ASCO Research Community Forum

Reducing Burdens of Feasibility Assessments for Conducting Clinical Trials

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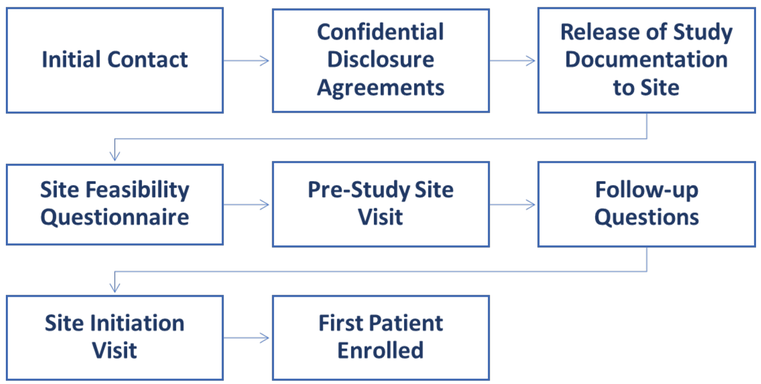
BACKGROUND

Current methods to assess trial site feasibility for clinical trial participation are perceived to be onerous. Figure 1 shows the key elements of the current feasibility assessment process. Industry sponsors and contract research organizations (CROs) often probe for unnecessary and/or duplicative information and requests. There are initiatives underway that aim to streamline these assessments. However, the immediate benefit for trial sites is questionable.

Centralized portals, for example, have potential but have limitations across clinical research scenarios and are facing increasing competition. The inefficiencies and variability across trials will continue to place undue burden on trial sites, particularly those with limited resources. Ultimately, patient access to novel treatments is at risk.

The American Society of Clinical Oncology (ASCO) Research Community Forum Task Force was formed to assess the problem and develop strategies to address feasibility assessment challenges. This initiative provided an opportunity to develop an evidence base and leverage existing momentum in the broader research community to establish more effective approaches for qualifying trial sites.

Figure 1. Current Key Elements of Site Feasibility Assessments



METHODS

Data were collected in 3 initial steps: 1) survey to assess the extent of site burden, 2) database of sample feasibility questionnaires (FQs), and 3) stakeholder meeting to discuss potential solutions. The task force then developed recommended best practices and obtained stakeholder feedback through a survey.

RESULTS

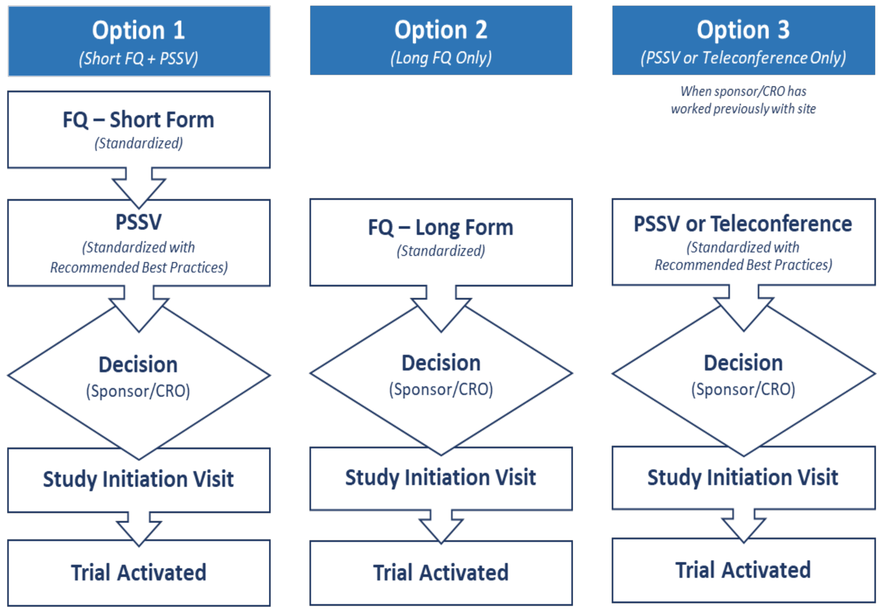
The Burden of Feasibility Assessments

- 113 research sites (66 community, 47 academic) reported completing 11 FQs and 4 pre-study site visits (PSSVs) on average per month. Each FQ took 4 hours and PSSVs took 10 hours on average to complete. All combined, respondents spent 113,904 staff hours on feasibility assessments per year.
- Most considered FQ and PSSV content redundant to information previously provided (81% and 91%, respectively) and FQs were similar between different sponsors (86%).
- Insufficient trial documentation from sponsors and CROs posed challenges for sites completing FQs.
- The time from first contact to first patient enrolled was 7 months on average.

Improving the Feasibility Assessment Process

- There were 40 respondents to stakeholder feedback survey about recommendations for process improvements (Figure 2).
- Respondents represented 19 academic- and 9 community-based sites, 8 industry sponsors, and 4 CROs.
- Most respondents preferred a model with a short FQ plus a PSSV when there was not a prior relationship.
- If there was a prior relationship, a PSSV or teleconference (only) was preferred. CRO respondents were the least supportive of these approaches.

Figure 2. Recommended Feasibility Assessment Process Improvements



FQ = Feasibility Questionnaire | PSSV = Pre-Study Site Visit

- All stakeholders identified time savings, expedited start-up, fewer staff resources, and cost savings as the greatest benefits.
- The greatest barriers to adoption were buy-in from sponsors and CROs and insufficient site information.

CONCLUSIONS

The current approach to identifying and qualifying sites for clinical trials poses a tremendous burden on oncology clinical practice resources. Inefficiencies delay time to enrollment and represent a significant barrier to community site participation in clinical trials. New methods that standardize, harmonize, and streamline site assessment, selection, and activation will expedite clinical trial enrollment, broaden trial access for patients and sites, and reduce costs.