Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies

IHI call 5 – topic 1

Update 04-07-2023: Slides 18 & 19 added for clarification

Salomé Koussoroplis
IHI Scientific Project Officer
27.06.23 • Online

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Before we start…

- We are recording this session and it will be published on the IHI website and B2Match platform.
- We will also publish the presentation slides.
- All information regarding future IHI call topics is indicative and subject to change. Final information about future IHI calls will be communicated after approval by the IHI Governing Board.

Before we start…

Questions

- Please use the **‘Join the discussion’ function** at the bottom right of the screen to ask questions.

Today’s session

- **Will cover**:
  - Introduction to IHI programme
  - IHI Call Topic
    - Challenge, need for public-private collaborative research, scope, outcomes & impacts, budget
  - Information on proposal submission & evaluation
  - Tips for writing a successful proposal

- **Will not cover** rules and procedures & how to prepare the financial proposal
  - These webinars are on the IHI website

Innovative Health Initiative

Public private partnership between:

- the **European Union** represented by the European Commission

&

- **Healthcare industry associations:**
  - **COCIR** (medical imaging, radiotherapy, health ICT and electromedical industries)
  - **EFPIA**, including **Vaccines Europe** (pharmaceutical and vaccine industries)
  - **EuropaBio** (biotechnology industry)
  - **MedTech Europe** (medical technology industry)

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COCIR Advancing Healthcare | efpia | EuropaBio The European Association for Bioindustries | MedTech Europe from diagnosis to cure | Vaccines Europe | Co-funded by the European Union

IHI´s General objectives

Through **cross sectoral, pre-competitive** collaboration:

- Turn health research and innovation into **real benefits for patients and society**
- Deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in **areas where there is an unmet public health need**
- Make Europe’s health industries **globally competitive.**

https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

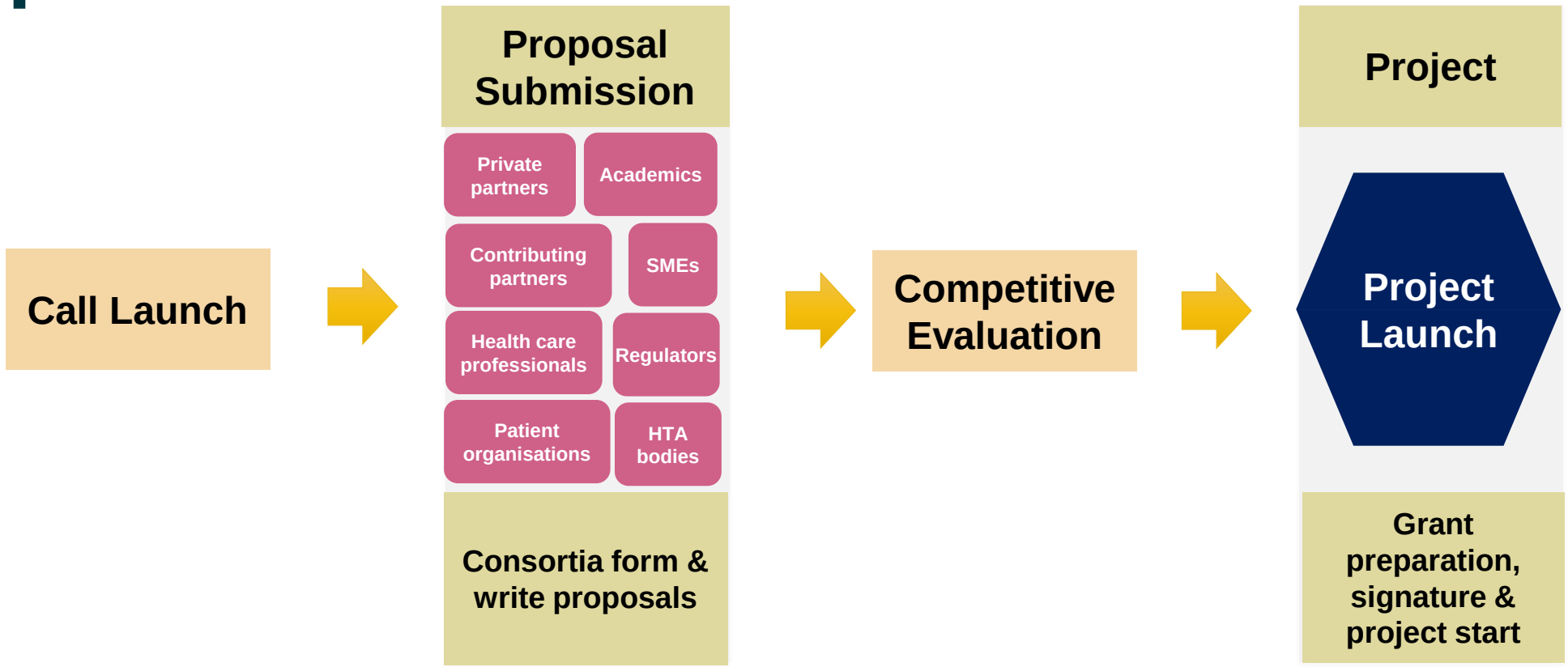
IHI Funding model

As a **public private partnership,** IHI's projects are funded by:

- **EU cash contributions**
  - Primarily supporting universities, research organisations, patient organisations, small and medium-sized enterprises (SMEs), and mid-sized companies.*
- **IHI industry associations** and **contributing partners**
  - Must **provide at least 45% of total project eligible costs (**usually via researchers participating in the project)

* Large companies can also receive EU funds

How does IHI work? single-stage procedure



Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies

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The challenge

Animals and animal-derived materials widely used in biomedical research & in development & production of health technologies

Legal obligation to replace, reduce and refine use of animals in research

Need for more human-relevant methods/strategies for assessment of safety and efficacy of new health technologies & for manufacturing

Animal testing are time-consuming, expensive & results not always reproducible & applicable to humans; animal-derived products require large amounts of animals

Although the potential of New Approach Methodologies (NAMs) and other non-animal approaches for the production/development/testing of new health technologies, more evidence & high-quality data needed to evaluate their performance & to support regulatory decision making

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Objectives

To develop New Approach Methodologies (NAMs) and other non-animal approaches, which could be more readily available and more efficient than the ones involving animals, and which should improve either the development (including efficacy and safety assessment) of new health technologies for infectious/non-communicable diseases or the production processes of such technologies

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Need for public-private, cross-sector collaboration

Cross-sectorial collaboration a must

to accelerate the development and use of effective NAMs and other non-animal approaches in the testing, development, and production of health technologies

Exchange of data, expertise and knowledge

to generate evidence on applicability of these approaches in industrial context & to support regulatory decision making

The value of involving partners with relevant expertise

industry (pharmaceutical, medical devices, *in vitro* diagnostics, vaccines), academia, SMEs + involvement of patients, regulators & policy makers

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Scope of the topic

- Develop new NAM/s or other non-animal approach/es (or combination) or use of existing ones in an innovative way for assessment or production of health technologies.
- Specify the context of use of these approaches & the way they can be integrated in workflows; plan their performance evaluation & validation and demonstrate added value in comparison with relevant established animal-based approaches.
- Generate evidence for robustness, reliability & applicability of these approaches in industrial context to support regulatory decision making
- Gather & produce high quality datasets to generate a solid knowledge base for supporting the use of NAMs and other non-animal approaches in the field of health technology and drive 3Rs implementation; ensure sustainability of results (scalable digital data repository)
- Establish a collaboration platform between all relevant (public & private) stakeholders, including regulatory agencies & policy makers (& patient organisations as relevant).
- Plan strong communication & dissemination to accelerate the implementation of NAMs and other non-animal approaches.
- Explore synergies and complementarities with relevant initiatives at national, European and international level.

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Expected outcomes

Actions to be supported under this topic must contribute to all the following outcomes:

- Implementation of NAMs & other innovative non-animal approaches, assessed & validated & found to be relevant, reproducible, predictive, standardized
- Improved animal to human translation/production processes & contribute to 3Rs implementation
- Establishment and availability of NAMs & other non-animal approaches for development, and/or production of health technologies that are fit-for-purpose to support regulatory decision making
- Access to high-quality data, new recommendations & best practices to incentivise the use of these approaches & integration in industrial processes; creation of scalable digital repositories to ensure sustainability
- Support regulators and policy makers to gain knowledge & get access to high-quality data to facilitate the development of harmonised guidance and requirements & uptake or translation into health policies.

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Expected impact

- **Break down silos**: bring together different stakeholders to foster the use of NAMs and other non-animal approaches in the efficient development, testing and production of safe and effective innovative health technologies.
- **Improve public health:** patients will benefit faster from safe and effective health technologies developed using NAMs and other non-animal approaches that provide more human-relevant data and that are more predictive than current approaches.
- **Improve public health**: foster the development of health policies and standards on the use of NAMs and other non-animal approaches in health technologies.
- **Enhance competitiveness of the European health industry**: high quality innovative approaches and methodologies for the development and production of new health technologies, which can reduce the time and costs of processes while reducing the use of animals or animal-sourced biomaterials.
- **More sustainable/autonomous EU**: by achieving regulatory validation & uptake development such of approaches for development/testing/production of health technologies that are not dependent on shortages/issues with animal supply.

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Dissemination, exploitation & communication

- **Reserve budget** for effective Dissemination, exploitation & communication
- **Describe the dissemination, exploitation and communication measures** that are planned, and the target group(s) addressed, in particular:
    - Encourage the uptake of the results of the project through a strong communication and outreach plan
    - Allocating appropriate resources to explore synergies with other relevant initiatives and projects
    - If applicable, elements in line with the Availability, Accessibility and Affordability (3A) provisions

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Budget

IHI financial contribution:
~12 - 15M EUR

Contributions from project participants:
~12 - 15M EUR*

Project Budget

Total available IHI budget for this topic: 30M EUR

*At least 45%of the project budget must be covered by contributions from project participants

Simplified budget example

Single-stage call proposals

Type of participant	Total eligible costs + IKAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP,FC,IKAA)
'Public partners' (Universities, hospitals, SMEs, patient orgs, regulators..)	15 million	100%	15 million	0
Private members & contributing partners (requested funding = 0)	15 million	100%	0	15 million
Private members & contributing partners ('Hybrid')	10 million	100%	5 million	5 million
Total	**40 million**	**100%**	**20 million (50%)** Public funds	**20 million (50%)** Private funds

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Simplified budget example

<u>Two-stage</u> call Full proposal

<u>Not eligible for funding</u> : pre-identified private members and contributing partners
Large companies with annual turnover > 500 M

Type of participant	Total eligible costs + IKAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP,FC,IKAA)
'Public partners' (Universities, hospitals, SMEs, patient orgs, regulators..)	20 million	100%	20 million	0
Pre-identified Private members and Contributing partners (not eligible for funding)	20 million	100%	0	20 million
Total	**40 million**	**100%**	**20 million (50%)** Public funds	**20 million (50%)** Private funds

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Proposal Submission & Evaluation

Proposal Template: Parts A, B & Annexes

- **Part A** is **administrative & researcher data** that is entered in webforms.

