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UNIVERSITÀ degli STUDI di CATANIA

MASTER IN DRUG REGULATORY AFFAIRS

CERD CENTRO PER LA RICERCA E LA CONSULTAZIONE IN DISCIPLINE REGOLATORIE DEL FARMACO
CENTRE FOR RESEARCH IN REGULATORY AFFAIRS AND HTA

Coordinator: **Filippo Drago**

EUROPEAN REGULATORY CONFERENCE

Forum of European Regulatory Experts
for the minimization of interstate discrepancies

Towards a European Pharmaceutical Harmonization: Clinical evidence versus clinical benefit

"Adaptation processes in the regulatory world are too long: we cannot wait that a change is made through an adaptation process, we have to anticipate the adaptation".
(Francis Megerlin)

Catania, February 21st, 2020

Biological Tower, Via S. Sofia, 97
Aula Magna "Umberto Scapagnini"

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SCIENTIFIC PROGRAM

09:30-10:30	Registration
10:30-10:45	**Welcome address** **Filippo Drago, Francesco Priolo, Alessandro Mugelli**
	Chairman **Francis Megerlin**
10:45-11:30	Introductory lecture **Facing old and new difficulties towards a European Pharmaceutical Union** **Guido Rasi**
11:30-12:00	**Value-based pricing of drugs in the UK** **Kenneth Paterson**
12:00-12:30	**How clinical effectiveness is used in France to triage innovative drugs?** **Olivier Wong**
12:30-13:00	**The comparator in clinical trials: the German model** **Jan Geldmacher**
13:00-13:30	**Early access procedures: is it always an advantage? Do we need a harmonization?** **Patrizia Popoli**
13:30-14:30	*Lunch break*
	Chairman **Olivier Wong**
14:30-15:00	**Early access programs in Italy: pros and cons** **Claudio Jommi**
15:00-15:30	**Innovation in drug development: do we need a common parameter?** **Francis Megerlin**
15:30-16:00	**The issues around a harmonized HTA approach in Europe from a German system´s perspective** **Frank-Ulrich Fricke**
16:00-16:30	**Funding orphan medicinal products beyond price** **Oriol Morales Solá**
16:30-17:00	**Influence of Europe-Japan interactions on the European drugs regulatory and reimbursement systems** **Isao Kamae**
17:00-17:30	**Concluding remarks** **Filippo Drago**

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