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.

Proposed draft amendments to the Commission's Proposal for a Biotech Act regulation

The CPME response to the European Commission questionnaire on the Biotech Act may be accessed here, the CPME statement on this matter may be accessed here and the CPME response to the European Commission Clinical Trials Study Survey may be accessed here.

Amendment 1	
Recital 139, page 62	
Text Proposed by the Commission	**CPME Proposed Amendment**
(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for vulnerable populations, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.	(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for ~~vulnerable~~ populations **in situations of particular vulnerability**, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of ~~vulnerable~~ populations **in situations of particular vulnerability**, in this context, such as **incapacitated** subjects, minors**,** ~~and~~ pregnant or breastfeeding women **and elderly**, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki **and Declaration of Taipei regarding research involving health data**.
Justification	
We propose to rephrase the wording of vulnerable populations to populations in situations of particular vulnerability throughout the proposal, in line with the WMA Declaration of Helsinki[1]. Also, elderly people should also be considered in the context of populations in situations of particular vulnerability. A reference to the WMA	

[1] https://www.wma.net/policies-post/wma-declaration-of-helsinki/, last accessed on 18 February 2026.

Declaration of Taipei regarding research involving health data should also be made in this provision.	
Amendment 2	
Article 58 Biotech Act, pages 125-126 Amendments to Regulation (EU) No 536/2014	
Text Proposed by the Commission	**CPME Proposed Amendment**
Article 5 – Submission of an application the following Articles 5a and 5b are inserted: Article 5b Validation of Part I of the application dossier Validation of Part I of the application dossier 1. Within seven days from the submission date, the reporting Member State shall validate Part I of application dossier referred to in Article 6 and notify the sponsor, through the EU portal, of the following: (a) whether the clinical trial applied for falls within the scope of this Regulation; (b) whether the application dossier is complete in accordance with Part I of Annex I; (c) whether it confirms that the clinical trial is a minimal-intervention or a low- intervention clinical trial, respectively, if such a claim was made by the sponsor. 2. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 1, the clinical trial applied for shall be deemed to fall within the scope of this Regulation and the application dossier shall be considered complete and, if applicable, the clinical trial shall be considered a minimal-intervention or low-intervention clinical trial. 3. Where the reporting Member State finds that the application dossier is not complete, or that the clinical trial applied for does not fall within the scope of this Regulation, or, if applicable, has doubts whether the clinical trial is a minimal-intervention or low-intervention clinical trial, the reporting Member State shall:	Article 5 – Submission of an application the following Articles 5a and 5b are inserted: Article 5b Validation of Part I of the application dossier Validation of Part I of the application dossier 1. Within seven days from the submission date, the reporting Member State shall validate Part I of application dossier referred to in Article 6 and notify the sponsor, through the EU portal, of the following: (a) whether the clinical trial applied for falls within the scope of this Regulation; (b) whether the application dossier is complete in accordance with Part I of Annex I; (c) whether it confirms that the clinical trial is a minimal-intervention or a low- intervention clinical trial, respectively, if such a claim was made by the sponsor. ~~**2. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 1, the clinical trial applied for shall be deemed to fall within the scope of this Regulation and the application dossier shall be considered complete and, if applicable, the clinical trial shall be considered a minimal-intervention or low-intervention clinical trial.**~~ **2. The reporting Member State shall involve its competent ethics committee in the assessment pursuant to (1) (c).** 3. Where the reporting Member State finds that the application dossier is not complete, or that the clinical trial applied for does not fall within the scope of this Regulation, or, if applicable, has doubts whether the

