Implementation of the EU Clinical Trials Regulation
Update for the Swiss Federal Office of Public Health
- June 2024 -

1. European Union

CTIS

At its meeting on 14 June 2024, the Management Board of the European Medicines Agency (EMA) was updated on the launch of a new version of the Clinical Trial Information System (CTIS) that would take place on 18 June 2024[1]. The new CTIS version displays data and documents on clinical trial applications in line with the timelines defined in the revised transparency rules (please refer to the Transparency section for further information on guidance in relation to this topic).

Table 1: Selected KPIs on the CTR's implementation (31 January 2022 to 31 May 2024)

Number of initial CTAs submitted under the CTR in CTIS	Total 5508			
	New initials 3415	Transitioned 1739	Resubmissions 354	
Number of initial CTAs submitted under the CTR in CTIS per status	Under evaluation 989	Authorized CTAs 3441	Non-authorized & non-valid CTAs 138	Withdrawn & lapsed CTAs 622
Number of CTs with a decision in CTIS per sponsor type & scope	Commercial		Non-commercial	
	Mono-national 645	Multi-national 1748	Mono-national 1100	Multi-national 265
Average days from submission to decision for new initial applications in May 2024	All ~110			

Abbreviations: CT = clinical trial; CTA = clinical trial application; CTR = Clinical Trials Regulation[2]; KPIs: Key Performance Indicators | Source: EMA[3]

At the EMA Management Board meeting on 21 March 2024, it was reported that the CTIS audit will take place either in 2025 or 2026[4]. The audit should assess whether the CTIS can adequately operate and support the implementation of the CTR and its guidance. At the same meeting, the European Commission highlighted that the CTIS must ensure that Member States and sponsors can comply with the obligations they have under the CTR[5].

It was also reported that only 20% of the transitioning clinical trials have been moved to the CTIS while the three-year transitional period ends on 30 January 2025; sponsors have been strongly advised to submit the applications as soon as possible considering the time necessary for completing the authorization procedure, which can take up to three months[6]. Please refer to the Guidance and Acts section for guidance on the transition from the CTD to the CTR.

Separately, new CTIS features were rolled out in May 2024 to collect information on how Individual Patient Data (IPD) will be shared with other researchers. These features are designed to comply with World Health Organization (WHO) requirements as the CTIS is a registered data provider for the organization[7].

Transparency

As reported in the previous section, the new transparency rules coincided with the launch of the new version of CTIS on 18 June 2024. A key change in the transparency rules is the deletion of the so-called "deferral mechanism", under which clinical trial sponsors were previously allowed to delay the disclosure of certain trial data and documents by up to seven years after the end of the trial in order to protect commercially confidential information. At the exception of the field regarding strength in the product section that is still in discussion regarding the level of confidentiality from a commercial perspective, data on CTIS trials are now made publicly available in line with the principles and timelines defined in the revised transparency rules[8]. Additional features such as an advanced search function will be implemented in the future to facilitate access to this data.

In this context, ACT EU issued an updated guidance and a related annex on how to approach the protection of commercially confidential information when using the CTIS on 18 June 2024[9]. The updated document reflects the changes in the transparency rules and a section on how to deal with trials that were uploaded prior to 18 June 2024 ("historical trials"). An updated version of the quick guide for users on revised CTIS transparency rules and historical trials was also made available on 21 June 2024[10].

Guidance and Acts

In March 2024, the European Commission published version 6.8 of its Q&A document on the rules for the governance of medicinal products in the EU under the CTR[11]. The updates concern the sections on auxiliary medicinal products (AxMP), Good Laboratory Practice (GLP), and on

how to protect commercially confidential information in case the sponsor of a clinical trial is not the product owner (PO) of the investigational medicinal product (IMP). Such aspects are also covered in further guidance described in this section. In June 2024, the Heads of Medicines Agencies' (HMA's) Clinical Trials Coordination Group (CTCG) published a Q&A document that is to be read as an addendum to section 7 of the above document[12]. It provides further details on annual safety reports, safety relevant notifications, and requests for information sent within the 'ad hoc' workflow used for supervision of clinical trials. Separately, an updated version of the recommendations on the use of AxMP in trials was published in March 2024[13]. Updates in the document concern the requirements for unmodified authorized AxMP as well as changes in the annexes.

