WSQMS Homepage Apr 20, 2023

Clinical Trials Information System (CTIS) – Sponsor Handbook

12 April 2023 – the EMA published v3.02 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

Reflection Paper on the Use of Interactive Response Technologies (Interactive Voice/Web Response Systems) in Clinical Trials, with Particular Emphasis on the Handling of Expiry Dates

5 April 2023 – the EMA published the reflection paper on the use of IRTs in clinical trials.

Over the last 15 years there has been an increasing utilization of interactive response technology (IRT), encompassing both interactive voice response systems (IVRS) utilizing the telephone or tone dialers and interactive web response systems (IWRS) utilizing the internet. These systems were developed initially to optimize drug availability at sites; however, this has expanded into other areas such as emergency unblinding (code-breaking), dose titration and expiry date updating. This of course may, if not handled appropriately, pose an increased risk to the patient and so IRT is of increasing interest to national competent authorities (NCAs).

This paper seeks to provide guidance on what NCAs expect from such systems and in particular their use for handling of the expiry date of the Investigational Medicinal Product (IMP). These positions will form suggestions for sponsors and IRT providers on the validation requirements for systems.

Read the pdf

EMA GCP IWG Points to Consider Regarding the Management of Ongoing Clinical Trials Impacted by Political Conflicts, Natural Disasters or Other Major Disruptions

5 April 2023 – the EMA published GCP IWG points to consider regarding the management of ongoing clinical trials impacted by disruptions in society.

This points to consider document draws from the experience of past major disruptions in society, including the Covid-19 pandemic and the most recent developments of the Russo-Ukrainian War. These are varied in nature but may have similar, multiple consequences on clinical trials performed in the affected geographical areas. This document aims to help sponsors address the resulting challenges and mitigate risks to the rights, safety, dignity, and well-being of trial participants — a particularly vulnerable population — and to the scientific value of the clinical trials.

Read the pdf

A Risk-Based Approach to Monitoring of Clinical Investigations

12 April 2023 – the FDA published final Q&A guidance on risk-based monitoring of clinical investigations for industry.

This guidance provides information on risk-based approaches to monitoring the conduct of clinical investigations of human drug and biological products, medical devices, and combination products. Clinical investigation monitoring is a quality control tool for determining whether investigation activities are being carried out as planned. This guidance contains recommendations on planning a monitoring approach, developing the content of a monitoring plan, and addressing and communicating monitoring results.

Read more online

Using Innovative Communication Methods to Increase Awareness and Understanding of CDER Guidance Documents: CDER's Guidance Snapshot Pilot Program

10 April 2023 – the FDA published their Center for Drug Evaluation and Research (CDER) guidance snapshot pilot program.

The program communicates guidance recommendations to multiple stakeholder audiences using visuals, plain language, and other innovative technologies to increase awareness and understanding of CDER's often complex guidance documents.

Read more online

Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision-Making

5 April 2023 – the FDA published draft guidance on patient-focused drug development for industry, FDA staff and other stakeholders. Submit comments by 5 July 2023.

This guidance (Guidance 4) is the fourth in a series of four methodological patient-focused drug development (PFDD) guidance documents that describe how stakeholders (patients, caregivers, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making.

Read more online

Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients (API) Under Section 506C of the FD&C Act

5 April 2023 – the FDA published draft guidance on notifications of changes in the production of finished products or API.

This draft guidance assists applicants and manufacturers in providing FDA timely, informative notifications about changes in the production of certain finished drugs and biological products, as well as certain active pharmaceutical ingredients (API) that may, in turn, help the Agency in its efforts to prevent or mitigate shortages. The guidance also explains how FDA communicates information about products in shortage to the public.

Read more online

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions (DSF)

3 April 2023 – the FDA published the draft guidance on marketing submission recommendations for AI/ML-enabled devices. Submit comments by 3 July 2023.

This draft guidance describes a least burdensome approach to support iterative improvement through modifications to an ML-DSF while continuing to provide a reasonable assurance of device safety and effectiveness. The draft guidance provides recommendations on the information to be included in a Predetermined Change Control Plan (PCCP) provided in a marketing submission for ML-DSF.

Read more online

Good Clinical Practice for Clinical Trials

6 April 2023 – the UK MHRA published updated guidance on GCP for clinical trials.

Good clinical practice (GCP) is a set of internationally-recognized ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people.

The "GCP inspection dossier clinical trial spreadsheet" has been updated.

