Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies

15 June 2022 — FDA issued draft guidance for comments by 14 September 2022.

This guidance describes a standards recognition program for regenerative medicine therapies (SRP-RMT) at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate. CBER encourages the use of appropriate standards in the development of CBER-regulated products. The use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. This program is modeled after the formal standards and conformity assessment program or S-CAP for medical devices.

Read more online

Q9(R1) Quality Risk Management

14 June 2022 — FDA issued draft guidance for comments by 15 July 2022.

In the pharmaceutical sector, the principles and framework of ICH Q9, coupled with the official ICH training material that supports this guideline, are instrumental in enhancing the application of effective quality risk management by industry and regulators. The importance of quality systems has been recognized in the pharmaceutical industry, and it is evident that quality risk management is a valuable component of an effective quality system.

Read more online

Electromagnetic Compatibility (EMC) of Medical Devices

6 June 2022 — FDA issued guidance on EMC for industry and FDA staff.

This guidance document provides the FDA's recommendations on testing to assess the electromagnetic compatibility of medical devices and information to include in the labeling. This guidance applies to medical devices, including in vitro diagnostics, and accessories that

are electrically powered or have functions or sensors that are implemented using electrical or electronic circuitry. The recommendations are intended to promote consistency and facilitate efficient review of electromagnetic compatibility in device submissions.

Read more online

Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments

29 June 2022 — FDA issued draft guidance for comments by 28 September 2022.

This guidance (Guidance 3) is the third in a series of four methodological patient-focused drug development (PFDD) guidance documents that describe how stakeholders (patients, caregivers, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making. When finalized, Guidance 3 will represent the current thinking of CDER, CBER, and CDRH on this topic.

Read more online

Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment

27 June 2022 — FDA published final industry guidance on the treatment of bladder cancer.

This guidance provides recommendations to sponsors regarding the development of drugs and biological products regulated by CDER and CBER for the adjuvant treatment of muscle-invasive bladder cancer. The guidance includes recommendations regarding eligibility criteria, choice of comparator, follow-up imaging assessments, determination of disease recurrence, analyses of disease-free survival (DFS), and interpretation of trial results. Although FDA may consider endpoints other than DFS for the adjuvant treatment of muscle-invasive bladder cancer, this guidance is focused on clinical trials with DFS as the primary efficacy endpoint.

Read more online

Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment

27 June 2022 — FDA published final industry guidance on the treatment of renal cell carcinoma.

This guidance provides recommendations to sponsors regarding the development of drugs and biological products regulated by CDER and CBER for the adjuvant treatment of renal cell carcinoma. The guidance includes recommendations regarding eligibility criteria, choice of comparator, follow-up imaging assessments, determination of disease recurrence, analyses of disease-free survival (DFS), and interpretation of trial results. Although FDA may consider endpoints other than DFS for the adjuvant treatment of renal cell carcinoma, this guidance is focused on clinical trials with DFS as the primary efficacy endpoint.

Read more online

Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics

27 June 2022 — FDA issued draft guidance for comments by 25 September 2022.

This guidance provides recommendations to assist industry in the development of oligonucleotide therapeutics under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR parts 312 and 314. Specifically, this guidance represents the FDA's recommendations for certain evaluations including pharmacokinetic, pharmacodynamic, and safety assessments during oligonucleotide therapeutic development, including: (1) characterizing the potential for QTc interval prolongation, (2) performing immunogenicity risk assessment, (3) characterizing the impact of hepatic and renal impairment, and (4) assessing the potential for drug-drug interactions. This guidance provides recommendations on when to conduct these assessments and what types of assessments are suitable to address these questions.

Read more online

Assessing the Effects of Food on Drugs in INDs and NDAs – Clinical Pharmacology Considerations

24 June 2022 — FDA published final guidance.

This guidance provides recommendations to sponsors planning to conduct food-effect (FE) studies for orally administered drug products under investigational new drug applications (INDs) to support new drug applications (NDAs) and supplements to these applications for drugs being developed under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). This guidance revises and replaces part of the 2002 FDA guidance entitled Food-Effect Bioavailability and Fed Bioequivalence Studies (December 2002).

