

An aerial photograph showing a dense green forest in the foreground, with a city skyline visible in the distance under a cloudy sky. The text is overlaid on the upper portion of the image.

INVESTING IN ENTREPRENEURS THAT IMPROVE  
HEALTHCARE

Investment Area of Interest:  
**Clinical Research**

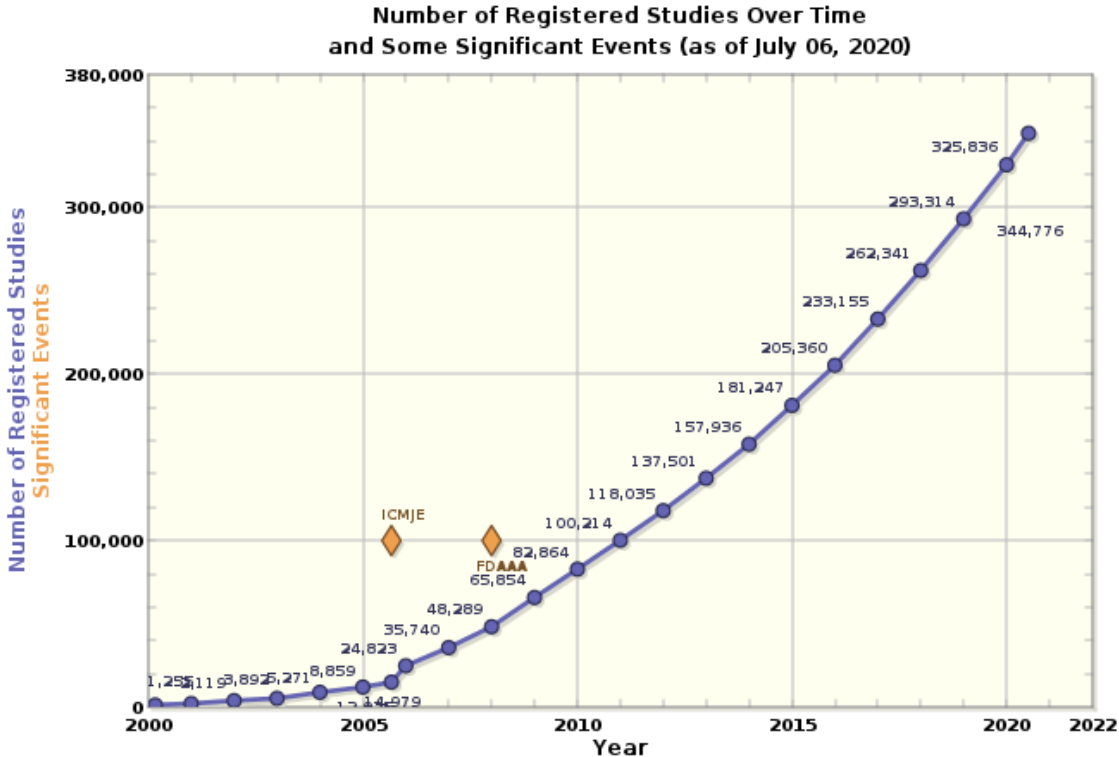
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**September 2020**

A special thanks to [William Blair](#) for allowing FCA to incorporate their company specific market research.

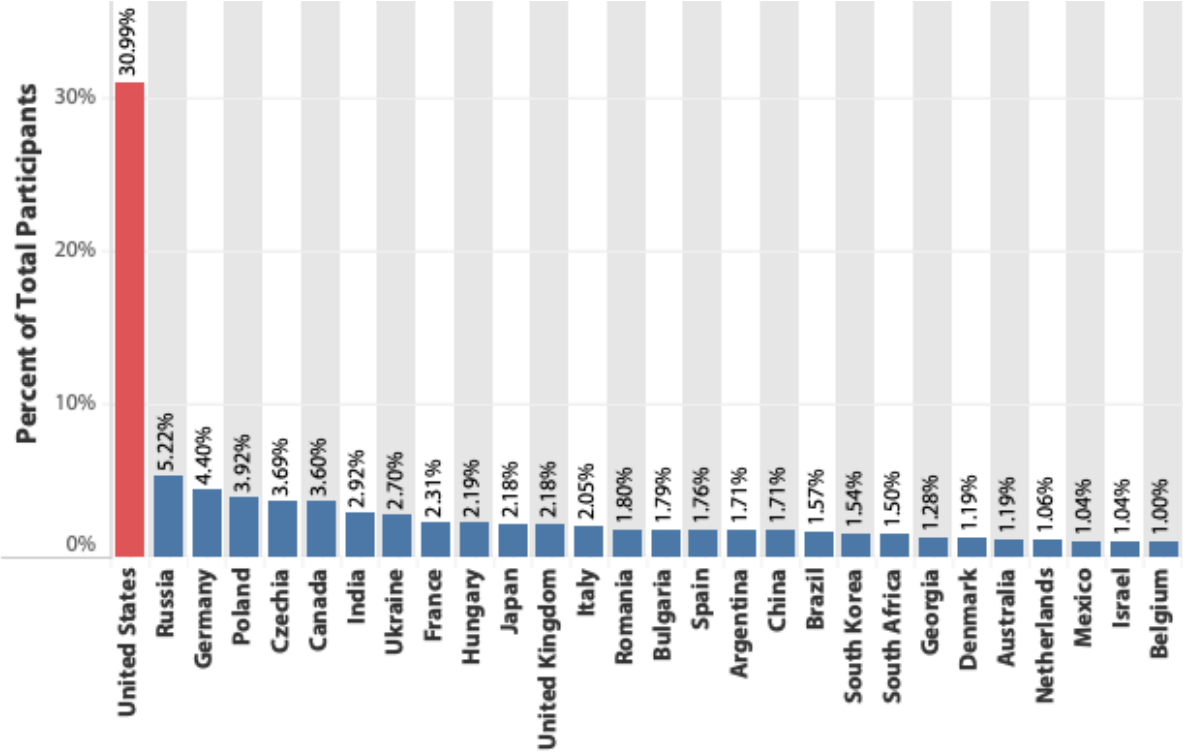
# Overview of the Clinical Trial Industry

In 2019, there were 325,836 registered ongoing clinical trials. Trials spanned locations across all 50 states and 216 countries.<sup>1</sup> The United States contributed the most participants to clinical trials globally, with US participants making up 30.99% of the total.<sup>2</sup> The cost to bring a new drug to market ranges from \$1 to \$2.4 billion. The rise in FDA drug approvals has not matched the increase in R&D costs over the past two decades.<sup>3</sup> While clinical research is on the rise globally, barriers continue to persist that inhibit researchers from completing trials. Interestingly, only half of the drugs rejected in the FDA approval process are due to lack of efficacy.<sup>3</sup> In many cases, failures to submit forms and meet FDA timelines cause trials to derail. In later stages, trial delays can be attributed to management inexperience, unexpected costs, and poor communication with FDA reviewers.



Source: <https://ClinicalTrials.gov>

These factors, along with the underlying risk of a treatment ineffectiveness, combine to pose a significant barrier to entry for many health systems. This leaves researchers siloed in major health systems, with communication barriers and a shortage of trial participants. For effective clinical research, and eventual new treatments, researchers are looking to modernize their processes through software and tech-enabled research services.



