HEALTH PROOF HELSINKI

Testing Environments and Expert Services for Healthtech and Wellbeing Companies

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HEALTH PROOF HELSINKI

(= Members of the Ecosystem)

- ✓ Metropolia University of Applied Sciences (Coordinator)
- ✓ City of Helsinki
- ✓ HUS Helsinki University Hospital

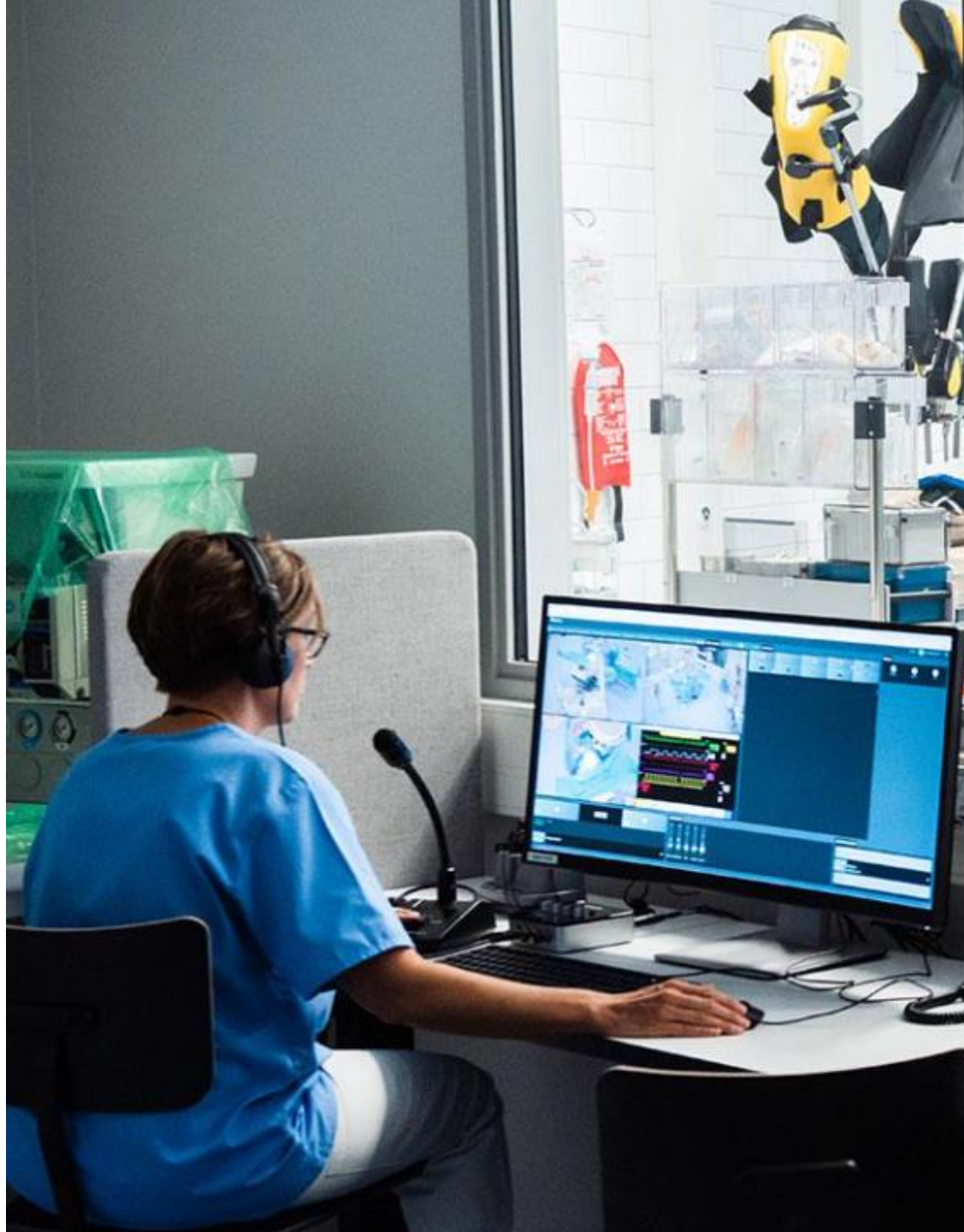
Metropolia
University of Applied Sciences

