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Decentralized Clinical Trial Case Study: Five-stage Process for Recruiting and Completing a Site-less Clinical Study in Less Time and Lower Cost than Traditional Methods

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Abstract: Healthcare delivery models have been thrust towards virtual care delivery, including site-less virtual clinical trial recruitment. Digital health technologies give trial participants a choice of participating from the convenience of home rather than traveling to a trial site, which can increase participant engagement and retention. In this case study, a five-stage process is illustrated in which a 1,000-patient virtual clinical trial was completed in just seven months at a cost 30% lower than traditional site-based recruitment. Participants were located, educated, and navigated through a successful multi-step virtual clinical trial for an at-home colon screening test. The locating and screening of patients were conducted via paid social media ads. Next, respondents were contacted by telephone by patient education specialists for additional screening, education, and support. Per protocol, it was confirmed that participants were scheduled for a colonoscopy with their preferred local provider. Finally, sample collection kits were sent to participants home. Overall, the trial achieved a timeline of six months from the first participant to final analysis, followed by dataset review and analysis in just five days. Among the lessons learned was that the trial was more efficiently conducted with the 83bar virtual process than relying on third-party sites and remote investigators to help with the study. Additionally, social media is the best way to find the right patients in the least amount of time.

Keywords: Virtual Clinical Trial, Decentralized Clinical Trial, Patient Recruitment, Patient Education, Patient Activation

1. Introduction

Even before the Covid-19 pandemic nudged the healthcare system towards a more virtual delivery model, many sponsors and service firms were working on developing site-less virtual clinical trial recruitment.

There is growing recognition by stakeholders from across the clinical trials enterprise that transformational change in the way traditional clinical trials are conducted is needed to address systemic challenges and meet the needs of patients. An emerging trend in the clinical trial landscape has been the incorporation of digital health technologies into study design. Such virtual clinical trials can leverage digital health technologies to collect information at each stage of the clinical trial, improving trial participant recruitment and retention, enabling online-based informed consent, the measurement of real-time clinical endpoints, and continuous tracking of adverse events. [1]

Digital health technologies give trial participants a choice of participating from the convenience of home rather than traveling to a trial site, which can increase participant engagement and retention. [2-5]

Participation from home may be particularly important for engaging patients with mobility issues or those who live in rural areas, which can be far from the research centers at which studies are conducted. Additionally, data collected through digital health technologies enable continuous real-time data collection of endpoints during the course of a

trial participant's daily life. [6]

Researchers and providers can use information collected through digital health technologies to enhance monitoring and improve understanding of treatment effects and disease progression. This type of insight is useful in creating patient-friendly communications, and eventually, more patient-centric commercialization of new treatments upon successful clinical trials. [7, 8]

The purpose of this article is to illustrate one initiative by 83bar and its client sponsor to complete a 1,000-patient virtual clinical trial in just seven months at a cost 30% lower than traditional site-based recruitment.

2. Description

During the period of August 26, 2019 to March 30, 2020, the campaign successfully located, educated, and navigated 1,402 patients through a multi-step virtual clinical trial to evaluate an at-home colon screening test.

The approach for this campaign included a five-stage process. First, patients were required to complete a pre-screening survey. Then, patients completed a second screening process and detailed enrollment intake via telephone with an 83bar patient education specialist. Once that was done, patients were required to collect and return an at-home stool sample via a provided kit. Finally, they attended and self-financed an in-office colonoscopy procedure with a gastroenterologist of their choice. Assistance with the medical records collection process was provided by 83bar.

The patients were eligible for a nominal stipend upon completing all required tasks in a defined time period. The key inclusion and exclusion criteria consisted of: age 45 or older, no colonoscopy in the last ten years, and an average risk of colon cancer.

2.1. Stage One: Pre-Study Pilot

To determine viability of this approach, 83bar developed and conducted a small-scale pilot to refine processes and compare models best suited for a large 1,000-patient study. The virtual patient activation campaign was conducted simultaneously with a partner vendor's traditional recruitment campaign at six separate gastroenterology offices.

The results were conclusive (table 1).

