



December 10th, 2021
Virtual meeting

XIV FORESIGHT TRAINING COURSE

*The health emergency: regulatory
crash and future perspectives*

Registration link:

<https://attendeegotowebinar.com/register/7652766274668351756>

Introduction

This past year we have witnessed unprecedented responses to the COVID-19 emergency that led the scientific community to an unparalleled mobilisation and sharing of information between researchers, companies, regulators, healthcare professionals, patient representatives and public health bodies. This resulted in the approval of several vaccines and medicines against this new disease to get the pandemic under control.

The **XIV Foresight Training Course** (FTC) *“The health emergency: regulatory crash and future perspectives”* will run virtually on December 10th, 2021 at 11:20 AM CET.

In particular, the first session of the event will be focused on the **extraordinary regulatory measures** put in place by the international and national authorities to face the emergency, the lessons learnt from the pandemic and their impact on future actions that might improve the healthcare system in Europe.

The European Medicines Agency (EMA) adapted its assessment procedures, by using the **rolling review process**, to achieve the authorisation of safe and effective treatments and vaccines for COVID-19 within the shortest possible time frame, as well as a **rapid scientific advice** procedure has been put in place.

In addition, **conditional marketing authorisations** have been granted by the European Commission (EC) to expedite the approval of treatments and vaccines, on the basis of available evidence as soon as it became available from ongoing studies.

Several challenges occurred in the clinical practice as well as in the conduct of **clinical trials** due to limitations in the access to healthcare facilities and trial staff availability. The [Guidance on the management of clinical trials during the COVID-19 pandemic](https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf)¹ has been published in February 2021.

In this framework the use of innovative **digital technologies**, such as Electronic Medical Records, Health Apps and other medical devices, collecting **health data** regularly, has been widely enhanced. This can support the management and monitoring not only of COVID-19 patients but also other diseases.

An insight on the value of the use and sharing of health data will be provided in the second and third sessions of the course.

What is left of all these changes? How will they influence the future?

Discover more by registering to the event [here](#)!

¹ https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf



AGENDA (CET time)

11:20 **Welcome and introductory remarks**

Adriana Ceci & Enrico Bosone

Session 1 – How the European regulatory framework reacted to the COVID-19 emergency: extraordinary and challenging measures

Viviana Giannuzzi

11:30 **Regulatory process and COVID-19 treatments: how to deal with the organisational and scientific challenges at the European Medicines Agency level?**

Fergus Sweeney, Clinical Studies and Manufacturing Task Force, European Medicines Agency

12:00 **Clinical research after the COVID-19 era: the current scenario and the upcoming application of the Clinical Trials Regulation**

Martine Dehlinger-Kremer, European CRO Federation - EUCROF & PRA Health Sciences

12:30 **Decentralized Clinical Trials: strengths and weaknesses of safety management**

Maria Grazia Felisi, Consorzio per Valutazioni Biologiche e Farmacologiche

13:00 **Strengthens and weakness of General Data Protection Regulation implementation for paediatric research**

Annagrazia Altavilla, Espace Ethique PACA-Corse/AP-HM

13:30 **Q&A session**

13:50 **Break**

Session 2 - Connecting and sharing health data: the repurposing approach

Chair - TBD

14:30 **The therapeutic value of drug repurposing and repositioning**

Oscar Della Pasqua, University College London

14:50 **Artificial Intelligence tool to predict drug efficacy and safety profile**

Aris Persidis, Biovista

15:10 **Data Space and Regulatory Decision making**

Ine Skottheim Rusten, The Norwegian Medicines Agency

15:30 **Health data collection and FAIRification**

Marco Roos, Leiden University Medical Centre

15:50 **Break**

Session 3 - The power of data sharing to enhance evidence for innovative treatments

Chair - TBD



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FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

- 16:00 **Federated learning as a tool for gathering knowledge from multiple data sources**
George Drosatos, Athena Research and Innovation Centre
- 16:20 **European Reference Networks and patients' registries initiative**
Maurizio Scarpa, European Reference Network for Hereditary Metabolic Disorders – MetabERN
- 16:40 **Collaborative platforms on haemoglobinopathies**
Fedele Bonifazi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus
- 17:00 **The Duchenne Data Platform**
Nawel van Lin, Center for Molecular and Biomolecular Informatics, Radboud Institute for Molecular Life Sciences, Radboud University Medical Center
- 17:20 **Collaborative networks against COVID-19: Lessons learned from LEOSS, NAPKON, ORCHESTRA**
Jörg Janne Vehreschild, University Hospital of Cologne
- 17:40 **Q&A session**
- 18:00 **Discussion and final remarks**
TBD