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PEER REVIEWED

Clinical Project Managers Stuck Betwixt and Between

Andy Mehrotra

Why today's project leads need to evolve their role as part of strategic contract research organizations

It's no secret that contract research organizations (CROs) are playing a larger role in supporting the clinical trial process today than even just five years ago. As the structure of clinical trials becomes more complex—with stringent regulatory requirements, a greater number of international trial sites, more assessments, and higher volumes of data to manage—life sciences companies are expanding the role of the CRO. Further, the Pharmaceutical Research and Manufacturers of America (PhRMA) organization notes that today's clinical trials feature increasingly complicated clinical trial designs and procedures that demand more staff time and effort.{1}

The evolution of the CRO is driven in large part by the increased focus on novel medicines for rare diseases. In 2015, nearly half (47%) of all drugs approved by the U.S. Food and Drug Administration were rare disease drugs, including therapies for cancer, cystic fibrosis, difficult-to-treat high cholesterol, and several enzyme deficiency disorders, with currently 566 medicines still in development.{2}

These products provide treatment options for patients where there were few or none previously available, and while this is transformative for society, it dramatically complicates underlying clinical trials processes. Suddenly, there are more scientific unknowns, fewer specialized

clinicians to serve as investigators, smaller patient populations to take part in trials, and often more complicated drug delivery mechanisms.

Wanting to remain focused on core competencies in the development of these targeted drugs, life sciences companies are leaning more heavily on contracted resources to manage processes and identify risks, remove inefficiencies, and accelerate time to market. Consequently, the role of CROs is moving from transaction problem-solver to long-term strategic partner; as a result, CROs are turning to new project management business models to support their new role.

"The move to a strategic partnership with CROs is well under way," explained Chris Meyer, senior director of program management at Axial Biotherapeutics, a biopharmaceutical company harnessing the link between the human gut microbiome and the central nervous system to develop a new class of biotherapeutics for people with neurological diseases and disorders. "Both large and small biotechs are looking to maximize research investment by improving timelines and managing expenses through strategic CRO alliances. By creating these partnerships and intertwining them through the burgeoning pipeline, companies can gain valuable insights into ways to improve timelines and manage expenses."

From Tactical Administrator to Strategic Partner

To keep pace with new expectations, sponsors demand that their CRO project managers (PMs) have next-level competencies. In the past, PMs followed defined processes to complete clinical activities on time and within the scope of the sponsor's objectives. They worked according to simple management practices, adhering to the triple constraints of time, cost, and quality.{3}

Now, PMs must add new responsibilities for risk management, governance, innovation, and return on investment (ROI). They must have the management skills to communicate and engage with larger internal teams, external vendors, and customers. In addition, PMs must be proficient in analyzing larger subsets of data to pinpoint the outliers and report results to sponsors.

Rather than putting out fires, new expectations include proactively identifying key risk indicators that can affect trial results. Taking the role of "CEO" of the project, these leaders must look at the entire project cycle to ensure objectives are aligned with sponsors' goals, while finding new opportunities to decrease cost and speed time to market.{3}

"In the past, PMs were expected to execute narrowly defined scopes of work," Meyer notes. "Now, they must take a more holistic approach to ensure all stakeholders are working in lockstep with the project's expectations and hitting key milestones, plus they must manage risk and foresee potential hurdles that could cause delays, costs, or even failure."

Leslie Jones, executive director of clinical operations at ResearchPoint Global, a full-service CRO for small to mid-sized pharmaceutical and medical device companies, recognizes this new dynamic.

"PMs must be able to see risk and mitigate it before it happens, and even offer a solution before it becomes a problem," Jones says. "The buck stops at the PM today. Because there is a variety of new technology in place everywhere across the life sciences industry, there is an expectation that PMs should be able to see everything that is happening in the trial so they can manage risk. This isn't a new idea, but the additional expectations are. Sponsors expect CRO PMs to identify issues early, offer solutions, and effectively implement the changes."

It's Hard to Build a Skyscraper if All You Have is a Chisel

Despite the increase in responsibility, PMs aren't receiving the additional training and advanced technology needed to succeed. While skillsets and knowledge of the clinical trial process are critical, PMs also need tools to support them in collaborating with different stakeholders, analyzing larger pools of data, documenting tasks, and foreseeing risk. They need a platform that supports a seamless integration with sponsor companies, providing for transparency and communications as biotech companies want to retain oversight of operations. In some cases, smaller pharmaceutical companies depend on the CRO technological infrastructure.

