

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Title

[The Title is short yet powerful description of the study to be undertaken. It may include phase, design, site, drug, and target disease(s)]

Example: A phase II, randomized, double-blind, placebo-controlled, multi-center study of the effects of XXXX on infarct size in subjects with diabetes mellitus presenting with acute myocardial infarction.

Study Summary

Title	
Short Title	
Methodology/Design	
Study Duration	
Study Centre(s)	
Objectives	
Number of patients	
Source of patient population	
Diagnosis and Inclusion Criteria	
Exclusion Criteria	
End points	
Type of homoeopathic approach (Acute/Chronic/Individualized/Miasmatic)	
Dose & Route	
Repetition & Frequency	
Duration of treatment/therapy	
Whether Placebo controlled, if yes, details of placebo	
Statistical methodology to be used	
Study Team (Names only)	
Protocol preparation team (Names only)	
Protocol amendments	
Revisions	

**DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS–
VERSION-I**

Study Team

S. No.	Name	Degree/ Affiliation	Correspondence Address	Contact Number	Email Id	Role in study	Has similar work undertak en by the team member in past?

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Table of Contents

Study Summary	1
Study Team	2
List of Abbreviations	6
Introduction	6
Background information	6
Preclinical studies done	6
Prior research work done/Clinical research/Case Studies/Case Series/Observational/Cohort etc.	6
Rationale/need of undertaking study	6
Proposed/Expected role (Hypothesis) of Homoeopathy in condition(s) to be studied	6
Study Objectives	6
Primary objective(s)	6
Secondary objective(s).....	6
Study Design	6
Type of design adopted	6
Phase of the study (in details).....	6
Endpoints	7
Primary endpoint(s)	7
Secondary/Safety end points	7
Subject Selection	7
Inclusion Criteria	7
Exclusion Criteria.....	7
Proposed sample size.....	7
Subject Screening, Recruitment	7
Source of Patient Population	7
Screening Process	7
Recruitment/Enrolment of Subjects	7
Study Site	7
Randomization	7
Flow diagram of enrolment, screening and allocation (As per CONSORT)	8
Outcome measures	9
Primary Outcome Measure.....	9
Secondary Outcome Measure	9

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Sensitivity/Specificity/Reliability of Investigations to be done.....	9
Repetition of Investigation – Investigative Follow up	9
Follow Up	9
Treatment	9
Study Drug(s).....	9
Treatment Regimen	9
Procurement and Administration of Study Drug	9
Selection of Medicine	9
Selection of Potency	9
Dose	9
Prescription.....	9
Change of Prescription.....	10
Subject Compliance Monitoring	10
Steps to Maximize Adherence and Retention	10
Withdrawal	10
When and How to Withdraw Subjects.....	10
Early Withdrawal of Subjects	10
Data Collection and Follow-up for Withdrawn Subjects.....	10
Statistical Plan	10
Sample Size Determination.....	10
Statistical Methods	10
Subject Population(s) for Analysis	10
Safety and Adverse events	10
Definitions.....	10
Recording of Adverse Events	10
Reporting of Serious Adverse Events and Unanticipated Problems.....	10
Unblinding Procedures.....	10
Stopping Rules	11
Monitoring	11
Data Handling and Record Keeping	11
Confidentiality.....	11
Source Documents.....	11
Records Retention.....	11

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Study Monitoring, Auditing, and Inspecting	11
Auditing and Inspecting	11
Ethical Considerations.....	11
Data and Safety Monitoring Board (DSMB)	11
Study Finances	11
Logistics and Manpower	11
Budget requirements (head wise and item wise) with detailed break-up year wise	11
Total Grant-in-Aid required for the study.....	11
Publication Plan	11
Study time line/Milestones	12
Protocol amendment	12
References	12
IPR values	12
Annexure	12
Case Taking Proforma	12
Logistics required	12
Patient Information Sheet	12
Consent Form.....	12
Family History Form	12
Memorandum of Understanding	12
Etc.	12

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

List of Abbreviations

Introduction

The introduction should be written in a simple yet informative way. It must be addressed in a clear manner so that it is comprehensible to readers who don't have specialist knowledge in that area. It must clearly state and, if helpful, illustrate the background work done. It must include a summary of a search of the literature to indicate why this proposal is necessary and what it aims to contribute to the field. The section should end with a brief statement of what is being reported in the article. Broadly the subsections of introductions may be:

Background information

Preclinical studies done

Prior research work done/Clinical research/Case Studies/Case Series/Observational/Cohort etc.

Rationale/need of undertaking study

Proposed/Expected role (Hypothesis) of Homoeopathy in condition(s) to be studied

Study Objectives

Primary objective(s)

Secondary objective(s)

Study Design

Type of design adopted

Phase of the study (in details)

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Endpoints

Primary endpoint(s)

Secondary/Safety end points

Subject Selection

Inclusion Criteria

Exclusion Criteria

Proposed sample size

If same size is calculated on the basis of previous pilot/clinical research, a clear explanation must be given here.

