



Digital Health

Strategic and Transformation Area

Office Més Sant Pau

Hospital de la Santa Creu i Sant Pau

Digital Health Unit



Mission

To facilitate and promote the digital and innovative transformation of health services in the Hospital and the healthcare environment, with the aim of:

- Facilitating the care work of health care personnel
- Improving the quality, accessibility and sustainability of services to the public
- Generating evidence for adoption



Vision

To become a **reference unit for the promotion of digital health** in the hospital environment and the clinical validation of digital health solutions:

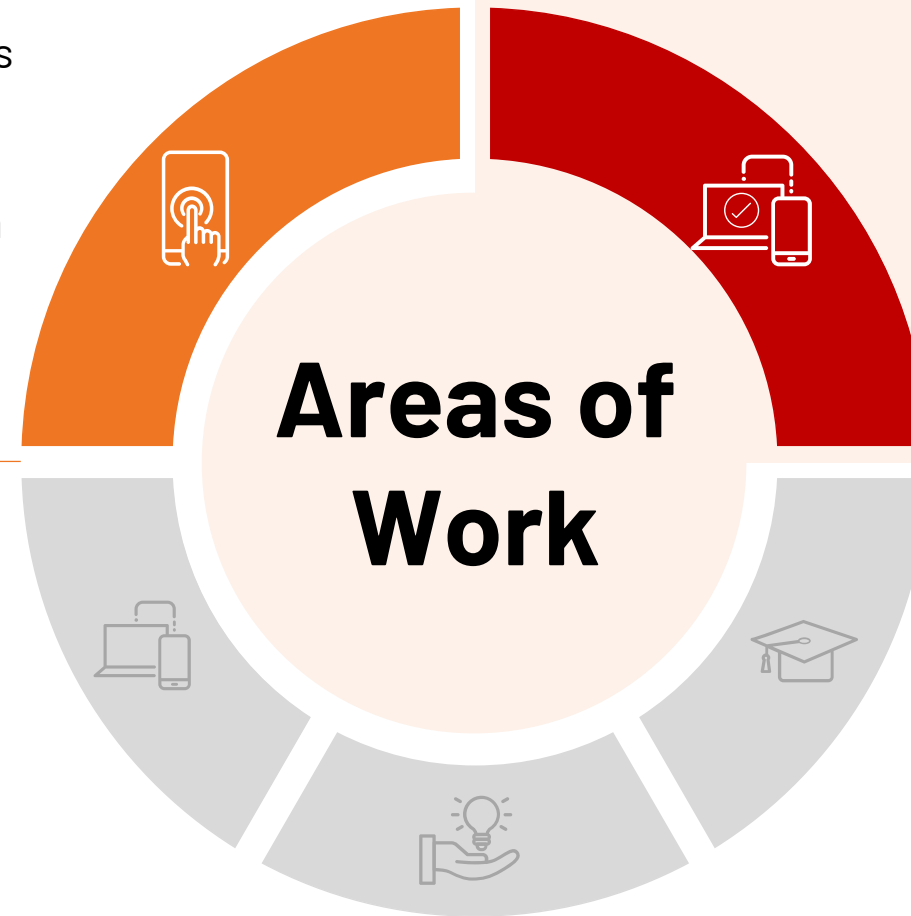
- At an internal level in the hospital
- At a national and international level in the digital health ecosystem (health administrations, suppliers, research centres, companies, universities, etc.).

PROMOTION OF INNOVATIVE DIGITAL HEALTH SOLUTIONS

- Support to healthcare professionals
- Follow-up from ideas to implementation
- Collaboration with other services in the hospital (IT, legal, etc.)
- Alignment with the strategic plan

CLINICAL VALIDATION CENTER FOR DIGITAL HEALTH SOLUTIONS

- Clinical validation of digital solutions to generate evidence
- Market exploration and analysis towards adoption.



ADOPTION OF DIGITAL SOLUTIONS

- Technology transfer
- Security and quality
- Digital healthcare routes

TRAINING IN DIGITAL HEALTH

- Learning Campus Sant Pau
- Internal and external training
- Knowledge promotion
- Internships with universities

