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Insight Brief

TRANSFORMING PATIENT RECRUITMENT THROUGH PATIENT AND SITE ENGAGEMENT

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EXECUTIVE SUMMARY

With 11% of clinical research sites failing to enroll a single patient, and 37% of sites under-enrolling, the need for improved efficiency is evident. Studies involving fewer sites have potential to improve on this performance, taking advantage of the best leaders in each therapeutic area, reducing travel and administrative costs, and aligning processes for easier start-up.

This insight brief examines IQVIA's innovative approaches to patient and site engagement, such as pioneering early planning, innovative partnerships, new technology and communication tools, working with patient advocacy groups, precision enrollment and the IQVIA Infosario™ Site Gateway platform.

INTRODUCTION

Some 11% of research sites industry-wide fail to enroll a single patient, with 37% of sites under-enrolling, creating inefficiency and lost productivity.[1] This represents a waste of time and money benefiting neither sponsors nor other research stakeholders. Studies involving fewer sites have potential to improve on this performance, taking advantage of the best leaders in each therapeutic area, reducing travel and administrative costs, and aligning processes for easier start-up.

Studies involving fewer sites hold promise in improving clinical trial efficiency, drawing on the expertise of therapeutic experts, minimizing costs and optimizing processes for easier start-up.

Early planning is a major factor in trial success – including identifying patient pathways in each country, understanding patient and investigator perspectives, and applying these insights to trial design and implementation. Patient advocacy groups are an important source of information about patient preferences, helping inform study design and tailored communication programs and flag potential enrollment and retention risks. For rare conditions, online sources of patient-generated content can also be mined using social listening tools to help understand how patients experience a particular condition. Early engagement with sites, clinical and medical teams, and in-country regulatory specialists is also critical to successful enrollment planning.

This insight brief examines new and innovative solutions to get drugs to patients faster, via improved patient and site engagement.

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APPROACHES TO IMPROVE PATIENT AND SITE ENGAGEMENT

PIONEERING EARLY PLANNING

Enrollment remains critical to the success of a clinical trial, with proper upfront planning playing a key role in today's competitive and complex clinical research landscape. Investing time in the trial planning stage can yield major benefits. For example, patient perspectives gathered through focus groups, advisory boards or surveys can provide valuable insights into how a protocol design may impact patients from a day-to-day perspective, and what changes might make it easier and less burdensome for a patient to participate. Equally, insights from physicians can help build understanding of how they treat patients, and how the protocol design fits in or competes with the standard of care in each healthcare system where the trial will be conducted. Engaging with investigators in the planning stages of a sponsor's clinical program can also build interest and enthusiasm.

DRIVING ENROLLMENT SUCCESS

Elements of an approach to drive enrollment success include:

- **Understanding the patient journey** and applying this to study planning, through the use of focus groups, surveys and interviews with physicians and patients.
- **Incorporating feedback in protocol design and study tool development** to decrease protocol amendments and increase patient and investigator engagement.
- **Upfront recruitment planning** and program-level recruitment strategies enable proactive enrollment risk management.

If a study is close to start up, it may not be feasible to conduct in-depth interviews with physicians or patients. In such cases, the Internet provides a wealth of information from people discussing their conditions. This content can be mined via social listening tools, to gain a better understanding of how patients experience a particular condition, and to inform study communication programs and flag potential enrollment and retention risks.

Early site engagement is critical to successful enrollment planning. Understanding the patient journey and their interactions with sites can reveal unexpected insights and challenges, helping identify and mitigate risks upfront. Clinical and medical teams should also be included in recruitment strategy discussions and planning at an early stage, helping ensure planned strategies are effective and efficient, and communication materials are appropriate and helpful for the target patient population, as well as for the investigators and site staff. Several strategies can help sites identify patients ahead of activation, including pre-screening of electronic health records (EHRs) or paper charts, and building online communities of interested patients.

INNOVATIVE PARTNERSHIPS: A STRATEGIC RELATIONSHIP WITH DAVITA CLINICAL RESEARCH

IQVIA recently entered into a new strategic relationship with DaVita Clinical Research, a subsidiary of DaVita HealthCare Partners, Inc. (Figure 1).[2,3] DaVita is an established leader in kidney care, chosen by more than 7 million patients, and has relationships with leading nephrologists as well as an established infrastructure of dialysis centers. IQVIA and DaVita are aligning processes to accelerate timelines when working together as well as leveraging DaVita's access to de-identified patient data to provide data-driven enrollment estimates. Combining DaVita's deep knowledge of renal patients with IQVIA's expertise in clinical research will help provide exceptional delivery for studies in nephrology, driving faster and more predictable timelines.

