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CAREER ADVICE

A trial-blazer in clinical research

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Abstract

Founded in 2005, Gallipoli Medical Research (GMR) is a leading independent medical research institute located in Greenslopes, Brisbane, Queensland. GMR strives to enrich and restore lives through pioneering medical research that transcends the laboratory to deliver meaningful and tangible real-world solutions. In 2006, GMR launched its clinical trials program at one of Australia's largest private hospitals, with the focus on advancing healthcare through innovative treatments and emerging therapies, with a particular focus on oncology, liver, and respiratory diseases. Dr Suzanne Elliott is the Associate Director of Clinical Trials at GMR. Here, Dr Elliott discusses her transition from laboratory-based research into the clinical trial industry and shares her insight, advice, and pioneering contributions to industry, government, and the clinical trial research landscape across her diverse 30-year career.

INTRODUCTION

The biomedical research sector in Queensland continues to expand, creating valuable opportunities for scientific breakthroughs, research partnerships, and professional advancement, including through its clinical trial programs. Queensland's outstanding clinical trial capability covers all phases (from first-in-human through to Phase IV) and is underpinned by a network of world-class universities, hospitals, medical research institutes, and clinical trial facilities.[1] One such facility is the Gallipoli Medical Research (GMR) Clinical Trial Unit (CTU), located at the Greenslopes Private Hospital in Brisbane. The GMR clinical trials program has continued to grow following its inception in 2006 and the expansion of designated clinical trial laboratory facilities in 2011. The GMR CTU staff provide trial co-ordinating activities to their commercial research partners with the management and co-ordination of both national and international trials, which enables patients to access new and emerging medications that may improve patient health outcomes. Today, the focus of GMR's clinical trial program is on liver disease, respiratory illness, and oncology, including hematology. In this article, we speak with Dr Suzanne Elliott, the Associate Director of Clinical Trials at the GMR CTU (Figure 1).

Alex Johnston (AJ): Suzanne, can you give us an overview of your career?

Suzanne Elliott (SE): Inspired by a character on the forensic pathology show "Quincy" and his technician, I decided to study my undergraduate in Medical Laboratory Science at the Queensland Institute of Technology (QIT). Following work in a number of private and public pathology services, it was suggested to me to undertake further research in a Masters degree and then PhD. It was the mid to end of the 1980s and the beginning of the molecular biology era – I remember thinking, "This is the future in medical science!" I was in the first cohort of Queensland University of Technology (QUT) post-graduates awarded an Australian Health Practitioner Regulation Agency (APHRA) PhD Scholarship. I handed in my thesis in molecular oncology at the end of 1992, when I was 8 months pregnant. In 1993, I commenced my first post-doctoral position at the Queensland Institute for Medical Research (QIMR). The viral vaccine study I worked on, under Investigator Professor Denis Moss, was a joint research project

Figure 1. Dr Suzanne Elliott is the Associate Director of Clinical Trials at Gallipoli Medical Research Clinical Trial Unit, Brisbane, Australia.

between National Institutes of Health and the Cooperative Research Centre for Vaccine Technology (CRC-VT). This also involved having the project managed collaboratively with Commonwealth Serum Laboratories (CSL) Limited to develop a prototypic glandular fever vaccine. Here, I was involved in various research activities including establishing novel pre-clinical animal models, immunological assays and evaluating different vaccine formulations. It was an industry-driven project, but I still had to publish other related research, be involved in securing grants and overseeing students. In 1998, I joined Vaccine Solutions, a spin-off company of the CRC-VT, based at QIMR. Vaccine Solutions facilitated the project and intellectual property (IP) management for the CRC-VT and I negotiated continuing some research work at the same time. This involved clinical trials in adoptive immunotherapy for patients who developed post-transplant lymphoproliferative disease, malaria vaccine trials and other oncology trial research. I then moved to become the first QIMR Regulatory Affairs Manager in 2001, where I used my clinical trial development and ethics knowledge to oversee Investigator-initiated clinical trials and the establishment of the staffing roles and processes within the manufacturing cell therapy and vaccine pre-clinical formulation facility, now known as Q-Gen in the Clive Berghofer Cancer Centre.

I left academia to commence in the commercial world of clinical trials as the Operations Manager at Q-Pharm (an early phase clinical trials company) in 2003 and eventually became Deputy CEO. In 2016, I joined Gallipoli Medical Research (GMR) where I am now Associate Director of Clinical Trials.

AJ: What motivated your move from laboratory-based research into clinical trials?

SE: Part of the reason I left academia was the pressure to publish and secure grant after grant – there's so much competition to get what was then, and still is, limited funding for medical research. I also wanted to see translation beyond benchwork. I've now been able to see all the different stages of a clinical drug development pipeline. For example, a drug that started in a Phase I trial undertaken at Q-Pharm in healthy participants, progressed to a joint Phase II trial at Mater and Q-Pharm for cystic fibrosis, which then progressed to the GMR CTU for a Phase III Trial. When I joined the GMR CTU, this drug trial was audited by the Food and Drug Administration (FDA), resulting in no significant findings. It was rewarding to see the various stages of the clinical trial life-cycle of this drug.