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Software and Artificial Intelligence (AI) as a Medical Device

6 April 2023 – the UK MHRA published guidance on software and AI as a medical device.

Software (including AI) plays an essential part in health and social care. In the UK, many of these products are regulated as medical devices (or as in vitro diagnostic medical devices (IVDs). This guidance provides access to important Software Group outputs that might be of assistance.

Read more online

How to Draft a Direct Healthcare Professional Communication

4 April 2023 – the UK MHRA published updated guidance for marketing authorization holders on drafting direct healthcare professional communications (DHPCs).

A direct healthcare professional communication (DHPC) aims to ensure safe and effective use of a marketed medicine. Letters are sent directly to healthcare professionals by marketing authorization holders or by the licensing authority. Direct healthcare professional communication letters should always include a 'Call for reporting' section to outline national arrangements for reporting suspected adverse drug reactions. Changes were made to the 'Call for reporting' template.

Read more online

Announcements on Clinical Trials with Medical Devices and Performance Studies with Vitro Diagnostic Medical Devices

13 April 2023 – the Swissmedic announced on submissions for combined trials with medical devices and vitro diagnostic medical devices.

Swissmedic has updated the guidance for the submission of combined trials, and for submissions for already authorized trials that are newly becoming combined trials. The corresponding information can be found in Annex A7 of the Swissmedic information sheets for combined trials of medicinal products and medical devices and for combined trials of medicinal products and companion diagnostics / IVDs.

Read more online

The ICH M7(R2) Guideline Reaches Step 4 of the ICH Process

6 April 2023 – the ICH announced ICH M7(R2) guidelines reaches step 4.

The ICH M7(R2) Guideline on the "Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk" and the accompanying M7(R2) Addendum "Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes" have reached Step 4 of the ICH Process on 3 April 2023.

In addition, ICH publishes the accompanying "Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk" Questions and Answers which were adopted on 24 May 2022 to provide additional clarification, promote convergence and improve harmonization of the considerations for assessment and control of DNA reactive (mutagenic) impurities found in ICH M7(R2).

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Annual Report of the Good Manufacturing and Distribution Practice Inspectors Working Group 2022

28 April 2023 – the EMA published revision 1 of the 2022 GMP/GDP IWG Annual Report.

This document is the annual report of the GMP/GDP Inspectors Working Group (GMP/GDP IWG) for the year 2022. The GMP/GDP IWG provides input and recommendations on all matters relating directly or indirectly to Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP). The GMP/GDP IWG focuses on harmonization and coordination of GMP and GDP related activities at the EU level and maintains close cooperation with international partner authorities. This annual report is set out in line with the format and objectives of the 2021 – 2023 3-year work plan.

Read the pdf

News Bulletin for Small and Medium-Sized Enterprises (SME)

28 April 2023 – the EMA published SME Newsletter – Issue 58.

In this issue, the SME Office newsletter includes the following topics:

- Scientific guidelines for human medicines: quality guidelines, clinical guidelines, Multidisciplinary guidelines
- Regulatory and procedural guidelines for human medicines
- Clinical trials
- Pediatric medicines

- Priority Medicines (PRIME)
- Veterinary medicines: regulatory and procedural guidelines
- Fees payable to the EMA
- Events and reports of interest
- Registered SMEs
- Contact details

Read the pdf

Biosimilar Medicines

26 April 2023 – the EMA published an updated statement and Q&A guidance on the scientific rationale supporting interchangeability of biosimilars medicines in the EU.

Statement on the Scientific Rationale Supporting Interchangeability of Biosimilar Medicines in the EU

This joint EMA-HMA statement explains the rationale for considering biosimilars approved in the EU as interchangeable from a scientific perspective. Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. How this is implemented is the responsibility of the individual member states.

Q&A Statement

Following the publication of the joint EMA-HMA statement on interchangeability of biosimilar medicinal products approved in the EU, both EMA and National Competent Authorities (NCAs) have received questions for clarification from healthcare professionals and other members of the public. This questions and answers (Q&A) document addresses follow-up questions received after publication of the statement.

Updated Statement Q&A Statement

Clinical Data Publication

25 April 2023 – the EMA announced resumption of publishing clinical data submitted by pharmaceutical companies.

EMA intends to gradually resume clinical data publication beginning September 2023, having previously suspended this activity for all products, except treatments and vaccines for COVID-19.

