EULAC PerMed

Clinical Trials Regulatory and Funding Information by EU-LAC PerMed

EULAC PerMed has been funded by the European Union´s Horizon 2020 Research and Innovation Programme under Grant Agreement (GA) Nº 825173

Table of contents

1. Introduction

This document, entitled "*Clinical Trials Regulatory and Funding Information by EU-LAC PerMed"*, aims to compile the information of the **EU-CELAC Virtual Helpdesk**, which has been hosted on the EULAC PerMed website. This tool aimed to provide information on regulatory and funding agencies regarding clinical trials in Latin America and Europe, and to facilitate the establishment of partnerships in clinical trials on personalised medicine across countries and regions.

This report is a step towards the accomplishment of the **EU-LAC PerMed Exploitation Plan**, prepared within the Work Package 6 (Communication and Dissemination). The main objective of this Exploitation Plan was to provide and explore actions that enable that the project's results and outputs will continue to be usable and available for future stakeholders identified withing the project: health professionals, scientists, policy-makers, general public and other stakeholders including pan-European infrastructures and Research Organisations.

This document will be organized into three main sections, each described below: regulatory requirements for clinical trials, information on funding agencies for clinical trials and mapping areas of interest in personalized medicine. Finally, there will be acknowledgments section.

1.1. Context

EU-LAC PerMed project - *Widening EU-CELAC policy and research cooperation in Personalised Medicine*- was launched in January 2019 and ended in December 2022. Funded by the Horizon 2020 Programme of the European Commission, it has been implemented by a bi-regional consortium of eleven organizations from ten countries (Spain, Germany, Brazil, Italy, Chile, France, Uruguay, Panama, Israel, and Argentina).

EU-LAC PerMed aimed to promote and raise awareness of Personalised Medicine, fostering dialogue and cooperation between EU and LAC (Latin American and Caribbean) countries in this field. Its main goal has been to integrate countries from the CELAC region into **ICPerMed** and its activities, as a means to widen the international scope of Personalised Medicine (PerMed) Research and Innovation (R&I) related policies, increasing and encouraging a worldwide implementation of PerMed approaches across the whole healthcare value chain.

The project has also worked towards facilitating the introduction of PerMed for the benefit of patients, citizens and society, with the ultimate goal of contributing to the United Nations (UN) Sustainable Development Goal nº 3, which is to "Ensure healthy lives and promote well-being for all at all ages".

2. Regulatory requirements for clinical trials

The following table includes, for nine countries, a brief description of the regulatory framework for clinical research, the main component authority to consult for clinical study authorization, the main authority to consult for marketing authorization and other regulatory bodies that must approve clinical studies.

Country	Brief description of the regulatory framework for clinical research	Main competent authority to consult for clinical study authorization	Main authority to consult for marketing authorization	Other regulatory bodies that must approve clinical studies
Argentina	Clinical research regulation is inscribed in several of legal provisions: ANMAT Disposition No. 969/97 on the Applicable Regime to the Clinical Studies for Medical Devices. ANMAT Disposition No. 6677/10 on Good Clinical Practices Regime for Clinical Pharmacological Studies. MH Resolution No. 1480/11 on Guidelines for Clinical Investigations on Human Beings.	Ethics Committee Enrique T. Segura IBYME-CONICET.	National Administration of Drugs, Foods and Medical Devices (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica-ANMAT).	National Register of Persons (Registro nacional de las personas - RENAPER). Approval of patient information sheets and consent forms by the National Authority for Data Protection. Independent ethics committees (Comités Independientes de Ética).
Brazil	Clinical regulation is composed of a broad series of laws, rules and	National Health Surveillance Agency (Agência Nacional de	National Health Surveillance Agency (Agência Nacional de Vigilância	Brazilian Registry of Clinical Trials (Registro Brasileiro de

