

Issue 4  
September  
2017



**TARGET**  
Nutrition Study

Newsletter

The Augmented versus Routine approach to Giving Energy Trial

Recruitment

3046/4000

### Study update — recruitment

- New Zealand enrolled their 1,000th patient — 24 August 2017
- Australia enrolled their 2,000th patient — 31 August 2017
- New estimated recruitment completion date—13 November 2017



### Study update — interim analysis

- All data is entered for interim analysis — thank you so much for your amazing support and fantastic data management.
- The last of the data queries raised by the statistician — sent this week.
- DSMC meeting for interim analysis—20 September 2017.
- DSMC correspondence will be sent to sites as soon as received from Professor Cook.



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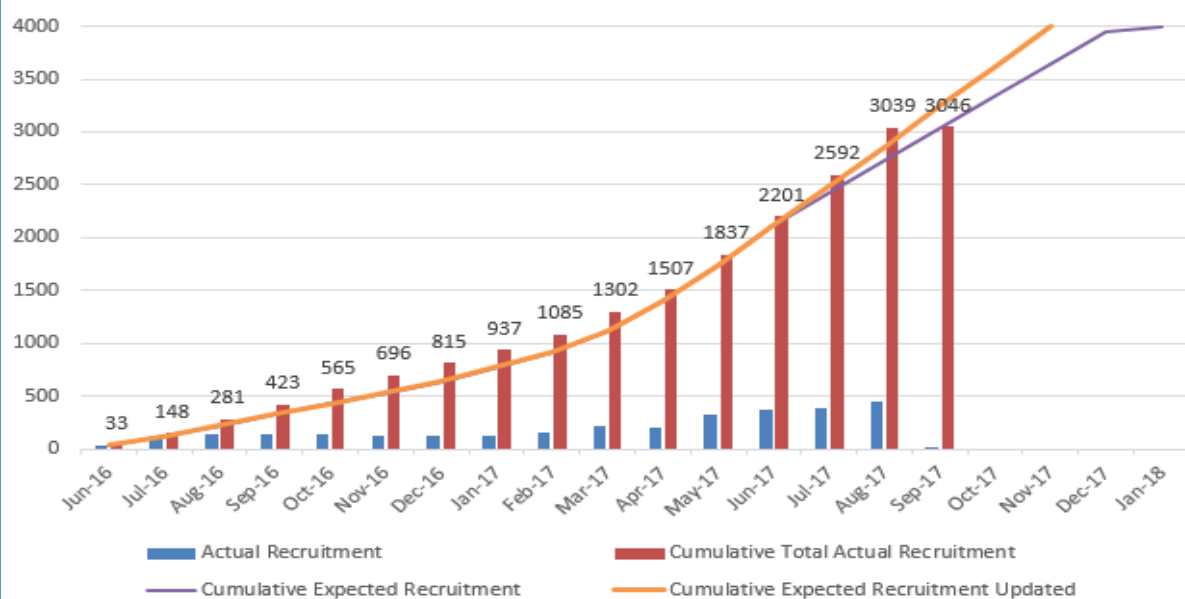
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## Recruitment



## Having trouble finding the APD number?

Talk to your local APD data collector to source this information. The APD number is called the “patientID”. The patientID is created by your APD data collection software and is available as part of the export file that is submitted to ANZICS CORE each quarter.

If you use AORTIC as your data collection software we can provide you with a query to extract this information.

Contact Jane Parker on +61 439 173 414 or [jane.parker@monash.edu](mailto:jane.parker@monash.edu) to discuss

## Interim analysis data cleaning — main issues

1. TARGET EN bags are being hung for > 24 hours which is a protocol deviation. Bags should not be hung for > 24 hours, apart from being an instruction from the manufacturer it is also an ICU policy. Bags hung for > 24 hours is the most frequent protocol deviation we are reporting.
2. Entering a cessation (CRF 3) and interruption (CRF 4 daily data) which were the same event (only capture event once) – definitions in data dictionary pages 27 and 32.
3. Lots of reasons for interruptions (CRF 4 daily data) in “Other” category that could fit one of the pre-defined options from the drop down menu – definitions in data dictionary pages 32 and 33.
4. Blood glucose control (CRF 4 daily data) high and low values mixed up – a report is now available on the database under “Reports” called “Invalid range – Blood glucose control”. Check it out!
5. Blood glucose control (CRF 4 daily data) – consider finger prick, ABGs and labs to collect these data – data dictionary reference page 39.
6. CRF 3 (Protocol EN administration) data not matching up with CRF 4 daily data.
  - Make sure the start/stop dates match up with the daily data dates.
  - Check that if the TARGET EN is recommenced that the date of recommencement and cessation is entered into CRF 3.
  - Data dictionary reference pages 26 to 29.
7. Incorrect baseline categorisation – check the patient’s age before categorisation. In some instances patients less than 40 years of age were categorised in the 65 years and over group – data dictionary reference pages 24 and 25.
8. When oral diet commences, TARGET protocol EN is ceased, even if supplemental EN is running in the background or overnight to support nutrition until the patient is taking a full diet – protocol reference page 33; data dictionary reference pages 30 and 31.



