# CLINIALS Smart Algorithm (SA)

### Driven clinical trial participant recruitment platform

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## **CASE STUDY T2 DIABETES**

Regent 1 is a study evaluating a new way to help the body regulate blood sugar level outside of insulin or other existing medication. A unique type of catheter is used to deliver electrical pulses to the small intestine. The therapy stimulates new cells to grow, increases the bodies ability to control its blood sugar level.

The study was looking for participants with type 2 diabetes, both using and not using insulin. In total, over 44 days of advertising Clinials was able to find 91 interested participants with type 2 diabetes who went through prescreening and left their details for further contact. Out of these 91 participants, Clinials prescreening questions filtered out 54 commonly for criteria relating to BMI and age.

The Clinials platform not only saved the sites valuable time, it also meant that nearly every single day a participant willing, engaged and wanting to be a part of the trial - who had already passed pre-screening and was likely eligible for the trial was found. The sponsor also had full visibility of site and advertisement performance.





## CASE STUDY SEVERE ECZEMA

An American sponsor searching for participants to enrol in a atopic dermatitis study within Australia called on Clinials for their expertise in using non-finite recruitment methods. The sponsor and sites knew that despite Atopic Dermatitis affecting millions of people worldwide, their stringent protocol would only allow for very few eligible participants. Atopic Dermatitis is common, however, this study was looking for participants where over 10% of their body was affected by Eczema (moderate to severe level). An EASI score was used to determine the severity of participants Eczema set at a score  $\geq$  15, along with other prerequisites. The protocol also required participants to withhold from drinking for 16 weeks and complete 5 site visits in person.

One of the biggest challenges for this study was finding participants who were able to meet the criteria, without the sites having to wade through hundreds of applications which weren't relevant. Clinials created a visual prescreening method that allowed for patients to create their own EASI score, without using any medical jargon. Unlike other trials, for the eczema study a specialist completed the secondary screening of participants and recorded the result within the platform. Usually such a task is completed by clinical sites. The flexibility of the Clinials platform enable this unique trial setup to be successful.

Because of the strict protocol and only having one site, Clinials put together a marketing campaign utilising both social media and google ad words to get in touch with people suffering severe eczema. This combination meant participants coming through to the trials landing page were pre-qualified and likely had eczema. In total, there were 233 submissions for this trial, which with Clinials prescreening platform 18 eligible participants were identified and 77 needing secondary review by the site. In total, we helped recruit over the protocol goal of 12 and saved the sites screening 138 participants who weren't eligible.



### **CASE STUDY LUMBAR PAIN**

The Lumbar Study aimed to test the safety and efficacy of a non opiate pain medication. The non addictive/non opiate drug was given as an injection directly into the bloodstream and required two nights at the PARC site. Participant pain scores would be assessed and compared to determine the effectiveness of the treatment.

The Lumbar Study was looking for participants who experienced shooting pain down the back of their leg between 3 - 13 months. Over 32 days of advertising, Clinials found 139 interested participants suffering from lower back pain. These 139 participants completed the online prescreening form and left their personal details to be contacted for further screening. Of these 139 participants, Clinials filtered out 47 using an automated eligibility check on the prescreening questionnaire.

Overall, the Lumbar Study advertising campaign reached a total of 143,589 people, with a lead cost of \$40 per eligible and engaged participant. In addition, the advertising for this trial was limited to Adelaide alone.



## CASE STUDY COVID-19 BOOSTER

The Covid-19 booster trial evaluated the safety and immunogenicity of two booster doses of a new vaccine for coronavirus. The vaccine was given to adults who have previously received other vaccines for coronavirus, and was one of the most popular studies on the Clinials platform in 2022. The study came to us as a last resort to increase the numbers of participants completing the trial, and was time sensitive with a maximum of 4 weeks until closing recruitment.

Because of the strict timeline, Clinials expedited the trial and was able to get all materials needed and set up within 2 days, with advertising beginning the next day. In total, over 26 days of advertising 559 people went through prescreening and gave their expression of interest for the trial. Because the trial was only allowing certain vaccines, Clinials was able to save the sites valuable time by identifying 136 eligible participants for the clinicians to contact - a must when trying to screen huge amounts of participants in a short time.

In total, each eligible participant cost \$28 to recruit and **minimised the work needed to** screen participants by over 4 times.

## CASE STUDY VACCINATION

When the sponsor of a dengue vaccination trial realized that their site location, which was not endemic for dengue, was impeding the accumulation of participants, they knew they needed to shift their approach. Clinials recognized that the goal posts needed to be changed and devised a creative solution.

Instead of solely focusing on dengue, Clinials launched a comprehensive vaccine campaign for travel, giving participants the opportunity to select the vaccine(s) that interested them. This initiative served a dual purpose – it acted as a recruitment strategy for the Dengue Vaccine trial and helped to fill other trials, such as Pneumococcal, Covid, and RSV, at the site. From January 16th, 2023 to February 16th, 2023, the number of eligible participants skyrocketed from 14 to 138 submissions of interest, and 42% of them were booked for a dengue vaccine in just four short weeks.

The site and Clinials collaborated to take participants through each vaccine, resulting in a higher uptake of the dengue vaccine by explaining the trial and its benefits to the participant. Previously, the dengue vaccine was only available to residents of countries that were endemic for dengue, leaving Australian tourists who visited these hotspots vulnerable. By reframing the approach, the site was able to recruit four times the original amount of participants in just one month compared to the two months it previously took to recruit only 14.

