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	Cristina	COZZINI	Senior Scientist	GE HealthCare	BESTCaRe - Biomarkers for AI Enabled patient Specific Treatment for Cancer in Radiotherapy
2	Tobias	HECKEL	Research & Technology Manager	Siemens Healthineers	BREATHE - Biomarker-aided Refinements in the Assessment and Treatment of Lung cancer for Health Enhancement
3	Ralf	HOFFMANN	Principal Scientist	Philips	BRECISE - Biomarker Research and Evaluation for Clinical Implementation and Supporting Systems Enhancement
4	François-Clément	BIDARD	Professor of Medical Oncology	Institut Curie	Biomarker validation – Consortium proposal
5	Daniela Maria	CIRILLO	Head EBPU IRCCS OSR	Vita-Salute San Raffaele University	valiDation of biOmarkers to iMprove dIagnosis and maNagement Of infEctious diSeases (DOMINOES)
6	Milena	CAVIC	Senior Research Associate	Institute for Oncology and Radiology of Serbia	Clinical utility and implementation of circulating tumor DNA (ctDNA) across the patient journey
7	Hendrik	LAUE	Key Scientist Quantitative and Dynamic Image Analysis	Fraunhofer MEVIS	Biomarker Validation - Quantitative MRI
8	Karim	LEKADIR	ICREA Professor	University of Barcelona	AI-Driven Imaging Biomarkers
9	Michael	LEVIN	Professor of International Child Health	Imperial College London	Bringing Biomarkers for Infectious and Inflammatory Disease into Clinical Use
10	Carles	BLASCO	R&D Project Manager	ISABIAL - Alicante Institute for Health and Biomedical Research	Integrative analysis of biomarkers to improve monitoring of neurological and heart diseases
11	Donato	BONIFAZI	CEO	CVBF-EPTRI	Biomarkers in paediatric diseases diagnosis, treatment and monitoring– EPTRI Thematic Research Platform on Paediatric Biomarkers & Biosamples
12	Somik	CHAKRAVARTY	Fundraising Manager/Grant writer	Institute of Biological and Medical Imaging @ Helmholtz Munich	Pushing the boundaries of biomedical imaging and sensing methods
13	William	LEENDERS	CSO	Predica Diagnostics BV	Precision diagnosis of Lung Cancer
14	Tina	SMETS	Business Development Manager	Flemish Institute for Technological Research (VITO)	Protein biomarker validation in (neurodegenerative) disease
15	Aureli	SORIA-FRISCH	Director of Neuroscience BU	Starlab Barcelona SL	Neurotechnology as a Service (NTaaS)
16	Jean-Philippe	THEURILLAT	Associated Professor & Group Leader	Institute of Oncology Research, University of Southern Switzerland	Clinical validation of biomarkers for diagnosis, monitoring disease progression, and treatment response
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IHI Call Days | Call 7

Topic 3
BESTCaRe

Biomarkers for AI Enabled patient Specific Treatment for Cancer in Radiotherapy

Contact person name: Cristina Cozzini, Timo Schirmer, Elaine Long
Organisation: GE HealthCare

Contact person name: Luca Boldrini, Evis Sala, Saverio Gravina
Organisation: Policlinico Gemelli

E-mail: cristina.cozzini@gehealthcare.com;
Link to:

- Marketplace opportunity BESTCaRe

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BESTCaRe: Challenges

- Radiotherapy (RT) is received by more than a half of all cancer patients. It is often combined with surgery, cytotoxic chemotherapy, and immunotherapy. Technological advances in recent years have decreased RT toxicity by tailoring dose delivery to the tumor while minimizing the dose to the healthy organs.

- As treatment options increase, there is an unmet clinical need to select patient specific treatment and to optimize treatment response monitoring:
  - How can we determine which therapy or combination of therapies is optimal for the patient?
  - How can we balance the need for treatment with toxicity risks?
  - Can immunotherapy boost the therapeutic value of RT?

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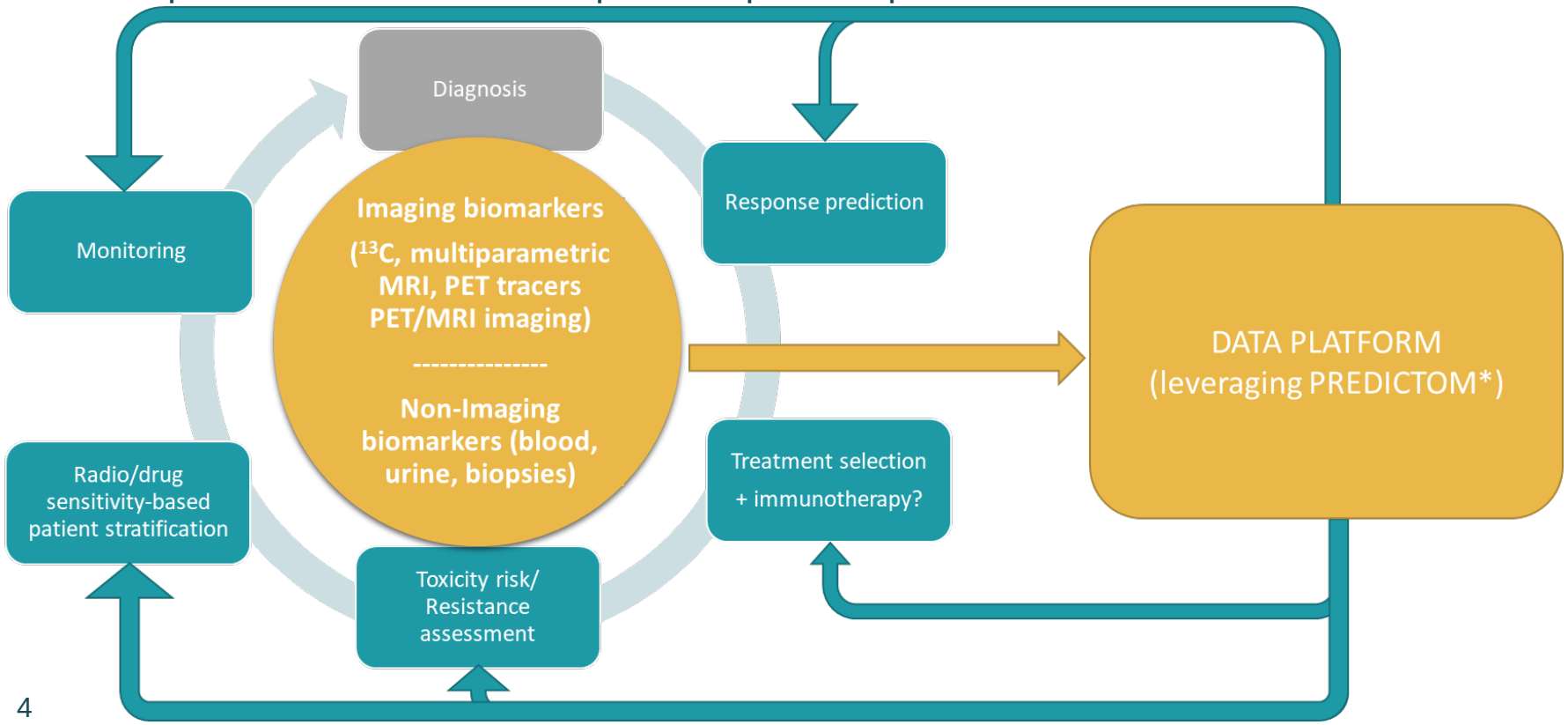
BESTCaRe: Objectives

We propose to develop a digital platform and a set of PET and MRI imaging biomarkers that together with non-imaging biomarkers will enable AI analytics for cancer treatment response prediction and monitoring.

The goal is to minimize toxicity risks, assess radio and/or drug resistance and predict treatment response for better patient stratification and optimized patient specific outcomes.



GE HealthCare expertise and support for clinical studies on:

MRI biomarkers as 13C, multiparametric MRI and PET/MRI imaging can offer both local and global non-invasive tools to assess
tumor heterogeneity; changes in lesions; true progression from pseudo progression.

PET diagnostics holds the key to more confidently identifying radiotherapy treatment, or treatment combinations, likely to be most effective for each individual patient

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*PREDICTOM: Prediction of Neurodegenerative Disease using an AI driven Screening Platform

This project has received funding from the Innovative Health Initiative Joint Undertaking, under Grant Agreement nº 101132356.

Expertise and resources offered

- Building upon:
  - EIT Health funded Deep MR-only Radiation Therapy [1] activity.
  - IHI funded PREDICTOM [2] platform (Alzheimer Disease biomarker screening platform)
- Policlinico Gemelli:
  - One Comprehensive Cancer Center serving **+ 50.000** Cancer Patients
  - + 1.800 Acitive Research Projects , + 1.400 Scientific Publications

Gemelli

BEST HOSPITALS 2023 Newsweek statista
1° OSPEDALE IN ITALIA
POLICLINICO UNIVERSITARIO A. GEMELLI

2018
Recognition as "research hospital" by the Italian Ministry of Health in *Personalized Medicine* and *Innovative Biotechnologies.*

2021
Joint Commission International (JCI) accreditation.

2021
Partnership with *Organization of European Cancer Institutes (OECI).*

Preliminary partners:

COCIR
GE HealthCare*
Clinical partners:
Gemelli Hospital

*IKOP - in-kind contributions to operational activities

Potential partners/Expertise requested:

Pharma partners
Companies **bringing in-kind contributions** with expertise in:

- non-imaging Biomarkers
- AI Tools for:
  - toxicity risk and/or resistance prediction,
  - response prediction,
  - treatment monitoring.

[1] This project has received funding from the Innovative Health Initiative Joint Undertaking, under Grant Agreement nº 101132356.

[2] Deep MR-only Radiation Therapy activity (project numbers: 19037, 20648, 210995) has received funding from EIT Health. EIT Health is supported by the European Institute of Innovation and Technology (EIT), a body of the European Union and receives support from the European Union's Horizon 2020 Research and innovation program

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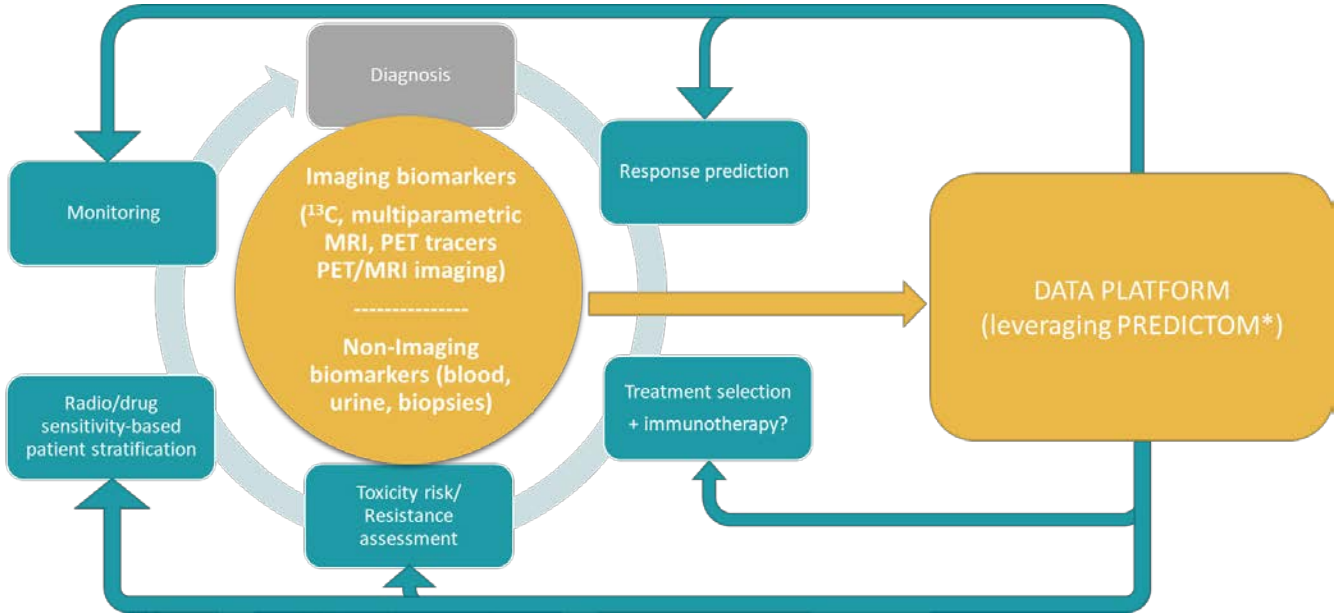
Contacts



GE HealthCare

Cristina Cozzini, cristina.cozzini@gehealthcare.com

Timo Schirmer timo.schirmer@gehealthcare.com

Elaine Long Elaine.Long2@gehealthcare.com

Policlinico Gemelli

Luca Boldrini luca.boldrini@policlinicogemelli.it

Evis Sala evis.sala@policlinicogemelli.it

Saverio Gravina saverio.gravina@policlinicogemelli.it

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

BREATHE

Contact person name: Tobias Heckel, Gaby Marquardt, Mark Dethlefsen
Organisation: Siemens Healthineers
E-mail: tobias.heckel@siemens-healthineers.com
gaby.marquardt@siemens-healthineers.com

Link to:

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

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BREATHE | Mission Statement

Biomarker-aided Refinements in the Assessment and Treatment of Lung cancer for Health Enhancement

Lung cancer remains one of the most common and deadliest cancers

Survival rates could be drastically improved through

- Earlier detection
- The use of personalized medicine for treatment

Urge to verify clinically applicable biomarkers and to combine digital and blood-based biomarkers in a multimodal fashion to improve patient outcomes along the entire patient journey

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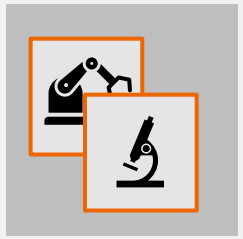
BREATHE | Objectives

Better outcomes through the integrated use of multimodal biomarkers

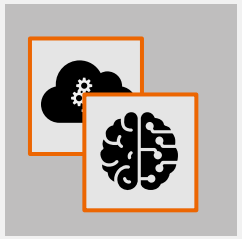
Screening | Detection & Diagnostics | Therapy Decision | Treatment | Outcome & Follow-up | Relapse

Verify multimodal biomarkers for the early detection of lung cancer as well as for risk stratification



Apply new technologies for the collection, purification and measurement of novel types of biomarkers

Verify biomarkers to improve treatment selection and to improve the access to personalized medicine

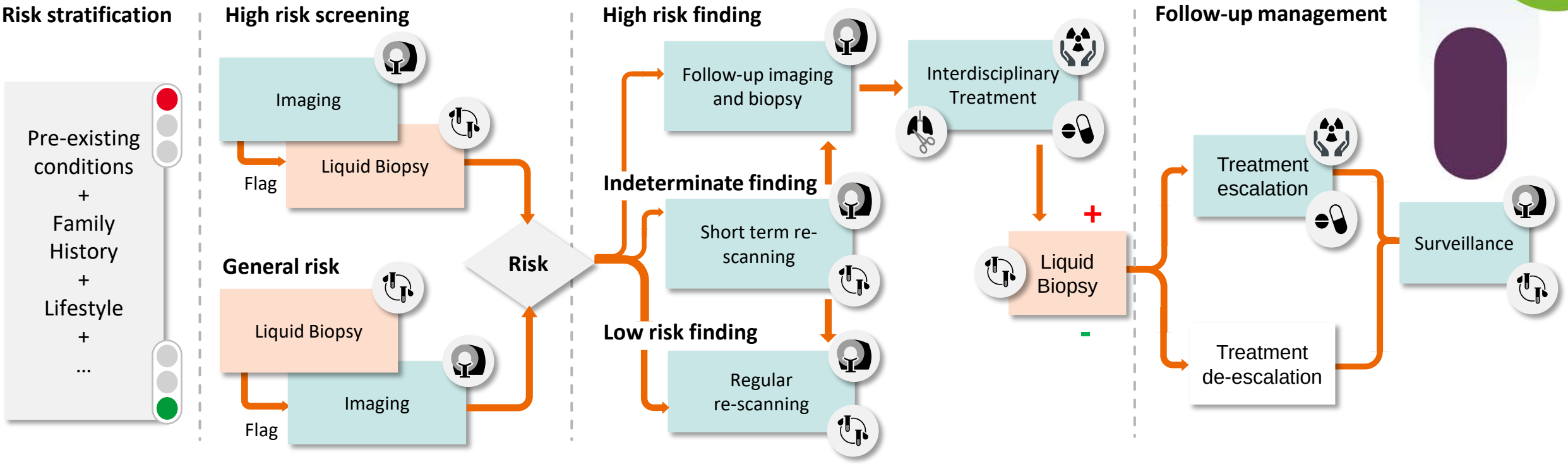


Provide a Digital Platform enabling the analysis and interpretation of multimodal biomarker data

Develop a regulatory strategy including the possibility to include liquid biopsy into reimbursement pathways

BREATHE | Main activities

Advance liquid biopsy and multimodal biomarkers in clinical studies for screening, risk assessment, treatment response prediction and the management of the patient follow-up care in lung cancer



Earlier detection of cancer in high risk and not at-risk populations, faster diagnosis, less interventions on benign findings, prediction of therapy response and early detection of disease recurrence

