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White Paper

CLINICAL TRIALS REGULATION

The EU Clinical Trials Regulation – What You Need to Know

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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.

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Introduction - SIGNIFICANT CHANGES UNDER REGULATION

As of 31 January 2022, the EU Clinical Trials Regulation No 536/2014 (CTR) became applicable in all EU/ European Economic Area (EEA) Member States replacing the EU Clinical Trials Directive (2001/20/EC) (CTD). On the same day, the Clinical Trials Information System (CTIS), go-live version was opened for users to submit clinical trials on medicinal products for human use under a coordination authorisation procedure.

The deadline for the European Commission to implement the CTR was to set up fully functional portal which has workspace for sponsors, national Competent Authorities (NCA) and the European Commission. The portal which allows clinical trials' sponsors to apply with a single application which covers submissions to NCAs, Ethics Committees, and public registration of the clinical trial in all EU/EEA Member States.

In July 2021, the European Commission announced in the Official Journal of the European Commission that the new portal named Clinical Trials Information System (CTIS) is fully functional and at the same time, ready for use after six months of its publication, on 31 January 2022.

The announcement stated that Members States, Sponsors and Contract Research Organizations (CROs) started preparing intensively for the changes in the clinical trials environment.

Fortunately, the CTR foresees a 3-year transition period for sponsors to use CTIS.

During the first year starting from the CTIS go-live date until 31 January 2023, sponsors will be able to choose whether to apply for a new Clinical Trial Application (CTA) under the regime of the CTD, including using EudraCT, national portals or CESP (Common European Submission Portal) or to apply under the new CTR using CTIS.

During the second and third year until 31 January 2025, the EudraCT and CESP will not be available for new CTAs. From 31 January 2023, all new CTAs must be submitted under the CTR using CTIS. CTAs that were submitted under the CTD prior to 31 January 2023, will be able to continue to run and be completed under CTD for an additional two years maximum.

By 31 January 2025, trials submitted under the CTD must either have ended in the EU/EEA or have been transitioned to the CTR via CTIS. If sponsors are running trials that they expect to continue beyond 31 January 2025, sponsors will need to transition them to the CTR before the transition period expires.

Additionally, data submitted through the CTIS will be collected and stored in the EU database. The CTIS will harmonise and simplify the end-to-end application process over the life cycle of clinical trials, harmonise assessment of safety reporting of trials, accessing electronic reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) by Sponsors and re-routing to Member States, providing one single decision. In addition, the CTIS will offer searchable clinical trial information to the patient, healthcare professional and the general public. The results of clinical trials will be shared in the CTIS in layman's language.

This white paper provides information on how to be prepared for the new initial clinical trial authorization and substantial modification procedures under CTR.

Furthermore, it describes how to smoothly perform the transition of ongoing studies into the CTIS.

Apart from that, it presents requirements for streamlined reporting and public disclosure of data.

SIGNIFICANT CHANGES UNDER REGULATION

Definitions

The Clinical Trials Regulation has retained some definitions and refined others. For example the definition of "clinical study": "Any investigation in relation to humans intended: (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; (b) to identify any adverse reactions to one or more medicinal products; or (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products" is similar to the definition in the CTD, but a "clinical trial" is defined more narrowly as a subset of a clinical study. The CTR defines a non-interventional clinical trial as "a clinical study other than clinical trial".

The CTR introduces new elements like Low-intervention Trial and Auxiliary Medicinal Product. A Low-intervention Trial is defined as a new category of a trial which must fulfil the main conditions mentioned in the Regulation, but requires less stringent rules, for example, regarding insurance, monitoring and Investigational Medicinal Product (IMP) traceability. The precise interpretation of this definition is left to each Member State where an application for authorisation of a clinical trial or of a substantial modification will be submitted (Member State Concerned; MSC). Auxiliary Medicinal Product (AuxMP) is defined as a medicinal product used in a clinical trial, for example, for background treatment or rescue medication, but not as an investigational medicinal product.

