ROUNDTABLE SUMMARY

February 04, 2025

Pharma Ignite | SCRIP CITELINE COMMERCIAL

Perceptive Roundtable: Unlocking Insights For Smarter Trial Solutions

Roundtable participants:

Mia Carter, Senior Manager, Product Delivery, ICON
Jacqui Cauble-Abogabal, Director, Study Management, Pfizer
Matt Cocking, Global Head of Business Development and Marketing, AG Mednet (a Perceptive MI partner)
Doug Cookson, SVP Commercial, Perceptive eClinical
Daoying Hu, Director, Data Science & Digital Health, Johnson & Johnson
Asma Kasuba, Senior Director, R&D Data Science and Digital Health, Johnson & Johnson
Gillian Livock, Chief Growth Officer, Evinova
Kara MacGowan, Director, Regional Clinical Trial Operations, Pfizer (Seattle Genetics)
Mario Papillon, CEO, Perceptive eClinical
Dawn Sorenson, Director, IRT Center of Excellence, Daiichi Sankyo, Inc.
Anita Zagaja, Clinical Supply Chain Manager, Bayer Pharmaceuticals

Sarah Karlin-Smith, Senior Writer, Pink Sheet, Citeline (Moderator)

KEY THEMES

- Rethinking RTSM Capabilities
- AI-Driven Forecasting
- Next-Generation Solutions
- Measuring Success
- Future Collaborations

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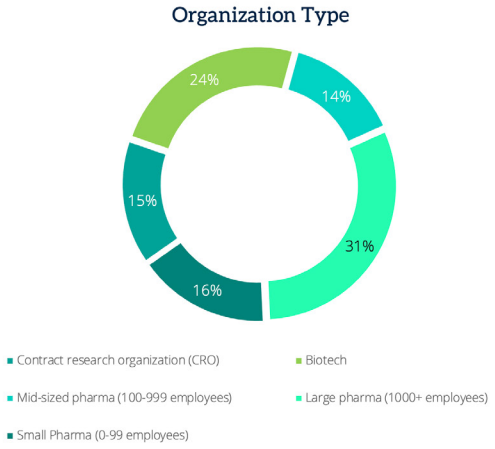
OVERVIEW

Conducting clinical trials is extremely complex. Among the complexities is working with multiple sites on patient enrollment, getting the right quantities of the right drugs to the right sites, conducting the trial, and gathering the necessary data from sites. There are numerous operational and supply chain challenges at every step in the process.

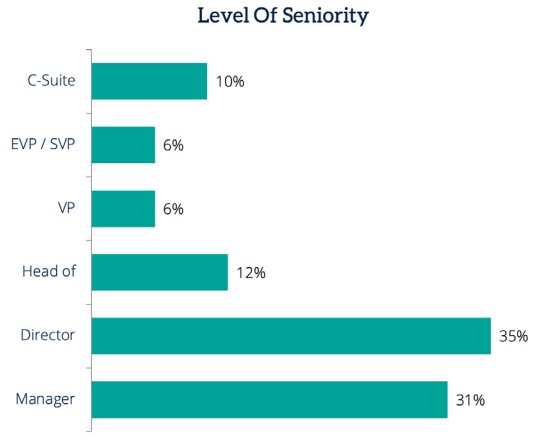
The participants believe that the use of tools and technologies, such as artificial intelligence (AI)-driven forecasting and improved workflows, can improve the efficiency of trials. But many barriers exist including ensuring the validity of the data, lack of a common language, lack of data integration, and organizational silos. Still, despite these challenges, pharma leaders are hopeful that technology can streamline and accelerate trials.

CONTEXT

During the roundtable, held in Orlando alongside SCOPE, Citeline's Sarah Karlin-Smith summarized findings from a recent Perceptive/Citeline survey about eClinical trends and innovation in 2025. This survey was conducted among more than 100 senior leaders of small, mid-sized, and large pharmaceutical companies, along with leaders from biotech companies and contract research organizations from across the globe.



Question: What type of organization do you work for?
Base: All respondents (n=109).



Question: Which of the following best describes your level of seniority?
Base: All respondents (n=109).

