INA-RESPOND

INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

NEWSLETTER

FEBRUARY 2018

INA-RESPOND ACTIVITIES

STEERING COMMITTEE & INVESTIGATOR MEETINGS

NATIONAL INSTITUTE OF HEALTH RESEARCH AND DEVELOPMENT

MINISTRY OF HEALTH REPUBLIC OF INDONESIA

2018

INA-RESPOND newsletter

EDITOR-IN-CHIEF

M. Karyana

EXECUTIVE EDITOR

Herman Kosasih

CREATIVE DIRECTOR

Dedy Hidayat

ART DIRECTOR

Antonius Pradana

SENIOR WRITERS

Aly Diana, Dona Arlinda, Herman Kosasih, M. Helmi Aziz, Mila Erastuti

REVIEWERS & CONTRIBUTING WRITERS

Anandika Pawitri, Dona Arlinda, Dedy Hidayat, Herman Kosasih, Lois E. Bang, Louis Grue, Maria Intan, Neneng Aini, Nurhayati

THANK YOU

INA-RESPOND Network and Partners

INA-RESPOND Secretariat

Badan Penelitian dan Pengembangan Kesehatan, RI
Gedung 4, Lantai 5

Jl. Percetakan Negara no.29, Jakarta, 10560

www.ina-respond.net

In This Issue

INA-RESPOND Newsletter

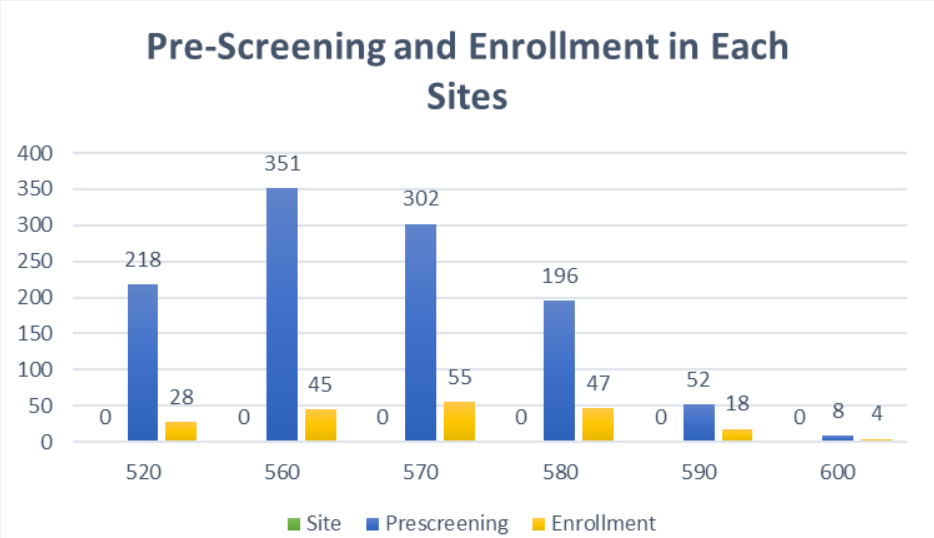
TRIPOD & INA-PROACTIVE Study Updates

BY: CALEB L. HALIM, M. HELMI A, LOIS E. BANG, MARIA INTAN, NENENG AINI

INA102

Screening and Enrolment

By the end of January, sites teams had enrolled 197 participants, with RSUD dr. Soetomo as the top recruiter (55 participants). Enrolment progress can be seen in the graphic on the right.



*Site number:

520 – RSUP Sanglah, Denpasar
560 – RSUP dr Kariadi, Semarang
570 – RSUD dr Soetomo, Surabaya
580 – RSUP dr Sardjito, Yogyakarta
590 – RSUP Persahabatan, Jakarta
600 – RSUP H Adam Malik, Medan

MDR-TB Workshop at RSUD. *Persahabatan*, Jakarta

On 7-8 February 2018, site specialists, biostatistician, and monitor from Secretariat attended the 15th Scientific Respiratory Medicine Meeting held by the Department of Pulmonology and Respiratory Medicine, Faculty of Medicine, *Universitas Indonesia-Persahabatan* Hospital.

