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REGULATORY

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CROMSOURCE is an international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialised in clinical development and staffing solutions.

Contents

MEDICINAL PRODUCTS/DRUGS

Europe

News from the European Commission

EU Clinical Trials Regulation Date of Application

The Clinical Trials Regulation (EU) No 536/2014 (EU CTR) applies from 31 January 2022 in all EU/European Economic Area (EEA) Member States. It replaces the EU Clinical Trials Directive (2001/20/EC) (CTD).

The EU CTR aims to harmonise the approval process for clinical trials, increase coordination between Member States, as well as maintain the highest level of standards for patient safety, and increase transparency of clinical trial information.

The Clinical Trials Information System (CTIS) is the business tool of the EU CTR. The CTIS go-live version also applies from 31 January 2022. The CTIS allows clinical trials' sponsors to apply with a single application which covers submissions to national competent authorities, ethics committees, and public registration of the clinical trial in all EU/EEA Member States.

The Clinical Trials Regulation foresees a 3-year transition period for sponsors to use CTIS.

Sponsors will be able to choose whether to apply for a new clinical trial application (CTA) under the regime of the CTD or to apply under the new legislation, the EU CTR, using CTIS. 31 January 2023 is the latest date for submission of a new clinical trial application (CTA) under the CTD.

From 31 January 2023, submission of initial CTAs under the CTD will no longer be possible. Such applications must be submitted under the EU CTR using CTIS.

Interventional clinical trials in humans, registered under the CTD before 31 January 2023 and involving at least one site in the EU/EEA where the trial is still ongoing (not held or ended in the EU/EEA) will be still able to run until 31 January 2025.

By 31 January 2025, these clinical trials must either have ended in the EU/EEA or have been transitioned to CTIS.

To prepare for the submission under EU CTR via CTIS or the transition of ongoing studies to CTIS, the European Commission revised and updated a number of documents in Volume 10 EudraLex.

In September 2021, the European Commission published Draft - Questions and Answers Document - Regulation (EU) 536/2014 – Version 5.0. The Q&As document has been updated by several questions including arrangements for the transitional period. The document has also been sent for discussion to the Expert Group on Clinical Trials. Updated versions of the document will be published progressively.

Safety Assessment of Clinical Trials Under EU CTR

The European Commission published Implementing Regulation (EU) 2022/20 setting up the rules and procedures on the cooperation of the Member States in safety assessment of clinical trials. The Regulation (EU) 2022/20 applies on 31 January 2022, the same day as a Date of Application (DoA) of the EU CTR and CTIS go-live version.

The Regulation (EU) 2022/20 aim is to harmonise the safety standards through the Member States in the assessment of the safety of the investigational medicinal products and at the same time ensure that that the rights of subjects, their safety and well-being are protected, and that the generated data are reliable and robust.

The implementing regulation provides new definitions such as 'Safety assessing Member State', 'Lead safety assessing Member State', 'Multi-national active substance' or 'Screening of suspected unexpected serious adverse reactions'. A safety assessing Member State will perform the coordinated assessment of Suspected Unexpected Adverse Reactions (SUSARs) and Annual Safety Reports (ASRs) for trials in the EU using the same active substance as the "investigational medicinal product".

The Regulation (EU) 2022/20 states that the Member States may levy a fee when they carry out safety assessment activities as a safety assessing Member State.

Accelerating Clinical Trials in the EU (ACT EU)

The European Commission (EC), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) have launched a new initiative to promote clinical research in the EU/European Economic Area (EEA). A Document has been published, Accelerating Clinical Trials in the EU (ACT EU). "The paper includes high-level regulatory network objectives, governance, organisation, 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."

This initiative uses the momentum of the application of the EU Clinical Trials Regulation on 31 January 2022 in the EU/EEA to further promote the development of high quality, safe and effective medicines in the European environment for clinical trials.

News from the European Medicines Agency (EMA)

The source of each news item below is the EMA website: https://www.ema.europa.eu/

Clinical Trials in the European Union - New EMA Website and Other Sources of Information of CTIS Setting

On 31 January 2022, the EMA launched a new public Clinical Trials website to support the launch of CTIS. The new website includes combined information of the CTIS for sponsors and authorities and anyone to publicly search information on clinical trials authorised through CTIS.

