Flexible approaches to eCOA administration in clinical trials: The site perspective

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Abstract

The Critical Path Institute convened the Support *Flexible Approaches to PRO Data Collection* project as part of the *eCOA: Getting Better Together Initiative* which was instigated to identify and address common challenges and drive positive change with eCOA implementation in clinical trials.

The project aimed to identify clinical trial stakeholders' concerns related to electronic PRO (ePRO) implementation and propose areas of improvement via simplification and flexibility. One workstream focused on patient-/site-centric approaches for simplification and surveyed representatives of clinical sites and site monitors for their perspectives. A semi-structured questionnaire was developed and distributed via snowball sampling to site professionals and clinical research associates (CRAs) that had ePRO experience who had been identified via representative groups or sponsor-led site networks. Responses were received from various site roles across a range of global regions; the largest contribution was from the United States. Topics raised included helpdesk capabilities, technical concerns, device types, and user interfaces among others and are discussed further in this paper. The feedback derived from the questionnaire provided the basis for concrete ideas that sponsors should consider incorporating into protocol design for participant visits, technology use, devices, and methods of back-up data collection.

Read the full publication here.