

Methodology of clinical research and statistics

TUESDAY, 18 JUNE 2019

- 08.55** **Welcome and Introduction**
M. P. Amato (Florence, IT)
- 09.00 - 10.30** **Session 1: Basic concepts**
Chairs: M.P. Amato (Florence, IT), B. Uitdehaag (Amsterdam, NL)
- Statistics**
- 09.00 The hypothesis test: the meaning of p value, sample size and power. How to interpret statistical results of a study
M.P. Sormani (Genoa, IT)
- 09.30 Statistical tests: non-parametric vs parametric approaches, univariate and multivariate methods
A. Signori (Genoa, IT)
- 10.00 Discussion
- 10.30 - 11.00** **Coffee Break**
- 11.00 - 12.30** **Session 1: Basic concepts (continued)**
Chairs: M.P. Amato (Florence, IT), B. Uitdehaag (Amsterdam, NL)
- Study design**
- 11.00 Etiological studies: cohort, case-control and nested case-control study design
H. Tremlett (Vancouver, CA)
- 11.30 Clinical trials: from animal models to phase 3. The standard designs in MS
G. Cutter (Birmingham, US)
- 12.00 Discussion
- 12.30 - 14.00** **Lunch Break**
- 14.00 - 15.30** **Session 2: Observational studies: study design and methods**
Chairs: M Trojano (Bari, IT), S Vukusic (Lyon, FR)
- 14.00 Propensity scores and methods for adjusting for baseline confounders
E. Hernández Martínez-Lapiscina (Barcelona, ES)

- 14.30 Statistical methods for causal inference
K. Fitzgerald (Baltimore, US)
- 15.00 Causality and Risk: specific issues in multiple sclerosis
A. Ascherio (Boston, US)
- 15.30 -16.30 Group discussion: Examples from the recent literature on observational
studies from comparative effectiveness**
H. Tremlett (Vancouver, CA), A. Ascherio (Boston, US), K. Fitzgerald (US),
E. Hernández Martínez de Lapiscina (Barcelona, ES)
- 19.00 Dinner at the hotel**

WEDNESDAY, 19 JUNE 2019

- 09.00 - 10.00 Session 3: Prognostic factors and treatment effect modifiers**
Chairs: M. Tintoré (Barcelona, ES), T. Derfuss (Basel, CH)
- 09.00 The study of prognostic factors. Examples in MS
S. Perez-Hoyos (Barcelona, ES)
- 09.30 The study of treatment effect modifiers. Examples in MS
B. Healy (Boston, US)
- 10.00 Discussion
- 10.30 - 11.00 Coffee Break**
- 11.00 - 12.30 Session 4: Beyond clinical trials**
Chairs: L. Kappos (Basel, CH), C. Nos (Barcelona, ES)
- 11.00 Adaptive designs
J. Chataway (London, UK)
- 11.30 Meta analyses and network meta-analyses
C. Tur (London, UK)
- 12.00 Discussion
- 12.30 - 14.00 Lunch Break**

- 14.00 - 16.00** **Session 4: Beyond clinical trials (continued)**
Chairs: L. Kappos (Basel, CH), C. Nos (Barcelona, ES)
- 14.00 Pragmatic trials
T. Van Staa (Manchester, UK)
- 14.30 Postmarketing, observational studies
E. Gemmen (Rockville, US)
- 15.00 Artificial intelligence methodology
M. Piana (Genoa, IT)
- 15.30 Discussion
- 16.00 - 16.30** **Coffee Break**
- 16.30 - 18.00** **Session 5: From published evidence to clinical decision**
Chairs: X. Montalban (Toronto, CA), H. Tremlett (Vancouver, CA)
- 16.30 Overview on the methodology for clinical practice guidelines development:
From assessing the right question until the formulation of recommendations
S. Pilling (London, UK)
- 17.00 Experiences adopting and implementing GRADE methodology for treatment
guidelines
S. Otero (Barcelona, ES)
- 17.30 Discussion
- 19.00** **Summer School Dinner**

THURSDAY, 20 JUNE 2019

- 08.30 - 10.30** **Practical session - Part One**
- Group leaders: M.P. Sormani (Genoa, IT), G. Cutter (Birmingham, US),
B. Healy (Boston, US), S. Perez-Hoyos (Barcelona, ES)
- Trainers: A. Signori (Genoa, IT), F. Bovis (Genoa, IT), L. Carmisciano (Genoa,
IT), C. Tur (London, UK), E. Hernández Martínez de Lapiscina (Barcelona, ES)
statistical tests and analysis using SPSS or other statistical software

Group 1 - Session 1: Basic statistical analysis: importing data, data description, distributions, correlations, t-test, chi-square, parametric vs non parametric approaches, linear regression

Group 2 - Session 2: Logistic regression, KM and Cox model, multivariate analysis

10.30 - 11.00

Coffee Break

11.00 - 13.00

Practical Session - Part Two

Group 1 - Session 2: Logistic regression, KM and Cox model, multivariate analysis

Group 2 - Session 1: Basic statistical analysis: importing data, data description, distributions, correlations, t-test, chi-square, parametric vs non parametric approaches, linear regression

13.00 - 13.15

Conclusion and Goodbye

M. Tintoré (Barcelona, ES), M.P. Sormani (Genoa, IT)

13.15

Lunch and individual departure