ROBERT HEMMINGS

PARTNER AT CONSILIUM SALMONSON AND HEMMINGS

PROFILE

Almost two decades at the heart of medicines regulation in the EU.

Expert in clinical trial design, and critical appraisal of clinical trial data. Chartered Statistician at the UK's Royal Statistical Society.

Member of the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA) for 11 years and Rapporteur for a portfolio of over 50 products.

Chaired EMA's Scientific Advice Working Party and EMA groups for Biostatistics, Modelling & Simulation and Extrapolation.

Extensive experience across all therapeutic areas, including innovative therapies, rare diseases and development of biosimilars.

An exemplary communicator. Expert in explaining technical concepts and in facilitating complex multi-disciplinary discussions.

PREVIOUS WORK EXPERIENCE

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)

A regulator for almost 20 years, I headed the group of statisticians and pharmacokineticists and represented the Agency on multiple external groups including the UK's Accelerated Access Collaborative and various initiatives on use of real world data, including the Advisory Board for IMI GetReal. My primary role at MHRA was to serve the EU regulatory network:

MEMBER OF THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) AT THE EUROPEAN MEDICINES AGENCY (EMA) FOR 11 YEARS

I was co-opted to the committee because of my expertise in clinical trial methodology and epidemiology. Fulfilling this role required active participation across the breadth of the committee's work including developing lists of questions, engaging with companies at oral explanations, in risk-benefit decisions and multiple aspects of broader regulatory policy. I managed an extensive portfolio of rapporteurships in both pre- and post-authorisation phases and co-authored multiple therapy-area and regulatory guidance documents, including those related to Conditional Marketing Authorisation, Fixed Combination Medicinal Products and Post-Authorisation

EDUCATION

BSc Mathematics, University of Nottingham.

MSc in Statistics with Applications in Medicine, University of Southampton, awarded with Distinction.

CONTACT

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(currently under development)

Efficacy Studies. I was heavily involved in the development and implementation of the EMA's PRIME scheme.

CHAIR OF THE SCIENTIFIC ADVICE WORKING PARTY (SAWP) AT THE EMA FOR 8 YEARS; MEMBER FOR A FURTHER 2 YEARS.

I chaired discussion of over 4000 Scientific Advice procedures, facilitating complex multi-disciplinary discussions and personally developing methodological standards and regulatory policy across the breadth of therapeutic indications and classes of medicinal product.

EUROPEAN MEDICINES AGENCY: MEMBER AND CHAIR OF BIOSTATISTICS WORKING PARTY, MODELLING AND SIMULATION WORKING PARTY AND EXTRAPOLATION WORKING GROUP.

I was key to developing the role of quantitative sciences in EU medicines' regulation. I served as the inaugural chair of the Biostatistics and Modelling and Simulation working parties establishing the role of these disciplines and developing methodological standards to support regulatory decision making. I co-authored multiple regulatory guidance documents, including those on adaptive designs, missing data, subgroups and extrapolation. In proposing the revision to ICH E9 and representing EU on the ICH Expert Working Group I have helped to provide a solution for improved clinical trial design and interpretation, developing the concept of the estimand and a framework for its implementation.

ASTRAZENECA

Prior to joining MHRA, I was a clinical trial statistician working in early and late phase development predominately in the oncology, respiratory and CNS therapeutic areas.

PRESENTATIONS AND PUBLICATIONS

I have written publications and have given over 200 external presentations on methodological matters, clinical topics and on regulatory policy at international meetings all around the world.