A new guidance providing recommendations on GLP principles for clinical trial applications under the CTR was published in March 2024 by the HMA[14]. The document provides details on common approaches and requirements regarding Organisation for Economic Co-operation and Development (OECD) GLP compliance of pivotal non-clinical data submitted to support a clinical trial application, and on regulatory acceptability for sponsors, test facilities, and other interested parties.

In March 2024, the European Commission issued the fifth version of its guidance on rules applying to clinical trials in the EU[15]. The guidance provides sponsors and investigators with a quick guide about the rules and procedures of the CTR. The change concerns Annex I to reflect the content of a CTCG best practice guidance on the naming of documents.

The European Commission published the fourth version of its guidance document dedicated to the transition from the CTD to the CTR[16]. Updated on 4 May 2024, this guidance is designed to provide sponsors with guidance on aspects such as which and when clinical trials are to be transitioned, specific steps to be taken to achieve the transition, expectations regarding the documentation, and whether a Member State Concerned (MSC) can be added to a clinical trial after its transition to the CTR. The updated content reflects the most recent state of agreements between National Contact Points. On a related topic, the CTCG published an updated version of the guide for sponsors of multinational clinical trials with different Part I document versions approved in different Member States under the CTD that will transition to the CTR[17]. In March and April 2024, an updated version of the CTCG best practice guide and its annexes on substantial modifications were published[18]; the documents provide guidance for sponsors on harmonized requirements agreed by CTCG members for updating Part I documents in line with the CTR at the time of the first Part I substantial modification after a minimum trial dossier was transitioned from the CTD to the CTR.

Related Initiatives

As reported in previous editions of this report, the initiative "Accelerating Clinical Trials in the EU" (ACT EU) oversees CTIS operations. On 19 April 2024, the report of its January 2024 workshop on clinical trials analytics were published[19]. In early 2024, the ACT EU Multi-Stakeholder Platform Advisory Group (MSP AG) was established. The MSP AG consists of patients/consumers organizations, EU trade organizations, healthcare professional organizations, non-commercial European clinical data and translational research organizations and networks, and research funders[20]. The MSP AG has held three meetings in 2024.

The European Commission, National Competent Authorities, Ethics Committees, and the EMA published the analysis report of the COMBINE project in May 2024[21]. Established in 2023, the COMBINE project aims to address the issues linked to the interface between the CTR, the Medical Devices and In Vitro Diagnostics Regulations (MDR and IVDR). The report maps out the current challenges faced when conducting combined studies and possible ways forward to streamline the regulatory landscape.

Finally, ACT EU launched two new advice pilots to improve clinical trials in Europe[22]. The first pilot offers advice to developers of medicinal products on clinical trials and requirements for marketing authorization applications by consolidating the views of the Scientific Advice Working Party (SAWP) and the Clinical Trials Coordination Group (CTCG) to minimize avoidable divergences[23]. The second pilot, referred to as the pre-clinical trial application pilot, provides technical and regulatory support on the dossier of a clinical trial application prior to its submission in the CTIS by providing consolidated views between different Member States on pre-submission topics[24].

Austria

For Austria, ACT EU reported a total of 266 new initial clinical trial applications submitted since 31 January 2022: 238 multinational clinical trial applications in which the country was an MSC (of which 40 where Austria was a Reporting Member State), and 28 mono-national clinical trial applications[25]. A total of 381 clinical trials have been authorized in Austria since January 2022. Austria's Federal Office for Safety in Health Care (BASG) updated its webpage on rules and regulations in May 2024, where it explains the changes in the status of the role of national applicant under the CTR and provides additional guidance[26]. In January 2024, the BASG updated its dedicated page on the CTR, reminding sponsors of the need to transition from the CTD to the CTR[27].

Finally, the BASG reported the publication of the website of the Austrian ethics committees' platform on 19 January 2024[28]. The website brings together five ethics committees designated

by the Federal Ministry of Social Affairs, Health, Care, and Consumer Protection under Article 29 of the Medicinal Products Act (AMG)[29].

France

For France, ACT EU reported a total of 1194 new initial clinical trial applications submitted since 31 January 2022: 859 multinational clinical trial applications in which the country was an MSC (of which 142 where France was a Reporting Member State), and 335 mono-national clinical trial applications[30]. A total of 1552 clinical trials have been authorized in France since January 2022.

