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My expectation is that AI should shave years, not months, from drug development timelines

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As chief development officer of Moderna, Dr Melanie Ivarsson OBE spearheaded the rapid development of a COVID-19 vaccine that helped the world emerge from the pandemic. Now back in the UK and drawing on over 25 years of clinical development leadership across Lilly, Pfizer, Takeda, and Moderna, Dr Ivarsson recently joined the scientific advisory board of PhaseV, an AI-driven solutions provider for the clinical research industry. In an exclusive conversation with PharmaBoardroom, she gives her insider take on the true potential of AI to reshape the drug development process.

What has changed in how medicines are developed since you started in the pharma industry around the turn of the millennium, and what challenges persist?

When I started out, the process for monitoring drug products, ensuring quality, and collecting data was incredibly manual. Everything was done on paper, using three-part NCR forms. We would assess how the data was being collected, monitor it with sticky notes, strip out bits of paper, and send them off. Then, the data would be manually entered into a database.

The first major change occurred 20 years ago, when electronic data capture was introduced. This innovation promised to significantly speed up the process by allowing direct data entry into databases, although this revolution has not materialised and it still takes about the same time

today to lock a database with electronic data capture as it did with manual data entry.

The next major shift, which is happening now, is AI. Today, we have real-time access to trial data, which allows us to design trials more efficiently and make adjustments in real time as needed, improving both data quality and patient experience.

However, while these technological advances are impressive, the challenge is in incorporating them into our processes in a way that truly enhances outcomes. The industry tends to be risk-averse, focusing on maintaining the highest possible quality, which is obviously vital. But this cautious approach can stifle innovation.

AI should be viewed as a team member. It shouldn't be feared or double-checked at every step; instead, it should be integrated into the process. This is where we're likely to see significant progress.

Where do you see the greatest levels of optimism and fear towards AI within pharma?

Right now, we are seeing a very enthusiastic approach from senior executives. They understand the impact that AI will have on every part of drug development, from research and compound discovery to development and commercialisation. It's a heavily regulated environment, though, so regulators need to help companies navigate AI's integration, and we're starting to see progressive signals from bodies like the US FDA and UK MHRA.

However, the real challenge lies in implementation. While senior leadership is on board, there's often hesitancy further down in organisations, especially if adopting new technology could slow things down. Speed tends to be highly rewarded, and if employees are unsure whether AI will assure quality or risk delays, they become concerned.

That's why it's so important for leaders to communicate effectively within their organisations. Leaders need to stay closely connected with their teams and make sure the message is understood and embraced. You can't simply throw new technology at people and expect it to work without proper guidance and support.

How would you attempt to ease the anxiety around AI use for those who fear it may be coming to replace them?

As I mentioned, we need to treat AI like a team member. Companies like PhaseV are taking vast amounts of data – far more than any individual could ever process – and turning it into actionable insights. This enables smarter, faster decisions and allows people to do their jobs better.

Almost everyone working in clinical development feels there's more to do each day than there are hours available. AI helps address that. It is not about replacing people; it is about empowering them. For example, PhaseV's dashboards give teams the data they need in real time to make the right decisions and move faster.

When we were developing the COVID vaccine at Moderna, we tried to build some of that functionality manually, with updates twice a day; morning and evening. The first thing I would do each morning was turn on my computer to check the dashboard and see what actions we needed to take. Today, platforms like PhaseV automate that process and deliver continuous, real-time analysis, meaning less time pulling data together and more time thinking, collaborating, and making the right decisions as a team.

With several companies in the AI/drug development space making big promises and raising hundreds of millions of dollars, why did you choose to join the PhaseV advisory board and what differentiates their offering?

In a crowded marketplace, PhaseV stood out because of its team. In my initial conversations with CEO Dr Raviv Pryluk and other members of the leadership team, their conception of innovation and of the customer were really striking.

They respect the roles of different team members within an organisation. Rather than creating a technology and handing it off, they've developed a tool that can be used differently by each stakeholder, whether that's a clinical operations lead, a clinician, or a statistician. They are also very humble about what they don't know, asking the right questions and listening to people who have firsthand experience.

