The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME response to the European Commission Clinical Trials Study Survey

On 13 November 2025, the CPME Board adopted the 'CPME response to the European Commission Clinical Trials Study Survey' (CPME 2025/193 FINAL).

Contribution ID: 82e52cfc-70fd-4df6-a301-a5ce47f426d4
Date: 25/11/2025 15:27:06

Clinical Trials Study Survey

Fields marked with * are mandatory.

Introduction

The Clinical Trials Regulation (Regulation (EU) No 536/2014) is a European law that sets rules on how clinical trials should be conducted in Europe (EU/EEA). The Regulation was introduced in 2014 to improve the efficiency, transparency and harmonisation of clinical research in Europe (EU/EEA) and replaced the previous legislation, the Clinical Trials Directive (2001/20/EC). A new online platform, the Clinical Trials Information System (CTIS), is a pivotal component of the Regulation. CTIS serves as a single interface for interaction between researchers and companies who run clinical trials and regulatory authorities across Europe (EU/EEA) who review and approve them.

This targeted survey aims to gather evidence and knowledge for a study conducted by an external contractor that will support the Commission's report on the application of the Clinical Trials Regulation.

The survey covers aspects of the relevance, coherence, impact, implementation, and EU added value of the Regulation.

1 An endorsement letter from the European Commission can be found here:

CTR_study_Endorsement_letter_Consultation_activities.pdf

About you

* 1 I am giving my contribution as

- ○ Academic/research institution
- ○ Business association
- ○ Company/business
- ○ Patient organisation
- ◉ Healthcare professional
- ○ Hospital or healthcare institution
- ○ Public authority

- ○ Other (please specify)

*3 Role in Clinical Trials

- ○ Commercial sponsor of clinical trials
- ○ Non-commercial sponsor of clinical trials
- ○ Clinical trial investigator
- ○ Clinical research organisation (CRO)
- ○ Clinical trial personnel
- ○ Competent authority
- ○ Ethics committee
- ○ Patient organisation
- ◉ Other (please specify)

4 Please specify 'other' role

European Doctors

*5 Country where you or your organisation are/is based

Please add your country of origin, or that of your organisation.

This list does not represent the official position of the European institutions with regard to the legal status or policy of the entities mentioned. It is a harmonisation of often divergent lists and practices.

○ Afghanistan	○ Djibouti	○ Libya	○ Saint Martin
○ Åland Islands	○ Dominica	○ Liechtenstein	○ Saint Pierre and Miquelon
○ Albania	○ Dominican Republic	○ Lithuania	○ Saint Vincent and the Grenadines
○ Algeria	○ Ecuador	○ Luxembourg	○ Samoa
○ American Samoa	○ Egypt	○ Macau	○ San Marino
○ Andorra	○ El Salvador	○ Madagascar	○ São Tomé and Príncipe
○ Angola	○ Equatorial Guinea	○ Malawi	○ Saudi Arabia
○ Anguilla	○ Eritrea	○ Malaysia	○ Senegal
○ Antarctica	○ Estonia	○ Maldives	○ Serbia

- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand

- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d’Ivoire
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela

- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

6 First name

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7 Surname

Teixeira Pereira

8 Email

diogo.teixeira.pereira@cpme.eu

* 9 Please indicate whether you are happy to be contacted for other stakeholder consultation activities in this study. If yes, please make sure to provide your email address above.

- (•) Yes
- ( ) No

* 10 Organisation name

255 character(s) maximum

Standing Committee of European Doctors (CPME)

* 11 Organisation size

- (●) Micro (1 to 9 employees)
- ( ) Small (10 to 49 employees)
- ( ) Medium (50 to 249 employees)
- ( ) Large (250 or more)

* 12 Geographical scope of organisation

- (●) International
- ( ) Local
- ( ) National
- ( ) Regional

☑ I agree with the attached Data Protection Notice

HaDEA-DPN-CTR-targeted-survey.pdf

Relevance

1 To what extent do you agree each of the following objectives of the Clinical Trials Regulation were relevant in the EU/EEA **at the time the Regulation was adopted (2014)?**

