

The Site Council

Healthy Relationships with Healthy Sites

Site Council Leadership Forum 2026: Synopsis

Session 1: Clinical Trial Study Startup

This session focused on the significant "pain points" encountered during the study startup process. Key issues identified included:

- **Lack of Communication:** Stakeholders frequently suffer from a lack of transparent, timely communication regarding contracts and budgets.
- **Defining "Startup":** Participants disagreed on when startup actually begins, with some citing the feasibility questionnaire and others pointing to site selection or contract execution.
- **Proposed Solution:** The group agreed on the need for a dynamic "roadmap" or timeline created collaboratively by sites, sponsors, and CROs to track responsibilities and milestones.

Session 2: Patient Enrollment

The discussion centered on the gap between projected and actual patient enrollment numbers. Major themes included:

- **Optimistic Projections:** Sites often over-report potential enrollment to secure studies, which negatively impacts the sponsor's resource planning.
- **Protocol Complexity:** Overly restrictive enrollment criteria often make it impossible to find eligible "healthy sick" patients.
- **Proposed Solution:** CROs and sponsors should move beyond simple "how many patients" questions and engage sites earlier in protocol design to ensure feasibility.

Session 3: Rationalizing Technology

This session addressed the overwhelming number of technology platforms sites are forced to use. Key points included:

- **Platform Proliferation:** Sites often have to manage dozens of different systems (EDC, ePRO, IVRS) with redundant training and separate logins.
- **Disrupted Workflow:** Many technologies are implemented without site input, often disrupting clinical workflows and costing sites time and money.
- **Proposed Solution:** Greater use of Single Sign-On (SSO) systems and "concierge" tech support to bridge the accountability gap between vendors and sites.

Session 4: Financial Management and Revenue

Participants discussed how to ensure sites receive the revenue they deserve in a timely manner. Issues included:

- **Hidden Budget Assumptions:** Sponsors often bundle procedure costs into "per-visit" fees, making it difficult for sites to justify higher costs for complex visits.
- **Uncompensated Time:** Significant "coordinator time"—such as chasing patients or answering daily emails—is rarely reimbursed.
- **Proposed Solution:** Adopting a hybrid budget model that uses procedure-based payments during activation and visit-based payments after the first patient is enrolled.

Session 5: Mitigating Study Delays and Cancellations

This session explored the devastating impact on sites when studies are suddenly halted.

- **Financial and Reputational Risk:** Sites may invest millions in pre-screening only to have a study cancelled with minutes of notice, damaging their reputation with local patient communities.
- **Biotech Vulnerability:** Smaller companies are often "funding-dependent," and a negative Phase II result can end a study instantly.
- **Proposed Solution:** Sites should request a 10% non-refundable up-front payment or separate "startup contracts" to cover initial investments before recruitment begins.

Session 6: Identifying and Resolving Pain Points

The final technical session focused on the systemic lack of professional pathways for new researchers.

- **Intolerance for "Naive" Investigators:** The industry often refuses to hire new Principal Investigators (PIs) because they lack experience, yet provides no clear path for them to gain it.
- **Refiner Culture:** The group noted that the industry is often "problem-centric," spending more time identifying what is wrong than implementing improvements.
- **Proposed Solution:** Establishing formal mentorship programs where experienced PIs help "naive" investigators through their first few trials.

Session 7: Foster Mutually Beneficial Relationships?

The Core Problem: Technology Overload and Lack of Input

The primary issues identified by the participants include:

- **Lack of Site Consultation:** Sponsors often implement new technologies (like eConsent or automated health record connections) without consulting the sites that must use them.

- **System Proliferation:** Sites are forced to manage an overwhelming number of platforms (often 5 to 10 per trial), each requiring separate logins, passwords, and redundant training.
- **Workflow Disruption:** Poorly implemented technology often interrupts clinical workflows, leading to "coordinator burnout" and increased costs for the sites.
- **Training Fatigue:** Research staff are often required to complete the exact same training for every new study, even if they have used the system for decades.

Proposed Solutions:

The group brainstormed several actionable solutions to improve technology integration:

- **Standardized Training:** Use "certificates of training" valid for a 12-month period to avoid redundant sessions.
- **Single Sign-On (SSO):** Sponsors and CROs should invest in vendors that offer single sign-on capabilities to reduce the number of credentials coordinators must manage.
- **"Concierge" Tech Support:** Implement human, system-agnostic support roles to bridge the accountability gap between tech vendors and clinical sites.
- **Site Feedback Loops:** Build site feedback into the vendor re-qualification process so sponsors know which technologies sites find most effective.
- **Flexible Licensing:** Shift to enterprise-level licensing for high-demand tools (like EHR-to-EDC connectors) so sites can opt in based on their specific needs rather than an "all or none" approach.

Future Outlook: Transparency and Accountability

The moderator concluded that the industry must move away from seeing sites as a "second thought" in software development. The ultimate goal is to create a "collaborative learning enterprise" where transparency allows stakeholders—up to the CEO level—to see where bottlenecks exist in real-time.

Closing Remarks

The moderator concluded the conference by outlining the next steps for turning these discussions into actionable industry standards.

- **Process Continuation:** All materials will be transcribed and used to create formal "problem/solution" documents to be shared via Google Docs.
- **Available Resources:** The moderator highlighted existing tools on the Site Council website, including 11,000 FDA GCP Q&As, a Fair Market Value calculator, and Clinical Research Terminology Codes.
- **Future Vision:** The ultimate goal is to turn clinical research into a "collaborative learning enterprise" through better transparency and shared best practices.