



Harnessing collaborative intelligence for augmented clinical development decisions

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Abstract

The emergence of collaborative intelligence, which combines the cognitive abilities of humans with the computational power of machines, has the potential to revolutionize clinical development decision-making. By forming strategic partnerships between human experts and artificial intelligence (AI), we can address longstanding challenges in drug development such as study initiation, enrollment difficulties and achieving representative patient demographics in clinical trials.

Collaborative intelligence helps optimize clinical trials by leveraging collective knowledge and innovative approaches to enhance patient enrollment in complex populations and engage diverse communities. To fully capitalize on the benefits of this approach, it's essential to establish a clear vision, devise a robust data strategy and redefine business roles and processes to effectively guide AI and machine learning (ML) technologies. Teams also must foster a cultural shift toward collaborative decision-making.

We're now at a critical juncture where the creation of strategic collaborative intelligence is pivotal for sponsors to overcome historical obstacles and drive advancements in drug development. This paper explores the potential of harnessing collaborative intelligence to augment evidence-driven decisions in clinical development, offering insights into the key considerations and steps necessary for successful implementation.

Convergence of AI and collaboration open a new path to medical breakthroughs

AI has permeated every facet of our lives, profoundly transforming industries and societies, particularly in [the wake of the COVID-19 pandemic](#). It has become increasingly evident that the true power lies in the collaboration between humans and AI, giving rise to the concept of collaborative intelligence. This synergistic partnership enables humans and machines to combine their strengths, reason together, tackle complex problems and collectively enhance decision-making processes.

We observe a compelling example of the potential of collaborative intelligence in the world of chess. The epic encounters between the "Beast of Baku" and the enigmatic "01000010100001" demonstrate that the partnership between human and AI can transcend individual capabilities. In this contest, the chess grandmasters and AI systems complemented each other, ultimately surpassing what either could achieve alone.

Inspired by this realization, the concept of the centaur chess player emerged—a hybrid entity that marries human intuition, creativity and empathy with the computational might of a computer. By harmoniously combining these distinct faculties, the centaur chess player outperformed both individual humans and AI players, showcasing the immense power of collaborative intelligence.

This example serves as a testament to the transformative potential of collaborative intelligence in domains far beyond chess. In the field of clinical development, where the stakes are high and the challenges multifaceted, harnessing the collective intelligence of humans and machines can revolutionize evidence-driven decision-making. By strategically integrating AI technologies with the expertise and experience of clinical professionals, we can overcome long-standing hurdles that have hindered progress in drug development.

In this paper, we delve into the concept of collaborative intelligence and explore its applications in augmenting clinical development evidence-driven decisions. We will examine the untapped opportunities it presents, such as optimizing clinical trials, addressing enrollment complexities and ensuring diverse and representative patient populations. Moreover, we will outline the essential considerations and steps required to cultivate effective collaborative intelligence, including establishing a clear vision, formulating a comprehensive data strategy, redefining business roles and processes and nurturing a culture that embraces collaboration.

At this critical juncture, where advancements in AI and clinical development converge, leveraging collaborative intelligence is paramount for sponsors and stakeholders. By harnessing the collective wisdom of human expertise and the computational prowess of machines, we can overcome historical barriers and forge a path toward accelerated and more efficient drug development. Through this exploration, we aim to provide insights and guidance for leveraging collaborative intelligence in clinical development, fostering a new era of evidence-driven decision-making that propels us toward improved patient outcomes and medical breakthroughs.



