Victoria: where clinical trials continue apace, despite global pandemic

BY BRIDIE SMITH

There is no denying it. The global pandemic that is Covid-19 has impacted the way clinical trials around the world are conducted.

In Australia, the state of Victoria has weathered the onslaught better than most. Covid-19 interruptions have been minimal and social distancing requirements have not markedly hindered the operation of clinical trials. Where there has been an effect, smart thinking, innovative approaches and reliable telecommunications has minimised disruption.

> *"Notwithstanding the border restrictions, we're open for business,"* said Dr Amanda Caples, Lead Scientist for the state of Victoria. *"While people can't travel, we have good, reliable telecommunications. International companies can do clinical trials here because it's business as usual in Victoria."*

As Covid-19 spread rapidly across the globe, Victoria's health system stood ready to receive a flood of patients. Overseas experience had heightened concerns that the state's hospitals might be overwhelmed.

From top in order of mention: Dr Amanda Caples, *Lead Scientist for the State of Victoria.* Dr Megan Robertson, *Director of Research*, St Vincent's Hospital Melbourne. Nathan Elia, *Global Victoria's senior director of trade and investment.* Tina Soulis, *Chief executive of Neuroscience Trials Australia.*

Dr Megan Robertson is director of research at St Vincent's Hospital Melbourne where there are currently more than 1000 clinical studies underway, 20 of them related to Covid-19 and up to 300 of them clinical trials.

An intensive care specialist by training, Dr Robertson was anxious about how the state's health system would cope.

> "*There was significant concern that there would be overwhelming patient need and inadequate resources*," she said.

But the feared flood of patients never arrived. In a strange way, the experience has further enhanced Victoria's reputation as a global destination for clinical trials.

> "*It demonstrated the quality of our public health system and our ability to mobilise around a common threat*," Dr Caples said.

Nationally, the pandemic was nowhere near as disruptive to the health system as feared. As of June 4, Australia had 7,237 Covid-19 cases, with 102 deaths recorded. Community transmission has remained largely under control.

> "*Our hospital system has been able to get back to business as usual which means that the clinical trials are now able to be done because we are not dealing with an overloaded health system*," Dr Caples said.

In a perverse way, she believes the experience has demonstrated Victoria's ecosystem of drug discovery, clinical trials and strategic capability to rapidly pull together and be part of the global drug exercise.

> "*This positions us as a place that does good science, does good medicine and is contributing to a common problem*,"

Nathan Elia, Global Victoria's senior director of trade and investment, is based in Boston in the US. He said the quick response by Australia's state and federal governments minimised disruption to both the clinical studies underway and those that were yet to start.

> *"A lot of those initial stage programs that hadn't started are now starting to get ramped up and my phone hasn't stopped ringing, quite frankly, since the beginning of April from companies that had been on the fence about doing studies in market."*

Victoria has over 35 per cent of Australia's dedicated phase 1 facility beds in the country, making it a national leader.

Industry-sponsored phase 2 trial sites in Victoria numbered more than 120 in 2017, close to double the number a decade earlier. These sites are largely in areas considered Victoria's top three specialist areas: primarily cancer, neuroscience and immunology.

However the state has an established track record in industry-sponsored trials across a diverse range of fields – from infection treatments, lung and diabetes to cardiovascular and asthma.

In all fields of clinical trials, the necessary restrictions associated with Covid-19 have prompted new approaches to keep trials running in Victoria. In each case, innovation was the key.

The sector's nimble response saw drug delivery services, home visits, remote monitoring of databases and sponsors accessing medical records remotely quickly became the norm.

> "*We've had the bonus of innovation without the downside of it overwhelming our health service. We have all learnt to work in new ways,*" Dr Robertson said.

Chief executive of Neuroscience Trials Australia Tina Soulis said while Australia is emerging from lockdown, some of the innovative changes made would likely remain.

> "*They are more efficient, less costly for the client because there's no travel involved and there's less risk for staff,*" Dr Soulis said.

If the sector thought activity would pause or drop-off due to Covid-19, it was wrong.

> "*What has really astounded us is that we've had a huge amount of interest in new studies,*" Dr Robertson said. *"A lot of companies are getting themselves set up and ready to go over the next two to six months*."

Dr Robertson said one company which planned to do a study in five centres in the US realised it would no longer be possible to undertake the gastroenterology study there and relocated to St Vincent's Melbourne.

It's been a similar experience at Neuroscience Trials Australia.

> "*In the first four weeks of lockdown, there was radio silence*," Dr Soulis said.
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> "*The past four weeks have seen us run off our feet with expressions of interest, requests for proposals and people re-engaging with us that we spoke to a year ago. There are a lot of people who want to start their projects here now and then expand to the US*."

Dr Soulis outlined one example where an overseas company behind a new product being assessed in the clinic for oncology and alzheimers realised that the mode of action could apply to treating Covid-19's respiratory symptoms. Recruitment for a trial of Covid-positive patients displaying respiratory problems is now underway in the US and Neuroscience Trials Australia is working with a US partner to recruit and do the lab work as global project manager.

"It nicely demonstrates that we can still add value and claim the R&D tax incentives," she said.

Australia has an internationally recognised regulatory framework and intellectual property protection.

The federal government's R&D tax incentive scheme means whatever a company with a turnover of less than $20 million spends in Australia, be it for a clinical trial or manufacturing a product, 43.5 per cent can be claimed back. Taking the exchange rate into account, it can mean Australia can be up to 60 per cent cheaper than the US.

On top of this, getting regulatory approval to commence a trial in Australia is efficient and seamless thanks to the country's clinical trials notifications scheme. A streamlined ethics committee approval process exists in Victoria, with just one accredited ethics committee required to sign off on a trial which may involve multiple institutions.

"*That can save a lot of time, we're talking months*," Dr Robertson said.

Victoria benefits from Australia's well-resourced, high quality health system. Upon these solid national foundations, Victoria has excelled as the state where almost half of the nation's health and medical research activity is undertaken.

The epicentre of this research is in Australia's largest biomedical precinct, the Parkville Precinct, in the state's capital of Melbourne.

Here the public health system and research sectors are closely aligned. Many are located within a single postcode, including the Florey Institute of Neuroscience and Mental Health, the Walter and Eliza Hall Institute, the Royal Melbourne Hospital, the Peter Doherty Institute for Infection and Immunity, the Victorian Comprehensive Cancer Centre and BIO21.

"*This concentration of clinical and research institutions improves the quality of the thinking and the output from the clinical trials because you've got the benefit of the connection between the lab to the bedside and bedside to lab*," Dr Caples said.

So, when it comes to selecting a place in the world to conduct clinical trials, why Victoria?

"*The quality of the product is of global standard,"* Dr Caples said. *"Our regulatory environment is recognised around the world and we have the ecosystem to troubleshoot any time problems*."