CO-CREATION OF VALUE

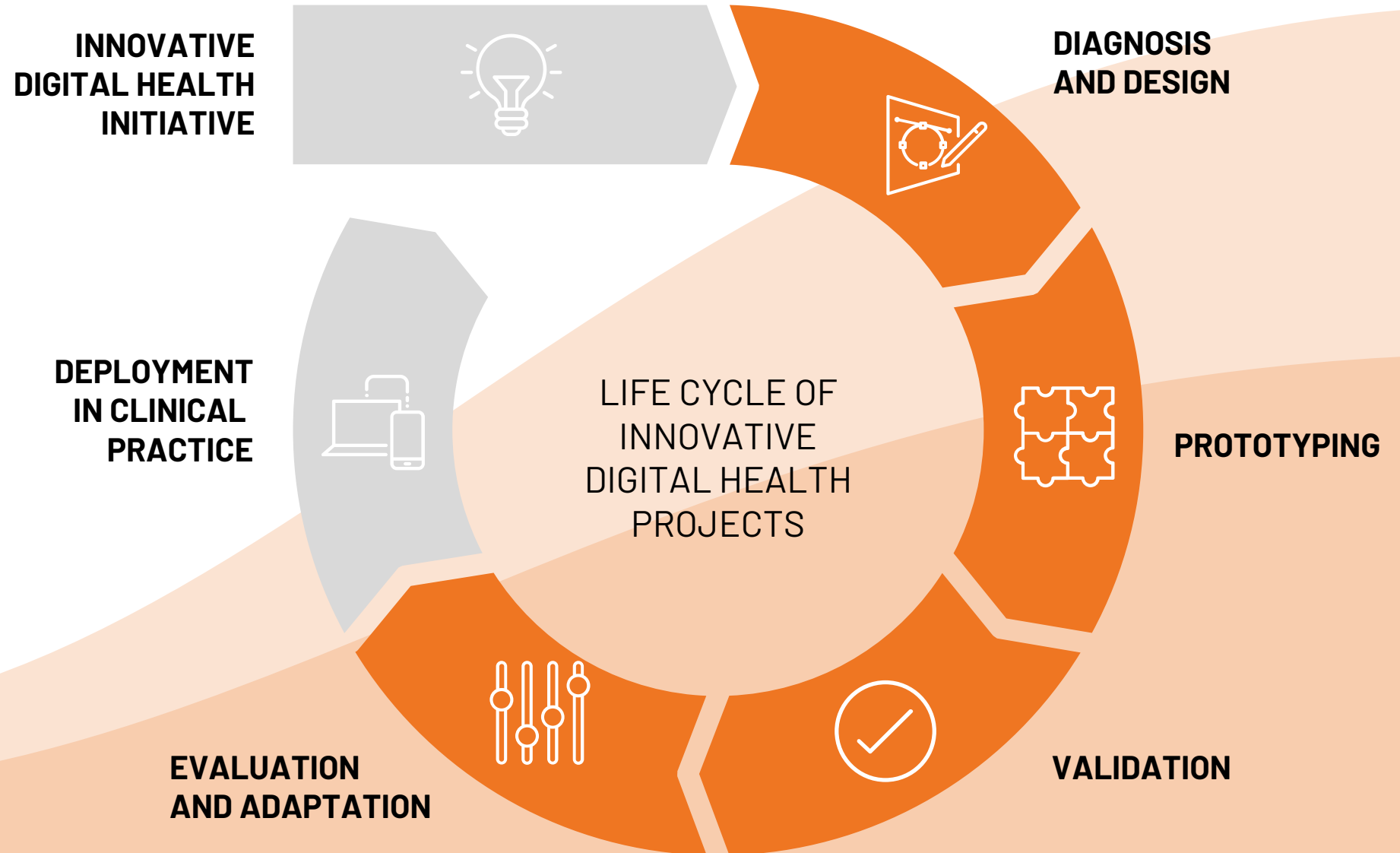
- Scientific production, IP and patents

How do we work?

SERVICES OFFERED

by the Unit:

- Direct support to healthcare professionals
- Collaboration with other areas and services



Digital Health Team



MAR GOMIS
Director

- **Specialist in clinical pharmacy and International Doctor of Medicine**
- Expert in coordination and implementation of digital health projects



JESÚS BERDÚN
Operations Coordinator

- **Telecommunications engineer**
- Expert in digital health with >10 years experience in health and social care



GERARDO ONTIVEROS
Information Systems Coordinator

- **Technical and functional expert in digital health environments**
- Systems analyst and interoperability expert
- Innovation projects in hospitals



LAURA MUÑOZ
Responsible for Statistics and Epidemiology

- **Graduate in statistics with >20 years experience** providing methodological support and data analysis
- Expert in health evaluation, clinical and epidemiological research



REBECA PELEGRÍN
Head of mHealth projects

- **Specialist in clinical pharmacy, experience in cardiology**
- Expert in people management and multidisciplinary projects



ANNA DE DIOS
Head of mHealth projects

- **Specialist in clinical pharmacy, experience in cardiology**
- Coordination of multi-disciplinary eHealth projects
- Expert in mobile health project management



BEA FERNÁNDEZ-MONTELLS
Support Projectes

- **Biomedical engineer focused on supporting users** in digital health
- Expert in data analysis, health processes and patient management

NURSE
Study Coordinator

- Expert in the care and needs of patients, families and carers
- Graduate in nursery and trained as a study coordinator to support digital innovation

MEDICAL WRITER

- Scientific production and generation of evidence
- Publication in relevant journals and congresses


Collaboration with other areas





Clinical Validation Center for Digital Health

Hospital de la Santa Creu i Sant Pau

A woman with blonde hair tied back is wearing a white VR headset with large circular speakers on the sides. She is looking upwards and to the right. The background is a futuristic, blue-toned environment with large, dark blue, angular shapes that resemble stylized letters or symbols. The overall lighting is cool and blue.

The **Clinical Validation Center for Digital Health** aims to ensure **feasibility, safety and clinical effectiveness** as well as to **promote adoption** of innovative health technologies proposed by companies and public entities in the health and social care sector.

Assessing the Clinical Robustness of Digital Health Startups: Cross-sectional Observational Analysis

Sean Day ¹, Veeraj Shah ^{1 2}, Sari Kaganoff ¹, Shannon Powelson ³, Simon C Mathews ⁴

Affiliations + expand

PMID: 35723914 PMCID: [PMC9253972](#) DOI: [10.2196/37677](#)

[Free PMC article](#)

Abstract

Background: The digital health sector has experienced rapid growth over the past decade. However, health care technology stakeholders lack a comprehensive understanding of clinical robustness and claims across the industry.

Objective: This analysis aimed to examine the clinical robustness and public claims made by digital health companies.

Methods: A cross-sectional observational analysis was conducted using company data from the Rock Health Digital Health Venture Funding Database, the US Food and Drug Administration, and the US National Library of Medicine. Companies were included if they sell products targeting the prevention, diagnosis, or treatment phases of the care continuum. Clinical robustness was defined using

“Clinical robustness”, defined as the sum of the number of regulatory filings and clinical trials.

From the 224 digital health companies with an average age of 7.7 years included in the study:

- 44% had a clinical robustness score of 0
- 20% had a clinical robustness score of 5 or more
- The average clinical robustness score for all companies was 2.5 (clinical trials: 1.8 and regulatory filings: 0.8)

Many digital health companies have a **low level of clinical robustness** and do not make many claims as measured by regulatory filings, clinical trials, and public data shared online.