Percent of Participants in Clinical Research

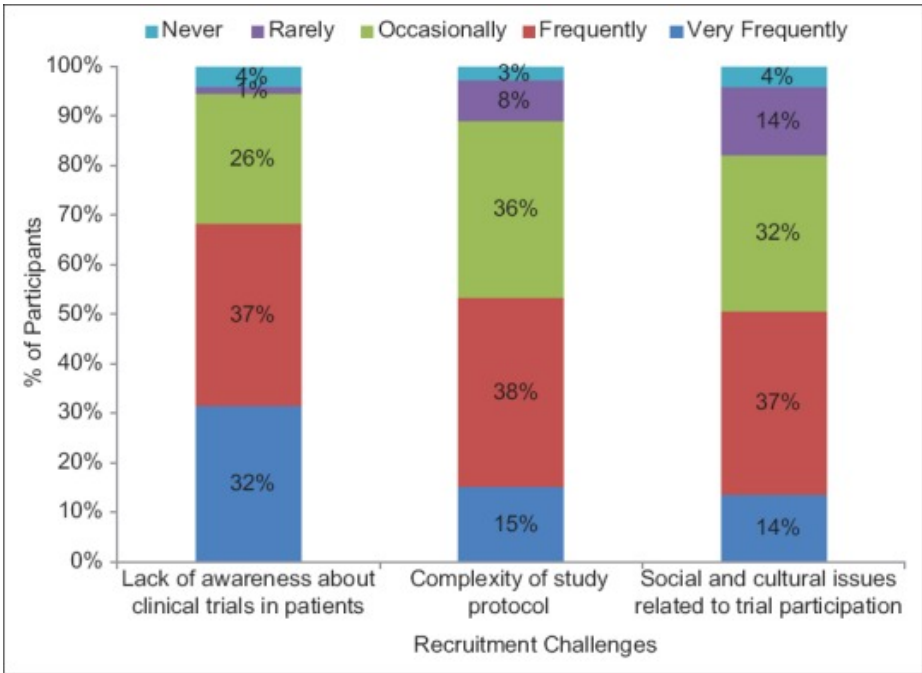
In this report, we will look at problems and solutions across these areas of clinical trial research. Additionally, we will highlight specific examples from more than a dozen startups that are trying to improve the workflow and outcomes of clinical trials. Opportunity exists for tech enabled services to improve clinical trial processes. The Covid-19 pandemic has accelerated change within the clinical trial process. FCA believes that this is a vital area of the healthcare industry and improving processes here will increase the quality of patient care.

# Patient Recruitment and Retention

## Current Problems

Successful recruitment and retention of research participants are two of the biggest challenges facing clinical researchers. The inability to retain patients inhibits researchers from achieving medical advances. Delays in the creation of these new innovative products due to inefficiencies of patient recruitment and retention results in over \$8 million per day in opportunity cost. This staggering statistic leads this sector’s market size value is currently estimated at \$3.2 billion with an annual growth rate of 4% until 2030.<sup>40</sup>

The most common barriers found by researchers in subject recruitment are a lack of awareness of trials by patients, complexity of study protocol, and social and cultural issues related to trial participation.<sup>5</sup> Generally, most of the issues surrounding patient recruitment stem from a lack of education or awareness of clinical research. Thirty-seven percent of researchers polled found trial awareness as a major challenge in subject recruitment.<sup>5</sup> Only 0.01167% of the United States population participates in clinical research; however, the United States is the leader in clinical research participants globally by a wide margin.<sup>2</sup> Patient recruitment remains one of the most expensive areas of clinical trials, consuming up to 40% of total trial expenditures.<sup>23</sup>



Challenges faced by Indian investigators in patient recruitment process (n = 73)

Equally important, patient retention is necessary for successful trials. When recruited patients rescind, it causes cost overruns and corrupts essential trial data. The most common issues for lack of patient retention as found by researchers are as follows: fear of side effects, change of residence, experience of side effects, fear of study procedures, and poor compliance to study protocols.<sup>5</sup> Participants should be educated on trial protocol prior to consent in order to increase retention.

Researchers cannot rely on primary care doctors to promote clinical trials. Even though they are one of the most effective sources of trial exposure, primary care physicians do not have incentives to promote various clinical trials. Efforts to market trial educational materials to primary care physicians may prove unfruitful.

Participant education is also valuable in relation to the screening process. Weeding out ineligible participants prior to evaluation saves valuable time and resources. Researchers create strict screening parameters for trial participants in order to guarantee data shows treatment efficacy.<sup>7</sup> Furthermore, it is necessary to fully vet patients before admittance to the trial for both patient safety and trial validity.

## *Potential Solutions*

Traditionally, clinical trials are accompanied by burdens for both researchers and patients. To lessen the burdens and overcome barriers, digital advertising and software tools can be leveraged. By using technology, a pool of targeted applicants can be created with improved efficiency. By creating a large group of easily queried, pre-screened applicants, researchers can reduce the frequency of participant dropouts and improve recruiting efficiency.<sup>8</sup>

Additionally, potential candidates who fit the research parameters will seldom seek trials on their own. There is an opportunity for a software-based service to bridge this gap, providing increased efficiencies for researchers as well as novel treatments for patients in need.

The utilization of digital advertising allows researchers to spend trial dollars economically in order to further reach potential trial candidates. Clinical trial advertisements that alleviate participant worries, while clearly promoting the trial with simplicity, may see increased

effectiveness. Targeted advertisements allow researchers to shape trial perception to potential candidates.

Supplementing digital advertising efforts with the mining of electronic health records (EHR) can give clinical trials a competitive advantage. By utilizing trends in EHR data, researchers may find target populations with higher efficiency. Given that EHR data may not be contained in easily minable formats, the deployment of artificial intelligence can give researchers leads to previously unnoticed potential patients. Pairing data mining with digital marketing efforts could potentially conserve trial resources by focusing recruitment on targeted populations.

Open communication and ongoing support for trial participants are needed for participant retention. At times, patients worry about trial complexity or the occurrence of negative side effects. A straightforward communication platform can give comfort to trial participants and increase rates of patient retention.<sup>6</sup>

While securing participants and clear communication are crucial for trial success, they are not the primary goals of the trial researcher. Companies such as Clara, Antidote and Deep 6 AI offer software solutions for researchers facing patient recruitment and retention problems.

### *Specific Examples*

Clara, a San Francisco based technology company, offers solutions to patient recruitment. Traditionally, recruitment is located at a brick and mortar research location. Clara opens the door for virtual recruitment and software-enabled retention focused activities. By working with health partners, Clara creates a diverse patient pool to assist researchers in populating trials. Clinical trials using Clara for patient recruitment saw a 75% acceleration in enrollment. The average time to full recruitment under traditional methods is twelve weeks. With Clara, that timeline is reduced to three weeks.<sup>6</sup>


Similarly, Antidote, a London based firm uses precision recruitment to deliver high-quality patient engagement and referrals through data-driven insights. By collecting data from partner organizations, Antidote analyzes patient trends to develop target profiles.<sup>7</sup> This allows Antidote to prescreen patients that fit trial parameters. By concentrating only on prescreened candidates,

researchers are able to use resources more efficiently, while accelerating the clinical trial. For example, in a United Kingdom based study focused on treatments for extreme asthma, Antidote started with a patient pool of 8,000. Researchers in this study aimed for thirty consenting candidates and feared the trial would fail due to a lack of participation. Through a custom landing page for candidates, digital marketing efforts, and social media outreach, Antidote was able to deliver 56 consenting patients in fourteen months. This outpaced researchers' estimates by four months, saving trial resources and expediting research.<sup>8</sup>


Los Angeles based Deep 6 AI takes a different approach by leveraging expertise in artificial intelligence to better serve researchers. Deep 6 AI exponentially accelerates recruitment by applying artificial intelligence and natural language processing to all clinical data to find eligible patients.<sup>9</sup> The company's software analyzes structured data, such as ICD-10 codes, as well as unstructured clinical data, including doctors' notes, pathology reports, operating notes and other important medical data in free-text form that cannot be searched easily with other methods.<sup>9</sup> By combing through unstructured data, Deep 6 AI gleans deeper insights than competing firms who may only analyze formatted data.

