Stellungnahme des Bundesverbands Medizinischer Auftragsinstitute e.V. (BVMA) zum Biotech Act I

9. März 2026

Einleitung

Der BVMA wurde im Juli 1991 als Vertretungsorgan der in Deutschland tätigen CROs (Contract Research Organisations) gegründet. Mit etwa 50 Mitgliedern im Bereich klinische Forschung repräsentieren die Mitgliedsfirmen mit ihren etwa 8.000 Mitarbeitern mehr als 80% der Beschäftigten im deutschen CRO-Markt. In der klinischen Forschung werden Aktivitäten zu etwa 60% „outgesourct", so dass der BVMA ein wesentlicher Interessensvertreter in diesem Bereich darstellt. Im Bereich Industrie-initiierter Studien werden 80-90% der klinischen Studien mit Beteiligung von CROs durchgeführt.

Mit dem im Dezember 2025 vorgelegten Vorschlag für einen **European Biotech Act I** setzt die Europäische Kommission ein wichtiges Signal zur Stärkung der Biotechnologie in Europa. Angesichts des intensiven internationalen Wettbewerbs um Innovation, Investitionen und klinische Forschung ist es dringend erforderlich, die regulatorischen und strukturellen Rahmenbedingungen für biomedizinische Forschung und Entwicklung in der Europäischen Union weiter zu verbessern.

Der vorliegende Entwurf greift zentrale Herausforderungen auf und enthält insbesondere für die klinische Forschung Ansätze, die geeignet sind, die Attraktivität des Studienstandorts Europa zu erhöhen. Dazu zählen unter anderem Maßnahmen zur Verkürzung von Genehmigungsfristen, zur stärkeren Harmonisierung zwischen den Mitgliedstaaten sowie zur Verbesserung der regulatorischen Koordinierung.

Gleichzeitig zeigt die praktische Erfahrung der vergangenen Jahre, dass bestehende Defizite im europäischen Regulierungsrahmen – insbesondere im Zusammenhang mit der **Verordnung über klinische Prüfungen (CTR)** und der **Medizinprodukteverordnung (MDR) sowie der In-vitro-Diagnostika-Verordnung (IVDR)** – nur begrenzt durch punktuelle Anpassungen einzelner Regelungen behoben werden können. Um Europa im globalen Wettbewerb um klinische Forschung wieder stärker zu positionieren, sind daher über einzelne Korrekturen hinausgehende Verbesserungen erforderlich.

Vor diesem Hintergrund begrüßt der BVMA die Zielrichtung des European Biotech Act ausdrücklich. Entscheidend wird nun sein, die angekündigten Maßnahmen zügig umzusetzen und dabei sicherzustellen, dass regulatorische Verfahren in der Praxis tatsächlich effizienter, verlässlicher und stärker harmonisiert werden. Nur so kann Europa seine Wettbewerbsfähigkeit als Standort für klinische Forschung und biotechnologische Innovationen nachhaltig stärken.

Vorschläge des BVMA

Wie in der Einleitung erwähnt, bewertet der BVMA die Initiative für einen European Biotech Act als überaus positiv. Gleichzeitig sehen wir in einzelnen Bereichen weiterhin erhebliches Verbesserungspotenzial, um die praktischen Abläufe klinischer Forschung in der Europäischen Union effizienter, harmonisierter und international wettbewerbsfähiger zu gestalten.

