



Merry Christmas from the HONEYPOT Study

WE ARE ON THE HONEYPOT HOME STRETCH!

Can you *bee*-lieve it, we only need 22 additional participants in the trial *bee*-fore we reach our recruitment target of 370! If each site randomises 1 or 2 more *bee*-fore February 2011, we're on easy street.

On *bee*-half of the HONEYPOT Trial Management Committee, thank you to all site Investigators and Coordination staff for their efforts in 2010. The recruitment rate has *been* great, and we look forward to celebrating participant #370 with you all.

Bee good,

Alicia Morrish & Liza Vergara, AKTN



Recruitment Update

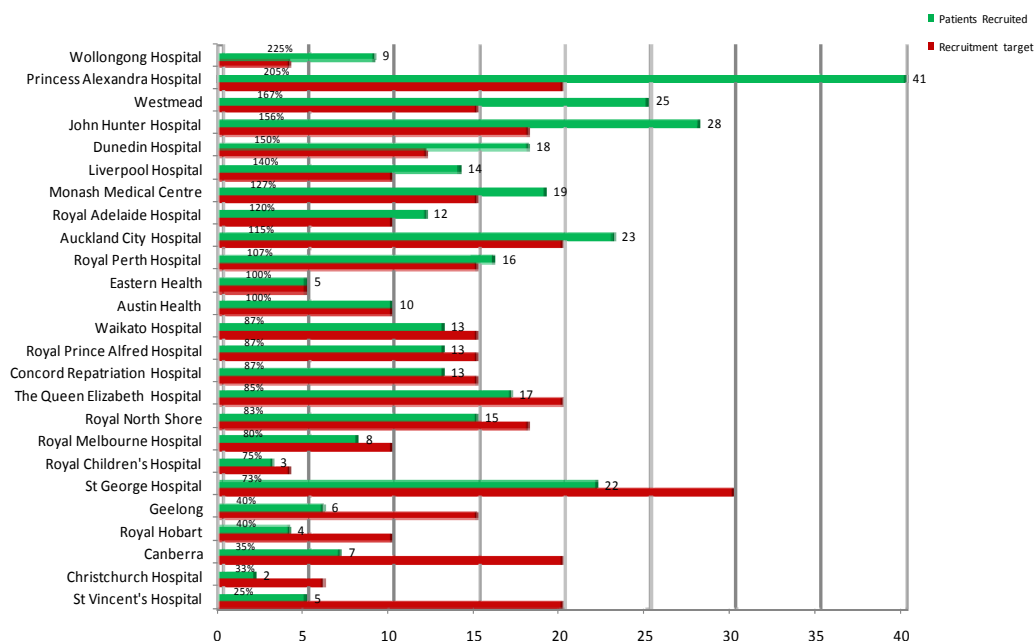
After a late recruitment drive in June 2010, there are now 26 HONEYPOT sites up and running.



The top 5 recruiting sites are:

- Princess Alexandra Hospital (41 pts)
- John Hunter Hospital (28 pts)
- Westmead Hospital (25 pts)
- Auckland City Hospital (23 pts)
- St George Hospital (22 pts)

Congratulations to all past and present staff from these sites, and thank you for your contribution to the trial.

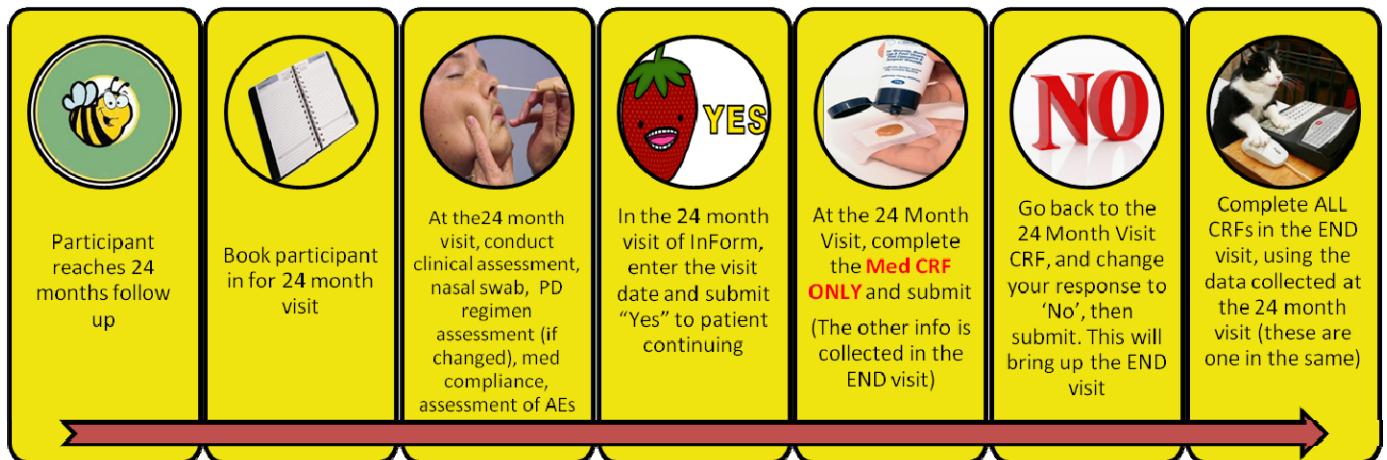


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End of trial visit (END)

Several sites have asked about how to end follow up for their participants that are approaching the 24 month follow up visit. The flow chart below indicates how end of follow up is to occur for participants who have made it through 24 months of trial follow up.