	resolutions, and a compendium of these is produced and made publicly available by the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitaria - ANVISA).	Vigilância Sanitária – ANVISA).	Sanitária – ANVISA).	Ensaios Clínicos - ReBEC). National Research Ethics Committee (Comissão Nacional de Ética em Pesquisa - CONEP).
Chile	The principles and the overarching framework for clinical research in Chile are inscribed in the 20.120 Law on Scientific Research in Human Subjects, Their Genome and the Prohibition of Human Cloning and in the Technical Norm 57 – Regulation for the Execution of Clinical Trials that Utilize Pharmaceutical Products in Human Beings.	Public Health Institute (Instituto de Salud Pública).	Public Health Institute (Instituto de Salud Pública).	National accredited scientific ethics committees (Comités de ética cientificos acreditados).
Costa Rica	The Regulatory Law on Biomedical Research defines the regulatory framework for clinical research in Costa Rica.	National Health Research Council (Consejo Nacional de Investigación en Salud - CONIS)	Ministry of Health (Ministerio de Salud).	Scientific Ethics Committees (Comités Éticos Científicos - CEC).
Italy	Authorisation of clinical trials is regulated by Legislative Decree	The competent authority for all clinical trials from Phases I to IV is the Italian	Italian Medicines Agency (Agenzia Italiana del Farmaco).	The National Observatory on Clinical Trials (OsSC) manages the authorisation

	211/2003, and its corresponding amendments. The Ministerial Decrees of May 12, 2006 and February 8, 2013 detail the requirements of ethics committees, while insurance requirements are set out in the Ministerial Decree of July 14 2009.	Medicines Agency (AIFA).		process of clinical trials (Phase I-IV) that are conducted in Italy, and provides a real time picture of the clinical research progress in the country. Clinical trials must be approved by validated ethics committees. The National Coordination Center for Ethical Territorial Committees coordinates, guides and monitors the evaluation activities of ethical aspects related to experimentations for clinical trials on medicinal products for human use and on medical devices, performed by the forty territorial ethics committees. Medical devices are regulated by the Ministry of Health Directorate General for Medicines and Medical Devices using the

				National Health Information System (NSIS).
Panama	Clinical research is regulated by Decree Law 84 of May 14, 2019, Decree 512 of June 28, 2019, and Ministerial Act 400 of June 7, 2021. These laws are enforced by the Ministry of Health, and all documents and procedures can be found here.	Ministry of Health (Ministerio de Salud).	Ministry of Health (Ministerio de Salud).	-
Peru	The Regulatioin for Clinical Trials for Peru is stipulated in the Supreme Decree N° 021-2017-SA.	National Institute of Health (Instituto Nacional de Salud).	Directorate General of Drug Supplies and Drugs (Dirección General de Medicaments Insumos y Drogas - DIGEMID).	Peruvian Clinical Trial Registry (Registro Peruano de Ensayos Clinicos - REPEC).
Spain	Regulation for clinical trials in Spain is inscribed in the Royal Decree 1090/2015. Furthermore, the Law 14/2007 on Biomedical Research outlines other key principles to be applied to clinical research.	Spanish Agency for Medicines and Medicinal Products (Agencia Española del Medicamento y Productos Sanitarios - AEMPS).	Spanish Agency for Medicines and Medicinal Products (Agencia Española del Medicamento y Productos Sanitarios - AEMPS).	Ethics Committees accredited for drug research (Comités de Ética de la Investigación con medicamentos). Spanish Registry for Clinical Trials (Registro Español de Estudios Clínicos).
Uruguay	Research on human subjects, including clinical research is regulated by Decree 379/008 and Ministerial Ordinance 827/016.	Ministry of Public Health (Ministerio de Salud Pública).	Ministry of Public Health (Ministerio de Salud Pública).	Institutional ethics committees where the research will be undertaken, and in particular cases the National Ethics

	Furthermore, Decree 189/98 provides the national framework for the application of ICH GCP guidelines, and Decree 158/019 provides the framework for ethics committees overseeing research. All documents can be found here.			Commission for Research (Comisión Nacional de Ética en Investigación).

3. Information on funding agencies for clinical trials

The following table includes, for ten countries, information about the main national funding body for clinical research and other local funding bodies that can support PM research.

Country	Main national funding body for clinical research	Other local funding bodies that can support PM research
Argentina	National Agency for the Promotion of Research, Technological Development and Innovation (Agencia Nacional de Promoción de la Investigación, el Desarrollo Tecnológico y la Innovación - ANPCYT).	Garrahan Pediatric Hospital (Hospital Pediatrico Garrahan). National Cancer Institute (Instituto Nacional del Cáncer). National Council of Scientific and Technical Research (Consejo Nacional de Investigaciones Científicas y Técnicas). Sales Foundation (Fundación Sales). Susan Komen Foundation (Fundación Susan Komen). University of Buenos Aires (Universidad de Buenos Aires).

