



INNOVATORS

SUPPORTING SCIENCE

24

To an outsider, it seems strange that clinical trials that have the potential to advance science and even save lives should struggle to find recruits.

But despite the fact that the very people needed to try out new treatments are those who stand to benefit from them, the pharmaceutical industry has historically found this aspect of its work particularly challenging.

“Twenty per cent of sites looking to trial a new drug end up recruiting no candidates at all, while 70% of trials take longer to find enough people than the programme originally allowed for,” explained Alistair Crombie, managing director of Sussex Innovation Centre-based One Research.

The problem in the past has been that recruiting volunteers to take part in trials has been left to the researchers who are running the trials, and that’s not necessarily where their expertise lies.

“Researchers want to get on with running the trial and disseminating the results,” explained Alistair.

“They generally don’t have the resources to get out

CLINICAL TRIALS CAN BE A TRIAL THEMSELVES WHEN RESEARCHERS ARE LEFT TO FIND THE RIGHT CANDIDATES. ONE RESEARCH AIMS TO TACKLE THE PROBLEM BY FOCUSING ON COMMUNICATIONS.

there and find the right people and in many cases it is not the most effective use their time.”

Alistair realised in 2009 that the situation would not improve until the industry began placing a greater emphasis on communicating with patients – and that was the inspiration behind setting up One Research, which he now runs with business partner Nick Thomsitt, the company’s operations director.

One Research finds and assesses potential trials recruits from all over the country – and overseas – and then keeps their details on a database so that they can be contacted when a new trial is announced.

“It means we already have a group of people, pre-screened, informed and keen to take part,” said Nick.

“Traditionally, recruitment does not begin until after the trial has been designed, which puts added

time pressure on what is already a difficult task for a scientist who wants to be focusing on the science.

“One Research avoids that problem by keeping an updated and detailed database of people in a range of locations who want to join a trial at some time in the future. Researchers can assess and enroll volunteers from that list.”

The other benefit of the One Research approach is that those who sign up have already been fully briefed on what joining a trial involves, what their rights and responsibilities are and all the other issues that can take up valuable time but which need to be dealt with carefully and sympathetically.

In the past, patients who might have been suitable for a trial would generally receive a ‘cold call’ from a researcher asking if they would take part – or they might be referred by their GP. As Nick explained, though: “Given the time pressure on doctors, expecting them to support the recruitment process in this way is optimistic.”

One Research uses a carefully-trained team to recruit candidates and talk them through the process, and has a multi-lingual capacity to support large-scale trials that cover more than one country. “When a suitable trial is launched, the cohort is ready, waiting and briefed,” explained Alistair.

“One Research sets out to use good communications principles to make the whole area of trials recruitment more patient-focused and take the pressure away from busy clinicians.”

Alistair has a background working with medical charities and set up One Research five years ago when he realised the scale of the problem facing



› Alistair Crombie, left, and Nick Thomsitt

sponsors and researchers.

He recalled: "It seemed strange that there wasn't a clear and simple process in place for something so important, and after looking at how it was done I realised that it was too reactive and not strategic enough."

Today One Research works with Novo Nordisk in support of its volunteer outreach programme for diabetes research and is also sparking interest among other healthcare companies.

To support the approach to potential new clients across the UK, the US and Europe, One Research commissioned a white paper that has been authored by the team at the Sussex Innovation Centre.

The white paper, entitled Improving standards of patient recruitment and retention in clinical trials, bears out the problems experienced by the industry and lends valuable weight to the One Research approach.

As an example, it points out: "While the first hurdle faced by researchers is in recruiting the appropriate numbers in order to conduct a study, efforts are further hampered by an industry-wide acceptance that a significant percentage of patients will drop out of any trial before it is completed."

As Nick explained: "Because we talk in advance and in detail with the volunteers before they go on

the database, we know that they are less likely to drop out because the process is not what they were expecting."

With researchers needing to recruit anything from a few hundred to several thousand people for a large scale, multi-centre trial, often involving more than one country, Alistair and Nick are convinced that taking a communications approach to the issue is the most effective way forward.

