Investment Thesis Report: Decentralized Clinical Trials, eSourcing, and Remuneration for Trial Patients

October 2023

Contents

Abstract

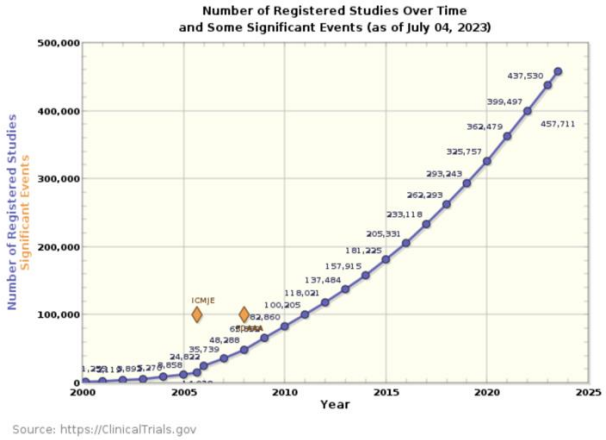
The Covid-19 pandemic has significantly reshaped the landscape of the healthcare industry, prompting widespread disruptions and adaptations. More specifically, the clinical trial industry has experienced notable transformations following the pandemic, necessitating innovative approaches to ensure the continuity of research and drug development amidst unprecedented challenges. Due to the pandemic's unforeseen nature, healthcare resources and clinical trial sites were redirected in response to the worldwide health emergency and social distancing mandates affected the operating of clinical trial research. It has been shown that patient enrollment,

protocol adherence, trial operation systems, and data collection were all negatively impacted by the pandemic.[1] Following the pandemic, clinical trial sites are exploring new technology innovations to simplify and fix the many challenges faced by clinical trials today. Advanced technology for clinical trials would lead to many benefits, including faster recruitment, higher patient retention rates due to improved patient experience, advanced data collection, and virtual patient observation.[2] Perhaps the most valuable benefit from advancing technology, however, is the implementation of decentralized clinical trials, clinical trials executed through telemedicine and technology different from the traditional clinical trial model.

This report will discuss clinical trial operations and the improvements that could be made to better the clinical trial industry. Specifically, we will provide extensive information on decentralized clinical trials, as well as briefly discuss eSourcing data in clinical trials and remuneration for trial participants. Additionally, several startup companies within these sectors of the healthcare industry will be highlighted. There is great potential to improve the inefficiencies that exist in the clinical trial industry through technological advancements and strategic investments. As previously mentioned, the pandemic deteriorated various aspects of the healthcare industry, which ultimately served as the catalyst for innovative, technological change. FCA believes that clinical trial technology and innovation is an essential area of the healthcare industry and that refining this will improve the overall quality of patient care.

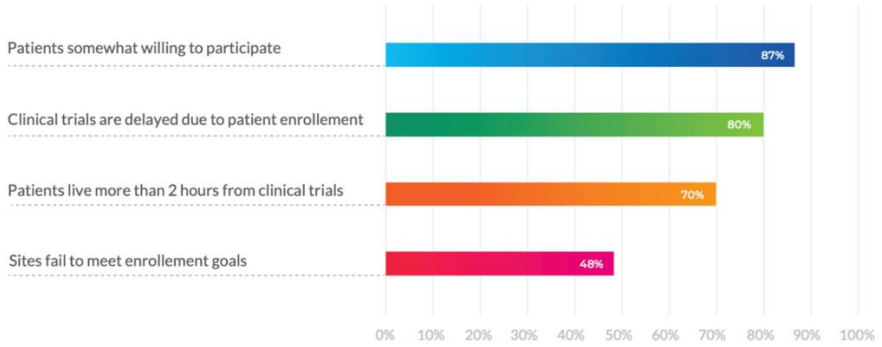
Traditional and Decentralized Clinical Trials (DCTs)

As of July 2023, there are 457,711 registered clinical trials occurring all over the world. 36% of the world's clinical trials are hosted in the United States, the most out of any country.[3] As shown by the graph below, the number of registered clinical trial studies has been on a steady upward trajectory since 2000. In 2021, the market size for global clinical trials was valued at $47 billion and is expected to grow at an annual growth rate of 5.8% from 2022 to 2030.[4]



The inefficiencies that exist in traditional clinical trials have led to a major impediment to the advancement of medical research and the timely development of new treatments and therapies. The two biggest challenges faced by traditional clinical trial companies today are the extensive amount of time and high costs associated with in-person clinical trials.[5] Nearly 80% of all traditional clinical trials are not completed on time,[6] leading to extreme losses for the companies who continue to pay overhead, such as salaries and rent, and who must delay the launch of new products because of the longer trial study period. Additionally, 70% of trial patients live over two hours away from their nearest study site,[7] making it difficult and more expensive to recruit

trial participants. The inaccessibility to clinical trials has led to the underrepresentation of racial and ethnic minorities, which is a growing concern considering various groups of people react differently to pharmaceutical and medical products. Decentralized clinical trials can aid in combating all the aforementioned downsides associated with traditional clinical trials.



Challenges in traditional clinical trials 8

The pandemic brought about many changes to the clinical trial industry and further accelerated the importance and broader adoption of decentralized clinical trials. The pandemic interrupted and suspended many ongoing clinical trials due to health concerns and social distancing mandates,[9] which was extremely harmful to patients awaiting new medicines and therapies. While this disruption in clinical trials was damaging, it did open the door to a new format regarding clinical trial operations and the overall health industry. The pandemic led to the adoption of virtual interactions in all aspects of life, even the healthcare industry. The expensive, inefficient, nondiverse, and obscure geographical[10] aspects of traditional clinical trials make the ease and convenience of decentralized clinical trials incredibly attractive to patients, sponsors, and investors alike.

Telehealth has increasingly gained traction in recent years, largely due to the rise of Zoom[11] and other competitors in this space. The use of telemedicine was only compounded by the pandemic.

A survey conducted in November 2022 showed that 90% of Americans had used telehealth in the past year,[12] and 37% of Americans consistently used telemedicine in 2021.[13] A study focused on patient satisfaction when using telemedicine showed that 42% were "extremely satisfied" with their virtual health experience.[14] Another report found that 98% of patients reported satisfaction with the use of telemedicine.[15] As stated by McKinsey and Company, "the telehealth era is just beginning, with more gains in quality, affordability, and accessibility on the way,"[16] so it would only make sense that clinical trials have followed suit in this innovative and advanced form of healthcare.