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**Patient / Site Recruitment Related Software and Tech-Enabled Services**




**Elligo’s state-of-the-art technology platform provides flexible and agile multitherapeutic and geographic reach, enabling access to a spectrum of physicians and patients.**




Connects with the 97% of health providers that do not currently offer research options. Provides physicians with the infrastructure and expert personnel to integrate clinical trial options.




Engaging an ever-increasing number of healthcare physicians and their patients, reducing clinical trial delays.




\$35M funded since 2016, Series C funding most recently. Series B led by Noro-Moseley Partners & Hatteras Venture Partners. Series C led by Piper Jaffray Merchant Banking.




Austin, TX  
<https://www.elligohealthresearch.com/>




**Deep 6 AI applies artificial intelligence and natural language processing to all clinical data to find eligible patients for clinical trials faster, accelerating recruitment exponentially.**




Deep 6 AI’s software analyzes structured data, such as ICD-10 codes, unstructured clinical data, and other important medical data in free-text form that cannot be searched easily.



Takes an inefficient process and makes it efficient with software.



\$17M in funding since 2015  
 Point 72 Ventures



Los Angeles, CA  
<https://deep6.ai/>



# TrialSpark

TrialSpark is a tech-enabled drug development partner using standardized trial sites to reimagine the clinical trial process.



With a network of standardized trial sites and a best-in-class technology platform, TrialSpark runs end-to-end clinical trials as an alternative to traditional CROs.



TrialSpark's approach enables access to research for the 98% of physicians and patients that the industry has historically failed to include.



\$17M in funding since 2015



New York, NY  
<https://www.trialspark.com/>



Digital matching service that links trial volunteers with potential studies. Supply patient support to improve trial retention rate.



Simplifies patient recruitment process for researchers and clinical trial volunteers. Provides matching for 50,000+ studies to possible volunteers.



Incentive for both patient and researcher by simplifying complexity in the recruiting process for the patient, while reducing recruitment costs researchers.



\$10.1M raised since 2015  
Last round of capital was led by Khosla Ventures & Founders Fund.



San Francisco, CA  
[www.clarahealth.com](http://www.clarahealth.com)



Antidote is on a mission to transform the way that sponsors, and patients connect in order to accelerate medical research.



Using 300+ partner organizations Antidote creates target profiles using parameters from researchers to best fit applicants to studies. options.



Engaging an ever-increasing number of healthcare physicians and their patients, reducing clinical trial delays.



\$28.9M funded since 2011. Octopus Ventures, Smedvig Ventures, Merck Global Health Innovation Fund, and Amadeus Capital Partners are lead investors



London England, UK

<https://www.antidote.me/>



**TriNetX**

TriNetX a health research network that connects drug development from pharmaceutical company to study site, and investigator to patient by sharing data to make clinical and research easier and more efficient.



Real-time access to patient populations, driven and refreshed by electronic medical record (EMR) data options.



The ability to explore, assess, and download fully anonymized data from a select set of TriNetX Research Healthcare Organizations members.



\$42.5M funded since 2013, Series D funding most recently. Series D led by Merck Global Health Innovation Fund



Cambridge, Massachusetts

[www.trinetx.com](http://www.trinetx.com)

## ReifyHEALTH

Reify Health provides cloud based software to help the development of new and life saving therapies. Reify serves thousands of CRO's.



Get a patient database designed for the site's workflow. Add patients individually or bulk import from your EMR.



The ability to manage recruitment across all trials, sponsors, and CROs.





















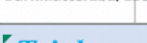

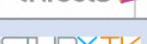
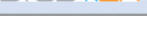
\$39.6M funded since 2012, Series B funding most recently, led by Battery Ventures



Boston, Massachusetts

<https://www.reifyhealth.com/>

## Additional Companies of Interest

Company	Description	Relevant Investors	Last Round	Sub-Category
 DEEP6 AI	AI-based software for clinical trial patient identification and recruiting		\$17M (Nov-19)	Patient / Site Recruitment
	AI-enabled patient recruitment and matching software for clinical trials	N/A	N/A	Patient / Site Recruitment
 ELLIGO HEALTH RESEARCH	Clinical research platform for research site and patient identification		\$20M (May-19)	Patient / Site Recruitment
 FindMeCure	Clinical trial listing and application website		N/A (Jul-17)	Patient / Site Recruitment
 EmergingMed	Clinical trial listings and patient calling center		N/A	Patient / Site Recruitment
 EmpiraMed	Clinical trial patient recruitment and management platform	N/A	N/A	Patient / Site Recruitment
 ClinicalConnection	Clinical trial portal provides a suite of patient recruitment services	N/A	N/A	Patient / Site Recruitment
 CRIO	Clinical trial recruitment and engagement platform	Various Angels	ND (May-18)	Patient / Site Recruitment
 inato	Clinical trial site matching and selection software for biopharma and CROs		\$14M (Feb-20)	Patient / Site Recruitment
 deep lens	Cloud-based pathology platform that identifies patients for trials at diagnosis		\$14M (Apr-19)	Patient / Site Recruitment
 myTomorrows	Experimental treatment advertising and recruitment hub		\$10M (Jan-17)	Patient / Site Recruitment
 Mendel ai	Network of sites to create trial opportunities for doctors within existing practices	Sequoia Capital, Thrive Capital	\$70M (Oct-18)	Patient / Site Recruitment
 mosio	Oncology-focused real-world evidence for patient matching / recruitment		\$2M (Jul-2017)	Patient / Site Recruitment
 MASSIVEBIO	Oncology-specific clinical trial matching site and patient / oncologist network		N/A	Patient / Site Recruitment
 patientwing	Online clinical trial listing network		\$1M (Feb-18)	Patient / Site Recruitment
 ProofPilot	Online clinical trial recruiting and enrollment network		\$2M (Nov-14)	Patient / Site Recruitment
 SubjectWell	Online patient recruitment and referrals hub for clinical trials	Frontier Venture Capital, Geekdom Fund	\$10M (May-19)	Patient / Site Recruitment
 SureClinical	Online patient support communities for chronic conditions		\$11M (Apr-18)	Patient / Site Recruitment
 DarkMatter2bd, LLC	Patient and investigator recruitment and KOL / HCP databases	N/A	N/A	Patient / Site Recruitment
 Trialx	Patient recruitment management software for clinical trials	N/A	N/A	Patient / Site Recruitment
 trifecta	Patient recruitment website that builds communities with similar disease states	Kinderhook Industries	ND (Mar-18)	Patient / Site Recruitment
 STUDXIK	Patient-centric platform to ease access to clinical trials	Rough Draft Ventures, Abstract Ventures	\$7M (Jan-20)	Patient / Site Recruitment

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## Clinical Trial Operations

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### *Current Problems*

Administrative duties may cause added stress when completing research. Researchers are tasked with medical license upkeep, data entry, adherence to FDA guidelines, and consistent communications with participants.<sup>3</sup> These operational tasks, which must be done at the same time as core research, can lead to missed FDA deadlines or data inaccuracy. These tasks and the trials themselves are far from cheap. In 2020, the market size for clinical trial operations stands a whopping \$18.4 billion and is growing at a CAGR rate of 7.83%.<sup>42</sup> Finding a way to cut costs is at the top of many healthcare tech companies' lists.

