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Regulatory Agency Updates

Clinical Trials' Transition to New EU System – One Year Left

All ongoing clinical trials in the EU must be transitioned to the Clinical Trials Information System (CTIS) by 31 January 2025. This date marks the end of a three-year transition period that began when the Clinical Trials Regulation (CTR) became applicable in the EU.

Read more online

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

The EMA intends to migrate the Centrally Authorized Products (CAPs) and non-Centrally Authorized Products (non-CAPs) data held in the eXtended Eudravigilance Medicinal Product Dictionary (XEVMPD) and submitted by marketing authorization holders (MAHs) under the Art.57 (2) legal obligations into the ISO IDMP-compliant data format and terminologies.

This chapter provides information on the approach followed by the EMA to enable the transformation and migration of the data to the PMS.

Read more online

CTIS Newsflash

Key updates:

- The December 2023 report on the implementation of the Clinical Trials Regulation (CTR) is now available on the ACT EU website.
- Tips for users of the CTIS helpdesk are now available on the CTIS website.

Read more online

Getting Started with CTIS: Sponsor Quickguide

To get started with CTIS, sponsors must decide on their user management approach and complete registrations.

Read more online

ICH Q14 Analytical Procedure Development

(effective 14 June 2024)

This guideline describes science and risk-based approaches for developing and maintaining analytical procedures suitable for the evaluation of the quality of drug substances and drug products.

Read more online

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Clinical Data Publication

By proactively publishing clinical data, EMA intends to help:

- avoid duplication of clinical trials, foster innovation and encourage development of new medicines;
- build public trust and confidence in EMA's scientific and decision-making processes;
- academics and researchers to re-assess clinical data.
- "Resumption of clinical data publication for all medicines" was updated.

Read more online

Concept Paper on the Revision of the Guideline on the Clinical Evaluation of Medicinal Products Intended for the Treatment of Hepatitis B

(submit comments by 30 April 2024)

This concept paper addresses the need to update the guideline on the clinical evaluation of medicinal products intended for the treatment of Hepatitis B (CHMP/EWP/6172/03)1. This guideline was originally adopted by CHMP on the 23 February 2006 and came into effect on the 1st of September 2006. In recent years there have been several applications for scientific advice on new products and treatment strategies aimed at achieving functional cure, including finite and combination treatment regimens. Therefore, a revision of the guideline is necessary to reflect these new developments and the implications for clinical development programs.

Read more online

Multi-Annual HMA-EMA AI Workplan: 2023-2028

This first version of the BDSG multi-annual AI workplan focuses on four critical dimensions to facilitate the development and use of responsible and beneficial AI.

Read more online

Big Data Steering Group (BDSG): 2023 Report

2023 marked significant progress in the transformation to data-driven regulation continued, in line with the Network Strategy to 2025 and BDSG workplan. The fourth BDSG workplan was published in July 2023 to progress the activities launched in 2020 and to address new topics.

This report is based on the third BDSG workplan and provides a summary of the key activities and achievements of the BDSG in 2023.

Read more online

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Major Update of the EMA User Guide for Micro, Small and Medium-sized Enterprises (SMEs)

The revised user guide offers comprehensive information on the EU legislative framework for medicines, outlining requirements for the development and authorization of medicines for human and veterinary use. It follows the chronological stages of medicine development, and has become a reference source of information for SME and academic developers, supporting them to navigate the system of medicine regulation in the EU. The new release incorporates significant updates to reflect major changes in the EU's legal and regulatory framework for human and veterinary medicines:

- Veterinary Regulation: the document has been fully revised to align with the veterinary regulation
- Clinical Trials Regulation (new section 4.4): provides an overview of the clinical trial regulation and Clinical Trials Information System (CTIS)
- Medical Devices Regulation (new section 4.8): offers insights into medical device regulation for human medicines

Read more online

Guideline on the Clinical Evaluation of Anticancer Medicinal Products

The purpose of this guideline is to provide guidance on all stages of clinical drug development for the treatment of malignancies, including drug resistance modifiers or normal tissue protective compounds.

Read more online

Multi-Stakeholder Workshop on Data Quality Framework for Adverse Drug Reaction (ADR) Reporting

(1 March 2024)

The aim of this workshop is to bring together experts in the field to build on their extensive experience and knowledge relating to ADR data quality.

Read more online

IRIS Guide for Applicants

This guide has been produced to show applicants how to use the IRIS platform to prepare, submit and manage an application and/or data for a scientific procedure (orphan designation application, scientific advice, ITF briefing meeting requests, PRIME, marketing status reports, inspections and veterinary signal management) and related activities, or applications for Parallel Distribution procedures.

This revision added instructions to manage regulatory procedures in IRIS in existing section (main changes in yellow) and added a new section dedicated to Product Lifecycle Management procedures (section title in yellow).

