*Category: Trial Start-up and Activation – Completed Project*

**Reducing Burdens of Site Feasibility Assessments for Conducting Clinical Trials**

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**1. Background**

Current methods to assess trial site feasibility for industry-funded clinical trials are onerous. 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 imitations 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 treatment options is at risk.

**2. Goals**

The American Society of Clinical Oncology (ASCO) Research Community Forum convened a task force 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.

**3. Solutions and 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.

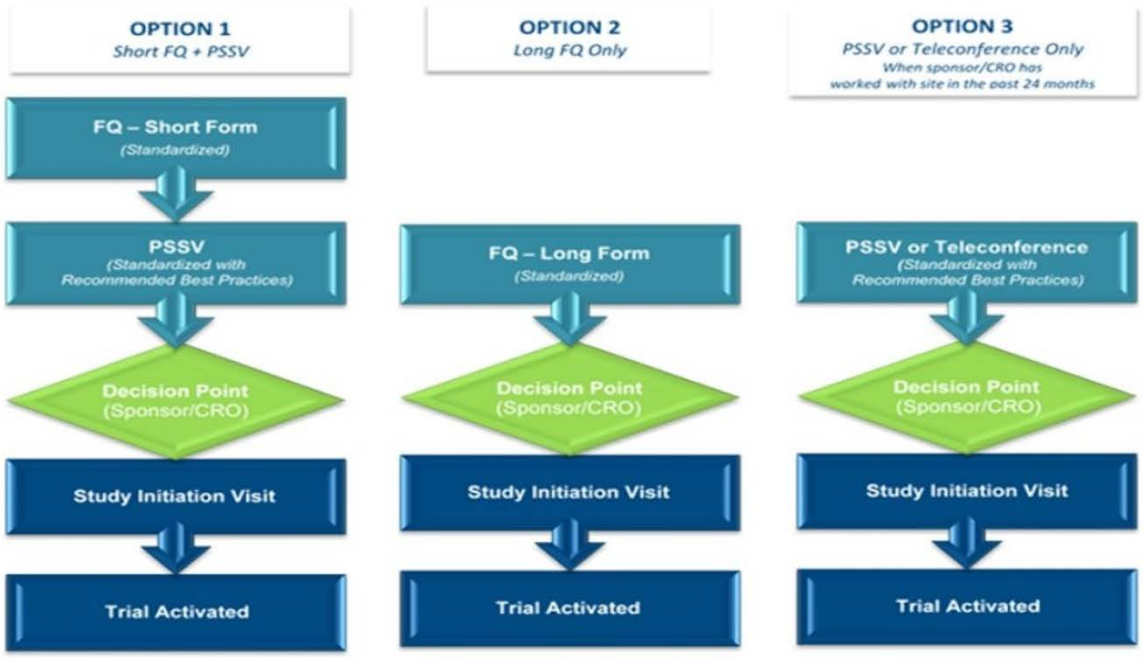
**4. Outcomes**

113 oncology practices (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 similar between different sponsors (86%). Insufficient trial documentation from sponsors and CROs pose challenges for sites completing FQs. The average time from first contact to first patient enrolled was 7 months.

There were 40 respondents to stakeholder feedback survey about recommendations for process improvements (Figure 1). Respondents represented 19 academic- and 9 community-based sites, 8 industry sponsors, and 4 CROs. Most 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. 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.

**Figure 1. Feasibility Assessment Process Improvement Recommendations**




FQ, feasibility questionnaire; PSSV, pre-study site visit; CRO, contract research organization

**5. Lessons Learned**

Site feasibility assessments for industry-sponsored trials are important for all stakeholders. However, current methods are inefficient and time and resource intensive. Patient access to novel treatment options are hindered with trial delays and when sites are unable to participate in clinical trials due to resource constraints. This initiative helped elucidate challenges for sites and provided insights about the viability of a fundamental change with site feasibility assessments. In 2020, ASCO will release formal recommendations to address feasibility assessment burdens, including improving processes, standardizing and minimizing questions, and using portals that are effective across *all* trials and clinical research scenarios.