Human-Centered Design in AI-Enabled Clinical Trials: A Cognitive Systems Engineering Perspective

Asha Golveo

Embry-Riddle Aeronautical University

MSHF 653 Cognitive Systems Engineering

Abstract

As clinical trials continue to integrate artificial intelligence (AI), automation, and wearable devices, the clinical trial system and its implementation will increase in complexity, demanding a reevaluation of its sociotechnical system. This course case analysis (CCA) explores the transformation of clinical trials from manual, paper-based systems to AI-enabled, data-driven joint cognitive systems (JCS). Drawing on principles from human factors and cognitive systems engineering (CSE), the analysis identifies key challenges in AI integration, including algorithmic bias, usability barriers, trust, data inconsistency, and workflow misalignment. To address these challenges, the CCA applies CSE methods and proposes solutions that support AI training, operator onboarding, and the design of intuitive, context-aware systems. The analysis emphasizes that clinical trial success requires human-centered design, transparent AI systems, and adaptive workflows that accommodate diverse populations and global research environments. Human factors principles such as usability, simplicity, and mental model alignment are emphasized to support inclusive design, reduce cognitive load, and enhance participant engagement. By applying human factors principles throughout the design and implementation process, clinical trials can become more efficient, inclusive, and resilient. The analysis concludes that a human-centered, systems-based approach is essential for the ethical, effective, and sustainable integration of AI in clinical trial implementation.

The Evolution of Clinical Trials

Clinical trials are essential to the research and development process for new medical treatments and interventions, providing data that help clinicians make informed decisions about patient treatment strategies. Throughout the different phases, clinical trials must follow Good Clinical Practice (GCP) dictating quality standards for how trials are designed, conducted, documented, and reported. Clinical trials are highly regulated to ensure the integrity and credibility of clinical research, in addition to protecting the safety and rights of human participants. Implementation of a clinical trial involves careful coordination among sponsors, researchers, regulatory bodies, and participants. As clinical trials become more technology driven, the principles of human factors and cognitive systems engineering are pivotal to designing protocols that optimize performance, safety, and successful trial outcomes. An analysis of clinical trials from 2010 to 2017 found that around 90% of drug development projects fail during phase 1-3 of clinical trials, while the failure rate is even higher than 90% when including preclinical stages (Sun et al., 2022). Considerable effort has been invested to improve drug efficacy, including the use of machine learning computational tools and artificial intelligence (AI) to improve drug design. However, this course case analysis will focus on the use of technology during clinical trial implementation to address recruitment and data quality challenges, focusing on the strengths and limitations of these joint cognitive systems they create.

Before the use of automation and AI in clinical trials, the process was mostly manual from patient selection, recruitment, data collection, and analysis. Researchers selected patients by manually reviewing patient records, and recruitment strategies relied on advertisements in medical journals and flyers. Traditionally, researchers also utilized patient databases, medical records, and relationships with healthcare providers and community organizations for referrals.

However, these traditional methods did not always yield the best candidates, or recruit enough eligible participants. Furthermore, data collection and management relied on paper-based forms and spreadsheets, requiring manual data entry that was time-consuming and error-prone. In some cases, patients were responsible for tracking progress in patient diaries. Automation introduced digital tools such as electronic health records (EHR) to identify potential participants, online pre-screening questionnaires, targeted advertisements on online platforms to reach a wider population, mobile health applications to track patient progress, and wearable devices for remote monitoring. The evolution of clinical trials has now reached the stage of AI utilization to analyze large data sets and further automate repetitive tasks. AI algorithms can analyze patient databases and EHR to identify potential trial participants, provide real-time data monitoring, and perform complex data analysis to make predictions that may be missed by traditional methods.

Integration of Automation and Artificial Intelligence

The integration of AI transforms the human-machine role from the traditional controller-worker to a more explicit representation of a joint cognitive system (JCS), where the machine agent functions as a cognitive assistant trained with human knowledge, effectively sharing the load of cognitive tasks, with autonomy. The human's role in gathering information, interpretation, and decision-making is delegated to the AI, while the human maintains final control and decision-making power. In prior human-machine relationships, interactions consisted of humans using digital tools to accomplish a goal while maintaining responsibility for higher-level cognitive functions. This new system is a partnership where each agent's strengths complement the other agent's weaknesses. Human agents obtain access to advanced proficiencies from machine agents, while machines acquire knowledge from human intelligence and adaptability

(Korteling et al., 2021). While machines can outperform humans in processing speed, accuracy, and sophisticated computations, they lack the human abilities of creativity, flexibility, and emotional intelligence. Roles are redefined in this system where humans relinquish direct and physical control, in turn accepting implicit controls of maintenance and management. Humans must train the AI model, evaluate its performance, and re-train the AI when it fails to meet acceptable performance criteria. This redefinition of roles can expose challenges and limitations of the human-machine relationship, as humans harbor individual mental models about the work, and how they interpret machine state.