Read more online

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Regulatory Agency Updates

Policy on the Determination of the Condition(s) for a Pediatric Investigation Plan/Waiver (Scope of the PIP/Waiver)

The aim of this policy is to propose a systematic approach based on the characteristics of the product and an independent classification of diseases and conditions to provide a more reliable and predictable framework for applicants and the PDCO in identifying the scope of a PIP or a waiver, and to facilitate the evaluation.

Read more online

Clinical Trials Information System (CTIS) Sponsor End User Training Programs

The following Training Programs are open to sponsor users of the new CTIS: commercial and non-commercial sponsors as well as Contract Research Organizations (CROs).

12-15 February 2024
8-11 April 2024
10-13 June 2024

Human Medicines: Highlights of 2023

The overview of the 2023 key recommendations published includes figures on the authorization of medicines and a selection of new treatments that represent significant progress in their therapeutic areas as well as newly issued negative opinions for 3 medicines and guidance on additional uses for 77 existing medicines.

Read more online

Guidance on Pediatric Submissions via Syncplicity Web Client

The Syncplicity Web Client submission channel is required for all applicants and all types of pediatric submissions. A Research Product Identifier (RPI) number is required and mandatory for all pediatric procedures.

Read more online

Scientific Guidelines with Summary-of-Product-Characteristics (SmPC) Recommendations

This document only includes adopted scientific guidelines which refer specifically to the SmPC. For complete information on scientific guidelines, please refer to the European Medicines Agency website

Read more online

IRIS Guide to Registration and RPIs

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 more online

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Regulatory Agency Updates

Pharmacovigilance Inspectors' Working Group (PhV IWG)

Annual report of the Pharmacovigilance Inspectors' Working Group for 2021 and 2022

Annual Report

Work plan for the Pharmacovigilance Inspectors' Working Group (PhV IWG) for 2024-2026

Work Plan

Q & A to Stakeholders on the Implications of Regulation (EU) 2023/1182 for Centrally Authorized Medicinal Products for Human Use

This practical guidance document includes information related to the impact of Regulation (EU) 2023/1182 on medicinal products for human use authorized pursuant to Regulation (EC) No 726/2004 (centrally authorized medicinal products - CAPs). When not specifically mentioned the guidance below applies as of the date on which Regulation (EU) 2023/1182 becomes applicable (for further information please see Section 9 below). For the impact of Regulation (EU) 2023/1182 on medicinal products authorized by EU/EEA Member States (Nationally Authorized Products (NAPs), including medicinal products authorized through Mutual Recognition Procedures (MRPs) and Decentralized Procedures (DCPs)) for human use, applicants/marketing authorization holders are advised to contact the relevant national regulatory authorities.

Read more online

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Training Course (self-paced)

The training focuses on:

- Explaining the guidance and specifically the mandatory data elements necessary for the electronic submission of information on authorized and unauthorized (referred to in the XEVMPD as 'development') medicinal products;
- Applying the format of the eXtended EudraVigilance Product Report Message (XEVPRM);
- The use of the XEVMPD data entry tool (EVWEB).

It includes exercises in the XEVPRM data entry tool (EVWEB) for the electronic submission and maintenance of development medicinal products.

Read more online

ICH Q5A(R2) Guideline on Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin

(effective 14 June 2024)

This guideline describes the evaluation of the viral safety of biotechnology products including viral clearance and testing, and it outlines what data should be submitted in marketing applications for those products.

Read more online

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Overview of Comments on ICH E6 (R3) Guideline

These comments are in response to the most recent ICH E6 (R3) guidelines and will be sent to the EWG for consideration in the context of Step 3 of the ICH process.

Read more online

ICH Q2(R2) Guideline on Validation of Analytical Procedures

This guideline presents elements for consideration during the validation of analytical procedures included as part of registration applications. ICH Q2(R2) provides guidance on selection and evaluation of the various validation tests for analytical procedures. This guideline includes a collection of terms and their definitions, which are meant to bridge the differences that often exist between various compendia and documents of the ICH member regulatory authorities.

Read more online

Concept Paper on the Establishment of a Guideline on the Development and Manufacture of Human Medicinal Products Specifically Designed for Phage Therapy

(submit comments by 31 March 2024)

This concept paper proposes to establish a scientific guideline for the pharmaceutical development and manufacture of bacteriophage medicinal products intended for the therapeutic treatment or prophylaxis of one or more specific bacterial infection(s) or infectious disease(s) in humans.

Read more online

EudraVigilance Training and Support

The dates for the virtual live hands-on training course on using the enhanced EudraVigilance system are as follows:

- 04 - 08 March 2024
- 15 - 19 April 2024
- 13 - 17 May 2024
- 03 - 07 June 2024
- 24 - 28 June 2024

Read more online

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18th Industry Stakeholder Platform - Operation of European Union (EU) Pharmacovigilance

This virtual meeting aimed to inform, get feedback and foster dialogue between industry and the EU regulators.