Figure 1. Partnering with DaVita to combine expertise in renal care, reduce timelines and increase participant enrollment

THE IQVIA DAVITA STRATEGIC ALLIANCE COMBINES WORLD-CLASS RENAL CLINICAL CARE EXPERTISE WITH INDUSTRY-LEADING CLINICAL ACUMEN, OFFERING STREAMLINED TIMELINES AND EXTENSIVE PATIENT KNOWLEDGE.

IQVIA brings over 30 years of clinical expertise, established processes and cutting-edge technology to transform clinical development.

DaVita, an established leader in kidney care chosen by over 7 million patients, brings leading nephrologists, an established infrastructure of dialysis facilities and a deep understanding of these patients.

Meeting the demands of nephrology clinical studies by incorporating study conduct into dialysis operations through a patient population available for potential trial enrollment, to decrease complexity and speed timelines.

START RECRUITMENT EFFORTS BEFORE THE STUDY BEGINS

Key elements of early recruitment efforts include:

- **Starting** with a protocol impact analysis and considering the patient journey to positively impact study success downstream
- **Creating** a study recruitment strategy including the clinical and medical teams
- **Devising** a country-level patient strategy by surveying in-country regulatory staff for up-to-date information on what can and can't be used

INNOVATIVE PARTNERSHIPS: ENHANCING OUTCOMES FOR MEDICAL ASSOCIATES RESEARCH GROUP

Medical Associates Research Group (MARG; San Diego, CA[4]) is an IQVIA Partner site that has always met or exceeded both enrollment and quality expectations. This group wanted to further enhance its patient recruitment and retention processes. The Principal Investigator and Research Director contacted MARG's site relationship manager and the leadership of IQVIA's Site and Patient Networks for support in reaching out to a diseasespecific patient community – in the area of inflammatory bowel disease – to explore all opportunities to engage potential research participants. A joint program included an enhanced social media presence, focusing on Facebook[5], with the goal of building solid working relationships and collaboration with local, disease-focused patient advocacy groups. IQVIA also provided tools to support elements of recruitment and retention, such as the informed consent process and study road maps.

MEDICAL ASSOCIATES RESEARCH GROUP CASE STUDY SUMMARY

- **Opportunity:** MARG, a well-performing Partner site, had a call to action to increase enrollment by engaging the inflammatory bowel community.
- **Action:** IQVIA's Site and Patient Networks team engaged experts and developed a roadmap.
- **Results:** Increased social media following and achieved successful outreach to this disease-specific community, resulting in enhanced investigative site and study participation.

INNOVATIVE PARTNERSHIPS: OPTIMIZING RECRUITMENT FOR TRIALS AT RALEIGH NEUROLOGY

Enabling sites to enroll patients is critical to study success. In early 2016, IQVIA initiated an innovative project with Raleigh Neurology, in which IQVIA provided assistance in identifying potential matches for clinical trials based on EMR chart reviews and screening of patients with scheduled appointments. An IQVIA patient recruitment specialist was based on-site at Raleigh Neurology, working closely with the partner's research team to help optimize recruitment for two trials. Tactics included providing sites with training on how to hold local events, support for placing local media advertisements, and patient prescreening support through digital or call center technology.

Digital patient communities can be built to engage patients throughout their entire participation in a trial.

A private, moderated peer-to-peer community offers the following:

- Influences patient adherence to treatment
- Maintains patient engagement during treatment and for planned extension studies
- Facilitates collection of patient input for study design
- Provides a safe, moderated environment for patients to share their realities
- Shows insights into patient and site experiences, leading to improved issue identification and resolution
- Offers the ability to educate patients regarding their disease and treatments
- Has the potential to integrate into the larger disease communities across a portfolio.

TOOLS FOR OPTIMUM PATIENT ENGAGEMENT

Developing compelling study materials for patients can be a key engagement tool to raise awareness and increase interest from patients in study participation. Insights from patients can be used to develop compelling branding and messaging. By listening to patient perspectives and understanding what tools work best, toolkits can be tailored to include only those materials each site will find helpful in their recruitment and patient engagement efforts. Beyond printed tools, web portals for patient pre-identification for sites and for pre-screening of patients can help drive incremental enrollment by identifying additional interested and qualified patients.

