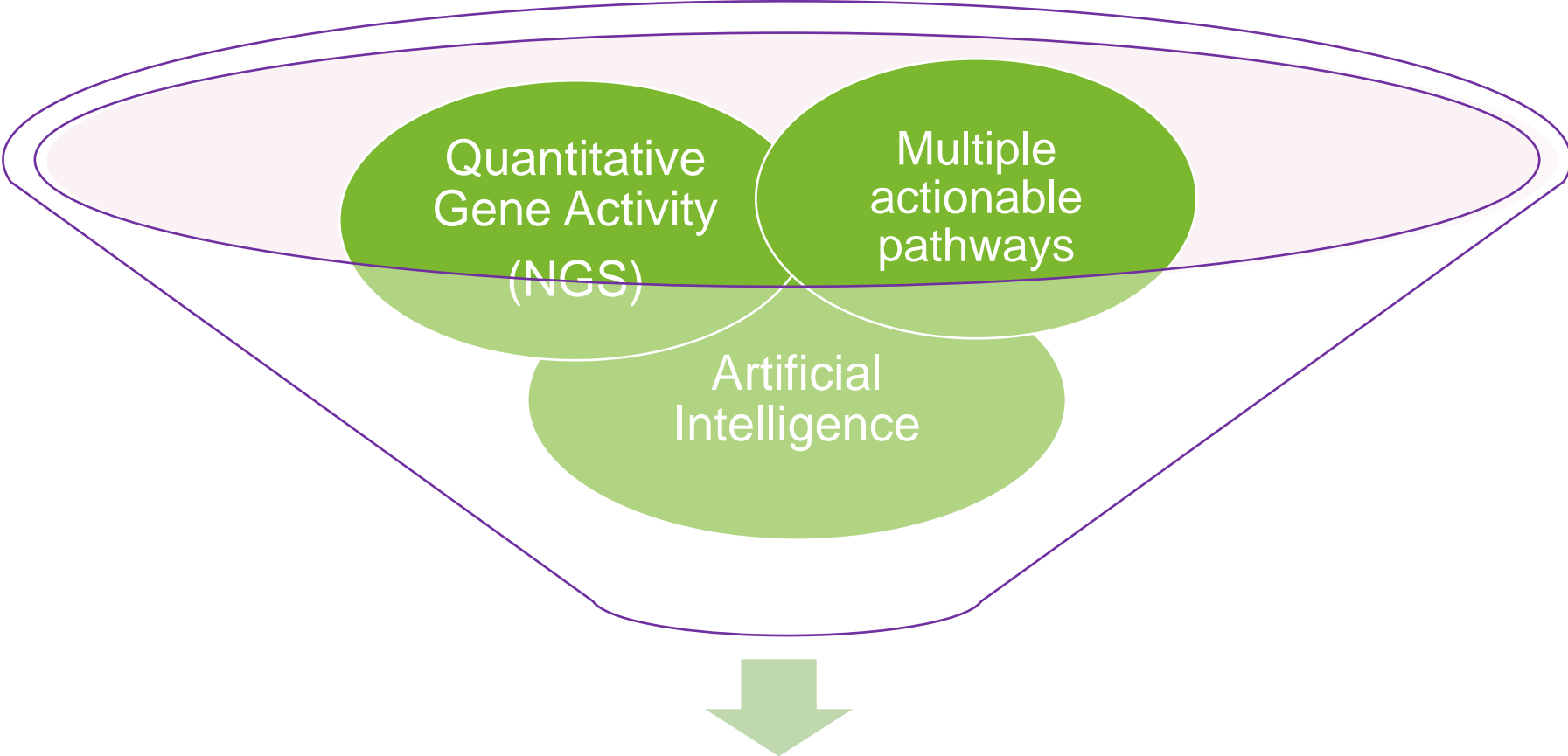
Phenotype/cell behaviour



Genome

Genotype

Our solution: High throughput ciRNAseq platform using inversion probes



**Early detection and EFFECTIVE
PERSONALIZED TREATMENT**



Proof of concept for diagnostic and prognostic value in cancers

Cervical Cancer



Cervical smears

Prostate/Renal/Brain Lung Cancer



FFPE tissue

fresh/cryotissue

Metastatic Cancer



blood

doi: 10.1016/j.ccell.2022.08.006
doi: 10.1186/s12916-022-02386-1
doi: 10.1038/s41379-019-0369-7
doi: 10.1186/s40478-019-0826-z
doi: 10.3389/fonc.2019.00117
doi: 10.3390/cancers11121971

Use Case: Cervical Cancer screening - improved stratification

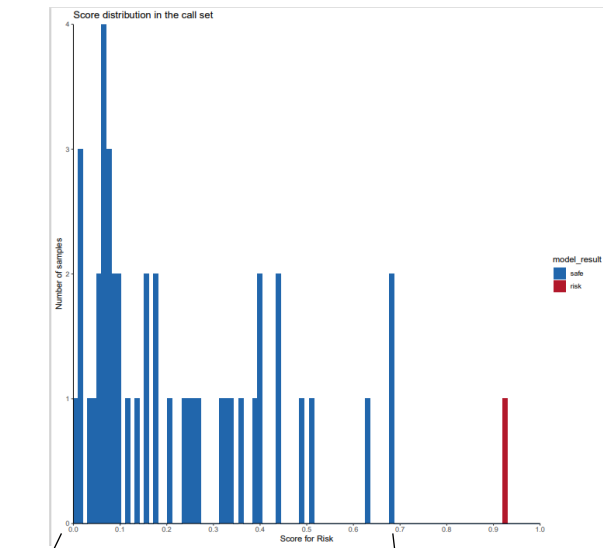
CervicaDx: ciRNAseq triage on HPV-positive scrapes to reliably stratify women at risk



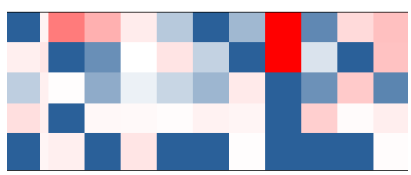
Cervical smears

- hrHPV activity
- HPV genotype
- HPV-induced human genes
- Microbiome

Algorithm:
○ Risk assessment for cervical cancer



HPV DNA positive & low risk



High risk

Andralojc et al. BMC Medicine (2022) 20:206
<https://doi.org/10.1186/s12916-022-02386-1>

BMC Medicine