Topics included:

- artificial intelligence in pharmacovigilance;
- update on good pharmacovigilance practice;
- risk management plans, including EMA transparency measures and guideline on specific adverse reaction follow-up questionnaires;
- updates on PASS with the catalogues to replace the current ENCePP resources database, and the EU PAS register
- EudraVigilance update.

Read more online

European Medicines Agency Pre- and Post- Authorization Procedural Advice for Users of the Centralized Procedure

The following questions were revised:

Pre-Authorization (link to questions)

- 2.4. What is the procedure for appointment of Rapporteurs/Co-Rapporteurs and their assessment teams?
- 5.1.11. Can EMA assessment or inspection documents be shared with regulators outside the EU?
- 5.1.12. How can I change the applicant for an ongoing marketing authorization application?
- 5.2.1. When can I expect a pre-authorization GMP inspection and how are they conducted?

Post-Authorization (link to questions)

- 1.6. Can my Type IA/ IAIN be part of worksharing?
- 16.14. When and how will the RMP Summary be published on the EMA website?

Risk Management Plans (RMP) in Post-Authorization Phase: Questions and Answers

The following question was revised:

- 14. When and how will the full RMP be published on the EMA website? Rev. Dec 2023

All post-authorization RMP updates assessed and approved in procedures concluding on or after 20 October 2023 will trigger the publication of the full RMP (body and Annexes 4 & 6).

Read more online

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Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products

This guidance is intended to assist sponsors, including industry and academic sponsors, developing CAR T cell products. In this guidance, we, FDA, provide CAR T cell specific recommendations regarding chemistry, manufacturing, and control (CMC), pharmacology and toxicology, and clinical study design.

Read more online

Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products

(submit comments by 29 April 2024)

The purpose of this guidance is to provide FDA's expectations for, and recommendations on, use of a standardized approach for collecting and reporting race and ethnicity data in submissions including information collected and reported from clinical studies and clinical trials for FDA-regulated medical products.

Read more online

Human Gene Therapy Products Incorporating Human Genome Editing

In this guidance, we, FDA, are providing recommendations to sponsors developing human gene therapy products incorporating genome editing (GE) of human somatic cells. Specifically, this guidance provides recommendations regarding information that should be provided in an Investigational New Drug (IND) application in order to assess the safety and quality of the investigational GE product, as required in Title 21 of the Code of Federal Regulations 312.23 (21 CFR 312.23). This includes information on product design, product manufacturing and testing, nonclinical safety assessment, and clinical trial design.

Read more online

ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs

This guidance is intended to assist applicants in preparing and submitting amendments to tentatively approved abbreviated new drug applications (ANDAs), including requests for final approval. This guidance provides recommendations on the timing and content of amendments to tentatively approved ANDAs to facilitate submission in a timely fashion to enable final approval on the earliest date on which the ANDA may lawfully be approved based on patent and/or exclusivity protections ("earliest lawful ANDA approval date").

Read more online

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Revising ANDA Labeling Following Revision of the RLD Labeling

This guidance is intended to assist applicants and holders of an abbreviated new drug application (ANDA) in updating their labeling following revisions to the approved labeling of a reference listed drug (RLD). This guidance provides recommendations on identifying RLD labeling updates and submitting ANDA amendments or supplements to update generic drug labeling.

Read more online

Characterization of Metallic Coatings and/or Calcium Phosphate Coatings on Orthopedic Devices

(submit comments by 22 March 2024)

This draft guidance document provides the FDA's recommendations on information to support premarket submissions for metallic coatings and/or calcium phosphate coatings on orthopedic devices. This guidance applies to metallic coatings, calcium phosphate coatings, or metallic and calcium phosphate dual coatings on orthopedic devices. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of submissions for orthopedic devices which contain metallic and/or calcium phosphate coatings.

Read more online

Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin

The guidance is intended to describe risk-based principles and mitigation strategies to assure the viral safety of biotechnology products, including the data necessary to submit in a marketing application.

Read more online

Requests for Reconsideration at the Division Level Under Generic Drug User Fee Amendments (GDUFA)

(submit comments by 11 March 2024)

This draft guidance provides recommendations on the procedures for applicants of abbreviated new drug applications (ANDAs) that wish to pursue a request for reconsideration within the review discipline at the division level or original signatory authority.

Read more online

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Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile

This guidance document updates and clarifies the information regarding sterilization processes that we recommend sponsors include in 510(k)s for devices labeled as sterile. This guidance document also provides details about the pyrogenicity information that we recommend sponsors include in a 510(k) submission.

