

# Interregional Coordination for a fast and deep uptake of Personalised Health - Regions4PerMed

## Report

### KEY AREA 4: INNOVATION FLOW IN THE HEALTHCARE

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PROJECT FULL TITLE	Interregional coordination for a fast and deep uptake of personalized health
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## Table of Contents

<b>1. ELIXIR as a model of research infrastructure .....</b>	<b>3</b>
<b>2. Fraunhofer IZI as applied research organization .....</b>	<b>4</b>
<b>3. Galician immunotherapy manufacturing center .....</b>	<b>5</b>
<b>4. MedeA Project .....</b>	<b>6</b>
<b>5. European Assistance For Innovation Procurement (EAFIP) .....</b>	<b>7</b>
<b>6. Código100 .....</b>	<b>8</b>
<b>7. Lombardy Cluster Technologies for Living Environments .....</b>	<b>10</b>
<b>8. Galician Network of Health Living Labs (LABSAÚDE) .....</b>	<b>12</b>

## 1. ELIXIR AS A MODEL OF RESEARCH INFRASTRUCTURE

Project   Initiative title		ELIXIR
Organization name		ELIXIR
Country		United Kingdom
Region		East-Cambridgeshire
Contact person		Gary Saunders
Contact email		gary.saunders@elixir-europe.org
Website		<a href="https://elixir-europe.org/about-us/who-we-are/hub">https://elixir-europe.org/about-us/who-we-are/hub</a>
Keywords		Genome, bioinformatics, interoperable standards, infrastructure for biological data, B1MG and European Joint program of rare diseases
Duration		Not limited
Area of application		Bioinformatics research infrastructure
DESCRIPTION	Main challenges tackled	Huge amounts of data have been produced during the last years, most research centers are not able to store or transfer this data or lack the expertise to analyze this data. ELIXIR provides a sustainable and interoperable federated infrastructure for the management of sensitive human data at regional, national and international level. Thus, researchers can use ELIXIR facilities to easily access, find, store, transfer and analyze the datasets that match with their needs.
	Objectives	ELIXIR main mission is to construct and operate in a single infrastructure for human genomics and translational data in Europe by a federated system. ELIXIR consists of ELIXIR Hub that coordinates the work across ELIXIR and ELIXIR Nodes which coordinates the work locally.
	Main concept and methodologies involved	ELIXIR is an intergovernmental organization that coordinates and develops life science resources for researchers across Europe. Through ELIXIR, researchers can access, store, transfer and analyze data by "compute platform" and "tools platform". ELIXIR also provides researchers standards by "interoperability platform" and linkages between data and literature by "data platform".
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative)	The main impacts of ELIXIR are related to different initiatives in genomic data resources: <ul style="list-style-type: none"> <li>• ELIXIR is part of the strategic partnership Global Alliance for Genomics &amp; Health (GA<sub>4</sub>GH), to simplify searching for and request access to potentially identifiable data in regional, national and international genomic data resources.</li> <li>• ELIXIR is the coordinator of Beyond One Million Genomes project (B1MG): Through its project, the ELSI toolkit was developed, which is a federated secure cross-border technical infrastructure and a B1MG maturity model for Personalised Medicine.</li> <li>• By-COVID project is a € 12 million Horizon Europe project for the identification of the data challenges to overcome for an effective pandemic response.</li> <li>• ELIXIR developed different programs to support researchers such as compute platform, data platform, interoperability platform, training platform or tools platform.</li> </ul>
	Funding and Investments (please specify the source: public, private, Structural or other types of funds)	The ELIXIR Hub and nodes compete together for grant funding under Horizon 2020 and the Innovative Medicine Initiative (IMI). Additionally, the ELIXIR Hub is funded through membership fees.
	Key stakeholders involved	Researchers, computer scientists, industry

