

## MODELLING&SIMULATION: RESEARCH METHODOLOGIES FOR SMALL POPULATIONS IN RARE DISEASES

Hotel Excelsior Bari, Italy

4-5 July 2022

### AGENDA

#### 4 July 2022

Time	Speaker and Affiliation	Session name/Topic
09.00 – 09.10	D. Bonifazi, CVBF	Welcome address
09.10 – 10.00	A. De Luca, University of Bari 'Aldo Moro'	Developmental pharmacology and toxicology in drug discovery: what is needed for translational pre-clinical studies
10.00 – 10.50	S. Lorenzetti, Italian National Institute of Health	In utero exposure to chemicals: the case of hepatoblastoma
10.50 – 11.10		<i>Coffee Break</i>
11.10 – 12.00	C. D. Altomare, University of Bari 'Aldo Moro'	QSAR in designing and repurposing drugs for small populations
12.00 – 13.00	O. Nicolotti, University of Bari 'Aldo Moro'	Data and models of human health endpoints in predictive toxicology
13.00 – 14.00		<i>Lunch Break</i>
14.00 - 15.30	F. Ciriaco, University of Bari 'Aldo Moro'	Practical session: A web platform for in-silico ADMETox profiling
15.30 – 15.40		<i>Coffee Break</i>
15.40 – 17.10	N. Amoroso, University of Bari 'Aldo Moro'	Practical session: Machine learning approach for prediction of developmental toxicity of chemicals
17.10 – 17.40		Q&A session
17.40 – 18.00		Conclusions



5 July 2022

Time	Speaker and Affiliation	Session name/Topic
09.00 – 09.50	O. Della Pasqua, University College London	PK/PD modelling and simulation: utility in drug development
09.50 – 10.40	O. Della Pasqua, University College London	Off-label use of medicinal products
10.40 – 11.00	<i>Coffee Break</i>	
11.00 – 11.30	G. Migliaccio, CVBF	Use of Experimental medicinal products: the regulatory point of view
11.30 – 12.00	V. Giannuzzui, Gianni Benzi Foundation	How to implement innovative research methodologies in the EU regulatory framework
12.00 – 12.50	A. Gissi, ECHA, Helsinki, Finland	Regulatory use of QSAR models: the perspective of the European Chemicals Agency (ECHA)
13.00 – 14.00	<i>Lunch Break</i>	
14.00 – 15.30	Case study: Dose rational and prediction of therapeutic exposure from preclinical models (O. Della Pasqua)*	
15.30- 16.50	<i>Coffee Break</i>	
15.50 – 17.10	Case study: Clinical Trials simulations: protocol optimisation for small populations (O. Della Pasqua)*	
17.10 – 17.40	Q&A session	
17.40 – 18.00	Conclusions	

\* to be able to execute the case studies please Install on your pc the following softwares R: <https://cran.r-project.org/>. R Studio: <https://www.rstudio.com/products/rstudio/download/>.