Helsinki

HUS Helsinki University Hospital

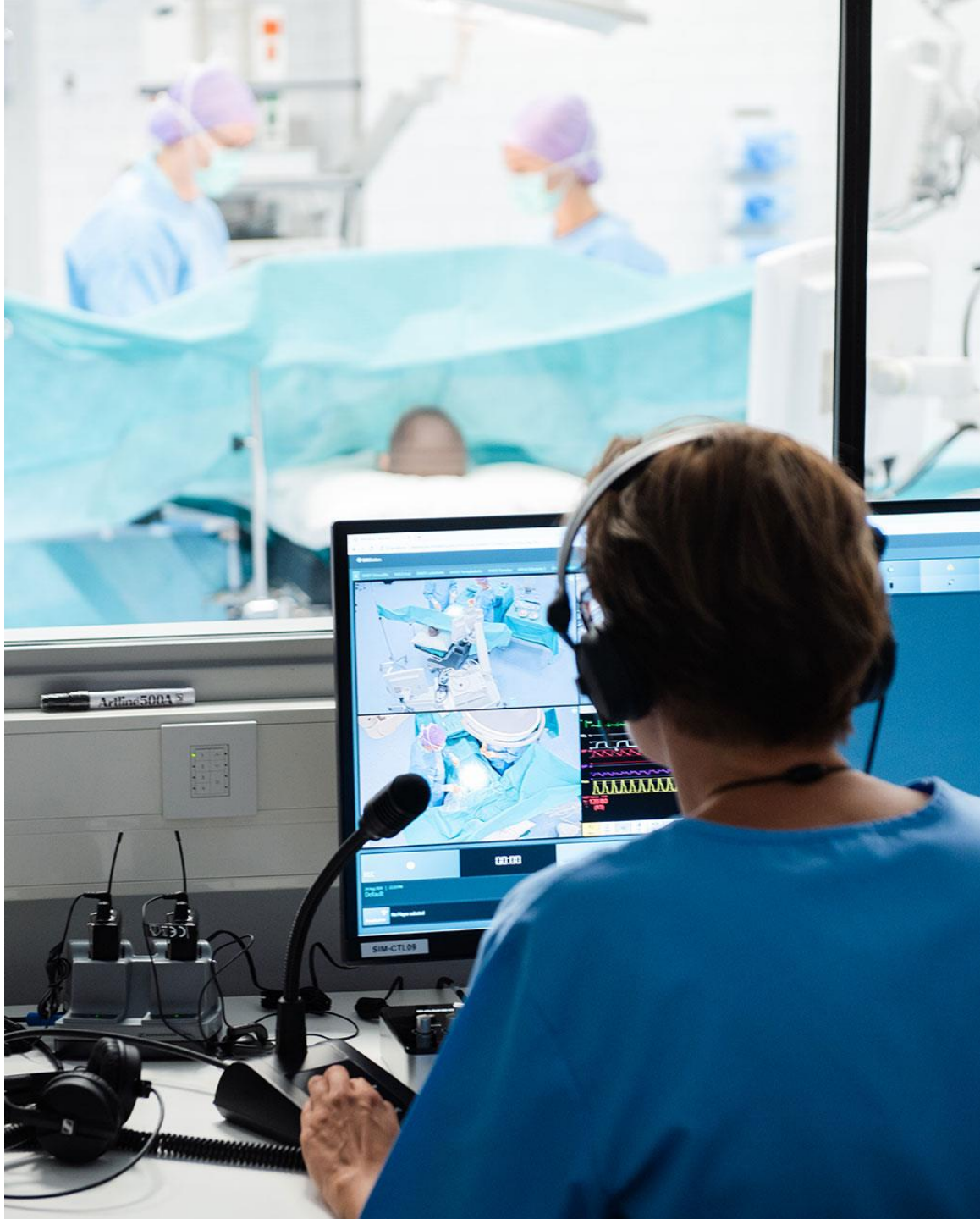
GOAL

We aim to create a smooth access for health and wellbeing technology companies to ecosystem expertise, facilities and equipment in various stages of their product development through a unified and coherent customer journey



HOW?

- Develop a service concept (ethics, regulations, contracts) for pre-clinical, clinical testing and research by combining the efforts of three major Finnish public RDI environments and expertise
- Better serve company testing needs – pilots/use cases early on
- Ensuring continuity, visibility, and collaboration
- Capital district testing and RDI ecosystem



WHY TOGETHER?

