



A relationship-based approach to improving clinical trials: The imCORE research network experience



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ABSTRACT

The rapid evolution of cancer immunotherapies has increased demand for timely introduction of new therapies and subsequently increased the demand on leading cancer research institutions worldwide. As a leader in cancer therapy research, Roche created the immunotherapy Centers of Research Excellence (imCORE) Network, a worldwide research network designed to more closely connect members in an open environment of shared information, expertise, and decisions. This network is dedicated to increasing the understanding of the underlying science in order to prioritize and accelerate the most promising new treatment options for patients. The network consists of two key pillars, Roche-sponsored clinical trials operational excellence and the imCORE network scientific collaborations. This paper focuses on the Roche-sponsored trial clinical operational excellence aspects of the network. This special contribution introduces the rationale, design, and success factors of sponsored trials within the imCORE Network, including critical components and examples of tangible improvements to clinical trial operations between the company sponsor and the trial sites. Pivotal success factors have included relationship architecture and management, transparent communication channels, open information-sharing, and the development of new processes and tools to overcome historical inefficiencies and challenges of all sizes. The shared dedication of stakeholders to cancer therapy innovation, operational improvement of clinical trials, and a durable, sustainable worldwide research collaborative has made this component of imCORE effective to date. The authors share this experience with the broader research community for the first time, in the same spirit of collective advancement of care for patients with cancer.

1. Introduction

The rapidly evolving field of cancer immunotherapy (CIT) has mobilized the biopharmaceutical industry to develop promising new treatments with an implicit need to expedite the pathway of new therapies from bench to bedside. This race to bring innovative treatments to patients has engendered heightened levels of competition for the attention of and partnership with leading cancer research institutions. Recognizing this reality, Roche created a worldwide network of leading CIT centers: the immunotherapy Centers of Research Excellence

(imCORE) Network. The vision of this network is to partner with globally recognized expert research institutions to accelerate the advancement of CIT science by sharing ideas and data, collaborating on research, and streamlining the operational delivery of the Roche portfolio while deepening the collective understanding of the underlying science in order to prioritize and accelerate the most promising new treatment options for patients. The network consists of two key pillars, Roche-sponsored clinical trial operational excellence and the imCORE network scientific collaborations. This paper is focused on the Roche-sponsored clinical trial operational excellence aspects of the network.

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2. Historical perspective on sponsored clinical trial alliances

Creation of a research network was not a novel idea, site networks and sponsor/site networks have existed for many years. Sponsors typically established these networks to facilitate the operationalization of clinical trials and provide a broader enrollment base for the sponsor and clinical trial opportunities for patients. That said, these networks worked with sites at the study level, recreating the process and procedures each time a new study began leading to duplicative work and redundant efforts on the part of study teams. Often times, these alliances or networks were sponsor run, meaning the sponsor dictated the direction and goals of the network which does not result in a true alliance or partnership.

Although these networks and alliances served their purpose, something was missing. The alliances were typically site specific without goals greater than themselves and the company. Scientific collaboration was also limited by the transactional nature of these networks. Finally, this transactional nature did not facilitate long term collaboration or innovation.

3. Rationale for a relationship based network

3.1. Importance of site-sponsor relationships

Regardless of the industry, business leaders agree that developing long term mutually beneficial relationships is critical to business success. According to Ruth Dubinsky, principal of Clarity Consulting (Ambler, PA) “sponsors and sites are happier and do better work when they intentionally form relationships” [1]. According to the 2017 CenterWatch Global Investigative Site Survey, however, sponsors still have room for improvement in this area [2]. Sites identified the following domains to be very important when working with sponsor companies: communication and escalation path, protocol study design and planning, and budgets and contracts [2]. These were consistently rated as needing improvement across multiple companies including Roche. Roche has made a commitment to lead the industry in this effort to strengthen the site-sponsor relationship by developing and implementing a patient- and site-centric approach: imCORE is leading these efforts through investment in a dedicated alliance management team.

