Dr Paul Peter Tak, biotech expert, business leader and entrepreneur, explains that while experimental medicine can boost innovation, it is not without its challenges

# Innovation in development: the disruptive advantages of experimental medicine

Just over 140 years ago, the world's first industrial-sized research and development laboratory opened. As someone who has devoted his working life to finding new research and development breakthroughs, I am envious of the explosion of activity that made the lab's owner, Thomas Edison, one of history's most remarkable inventors. But it's his *process* of innovation that inspires me, as much as his life-changing creations.

After hitting a brick wall with one approach, he famously said: "I have not failed. I've just found 10,000 ways that won't work."

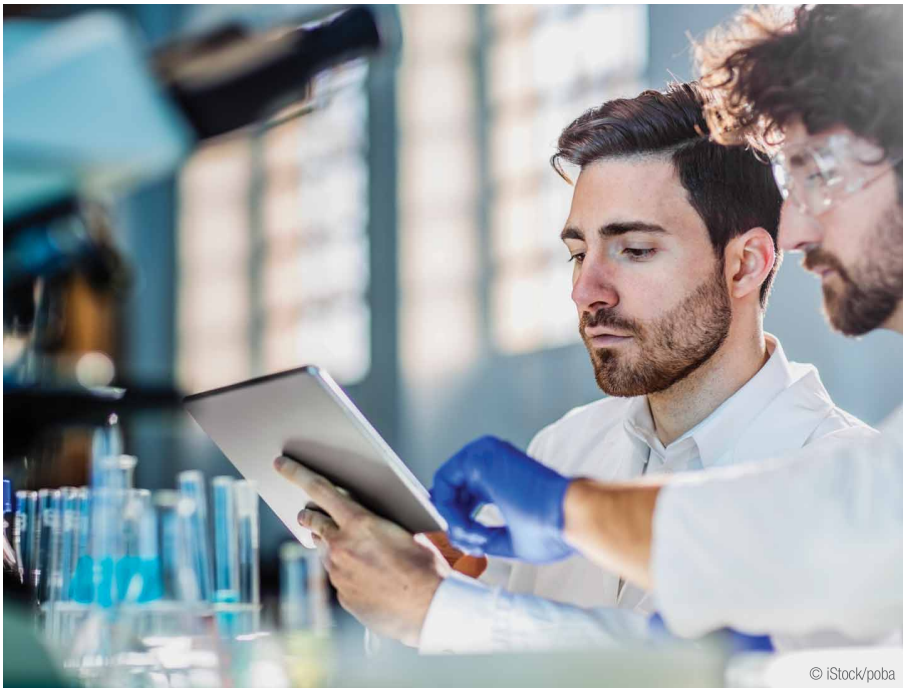
And so it is in pharma R&D. Though we strive to find the best treatments and deliver them swiftly to patients, many of our efforts will be unsuccessful. These frustrating mis-steps are crucial, however, because, like Edison, they take us closer to our ultimate goal, provided we react with agility.

This begs the question: Can we discover which treatments are unlikely to be successful, earlier on?

## Experimental medicine

We might address this question using 'experimental medicine', a new approach to clinical development which I am confident will reap significant rewards for the industry, especially around decision making timelines. As opposed to relying on large-scale trials which require significant investments over long periods of time without the guarantee of success, experimental medicine takes a more disruptive approach.

This way, programmes that are unlikely to deliver transformational medicines early on can simply be halted. It also means that scarce resources can be allocated to fewer priority assets with positive signals, and that these can be sufficiently backed.



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Considering that decisions are made based on a relatively small, high density of data clinical trials, these three questions should be asked:

1) Are there trends towards clinical improvement?
2) Do we hit the pathway in the right way?
3) Does this translate into changes in biomarkers associated with common final pathways known to be relevant for clinical success?

If you hit the mechanistic pathway but answer 'no' to all these questions, it is unlikely that the medicine is transformational – and the programme should be stopped.

## Boosting efficiency

Although in some ways effective, the current model of pharmaceutical development is slow, expensive and unsustainable. What we need is to implement approaches with a greater and faster probability of success, liberating scientists to accelerate or discontinue with maximum efficiency.

I vividly remember the first patients with rheumatoid arthritis who were treated with anti-TNF antibodies in the nineties. Until that time, most patients were severely disabled by their disease but after treating only a few, we knew we were watching clinical effects we'd never seen before. It was a therapeutic revolution.