Tomorrow’s Cures Today: The Art of Executing Large-Scale Research Programs

Case Study: University of Pittsburgh Precision Medicine

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In 2016, academic medical centers (AMCs) graduated nearly 19,000 medical doctors with a foundational knowledge of biomedical research, carried out over $12 billion in biomedical research (more than half of the National Institute of Health’s (NIH) annual extramural funding), and hosted over 26,000 NIH-funded research projects engaging over 18,000 principal investigators while representing only 5 percent of the nation’s hospitals. Research activities taking place at AMCs not only contribute to the training of all MD-PhDs but have resulted in major advancements like the first neonatal intensive care unit, the first gene therapy for cystic fibrosis, the first pancreas transplant and the polio vaccine.

The nation relies on these institutions to develop cutting-edge discoveries and deploy treatments in areas such as cancer, genomics and medical diagnostics by engaging a broad range of clinical research participants that are representative of the U.S. population through large-scale research studies. For researchers to discover safe and effective treatments and cures that will impact future patient populations, AMCs must be appropriately prepared to fulfill the core requirements needed to launch large-scale research initiatives.
To have the most profound impact on the future of medicine, AMCs must effectively translate biomedical discoveries into practice. This process ultimately requires the enrollment of large numbers of eligible participants into large-scale and often geographically dispersed studies. This type of research initiative is on the rise and these clinical trials position AMCs to collaborate and develop effective therapies that will influence and change how healthcare is delivered in the future. We are seeing the number of NIH P30 Grants or Center Core Grants continue to increase (Figure 1), supporting shared resources and research facilities led by a large number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem.5, 6

However, the initiation of such large studies can be delayed or even at-risk due to operational and strategic challenges facing these organizations. As true leaders with superior planning, management and execution capabilities emerge, we are already starting to see an overall shift in how the NIH awards funding. As an example, the NIH’s Clinical and Translational Science Award (CTSA) program is evolving into “hubs” or “centers” that are awarded funds to lead or coordinate major activities based on demonstrated capabilities, such as innovative clinical trial approaches, recruitment education, enrollment, informatics solutions and data management.

This type of research initiative is on the rise and these clinical trials position AMCs to collaborate and develop effective therapies that will influence and change how healthcare is delivered in the future.

![Figure 1](https://report.nih.gov/fundingfacts/fundingfacts.aspx)
Researchers have been leveraging the power of collaboration for years. Some projects are driven by individual collaboration by researchers at different organizations, while other organizations have developed formal collaboration through shared investments and missions. In this new frontier, however, these collaborations take on much more complex permutations, driven by both funders and awardees. For example, some funders may decide that large-scale research endeavors will be more successful by leveraging the strengths of different organizations, and so may award different components of the project to different awardees (i.e., organizations may be designated as performance sites, data coordinating sites, etc.). Or, one single awardee may determine that they need to sub-contract other organizations in different geographic regions to reach enough participants.

While the requirements to successfully execute small and large-scale research initiatives may be similarly identified, the risks associated with large-scale programs greatly amplify the need to develop advanced capabilities or secure experienced or specialized resources (e.g., project management, information technology, marketing, operational design, process improvement, etc.). In addition, AMCs must approach members of the community with more sophisticated preparation and messaging to garner a large research pool. They must also effectively manage resources to be more efficient with the research initiative and apply discipline and rigor to governance, communication and reporting. Each large-scale research initiative must incorporate long-term project management support and commence with a strategic and operational planning phase.

**Successful Execution of Large-Scale Research Initiatives**

The five key elements that can position organizations to successfully execute large-scale research initiatives include:

1. Project Management
2. Operational Planning & Execution
3. Information Technology & Analytics
4. Research Informed Community
5. Engagement & Recruitment

Without these core elements in place, AMCs will struggle to successfully execute large-scale research initiatives on time, on budget and within the parameters set by the grant issuer.
Key Requirements for Success

Foundational Requirements

When planning for the development of a large-scale research initiative, academic medical centers must come equipped with several foundational prerequisites. First, the AMC must not only have a fundamental desire to advance medicine through research and discovery embedded throughout the organization, but also the scale to pursue a large research effort. Successfully executing a large-scale research project, that spans vast geographies and impacts hundreds of thousands of research participants, should not be pursued if commitments from the AMC and its leadership are not fully established.