The 2-day workshop titled Multi Drug Resistance of TB was held at *Persahabatan* Hospital and invited many experts as speakers. One of the experts, Dr. Erlina Burhan, led some discussions of study cases. In addition, dr. Budi and dr. Diah (TRIPOD study's Co-PIs from *Persahabatan* hospital) gave a presentation on *Typical Errors in Diagnostic of MDR TB by Using Genotype and Phenotype*.

Some interesting topics were delivered in this workshop, such as Dealing with Side Effects of Short Term Regimen Drug, TB Therapy Management, Pre-extreme Drug Resistant and Extreme Drug Resistant TB. In addition, we got the chance to learn the characteristics and therapy management given to TB patients at different hospitals in Indonesia from the discussion sessions.

Site Preparation Visit at RSUP dr. Wahidin Sudirohusodo

Site 550 – RSUP Wahidin Sudirohusodo : The IRB Reliance has been signed and approved, so we can continue with the next step, the Site Preparation Visit (SPV), which will be performed on 13-14th February 2018. During the SPV, Lab Trainer from RSU Tangerang will hold a Lab Training for lab technicians on PBMC and specimen handling.

Hopefully, the SPV will run smoothly and all requirements can soon be completed, so we can activate the site as our 7th active site.

Enrolled patients towards target recruitment

TRIPOD enrolment target is 1,357 participants. So far, we have had 197 participants enrolled. Although the number is still growing, we need to bear in our mind that the study has been ongoing for 11 months. Recruitment period for the study is two years, which mean we have less than 1.5 years to recruit participants. Hopefully, all study team members can do their best to raise the enrolment number.

INA104

Screening and Enrollment

dr. Hening Tirta Kusuma, who joined us as a research assistant (RA) at site 610 (RSUD Tangerang), has enrolled six adult participants and two pediatric participants up to 6 February 2018. Enrolment progress could be seen in the figure below.

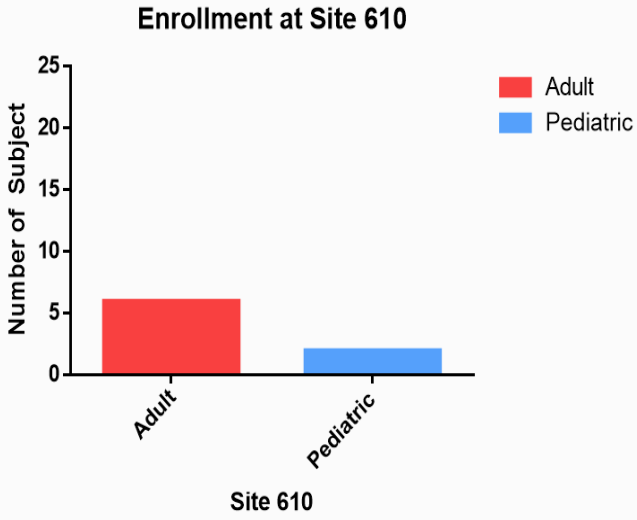
Site Preparation Visit and Site Initiation Visit (SIV)

Four study sites have signed the contract and agreement for INA-PROACTIVE study. Site 610 was activated on 9 January 2018 and has started recruiting participants since 10 January 2018.

By the end of February 2018, we expect to have three more sites activated for the study. INA-RESPOND Secretariat along with research assistants from site 600 (dr. Keumala At Thaariq), site 550 (dr. Munawir and dr. Khaerul Muqsith), and site 530 (dr. Bramantya Wicaksana) are currently preparing the sites for their SPV and activation.

SPV for site 600 (RSUP H. Adam Malik, Medan) is scheduled for 7-8 February 2018; SPV for site 550 (RS Wahidin Sudirohusodo) is scheduled for 13-14 February 2018; and SPV for site 530 (RSUP Cipto Mangunkusumo) is estimated to be conducted in the last week of February.

After the SPV, INA-RESPOND Secretariat will conduct SIV before the three sites can be activated. For the time being, SIV for the three sites is scheduled on 12-13 February (Site 600), 19-20 February (Site 550), and 22-23 February (site 530). Hopefully, with their activation, the number of participants will increase significantly.



Protocol and Training Updates

Protocol version 1.0 and all required documents for ethical clearance were submitted to National Institute of Health Research and Development (NIHRD) Ethics Committee (IRB), and the approval was obtained on 18 January 2018.

