

EULAC PERMED DISCUSSES ETHICAL, LEGAL AND SOCIAL ASPECTS RELATED TO PERSONALISED MEDICINE IN TWO IMPORTANT EVENTS

Madrid, 9 December 2020

Two important events were organised by **EULAC PerMed**, a European Project funded by Horizon 2020 Research and Innovation Program, which is working towards integrating Latin American and Caribbean (LAC) countries in the international consortium ICPeMed, in November:

- The **2nd EULAC PerMed Technical Workshop “Ethical, Legal and Social Aspects Related to Personalised Medicine”** on November 17-18, 2020
- The **3rd Virtual Summer School “Implementation Research in Personalized Medicine: Ethical, Legal and Social Aspects perspective”** on November 24-26, 2020

Both events dealt with the important issue of what Ethical, Legal and Social Aspects (ELSA) apply to Personalised Medicine (PM) research. Due to the COVID19 pandemic, both events took place as online virtual events, and this enabled greater participation, with people joining from both EU and LAC countries.

2nd EULAC PerMed Technical Workshop “Ethical, Legal and Social Aspects Related to Personalised Medicine”

On November 17 and 18th, 2020 the EULAC PerMed project hosted its second Technical Workshop, focusing on the Ethical, Legal and Social Aspects (ELSA) related to Personalised Medicine (PM). Co-organized by the Chief Scientist Office of the Ministry of Health of Israel and the Research and Development Agency of Chile (ANID), the workshop gathered participants from 13 nations to listen to 14 speakers from nine different countries. The co-organizers were widely supported by the ELSA Task Force, composed of 6 ELSA experts from Europe and the Latin America and Caribbean (LAC) region.

The objective of the workshop was to exchange insights on key ethical, legal and social issues in PM research and implementation in EU and LAC regions and to identify recommendations for future bi-regional collaborations in the field of PM. The attendees belonged to the research and clinical care community that directly works with PM in both regions, including investigators, PhD students, project managers, clinicians and paramedical personnel. The audience also included policy makers, representatives of ethics committees, and of funding bodies and other regulatory bodies who regulate PM research or policies on PM in the health systems.



Prior to the workshop, all participants received suggested pre-reading material, selected by the ELSA Task Force and the organizers. The workshop began with an introductory keynote speech that set the scene on the ELSA aspects of PM. The talks, divided into six sessions, then covered the following topics: informed consent and liability, privacy and confidentiality in clinical care, equal



access to personalised care, access to existing data research, how to translate PM from research to clinical care and the ELSA implications of this process, and the ethical, social and legal aspects related to multinational collaborations in clinical research. The ELSA Task Force members moderated each of the sessions, and chaired the active discussions.

The fourteen talks gave complementary perspectives from both the EU and the LAC regions, and presented the challenges of both the research and the clinical settings. This second aspect was highlighted as an area of interest for ELSA related to PM, as the lines dividing research and clinical care in the field of PM can often be blurred.

Following this workshop, a policy brief will be developed by the Task Force, focusing on the overarching principles to keep in mind when addressing the ELSA challenges of PM research, and providing recommendations for bi-regional and multinational PM cooperation. This brief will be accessible through the EULAC PerMed website, as well as selected slide sets and videos of the presentations made during the workshop.

3rd Virtual Summer School “Implementation Research in Personalized Medicine: Ethical, Legal and Social Aspects perspective”

The **3rd EULAC PerMed Summer School** was organized on November 24-26th, 2020 as a virtual training event. Organized by the Italian Ministry of Health with the support of APRE (the Agency for the Promotion of European Research) and the contribution of the EULAC PerMed Consortium, the summer school focused on the implementation of PM research in LAC countries, while emphasizing the ELSA perspective. Implementing PM research is one of the most important challenges for every health system, and including the ELSA perspective as a transversal task on this complex landscape is needed in order to achieve a successful implementation.

The summer school was designed to promote and facilitate interactions between speakers and participants. It also sought to assist in creating a research networking environment between EU & LAC countries and contribute to improving the multidisciplinary approach in the PM research field. To facilitate this interactions, multiple choice questions were launched during the talks both to understand the background knowledge of the participants and to assess the information that they learned.

