

EDITION 2026.09.22-ANALYSIS-1

Define the target. Map the units.

Start with the scientific quantity or decision, then preserve the design structure that makes the analysis possible. Do not begin with a test menu.

This record supports collaboration. It is not statistical certification.

Use it to expose decisions for qualified review. It does not calculate sample size, choose a model, approve a design, establish causality, or replace a statistician or biostatistician.

Scientific question
Population or system, exposure or intervention, comparator, outcome, time point, and decision context.

Target quantity or contrast
What exactly should be described, estimated, predicted, compared, or decided?

Claim the design could support
Write the narrowest claim the study could support if the evidence is adequate.

Claim outside scope
Name the causal, population, time, outcome, or mechanism claim this design cannot establish.

Unit hierarchy

Unit	Definition in this study	Count and grouping	Dependence or repetition
Sampling unit			
Experimental or exposure unit			
Observation or measurement unit			
Analysis unit			

Design and reporting boundaries: [ICMJE](#), [STROBE](#), [ARRIVE 2.0](#), and [NIH rigor guidance](#). Apply only the sources that match the study.

ONE DEFINITION FOR ONE ANALYSIS-READY VARIABLE

Freeze the meaning. Reconcile the denominator.

A stable label can hide a changed time point, scale, transformation, aggregation, threshold, or analysis population. Record the actual data state used for every result.

Outcome or variable	Measurement and units	Analysis metric and aggregation	Time point and role	Derivation, coding, or transformation

CONSORT 2025 separates the measurement variable, participant-level analysis metric, aggregation method, and analysis time point. Use that distinction where relevant without treating randomized-trial guidance as universal. [Open source C](#).

Analysis population ledger

Stage or population	Count	Rule or reason	Timing and decision owner
Eligible or available			
Assigned, sampled, or exposed			
Observed for this outcome			
Included in primary analysis			
Included in sensitivity analysis			

Missingness and censoring
Amounts, reasons, timing, assumptions, method, and uncertainty.

Exclusions and data corrections
Rule, timing, rationale, affected units, and whether prespecified.

Outliers and influential observations
Definition, diagnostic, action, rationale, and result with or without action.

Analysis-ready data version
File or immutable identifier, date, code version, dictionary, and owner.

Outcome and population controls: [CONSORT outcomes](#), [CONSORT missing data](#), and [STROBE](#). Missing data are assumptions to document and test, not empty cells to erase.

ONE ROW FOR ONE PLANNED OR REPORTED ANALYSIS

Preserve the warrant. Expose the defaults.

A knowledgeable reader should be able to see why the method answers the target for this design and data state, then reproduce the reported result in principle.

Analysis ID and role	Target, outcome, population	Method and design warrant	Covariates, interactions, dependence	Assumptions, diagnostics, validation

☐ Primary

☐ Secondary

☐ Sensitivity

☐ Supplementary

☐ Exploratory

☐ Changed after plan

Uncertainty and decision context

Estimate and uncertainty
Effect or target estimate, scale, interval or other uncertainty measure, and interpretation.

Multiplicity
Families of questions, outcomes, time points, subgroups, models, and any control or explicit non-control.

Software and execution
Software, package, version, code or command locator, random seed where relevant, and runtime environment.

Result-changing condition
What diagnostic, assumption, sensitivity result, or alternative specification would narrow or change the claim?

Threshold warning. A p-value is not the probability that the hypothesis is true, the probability that chance produced the data, an effect size, or a measure of importance. Preserve the model, estimate, uncertainty, design, multiplicity, and scientific context. [ASA statement](#).

FROM ESTIMATE TO BOUNDED CONCLUSION

Test the dependence. Narrow the claim.

Show which assumptions and choices carry the result. Then link the scientific claim to the estimate, uncertainty, robustness record, and limitation.

Issue or assumption	Main approach	Sensitivity or alternative	Result comparison	Effect on claim

Deviation record

Plan item	What changed and when	Reason and evidence	Classification	Reporting location

Result-to-claim record

Bounded result

Analysis ID, population, estimate, uncertainty, model, and exact table or figure locator.

Robustness statement

Which sensitivity results support, narrow, or destabilize the result?

Scientific claim

State only what the design and analysis support. Preserve association, prediction, description, or causal language accurately.

Limit and next decision

What remains uncertain, how it affects use, and what decision should or should not follow?

Clinical-trial alignment and sensitivity: [ICH E9\(R1\)](#). Prespecification and exploration: [ICMJE](#) and [CONSORT](#). These sources have different scopes.

EVIDENCE CHECKED SEPTEMBER 22, 2026

Audit the chain before release.

A result can be precise, reproducible, and still answer the wrong question. Run all eight tests independently and repair the first failed handoff.

1 Target test The primary scientific question and target quantity, contrast, prediction, or decision are explicit. ☐	2 Unit test Sampling, experimental, observation, and analysis units plus dependence are named and consistent with the model. ☐
3 Outcome test Variables, metrics, aggregation, time points, coding, transformations, and primary or secondary status are traceable. ☐	4 Population test Every reported analysis count reconciles with eligibility, attrition, exclusion, missingness, censoring, and protocol deviations. ☐
5 Method test The method is warranted by the question, design, data structure, and assumptions, with software and versions recorded. ☐	6 Uncertainty test Magnitude, direction, uncertainty, multiplicity, missing-data assumptions, and material robustness checks accompany the result. ☐
7 Provenance test Prespecified, changed, supplementary, sensitivity, and exploratory analyses are distinguished with versions and reasons. ☐	8 Claim test Each central claim is linked to an analysis, estimate, uncertainty, robustness result, limitation, and stable result locator. ☐

Primary-source register

A. ASA Statement on Statistical Significance and P-Values American Statistical Association / Six principles on p-values and statistical significance Open source	B. Preparing a Manuscript for Submission to a Medical Journal International Committee of Medical Journal Editors / Methods, Statistics, Results, and Discussion Open source
C. CONSORT 2025 Item 14: Outcomes CONSORT-SPIRIT Group / Outcome definition components Open source	D. CONSORT 2025 Item 21a: Outcome Comparison CONSORT-SPIRIT Group / Primary and secondary outcome analysis methods Open source
E. CONSORT 2025 Item 21c: Missing Data CONSORT-SPIRIT Group / Planning, analysis, reporting, and sensitivity guidance for missing data Open source	F. ICH E9(R1) Addendum on Estimands and Sensitivity Analysis in Clinical Trials International Council for Harmonisation / Sections A.2 through A.6 Open source
G. STROBE Checklists STROBE Initiative / Cohort, case-control, and cross-sectional reporting checklists Open source	H. ARRIVE Guidelines 2.0 NC3Rs / Essential 10 and Recommended Set Open source
I. Rigor and Reproducibility in NIH Applications: Resource Chart National Institutes of Health / Scientific rigor and biological variables Open source	J. SAMPL Guidelines EQUATOR Network / Guiding principles and basic statistical reporting Open source

Reuse.

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Maintenance.

Recheck all primary sources after a material revision and no later than 90 days after this review. At the time of use, verify the study-specific protocol, statistical analysis plan, reporting guideline, journal instructions, software version, data slate, and any regulatory, funder, or institutional requirements.