

Transforming Clinical-Trial Patient Recruitment and Retention

The swelling demand for clinical-trial recruitment and retention services spurs startup opportunity

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Key takeaways

- The steady growth in drug development is expanding the clinical-trials market, which is estimated to be worth \$65.0 billion by 2025.
- Running complicated clinical trials is typically not a core competency of drug developers, creating an opportunity for startups, particularly in the areas of patient recruitment and retention.¹
- Startups are aiming to increase patient retention by creating medication adherence and tracking technology, biometric monitoring devices, AI-powered direct observational therapy, and personalized platforms.

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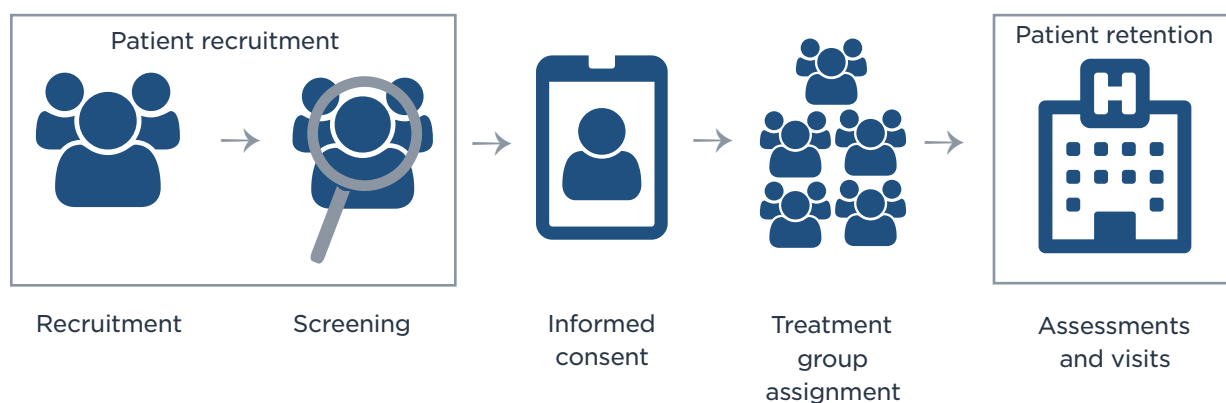
Overview

Conducting a clinical trial is a grueling, yet critical, step in the drug-development process. One of the biggest struggles researchers face when conducting trials is recruiting and retaining patients. Up to 86% of clinical trials fail to reach recruitment goals within their targeted timeframe,² and clinical trial dropout rates are around 30%.³ Delays in product launch, due to the inability of sponsors to recruit or retain patients, are highly common and increase cost, deplete resources, and prolong time to market.

These challenges have led drug developers to outsource their patient recruitment-related needs, creating an opportunity for startups focused on this niche. Contract service providers employ a variety of patient outreach methods, including social media, mobile technologies, and electronic health records (EHRs). An emerging focus on real-world evidence and broad datasets can also help identify the best target populations to expedite the recruitment process. Although some big pharma players carry out patient recruitment in-house, the growing complexity of clinical trials and the demand for niche patient populations for studies evaluating orphan drugs and other personalized medicines is likely to increase demand for providers of clinical-trial recruitment and retention services.

Clinical trials typically follow a process that can be broken down into five steps. We believe the largest opportunity for startups resides in the areas of recruitment and retention, a market we estimate currently represents a roughly \$3.2 billion opportunity and that Roots Analysis forecasts to reach \$5.3 billion by 2030.⁴ This represents a relatively small component of the overall clinical trial market, which is estimated to be worth \$65.0 billion by 2025.⁵ The remaining clinical trial processes of providing informed consent and assigning test groups are more likely to be carried out by drug developers and do not represent attractive stand-alone opportunities.

Steps in conducting a clinical trial



2: "Clinical Trials Recruitment Planning: A Proposed Framework from the Clinical Trials Transformation Initiative," *Contemporary Clinical Trials*, Grant D. Huang et al., January 9, 2018.

3: "Patient Recruitment and Retention Services Market, 2019-2030 (COVID-19 SERIES)," *Roots Analysis*, February 2019.

4: *Ibid.*

5: "Investing in Anti-Aging and Longevity," *Parameter*, Amrit Singh, March 31, 2019.