In a clinical trial, the agents collaborate toward common goals of optimal patient recruitment, efficient data collection, exploratory data analysis, and increased participant engagement. Cognitive tasks are shared amongst clinicians, coordinators, AI algorithms, and digital platforms. In the recruitment process, the AI flags eligible participants based on EHR data and eligibility requirements, the human reviews and approves for eligibility appropriateness, and the system schedules outreach to the patient using forms and literature created by the human. The AI accelerates the speed of recruitment through its ability to analyze vast amounts of data, detect patterns that a human may fail to notice, while streamlining the process and easing the human's cognitive load. AI powered clinical trial matching systems utilize natural language processing (NLP) to analyze patient data and learn the clinical trial protocols. However, data consistency and standards have not been clearly defined to allow robust evaluation of the tools, and quality discrepancies of real-world patient data can pose challenges to successfully integrating AI into clinical trials (Zhang et al., 2023). Furthermore, data privacy laws and competition between institutions regarding proprietary data can hinder data integrity. Data inconsistencies can lead to

inappropriate AI training, leading to misalignments in shared understanding between the human and machine.

Data collection and analysis is another area of AI integration, expanding the use of digital tools as repositories for patient data, to systems collecting and processing real-time data for predictive analysis. Since 2012, clinical studies have increasingly utilized wearable devices for data collection, suggesting this trend will continue as the public increases their use and comfort with commercial wearable devices (Miyakoshi & Ito, 2024). Wearable devices in this context are defined as technology with sensors and/or smartphone applications, with the ability for continuous monitoring and real-time data communication. Commercial fitness trackers are the most popular wearable devices, including smartwatches that have integrated fitness tracking capabilities into their design. Wearables can collect vital sign data such as heart rate, blood pressure, skin temperature, ECG, breathing rate, and heart rate variability, thereby collecting extensive data while reducing the reporting burden on trial participants. Notable examples of clinical trials utilizing wearable devices are the Apple Heart Study, mPower Study, DETECT Study, and Biobeat Hypertension Management Study (Perez et al., 2019; Bot et al., 2016; Radin et al., 2022; Nachman et al., 2021). Wearable devices allow for remote real-time data collection, allowing clinicians and researchers to monitor patient health, and identify potential needs for intervention. When this data is integrated into the AI system, the AI can continuously monitor patient data throughout the trial and notify researchers about potential issues.

The integration of wearable technology and AI into clinical trials introduces increasing complexity in this sociotechnical system. From a participant perspective, human patients are a diverse group with varying comfort and mental models of technology interaction. Patient experience is vital to the success of a trial, influencing patient engagement and compliance with

device usage. Human factors principles of usability, comfort, explainability, simplicity, and intuitive interface design are vital in the process of wearable device selection. Smartphones and smartwatches have reached broad adoption, 85% and 31% of Americans, respectively (Shandhi et al., 2024). However, different manufacturers and operating systems create distinct user experiences, affecting the human participant's understanding of the device's operation and feedback loops. Misalignment between the device's interface and the user's mental models can overwhelm the user, leading to frustration and potential errors, and generating excessive cognitive load in an already delicate situation. Visual design elements can affect how participants interpret information, overemphasizing attention on irrelevant information or encouraging users to misinterpret their health data. Furthermore, devices may be uncomfortable or difficult to use on different body types, introducing inconveniences that interfere with the participant's daily life. These challenges with wearable device usage are further complicated when integrating AI into the monitoring and predictive analysis process. Concerns about trust, ethics, automation bias, algorithmic bias, data privacy, and transparency are primary factors affecting system performance and failure potential.

