Stanford eCorner

Innovation-Driven Engagement with Regulators

09-03-2022

URL: https://stvp.stanford.edu/clips/innovation-driven-engagement-with-regulators

Stanford professor Russ Altman acknowledges that startups often fear regulators, but insists that in the biotech space, the FDA is keen to work with companies to bring products to market and advise startups as part of an open dialogue. In the context of AI-driven drug development, GSK senior VP and Global Head of AI/ML Kim Branson adds, an evolving conversation between industry and government will lead to new ways of ensuring the safe delivery of cutting-edge therapies.

Transcript

- For prospective founders looking 00:00:07,000 to build in the intersection of ML/AI and health, do you think governmental regulators and interventions are a reason to worry about progress happening too slowly? And is that a big enough to deterrent not to get into the area? And that's the specific question, but let's generalize a bit to the role and the interaction between and among regulators and industry and how that plays out, how you think that plays out.. And we'll go to Russ first, 'cause Kim, you just answered, but I definitely want to go to you afterwards 'cause it touches on what you just described.. - Yeah.. 00:00:44,060 That is a great question because it seems so obvious that regulation could only be a thing that slows things down and kind of torpedoes some of your best efforts.. And let me say that I've had conversations with CEOs of extremely famous, extremely large tech companies in the Silicon valley, who will say, we will not engage.. Now, this is old information, this was 10 years ago, but 10 years ago they would uniformly say to me, we will not engage in a project within our company if we see the FDA anywhere near it.. And I just wanna say that the world has changed and the FDA has changed.. So first two sentences on my credentials on this, I am the co-PI of an FDA funded center of excellence on regulatory science, where we have collaborations between FDA scientists and UCSF and Stanford scientists in areas that are critical for the FDA to understand.. And you will not be surprised to learn that digital health and AI is one of the areas that they come to us a lot.. There are several of these centers but around the country, but you will not be surprised to learn that we're the one who gets a lot of the interest for AI and ML in health, and we've had several projects with them..

The FDA scientists are extremely interested and caring about bringing these technologies to patients, their entire professional is to protect the health of the American public while allowing drugs diagnostics and therapeutics including AI therapeutics and many of you will know this, some have been approved.. And so it seems scary, but I have seen over and over again, that even for a startup, there is a very well understood way to have a pre-submission meeting with the FDA where you describe the technology that you're developing, you describe everything you can about it.. It's kind of a confidential meeting so this is not on the public record.. And then they give you an assessment of what their questions would likely be.. They do that at the meeting, but they also go back think and talk, and then send you a letter with these concerns so that you don't have too much of a moving target where now they can't guarantee because things happen, but they give a best effort of what you would need to do to demonstrate the safety or efficacy of this, whatever this tool is.. And I've talked to startup people and it starts out scary.. They usually wait too long for that meeting, 'cause it kinda reminds me of a PhD student who doesn't want to do their defense because everything is not finished or even their quals and I tell them, just get in front of your committee and tell them where you are, it will be useful and it's the same thing for founders.. They're so worried about the FDA interaction that they actually delay it too long.. You're allowed to have more than one of these meetings, you don't have to have all the answers at the first meeting.. And it's extremely unlikely that you say something that torpedoes your entire effort because the FDA is not out to torpedo your effort, but they're out to set expectations..

so I hope that wasn't too long, but I'm actually bullish that the FDA is learning how to spell AI, understands there's a tsunami of things coming to them and it is staffing up or else getting collaborative help like rom our center to make sure that they can obey all the laws about their response times for various submissions.. So I wouldn't be afraid of the FDA and in fact, I would engage with them ASAP so that you can see that they're just real scientists who are just trying to protect the public and help you get your products out the door.. And I'd be interested to hear what Kim's experience that's usually for startups.. I wonder if GSK has the same experience as a 300 year old big drug company.. - Oh yeah.. 00:04:50,480 And Kim also broadened to how GSK thinks about that regulators and GSK each involved in this emerging set of principles.. - Yeah..

00:05:02,230 I mean, I've had experience from the startup side and also from the company side.. And I think the first thing I learned from startup stuff is, yeah, we wait too long, but turns out the regulators are people too.. And a lot of 'em are really passionate scientists and I think that's, it's really important to understand like, okay, we actually have regulation, lots of industries, there's regulation running a food truck, there's regulation in If you wanna sell your product, this is the people you have to talk to, but actually engage them early on and having a dialogue..

And they're quite open to understanding how to do things.. A lot of it is they're seeking to understand, and they'll tell you why this particular regulation, why they think like this and you can have a dialogue, whether that's a case or not.. And it's actually one of those things you're sort of not taught.. You kind of have this thing.. The FDA is like the IRS, it's only a bad thing.. Very different department.. They're for a very different reason and you can engage them.. And I think the other thing is that what people fail to understand is that environment is a constant dialogue between industry and the regulator.. So from the GSK perspective, we could have conversations with them.. I'm like, we're helping develop like what is good machine learning practice for building medicines..

Should the same thing of how we do update softwares for a pacemaker, be the same thing for updating software that I'm trying to do a diagnostic, you know, for a competition pathology algorithm.. And actually how even should the regulator validate work? So previously in drug discovery run a clinical trial I get all my primary data, we do some statistical analysis, we give the FDA, they check our homework, say we get the same conclusion, there's a debate.. I'm glossing over this in horrible terms and Russell is smiling, but that's kind of the process and off they go.. For machine learning algorithm, why doesn't the regulator have their own independent set of data that I don't have.. It's an API.. Why don't they decide they're gonna call at any time? Why don't they can continuously monitor something in production if they wanted to? We do have monitoring in production right now in the pharmaceutical industries, adverse drug reports.. There is a parallel for these types of things.. So what you have to do is have a conversation with the regulator.. You need to talk to 'em about this sort of stuff saying, "Hey, we think this is how you could do it." And also explain to them the types of people they need to be hiring on training.. You know, they need software engineers, they've got really great statisticians that the FDA and people like that because they've needed to have them to understand new trial designs..

So it's an evolving concept.. And I would say the more you engage with them and tell them what you want to do and how to do something you get to know people there and you can actually, as a small 20 person company or a giant pharmaceutical company, have these conversations with them as well.. And I think that's a really important thing is to engage in that dialogue and the regulatory environments are there for a reason.. Now it may not evolve in law as fast as you want, but this is where I think that typically there is always a path to work with them to do something.. Because as Russ said, they are highly motivated to try and change healthcare.. Because the other thing is if they just no to everything and I know Russ probably have been to sale of, there was a famous regulator who said no to everything that never allowed a single drug in, in their entire career.. But that also doesn't work, and that leads to a backlash against that sort of thing.. And then once that happens, we lose, we end up having building things aren't as safe.. So there is that interplay, so I think it's very important to engage, involve and realize it's an evolving thing and you can push on it, the laws aren't static.. You can campaign for change and give really strong reasoning for doing that, and it's an educational component as well..

And you'll learn from them...