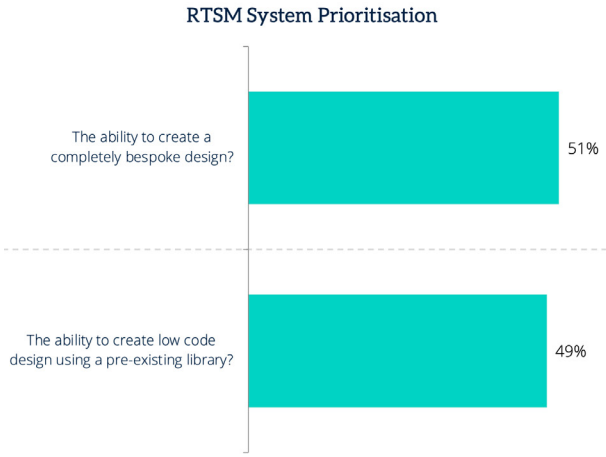
Then, Karlin-Smith led an interactive discussion looking at rethinking randomization and trial supply management (RTSM) capabilities, AI-driven forecasting, next-generation solutions, measuring success, and future collaborations.

KEY TAKEAWAYS

Rethinking RTSM Capabilities

The survey found that about half (51%) of respondents prioritized the ability to create completely bespoke design RTSM systems. The key reasons these respondents preferred bespoke systems were customization, the need for accuracy and integrity, optimization, and partnerships.

The other half (49%) of respondents preferred the ability to create low-code design using a pre-existing library. Respondents who favor low-code, pre-existing RTSMs cite simplicity, reliability, integrity, and cost effectiveness as driving their preference.



Question: What is more important for your Randomization and Trial Supply Management (RTSM) system? Base: All respondents (n=107).

Reasons For RTSM System Prioritisation:

Summary Of Verbatims[1]:

- **Customizable:** tailored solutions to meet specific requirements.
- **Accuracy/Integrity:** ensure data accuracy and integrity.
- **Optimization:** enhances efficiency and delivers better outcomes
- **Partnerships:** leverage knowledge and expertise.

Summary Of Verbatims[1]:

- **Simplicity:** easier to manage and implement.
- **Cost-effective:** low-cost pre-existing approach.
- **Reliable:** proven methodologies.
- **Regulatory/Security:** reduced regulator and data risk

Question: Please explain why it is most important for your RTSM system? Base: All respondents (n=59). [1]**Note:** for all verbatims see slides 28-29.

The participants shared ideas on how RTSM systems can evolve to better address the complexities of modern trials:

- **By pushing additional screening data into the electronic case report form (eCRF).** Pushing real-time screening data into the eCRF, so clinicians can see it, can help sites.

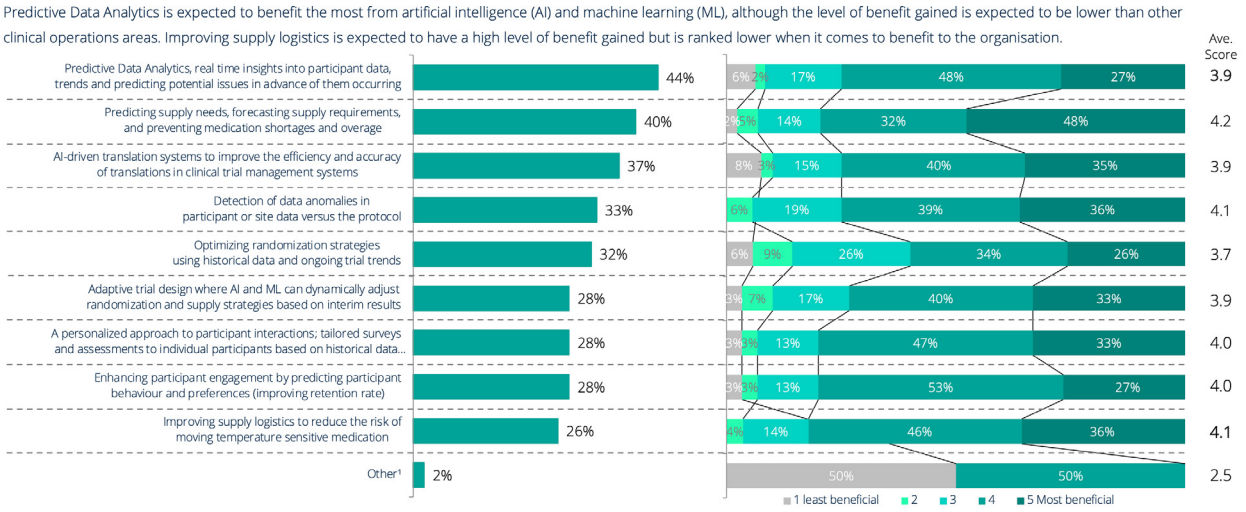
> "Can they push some real-time data into our eCRF so our clinicians can get a peek at it? This would be one area, at least from an operation standpoint, that would make it easier for our clinicians to feel good about the patients that are coming in."
>
> *Kara MacGowan, Pfizer (Seattle Genetics)*

