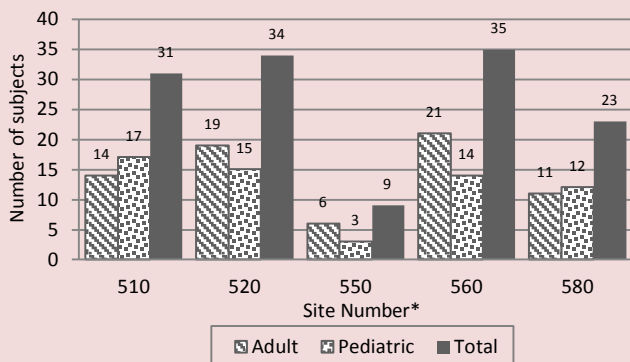


AFIRE STUDY

Entering the 19th week of recruitment, a total of 132 subjects have been enrolled by 5 sites. **Site 510** is November's top recruiter with 10 subjects recruited between November 1-24.

Enrollment Progress per 24 Nov 2013



Detailed screening and enrollment progress is available in portal folder: Studies\INA101\Screening progress.pdf or go to the following link:

<https://ina-respond.s-3.com/EdmFile/getfile/797233>

*510 – RSHS, Bandung 520 – RS Sanglah, Denpasar
550 – RS Wahidin, Makassar 560 – RSDK, Semarang
580 – RS Dr. Sardjito, Yogyakarta

TB STUDY

objectives are to determine the rates of MDR TB and various treatment outcomes of new and previously treated cases.

We are getting closer to get the protocol finalized after meetings with TB Expert Committee, Investigators, and National TB Program (NTP) team. There are several outstanding research questions from the current National TB Program, and it is expected that this TB cohort study able to close the gap. A meeting has been scheduled on **December 17** in Jakarta between members of NTP, TB Operational Research Group (TORG), representatives from INA-RESPOND sites, NIHRD, US-NIH, and USAID. We are looking forward to having the final Protocol by the end of the meeting.

HIV/AIDS Study

is the next important milestone for INA-RESPOND Network. Mapping of present HIV research in Indonesia and current research need is vital before we develop the study protocol. Therefore, HIV experts from Indonesia's Ministry of Health, National AIDS Commission, WHO, and several donor agencies in Indonesia will gather in Jakarta on **December 18**.



Site Award

In an effort to honor and value site research teams' dedication and contributions to AFIRE study and to achieve the highest standard of study conduct. The INA-RESPOND network announces its first annual Site Award.

The Site Award is a recognition that a site may receive for outstanding performance and commitment towards making the AFIRE study a success.

Awardees will receive a free trip to attend meetings or professional development opportunities and a certificate from the INA-RESPOND network. To be eligible for this award, a site should be actively enrolling patients for the AFIRE study since October 2013. All active sites will be reviewed based on the following criteria:

- ✓ Subject enrollment rate (%)
- ✓ Study compliance
- ✓ CRF submission timeliness and accuracy
- ✓ Number of Protocol Violation

Closing date for consideration is December 29 and the result will be announced in the January issue Newsletter.

For more details about the Site Award, please contact INA101SiteSupport@s-3.com



INA-RESPOND Manuscript Writing Workshop

INA-RESPOND proudly organizes a 5-day Manuscript Writing Workshop at Lumire Hotel, Jakarta on **January 13-17, 2014**. The objective of the workshop is to assist 24 scientists from INA-RESPOND sites to publish their research results in respective journals. In addition, courses on the art of writing, presenting data, and statistical analysis will be given by experts from NIAID and NIHRD in the morning sessions.

We welcome two additional participants from each INA-RESPOND site to attend the morning courses. Please do not hesitate to spread this news to your colleagues. Kindly contact your Steering Committee member to sign up.

The morning course is FREE* of charge. However, a small fee will be imposed to additional participants for refreshments during the course.

For questions, email manuscript.inarespond@gmail.com.

*INA-RESPOND will not cover transportation, lodging and meals (B/L/D) for the 2 participants from site. Refreshment fee is Rp. 350.000.

