



Associazione Farmaceutici Industria  
Società Scientifica



Regione  
Lombardia



## 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

**13<sup>th</sup> 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.

The official language of the Conference is English. **Simultaneous translation will be provided.**

The live streaming will be available from 8.45 am of 13 October until the end of the event on the following link:

**EUROPEAN CLINICAL TRIAL DAY LIVE STREAMING**

#### Scientific and Organizing Committee

- Liliana Burzilleri - 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)

12:00 - 12:40

**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 clinical research be more competitive and attractive?**

#### Morning agenda

##### Chairs:

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

- Sergio Scaccabarozzi - Roche
- Marco Scatigna - Sanofi

09:00 - 09:30

#### Welcome and introduction

09:00 - 09:10

##### AFI:

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

12:40 - 13:00

#### Discussion

13:00 - 14:30

*Lunch*

09:10 - 09:30

##### Regione Lombardia:

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

#### Afternoon Agenda

##### Chairs:

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

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?**

14:30 - 14:45

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

- Ann Marinus - EORTC

09:30 - 09:50

- Giuseppe Recchia - Fondazione Smith Kline
- Claude Farrugia - EIPG President

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

09:50 - 10:05

- Maria Antonia Serrano Castro - AEMPS Spain

15:00 - 15:15

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

- Carlo Tomino - IRCCS San Raffaele of Rome

10:05 - 10:20

- Sandra Bright - HPRA Ireland

10:20 - 10:35

- Italian Ministry of Health

10:35 - 10:50

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

15:15 - 15:30

**Ethic in Clinical Research: role of Ethic Committee**

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

10:50 - 11:05

- Sheuli Porkess - EFPIA

11:05 - 11:30

#### Discussion

11:30 - 12:00

*Coffee break*

15:30 - 16:15

#### Discussion and conclusions

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

##### Chairs:

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



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#### Scientific Secretariat AFI

Viale D. Ranzoni, 1 - 20149 Milan, Italy

Phone: +39 02 4045361

Fax: + 39 0248717573

[segreteria@afiscientifica.it](mailto:segreteria@afiscientifica.it) - [www.afiscientifica.it](http://www.afiscientifica.it)

#### Organizing Secretariat NEW AURAMEETING SRL

Via Rocca d'Anfo, 7 - 20161 Milan, Italy

Phone: +39 02 66203390

Fax: +39 02 66200418

[info@newaurameeting.it](mailto:info@newaurameeting.it) - [www.newaurameeting.it](http://www.newaurameeting.it)

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**REGISTRATION FORM** • Please send within 3<sup>rd</sup> October to NEW AURAMEETING srl • Via Rocca d'Anfo 7 • 20161 Milano  
• Phone: +39 02 66203390 • Fax: +39 02 66200418 • [info@newaurameeting.it](mailto: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.

LAST NAME

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JOB POSITION

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