A total of 75 people participated in the summer school, coming from different backgrounds: PM researchers, ethical researchers, members of ethical committees, healthcare workers, University of Ethics' professors and students, scientific officers and project managers from health funding institutions. The virtual format facilitated the participation of applicants from 19 countries (Argentina, Brazil, Chile, Colombia, Mexico, Panama Peru, Uruguay and Venezuela from LAC region) and 13 high level speakers from 11 different countries (geographical and gender balanced).

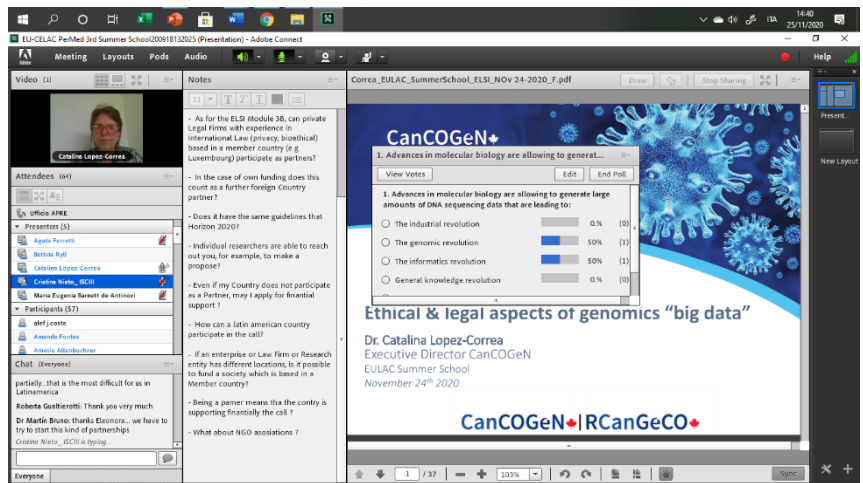
Throughout the sessions that took place during three days, different topics were presented and discussed. The first day started with a presentation of the LAC perspective on capacity, consent, and vulnerability of PM research, followed by an overview of the ethical issues concerned with genomic testing on children with rare diseases and a talk about the social and legal aspects of PM research in oncology. After a short break, talks focused on the applicability of the European regulations on data protection (GDPR) and finished off with the social and ethical aspects of Artificial Intelligence (AI), as AI has been one of the main areas contributing to the re-engineering of healthcare paradigms.

The second day-session began with a short introduction of the [ERA PerMed](#), a European initiative that funds cross-country collaborative research on PM, and that will launch a new call for proposals in 2021. It was followed by talks about Big Data and Genomics Data; the challenge and the necessity of sharing data; and ELSA issues to be considered for patient recruitment in PM clinical research. The day ended with a very interesting talk focused on the patient's perspective of PM.





During the last day-session, and after a short introduction of the [ICPerMed Recognition Best Practice Award](#), participants learned about ELSA and Health technology assessment, regulatory and policy aspects of PM implementation research and heard an interesting review of national m-health regulations in the LAC region. A practical case was discussed in three virtual rooms: ethical and legal challenges of CRISPR–Cas9 under the aspect of genetic engineering, clinical applications and gene therapy. Each group discussed the case under a different perspective, sharing the conclusions with the rest of the participants: R1: Scientifics and clinics; R2: patient and family associations and R3: governmental agencies and interdisciplinary policy institutes. As a final talk, a complete vision of the clinical research in LAC countries was given. As every Summer School, the day ended with a final test and a Quality survey, which were conducted online this time.



As a final remark, three issues were pointed out as key aspects to support the implementation of PM research: connecting countries healthcare reality with policy level, bringing together health and innovation policy and aligning international and national incentives and priorities.

This event will be accessible through the EULAC PerMed website, as well as selected slide sets and videos of the presentations made during the three days.

For more information on the workshop, the ELSA Task Force, the Summer School and access to all presentations and videos, please visit:

www.eulac-permed.eu

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