While AI adoption is growing in many industries, public understanding and trust of AI varies by context and demographics (Ognyanova & Singh, 2025). Misconceptions exist about AI's capacity for emotional intelligence and inherent bias, while significant concerns exist regarding algorithmic bias and lack of transparency in how AI systems make decisions. Many AI models, particularly deep learning algorithms, function as "black boxes" failing to elucidate their decision-making processes. This lack of transparency can pose significant challenges in integrating AI in clinical trials when clinicians are unable to understand, build trust, and effectively utilize AI recommendations. Explainability is also an ethical issue when accounting

for algorithmic bias, a problem that can appear when AI models are trained on data that reflects societal prejudices, leading to discrimination and inequity in the AI's recommendations (Obermeyer et al., 2019). Algorithmic bias and inequity can erode public trust in AI, potentially damaging patient recruitment and clinician adoption. Furthermore, incorporating AI into existing clinical trial workflows can be challenging as disruptions or misalignments may lead to inefficiencies, errors, or resistance from clinical staff, ultimately affecting trial outcomes (El Arab et al., 2025). AI systems require ongoing maintenance to ensure continued accuracy and relevance, with potential for degraded performance and potential errors in the clinical trial process if regular updates and monitoring are not practiced.

Application of Cognitive Systems Engineering

Cognitive systems engineering (CSE) methods of cognitive analysis can be applied to the clinical trial process to optimize efficiency, effectiveness, and safety of its operation. Cognitive Task Analysis (CTA) can be employed to train other humans in the system, and in this context, employed to train the AI model. Expert knowledge on how to understand and use AI is essential to the comfort and appropriate utilization of the AI system, in addition to providing the explainability that novice users need. CTA can capture accurate and comprehensive detail of the cognitive processes required to perform a task, allowing trial coordinators to create training programs and manuals for distribution to various trial sites. CTA may also have significant benefits when training trial participants on how to use wearable technology, a strategy that can address the fragmentation of existing commercial devices. The artefacts produced by the CTA are particularly valuable for training novices on emerging technologies, where the availability of seasoned operators is limited, and developing trust is a determinant. Moreover, CTA can be

employed to improve AI model performance, specifically the areas of analysis and decision-making. By understanding the mental process of experts (clinicians/researchers) when making recruitment decisions, the AI model is trained on the nuances and language of that specific medical field, thereby training the AI to make better predictions that reflect human capabilities of intuition and adaptability.

The growing integration of technology, and globalization of clinical trials, has the potential to reduce operational costs and expand recruitment outreach (Jeong et al., 2017). However, CSE principles become exceedingly vital to designing these complex sociotechnical systems to ensure they can operate efficiently under various environments and contexts. Clinical trial globalization introduces additional team complexity as operators with different cultures and experiences must collaborate together. Cognitive Work Analysis (CWA) focuses on analyzing human cognitive processes within their context, including their environment, artefacts, and other people. This framework can be an essential tool for analyzing teamwork and collaboration in a distributed system, and designing complex sociotechnical systems that contain disparate people and technology. In addition, CWA can be used to analyze why previous clinical trials were unsuccessful, and apply those observations to design protocols with optimal structure, staffing, and defined roles. CWA can analyze existing work practices and identify areas for improvement, including areas where integrating technology could improve efficiency, and areas where AI can be used to reduce cognitive load. CWA can help trial coordinators create systems that support workers in adapting to new environments and technologies.

Computational cognitive models (CCM) and simulation tools can also be employed to understand how clinicians, coordinators, and patients interact with complex trial tasks, or AI systems under varying conditions. CCM allows researchers to test and refine theories of

cognition, and make predictions about behavior when humans interact with new technology. CCM can help trial designers understand how users will perceive and interpret the functionality of a system, allowing designers to create systems that are easier to learn and use. ACT-R or GOMS models can be employed to model clinician-AI interactions, predicting how clinicians will respond to AI-based decision support tools. This approach can identify where cognitive load or interface confusion may occur, and allow for better optimization of timing and format of AI outputs. Simulation can be a promising tool in evaluating how AI and human decisions interact to affect trial outcomes. By simulating "what-if" scenarios, and modeling combined human-AI error rates and detection latency, clinical trial coordinators can determine where human review is most valuable. Furthermore, simulation tools can be employed to model patient adherence to wearable devices, in addition to modeling patient interactions with digital forms. Clinical trials benefit from the diversity of trial participants, and simulation can help coordinators understand how populations with varying levels of tech literacy, motivation, and access respond to systems. These models can be used to understand how user behavior will change under different incentives or reminder systems, allowing for improved communication and training strategies.