However, much of the existing project management tools are generic applications without specific industry functionality—think spreadsheets, e-mail, static slides, and basic file sharing systems. Limited in breadth, these tools don't have key features PMs need to do their jobs efficiently, such as automated workflows, concurrent document review, and data management/analysis.

These legacy systems are usually incompatible with other systems, too, making it difficult for PMs to collaborate with sponsors and key partners in real time or leverage other technologies in house. Worse still, PMs often lack real-time visibility into trial processes worldwide—how can they be expected, therefore, to identify potential risk early and proactively avert problems? It's like trying to build a skyscraper with just a chisel.

"When project or program managers are stuck using rudimentary tools that are not intrinsically integrated or designed for their needs, they end up wasting precious time updating databases and trying to determine the latest file versions or who completed what task when," explains Meyer. "These menial administrative duties steal time away from more strategic, value-add work for the PM—yet the expectations remain the same."

To shift from a "customer-vendor" model to a strategic partnership, both the CRO and sponsor must work on a platform that eliminates redundant work and provides a single source of truth for all players. Cloud-based enterprise project collaboration (EPC) software, for example, brings together internal and external project stakeholders onto a single platform for streamlined communication, coordination, and collaboration.

By centrally connecting pertinent information from disparate sources, EPC software enables PMs to make more informed decisions and work proactively with teams to meet objectives. The software also ensures accurate and timely, two-way transparency, so both the CRO and the sponsor know exactly what is happening at any given time.

Meredith Gartner is a senior project manager at Advanced Clinical, a clinical development organization that provides CRO, full service partnership, quality and validation, and strategic talent acquisition services for biopharmaceutical and medical device organizations. Her team uses various systems along with Excel to manage tasks and dashboards, but sees the value in

project collaboration software to eliminate the arduous back-and-forth communications for status updates.

"Any system that turns the tedious, status-tracking part of this role over to a robust, data-driven system that allows team members to take ownership of their assigned tasks would dramatically improve productivity and the success of the trial," Gartner says. "I would love a system that pulls me out of the weeds so I can stay focused on the big picture."

According to Meyer, who implemented EPC software at a previous organization and is planning to do the same at Axial, "By combining the basic functionality of existing tools along with innovative new features designed to support the needs of an expanded job, this advanced software enables the PM to work much more efficiently and strategically. With greater transparency into processes from end to end, the PM can proactively monitor team progress and identify potential risks that can hinder progress. Overall, EPC supports a shift in the mentality of how to manage clinical trials."

Gartner expects that today's intense demands on clinical trial PMs will grow. "Already, people say that a PM can make or break a trial—that's pressure," she concludes. "Technology will make things easier in some ways—if it evolves to meet our changing needs. If it doesn't, conversely, technology will exaggerate expectations and put PMs into a no-win situation."

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Leveraging Institutional Tools and Resources to Track Clinical and Translational Research Services

Beatrice A. Boateng, PhD; Amy Jenkins, MS, CCRP, CCRC, CCRA; Anthony McGuire; Rhonda Jorden, MBA; Laura P. James, MD

Among the many challenges they face when conducting clinical and translational research, investigators must write detailed protocols, ensure compliance with a wide range of regulatory issues, and seek input and assistance from specialists such as biostatisticians, community engagement experts, and others. Less experienced or early-stage investigators may not know where to go within an institution to receive help in planning and conducting studies.

With support from a Clinical and Translational Science Award (CTSA) received in 2009, the University of Arkansas for Medical Sciences (UAMS) established the Translational Research Institute (TRI) and consolidated research services across the campus. In doing so, it became apparent that the institution did not have a robust process for tracking usage of research services, which is important for efficiently providing research support to the clinical and translational research enterprise.

The goal was therefore 1) to make it easier for researchers to find the help they need, and 2) to develop a system that allows the continuous monitoring of requests in order to efficiently provide the services.

Background

In the third quarter of 2014, TRI project leaders developed a process for tracking the type of services needed by researchers. This was initially setup as an electronic form that included contact information; project title; institutional review board (IRB) identification (ID) number; menu of services available (and a general option for services not available on the menu); a brief description of the request; and the ability to upload related documentation. The form was embedded into the TRI website, and investigators who called or e-mailed a request were re-directed to request services through the form.

