



2011 Survey of Privately Funded Clinical Research Activity

February 2012



Report on the 2011 Survey of Privately Funded Clinical Research in Australia

Introduction

The Clinical Trials Action Group was set up by the Australian Government in October 2009 to ensure Australia maintains its international competitiveness in clinical trials and to secure continued investment in the sector. In its final report, the Action Group made 11 recommendations, aimed at improving patient recruitment and making the process of initiating new clinical trials significantly more efficient. It also sought metrics to be collated on the value and performance of Australian clinical trials with previous estimates suggesting that companies spend around \$450 million on conducting clinical trials in Australia each year. [1] As the data in this report shows, private investment is significantly higher than previously thought. In fact, this survey gives the most accurate picture yet of the nature and economic importance of private investment in medical research in Australia.

Methods

With the assistance of the Commonwealth Department of Industry, Innovation, Science, Research and Tertiary Education [2], the Pharmaceuticals Industry Council [3] administered a brief web-based survey to gauge the level of privately funded clinical research activity in Australia. The survey consisted of 4 substantive questions, focusing on investment, employment and the level and type of activity in Australia. [4] Companies were asked to report data on activities conducted in the 2010 calendar year.

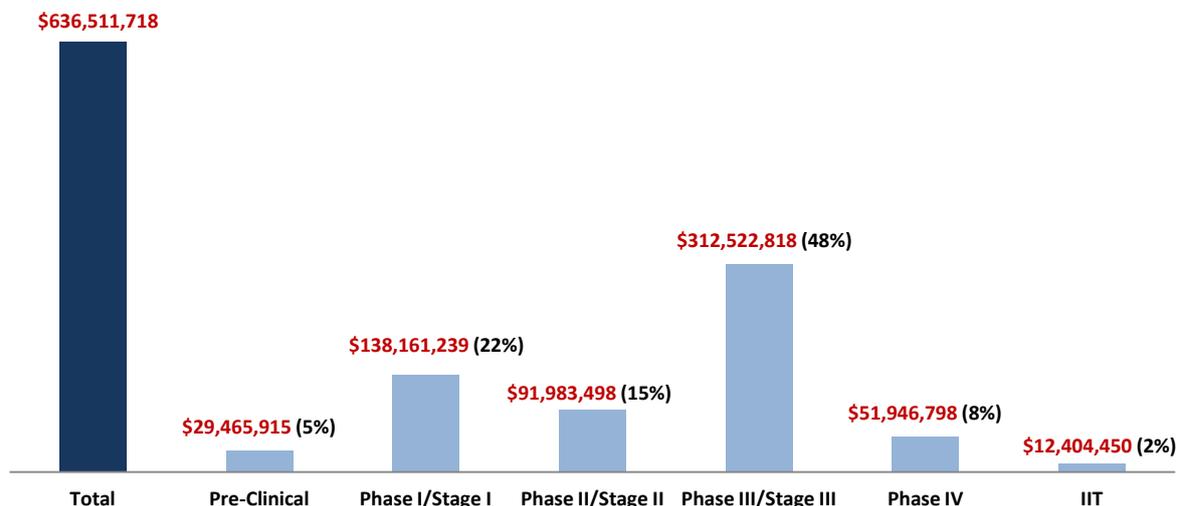
The survey was sent by email to the relevant members of AusBiotech, the Medical Technology Association of Australia, IVD Australia and Medicines Australia and to contract research organisations which are not members of any of the four associations. [5] In all, some 220 companies received the survey, of which more than 100 was eliminated as potential respondents because they did not, at the time, conduct any type of clinical research in Australia. The final sample size was 104.

Results

53 companies responded to the survey, including 28 "pharmaceutical companies", 14 "contract research organisations", 7 "medical device or medical technology companies", and 4 "biotechnology" companies. While the response rate was only 50%, it captured a vast majority of the investment in clinical research in Australia.

