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OPINION/PERSPECTIVE/COMMENTARY

Leveraging Decentralized Clinical Trial Management Systems (dCTMS) to Advance Science: Exploring Challenges Related to the Diffusion of Innovation and Its Execution

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DOI: https://doi.org/10.30953/bhty.v7.305

Keywords: blockchain, CTMS, decentralized clinical trials, drug development, healthcare, pharmaceutical industry, solutions, decentralized clinical trials management systems, dCTMS

Abstract

Decentralized clinical trials (DCTs) recently gained attention in research necessary for drug development. While the COVID-19 pandemic proved to be a challenging time in this arena, drug development was a critical area of emphasis in the rapid advancement of vaccines. The DCTs were necessary to allow research activities to occur across many locations. The use of DCTs can profoundly impact reshaping healthcare by enabling participants to partake in clinical trials remotely; however, implementation challenges must be considered as technology expands. A working group of participants was assembled during an interactive learning exercise at the Conv2X conference (2023) to explore challenges related to the diffusion of innovation among key stakeholders. Pain points experienced with using and implementing technologies were identified, and an innovative solution using a blockchain-anchored option was presented. Participants were divided into three stakeholder groups: patients, payers, and pharmaceutical sponsors. After a time of discussion, the groups reconvened for review. Several themes that can be supported by blockchain technology emerged. These include enhanced efficiencies, patient experience, and demographic diversity, as well as data integrity, privacy, security, and cost-effectiveness. Future research might focus on strategies to facilitate the adoption of the idea across key stakeholder groups.

Received: March 10, 2024; Accepted: April 4, 2024; Published: April 30, 2024

Clinical trials and their associated regulatory processes are critical to drug development. The COVID-19 pandemic proved to be a challenging time, yet it spawned a host of innovations. Drug development was a critical area of emphasis for developing COVID-19 vaccines, and decentralized clinical trials (DCTs) were necessary to allow research activities to continue.[1–3] In a DCT, some or all trial activities occur at locations other than a traditional clinical site, including the patient's home or a local healthcare facility or laboratory.[1] In recent years, significant strides in technology have occurred, which make it widely available (e.g., smartphones, artificial intelligence (AI), wearables, etc.). Regardless of the stunning advancements and the critical nature of data sharing necessary for the timely approval of new drugs, the use of select emerging technologies in clinical trials lags.

The essence of "decentralization" represents a shift in the locus of power or authority. In a fully decentralized model, study activities are executed without in-person contact. This description suggests that DCTs would have a structural reordering, yet that has not been the case. The DCTs in the current state are a misnomer in that they represent a change in the locus of trial conduct/locations—from sites to alternative locations (e.g., patient homes). Currently, DCTs exist along a continuum, with some believing that many trials (e.g., oncology-related) may never be fully decentralized due to complexity and sponsor-mandated in-person interactions for safety and regulatory purposes.[1,4]

Aware of DCTs' promise and challenges, the U.S. Food and Drug Administration (FDA) is issuing resources and guidelines to address their novel development in healthcare.[1] Simultaneously, technical hurdles that slow their adoption should also be explored.

This exploratory exercise aimed to assess, analyze, and synthesize stakeholder opinions related to the current challenges slowing the diffusion of innovation for DCTs and capture considerations among three key groups (i.e., patients, payers, and pharmaceutical sponsors). The diffusion of innovation refers to a five-step process (i.e., knowledge, persuasion, decision, implementation, and confirmation) by which an individual decides to adopt an idea at a certain speed.[5]

Methods

Conference Session / Workgroup

ConV2X is a global conference advancing the business of health with blockchain technology. The 2023 conference highlighted pivotal drivers accelerating the adoption of blockchain solutions.[6] During a 60-minute interactive learning exercise, a convenience sample of conference attendees, primarily industry practitioners and experts, participated in a workgroup to explore considerations related to DCT uptake and delayed diffusion of innovation across key stakeholders. This activity was completed as part of a conference session and was intended for something other than research. Attendees voluntarily and anonymously participated, and no identifying information was linked to responses. Furthermore, opinions were presented as group consensus and did not include individual participant comments.