Two sites (site 530 and 610) don't have IRB Reliance agreement with NIHRD IRB. Site 530 need to submit the study documents required by their local ethics committee in order to start the study. As for site 610, even though ethical clearance have been given, study team will have to re-submit the protocol and ICF because there have been some amendments to the two documents.

During the INA-PROACTIVE Investigator Meeting which was held on 23 January 2018, inputs were given by participants to have a more comprehensive and accurate data collection. These inputs are currently being discussed by the protocol team. Amendments to the protocol will be made to reflect the changes.

Last but not least, study team from each site have completed Good Clinical Practice (GCP) training and other trainings related to the study. We hope this means a good start for the INA-PROACTIVE study and we can all keep up the good work.

NETWORK STEERING COMMITTEE & INVESTIGATOR MEETINGS IN INA-PROACTIVE PREPARATION WEEK

INA-RESPOND Secretariat, NIHRD, Jakarta

INA-RESPOND Newsletter

INA-PROACTIVE PREPARATION WEEK

BY: M. HELMI A, CALEB L. HALIM, LOIS E. BANG, DEDY HIDAYAT, AMELIA VINA

The Network Steering Committee (NSC) meeting was successfully held on 22 January 2018 at Double Tree Hotel, Jakarta. Like previous NSC meetings, important issues related to the network's studies as well as the future of the network were discussed. During this meeting, two members of NSC were introduced: dr. Irmansyah, SpKJ (replacing Dr. Nana Mulyana) as the new head of NIHRD Center 2 and dr. Mardianto from Adam Malik Hospital, Sumatera Utara.

TRIPOD study was discussed first in the study updates section, and there was an intense discussion related to TB new case recruitment compared to MDR TB and involvement of new satellite sites for TRIPOD study which might be hard to perform due to complicated approval of permit. A collaboration with primary health centers and private hospitals was suggested during this discussion, and follow-up of this ideas will be evaluated. The INA-PROACTIVE will accelerate site activation; 4 sites are currently working on their site contract and site preparations related to the study. Meanwhile, site 610 (RSUD Tangerang) was activated and has been recruiting participants since January 2018. The AFIRE study highlights the new findings related

to newly-diagnosed HIV subjects while PEER PEPPES study highlights the fatal cases related to multiple infections of organisms in several participants.

The next intense discussion was related to the role of INA-RESPOND reference laboratory in terms of laboratory services and outbreak investigation. The role of INA-RESPOND reference laboratory should be limited in research context not in public health service context. The NSC suggested that this issue should be mentioned in the protocol to minimize regulation issues with the government reference laboratory. Next, Dr. Cliff Lane, NIAID Deputy Director for Clinical Research and Special Projects, gave an assurance to NSC members that financial support will be still provided for INA-RESPOND network despite the funding issues in the United States (US) related to NIAID. The contract between NIH and Leidos is extended to June 15, 2018 and follow-up related to the contract will be determined by the US government.

Despite the funding issues, INA-RESPOND continued to propose four study concepts. The first one is Dolutegravir study which has concerns about the drug availability after the study is finished. Therefore, coordination with policy makers related to drug distribution should be ensured before the study starts. The schistosomiasis study was discussed next and based on the discussion in December 2017, INA-RESPOND was asked to conduct a study related to the vector instead of conducting study on the people. The Xpert-HIV1 evaluation study already recruited 58 subjects, and statistical analysis will be performed for three different methods. Last proposed study was the Antimicrobial Resistance (AMR) study which will be submitted to PEER grant and aim to combat the antimicrobial resistance and support new policies related to antibiotic prescription/administration in Indonesia.

The last agenda was the INA-RESPOND upcoming events. The first upcoming events is the Open Clinica Training which will be held in February 2018, and each site must send at least one representative to attend this training. The next training is the IRB/Ethics Committee training which will be held in July 2018. The last events discussed are the INA-RESPOND seminar which will be held in October 2018 in Bandung in conjunction with the 1st annual Scientific Meeting of the Indonesian Society of Tropical and Infectious Disease and the 8th annual Bandung Infectious Disease Symposium.

