AN AUDIENCE WITH…

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How healthy is the biomedical innovation engine? To figure out how to start even thinking about this oft-asked but nearly impossible to answer question, the Brookings Institution, Washington DC, USA, held a one day meeting in June. Leading the discussion was Mark McClellan, Director of the Institution's Center for Health Care Reform and former commissioner of the US Food and Drug Administration (FDA) and administrator of the Centers for Medicare & Medicaid Services. The next step, he told **Asher Mullard**, is to put together a dashboard of metrics that measure the inputs, outputs and the value derived from drug research and development (R&D).

Why did you hold this meeting?
Biomedical innovation is crucially important. But we are facing some big challenges right now, including the high cost of innovation and questions about what we're getting for what we're spending. It seems like now is a critical time for us to figure out whether we can do a better job of identifying the factors that are contributing to progress, how we're doing, and how we can do it better.

One aim of the meeting was to come up with better metrics to monitor the state of biomedical innovation. Where are you at in this endeavour?
There are lots of ways in which progress can be measured, but none of these are perfect. That said, there is currently a much better array of measures related to these questions about innovation than we've ever had before, and that was another key message that came out of the conference.

We already have good measures for tracking all of the [financial] inputs to the system. We discussed measures of what is going on in the public sector, in terms of input from the US National Institutes of Health (NIH), but also in terms of the private sector, the venture community, industry and other sources of spending. And then we discussed a number of measures that attempt to capture how productive the research has turned out to be. For example, the extent to which compounds that are being developed in the laboratory are progressing through different phases of clinical testing, and the extent to which they proceed through the FDA's regulatory process. And finally, on the results side, we discussed not just measures of the numbers of new drugs approved, but also measures related to the impact of those products on health — for example, by looking at whether drugs are approved using priority, accelerated or breakthrough pathways.

One of the bottom-line points of discussion from the meeting was that we are not that far from having some more truly valuable measures that will not just look at the cost and time of drug development, but also at the impact in terms of patient health. These could help us to figure out how long it takes and how much it costs to improve the health of patients.

This seems to jive with what has been happening more generally in the drug development process as well. There has been a shift away from blockbusters and towards discovering personalized therapies that have the potential to make a unique impact on patient health. And while that shift has a lot of costs associated with it, there are some signs that we could, as a result, be getting more efficient at developing targeted and individualized treatments.

Are the data for compiling these metrics already available?
The data that are needed are out there, but they are generally not collected in a standard and ongoing way.

The kind of thing a meeting like this can help with is to build a consensus between the public and private sectors of what data could be shared and how we can produce a more meaningful ongoing set of productivity measures. These data could be useful for determining the impact of things such as regulatory policy development, changes in the FDA's approval pathway and shifts in reimbursement policies. A move towards more value-based metrics — which is part of where the regulatory process is heading anyway — would be a valuable addition to the types of measures we currently have.

The interpretation of metrics can also be challenging. If you track the progress of candidates through clinical trials, for example, it is unclear whether a decrease reflects declining innovation or smarter decision-making. How do you circumvent this?
The simplistic approach of looking at volume or intensity — the number of trials, for example, or how big they are — is not a good measure of productivity. You really need to focus on what you are getting for your money. That's yet another reason to focus on the impact of new treatments on health, and this is getting easier to do with the bigger emphasis on markers — which may not turn out to be valid — based on the post-marketing collection of data about the impact of treatments on health.

You also asked the speakers to discuss policies that they think could boost biomedical innovation. Which of these piqued your interest?
One interesting proposal came from [NIH Director] Francis Collins, regarding a more efficient way of doing clinical trials. Collins discussed clinical trial networks, and, although he didn't expand on this in detail, I think what he was discussing was the development of an extensive effort that might use electronic data systems to coordinate trials not just in academic centres but in the broader community as well. Whether this would be an outgrowth of existing trial networks or of capability that is coming out of information technology projects like the Sentinel pharmacovigilance system is less clear, but it sounds like a promising direction.

What happens next?
There is more willingness than ever before to put together something like a dashboard: a key set of consistently calculated measures. That is what we are working on now, along with other groups who track data on investments or on R&D.