REGULATORY FOCUS

Electronic platforms for submission of clinical trial information

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This article provides guidance for use of the European electronic platforms for retrieving and submitting information about clinical trials and compares them with other similar regional electronic databases, such as the US Food and Drug Administration's MyStudies mobile app and Switzerland's national platform, swissethics. The authors present an overview of some of the main international portals, available and under development, and provide an analysis of their specific aspects, including functionality and user experience, and a comparison of them, where feasible.

Introduction

As communication with regulatory agencies via electronic portals becomes more mainstream, regulatory professionals with varying backgrounds need to understand not only how portals differ from agency to agency, but that they serve a variety of purposes.

The European regulation for clinical trials on medicinal products for human use (Regulation EU No. 536/2014) has been updated and revised to assure trials are being conducted in the best interests of the patients.[1] In the past, most transmission and submission of information was paper-based, but that method

is no longer deemed adequate or appropriate. To facilitate electronic transmission of the relevant information and records, the European Medicines Agency (EMA) working on the development of an electronic portal for communicating relevant regulations. This was not a simple feat. The agency had vastly underestimated the complexity of such a tool, as evidenced by the multiyear delay in getting the portal operational (the latest estimate for its launch is the second half of 2021). Although this might seem a mere technicality, it is not, because the EMA, along with the European Commission, has stipulated that the regulations can come into force only once the portal is operational. In general, a portal is a website that collates specific information from various sources and facilitates access to that information.

This article, a follow-up to our 2017 article,[2] addresses the functionality and usability of the EU portal and database system, now known as the Clinical Trials Information System (CTIS), from the perspectives of various stakeholders, including ethics committees, principal investigators and clinical research organizations, and aims to demonstrate the extent to which the portal meets user expectations and requirements. As a comparison, we have included a preview of US Food and Drug Administration's (FDA's) MyStudies app.

From the EU Clinical Trials Register to the EU Portal and Database

The EU Clinical Trials Register is a publicly available database of information from the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT).[3] Since its launch in 2011, the register has been consistently been improved to allow for greater public access to information on clinical trials in the European Union (EU).

The EU Clinical Trials Register allows searches for information on protocol and trial results for:

- interventional clinical trials for therapies conducted in the EU and the European Economic Area (EEA)
- clinical trials conducted outside of the EU/EEA that are linked to European pediatric-medicine development

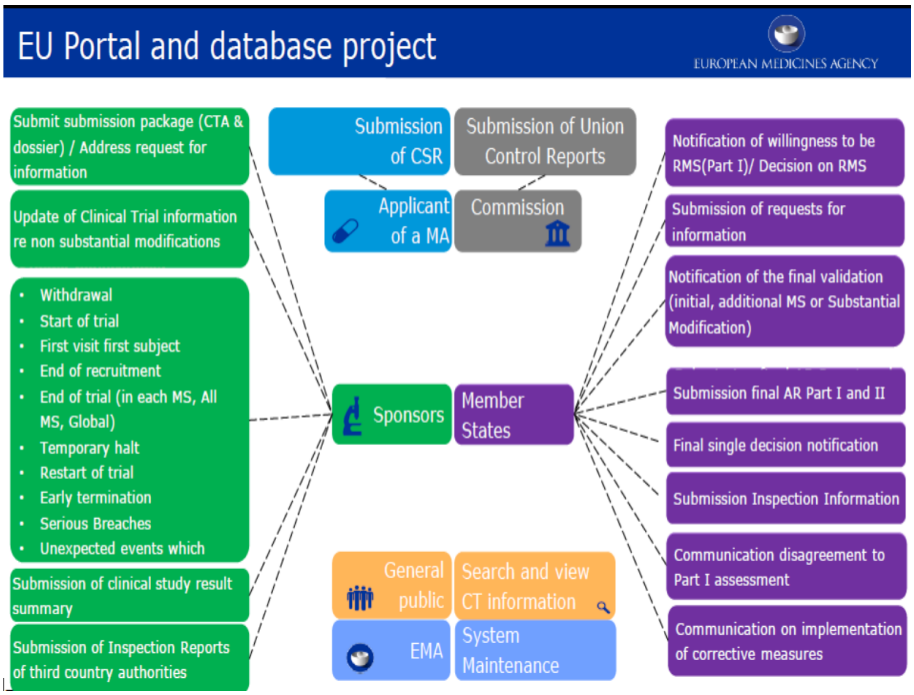
The register contains information on clinical trials started in the EU/EEA after 1 May 2004. In addition, it provides information on older pediatric trials covered by an EU marketing authorization.

