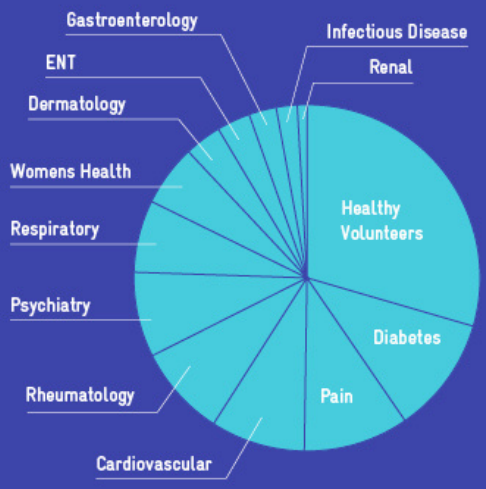
Newsletter

2nd Edition, 2022

Paratus Clinical

Welcome to the second edition of the Paratus Clinical newsletter. We have had a great start to 2022, having just wrapped up a number of studies including a Hypercholesterolemia study, a migraine pain study and a gout study. Our gout study required a long study visit without an overnight stay. Continue reading below for more details on how we managed such a long visit.

We are now coming into the colder months in Australia and are gearing up for 7 vaccine studies in RSV, Influenza, Dengue Fever and a study for a Covid-19 booster vaccine. Not only are we successful in running vaccine studies, we also run trials across a range of therapeutic areas as outlined below.



Therapeutic area breakdown

- An average of 800+ patients across all sites for Healthy Volunteer and Vaccine studies
- Each site has over 200 patients for Rheumatology and Pain studies
- Each site has over 100 patients for Womens Health, Cardiology and Psychiatry studies

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An interview with Carolyn

CAROLYN CASEY

CHIEF OPERATIONS OFFICER

How long have you been involved in clinical research and what appealed to you about the industry?

I have been involved in the clinical research world for almost 20 years. Throughout my university days studying law I became passionate about medicine & the law and bioethics. After graduating and spending a few years in private practice, I realised my heart lied in science/law and medicine and I began to explore career opportunities in in the area of bioethics and landed a role at The Children's Hospital at Westmead managing the Human Research Ethics Committee. From there my role continued to grow and eventually as the research division grew my role changed to one of governance and compliance including research contract and quality management. In these roles I got to experience the world of both commercial and non-commercial clinical trials and went on to work within and consult to both pharmaceutical companies, medical research institutes and private clinical trial sites. The appeal was not only the ability to use my legal skills in an area I was passionate about, but I was also able and continue to develop a deep understanding and appreciation of the entire process of bringing a therapeutic good to market from conception to sale. A true appreciation for what is involved for both commercial and non-commercial researchers, participants, and the end consumers. During my time at the hospital, I also got to see the incredible direct positive impact of clinical research.

You have worked in a variety of roles within the industry, do you have a favourite or memorable moment?

I won't call out a favourite role that is too hard and there have been many memorable moments. However, my most memorable moment has been with Paratus; the set up and conduct of the Novavax COVID19 Phase II clinical trial vaccine (June 2020). We were in the midst of lockdown and the entire world did not know what the fate of living with the virus would be. To see our team, client, and our volunteers (the general public) come together for not their own benefit but the benefit of everyone as a whole, the way traditional views on the conduct of clinical research were reimagined and to see change management in action at lightning speed, is something I will never forget and am immensely proud of. Now the drug is registered and available in Australia that pride and sense of accomplishment is cemented.

Where do you see Paratus Clinical heading in the next 2-5 years?

Since I commenced with Paratus the journey has been one of growth and improved quality. Year on year we continue to grow not only in size, but the opening of new sites, employment of new staff and delivering more and diverse studies. We also pride ourselves on delivering high quality data which we know all our clients are all looking for. I see not only this continuing in the next 2 – 5 years but our quest to improve through working more closely with our clients to ensure a better experience for them and our volunteer participants. We will have a strong focus on vaccine research at our existing sites and I see us opening or collaborating with new sites that can cater to more specialist studies.

Where do you see the future of clinical research in a post-Covid world?

The future is bright! The clinical research literacy of the world has changed forever. Although there is scepticism and questioning of the process, it is a discussion that many more are willing to be involved in and we can see through our recruitment there is more wiliness to be involved in clinical research and better understanding of what is involved. I am sure many of my research colleagues would agree many friends and family had no idea or interest in what we did pre COVID, now it's often the talking point.

CASE STUDY

GOUT PK SAMPLES

Background

A biotech company working with an Australian CRO looking for a site capable of long patient visits for their Ph2a Gout study

Requirement

The study required 9 PK samples across a 10 hour period with no overnight stay

Outcome

- Patients were onsite for 12 hours + and were constantly monitored by site staff throughout this period
- Patients were provided with office space to work from, lunch and drink vouchers for local cafes and entertainment to fill in their time
- Positive participant feedback - "Comfortable, relaxed environment with lovely staff. A room with a desk was provided so I could continue to work in my business. Staff very nice, made to feel at ease"