**Nonclinical Study Report Template**

*For use with Benchling data sources (Notebook, Results, Registry, Inventory, Workflows, Attachments)*

**Instructions for use:**

* Populate only sections that have data; omit the rest without placeholders.
* Prefer structured Benchling objects (Results tables, Registry entities, Inventory lots, Workflow tasks) and include their IDs/URLs for traceability.
* Always include units, timestamps, instrument/software versions, and QC flags alongside numeric data.
* Record exclusions/deviations in the Deviations section with impact and rationale.

0) Front Matter & Metadata

* Study title; study/stage IDs; Benchling Project(s)
* Authors & roles; creation/revision dates; GLP/GMP flag; site/lab
* Linked SOPs/protocols; version history; persistent object IDs/URLs

*Change Log (example table):*

|  |  |  |  |
| --- | --- | --- | --- |
| Date | Version | Author | Description of Change |
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# 1) Executive Summary / Abstract

* Objectives, design type, population/specimen, key endpoints
* Top-line results (effect sizes/CI), major deviations/safety issues
* Brief recommendations/next steps

# 2) Background & Rationale

* Prior work and references
* Hypotheses or objectives motivating endpoints

# 3) Study Design & Governance

* Design type (exploratory/confirmatory; randomized/observational/in vivo/in vitro)
* Primary/secondary endpoints; success criteria; sample size rationale
* Randomization/stratification; blinding; allocation ratio
* Schedule/timeline; roles & approvals (IACUC/IRB/QA)

*Design Summary (example table):*

|  |  |
| --- | --- |
| Item | Details/Value |
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# 4) Materials, Subjects, and Reagents

* Organisms/cell lines/subjects (species/strain/genotype/sex/age), specimen IDs
* Reagents (name, supplier, lot, expiry), media/buffers
* Devices/instruments (model/firmware), storage & handling

*Bill of Materials (example table):*

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| --- | --- | --- | --- | --- | --- | --- |
| Category | Name/ID | Supplier | Lot | Expiry | Quantity/Unit | Notes/URL |
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# 5) Methods & Procedures

* Linked SOPs/protocols; step order & timing
* Setpoints & ranges; dosing schema; sampling plan
* Acquisition settings; preprocessing pipelines; calibration logs

*Parameter Setpoints (example table):*

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| Operation/Assay | Parameter | Target | Min | Max | Unit | SOP/URL |
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# 6) Experimental Groups / Conditions

* Group/arm names; inclusion/exclusion; allocations
* Planned vs actual doses/conditions; per-subject baseline metrics
* Record partial doses and exclusions

*Allocation & Dosing (example table):*

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| --- | --- | --- | --- | --- | --- | --- |
| Group | Subject ID | Sex/Genotype/Strain | Baseline Metric(s) | Planned Dose/Condition | Actual Dose/Condition | Notes |
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# 7) Data Capture & Quality

* Raw Results tables; variable names/units; QC flags; missingness
* Instrument calibration; assay acceptance criteria; audit trail pointers

*QC Summary (example table):*

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| --- | --- | --- |
| Metric | Result/Value | Notes/Link |
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*Data Dictionary (example table):*

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| --- | --- | --- | --- | --- | --- |
| Variable | Description | Unit | Allowed Values | Source Table | QC Flag(s) |
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# 8) Statistical Analysis Plan (SAP)

* Pre-specified tests/models; transformations; covariates; multiplicity control
* Software & version; alpha; handling of missing data/outliers

*SAP Summary (example table):*

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| --- | --- | --- | --- | --- | --- | --- |
| Endpoint | Analysis Method | Covariates | Transformations | Missing Data Handling | Alpha | Software/Version |
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# 9) Results

* Per-endpoint outputs (tables/figures), summary stats (mean/SD/CI), model outputs
* Effect sizes and p-values (if applicable), annotated units and N
* Auto-generate standardized tables/figures per endpoint

# 10) Deviations, Amendments, and Issues

* Protocol deviations; instrument failures; sample exclusions (who/when/why)
* CAPAs and impact assessment

*Deviation Log (example table):*

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| --- | --- | --- | --- | --- | --- |
| ID | Date/Time | Description | Impact | Resolution/Corrective Action | Included/Excluded |
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# 11) Safety / Ethics / Compliance

* IACUC/IRB approvals; consent/assent statements; adverse events/humane endpoints
* Data privacy and compliance statements
* Benchling’s AI features should generally leave this section in place, but empty as a placeholder for the user to fill in themselves later, as this information is generally not stored in Benchling.

# 12) Discussion

* Interpretation of results vs objectives; comparisons to prior work
* Biological/technical plausibility; sensitivity analyses

# 13) Limitations

* Design/measurement limitations; generalizability; data gaps; unmeasured confounders

# 14) Conclusions & Next Steps

* Whether success criteria met; recommended follow-ups (optimization, scale-up, validation)
* Transfer-ready parameters and decisions

# 15) References

List references in a numbered format with DOIs/URLs where available.

# 16) Appendices (Include only if data exist)

* A. Data Tables (raw/long-form) — export of Benchling Results with units & QC flags
* B. Figures & Plots — source image files + caption TSV
* C. Data Dictionary — variable name, description, unit, allowable values
* D. Provenance & Reproducibility — code/environment versions; workflow run IDs; parameter JSON; processing history
* E. Regulatory/QC Artifacts — calibration certificates; audit trail excerpts; acceptance criteria checklists

# LLM Extraction Rules (Benchling-aware)

* Prefer structured objects over free text; include object IDs and URLs.
* Surface units, instrument model/serial, software version, and timestamps with each numeric variable.
* Detect groups/arms/conditions from tags/schema fields (e.g., group, dose\_mg\_per\_kg, treatment) or columns; compute N, mean, SD/SE, 95% CI.
* Exclude rows flagged as failed/invalid; list exclusion criteria in Deviations.
* Only render a section if ≥1 relevant datum exists; otherwise omit.
* Attach provenance links and a data dictionary to support FAIR reuse and auditability.