As trials progress through different phases, researchers must develop insightful reports for regulators, investors, and patients which requires valuable time and resources.<sup>10</sup> When researchers are tasked with creating external reports and must revisit data analysis, costs may increase past projections. Twenty-two percent of clinical trials failed during Phase III testing due to lack of funding.<sup>10</sup>

When trials require research to be done at multiple locations, monitors and researchers travel to various research sites to check for procedure adherence. This is necessary to ensure the safety of the patient and validity of the data gained. Often, study staff will be required to enter data into both paper and software-based databases multiple times for verification. Even though this process is necessary to successfully conclude efficacy of treatment, it can be costly and highly time-consuming.

In many cases, there is a shortage of trained study staff necessary to implement research protocols which adhere to the researchers' parameters. For example, in Ebola research located at rural African trial sites, staff trained for patient recruitment, education, and treatment are not available.<sup>11</sup> This can lead to corrupted data and errors in procedure, risking trial validity and patient safety.

Surprisingly, lack of situational awareness can be a factor involved in clinical trial failure. Researchers need to be aware of the progress of trial progression, patient progress, and any protocol deviations that may arise.<sup>10</sup> Ensuring that study staff adhere to trial design and that all

protocols are followed to meet FDA regulations is essential to the success of clinical trials. Lack of communication between study staff, patients, and researchers can increase the chance of errors in reporting and patient adherence. Reliance on traditional channels of communication may not be enough for patient engagement. Patients' increasing dependence on telehealth, combined with their expectation for instant support, leaves some antiquated clinical trial sites underprepared to serve. Effective communication with study staff can relieve some of the anxiety felt by participants. Patients who found site visits stressful are twice as likely to drop out from a trial.<sup>10</sup> Approaching patient participation in a non-traditional way can ease patient stressors.

Patients may be required to purchase results for trials in which they participated.<sup>10</sup> Patients may feel a lack of respect for the time, energy, and risk they invested into the trial. Patients who found trials too complex, or confusing, were more likely to disengage from trial participation.

### *Possible Solutions*

The utilization of workflow management software can assist researchers in organization and document management thus allowing researchers to focus on core responsibilities instead of administrative duties. By removing the inherent bulkiness associated with paper-based systems, study staff can screen, educate, and enroll more patients while maintaining procedural standards. Clarity between study staff and researchers can ensure accurate data and procedure adherence. Workflow management software gives researchers access to the systems at the study site which enables easy transfer of documents and data. The ability to remotely connect to trial resources can also improve workflow and research efficiency. Also, the responsibility to accurately store trial materials no longer falls on the study staff. Primary researchers can categorize the documents and data obtained off site.<sup>11</sup>

Minimizing patient burden and maximizing patient experience are key items often overlooked in clinical trials.<sup>10</sup> Providing educational resources for patients can ease worries of adverse side effects, and calm patients who feel the treatment may be too complex. Allowing patients to use their own internet enabled devices to access reports and educational materials may be a way to bridge the gap between patient worry and patient knowledge. Patients may have adverse side effects or experience symptoms outside of the research setting and the ability to remotely contact support staff can drastically decrease the anxiety on patients. Additionally, when

patients' personal devices are linked to the research databases, electronic surveys can be implemented to provide further insight from the patients. Data gained from patients can be instantly accessed by researchers.<sup>11</sup> This removes data entry tasks that would otherwise consume time of the study staff. Bring your own device (BYOD) connectivity is an inexpensive way to better engage patients as well as increase data accuracy and detail.

By leveraging the benefits of a telehealth approach, researchers can virtually educate and guide study staff. Software based supervision gives researchers the ability to virtually monitor sites instead of physically traveling to sites which is especially helpful in locations where trained medical staff is unavailable.<sup>11</sup> Researchers are able to remotely access patients in various locations which is valuable in areas affected by infectious disease, much like recent changes in healthcare procedures during the COVID-19 pandemic. Telehealth usage allows trials to progress with advanced speed, while maintaining effective communication with trial patients.

Researchers should create a clear plan of action toward meeting FDA deadlines. For study staff on site, the ability to use electronic reporting can increase efficiency with patient facing procedures. The use of automated prompts for patients and staff reduces the frequency of missed reporting events enabling the trial to stay on track and not place undue burden on study staff.<sup>11</sup> Scheduled notifications of missed events can give researchers insight into which trial sites are underperforming, allowing for near real-time changes in policy or staffing. Automated templates for reports can be utilized to improve the professionalism of trial materials exported to third parties. Combining branded templates with workflow software and BYOD benefits may lead to highly efficient data capturing and analysis.

### *Specific Examples*

Clinical Ink, an FCA Health Innovations portfolio company based in Winston Salem, NC and Philadelphia, PA, allows for researchers to deploy ePRO software systems to patients without tasking study staff with native software development.<sup>12</sup> Clinical Ink's Lumenis ePRO solution can be integrated into a Bring Your Own Device program. With simple training, project professionals are fully capable of designing, developing, and deploying functional prototypes for testing and review.<sup>12</sup> The implementation of BYOD options increases trial app usage as compared to study issued phones. According to "Successful BYOD in Any Phase", a Whitepaper by Gena Gough,



Clinical Ink had exceptional compliance. In this study, allergy symptom scores were collected every 30 minutes for the first three hours on site and then every 60 minutes at home for the following nine hours on visit days, which occurred every two weeks. To enter their data, patients downloaded the Lumenis app on their own Android or iOS smartphone. When the patients logged into the app, they saw the symptom score rating, the day's agenda, the training diary, and an overview explaining how to rate their symptoms. To encourage compliance, preconfigured pop-up reminders were set, and site staff had access to the data in real time in order to identify if that patient was eligible to continue in the trial. This real-time monitoring was also available to the CRO and sponsor. Ninety percent of the 275 enrolled subjects utilized their own phones to submit their data at 16 timepoints per day for three days, two weeks apart. Ten percent of subjects used provisioned devices for various reasons (old phones, not smartphones, used work-provided phones and lacked permission to use, incompatible devices such as a Blackberry). This study had an overall compliance rate of 98.3% with 86% of the subjects being 100% compliant. Another 9% of the patients missed one timepoint, demonstrating a 94% compliance rate. The remaining 5% missed two or more timepoints, making them 88% compliant or below. Most commonly, the last timepoint of the day was missed, which, depending on the patient's start time, may have coincided either with dinner time or bedtime.<sup>13</sup>

Javara Research, an FCA Health Innovations portfolio company, is an Integrated Research Organization (IRO) that is driven to change the clinical research experience and expand access to clinical trials—for both providers and patients. Javara delivers first-class clinical research services to healthcare organizations by providing the infrastructure necessary to successfully conduct trials.

For example, as the Covid-19 pandemic was growing in the U.S, Javara was contacted by Oracle about its Therapeutic Learning System (TLS). Oracle created this tool to help identify and diagnose illness in patients. Soon after, Javara learned of Wake Forest Baptist Health's (WFBH's) interest in creating an epidemiology study for public serosurveillance testing. The Javara team immediately began brainstorming how these two concepts could come together, since these organizations and their missions would make a strong fit. Javara introduced WFBH and Oracle to one another, and Scanwell was also later brought into the discussion. Soon, Javara, Oracle, WFBH, and Scanwell all entered into a commitment to the collaboration. Each organization played a different



role in the study. Oracle's role was to oversee the study's technology operation. WFBH contributed by leading the study design process through its PIs and a call center for patients. Javara, an expert in clinical trial conduct, oversaw the logistics of the study between all parties, ensuring all aspects integrated smoothly. Scanwell produced at-home test kits for study participants. This research study will significantly impact the information collected about COVID-19. "By allowing healthcare systems to collect this real-world data throughout the United States, this will allow policy makers, state officials, healthcare administrators identify early warning signs of potential COVID-19 flareups, make more informed decisions around the safest time to reopen communities and where to enforce contact tracing", says Kathy Vandebelt of Oracle. Being able to execute at rapid speed while facilitating collaboration across multiple stake holders is why Javara is positioned as a leader in the industry.