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* To simplify and streamline the assessment processes, reduce administrative burden for sponsors by establishing one single set of rules directly applicable in all EU/EEA countries for the processing of clinical trial applications	( )	( )	( )	( )	( )	(●)
* To improve information-sharing between Member States and foster collaboration on safety assessment	(●)	( )	( )	( )	( )	( )
* To increase transparency of information on clinical trials for the public	(●)	( )	( )	( )	( )	( )
* To reduce administrative burden by establishing a single, common IT system across Europe	( )	( )	( )	( )	( )	(●)

* To conduct clinical trials that protect the rights, safety, dignity and well-being of clinical trial subjects and generate reliable and robust data that are useful for the later steps in the life cycle of medicines	◉	○	○	○	○	○

2 To what extent do you agree each of the following objectives of the Clinical Trials Regulation are relevant in the EU/EEA **today**?

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* To simplify and streamline the assessment processes, reduce administrative burden for sponsors by establishing one single set of rules directly applicable in all EU/EEA countries for the processing of clinical trial applications	○	○	○	○	○	◉
* To improve information-sharing between Member States and foster collaboration on safety assessment	◉	○	○	○	○	○
* To increase transparency of information on clinical trials for the public	◉	○	○	○	○	○
* To reduce administrative burden by establishing a single, common IT system across EU/EEA countries	○	○	○	○	○	◉
* To conduct clinical trials that protect the rights, safety, dignity and well-being of clinical trial subjects and generate reliable and robust data that are useful for the later steps in the life cycle of medicines	◉	○	○	○	○	○

3 To what extent do you agree each of the following objectives of the Clinical Trials Regulation are relevant in the EU/EEA **in the future (i.e. the next five years)**?

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know

* To simplify and streamline the assessment processes, reduce administrative burden for sponsors by establishing one single set of rules directly applicable in all EU/EEA countries for the processing of clinical trial applications	○	○	○	○	○	◉
* To improve information-sharing between Member States and foster collaboration on safety assessment	◉	○	○	○	○	○
* To increase transparency of information on clinical trials for the public	◉	○	○	○	○	○
* To reduce administrative burden by establishing a single, common IT system across Europe	○	○	○	○	○	◉
* To conduct clinical trials that protect the rights, safety, dignity and well-being of clinical trial subjects and generate reliable and robust data that are useful for the later steps in the life cycle of medicines	◉	○	○	○	○	○

4 To what extent are the following emerging needs or challenges adequately addressed by the Clinical Trials Regulation?

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* Emergence of new technology	○	○	○	○	○	◉
* Emergence of AI	○	○	○	○	○	◉
* Emergence of new trial types	○	○	○	○	○	◉
* Focus on real world evidence	○	○	○	○	○	◉
* Fast-tracking needs in light of public health emergencies	○	○	○	○	○	◉

5 Are there other emerging needs or challenges that the Clinical Trials Regulation does not currently address?

Clinical research is essential for the EU citizens to access innovative treatments and medicines. Medical progress should therefore stay a constant priority of our public health policies. CPME welcomes the efforts made by the Commission to produce a sound legislative framework. Harmonization of the procedures is an important step forward towards less red tape and can be supported.
Ethics committees should be involved in both Parts of the authorisation procedure for a clinical trial; when a substantial modification is applied for by the sponsor; as well as being notified of the results of the safety reporting procedure. Finally, a greater emphasis should be put on the role of Ethics committees in the clinical trials conducted in emergency situations.

Coherence

1 To what extent is the Clinical Trials Regulation coherent (i.e. compatible and consistent) with the following EU legislative and regulatory frameworks:

	Fully coherent	Mostly coherent	Partially coherent	Not coherent at all	Not applicable	I don't know
* Advanced Therapy Medicinal Products (ATMP) Regulation (Regulation (EC) No 1394/2007)	○	○	○	○	○	◉
* Artificial Intelligence Act (Regulation (EU) 2024/1689)	○	○	○	○	○	◉
* Commission Directive on Good Clinical Practice (Directive 2005/28/EC)	○	○	○	○	○	◉
* Commission Directive on Human Tissues (Directive 2004/23/EC)	○	○	○	○	○	◉
* Commission Directive on Pharmacovigilance (Directive 2010/84/EU)	○	○	○	○	○	◉
* Commission proposals for new pharmaceutical legislation (Pharmaceutical Regulation, Pharmaceutical Directive)	○	○	○	○	○	◉
* Community Code on Medicinal Products (Directive 2001/83/EC)	○	○	○	○	○	◉
* Cross-border Healthcare Directive (Directive 2011/24/EU)	○	○	○	○	○	◉
* European Health Data Space (EHDS) (Regulation (EU) 2025/327)	○	○	○	○	○	◉
* General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679)	○	○	○	○	○	◉
* GMO framework (the Contained Use Directive 2009/41/EC and the Deliberate Release Directive 2001/18/EC)	○	○	○	○	○	◉
* Health Technology Assessment (HTA) Regulation (Regulation (EU) 2021/2282)	○	○	○	○	○	◉
* In Vitro Diagnostic Medical Devices Regulation (IVDR) (Regulation 2017/746)	○	○	○	○	○	◉

* Medical Devices Regulation (Regulation (EU) 2017/745)	○	○	○	○	○	◉
* Orphan Medicinal Products Regulation (Regulation (EC) No 141/2000)	○	○	○	○	○	◉
* Regulation on Medicinal products for paediatric use (Regulation (EC) No 1901 /2006)	○	○	○	○	○	◉
* Substances of Human Origin (SoHO) Regulation (EU) 2024/1938	○	○	○	○	○	◉

2 Are there any other EU Regulations, Directives, or frameworks that the Clinical Trials Regulation intersects with?
If so, please describe them and comment on whether you consider these intersections to be coherent or well-aligned with the Clinical Trials Regulation.

3 What are the main issues causing incoherence between the Clinical Trials Regulation and the legal or regulatory frameworks you indicated are 'partially coherent' or 'not coherent at all'?

4 Please list any national measures related to the Clinical Trials Regulation in the country you represent or work in:

5 If you consider any of the national measures you mentioned above to be 'partially coherent' or 'not coherent at all' with the Clinical Trials Regulation, please explain which national measures and why.

Impact

1 To what extent has the Clinical Trials Regulation helped to:

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* Facilitate multinational clinical trials	○	○	○	○	○	◉

* Encourage more innovation and scientific and technological progress	○	○	○	○	○	◉
* Enhance the protection of the rights, safety, dignity and well-being of clinical trial participants	○	○	○	○	○	◉
* Increase EU/EEA attractiveness and competitiveness for conducting clinical trials	○	○	○	○	○	◉
* Increase transparency among Member States	○	○	○	○	○	◉
* Increase collaboration among Member States	○	○	○	○	○	◉

8 To what extent do you agree that:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I don't know
* The Clinical Trials Regulation supports free movement of medicinal products used in clinical trials	○	○	○	○	○	◉
* The free movement of medicinal products used in clinical trials has improved under the Clinical Trials Regulation, when compared to the Clinical Trials Directive	○	○	○	○	○	◉

9 How could the Clinical Trials Regulation be improved to further ensure free movement of medicinal products for human use employed in clinical trials?

-

Implementation

1 In your opinion, how **effective** has the implementation of the Clinical Trials Regulation been at:

effective refers to how well the Clinical Trials Regulation (CTR) achieves its intended goal

	Highly effective	Effective	Neither effective nor ineffective	Ineffective	Highly ineffective	I don't know
* EU/EEA level	○	○	○	○	○	◉
* national level (the country you are based in)	○	○	○	○	○	◉

2 In your opinion, how **efficient** has the implementation of the Clinical Trials Regulation been at:

efficient refers to how well the CTR achieves its purpose using the least time, effort, or resources

	Highly efficient	Efficient	Neither efficient nor inefficient	Inefficient	Highly inefficient	I don't know
* EU/EEA level	○	○	○	○	○	◉
* national level (the country you are based in)	○	○	○	○	○	◉

Administrative costs and burden

1 How have administrative costs related to clinical trial application and/or processing changed for your organisation under the Clinical Trials Regulation, compared to the Clinical Trials Directive (CTD, the previous legislation) in terms of the following costs?

