THE 4 Cs OF SITE ENGAGEMENT

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What is engagement? Per the dictionary, it is a commitment to be present. Site engagement is a multi-faceted commitment between researchers and investigative sites intended to be mutually beneficial, and ultimately bringing new therapies to patients in need more efficiently. There are many articles on site engagement, but they are for typical indications. Put those aside bacause they don't apply to rare disease research. Here's why:

- Treaters of rare diseases vary widely in their background and knowledge of clinical research. One thing they all have in common is putting patients first. This means they want to do whatever they can, taking the swiftest possible route, to get relief to their patients. Often, in rare diseases, the patients and caregivers are knocking on the doors, eager to get their hands on new potential treatments. The treaters, who become investigators, begin taking their first steps into the clinical research world.
- No two rare disease trials are the same. There are tried-and-true tactics to be applied to maximize site engagement – benefiting the investigators, the sponsors, and, most importantly, the patients. Think of these as the 4 Cs of site engagement.

WHAT ARE THE 4 Cs?

CUSTOMIZE the approach for each site with regard to communication, hands-on training, and site management. As an example, we may be working with physicians or geneticists that have no prior clinical research experience but due to the ultra-rare patient population in their country, we would like to select them to be a clincial trial investigator. The team would tailor the approach for initial meetings and discussions to include introductions to ICH/GCP and define the roles of investigator, monitor, and sponsor. Further to that, the team should assist with completion of required documents for the local ethics submission and ensure CRA support on-site the day of the first patient screening and again for first patient dosing. This type of guidance and support is crucial to ensure the new therapy is made available to the patient. This level of support forms a solid foundation for the relationship that will help foster collaboration in the future.

CONSOLIDATE interactions, meaning reduce the number of vendor interactions with the site. Ideally, there is a single point of contact for the study operations from beginning to end. This reduces number of contacts interacting with the site and ensures consistency in the messaging throughout the study period. Rapport with the site will be developed earlier in the study.

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CONVERSE by providing forums to review enrolled patients' status/progress and for peer-to-peer interaction across the participating sites. This can occur via teleconference with supporting visual presentation highlighting key study updates and progress, followed by roundtable style discussion from each participant on how their enrolled patient is doing clinically and for upcoming assessments. This environment fosters questions and answers among peers – nurses, coordinators, therapists, and physicians – who can learn from each other and apply techniques in their clinical centers.

CONGREGATE in person. One of the most effective ways to engage someone is through face-to-face interaction. In rare disease research, incorporating face-to-face interactions as early as possible yields success. Seek opportunities at upcoming conferences, regional advocacy, or other organizational meetings to meet with your investigators. Due to the geographically widespread nature of these studies, a central investigator meeting is not the most efficient. Instead, send a medical or operations lead to meet with the centers to provide firsthand information of study timelines, plans, and next steps. Once a study is enrolling and treating patients, hosting a workshop for in-depth training of study specific assessments and/or other requirements is an excellent medium to solicit and provide feedback and ensure consistency in training.

ABOUT TRICIA MCCAIN

Tricia McCain brings multiple perspectives to the Rare Disease team, having been a Child Life specialist caring for the patients, a study coordinator at a children's hospital, monitor and project management of global, multi-service teams in rare disease and pediatric indications. She currently serves as Senior Director, Rare Diseases, at Worldwide, providing support to clients and teams during all phases from development planning to proof-in-concept, including patient advocacy liaison. Her passion for helping others shines through her enthusiasm and willingness to not leave any stone unturned.