A webinar providing details of the relaunch will be held on 16 May 2023. The webinar will focus on the background and scope of the re-start, while also providing guidance for applicants and industry stakeholders, including small and medium-sized enterprises intending to submit clinical data for publication.

Clinical Data Publication Relaunch 16 May 2023 Webinar Registration

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EMA Pre-Authorization Guidance for Users of the Centralized Procedure

25 April 2023 – the EMA published the pre- / post-authorization guidance for users of the centralized procedure.

European Medicines Agency pre-authorization procedural advice for users of the centralized procedure

Revised section 4.1: How and to whom should I submit my dossier?

Read the pdf

Reflection Paper on Establishing Efficacy Based on Single-Arm Trials (SATs) Submitted as Pivotal Evidence in a Marketing Authorization

21 April 2023 – the EMA published the draft reflection paper for consideration on evidence from single-arm trials.

Randomized controlled trials (RCTs) are the standard for providing confirmatory evidence on the efficacy of a new treatment. However, in a relevant proportion of marketing authorization applications the pivotal clinical data stems from single-arm trials (SATs). This is observed across different therapeutic areas, including for rare diseases.

The purpose of this reflection paper is to outline the current thinking about SATs that are submitted as pivotal evidence for establishing efficacy in marketing authorization applications.

Read the pdf

IRIS Guide to Registration and RPIs

20 April 2023 – the EMA published version 2.14 on preliminary requirements for all IRIS submissions, including substance and Research Product Identifier (RPI) registration.

This guide has been produced to help new users of IRIS complete the prerequisite steps before accessing the platform.

Read the pdf

ICH S12 Guideline on Nonclinical Biodistribution Considerations for Gene Therapy Products

20 April 2023 – the EMA published step 5 of the ICH S12 guideline.

The objective of this guideline is to provide harmonized recommendations for the conduct of nonclinical biodistribution (BD) studies in the development of gene therapy (GT) products. This document provides recommendations for the overall design of nonclinical BD assessments. Considerations for interpretation and application of the BD data to support a nonclinical development program and the design of clinical trials are also provided. The recommendations in this guideline endeavor to facilitate the development of GT products while avoiding unnecessary use of animals, in accordance with the 3Rs (reduce/refine/replace) principles.

Read the pdf

European Health Union: Commission Proposes Pharmaceuticals Reform for More Accessible, Affordable and Innovative Medicines

26 April 2023 – the European Commission proposes largest revision to pharmaceutical legislation in over 20 years.

The Commission is proposing to revise the EU's pharmaceutical legislation - the largest reform in over 20 years - to make it more agile, flexible, and adapted to the needs of citizens and businesses across the EU. The revision will make medicines more available, accessible and affordable. It will support innovation and boost the competitiveness and attractiveness of the EU pharmaceutical industry, while promoting higher environmental standards.

Read more online

Frequently Asked Questions: Council Recommendation on Stepping up EU Actions to Combat AMR in a One Health Approach

26 April 2023 – the European Commission published the Q&A guidance on recommendation to combat antimicrobial resistance (AMR) in one health approach.

One of the main objectives of this Recommendation is to foster a prudent use of antimicrobials. Therefore, it recommends concrete targets on AMR and antimicrobial consumption in the human sector. In addition, the Recommendation aims to boost national

One Health action plans on AMR, improve infection prevention and control, foster research and innovation, incentivize innovation and access to antimicrobials and other medical countermeasures, reinforce surveillance and monitoring of AMR and antimicrobial consumption, enhance global cooperation, and improve public awareness, education, and training of professionals.

Read more online

Frequently Asked Questions: Revision of the Pharmaceutical Legislation

26 April 2023 – the European Commission published Q&A guidance on the revision of the pharmaceutical legislation.

The Commission is proposing an ambitious revision of the EU pharmaceutical legislation to achieve the following main objectives:

1. Create a Single Market for medicines ensuring that all patients across the EU have timely and equitable access to safe, effective, and affordable medicines;

2. Continue to offer an attractive and innovation-friendly framework for research, development, and production of medicines in Europe;

3. Reduce drastically the administrative burden by speeding up procedures significantly reducing authorization times for medicines, so they reach patients faster;

4. Enhance availability and ensure medicines can always be supplied to patients, regardless of where they live in the EU;

5. Address antimicrobial resistance (AMR) and the presence of pharmaceuticals in the environment through a One Health approach;

6. Make medicines more environmentally sustainable.

Read more online

Data Standards Catalog

28 April 2023 – the FDA published version 9.1 of the final updated guidance of the data standards catalog.

The FDA Data Standards Catalog (Catalog) lists the data standards and terminologies that FDA supports for use in regulatory submissions to better enable the evaluation of safety, effectiveness, and quality of FDA-regulated products. In addition, the FDA has the statutory and regulatory authority to require certain standards and terminologies which are identified in the Catalog with the date the requirement begins and, as needed, the date the requirement ends, and information sources.

