
WSQMS Homepage Mar 6, 2023

## Human Variations Electronic Application Form (eAF)

**22 February 2023 – the EMA published the video recordings regarding eAF.**

These short webinars address access management questions from users of PLM portal and web forms users after the release.

Q&A Clinic: Session 6 Q&A Clinic: Session 5 Public Training on Human Variations

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## Clinical Trials Information System (CTIS) Training Materials – Latest Updates

**21 February 2023 – the EMA published version 1.2 of the CTIS training materials.**

This document aims to help users to easily identify which are the latest updated materials on the EMA website and which materials have been developed since the last time users have consulted them.

Read the pdf

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## ICH Guideline M13A on Bioequivalence for Immediate-release Solid Oral Dosage Forms

**16 February 2023 – the EMA published step 2b of the ICH M13A consensus guideline.**

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.

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## Clinical Trials Information System (CTIS) Bitesize Talk: Annual Safety Report (ASR)

**15 February 2023 – the EMA published the video recording of the ASR bitesize talk.**

This bitesize talk on CTIS provides an opportunity for sponsors to learn about the Annual Safety Report that is submitted via CTIS.

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## Questions and Answers – Clinical Trials Information System (CTIS) and Clinical Trials Regulation (CTR)

**15 February 2023 – the EMA published the Q&A guidance on CTIS and CTR prepared by the query management working group.**

This document aims at informing on the technical aspects of the Clinical Trials Regulation (EU) No 536/2014 with a view to facilitating its implementation.

This document provides answers to questions regarding CTIS and the CTR that were raised by representatives of sponsor associations, including the Association of Clinical Research Organizations (ACRO), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) and the European Clinical Research Organization Federation (EUCROF).

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## Questions & Answers Regarding Cannabis-derived Medicinal Products and the Scope of EU Herbal Monographs for Herbal Medicinal Products within the EU Medicines Legislation

**15 February 2023 – the EMA published Q&A guidance on herbal medicinal products.**

These Q&A aim at clarifying regulatory requirements to obtain a marketing authorization for medicinal products in the EU (Q1) and at explaining the work of Committee on Herbal Medicinal Products (HMPC) regarding EU herbal monographs (Q2, Q3), as stakeholders involved in the manufacturing of Cannabis-derived substances may not have extensive experience with the EU pharmaceutical regulatory system.

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## Pediatric Addendum on the Guidelines on Clinical Investigation of Medicinal Products for the Treatment and Prophylaxis of Venous Thromboembolic Disease

**14 February 2023 – the EMA published the pediatric addendum of the guideline on clinical investigation for the treatment and prophylaxis of venous thromboembolic disease.**

This document includes guidance on pediatric clinical medicine development, highlighting pediatric specific issues and differences from the treatment and prophylaxis of venous thromboembolism in adults.

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## EMA/HMA Big Data Stakeholder Forum 2022 Report

**13 February 2023 – the EMA published the December 2022 Big Data Stakeholder Forum report.**

This report offers a high-level summary of the forum presentations as well as highlights from the front row comments with stakeholders. All five sessions were included:

- Session 1: Report on implementation of the HMA-EMA Big Data Task Force priority recommendations
- Session 2: Big Data - DARWIN EU ® and data quality
- Session 3: Big Data - data discoverability, skills, processes and capability
- Session 4: Big Data - data governance, international and veterinary
- Session 5: View to the future

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## ICH Guideline Q9 (R1) on Quality Risk Management

**6 February 2023 – the EMA published step 5 of the ICH Q9 (R1) guideline on quality risk management.**

This document provides principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality. These aspects include development, manufacturing, distribution, and the inspection and submission/review

processes throughout the lifecycle of drug substances, drug products, biological and biotechnological products.

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## IRIS Guide to Registration and RPIs

**6 February 2023 – the EMA published version 2.12 of the IRIS guide to registration and RPIs.**

This guide documents describes 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).

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## Accelerating Clinical Trials in the European Union (ACT EU)

**3 February 2023 – the EMA published the priority action 3 concept paper: an EU multi-stakeholder platform for improving clinical trials.**

This paper describes a proposal for the creation of a multi-stakeholder platform (MSP) that aims to promote dialogue and collaboration for improving clinical trials in the EU. The success of clinical trials relies on a multitude of stakeholders. The creation of a common platform will provide further opportunities for interactions between stakeholders, therefore promoting a shared understanding of the respective roles, needs and perspectives.