The CTR uses the term "substantial modification" instead of "substantial amendment" used by CAs and ECs in accordance with the CTD. The two definitions are comparable and cover any changes to any aspect of the clinical trial which is made after notification of a decision, and which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial.

Initial Authorisation Procedure under CTR

Submission

One of the main aims of the CTR for the authorisation procedure is for the sponsor/applicant to submit one application dossier, including a single set of documents in harmonised format via the CTIS regardless of how many Member States are participating in the trial. Each Member State will issue one decision per study.

The CTIS will have sponsor workspace (for sponsors, Marketing Authorisation Applicants (MAAs)) and authorities' workspace (for Member States, European Commission and European Medicines Agency (EMA). At the sponsor workspace, a sponsor or CRO will have the CTIS User Administrator role, which will cover:

- Assigning new role or clinical trial access;
- Amending role or clinical trial access;
- Revoking role or clinical trials access;
- Approving or rejecting user request for role;
- Monitoring the work flow of the clinical trial.

To get access to the CTIS, all users will need register by themselves in the EMA Identity and Access Management System (IAM). Users will receive their login credentials, a default role that will allow them to access the CTIS and perform a limited number of activities like to request a role or update personal profile. In order to perform clinical trial activities for the particular study, the CTIS User Administrator will need to assign in the system, the user with his/her business role. The CTIS User Administrator will be also able to perform all sponsor's/CRO's business activities in CTIS.

The assigned user with the role, for example, "submitter" will submit the harmonised format of the application dossier for the clinical trial simultaneously to all Member States where a clinical trial is going to be conducted. The application dossier will consist of:

- Part I Scientific Review – to be assessed jointly by all MSCs; and
- Part II Ethical Review – to be assessed by each MSC's Ethics Committee separately.

The required content of the application dossier is presented in Table 1.

Part I (Global, Scientific review) Refers to Annex I of CTR (Sections B to J, Q)	Part II (National, Ethical Review) Refers to Annex I of CTR (Sections K to R) Information per Member State Concerned
Cover Letter	Recruitment arrangements specific for the MSC
EU Application Form	Subject Information, Informed Consent Form and Informed Concerned Procedure - in national language
Protocol	Suitability of the Investigator-specific for the MSC
Investigator's Brochure/ Summary of Product Characteristic (SmPC)	Suitability of the facilities-specific for the MSC
Documentation relating to compliance with GMP for the investigational medicinal product (MIA, QP, CoA)	Proof of Insurance cover or indemnification-global or local
Investigational Medicinal Product Dossier (IMPD)	Financial and other arrangements
Auxiliary medicinal product dossier, if applicable	Proof that data will be processed in compliance with Union Law on Data protection
Scientific advice and Paediatric Investigational Plan (PIP), if applicable	
Labels	
EU Legal Representative, if sponsor is out from the EU/EEA	
Proof of payment of fee (information per MSC)	

Table 1. List of required documents for the initial application under CTR

Annex I, Application Dossier for the Initial Application:

https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

The language used for the application dossier should be common in the medical field (i.e., English), but documents addressed to the subjects should be in their national and understood language(s). The CTIS User Administrator/User can submit Part I and Part II together, but there is also the possibility for them to submit only Part I for review and agreement; Part II may be submitted up to two years after Part I assessment has been completed.

Part II dossier may include recently published by the European Commission, harmonised templates and documents such as Investigator Curriculum Vitae (CV), declaration of interest, site and facilities suitability, recruitment and informed consent procedure, and payment of compensation.

Using harmonised templates by NCAs or sponsors across all of the EU will be not mandatory, but strongly recommended by the European Commission. In the application dossier, the sponsor shall propose one of the MSCs as the Reporting Member State (RMS), which will coordinate the validation and evaluation of the assessment process of the application. There should be one RMS for each study/protocol. If no MSC is willing to be the RMS or more than one MSC is willing to be the RMS, then the RMS should be selected by agreement among the MSCs. In case of only one MSC participating in the clinical trials that MSC will automatically be the RMS. The RMS shall notify the sponsor and, if applicable, other MSCs, that is the RMS within six working days from the submission of the application dossier through the CTIS.