- **Part B** is the **narrative part** that includes three sections:
  - Excellence
  - Impact
  - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**

- **Annexes:**
  - Participant type
  - Budget details
  - Coordinator declaration
  - If relevant, IKAA
  - Clinical studies template*

*If no clinical studies included in the proposal, please upload a statement to confirm that no clinical studies is foreseen.

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Evaluation Criteria (1/2)

- **Excellence**
  - Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
  - Soundness of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.
- **Impact**
  - Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.
  - Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

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Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall
  - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.

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Tips for applicants

Tips for applicants

- Read all the call-relevant material, especially the topic text

https://www.ihi.europa.eu/apply-funding/future-opportunities

- Watch the “Rules and Procedures” and “preparing the financial part of the proposal” webinars

Tips for applicants

- Form your consortium **early**
  - Always think “public-private partnership“
  - Include partners bringing **in-kind contributions**

- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria

- Consider & plan for the potential **regulatory impact** of results

Finding project partners

You'll need to build or join a consortium!

- Network with **your contacts & IHI Call Days participants:**
  - https://ihi-call-days.ihi.b2match.io/
  - Use EU Funding & Tenders portal **partner search tool:**
  - https://europa.eu/!QU87Nx
- Get in touch with your **IHI national contact point**:
  - https://europa.eu/!D7jyMy
- Network on social media:
  - www.twitter.com/IHIEurope
  - be.linkedin.com/company/innovative-health-initiative

Pitching Session

Today 27 June 2023, 11:10 – 12:10 **Brussels time**

Join via the B2Match platform: https://ihi-call-days.ihi.b2match.io/

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Geir	Klinkenberg	Research manager	SINTEF	Validated and standardized in vitro and in silico models for prediction of organ toxicity and associated immune responses from biodegradable and inert synthetic polymers
2	Margarida	Diogo	Assistant Professor	IBB - Institute for Bioengineering and Biosciences	hiPSC technology for Engineering Human Tissue Models
3	Gael	Roue	Group leader and EU-Interreg project coordinator	Josep Carreras Leukemia Research Institute	Implementation of a new immunocompetent non-animal PDX model of hematological cancer for immunotherapeutic drug discovery
4	Aydanur	Aydin	Academician	Gumushane University	Developing a smart phone application for breast cancer patients that can be used after the surgery
5	Frank	Bringezu	Principal Scientist	Merck KGaA	ViCoGs to replace concurrent controls in animal studies
6	Eva	Gonzalez	Head of Innovation Department	BIOLAN	In-vitro selection of nanobodies for healthcare applications
7	Jerome	Martinez	Senior Scientist R&D Immunoassays - Biomolecules Analysis Platform	BioMérieux	Fetal Bovine Serum - Compassionate Alternatives for Research Ethic and Sustainability
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How to book your meetings via the B2Match platform

Book your meetings in 4 easy steps

1. Make yourself available
2. Look for partner on the participants or organisation tab
3. Select date, time, attendees (up to eight per meeting), add message
4. Send the meeting request and wait for the reply

Step by Step guide on how to book meetings: https://europa.eu/!FkjV9n

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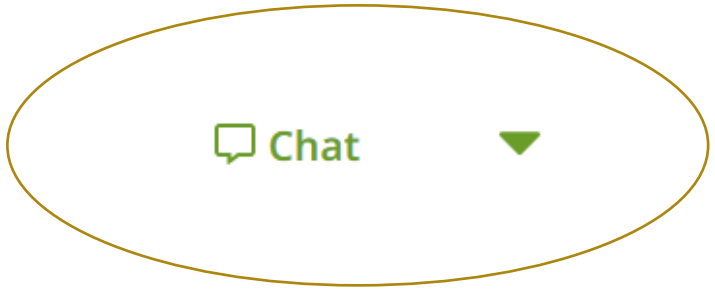
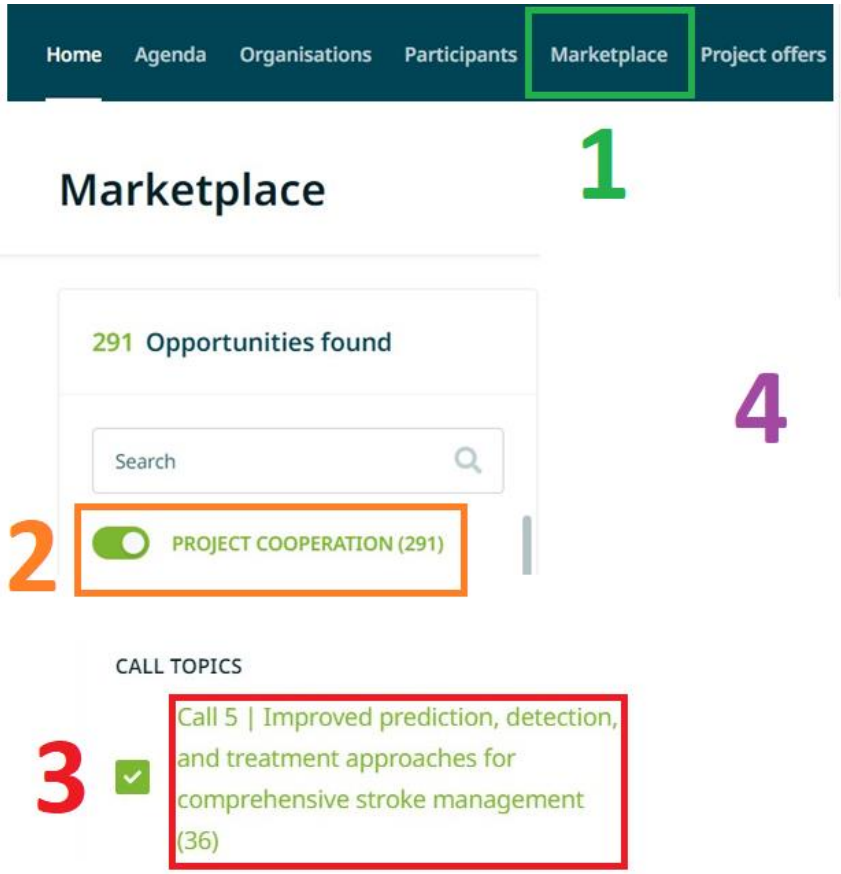
Questions time

If you want to ask a question please use the chat function on the right corner of your screen



Marketplace



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PROJECT COOPERATION — Updated on June 21, 2023

EEG based Triage of Stroke Patients

What type of organisation are you looking for? (Question for consortium/coordinator seeking partners)

What kind of expertise are you looking for? (Question for consortium/coordinator seeking partners)

PROJECT COOPERATION — Updated on June 21, 2023

Medical image analysis and segmentation

We would like to join a consortium and can contribute the following expertise:

Medical image data are used in a variety of ways for diagnosis, treatment planning, monitoring of interventions, observation of condition changes and documentation. Common image modalities range from

PROJECT COOPERATION — Updated on June 21, 2023

Remote vital functions monitoring, evaluation and smart interventions

Our research center focuses on the collection, remote monitoring, and evaluation of vital data.

What do we bring to the consortium?

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#IHICallDays

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Call 5

26 June	15:00-16:30	IHI rules & procedures
27 June	10:00-12:10	Non-animal approaches for health technologies
27 June	14:00-16:10	Theranostics solutions
28 June	14:00-16:10	Stroke management
29 June	10:00-12:10	Synthetic data generation
29 June	14:00-15:30	The financial part of the proposal

Online event

Register now

COCIR efpia EuropaBio MedTech Europe from diagnosis to cure Vaccines Europe Co-funded by the European Union

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Thank you for your attention

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

We are taking now a 5 minutes break

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IHI Call Days | Call 5

Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies

Validated and standardized in vitro and in silico models for prediction of organ toxicity and associated immune responses from biodegradable and inert synthetic polymers

Contact person name: Geir Klinkenberg

Organisation: SINTEF

E-mail: geir.klinkenberg@sintef.no

Link to:

- Marketplace opportunity (Hanne Haslene-Hox)
- Participant profile (SINTEF AS, Dept. of Biotechnology and Nanomedicine)

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Challenges and objectives

- We will validate and standardise *in vitro* and *in silico* efficacy and safety models for the screening and prediction of drug effects
  - ATMPs, novel drugs and formulated drugs are poorly characterized by current *in vitro* models, as they frequently interact with scaffold material used in such 3D models
  - There is a high need for validated and **standardized animal-material free 3D models** will be delivered to be used for drug efficacy and safety testing
  - We aim to provide organ-specific tissue-models that can represent physiologically relevant uptake and exposure kinetics and yield meaningful read-outs for drug development and evaluation in a high-throughput manner.