Read more online

Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures

21 June 2022 — FDA issued draft guidance for industry and FDA staff. Submit comments by 22 August 2022.

This draft guidance document provides the FDA's recommendations on non-clinical performance testing to support premarket submissions for gynecologic and general laparoscopic power morcellation containment systems and may also help manufacturers comply with the special controls related to non-clinical performance data for these devices. This guidance applies to the tissue containment systems used during a power morcellation procedure for gynecologic use and for general use and provides recommendations on (1) test methods, (2) test parameters, and (3) test acceptance criteria. The recommendations are intended to promote consistency and facilitate efficient review of gynecologic and general laparoscopic power morcellation containment systems submissions. The recommendations are being made to ensure that the non-clinical test methods can effectively identify safety

issues related to damage of the tissue containment system and subsequent leakage of any cancer cells and other contents.

Read more online

Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions

16 June 2022 — FDA published the final guidance for industry and FDA staff.

This guidance document provides FDA's recommendations on the information, technical performance assessment, and user information that should be included in a premarket submission for radiological devices that include quantitative imaging functions. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of premarket submissions for radiological devices that include quantitative imaging functions.

Read more online

Mandatory Use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on Training Using the EudraVigilance System

15 June 2022 — EMA announced EudraVigilance System online training course.

This training course covers the use of the ISO ICSR/ICH E2B(R3) format and related ISO standard terminology for pharmaceutical form and route of administration for reporting individual cases of suspected side effects to EudraVigilance.

Read more online

Changing the Name or Address of a Sponsor

9 June 2022 — EMA announced update for submitting a request to change the name or address.

Sponsors need to use EMA's IRIS platform to request changes to their name or address. The EMA is not able to process any requests outside of IRIS.

Read more online

Orphans: Regulatory and Procedural Guidance and Forms

9 June 2022 — EMA announced updated procedural guidance documents on orphan designation.

The following regulatory and procedural guidance and forms on orphan designation were updated:

- Template - Translations required with the submission of an application for orphan medicinal product designation
- Procedural advice for post-orphan medicinal product designation activities:

Guidance for sponsors

- Checklist for sponsors applying for the transfer of Orphan Medicinal Product (OMP) designation
- Template - Translations required with the submission of an application for transfer of orphan medicinal product designation

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Article 57 User Interface (UI) Installation Guide

7 June 2022 — EMA published updated installation guide on article 57 UI components and initial set-up.

This document provides detailed steps to follow to install Article 57 components on users' computers to support the use of the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) data-entry tool user interface known as EVWEB.

Read the pdf

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eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) User Manual

7 June 2022 — EMA published version 5.7 of the EVWEB user manual.

The below sections were amended following the publication of version 5.6 in October 2021:

- 1.5. EVWEB
- 4.8. Save, Reload and Send an XEVPRM
- 4.9. Use EV Post functionality
- 4.10.1. Exporting results of a simple query

Read the pdf

Workshop Report on Data Quality Framework for Medicines Regulation

29 June 2022 — EMA published workshop report on data quality framework for medicines regulation.

The workshop was an initiative of HMA, EMA and TEHDAS meant to share both the current progress on building a data quality framework for medicines regulation and to solicit the comments and ideas of experts in this field to help shape the drafting process. Breakout sessions focused on particular use cases with fruitful discussions on the current data quality landscape and how the future of data quality in medicines regulation should look in the clinical and non-clinical areas.

Read the pdf

Updated IRIS Guide for Industry and Individual Applicants

28 June 2022 — EMA published the updated IRIS guide on how to create and submit scientific applications.

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

Read the pdf

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

20 June 2022 — EMA published updated pre-authorization Q&A guidance.

This guidance document addresses a number of questions which users of the centralized procedure may have. It provides an overview of the European Medicines Agency's position on issues, which are typically addressed during the course of pre-submission meetings.