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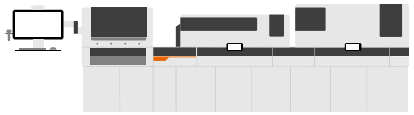
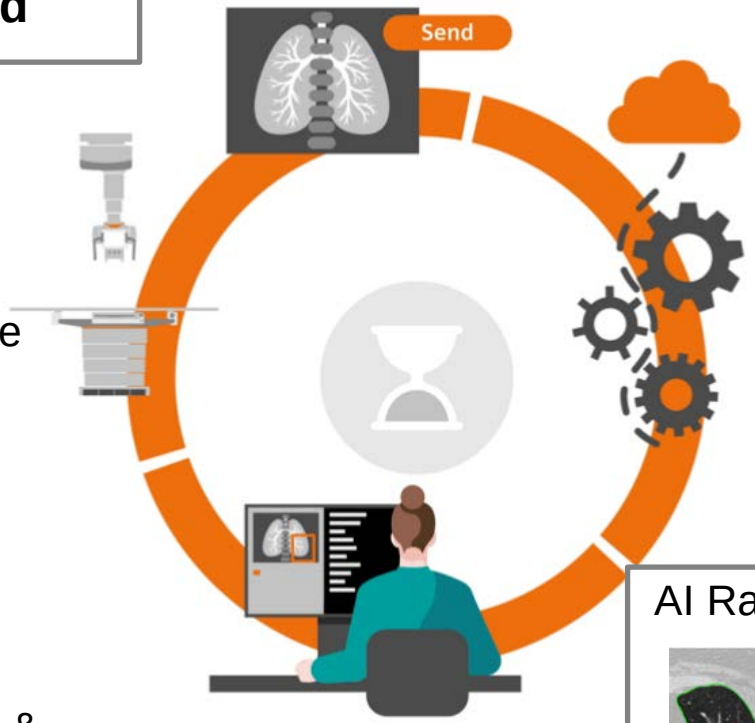
BREATHE | Expertise offered

10 clinical partner &

2 SMEs identified

imaging and blood-based biomarker in the clinical setting

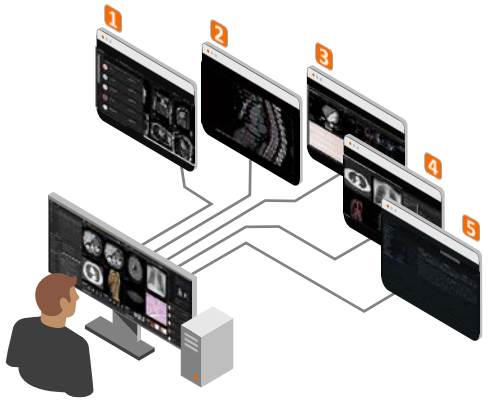




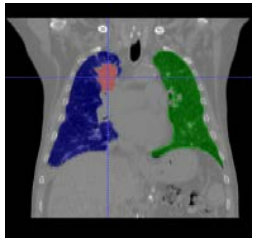
AI-supported image analysis

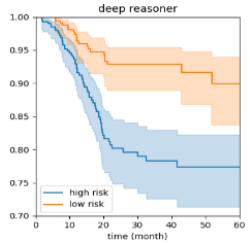
teamplay digital health platform

Integrated diagnostics: One workspace

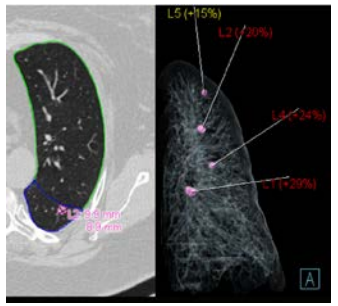


Deep Profiler for radiation therapy (SBRT) outcome optimization





AI Rad Companion



Market Research & Health Economics Studies

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RAD-AI study for SBRT personalization in lung cancer: NCT05802186
Lou B et al., An image-based deep learning framework for individualizing radiotherapy dose: retrospective analysis of outcome prediction, Lancet Digital Health. 2019; 1: e136-e147.
Randall J. et al., Image-Based Deep Neural Network for Individualizing Radiotherapy Dose Is Transportable Across Health Systems, JCO Clinical Cancer Informatics 2023 :7.

BREATHE | Expertise requested

We are looking for partners that complement Siemens Healthineers diagnostics, imaging and radiotherapy capabilities

- Pharmaceutical Partner
  → *biomarkers for precision medicine and therapy decision*
- Technology Development & Biotech Partner
  → *novel technologies for sample preparation and sensing*

  → *additional candidate biomarker from Biotech for clinical validation*
- Clinical Partner
  → *clinical samples, clinical evidence*
- Regulatory Partner (SMEs, NGOs)
  → *prepare for approval process and explore path to reimbursement*
- Patient Representation
- …

Expected duration / budget: 4-5 years / 30mil €

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Topic 3: Clinical Biomarker Validation

BRECISE

Biomarker **R**esearch and **E**valuation for **C**linical **I**mplementation and **S**upporting **S**ystems **E**nhancement

Contact person name: Ralf Hoffmann

Organisation: Philips

E-mail: ralf.hoffmann@philips.com

Link to Market Place: link

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BRECISE

Challenges

- A limited number of prognostic, and predictive oncology biomarkers are subjected to rigorous clinical testing, hindering progress in precision medicine;
- Novel NGS, multi-modality, AI next-generation biomarkers lack accessible and affordable technologies with fast turnaround times for clinical use;

Objectives

- Create a framework to support oncology driven biomarker validation and scaling;
- Enhance associated biomarker NGS technologies;
- Establish collaborative data sharing strategies to scaling up clinical biomarkers validation/development;
- Provide a regulatory and market acceptance strategy;
- Develop a dissemination strategy and plan and create educational resources for healthcare professionals;

Expected Impact

- Availability of clinically validated NGS biomarkers to support the HCP in treatment decision making, and to improve patient outcomes and patient satisfaction;
- Validated biomarker technologies to enable the researchers to develop safer and more effective personalised treatments;
- Increased competitiveness of European health industries;

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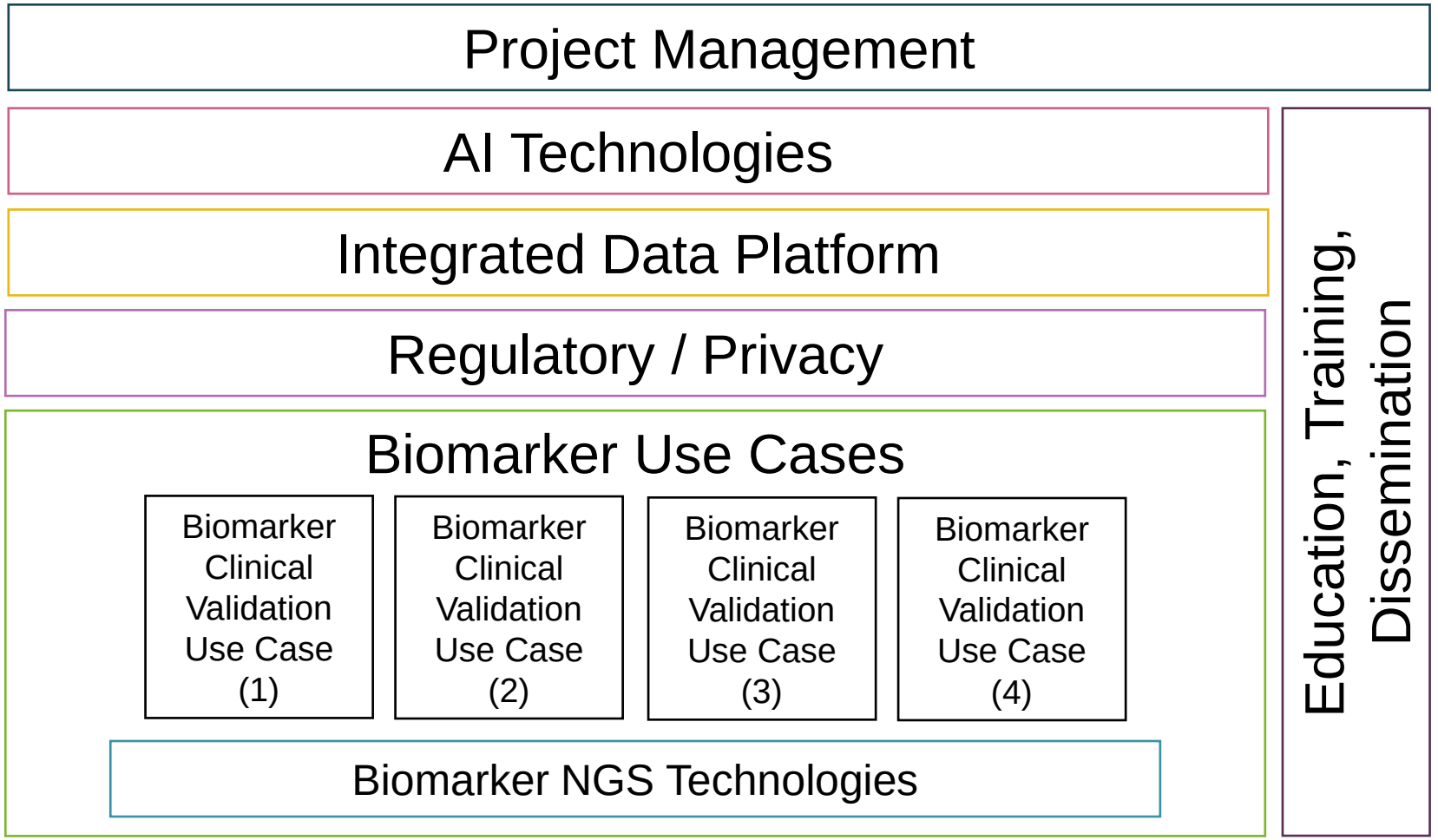
Main activities



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Expertise and resources offered

- MedTech, Diagnostic Technology, AI Technology, IT Technology, Clinical, Academic;
- We will bring IKOP and IKAA to the project.

* IKOP - in-kind contributions to operational activities
** IKAA - in-kind contribution to additional activities

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Expertise requested

- Pharma
- Biotech/Pharma
- Biobanks and data registries
- Regulatory

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Who we are

- **Prof. Francois-Clement BIDARD, MD PhD**

Medical Oncologist, Head of Circulating Tumor Biomarkers lab

N~200 papers, h-index = 46 (Clarivate) / 59 (Google)

- **Institut Curie:**

Largest center for breast cancer in EU (4,000 new cases / year)

Awarded « National Institute for Women's Cancers » by French gov. in 2023

(One of) the best cancer biology research center in France

Excellent environment

Clinical operations: Full ressources to set up, promote, run and report clinical trials

Translational research: Certified biobank, certified health data repository, enthusiast pathologists…

Industry-friendly: certified tech transfer office, many large scale (M€) collaborations ongoing

Our experience in demonstrating the clinical utility of biomarkers

STIC CTC trial (N= ~800 ER+ mBC pts)

First and only trial to show **circulating tumor cell count** improves the choice between treatment options

- ➔ Short term results: Bidard FC, JAMA Oncology 2021 (IF=28)
- ➔ Long term survival: Bidard FC, J Clin Oncol 2023 (IF=50)

PADA-1 trial (N= 1,017 ER+ mBC pts)

First and only trial (to date) to show the clinical utility of **ctDNA monitoring** in mBC patients

Very original trial design now copy-pasted by industry to register new drugs

- ➔ Short term results: Bidard FC, Lancet Oncology 2022 (IF =54)

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Our consortium

Antibody-Drug Conjugate

Biomarker campaing (before / during / after)

- **Functionnal imaging:** PET/CT with new radiotracer + AI analysis
- **Tumor biopsy:** Multiplex Digital Pathology + AI analysis / Spatial transcript.
- **Liquid biopsy:** ctDNA (includ. fragmentomics) / CTC

Iry objective:

- Validate one BM (+explore others)
- Or more complex stat approach

depending on BM TRL

Acceptable variations:

- IO agents / radiotracers
- Other diagnostic/therapeutic radionuclide

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What we are looking for

New clinical-grade radiotracer related to ADC targets (HER2, TROP2, etc)

ADC

Multiplex Digital Pathology

Spatial transcript.

ctDNA (includ. fragmentomics)

CTC

Acceptable variations:

- IO agents / radiotracers
- Other diagnostic/therapeutic radionuclide

Already secured

Clinical sites to enroll metastatic breast cancer patients	France
AI *academic* expertise in nuclear medicine & digit. Path	France
Company to coordinate grant application/execution	Spain

Please contact fcbidard@curie.fr and shufang.renault@curie.fr

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1	Cristina	COZZINI	Senior Scientist	GE HealthCare	BESTCaRe - Biomarkers for AI Enabled patient Specific Treatment for Cancer in Radiotherapy
2	Tobias	HECKEL	Research & Technology Manager	Siemens Healthineers	BREATHE - Biomarker-aided Refinements in the Assessment and Treatment of Lung cancer for Health Enhancement
3	Ralf	HOFFMANN	Principal Scientist	Philips	BRECISE - Biomarker Research and Evaluation for Clinical Implementation and Supporting Systems Enhancement
4	François-Clément	BIDARD	Professor of Medical Oncology	Institut Curie	Biomarker validation – Consortium proposal
5	Daniela Maria	CIRILLO	Head EBPU IRCCS OSR	Vita-Salute San Raffaele University	valiDation of biOmarkers to iMprove dIagnosis and maNagement Of infEctious diSeases (DOMINOES)
6	Milena	CAVIC	Senior Research Associate	Institute for Oncology and Radiology of Serbia	Clinical utility and implementation of circulating tumor DNA (ctDNA) across the patient journey
7	Hendrik	LAUE	Key Scientist Quantitative and Dynamic Image Analysis	Fraunhofer MEVIS	Biomarker Validation - Quantitative MRI
8	Karim	LEKADIR	ICREA Professor	University of Barcelona	AI-Driven Imaging Biomarkers
9	Michael	LEVIN	Professor of International Child Health	Imperial College London	Bringing Biomarkers for Infectious and Inflammatory Disease into Clinical Use
10	Carles	BLASCO	R&D Project Manager	ISABIAL - Alicante Institute for Health and Biomedical Research	Integrative analysis of biomarkers to improve monitoring of neurological and heart diseases
11	Donato	BONIFAZI	CEO	CVBF-EPTRI	Biomarkers in paediatric diseases diagnosis, treatment and monitoring– EPTRI Thematic Research Platform on Paediatric Biomarkers & Biosamples
12	Somik	CHAKRAVARTY	Fundraising Manager/Grant writer	Institute of Biological and Medical Imaging @ Helmholtz Munich	Pushing the boundaries of biomedical imaging and sensing methods
13	William	LEENDERS	CSO	Predica Diagnostics BV	Precision diagnosis of Lung Cancer
14	Tina	SMETS	Business Development Manager	Flemish Institute for Technological Research (VITO)	Protein biomarker validation in (neurodegenerative) disease
15	Aureli	SORIA-FRISCH	Director of Neuroscience BU	Starlab Barcelona SL	Neurotechnology as a Service (NTaaS)
16	Jean-Philippe	THEURILLAT	Associated Professor & Group Leader	Institute of Oncology Research, University of Southern Switzerland	Clinical validation of biomarkers for diagnosis, monitoring disease progression, and treatment response
17	Jérémie	THIBLET	Chief Growth Officer	NeoVentures Biotechnology Europe	PAMD: Validation of biomarkers for Personalized treatment of Age-related Macular Degeneration (AMD)
18	Aad	VAN DER LUGT	Chair Department of Radiology & Nuclear Medicine, Erasmus MC Rotterdam	European Imaging Biomarker Alliance (EIBALL)	EIBALL Could be a partner for your project
19	John	WATERTON	Scientific Director	Bioxydyn Ltd	Clinical validation of imaging biomarkers

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

valiDation of biOmarkers to iMprove dIagnosis and maNagement Of infEctious diSeases (DOMINOES)

Contact person name: Daniela Maria Cirillo

Organisation: Vita Salute San Raffaele University, Milan

E-mail: cirillo.daniela@hsr.it

Link to:

- Marketplace opportunity
- Participant profile

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Challenges and objectives

Antimicrobial resistance (AMR) is one of the top global public health and development threats.

Biomarkers for early detection of bacterial and fungal infections and drug resistance determinants are instrumental for timely delivering safer and effective personalised treatment, ensuring the appropriate use of new drugs while minimising selection and spreading of drug resistance. .

This project aims to develop and validate new tests based on a biomarker-driven approach for the early diagnosis of infections sustained by bacterial pathogens, *M. tuberculosis* and fungi, and for monitoring of treatment response

To reach this purpose, diagnostic platforms and molecular technologies for the identification and characterization of Multi Drug Resistant Organisms (MDROs), mycobacteria and yeast directly from the collected specimens (e.g., blood) will be developed and validated.