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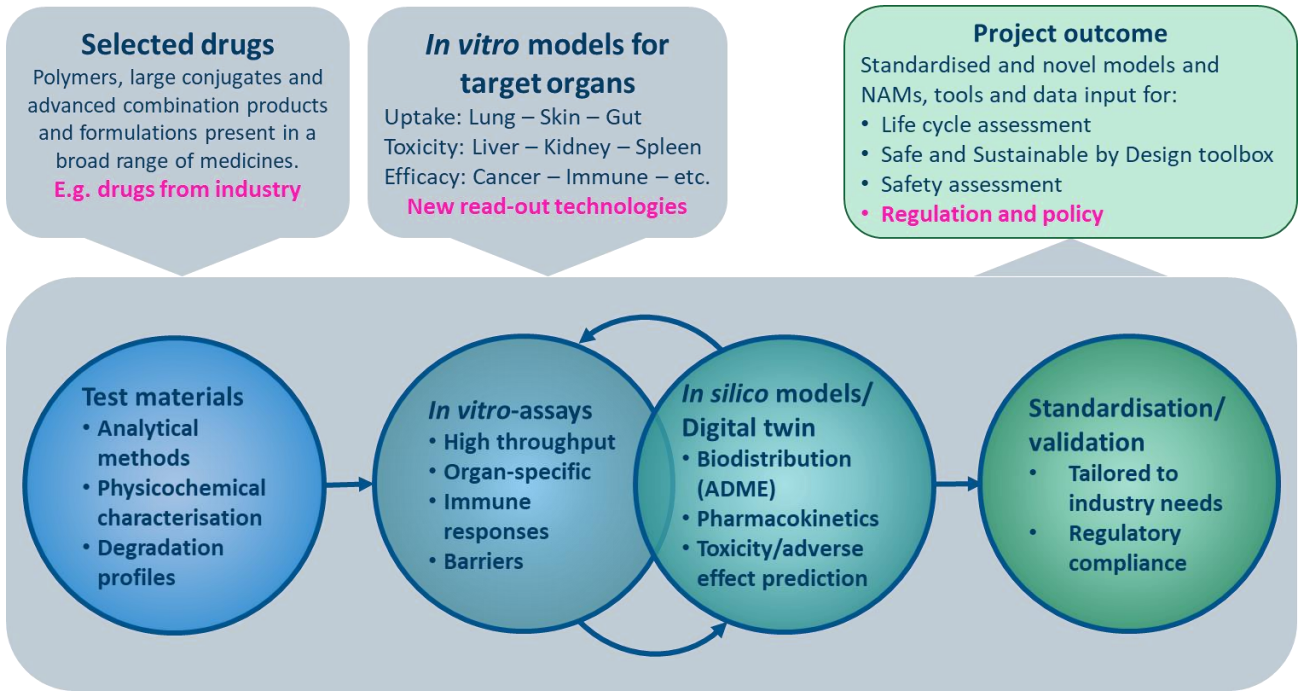
Main activities

- Standardize 3D multicellular models that recapitulate organ-specific characteristics and barrier models.
- Develop and standardize immune-enhanced *in vitro* assays
- Implement barrier models for the most common exposure routes (skin, lung, gut).
- Develop *in silico* and digital twin models
- Demonstrate transferability of developed NAMs



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Expertise and resources offered

- Interdiciplinary consortium of research partners providing
  - organ-specific and immune models
  - high-throughput screening
  - standardization for regulatory preclinical documentation
  - material development
  - analytical characterization of drugs and materials
- State-of-the-art infrastructure for screening, material, process and drug development, and production

- **No IKOP or IKAA**

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Expertise requested

- SMEs with interesting NAMs, readout technologies, or use cases.
- SMEs or companies working on new animal-free products.
- Large companies interested in testing and implementing new NAMs
- Regulatory bodies/policy makers
- Insight in market needs, requirements from new NAMs and industry user knowledge

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IHI Call Days | Call 5

Topic name: Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies

hiPSC technology for Engineering Human Tissue Models

Contact person name: Margarida Diogo

Organisation: Institute for Bioengineering and Biosciences (iBB)

E-mail: margarida.diogo@tecnico.ulisboa.pt

Link to: https://ihi-call-days.ihi.b2match.io/participations/203006

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Challenges and objectives

- The use of animals in biomedical research and development raises **serious ethical issues**
- Animal testing requires time-consuming protocols, high costs for animal supply, and the results are **not always reproducible** and **applicable to humans**
- It is crucial to develop alternatives allowing **significant reduction of animal usage and animal suffering level**
- This proposal aims to establish non-animal approaches, based specifically on the use of **human organoids** derived from induced pluripotent stem cells, for the efficient development and testing of safe and effective innovative therapies. These non-animal approaches may be used specifically for:
  - Disease modeling (infectious and/or non-communicable diseases)
  - Drug testing
  - Toxicology assays

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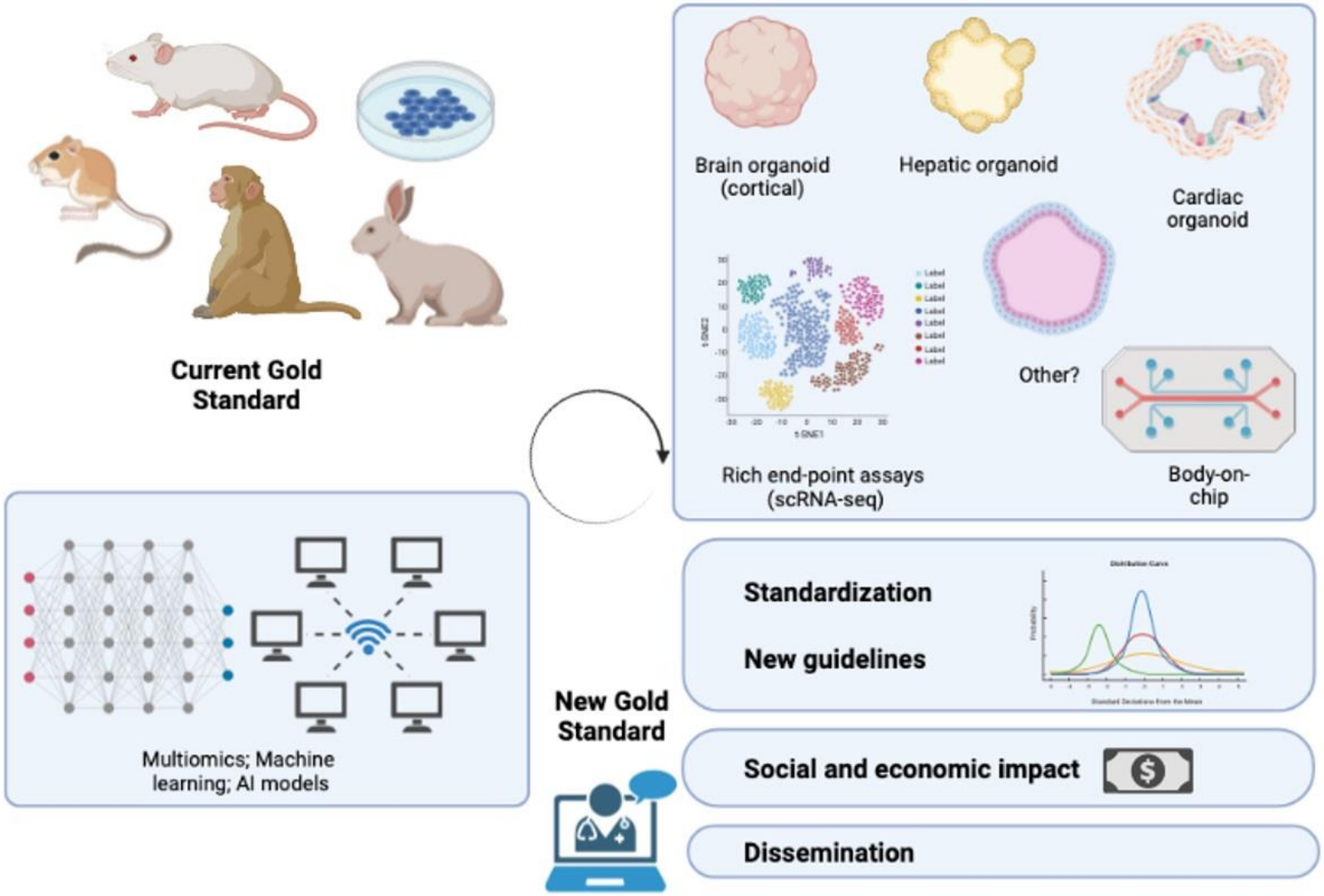
Main activities



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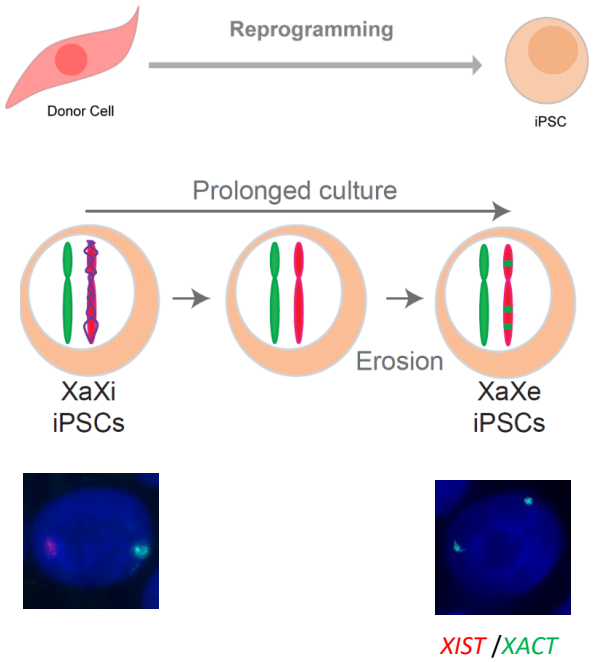
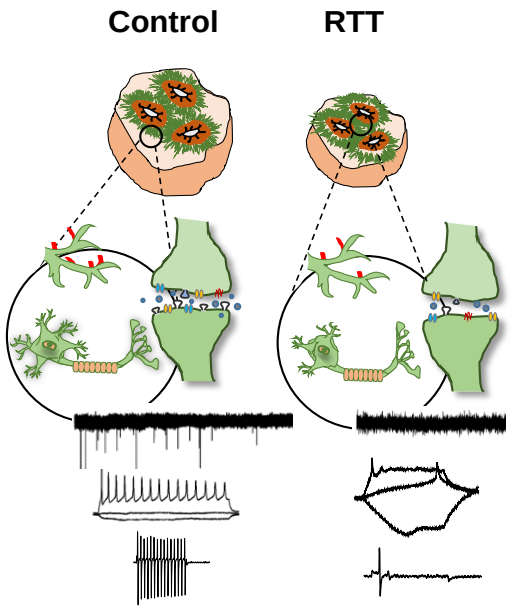
Expertise and resources offered

