# *Bayesian approaches in the regulation of medicines: current and future potential*

**Invited Talk by Professor Deborah Ashby, Imperial College London**

**Abstract:**

Medicines have been regulated in the UK and other jurisdictions for over fifty years. As the science underpinning new medicines has evolved, so has the regulation. ICH-E9, has endured as the main guidance for statistical principles, despite being written twenty years ago, although there are now many more detailed guidelines on particular topics. The role of Bayesian methods has also evolved, and in this talk we review where these are currently playing a role in drug regulation, and in particular their future potential in the area of benefit-risk decision-making.