WSQMS Homepage Feb 28, 2023

Use of Clinical Trials Information System (CTIS) Becomes Mandatory for New Clinical Trial Applications (CTAs) in the EU

31 January 2023 – the EMA announced mandatory use of CTIS for new CTAs in the EU.

From 31 January 2023, all initial clinical trial applications in the European Union (EU) must be submitted via the Clinical Trials Information System (CTIS). CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data.

Read more online

Q&A on the Protection of Commercially Confidential Information and Personal Data while Using CTIS

31 January 2023 – the EMA published Q&A guidance on confidential information and personal data when using CTIS.

This Q&A document has been created to provide preliminary guidance to CTIS users on how to protect personal data and commercially confidential information (CCI) in CTIS, the EU databased established in accordance with the requirements of Regulation (EU) No 536/2014 (CTR).

Read the pdf

Quick Guide for Sponsors – Regulation 536/2014 in Practice (Eudralex vol. 10)

30 January 2023 – the European Commission (EC) published the quick guide for sponsors on EU regulation 536/2014 in practice.

This is a quick guide on the main rules and procedures of the Clinical Trials Regulation (EU) No 536/2014 (CTR) for sponsors who wish to conduct clinical trials (national and multinational) in the European Union (EU) / European Economic Area (EEA) or have ongoing clinical trials in this region. The list of documents applicable to clinical trials authorized under Regulation (EU) No 536/2014, are published at the Eudralex Volume 10 website. The first document recommended for reading is the Questions and answers document – Regulation 536/2014 (Q&A –CTR) in chapter V. Additional documents (guidelines, guidance, recommendation papers, Q&As) to be considered are given in chapter 6.

Read the pdf

Guide on CTIS Common Features: Overview of CTIS Workspaces and Common System Functionalities

30 January 2023 – the EMA published Module, version 2 of the updated CTIS training program.

This document outlines the main CTIS common features available across the various tabs in both Authority and Sponsor workspaces. These features enable users to perform actions supporting their day-today business throughout the life cycle of a clinical trial. Users will find a general description of the characteristics of the buttons that support these features and some guidance for the access and navigation in CTIS.

Read the pdf

Transitional Trials from EudraCT to CTIS

26 January 2023 – the EMA published Module 23, version 1.3 as well as FAQs of the CTIS training program.

Quick Guide: Transitional trials from EudraCT to CTIS (sponsor users)

Quick Guide

FAQs of the CTIS training program

FAQs

Clinical Trial Information System (CTIS) Evaluation Timelines

26 January 2023 – the EMA published version 1.2 of the CTIS training program on evaluation timelines.

This document is for CTIS Member States and sponsors and includes:

- an overview of timelines and deadlines across the Clinical Trial Application process
- an explanation of the potential implications on the timeline of the application process (i.e. timers in CTIS are dynamic).Users are advised to check CTIS on a daily basis during crucial times in their clinical trials application process.

Read the pdf

New Organization First User QPPV/RP or Change of EU QPPV/RP

20 January 2023 – the EMA published updated guidance on EU QPPV/RP.

If a change of qualified person for pharmacovigilance/responsible person for EudraVigilance (QPPV/RP), named person or legal representative within the organization occurs, you need to notify EMA. There are 2 possible scenarios:

- There is still a QPPV/RP in your organization – change of QPPV/RP
- There is no QPPV/RP in your organization – first user QPPV/RP of a new organization

Read the pdf

Products Management Services (PMS) – Implementation of International Organization for Standardization (ISO) Standards for the Identification of Medicinal Products (IDMP) in Europe

18 January 2023 – the EMA published the implementation of ISO for the identification of medicinal products in EU.

Introduction to the EU implementation guide and updated Chapter 7 migration guide

EU Implementation Guide
Chapter 7 Migration Guide

EMA Certificates of Medicinal Products – Instructions on How to Fill the Application Form

16 January 2023 – the EMA published instructions on how to fill out the application form for EMA certificates of medicinal products.