Reprogramming and Epigenetic Fidelity of iPSCs

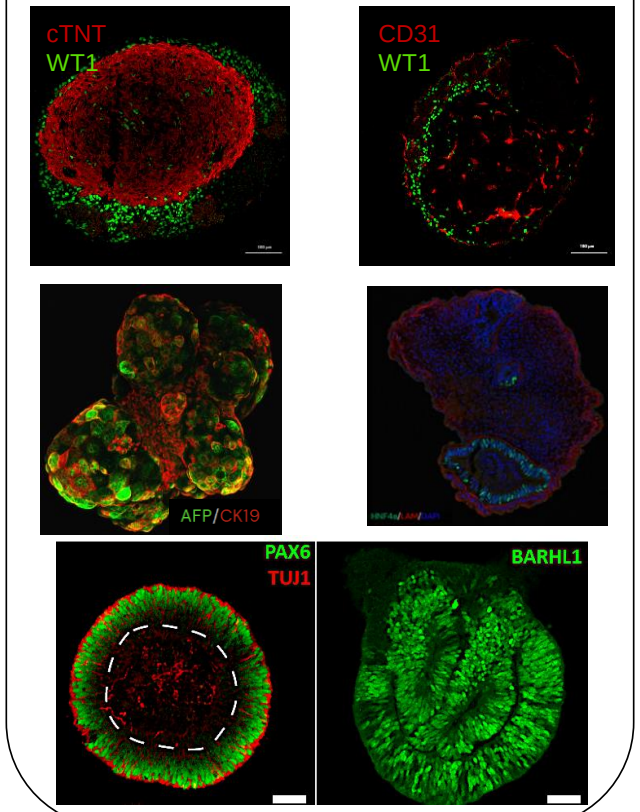


Modeling Neurological Disorders using Organoids

Forebrain organoids



Engineering Novel Cardiac, Cerebellum and Hepatic Organoids



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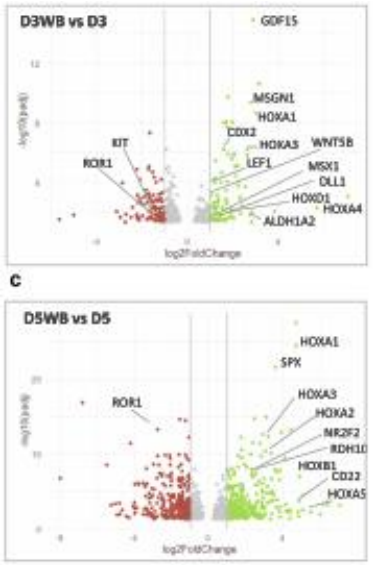
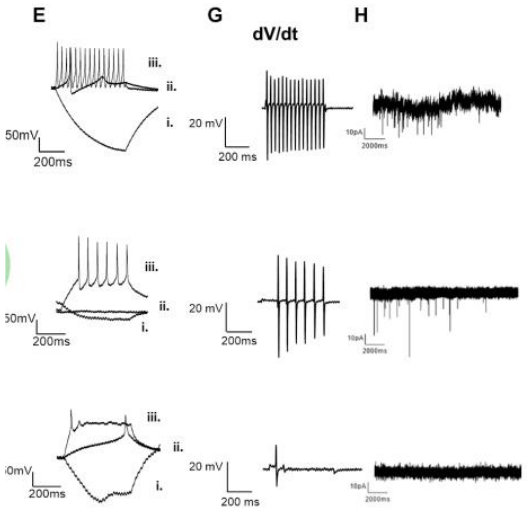
Expertise and resources offered

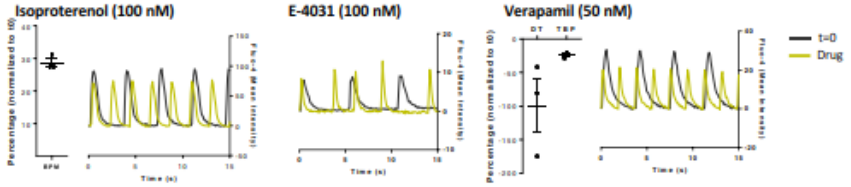
In-depth molecular, structural and functional characterization of Organoids



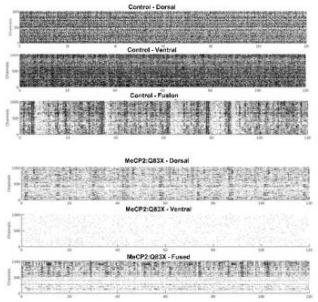
Bulk RNA-seq Transcriptomics



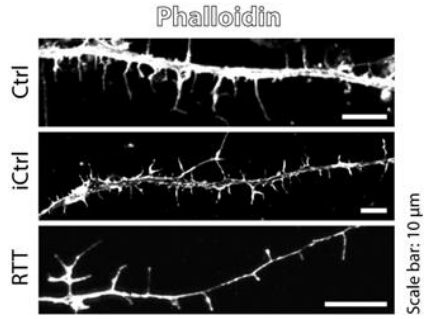
Single Cell Patch Clamp Electrophysiology



Calcium Transient Analysis (single-cell and 3D)



Extracellular Recordings (HD-MEA)



Confocal Microscopy Images

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Expertise requested

Machine Learning, Data Analysis and Integration Experts

Organoids-on-a-chip experts

Standardization experts

Regulatory experts

Pitching Session

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IHI Call Days | Call 5

Topic 1: Accelerating the implementation of new approach methodologies and other innovative non-animal approaches for the development, testing and production of health technologies

Implementation of a new immunocompetent non-animal PDX model of hematological cancer for immunotherapeutic drug discovery

Contact person name: **Gaël Roué**, PhD

Organisation: **Josep Carreras Leukaemia Research Institute**

E-mail: **groue@carrerasresearch.org**

Link to:

- Marketplace opportunity: **https://ihi-call-days.ihi.b2match.io/participations/263951/opportunities**
- Participant profile: **https://ihi-call-days.ihi.b2match.io/participations/263951**

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Challenges and objectives

- **Limitations** of current mice PDX models in hematological cancer research:
  - reduced engraftment rates (<40%)
  - long and costly process requiring a large number of mice for stable PDX (3 generations, > 6 months)
  - requires an elevated quantity of fresh surgical material -> not compatible with timely implementation for the design of personalized treatments
  - Immunocompromised models not suitable for immunotherapeutic drug development
- **Solutions** offered by the chicken embryo chorioallantoic membrane (CAM) assay:
  - low-cost and highly efficient mimetic of the mouse PDX model
  - extremely low input of clinical sample (fresh/frozen)
  - naturally immuno-competent
  - optimal engraftment rates (closed to 100% in aggressive blood cancers)
  - quick (< 2 weeks) and reliable evaluation of the effectiveness of different therapeutic options, taking into account the spatial architecture of the original tumor and the complex composition of the tumor microenvironment
  - faster tumor implantation (a few days) and post-treatment processing (<3 weeks)
  - > 15 distinct readouts and applications for drug efficacy/safety
  - improved reproducibility
  - non-animal *in vivo* model and convincing replacement strategy in drug development pipeline (compliance of the 3R rule)

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Main activities

- **Our mission** : to foster personalized medicine in blood cancers, by using chick embryo chorioallantoic membrane (CAM) as a predictive model for drug safety and efficacy assays and patient-centered immunotherapy design

- **Sector**: (immunotherapeutic) drug development and cell-based therapies

- Technology **already implemented** and first immunocompetent B-cell lymphoma avatars already available

- Suitability for leukemia/lymphoma modelling and small molecule development already established in **several recent high impact publications**.

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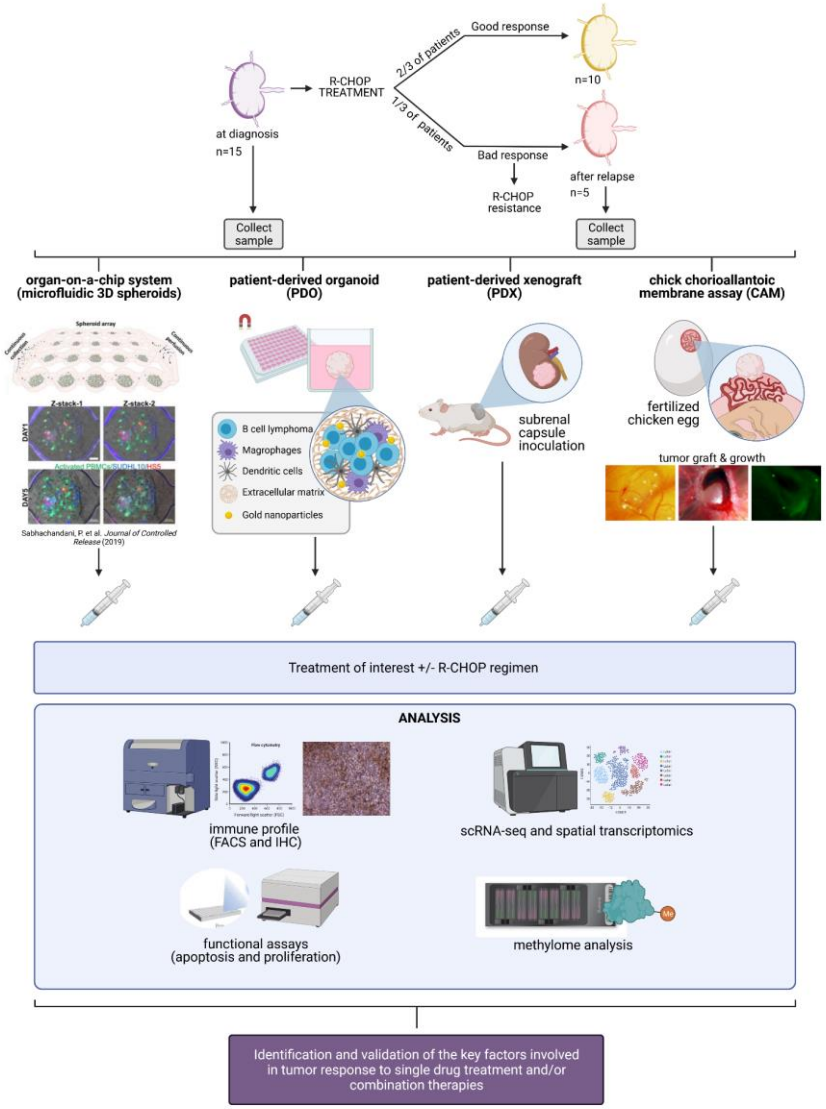
Expertise and resources offered

- Expertise in **innovative preclinical modelling** (3D organotypic spheroids, mice and CAM-derived PDX), **drug development** (computational chemistry, synthesis) and **biomarkers discovery**
- Biobank with a large and fully annotated collection of different hematological neoplasms
- **Multiomics** tumor characterization at single cell level
- Recent leadership of a **EU-funded consortium** (PROTEOblood) involving key academic institutions (Inserm, CNRS) and private partners



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Expertise requested

- **Industrial partners** (SME/large companies) willing to assess the safety and efficacy of new immunotherapeutic agent-based regimens in physiologically-relevant *in vivo* avatars

