WSQMS Homepage Jan 5, 2022

Innovative Licensing and Access Pathway

On 30 December 2021, the UK MHRA updated the guidance on a new pathway supporting innovative approaches to the safe, timely and efficient development of medicines to improve patient access.

The Innovative Licensing and Access Pathway (ILAP) aims to accelerate the time to market, facilitating patient access to medicines. These medicines include new chemical entities, biological medicines, new indications and repurposed medicines.

Horizon scanning and regulatory science will make sure the pathway is at the forefront of cutting-edge developments and has the framework to develop evidence-based practice as new technologies and methods emerge.

The section on Overview of Innovation Passport applications was added on 28/12/2021.

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Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology

On 22 December 2021 the FDA published the draft guidance for industry and FDA staff. Comments may be submitted until 22 February 2022.

This draft guidance provides the FDA's testing and design recommendations that apply to design considerations, non-clinical testing, animal studies, and labeling to support premarket submissions for medical devices with physiologic closed-loop control (PCLC) technology. The design and testing will depend on a variety of factors, including, but not limited to, the energy or article being delivered, testing environment, level of automation, training of the user population, patient population, properties of the physiologic-measuring sensor, method of control algorithm design, and properties of the delivery system. The recommendations are intended to promote consistency and facilitate efficient review of medical devices with physiologic closed-loop control technology submissions.

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Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

On 22 December 2021 the FDA published the draft guidance for industry, investigators, and other stakeholders. Comments may be submitted until 22 March 2022.

This guidance provides recommendations to sponsors, investigators, and other stakeholders on the use of digital health technologies (DHTs) to acquire data remotely 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.

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Clinical Trials on Medicinal Products in Switzerland

On 20 December 2021 the Swissmedic announced the paperless submission as of 1 January 2022.

As of January 01, 2022, the sponsors, investigators or research institutions conducting clinical trials with medicinal products in Switzerland will have the option to minimize the previously required paper submission of the application by using the form "Confirmation electronic submission".

This form allows sponsors/applicants to confirm for every submission that they agree to Swissmedic processing the application using the documents provided on CD/DVD. Please send the Swissmedic the handwritten ("wet-ink") signed paper document ("Confirmation electronic submission") together with the CD/DVD. No other paper documents are required for this submission.

For each additional submission of application documents on CD/DVD (e.g. in connection with a response to formal deficiencies, etc.), this form must be prepared again and submitted with the CD/DVD.

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Clinical Drug Trial Investigator Charged with Insider Trading

On 20 December 2021 the U.S. Securities and Exchange Commission (SEC) disclosed insider trading charges against investigator.

The Securities and Exchange Commission today announced charges against Daniel V.T. Catenacci for insider trading in the securities of biotechnology company Five Prime Therapeutics, Inc. in advance of the company's November 10, 2020 announcement that it had achieved positive drug trial results for its flagship cancer drug Bemarituzumab.

The SEC's complaint alleges that Catenacci, a Chicago, Illinois based medical school professor, entered into a consulting agreement with Five Prime to serve as a lead clinical investigator for the company's Bemarituzumab drug trial. Through this role, Catenacci allegedly learned material nonpublic information about the positive drug trial results for Bemarituzumab. According to the SEC, shortly after he allegedly learned of the positive results, Catenacci purchased 8,743 shares of Five Prime. After it publicly announced the

positive drug trial results, Five Prime's share price increased over 300%. The next day, Catenacci allegedly sold all of his shares, realizing illicit gains of $134,142.

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Progressive Roll-out of In Vitro Diagnostic Medical Devices Regulation

On 17 December 2021 the European Commission released the progressive roll-out of in-vitro diagnostic medical device regulations beginning 26 May 2022.

In the context of the COVID-19 pandemic Member States, health institutions and economic operators redeployed financial and other resources to address the unprecedented challenges of the crisis. By doing so, they delayed the implementation of the In Vitro Diagnostic Medical Devices Regulation of 2017, which introduced certain requirements for medical devices and a stronger role for so-called conformity assessment bodies. To prevent disruption of supply of essential healthcare products as a result of these delays, the Commission proposed in October a progressive roll-out of the Regulation of 2017. The adoption of this proposal by the co-legislators will keep the supply of these essential healthcare products flowing.

The amending Regulation does not change any requirements of the original In Vitro Diagnostic (IVD) Regulation of 2017. It only changes the dates of application of some of these requirements for certain medical devices.