(a) inform the sponsor thereof through the EU portal and shall set a deadline of maximum seven days for the sponsor to comment on the application or to complete the application dossier through the EU portal; (b) within seven days from the submission of the comments or the completed application dossier referred to in point (a) notify the sponsor as to whether or not the application complies with the requirements set out in paragraph 1 points (a), (b) and (c). In case the reporting Member State requests the sponsor to comment on the application pursuant to this paragraph, the period referred to in paragraph 1 may be extended by a maximum of 14 days. 4. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 3, point (b), the clinical trial applied for shall be deemed to fall within the scope of this Regulation, the application dossier shall be considered complete in accordance with Part I of Annex I and the clinical trials is deemed to be a minimal-intervention or a low-intervention clinical trial, if claimed by the sponsor. 5. Where the sponsor has not provided comments or completed the application dossier within the period referred to in paragraph 3, point (a), the application shall be deemed to have lapsed in all Member States concerned.	clinical trial is a minimal-intervention or low-intervention clinical trial, the reporting Member State shall: (a) inform the sponsor thereof through the EU portal and shall set a deadline of maximum seven days for the sponsor to comment on the application or to complete the application dossier through the EU portal; (b) within seven days from the submission of the comments or the completed application dossier referred to in point (a) notify the sponsor as to whether or not the application complies with the requirements set out in paragraph 1 points (a), (b) and (c). In case the reporting Member State requests the sponsor to comment on the application pursuant to this paragraph, the period referred to in paragraph 1 may be extended by a maximum of 14 days. ~~**4. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 3, point (b), the clinical trial applied for shall be deemed to fall within the scope of this Regulation, the application dossier shall be considered complete in accordance with Part I of Annex I and the clinical trials is deemed to be a minimal-intervention or a low-intervention clinical trial, if claimed by the sponsor.**~~ 5. Where the sponsor has not provided comments or completed the application dossier within the period referred to in paragraph 3, point (a), the application shall be deemed to have lapsed in all Member States concerned. In the case of investigator-initiated clinical trials, the sponsor may, before the expiry of the period referred to in paragraph 3, point (a), request a duly justified extension of that period. The reporting Member State shall assess the request and may grant a reasonable extension where justified by the non-commercial nature of the trial and the organisational constraints of the sponsor. During the granted extension, the application shall not be considered to have lapsed in the Member States concerned.

Justification
If the reporting Member State has not notified the sponsor within the period referred to in paragraph 3, point (b), the clinical trial applied for shall not be deemed complete and, for preserving patient safety, cannot be considered neither complete nor automatically considered minimal-intervention or a low-intervention clinical trial, if claimed by the sponsor. Consequently, point 2 and 4 of the provision should be deleted. Aso, assessing whether a clinical trial falls within the scope of Regulation (EU) No 536/2014 or whether it is a low-intervention or minimal-intervention clinical trial requires clinical and pharmacological expertise and is one of the key tasks of the responsible ethics committee. Against this background, in line with the mandatory involvement of the reporting Member State's ethics committee in the assessment of Part 1 of the assessment report, it should also be ensured that the reporting Member State's competent ethics committee is involved in the validation of Part 1 of the assessment report. This requires sufficiently long deadlines. Furthermore, strict and non-flexible deadlines, coupled with automatic lapsing of applications, may disproportionately affect investigator-initiated clinical trials, which are typically conducted by academic sponsors with limited administrative and regulatory support compared to commercial sponsors. Without the possibility to request a justified extension, such provisions risk discouraging independent, publicly driven research and reducing the diversity of clinical evidence generated within the Union.

Amendment 3

Chapter IV, Extension of the supplementary protection certificate
Article 27 Biotech Act, page 94

Text Proposed by the Commission	CPME Proposed Amendment
Article 27 **Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union** 1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:	~~**Article 27**~~ ~~**Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union**~~ ~~**1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:**~~

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union; (b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease; (c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States; (d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.	~~(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;~~ ~~(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;~~ ~~(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;~~ ~~(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.~~
Justification	
There are already incentives for innovation in the context of the revised general pharmaceutical legislation, and there should not be a new incentive (12 months) in the Biotech Act on top of the total protection that companies already enjoy. The European Commission's study on the legal aspects of Supplementary Protection Certificates in the EU showed the inefficacy of Supplementary Protection Certificates. Moreover, creating an additional year of protection would delay the entry of generics and biosimilars, resulting in additional pressure on healthcare budgets. Consequently, this provision should be deleted.	
Amendment 4	
Article 58(1) Biotech Act, page 122 **Amendments to Regulation (EU) No 536/2014**	
Text Proposed by the Commission	**CPME Proposed Amendment**
Article 2, Clinical Trials Regulation, point 21 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards;'	Article 2, Clinical Trials Regulation, point 21 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards;'

