Supplementary File 3

Prospective statistical, qualitative, mixed-methods and economic analysis plan

Version 1.4 - 17 August 2026

Companion to: Implementing a competency-based Advanced Field Epidemiology Training Programme in Sierra Leone: protocol for a mixed-methods pilot evaluation

1. Purpose and governance

This plan fixes principal estimands, denominators, preparation rules, methods, progression rules and reporting shells before enrolment. The Independent Research and Evaluation Team (IRET) owns the research database, fidelity adjudication, data locks, analysis code, interpretation and scientific reporting. Programme personnel supply source records and answer factual queries but do not change analytic classifications or locked results. Overall fidelity is the single primary outcome. Field-practice attainment, retention, acceptability, appropriateness, perceived feasibility and primary-data completeness are key secondary outcomes. Any change to the primary outcome, progression rule or principal analysis occurs before the relevant data are examined and enters the public amendment log.

2. Analysis populations

Population	Definition/use
Enrolled cohort	All residents who accept a programme place and start orientation. Used for reach, retention, interruption and graduation denominators.
Active cohort at timepoint	Residents enrolled and not permanently withdrawn at the start of the measurement window. Used for dose and milestone opportunity descriptions.
Research-consenting cohort	Residents who consent to the relevant survey/interview/linkage. Used for individual-level research analyses unless ethics approves a waiver.
Programme actor population	All assigned mentors, supervisors, faculty, assessors and programme managers. Survey response denominators report invitations and completion.
Site population	All eight accredited sites, plus invited sites when adoption is analysed.
Decision-user sample	Products with a named decision owner and purposively selected users for uptake/contribution verification.

3. Primary questions and estimands

Question	Estimand/interpretation
Q1 Fidelity	At each quarter and Month 24, among components due and applicable, what exact proportion is independently verified as met, which components and critical components meet standard, and how do results change under prespecified sensitivity rules?
Q2 Feasibility	What proportions of enrolled residents remain active and complete at least 68 qualifying weeks by Month 24 or the approved window?
Q3 Stakeholder experience	What are the stakeholder-group AIM, IAM and FIM means and distributions at each wave, and what qualitative findings explain them?
Q4 Study-process feasibility	What proportion of required primary-data fields is complete by source and wave?
Q5 Safety	What serious safety, safeguarding, privacy or integrity events occur, how quickly are they addressed and do any remain unresolved?
Q6 Readiness	Do integrated findings meet green, amber or red criteria for wider implementation?

4. Sample-size precision

The 15 residents constitute the complete first implementation cohort. The unit being piloted is the programme delivery system across residents, eight sites, mentors, supervisors, committees and support functions. No minimum detectable effect governs the design. For an observed proportion of 12/15 (80.0%), the Wilson 95% confidence interval is approximately 54.8% to 93.0%; for 13/15 (86.7%), it is approximately 62.1% to 96.3%. These intervals can identify large feasibility failures or strong performance but do not support modest effects, stable subgroup comparisons or complex adjusted models. Repeated programme-actor, site and qualitative evidence strengthens explanation but does not enlarge the resident denominator. Resident subgroup analyses remain descriptive.

5. General statistical principles

- Use two-sided 95% confidence intervals and exact denominators; do not use a p-value threshold to label pilot success.
- Report the primary outcome and every key secondary outcome even when the progression decision is clear from a critical failure.
- Describe distributions and floor/ceiling effects before choosing mean/standard deviation or median/interquartile range.
- Retain programme interruptions, transfers and extensions in cohort flow and report reasons.
- Use reproducible scripts, a locked data dictionary, version control and an analysis decision log.

- For paired resident change, a nonparametric bootstrap uses 10,000 resident-level resamples and percentile intervals when the observed distribution supports resampling. The report states the number of unique resamples. When resampling is unstable, observed paired changes and ranges are reported without a bootstrap interval.
- Suppress cells smaller than five and avoid inferential subgroup models that risk disclosure or unstable estimates.