Ensure you retain all source documentation and other information from the trial, and Liza will contact all sites during 2011 and 2012 to discuss close out visits, data queries and archiving.

Monitoring Update

Liza has *been* a busy *bee* monitoring HONEYPOT sites during 2010. All sites, with the exception of the newest 3 to join the trial (Royal Hobart Hospital, Eastern Health, Western Health) have *been* visited at least once, and most have now had repeat visits. Liza will continue to monitor during 2011, while 2012 will mostly *bee* concerned with study close-out visits.



A reminder that the data resolution forms Liza leaves after the monitoring visit should *bee* completed, or at least attempted, before the next monitoring visit. You will find it easier if these are done soon after the monitoring visits while the issues are still fresh in your memory.

Monitoring visits are not just about source data verification; the visits provide a unique opportunity to ask Liza questions about the trial one-on-one, and to confirm you are all doing great work at the sites. So HONEYs, please feel free to pepper Liza with all of your questions (no matter how silly they may seem) when she comes to visit you.

Data Completion

As the trial *bee*-gins the down-ward slope to completion, the AKTN statistician *bee*-gins the arduous task of data cleaning. In order to make the HONEYPOT data as useful as possible, and reflect the hard work you have all put into the study visits, please ensure your data is as complete as possible.

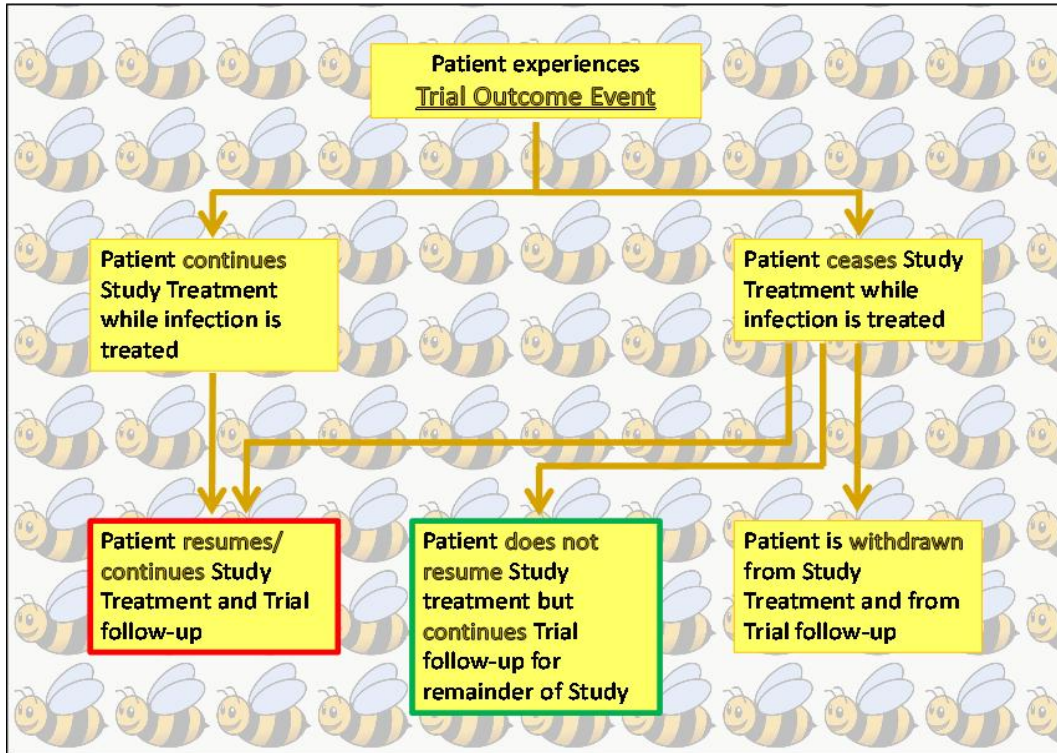
Next year, Liza will contact each site with more information on which data fields are commonly being left incomplete, and how you can resolve data inconsistencies.



Trial Outcome event—what next?

There is still some confusion about what to do in terms of treatment and follow up after a trial participant experiences a trial outcome event. As a reminder, please read the diagram below (first published in the December 2009 Newsletter) which explains the process.

The preferred option is highlighted in **Red**, with our second preference in **Green**, but clinical decisions are left to the discretion of the treating physician.



Frequently Asked Questions

Q: what do you do with a non-compliant participant, eg one who uses Medihoney infrequently, not as directed, or not at all?

A:

1. record a deviation on the HONEYPOT protocol deviation log and fax it to Liza
2. record the compliance issue on the Med eCRF (if participant is using the product less than 80% of recommended time)
3. ask the participant to use the product as per the protocol. Failing that, ask the Investigator or the treating physician to reiterate to the participant the importance of using the product as instructed. If the participant continues to use Medihoney sporadically or not at all, this **will need to be recorded on the Med eCRF at each subsequent visit**, for as long as the participant is misusing the product.

Q: how do I record a nasal swab that is negative for *Staph aureus*, but positive for another strain of staphylococcus, eg *Staph epidermis*?

A: only the presence *Staph aureus* needs to be recorded on the NSwab eCRF, due to its likelihood of contributing to catheter-associated infections. The result in this example would be recorded in the NSwab eCRF as "negative", or "non-carrier for *Staph aureus*" in the Randomisation eCRF.



For Further
Information :



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