Prior to the assessment, broad "pain points" in existing technology utilization were presented. These included:

1. the lack of availability of real-time data driven by substantially batch-driven processes;
2. the presence of multiple systems for various parts of the processes exacerbating inefficiencies;
3. the need for manual, risk-based monitoring and source data verification as a governance process;
4. the presence of data integrity issues; and finally,
5. the disconnect between operational activity and delayed payments to study participants.

Additionally, a representative from Bloqcube® demonstrated an innovative approach that uses a blockchain-anchored solution, executed on an iPad and Cloud, to fully integrate and decentralize trial management activities remotely in real-time.

After introductions, the participants were subdivided into three stakeholder groups (Table 1).

At the center of all activity, patients were the payers. They have a balanced role in ensuring adequate returns for shareholders and reaching intended users. The purpose of the small group discussions was to identify (1) problem definitions, (2) potential solutions, and (3) value across each stakeholder group. After the discussion, the participants reconvened for presentations by each group and an overall discussion.

Results

Patients

The participants noted current challenges patients encounter when participating in classic clinical trials, including travel times to participating sites, a lack of communication, delays in payments, and discomfort with consent disclosures. Furthermore, ethical dilemmas (e.g., access, placebos) were identified, especially in life-saving drug trials. Finally, the discomfort caused by the lack of transparency and access to the study results can be problematic.

Consensus solutions that were identified included true decentralization and distributed ledger technologies (e.g., blockchain and gamification) to improve acceptance. Patient-centric, remote systems can facilitate electronic data collection remotely from the patient's location. Additionally, using digital companion coaches or advocates may alleviate concerns, and creating shared incentive models could also enhance participation while working within an ethical framework. Regarding value, the group agreed that this is a complex challenge. They concurred that the speed of the trials and dissemination of approved drugs could serve as a value indicator, assuming other quality parameters are met.

Payers

The participants noted that payers were likely concerned about cost containment and the efficacy of new drugs

Table 1. Three stakeholder groups are involved in the challenges that slow the diffusion of innovation for DCTs and capture considerations

Stakeholders	Activities
Patients	Study subjects for clinical trials who later become consumers of the product.
Payers	Government entities or health insurance providers assess the costs and benefits of new drugs. Play a key role in Western economies.
Pharmaceutical Sponsors	Creators and drivers of innovation.

DCTs: decentralized clinical trials.

Citation: Blockchain in Healthcare Today 2024, 7: 305 - https://doi.org/10.30953/bhty.v7.305

compared to current treatments or the "gold standards." Additionally, because payers do not fund clinical trials, there is a level of uncertainty as they do not control key elements and risk a study population that is disparate from the populations they serve.

There was consensus among participants that one solution is value-based contracting, where costs are tied to results. Other solutions may include phase four studies to assess long-term risks/benefits and smart contracts to automate inefficient processes. Efforts to cut costs could be achieved by placing greater emphasis on remote monitoring rather than current approaches. Value can be improved by allocating more funds to more effective drugs and using more efficient processes.

Pharmaceutical Sponsors

First, participants emphasized that a primary goal for pharmaceutical sponsors includes driving innovation for fast drug development (e.g., COVID-19 vaccines). Related issues include the cost of drug development, the regulatory processes for approval, and data security. The group also emphasized the pivotal role and the need to protect intellectual property in drug development, which is crucial to original inventions.

Participants highlighted the need for solutions such as DCTs for patient recruitment, ethically leveraging monetary incentives, and ensuring data integrity. Another idea expressed was to share negative results to facilitate learning science. Participants agreed that a smooth process is critical. Cloud-based systems combined with blockchain and cryptographic security can provide a seamless flow of compliant data while minimizing the vulnerability to ransomware attacks.