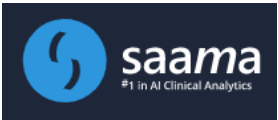




Florence Healthcare, an electronic document workflow and remote site access platform, enables researchers to remotely connect to sites, sponsors and CROs. Remote connection allows for collaboration on documents, data, and workflows in real-time from any physical location. This capability can combat issues often faced in infectious disease trials or hard to reach trial sites. Researchers can facilitate remote start-ups, monitoring, and management. In addition, Florence can help researchers strengthen regulatory compliance. Florence's systems ensure inspection readiness across research sites.

Florence partnered with a top-10 CRO to enable remote site access at fifteen paper-based research sites in Australia in only three days by deploying electronic Investigator Site File.<sup>15</sup> In order to achieve this rapid deployment, Florence equipped clinical research associates to train and onboard site staff during the Site Initiation Visit. Currently 7,200 investigators are using Florence's software-based tools to increase efficiency in their research.

Viedoc, a document capture software, also engages with CROs and sponsors to bring software-based tools to trials and has engaged in over 2,000 clinical trials with 600,000+ patients.<sup>16</sup> Viedoc worked with Oslo University Hospital to update research workflows. Oslo University Hospital has over 20,000 employees and is the biggest contributor to medical and healthcare research conducted in Norwegian hospitals.<sup>16</sup> Viedoc was able to train the team in Oslo on how to build and manage the study through the administration of the Viedoc platform. After six months, Oslo University Hospital had six studies in production, three in the final quality control

stage, two studies being built, and eight more studies in the pipeline. Oslo University Hospital was impressed with the expedited progress made using Viedoc's platform.<sup>16</sup>

### Clinical Operations Related Software and Tech-Enabled Services

 <p><b>Actionable insights, driven by AI-powered clinical analytics platform, gives intelligence required to manage risk and improve performance across studies, systems, sites, and vendors.</b></p>	 <p>Saama's workflow platform enables key stakeholders to access vital study data for much-needed oversight.</p>
	 <p>Saama's suite of applications ensures that enrollment, CRA turnover, regulatory documentation, and other issues don't cause unnecessary study delays.</p>
	 <p>\$75.8M funded, Carrick Capital Partners led Series A</p>
	 <p>San Francisco, CA <a href="https://www.saama.com/">https://www.saama.com/</a></p>



**YPrime offers software solutions that reduce statistical integrity risk while delivering submission ready data at the end of the project.**



YPrime offers out of the box solutions for simplified Phase I trials, to full featured systems that can support global Phase III trials.



YPrime provides design recommendations, manages scope, as well as communicates and mitigates risk early to keep studies on track



\$12.5M Funded since 2006, Flexpoint Ford led a private equity round. Series A led by Ballast Point Ventures



Philadelphia, Pennsylvania  
<https://www.yprime.com/>



**Medrio is a provider of eClinical technology for early-phase pharma, device, and diagnostics clinical trials.**



Medrio's cloud-based electronic data capture, eSource, eConsent, and ePRO solutions deliver fast, flexible, and tools for the collection and management of clinical data reported.




Medrio's tools for study sponsors and CROs accelerate the collection of clinical trial data across drug, device, diagnostic, and animal health trials.




\$32M in funding since 2005, Venture Round led by Questa Capital Management




San Francisco, CA  
[www.medrio.com](http://www.medrio.com)




**Castor is a cloud-based clinical data platform, enabling researchers to easily capture and integrate data from clinicians, patients, devices, wearables, and EHR systems.**




Continuously capture data from devices, patients (ePRO), and EMR systems to meet regulatory, marketing and product development needs, including PMS, PMCE, and RWE.



Software solutions for clinical trials with a focus on ease of use and regulation compliance.











\$7.5M funded since 2011, INKEF Capital led Series A



Amsterdam, The Netherlands  
<https://www.castoredc.com/>

**Additional Companies of Interest**

Company	Description	Relevant Investors	Last Round	Sub-Category
 trials.ai	Big data and analytics tools for optimizing trial protocols and design	JLBAS, Teal Ventures	\$1M (Oct-19)	Trial / Protocol Design
 formedix	Clinical study design, review, and automation software		N/A (Oct-12)	Trial / Protocol Design
 protocols.io	Professional network for sharing clinical trial protocols		\$4M (Jan-20)	Trial / Protocol Design
 Cytel	Strategic consulting and software solutions for clinical trial design	New Mountain Capital	ND (Oct-17)	Trial / Protocol Design, Clinical Analytics
 Complion	eRegulatory Solution for High-Performing Clinical Research Sites, Sponsors, and CROs	Beringea, Ohio Innovation Fund	\$7M (Feb-19)	Virtual Trials
 Viedoc	EDC, ePRO, eCRF, CTMS and patient management software		ND (Nov-19)	Trial / Protocol Design, RTSM / IWRS / IRT,
 Complion	eRegulatory Solution for High-Performing Clinical Research Sites, Sponsors, and CROs	Beringea, Ohio Innovation Fund	\$7M (Feb-19)	Virtual Trials
 DEVANA solutions	Cloud-based SaaS provider			Virtual Trials

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# Patient Engagement

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## *Current Problems*

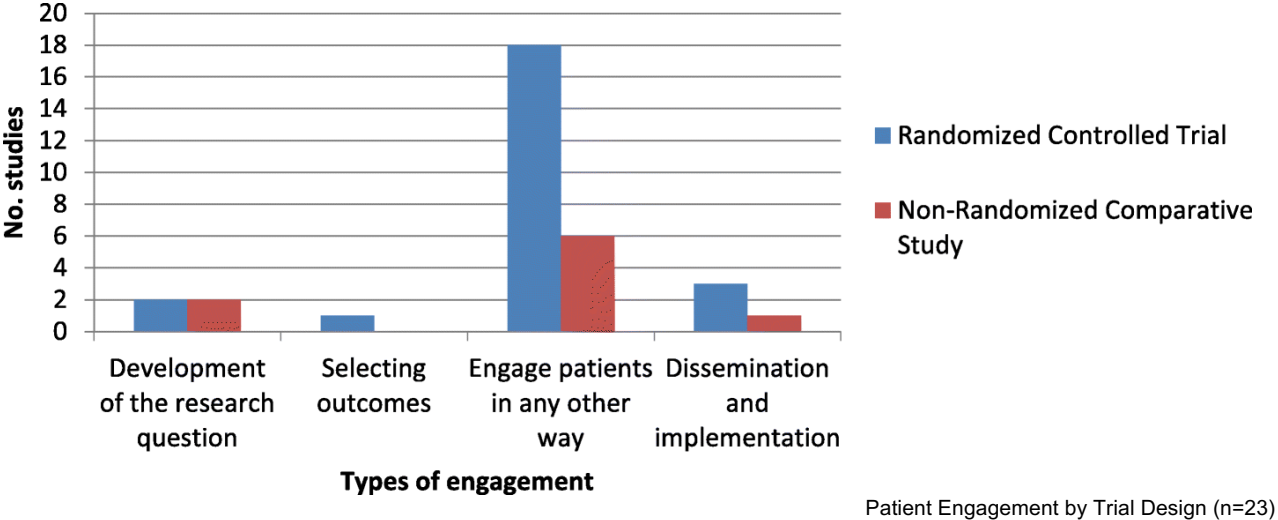
Many trials fail due lack of patient engagement. To combat patient disengagement, study staff and researchers take on the role of educator which requires time commitment and trial resources to onboard trial participants. Patients are an integral part of research and can be viewed as an investment. The data gained from patient participation is an invaluable part of the trial. The current market size for patient engagement solutions sits at \$11.8 billion with a 17.3% CAGR. There is a clear, growing demand for a healthier amount of engagement because patients who are not engaged lead to noncompliance of patient protocol or negligence in reporting to researchers.<sup>41</sup> These patient behaviors can corrupt data validity and derail clinical trials.