This form is intended for requesting EMA certificates of medicinal products only. It can be used as of date of publication. Requests cannot be submitted on any other form. A complete request includes Part A and Part(s) B of the form and, if applicable, a statement of

composition and permission from the marketing-authorization holder (MAH) to obtain the certificates on their behalf.

Read the pdf

ICH Guideline M10 on Bioanalytical Method Validation and Study Sample Analysis – Questions and Answers

13 January 2023 – the EMA published updated Q&A guidance on ICH guideline M10.

This Q&A document is intended to provide additional clarification and to promote convergence and improve harmonization of the bioanalytical method validation and study sample analysis.

Read the pdf

Coordination of Pharmacovigilance Inspections

12 January 2023 – the EMA published updated Q&A guidance on human PV inspections.

The following question was added:

- What is the day zero for ICSRs described in physical/hard copy local journals? New January 2023

This Q&A aims at clarifying the interpretation of day zero for medical literature reports contained in physical/hard copy local journals received by an organization / Marketing authorization holder / Applicant.

Read more online

ICH Guideline Q13 on Continuous Manufacturing of Drug Substances and Drug Products

6 January 2023 – the EMA published updated ICH guideline Q13, step 5.

This guideline describes scientific and regulatory considerations for the development, implementation, operation, and lifecycle management of continuous manufacturing (CM). Building on existing ICH Quality guidelines, this guideline provides clarification on CM concepts and describes scientific approaches and regulatory considerations specific to CM of drug substances and drug products.

Read the pdf

Guidance on Good Manufacturing Practice and Good Distribution Practice: Questions and Answers

5 January 2023 – the EMA published updated Q&A guidance on GDP.

The following two questions were added to the GDP requirements in January 2023:

- May a broker have broker activities between parties outside the EEA?
- May a broker have broker activities for medicinal products without a marketing authorization in the EEA (but with a marketing authorization in a county outside the EEA)?

Read more online

Eudravigilance Registration Documents

4 January 2023 – the EMA published updated instructions for Eudravigilance registration documents.

The instructions include the following scenarios:

- "Registration of the headquarter for Marketing Authorization Holders (MAHs)"
- "Registration of the headquarter for commercial and non-commercial sponsors"
- "Registration of the headquarter of National Competent Authorities"

Read the pdf

M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms

31 January 2023 – the FDA published draft guidance on ICH M13A. Submit comments by 3 April 2023.

This guideline is intended to provide recommendations on conducting bioequivalence (BE) studies during both development and post approval phases for orally administered immediate-release (IR) solid oral dosage forms designed to deliver drugs to the systemic circulation, such as tablets, capsules, and granules/powders for oral suspension.

Read more online

Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products

31 January 2023 – the FDA published the draft guidance on the design and conduct of externally controlled trials. Submit comments by 2 May 2023.

This guidance provides recommendations to sponsors and investigators considering the use of externally controlled clinical trials to provide evidence of the safety and effectiveness of a drug product. In an externally controlled trial, outcomes in participants receiving the test treatment according to a protocol are compared to outcomes in a group of people external to the trial who had not received the same treatment. The external control arm can be a group of people, treated or untreated, from an earlier time (historical control), or it can be a group of people, treated or untreated, during the same time period (concurrent control) but in another setting.

Read more online

Acromegaly: Developing Drugs for Treatment

30 January 2023 – the FDA published draft guidance on developing drugs for the treatment of acromegaly. Submit comments by 31 March 2023.

The purpose of this guidance is to provide recommendations to sponsors regarding clinical development of drugs for the treatment of patients with acromegaly. This draft guidance is intended to serve as a focus for continued discussions among the Division of General Endocrinology, pharmaceutical sponsors, the academic community, and the public.

Read more online

Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

27 January 2023 – the FDA published draft guidance on recommendations for evaluating donor eligibility using individual risk-based questions.

The FDA issues this draft guidance to receive comments on revised recommendations for evaluating donor eligibility using individual risk-based questions. This draft guidance, when finalized, will provide blood establishments that collect blood or blood components, including Source Plasma, with FDA's revised donor deferral recommendations for individuals with increased risk for transmitting human immunodeficiency virus (HIV) infection.