Value

An alternative definition of "Value" often used in healthcare is quality divided by cost. The participants agreed that cost often becomes a primary focus, as it is easily measured. However, it has a natural limit on the extent of value. If the primary focus shifts to quality instead of cost, there is greater latitude for significant value gains. It is important to track and manage different stakeholder perspectives to ensure that innovative solutions are well accepted and absorbed.

Discussion

While DCTs are a worthy end goal, the true worth is the ability to engage study subjects at a level of multiples of growth with a resulting improvement in drug development in many areas. Participants shared potential problems and solutions within multiple stakeholder groups. Several themes that can be supported by blockchain technology emerged across all three stakeholder groups. Consistent with current literature,[7,8] these themes included enhanced efficiencies, patient experience / demographic diversity, data integrity/privacy/security, and cost-effectiveness.

Improved efficiencies were suggested with regulatory practice automation and risk-based monitoring. In a recent report, McKinsey & Company suggested that the greatest opportunity for sponsors to accelerate clinical trials is to increase the speed and improve the efficiency of clinical trial enrollment.[9] These improvements will benefit patients, payers, and pharmaceutical companies. Additionally, using decentralized models can foster a more robust study population and meet the needs of many patients with a disease with no known therapies.[9]

Of equal importance are data integrity, security, and privacy, which promote patient comfort and fidelity in clinical trials. Blockchain technology streamlines monetary exchange by removing the need for intermediaries to complete transactions faster and more efficiently. Managing trial subject consents and clinical trials is an area in which blockchain can improve the efficiency, accountability, audit ability, and transparency of researchers and practitioners in healthcare. Data also suggests that blockchain technology reduces monitoring visit time and cost while improving patient trust and sense of empowerment compared to conventional clinical trial management.[10]

While many key insights supporting blockchain technology were explored and supported, several points of consideration, not widely discussed during the session, include the appropriateness of use, regulatory standards, and data privacy.

Blockchain technology offers solutions to several challenges identified by the participants; however, it is not always the best solution.[1,4] Guidance on when and when not to use blockchain-based solutions is readily available (Figure 1). Additionally, the Decentralized Trials & Research Alliance (DTRA) developed a rubric to provide a consistent framework when evaluating the evidence of success, patient experience, site impact, operational and technical feasibility, and regulatory and ethical compliance.[11] Furthermore, the FDA has published draft guidance on decentralized trials, and it is recognized that many clinical trials already include decentralized elements.[1,12] A DCT, when performed at a patient's home, requires additional safeguards from a data privacy governance given the Health Insurance Portability and Accountability Act (HIPAA), the General Data Protection Regulation (GDPR), and similar legislation. The FDA regulatory requirements are the same for DCTs and traditional site-based clinical trials.[12] While blockchain, known for its robustness and transparency, may inherently pose unique challenges in maintaining data privacy and complying with security standards, capturing data and working with it using paper is sub-optimal.[13] In the rapidly evolving world of blockchain technology, privacy and security remain at the forefront.[13] A blockchain-driven data