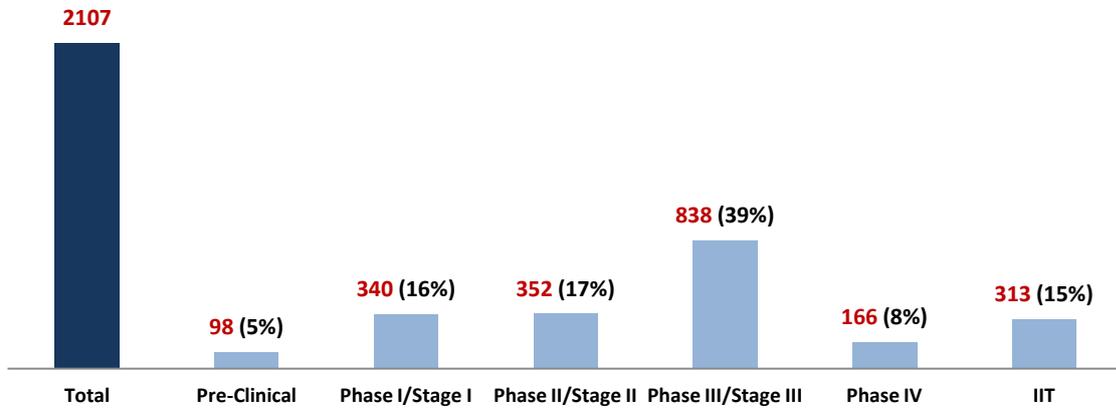
Reported Expenditure

Companies reported a total expenditure in 2010 of \$636,511,718. Expenditure on Phase III/ Stage III studies accounted for nearly half of the total. [6]



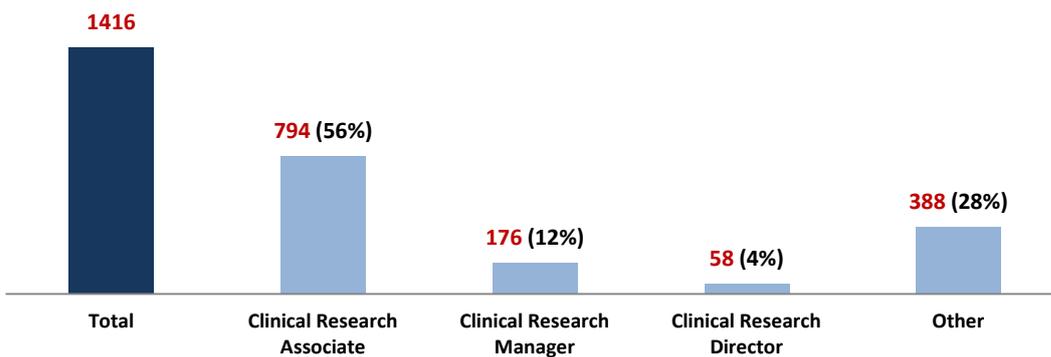
Reported Activity

Companies reported conducting 2107 studies in 2010. Phase III/Stage III studies accounted for the largest share of the total activity. [7]



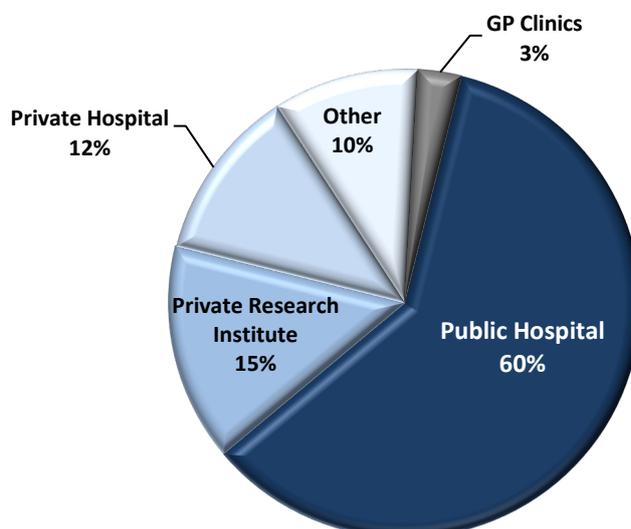
Reported Employment

Companies reported employing 1416 people in clinical research-related roles, with clinical research associates accounting for more than half of the total. [8]



