Appropriate Designations of the Roles of Sponsor and Sites in Data Processing Agreements (DPA) in Clinical Trial Agreements (CTA)

There is inconsistency across the EU in terms of how Data Protection Supervisory Authorities (SA), medicines and healthcare regulators and agencies, ethics committees, and other parties involved in clinical trials view the roles of Sponsors and Investigators/Sites with respect to what party is independent/joint controller and processor of the trial participant personal data in the context of clinical trials/research. There are currently three approaches followed across the EU depending on the jurisdiction (further jurisdiction specific information available in Appendix A).

1. **Independent Controller –** Sponsor is independent controller of the personal data of participants contained within the trial data. Site is independent data controller of the personal data contained within the participant medical record and trial data.
2. **.Independent Controller/ Processor –** Sponsor is independent controller of the personal data of participants contained within the trial data. Site is the processor for the Sponsor with respect to processing of the personal data of participants contained within the trial data for the purpose of the clinical trial. It is acknowledged within this approach that the Site remains independent controller of the personal data contained within the participant medical record.
3. **Joint Controller –** Sponsor and Site are joint controllers of the personal data of participants contained within the trial data. It is acknowledged within this approach that the Site remains independent controller of the personal data contained within the participant medical record.

The concepts of joint controller, independent controller and processor are defined at an EU level and there is no clear justification for inconsistent application of these concepts in CTA DPAs across Member States in circumstances where the protocol, trial design and the roles of Sponsors and Sites are consistent. The divergent approaches result unjustifiable inconsistencies across the EU in terms of who is independent or joint controller of trial participant data, the need to develop/adhere to and negotiate multiple templates for a single trial in the EU representing a waste of resources, cost and delays in trial initiation activities, ultimately impacting the attractiveness of the EU as a clinical trial destination. This may also expose Sponsors to risk, e.g., should their lead SA make a determination that Site is their processor and they have not implemented Article 28 provisions as required by the GDPR.

Purpose of this Submission

These issues are not new, and we acknowledge the previous efforts made by the International Pharmaceutical and Medical Device Privacy Consortium (IPMPC) in collaboration with the European Federation of Pharmaceutical Industries and Association (EFPIA) to address this at an EU level. However, with the increasing use of new and innovative technologies in clinical studies (e.g. decentralized clinical trial technologies involving the use of participant facing platforms and remote data collection and AI) and the associated complexity in contracting models, the case for a unified EU approach has never been clearer. ACRO is therefore supportive of seeking guidance on this topic at an EU level from the European Data Protection Board (EDPB) geared towards aligning the industry on a harmonized position.

ACRO is seeking to align with the IPMPC with a view to appropriately positioning the issue with EFPIA for the purposes of engaging with the EDPB.

Current Industry Approach

ACRO members have aligned on this topic and have identified independent controllership to be the approach preferred by most large Sponsors and the approach that is generally accepted by Sites. ACRO recognizes the strong arguments in support of both the independent controller, processor and joint controller positions. For example, a trial is often initiated by a Sponsor, and the protocol and CTA often do not grant the Investigator/Site a significant degree of discretion in the categories of personal data that may be processed, or the means of processing (favouring a processor designation for the Investigator/Site). Further, there are circumstances in which a Site/Investigator and Sponsor may jointly determine the categories of data collected or the means of processing in the protocol (favouring a joint controller designation). However, the following factors are persuasive in pursuing the independent controller designation in the majority of CTA DPAs:

- **The regulatory framework for clinical trials imposes independent legal obligations on Sites/Investigators in respect of personal data contained within the trial data, which are inconsistent with processor designation.** These independent regulatory obligations on Investigators are fundamental to both the Clinical Trials Regulation 536/2014 (**CTR**) and the ICH Guideline for good clinical practice E6(R3) adopted on 6 January 2025 (**GCP**). To take just a few examples, under Section 2.12.11, Annex I of GCP: " The Investigator / Institution should have control of all essential records generated by the Investigator / Institution before and during the conduct of the trial." Under the CTR, the purpose of the Investigator's Brochure is to provide the investigators and others involved in the clinical trial with information to facilitate their unbiased risk-benefit assessment of the appropriateness of the clinical trial – this indicates a degree of autonomy and decision-making that is not consistent with processor status. Further examples of these independent obligations on Sites/Investigators in respect of personal data within the trial data are set out at Appendix B. Importantly, these obligations apply to personal data in the CRFs shared with the Sponsor, and these obligations cannot be reconciled with a processor designation.

- **Independent ethical duties of Investigators/Sites to participants.** Investigators, as registered and regulated healthcare professionals, are subject to their own independent legal and ethical obligations in respect of the personal data of participants, such as local laws on participant confidentiality in the UK, or local laws on medical secrecy in France. These ethical obligations of healthcare professionals supersede any contractual obligations that may be imposed on an Investigator/Site by the Sponsor by virtue of a CTA or clinical trial protocol. This is further supported by GCP, which consistently emphasizes the need for Investigator control over personal data within the trial data. This need for Investigator control over the purposes and means of processing is not consistent with a processor designation.
- **Greater protection of the personal data of trial participants.** The core goal of privacy contractual measures between the Sponsor and Site is the protection of the fundamental right to privacy of participants. In the absence of mandatory templates and/or specific local guidance to the contrary, ACRO predominantly observe Sponsors and Sites adopt independent controller contractual positions. This approach appears to ensure greater supervision by SAs of processing operations in multi-centre trials, and therefore greater protection of their fundamental rights. We can apply this to the example of a trial that is sponsored by a Spanish company, where there are Sites in France, the UK and Germany. In this example, in each of France and the UK, the Investigator acts as processor of the Sponsor in respect of trial data (in accordance with local requirements). This approach limits the competence of each of the French and UK SA to fully supervise the processing operations of the Site in their jurisdiction. However, in Germany, the Site is a joint controller together with the Sponsor. This means that the Site falls under the direct supervision of the relevant German SA, including in respect of the processing of trial data by that Site.
- **Practical benefits in documenting obligations to trial participants.** Further, where Sponsors and Sites adopt independent controller contractual positions, this approach appears to best facilitate the inclusion of reasonable privacy obligations on both parties. In particular this approach facilitates the documenting of an appropriate level of cooperation between the Sponsor and Site in protecting the privacy rights of participants in the execution of the clinical trial (e.g. with regards breach reporting and data subject rights), while leaving the Site sufficient autonomy to protect the privacy of its participants in the whole. This approach avoids including potentially conflicting Site obligations as processor acting on behalf of the Sponsor, when in practice, the Sponsor and Site/Investigator collaborate closely as highly regulated and sophisticated parties in (for example) developing the protocol.
- **Lack of consensus.** There is a lack of consensus across the industry and SAs on the GDPR designation of Sites. Across the EU, SAs and local Ethics Committees have taken positions that deviate from the Sponsor as independent controller and Site as processor example provided in the current limited EDPB guidance. In fact, the majority of EU jurisdictions that have issued guidance or mandatory CTA templates on this issue have aligned themselves with the independent controller role designations, indicating that local regulators do not feel they are bound to follow the example in the EDPB guidance. For example, guidance and local practice in Germany, Italy, Netherlands, Greece and Spain designates the Sites as either independent or joint controllers.