Next, the AMC must have the funding in place to perform such large endeavors. On average, for every dollar of sponsored research a medical school or academic medical center receives, they contribute an additional $0.53 of their own resources (an average investment of $111 million per medical school). As we will see with the University of Pittsburgh case study at the end of this paper, their capabilities were built through NIH’s CTSA program managed by the National Center for Advancing Translational Sciences (NCATS). NCATS is one of 27 Institutes and Centers (ICs) at NIH. It strives to develop innovations to reduce, remove or bypass costly and time-consuming bottlenecks in the translational research pipeline to speed up the delivery of new drugs, diagnostics and medical devices to patients.

However, affiliation with an NIH Center is not required to pursue large-scale research projects. While NIH funding remains the predominant source of funding for biomedical research carried out at medical schools and academic medical centers (Figure 2), AMCs are successfully securing funding through other federal sources like the Department of Defense, Department of Veterans Affairs, Department of Energy, etc. in addition to pursuing non-federal funding sources by partnering with pharmaceutical and biotech companies. Some AMCs are partnering with venture capitalists to develop relationships with innovative companies seeking clinical partners for projects focused on advanced diagnostics for genetic anomalies.

Research Portfolio of an AMC

Figure 2

Table: Sponsored Programs Expense by Sponsor Type

<table>
<thead>
<tr>
<th>Sponsor Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>61%</td>
</tr>
<tr>
<td>Other Federal</td>
<td>9%</td>
</tr>
<tr>
<td>State and Local</td>
<td>7%</td>
</tr>
<tr>
<td>Industrial/Corporate</td>
<td>3%</td>
</tr>
<tr>
<td>Foundations, Associations, Not-for-Profits</td>
<td>9%</td>
</tr>
<tr>
<td>Subaward/Subcontracts</td>
<td>10%</td>
</tr>
<tr>
<td>Other Sponsors</td>
<td>2%</td>
</tr>
</tbody>
</table>

Note: Other Federal includes such departments as: Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, Department of Defense, Department of Veterans Affairs, Department of Energy

Source: Academic Medicine Investment in Medical Research: Technical Report, AAMC, Published in 2015, Data from FY2013.
In addition to financial resources, the AMC must have internal human resources available and accessible to support the research initiative. Researchers who depend on external funders have experience in scaling teams up and down. When principal investigators are writing their grant application, they must approximate their staffing needs. Then, upon being awarded the grant, the investigators will distribute the grant-related work across existing staff or contract new staff.

Researchers also need support from regulatory experts who are well versed in working with Institutional Review Boards (IRBs) and navigating the complexity of human subject research. AMCs that want to participate in larger-scale research projects will need to apply this same thinking to a broader scale to plan not just the number of staff needed, but how those staff will work together, in a myriad of potential role and space configurations while assuring effective communications across the team of individuals that supports the grant.

**Advanced Requirements**

For AMCs to successfully implement large-scale research initiatives, an emphasis must be placed on several strategic and operational components, otherwise the research project is at-risk for delay, or worse, overall failure of the project. It is essential for enterprise leaders to start with strategic and operational planning to set the work in motion. To ensure effective implementation, project management capabilities must also be established at the outset.

**1. Project Management**

In the academic research setting, structured project management processes often face resistance for adding layers of additional planning and reporting that can appear to take away from the overall purpose of the project. Full-scale, industry-style project management can quickly become administratively burdensome. As described in the case study (page 12), value-add processes and tools were developed for University of Pittsburgh that were focused exclusively on optimizing daily operations. A program management function was created to provide a standard, repeatable implementation methodology, tools and reporting to increase efficiency and effectiveness.