	Decreased by more than 50% compared to under CTD	Decreased by 20 to 50% compared to under CTD	Decreased up to 20% compared to under CTD	Did not change materially compared to under CTD	Increased up to 20% compared to under CTD	Increased by 20 to 50% compared to under CTD	Increased by more than 50% compared to under CTD	I don't know
* Direct financial costs per clinical trial (in Euros)	○	○	○	○	○	○	○	◉
* Human resources costs per clinical trial (e.g. time spent, staff hired/terminated)	○	○	○	○	○	○	○	◉

2 Please provide details of average changes in administrative costs per clinical trial under the Clinical Trials Regulation compared to the Clinical Trials Directive.

- Please record increases in the column labeled “Increase”.
- Please record decreases in the column labeled “Decrease”.

	Increase	Decrease
Euros per clinical trial application/processing		
Staff hours per clinical trial application/processing		
Full time equivalent (FTE) staff required per clinical trial application/processing		

4 Which aspects of the administrative workload could be reduced or simplified without compromising the Regulation's objectives?

Environmental and societal costs

* 1 In your view, how have overall societal costs (e.g. costs on the health care system, patient access to medicines) changed under the Clinical Trials Regulation, compared to the Clinical Trials Directive (CTD, the previous legislation)?

- Decreased by more than 50% compared to under CTD
- Decreased by 20 to 50% compared to under CTD
- Decreased up to 20% compared to under CTD
- Did not change materially compared to under CTD
- Increased up to 20% compared to under CTD
- Increased by 20 to 50% compared to under CTD
- Increased by more than 50% compared to under CTD
- I don't know

* 4 In your view, how have the overall environmental costs (e.g. emissions related to data storage/trial logistics and operations, waste generated during the process, consumption of paper/energy) changed under the Clinical Trials Regulation, compared to the Clinical Trials Directive (CTD, the previous legislation)?

- Decreased by more than 50% compared to under CTD
- Decreased by 20 to 50% compared to under CTD
- Decreased up to 20% compared to under CTD
- Did not change materially compared to under CTD
- Increased up to 20% compared to under CTD
- Increased by 20 to 50% compared to under CTD
- Increased by more than 50% compared to under CTD
- I don't know

Clinical trial applications

1 To what extent has the Clinical Trials Regulation:

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* Simplified the assessment process for clinical trial applications	○	○	○	○	○	◉
* Improved clinical trial approval timelines	○	○	○	○	○	◉
* Made clinical trial approval timelines more predictable	○	○	○	○	○	◉

2 To what extent do you agree with the following statements about the Clinical Trials Regulation (CTR):

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* The CTR harmonised overall timelines to provide better predictability and clarity on the overall process of a clinical trial compared to the Clinical Trials Directive (CTD)	○	○	○	○	○	◉
* The harmonised maximum timelines for submission and approval of clinical trials help to facilitate the submission and processing of clinical trial applications	○	○	○	○	○	◉
* The CTR improved how quickly trials are initiated across multiple countries compared to the CTD	○	○	○	○	○	◉

3 To what extent do you agree that the timelines set in the Clinical Trials Regulation are adhered to by:

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know

* National Competent Authorities	○	○	○	○	○	◉
* Ethics Committees	○	○	○	○	○	◉
* Sponsors	○	○	○	○	○	◉

4 How consistent are processes across EU/EEA countries for the following stages of a clinical trial application under the Clinical Trials Regulation?

	Highly consistent	Consistent	Somewhat consistent	Inconsistent	Highly inconsistent	I don't know
* Submission of applications	○	○	○	○	○	◉
* Validation of applications	○	○	○	○	○	◉
* Assessment of applications	○	○	○	○	○	◉
* Authorisation of applications	○	○	○	○	○	◉

Collaboration between ethics committees

1 From your perspective, to what extent do ethics committees across EU/EEA countries vary in:

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* Responsibilities	○	○	○	○	○	◉
* Resources	○	○	○	○	○	◉
* Capacity	○	○	○	○	○	◉

Data generation

* 1 Overall, to what extent do you agree the Clinical Trials Regulation has improved the evidence generated for research and development (i.e. improved reliability and robustness), when compared to the Clinical Trials Directive?