The traditional clinical trial process involves multiple phases. It typically begins with preclinical research conducted by scientists and researchers, followed by Phase I trials involving a small group of healthy volunteers, supervised by medical professionals. Phase II trials expand the participant pool to a larger group of patients, and Phase III trials further increase the sample size to evaluate the treatment's efficacy and potential side effects.[17] Throughout these phases, various parties play critical roles. Clinical trial sponsors oversee and pay for the trials, along with collect and analyze the data.[18] Pharmaceutical and biotech companies spearhead the trials, designing the protocols and providing the investigational products. Contract research organizations ("CROs") are often engaged to manage the operational aspects of the trials, including patient recruitment, data collection, and site monitoring. Investigative sites, such as hospitals and clinics, actively enroll and treat the trial participants under the guidance of principal investigators ("PIs") who are typically medical doctors or healthcare professionals. Regulatory agencies, such as the FDA in the United States,[19] oversee and review the trial data to ensure the safety and efficacy of the

intervention before granting approval for market release. It is evident that traditional trials are complex and contain a lot of moving parts and people.

Decentralized trials, also known as DCTs, are defined as studies "executed through telemedicine and mobile/local healthcare providers, using processes and technologies differing from the traditional clinical trial model."[20] In 2021, more than 1000 clinical drug trials worldwide included a virtual or decentralized element,[21] and this number is expected to rise through 2023. DCTs experienced a 15% reduction in participant dropout rates compared to traditional clinical trials.[22] There are numerous benefits for both clinical trial sponsors and participants when operating through a decentralized clinical trial.

Benefits for Trial Participants:

1. Participants in DCTs can participate from anywhere in the world and at more convenient times that fit their schedule, which increases the diversity, recruitment, and retention rates among patients.
2. Participants save money due to the elimination of travelling to obscure onsite trial locations.
3. DCTs assuage any lingering fears of human interaction following the pandemic because patients can participate in trials from the comfort of their own homes.
4. If the technology is implemented effectively, there exists an open line of communication between the trial participants, sponsors, and doctors. This open communication makes it much easier for participants to carry out their role and share their immediate thoughts and responses.

Benefits for Trial Sponsors:

1. DCTs expand the potential pool of trial participants outside those who live near traditional testing sites, while also making it easier for participants to stay in the trial due to its remote, cellular nature. These two factors improve patient recruitment and patient retention which is beneficial for the trials and sponsors.
2. DCTs remove the need for study sites and reduce the time taken to find participants, monitor the study, and collect the data, resulting in increased trial efficiency and lower costs for sponsors.
3. Data and measurements taken from DCTs can be more frequent, possibly even continuous, because follow-up appointments are not restricted by scheduled clinic visits,[23] leading to more accurate results and improvements of the object being tested.
4. DCTs allow for constant, real-time data collection through remote monitoring, which allows sponsors to recognize and quickly react to any participant complications that may arise.

The benefits listed above ultimately lead to more efficient and successful clinical trials, which are advantageous and beneficial to participants, sponsors, and the healthcare industry as a whole.

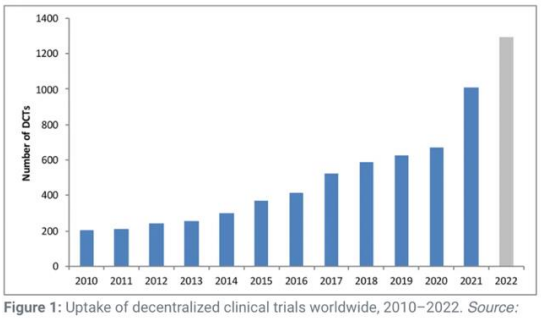
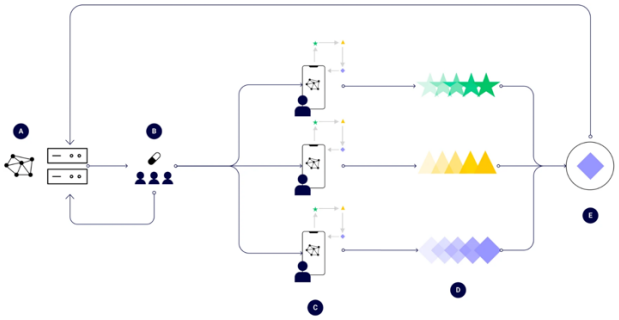


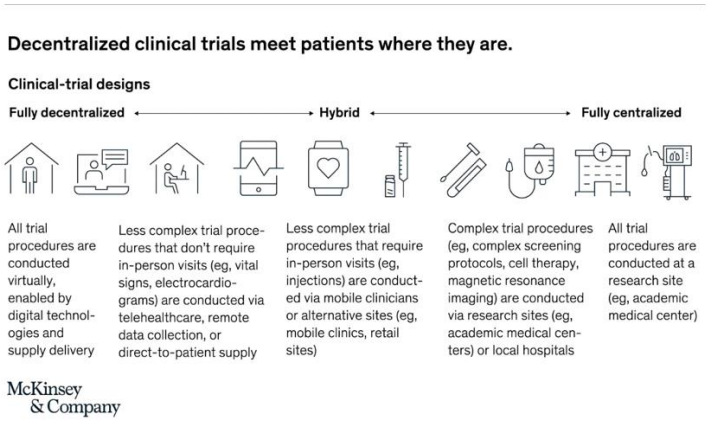
Figure 1: Uptake of decentralized clinical trials worldwide, 2010–2022. *Source: adapted from Clinical Trials Arena, 2022 (1).*

As seen in the chart above, the number of DCTs has been consistently increasing since 2010. The graph shows a large jump in the number of DCTs from 2020 to 2021/2022, which is most likely a result of the pandemic.



A A protocol is created and is digitally disseminated to consenting participants-to-be in a DCT, **B** Participants in a DCT are randomly exposed to a medical intervention, **C** Participants process their own data (e.g., digital biomarkers), **D** Findings are aggregated from each participant, and **E** The overall effect of the intervention is estimated as overall estimate, aggregated, and sent back.

Above is a process diagram for the decentralized execution of federated clinical trials.[24] Letter C in the above graphic further emphasizes how each patient in a DCT operates on their own device, which is a main advantage of decentralized trials.



25

This McKinsey and Company graphic illustrates the full spectrum of clinical trials from fully decentralized to fully centralized trials. It highlights the characteristics of the three different formats of clinical trials. While McKinsey and Company do not explicitly state that one trial format is more favorable than the other, they do emphasize how DCTs "meet patients where they are," which is undoubtedly more convenient for the patients.

Challenges and Risks

While decentralized clinical trials hold tremendous potential to transform the landscape of medical research and healthcare overall, it is crucial to recognize and address the inherent challenges and risks associated with this innovative approach.