Investigator Meeting, GCP, and HIV Training

On 23-26 January 2018 we had three interesting events related to INA-PROACTIVE study: Investigator Meeting (IM), Good Clinical Practice Training (GCP), and HIV training updates. INA-PROACTIVE core team, secretariat, and research team members from all first eleven sites attended the 4-day meeting. On the first day, during the Investigator Meeting, our newest NSC member, dr Irmansyah Sp.KJ, and dr. M Karyana gave an opening remarks which expressed several concerns about the number of sites, how to activate 11 sites by July

2018, research data management, and funding regulation for research by Indonesian government.

Later, our study's protocol specialist, dr. Dona Arlinda, presented the INA-PROACTIVE protocol and the lesson learned from the INA-PROACTIVE activated site (Site 610 – RSU Kabupaten Tangerang). Deep discussion and concerns related to INA-PROACTIVE protocol were shared by each site, such as the use of GeneXpert machine, the distribution of the GeneXpert machine, other methods to evaluate the HIV-1 viral load, whether INA-PROACTIVE study should recruit suspected HIV-positive patients, and standardization of standard of care in each site.

Our research assistant from site 610, dr. Hening Tirta K. shared her experience on filling the source document worksheet (SDW) and on how good interpersonal communication skills are required since the study asks its participants some sensitive questions. All those inputs were integrated in the latest version of protocol, SDW, and Case Report Forms (CRF), which will then be submitted to NIHRD IRB. After the intense discussion, the other sites' preparation and trainings including the site regulatory-start up, safety reporting, data management, specimen management, and repository system were presented by INA-PROACTIVE team. All of these trainings will be repeated during the site preparation visit (SPV) and adjusted for each site.

On the 24-25th, GCP training coordinated by *Badan Pengawas Obat dan Makanan (BPOM)* team was held. The GCP training aimed to help all participating researchers and staff to assure the safety, integrity, and quality of clinical trials by addressing several elements such as the design, conduct, and reporting of the study. During this GCP training BPOM described the responsibilities of investigators, sponsors, monitors, and IRBs in the conduct of clinical trials in an interactive way. Several quizzes were made to make the training more communicative and attractive for the participants. On the last day of the GCP training, a test was administered, and three research assistants: dr. Syndi Nurmawati (Site 510), dr.

Kartika Paramita (Site 550), and dr. Myrna Evanda Adeline (Site 570) came out as the winners with the highest scores.

On the last day, HIV training updates was held. The training/updates was aimed for INA-PROACTIVE research assistants to get a good idea of INA-PROACTIVE research. Experts in HIV were invited to give an overview of the epidemiology, diagnostic (screening and confirmation tests), treatment principles (side effect, national guideline, and drug interactions), pediatric management, and common co-infections and comorbidities. –end–

A Seoul Virus (SEOV) Meeting

SEOV FOLLOW-UP IN CROSS SECTORAL DISCUSSION

BY: M. HELMI A

On behalf of INA-RESPOND, dr. M Karyana, dr. Khie Chen, dr. Herman Kosasih, dr. Dewi Lokida, Mr. Ungke Anton Jaya and dr. M Helmi Aziz attended the invitation from Ditjen P2P (*Direktorat Jenderal Pencegahan dan Pengendalian Penyakit*) to present our findings related to Seoul Virus (SEOV) infection in two AFIRE subjects. The meeting was successfully held on 16 January 2018 at *Ruang Rapat Ditjen P2P Gedung B*.

SEOV belongs to hantaviruses from Bunyaviridae family which have rodents as a carrier. For SEOV itself the carriers are *rattus rattus* and *rattus norvegicus* which are easily found in urban areas such as Jakarta and Surabaya, where the two findings come from. The rodent-borne features of SEOV made the meeting very interesting as several public health practitioners from *Sub-*

dit Zoonosis, Pelayanan Kesehatan Primer, and *Kasubdit Pencegahan dan Pemberantasan Penyakit Hewan* also attended the meeting.

The meeting was opened with dr M. Karyana's presentation about INA-RESPOND and capacity building in infectious diseases research. Later, dr Khie Chen gave a presentation about the AFIRE study, SEOV overview, and how INA-RESPOND found SEOV in two subjects. After the presentation a discussion was started. Surprisingly, during the discussion, we found out that RIKUS (*Riset Khusus Vektor dan Reservoir Penyakit*) Vektora found hantaviruses in 14 different type of rodents from 22 provinces in Indonesia. This information supports our finding that SEOV and hantaviruses are circulated in Indonesia.

