

Trends in Subject Recruitment 2010

An intelligence-driven end-to-end approach
defines new recruitment methods.

The Next Generation of Recruitment is Here

Helen West

I was recently asked if patient recruitment is getting smarter. A tough question but one that everyone responsible for recruitment needs to be continually asking. Important evolution has taken place in the patient recruitment landscape. Strategies are being implemented in ways that are increasingly better suited to the particular needs of not just a given trial, but to individual sites. Outreach tactics have become more specific by orders of magnitude. Many study sponsors are showing that they understand the importance of feeding outcomes back to recruitment groups so that metrics can be captured and used to improve performance.

A growing group of sponsors also demonstrates a commitment to incorporating best recruitment practices into their standard operations and consistently including recruitment resources in their program plans to avoid rescue scenarios. There are strong indications that these behaviors will expand as study teams experience their positive impact on performance.

Patient recruitment is getting smarter. In fact, the use of intelligence derived from a host of data sources is introducing a new generation of recruitment that has the potential to significantly reshape how we think about and approach the entire patient recruitment

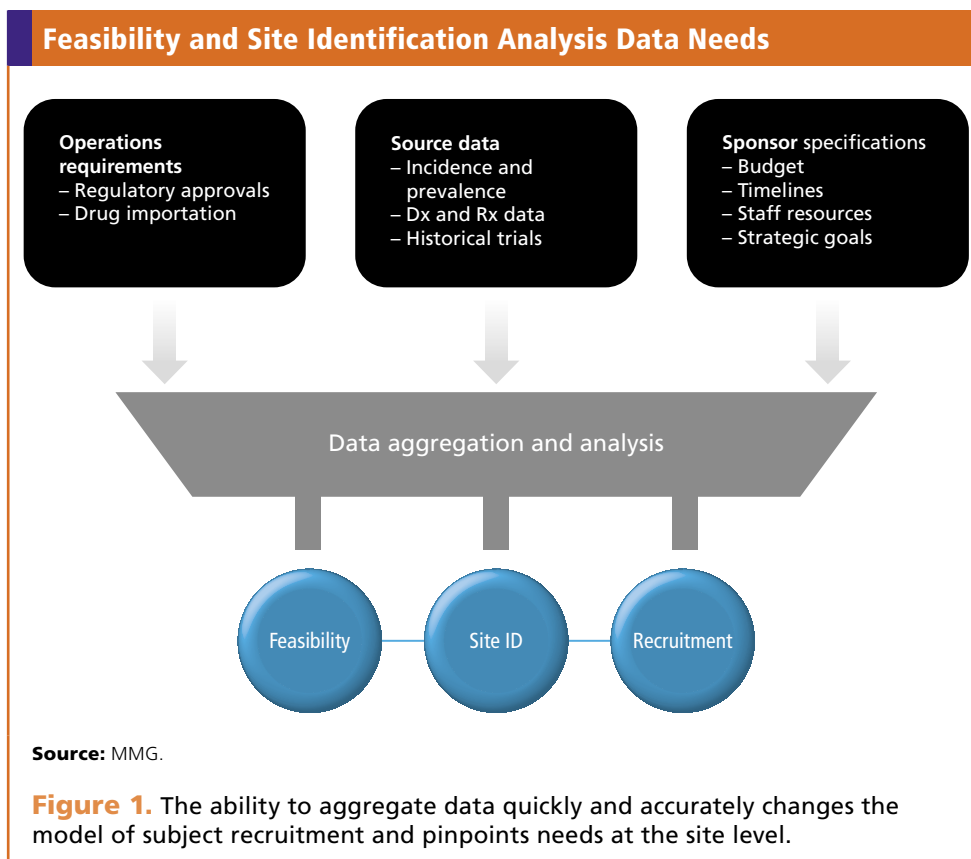
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continuum, from protocol feasibility, through site identification, to fueling recruitment. Here is a tour of an intelligence-driven end-to-end recruitment methodology that is driving recruitment performance to new heights.