Brazil	Ministry of Health (Ministério da Saúde).	Foundation for the assistance of research of the State of Minas Gerais (Fundação de Amparo à Pesquisa do Estado de Minas Gerais - FAPEMIG). Foundation for the assistance of research of the State of Sao Paolo (Fundação de Amparo à Pesquisa do Estado de São Paulo - FAPESP). National Research Council (Conselho Nacional de Pesquisa – CNPq). State Foundations for Research (Fundaçaoes Estaduais de Amparo à Pesquisa).
Chile	National Agency for Research and Development (Agencia Nacional de Investigación y Desarrollo - ANID).	Corporation for the Promotion of Production (Corporación de Fomento a la Producción -CORFO).
Costa Rica	Research and Technological Innovation Fund (Fondo de Investigación e Innovación Tecnológica - FIIT)	National council for Scientific and Technological Research (Consejo Nacional para Investigaciones Científicas y Tecnológicas - CONICIT).
Germany	German Research Foundation (Deutsche Forschungsgemeinschaft - DFG).	Federal Ministry of Education and Research (Bundesministerium für Forschung und Bildung - BMBF). German Cancer Aid / Deutsche Krebshilfe (DKH).
Italy	Ministry of Health (Ministero della Salute).	AIRC Foundation for Cancer Research in Italy (Fondazione AIRC per la Ricerca sul Cancro - AIRC). Cariplo Foundation / Fondazione Cariplo. Lombardy Region (Regione Lombardia).
Panama	National Secretariat of Science, Technology and Innovation (Secretaría	-

	Nacional de Ciencia, Tecnología e Innovación).	
Perú	National Ministry of Health (Ministerio de Salud de la Nación).	Cayetano Heredia University (Universidad Cayetano Heredia). National Council for Science, Technology and Scientific Innovation (Consejo Nacional de Ciencia, Tecnología e Innovación Tecnológica - CONCYTEC). San Agustín de Arequipa National University (Universidad Nacional de San Agustín de Arequipa). San Marcos University (Universidad San Marcos).
Spain	National Health Institute Carlos III (Instituto de Salud Carlos III).	Ministry of Economic Affairs and Digital Transformation (Ministerio de Asuntos Económicos y Transformación Digital).
Uruguay	National Agency for Research and Innovation (Agencia Nacional de Investigación e Innovación - ANII).	Sectorial Commission for Scientific Research (Comisión Sectorial de Investigación Científica - CSIC).

Additionally, the following international organizations and programs that can fund Personalised Medicine Research in LAC and EU countries:

- European Commission.
- ERA PerMed.
- NIH.

4. Mapping areas of interest in Personalised Medicine

The findings of a dedicated survey have been summarized here, presenting the main areas of interest for collaborations in clinical trials in Personalised Medicine. The survey was carried out in December 2020, and was circulated to stakeholders, participants, and potential collaborators of the EULAC PerMed project.

A long version of the survey aimed at collecting information on areas of interest in research or ongoing projects related to Personalised Medicine, and a shorter version was focused on regulatory and funding information. A total of 28 participants answered the survey (26 for the long version, 2 for the short version). Most of the respondents were from Argentina and Brazil

(five from each country). In total, eight (30.8%) of the respondents were from Europe, with the majority of the participants being from Italy (three).