RESEARCH ARTICLE Open Access

Targeted RNA next generation sequencing analysis of cervical smears can predict the presence of hrHPV-induced cervical lesions

Karolina M. Andralojc^{1,2†}, Duaa Elmelik^{1†}, Menno Rasing³, Bernard Pater³, Albert G. Siebers^{4,5}, Ruud Bekkers^{6,7}, Martijn A. Huynen⁸, Johan Bulten⁴, Diede Loopik², Willem J. G. Melchers^{7†} and William P. J. Leenders^{1,3,2†}





Research and Clinical:

Radboudumc



Looking for:

Large companies:

Diagnostics: development, certification + marketing.
High Throughput (Robotics)
Sequencing

Academia and knowledge centers: Research and clinical

SME: Communication science, Data handling, AI, Sampling, RNA isolation





PREDICA

Diagnostics



marco.deboer@predicadx.com



www.predica-diagnostics.com



06 4444 8450

IHI Call Days | Call 3

- Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Early Lung Cancer Screening

Contact person name: Dominik Geller,
Organisation: [Hygiaso IHI profile](#), www.Hygiaso.eu
E-mail: dominik@hygiaso.ch , +41794317822
Link to marketplace:
- [Early Cancer Screening - Lung Cancer and other prevalent solid tumors](#)

