Guideline on Requirements for Chemical and Pharmaceutical Quality Documentation Concerning Investigational Medicinal Products (IMPs) in Clinical Trials

On 28 January 2022 the EMA published guidance to define harmonized requirements for documentation submitted throughout the EU.

This guidance addresses the documentation on the chemical and pharmaceutical quality of IMP dossiers containing chemically defined drug substances, synthetic peptides, herbal substances, herbal preparations and chemically defined radio-active/radio-labelled substances to be submitted to the competent authority for approval prior to beginning a clinical trial in humans.

Read the pdf

Risk-Adapted Approach to Clinical Trials and Risk Assessments

On 28 January 2022 the MHRA issued guidance on how to implement a dual strategy for a risk-adapted approach to clinical trials in the UK.

The first part of the strategy is the stratification of trials into type A, B or C dependent upon the use of the investigational medicinal product (IMP) in relation to its marketing authorization or an unlicensed IMP, i.e. the risks associated with the IMP. This would impact on the MHRA authorization process, indicate potential changes to trial documentation requirements and inform the safety monitoring plan.

The second part is a bespoke approach. This is a trial-specific risk assessment to identify specific vulnerabilities in the trial conduct that could impact on the trial results and the protection of trial participants safety, rights and wellbeing. This risk assessment would document the mitigations for specific identified risks and any adaptations from traditional GCP. These would then be developed such that there would be risk proportionate management and monitoring of the trial.

Read more online

Oversight and Monitoring of Investigational Medical Product (IMP) Trials

On 28 January 2022 the MHRA issued guidance to assist sponsors and those conducting trials on implementing adequate oversight and monitoring processes for trials of IMPs.

UK legislation requires that the sponsor assures themselves that the trial is being conducted according to:

- the principles of GCP
- the legislation
- the authorization from the competent authority
- the favorable opinion from the ethics committee
- the trial protocol and procedures

The sponsor's oversight and monitoring can be regarded to encompass all the activities undertaken by the sponsor during the conduct of the trial that are there to ensure the participants' rights and wellbeing are protected, the reliability of the trial data and hence the trial results and that the trial is conducted in accordance with the legislation. It is the sponsor's "safety net" to check that the trial protocol, procedures, training etc. that have been implemented in order to get it right first time are functioning correctly.

Read more online

Good ANDA Submission Practices

On 26 January 2022 the FDA issued the final guidance for industry.

This guidance is intended to assist applicants preparing to submit to FDA abbreviated new drug applications (ANDAs). This guidance highlights common, recurring deficiencies that may lead to a delay in the approval of an ANDA. It also makes recommendations to applicants on how to avoid these deficiencies with the goal of minimizing the number of review cycles necessary for approval.

Read more online

Information Requests and Discipline Review Letters Under the Generic Drug User Fee Amendments

On 26 January 2022 the FDA issued the final guidance for industry.

This guidance explains how FDA will issue and use an information request (IR) and/or a discipline review letter (DRL) during the assessment of an original 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)), as contemplated in the Generic Drug User Fee Amendments of 2017 (GDUFA II). This guidance does not apply to an amendment made in response to a complete response letter (CRL), a supplement, or an amendment to a supplement.

Under the Generic Drug User Fee Amendments of 2012 (GDUFA I), FDA committed to performance goals for acting on received ANDAs. FDA also committed to performance goals

for acting on received ANDAs under GDUFA II. In addition to these performance goals, FDA is now committed to provide applicants preliminary thoughts on possible deficiencies as each assessment discipline finishes its initial assessment of its portion of the received application (except when that assessment results in the ability to act on such application).

Read more online

Principles of Premarket Pathways for Combination Products

On 26 January 2022 the FDA issued the final guidance for industry and FDA staff.

This guidance presents the current thinking of FDA on principles for premarket review of combination products. This guidance offers general, high-level information regarding what combination products are, coordination within FDA and interaction between FDA and sponsors regarding combination product regulation, and how combination products are reviewed by FDA before they are marketed. The remainder of this guidance focuses on how to determine which type of premarket submissions may be appropriate for combination products. The Agency has published guidance on premarket review issues relevant to specific categories of combination products and will continue to use such guidance as needed to provide more detailed information on specific premarket considerations and specific types of combination products.

