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Title: Regulatory Hot Topics: Non-inferiority and equivalence comparisons in clinical trials; Use of external controls and real world evidence to support regulatory decision-making

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This session will cover two topics where recent developments are underway:

Non-inferiority and equivalence comparisons in clinical trials

In 2024 the EMA CHMP published a Concept Paper on the Development of a Guideline on Non-Inferiority and Equivalence Comparisons. The draft guideline has just been published: Draft guideline on non-inferiority and equivalence comparisons in clinical trials and the deadline for comments is the end of May 2026. This is perfect timing for the revised guideline and industry comments to be discussed.

Use of external controls and real world evidence to support regulatory decision-making

The need for guidance on use of external controls and real world evidence respectively have been acknowledged by regulatory authorities. With various initiatives in progress including development of an EMA Reflection Paper and workshop on the use of external controls for evidence generation in regulatory decision-making, and MHRA guidance on the use of real-world data in clinical studies to support regulatory decisions, it is timely for this broad topic to be discussed.