Read more online

Cannabis and Cannabis-Derived Compounds: Quality

Considerations for Clinical Research

23 January 2023 – the FDA published the final guidance on quality considerations for clinical research of cannabis and cannabis-derived compounds for industry.

This guidance outlines FDA's current thinking on several topics relevant to clinical research related to the development of human drugs containing cannabis or cannabis-derived compounds.

Read more online

Mpox: Development of Drugs and Biological Products

17 January 2023 – the FDA published draft guidance on Mpox drug development. Submit comments by 21 March 2023.

FDA is issuing this guidance to support sponsors in their development of drugs for mpox. This guidance provides nonclinical, virology, and clinical considerations for mpox drug development programs, with a focus on recommendations to support initiation of clinical trials.

Read more online

Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases

17 January 2023 – the FDA published draft guidance on identifying optimal dosage for the treatment of oncologic diseases.

This guidance is intended to assist sponsors in identifying the optimal dosage(s) for human prescription drugs or biological products for the treatment of oncologic diseases during clinical development prior to submitting an application for approval for a new indication and usage.

Read more online

Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products –Content and Format

12 January 2023 – the FDA published draft guidance on labeling for industry. Submit comments by 14 March 2023.

This guidance is intended to assist applicants in developing the DOSAGE AND ADMINISTRATION section of labeling as described in 21 CFR 201.57(c)(3), a regulation governing the content and format of this section of human prescription drug and biological

product labeling to ensure that this section contains the dosage- and administration-related information needed for safe and effective use of a drug.

Read more online

Format and Content of a Risk Evaluation and Mitigation Strategy (REMS) Document

4 January 2023 – the FDA published the final guidance on the format and content of REMS documents.

This guidance provides updated recommendations for the format and content of a risk evaluation and mitigation strategy (REMS) document for a prescription drug product, including a biological drug product. An REMS document, which is part of an REMS that is required by FDA, establishes the goals and requirements of the REMS.

Read more online

Innovative Licensing and Access Pathway

27 January 2023 – the UK MHRA published updated guidance on an innovative licensing and access pathway.

The Innovative Licensing and Access Pathway (ILAP) aims to accelerate the time to market, facilitating patient access to medicines. These medicines include new chemical entities, biological medicines, new indications and repurposed medicines.

Read more online

MHRA Innovation Office: Guidance and Support

26 January 2023 – the UK MHRA announced their innovation office can provide regulatory advice.

The Innovation Office is open to queries relating to products or technologies that challenge the current regulatory framework, particularly those early in their development phase or in areas of regulatory uncertainty or fields undergoing rapid change.

Read more online

Notify the MHRA about a Clinical Investigation for a Medical Device

20 January 2023 – the UK MHRA published updated guidance on how to notify the MHRA of a clinical investigation for a medical device.

Updated guidance includes information on how to submit the SAE reporting form using the new MORE portal.

Read more online

Good Clinical Practice for Clinical Trials

11 January 2023 – the UK MHRA published updated guidance on upholding GCP standards and what to expect from an inspection.

To ensure compliance with GCP, MHRA:

- asks trial sites to notify them of serious breaches
- carries out inspections of trial sites where serious breaches are reported
- carries out inspections of trial sites that sponsor clinical trials, mostly based on a risk assessment
- carries out inspections of sites when companies apply for marketing authorizations

Read more online

Announcements on Clinical Trials with Medical Devices

27 January 2023 – the Swissmedic published updated forms used to report SAEs.

During category C clinical investigations (pre-market clinical investigations) sponsors have to report certain serious adverse events and device deficiencies with Excel tables. The European guidance and the form for tabular summary reporting have been updated. MDCG 2020-10/1 rev. 1 (updated guidance) and MDCG 2020-10/2 rev. 1 (updated Excel form for summary reports) should be implemented also for reports in Switzerland.

Read more online

Changes to the Guidance Document Authorization of Human Medicinal Products under Art. 13 TPA

15 January 2023 – the Swissmedic published updated guidance on changes to the guidance document authorizing the use of human medicinal products.

