# SCE 0910 Public Evidence Appendix

Reading trial registries

**Literature review date:** September 13, 2026

**Controlling principle.** A clinical-trial registry is a transparency and accountability record. Registration can identify a study, sponsor, developmental phase, recruitment status, prespecified outcomes, and posted results, but it is not evidence that a treatment is effective and does not constitute regulatory or registry endorsement.

## Point-by-point framework

| Controlling Point | What the field tells you | What it does not establish |
|---|---|---|
| Registration numbers | A unique identifier used to track the exact study across records and publications. | Study quality, positive results, authorization, or endorsement. |
| Sponsors | The organization or entity responsible for initiating or overseeing the study under the applicable framework. | That commercial, academic, governmental, or nonprofit funding automatically makes a study valid or invalid. |
| Study phase | The developmental stage for studies to which conventional phases apply. | Methodological quality, efficacy, or regulatory approval. |
| Recruitment status | Whether a study is enrolling, active, suspended, terminated, withdrawn, or completed. | That a recruiting treatment works or that a completed study had positive results. |
| Primary endpoint | The main prespecified outcome intended to answer the principal study question. | That later emphasis on a different outcome was prespecified or confirmatory. |
| Results posting | Whether structured study results are publicly available in the registry. | That posted results have been peer reviewed or that absent results prove a negative study. |
| IND claims | A claim concerning U.S. investigational regulatory status that requires exact product/protocol verification. | FDA approval, efficacy, endorsement, or proof that the IND applies to the treatment offered to a particular patient. |
| Why registration does not equal endorsement | Registry inclusion documents a public study record and improves transparency. | Independent validation of scientific rationale, product quality, ethics, safety, efficacy, or commercial claims. |

## Evidence-handling rules

Registry records should be cross-checked against protocols, statistical analysis plans, publications, conference reports, regulatory materials, and sponsor claims when relevant. Changed outcomes, altered time frames, inconsistent enrollment, missing adverse events, or mismatched product descriptions require explanation rather than assumption.

For MSC and extracellular-vesicle studies, the registry number does not make products interchangeable. Tissue source, donor characteristics, manufacturing, culture or isolation method, characterization, potency, dose, route, schedule, indication, and handling remain part of product identity.

## Principal references


1. 1. U.S. National Library of Medicine. ClinicalTrials.gov: Protocol Registration Data Element Definitions for Interventional and Observational Studies.

2. 2. U.S. National Library of Medicine. ClinicalTrials.gov: Results Data Element Definitions and quality-control review resources.

3. 3. World Health Organization. International Clinical Trials Registry Platform: Trial Registration Data Set and registry standards.

4. 4. International Committee of Medical Journal Editors. Clinical Trials Registration policy and recommendations.

5. 5. U.S. Food and Drug Administration. Investigational New Drug (IND) Application resources and applicable regulations, including 21 CFR Part 312.

6. 6. U.S. Food and Drug Administration Amendments Act of 2007 and 42 CFR Part 11 requirements for registration and results information for applicable clinical trials.

7. 7. International Council for Harmonisation. E6(R3) Good Clinical Practice. 2025.

8. 8. CONSORT Group. CONSORT 2025 Statement and explanatory materials addressing prospective registration, prespecified outcomes, protocol access, and transparent reporting.