As part of our company's history and evolution we have engaged in several site-focused strategic alliances. The original intent of these collaborations was to foster improved scientific collaboration and exchange of information. While furthering the underlying science was the primary focus in the creation and success of the alliances, operational engagement was also critical in truly advancing scientific initiatives. These initially small number of site alliances helped set up the framework for the larger effort to create a network of sites engaging in both ISR and Roche-sponsored studies in CIT. For example, the prior existing company sponsored trial alliance agreements paved the way for the current imCORE model. These agreements outlined the purpose, structure, and management of the alliance as well as the type and cadence of information to be exchanged, mutually agreed trial management timelines, and the alliance management roles at the sites and at Roche. One of the original agreements required the development of a Master Network Management Plan focusing on the sharing of site and institutional knowledge. The evolution of this plan, the alliance roles, and the subsequent iterations of the alliance agreements provided an informed foundation for the imCORE framework initially set up to deliver on company sponsored CIT studies.

With the idea of the imCORE network, we set out to build a network unique to the biopharma industry where the site-sponsor relationship serves as the foundation for driving both collaborative scientific investigations and operational efficiencies. This type of partnership had never existed before and the power and potential impact of the relationship between sites and sponsors on this scale remained unknown.

The company set out to test the potential impact of site-sponsor relationships on the clinical drug development process with the hypothesis and hope that it could revolutionize how we work with sites in the future. This paper provides an overview of the origin of imCORE with a focus on the strategic importance of the site-sponsor relationship and the mutual value that is derived from this approach. The imCORE network supports all scientific collaborations, including institution-sponsored research (ISR), site collaborations, and company-sponsored clinical trials. Communication and operational improvements are highlighted as key drivers in creating and sustaining meaningful site-sponsor relationships that better facilitate clinical trial operations and ultimately make the introduction of novel therapies to patients more efficient.

4. Network site selection

With the influx of promising checkpoint inhibitors along with the evolution of personalized medicine and innovative compounds across the CIT space since 2011, collaborative research and academic partnerships have become increasingly important as demand for and delivery of new therapeutics to patients has accelerated. In 2014, Roche began evaluating a group of leading cancer research institutions based on rigorous criteria, including experience in CIT and early phase clinical research, commitment to operational efficiency and improvement, and the value that each site brought to the broader network and to patients with cancer. Multiple tools were used from internal analytics to global intelligence platforms to identify potential sites with the following core characteristics:

- phase I CIT experience
- proven track record of successfully conducting early phase trials
- the ability to scale-up to later stages of development

Once an initial list was established, the sponsor team identified their top tier sites and met with each of these site's operational and scientific leadership to share the vision and purpose of the Network and to establish mutually beneficial partnerships dedicated to CIT innovation. They completed a site score card to objectively evaluate each site based on key criteria including immunotherapy experience, study experience, performance metrics and site specific scientific and operational capabilities and expertise. Sites were selected based on the outcomes of these meetings and were invited to participate in the network.

Since 2014, the imCORE Network has grown to include 26 sites and is comprised of top academic and research institutions worldwide. The membership is not fixed at a specific number, however currently there is no plan to add additional sites. That said, sites interested in joining the network would be required to go through the evaluation process and would need to meet an unmet need in the network based on their capabilities. The mission of the sponsored trial side of the network is to “accelerate the clinical development and delivery of innovative cancer immunotherapies to patients by maximizing operational efficiencies through collaboration of best practices, continuous enhancement of tools, and consistently leveraging shared resources within the Network.”

5. Network infrastructure and stakeholders

The principal management roles in each site-sponsor relationship are presented in [Table 1](#), however several other key stakeholders from each organization are active and important participants in the shared effort.

5.1. ARM-SAM relationship

The imCORE network is fundamentally about collaborative relationships to advance and accelerate CIT science together for patients.

Table 1
Principal stakeholders in each alliance relationship.