Application of Art. 13 TPA for temporary authorization according to Art. 9a TPA was previously only possible for new authorizations of human medicinal products with a new active substance. Subject to certain conditions, assessment is now also possible in application of Art. 13 TPA for temporary additional indications for human medicinal products with a new active substance as well as for human medicinal products with a known active

substance where an application is being made for an indication that has not previously been authorized.

Read more online

Notification in Accordance with Art. 10 IvDO for Devices Manufactured in Healthcare Institutions

12 January 2023 – the Swissmedic published guidance on notification for devices manufactured and used in healthcare institutions.

The new version of the form for notification of devices manufactured and used in healthcare institutions in accordance with Art. 10 of the Ordinance on In Vitro Diagnostic Medical Devices (SR 812.219) specifies how several devices can be grouped together in a joint notification.

Read more online

Dealing with Certification Gaps (MDCG 2022-18)

12 January 2023 – the Swissmedic published guidance on dealing with certification gaps (MDCG 2022-18).

Switzerland is implementing equivalent medical devices legislation to the EU in order to ensure the same level of protection. MDCG 2022-18 is being implemented as follows in Switzerland:

- Confirmations ("written communications") from the responsible European medical device authorities stating that they have granted a period of grace under MDCG 2022-18 will be accepted in Switzerland. The manufacturers' Swiss authorized representatives (CH-REPs) are responsible for verifying these confirmations.
- In the absence of a confirmation by a responsible European authority, Swiss manufacturers and Swiss authorized representatives can inform Swissmedic of the certification gap. Assuming the conditions stipulated by MDCG 2022-18 are met, Swissmedic will accept a period of grace for restoring conformity and confirm this in writing.

Read more online

ICH E2B(R3) Q&As Reach Step 4 of the ICH Process

23 January 2023 – the ICH announced the updated E2B(R3) Q&A guideline has reached step 4.

As of 17 January 2023, the updated ICH E2B(R3) Q&As Version 2.4 for the ICH E2B(R3) Guideline: Electronic Transmission of Individual Case Safety Reports (ICSRs) has reached Step 4 of the ICH Process.

Read more online

ICH Q9(R1) Guideline Reaches Step 4 of the ICH Process

20 January 2023 – the ICH announced Q9(R1) guideline on Quality Risk Management has reached step 4.

The ICH Q9(R1) Guideline on Quality Risk Management has reached Step 4 of the ICH Process on 18 January 2023.

This Guideline is intended to provide guidance on the principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality.

Read more online

Interested in a Partnership with Widler & Schiemann AG?

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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E-mail:info@wsqms.com

Clinical Trials Information System (CTIS) – Sponsor Handbook

22 December 2022 – the EMA published version 3.01 of the CTIS sponsor handbook.

The Handbook addresses key questions on CTIS and provides a compilation and references to key guidance, technical information, recommendations, training materials, and supportive documentation to facilitate the submission and assessment of CTAs and additional information during the lifecycle of a trial.

Read the pdf

Clinical Trials Highlights

21 December 2022 – the EMA published Issue 12 of the Clinical Trials Highlights newsletter.

Since the launch of CTIS on 31 January 2022, almost 200 clinical trial applications have been authorized and over 200 are under evaluation. During this time, EMA has collaborated with Sponsor and Member State users to identify and successfully resolve technical issues, providing proactive hands-on support to the CTIS user community and strengthening the system ahead of its compulsory use.

As of 31 January 2023, sponsors must submit all initial clinical trial applications under the CTR using CTIS and can no longer submit via the processes outlined in the Clinical Trials Directive.

Read the pdf

EU Guideline on Orphan Applications (for Designation and Transfer) - 2022/C 440/02

19 December 2022 – the European Commission published the guideline on orphan applications.

This guideline gives supplementary advice on the information sponsors must provide when applying for designation of a medicinal product as an orphan medicinal product. It covers

both the format and content of the application, and should be followed unless good reasons are given for deviating from it.

Read more online

Updated IRIS Guide to Registration and RPIs

16 December 2022 – the EMA published updated preliminary requirements for all IRIS submissions, including substance and Research Product Identifier registration.

