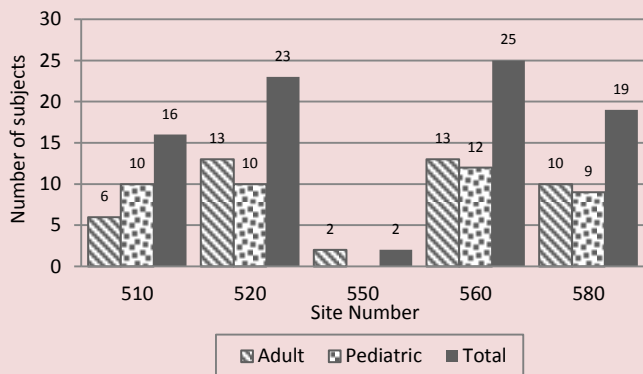


AFIRE STUDY

Enrollment Update. Currently, 5 out of 8 sites have started enrolling subjects. Site 550 started enrolling subjects on 07 Oct 2013. So far, 85 subjects have been enrolled. Dengue and typhoid fever are the most frequent diagnosis found.

Enrollment Progress per October 26, 2013



Congratulations to **site 560** as the current top recruiter!

Detailed screening and enrollment progress is available on portal folder: Studies\INA101\Screening progress.pdf

Or get the file here: <https://ina-respond.s-3.com/EdmFile/getfile/797233>

Site Operation meeting was held on Oct 17, 2013 at NIHRD, Jakarta to resolve some issues and questions that had come up during the subject recruitment. Site PI and Co-PI from site 510, 520, 550, 560, and 580 came to attend the meeting. Minutes of meeting is available on Portal at

<https://ina-respond.s-3.com/edm/index/798521>

Specimen Repository. LIMS team at NIHRD has received specimens from site 510, 520, 560, and 580. All specimens were received in good condition.



Frequently Asked Questions:

Q: Can we enroll referral patients from outpatient polyclinic in hospitals/health care unit/private clinic who have received intervention?

A: Referral patients from outpatient polyclinic who have received medical interventions (except for blood tests) cannot be enrolled into the study.

Q: Who can act as the subject's legal guardian when subject's parents are not available?

A: A "Legal Guardian" is a person who has the legal authority (and the corresponding duty) to care for the personal and property interests of another person, called a ward. In Indonesia, a legal guardian often has family relation (legally or biologically) to the ward. A legal guardian is not a neighbor, friend, or maid of the family.

Q: How to record signs and symptoms information that occurs after screening and enrollment visit? Is the data recorded into CRFs at Screening and Enrollment Visit?

A: Signs and symptoms that occur after screening and enrollment visit are recorded into SDW. RAs cannot add the information into CRFs screening and enrollment visit.

Complete FAQ can be obtained by accessing the Portal at

<https://ina-respond.s-3.com/edm/index/796347>

Document Update!

- **INA101 Manual of Procedure Version: 4.0** dated October 17, 2013. The document is available on Portal at <https://ina-respond.s-3.com/edm/index/798412>. Please do not hesitate to contact Site Support if you have any questions.

Site Principal Investigator & Co-PIs are individuals responsible for the conduct of the clinical trial at a trial site.

Responsibilities:

1. Maintain overall authority and responsibility for proper conduct of the study in compliance with all applicable regulatory guidelines.
2. Supervise study staffs, ensuring appropriate delegation of responsibility.
3. Ensure that all research staffs are informed about the protocol and properly trained.
4. Attend INA-RESPOND trainings, meetings, and conference calls.
5. Conduct study site team meetings and trainings.
6. Oversee development of Site SOPs, study preparation documents and plans, and other site and quality management documents.
7. Facilitate and maintain communication and collaboration with relevant hospital and medical faculty directors, department heads and clinicians.

For more information (including Roles and Responsibilities), please refer to:

- ✓ Surat Keputusan Kepala Badan Litbangkes No. HK.02.03/I.III.1/4314/2013 tentang Tim Peneliti Daerah untuk pelaksanaan Penelitian AFIRE.

