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# Implementation of the EU Clinical Trials Regulation Update for the Swiss Federal Office of Public Health - December 2022 -

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## 1. European Union

On 12 October 2022, the European Medicines Agency (EMA) published the minutes of the 116<sup>th</sup> meeting of its Management Board, which was held on 15 and 16 June 2022. The Board was provided with, among other aspects, a report on the implementation of the Clinical Trials Information System (CTIS) and an update on the initiative on Accelerating Clinical Trials in the European Union (ACT EU). As of 31 January 2023, the CTIS will fully replace the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) for the submission of all new clinical trial applications. During the current transition phase from EudraCT to CTIS, a CTIS Early Phase Oversight Group is responsible for the management of critical issues and advice on system improvements; this group reports to the ACT EU Steering Group that oversees CTIS operations. The EMA is working toward addressing the backlog of remaining technical issues and on further improvements. Substantial efforts will be invested in explaining the benefits of the CTIS to the stakeholders. It was noted that >95% of the CTIS training module catalogue has been uploaded to the EMA website.<sup>1</sup> Key Performance Indicators (KPIs) on the use of the CTIS are regularly published by the EMA; selected KPIs are shown in Table 1 for a reporting period until 31 October 2022.<sup>2</sup>

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

Number of initial CTAs submitted under the CTR in CTIS	<b>374</b>			
Number of initial CTAs submitted under the CTR in CTIS per status	Under evaluation <b>163</b>	Authorized CTAs <b>121</b>	Non-authorized or non-valid CTAs <b>15</b>	Withdrawn & lapsed CTAs <b>75</b>
Number of CTs with a decision in CTIS per sponsor type & scope	Commercial		Non-commercial	
	Mono-national <b>36</b>	Multinational <b>32</b>	Mono-national <b>54</b>	Multinational <b>7</b>
Average days from submission to decision for initial CTAs	<b>84</b>			

Abbreviations: CT = clinical trial; CTA = clinical trial application; CTR = Clinical Trials Regulation

Source: EMA<sup>2</sup>

It was also announced during the Management Board meeting that the Heads of Medicines Agencies (HMA), European Commission, and EMA have developed a detailed ACT EU program delivery plan and a preliminary stakeholder mapping. A Questions and Answers (Q&A) document providing guidance on the planning/conduct of complex clinical trials was adopted in May 2022. Processes to deliver on the priority actions (PAs) and other steps to finalize and present the ACT EU workplan to the EMA Management Board in October 2022 were outlined. It was decided to establish a face-to-face ACT EU Matrix meeting to provide a forum for HMA, European Commission, and EMA representatives across the network to collaborate on all the PAs and to agree on procedures for a fruitful collaboration. The first meeting of the ACT EU Matrix took place on 19 and 20 September 2022; the ACT EU Matrix is expected to meet on a yearly basis. The EMA Management Board was also informed that calls for Seconded National Experts (SNEs) will be launched to support the clinical trial-related activities of the European Commission or the Agency.

In August 2022, the European Commission, HMA, and EMA published the ACT EU 4-year workplan for 2022 to 2026<sup>3</sup>, which builds on the Clinical Trials Regulation (Regulation [EU] No 536/2014<sup>4</sup>; CTR) and European regulatory network activities for the support of clinical trials and lays out deliverables and timelines. The workplan emphasizes key development areas such as innovative and robust methodologies in clinical trials and collaborations across stakeholders. The workplan is based on the EMA network strategy to 2025 recommendations<sup>5</sup> and European Commission's Pharmaceutical Strategy for Europe<sup>6</sup> and aligns with the 10 PAs for ACT EU<sup>7</sup>. The deliverables/timelines for 2023 include, among other measures, establishing a specific support process to facilitate academic research in the EU, including for large multinational trials, focusing on training and trouble-shooting activities for problems with the CTIS encountered by

clinical trial sponsors, establishing a multi-stakeholder platform to discuss proposals to improve the clinical trials environment, supporting the adoption and implementation of revised EU guidelines with regards to good clinical practice, providing guidance on decentralized clinical trials (already by the end of 2022), and delivering a methodology roadmap for the identification and prioritization of critical advances in clinical trial methodology.<sup>8</sup>

On 26 September 2022, an updated version 6.2 of the CTR Q&A was published which, among other updates, included a new question on how patient facing documents are expected to be submitted.<sup>9</sup>

On 7 October 2022, highlights from the EMA Management Board October 2022 meeting held on 6 October 2022 were published. The Management Board was informed that most clinical trial application submissions via CTIS resulted in successful approval. However, some technical issues required intensive support for a small number of users. Member States were advised to use all available resources for collaboration with stakeholders to prepare for the obligatory use of the CTIS as of 31 January 2023.<sup>10</sup>

On 21 October 2022, the 11<sup>th</sup> issue of the Clinical Trials highlights newsletter was published, mostly covering updates on CTIS-related aspects but also informing about the publication of the ACT EU 4-year work plan for 2022 to 2026, the 3<sup>rd</sup> Big Data Steering Group workplan for 2022 to 2025, and about other events/news. The newsletter announced that the inaugural meeting of the CTIS Forum, which gathers representatives from CTIS users, Member States, sponsors, clinical research organizations, patients and healthcare professionals, took place on 12 October 2022. The Forum will meet on a quarterly basis to exchange experiences with the CTIS.<sup>11</sup>