	Where informed consent is obtained through electronic systems, methods or processes, such systems shall be designed to reflect the continuous and evolving nature of informed consent. They shall ensure that the subject is able to review, modify and withdraw consent at any time in a manner that is as simple and accessible as the act of giving consent.'
Justification	
Informed consent should not be reduced to a one-time administrative act, particularly in the context of clinical trials involving vulnerable groups. It must instead be viewed as a living, dialogical process that evolves alongside the participant's circumstances and the progression of the study. By embedding reversibility and participant engagement into the digital consent process, we can ensure that clinical trial acceleration does not come at the expense of ethical standards.	
Amendment 5	
Article 58(2) Biotech Act, page 124 Amendments to Regulation (EU) No 536/2014	
Text Proposed by the Commission	**CPME Proposed Amendment**
'Article 3 *General principles* 1. A clinical trial may be conducted only if: (a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests; and (b) it is designed to generate reliable and robust data. 2. Member States concerned shall cooperate closely and efficiently to ensure the effective and timely application of the provisions of this Regulation. 3. Member States shall take into account whether a clinical trial is a minimal-intervention or low-intervention clinical trial and, where this is the case, adapt the regulatory requirements throughout the lifecycle of such clinical trial, in particular with regard to the application dossier, the authorisation procedures, the safety reporting and oversight.'	*'Article 3* *General principles* 1. A clinical trial may be conducted only if: (a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests, **in line with the Declaration of Helinski and the Declaration of Taipei**; and (b) it is designed to generate reliable and robust data. 2. Member States concerned shall cooperate closely and efficiently to ensure the effective and timely application of the provisions of this Regulation. 3. Member States shall take into account whether a clinical trial is a minimal-intervention or low-intervention clinical trial and, where this is the case, adapt the regulatory requirements throughout the lifecycle of such clinical trial, in particular with regard to the application dossier, the authorisation procedures, the safety reporting and oversight.'
Justification	
There should be a reference to both Declarations of Helsinki on ethical principles for medical research involving human participants, including research using identifiable human material or data, recently revised in October 2024. This Declaration is the internationally accepted standard for designing, conducting, recording and reporting clinical trials. The Declaration of Helsinki underlines, among others, that the rights, interests, and well-being of research participants must always take precedence over scientific and societal interests.	

Also, it's also worth referring to the Declaration of Taipei[2] on Ethical Considerations regarding Health Databases and Biobanks extends the ethical rules into virtual spaces and thus is highly relevant for developments in conventional and especially new avenues of research.

Amendment 6

Article 58(e), page 122
Amendments to Regulation (EU) No 536/2014

Text Proposed by the Commission	CPME Proposed Amendment
Amendment to article 2 of the Clinical Trials Regulation point (21) is replaced by the following: '(21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards;'	Amendment to article 2 of the Clinical Trials Regulation point (21) is replaced by the following: '(21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of **and having understood** all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards; **Patients and participants shall be made explicitly aware of their rights, the scope of data usage, and their ability to withdraw consent at any time.**'

Justification

The purpose of this addition is to emphasise that informed consent is not satisfied merely by the provision of information. The ethical and legal standard requires that the information be communicated in a manner that enables the individual subject to understand what is relevant and necessary for him or her in order to make an autonomous and well-considered decision. This clarification becomes particularly important in the context of electronic informed consent procedures, as envisaged in the Commission's proposed amendment. While electronic systems may facilitate documentation and accessibility, they also risk reducing the consent process to a formal or technical exercise unless explicit attention is paid to the requirement of genuine understanding. The proposed CPME amendment aligns with the standard articulated in the Declaration of Helsinki, which states: "After ensuring that the potential participant has understood the information, the physician or another qualified individual must then seek the potential participant's freely given informed consent, formally documented on