While the researchers simply completed a form, the research services coordinator had to manually enter the information into a Microsoft Access® database. Although the process was time consuming and manually intensive, it provided baseline information on the type of research services needed by UAMS researchers. It also allowed the institution to build capacity in the areas that were lacking.

In 2015, TRI conducted an internal evaluation of the process and determined that it did not adequately capture the entire scope of, or all the research services utilized through, a single request. Problematic areas included:

1) One form completed by a researcher could lead to the utilization of multiple research services, and this was not tracked by the process in place.
2) It was challenging to easily determine which services were over-utilized or under-utilized, which would allow resources to be shifted to over-utilized but under-resourced service areas.
3) The institution rarely captured timely researcher feedback on their experiences and satisfaction interacting with service providers.

The TRI project leaders subsequently worked with key stakeholders to identify, categorize, and create workflows for the 25 research services available through TRI. Recognizing the need for continuous engagement of key stakeholders, monthly meetings were held to update stakeholders on the development of the system. TRI then explored tools within the institution that could be modified for its needs and be integrated into existing databases.

The goal was to standardize processes and provide a single gateway for requesting research services. TRI also wanted to better track the utilization and impact of the services offered. The solution, therefore, had to have two parts: the researcher view that enabled researchers to easily request services, and the administrative view that allowed TRI to track requests in real time.

Identifying the Right Tool for the Job

From the researcher perspective, TRI wanted to continue to have a simple form that allowed researchers to easily request services without entering redundant information, such as their contact details. The desire was for researchers to provide enough information to minimize miscommunication on the type of services needed, and to allow the service area to process the request.

From the administrative point of view, TRI envisioned a system that could capture real-time data from multiple sources into a single dashboard that would allow leaders to view key metrics, such as the number and type of requests and the quality of, and satisfaction with, the research services provided.

The search led TRI to a service management tool used by the institutional information technology (IT) department to address campus-wide, computer-related issues. The tool was already integrated into institutional human resources databases, thus allowing for easy capture of the contact information of researchers requesting services. Another positive aspect to using an existing product was widespread familiarity with the tool throughout the institution, since it had already been used by the IT department.

The tool enabled TRI to build two interfaces—a simple form that allows researchers to easily select services needed, and an administrative portal with dashboards that provide real-time visual representation of metrics and key performance indicators over time. The administrative portal also allows administrators to process incoming requests, view in-depth details about the requests (e.g., the IRB numbers and investigators' demographics), track the fulfilment of those requests, track communication between TRI staff and the investigators, run metrics reports, and request

feedback from researchers requesting services (see Figure 1). The data obtained are then shared with key leadership for data-driven decision-making.