- **Academic partners** involved in early preclinical development of new immunotherapeutic approaches and interesting in immuno-competent, non-animal *in vivo* models

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IHI Call Days | Call 5

Topic 1

DEVELOPING A SMART PHONE APPLICATION FOR BREAST CANCER PATIENTS THAT CAN BE USED AFTER THE SURGERY

Contact person name: **AYDANUR AYDIN*,** AYLA GÜRSOY

*Assist. Prof. Dr., Gümüşhane Üniversitesi, Health Science Faculty, Department of Nursing

** Prof. Dr., Antalya Bilim Üniversitesi, Health Science Faculty, Department of Nursing

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Challenges and objectives

First Step in ADDIE: Analysis	• The analysis is the first step of ADDIE model in the design of educational materials. At this stage, it is necessary to create the "overall picture" of the instructional design integrity. This is a "contemplative" stage where it is necessary to think about the patient-centred approach for the design of of materials.
Second Step in ADDIE: Design	• In this part, the information gathered from the analysis phase, in conjunction with the theories and models of instructional design, is meant to explain how the learning will be acquired. At this stage, what will be the information content that the application will provide to the patient, how this information will be transferred (text, video, picture, etc.).
Third Step in ADDIE: Development	• The development of the software for the mobile app was handled by the software company in interactive contact with the researcher. The ".apk" extension file was created on the platform to be downloaded directly to the users' smartphones in the case of the patients in the intervention group.
Fourth Step in ADDIE: Implementation	• The implementation phase represents the first phase of making the entire app. It was proposed to conditionally divide this phase into two parts: a test and a final implementation phase.
And Last ADDIE Step: Evaluation	• The app made available to the patients was downloaded to the phones by the researcher. In addition, a promotional brochure was prepared with the software developer who developed the app.

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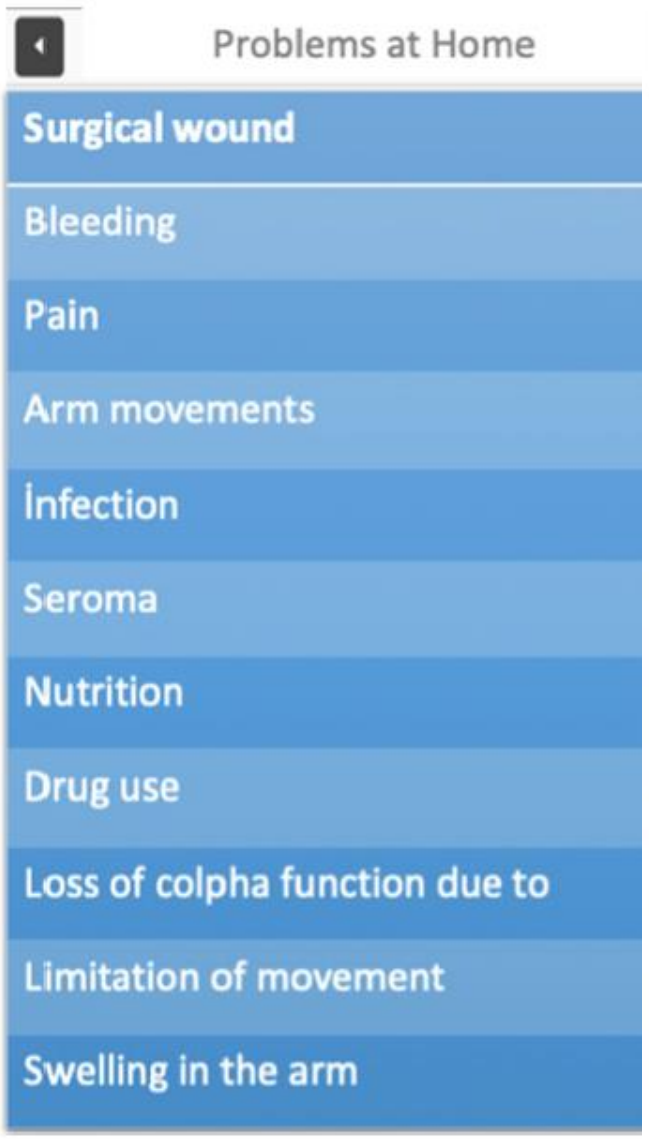
App background



THANK YOU FOR ATTENTION

Assist. Prof. Aydanur AYDIN

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IHI Call Days | Call 5

Virtual Control Groups (ViCoG)

ViCoGs to replace concurrent controls in animal studies

On behalf of the ViCoG Team

Contact person name: Frank Bringezu

Organisation: Merck Healthcare KGaA

E-mail: frank.bringezu@merckgroup.com

URL: https://etransafe.eu/etransafe-announces-the-launch-of-the-etransafe-vicog-initiative/

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Challenges and objectives

- The project aims to build virtual control groups to replace concurrent controls in animal studies
- Reduction of up to 25% of animals (3Rs)
- Cost savings (Non-Human Primate costs > 40 k€/animal)
- The project is fully in line with the objectives to reduce animal use in different industry fields with the help of New Approach Methodologies (NAM)
- Support AI driven applications (*e.g.*, for creations of virtual animals or digital twins)

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Main activities

- Develop a validated database for ViCoGs
- Provide statistical procedures for retrospective and prospective evaluation of the performance of ViCoGs
- Matching procedures for Qualification of ViCoGs
- Development in close collaboration with regulatory authorities to achieve acceptance

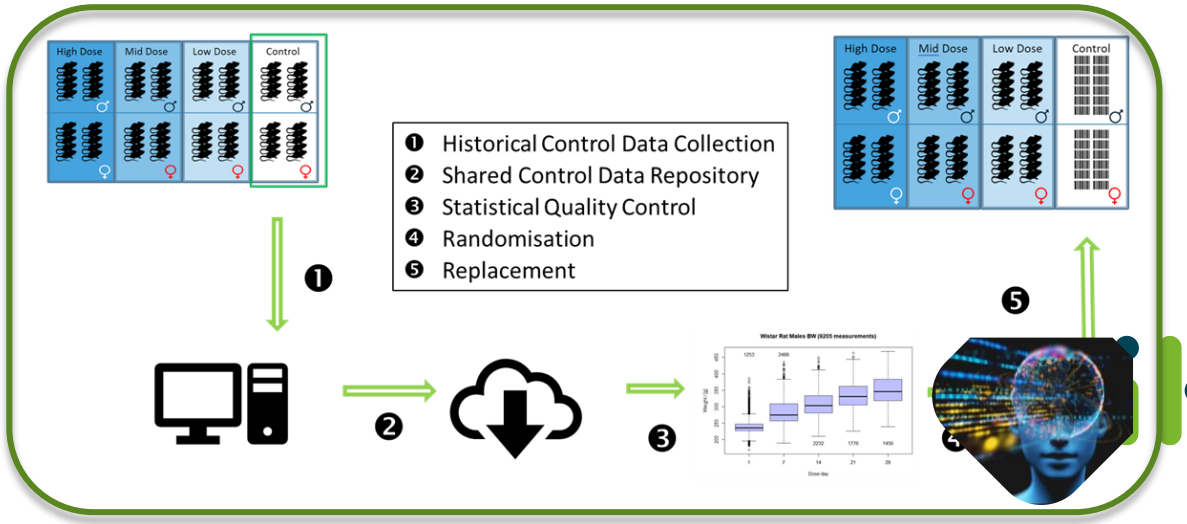

ALTEX preprint
published March 31, 2020
doi:10.14573/altex.2001311

Food for Thought …

Introducing the Concept of Virtual Control Groups into Preclinical Toxicology Animal Testing

Thomas Steger-Hartmann[1], Annika Kreuchwig[1], Lea Vaas[1], Jörg Wichard[1], Frank Bringezu[2], Alexander Amberg[3], Wolfgang Muster[4], Francois Pognan[5], Chris Barber[6]

[1]Bayer AG, Pharmaceuticals, Investigational Toxicology, Berlin, Germany; [2]Merck Healthcare KGaA, Biopharma and Non-Clinical Safety, Darmstadt, Germany; [3]Sanofi, Preclinical Safety, Frankfurt, Germany; [4]Roche Pharmaceutical Research & Early Development, Pharmaceutical Sciences, Roche Innovation Center, Basel, Switzerland; [5]Novartis Institute for Biomedical Research, Basel Switzerland; [6]Lhasa Ltd. Leeds, UK



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Expertise and resources offered

EFPIA & Associated (IKOP, IKAA)	SMEs & Academic partners in discussion	Regulatory Outreach
Merck Healthcare **Bayer AG** **Sanofi** **Roche** **Novartis** Astra Zeneca BASF Bristol Myers Squibb Boehringer Charles Rivers CLS Behring Instem Ipsen Labcorp NovoNordisk Orion Pharma Pfizer Servier UCB	Synapse, Madrid **Fraunhofer ITEM, Hannover** BSC, Barcelona CAAT Europe Deciphex MBIS, Barcelona TU Dortmund UPF/IMIM, Barcelona	Phuse

In kind contributions from EFPIA will include control data of *in vivo* studies. Current estimates amount to >1000 GLP studies with > 30.000 animals.

Bold: partners contributed control data to pilot ViCoG DB v1.3

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Expertise requested

SME & Academic *	Expertise
N.N.	Computer System Validation (GLP – OECD 17)
N.N.	Statistical Support
N.N.	Cloud based database development
N.N.	Data visualization
N.N.	Digital Pathology – image processing
N.N.	Sustainability development
N.N.	Possibility for regulators to contribute

* Any partner in the proposed consortium needs to be able to contribute key expertise

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ViCoG

Outlook

- The project requires close collaboration and ideally membership of regulatory agencies (EMA, FDA, EPA, ECHA, EFSA).
- It is intended to start with systemic toxicity studies but extend the scope to other type of animal studies including also pharmacological studies
- A strong collaboration is foreseen with IMI2 Big Picture and other partners

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IHI Call Days | Call 5

Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies

In-vitro selection of nanobodies for healthcare applications

Contact person name: Eva Gonzalez

Organisation: BIOLAN MICROBIOSENSORES

E-mail:egonzalez@biolanmb.com

Link to:

- Marketplace opportunity
- Eva Gonzalez

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Challenges and objectives

- BIOLAN is a Spanish SME focused on the development of analytical tools for the agri-food and healthcare sectors.