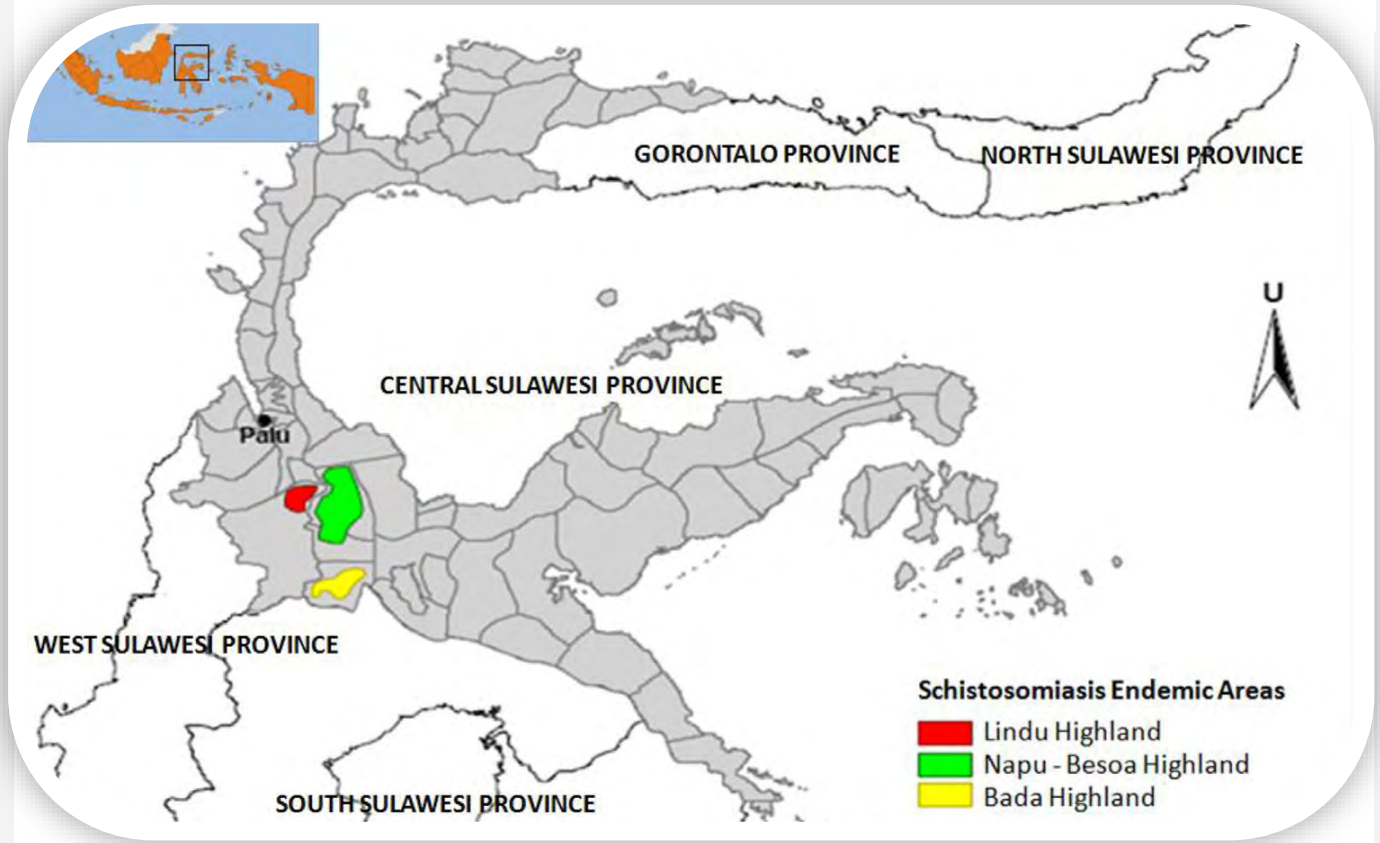
The discussion continued with questions on how we should develop a clinical algorithm/pathway to diagnose SEOV and hantaviruses in primary health center, since the SEOV and hantaviruses diagnostic tools are not available on primary health center. Two ideas were discussed for that question. The first one is that we should know the SEOV and hantaviruses sero-epidemiology on that area as well as the rodent surveillance since they are the carriers of the disease. Secondly, a reference laboratory to diagnose SEOV should be available. Therefore, increasing laboratory capacities on diagnosing SEOV and hantaviruses is urgently needed. There are three criteria according to CDC related to hantaviruses laboratory profile for diagnosis; 1. Detection of hantavirus-specific IgM or rising titers of hantavirus-specific IgG; 2. Detection of hantavirus-specific RNA sequence by polymerase chain reaction in clinical specimens; 3. Detection of hantavirus antigen by immunohistochemistry. The first criteria, the antibody-based criteria, is the applicable one in primary health care setting as a diagnostic tool, while the two others are applicable in reference laboratory.

