The Site Council

Healthy Relationships with Healthy Sites

The Site Council Dream

Preamble

The Site Council consists of clinical research sites, site networks, academic medical centers, and health systems that have agreed to speak with a common voice to build a future clinical research enterprise in which study sponsors have healthy relationships with healthy sites. We dedicate ourselves to the professional conduct of clinical research studies and the advancement of the clinical research enterprise. We believe that fruitful collaboration is the shortest path to developing the new medical treatments needed by the peoples of the world. We commit our energy and resources, including those provided by our study sponsors, to conduct clinical studies in a safe, ethical, efficient, high-quality and timely manner. We believe that healthy study sponsor and CRO relationships with healthy sites that meet their commitments to sponsors are in everyone's interest, including patients.

The growing number and complexity of clinical research studies are overwhelming site capacity. The best way to increase capacity is for all parties to work together to increase the productivity and growth of current sites and the formation of new ones.

The increasing complexity of medical treatments, study protocols, technology, regulation, etc., makes it harder and harder for sites to meet their commitments to study sponsors. The industry's cost structure and timelines may be unsustainable. Without a concerted, collaborative effort to address site and other industry challenges, the sustainability of the clinical research enterprise itself is at risk.

The clinical research enterprise has been wrestling with the same problems for over 40 years. Let's try a new, more strategic and collaborative approach to eradicating them.

The Site Council Dream

We dream of a future in which sites can reliably meet their commitments to study sponsors and CROs (collectively "sponsors"): expeditious study startup and accurate and timely data from an agreed-upon number of study participants, safely obtained in compliance with regulatory and ethical requirements.

Our dream is aspirational. It is not a set of requirements, demands or contractual obligations. Rather, our goal is to collaboratively work toward a future in which our dream is realized. All we ask is that sponsors work in good faith, over time, to help us achieve a future in which study sponsors and CROs have healthy relationships with healthy sites. Sponsors can address the Site Council Dream in the manner that best fits their own priorities and resources. We understand that some elements of the dream are more easily achieved than others, that some elements may be impractical in certain studies, and that study sponsors and CROs often cannot control each other's decisions and actions. Given these caveats, we respect and support sponsors who make a good-faith effort to help us achieve our dream.

As shown below, the Site Council Dream consists of six main parts that are illustrated by examples. It will evolve to reflect the changing priorities and circumstances of both sites and sponsors.

The Site Council Dream represents the site perspective. Study sponsors and CROs have their own needs and perspectives, as described in the table below. We look forward to seeing those needs and perspectives clearly articulated at a detailed level.

Site Performance Dimensions

Dimension	Considerations
Productivity	How much of the desired output (e.g., data) does the site produce?
Expertise	How expert is the site in the therapeutic area and other aspects of the study?
Speed	How quickly does the site start up, enroll study participants, enter data, etc.?
Reliability & Risk	How reliably and risk-free does the site perform its responsibilities, e.g., study participant enrollment and study documentation?
Quality	How good is the site's quality, measured by its quality assurance program (SOPs, training, processes and supervision), GCP compliance, data queries, site monitor findings, etc.?
Responsiveness	How quickly and completely does the site respond to sponsor directions and requests?
Leadership	To what extent is the investigator a key opinion leader or influencer in their local community, nationally or internationally? To what extent does the site's reputation add luster to the study?
Safety	How well does the site protect the health and safety of its study participants by preventing and addressing adverse events?
Diversity	How well does the site recruit study participants from the diverse populations needed by the study?
Other	How does the site rate on other attributes of value to the sponsor, e.g., scarcity, experience, motivation or specialized expertise, equipment or services?

We understand that the challenges are great; if they were easy, we would have met them by now. Nevertheless, sitting on the sidelines and accepting the *status quo* is no longer a viable strategy. And, we must always remember, patient lives are at stake.

- ❑ **The Dream of Essential Information**
  - Seeing information about upcoming, ongoing, delayed or canceled studies
  - Seeing a sufficient synopsis of the protocol with the feasibility questionnaire
  - Seeing a useful explanation as to why our site has not been accepted into a study
  - Seeing a transparent, itemized and complete study budget

- Seeing the pertinent parts of the study protocol and other applicable information before finalizing the budget
- Seeing a complete package of documents and materials at study startup

Sites believe that sponsors often expect them to estimate enrollment, accept studies, negotiate contracts and budgets, conduct studies, and maintain sustainable clinical research operations without the necessary information. If a study sponsor has unrealistic timelines and inadequate resources, that should not be the site's problem. In exchange for the information that sites need from sponsors, sites must provide the information that sponsors need from sites.

❑ The Dream of Professional Autonomy

- Staffing studies with competent personnel of the site's choice
- Using our GCP-compliant SOPs
- Working within realistic timelines, especially for study startup and enrollment
- Entering data only once and uploading documents only once
- Receiving good study technology training, manuals, sandboxes and support
- Using technologies of our choice (connecting to the sponsor's technologies)
- Employing universal single sign-on (one username and password for all technologies)

While sponsors may need to give direction and guidance to inexperienced sites, they should give proven sites authority over their own operations, subject to regulatory obligations of governance. In exchange, sites must conduct clinical research studies properly. Sponsors should give sites adequate notice of deadlines and sufficient time to complete their tasks, especially when tasks or timelines change. In exchange, sites should complete their tasks per these timelines.

