BBS and EFSPI Workshop

Bayesian Drug Development through the lens of ICH M15

Why Bayes? When Bayes? And how do we know when to trust it?

Biozentrum Basel and hybrid online

December 10, 2026 - 14:00-18:00

Hybrid and F2F at Biozentrum Basel, Hörsaal U1.101

Registration and Costs: registration mandatory (will be put online soon), attendance will be free virtually, there may be a small fee when attending F2F.

Organizers:
Michael Krams (Berry Consultants), Kaspar Rufibach (Merck KGaA), Lilla Di Scala (J&J), Marisa Bacchi (AlfaSigma).

Objective of the workshop:
The workshop asks three fundamental questions: WHY BAYES? What important drug-development problems can Bayesian thinking help solve? WHEN BAYES? When is the potential gain sufficiently relevant to justify additional assumptions and model influence? HOW DO WE TRUST IT? What evidence and evaluations are needed before Bayesian information can materially influence an important development or regulatory decision? The workshop provides expert and regulatory views in how to untangle these questions.

ICH M15 may provide a useful common language for answering them. Its concepts of context of use, model influence, consequence of a wrong decision, model risk, technical criteria and proportionate evaluation provide a framework through which the value and credibility of Bayesian approaches can be considered together.

Confirmed speakers: John Scott (FDA), Representative from EMA (tentative), Andy Grieve (UCB), Nicky Best (GSK), Scott Berry (Berry Consultants), Kaspar Rufibach (Merck KGaA) and Michael Krams (Berry Consultants).

Additional participants and speaker allocations remain tentative and will be confirmed shortly.

Tentative program at a glance

Time	Session	Purpose
14:00–14:05	Opening – WHY BAYES?	Frame the drug-development problem and establish the central questions for the afternoon.
14:05–14:55	Session 1 – WHY BAYES? From the Drug-Development Problem to the Bayesian Workflow	Establish where Bayesian thinking can create genuine development value and use ICH M15 context of use to identify when additional Bayesian evidence assessment is needed.
14:55–15:45	Session 2 – WHEN BAYES? The Toolbox: Value, Risk, Influence and the Consequences of Being Wrong	Explore how the potential value of Bayesian information should be balanced against model influence, decision risk and what is at stake.
15:45–16:15	Break	30 minutes
16:15–17:05	Session 3 – HOW DO WE TRUST IT? Put It to the Test	Apply the framework to realistic development cases and ask whether the Bayesian approach provides sufficient added value – and sufficient assurance – to justify its use.
17:05–17:55	Looking Back into the Future – WHERE DOES BAYES TAKE US?	Consider which drug-development problems Bayesian approaches may solve routinely by 2036, what will remain difficult, and how regulatory assessment may evolve.
17:55–18:00	The Basel Verdict	Repeat the central questions, summarize movement in the room and close.