Writing a Study Protocol for Therapeutic Recreation Studies in Canada

(Based on ICH-GCP Guidance Document)

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“Standard” Headings

- Title Page
- Table of contents
- List of abbreviations
- Introduction (background information)
- Objectives
- Study Procedures (overview – trial design)
- Medicine & Dosage
- Study Procedures (detailed, by period and/or by phase, treatment of subjects)

“Standard” Headings cont’d.

- Patient Population (incl./excl., withdrawal criteria)
- Efficacy and Safety Parameters
- Statistical Analysis
- Ethical and Regulatory Considerations
  - Approval, Informed Consent Procedure, Confidentiality & Record Keeping, Adverse Reactions, Monitoring, Publication of Results
- References
- Appendices

Example of Protocol Structure (Table of Contents)

Protocol CONTENT

Objectives

- Clear statement detailing **WHAT** is being investigated - follows from identified corporate need
- Define what questions are to be answered from the study: primary vs. secondary outcomes (GCP 6.3 & 6.4)
- Define which of the research questions are most important/critical for product registration and/or marketing

Trial Design - Feasible ?

- When the trial design doesn't work:
  - state of technology does not allow for data collection
  - equipment needed is too expensive to buy or operate
  - too many subjects required
  - too much manpower required
- May need to re-work objectives to allow for more feasible trial design

Patient Population

Inclusion Criteria: minimum criteria required for the subjects/patients to be included in trial

Exclusion Criteria: the presence of any one criterion renders the subject/patient ineligible to be included in the trial

Withdrawal Criteria: when, how, replacement of subjects, timing of data collection, follow-up (GCP 6.5.3)

Introduction

- Background on disease/medicines currently used
- What are the limitations of current therapy
- Pre-clinical & clinical data on new medicine
- Summary of known & potential risks
- Background of hypothesis being tested
- Rationale for the trial (GCP 6.2)

Introduction

Be sure to highlight advantages (real or proposed) of the new therapy over current therapy

Introduction

Sources of information

- previous protocols
- literature review
  - journal articles
  - books
  - treatment guidelines
- physicians
- Therapeutic recreation advisory boards

Efficacy and Safety Parameters

Dependent upon trial objectives/design

Efficacy parameters (GCP 6.7)

- primary and secondary outcomes
- method of evaluation

Safety parameters (GCP 6.8)

- method and timing for assessment and recording of AEs
- procedures for eliciting reports and type of follow-up

Study Procedures - Methodology

- Time and events schedule
- List of specific measurements and evaluations
  - Screening phase
  - Baseline phase
  - Treatment phase
  - Post-treatment phase

Study Procedures-Discontinuation

- When & how to withdraw subjects from the trial
- Type & timing of data collected for withdrawn subjects
- Whether or not to replace subjects
- Follow-up procedure for withdrawn subjects
- Reason for withdrawal (GCP 6.5.3)

Statistical Analysis

- Size of treatment effect that is deemed clinically significant
- Sample size calculation & justification
- Plan of analysis
- Significance level
- Interim analysis, if applicable
- Procedure for accounting for missing data, withdrawals, etc. (GCP 6.9)

Ethical, Regulatory and Administrative Issues

- Consent: Procedure for administration of informed consent
- REB review: Institutional reviews for approval
- Statement of GCP compliance (GCP 6.2.5)
- Confidentiality statement
- Record retention: who is responsible and how long

Ethical, Regulatory and Administrative Issues, cont'd

- Monitoring: timing and purpose of monitoring
- Publication policy (GCP 6.15)
- Direct access to source documents (GCP 6.10) ….."the sponsor should ensure that it is specified in the protocol that the investigator/ institution will permit direct access to source documents"

Ethical, Regulatory and Administrative Issues, cont'd

- SAE reporting: responsibilities of sponsor and investigator
- Procedures used with early termination of subjects/study
- General considerations for CRF completion and handling
- Procedures for developing study budgets and schedule of payments

Title Page (as per GCP 6.1)

- Title
- Protocol identifying number
- Protocol version number
- Date
- Amendment number and date, if applicable
- Sponsor’s name and address and telephone number

Title Page, cont.

- List and signatures of main/resource people involved (titles, addresses, contact numbers)
  - Protocol authors (Therapeutic recreation Specialist and Statistician)
  - Sponsor's Monitor
  - Sponsor's Study Manager
  - One consulting/co-ordinating Investigator (or qualified Therapeutic Recreation Specialist)

Title

Should include at least:

- Interventions
- Applications

Optional:

- study design
- study objectives
- duration of therapy

Next page…

- Table of contents
- List of abbreviations

References

- list of publications referenced in the protocol
- general guidelines for referencing are available on the Internet
- be sure to read and use original source article

Appendices

Study Flow Chart

Questionnaires:

- Specifically developed by company/investigators to be used in study
- Other standardized questionnaires used in study

Guidelines for:

- use of devices used in the study

Appendices-con't

Used to be, but no longer:

- Tri-council Policy Statement - Canada
- Copy of ICH GCP
- Copy of informed consent form
- Copy of the CRF

Study Overview/Synopsis/Outline

- Type of study design
- Study Objectives
- Method of randomization
- Study duration (number of days, weeks)
- Number and type of visits/periods

Reference

ICH-GCP Guidelines: www.ICH.org