Title: **Pfizer Pharmacy Grant to attend the 2015 Australian Clinical Trials Alliance International Symposium**

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INTRODUCTION

The Australian Clinical Trials Alliance (ACTA) 2015 International Clinical Trials Symposium was held during the month of October in Sydney. This conference presented a unique opportunity to join colleagues from across a broad range of disciplines including pharmacy, medicine, nursing, consumers and industry. The theme was to review advances in embedded clinical research from around the world while articulating the vision for clinical trial registries within Australian and local health systems. My sincere gratitude to Pfizer and SHPA for approval of a grant to be apart of this pivotal symposium.

Australia is known to perform robust trials with high integrity. The Townsville Hospital is a relative late-comer to the clinical trial service having been established only five years ago. At first, approximately 10-15 trials were managed, however this has now grown to over 100 local, national and international trials in 2015.

My position of clinical trials pharmacist covers all disciplines within the hospital. Because of the dynamic nature of trials, variability between specialities and relative isolation of regional geometry; I feel it necessary to keep up-to-date not only within Australia but worldwide.

All clinical trials pharmacist's within Australia strive for the highest level of service with increase health outcomes for patients and expanded access to medications and treatments that would not normally be available. As a specialist discipline of pharmacy practice, it is pivotal clinical trial pharmacists are trained and educated with

up-to-date knowledge of advancements and information as to provide the highest level of care. Australian hospital pharmacies are slowly building a reputation for the assistance provided to conducting robust trials of high integrity, and the ability to help recruit participants and provide essential medication education on new interventions or methodologies. It is essential we continue along this path of excellence.

With very limited clinical trial infrastructure and support systems in place for most Australian hospitals – especially regional - the clinical trial pharmacist is being called upon to be a "champion" of research within their hospital and health service. For example, my expertise and knowledge is being utilised to rural and remote health centres that fall within our catchment with increased participation in research and clinical trials. These rural and remote health centres now have the ability to instigate their own projects and offer specialised treatments to their patients knowing that I will form part of a crucial support network. With the introduction of Telehealth and Teleoncology, more and more patients are receiving treatments without commuting to larger hospitals.

Australia has a unique population, climate and geography making it an appealing place for the conduct of research. It is imperative that as Australian hospital pharmacists, we are prepared and armed with information and innovation to ensure the integrity of research as to help protect our participants and everyone involved.

PROCEEDINGS

The symposium provided information and updates on many topics both nationally and internationally, however the following were highlights for the week.

Consumer engagement and education in trials and research

It is well known that recruitment is one of the main reasons clinical trials fail. A presented theory behind this involves design to some extent, but also is a direct result of consumer understanding and education on clinical trials processes. The evidence behind this stems from health literacy and the fact that patients do not present to hospital and forwardly ask to be involved in trials – or – ask the question "does this hospital participate in clinical research". A simple explanation of Health literacy is the degree to which individuals have the capacity to obtain, process and understand basic health information and services to make health decisions. It was quoted that 60% of the Australian population don't have basic health literacy which is proven to decline with age and increasing co-morbidities. Therefore the lack of active participation in trials by consumers could be due to the human nature reaction to distance your-self from the unknown, which in some cases could be potentially beneficial therapies simply due to missing or uncommunicated information.

A possible solution involves a nationally accredited consumer training program for trials and research. ACTA have pre-emptily adopted such a program developed by the United Kingdom National Health Service. The obstacle to its initiation is money. With the recent fiscal scrutiny in public and private hospitals, the room attendees didn't seem confident in the program for at least some months once a consortium was

formed and funding secured. An alternative interim solution put forward was to incorporate this program as an additional standard in the National Commission on the Safety and Quality Health Care for Public hospitals. The result would be a mandatory requirement for hospitals to educate our consumers on trials and research before accreditation success. The ultimate aim however is for our consumers to obtain the knowledge and information which would allow them to make adequate decisions regarding health, trials and research.

Investing in research – what is the return?

Keynote speaker Professor Tom Walley from the United Kingdom National Institute for Health Research gave a very informative presentation on the return of investment for clinical trials. The health professionals familiar with the UK health system are aware of its robustness and where not dis-similar to our government, the demand for value for money. A common question asked is if clinical trials are feasible from a health economic point of view. The simple unified answer internationally is yes they are.

The Womens Health Initiative (WHI) Trial is a perfect example of the attractive return of investment for clinical trials. The WHI trial budget was $260 million to conduct, being the largest and most expensive trial of its kind and time. The WHI trial investigated Hormone Replacement Therapy (HRT) and the effects on cardiovascular and osteoporosis for menopausal women. The trial was stopped early due to the results showing completely the opposite, by increasing cardiovascular disease, blood clots and breast cancer. Consequently, the use of HRT dropped and it was estimated a return of $140 to the health system for each $1 spent on the trial ($37 billion over 10

year period). For Australia, the average return on investment for clinical trials is $2.17 for each $1 spent (NHMRC). This example was one of many that make it clear clinical trials and research do have returns on invested finances even if the results are not in line with hypotheses.

Randomisation – do we need it?

Professor Donald Berry from the MD Anderson Cancer Centre in Texas put forward a tantalising presentation as to the need for randomisation in clinical trials. This pivoted around the ideology of giving half our population an ineffective therapy. Using a leukaemia trial as an example, Professor Berry explained to the audience the background and methods for the concept of adaptive randomisation. Adaptive randomisation refers to a scheme in which the probability of treatment assignment changes according to the response of participants on the assigned treatments already in the trial. For the aforementioned leukaemia trial, approximately 37% of the population was saved from being randomised to an ineffective intervention. Professor Berry's latest work in the breast cancer trial I-SPY2 has demonstrated the potential to deliver new, effective treatment options more rapidly to patients who would most benefit while dramatically reducing the time and costs currently required to evaluate experimental therapies.

CONCLUSIONS

The ACTA 2015 international clinical trials symposium was overall a very rewarding experience. The conference allowed me to network and seek expert reviews on a local clinical trial where I am a chief investigator. I sought review of the trial protocol by a visiting epidemiologist, and since have now moved to a major design change. We will be adopting a cross-over methodology allowing us benefits such as reduced sample size, duration, costs and ability to use patients as their own controls. Using participants as there own controls are particularly appealing for trials in the field of Neuropathic pain, where patients are generally reluctant to participate due to the chance of being allocated placebo. Additionally, and important contact was made with a GMP accredited production facility Phebra, who we now have on board as a sterile vial contact for future trials that have infusions as the intervention.

Once again I would like to thank Pfizer and the SHPA for the opportunity to attend this symposium.

Kind Regards

Kelvin Robertson