This approach will be paired with the simultaneous measurement of relevant biomarkers of host response. Artificial-intelligence (AI)-based algorithms will then be developed to ensure the streamlining interpretation of the results obtained

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Main activities

WP1 Platforms for rapid diagnostic of life-threatening infections (end to end sensitive solution for diagnosis of sepsis with biomarkers)

WP2 Biomarker based approach to determine treatment response in life-threatening and hard to treat infections

WP3 Next generation of companion diagnostics for new anti-TB drugs (phenotypic and genotypic approach)

WP4 Biomarkers for TB management and care

WP5 Trials for the validation of MDROs biomarkers and diagnostic multiparametric platforms and regulatory aspects

WP6 Trials for the validation of TB biomarkers and diagnostic platforms and regulatory aspects

WP7 AI

WP8 Management and communication

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Expertise and resources offered

The Current Consortium Already Includes:

- Industries (EFPIA And Medtech)
- SME
- Non-profit Organizations
- Highly Experienced Academic Partners
- Patients' Organizations

Expertise requested

Academia, SME and Industrial partners (ABLE TO CO FINANCE) to collaborate with the existing consortium.

PARTNERS SHOULD HAVE:

Experience in biomarkers fitting our concept and in needs of clinical validation

Advanced and innovative technologies to be adapted for the scope

Experience with phages, circulating vesicles and AI development for diagnostics

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

Clinical utility and implementation of circulating tumor DNA (ctDNA) across the patient journey

Contact person name: Remond Fijneman
Organisation: Netherlands Cancer Institute
E-mail: r.fijneman@nki.nl
Link to Marketplace opportunity: https://ihi-call-days.ihi.b2match.io/participations/323306/opportunities
Link to Participant profiles:

- Remond Fijneman: https://ihi-call-days.ihi.b2match.io/components/25061?query=fijne
- Claus Lindbjerg Andersen: https://ihi-call-days.ihi.b2match.io/components/25061?query=andersen
- Milena Cavic: https://ihi-call-days.ihi.b2match.io/components/25061?query=cavic
- Lygature: https://ihi-call-days.ihi.b2match.io/components/25061?query=verjans

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Challenges and objectives

Main challenges:

ctDNA biomarker clinical applicability has been demonstrated to determine '**who/how/when to treat**'.

However, clinically ctDNA-testing is not widely applied:

- **Utility**: ctDNA clinical utility remains to be demonstrated.
- **Implementation**: ctDNA implementation in clinical practice remains to be regulated.

Main objective:

- Improve care for patients with cancer by **bringing ctDNA molecular diagnostics to clinical implementation**.

Expected outcomes & impact:

- **ctDNA-guided precision medicine**
  - Better patient selection (treatment escalation/de-escalation)
  - Earlier recurrence detection (timely intervention for greater effect)
  - Precise monitoring of therapy response (earlier termination of ineffective therapy – avoiding toxicity)
  - Improved quality of life (right treatment for the right patient; right treatment duration).
- EU **regulatory framework**
  - ctDNA test regulatory qualification; reimbursement; implementation.

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Main activities

ctDNA-UI: Circulating tumor DNA (ctDNA) across the patient journey

Utility

ctDNA-guided precision medicine

ctDNA clinical validation studies

Patient journey	colon cancer	rectal cancer
Prognosis & surveillance	MRD testing watch-and-wait	MRD testing watch-and-wait
Treatment selection and prediction	Drug sensitivity	Drug/radio sensitivity
Treatment response monitoring	Metastatic CRC and other types of cancer	

FAIR data stewardship

Health Technology Assessment

Implementation

Regulatory Framework

Availability, Affordability, Accessibility

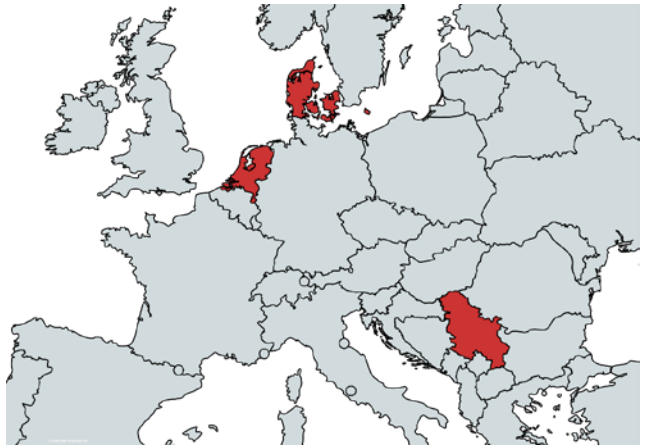
- ❑ ctDNA test regulatory qualification
- ❑ ctDNA test reimbursement
- ❑ ctDNA test implementation

Involve and organize stakeholders, *a.o.*

- ➢ Regulatory authorities (EU, national)
- ➢ Health economists (HTA)
- ➢ Health insurance companies
- ➢ Private partner representatives
- ➢ Health professionals
- ➢ Patient advocates

Expertise and resources offered

- Current partners:



- NL – Netherlands Cancer Institute, Amsterdam
- DK – Aarhus University Hospital, Aarhus
- RS – Institute for Oncology and Radiology of Serbia, Belgrade
- NL – Lygature, Utrecht

- Our expertise:
  - **colon cancer** and **rectal cancer** observational and interventional ctDNA biomarker studies*
  - FAIR data stewardship expertise
  - Health Technology Assessment expertise
  - Program management and communication
- Our resources:
  - availability of **clinical study data and samples**, from observational and interventional studies
  - **infrastructure** to run multicenter and multinational **prospective clinical validation studies**

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* See ORCID IDs: 0000-0003-2076-5521 ; 0000-0002-7406-2103 ; 0000-0002-7604-9295

Expertise requested

- We are looking for private partners to team up in the consortium:
  - **ctDNA biomarker companies**: *a.o.* clinical validation of ctDNA assays and paving the path to ctDNA test regulatory qualification and reimbursement
  - **Pharmaceutical companies**: *a.o.* patient selection for interventional trials
  - **Imaging** and **AI companies**: *a.o.* combining ctDNA and imaging modalities

- We are looking for expertise in the fields of:
  - **Regulators** (EU; governmental; healthcare providers; ..) involved in biomarker test regulatory qualification; reimbursement; implementation

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Biomarker Validation

Quantitative MRI

Contact person name: Hendrik Laue
Organisation: Fraunhofer MEVIS
E-mail: hendrik.laue@mevis.fraunhofer.de

Link to:

- https://ihi-call-days.ihi.b2match.io/participations/325052/opportunities
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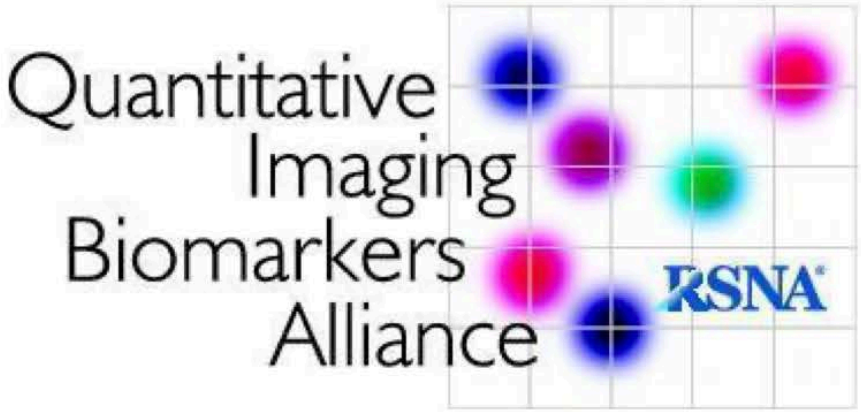

QIBA Profile:
DCE-MRI Quantification (DCEMRI-Q)

Profile submitted for Stage 2: Consensus

- Global expert consensus
- Provide calibration and standardization workflows
- Monthly meetings (second Monday of the month, 6 pm CET)

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Amsterdam UMC

Fraunhofer

MEVIS

Erasmus MC

University Medical Center Rotterdam

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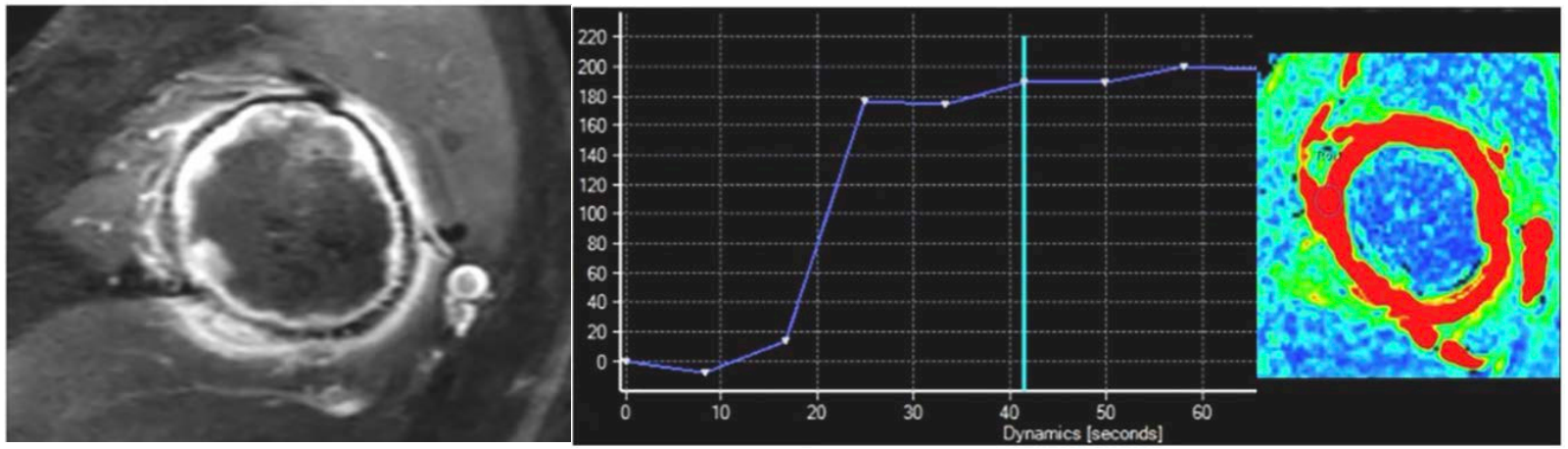
Dynamic contrast enhanced (DCE) MRI

- DCE-MRI measures contrast enhancement over time
- assess changes in microvasculature/perfusion non-invasively
- literature shows value of DCE-MRI as a biomarkers for
  - cancer
  - inflammatory disorders



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Griffith JF, Yip SWY, van der Heijden RA, Valenzuela RF, Yeung DKW. Perfusion Imaging of the Musculoskeletal System. Magn Reson Imaging Clin N Am. 2024 Feb;32(1):181-206.

Challenges and objectives

- DCE-MRI is currently only used **qualitatively** in the clinic
- We plan to: standardize
  - acquisition sequence and hardware
  - analysis methods (model, T1, B1, AIF)
- Our goal: introduce widely accepted biomarker to:
  - predict outcome
  - assess treatment efficacy
  - adjust therapies
- Our target:
  - **bone** and **soft tissue tumours**
  - **rheumatoid arthritis (RA)**

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Main activities

- Set up a standardized quantitative workflow
- Make it clinically implementable
- Motivate and aide multicenter clinical trials for DCE MRI parameters as biomarkers

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Expertise and resources offered

- Clinical data and expertise from multiple hospitals
- Quantitative Imaging in MRI
  - Multi vendor expertise (Philips, GE, Siemens)
  - Sequence implementation
  - Sequence calibration phantoms and tools (T1, B1)
- Standardized evaluation software for DCE
  - Motion correction
  - Calibration with T1 and B1 maps
  - Standardized parameters (K^{trans}, v_e, AUC, T_1,…)

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Expertise requested

- SME, pharmaceutical companies, research Institutes:
  - Clinically relevant treatment for bone and soft tissue tumors or Rheumatic Arthritis (RA)
  - High relaxivity, low Gd concentration contrast agent manufacturer
- Clinics
  - MRI based clinical studies
  - Treatment of bone and soft tissue tumors or RA

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Clinical Validation of Biomarkers

AI-Driven **Imaging** Biomarkers

Contact person name: Prof. Karim Lekadir

Organisation: University of Barcelona

E-mail: karim.lekadir@ub.edu

Link to:

- Marketplace
- My profile

AI4Health Imaging

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Challenges

- Emerging AI-driven imaging biomarkers are promising:
  - Radiomics
  - Radiogenomics
  - Deep learning based biomarkers
  - Integrative biomarkers
    (Imaging + Clinical + Biological)

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Challenges

- But there is a lack of validation and evidence regarding their:
  - Efficacy and safety
  - Reliability and trustworthiness
  - Applicability (e.g. regulatory compliance)

- Consequently, **clinical deployment has been very limited**

Objectives:

1. Bridge the gaps in the validation of AI-driven imaging biomarkers
2. Implement a comprehensive validation platform linked to EU data
3. Define holistic, standardised validation criteria, metrics and methods
4. Implement three use cases that address clinical and industrial needs
   (1) diagnosis, (2) prognosis, (3) treatment

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Expertise and resources offered

- www.eucanimage.eu
- www.cancerimage.eu
- www.procancer-i.eu
- www.incisive-project.eu
- www.radioval.eu
- www.primage.eu
- www.chaimeleon.eu
- www.future-ai.eu

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Expertise and resources offered

- 100+ institutions
- 25 countries
- 30+ hospitals
- 8 Interest Groups:
  - AI
  - Data
  - Clinical validation
  - ELSI

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Expertise and resources offered

- Federated data repository
- 100,000s patients
- Millions of images
- Non-imaging data
- 7 clinical domains

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Expertise and resources offered

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Activities: Technology

Deliver a holistic, cost-effective, user-friendly validation platform:

- IMAGE DATA CATALOGUE
- FEDERATED DATA LINKAGE
- IN-SILICO VALIDATION
- PROSPECTIVE VALIDATION
- CONTINUOUS VALIDATION
- REGULATORY APPROVAL

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Activities: Validation

Implement in-depth validation studies of new imaging biomakers:

- Diagnosis biomarkers
- Prognosis biomarkers
- Treatment biomarkers

- **Breast**
- **Colorectal**
- **Prostate**
- **Liver**
- **Lung**
- **Brain**
- **Cardiac**

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Expertise requested

1. Technology companies
2. Pharma companies
3. MedTech SMEs
4. BioTech SMEs

Contact us:
karim.lekadir@ub.edu

- **Co-define validation use cases**
- **Co-lead platform development**
- **Co-lead clinical validations**
- **Co-define exploitation routes**

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Clinical Validation of Biomarkers for Diagnosis, monitoring of disease progression and treatment response

Bringing Biomarkers for Infectious and Inflammatory Disease into Clinical Use

Contact person name: Professor Mike Levin

Organisation: Imperial College London and the DIAMONDS Consortium

E-mail: m.levin@imperial.ac.uk

Link to: https://www.diamonds2020.eu

- Marketplace opportunity https://ihi-call-days.ihi.b2match.io/components/25062?query=diamonds
- Participant profile https://ihi-call-days.ihi.b2match.io/components/25061?query=michael%20levin

DIAMONDS
MAKING DIAGNOSIS PERSONAL

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Challenges and objectives

- Main objective: **to accelerate the development and clinical application of host-response biomarker tests for diagnosis and prognosis of infectious and inflammatory diseases**
  - What problems are you trying to solve?
    - Lack of rapid, reliable diagnostics for infectious and inflammatory diseases
    - Biomarker test development process is costly and prone to failure
  - Is your project suitable for IHI?
    - Yes! This can only be done in multi-sectoral partnership
  - Potential results and expected impact
    - Progress multiple novel host-response gene expression and protein biomarker tests towards preparation for regulatory approval, each with different use-cases

