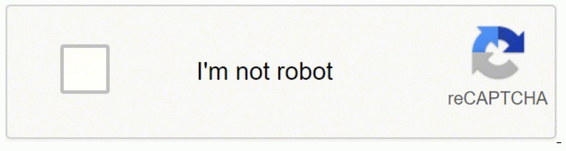
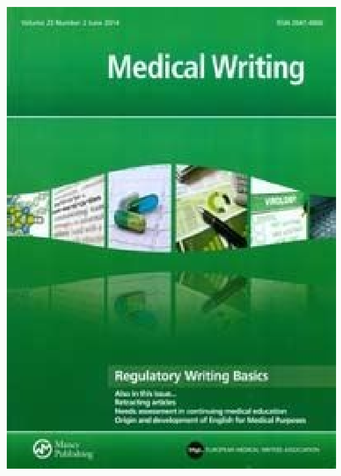


Next

Investigator brochure template medical device



Regulatory

Clinical Investigation of Medical Devices: Promoting Convergence

Abstract
The safety, performance and effectiveness of medical devices are evaluated by clinical investigation before they enter the market. The integrity of the data is ensured using international standards like ISO 14155:2011 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice, or ICH E6 Guideline for Good Clinical Practice (GCP) or other GCPs. A clinical investigation design should be made which is appropriate and acceptable by many regulatory authorities that acts as a "gateway" for data transportability and removes all trade barriers. This article brings out the differences between ISO GCP and ICH GCP. Also, it discusses the need for harmonising various GCP standards. Since consistency is essential among GCPs to avoid duplication of work and to allow data from a clinical investigation to be used in another country for marketing approval (data transportability); so it is important that the standards are harmonised.

Keywords: Clinical Investigation Plan, Harmonisation-by-Doing, ISO14155, Convergence, Good Clinical Practices

Introduction

Regulations for conducting medical device (MD) clinical trials around the world have varied widely. Complications that arise between trials conducted under different protocols make bringing a device to market difficult in a stricter country. Data may be considered questionable given different requirements[1]. Reciprocal acceptance of Good Clinical Practices (GCPs) would facilitate multinational studies and promote the use of clinical data to support regulatory submissions in multiple countries [2].

Objectives

- To bring out the differences between international standards like ISO 14155:2011 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practices (GCP) or ICH E6 GCP.
- To discuss the advantages of harmonisation of these guidelines for the benefit of the medical device industry and public health.

ISO 14155:2011

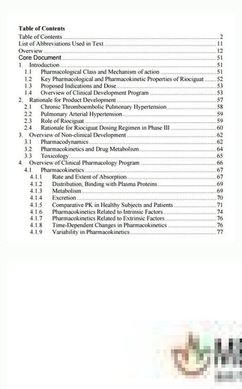
ISO 14155:2011 addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.
The principles set forth in ISO 14155:2011 also apply to all other clinical investigations and should be followed as far as possible, depending on the nature of the clinical investigation and the requirements of national regulations. ISO 14155:2011 specifies general requirements intended to protect the rights, safety and wellbeing of human subjects, ensure the scientific conduct of the clinical investigation and the credibility of the results, define the responsibilities of the sponsor and principal investigator, and assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.[3]

ICH GCP

The ICH-GCP is a harmonised standard that protects the rights, safety and welfare of human subjects, minimises human exposure to investigational products, improves quality of data, speeds up marketing of new drugs and decreases the cost to sponsors and to the public. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected and consistent with the principles of the Declaration of Helsinki, and that the clinical trial data is credible. [4,5]

Differences [6]