This guide has been produced to help new users of IRIS to complete the prerequisite steps before accessing the platform. Most of these steps are independent from the IRIS platform and are similar to those to obtain registration to use other European Medicines Agency (EMA) systems, such as Management Services for Substances, Products, Organization and Referentials (SPOR).

Read the pdf

Q&A: Good Clinical Practice (GCP)

16 December 2022 – the EMA published updated GCP Q&A guidance.

This updated Q&A added B. GCP Matters, Question.17, which focuses on how sponsor oversight of such activities can be demonstrated and should be considered in combination with Q&As B.2, B.8 and B.11, which contain general considerations on how contracting should be addressed.

Read more online

Clinical Pharmacology and Pharmacokinetics: Questions and Answers

16 December 2022 – the EMA published updated Q&A guidance on guideline requirements for parenteral oily solutions.

Section 3 Bioequivalence (general) - Question 3.12:

Clarification on Appendix II of the Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1/Corr**) on whether viscosity and/or other in vitro comparative data are needed to demonstrate comparable physicochemical characteristics of oily solutions, sufficient to support a biowaiver.

Read more online

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) User Manual

15 December 2022 – the EMA published version 5.8 of the XEVMPD data-entry tool user manual.

This user manual is part of the official documentation prepared by the European Medicines Agency (EMA) to support marketing authorization holders (MAHs) and sponsors of clinical

trials using the eXtended EudraVigilance Medicinal Product Dictionary data-entry tool (EVWEB) and focuses on EVWEB functionalities based on the XEVPRM format published by the Agency on 31 January 2014 and available in the EVWEB production environment as of 16 June 2014.

Following the publication of version 5.7 in June 2022, the links to the EMA Service Desk were amended through-out the document.

Read the pdf

Functional Specifications for the European Database on Medical Devices (EUDAMED)

14 December 2022 – the European Commission published guidance on functional specifications for EUDAMED.

Article 34 of Regulation (EU) 2017/745 obliges the Commission to draw up the functional specifications for EUDAMED in collaboration with the MDCG. This document will also be a reference for the independent audit to be performed for verifying that Eudamed has achieved full functionality.

Read the pdf

Recommendation Paper on Decentralized Elements in Clinical Trials

13 December 2022 – the European Commission published the recommendation paper on decentralized elements in clinical trials, version 01.

The recommendation paper will address the roles and responsibilities of the sponsor and investigator, electronic informed consent, IMP delivery, trial related procedures at home, data management and monitoring in a decentralized clinical trial setting. The intention of this recommendation paper is to facilitate the use of decentralized elements in clinical trials in the EU/EEA.

Read the pdf

Guidance for Applicants/MAHs Involved in GMP, GCP and GVP Inspections Coordinated by EMA

13 December 2022 – the EMA published version 3.1 of guidance for applicants/MAHs involved in GMP, GCP and GVP inspections coordinated by EMA.

These GMP inspections are requested by the Committee for Medicinal Products for Human Use (CHMP) and/or the Committee for Medicinal Products for Veterinary Use (CVMP) in order to verify compliance with GMP of sites responsible for the manufacture of centrally authorized products.

These GCP inspections are requested by the CHMP in order to verify compliance with GCP for centrally authorized products, in accordance with Article 57 of Regulation (EC) No. 726/2004 and Article 78 of Regulation (EU) No 536/2014.

These GVP inspections are requested by the CHMP in order to verify compliance with GVP for centrally authorized products, in accordance with Article 57 of Regulation (EC) No. 726/2004 and CVMP, in accordance with Article 57 of Regulation (EC) No. 726/2004 and Articles 123 and 126 of Regulation (EU) 2019/6.

Read the pdf

Joint Audit Program for EEA GMP Inspectorates (JAP)

8 December 2022 – the EMA published revision 3 of the audit notification template for EEA GMP inspectorates (JAP).

The Joint Audit Program (JAP) forms an essential part of the quality system adopted by good manufacturing practice (GMP) inspectorates in the European Economic Area (EEA), aiming to ensure consistency of GMP standards and a harmonized approach throughout Europe.