The traditional site-based model used EHR analysis and intra-practice recruitment. This method identified eleven candidates, only one of which completed the study.

In contrast, the 83bar virtual model used social media and a rapid response contact center as a recruitment method which successfully recruited 3,724 candidates, of which 43 completed the study.

Table 1. *Results of Pre-Study Pilot.*

	83bar Virtual Model	Traditional Site-Based Model
Recruitment Method	Social Media + Rapid Response Contact Center	EHR Analysis and Intra-Practice Recruitment
No. of Candidates Recruited	3,724	11
No. of Study Completions	43	1

From this small-scale pilot, it was observed that gastroenterologists were not as effective in recruiting patients as the 83bar process and delivered only a tiny fraction of total candidates and study completions.

This was consistent with prior experience in attempting to rely on busy specialty practices to recruit for clinical trials among everyday patients. [9]

The decision from the pilot was to proceed with the 83bar process. Based on the results, the trial sponsor anticipated less time spent contracting with vendors to procure trial sites, less time needed to train and activate trial sites, and fewer resources allocated to managing relationships with trial sites.

2.2. Stage Two: Locate and Screen Patients via Paid Social Media Ads

Based on learnings from the smaller pilot study, 83bar worked closely with the study sponsor and partner vendors to design an end-to-end virtual patient activation campaign.

Social media was deployed because it is an effective platform for reaching adults, including those aged >65. Since 2016, 83bar has consistently generated better cost per acquisition metrics via Facebook than any other platform. [10] Creative ads (figure 1) were optimized to attract patients at the lowest cost and supplemented with micro-targeted outreach to enrich demographic diversity.

The responses from each source varied. Facebook accounted for 85% of leads generated; Instagram 10%; and the remaining 5% from other channels. On the other hand, the demand generated by age was a bit more equative. Patients ages 45-54 made up 47% of the demand; patients ages 55-64 made up 41%; and patients 65 or older made up 13%. In total, 68,075 potential patients were located exclusively through paid social media advertising.

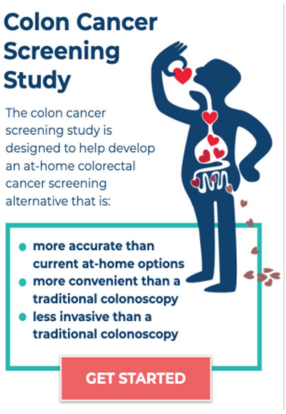

Figure 1. *Example of creative ad for patient recruitment.*

2.3. Stage Three: Screen, Educate, and Support Patients Via a Rapid Response Contact Center

83bar patient education specialists (telenurses) contacted 31,877 potential patients via telephone during the recruitment period. Nearly 2,400 total patients were then enrolled in the study.

The rapid response of the 83bar Clinical Contact team helped patients understand the study commitment, captured consent, navigated insurance, simplified scheduling, coordinated stool sample collection, and facilitated the patient-facing medical records collection process.

Further assessment by 83bar patient education specialists resulted in disqualification of approximately 11% of candidates. The top three reasons patients disqualified from study participation were advanced colon cancer risk due to family history (26.4%), inability to self-finance colonoscopy (21.5%), and insufficient time to provide a sample prior to colonoscopy (11.6%).

2.4. Stage Four: Prepare Patients to Visit any Gastroenterologist

Because no physical offices were onboarded for the trial, study participants were free to choose their own provider. After their colonoscopy was completed, patient medical records were sent from the gastroenterologist to a designated, central pathologist for review. A significant finding at this stage was that 83% of potential patients did not have a colonoscopy previously scheduled before speaking to an 83bar patient education specialist. On average, it took 5.1 weeks after a completed colonoscopy for medical records to be transmitted to the central pathologist, with 650 completed in less than 3 weeks.

2.5. Stage Five: Custom Integrations for 100% Visibility

With so many activities being managed virtually, it was essential that all patient progress be trackable in real-time, documented and time-stamped for analytics.