Specific points of emphasis of the methodology include:

- Using a single point of contact to document and manage communication channels and executive-level reporting across the program for the research initiative’s milestones, deliverables and status.
- Creating and reinforcing program governance (key decision making) and accountability. Investigators often have many competing priorities in addition to running a research program — running a department, keeping clinic hours, doing patient rounds and teaching classes; maintaining momentum and keeping focus on the success of the research project is imperative.
- Developing an integrated, shared plan at the correct level of detail to accurately track project schedules and resources with flexibility for changes.
- Encouraging collaboration and knowledge exchange across the cooperating departments.
- Implementing a simple, informative, repeatable mechanism for managing and communicating issues and risks, and identifying resource constraints.
- Identifying and measuring key performance indicators (KPIs) early and throughout the program.
On any large-scale research initiative, project management may have several areas to track progress including: internal capability development, participant recruitment, changes from the grant issuer, and coordination among sites and/or other research organizations. By deploying a cross-functional project management team that leverages existing technology (e.g. standard methodology, templates, tools, etc.), the project will ensure better coordination and effective communication.

Most importantly, given the complexities associated with shifts in the grant issuer’s view on scope, participant requirements, launch date, etc., the necessary changes can be incorporated comprehensively with minimal interruptions to the project.

### 2. Operational Planning and Execution

AMC research leaders are responsible for determining how participants will enroll in their research study. Historically, research participants are asked to meet the researchers only at the host institution to participate, however, leaders embarking on large-scale research initiatives can benefit from looking to how their clinical counterparts have developed ambulatory care networks or other forms of integrated delivery systems to increase access. Often, regulatory experts as partners/advisors are leveraged during this planning process.

It is critical that operational planning include all aspects of the end-to-end participant experience from initial contact with the enrollment site for scheduling, patient arrival and registration, visit flow for the study, through post visit communications. The first steps in operational planning should include defining the participant experience sought to be achieved, determining the characteristics of the ideal research participants and understanding where they reside. Below, in Figure 3, you will find a decision tree that AMC leaders could utilize to determine the types of enrollment sites that best fit the desired study population.
Many AMC research leaders will determine that, given the scale of these projects, they will need at least some physical enrollment sites, and will have to choose between enrolling patients in a temporary, standalone site, or within an existing clinical setting that is providing patient care.

The participant experience is a key enrollment factor and, ultimately, increases the likelihood for referrals and a high engagement and retention percentage. It may appear that a patient visit for research can be executed in the same manner as a routine clinical appointment to an ambulatory practice and therefore can take place in an existing clinic. However, research participants, particularly involved in complex large-scale research initiatives benefit from a research-dedicated site that has prompt intake and a seamless visit cycle with specifically trained staff, dedicated exam rooms, necessary data intake support/education and controlled/predictable capacity.

AMCs must design each of their programs within their own capabilities, considering such factors as staffing resources, ambulatory practice capacity and physical space constraints to support minimum requirements for the research initiatives. AMCs should assess the scale of the opportunity to recruit from clinical practices and determine if there are trade-offs when selecting standalone sites versus embedded sites. AMCs can find ways to attract their target population using either structure but must ensure that the participant experience is seamless, convenient and efficient. Figure 4 highlights a few of the pros and cons for each type of site.

