23 October 2020

Virtual meeting

XIII FORESIGHT TRAINING COURSE

Challenges for Researchers and Regulators facing the pandemic crisis

Registration link: https://register.gotowebinar.com/register/6449358485818777872

FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

INTRODUCTION

The unprecedented **COVID-19 emergency** has had a huge impact on the whole society as well as on the prompt availability of effective medicines, questioning the Pharmaceutical System worldwide. The Coronavirus pandemic has also highlighted the need to revise some of the cornerstones of the **European Pharmaceutical System** and of the drug development process in order to properly meet patients' needs and ensure them timely access to medicines under all circumstances.

Annually, Fondazione Gianni Benzi organises the **Foresight Training Course** (FTC), a short international course aimed to promote pharmacological research and innovation. The pandemic has had an impact on our activities too, but we do not give up!

Therefore, this year, due to the restrictions enforced, the **XIII FTC "*Challenges for Researchers and Regulators facing the pandemic crisis*"** will run virtually and in a shorter version on **23 October 2020 at 09:30 AM (CEST)**. It will be focused on the proposed **European Union (EU) new strategy**, just launched, that aims to improve and accelerate patients' access to high-quality, safe and affordable medicines and to support further innovation in the European pharmaceutical industry.

The first session of the course will exactly address this new European strategy, giving way to the Health Authorities and Regulators as well as to different stakeholders involved in the announced revolution of the EU Pharmaceutical System.

Moreover, during the Course it will be discussed how the unexpected pandemic framework is encouraging and, sometimes, forcing the European Regulatory Pharmaceutical System to change to be more efficient and closer to the urgent patients' needs.

Experts from companies, healthcare professionals, researchers and patients' groups will share their contribution representing the key points to be discussed during the meeting.

Fondazione Benzi, that has always been actively committed in contributing to the regulatory debate, will gather all the considerations from stakeholders and will guide this process.

The EU pharmaceutical debate includes the proposal to revise two main EU Pharmaceutical System pillars: the **Orphan Medicines Regulation** and the **Paediatric Regulation**, that will be deeply considered in a dedicated window of the meeting in order to discuss possible improvement and administrative simplification without reducing their relevance for patients, companies and researchers.

Instructions to register and join the event:

Register for free to the course by clicking here. Feel free to share the link among your contacts. After the registration, you will receive a confirmation email from GoToWebinar system including a unique link to join that is strictly personal so please do not share it. You can dial in by phone using the phone numbers including in the confirmation email. Consult the useful guide for attendees for more information. Do not hesitate to contact us at: info@benzifoundation.org for any support.

AGENDA

23 October 2020

09:30 - 09:40 **Introductory remarks**
Fedele Bonifazi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

Session 1 - The European pharmaceutical system: strengths and weaknesses

Chair Adriana Ceci & Vincenzo Salvatore

09:40 - 10:00 **The new Pharmaceutical Strategy for Europe - Timely patient access to affordable medicines: key points and challenges**
Fabio D'Atri, DG SANTE - European Commission

10:00 - 10:20 **The increased value of the EC consultation to promote the new strategy**
Viviana Giannuzzi & Enrico Bosone on behalf of Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

10:20 - 10:40 **Company perspective**
Ansgar Hebborn, La Roche AG

10:40 - 11:00 **Patients' perspective**
François Houyez, EURORDIS

11:00 - 11:20 **Q&A session**

11:20 – 11:40 **Coffee Break**

Session 2 - The COVID-19 emergency accelerates research and development of new medicines and vaccines

Chair Cosimo Altomare & Fedele Bonifazi

11:40 - 12:00 **The EMA regulatory framework for timely approval of new and innovative drugs and vaccines in the pandemic era**
Marco Cavaleri, European Medicines Agency

12:00 - 12:20 **Company perspective**
Martin F. Ryser, Janssen-Cilag SpA

12:20 - 12:40 **Impact of COVID-19 on Clinical Trials. New approaches that can be taken for future trials**
Martine Dehlinger-Kremer, European CRO Federation - EUCROF & PRA Health Sciences

12:40 - 13:00 **Academia perspective**
Andrea Gambotto, University of Pittsburgh School of Medicine

13:00 - 13:10 **Q&A session**

13:10 - 14:00 **Break**

Session 3 – Special insights on pharmaceutical R&D plans and rules in the framework of the pharmaceutical system reform

Chair Fabio D'Atri & Paola Baiardi

14:00 - 14:30 **Orphan Regulation faced with changes in the EU pharmaceutical system**
Viviana Giannuzzi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

Discussant: Violeta Stoyanova-Beninska, Committee for Orphan Medicinal Products at EMA

14:30 - 15:00 **Strategic considerations regarding paediatric medicine development – Enpr-EMA reflections**
Pirkko Lepola, European Network of Paediatric Research at the European Medicines Agency

Discussant: Donato Bonifazi, European Paediatric Translational Research Infrastructure - EPTRI

15:00 - 15:30 **Research and innovation for new and advanced medicines: the role of Artificial Intelligence**
Francesca Mazzi, Queen Mary University of London

Discussant: Fedele Bonifazi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

15:30 - 16:00 **Ethical concerns and risks in health emergency: patients protection and fundamental rights**
Annagrazia Altavilla, Espace Ethique PACA-Corse/AP-HM

Discussant: Marek Migdal, The Children's Memorial Health Institute

16:00 - 16:20 **Discussion and final remarks**