



The year is off to a great start with STRIDER NZAus recruitment reaching halfway!

The goal: to complete recruitment in 2016!!

Recruited
to date
61 / 122

New recruits this month at Mater Mother’s Brisbane with two recruits; Wellington Hospital, Women’s & Children’s Hospital Adelaide, Royal Women’s Melbourne and Auckland Hospital each with one woman recruited.

STRIDER NZAus Serious Adverse Events (SAEs) and your reporting responsibilities

SAE reporting is an essential role of the Investigators at each participating hospital in order to meet the protocol and regulatory requirements (HREC, TGA, GCP) and ensure that we can maintain oversight of the safety of all participants during the trial. If you have any questions please contact us at any time.

The STRIDER protocol defines the following as SAEs and these MUST be reported:

- Maternal death
- Fetal death
- Neonatal death
- Maternal life threatening event
- Maternal persistent or significant disability or incapacity
- Major antepartum or postpartum haemorrhage (>1000ml)
- Maternal hospitalisation or prolonged hospitalisation not related to preeclampsia, IUGR or standard postnatal recovery
- Unexpected congenital anomaly/birth defect
- Other medically important event considered to be an SAE by Investigator

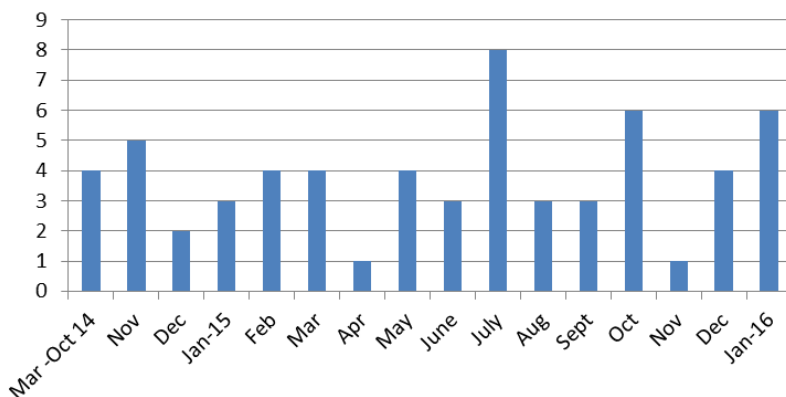


When? within 24 hours of becoming aware of the event except where the SAE is felt to be related to the underlying severe IUGR / pregnancy and there are no concerns that it is related to the study drug (Expected SAE). We recommend that you follow the 24 hour reporting timeframe for all events, even if you believe it is an Expected SAE.

How to report? Complete **SAE form 10b** hard copy form and in the eCRF. **Report to both the Auckland coordinating centre and for Australian centres to your HREC** (and governance office if required).

	Active	Women Recruited
Mater Mother’s, Brisbane	✓	16
National Women’s, Auckland	✓	15
Royal Women’s, Melbourne	✓	7
Royal Brisbane Women’s Hospital	✓	6
Women’s & Children’s, Adelaide	✓	6
KEMH, Perth	✓	5
Christchurch Women’s Hospital	✓	3
Wellington Hospital	✓	2
RHW, Sydney	✓	1
RPA, Sydney	✓	0
Mercy Hospital for Women, Melbourne	X	-
The Townsville Hospital, Queensland	X	-

STRIDER monthly recruitment



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