Figure 1: Graphic Representation of the User and Administrative Back-End
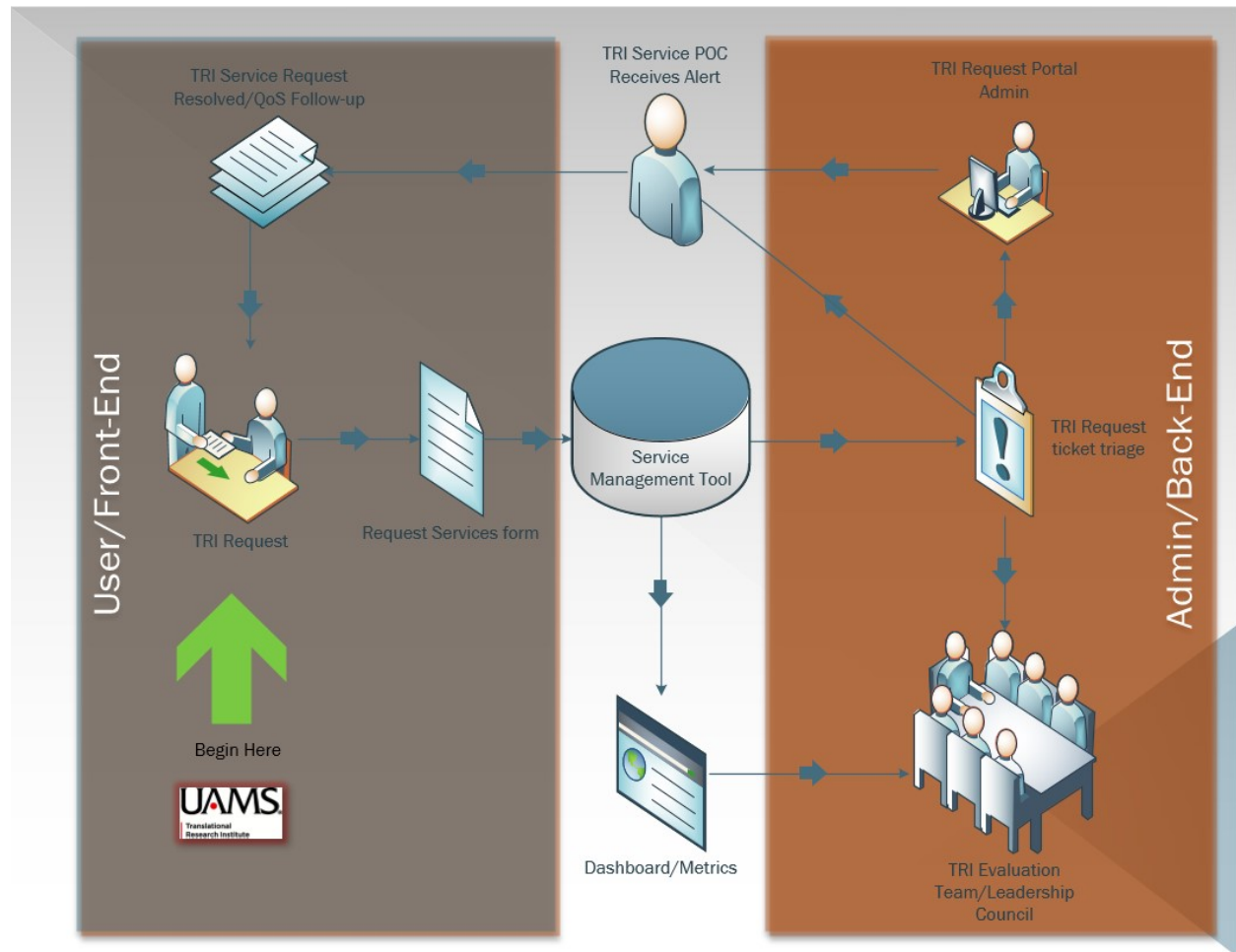
Tracking Metrics for Research Services

TRI's attempts to track research service utilization have undergone multiple iterations since 2014. Goals included determining if the new process implemented in 2016 made any difference in key metrics such as the number and type of services requested, and the quality of and satisfaction with services provided, both of which are expanded upon in the following sections.

Number and Type of Services Requested

The service management tool has allowed for better capture of the number and type of services requested. After the launch of the new system in March 2016, TRI staff noticed an increase in service requests. Monitoring of the data for six months (see Figure 2) revealed the unit was still not capturing all the services utilized; only the number of individual requests was known, and not the number of services requested in each request.

A modification implemented in the workflow in November 2016 resolved the deficiency. For instance, TRI received 64 individual requests in the month of January 2017, and was able to translate the specifics into a total of 244 services requests (an average of three to four research services per individual request). In addition to the number of requests, staff were able to capture the services most utilized (see Figure 3), and to view the number of requests that are completed and closed and the number still open in real time.