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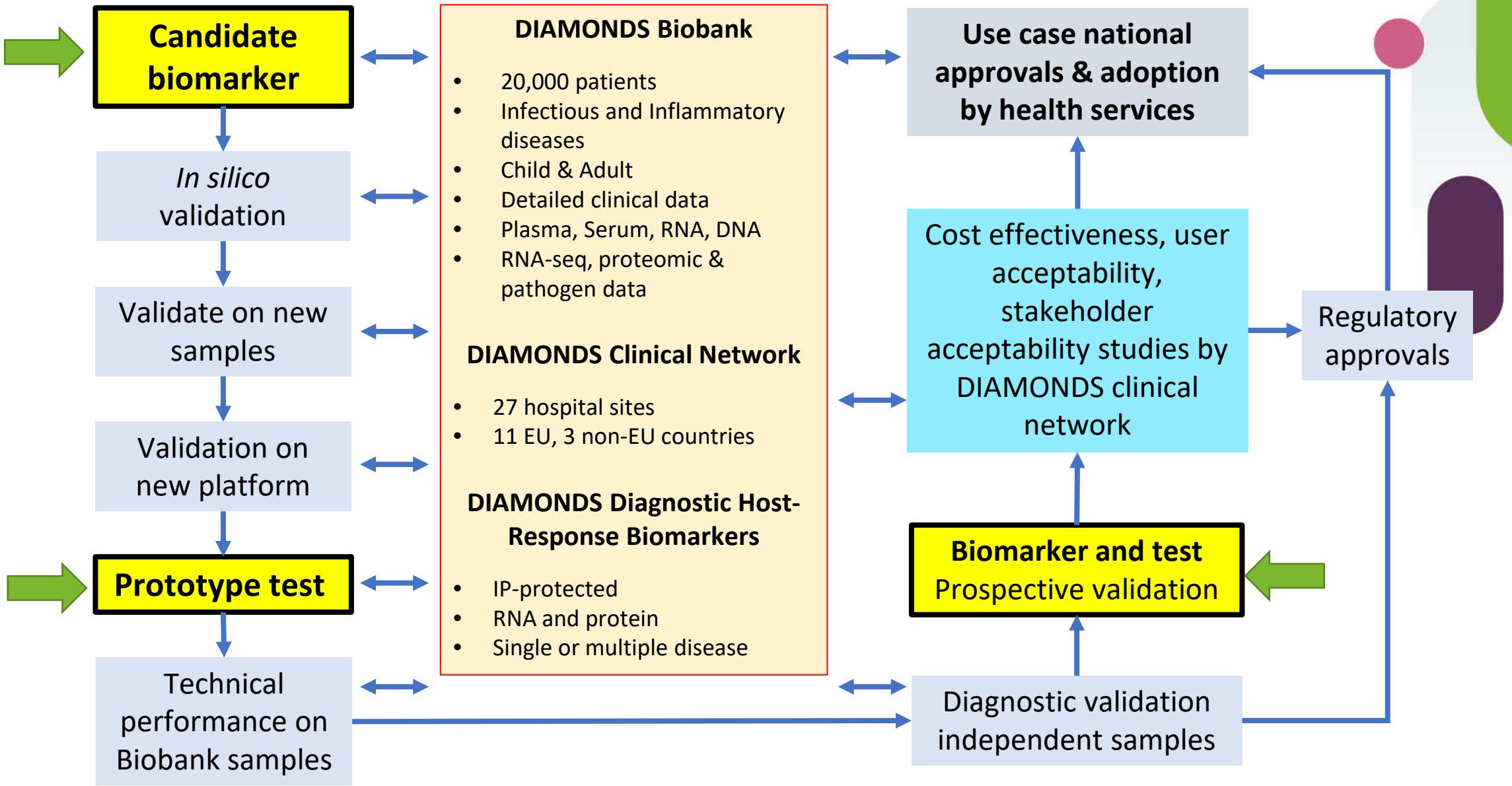
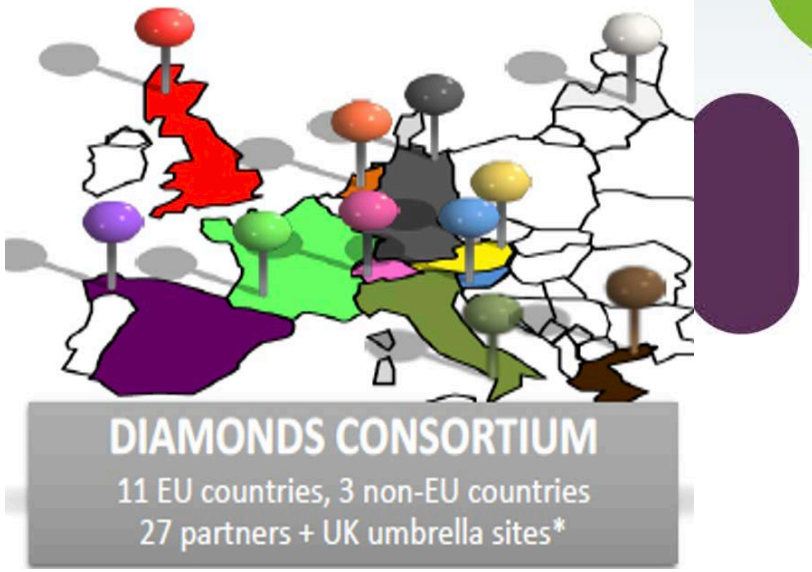
Main activities: accelerating the biomarker test development pipeline



Expertise and resources offered

- **DIAMONDS Consortium**
  - Track record:15 years of consecutive large EU grants
- Proven expertise:
  - Clinical recruitment and phenotyping
  - RNA /Proteomic analysis
  - Bioinformatics and biomarker discovery
  - Test platform development and evaluation
  - Cost effectiveness and clinical utility
- IP for RNA and protein biomarker signatures for infectious and inflammatory diseases: bacteria, viruses, TB, malaria, inflammatory diseases, severity of illness



(The Gambia, Taiwan, Nepal)
plus other collaborators globally

DIAMONDS
MAKING DIAGNOSIS PERSONAL

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Expertise requested

- Companies with candidate biomarkers, test platforms, or both, for infectious and inflammatory diseases
  - Who want to co-develop and test them using our biobank, our biomarker signatures, and/or our clinical network
  - Who can make significant contribution in kind
  - Are willing to work pre-competitively alongside others recognising there are many potential biomarker combinations and use cases
- Regulators, foundations, advocacy groups

DIAMONDS
MAKING DIAGNOSIS PERSONAL

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Today 25 January 2024, 14:30 – 16:00 **Brussels time**

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3	Ralf	HOFFMANN	Principal Scientist	Philips	BRECISE - Biomarker Research and Evaluation for Clinical Implementation and Supporting Systems Enhancement
4	François-Clément	BIDARD	Professor of Medical Oncology	Institut Curie	Biomarker validation – Consortium proposal
5	Daniela Maria	CIRILLO	Head EBPU IRCCS OSR	Vita-Salute San Raffaele University	valiDation of biOmarkers to iMprove dIagnosis and maNagement Of infEctious diSeases (DOMINOES)
6	Milena	CAVIC	Senior Research Associate	Institute for Oncology and Radiology of Serbia	Clinical utility and implementation of circulating tumor DNA (ctDNA) across the patient journey
7	Hendrik	LAUE	Key Scientist Quantitative and Dynamic Image Analysis	Fraunhofer MEVIS	Biomarker Validation - Quantitative MRI
8	Karim	LEKADIR	ICREA Professor	University of Barcelona	AI-Driven Imaging Biomarkers
9	Michael	LEVIN	Professor of International Child Health	Imperial College London	Bringing Biomarkers for Infectious and Inflammatory Disease into Clinical Use
10	Carles	BLASCO	R&D Project Manager	ISABIAL - Alicante Institute for Health and Biomedical Research	Integrative analysis of biomarkers to improve monitoring of neurological and heart diseases
11	Donato	BONIFAZI	CEO	CVBF-EPTRI	Biomarkers in paediatric diseases diagnosis, treatment and monitoring– EPTRI Thematic Research Platform on Paediatric Biomarkers & Biosamples
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13	William	LEENDERS	CSO	Predica Diagnostics BV	Precision diagnosis of Lung Cancer
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15	Aureli	SORIA-FRISCH	Director of Neuroscience BU	Starlab Barcelona SL	Neurotechnology as a Service (NTaaS)
16	Jean-Philippe	THEURILLAT	Associated Professor & Group Leader	Institute of Oncology Research, University of Southern Switzerland	Clinical validation of biomarkers for diagnosis, monitoring disease progression, and treatment response
17	Jérémie	THIBLET	Chief Growth Officer	NeoVentures Biotechnology Europe	PAMD: Validation of biomarkers for Personalized treatment of Age-related Macular Degeneration (AMD)
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Days | Call 7

Topics:

- Improving clinical management of heart disease from early detection to treatment
- Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

Integrative analysis of biomarkers to improve monitoring of neurological and heart diseases

Contact person name: **Carles Blasco**

Organisation: ISABIAL - Alicante Institute for Health and Biomedical Research

UMH - Miguel Hernández University, ITI - Instituto Tecnológico de Informática

E-mail: blasco_car@isabial.es

Link to:

- Marketplace opportunity
- Participant profile

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Challenges and objectives

- **Problem to solve**
  - In non-communicable diseases, a concise and personalized monitoring of disease progression is challenging since there are **no key biomarkers** in the clinics that appropriately track the course of the disease. As a result, therapeutic interventions cannot be timely administered.
  - We aim to identify and validate **novel clinical biomarkers** that could facilitate the **early detection of disease worsening** in neurological and/or cardiovascular diseases.

- **How?**
  - Using a comprehensive, integrative and technological approach to accurately identify and track relevant molecular and biomechanical biomarkers for evaluating the progression of these non-communicable diseases.

- **Potential results and expected impact**
  - R1: AI-based Risk Assessment Model for the early identification of disease worsening (disease prognosis) in e.g. Parkinson's, Multiple Sclerosis, heart failure (others also possible).
  - R2: Analysis of results obtained by the application of different treatments to optimize them.
  - I1: Mitigated economic and health burdens result from the proactive identification of disease progression.
  - I2: Novel tools/approaches: A new tool validated with a cohort of patients from Alicante.
  - I3: Improvement of the quality of life for patients (e.g., five point improvement in the “Minnesota living with heart failure questionnaire” for at least 75% of patients).

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Main activities

We could address the following activities:

- Recruitment of volunteers for biological sampling and biomechanical analysis in neurological and cardiovascular diseases.
- Discovery / validation / assessment of biomarkers associated with early worsening of neurological and cardiovascular diseases, mainly based on circulating nucleic acids in body fluids and biomechanical parameters.
- Signal and biomarkers information treatment to accommodate it for posterior AI techniques application.
- AI-based feature discovery related to illness worsening prognosis in high dimensional spaces of heterogeneous features.
- Development of prognosis models to predict the risk of near or medium future unfavourable clinical progression.

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Expertise and resources offered

We are an alliance of three Spanish institutions located in Alicante and Valencia region, bringing expertise and logistic capabilities to address some needs of any potential consortium project related with our initiative

- **ISABIAL** https://isabial.es *(Health research institute):* linked to a public hospital facilitating access to patient cohorts and bringing expertise in assessing fluid molecular biomarkers.
  - **Patient's cohorts:** Parkinson's disease n = 60; Multiple Sclerosis n = 60; Cardiovascular disease n = 250 (CVD risk 150; AMI 50; HF 50).
  - **Technical expertise and resources:** Cutting-edge technologies and expertise for liquid biopsies, biobanking, isolation and characterization of extracellular vesicles, multiomics sequencing and analysis (small RNA sequencing, Single cell RNA-seq; bulk RNA-seq; DNA methylomics; circular DNA), RNA identification and quantification (qPCR) and protein analysis (Multiplex ELISA) .
- **UMH** https://www.umh.es *(University)*: proficiency in the analysis of physiological and biomechanical signals.
  - **Expertise in biomechanical and signal analyses:** encompassing ECG, inertial sensors, 3D systems, EMG, and dynamometry, focusing on autonomic nervous system function, gait patterns, balance impairments, and muscle weakness.
- **ITI** https://www.iti.es (*ICT research & technology centre*): specialized in data cycle technologies, brings expertise in applying AI and ML techniques to develop predictive models for classification, risk estimation, and stratification.
  - **Technical expertise:** integration of heterogenous datasets (including genetic information, clinical data, medical imaging, and various medical test results); generate AI-based risk-assessment and/or predictive models
  - **Assets:** SEQENS, a novel AI inductive algorithm developed by ITI (https://pubmed.ncbi.nlm.nih.gov/36521355/) for the identification and selection of relevant variables in scenarios with large number of variables compared to the number of observations

Expertise requested

- We are **looking to join a consortium** on either of the following topics (different diseases addressed and different cohorts)
  - IHI Call 7 Topic 1 : “Improving clinical management of heart disease from early detection to treatment”
    → Expertise and contributions to ***Cardiovascular diseases***
  - IHI Call 7 Topic 3 “Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response”
    → Expertise and contributions to **neurological diseases**

- If needed, we could **support/lead a Spanish sub-consortium**

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IHI Call Days | Call 7

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

Biomarkers in paediatric diseases diagnosis, treatment and monitoring– EPTRI Thematic Research Platform on Paediatric Biomarkers & Biosamples

Contact person name: Donato Bonifazi

Organisation: European Paediatric Translational Research Infrastructure

E-mail: dbonifazi@eptri.eu

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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

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Challenges and objectives: the EPTRI perspective in EU

- EPTRI AISBL (Association Internationale Sans But Lucrative) 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 research units grouped 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 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.

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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

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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, characterisation and validation** 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
- 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& writing

- **Regulatory qualification process of paediatric biomarkers**
- Contacts with patients' associations/YPAG for age tailored training/empowerment approaches starting from early childhood
- **Regulatory compliant Data Sharing/Material Transfer Agreements**

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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

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Institute of Biological and Medical Imaging
IBMI
Helmholtz Munich

Prof. Dr. Vasilis Ntziachristos
Director

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Contact us:
somik.chakravarty@helmholtz-munich.de

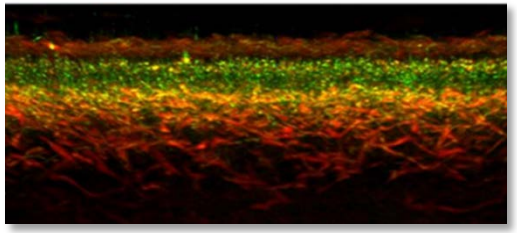
IBMI: Our expertise

Pushing the boundaries of biomedical imaging and sensing methods

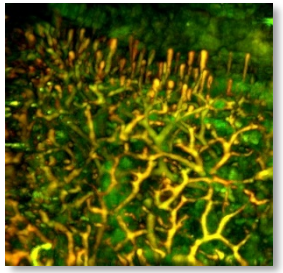
Multi-spectral optoacoustic tomography (MSOT) Raster-scan optoacoustic mesoscopy (RSOM)

Label-free biomarkers resolved by Optoacoustics:

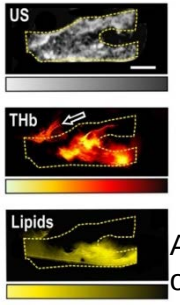
- 64 microvascular morphology features per wavelength
- 5 single capillary endothelial function features
- 5 total endothelial function features
- Single capillary & total tissue oxygen saturation (SO_2)
- Oxygen demand /metabolism (rate of (SO_2) change).
- Lipid metabolism (rate of lipid content change)
- Melanin



An RSOM image of healthy skin



Nailfold microvascular scleroderma



Atherosclerosis plaque

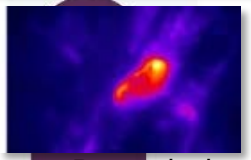
Publications:

- Morphophysiological skin features for **diabetes** discovery and monitoring (2023) *Nat Biomed Eng*
- Skin biomarkers for **diabetes** (2023) *Nat Light Sci & Appl*
- Biomarkers for atopic **dermatitis** skin lesions (2023) *Photoacoustics*
- Intrahepatic lipids in patients with **hepatic steatosis** (2023) *Photoacoustics*
- **Melanoma** microvasculature in vivo (2022) *Nat Comm*
- In vivo detection of **lymph node metastases** in oral cancer (2022) *Photoacoustics*
- Precision monitoring of **psoriasis** treatment (2022) *Sci Transl Med*
- Label-free analytic histology of **carotid atherosclerosis** (2022) *Photoacoustics*
- Lipid and hemoglobin contrast in human **carotid atherosclerosis** (2021) *Photoacoustics*
- Nailfold microvascular structure to diagnose **scleroderma** (2018) *Photoacoustics*
- **Psoriasis** biomarkers (2017) *Nat Biomed Eng*
- Peripheral **nerve vascularization and morphology** (2023) *Adv Sci*

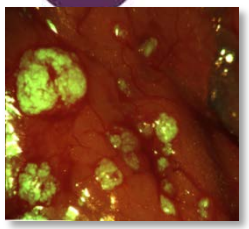
Fluorescence molecular imaging (FMI)

Beyond conventional "photographic“ FMI:

- Realtime FMI and endoscopy
- Fluorescence and color cryo-slicing
- Standardization and benchmarking
- Hybrid FMT/XCT imaging



Barrett lesion



Intraoperative tumor-specific FMI in ovarian cancer

Publications:

- Dysplasia in Barrett‘s esophagus (2022) *Eur J Nucl Med Mol Imaging*
- Detection of early esophageal neoplastic **Barrett lesions** (2023) *J Nu Med*
- Intraoperative tumor-specific FMI in **ovarian cancer** (2011) *Nat Med*