The last four examples of professional autonomy involve technology. The rapid proliferation of technology has become a major source of inefficiency in the clinical research industry. Because study sponsors select so much of the technology employed by sites, sites must often deal with unfamiliar technologies within each study, to say nothing of a multitude of technologies across studies. Technology would be a far smaller problem if each site were able to select a small set of technologies that meet its needs and those technologies communicate to each other and to the technologies employed by sponsors through standard connectors (APIs).

❑ The Dream of Fair & Timely Compensation

- Receiving fair compensation with remittance advices for all services provided and reasonable costs incurred (performance-based, inflation-adjusted, including costs discovered or imposed after budget negotiation (e.g., protocol amendments, new requirements, new site monitors), technology, training, delays and cancellation)
- Receiving timely payment on a monthly basis without holdbacks
- Receiving payment for uncapped screen failures, when appropriate

Many sites consider compensation their top issue with sponsors. Sites consider it very unfair when, through no fault of their own, they are held to a study budget that does not reflect actual costs. Untimely payment is a perennial site complaint. Sites have to pay their personnel, landlords and suppliers in a timely manner, so it is natural for sites to expect sponsors to do the same. Many sites have

limited financial resources. The cost of financing receivables has become onerous. Sites waste a lot of time on collections.

Many sites believe sponsors treat them worse than the sponsor's other vendors. Sponsors can blame slow payment on short staffing or deficiencies with their accounting systems, but such excuses carry little water with sites. Sponsors should pay sites in a timely manner with informative remittance advices. In exchange, sites must submit timely and accurate invoices to sponsors for properly completed work. If a sponsor's payment process is deficient, it should advance funds to cover a reasonable percentage of the estimated balance outstanding to sites. In exchange, sites must reliably perform work that justifies advances.

Proven sites believe they have earned the privilege of uncapped screen failures, when appropriate, and no holdbacks. In exchange, sites must not abuse these privileges.

- ❑ **The Dream of Proficient Governance**
    - Receiving competent and efficient monitoring onsite and remotely
    - Obtaining timely action (e.g., review of patient recruitment materials and delivery of lab kits)
    - Being free of redundant rater, technology and other training

Sites understand that the sponsors have legitimate regulatory, operational and other reasons to govern sites. Sites expect this governance to be performed in a competent, efficient and timely manner that does not impose unnecessary costs on the site or interfere with its legitimate conduct of the study. In exchange, sites must facilitate such governance so as to not impose unnecessary costs or delays on the sponsor.

- ❑ **The Dream of Patient Centricity**
    - Obtaining support for appropriate diversity, equity and inclusion activities
    - Being able to accommodate study participant preferences (e.g., visit locations and data capture methods)
    - Being able to inform study participants of their study treatment and study results in a timely manner

Many sites are tackling issues of patient centricity, including diversity, equity and inclusion. They expect support and cooperation from sponsors for these efforts. In addition to the ethical implications, patient centricity helps sites build strong relationships with potential study participants and their local communities, thereby facilitating current and future studies. In exchange, sites must design and conduct such activities properly and cooperate with the sponsor's patient-centricity activities.

As a result, site personnel waste huge amounts of time learning, signing into, and redundantly entering data and uploading documents.

- ❑ **The Dream of a Collaborative Relationship**
    - Having a voice in study design, technologies, solution providers, and processes
    - Being free of redundant feasibility questionnaire requests
    - Receiving timely and effective responses to questions and issues, with robust escalation paths

- Experiencing non-solicitation of study coordinators during a study and for some time thereafter (subject to applicable law)

Clinical research is a highly interdependent industry. Because of the complexity of clinical research today, sponsors can no longer design studies without substantial input from sites, including investigators — and their study coordinators — who are not scientific key opinion leaders. Sites understand that sponsors may not be able to consult with every site, but they do not want to deal with the impact of decisions that were made without adequate site input. In exchange, sites that are consulted must provide thoughtful and timely input. Sites must accept that they may not agree with other sites on the best way to conduct a study and that sponsors are the ultimate authorities over their studies.

Similarly, sites understand that they cannot conduct clinical studies without consulting with the sponsor, when appropriate. When a question or problem arises, e.g., when there is a participant eligibility or safety issue, sites need a timely and useful response for obvious reasons. If an issue is not addressed in a timely and effective manner, sponsors should provide an escalation path that, in some cases, goes through the CRO to the sponsor. In exchange, sites must raise and escalate issues judiciously and understand that sponsors may not be able to respond instantaneously.

Hiring away a site's study coordinator who is working on a sponsor's study is self-defeating and damaging to the site/sponsor relationship, as is a site hiring away the sponsor's clinical research associate on the study.

Limitations

The Site Council Dream has four limitations. First, sites must earn the dream by doing good work and not abusing their rights. Second, the realities of a clinical research study may make certain elements of the dream impractical. Third, even if a study sponsor works in good faith to implement the Site Council Dream, full implementation may take years or may currently be impractical, e.g., given the current lack of technology interoperability. Fourth, sponsors and CROs often cannot control each other's decisions and actions. Complicating this last limitation, CROs take undeserved blame when they cannot tell sites that their hands are tied by their client, the study sponsor.