Electronic Application Form (eAF) – Product Management Service (PMS) Newsletter

15 May 2023 – the EMA published Issue 3 of the eAF–PMS newsletter.

This 3rd edition of the eAF-PMS Newsletter highlights the latest news, upcoming events and activities planned for the next months. An updated timeline of the web-based Human Variations electronic application form (eAF) accessible from the Product Lifecycle Management (PLM) Portal is now available to all interested stakeholders. The timeline highlights important milestones to be achieved in the upcoming months with regards to the release of new functionalities, User Acceptance Testing (UAT) and start of the transition period.

A version of the timeline highlighting impacts on the eAF users in the different periods is also available for consultation.

Read the pdf

EMA Annual Report 2022

15 May 2023 – the EMA published its 2022 Annual Report.

The report provides an overview of the Agency's activities to protect and promote public and animal health in the EU. The digital report outlines the most important highlights regarding the evaluation and monitoring of human and veterinary medicines and a selection of key figures. It also contains an interactive timeline of important milestones in 2022, with advanced functionalities that allow readers to explore each topic in more depth by accessing additional documents, audio-visual materials and infographics.

Read more online

IRIS Guide to Registration and RPIs

12 May 2023 – the EMA published version 2.14 of the IRIS guide for all 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).

Minor changes to section 8 include "Requests for a new Research Product Identifier" (see changes highlighted in yellow).

Read the pdf

Concept Paper on Revision of the Guideline on Clinical Investigation of Medicinal Products in the Treatment of Patients with Acute Respiratory Distress Syndrome (ARDS)

4 May 2023 – the EMA proposed guideline will replace the Guideline on clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome. Submit comments by 31 July 2023.

This concept paper concerns the guideline that is intended to provide guidance for the evaluation of new medicinal products for prevention and treatment of ARDS. The guideline came into effect in April 2007. There are several new agents in development for the treatment of ARDS. In recent requests for CHMP scientific advice on the development of new agents intended for the treatment of ARDS, several issues have emerged as being central to development programs.

Read the pdf

Interim Guidance Document on How to Approach the Protection of Personal Data and Commercially Confidential Information While Using the Clinical Trials Information System (CTIS)

3 May 2023 – the EMA published version 1.0 of the interim guidance on protecting personal data and confidential information while using the CTIS.

This guidance document and accompanying annex help CTIS users navigate through the system functionalities and understand the main principles to be followed to enable

protection of personal data and commercially confidential information while using CTIS and publishing clinical trials data and documents.

Interim Guidance Annex

Commission Guidance on the Content and Structure of the Summary of the Clinical Investigation Report

8 May 2023 – the Official Journal of the European Union published the summary document on the clinical investigation report for the medical device.

This document is intended to provide Commission guidance, in accordance with Article 77(6) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (hereafter: the MDR), for the content and structure of the summary of the clinical investigation report.

This guidance aims to ensure that the summary of the clinical investigation report presents information about the design, conduct, analysis and results of the clinical investigation in terms and in a format that are easily understandable to the intended user of the medical device.

Read more online

Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components

11 May 2023 – the FDA published final guidance on implementing the full-length and abbreviated donor history questionnaires and accompanying materials.

This guidance recognizes, as acceptable, the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 4.0 dated May 2023, prepared by the AABB Donor History Task Force1. This guidance also provides recommendations to licensed establishments on how to report implementation of the acceptable AABB donor history questionnaires and accompanying materials (DHQ documents) under Title 21 of the Code of Federal Regulations 601.12 (21 CFR 601.12).

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

11 May 2023 – the FDA published final guidance on the recommendations for evaluating donor eligibility using individual risk-based questions.

This guidance provides you, 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. We also recommend that you make corresponding revisions to your donor educational materials, donor history questionnaires and accompanying materials, along with revisions to your donor requalification and product management procedures.

Read more online

FDA Guidance on ICH Q9(R1) Quality Risk Management

3 May 2023 – the FDA published final guidance on the ICH Q9(R1) quality risk management.

The purpose of this document is to offer a systematic approach to quality risk management that leads to better, more informed, and timely decisions. It serves as a foundation or resource document that is independent of, yet supports, other ICH Quality documents and complements existing quality practices, requirements, standards, and guidelines within the pharmaceutical industry and regulatory environment. It specifically provides guidance on the principles and some of the tools of quality risk management that can enable more effective and consistent risk- based decisions, both by regulators and industry, regarding the quality of drug substances and drug (medicinal) products across the product lifecycle.