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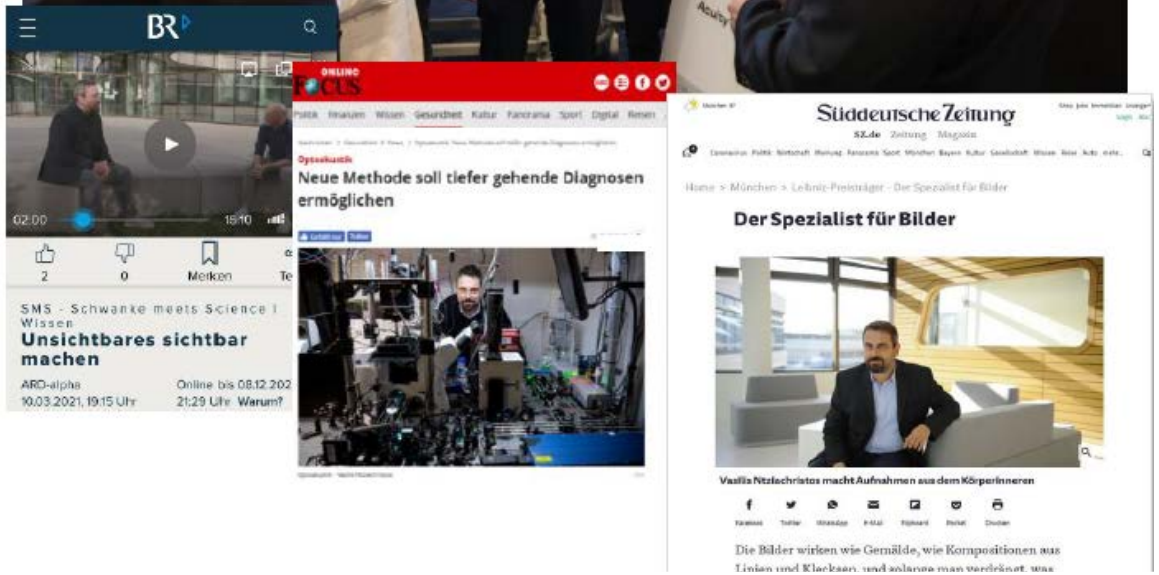
IBMI: World-leading Optoacoustic Imaging



900+ PUBLICAT-IONS

31,000+ CITATIONS

PRESTIGIOUS AWARDS

25+ EU GRANTS

COMPANY SPIN-OFFS

INDUSTRIAL COLLABOR-ATIONS

German Innovation Award

Der Deutsche Innovationspreis

Preisträger 2014

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TUM

IBMI: How can we contribute to IHI Call 7 Topic 3

Expertise in optoacoustic and FMI imaging modalities,
identification of novel disease biomarkers, technical & and clinical validation, standardization, and AI integration

Imaging Modalities and Biomarker Identification

- Developing advanced imaging technologies
- Novel **biomarkers** for accurate **disease detection** – many **label-free** and **non-invasive**
- Proven capabilities in **performance**, **repeatability**, and **reproducibility** studies

Standardization Services:

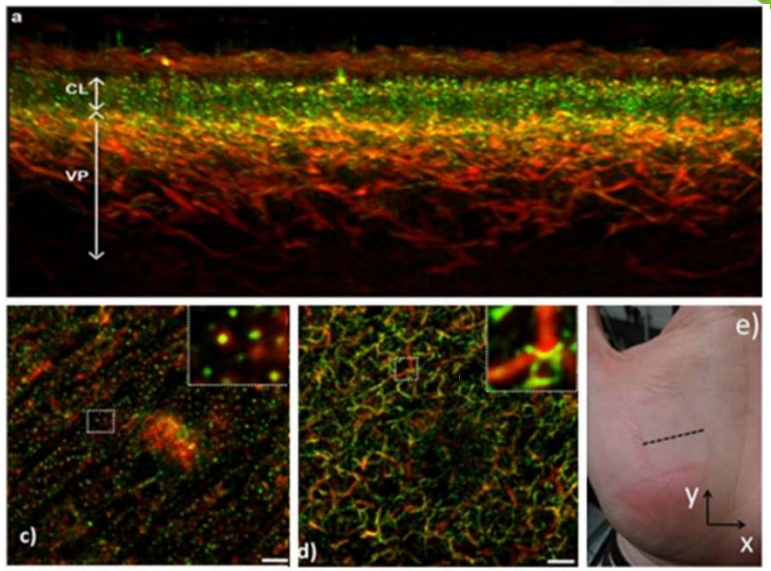
- Conducting **phantom studies** for robust image acquisition
- Access to state-of-the-art translational labs for **technical validation**

AI and Data Methodology:

- Provision of **extensive datasets** for algorithm validation
- **AI tools** for combining biomarkers from diagnostics and imaging modalities
- Adherence to **rigorous ethics-based testing** and data management standards

Leading Scientists and Clinical Collaboration:

- Our team comprises **renowned scientists** in the field
- Global partnerships with clinical sites for **preclinical and clinical validation** studies/trials



An RSOM image of healthy skin

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Contact us:

somik.chakravarty@helmholtz-munich.de

Visit us:

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IHI Call Days | Call 7

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

Precision diagnosis of Lung Cancer

Contact person name: William Leenders (CSO) – Marco de Boer (CEO)

Organisation: Predica Diagnostics BV

E-mail: william.leenders@predicadx.com - marco.deboer@predicadx.com

PREDICA Diagnostics

[IHI Call Days | Participations (b2match.io)]

[Predica Diagnostics (predica-diagnostics.com)]

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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 **effective personalized treatment**

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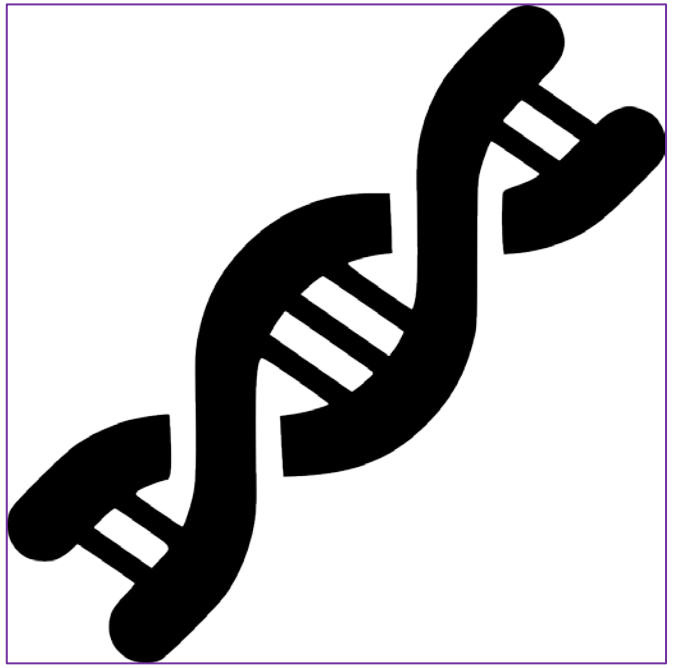
* Epidemiology, and End Results (SEER) Program. (www.seer.cancer.gov) SEE Stat database: Incidence for persons aged 50 – 79 diagnosed 2006 – 2015.

Genome analysis must be complemented with Phenotyping

Patient

Pathology/disease



Genome

Genotype

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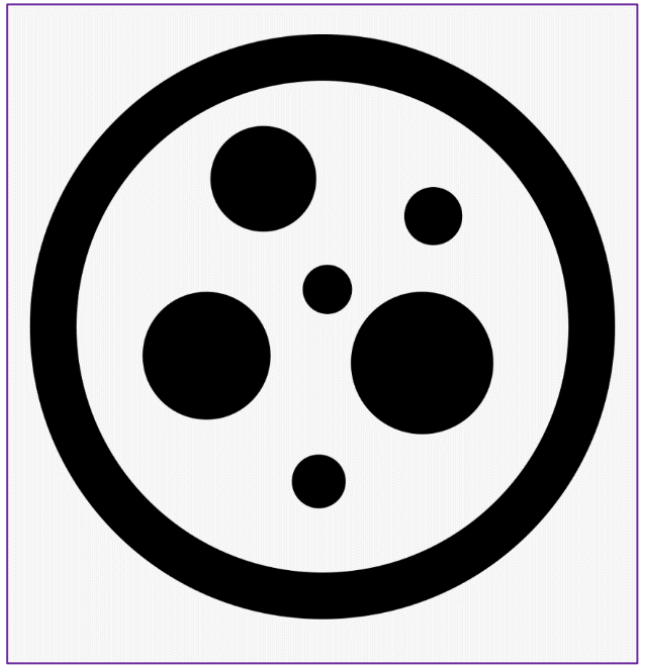
Genome analysis can be complemented with Phenotyping

from Genomics to Phenomics

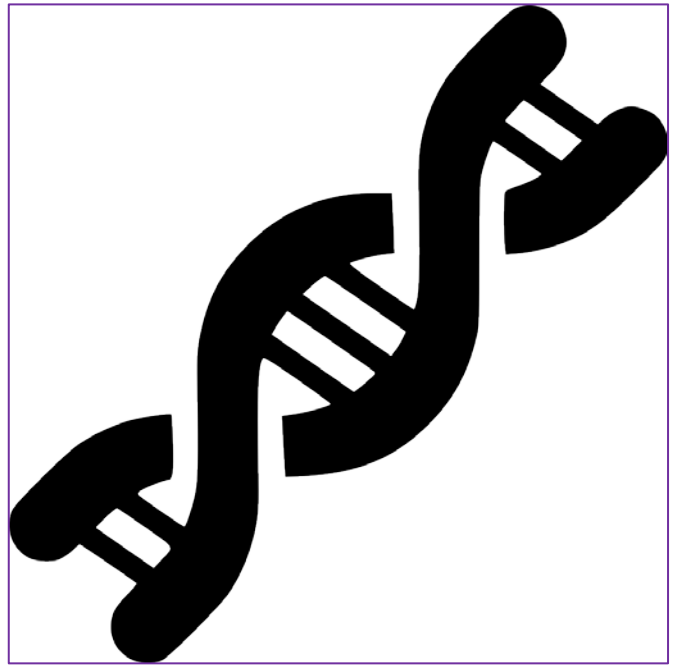
Patient

Pathology/disease



Signaling Pathways

Phenotype/cell behaviour



Genome

Genotype

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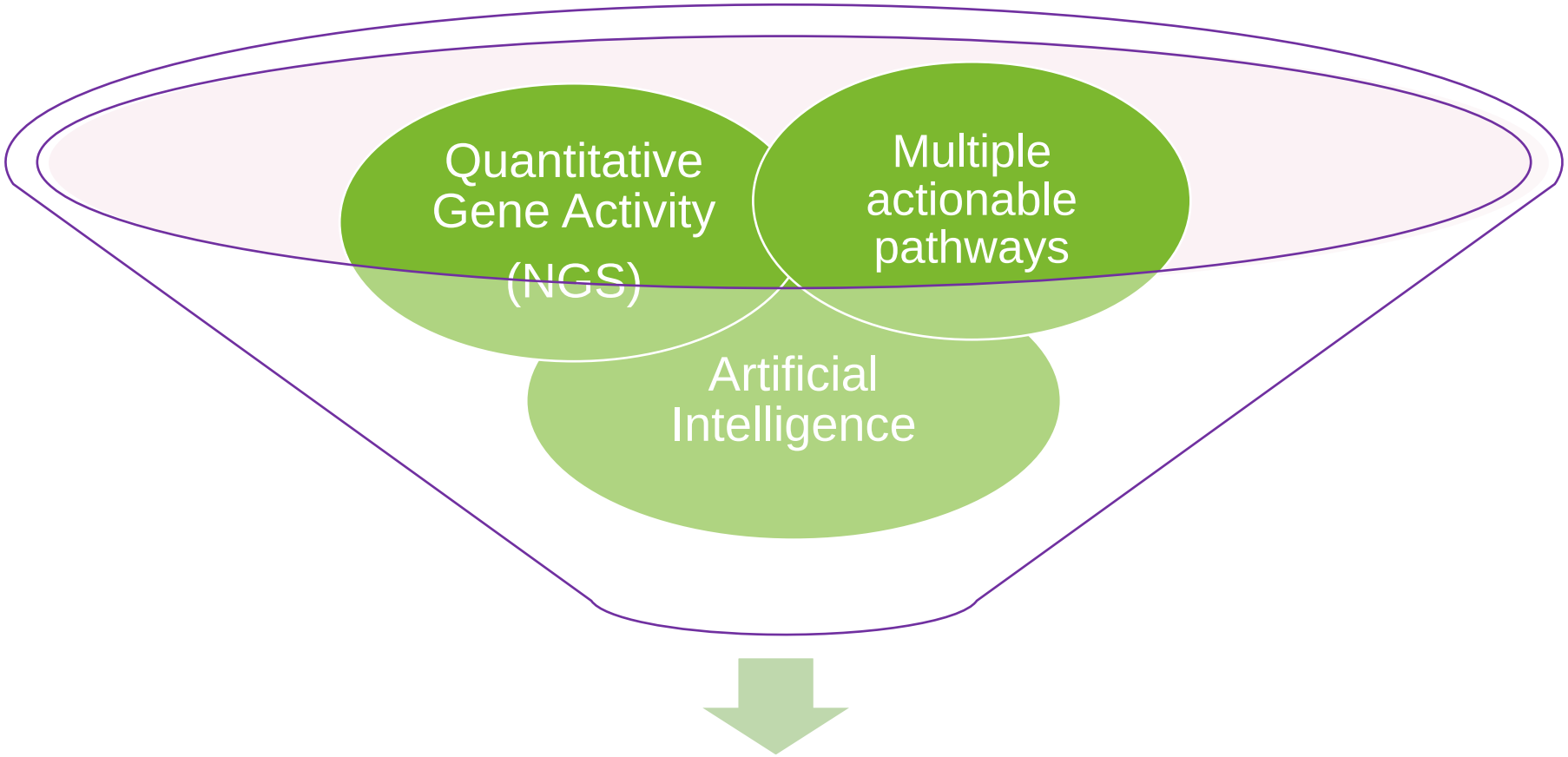
Our solution: High throughput ciRNAseq platform using inversion probes



Early detection and EFFECTIVE PERSONALIZED TREATMENT

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CervicaDX_ciRNAseq - Predica Diagnostics BV - YouTube

Lung Cancer

- Primary cause of cancer mortality worldwide.
- Many therapeutic options available, but ***many fail due to absence of or just suboptimal companion diagnostics***
- Patient survival can be improved with early diagnosis and biomarker and mutation analysis for personalized therapy.
- Predica has the technology to identify actionable pathways in tissue, bronchoalveolar lavage and blood, and thereby:
  - provide data-based guidance for most efficient therapy to medical oncologists
  - prevent dangerous overtreatment
  - reduce unnecessary healthcare costs

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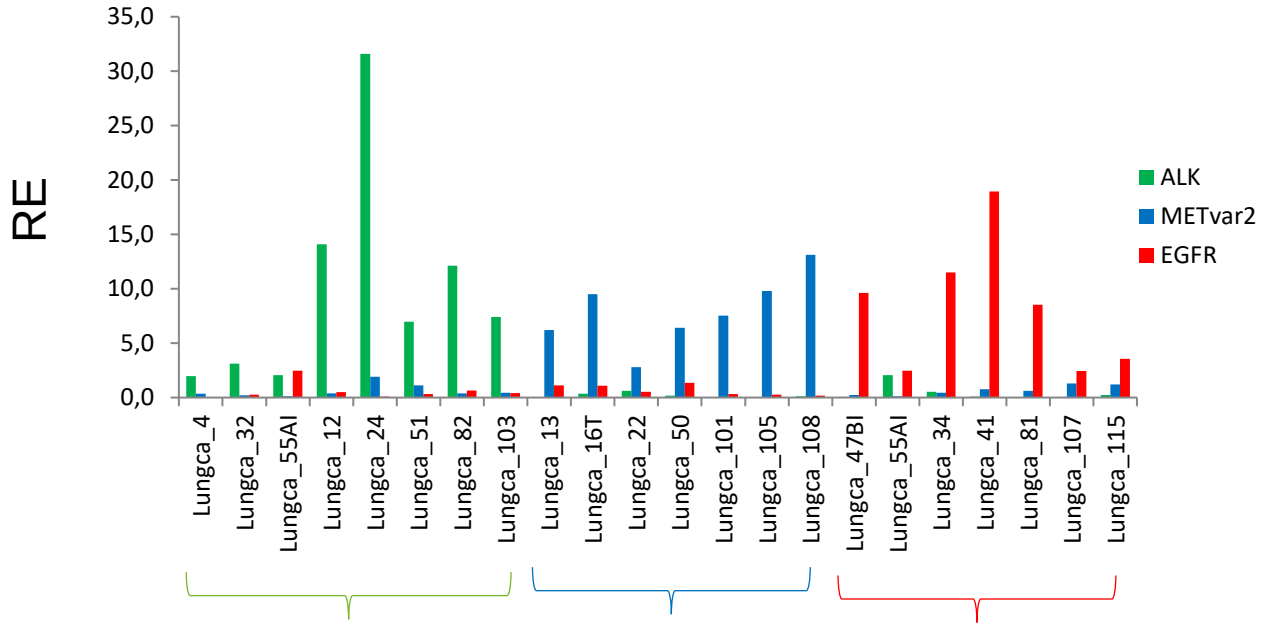
PoC study lung cancer

ciRNAseq for measuring ~700 gene transcripts in

- 83 primary lung cancers
- 24 lung cancer metastases (brain)
- 8 non-tumor lung tissues



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PoC study lung cancer

ciRNAseq for measuring ~700 gene transcripts in

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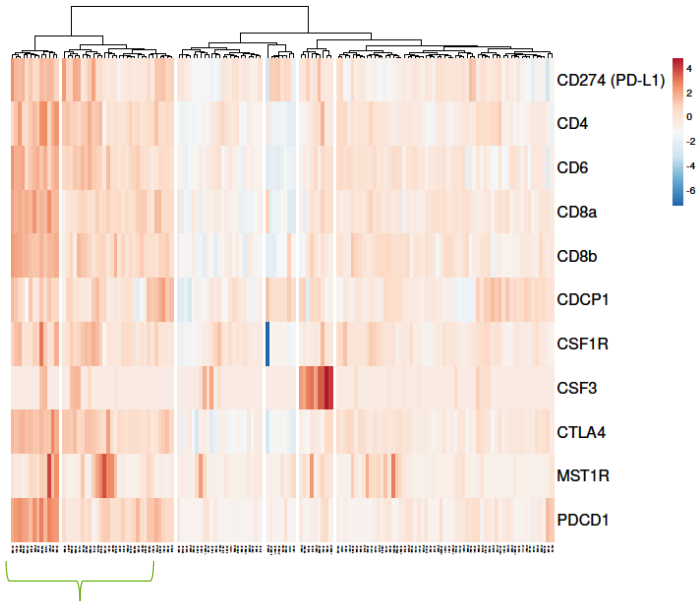

Predicted sensitivity to ICI

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We offer biomarker expertise and access to the clinic

- We have designed and validated proprietary probes to detect expression of and mutations in:
  - relevant tumor suppressor and oncogenes (BRAF, KRAS, PTEN, EGFR, cMET, ALK, NTRK1-3, RET, etc).
  - Cells in the tumor microevironment (e.g. immune cells; fibrosis, angiogenesis).

