Dr. M.K. Bhan Young Medical Faculty PhD Program

FORMAT FOR CONCEPT NOTE

Based on the ICMR 4-D Classification of Medical Research

D1: DISCOVERY — Generating new biomedical knowledge
D2: DESCRIPTION — Studying health and disease in populations
D3: DEVELOPMENT — Creating and evaluating health products and technologies
D4: DELIVERY — Implementing evidence-based interventions in health systems

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Department of Health Research / Indian Council of Medical Research

HOW TO USE THIS FORMAT

Read these instructions carefully before beginning your concept note / LOI.

Purpose of This Format

This format is designed to guide medical faculty members applying to the ICMR Young Medical Faculty PhD Programme in preparing a structured, high-quality Concept Note / Letter of Intent (LOI). The format is aligned with the ICMR 4-D classification of medical research.

General Submission Instructions

Step 1: Classify your research domain: Before writing anything, complete the Domain Classification Tool in Part A. Identify your primary research domain (Discovery, Description, Development, or Delivery). Discuss your classification with your proposed supervisor/guide before proceeding.

Step 2: Use only the relevant section: Complete ONLY the section in Part B that corresponds to your identified domain (Section 1, 2, 3, or 4).

Step 3: Observe all word limits: Word limits are shown in red after each section heading, e.g., [Maximum: 300 words]. Submissions exceeding word limits by more than 10% will not be considered. Word limits apply to the candidate's written response only — not to the instructional text provided in this format.

Step 4: Check the Information Icon ⓘ **:** Right-click within the text box or click the information icon located next to each section heading to view guidance notes for completing that section.

Step 5: Use the Outcome Definition Table: All sections include an Outcome Definition Table. This must be completed with the primary and secondary outcomes of your proposed study. Do not leave it blank.

Step 6: Prepare the Gantt Chart: Include a Gantt chart for your entire proposed research timeline (maximum 5 years). All major milestones must be clearly labelled and mapped **objective-wise**. Follow the provided Gantt chart format, the final document must be uploaded in PDF format, with a file size not exceeding 1MB.

Step 7: Cite appropriately: Provide a Bibliography (maximum 20 references) in Vancouver format. Cite references within the text using superscript numbers.

About the ICMR 4-D Framework

The 4-D framework was adopted by ICMR to classify research grants into four complementary domains. Together, these four domains encompass the full translational spectrum of medical research — from laboratory discovery to clinical development and community delivery.

The PhD research framework is based on the same framework. It is designed to ensure that research proposals are evaluated using criteria appropriate to their domain, and that candidates receive feedback aligned with the nature of their work.

⚠ NOTE: The 4-D Classification Tool in Part A must be completed before submitting your concept note. Submissions without a completed classification tool will not be reviewed.

PART A: 4-D DOMAIN CLASSIFICATION TOOL

Complete this tool before writing your concept note. Identify your primary research domain and proceed to the corresponding format in Part B.

A.1 Understanding the ICMR 4-D Framework

The Indian Council of Medical Research classifies medical research into four domains, known as the 4-D framework. Every research proposal submitted under the Young Medical Faculty PhD Programme must be classified into one of these four domains. Your choice of domain determines the format you must follow and shapes the kind of scientific contribution expected from your thesis.

Table A1: Overview of the ICMR 4-D Research Domains

Domain	Core Question Answered	Primary Research Intent	Typical Study Designs	Some Illustrative Examples
DISCOVERY (Section 1)	What are the biological mechanisms, biomarkers, molecular pathways, or causal agents?	Generate new scientific knowledge through experimental, molecular, or translational research	Laboratory / experimental studies; omics; cohort for biomarker discovery; translational studies; systems biology	Novel biomarker for preeclampsia; antibiotic resistance mechanism; microbiome–disease associations; AI-driven drug target discovery
DESCRIPTION (Section 2)	What is the distribution, frequency, or determinants of health and disease in a population?	Measure and characterize health phenomena in defined populations using observational methods	Cross-sectional; cohort; case–control; surveillance; registry-based; ecological / correlational	Prevalence of hypertension in urban slums; clinical profile of MDR-TB; disease burden estimation; risk factor analysis
DEVELOPMENT (Section 3)	Can we develop, formulate, or evaluate a new product(s)/tool(s)/ intervention(s) for optimal health across life course?	Create or evaluate something new — a drug, vaccine, diagnostic, device, or health technology	Pre-clinical studies; Phase I–III clinical trials; diagnostic accuracy studies; device validation; HTA	Phase I safety of novel antifilarial; sensitivity/specificity of rapid dengue diagnostic; nanoparticle drug delivery pre-clinical evaluation, Efficacy of interventions to improve birth outcomes
DELIVERY (Section 4)	How do we effectively deliver evidence-based interventions in real-world health systems?	Bridge the evidence-to-practice gap through implementation and health systems science	Hybrid effectiveness-implementation trials; stepped-wedge; mixed-methods; programme evaluation; CBPR	Barriers to DOTS implementation; CHW-led mHealth strategy for diabetes; process evaluation of hospital infection control

A.2 Module 1: Core Classification Questionnaire

Answer ALL FOUR questions (Q1–Q4) independently. Base your answers strictly on the PRIMARY aim of your proposed PhD research — not on secondary or supporting elements. Mark YES or NO for each question.

⚠ **NOTE: Multiple YES answers are possible if your research spans more than one domain. In that case, identify the domain that best reflects your PRIMARY thesis aim. Consult your proposed supervisor before finalising your domain classification.**

Table A2: Domain Classification Questionnaire

Q#	Question	Your Research Domain if YES	Mark YES / NO
Q1	Is the PRIMARY goal of your proposed research to discover or generate NEW knowledge about biological mechanisms, molecular pathways, pathogens, disease processes, or biomarkers — using experimental, molecular, omics, systems biology, or translational approaches?	**DISCOVERY (Section 1)**	□ YES □ NO
Q2	Is the PRIMARY goal of your proposed research to measure, describe, or quantify the frequency, distribution, patterns, or determinants of health outcomes or disease in a defined population — using observational designs (cross-sectional, cohort, case-control, surveillance, or registry-based)?	**DESCRIPTION (Section 2)**	□ YES □ NO
Q3	Is the PRIMARY goal of your proposed research to develop, formulate, optimise, or clinically evaluate a new or improved health product, intervention, diagnostic test, medical device, or health technology — including assessment of its safety, efficacy, performance, or cost-effectiveness?	**DEVELOPMENT (Section 3)**	□ YES □ NO
Q4	Is the PRIMARY goal of your proposed research to understand how, where, when, or why an evidence-based intervention is (or is not) being implemented, adopted, sustained, or scaled up in real-world health systems or community settings — using implementation science frameworks and methods?	**DELIVERY (Section 4)**	□ YES □ NO

A.3 Domain Selection Guide

- **One "YES" only:** Proceed directly to the format for that domain in Part B.
- **More than one "YES":** Your research may span multiple domains. Identify the domain that best reflects the PRIMARY aim of your thesis — the domain whose research question is most central to your hypothesis and objectives. The other domains may inform your study but are secondary.
- **No "YES":** Your research question may not be clearly framed yet. Discuss with your proposed supervisor and revisit the question after refining your research idea.

A.4 Disambiguation Guide for Borderline Cases

If you are uncertain about your domain after completing the questionnaire, use the table below to resolve common ambiguous situations:

Table A3: Disambiguation Guide

Borderline Situation	Classification Guidance
My study collects epidemiological data AND measures biomarkers	*If the primary aim is to characterise biomarkers and understand mechanisms → Discovery.* *If the primary aim is to estimate burden or determine risk factors in a population → Description.*

	Choose based on which question drives your PRIMARY hypothesis and objectives.
My study evaluates an intervention in patients	*If the intervention is a NEW drug, vaccine, diagnostic, or device and you are testing safety/efficacy → Development.* *If the intervention is already evidence-based and your focus is on HOW to deliver it → Delivery.*
I am using AI / machine learning methods	*Developing and validating a new AI model for disease prediction or diagnosis → Development.* *Using AI/ML as a tool to answer a biological discovery question → Discovery.* *Using AI for health systems optimisation or programme monitoring and your focus is on HOW to deliver it → Delivery.*
I want to study both biological mechanisms AND epidemiology	*Choose Discovery if the primary question is mechanistic (What is the pathway or biomarker?).* *Choose Description if the primary question is population-level (What is the burden or risk factor?).*
I am conducting a health systems intervention study	*Delivery, if the intervention is already evidence-based and the focus is on implementation.* *Development, if the health systems intervention is NOVEL and its effectiveness is being assessed for the first time.*
I am building a disease registry or cohort	*Description, if the primary purpose is to describe disease burden, natural history, or epidemiology.* *Discovery, if the primary purpose is biological discovery using cohort samples (biomarkers, omics, mechanisms).*
I am conducting a programme evaluation	*Delivery, if the evaluation focuses on implementation outcomes (fidelity, uptake, sustainability).* *Description, if the evaluation primarily measures health outcomes in a population (burden reduction, coverage rates).*

A.5 Module 2: Domain Confirmation Checklist

After identifying your domain using the questionnaire above, verify your classification using the confirmation checklist below. Tick all boxes that apply to your research. A majority of ticks in one domain confirms your classification. Share this completed checklist with your proposed supervisor.

