The Engagement Equation

Patient engagement is critical to any clinical trial of the modern world. New tools and techniques must be utilised to take full advantage of a trial's efficiency at all stages

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Patient engagement not only impacts study timelines and budgets, but it is a key driver for clinical trial success. As the marketplace has become more dynamic with the introduction of new tools and technologies, engagement pathways have expanded. As a result, a corresponding shift in mindset needs to occur. Engagement must be recognised as starting well before the patient's first visit, at the time of study awareness. Recruitment and retention must also be recognised as unified under the umbrella of engagement, rather than as separate concepts. Finally, a shift is needed from a patient-centric mindset to a study-centric mindset, where emphasis moves to the study community and the tools that can be utilised to maximise study efficiency.

Being Study-Centric

Identifying the problem, defining success, and building solutions are the cornerstones for study centricity. To be effective, one needs to identify potential roadblocks that may impact study efficiency. They may be protocol-based, such as the number or frequency of study visits, impacting patients and sites alike, or they may impact the entire study community, such as the overall length of the study. However, once identified, defining success with key performance indicators (KPIs) is important. In the event of a burdensome visit schedule, limiting the number of schedule changes could be considered. Once the KPI has been determined, one is then in a position to build the solution. In this case, perhaps it is a travel programme designed to remove burden, supporting patients getting to and from study appointments while also offering a reimbursement option.

Problems for Engagement

To illustrate the value of a study-centric approach, a common problem that affects almost all clinical studies in one way or another will be examined: time. Its impact on engagement extends to study start-up, recruitment, approval of materials, appointment schedules, travel and reimbursement, and time for physicians to spend with patients. To assess this challenge, this article will examine it outside of the clinical research industry, in another industry affected by time: the restaurant industry. Lastly, how that industry responded and whether any correlations to the clinical research industry exist will be looked at.

The Time Conundrum

Long lines for tables, reservation hassles, and finding locations were just a few of the time-related challenges affecting customers in the restaurant industry. Customers had to call the restaurant and wait on hold – sometimes for an extended period of time – to speak with a host or hostess to book a reservation. Customers dining during peak hours had long wait times. If new to a city, finding a restaurant required time-consuming research.

The introduction of OpenTable®, and similar services that followed, changed this. This online restaurant reservations provider connected (via a website and mobile app) restaurants with diners, streamlining the reservation process. OpenTable enabled diners to see what restaurants had availability, select a restaurant based on diner reviews, menus, and other helpful information, and easily book a reservation. With just a few clicks, a diner could secure a table. Not only were diners satisfied, but, as service levels improved and capacity was maximised, restaurant profits increased.

However, OpenTable did not eliminate the old process. People who prefer calling the restaurant to book a reservation can still do so. For restaurants, the power to control the number of tables released to OpenTable for online booking remains in their hands. OpenTable successfully created an omni-platform solution that did not eliminate the old way of doing things, but also provided customers with new and more efficient options.

Can insights be applied to clinical trial engagement and create solutions that affect time, save money, and are more study-centric? It will be examined in the context of a familiar engagement equation – keeping in mind an engagement umbrella that encompasses everything from pre-start-up, to start-up, to recruitment and retention, all the way through to results at the end of the study. The equation is designed as a common denominator for calculating enrolment success regardless of the breadth and scope of a study and despite the indication or nature of the investigational drugs or procedures.

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E=RTS Engagement Equation

Enrolment (e) = rate (r) x time (t) x sites (s)

While each scenario will vary from one study to the next, every study's recruitment or enrolment feasibility can be quantified through the use of this formula. E equals the number of randomised patients needed; r equals the randomisation rate (the number of patients per site per month); t equals the enrolment time period in months; and s equals the number of sites actively randomising patients.

The equation offers a baseline for the start of every recruitment programme. It drives solutions as it identifies the variables that need to be impacted. Revisiting it throughout the course of the programme is essential to ensure efforts remain on track and produce the desired results.

Impacting Rate

Putting the equation to work, one can see where rate is impacted. One hundred patients need to be enrolled at 10 sites, with the expectation that each site can enrol one patient per month. It will take 10 months to enrol the study. If this is related this to time, one might question why additional support is needed. To stay on track, each site has to deliver one patient per month, and an enrolment window is 10 months. However, to accelerate screening and enrolment rates, outreach efforts could be added – such as tools and tactics to engage the study community. These could include local advertising or enhanced database outreach (beyond the site's patient panel). Site-based apps, as well as referral and document management systems can support site staff so they are spending less time on administrative functions and more time on recruitment.

Examining the equation, additional outreach might impact the rate, even if it is just by 10%. Instead of getting one patient per site per month, 1.1 patients per site per month will now be gained. The initial 10-month enrolment period is reduced to 9.09 months. That is almost a full month saved, streamlining the processes, removing the administrative burden from the sites, and saving a month in time. From a sponsor perspective, profits are increased by shortening potential time to market, similar to what was seen in the restaurant industry where profits increased as a result of efficiencies introduced by OpenTable.