[2] https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/, last accessed on 18 February 2026.

paper or electronically. If the consent cannot be expressed on paper or electronically, the non-written consent must be formally witnessed and documented. Also, it is essential that patients and participants are made explicitly aware of their rights, the scope of data usage, and their ability to withdraw consent at any time.
Amendment 7
Article 35 (1) f) of Regulation (EU) 536/2014, existing legislation

	CPME Proposed Amendment
/	~~**(f) the clinical trial poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.**~~

Justification
The Declaration of Helsinki requires that interventions involving patients who are unable to give consent must either promise direct individual benefit <u>or</u> involve only minimal risks and burdens (Article 28, '… is likely to either personally benefit them or if it entails only minimal risk and minimal burden'). The current Art. 35 however requires that these criteria are both fulfilled (see Art. 35 (1) lit.b and f)) and is thus stricter than the Declaration of Helsinki. Measures that involve only minimal risks and burdens and still promise clinically relevant benefits are rare in the care of emergency patients who are unable to give consent, who are often seriously ill and require surgical care and/or intensive medical treatment. The restriction included in letter f makes inclusion of many emergency patients in clinical trials considerably more difficult and counteracts efforts to obtain reliable study results in this sensitive area. Lit. f) should therefore be deleted.
Amendment 8
Article 83 of the Clinical Trials Regulation, page 156

Text Proposed by the Commission	
Article 83 is replaced by the following: 'Article 83 Competent authorities and ethics committees 1. Member States shall designate one national contact point to which they confer responsibility for the implementation and practical application of this Regulation. The Commission shall publish a list of national contact points. 2. Each Member State shall communicate the contact point referred to in paragraph 1 to the Commission. Member States shall ensure that competent authorities and ethics committees: (a) have the necessary powers to perform all the	

necessary regulatory actions and inspections, pursuant to this Regulation. (b) have, or have access to, a sufficient number of suitably qualified and experienced personnel, human and financial resources, operational capacity, and expertise, including technical expertise, for the effective and efficient performance of their tasks they have been made responsible for pursuant to this Regulation.';	
Justification	
We welcome this provision on Member States shall ensuring that competent authorities and ethics committees are adequately resourced and have the necessary experts and financial resources for the performance of their activities.	
Amendment 9	
Article 83a for the Clinical Trials Regulation, pages 156-157	
Text Proposed by the Commission	**CPME proposed amendment**
Communication and coordination between competent authorities and between ethics committees. 1. Where more than one competent authority and ethics committee are responsible for performing regulatory activities or inspections in a Member State for the purpose of applying this Regulation, Member States shall ensure efficient and effective coordination among all the competent authorities and ethics committees concerned in order to guarantee the consistency and effectiveness of the regulatory activities or inspections performed on their territory. 2. Within those Member States, the competent authorities shall cooperate with each other. They shall communicate information to each other for the effective implementation of the regulatory activities and inspections provided for in this Regulation.	Communication and coordination between competent authorities and between ethics committees. 1. Where more than one competent authority and ethics committee are responsible for performing regulatory activities or inspections in a Member State for the purpose of applying this Regulation, Member States shall ensure efficient and effective coordination among all the competent authorities and ethics committees concerned in order to guarantee the consistency and effectiveness of the regulatory activities or inspections performed on their territory. **In such coordination, ethics committees shall be involved on equal terms with competent authorities. Coordination mechanisms shall not be used to override or unduly influence the ethical review of an ethics committee.** 2. Within those Member States, the competent authorities shall cooperate with each other. They shall communicate information to each other for the effective implementation of the regulatory activities and inspections provided for in this Regulation**, and shall share all relevant information with ethics committees necessary for the performance of their**