1. Decentralized clinical trials require internet connectivity, which can hinder accessibility for patients in remote areas of the world. An estimated 37% of the world has never used the internet,[26] and 6% of the United States is without access to normal-speed internet service.[27] Patients who lack a reliable internet network or tech savviness could potentially be excluded from all DCTs, which limits diversity in the study population and potentially leads to skewed or incomplete results, compromising the validity and generalizability of the findings.
2. The increase in decentralized clinical trials could potentially eliminate research sites as a whole,[28] since DCTs virtualize the process of clinical trials. The complete removal of research sites would harm certain trial patients that may need aid and instruction from on-site medical staff. While statistics do show that majority of telemedicine patients are satisfied with their experience, there are some who do not engage in telehealth for various reasons. For the patients that still desire to be seen in-person, some form of on-site medical staff is necessary to guarantee that all patients are adhering to the trial protocols.
3. Data privacy is a major concern in decentralized trials.[29] DCTs use technology that transfers patient data from wearable technology and remote locations to sites, sponsors, and CROs, but it can be difficult to find the right technology platform for a specific

clinical trial. DCTs operate with a risk of revealing patients' private data and health information due to the transfer of data through multiple technological platforms.

4. There is a high risk of protocol violations due to patients' manual errors in DCTs. When patients record their data from a remote location, there is always a risk that they misused the device or entered the data incorrectly.[30] Even though traditional clinical trials are less convenient than DCTs, on-site visits usually guarantee that all trial rules and regulations are followed exactly as they should be.
5. Widespread remote participation in DCTs results in a substantial increase of data volume and variety,[31] recently coined as "data chaos." This expansion in data sources, while vital for the healthcare industry, can also be difficult for clinical trial teams to manage.

Potential Solutions

Addressing the challenges inherent in decentralized clinical trials necessitates the exploration and implementation of potential solutions that leverage patient-centric approaches and innovative technologies.

By implementing a hybrid clinical trial model, many of the problems with DCTs could be eliminated. Nearly all CRO's and many other players, including FCA Health Innovations II portfolio company Javara, are already implementing hybrid DCTs. In fact, a WCG study showed that 88% of clinical trial research sites have already held hybrid trials, which integrates remote technology and in-person site visits.[32] Hybrid trials provide patients with options for data tracking outside of wearable devices and virtual apps, since there is the possibility that not every

patient knows how to operate advanced technology or has access to an internet network. A hybrid model also ensures that research sites will not lose their role in the clinical trial process as a source of guidance as needed. Patient-centricity is a main priority in hybrid trials, which helps improve patient retention and diversity.[33]

Decentralized trials utilize technology at a much higher capacity than traditional clinical trials, so the software used by researchers plays a large role in the trial's success. Trial sites, sponsors, and CROs must find and distribute a secure, private technology tailored for DCTs. The use of federated computing ("FC") and a "zero trust" approach protects trial participants' data and privacy.[34] Additionally, the technology must be scalable and relatively easy to use, or the attractive accessibility aspect of DCTs will be lost.

The utilization of a cloud-based centralized data management platform enables clinical trial teams to streamline data management, reduce costs, alleviate timeline delays, and enhance cycle times. In essence, these platforms revitalize data infrastructure by consolidating data sources into a cohesive and reliable repository. Notably, the implementation of a cloud-based platform, coupled with proficient data configuration, management, and statistical analysis, has demonstrated remarkable results, with certain companies experiencing a notable 50% reduction in cycle time[35] from the last patient's last visit (LPLV) to database lock.

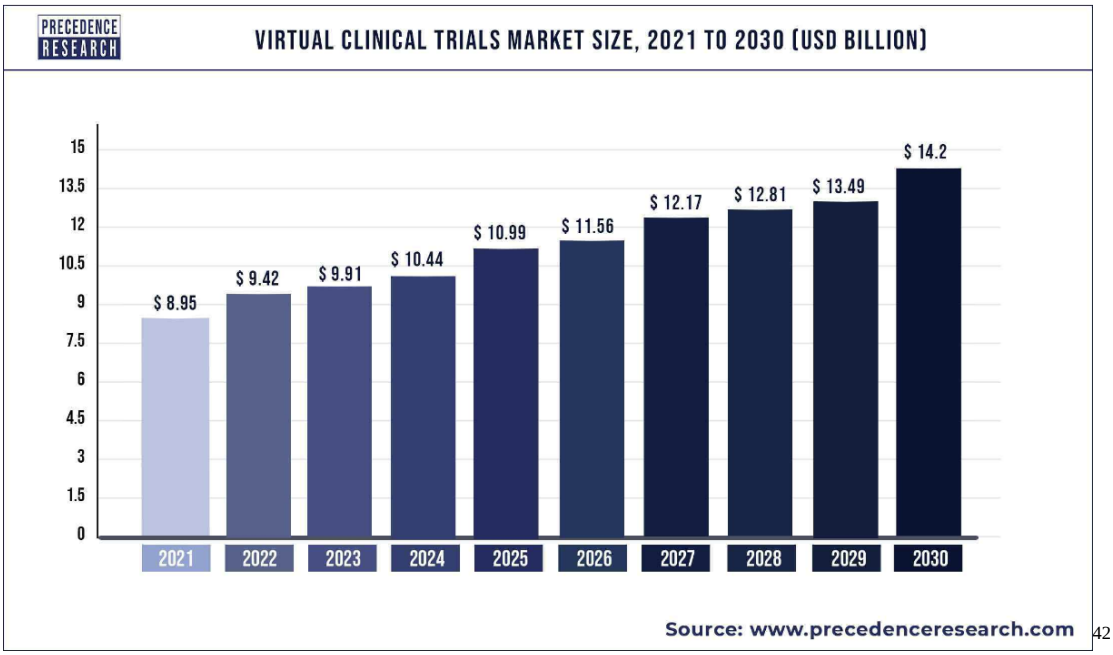
More recently, artificial intelligence technologies are revolutionizing decentralized clinical trials processes. AI enables targeted patient recruitment and retention through the analysis of diverse data sources, ultimately improving engagement and representation. Secondly, AI optimizes trial

design by analyzing historical data and simulating scenarios, resulting in more efficient and cost-effective studies.[36] Real-time data analysis using AI-driven platforms allows for monitoring, early detection of safety and misuse issues, and quicker decision-making for both the patient and sponsor.[37] Personalized interventions based on individual patient data enhance treatment adherence and evaluation accuracy. Furthermore, AI automates regulatory compliance by validating and analyzing data, monitoring participant integrity, and identifying inconsistencies in real-time.[38]

