

# XVI Foresight Training Course

## Repurposing to cover unmet needs: the current scenario in Europe and the proposed changes to the pharmaceutical legislation

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18 DECEMBER 2023

AULA 5, DIPARTIMENTO DI FARMACIA-SCIENZE DEL FARMACO  
UNIVERSITA' DEGLI STUDI DI BARI

Campus Universitario Ernesto Quagliariello  
via E. Orabona, 4 - Bari (Italy)



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# INTRODUCTION

**Drug repurposing** or repositioning is defined as the process of finding new uses outside the scope of the original medical indication for existing drugs. It might relate to new patients populations, dosage forms or routes of administration.

Currently, repurposing represents an **emerging and dynamic drug development strategy** as it is expected that the development of a repurposed drug would be quicker with reduced costs and development risks. Approved drugs have been used and studied in case of urgent needs to make new therapies available to patients, like COVID-19 pandemic. In settings with special needs, like **paediatric and rare diseases**, characterised by well-known challenges, repurposing has been also considered as an opportunity to cover **unmet medical needs**.

Moreover, the recent proposal to revise the **pharmaceutical legislation**, released by the European Commission, includes impactful changes specifically dealing with repurposing. Debates on this and possible outcomes are ongoing both at European and national level.

In this perspective, this year, Fondazione Gianni Benzi, in collaboration with Università degli Studi di Bari Aldo Moro, organises the **XVI Foresight Training Course**, dedicated to repurposing aimed to cover unmet medical needs.

The following keynote topics around repurposing will be discussed:

- Current and proposed **regulatory provisions** and decision-making to be undertaken in the EU for Research & Development (R&D) and marketing authorisation;
- **Industry and academic approaches** and collaboration to repurposing as a R&D opportunity;
- **Commercial perspectives and strategies** to repositioning drugs;
- The meaning of repurposing in the **paediatric context**;
- Need for **specific formulations** to comply with the patient needs;
- Tools potentially supporting R&D of repurposed drugs, maximising the pharmacological approach and the evidence needed to endorse the use of these drugs, such as **in-silico approaches and real world data**;
- Possible impact of changes proposed by the European Commission to the **Pharmaceutical Legislation** under **Articles 48 and 75** of the proposed Regulation.

Renowned 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.

**Scan to discover more**



**Course Scientific Committee**

Viviana Giannuzzi

Nunzio Denora

Fedele Bonifazi

Francesco Leonetti

**9:15AM**      **Registration and Welcome**

**9:30AM**      **Introductory remarks**

Fedele (Duccio) Bonifazi, Fondazione per la Ricerca Farmacologica  
Gianni Benzi Onlus  
Cosimo Altomare, Università degli Studi di Bari

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**9:45AM**      **Session 1 - Developing and marketing repurposed medicines and the main actors playing in this framework**

**Chairs:** Adriana Ceci, Nunzio Denora

**Drug repurposing and the revision of EU pharmaceutical legislation**

Vincenzo Salvatore, Università degli Studi dell'Insubria

**Public-private partnerships to repositioning old drugs**

Billy Amzal, Quinten Health, EUCOPE

**The pathway of repurposed drugs to patients: barriers and facilitators of market access**

Arianna Bertolani, Consorzio per Valutazioni Biologiche e Farmacologiche

**Repurposing as an opportunity for rare disease patients**

François Houyez, EURORDIS

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**11:45AM**      **Round table: How can repurposing meet therapeutic needs in paediatrics?**

**Chair:** Fedele (Duccio) Bonifazi

**Introduction:** Viviana Giannuzzi, Fondazione per la Ricerca Farmacologica  
Gianni Benzi Onlus

**Panelists:**

Oscar Della Pasqua, University College London

Lucia Ruggieri, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

Serena Tongiani, Indena

Claudia Fuchs, EURORDIS

Mariateresa Loiotine, Policlinico di Bari

Paola Muggeo, Policlinico di Bari

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**1:00PM**      **Light Lunch**