## 2. FRAUNHOFER IZI AS APPLIED RESEARCH ORGANIZATION

Project   Initiative title		Fraunhofer Institute for Cell Therapy and Immunology (IZI)
Organisation name		The Fraunhofer-Gesellschaft (FhG)
Country		Germany
Region		Free State of Saxony
Contact person		Thomas Tradler
Contact email		thomas.tradler@izi.fraunhofer.de
Website:		<a href="https://www.izi.fraunhofer.de/en.html">https://www.izi.fraunhofer.de/en.html</a>
Keywords:		Research infrastructure, Cell and Gene Therapies, Clinical trials, Applied research
Duration:		Not limited
Area of application		Cell and Gene Therapy Research & Development Value Chain
DESCRIPTION	Main challenges tackled	To conduct Research and Development (R&D) activities in the field of biotechnology, pharmaceuticals, and medical engineering via research contracts for companies, hospitals, diagnostic laboratories and research institutes.
	Objectives	The Fraunhofer IZI investigates, develops, optimizes, and validates methods and solutions in four business fields: cell and gene therapy, drugs and vaccines for human and veterinary medicine, molecular diagnostics and immunodiagnostics focuses on the discovery and clinical validation of DNA and RNA as well as extracorporeal therapies.
	Main concept and methodologies involved	The Fraunhofer IZI is a professional service provider in the field of R&D. It performs research and capabilities as well as conducting and pursuing internal and joint (R&D) project in close collaboration with industry and academia. The cell and gene therapy strategy involves the entire value chain from early development through Good Manufacturing Practices (development and manufacturing) to clinical trials. The strategy of facilitating the innovation flow starts with applied research activities jointly with industry and academic partners to promote knowledge and innovation. The second step is the excellence research partnerships with international partners to develop innovative technologies and products and the part three of the strategy is the creation of spin-off companies and the support for establishing subsidiaries of international companies in Germany.
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative (max 200 words)	Thanks to the strategy of fostering the innovation flow, joint research and contract research projects (with companies such as Novartis, Daiichi-Sankyo); international research partnerships (with, i.e., McMaster University, Monash University); the creation of spin-off companies (Ribonomix GmbH, Bioville, or Epitepic); gain expertise and knowledge by supporting the establishment of international companies in Saxony (Bellaseno or Apocell) or formation of cluster for regional development (SaxoCell®) were possible.
	Funding and Investments (please specify the source: public, private, Structural or other types of funds)	In 2020, the budget of Fraunhofer IZI was € 37,9 million (48,3% from industry, 28,6% German national and regional government, 22,2% from other and 0,9% from EU). IZI partners were 179 industries and 172 from Academia in 2020.
	Key stakeholders involved	Industry, researchers, innovative centers

### 3. GALICIAN IMMUNOTHERAPY MANUFACTURING CENTER

Project   Initiative title		Galician Immunotherapy Manufacturing Center
Organisation name		Galician Health Service (SERGAS-GALARIA)
Country		Spain
Region		Galicia
Contact person		Mariona Baliu-Piqué
Contact email		Maria.Baliu.Pique@sergas.es
Website:		Not available: <a href="https://www.youtube.com/watch?v=2P2qNyAMGFg">https://www.youtube.com/watch?v=2P2qNyAMGFg</a>
Keywords:		Immunotherapies, clinical trials
Duration:		Not limited
Area of application		Cellular Immunotherapy Research Unit
DESCRIPTION	Main challenges tackled	The first steps for the creation of a centralized manufacturing center for cellular immunotherapies for Galicia.
	Objectives	To facilitate the access for Galician population to new therapies produced in this center.
	Main concept and methodologies involved	The Galician immunotherapy manufacturing center, the first center based in Galicia, which focus on clinical and research activities. It is based on the production of Advanced Therapy Medicinal Products (ATMP), promotion and development of new clinical trials. Its research activity is based on the mobilization of research projects, union of research groups and lines in competitive calls to boost the execution, testing and validation of new drugs at research level.
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative)	Establishment of a partnership among SERGAS, Hospital Clínic de Barcelona and IDIBAPS to produce new Chimeric Antigen Receptor T-cell (CAR-T) drugs for hematologic cancer treatment. Building-up the Cellular Immunotherapy Research Unit in Galicia.
	Funding and Investments (please specify the source: public, private, Structural or other types of funds)	The Galician immunotherapy manufacturing center was initially funded with more than € 3 Million (100% public nature).
	Key stakeholders involved	Clinicians, researchers, hospitals, universities, research foundations and institutes