Arti Medhavy (AM): Can you walk us through a typical day in your current role?

SE: Every day is different. I do my morning rounds to check in with my staff. We have a lovely team culture at the GMR CTU. I have 20 staff in my unit: there's the ethics and governance team, data managers, and the Clinical Trial Co-ordinators (CTC), clinical trial assistants and the start-up and finance team. Once I gauge the status of our trials, I move on to executive duties. Strategic planning is critical for bringing in business. Sponsors (the entity taking responsibility for the initiation, management, and/or financing of a clinical study or trial) will send us feasibilities for clinical trials, so we need to decide whether to pursue or decline these trials based on our resources, experiences with similar trials and whether we can effectively recruit for the trial. If our CTU is selected, the Sponsor will conduct a pre-study visit, then selection and we can begin start-up activities and commence the trial.

AJ: What is your preferred clinical trial phase or therapeutic area?

SE: In oncology, our aim is to take on studies that include different stages of disease, from the initial diagnosis (first line) to first and second relapses. We can then potentially enrol patients between our studies to provide them with better options for continued trials. You can't take on every study, so it's all about finding a balance between the ability to recruit and current resources. Our clinical trials are 75–85% oncology and the rest are respiratory and liver disease trials. Every clinical trial phase has its own challenges. I think Phase I trials in healthy volunteers at Q-Pharm were challenging albeit easier to manage compared to Phase I oncology trials, but in both there are greater expectations,

monitoring, and oversight from the Sponsor. I do like patient-focused studies. Not all drugs and not all trials work, but when they do it's really satisfying. Due to the trials conducted in melanoma at Greenslopes Private Hospital since about 2011, there are several melanoma patients who had an initial terminal prognosis, and who are still alive today after the new checkpoint inhibitor clinical trials, which is just amazing.

AJ: Have you had to deal with unexpected challenges during your career?

SE: I think the two biggest challenges were in the wake of significant severe adverse events reported during Phase I drug clinical trials overseas both in 2006[2,3] and 2016.[4,5] In 2006, we were about to start dosing in a Phase I healthy volunteer new drug-class monoclonal antibody trial when a London-based Phase I healthy volunteer trial of a different targeted monoclonal antibody reported significant serious adverse events. Some participants became critically ill. Then in a Phase I trial in France in 2016, one participant died, and others developed serious medical issues. This coincided with the dosing of another Phase I trial in our unit of a drug that the general public and our trial participants could have been worried about due to the extra media attention. It was 11 pm when I was still working and read the breaking news. I immediately contacted our Sponsor in the USA. I also called our staff to be prepared for any questions by the trial participants to allay their fears. I informed the Ethics Committee and the overarching Institution to ensure that all parties were briefed on the event. Although unrelated to our trial, they all needed to be updated. These were critical events that had the potential to jeopardise the reputation of all early phase drug development and clinical trials. There were new and reviewed international regulation changes following these events, which were implemented during my term at Q-Pharm and provided the foundation for clinical trial review at all Ethics Committees. Another challenge and passion of mine is in educating people about the drug development process. Specifically, that the drugs and vaccines we are using today came from a sequence of many clinical trials under a thorough regulatory oversight. Ultimately, we need to be able to recruit participants to take part in clinical trials, to allow new therapies to be developed and registered for use in patients.

Danielle Stanisic (DS): What are your most memorable moments from your career?

SE: I think handing in a PhD while I was 8 months pregnant [laughs] was probably the hardest. In 2018, I was awarded the inaugural QIMR-Berghofer-sponsored Life Science Queensland Woman of Influence Award. I was also involved in the Queensland Clinical Trial Network, where we conducted road shows around Australia. I attended Bio USA in San Diego, and Boston, Bio Japan and Bio Korea, where I did presentations on the benefits of bringing clinical trials to Australia. I was also invited to talk at the Therapeutic Goods Administration (TGA; the medicine and therapeutic regulatory agency of the Australian government) about an Epstein Barr vaccine trial I was involved in. As an Adjunct Associate Professor at the University of Queensland (UQ), I was involved in assisting in some coursework development in the Master of Pharmaceutical Industry Practice. I am very proud of my contributions to the clinical trial landscape in Queensland.

AM: Do you think there are any barriers facing women in clinical research?

SE: In the 1990s, we didn't have the amazing maternity leave that is offered today – I balanced parenting my 5-month-old with full-time work. When I had my second child, 4 years later, maternity leave was a little better but still challenging for work-life balance as a post-doc. I also worked full-time and studied part-time while raising two kids to have a better understanding of clinical trial regulations, but that was my choice. For mothers these days, I think it comes down to your choice of the work-life balance, what support you have and an expectation that work goes beyond normal hours. For me, self-doubt was also a barrier. I think it is improving, but I do believe in the past that women had greater challenges to maintain a scientific research career. But my motto now, and for both my girls, is to "Go for it" and aim high, because you never know. Sometimes you've just got to put yourself out there.