- **By having a workflow application in the RTSM.** Because of the complexity of the workflows in a clinical trial, functionality within the RTSM to help manage the workflow would be of great value.

> "Having a workflow application in the RTSM . . . which brings everything together in an interface that makes it easier and more intuitive, would be a great benefit."
>
> *Asma Kasuba, Johnson & Johnson*

- **By providing accurate data to data science teams.** Daoying Hu, Director, Data Science & Digital Health, Johnson & Johnson, said a challenge for data science teams is conducting analysis on the local level. Ideally, data science teams will be able to use data to make site-level predictions about the future based on actual enrollment data. But this isn't always possible.

> "We have a baseline, but we try to use actual enrollment figures . . . to predict the active sites . . . and to give additional insights to our supply team."
>
> *Daoying Hu, Johnson & Johnson*



Question: Which clinical operations areas will benefit your business the most when considering artificial intelligence (AI) and machine learning (ML)? (Please select all that apply) Base: All respondents; multiple answers permitted (n=109). ¹Other: No comments.

Question: On a scale of 1 to 5, with 1 being least beneficial and 5 being most beneficial, please rate the level of benefit gained from artificial intelligence (AI) and machine learning (ML) for the following clinical operations areas: Base: All respondents, multiple answers permitted (n=109).

As Citeline research data shows, predictive data analytics is seen as the clinical operations area that is expected to benefit the most from AI and ML, followed by predicting supply chain needs, forecasting supply requirements, and preventing medication shortages.

- **By better integration with interactive response technology (IRT).** Issues with IRTs related to RTSM systems are that they aren't designed to capture all the necessary information and don't necessarily integrate well.

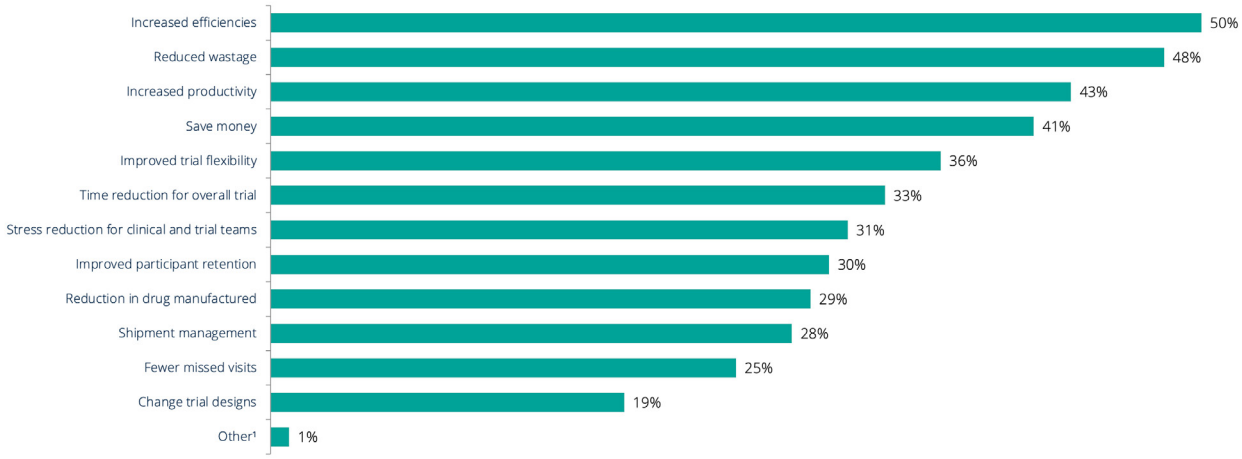
> "We should make our IRT systems flexible."
>
> *Anita Zagaja, Bayer Pharmaceuticals*

> "An IRT system is not designed to capture all data points. Rather it is designed to capture data points needed for patient/subject enrollment, screening, randomization and dispensation and accountability. Anything more requires customization. We do customize when needed using our integration team."
>
> *Mia Carter, ICON*

> "We do try to align with study teams in collecting this data and then integrating; integration is a big part. We use many systems . . . and have to go into different systems to collect the information we want. Unfortunately . . . I don't know or foresee . . . where we would have just one place to get a report. I think we have to get used to going to all these different [systems] to get information."
>
> *Anita Zagaja, Bayer Pharmaceuticals*

AI-Driven Forecasting

Among survey respondents, the main benefits of AI-based drug supply forecasting across the clinical trial process were increased efficiency and reduced wastage.