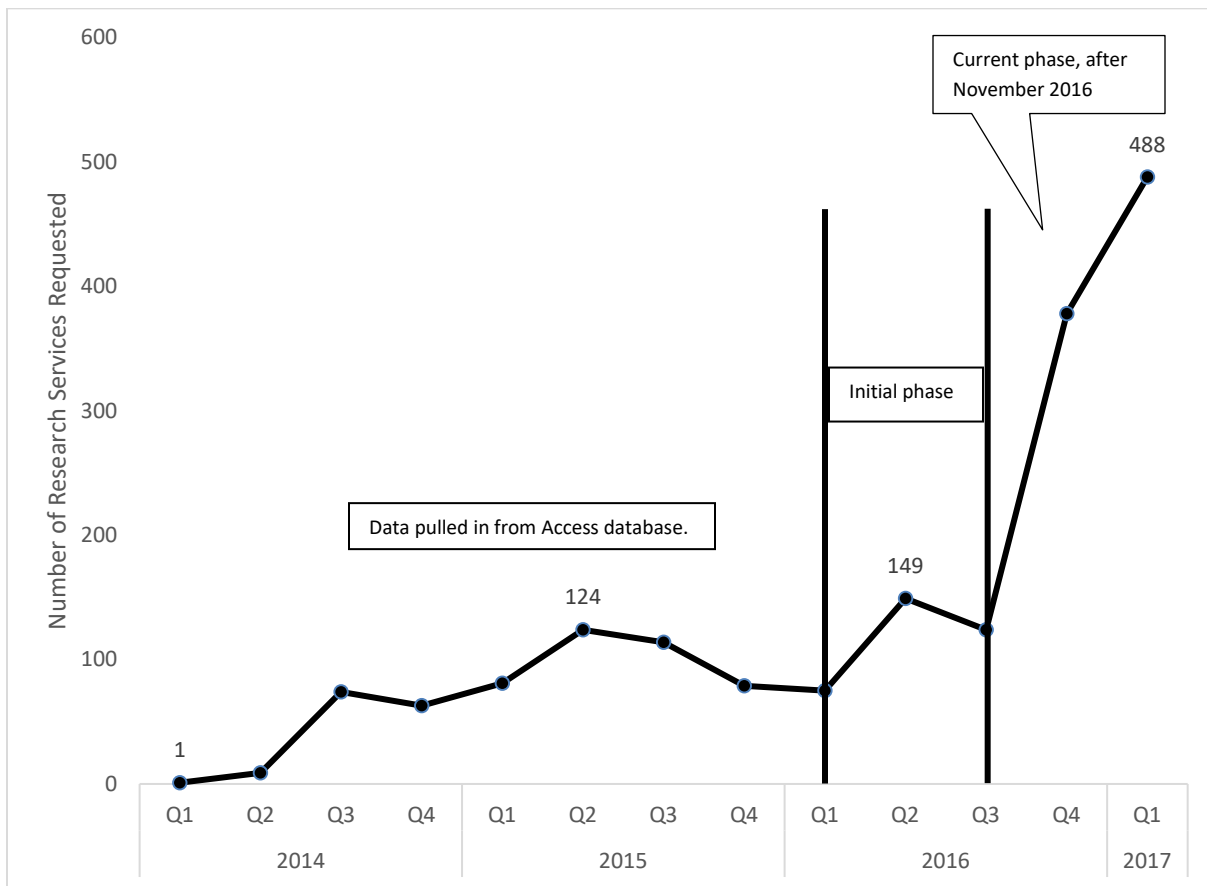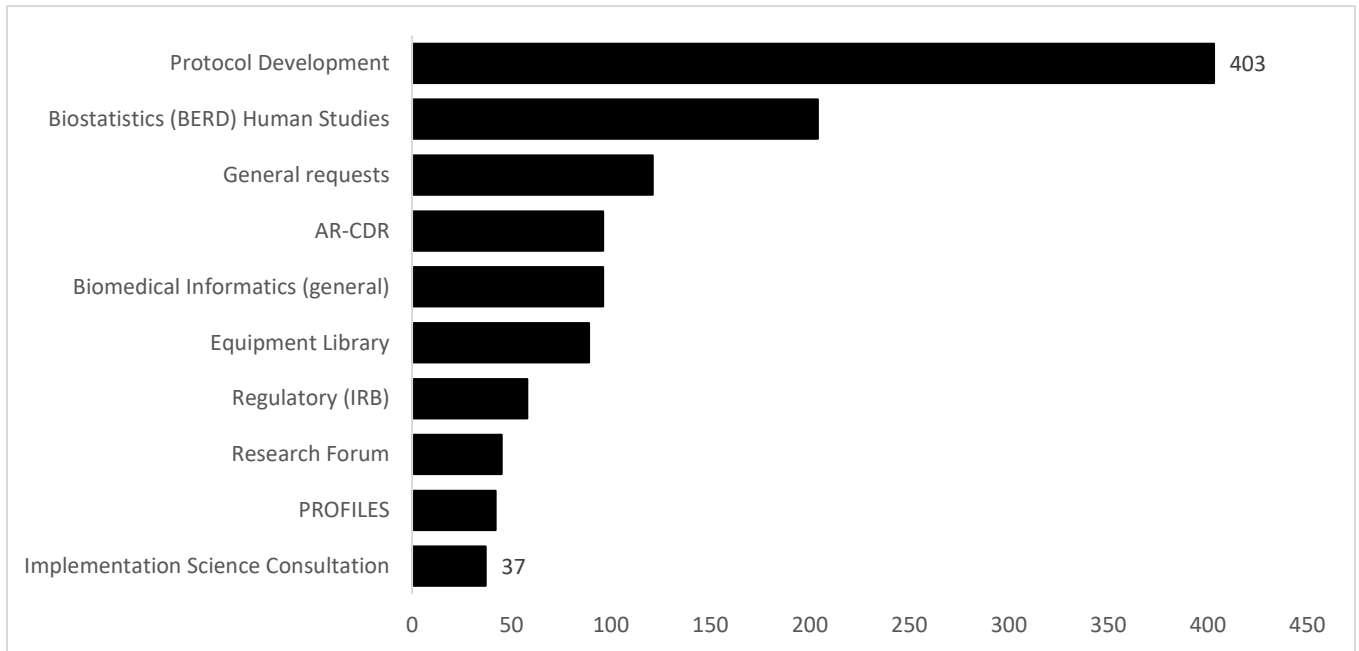**Figure 2: Research Services Requested Over Time (Through March 2017)**