Working with patient advocacy groups in clinical trials can break down barriers to participation and facilitate recruitment, and is a way to obtain patient input for protocol or study design. Understanding

the patient experience allows a clear view of barriers to patient participation, enabling enhancement of patient recruitment and retention services and tools. Periodic feedback from patients facilitates a nimble response to any issues, helping to improve both patient and site experiences. Relationships with patient advocacy groups are developed across a wide range of therapeutic areas to gain patient insights, connect patients to investigative sites, and to open communications for future study needs.

DEVELOPING INNOVATIVE SITE COMMUNICATION TOOLS

Sites engagement can be improved using simpler documents from regulatory start-up through to study conduct and database lock. Regular communications with sites bring personnel up to date and facilitate information sharing among and between sites, via Site Connect newsletter, Google hangouts and IQVIA's Site Vision Forum meetings. It is important to consider how the tools and materials developed for recruitment are deployed to sites. Making sure all tools are ready in time for the investigator meeting, when they can be explained and reviewed, is the best practice.

WORKING WITH ADVOCACY GROUPS TO EMPOWER PATIENTS TO DRIVE STUDY SUCCESS

Building relationships with advocacy groups enables IQVIA to:

- **Develop** comprehensive knowledge of the patient experience.
- **Facilitate** introductions between investigative sites and local groups.
- **Leverage** patient insights to engage patients.
- **Implement** patient-centric operations.

Additionally, clinical research associates (CRAs) should be trained to help sites utilize study-related tools to maximize the impact of these materials. Figure 2 provides an example of the tactics used to help certain sites to meet their goals.

Figure 2: Helping sites meet their goals through innovative communication

INNOVATIVE COMMUNICATION

- **Site Connect newsletters** keep you informed of industry developments
- Our **Physician-to-Physician LinkedIn Community** enables over 2,000 members to share information and insights
- **Google Hangouts** introduce "hot topics" and allow you to meet the experts
- **Feedback surveys** identify your needs so we can address them
- **Focus groups** explore ways to align processes and increase efficiencies
- **Early engagement** allows for advice on protocol development
- **Webinars** hosted by Society of Clinical Research Sites presented by IQVIA

USING NEW TECHNOLOGY: THE IQVIA INFOSARIO SITE GATEWAY PLATFORM

IQVIA Infosario Site Gateway is an important enabler of IQVIA's various services and capabilities to better engage patients and sites. Based on insights from investigator working groups, site surveys and industry data, sites experience substantial administrative burden when participating in studies. This burden is a major reason for physicians deciding not to participate in studies, and for sites to under-perform.

The Infosario Site Gateway technology solution combined with our people and processes makes life easier for sites, reducing study team workload and cycle times, and driving quality and compliance. The platform's guiding principle is to automate and simplify processes and document collaboration wherever possible.