Question: Where can AI technologies linked to drug supply forecast impact your clinical trials from drug manufacturing to supply chain? (Please select all that apply)
Base: All respondents; multiple answers permitted (n=109).

The participants were asked about the main benefits of AI-based drug supply forecasting as well as barriers to adoption in supply chain optimization. They focused on the challenges and barriers associated with adopting AI-driven forecasting. These barriers include:

- **Data validity.** AI is based on data. For any organization to trust and use AI, they must trust the validity of the underlying data, which is often not the case today.

> "My concern with predictive AI is the source of the data . . . where that data is derived from, the validity of that data."
>
> *Jacqui Cauble-Abogabal, Pfizer*

- **Confidentiality.** In order for data to be valid, there must be confidentiality from all data sources. Lack of confidentiality limits the ability to pull together data, which limits the use and effectiveness of AI-driven forecasts.

> "Confidentiality is the biggest barrier [to AI-driven forecasts] . . . Until we're able to preserve confidentiality while being able to pull . . . from a data lake that has all drug information across all studies, it's very hard to be able to rely on that drug forecast."
>
> *Dawn Sorenson, Daiichi Sankyo, Inc.*

- **Forecast accuracy.** Forecasts are most accurate in the short term, while accuracy decreases with a longer time horizon.

> "All of our forecasts are based on benchmarks . . . once the study is actually enrolling, we replace benchmarks with actual site-level trial data . . . we do some predictive modeling. Of course, it's most accurate in the closer-term window, like 30 days, but as we go out 60 to 90 days, it's less accurate."
>
> *Asma Kasuba, Johnson & Johnson*

- **Supply chain timing.** Forecast accuracy is lower when looking out 60 or 90 days. However, for supply chain teams, 90 days is not enough time to make certain decisions. Sometimes, human intervention is needed to override what the model is saying.

> "We look at what our local site managers are saying and what the model is telling us . . . and sometimes there is a conflict."
>
> *Asma Kasuba, Johnson & Johnson*

- **Silos.** Too often, there are too many silos—including data silos—which hinders the forecasting process and the supply chain. This can affect the validity of the data and the overall supply chain effectiveness. Cross-functional collaboration is essential.

Despite these barriers, the participants are hopeful about AI-driven forecasting. However, human involvement in the process remains essential.

> "AI data is excellent, but the human aspect is important."
>
> *Jacqui Cauble-Abogabal, Pfizer*

Next-Generation Solutions

Participants were asked their thoughts on innovations that would be most likely to redefine trial management. They didn't mention specific technologies or types of innovations—instead, they focused on **innovations that can reduce complexity and improve integration**.

> "How do we make it easier for participants to participate [in trials]? . . . How do we reduce the burden on sites, based on everything we are asking them to do? How do we use technology to simplify it even further? . . . How do we reduce that complexity and simplify the technology while still supporting the endpoints that are needed for outcomes?"
>
> *Gillian Livock, Evinova*

Some participants believe standardized terminology is essential for clearer communication among stakeholders, reducing the risk of misinterpretation and enabling more reliable and accurate clinical outcomes. Adopting standard language could also streamline regulatory submissions and approvals, potentially speeding drug development.

However, there was skepticism regarding the industry's ability to voluntarily establish and adopt these standards without regulatory enforcement from an influential body like the FDA. Despite this, several participants expressed optimism that the industry could proactively come together to develop practical standards, recognizing the shared benefits of improved integration and data sharing.