- ○ To a large extent
- ○ To a moderate extent
- ○ To some extent
- ○ To a small extent
- ○ Not at all
- ◉ I don't know

2 To what extent have the following aspects of the Clinical Trials Regulation allowed for the generation of more reliable and robust clinical trial data:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I don't know
* The possibility to have a common authorisation for multinational trials	○	○	○	○	○	◉
* The streamlining of overall application procedures through the coordinated assessment	○	○	○	○	○	◉

Artificial Intelligence in clinical trials

An AI system is a computer-based technology that can use data to make predictions, recommendations, or decisions that affect real or digital environments. Unlike traditional software, AI can learn, reason, or adapt rather than just follow fixed rules. It may work automatically or with human input, and it can keep improving after it has been deployed. AI systems can be used on their own or as part of another product, such as software built into medical devices or online tools.

1 Which administrative procedures/documents do you **currently use** AI tools for, in part or whole?

	Yes	No	I don't know
* Preparation of clinical trial protocol	○	○	◉
* Preparation of investigator brochure	○	○	◉
* Preparation of monitoring plan	○	○	◉
* Preparation of clinical trial application	○	○	◉
* Preparation of regulatory authority submissions	○	○	◉
* Preparation of ethics committee submissions	○	○	◉
* Preparation of informed consent forms	○	○	◉
* Preparation of annual safety report	○	○	◉
* Preparation of validation report	○	○	◉
* Assessment of clinical trial application	○	○	◉
* Validation checks	○	○	◉
* Consolidation	○	○	◉
* Assessment report preparation	○	○	◉

2 To what extent **would** the following administrative procedures/documents benefit from AI support?

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* Preparation of clinical trial protocol	○	○	○	○	○	◉
* Preparation of investigator brochure	○	○	○	○	○	◉

* Preparation of monitoring plan	○	○	○	○	○	◉
* Preparation of clinical trial application	○	○	○	○	○	◉
* Preparation of regulatory authority submissions	○	○	○	○	○	◉
* Preparation of ethics committee submissions	○	○	○	○	○	◉
* Preparation of informed consent forms	○	○	○	○	○	◉
* Preparation of annual safety report	○	○	○	○	○	◉
* Preparation of validation report	○	○	○	○	○	◉
* Assessment of clinical trial application	○	○	○	○	○	◉
* Validation checks	○	○	○	○	○	◉
* Consolidation	○	○	○	○	○	◉
* Assessment report preparation	○	○	○	○	○	◉

3 Which administrative procedures do you **currently use** AI tools for, in part or whole?

- ☐ Review of clinical trial protocol
- ☐ Review of investigator brochure
- ☐ Review of informed consent forms
- ☐ Other procedures (please specify)
- ☐ I don't use AI

5 To what extent **would** the following administrative procedures benefit from the use of AI tools?

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* Review of clinical trial protocol	○	○	○	○	○	◉

* Review of investigator brochure	○	○	○	○	○	◉
* Review of informed consent forms	○	○	○	○	○	◉

6 Please specify what other administrative procedures would benefit from the use of AI:

7 What is the impact of using AI in your work on the following:

	Large positive impact	Small positive impact	No change	Small negative impact	Large negative impact	I don't know	I don't use AI
* Resources	○	○	○	○	○	◉	○
* Time saving	○	○	○	○	○	◉	○
* Consistency of documentation	○	○	○	○	○	◉	○
* Increased predictability of the assessments	○	○	○	○	○	◉	○

* 8 What size cost reduction do you think is possible by better uptake of AI in clinical trial application/assessment procedures?