Clinical trials conducted outside of the two regions are included if they form part of a pediatric investigation plan (PIP) or if they are sponsored by a marketing authorization holder and involve the use of a medicine in the pediatric population as part of an EU marketing authorization.

Data resulting from these trials are entered into the database by the sponsors and, once sponsors have validated the data, they are published through the register. EMA regulators use the register to obtain data on clinical trial protocols.

In 2015, the EMA management board created a new system architecture for an EU portal and the existing EU clinical trials register database, under the new clinical trial regulation, EU No. 536/2014.[4,5] This provides opportunities for widening the usability and functionality of the database (**Figure 1**).[6]

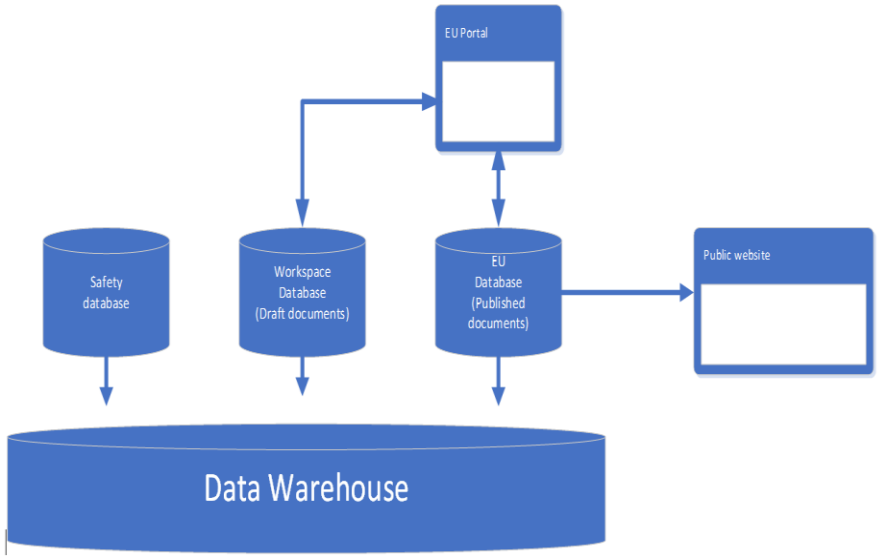
Figure 1. EU portal and database project: activities in the system



The IT architecture for the EU portal uses the International Organization for Standardization for the identification of medicinal products (ISO IDMP) standard for all underlying databases or data warehouses. The ISO IDMP standard is based on the four domains of master data in the pharmaceutical regulatory processes: substance, product, organization and referential master data (SPOR).[7,8]

The portal system consists of three databases and one underlying data warehouse. The first database is used as a workspace where the sponsors and member states can work on draft versions of submitted documents. The results are then transmitted via the EU portal to the EU Clinical Trials Register database, where they can be viewed. The third database is used exclusively for reporting trial safety information.[9] Still, the repository is synchronized with the data warehouse (**Figure 2**).

Figure 2. EU portal and database scheme



The data warehouse is used for combined reporting purposes for the EMA, EU member states and the European Commission. Sponsors and the public can only view predefined reports.

Since June 2019, the project has been using a new agile, iterative delivery model, whereby users work on a planned and predefined number of items within in fixed, four-week periods of time known as "sprints." Goals are set for each sprint cycle, and once the goals have been met, the information can be released. Sometimes, several sprint cycles are needed to refine the information before the goals are met.

The latest release within the agile delivery model was successfully validated in December 2019. The release, which was originally nominated by member states, sponsor organizations and European Commission product owners, enhances functionality within the portal—or Clinical Trial Information System (CTIS)—relating to submission of and access to data, data transparency, assessment of the process, management of user access and user oversight.[10]

The CTIS will contain information on clinical trials in the EU for which applications have been submitted under the framework of Regulation No. 536/2014 or that have been transitioned, at the end of transition period, from current legal framework (Directive 2001/20/EC). There has been some progress with the implementation and the validation of the IT infrastructure and framework in recent years. However, it has become clear that there will not be a direct link between the EU portal and the FDA's MyStudies app.[11]

The intention instead is to create a link with the World Health Organization's (WHO's) International Clinical Trials Registry Platform (ICTRP) and to populate CTIS data onto ICTRP, as is currently done with the public version of the EudraCT database.[12]

In December 2019, EMA management board agreed to commence an audit of the system in December 2020, following an audit readiness assessment by the nominated product owners, the EMA, and the IT supplier.

