



Dr Simon Day

CURRICULUM VITAE

Personal details

Name	Simon Day
Education	BSc Statistics and Computer Science PhD Design of Clinical Trials

Professional experience

Current position

- Biostatistics Expert, NDA Advisory Board

Previous positions

- 2006-2013: Staff Statistical Scientist. Roche Products Ltd
- 2005-2006: Manager Gastrointestinal, Nutritional and Blood Therapies Unit, MHRA
- 2002-2006: Manager Statistics Unit, MHRA
- 1994-2001: Manager, Clinical Biometrics, Leo Pharmaceuticals
- 1990-1994: Head of Clinical Data Services, Lilly Research Centre Ltd
- 1989-1990: Statistician, The London School of Hygiene and Tropical Medicine
- 1987-1989: Statistician, The Hospital for Sick Children, Great Ormond Street
- 1984-1987: Statistician, The London Hospital Medical College

Areas of Expertise

Simon Day is a biostatistician with general interests in clinical trials, and particularly equivalence trials, interim analyses and data monitoring committees, bioequivalence studies, development of biosimilars, development of orphan medicinal products, and the regulatory process associated with drug and biologics development.

He has run training programmes on general drug development, clinical trial design, regulatory procedures and strategy, data monitoring committees and interim analysis, equivalence and non-inferiority study designs, and general statistical issues in clinical trials.

He has wide industrial experience at senior levels and has substantial experience preparing and reviewing regulatory submission documents, briefing documents for Scientific Advice procedures and responses to regulatory agency questions, as well having represented Sponsors at meetings with European and US regulatory agencies.

Major projects

- Lead author for CHMP Guideline on Clinical Trials in Small Populations
- Joint course developer and lead presenter on FDA course on Science of Small Clinical Trials
- Joint Editor, *Statistics in Medicine* (since 2013)
- Joint Editor, *Journal of the Royal Statistical Society Series A* (2009–2012)
- President of the International Society for Clinical Biostatistics (2001–2002)

Academic/Other Appointments

- Associate on the teaching faculty at the Johns Hopkins University, Baltimore
- Chair of the External Advisory Board, Dept of Statistics, University of Oxford
- Elected Fellow of the Society for Clinical Trials (2012)

Associations

- Royal Statistical Society
- Society for Clinical Trials
- International Society for Clinical Biostatistics
- Statisticians in the Pharmaceutical Industry (PSI)
- International Conference on Rare Diseases and Orphan Drugs (ICORD)
- Drug Information Association

Publications

Approximately 100 peer-reviewed and/or invited papers, book chapters, etc., in international statistical and medical journals and textbooks; 80 shorter communications (editorials, letters, reviews, etc.) and 60 abstracts accepted at scientific meetings.

Two books:

Day S. *Dictionary for Clinical Trials*. Wiley, 2nd edition 2007.

Machin D, Day S and Green SB (Eds). *Textbook of Clinical Trials*. Wiley, 2nd edition 2006.

The complete publication list available upon request.