Read more online

Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation

On 26 January 2022 the FDA issued the final guidance for industry, FDA staff, and other stakeholders.

FDA is issuing this guidance to describe principles that should be considered when using Patient-Reported Outcome (PRO) instruments in the evaluation of medical devices and provide recommendations about the importance of ensuring the measures are fit-for-purpose. This guidance is not meant to replace the Patient-Focused Drug Development (PFDD) guidance series.

Read more online

Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

On 26 January 2022 the FDA issued the final guidance for industry, FDA staff, and other stakeholders.

FDA is pursuing various efforts for encouraging voluntary patient engagement in clinical studies, including issuing this guidance. FDA believes medical device clinical studies designed with input from diverse patient advisors, including those from racially and ethnically diverse populations, may help to address common challenges faced in these clinical studies.

While FDA acknowledges that patient engagement may be beneficial across the total product lifecycle, this guidance focuses on the application of patient engagement in the design and

conduct of medical device clinical studies.

Read more online

Revising ANDA Labeling Following Revision of the RLD Labeling

On 25 January 2022 the FDA published the draft guidance for industry. Comments may be submitted until 25 March 2022.

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

This guidance revises the guidance for industry Revising ANDA Labeling Following Revision of the RLD Labeling (April 2000). After it has been finalized, this guidance will replace the April 2000 guidance. Significant changes from the 2000 version include updates to outdated details about how to obtain information on changes to RLD labeling and how to submit revised ANDA labeling to FDA.

Read more online

Regulatory Harmonization of Clinical Trials in the EU: Clinical Trials Regulation to Enter into Application and new Clinical Trials Information System (CTIS) to be Launched

On 25 January 2022 the EMA released the news about the CTIS launching on 31 January 2022.

On 31 January 2022, the Clinical Trials Regulation (CTR) will come into application harmonizing the submission, assessment and supervision processes for clinical trials in the European Union (EU). The backbone of the changes brought about by the CTR is the new Clinical Trials Information System (CTIS). CTIS is a single entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data which includes a public searchable database for healthcare professionals, patients and the general public.

Read more online

Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

On 21 January 2022 the FDA published the draft guidance for industry, investigators, and other stakeholders. Comments may be submitted until 22 March 2022.

This guidance provides recommendations for sponsors, investigators, and other stakeholders on the use of DHTs for remote data acquisition from participants in clinical investigations evaluating medical products.

DHTs may take the form of hardware and/or software and may be used to gather health-related information from study participants and transmit that information to study

investigators and/or other authorized parties to evaluate the safety and effectiveness of medical products.

Read more online

Electronic Application Form (eAF) and Cover Letter Tool

On 20 January 2022 the MHRA updated the guidance on how to complete the eAF and cover letter.

This tool is designed to help applicants determine the additional information required in the Cover Letters and eAFs of initial and variation applications contained in the "eAF and Cover Letter Advice Tool" .zip file.

The user should answer all of the questions in the tool fully to make sure that all the correct information required for the application is included. Failure to submit the appropriate information in the cover letter and the dossier may result in the application being invalidated.

Read more online

Clinical Trials Information System (CTIS) Sponsor End User Training Program – March 2022

On 18 January 2022 the EMA announced the CTIS sponsor end user training program being held from 1 March to 4 March 2022, for the new way of submitting, managing and reporting a clinical trial via the CTIS.

EMA has developed this training program to support sponsor user preparedness for the new Clinical Trials Information System and the new method for submitting a clinical trial application and managing the life cycle of a clinical trial in the European Union (EU) and the European Economic Area (EEA).

On-demand components, which must be completed before accessing the live offering, include Introduction to Clinical Trials Regulation (CTR), transparency, data protection and CTIS Sponsor User Personas.

Key topics covered during the live training will include:

- Overview of CTIS components and system functionalities
- Management of users and tools for workload planning and management
- How to create, submit, update and withdraw an application
- How to manage a clinical trial through CTIS and submit Clinical Study Reports (CSRs)

A blended learning approach will be used, offering on-demand components as well as live virtual instructor-led offerings.

For users who plan to train others in their organization, a separate module on training design and delivery can be added.

