

15.30-16.00 Coffee break

16.00-18.30 **Session 3. Measures of outcome in allergic diseases**
Chairpersons: *M. Kowalski, P. Folino Gallo*

Clinical vs surrogate end-points. Qol and patient-reported outcome measures
L. Corbetta, I. Baiardini, F. Braido

End-points in clinical trials of asthma - *L. Fabbri*

End-points in clinical trials of rhinitis and rhinosinusitis
J. Mullol

End-points in clinical trials of ocular allergy - *St. Bonini*

End-points in clinical trials of allergic skin diseases
T. Zuberbier

End-points in pediatric allergic and respiratory diseases
K-H. Carlsen

Free evening

JULY 8TH

08.30-11.00 **Session 4. Clinical trials of anti-allergic and anti-asthmatic drugs**
Chairpersons: *E. Nizankowska-Mogilnicka, L. Fontana*

Clinical trials of anti-allergic drugs - *G.W. Canonica, M. Triggiani*
Anti-histamines.
Anti-leukotrienes.
Nasal steroids

Immunotherapy trials
Ph. Bousquet, G. Passalacqua, F. Bonifazi
Subcutaneous and sublingual immunotherapy. Anti-IgE

Clinical trials of anti-asthmatic drugs - *P.L. Paggiaro, V. Brusasco*
Bronchodilators. Inhaled topical steroids

Clinical trials in Pediatric Allergy and Clinical Immunology
K.C. Lodrup Carlsen, A. Fiocchi

11.00-11.30 Coffee break

11.30-13.00 **Workshop. The GA²LEN Clinical Trials platform**
Participation restricted to representatives of GA²LEN Units and Collaborating Centers
Chairpersons: *D. Passali, P. Palange*

ROUND TABLE

Is your site ready for clinical trials?
Discussants: *C. Tomino (Regulatory aspects); P. Rossi (EMEA and the Pediatric Network)*

ROUND TABLE

The expectations of Pharmaceutical and Biotech Companies
Discussants: *S. Bonini, T. Zuberbier*

With the participation of Faculty members and GA²LEN Units' representatives

Rome

July 6th - 8th 2009



GA²LEN - EAACI Summer School

Course on Clinical Trials

Congress Venue:
Italian National Drug Agency
AIFA
Via della Sierra Nevada 60, Roma

Sala Cappella



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Course Directors:

S. Bonini, T. Zuberbier

Scientific Board:

*J. Bousquet, Ph. Bousquet,
P. Burney, K-H. Carlsen,
G. Joos, M. Kowalski,
I. Lotvall, P. Palange,
D. Passali, C. Tomino*

Scientific Secretariat:

M. Bresciani, C. Gramiccioni, F. Mariani

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Endorsed by the:

- *World Allergy Organization (WAO)*
- *European Academy of Allergy and Clinical Immunology (EAACI)*
- *Italian Guidelines for COPD, Rhinitis and Asthma (LIBRA)*

AIMS

The Course is aimed at:

- *providing basic information on the role of clinical research in compliance with Good Clinical Practice for clinical allergists and young investigators.*
- *describing the requirements for designing and performing clinical research both in the context of contracts with pharmaceutical or biotech companies and as a site-originated independent research.*
- *producing a clinical Manual to be used as a booklet for clinical trials.*

Upon completion of the Course participants should be able to:

- *discuss terminology that is commonly used in clinical research (observational and interventional studies, RCTs, phase I-IV trials, etc.);*
- *discuss the role of Evidence Based Medicine in guiding clinical practice through a critical evaluation of published clinical research and systematic reviews/metanalysis;*
- *define criteria for an accurate study design (question, patient recruitment, SOPs, outcomes, sample size, power of the study and statistics ,etc);*
- *describe the standard requirements for establishing clinical research operations (PI commitment, staff, regulations, ethics and informed consent, contacts and contracts with sponsors, ethic committees, IRBs, CROs , hospital administration, regulatory agencies, etc).*

STRUCTURE

A 2-days course for up to 50 participants. Four sessions and one hand on session followed by two Round Tables with the participation of representatives of Centers part of the GA²LEN Clinical Trials Platform.

JULY 6TH

Arrival and Registration

- 19.00** Transfer of participants from the hotel to the Private Club of The Ministry of Foreign Affairs
- 20.00-23.00** Welcome Reception and Buffet. Transfer to the hotel

JULY 7TH

- 08.30-08.50** Welcome and Introduction to the Course - *S. Bonini, T. Zuberbier* Course objectives. The GA²LEN Clinical Trials Platform.

- 08.50-10.30** **Session 1. Clinical Research in Allergy and Clinical Immunology**
Chairpersons: *C. Akdis, R. Gerth van Wijk*

Clinical Research in Allergy and Clinical Immunology - *S. Bonini*
Why Clinical Research in Allergy and Clinical Immunology? The GA²LEN Network. Type of studies (Pre-clinical and in vitro, observational, cohort and interventional studies)

Pre-clinical studies - *G. Joos*
Animal models of allergic and respiratory diseases and animal pre-clinical studies

In vitro tests as surrogate markers in clinical trials of allergic diseases - *M. Akdis*
In vitro tests in clinical trials of allergic diseases

Evidence-Based Medicine
H. Schunemann
How to collect and grade evidence

- 10.30-11.00** Coffee break

- 11.00-13.00** **Session 2. Randomised Clinical Trials**
Chairpersons: *J. Bousquet, C. Tomino*

Reporting and publishing clinical trials - *A. Liberati*
Scientific and ethical issues in planning, reporting, publishing and disseminating results of RCTs.

Randomised clinical trials
C. Tomino
European Legislation of clinical trials. Registries of clinical trials. Commercial and non-commercial clinical trials. Drug registration. Good Clinical Practice and Standard Operational Procedures. Study design, sample size, power of the study and statistics.

Funding opportunities
The IMI initiative - G. Ruberti
The 7th EU Framework Programme - S. Vella

- 13.00-14.00** Lunch

- 14.00-15.30** **Hand on session**
Chairperson: *W. Marrocco*
Tutors: *E. Compalati, F. Trotta*
Evidence-Based Medicine. Cochrane reviews and metanalysis. Literature search strategies and softwares. Clinical trials vs real life.

One pc station will be available for every two participants.