DISCOVERY — Confirmation Checklist

Tick all that apply to your proposed research:

□ My study uses laboratory, molecular, or experimental methods (wet lab, omics, bioinformatics, imaging)

□ The primary output will be new biological knowledge (mechanisms, biomarkers, causal pathways, or novel disease insights)

□ My study tests a biological hypothesis or aims to generate one (hypothesis-generating exploratory discovery)

□ My study will use human samples or cell lines primarily to answer a biological or mechanistic question

□ Methods may include: genomics, transcriptomics, proteomics, metabolomics, microbiome, pathogen discovery, AI/bioinformatics

DESCRIPTION — Confirmation Checklist

Tick all that apply to your proposed research:

□ My study uses an observational design (cross-sectional, cohort, case-control, surveillance, registry, or ecological)

□ The primary output will be epidemiological data (prevalence, incidence, risk factors, distribution, natural history) and/or qualitative analysis to answer the 'why' question

□ My study does not involve testing a new intervention, product, or implementation strategy

□ The study will inform health policy, clinical guidelines, or programme planning through epidemiological evidence

□ Outcomes are measured at the population or clinical level (rates, proportions, associations, distributions)

□ Methods may include: structured interviews, validated questionnaires, clinical record review, laboratory testing for exposure/outcome assessment, clinical examinations for exposure/outcome assessment, qualitative methods (in-depth interviews, FGDs, observation), mixed methods

DEVELOPMENT — Confirmation Checklist

Tick all that apply to your proposed research:

□ My study involves developing, formulating, or manufacturing a new product or technology (drug, vaccine, diagnostic, device)

□ My study tests safety, tolerability, dose, pharmacokinetics, or efficacy of a new product or intervention

□ My study has regulatory dimensions (DCGI/CDSCO IND, CTRI registration etc.,)

□ The primary output will be safety/efficacy/performance data about a specific product or technology

□ My study involves a defined comparator (placebo, standard of care, or reference standard)

□ Methods may include: pre-clinical studies, Phase I–III trials, diagnostic accuracy studies, device bench testing, health technology assessment

DELIVERY — Confirmation Checklist

Tick all that apply to your proposed research:

□ The intervention I am studying is already proven effective; my focus is on HOW it is delivered in practice

□ My study involves working with health systems, health workers, patients, or communities to improve delivery

□ My study uses or plans to use implementation science frameworks (Eg., RE-AIM, CFIR, COM-B, Proctor taxonomy)

□ The primary output will inform scale-up, policy adaptation, or programme improvement

□ My study uses mixed methods or qualitative methods (in-depth interviews, FGDs, observation) alongside quantitative data

□ Methods may include: hybrid trials, cluster randomized trials, stepped-wedge, process evaluation, interrupted time series, programme evaluation

⚠ NOTE: Complete this tool before beginning Part B. Record your selected domain here:
Selected Domain: _____

PART- B; SECTION 1: DISCOVERY RESEARCH

Discovery: Generation of new scientific knowledge through basic and translational research. Includes identifying disease mechanisms, novel biomarkers, pathogens, molecular pathways, and risk factors.

1.1 Title

[Maximum: 25 words]

The title should be concise but informative and clearly indicate:

- What is being studied (e.g., biomarker, disease mechanism, pathogen, molecular pathway)
- Who or what population/system is involved (e.g., pregnant women, newborns, cohort specimens)
- The scientific approach or key outcome (e.g., 'a prospective cohort study', 'using whole-genome sequencing')

1.2 Abstract

[Maximum: 250 words]

Structure the abstract around the following five elements:

- Problem – What is the major scientific gap or unmet knowledge need?
- Question – What do you want to discover or elucidate?
- Approach – How will you discover it (broad methodology, study design)?
- Innovation – What is new about this work (new technology, unique cohort, novel question)?
- Impact – Why will the discovery matter (scientific, clinical, or policy significance)?

1.3 Background

[Maximum: 400 words]

Briefly describe the scientific problem and the knowledge gap. Avoid an exhaustive literature review; instead, synthesize the key evidence. Include:

- Current understanding of the disease/condition or biological phenomenon
- Key published findings (brief synthesis, not exhaustive citations)
- Major limitations in existing knowledge — what is unknown?
- Why this specific research is needed now (urgency, feasibility, new technology, or unique access)

Suggested structure: Burden of disease → Gaps in mechanistic understanding → Absence of validated biomarkers or predictive tools → Translational need

1.4 Rationale for the Study

[Maximum: 300 words]

Elaborate on why this research is necessary and timely. Address:

- Why the problem requires new scientific discovery (not descriptive data alone)
- How your study could advance the frontier of scientific knowledge
- Why the population, cohort, biological samples, or data source is unique or particularly valuable
- Relevance to local, national, and international scientific and clinical context

Examples of strong rationale elements: Unique patient cohort with longitudinal follow-up; Access to advanced omics or AI platforms; Large biobanked sample sets; Strong translational potential from bench to bedside

1.5 Research Question

[Maximum: 100 words]

Based on the Background and Rationale, state the primary Research Question. It should clearly frame the scientific problem your research will address.

The Research Question must satisfy the FINER criteria: Feasible, Interesting, Novel, Ethical, and Relevant.

A well-formed discovery research question typically includes:

- The health condition or biological phenomenon under study
- The population, cohort, or biological system
- The factor being investigated (mechanism, biomarker, pathogen, risk factor, molecular pathway)

1.6 Hypothesis

[Maximum: 200 words]

State clearly whether your research is (i) hypothesis-driven or (ii) exploratory discovery (hypothesis-generating). Choose ONE of the following sub-sections:

Provide a dropdown option for applicants to select the appropriate hypothesis (i) or (ii). Based on the selected option, the corresponding text box should be enabled, and the relevant guidance for that hypothesis should be displayed under the information icon .

1.6.1 Hypothesis (for hypothesis-driven research)

A hypothesis is a testable scientific presumptive statement based on existing evidence or theory. It proposes a possible explanation or relationship that the study will evaluate.

- Write ONE primary hypothesis (the study is centred around this)
- The statement must be specific and testable
- Link biological mechanisms, exposures, or predictors to measurable outcomes
- You may add 1–2 supporting secondary hypotheses

Common patterns: *'Because [biological mechanism], [intervention/exposure] will result in [outcome]' OR '[Exposure/molecular factor] is associated with [outcome] in [population]'*

1.6.2 Exploratory Discovery Question (for hypothesis-generating research)

If the study is primarily exploratory (no strong prior evidence to form a testable hypothesis), state clearly that the study aims to generate a hypothesis. *Example:*

"This study aims to discover novel [biomarkers / biological mechanisms / microbial risk factors / molecular pathways] associated with [disease / outcome] in [population / system], with the intent to generate testable hypotheses for future confirmatory research."

1.7 Research Strategy / Approach

1.7.1 Objectives

[Maximum: Primary Objective: 100 words | Secondary Objectives (2–4): 250 words total]

(i) Primary Objective — The central purpose of the study, consistent with the primary hypothesis or exploratory research question. Include:

- An action verb (identify, discover, characterise, determine, evaluate, investigate, assess)
- What is being studied (the biomarker, mechanism, pathogen, risk factor, etc.)
- The outcome or relationship of interest
- The population, cohort, or biological system

(ii) Secondary Objectives (2–4) — These should address additional dimensions of the research problem (*e.g., mechanistic sub-questions, validation in a secondary cohort, subgroup analyses, translational endpoints*). Each must be clearly achievable within the study.

No need for a text box here instead a table with columns for primary objective with 100 words and secondary objectives (2-4) with 250 words can be in inserted.

Objective Type (Primary/Secondary)	Text Field
(Primary/Secondary)	

1.7.2 Study Design

[Maximum: 300 words]

Describe the overall study design and provide a study flow overview. Specify the design type:

- Prospective / retrospective cohort study for biomarker discovery
- Cross-sectional study for prevalence of molecular markers
- Case–control study for aetiological discovery
- Experimental (in vitro / in vivo / ex vivo) study
- Systems biology / omics discovery approach (unsupervised or supervised)
- Translational study (combining clinical specimens with experimental validation)

Justify the chosen design and describe the study flow: how participants/samples will be enrolled/collected, processed, and analysed.

1.7.3 Outcomes

[Maximum: 300 words + Outcome Definition Table below]

(i) Primary Outcome — Ideally one primary outcome directly linked to the central research question. This is the main variable that directly addresses the core hypothesis or discovery aim. Specify:

- What will be measured (biomarker level, gene expression, pathway activation, pathogen load, etc.)
- How it will be measured (assay, technique, platform, unit of measurement)
- When it will be measured (timepoint, sample type)
- For hypothesis-driven research: state the expected effect size and whether the study is powered for this outcome

(ii) Secondary Outcomes (2–4) — Additional variables that support, extend, or provide context to the primary outcome. These may include mechanistic endpoints, subgroup analyses, exploratory biomarkers, or translational readouts.

Complete the Outcome Definition Table for all proposed outcomes:

Outcome Type (Primary/Secondary)	Outcome Name	Outcome Description (operational definition)	Measurement Method / Tool	Timepoint(s)	Unit / Scale & Cut-off (if applicable)

1.7.4 Study Population or Samples

[Maximum: 250 words]

Describe:

- Participant/sample recruitment: setting, eligibility criteria (inclusion and exclusion), timing
- Biological samples to be used or collected: type (blood, tissue, urine, stool, biopsy, cell lines, animal tissue), volume/quantity, and timing of collection

- If using an existing biobank or cohort: describe the biobank/cohort, sample availability, and ethical permissions for use

1.7.5 Data and Sample Collection

[Maximum: 300 words]

Describe the type of data and samples to be collected, and the time points:

- Clinical data: relevant clinical variables, data sources (medical records, CRF, wearables)
- Environmental or exposure data (if applicable): source, measurement
- Biological samples: collection protocol, processing (centrifugation, aliquoting), storage conditions (temperature, biobanking), labelling, and chain of custody
- Existing datasets: describe the dataset, access permissions, and data governance

1.7.6 Experimental Methods / Analysis

[Maximum: 350 words]

Describe the laboratory techniques, experimental methods, and computational tools to be used (wherever applicable). Include:

- Molecular biology / laboratory techniques: sequencing (WGS, RNA-seq, 16S), proteomics, metabolomics, ELISA, PCR, flow cytometry, imaging, histopathology
- Omics platforms and bioinformatics pipelines: specify tools, databases, and analytical workflows
- Computational / AI methods: machine learning models, network analysis, pathway enrichment
- Quality control measures: assay validation, internal controls, batch effects, reproducibility

Justify the choice of methods in relation to the research question and available resources.