- ○ Large reduction
- ○ Small reduction
- ○ No change
- ○ Small increase
- ○ Large increase
- ◉ I don't know

Uptake of digitalisation

1 Which of the following digital tools have you **used** in a clinical trial in the EU?

- ☐ e-consent
- ☐ Wearables
- ☐ Remote monitoring
- ☐ Remote source data verification
- ☐ Telemedicine
- ☐ Other (please specify)
- ☐ Not applicable
- ☑ I don't know

3 Which of the following digital tools have you **assessed for use** in a clinical trial in the EU?

- ☐ e-consent
- ☐ Wearables
- ☐ Remote monitoring
- ☐ Remote source data verification
- ☐ Telemedicine
- ☐ Other (please specify)
- ☐ Not applicable
- ☑ I don't know

5 Which of the following digital tools are you **aware are being used** in a clinical trial in the EU?

- [ ] e-consent
- [ ] Wearables
- [ ] Remote monitoring
- [ ] Remote source data verification
- [ ] Telemedicine
- [ ] Other (please specify)
- [ ] Not applicable
- [x] I don't know

7 To what extent can the following digital tools help improve access to clinical trials?

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
* e-consent	○	○	○	○	○	◉
* Wearables	○	○	○	○	○	◉
* Remote monitoring	○	○	○	○	○	◉
* Remote source data verification	○	○	○	○	○	◉
* Telemedicine	○	○	○	○	○	◉

8 Please specify which other digital tools could help improve access to clinical trials:

All Clinical trials should be registered in the EU database prior to their start. Sharing the results and making them available to the public is a matter of trust in medical research. While CPME shares the view that commercially confidential information is critical to pharmaceutical companies, CPME insists that all results, whether they are positive, negative or inconclusive, should be made publicly available. This includes Phase I trials data which are currently not made public.

9 What impact do digital tools have on clinical trials in the EU with regard to the following aspects?

	Large positive impact	Small positive impact	No change	Small negative impact	Large negative impact	I don't know	Not applicable
* Data quality	○	○	○	○	○	○	◉
* Patient recruitment and/or retention	○	○	○	○	○	○	◉
* Time requirements	○	○	○	○	○	○	◉
* Cost requirements	○	○	○	○	○	○	◉

Patient safety

1 Overall, to what extent do you agree with the following statements:

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know	Not applicable
* The Clinical Trials Regulation has improved the safety of clinical trials	○	○	○	○	○	○	◉
* The Clinical Trials Regulation has simplified safety reporting	○	○	○	○	○	○	◉
* The coordinated review introduced by the Clinical Trials Regulation has an added value in terms of safety	○	○	○	○	○	○	◉
* The more detailed guidelines for informed consent introduced by the Clinical Trials Regulation help increase safety	○	○	○	○	○	○	◉

2 Please elaborate on your answers on patient safety given above:

CPME urges that any revision of the Clinical Trials Regulation to recognise ethical standards in early-stage and pre-clinical development, as well as in clinical trials, as key to patient safety, as enshrined in the WMA Declaration of Helsinki and Declaration of Taipei. While respecting Member States' prerogatives on ethics, CPME calls for alignment with the high standards of the Clinical Trials Regulation. It stresses the need to maintain these standards, ensure effective implementation, and promote transparency through financial support to the biotechnology sector.
Regarding the clinical trials conducted outside the Union, CPME is concerned about the weak guarantees on patient safety. EU trials include very often countries from all over the world. More should be said on multinational trials, and more should be proposed to protect the patients, otherwise, this might be seen as encouraging a two-tier system of research ethics.
Qualified medical doctors have the necessary scientific skills and experience to be aware of the risks and inconveniences of a clinical trial. Thanks to their training, knowledge and experience, medical doctors have the required ethical insight for the good conduct of trials. CPME strongly advocates for the protection of patients and fears that without a broad recognition of the role of medical doctors in the conduct of the clinical trials, patient safety would be at stake. The inclusion of physicians in the assessing team of the application for a clinical trial is therefore more than necessary. Physicians should also be the ones informing the subjects before they give consent of the objectives, risks and inconveniences of the trial.