Other clinical evaluation trends

MOBILE APPS ASSESSMENT

NATIONAL



Development guidelines and accreditation¹

- Usability and accessibility
- Technology
- Security
- Functionality and content



Guidelines and Health Apps Catalogue²

- Design
- Quality
- Safety
- Confidentiality



Catalog of Health Apps³

- Popularity
- Trust
- Utility

INTERNATIONAL

Germany's Digital health applications (DiGA)⁴

- Health apps and web applications available on prescription by professionals
- Requirements for quality of medical content, data protection, and effectiveness

CEN-ISO/TS 82304-2 quality label for health and wellness apps⁵

- Label2Enable EU Project
- Health and safety
- Easiness of use
- Security of data
- Robustness



¹ <https://ticsalutsocial.cat/en/projacte/mhealth/#>

² <https://www.fundacionisys.org/es/apps-de-salud/catalogo-de-apps>

³ <http://www.calidadappsalud.com/en/>

⁴ <https://gesund.bund.de/en/digital-health-applications-diga>

⁵ <https://label2enable.eu/news/testing-of-the-eu-certification-scheme-for-health-and-wellness-apps-is-underway-app-manufacturers-can-still-get-involved>

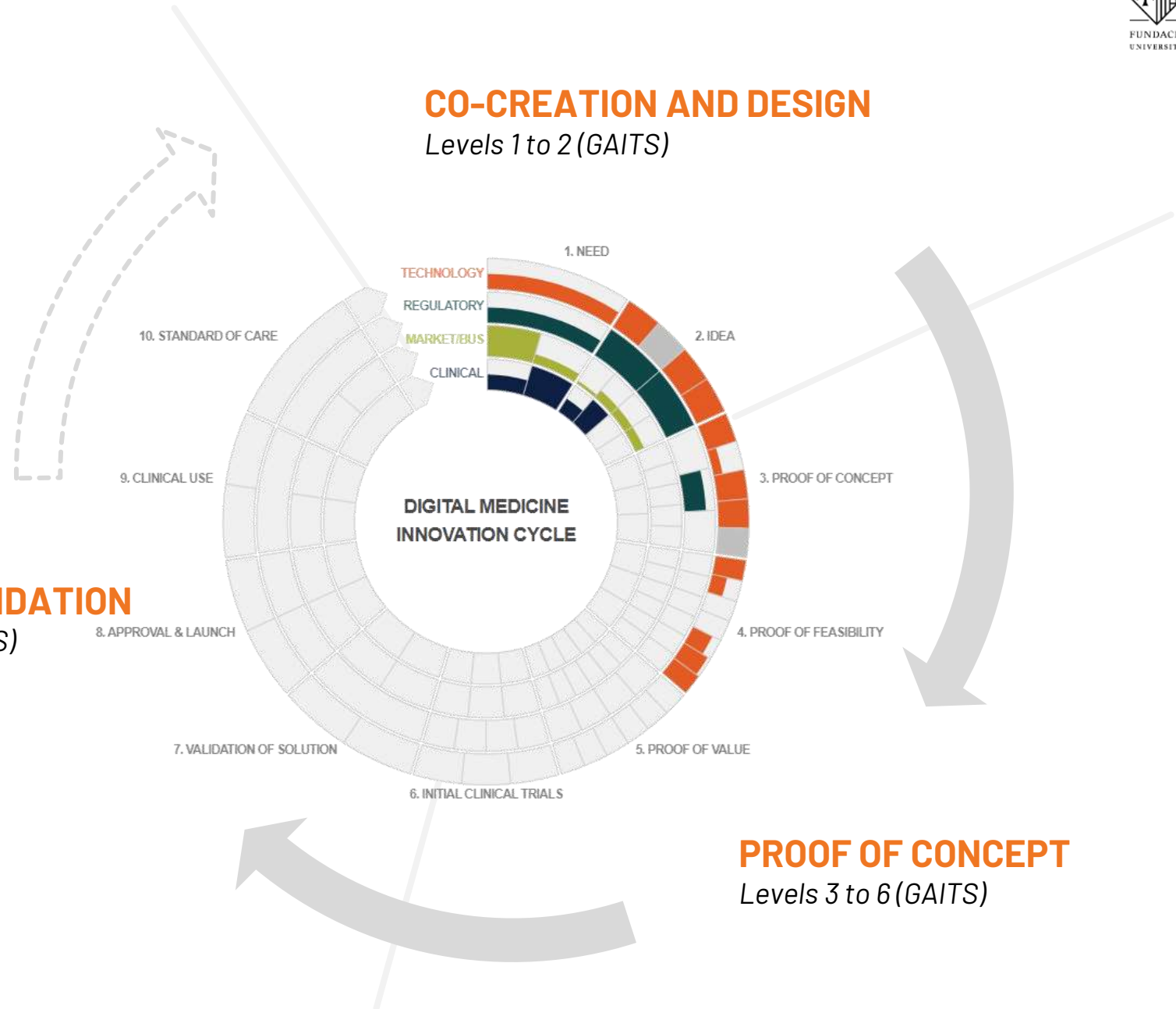
Innovation cycle in digital health

MATURITY ANALYSIS OF THE SOLUTION AND VALUE PROPOSITION

CLINICAL VALIDATION Levels 7 to 10 (GAITS)

CO-CREATION AND DESIGN Levels 1 to 2 (GAITS)

PROOF OF CONCEPT Levels 3 to 6 (GAITS)



What does the Center offer?