Management role	Key responsibilities
Alliance Relationship Manager (ARM)	<ul style="list-style-type: none"> ● Sponsor's primary operational contact ● Internal subject matter expert on the site's processes, capabilities and structure; works to maintain and deepen institutional expertise ● Internal sponsor advocate for site, working to create new opportunities for site ● Build longitudinal relationships with their respective SAMs and partner on topics ranging from preliminary identification of site study interest and study start-up to follow-up on data management issues and trends
Site Alliance Manager (SAM)	<ul style="list-style-type: none"> ● ARM's counterpart at the site ● Single point of contact, network representative and advocate for company sponsored studies within their institution ● Works directly with the ARM, helps to facilitate issue escalation and resolution through knowledge of their institution's framework, structure, and decision-making pathways
Lead Site Principal Investigator (PI) Scientific Alliance Relationship Manager (sARM)	<ul style="list-style-type: none"> ● Site's main point of contact for scientific strategy and scientific leadership for company-sponsored trials and ISR ● Sponsor's primary scientific collaborations contact ● Focused on multi-site scientific collaborations and ISRs

The key relationships that imCORE provides for the company-sponsored trials operational perspective is the ARM-SAM relationship which has been shown to be critical to the overall success of each alliance. Built on a foundation of trust and collegial support, each party has a clear focus on issue resolution and on building a lasting relationship. This is an important departure from the typical, transactional study-based approach to running clinical trials. The direct link from site to sponsor (and vice versa) facilitates greater, timely transparency, rapid resolution of issues, and a shared commitment to proactively working together with a common understanding. Both sides act as advocates within their organizations on behalf of the alliance and with partnership-oriented perspectives. The strength of this relationship allows for open dialogue regarding process improvement and problem-solving within both the sponsor and the site. These open discussions also allow for identification of trends and process integrity at a network-wide level as opposed to an individual site, magnifying the benefit and impact of the network relationship.

6. Communications

Like any relationship, the ARM-SAM relationship is only as strong as its communication pathways. Without clear, consistent and streamlined communication the relationship would fail. Prior to the imCORE Alliance, communication channels were muddled by inconsistent communication plans, lack of role clarity, accountability and responsibility among the sponsor, Contract Research Organization (CRO) and site. This led to confusion about appropriate points of contact, delays, and increased frustration for all involved. Sites would often struggle for answers to simple questions related to timelines or protocol clarifications because there were multiple layers within the sponsor between the site and the decision-maker. With that in mind, one of the first acts of the alliance was to establish clear communication channels, the foundation of which was the single point of contact (SPOC) structure. Critical to imCORE's success, the SPOC framework through the ARM and SAM roles allows for dedicated and accelerated bi-directional communication between site and sponsor. Through this pathway, strategic planning, portfolio oversight and operational issues are discussed and the pitfalls of third-party involvement in communications can be prevented. This pathway also expedites issue escalation and resolution, which were significant challenges historically raised by the study sites.

The company implemented a variety of communication strategies to complement the SPOC structure and ensure consistent messaging, transparency, and organized contact with each of the imCORE sites. These communication strategies are described in the following sections.

6.1. Meetings

The implementation of monthly teleconferences between each

ARM-SAM team has been an important requirement in the communication strategy. Set up from the inception of the site alliance, these site-specific calls include shared discussions on study status, new studies, outstanding issues, forecasted deliverables (e.g., first patient enrolled), process alignment, and other topics. Attendance varies by site and region based on need, volume of work, deliverables and ongoing initiatives. Site-specific trends are identified and discussed during these regular meetings, and site-specific solutions are developed and reinforced. For example, a typical meeting might include discussion of the site's commitments and plans related to patient enrollment; a review of data management trends across multiple studies at the site; and root-cause analysis of identified issues with brainstorming of viable solutions. These meetings are co-owned and driven by the ARM-SAM who are jointly accountable for the decisions and of the meetings. The collaborative approach of these meetings has set them apart from historical norms of site-sponsor meetings, and further distinguishes the imCORE Network from other sponsor-established networks.

In addition to regular teleconferences, the ARMs visit their sites annually at a minimum. These face-to-face meetings help to further support and nurture the relationship and depth of the alliance, and to broaden stakeholder interactions and imCORE awareness within the site's institution. These in-person meetings often serve as an opportunity to meet new staff, increase the engagement in imCORE across the organization, and focus work on operational process improvement. From the ARM-SAM perspective, these more personal meetings are also a cornerstone of the ARM-SAM relationship within the alliance.