Figure 3: The 10 Most Requested Research Services (Through March 2017)

Service	Count
Protocol Development	403
Biostatistics (BERD) Human Studies	
General requests	
AR-CDR	
Biomedical Informatics (general)	
Equipment Library	
Regulatory (IRB)	
Research Forum	
PROFILES	
Implementation Science Consultation	37

The most utilized service is a protocol development resource for investigators writing protocols for investigator-initiated research. Researchers are first provided with a variety of tools and customizable templates to write their draft protocol. Prior to IRB submission and upon request, skilled staff review the document for coherence of objectives, study design, and methodology. They further work with researchers to make recommended changes based upon local and federal regulations, IRB policies, Good Clinical Practice guidelines, and other considerations.

The general requests category is used when researchers have a question or request that does not fit into any of the other described service categories. Examples of requests falling into this category include questions about local research processes or policies, assay availability, and getting connected with someone in a particular area of expertise. Should a general request fit into one of the established services after further inquiry, TRI staff redirect the request to that service area.

The use of the service management tool has led to an increase in awareness of the type of services offered and, as noted in Figure 2, there has been a significant increase in the number of services requested. TRI staff are beginning to also track the potential impact of these services. Anecdotal feedback received indicated that researchers who utilize the protocol development services are less likely to have issues with the protocol when submitted to the IRB. Also, the biostatics services offered through TRI provide research design and analysis assistance to researchers.

Researchers are encouraged to seek consultations in the early development process of their research or grant ideas. With more than 50 faculty and staff, the biostatistics team has contributed to securing more than $91 million of national, peer-reviewed grants for researchers from 2014 to 2016. This amount includes $41 million received for the institution to act as a data coordinating center for a pediatrics clinical trials network.

Quality and Satisfaction With Services Provided

Assessing satisfaction of services provided is an integral part of the business community, but is something rarely adopted in the research services community. TRI wanted to use a simple, validated instrument to capture various aspects of research services, so staff modified a validated instrument known as ServQUAL, which assesses service quality on five dimensions.{1} ServQUAL has been widely used in service-oriented industries{1} and in hospital settings.{2–5}

Our final instrument included 10 items assessing three dimensions of quality applicable to research services on a Likert scale ranging from strongly disagree (1) to strongly agree (7). The dimensions being rated were: 1) Responsiveness—willingness to help and respond to investigator needs (four items); 2) Reliability—ability to perform research services dependably and accurately (three items); and 3) Empathy—the extent to which caring, individualized service is provided (three items). The instrument also included two items on a 10-point Likert scale assessing expectations and overall satisfaction with research services provided, and two spaces for open-ended feedback (e.g., on what we could have done differently and any particular person or issue that stood out).

A 2014 pilot of the instrument prior to the implementation of the service management tool received a 85.5% satisfaction rate. Subsequently, we observed improvements in perceptions of quality of services provided and satisfaction rates greater than 95% for most of the research service areas. We now provide monthly service utilization reports and annual satisfaction reports to each of the service areas.