Then there's the pace of innovation. The speed at which they're working and attracting interest from major industry partners is phenomenal. And what they're creating is genuinely what customers need: something straightforward to use, that improves day-to-day work, and ultimately makes teams more effective.

Finally, the passion the team has for making a real impact on healthcare was very compelling. That combination made it an easy decision for me, and I was genuinely thrilled to join their advisory

board.

Many of the major roadblocks to improving the clinical trial process are quite prosaic: staff turnover, infrastructure gaps, patient mistrust, and lack of information. Given this, are we at risk of over-promising what AI can truly deliver?

There is always a risk of over-promising with new technologies. The move from paper case report forms to electronic data capture 20 years ago was supposed to revolutionise everything, but it fell short because we didn't fully embrace the opportunity or adapt our processes.

AI is another inflection point for the industry, but its impact will depend entirely on how it is implemented and adopted. Additionally, AI will not solve every problem. Issues like patient pathways, staff shortages, and infrastructure will require other types of solutions.

That said, AI can have a huge impact if it is integrated effectively. We're already seeing major investments in the hospital and healthcare sectors. What's crucial is collaboration across stakeholders: industry, regulators, hospitals, investigator sites. Too often, silos slow progress, and right now there's something of a race between companies and sectors to adopt AI quickly. The real success will come from working together, sharing data, and improving processes in a way that benefits patients.

What lessons could pharma learn from Operation Warp Speed - a period of unprecedented collaboration at a supercharged pace - as it attempts to embed AI into the drug development process? When might we start seeing a genuine impact?

That period was really extraordinary: the best collaboration I have ever seen between industry and regulators, all working together for the common good. That spirit is something we should try to emulate with AI.

Looking ahead, I think AI will impact every stage of the development pathway. In drug discovery, we should see far better "shots on goal," with compounds that are more on target and less likely to fail later.

Data will be critical. Federated and curated datasets will allow us to train models effectively, for example learning from everything that has been done in a particular disease to design the optimal trials of the future. There are still gritty operational processes - contracting, study setup, physically

getting drugs to sites – that AI may not solve immediately, but even here we see progress. AI tools in the legal sector suggest contracting timelines could shrink from months to days, provided people are comfortable adopting them.

My expectation is that AI should shave years, not months, from drug development timelines in well-identified areas, through optimised trial design, smarter site selection, and better real-time trial execution. What we can do with the data once it is collected will also be transformative, providing insights for rapid improvement. And with regulators beginning to commit to using AI in data assessment, approval timelines should also shorten. Taken together, I see this as the next major inflection point for the industry.

Are there any therapeutic areas where you are particularly optimistic about AI's ability to move the dial?

I think AI will apply across all areas, but will have a particularly strong impact in those where we already have large amounts of data. For example, around 40 percent of clinical trials are in oncology, and there have been huge recent advances in Alzheimer's research, metabolic diseases such as obesity, and in vaccines and infectious disease. These are also priority areas for governments because of their societal costs. Alzheimer's, cancer, and metabolic and cardiovascular disease are clear targets for AI-driven impact.

But where I see enormous potential is in rare diseases. AI could speed up trials significantly, for example by analysing natural history or control data in ways that currently take months of manual chart review. With the right applications, this work could be done much faster, which would be incredibly impactful for rare disease communities.

Having had a long career in big pharma, and now working adjacent to that world as a scientific advisor, how have you found the transition? What kind of impact are you hoping to have in this less hands-on role over the next few years?

Over the past six months, I've taken the time to step back and look at the industry from a completely different perspective. When you are in a day-to-day leadership role, so much of your energy is taken up by managing people, timelines, and operational details. Now, I'm enjoying the chance to look at the industry from different angles.

I feel I've adjusted well, and what excites me most is identifying where the next big investments will be and how people need to work together. Collaboration – around new technologies, partnerships, and implementation – is going to be the key to progress.

Stepping back has given me the privilege of a bird's-eye view. I've had some amazing conversations with inspiring people that I wouldn't have had otherwise, and I'm very grateful for that.

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