Increase Early Diagnosis

Lung Cancer

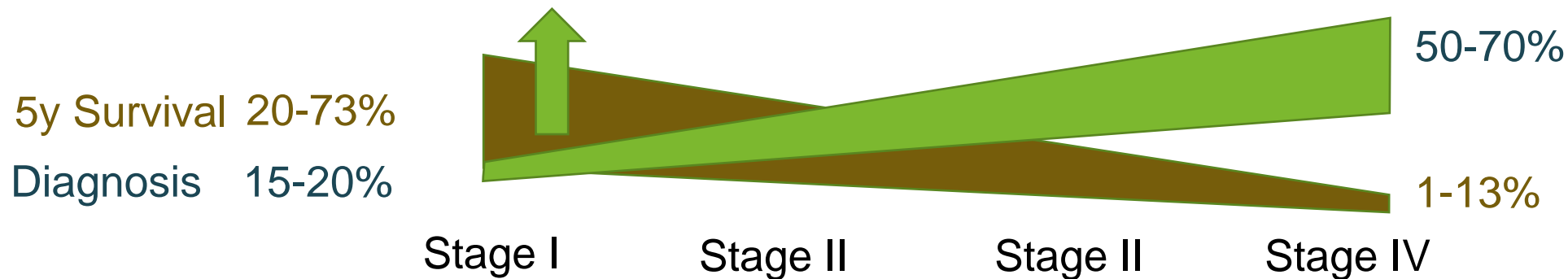
- Leading cause of cancer deaths (400k deaths pa in EU)
- Late diagnosis = poor prognosis

Diagnosis

- Low sensitivity and specificity in early stage cancer
- Burdensome confirmation (CT, biopsy, long ambiguity, repeat procedures)

Health Budget

- Emerging screenings are costly
- Compromise on eligibility criteria
- Substantial budget spent on confirmed negatives



Main activities

With

- Innovative and established tests
- Complementary markers (exposure and behaviour)
- Health data sharing
- Early interventions

- Evaluate screening tools and channels in a study
- Better characterise early LC patients
- Provide evidence and platform to make these tools and data available

- ↑ Outcomes
- ↓ Patient burden
- ↑ Health budget efficiency

Expertise and resources offered*



- Subject consenting and permitted data linking
- Channel to digitally exchange with patients, consumer testing, DCT and RWD sourcing
- IDERHA participant. Subject-controlled access cancer population

Plus innovative tests such as e.g.



- Highly sensitive and specific all-type solid tumor test, complementing genomic tests in particular for early stage tumors

... and further tools test, activity or exposure analysis, which could brought-in by additional partners

* Hygiaso and 4D Lifetec are Swiss Start-Ups and their consortium contribution will therefore not absorb any EU funding (associated partners from 3rd country).



Expertise requested: Call For Partners Vested in (Lung) Cancer

- Pharma
- Diagnostics
- MedTech
- HC Provider
- Research
- Payer

Shared interest
to identify
patients earlier

- **Industry consortium lead**
- Coordinator
- Industry, academic contributions: test, lab, study design/mgmt, HTA, data, finance

Option to include:

- Further cancer types or linked diseases
- Additional diagnostic modalities or devices
- Early interventions/prevention (e.g. behavioural/medical)

Leveraging IMI/IHI initiatives, partners, data and tools
(e.g. H2O, IDERHA (IHI Call 1), EHDEN, OPTIMA, ...), **compounding their effect**

IHI Call Days | Call 3

Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Eforto - physical reserve monitoring a digital biomarker of frailty