SERVICES

- **Personalized consultancy** in the field of digital health and definition of clinical protocols for validation
- **Agile methodologies** for clinical validation of technology
- **Quality standard** from Hospital de Sant Pau i la Santa Creu
- **Access to patients**, with a sample suitable for validation thanks to the hospital network
- **Assessment for requirements** on technology, ethics and regulation at national and European level
- **Dissemination of results** from clinical validation
- **Technology transfer analysis** in clinical practice

PRODUCTS



CO-CREATION, DESIGN AND
PROOF-OF-CONCEPT OF
DIGITAL HEALTH SOLUTIONS



ROADMAP FOR VALIDATION,
MATURITY AND
DEPLOYMENT OF DIGITAL
SOLUTIONS



CLINICAL VALIDATION OF
DIGITAL SOLUTIONS IN A
HEALTHCARE ENVIRONMENT

Validation Center Products



CO-CREATION, DESIGN AND PROOF OF CONCEPT

- PUBLIC-PRIVATE COLLABORATION activities
- Personalized consulting in the field of digital health
- Review of healthcare routes in a digital key and search for digital solutions
- Joint identification and analysis of needs in the health field
- Focus groups for the co-creation of innovative digital solutions
- Analysis of user experience and interfaces (UX/UI)
- Proof of concept and value of digital solutions in the hospital environment
- Advice on ethical aspects and regulation of sanitary device
- Intellectual property management

Validation Center Products



VALIDATION ROADMAP

- INITIAL COMMITMENT* from the hospital for validation.
- Design of the clinical protocol with the standard requirements required by the Ethics Committee
- Pre-evaluation by the CEICT and the CEIm* of the clinical protocol and review of ethical and legal aspects
- Analysis of functional and technical, organizational, technological, logistical requirements and other details necessary for the study
- Detailed budget of the items for the execution of the validation, including the activities and schedule
- Regulatory analysis for market access (optional)
- Valid documentation for other validations that the client wants to carry out in other centers

* Subject to a favorable result of Validation Roadmap

** CEIm, Comité Ético de la Investigación con Medicamentos;
CEICT, Subcomité Ético de Investigación Clínica y Tecnológica