Summary

This course case analysis explores the evolving role of automation and AI in the implementation of clinical trials, emphasizing the implications for human-machine collaboration. Traditionally, clinical trials relied on manual processes for recruitment, data collection, and monitoring, often leading to inefficiencies and human error. The integration of AI and digital tools have shifted clinical trials towards more automated and data-driven approaches, enabling faster recruitment, increased patient diversity, real-time monitoring, and enhanced data analysis.

However, AI integration introduces significant challenges related to data inconsistency, algorithmic bias, automation bias, explainability, and trust. The benefits of automation and AI have also allowed for the growth of clinical trial globalization, introducing the benefits, and further contributing to the complexity of sociotechnical systems. Furthermore, the integration of wearable devices further complicates system usability and participant engagement, particularly among diverse patient populations with varying levels of technological literacy. The analysis emphasizes the application of JCS and CSE principles to evaluate how cognitive tasks are distributed between human and machine agents, with the goal of improving AI training, operator training, participant engagement, workflow alignment, and system resilience. CCM and simulation tools are proposed to predict user behavior, optimize clinician-AI interaction, and identify system failure points. Human factors principles are highlighted to design clinical trials that are not only technologically advanced, but also safe, inclusive, and effective across diverse settings.

Conclusion

The integration of artificial intelligence (AI), automation, and wearable technologies into clinical trials has introduced significant opportunities to enhance efficiency, recruitment, and data quality. However, as this case analysis has shown, these advances also bring substantial challenges related to system usability, data consistency, algorithmic bias, user trust, and workflow misalignment. To address these issues, a human-centered and systems-oriented approach is proposed:

1. Ensure the usability and inclusiveness of health technologies by applying human factors principles in system design.

2. Apply CTA, CWA, modeling, and simulation tools to optimize system performance.
3. Developers and trial designers must commit to transparency to address the issues of algorithmic bias, explainability, and trust.

Recommendations

Ensuring the usability and inclusiveness of health technologies can be accomplished by prioritizing simplicity, comfort, and intuitive interfaces. Implementing user testing, iterative prototyping, and accessibility standards during the development of digital tools and wearable devices will reduce the risk of cognitive overload and increase user frustration. Apple's Human Interface Guidelines is a framework for cognitive ergonomics that emphasizes consistency in design, focusing on "clear visual hierarchies, intuitive navigation patterns, and familiar icons to align with users' mental models" (Deore et al., 2023).

CTA offers a structured method for capturing expert knowledge that can inform both human and AI training. The knowledge obtained from CTA can enable the creation of effective onboarding materials for clinical trial operators and participants, which is particularly important in trials involving commercial health technologies unfamiliar to users. Furthermore, understanding how clinicians make nuanced decisions regarding recruitment and diagnosis can help designers develop AI systems that better reflect real-world judgment and adaptability. CWA provides a framework for aligning new technologies with existing workflows, team structures, and environmental constraints. This approach can guide the integration of AI tools into clinical workflows without causing disruptive misalignments, focusing on areas where AI should augment human work, as opposed to areas where human judgment should remain primary. The

deployment of CCM and simulation tools can enable trial designers to predict user behavior, simulate human-AI interactions, and test “what-if” scenarios before implementation. This approach can identify critical points where user confusion, error, or non-compliance is likely to occur, supporting the design of more resilient and adaptive systems. Modeling can also be used to personalize participant engagement strategies based on tech literacy, motivation, and demographics.

To overcome issues of algorithmic bias, explainability, and trust, developers and trial designers must commit to transparent AI development. Transparency is crucial for building trust in AI systems, validating their results, and ensuring ethical deployment. It also helps identify and mitigate potential biases, and ensure accountability. Responsible AI development can include training AI models on diverse representative data, using transparent algorithms where possible, and incorporating explainable AI (XAI) tools to help clinicians understand and verify machine-generated outputs. Establishing ongoing feedback loops for monitoring AI performance and retraining models based on real-world data ensures continuous improvement and accountability.