The audit program, its procedures and templates form the complete set of documents used in the JAP.

Read the pdf

EMA Human Regulatory Update on Medical Devices

8 December 2022 – the EMA updated guidance on medical devices.

EMA has distinct regulatory responsibilities per category of medical device, including in vitro diagnostics. They are as follows:

- Medicines used in combination with a medical device — EMA assesses the safety and effectiveness of medicines used in combination with a medical device. This is part of a centralized procedure application for the medicinal product.
- Medical devices with an ancillary medicinal substance — the notified body must seek EMA's scientific opinion on the quality, safety, and usefulness of the ancillary medicinal substance in three cases: if the ancillary substance is derived from human blood or plasma; if it has been previously evaluated by the EMA; or if it falls within the mandatory scope of the centralized.
- Companion diagnostics ('in vitro diagnostics') — the notified body must seek EMA's scientific opinion on the suitability of the companion diagnostic to the medicinal product if the latter falls within the scope of the centralized.
- Medical devices made of substances that are systemically absorbed — the notified body must seek the scientific opinion of a competent authority. The EMA provides scientific opinions on the compliance of the substance with the requirements laid down in Annex I to Directive 2001/83/EC.
- High-risk medical devices — EMA supports the medical device expert panels that provide opinions and views to notified bodies on the scientific assessment of certain high-risk medical devices and in vitro diagnostics.

Read more online

EMA EudraVigilance Registration Documents and Manual

7 December 2022 – the EMA published the updated EudraVigilance registration related documents and manual.

To set-up a new organization in EudraVigilance (EV) Production or XCOMP (test) system, the following series of steps need to be followed:

1. EMA EudraVigilance Registration Documents

2. New Organization First User QPPV/RP or Change of EU QPPV/RP

3. Vendor registration in the EudraVigilance external compliance testing environment (XCOMP)

4. EMA EudraVigilance Registration Manual

EMA Registration Documents New Organization First User Vendor Registration EMA Registration Manual

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Human Variations Electronic Application Forms (eAF) (DADI) Go-live Q&A Session

6 December 2022 – the EMA published the Q&A guidance on human variations eAF go-live Q&A session held on 27 October 2022 and 8 November 2022.

The web-based electronic application forms (eAF) will replace PDF eAFs used for regulatory submissions in the new dedicated PLM portal. These Q&A sessions attempted to address questions from industry and national competent authorities' stakeholders concerning the release of the web-based variations eAF for Human CAPs.

Human Variations eAF go-live Q&A session (27 October 2022) Human Variations eAF go-live Q&A session (8 November 2022)

ICH Guideline E8 (R1) on General Considerations for Clinical Studies

2 December 2022 – the EMA published step 5 of ICH Guideline E8 (R1).

This document provides guidance on the clinical development lifecycle, including designing quality into clinical studies, considering the broad range of clinical study designs and data sources used.

Read the pdf

Manual on Borderline and Classification for Medical Devices under Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on in vitro Diagnostic Medical Devices

In December 2022 – the European Commission published version 2 of the manual on borderline and classification for medical devices.

This document, hereafter called the Manual, records the agreements reached by the Member State members of the Borderline and Classification Working Group (BCWG)

following the exchanges under the Helsinki Procedure under Regulation (EU) 2017/745 on medical devices (the MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR).

Read the pdf

Controlled Correspondence Related to Generic Drug Development

21 December 2022 – the FDA published draft guidance on controlled correspondence related to generic drug development.

This guidance provides information regarding the process by which generic drug manufacturers and related industry or their representatives can submit to FDA controlled correspondence requesting information related to generic drug development. This guidance also describes the Agency's process for providing communications related to such correspondence.