**Benefits of Permanent Enrollment Sites, by Setting**

<table>
<thead>
<tr>
<th>Standalone Physical Site</th>
<th>Embedded within a Clinical Setting</th>
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<tbody>
<tr>
<td>Research participants will not have to comingle with sick patients (i.e., urgent care waiting rooms)</td>
<td>Renting space within a larger clinical space may yield many of the exam room requirements (i.e., sinks)</td>
</tr>
<tr>
<td>Research participants will not expect or assume that enrollment staff are clinical providers who can provide medical treatment</td>
<td>The brand of the clinical partner may be known to many potential participants, helping recruitment</td>
</tr>
<tr>
<td>Aesthetic/décor and wayfinding can be controlled, and physical plan could be modified to maximize patient flow and square footage available</td>
<td>Clinical spaces often have parking nearby</td>
</tr>
<tr>
<td>Lease agreement may be more permanent than if space is being “borrowed” from clinical partners (i.e., if a clinical partner decides to expand and needs the space back)</td>
<td></td>
</tr>
</tbody>
</table>

Existing call or screening center configuration and capacity should also be considered. Existing workflows to manage incoming and outgoing call volumes will most certainly be impacted by the introduction of a large-scale research program. Both the volume and duration of associated research participant interactions can vary significantly from existing clinical demands. These infrastructure elements can be leveraged to provide key engagement and customer service capabilities that can directly support enrollment efforts.

Finally, program directors must design a care model that balances resources with the desire to fully support participants through the entire participant experience. As noted above, without a positive participant experience, researchers will struggle to build a large enrollment network.
3. Information Technology and Analytics

Information technology (IT) leadership and/or senior personnel must be included and active in the operational planning stages. Requirements gathering is a lengthy, iterative process that should be started as early as possible. Complete stakeholder involvement is critical to creating a unified understanding of the program goals and the tools needed to support success. By participating in the early stages of development, IT will be able to better understand and support program goals and direction. Ideally, for a large-scale research study, dedicated IT staff (support/development) should be considered to reduce the impact of competing priorities and delays in new requirements and functionality.

Healthcare organizations have spent millions of dollars on electronic health records (EHRs) and have been generating data for years. Using patient information for research is extremely valuable, however, the data resides across multiple business units, departments and owners, making it difficult for investigators to consistently obtain their data. Additionally, the data sets are distinct (system specific) and often need to be normalized and harmonized before any comparisons or analysis can be performed. Early detection of the pathways to request access or partnership/buy-in from the data owner groups is critical.

Ultimately, a “build vs. buy” decision will likely need to be discussed and decided for several solutions, such as scheduling, call center/screening and visit management systems (Clinical Trials (or Research) Management Systems (CTMS or CRMS)). Depending on the resources available, custom solutions may be preferred to create maximum flexibility for achieving deadlines. Custom solutions may also eliminate the additional burden placed on IT departments that are typically designed and staffed to almost solely be focused on supporting the priorities of the clinical enterprise. If dedicated IT resources are limited, out-of-the-box solutions may be preferred to address immediate needs. In either case, a requirements gathering exercise will go a long way in setting the direction for preferred solutions.

Specific data generated by these systems will be important and have high value upon program execution, so an analytics strategy should also be part of the research study’s IT component. Program governance (perhaps predicated by funding source) likely will define a limited or starter set of metrics that measure various aspects and outcomes directly related to the program goal – most commonly meeting recruitment goals (by demographic, disease type, etc.). However, a strategy to identify additional metrics should be considered to develop intelligence and identify trends, particularly in longitudinal, long-term or geographically dispersed studies. Understanding clinic or enrollment center operations (location throughput, appointment length) is critical to adjusting staffing and availability. Monitoring and measuring communication effectiveness (unique visitors to website, registrations based on email campaigns, inbound/outbound call center interactions) directly affect the controls placed on engagement methods employed. Visualization tools to report and understand the data may be leveraged, purchased (in the University of Pittsburgh study below, Tableau) or developed depending on the priorities and capabilities of the IT group.

Beyond initial findings and as development moves to implementation, IT should continue to stay involved and be integrated into operational planning and execution to ensure alignment with the program’s evolving priorities.
4. Research-Informed Community

Fostering a communal understanding of the importance and role of clinical research is the underpinning to address a major research hurdle: accruing participants. To share the impact of research efforts, AMCs should create and maintain programs that actively educate and highlight opportunities to participate or allow self-selection using eligibility criteria. The result is a pool of informed, qualified community members who may be able to support research opportunities.