Norberta Balaisyte

UniWeb BV

norberta.balaisyte@uniweb.eu

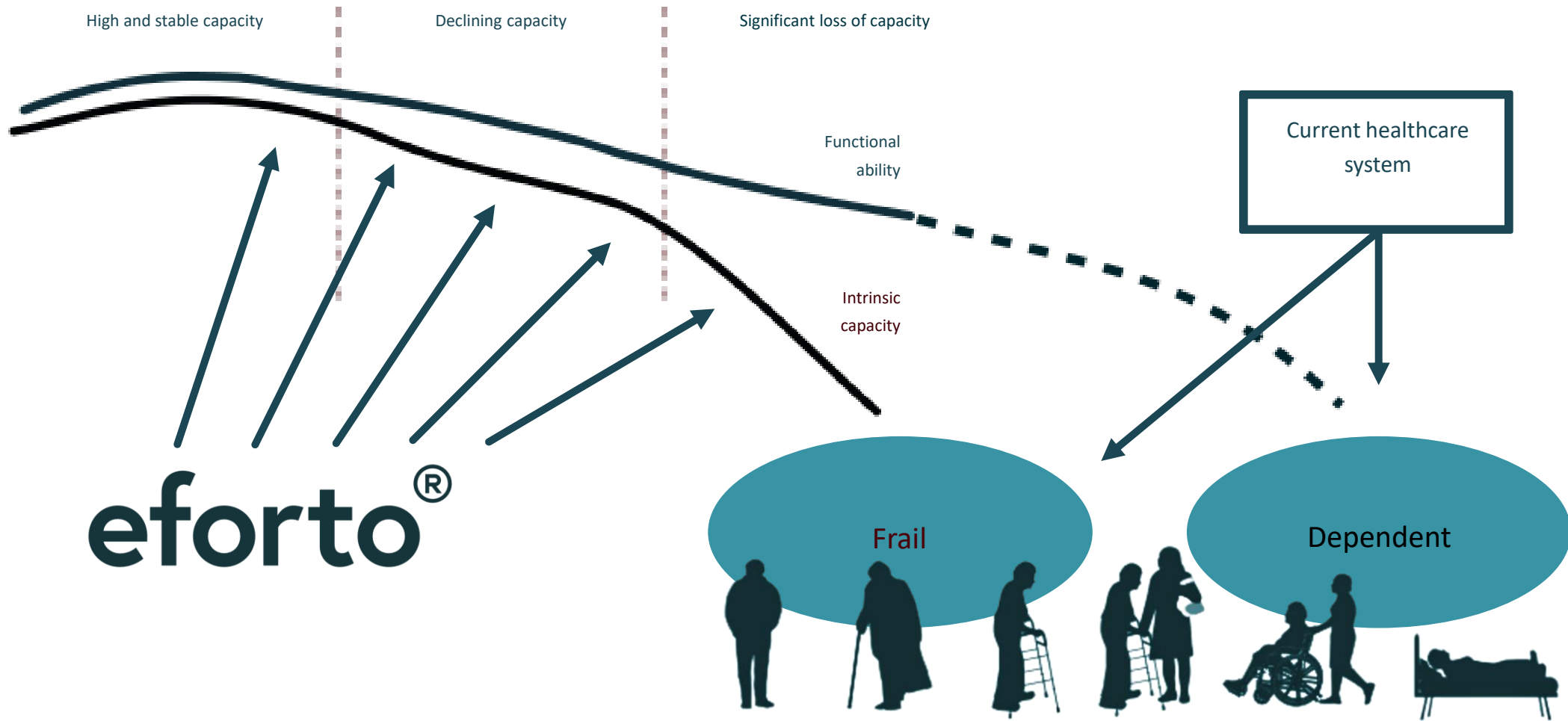


50% frail

1 billion older adults

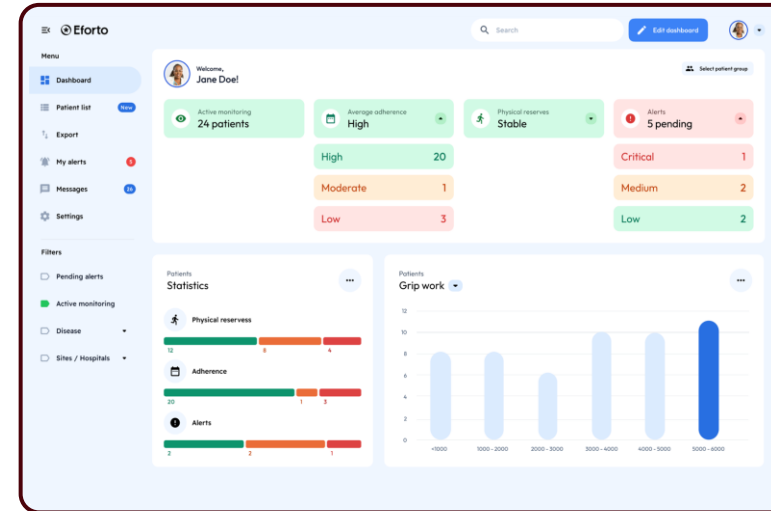
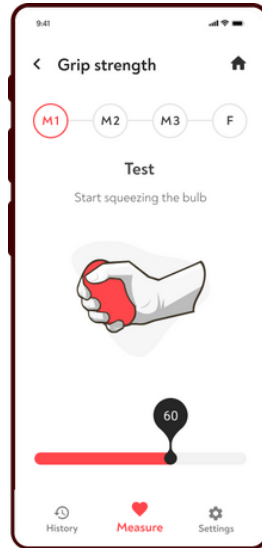
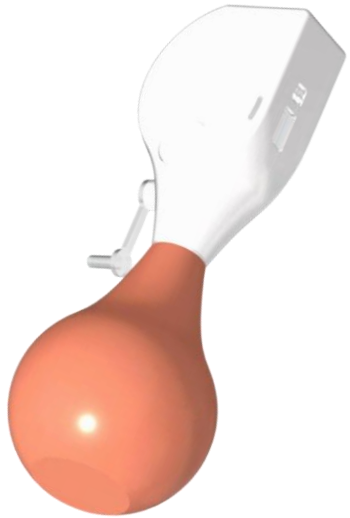
3x higher risk

- falls & fractures
- hospitalization
- dependency in daily activities
- institutionalisation
- premature mortality



Muscle fatigability monitoring as a biomarker of a person's physical reserves.

Eforto[®] system



Dynamo meter

- Specifically designed for frail patients
- Lightweight
- Comfortable grip



Mobile app

- Interactive guidance
- Can be used by the patient at or assisted by a HCP



Telemonitoring platform

- Provides clinical reporting
- Privacy design
- API for interoperability

More information:

eforto.com



Rudi Tielemans
CEO & founder



Ivan Bautmans
Science Liaison



Maria Brites
Lead eforto hardware



Cindel Bonneux
Product owner / PM



Pieter Stas
Quality & Compliance



Igor Magdalenic
Business Advisor

Our goals

To deliver Eforto as a comprehensive and feasible tool to **assess and monitor physical reserves** as a **frailty biomarker**.

To **empower patients**, provide **decision support** for HCPs and gather anonymized data to **inform policy making** for tertiary end-users.

To provide **better and in time care** for the **world fastest growing population**.

For this topic we can:

- Provide an evidence-based, scalable digital biomarker system to monitor physical reserves
- Provide an online tele-monitoring platform that produces clinical reporting with interoperability and privacy by design
