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.
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.
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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.