- **Supporting rationale for independent controller position in existing Member State guidance.** In seeking to understand the rationale from local jurisdictions for considering that the Sponsor and Site are independent controllers, the guidance from Spain and Italy is particularly helpful. Both jurisdictions agree that the Site is the independent controller of the participants' medical records and trial data, and the Sponsor is the independent controller of the pseudonymized trial participant data generated during the performance of the clinical trial. Both jurisdiction's SAs consider that the sole processor in a clinical trial is the CRO or other third parties who process the personal data contained within the trial data on behalf of the Sponsor. While Germany has adopted the position of being a joint controller (largely due to the perceived common purpose and interdependence between Sponsor and Site with regard to the clinical trial), the remaining rationale coming from that jurisdiction holds true for the independent controller designation also. For example, the idea that the Site must only follow Sponsor's instructions (a requirement of Article 28 GDPR) is at odds with the general principle that the primary duty of the Site is participant care (e.g., the Investigator will make medical decisions independently of the Sponsor and in fact have a legal and ethical obligation to do so). The personal data of individuals, even in the context of the clinical trial, is not exclusively processed for the purposes of that clinical trial but also for medical care.
- **EDPB Guidelines.** In the absence of specific local guidance, it is generally considered that the current limited EDPB guidance leaves sufficient scope for an independent controller interpretation. The guidance indicates that the designation of the Site for clinical trial purposes will be a fact-specific analysis. The facts above are relevant to that analysis and support a position where the Sponsor and Site are independent controllers. Therefore, ACRO considers that it would not be prudent to rely on the EDPB example in isolation, even in the absence of local guidance. The EDBP guidelines have also been subject to strong criticism, further underlining the lack of consensus across the industry on the designation of trial Sites during clinical trials. ACRO agrees with the critique of the current guidance included in the letter by EFPIA and IPMPC to Dr. Andrea Jelinek, Chair of the European Data Protection Board, Re: Guidelines 07/2020 on the concepts of Controller and Processor in the GDPR dated 19 October 2020 (available here).

Factoring in the above, the Sponsor and Site designation of independent controllers reflects the broader/prevalent industry standard on this complex issue. Working with some of the largest pharmaceutical companies in the world, ACRO members are tuned into the positions reached by those companies on this issue, and the approach that is generally accepted by Sites.

Authors and Collaborators

The designation of the roles of Sponsors and Sites in clinical trial data processing agreements has long been a source of inconsistency across EU jurisdictions. Divergent interpretations by regulators, ethics committees, and data protection authorities have led to inefficiencies, delays, and increased compliance risk for trial stakeholders. With the growing complexity of decentralized trials, remote data collection, and AI-driven technologies, these challenges have intensified. In 2025, ICON re-ignited this industry discussion seeking feedback from ACRO, EFPIA and IPMPC committee members before authoring this position paper to advocate for a harmonized EU approach that reduces operational friction, mitigates legal uncertainty, and supports timely clinical trial initiation. By clarifying roles and responsibilities under GDPR, ICON aims to foster alignment across industry bodies and regulators, ensuring that innovation in clinical research is not hindered by fragmented privacy frameworks.

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Appendix A

Country Specific Guidelines – Mandatory Templates

Country	Designation of roles of Sponsor and Site	Mandatory Template or Country Specific Guidelines
	Sponsor independent controller, Site processor of the personal data contained in the trial data.	Mandatory Template
Germany	Joint controller.	Country Specific Guidelines
Spain	Independent controller.	Mandatory Template
Italy	Independent controller.	Mandatory Template
Netherlands	Joint controller.	Mandatory Template - a new draft template CTA currently being considered.
France	Sponsor Independent controller, Site processor.	Mandatory Template
Belgium	Sponsor Independent controller, Site processor.	Mandatory Template
Greece	Most sites consider themselves to be an independent controller – very broad approach. Other sites regard themselves as processor and Sponsor as independent controller.	Mandatory Template - Sponsor to sign off on appropriate template to use.
Denmark	Independent controller.	National template is recommended but due to be made mandatory shortly.
Ireland	Sponsor independent controller, Site processor.	Mandatory template expected to be released shortly.
Austria	Joint controller.	Country Specific Guidelines.
Poland	Sometimes dual roles set out – Site independent controller and PI Sponsor's processor.	Neither.
Portugal	Often see requests for Sites as processor and Sponsor as independent controller.	Neither.

