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STAT - Q&A: FDA wants to (computer) model the way to better, data-driven clinical trials

Strong data science is critical to getting a better understanding of clinical trial results — and perhaps no one understands that better than the Food and Drug Administration.

So the agency's Oncology Center for Excellence has harnessed computer modeling tools to help make better sense of clinical data — so as to help guide companies into developing better clinical trials. It's a collaborative effort, with FDA working with academia and other government agencies to help make sense of the jumbles of data that are presented to FDA.

We talked with Dr. Sean Khozin, who leads the division of oncology regulatory science and informatics at FDA. Here's the conversation, edited for clarity:

In what way is FDA interested in computer modeling for clinical trials?

From an oncology perspective, there are a lot of different ways of thinking about this. Using modeling and simulation, instead of doing a clinical study or a preclinical study, is directly connected to being able to collect data — and build a community that can analyze it and then build predictive models.

No single organization, or company, will be able to collect enough data to be able to build highly predictive models that can be used potentially for in silico clinical trials. So we're focused on building that community, and collaboration, to take us through that new world where all decisions are data-driven and quantified.

So does FDA have anything special to offer in this exciting world of data science?

We have a lot of data, and we have a very unique vantage point into the world of drug development. We know what's hype and what's not. So being able to have a transparent, and pre-competitive, outlook towards data science, we can really enable innovation that can improve public health — which is really the mission of the FDA.

We're aggregating all of our clinical trial data. The drug applications sent to the FDA actually contain the raw data — so we're doing predictive analytics and meta analyses. They're informing some of the decisions that we're making internally in terms of engaging with companies and working with them to design their clinical trials.

Companies actually meet with the FDA to get advice on how to design clinical studies. So by having this predi ctive, data science approach informing ourselves, then we can disseminate that information and make better recommendations to the industry on how to design better clinical studies.

And the other component is going beyond clinical trial data. We're looking at electronic health record data, real world evidence, we are also looking at sensors and the internet of things to capture both intrinsic patient characteristics, and their extrinsic activities.

With sensors, for instance, we're doing a study at the National Cancer Institute where we're developing novel endpoints based on sensor data.

Once we validate this and create individual use cases, then other firms can build on this foundational work — which may be too high of a risk for anyone else to do. But someone should, because it's good for public health.

Data science is a lucrative profession. How do you lure these scientists to a government job?

We have two entrepreneurs-in-residence, who would never find themselves in government — but we needed their programming skills. These are temporary positions created by Health and Human Services to support this kind of innovation.

We also have postdocs from academic institutions, so it's all very academic — kind of like an incubator or accelerator for collaborative oncology regulatory science.

Many people don't decide to become entrepreneurs: They want to change the world. So we've been able to appeal to that sense of citizenship and public service, to help with how the regulatory process works. There's been a brain drain, where programmers are developing social media platforms, for instance — and that may not have societal value. But by encouraging these entrepreneurs and talent to do something that can move the needle and make an impact on society — well, we can then unleash them from FDA to bring disruptive innovation to a sector that's been traditionally resistant to change.

How does FDA policy work in this brave new world of digitizing everything?

Some people say we're going towards the fourth industrial revolution. It's all about data and collaboration, and some of the old ways just aren't scalable anymore. But you'd be surprised: In this data-driven world we're envi sioning, you don't necessarily need new policy. If you look at the wording of the laws, there's so much flexibility built in. How we approve drugs is based on evidence. And evidence changes — it's a moving target. Every gen eration is evolving, so most of the regulations are very neutral.