ISO 14155:2011	ICH GCP
ISO technical committee – regulators and (predominantly) medical device industry	Joint initiative – regulators and pharmaceutical industry
Goal – international standardisation of clinical investigations of medical devices	Goal – harmonise requirements in order to aid global drug development
ISO14155 assesses clinical performance	ICH GCP assesses efficacy
Investigator is qualified by education, training and experience	Investigator is a qualified physician or dentist
ISO 14155:2011: investigator brochure to contain a summary of relevant manufacturing processes and related validation processes	ICH GCP – in accordance with applicable Good Manufacturing Practice
ISO 14155:2011 Clinical Investigation of Medical Devices for Human Subjects-GCP – not globally adopted	ICH GCP guidance introduced in 1996 – widely adopted in USA, Europe, Japan and many others
Adverse events • Adverse device effect – insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device • Device deficiencies – inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance • Adverse events not restricted to subjects – can also be users or other persons	Adverse event is related to the drug. Due to the systemic nature of drugs, all adverse events will need to be captured and analysed as potentially related to the drug.
Reporting – ISO 14155:2011 doesn't differentiate the reporting of foreseeable adverse events and anticipated adverse device effects from unanticipated events / effects	Reporting serious reactions, product quality problems, therapeutic inequivalence / failure with drugs



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Medical writing for regulatory submission in clinical research and its challenges

Regulatory medical writing in clinical trials requires medical writers to possess sufficient knowledge of the regulatory guidelines of concerned authorities of specific countries and needs to have dedication and commitment to handle large volumes of regulatory data. A professional regulatory writer needs to have sufficient understanding of the drug development process to determine the important documents that need to be written and submitted for regulatory submissions.

Regulatory submissions challenges in clinical trials

Regulatory Writing and Publishing poses many challenges for the medical writers in the writing and development of critical documents like Clinical Study Report, Investigator's Brochure, and clinical trial protocol development and in the preparation of documents for FDA meetings and briefings.

The Clinical Study Report (CSR) is a critical document that provides an integrated report comprising the clinical and statistical description of the investigational study of therapeutic or prophylactic drugs in a single report with relevant tables, figures, and appendices. A medical writer will face challenges in understanding the guidelines and statutory requirements and also developing suitable document template that covers all current regulatory requirements.

Investigator's Brochure is an essential regulatory document that provides an overview of the clinical and non-clinical findings of the trial study and is primarily used as an investigator guide to assessing the risks and benefits of the product under investigation. The major challenge commonly faced by the regulatory medical writer in the preparation of Investigator's brochure include

5. RISK MANAGEMENT

5.1 Summary of the risk analysis
A description summary of the results of the risk analysis carried out on the investigative device, may be worth referencing the complete risk analysis report, if included e.g. as an appendix of the Clinical Investigation Plan (CIP).

Benefit/Risk analysis to include identification of hazards and estimated risks associated with the manufacture (including factors relating to device choice, choice of materials, software) and the use of the device, together with the description of what actions have been taken to minimise or eliminate the identified risks.

5.2 Results of the risk assessment
Describe the process and results of the risk assessment for the investigative device.

5.3 Anticipated risks, contra-indications, warnings
Describe any anticipated risks, contra-indications and warnings that are associated with the investigative device.

6. REGULATORY AND OTHER REFERENCES

List of relevant Standards applied in full or in part, or description of solutions adopted to meet the essential requirements of the Directive if relevant standards have not been fully applied.

6.1 List of International standards

List the international standards complied with in full or in part; e.g. ISO 14155, ISO 14971, ISO 13485

6.2 Statement of conformity with national regulations

Include a statement of conformity with the National regulations

6.3 List of references

List of references utilised in this document.

Clinical investigator brochure template medical device.

