

To validate how
Consentic's electronic
consent forms made
positive impacts on the
enrolment process for
clinical trials and
reduced time
pressures placed on
hospital staff at a
Victorian hospital

Purpose of the Case Study



Project Overview

Processing patients through the consent portion of a clinical trial has become significantly time consuming and laborious for clinical trial staff.

Over 12 months, patients undergoing hip and knee surgeries were offered participation in a clinical trial. Key metrics were measured by the research team at a Victorian hospital using Cogniom's TANDM Suite.

Over 24 patients were assessed using a randomized controlled trial methodology.

Amongst other things, the time taken to consent, and time to clinical trial enrollment were recorded.

54% of participants were female with 46% male. The most common education level was high school at 42%, with the most common age group being 61-80 years, which was heavily influenced by the type of surgery.





Workflows Studies

The traditional paper-based clinical trial consent process required paper documents prepared and printed (>30 pages), and training to ensure their full understanding of the clinical trial, followed by a wet ink signature.



Admin Support. Clinical Nurses were required to prepare and print long documents and physically deliver them to patients



Education. Clinical Nurses were required to educate patients about the clinical trial they were undergoing to understand risks/benefits



Follow up. Patients were required to prove satisfactory understanding of their participation in the clinical trial, requiring multiple follow ups



Final Consent. Clinical Nurses had to follow up paperwork, answer questions from patients and family and gain final signatures for consent.

Actions Taken

Using the TANDM Suite, the clinical research team from a Victorian hospital recorded timings of the consent process both with paper and Consentic's digital eConsent.

The clinical trial was focused on a rehab app following knee surgery. Over 24 eligible patients were timed and measured throughout the consenting portion of their clinical trial to discover what the efficiency gains would be.

They found that there was a tremendous difference in the time it took to onboard patients into the study comparatively.



12 month Self-Reporting. Using the TANDM Suite, Clinical Nurses crowd sourced their workflow timings and sent their findings instantly to real-time online dashboards.



Comparing Processes. 24 patient consent processes were monitored evenly split between paper based and using electronic forms (RCT methodology).



Front Line Research Team. Volunteer Clinical Nurses captured data and insights to form a collective baseline that captured the improvements that were seen during the Consentic pilot on site.



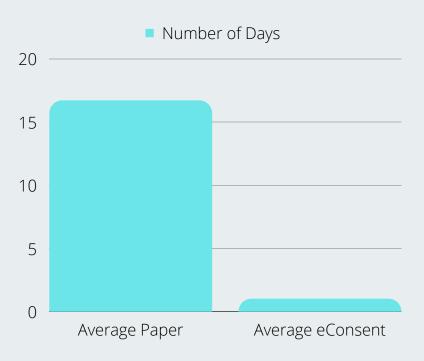
Final Impacts. It was found that paper based methods took just over 16 days to process a single patient compared to those who use Consentic which took only a single business day.





Outcome Results

Throughout the study, the average time across the consent workflow for 11 patients (per method type) was analysed and reported in real-time using the TANDM Suite.



About TANDM Suite

TANDM Suite helps teams and organisations quantify the total impact of new innovations. Organisations get real-time reporting on the value of solutions like Consentic with total time savings, total costs reductions, and overall employee/customer experiences improved – all in one place.

Average Consenting Process Time in Days

17 DAYS to complete consent with paper

1 DAY to complete consent with eConsent

94% Decrease in total time to complete patient consent

t via

16x Faster to gain consent via electronic forms

1

With Consentic's eConsent process, the clinical trial consent was completed on the same day, compared to paper consent where there were lags of 17 days per clinical trial participant, on average.

To put it into perspective, of the 365 days data was collected for this trial, 200 of them were collectively spent recruiting and enrolling just 12 patients.

With Consentic proving to be <u>sixteen times faster</u> in gaining consent, the opportunity to enroll more patients and/or increase the capacity of clinical trials is a massive benefit.