(<https://ina-respond.s-3.com/edm/index/795931>)

- ✓ Investigator's Qualifications and Agreements (ICH E6, Section 4.1)
- ✓ Adequate Resources (ICH E6, Section 4.2)
- ✓ Investigational Product(s) (ICH E6, Section 4.6)

TB STUDY

is the next INA-RESPOND study. This study is designed to answer the need of the researchers, clinicians and program in determining the proportion of MDR TB in each participating hospital and factors associated with the success of treatment.

It is a cohort study that will follow TB patients for 6-24 months. The protocol draft version 0.4 has been discussed by the protocol core team and is expected to be finalized during TB meeting in Jakarta on December 16, 2013.

The implementation of this study next year will confirm that INA-RESPOND is beneficial and responsive to the research needs of Indonesia and the international community.

**INA-RESPOND
WEBSITE**

Language Editor: **Dedy Hidayat**
 Content Editor: **M. Karyana**
 Design and Art: **Rosina Bignall** and **Dedy Hidayat**
 Columnists: **Dedy Hidayat, Herman Kosasih, Kanti Laras, Nurhayati, Sonia Kusumawardani, etc.**
 Contributors: **All network members**
 Thanks to: **INA-RESPOND Network and Partners**
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October 2013 was an important and exciting month in the INA-RESPOND network's calendar as it was the month when we officially launched the first edition of the INA-RESPOND Newsletter. This month, we are rekindled by the initiation of the INA-RESPOND website. The launch of the INA-RESPOND newsletter and website is symbolic of how the INA-RESPOND network demonstrates its growing interest and commitment to improving the health of the people of Indonesia. The network aims to do this by actively encouraging and supporting activities and studies, and by giving the network's members and other potential hospitals / universities greater opportunities to learn about and participate in the research.

Through this website, which is available in both English and Indonesian language, we are encouraging people to spread the word about the INA-RESPOND network and about the studies and workshops that the network is / will be conducting in the future. We look forward to having a great and wonderful communication and relationship with all members of the network and potential collaborators; for both the people of this country and everyone in this community. –dh.

**GETTING AROUND THE
INA-RESPOND WEBSITE**

Getting around the INA-RESPOND website (www.ina-respond.net) is very easy. You can clearly locate the main menu just under the slideshow banner and access it to get information about the network and its upcoming and recent activities. You can also contact the Chair of INA-RESPOND if you have interesting ideas or questions for / about the network by choosing the Contact Us menu.

To get more information on studies, workshops, or network's publication, you can explore the Latest News menu located on the right-hand side of the screen.

Worried that you might not know or understand the content of the website? The INA-RESPOND website is available in English and Indonesian, so you can relax and kiss your worry away. ☺



THE INA-RESPOND NETWORK'S WEBSITE: WWW.INA-RESPOND.NET

INA-RESPOND Manuscript Writing Workshop

Manuscript writing workshop is rescheduled to December 09-13, 2013 in Jakarta. Scientists and statisticians from the US-NIH, US-CDC, NIHRD, and Indonesian Universities will share their expertise in guiding Indonesian researchers to prepare their manuscripts for publications.

To all the selected authors, please submit your progress to your mentor and the secretariat and follow the updates in the next INA-RESPOND newsletter or send an email to:

manuscript.inarespond@gmail.com

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

- 04 Nov – **Prof.Dr.Mansyur Arif, PhD, SpPK(K)** (NSC)
- 05 Nov – **Rina Sirait, S.Kom** (Site 560)
- 07 Nov – **dr. Mutiara Rizky Haryati** (Site 570)
- 11 Nov – **Dwi Sriyanti** (Site 550)
- 16 Nov – **dr. Akbar Fahmi** (Site 570)
- 18 Nov – **Dr Vivi Lisdawati, M.Si, Apt** (NSC)
- 28 Nov – **Widoretno, S.Si, M.Si** (Core Team)



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