6. Implementation fidelity analysis

The primary fidelity estimand at Month 24 is 100 × the number of due and applicable components independently adjudicated as met divided by the number due and applicable. The same calculation is reported quarterly. Components form the complete prespecified programme set rather than a sample from a wider population, so the aggregate fidelity percentage receives no binomial confidence interval. Each component's numerator, denominator, status, evidence identifiers and class are reported, and all critical components receive separate pass/fail presentation.

The primary status rule codes met as 1 and partial, not met, unknown or unresolved disagreement as 0. Not-due components are excluded from interim denominators. Not-applicable components are excluded only after written IRET adjudication and are listed with rationale. The analysis reports adherence/content, dose/timeliness, reach/coverage, quality, responsiveness and fidelity-preserving adaptation using the component mapping in Supplementary File 2 and the workbook.

Quarterly outputs include a component matrix, critical-component table, numerator/denominator table and trajectory heatmap. Programme-level components are displayed separately from resident- or site-level components. Wilson intervals apply only to resident- or site-level proportions such as field-week attainment or site accreditation, not to the 20-component census score.

Sensitivity analyses compare: unknown or disputed evidence coded as failure versus excluded; strict Month-24 timing versus approved completion windows; original-form delivery versus approved fidelity-preserving adaptation; and all due components versus components supported by the highest evidence tier. Reviewer agreement is reported as exact agreement and a disagreement table, with kappa only when status variation supports estimation. Joint displays connect component status with CFIR determinants, adaptation records, participant responsiveness, cost, equity, safety and corrective-action feasibility [27,33,36,37,43].

7. Other outcome-specific quantitative analyses

Codes	Domain	Planned quantitative output
O03	**Overall fidelity**	**Exact quarterly and Month-24 component census score; component and critical-component matrix; numerator/denominator table; status trajectory; source-quality, adaptation and timing sensitivities; reviewer agreement; no sampling CI for aggregate score.**
O01-O02, O04-O05	Reach, adoption, field weeks and retention	Counts, resident/site proportions with Wilson intervals, cohort flow, time at risk, interruptions and reasons.
O06-O08	AIM/IAM/FIM	Item distributions, scale mean/SD and 95% CI by stakeholder group/wave; internal consistency; longitudinal descriptive plots; open-text linkage.
O09-O12	Data and delivery process	Completeness, session/exercise dose, mentor contact, progression timeliness; numerator/denominator and trend.
O13-O15	Portfolio and outbreak evidence	Completion proportion, rubric distributions, authentic investigation counts, analytic-leadership proportion, timeliness and site opportunity.
O16-O20	Research, thesis and publication	Milestone completion and cumulative incidence, median actual month, delay reasons, publications by channel and status through M30.
O21	Competency change	Baseline/M12/M24 distributions, paired mean or median change, bootstrap CI and exploratory linear/ordinal mixed model if assumptions permit.
O22	Assessor agreement	Weighted kappa with confidence interval for ordinal critical decisions; two-way random-effects absolute-agreement ICC for composite score.
O23-O24	Uptake and contribution	Recommendation status proportions; verified changes by type; time to decision; contribution-strength rubric and narrative.
O25	Cost	Total/component cost and unit costs; annualized capital; payer and programme/evaluation separation; sensitivity ranges.
O26-O28	Equity, safety and sustainability	Opportunity/outcome differences; incident summaries; sustainability scorecard and qualitative explanation.

8. Denominator and timing rules

Outcome	Denominator and event rule
Field-practice attainment	Enrolled cohort; numerator completes at least 68 verified qualifying weeks by Month 24 or a preapproved completion window not exceeding three months.
Retention	Enrolled cohort; active at Month 12 and Month 24. Temporary interruption is retained and described; permanent withdrawal is not recoded as missing.
Portfolio completion	Enrolled cohort and active cohort both reported. Completion requires all eight categories and every critical criterion at least competent.

Outcome	Denominator and event rule
Outbreak requirement	Enrolled cohort; two authentic investigations and one analytic leadership role. Opportunity failure and resident-performance failure are reported separately.
Thesis/dissertation	Enrolled cohort; independent approval after defence and corrections. Approved extension status is shown separately from on-time completion.
Internal publications	Enrolled cohort; two editorially accepted/published outputs from distinct products. Submission without internal editorial acceptance does not count.
Peer-reviewed manuscript	Enrolled cohort; independently certified lead-author manuscript submitted to a legitimate journal. Acceptance/publication is tracked through M30.
Recommendation uptake	Recommendations with a named decision owner and follow-up plan; report resident-level reach and recommendation-level implementation.

