Wednesday 24 July 2024

14:00-15:30 Invited Session 7 (Main Room)

Regulators' view of randomized and non-randomized evidence in drug development (Chairs: Adbel Babiker, Giota Touloumi)

Use of Real-World Evidence in EU regulatory decision making

Andrew Thomson (European Medicines Agency, Netherlands)

This talk will discuss some of the thinking that goes into the acceptability of Bayesian methods for regulatory decision making. Specific focus will be on paediatric extrapolation, where external data is explicitly leveraged, and other designs such as Bayesian platform designs which may not leverage external information but decision making during and at the end of the trial is conducted within the Bayesian paradigm. The importance attached to Type 1 error control by regulatory agencies is well known, and the transference of this concept into the Bayesian paradigm, whilst ensuring regulatory standards are met, will be discussed.