Read more online

M11 Clinical Electronic Structured Harmonized Protocol (CeSHarP)

21 December 2022 – the FDA published draft guidance on the ICH M11 clinical electronic structured harmonized protocol.

- Structure and Content: Clinical Electronic Harmonized Protocol
- Technical Specification: Clinical Electronic Harmonized Protocol
- Template: Clinical Electronic Structured Harmonized Protocol

M11 Structured Content M11 Technical Specifications M11 Template

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Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

15 December 2022 – the FDA published final guidance on drug labeling for cardiovascular outcome claims for hypertension.

This guidance is intended to assist applicants in developing labeling for cardiovascular outcome claims for drugs that are indicated to treat hypertension. With few exceptions, current labeling for antihypertensive drugs includes only the information that these drugs are indicated to reduce blood pressure; the labeling does not include information on the clinical benefits related to cardiovascular outcomes expected from such blood pressure reduction.

Read more online

Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection

15 December 2022 – the FDA published the draft guidance for industry on circumstances that constitute delaying, denying, limiting, or refusing a drug or device inspection.

This draft guidance describes the types of behaviors (actions, inactions, and circumstances) that the FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection to include both drugs and devices.

Read more online

Pulmonary Tuberculosis: Developing Drugs for Treatment

14 December 2022 – the FDA published draft guidance on developing drugs for treatment of pulmonary tuberculosis. Submit Comments by 13 February 2023.

The purpose of this guidance is to assist sponsors in the clinical development of investigational drugs for the treatment of pulmonary tuberculosis (TB). This guidance does not address the development of drugs for latent TB infection or for extrapulmonary TB.

Read more online

Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe

14 December 2022 – the FDA published final guidance on failure to respond to an ANDA complete response letter.

This guidance is intended to assist applicants of abbreviated new drug applications (ANDAs), which were submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)), in responding to complete response letters (CRLs) from FDA. This guidance provides information and recommendations regarding potential courses of action for an ANDA applicant after issuance of a CRL, as well as the actions that FDA may take if the applicant fails to respond to that CRL.

Read more online

Content of Human Factors Information in Medical Device Marketing Submissions

9 December 2022 – the FDA published the draft guidance on medical device marketing submissions for industry and FDA staff. Submit comments by 9 March 2023.

This guidance includes FDA's recommendations for the content of human factors and usability information to be included in marketing submissions. The marketing submission should, where appropriate, demonstrate that the needs of the intended users were considered in the device design and that the device is safe and effective.

Read more online

Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers

9 December 2022 – the FDA published draft guidance on the VMSR program for industry and FDA staff. Submit comments by 7 February 2023.

FDA is issuing this draft guidance to help manufacturers better understand and use the Voluntary Summary Malfunction Reporting (VMSR) Program. This guidance clarifies FDA's approach for determining the conditions for submitting medical device reports (MDRs) and permits manufacturers of devices in eligible product codes to report certain device malfunctions in summary form on a quarterly basis.

Read more online

Drug Products Labeled as Homeopathic

7 December 2022 – the FDA published final guidance on homeopathic drug products for FDA staff and industry.

This guidance describes how FDA intends to prioritize enforcement and regulatory actions for homeopathic drug products marketed in the United States without the required FDA approval. FDA has developed a risk-based approach under which the Agency intends to prioritize enforcement and regulatory actions involving certain categories of such products that potentially pose a higher risk to public health.

Read more online

Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD-1) or Programmed Cell Death-Ligand 1 (PD-L1) Blocking Antibodies for Treatment of Patients with Cancer

6 December 2022 – the FDA published final guidance on PK-based criteria to support the approval of alternative dosing regimens for PD-1 or PD-L1 blocking antibodies for treating cancer patients.

This document provides recommendations for sponsors of investigational new drug applications (INDs) and biologics license applications (BLAs) under 42 U.S.C. § 262 and 21 CFR Parts 312 and 601 on the use of pharmacokinetic (PK)-based criteria to support the approval of alternative dosing regimens for programmed cell death receptor-1 (PD-1) or programmed cell death-ligand 1 (PD-L1) blocking antibodies. This guidance is based on accumulated scientific and regulatory experience for PD-1 and PD-L1 drugs, and as such, does not address development of alternative dosing regimens for other drugs or biologics, changes in route of administration, or novel formulations of previously-approved PD-1/PD-L1 products.