9. Missing data and data-quality analyses

Primary feasibility outcomes use observed programme evidence with explicit missing and unknown categories; no imputation improves apparent feasibility. For fidelity, partial, unknown and unresolved disagreement count as not met in the primary analysis; not-applicable exclusions require written IRET adjudication. A missing source record is not assigned to resident performance. The IRET determines whether the underlying activity did not occur, the documentation failed or the status remains unknown. Survey nonresponse is reported by role and wave. Exploratory multiple imputation is considered only when missing-at-random assumptions, predictors and disclosure controls are defensible.

Data-quality analysis reports completeness, lateness, invalid values, duplicates, chronology errors, source verification, reviewer disagreement and query closure. Before each analysis, the IRET data manager issues a validation report; the fidelity lead signs the component adjudication file; and the research lead signs a read-only data lock. Programme staff receive a bounded factual-query period before lock. Any post-lock correction creates a new dataset version, correction record and rerun log.

10. Longitudinal and exploratory analyses

Resident-level repeated continuous measures may use a linear mixed model with a random resident intercept, categorical time and a parsimonious independent residual structure. A more complex covariance structure is not fitted unless the number of observations, convergence and information criteria support it. Ordinal workplace ratings may use cumulative-link mixed models only when category counts and convergence permit. All models are exploratory and usually unadjusted except for prespecified baseline score. Site effects remain descriptive because eight sites do not support stable complex multilevel estimation. When a model is unstable, the analysis defaults to paired displays, observed change estimates and transparent uncertainty.

11. Assessor agreement and assessment validity

All thesis or dissertation decisions and at least 25% of other high-stakes products are double rated. Weighted kappa is reported with the full confusion matrix only when enough observations and variation support it. Composite-score reliability uses a two-way random-effects, absolute-agreement ICC only when stable. Otherwise, exact agreement, score differences and disagreement patterns replace the coefficient. Fidelity-reviewer agreement is analyzed separately from product-assessor agreement. The assessment-validity argument links blueprint coverage, authenticity, scoring, generalization, extrapolation and decision consequences [44-46].

12. Qualitative analysis

The IRET qualitative team uses maximum variation by role, site, profession, progression and experience, with selected longitudinal reinterviews. Interviewers train in the protocol, ethics, qualitative interviewing, power dynamics, distress, confidentiality and reflexivity and remain independent from teaching, supervision, assessment and progression. Information power is judged from question and sample specificity, dialogue quality, theory and analytic strategy. The Framework Method uses CFIR, implementation outcomes, fidelity dimensions, mechanisms, adaptations, equity, burden, safety and sustainability, while open coding permits new concepts. At least 20% of transcripts per wave receive independent coding. Longitudinal engagement, triangulation, negative cases and bounded stakeholder interpretation support credibility; context supports transferability; versioned codebooks and audit trails support dependability; reflexive records and independent review support confirmability [27,38,41].

13. Mixed-methods integration

Integration occurs at design, sampling, analysis and interpretation. Joint displays align outcome estimates and component-level fidelity with qualitative explanations, adaptations, cost, equity, safety and site context. Relationships are classified as convergence, complementarity, dissonance or silence. Dissonance triggers source review, stakeholder interpretation or bounded additional analysis and remains visible [39,40].