The company also hosts an annual, network-wide face-to-face meeting attended by SAMs, ARMs, leadership, study team members and other representatives based on the meeting agenda (i.e. CRO colleagues & affiliates). These meetings provide updates from ongoing work and include workshop activities organized to identify and prioritize areas of focus in the coming year. Attendees are also able to focus on the alignment of values and priorities in a think tank-like environment that challenges existing roadblocks and entrenched practices in clinical trial conduct. This meeting is another key distinguishing feature of imCORE and has allowed the SAMs to build an organic international peer network. It is the philosophy of the company that providing sites with unique opportunities to exchange information as a research community (outside of the larger industry-focused meetings) provides for a more creative, open and trusting environment that can produce new and innovative solutions with a unified voice. Additionally, this meeting serves as an annual check in and source of site feedback as to what is and is not working within the operational side to the network. Through workshops specifically designed to gather feedback and test the pulse of network members we capture constructive feedback from network membership which we then analyze and use to improve on the way we work. We also utilize an anonymous survey to capture feedback about the meeting itself in order to improve year on year.

Another approach taken to reach the entire collaborative has been

through network-wide virtual forums that address both operational and scientific topics. Topics presented at the operational forums can include network communications, event or conference planning, and/or troubleshooting network-wide issues, and both ARMs and SAMs are invited to present. These forums are critical to network messaging and supporting site collaboration efforts and the site-to-site relationship. From a scientific perspective, the company also hosts network-wide teleconferences that showcase new molecules and scientific advancements. These meetings enhance early engagement, provide information to imCORE sites, and have forged a new pathway for site feedback and idea exchange.

The company also organizes periodic site-specific portfolio reviews that often occur in parallel with major oncology congresses. These meetings are coordinated by the ARM-SAM team, each working with their respective leadership and stakeholders to drive the agenda and ultimately the success of the meeting, and arranged to maximize attendance and engagement. These meetings provide regular, early insight into the company therapeutic portfolio and initiate or deepen scientific collaborations.

Finally, the SAMs On Site (SOS) program offers another opportunity to impact clinical trial operations by inviting SAMs from imCORE sites to visit one of the company campuses, a practice that was not historically common. Prior to the SOS program, the primary opportunities for study teams to interact with sites were at investigator meetings or national congresses, which focused on study-specific issues and did not allow for broader strategic discussions or meaningful development of relationships. The SOS program provides an alternative approach for meaningful exchange that underscores an investment in the relationship. While on site, the SAMs have the opportunity to meet and get to know leadership, meet with study teams about study specific issues, educate clinical operations teams about how to work with their institutions, and interact with specific departments. This gives the opportunity to the SAMs to showcase their site capabilities and provide necessary site perspective to a wide audience of company staff involved in clinical trials. At each of these touchpoints the SAMs provide site feedback and perspective related to processes and procedures, and in turn are able to better understand how sponsor professionals operate on a daily basis. This invested time and face-to-face interaction strengthens not only the bond between SAMs and ARMs, but also the bond between the site and the broader sponsor organization.

6.2. Communication via technology

Aside from meetings, several other mechanisms are utilized to ensure efficient and effective information-sharing. The imCORE HUB is a web interface that serves as a central repository for all imCORE information to company employees, imCORE sites, and CROs. The goal of the HUB is to provide study teams and other stakeholders with the information they need to perform clinical trials at imCORE sites, ensuring available information is accessible and ultimately reducing operational burden on sites and study teams. This is a significant improvement from the traditional model where each study team repeatedly asks the site for the same information, essentially duplicating the process for each clinical trial. Within the HUB there is a Playbook for each site that houses key documents and information about each site's institutional practices. The ongoing maintenance of the Playbook documents is a joint effort between the SAMs and ARMs which ensures that the information in the Playbook for each site is kept current. The HUB and the Playbook were initiated within the imCORE Network prior to industry wide initiatives such as SIP and Investigator Databank and admittedly has similar intent and purpose. How it evolves in the presence of these other platforms has yet to be seen as we collaborate closely with our network sites to understand what works best for both parties in the context of these new initiatives. The Dashboard is a database that provides both site and company personnel with detailed metrics on company-sponsored studies for imCORE sites,

and also resides in the HUB. All metrics in the Dashboard are collated in real-time and include data regarding study start-up, conduct and data entry. In addition to regular review of their own performance metrics, the company has incorporated functionality that allows sites to compare themselves to similar institutions anonymously. This benchmarking ability encourages best practice discussions and friendly competition.