Current Trends and the Market

The global decentralized clinical trial market is experiencing significant growth and is poised for further expansion in the coming years. The market, valued at $8.95 billion USD in 2021, is projected to have a CAGR of 5.27% to reach $14.2 billion USD by the year 2030.[39] The adoption of DCTs is driven by various factors, including the increasing demand for patient-centric healthcare, advancements in digital technologies, and the need for more efficient and cost-effective clinical research. The key players in the global DCT industry include Medidata, IQVIA, Labcorp, PRA Health Sciences, and Parexel, together holding over 45% of the market. Additionally, North America is the largest production region in the decentralized clinical trial space, with over 60% market share.[40] Studies have revealed that DCTs yield a higher ROI than traditional clinical trials,[41] making this space a promising opportunity for investors. Investors can expect to generate significant profits since research suggests that the decentralized clinical trial industry has the potential to deliver attractive financial returns. With a growing number of pharmaceutical companies, contract research organizations, and technology providers investing in DCT infrastructure, the global decentralized clinical trial market is expected to witness

substantial growth and present lucrative opportunities for investors across the healthcare industry. FCA identifies decentralized clinical trial companies as a strong investment opportunity, given their potential to revolutionize the clinical trial landscape by enhancing patient access, improving data quality, reducing operational costs, and accelerating trial timelines.



[42]

The chart above depicts the forecasted size of the virtual clinical trials market. As shown, there is a steady uptake in the market size exhibiting substantial growth in the virtual clinical trial industry.

eSourcing for Data

The FDA defines source data as "all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation."[43] eSourcing in clinical trials refers to the use of electronic data sourcing methods and technologies to streamline and enhance the

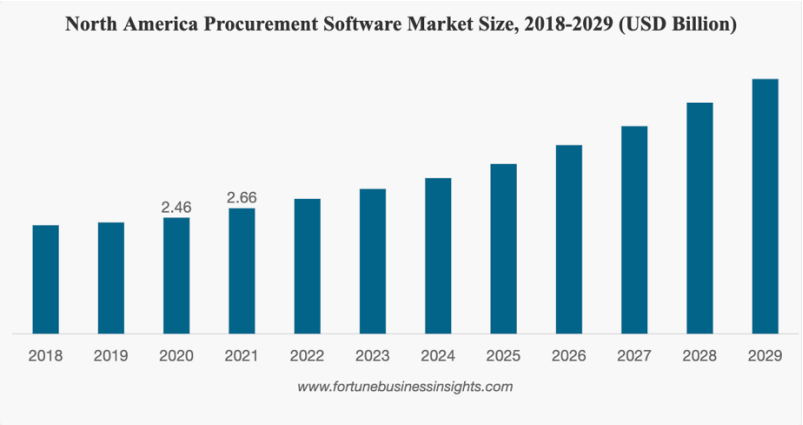
procurement and vendor selection process within the clinical trial industry.[44] Traditionally, the sourcing process in clinical trials involves manual and paper-based methods, which could be time-consuming, prone to errors, and lack transparency. However, with the advancement of technology, eSourcing has emerged as a more efficient and effective alternative, used to automate and centralize the entire data sourcing process for clinical trials.

By leveraging eSourcing in clinical trials, several benefits can be achieved:

1. Automation of the sourcing process reduces the time and effort required to identify, evaluate, and select vendors. It streamlines communication and eliminates the need for physical documentation and manual data entry. Consequently, this can lead to significant cost savings and faster trial initiation.
2. eSourcing platforms provide standardized evaluation criteria, enabling a fair and objective assessment of trial vendor capabilities. With a more comprehensive analysis of bids, the identification of the most qualified vendors for a certain trial is facilitated.
3. eSourcing provides a transparent audit trail of the entire sourcing process, ensuring compliance with regulatory requirements and industry standards. It promotes accountability, traceability, and regulatory oversight.
4. The platforms generate comprehensive reports and analytics, enabling data-driven decision-making. These insights allow stakeholders to identify trends, assess the vendor performance, and optimize future sourcing activities.

The industry in which eSourcing sits is experiencing massive growth and should continue to do so. The global procurement software market is projected to grow from $6.67 billion USD in

2022 to $13.8 billion USD by 2029, at a CAGR of 10.9% in the forecast period.[45] This rapid market growth can be accredited to many factors, such as the growing usage of cloud-based software, increased implementation of digitization to cut costs, and streamlining of the sourcing process. As seen in the table below, the procurement software market in North America specifically follows a stable, upward trajectory.



In 2013, FCA invested $4.4 million in Clinical Ink,[46] an eSource solutions company. Clinical Ink's eSource clinical technology captures and integrates clinical trial electronic data from sites, clinicians, and patients in real time.[47] During FCA's investment period, Clinical Ink grew from approximately 15 employees to 100 employees as well as quadrupled their revenues before the company was acquired by GI Partners, a leading private equity firm in 2020.[48]

It is worth noting that eSourcing is just one specific aspect of digital transformation in clinical trials aimed at improving efficiency, data quality, and patient outcomes. FCA believes that investing in a company designed to streamline the eSourcing process presents a compelling opportunity due to the growing market demand of DCTs, potential for disruptive innovation, and the scalability of the sourcing technology, which has demonstrated significant efficiency gains and cost savings in the clinical trials industry.

Remuneration for Trial Participants

Remuneration is defined as "compensation, in the form of check, gift card, etc., for participating in a research study."[49] Payments to clinical trial participants are not considered a benefit for participants, but rather a recruitment incentive.[50] Remuneration brings up the question of whether clinical trial companies should additionally pay for their participants' expenses. It is up to the clinical trial sponsors to decide whether they reimburse participants for their money spent on gas while traveling to the trial sites or the food eaten during the extensive trial hours. Participant compensation potentially raises questions surrounding how much and for what reason participants should be paid, which should be addressed by the Institutional Review Board. Additionally, there exists a longstanding debate over the ethical implications of remuneration in trials, as some people believe it can be coercive to participants, while others believe it is a proper way to show gratitude for trial participants' time and effort. Nonetheless, clinical trial compensation has existed for many years and does not seem to be going away anytime soon.

A company stating that it will reward trial participants in the form of compensation is one step, but delivering the payment to participants is another hurdle. Fulfilling payments to trial participants requires extensive administrative support from on-site staff.[51] Lack of comprehensive understanding regarding the time requirements for payment administration tasks may result in delayed payments, potentially straining the participant-site relationship. To avoid such issues, assigning these responsibilities to a research coordinator requires careful consideration and adequate support. Even better, a software that establishes a streamlined payment process for all trial participants, on-site or remote, would greatly improve the remuneration process and participant experience.