- Before outreach: 100 (enrolment) – 1 (rate) x time x 10 (sites)
- After outreach: 100 (enrolment) – 1.1 (rate) x time x 10 (sites)
- Result: time = 9.09 (months)

Impacting Enrolment

One area to explore in the effort to impact enrolment is lowering withdrawal rates. This can be done by implementing services that decrease participation burden, such as travel support for studies involving international or complex travel or reimbursement for study visits that require significant out-of-pocket expenses. By facilitating access to the study sites and ensuring patients are reimbursed in real time, patient experience is improved. Metrics have shown that these tactics can lower withdrawal rates by approximately 60%. Other areas to consider include dynamic messaging to ensure patients feel educated and recognised and omni-platform access to information. This draws a parallel to OpenTable where customers have the option of using the app, website, or calling to book a reservation.

Looking at this in the context of the equation, if required to enrol 100 patients and assuming a 20% attrition rate – expecting 20 patients to withdraw – if rates can be lowered by 60%, only 88 patients have to be enrolled, shortening enrolment by 1.2 months.

Before Reimbursement

- 100 (enrolment) = 1 (rate) x time x 10 (sites)
- After reimbursement /Travel programme: 88 (enrolment) = 1 (rate) x time x 10 (sites)
- Result: time = 8.8 months

Impacting Enrolment and Rate

If one needs to come in on time, how is enrolment and rate impacted? Calculating the withdrawal rate reduction and the increase in screening rates, the timespan is actually down to eight months overall, saving a total of two months with a comprehensive engagement programme.

> **"The key to success is identifying and selecting products and services that leverage time and savings – essentially products and services that create time-related efficiencies while reducing nonproductive time"**

No engagement support	100 Enrolment	=	1 Rate	x	10 Time	x	10 Sites
Recruitment-only support	100 Enrolment	=	1.10 Rate	x	9.09 Time	x	10 Sites
Recruitment-only support	88 Enrolment	=	1 Rate	x	8.8 Time	x	10 Sites
Full-engagement support	88 Enrolment	=	1.10 Rate	x	8 Time	x	10 Sites

Figure 1: Patient Engagement

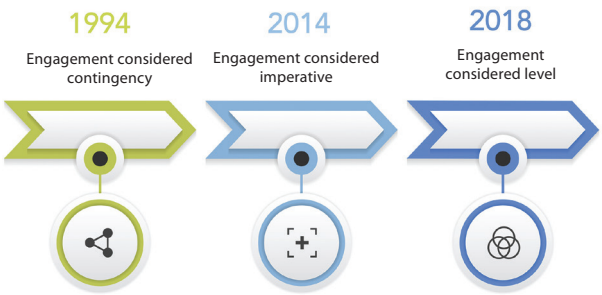

Figure 2: Evolution of Patient Engagement

- 88 (enrolment) = 1.10 (rate) x time x 10 (sites)
- Time = 8 (months)

In Figure 1, the summarised impact of the different levels of support is demonstrated. For instance, with no engagement support and sites performing as planned, enrolling in 10 months is possible. If only recruitment support is required, or perhaps retention support because it is a long study, or full engagement because of a complex protocol, a variance of anywhere from 1-2 months can be saved. The caveat is the 10% increase in screening rates – it is condition- and country-specific. The 10% increase could be upwards of 67% – potentially getting 1.8 patients per site per month if it is a rare condition.

When applying the time savings across multiple studies, the benefit is maximised. By saving two months over 10 studies with an enterprise model, not only sponsor time is saved, but money as well.

The key to success is identifying and selecting products and services that leverage time and savings – essentially products and services that create time-related efficiencies while reducing nonproductive time. From a broader perspective, whether it is time or another factor that is increasing patient and/or site burden, success hinges on identifying the problem and building a solution – the core of study centricity.

Community Voice

To determine if the products and services are satisfying the needs of the community and are effective in supporting engagement, querying the audience for their feedback is important. One useful method is the net promoter score, an established and validated customer-experience metric introduced in the Harvard Business Review in 2003. Using a scale from 1-10, it evaluates how people are interacting with an experience.

The resulting data is essential to understanding how engagement programmes are performing and whether adjustments are necessary.

Not too long ago, engagement was considered a contingency effort. Today, study sponsors not only consider it an imperative, but on an enterprise level, across multiple studies. As sponsors take a proactive approach to clinical trial planning and execution, they must do so with an appreciation for study centricity and the benefits it can yield for the entire study community.

About the authors

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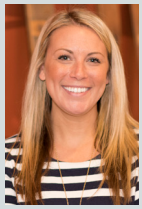

Sarah Mandracchia at BBK Worldwide has more than a decade of experience translating complex market research and patient insights into effective media strategies for global patient recruitment campaigns. Sarah is responsible for upholding strategic direction and imperatives throughout the lifecycle of clinical trial programmes.

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