Validation and Assessment

The overall process, when Part I (Scientific Review) and Part II (Ethical Review) are submitted together, consists of two steps: validation and assessment.

The dossier is validated by the RMS within ten days from submission taking into account comments expressed by the other MSCs. If there is no feedback from MSCs the application dossier shall be considered complete. If there is a request for information or any inquiries, the RMS sends a request for information (RFI) to the sponsor and one clock stop is allowed. The sponsor has maximum ten days to respond. The sponsor's failure to reply will lead to the automatic withdrawal of the application in all MSCs. The RMS has five days following receipt of the response to confirm validation to the applicant. If the RMS has not notified the sponsor within five days, the application dossier shall be considered complete.

Once the validation process is completed, Parts I and II are assessed in parallel within 45 calendar days and up to 76 calendar days if there are any questions requiring an extension.

Assessment of Part I and Part II submissions is carried out as follows:

- Part I Assessment: Scientific Part

In case of a multinational trial all MSCs must collaborate in the evaluation and the 45 days reporting period is then divided as follows:

- Initial assessment: within 26 days the RMS submits an initial Part I draft assessment report to MSCs (in case of trials involving an advanced therapy or a biotechnology medicinal product, the RMS extends the period by 50 days);
- Coordinated review: within 12 days MSCs review and provide comments to the RMS;
- Consolidation: within seven days the RMS consolidates the input from MSCs.

The RMS, considering issues raised by MSCs, may extend the reporting period up to 31 calendar days. Only the RMS can request for information (RFI) from the sponsor. The sponsor has maximum 12 calendar days to respond. Lack of response will be considered as withdrawal of the application in all MSCs.

The sponsor's responses are sent to all MSCs for joint coordinated review and the MSCs provide feedback to the RMS within 12 calendar days. The RMS consolidates the input from MSCs within seven days and prepares the final assessment report.

Part II Assessment: Ethical Part

Part II covers aspects typically examined by Ethics Committees and will be conducted separately by each MSC individually for its own territory. Each MSC shall complete its assessment of Part II within 45 calendar days from the validation date.

To obtain and review additional information from the sponsor the Ethics Committee (EC) or the National Competent Authority on behalf of the EC, may request an extension of the initial assessment up to 31 calendar days. All MSCs and ECs have the same deadlines but, independently and separately, can request an extension. The sponsor gets maximum 12 calendar days to reply. In case of lack of responses, the clinical trials submission will be withdrawn in all MSCs. Within the 31 days' extension and after receiving sponsor's responses, each MSC has 19 days for final assessment of ethical review.

Decision

The Regulation says that within five days of the final Part I assessment report or Part II assessment by each MSC, whichever is later, a single decision must be communicated to the sponsor. The Ethics Committee review may encompass aspects addressed in Part I (Scientific) and Part II (Ethical) of the assessment report. The final decision is made after Part I and Part II assessments are completed. The clinical trial may be found acceptable or acceptable subject to conditions, or it may be refused for all MSCs. The overall process of initial authorisation under the CTR is illustrated in Figure 1.