The recruitment team worked together to design multiple integrations, including: (a) Kit Delivery & Tracking, the platform triggered the delivery of stool sample collection kits then tracked all packages via a custom import of FedEx data; (b) EDC Data Sync, the campaign connected to a partner vendor to ensure all recruitment data was synced with patient and medical record data; (c) Lab Portal, the campaign developed a custom portal to help the sponsor's laboratory better prepare for daily sample processing; and (d) Data Integrity and Security.

3. Results

A summary review of the patient recruitment data (table 2) shows a funnel-type flow of candidates who proceeded from stage to stage. For further insight, the time required to complete each milestone of the study was analyzed (figure 2).

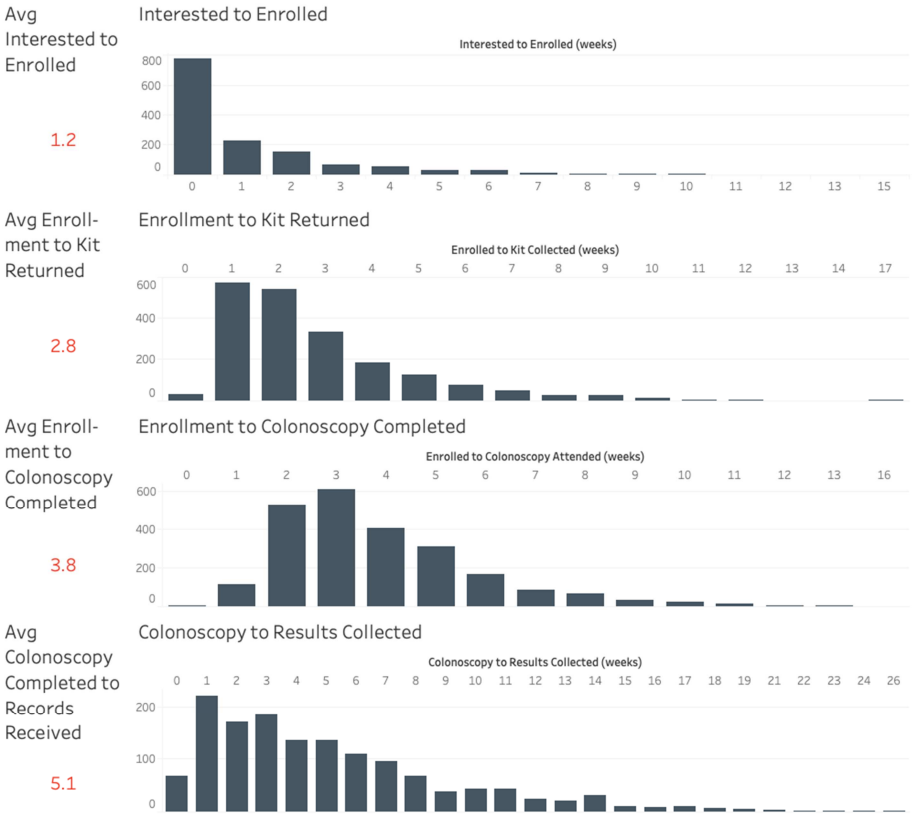

Figure 2. *Patient Recruitment Results.*

Table 2. *Summary Review of Results.*

Potential patients recruited via paid social media =	68,000+
Patients contacted =	31,000+
Patients enrolled =	Nearly 2,400
Stool samples collected and returned to lab =	Nearly 2,000
Colonoscopies completed =	Nearly 1,800
Study completions (40% above goal) =	1,402

A timeline review of this virtual trial process was two months of development, five months of active recruitment, and two months of closeout.

The final average time from online screener to study completion was 80 days (ranging from 15 to 225 days).

Specific results at each stage are presented (figure 3).

4. Lessons Learned

The trial was more efficiently conducted with the 83bar virtual process than relying on third-party sites and remote investigators to help with the study. Social media is the best way to find the right patients in the least amount of time.

