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 Lapisca (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 Lapiçcina (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