Quick Guide & FAQs: Clinical Study Reports Submission - CTIS Training Program - Module 13

On 28 October 2022 the EMA published Module 13 of the quick guide and FAQs guidance on CTIS training program.

Select the links below to access the Quick Guide and FAQs: Clinical Study Reports Submission, respectively.

Read the Quick Guide Read the FAQs

ICH Guideline, Clinical Study Protocol Template and Technical Specifications

On 26 October 2022 the EMA published Step 2b of the ICH M11 related guidelines.

The purpose of this new harmonized guideline is to introduce the clinical protocol template and the technical specification to ensure that protocols are prepared in a consistent fashion and provided in a harmonized data exchange format acceptable to the regulatory authorities.

Read more online

Quick Guide - Part I & Part II: How to Evaluate a Clinical Trial Application: Assessment and Decision - CTIS Training Program - Module 08

On 24 October 2022 the EMA published the quick guide parts I & II guidance on CTIS training program of module 08, version 1.4.

Select the links below to access Parts I and II of the CTIS Training Program, Module 8.

Read Part I Read Part II

Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials

On 31 October 2022 the FDA published the draft guidance on measuring and recording growth and evaluating pubertal development in pediatric clinical trials for industry.

This guidance is intended to assist sponsors in monitoring growth and, when appropriate, pubertal development in clinical trials that enroll pediatric participants with rare and common diseases. This guidance provides recommendations for the most appropriate methods for measuring and recording growth and evaluating pubertal development for evaluation of safety.

Read more online

Multiple Endpoints in Clinical Trials

On 21 October 2022 the FDA published the final guidance on multiple endpoints in clinical trials for industry.

This guidance provides sponsors and review staff with the Agency's thinking about the problems posed by multiple endpoints in the analysis and interpretation of study results and how these problems can be managed in clinical trials for human drugs, including drugs subject to licensing as biological products.

Read more online

Human Gene Therapy for Neurodegenerative Diseases

On 21 October 2022 the FDA published the final guidance on developing human gene therapy for neurodegenerative diseases.

This guidance provides recommendations to sponsors developing human gene therapy (GT) products for neurodegenerative diseases affecting adult and pediatric patients. This guidance focuses on considerations for product development, preclinical testing, and clinical trial design.

Read more online

Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Health Care

On 21 October 2022 the FDA published the draft guidance for industry and FDA staff. Submit comments by 20 December 2022.

This guidance proposes select updates to the guidance that clarify how the program may be applicable to certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions in populations impacted by health and/or health care disparities.

Read more online

Tissue Agnostic Drug Development in Oncology

On 17 October 2022 the FDA published the draft guidance on tissue agnostic drug development in oncology for industry.

This guidance provides recommendations to sponsors regarding considerations for tissue agnostic drug development in oncology. This guidance describes the development of tissue agnostic drugs, scientific considerations in determining when tissue agnostic oncology drug development may be appropriate, and, if appropriate, issues to be addressed during such development.

Read more online

Acute Myeloid Leukemia: Developing Drugs and Biological Products for Treatment

On 17 October 2022 the FDA published the final guidance on acute myeloid leukemia treatment for industry.

The purpose of this guidance is to assist sponsors in the clinical development of drugs and biological products for the treatment of acute myeloid leukemia (AML). Specifically, this guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for the development of drugs to support an indication of treatment of AML, including indications limited to an individual phase of treatment (e.g., maintenance, transplantation preparative regimen, etc.).

Read more online

Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer Immunotherapeutic Clinical Trials

On 17 October 2022 the FDA published the draft guidance on immune-mediated adverse reactions in cancer immunotherapeutic clinical trials for industry.

This guidance provides recommendations regarding the data that should be collected and evaluated to assess whether adverse events qualify as imARs and the data on imARs that should be included in a new drug application (NDA) or biologics license application (BLA) for a cancer immunotherapeutic drug.

Read more online

Guidance on Pharmacovigilance Procedures

On 25 October 2022 the UK MHRA published the updated guidance on PV procedures.

The guidance on Pharmacovigilance Procedures has been updated to include further details on submission requirements and updates for the MHRA, including the following:

- Risk Management Plans (RMPs) and Post Authorization Safety Studies (PASS)
- Periodic Safety Update Reports (PSURs) with updates for submissions in Northern Ireland
- MHRA Safety Reviews and Safety Communications

Read more online

Software and AI as a Medical Device Change Program

On 17 October 2022 the UK MHRA introduced a roadmap for software and AI as a medical device change program.

The MHRA announced the Software and AI as a Medical Device Change Program, a program of work to ensure regulatory requirements for software and AI are clear and patients are protected.

Read more online

ICH E19 Introductory Training Presentation Available

On 25 October 2022 the ICH announced the E19 introductory training presentation available.

The ICH E19 Guideline on A Selective Approach to Safety Data Collection in Specific Late-stage Pre-approval or Post-approval Clinical Trials reached Step 4 of the ICH Process in September 2022.

Read more online

ICH M11 Draft Guideline Reaches Step 2

On 21 October 2022 the ICH announced the ICH M11 draft guidelines reached step 2 of the ICH process.

This new guideline is proposed to provide comprehensive clinical protocol organization with standardized content, with: a Template which presents the format and structure of the protocol, including the table of contents, common headers, and contents; and a Technical Specification which presents the conformance, cardinality, and other technical attributes that enable the interoperable electronic exchange of protocol content.

Read more online

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Should you be interested in a partnership where you will add your personal or your company's technical and professional expertise, please contact any of the Partners as a starting point of a dialogue or write an e-Mail to info@wsqms.com.

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