



VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

28–30 January, 2026 – Szeged, Hungary

FP-12

DOI: [10.14232/syrptbrs.2026.71](https://doi.org/10.14232/syrptbrs.2026.71)

Increasing the effectiveness of feasibility through early PI involvement

Dominika Csajbók, Dorina Gabriella Dobó, Ildikó Csóka

Institute of Pharmaceutical Technology and Regulatory Affairs, University of Szeged, Szeged, Hungary



The objective of this study was to examine the impact of the Principal Investigator's (PI) early involvement in the feasibility phase on the efficiency of clinical trial start-up processes and the number and cost of protocol amendments. Amendments to clinical trial protocols are a frequent occurrence and can result in significant financial expenditure [1]. These amendments are often the consequence of an inadequate evaluation of site capabilities, patient population characteristics, and the practical realities of clinical procedures during the initial planning stages [2].

The present research is grounded in a mixed-methodology approach, integrating qualitative interviews with investigators, clinical research associates (CRAs), and sponsor representatives, complemented by the analysis of real-life clinical trial initiation cases. A particular emphasis was placed on identifying feasibility-related gaps that resulted in protocol modifications, delayed recruitment, or site withdrawal.

The study evaluates how structured early PI engagement—including protocol review, patient pathway assessment, and feasibility-driven feedback—can prevent such issues. Findings indicate that involving the PI early significantly improves feasibility accuracy by aligning protocol requirements with real clinical settings [2, 3]. Sites where investigators reviewed protocols during feasibility showed fewer amendments, faster recruitment, and better protocol adherence.

Early PI input also enabled identification of unrealistic inclusion/exclusion criteria, excessive visit burden, and impractical procedures before regulatory submission. This supports the view that feasibility should not be treated as a purely operational task but as a strategic, multidisciplinary process requiring strong clinical leadership. Integrating investigators early allows sponsors to design more realistic protocols, reduce unnecessary amendments, and improve trial efficiency [1, 4].

The study highlights early PI involvement as a key factor in successful and cost-effective clinical trial initiation. The financial and timeline impact of amendments further underlines this need, as amendments are consistently associated with increased cost and delays [5, 6].

References:

1. Getz KA. Protocol amendments and clinical trial performance. *International Journal of Environmental Research and Public Health*. 2014;11(5):5069–5084.



VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

28–30 January, 2026 – Szeged, Hungary

2. Joshi S, et al. Feasibility-driven protocol design and amendment reduction. *Clinical Trials*. 2023;20(4):477–486.
3. Kurbegov D, et al. Early investigator engagement in protocol development. *Journal of Oncology Practice*. 2021;17(12):1020–1028.
4. Bruneau B, et al. Protocol complexity and amendment burden. *Contemporary Clinical Trials Communications*. 2024;28:100876.
5. Applied Clinical Trials. Protocol Amendments: A Costly Solution. *Applied Clinical Trials Online*. 2025. Accessed: 12 Jan 2026.
6. ICON plc. Controlling Complexity for Regulator-Ready Protocols: Impact of Amendments on Cost and Timeline. *Clinical Ops Insights (ICON blog)*. 2025. Accessed: 12 Jan 2026.