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WSQMS Homepage Feb 21, 2022

EudraVigilance: Updated Electronic Reporting

On 15 February 2022 the EMA announced an update to electronic reporting in EudraVigilance.

As of February 2022, the test environment (XCOMP) will no longer accept the ICH E2B (R2) message format. Instead, users need to report ICSRs using the ISO ICSR/ICH E2B(R3) format and related ISO standard terminology for pharmaceutical form and route of administration.

This change supports the ISO ICSR/ICHE2B(R3) format and related terminology which will be mandatory on 30 June 2022.

Read more online

Big Data Highlights – Issue 1

On 15 February 2022 the EMA published the first edition of the newsletter on Big Data.

The first edition of the newsletter on Big Data reports on the implementation of the HMA-EMA Big Data Steering Group (BDSG) workplan 2021-2023 and the data and digital pillar of the Network Strategy 2025.

The BDSG was established in May 2020 with the mandate to take forward and advise on implementation of the priority recommendations set out in the Big Data Task Force final report (phase two).

Read the pdf

Update to Guidance Document: Risk Management Plan (RMP) ICH E2E Information for HMP Submission

On 15 February 2022 the Swissmedic announced the updated guidance on RMP ICH E2E submission information for human medicinal products.

Based on established common practice, clarifications on the obligation to submit an RMP in connection with applications for authorization have been added to section 6.

Experience has shown that RMP updates were also being submitted to Swissmedic for review when no relevant content changes had been made. In light of this, the RMP update submission requirements in section 7.1 and its subsections have been clarified and/or redefined.

The "Switzerland-specific Annex (SSA)" on RMP has been newly included. This substantiates and presents any deviations as regards safety concerns or implementation of pharmacovigilance activities or risk-minimizing measures in Switzerland relating to the RMP submitted (usually EU RMP).

Submission of study results from the pharmacovigilance plan, of educational materials and of RMP summaries have been addressed in sections 9 and 10.

The revised guidance document is valid effective 1 March 2022.

Read more online

Updated Guidance on the Management of Clinical Trials During the COVID-19 (Coronavirus) Pandemic

On 10 February 2022 the European Commission announced the updated guidance on the clinical trials management during the COVID-19 pandemic in Europa.

The COVID-19 pandemic has been continuously putting national health care systems under high pressure. In some Member States the capacity of the health-care system has been at its limits since the beginning of the pandemic. Against this background, pragmatic and harmonized actions are required to ensure the necessary flexibility and procedural simplifications needed to maintain the integrity of the trials, to ensure the rights, safety and wellbeing of trial participants and the protection and safety of clinical trial staff during this prolonged global public health crisis. The points mentioned below are intended to provide guidance and clarity for all parties involved in clinical trials during this time. It should be noted that the simplification measures proposed in this document will only last during the current public health crisis until the revocation of this Guidance, when there is a consensus that the period of the COVID-19 outbreak in the EU/EEA, has passed.

This document sets out to include most of the current guidance across Member States with the aim of serving as a harmonized EU-level set of recommendations.

Read more online

Initiation of DARWIN EU® Coordination Centre Advances Integration of Real-World Evidence into Assessment of Medicines in the EU

On 9 February 2022 the EMA announced the establishment of the Coordination Centre with Erasmus University Medical Center Rotterdam for the DARWIN EU.

The role of the Coordination Centre is to develop and manage a network of real-world healthcare data sources across the EU and to conduct scientific studies requested by medicine regulators and, at a later stage, requested by other stakeholders.

The vision of DARWIN EU® is to give EMA and national competent authorities in EU Member States access to valid and trustworthy real-world evidence on diseases, patient populations,

and the use, safety and effectiveness of medicines, including vaccines, throughout the lifecycle of a medicinal product.

Read more online

Updated IRIS Guide for Applicants

On 7 February 2022 the EMA issued version 2.6 of the IRIS guide for applicants.

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

Joint Implementation and Preparedness Plan for Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)

On 7 February 2022 the European Commission announced an update of the joint implementation plan for IVDR.