The aim of the audit readiness assessment was to identify critical business blockers, and it resulted in an updated plan outlining the items that still need to be developed, or fixed, for audit.[13] The product owners will work with the EMA and the supplier to analyze and design the items in the first few months of 2020 to ensure efficient delivery.

The FDA MyStudies app

The MyStudies mobile app is available for free.[14,15] It is designed to facilitate the direct input of "real-world data" by patients, and can then be linked to electronic health data supporting traditional clinical trials, pragmatic trials, observational studies and registries.

Various types of research trials can be supported on MyStudies, including, but not limited to, clinical research trials, observational studies and registries. Private and public organizations can use the app, which can be uniquely customized. The codes in MyStudies are open and comply with the US Health Insurance Portability and Accountability Act of 1996 (HIPAA).[16] Furthermore, informed consent and qualitative data, such as questionnaires, can be obtained from the trial participants more efficiently than is the case with paper records.

MyStudies is an open-sourced platform that can be downloaded on the GitHub software development platform. (It currently cannot be downloaded from the Apple's App Store or the Google Play Store.) After downloading the app, an organization can customize it to meet the needs of the organization. The FDA is currently engaged in two demonstration projects using the MyStudies app with the LimitJIA trial and the CARRA registry.[17] Both organizations will be releasing their rebranded app in the future.

There are no demonstrations available for download, but it is recommended that users watch the FDA MyStudies webinar on the app.[18]

FDA contracted with Harvard Pilgrim Health Care Institute to develop the app, and Harvard Pilgrim, in turn, subcontracted with Boston Technology Corporation and LabKey to codeveloped the app. There are no FDA guidelines on using MyStudies, but the agency recognizes that, because the software is open source, organizations may use the software if they so wish.

The MyStudies system has an interface that could allow an external system, such as the EU portal, CTIS, to retrieve data from the MyStudies storage environment. Enhancements are currently being designed to allow more straightforward integration between MyStudies and external systems. It is important to note that the MyStudies system was designed with the US regulatory framework in mind, so any integration with a non-US–based system should consider local regulations on data privacy and clinical trial research.[19]

For those interested in using or further developing the MyStudies app, it is recommended they:

- Test the new release for FDA MyStudies GitHub with the agency's IT support department.[20]
- Read the instructions on the Google cloud about expanding the MyStudies platform.[21]

Note: FDA is developing a four-part series of guidance documents for patient-focused drug development "to better inform medicinal product development and regulatory decision making."[22]

The MyStudies app will facilitate the collection of real-world evidence through mobile devices and expand the diversity of information for clinical trials.[23]

Figure 3. Get in touch: FDA MyStudies on the Google cloud marketplace

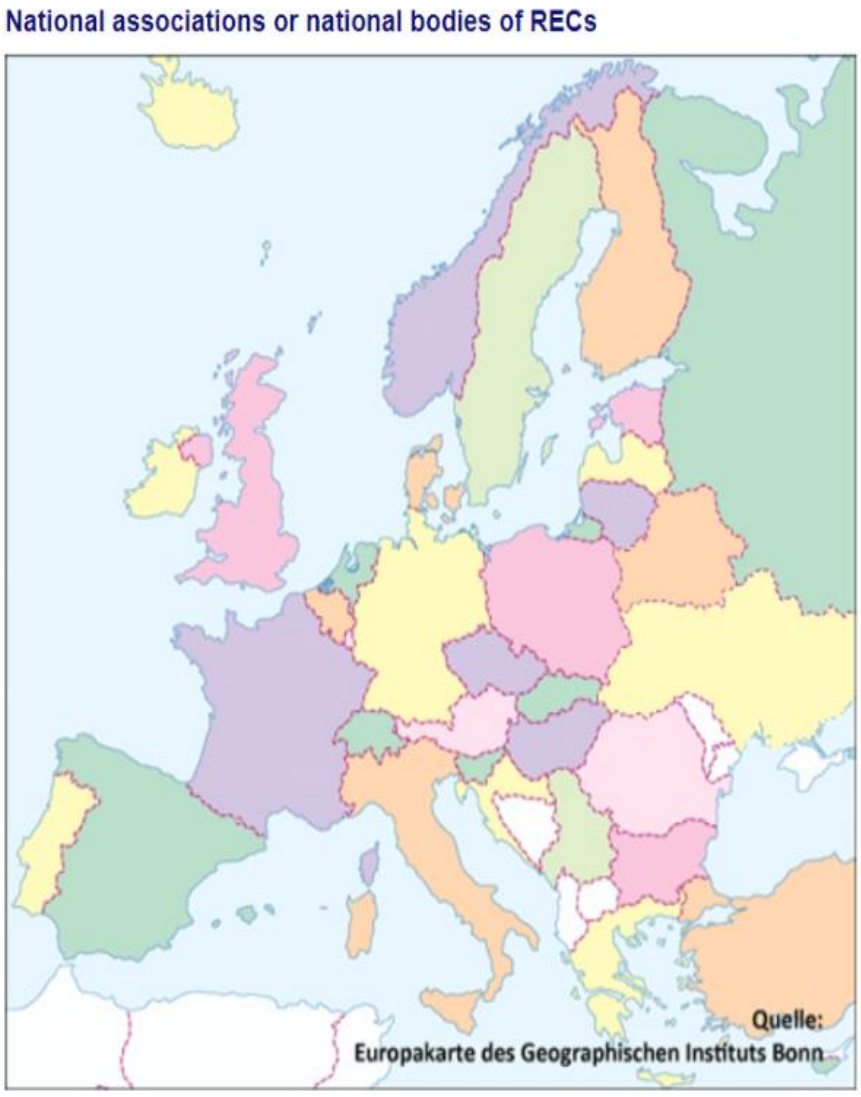
Unlike the EU portal, which is a mandatory interface for the submission of clinical trial data and documentation, FDA's MyStudies app is, in general, a voluntary-use technical tool aimed at enhancing the collation of real-life, evidence-based data in clinical trials.[24-29]

