

Charter: Priority Topic AI

Objective: AI will reshape drug development. We will purposefully influence this reshaping, leveraging our unique combination of drug development experience and deep quantitative expertise. We will develop a vision and strategy for embracing the opportunities offered by AI to quantitative drug developers. We will help statistical methodologists, and quantitative scientists more generally, to adopt AI sensibly and effectively as a tool, and to further our value proposition in the AI era, in close linkage with other cross-functional AI efforts in drug development.

Expected Impact: Improve the effectiveness, efficiency and decision quality in drug development, through a greater influence of methodologists and quantitative scientists more generally, on drug development strategy and decision-making.

Key stakeholders and resources		Scope, Workplan, and Deliverables	
Priority topic lead	Marc	<p>Scope: Understand how AI may reshape our work as statistical methodologists and quantitative drug developers. Purposefully influence this process, by proposing effective ways of integrating AI as a tool, as well as pertinent updates to our skill profile, ways of working, and value proposition.</p> <p>Value proposition</p> <ul style="list-style-type: none"> - Develop crisp position 2-pager → thorough publication - Run workshop / event on the topic <p>Regular engagement and visibility</p> <ul style="list-style-type: none"> - Series of “vignettes” on methodologists’ / statisticians’ use of AI (channels tbc), leading to a “collection” (2026+) - Promote this topic and the activities of this team internally in our companies (2026+) <p>Other topics</p> <ul style="list-style-type: none"> - Create overview / mindmap of AI for methodologists and statisticians - Map out a methodologists’ / statisticians’ workflow and relate AI to it (or rather: reshape it in light of AI) - Devise talent pipeline strategy, e.g. how to train the next generation of methodologists 	
Team	Baldur, David, Kaspar, Klaus, Mike, Mouna, Aris		
Working groups	<p>Value proposition: Marc, Baldur, Kaspar, David, Mouna</p> <p>Vignettes: Baldur, Klaus</p> <p>Mindmap: Marc, Klaus, Mouna</p> <p>Workflow: Kaspar</p> <p>Talent pipeline strategy: Baldur, David</p>		
Key Linkages		High-level timelines	
<p>Other priority topics: NA</p> <p>EFSPI/ASA SIGs: EFSPI Statistical Leaders</p> <p>Regulatory initiatives (e.g. Concept paper):</p> <ul style="list-style-type: none"> • FDA & EMA Good AI Practice • FDA Draft Guidance on Use of AI • EMA Reflection Paper on Use of AI 		Key Milestones	Target date
		<ol style="list-style-type: none"> 1. Position 2-pager 2. Vignettes 3. Mindmap 4. Workflow 5. Talent pipeline strategy 6. Event 7. Value proposition publication 	<ol style="list-style-type: none"> 1. 30.06.2026 2. Monthly 3. 31.08.2026 4. 31.09.2026 5. 30.10.2026 6. Q4 2026 (with BBS) 7. 31.12.2026