Aus unserer Sicht sollten im weiteren Gesetzgebungsprozess insbesondere folgende Punkte berücksichtigt werden:

- **Weitere Verkürzung der Validierungs- und Bewertungsfristen für Studienanträge**
  Die vorgeschlagenen Verkürzungen der Fristen für Validierungs- und Bewertungsphasen stellen zwar einen wichtigen Fortschritt dar. Um jedoch international wettbewerbsfähige regulatorische Zeitabläufe zu gewährleisten – insbesondere im Vergleich zu den Vereinigten Staaten – sollte eine Verkürzung der Genehmigungsfristen für **multinationale** klinische Prüfungen von derzeit 106 Tagen auf **60 Tage** (statt wie aktuell vorgesehen 75 Tage) einschließlich Validierung und Ethikbewertung vorgesehen werden. Für klinische Prüfungen, die nur in **einem Mitgliedstaat** durchgeführt werden, sollte angestrebt werden, dass Validierung und Bewertung eines Antrags grundsätzlich innerhalb von **30 Kalendertagen** nach Einreichung abgeschlossen werden

- **Weitere Stärkung der Rolle des berichterstattenden Mitgliedstaats**
  Der berichterstattende Mitgliedstaat sollte eine klar stärkere koordinierende Rolle einnehmen. Wenn Elemente der ethischen Bewertung nicht mit den geltenden regulatorischen Anforderungen vereinbar oder nicht angemessen und verhältnismäßig sind, um die Sicherheit der Versuchspersonen sowie die Verlässlichkeit und Robustheit der Studiendaten zu gewährleisten, sollten diese nicht in den Bewertungsbericht aufgenommen werden. Ebenso sollten Stellungnahmen anderer betroffener Mitgliedstaaten unberücksichtigt bleiben können, wenn sie zu Widersprüchen oder redundanten Bewertungen führen. Es kann auch nicht sein, dass RFIs aus den beteiligten Mitgliedsstaaten unkonsolidiert und teilweise in Landessprache einfach an den Antragsteller geschickt werden.
  Auch im Rahmen der Part-II-Assessments könnte die Rolle des berichterstattenden Mitgliedstaats weiter gestärkt werden. Eine stärkere Koordinierung auf europäischer Ebene würde dazu beitragen, nationale Unterschiede zu reduzieren und die Konsistenz der Bewertungen zu verbessern.

- **Unterstützung des berichterstattenden Mitgliedstaats**
  Die Rolle des berichterstattenden Mitgliedsstaats wird gemäß dem aktuellen Entwurf des EU Biotech Act zwar aufgewertet, ohne diesem aber „Hands-on“ Unterstützung zur Verfügung zu stellen. Die CTAG-Rolle ist nur beratend und die Rolle der EMA ist aktuell begrenzt auf die Bereitstellung eines funktionierenden CTIS-Systems. Ein

Wissenschaftliches Sekretariat bei der EMA könnte dem berichterstattenden Mitgliedsstaat Unterstützung bereitstellen

- **Bessere Koordination von Part I- und Part II-RFIs**
  Eine engere Abstimmung von Requests for Information (RFIs) im Rahmen der Part-I- und Part-II-Bewertung ist dringend erforderlich. Derzeit führen parallele oder zeitlich versetzte Rückfragen häufig zu Verzögerungen und zusätzlichem administrativen Aufwand für Sponsoren. Insbesondere sollten Part I RFIs nicht Part II RFIs nachgelagert sein, um z.B. wiederholte Protokollupdates und damit verbundene zeitliche Verzögerungen zu vermeiden

- **Reduzierung der betroffenen Mitgliedsstaaten, die reviewen**
  Bei multinationalen Studie mit mehr als zwei beteiligten Mitgliedsstaaten sollten nur zwei Mitgliedsstaaten den Part I (perspektivisch natürlich auch den Part II) bewerten müssen. Das würde viele Ressourcen sparen und die Möglichkeit einer weiteren Verkürzung der Reviewzeiten ermöglichen. Es muss das Ziel der EU sein, Redundanzen zu vermeiden, Harmonisierung voranzutreiben und damit als eine Region wahrgenommen zu werden. Es stellt sich die Frage, warum bei einer klinischen Prüfung mit 10 Mitgliedsstaaten alle 10 dasselbe prüfen und reviewen. Das macht diese Prüfung nicht besser und sicherer.