1.7.7 Data Management

[Maximum: 200 words]

Describe the systems and procedures for managing the study data. Include:

- Data entry system: paper-based or electronic (REDCap, Excel, custom database); specify the software
- Data cleaning: handling of missing values, outliers, and inconsistencies
- Data validation: double data entry, automated range checks, audit trails
- For biological/omics data: sample tracking systems (barcode-based), LIMS if applicable
- Integration of laboratory data with clinical datasets: linkage strategy and quality assurance
- Data security, backup, and access control

1.7.8 Data Analysis Plan

1.7.8.1 Basis of Sample Size Estimation

[Maximum: 300 words]

Justify the proposed sample size appropriately for the type of discovery research:

- For exploratory / hypothesis-generating studies: a formal power-based calculation may not be feasible. Justify using: ability to detect preliminary signals; expected number of outcome events; precedent from similar discovery studies; available specimens or feasibility constraints; precision of preliminary estimates
- For biomarker or omics studies (two-stage discovery): justify the use of a discovery set (initial signal detection) and a validation set (independent cohort for reproducibility)
- For case-control discovery studies: provide the standard formula for proportions or means

Your sample size narrative should address: Why is this number reasonable? Is the study discovery or confirmatory? Is there a validation plan? Are dropout and poor-quality samples accounted for?

1.7.8.2 Plan of Analysis

[Maximum: 300 words]

Describe the analytical strategy for the primary and secondary outcomes. Include wherever applicable:

- Statistical methods: descriptive statistics, inferential tests, regression modelling, survival analysis, mixed models
- Omics / bioinformatics analysis: differential expression, enrichment analysis, network analysis, dimensionality reduction, clustering
- Validation strategies: internal cross-validation, bootstrap, independent validation cohort
- Machine learning models: algorithm choice, training/validation/test split, performance metrics (AUC, sensitivity, specificity, F1)

1.8 Reporting of Results

[Maximum: 100 words]

Briefly describe how the results will be reported and justify the approach. Include:

- Reporting guidelines to be followed *(e.g., STROBE for observational studies; TRIPOD for prediction models; MIQE for qPCR; MIAME for microarray)*

1.9 Ethical Considerations

[Maximum: 250 words]

If the concept note is selected, funding will be released only upon obtaining Institutional Ethics Committee (IEC) approval. All research involving human participants, animals, biological materials, or identifiable data must receive prior approval from the relevant committees.

Describe:

- Ethics Review: Specify the Institutional Ethics Committee (IEC) for human samples/data and Institutional Animal Ethics Committee (IAEC), if applicable. Indicate approval status (obtained/pending/to be applied).
- Use of Biological Materials/Data: Clearly describe the type and source of biological samples (e.g., blood, tissue, genomic data) or datasets and their intended use. Confirm that appropriate permissions for collection, storage, and future use (including biobanking) will be obtained.
- Informed Consent: Describe consent procedures, including provisions for broad or tiered consent for future use of samples/data. Justify any waiver of consent for de-identified retrospective datasets, if applicable.
- Privacy and Confidentiality: Outline safeguards such as coding/anonymisation, restricted access, and secure storage, particularly for sensitive genetic data.
- Risks and Benefits: Address potential informational risks (e.g., privacy breach, stigma) and expected scientific and societal benefits.
- Biobanking and Data Sharing: Describe governance for sample storage, duration, access, and any plans for data/sample sharing, including appropriate agreements.
- Vulnerable Populations: If applicable, describe additional safeguards and justification for inclusion (e.g., pregnant women, children, endangered/marginalised groups, etc.).

1.10 Expected Outcomes / Deliverables

[Maximum: 100 words]

State clearly what will be known or achieved at the end of this study if all objectives are met. Include: new biological knowledge generated; validated biomarkers, mechanisms, or tools; data outputs (datasets, models); publications and conference presentations expected.

1.11 Detailed Project Timeline (Gantt Chart)

Present a month-by-month Gantt chart for the full project duration (maximum 5 years). Include all major activities: ethics approval, participant recruitment / sample collection, laboratory analysis, bioinformatics / computational work, data analysis, thesis writing, and submission.

⚠ NOTE: The Gantt chart may be inserted as a table within the document or as an embedded Excel/PowerPoint figure. Ensure all major milestones are clearly labelled.

1.12 Bibliography

List all references cited in the concept note in Vancouver format. Maximum 20 references.

PART- B; SECTION 2: DESCRIPTION RESEARCH

Description: Studying the distribution, frequency, patterns, and determinants of health and disease in defined populations using observational epidemiological methods.

2.1 Title

[Maximum: 25 words]

The title should be concise but informative and clearly indicate:

- What is being described (e.g., prevalence, incidence, distribution, clinical profile, natural history, risk factors)
- Who or what population (*e.g., pregnant women, newborns, hospital patients*)
- Location and time (*e.g., 'in a tertiary care hospital in North India, 2024–2026'*)
- Study design, if informative (e.g., *'a cross-sectional study', 'a prospective cohort'*)

2.2 Abstract

[Maximum: 250 words]

Structure the abstract around the following five elements:

- Problem – What is the major epidemiological gap or unmet descriptive knowledge?
- Question – What do you want to describe, quantify, characterize or explain?
- Approach – How will you describe it (study design, quantitative/qualitative/mixed approach, population, data sources)?
- Innovation – What is new (unique population, novel data source, contemporary data, new methodology)?
- Impact – Why will the descriptive data matter (policy, clinical practice, programme planning)?

2.3 Background

[Maximum: 400 words]

Briefly describe the public health problem and the knowledge gap. Include:

- Current understanding of the disease/condition at global, national, and local levels
- Key published findings (brief synthesis, not exhaustive)
- Major limitations in existing knowledge (outdated data, missing populations, methodological gaps)

2.4 Rationale for the Study

[Maximum: 300 words]

Elaborate on why this descriptive research is necessary. Address:

- Why new descriptive data is needed now (data gaps, practice/policy need, changing epidemiology*)*
- Why your setting or population, is unique, valuable, or practice/policy-relevant
- Local, national, and international relevance
- Clinical, policy, or programmatic importance of the proposed findings

Suggested structure: Current global/national evidence → Gaps in local/regional knowledge → Need for updated or context-specific data → Practice/Policy/Programme relevance

2.5 Research Question

[Maximum: 100 words]

Based on the Background and Rationale, state the primary Research Question. It should clearly frame the descriptive problem your study will address.

The Research Question must satisfy the FINER criteria: Feasible, Interesting, Novel, Ethical, and Relevant.

A well-formed description research question typically:

- Can be descriptive or analytical depending on the primary focus of the study
- Is measurable using the proposed study design and data
- Clearly defines the population, the variables (outcome/exposure) of interest, and the study context

2.6 Hypothesis

[Maximum: Not required for pure descriptive studies]

In purely descriptive studies (cross-sectional, case series), a formal hypothesis establishing a cause–effect relationship is not required. Leave this section blank or write 'Not applicable – descriptive study'.

If your study has an analytical component (e.g., comparing risk factor prevalence between sub-groups, or testing the association between an exposure and an outcome), state your analytical hypothesis here using the PECOT format. PECOT stands for: Population, Exposure, Comparison, Outcome, and Time.

P – Population/Patient/Problem: The patient group or problem of interest.

E –Exposure: The treatment, exposure, or action being considered.

C – Comparison: The alternative or control (e.g., usual care, placebo, different expsoure/treatment, or no treatment).

O – Outcome: The desired or measured effect (e.g., symptom reduction, improved diagnosis, lower mortality).

T – Time: The timeframe to assess the outcome or duration of study.

2.7 Research Strategy / Approach (Dropdown option should be given to select Descriptive/Analytical Study. Based on the selection Outcome table and Exposure table will change. If it is a descriptive study only **Outcome table** will open up and in case of analytical study both **Outcome table and Exposure table** should open up.

2.7.1 Objectives

[Maximum: Primary Objective: 100 words | Secondary Objectives (2–4): 250 words total]

(i) Primary Objective — The central purpose of the study, consistent with the primary research question, driving the study design and sample size. Use the format:

Quantitative: "To [describe / estimate / assess / characterize] the [main variable] among [population] in [location] during [time period]."

Qualitative: "To [explore/understand/describe/explain/examine] the [main variable] among [population] in [location] during [time period]."

Include:

- An action verb (describe, estimate, assess, characterise, determine, measure, document, explore, understand, explain etc.)
- The variable/domain of interest (prevalence, incidence, mortality, clinical profile, risk factors, experiences, perceptions etc.)
- The population (with eligibility criteria)
- Location and time period

(ii) Secondary Objectives (2–3) — Address additional dimensions: distribution patterns, sub-group differences, factors associated with the outcome, health-seeking behaviour, or validation of measurement tools.

No need for a text box here instead a table with columns for primary objective with 100 words and secondary objectives (2-4) with 250 words can be in inserted.