  (total 1,200 gene transcripts)

- We have close collaboration with leading institutes:

Radboudumc university medical center

CHARITÉ UNIVERSITÄTSMEDIZIN BERLIN

Amsterdam UMC University Medical Centers

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Expertise requested

- Technology-oriented partners with expertise in imaging and image-based tissue sampling (imaging, bronchoscopic biopsies).
- Pharmaceutical Partners looking for optimal companion diagnostics to new treatment modalities.
- Clinical partners interested in implementing Predica's technology as side study in planned clinical trials by providing blood, tissue biopsies, lavage material.

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PREDICA
Diagnostics

marco.deboer@predicadx.com

www.predica-diagnostics.com

+31 6 4444 8450

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Pitching Session

Today 25 January 2024, 14:30 – 16:00 **Brussels time**

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IHI Call Days | Call 7 – topic 3

Protein biomarker validation in (neurodegenerative) disease

Partner seeking consortium/coordinator

Tina Smets

VITO

Tina.smets@vito.be

IHI Call Days | Participations (b2match.io)

IHI Call Days | My dashboard (b2match.io)

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Challenges and objectives

- We can contribute as a partner to:
  - Consortia in need of analytical protein biomarker validation based on Mass Spectrometry (LC-MS)
  - Provide expertise on high-throughput analyses incl. Olink technology read-out
  - Consortia seeking Extracellular Vesicle expertise

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Expertise and resources offered

- LC-MS based dataset results from biomarker discovery study in CSF and CSF-derived Extracellular Vesicles (stratification of Alzheimer's disease, Lewy Bodies Dementia, Parkinson's disease (PD, PD-MCI, PDD) (Hirschberg et al., 2023, Journal of Extracellular Vesicles)
- Mass Spectrometry expertise in large clinical cohorts downscaled to single cell level and Olink certified assay provider
- Extracellular Vesicle isolation and characterization in variety of sample types (incl. brain-derived EVs from plasma)

*MCI: Mild Cognitive Impairment
*PDD: Parkinson's Disease Dementia

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Expertise requested

- Research institutes having access to large biobanks
- Regulatory specialists
- Patient organisations
- SME biotech and pharma companies

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IHI Call Days | Call 7

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

Neurotechnology as a Service (NTaaS)

Contact person name: **Aureli Soria-Frisch (PhD)**

Organisation: Starlab Barcelona

E-mail: aureli.soria-frisch@starlab.es

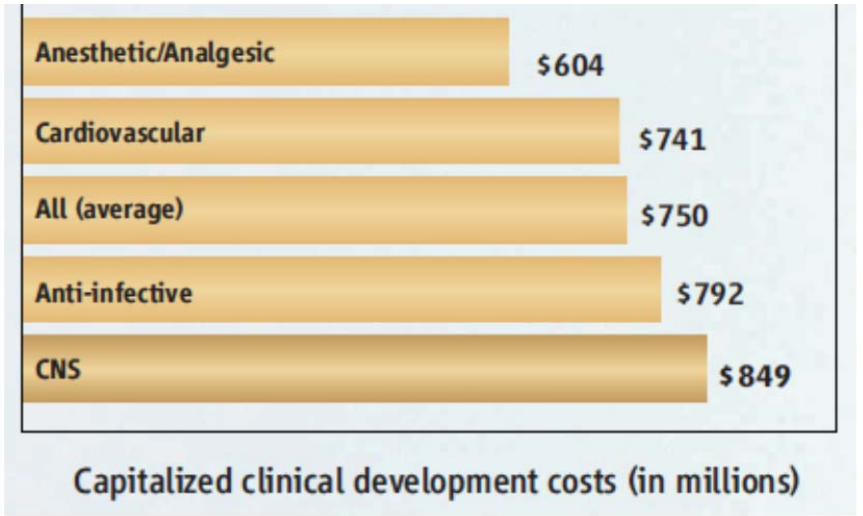
Link to:

- Marketplace opportunity https://ihi-call-days.ihi.b2match.io/participations/192266/opportunities
- Participant profile https://www.starlab.es

Brain Health needs a new approach

- Lack of modern decision tools for mental health and diseases
- Large misdiagnosis rates
- Large development costs on CNS drug development
- Difficult to find data on efficacy to support regulatory processes
- Lack of user-centric design in brain data services

YOUR NEIGHBOR WITH EPILEPSY	YOUR GRANDMA WITH ALZHEIMER'S	YOUR FRIEND WITH DEPRESSION	YOUR DAD WITH PARKINSONS
(50M PATIENTS WORLDWIDE)	(90M PATIENTS WORLDWIDE)	(240M PATIENTS WORLDWIDE)	(5M PATIENTS WORLDWIDE)



20% PEOPLE MENTAL HEALTH PROBLEMS

CNS HIGH RISK

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Solution: Neurotechnology as a Service (NTaaS)

- Wireless easy-to-use EEG Medical Grade Hardware (CE, FDA)

Dry electrodes

Starlab® LIVING SCIENCE

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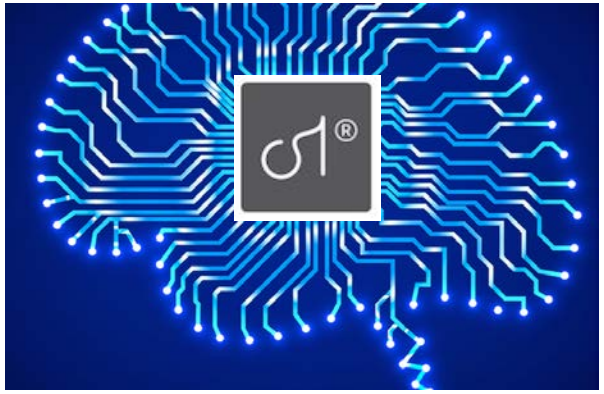
Neurotechnology as a Service

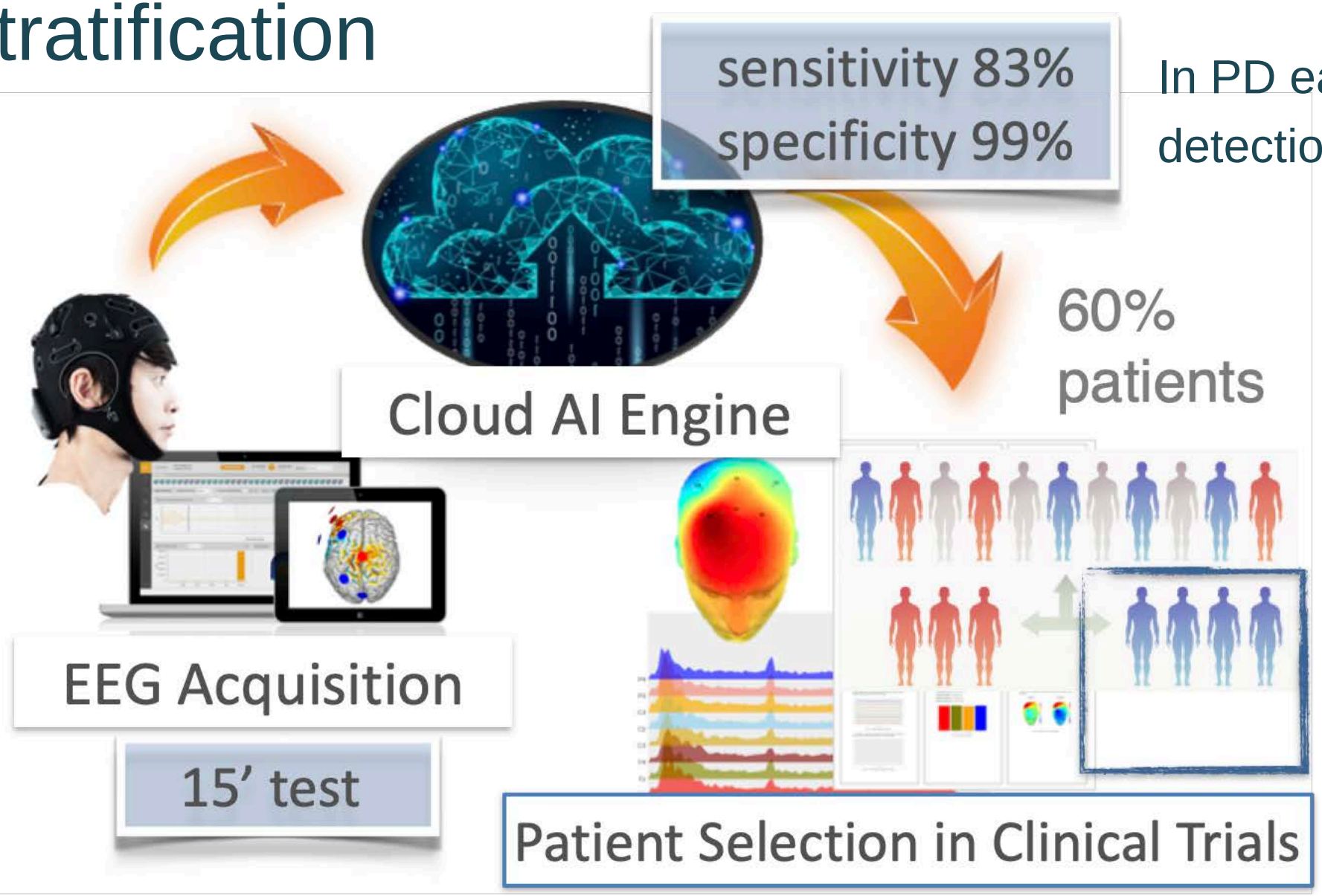
- Wireless easy-to-use EEG Medical Grade Hardware (CE, FDA)



- Machine learning platform for EEG, developed over 10 years
- Proprietary KAI framework

- Protocol preparation
- Data collection
- Advanced Signal Processing
- Machine learning for brain health, trial recruitment, and drug response

NTaaS for Neurodegenrative stratification



In PD early detection

EEG Neurometrics Portfolio

Looking for a building consortium

info@starlab.es

Pitching Session

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Institute of Oncology Research

Università della Svizzera italiana

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

IHI Call 7 Pitch, topic 3.

Prof. Dr. med. Jean-Philippe Theurillat, Institute of Oncology Research, Bellinzona, USI

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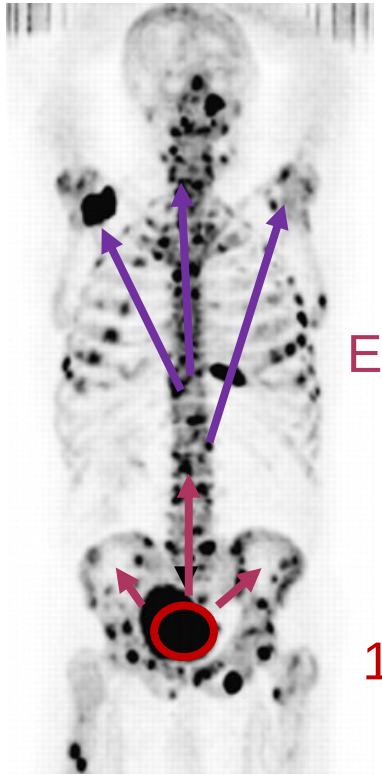
Prostate Cancer (PCa) Progression



Even-Sapir E, et al. JNM 2006

Lethal PCa

↑

Early Metastatic PCa

↑

Primary PCa
1 out of 8 Men

- Biomarkers
  1. Prognostic
  2. Predictive/Drug Target

Harmonized large data sets of biologically relevant features

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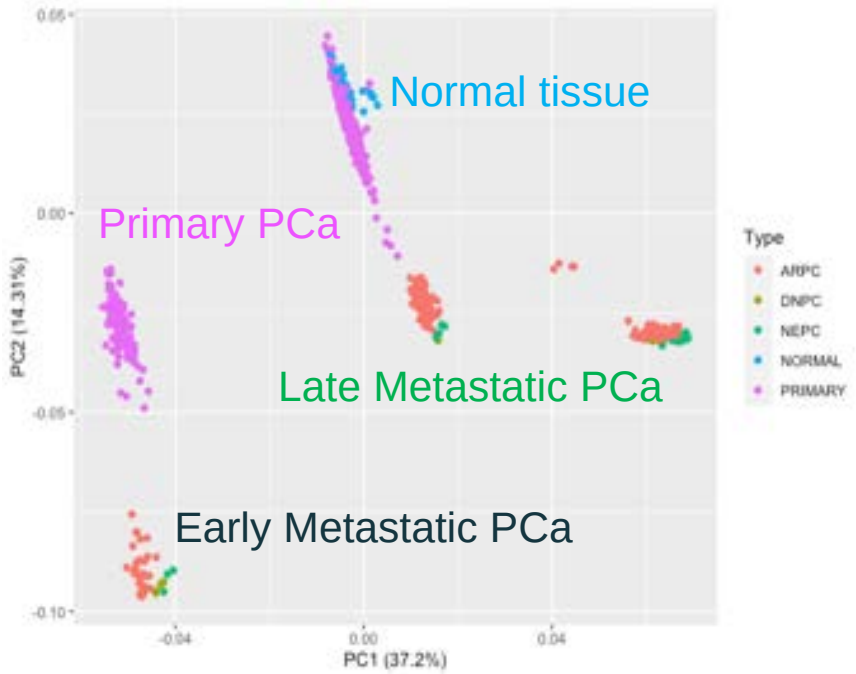
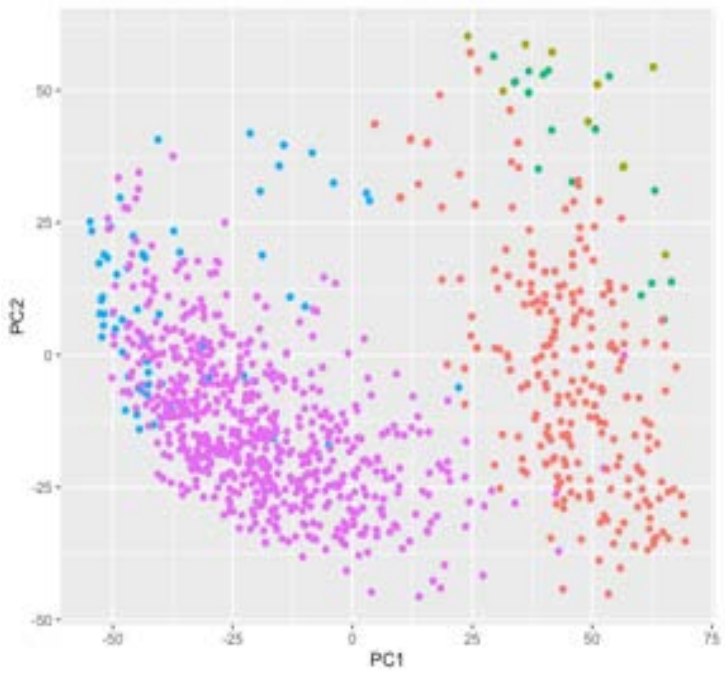
Harmonization of RNA sequencing data

