



# MACHINE LEARNING IN DRUG DEVELOPMENT: A Conversation With GNS Healthcare's Iya Khalil



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► By Laura Helbling

**SUPERCOMPUTING COULD MEAN MAJOR PROGRESS FOR pharma** – particularly when the machine can predict interventions.

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GNS Healthcare Co-Founder Iya Khalil uses machine learning to reverse engineer huge amounts of data, in a way that can help speed and improve advances throughout in pharma R&D and beyond.

“I can actually do what/if simulations and simulate the impact of the intervention, simulate what happens if I have a drug on or off in that patient and maybe if that patient had lower levels of a certain molecular readout they would have responded better, or if that patient had a certain genotype they would have responded better,” Khalil said in an interview at the BIO annual meeting in San Diego. “So essentially we take these massive amounts of data and we reverse engineer or learn the causal models underlying that data and it’s machine learning because we’re using high performance super computing power to learn those models.”

GNS works with health plans, health systems, pharma companies and disease foundations – they recently announced June 19 a collaboration with Genentech to leverage machine learning for the development of novel cancer therapies.

Khalil said in an interview that that collaboration was spurred by Genentech’s investment in collecting datasets – both genomic data, aggregated clinical data, and health record data, as well as data from their own trials and collecting tumor and patient samples. “This is great because now we can actually observe what is happening in these patients on a molecular genomic level as

well as a clinical longitudinal type level,” Khalil said. GNS’ causal machine learning engine can learn how a given system is configured and determine the right intervention.

The “engine” can be used on the R&D side – and also on the commercial side. “As the patients use the drug, data is generated on the drug, and so we might notice that even though the drug was FDA-approved and now has a reimbursement formulary of second line, actually there have been a bunch of people who are on existing first-line treatments and those aren’t working so well and maybe we should be putting the patients on this drug,” Khalil said.

## Using Real World Data

Khalil noted that the 21<sup>st</sup> Century Cures Act provides a “path to use those real world insights” but noted that the new information doesn’t have to necessarily go back to FDA. “It could be that a health plan now changes its formulary based on those insights,” she said.

Khalil discussed the challenges of crowded disease classes, like rheumatoid arthritis and diabetes, where it can be a struggle for payers in trying to determine access levels when there are so many treatments.

“Payers though still need that real world evidence to justify paying for some of the patients’ more expensive treatments,” Khalil said. “But I think that with the real world data what we can do is we can figure out which patients should get the more innovative more expensive treatment and so that patients who aren’t going to respond to them – we don’t need to give them that, we can give them other drugs that are already out there that are less expensive. I think that’s what the analysis of real world data with causal machine learning can help us figure out.”

Khalil argues that real world data is becoming as important as clinical data as real world data collection tools improve.

“I think those walls [of what constitutes clinical evidence] are kind of coming down because we can’t be blind to the fact that we are getting data outside of the clinical trial setting and massive amounts of it in ways that we’ve never seen before,” Khalil said. “It’s going to become our responsibility to use that data in a meaningful way for patients. We can’t ignore that. And so I see us evolving into a mode where real world data becomes just as important as the clinical trial data, and where we could use real world data – not saying it’s one or the other, they’re both important – but we could use real world data to help accelerate the generation of hypotheses that lead to better, well-designed trials.”

### **Real World Data Driving Value-Based Contracting**

Real world data can help quantify value in multiple ways, she said, such as identifying patients and biomarkers to determine who should get what treatment and “we can guarantee what the response looks like, X or Y,” she said. Khalil argues that pharma companies can more easily transition to value-based contracting models “because they know who to go at risk for and it becomes clear who’s actually getting value.”

Real world data can also help understand how drug costs fit in with the rest of healthcare costs. “If you were coming up with a new breakthrough treatment for a disease and for that entire cohort, other kinds of costs have come down,” Khalil said. “ER visits are going down; hospital visits are going down. Better quality of life, less sick days, then that will help you kind of see again the value of that versus everything else because right now we look at drug

costs like it’s this own independent siloed thing, not relative to everything else that’s happening.

Khalil acknowledged that collecting data remains a logistical challenge. “A biologist can’t wake up one day and go I want to understand endometrial cancer. And then here’s a data set, grab it, and start understanding and analyzing,” she said. “You actually have to do a study. Collect samples, get permission to combine it with their clinical records. So there is no world where all our data lays on some big giant cloud.”

She highlighted ongoing initiatives where individuals on drug therapy also have their information incorporated into a digital health app; such models could also include collaboration among pharma, patients and payers.

“I think that’s going to be a big part of the future of how we think about drugs so they’re not just getting used in isolation but they’re part of a digital platform that integrates things about the sort of total care and lifestyle,” Khalil said. “It could soon be that most of the data that we’re going to get on our health is not going to come from your interaction with a physician, it’s going to come from everything else that you do outside of that and all the digital tools that you interact with and platforms.”

Khalil doesn’t see a disparity of potential for larger vs smaller drug companies using artificial intelligence and machine learning. “I really think it’s about the leadership and the people at the leadership level understanding that the change is coming,” she said. “And how can they leverage that to be more competitive, how can they leverage that to create more value.”

*Published online 07/04/2017*