In May 2024, the National Commission on Informatics and Liberties (CNIL) opened a public consultation ahead of a revision of the health data guidance (referred to as "reference frameworks") following the entry into application of the CTR, among other aspects[31]. The CNIL is a regulatory body in charge of overseeing the implementation and application of laws on data privacy. The aim of this consultation is to identify both the changes to be made to the reference frameworks concerned, and the subjects on which it might be appropriate to adopt a new reference framework or recommendations. Stakeholders are invited to comment on three updated reference frameworks that are relevant to decentralize and/or dematerialize clinical trials: best practices for remote quality control, for the home-monitoring of health research, and for the electronic send out of information to patients. The consultation closes on 16 July 2024.

In the first half of 2024, the National Agency for the Safety of Medicines and Health Products (ANSM) updated two webpages reminding stakeholders of the obligations for sponsors to transition their clinical trials from the CTD to the CTR until 31 January 2025 and of the ongoing expedited evaluation procedure set up by the CTCG and that is open until 16 October 2024[32].

As previously mentioned in the last editions of this report, a draft law on innovation in healthcare is currently being discussed by the French Parliament. The text was transmitted to the lower house (National Assembly) in 2022 and is being discussed by the Social Affairs Committee of the French National Assembly[33]

Germany

For Germany, ACT EU reported a total of 1108 new initial clinical trial applications submitted since 31 January 2022: 861 multinational clinical trial applications in which the country was an MSC (of which 268 where Germany was a Reporting Member State), and 247 mono-national clinical trial applications[34]. A total of 1425 clinical trials have been authorized in Germany since January 2022.

Germany's Federal Institute for Drugs and Medical Devices (BfArM) updated a webpage providing information on the CTIS in March 2024[35]. The webpage highlights that sponsors that have clinical trials approved under the CTD and that are expected to run beyond 30 January 2025 must transfer their audits to the CTR and the CTIS.

In January 2024, the German government proposed an amendment to the Medical Research Act[36]. Among other changes, the revision proposes to establish a "federal ethics committee" that will deal with certain types of products, and complex or otherwise urgent applications. The association "Working Group of Medical Ethics Committees" (AKEK) is also proposed as lead to issue guidance based on the CTR to German ethics committees. The proposed legislation also contains measures to facilitate decentralized clinical trials, reorganize the portfolio of responsibilities between BfArM and the Paul-Ehrlich-Institut (PEI), and to make the use of electronic informed consent easier. The German Parliament completed the first reading of the draft legislation on 6 June 2024, referring the proposals to the lead Healthcare Committee for further discussions[37].

Italy

For Italy, ACT EU reported a total of 926 new initial clinical trial applications submitted since 31 January 2022: 828 multinational clinical trial applications in which the country was an MSC (of which 97 where Italy was a Reporting Member State), and 98 mono-national clinical trial applications[38]. A total of 1250 clinical trials have been authorized in Italy since January 2022.

Italy continued to roll out measures to implement the CTR with a particular focus on ethics committees in 2024. Ethics committees in Italy are organized in a tiered manner, with national ethics committees, so-called territorial ethics committees (TECs), as well as local ethics committees. On 22 May 2024, the National Coordination Center for Ethics Committees (CCNCE) published a report on the 40 TECs, covering aspects including their establishment, activities, the number of evaluated studies, and potential issues that are currently faced[39]. Among other aspects, the reports highlights that there remain issues to be addressed; those issues include the fact that not all TECs are fully operational and that some TECs are not fully able to carry out tasks assigned by the legislation due to their current composition or lack of resources for instance.

Separately, the CCNCE made available a guidance document that aims to streamline the evaluation of Part II of the clinical trial applications by the TECs in May 2024[40]. The document was produced after a lack of homogeneity in the TECs' assessment was observed, leading to the blocking of applications and decreasing the attractivity of Italy for clinical trials.

Other EU Member States and European countries

Denmark

The Danish Medicines Agency (DKMA) reminded stakeholders on 11 June 2024 of the upcoming deadline for the transition from the CTD to the CTR and provided an overview of available resources on this topic[41]. An updated version of the agency's guide to transition from EudraCT to the CTIS was made available on 18 April 2024[42].

Malta

In February 2024, the Malta Medicines Authority issued a guidance document for sponsors of clinical trials conducted under the CTR in Malta[43]. The document aims to support applicants that would like to submit clinical trial applications, amendments, and notifications to the agency.

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