The prominent player in the realm of clinical trial remuneration is known as Greenphire. A pioneering and leading force in the industry, Greenphire specializes in enhancing the compensation process for participants in clinical trials. Greenphire offers multiple services around clinical trial budget generation, site payments, concierge travel services, as well as participant reimbursement. Their predominant approach involves utilizing versatile payment methods such as Visa gift cards and similar options to ensure timely and convenient compensation for clinical trial participants. Greenphire's success is underscored by its substantial influence and size. Greenphire has worked with sites, sponsors, and CROs from 75 countries and provided over 20 million participant payments since 2008.[52] Boasting a robust workforce, the company's reputation gained further validation when it was acquired by the private equity firm Thoma Bravo for an impressive $1.1 billion USD,[53] a testament to their standing and achievements within the clinical trial participant reimbursement landscape.

While Greenphire currently occupies most of the direct to sponsor market, there are a few aspects of their business model that smaller competitors believe could be innovated. One noteworthy startup that has made significant strides in the realm of clinical trial participant payment is nmible. Instead of offering a wide range of services, nmible is laser focused on streamlining and enhancing the compensation process for individuals participating in clinical trials by removing the reimbursement process for sites while still supporting the patient. Greenphire offers a site facing portal to enable hospital staff to make payments to pre-paid plastic cards (or ACH). This has prompted nmible to create an advanced and secure app, which Greenphire currently does not have, to engage patients directly and prioritize efficient and protected payment methods, ultimately enabling participants to submit expenses from anywhere,

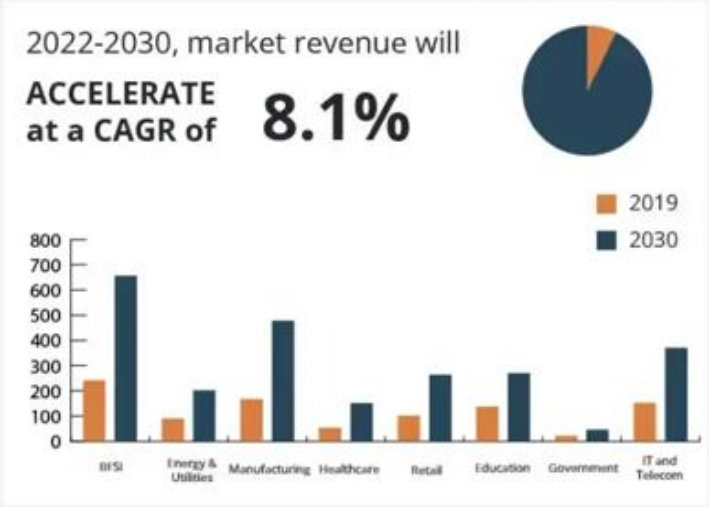
as soon as costs are incurred, as well as receiving a range of pay-out options to suit the individual needs of patients. Greenphire also collects and stores significant Personally Identifiable Information ("PII") data, which could cause some challenges in certain markets, namely the EU. Nmible instead utilizes tokenized solutions to limit storing of PII data. There is also room for competitors to offer white label integration to 3rd party systems.

Another startup competitor to Greenphire is Mural Health, which was actually started by the founder of Greenphire. Mural Health has carved its niche by providing payment solutions tailored to the individual needs of participants. Mural is a similar iteration of Greenphire but has improved its technology, payment methods in removing plastic cards, and patient facing interface through the use of a mobile app to allow for communication between patients and hospital staff, which Greenphire did not offer. Mural Health's management platform allows hospital staff to process and track payments on a dashboard and see underlying analytics, including participant feedback that is collected via the mobile app. Mural Health's patient focused approach and improved flexibility makes them a strong competitor to Greenphire. One potential hurdle the company could face is the increased management of another system and login for hospitals. There is already tremendous system saturation in clinical trials, so this could be unappealing for hospitals, especially given the rise of decentralized clinical trials.

With a focus on patient-centric design and a commitment to simplifying the compensation process, nmible and Mural Health have gained recognition for their role in elevating the participant experience. These startups reflect the industry's evolution in reshaping the way

compensation is managed and reinforcing the importance of a patient-first perspective in clinical trial research.

The global compensation software market size was $1.2 billion USD in 2021 and is expected to reach a CAGR of 8.1% during 2022-2030.[54] Currently, compensation software is not commonly utilized in the healthcare industry, providing a unique opportunity for companies and investors to tap into this uncharted market with a focus on streamlining payment processes, mitigating delays, and fostering positive relationships between participants and studies.



[55]

The graphic above shows the forecasted market growth of the global compensation software market. As noted, the healthcare industry is the second to last in revenue for the global compensation software market, allowing room for a strategic investment from FCA in a healthcare compensation company.

Startup Companies within Decentralized Clinical Trials, eSource, and Remuneration

VivoSense develops and validates real-world digital clinical measures and provides end-to-end services and solutions for their delivery in regulated clinical trials

Delivering novel digital biomarkers from wearable sensor data, which constitute primary and secondary clinical endpoints in regulated international pharmaceutical trials

VivoSense enables the world's best researchers to obtain the highest quality, real-world data and analyze it appropriately and accurately

Raised $25 million in a Series A round; estimated $4.5 million in revenues per year

Newport Coast, California

Jeeva optimizes decentralized clinical research to make clinical research innovation accessible to patients regardless of their location

The Jeeva eClinical Cloud is a human-centric SaaS platform enabling clinical research at scale

Jeeva identified a major barrier to entry for clinical trials in the travel requirements expected of participants, leading to untimely patient recruitment, retention, and trial lifecycles

Jeeva has a raised a total of $2.1 million in funding; estimated annual revenue is $2.2 million

Manassas, Virginia

ObvioHealth is a virtual research organization (VRO) that conducts decentralized clinical trials that deliver stronger therapeutic evidence

ObvioHealth utilizes technology to develop more precise and accessible measurement tools to capture the most accurate and detailed data, allowing health innovations to reach the market sooner

ObvioHealth provides robust data capture without the burden on trial participants and sponsors. The company developed and launched one of the first DCT apps, enabling people to partake in trials from anywhere

ObvioHealth currently has 8 investors and recently cancelled a Series C round; estimated yearly revenues of $12 million

New York, NY

Deep 6 AI is a research software company that connects all clinical research stakeholders using artificial intelligence (AI)

Deep 6 AI utilizes artificial intelligence on medical records to find a greater number of qualified trial participants, accelerating clinical trial recruitment and the time it takes to get cures to market

Deep 6 AI aims to solve the problems surrounding clinical trial patient recruitment and retention. Additionally, Deep 6 AI supports the faster integration of treatments to market

Deep 6 AI reports estimated revenues of $8.5 million; total funding is $44.85 million

Pasadena, CA

Aural Analytics

Aural Analytics is a speech neuroscience company that works with healthcare leaders in the clinical research setting

Aural Analytics offers a user-friendly platform called Speech Vitals, which utilizes structured speech prompts to directly collect validated objective information related to diseases from patients in both remote and on-site clinical trial environments

?

