Perspectives from CROs on the Australian clinical trial environment

AusBiotech asked a number of clinical research organisations (CROs) for their perspectives on the trends and important happenings in the operating environment for clinical trials in Australia. The following are their responses.

The future for clinical trials in Australia

Anthony Bishop, Director Business Development, Quintiles

The clinical trial ecosystem in Australia is an intricate web involving pharma companies, CROs, clinical trial sites, patients, ethics committees, and many branches of the government. A number of trends are evident:

1. Population, GDP per capita and healthcare spending are all growing.
2. About 500 clinical trials of all types (pharma, biotech, academic) are going on in Australia.
3. The proportion of outsourced trials is growing and with that the outsourced market is growing.
4. The R&D Tax Inventive and the Clinical Trials Notification (CTN) scheme make Australia an attractive place for early phase development with many local and international companies participating.
5. Broadly there are more biotherapies as oncology becomes a bigger portion of total trials. Clinical trials related to rare diseases are increasing.
6. Technology continues to impact clinical trial execution.
7. The Therapeutic Goods Administration (TGA) has moved into electronic submissions – early days yet but promising.
8. Australia remains a key place in global clinical development, but the Asian region continues to grow as a competitor.

Australia is a growing but mature clinical trial environment. What can we imagine dramatically impacting the clinical trial ecosystem in the coming years? Here are a few broad areas we all need to think about, add to our conversations and begin incorporating into our planning:

- Regenerative medicine: Currently trials utilising stem cells have very long regulatory review times. How can we normalise these new therapeutic modalities in the current system?
- 3-D Printing: It is predicted that within a decade solid organs will be printable. How will we run clinical trials for that?
- Big Data: new information becomes apparent when data from disparate sources is aggregated and analysed. How will we integrate this data into our clinical trials and what status will it have compared to the data we collect now?
- Social media: Already a part of patient recruitment strategy for some trials. How much further will social media become a part of clinical trials?
- Telemedicine: How will we run clinical trials in an environment where treatment is offered by telemedicine and through applications on our phones?

The entire biopharma industry, regulators, governments, healthcare practitioners, healthcare providers and service providers need to be thinking and talking about these innovations to make sure our ecosystem is capable of growing with them. We are pleased to be part of the conversation.

Sector collaborations key to maximising the development of new medicines and medical devices

Dr David Lloyd, Managing Director, Southern Star Research

Despite the high rate at which promising research discoveries are made in Australia, the translation of this science into effective pharmaceutical compounds and medical devices is surprisingly low. Yet, recent reports have suggested that this trend could be reversed if collaborative relationships between researchers and other relevant sector stakeholders were cultivated – the aim being to utilise the resources available from each party to accelerate the development and commercialisation of Australian medical innovations.

The clinical research sector in Australia is both sizeable and diverse with stakeholders including pharmaceutical and biotech companies, hospitals and clinics, academia, research institutes, government departments, ancillary service providers and not-for-profit organisations. Therefore, when considering the sheer breadth and volume of potential collaborators, it is clear that the research expertise, material assets and support services available are potentially monumental. It is these resources that can then be harnessed in the development of a framework that allows for the successful planning, implementation and completion of clinical research activities.

By instilling a collaborative approach between stakeholders active in the scientific research space, the significant resources available can be combined and utilised thereby maximising the efficiency of the clinical research and devopment (R&D) process.

Scientists who are active in academia or the biotech space, bring their passion and scientific understanding. Third parties including CROs, patient advocacy groups and specialist Phase I units can further assist by providing the required implicit and tacit resources needed to move through a successful clinical trials program – one that provides maximum benefits to multiple parties.

Given that the investment in terms of time and money to develop a new therapeutic or device are significant and that the milestones during development can be difficult to reach, a collaborative approach, which implements all available resources to help ensure the success of clinical research for Australian innovations is a sound idea.

Australia offers multiple drawcards as a clinical trial location

Dr Tina Soulis, General Manager, Neuroscience Trials Australia – a business within The Florey Institute of Neuroscience and Mental Health

Clinical trials continue to be a strength of the Australian research and development landscape. There are many advantageous reasons as to why companies continue to choose Australia

as a destination, particularly for early phase development. First and foremost, our regulatory landscape offers a straight-forward and inexpensive platform whereby a new innovative treatment, therapy or device can be taken to Phase I or beyond in a short period of time. To add value to this, there is no law-abiding requirement such as opening up and submitting an Investigational New Drug (IND) application. That process alone involves a lengthy process that takes months and costs a lot more than the $330 CTN scheme.

The fact that we are Western country and the essential clinical trial documentation such as informed consent forms do not have to be translated is also seen as a definite advantage over many of our neighbours. These documents are expensive to translate and take time to process.

Whilst Australia is seen as an overall expensive country to undertake trials, we have learnt that trial sponsors will pay for the privilege of good quality data offered by the low drop-out rates and minimal cost to follow up trial patients.

Australia also has a unique and collaborative approach to trials. There are currently over 86 specialist clinical trial networks that offer efficient access to the capabilities of many therapeutic areas and quick turn around on feasibility information, making the selection of Australian sites relatively hassle-free. In addition, many of these networks also offer value added options such as being able to negotiate the trial costs on behalf of all member sites.

Trends in clinical trials in Australia

Gabrielle McKee, Chief Operating Officer & Executive Director, Clinical Network Services (CNS) Pty Ltd

The saying about a rising tide raising all boats could be applied to early phase clinical trials in Australia with the Government's R & D Tax Incentive 45% cash back scheme providing the tide. Many of CNS's client base is taking advantage of the scheme to obtain their 'first in man' or other early human data from trials in Australia at one of the expert Phase 1 units, claiming the refund for all of the costs incurred by all of the Australian service providers to fund further parts of the program in Australia. After Phase 1, CNS's clients are retaining their Australian entity and relationship with CNS and the high quality investigator sites to perform more of the Phase 2 and part of the Phase 3 program for their product. Bottom line is we are all busier than ever before!

In terms of development targets, we have seen an increase in the number of small to medium size enterprises investigating vaccines – prophylactic and therapeutic, and gene therapies. CNS's Biodesk team is supporting many clients through the OGTR (Office of the Gene Therapy Regulator) licencing process for these therapies to start their trial in the most efficient timeline possible.

There has been in increase in the complexity of these clinical trials in for example, biological sample management, imaging requirements, investigational product handling or patient dosing regimens. These complexities require careful solution focussed clinical project management to support our clients and investigator sites to deliver the trial data to the highest quality standard.