Low levels of patient healthcare literacy contribute to lack of patient engagement. When patients are not educated about the trial, they tend to be concerned with possible negative symptoms from treatments, as well as treatment efficacy. Patients express worry about the lack of continuing education as trials progress; specifically, that the educational materials lack flexibility to meet patient needs.<sup>17</sup>

Additionally, administrative barriers often affect patient willingness to participate in studies. The time constraint associated with completing documents and questionnaires often negatively influences patient participation.<sup>18</sup> The added administrative efforts compounded with complex or confusing documents can lead to patient disengagement.

The timing of trials and related protocols can be an issue for clinical trials. Researchers experience decreased patient engagement when protocols infringe on routine activities. This effect is compounded in cases where trial treatment must take place in a specialized location or administered by specialized medical professionals.<sup>18</sup> Resource constraints outside of researchers' control can negatively impact the trial. In these instances, the trial must coordinate to find availabilities.

Interestingly, many trials do not report patient engagement activities, even though they are encouraged to do so by sponsoring organizations. Many studies fail to adopt a Patient Oriented Research approach.<sup>19</sup> The absence of engagement focused leadership leads to activities that may discourage patient engagement.

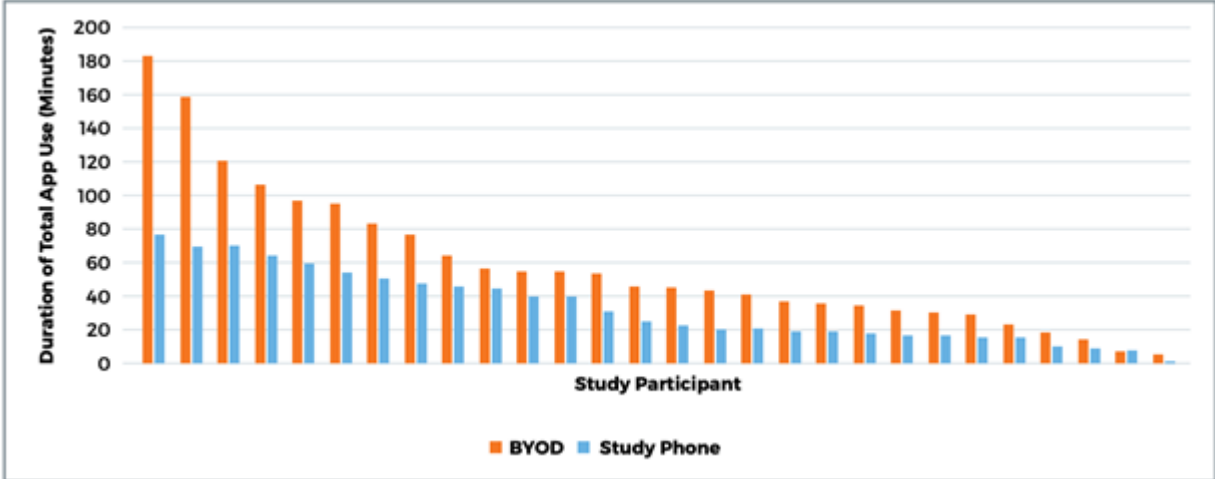


Furthermore, the reporting standard for patient engagement is inconsistent.<sup>19</sup> Generally, there is a lack of detail in reporting of patient engagement activities even though there is a great amount of detail in other trial design aspects. By inconsistently underreporting engagement activities, researchers and sponsors deprive the general research community of activities that can improve overall study validity and design. Poor reporting can be partially responsible for the low prevalence of patient engagement in clinical trials.<sup>19</sup>

**Possible Solutions**

Participant education is vital to foster engagement by patients. The implementation of educational software for patients can relieve some of the responsibilities of study staff and give patients greater access to educational materials. With improved access, patients are more likely to be educated on trial protocols and have improved communications with study staff. Utilizing software that connects researchers to patients can increase patient engagement. When patients feel that their questions about procedure or side effects can be quickly answered, perceived complexity about the trial may be diminished. A more educated patient will engage and adhere to the protocols at greater frequency as compared to patients who view the protocols as complex.<sup>5</sup>

To overcome issues with patient adherence to protocol, researchers can utilize software services that send notifications to patients' personal devices. Patients often forget to take medication or report symptoms, so by sending reminders, patients' trial experience will be improved. Likewise, by offering surveys and prompts to patients with the ability to respond remotely, the administrative responsibilities are decreased for trial participants and study staff. Researchers should look for software platforms that give study staff the ability to manually create and release custom questionnaires. By creating in-house questionnaires, researchers can better validate and understand data created by patient responses. Adding the ability for patients to respond to questionnaires via smartphone or personal device can further increase patient engagement. Instead of commuting to a research site for data collection, patients can respond to questionnaires from the comfort of home. Bring Your Own Device methods can be used to engage patient responses. Patients are more likely to use their personal devices with trial software downloaded than a study issued phone.<sup>13</sup>



Duration of Total App Use by Study Participant, 13

The application of wearable devices can give researchers frequent or even continuous data capture abilities.<sup>20</sup> This will allow researchers to collect data on treatments outside of study site visits and traditional questionnaires.

Similar to many paperless systems emerging in healthcare today, the application of a document management system that integrates with the patient screening process will improve the patient

experience. Removing the burden of paperwork can speed up the admittance of patients to the trial and simplify overall trial experience.

### *Specific Examples*

Koneksa Health, based in New York, provides trials with software solutions to capture, monitor, and analyze patient generated data.<sup>20</sup> Electronic Clinical Outcome Assessments (eCOAs) have been demonstrated to dramatically improve the reliability of patient reported data when compared to traditional questionnaires and diaries.<sup>21</sup> Koneksa's mobile responsive software can improve the accessibility of eCOAs, providing a cost effective and flexible platform to reach patients more frequently on any internet-enabled device. Koneksa enables study staff to send scheduled automatic reminders to trial participants. Reminders can be configured to send alerts to complete study items, file reports or sync trial devices.

Koneksa joined Merck & Co. Inc to review the accuracy and sensitivity of mobile health technologies that measure heart rate and blood pressure. Through the study, they found that implementing mobile technologies is feasible for detecting the effects of therapeutic intervention. Additionally, patients reported higher satisfaction using at-home data collection as compared to in-clinic visits, especially the convenience and ease of use.<sup>22</sup>

PatientWing (formally VitalTrax) created the clinical trial network, Wing, which is focused on connecting patients to trials. Wing gives trials more visibility virtually, which is increasingly important during the ongoing COVID-19 pandemic.<sup>24</sup> Wing offers a solution for barriers in patient enrollment. Wing simplifies the enrollment and participation process by offering virtual platforms for study staff and patients.

PatientWing simplifies the screening process for study staff by promoting trials to interested volunteers based on trial location and target conditions. PatientWing presents trial information in a simple format which shows interested patients trial information, participation criteria, requirements and benefits.<sup>25</sup> Patients are prompted to answer questions through a secure application portal. This data is sent directly to study coordinators resulting in more efficient recruiting and a less burdensome application process for the patient. PatientWing offers 24/7



online application and is consistently within the top results of over 350,000 internet searches for trials.<sup>26</sup>

Playa Vista, California based Science 37 acts as an additional virtual site to a trial's traditional site-based approach. Current trial offerings are limited to the geographic region where they take place. This limits the trial to 5% of the total patient population. Adding Science 37's "Metasite" can give researchers access to the other 95% of patients through virtual channels.<sup>27</sup> Data can be collected an exact manner to match standards at physical trial locations while operating more efficiently. By adapting to a virtual channel, trials may reduce risk from unforeseen events, like the current pandemic.