The potential power of collaborative intelligence

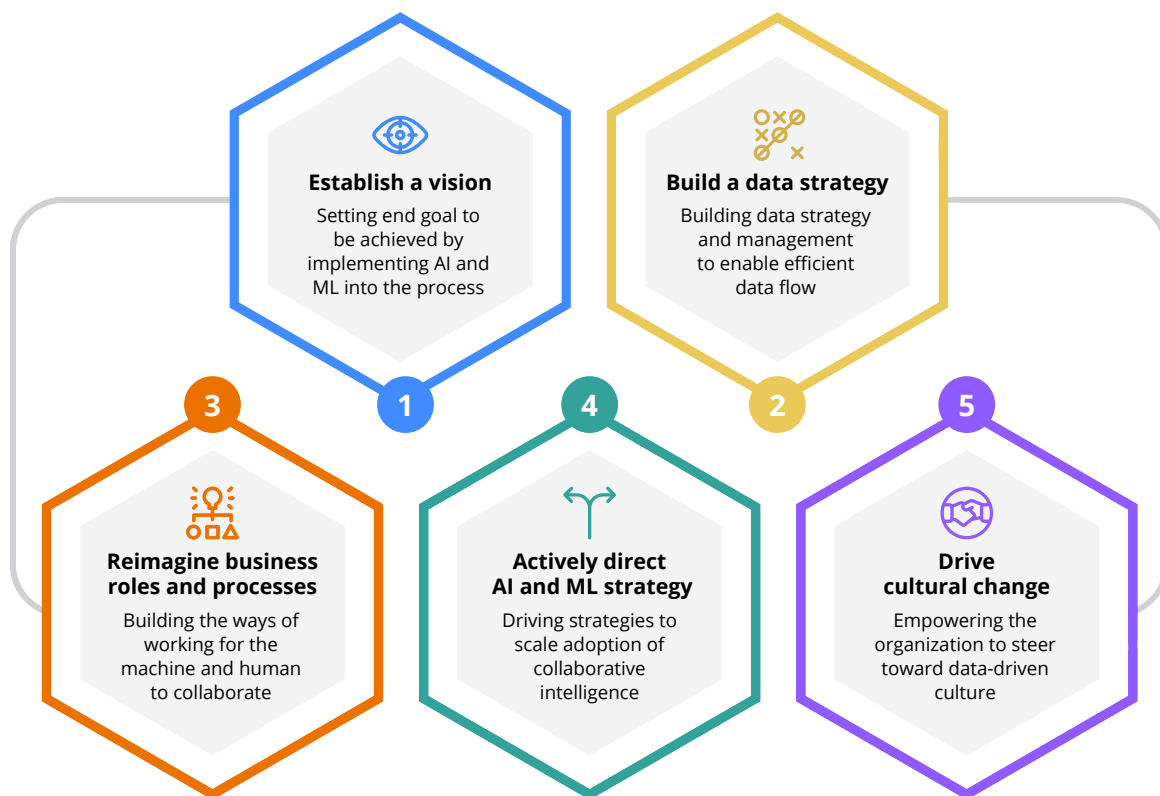
Despite exponential increases in R&D costs, the success rates of clinical trials have remained stagnant in recent years. Industry reports indicate that 80% of clinical trials fail to meet their initial enrollment targets within the designated timeframe, leading to operational failures and significant delays in delivering potentially lifesaving therapies. These challenges have a direct and adverse impact on global public health. However, by harnessing the collective intelligence of humans and AI through collaborative intelligence, we can explore untapped avenues in healthcare, accelerate the clinical development cycle and enhance cost-effectiveness in drug development.

One crucial application of AI in clinical trial operations is the reduction of study design complexity without compromising scientific integrity, alleviating burdens on sites and patients and facilitating efficient operational execution. For instance, the digitalization of protocols and machine analysis of the schedule of activities can help identify and minimize trial complexities, giving organizations a competitive edge. However, it's important to maintain a manual check to review the machine's considerations and options, ensuring that scientific principles are not compromised. The global clinical research landscape is undergoing a pivotal transformation across all therapy areas, aiming to expedite the approval of life-changing therapies, reduce trial complexities and expand the global research footprint.

