ClinOne

Case Study – Clinical Trial Enrollment

ClinOne mobile technology impact on clinical trial enrollment.

Background

An ongoing study for a global Sponsor was seriously behind in its enrollment. Enrollment was to be completed by July 2017, however updated recruitment forecasts projected that enrollment would actually not be completed until December 2017, 5 months behind schedule. It was determined that study sites needed help with patient engagement, screening and enrollment.

ClinOne Solution

ClinOne's mobile technology for research sites was deployed along with its patient-facing ClinTrialConnect. ClinOne's mobile clinical trial application is designed to increase enrollment through point-of-care access to clinical trial content and screening criteria and provides a capability to deliver continuous communications. ClinTrialConnect provides an IRB-approved study-content micro-website which patients can access and share with their families.

Implementation and Utilization

ClinOne implementation was completed in less than 4 weeks. Although available, the Sponsor made the decision to forego training on ClinOne's core modules, however 7 of the 87 sites requested specific training on ClinTrialConnect.

Site utilization of ClinOne mobile technology was 98.8 percent across 87 sites. Only one research site did not utilize the mobile technology after deployment. On average, there were 2.4 active users per site.

Over a 6-month period the system generated approximately 288 communications, reminders, and updates to each site which equated into 25,392 notifications across all site users. More postings of information by the Sponsor into the Community section of

ClinOne's technology could have possibly yielded an even greater impact on recruitment results.

Results

Patient enrollment increased by 93% with the implementation of ClinOne. As a result, the Sponsor completed patient enrollment ahead of LPFI date by 2 weeks (June 2017), saving 5.5 months from patient recruitment timelines. The average monthly enrollment rate 5 months prior to ClinOne deployment was 30 patients per month, while the 5-month average monthly enrollment post ClinOne deployment was 58 patients per month.

Patients Enrolled Per Month
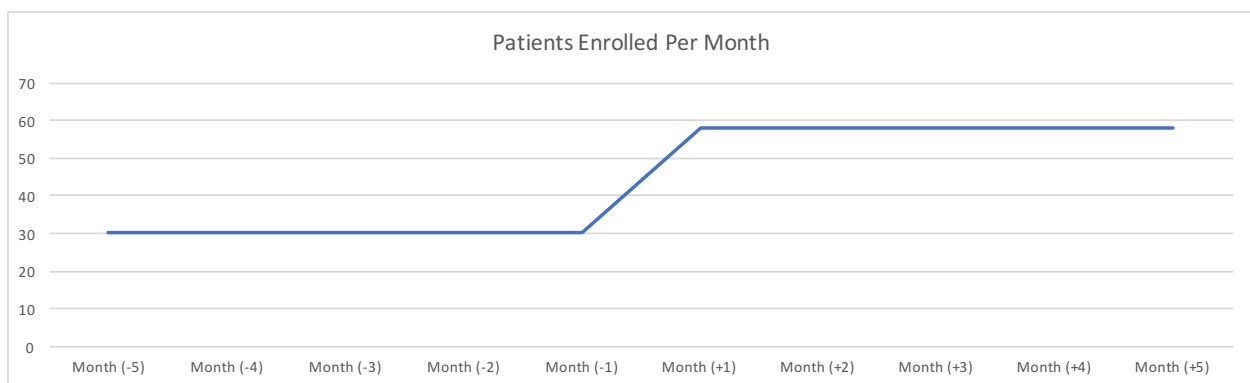
Further Analysis

How did ClinOne's mobile technology have such an impact on clinical trial enrollment?

Point-of-care screening was a critical factor for maximizing enrollment at each research site but screening I/E criteria was rarely made available within a treatment room while the Investigator and patient were interacting. As a result, patient screening and clinical trial consideration opportunities were simply being overlooked. ClinOne's mobile technology allowed for access to the latest study screening criteria anytime, everywhere.

Secondarily, when there are competing studies at a research site (competing studies are present 72% of the time) the clinical trials with easy to use supporting technologies will take preference amongst site staff over a competing study where screening information is not as readily available or time consuming to access. ClinOne's superior accessibility via its mobile technology and incredible ease of use ensured study preference with site staff.

Lastly, Sponsor-to-site communication was ineffective due to infrequency or lack of relevance, even with CRA-lead communications. In comparison, ClinOne generated 2 emails and 2 mobile notifications weekly, individualized to each of the 529 site users across 87 sites based on their ClinOne utilization. The continuous, relevant communications strengthened the Sponsor – Site relationship and established the Sponsor's study as 'top of mind' with site staff.