The following sections were revised:

- 3.3.3. What information regarding transfer of test methods is required for different active substance or finished product release testing sites in the MAA? Rev. Jun 2022
- 5.1.1. How long does it take for my application to be evaluated? Rev. Jun 2022
- 5.1.11. Can EMA assessment or inspection documents be shared with third parties? Rev. Jun 2022
- 5.2.1. When can I expect a pre-authorization GMP inspection and how are they conducted? Rev. Jun 2022
- 5.2.2. When can I expect a pre-approval GCP inspection and how are they conducted? Rev. Jun 2022
- 5.2.3. What is the fee for a GMP/GCP/GLP pharmacovigilance inspection? Rev. Jun 2022

Read the pdf

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

20 June 2022 — EMA published updated Q&A guidance on extensions of marketing authorizations.

This guidance document addresses a number of questions which marketing authorization holders (MAHs) may have on post-authorization procedures. It provides an overview of the Agency's position on issues, which are typically addressed in discussions or meetings with MAHs in the post-authorization phase. The following sections were revised:

- 3.21. Do I need to confirm the maintenance of my orphan designation when applying for a type II variation? Rev. Jun 2022

- 4.7. Do I need to confirm the maintenance of my orphan designation when applying for an extension application? Rev. Jun 2022
- 10.6. When, how and to whom shall I submit my annual re-assessment application? Rev. Jun 2022
- 19.5. How to choose the implementation date? Rev. Jun 2022

Read the pdf

Guidance on Handling of Decentralized and Mutual Recognition Procedures Which are Approved or Pending

24 June 2022 — MHRA published updated guidance on the approach the MHRA intends to take for products approved or pending in decentralized procedure (DCP) or mutual recognition procedures (MRP).

This guidance describes the approach the MHRA intends to take for products already approved or that are included in ongoing DCPs or MRPs with UK in respect of NI (UK(NI)) as a Concerned Member State (CMS).

The section 'Guidance for The Conversion of PLGB or PLNI licenses to PL' was newly added.

Read more online

Marketing Authorization Application (MAA) Submission Dates for 150-days National and European Commission Decision Reliance Procedures

20 June 2022 — MHRA published updated guidance on MAA submission dates.

The MHRA will operate a 150-day Assessment route for high-quality marketing authorization applications (MAAs). Submission deadlines were updated.

Read more online

Compliance Monitor (CM) Overview and Application Process

15 June 2022 — MHRA published updated guidance on the eligibility of the compliance monitor.

From April 2022, the MHRA will be running a pilot scheme to monitor companies that fail to comply with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) protocols and are referred to the Inspection Action Group (IAG) following an inspection that has resulted in the initiation of a compliance process.

Companies that enter the pilot scheme will use consultant(s) selected from the MHRA CM register to monitor the implementation of an agreed upon Compliance Protocol (CP). The ability to act as a CM will be based on the principles of eligibility and suitability, which now includes residence in the United Kingdom.

Read more online

Questions and Answers - Complex Clinical Trials

2 June 2022 — European Commission published updated Q&A guidance on complex clinical trials, version 2022-05-23.

This Q&A document provides guidance and seeks to support sponsors, clinical trialists and applicants regarding scientific aspects and the planning, set-up, submission for obtaining CT authorization (CTA), conduct, reporting and transparency, analysis and interpretation of complex clinical trials (CCTs) under the EU Clinical Trials Regulation (EU CTR) as well as their use in submissions for marketing authorization.

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European Medicines Agency's Data Protection Notice for EudraVigilance Human (EV)

15 July 2022 — EMA published updated data protection notice for EudraVigilance Human.

This Data protection notice explains the most essential details of the processing of personal data in the context of the operation of EudraVigilance Human (EV) established in accordance with the requirements of Article 24(1) of Regulation (EU) No 726/2004. The European Medicines Agency (hereafter referred to as "the Agency"), in collaboration with Union Member States and the European Commission, has set up and maintains the EudraVigilance database and data processing network2 to collate and analyze information on suspected adverse reactions regarding investigational medicinal products (IMPs) studied in clinical trials and medicinal products authorized in the EU.

