

## HONEYPOT Newsletter

Volume 3

June 2009

The HONEYPOT Trial is proceeding very well, with most sites active and recruiting, and over 1/3 of the recruitment target already reached.

State/Country	Site	State/Country	Site
NSW	Blacktown/Westmead Hospitals		
NSW	Concord Repatriation General Hospital	Vic	Austin Health
NSW	John Hunter Hospital	Vic	Geelong Hospital
NSW	Liverpool Hospital	Vic	Monash Medical Centre
NSW	Orange Base Hospital	Vic	Royal Melbourne Hospital
NSW	Royal North Shore Hospital	Vic	St Vincent's Hospital
NSW	Royal Prince Alfred Hospital	WA	Royal Perth Hospital
NSW	St. George Hospital	NZ	Auckland City Hospital
NSW	Wollongong - Illawarra Regional Hospital	NZ	Christchurch Hospital
Qld	Princess Alexandra Hospital	NZ	Dunedin Hospital
Qld	Rockhampton Base Hospital	NZ	Palmerston North Hospital
Qld	Royal Children's Hospital	NZ	Starship Children's Hospital
SA	Flinders Medical Centre	NZ	The Canberra Hospital
SA	Royal Adelaide Hospital	NZ	Waikato Hospital
SA	The Queen Elizabeth Hospital	NZ	Whangerei Hospital

### Trial Documentation

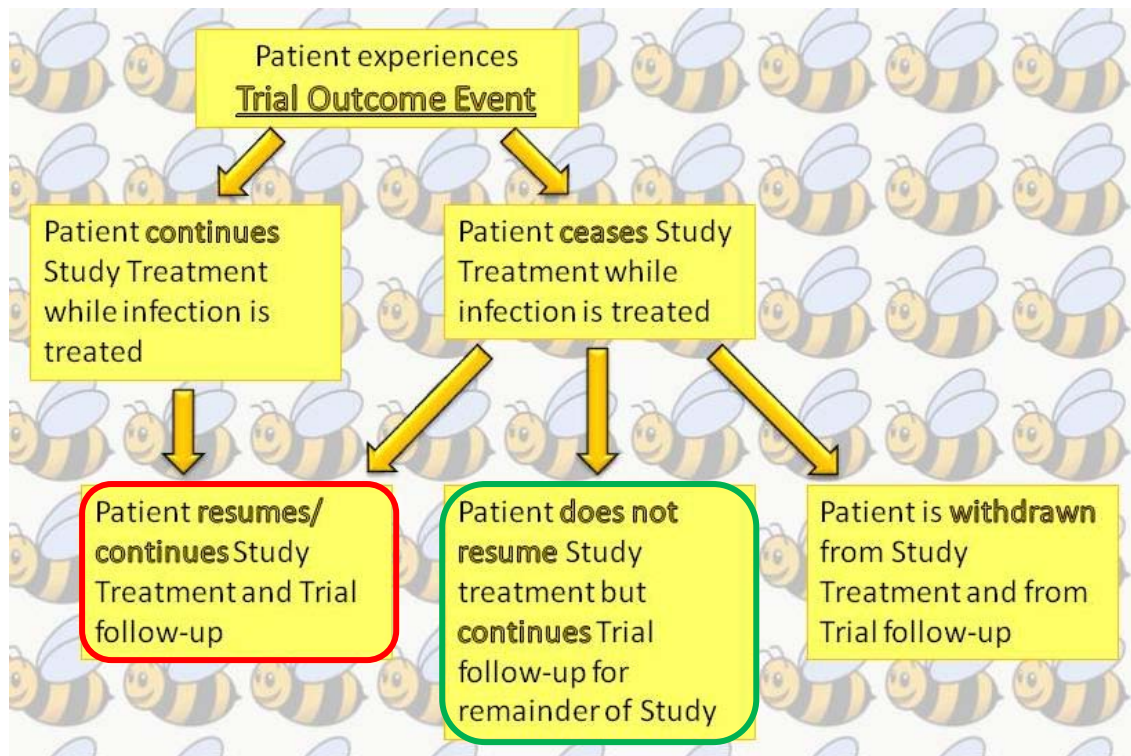
Since the last Newsletter was published in June, there has been a lot of activity with regard to trial documentation. Based on issues raised at the three Study Coordinator Meetings that were held earlier in the year, and additional feedback received from active sites, several minor changes and clarifications were made to the Protocol, resulting in Protocol version 5.0 being released in June. The amendments were approved by the University of Queensland's Human Research Ethics Committee (HREC), and subsequently distributed to all sites. Most sites have now submitted version 5.0 and received approval from their Local or Site HRECs, and are now conducting the trial according to this version.