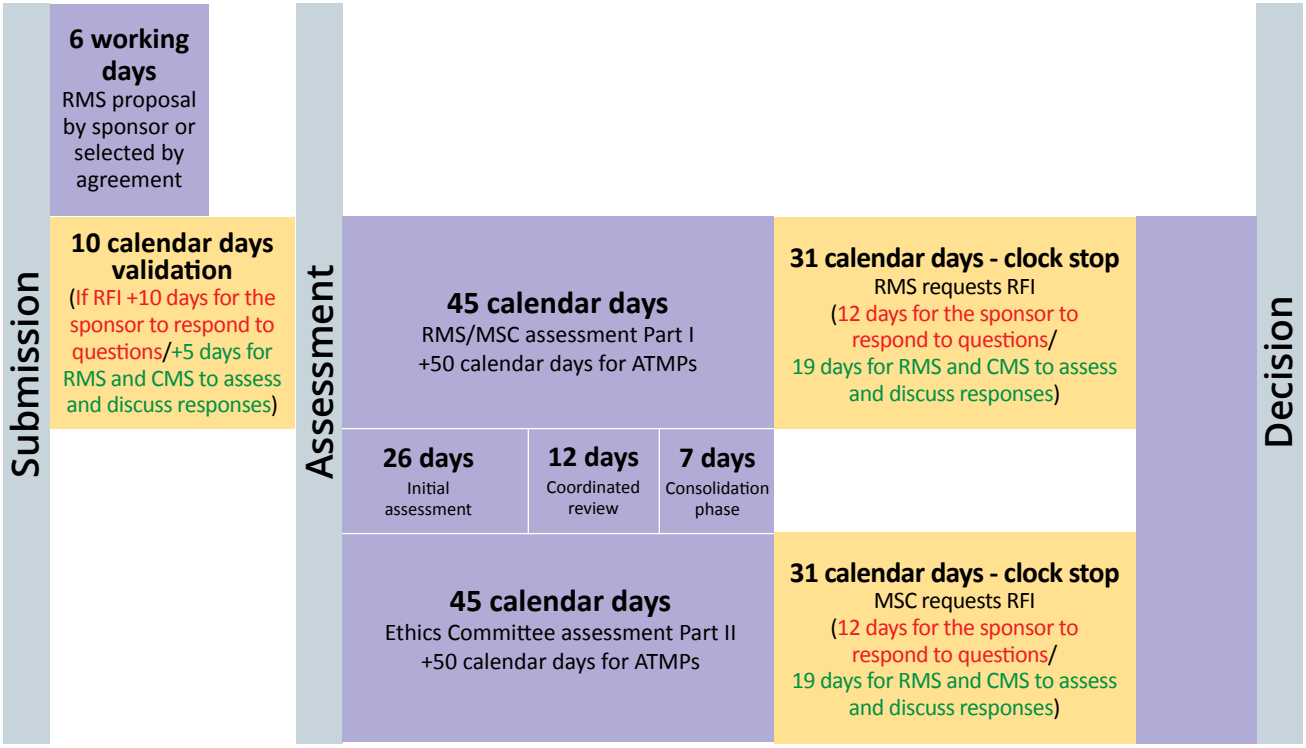

Figure 1. An overall process of Initial Authorisation Procedure under CTR

Chapter II, Authorisation Procedure for a Clinical Trial:
https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

If a MSC does not give its decision within the regulated timeframe, then the conclusion of the RMS Part I assessment report will automatically be considered as MSC decision. Where the conclusion of the RMS regarding Part I of the assessment report and clinical trial is not acceptable, that conclusion shall be deemed to be the conclusion of all MSCs.

A MSC can refuse to authorise a clinical trial if it disagrees with the conclusion of the RMS regarding Part I or an Ethics Committee can issue a negative opinion in a MSC. The MSC shall provide for an appeal procedure in respect of such refusal.

Individual Member States may decline to participate in a trial even when others have already accepted it. The application can be withdrawn at any time by the sponsor, up to the reporting date, but only if withdrawn in all MSCs.

Resubmission of the clinical trial is possible in the MSC in which the study has been refused, but it will be considered as a separate new Clinical Trial Application with a new EU CT number.

Substantial Modification Procedure

According to the CTR, only substantial modification needs approval prior to implementation. A substantial modification may affect a change to Part I, Part II or to both parts of the submitted application dossier. The RMS for the authorisation of a substantial modification shall be the same RMS as for the initial authorisation procedure. If the substantial modification concerns only Part I (e.g., Protocol, Investigator's Brochure or IMP Dossier), the RMS in cooperation with MSCs shall validate the application within six calendar days. If there are any questions, the sponsor will get a maximum ten days to provide a response and the RMS five days to confirm the validation. The assessment report shall be completed within 38 calendar days or 69 calendar days in case of request for additional information to the sponsor. Within five days, each MSC shall communicate to the sponsor their decision on substantial modification.