- The objective of BIOLAN within this project is to select and produce synthetic nanobodies as recognition elements for developing advanced diagnostic devices for healthcare applications

    - Overcome the use of animals for the production of molecular recognition elements such as antibodies and nanobodies
    - Deliver synthetic molecular recognition elements with enhanced characteristics:
        - Fast screening
        - High batch-to-batch reproducibility
        - High specificity and afinity
        - High stability

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Main activities

- Project main activities:

  Once identified the target(s) analyte(s):

  - Selection of nanobodies against the specific target(s)

  -Characterisation of nanobodies

  -Application as molecular recognition elements for healthcare applications

Expertise and resources offered

- BIOLAN has developed a platform for delivering nanobodies able to recognize any potential antigen:
  - Synthetic nanobody library
  - Screening protocols defined (no fagos required)
  - Expression on E. coli
  - Purification
  - Platform validated with the selection of a nanobody specific for lysozyme
  - Two nanobodies under development at the moment

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Expertise requested

- BIOLAN is looking for a consortium interested in the application of these novel synthetic molecular recognition elements for healthcare diagnostics
- Profiles for desired partners include:
    - SMEs
    - Large companies
    - Research institutes

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FBS – CARES

Fetal Bovine Serum - Compassionate Alternatives for Research Ethic and Sustainability

Replacement in Biopharmaceuticals : overcome an ethical concern

Jérôme MARTINEZ

BIOMERIEUX

jerome.martinez@biomerieux.com

IHI Call#5, Topic #1

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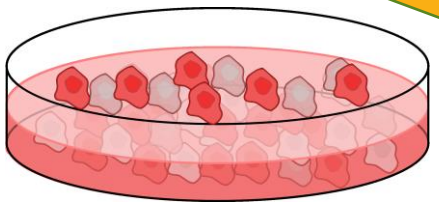
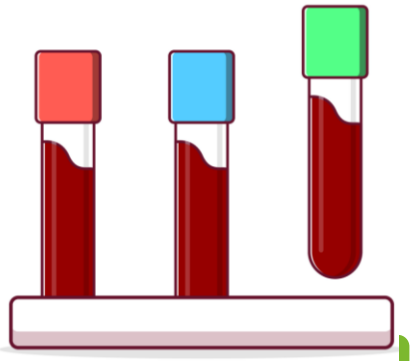
FBS – CARES

Behind this….





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FBS – CARES … is hidden that!

Major ethical concerns via inhumane

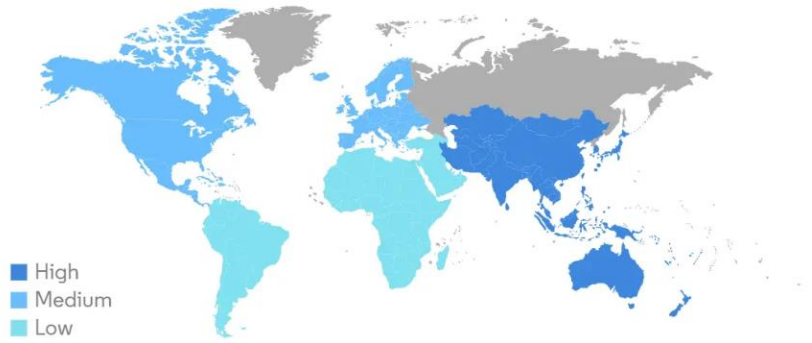
Fraud

Price instability

Contamination risk (prion, viruses,

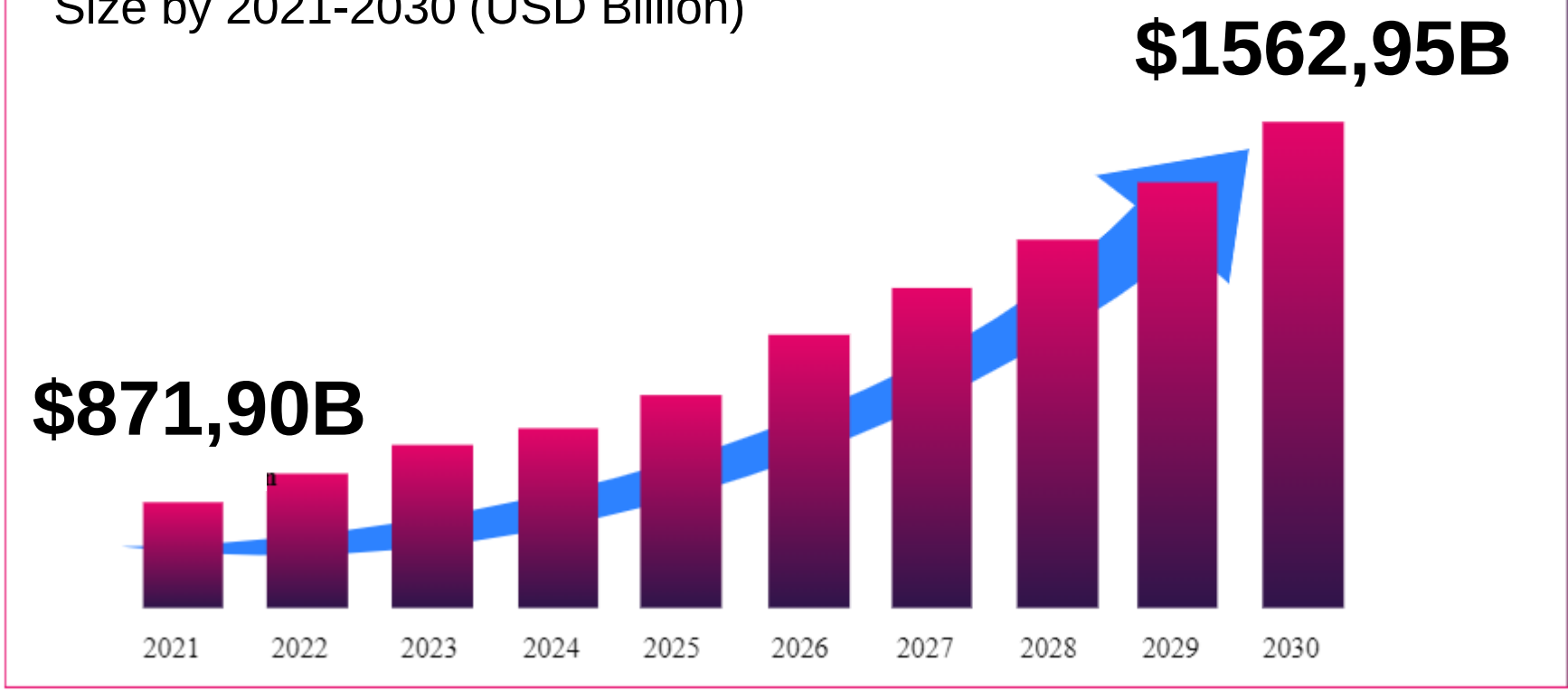
Major lot-to-lot Bio variability

FBS – CARES



Fetal Bovine Serum Market

Size by 2021-2030 (USD Billion)



Market Research Community

6.7%

Global Market CAGR
2022-2030

SOURCE
https://marketresearchcommunity.com/

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FBS – CARES

- Existing replacement solutions available on the market for cells culture media mainly : HPL, HI-CF,….

  (excluded from the project scope)

- Use of FBS for the new development of bioMérieux immunoassays-based IVD reagents is now stopped…

- … but FBS replacement in previously marketed reagents, need to be at the same performances

FBS – CARES

- FBS composition and role of components are unclear :
  - Interferences blocker
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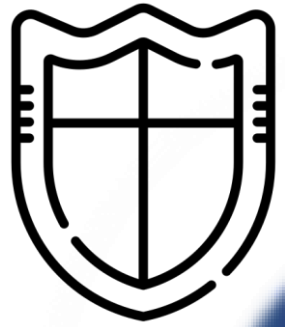
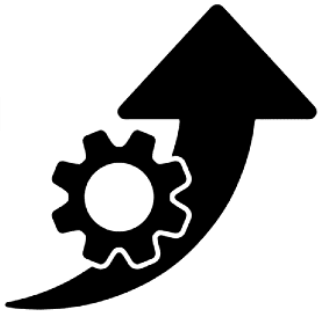
  - Stability enhancer
  - …





The technical blocking point we would like to solve :

1. Characterization of FBS component roles in biopharmaceutical usage (excl. cell culture)
2. Identify NAM (New Approach Methodologies) substituents according to these roles with 3R approach - Non animal and/or synthetic substituents

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FBS – CARES

Desired partners

- IVD players or biopharmaceutical companies : (harmonization of practices)
- Research Institutes
- Start-ups
- SME
- Regulatory bodies

>> Partners willing to move forward with impacting ethical & CSR actions

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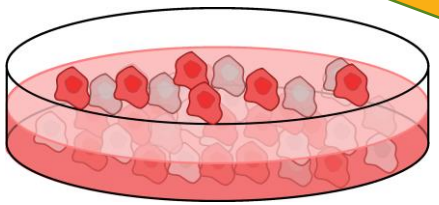

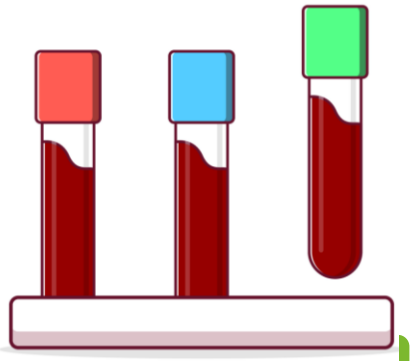

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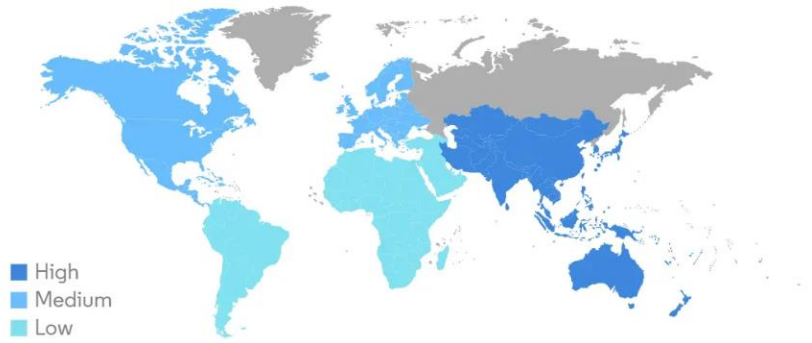