The submission of data using standards or terminologies not listed in the Catalog should be discussed with the Agency in advance. Where the Catalog expresses support for more than one standard or terminology for a specific use, the sponsor or applicant may select one to use or can discuss, as appropriate, with their review division. Sponsors and applicants should review the Catalog terms below, as well as any references associated with specific standards or terminologies. Starting in v9.0, dates throughout are listed as (MM/DD/YYYY).

Read more online

Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment

19 April 2023 – the FDA published draft guidance on developing drugs for treating acute radiation syndrome. Submit comments by 19 July 2023.

The purpose of this draft guidance is to provide information and recommendations to assist sponsors and other interested parties in the development of drugs to prevent or treat acute radiation syndrome (ARS) caused by exposure to ionizing radiation from accidental or deliberate events. Generally, drugs developed for such indications will require approval under the regulations commonly referred to as the Animal Rule.

Read more online

Regulating Medical Devices in the UK

28 April 2023 – the UK MHRA published the updated guidance on regulating medical devices in the UK and EU markets.

This guidance was updated primarily to reflect an intended extension to acceptance of CE marked medical devices on the Great Britain market beyond 30 June 2023. This guidance has been updated with changes to 'Summary of key requirements for placing a device on the Great Britain market', 'Registrations in Great Britain', 'UKCA marking', 'CE marking and Notified Bodies', 'Labelling requirements' and 'Regulation of medical devices in Northern Ireland' Reference Guides.

Read more online

Implementation of the Future Regulations for Medical Devices

27 April 2023 – the UK MHRA published the updated guidance on the implementation of medical devices future regime.

The government intends to introduce regulations in future that will implement a substantial reform of the current regulatory framework for medical devices in the UK. This guidance has

been updated to reflect that the government is now aiming for core aspects of the future regime for medical devices to apply from 1 July 2025.

Read more online

Register Medical Devices to Place on the Market

27 April 2023 – the UK MHRA published updated guidance on registration of medical devices to place on the market.

This guidance was updated to include information on the registration of certain CE marked medical devices in scope of transitional arrangements under the EU Medical Devices Regulation. It was also updated to reflect an intended extension to acceptance of CE marked medical devices on the Great Britain market beyond 30 June 2023.

Read more online

MORE Platform Application Programming Interface (API) Integration

24 April 2023 – the UK MHRA published the instructions and reference guides for integrating with the new production MORE platform API.

These documents will allow you to set-up Application Programming Interface (API) functionality on the new production Manufacturer's On-line Reporting Environment (MORE) reporting platform and validate a report prior to starting submission.

MORE Platform API
MORE User Reference Guide - Incident Submissions
MORE User Reference Guide - Registrations

Access Consortium Offers Pipeline Meetings to Pharmaceutical and Biotechnology Companies

24 April 2023 – the Swissmedic announced the Access Consortium is offering joint pipeline meetings to pharmaceutical and biotechnology companies.

Pipeline meetings between the regulatory authorities and pharmaceutical and biotechnology companies are an opportunity to exchange information on new developments and collaborate on new possibilities.

The meetings will also help Access regulators plan and prepare for future work-share applications. Stakeholders must submit a request for a pipeline meeting.

Read more online

Swissmedic Becomes an Official Observer in the International Medical Devices Regulators Forum (IMDRF)

24 April 2023 – the Swissmedic announced the IMDRF granted the Swiss Agency for Therapeutic Products the status of Official Observer at Management Committee Meetings.

The IMDRF is comprised of regulatory authorities from around the world and aims to accelerate international harmonization and revision of medical device regulations. This provides an important basis for reducing regulatory effort for both authorities and companies and for exploiting synergies through regulatory cooperation.

At Swissmedic's request, the IMDRF granted the Swiss Agency for Therapeutic Products the status of Official Observer at Management Committee Meetings. This new status is an important interim step towards Swissmedic's strategic objective of being admitted as a member of the Management Committee.

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