AM: What advice would you give to early career researchers (ECRs) who are interested in working on clinical trials but lack prior clinical trial experience?

SE: My senior co-ordinating staff at GMR CTU usually come through as clinical trial assistants. Some post-docs aspire to start as a CTC but lack experience interacting with patients and an understanding that doing a PhD will equate to years of onsite trial co-ordination. Whether collecting patient samples for biobanks or consenting participants, having those interactions are important. It would be useful to complete a Good Clinical Practice (GCP) training course. Never underestimate ethics and governance as an area to get into. This area is so critical to all research, including clinical trials, so if you know all your ethics between public, private and academia and you're a good communicator, you'll have a job for life. Take opportunities to do project management in science if you want to pursue managerial roles. Being on

committees, such as scientific safety or clinical trial protocol committees, is great for networking opportunities. At GMR CTU we implemented a Clinical Research Graduate Program for clinical trial assistants as a means of cross-training and staff retention. Several sites are now introducing these clinical research internships which provides a brilliant opportunity to enter this industry.

AJ: What is your advice to people that are aiming to advance their careers into leadership roles in the clinical trial industry?

SE: There are commercial-academic grant opportunities through organisations like Advance Queensland or the REDI fellowship system. In this career don't expect everything to be given to you. I put myself through the University of New South Wales' Graduate Diploma in Drug Development and joined committees in my own time. Besides learning a lot in the clinical trial arena, networking and meeting brilliant researchers from various organisations presents a unique opportunity to raise your profile. This could facilitate exciting career prospects for you in the future. I volunteer in various clinical trial steering committees and guest lecture at both QUT and UQ, which also provides opportunities to promote education in the clinical trial field. Being involved in mentoring programs is also great. I love mentoring students through the Industry Mentoring Network in STEM (IMNIS) program. I've learned from students, and I love to give back. I provide insights into their options to stay in academia, undertake a hybrid role, or move to Sponsor/drug development work. I use my various roles over my career and my networks to provide them leads to follow up and contact.

DS: Do you have any additional career milestones you would like to reach?

SE: I thought my next goals would be to work in a big pharmaceutical company, and/or go overseas to work. I'm not retiring yet, but I'll be nearing this time over the next 5 years or so. However, I still feel like I've got so much to give. I may want to do consulting work and other small projects.

AJ: What do you see changing in the future in the clinical trial industry?

SE: I'm intimidated by artificial intelligence (AI) [all laugh]. I heard a talk from TrialKey, who are experimenting with *in silico* models to predict where to place clinical trials for the best outcomes. I think AI can streamline processes like recruitment and budgeting, and Sponsors will adopt these AI-prediction models. However, we still need people that understand trial complexities and have knowledge about the participants and the environment. A positive move has been the decentralisation of clinical trials, to take trials to patients, even as a hybrid design, to allow trial participant inclusivity to recruit outside of capital cities. Queensland Health have been the pioneers and leaders in Tele-Trials which has been a gamechanger in this area.

DS: Thank you for your time and providing us an insight into your amazing career.

CONFLICT OF INTEREST

Dr Suzanne Elliott is an employee of Gallipoli Medical Research.

AUTHOR CONTRIBUTIONS

Alex Johnston: Conceptualization; writing – original draft. **Arti Medhavy:** Conceptualization; writing – original draft. **Suzanne Elliott:** Conceptualization; writing – original draft. **Danielle I Stanisic:** Conceptualization; writing – original draft; writing – review and editing.

DATA AVAILABILITY STATEMENT

Not applicable.

REFERENCES

1. Clinical Trials Queensland. Homepage Clinical Trials Queensland [Internet]. Brisbane, QLD: Clinical Trials Queensland. https://www.clinicaltrialsqld.com. Accessed January 20, 2025.
2. Suntharalingam G, Perry MR, Ward S, *et al*. Cytokine storm in a phase 1 trial of the anti-CD28 monoclonal antibody TGN1412. *N Engl J Med* 2006; **355**: 1018–1028.
3. Eastwood D, Findlay L, Poole S, *et al*. Monoclonal antibody TGN1412 trial failure explained by species differences in CD28 expression on $CD4^+$ effector memory T-cells. *Br J Pharmacol* 2010; **161**: 512–526.
4. Kaur R, Sidhu P, Singh S. What failed BIA 10-2474 phase I clinical trial? Global speculations and recommendations for future phase I trials. *J Pharmacol Pharmacother* 2016; **7**: 120–126.
5. Eddleston M, Cohen AF, Webb DJ. Implications of the BIA-102474-101 study for review of first-into-human clinical trials. *Br J Clin Pharmacol* 2016; **81**: 582–586.