

# How Merck Uses AI to Improve Clinical Research

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**Steve Odland:** [00:00:00] Welcome to C-Suite Perspectives, a signature series by The Conference Board. I'm Steve Odland from The Conference Board and the host of this podcast series. And in today's conversation, we're going to talk about how AI is transforming clinical trial design, biomarker discovery, and precision medicine.

Joining me today is Jennifer Sheller, the senior vice president and head of global clinical trial operations at Merck. Jennifer, welcome.

**Jennifer Sheller:** Thank you. Pleasure to be here.

**Steve Odland:** This whole introduction of AI to the pharmaceutical development process is relatively new, but for our listeners who may not be familiar, can you just kind of highlight how was it done before? And then how does AI now change that?

**Jennifer Sheller:** Sure. So I'm in the clinical trial operations space. I'm head of our organization for Merck, where we're essentially the group that's leading the design and delivery of clinical trials. And I would say [00:01:00] AI is a journey, a continuous journey for us and peers in our industry.

This has been a sector that's been very lagging in modernization. It's a very risk-averse, conservative environment. It's heavily regulated, lots of standards, et cetera. So the way that we're approaching it, at least in the operational side, is really looking at our ways of working, ensuring that they're fit for purpose, aligning with—we actually have new regulatory guidance that actually encourages focusing on working in a risk-proportionate manner, really reducing burden.

So we're bringing together the mindset of Lean Six Sigma, the tech enablement, and then those clinical research experts all coming together to evaluate our processes and ways of working. So where we can apply not just AI, but also automation for repeat activities as really levers to move things quickly and help with quality, as well. Taking a lot of the manual steps and burden out of the [00:02:00] system.

**Steve Odland:** So before AI, I presume the process was a lot slower to advance these drugs through various clinical trials. I presume AI is intended to speed that up, yeah?

**Jennifer Sheller:** Definitely accelerate, accelerate insights. And really the first step I would say is making sure your data is ready. So we've spent the last few years strengthening our data foundation in a program, what we called is zero gravity.

It's really like lifting the heaviness of the spaghetti architecture and the point-to-point connections across many different systems that are connecting data for clinical trials, which has led to a lot of fragmented data collection, repeat data collection. Then you have to reconcile that across the system. So we spent the last few years with that program. And then our next level is really bringing all of that data, that data's in a single harmonized environment. But now we need to optimize.

So we're building an AI-enabled semantic layer, which will allow for [00:03:00] accelerated data acquisition to consume across a lot of diverse sources, modalities. Reducing the time and effort it takes to turn data into decisions, essentially. So I think we can't skip over the data readiness and the data foundation layer to really enable the best of AI.

So that's sort of an in-flight activity. While we're also, we have multiple use cases I can share about AI for acceleration, identifying patients quicker, and running our operational processes more efficiently and effectively.

**Steve Odland:** AI is just such a new frontier. It's a new thing. You can't pick up the newspaper these days without seeing something about AI hallucinating or doing something crazy. I don't know if the story, the stories are fun, but how do you quality control the use of AI through this process?

**Jennifer Sheller:** Yeah, I mean, so for us, human in the loop is essential. We are in a regulated, good clinical practice environment [00:04:00] where patient safety and data integrity are paramount to secure. So leveraging AI to give first draft of documents to develop meeting minutes, as an example, which may sound trivial, but that's a lot of that documentation is required. And teams spend hours every week documenting how we're doing our quality controls and oversight so that when the regulators come, we can show our compliance to all the regulations.

When you think of regulations, we have not only global standards, which can be 60 to a hundred pages of ways of working globally, but then clinical trials are not done in just the US or just one country. We run in, typically, 20 to 30 countries for a given clinical trial. So you also have to then follow the rules from the global level to the country level. And then

you're dealing with healthcare institutions around the world, each also having their own set of requirements. So it's a complicated ecosystem that you have to manage with human in the loop.