Research Location

A majority of the reported research was conducted at public hospitals, followed by private research institutes and private hospitals. Among "Other" locations, companies identified "specialist clinics" and "independent Phase I units". [9]



Discussion

In their forward to the Clinical Trials Action Group report, then Ministers for Health & Ageing (Nicola Roxon MP) and Innovation & Industry (Senator Kim Carr) acknowledged that the "clinical research industry" brings "hundreds of millions of dollars annually into Australia's health system". The Action Group's final report estimated that, each year, private companies spend approximately \$450 million on conducting clinical research in Australia. As data in this report shows, actual expenditure is significantly higher.

Phase III studies are by far the largest component of clinical research in Australia; 48% in terms of expenditure and 39% in terms of the number of studies. However, early stage research (i.e., pre-clinical, Phase I and Phase II) are major areas of investment as well; collectively, early stage research accounts for 42% of the total expenditure. This is important because early stage clinical research has a higher potential to deliver spillover benefits to the Australian economy, compared to late stage clinical research. [10]

The data from the survey shows that, in a strictly economic sense, the main beneficiaries in Australia of private investment in clinical research, apart from those employed in the industry of course, are public hospitals. Of the total reported activity in 2010, 60% was conducted at public hospitals across Australia. This is another important finding as private investment are not only a direct cash injection into Australia's public health system, but also a means of subsidising the delivering of healthcare to Australian patients. The higher the investment, the higher the cash injection, the higher the subsidy and, ultimately, the higher the benefit to Australian patients.

Notes

- [1] Commonwealth of Australia, 2010, Clinically Competitive: Boosting the Business of Clinical Trials In Australia
- [2] The Department of Industry, Innovation, Science, Research and Tertiary Education assisted with the design of the survey questionnaire.
- [3] The Pharmaceuticals Industry Council is a peak body which represents three industry sectors, including the research-based and generic medicines sectors and the biotechnology sector.
- [4] The survey was administered using SurveyMonkey.com.
- [5] AusBiotech is a peak body which represents the biotechnology sector in Australia. Medical Technology Association is a peak body which represents the medical device and medical technology sectors in Australia. IVD Australia is a peak body representing Australian sponsors and manufacturers of in vitro diagnostics. Medicines Australia is a peak body which represents the research-based pharmaceuticals industry in Australia.
- [6] Survey Question: What was your company's (Australian-based)/local business unit's (multi-nationals) total expenditure in Australia in the 2010 calendar year on: Pre-Clinical research; Phase I/Stage I; Phase II/Stage II; Phase III/Stage III; Phase IV; and Investigator Initiated Trials?
- [7] Survey Question: What was the total number of trials/studies/investigations your company (Australian-based)/local business unit (multinationals) sponsored/undertook in Australia during the 2010 calendar year? This includes projects that were initiated, ongoing and completed during this period in: Phase I/Stage I; Phase II/Stage II; Phase III/Stage III; Phase IV; and Investigator Initiated Trials?
- [8] Survey Question: What was the total number of staff [FTE] in your company (Australian-based)/local business unit (multinationals) to work on activities directly related to the conduct of clinical research in the 2010 calendar year? Indicate by role: Clinical Research Associate; Clinical Research Manager; Clinical Research Director; Other?
- [9] Survey Question: Across all trials/studies/investigations sponsored/undertaken by your company (Australian-based)/local business unit (multinationals) in the 2010 calendar year, approximately what percentage of the site would be: Public Hospitals; Private Hospitals; GP Clinics; Private Research Institutes; Other?
- [10] Commonwealth of Australia, 2009, Pharmaceuticals Industry Strategy Group: Final Report