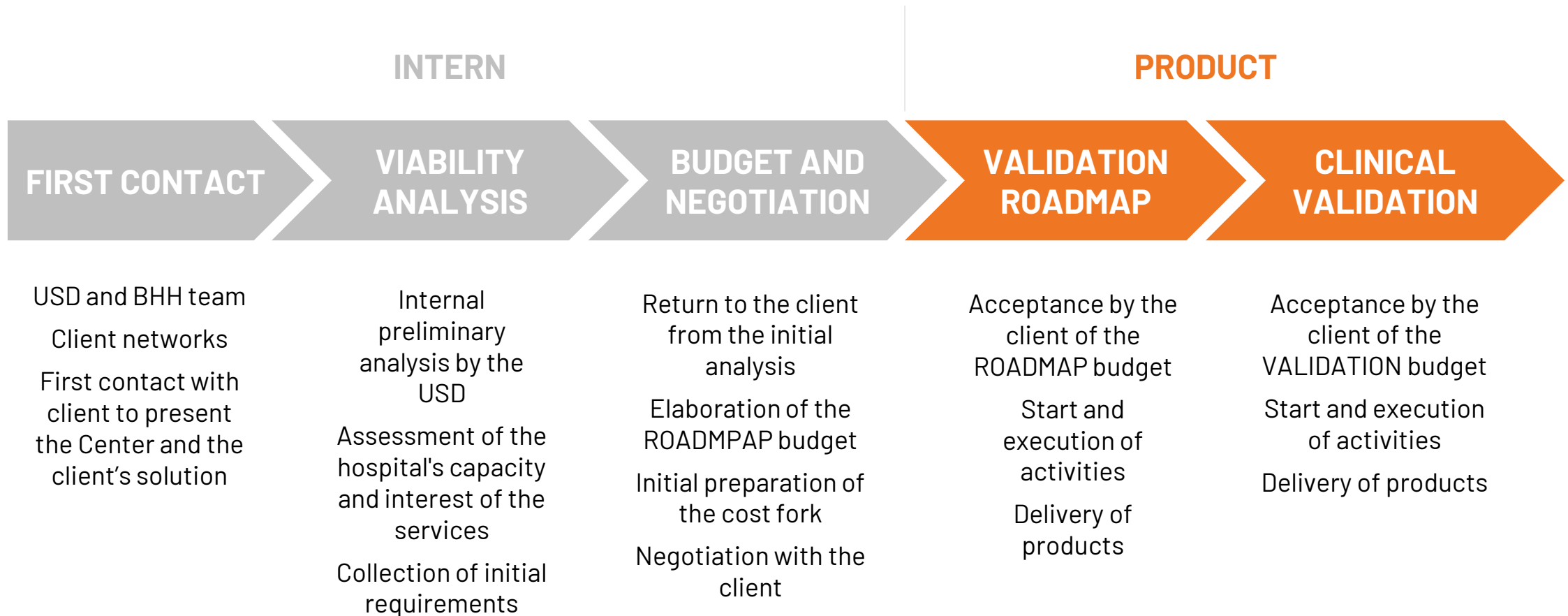
Validation Center Products



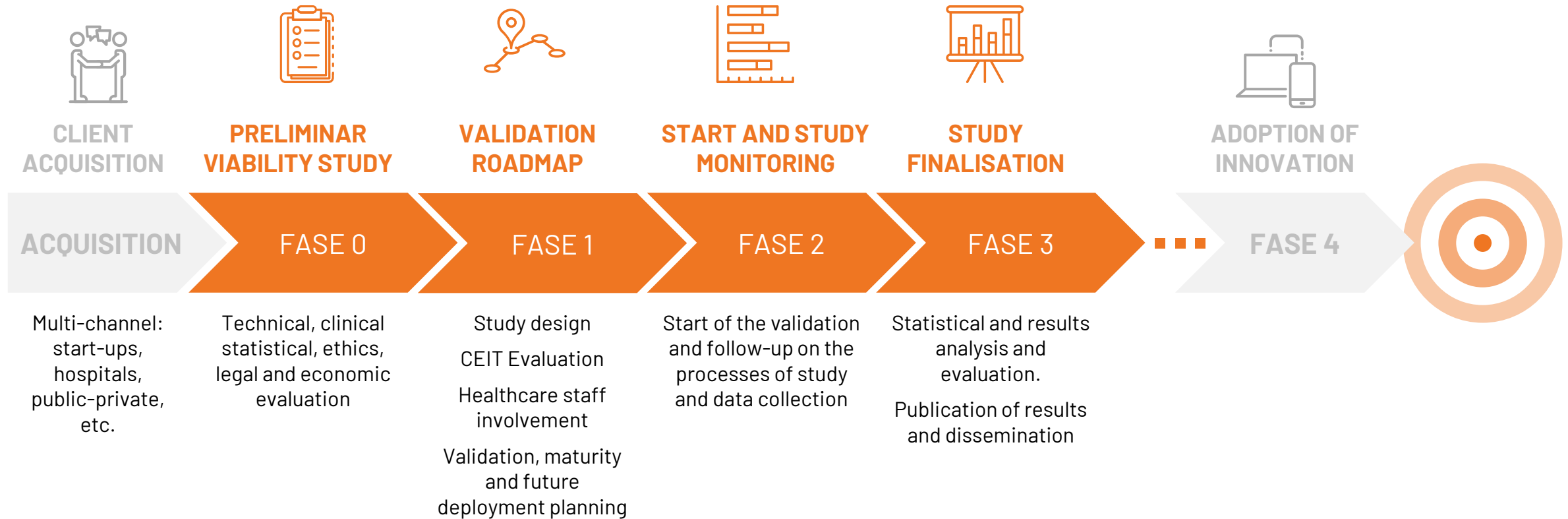
CLINICAL VALIDATION OF DIGITAL SOLUTIONS

- APPROVAL OF THE CLINICAL PROTOCOL BY THE CEIM
- Hospital validation preparation activities
- Deployment of new healthcare routes and integration of the digital solution
- Definition of inclusion/exclusion criteria and patient recruitment
- Execution of clinical validation activities, including monitoring of study procedures and data collection
- User experience and interfaces analysis (UX/UI)
- Statistical analysis and evaluation of results
- Publication of results and communication
- Assessment of the future adoption of the solution in the hospital

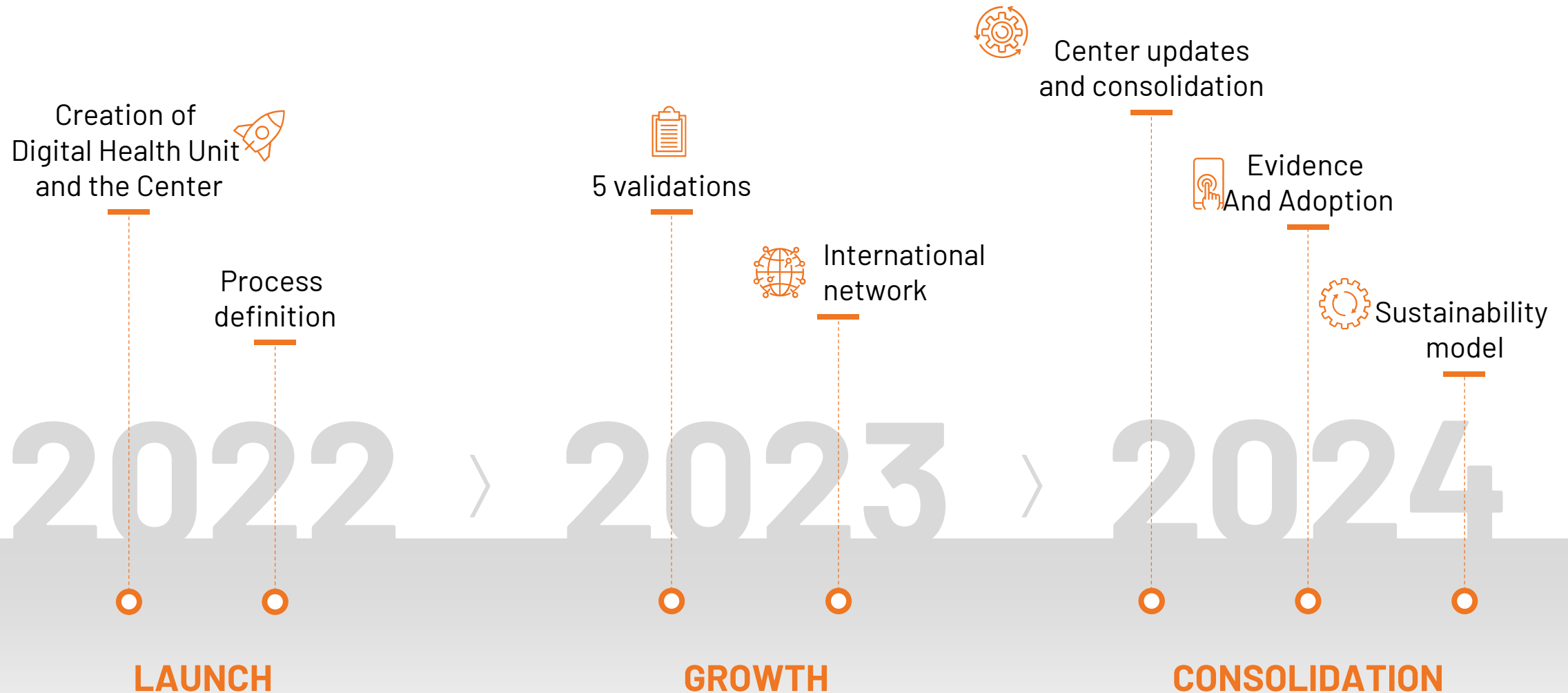
Customer Journey



Clinical validation process



Roadmap of the Center



What are the benefits for stakeholders?