- **Verbesserung von Funktionalität und Nutzerfreundlichkeit des CTIS**
  Das Clinical Trials Information System (CTIS) ist ein zentrales Instrument für die Umsetzung der europäischen Studienregulierung. Seine Funktionalität und Anwenderfreundlichkeit müssen jedoch dringend verbessert werden, damit das System den üblichen digitalen Standards entspricht und den administrativen Aufwand für alle Beteiligten reduziert.

- **Förderung von KI, Digitalisierung und regulatorischen Sandkästen für innovative Studienansätze**
  Der Entwurf des EU-Biotech Act setzt wichtige Impulse für KI-gestützte Innovationen, etwa durch Leitlinien der EMA zu KI-basiertem Studiendesign und zur Datenanalyse. Gleichzeitig fehlen bislang harmonisierte europäische Standards für zentrale digitale Prozesse wie elektronische Einwilligung (eConsent), digitale Studiendokumentation oder dezentrale Studiendurchführung. Ohne solche Rahmenbedingungen besteht die Gefahr, dass strategische Förderansätze und die praktische Umsetzung innovativer Studienmethoden auseinanderfallen.

- **Präzisierung der Definition „wesentliche Änderung“ in Artikel 2 Absatz 13 der Verordnung (EU) Nr. 536/2014**
  Die Definition sollte auf Änderungen beschränkt werden, die erhebliche negative Auswirkungen auf die Sicherheit oder Rechte der Studienteilnehmer oder auf die Zuverlässigkeit und Robustheit der Studiendaten haben, also Änderungen, die das Nutzen-Risiko-Verhältnis verschlechtern. Eine solche Klarstellung würde die schnellere Umsetzung sicherheitsrelevanter Anpassungen außerhalb dringender Sicherheitsmaßnahmen ermöglichen und gleichzeitig betriebliche Anpassungen erleichtern. Änderungen infolge unerwarteter Ereignisse sollten weiterhin als **Urgent Safety Measures (USM)** gemeldet werden, während Änderungen mit neutralem oder positivem Einfluss auf das Nutzen-Risiko-

Verhältnis gemäß Artikel 81.9 als **Non-Substantial Modifications (NSM)** gemeldet werden könnten.

- **Einheitliche europäische Vorlagen und Templates**
  Die Europäische Kommission könnte zusätzlich zur Harmonisierung beitragen, indem sie standardisierte europäische Vorlagen bereitstellt, beispielsweise für Einwilligungserklärungen oder Vertragsmuster. Dies würde den administrativen Aufwand reduzieren und die Durchführung multinationaler Studien erleichtern.

Zusätzliche Ausführungen und weitergehende Empfehlungen inklusive konkreter Vorschläge zur Anpassung des Wortlauts des Biotech Acts haben wir in der nachfolgenden Tabelle zusammengefasst. Diese Punkte wurden in englischer Sprache verfasst, da es um detaillierte Empfehlungen zur Änderung oder Ergänzung des Wortlauts des Entwurfs des Biotech Act I geht, der derzeit auf Englisch vorliegt.

Part of the proposal	**Comment**
Article 58 of the EU biotech act, Amendment to Regulation (EU) 536/2014	
Page 60 recital 132	Recital 132 should be supplemented with the following: *"If the part II assessment of translated part I documents might lead to part I related RFI considerations, it should be ensured that the assessment reports will be coordinated to avoid part II considerations that will have impact on part I documents after the part I assessment has been completed."*
Article 5b (1) (Validation)	It must be ensured that, if substantive considerations are made at this stage, reference can be made to the forthcoming assessment of the relevant part (Part I or Part II) in order to respond to the considerations, as seven days may be too short a period to respond to requests for information, for example to obtain updated site documents.
Article 6 (2), review by the ethics committee	The new Article 6 (2) *"The reporting Member State shall draw up an assessment report. The assessment of the aspects referred to in paragraph 1 shall constitute Part I of the assessment report.* *The ethics committee of the reporting Member State shall review, from the ethical perspective, aspects covered by Part I of the assessment report. That ethical review shall complement the scientific and regulatory assessment and shall cover Part I of the application dossier in order to evaluate whether the subjects' rights, safety and well-being are being ensured in the clinical trial."* should be supplemented with the following: *If elements of the ethical review are not in accordance with the law of the Member State concerned or are not in accordance with the Regulation (EU) 536/2014 or are not in accordance with the Regulation (EU) 2016/679 or are not appropriate and proportionate to ensure the safety of the subject and the reliability and robustness of the data generated in the clinical trial then the*