Appendix B

Independent regulatory obligations on Investigators/Sites in connection with clinical trial data under the CTR and GCP

Source	Obligation on Investigator/Sites in connection with clinical trial data
Art.30(4), CTR	The Investigator has an independent obligation to ensure that no data for the clinical trial are collected from individuals that refuse to participate in or have withdrawn from the clinical trial.
Art.47, CTR	The Sponsor *and* the Investigator shall ensure that the clinical trial is conducted in accordance with the protocol and with the principles of good clinical practice – this is a shared responsibility.
Art.49, CTR	The Investigator must be a medical doctor as defined in national law, or a person following a profession which is recognised in the Member State concerned as qualifying for an Investigator because of the necessary scientific knowledge and experience in participant care. This indicates that the Investigator role is a highly regulated and specialised role in its own right, subject to its own complex and independent legal and ethical obligations under national laws.
Art.73, CTR	A principal investigator shall ensure compliance of a clinical trial at a Site with the requirements of the CTR. The principal investigator shall assign tasks among the members of the team of investigators in a way which is not compromising the safety of subjects and the reliability and robustness of the data generated in the clinical trial at that Site. This indicates a significant degree of autonomy and decision-making that is inconsistent with the position of Investigator as a mere processor.
(E) Annex I, CTR	The purpose of the Investigator's Brochure (**IB**) is to provide the investigators and others involved in the clinical trial with information to facilitate their unbiased risk-benefit assessment of the appropriateness of the clinical trial – this indicates a degree of autonomy and decision-making that is not consistent with processor status.

Section 2.3.1, Annex I, GCP	The Investigator may delegate trial-related activities to other persons or parties. The Investigator may be supported by the Sponsor in the identification of a suitable service provider(s); however, the Investigator retains the final decision on whether the service provider intended to support the Investigator is appropriate based on information provided by the Sponsor (see section 3.6.5). This would include where the Investigator delegates trial-related activities involving the processing of personal data. Further, the Investigator (not Sponsor) retains the ultimate responsibility and should maintain appropriate oversight of the persons or parties undertaking the activities delegated to ensure the rights, safety and well-being of the trial participants and the reliability of data. This indicates a significant degree of autonomy and decision-making that is inconsistent with the position of the Investigator as a mere processor.
Section 2.12.2, Annex I, GCP	The Investigator/Site should maintain adequate source records that include all pertinent observations on each of the trial participants under their responsibility. This is an independent obligation on the Investigator/Site, rather than the Sponsor.
Section 2.12.2 and 2.12.5, Annex I, GCP	The Investigator is responsible for ensuring that source records are attributable, legible, contemporaneous, original, accurate and complete. It is also the Investigator that is responsible for defining what is considered to be a source record(s) in the first place, the methods of data capture and their location prior to starting the trial, and the Investigator is required to update this definition when needed. Further, the Investigator is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. This level of decision-making and autonomy is not consistent with processor status.
Section 2.12.5 and 2.12.6, Annex I, GCP	Investigators must endorse any changes or corrections to CRFs – this goes beyond simply following instructions.
Section 2.12.14, Annex I, GCP	Upon request of the ethics committee or regulatory authority, the Investigator/Site should make available for direct access all requested trial-related records. This cannot be blocked by the Sponsor.

Section 2.4.6, Annex I, GCP	The Investigator has independent reporting obligations to ethics committees, including on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.
Section 1.4.8(c), GCP	The Investigator should comply with independent reporting obligations related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the ethics committee.
Section 2.6.2, Annex I, GCP	The Investigator may independently terminate or suspend a trial without Sponsor agreement.
Section 2.12.11, Annex I, GCP	The Investigator / Site should maintain the trial records as specified in Appendix C of GCP and as required by the applicable regulatory requirement(s). The Investigator/Site should have control of all essential documents and records generated by the Investigator/Site before, during, and after the trial.