FOR CITIZENS

- Access to quality and safe health technologies
- Health technology prescription validated in controlled environments
- Satisfaction with the assistance received thanks to the improvement of assistance routes



FOR COMPANIES

- Agile clinical validation with the Sant Pau quality standard, helping to reduce economic and time costs for product launch to market
- Access patients and professionals thanks to the hospital network
- Product showcase and analysis of adoption in the health sector



FOR THE HOSPITAL

- Cultural change and transformation of healthcare processes, impact on quality of care
- International benchmark in innovation transfer, access to technology through BHH and returns in publications and intellectual property
- International network for digital health transformation



Previous experiences in Digital Health

Hospital de la Santa Creu i Sant Pau

Digital health experiences



mHeart
Heart Transplant
follow-up

mHeart
Implementation
in clinical practice

EMMA Salud
Onco-haematology
patient monitoring
(stem cell transplant)

EMMA Salud
Breast Cancer

EMMA Salud
Colorectal cancer

*"Spanish coordination team
for mHealth deployment
(SEFH)"*

MyPlan
Chronic complex
Patient monitoring
(Heart Failure)

MyPlan
HIV, Migraine

OMOP
RWD, RWE

2016

2020

2022

2016

2019

2020

2020

2021

2021-22

2022

2023

**32 PROJECTS, MORE THAN 420 PATIENTS CURRENTLY INVOLVED,
WITH A TARGET POPULATION OF 10.350**

mHeart

IMPROVEMENT OF THERAPY MANAGEMENT AND CLINICAL CARE AFTER HEART TRANSPLANTATION

Level 9 (GAITS) - Clinical use

DESCRIPTION OF THE SOLUTION

- Web/App that connects a multidisciplinary healthcare team and heart transplant patients, integrated into the EHR
- It aims to **increase communication and information** received, and anticipated follow up based on the patient's registers empowerment

Main features:

- Therapy management
- Vital signs monitoring
- Symptoms registration
- PROMS and PREMS
- Asynchronous/synchronous communication



- Launch date: 2016
- Clinical practice: 2019
- Involved patients: 160

mHeart

IMPROVEMENT OF THERAPY MANAGEMENT AND CLINICAL CARE AFTER HEART TRANSPLANTATION

IMAGES OF THE SOLUTION

- Website for professionals
- Patient list with indicators in colours
- Activity measures
- Messaging
- Integration with EHR

The screenshot displays the mHeart professional interface. At the top, there is a navigation bar with the mHeart logo and several icons for 'Pacientes', 'Mensajes', 'Informes', 'Appds', 'Videoconferencia', 'Formación', and 'EHR'. Below this is a 'Lista de Pacientes' section with a search bar and a dropdown menu set to '10' pacientes. The main area contains a table of patients with columns for 'Nº historia', 'Nombre', 'Usuario', 'Fecha de alta', and 'Última actividad'. Each row includes a row of colored indicators (green, red, orange) and a trash icon. At the bottom, there is a pagination control showing 'Total: 11 pacientes' and 'Anterior 1 2 Siguiente'.

Nº historia	Nombre	Usuario	Fecha de alta	Última actividad	Indicadores	Acciones
5845845845845	Apple Developer	AppDev01	17/01/2018	05/02/2022	●	🗑️
1234	Gemma Ferrer Falcón	gemfer02	14/01/2019	20/01/2022	●	🗑️
1234	José Antonio Jarque	jarque03	11/01/2021	23/01/2021	●	🗑️
123457	LUIS PEVIDAL LOPEZ	LUPEV01	19/06/2018	11/09/2018	●	🗑️
000000000000	Mar Gomis Pastor	MarGom05	26/11/2018	01/02/2022	●	🗑️
342342234234234234	Martín Varela	MarVar05	27/11/2018	30/11/2021	●	🗑️
123321	Paciente Prueba	PacPru010	13/09/2018	13/09/2018	●	🗑️
12345678	Samuel Prueba	sampri01	20/01/2022	20/01/2022	●	🗑️
1232323	SARA IBAÑEZ GARCIA	SARIBA02	05/02/2020	04/03/2020	●	🗑️
HS-01234 PRUEBAS	TRILEMA PRUEBAS VICENTEPELLICER	TREPRU01	09/06/2018	12/02/2022	●	🗑️

mHeart

IMPROVEMENT OF THERAPY MANAGEMENT AND CLINICAL CARE AFTER HEART TRANSPLANTATION

IMAGES OF THE SOLUTION

- Mobile App for patients
- Agenda and reminders
- Follow-up on therapeutic accomplishment
- Drug administration indications
- PROMs and PREMs



MyPlan

IMPROVEMENT OF THERAPY MANAGEMENT AND CLINICAL CARE FROM HOME FOR CHRONIC COMPLEX POPULATIONS

Different Levels (GAITS) – From Needs to Clinical Trials



DESCRIPTION OF THE SOLUTION

- Multifunctional web/app platform for chronic complex patients

Main features :

- Therapy management
- Vital signs monitoring
- Exercise follow up
- Symptoms and adverse events registration
- PROMS and PREMS
- Asynchronous / Synchronous communication

▪ Exercise adherence in HF

- Launch date: AUG 2020
- Patients: 92
- Objective: improve exercise adherence

▪ HIV

- Launch date: APR 2021
- Patients: 31
- Objective: improve adherence

▪ Migraine

- Launch date: JAN 2022
- Patients: 52
- Objective: improve quality of life

▪ Endometriosis

- Launch date: PENDING
- Objective: reduce in-clinic visits and improve pain management