Read more online

Decentralized Clinical Trials for Drugs, Biological Products and Devices

3 May 2023 – the FDA published draft guidance on the implementation of decentralized clinical trials (DCTs) for drugs, biological products, and devices. Submit comments by 1 August 2023.

This draft guidance provides recommendations for sponsors, investigators, and other stakeholders regarding the implementation of decentralized clinical trials (DCTs) for drugs, biological products, and devices. In this guidance, a DCT refers to a clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites.

In fully decentralized clinical trials, all activities take place at locations other than traditional trial sites. These trial-related activities may take place at the homes of trial participants or in local health care facilities that are convenient for trial participants. In hybrid DCTs, some trial activities involve in-person visits by trial participants to traditional clinical trial sites, and

other activities are conducted at locations other than traditional clinical trial sites, such as participants' homes.

Read more online

Study Data Technical Conformance Guide – Technical Specifications Document

1 May 2023 – the FDA published final guidance on the study data on technical conformance for the electronic submission.

This Guide provides technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format in INDs, NDAs, ANDAs, and BLAs. The Guide is intended to complement and promote interactions between sponsors and FDA review divisions. However, it is not intended to replace the need for sponsors to communicate directly with review divisions regarding implementation approaches or issues relating to data standards.

Read more online

ICH S12 Nonclinical Biodistribution Considerations for Gene Therapy Products

1 May 2023 – the FDA published the final ICH S12 guidance on nonclinical biodistribution (BD) studies for gene therapy (GT) products.

The final guidance provides harmonized recommendations for the conduct and overall design of nonclinical biodistribution (BD) studies for gene therapy (GT) products. The recommendations in the guidance endeavor to facilitate the development of investigational GT products, while avoiding unnecessary use of animals, in accordance with the 3Rs (reduce/ refine/ replace) principles.

Read more online

Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products

1 May 2023 – the FDA published final guidance on developing nicotine replacement therapy drug products.

The document provides guidance to assist sponsors in the clinical development of nicotine replacement therapy (NRT) drug products, including but not limited to those intended for smoking cessation and related chronic indications.

Read more online

Reporting Adverse Incidents Involving Software as a Medical Device under the Vigilance System

15 May 2023 – the UK MHRA published guidance on reporting adverse incidents involving software as a medical device.

This guidance provides information for manufacturers of Software as a Medical Device. It outlines events that may cause indirect harm and are therefore reportable.

Read more online

Register Medical Devices to Place on the Market

15 May 2023 – the UK MHRA published the updated guidance on registering medical devices to place on the market.

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).

Reference guides and new video tutorials have been added.

Read more online

Guidance on Qualified Person Responsible for Pharmacovigilance (QPPV) Including Pharmacovigilance System Master Files (PSMF)

11 May 2023 – the UK MHRA published updated guidance on pharmacovigilance system requirements.

New guidance has replaced the previous section; 'Notification of QPPV and PSMF details to the MHRA by existing holders of UK marketing authorizations'. This guidance replaces the previous requirement to submit a Type IA(IN) variation and an accompanying eCTD sequence to make these changes. This has been simplified and only an update notification is required, there is no requirement to submit an eCTD sequence.

Read more online

Notify the MHRA about a Clinical Investigation for a Medical Device

11 May 2023 – the UK MHRA published updated guidance on notifying the MHRA of a clinical investigation for a medical device.

A clinical investigation needs to be carried out as part of the process to obtain a UKCA / CE / CE UKNI marking for a medical device. The MHRA should be informed at least 60 days before starting the investigation. Validation Checklist text and accompanying document have been added.

Read more online

ICH E6(R3) Good Clinical Practice Guidance – Step 2 Public Consultation

2 May 2023 – the UK MHRA Inspectorate announced Step 2 – Public Consultation – of the ICH GCP guidance.

The International Council for Harmonization (ICH) Expert Working Group for ICH E6(R3) (EWG) has been updating the ICH E6(R2) Good Clinical Practice (GCP) guideline.