2:00PM

## **Session 2 - The role of academia, research centres, patients, companies and SMEs in repurposing pathways**

**Chairs:** Enrico Bosone, Viviana Giannuzzi

### **In-silico structure-based platforms for drug repurposing**

Cosimo Altomare, Università degli Studi di Bari Aldo Moro

### **Pharmaceutical technology platforms repurposing active pharmaceutical ingredients**

Nunzio Denora, Università degli Studi di Bari Aldo Moro

### **Preclinical research on repurposed drugs for rare and paediatric diseases**

Annamaria De Luca, Università degli Studi di Bari Aldo Moro

### **Application of in-silico technologies for the repurposing of medicinal products in rare paediatric diseases: Lessons from a case study in heart failure**

Oscar Della Pasqua, University College London

### **Experience and plans from companies and SMEs**

Billy Amzal, Quinten Health, EUCOPE

Veronica Casalini, Roche S.p.A.

Serena Tongiani, Indena

### **REMEDI4ALL – A new European consortium to drive patient-centric drug repurposing in rare disease and beyond**

Claudia Fuchs, EURORDIS

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4:00PM

## **Round table: what about repurposing under Article 48 of the proposed EU Regulation?**

**Chair:** Vincenzo Salvatore

**Introduction:** Vincenzo Salvatore, Università degli Studi dell'Insubria

### **Panelists:**

Billy Amzal, Quinten Health, EUCOPE

Enrico Bosone, SIARV

François Houyez, EURORDIS

Flora Musuamba Tshinanu, University of Namur, EMA Modelling and Simulation Working Party

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5:00PM

## **Final remarks**

Fedele (Duccio) Bonifazi & Viviana Giannuzzi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

Nunzio Denora, Università degli Studi di Bari Aldo Moro



# List of chairs and speakers

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## **Fedele (Duccio) Bonifazi**

Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus, President

## **Cosimo Altomare**

Università degli Studi di Bari Aldo Moro, Department of Pharmacy-pharmaceutical Sciences, Coordinator of the M.Sci. Degree in Pharmacy and Industrial Pharmacy

## **Adriana Ceci**

Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus, Board Member and Scientific Office of the Presidency

## **Nunzio Denora**

Università degli Studi di Bari Aldo Moro, Department of Pharmacy-pharmaceutical Sciences, Professor

## **Vincenzo Salvatore**

Università degli Studi dell'Insubria, Department of Economics, Professor; BonelliErede law firm (Milan), Counsel

## **Billy Amzal**

Quinten Health, CEO; European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

## **Arianna Bertolani**

Consorzio per Valutazioni Biologiche e Farmacologiche, Head of Project Development

## **François Houyez**

EURORDIS – Rare Diseases Europe, Information & Access to Therapies Director & Health Policy Advisor

## **Viviana Giannuzzi**

Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus, Head of Scientific Department; European Medicines Agency's Paediatric Committee, Member

## **Oscar Della Pasqua**

University College London, Pharmacology, Professor

## **Lucia Ruggieri**

Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus, Researcher

## **Serena Tongiani**

Indena, Chief Portfolio Officer

## **Claudia Fuchs**

EURORDIS – Rare Diseases Europe, Drug Repurposing Projects Senior Manager

## **Mariateresa Loiotine**

Paediatric Oncohaematology Unit, Policlinico di Bari - Department of Paediatric Science and Surgery, Study Coordinator

## **Paola Muggeo**

Paediatric Oncohaematology Unit, Policlinico di Bari - Department of Paediatric Science and Surgery, Physician

## **Enrico Bosone**

Società Italiana Attività Regolatorie, Accesso, Farmacovigilanza, President

## **Annamaria De Luca**

Università degli Studi di Bari Aldo Moro, Department of Pharmacy-pharmaceutical Sciences, Professor

## **Veronica Casalini**

Roche S.p.A., Regulatory Affairs Manager

## **Flora Musuamba Tshinanu**

University of Namur, Department of Pharmacy, Professor; EMA Modelling and Simulation Working Party, Member