PMDA Guidance on Risk Management Plan (RMP)

On 29 July 2022 the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) posted RMP page renewal, Q&A, templates, instructions and publication.

The RMP is a document which shows the consistent risk management of drug from the development phase to the post-marketing phase. The RMP aims that the risks of drugs are evaluated at regular intervals or in response to the progress of post-marketing surveillance and a set of pharmacovigilance activities to minimize the risks of drugs. Sharing the published information among medical professionals is meant to ensure further enhancements of post-marketing safety measures.

Read more online

Register Medical Devices to Place on the Market

On 28 July 2022 the MHRA updated the guidance on 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).

The updated version added new section 'Coronavirus Test Device Approval (CTDA) and Registering with MHRA'.

Read more online

Qualification Opinion of the Use of Enroll-HD (A Huntington's Disease Patient Registry) as a Data Source and Infrastructure Support for Post-Authorization Monitoring of Medical Products

On 28 July 2022 the EMA published the qualification opinion on the use of Enroll-HD as a data source and infrastructure support for post-authorization monitoring of medical products.

High-quality disease-specific patient registries are important tools for the improvement of disease epidemiology understanding and the advancement of therapeutics. They can be used for recruitment in clinical trials, natural history studies, clinical epidemiology research, health economic studies, and the collection of bio-samples. These patient registries are foundational to drug discovery and development as well as the advancement of clinical care.

The Enroll-HD data collected per the Enroll-HD protocol can be a source of secondary data for drug utilization studies and post-authorization safety and efficacy studies (PASS and PAES). Specific PASS/PAES studies can also be nested in Enroll-HD, in which case the Enroll-HD data specified by the PASS/PAES protocol becomes primary data for PASS/PAES studies.

Read the pdf

Laser-Assisted in Situ Keratomileusis (LASIK) Lasers - Patient Labeling Recommendations

On 28 July 2022 the FDA published the draft guidance on patient labeling recommendations for LASIK lasers for industry and FDA staff. Submit comments by 26 October 2022.

This draft guidance recommends content and formatting for patient labeling information for laser-assisted in situ keratomileusis (LASIK) devices. FDA is issuing this guidance to help ensure that both physicians can share and patients can understand information on the benefits and risks of these devices. The recommendations are being made based on concerns that some patients are not receiving and/or understanding information regarding the benefits and risks of LASIK devices. These labeling recommendations are intended to enhance, but not replace, the physician-patient discussion of the benefits and risks of LASIK devices that uniquely pertain to individual patients.

Read more online

General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products

On 27 July 2022 the FDA published the final guidance on general clinical pharmacology considerations for neonatal studies

for industry.

This guidance is intended to assist sponsors of investigational new drug applications (INDs) and applicants of new drug applications (NDAs), biologics license applications (BLAs), and supplements to such applications who are planning to conduct clinical studies in neonatal populations. This guidance provides recommendations for neonatal clinical pharmacology studies, whether the studies are conducted pursuant to section 505A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), section 505B of the FD&C Act, or neither. Effectiveness, safety, or dose-finding studies in neonates involve assessing clinical pharmacology information, such as information regarding a product's pharmacokinetics (PK) and pharmacodynamics (PD) to inform dose selection and individualization. As such, the general considerations described in this guidance apply to any neonatal studies which incorporate clinical pharmacology assessments. This guidance does not discuss the timing to initiate neonatal studies. Questions regarding the appropriate timing for the initiation of neonatal studies should be discussed with the relevant FDA review division.

Read more online

Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings

On 27 July 2022 the FDA published the final guidance on cancer clinical trial eligibility criteria for industry.

This guidance provides recommendations to clinical investigators and sponsors regarding the inclusion of patients who have not received available therapy (commonly referred to as existing treatment options) for their cancer in clinical trials of drugs and biological products for the treatment of cancer in the non-curative setting (i.e., when there is no potential for cure or prolonged/near normal survival). For the purpose of this guidance, non-curative is generally defined as 1) unresectable, locally advanced, or metastatic disease in solid tumors or 2) hematologic malignancies with unfavorable long-term overall survival.

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ICH Guideline M10 on Bioanalytical Method Validation and Study Sample Analysis – Frequently Asked Questions (FAQ)

On 27 July 2022 the EMA published the FAQ on ICH guideline M10, step 5.

Concentration measurements of chemical and biological drug(s) and their metabolite(s) in biological matrices are used as part of regulatory decisions regarding the safety and efficacy of drug products. It is therefore critical that the bioanalytical methods used are well characterized, appropriately validated and documented in order to ensure reliable data to support regulatory decisions.

To support the implementation of ICH M10, the Expert Working Group has developed a series of FAQs.

