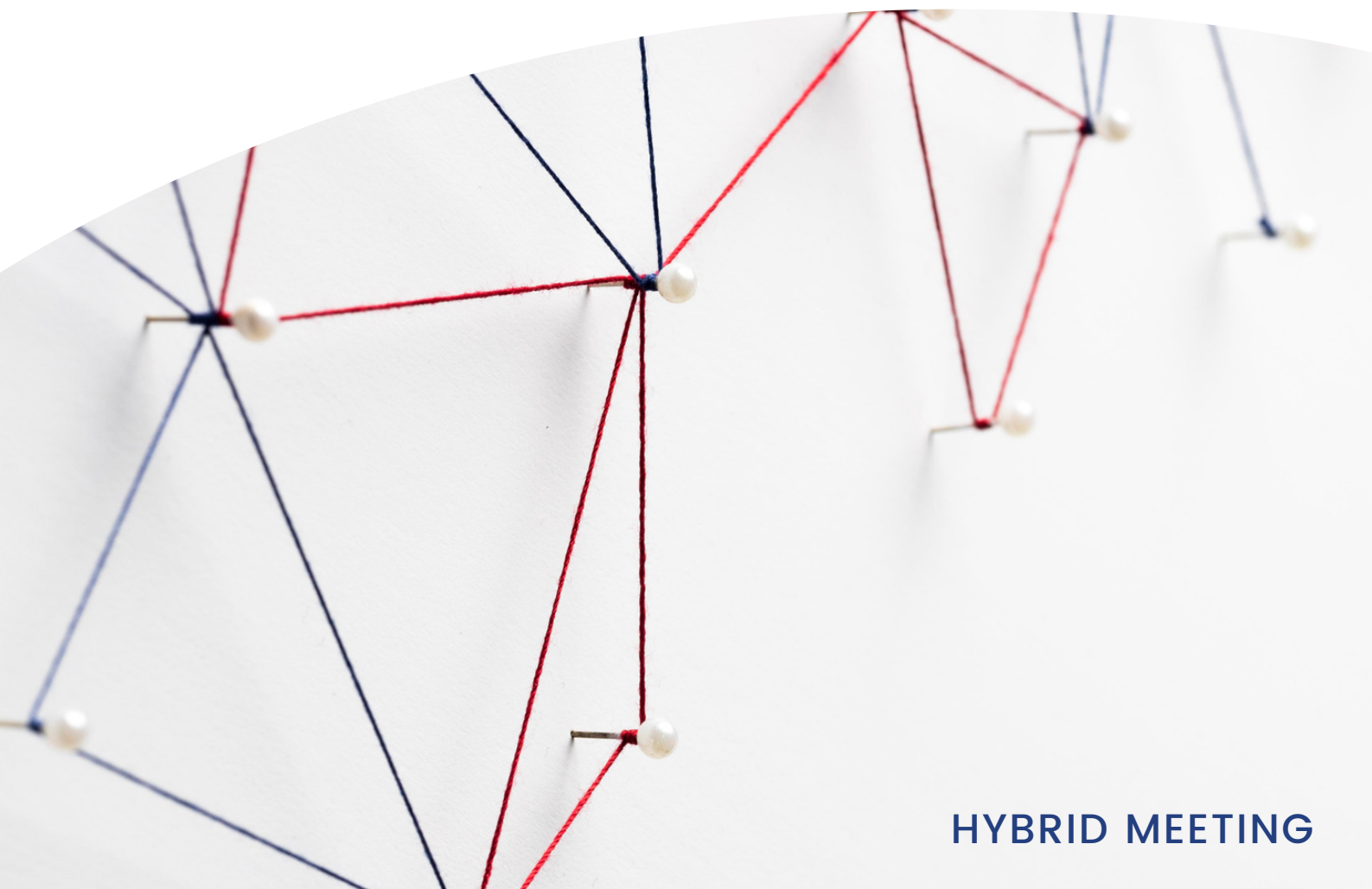


XV Foresight Training Course

BOOSTING RESEARCH AND INNOVATION IN A CHANGING REGULATORY FRAMEWORK



HYBRID MEETING

15 DEC | 4:30 PM CET | SALA LEOGRANDE - EX PALAZZO DELLE POSTE
16 DEC | 9:00 AM CET | PIAZZA C. BATTISTI, 1
BARI, ITALY

SUPPORTED BY:



Master Biennale di II livello in
Discipline Regolatorie "G. Benzi"

XV Foresight Training Course

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, Italy 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 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?