3 What challenges remain for patient safety under the Clinical Trials Regulation?

CPME strongly believes that priority should always be given to the safety, rights and well-being of the individual. This priority should prevail over all other interests. The World Medical Association Declaration of Helsinki on Ethical principles for medical research involving human subjects puts in its Article 6 the well-being of the subject on the forefront. This is however not taken into account in the preparation of this legislation. CPME calls on the well-being of the patient to be included to the Act, as well as its prevalence over all other interests.
The WMA Declaration of Helsinki (https://www.wma.net/policies-post/wma-declaration-of-helsinki/) and Declaration of Taipei (https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/) set out ethical principles for medical research underlining that rights, interests, and well-being of research participants must always take precedence over scientific and societal interests. This provides an ethical anchor for methodological choices to maintain high standards in clinical trials and ensure effective implementation of the CTR.

Clinical Trial Information System

* 1 Overall, how has the Clinical Trials Information System (CTIS) affected the administrative burden for your organisation compared to EUDRACT?

- ○ Substantially decreased administrative burden
- ○ Slightly decreased administrative burden
- ○ No change
- ○ Slightly increased administrative burden
- ○ Substantially increased administrative burden
- ○ My organisation does not use CTIS
- ◉ I don't know

* 2 How acceptable is the administrative burden associated with the CTIS considering the objectives of the Clinical Trials Regulation?

- ○ Completely unacceptable
- ○ Somewhat unacceptable
- ○ Neither acceptable nor unacceptable
- ○ Somewhat acceptable
- ○ Completely acceptable
- ◉ I don't know

3 To what extent do you agree with the following statements about the Clinical Trials Information System (CTIS) (compared to EUDRACT):

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I don't know
* The CTIS public portal has helped increase transparency on the conduct and results of both ongoing and completed clinical trials.	○	○	○	○	○	◉
* The CTIS increases transparency by making clinical trial information and data more easily available.	○	○	○	○	○	◉
* The training, guidance, and user support services provided to assist sponsors and authorities in fulfilling the transparency obligations set out in the Clinical Trials Regulation are useful (e.g. regarding the protection of personal data and commercially confidential information).	○	○	○	○	○	◉
* The CTIS reduces fragmentation by enabling a single submission and coordinated assessment process for clinical trial applications across EU/EEA countries.	○	○	○	○	○	◉
* The CTIS reduces complexity of applications for multinational clinical trials across EU/EEA countries.	○	○	○	○	○	◉
* The CTIS harmonises assessment processes for applications for multinational clinical trials.	○	○	○	○	○	◉
* The CTIS can handle the complexity of multinational trials.	○	○	○	○	○	◉

4 To what extent do you agree with the following statements regarding the CTIS:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I don't know
* The information allows you to avoid duplication of clinical trials	○	○	○	○	○	◉

* The information allows you to avoid repetition of unsuccessful trials	○	○	○	○	○	◉
* The information allows you to identify areas where more research is needed	○	○	○	○	○	◉
* The information allows you to evaluate and monitor clinical trials	○	○	○	○	○	◉
* The information allows researchers to understand how to tailor new research based on previous experience and lessons learned	○	○	○	○	○	◉

5 Is there information that would be useful to you that the CTIS does not provide currently?

6 What kind of impact has CTIS had on the following processes (compared to EUDRACT):

	Substantially improved	Moderately improved	Not changed	Moderately worsened	Substantially worsened	I don't know
* the overall application process for clinical trials	○	○	○	○	○	◉
* operational efficiency of managing multinational trials	○	○	○	○	○	◉
* compliance reporting processes across different EU /EEA countries	○	○	○	○	○	◉
* the speed and efficiency of trial approvals and monitoring	○	○	○	○	○	◉
* ensuring data accuracy and completeness	○	○	○	○	○	◉
* user-friendliness	○	○	○	○	○	◉

7 To what extent do you agree the following aspects of the CTIS have helped simplify the clinical trial application system:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I don't know
* The revised CTIS transparency rules from 18 June 2024	○	○	○	○	○	◉
* The new version of the CTIS public portal	○	○	○	○	○	◉
* The rationalising of the amount of documents published	○	○	○	○	○	◉
* The removal of the deferral mechanism for every trial category	○	○	○	○	○	◉

Decentralised trials

1 To what extent does the Clinical Trials Regulation support decentralised clinical trials?

- ○ To a large extent
- ○ To a moderate extent
- ○ To some extent
- ○ To a small extent
- ○ Not at all
- ◉ I don't know

2 How has the situation for decentralised clinical trials under the Clinical Trials Regulation changed compared to the situation under the Clinical Trials Directive?