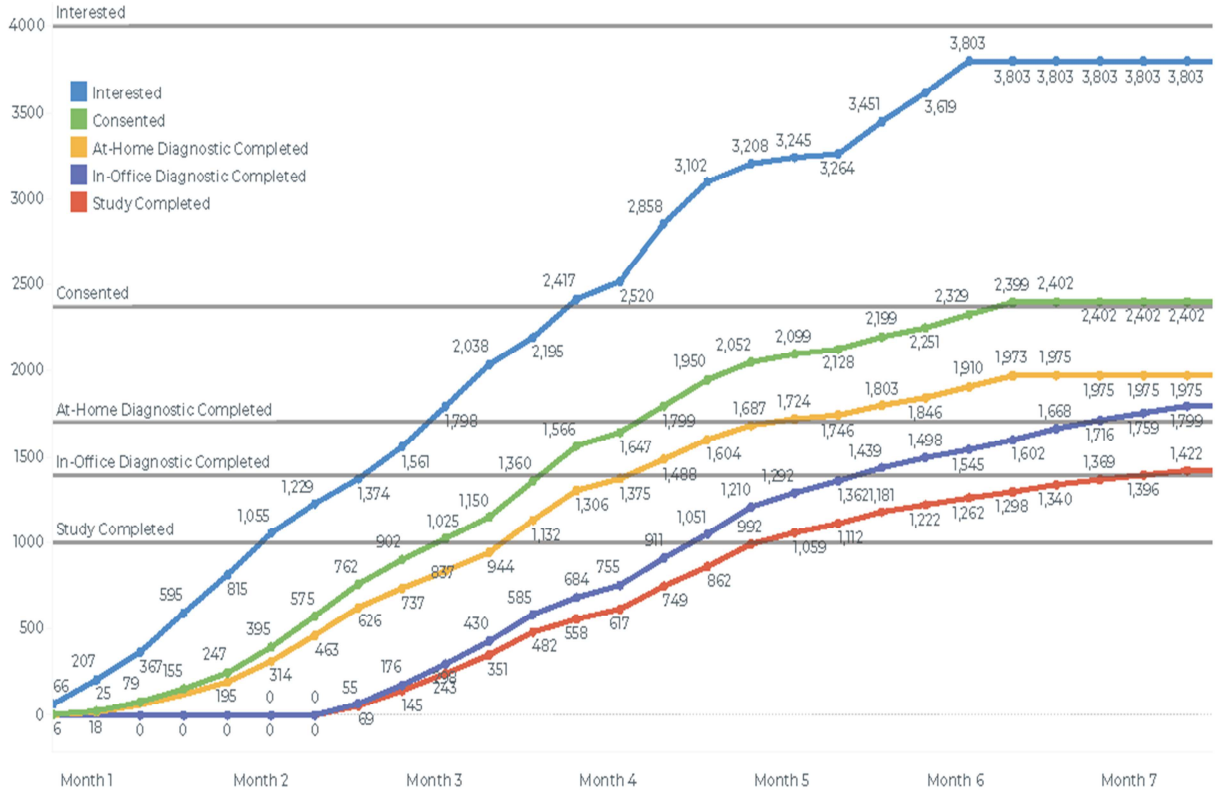

Figure 3. *Patient Recruitment Results by Stage.*

Social platforms, such as Facebook and Instagram, are the fittest channels for this. Patients responded well to the virtual approach and found the response times to be satisfying and motivating for them to move forward with the study. This is relevant to consider as many patient advisors often recommend ways to stay connected with the sponsor when the product comes to market. [11-15]

As shown above, the numbers illustrate that this campaign was able to locate more patients and deliver more study completions in the least amount of time for a lower cost, thus ensuring the efficiency of the program.

Some of the older patients may not be as tech-savvy which may make the program perhaps a bit more challenging for them. Also, taking into account the time that it may take each patient to return each test kit, this factor can significantly delay the process.

This successful campaign helped the 83bar client secure Breakthrough Device designation from the FDA and funding for a large pivotal study to begin recruitment in late 2020. [16]

5. Conclusion

This case study demonstrates a process in which virtual clinical trial recruitment can be achieved in significantly less time than a traditional site-based model, often at a reduced cost. Although logistical hurdles exist, partnering with capable solution-oriented vendors can help bring studies into the new virtual future and help augment or replace expensive, traditional site-based recruiting.

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