A database with basic contact information of local community members that have consented to be considered or have a general interest in being matched for research studies is a quick and effective starting point to manage a research community. Such databases may be first assembled by pulling data from the AMC’s EHR as well as other web-based patient or customer portals. Education can be further supported by branding the database in a customer-centric way that encourages community health and the sharing of information. Before research participants elect into the registry, the AMC must have the appropriate regulatory approvals in place to not only store the data but also match the participant based on relevant personal health data and it may be helpful to engage a regulatory expert during this stage.

As discussed in the case study below, the University of Pittsburgh assembled their registry database by first obtaining a signed outreach waiver from patients while they were in the hospital or clinic setting. This waiver granted the University of Pittsburgh the ability to contact these individuals regarding studies for which they match. In addition, each time University of Pittsburgh carries out a large-scale research study, researchers have their participants sign up to be in the registry, so the next time a study is conducted, the university will have more people to target for outreach. There are also some institutions that are taking the approach of an opt-out for their patients to learn about research opportunities.

Marketing to participants in the research registry requires fewer resources (e.g., direct mailings only) and may require less sophisticated messaging, as these participants may already have experience participating in research projects. The registry may also be augmented by including the AMC’s faculty, staff and dependents who already understand the value of biomedical research.

5. Engagement and Recruitment

Marketing must be used as a tool to engage both the participants and the community at large about the research program. Organizations should begin with an inventory and assessment of currently established or employed outreach methods – portals, social media, U.S. mail, phone, etc. – and look for gaps against program enrollment requirements. In the University of Pittsburgh case study referenced below, the research project team focused its tailored messaging across multiple channels adjusted specifically according to target audiences and capacity. For AMCs pursuing large-scale research initiatives, the traditional “request to participate” messaging should be executed by first understanding the various motivations of community members, and then by tailoring messages about the benefits of participation to each of those groups.

If the research project is not focused on participants with a specific disease type, recruitment will likely require reaching participants beyond the clinical setting, such as social and traditional media and even travel-oriented locations (i.e., bus stops, billboards). These social and traditional media advertising methods may be familiar to some AMCs who have pursued clinical network strategies to reach a broader geography of patients. Other AMCs who have not refined their consumer engagement strategy may require engaging outside support to assist with the effort. In these cases, the specific messaging employed is critical in conveying the importance of voluntary participation (“the greater good”). Compensation models of varying value are also a commonly employed technique (where allowed by regulatory guidelines) to encourage and acknowledge participation.
The Long Lasting Impact

Academic medical centers that successfully execute large-scale research initiatives using proven strategic and operational frameworks will experience benefits across all mission areas. By leveraging the power of multiple assets from across the tripartite mission, AMCs can strengthen the education, clinical and research missions of their organization. Large-scale research initiatives foster physician and research faculty recruitment while providing a rich environment for young scientists to learn and grow. By strengthening overall brand recognition of the AMC through effective research participant marketing campaigns, the AMC is also able to garner increased clinical referrals. Large-scale research initiatives may also serve to distinguish the AMC’s specialty care services from regional and national competitors.

Most importantly, AMCs that effectively implement large-scale research initiatives by using the proven methods described above, will accelerate the process of discovery, so tomorrow’s cures may be here sooner. By improving the research participant experience, AMCs will be more effective in reaching enrollment targets not only for current studies but also future programs. At the same time, relationships with organizations like NIH will be strengthened as the AMC emerges as a leader in successful implementation.

