

We are delighted to introduce this first issue of INA-RESPOND Newsletter. There is a lot of exciting development at the INA-RESPOND Network, with highlights on AFIRE (INA101) Study recruiting its first subjects. Over the coming months we will keep you updated through this newsletter. We hope you will find this newsletter to be a great source of useful information.

AFIRE STUDY

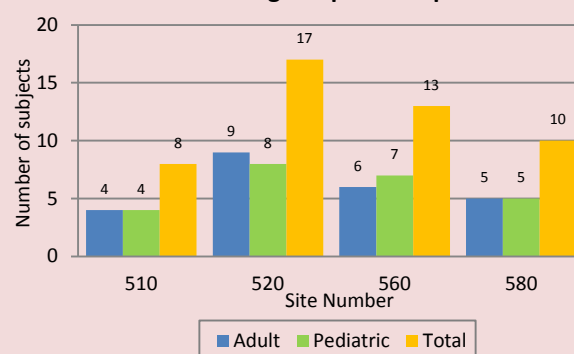
is an observational cohort study of hospitalized patients with fever. The primary objective of the study is to identify the etiology of acute febrile illness cases and evaluate clinical manifestations and outcomes. Currently, 4 out of 8 sites have started enrolling subjects.

Congratulations to **site 520** 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>

Enrollment Progress per 28 Sep 2013



Site Number	510	520	560	580
First Screening Date	04 Sep 2013	18 Jul 2013	19 Aug 2013	26 Aug 2013

Frequently Asked Questions:

Q: Can we enroll a patient who was referred from Emergency Room at another hospital?

A: No, patient that was previously admitted to ER – no matter how short the stay was – cannot be enrolled.

Q: I have a 12 years old patient who requires Assent and also Parental Consent before participating in the study. Where do the patient and his parent should sign in the Assent Form?

A: Both patient and his parent should sign on the Assent Form (last page of the INA101 Assent Form).

Q: How to fill in SDW page 6 or CRF page 4.0?

A: For examples on how to fill in Informed Consent sections, kindly refer to Annotated Source Document Worksheet SPV slide, available on portal: Studies\INA101\Study Documents and resources\Training Resources\Annotated Source Document Worksheet.pdf. Go to page 7 – 11.

Please also keep in mind that as mentioned in Site SOP for Obtaining Informed Consent section 6.12, the researcher obtaining informed consent should provide a brief overview of the consent process. Space is provided in SDW page 7 for this purpose.

Q: If the attending physician takes blood/other biological specimens before the subject signs the Informed Consent Form (ICF), can the specimen be collected for AFIRE study?

A: No. The specimens cannot be collected for the study. The specimens can be collected for study after the subject signs his/her ICF.



REMINDER!

- Please do not forget to upload CRF transmittal form with file naming **CRFTRANSMITTALFORMDDMMMYYYY** along with CRFs.
- For any questions related to INA101 study, please refer to MOP or CRF Completion Guidelines.

Weekly INA101 Operations Call is held every Thursday, 12:00 – 13:00 WIB to discuss day to day study conduct questions. All active sites are invited to join the call. If you would like to raise questions, it will be great if you can send your questions to INA101SiteSupport@s-3.com by Thursday 10:00 WIB.

SEPSIS STUDY

is an observational study to identify the etiology, management, and outcome of community-acquired sepsis and severe sepsis in children and adults in Southeast Asia. The study will take place in Thailand, Vietnam, and Indonesia - the partner countries of South East Asia Infectious Diseases Clinical Research Network (SEAICRN). Ethics Committee approvals have all been completed in Vietnam and are currently in progress in Thailand. Site contracts are being prepared and should be finalized soon. Protocol training will begin over the next 2 months before subjects are enrolled.

TB Study

protocol is currently being developed, led by DR. dr. Erlina Burhan, M. Sc., Sp.P (K) from Persahabatan Hospital. The protocol objectives are to determine the MDR-TB prevalence in Indonesia and factors affecting TB treatment outcomes. The study result will be beneficial in supporting National TB Program as Indonesia's TB ranks fifth in the world with a prevalence of 285 per 100,000, an incidence rate of 189 per 100,000, and a mortality rate of 27 per 100,000. The six sites participating in this study are estimated to be rolled out in 2014.

INA-RESPOND Portal is up and running!

The portal is available at <https://INA-RESPOND.s-3.com>

How to login?

- Login to <https://ina-respond.s-3.com/login>
- Click "Forgot your username and password".
- Enter your email address.
- Wait until you receive username and password in your email, and then login again.

Password must be:

- at least 8 characters.
- combination of 3 of these 4 characters: CAPITAL LETTERS, small caps, numb3rs, or \$ymbol.

The portal serves as the repository of record for all INA-RESPOND information including network-level, site-specific, and study-specific information.

Please contact INA.Secretariat@s-3.com if you have problems logging in.

Getting around the INA-RESPOND Portal

Breadcrumbs

- INA-RESPOND Legal Umbrella : *Network Operations\Policies and Procedures\Legal Umbrella*
- Site Operational Call Notes : *Studies\INA101\Protocol Team\Call and Meeting Summaries*
- INA101 Memo : *Studies\INA101\Study Documents and Resources\Announcements and Correspondence*
- CRF/DCF/ODCF Submissions : *Studies\INA101\Site Submissions ans Secretariat Responses\Site Number\Data Management Submissions*
- Regulatory documents Submissions : *Studies\INA101\Site Submissions ans Secretariat Responses\Site Number\Regulatory Submissions*
- Training slides : *Studies\INA101\Study Documents and Resources\Training Resources*

NEXT EVENT

INA-RESPOND Manuscript Writing Workshop (MWW) will be held in Jakarta from 4 – 8 November 2013. 24 Abstracts covering various topics, namely Dengue/Arbovirus, Malaria, TB/HIV, Influenza, and miscellaneous infectious diseases. Upon completion of the workshop, final drafts are expected to be ready for submission to appropriate journals.

So, let's get your Manuscript ready! MWW team is reachable at manuscript.inarespond@gmail.com.

Best Wishes

for INA101 team member celebrating their birthday in October:

- 9 Oct – dr. Antonius Pudjiadi, Sp.A(K) (530)
- 15 Oct – dr. Ninny Meutia Pelupessy, Sp.A (550)
- 16 Oct – dr. Dwiyantri Puspitasari, Sp.A (570)
- 20 Oct – dr. Abu Tholib Aman, MSc, PhD, SpMK (K) (580)
- 21 Oct – dr. Nurhayana Sennang, M.Kes, Sp.PK, DMM (550), Handoko Setiawan (540)
- 30 Oct – dr. Iman Firmansyah, Sp.PD, FINASIM (540)



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