It provides a link to Log in to the sponsor/authority's workspace using EMA account, explains how to register in the CTIS, gives links to the training materials and support materials and the link to the CTIS User Support Service. Everyone may find EMA news and events related to clinical trials in the EU and the EEA. The useful tool is 'searching for clinical trials' which now provides limited information on individual clinical trials in the EU/EEA. However, it will gradually contain more information.

Moreover, the EMA provides online modular training programme with 23 modules of 24 planned. In December 2021, modules related to the CTIS public search (Module 22), and Union Controls (Module 21) were published. The Module 23 on transition of ongoing trials from CTD/EudraCT to CTR/CTIS was published by end of January 2022.

Furthermore, the EMA reopened the CTIS training environment (CTIS Sandbox) (Survey 2.0) for those sponsor organisations who did not respond in October 2021 for Survey 1.0. The survey is to express interest and including a self-assessment of need and urgency for access to the CTIS training environment. If the sponsor organisation already has participated in Survey 1.0, participation in Survey 2.0 is prohibited unless sponsors organisations clinical trial submission plans have changed since Survey 1.0.

In November 2021, the EMA also updated the Sponsor handbook, v 2.0. New sections for data fields and documents specifications and training environment have been added. Also, the section of SUSARs reporting and User personas and organisation models have been updated.

In 2022 the EMA offers sponsor end user training courses, organised by DIA.

Additionally, new live, virtual, hands-on training courses on EudraVigilance, organised in liaison with DIA, are offered by the EMA from March 2022, for clinical trial sponsors who will directly report suspected unexpected serious adverse reactions (SUSARs) to EudraVigilance via EVWEB.

Guidance on Requirements for Quality Documentation in Clinical Trials

The EMA published final revision 2 of Guidance on requirements for quality documentation concerning biological investigational medicinal products in clinical trials and Guidance on requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials. Both come into effect on 31 January 2022.

These guidelines are connected to the Clinical Trials Regulation (EU) No. 536/2014 (EU CTR) applicable on 31 January 2022. The changes in these guidelines refer to the "substantial modification" sections. The sections describe which quality changes require submission of substantial or non-substantial modifications to the Investigational Medicinal Product Dossier (IMPD) in line with the provisions of the EU CTR.

A summary table of changes to IMPD indicating which type of modification should be submitted in each case is attached to both chemical and biological IMP guidelines.

Protection of Personal Data in the CTIS

The EMA published a joint controllership arrangement which describes the processing of personal data in CTIS, in accordance with the General Data Protection Regulation (GDPR) and the Regulation (EU) 2018/1725 on the protection of personal data by EU institutions and agencies (EUDPR).

The joint controllership arrangement describes the roles and responsibilities of each Party (European Commission, EMA, Member States, commercial, non-commercial organisations and academia acting as sponsors of clinical trials and marketing authorisation applicants/holders) regarding the processing of personal data in CTIS. It sets out the measures they must put in place to ensure that personal data in CTIS is securely processed, and covers how the parties are to handle any personal data breaches.

Each Party shall implement appropriate organisational measures to ensure the security of processing of personal data in CTIS. Access to personal data will be stored in the secure domain of the CTIS.

Annex I of the joint controllership arrangement provides contact points for cooperation between the Parties and for Data Subjects. Annex II includes a data protection notice which explains the most essential details of the processing of personal data in the context of the operation of the CTIS, including the EU Portal and the EU Database.

News from Individual Countries

The United Kingdom

Proposals for Legislative Changes for Clinical Trials

The Medicines and Healthcare products Regulatory Agency (MHRA) published for an open consultation the proposals for legislative changes for clinical trials. As a result of leaving the European Union, the UK now has the opportunity to create a world-class sovereign regulatory environment for clinical trials helping the development of innovative medicines.

These proposals are to update the current UK legislation that governs clinical trials, The Medicines for Human Use (Clinical Trials) Regulations 2004" (SI 2004/1031), as amended and shape the future legislation for clinical trials.

These proposals consider ways to reduce the burdens and obstacles faced by sponsors conducting clinical trials while ensuring that the focus remains on the safety of those taking part in the trials. To reflect that trial design and operation is developing alongside developments in the items that trials explore, the MHRA proposes removing the more prescriptive components of the Act in favour of introducing greater flexibility and risk-proportionality. The suggested changes are aimed at ensuring that trial participants and their safety are at the forefront of the legislation. These proposals also take steps to reduce bureaucracy to support an environment conducive to efficient and effective clinical trials.

