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Recruitability and Retention: The Challenges of Vaccine Trial design

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Clinical trials are essential for the development of new preventative and therapeutic vaccines in infectious diseases and other therapeutic areas. Trial designs vary based on the nature of the disease; the intended population; the phase of development; the frequency of prime and boost doses; and the length of time associated with follow up activity. Vaccine trial participation is affected by external factors such as the constant community challenge to partake in routine vaccination schedules, and social media commentary by pro- and anti-vaccination advocates, and educational programs on the consequences of non-vaccination. Q-Pharm has undertaken 23 vaccination trials over 13 years. The majority of these trials have been in healthy volunteers for preventative vaccines, with some now registered in Australia and the USA. Recruitability and retention of participants has been impacted by the frequency and timing of prime and boost vaccinations and the duration of follow up. Realistic assessment and understanding of these factors needs to be considered by all parties involved, for early and accurate estimation of participant withdrawal rates and collection of valid data. In Australia, clinical trials involving seasonal vaccines, such as influenza, need to commence early enough to allow immunological responses to be completed before the Southern hemisphere immunisation schedules begin in March/April. Data will be presented that supports our recommendations for establishment of appropriate eligibility and on-trial demands of participants that will enhance recruitment and retention.

Biography

Suzanne Elliott is the Operations Manager, Chief Scientific Officer and Deputy CEO of Q-Pharm, a Brisbane-based clinical trials company. She has a PhD in molecular oncology from QUT/ Mater Hospital and a post-doctoral career in developing a prototypic vaccine for Glandular Fever with the QIMR Berghofer Eptein Barr Virus group. Subsequent roles at Vaccine Solutions and as the QIMR Berghofer Regulatory Affairs Manager, involved immunotherapy trials for post-transplant lymphoproliferative disease, Hodgkin's Disease, malaria, prostate cancer and melanoma. Suzanne has qualifications in Drug Development from the University of New South Wales and is an accredited Research Trainer in Good Clinical Practice. Currently the Q-Pharm Scientific and Operations Manager she has responsibility for oversight of 'all of company' clinical trial project management and with special interests in early phase adaptive drug design, malaria challenge studies, vaccine studies and research ethics.

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