We believe study sponsors are increasingly joining with patient recruitment firms, which are also partnering among themselves to combine complementary service offerings. For example, TrialScope enables sponsors to securely share clinical trial data and recruitment opportunities with a vetted network of patient recruitment companies, healthcare organizations, and patient advocacy groups. This industry has also seen consolidation as multiple smaller players have been acquired by more established entities to expand geographical reach. For example, Clinical Trial Connect, which develops an online patient-finder platform, was acquired by TrialScope for an undisclosed amount in October 2019, and Akcelis, which develops patient recruiting and retention solutions, was acquired by Pivotal SL for an undisclosed amount in March 2020.

Notable patient recruitment and retention VC deals

COMPANY NAME	DEAL SIZE (\$M)	CLOSE DATE	POST-MONEY VALUATION (\$M)	DEAL TYPE
Medable	\$25.7	April 28, 2020	N/A	Late-stage VC
TrialBee	\$12.0	April 28, 2020	N/A	Late-stage VC
Circuit Clinical	\$2.2	April 16, 2020	N/A	Early-stage VC
Clara Health	\$11.0	April 14, 2020	\$45.0	Early-stage VC
Tempus Labs	\$100.0	March 13, 2020	\$5,000.0	Late-stage VC
Verana Health	\$100.0	February 5, 2020	\$250.0	Late-stage VC
Inato	\$14.0	February 4, 2020	\$39.4	Early-stage VC
Ripple Science	\$2.5	December 23, 2019	\$6.4	Seed
Deeplink Medical	\$5.5	December 3, 2019	\$14.3	Early-stage VC
Deep 6 AI	\$17.0	November 25, 2019	\$51.0	Early-stage VC

Source: PitchBook

Notable patient recruitment and retention exits

COMPANY NAME	DEAL SIZE (\$M)	CLOSE DATE	POST-MONEY VALUATION (\$M)	EXIT TYPE	INVESTOR
Canale Communications	\$31.0	November 26, 2019	\$31.0	M&A	UDG Healthcare (LON: UDG)
CENTOGENE (NAS: CNTG)	\$56.0	October 28, 2019	\$278.1	IPO	N/A
Akcelis	N/A	March 3, 2020	N/A	M&A	Pivotal SL
Clinical Trial Connect	N/A	October 22, 2019	N/A	M&A	Trial Scope

Source: PitchBook

Summary of patient recruitment industry

Patient recruitment companies aim to find participants and onboard them into the trials process. Researchers spend over \$2 billion annually to recruit patients for clinical trials,⁶ and we believe this market is growing at a rate of about 16% annually, fueled by increasing study complexities, regulatory requirements, and competition in the industry to retain patients for successful study completion.

On average, clinical trials consume 60% of drug development costs, with 32% of trial costs funneling into patient recruitment and retention. It costs from \$20,000 to \$30,000 to begin a trial site.⁷ Typically, patients are found through advertisements and referrals. In recent years, there has been a surge in online recruitment channels, with the most prominent channels including social media and paid-search advertising. While these new methods increase reach and diversity, patient recruiting remains complicated due to the following factors:

- An overwhelming number of clinical trial options that decreases patients' ability to determine best-fit trials
- Participant time burden and lack of participation incentives
- Lack of provider referrals and inability to find patients with less-common conditions
- Patient and physician notion that trials are a last resort and should only be pursued after all other treatment options have failed

6: "Successful Patient Recruitment Calls for a Calculated Approach," Beroe, Sapna Rani, July 17, 2017.

7: Ibid.

Traditional versus emerging methods of patient recruitment

TRADITIONAL METHODS OF PATIENT RECRUITMENT

- Investigator referrals
- Print media (newspaper, postures, brochures, flyers)
- Radio & TV
- Call centers
- Local community outreach

EMERGING METHODS OF PATIENT RECRUITMENT

Digital platforms	Social media	Mobile technology
• Online advertising • Patient advocacy groups • Pro databases • Online patient communities • Online trial registry • E-mails	• Facebook • Twitter • YouTube • Blogs	• Mobile apps • Text messaging

Source: Beroe Analysis

Numerous startups focused on recruiting patients and determining eligibility have emerged. Deep 6 AI uses artificial intelligence to analyze structured and unstructured clinical data into new data points that can be used to match clinical trial criteria, making it easier for researchers to identify and contact potential participants. TrialSpark developed an online platform aiming to increase trial access to patients who are unlikely to be referred to trials through their healthcare provider.

