

Charter: Priority Topic Estimands

Objective: The group currently faces a strategic dilemma: the core technical estimand work is largely mature, but clinician engagement with the framework remains very low. We lack the evidence to confidently choose between stepping back and stepping up. This option resolves that uncertainty through a diagnostic phase before committing to

- **Path A (activate):** Launch a clinical engagement programme with concrete deliverables if diagnostic confirms clinician appetite and feasible champions
- **Path B (deprioritize):** Confirm structured deprioritization with active liaison model with EIWG if conditions are unfavourable.

Expected Impact: We ensure that whatever path we take on Estimands is grounded in evidence rather than assumption - either engaging clinicians with confidence that the conditions for success exist, or deprioritizing with confidence that we are not walking away from a solvable problem.

Key stakeholders and resources		Scope, Workplan, and Deliverables
Priority topic leads	David Wright	<p><i>More detailed information on what shall be achieved and how we intend to achieve this.</i></p> <p>Specifically, we will:</p> <ul style="list-style-type: none"> • Quantify the clinician engagement gap through a short survey (≥5 companies, ≥30 responses, in May/June) and 5–8 structured interviews with clinical/regulatory leaders (identified through EFPIA links) • Assess root causes for low engagement (e.g., perceived as jargon, no visible impact on decisions, too technical materials) • Test EIWG's appetite for a joint clinical engagement taskforce • Synthesize findings into a clear recommendation • Apply pre-agreed decision criteria after 6 months to select the path forward transparently.
Team	Previously involved: Mouna Akacha, David Wright, Kaspar Rufibach, Stefan Englert, Marcel Wolbers, Tobias Muetze, Vivian Lanius Future: As above	
Working groups	<p><i>Phase A (H12026):</i> <i>Diagnostic Taskforce - small group (3–4 people from EFSPi Stats Methods Leaders + EIWG) to design and distribute a focused survey to clinical development leads; conduct structured interviews with clinical/regulatory leaders across member companies + synthesize findings</i></p> <p><i>Phase B (Q4 2026 onwards):</i> <i>If Path A activates: Joint EFSPi–EIWG Clinical Engagement Taskforce - membership includes clinical and regulatory Estimand champions to be identified during the diagnostic phase</i></p> <p><i>If Path B confirms: No working group required — lightweight liaison model only</i></p>	

Key Linkages	High-level timelines	
<p><i>Describe here linkage to activities of other groups and stakeholders, which can support or would be impacted</i></p> <p>Other priority topics: None EFSPi/ASA SIGs: EFSPi/EFPIA EIWG, North American Estimand group EFPIA</p> <p>Regulatory initiatives (e.g. Concept paper): Possible webinar on ICH E9 (R1) being organised by Frank Petavy (EMA)</p>	Key Milestones	Target date
	<p>First align with EIWG on plans – end of May 2026 Diagnostic survey distributed to ≥5 companies – end of June 2026 5–8 clinical leader interviews completed – end of August 2026 Diagnostic report finalized and reviewed – end of September 2026</p> <p>Decision point: Path A or Path B selected – end of October 2026</p> <p>If Path A: Joint taskforce launched with ≥5 members including ≥2 non-statisticians – Q4 2026 If Path B: Quarterly liaison summaries delivered Ongoing quarterly</p>	<p>First check end of Q2 2026 with a further review to reflect on this approach at the end of 2026.</p>