ENSURING ACCESSIBILITY OF RELEVANT DATA:

How a new software solution was developed to improve management of Australian clinical trials

aining a birds-eye-view of clinical trials across the country is a goal we all have a stake in. And being able to discern trends and conduct in depth analyses that can in turn influence policy and support growth across our sector is the ultimate aim. Now, after 18 months of dedicated work by specialist teams at Cancer Trials Australia (CTA) and Cardiobase a Melbourne-based healthcare solutions company—we are one step closer to realising this goal.

"For many years we sub-licenced an established clinical trial management system (CTMS) to our Member hospitals throughout Australia" said Kurt Lackovic, CEO of CTA.

"We were able to prove the utility of a coordinated approach to trial management, as well as centralise the dedicated support required to underpin the use of a CTMS, across hundreds of clinical trials undertaken at clinical sites across multiple Australian states. However, that CTMS was not designed for an Australian context, nor did we have the ability to evolve it to meet emerging requirements. We sought a solution to both improve the quality and timeliness of data capture, as well as enable us to better utilise the data that our hospital Members collect." said Kurt.

Together, CTA and Cardiobase developed a customised software solution called Clinibase, which is now deployed across Victorian and New South Wales hospitals in both metropolitan and regional settings. Clinibase significantly reduces the administrative burden and improves data insights gathered for trials, with ongoing updates planned.







Clinibase collects vitally important data, including how many trials are recruiting, the types of trials being undertaken, how many patients have been recruited, the type of patients being recruited, the length of time a participant spends on trial and how much work the study coordinators need to undertake for any one clinic visit, among many other key metrics.

Much of the groundwork for this partnership was laid with the help of CTA's Information Systems Manager, Emily England, who began sounding out potential technology partners to work with side by side on the project.

"The world has changed; we can no longer be tolerant of 'dead end data' that just sits inside a system and isn't fully used or understood," said Emily.

"While we have always utilised the data collected to support our management services for Members, we knew there was so much more untapped potential for analysis, and for the system to extend into providing additional functionality and context for study coordinators and nurses, so they could more easily focus on their patient-facing work. We also wanted a system that was so user friendly and readily adopted, that it would propel us towards the ultimate goal of being able to show the full picture of clinical trials across the country."

"Building a custom software solution from scratch requires a cross-functional team with vision and grit, coupled with a proven, strong understanding of the real experience of end users, the clinical sites themselves; this is where CTA and Cardiobase really came together - we needed a partner that knew our sector intimately and that had a true Australian focus in their sights."

"Initially our work with CTA was scoping the issue, to really understand the obstacles and drivers," said Jason Wagstaff, CEO of Cardiobase. "We quickly came up with elegant solutions and it was clear that we were onto a real winner"

"This project had a genuine 'start-up' pace and spirit to it, which allowed us to relentlessly focus on the outcomes resulting in a solution that has transformed people's work," said Jason.

"We were excited at the outset because this project gave us the chance to work with committed individuals who wanted to innovate across the whole system. We liked the fact that CTA came to us with a genuine opportunity—no one had considered the nuanced clinical and administrative problems that they were working towards solving, and our partnership was able to work on that holistically," said Jason.

Requirements of various user types were defined, and the subsequent proof-of-concept system was piloted at a single, clinical trial site in February of 2021. The initial results were so successful that the trial site switched over to the proof-of-concept software the following week. Fast forward to January 2022, and all of CTA's service Members are now successfully utilising Clinibase.

"The system we have now supports totally different conversations about the role that data plays in improving the way we all work together," said Emily England.

"We can now use the data captured within Clinibase to give back to our Members – providing them with deeper business intelligence, and freeing them further to focus on their clinical work," said Emily.

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The entire rollout to clinical sites occurred during COVID-19 lockdowns, which against all the odds did not hinder the fast delivery schedule. And what's more, the solution continues to be consistently upgraded and evolved to keep pace with the ever-changing nature of clinical trials, something that was out of reach with the previous system.

Chief Operating Officer at Cardiobase, Mark Johnson, knew that the system had to hit the ground running if it was to be a success from the outset.

"Without access to a partnership that allows CTA and Members to innovate, the rapid pace of clinical trial work is constrained. And that's not ideal for anyone," said Mark.

"We saw the opportunity to create technology that would support and enable agility and innovation. Clinical trials continually evolve, so it's a huge advantage to have a solution that can accommodate change over time, and be expanded to collect additional data points as the need arises. We can evolve the product as legislation, trial design and guidelines change, right where the activity is happening," said Mark.

"We are using cutting edge technology here, a best-ofbreed solution and we provide functionality releases very quickly, several times a week in fact. It's continual integration and deployment, feature by feature," said Mark.

The data collected through Clinibase, and the insights that affords, are vitally important. This allows critical oversight of clinical trials across many Australian hospitals. "The world is hungry for useful data. State governments are now asking for more detailed information to help improve decision-making, and we can now support our Members in providing this. CTA's driving principle is to improve access for Australians — while this is focussed mainly on improving patients' access to emerging therapies and increasing hospitals' access to appropriate funding and resources, it also includes ensuring decision-makers' have access to trusted, reliable data," says Kurt.

Clinibase's customised reporting functionality will also support users with mandated reporting as part of the National Clinical Trials Governance Framework (NCTGF). The NCTGF, which will be implemented across Australia later this year, seeks to help reduce clinical trial startup times, optimise pre-approval and recruitment timeframes, and improve consistency in trial delivery. Reporting of metrics associated with clinical trial activity will feature in the accreditation of hospitals that conduct clinical trials.

With a robust, fit-for-purpose software solution now supporting the conduct of clinical trials across multiple states, Australia is even more attractive as a destination of choice for global biotech and pharmaceutical companies to undertake their clinical activities, which is something CTA has championed since its inception almost 20 years' ago. And ultimately, it is Australian patients that are the beneficiaries.