In cases where the substantial modification concerns only Part II (e.g., recruitment arrangement, additional site in a MSC) only the MSC, is involved in the assessment. The same timeframes apply for Part II as for Part I, including 19 days for ethical review.

When the changes affect both Parts I and II (e.g., change of main objective of the clinical trial or addition of a trial arm, or placebo group), both will be run in parallel with the same timeframe. As is the case with initial authorisation, the RMS will take the responsibility for coordinating the validation and evaluation of the assessment process of the application.

Addition of a Member State

After a clinical trial has received the initial authorisation decision, the sponsor may apply to the same RMS for adding another Member State. The procedures are the same as for initial submission. The User Administrator/ user must submit Part I and Part II through the CTIS for MSC evaluation, comments or disagreement to the clinical trial. The submission shall be done through the CTIS and the MSC shall notify its decision to sponsor within 52 calendar days or 83 calendar days depending on whether comments have been raised and required answer from the sponsor.

Streamlined Reporting

Under the CTR, the sponsor submits all Suspected Unexpected Serious Adverse Reactions (SUSARs) through the dedicated new module of the EudraVigilance. The EudraVigilance clinical trial module for the electronic reporting of SUSARs is upgraded in the CTIS. Upgraded module is a part of CTIS in accordance with Article 40 to 44 of the CTR and is maintained by the EMA. The EMA will forward the safety information electronically to all MSCs. The Development Safety Update Reports (DSURs) should be submitted through the CTIS. SUSARs reporting should be shared with the Ethics Committees, but some countries discuss a wave for this. 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 applied on 31 January 2022, on the same day as Date of Application (DoA) of the CTR and CTIS go-live version.

Implementing the regulation harmonizes rules concerning MS cooperation in assessing information reported to the relevant Ethics Committee. The EMA is also a controller of the CTIS and is responsible for avoiding unnecessary duplication between the EU database and the EudraCT and EudraVigilance databases.

The safety reporting via upgraded EudraVigilance module in the CTIS is effective on 31 January 2022. It streamlines safety reporting and end-to-end electronic solution for safety reporting of clinical trials. The CTR has kept the same timeframes for reporting SUSARs and DSURs as specified under the CTD: fatal and life-threatening SUSARs - as soon as possible and in any event not later than seven days after the sponsor became aware of the reaction; other SUSARs - within 15 days; DSURs - yearly.

The CTD had no provisions to notify the CA/EC of the start of a clinical trial (first patient first visit; FPFV). The only requirement was to inform the CA/EC about: the end of the trial (within 90 days); a temporary halt and early termination (within 15 days). The CTR requires harmonised reporting of all clinical trial lifecycle events by obligating the sponsor or his delegated user (e.g., Contract Research Organisation (CRO)) to notify each MSC within 15 days of all events listed in Table 2. The notification of events must be managed through the CTIS.

Notification to be submitted	Timeframe permitted
Start of the trial in each MS	Within 15 days
Inclusion of first patient in each MS	Within 15 days
End of recruitment in each MS	Within 15 days
End of trial in EEA to all MSC	Within 15 days
Early termination to each MSC	Within 15 days
Global end of trial (including 3rd world countries) to all MSC	Within 15 days
Temporary halt and reason to each MSC (max. 2 years)	Within 15 days
Restart clinical trial after temporary halt to each MSC (SM when halt was due to safety)	Within 15 days
Restart recruitment	= Restart clinical trial
Unexpected events	Within 15 days
Serious breach report	Within 7 days
Urgent safety measures	Within 7 days
Third country Inspectorate inspection	No timelines