A new legislative framework on medical devices, comprising Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) was adopted by the Council and the European Parliament in April 2017. This new framework sets high standards of quality and safety for medical devices and aims at ensuring the smooth functioning of the internal market. The MDR was envisaged to apply from 26 May 2020. In contrast, the IVDR has a date of application of 26 May 2022. In March 2020, the Medical Device Coordination Group (MDCG), composed of experts appointed by Member States, endorsed a joint implementation plan on the implementation of the MDR. The plan listed priority actions for the Member States and Commission services, to be monitored at the level of the MDCG. The MDR joint implementation plan recognized the need to carry out a similar exercise for the IVDR. The present document therefore proposes a draft joint implementation plan for the IVDR.

Read more online

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

On 7 February 2022 the MHRA updated the guidance on managing the clinical trial authorization, reporting safety issues and completing the end-of-trial study report.

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. Combined review offers a single application route and coordinated review leading to a single UK decision for CTIMPs.

Please note: CTIMP initial applications via combined review should be started and submitted using the new part of Integrated Research Application System (IRAS) and not in the standard part of IRAS. While the regulatory requirements and fees remain the same, the application

submission, processing and assessment steps outlined below refer to non-combined review applications. For Combined review applications please refer to the Health Research Authority website.

Read more online

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

On 7 February 2022 the MHRA updated guidance on how to implement the 'Written Confirmation' process for active substances manufactured in Great Britain.

A Written Confirmation confirms that, for a third country exporting Active Substances to the EEA:

- the standards of Good Manufacturing Practice (GMP) are equivalent to those in the EU/EEA
- the manufacturing plant is subject to regular inspections (which may be both announced and unannounced)
- significant non-compliance events would be communicated to the EEA without delay

A template for the Written Confirmation can be found on the European Commission website. The requirement for the Written Confirmation is stated in Article 46b(2)(b) of Directive 2001/83/EC.

Read more online

Clinical Pharmacology Considerations for Antibody-Drug Conjugates

On 7 February 2022 the FDA published the draft guidance. Comments accepted through 6 May 2022.

This guidance provides recommendations to assist industry and other parties involved in the development of antibody-drug conjugates (ADCs) with a cytotoxic small molecule drug or payload. Specifically, this guidance addresses the FDA's current thinking regarding clinical pharmacology considerations and recommendations for ADC development programs, including bioanalytical methods, dosing strategies, dose- and exposure-response analysis, intrinsic factors, QTc assessments, immunogenicity, and drug-drug interactions (DDIs).

Read more online

Update – Guideline on the Requirements for Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials

On 4 February 2022 the European Commission announced revision 2 on the requirements for quality documentation of biological IMPs in clinical trials.

This guideline addresses the specific documentation requirements on the biological, chemical and pharmaceutical quality of IMPs containing biological / biotechnology derived

substances.

Moreover, this guideline lists, as regards documentation on the biological, chemical and pharmaceutical quality of the IMP, examples of modifications which are typically considered as 'substantial'.

The guidance outlined in this document applies to proteins and polypeptides, their derivatives, and products of which they are components (e.g. conjugates). These proteins and polypeptides are produced from recombinant or non-recombinant cell-culture expression systems and can be highly purified and characterized using an appropriate set of analytical procedures. The guideline also applies to Auxiliary Medicinal Products containing these proteins and polypeptides as active substances. The requirements depend on the type of the product (authorized / not authorized / modified / non-modified medicinal product).

Read more online

Update – Guideline on the Requirements to Chemical and Pharmaceutical Quality Documentation Concerning Investigational Medicinal Products in Clinical Trials

On 4 February 2022 the European Commission announced the revision 2 on the requirements for quality documentation of chemical and pharmaceutical IMPs in clinical trials.

This guideline addresses the documentation on the chemical and pharmaceutical quality of IMPs and Auxiliary Medicinal Products containing chemically defined drug substances, synthetic peptides, synthetic oligonucleotides, herbal substances, herbal preparations and chemically defined radioactive/radio-labelled substances to be submitted to the competent authority for approval prior to beginning a clinical trial in humans. It includes the requirements for IMPs and Auxiliary Medicinal Products to be tested in phase I, phase II, phase III and phase IV studies as well as the requirements for modified and unmodified comparator products and IMPs to be tested in generic bioequivalence studies.