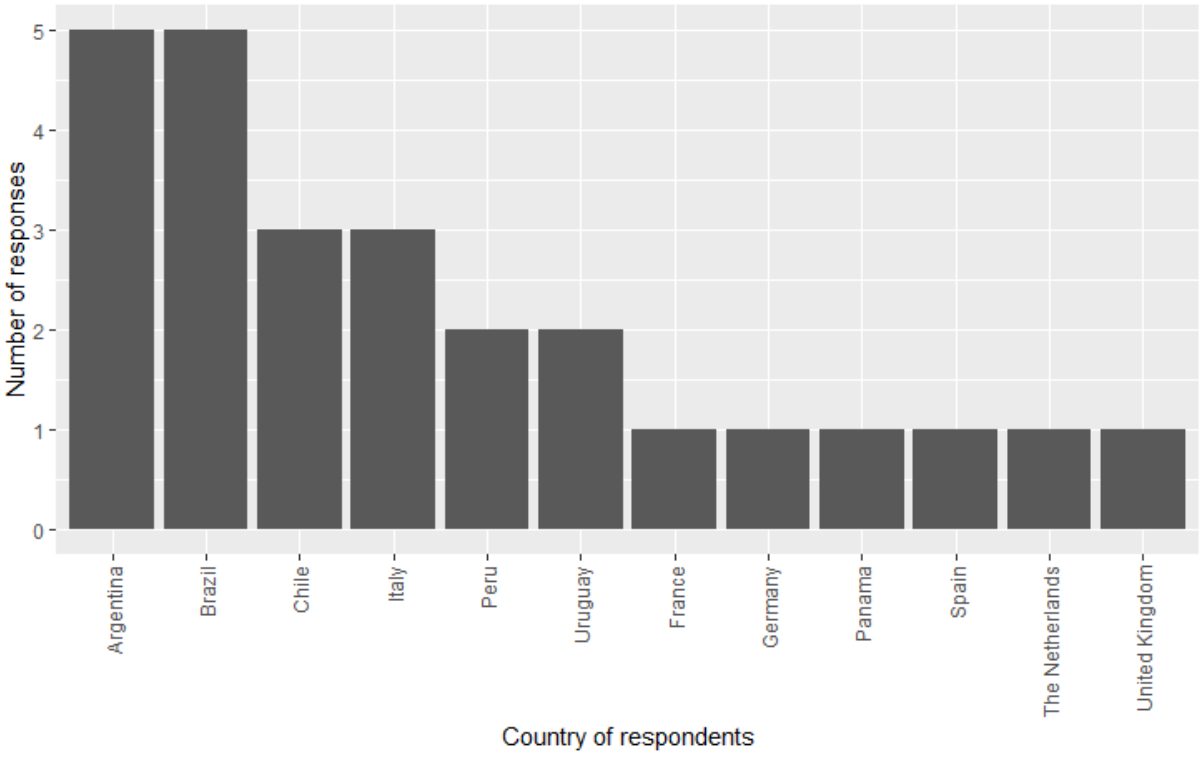

Figure 1. Countries of the survey's participants.

4.1. Areas of interest in personalized medicine research

We asked participants to list a maximum of five areas of interest in personalized medicine research, and five potential areas of collaboration in personalized medicine research. Since these were open questions, we generated word clouds to summarize the participants' responses using R's 'wordcloud' package. We analyzed responses for all participants, for respondents from Latin America and for those from Europe.

Based on our results, cancer, bioinformatics, genomics, machine learning, artificial intelligence, and health systems were prioritized by participants as areas of interest in personalized medicine research (Figure 2). Similar results were observed for participants from Latin America (Figure 3), whereas the areas of interest identified by participants from Europe were cancer, radiomics, bioinformatics, epidemiology, imaging, modelling, and machine learning (Figure 4).

Figure 2. Areas of interest in personalized medicine research, all participants

Figure 3. Areas of interest in personalized medicine research (participants from Latin America)

Figure 4. Areas of interest in personalized medicine research (participants from Europe).

4.2. Potential areas of collaboration between Latin America and Europe

When asked about potential areas of collaboration across regions, the areas most frequently mentioned were health data, cancer, genetics, machine learning, artificial intelligence, imaging, sequencing, and rare diseases (Figure 5). Responses from participants from Latin America identified similar potential areas of collaboration. Genomics, and analysis of genetic variants were also areas frequently identified by participants from this region (Figure 6). On the other hand, according to participants from Europe, potential areas of collaboration in personalized medicine were cancer, data analysis, medical imaging, and omics (Figure 7).

Figure 5. Potential areas of collaboration in personalized medicine research, all participants.

Figure 6. Potential areas of collaboration in personalized medicine research (participants from Latin America).