- Multidisciplinary research ecosystem
- Member offerings complement each other
- Metropolia can involve students in the RDI work
- Metropolia has data, AI, ICT, XR, 5G, automation and IOT experts and environments
- HUS's focus on data, digitalisation and scalable AI solutions, HUS Data Lake, HUS Acamedic cloud research environment
- City of Helsinki provides access to its real-life testing environments and experts in primary healthcare and social services

MEMBERS' OFFERINGS

Metropolia

Early stage pre-clinical testing environments and expertise

City of Helsinki

Primary health care and social services testing environments and expertise

HUS

Specialised health care and diagnostics testing environments and expertise

OUR SERVICES:

	Early Concept Phase	Prototype Phase	Pre-market Product	CE Marked Product
Expert Assessment	X			
Proof of Concept (PoC)	X			
Prototyping	X	X		
Usability Testing in the Target Environment		X	X	X
Product Validation against the Reference Measurement		X	X	X
Clinical Device Trial			X	
Use of Patient Registry Data in Product Development (Registry Research)		X	X	X

On the following slides the services we offer are described in more detail.

EXPERT ASSESSMENT

Service Benefit:

- With the help of an expert assessment, you ensure that the solution you are developing is suitable for the customer's needs, processes and operating environment and easy to implement at various healthcare units
- Helping to assess which healthcare units might need the solution you are developing. This helps facilitate the marketing of the solution

Service Description:

- An expert will evaluate the suitability of the product or service you are developing for healthcare processes. The expert also investigates what the regulatory requirements are for the product or service.

Deliverable: Expert Assessment Report

PROOF OF CONCEPT (POC)

Service Benefit:

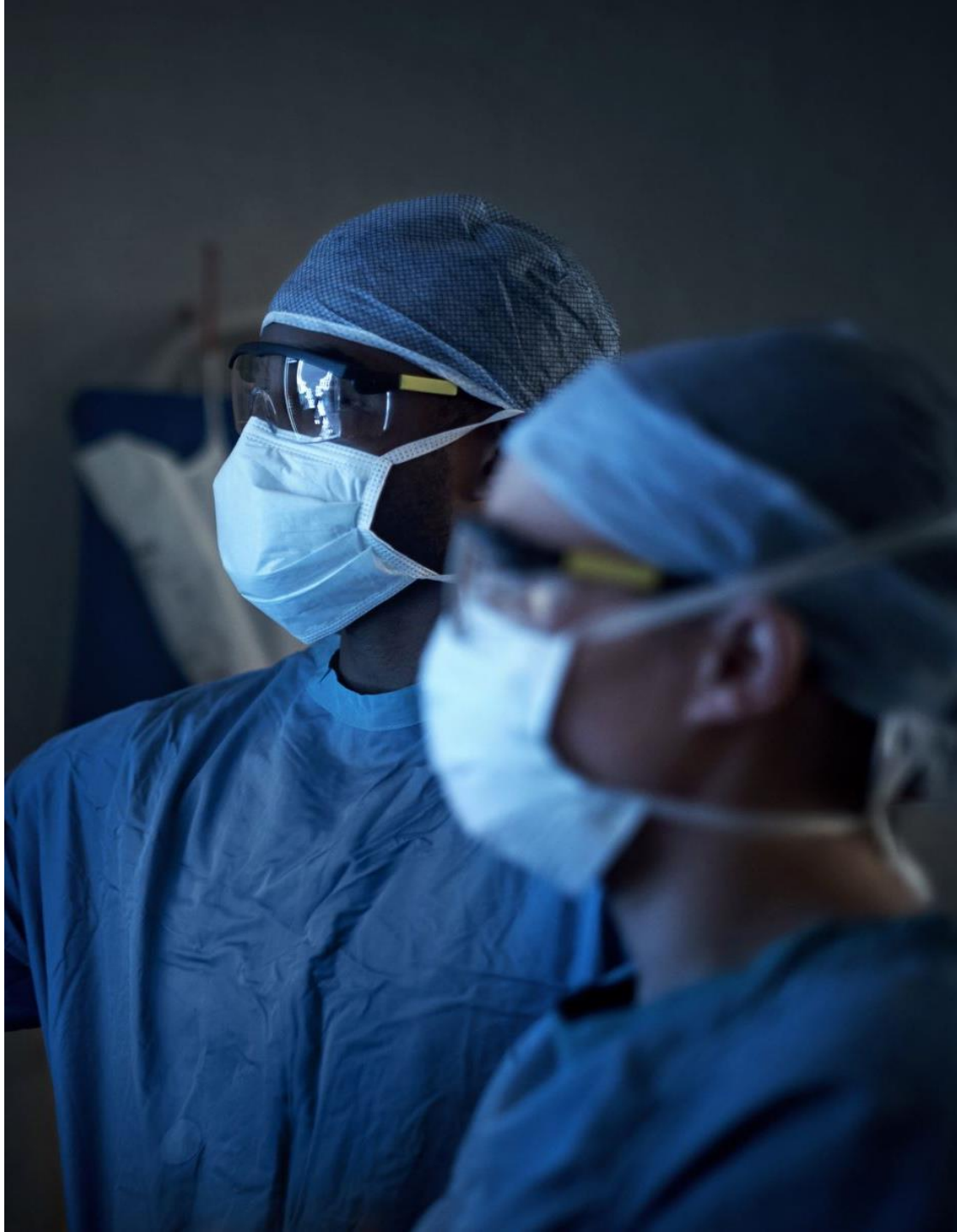
- Proof of Concept (PoC) means the validation of a particular method or idea to demonstrate its suitability
- We help ensure that the starting point for development is a solution to the customer's real problem
- Anticipating the need and demand for a product or service significantly reduces the risk of wasting resources and business potential