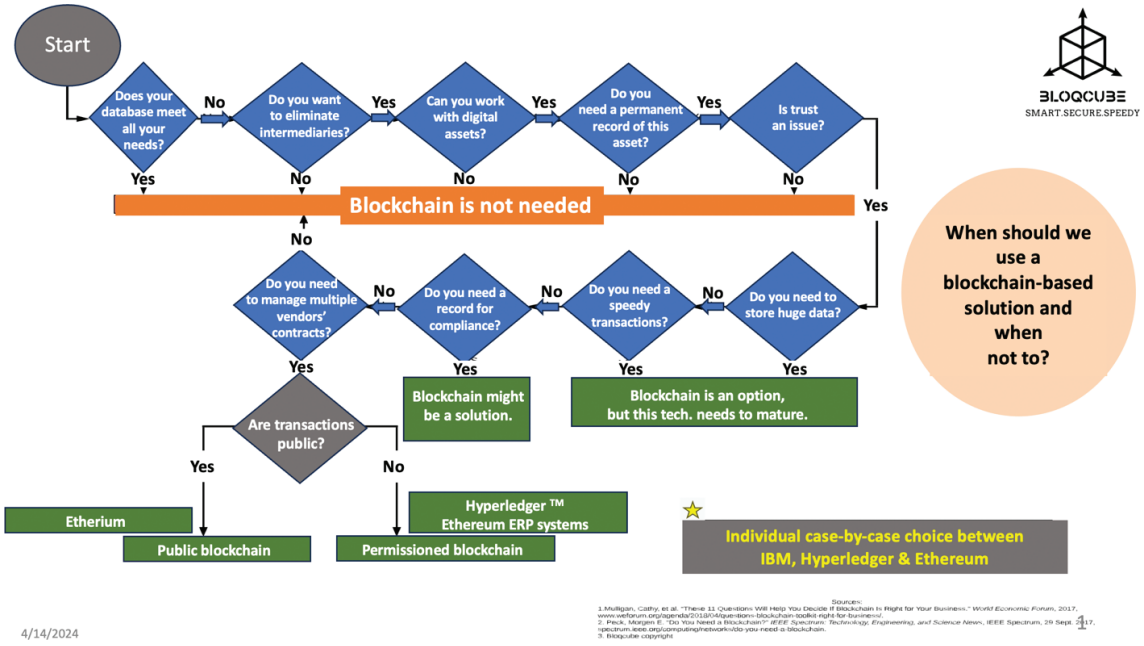

Fig. 1. When should we use a blockchain solution and when not to.

protection solution permits a high level of confidentiality for patients' records/data.

This exercise has several limitations. First, the focus groups consisted of a convenience sample of conference participants. Additionally, the presentation and discussions were completed within a limited amount of time. Lastly, it must be noted that the areas of discussion represent a small overview of the canvas of options for clinical trial systems.

Conclusion

Key stakeholders offer a unique perspective that can leverage current technologies and facilitate the adoption of truly decentralized clinical trial management systems (DMS). Additional research is needed to facilitate the pervasive implementation of blockchain technology and address challenges related to health diagnostics, patient care processes in remote monitoring or emergencies, data integrity, and fraud avoidance.[7] Despite the promising value proposition of blockchain technology in clinical trials, broad adoption will require the industry to overcome technological barriers.[10] Future research may include additional stakeholders, such as researchers, regulators, healthcare providers, and others involved in clinical trials who may not be familiar with this technology. The DCTs are a promising approach to improve the efficiency, patient experience, demographic diversity, and cost-effectiveness of clinical research.[3,8]

This exercise explored how blockchain technology and decentralized clinical trial management systems (dCTMS) can positively impact patients, payers, and pharmaceutical sponsors by improving efficiencies, patient experiences, demographic diversity, data management, and cost-effectiveness. Although several solutions have been developed, challenges with adoption still need to be addressed. The diffusion of blockchain technology is highly applicable and can reshape the future of healthcare by increasing study participation in clinical trials; however, understanding and overcoming the challenges of adoption is essential.

Funding

None.

Financial and Non-Financial Relationships and Activities

The author declares the following competing financial interest. The author holds equity ownership in Bloqcube®.

Contributor

Rama Krishna Rao independently chaired and facilitated the interactive learning session, workgroups, and all products resulting from the discussions.

Data Availability Statement (DAS), Data Sharing, Reproducibility, and Data Repositories

Original data were not generated for this editorial.

Application of AI-Generated Text or Related Technology

None applied.

Citation: Blockchain in Healthcare Today 2024, 7: 305 - https://doi.org/10.30953/bhty.v7.305

Acknowledgments

The author thanks the conference attendees who participated in the learning session and workgroups.

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