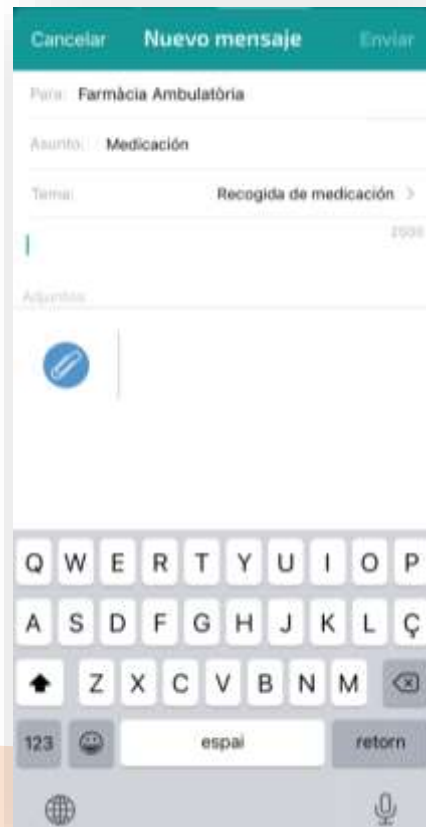
▪ Rheumatology

- Launch date: PENDING
- Objective: promote healthy lifestyle and exercise

MyPlan

IMPROVEMENT OF THERAPY MANAGEMENT AND CLINICAL CARE FROM HOME FOR CHRONIC COMPLEX POPULATIONS

IMAGES OF THE SOLUTION



EMMA Salud

IMPROVEMENT OF THERAPY MANAGEMENT AND CLINICAL CARE ONCO-HEMATHOLOGY PATIENTS

Level 7(GAITS) - Validation of Solution

DESCRIPTION OF THE SOLUTION

- Web/App that connects a multidisciplinary healthcare team and onco-hematology patients
- Aim: to increase the communication and information received, anticipated follow up and treatment adjustments based on the patient's registers and patients' empowerment regarding their health.

Main features :

- Therapy management
- Vital signs monitoring
- Exercise follow up
- Symptoms and adverse events registration
- PROMS and PREMS
- Asynchronous / Synchronous communication



▪ **Allogeneic stem cell transplant**

- Launch date: AUG 2020
- Patients: 28 (PILOT) + 22 (CT)
- Objective: reduction in hospital admissions and emergency department consultations

▪ **Breast Cancer**

- Launch date: APR 2021
- Patients: 40 (PILOT) + 69 (CT)
- Objective: implementation of a telematic psychosocial follow up

▪ **Colorectal Cancer**

- Launch date: JAN 2022
- Patients: 22
- Objective: pharmacogenetics and telemedicine Integration in the adverse events to chemotherapy follow up

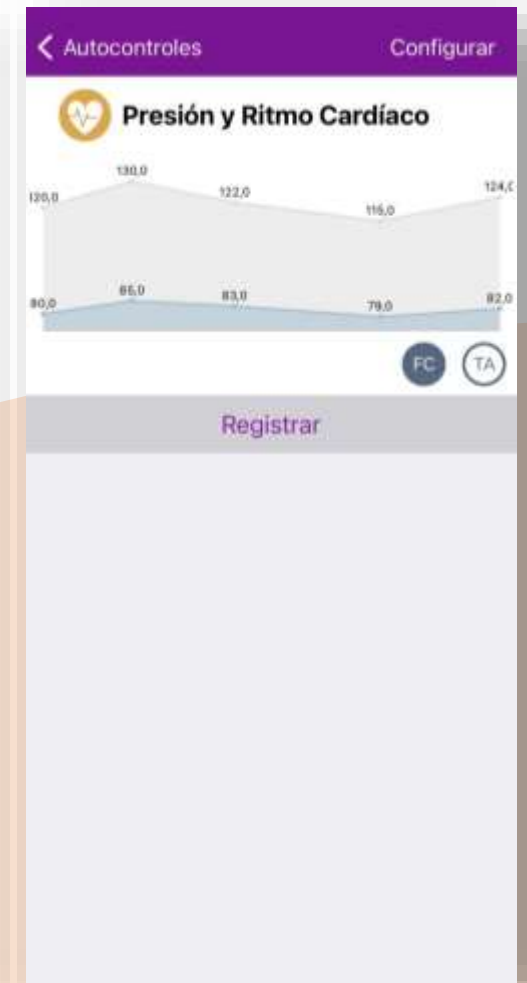
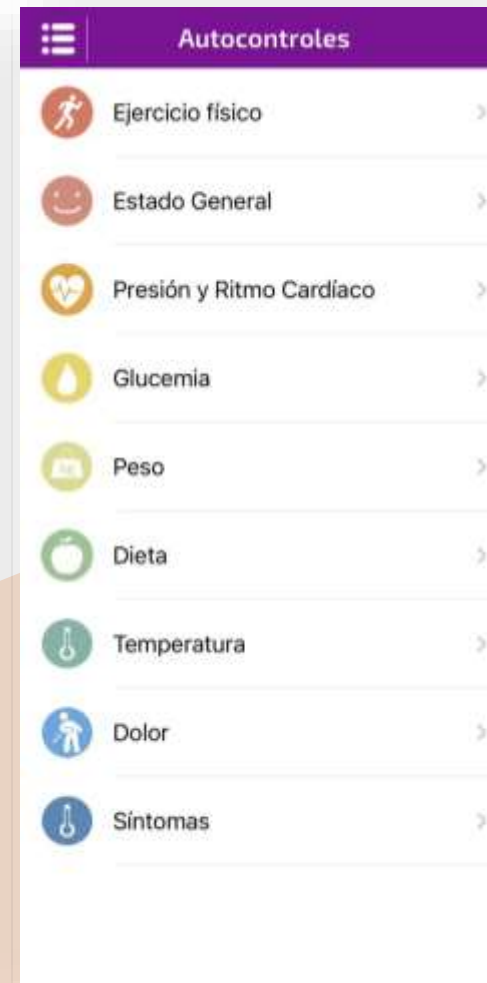
▪ **Myeloma**

- Launch date: PENDING
- Objective: improve patients' experience

EMMA Salud

IMPROVEMENT OF THERAPY MANAGEMENT AND CLINICAL CARE ONCO-HEMATHOLOGY PATIENTS

IMAGES OF THE SOLUTION



OMOP Common Data Model (CDM)

STANDARDIZED CLINICAL DATA DATABASE ORIENTED FOR RESEARCH WITH OBSERVATIONAL DATA

DESCRIPTION

- Create an OMOP Common Data Model (CMD) database for Sant Pau's researcher community, becoming one a Spanish EHDEN Data Partner.