As you consider developing a large-scale research initiative at your institution, ask the following strategic questions:

1. Does our AMC have or can we contract for the necessary competencies such as:
   - Dedicated project management
   - Strategic and operational planning (market analysis, participant service processes, site design, etc.)
   - Information technology support
   - Developing or supporting a research-informed community
   - Program marketing and participant engagement

2. Does our organization possess the physical space requirements to support a large-scale research initiative?

3. How prepared is our organization to recruit, on-board and train the staff and clinicians required to successfully support the program?
A Success Story in the Making:
University of Pittsburgh Precision Medicine Initiative

UPMC is one of the largest non-profit health care systems in the United States. Serving the Western and Central Pennsylvania region, UPMC covers more than four million individuals in urban/suburban and rural areas across 22,479 square miles (49 percent of the state of Pennsylvania). As a $16 billion integrated health delivery system that is the dominant regional provider of medical services (60 percent market share in Allegheny County; 41 percent share over 29 counties), its facilities include 37 hospitals, more than 600 outpatient offices and over 3,600 employed physicians. UPMC has long understood the critical role of informatics in healthcare, with electronic patient data dating back to 1987 and significant investments in corporate partnerships with IBM, Oracle, Informatica, dbMotion and the Pittsburgh Health Data Alliance (to leverage big data for research) with University of Pittsburgh and Carnegie Mellon University.

Since 1995, The University of Pittsburgh has attracted nearly $9.5 billion of sponsored research support into Pittsburgh and Western Pennsylvania. It ranks seventh nationally in federally financed research and development expenditures and fifth among U.S. universities in terms of grants awarded to members of its faculty by the National Institutes of Health (over $513 million). At the center of those awards is the Clinical and Translational Science Institute (CTSI). Founded in 2006, CTSI is an integral part of a National Institutes of Health (NIH)-funded nationwide network that bridges the gap between innovative approaches to research and effective clinical and public health practice, health policy and community engagement in research.

CTSI is the academic home for synthesizing university-wide programs and new initiatives to promote a more comprehensive understanding of the tangible benefits to health practice that can be realized from clinical and translational research. CTSI-supported programs and resources extend across the campuses of the University of Pittsburgh. Through the establishment of 10 core divisions, CTSI is building institutional infrastructure, including educational, programmatic, facility and equipment resources, to support a wide range of clinical and translational research. CTSI services or supports more than 25 percent of the University’s NIH research portfolio, and published manuscripts from a broad range of translational research studies that directly benefitted from CTSI support have been cited more than 81,000 times in literature.

Since 1995, The University of Pittsburgh has attracted nearly $9.5 billion of sponsored research support into Pittsburgh and Western Pennsylvania.
UPMC and The University of Pittsburgh CTSI are active partners that collaborate on many initiatives to leverage its vast patient population, research-aware personnel, and extensive facilities to recruit research participants for diverse studies. Both are credited and recognized with being leaders in the “eds and meds” economic sector now responsible for more than one out of every five jobs in the greater Pittsburgh region.

In December 2015, The Chartis Group was engaged to assist with an application to the Precision Medicine Initiative Cohort Program (PMI Cohort Program) – now called the All of Us Research Program – by developing a five-year recruitment roadmap and providing a letter of support. The UPMC and University of Pittsburgh CTSI proposal was the highest scored application and the organizations moved forward with an anticipated $65 million award to develop a comprehensive approach to enroll over 150,000 research participants. The Chartis Group was further engaged to provide advisory services, strategic planning, overall project management and customer service training in addition to providing guidance on initial enrollment site set up, including a methodology for determining space requirements, staffing models, and process and data collection workflows. Branded as “PA Cares for Us Research Program”, it was selected to be the first to launch nationally and to-date has enrolled more than 40 percent of the nation’s participants.

Below we describe how the University of Pittsburgh is successfully implementing a large-scale research initiative along five key dimensions of strategic and operational planning.

1. Project Management

Full-time project management support was deployed primarily to ensure that regulatory policies and procedures, staffing, IT development and selected enrollment centers were prepared to be operational in time for program launch. Given the complexity associated with operating a large-scale research initiative, there is a need to achieve superior performance across cost, quality and experience. There were several key considerations that informed the approach taken to manage the development of the enrollment centers to support a streamlined and successful launch, including alignment and expediency.