To foster innovation in our approach, we must find new ways to address issues associated with emerging data elements that feed into new data models. Traditional key metrics that rely on years of research to identify suitable trial locations need to be revamped to avoid underappreciation of diversity and oversaturation in specific regions. Disparities in participation rates, with non-white populations often enrolling at rates significantly lower than their representation in the general population, highlight the urgent need for change. The rise of real-world scientific data, such as electronic health record claims, electronic medical claims and specialty lab data, along with operational data such as performance and quality metrics, necessitates the use of advanced predictive and proscriptive analytics models that thrive on collaborative intelligence. Consequently, many sponsors are establishing data science disciplines or expanding the role of data scientists within their organizations to build advanced analytic models that enhance patient-centricity and improve clinical trial efficiency. This requires early planning and the incorporation of collaborative intelligence, with AI and ML playing a vital role based on a well-defined data strategy and foundation.

FIGURE 1:

Strategic elements for building collaborative intelligence





Establish a vision

The establishment of a compelling vision for collaborative intelligence, empowered by AI and ML, in clinical development is driven by a transformative perspective that seeks to revolutionize the way we approach evidence-driven decision-making. This vision is rooted in the recognition of the persistent challenges and limitations in traditional approaches and the immense potential that collaborative intelligence holds for addressing them.

By embracing collaborative intelligence, we envision a future where clinical trials are optimized to an unprecedented degree. Complexities in trial operations are minimized through the utilization of natural language processing and ML algorithms, resulting in streamlined protocols and reduced burden on patients and sites. Trial planning becomes a data-driven endeavor, identifying the optimal intersection between patient clusters and high-performing sites. Predictive models guide site selection, ensuring representation of diverse populations and underserved communities. Patient enrollment is enhanced through AI-powered prediction of adherence drivers and personalized patient engagement strategies.

The vision of collaborative intelligence extends beyond the operational aspects of clinical development. We envision a future where advanced analytics models, fueled by real-world scientific data and operational metrics, transform decision-making processes. Predictive and prescriptive analytics guide the optimization of inclusion and exclusion criteria, sample sizes and trial designs, leading to more efficient trials, shortened enrollment periods and, ultimately, faster access to life-changing therapies for patients in need.

Moreover, collaborative intelligence enables us to break free from the constraints of traditional data collection methods. By automating data extraction into case report forms with AI and ML, we envision a future where time-consuming manual processes are replaced, reducing errors and accelerating data availability for analysis. This data transformation opens doors to enhanced data quality, improved trial efficiency and the ability to derive valuable insights from real-world evidence.

The overarching vision for collaborative intelligence in clinical development is to create a data-driven culture that fosters innovation, accelerates approvals of therapies and improves health outcomes. It is a vision that transcends individual use cases, aiming to transform the entire landscape of clinical development. Through the fusion of human expertise and AI capabilities, we can unlock novel insights, make evidence-driven decisions and drive advancements that impact the lives of patients worldwide. The vision is driven by the aspiration to optimize trial operations, revolutionize decision-making processes and accelerate access to life-changing therapies. It's a vision that leverages the power of data, human expertise and AI and ML technologies to reshape the future of evidence-driven medicine. By realizing this vision, we can usher in a new era of innovation, efficiency and improved patient outcomes in clinical development.



Building a data strategy

Developing a robust data strategy is vital to harnessing the full potential of collaborative intelligence in clinical development. A well-defined and comprehensive data strategy ensures that data is acquired, stored, processed and utilized effectively, forming the cornerstone for integrating human expertise and AI and ML technologies. To maximize the power of collaborative intelligence, focusing on the following key aspects is critical:

- **Data mastery:** Given the inherent complexity and messy nature of healthcare data, data mastering becomes a critical element. Leveraging master data management tools can assist in data mastering across multiple sources, but careful consideration and dedicated efforts are required for successful implementation. By mastering the data, we can ensure data quality, consistency and integrity, enabling reliable insights and informed decision-making.
- **Training for ML and AI systems:** To build effective ML and AI systems, understanding the training requirements is essential. This involves preparing and curating training data sets, establishing robust annotation processes and continuously updating and refining models to improve their performance. A well-designed training strategy is crucial for the successful integration of ML and AI into clinical workflows.
- **Establishing trusted data sources:** Creating a reliable and undisputed source of data is vital for building trust in the collaborative intelligence ecosystem. Establishing data governance frameworks and data quality control measures ensure that data is accurate, complete and consistent. Regular audits and validation processes help maintain data integrity and enable confident decision-making.
- **Articulating business rules:** Articulating and codifying business rules that govern the use and interpretation of data is essential for effective collaborative intelligence. These rules should be regularly updated based on evolving insights and factual evidence, promoting consistent decision-making and alignment with strategic goals.
- **Enhancing decision-making skills:** Providing high-quality coaching and training programs to employees is crucial for improving their decision-making powers. This includes developing a data-driven culture, fostering analytical thinking, and enhancing the ability to interpret and leverage insights derived from collaborative intelligence systems.



As an industry, it's imperative we adapt to the evolving landscape of clinical data requirements. Implementing innovative approaches such as structured data management and governance frameworks, centralized repositories for clinical trial data and the utilization of real-world data (RWD) in trials are crucial steps. Additionally, leveraging emerging solutions such as a data fabric, which offers a unified ecosystem for seamless data access and sharing in decentralized environments, holds great promise. A data fabric integrates architecture and technology, facilitating the execution of appropriate applications, at the right time, in the right place and against the right data.

By prioritizing these strategic elements and implementing a comprehensive data strategy, stakeholders can unlock the full potential of collaborative intelligence in clinical development. This empowers evidence-driven decision-making, accelerates innovation and ultimately leads to improved patient outcomes and transformative advancements in the field of healthcare.



Reimagine business roles and processes

To fully unlock the potential of ML and AI, we must integrate the collaborative element into our ways of working. Change management becomes instrumental in driving adoption across functions within the organization that are directly or indirectly impacted by AI and ML innovations. It's crucial to work alongside individuals in these functions, providing guidance to early experience teams to develop learning and development capabilities tailored to their specific needs. This collaboration is vital to prevent any noise within the organization that could impede the successful implementation of AI and ML systems. Organizing training sessions for employees is essential to familiarize them with the various collaborative ways of working with AI. These sessions can explore topics such as the contextual applications of AI and their impact on business. The underlying theme should focus on the practical experiences that AI engines bring to their roles, showcasing specific and representative use cases that demonstrate the transition from legacy models to the new AI- and ML-driven approaches.

To foster sustained adoption and ongoing improvement, establishing a governance oversight plan to understand how teams are utilizing the new technology to drive decisions is recommended. This includes implementing reinforcement learning mechanisms that integrate with workflows and notations, ensuring continuous refinement and enhancement of overall recommendations.

It's crucial to emphasize that the aim is not to replace human jobs but rather to create an environment where humans and machines collaborate effectively. By automating repetitive tasks with ML and AI engines, valuable capacity is freed up, enabling humans to focus on influencing decisions and leveraging their expertise. For instance, in the pharmaceutical industry, AI and ML site recommendations during study planning can be validated by medical site liaisons who contribute their knowledge through annotations to improve the accuracy of future recommendations. Collaborative intelligence thrives when humans train the initial models and facilitate ML through annotations, allowing the machines to learn the rules of the game and enhance their predictions over time. The models never reach a stage where they replace human intelligence. Instead, they augment decision-making capabilities, enabling more intelligent and evidence-driven choices. As collaboration progresses, a single and intelligent source of truth is built, consolidating insights and fostering a collective understanding within the organization.

The integration of collaborative intelligence in business roles and processes revolutionizes the way we work with ML and AI. It requires change management, targeted training and an emphasis on collaboration between humans and machines. By embracing this collaborative approach, organizations can tap into the combined strengths of humans and AI, driving innovation, enhancing decision-making and ultimately fostering a culture of continuous improvement and intelligent collaboration.