MHRA became a full member of ICH in May 2022. While feedback on the ICH E6(R3) can be provided via the ICH website, MHRA wishes to consult directly with UK stakeholders to compile and coordinate their comments to the EWG. Please monitor the MHRA website for announcement of the consultation.

Read more online

Medical Devices Swissmedic Hospital Inspections 2021/2022 Annual Report

12 May 2023 – the Swissmedic published the 2021/2022 annual report of the Swissmedic Hospital Inspections on Medical Devices.

Swissmedic monitors hospitals in the reprocessing, maintenance and vigilance of medical devices, in accordance with its legally defined mandate. The 2021 / 2022 annual report of Swissmedic hospital inspections shows the selection of hospitals, the number of deviations observed and the key deficiencies in the inspected areas.

The findings obtained from the hospital inspections show that there is considerable need for improvement and investment in Swiss hospitals in the areas of technical quality management, basic and further training of the reprocessing personnel and the infrastructure of the reprocessing departments.

Read more online

Changes to the Guidance Document GMP Compliance by Foreign Manufacturers and the Form Declaration by the Responsible

Person for Foreign Manufacturers

1 May 2023 – the Swissmedic published updated guidance documents on clarification of the requirements for the submission of audit reports.

Certain documents must be submitted by the Responsible Person (RP) as proof of the GMP compliance assessment of foreign manufacturers for an application for authorization (new application) or type IA/IAIN variation that can be notified after the event, a minor type IB variation that must be notified in advance or a type II major variation for an authorized human medicinal product, or for a new application or a variation with or without evaluation of an authorized veterinary medicinal product.

Swissmedic has clarified the conditions for the submission of an audit report as proof of the GMP compliance of foreign manufacturers from countries whose GMP control systems are not deemed to be equivalent to that in Switzerland.

These documents are valid as of 01 May 2023.

Read more online

Changes to the Forms for New Authorizations of and Variations to Human and Veterinary Medicinal Products

1 May 2023 – the Swissmedic published information on study design and data sources of RWE in application forms.

A new section on the use of real world evidence (RWE) has been added to the forms for new authorizations of and variations to human and veterinary medicinal products. If an application includes RWE in support of the proof of safety and efficacy, information on the study design and data sources of the RWE must now be included in the forms.

The amended forms are valid as of 1 May 2023. As is customary, the previous versions of the forms can continue to be used for a transitional period of three months.

Read more online

Modification of the Drug Master File (DMF) Form

1 May 2023 – the Swissmedic published the modified DMF form.

A line for details of a “Contact for enquiries” has been added to the DMF form in Part B, which is to be completed by the DMF holder. If a DMF holder is contacted by Swissmedic in writing, the letter will in future be addressed to the contact listed for the DMF holder. The details of the contact should help to ensure that letters from Swissmedic are received promptly by the DMF holder staff who are responsible for answering questions.

The revised DMF form is valid with effect from 1 May 2023. As is customary, the previous version of the forms can continue to be used for a transitional period of three months.

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

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WSQMS Homepage Jun 14, 2023

Questions & Answers on the Impact of Mutual Recognition Agreement (MRA) between the European Union and the United States as of 31 May 2023

31 May 2023 – the EMA published the Q&A guidance on the impact of MRA between the EU and the US.

As of 1 November 2017, for human medicines and 30 May 2023 for veterinary products, the EU Member States will not duplicate inspections conducted by the FDA. At the same time, it is expected that the FDA will not duplicate inspections conducted by a recognized authority.

Read the pdf

Q&A on Impact of EU-USA Mutual Recognition Agreement (MRA) on Marketing Authorization Applications (MAAs) and Relevant Variations – Revised May 2023

31 May 2023 – the EMA published Q&A guidance on impact of EU-US MRA on the MAAs and relevant variations.

In order to facilitate the verification of GMP compliance, applicants should submit all available documents as proof of GMP compliance for US manufacturing sites that have been previously inspected by US FDA.

Read the pdf

EMA Procedural Advice on Recommendations on Unforeseen Variations According to Article 5 of Commission Regulation (EC) No 1234/2008

31 May 2023 – the EMA published guidance on recommendations on unforeseen variations of authorized medicinal products for human use.

