



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>

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

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**

Company/companies association representative

11:00 am **Is repurposing an opportunity for generic developers?**

Generic developer/developers association representative

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

EURORDIS representative

12:00 pm *Break*

12:30 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

Panelists:

company/SME representative, patients representative, academia representative

1:30 pm **Lunch**

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

2:30 pm **In-silico structure-based platforms for drug repurposing**

Cosimo Altomare, Università degli Studi di Bari

2:50 pm **Pharmaceutical technology platforms repurposing active pharmaceutical ingredients**

Nunzio Denora, Università degli Studi di Bari Aldo Moro

3:10 pm **Preclinical research on repurposed drugs for rare and paediatric diseases**

Annamaria De Luca, Università degli Studi di Bari Aldo Moro

3:30 pm **Experience and plans from companies and SMEs**

Billy Amzal, Quinten Health

Veronica Casalini, Roche S.p.A.

4:00 pm ***Round table: what about repurposing under Article 48 of the proposed EU Regulation?***



FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS



UNIVERSITÀ
DEGLI STUDI DI BARI
ALDO MORO

Introductory remarks:

Vincenzo Salvatore, Università degli Studi dell'Insubria

Panelists: company/SME representative, patients representative, academia representative

5:00 pm

Final remarks

Fondazione per la Ricerca Farmacologica Gianni Benzi onlus