Objective Type (Primary/Secondary)	Text Field
(Primary/Secondary)	

2.7.2 Study Design

[Maximum: 300 words]

Specify the type of observational study, its purpose, setting, duration, and justification. Clearly mention the design and justify its suitability:

- Cross-sectional study: for prevalence estimation at a single time point
- Case series: for characterising clinical features in a small group of patients
- Observational cohort: for documenting natural history or longitudinal changes over time & to estimate the association between exposure and outcome
- Case – control study: to estimate the association between exposure and outcome

Describe the study site (community / hospital / school / clinic / laboratory), target and source population, and time-frame (start and end dates, duration).

Specify the approach (quantitative/qualitative/mixed method/multi-method).

2.7.3 Outcomes

[Maximum: 300 words + Outcome Definition Table below]

Quantitative outcomes in description research are the variables that will be measured and described (e.g., prevalence, incidence, rates, distributions, clinical characteristics, risk factor frequencies).

(i) Primary Outcome — Directly linked to the central research question and drives the sample size. Specify: What will be measured; How it will be measured; When it will be measured; Unit/scale; Cut-offs.

(ii) Secondary Outcomes (2–3) — Additional variables providing context, sub-group detail, or mechanistic insight to the primary outcome.

Complete the Outcome Definition Table for all proposed outcomes:

Outcome Type (Primary/Secondary)	Outcome Name	Outcome Description (operational definition)	Measurement Method / Tool	Timepoint(s)	Unit / Scale & Cut-off (if applicable)

Outcomes in qualitative research are interpretive insights providing a deep understanding of human behaviors, experiences, and social contexts. These may include themes and patterns, theory development, actionable insights, narratives etc.

2.7.4 Exposures (in case of analytical study)

[Maximum: 300 words + Exposure Definition Table below]

Exposures in description research are the variables that will be measured and used to link to the outcome (e.g., risk factors – socio-demographic, clinical, behavioral, structural etc).

Complete the Exposure Definition Table for all proposed exposures:

Exposure Name	Exposure Description (operational definition)	Measurement Method / Tool	Timepoint(s)	Unit / Scale & Cut-off (if applicable)

2.7.5 Study Population or Samples

[Maximum: 250 words]

Describe:

- Target population (whom does the study aim to generalise to?) and source population (from whom will participants actually be recruited?)
- Eligibility criteria: inclusion criteria (defining who qualifies) and exclusion criteria
- Recruitment strategy: site, method (consecutive enrolment, random sampling, cluster sampling, purposive sampling), timing
- Biological and other samples (if applicable): type, volume, timing, processing, and storage

2.7.6 Data and Sample Collection

[Maximum: 300 words]

Clearly specify the data collection methods, tools, and time points. Describe:

- Clinical data: relevant variables, collection procedures, measurement instruments
- Socio-demographic/behavioral/exposure-related data: relevant variables, collection procedures, measurement instruments
- Qualitative data: collection procedures (in-depth interviews, focus group discussion, observations)
- Data sources: medical records, hospital information systems, environmental exposure data, public datasets
- Biological and other samples (if applicable): type (blood, urine, stool, swabs), collection timing, processing, storage
- Data collection tools: structured questionnaires, interview/FGD guides, observation check-lists; specify whether validated instruments are used; if not, describe the development and pretesting plan

2.7.7 Measurement Methods

[Maximum: 350 words]

Provide information on measurement procedures. Include standardisation, pretesting, and validation where applicable:

- Clinical measurements: specify variables, measurement tools, standardisation protocols, inter-rater reliability measures
- Laboratory measurements: sample type; collection (fasting/non-fasting, timing); processing (centrifugation, aliquoting); storage (temperature, duration); assay techniques (ELISA, PCR, biochemistry, microbiology); quality control measures
- Questionnaire / interview data: describe pretesting, translation, back-translation (if applicable), and validation status of tools
- Computational / AI methods (if applicable): specify analytical platform and validation approach

2.7.8 Data Management

[Maximum: 200 words]

Describe:

- Data entry system: paper-based or electronic (REDCap); specify software
- Data storage: quantitative and qualitative (interviews, audio, notes); specify software
- Data cleaning: handling missing values, outliers, and inconsistencies
- Data validation: double data entry, automated range checks, audit trails
- For biological data: sample tracking (barcode systems), integration of lab with clinical data
- Data security, backup procedures, and access control

2.7.9 Data Analysis Plan

2.7.9.1 Basis of Sample Size Estimation

[Maximum: 300 words]

Provide a clear and justified description of the proposed sample size. Use the method appropriate to the research question (prevalence, mean, rate, proportion). Include:

- Formula used (state the standard formula for proportions or means, as applicable)
- Assumptions used: expected prevalence or mean; source of estimate (published literature, pilot study, surveillance, registry data)
- Desired precision (confidence interval half-width or margin of error)
- Confidence level (typically 95%)
- Design effect (if cluster sampling is proposed, justify the DEFF used)
- Adjustment for non-response or missing data (typically 10–20%)
- Final proposed sample size (stepwise calculation shown)

If no prior estimates are available, state this explicitly and justify the assumptions adopted.

For analytical observational studies, calculate sample size using target effect size (eg., OR, RR)

2.7.9.2 Plan of Analysis

[Maximum: 300 words]

Describe the statistical analytical strategy, including statistical software. Include where applicable:

- Descriptive analyses: frequency distributions, proportions, means, medians, standard deviations, confidence intervals
- Estimation of key outcomes: prevalence with 95% CI; standardised rates; incidence density if cohort-based
- Stratified or sub-group analyses: pre-specified stratification variables (age, sex, geography, clinical category)
- Comparative analyses (if applicable): Estimation methods for various measures of associations (eg., OR, RR), identification of confounders, adjustment of confounders, effect measure modification
- Biological data analyses (if applicable): specify laboratory data analysis approach

Describe the qualitative data analysis strategy, including the software in terms of data preparation, organizing and transcribing data, coding and categorization, thematic analysis. Specify approach used such as thematic analysis, content analysis, grounded theory, phenomenological analysis.

2.8 Reporting of Results

[Maximum: 100 words]

Briefly describe how results will be reported. Include:

- Reporting guidelines: STROBE (observational studies), COREQ (qualitative research)
- Dissemination: peer-reviewed publications, policy briefs, national programme reports, conferences

2.9 Ethical Considerations

[Maximum: 250 words]

If the concept note is selected, funding will be released only upon obtaining all required ethical approvals. All research involving human participants, identifiable datasets, or animals (if applicable) must receive prior approval from the relevant committees.

Describe:

- Ethics Review: Specify the Institutional Ethics Committee (IEC) for human studies and Institutional Animal Ethics Committee (IAEC), if applicable. Indicate approval status (obtained/pending/to be applied).
- Study Participants/Data Source: Clearly describe the study population and data sources (e.g., surveys, interviews, medical records, routine programme data, or existing datasets).
- Informed Consent: Outline consent procedures for all participant groups (e.g., patients, healthcare providers, community members). For studies using anonymised secondary or routine data, justify any waiver of consent, if applicable.
- Privacy and Confidentiality: Describe measures to protect participant identity, including de-identification, secure data storage, and restricted access.
- Risks and Benefits: Indicate minimal risk nature of descriptive/analytical studies, while acknowledging potential social or psychological risks (e.g., discomfort during interviews) and expected benefits such as improved understanding of health conditions or systems.
- Vulnerable Populations: If included, provide justification and describe additional safeguards to ensure protection and voluntary participation.

2.10 Expected Outcomes / Deliverables

[Maximum: 100 words]

State what will be known at the end of the study if all objectives are met. Include: epidemiological data generated; public health/practice/policy implications; datasets; publications and presentations.

2.11 Detailed Project Timeline (Gantt Chart)

Present a month-by-month Gantt chart covering: ethics approval, tool development/pretesting, participant recruitment, data collection, data cleaning and analysis, reporting, thesis writing, and submission.

⚠ NOTE: The Gantt chart may be inserted as a table within the document or as an embedded figure.

2.12 Bibliography

List all references cited in the concept note in Vancouver format. Maximum 20 references.

PART- B; SECTION 3: DEVELOPMENT RESEARCH

Development: Creating, formulating, optimising, or clinically evaluating a new or improved health product, intervention, diagnostic test, medical device, or health technology. Includes pre-clinical studies, Phase I–III clinical trials, and diagnostic / device validation.

3.1 Title

[Maximum: 25 words]

The title should clearly indicate:

- The product, intervention, or technology being developed or evaluated
- The stage of development (e.g., Phase II PK-PD study of', Phase- III, 'diagnostic accuracy of')
- The disease, condition, or clinical indication
- The target population or biological system (where applicable)

Examples: 'Diagnostic accuracy of a point-of-care lateral flow assay for [pathogen] in febrile children'

3.2 Abstract

[Maximum: 250 words]

Structure the abstract around:

- Problem – What is the unmet clinical or public health need that drives this development effort?
- Product / Intervention – What are you developing, formulating, or testing?
- Approach – At what stage of development? What methods will you use?
- Innovation – What is new or improved compared to existing alternatives?
- Expected Impact – What is the potential benefit if the development succeeds?