Disease Stages

Normalization & Batch Correction



Reprocessed Raw Data



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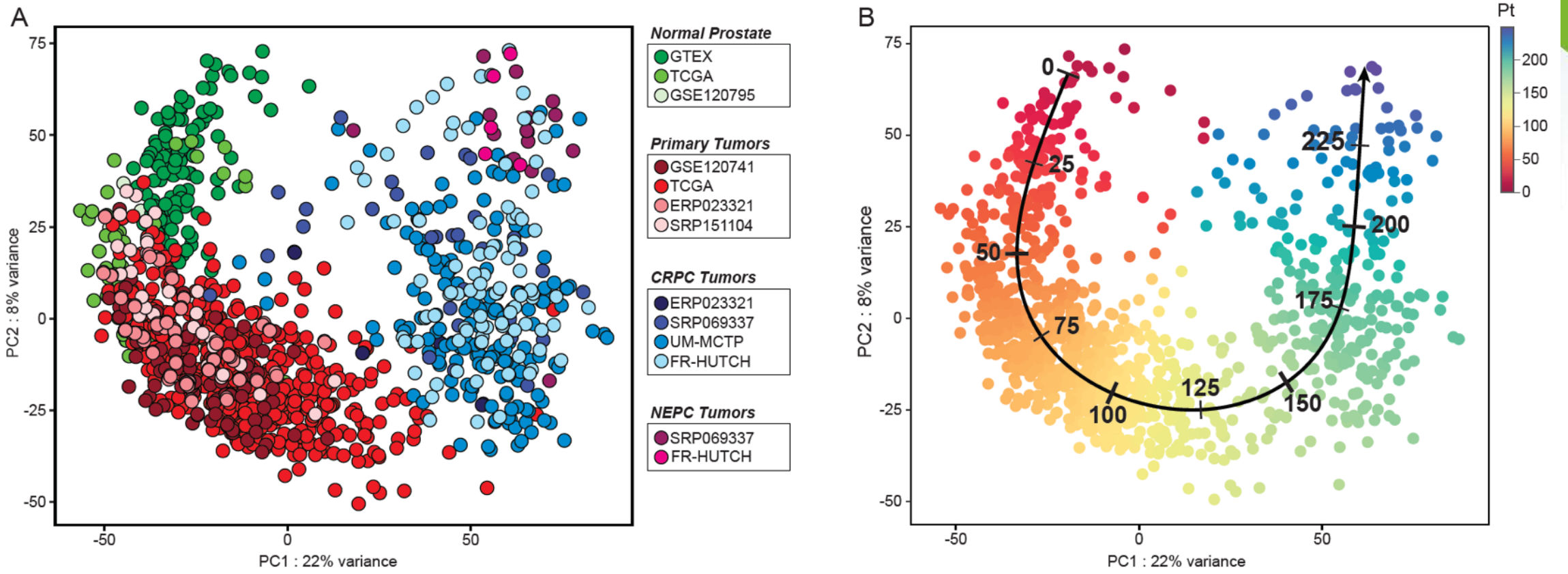
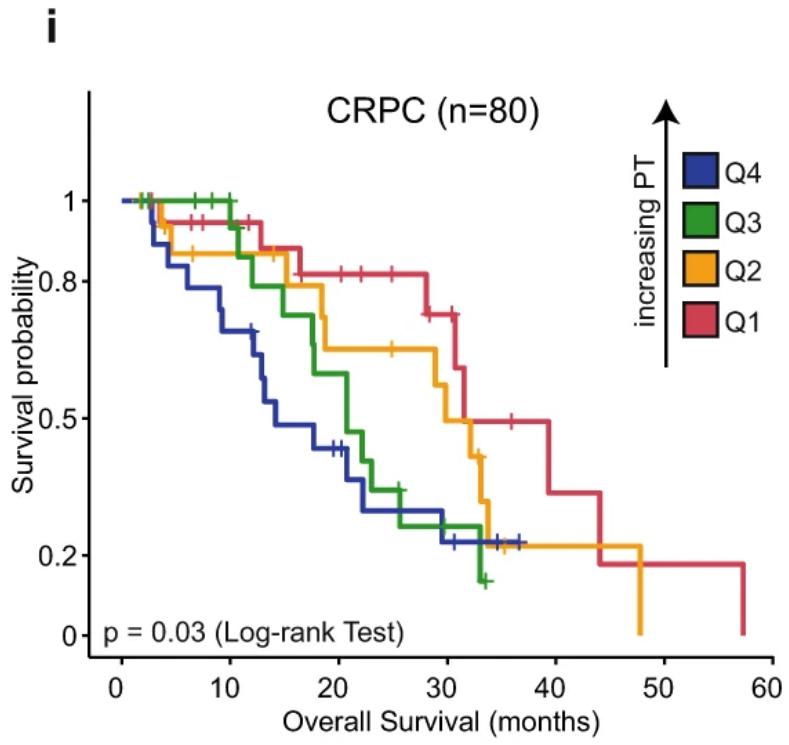
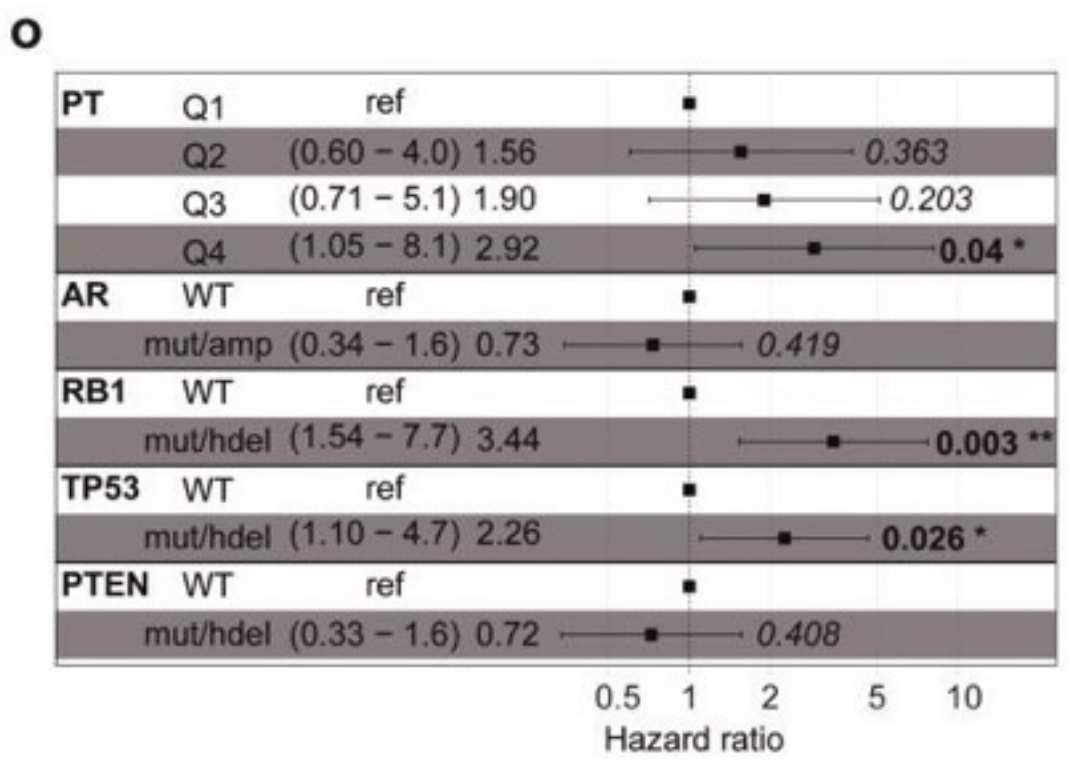
Harmonized Prostate Cancer Atlas



Bolis et al., Nat Comm, 2021

Pseudotime is an independent marker prognostic marker in metastatic disease



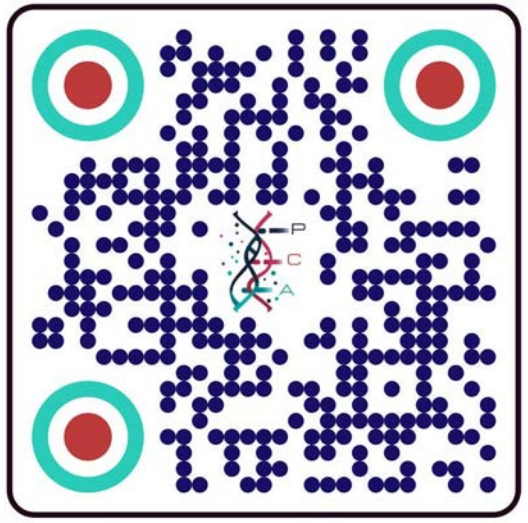


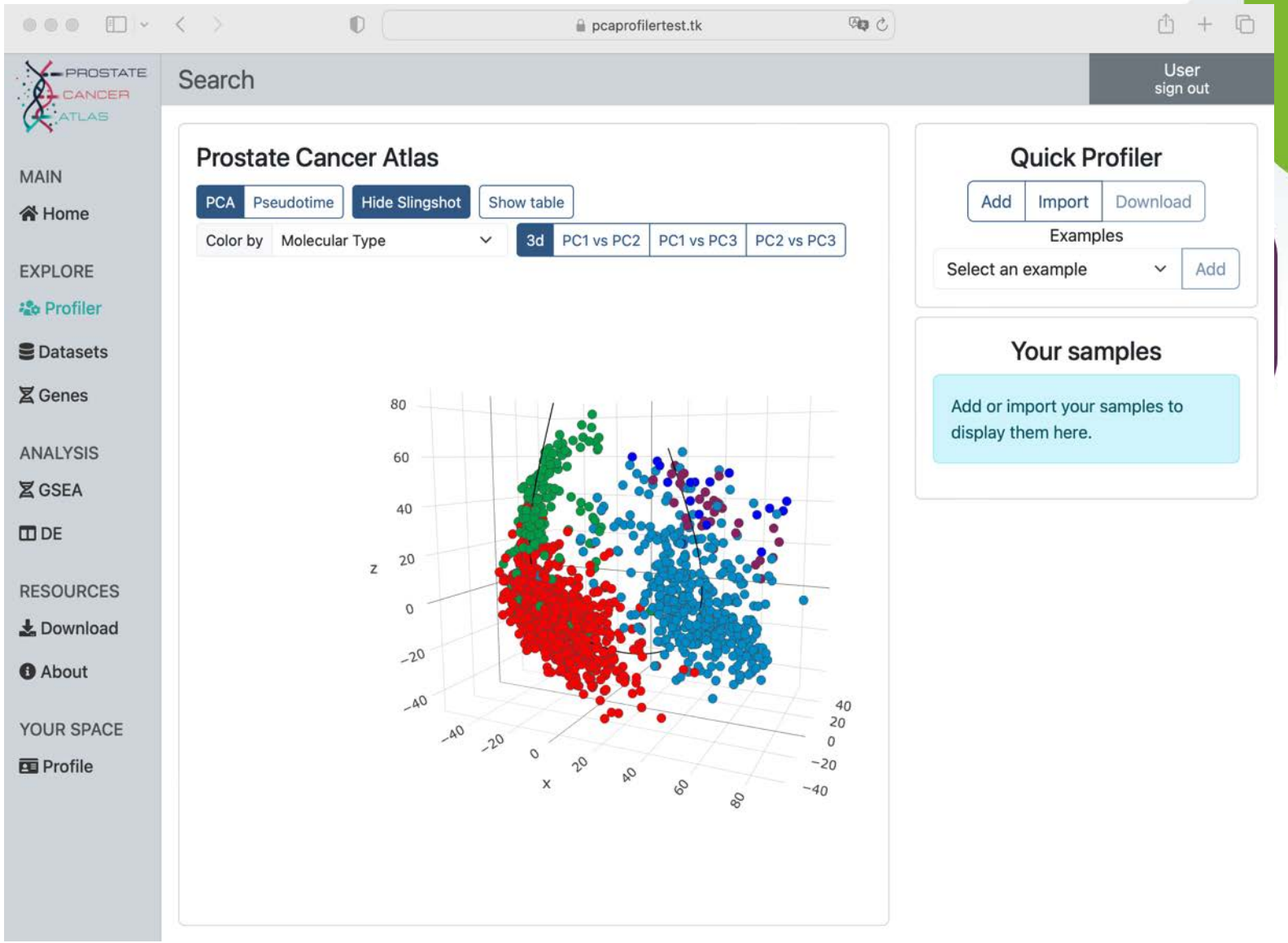
Institute
of
Oncology
Research

https://prostatecanceratlas.org

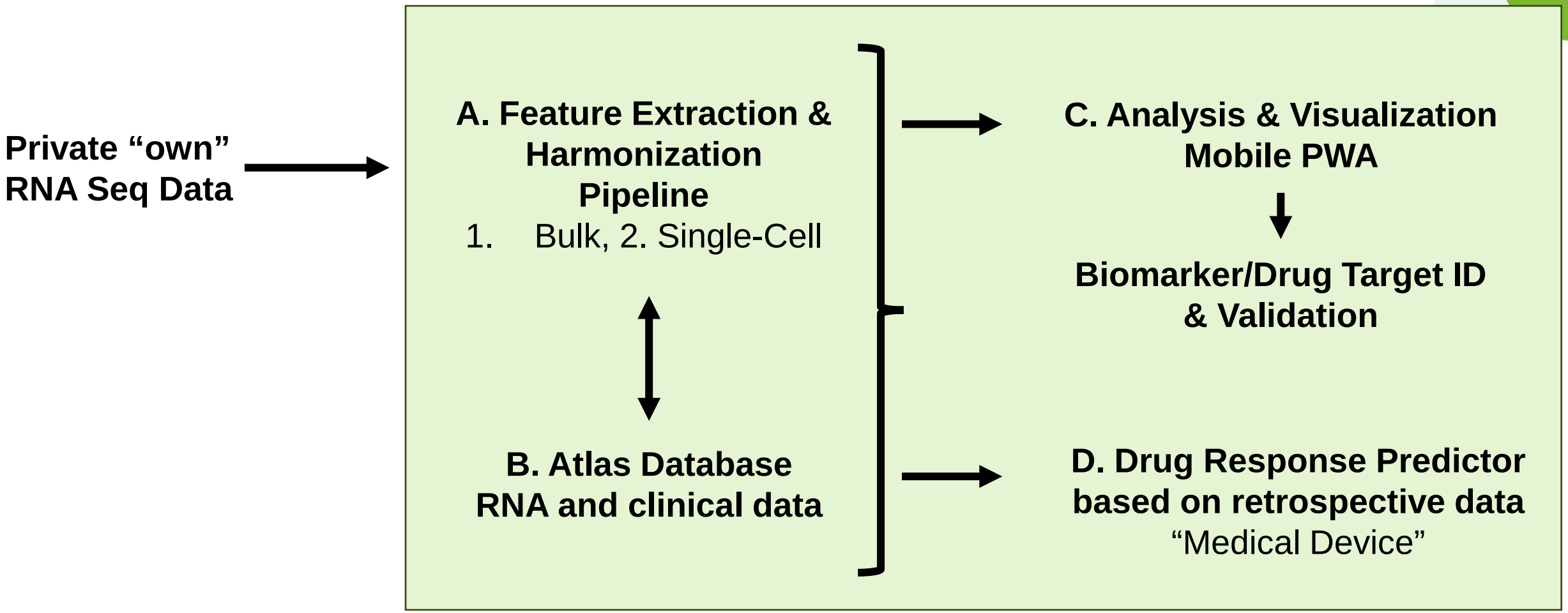
PROSTATE CANCER ATLAS

Scan Me





All-in-One Solution for RNA Data Analysis & Visualization

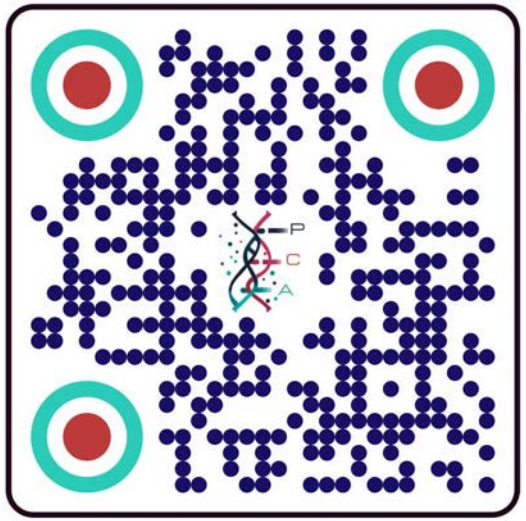


Institute of Oncology Research

Summary

PROSTATE CANCER ATLAS

Scan Me



- **Harmonized RNA sequencing data** enables integrated analysis of **disease progression** and efficient **biomarker development**
- **Interactive Portal/Web Tool** for the research community to **visualize** and **analyze** harmonized RNA data **also with external data** -> Predictive medical device
- **Contact**: Jean-Philippe.Theurillat@ior.usi.ch