7. Network enabled operational enhancements

These communication pathways support the ARM-SAM relationship and foster open dialogue that has been central to the network's success. Recognition and implementation of the outputs of this dialogue illustrate the impact and overall benefit of the site-sponsor relationship and the imCORE Network. Discussions are focused on operational improvement in an environment that encourages candid, productive input and feedback. As a result, numerous ideas and work streams have been initiated from these discussions. True to the partnership approach of imCORE, these work streams are co-led by ARM-SAM teams. Ideas are presented, discussed and prioritized within these subgroups. SAMs and ARMs work together to cultivate these ideas, develop strategies and gain endorsement from their peers in the network. This results in new and innovative processes at both the company and the study sites, some of which are described below.

7.1. Feasibility

The analysis of site capabilities to conduct a particular trial is an industry-wide practice saddled with inefficiencies. imCORE sites, comfortable in the context of their ARM-SAM relationships and the strength of the alliance, were quick to identify the need for a more efficient approach than the historical process that was regarded as cumbersome and redundant.

Based on the joint effort between ARMs and SAMs, the company developed a comprehensive site feasibility questionnaire to facilitate a more unified and consistent approach that would decrease site and study team burden. This allows the company to create and centrally store a site feasibility profile that outlines the institutional clinical research capabilities. These comprehensive profiles are reviewed and updated by the SAMs on a quarterly basis, replacing the need for redundant feasibility questionnaires from individual study teams.

By having these site profiles as the first filter in the feasibility process, study teams save time by accessing the data on the HUB when evaluating potential sites. Because of this process improvement, study teams only send a limited number of protocol-specific questions to imCORE sites to assess study feasibility and site interest, substantially limiting the burden of the feasibility process.

7.2. Line of sight

In addition to decreasing the burden of sharing duplicative information, there has also been a focus on improving the visibility of available information that might be important for imCORE stakeholders. The Line of Sight (LOS) tool was developed to provide increased transparency and understanding of planned studies. The LOS tool proactively provides study-specific information so sites can engage in earlier discussions about potential interest and capabilities, making resource and management planning more efficient. This benefit to both study teams and sites could only be possible through a strong and trusting alliance relationship. The LOS, provided quarterly, includes study-specific operational and regulatory timelines, as well as the global site selection strategy for studies starting within the next year. From the site's perspective, this tool provides critical information used to plan for upcoming company sponsored clinical trial opportunities. At the company, this tool helps drive early engagement and adoption of studies at imCORE sites.

7.3. Operational review board

The imCORE Operational Review Board (ORB), another result of ARM-SAM collaboration, is an opportunity for study teams to gain critical insight into study documents. Often sponsors ask scientific experts to review the study protocols during development but do not solicit operational feedback. The SAMs recognized that a lack of real-world patient and site perspective could hinder participation and engagement in company studies and lead to difficulties in protocol implementation, deviations, and amendments, stalled enrollment, and ultimately increased costs and protracted study timelines. The ORB was created for study teams to share protocols and other study documents so they can incorporate feedback based on the knowledge and experience of the network stakeholders. This is one of the unique activities the company has undertaken that not only decreases the operational burden at the site but also gives the site more power to reduce the burden of the clinical trial experience on their patients. This shift in the protocol design paradigm gives the sites a proactive platform to provide critical feedback on study design, helping them to facilitate meaningful improvements in the patient experience and to further strengthens their commitment to the alliance.

