



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 August 2025

EMA F2F multi-stakeholder workshop on tailored clinical approach for biosimilars

Agenda for the hybrid Workshop – 22 September 2025, Room 1A

Chair: René Anour – Vice-Chair: Niklas Ekman

Draft Agenda for Reflection Paper Workshop

<i>Intro session</i>	
<i>Session 1</i>	Tailored approach: Framework and utility of Comparative Efficacy Studies (CES)
<i>Session 2</i>	Quality comparability: Analytical, similarity approach and statistical issues
<i>Session 3</i>	Clinical studies: PK, PD, and immunogenicity aspects
<i>Session 4</i>	Overall discussion

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