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## Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment

**24 February 2023 – the FDA published draft guidance on developing drugs for treating neovascular age-related macular degeneration. Submit comments by 30 May 2023.**

This guidance is intended to provide recommendations to sponsors regarding eligibility criteria, trial design considerations, and efficacy endpoints to enhance clinical trial data quality and to foster greater efficiency in development programs for drugs for the treatment of neovascular age-related macular degeneration.

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## Guidance for Industry and FDA Staff – Diagnostic X-Ray, Ultrasound Systems and Laser Equipment

**21 February 2023 – the FDA published final guidance documents on diagnostic x-ray, ultrasound systems and laser equipment.**

Assembler's Guide to Diagnostic X-Ray Equipment
Performance Standard for Diagnostic X-Ray Systems and Their Major Components
Laser Products-Conformance (Laser Notice No. 56)
Marketing Clearance of Diagnostic Ultrasound Systems and Transducers
Medical X-Ray Imaging Devices Conformance with IEC Standards
Premarket Notification Submissions for Ultrasonic Diathermy Devices

## Product-Specific Guidance (PSG) Meetings Between FDA and ANDA Applicants Under GDUFA

**17 February 2023 – the FDA published draft guidance on requesting and conducting PSG meetings. Submit comments by 22 April 2023.**

This guidance provides recommendations to industry on product-specific guidance (PSG) meetings between FDA and a prospective applicant preparing to submit to FDA or an applicant that has submitted to FDA an abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)). Specifically, this guidance provides information on requesting and conducting PSG meetings with FDA (PSG teleconferences, pre-submission PSG meetings, and post-submission PSG meetings), as contemplated in the Generic Drug User Fee Amendments (GDUFA) Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III commitment letter).

This guidance is intended to provide procedures that will promote well-managed PSG meetings and help ensure that such meetings are scheduled and conducted in accordance with the time frames set forth in the GDUFA III commitment letter.

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## Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development

**10 February 2023 – the FDA published draft guidance on long-term clinical neurodevelopmental safety studies in neonatal product development.**

The purpose of this guidance is to provide a framework for considering whether and what type of long-term neurologic, sensory and developmental evaluations could be useful to support a determination of safety of a drug, biological product, or device (referred to as

'medical product' in this guidance) for use in neonates, and if so, which domains of neurodevelopment may be most applicable.

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

**1 February 2023 – the FDA published 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.

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## Manufacture of Investigational Medicinal Products – Frequently Asked Questions

**3 February 2023 – the UK MHRA inspectorate published FAQs on manufacturing IMP.**

This blog is related to the manufacture and supply of IMPs. The most common query received related to deciding if an activity should be considered as manufacture or reconstitution.

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## Completed Pediatric Studies - Submission, Processing and Assessment

**1 February 2023 – the UK MHRA published updated guidance on the submission, processing and assessment of all completed pediatric studies sponsored by Marketing Authorization Holders (MAHs).**

Changes were made to the completed pediatric studies guidance text. New suggested cover letter was uploaded.

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## Modifications to Guidance Document "Formal Requirements"

**13 February 2023 – the Swissmedic published clarification of documentation to be**

submitted for co-marketing medicinal products; conditions can be the subject of collective applications.

Regarding co-marketing medicinal products, the documents to be submitted for conversion of a co-marketing authorization to a stand-alone authorization have been clarified. The Questions and Answers on Co-Marketing HMP and on Variations and Extensions HMP have been updated accordingly.

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## Applications for Clinical Trials with Medicinal Products and ATMPs (Advanced Therapy Medicinal Products)

13 February 2023 – the Swissmedic announced clinical trial applications can be submitted via new eGov portal.

From early summer 2023, the new portal for clinical trials with medicinal products and ATMPs will be available to all sponsors, investigators, research institutions and their contractual partners for fully electronic submission of applications.

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## Swissmedic Journal – January 2023

6 February 2023 – the Swissmedic published the January 2023 edition of its journal.

The Swissmedic Journal contains information about:

- issues of current interest relating to therapeutic products
- legal regulations and requirements in the medicinal products and medical devices sector
- the risks of therapeutic products
- national and international framework conditions
- announcements about the receipt, rejection or withdrawal of complete applications for authorization, for additional indications or for extensions of authorization of medicinal products.

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