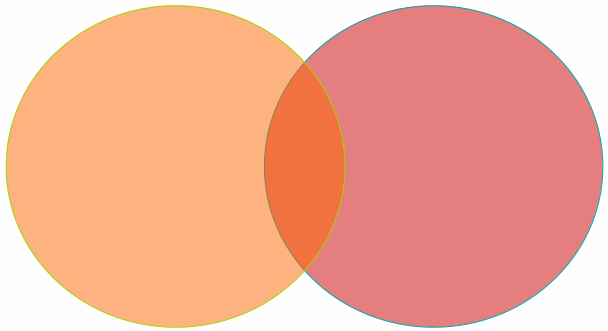
Regulatory Writing

Module 10 Topic 3

Regulatory Affairs versus Writing

RA Managers

Liaison between pharmaceutical company and regulatory bodies
Review
Summarize
Manage project eg, MAA
Guidelines and regulations
Development plans



Overlap

Write Summaries and Overviews Write Investigator Brochures

Write Paediatric Investigation Plans

Writers

Write Clinical Study Reports
Write protocols
Write manuscripts

Protocol

Protocol

- A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study.

Contents

- Protocol title and date, name and address of principal investigator, site(s) where study will be performed
- Background/Rationale/Literature Review - basis for doing the clinical research study
- Research Objectives and Purpose - an extension of the hypothesis/key questions-, can be combined with them
- Study Design (includes some or all of the following)
- Study population
- Subject eligibility – Inclusion/exclusion criteria

Protocol contents

- Study assessments - plan, procedures and methods
- Study conduct – History, investigations, evaluation
- Stopping rules or discontinuation criteria
- Dose, dosing schedules, etc for the treatment and control groups
- Medications permitted (other than the ones under test) and those not permitted during the trial
- Procedures for monitoring subject compliance
- Efficacy parameters and methods of assessing the same.
- Safety parameters and methods of assessing the same.
- Procedures for recording and reporting Adverse events

Protocol contents

- Statistical methods to be employed
- Quality control and assurance procedures
- Ethics
- Data Handling and record keeping
- Financing and Insurance
- Publication policy
- Supplements

Conclusion

- Protocol is the most important of all clinical trial documents
- It is also the first to be prepared and discussed with the investigators.
- It is a confidential document since it contains most useful information on an investigational drug.

Investigator’s Brochure

Investigator's Brochure

- The Investigator's Brochure is an axis document in a new drug's clinical development programme. Crucial to various processes that regulate clinical research into new drugs, its content is well defined
- The ICH E6 guideline specifies that an Investigator's Brochure should include information on the drug product to be investigated and its performance in non-clinical studies along with specific guidance to investigators on the drugs use
- The Investigator's Brochure is a multidisciplinary document, summarising information from each of the teams involved in a drug's development

IB-Purpose

- To provide information to the Investigator and others involved in a clinical study on such issues the appropriateness of dose, dose frequency/interval and the characteristics of the investigational medicinal product (IMP) – so that it can inform safety considerations and clinical management of study subjects during a clinical trial

Structure of an Investigator's Brochure

- The structure of an Investigator's Brochure structure is defined within ICH E6 (Section 7) [2]:
- Summary
- Introduction
- Physical, chemical, and pharmaceutical properties and formulation
- Non-clinical studies
- Effects in humans
- Summary of data and guidance for the Investigator

Summary of data and guidance for the investigator

- This section should provide an overall discussion of the nonclinical and clinical data, and should summarise the information from various sources on different aspects of the investigational product(s), wherever possible
- Where appropriate, the published reports on related products should be discussed
- Practical information is provided for the management of subjects being treated with the investigational product
- Information may also be drawn from published knowledge on other drugs in the same class

References, Supplements and Appendices

- References may be provided at the end of each section of the document or be given in a combined list at the end of the Investigator's Brochure
- References should not be made to Sponsor documents (as these may not be readily available to an investigator)
- A supplement should be considered as a separate, standalone document and not a revision or an appendix

References, Supplements and Appendices

- A supplement should adopt the format of the parent Investigator's Brochure
- Information provided in a supplement should be fully incorporated into the next revision of the Investigator's Brochure
- Appendices should be provided where additional information to support that summarised in the body of the document could be helpful

Informed Consent Form

Informed Consent: Definition (ICH-GCP 1.28)

- Voluntary confirmation of willingness of subject to participate in a clinical trial
- Informed about all aspects of trial relevant to the decision to participate
- Should protect the rights of the subject as a clinical study participant

Elements of Informed Consent

Necessary information to be provided to subjects

- That the trial involves research
- Purpose: that the trial is experimental
- Trial treatment and probability of random assignment to treatment
- Trial procedures, alternative procedures/ treatments; everything that will happen to them
- Risks and anticipated benefits
- Subject's responsibilities
- Confidentiality, voluntariness, access to subjects' records