- Help to develop preventative care pathways for age-related diseases
- Collaboration on developing implementation pathways
- Integration of the Eforto solution with other systems for interoperability
- Regulatory-compliant development and integration of digital systems

ISO 9001

ISO 27001

ISO 13485

We are looking for:

- Interdisciplinary collaboration with clinical research, industrial and public health partners in order to integrate Eforto solution into existent or to-be-developed care pathways
- Long-lasting collaborations with other parties interested in developing preventative solutions for elderly
- Large-scale studies where Eforto could be used to monitor patients' physical reserves to further refine our algorithm

IHI Call Days | Call 3

Topic: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Quibim: Transforming imaging data into actionable predictions

Contact person name: Ana Blanco

Organisation: Quibim SL

E-mail: anablanca@quibim.com

Link to:

- Marketplace opportunity: <https://ihi-call-days.ihi.b2match.io/participations/191964/opportunities>
- Participant profile: <https://ihi-call-days.ihi.b2match.io/participations/191964>

Challenges and objectives

- Increased availability of validated biomarkers for disease interception and diagnosis, tested in real-world settings.
- Advanced analytics/artificial intelligence supporting health research and innovation (R&I), resulting in wider availability of personalised health interventions to end-users.
- Researchers have new biomarkers for prediction and prevention to allow for the development of safer and more effective personalised interventions tailored to the individual's characteristics.