Read the pdf

ICH Guideline M10 on Bioanalytical Method Validation and Study Sample Analysis

On 27 July 2022 the EMA published the ICH guideline M10, step 5.

This guideline is intended to provide recommendations for the validation of bioanalytical methods for chemical and biological drug quantification and their application in the analysis of study samples. Adherence to the principles presented in this guideline will ensure the quality and consistency of the bioanalytical data in support of the development and market approval of both chemical and biological drugs.

Read the pdf

Clinical Trials Highlights - July 2022

On 25 July 2022 the EMA published the Clinical Trials Highlights, issue 10.

In this issue, the following topics are included:

- ACT EU multi-stakeholder events
- Survey on the implementation of the Clinical Trials Regulation
- Article published: 'Estimators for handling COVID-19 related Intercurrent Events with a hypothetical strategy'
- Introduction to the SAFE CT Joint Action
- Update on the consultation on draft guidance on the protection of personal data and commercially confidential information (CCI) in CTIS
- An academic sponsor's first experiences with CTIS
- CTIS release notes and known issues
- CTIS events update
- CTIS training material update
- CTIS training environment ('CTIS Sandbox') update
- Upcoming changes to EMA Account Management
- New KPIs to track the European clinical trials environment published
- Multi-factor authentication strategy at EMA

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Unique Device Identification (UDI): Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices

On 22 July 2022 the FDA published the final UDI guidance for industry and FDA staff.

FDA has updated this guidance to include FDA's compliance policy regarding Global Unique Device Identification Database (GUDID) submission requirements for certain class I devices considered consumer health products. Specifically, FDA does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I devices considered to be consumer health products that are required to bear a UDI on their labels and device packages. Additionally, FDA does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I and unclassified devices, other than implantable, life-supporting, or life-sustaining (I/LS/LS) devices, regardless of whether they are consumer health products, before December 8, 2022 (an additional 75 calendar days).

Read more online

Orange Book Questions and Answers Guidance for Industry

On 22 July 2022 the FDA published the final orange book Q&A guidance for industry.

This guidance is intended to assist interested parties (including prospective drug product applicants, drug product applicants, and approved application holders) in utilizing the Approved Drug Products with Therapeutic Equivalence Evaluations publication (the Orange

Book). This guidance provides answers to commonly asked questions that we have received from these interested parties regarding the Orange Book.

Read more online

Failure to Respond to an Abbreviated New Drug Applications (ANDA) Complete Response Letter (CRLs) within the Regulatory Timeframe

On 22 July 2022 the FDA published the final guidance on responding to complete response letters (CRLs) from FDA for industry.

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 (21 U.S.C. 355(j)), in responding to complete response letters (CRLs) from FDA. As described in regulation, ANDA applicants are required to take action after receiving a CRL. 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

Conducting Remote Regulatory Assessments Questions and Answers

On 22 July 2022 the FDA published the draft Q&A guidance on conducting remote regulatory assessments for industry.

FDA is issuing the draft guidance to describe the Agency's current thinking regarding its use of remote regulatory assessments (RRAs) in order to increase industry's understanding of RRAs and facilitate FDA's process for conducting RRAs. FDA has used RRAs to conduct oversight, mitigate risk, meet critical public health needs and help maximize compliance of FDA-regulated products. This draft guidance provides answers to frequently asked questions regarding what RRAs are, when and why FDA may use them, and how FDA may conduct them, among others.

Read more online

Real-Time Oncology Review (RTOR)

On 22 July 2022 the FDA published the draft guidance on real-time oncology review for industry. Submit comments by 20 September 2022.

The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected New Drug Applications (NDA) and Biologic License Applications (BLA) with oncology indications for review under the Real-Time Oncology Review (RTOR).

Read more online

Global Regulators Call for International Collaboration to Integrate

Real-World Evidence into Regulatory Decision-Making

On 22 July 2022 the EMA announced the availably of a joint ICMRA statement on international collaboration to enable RWE for regulatory decision-making.

The joint statement was developed following an ICMRA workshop on real-world evidence co-organized by EMA, US FDA and Health Canada, held in Amsterdam in June 2022.

In their statement, ICMRA members pledge to foster global efforts and further enable the integration of real-world evidence into regulatory decision-making. They identify four focus areas for regulatory cooperation:

- harmonization of terminologies for real-world data and real-world evidence;
- regulatory convergence on real-world data and real-world evidence guidance and best practice;
- readiness to address public health challenges and emerging health threats; and
- transparency.

Read the pdf

ICH Guideline M12 on Drug Interaction Studies

On 21 July 2022 the EMA published the draft ICH guideline M12, step 2b.