Domain	Quantitative	Qualitative	Context	Integrated conclusion
Fidelity/field weeks	Component-level quarterly fidelity, critical status and field-week estimates	How delivery, responsiveness and field opportunity were protected or lost	Source quality, adaptations, resources and corrective action	Integrated implication
AIM/IAM/FIM	Scale distributions by role/wave	Reasons for ratings and burden	Role/site differences	Refinement priority

Domain	Quantitative	Qualitative	Context	Integrated conclusion
Outbreak/research/publication	Completion, timing and quality	Opportunity, supervision and institutional mechanisms	Equity and cost	Recoverability/scale-up
System contribution	Verified uptake and changes	Decision-maker explanation and alternative contributors	Context and sustainability	Contribution claim strength
Safety/equity	Incidents and exposure differences	Experience of inclusion, coercion or protection	Corrective action	Non-negotiable decision

14. Economic analysis

The provider-perspective analysis uses time-driven activity-based costing. The base price year is 2026. Costs are reported in constant Sierra Leonean leones and converted to United States dollars using the mean official exchange rate for the costing period. Expenditure from another year is adjusted with the official consumer price index. Loaded labour rates include salary and approved benefits; donated labour and other in-kind resources receive documented opportunity-cost values. Common overhead is allocated by recorded staff time or documented resource use. Computers use a three-year base useful life and other durable equipment five years, with straight-line annualization and a 3% annual discount rate when timing spans more than one year. Research-only evaluation costs remain separate from routine delivery so decision-makers can estimate scale-up cost. The empirical report identifies every valuation source and date range.

Category	Examples	Class	Method
Personnel – programme	Director, coordinator, faculty, mentors, supervisors, assessors, administration and finance	Programme delivery	Time logs × loaded hourly rate
Personnel – evaluation	Investigators, data management, interviews, transcription, analysis and reporting	Research only	Time logs × loaded hourly rate
Resident support	Salary/stipend where applicable, protected time, travel, accommodation, communications and field allowances	Programme delivery	Financial ledger and host contribution
Training delivery	Venue, materials, learning platform, ECHO, printing, facilitation and low-bandwidth alternatives	Programme delivery/implementation strategy	Invoice and activity log
Field investigation	Transport, communications, PPE, specimen shipment, laboratory tests and emergency logistics	Programme/service	Event-specific microcosting
Digital infrastructure	Devices, software, servers, connectivity, power backup, maintenance and security	Capital/recurrent	Purchase price, annualization and use allocation
Research/thesis	Ethics, data collection, laboratory/field costs, supervision, examination, repository and corrections	Programme/academic	Milestone-specific ledger
Publication and dissemination	Internal editorial production, journal charges where approved, conference, policy brief and stakeholder meeting	Programme/academic	Output-specific ledger
Safeguarding and learner support	Safety training, incident response, wellbeing referral, accessibility and reasonable accommodation	Programme	Case/activity ledger
Governance and quality	Committee meetings, site accreditation, calibration, audit, feedback and adaptation tracking	Implementation strategy	Activity-based ledger
Contingency	Approved unplanned costs needed to protect core functions	Programme	Authorization and ledger

Sensitivity analyses vary staff time, in-kind valuation, overhead allocation, capital useful life, discount rate, cohort size, travel intensity and publication charges. Unit costs are reported per enrollee, retained resident, graduate, completed product, authentic investigation, internal publication, submitted peer-reviewed manuscript and approved thesis or dissertation [48].

15. Equity analysis

The ethics-approved equity variables may include geography, profession/sector, gender, disability/accommodation need, site type and baseline digital or quantitative access. The analysis compares exposure before outcome: outbreak opportunity, mentor contact, specialist access, protected research time and editorial support. It then describes progression, product quality, interruptions and completion. Small cells are suppressed, categories may be combined only when substantively defensible, and results are interpreted with qualitative evidence rather than ranking individuals or sites.

16. Progression and scale-up algorithm

Criterion	Green	Amber	Red
Overall implementation fidelity	≥80% components meet standard and all critical components met	60–79% or one remediable critical component missed	<60% or unresolved failure of a critical component
Resident retention at Month 24	≥80%	60–79%	<60%
Field-practice attainment	≥80% complete ≥68 weeks	60–79% complete ≥68 weeks	<60% complete ≥68 weeks