Read the pdf

Technology Capability Investment Plan

15 July 2022 — EMA published technology capability investment plan for becoming the digital hub for the European Medicines Regulatory Network.

EMA's technology capability investment plan aims to help the Agency develop into a customer-focused digital hub that provides high quality data and information services to the European medicines regulatory network. Its goal is to create technology and delivery methods that can support the implementation of key network strategic priorities by 2025.

Read the pdf

The ICH Drug Interaction Studies M12 Draft Guideline Now Available Online

15 July 2022 — ICH announced the availability of the M12 draft guideline presentation.

This Guideline provides general recommendations on how to evaluate the DDI (drug-drug interaction) potential of an investigational drug. It is recognized that the DDI evaluation is

generally tailored based on the specific drug, intended patient population, and therapeutic context.

Read the pdf

Horizon Scanning Case Study: Point of Care Manufacture

15 July 2022 — UK MHRA published the horizon scanning case study.

Horizon scanning at the MHRA leads to a proposed new framework to enable the supply and increase in the availability of innovative new medicinal products made at the point of care to patients.

Read more online

Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products — Content and Format

14 July 2022 — FDA published the final guidance for industry.

This guidance provides recommendations for developing the content and format of a patient Instructions for Use (IFU) document for human prescription drug and biological products, as well as drug-led or biologic-led combination products submitted under a new drug application (NDA) or a biologics license application (BLA).

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Joint Controllership Arrangement: EudraVigilance Human (EV) Personal Data Capture

13 July 2022 — EMA published legal framework for the purpose of processing personal data captured in EudraVigilance Human (EV) administered by EMA

Amongst the European Commission (hereinafter referred to as 'Commission' or 'European Commission'), the European Medicines Agency (hereinafter also referred to as 'the Agency' or 'EMA'), and the Member States of the European Union (EU)/European Economic Area (EEA) (hereinafter referred to as 'MS' or 'Member States') represented by National Competent Authorities (hereinafter referred to as 'NCAs').

Each of them a 'Party' and hereinafter collectively referred to as 'Parties', to be considered as 'joint controllers' for the purpose of processing personal data captured in EudraVigilance Human (EV) administered by EMA and covering the following system components:

1. EudraVigilance Gateway – the data processing network;

2. EudraVigilance Database Management system comprising the EudraVigilance Clinical Trials Module (EVCTM), the EV Post-Authorization Module (EVPM) and data quality management functionalities (recoding and duplicate detection);

3. EudraVigilance web reporting application (EVWEB) including Individual Case Safety Report (ICSR) creation, submission, re-routing to NCAs of Member States, querying and for EVPM ICSR download by marketing authorization holders;

4. EudraVigilance Data Warehouse and Analysis System (EVDAS) including signal detection, safety monitoring and data analysis functionalities;

5. Public Adverse Drug Reaction Reports portal (ADRReports.eu);

6. Extended Medicinal Products Dictionary (xEVMPD).

Read the pdf

GCP Inspection Site Report Template on Behalf of the EMA

12 July 2022 — EMA published the updated GCP inspection procedures for appendix 1 to INS-GCP-4 procedure for reporting of GCP inspections requested by the CHMP.

The GCP Inspectors Working Group has developed procedures for the coordination, preparation, conduct and reporting of GCP inspections requested by the EMA Committee for Medicinal Products for Human Use (CHMP) in the context of the centralized procedure.

These inspections are adopted by the CHMP and may be routine or may be triggered by issues arising during the assessment of the dossier or by other information such as previous inspection experience.

They are usually requested during the initial review of a marketing authorization application, but could arise post-authorization (e.g. inspection of studies conducted or completed as part of the condition of a marketing authorization, or because of concerns arising about the studies previously submitted).