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Guideline for the Notification of Serious Breaches of Regulation (EU) No 536/2014 or the Clinical Trial Protocol

On 17 December 2021 the EMA issued the final guideline for the notification of serious breaches of EU clinical trial regulation 536/2014 or the clinical trial protocol.

Management of serious breaches of clinical trials authorized in the Europe Union (EU)/ European Economic Area (EEA) is defined by Regulation (EU) No 536/2014, which states in Article 52:

"1. The sponsor shall notify the Member States concerned about a serious breach of this Regulation or of the version of the protocol applicable at the time of the breach through the EU portal without undue delay but not later than seven days of becoming aware of that breach.

2. For the purposes of this Article, a 'serious breach' means a breach likely to affect to a significant degree the safety and rights of a subject or the reliability and robustness of the data generated in the clinical trial."

The sponsor is responsible for the notification via the EU portal and EU database - part of the Clinical Trials Information System (CTIS). The sponsor may delegate this task to a service provider by means of a written agreement as described in Article 71 of the Regulation (EU) No 536/2014.

Notification should be made without undue delay and at the latest within 7 calendar days of the sponsor becoming aware of a serious breach.

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Inspection of Injectable Products for Visible Particulates

On 17 December 2021 the FDA published the draft guidance for industry. Comments may be submitted until 15 February 2022.

Visible particulates in injectable products can jeopardize patient safety. This guidance addresses the development and implementation of a holistic, risk-based approach to visible particulate control that incorporates product development, manufacturing controls, visual inspection techniques, particulate identification, investigation, and corrective actions designed to assess, correct, and prevent the risk of visible particulate contamination. The guidance also clarifies that meeting an applicable United States Pharmacopeia (USP) compendial standard alone is not generally sufficient for meeting the current good manufacturing practice (CGMP) requirements for the manufacture of injectable products. The guidance does not cover subvisible particulates or physical defects that products are typically inspected for along with inspection for visible particulates (e.g., container integrity flaws, fill volume, appearance of lyophilized cake/suspension solids).

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ICH Guideline Q9 (R1) on Quality Risk Management

On 16 December 2021 the EMA issued the ICH guideline Q9(R1) on quality risk management (step 2b) for public comments. Comments may be submitted until 15 March 2022.

Risk management principles are effectively utilized in many areas of business and government including finance, insurance, occupational safety, public health, pharmacovigilance, and by agencies regulating these industries. 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.

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Updated Clinical Trials Information System: Training and Support

On 16 December 2021 the EMA updated the training support for CTIS.

On 31 January 2022, the Clinical Trials Information System (CTIS) becomes the single-entry portal for submitting clinical trials information in the EU, supporting the day-to-day business processes of authorities and sponsors throughout the life-cycle of a clinical trial. There are additional reference materials available, including a Getting Started with CTIS: Sponsor quick guide.

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Referencing the Definition of “Device” in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents

On 15 December 2021 the FDA published the draft guidance for industry and FDA staff. Comments may be submitted until 14 February 2022.

The U.S. Food and Drug Administration (FDA or the Agency) recommends the consistent use of terms and definitions of legal significance. In light of recent amendments to section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as a result of the enactment of the Safeguarding Therapeutics Act, FDA is issuing this draft guidance to promote clarity regarding references to the terms “device” and “counterfeit device.”

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required.

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Clinical Trials Information System (CTIS) Sponsor User Training Program - January 2022

On 14 January 2022 the EMA announced the CTIS sponsor user training program.

EMA has developed this training program to support sponsor user preparedness with regard to the new way of submitting Clinical Trial Applications (CTA) in the EEA via the new Clinical Trial Information System.

A hands-on approach is taken on explaining and demonstrating the functionalities of the system, such as user management, how to submit an initial application as well as modifications, both substantial and non-substantial. Also, how to manage the life cycle of a Clinical Trial, how to apply Deferral rules and respond to a Request for Information (RFI) will be addressed.

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EMA EudraVigilance Registration Manual

On 14 January 2022 the EMA updated the EudraVigilance registration manual.

To set up a new organization in EudraVigilance Production or XCOMP (Test system), a series of steps need to be followed:

1. A person within the organization needs to be chosen as being responsible for managing the organization and its users in the EudraVigilance Production system. If the organization is a marketing authorization holder the primary responsible person will be a Qualified Person for Pharmacovigilance (QPPV); if the organization is a sponsor/non-commercial sponsor it will be a Responsible Person (RP).

2. Register for an EMA user account in the EMA Account Management portal, if you do not already have one – see section 2.

