Virtual 3rd EULAC PerMed Summer School
"Implementing PM Research into practice: Ethical, Legal and Societal Aspects perspective "
24th- 26th November 2020

Remarks at Closing.

A personal view by Rafael De Andres Medina,

Chair of the Assembly of Member Countries, ECRIN-ERIC

Many thanks for the invitation, in particular to Dr Maria Jose Ruiz and the Deputy Director General Dr Gaetano Guguielmi and the other member of his team.

As you may have been informed already ICPerMed is the acronym for International Consortium on Personalized Medicine. It wants to be global and become a global actor whose aims are:

- To establish **ICPerMed members as global leaders** in **Personalised Medicine** research.
- To support the **Personalised Medicine Science base** through a coordinated approach to **research**.
- To support research to investigate **the potential benefits** of **Personalised Medicine** approaches to **citizens** and **healthcare** systems.
- To pave the way for **Personalised Medicine** approaches for **citizens**.

A critical action in paving the way is the ***ICPerMed Best Practice Recognition,*** that in 2021 has its fourth edition.

In order to tackle these challenges **ICPerMed has** developed a **Vision** of how the use of PerMed approaches and promote **a "next generation" Medicine in 2030,** more centred on the individual's personal characteristics, implying education and literacy, with increased effectiveness, economic value and equitable access for all citizens to the best possible healthcare.

The ICPerMed Vision 2030 Paper establishes 5 key visions:

Vision 1: “Informed, empowered, engaged and responsible citizens”.

Vision 2: “Informed, empowered, engaged and responsible health providers”.

Vision 3: “Health systems enabling personally tailored and valuable health promotion, prevention, diagnosis and treatment for the benefit of citizens and patients”.

Vision 4: “Availability of health-related information and data for valuable treatment, care, prevention and research”.

Vision 5: “Economic value by establishing the next generation of Medicine”.

In order to strengthen the global efforts on Personalized Medicine (PM) and the cooperation of the EU and LAC countries to them, a unique Bi-regional consortium of governmental and funding organisations is shaped with the support of leading stakeholders as associated partners: EULAC-PerMed, that is the acronym for “Widening EU-CELAC policy and research cooperation in Personalised Medicine” and has the ambition to engage LAC countries in the ICPerMed and in the ERANet

ERAPerMed as vehicle for funding project by competitive calls, with the aim at advancing in the implementation of the *Action Plan of ICPerMed* based in the *Strategic Research and Innovation Agenda (SRIA)*, drafted by *PerMed2020* and within the *Vision 2030 of ICPerMed*.

EULAC-PerMed should be a vehicle for:

i) Mapping existing programmes, capacities and expertise and gaps in LAC countries.
ii) Facilitating the incorporation of LAC countries in ICPerMed and in the ERAPerMed.
iii) Fostering the participation of LAC countries in research mobility and transnational projects on PerMed, and a platform for EU-LAC collaboration on clinical trials PerMed focused.
iv) Cross-border learning from R&I and ELSA for implementing innovations between research capacities based in EU and LAC regions.

Another key aspect of the birregional collaboration is the geostrategical importance of the “science diplomacy” and so EULAC-PerMed aims to provide support to the EU-LAC JIRI SOM (Joint Initiative on Research and Innovation on Health Senior Officials’ Meetings) regarding on PerMed and within it to contribute to strengthening the EU-CLAC Joint Initiative on Research and Innovation on Health (JIRI-Health).

Among Key Word at the purpose are*: Personalized Medicine, International, LAC, EU, Health Research Programming; Research Funding Organizations; -Omics, Prevention, Healthcare, Populations, Citizens, Patients.*

For the first time in Mankind this Open Data Access and data sharing is technically possible and should be effectively feasible. There are clear benefits for the progress of Research and our societies if well implemented but it should take into account since inception populations, citizens and patients.

It should be distinghished Open Access to Data and Access to Data with no charge at all. Also Data Sharing and Open Access to Data are not the same as this last one is a broader concept.

EU is promoting Open Science and the European Open Science Cloud (EOSC) with the requirement of Open Access to scientific data and to include in a Project proposal a Data Management Plan (DMP) and implement it after too. Complying with it is a requirent for receiving EU funding. And compliying with GDPR is mandatory too for everybody interacting with data from European citizens.

