Associazione Farmaceutici Industria
Società Scientifica

AFI – Regione Lombardia

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
Piazza Città di Lombardia 1 (M2 – Gioia) Milan I
Palazzo Lombardia

➢ Scientific and Organizing Committee

Liliana Burzilleri, Regione Lombardia
Emiliano Celli, New Aurameeting
Lorenzo Cottini, High Research CRO - AFI
Guido Fedele, AFI

➢ Goals

The 536/14 regulation is going to be implemented in Europe (probably end of 2018), to increase the number of clinical trials and to support and facilitate the promoters in clinical trial starting and conduction.
In the meanwhile, the clinical research is rapidly changing: technology, big data, new drugs, precision medicine, advanced therapies, trial design (e.g. basket and umbrella trials).
This international meeting aims to understand if new EU Regulation is enough for those changes and how the Regulation can be implemented in each country to make Europe attractive.
International and national speakers (competent authorities, EMA, researcher, extra UE sponsors and CROs, institutions, academic sponsors, patients) will discuss about this crucial topic.

➢ Speakers

Among speakers will take part Mario Melazzini, AIFA General Director, Ministry of Health, Authorities of different countries, EMA, speakers of pharmaceutical companies and CRO.

➢ Main Topics

- The future of clinical research (adaptive, umbrella, basket trials, personalized medicine, trials with device and drugs): is the 536/14 regulation enough? How improve the clinical research?
- What can member states do and how they are working?
- Extra UE Sponsor and CRO point of view: how clinical research is changing? How EU is seen? How Europe can be competitive and attractive?
- Independent and collaborative Clinical Research: present and future for Europe
- Patient point of view and patient engagement: the role of expert patient in clinical trials
- Economic sustainability of clinical research, Recycling of data, big data and technology
- Clinical research and advanced Therapies
- How sites should be organized: administrations, facilities, staff, contracts, training
- Ethic in clinical Research: role of Ethic Committee

SCIENTIFIC SECRETARIAT - AFI
www.afiscientifica.it | segreteria@afiscientifica.it
Tel: +39 02 4045361 | Fax: +39 02 48717573
Viale D. Ranzoni 1, 20149 Milano

ORGANIZING SECRETARIAT - NEW AURAMEETING
www.newaurameeting.it | info@newaurameeting.it
Tel: +39 02 66203390 | Fax: +39 02 66200418
Via Rocca d'Anfo 7, 20161 Milano