Once potential participants are identified, several processes must take place before participation can occur. Clinical studies have inclusion criteria that must be met to qualify for participation. Candidates must first undergo a phone screen and then visit the research site for initial tests, which may involve laboratory and imaging diagnostics. In addition, most research sites will collect and analyze medical records. This can also be a complex process as health information is often spread across various EHRs, physicians' notes, pathology reports, and additional forms of documentation.

Other startups in the recruitment space focus on facilitating trial enrollment by determining eligibility and enabling communication with candidates throughout the enrollment process. For example, SubjectWell offers an online and mobile application that enables patients to search for and apply for trials, while also giving researchers the ability to manage enrollment status, schedule screening appointments, and send appointment and eligibility notifications. Other startups focus exclusively on determining patient eligibility. Verana Health partners with

medical associations to data-mine EHR records to assemble a large clinical database that accelerates medical record collection and recruitment of eligible patients.

Recruitment-related factors are pivotal to the pharmaceutical industry when assessing possible trial sites. TriNetX developed a network of healthcare organizations across 16 countries that helps clinical trial researchers find medical centers with large numbers of qualifying patients. This reduces the risk of selecting sites with few potential participants. The startup's longitudinal real-world database also provides real-time access to patient population data that is updated by electronic medical records. This can help determine trial feasibility and meet regulatory requirements.

Key drivers for patient recruitment industry

Evolving clinical research

The steady growth in clinical trial volume drives market opportunity for patient recruitment players.

- 290,000+ trials globally
- 32% clinical trial budget spend on recruitment
- 40% of patient enrollment tasks outsourced

Need for outsourcing due to enrollee shortages

Failure to recruit and retain patients leads to trial delays, inconclusive results, and excess costs.

- Rare-disease and precision-medicine trials require finer patient eligibility requirements and screening.
- Regulatory reviews and patient diversity requirements are becoming more stringent.
- 86% of trials do not reach recruitment targets in time.

Summary of patient retention industry

Patient retention remains a significant headwind with 89% of clinical trials lacking complete outcome data⁸ and 40% of patients becoming nonadherent,⁹ meaning they continue in the trial but fail to fully follow protocol. This lack of engagement leads to high dropout and nonadherence rates, along with inaccurate data collection. To compensate, trials that require many patients generally must be over-recruited to maintain statistical significance, which extends the length of the study and drives up costs.

8: "Are Missing Outcome Data Adequately Handled? A Review of Published Randomized Controlled Trials in Major Medical Journals," *Clinical Trials*, Angela M. Wood et al, 2004.

9: "Non-Adherence: A Direct Influence on Clinical Trial Duration and Cost," *Applied Clinical Trials*, Moe Alsumidaie, April 24, 2017.

In 2018, the global patient engagement solutions market was worth \$8.9 billion and could reach \$30.4 billion by 2026, with a 16% CAGR.¹⁰ This forecast includes patient-engagement technology for both clinical trials and general medical care.

One way to improve trial adherence is to employ the use of various patient-engagement technologies being developed by startups. These tools are intended to remove treatment obstacles and help patients take ownership of their health. We believe sponsors and research organizations are increasingly using digital technology tools including apps, web portals, social media, and instant messaging to connect with patients. Other patient-engagement tools include physical hardware such as tech-enabled pill bottles and biometric devices. Providers are also incorporating AI and game-like rewards into their apps. As patient-engagement technology becomes more common within the healthcare industry, we expect the emergence of more virtual or “site-less” clinical trials, which will enable researchers to access to a larger pool of candidates not bound to certain geographies.

In the remainder of this section, we summarize different types of companies exploring opportunities in this space.

Medication adherence and tracking

Startups in this space increase medication adherence with smart and virtual pillboxes. Companies in this space include:

- **Medisafe:** Developed a comprehensive mobile app that alerts patients and other stakeholders (e.g., trial researchers) when doses are missed. Has raised \$21.5 million in VC.
- **Dosesystem:** Provides a medication reminder and pill dispenser system to track daily dosage and ensure medications are taken on time.
- **Cohoro health:** Developed a medication inhaler tracker that tracks asthma medication use and symptoms. The tracker connects to the patient’s mobile application, which sends medication reminders and automatically records use and relief provided by inhalers. Raised \$17.4 million in VC.