This guidance covers medicinal products for Human use that have been authorized through the centralized procedure. The request shall apply only to variations whose classification is not provided for in the a.m. annex or guideline (i.e. unforeseen variations). The EMA cannot "reclassify" a variation already listed in the annex/guideline.

Read the pdf

Guide on Access to Unpublished Documents: Access to Documents Service

25 May 2023 – the EMA published a complementary guide to Policy 43 of the Access to Documents Service.

The present guide describes how the Agency deals with all written requests, especially requests made electronically, for access to any document originated, received or held by the Agency (i.e. reactive disclosure). The second one concerns proactive disclosure of EMA documents, either through the Agency's website or other sources of publication.

Read the pdf

IRIS Guide to Registration and RPIs

25 May 2023 – the EMA published the updated IRIS guide to registration and RPIS.

EMA released version 2.15 of the preliminary requirements for all IRIS submissions, including substance and Research Product Identifier registration. Outdated content was removed.

Read the pdf

Overview of Comments Received on ICH M11 Guideline, Clinical Study Protocol Template and Technical Specifications – Scientific Guideline

24 May 2023 – the EMA published the scientific guideline documents on ICH M11 guideline, clinical study protocol template and technical specifications.

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

Comments on the template
Comments on the technical specifications
Comments on the guideline

Clinical Trials Information System Webinar: Second Year of Transition

22 May 2023 – the EMA announced the upcoming CTIS webinar covering the second year of transition.

The EMA is organizing this open event on 4 July 2023 to provide:

• reflection on the implementation of the Clinical Trials Regulation;

• reflection on Transitional Trials and Ethics Committee assessment procedures;

• update on the current status of CTIS.

Read more online

ICH S5 (R3) Guideline on Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals

22 May 2023 – the EMA published step 5 of the ICH S5 (R3) guideline.

The purpose of this document is to recommend international standards for, and promote harmonization of, the assessment of nonclinical developmental and reproductive toxicity (DART) testing required to support human clinical trials and marketing authorization for pharmaceuticals. The guideline describes potential strategies and study designs to supplement available data to identify, assess, and convey risk. General concepts and recommendations are also provided that should be considered when interpreting study data.

Read the pdf

Clinical Trials Information System (CTIS) Bitesize Talk: How to Submit a Transitional Trial in CTIS

22 May 2023 – the EMA announced the online live CTIS bitesize talk on how to submit a transitional trial.

This bitesize talk on CTIS provides an opportunity for sponsors to learn how to create and submit transitional trials in Clinical Trials Information System (CTIS). The online event will take place on the 21st of June.

Read more online

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

17 May 2023 – the EMA published version 1.2 of the Q&A guidance on how to protect CCI and personal data in 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 database established in accordance with the requirements of Regulation (EU) No 536/2014 (CTR).

Read the pdf

Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products

26 May 2023 – the FDA published draft guidance on efficacy endpoints for clinical investigation of antidiabetic drugs and biological products. Submit comments by 24 August 2023.

This guidance is intended to help sponsors develop antidiabetic drugs for adults and children with type 1 diabetes mellitus (T1D) and/or type 2 diabetes mellitus (T2D). In this guidance, antidiabetic drugs refer to drugs intended to improve glycemic control, including drugs intended to reduce diabetes-related hyperglycemia (i.e., antihyperglycemic drugs) and drugs intended to mitigate iatrogenic hypoglycemia associated with diabetes management.

Read more online

Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products

25 May 2023 – the FDA published the final guidance on covariates in randomized clinical trials for drugs and biological products.

This guidance describes FDA's current recommendations regarding adjusting for covariates in the statistical analysis of randomized clinical trials in drug development programs. This

guidance provides recommendations for the use of covariates in the analysis of randomized, parallel group clinical trials that are applicable to both superiority trials and noninferiority trials. The main focus of the guidance is on the use of prognostic baseline covariates to improve statistical efficiency for estimating and testing treatment effects.

Read more online

Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers

25 May 2023 – the FDA published the final Q&A guidance on use of whole slide imaging in nonclinical toxicology studies.

This guidance provides information to sponsors and nonclinical laboratories regarding the use and management of whole slide images used during histopathology assessment and/or pathology peer review performed for good laboratory practice (GLP)-compliant nonclinical toxicology studies using non-human specimens.