Read more online

Reformulating Drug Products that Contain Carbomers Manufactured with Benzene

The purpose of this guidance is to provide recommendations for applicants and manufacturers on what tests should be performed and what documentation should be submitted or available to FDA to support the reformulation of drug products that use carbomers manufactured with benzene.

Read more online

Potency Assurance for Cellular and Gene Therapy Products

(submit comments by 27 March 2024)

This draft guidance provides recommendations for developing a science- and risk-based strategy to help assure the potency of a human cellular therapy or gene therapy (CGT) product. A potency assurance strategy is a multifaceted approach that reduces risks to the potency of a product through manufacturing process design, manufacturing process control, material control, in-process testing, and potency lot release assays. The goal of a potency assurance strategy is to ensure that every lot of a product released will have the specific ability or capacity to achieve the intended therapeutic effect.

Read more online

Quality Considerations for Topical Ophthalmic Drug Products

(submit comments by 26 February 2024)

This guidance discusses certain quality considerations for ophthalmic drug products (i.e., gels, ointments, creams, and liquid formulations such as solutions, suspensions, and emulsions) intended for topical delivery in and around the eye.

Specifically, the guidance discusses:

- Microbiological considerations.
- Approaches to evaluating visible particulate matter, extractables and leachables, and impurities and degradation products.
- Use of in vitro drug release/dissolution testing as an optional quality control strategy for certain ophthalmic dosage forms.
- Recommendations for design, delivery, and dispensing features of container closure systems (CCSs).
- Recommendations for stability studies.

Read more online

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Rare Diseases: Considerations for the Development of Drugs and Biological Products

This guidance is intended to assist sponsors of drugs and biological products for treatment of rare diseases in conducting efficient and successful drug development programs through a discussion of selected issues commonly encountered in rare disease drug development.

Read more online

Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

This guidance provides recommendations on the use of digital health technologies (DHTs) to acquire data remotely from participants in clinical investigations that evaluate medical products. DHTs for remote data acquisition in clinical investigations can include hardware and/or software to perform one or more functions.

Read more online

Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products

This guidance provides considerations for sponsors proposing to design a new registry or use an existing registry to support regulatory decision-making about a drug's effectiveness or safety.

Read more online

Master Protocols for Drug and Biological Product Development

(submit comments by 22 February 2024)

This guidance document provides recommendations on the design and analysis of trials conducted under a master protocol as well as guidance on the submission of documentation to support regulatory review.

Read more online

Data Standards for Drug and Biological Product Submissions Containing Real-World Data

This guidance provides recommendations to sponsors to help support compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) when submitting study data derived from real-world data (RWD) sources in applicable regulatory submissions using standards specified in the Data Standards Catalog.

Read more online

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510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review

(submit comments by 20 February 2024)

This draft guidance outlines FDA's current thinking on key aspects of the 510(k) Third Party Review Program and third party review of Emergency Use Authorization (EUA) requests by describing FDA's expectations for the reviews of 510(k) submissions and EUA requests by third party review organizations.

Read more online

MHRA

Medicines: Marketing Authorization Holders' Submission of Nitrosamine Risk Evaluation, Risk Assessment and Confirmatory Testing

Marketing Authorization Holders should review their manufacturing processes to identify and, if found, to mitigate the risk of nitrosamine impurities being present.

Updated information following the passing of the deadline for the submission and. additional guidance about lifecycle management is provided.

Read more online

Notify the MHRA about a Clinical Investigation for a Medical Device

Added template for submitting Quarterly Summary Reports.

Read more online

Project Orbis

Project Orbis is a program to review and approve promising cancer drugs helping patients access treatments faster.

The MHRA has recently updated its guidance in relation to Project Orbis and ILAP. There is no longer a requirement to obtain an Innovation Passport as part of the Project Orbis program.

Read more online

Register Medical Devices to Place on the Market

Updates are as follows:

- Updated 'Account Management Reference Guide' & 'Device Registration Reference Guide'
- Updated video for 'Registering a custom-made medical device'.
- Published reminder concerning legislation requirements for custom-made devices.

Read more online

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Implementation of Medical Devices Future Regime

This document provides an update on the intended timelines to implement the future core regulations.

Added 'Roadmap for the Implementation of the Future Regulatory Framework for Medical Devices' and information about 'future core regulations'.

Read more online

Exporting Active Substances Manufactured in Great Britain for Use in EEA and Northern Ireland

Updates are as follows:

- Updated 'Register of Written Confirmations for UK active substance manufacturers'.
- Updated the Written Confirmation PDF

Read more online

Updated Requirements for Dealing with Potential Nitrosamine Impurities in Medicinal Products

As communicated at the information event on 20 September 2023, Swissmedic continues to apply the acceptable intakes published by EMA. Marketing authorization holders are required to perform a risk-based evaluation of their medicinal products and synthetic active substances with the potential for nitrosylation and to submit the results to Swissmedic.

Read more online

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