	reporting Member State shall not consider these element for the assessment report. The rationale is: We have seen requests from ethics committees that showed a misunderstanding of legislation or that where not proportionate to the risk of the clinical trial. It appeared that the competent authorities recognized these deficiencies, but did not dare to ignore such requests. To enable non-consideration of inappropriate requests, the competent authorities have to be empowered to do so. Some of those request might just mean additional workload that is harmless, but others might increase the requirements in a way that impairs the conduct of trials, which could be unethical. One example is that ethics committees enforce for a clinical trial with an authorized medicinal product with a non-critical safety profile the same requirements as for a phase I clinical trial with an experimental medicinal product with an unknown safety profile.
Article 6 (5), consolidation	To the new Article 6 (5), after "*During the consolidation phase, the reporting Member State shall take due account of the considerations of the other Member States concerned and finalise Part I of the assessment report and shall record how all considerations have been dealt with.*" the following should be added: *"The reporting Member State shall omit considerations of the other Member States concerned that cause contradictions or redundancies in the assessment report."* Rationale: In reality, we often receive RFI considerations for Part I that are contradictory or differ from considerations on the same topic. The reporting member state should be instructed and empowered to produce actually consolidated RFIs.
Article 8, decision letter	To the new Article 8 the following new paragraph 3 is added: "*The single decision shall contain the following information:* *The name and address of the ethics committee that was involved in the assessment, list of the members of the ethics committee who were involved in assessing the application, a statement that the ethics committee is organized and operates according to GCP and the applicable regulatory requirements.*" Rationale: ICH E6(R3) is an international standard for clinical trials. Many clinical trials conducted in the EU are conducted by sponsors who are enforced to comply to this standard. Nevertheless, most decision letters do not contain this information, and ethics committees refuse to make it available, by arguing that Regulation (EU) 536/2014 has no provisions for these issues and that publication of list of ethics committee members is not permitted by Regulation (EU) 2016/679. As a consequence, this causes a considerable workload for sponsors who try to ensure that their essential records are compliant with ICH E6(R3). Often, these efforts are futile and