This guideline provides recommendation to promote a consistent approach in designing, conducting, and interpreting enzyme- or transporter-mediated in vitro and clinical drug-drug interaction (DDI) studies during the development of a therapeutic product. A consistent approach will reduce uncertainty for pharmaceutical industry to meet the requirement of multiple regulatory agencies and lead to more efficient utilization of resources.

Read the pdf

Good Laboratory Practice (GLP) for Safety Tests on Chemicals

On 21 July 2022 the MHRA updated the guidance on GLP

Any test facility which conducts, or intends to conduct, regulatory studies must comply with good laboratory practice (GLP) regulations when carrying out safety tests on: pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals

Cosmetics additives for human food and animal feed biocides.

The test facility must belong to the UK GLP compliance monitoring program, run by the UK GLP Monitoring Authority (UK GLPMA). The program is only open to facilities in the UK.

Two guidance were added: UK GLPMA Guidance on content of QA Statement 2022 & UK GLPMA Study Reporting Guidance 2022.

Read more online

Evaluation of Therapeutic Equivalence

On 21July 2022 the FDA published the draft guidance on evaluation of therapeutic equivalence of generic drugs. Submit comments by 19 September 2022.

The draft guidance explains the criteria FDA uses to evaluate the therapeutic equivalence (TE) of drug products and what the TE codes indicate. The guidance explains how FDA evaluates drug products for, and determines TE for, multi-source drug products to be listed in the Approved Drug Products With Therapeutic Equivalence Evaluations publication (the Orange Book). The guidance provides background on the fundamentals of TE and utilizes a question and answer format to provide more information on the therapeutic equivalence evaluation of approved drug products and assignment of TE codes in the Orange Book.

Read more online

Clinical Trials for Medicines: Apply for Authorization in the UK

On 18 July 2022 the MHRA updated the guidance on clinical trials for medicines.

The updated version added information on 'Requesting approval of trials with complex innovative designs'.

The MHRA supports the conduct of trials with complex innovative designs such as umbrella, basket, platform and master protocol plus submodules.

These trial designs are characterized by the presence of prospective major adaptations.

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WSQMS Homepage Aug 26, 2022

FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products

15 August 2022 — FDA published the technical specifications document of the final E2B(R3) guidance for industry.

The purpose of this technical specifications document is to assist submitters electronically submitting individual case safety reports (ICSRs) and ICSR attachments to FDA Adverse Event Reporting System (FAERS) database.

This document describes FDA's technical approach for submitting ICSRs, for incorporating its regionally controlled terminology, and for adding FAERS regional data elements that are not addressed in the International Conference on Harmonization's (ICH) E2B(R3) Implementation Guideline (IG), including the following FDA-regulated products:

- Drug products marketed for human use with approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs)
- Prescription drug products marketed for human use without an approved application
- Nonprescription human drug products marketed without an approved application)
- Biological products marketed for human use with approved biologic license applications (BLAs).

Read more online

EVVet3 Production - Release Notes

8 August 2022 — EMA published v1.6 release notes of EVVet3.

This release is the next iterative version of the Union Pharmacovigilance Database, v 1.6.

This version introduces a new functionality to Export in CSV the results table of a search in "Search AE Reports" section and corrections for some incorrect breed mappings.

Read the pdf

IRIS for Good Pharmacovigilance Practice (GVP) Inspections Training Session for Industry Users

9 August 2022 — EMA announced the GVP inspections training session on 7 September 2022.

This webinar aims to explain the GVP Inspections business process in IRIS highlighting the changes and answer any potential questions from industry users.

Topics that will be addressed in this webinar include:

- IRIS overview
- IRIS access management
- GVP Inspections business process, including demo of the Industry Portal

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Bioresearch Monitoring Technical Conformance Guide

5 August 2022 — FDA published technical specifications guidance on bioresearch monitoring technical conformance guide.

This Bioresearch Monitoring Technical Conformance Guide (Guide) provides current FDA specifications, recommendations, and general considerations for preparing and submitting Clinical Study-Level Information, Subject-Level Data Line Listings by Clinical Site, and a Summary-Level Clinical Site Dataset that are used by the Center for Drug Evaluation and Research (CDER) for planning of Bioresearch Monitoring (BIMO) inspections in electronic format for new drug applications (NDAs), biologics license applications (BLAs), and NDA or BLA supplemental applications containing clinical data that are regulated by CDER. It also applies when these data and information are submitted under certain investigational new drug applications (INDs) in advance of a planned NDA, BLA, or supplemental submission.

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Complex Generics News

5 August 2022 — FDA published up-to-date information on FDA's actions on complex generics.

To help patients access important medical treatments, FDA's Center for Drug Evaluation and Research works to better understand the scientific issues impacting complex generic development and assessment. FDA shares these scientific insights publicly, further enabling generic drug applicants to develop complex products and helping to ensure that applicants have the necessary information to prepare complete submissions.