But leveraging AI to bring forward, again, first drafts of things. I think [00:05:00] automation is also a great opportunity on repeat tasks. And then we're spending a lot of time in the trial-matching space to identify potential patients for clinical trials, which is a nice efficiency to find those precision medicine patients. The needle in the haystack, we like to say, of sort of more the rare patient populations who have a specific mutation.

But we are using, working with partners on AI to really comb through those electronic health records and all that unstructured data to identify those patients, versus nurses and doctors and teams at healthcare institutions spending hours on end to try to find a potential patient. So it's a blend of activities and opportunities.

**Steve Odland:** So it sounds like AI is really helping in improving clinical trial quality and patient safety. Is that fair?

**Jennifer Sheller:** Yeah, I would say the focus now, like one of our biggest use cases is the trial matching. So that's more so finding potential [00:06:00] patients for clinical trials. When you look at a clinical trial today, about 20% of the sites—we call them sites—they're the healthcare institutions that are activated.

And it takes a lot of work to get a site activated, because you have to send someone in the field to validate they have all the equipment and resources. The team there then needs to go through all of the ethics reviews and committees. We have to negotiate a contract and budget. It takes months. So going through all that, 20% of sites don't end up putting one patient in a clinical trial.

Leveraging AI, where we can use better insights on data, internal and external, is an area that has existed in our industry. And it's one we're certainly using, but we're building upon that to really couple that data insights, internal and external data, with a customer relationship management platform so that we can work end-to-end across all the different roles in clinical trials and not just have this potential site list. And then you kind of end up working in Excel and other ways to see how [00:07:00] you're going to follow up on that.

But having an end-to-end solution platform, this is something that we're building now. And I'll be ready in a few months, where we can take those AI-driven insights and build it into ways of working so that it's streamlined across the workflows, and the roles.

**Steve Odland:** So how do you prepare your workforce for this? Because it's one thing to introduce a tool, and IT, the CIO/CTO, they put it up, they've turned it on, and away you go. Except you don't, because people then have to figure out how to use it, where the guidelines are, and all that. How do you do the whole implementation with people?

**Jennifer Sheller:** Yeah. And I think bringing your workforce to elevate the business

problems. Like last year, I said to the team, "Guys, we need to do better in our inactive site percentages. You know, it's an industry problem, but it's something we can't accept." And so I said, how can we leverage AI to do better in this space?

And then they took it to that next level of building this customer relationship management platform where they're defining the [00:08:00] barriers and the solutions needed. And it wasn't all AI-driven in there. So I think bringing your workforce to help shed light on the business problem, but being as part of the solution.

But I've had to really integrate more technically minded folks into the problem-solving arena. So IT is a very strong partner for us. We've built in operations a centralized hub. It's an AI automation hub, so that we can have these business problems coming through and a team of experts who are well-versed in the technology to help problem-solve with the business and build solutions that will make their life easier, make work more efficient, get out of manual Excel trackers.

And we invest a lot, too, in teaching. So we have a foundational set of courses for people to have a common framework of understanding data, data models, and the principles of AI. And we have built different levels, beginner, intermediate, advanced. And then, we've also built a group of subject matter experts to [00:09:00] cascade the knowledge of not just AI, but also automation tools so more problems can be solved with those who understand the technology component. And then we'll continue to build on that.

And we share. Every month, we have different teams coming forward with solutions that they put in place that have solved their ways of working, reducing the administrative burden, and providing insights faster. So they'll share practical use cases that we catalog and that they can learn from.

And I've been on meetings where I've heard folks say, oh, I attended the tech forum last month, and I saw such and such, you know, use Power Apps to automate how we manage patient slots for early-phase clinical trial. And so I typed in a Copilot app to ask how to do it and repeat exactly what they're doing. So it sort of catches on.

And then the next wave is you have to look at it more enterprise-wide. And so, I've tasked all of our process owners to come together. We're working to digitize our [00:10:00] processes so we can better visualize it and where there's opportunity, but also, as they say, redesign the factory floor. And really relooking at our processes. Are they fit for purpose? Are there things you could delete? Do you have redundancy in roles? And where can you automate and leverage AI to get the same impact that you're working towards in this process?