Table 2. Clinical trial lifecycle: notification of events within 15 days
(CHAPTER VI, START, END, TEMPORARY HALT, and EARLY TERMINATION OF A CLINICAL TRIAL):
https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

Public Disclosure of Data

Prior to 1 May 2004 when EudraCT database was established, clinical trial information was confidential and available only to Member States' Competent Authorities, the EMA and the European Commission. After 21 July 2014, it became mandatory for sponsors to post clinical trials results in the EudraCT database. According to the CTR, the EU database will contain all relevant clinical trial information submitted through the CTIS. The information will be available publicly and will include: inclusion and exclusion criteria; main objectives and endpoints; the start and end dates of patient recruitment; and the trial end date. However, no subject personal data will be entered into the CTIS. To protect an individual's right to privacy and rights to personal data protection, some information regarding clinical trials will continue to need to be anonymised.

Sponsors may apply for deferral in the publication of clinical trials information in the CTIS. Request for deferral must be submitted only with the initial Clinical Trial Application submission. For example, for Phase II and III studies, the sponsor may request for deferring the publication of study protocol up to 5 years after the end of the trials in the EU/EEA.

The outcome of a clinical trial will also be published in the CTIS. The sponsor shall submit a summary of the results of the clinical trial to the CTIS within one year from the end of a clinical trial in all MSCs (as set out in Annex IV of the CTR). It shall be also accompanied by a summary written in a manner that is understandable to laypersons and translated into the Member State's national language (as set out in Annex V).

In addition, when clinical trials are intended to be used for obtaining a marketing authorisation for the medicinal product, the marketing authorisation applicant shall submit to the CTIS, the Clinical Study Report (CSR) within 30 days after "the day the marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, or the applicant for marketing authorisation has withdrawn the application".

3-YEAR TRANSMISSION PERIOD

By 31 January 2025, all clinical trials, authorised under the CTD, must either have ended in the EU/EEA or have been transitioned to CTIS. Sponsors will need to transition ongoing clinical trials under CTR before the 3-year period expires. Transition applications can be submitted at any time during the 3-year transition period. Transitioning a trial from the CTD to the CTR can take up to a period of 60 calendar days and up to a maximum of 106 days, if a Member State raises a Request for Information (RFI). It may be extended beyond 106 days, if the product falls within the definition of an Advanced Therapy Medicinal Product (ATMP). It also may be transitioned before 60-day automatically. Moreover, during transferring the study, no substantial amendments can be carried out under CTD.

Before preparing to transfer the study into CTIS, sponsors must switch all documents to the CTR. The most important is to consolidate a protocol that corresponds to what is already authorised in each of the MSCs. If the protocol is not consolidated, the sponsor should first submit the amendment under CTD in order to obtain the approval for the harmonised protocol from all NCAs and ECs and then submit it under the CTR via coordination authorisation procedure.

Other mandatory documents, meaning the entire initial submission dossier, should be also uploaded into the CTIS. In case the CTIS requests a document, which does not exist for the transitioning trial, then it is acceptable to upload a blank document with sufficient comment, for example, that the document does not apply and it has been enclosed only to allow the transition from CTD to CTR.

After transition of the Clinical Trial Application under the CTR and receiving from each MSC approval, all the requirements of the CTR will apply for transferred clinical trial.

CONCLUSION

Without doubt, the Clinical Trials Regulation changes the rules for authorisation of all phases (I-IV) of clinical trials on medicinal products for human use. It harmonises and centralises the processes from the start to the end of clinical trials. In addition, the information relating to clinical trials will become publicly available.

An independent CTIS audit, improving usability, quality and stability of the CTIS successfully finished, and on 31 July 2021, a major CTIS milestone had been reached. This allowed the European Commission to publish the full functionality of the CTIS, and the same announced on 31 January 2022 as the date of CTR application in the EU/EEA countries. To prepare everyone from the clinical trials environment, the EMA has published the CTIS Sponsor Handbook, providing key guidance, technical information and references for sponsors and collaborating organisations. Moreover, the EMA was hosting webinars on how end users can prepare for CTIS.