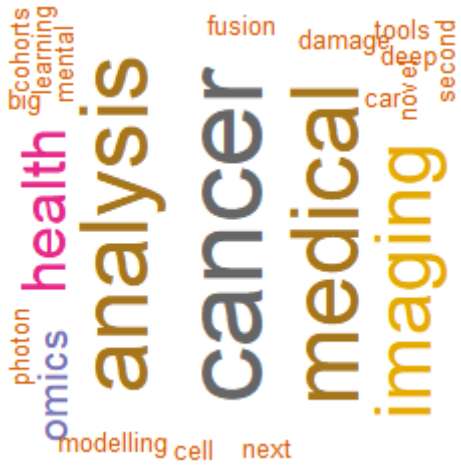

Figure 7. Potential areas of collaboration in personalized medicine research (participants from Europe)

5. Acknowledgements

Researchers from the following institutions contributed to this study:

- Bioinformatics and Genomics Laboratory, Department of Biological Chemistry, University of Buenos Aires (Argentina). http://www.qb.fcen.uba.ar.
- Bioinformatics Unit, Pasteur Institute of Montevideo (Uruguay), http://pasteur.uy/en/research/units/bioinformatic.
- Biomedical Imaging Group Rotterdam, University Medical Center Rotterdam (The Netherlands). https://bigr.nl.

- Bioscience Data Mining Group, CIDIE – UCC – CONICET (Argentina).
- Center for Genetics and Genomics, Institute of Science and Innovation in Medicine, Faculty of Medicine, German Clinic University of Development (Chile), https://medicina.udd.cl/icim.
- Center for Omics Sciences, San Raffaele Scientific Institute (Italy). https://research.hsr.it/en/centers/omics-sciences.html.
- Centre for Translational Bioinformatics at the William Harvey Research Institute, Queen Mary University of London (United Kingdom). https://www.qmul.ac.uk/c4tb.
- Clinical Genetics Section, Faculty of Medicine, University of the Republic (Uruguay), http://www.genetica.fmed.edu.uy.
- Computational Systems Biology Laboratory, University of Sao Paulo (Brazil). https://www.csbiology.org.
- Data Extreme Lab, National Laboratory of Scientific Computing (Brazil). http://dexl.lncc.br.
- Department of Health Informatics and Pathology Service, Italian Hospital of Buenos Aires (Argentina). https://www.hospitalitaliano.org.ar/#!/home/infomed/inicio.
- Department of Systems Engineering and Computer Science, CiTeSoft, National University of San Agustin of Arequipa (Perú), https://fips.unsa.edu.pe/departamento-academico-de-ing-de-sistemas-e-informatica.
- ETESA-UC Unit, Pontifical Catholic University of Chile (Chile), https://facultadmedicina.uc.cl/centros-y-programas/investigacion-clinica-uc/unidad-etesa-uc.
- Gonçalo Moniz Institute, FIOCRUZ. https://www.bahia.fiocruz.br.
- Health Research Directorate, Institute for Health Technology Assessment and Research – Social Security – ESSALUD (Peru), http://www.essalud.gob.pe/ietsi.
- Hormonal Carcinogenesis Laboratory, IBYME-CONICET (Argentina), https://www.ibyme.org.ar/laboratorios/15/carcinogenesis-hormonal.
- Institute of Medical Biometry and Informatics - Statistical Genetics Research Group , University of Heidelberg (Germany). https://www.klinikum.uni-heidelberg.de/en/medizinische-biometrie/forschung/arbeitsgruppen/statistical-genetics.
- Laboratory of Genetic and Molecular Analysis, University of Campinas (Brazil). https://lagm.cbmeg.unicamp.br/en/quemsomos.html.
- National School of Public Health, FIOCRUZ (Brazil). http://ensp.fiocruz.br.
- Research and Innovation Department, Sant Joan de Déu Health Park (Spain), https://www.irsjd.org/es/investigacion/investigacion-en-red.
- Research Group in Biotechnology, Bioinformatics and Systems Biology (GIBBS), Technological University of Panama (Panamá), http://biotecnologia.utp.ac.pa.
- Research Support Foundation of the State of Minas Gerais (Brazil), https://fapemig.br.

- Romagna Scientific Institute for the Study and Treatment of Tumors (Italy). https://www.irst.emr.it/it.
- Signal and Image Processing Laboratory, University of Rennes 1 (France). https://www.ltsi.univ-rennes1.fr.
- University of Concepcion (Chile), https://www.udec.cl.