So, I've had a call for action for like our five largest processes that we're tackling right now. And we've hit one, and the others are sort of in queue. And that's really the incremental way of doing this while you bring your workforce to the table and being a part of the journey.

It's not easy. We have people who struggle with using tools like Excel. I was just at a site conference over the weekend, and I think in the healthcare provider arena, that's a real gap out there. The digital acumen and just even on basic tools that have existed for quite a long time. So, the learning curve and the journey, we have to just tailor it to all the different levels of expertise and knowledge out [00:11:00] there.

**Steve Odland:** So Jennifer, we're talking about these digital health platforms. Where do you see them going? What are the new emerging technologies?

**Jennifer Sheller:** There's a lot of opportunity. I think we've only really scratched the surface on things that we can scale. Of course, there's great opportunity with generative AI and document authoring.

There's also great opportunity in the digitization of our protocols in clinical research, which is now a new foundation through our ICH framework, through, it's called M11. I think this is going to be an incredible opportunity to have standards and how protocols are digitized so that we can begin to automate all of the downstream, cascading setup activities and documents and systems that the protocol is the foundation that everything depends on. So this is a new piece to our regulatory framework, and sponsors are now working to build this and adopt it. We'll be ready in the next two months or so to go forward. But I see [00:12:00] this as a great opportunity.

I also see AI as an opportunity to help us with quality, with next best action, for across roles, to really give us insights on where we have outlier data, compliance issues. We have many different data sources in a clinical trial across different vendors. So, instead of having to reconcile across or uploading, downloading things, to really have more real-time insights for faster action for our teams, which ultimately is for patients and can help improve the quality of clinical trials.

**Steve Odland:** And something you said before, I think is so important, and it's probably true outside of pharmaceuticals. But in the AI process, in the implementation process, you have to have a human hand at juncture points, just to make sure that everything is going right. How do you quality control for that?

**Jennifer Sheller:** Yeah, and so we've just started with, it's called a GCP governance, where teams will bring forward—we, of course, have the AI [00:13:00] assessments that most companies have, and we also have a data privacy assessment.

But we have a framework and a governance to support teams on helping to define how you validate, continue to validate the AI model, how you validate the output, and refine the ways of working. And what level of QC coming in and out, really depends, I would say on the level of risk the activity is managing in a clinical trial.

For more operational type of activities, like managing recruitment rates, and driving more speed to where you need to follow up on operational delivery is, I would say, lower risk. In areas where you have signals on safety monitoring and quality indicators, you absolutely

need that clinical mind, that scientific mind, and the person who has the good clinical practice expertise to interpret that signal and understand what action to take.

But also, having transparency is really important on how the models are working, what they're pulling from, and just making sure that there's a [00:14:00] continuous improvement and assessment of how it's working.

**Steve Odland:** We're talking about how AI is transforming clinical trial design. We're going to take a short break, be right back.

Welcome back to C-Suite Perspectives. I'm your host, Steve Odland, from The Conference Board, and I'm joined today by Jennifer Sheller, the senior vice president and head of global clinical trial operations at Merck.

So we talked a lot about how AI is used in the process. Let's shift to the whole area of ethics and equity and responsible innovation. I'm not sure many of our listeners really understand how important that is and how cherished it is through the process. Maybe share Merck's philosophy on that.

**Jennifer Sheller:** I mean, there's a long history of regulation, ethics, and guidance in conducting human research, in clinical research. So already, of course, we have [00:15:00] very comprehensive data privacy rules and guardrails in place as we're managing patient data every day.

And we're also under the guardrails of regulations around the world. In the US, of course, you have HIPAA, you have GDPR in the EU for data privacy, patient privacy, and our international guidelines. So, there's already, I would say, very robust guardrails and controls in place to protect patient privacy and patient data.