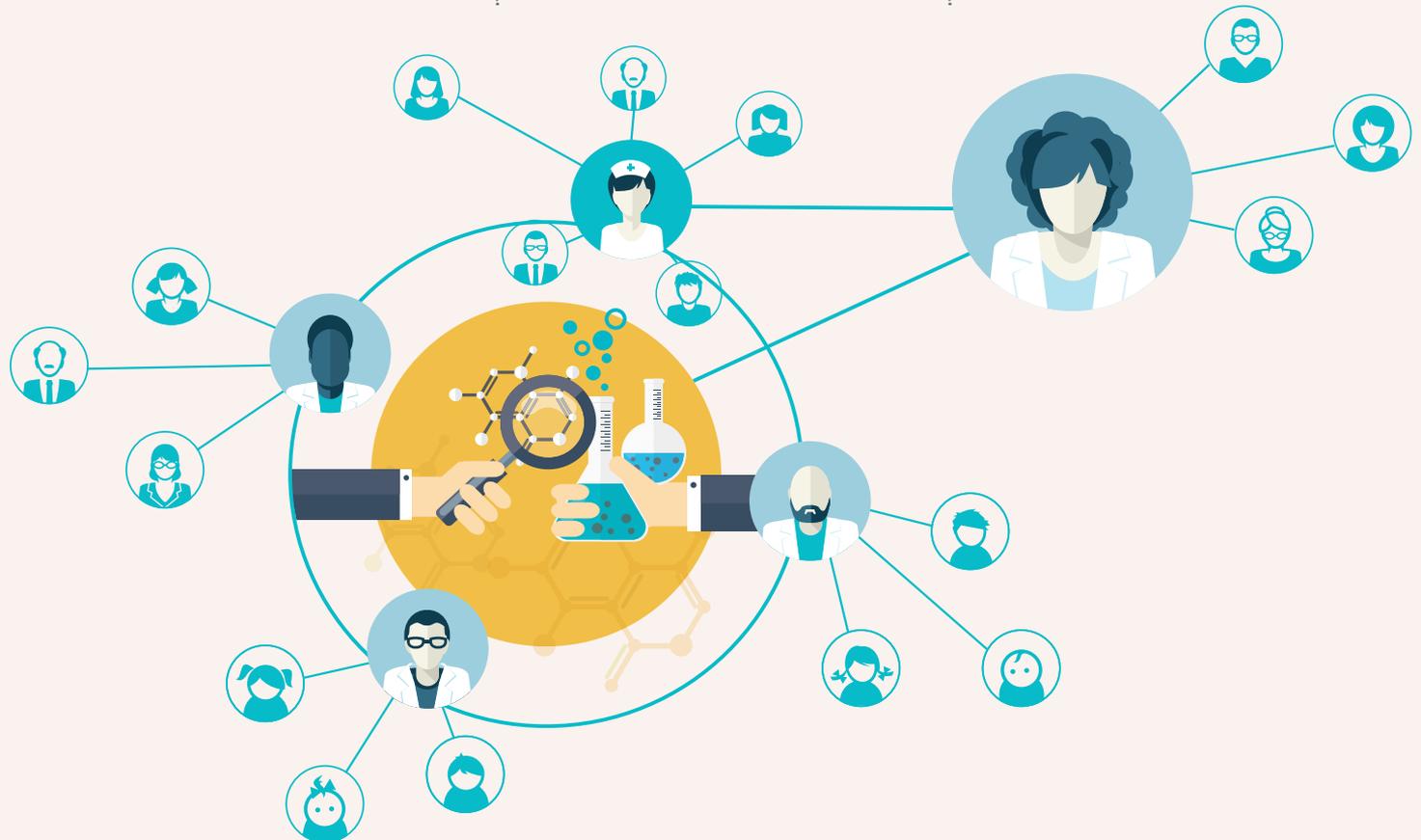
Nick also pointed out that although the innovative approach produced dramatic improvements, it was 'non-disruptive' as it did not involve "replacing existing staff or tearing up the rule book".

He explained: "We are just trying to make life easier for all those involved and, in particular, to help patients who are looking for an opportunity to contribute."

Alistair added that he hoped that joining a database of volunteers would in time be as simple as joining the blood donors register. At the moment, he said, volunteers were often routed through their primary care provider, which could then become a sticking point.

"We are confident that this new approach will help make the lives of those who are designing and running trials easier – and that has to be good news for the future health of all of us," he said.

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"The funding support we received through the Centre has directly resulted in the delivery of our research project, helping us to reach a range of potential clients and ultimately grow our business."

Alistair Crombie, MD, One Research



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