The project management team worked closely with university stakeholders to achieve true alignment and create the necessary and supporting agreements among all participants to establish a common understanding of the work to minimize disruptions during design and implementation. This was done by first identifying the likely partners – community, UPMC, etc. – who could be enlisted in some way to help University of Pittsburgh reach its program objectives. A disciplined approach was deployed to gain alignment with partners to ensure all intentions were transparent and agreements were clear; including internal arrangements. The team identified potential communication and coordination challenges, mainly related to ensuring local development and processes remained in line with national program guidelines that came out of various work groups, and proactively managed them to minimize their impact with as much collaborative effort as possible.
University of Pittsburgh also ensured expediency by effectively managing all required timelines via a well-organized approach to planning and execution, while minimizing “sacrifices” to the quality of the program itself. Stakeholders were engaged early and their roles were clearly defined. There was a range of engagement strategies deployed to ensure effective communication, define stakeholder involvement, and determine where negotiation was warranted throughout the project planning phases. The team reached early agreement regarding who would be responsible for making which key decisions. Also, a progress review guide was established with required stakeholders to ensure timely results while not defining everyone as a decision maker. University of Pittsburgh not only anticipated the potential compromises that may arise in the future but also established leading practice on Day One that provided a structure around space design, roles, workflows, and operating decisions.

2. Operational Planning and Execution

For the PA Cares for Us Research Program, the enrollment centers provided an opportunity to collect various types of data including bio-specimens and other individual information for a large participant cohort across a broad geography. The site selection process ensured that the “right” sites are selected in support of cost, quality, and experience – and with the required project timeframes in mind.

The process began with the end in mind, with a series of facilitated stakeholder, retreat-style work sessions. Stakeholders clearly articulated the desired and required cost, quality and experience objectives, as well as the associated timelines for the sites to open, and used this structure in a disciplined manner to guide the analysis and decision making. Data analysis was conducted with all potential sites and geographic regions in mind before narrowing the scope to a subset required for the near-term launch. Having a constellation of geographic sites ensured the right footprint and demographic reach for enrollment over the initial few years. University of Pittsburgh approached site selection as an analytic exercise using a qualitative lens to support the identification of sites to reach the program’s objectives. Leadership leveraged important geographic, demographic and registry data to support final decision making on defining “optimal” enrollment sites but remained both creative and open to an array of possibilities to maximize the success of the project.

3. Information Technology and Analytics

Similar to the operational planning process, IT development began with the end in mind by mapping the entire participant experience, from expressing interest to exit interview and compensation. The process was conducted over multiple sessions with representatives from all major stakeholder groups. The “map” put recruitment of the participant at the forefront of development and clearly set IT priorities.

The earliest system considerations were noted where internal development would enable desired functionality. Where significant gaps (in functionality or capacity) existed, technology purchasing was considered. Integration with national program systems were highlighted, and communication lines with those groups were immediately opened to negotiate specifications and requirements to support the optimal participant experience. This approach enabled the University of Pittsburgh CTSI IT team to take a leadership role and push national systems to meet as much of the defined workflow as possible at launch.
A key requirement of the PMI Cohort Program is the availability of patient EHR data to be securely shared with an awarded central data management group. Very early in the process, stakeholders from UPMC and the University Department of Biomedical Informatics were engaged to investigate data pathways and leverage new or existing tools to extract, securely store and share the protected patient information. A process was developed for both inpatient and outpatient data. Generated data files are loaded into a local, separate data mart. After data characterization and quality checks, data is extracted as .csv files and transferred securely using standardized, secure web protocols.

External to IT development but equally important, a legal document was negotiated and established to govern development, management, operation and security of a connection between systems owned by The University of Pittsburgh CTSI and the coordinating data center. Similar data sharing agreements may be applicable in large scale research programs to ensure ethical and appropriate use of technology over the course of program operations.