In addition, some EU guidelines have been released by the European Commission and at the date of application the CTR became applicable, change to examples include: “Detailed Commission guideline of 8 December 2017 on the Good Manufacturing Practice for investigational medicinal products pursuant to the second paragraph of the Article 63(1) of Regulation (EU) No 536/2014”; and “Template for IMP batch release”. The European Commission published harmonised templates and documents to support sponsors of clinical trials when submitting Part II elements of the application under the CTR.

A number of clinical trials guidance documents in Volume 10 of the EudraLex 10-volume collection of rules governing medicinal products in the EU are being revised and updated by the European Commission to bring them in line with the changes required by the CTR. The European Commission updates progressively Questions and Answers Document - Regulation (EU) 536/2014 and discusses some inconclusive questions with the Expert Group on Clinical Trials. In order to make a distinction between documents applicable to clinical trials authorised under CTD and documents relevant to clinical trials authorised under CTR, these documents are listed in two separate pages on the EudraLex Volume 10 website.

As of 31 January 2022, the Clinical Trials Regulation became applicable automatically for all EU Member States. Preparing for the changes was a challenge not only for sponsors or CROs but also for Member States. They had to set up communications between the National CA and the Ethics Committee, and to execute ethical review of the trial for the entire territory. The CTR does not give instructions on how to manage cooperation with the Ethics Committees. It says only that each MS is responsible for ensuring Ethics Committee meets CTR timelines and procedures for the ethical assessment Part II.

Furthermore, the sponsors and CROs must take into consideration some aspects of transition period and start preparations, and the sooner the better. The sponsors should also be aware that under the CTR, many of the requirements will be the same as under the CTD - for example timelines for safety reporting (SUSARs, DSURs), documents related to patients in national language or Annex 13 labelling requirements. For some sponsors, the challenge will be to prepare, consolidated protocol, especially for multi-national trials.

The EU CTR ushered the EU and EEA countries into a new era, in the way clinical trials are conducted for sponsors, Member States, CROs and especially for patients whose rights, safety, dignity and well-being will be better protected. Sponsors and their delegated users should become familiar with CTR requirements explained in this white paper for initial authorization, substantial modification, reporting safety information, notification of clinical trial events and plan properly for the transition of ongoing clinical trials from CTD to CTR.

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About the Author

David R. Dills - Director, Regulatory Services, CROMSOURCE

David joined CROMSOURCE in 2018 as Regulatory Services Department Director. He has more than 30 years of leadership experience in the pharmaceutical and medical device industry within the regulatory affairs and compliance space.

He has held positions of increasing responsibility with sponsors and service providers of various sizes, including large, global OEM's/sponsors, consultancies and a global CRO, as well as virtual, small, mid and large-sized enterprises.

He has worked with clients in ASEAN/APAC, EMEA and The Americas, and certainly with FDA and the global Health Authorities with product portfolios covering multiple therapeutic areas and medical specialties.

He is providing the global regulatory capabilities and regulatory intelligence support for clients and collaborating with our internal stakeholders. In addition, to being a professional member with industry associations, advisory boards, prolific speaker at industry events, he navigates the regulatory landscape throughout the product life cycle and regulatory crisis management. In addition, David is responsible for the development and launch of new services in the regulatory and strategic consulting space.

About CROMSOURCE

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialised 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-in-human, through all subsequent phases of pre- and post-approval research internationally.

We also support medical device projects through regulatory planning and execution, to pre- and post-market clinical investigations in Europe and North America.

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CROMSOURCE Quality
ISO 9001:2015 multi-site certified quality management system
ISO 14155:2020 conformity confirmed

European Headquarters
Via Giorgio De Sandre, 3
37135 Verona - Italy
Direct: +39 045 8222811

North American Headquarters
8000 Regency Parkway, Suite 575
Cary, NC 27518 - USA
Direct: +1 919 626 9882

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