This consultation is open from 17 January until 14 March 2022.

Combined Ways of Working (CWoW) Mandatory from 01 January 2022

The CWoW service becomes applicable in the UK from 1 January 2022 for all Clinical Trials of Investigational Medicinal Products (CTIMPs) and all combined trials of an investigational medicinal product (IMP) and an investigational medical device (IMD).

One of the benefits for sponsors, Contract Research Organisations (CROs) and investigators is the submission of a single application for Clinical Trial Authorisation and Research Ethics Committee (REC) opinion.

The submission must be done using a new, central UK portal, the Integrated Research Application System (IRAS) and all communication must be done via the new IRAS system. The review steps, Requests for Further Information (RFIs) or a consolidated initial outcome issue are similar to those required by the EU CTR. However, instead of maximum 12 calendar days for responding to the Member State Concerned under EU CTR, the UK applicants will have 14 calendar days with possibility to extend time, if needed. Such request for extension must be formally sent at clintrialhelpline@mhra.gov.uk. Applicants receive a final decision on their application within 10 days of receipt of a response to an RFI.

There is no change in the process to submit an application to ARSAC (Administration of Radioactive Substances Advisory Committee).

More information and step by step guide to use IRAS for combined review are available here.

Switzerland

Paperless Submission to the Swissmedic

The Swissmedic, the Swiss Agency for Therapeutic Products, announced that as of 1 January 2022 all new clinical trials with medicinal products must be submitted on CD/DVD. The applicant must only send the handwritten ("wet-ink") signed paper document ("Confirmation electronic submission") together with the CD/DVD. No other paper documents are required for CTA submission.

Italy

New Forms for Part II Dossier Created

On 18 January 2022, the Italian Medicines Agency (AIFA), in order to ensure procedural uniformity in the application of the Regulation in Italy from 31 January 2022, released guidelines and new documents required for Part II (country-specific) of clinical trial application. New forms, such as a CV template, declaration on conflicts of interest, patient expenses reimbursement and site-specific eligibility form were prepared in Italian and to be used for national Part II dossiers in case the submission is done under EU CTR in Italy.

Czech Republic

Instructions and Forms for Applicants Submitting Clinical Trial Under EU CTR

The State Institute of Drug Control (SUKL), the Czech Competent Authority published guidance KLH-CTIS-01 version 1 providing instructions for the applicants and requirements for documents to be submitted for Clinical Trials Authorisation of Part II under EU CTR.

Denmark

CTA Fees Updated

The Danish Medicines Authority (DMA) informed about fees change for Clinical Trials Authorisation (CTA) from 1 January 2022. The changes impact commercial clinical trials (CT) submitted under CTD. New fees have been added in case the DMA is Reference Member State (RMS) or Member State Concerned (MSC) in accordance with the Clinical Trials Regulation (EU) No 536/2014.

North America

United States of America

FDA Releases Guidance on Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

On 25 January 2022, the Food and Drug Administration (FDA) issued final guidance on Patient Engagement in the Design and Conduct of Medical Device Clinical Studies to provide recommendations for including patient perspectives in medical device clinical studies. This final guidance:

- Describes how device developers, sponsors and industry can voluntarily use patient engagement to improve clinical study design and conduct.
- Provides examples of approaches to consider when device developers, sponsors and industry wish to incorporate patient advisor input in clinical studies.
- Describes which patient engagement activities are generally not considered by the FDA to constitute an activity subject to the FDA's regulations regarding Institutional Review Boards (IRBs).
- Clarifies how sponsors can receive feedback from the FDA on plans to voluntarily include patient advisors' input on their clinical study through the Q-submission process.

Canada

Health Canada: Consultation for Proposed Amendments to the Medical Device Regulations

On 07 January 2022, from the Medical Devices Compliance Program, Health Canada is proposing regulatory amendments to the Medical Devices Regulations (MDR). These amendments will deliver on commitments outlined in the Health and Biosciences Regulatory Review to modernised compliance and enforcement oversight.

The proposed amendments for medical devices would:

- Streamline MDEL application requirements to reflect current practices
- Provide the Minister with new and expanded authorities over MDELs, including the ability to issue terms and conditions on an MDEL and partially suspend or cancel an MDEL to mitigate risks to health and safety
- Implement ministerial authority to order recalls of medical devices, harmonise the definition of a recall and clarify industry reporting obligations in guidance

Health Canada is taking a phased approach to modernising the MDR to address industry feedback.