**Steve Odland:** And so, the frameworks are not related to AI. I mean, the frameworks are in place, but as you introduce AI as a tool to use in this process, those frameworks are, I'm sure you're updating those frameworks and making sure that they're most useful and relevant given, the procedural differences, right?

**Jennifer Sheller:** Yeah. And I would say that the existing frameworks really apply in a technology-agnostic manner. And I would say where we need to double down on where we need [00:16:00] to re-consent, or continue to get new consent from patients is where you have materially new purposes and risks inherent with the data usage related to AI.

Today, there's a lot of technology and systems prosecuting on that data, with the controls in place. Our AI models are, internally here, are bound within our company. We use Copilot. It's sort of our citizen tool, our AI thought partner. And that's maintained within the bounds of our organization. And as teams are assessing patient data and using it in the AI models, then they would come forward with a framework where we would evaluate if additional steps are needed, if it's covered under the existing privacy rules and the patient consent.

So I think for me, it's really where we go beyond the technology bounds that we have today. And use of the data maybe for new models, or different use cases for that type of data, is where we need to think about consenting patients and providing different guardrails.

**Steve Odland:** So as you think [00:17:00] about Merck's responsibilities around ethical standards, and now, you've had these frameworks, you've had these standards forever. How, when you introduce the whole digital nature of the work, how do the ethical standards apply to digital health?

**Jennifer Sheller:** Yeah, I mean, trust from a patient perspective is really essential. And transparency. So, whether you're deploying AI or wearables, which has, I would say, slower adoption in clinical trials, but probably more of that to come. We need to make sure we're transparent with patients that we have duly provided, informed consent.

We also need to ensure that we're not over-collecting data, really ensuring that the data is fit for purpose. And just really having our obligation beyond even what the privacy regulations require, to make sure that we're using data that's really fit for purpose and essential to the research at hand.

And I think the other component, from a company standpoint, is making sure [00:18:00] you have some governance, that you operationalize ethics through a governance model, where you have a core set of principles, but you also have a way to oversee it and guide and direct teams, especially in this era of AI.

**Steve Odland:** Yeah. And HIPAA's been introduced and now been part of the whole medical scene for a long time. How does HIPAA apply to this?

**Jennifer Sheller:** Yeah, well, HIPAA is the privacy rule that covers the US patients. So when a patient signs up for a clinical trial, they're providing their authorization to use that clinical trial data for the research purposes, to have access by the sponsors, the sponsor delegates, the IRB, and ethics committee. And then you have similar frameworks across the globe, as you know, GDPR would sort of be the other one. But HIPAA's been part of clinical trials since HIPAA came about. It became a supplement to the informed consent form. And then you have different requirements, or privacy consent requirements, around the globe that we have to [00:19:00] adhere to. And for us, you know, we have teams that sit in offices in 50 countries around the world, and they're experts in the local regulations and making sure that we're following suit.

And from an AI perspective, I think the EU has been the most advanced in having clarity on regulation there. And I know there's been some guiding principles released otherwise, but that's really helped us shape our governance and ways that we are looking at AI governance across our teams.

**Steve Odland:** And AI really adds complexity, I would think, to the regulatory frameworks

because it's, in some ways, it kind of takes it out of the human hands. Going back to the point that you made earlier about how important it's to have the human hands in it. But when you're automating stuff, you got to make sure that input, output through privacy, all of the pieces of it still comply to all the rules in every country.

**Jennifer Sheller:** That's right. And prove it, right? With evidence. And I think we're really in the early stages here. Inspectors are asking, how are you using AI in [00:20:00] your trials? How are you ensuring human in the loop, and the oversight, and the proper methods to ensure quality?

But you know, as I mentioned earlier, there's a few cases that are scaled, and we're really just scratching the surface. So this is going to become a more prominent topic that we're really going to have to double down and ensure that we have those answers upfront, before we get going, and that we're clear and have continuous quality-control checks.