7.4. CRO imCORE network adoption

Along with other large pharmaceutical companies, Roche outsources much of its site monitoring and study management work to CROs, which has resulted in redundancies, communication issues and training gaps. The addition of a large CRO team brings additional layers of decision-making, reduces transparency and ultimately widens the gap between the sponsor and the site. As the role of the CRO in clinical trial operations continues to grow, a need was identified to address the downstream impact on study conduct. Global trends were identified through the SAM community and the company established a joint working group with the SAMs, ARMs and a representative from each CRO. The SAMs utilized their relationship with the ARMs and Alliance team to provide valuable feedback on areas for improvement in the sponsor-CRO-site relationship. This feedback was generally agnostic to the CRO or model for a given study and, with some country-specific considerations, much of the site feedback was consistent globally and a distinct theme of issues emerged. This insight raised the need and desire to improve the relationships among all parties and to create a more seamless interface across all company sponsored CIT trials.

Recognizing the value of face-to-face interactions, the working group agreed to focus on three key areas in the site and CRO relationships:

- 1 Improve Communication and Relationships: To enable greater understanding of roles and responsibilities, and to enhance transparency;
- 2 Training and Knowledge-Sharing with Roche CROs: To introduce subject matter experts (SMEs) and to increase awareness of imCORE;
- 3 Simplify Processes and Templates: To create efficiency and consistency.

Common issues that were identified as universal to the imCORE sites included: a lack of clarity regarding each CRO's specific requirements, process, and timelines; a lack of communication among key contacts to resolve issues, particularly with budgets, contracts, Informed Consent Forms and medical questions; inadequate handovers during Clinical Research Associate transitions, resulting in re-work for sites; and repeated requests for the same, basic information about the sites.

The outputs of this meeting were as follows:

- Creation of a CRO SPOC to support all imCORE activities;
- Development of a comprehensive training program for the CROs,

- including study site feasibility assessment, study start-up, budgets and contracts, monitoring, and project management;
- Introduction of the CRO SPOC in site alliance calls.

The imCORE CRO working group implemented practical communication channels among the CRO, the company study teams and the site, and created several new best practice documents and tools to increase knowledge and transparency among all stakeholders. While this remains an ongoing effort to improve knowledge-sharing and communication, the company has been better able to help sites navigate issues they encounter throughout the process.

7.5. Transforming site start up for at-risk submissions

The ARM-SAM relationship is utilized daily to address everything from simple study-specific questions to site-level process interventions. An important process intervention facilitated by the ARM-SAM relationship has been that related to "at-risk submissions." At-risk filing is when a site initiates a regulatory submission and approval process prior to regulatory clearance of the study protocol. Any protocol changes requested by the regulatory agency present a resource risk to the site related to the required protocol revisions and resubmission. Since a resubmission can be resource intensive and can delay site activation, most sites are resistant to making at-risk filings and do not include them in typical start-up processes. The potential benefit of at-risk submissions is approval and launch of the protocol as soon as regulatory clearance is achieved, which greatly accelerates the overall process.

Commercial Institutional Review Boards (IRBs) have accepted at-risk submissions for many years, however many of the imCORE sites do not use commercial IRBs nor have their institutions historically approved at-risk submissions. The ARM-SAM relationship has played a critical role in this decision-making process and in its execution. From the initial discussions and decision points related to at-risk submissions, representatives from the site and sponsor work together on strategy and timelines. The ARM and the SAM ensure there is mutual awareness of the steps required to ensure timely deliverables, minimize delays, and avoid wasted resources. The direct connection of the SAM and ARM allows for greater transparency and collaboration which, along with Line of Sight planning, facilitates timely communication and completion of protocol amendments and other key study documents.

At-risk submissions are not likely to become a regular practice, however, when appropriate, the company and imCORE sites have an established channel for serious consideration and implementation of shared decisions. The example of considering at-risk submissions further highlights the value and importance of open information exchange and mutual commitment in making a trial's rapid activation an operational reality.