Read more online

Generally Accepted Scientific Knowledge (GASK) in Applications for Drug and Biological Products: Nonclinical Information

25 May 2023 – the FDA published draft guidance on GASK in applications for drug and biological products. Submit comments by 24 July 2023.

This guidance describes instances in which it may be appropriate to rely on GASK to meet certain nonclinical safety requirements for new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)) and biologics license applications (BLAs) under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)).

Read more online

Study Data Technical Conformance Guide – Technical Specifications Document

24 May 2023 – the FDA published the final guidance on the Study Data Technical Specifications document.

This Guide provides technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format in INDs, NDAs, ANDAs, and BLAs. The Guide is intended to complement and promote interactions between sponsors and FDA review divisions.

Read more online

Pediatric Drug Development Under the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act: Scientific Considerations

18 May 2023 – the FDA published draft guidance on pediatric drug development. Submit comments by 17 July 2023.

The purpose of this guidance is to assist industry in developing data and obtaining information needed to support approval of drug products in pediatric populations. This guidance addresses selected clinical, scientific, and ethical issues regarding the development of drugs for pediatric use when such drugs are subject to the Pediatric Research Equity Act (PREA) and/or the Best Pharmaceuticals for Children Act (BPCA).

Read more online

Pediatric Drug Development: Regulatory Considerations — Complying with the Pediatric Research Equity Act and Qualifying for Pediatric Exclusivity Under the Best Pharmaceuticals for Children Act

18 May 2023 – the FDA published draft guidance on best pharmaceutical practices for pediatric drug development. Submit comments by 17 July 2023.

This guidance is intended to assist industry developing drug products to comply with the pediatric study requirements under the Pediatric Research Equity Act (PREA), and to describe the process for qualifying for pediatric exclusivity and the protections that pediatric exclusivity offers under the Best Pharmaceuticals for Children Act (BPCA).

Read more online

ICH E6 (R3) Good Clinical Practice

26 May 2023 – the MHRA Inspectorate published a blog on the ICH E6(R3) GCP guideline.

Andrew Fisher, Lead Senior GCP Inspector at the UK MHRA, published a blog about the changes to the ICH E6 GCP Guideline now that the updated version R3 has reached Step 2b and is available for public consultation.

“This blog is not intended to include every detailed change made or cover all text retained but should give you a flavor of the amendments made by the Expert Working Group.” (Andrew Fisher)

Read more online

Medical Devices Regulations: Compliance and Enforcement

17 May 2023 – the MHRA published updated guidance on how to report non-compliant medical devices.

MHRA is the designated authority that administers and enforces the law on medical devices in the UK. It has a range of investigatory and enforcement powers to ensure their safety and quality.

The government intends to extend acceptance of CE marked devices in Great Britain beyond 30 June 2023.

Read more online

Medical Devices: Software Applications (Apps)

16 May 2023 – the MHRA published updated guidance on medical device software applications.

The guidance describes what a software application medical device is and how to comply with the legal requirements.

Updated file 'Medical device stand-alone software including apps' to include information on the implementation of new regulations, updates to various links including MORE and new software vigilance guidance.

Read more online

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

16 May 2023 – the MHRA published updated guidance on the risk management of nitrosamine impurities.

MAHs should work with manufacturers of API and finished products in order to review the API and finished product manufacturing processes in light of the arrangements for preventing nitrosamine formation as well as contamination or cross-contamination.

Update for May 2023: Additional guidance about lifecycle management is provided.

Read more online

Swissmedic Publication, “Visible” Issue 7

30 May 2023 – the Swissmedic announced that the latest issue of “Visible” is available.

In the latest issue of the Swissmedic magazine “Visible,” readers can get to know all about Swissmedic and their employees and learn about the tasks they deal with on a day to day basis in the areas of authorization, market surveillance, licensing, legal affairs and support processes.

Read more online

ICH E6(R3) Draft Guideline Reaches Step 2 of the ICH Process

24 May 2023 – the ICH announced the ICH E6(R3) draft GCP guideline reached step 2 of the ICH process on 19 May 2023.

The E6(R3) draft Guideline and guidance for stakeholder public consultation comment collection are available for download on the E6(R3) website.

The guideline is composed of principles and annexes that expand on the principles with specific details for different types of clinical trials.

Read more online

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

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