AN AUDIENCE WITH…

Garry Neil


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Industry spends around US$30 billion a year on clinical trials, and even small improvements in how things are run could yield large savings. So ten top pharmaceutical companies decided to tackle trial inefficiencies by launching a non-profit industry-only corporation: TransCelerate BioPharma. The venture will be headed by acting CEO Garry Neil, who is also a partner at Apple Tree Partners and former Vice President of Science & Technology at Johnson & Johnson. Although TransCelerate's initial focus is on improving clinical trial execution, future precompetitive aspirations are bigger and broader, he tells **Asher Mullard**.

How did TransCelerate begin?

The initial conversations that led to the creation of TransCelerate came out of the Hever group, an annual meeting of research and development (R&D) chiefs from large and medium-sized pharma and people who have had that position in the past. Every year we discuss some of the problems that we share across the industry, and in May 2011 we started really thinking about moving beyond these discussions and trying to get something done.

In a follow-up meeting in August 2011, we thought more about the sorts of activities that could move the needle the most. Although there are many issues and bottlenecks in the R&D process — all the way from our incomplete understanding of basic biology to challenges in postmarketing product assessment — we decided to focus on clinical trial execution, where the spending is very large and there is an opportunity for quick wins.

After more meetings, TransCelerate was born at the May 2012 Hever meeting and launched in September.

You've announced five initial work streams. Tell us about these.

A first aim is to improve data standards. The Clinical Data Interchange Standards Consortium (CDISC), along with regulatory agencies and individual companies, have already started defining standards for collecting clinical data during trials. But as yet they haven't completed many therapeutic areas and we have not yet locked on to industry standards. By working with the CDISC, we can double down on their efforts and accelerate the process. We can provide a little bit of muscle and expertise, and help prioritize the areas that industry is most interested in.

This is a joint effort, which is emblematic of everything that we are trying to do. We will always work to identify the right groups to work with.

A second aim is to develop a shared user interface for investigator site portals. At the moment, investigators who work with different companies have to contend with different interfaces, each with their own look and feel. If we can standardize a single portal interface, it will make things easier for them and more efficient for us. We could also make this a single repository for important regulatory and training documents.

Third, we hope to develop standardized training protocols. Each company recruits investigators and needs to make sure they are up to speed and trained in clinical practices and in recruiting patients. But we're basically training investigators on exactly the same material. So why not adopt a common standard? There is also an opportunity to work with an external training and accreditation organization on this project. This way we won't all have to go through the process of continuously certifying and re-certifying investigators.

Fourth, we think we can do a better job on risk-based site monitoring, on focusing on the things that matter most with respect to data integrity and protection of subjects in our clinical trials. We can do analyses to see where we are most likely to run into problems and what kind of red flags we need to look out for. It's not just safety events we're interested in, but also things like making sure that trial volunteers have been properly advised and consented, and ensuring that fraud is not going on.

Fifth, we are looking to establish a more efficient way of providing marketed comparators to one another for trials. We don't really have an efficient way right now of planning, manufacturing, packaging or providing each other with such comparators.

We are also in the process of prioritizing new projects for 2013. And although our initial focus is on clinical trial execution, we think we will be able to address other types of problems eventually as well.

How much money do you think your projects will save?

It is hard to give a precise estimate. But because industry spends around US$30 billion a year on clinical studies, even small reductions in costs and increases in efficiency can make big differences. Our overall goal is not to spend less money though; it's just to spend it more efficiently.

How much funding do you have?

We're not disclosing this yet, but it is a substantial sum in the millions of dollars. Most of the resources are in the form of deployment of experts from within member companies, but substantial capital is involved as well.

How did you pick membership?

We thought it would be easiest to start with a manageable number, and that if we could get the big players engaged then the smaller players would follow.

But TransCelerate is fully open, and we are getting a lot of enquiries from other companies about joining. Smaller companies face the same challenges as we do. We know they have fewer resources, so we have a tiered membership agreement that places a lighter burden on them. We want them all to participate; we want to hear their voice and we want to leverage their expertise.

Although we have set TransCelerate up as a biopharma consortium, we've left the door open to all sorts of other models. We are having discussions with CROs, for example, about how they can work with us. And we want to work with patient advocacy groups, regulators and other players throughout the ecosystem as well.