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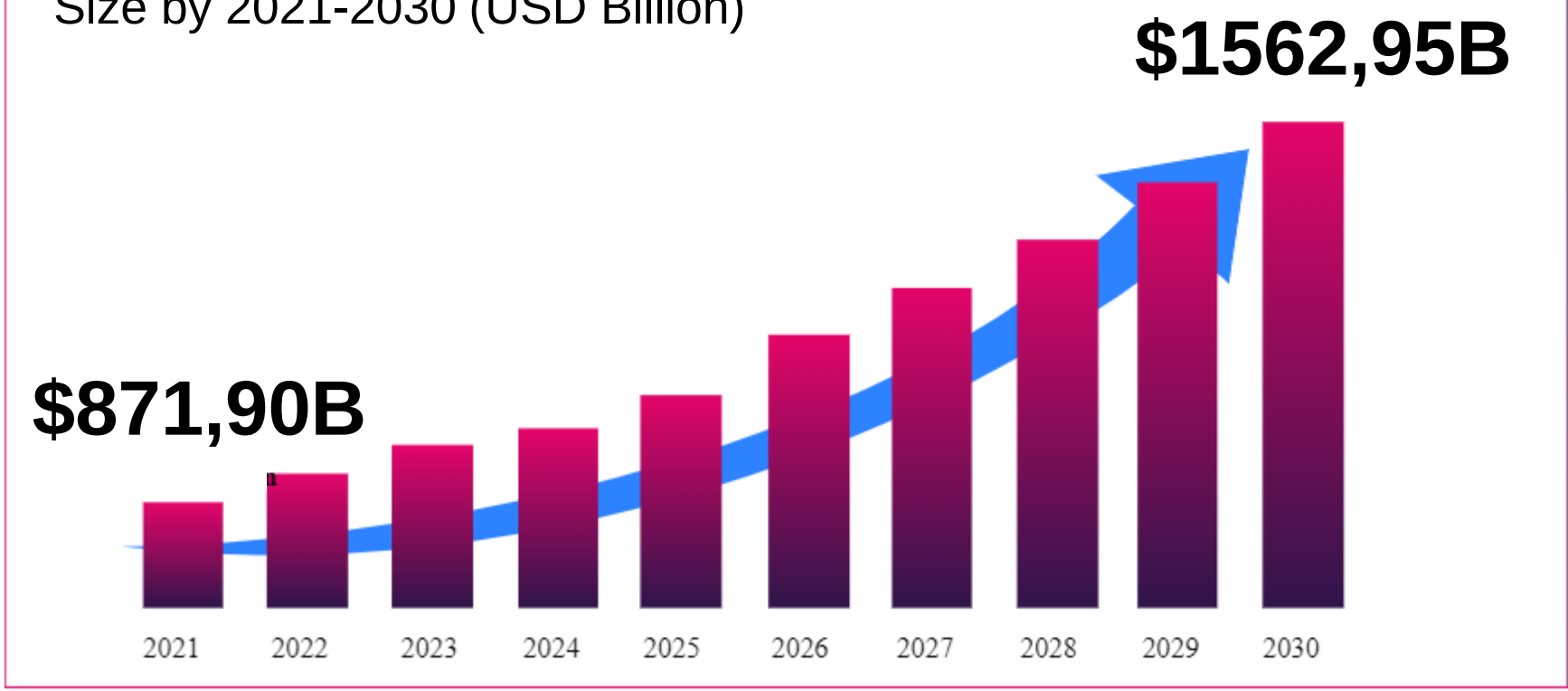

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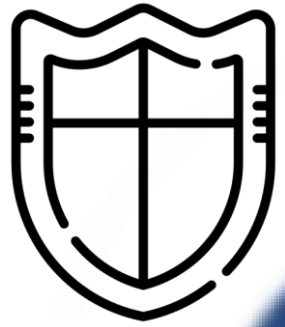

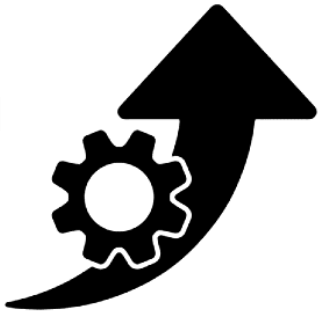

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7	Jerome	Martinez	Senior Scientist R&D Immunoassays - Biomolecules Analysis Platform	BioMérieux	Fetal Bovine Serum - Compassionate Alternatives for Research Ethic and Sustainability
8	Simone	Calzolari	CEO	ZeClinics	Accelerating human safety risk assessment with integrated approach
9	Daniela-Elena	Costea	Prof. in tumour pathology	University of Bergen	Tailoring *ex vivo* 3D multicellular models for use as predictive biological tools in the treatment of metastatic/recurrent head and neck squamous cell carcinoma

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IHI Call Days | Call 5

Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies

ZeClinics®

Powering discovery with Zebrafish

Contact person name: Simone Calzolari

Organisation: ZeClinics

E-mail: simone.calzolari@zeclinics.com

Link to:

- Marketplace Opportunity
- Participant profile

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Challenges and objectives

- Accelerating human safety risk assessment with integrated approach

The problem:

- ⅓ of drug candidates are toxic and Tox is the one of the major contributor of costs in drug development even more if detected in clinical/most-market phases.
- Animal models are not good predictors of tox
- Ethical issues with the use of animals

The project is suitable for IHI funding and fits with the draft call

Give concrete example of potential results and expected impact:

- Better **prediction** of tox
- Complete **eradication** of animal use

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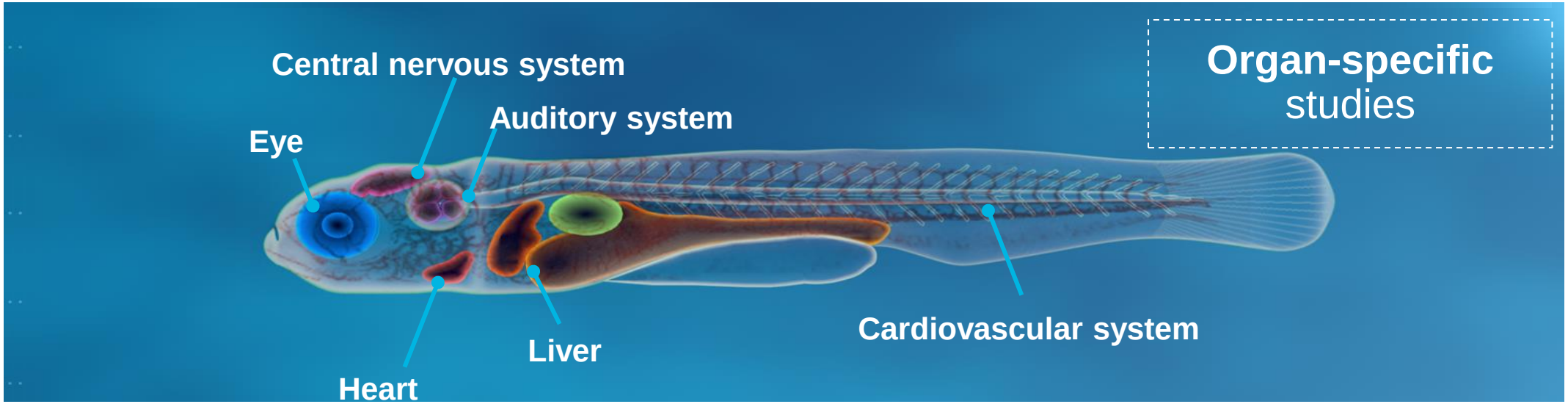
Why Zebrafish? – Non-Invasive In Vivo Insights

Zebrafish embryos' transparency and ex-utero development make them able to readily provide:



Direct *in vivo* visualization of cells, tissues, organs and embryonic development.

Same-subject simultaneous and sequential toxicology and efficacy assessments

Replacement

EU Directive 2010/63 lists embryos up to 5 dpf as non-animal, ***in vitro* models**.

Reduction

Same-subject simultaneous assessments require **less individuals**. Zebrafish = **less mammals** in regulatory phases.

Refinement

Non-invasive, *in vivo* data collection reduces stress and experimental artefacts.

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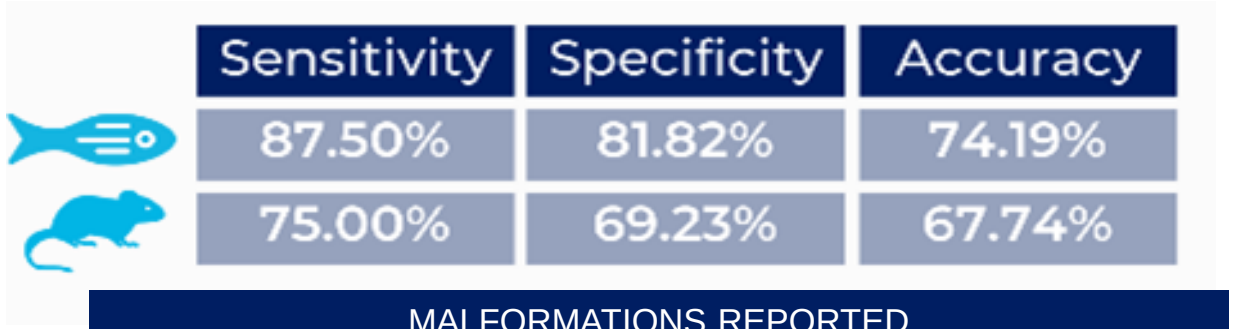
ZeTox – DevTox - Teratogenic prediction power



	Sensitivity	Specificity	Accuracy
	87.50%	81.82%	74.19%
	75.00%	69.23%	67.74%

MALFORMATIONS REPORTED	
Human	**Zebrafish**
Imatinib	
Skeletal alterations	Short body length
Craniofacial malformations	Craniofacial malformations
External ear malformations	Inner ear malformations
Dexamethasone	
Craniofacial malformations	Craniofacial malformations
Heart hypertrophy	Heart area
Defects on osteogenesis	Necrosis
Phenytoin	
Middle and inner ear defects	Inner ear defects
Thalidomide	
Limb malformations	Fin absence
Reversible stunted growth	Short body length