Scan the QR code to discover more!



15
Dec

Agenda

5 minutes for Q&A are foreseen at the end of each presentation

- 4:20PM **Welcome coffee**
- 4:30PM **Introductory remarks**
Fedele Bonifazi, Fondazione per la Ricerca Farmacologica
Gianni Benzi Onlus
Cosimo D. Altomare, Università degli Studi di Bari Aldo Moro

SESSION 1

The new course of clinical studies in Europe

Chairs – Adriana Ceci & Ralf-Dieter Hilgers

- 4:45PM **Regulatory challenges and future proof approaches to improve treatment for rare disease patients**
Violeta Stoyanova-Beninska, Medicines Evaluation Board,
Netherlands – Committee Orphan Medicinal Product, European
Medicines Agency
- 5:10PM **Accelerating Clinical Trials in the EU (ACT EU) initiative**
Lucia D’Apote, Amgen Inc.
- 5:35PM **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
- 6:00PM **Panel discussion**
Enrico Bosone, Società Italiana Attività Regolatorie, Accesso,
Farmacovigilanza – SIARV
Donato Bonifazi, European Paediatric Translational Research
Infrastructure – EPTRI
Rima Nabbout, Paris Descartes University – European Joint
Programme on Rare Diseases – EJP RD
Paola Baiardi, Fondazione Benzi Scientific Committee – Istituti
Clinici Maugeri
François Houyez, European Organisation for Rare Diseases –
EURORDIS
Nicola Amoroso, Università degli Studi di Bari Aldo Moro
- 7:00PM **Session wrap up**



FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS



**UNIVERSITÀ
DEGLI STUDI DI BARI
ALDO MORO**

16
Dec

SESSION 2

Innovative research methodologies

Chairs – Violeta Stoyanova-Beninska & Paola Baiardi

- 9:00AM **Regulatory qualification of innovative methodologies**
Flora Musuamba Tshinanu, EMA Modelling and Simulation Working Party – University of Namur
- 9:25AM **Innovative research methodologies application in paediatric orphan medicines**
Lucia Ruggieri & Annalisa Landi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus
- 9:50AM **Addressing randomization bias and using external data to improve evidence in rare disease clinical trials**
Rima Nabbout, Paris Descartes University – European Joint Programme on Rare Diseases
Ralf-Dieter Hilgers, RWTH Aachen University – European Joint Programme on Rare Diseases
- 10:15AM **Master protocol clinical trial designs**
Franz König, Center for Medical Statistics, Informatics and Intelligent Systems, Medical University of Vienna
- 10:40AM **Evidence from real-world data implementing paediatric medicines approval**
Carlo Giaquinto, Fondazione PENTA Onlus, conect4children network
- 11:05AM **Session wrap up**
- 11:15AM **Break**

SESSION 3

Implementation of Research and Innovation ecosystems: challenges and opportunities

TOPIC 1: Access to innovation

Chairs – Donato Bonifazi & Flora Musuamba Tshinanu

- 11:30AM **Costs and benefits of novel research methodologies**
Raffaele Lagravinese, Università degli Studi di Bari Aldo Moro
Fedele Bonifazi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

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11:55AM **Patients expectations in a new research and innovation ecosystem**

François Houyez, European Rare Diseases Organisation

12:20PM **Global challenges and industrial competitiveness**

Renato Dellamano, ValueVector

12:45PM **GREEN compounding and PHARMAceutical Repurposing for rare Diseases Innovation ecosystem a public-private initiative**

Sergio Fontana, Farmalabor S.r.l.

Nunzio Denora, Università degli Studi di Bari

1:15PM **Session wrap up**

1:30PM **Lunch**

TOPIC 2: Digital transformation to boost human research

Chairs – Fedele Bonifazi & Oscar Della Pasqua

2:30PM **In-silico screening approaches to aid drug discovery and repurposing**

Cosimo D. Altomare, Università degli Studi di Bari

2:55PM **Implementing biological target- and cell/organism-based screening in drug development**

Antonella Liantonio & Elena Conte, Università degli Studi di Bari

3:20PM **Establishing the probability of pharmacological success**

Oscar Della Pasqua, University College London

3:45PM **System biology and predictive models to develop innovative medicines**

Giorgio Reggiardo, Consorzio per Valutazioni Biologiche e Farmacologiche

4:10PM **Session wrap up**

4:25PM **Final remarks**

Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus
Università degli Studi di Bari Aldo Moro



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