The last discussion was on how we collaborate to control rodent-borne diseases (not only SEOV and hantaviruses, but also Rickettsia and Leptospira). In the last discussion, INA-RESPOND mentioned that it is willing to share the laboratory protocol to diagnose the rodent-borne diseases and integrate the human surveillance data with the rodent data from RIKUS Vectora. INA-RESPOND is also willing to give training related to rodent-borne diseases diagnosis, if needed. We hope by doing this collaboration we could get the comprehensive epidemiological data thus could inform or suggest a national policy to tackle the rodent-borne diseases in Indonesia.

INA-RESPOND Newsletter

ERADICATION OF SCHISTOSOMIASIS IN INDONESIA

BY: DONA ARLINDA



Schistosomiasis is an acute and chronic neglected parasitic tropical disease from infection by trematode flukes of the genus *Schistosoma spp*. The WHO estimated 78 countries worldwide were endemic for schistosomiasis in 2016, but only 52 countries had people requiring preventive chemotherapy with a total of 206.4 million. Of which, 111.2 million were school-aged children and 95.2 million were adults. About 92% of those people requiring preventive chemotherapy lives in African region, while 22,675 of them lives in Indonesia, the only country in South-East Asia region which still reports cases of schistosomiasis infection. (WHO 2016)

Schistosoma japonicum, the species responsible for schistosomiasis in Indonesia, was first reported in 1937 by Muller and Tesch in Lindu Valley of Central Sulawesi and a later prevalence survey conducted in 1940 and 1971 confirmed this finding. (Clarke 1974) *Schistosoma japonicum* is one of the six species of the trematode flukes (*S. mansoni, S. haematobium, S. mekongi, S. guineensis* and *S. intercalatum*). Aside from Indonesia, *S. japonicum* is also the cause of schistosomiasis in China and the Philippines. A 6-mm amphibious snail, *Oncomelania hupensis lindoensis* (Fig. 1), which lives in abandoned rice fields, along ditches, under dense wild canes, along creeks or seepage waters snail is the main intermediate host in Indonesia. In addition to the human and snails, *S. japonicum* can also infect 13 other wild mammalian hosts and

livestock (wild rodents (*Rattus exulans, R. hoffmani, R. chysocomusrallus, R. marmosurus,* and *R. celebensis*), wild pigs (*Sus scrofa*), wild deers (*Cervus timorensis*), wild celedu (*Crocidura nigripes*), wild civet cats (*Viverra tangalunga*), cattle (*Bos spp.*), water buffalos (*Bubalus bubalis*), horses (*Equus caballus*), and dogs (*Canis familiaris*), which complicates control efforts. (Sudomo 1974, Hadidjaja 1976, Oemijati 1976)

In Central Sulawesi, cases of schistosomiasis were reported in three isolated areas, i.e. Lindu, Napu, and Bada Valleys (Fig. 2). Integrated control efforts since 1974 to 2005 using a combination of mass drug administration (Praziquantel), water sanitation and hygiene, health education, and snail control through environmental management and molluscicide had successfully reduced human prevalence to ≤1%. However, diminishing funding, reduced staffing, and lack of coordination and collaboration between the Ministry of Health (MoH) and other ministries involved in the environmental and agricultural aspects of the control strategy had failed to bring down the prevalence even further. (Satrija 2015) In 2017, human prevalence in Lindu, Napu and Bada was 0.85%; 0.65% and 0.97%, respectively. Animal prevalence in those areas was 40%; 36.4% and 5.6%, respectively. While the range of prevalence in snails in Lindu, Napu and Bada was 1.2-14.5%; 0.4-40.7% and 11.4 -22.9%, respectively. (MOH 2017)