Read more online

E19 A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-Approval or Post-Approval Clinical Trials

5 December 2022 – the FDA published final ICH E19 guidance for industry.

This guidance is intended to provide internationally harmonized guidance on the use of selective safety data collection that may be applied in specific pre-approval or post-approval late-stage clinical trials. Selective safety data collection refers to the reduced collection of certain types of data in a clinical trial after thorough consideration of factors that would justify such an approach. By tailoring the method and streamlining the approach to safety data collection, it may be possible to carry out clinical trials with greater efficiency. This may

facilitate the conduct of large-scale efficacy and safety clinical trials with large numbers of participants and long-term follow-up. In all circumstances in which the use of selective safety data collection is considered, it is important that the welfare of every trial participant is safeguarded.

Read more online

ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions

2 December 2022 – the FDA published the draft guidance on the abbreviated new drug applications (ANDAs) for industry.

The FDA is issuing this revised draft guidance to incorporate program enhancements related to the content, timing, and assessment of a pre-submission facility correspondence (PFC) within the abbreviated new drug application (ANDA) assessment program agreed upon by the Agency and industry as part of the reauthorization of the Generic Drug User Fee Amendments (GDUFA III), as described in GDUFA Reauthorization Performance Goals and Program Enhancements, Fiscal Years 2023 through 2027 (GDUFA III commitment letter).

Read more online

Statistical Approaches to Establishing Bioequivalence

2 December 2022 – the FDA published draft guidance on statistical approaches to establishing bioequivalence for industry.

Requirements for submitting bioavailability (BA) and bioequivalence (BE) data in investigational new drugs (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplements; the definitions of BA and BE; and the types of in vitro and in vivo studies that are appropriate to measure BA and establish BE are set forth in part 320 (21 CFR part 320). This guidance provides recommendations on how to meet provisions of part 320 for all drug products.

Read more online

Reporting Individual Case Study Reports (ICSRs) to FAERS Using ICH E2B R3 Standards

14 November 2022 – the FDA announced a webinar on 13 January 2023 to discuss standards for reporting ICSRs to FAERS.

This session will describe the regional technical specification and implementation process for receiving safety reports to FAERS using ICH E2B (R3) and regional data elements. The session will include a discussion of regional E2B data elements for premarket and postmarket safety reporting and provisions for submission of safety reports to FAERS that satisfy requirements for safety reporting regulations and FDA Guidance.

Read more online

Medicines: Apply for a Parallel Import License

9 December 2022 – the MHRA published updated guidance on applying for a parallel import license.

The UK parallel import licensing scheme lets a medicine authorized in a European Economic Area (EEA) Member State be marketed in the UK, as long as the imported product has no therapeutic difference from the cross-referenced UK product.

The MR-DC product list in the section "Make a TaD variation" has been updated.

Read more online

Register Medical Devices to Place on the Market

6 December 2022 – the MHRA published updated guidance on the registration of medical devices.

All medical devices, including IVDs, custom-made devices and systems or procedure packs, must be registered with the MHRA before they can be placed on the market in Great Britain (England, Wales and Scotland).

Read more online

Updated Swissmedic / Swissethics Position Paper on Decentralized Clinical Trials (DCTs) of Medicinal Products

22 December 2022 – the Swissmedic updated the position paper on decentralized clinical trials of medicinal products.

The paper is addressed to researchers and sponsors as well as all those interested in clinical research. The position paper was revised and clarified where necessary.

Read more online

Clarification of Terminology for Combination Products (Medicinal Products with a Medical Device Component)

15 December 2022 – the Swissmedic published guidance on clarification of terminology for combination products.

Current status and revision of specification documents: all relevant information is described in section 2.5.15 of the Guidance document Formal requirements HMV4.

Read more online

Expansion of Scope of Temporary Authorizations

1 December 2022 – the Swissmedic published guidance on temporary authorizations.

Beginning 1 January 2023, temporary additional indications to make medicinal products for the treatment of life-threatening diseases will be available to patients as quickly as possible, and it will be possible for temporary authorization to be granted under certain conditions defined by law (Art. 9a TPA in conjunction with Art. 18 TPLO).

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 email us at info@wsqms.com.

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