3.3 Background

[Maximum: 400 words]

Describe the scientific and clinical context. Include:

- Current standard of care, available products or tools, and their limitations
- Scientific and biological basis for the proposed product or intervention
- Prior work by your group or others establishing pre-clinical or early-phase feasibility
- The specific unmet clinical or public health need that this development addresses
- Key supporting literature (brief, focused synthesis)

Suggested structure: Disease burden and current management gaps → Scientific rationale for the proposed product → Prior evidence of activity or feasibility → Unmet need and opportunity

3.4 Rationale for Development

[Maximum: 300 words]

Elaborate on why this development research is necessary and timely. Address:

- Why this product/intervention is needed (unmet need, therapeutic gap, diagnostic void)
- The scientific justification (mechanism of action, pre-clinical efficacy signals, prior human data)
- Why the proposer's institution or team is positioned to conduct this work (expertise, facilities, regulatory relationships, patient access)
- The translational pathway envisaged: from pre-clinical → Phase I → Phase II–III → regulatory approval → public health deployment
- National and international relevance (disease burden in India, regulatory pathway, potential for WHO pre-qualification or global deployment)

3.5 Research / Development Question

[Maximum: 100 words]

Frame a clear, focused central question for this development study:

- What product, intervention, or technology is being developed or evaluated?
- In what biological system or patient population?
- What is the key question being answered (safety? efficacy? performance? feasibility? cost-effectiveness?)

Apply FINER criteria: Feasible, Interesting, Novel, Ethical, and Relevant.

3.6 Hypothesis

[Maximum: 200 words]

State the central hypothesis about the expected performance of the product or intervention. Choose the pattern that matches your stage of development:

- Efficacy hypothesis: '[Product/Intervention X] will demonstrate [superior / non-inferior / adequate] [primary outcome] compared to [comparator] in [population]'
- Diagnostic accuracy hypothesis: '[Diagnostic tool X] will achieve sensitivity ≥[X]% and specificity ≥[Y]% compared to [reference standard] in [population]'

Supporting hypotheses (1–2): may address mechanistic endpoints, secondary efficacy parameters, dose-response relationships, or tolerability sub-groups.

State your hypothesis using the PICOT format. PICOT stands for PICOT is an acronym used to structure clinical and research questions in evidence-based practice: Population, Intervention, Comparison, Outcome, and Time.

In the context of clinical trials:

P – Population: The population of interest.

I – Intervention: The treatment being evaluated.

C – Comparison: The alternative or control (e.g., usual care, placebo, different intervention, or no treatment).

O – Outcome: The desired or measured effect (e.g., symptom reduction, improved diagnosis, lower mortality).

T – Time: The timeframe to assess the outcome or duration/type of study.

In the context of diagnostic/predictive/prognostic test evaluation:

P – Population: The population of interest.

I – Index test: The index test being evaluated.

C – Comparator test: The gold standard against which the candidate or index test is evaluated.

O – Outcome: The disease/outcome of interest for which the candidate/index test is being developed for.

T – Time: The timeframe to assess the outcome or duration/type of study.

3.7 Research / Development Strategy

3.7.1 Objectives

[Maximum: Primary Objective: 100 words | Secondary Objectives (2–4): 250 words total]

(i) Primary Objective — The single most important objective, directly addressing the central hypothesis. Include:

- Action verb (develop, evaluate, assess, validate, optimise, determine, characterise)
- What is being developed or evaluated (the product, intervention, or technology)
- Primary outcome (safety, efficacy, performance, proof-of-concept, feasibility)
- Population or biological system

(ii) Secondary Objectives (2–4) — Address mechanistic sub-questions, secondary endpoints, dose-finding, pharmacokinetics, subgroup analyses, feasibility, tolerability, or biomarker changes.

No need for a text box here instead a table with columns for primary objective with 100 words and secondary objectives (2-4) with 250 words can be in inserted.

Objective Type (Primary/Secondary)	Text Field
(Primary/Secondary)	

3.7.2 Stage of Development

Mark the stage that best describes your proposed research (tick all that apply if transitional):

- □ Pre-clinical (in vitro studies — cell lines, primary cells, organoids)
- □ Pre-clinical (in vivo studies — animal models; state species, strain, and model type)
- □ Pre-clinical to Phase I transition (first-in-human preparation: IND compilation, dose selection)
- □ Phase I — First-in-human: safety, tolerability, dose escalation, PK/PD
- □ Phase I/II — Combined safety and preliminary efficacy
- □ Phase II — Proof of concept, dose selection, and preliminary efficacy
- □ Phase II/III — Confirmatory or pivotal study
- □ Phase III — Large-scale confirmatory efficacy and safety study
- □ Diagnostic accuracy study — sensitivity / specificity vs. reference standard
- □ Medical device development — prototype design, bench testing, and performance validation
- □ Digital health / AI-based tool development and clinical validation
- □ Health Technology Assessment (HTA) — cost-effectiveness or budget impact analysis
- □ For Behavioural interventions or others, describe the development stages in the text box below

Insert text box here

3.7.3 Product / Intervention Description

[Maximum: 300 words]

Provide a detailed description of the product, intervention, or technology. Include relevant details for your development category:

- Drug / biologic: composition, formulation (tablet, injection, inhaler, patch), dose, route of administration, mechanism of action, pharmacokinetic profile (if known)
- Vaccine: antigen/s, adjuvant, delivery platform (viral vector, mRNA, subunit, live attenuated), immunisation schedule, cold-chain requirements
- Diagnostic test: analyte/target, detection principle (ELISA, PCR, LFA, sequencing), platform, specimen type, result interpretation
- Medical device: design, materials, function, user interface, intended use, classification (Class I/II/III, IVD)
- Digital health / AI tool: algorithmic approach, training data description, validation strategy, integration into existing health systems
- Prior evidence: summarise pre-clinical or earlier-phase data supporting safety and activity

3.7.4 Study Design

[Maximum: 300 words]

Specify and justify the study design. Include:

- Overall design (e.g., randomised double-blind placebo-controlled Phase II trial; prospective diagnostic accuracy study; parallel-arm device evaluation)
- Justification for the chosen design

- Blinding: open-label / single-blind / double-blind / triple-blind (justify)
- Randomisation (if applicable): method, allocation ratio, stratification variables
- Controls: placebo, active comparator, standard of care, historical reference (justify)
- Study flow/schema: brief narrative description of participant journey from screening to end of study
- Duration: total study duration, intervention period, and follow-up period

3.7.5 Outcomes

[Maximum: 300 words + Outcome Definition Table below]

(i) Primary Outcome — Should directly measure the central study endpoint. Common primary outcomes by study type:

- Phase I: incidence of dose-limiting toxicities (DLTs) at each dose level; maximum tolerated dose (MTD) or recommended Phase II dose (RP2D)
- Phase II: proof-of-concept efficacy endpoint (e.g., objective response rate, viral clearance, seroconversion rate)
- Phase III: clinical outcome (e.g., disease incidence, mortality, morbidity reduction, time to event)
- Diagnostic: sensitivity and specificity vs. reference standard (specify reference standard)

(ii) Secondary Outcomes (2–4): pharmacokinetic parameters (AUC, Cmax, t½), biomarker changes, patient-reported outcomes, acceptability, feasibility, immunological endpoints.

Complete the Outcome Definition Table for all proposed outcomes:

Outcome Type (Primary/Secondary)	Outcome Name	Outcome Description (operational definition)	Measurement Method / Tool	Timepoint(s)	Unit / Scale & Cut-off (if applicable)

3.7.6 Study Population / Participants

[Maximum: 250 words]

For clinical studies, describe:

- Detailed eligibility criteria: key inclusion and exclusion criteria (age range, health status, prior treatment, contraindications)
- Recruitment sites and method (tertiary care, multicentre, community-based)
- Planned sample size (brief overview; full justification in 3.7.10.1)
- Special or vulnerable populations: children, pregnant women, immunocompromised persons. State additional protections (assent, LAR consent, enhanced safety monitoring)

For pre-clinical studies, describe:

- Cell lines (name, source, passage number), primary cell preparations, or organoids
- Animal models: species, strain, age, sex, housing conditions, supplier, number per group, ethical approval

3.7.7 Description of Intervention and comparators OR candidate diagnostic tests and gold standard

[Maximum: 200 words]

3.8 Implementation Strategy

3.8.1 Data and Sample Collection

[Maximum: 250 words]

Describe:

- Clinical / safety data: variables collected at each study visit; data capture tool (paper CRF, electronic CRF; specify software)
- PK/PD samples: timing (pre-dose, post-dose intervals), volume, tube type, processing (centrifugation, aliquoting), storage conditions and duration
- Efficacy / biological samples: how clinical or biological outcomes will be measured, including assay validation status
- Adverse event (AE) monitoring: CTCAE grading version to be used; SAE reporting process and timelines (to IEC, CDSCO, sponsor)
- For diagnostics: index test procedure and reference standard test procedure, blinding of result readers, definition of equivocal results

3.8.2 Data Management

[Maximum: 150 words]

Describe:

- Data entry: paper CRF or electronic CRF (eCRF); specify software (e.g., REDCap, OpenClinica, proprietary eCRF)
- Data validation: automated range checks, data quality review cycles, query management
- Safety data monitoring: is a Data and Safety Monitoring Board (DSMB/DMC) required? What are the stopping rules? Is there a DSMB charter?
- Trial Master File (TMF): list key regulatory documents to be maintained
- Pharmacovigilance: SAE reconciliation, expedited reporting timelines to IEC and CDSCO

3.8.3 Data Analysis Plan

3.8.3.1 Sample Size Justification

[Maximum: 300 words]

Justify the proposed sample size, appropriate to the study type:

