



Federal Institute
for Drugs
and Medical Devices

Question to the industry panel

Question around the SAWP process

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One Scientific Question – Two Discussions?

Bridging the Clinical–Statistical Divide

Quite often **integrated question** on the design are **split into separate questions** on the **design incl. endpoints** and handling **intercurrent events** while the first is labelled clinical and the latter statistical.

- When statistical concerns affect the clinical question, how can sponsors avoid splitting “clinical” and “statistical” issues artificially?
- How can regulators help ensure that estimands, endpoints, intercurrent events, and missing data are discussed as one integrated scientific question?

Example Questions

1. Does the CHMP agree that the planned Phase 3 clinical development program for xxxxxx, including proposed design elements and endpoints, would support future registration in the proposed indication?
2. Does the CHMP agree with the estimand strategy for the primary and key secondary efficacy endpoints of the Phase 3 studies, including the handling of intercurrent events and missing data, and the estimator?