



# Unified approach to clinical trials:

Establishing a data-driven approach  
for sustained growth, productivity  
and compliance



Impact where it matters.®

# Assessing the current state of clinical trials

Clinical trials have evolved significantly post-pandemic—with dual emphasis: The focus on accelerating trials and making them more efficient and a continuing emphasis on patient centricity. This evolution has led to the introduction of a series of technologies and digital interventions that have not only increased the complexity of the data and technology landscape but also further increased the already-existing silos within the organization. While we have seen the emergence of several functional platforms around CDM/EDC, CTMS/Trial Operations and DCT/eCOA, what continues to be missing is a consistent cross-functional platform that can enable bidirectional data flow and support the feedback loop for better future trial design, execution and submission. In short, the platform investments have not necessarily delivered the full vision of a data-driven approach that learns from the past and feeds forward.

While technology is just one leg of the three-legged stool, the other two legs also pose their own challenges. The second leg, stakeholders, encompasses patients, sites, investigators and sponsors. And these continue to have differing experiences. The focus and emphasis on patient centricity has never been higher but still, the translation to actual patient participation, burden reduction and diversity has been gradual at best. The increased focus on patients has not necessarily helped the sites that continue to struggle with varied processes, technologies and expectations across sponsors. Sponsors continue to have a desire to drive better experiences for all stakeholders, but it remains an unsolved puzzle.

The last leg is the process. Unless there is strong sponsor business commitment and participation and a desire to relook at the way trials are designed and run, it will be difficult to make a significant impact. The focus must be on key business metrics across the protocol to submission spectrum, which were challenged during the pandemic and well supported by regulatory authorities. Though that was an unprecedented situation, some companies have been able to take some lessons and embed them. But the intent should be for the larger industry to adopt and drive these changes consistently so we can get drugs to patients faster.

The ZS-sponsored Everest Group research deep dives into the data and technology aspects while addressing the realities of people and process as a key basis for the decisions. It gives a view of the current landscape and covers a data-driven approach for unified clinical trials. It also outlines the relevance of emerging capabilities—especially AI—and highlights some key considerations for success.

ZS's call to action is for an initial assessment of the current state of clinical trials, especially across process and technology, and where investments are being made. The assessment should be followed by a standard, four-step approach to get started on the journey:

1. Define the end-state vision (each company will have a different starting point)
2. Align on the approach to achieve the vision
3. Build consensus across business and technology
4. Create a roadmap

The key to success will be to tie the standard assessment process back to the three-legged stool. Each sponsor needs to rise above the functional leadership and build a cross-functional senior leadership team comprising business and technology to define and align on the common vision of the future of clinical development. Sponsors need to build an end-to-end view of the clinical data flow both at the process and systems level. They then finally need to bring it all together with an interconnected systems landscape—with the right interfaces and user engagement that can rise above functional platform silos to deliver bidirectional data flow.

Get started today!

## Contact

For inquiries about ZS, please contact us [here](#).



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