Discovers valuable brain health data in speech signals through their speech analytics technology, which leads to better patient care and identifying health problems before symptoms appear

$

Raised $6.3 million; estimated annual revenues of $4.6 million

Scottsdale, Arizona

Savvy COOPERATIVE™

Savvy Cooperative is a patient-owned healthcare platform specifically designed to empower individuals to utilize their experiences in order to bring about positive transformations in the healthcare and clinical trial space

Their platform compensates patients for sharing their health experiences with companies who are looking to gain customer insights on their healthcare products

?

Companies often create products that do not impact their patients' lives because they do not actually ask their patient customers what they want, so Savvy Coop fixes this by matching patients with companies to provide their feedback

$

Raised a Series A round in 2020

Boulder, Colorado

MyClin is a platform for knowledge and collaboration between clinical trials, focused on data-driven oversight of trials

Enables secure sharing of documents among sites, sponsors, and CROs, while also automatically tracking study communications; centralizes and expedites study training and provides compliance scoring insights

Provides secure access to essential and personalized information/documents relevant to the clinical study, along with communication channel

Bootstrapped; estimated annual revenue of $580k

Philadelphia, PA

Delve Health is a decentralized clinical trial platform

Act as a DCT partner to CROs hosting clinical trials

Allows participants to use and wear their own devices, enabling participants and clinicians greater ability to conduct remote studies and increase participant engagement

Raised a $500k seed round in 2022; annual revenues estimated to be <$5 million

Minneapolis, MN

ClinEco is a web-based platform that connects all stakeholders, including sponsors, CROs, providers, and sites, of decentralized, hybrid, and traditional clinical trials. It is a Cambridge Healthtech Institute Company

Offers a robust clinical trial marketplace where all stakeholders explore, engage, and exchange insights with their own peers

Reduces the timeline of partnership selection in clinical trials; allows clinical trial companies to collaborate and share innovative health data

Estimated to have annual revenues between $1 to $5 million

Needham, MA

CRIO is a health tech company aimed at streamlining regulatory workflows in the clinical trial space that provides a single point of data capture

Enables remote monitoring and instant data review through their integrated eSource platform

The single point of data capture removes the additional step of re-entering data into the EDC, speeding up the entire trial process

Raised $17.2 million; annual revenue is estimated to be <$5 million

Boston, MA

ClinOne unifies, educates, and empowers patients, caregivers, and clinical trial sites through a single, integrated platform

	Provides a true single platform that can be conformed to any trial protocol while making the clinical trial process easier for all parties involved
?	Their goal is to improve clinical trial participation for patients, caregivers, and trial sites
$	Closed $3 million Series A round in April 2023; estimated yearly revenue of $2.6 million
	Denver, CO and Needham, MA

RxE2 is a pharmaceutical services organization that leverages their extensive network of pharmacies and pharmacists to improve how clinical trials are managed and conducted

	Work with extensive network of pharmacists and their patients to provide a steady stream of diverse clinical trial participants
?	Aims to decrease the number of clinical trials that fail due to lack of recruiting enough patients (50%)
$	Raised $3.5 million in 2021; received a PE investment from Badlands Capital in 2022; estimated revenue is <$5 million
	Fargo, North Dakota

trials.ai

Trials.ai utilizes artificial intelligence to assist clinical development teams in crafting enhanced studies, bettering the patient experience, and expediting the delivery of pharmaceuticals to market

Uses AI to enhance clinical trial protocols for efficiency, accuracy, and success

Efficiently designs better clinical trials using AI, since trial patients have limited time to wait for trials to be crafted

Latest deal type was M&A in February 2023; held 6 rounds of funding prior to M&A deal

San Diego, CA

PROOFPILOT

ProofPilot is a digital platform designed to automate and optimize the management of research protocols in clinical trials

A digital protocol automation platform and a clinical trial solution that offers software as a service (SaaS)

Aims to eliminate uncertainties, deviations from protocols, and guesswork, which fosters high-performance experiences for sites and trial patients

Raised a total of $15.7 million; last Series B round in 2022

New York, NY

patientwing

PatientWing is a patient engagement platform that recruits and connects patients with rare diseases or cancers to clinical trials

Includes a mobile app for patients and a cloud-based platform that provides a comprehensive system for collecting clinical trial data and engaging with patients

Improves access and clinical trial patient recruitment, which leads to more lifesaving treatments reaching the market

The company has 4 investors, with the latest financing round totaling $570k

Philadelphia, PA

PATTERN HEALTH

Pattern Health is a digital software company that helps researchers collect data and engage participants

Platform and solutions simplify the technical and compliance components of research and digital-first care delivery

Goal is to accelerate digital health innovation to improve patient care sooner

Raised $4.8 million; revenue is $3.2 million

Durham, NC

nmible is a clinical trial payment software solutions company

nmible provides clinical trial reimbursement solutions to the healthcare and life sciences industry

Offer a secure reimbursement software, meaning a faster and safer process than traditional prepaid cards

no information on funding or revenues

Harrow, United Kingdom

Mural Health offers a participant management platform that provides insightful trial analytics, communication between sites and patients, and payments for patients and caregivers

Their platform, Mural Link, helps manage the trial experience for patients and caregivers

Aim to make it simple and easy to be a participant in clinical trials; modernizes the way sites complete payments and patients receive them

Partners with Clinical Ink and Proof Pilot to streamline patient payment solutions; no information on funding or revenues

San Diego, CA

Company Profiles

These successful companies have experienced rapid expansion since the onset of the pandemic, playing a pivotal role in mitigating the challenges associated with traditional clinical settings through the implementation of innovative health technologies and software solutions. Each of these companies represents an enticing investment opportunity for FCA, providing access to the clinical trial, eSource, and participant remuneration sectors.

It is worth noting that even if the companies mentioned in this report do not align with FCA's current investment strategy, the continuous growth and increasing adoption of decentralized clinical trials ensure a steady stream of future innovations for potential investment opportunities.