Service Description:

- A PoC is usually small and incomplete, but can be used to demonstrate the functionality of a theory
- In validating a concept for a specific use, customers are tested to see if a particular product or service concept is interesting, attractive and functional for them
- If the product concept has already been concretized, users can test it in advance. This is to find out whether the product is interesting and functional even in real use cases
- The more the concept can be compared to a competing products - that is, benchmarked - the better and more reliably it can be tested
- Concept validation research is usually a concise and rapid process. Typically, concept validation is done as a qualitative study

- Please, note: This is not a clinical trial

Deliverable: Report



PROTOTYPING

Service Benefit:

- We can complement your product development resources and thus speed up your product development process

Service Description:

- We can design and manufacture a physical prototype for you, for example by 3D printing. We can also design and implement the electronics and / or software required for the product

Deliverable: Prototype

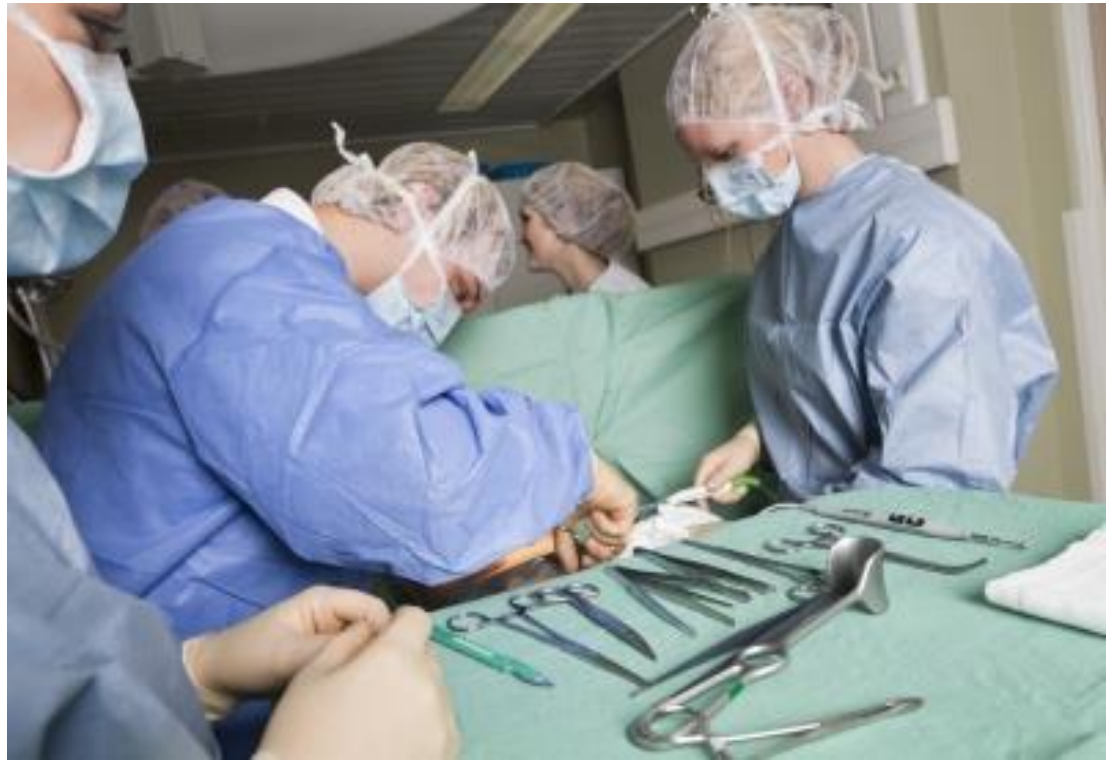
USABILITY TESTING IN THE TARGET ENVIRONMENT