MEDICAL DEVICES

EUROPE

News from the European Commission

Harmonised Standards under Medical Devices Regulation (EU) 2017/745 (MDR)

The European Commission has published Implementing Decision 2022/6 of 04 January 2022, which amends Implementing Decision (EU) 2021/1182 with regard to harmonised standards on bio-assessment of medical devices, sterilisation and aseptic processing of healthcare products and furthermore on quality of management systems and symbols to be used with information provided by the producer and processing of healthcare products and home light therapy appliances.

The document explains which devices are considered to be in compliance with the requirements of the MDR and moreover there is information of the request to amend existing harmonised standards for medical devices and to develop new standards. The Implementing Decision also covers the issue of the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) review of harmonised norms, which, together with the Commission, assessed the norms for conformity with the request made in the abovementioned Decision.

The Annex to the Implementing Decision contains the list of references of harmonised standards drawn up in support of the MDR.

Rules on MDR Application as Regards Electronic Instructions for use of Medical Devices

The European Commission has published the Implementing Regulation 2021/2226 of 14 December 2021 which specifies rules for the use of the Regulation (EU) 2017/745 (MDR) regarding electronic instructions for use of medical devices. Issues addressed in the regulation included the benefits of providing instructions for use for certain medical devices in electronic form instead of in paper form.

This included risk assessment issues, the availability of instructions in electronic form and the possibility of receiving instructions for use of certain medical devices in paper form upon request. Presented are also issues of security and consistency of instructions for use, which are provided in addition to the instructions, and the requirements of websites containing electronic instructions with regard to the processing of personal data.

Specified is also in which countries the above-mentioned instructions may be published and which standards the systems publishing them should follow. The Regulation provides information on the location of a label giving access to the electronic instructions and mentions guidelines for the content of such instructions, where in addition to text, video or audio files may be provided. It also describes how to proceed if part of the instructions for use is intended to be given to the patient.

Progressive Roll-Out for the In Vitro Diagnostic Regulation (IVDR)

In October 2021, the European Commission proposed a gradual roll-out of the IVDR to avoid delays in disruption of supply of essential products. The amending Regulation does not change any requirements of the original (IVDR). The IVDR will take effect on 26 May 2022, as planned.

The amending Regulation shifted the deadlines for some of these requirements for specific medical devices. For example, "for higher risk devices, such as HIV or hepatitis tests (class D), the new requirements will apply as from May 2025. For devices of the lower risk class C, such as certain influenza tests, the date of application is extended until May 2026, whilst for lower risk class devices (class B and A sterile), the application starts in May 2027."

"No change is proposed for CE-marked devices that do not require notified body involvement under the IVD Regulation, or for devices that are 'new', i.e., devices that have neither a notified body certificate nor a declaration of conformity under the current Directive 98/79/EC. For those types of devices, the IVD Regulation will therefore apply from 26 May 2022 as planned."

Guidance on General Principles of Clinical Evidence for In Vitro Diagnostic Medical Devices (IVDs)

The European Commission's Medical Device Coordination Group (MDCG) published a guidance document providing general principles of clinical evidence and guidance on the continuous process of performance evaluation for in vitro diagnostic medical devices, as set out in Regulation (EU) 2017/746 – In Vitro Diagnostic Medical Device Regulation (IVDR).

The guidance describes the approach by which collection, generation and documentation of supporting data for an IVD may be conducted prior to the placing on the market or putting into service. As the performance evaluation will be updated throughout the life cycle of an IVD, this document also addresses principles related to post-market surveillance, such as post-market performance follow-up.

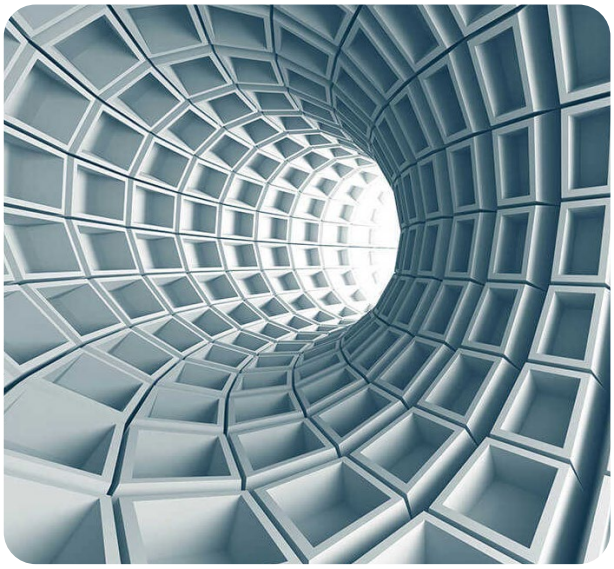
The document is dedicated to IVD manufacturers, investigators, study sponsors, regulators, notified bodies and other stakeholders when considering clinical evidence provided by manufacturers.