Actively direct AI and ML strategy

To successfully scale the adoption of collaborative intelligence, dedicated expertise is crucial to ensure the proper functioning, safety and responsible use of AI systems. This involves training AI and ML algorithms and teaching them how to interact effectively with humans. The following strategies can be employed to drive active direction and maximize the impact of collaborative intelligence:

- **Critical model selection:** Model selection plays a pivotal role in answering analytical questions and facilitating adoption. It's essential to consider the models that can provide the necessary insights while also instilling confidence and trust. Initially, simpler models that are easily explainable in their behavior can be employed to strengthen confidence and encourage adoption.
- **Monitoring and revalidation:** Establishing robust monitoring and revalidation processes is vital to validate the impact of ML on the business model. These processes ensure ongoing assessment of model performance and alignment with organizational goals. By continuously evaluating and refining models, we can drive continuous improvement and enhance the value derived from collaborative intelligence.
- **Identifying additional opportunities:** Human collaborators should proactively identify additional opportunities to expand and grow the AI and ML strategy. For instance, advanced predictive models can integrate RWD with trial intelligence to identify research clusters that have access to disease-representative patient population demographics. This participant-centric planning paradigm enables the deployment of innovative approaches like decentralized clinical trials (DCT) or hybrid trials, optimizing factors such as burden, cost, quality and speed in clinical trials.
- **Dynamic ML models:** Supervised learning is critical in building recommendation algorithms, particularly in the DCT environment. ML models should be continuously guided by human intelligence, ensuring their adaptability to changing circumstances. For example, the COVID-19 pandemic highlighted the need to quickly scale models to consider factors like bed capacity for site placement. By enabling more generalized assessments, these models can guide the exploration and adaptation of ML models, leveraging their specialized intelligence to predict value and impact more accurately.

By actively directing AI and ML strategies, organizations can drive the widespread adoption of collaborative intelligence. Careful model selection, robust monitoring processes and identification of new opportunities enable the continuous improvement and expansion of AI and ML applications. This dynamic approach ensures that the models remain responsive to evolving challenges and leverage human expertise to make informed decisions. As a result, collaborative intelligence becomes a powerful tool for predicting value, optimizing outcomes and driving transformative advancements in clinical development and beyond.



Drive cultural change

Promoting a data-driven culture is essential for harnessing the full potential of collaborative intelligence. This section explores strategies to drive cultural change within organizations, emphasizing the importance of knowledge sharing, access to information and data-driven decision-making. By fostering a culture that embraces collaborative intelligence, we can overcome operational challenges, accelerate market entry for potential therapies and positively impact human health.

- **Identifying stakeholders and understanding their needs:** A successful approach to driving cultural change begins with identifying stakeholders and understanding what is important to them. Each study team and indication nuances may vary in terms of site recommendations, so it is crucial to tailor the approach accordingly. To facilitate this process, two key questions must be answered: “What’s in it for me?” and “What do I lose?” By gaining insights into stakeholders’ motivations and concerns, organizations can craft compelling value messages and effectively address any potential challenges. This knowledge serves as a foundation for mapping out tailored journeys, guiding stakeholders from unawareness to advocacy.
- **Promoting data-driven decision-making:** Embracing collaborative intelligence requires organizations prioritize data-driven decision-making. This involves creating an environment where access to information is readily available and sharing knowledge is encouraged. By leveraging collaborative intelligence tools and insights, stakeholders can make informed decisions based on real-time data and evidence. Cultivating a culture that values and promotes data-driven approaches empowers individuals and teams to maximize the benefits of collaborative intelligence in their work.
- **Mitigating operational challenges:** Operational challenges such as delayed enrollment periods and protocol complexities have a significant impact on human health and the success of clinical development. Leveraging the power of collaborative intelligence can help address these challenges and accelerate the market entry of potential therapies. By integrating AI-based inputs and insights, organizations can enhance decision-making processes, optimize trial operations and improve patient outcomes. The risk of not embracing AI-based inputs far outweighs the potential benefits, making it imperative for organizations to proactively incorporate collaborative intelligence into their culture.