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Decommission of eSUSAR

3 August 2022 — MHRA inspectorate announced decommission of eSUSAR.

As of 30 September and beginning 1 October 2022, the MHRA is retiring the eSUSAR website in favor of Individual Case Safety Reports (ICSR) Submissions - providing users a more robust, stringent, and transparent way of expediting suspected unexpected serious adverse drug reactions (SUSARs) from Clinical Trials of Investigational Medicinal Products.

Read more online

EMA Initiatives for Acceleration of Development Support and Evaluation Procedures for COVID-19 Treatments and Vaccines

3 August 2022 — EMA published guidance on rapid formal review procedures related to COVID-19.

This document provides an overview of EMA's rapid formal review procedures related to COVID-19 and is mainly intended as procedural guide for developers. It complements other documents published under the guidance for medicine developers and companies on COVID-19 and the respective guidance provided for regular procedures published on the EMA website for research and development and for marketing authorization.

Read the pdf

Electronic Submission of Expedited Safety Reports From IND-Exempt BA/BE Studies

2 August 2022 — FDA published draft guidance for industry. Submit comments by 3 October 2022.

This draft guidance will assist prospective ANDA applicants in submitting expedited safety reports of serious adverse events (SAEs) from certain bioavailability (BA)/bioequivalence (BE) studies in electronic format. Under 21 CFR 320.31(d)(3), persons conducting human BA and BE studies in the United States that are exempt from the IND requirements under part 312 must report any serious adverse events from the study to FDA and to all participating investigators. SAEs had been submitted to OGD via email, telephone, or facsimile transmission with FDA forms as attachments. Enhancements to the FDA Adverse Event Reporting System (FAERS) will allow electronic submission of premarket safety reports in compliance with ICH guidance and data specifications for studies conducted under IND and BA/BE studies that are IND-exempt. The guidance provides specifications, recommendations, and general considerations to inform electronic submission of expedited safety reports.

Read more online

Clinical Trials for Medicines: Manage Your Authorization, Report Safety Issues

2 August 2022 — MHRA updated the guidance on clinical trials for medicines.

As of 1 January 2022 the combined review service, formerly known as Combined Ways of Working (CWoW), is now the way that all new Clinical Trials of Investigational Medicinal Products (CTIMPs) applications are prepared, submitted and reviewed.

In this updated version, one of the SUSAR reporting routes has been removed from the Suspected Unexpected Serious Adverse Reactions (SUSARs) section.

Read more online

Version 2.8 of Technical Documentation - UDI/Devices Registration

2 August 2022 — European Commission published the technical documentation version 2.8 for unique device identifier (UDI)/Devices registration.

This document clarifies the data to provide in EUDAMED for the UDI device registration module.

Read more online

Application for Priority Applicant Determination - Medical Devices

2 August 2022 — Australian Therapeutic Goods Administration (TGA) announced the availability of the application form for priority applicant determination of medical devices.

To apply for a priority applicant determination for your medical device(s), you must complete and submit this form along with sufficient supporting information addressing the relevant eligibility criteria.

Before submitting your application, please refer to the Priority applicant guidelines for medical devices (including IVDs). These guidelines outline the application process, the criteria your device must meet to be eligible for priority applicant determination, and how to pay your application fee.

The application form is available in pdf and Microsoft Word formats.

Read more online

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

2 August 2022 — EMA published Issue 56 of the SME Office Newsletter.

SME Office Newsletter publishes information for SMEs on the EU regulatory environment for medicines. In this issue, the following topics were included:

- Scientific guidelines for human medicines
- Clinical trials
- Regulatory guidance
- Veterinary medicines
- Fees
- New EMA Mandate under Regulation (EU) 2022/123
- Events
- Reports and workplans
- Registered SMEs
- Contact details

Read the pdf

Digital Application Dataset Integration (DADI) Q&A Webinar - Variations Form for Human Medicinal Products

2 August 2022 — EMA published the DADI Q&A webinar summary document.

This Question and Answer (Q&A) document is for information only and is based on insights available at the time of the DADI Q&A webinar on variations form for human medicinal products held on 12 July 2022. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the DADI and PMS project teams.

Read the pdf

Changes to Guidance Document Authorization Procedures for COVID-19 Medicinal Products During a Pandemic HMV4

1 August 2022 — Swissmedic published the revised guidance document effective 1 August 2022.

The marketing authorization holder must continuously monitor the efficacy of medicinal products used to prevent and/or treat COVID-19 against current SARS-CoV-2 variants according to the conditions imposed. In the present revision of the Guidance document, Swissmedic clarifies what information it needs once WHO classifies a SARS-CoV-2 variant as a variant of interest, variant of concern or lineage under monitoring (section 8).

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