Challenges and Limitations

TRI staff faced several challenges in striving to accurately capture the metrics needed to evaluate research services. Working with the IT department to understand the workflow process was the most challenging aspect of this process, in that it required (and continues to require) frequent communication. The main issue encountered was the inability to capture all the services requested (i.e., one researcher request was counted as one service requested instead of the potential multiple services per request).

Access to research services is through the TRI website. Although the website link is set to move directly to the research services form, customization of the menu of the service management tool is not possible, and it displays other menu options for services being used by the IT department. For instance, IT has menu links titled: Create a New Incidence or Create a New Problem, which can be confusing terminology for researchers. While having a separate iteration of the tool could address the menu issue, it is currently not financially feasible or cost effective to have a separate account.

Finally, institutional updates to the service management tool have periodically affected TRI's established research workflows, such as resending completed projects as new ones or *losing* requests that were sent during the update period. Despite these challenges, the processes now implemented are providing data and information that could not be captured before. TRI will continue to use the service management tool while monitoring and addressing issues that arise.

Conclusion

Through this process, TRI staff have observed significant improvements in communication between researchers and service areas. This can be credited, in part, to including key stakeholders in the design and implementation of the new processes.

TRI has eliminated underutilized services, better categorized services, and expanded the services offered from 25 to 31. Staff have minimized investigator and provider issues by providing more clarity and specificity to the service request form. They can also track metrics such as number and type of services requested and cost of services provided (estimated cost savings and monetary value of using TRI services). The dashboard ensures that TRI can streamline and standardize research processes, and identify opportunities for improvement.

Overall, data-driven decision-making is increasingly important for forecasting and predictive measures. The service management tool has provided the TRI unit at UAMS with a way to track and assess utilization of research services in real time.

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PROJECT MANAGEMENT: DELIVERING THE BIG PICTURE

Clinical Project Managers Stuck Betwixt and Between

LEARNING OBJECTIVE

After reading this article, participants will be able to identify the new responsibilities added to the role of the project manager and their impact.

DISCLOSURE

Andy Mehrotra: *Employee of EightSpokes*

1.   What percentage of drugs approved by the U.S. Food and Drug Administration in 2015 was for rare diseases?
a)   50%
b)   47%
c)   55%
d)   45%

2.   The challenges involved in clinical trials for rare diseases include all of the following EXCEPT:
a)   More scientific unknowns
b)   Fewer specialized clinicians
c)   Smaller patient populations
d)   Less complicated drug delivery mechanisms

3.   In the past, project managers (PMs) adhered to the triple constraints of:
a)   Time, cost, and quality
b)   Scope, planning, and initiating
c)   Complicated clinical trials, smaller populations, and budget
d)   More assessments, higher volumes, and stringent regulatory requirements

4.   According to the article, what new responsibilities must be added to the role of the PM?
a)   Manage expenses, manage time, and put out fires
b)   Trial design, problem solving, and team leader functions
c)   Risk management, governance, innovation, and return on investment
d)   Engage stakeholders, engage vendors, and ensure both are aware of sponsor requirements

5.   With added responsibilities, PMs must be proficient in:

a)   Business practices of both the sponsor and contract research organization (CRO).

b)   Several languages in order to work with global teams.

c)   Forming long-term strategic partnerships with stakeholders.

d)   Analyzing large subsets of data to pinpoint the outliers and report results to sponsors.

6.   What must PMs ensure when they take on the "CEO" role for a project?

a)   That the objectives are aligned with sponsors' goals, while finding new ways to decrease cost and increase speed time to market.

b)   That all inefficiencies are removed, and that there is effective communication with internal and external vendors.

c)   That key risk indicators are identified and reported to the sponsor.

d)   That all risks have been identified and mitigated.

7.   According to Leslie Jones of ResearchPoint Global, what do sponsors expect of CRO PMs?

a)   To move away from narrowly defined scopes of work.

b)   To provide reports of risk management to the sponsor on a monthly basis.

c)   To identify issues early, offer solutions, and effectively implement changes.

d)   To take a more holistic approach to ensure all stakeholders are working within project expectations.