3. Search for your organization in SPOR Organization Management System (OMS). If your organization is not present, it will need to be created – see section 3.3.

4. Submit a request to be registered as the QPPV/RP for the organization – see section 4.1.

5. Complete organization registration details in the EudraVigilance restricted area – see section 4.2.

6. Wait for EMA confirmation that WebTrader or Gateway transmission mode has been set up for your organization – see section 6.1.1.

Once the QPPV or RP is registered for the Production EudraVigilance system they will automatically also be registered for an XCOMP test account for the same organization.

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Accelerating Clinical Trials in the EU (ACT EU)

On 13 January 2022 the EMA launched an EU clinical trials transformation initiative.

On 13 January 2022, the European Commission (EC), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) launched an initiative to transform how clinical trials are initiated, designed and run, referred to as Accelerating Clinical Trials in the EU (ACT EU). The aim is to further develop the EU as a focal point for clinical research, further promote the development of high quality, safe and effective medicines, and to better integrate clinical research in the European health system.

This paper sets out proposals for the initial set up of an EU clinical trials transformation initiative: Accelerating Clinical Trials in the EU (ACT EU). The paper includes high-level regulatory network objectives, governance, organization, priority actions for 2022-2023, and resourcing. The implementation of ACT EU will contribute to delivering the Network strategy to 2025 and the Commission Pharmaceutical Strategy.

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European Commission Implementing Regulation (EU) 2022/20 of 7 January 2022 for Safety Assessment of Clinical Trials

On 10 January 2022 the EC released guidance on implementing the EU clinical trial regulation for Safety Assessment in Clinical Trials.

Regulation (EU) No 536/2014 lays down the legal framework for the conduct of clinical trials on medicinal products for human use in the Union to ensure that the rights of subjects ('participants'), their safety and well-being are protected, and that the generated data are reliable and robust. In particular, while the overall responsibility for ensuring participants' safety lies with the sponsor of the clinical trial, it is reinforced by additional oversight from the Member States including through their cooperation in the assessment of the safety of the investigational medicinal products.

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Clinical Trials for Medicines: How to Apply for Authorization in the UK

On 7 January 2022 the MHRA updated the guidance on the new combined review service.

As of 1 January 2022 the combined review service, [formerly known as Combined Ways of Working (CWoW)], is 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 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.

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Investigational COVID-19 Convalescent Plasma

On 7 January 2022 the FDA published the final guidance for industry.

FDA is issuing this guidance to provide recommendations to health care providers and investigators on the use of COVID-19 convalescent plasma or investigational convalescent plasma during the public health emergency. The guidance also provides recommendations to blood establishments on collection. This document supersedes the guidance of the same title issued in February 2021 (previous versions January 2021, November 2020, September 2020, May 2020, and April 2020).

Read more online

Notify the MHRA about a Clinical Investigation for a Medical Device

On 4 January 2022 the MHRA updated the guidance on how to inform them of a clinical investigation of medical devices.

The MHRA is working with the Health Research Authority (HRA) to develop a new coordinated assessment pathway which will streamline the review of clinical investigations involving medical devices.

During this phase of testing the MHRA Medical Devices review and the Research Ethics Committee (REC) review are being completed in parallel and information will be shared.

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eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Training

On 4 January 2022 the EMA updated the frequently asked questions about XEVMPD training.

At least one user from each organization should follow the XEVMPD training and obtain a “Notification of successful completion of the XEVMPD knowledge evaluation”. This is to ensure the quality of data submitted to the database. Also, “Notification of successful completion of the XEVMPD knowledge evaluation” is required from at least one user from each organization during the organization’s registration process with EudraVigilance before the data submission can begin:

- If your organization will be registering for the submission of authorized medicinal product data, at least one participant from your organization should perform the XEVMPD knowledge evaluation for the submission of authorized medicinal product data in the XEVMPD.
- If your organization will be registering for the submission of un-authorized (referred to in the XEVMPD as 'development') medicinal product data, at least one participant from your organization should perform the XEVMPD knowledge evaluation for the submission of development medicinal product data in the XEVMPD.

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Regulating Medical Devices in the UK

On 1 January 2022 the MHRA updated this guidance to reflect changes to the new medical device regulatory requirements.

This guidance provides information on the UK system, including for:

- getting your device certified
- conformity marking your device
- registering your device with the MHRA

This guidance is divided into sections on the different rules that apply in Great Britain, Northern Ireland and the EU. Great Britain is England, Wales and Scotland.

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