## Started recently?

### Current study documents:

Protocol v4—13 February 2017

Data Dictionary v3—14 April 2017

CRF—version 3

FAQ document—4 April 2017

NZ PIS/CF TARGET info and generic consent form v3—2 March 2017

AUS Master study brochure (NMA) v3—13 February 2017

AUS Master study brochure (WA) v2—27 February 2017

AUS Master study brochure (Tas) v3— 7 April 2017

**Please ensure all bags are marked at “Reconciled” on the Patient Summary page on the database when bags are checked against the Bag Inventory Log. Please don’t leave the bag status as “Finished” or “Opened” or “Assigned”.**

**Please check the co-enrolment list at <http://anzicrc.monash.org/target>**

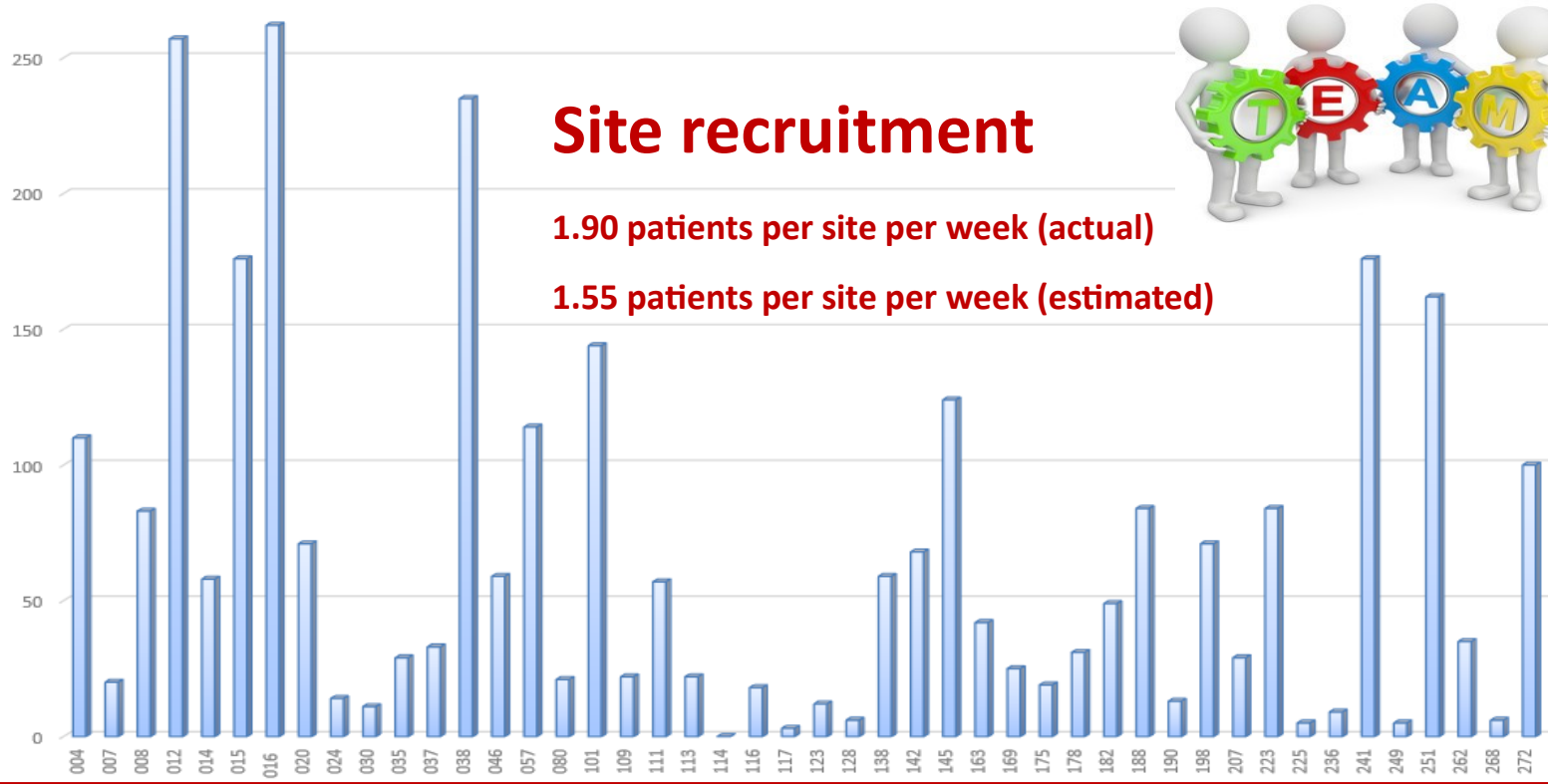
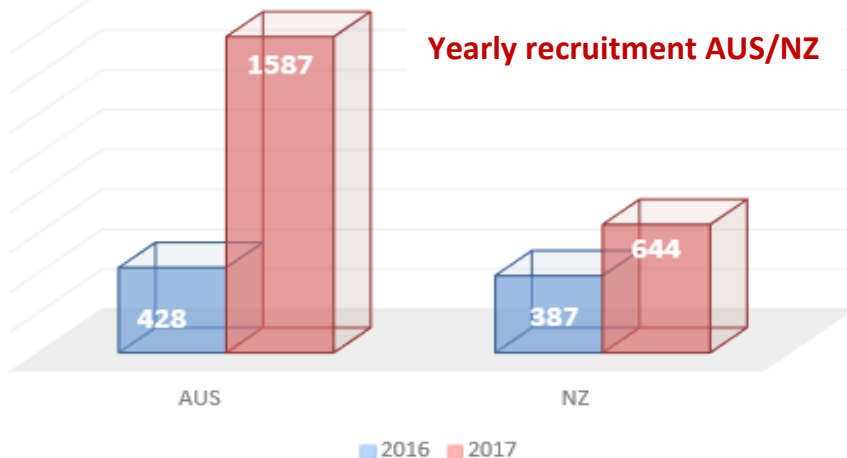
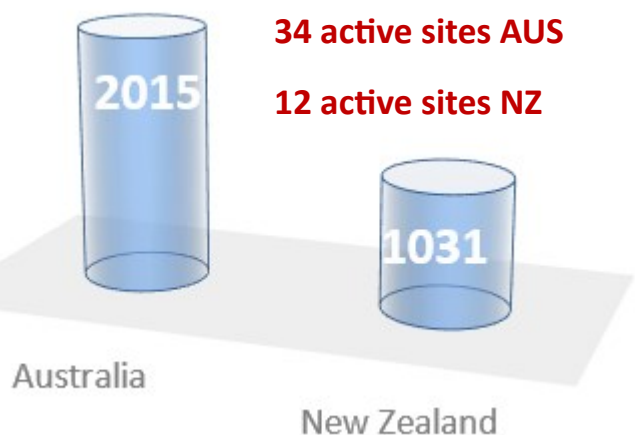
**It can be difficult to find the date of death for patients who have died after hospital discharge, check out the following websites (they may help):**

**Australia—<http://ryersonindex.org/search.php> Or check Births, Deaths & Marriages registry in your state.**

**New Zealand—<http://www.ryersonindex.org/nz.htm>**



# RECRUITMENT



## Study payments

### Australia

- All enquiries about study payments to the project manager ([Lorraine.little@monash.edu](mailto:Lorraine.little@monash.edu))
- The site is responsible for keeping up with completed patients, eligible for payment.
- Send a draft invoice to the project manager for review before a formal invoice is created.
- Ensure the Monash University Purchase Order (PO) number is documented on all TARGET study invoices.
- If you haven't been sent a PO number (or you can't find it) contact the project manager.
- Check the CTRA for payment information.

### New Zealand

- All enquiries about study payments to Sally Hurford ([Sally.Hurford@cddhb.org.nz](mailto:Sally.Hurford@cddhb.org.nz))
- A list of completed patients eligible for payments will be sent to sites regularly.
- Information about invoicing from Monash University will be sent out soon.