4. Research-Informed Community
The University of Pittsburgh began developing the Research Participant Registry in collaboration with CTSI ten years ago as means to inform and manage community research participation. Primarily, the Registry identifies and allows for recruitment of UPMC patients of all ages from every UPMC point-of-service location (approximately 4,000,000 outpatient visits and more than 150,000 inpatient hospitalizations per year), as well as community member volunteers, who may be eligible to participate in ongoing University of Pittsburgh clinical research studies. Registry participants can elect to be contacted about the PA Cares for Us Research Program, and receive personalized mailings about other studies in which they may have interest, or they may match based upon ICD-9/10 diagnosis criteria from their medical record and/or stated preferences.

In late summer 2016, and shortly before launching the PA Cares for Us Research Program, the Registry was rebranded as Pitt+Me. Pitt+Me uses enhanced study descriptions and social media to further educate and engage the community in research. Currently the Pitt+Me Registry has more than 121,000 active participants interested in learning more about research. The platform formed the basis for validating The University of Pittsburgh’s methodology to quickly recruit a large cohort as part of the national PMI program.
5. Engagement and Recruitment

The University of Pittsburgh focused on creating an environment and experience that serves the program needs while ensuring the highest level of participant and staff experience possible by thinking about marketing and recruitment from a holistic participant lens. A leading national creative production firm was hired to conduct interviews with participant cohorts and government representatives, and compile resulting data. The firm used the data to construct participant personas that helped define participant’s motivations or reservations to participate. This led to the development of marketing targets and revealed needs/concerns of potential local participants. Examples of key points that became important considerations for program design:

- Face to face interactions are important.
- Many questions exist on how study data/specimens may be used.
- A potential concern exists regarding the donation of bio-specimen.

The operations team, which was a collaboration of program leadership, clinical, administration and research staff, created participant engagement materials, designed the space, and planned daily site operations through the lens of the participant in support of a great experience and favorable word-of-mouth marketing. They infused leading practice into the design of the space and specific operations while customizing it based on the center’s purpose and anticipated population served. Clear standards (use of space, roles, workflows, etc.) were defined and guidelines were established on how to customize sites based on nuances to physical space, expected participants, unique clinical or process requirements, etc.

In addition, the staffing selection process favored aptitude and attitude to further emphasize a positive participant experience. Staff had clear roles, responsibilities and appropriate mechanisms defined to support all required work being completed in an expeditious manner. Extensive procedural training was provided, including one focused on soft skills for strong customer service.
Sources


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Vincent D’Itri is a Senior Manager with The Chartis Group. Mr. D’Itri has over 13 years of healthcare consulting experience working closely with leading academic medical centers and health systems. His areas of expertise include managing and leading NIH funded academic clinical research through grant writing, governance, operations, and program design in addition to healthcare operations and information technology, project management, system design and implementation and business analysis. Mr. D’Itri has particularly extensive experience working with members of the Clinical and Translational Science Awards consortium.

Kate Purnell
Former Engagement Manager

Kate Purnell is the Senior Director of the Adult Reconstruction and Joint Replacement (ARJR) service at the Hospital for Special Surgery. In her four years at Chartis, Ms. Purnell supported a range of prominent AMCs and other healthcare systems in enterprise strategic planning and service line planning, as well as through an M&A and an asset reconfiguration planning process. Ms. Purnell also led several ambulatory access and throughput engagements, from improving capacity management and operational throughput, to achieving best practices in call management and scheduling practices.
About The Chartis Group

The Chartis Group (Chartis) provides comprehensive advisory services and analytics to the healthcare industry. With an unparalleled depth of expertise in strategic planning, performance excellence, informatics and technology, and health analytics, Chartis helps leading academic medical centers, integrated delivery networks, children’s hospitals and healthcare service organizations achieve transformative results. Chartis has offices in Boston, Chicago, New York, Minneapolis and San Francisco. For more information, visit www.chartis.com.