December 10th, 2021

Virtual meeting

XIV FORESIGHT TRAINING COURSE

The health emergency: regulatory crash and future perspectives

Registration link:

https://attendee.gotowebinar.com/register/7652766274668351756

FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

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 11:15 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*[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 session 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

The time zone is Central European Time (CET)

At the end of each speech, 5 minutes for Q&A are foreseen.

11:15 ***Welcome***
Fedele Bonifazi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

11:20 ***Introductory remarks***
Enrico Bosone, SIARV
Maurizia Dossena, Master in Regulatory Science "G.Benzi" (University of Pavia)

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

Chairs - Viviana Giannuzzi & Vincenzo Salvatore

11:30 **Regulatory process in the COVID-19 era: 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

11:50 **Clinical research after the COVID-19 era: the current scenario and the upcoming application of the Clinical Trials Regulation**
Martine Dehlinger-Kremer, ICON Plc & European CRO Federation (EUCROF)

12:10 **Impact on Small and Medium-sized Enterprises: the opportunity of decentralized Clinical Trials in rare diseases**
Stefano Portolano, Azafaros

12:30 **Decentralized Clinical Trials: strengths and weaknesses of safety management**
Maria Grazia Felisi, Consorzio per Valutazioni Biologiche e Farmacologiche

12:50 **Strengthens and weakness of General Data Protection Regulation implementation for paediatric research**
Annagrazia Altavilla, Espace Ethique PACA-Corse/AP-HM

13:10 ***Panel discussion***

13:20 ***Break***

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

Chairs – Fedele Bonifazi & Marek Migdal

14:00 **The therapeutic value of drug repurposing and repositioning**
Oscar Della Pasqua, University College London

14:20 **Data Space and Regulatory Decision making**
Ine Skottheim Rusten, The Norwegian Medicines Agency

14:40 **Artificial Intelligence tool to predict drug efficacy and safety profile**
Aris Persidis, Biovista

15:00 **Health data collection and FAIRification**
Marco Roos, Leiden University Medical Centre

15:20 ***Panel discussion***

15:30 ***Break***

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

Chairs – Enrico Bosone & Paola Baiardi

15:40 **Federated learning as a tool for gathering knowledge from multiple data sources**
George Drosatos, Athena Research and Innovation Centre

16:00 **European Reference Networks and patients' registries initiative**
Maurizio Scarpa, European Reference Network for Hereditary Metabolic Disorders – MetabERN

16:20 **FAIR in practice: The Duchenne Data Platform**
Nawel van Lin, World Duchenne Organization

16:40 **Real-World Evidence Data in a Drug Submission Process: the EMA vs. FDA perspective**
Luca Pani, University of Miami

17:00 ***Panel discussion***

17:10 **Collaborative networks against COVID-19: Lessons learned from LEOSS, NAPKON, ORCHESTRA**
Jörg Janne Vehreschild, University Hospital of Cologne

17:30 **Real use of real-world data**
Fedele Bonifazi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

17:50 ***Panel discussion***

18:00 ***Final remarks***
Adriana Ceci & Viviana Giannuzzi