Science 37's Platform offers end-to-end trial management through a fully configurable system. This platform supports telemedicine, Bring Your Own Device, and wearables. Science 37 has been involved in the advancement of telemedicine for many years prior to the rapid increased interest in telehealth due to COVID-19. In 2016, Science 37 launched a virtual phase 2 trial with AOBiome which focused on acne treatment. In 2017, AOBiome reported successful results from the treatment, as well as successful virtual trial operations.<sup>28</sup> During 2018, Science 37 started ten studies with Novartis to peruse Novartis' goal of expanding virtual trials.<sup>23, 29</sup>


During 2016, Science 37 received \$35 million in series C funding, including investment from Amgen and Google. This shows interest from large technology players in telehealth and virtual trial software tools.


# Patient Engagement Software Enabled Companies


**CLINPAL**

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 Patients log in from anywhere, on any device. Study teams leverage powerful data and analytics across the entire lifespan of the trial.

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 \$2.62M FTD

 Stirling, United Kingdom  
<https://www.clinpal.com/>

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Lightship is a provider of enterprise-level, direct-to-patient clinical research solutions



Lightship partners with pharmaceutical companies to provide enterprise-level services conducting Direct-to-Patient (DtP) clinical trials.



Lightship eliminates the hurdles and inefficiencies of the traditional clinical trial model.



\$20M FTD, Series B led by McKesson Ventures



[Los Angeles, CA](#)  
[www.lightship.com/](http://www.lightship.com/)

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Decentralized trials, delivered on a global platform to unify Xclinical trial solutions.



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San Francisco, CA  
[www.medable.com](http://www.medable.com)



**PatchAi is a cognitive platform embedding an empathetic virtual assistant for patient engagement and real-time data collection**



PatchAi constantly learns and implements strategies to support the patient, adapting personality, tone and conversation according to their needs.



PatchAi is a solution for collecting quality ePROs and Real World Data under the banner of patient engagement.



\$1.012M in funding since 2018, Seed Round with Healthware Ventures



Milan, Italy  
<https://www.patchai.io/>

## Additional Companies of Interest

Company	Description	Relevant Investors	Last Round	Sub-Category
Be the Partner	Patient engagement and messaging for trial sponsors	Lehel	ND (Undisclosed Date)	Patient Engagement
ClinOne	Patient engagement and secure messaging portal for clinical trials		N/A	Patient Engagement
DELVE HEALTH	Patient engagement, educational content, and digital concierge	Hilltop Ventures, University of Colorado	\$4M (Mar-20)	Patient Engagement
medaptive health	Patient recruitment, engagement/ retention, and ePRO software		N/A	Patient Engagement
medidata	Patient surveys for trials, post-market monitoring, patient registry, etc.		\$1M (May-19)	Patient Engagement
SubjectWell	Patient recruitment, engagement/ retention, and ePRO software	Windham Venture Partners	\$10M (Jun-19)	Patient Engagement
PatchAi	Utilizes behavioral and social data to customize patient engagement programs	SAP.iO Foundry, Plug and Play Tech Center	N/A	Patient Engagement
TriNetX	Virtual assistant software for clinical trial subjects		\$1M (Jul-19)	Patient Engagement

A special thanks to [William Blair](#) for allowing FCA to incorporate their company specific market research.

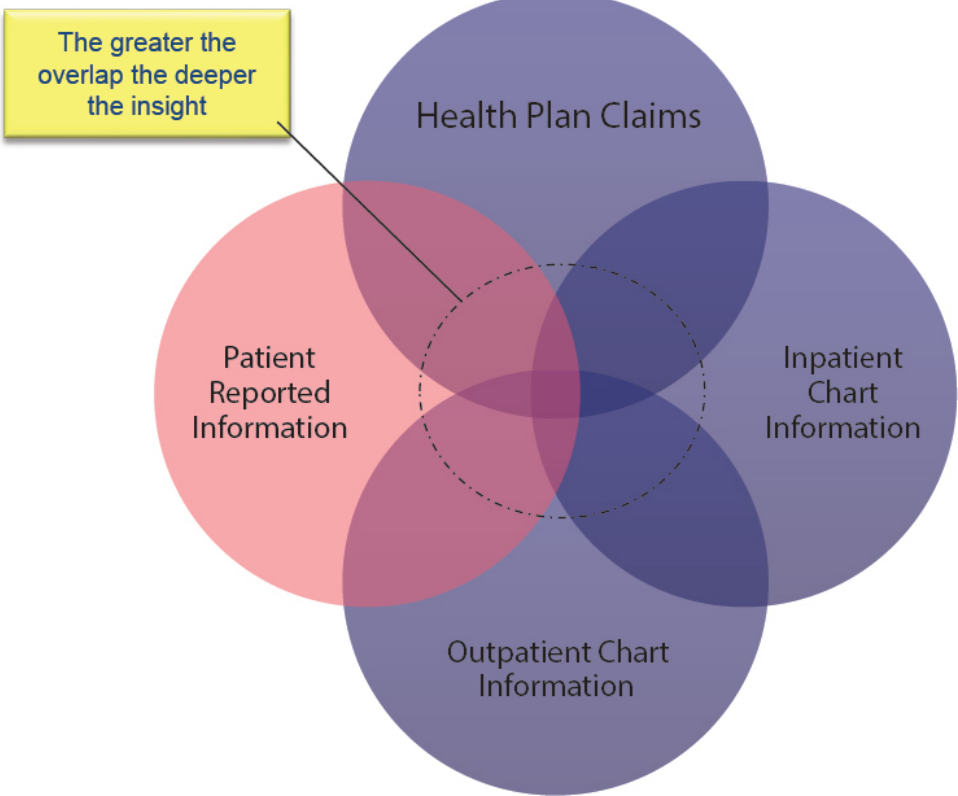
### *Current Problems*

Real-World Data (RWD) and Real-World Evidence (RWE) are becoming increasingly important for decision makers in healthcare, biopharma and the FDA. The 21<sup>st</sup> Century Cures Act, passed in 2016, places great emphasis on the use of these types of data for regulatory decisions, such as approval of new drugs.<sup>30</sup> While promising, RWD can be messy and unorganized. RWD may show a more representative picture of true patient population, however the data may give an incomplete view of a patient's journey. Current trials may not have access to large amounts of RWD or fail to possess tools to analyze extremely large amounts of RWD. Similarly, reporting on the outcomes of trials and data analysis is inconsistent.<sup>31</sup> With the rapid advancement in technology and data storage, the demand for RWD is overwhelming. With a current market size of over \$672 million and an estimated CAGR of 13.9% until 2026, health-tech companies are swarming this sector to find an efficient way for this data to be mined and used efficiently.<sup>43</sup>

Real World Data is collected through many non-traditional sources. Due to the increased amount of consumer technology with biosensors, large swaths of data are created. RWD is defined by Congress as, "data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials."<sup>30</sup> RWE is derived from trends in RWD which is collected from HER data, claims and billing activities, product and disease registries, patient-generated data (wearables), and other sources such as mobile devices. Given the vast array of sources for RWD, researchers may struggle with the interpretation, transfer, and collection of RWD. In addition, there is no standard for normalizing the data. Researchers, especially those with smaller sponsors, will face difficulties effectively using RWD.