Driving cultural change to foster a data-driven collaborative intelligence culture is crucial for organizations aiming to unlock the full potential of AI and ML technologies in clinical development. By understanding stakeholders' needs, promoting data-driven decision-making and mitigating operational challenges, organizations can cultivate a culture that embraces collaborative intelligence. This cultural shift empowers individuals and teams to make informed decisions, accelerate market entry for potential therapies and ultimately improve human health.

Remove barriers to unleash the potential of collaborative intelligence

In our relentless pursuit to improve patient outcomes and meet the needs of those in critical conditions, we must embrace collaborative intelligence as a catalyst for creativity and innovation. By embedding collaborative intelligence into our clinical development processes, we can overcome the toughest challenges and revolutionize the landscape of healthcare. To embark on this transformative journey, we must start by building trust and support. By focusing on models such as reinforcement learning that can be influenced by human intelligence models that fall short as classification engines that can be easily explained, we establish a solid foundation for collaboration between humans and machines.

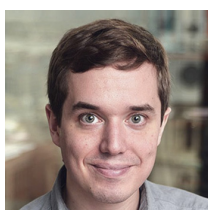
As this collaboration gains momentum, scaling becomes an art. Effectively deploying the strategic elements we have explored in this white paper becomes crucial. By showcasing measurable outcomes and tangible value, we can win the support of stakeholders who may be resistant to change, gradually driving incremental progress toward data-driven decision-making. Above all, we must remain passionate and driven. The urgency lies in the fact that patients are eagerly waiting for breakthroughs that can transform their lives. By embracing collaborative intelligence, infusing innovation and accelerating our momentum forward, we honor our commitment to those who rely on us for life-changing therapies.

Together, let's unleash the full potential of collaborative intelligence, break through barriers and chart a new course toward a future where patient-centricity, evidence-driven decision-making and innovative solutions converge to reshape the landscape of healthcare.

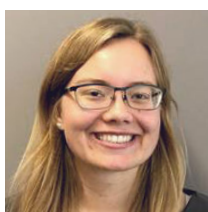
About the authors



Oriol Serra Ortiz serves as an associate principal in ZS's Barcelona, Spain, office, spearheading both the clinical planning practice within ZS and the firm's sponsored cross-industry Clinical Feasibility Consortium. His work is focused on assisting clients in accelerating drug development and optimize trial outcomes. With extensive leadership experience, Oriol has orchestrated strategy and analytics in clinical planning and design optimization across leading pharmaceutical companies, contract research organizations and technology services. His innovative approach has facilitated the large-scale implementation of solutions, strengthened by collaborative intelligence.



Scott Sandford leads the ZS team focused on Janssen R&D and is based in our Princeton, N.J., office. Since joining ZS in 2014, Scott has gained broad experience leading teams in a variety of pharmaceutical strategy engagements in both the commercial and R&D domains. Since shifting his full focus to R&D, he has worked with large pharmaceutical clients in development of vision, mission, strategic priorities, operating models, roles, training and more. This work often focuses on organizational evolution to embrace what is possible with data and technology. In addition to strategy development, Scott and his teams embrace the opportunity to help client teams successfully pull through co-created designs.



Sarah Harmon is based in ZS's Princeton office. Her experience spans a wide array of topics within clinical development, ranging from articulating diversity, equity and inclusion and CAR-T supply chain approaches for top 10 sponsors to applying deep data science techniques to trial acceleration efforts. This latter area has been a particular focus, as has driving narratives of the true value that data science can bring to the field. She has published works in the areas of elevating clinical supply chain voice as part of cellular and gene therapies, as well as broader topics such as insourcing and outsourcing considerations for clinical operations functions.



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