Service Benefit:

- Usability testing ensures that your product or service meets user expectations
- Once a product has been user tested at the concept or prototype stage, it is likely that the product will no longer have significant usability problems at the end of the product development process

SIMULATION HOSPITAL

- Metropolia has made substantial investments to infrastructure
- An internationally unique, fully equipped and standards-compliant simulation hospital, with an ambulance, reception facilities, delivery room, operating room and intensive care unit
- Simulation hospital can be used for developing patient/client care in a simulation environment



PRODUCT VALIDATION AGAINST REFERENCE MEASUREMENT

Service Benefit:

- Product development with real data
- We act as an external party that can demonstrate the functionality of a product or service
- You can use our evidence of the effectiveness of your product or service in your marketing
- In our research activities, we follow good research practice and research ethical guidelines

Service Description:

- We can find users for you that are best suited to your needs to use your product or service, collect data generated by your product or service, and generate reference data by reference measurement

- If you wish, we can provide you with comprehensive research services, including the preparation of a research plan, the application of an ethical review of the research, the collection of data, the quantitative and qualitative analysis and reporting of the data, and the preparation of a follow-up plan. If you wish, we will publish the results of the study

Deliverables: Report and data

CLINICAL DEVICE TRIAL

Service Benefit:

- In order to be placed on the market in the EU, a medical device or IVD device must be CE marked. As a requirement for obtaining the CE marking, a clinical trial must be performed by the manufacturer of the medical device
- If the evaluation requires a clinical device trial, you can have it performed by us. A clinical device study evaluates the performance of a device (performance and safety) in the right operating environment & in the right patients

Service Description:

- First, your company draws up a research plan. You may also, if you so wish, outsource the execution of the research plan to an operator providing clinical research services
- After receiving your research plan, we select the researcher in charge of the research and assist in applying for a research permit and ethical review. Patients are recruited and the study is conducted at HUS according to the study plan. The responsible researcher is always either a doctor or a dentist. In conducting clinical device trials, we comply with the law and the provisions of the authorities. We will notify Fimea of a clinical device study before starting the study

Deliverable: Report as agreed in the research plan. Reporting of results may also involve scientific publications. This will be agreed upon separately

Please, note: An agreement is made with HYKS-instituutti Oy for the assignment. All externally funded research at HUS that involves HUS patients and / or resources is managed by the HYKS-instituutti Oy

USE OF PATIENT REGISTRY DATA IN PRODUCT DEVELOPMENT (REGISTRY RESEARCH)

Service Benefit:

- The company can test the software products it develops with genuine patient data
- Patient information is pseudonymous, meaning that personally identifiable information has been removed

Service description:

- For example, when developing models based on machine learning for image analytics, the algorithm is first given data asking it to make decisions based on that. After this, a different set of data is used to determine how well the model has learned
- Testing with real patient data is possible by applying for permission to use patient data (data permit). You will first ask the HUS information service if the data you need is available and then you will apply for a data permit at the HUS research service. Once the permit is granted, the data will be available for processing in HUS's secure data processing environment (HUS Acamedic)

Deliverable: Possibility to use patient registry data according to the data permit.

IN COLLABORATION WITH:

HEALTH CAPITAL HELSINKI

BUSINESS FINLAND

GE Healthcare

DISIOR

CleverHealth Network

Health Incubator HELSINKI

Aalto University

REACH OUT TO US

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