Main activities





- Radiomics, deep features and Deep learning-based tissue phenotyping
- Identification of imaging biomarkers as surrogate endpoints/outcomes
- Patient finding by RWE analysis for synthetic control arms
- Predictive AI models generation
- Digital biomarkers, candidates to be cleared as future CDx
- Implementation and deployment of AI/ML

Expertise and resources offered

- Quibim aims to become the leader in virtual biopsies, using quantitative imaging biomarkers to unlock complex diseases signals in medical images and building whole-body imaging solutions for systems biology.
- Our strategic lines are (1) Companion Diagnostics for Biopharma partners, (2) World Leading Algorithms for Medical Imaging Hardware, (3) AI-first Workflow System for Real-World Evidence specialists, and (4) Biomarker Discovery for Research Consortia.

Expertise and resources offered

RWE projects

Project	 PRIMAGE Medical Imaging Artificial Intelligence Childhood cancer research	 pain360	 ProCancer-I	 chAIMeLeon	ProCanAid.	DIPCAN	RadioVal	FLUTE	EUCAIM
Period	2018 - 2022	2020 - 2024	2020 - 2024	2020 - 2024	2021 - 2024	2021 - 2024	2022-2026	2023-2026	2023 - 2027
Topic	In-silico and AI in pediatrics cancer	AI in neuroimaging for chronic pain	Prostate cancer repository	Pan-cancer (lung, breast, prostate, rectal) repository	Prostate cancer digital twin	Advanced stage metastatic patients	Breast Cancer Research - Radiomics	FD and multi-party computation for Prostate Cancer	European digital federated infrastructure of cancer images
Funding organism	European Commission - H2020	European Commission - H2020	European Commission - H2020	European Commission - H2020	MICINN - Líneas Estratégicas 2021	MINECO - Misiones IA 2021	European Commission - HE	European Commission - HE	European Commission - Digital
Total project budget	+10M	6M	9,9M	+8M	+1,4M (Quibim: coordinator)	7,7M	5,8M	6,9M	+35M
Committed Patient Data	3.300	9.850	17.000	20.000	500	2.000	>6.000	TBD	>90.000



IHI Call Days | Call 3

- ## Rhino Health

Privacy-Preserving Data Collaborations across Life Sciences

Contact person name: Malhar Patel, MD

Organisation: Rhino Health

E-mail: malhar@rhinohealth.com

Link to:

- [Marketplace opportunity](#)
- [Participant profile](#)

Challenges and objectives: Rhino Health improves AI in life sciences

- Healthcare AI has great potential, but impact slowed by **low generalizability**
 - AI **performance deteriorates** when deployed on new populations
 - **Human bias**, encoded in siloed training data, can be propagated
 - High complexity and no honest broker makes **data collaborations difficult**
 - Regulatory complexity in Europe (**e.g., GDPR**) increases barriers to collaboration
- Rhino Health Platform (RHP) **lowers barriers to collaborations**, facilitating **projects**
 - Edge computation **alleviates data sharing** and **instills trusts** among collaborators
 - **Federated learning** (FL) improves algorithm performance and generalizability
 - RHP provides **end-to-end workflow** support through AI development features
- RHP has **facilitated many large projects already**, including:
 - [American College of Radiology](#): Distributed computation and registries
 - [National Cancer Institute](#): Cancer centers use FL to improve detection of GI-cancer
 - [Federated Learning for Medicine](#): FL consortium translates research to the clinic