#### 4. MEDEA PROJECT

Project   Initiative title		Clinical Implementation of an e-Health based Pharmacogenetics and Personalised Prescription System
Organisation name		Clinical Research Center of the Health Area of Badajoz of the Extremadura Health Service (SES)
Country		Spain
Region		Extremadura
Contact person		Adrián Llerena
Contact email		allerena@unex.es
Website:		<a href="https://www.proyectomedea.es/en/home/">https://www.proyectomedea.es/en/home/</a>
Keywords:		Genetic and genomic information, clinical data collection, e-health Drug prescription, Prevention and Intervention, clinical trials
Duration:		2017-2022
Area of application		Public procurement of innovation in pharmacogenetics and pharmacogenomics project
DESCRIPTION	Main challenges tackled	A health innovation program that looks forward the promotion of research, development and innovation in private companies for the development of personalised prescription system through the use of Public Procurement of Innovation (PPI). The first challenge for the companies, during the competitive call, is to develop a clinical decision support system with a clinical visualization supporting tool, named Personalised Oriented Prescription System (PoPS). The second challenge is the genotyping and the third challenge is the evaluation of the adverse drug reaction. The last challenge for the companies is to develop a tool for clinical trials.
	Objectives	In addition to encourage the private sector to develop and validate a personalised prescription program integrated in the electronic medical data record, MedeA also aims to generate an individualized selection strategy avoiding unnecessary risks and increase the effectiveness of the studies.
	Main concept and methodologies involved	Personalised Oriented Prescription System (PoPS) is based on three databases: genetic biomarkers, the drug-drug interactions and the electronic medical record data. Altogether will offer a screening and prevention model for adverse drug reactions (ADR)
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative)	At the end of MedeA project, there will be a personalised prescription system validated under real clinical conditions in the Extremadura Health System linked to the electronic prescription system. This will include the genetic information together with other relevant information for its use for patients in polytherapy and for prediction and prevention of Adverse Drug Reactions (ADR).
	Funding and Investments (please specify the source: public, private, Structural or other types of funds)	The budget of MedeA project is € 5,3 Million for integration of personalised prescription program in the electronic medical records.
	Key stakeholders involved	Patients, clinicians, pharmacists, medical personnel

## 5. EUROPEAN ASSISTANCE FOR INNOVATION PROCUREMENT (EAFIP)

Project   Initiative title		EAFIP Initiative
Organisation name		DG Connect of European Commission
Country		Belgium
Region		Brussels
Contact person		-
Contact email		<a href="https://eafip.eu/CONTACT/">HTTPS://EAFIP.EU/CONTACT/</a>
Website:		<a href="https://eafip.eu/">https://eafip.eu/</a>
Keywords:		Innovation, procurement, unmet needs, value-based healthcare, technology readiness level (TRL)
Duration:		Not limited
Area of application		Innovation procurement in healthcare sector
DESCRIPTION	Main challenges tackled	To promote good practices and reinforce the use of innovation procurements in different fields by following the same key strategic steps.
	Objectives	The objective of the AEFIP-initiative is to promote and support other public procurers to use Pre-commercial Procurement (PCP) and Public Procurement of innovation (PPI) and boost the digital-green economy recovery through Innovation Procurement tools (PCP & PPI).
	Main concept and methodologies involved	The whole cycle of innovation procurement starts with the curiosity driven research until the actual deployment of the solutions, sectors that are involved are procurers, healthcare professionals, researchers and industry. The full-blown application of EAFIP methodology encompasses 10 steps, being critical for the success of the operation, the first five preparatory steps including business case methodology before launching a procurement.
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative)	Thanks to this methodology, a knowledge-packed toolkit with 3 modules was created, EAFIP-methodology provided free of charge technical and legal assistance to public procurers in the development and implementation of innovation procurement tools. EAFIP has also organized a series of webinars and workshops to explain the EAFIP methodology for innovation procurement.
	Funding and Investments (please specify the source: public, private, Structural or other types of funds)	EAFIP initiative started in 2015 financed by EU Commission (DG Connect).
	Key stakeholders involved	Legal advisors, procurers, policymakers