8.   What are the challenges that PMs face with their increased responsibility?

a)   PMs are not receiving additional training and existing PM tools are generic applications.

b)   Sponsor and CRO electronic systems are not compatible with systems used by most sites.

c)   Keeping pace with new expectations is impossible under increasing regulatory pressures.

d)   Limited resources are available from sponsors and sites even for potential breakthrough products.

9.   EPC software enables PMs to make informed decisions and work proactively. It also ensures that:

a)   Redundant tasks are eliminated.

b)   Accurate and timely two-way transparency.

c)   Compatibility of systems across all interfaces of CRO and sponsor.

d)   Activities are completed on time and within the scope of sponsor objectives.

10.   According to Meyer, who implemented EPC software, the greater transparency in processes allows the PM to:

a)   Include key stakeholders and receive feedback from them using encrypted communications.

b)   Make more informed budgeting decisions and work proactively with teams for study start-up.

c)   Proactively monitor team progress and identify potential risks that can hinder progress.

d)   Bring internal and external project stakeholders together onto a single platform that is streamlined.

Leveraging Institutional Tools and Resources to Track Clinical and Translational Services

LEARNING OBJECTIVE

After reading this article, participants will be aware of research services that can be utilized within their institutions.

DISCLOSURE

Beatrice A. Boateng, PhD; Amy Jenkins, MS, CCRP, CCRC, CCRA; Anthony McGuire; Rhonda Jorden, MBA; Laura P. James, MD: *Nothing to disclose*

11. Who established the Translational Research Institute (TRI) referred to in this article?
a) The Clinical and Translational Science Award Program
b) The University of Arkansas for Medical Sciences
c) An institutional review board (IRB)
d) The Association of Clinical Research Professionals

12. When was a process for tracking the services required by researchers developed by TRI?
a) 1st quarter of 2014
b) 1st quarter of 2015
c) 3rd quarter of 2014
d) 2nd quarter of 2015

13. What was the determination of the internal evaluation conducted in 2015?
a) The process correctly captures investigator feedback and allows easy decisions about which services are over-utilized or under-utilized.
b) Information should be manually entered by the research services coordinator.
c) Researchers had difficulty uploading related documentation to the form embedded into the TRI website.
d) The process did not adequately capture the entire scope of research services utilized in a single request.

14. The TRI project leaders recognized the need for continuing engagement with key stakeholders. How did they meet this need?
a) Stakeholders had to categorize research services.
b) Monthly meetings were held to update key stakeholders.
c) Key stakeholders were invited to assist with creating workflows.
d) Stakeholders had to identify research services required at the institutional level.

15.   What was an advantage of using an existing service management tool utilized by the institution's information technology (IT) department?
a)   The IT department would be able to assist with technical issues.
b)   The IT department would maintain a back-up of all the information.
c)   There was widespread familiarity with the tool throughout the institution.
d)   TRI would get buy-in from the key stakeholders on many future systems that were in the pipeline.

16.   The new service management tool allowed for:
a)   More requests to be entered into the database.
b)   Better capture of the number and type of services requested.
c)   An easy tracking of utilization of research services required by researchers.
d)   Researchers to be able to select and track key performance indicators over time.

17.   What modification of information that staff could access, in addition to number of requests and services utilized, was implemented in November 2016?
a)   Staff would know the number and type of individual requests received on a monthly basis.
b)   Staff would be able to view all the input received from key stakeholders.
c)   Staff could view multiple sources in a single dashboard and track metrics and quality of services.
d)   Staff would be able to view the number of requests completed and closed and the number still open in real time.

18.   Which service was most utilized by researchers?
a)   Implementation Science Consultation
b)   Biostatistics Human Studies
c)   Protocol Development
d)   Regulatory (IRB)

19.   Skilled staff would review the draft protocol and take into consideration:
a)   The institution's standard operating procedures, qualifications, and experience of investigator and their staff.
b)   Budget requirements for the protocol.
c)   Assay availability for a particular aspect of the protocol.
d)   Local and federal regulations, IRB policies, and Good Clinical Practice guidelines.

20.   Through the processes implemented, what has TRI managed to do?
a)   Include key stakeholders in the design and receive anecdotal feedback from them.
b)   Eliminate underutilized services and expand services offered from 25 to 31.
c)   Secure $41 million for peer-reviewed grants for researchers.
d)   Assess the quality of protocol execution and research services on five dimensions.