



Medical Research Institute of New Zealand

– NovelSTART trial for Asthma treatment



The NovelSTART (Symbicort Turbuhaler Asthma Reliever Therapy) trial is a randomised controlled study of combined reliever/preventer medication for intermittent or mild asthma.



It is a 52-week, open label, parallel group study operating 24/7 in sites in New Zealand, Australia, Britain, and Italy.



To date there are 15 different research institutions involved – a combination of hospitals, independent private medical research institutes, and private “for profit” research institutes.



The study is funded by AstraZeneca and utilises NZ-based Adherium’s electronic ‘smart-inhalers’ which take recording accuracy to a new level.

○ The reason and motivation – current ineffective treatments

People with persistent intermittent or mild asthma often use a reliever inhaler like Ventolin. They may also use a preventer (such as Flixotide) which should be taken as regular therapy (e.g. twice a day) to control symptoms.

However, patients frequently don’t use their medication as prescribed, and GPs may not prescribe preventers according to recommended guidelines, so there is a known discrepancy between the treatment guidelines and what actually happens in general clinical practice.

Researchers, physicians, the pharmaceutical industry and guideline authors have been looking for many years for a better ‘real world’ treatment; one

that makes it easier for the patient to use and that is effective, but funding of randomised controlled trials to provide the evidence for new treatments has been a challenge.

With the Novel START study, we hope to be able to answer the question of whether a combined therapy is safe and effective for the treatment of mild asthma.

○ How the trial works – with leading-edge electronic monitoring technology

675 adult participants are randomly allocated to receive one of the following regimens:

- Short acting beta agonist (SABA), or
- Regular inhaled corticosteroid (ICS) and short acting beta agonist (SABA) separately, or
- Combined ICS/ SABA

Cutting edge Smart inhalers supplied by Adherium are being used, which collect each medication use event, this data is then uploaded to the Smart inhalerLive system at each study visit.

“The ability to accurately monitor patients’ medication use and ensure that the study data is captured objectively and accurately is incredibly useful,” said MRINZ Director Richard Beasley.

○ How to do the challenging data collection & analysis?

Mark Holliday of MRINZ said the selection of software and suppliers depends on the nature of each study they do, and there is no one-size-fits-all solution. For NovelSTART, they required a multinational, multi-centre, study, and knew this would be complex so it couldn't be done in-house.

Mark speaks about the key reasons for choosing Spiral for the job, using Spinnaker software:

- “There is real value in having someone local where it's easy to have meetings – as it's hard to know what is going to happen when you start out with a trial like this.
- The support element is really important for these studies, and we had a very good experience of Spiral with the previous HEAT trial. They were very responsive to our needs including randomising patients at any point in time, so we knew Spiral could handle the required level of intensity.
- The usability of the system is really important, especially from the site user's point of view – and we've had very good feedback about Spinnaker being intuitive and easy to use.
- The system needed to work as it's supposed to, as it did in the HEAT

trial, unlike many other industry systems. The worst thing you can do for any trial is put people off entering data.

- The cost was feasible, unlike several other systems that didn't have the level of support without paying far more than we could fund.
- The ‘Practical’ study focusing on mild asthma dovetailed together nicely with NovelSTART.”

“Overall: Spiral came up trumps for functionality, cost and support”

○ How the trial is panning out

Mark updates us on his experience so far:

“Fantastic... most of the work is done and we are in the middle of doing a quite detailed addition to the study. We're really impressed with what Spiral is able to do in a short time, and when issues arise, they are dealt with asap.

The Spinnaker system has been completely stable with no downtime issues. It handles randomisation very well and you need it to be operating 24/7 in all time zones, as patient can visit any of our sites at any time.

The expected benefits of doing ‘Practical’ along side NovelSTART using the Spiral system have been realised in terms of the synergy of management, combined participation, reporting analysis, and training.”

○ Looking forward

“What we are doing now is probably the last big development phase, with maybe just a few tweaks continuing, but it should taper off as most sites are up and running.

It's really hard to find anything that Spiral could have done better during the project.

We look forward to seeing the same high quality results in NovelSTART and Practical as we did in the HEAT trial.”

“Novel Start was different for us, being a community-based rather than hospital-based study. This meant we needed to structure the work-flow in Spinnaker slightly differently and aim for even greater ease of use.

When participants visit their medical centre, a clinician/ investigator needs to collect and review critical data using Spinnaker on a computer or iPad – on the spot. **The robust nature of Spinnaker means we can do this for any country, any time.**

In the last phase of development we employed database integration techniques to provide the investigator with an immediate update on inhaler actuations – so they can discuss any issues directly with the participant during the visit.”



AUDREY SHEARER
Managing Director, Spiral Web Solutions

