



FONDAZIONE  
PER LA RICERCA FARMACOLOGICA  
**GIANNI BENZI**  
ONLUS



**UNIVERSITÀ**  
DEGLI STUDI DI BARI  
ALDO MORO



## **XVI Foresight Training Course**

*Repurposing to cover unmet needs: the current scenario  
in Europe and the proposed changes to the  
Pharmaceutical Legislation*

**18 December 2023**

**Università degli Studi di Bari Aldo Moro – Bari, Italy**

**Course Scientific Committee**

Nunzio Denora, Francesco Leonetti, Viviana Giannuzzi,  
Fedele Bonifazi



**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**, that is dedicated to repurposing aimed to cover unmet medical needs. The Course will be held on **18 December in Bari, Italy** at Università degli Studi di Bari and **online**.

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, like **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.

The course is **free of charge** for students, researchers, representatives from patients' associations and not for profit organisations.

**Registration link:** <https://forms.office.com/e/85vPnKg0fQ>

**SUPPORTED BY:**



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



SOCIETÀ ITALIANA DI FARMACOLOGIA



## AGENDA (CET time)

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

**9:15 am**      **Welcome**

**Introductory remarks**

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

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

**10:00 am**      **Repurposing old and new drugs within the EU pharmaceutical legislation**

Vincenzo Salvatore, Università degli Studi dell'Insubria

**10:30 am**      **Public-private partnerships to repositioning old drugs**

Billy Amzal, Quinten Health, EUCOPE

**11:00 am**      **The pathway of repurposed drugs to patients: barriers and facilitators of market access**

Arianna Bertolani, Consorzio per Valutazioni Biologiche e Farmacologiche, European Paediatric Translational Research Infrastructure (EPTRI)

**11:30 am**      **Repurposing as an opportunity for rare disease patients**

François Houyez, EURORDIS

**12:00 pm**      *Break*

**12:20 pm**      ***Round table: Should we consider the extension of the indication to paediatrics as repurposing?***

*Introductory remarks:*

Viviana Giannuzzi, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

Oscar della Pasqua, University College London

*Confirmed Panelists:*

Serena Tongiani Indena

Lucia Ruggieri, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

EURORDIS representative

**1:20 pm**      ***Lunch***

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

**2:20 pm**      **In-silico structure-based platforms for drug repurposing**

Cosimo Altomare, Università degli Studi di Bari Aldo Moro

**2:40 pm**      **Pharmaceutical technology platforms repurposing active pharmaceutical ingredients**

Nunzio Denora, Università degli Studi di Bari Aldo Moro



- 3:00 pm**      **Preclinical research on repurposed drugs for rare and paediatric diseases**  
Annamaria De Luca, Università degli Studi di Bari Aldo Moro
- 3:20 pm**      **Experience and plans from companies and SMEs**  
Billy Amzal, Quinten Health  
Veronica Casalini, Roche S.p.A.  
Serena Tongiani, Indena
- 3:50 pm**      **REMEDi4ALL – A new European consortium to drive patient-centric drug repurposing in rare disease and beyond**  
Claudia Fuchs, EURODIS
- 4:10 pm**      ***Round table: what about repurposing under Article 48 of the proposed EU Regulation?***  
*Introductory remarks:*  
Vincenzo Salvatore, Università degli Studi dell'Insubria  
*Confirmed panelists:*  
Billy Amzal, Quinten Health, EUCOPE  
EURORDIS representative  
academia representative
- 5:10 pm**      **Final remarks**  
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