Research Performing Organizations (RPOs), researcers and Research funding agencies and ministries must be committed to it from now and after.

Technical and precedural Interoperability should be pursued and non technological barriers avoided and overcome. Cibersecurity should not be denied. What to do with data after a project´s end should not be avoided but be a “must”. Relibility must be a requirement. Data repositories and data bases should be reliable and cibersecurity secured. A repository or data base has data from partners out of the hosting institution and enven far from the country in which the hosting institution is legally registered. We all should be aware on the implications regarding repositoires and data bases in the cloud. This is matter of responsable Research behaviour and a duty to contruct trust by our populatations and citizens. Without trust it will be rather more difficult the cooperation of citizens, populations and rearchers.

Reengeneering of processes, institutions, and profesional roles are necessary because e-Health, m-Health are here already and will remain and with AI have deep implications in our lives and for our health care systems. The join effort of politics, policy makers, health care workers, populations, citizens and patients with mutual complicity is necessary.

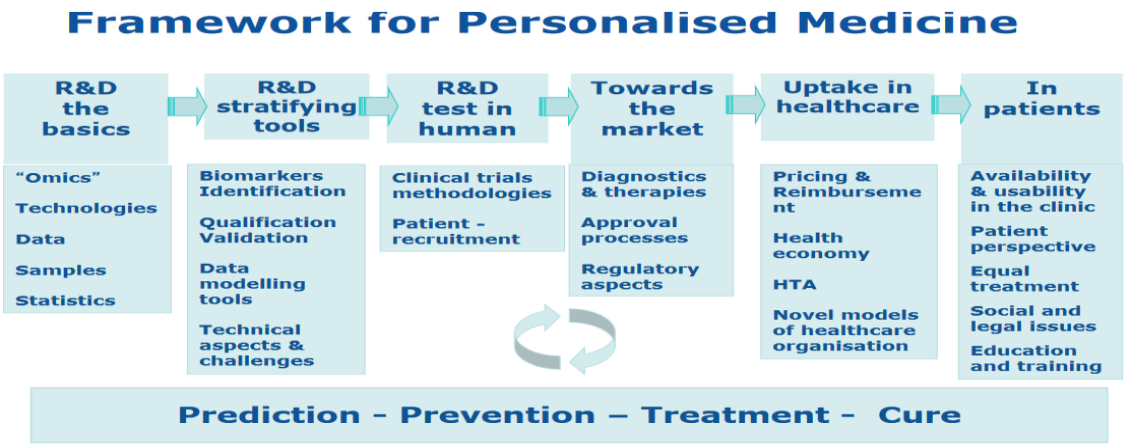
Health data and scientific data has not the same legal consideration and legal protection. Citizens and patients are the owner of their health data. It is also a matter at the core of our System of Freedom. Effective Informed consent and patients and citizens enpowerment is critial. Annonimization of data in effective manner to ensure personal privacy is an important issue.

At least there are four legal legal frameworks that matters in these issues: Roman-French, German, and sino asitic based one and based in the common law.

This 3rd Summer School is an action of EULAC-PerMed that is the acronym for “Widening EU-CELAC policy and research cooperation in Personalised Medicine”·

The issue is not if PM, Digital Health and AI will arrive or not to our societies and lifes but when and how - organized and equitable or in a caotic manner -. A key issue is to avoid the technological divide between inter and intra countries populations, and among patients and citizens that have efficient access to and those ones that do to have it and so.

The facilitation of the introduction of PM for the benefit of patients, citizens and society, also implies the ultimate goal of contributing to the UN Sustainable Development Goal nº 3,that is to "*Ensure healthy lives and promote well-being for all at all ages*".



Genomic and other 'omics' technologies generate a large amount of data. Analysing the consequences of the significant increase in health information that will be brought about by Personalized Medicine, this 3 days course has tried to provided practical information on how to manage related ethical, legal, and social aspects.
to address key issues in biomedical research involving human subjects, human biological samples and associated medical data: ethics, legal issues, privacy and data protection, data standardisation and the implementation of sample workflows in a clinical context.
In the future, there may hopefully be face to fase networking after the Covid-19 be controlled.

The effort will continued by the European Partnership PerMed. A call on this may be included in the draft of the work programme 2021-2022 of the Health cluster of Horizon Europe.

Coinception from the beginning. All of you are invited and be actors in the PM process.