	leave sponsors with the frustrating impression that ICH E6(R3) applies only to them, but not to ethics committees.
Article 14c, combined studies	The wording of the new Article 14c (1) should be modified from *"This Article applies to combined studies in which a clinical trial is combined with a performance study of an in vitro diagnostic medical device that is subject to authorisation pursuant to Article 58(1) of Regulation (EU) 2017/746, or is combined with a clinical investigation of a medical device that is subject to authorisation according to Article 62 of Regulation (EU) 2017/745."* to *This Article applies to combined studies in which a clinical trial is combined with a performance study of an in vitro diagnostic medical device that is subject to authorisation pursuant to Article 58(1) of Regulation (EU) 2017/746 or validation pursuant to Article 66 (7) of Regulation (EU)) 2017/746 or notification pursuant to Article 70 (1) of Regulation (EU)) 2017/746, or is combined with a clinical investigation of a medical device that is subject to authorisation according to Article 62 of Regulation (EU) 2017/745 or validation according to Article 70 (7) of Regulation (EU) 2017/745 or notification according to Article 74 (1) of Regulation (EU) 2017/745.* The rationale is: Not all performance study or clinical investigation are subject to authorization. Combination of regulatory procedures would help to reduce the workload also for performance studies or clinical investigations that are subject to validation or notification procedures.
Article 27a, Core dossier	How will the core dossier be managed in CTIS if different CROs will support different trials of one IMP?
Article 28 (1)	"*Directive 95/46/EC*" should be replaced by "*Regulation (EU) 2016/679*".
Article 81 (10)	The wording "national data protection legislation implementing Directive 95/46/EC" should be replaced by "Regulation (EU) 2016/679".
Article 93, Data Protection	For the sake of harmonization with revision of Regulation (EU) 2017/745 the following should be included in Article 93 of Regulation (EU) 536/2014: *"The processing of personal data in the context of a clinical trial, including the secondary use of personal data initially collected for other studies, shall be deemed to be carried out for scientific research purposes as referred to in Article 9(2), point (j), of Regulation (EU) 2016/679 of the European Parliament and of the Council."*
Annex I, section B, 7	The list of elements to be included in the cover letter template should be shortened drastically. Only information that is not part of the IS submission form should be requested in the cover letter. That fact that Regulation (EU) 536/2014 Annex I, section B, 7 features a long list of elements appears to encourage the Clinical Trials Coordination Group to produce templates of cover letters that grow longer from version to version. It would reduce workload for the sponsor if the same pieces of information would not have to be provided redundantly at different spots in the application.

Annex I, section B, 17	This section about the elements of the clinical trial protocol should be replaced by a reference to Appendix B of ICH E6(R3). This ICH guideline is an international standard and a modernized version is available since 2025. In addition, ICH M11 provides an even more refined set of protocol elements. It would reduce workload for sponsors if they would not have to check their protocols according to the list in Regulation (EU) 536/2014, while the have already checked the protocol according to the list in Appendix B of ICH E6(R3).
Annex I, section M, 64	The following should be deleted: *"64. A list of the planned clinical trial sites, the name and position of the principal investigators and the planned number of subjects at the sites shall be submitted."* Rationale: The sponsor has to enter the clinical trial sites into the Parts II in CTIS already. If a EU member states wants to know which clinical trial sites are participating in the clinical trial, they may consult the online Parts II CTIS sections. If Annex I, section M, 64 was deleted, this would eliminate totally unnecessary sponsor workload. It makes no sense to have the same information redundantly in the application package in CTIS. Concerning the planned number of subjects at the sites: This is just meaningless information. It is impossible to predict the number of subjects. Even if these numbers are presented in a neat table, they are not promoted to be more factful.
Annex I, section N, 67	The following amendment should be added: In Annex I, section N, 67, the wording *"67. A duly justified written statement on the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product and including a description of the suitability of facilities, equipment, human resources and description of expertise, issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned, shall be submitted."* Should be replaced by *"67. A duly justified written statement on the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product and including a description of the suitability of facilities, equipment, human resources and description of expertise, issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned, shall be submitted. For clinical trials investigating authorized medicinal products, a confirmation of the suitability issued by the head of the clinic/institution at the clinical trial site or by some other responsible person is sufficient and no more details about the clinical trial sites should be requested.* *The availability of a deputy of the principal investigator must not be requested."*