7.6. Site collaborations for process improvement

The relationship-based approach also led to a project conceived and developed by SAMs working together across site, country, and language barriers. Through the strength of the ARM-SAM relationship the ARM team encouraged the SAMs in the network to leverage the relationships that had been built in order to partner on a new project sponsored by SAMs. Working together, a small team of SAMs from a subset of sites are working on developing a way to optimize the startup phase of collaborative multi-site ISRs at a site level to maximize efficiencies and learnings. They presented the details of their ideas to the company and it is currently under consideration within the appropriate work streams. This work exemplifies the potential of non-competitive collaborations aligned with the charge from Ruth Dubinsky that "sponsors and sites are happier and do better work when they intentionally form relationships." [1]

8. Lessons learned

Throughout the implementation of the sponsored trials side of the imCORE Network we have learned a number of lessons and best practices. The main learnings are as follows:

- Ensure clear expectations for site selection, performance and network participation at the point of site qualification and network entry discussions. Where possible, expectations should be written into the alliance agreements in a measurable and binding way such that all parties are accountable to their parameters. While improvement in metrics are important to drive towards, it's important to also recognize the value of committed partnerships and innovation which are not easily measured by standard metrics.
- Site and sponsor leadership support are critical to alliance success.
- Face-to-face interactions are essential to relationship and community building. The stronger the relationships the stronger the alliance.
- Joint (sponsor and site) network vision and initiative leadership ensures deeper collaboration and overall commitment to the network.

8.1. Impact measurement

At this time in the evolution of the network we have established baseline site data and a framework within which to operate, however, due to the complexity of the clinical trial environment across a large organization we are only now beginning to understand how best to tangibly measure the network's impact. We are working in close collaboration with our sites & leadership to further define the impact of the imCORE network both at the site, sponsor and patient level. We have found the wide variability of early phase clinical trial designs and start up processes, country regulatory framework complexities and unique site requirements make a simple assessment of start-up and/or enrollment impact challenging. After much consideration we have identified 3 areas from which to gather empirical data from each site. These categories are: committed partners, innovative clinical research, and operational performance. We feel the combination of these three metric categories will provide a more comprehensive view of the value that each site & the sponsor brings.

8.2. Outcomes

The company sponsored clinical trials pillar of the imCORE Network is a site-centric, transparent, relationship-based commitment that empowers and facilitates operational improvements to clinical trials. A review and assessment of the multiple facets of the network today reveals the following 4 key outcomes:

- Improved Communication: The inevitable issues of large undertakings such as clinical trials can be more readily raised and solved in a shared responsibility framework across regions and different regulatory requirements.
- Collaboration: The imCORE research community have fostered interactions among previously disconnected study sites and stakeholders, accelerating information-sharing and problem-solving as a collective learning organization. This unique and collaborative approach provides a broader perspective and insight that did not exist prior to imCORE.

- Operational Efficiencies: The imCORE Network has produced a host of value-added tools and process improvements that have accelerated clinical trial timelines and enhanced the conduct of company-sponsored clinical trials.
- Improved Patient Experience: While the value of being part of the network is most directly experienced by imCORE members, many of the clinical trial enhancements are also improving the patient experience through improved protocol design and study communication.

In summary, stakeholder communication, collaboration, community knowledge-sharing, and continuous commitment to the improvement of study operations have been clear value drivers in the ongoing effectiveness of the imCORE Network helping to improve the lives of patients in the fight against cancer.

9. Future of the imCORE network

As the network continues to evolve, we will rely on the co-creative spirit to continue to drive the network forward. One key focus area for our future may be to follow the Transclerate model of sponsor-to-sponsor collaboration. Recent meetings with our sites and our own experiences through participation in Transclerate and SIP have brought to light this opportunity for improvement in how our network functions. This work might entail inclusion of other sponsors on innovative project and process improvement activities. As this is a cultural shift in the way sponsor companies work, the initial steps would be to identify other sponsors who value and understand the impact of collaboration and who also desire to work together.

It's clear that technology and its integration into the way we work with our sites to implement clinical trials will be a focus in the coming years. The direction of the industry will fuel this process as technological integration into clinical trials is already ongoing and growing in importance and impact daily. Proven pathways, such as remote monitoring are embraced by many sponsors and new initiatives such as direct data transfer are being piloted currently. The network and its ability to generate and collaborate on innovative ideas rooted in the reality of clinical practice will be a critical partner in understanding where technology gaps are and how to best fill those gaps. Regardless of the direction, what we do know is that relationships are the foundation upon which we have built this network and their strength will continue to sustain the network long into the future.

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