



Associazione Farmaceutici Industria
Società Scientifica



Regione
Lombardia

Endorsed by



International Conference

European Clinical Trial Day, the future of clinical research: is the 536/14 regulation enough?

Regulatory Authorities, Ethic Committees, Sponsors, Researchers, Sites and Patients

13th October 2017 – Auditorium G. Testori

Palazzo Lombardia - Piazza Città di Lombardia 1, Milano

(Underground M2 Stop Gioia - M5 Stop Isola)

The 536/14 regulation, aimed to increase the number of clinical trials and to support and facilitate the Sponsors in trial start up and conduction, is planned to be implemented in Europe soon (expected within 2019).

In the meanwhile, the clinical research environment is rapidly evolving due to new technologies, big data collection, new drugs, precision medicine, advanced therapies, development of new methodology and clinical trial design (e.g. basket and umbrella trials). This international meeting is aimed to discuss and evaluate whether the new EU Regulation will effectively improve the European competitiveness and how it will be implemented in different European countries.

International and national speakers (competent authorities, clinical researchers, EU and extra EU sponsors, CROs, institutions, academic sponsors and patients) will discuss about this key topic.

Attendance is free, however application is compulsory for organizing reason.

Scientific and Organizing Committee

- Liliana Burzillieri - Regione Lombardia
- Emiliano Celli - AFI-New Aurameeting
- Lorenzo Cottini - AFI-High Research
- Guido Fedele - AFI

08:00 - 09:00

Registrations

(Recommended punctuality due to metal detector controls)

clinical research be more competitive and attractive?

- Sergio Scaccabarozzi - Roche
- Marco Scatigna - Sanofi

Morning agenda

Chairs:

- Lorenzo Cottini - AFI-High Research
- Luisa Minghetti - ISS (Higher Health Institute)

12:30 - 13:00

Discussion

13:00 - 14:30

Lunch

09:00 - 09:30

Welcome and introduction

09:00 - 09:10

AFI:

- Alessandro Rigamonti - AFI President
- Claude Farrugia - EIPG President

09:10 - 09:30

Regione Lombardia:

- Regione Lombardia President *invited*
- Welfare Councillor *invited*
- Giovanni Daverio - Welfare Regione Lombardia General Director *invited*
- Liliana Burzillieri - Welfare Regione Lombardia

Afternoon Agenda

Chairs:

- Guido Fedele - AFI
- Sandra Petraglia - AIFA (Italian Medicines Agency)

14:30 - 14:45

Independent and collaborative Clinical Research: present and future for Europe- the point of view of academic promoter

- EORTC - *invited*

09:30 - 11:05

The future of clinical research (adaptive, umbrella, basket trials, personalized medicine, trials with device and drugs): is the 536/14 regulation enough? How to improve clinical research? What can Member States do and how are they working?

09:30 - 09:50

- Giuseppe Recchia - Fondazione Smith Kline

09:50 - 10:05

- María Antonia Serrano Castro - AEMPS Spain

10:05 - 10:20

- Belgium *invited*

10:20 - 10:35

- Italian Ministry of Health

10:35 - 10:50

- Mario Melazzini (General Director), Sandra Petraglia - AIFA (Italian Medicines Agency)

10:50 - 11:05

- EFPIA

14:45 - 15:00

Patients' point of view and patients' engagement: the role of expert patients in clinical trials

- Paola Kruger - Patients Expert EUPATI Fellow

15:00 - 15:15

Economic sustainability of clinical research, big data and technology, data publication/disclosure

- Claude Farrugia - EIPG President

15:15 - 15:45

Discussion

15:45 - 16:00

How sites should be organized: administrations, facilities, staff, contracts, training

- Carlo Tomino - IRCCS San Raffaele of Rome

11:05 - 11:30

Discussion

11:30 - 12:00

Coffee break

16:00 - 16:15

Ethic in Clinical Research: role of Ethic Committee

- Paolo Casali - Ethical Committee National Institute of Cancers of Milan

Chairs:

- Giuseppe Caruso - Farmindustria
- Lorenzo Cottini - AFI-High Research

16:15 - 17:00

Discussion and conclusions

- Lorenzo Cottini - AFI-High Research
- Guido Fedele - AFI
- Sandra Petraglia - AIFA (Italian Medicines Agency)

12:00 - 12:30

Extra EU and EU Sponsors' point of view: how is clinical research changing and evolving? How is European competitiveness perceived by Sponsors? How can European



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13th October 2017 – Auditorium G. Testori Palazzo Lombardia - Piazza Città di Lombardia 1, Milano (Underground M2 Stop Gioia - M5 Stop Isola)

REGISTRATION FORM • Please send within 3rd October to NEW AURAMEETING srl • Via Rocca d'Anfo 7 • 20161 Milano
• Phone: +39 02 66203390 • Fax: +39 02 66200418 • info@newaurameeting.it • Free entrance while seats last • In case
of impossibility to attend, please delay the presence even few days before the meeting to let seats to other interested people.

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