	ethical review functions. **Member States shall ensure that ethics committee are adequately resourced, have appropriate multidisciplinary composition, and robust conflict-of-interest rules to enable them to perform their functions independently and effectively.**
Justification	
Ethics committees shall be involved on equal terms with competent authorities. Coordination mechanisms shall not be used to override or unduly influence the ethical review of an ethics committee. Also, Ethics Committees should be adequately resource and this should be reflected in this provision.	
Amendment 10	
Article 85 of the Clinical Trials Regulations, page 157	
Text proposed by the Commission	**CPME proposed amendment**
Article 85 is replaced by the following: 'Article 85 Clinical Trials Coordination and Advisory Group 1. A Clinical Trials Coordination and Advisory Group (CTAG) is hereby established. 2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence. 3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant.	Article 85 is replaced by the following: 'Article 85 Clinical Trials Coordination and Advisory Group 1. A Clinical Trials Coordination and Advisory Group (CTAG) is hereby established. 2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence. 3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant.

4. The CTAG shall use its best endeavors to reach consensus. If such consensus cannot be reached, the CTAG shall decide by a majority of its members. Members with diverging positions may request that their position and the grounds on which they are based are recorded.	4. The CTAG shall use its best endeavors to reach consensus. If such consensus cannot be reached, the CTAG shall decide by a majority of its members. Members with diverging positions may request that their position and the grounds on which they are based are recorded.
5. The CTAG shall in particular have the following tasks: (a) to support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Regulation;	5. The CTAG shall in particular have the following tasks: (a) to support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Regulation;
(b) to assist the Commission in providing the support referred to in the second paragraph of Article 84; (c) to prepare recommendations on criteria regarding the selection of a reporting Member State;	(b) to assist the Commission in providing the support referred to in the second paragraph of Article 84; (c) to prepare recommendations on criteria regarding the selection of a reporting Member State;
(d) to provide strategic steering on a common approach for the application of this Regulation and on the support of the clinical trials ecosystem in the Union;	(d) to provide strategic steering on a common approach for the application of this Regulation and on the support of the clinical trials ecosystem in the Union;
(e) to contribute to the development of guidance aiming to ensure effective and harmonised implementation of this Regulation.	(e) to contribute to the development of guidance aiming to ensure effective and harmonised implementation of this Regulation.
(f) to contribute to the development of guidelines on the use of the artificial intelligence models and systems in clinical trials in accordance with Article [xx] Regulation (EU) .../... [European Biotech Act]*;	(f) to contribute to the development of guidelines on the use of the artificial intelligence models and systems in clinical trials in accordance with Article [xx] Regulation (EU) .../... [European Biotech Act]* **and in collaboration with scientific experts and healthcare professionals**;
(g) to provide advice, either of its own initiative or at the request of the Commission, in the assessment of any issue related to the implementation of this Regulation;	(g) to provide advice, either of its own initiative or at the request of the Commission, in the assessment of any issue related to the implementation of this Regulation;
(h) to contribute to harmonised administrative practice with regard to clinical trials in the Member States;	(h) to contribute to harmonised administrative practice with regard to clinical trials in the Member States;
(i) to provide a recommendation before setting up a regulatory sandbox.	(i) to provide a recommendation before setting up a regulatory sandbox.
6. The CTAG shall be chaired by a representative of the	