the researcher’s brochure (ib) is delivered to clinicians, researchers and other health professionals involved in clinical trials (e.g., clinical trial coordinators and study nurses.) ib is a collection of non-clinical and clinical data relevant to the study of the drug in humans, it is the most comprehensive single document that summarizes information about a drug in research. The researcher’s brochures are prepared by the promoter, who also controls the distribution of the document. the ib of a clinical trial is presented to the competent national authorities (anc) for approval along with the request for clinical trial (CTA).Why are the researcher's brochures important?The ib provides the researcher and other staff with basic information about the drug in research to help them work according to the study protocol. provides the clinical doctor or potential investigator with the information they need to evaluate the suitability of a trial, including the benefit-risk relationship, independently and impartially. Ib information also provides information that supports the clinical management of test participants during the clinical trial, including information on dosage, dose frequency, management methods, and safety control procedures.What does a researcher's brochure contain?According to the legal framework of good clinical practices in clinical trials, ib's information should be "concise, simple, objective, balanced and non-promotional."This is especially important to ensure that the researcher is informed and informed. Researchers who generated the data should approve the content of the ib, which should be revised and updated at least once a year or when it issignificant new data.Product: Information about the name of the sponsor and the identity of the product (search number, generic and commercial names). A confidentiality statement with instructions on how to treat the document as confidential and for the exclusive use of the research team, review boards and ethics committees. A compilation of results obtained from non-clinical and clinical studies of medicine. Background information on the properties and history of the investigational medicinal product. Folleto del investigador: Table of contents Un IB contiene las siguiente secciones: SummaryGuidance for the investigator, highlights important information relevant to the development stage of the product. IntroductionBasic information, basis for conducting research, chemical and generic name of the active substance (and trade name where applicable) in the investigational product, and planned indication. Physical, chemical and pharmaceutical properties and formulationRelevant properties of the product and (inactive) ingredients, including similarities to other known compounds; instructions for storage and handling of the product. Non-clinical studiesComplementary results of pharmacology, toxicology, pharmacokinetics and metabolism; explanations of the methodology used, results and relevance of the findings; information on animal/laboratory studies and doses. This summary should also contain a discussion of the relevance of the conclusions to the compound and the possible adverse and unwanted effects on humans. Effects on humansSummary of data and guidance for researchers How is the researcher’s brochure regulated? Regulatory authorities (such as the European Medicines Agency (EMA) and National Competent Authorities (NCA)) require an updated IB for any drug being studied. An IB is submitted to regulatory authorities together with clinical trial (CTA) application, and regulatory authorities also review any IB update to make sure it isIn some cases, for example, if the product under investigation already has a Marketing Authorization (MA) and doctors are familiar with its pharmacology, a comprehensive IB may not be required. In such cases, the Summary of Product Characteristics (SPC) Â” or, where permitted by the regulatory authorities, a package leaflet or label Â”Â” can be used as an appropriate alternative to the IB. However, the substitute must provide up-to-date, complete and detailed information on all aspects of the investigative product that may be important to the investigator.If a marketed product is being considered for a new use (a new indication), a specific IB should be prepared for that new use. When relevant new information becomes available, researchers and Research Ethics Committees (RECs) should be informed “to the extent possible, prior to inclusion in the revised IB.A2 “4.01 Â”V1.1 The Researcher’s Brochure is a well-known document required to obtain clearance. to conduct a clinical research study on a medical device, in order to evaluate its safety and performance in a clinical environment. The researcher’s brochure is a well-known document requested by different regulations and competent authorities whose function is to review the documentation about the clinical trial and the product involved in the clinical trial before granting the authorization to conduct the specific study. We have already discussed the requirements for clinical evaluation according to the European Medical Device Regulation, and QualityMedDe has made available a specific Clinical Investigation Procedure aligned with the requirements of the EU MDR Regulation. In this article we will review the requirements associated with the researcher’s brochure according to the European Medical Devices Regulation 2017/745 and the European Medical Device Regulation In Vitro 2017/746. 