Research ethics committees: EUREC and the local network in Italy

The European Network of Research Ethics Committees (EUREC) is comprised of the national research ethics committees (RECs), associations or groupings in

European countries (**Figure 4**). We mentioned in our 2017 article that the network published the new Regulation No. 536/2014 on clinical trials on medicinal products for human use, which repealed Directive 2001/20/EC.

Figure 4. National associations or national bodies of RECs



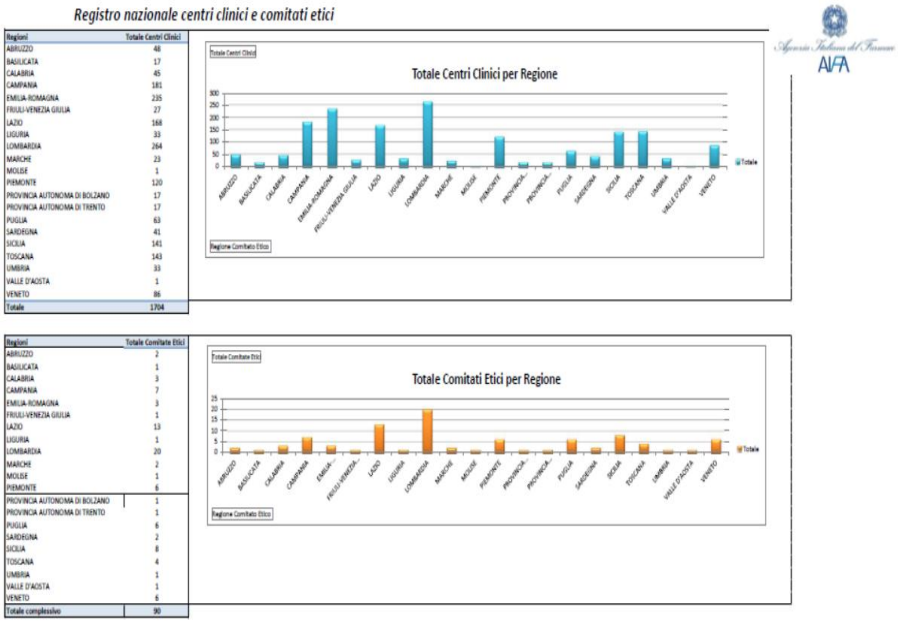
Austria | Belarus | Belgium | Bulgaria | Cyprus | Czech Republic | Denmark | Estonia | Finland | France | Germany | Greece | Hungary | Ireland | Italy | Latvia | Lithuania | Luxembourg | The Netherlands | Norway | Poland | Portugal | Romania | Slovakia | Spain | Sweden | Switzerland | Ukraine | United Kingdom

Concerning the European portal and database, EUREC has no official update from the EMA expert group that is following this project.[30,31]

All the materials for training in research ethics and regulation are available on the EUREC website.[32]

Each European country has a national network of local ethics committees that vary in organizational structure, competences and activities.[33] While it is not possible to provide an overview of each country's network, we will focus here on the Italian Drug Agency, as an example. **Figure 5** shows the agency's official national register of clinical centers and ethics committees.[34]

Figure 5. National registry of clinical centers and ethics committees with the geographical distribution in the various regions of Italy (updated 19 May 2019)



The Italian government passed Law No. 3 on 11 January 2018, which allowed for important changes in the procedures for the authorization of clinical trials (Article 1) and the organization and operation of ethics committees (Article 2).