Commission. The chair shall not take part in votes of the CTAG. 7. The CTAG may issue recommendations and opinions on matters related to clinical trials and shall endorse any guidance related to the application of this Regulation. The Commission shall publish the guidelines endorsed by the CTAG. 8. The CTAG shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State. Any item of the agenda of the meeting shall be placed at the request of the Commission or a Member State. 9. The secretariat shall be provided by the Commission. 10. The CTAG shall draw up its rules of procedure. The rules of procedure shall be made public.	6. The CTAG shall be chaired by a representative of the Commission. The chair shall not take part in votes of the CTAG. 7. The CTAG may issue recommendations and opinions on matters related to clinical trials and shall endorse any guidance related to the application of this Regulation. The Commission shall publish the guidelines endorsed by the CTAG. 8. The CTAG shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State. Any item of the agenda of the meeting shall be placed at the request of the Commission or a Member State. 9. The secretariat shall be provided by the Commission. 10. The CTAG shall draw up its rules of procedure. The rules of procedure shall be made public.
Justification	
We welcome this inclusion to the Clinical Trials Coordination and Advisory Group to contribute to the development of guidelines on the use of the artificial intelligence models and systems in clinical trials. Such guidelines should be developed in close collaboration with scientific experts and healthcare professionals.	
Amendment 11	
Chapter V, Enhancing Competitiveness in Biosimilars Article 28, page 95	
Text proposed by the Commission	**CPME proposed amendment**
Guidance by the Agency on biosimilars The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	**Guidance by the Agency on biosimilars** The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. ~~**The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.**~~ **Any regulatory flexibility or guidance shall not compromise the robustness of the evidence base of**

	biosimilar development and approval.
Justification	
There shall not be a potential reduction of the clinical data required for the development and approval of biosimilars. Clinical data remain pivotal to ensure quality, safety and efficacy of biosimilars. Any regulatory flexibility or guidance shall not compromise the robustness of the evidence based supporting of biosimilar development and approval and this provision should be revised accordingly.	
Amendment 12	
Chapter V, Enhancing Competitiveness in Biosimilars Article 29, page 95	
Text proposed by the Commission	**CPME proposed amendment**
Biotechnology health strategic projects for biosimilars To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars only where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)] and fulfil either of the following conditions: (a) they contribute to the setting up and extension of innovative biomanufacturing capacity, and infrastructures for analytical testing procedures; (b) they contribute to the research, development and marketing authorisation of biosimilars, and where appropriate to strengthening the use of platform technologies; this includes analytical methodologies that would reduce the need for clinical data for biosimilars, without affecting their quality, safety and efficacy.	**Biotechnology health strategic projects for biosimilars** To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars only where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)] and fulfil either of the following conditions: (a) they contribute to the setting up and extension of innovative biomanufacturing capacity, and infrastructures for analytical testing procedures; (b) they contribute to the research, development and marketing authorisation of biosimilars, and where appropriate to strengthening the use of platform technologies; this includes analytical methodologies that would reduce the need for clinical data for biosimilars, without affecting their quality, safety and efficacy. **(c) they contribute to a more equitable and affordable access of patients to the medicines they need and overall to having more sustainable healthcare systems.**
Justification	
Biosimilars that result from biotechnology health strategic projects should contribute to a more equitable and affordable access of patients to the medicines they need and overall to having more sustainable healthcare systems. Consequently, this should be reflected in this provision.	

Amendment 13	
Article 85 of the Clinical Trials Regulations, page 150	
Text proposed by the Commission	**CPME proposed amendment**
(30) in Article 33, the following second paragraph is inserted: 'Women who become pregnant or begin breastfeeding while participating in a clinical trial shall not be automatically excluded from participation in the clinical trial.'	(30) in Article 33, the following second **and third** paragraph is inserted: **(2)** 'Women who become pregnant or begin breastfeeding while participating in a clinical trial shall not be automatically excluded from participation in the clinical trial.' **(3) 'The responsible inclusion of pregnant or lactating women should be considered systematically, and their exclusion must be justified'** **(4) 'The protection of groups in situations of particular vulnerability shall be ensured in accordance with the principles set out in the Declaration of Helsinki.** **(5)In the assessment and approval of clinical trials, particular attention shall be paid to persons who are less able to protect their own interests. The acceleration of trial approval procedures shall not, under any circumstances, compromise the safety, dignity, or rights of those vulnerable groups.'**
Justification	
Principal investigators and sponsors should systematically consider the inclusion of pregnant or lactating women in clinical trials and formally justify any exclusion. This provision should be interpreted in the context of Article 33(a) ('the clinical trial has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved', *in* Regulation 536/2014, Clinical Trials Regulation). While protecting the health of women and their embryos, fetuses, or children remains paramount, over-protection that limits access to beneficial research is recognised as potentially detrimental. Encouraging responsible inclusion can facilitate more clinical trials involving pregnant or lactating women, particularly for new indications of existing medicinal products for which real-world safety data are available. Also, the protection of vulnerable research participants — such as children, incapacitated persons, and pregnant women — must be legally enforceable through an article, not merely outlined in a recital. While a recital expresses intent, an article creates a binding obligation. This distinction is critical in the context of accelerated clinical trials, where the risk of deprioritizing vulnerable groups may increase.	