When compiling the quality part of the IMPD for phase II and phase III clinical studies, the larger and longer exposure of patients to the product have to be taken into account compared to phase I clinical studies. Based on the diversity of products to be used in the different phases of clinical trials, the requirements defined in this guideline can only be of an illustrative nature and cannot be expected to present an exhaustive list. IMPs based on innovative and/or complex technologies may need more detailed data to be submitted. For certain situations, e.g. where the drug substance from the specific source to be used for an IMP is already included in a medicinal product authorized within the EU, not all the documentation outlined in the following chapters need to be submitted in the IMPD, but a simplified IMPD will suffice.

Read more online

Updated Reflection Paper on the Use of Interactive Response Technologies (Interactive Voice/Web Response Systems) in Clinical Trials, with Particular Emphasis on the Handling of Expiry Dates

On 4 February 2022 the EMA announced the new version of the reflection paper on the use of IRTs in clinical trials.

This reflection paper was initially published on 10 December 2013 under reference EMA/INS/GCP/600788/2011. It was updated in view of the entry into application of the Clinical Trials Regulation (CTR) No. 536/2014, only to clarify that the removal of expiry dates from the labels is not allowed for clinical trials conducted under the CTR (see section 2.3 of the reflection paper). The rest of the reflection paper was not reviewed and reflects the state of thinking at the time of initial publication. Additional information on the expected requirements for interactive response technologies may be found in the Guideline on computerized systems and electronic data in clinical trials, once finalized.

This paper seeks to provide guidance on what national competent authorities (NCAs) expect from such systems and in particular their use for handling of the expiry date of the Investigational Medicinal Product (IMP). These positions will form suggestions for sponsors and IRT providers on the validation requirements for systems. Specific computer system validation is not discussed in detail since this is the subject to a large number of other publications. This paper is aimed at sponsors and providers of such systems.

Currently, the information surrounding the use of IRT in the clinical trial authorization (CTA) applications is only included with reference to IRT use in randomization where this function is outsourced. As a consequence, the NCA might have little knowledge of the extent of use of these systems, particularly where the system is an in-house one. For this reason, it would be helpful if Appendix I be completed by the sponsor and submitted to the NCA along with the CTA.

Read the pdf

Drug Product Tracing: The Effect of Section 585 of the FD&C Act

On 3 February 2022 the FDA published the final guidance on the Q&A.

The FDA is issuing these questions and answers to assist industry and State and local governments in understanding the effects of section 585 (Uniform National Policy) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee- 4), added by Title II of the Drug Quality and Security Act (DQSA), which was enacted on November 27, 2013, on drug product tracing. Title II, which is also referred to as the Drug Supply Chain Security Act (DSCSA), establishes a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to pass, receive, and maintain certain product and distribution information. Section 585 requires there be a uniform national policy, preempting States from establishing or continuing in effect certain standards and requirements. FDA is issuing this guidance to: (1) help industry and States understand the law as it is currently in effect; and (2) clarify the effect of section 585(a) on any regulation of drug product tracing by States.

Read more online

Population Pharmacokinetics

On 3 February 2022 the FDA published the final guidance for industry.

This guidance is intended to assist sponsors and applicants of new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and investigational new drugs (IND) applications in the application of population pharmacokinetic (PK) analysis. Population PK analysis is frequently used to guide drug development and inform recommendations on therapeutic individualization (e.g., through

tailored dosing) (Marshall et al. 2015; Lee et al. 2011; Bhattaram et al. 2005). Adequate population PK data collection and analyses submitted in marketing applications have in some cases alleviated the need for postmarketing requirements or postmarketing commitments.

Read more online

Assessment of Pressor Effects of Drugs

On 3 February 2022 the FDA published the draft guidance for industry.

This draft guidance is intended to advise sponsors on the premarketing assessment of a drug's effect on blood pressure. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure is, therefore, an important consideration in risk assessment and product labeling.

The recommendations in the guidance are generally applicable to new drugs with systemic bioavailability and to approved drugs for a new indication/population with a higher cardiovascular risk or when a new dosing regimen results in significantly higher or more prolonged exposure.

Read more online

Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling–Content and Format

On 3 February 2022 the FDA published the draft guidance for industry. Comments accepted until 5 April 2022.