Sepsis Study

is planning to recruit 2,250 patients (1,125 adults and 1,125 children) with sepsis or severe sepsis patients across all sites. Total length of time that subjects will be in the study is between 28 to 35 days. INA-RESPOND foresees the study will start in Indonesia around 3 months after Thailand or Vietnam starts the study. INA-RESPOND is planning a meeting to discuss the Sepsis Study on January 11, 2014 at NIHRD, Jakarta.

Notes to File (NTFs)

also known as Memo to File are written to identify a discrepancy or problem in the conduct of the clinical research study, note the root cause of the identified problem, identify the corrective action taken to prevent recurrence of the problem, and document that the corrective action has resolved the problem.

Over the years, the use of notes to file has evolved from a last resort solution to a common working practice amongst clinical teams, bordering on misuse and abuse of this tool. The need to document long drawn-out explanations in the NTFs stems from our need to assign a reason for why and how a deviation happened and to document it. It is perfectly acceptable that during the course of clinical trial conduct, there are accidental deviations from the protocol. These do not always need to be explained and analyzed via NTFs as long as the site team and the monitoring team realize the error and ensure that it does not get repeated. The more important action item, rather than generating NTFs, should be to ensure training of all parties involved and assessing and communicating the impact of the deviation to the clinical team.

-USE- In general, NTFs are used in the following instances:

To document the reason for missing, delayed or erroneous documents in the site master file.

To explain protocol deviations or investigator site practices that are different from the norm or from what is prescribed in the protocol.

-MISUSE- One of the most common ways to misuse an NTF is to use it in place of source documents. This happens when the investigator site staff misses out essential information about trial conduct for subjects in their respective source documents or medical records. It can even happen when the documentation in the source document needs further clarification. In such cases, all additional information and clarifications are documented on NTFs instead of entering them in the source documents directly. Alternatively, it can also happen that since these issues are already documented in the NTF, they often get omitted from places where they should be documented like the monitoring visit reports and site correspondence.

There are some alternatives as the information documented on NTFs logically belongs to one or more of following locations:

The subject's source document file.

The monitoring or site visit report where that issue was first noted and discussed with the site staff.

The correspondence between the site staff and the monitoring team, internal correspondence within the sponsor/contract research organization (CRO) teams or correspondence with the ethics committee and regulators.

It is important that all of us stop and think before generating the next NTF, whether it is necessary to do so or can the documentation of this issue be done more appropriate elsewhere.

Source: *Perspect Clin Res.* 2011 Jan-Mar; 2(1): 38-40. doi: 10.4103/2229-3485.76289

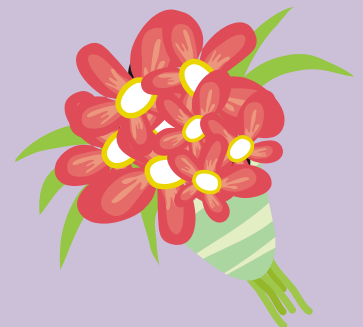
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3088955/>

INA-RESPOND template of note to file is available at <https://ina-respond.s-3.com/edm/index/797968>



Best Wishes for INA101 team members celebrating their birthday in December:

- 06 Dec – **dr. Bacht Alisjhabana** (NSC), **dr. M. Karyana** (NSC)
- 16 Dec – **dr. Delima** (Core Team-NIHRD)
- 21 Dec – **Dedy Hidayat S., S. Kom** (Secretariat)
- 24 Dec – **dr. Dian Wahyu Tanjungsari** (Site 540), **dr. Ketut Jaya Ningrat** (Site 520)
- 28 Dec – **Prof. Ketut Tuti Merati** (Site 520)
- 29 Dec – **Prof. Ida Parwati** (Site 520), **dr. Linda Choerunissa** (Site 520)



And Congratulations to **dr. Ni Made Tyas Dwi Arsanti** (Site 520) and husband on your wedding day 14 Nov 2013

Save the Date for upcoming INA-RESPOND meetings:

December 2013 : 17 – TB Meeting; 18 – HIV Meeting

January 2014 : 9-10 – NSC Meeting; 11 – Sepsis Meeting; 13-17 – Manuscript Writing Workshop

We would like to hear from you. Please send feedback about the newsletter to INA.Secretariat@s-3.com