## 6. CÓDIGO 100

Project   Initiative title		Código100
Organisation name		Galician Health Service (SERGAS), Galician Health Knowledge Agency (ACIS)
Country		Spain
Region		Galicia
Contact person		José María Romero Fidalgo
Contact email		<a href="mailto:codigo100@sergas.es">codigo100@sergas.es</a>
Website:		<a href="https://codigo100.sergas.es/">https://codigo100.sergas.es/</a>
Keywords:		Innovation, Public Procurement of Innovation Technology, Prototype, healthcare
Duration:		2016-2021
Area of application		Personalised Medicine, Public Health Services
DESCRIPTION	Main challenges tackled	Código100 is an innovation plan focused on ageing, one of the main priorities of the Autonomous Community of Galicia.
	Objectives	<p>Código100 aimed to obtain ideas from patients, professionals and companies in the sector. The ideas were grouped around the three main lines:</p> <ul style="list-style-type: none"> <li>- Patient empowerment: to strengthen the rights and capacities of citizens.</li> <li>- Therapies: to increase the Personalised Medicine in SERGAS by developments in biotechnology and the biomedical area.</li> <li>- Professional solutions: to increase and gain skills of clinical personnel, update the system and promote an innovative culture among professionals.</li> </ul> <p>Código100 promoted solutions that brought clear healthcare benefits within SERGAS as well as acted as a catalyst for innovation in the healthcare sector.</p>
	Main concept and methodologies involved	The first task of Código100 involved the implementation of a market survey stage to detect the needs required for each project. The information exchanged during this consultation stage was essential to address real healthcare challenges through technological solutions that had not currently existed.
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative)	<p>As a result of Código100, different products were developed and purchased by SERGAS, such as:</p> <ul style="list-style-type: none"> <li>- the SIPAD: a mobile APP for diabetes patients.</li> <li>- CADIA: a technology that applies artificial intelligence for image.</li> <li>- SHARE, which is a large platform containing all kind of multimedia content to provide patients clinical information. It analyses the patient profile and detects the main areas that patient is interested in obtaining information, creating personalised content for each patient.</li> <li>- e4Quant: a quantitative test of apolipoprotein E4 detection in human plasma designed by Biocross for prediction of Alzheimer disease progression.</li> <li>- PharmaHIC-ReTER Test by Healthincode: a Next Generation Sequencing for genetic biomarkers related to the response to biological drugs for rheumatology.</li> <li>- PQreader+Promonitor Test by Progenika Biopharma: an integrated point of care solution for quantitative monitoring of biological drugs and qualitative monitoring of anti-drug antibodies in human blood for rheumatology uses.</li> <li>- OMTX100 by Oncomatrix: a non-invasive diagnosis of solid tumor (colon and lung cancer) in blood exosomes using a novel combination of genes expressed in tumor epithelial cells and in tumor microenvironment cells.</li> </ul>



	<p>Funding and Investments (please specify the source: public, private, Structural or other types of funds)</p>	<p>Código100 was funded by € 13 million (80% from ERDF funding by collaboration with the Ministry of Science and Innovation).</p>
	<p>Key stakeholders involved</p>	<p>General practitioners, clinicians, researchers</p>

## 7. LOMBARDY CLUSTER TECHNOLOGIES FOR LIVING ENVIRONMENTS

Project   Initiative title		Lombardy Cluster Technologies for Living Environments
Organisation name		<b>TAV - TechForLife Cluster</b>
Country		Italy
Region		Lombardy
Contact person		Cristina De Capitani
Contact email		<a href="mailto:cristina.decapitani@polimi.it">cristina.decapitani@polimi.it</a>
Website:		<a href="https://duster.techforlife.it/">https://duster.techforlife.it/</a>
Keywords:		Technology, Healthcare, Innovation
Duration:		From 2013 to now
Area of application		Clinical developments
DESCRIPTION	Main challenges tackled	This network focuses on the management of chronicity and development of new innovative technologies to tackle the chronicity.
	Objectives	The Cluster was created with the aim of facilitating and supporting research, innovation and training in the Lombardy region by acting as a catalyst of multidisciplinary and multiprofessional skills and expertise. It also supports and facilitates the commercial development of the Cluster. In terms of personalised medicine, the Cluster of Technologies for Living Environment (Cluster TAV) focuses on the patient lifestyle, including nutrition and rehabilitation that affects the management of chronicity.
	Main concept and methodologies involved	<p><b>The Cluster TAV supports and promotes research, innovation and training in the development of technologies for the living environment, by a synergistic relationship between industry and research.</b></p> <p><b>To support the innovation process, the Cluster promotes collaboration and dialogue between partners and establishes a regulatory and institutional ecosystem that enables to start and participate in common projects on personalised medicine.</b></p>
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative)	<p>Thanks to this network, different services, enterprises, products and projects were developed, such as:</p> <ul style="list-style-type: none"> <li>- NIA developed by a clinical center from Lombardy Cluster, is a modular software medical device for telemonitoring and predictions for neurodegenerative diseases;</li> <li>- Math Biology is a start-up that develops a biosensor and artificial intelligence technologies to Deep Metabolism Assessment (DMA). DMA is a decision support system by non-invasive diagnosis for medical personnel.</li> <li>- Personalised upper limb rehabilitation is a product that combines physical rehabilitation with digital interface for clinicians.</li> <li>- Virtual supermarket is a tool that combines personalised physical and cognitive training for patients that suffered heart attacks and strokes.</li> </ul> <p>Or the SPATIALS3 project which objective is to create an integrated hub of research, development and innovation in the context of nutrition by developing functional food with nutritional needs of consumers based on four different pathologies.</p>