INFOSARIO SITE GATEWAY VISION

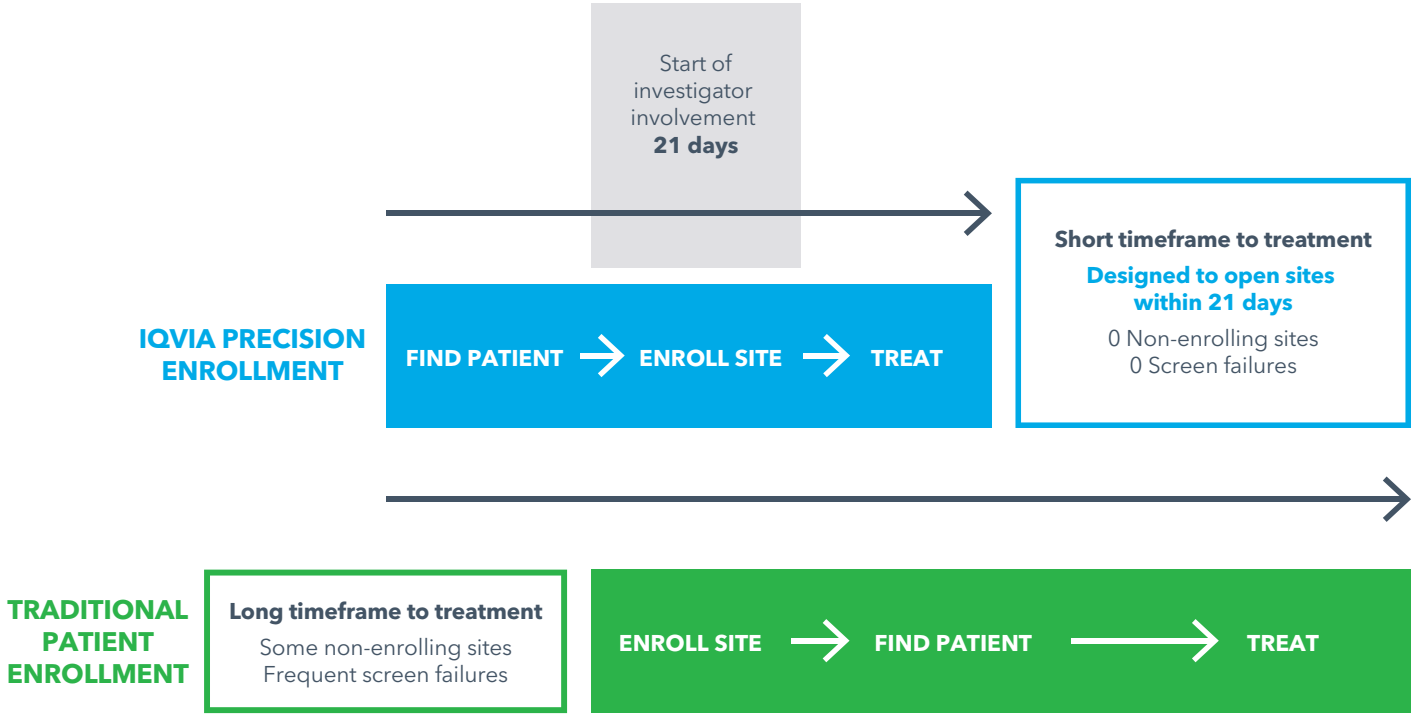
Reduce administrative burden of our sites and drive study success with Infosario Site Gateway, in areas such as:

- **Reduced timelines**, through a document center that expedites document collaboration and tracking (with eTMF integration)
- **Enhanced compliance**, through electronic safety letter distribution and automated compliance tracking
- **Increased site visibility**, by developing site profiles to prepopulate key forms, such as site ID surveys
- **Strengthened oversight**, using enhanced laboratory management to provide near-real-time visibility into lab results and reports

NOVEL APPROACHES TO ACCELERATE SITE STARTUP

IQVIA recently launched two pioneering approaches to accelerate patient identification and site startup in oncology studies: IQVIA Precision Enrollment, and in Europe, the Early Phase Oncology Network (Figure 3). IQVIA has built a network of oncology sites that uses master contracts and disclosure agreements, as well as centralized institutional review board (IRB) capabilities, to streamline patient identification and start-up. This IQVIA Precision Enrollment approach accelerates patient identification and site startup in oncology studies, addressing the increased focus on rare populations, and using technology platforms to quickly identify patients. This way, when a patient is identified, the remaining startup processes can be rapidly completed, and the site is opened within 21 days. In Europe, IQVIA's Early Phase Oncology Network connects multiple sites with international Key Opinion Leaders; participants work together in a dedicated network, including an advisory board.

Figure 3: Leverage site networks to drive more efficient oncology study enrollment



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5. https://www.facebook.com/MARGInc/

ABOUT THE AUTHORS

KIMBERLY RAY
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Kimberly Ray has a long career at IQVIA, spanning a variety of roles across the drug development continuum. Over the past five years, she has focused on enhancing the investigator and site experience in clinical trials. She led the Site Identification and Start-up Teams across the Americas, oversaw site relationships, and currently serves in a leadership role focused on strengthening relationships with sites and patient advocacy groups to enhance their impact on clinical trials.

BERNADETTE TOSTI
Senior Director of Patient Recruitment, Site and Patient Networks, IQVIA

Bernadette Tosti brings over 10 years of healthcare marketing, clinical trial recruitment and retention, and digital recruitment technology experience to her role at IQVIA. Prior to assuming her role as Head of Patient Recruitment Programs, Bernadette was responsible for IQVIA's Health Engagement & Communications' clinical business development including strategic insight on digital patient engagement solutions for recruitment and retention. Previously, Bernadette served in patient recruitment and product marketing roles in various organizations. During her tenure at IQVIA, she has helped develop innovative technology solutions for recruitment of patients into clinical trials and supported development of IQVIA's patient communities. Bernadette has spoken at several industry conferences on the impact of patient recruitment and retention solutions on clinical trial enrollment performance.

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