This guidance provides recommendations to help ensure that clinically relevant immunogenicity information is included and distributed appropriately across sections and subsections of product labeling, in accordance with regulatory requirements for the content and format of human prescription drug and biological product labeling. The goal of appropriate inclusion and distribution of clinically relevant immunogenicity information in the labeling is to enable health care practitioners to easily access, understand, and use this information to inform prescribing decisions and patient management, and to help enable safe and effective use of applicable products.

When finalized, this guidance will supersede the immunogenicity labeling-specific recommendations in the guidance for industry entitled "Labeling for Biosimilar Products" and "Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products--Content and Format."

Read more online

Mandatory Use of ISO ICSR/ICH E2B(R3) and EDQM Terminology for Dosage Forms (DF) and Routes of Administration (RoA)

On 3 February 2022 the EMA published guidance on the mandatory use of ISO ICSR/ICH E2B(R3) and EDQM Terminology for DF and RoA.

The new EudraVigilance system launched in November 2017 supports the submission and analysis of reports of suspected adverse reactions in the pre- and post-authorization phase

based on the International Organization for Standardization (ISO) Individual Case Safety Report (ICSR) standard – ISO 27953-2.

The use of the ISO Individual Case Safety Report (ICSR) format is set out in Article 26(2)(a) of the Commission Implementing Regulation (EU) No 520/20122 and the modalities on how to implement and apply the ISO ICSR standard are defined in the ICH E2B(R3) documentation.

Additionally, ICH E2B has agreed5 to use the ISO standard terminology on pharmaceutical dose forms and routes of administration6 as set out in Article 25(f)(1) of Commission Implementing Regulation (EU) No 520/2012.

Following a transitional period and consultation with the relevant stakeholders, the EMA Management Board announced in December 2019 that ISO ICSR standard and the Individual Case Safety Report standard and the ISO terminology on pharmaceutical dose forms and routes of administration maintained by EDQM should be implemented by all the stakeholders by 30th June 20227 in relation to reporting obligations to EudraVigilance (pre- and post-authorization).

This change management document describes the activities performed by the EMA to support the stakeholders during the implementation of the above-mentioned standards.

Read the pdf

EudraVigilance: Obtaining EDQM terms from SPOR

On 3 February 2022 the EMA published the EudraVigilance guidance on obtaining EDQM terms from SPOR.

The Routes of Administration and Dosage Form terms in the EDQM Standard Terms database comply with the ISO 11239 standard. The content of the EDQM Standard Terms database is updated on a continuous basis, with new or revised terms available to users as soon as they are available (see https://standardterms.edqm.eu/). The EudraVigilance system synchronizes the EDQM code lists every Sunday night with the SPOR RMS system so that the following Monday new terms are added and updates to pre-existing terms are made. Organizations should also aim to regularly update their systems with EDQM changes to ensure that they are exchanging up-to-date terms, and they are able to process ICSRs downloaded/routed from EudraVigilance correctly and to avoid rejections of submissions of ICSRs if terms are marked as non-current by EDQM.

Read the pdf

Clinical Trials Information System (CTIS): Updated Online Modular Training Program

On 3 February 2022 the EMA announced the availability of version 1.1 of online modular CTIS training program.

The EMA developed this training material to enhance public access to information on the CTIS. The training program is divided into learning modules targeted for the different user groups involved in CTIS. These modules aim to ensure a clear understanding of the different processes of the system.

Each module contains a brief summary of the topics it covers and includes interactive learning materials targeted for different user groups. These consist of e-learning modules,

quick guides, step-by-step guides, infographics, videos, instructor guides and other helpful learning tools.

Read the pdf

Updated Questions and Answers Document – Clinical Trials Regulation (EU) 536/2014

On 1 February 2022 the European Commission published version 5 (January 2022) of the updated Q&A guidance on the Clinical Trials Regulation.

This document aims at informing on the technical aspects of Commission Clinical Trials Regulation (EU) No 356/2014 with a view to facilitating its implementation.

This document sets out frequently-asked 'questions and answers' regarding the implementation of the rules on clinical trials. All updates to this questions and answers document are presented and discussed within the “Expert group on clinical trials” and reflects the view of the group. This group is chaired by the Commission and is composed of representatives of all EU Member States and EEA contracting parties.

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