### Site Status / Recruitment

14 sites are now "active" in the study, which means all of their study documentation is up to date and they have met all of the requirements for the ICH GCP (Good Clinical Practice) guidelines. 7 of these sites have successfully randomised patients to the trial, and recruitment hit 42 patients this week! Congratulations to staff the following sites that now have patients active in the HONEYPOT Trial; Auckland City Hospital, Christchurch Hospital, Concord Repatriation General Hospital, Monash Medical Centre, Princess Alexandra Hospital, Royal Adelaide Hospital, and The Queen Elizabeth Hospital.

## End of Study – when to withdraw, when to continue follow up?

We have had several queries about what to do if a patient reaches a Trial Outcome Event. The following flowchart should help clarify the choices available. 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

**Question:** Are patients enrolled in other trials eligible for inclusion in HONEYPOT?

**Answer:** Absolutely! As long as the patients meet all inclusion criteria and no exclusion criteria, there is no reason they can't be involved in other clinical trials at the same time as HONEYPOT. It is a good idea to check with the Study Coordinator or Sponsor of any other trials your patients may be involved in though, to ensure they do not have any restrictions of this kind.

**Question:** In what time frame must the Baseline visit occur with regards to Randomisation?

**Answer:** The Baseline visit must be within 14 days of Randomisation (after Randomisation). This is to ensure the currency of the nasal swab that is conducted at Randomisation. At some sites however, it may be more convenient for the Baseline visit (or at least some of the Baseline assessments) to occur *prior* to Randomisation. This is also acceptable, just be sure to record the dates accurately. If Baseline is conducted prior to Randomisation, the information will need to be recorded on visit stickers or paper based CRF template first, as the electronic CRF is not made available in InForm until after Randomisation.

**Question:** Are patients randomised to the control arm who are not nasal carriers of *S. aureus* required to maintain a Medication Diary?

**Answer:** No, if a Control arm patient is not a nasal carrier of *S. aureus*, then no medication is required, and as a result no Medication Diary is required. The trial Medication Diaries have been provided as non-compulsory trial resources and are therefore not considered source documents. A site or patient may chose not to maintain one, as long as they can reliably relay their study medication compliance at their bimonthly study visits.

## Sites in the News

### The Queen Elizabeth Hospital

Congratulations to Dr Stephen McDonald, Tania Barnard and team at TQEH for being the first non-Chief PI site to randomise a patient to the HONEYPOT Trial.

### Princess Alexandra Hospital

The first HONEYPOT site monitoring visit was held at Princess Alexandra Hospital on Wednesday 17<sup>th</sup> of December. The visit went very smoothly; hopefully an indication of HONEYPOT monitoring visits to come!

### Princess Alexandra Hospital

Congratulations to our HONEYPOT Chief PI, Professor David Johnson, in being chosen as a finalist in the Queensland Australian of the Year awards. Prof Johnson was named as a top-four finalist from a field of over 3000 people. Well done Prof Johnson!

### Flinders Medical Centre and Rockhampton General Hospital

A warm welcome to Dr Rajiv Juneja, Kathy Hill, and Dr Thin Tan from our two newest HONEYPOT sites.

### **Honey funnies**

Q: Who is the bees' favourite singer?

A: Sting!

Q: Who is the bees' favourite pop group?

A: The bee gees!

Q: Who is the bees' favourite classical composer?

A: Bee-thoven!

Q: What does a queen bee do when she burps?

A: Issues a royal pardon!