Main activities

- The Rhino Health Platform (RHP) is relevant for **any project** that:
 - **Benefits from data sharing** across multiple stakeholders
 - Needs robust end to end **AI development tools**
 - Considers **clinical translation and commercialization** across geographies

Expertise and resources offered

- Rhino Health Platform (RHP)
 - Access via easy-to-use **GUI and SDK**
- Project execution support
 - RHP **installation** (including IT Security clearance)
 - RHP **onboarding** and **training**
 - RHP **monitoring** and **maintenance**
 - (case-by-case) AI and data science expertise
- Partnership opportunities
 - Extensive **network of hospitals and KOLs** in Israel, UK, EU, and US

Expertise requested

- **Large companies and biopharma**, with:
 - Interest in pursuing a project with **high clinical and business impact**
 - Dare to **operate on the cutting edge** and **push the field** of healthcare AI
- **Research institutes and hospitals**, that:
 - **Want to use** diverse patient data to unlock innovation
 - Are committed to **preserve patient privacy**
- **SME's**, with:
 - Expertise in **healthcare AI or data science**
 - Note: Rhino Health can provide this type of expertise if required



Pitching session on:

Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Presentation order	First Name	Last Name	Job position	Organization	Country
1	Oscar	Franco	Director of Department, Professor of Public Health	University Medical Center Utrecht - Julius Center for Health Sciences and Primary Care	Netherlands
2	Alessandra	Renieri	Full Professor, Director of Medical Genetics Unit, University of Siena	University of Siena	Italy
3	Jan	Baumbach	Professor	University of Hamburg	Germany
4	Svitlana	Surodina	CEO	Skein	United Kingdom
5	Oliver	Schmidt	Innovation Owner Clinical Condition Liver Cancer	Siemens Healthineers	Germany
6	Ana	Solana Sanchez	Lead MR scientist	GE Healthcare	Germany
7	Donato	Bonifazi	CEO	CVBF-EPTRI	Italy
8	Nadine	Nottrodt	Project manager	Fraunhofer ILT	Germany
9	Thomas	Hendel	Science Manager	Helmholtz Munich	Germany
10	Rachel	Steeg	EBiSC Project Manager	European Bank for induced Pluripotent Stem Cells	Germany
11	Anthi	Dzouveilidou		Collaborate Healthcare IKE	Greece
12	Arne-Christian	Faisst	CEO	4D Lifetec AG	Switzerland
13	Miroslav	Konecny	Project manager	GLYCANOSTICS, s.r.o.	Slovakia
14	Jan	Zuidema	CBO	Vivomicx	Netherlands
15	Marco	de Boer	CEO	Predica Diagnostics BV	Netherlands
16	Dominik	Geller	Founder & CEO	Hygiaso Ltd	Switzerland
17	Norberta	Balaisyte	Business developer	UniWeb BV	Belgium
18	Ana	Blanco Sanchez	Grants and Innovation Coordinator	Quibim SL	Spain
19	Malhar	Patel	Head of Clinical Engagement	Rhino Health, LTD	Israel

If you want to interact with other participants please use the chat function on the top right corner

Chat

How to contact the presenters?

Home Call days Agenda ▾ Organisations Participants Marketplace Project offers ▾ Pitchers - Call 3 Sessions



14:30 - 15:30	Matchmaking time - Topic: Strengthening the Advanced Therapy Medicinal Products (ATMP) therapeutic modalities for rare diseases
15:30 - 16:30	Pitching Session - Topic: Strengthening the Advanced Therapy Medicinal Products (ATMP) therapeutic modalities for rare diseases
Wednesday, December 14, 2022	
09:30 - 11:00	Info Session - Topic: Screening platform and prevention of diseases of unmet public health
11:00 - 11:30	Matchmaking time - Topic: Screening platform and prevention of diseases of unmet public health
11:30 - 13:00	Pitching Session - Topic: Screening platform and prevention of diseases of unmet public health
13:30 - 15:00	Info Session - Topic: Patient input and patient outcomes, support decision innovation
15:00 - 16:00	Matchmaking time - Topic: Patient input and evidence to improve patient outcomes, support decision innovation
16:00 - 17:00	Pitching Session - Topic: Patient input and evidence to improve patient outcomes, support decision innovation

