

Training for Clinical Researchers Survey Results

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Professional Development for the Therapeutics Industry™

The Survey

- A short snapshot of registrants
- 63 respondents
- Range of types of human research
- 60% Investigators and 40% co-ordinators
 - All highly qualified
 - How well qualified in research method?

Why is Research Done?

- To improve interventions and patient treatment – change practice
- To develop new treatments – patents and commercialisation
- To “find out more” and publish results

What does success look like?

- Success with the regulator
 - Success with patent office or commercial partner
 - Success with the publisher
- Improved patient outcomes

Requirements for Success

- Quality Research
- **EVIDENCE** of quality
 - Subject welfare has been protected
 - Ethics, governance, safety management
 - Data integrity has been protected
 - Design, systems and processes (method)
 - Analysis and reporting

Who sets the standards?

- NHMRC – for all human research
- Regulators, and the ICH
 - ICH-GCP Guidelines set international standards for both subject welfare and data integrity
- 32% of respondents said they were hazy or unaware of these standards

Risk of not getting it right

- Delays – at approvals stage
- Rejection
 - By peers and by publishers
 - By regulators – no change in practice
 - By commercialisation partners – no change in practice
- Liability – personally and for institution

How to build in Quality

- Knowing the requirements and guidelines
- Applying these in practice
- Building a quality research team
- Start to finish approach
- 6% had no training in research method
- 24% had no training in GCP

Where do you gain the knowledge in research method and GCP?

- Undergraduate training – 0%
- Post-graduate training – 30% said this provided training in research method
- NHMRC – provide 0% in both categories and 1% of participants funded through NHMRC
- Institutions provide 23% of training and funding for 59% of participants
- Sponsors – provide 11% and fund 16% of participants

Why are researchers at risk?

- Lack of funding – 50%
- Lack of time – 24%
- Don't know where to get training – 19%

A proposed solution

- Dedicated approach to training researchers in institutions
 - Dedicated time
 - Dedicated funding
- Mandated training requirements
 - For students – undergrad and post-grad
 - For researchers and research staff

What are the benefits?

- Less risk of delay or rejection
- Raises the profile of research in our healthcare system
 - Attracts staff
 - Attracts funding
- Flow-on benefits to Australian patients
 - Earlier access to improved treatments

Your Wishlist

- 95% say more training is required.....suggestions
- Application of GCP – around 60%
 - Ethics
 - Recruitment
 - monitoring
- Protocol development
- Data analysis
- Standardisation of training

Thank You!

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