FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO

XV Foresight Training Course

Boosting research and innovation in a changing regulatory framework

15-16 December 2022

Sala Leogrande, Ex Palazzo delle Poste – Bari, Italy

Introduction

The current scenario for clinical research is challenging. A new regulatory framework for clinical research in Europe is crucial to create a favourable environment for innovation and for development of high quality, safe and effective medicines in the interest of patients.

Starting from this premise, the XV Foresight Training Course "***Boosting research and innovation in a changing regulatory framework*",** will be run as a hybrid meeting on 15-16 December 2022 in Bari and online. The course aims to highlight the efforts made in Europe to **foster research and innovation** in a changing scientific, social and economic setting.

The session 1 of the course will be dedicated to the expectations of the new **Clinical Trials Regulation** and the **Accelerating Clinical Trials in the EU initiative**. The focus will be on how **innovative methodologies** are transforming the way to gather evidence in the pharmaceutical field.

During the session 2, an insight on the implementation of such methodologies, including complex trial designs, master protocols, adaptive designs, the use of Real-World Data and application of computational approaches, into all the phases of medicines discovery and development, will put the spotlight on the **paediatric and rare diseases research**.

The **Digital Revolution** will be the core of the session 3. During the session both challenges and opportunities of the application of innovative digital and in silico approaches to boost research will be addressed.

Relevant experts in the field, including representatives from the European Institutions, academia, companies and patients will provide their contribution to the discussion, aimed to gather the point of view of all the stakeholders involved in the medicine research & development process.

How these perspectives will be implemented to enhance the needed transformation?

Register for the event at the following link: https://forms.office.com/r/dDUtkAGZDh

The course is free of charge for students, researchers, representatives from patients' associations and not for profit organisations. A registration fee is foreseen for participants from for-profit organisations. Additional details at: https://bit.ly/3elz0eL

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AGENDA (CET time)

15 December 2022	
5:00 pm	***Introductory remarks*** Fedele Bonifazi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus Cosimo Altomare, Università degli studi di Bari Aldo Moro
Session 1 – The new course of clinical studies in Europe Chairs -	
5:15 pm	**The expectation of the European Clinical Trials Regulation**
5:35 pm	**Accelerating Clinical Trials in the EU (ACT EU) initiative** Lucia D'Apote, Amgen
5:55 pm	**Clinical trial design in the era of precision medicine**
6:15 pm	**How to implement innovative research methodologies in the EU regulatory framework in paediatric and adult studies** Viviana Giannuzzi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus
6:35 pm	**Panel discussion** Enrico Bosone, Società Italiana Attività Regolatorie, Accesso, Farmacovigilanza Donato Bonifazi, European Paediatric Translational Research Infrastructure Rima Nabbout, Paris Descartes University – European Joint Programme on Rare Diseases Paola Baiardi, FGB Scientific Committee, Istituti Clinici Maugeri François Houyez, European Organisation for Rare Diseases - EURORDIS
7:35 pm	***Q&A session & wrap up***
8:05 pm	***Dinner***

16 December 2022	
Session 2 – Innovative research methodologies Chairs –	
9:00 am	**Regulatory qualification of innovative methodologies** Flora Musuamba Tshinanu, EMA Modelling and Simulation Working Party, University of Namur
9:20 am	**Innovative research methodologies: the current approach in paediatric and orphan medicines** Lucia Ruggieri & Annalisa Landi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus
9:40 am	**INNOVATIVE methodologies to fill the gap in clinical trials in rare and very rare diseases** Rima Nabbout, Paris Descartes University – European Joint Programme on Rare Diseases

	Ralf-Dieter Hilgers, RWTH Aachen University – European Joint Programme on Rare Diseases
10:00 am	**Master Protocols Clinical Trial Designs** Franz König, Center for Medical Statistics, Informatics and Intelligent Systems, Medical University of Vienna
10:20 am	**The use of real-world data to improve treatment for rare disease patients** Violeta Stoyanova-Beninska, EMA Committee for Orphan Medicinal Products
10:40 am	**Evidence from real-world data implementing paediatric medicines approval** Carlo Giaquinto, Fondazione PENTA Onlus, conect4children network
11:00 am	***Break***
11:10 am	**Costs and benefits of novel research methodologies** Fedele Bonifazi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus Raffaele Lagravinese, Università degli Studi di Bari Aldo Moro
11:30 am	**Patients' expectations in a new research and innovation ecosystem** François Houyez, European Rare Diseases Organisation - EURORDIS
11:50	**Q&A session**

Session 3 - Implementation of Research and Innovation ecosystems: challenges and opportunities	
	Topic 1: Digital transformation to boost human research Chairs -
12:10 pm	**In-silico screening approaches to aid drug discovery and repurposing** Cosimo Altomare, Università degli Studi di Bari Aldo Moro
12:30 pm	**Implementing biological target- and cell/organism-based screening in drug development** Antonella Liantonio & Elena Conte, Università degli Studi di Bari Aldo Moro
12:50 pm	**Establishing the probability of pharmacological success** Oscar Della Pasqua, University College London
1:10 pm	**Q&A session**
1:30 pm	***Lunch***
	Topic 2: Access to innovation Chairs -
2:30 pm	**System biology and predictive models to develop innovative medicines** Giorgio Reggiardo, Consorzio per Valutazioni Biologiche e Farmacologiche
2:50 pm	**Global challenges and industrial competitiveness** Renato Dellamano, VALUEVECTOR S.r.l.
3:10 pm	**GREEN compounding and PHARMAceutical Repurposing for rare Diseases Innovation ecosystem a public-private initiative** Nunzio Denora, Università degli Studi di Bari Aldo Moro
3:30 pm	**Q&A session**

4:00 pm	***Final remarks*** FGB