

EMA Consultation: Draft ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials, step 2b - Revision 1

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<http://www.biometricsociety.net/2017/10/21/ema-consultation-draft-ich-e9-r1-addendum-on-estimands-and-sensitivity-analysis-in-clinical-trials-to-the-guideline-on-statistical-principles-for-clinical-trials-step-2b-revision-1/>

The European Medicines Agency has released for public consultation following guidance document:

[Draft ICH E9 \(R1\) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials, step 2b – Revision 1](#)

The E9(R1) addendum aims to clarify and extend ICH E9 by elaborating on the choice of estimand and sensitivity analysis in clinical trials, providing a framework to align its planning, design, conduct, analysis and interpretation. Having clarity in the trial objectives and accounting explicitly for intercurrent events when describing the treatment effect of interest at the planning stage of a clinical trial are crucial for a clear description of the effects of a medicine.

The proposed framework aims to facilitate dialogue for the disciplines involved at the planning level of the trial and also between sponsors and regulators regarding the treatment effects of interest that a clinical trial should address. The statistical analysis, aligned to the estimand, will be associated with assumptions and data limitations, the impact of which can be investigated through sensitivity analysis, whose definition and role are clarified in this addendum.

Deadline for comments is **28 February 2018**.

The document is also available by clicking [here](#).

Comments should be provided using this [template](#) and sent to ich@ema.europa.eu.

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For more information on the European regulatory system for medicines, please consult our [brochure](#).

We would be grateful if you could disseminate this email to anyone else who might be interested in these documents.

With kind regards,

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