Main features :

- Accommodates data from various sources, anonymized health data records
- Standardized way to represent data structure (CDM) and semantic content (standardized vocabularies)
- Real World Data (RWD) and Real World Evidence (RWE) research
- Structuration of unstructured data with technology based on Natural Language Processing (NLP)
- Availability of open source tools for OMOP: WhiteRabbit, Atlas, R packages

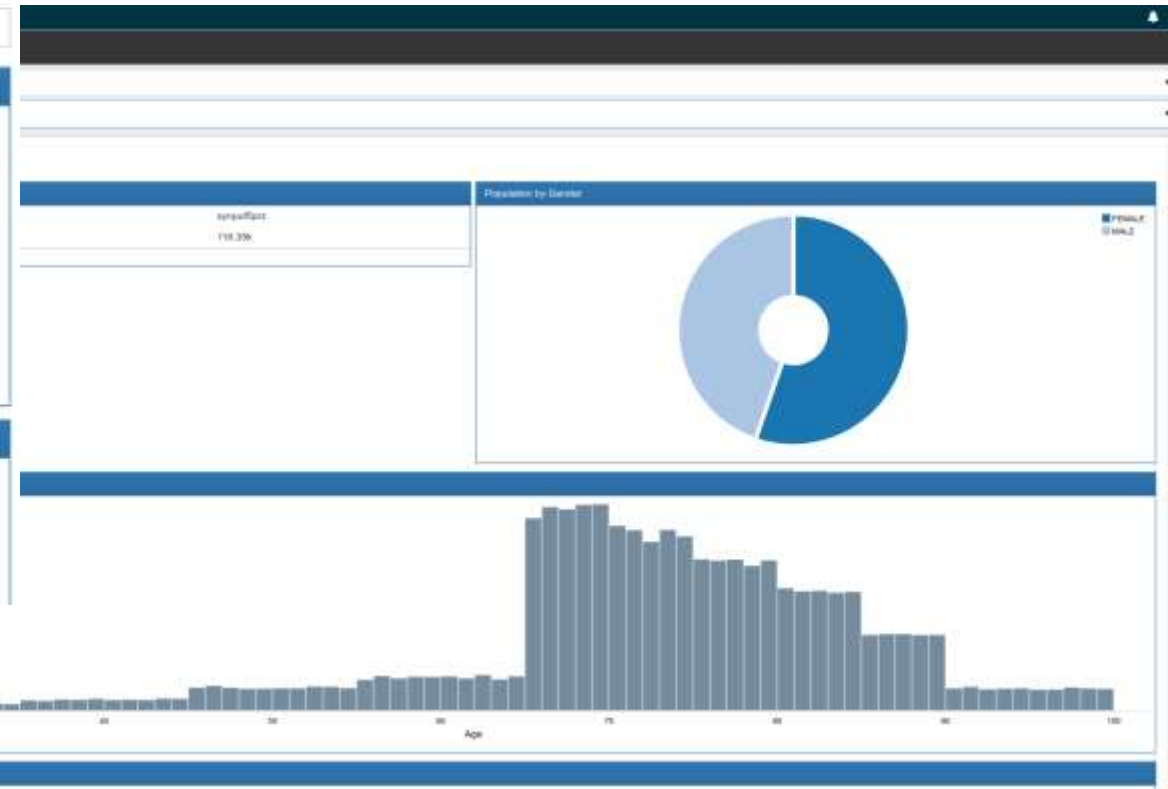


- OHDSI – Observational Health Data Sciences and Informatics
- EHDEN is the European partner of OHDSI and a network of data and clinical evidence supporting OMOP standard
- Horizon Europe coordinated by Erasmus Universitair Medisch Centrum of Rotterdam, Netherlands
- Implementation: 2022-2023
- Deployment: 2023
- Involved patients: full EMR

OMOP Common Data Model (CDM)

STANDARDIZED CLINICAL DATA DATABASE ORIENTED FOR RESEARCH WITH OBSERVATIONAL DATA

The screenshot shows the ATLAS software interface for defining a cohort. The left sidebar contains navigation options: Home, Data Sources, Search, Concept Sets, Cohort Definitions (selected), Characterizations, Cohort Pathways, Incidence Rates, Profiles, Estimation, Prediction, Jobs, Configuration, and Feedback. The main content area is titled 'Cohort #1770710' and shows the definition 'New users of ACE inhibitors as first-line monotherapy for hypertension'. Below this, there are tabs for Definition, Concept Sets, Generation, Reporting, Export, and Messages. The 'Definition' tab is active, showing a text input field for a description. The 'Cohort Entry Events' section includes a list of criteria: 'a drug exposure of ACE inhibitors for the first time in the person's history' and 'with continuous observation of at least 365 days before and 0 days after event index date'. The 'Inclusion Criteria' section lists two criteria: 'has hypertension diagnosis in 1 yr prior to treatment' and 'Has no prior antihypertensive drug exposures in medical history'. The bottom left corner features the Apache 2.0 logo and the OHDSI logo with the text 'open source software provided by OHDSI join the journey'.



Final take-aways



- **DIGITAL HEALTH IS NOT JUST ABOUT TECHNOLOGY!!!**
- Know your context (different dimensions: economic, socio-political, financial, technological, etc.)
- Organizational aspects are key, involve your workforce
- Digital Competencies of citizens and healthcare professionals
- Legal aspects and regulation
- Processes to generate evidence and plan adoption

Gràcies!

Unitat Salut Digital
Hospital de la Santa Creu i Sant Pau

