ICH E3 CSR Section Checklist

The 16 sections in review order. Tick each as drafted, then again at QC.

- ☐ 1. Title page: study, product, design, sponsor, dates, compliance statement
- ☐ 2. Synopsis (about 3 pages), reconciled line by line against final results
- ☐ 3. Table of contents, regenerated after final pagination
- ☐ 4. Abbreviations and definitions, maintained against final text
- ☐ 5. Ethics: IEC/IRB review, GCP statement, consent process
- ☐ 6. Investigators and administrative structure (detail in 16.1)
- ☐ 7. Introduction: the study in its development context
- ☐ 8. Objectives, in the protocol's wording
- ☐ 9. Investigational plan: design, population, treatments, endpoints, QA, statistics including estimands where E9(R1) applies
- ☐ 10. Study patients: disposition flow, protocol deviations
- ☐ 11. Efficacy: datasets analyzed, demographics, compliance, primary then secondary results as pre-specified
- ☐ 12. Safety: exposure, AEs, deaths and SAEs with narratives referenced, labs, vital signs
- ☐ 13. Discussion and conclusions: interpretation only here, no new results
- ☐ 14. Summary tables and figures cited in the text
- ☐ 15. References, matched one to one with citations
- ☐ 16. Appendices, complete per the page 2 inventory
- ☐ Cross-check: every number in text traces to a section 14 display; every display traces to 16.2 listings
- ☐ Planned vs actual: analysis changes reported with timing relative to unblinding

Appendices, Inputs and QC

Appendix inventory 16.1 to 16.4, the input set, and the pre-signoff checks.

Appendix inventory

- [ ] 16.1 Protocol + all amendments; sample CRF; IEC/IRB information; investigator lists and CVs; signatures; randomization documentation; audit certificates; statistical methods incl. final SAP
- [ ] 16.2 Patient data listings: discontinuations, deviations, exclusions from analyses, demographics, compliance, individual efficacy data, AE listings, laboratory listings
- [ ] 16.3 CRFs: deaths, other SAEs, withdrawals for adverse events; others where required
- [ ] 16.4 Individual patient data listings where the region requires them
- [ ] Appendix set paginated, bookmarked and navigable; versions match the final analysis

Inputs before results drafting

- [ ] Final protocol and every amendment
- [ ] Final statistical analysis plan
- [ ] Final TLFs from the final analysis
- [ ] Patient narratives
- [ ] Bioanalytical / PK reports where applicable
- [ ] Randomization documentation
- [ ] Appendix 16.1 administrative record

QC before signoff

- [ ] Every number verified against its source TLF
- [ ] Synopsis reconciled against results sections
- [ ] All cross-references opened and checked
- [ ] Planned vs actual checked against amendments and SAP history
- [ ] Terminology, precision and population labels consistent
- [ ] Appendix inventory reconciled
- [ ] QC findings documented and retained

eCTD placement

Module 5.3.5, granulated by study type (5.3.5.1 controlled, 5.3.5.2 uncontrolled, 5.3.5.3 pooled analyses, 5.3.5.4 other); body, appendix groups and synopsis as separate navigable documents. Post-signoff data changes go in a CSR addendum filed alongside the original.

Notes