I think, when you think about clinical trials today, you collect data in your electronic health record. Your healthcare provider writes in how you're being treated, your care, your adverse events. And then from there, we have double data entry, because then you have to have that same healthcare provider or delegate then figure out, what do I pull from my electronic health record into the electronic data capture for the industry, for the clinical trial? And that's, it's kind of crazy that that's where we are today.

But you can imagine in the world of EHR, where the structured data is, people have already [00:21:00] figured out how to map that over into the electronic data capture. But now the opportunity is, I would say, with AI, natural language processing, and moving all that unstructured data, all those notes in the charts, where you have some of those adverse events and other important data points, and figuring out how to leverage AI to move that data over to the clinical research ecosystem.

And from there, I think that's really where we're going to have to figure out this framework from a privacy standpoint, because we really haven't, in this industry, done a whole lot of transferring directly of the health records into our systems. There's only been a few pockets of it here and there on things like lab data and vital signs, some of the easier map data. But to me, that's really a big area of opportunity. And it's also going to be a big area that we're going to have to align globally on, on the controls in place for that.

**Steve Odland:** A lot of companies outside of pharma are struggling with their AI implementation because their employees tend to [00:22:00] not be really schooled on it or not be disciplined. And so their IP is getting out beyond their firewalls and into the competitive environments, and people are losing their IP as a result of that.

So, it just sounds like, this has to be, in your world, all of this use needs to be completely buttoned up. It's not like you can look at paper logs or hard drives within a controlled environment when you're dealing with all of these automation and software tools. It's got to be really challenging.

**Jennifer Sheller:** Yeah, and we are fully firewalled in that regard, but it's really great for our teams, right? Like we have Microsoft Copilot, which takes our team, some of my team members describe them as being gen 2.0 with using Copilot and just taking some of the manual activities out of the system. But it's fully firewalled. We have our own sort of GPTeal, we call it, the Merck teal, generative AI, you know, Copilot, that combs through all of our documents and systems and where you can easily [00:23:00] pull out, is there a process on this? Give me a reference.

And so we've given a lot of tools and support for our teams. But then it's, clinical research is a very busy space. Many industries have their workforce very busy. So it's really, what can you take out of the system to allow your employees to pause and learn? Versus you just keep adding, and people get stressed when you have change.

And so you really have to be disciplined on taking meetings out of the system, taking extra to-dos out of the system so you can free your workforce up to really focus on enabling them to be upskilled and learn and apply. I think, most importantly, is requiring people to actually apply the AI technologies into their work.

**Steve Odland:** So just, final thoughts here. How do you see the future rolling out here? Future, I don't know how far you can see, but for at least the next few years. Between rapid innovation and ethical guardrails and the implementation of AI, all the stuff we've talked about, where's it going?

**Jennifer Sheller:** I mean, it needs to start with a clear [00:24:00] value proposition. Innovation should begin with clear, evidence-based rationale that demonstrates the potential impact in our world for patients. So the value piece has to be clear, and safety and ethics can't be an afterthought. It's got to be built in with our ways of working, which means we have to be more principled on risk assessments, on the human oversight, across all of our innovation.

And I think it's important that, all of the innovation models here, you need to have the people who have the domain expertise, the technical expertise, and those, perhaps with an expertise in patient privacy. And for me, I've also added my Lean Six Sigma group into the mix, so we're keeping things fit for purpose and removing the waste.

This evolution is really forcing us to really reevaluate our ways of working and where we can simplify. So I think it's a great opportunity. It's proceed, proceed fast, but proceed thoughtfully and governed, and make [00:25:00] sure that you're not just leaving your teams hanging out there to figure this out themselves.

**Steve Odland:** Yeah. Wow. Got a lot going on here. I know that our listeners will be incredibly impressed with the progress that you all have made and how you use all of this.

Jennifer Sheller, the SVP and head of global clinical trial operations at Merck, thanks for being with us today.

**Jennifer Sheller:** Thanks so much. It's been a pleasure.

**Steve Odland:** And thanks to all of you for listening to C-Suite Perspectives. I'm Steve Odland, and this series has been brought to you by The Conference Board.

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