Data Types and Sources

The following are some data categories that can contribute to analyses that inform the feasibility, site identification, and recruitment continuum:

- Health care claims data
- Pharmacy data
- Electronic medical records
- Laboratory testing data
- Disease incidence/prevalence data
- Consumer data
- Media exposure data
- Historical trial data



Some are public data and others can be purchased in various configurations at a range of cost points. Some are available only in the United States and others can be obtained by country. Depending on the data constellation and acquisition strategy, certain data types can be linked at the physician or patient level in support of all three phases of the continuum. Examples of highly specific questions that can be answered using combined data sets include:

- How many patients with disease X are taking medication Y in a radius of Z miles around study center 1?
- What countries have both the most patients with condition X and have performed well in similar past trials for indication Y?
- Which nonresearch physicians around study center 1 have the most patients with condition X, and which of these have an existing referral pathway to a given PI?
- Which newspapers and TV and radio stations are

- most popular with study population X in market Y?
 - Which potential PIs have privileges at hospital X, or at the most local hospitals?
 - Which PIs have the most access to patients with condition X who are of a certain ethnicity?
 - What is the predominant first-line therapy at center X for cancer Y?
 - How many patients in a radius of X around study center 1 have certain risk factors for condition Y?
- And the list goes on. Imagine the protocol amendments that can be avoided, the reduction in nonperforming sites that can be achieved, and the optimization of recruitment strategies that is afforded with this level of intelligence. But alas, data are data; and garbage in, garbage out. The trick is knowing which data to harvest, finding the best sources for it, and having tools to pull all the data together so it can be properly and efficiently analyzed.

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More Is More

Applying health care claims and other data is not in itself new to the clinical trial space. Both marketing and clinical development teams have looked to prescription and procedure data to guide indication strategy, protocol development, and site identification. However, these assessments have been largely based on singular data sets, or small numbers of multiple data sets analyzed separately, to answer much higher level feasibility questions (how many patients have a condition and where are they clustered) and to provide basic site identification guidance (which physicians treat the most patients with condition X). With the exception of targeting outreach to high-density disease areas, data resources secured for feasibility and site identification have not been applied to recruitment strategies to their full potential.

The integrity of feasibility and site identification analyses and the quality of the resulting decisions are strengthened by the integration of multiple types of supporting data. The challenge is getting the data to “talk” to each other. We need the ability to accurately and quickly mesh together and cross reference data sets with multiple differing attributes, and to tie medical care data with clinical trial intelligence and consumer data. Data aggregation experts have created a tool for these purposes specifically for clinical trials. The system also performs rapid “what if” sce-

nario analyses to quantify the impact on time and cost of study design changes (tweaking eligibility criteria) and site allocation options (take out China, add in Switzerland). The results are provided in many flavors of reports and visually depicted in maps to help teams see both the big picture and the critical details.

Case studies show that this model is improving the recruitment outlook for trials. It is identifying sites that have greater recruitment potential for specific studies. The intelligence is also informing and accelerating the development of study-level and site-specific recruitment plans to pinpoint needs and maximize performance. Furthermore, some of the data sets, such as pharmacy data, are being used in the execution of highly specific outreach tactics.

Looking Forward

Despite the positive momentum, recruitment still suffers from late planning and insufficient resources. This thinking needs to be challenged for recruitment to advance. Recruitment is a critical component of study feasibility, not a by-product of that process. This end-to-end solution uncovers recruitment vulnerabilities early to improve performance from the top down. There is still no silver bullet for patient recruitment, and this model is not suited to every study. More experience is needed to guide best practices and define the cost-benefit thresholds for study types and therapeutic areas. Just as with the adoption of eCRFs and other clinical trial technologies, it's time for our practices to catch up with the tools and resources that have become available to us. The opportunity to be smarter is here.

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