- Phase I dose-escalation: describe the dose-escalation rule (3+3 design, accelerated titration, or model-based BOIN/CRM). State the number of patients per cohort, maximum cohorts, and total sample size.
- Phase II: provide a formal sample size calculation based on expected primary endpoint rate, detectable difference, α (typically 0.05), and power (typically 80–90%)
- Phase III: provide full sample size calculation with all assumptions (event rate, hazard ratio or effect size, type I and II error rates, accrual and follow-up periods, drop-out rate)
- Diagnostic accuracy: use the appropriate formula based on expected sensitivity/specificity, desired precision (CI half-width), and expected prevalence in the study population
- For development of clinical prediction model or biomarker panel-based predictive or diagnostic tools, use the ‘pmsampsize’ method by Riley et. al.,
- For validation of clinical prediction model or biomarker panel-based predictive or diagnostic tools, use the ‘pmvalsampsize’ method by Riley et. al.,
- Pre-clinical: justify cohort/group sizes using precedent studies, pilot data, or statistical power for the primary biological endpoint
- Account for anticipated dropout, loss to follow-up, protocol deviations, unusable samples, or manufacturing failures

3.8.2.2 Plan of Statistical Analysis

[Maximum: 300 words]

Describe:

- Analysis populations: Intent-to-Treat (ITT), Per-Protocol (PP), Modified ITT (mITT)
- Primary analysis: specify the statistical test, significance level (α)
- Safety analysis: summary of AEs by CTCAE grade, SAEs, discontinuations; laboratory parameter shift tables
- Efficacy analysis: primary and secondary efficacy endpoints; confidence intervals
- Interim analyses (if planned): state the timing, stopping rules, and alpha-spending function (Haybittle-Peto, O'Brien-Fleming)
- For diagnostic studies: 2×2 table analysis; sensitivity, specificity, PPV, NPV, AUC-ROC; kappa for agreement
- For AI/ML tools, clinical prediction models and predictive/diagnostic biomarker panels: training/validation/test split rationale or k-fold cross validation or bootstrapping; performance metrics; calibration and external validation plan

3.9 Ethical Considerations

[Maximum: 250 words]

If the concept note is selected, funding will be released only upon obtaining all required ethical and regulatory approvals. All studies involving human participants, animals, biological materials, or identifiable datasets must receive prior approval from the relevant committees.

Describe:

- Ethics & Regulatory Review: Specify the Institutional Ethics Committee (IEC) for human studies and Institutional Animal Ethics Committee (IAEC), if applicable. Indicate approval status (obtained/pending/to be applied)
- Clearly specify whether approvals from relevant regulatory authorities (e.g., DCGI/CDSCO, CTRI, CPCSEA, RCGM for genetic or biotechnology-related studies) are required, and indicate their current status (obtained/pending/to be applied).
- Informed Consent: Describe procedures for obtaining informed consent from participants or legally authorized representatives, including details of study procedures, risks, benefits, and rights.
- Use of Biological Samples/Data: Clearly state the source, storage, and intended use of biological samples or datasets. Confirm that appropriate permissions for collection, storage, and future use (including biobanking) will be obtained.
- Risk and Benefits: Outline potential risks (including procedural or biological risks) and anticipated benefits.
- Safety Monitoring: Describe plans for monitoring, reporting, and managing adverse events, including referral and medical care. Mention oversight mechanisms (e.g., DSMB, if applicable).
- Privacy and Confidentiality: Ensure secure storage, restricted access, and de-identification of participant data and samples.
- Compensation and Insurance: Clearly state provisions for insurance and compensation (e.g., free medical management) for research-related injury, as per guidelines.
- Vulnerable Populations: Include justification and additional safeguards, if involved (e.g., pregnant women, children, endangered/marginalised groups, etc.).

3.10 Expected Outcomes / Deliverables

[Maximum: 100 words]

State what will be known or achieved at the end of this study if all objectives are met.

3.11 Detailed Project Timeline (Gantt Chart)

Present a month-by-month Gantt chart. Include all major activities:

⚠ NOTE: For studies requiring CDSCO/DCGI approval, allow adequate time (6–18 months) for regulatory review and approval in the Gantt chart.

3.11 Bibliography

List all references cited in the concept note in Vancouver format. Maximum 20 references.

PART- B; SECTION 4: DELIVERY RESEARCH

Delivery: Studying the implementation, scale-up, and optimisation of evidence-based interventions in real-world health systems and communities. Covers implementation science, health systems research, programme evaluation, process evaluation, and policy research.

4.1 Title

[Maximum: 25 words]

A strong title for a delivery/implementation research concept note must reflect four elements:

- An action word or phrase (e.g., 'Improving', 'Evaluating', 'Identifying gaps in', 'Scaling up')
- The evidence-based intervention or programme being studied for delivery
- The specific implementation outcome or health systems challenge (e.g., fidelity, uptake, sustainability, barriers)
- The target population and geographic or health system setting

Examples: 'Evaluating barriers to and facilitators of DOTS implementation in urban slums of Delhi: a mixed-methods study'; 'Improving fidelity of community health worker-led diabetes care in rural Rajasthan: a hybrid effectiveness-implementation trial'

4.2 Abstract

[Maximum: 300 words]

Structure the abstract around the following five elements:

- Problem – What is the implementation gap or health systems failure? (What is supposed to happen vs. what is actually happening, and where?)
- Question – What do you want to learn about delivery, uptake, fidelity, or sustainability?
- Approach – What implementation study design, phases, and methods will you use?
- Innovation – What is new: the implementation strategy, context, framework, or research approach?
- Impact – What policy or programme change could result from this research?

4.3 Background

[Maximum: 500 words]

The background for an implementation research concept note must go beyond the disease burden — it must characterise the implementation problem, not just the clinical problem. Include:

- Health system and service delivery context: the delivery platform (community, facility, referral network, national programme), relevant policies and schemes, and known system-level barriers (infrastructure, workforce, financing, equity)
- Problem statement — the implementation gap: What is supposed to happen (policy mandate or evidence-based standard)? What is actually happening in practice (observed coverage, fidelity, or quality)? Where is the slippage? For whom is the gap most pronounced? Why does this gap matter for health outcomes?
- Current policies, programmes, and service delivery arrangements: describe existing guidelines, national schemes, and the implementation pathway from policy to frontline delivery — identify where breakdown occurs
- Evidence gap: explain what is already known and what is missing, particularly in real-world implementation. In implementation research, the gap is typically not 'does the intervention work?' but 'how to deliver it effectively in this context, for this population, at this health system level?'
- Why implementation research — and not an efficacy trial or prevalence study: explicitly defend why IR is the appropriate design. The central unanswered question must be about implementation, adaptation, uptake, delivery, or sustainability — not efficacy or epidemiological burden

Suggested structure: Health system context and disease burden → Evidence-to-practice gap (what works vs. what is being delivered) → Current policy and programme landscape → Evidence gap in implementation → Why IR is needed now

4.4 Rationale for the Study

[Maximum: 400 words]

Elaborate on why this implementation research is necessary and timely. Address:

- Scientific rationale: what new implementation knowledge will be generated — determinants of implementation, mechanisms of change, strategy effectiveness, transferability, or adaptation lessons
- Programmatic / policy rationale: who are the primary users of the findings (district health managers, NHM, MoHFW, hospital leadership, professional bodies, international agencies)? What is the policy window or programme opportunity that makes this research timely?
- Contextual relevance: why this specific setting, population, or context is important, underserved, or policy-relevant. Do not describe the context generically — show its unique implementation relevance
- Potential for scale-up and value addition: how findings could inform adaptation, scale-up, or integration into routine systems. What is new compared with routine monitoring, previous pilots, or existing literature?

4.5 Research / Implementation Question

[Maximum: 100 words]

Based on the Background and Rationale, state the primary Research/Implementation Question. It should clearly frame the implementation problem your study will address.

The Research Question must satisfy the FINER criteria: Feasible, Interesting, Novel, Ethical, and Relevant.

A well-formed implementation research question addresses:

- What intervention is being studied for implementation?
- What implementation outcome(s) are of interest (acceptability, feasibility, fidelity, adoption, penetration, sustainability)?
- In what setting, health system level, and for what population?
- How, why, for whom, or under what conditions? (the key implementation science lens)

4.6 Implementation Hypothesis / Proposition

[Maximum: 200 words]

State clearly whether your research is (i) hypothesis-driven or (ii) exploratory / formative (hypothesis-generating). Choose ONE of the following sub-sections:

4.6.1 Formal Implementation Hypothesis (for comparative or interventional studies)

An implementation hypothesis is a testable statement about the expected effect of an implementation strategy on a defined implementation outcome. State using PICOT format:

- P – Population: the health workers, patients, or communities receiving the implementation strategy
- I – Implementation Strategy: the specific strategy or bundle being tested
- C – Comparison: current practice, standard delivery, or an alternative implementation strategy
- O – Outcome: the primary implementation outcome (e.g., fidelity, coverage, adoption)
- T – Time: the timeframe over which the outcome will be assessed

Example: '[Implementation strategy X] will significantly improve [fidelity / coverage / adoption] of [intervention Y] compared to [current practice / control condition] in [setting Z] over [timeframe]'

4.6.2 Exploratory Implementation Proposition (for qualitative or formative studies)

For qualitative, formative, or exploratory designs where no formal testable hypothesis is appropriate, state a clear implementation proposition. Example:

"This study aims to understand the multi-level barriers and facilitators affecting the [uptake / fidelity / sustainability] of [intervention] among [providers / patients / health managers] in [setting], using a [CFIR / COM-B / RE-AIM] framework."

Supporting propositions (1–2): may address secondary implementation outcomes, health outcomes, economic dimensions, or stakeholder sub-groups.