References

Bot, B. M., Suver, C., Neto, E. C., Kellen, M., Klein, A., Bare, C., Doerr, M., Pratap, A., Wilbanks, J., Dorsey, E. R., Friend, S. H., & Trister, A. D. (2016). The mPower study, Parkinson disease mobile data collected using ResearchKit. Scientific data, 3, 160011. https://doi.org/10.1038/sdata.2016.11

Deore, S.S., Joshi, S., & Belhe, A. (2023). Cognitive Ergonomics in Design: Enhancing User Interaction through Intuitive Interfaces. The Indian Journal of Technical Education,Vol. 46 No. 2

El Arab, R. A., Abu-Mahfouz, M. S., Abuadas, F. H., Alzghoul, H., Almari, M., Ghannam, A., & Seweid, M. M. (2025). Bridging the Gap: From AI Success in Clinical Trials to Real-World Healthcare Implementation-A Narrative Review. Healthcare (Basel, Switzerland), 13(7), 701. https://doi.org/10.3390/healthcare13070701

Jeong, S., Sohn, M., Kim, J. H., Ko, M., Seo, H. W., Song, Y. K., Choi, B., Han, N., Na, H. S., Lee, J. G., Kim, I. W., Oh, J. M., & Lee, E. (2017). Current globalization of drug interventional clinical trials: characteristics and associated factors, 2011-2013. Trials, 18(1), 288. https://doi.org/10.1186/s13063-017-2025-1

Korteling, J. E. H., van de Boer-Visschedijk, G. C., Blankendaal, R. A. M., Boonekamp, R. C., & Eikelboom, A. R. (2021). Human- versus Artificial Intelligence. Frontiers in artificial intelligence, 4, 622364. https://doi.org/10.3389/frai.2021.622364

Miyakoshi, T., & Ito, Y. M. (2024). Assessing the current utilization status of wearable devices in clinical research. Clinical trials (London, England), 21(4), 470–482. https://doi.org/10.1177/17407745241230287

Nachman, D., Gilan, A., Goldstein, N., Constantini, K., Littman, R., Eisenkraft, A., Grossman, E., & Gepner, Y. (2021). Twenty-Four-Hour Ambulatory Blood Pressure Measurement Using a Novel Noninvasive, Cuffless, Wireless Device. American journal of hypertension, 34(11), 1171–1180. https://doi.org/10.1093/ajh/hpab095

Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019). Dissecting racial bias in an algorithm used to manage the health of populations. Science (New York, N.Y.), 366(6464), 447–453. https://doi.org/10.1126/science.aax2342

Ognyanova, K., & Singh, V. (2025, March 25). National AI Opinion Monitor: AI trust and knowledge in America. https://doi.org/10.31219/osf.io/ryv86_v1

Perez, M. V., Mahaffey, K. W., Hedlin, H., Rumsfeld, J. S., Garcia, A., Ferris, T., Balasubramanian, V., Russo, A. M., Rajmane, A., Cheung, L., Hung, G., Lee, J., Kowey, P., Talati, N., Nag, D., Gummidipundi, S. E., Beatty, A., Hills, M. T., Desai, S., Granger, C. B., … Apple Heart Study Investigators (2019). Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation. The New England journal of medicine, 381(20), 1909–1917. https://doi.org/10.1056/NEJMoa1901183

Radin, J. M., Quer, G., Pandit, J. A., Gadaleta, M., Baca-Motes, K., Ramos, E., Coughlin, E., Quartuccio, K., Kheterpal, V., Wolansky, L. M., Steinhubl, S. R., & Topol, E. J. (2022). Sensor-based surveillance for digitising real-time COVID-19 tracking in the USA (DETECT): a multivariable, population-based, modelling study. The Lancet. Digital health, 4(11), e777–e786. https://doi.org/10.1016/S2589-7500(22)00156-X

Shandhi, M. M. H., Singh, K., Janson, N., Ashar, P., Singh, G., Lu, B., Hillygus, D. S., Maddocks, J. M., & Dunn, J. P. (2024). Assessment of ownership of smart devices and the

acceptability of digital health data sharing. NPJ digital medicine, 7(1), 44. https://doi.org/10.1038/s41746-024-01030-x

Sun, D., Gao, W., Hu, H., & Zhou, S. (2022). Why 90% of clinical drug development fails and how to improve it?. Acta pharmaceutica Sinica. B, 12(7), 3049–3062. https://doi.org/10.1016/j.apsb.2022.02.002

Zhang, B., Zhang, L., Chen, Q., Jin, Z., Liu, S., & Zhang, S. (2023). Harnessing artificial intelligence to improve clinical trial design. Communications Medicine, 3(1), 191–191. https://doi.org/10.1038/s43856-023-00425-3