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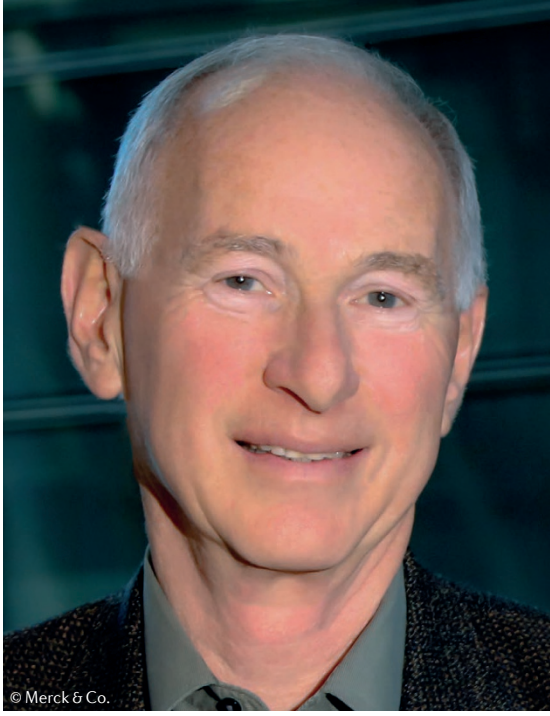
AN AUDIENCE WITH…

Michael Rosenblatt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Although biopharma start-up companies have to be laser-focused on translational science, this single-mindedness sometimes comes at the expense of clinical development expertise. The venture capital group Flagship Ventures has now named Michael Rosenblatt as Chief Medical Officer to help its portfolio of companies fill that experience gap. Rosenblatt was Chief Medical Officer at Merck & Co. for 7 years prior to this role, and Dean of Tufts University School of Medicine before that. He talks with **Asher Mullard** about his new job, and his novel proposal for how to handle the reproducibility crisis.

Why does a venture capital group, with a focus on company creation, need a Chief Medical Officer?

It's our impression that this is something that hasn't been done before in the venture capital world. Often the young companies that we are supporting are very close to innovation, but their experience and insight is really focused on the earliest stages of drug discovery. And they don't tend to have a lot of experience in clinical trials and clinical research.

The drug development game has changed a lot over the past 10 years. It used to be that success entailed having an idea, making a drug, and getting it approved. Now, that is just the middle of the game. You also have to convince physicians, payers and patients that your invention has value. And to do that you really have to start thinking about value very early on. This is something that big pharma has been doing over the past several years, and is getting better at it. But there has been much less of this happening in the biotech sector. These are things that I can bring to the table.

It is hard to demonstrate value preclinically, and I don't know how much value you can demonstrate even in phase I trials. But if you are not thinking very early on about demonstrating value for payers and patients, you may not be designing your programmes in a way that will maximize the possibility of long-term success. You may never get a chance to do these studies, but your company will be more valuable if you've thought about how to do them.

You'll also assess ideas for new start-up companies, addressing head on the 'reproducibility crisis', in which up to two-thirds of published data cannot be replicated. You've proposed that universities should offer money-back guarantees to licensees to offset the risks of irreproducibility. How was this proposal received?

It has been a mixed response, but I don't think the proposal was fully understood. My proposal was more of an incentive or reward for standing behind reproducible data than a punitive "money-back" guarantee. Drug companies might pay more for data that a university will guarantee is reproducible. Maybe you can get twice the amount of money that you would normally get. Some people thought I was suggesting a penalty, but what I was really trying to do was reward people for reproducible data.

Also, I wasn't proposing a policy. I was proposing a pilot project. The causes of irreproducible data are multifactorial, and there is probably not a single solution. But my feeling was that this solution might encourage a cultural change, where a few universities might start thinking differently about reproducibility as a means to get paid more. And that might generate a ripple effect, putting pressure on others to come up with reproducible data as well.

Also, to be clear, I wasn't proposing that the project had to succeed for universities to get paid. I know that 90–95% of projects don't lead to drugs. All I was saying is that the data forming the basis of the collaboration should be reproducible.

As far as I know, nobody has taken the bait yet. But I've heard from two or three research organizations that have said they like the idea.

Might you consider such a pilot project in your new capacity as a venture capitalist?

I would love to try the experiment. I hope that a really high-quality lab, with high confidence in their data, will step up, and then maybe we might get a chance to try it out.

You are also tasked with thinking about the ethical issues that Flagship's portfolio companies must grapple with. What kind of questions do you expect to tackle here?

I'm really excited about this. There will be questions that are asked in the next 10 years that have never been asked before because they couldn't have been asked. I haven't yet had a chance to think deeply about the implications of CRISPR and gene therapies, so let me put that aside for the moment. But something that I have given a lot of thought to is access to experimental drugs.

When patients ask for access to experimental drugs through compassionate use programmes, companies have to decide who gets the drugs. And this can put a huge burden on companies, especially the smaller ones that might not have a revenue stream or a solid supply line. Compassionate use can also slow down clinical development plans. So, how should start-ups think about compassionate use?

At Merck, we generated guidelines for who would be eligible for compassionate use drugs. And rather than having a committee with experts looking at every single case, we set up a committee only to look at the complicated cases. I think there is an opportunity to do things similarly with start-ups, in which industry and non-industry experts can work together to review complicated compassionate use requests.