4.7 Research / Implementation Strategy

4.7.1 Objectives

[Maximum: Primary Objective: 100 words | Secondary Objectives (2–4): 250 words total]

(i) Primary Objective — The single central implementation objective, directly addressing the primary research question. Objectives must be SMART: Specific, Measurable, Achievable, Realistic, and Time-bound. Use the format:

"To [evaluate / assess / identify / describe / measure / compare] the [implementation outcome: fidelity / barriers / uptake / sustainability] of [intervention] among [implementation actors and/or recipients] in [setting] over [timeframe]"

Common objective types in IR:

- Assessing barriers and facilitators to implementation (formative objective)
- Testing or evaluating a specific implementation strategy (primary objective)
- Measuring implementation outcomes (fidelity, coverage, acceptability, sustainability)
- Evaluating costs or cost-effectiveness of the implementation strategy
- Examining health/service outcomes resulting from improved implementation

(ii) Secondary Objectives (2–4) — address additional implementation outcomes, health outcomes, economic dimensions, sub-group comparisons, or stakeholder perspectives. Each must be clearly achievable within the study.

No need for a text box here instead a table with columns for primary objective with 100 words and secondary objectives (2-4) with 250 words can be in inserted.

Objective Type (Primary/Secondary)	Text Field
(Primary/Secondary)	

4.7.2 Conceptual and Theoretical Basis

[Maximum: 300 words]

Describe the conceptual and theoretical foundation guiding the study:

- Conceptual framework: provide (or describe) a framework showing the relationship between context, implementation strategies, mechanisms, implementation outcomes, service outcomes, and longer-term health outcomes. A diagram is strongly recommended — attach as an annex if needed
- Implementation science framework(s): specify the framework(s) guiding the study and how each will be used:

RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) — programme spread and impact

CFIR (Consolidated Framework for Implementation Research) — multi-level implementation determinants

Proctor's Taxonomy — for classifying and measuring implementation outcomes (acceptability, adoption, appropriateness, feasibility, fidelity, penetration, sustainability)

COM-B (Capability, Opportunity, Motivation, Behaviour) — implementer behaviour change

EPIS (Exploration, Preparation, Implementation, Sustainment) — phase-specific processes

TDF (Theoretical Domains Framework) — provider behaviour and clinical decision-making

- Theory of Change / Logic Model: describe the pathway through which the implementation strategy will improve uptake, fidelity, coverage, quality, or health outcomes. Link inputs → activities → mechanisms → implementation outcomes → service outcomes → long-term impact
- Key assumptions: list the major assumptions underlying the design and expected implementation pathway (e.g., workforce availability, supply-chain stability, community receptiveness, sustained policy support)

Justify the choice of framework(s) and map each to your specific research questions and objectives.

4.7.3 Study Design

[Maximum: 300 words]

State the overall study design clearly and justify its suitability for the objectives and context. Select the design(s) that apply:

□ Mixed-methods implementation research (concurrent quantitative and qualitative components) *this information should be shown in the information icon*

□ Type I Hybrid Effectiveness-Implementation Trial (primarily testing effectiveness; observing implementation)

□ Type II Hybrid Effectiveness-Implementation Trial (simultaneously testing both)

□ Type III Hybrid Implementation Trial (primarily testing implementation strategy; observing health effectiveness)

□ Stepped-wedge cluster randomised trial

□ Cluster randomised controlled trial (implementation strategy as intervention)

□ Quasi-experimental / pre-post study with control group

□ Interrupted time series analysis

□ Realist evaluation (context-mechanism-outcome configuration)

□ Implementation process evaluation (mixed-methods; no comparator)

□ Qualitative implementation study (in-depth interviews, FGDs, ethnographic observation)

□ Programme evaluation (pre-post; audit and feedback; coverage survey)

□ Economic evaluation alongside implementation study

After selecting the design, describe:

- Justification for the chosen design in relation to objectives and context
- Study phases (typical IR phases: Preparatory/Formative → Co-Design and Adaptation → Implementation → Evaluation → Dissemination). State the proposed duration of each phase.
- Overall study flow from baseline to dissemination

4.7.4 Implementation and Health Outcomes

[Maximum: 300 words + Outcome Definition Table below]

(i) Implementation Outcomes — using Proctor et al.'s taxonomy, specify which implementation outcomes your study will measure:

- □ Acceptability — satisfaction of stakeholders with the intervention and its delivery
- □ Adoption — decision to employ the intervention in a given setting
- □ Appropriateness — perceived fit of the intervention with the setting, providers, and patients
- □ Feasibility — extent to which the intervention can be successfully used within existing resources
- □ Fidelity — degree to which the intervention is delivered as intended (adherence to protocol)
- □ Penetration / Reach — integration of the intervention into routine service delivery (coverage)
- □ Sustainability — extent to which the intervention is maintained or institutionalised over time
- □ Cost / Cost-effectiveness — economic evaluation of the implementation effort

(ii) Service / Clinical / Behavioural Outcomes — patient-level or population-level health outcomes expected to improve as a result of successful implementation (e.g., treatment success, quality of care, utilisation, adherence, patient outcomes). These are secondary to implementation outcomes in a Delivery study.

(iii) Contextual Variables — variables related to setting, system readiness, staffing, infrastructure, leadership, and other implementation influences that will be measured.

For each outcome, specify: operational definition; level of measurement (individual / facility / population); numerator and denominator where applicable; data source and respondent; timing.

Complete the Outcome Definition Table for all proposed outcomes. For each implementation outcome specify: level of measurement, numerator/denominator (where applicable), data source, timing, and respondent.

Outcome Type & Name	Outcome Description (operational definition)	Level of Measurement (individual / facility / pop.)	Numerator / Denominator (if applicable)	Data Source & Respondent	Timepoint(s)

4.7.5 Study Setting and Population

[Maximum: 250 words]

Describe the implementation setting:

- Geographic setting: state, district, urban/rural/tribal; geographic considerations affecting implementation
- Health system / programme setting: delivery platform (community, sub-centre, PHC, CHC, district hospital, medical college, national programme); staffing and governance structure
- Number and criteria for selection of implementation sites

Describe the study population separately for each group:

- Intervention recipients (patients, community members): eligibility criteria, expected number, recruitment strategy
- Implementation actors (ASHA/ANM/nurses/physicians/programme managers): role in the study, number, selection criteria
- Other stakeholders (policymakers, community leaders): role and how they are included

For IR: note that participant exclusion criteria are often minimal because the intervention is delivered at population level. Research components aim to include the full range of relevant actors.

4.7.6 Evidence-Based Intervention and Implementation Strategy

[Maximum: 300 words]

This section covers WHAT is being implemented (the intervention) and HOW it will be implemented (the strategy). Describe both components:

(i) The Evidence-Based Intervention:

- Description: clinical, public health, service delivery, or programmatic purpose and components
- Evidence base: summarise key trials, systematic reviews, or guidelines establishing effectiveness
- Current implementation status: is it being delivered, partially delivered, piloted, policy-mandated but under-implemented, or newly introduced?
- Core and adaptable components: identify which elements must remain unchanged (fidelity-critical) and which may be contextually adapted

(ii) The Implementation Strategy / Strategies:

- Describe the strategy or bundle of strategies that will be used to improve, enable, or sustain implementation. Although strategies may be refined through formative research, describe the prototype strategy based on existing knowledge
- For each component: what it is; who delivers it; to whom; when; how often; through what platform. Use standardised nomenclature where possible (Powell et al.'s ERIC Compilation of Implementation Strategies: training and education; audit and feedback; clinical decision support; academic detailing; task-shifting; community health worker engagement; mHealth reminders)
- Justification: why these strategies are expected to address identified barriers (based on prior evidence, theoretical frameworks, and/or stakeholder input)
- Actor/stakeholder mapping: role of each actor in strategy delivery; which aspects must be delivered as intended (fidelity-critical) and where contextual tailoring is permitted

4.7.7 Stakeholder Engagement and Co-Design

[Maximum: 200 words]

⚠ NOTE: Stakeholder engagement is a distinguishing feature of implementation research. A weak engagement plan is a common reason for Delivery proposals to be rated unfavourably.

Describe:

- Stakeholder identification: policy, management, frontline implementation, community, and research levels
- Engagement approach: how stakeholders will be involved across design, implementation, interpretation, and dissemination (community advisory boards, co-design workshops, technical working groups, steering committees)
- Community and end-user involvement: how intended beneficiaries or users will inform the study
- Use of stakeholder input: how feedback will shape tools, implementation strategies, adaptations, and interpretation of findings
- Decision-making and governance: who sits on advisory/steering groups; how input is documented and acted upon

4.7.8 Formative Research

[Maximum: 200 words]

Describe the formative work needed before the implementation phase begins:

- Purpose: what is the objective of the formative phase — understanding barriers and facilitators, system readiness assessment, workflow mapping, feasibility check?
- Areas of inquiry: implementation barriers, provider perceptions, community acceptability, health system readiness, resource constraints, stakeholder priorities

- Methods: in-depth interviews, focus group discussions, structured observation, workflow mapping, document review, baseline quantitative survey (as applicable)
- Use of findings: how formative findings will directly inform the implementation strategy, co-design process, and study tools

4.7.9 Data and Sample Collection

[Maximum: 300 words]

Quantitative data collection:

- Routine health system records: HMIS, NIKSHAY, HWC portal, facility registers, DHIS2; describe access procedure and data governance
- Structured surveys / questionnaires: specify validated tools (name and citation); describe pretesting and cultural adaptation
- Facility / provider assessments: structured observation checklists for fidelity; record review; coverage surveys
- Timing: baseline; midline (if applicable); endline; continuous programme monitoring

Qualitative data collection:

- In-depth interviews (IDIs): stakeholder groups; number; time points; sampling strategy; approximate duration
- Focus group discussions (FGDs): with which groups; number of FGDs; group size; time points
- Observation: structured or unstructured; setting; duration; documentation method
- Document review: policy documents, programme guidelines, meeting minutes, training records