One particularly important provision of the law is the establishment, within the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA), of the National Centre for the Coordination of Regional Ethics Committees for Clinical Trials of Medicines and Medical Devices for Human Use.

According to the law, the center:

- is responsible for the coordination, guidance and monitoring of the assessment of the ethical aspects concerning clinical trials on medicinal products for human use performed by the local ethics committees

- intervenes, as requested by individual local ethics committees, to provide support and advice
- may be involved in procedures regarding the evaluation of clinical studies that require review after adverse event reports
- monitors the activities performed by the local ethics committees and reports breaches of the terms set out in Regulation No. 536/2014
- suggests that the ministry of health suppress noncompliant local ethics committee in cases of inertia or failure to comply with the terms of the regulation
- provides general guidance in the interest of procedural uniformity and compliance with the terms for the assessment of clinical trials on medical devices and medicines for human use

To date, the ethics committees have not harmonized with the EU clinical trial portal and database or CTIS. Harmonization refers to having a single submission for authorization of a clinical trial to a national competent authority and ethics committee and for public registration in the primary register of clinical trials.[35]

Managing clinical trials through a variety of clinical platforms

In Europe, submitting information for a clinical trial has become increasingly standardized within the last 25 years. While harmonization of submission steps within the member states of the European Union was one of the major goals of Directive 2001/20/EC, and especially Regulation No. 536/2014, there are still some issues, such as patient-informed consent, that remain under the governance of locoregional authorities, conducted mainly by ethics committees.

Therefore, submitting for clinical trials using pharmacological substances or advanced therapy medicinal products (ATMP) is a two-step procedure in most of the European member states and as well as non-EU states, such as Switzerland, requiring submission to local ethics committees and medicinal agencies, such as the EMA for Europe, or Swissmedic, the Swiss Agency for Therapeutic Products.[36] With the change from paper-based to electronic submission, researchers hoped to reduce their administrative workload and to be able to submit simultaneously to local and superordinate agencies through a single-entry portal. That would, however, presuppose a nearly complete harmonization between ethics committees and medicinal agencies, as well as a crossover between ethics committees and medicinal agencies of member states.

As we have already discussed, at least for the ethics committees, harmonization has not yet been attained in Europe. Because Switzerland is not an EU member state, its relationship with the EU is regulated by bilateral treaties that explicitly do not subordinate the country under the governance of the EMA. Switzerland has subsequently come up with a national platform, called swissethics,[37] that serves as a gatekeeper for all clinical protocols that will be evaluated by one of the seven ethics committees, depending on the region of interest. According to Switzerland's federal administration, there are several ethics committees

representing different cultural and linguistic regions within Switzerland. The platform also serves as database for national and international legislation, provides information about training in good clinical research practice, and provides templates for different types of documents, such as patient-informed consents, recruitment of study participants, or insurance. Completed trial documentation can easily be uploaded to the platform for consultation with the leading ethics committee and correspondence with the principal investigator or the national coordinating center. In the case of multicenter trials, it is possible to submit to one or more of the Swiss ethics committees.

Although swissethic's harmonization with the various ethics committees is working fairly well, documentation for clinical trials is not posted directly and simultaneously to Swissmedic, the national competent authority.

Articles 80 and 81 of the Regulation No. 536/2014 have assigned the EMA to create an EU portal and database that is "technically advanced and user-friendly so as to avoid unnecessary work." That goal is easily achievable when submitting for a monocentric, national trial. However, the process is considerably more complex for submission of a multicenter or international clinical trial carried out in several countries, some of which are EU member states and others, not. This may be especially challenging for public sponsors if they are not supported by professionals trained in facilitating the submission of multicenter trials globally.

The BAMI trial[38] is an excellent example for demonstrating the complexity of the submission process to be by public sponsor of ATMP.

Especially in complex situations, as was the case for the BAMI trial, the voluntary harmonization process was quite time- and resource-consuming and was possibly responsible for delays in patient recruitment, as has been documented by Christine Hauskeller.[39] In such situations, even electronic platforms for submission of protocols for clinical trials may not help in overcoming administrative hurdles. In the case of the BAMI trial, the difficulties were likely due to the lack of common, harmonized standards for the submission of ATMP-based trials.