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Pitching Session

Today 25 January 2024, 14:30 – 16:00 **Brussels time**

Number	First Name	Last Name	Job position	Organization	Title of the presentation
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3	Ralf	HOFFMANN	Principal Scientist	Philips	BRECISE - Biomarker Research and Evaluation for Clinical Implementation and Supporting Systems Enhancement
4	François-Clément	BIDARD	Professor of Medical Oncology	Institut Curie	Biomarker validation – Consortium proposal
5	Daniela Maria	CIRILLO	Head EBPU IRCCS OSR	Vita-Salute San Raffaele University	valiDation of biOmarkers to iMprove dIagnosis and maNagement Of infEctious diSeases (DOMINOES)
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7	Hendrik	LAUE	Key Scientist Quantitative and Dynamic Image Analysis	Fraunhofer MEVIS	Biomarker Validation - Quantitative MRI
8	Karim	LEKADIR	ICREA Professor	University of Barcelona	AI-Driven Imaging Biomarkers
9	Michael	LEVIN	Professor of International Child Health	Imperial College London	Bringing Biomarkers for Infectious and Inflammatory Disease into Clinical Use
10	Carles	BLASCO	R&D Project Manager	ISABIAL - Alicante Institute for Health and Biomedical Research	Integrative analysis of biomarkers to improve monitoring of neurological and heart diseases
11	Donato	BONIFAZI	CEO	CVBF-EPTRI	Biomarkers in paediatric diseases diagnosis, treatment and monitoring– EPTRI Thematic Research Platform on Paediatric Biomarkers & Biosamples
12	Somik	CHAKRAVARTY	Fundraising Manager/Grant writer	Institute of Biological and Medical Imaging @ Helmholtz Munich	Pushing the boundaries of biomedical imaging and sensing methods
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14	Tina	SMETS	Business Development Manager	Flemish Institute for Technological Research (VITO)	Protein biomarker validation in (neurodegenerative) disease
15	Aureli	SORIA-FRISCH	Director of Neuroscience BU	Starlab Barcelona SL	Neurotechnology as a Service (NTaaS)
16	Jean-Philippe	THEURILLAT	Associated Professor & Group Leader	Institute of Oncology Research, University of Southern Switzerland	Clinical validation of biomarkers for diagnosis, monitoring disease progression, and treatment response
17	Jérémie	THIBLET	Chief Growth Officer	NeoVentures Biotechnology Europe	PAMD: Validation of biomarkers for Personalized treatment of Age-related Macular Degeneration (AMD)
18	Aad	VAN DER LUGT	Chair Department of Radiology & Nuclear Medicine, Erasmus MC Rotterdam	European Imaging Biomarker Alliance (EIBALL)	EIBALL Could be a partner for your project
19	John	WATERTON	Scientific Director	Bioxydyn Ltd	Clinical validation of imaging biomarkers

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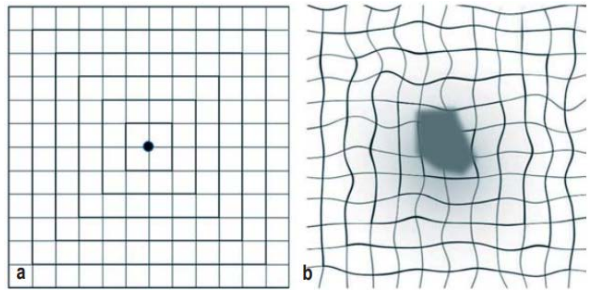
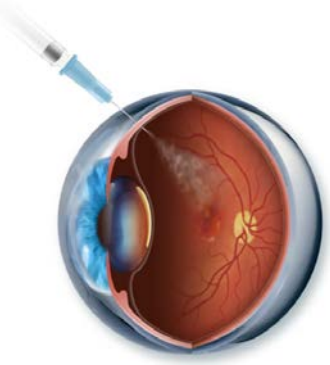
Topic 3: Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

PAMD: Validation of biomarkers for Personalized treatment of Age-related Macular Degeneration (AMD)





Jeremie THIBLET - NeoVentures Biotechnology Europe
jthiblet@neoventures-eu.com

Nikos Dervenis, MD, PhD and Sofia Androudi, MD, PhD University Eye Clinic - University of Thessaly nikosdervenis@gmail.com and androudi@otenet.gr

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Challenges and objectives

Problem

Wet Age-related Macular Degeneration (also called neovascular AMD - nAMD) remains one of the most common progressive retinal degenerative macular diseases

There is a high variability in patient response to therapy with anti-VEGF agents: Extensive multivariate analyses are required to **predict response to anti-VEGF and other treatments**

Objectives

Implementation of an efficient methodology to **progress clinical use of Plasma Biomarkers** (relying on established correlation with imaging technologies) to **predict response to treatments**

Plasma Biomarkers validation with regulatory acceptance: **IVD for predicting treatment responses** for nAMD patient

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Results and Impact

Potential results

Clinically validated methods using plasma biomarker-based approaches that assess individuals according to their response to treatments and support medical management decisions for nAMD patients

Available, Accessible, and Affordable testing technologies validated in clinical settings for nAMD patients

Improved nAMD patient management and outcome

Expected impact

Reduced diagnostic/therapeutic burden for patients

Reduced economic burden on the European healthcare system

Facilitating access to the market for better and new AMD treatments

New biomarker validation methodology that can scale to other complex diseases

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Main activities

- **Biomarker Validation Plan Development**
  - → Deep data from plasma with DNA aptamers technology in correlation with the latest imaging modalities AMD (Optical coherence tomography (OCT) and others)
  - → Phenotypic mapping and patient clustering – 1000 patients
  - → Development of standardized qPCR test using DNA aptamers with ML enhancement for the prediction of disease progression and response to treatments
  - → Retrospective study (Prospective study optional but not mandatory)
- **Digital collaborative sharing platform**
  - → Enabling data analysis and tracking
  - → Evolution toward professional healthcare usage
- **Multi-center validation studies**
  - → Validate methodology for widespread clinical use.
- **Collaboration with patient advocacy groups**
  - → Incorporate the patient's perspectives and experiences into the process.
- **Regulatory and market acceptance strategy**
- **Dissemination plan**
  - → Aimed at healthcare professionals, patients, researchers and industry partners
  - → Develop educational resources and training programs for healthcare professionals

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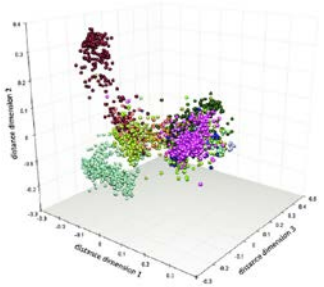
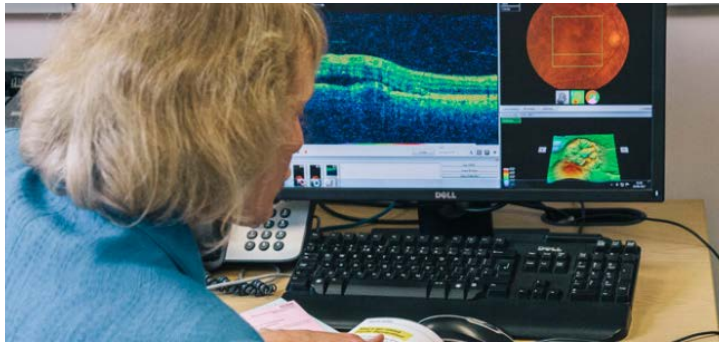
Expertise and resources offered

- **Biomarker discovery, validation, and testing** (Deep data and multivariate analyses in plasma samples using **innovative DNA Aptamer technology with Machine Learning**)
- **Medical expertise and access to samples** (nAMD)
- **Imaging expertise** (nAMD diagnosis)





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Expertise requested

- **Pharmaceutical partners with focus on nAMD**

→ existing and new Treatments/Therapies

- **Additional clinical research partners and healthcare professionals**

→ clinical samples and nAMD clinical expertise

- **Software Technology Developers**

→ Collaborative sharing Platform

→ Machine learning to combine automated image analysis with deep data

- **Patient representation association**
- **Regulatory strategy partner**
- **Project Management Partner**
- **Dissemination / Public involvement partner**

- **In-kind Contributors**

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Clinical Validation of Biomarkers

EIBALL Could be a partner for your project

Contact person name: Prof. Aad van der Lugt
Organisation: The European Imaging Biomarker Alliance (EIBALL)
E-mail: a.vanderlugt@erasmusmc.nl

Link to:

- Marketplace opportunity: IHI Call Days | Pitchers - Call 7 (b2match.io)
- Participant profile: IHI Call Days | Marketplace (b2match.io)

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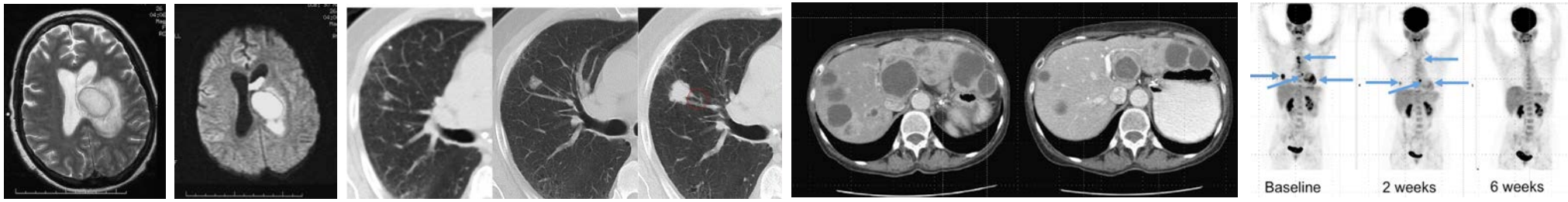
Challenges and Objectives

- Suitable for IHI
  - Quantitative Imaging Biomarkers are relevant for **diagnosis, monitoring disease progression, selecting the optimal therapeutic treatments, or assessing treatment response**.
- Problems with Imaging Biomarkers
  - Heterogeneity in acquisition and (automated) quantitative analysis
  - No consensus in methodology for technical and clinical validation
  - Clinical validation is frequently lacking
- Potential Results
  - Validated Imaging Biomarker Profile (Protocol for acquisition and analysis which includes one or more performance claims, which tells you what quantitative results can be achieved by following the Profile. E.g. accuracy, CoV, %change that can be measured
  - Based on QIBA Expertise and Metrology (International Standard)



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Main activities of EIBALL

As part of the **European Society of Radiology** we

- Promote and teach the right methodology for technical imaging biomarker validation based on the rigor metrology rules developed by QIBA.
- Support the imaging community with clinical imaging biomarker validation
- Support imaging departments with implementation of imaging biomarkers in clinical practice

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Expertise and resources offered

Expertise in Technical validation: performance (biomarker profiles)

- Repeatability studies / Reproducibility studies (interscan variability (acquistion), Interobserver variability (detection / measurements / segmentation), Variability between software packages (e.g. segmentations).
- We can provide access to multiple centres of Excellence in Technical Biomarker Validation.
- We could provide access to large data sets for validation of image analysis algorithms.
- We have extensive expertise in deploying the right methodology for technical biomarker validation based on the rigor metrology rules developed by QIBA.

Expertise in Clinical validation (EIBALL)

- Validation for Diagnostic biomarkers / Imaging Biomarkers as Surrogate Endpoints / Prognostic Imaging Biomarkers
- Network of Centres of Excellence in Clinical Biomarker Validation (per disease type) these centres have already a strong collaboration between imaging department and clinical departments.

Expertise with implementation of biomarkers

- Network with the professional Societies (ECR, ESMRMB, ISMRM, RSNA)

Project Management (EIBIR)

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Expertise requested

- Large companies
  - in need for expertise on Imaging Biomarker Validation
- SME
  - In need of image data sets for development and validation of automated imaging biomarker extraction

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

Clinical validation of imaging biomarkers

Contact person name: John Waterton

Organisation: Bioxydyn Ltd

E-mail: john.waterton@bioxydyn.com

Link to:

- Marketplace opportunity
- Participant profile

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Challenges and objectives

- Background: two types of biomarkers used in drug development and healthcare:
  - biospecimen (e.g. blood test, biopsy) - often proprietary
  - biosignal (e.g. ECG, MRI) - often non proprietary, ideal for PPP
- Challenge:
  - Distinct roadmap for biosignal/imaging biomarkers including MRI (iterative and dynamic)
  - MRI scanners are not designed, regulated, marketed, or maintained as measurement devices
- Problem:
  - Academic MRI innovation translates slowly or not at all
  - Often inadequate platform of evidence for validity
  - Missed opportunity for personalized healthcare
- Is your project suitable for IHI: yes, see previous successful PPPs in EU (IMI) & US (FDA BQP)
- Potential results:
  - Worked examples in important disease areas (see slide 5)
  - Guidance for innovators on how to identify and mitigate confounds for each biomarker
  - Guidance on how to create and evaluate an evidence base for each context of use
  - Metrology for scanner hardware and software, phantoms, analysis software, QA, training and accreditation
- Scope:
  - All quantitative MR biomarkers: existing, investigational and yet-to-be-invented
  - All makes and model of scanner

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Main activities - MRI biomarkers

- Four pillars
  1. Repeatability: same-subject-same-scanner for efficacy of investigational drug
  2. Reproducibility: comparable results from all scanners worldwide for personalized healthcare, CDx and drug safety
  3. Treatment effect size
  4. Accuracy and interpretation (clinical-biomarker correlation)
- Clinical studies in relevant disease areas (slide 5)
- Design protocol, implement, acquire, analyse, report, QA
- Metrology using valid test objects (phantoms)

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Expertise and resources offered

- Bioxydyn has extensive expertise in validating and deploying MRI biomarkers in patients and volunteers
  - For pharma clients in development of new drugs
  - In academic and charity studies
  - In oncology, neurology, rheumatology, hepatology, pulmonology, cardiovascular, drug safety, etc
  - VoxelFlow image analysis platform fully regulatory compliant and auditable
- Bioxydyn's senior team include thought leaders in imaging biomarker validation (Waterton, Parker)

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Expertise requested

Large companies or academic

- Clinical science: oncology, neurology, rheumatology, hepatology, pulmonology, cardiovascular, drug safety, etc
- Clinical trial sponsorship
- Cross-validation with biofluid and biospecimen biomarkers

Large company or SME

- Regulatory science
- Metrology and statistics

SME

- Innovative phantoms

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OPEN

Imaging biomarker roadmap for cancer studies

James P. B. O'Connor[1], Eric O. Aboagye[2], Judith E. Adams[3], Hugo J. W. L. Aerts[4], Sally F. Barrington[5], Ambros J. Beer[6], Ronald Boellaard[7], Sarah E. Bohndiek[8], Michael Brady[9], Gina Brown[10], David L. Buckley[11], Thomas L. Chenevert[12], †Laurence P. Clarke[13], Sandra Collette[14], Gary J. Cook[5], Nandita M. deSouza[15], John C. Dickson[16], Caroline Dive[17], Jeffrey L. Evelhoch[18], Corinne Faivre-Finn[19], Ferdia A. Gallagher[8], Fiona J. Gilbert[8], Robert J. Gillies[20], Vicky Goh[5], John R. Griffiths[8], Ashley M. Groves[16], Steve Halligan[16], Adrian L. Harris[9], David J. Hawkes[16], Otto S. Hoekstra[21], Erich P. Huang[22], Brian F. Hutton[16], Edward F. Jackson[23], Gordon C. Jayson[24], Andrew Jones[25], Dow-Mu Koh[15], Denis Lacombe[26], Philippe Lambin[27], Nathalie Lassau[28], Martin O. Leach[15], Ting-Yim Lee[29], Edward L. Leen[2], Jason S. Lewis[30], Yan Liu[26], Mark F. Lythgoe[31], Prakash Manoharan[1], Ross J. Maxwell[32], Kenneth A. Miles[16], Bruno Morgan[33], Steve Morris[34], Tony Ng[5], Anwar R. Padhani[35], Geoff J. M. Parker[1], Mike Partridge[9], Arvind P. Pathak[36], Andrew C. Peet[37], Shonit Punwani[16], Andrew R. Reynolds[38], Simon P. Robinson[15], Lalitha K. Shankar[13], Ricky A. Sharma[16], Dmitry Soloviev[8], Sigrid Stroobants[39], Daniel C. Sullivan[40], Stuart A. Taylor[16], Paul S. Tofts[41], Gillian M. Tozer[42], Marcel van Herk[19], Simon Walker-Samuel[31], James Wason[43], Kaye J. Williams[1], Paul Workman[44], Thomas E. Yankeelov[45], Kevin M. Brindle[8], Lisa M. McShane[22], Alan Jackson[1] and John C. Waterton[1]

Abstract | Imaging biomarkers (IBs) are integral to the routine management of patients with cancer. IBs used daily in oncology include clinical TNM stage, objective response and left ventricular ejection fraction. Other CT, MRI, PET and ultrasonography biomarkers are used extensively in cancer research and drug development. New IBs need to be established either as useful tools for testing research hypotheses in clinical trials and research studies, or as clinical decision-making tools for use in healthcare, by crossing 'translational gaps' through validation and qualification. Important differences exist between IBs and biospecimen-derived biomarkers and, therefore, the development of IBs requires a tailored 'roadmap'. Recognizing this need, Cancer Research UK (CRUK) and the European Organisation for Research and Treatment of Cancer (EORTC) assembled experts to review, debate and summarize the challenges of IB validation and qualification. This consensus group has produced 14 key recommendations for accelerating the clinical translation of IBs, which highlight the role of parallel (rather than sequential) tracks of technical (assay) validation, biological/clinical validation and assessment of cost-effectiveness; the need for IB standardization and accreditation systems; the need to continually revisit IB precision; an alternative framework for biological/clinical validation of IBs; and the essential requirements for multicentre studies to qualify IBs for clinical use.

Correspondence to J.P.B.O'C.
Cancer Research UK Manchester Institute, University of Manchester, Wilmslow Road, Withington, Manchester M20 4BX, UK.
james.o'connor@manchester.ac.uk

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A biomarker is a "defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention, including therapeutic interventions" (REFS 1,2). The current FDA–NIH Biomarker Working Group definition — adopted in this consensus statement — states explicitly that "molecular, histologic, radiographic or physiologic characteristics are examples of biomarkers" (REF. 2). This approach seeks to clarify inconsistency in terminology, because some previous definitions have restricted

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QuIC ConCePT

EORTC

The future of cancer therapy

CANCER RESEARCH UK

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Thank you for your attention

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MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union