Amendment 14	
CHAPTER VI, ARTIFICIAL INTELLIGENCE AND DATA AS BIOTECHNOLOGY ENABLERS, Article 31, page 96	
Text proposed by the Commission	**CPME proposed amendment**
Guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products 1. The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring. Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office. Such guidance shall ensure full coherence with the requirements laid down in Regulation (EU) 2024/1689 and with any guidance issued under that Regulation regarding general-purpose AI models or AI systems. 2. In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders as appropriate. To the extent that the guidance concerns the deployment and use of systems based on advanced technologies, including AI, across the clinical trials lifecycle, the Agency shall further cooperate with the Clinical Trials Coordination [and Advisory] Group ('CTAG') referred to in Article [85] of Regulation (EU) No 536/2014, with the Medical Device Coordination Group ('MDCG') referred to in Article 103 of Regulation (EU) 2017/745 and with the Artificial Intelligence Board referred to in Article 65 of Regulation (EU) 2024/1689, as appropriate and shall publish that guidance in agreement with the consulted entities referred to in this subparagraph. 3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced technologies, including AI, in the procedures for the authorisation of	**Guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products** 1. The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring. Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office. Such guidance shall ensure full coherence with the requirements laid down in Regulation (EU) 2024/1689 and with any guidance issued under that Regulation regarding general-purpose AI models or AI systems. 2. In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders as appropriate. To the extent that the guidance concerns the deployment and use of systems based on advanced technologies, including AI, across the clinical trials lifecycle, the Agency shall further cooperate with the Clinical Trials Coordination [and Advisory] Group ('CTAG') referred to in Article [85] of Regulation (EU) No 536/2014, with the Medical Device Coordination Group ('MDCG') referred to in Article 103 of Regulation (EU) 2017/745 and with the Artificial Intelligence Board referred to in Article 65 of Regulation (EU) 2024/1689, as appropriate and shall publish that guidance in agreement with the consulted entities referred to in this subparagraph. 3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced technologies, including AI, in the procedures for the authorisation of

medicinal products.	medicinal products. 4. The guidance referred to in paragraphs 1 to 3 shall ensure that, where systems based on advanced technologies, including artificial intelligence, are used in the lifecycle of medicinal products, appropriate human oversight is maintained. In particular, doctors and patients shall remain appropriately involved in the oversight of AI-assisted analysis, taking into account their experiential and contextual knowledge to ensure that outputs are accurate, reliable, and contextually meaningful. (5) The guidance shall ensure that systems based on advanced technologies, including artificial intelligence, incorporate appropriate safeguards for data security and traceability. Such safeguards shall enable data to be traced back to their original context and to the individuals – both experts and participants – who generated them. It ensures that the data retain their meaning and validity throughout the research process. (6) The guidance shall promote the establishment of a governance framework for the responsible use of systems based on advanced technologies, including artificial intelligence. That framework shall ensure transparency, context preservation and meaningful human oversight, with a view to preventing the generation or use of outputs that may be unreliable or harmful.
Justification	
The use of AI throughout the lifecycle of biotech products, including clinical research, introduces significant challenges in terms of transparency, oversight, and the preservation of context. Current amendments to the Clinical Trials Regulation do not address the implications of AI in participant selection, data interpretation, and decision-making processes. AI should accelerate progress in healthcare, but this can only happen if it is used responsibly and ethically. Addressing these issues is crucial to ensuring that AI contributes meaningfully to better health outcomes while maintaining public trust.	