Read the pdf

Information about the Raw Data Proof-of-Concept Pilot for Industry

12 July 2022 — EMA announced the availability of access to raw data for marketing authorization and post-authorization applications submitted to the EMA.

The purpose of this document is to provide an overview about the proof-of-concept (PoC) pilot on the submission and analysis of 'raw data' from clinical studies as part of selected initial marketing authorization applications (iMAAs) and post-authorization applications submitted to the EMA.

Read the pdf

Consultation on Regulatory Guidelines for Laboratory Developed Tests (LDTs)

12 July 2022 — Singapore Health Sciences Authority (HAS) announced the release of a draft regulatory guidelines for LDTs for stakeholders' consultation.

The document provides an overview of the scope of LDTs and the regulatory requirements applicable, which includes Product controls, Manufacturing Quality controls and post-market controls. The Consultation period for this document is from 12 July 2022 to 12 August 2022.

Read more online

OPEN Pilot: One-year Review and Recommendations

7 July 2022 — EMA published the OPEN Pilot report.

The pilot phase of the OPEN Initiative (Opening our Procedures at EMA to Non-EU authorities) is intended to run for the duration of the declared COVID-19 pandemic. Regulators from Australia, Canada, Japan, Switzerland and the World Health Organization participate in the pilot under the terms of existing confidentiality arrangements. These non-EU experts are invited to attend and contribute to ETF and CHMP evaluations and discussions for COVID-19 vaccines and therapeutics. All regulators keep full scientific and regulatory independence in their final decision making.

Read the pdf

Identifying Trading Partners Under the Drug Supply Chain Security Act

5 July 2022 — FDA issued the draft guidance for industry. Submit comments by 05 September 2022.

The FDA is issuing this guidance to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA). This guidance revises the Agency's draft guidance for industry Identifying Trading Partners Under the Drug Supply Chain Security Act (August 2017) to address the status of some entities as trading partners (e.g., private-label distributors, salvagers, and returns processors and reverse logistics providers), provide clarification on certain drug distribution scenarios, and address the interpretation of section 582(a)(7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which discusses third-party logistics providers (3PL) licensure status prior to the effective date of the forthcoming regulations establishing licensure standards.

Read more online

Guideline on Advertising, etc. of Medicinal Products for Human Use

5 July 2022 — Danish Medicines Agency updated guideline on advertising of medicinal products for human use.

The rules on advertising of medicinal products for human use are found in Part VII (sections 63-70) of the Danish Medicines Act, Executive Order no. 849 of 29 April 2021 on Advertising, etc. of Medicinal Products for Human Use (the Advertising Order) as amended by Executive Order no. 134 of 25 January 2022 and Executive Order no. 1244 of 12 December 2005 on the Supply of Medicinal Product Samples as amended by Executive Order no. 117 of 25 January 2022.

The Advertising Order lays down rules on medicinal product discounts, and sections 71A-71C of the Danish Medicines Act and section 3B of the Danish Pharmacy Act lay down rules on bonuses and discounts offered in connection with the sale of pharmacy-only medicinal products.

Read more online

Guidance on Applying the 2021 Advertising Code Rules

1 July 2022 — Australian Therapeutic Goods Administration (TGA) published the guidance on applying the advertising code rules for therapeutic goods.

For therapeutic goods that can be advertised to the public, advertising must comply with the requirements in the Act and the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021.

Some fundamental requirements apply to advertising of all types of therapeutic goods. It's recommended to read the Code and the Guidance together when checking your advertising compliance. All advertising must comply with the 2021 Code rules from 1 July 2022.

Read the pdf

Questions & Answers - Practical Arrangements on the Companion Diagnostics Consultation Procedure to the European Medicines Agency by Notified Bodies

1 July 2022 — EMA published updated Q&A guidance on diagnostic consultation procedures.

This Q&A guidance describes the practical arrangements on the Companion Diagnostics Consultation Procedure to the EMA by notified bodies.

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