Subject Screening, Recruitment

Source of Patient Population

Screening Process

Recruitment/Enrolment of Subjects

Study Site

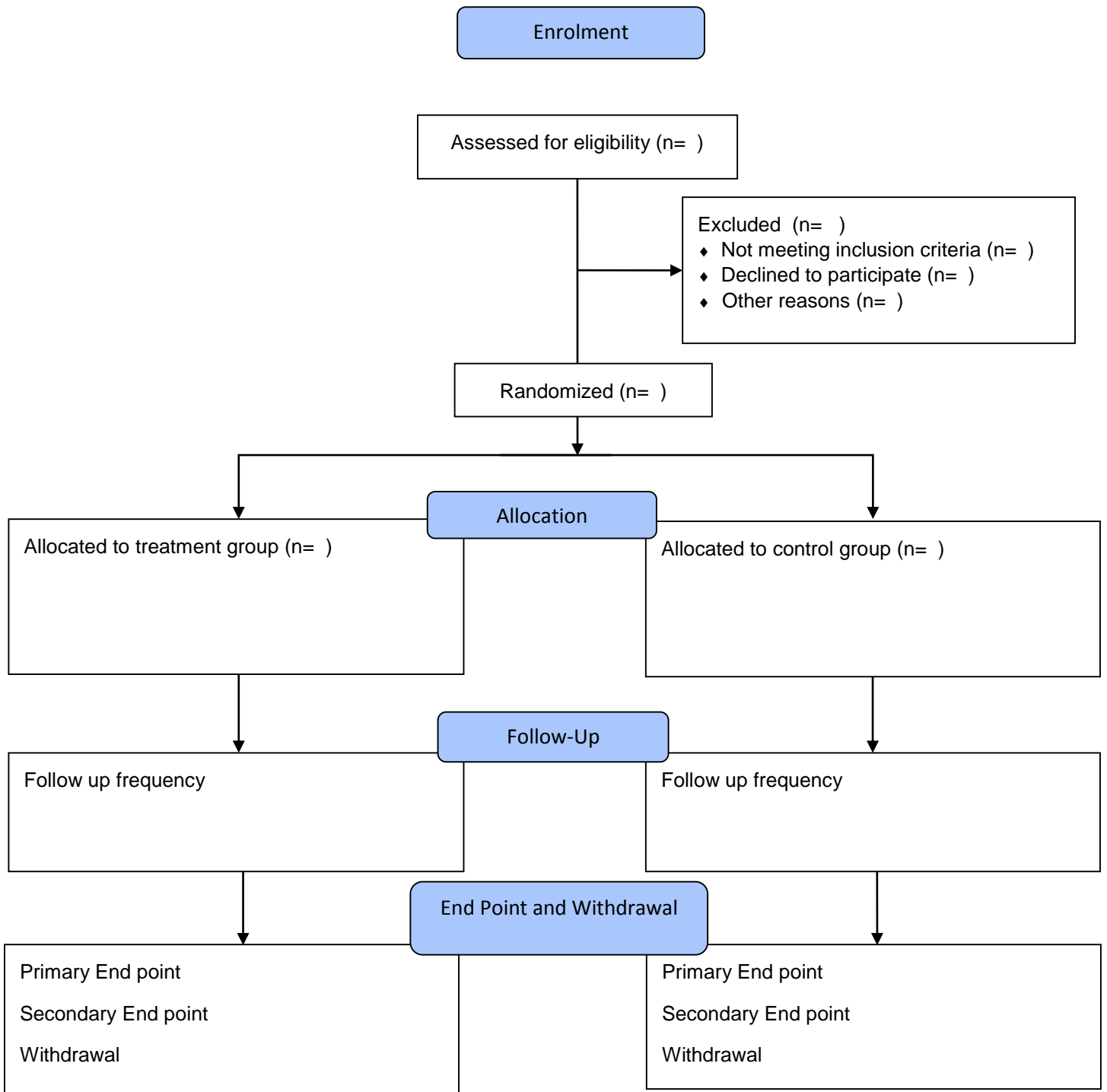
Randomization

Method for Assigning Subjects to Treatment Groups

Description of Intervention and Control group(s) and their allocation

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS— VERSION-I

Flow diagram of enrolment, screening and allocation (As per CONSORT)



DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Outcome measures

Primary Outcome Measure

Secondary Outcome Measure

Sensitivity/Specificity/Reliability of Investigations to be done

Repetition of Investigation – Investigative Follow up

Follow up outcome measures table

Follow Up

The follow up may be depicted in flow chart which is easier to comprehend.

Treatment

Study Drug(s)

Treatment Regimen

Procurement and Administration of Study Drug

Selection of Medicine

Selection of Potency

Dose

Prescription

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Change of Prescription

Subject Compliance Monitoring

Steps to Maximize Adherence and Retention

Withdrawal

When and How to Withdraw Subjects

Early Withdrawal of Subjects

Data Collection and Follow-up for Withdrawn Subjects

Statistical Plan

Sample Size Determination

Statistical Methods

Subject Population(s) for Analysis

Safety and Adverse events

Definitions

Recording of Adverse Events

Reporting of Serious Adverse Events and Unanticipated Problems

Unblinding Procedures

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Stopping Rules

Monitoring

Data Handling and Record Keeping

Confidentiality

Source Documents

Records Retention

Study Monitoring, Auditing, and Inspecting

Auditing and Inspecting

Ethical Considerations

Data and Safety Monitoring Board (DSMB)

Study Finances

Logistics and Manpower

Budget requirements (head wise and item wise) with detailed break-up year wise

Total Grant-in-Aid required for the study

Publication Plan

DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Study time line/Milestones

Protocol amendment

References

Preferably in Vancouver style

IPR values

Annexure

Case Taking Proforma

Logistics required

Patient Information Sheet

Consent Form

Family History Form

Memorandum of Understanding

Etc.