> "There is a need for standard terminology . . . as an industry, we have to agree on that."
>
> *Mia Carter, ICON*

> "How do we as an industry drive that?"
>
> *Doug Cookson, Perceptive eClinical*

> "Until a regulatory agency like the FDA requires it, no one's going to use common terminology . . . people are always going to opt out unless there is a regulatory reason why it has to be the same way."
>
> *Dawn Sorenson, Daiichi Sankyo, Inc.*

> "I do believe there's a will . . . I do believe companies, and pharma and the vendors, need to come together willingly to set standards."
>
> *Mario Papillon, Perceptive eClinical*

There was hope that standards could lead to greater integration, data sharing, and use of open source tools which could accelerate trials. However, some were skeptical.

> "It may not be one solution, but how do you get this capability [to make it easier for participants to participate in trials]? By seamlessly linking all those point solutions together."
>
> *Gillian Livock, Evinova*

> "A lot of technology companies decide to start open source coding . . . and you can see that in the acceleration of technology in the last five to ten years. If pharma was willing to do the same . . . I think it would accelerate."
>
> *Mario Papillon, Perceptive eClinical*

While industry-wide standards may be lacking, there are examples where site networks are working together, which at least results in technology standardization.

> "There's an interesting stat that just came out: 20% of all phase 3 studies are using a site network or an SMO. So those folks are standardizing their technology, their infrastructure; they probably have a more mature operation on the tech side of things."
>
> *Matt Cocking, AG Mednet (a Perceptive MI partner)*

Measuring Success

The participants discussed metrics or KPIs to assess the effectiveness of next-generation trial solutions.

Hu said: "A lot of old metrics still apply." Traditional metrics include cycle time, productivity, and cost. However, while metrics in the past tended to emphasize speed, more attention is being paid to cost metrics.

> "We've started to talk more about cost . . . the cost of failures, metrics like per patient startup costs. There are new metrics we didn't see in the past."
>
> *Daoying Hu, Johnson & Johnson*

Another area receiving attention is diversity measures. However, some diversity data is not necessarily data for clinical research purposes, but to understand the site.

> "You look at diversity within clinical trials. Measures of diversity include gender, race, socioeconomic."
>
> *Doug Cookson, Perceptive eClinical*

> "We weren't capturing diversity data up until three, four years ago."
>
> *Jacqui Cauble-Abogabal, Pfizer*

> "For newer studies, we have diversity metrics . . . it could be the total diversity percentage we want to achieve . . . which are racial and ethnicity targets . . . We also use social determinants of health in clinical planning and execution; we are diving into non-medical data. We are looking at transportation, insurance, education, language to give more of a sense around the catchment area of selected sites."
>
> *Daoying Hu, Johnson & Johnson*

> "An observation: it sounds like the diversity action plans are still top of mind."
>
> *Matt Cocking, AG Mednet (a Perceptive MI partner)*

Future Collaborations

Participants have interest in collaborations, but also see barriers. One challenge is greater cooperation and collaboration within organizations, which requires alignment around clear goals.

> "All parties should be involved sooner rather than later by sharing an end goal and what we want to accomplish—collaborators help us get there."
>
> *Mia Carter, ICON*

Regarding external collaborations, there is hope that standard language and greater integration will make data sharing easier. However, while organizations state their desire to share data, when the time comes, they are often reluctant to do so.

> "Everyone says they want to share. They all want to have a common dataset. It's all great, rainbows and butterflies. But when push comes to shove, it's all about proprietary information . . . in totality, each company is not sharing."
>
> *Dawn Sorenson, Daiichi Sankyo, Inc.*

Other participants agreed with Dawn Sorenson's comment about professing a willingness to share, but not really being open to sharing.

> "I think there is a lot of interest . . . but when push comes to shove, how do you actually do the sharing?"
>
> *Kara MacGowan, Pfizer (Seattle Genetics)*

CONCLUSION

While conducting clinical trials is extremely complex—due to all of the operational, supply chain, and regulatory requirements—eClinical technology and RTSM are leading to operational improvements and are prompting the pharma and biotech industries to rethink strategies, tools, and success measures.

Despite various barriers to adoption and use of AI and other technologies, industry leaders see greater potential in technology to improve and accelerate clinical trials.

Greater collaboration across industry stakeholders will be essential to overcoming these barriers. By aligning on common goals, sharing best practices, and working toward standardized terminology, organizations can enhance communication, streamline regulatory processes, and accelerate innovation. The collective commitment to collaborative solutions will be crucial for translating technological advancements into tangible improvements, ensuring that new treatments reach patients more effectively and efficiently.