- ○ Substantially improved
- ○ Moderately improved
- ○ Not changed
- ○ Moderately worsened
- ○ Substantially worsened
- ◉

I don't know

5 To what extent do digital tools and decentralised clinical trials enable broader access to the following types of clinical trials?

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
Paediatric trials	○	○	○	○	○	◉
Trials for participants with decreased mobility	○	○	○	○	○	◉
Cross-border clinical trials	○	○	○	○	○	◉

7 To what extent do digital tools contribute to:

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
Reduction in time for recruitment of participants	○	○	○	○	○	◉
Smaller attrition rate	○	○	○	○	○	◉
Access to untapped patient populations	○	○	○	○	○	◉
Overall shortening of the clinical trial	○	○	○	○	○	◉

Low-intervention trials

1 To what extent does the Clinical Trials Regulation support low-intervention clinical trials?

- ○ To a large extent
- ○ To a moderate extent
- ○ To some extent
- ○ To a small extent
- ○ Not at all
- ◉ I don't know

2 To what extent does the Clinical Trials Regulation support low-intervention clinical trials through:

	To a large extent	To a moderate extent	To some extent	To a small extent	Not at all	I don't know
Simplified procedures	○	○	○	○	○	◉
Reduced administrative burden	○	○	○	○	○	◉
Reduced scrutiny regarding monitoring	○	○	○	○	○	◉
Reduced scrutiny regarding requirements for the contents of the master file	○	○	○	○	○	◉
Reduced scrutiny regarding traceability of investigational medicinal products	○	○	○	○	○	◉

3 How would you describe the situation for low-intervention clinical trials under the Clinical Trials Regulation compared to the situation under the Clinical Trials Directive?

- ○ Substantially improved
- ○ Moderately improved
- ○ Not changed
- ○ Moderately worsened
- ○ Substantially worsened
- ◉ I don't know

Added value

1 To what extent do you agree that a common EU-level Clinical Trials Regulation has added value compared to the Clinical Trials Directive which had to be transposed into national law by Member States?

- ◉ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○

I don’t know

2 Can you explain what the added value of the Clinical Trials Regulation is?

Survey close

1 If you have any further comments to add on the application of the Clinical Trials Regulation, please share them below. Please feel free to include links to websites or publications on this topic.

To clarify that the geographical scope of organisation if regional – European, we selected the option ‘International’ because it would require to select a level of governance which doesn’t apply to us.

We will input on 'Collaboration between ethics committee' in a separate statement.

Please see CPME position on the deployment of AI in healthcare - sector specific challenges: https://www.cpme.eu/api/documents/adopted/2024/11/cpme_ad_09112024_073.final.policy.on.deployment.of.ai.in.healthcare.pdf

https://www.cpme.eu/api/documents/adopted/2025/10/cpme.2025-175.final.response.questionnaire.biotech.act.pdf

https://www.cpme.eu/api/documents/adopted/2025/05/cpme.2025-092.final.statement.biotech.act.pdf

https://www.wma.net/policies-post/wma-declaration-of-helsinki/

2 Please upload or provide details of any relevant resources (e.g. publications, reports) that would be useful for the Commission’s report on the application of the Clinical Trials Regulation.

Only files of the type pdf,doc,docx,odt,txt,rtf are allowed

0afbc997-b3ac-4461-9ca6-55472eb8412b/cpme.2025-092.final.statement.biotech.act__1_.pdf
cdedc0bd-fe0b-46bc-a27e-2d8f72c90a19/cpme.2025-175.final.response.questionnaire.biotech.act__1_.pdf
615cb0a4-ca94-49a9-854b-45b835882184/cpme_ad_09112024_073.final.policy.on.deployment.of.ai.in.healthcare.pdf

Background Documents

Data Protection Notice - Targeted Survey

Endorsement Letter - HaDEA

Contact

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