In June of 2022, **VivoSense** joined The Decentralized Trials and Research Alliance (DTRA), a coalition of healthcare companies, regulators, and patients, dedicated to advancing new technologies in decentralized clinical research. VivoSense CEO, Dudley Tabakin, stated "We believe digital clinical endpoints derived from connected devices and wearable sensors can improve patient research and care and ultimately enhance the efficiency and efficacy of decentralized trials."[56]

The **Jeeva Informatics** website highlights how decentralized clinical trials improve the efficiency of practices in the healthcare industry.[57] Jeeva's CEO, Harash Rajasimha, shared "Decentralized clinical trials eliminate the heavy burden of patient travel and makes the process simpler and more efficient."[58]

ObvioHealth's website shares how decentralized clinical trials deliver stronger evidence than traditional clinical trials.[59]

Savvy Cooperative published a blog post about the importance and necessity of diversity in clinical research,[60] which DCTs promote due to their accessibility for many different groups of people.

Delve Health discusses the many benefits of wearable devices and biosensors, a large component of DCTs, that extend beyond enhanced data collection. A Delve Health article states that these devices promote "participant engagement; patient safety and convenience; and study staff efficacy. As technologies continue to advance and challenges are addressed, we can anticipate a continued boom in the use of wearables and biosensors, leading to more efficient, patient-centric and impactful clinical trials."[61] Furthermore, another article published by Delve Health shares how "Virtual clinical trials and digital healthcare are the future of real-world solutions for many of the woes facing the clinical research enterprise. Technology platforms help to close the gap in equity and bring quality healthcare and equal opportunities to participate in clinical trials—saving patient lives."[62]

CRIO's website provides a synopsis of the FDA's Decentralized Clinical Trials Draft Guidance. Their article states that "DCTS may enhance convenience for trial participants, reduce the burden on caregivers, and facilitate research on rare diseases and diseases affecting populations with limited mobility or access to traditional trial sites. This may help improve trial participant engagement, recruitment, enrollment, and retention of a meaningfully diverse clinical population."[63]

In March of 2023, **Mural Health** and **Proof Pilot** announced a strategic partnership to further progress and develop clinical trial innovations.[64] Additionally, **Mural Health** announced a partnership with Clinical Ink,[65] a former FCA portfolio company previously mentioned. Mural

Health's strategic partnerships prove its success in the clinical trial space by demonstrating its ability to collaborate with industry leaders and leverage their expertise to further enhance participant compensation solutions.

Next Steps

Decentralized clinical trials offer an exciting and promising investment opportunity that has the potential to reshape the healthcare industry. By shifting away from traditional, site-based trials, DCTs address key challenges and limitations, paving the way for more efficient, patient-centric research practices.

One of the significant advantages of DCTs is the expanded access to a diverse and global pool of participants. By leveraging digital technologies, remote monitoring, and virtual interactions, these trials can reach individuals who may have been previously underserved or faced geographical barriers. This expanded reach not only improves participant recruitment but also enhances the generalizability and diversity of trial data, resulting in more robust and representative results.

Moreover, DCTs enable real-time data collection and analysis, providing researchers with a wealth of high-quality, timely information. This not only accelerates the pace of research but also allows for adaptive trial designs and faster decision-making. The ability to collect data remotely also reduces the burden on participants, leading to improved compliance and retention rates.

DCTs offer significant advantages for trial participants as well. By reducing the need for frequent site visits, DCTs minimize the disruption to participants' daily lives and improve overall patient experience. This patient-centric approach fosters higher engagement, leading to more accurate and meaningful data. Additionally, remote monitoring and data collection minimize travel costs for participants and researchers, making trials more accessible and cost-effective.

While the field of decentralized clinical trials is still evolving, investing in companies that are at the forefront of this transformative shift can yield significant returns. Furthermore, the investment in decentralized clinical trials aligns with the broader mission of FCA: driving innovation and improving healthcare outcomes. By embracing this disruptive approach, we contribute to advancing the field of clinical research, fostering patient-centricity, and accelerating the development of life-changing therapies.

The investment potential in decentralized clinical trials is immense. By recognizing the transformative power of decentralized clinical trials, investors are granted the opportunity to generate substantial financial returns while making a positive impact on healthcare delivery and patient well-being. Through strategic investments and a commitment to ongoing adaptation, investors can navigate the evolving landscape of decentralized clinical trials and position itself as a leader in this exciting and promising field of healthcare.

FCA Venture Partners is a venture capital firm investing in early-stage healthcare technology and technology-enabled healthcare services companies that improve patient care, reduce costs, and increase efficiency. FCA manages $200 million and invests across the Series Seed to Series B stages. Our firm brings portfolio companies valuable healthcare insights, connections, and board-level experience to accelerate growth and build disruptive and sustainable businesses. Based in Nashville, the epicenter of healthcare innovation, with a strategic network in Charlotte and Winston-Salem, NC, our team has a decades-long track record including more than 60 investments in the rapidly changing healthcare industry.