2017/746.Main requirements The requirements for the researcher's brochure are defined in chapter II of Annex XV of the Regulation. Specifically, chapter II is defining the documentation necessary to support the request to request authorization to carry out clinical studies. The Regulation details the specific documents that must be included in the researcher's brochure, which should be presented to the specific competent authority. As explained in the introductory part of Chapter II, XV Section of the MDR: The researcher's brochure (IB) contains clinical and non-clinical information on the research device that is relevant to research and available at the time of application. In addition, it is important to mention that changes in the researcher's brochure must be handled carefully and the researcher will be informed in a timely manner of any change or update performed. Specifically, these are the necessary documents / topics to include them in the researcher's brochure. First, you have to include information necessary to identify and describe the device clearly. This may include the planned use declaration and the classification of the device according to Annex VIII. It is necessary to include the instructions to install, maintain and correctly clean the device, if applicable. In this part, it is also necessary to include information that must be placed on the label and instructions necessary for use, including the need to perform the formation to the end user (patient, health professional or any other person involved) in use Of the device. This requirement is mainly related to all the information necessary to use the device securely, including information related to labeling, IFU and related topics. The following section of the researcher's brochure is related to the results of the preclusive tests on the device. These tests may include, as mentioned specifically in the regulation regulation calculations, in vitro testing, ex-live testing, animal testing, mechanical or electrical testing, reliability testing, sterilization validation, verification and validation of software, performance testing, biocompatibility assessment and biological safety, as appropriate. In this context, all relevant clinical data collected through a different method will also be included in this section of the researcher's brochure. Information on risk management should be included, including specific information on undesirable side effects, warnings and the summary of benefit/risk analysis. In addition, detailed information should be included on compliance with the relevant general security and benefits requirements, as set out in annex I to the Regulations. This may take into account all common harmonized standards and specifications used to provide evidence of compliance with the General Security and Performance Requirements. It is important to mention that we have already discussed in separate articles about common specifications and how they can be used to demonstrate compliance with specific general safety and performance requirements. In the event that specific rules or common specifications have been met only partially, this should be clearly mentioned in the researcher ' s brochure. As an additional note, we have also been discussing the issue of the General Safety and Performance Requirements, including a pre-complete checklist that provides a complete guide on how GSPR compliance is possible. for the researcher ' s brochure on a health product containing a medicinal substance or containing human blood or plasma derivatives or productsthat use unviable tissues or cells of human or animal origin, or their derivatives. We have discussed the ISO 22 442-1 standard and the application of the risk management process for health products that contain tissues or cells of animals or human derivatives. Specifically, in the context of the researcher's brochure, for this type of products it is necessary to include: detailed information about the medicinal substance or on the tissues, cells or derivatives included in the product; Â tests of the added value of the incorporation of such components in relation to the clinical benefit and/or the safety of the product. Finally, a final requirement is mentioned in chapter II, paragraph 2, of annex XV to the EU Directive MDR 2017/745. Specifically, the researcher's brochure should contain: A detailed description of the clinical procedures and diagnostic tests used in the course of clinical research and, in particular, information on any deviation from the usual clinical practice. Conclusions It is important to mention that this article did not take into account all requirements associated with the clinical research process according to the EU MDR. Instead, this article focused specifically on the contents of the researcher's brochure, a mandatory file that must be submitted to the specific competent authority to obtain authorization to conduct a clinical study on a health product, in order to collect data on the safety and functioning of the product. We have been discussing the content of the researcher's brochure, the main requirements associated with this specific file in relation to the EU MDR.QualityMedDev Newsletter QualityMedDev is an online platform focused on quality and regulation issues for the medical device business. Thanks to the QualityMedDev newsletter, youStay up to date with the latest articles posted on the website, along with news from the regulatory world, especially in the context of the new EU MDR and IDDR. QualityMeddev is one of the largest online platforms supporting the medical device business for regulatory compliance issues. We offer regulatory consulting services across a wide range of topics, from EU MDR and IVDR to ISO 13 485, including risk management, biocompatibility, software usability and verification and validation. If you have a topic for which you would like to have more information or need template or documentation that is currently not available in our QualityMeddev store, please do not hesitate to contact us and we will do our best to fulfill your request. We recently introduced our compliance kits related to the EU surveillance activities MDR 2017/745 and Post-Market. These compliance kits include different guidelines, e-books, templates and procedures that are essential. In addition, do not hesitate to look at our EU MDR e-book compiling a lot of information on topics related to the Regulation of European Medical Devices. Regulation.

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