One of the challenges for the EU portal will be to build up a common, harmonized frame that accommodates the differences between classic pharmacological products and ATMPs, which include gene therapy, cell-based therapy (which may be completely "cell-free") and tissue-engineered structures (e.g., patches or other tissue). In addition, all types of ATMPs may be combined with devices such as a tissue-engineered cardiac valve prosthesis. This heterogenic group of different types of ATMPs cannot readily be compared with classic pharmacological drugs, therefore, another level of harmonization needs to address clinical trials with advanced therapies for an as-yet unmet need.

Until that goal has been achieved, from the viewpoint of a public sponsor, the ideal trial portal would be a centralized platform serving as distribution tool from where all locoregional ethics committees (as well as all superordinate

national or European authorities) may obtain, revise, comment and finally accept or decline clinical trials for all of Europe.

Conclusion

The EU portal and database project will merge the interests of sponsors, locoregional and national authorities with the technical and regulatory requirements of the EMA.

In an article comparing EMA and FDA decisions for new drug marketing approvals (NDAs) during 2014-2016, Kashoki and colleagues reported that the agencies had concordance in 91%-98% of NDAs.[40,41] The authors noted that "divergence in approval decisions, type of approval, and approved indication were primarily due to differences in agencies' conclusions about efficacy based on review of the same data or differing clinical data submitted to support the application. This high rate of concordance suggests that engagement and collaboration on regulatory science has a positive impact."

Clinical Trials Information System (CTIS) will contain the centralised EU portal and database for clinical trials foreseen by the Regulation.

The EMA is in the process of developing a database system, the CTIS, that will incorporate the centralized EU portal and database for clinical trials overseen by Regulation No. 536/2014. The database is tailored for specific European regulatory compliance components, which are not necessarily the same regulatory requirements as those of the FDA. Despite the differences in local regulations, storage components of the FDA MyStudies system API layer conveniently allow external systems, such as the CTIS, to retrieve data from MyStudies, allowing the information technology integration with the CTIS. Additional layers of regulatory components can be added per EMA regulations. This is a crucial component that could aid pharmaceutical companies warranting approvals from different agencies, such as the EMA and FDA.

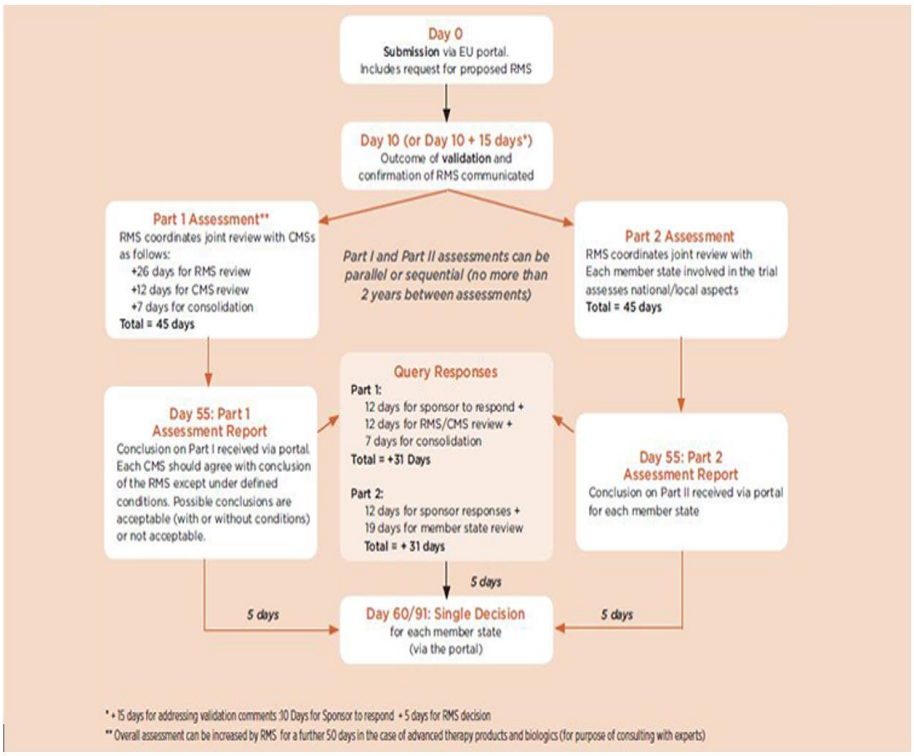
Despite best efforts from the EMA and service providers, there is to date no guaranteed date for the correct working of CTIS. Consequently, the clinical trial regulation cannot come into effect as the mandated portal is unavailable. However, the FDA's smart and easy-to-use MyStudies app is already available and subject to continuous improvements and updates.