The Annex II to the guidance contains the information of frequency for updates of reports such as Post Market Surveillance Plan or Post-Market Performance Follow-Up (PMPF) in accordance with the IVDR.

Guidance on Classification Rules for In Vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 (IVDR)

This guidance, published by the Medical Device Coordination Group (MDCG), relating to the application of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) addresses the classification of in vitro diagnostic medical devices (IVDs) and provides clarifications on the classification rules as set out under Annex VIII. This classification guidance also applies to diagnostic, or information society services performed on EU patients or devices put into service through distance sales.

The guidance contains principles of classification and explanation of the IVDR classification rules with exhaustive description of rationale for such classification and examples of devices typically falling under each rule.



Substantial Modification Template for Clinical Investigations Under MDR

The Medical Device Coordination Group (MDCG) created a template for Substantial modification of clinical investigation under MDR. The MDCG recommends using the template by the Competent Authorities and sponsors. Once the EUDAMED module for clinical investigations is completely functional, it is expected that this template will be removed. The document is available for download as an attachment.

EUDAMED Implementing Act

On 26 November 2021, the European Commission's published Implementing Regulation (EU) 2021/2078, laying down rules for setting up and maintenance of the European Database on Medical Devices (EUDAMED).

The Regulation 2021/2078 states that the Commission will own EUDAMED and will exercise administrative rights for technical and administrative support, ownership and processing of personal data. Information such as the names and contact details of actors and authorised users will be processed in EUDAMED. Regulation 2021/2078 establishes the provisions for accessing EUDAMED, the registration process, the nomenclature to be used in EUDAMED, functioning rules, websites for testing and training purposes, IT security, and fraudulent user activity within EUDAMED. The Commission will take all necessary steps to prevent any malfunction and, if one does arise, to identify it as soon as possible.

The final EUDAMED modules: Clinical Investigations and performance studies, Vigilance and post-market surveillance, Market Surveillance will be released when EUDAMED is fully functional.

The Commission's EUDAMED timeline: https://ec.europa.eu/health/system/files/2022-01/md_eudamed_timeline_en_0.pdf

EUDAMED - European Database on Medical Devices

EUDAMED Time line

The European Commission targets

Q4 2022	Q1-Q2 2023	Q2 2023	Q2 2023	Q4 2023	Q2 2025
End of the EUDAMED MVP[1] development for all six modules	Independent **Audit**	Audit results presented to the Medical Devices Coordination Group (MDCG)	EUDAMED has achieved full functionality following the outcome of the Audit **Publication of a Commission notice** in the *Official Journal of the European Union* **(OJEU)** The full EUDAMED system is ready Only the first 3 modules, with features available on voluntary basis, are in production	End of 6 months transitional period after publication of the notice in the OJEU Fully functional EUDAMED (all 6 modules) goes live The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance modules**	End of 24 months transitional period after publication of the notice in the OJEU The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **UDI/Device and NB & Certificate modules**

[1] EUDAMED Minimum Viable Product (MVP) means that the system developed implements at least the minimum Medical Devices Regulations requirements and allows competent authorities and all stakeholders to comply with their legal obligations.

Notice to 3rd Country Manufacturers of SARS-CoV-2 In Vitro Diagnostic Medical Devices (IVDs)

The European Commission's Medical Device Coordination Group (MDCG) published a notice addressed to manufacturers of SARS-CoV-2 IVDs who are outside of the EU or European Economic Area (EEA) and who are planning to sell their IVDs on the EU market.

The notice underlines the need for a designation of an Authorised Representative in the EU and EEA and providing a good-quality translation into the official language(s) of the Member State of the instructions for use and labels. SARS-CoV-2 self-tests with valid certificates produced in conformity with Directive 98/79/EC may continue to be placed on the market until 27 May 2025, according to Article 110 of IVDR.

Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR)

The Medical Devices Coordination Group (MDCG), has endorsed a document containing questions and answers on Articles 13 and 14 of MDR and IVDR.

Their aim is to provide further clarifications on the operational and practical implementation of Articles 13 and 14 and other related obligations of importers and distributors under the Regulations. In addition, this document provides explanations as to what happens if an EU-based distributor obtains its products directly from a non-EU manufacturer or distributor, and further answers questions such as whether there can be several importers of a device model from one manufacturer and whether individual shops, local pharmacies, retailers or other individuals can be considered as distributors.

Other questions and answers explain importers responsibility for labelling, packaging or accompanying documentation. Regarding registration obligations, two key questions were answered - whether importers and distributors have an obligation to register with EUDAMED and, as for importers themselves, whether they have additional verification obligations.

The final part of the document is annotated with practical examples.

Application of MDR Requirements to "Legacy Devices" and to Devices Placed on the Market Prior to 26 May 2021 in Accordance with Directives 90/385/EEC or 93/42/EEC

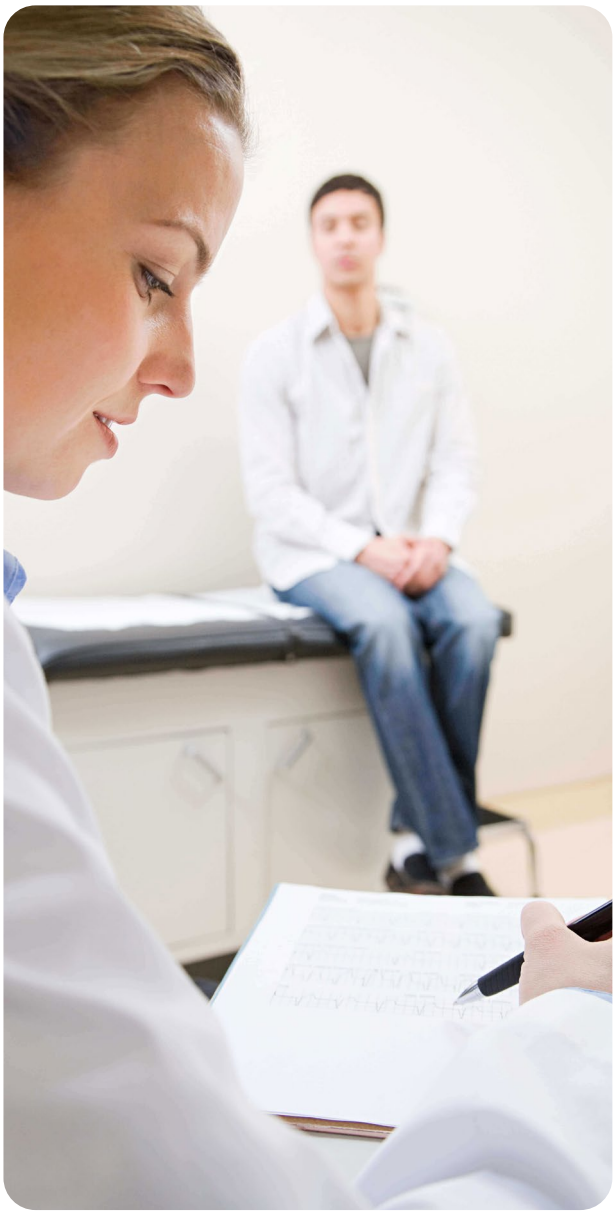
The Medical Device Coordination Group (MDCG), set up an ad hoc task-force regarding the application of transitional provisions laid down in Article 120(3) of Regulation (EU) 2017/745 (MDR) and the consequential application of MDR to 'legacy devices' and 'old' devices (devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC or in accordance with the applicable rules before the Directives had entered into force).

In October, the MDCG published the task-force report from the meeting as MDCG guidance.

The guidance presents proposals for actions concerning periodic safety update reports, which focus, inter alia, on the production and updating of periodic safety update reports by manufacturers and on the supervision by notified bodies of whether the manufacturer has made the necessary adjustments in accordance with the new requirements of the MDR.

The guidance underlines that the MDR requirements do not generally apply to "old" products and the practical aspects associated with market surveillance activities on "old" products should be clarified within the Market Surveillance Working Group.

A table illustrating the MDR requirements applicable or not applicable to 'legacy equipment' is attached as an annex.