	Funding and Investments (please specify the source: public, private, Structural or other types of funds)	The <b>TAV - TechForLife Cluster is sustained by annual fees from TAV partners, participation as partners in different projects.</b>
	Key stakeholders involved	General practitioners, clinicians, researchers, patients, industry

## 8. GALICIAN NETWORK OF HEALTH LIVING LABS (LABSAÚDE)

Project   Initiative title		Galician Network of Health Living Labs (LABSAUDE)
Organisation name		University Hospital Complex of Ourense (CHUO), Galician Health Service (SERGAS), Galician Health Knowledge Agency (ACIS)
Country		Spain
Region		Galicia
Contact person		José María Romero Fidalgo
Contact email		labsaude@sergas.es
Website:		<a href="https://labsaude.sergas.es/">https://labsaude.sergas.es/</a>
Keywords:		Technology, Personalised Medicine
Duration:		From 2015 to now
Area of application		Personalised Medicine, personalised technologies, Public Health Services, open innovation, Technological Readiness Level (TRL) 7 or higher
DESCRIPTION	Main challenges tackled	Living Lab of Ourense is the first Living Lab from Galician Network of Health Living Labs (LABSAUDE) to provide an environment for patients, medical and health personnel, and biomedical companies to share knowledge and design, test and evaluate together innovative solutions with healthcare real needs.
	Objectives	<p>The <b>Galician Network of Health Living Labs - LABSAÚDE</b>, is an initiative that will convert Galician Hospitals and health centers into authentic testing laboratories for new solutions, products or services related to health and thus create an ecosystem of multidisciplinary and multisectoral co-creation networks (health professionals, administration, patients and industry) focused on end users.</p> <p>The Living Lab of Ourense is the pilot project from LABSAÚDE. The aim of the network is to spread the creation of this type of end-user-tailored settings to the rest of the Galician hospitals.</p>
	Main concept and methodologies involved	<p>Thanks to the Living lab of Ourense, SERGAS is testing a real future situation in where patients suffer with two or more chronic diseases and need more socio-health care services, that situation is forecast for 2050 throughout Europe.</p> <p>Within this initiative, the solutions for healthy ageing that issue in Ourense will become an international benchmark.</p> <p>Different innovation lines are expected for Living Lab scenarios in the context of LABSAÚDE: elderly and/or chronic patients care, Patient empowerment; ICT/ Telemedicine and teleservice; Robotics and virtual reality; Impact of the environment in hospital stays; or Other (biosafety, new materials, nutrition...)</p>
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative)	<p>For example, the first Galician Living Lab from LABSAÚDE has therapy wards such as electro-stimulation room to prevent muscle atrophy in patients with severe stroke. Wards are also available for testing and evaluating solutions based on the use of new technologies, for example dynamic posturographer for rehabilitation after hip fractures. In total, there are 15 wards that enable to continuously test the experience of patients and check their response to innovative formulas to address ageing-diseases (i.e., respiratory rehabilitation in patients with exacerbated COPD).</p> <p>It also allows to develop and scale solutions as a spearhead towards the</p>

		market by public call for project selection.
	Funding and Investments (please specify the source: public, private, Structural or other types of funds)	The facilities of the Living Lab of Ourense were built by PPI-based project Hospital2050.
	Key stakeholders involved	Medical and healthcare professionals, biomedical companies, patients