Biometric monitoring devices

Biometric monitoring devices (BMDs) provide raw sensor data that allows researchers to better track patient behaviors; this is especially helpful when trials are conducted virtually. For example, if a patient is required to exercise daily, a fitness tracker can provide data and insight into their behavior. This helps researchers ensure patients are adhering to trial requirements and allows them to validate data and re-engage noncompliant patients. Furthermore, BMDs with real-time data acquisition capabilities enable statistical comparison at an individual level, supporting personalized medicine. However, to be used in clinical trials, BMDs must be FDA approved—an expensive and lengthy procedure. As a result, many BMD startups sell to individual consumers and do not target clinical trials. However, we do see several startups developing platforms that connect to externally provided biometric devices. Companies in this space include:

¹⁰: “Patient Engagement Solutions Market to Reach USD 30.36 Billion by 2026,” Reports And Data, November 25, 2019.

- **Kinsa:** Created a smartphone-connected thermometer application. The company's thermometer connects to a mobile device and uses the display, power, and processing of the smartphone to determine a precise temperature reading, enabling users to get real-time information on their temperature, symptoms, and medication. Raised \$33.8 million in VC.
- **Empatica:** Developer of wearable devices with clinical quality sensing designed to track human behavior in daily life. The company's devices are used to analyze and monitor autonomic nervous system disruptions and heart rate variability as well as to detect unusual events such as convulsive seizures in real time. Empatica was the fifth-most-used BMD in clinical trials as of April 2019.¹¹ Raised \$5.4 million in VC.
- **ObvioHealth:** Developed a mobile application, ClaimIt, which can integrate data from external BMDs, thus accelerating data gathering and monitoring. Raised \$5.6 million in VC.

Direct observational therapy

Directly observed therapy (DOT) involves an AI application or person watching a patient take their medication. Research indicates that patients who receive DOT complete treatment 86% to 90% of the time versus 61% of the time for self-administered therapies.¹² Companies in this space include:

- **AiCure:** Uses picture and facial recognition algorithms to track adherence. Patients use their phones to film themselves swallowing a pill, and AiCure confirms that the right person took the right pill. Raised \$68.5 million in VC.
- **Emocha Mobile Health:** Developed a mobile application that uses AI to provide visual confirmation of medication adherence. Raised \$3.8 million in VC.

Personalized platforms

Personalized platforms digitize the clinical-trial process by connecting patients with researchers, providing educational resources and medication, and supplying appointment- and symptom-tracking tools. Some platform creators are attempting to enhance the user experience by integrating game-like rewards and personalized features. Companies in this space include:

- **HealthPrize:** Created a medication adherence program that motivates patients through incentives. HealthPrize has published studies suggesting a boost in patient adherence resulting from the use of interactive software products that provide game-like rewards for adherence. Raised \$14.7 in VC.
- **Catalia Health:** Developed a cloud-based patient-care management platform designed to offer an AI-enabled personalized healthcare robot, Mabu. The platform combines AI psychology and medical practices to deliver care and learn each patient's personality, interests, and treatment challenges, enabling Mabu to create unique conversations tailored to each patient's personality and circumstances. Raised \$7.8 million in VC.

¹¹: "Wearables in Clinical Trials: Opportunities and Challenges," Valencell, Ryan Kraudel, April 1, 2019.

¹²: "Directly Observed Therapy (DOT) Assessment Tool," Minnesota Department of Health, ND.

Key drivers for patient retention industry

Evolving clinical research

The growth in clinical trials, especially virtual trials, drives market opportunity for patient retention players.

- 89% of clinical trials lack complete outcome data.
- 40% of patients become non-adherent within five months.
- Virtual and site-less trials have grown.

Vast application and funding opportunities

- The trend toward patient-centric care coupled with the rise of chronic disease and geriatric populations has led to an uptake of patient-centric engagement tools.
- The National Institute of Health has invested in many patient-engagement tools such as AICure. The SBIR/STTR aims to fund startups that stimulate technological innovation, meet Federal (R&D) needs, and increase commercialization to transition R&D into results.
- The FDA is working with stakeholders, including the Clinical Trial Transformation Initiative, to evaluate virtual clinical trials and mobile technologies that enhance patient engagement.