Pitching Session Room 3
620 participants signed up for this session

DESCRIPTION:

Presentation order	Presentation title	First Name	Last Name	Job position	Organisation	Country
1	Global Research Initiative for Patient screening on NASH - (GRIP on NASH)	Oscar	Franco	Director of Department, Professor of Public Health	University Medical Center Utrecht - Julius Center for Health Sciences and Primary Care	Netherlands
2	Molecular biomarkers and clinical assessment of rare and common disorders	Alessandra	Renieri	Full Professor, Director of Medical Genetics Unit, University of Siena	University of Siena	Italy
3	Privacy-preserving AI for medical mechanotyping	Jan	Baumbach	Professor	University of Hamburg	Germany
4	Distributed data valuation technology and decision support system	Svitlana	Surodina	CEO	Skain	United Kingdom
5	ENGAGE - The challenge of liver cancer screening and outcome prediction	Oliver	Schmidt	Innovation Owner Clinical Condition Liver Cancer	Siemens Healthineers	Germany
6	PREDICTOM - Prediction of Neurodegenerative Disease using an AI driven Screening Platform	Ana	Solana Sanchez	Lead MR scientist	GE Healthcare	Germany
7	Biomarkers for diseases of public health interest - EPTRI Thematic Research Platform on Paediatric Biomarkers & Biosamples	Donato	Bonifazi	CEO	CVBF-EPTRI	Italy
8	Highspeed RAGE - Analytical platform for Highspeed cohort screening using Raman enhanced cell analysis	Nadine	Notrodt	Project manager	Fraunhofer ILT	Germany
9	NAKO - German National Cohort - a resource for health data and biosamples	Thomas	Hendel	Science Manager	Heimholtz Munich	Germany
10	European Bank for iPSCs	Rachel	Steag	EBISC Project Manager	European Bank for induced Pluripotent Stem Cells	Germany
11	Health, Clinical and Multi-omics Data Integration & Interpretation for precision health - prevention and management of chronic diseases	Antni	Douvididou	Special Projects Officer	Collaborate Healthcare IKE	Greece
12	High Sensitivity in Early Cancer Screening	Arne-Christan	Faist	CEO	4D Lifetec AG	Switzerland
13	Mind the Gap - Manufacturing of Immunoassay & Development of The Glycan Analysis Protocol	Miroslav	Konecny	Project manager	GLYCANOSTICS, s.r.o.	Slovakia
14	Last resort for hard to treat lung tumors	Jan	Zuidema	CBO	Vivomic	Netherlands
15	Novel 'targeted RNA sequencing technology' - oRNAseq	Marco	de Boer	CEO	Predica Diagnostics BV	Netherlands
16	Early Lung Cancer Screening	Dominik	Geller	Founder & CEO	Hyglass Ltd	Switzerland
17	Eforo - physical reserve monitoring a digital biomarker of frailty	Norberta	Balaisyte	Business developer	UniWeb BV	Belgium
18	Quibim: Transforming imaging data into actionable predictions	Ana	Bianco Sanchez	Grants and Innovation Coordinator	Quibim SL	Spain
19	Privacy-Preserving Data - Collaborations across Life Sciences	Malhar	Patel	Head of Clinical Engagement	Rhino Health, LTD	Israel

SPEAKERS:

- Norberta Balaisyte**
Business developer at UniWeb BV
- Jan Baumbach**
Professor at University of Hamburg
- Ana Blanco Sanchez**
Grants and Innovation Coordinator at Quibim SL



Thursday, December 15, 2022



Thank you for your attention

ihi.europa.eu