	Rationale: We see that in some member states comprehensive suitability documentation is requested for any type of clinical trial. These requests are never "adapted to the nature and use of the investigational medicinal product". In countries like Spain, only a simple statement by the director of the trial site is requested. Although that approach might appear to be too simplistic, we have no knowledge about evidence that clinical trials in Spain show a lower degree of safety of the subjects and a lower reliability and robustness of the data generated in the clinical trial. In absence of evidence that the Spanish approach impairs safety of the subjects and the reliability and robustness of the data we request to follow the Spanish approach. In addition, we see that in Austria and Germany the availability of a deputy of the principal investigator is requested for any type of clinical trials. We agree that for first in human trials or for trials with risky treatments and/or indications there should be a replacement regime for situations when the principal investigator is absent. However, we disagree that this involves inevitably a single person with a qualification similar to that of the principal investigator. The replacement regime could also consist of several persons who collectively have the necessary qualifications and experience of the principal investigator. Finally, if the clinical trial is of low risk (e.g., because the investigational medicinal product is authorized and has a good risk profile or because there is evidence that the application of the investigational medicinal product involves low risks), then no deputy of the principal investigator should be requested at all. In such cases the setting is similar to the regular treatment by a family doctor, who might also have no deputy.
Annex I, section R, 73	"*Directive 95/46/EEC*" should be replaced by "*Regulation (EU) 2016/679*".
Other issues, which are not already part of the Biotech Act but with should be added to it	
Regulation (EU) 536/2014, Definitions	The 'Substantial modification' definition should be specified in more detail (e.g., in the recitals) as we often have discussions what "*substantial impact* on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial" means.
Article 36 Regulation (EU) 536/2014, Notification of the start of a clinical trial	The following amendment should be added: In Article 36, the paragraphs 2 and 3 are deleted. These paragraphs read: *"2. The sponsor shall notify each Member State concerned of the first visit of the first subject in relation to that Member State through the EU portal. That notification shall be made within 15 days from the first visit of the first subject in relation to that Member State.* *3. The sponsor shall notify each Member State concerned of the end of the recruitment of subjects for a clinical trial in that Member State through the EU portal.* *That notification shall be made within 15 days from the end of the recruitment of subjects. In case of re-start of recruitment, paragraph 1 shall apply."*

	Rationale: While the deletion of Articles 36 (2) and 36 (3) would reduce the workload of the sponsor, this deletion would not have any impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial. The workload of the sponsor does not only concern interaction with CTIS but also tracking of the first visits and end of recruitment per country, documentation of the notification in central and local study files. Article 36, paragraph 1
Article 37 Regulation (EU) 536/2014, End of a clinical trial	The following amendment should be added: In Article 37, the paragraphs 1 and 2 are deleted. These paragraphs read: *"1. The sponsor shall notify each Member State concerned of the end of a clinical trial in relation to that Member State through the EU portal.* *That notification shall be made within 15 days from the end of the clinical trial in relation to that Member State.* *2. The sponsor shall notify each Member State concerned of the end of a clinical trial in all Member States concerned through the EU portal.* *That notification shall be made within 15 days from the end of the clinical trial in the last Member State concerned."* Rationale: While the deletion of Articles 37 (1) and 37 (2) would reduce the workload of the sponsor, this deletion does not have any impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial. The workload of the sponsor does not only concern interaction with CTIS but also tracking of end of clinical trial data per country, documentation of the notification in central and local study files. In addition, deletion of Article 37 paragraphs 1 and 2 would resolve an inbuilt-non-compliance. The reason is that for multi-national trials it is often not possible to say whether the patient before the last patient in one country is actually the last patient in that country. It might be, but it also might be that the last patient will be enrolled in one of the other countries. This has often the effect that the end of the trial in most countries is reported later than 15 days after the end of the trial in that country. The same applies for dose escalation trials even in only one EU member state. The remaining Article 37, paragraph 3 (*"The sponsor shall notify each Member State concerned of the end of a clinical trial in all Member States concerned and in all third countries …"*) enables sufficient overview.
Article 37 Regulation (EU) 536/2014, timing for the notification of study results	The following amendment should be added: Article 37 paragraph 4, which reads *"Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial. The content of that summary is set out in Annex IV."*