S. Jarque et al., (2020)

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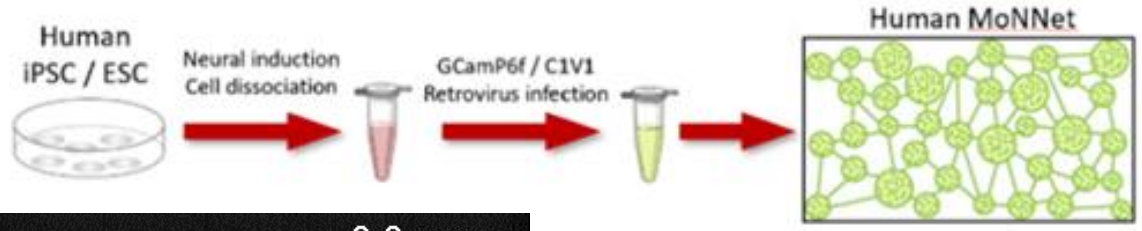
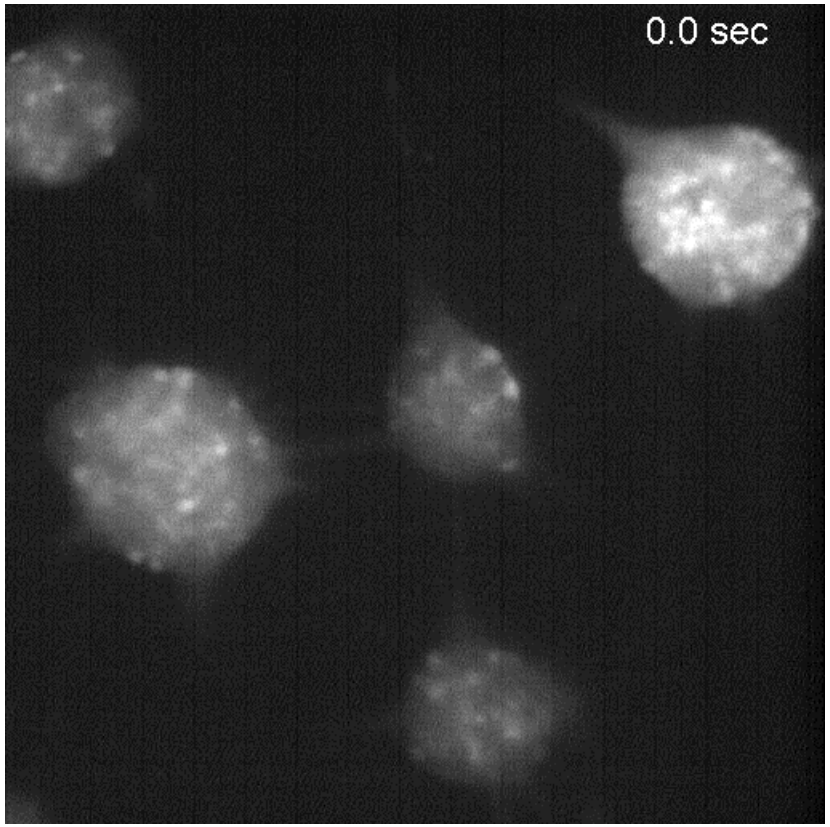
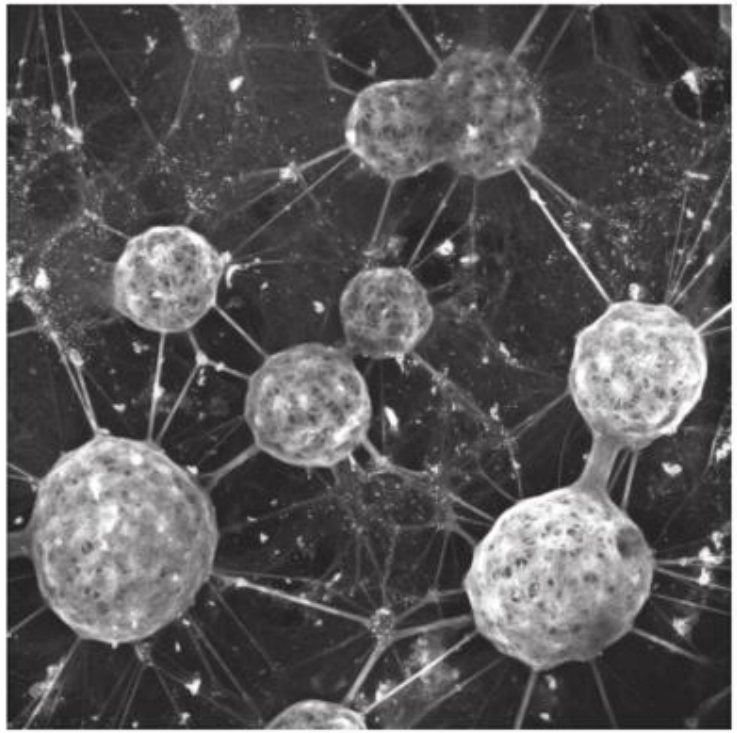
ZeNeuroid: human iPSC derived neurospheres networks







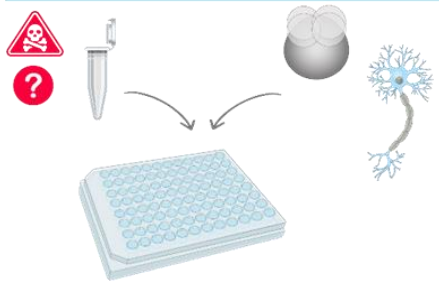
Main activities

Integrated Approach for Testing and Assessment

1. Non-testing Methods

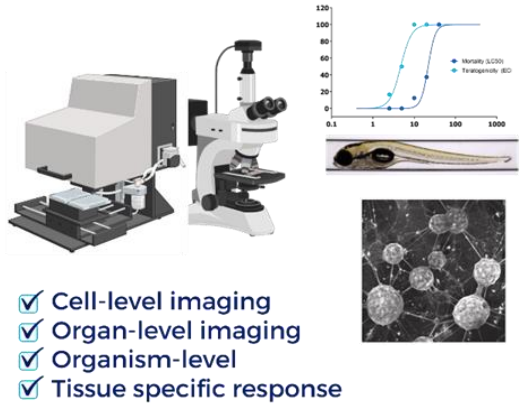
- Systematic Literature Review
- QSAR
- PBK/reverse dosimetry
- Other methods....

2. Experimental System(s)



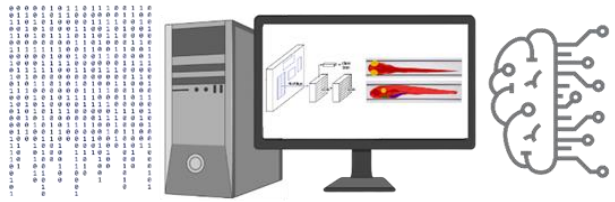
- ☑ High throughput (multi-wells)
- ☑ Whole organism
- ☑ Human biology
- ☑ Non-animal testing

3. Automated Screening Technology



- ☑ Cell-level imaging
- ☑ Organ-level imaging
- ☑ Organism-level
- ☑ Tissue specific response

4. Deep learning



Experimental data

5. Increased Predictivity

5a) Alternative vs traditional models

5b) Additional Infotmation Sources

- ADME
- Epidemiological Studies
- Omics
- Other Methods...

6. Human Risk Assessment

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Expertise and resources offered

- More than 10 years of experience in **toxicology using zebrafish**
- High-throughput screenings
- Combination of transcriptomic, phenotypic and **AI tools**
- Exclusive top-notch human bioengineering platform to study **neural connectivity** diseases.

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Expertise requested

- Non-testing Methods: Computational Modeling (QSAR, Read-across, Systematic Literature Review, PBK/reverse dosimetry, IVIVE, AOP formulation, etc…)
- Testing Methods: human and zebra fish cell-based assays for non-neuronal tissues (2D/3D cell culture, organs-on-chips, multi-organ on a chip), Omics, ADME.
- Regulators: experts in **ICH guidelines** and NAMs regulatory acceptance.

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Pitching Session

Today 27 June 2023, 11:10 – 12:10 **Brussels time**

Join via the B2Match platform: https://ihi-call-days.ihi.b2match.io/

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Geir	Klinkenberg	Research manager	SINTEF	Validated and standardized in vitro and in silico models for prediction of organ toxicity and associated immune responses from biodegradable and inert synthetic polymers
2	Margarida	Diogo	Assistant Professor	IBB - Institute for Bioengineering and Biosciences	hiPSC technology for Engineering Human Tissue Models
3	Gael	Roue	Group leader and EU-Interreg project coordinator	Josep Carreras Leukemia Research Institute	Implementation of a new immunocompetent non-animal PDX model of hematological cancer for immunotherapeutic drug discovery
4	Aydanur	Aydin	Academician	Gumushane University	Developing a smart phone application for breast cancer patients that can be used after the surgery
5	Frank	Bringezu	Principal Scientist	Merck KGaA	ViCoGs to replace concurrent controls in animal studies
6	Eva	Gonzalez	Head of Innovation Department	BIOLAN	In-vitro selection of nanobodies for healthcare applications
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IHI Call Days | Call 5

Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies

Presentation title

Contact person name: Daniela Elena Costea

Organisation: University of Bergen

E-mail: daniela.costea@uib.no

Link to:

- https://www.uib.no/en/rg/experimentalpathology
- https://www.uib.no/en/ccbio/107681/daniela-elena-costea

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Challenges and objectives

- Our aim is to tailor our *ex vivo* 3D multicellular models for use as predictive biological tools (*in vitro* avatars for functional precision therapy) that can be implemented into the current clinical scheme of treatment of metastatic/recurrent head and neck squamous cell carcinoma (M/R HNSCC).
  - M/R HNSCC patients benefit from only a very limited number of alternative treatment strategies, and those available are associated with high toxicity and low benefit, making this type of cancer a major clinical challenge.
  - Our 3D tumor models can be used for the novel concept for personalized cancer therapy called ‘clinical trials in a dish’.
  - A ready-to-use pipeline to produce ex vivo 3D multicellular spheroids for drug testing within 20-30 days from the time of biopsy can be developed and integrated in the current clinical package for M/R and primary HNSCC patients.

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Main activities

- Assessment of ex vivo 3D multicellular models as predictive tools in M/R HNSCC
- CTiD for testing patient's response to standard care drugs
- CTiD for identification of new drugs/compounds for treatment of M/R HNSCC
- Optimization of the pipeline for generation of ex vivo 3D models for drug testing suitable for clinical integration for personalized M/R HNSCC treatment

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Expertise and resources offered

- Clinical oncology
- Pathology
- Primary cell isolation
- In vitro 3D modelling
- IMC (Hyperion technology)

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

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Expertise requested

- Proteomics
- Drug testing platforms
- Other centers for a multicenter study