Criterion	Green	Amber	Red
Portfolio and graduation requirements	≥80% complete all critical requirements within three months of scheduled end	60–79% or delays judged recoverable	<60% or widespread non-recoverable gaps
Mentorship dose	≥80% of planned contacts completed	60–79%	<60%
Acceptability, appropriateness and feasibility	Each stakeholder group mean ≥4.0/5 and no major unaddressed qualitative concern	Mean 3.0–3.9 or remediable concerns	Mean <3.0 or persistent major concern
Primary-data completeness	≥90%	75–89%	<75%
Safety, safeguarding and integrity	No unresolved serious event; corrective systems function	Serious event resolved with verified corrective action	Unresolved serious event, coercion, retaliation, material privacy breach or assessment/scientific-integrity failure

Decision sequence: (1) check critical safety and fidelity failures; (2) classify each criterion; (3) review data quality and uncertainty; (4) integrate qualitative concerns and equity; (5) estimate corrective-action feasibility and cost; (6) record decision and minority view. Any unresolved serious safety/integrity event or unresolved failure of a critical component prevents scale-up, irrespective of the aggregate score.

Threshold rationale: the 68-week criterion follows Advanced FETP accreditation. The 80% thresholds require delivery to most of the complete first cohort while allowing a limited recoverable interruption. A stakeholder-group mean of 4/5 represents affirmative agreement. Ninety-percent data completeness supports dependable decisions while allowing limited operational missingness. Safety, safeguarding and integrity are non-compensatory. Amber ranges identify recoverable shortfalls; red identifies widespread or unresolved critical failure. These rules are prospective pilot decision aids rather than empirically validated universal cut-offs.

17. Planned reporting shells

Output	Content
Table A	Cohort, sites, programme actors and baseline context.
Table B	Primary fidelity component matrix and exact aggregate score, every critical component, key secondary feasibility outcomes with appropriate confidence intervals, and progression classification.
Table C	Quarterly independent fidelity verification, evidence quality, adaptations, resource use, data queries and corrective action by programme phase.
Table D	Portfolio, outbreak, research, thesis and publication outcomes.
Table E	Recommendation uptake, system contribution, cost, equity and safety.
Figure A	Cohort flow and resident milestone completion.
Figure B	Quarterly fidelity and field-practice accumulation.
Figure C	AIM/IAM/FIM distributions and qualitative integration.
Joint display	Determinants, outcomes, mechanisms, adaptations and scale-up implications.

18. Analysis release and dissemination outputs

The IRET leads analysis and prepares every research output. Quarterly dashboards contain component-level fidelity, data quality, safety and corrective-action status. Formal products are a Month-12 interim report, Month-24 final implementation and scale-up report, Month-30 follow-up report, plain-language participant and site summaries, a national policy brief, the primary mixed-methods empirical article and conference outputs. Distinct secondary papers on cost or assessment are prepared only when their questions and results do not duplicate the primary article.

Before external release, NPHA and programme leaders receive a fixed 15-working-day review for factual accuracy, confidentiality, legal restrictions and third-party data rights. The review does not permit alteration of locked analyses, removal of unfavorable findings or publication veto. The IRET records comments, decisions and unresolved disagreements. Urgent safety findings follow immediate reporting duties. Supplementary File 4 gives the full audience, product, timing, lead and review plan.

19. Reproducibility and archive

The analysis repository contains the protocol, IRET terms of reference and conflicts, amendment log, data dictionary, source-evidence register, two-reviewer fidelity files, adjudication log, signed data locks, de-identification specification, quality reports, locked analysis plan, scripts, software and package versions, output log, joint displays, dissemination review log and disclosure review. Scripts use relative paths and regenerate outputs from approved datasets. Manual recoding appears in an auditable correction file.

Version record

1.1 - 21 July 2026: initial prospective protocol package. 1.2 - 17 August 2026: expanded complete-cohort rationale, model fallbacks, assessment validity, qualitative trustworthiness and economic assumptions. 1.3 - 17 August 2026: assigned analysis to an independent research and evaluation team; added fidelity estimands, no-CI rule for the component census, status and applicability rules, reviewer agreement, source-quality and adaptation sensitivities, data-lock governance, outcome reporting shells and dissemination-release controls. The corresponding

author will reconfirm study status before upload. 1.4 - 17 August 2026: final audit aligned the key-secondary outcome hierarchy, two-figure protocol, field-practice delivery component, no-CI fidelity rule and independent dissemination controls.

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