News from Individual Countries

Italy

National Implementation of the MDR

The Ministry of Health (MoH), the Italian Competent Authority for clinical trials with medical devices published the Circular of 12 November 2021 providing guidance for stakeholders to clarify some aspects necessary for the implementation of the Regulation (EU) 2017/745 (MDR) and until EUDAMED is not fully functional.

The document concerns the provisions on the national database, manufacturers of custom-made devices, legacy devices, notified bodies, advertising, the use of harmonised standards, the products of Annex XVI of the MDR, tariffs and penalties.

Switzerland

Information Sheet for Clinical Trialswith Medical Devices

The Swissmedic, the Swiss Agency for Therapeutic Products published the Information sheet for sponsors, Contract Research Organisations (CROs), and clinical investigators of the authorisation process, reporting requirements of sponsors and the surveillance of clinical trials with medical devices. The document has been prepared in accordance with the Medical Devices Ordinance (MedDO) in the context of agreements between Switzerland and the EU.

North America

United States of America

FDA Participates in New 'Collaborative Communities' to Address Emerging Challenges in Medical Devices

The Food and Drug Administration (FDA) announced in late 2021, participation in several new collaborative communities aimed at addressing challenges in patient health care. Collaborative communities are a continuing forum where private and public sector representatives of the community work together on medical device challenges to achieve common objectives and outcomes.

The FDA currently participates in 12 collaborative communities, which are established, managed and controlled by external stakeholders. Collectively these communities are charting paths to accelerate and address regulatory science and other knowledge gaps to aid in medical device review and oversight. They may also impact the delivery of healthcare and change clinical care paradigms. Some of these collaborative communities include:

- Collaborative Community on Ophthalmic Imaging
- Xavier Artificial Intelligence (AI) World Consortium
- Heart Valve Collaboratory (HVC)
- Wound Care Collaborative Community
- Pathology Innovation Collaborative Community (PICC)
- MedTech Colour Collaborative Community on Diversity and Inclusion in Medical Device Product Development and Clinical Research (MedTech Colour Collaborative Community)
- Digital Health Measurement Collaborative Community (DATAcc)

The FDA reached the goal set as part of CDRH's 2018-2020 Strategic Priorities of participating in at least 10 new collaborative communities by 31 December 2020.

Canada

Health Canada Consultation: Guidance on Clinical Evidence Requirement for Medical Devices

Health Canada announced the development of the draft Guidance on clinical evidence requirements for medical devices and its companion piece which provides manufacturers a list of examples to consider. This guidance document is the result of a commitment under the Medical Devices Action Plan to improve the safety and effectiveness of medical devices and how they get to the Canadian market.

This consultation contains Guidance on clinical evidence requirements for medical devices and Companion document: Examples of clinical evidence requirements for medical devices.

Focus of this consultation is to engage with medical device stakeholders, primarily: manufacturers of class II to IV medical devices and regulatory representatives.

OTHER "HOT" TOPICS IN EUROPE

BREXIT Updates

Import of IMPs from Listed Countries to Great Britain (GB)

From 01 January 2022 a UK Manufacturing and Import Authorisation (UK MIA(IMP)) will be required to verify that Investigational Medicinal Products (IMPs) have been certified by a Qualified Person (QP) in a listed country (the 'oversight process').

In case of an IMP import into GB from a country on the list, an applicant will need to hold a UK MIA(IMP)) that authorises import.

The authorisation should specify "Importation of QP certified IMPs from a country on the 'approved country for import list'" as free text within "Other importation activities" in section 2.3 of the licence.

The UK MIA(IMP) holder responsible for the oversight process should be named on the Clinical Trial Authorisation in addition to the listed country site of final batch certification.

An oversight process under a UK MIA(IMP) is not required when:

- QP certified IMPs are supplied from the EU/ European Economic Area (EEA) to Northern Ireland
- QP certified IMPs are supplied from the EU/ EEA for use at Northern Ireland clinical trial sites and are then onward supplied to Great Britain
- IMPs are QP certified by a Northern Ireland MIA(IMP) holder

See also: Importing investigational medicinal products into Great Britain from approved countries - GOV.UK (www.gov.uk)

Supply of IMPs to Northern Ireland

As of 01 January 2022, Investigational Medicinal Products (IMPs) can be supplied from Great Britain (GB) (England, Scotland and Wales) to Northern Ireland with a pragmatic approach to applying European Union (EU) rules on importation requirements. IMP may also be supplied to Northern Ireland directly from the EU/ European Economic Area (EEA).

