



IMI2 Project ID 101034366
FACILITATE

FrAmework for Cllnical trlal participants daTA reutilization for a fully Transparent and Ethical ecosystem

WP2 – Legal and Data
Privacy framework

D2.6 Legal clauses

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1. Executive summary

The deliverable D2.6, initially intended to develop legal clauses for investigator contracts to facilitate the return of individual participant data (RoIPD), has been deemed out of scope due to several reasons. Currently, partners returning patient data do not address this in contracts, and the inclusion of such clauses depends on future clarity regarding the RoIPD process. Without a defined process, specific legal clauses cannot be drafted. Instead, the focus will be on guiding sponsors to adopt and implement FACILITATE's principles and ethical frameworks for data return. All EFPIA partners have confirmed their agreement with this decision in writing.

2. Introduction

Deliverable 2.6 (D2.6) was originally conceived to develop legal clauses to be incorporated into contractual agreements among parties conducting clinical trials, particularly between sponsors and investigators or investigational sites. These legal clauses were intended to address roles such as data controllers, processors, or joint controllers in the context of returning individual participant data (RoIPD). However, after an in-depth review of the deliverable's scope and discussions with stakeholders, it has become clear that fulfilling this objective would not align with the core priorities and scope of Work Package 2 (WP2) as originally envisioned.

WP2 was primarily tasked with addressing significant legal and ethical issues related to RoIPD and secondary data use, prioritizing participant rights and harmonizing privacy frameworks across Member States. Based on extensive consultation, including consensus from EFPIA partners, the development of legal clauses for contractual agreements was determined to be outside the scope of WP2. Instead, WP2 currently focuses on providing participant-centric ethical and legal guidance for the RoIPD process. This document details the rationale behind this decision and outlines how WP2's efforts will be realigned to maximize the value of its deliverables while addressing stakeholder needs.

3. Justification for Elimination of Objective [D2.6]

3.1 Misalignment with Core Objectives of WP2

WP2's primary mission is to provide an ethical and legal framework for RoIPD that centers on participant rights and ensures compliance with GDPR and CTR. This includes creating resources such as privacy notices and informed consent forms and aligning regulatory practices across Member States. Developing contractual legal clauses, however, pertains more to internal operational agreements between trial parties, which do not directly impact participant engagement or data rights. Thus, this objective does not align with WP2's participant-centric mandate.

3.2 Focus on High-Level Frameworks Over Operational Specifics

WP2 aims to address overarching legal and ethical challenges related to RoIPD, emphasizing frameworks that can guide diverse stakeholders across Member States. The development of specific

contractual clauses for sponsors and investigators introduces an additional layer of operational complexity and specificity, which detracts from the broader goal of creating universally applicable guidance.

3.3 Complexity Beyond the Mandate of WP2

Developing legal clauses requires evaluating diverse contractual frameworks, jurisdictional requirements, and trial designs, which vary significantly among partners. These differences make it impractical to create a single set of template clauses. Moreover, this level of detail exceeds the scope of WP2, which is focused on delivering broad legal and ethical guidance rather than operational tools for individual partners.

3.4 Consensus Among EFPIA Partners

EFPIA partners have confirmed in writing that they do not anticipate the inclusion of such legal clauses in their current or future contracts. Partners emphasized that the necessity and content of legal clauses would depend on the specific solutions and platforms developed for RoIPD, which will differ among partners. Thus, a standardized approach to legal clauses is not feasible within the current scope of FACILITATE.

3.5 Shifting Priorities to Ethical and Practical Guidance

In lieu of developing legal clauses, WP2 will focus on providing actionable guidance to sponsors for implementing FACILITATE's principles and ethical frameworks. This approach ensures that WP2's deliverables are directly applicable to stakeholders and supports the ethical and participant-centric goals of the FACILITATE project.

4. Re-evaluation of D2.6 convening outcome

As provided, D2.6 requires the development of legal clauses that are to be inserted in investigators' contracts to enable the return of data. To develop this deliverable, WP2 is to draw on expertise from EFPIA partners to develop these legal clauses.

WP2 has discussed this deliverable in detail and has reached consensus in its WP2 bi-weekly meeting on Monday 23 September that D2.6 is out of scope for the following reasons:

- Partners that currently return patient data do not have any legal clauses on the return of patient data in any contract.
- If contracts are to be included in the future, it very much depends on the solution to return of patient data.
- FACILITATE partners are in the process of developing their own platforms that should follow the principles and ethical frameworks provided by FACILITATE, but there will be differences in the implementation of these platforms. As such, if partners were to include legal clauses,

they will differ from partner to partner, and it would not be possible to develop template legal clauses.

- EFPIA partners were clear that the insertion of any legal clauses is not anticipated.

Given these premises, the focus, and indeed the value of FACILITATE, is on providing guidance regarding the uptake and implementation of the principles and ethical frameworks as developed by FACILITATE in the organization of Return of individual participant data processes by sponsors.

5. Agreement with EFPIA partners

All EFPIA partners consulted agreed that developing legal clauses for contractual agreements as part of Deliverable 2.6 falls outside the core scope of the FACILITATE project. However, several partners provided comments that reflect nuances in their positions and insights into potential challenges. Among which:

- The need to emphasize the importance of addressing this requirement through EFPIA to ensure consensus among partners. They noted that without a unified approach, negotiating site contracts individually could become highly challenging.
- One partner pointed out that the need for legal clauses would vary among partners and depend on the final solution adopted for RoIPD and the implementation of individual partner platforms.
- Another partner also supported the exclusion of this objective but highlighted the challenges of implementing legal clauses across partners. They noted that while FACILITATE provides guiding principles and ethical frameworks, differences in how partners develop and implement their own platforms would make it impractical to create standardized legal clauses applicable to all partners.

In summary, while all EFPIA partners agreed to exclude the development of legal clauses from the scope of Deliverable 2.6, several partners emphasized the need for flexibility and partner-specific approaches to legal and contractual matters. These comments underscore the importance of focusing FACILITATEs' efforts on broader ethical and legal frameworks rather than operational details that vary significantly across partners.

6. Conclusion

Deliverable 2.6 has been refocused to align with the priorities of WP2 and the FACILITATE as it has developed over time. Rather than developing specific legal clauses for contractual agreements, WP2 will concentrate on its core mandate of creating a participant-centric ethical and legal framework for RoIPD. This shift ensures that the deliverables remain relevant, actionable, and aligned with the needs of stakeholders while avoiding undue complexity and misalignment with the project's objectives. The FACILITATE consortium, including EFPIA partners, supports this decision, ensuring that WP2's contributions are both impactful and practical in advancing the RoIPD process.