The complexity of these electronic platforms is a challenge for regulatory affairs experts and will require demanding investments for pharmaceutical companies and public sponsors, such as the hospital research centers. This article has provided a preview on the possible scenarios in coming years and has attempted, as much as possible, to simplify the technical and information technology language. It is undeniable that the existing nonhomogeneities in the organization, structure, competences and activities of the ethics committees in several EU countries, and more generally, differences in the matter of health legislation, limit the implementation of the EU portal and database for clinical trials.

The authorization and oversight of clinical trials remains the responsibility of member states, with the EMA managing the CTIS and supervising content publication on the public website.

The EU regulation introduces a new procedure, new timelines, and revised application content, and although it may increase or decrease the overall timelines in some submissions, it will bring with it increased predictability for clinical trial start-up in the EU (**Figure 6**).

Figure 6. Approval application process



Significant changes are coming for competent authorities, ethics committees and sponsors:

At the member state level, ethics committees and competent authorities will need to agree on how to work together to achieve the review outcome within the required timelines.

At the EU level, member states will need to agree how to work together to achieve what is required to complete the application review.

Industry clinical trial sponsors will need to prepare to confirm country selections without negatively affecting planned study start-ups (i.e., avoiding multiple applications to add member states), respond to application review queries within shorter timelines, and manage changes so they can be submitted when needed, rather than waiting for an ongoing application to be completed.[42,43]

Acronyms

Clinical Trial Information System (CTIS)
European Economic Area (EEA)
European Medicines Agency (EMA)
European Union (EU)
Food and Drug Administration (FDA)
International Organization for Standardization for the identification of medicinal products (ISO IDMP)
Pediatric Investigation Plan (PIP)
Substance, Product, Organisations and References (SPOR)

References

1. European Medicines Agency. *Clinical Trial Regulation*. https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation. Accessed 12 May 2020.
2. Schmitt S, Bonacci F, Lisini D and , Mascilongo V. "Impact of the revised EU clinical trial regulation." *Regulatory Focus*. 24 April 2017. https://www.raps.org/regulatory-focus/news-articles/2017/4/impact-of-the-revised-eu-clinical-trial-regulation. Accessed 12 May 2020.
3. EU Clinical Trials Register. https://eudract.ema.europa.eu. Accessed 12 May 2020.
4. European Medicines Agency. Management board. https://www.ema.europa.eu/en/about-us/who-we-are/management-board. Accessed 12 May 2020.
5. European Commission. Clinical trials—Regulation EU No. 536/2014. https://ec.europa.eu/health/human-use/clinical-trials/regulation_en. Accessed 12 May 2020.
6. Manent N. EU CT portal and database. European Medicines Agency. Presentation at SME information day: The new clinical trial regulation. 20 March 2017. https://www.ema.europa.eu/en/documents/presentation/presentation-eu-ct-portal-database-noemie-manent_en.pdf. Accessed 12 May 2020.
7. European Medicines Agency. Data on medicines (ISO IDMP standards): Overview. https://www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview. Accessed 12 May 2020.
8. European Medicines Agency. Substance, product, organization and referential (SPOR) master data. https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/substance-product-organisation-referential-spor-master-data. Accessed 12 May 2020.
9. Pioppo L. Key features and objectives of Regulation EU No. 536/2014—What is new, what has changed? European Medicines Agency. Presentation at SME information day: The new clinical trial regulation; 20 March 2017. https://www.ema.europa.eu/en/documents/presentation/presentation-key-features-objectives-regulation-eu-no-536/2014-laura-pioppo_en.pdf. Accessed 12 May 2020.
10. Op cit 1.
11. Official reply from the Service Desk of the European Medicines Agency. 2019.
12. World Health Organization. International Clinical Trials Registry Platform (ICTRP). https://www.who.int/ictrp/en/. Accessed 12 May 2020.