Process documentation:

- How implementation processes, adaptations, and deviations will be recorded — process logs, reflective diaries, field notes, supervisor records

4.7.10 Data Management

[Maximum: 200 words]

Describe:

- Data flow: how data will move from collection to storage to analysis
- Quantitative data entry: REDCap, KoBoToolbox, Excel, DHIS2; specify software and version
- Qualitative data: audio recording (consent procedures); transcription (verbatim or summarised); de-identification; secure storage
- Data cleaning and validation: completeness checks, consistency checks, range validation, audit trail maintenance
- Data security: encryption, password protection, server location, regular backups
- Data linkage (if applicable): linkage key for linking routine records with primary data; privacy safeguards
- Data access and roles; data retention and archiving after study completion

4.7.11 Data Analysis Plan

4.7.11.1 Basis of Sample Size Estimation

[Maximum: 300 words]

Justify the proposed sample size appropriate to the study design:

- Cluster RCT / hybrid trial: use cluster RCT formula accounting for intraclass correlation coefficient (ICC), number of clusters, cluster size, and expected between-arm difference. State the source of the ICC estimate
- Quasi-experimental / pre-post: justify based on detectable difference, α, and power for the primary implementation outcome

- Interrupted time series: justify the number of data points before and after the implementation change (minimum 6 pre and 6 post points is generally recommended)
- Qualitative study: justify using saturation principles; describe the iterative sampling approach and saturation check procedure (typically 8–15 IDIs per stakeholder group; 3–6 FGDs per category)
- Mixed-methods: justify quantitative and qualitative components separately; state the integration point
- Account for anticipated site-level dropout, cluster loss, or non-participation

In IR, the entire eligible population may receive the implementation strategy. However, a sample may be needed for outcome evaluation (coverage surveys, patient-level assessments). Justify sample size in relation to operational feasibility, clustering, and precision around implementation outcomes.

4.7.11.2 Plan of Analysis

[Maximum: 400 words]

Provide an overview of how the analysis will answer each objective:

Quantitative analysis:

- Descriptive analysis: frequencies, proportions, means for implementation outcomes and coverage
- Analytical methods: multilevel modelling (clustered data); difference-in-differences; interrupted time series analysis (ITSA); generalised estimating equations (GEE); pre-post comparison; subgroup analysis
- Analysis of implementation outcomes: how acceptability, fidelity, feasibility, coverage, and sustainability will be quantified
- Missing data: complete case analysis, multiple imputation, sensitivity analysis

Qualitative analysis:

- Coding approach: inductive (open coding), deductive (framework-based), or combined
- Analytical method: framework analysis (most common in health systems IR); thematic analysis; grounded theory; realist synthesis (justify choice)
- Analysis of context and mechanisms: how contextual influences and mechanisms of change will be interpreted across sites or sub-groups
- Trustworthiness: credibility (member-checking, peer debriefing); dependability (audit trail); confirmability (reflexivity statement); transferability (thick description)
- Software: NVivo, Atlas.ti, MAXQDA (state and justify)

Mixed-methods integration:

- Integration approach: convergent; explanatory sequential (quant then qual to explain); or exploratory sequential (qual then quant to test) — justify choice
- Integration technique: joint display; mixed-methods matrix; narrative weaving; meta-inference

4.7.12 Process Evaluation

[Maximum: 200 words]

Describe the process evaluation embedded within the study:

- Purpose: why process evaluation is needed to explain implementation success, failure, or variation across sites or time points
- Key questions: Was the strategy delivered as planned? What helped or hindered implementation? How did context shape outcomes? What adaptations occurred?
- Process indicators: dose delivered; dose received; fidelity; participation rate; coverage; timing
- Methods: field notes, supervision records, implementation logs, fidelity observation checklists, routine programme dashboards, periodic IDIs with implementation actors

- Interpretation: how process findings will help explain outcome variation and inform theory of change refinement

4.8 Ethical Considerations

[Maximum: 200 words]

If the concept note is selected, funding will be released only upon obtaining Institutional Ethics Committees (IEC) approval. All research involving human participants requires IEC approval.

Describe:

- Ethics review: name the IEC; state approval status (obtained / pending / to be applied).
- For multicentric or multi-site studies, clearly specify the process for obtaining ethical approvals—whether a single approval will be secured by the host institute for all participating sites or if separate approvals will be obtained at each project site.
- Informed consent: procedures for each participant category (patients, providers, policymakers).
- Ethical justification: why the study is ethically acceptable and socially valuable.
- In programme-level IR with routine data, a waiver of informed consent may be applicable — justify explicitly if this is the case.
- Privacy and confidentiality: de-identification procedures; data storage protections
- Risks and benefits: potential risks or burdens for participants or health systems; expected benefits to individuals and communities.
- Vulnerable participants: special safeguards if involving children, pregnant women, or marginalised communities.

4.9 Sustainability, Scale-up, and Knowledge Translation

[Maximum: 200 words]

Describe:

- Sustainability and institutionalisation: what may continue beyond the project period and how. Explain how successful elements of the implementation strategy could be embedded within routine health system structures without external project support
- Scale-up readiness: what evidence or conditions would support expansion to other sites, districts, or states
- Transferability: which findings may apply to other settings and what contextual adaptation would be needed
- Dissemination and knowledge translation: identify primary audiences (policymakers, programme managers, implementers, communities, researchers); describe dissemination products (policy briefs, manuscripts, programme reports, stakeholder workshops, media engagement); explain how results will be translated into decisions, guidelines, or programme improvements

4.10 Potential Challenges and Limitations

[Maximum: 200 words]

Anticipate and address potential problems. Include:

- Operational challenges: staffing turnover, supply-chain disruptions, access constraints, data quality limitations, coordination across partners, community resistance
- Methodological limitations: design constraints, measurement limitations, potential biases (selection, response, fidelity drift), or limited generalisability
- Contextual uncertainties: risks related to policy changes, programme restructuring, disease outbreaks, or health system disruptions
- Mitigation measures: for each identified challenge, provide a corresponding mitigation strategy

4.11 Expected Outputs, Outcomes, and Impact

[Maximum: 150 words]

State clearly what will be produced and achieved if all objectives are met. Include:

- Immediate outputs: implementation tools, training packages, process data, adapted protocols, policy briefs, cost estimates
- Short-term outcomes: improved fidelity, acceptability, reach, provider practices, service uptake, programme coverage
- Long-term impact: improved health outcomes, stronger health systems, scalable implementation models, institutionalised programmes
- Contribution to policy and practice: how findings may influence routine programmes, national guidelines, or policy decisions
- Academic outputs: peer-reviewed publications, conference presentations, PhD thesis

4.12 Detailed Project Timeline (Gantt Chart)

Present a month-by-month Gantt chart for the full project duration (maximum 5 years). Include all major activities across each phase.

⚠ NOTE: Allow adequate time for stakeholder engagement, ethics approvals from multiple sites (if multicentre), and iterative qualitative data collection cycles in the Gantt chart. IR studies typically require a longer preparatory phase than clinical or epidemiological studies.

4.13 Bibliography

List all references cited in the concept note in Vancouver format. Maximum 20 references. Ensure key implementation science literature is cited alongside clinical/epidemiological references.

References:

SECTION A — ICMR 4-D Framework and Programme Context

- Indian Council of Medical Research. Guidelines for Extramural Research Programme. New Delhi: ICMR, Department of Health Research; 2023. Available from: https://epms.icmr.org.in/extramuralstaticweb/pdf/Adhoc/Guidelines_for_Extramural_Research_Programme.pdf
- Bahl R. Understanding the 4Ds — Discovery, Description, Development and Delivery [Video lecture]. Indian Council of Medical Research; 2026 Mar. Available from: https://www.youtube.com/watch?v=DmCpez-ySLA

SECTION B — Research Question Formulation (All Domains)

- Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing Clinical Research. 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2013. [Source of FINER criteria]

SECTION C — Reporting Guidelines (Sections 1 and 2: Discovery and Description)

- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. Lancet. 2007;370(9596):1453–1457. PMID: 18064739.
- Collins GS, Reitsma JB, Altman DG, Moons KG. Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD): the TRIPOD statement. BMJ. 2015;350:g7594. doi:10.1136/bmj.g7594. PMID: 25569120.
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- Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, et al.; RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. PLoS Med. 2015;12(10):e1001885. doi:10.1371/journal.pmed.1001885. PMID: 26440803.
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- Des Jarlais DC, Lyles C, Crepaz N; TREND Group. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement. Am J Public Health. 2004;94(3):361–366. doi:10.2105/ajph.94.3.361. PMID: 14998794.

SECTION D — Clinical Trial and Product Development Methods (Section 3: Development)

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline: Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). Geneva: ICH; 2016. Available from: https://www.ich.org/page/efficacy-guidelines
- Central Drugs Standard Control Organisation. New Drugs and Clinical Trials Rules, 2019. New Delhi: Ministry of Health and Family Welfare, Government of India; 2019.
- Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al.; for the CONSORT Group. CONSORT 2025 statement: updated guideline for reporting randomised trials. BMJ. 2025;388:e081123.

SECTION E — Implementation Science Frameworks (Section 4: Delivery)

- Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999;89(9):1322–1327. doi:10.2105/ajph.89.9.1322. PMID: 10474547.
- Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012;50(3):217–226. doi:10.1097/MLR.0b013e3182408812. PMID: 22310560.
- Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. BMJ. 2015;350:h391. doi:10.1136/bmj.h391. PMID: 25662947.

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