In November 2022, the European Commission issued a list of national contact points for the CTR.<sup>12</sup> Furthermore, a Delegated Regulation amending the CTR on labelling requirements for unauthorized investigational and unauthorized auxiliary medicinal products for human use was published in the EU Official Journal. Briefly, the period of use can now be omitted from the immediate packaging in specific cases.<sup>13</sup>

## Austria

The Federal Office for Safety in Health Care (BASG) noted that clinical trial application submissions to the BASG are valid until 30 January 2023. Thereafter, all initial applications for new clinical trials must be submitted via the CTIS.<sup>14</sup> On 7 October 2022, the Ordinance on the obligation to report non-interventional studies was repealed; the reporting obligation for non-interventional studies therefore no longer applies. Hence, there is no longer a legal basis to notify the BASG of, e.g., changes to ongoing non-interventional studies, end-of-study

notifications, and final reports of non-interventional studies. This applies to each individual case; no study-specific confirmations need to be issued. Moreover, the public registry for non-interventional studies has been discontinued.<sup>15</sup>

In this context, the Federal Ministry for Social Affairs, Health, Care and Consumer Protection and BASG issued a joint guideline on the differentiation of clinical studies (i.e., clinical trials, non-interventional studies) from other studies. The guideline also provides rules for other studies with medical devices or *in vitro* diagnostics (IVDs). Important topics covered are, for instance, the repealed notification requirements for non-interventional studies, the categorization of studies with approved medicinal products used within normal clinical practice in Austria as non-interventional, and the possibility of linking retrospective data evaluations or non-interventional studies with evaluations from biobanks.<sup>15;16</sup>

In August 2022, the BASG updated its regulation on fees, which entered into force as of 15 August 2022<sup>17</sup>, and published the list of changes.<sup>18</sup> Furthermore, slides from a lecture on the interface between the CTR and Regulation (EU) 2017/746 (IVDR)<sup>19</sup> with regard to biomarker-based clinical trials with medicinal products held in May 2022 were uploaded.<sup>20</sup>

## France

On 12 July 2022, the lower house of the French Parliament, the National Assembly, concluded the first reading of a draft law on health innovation, which started in the upper house, the Senate, in November 2021<sup>21</sup>. As previously reported in the last edition of this update, the text aims, among other aspects, to facilitate clinical trials in ambulatory settings, to link ethics committees to a university hospital, and to centralize the sponsor trial application's submission process to the French National Agency for Medicines and Health Products Safety (ANSM) and the ethics committee via a dedicated portal.

Separately, the ANSM updated its Q&A on the entry into application of the CTR<sup>22</sup> on 4 October 2022. On the same day, frequently asked questions (FAQ) were published to address questions raised by stakeholders during a webinar on the CTR that took place in April 2022.<sup>23</sup>

## Germany

In July 2022, the Federal Ministry of Health and the Paul Ehrlich Institute announced that blood sampling and non-invasive tests bearing minimal risk/burden for study participants are considered part of routine clinical practice in the following type of studies: a) studies with a vaccine approved for the prevention of an existing or imminently threatening communicable disease and b) if a population-wide supply of these types of vaccines is needed. Thus, such

studies are considered non-interventional and no application procedure for the conduct of the study is required.<sup>24</sup>

On 12 October, the Paul Ehrlich Institute updated its webpage containing information on requirements for clinical trials with genetically modified organisms (GMOs).<sup>25</sup> In November 2022, the webpage on Compassionate Use Programs was updated.<sup>26</sup>

The Federal Institute for Drugs and Medical Devices published slides from three lectures held in October and November 2022. The first lecture provides a brief overview of the scientific requirements and regulations for the conduct of clinical trials with investigational medicinal products (IMPs).<sup>27</sup> The second lecture discussed regulations on the preclinical documentation, the ICH M3 (R2) guideline, as well as the Investigator's Brochure with a specific focus on nonclinical studies.<sup>28</sup> The third lecture provided an introduction to quality aspects of IMPs and to the legal background on IMPs for children and adolescents.<sup>29</sup>

## Italy

In Italy, the transfer of clinical trials to the CTIS requires an approbation of the trial, or its last substantial modification, by the Italian Medicines Agency (AIFA) and an opinion of the ethics committees. A list of ethics committees for the assessment of CTAs was published.<sup>30</sup> On 14 November 2022, the AIFA issued a text<sup>31</sup> noting that the ethics committees shall scrupulously follow the timelines set in the Legislative Decree 211/2003<sup>32</sup> when carrying out the activities they are responsible for. Furthermore, in collaboration with the National coordination center of ethics committees (CCNCE), the AIFA issued a "Guide to compiling the Part II evaluation report (Assessment Report Part II) Version 1.0 (October 2022)"<sup>33</sup> to support the ethics committees in compiling the assessment report.<sup>34</sup>

In addition, several contracts and other templates and forms relevant to clinical trials under the CTR were adopted/updated, including an updated version of the "Guide to the preparation of the documents referred to in article 7 (1) of Regulation (EU) no 536/2014".<sup>35</sup>

## Other EU Member States and European countries

In June 2022, EU Member States reported on the implementation of the CTR at national level to the EMA Management Board. It was highlighted that significant work has been done at national level to adapt national legislation, templates, and fees to the CTR. However, there remains a number of processes that need improvement, and national authorities need to involve sponsors and ethics committees to a greater extent.<sup>1</sup>

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