Brian Bradberry, executive director in the Center for Observational Research at Amgen Inc., identified barriers limiting the adoption of RWE. He lists the mistrust of data captured outside of a randomized controlled trial (RCT) as a current limitation. It is common practice for medical programs to teach RCT as the top tier in data validity. While RCTs have been the standard, leveraging RWE will allow for more efficient and nuanced outcomes.<sup>32</sup> RCTs do not have the capability to determine how the treatment will be used in the real world. Patient age, race, gender and comorbidities may be different in the trial environment than in actuality. Even though treatment effectiveness and safety can be determined through clinical trials, precisely which

patients would best benefit from the treatment is difficult to ascertain through a RCT. Treatment performance in a real-world environment is not collected until after the treatment has gone to market. While there are benefits to RWD and RWE, currently researchers focus mainly on collecting data through RCT.



SOURCE: Wilson presentation, September 19, 2017.

Smaller trials may be limited in their ability to internally access and mine large amounts of Real-World Data. Thirty-five percent of RWD users from a SHYFT analytics poll identify access to quality data as a significant barrier. Additionally, 30% of respondents identified shortfalls in applying RWD to develop RWE. Eighty-five percent of biopharma outsource some amount of RWD mining and analysis. Only 15% of biopharma firms access RWD internally. To some smaller sponsors, the cost of adopting an inhouse RWD analytics team may be too high. Real World Evidence in biopharma is expected to grow 15% from 2019 to 2024. Currently the industry size is estimated at \$1.64 billion. With nearly 80% of clinical trials being delayed due to failures in recruitment, RWE helps ensure availability of patients.<sup>33</sup>

### Solutions

Researchers are tasked with collecting and analyzing large swaths of real-world data. It is nearly impossible for sponsors and researchers to build data mining and analysis software in-

house. Researchers can leverage preexisting tools to overcome the barriers surrounding the large amount of RWD available. Due to the prevalence of RCTs in clinical research, legacy systems may not support RWD and there may be push back from trial sponsors and administrators. While RWD and RWE are relatively new, these are classic issues that organizations face as they try to develop new areas of research.

Determining effective outcomes in Real-World Evidence requires a large amount of Real-World Data. Partnering with services that collect and organize RWD can give trial staff access to extremely large amounts of real-world data. For example, Amgen launched an RWD portal in 2016 that queries records from 150 million patients.<sup>34</sup> Trials should strive to adopt services and software that give them the ability to access vast amounts of RWD without the burden of RWD storage and maintenance. Data analysis professionals can use queries that are familiar to them to search swaths of RWD. Pairing insights gained in the form of RWE with outcomes from a randomized controlled trial will give a clearer picture of treatment efficacy, safety, and real-world use cases.

RWD bridges the gap between clinical trial patients and real-world patients. In a process called “extension”, researchers combine RCTs with RWD gathering techniques.<sup>32</sup> For example, patients in an RCT consent to data collection through wearables and the mining of their HER data. This allows the researchers to follow up with patients after the completion of the trial. The second method of bridging the gap between RCT and RWD is “augmentation”. In augmentation, RWE is used as control data in a single arm trial. Lastly, is “enrichment”. Enrichment is the process where data collected from researchers and patients is combined with secondary data from HER sources.<sup>32</sup> The distinction from extension types of integration is that enrichment happens during the time frame of a RCT.

### *Specific Examples*

Aetion, a New York based Real-World Data analytics company, offers the “Aetion Evidence Platform”. This platform gives users the ability to perform rapid cycle analytics to generate real-world evidence at scale. The Aetion platform was used by Dr. Shirley V. Wang, leader of a Harvard Medical school team, to reproduce 31 published studies. Dr. Wang’s team used two commercial databases and one HER database to recreate the studies. This process is the largest real-world data reproducibility study completed.<sup>35</sup>

Aetion's platform can connect to various types of data sets. Using connections with global partners, Aetion is able to identify and use fit for purpose data sets. Their platform can be deployed on-site or through the cloud. Aetion is currently partnered with 13 of the top 20 biopharma firms as well as the FDA.<sup>35</sup>

SHFYT Analytics, based in New York, focuses on the data analytics and management side of RWD. The QUAMTUM platform offered by SHFYT allows researchers to browse clinical vocabularies and find relationships in RWD. This platform gives trials access to large amounts of RWD metadata and the ability to run rapid cycle analysis. QUANTUM can generate reports in hours based off of selected queries. Users can test and validate clinical trial design protocols by testing unlimited sets of hypotheses around trial populations, size, methodology and sites.<sup>36</sup>

A top five pharmaceutical company partnered with SHFYT prior to bringing a new biotech drug to market. Challenges surrounding the launch included low quality data with poor data integration to support client needs. SHFYT delivered software products LUMEN and STRATA which were able to clean the data and provide insights that were previously lost within the messy data.<sup>37</sup>




ValueCentric, an IQVIA company, is a data aggregation platform with specialties in pharma and medical technology. ValueCentric can streamline the administrative side of clinical trials. Their platform analyzes email attachments, third party data and manufacturer data to develop reports for administrators.<sup>38</sup> ValueCentric optimizes reports for smartphones and tablets and integrates across all platforms for sponsors and providers. Using ValueCentric's platform, researchers can easily search HER for patient populations with specific requirements.<sup>39</sup>




Real World Evidence & Analytics Software Enabled Companies





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-  \$74M raised, Series B latest round of funding
-  Boston  
<http://nference.ai/>

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-  Leverage risk-adjusted patient outcomes and metrics for understanding and comparing treatments for an increasing number of health conditions.
-  OM1 is the Principal Investigator for the U.S. Agency for Healthcare Research and Quality (AHRQ) Outcome Measures Framework (OMF).
-  Series C was the latest round of funding, \$86M funded total.
-  Boston  
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\$620M funded, Latest funding was Series G



Chicago, IL  
[www.tempus.com](http://www.tempus.com)



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The Healthcare Map as our foundation, we offer a suite of powerful software applications that enable providers to deliver exceptional value to customers, colleagues, and patients.



Komodo Health believes that smarter, more innovative uses of technology are essential for reducing the burden of disease.











\$50M in total funding, Series C.



San Francisco, CA  
<https://www.komodohealth.com/>

## Additional Companies of Interest

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Company	Description	Relevant Investors	Last Round	Sub-Category
 biospatial	Data analysis AI with focus in EMS data		\$10M (Jun-18)	Clinical Analytics
 doLoopTech <small>Analytics. Software. Solutions.</small>	NLP for medical content recommendation		N/A (Oct-17)	Clinical Analytics
 Protocol First	Advanced EDC Built for Oncology			Clinical Analytics
 Evidence Partners	Pharma-focused literature review search engine		N/A	Clinical Analytics
 PINNACLE <sup>21</sup>	Software and consulting for clinical trial data aggregation and quality mgmt.		N/A	Clinical Analytics
 VITA DATA SCIENCES	Statistical analysis and data visualization software and IT services		N/A	Clinical Analytics
 PREVAIL	Trial data integration and predictive analytics software		N/A	Clinical Analytics
 Commonwealth Informatics	Cloud-based clinical data analytics and pharmacovigilance software	Genpact (NYSE:G)	ND (Jun-18)	Clinical Analytics, Safety / Pharmacovigilance

A special thanks to [William Blair](#) for allowing FCA to incorporate their company specific market research.

## Conclusion

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As processes within clinical trials continue to progress, technology will become more central in creating efficiencies. Covid-19 has forced many elements of the clinical trial process to shift, becoming more technology dependent. This shift has changed the way regulators, providers, and patients operate within the clinical trial process. With value-based care becoming more central, efforts to find new therapies are increasing each year, which further increases the pressure on the clinical trial system. With these tailwinds moving the industry forward at a rapid pace, FCA is interested in making more investments in tech enabled start-ups solving inefficiencies in the clinical trial process.

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