	is replaced by *"Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned and in all third countries in which the clinical trial has been conducted the sponsor shall submit to the EU database a summary of the results of the clinical trial. The content of that summary is set out in Annex IV."* Rationale: Many clinical trials that are subject to the Regulation (EU) 536/2014 are conducted in EU member states **and** in third countries. If such a trial ends in the EU long before it ends in third countries, the sponsor is enforced to prepare two reports, one that is based on EU results only and one that is based on the results of the whole clinical trial. This makes little sense and increases the workload for the sponsor without increasing the safety of the subjects and the reliability and robustness of the data generated in the clinical trial.
Article 40 Regulation (EU) 536/2014, Electronic database for safety reporting	The following amendment should be added: In Article 40, the paragraph 2 "*The Agency shall, in collaboration with Member States, develop a standard web-based structured form for the reporting by sponsors to the database referred to in paragraph 1 of suspected unexpected serious adverse reactions."* is replaced by: *"The Agency shall, in collaboration with Member States, develop a module of the EU portal that enables reporting by sponsors to the database referred to in paragraph 1 substance reports, product reports and suspected unexpected serious adverse reaction."* Rationale: It puts an enormous burden to sponsors to get access to the EudraVigilance database. This interaction with the EudraVigilance database necessitates the sponsor to have available not only staff that is trained to interact with CTIS but also staff that is trained to interact with EudraVigilance. However, it should be possible to implement a safety module in CTIS that transforms CTIS into "the online system for the regulatory submission, authorisation and supervision of clinical trials in the European Union and the European Economic Area" which the EMA claims it to be.
Article 81 Regulation (EU) 536/2014, non-substantial modifications	The following amendment should be added: In Article 81, the following section 9a should be added: *"9a. The sponsor may update in the EU database information on any changes to the clinical trials that are not substantial modifications and that are not relevant for the supervision of the clinical trial by the Member States concerned. The sponsor may update in the EU database documents that constitute changes to the clinical trials that are not substantial modifications. EU member states concerned shall not be entitled to regard any modification as substantial solely because it is a modification of a document that was subject to authorization."*

	One rationale is that (1) not-substantial modifications are a reality of clinical trials and (2) that Regulation (EU) 536/2014 has no provisions for handling them. Another rationale is that we see EU member states that classify any modification of an investigator brochure as substantial. This approach undermines the very concept of "substantial".
Article 96 Regulation (EU) 536/2014, Repeal	Article 96 should be amended as follows: In Article 96, the following paragraph 3 is added: *"3. Directive 2005/28/EC is repealed as from the date referred to in the second paragraph of Article 99."* Rationale: There is confusion whether Directive 2005/28/EC is still in force or not. https://eur-lex.europa.eu lists it as "in force" while it should no longer be in force.
Payment	The way in which payments are made should be standardized across all member states and must not lead to delays due to validation RFIs e.g., which is true for the e-kolok process in Slovakia.
Medical Devices not assessed for one or more of the purposes as defined in Art. 62 (1) MDR in the context of a clinical trial with a medicinal product	The Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 [dated 16Dec2025] proposes to delete Article 82 MDR. As a consequence, a legal gap would arise for clinical trials where a non-CE-marked medical device or in vitro diagnostic medical device will be used but where the clinical investigation is not carried out as part of the clinical evaluation for conformity assessment purposes, for one or more of the purposes as defined in Art. 62 (1) MDR, insofar as the legal deployment of the medical device as part of the clinical trial would be subject to differing national legislations instead of bringing this aspect under harmonized rules. The same holds true where a device that already bears the CE marking is being used outside of its intended purpose but not being investigated for any of the purposes as defined in Art. 62 (1) MDR. The amended Regulation (EU) 536/2014 should make clear that in such cases any aspects in relation to the safe use of such medical device will be assessed by the Member States as part of the authorization procedure per Regulation (EU) 536/2014.

Schlussbemerkung

Diese Stellungnahme fokussiert auf konstruktive Empfehlungen zur Verbesserung, insbesondere in Ergänzung und Konkretisierung zu jenen der Initiative Studienstandort Deutschland (ISD). Der BVMA trägt die in der Stellungnahme der ISD hervorgehobenen Argumente zur Unterstützung und Priorisierung wichtiger Maßnahmen des EU Biotech Acts mit.

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