13. European Medicines Agency. Functional specifications for the EU portal and EU database to be audited. https://www.ema.europa.eu/en/documents/other/functional-specifications-european-union-eu-portal-eu-database-be-audited_en.pdf. Published 25 March 2020. Accessed 12 May 2020.
14. Food and Drug Administration. FDA's MyStudies Application (App). https://www.fda.gov/drugs/science-and-research-drugs/fdas-mystudies-application-app. Released 18 January 2019. Accessed 12 May 2020.
15. Food and Drug Administration. An introduction to FDA MyStudies: An open-source, digital platform to gather real-world data for clinical trials and research studies. https://sbiaevents.com/files2/MyStudies-Slides.pdf. Presented 9 May 2019. Accessed 12 May 2010.
16. US Department of Health &and Human Sciences. Summary of the HIPAA security rule. https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html. Last reviewed 26 July 2013. Accessed 12 May 2010.
17. GitHub. FDA MyStudies mobile application system. https://github.com/PopMedNet-Team/FDA-My-Studies-Mobile-Application-System. Accessed 12 May 2020.
18. Op cit 15.
19. Quinto K. US Food and Drug Administration, Center for Drug Evaluation and Research. Official written feedback, 2019.
20. Op cit 17.
21. Rogers J. Google Cloud and FDA MyStudies: Harnessing real-world data for medical research. https://cloud.google.com/blog/topics/healthcare-life-sciences/fda-mystudies-comes-to-google-cloud. Posted 7 January 2020. Accessed 12 May 2020.
22. US Food and Drug Administration. FDA patient-focused drug development guidance series for enhancing the incorporation of the patient's voice in medical product development and regulatory decision making. Last updated 29 August 2019. https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical. Accessed 12 May 2020.
23. Kent J. FDA launches app to support clinical trials, real-world evidence collection. Published 12 November 2018. https://healthitanalytics.com/news/fda-launches-app-to-support-clinical-trials-real-world-evidence-collection. Published 12 November 2018. Accessed 12 May 2020.
24. Op cit 15.
25. Op cit 21.
26. Op cit 22.
27. Labkey website. FDA MyStudies mobile app: an open-source, digital platform to gather real world data for clinical trials and research studies.2019. https://www.labkey.com/case%20study/fda-mystudies-mobile-app/. 2019. Accessed 12 May 2020.
28. US Food and Drug Administration. https://www.fda.gov/downloads/Drugs/ScienceResearch/UCM625206.pdf. Accessed 12 May 2020.
29. Wyner Z, Dublin S, Reynolds J, et al. FDA MyStudies app: A patient-centered outcomes research trust fund enabler for distributed clinical trials and real-world evidence studies. https://aspe.hhs.gov/system/files/pdf/259016/AppendicesCollectionPatientProvidedInfo.pdf. Published 10 October 2018. Accessed 12 May 2020.

30. Op cit 28.
31. Op cit 29.
32. Rete Italiana Comitati Etici [Italian Network of Ethics Committees]. https://retecomitatietici.apss.tn.it/. Accessed 14 May 2020.
33. European Network of Research Ethics Committees website. National associations or national bodies of RECs. http://www.eurecnet.org/information/index.html.
34. European Network of Research Ethics Committees website. Training materials. http://www.eurecnet.org/materials/index.html. Accessed 15 May 2020.
35. Petrini C. Are the Italian ethics committees ready for Europe? Commentary. Ann Ist Super Sanita. 2018;54(4):270–1. http://old.iss.it/binary/publ/cont/ANN_18_04_02.pdf. Accessed 12 May 2020.
36. Registro nazionale centri clinici e Comitati etici [National Register of Clinical Centers and Ethics Committees]. AIFA website. http://www.agenziafarmaco.gov.it/content/registro-nazionale-centri-clinici-e-comitati-etici. Accessed 12 May 2020.
37. Hauskeller C. Can harmonized regulation overcome intra-European differences? Insights from a European Phase III stem cell trial. Regen Med. 2017;12(6):599-609. https://www.futuremedicine.com/doi/10.2217/rme-2017-0064?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov. Accessed 12 May 2020.
38. Swissmedic website. https://www.swissmedic.ch/swissmedic/en/home.html. Accessed 12 May 2020.
39. Op cit 35.
40. swissethics website. https://swissethics.ch/en/. Accessed 12 May 2020.
41. Kashoki M, Hanaizi Z, Yordanova S, et al. A comparison of EMA and FDA decisions for new drug marketing applications 2014-2016: Concordance, discordance, and why. Clin Pharmacol Ther. 2020;107(1):195-202. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6977394/. Accessed 12 May 2020.
42. Mathur A, Arnold R, Assmus B, et al. The effect of intracoronary infusion of bone marrow-derived mononuclear cells on all-cause mortality in acute myocardial infarction: rationale and design of the BAMI trial. Eur J Heart Fail. 2017;19(11):1545-50. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6607485/. Accessed 12 May 2020.
43. Kirk JL. EU clinical trials regulation: The application process. *Pharmaceutical Engineering*. March-April 2017. ISPE website. https://ispe.org/pharmaceutical-engineering/march-april-2017/eu-clinical-trials-regulation-application-process. Accessed 12 May 2020.

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