Works Cited

[1] https://ascpt.onlinelibrary.wiley.com/doi/full/10.1002/cpt.2534#:~:text=The%20analyses%20indicate%20that%20the,2020%20as%20compared%20with%202019.
[2] https://www.news-medical.net/life-sciences/How-is-Technology-Advancing-Clinical-Trials.aspx#:~:text=These%20include%20faster%20recruitment%20and,centric%20approach%20can%20be%20introduced.
[3] https://clinicaltrials.gov/ct2/resources/trends
[4] https://www.grandviewresearch.com/industry-analysis/global-clinical-trials-market
[5] https://climedo.de/en/blog/decentralized-or-traditional-clinical-trials-in-comparison/#:~:text=Traditional%20clinical%20trials%20often%20lack,has%20to%20be%20significantly%20higher
[6] https://climedo.de/en/blog/decentralized-or-traditional-clinical-trials-in-comparison/#:~:text=Traditional%20clinical%20trials%20often%20lack,has%20to%20be%20significantly%20higher.
[7] https://climedo.de/en/blog/decentralized-or-traditional-clinical-trials-in-comparison/#:~:text=Traditional%20clinical%20trials%20often%20lack,has%20to%20be%20significantly%20higher.
[8] https://www.certara.com/blog/collaborative-digital-technology-enables-patient-centric-healthcare/
[9] https://www.jacc.org/doi/full/10.1016/j.jacbts.2021.01.011?cookieSet=1
[10] https://link.springer.com/content/pdf/10.1007/s43441-019-00006-4.pdf?pdf=button%20sticky
[11] https://www.definitivehc.com/resources/healthcare-insights/top-telehealth-companies-market-share
[12] https://www.prnewswire.com/news-releases/survey-reveals-90-of-americans-used-telehealth-in-the-past-year-301718124.html#:~:text=Results%20from%20the%20November%202022,%2C%20teledentistry%2C%20and%20vision%20appointments.&text=Additionally%2C%2071%25%20of%20users%20accessed%20telehealth%20using%20their%20smartphones.
[13] https://www.forbes.com/sites/forbestechcouncil/2022/12/27/telemedicine-and-telehealth-in-2023-and-beyond-from-leveling-out-to-leveling-up/?sh=303f17a15484
[14] https://www.singlecare.com/blog/news/telehealth-statistics/
[15] https://www.mckinsey.com/industries/life-sciences/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials
[16] https://hbr.org/2022/05/the-telehealth-era-is-just-beginning
[17] https://www.fda.gov/patients/drug-development-process/step-3-clinical-research
[18] https://www.cancer.gov/publications/dictionaries/cancer-terms/def/clinical-trial-sponsor
[19] https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies#:~:text=Clinical%20trials%20are%20research%20studies,safe%20and%20effective%20in%20people.
[20] https://files.pitchbook.com/website/files/pdf/Pandemic_has_cetralized_SelectPresentation_20221117.pdf
[21] https://www.pharmtech.com/view/will-decentralized-clinical-trials-become-mainstream-
[22] https://files.pitchbook.com/website/files/pdf/Pandemic_has_cetralized_SelectPresentation_20221117.pdf
[23] https://link.springer.com/content/pdf/10.1007/s43441-019-00006-4.pdf?pdf=button%20sticky
[24] https://www.nature.com/articles/s41746-021-00473-w
[25] https://www.mckinsey.com/industries/life-sciences/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials
[26] https://www.itu.int/hub/2021/11/facts-and-figures-2021-2-9-billion-people-still-offline/
[27] https://www.fcc.gov/reports-research/reports/broadband-progress-reports/eighth-broadband-progress-report#:~:text=Notwithstanding%20this%20progress%2C%20the%20Report,lack%20access%20to%20this%20service.
[28] https://florencehc.com/learn/blog-posts/9-challenges-and-risks-for-launching-decentralized-trials
[29] https://link.springer.com/content/pdf/10.1007/s43441-019-00006-4.pdf?pdf=button%20sticky
[30] https://florencehc.com/learn/blog-posts/9-challenges-and-risks-for-launching-decentralized-trials
[31] https://themedicinemaker.com/discovery-development/pharma-clinical-trials-decentralization-and-digital-trends
[32] https://www.wcgclinical.com/covid-19/covid-19-trial-insights/
[33] https://www.pharmasalmanac.com/articles/evolving-solutions-to-optimize-clinical-trial-decentralization
[34] https://link.springer.com/article/10.1007/S43441-019-00006-4

[35] https://themedicinemaker.com/discovery-development/pharma-clinical-trials-decentralization-and-digital-trends
[36] https://www.starmind.ai/resources/how-using-ai-in-clinical-trials-accelerates-drug-development#:~:text=By%20finding%20patterns%20in%20data,populations%2C%20treatment%20regimens%20and%20dosages
[37] https://www.iconplc.com/insights/digital-disruption/ai-and-clinical-trials/
[38] https://www.iconplc.com/insights/digital-disruption/ai-and-clinical-trials/
[39] https://www.precedenceresearch.com/virtual-clinical-trials-market
[40] https://www.marketwatch.com/press-release/forecast-decentralized-clinical-trials-dcts-market-2023-2030-upcoming-report-2023-04-13
[41] https://www.appliedclinicaltrialsonline.com/view/new-data-reveals-dcts-yield-better-clinical-trial-roi
[42] https://www.precedenceresearch.com/virtual-clinical-trials-market
[43] https://florencehc.com/learn/blog-posts/what-is-esource?utm_source=google&utm_medium=search&utm_campaign=esource-blog&gclid=Cj0KCQiA7bucBhCeARIsAIOwr-_XyKIx8C-AJFBaBVRQvDDRWOUHHoLGVqFVH7eFyc9OItQLU4eIdQMaAoEMEALw_wcB
[44] https://blog.onestudyteam.com/esource-in-clinical-trials#:~:text=What%20is%20eSource%20in%20clinical,to%20labs%2C%20to%20medication%20logs.
[45] https://www.fortunebusinessinsights.com/procurement-software-market-107099
[46] https://www.fcavp.com/insights/2020/8/13/fca-venture-partners-portfolio-company-clinical-ink-acquired-by-gi-partners
[47] https://www.clinicalink.com/
[48] https://www.fcavp.com/insights/2020/8/13/fca-venture-partners-portfolio-company-clinical-ink-acquired-by-gi-partners
[49] https://www.umc.edu/Research/Research-Offices/Clinical-Trials/Researchers/Road-Map/Study-Conduct/Participant-Management/Remuneration-Reimbursement.html#:~:text=Remuneration%20is%20compensation%2C%20in%20the,participation%20in%20a%20research%20study.
[50] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects
[51] https://trialfacts.com/articles/trial-compensation/
[52] https://greenphire.com/
[53] https://www.pehub.com/thoma-bravo-values-greenphire-at-1-1bn-as-tech-transforms-clinical-research/
[54] https://www.reportsanddata.com/report-detail/compensation-software-market
[55] https://www.reportsanddata.com/report-detail/compensation-software-market
[56] https://www.vivosense.com/blog/vivosense-joins-dtra-to-accelerate-adoption-of-decentralized-trials
[57] https://jeevatrials.com/eclinical-platform/
[58] https://jeevatrials.com/blog/this-startup-is-on-a-mission-to-decentralize-cell-and-gene-therapy-clinical-trials/
[59] https://www.obviohealth.com/solutions/decentralized-clinical-trials
[60] https://www.savvy.coop/blog/the-imperative-of-diversity-in-research
[61] https://delvehealth.com/the-use-of-wearables-and-biosensors-in-clinical-trials-is-booming/
[62] https://delvehealth.com/how-social-determinants-of-health-affect-clinical-trials-and-what-eclinical-solutions-can-do-to-help-level-the-playing-field/
[63] https://clinicalresearch.io/blog/running-a-study/the-fdas-decentralized-clinical-trials-draft-guidance-explained/
[64] https://www.muralhealth.com/blog/mural-health-and-proofpilot-partner-to-streamline-payments
[65] https://www.globenewswire.com/news-release/2023/04/12/2645282/0/en/Clinical-ink-Announces-Strategic-Partnership-with-Mural-Health-for-New-Patient-Payment-and-Logistics-Capabilities.html