Qualified Person (QP) certification will continue to be required to use an IMP in a UK, Northern Ireland or Great Britain clinical trial. QP certification done in Great Britain will enable supply of IMP to Northern Ireland. QP certification done in the EU/EEA will also enable supply of IMP to Northern Ireland via Great Britain.

Batch testing may be performed outside the EEA, including in Great Britain or Northern Ireland, where this is performed to standards equivalent to those required by the UK and EU.

Substantial Amendments to Clinical Trials if changes on Investigational medicinal product (IMP) certification and importation

A substantial amendment to be submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) when any IMP manufacturing, importation or certification site relevant for supply of IMP to an ongoing UK trial is added or changed.

A substantial amendment is not to be submitted if the sponsor retains an existing UK IMP release site for the UK trial and includes an EU/EEA release site for trials in the EU/ European Economic Area (EEA).

OTHER "HOT" TOPICS FROM THE UNITED STATES

FDA's 2021 Annual Report Released

On 31 January 2022, the Food and Drug Administration (FDA) published the Centre for Devices and Radiological Health (CDRH) 2021 Annual Report. The past year presented the U.S and the world with an extraordinary set of unique health-related challenges along with FDA's ongoing mission of protecting public health and spurring medical device innovation. The report includes a message from the CDRH director and information about the FDA COVID-19 response, patient science and engagement, device safety, device innovation and customer service.

Many Important Drugs Approved in 2021 as COVID-19 Pandemic Continues

U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) approved a wide variety of safe and effective new drug therapies in 2021 despite challenges brought on by the ongoing COVID-19 pandemic. These new approvals, span a wide range of diseases and conditions.

More details about CDER's drug approvals for 2021 – including specific examples of notable approvals – are available in the annual New Drug Therapy Approvals report. FDA's Center for Biologics Evaluation and Research (CBER) approves important therapies as well. In 2021, CBER approved the first COVID-19 vaccine.

About CROMSOURCE

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialising in clinical development and staffing solutions. CROMSOURCE was founded in 1997, more than 25 years ago. Its successful growth has been built on stability, integrity, and high levels of customer satisfaction, all of which contribute to a high rate of repeat and referral business. We have grown steadily, but responsibly, to become an organisation of over 350 organised and well-trained experts.

A well-established full service CRO, **CROMSOURCE** is unique in offering an end-to-end guarantee covering trial timelines, enrolment and contract price. This guarantees our clients that their trials are delivered on time and within the contract price with no CRO-initiated change orders. **CROMSOURCE** operates through offices across all regions of Europe and North America and delivers a comprehensive breadth of services.

CROMSOURCE supports the full spectrum of clinical development via our Pharmaceutical, Medical Device and Staffing Solutions divisions. We seamlessly move biopharmaceutical products from first-into-human through all subsequent phases of pre- and post- approval research internationally.

We also support medical device projects through regulatory planning and execution, to pilot and pivotal clinical investigations in Europe and North America.

Global Reach

CROMSOURCE, with world headquarters in Verona, Italy, is a leading CRO in Europe and the US with a solid infrastructure and operational subsidiaries in Belgium, Germany, Poland, Russia, Spain, Switzerland, the UK, the Netherlands, and the US.

From our office locations across Europe and North America, **CROMSOURCE** employs experienced field-based teams around the globe to provide expert capabilities in regions including the Middle East, Africa, APAC, and South America.

It's a simple concept, really. Quality data. On time. On Budget. Guaranteed.

At CROMSOURCE we believe experts should keep their word. With more than 25 years of success we provide the industry's only End-to-End Guarantee™. Starting at the RFP stage with our uniquely detailed Feasibility Plus™ process we guarantee:

1. Your study will start on time
2. We will enroll 100% of the contracted patients
3. We will finish on time with a set date for database lock
4. The price you contracted is the price you pay. There will be no CRO-initiated changes-in-scope.

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FEASIBILITY PLUS™
GUARANTEED ENROLLMENT & TIMELINES

We know that budgets must be competitive, and you can rest assured that our End-to-End Guarantee™ does not come with a premium price.

As an ISO-certified organisation, you can also rest easy about quality.

Don't you owe it to your project to learn more? Contact us to request more information.