In early 2018, the MoH launched an integrated roadmap for eradication of schistosomiasis in Indonesia. The program integrated several ministries and was divided into 3 phases, i.e. acceleration phase (2018-2019), maintenance phase (2020-2024), and declaration of eradication (2025). The acceleration phase target is to effectively mobilize resources and control efforts so that zero prevalence in human, animal and snail is achieved by the end of 2019. After maintaining zero prevalence for 5 consecutive years, it is hoped that the eradication of schistosomiasis in Indonesia can be declared in 2025. (MOH 2017)

At the central government level, five ministries (Ministry of Health, Ministry of Agriculture, Ministry of Public Works, Ministry of Villages, and Ministry of the Environment) coordinated by Ministry of National Development (Bappenas) developed an integrated eradication program and supervise the implementation. At the local government level, the local planning agency (*Bappeda*) in Central Sulawesi carry on the plan from *Bappenas* to local planning agency in districts of Poso and Sigi. The MOH and local health offices are responsible for the eradication activities on human and snail, while animal infection will be the focus of Ministry of Agriculture.

Praziquantel 40 mg/kg body weight will be given as annual mass drug administration in 2018 and 2019, as will surveillance on snail infection. Total human surveillance will be conducted in 2019 after the second MDA. Supporting activities such as capacity building for schistosomiasis laboratory and diagnostics will be implemented simultaneously. Other activities such as animal treatment and surveillance, provision of clean water and latrines, health education and mass campaign, environmental modification (agroforestry, drainage, and infrastructure), etc will also be implemented simultaneously by other related district offices. Everybody has to work together to achieve the acceleration target of zero prevalence in human, animals, and snails in 2020.

INA-RESPOND Newsletter

SITE PREPARATION AS PART OF QUALITY MANAGEMENT SYSTEM

BY: MILA ERASTUTI, LOUIS GRUE

According to the INA-RESPOND Standard Operating Procedures (SOP) and guidelines, Site Initiation Visit (SIV) is usually performed a week after the Clinical Research Site Specialist (CRSS), Data Management, and the Protocol Specialist have performed Site Preparation Visit (SPV). During the SPV, the investigator and site team are trained on the protocol and study procedures to ensure the team is ready to perform the study at the site hospital. The SPV provides the site with the tools needed for the study, so the site is ready for the SIV.

SIV is performed by Clinical Research Associate (CRA) to review study procedure and to discuss approved approaches for recruitment, screening, and enrollment with the investigator and key study personnel. It is scheduled once the investigators have satisfied initial regulatory requirements, such as having the IRB approval and the signed contract. CRA will meet key site personnel who will be overseeing the conduct of the study. The investigators *are required* to attend the SIV to review the protocol requirements and Manual of Procedure (MOP), as well as to discuss the regulatory requirements. CRA will ensure that the following activities stated in the Site Initiation Visit SOP (S-INA-CRM-001) are completed:

- review the objectives, study design, eligibility criteria, study procedures, and schedule of events;
- review the regulatory obligations with the investigator as specified on the protocol agreements required by NIAID;
- review IRB/EC requirements, including the approval of the protocol and documented approval of the Informed Consent Form, approval of all advertisements and protocol amendments, and annual approval of the protocol and the Informed Consent Form;
- review the requirements for source documentation and record-keeping to verify and validate the clinical data;
- review the general instructions for CRF completion and the procedure for correcting recorded data;
- review the obligations and procedures for the timely reporting of Adverse Events (AE) and Serious Adverse Events (SAE) as required by the protocol;
- conduct a tour of the facility to ensure there is adequate space to conduct the study;
- review the Investigator/Site Regulatory file for completeness and accuracy;
- collect any outstanding or updated essential documents from the clinical research sites for filing at INA-RESPOND; and
- sign the Site Visit Log to document attendance. The Site Visit Log will be used throughout the study to document the dates CRA conducts monitoring visits.

Several days prior to SIV, CRA will send a study

case to the Research Assistant (RA) via email and ask RA to complete Source Document Worksheet (SDW) and Case Report Form (CRF). During the SIV, CRA will invite the Investigator and study team to join the first session in the SIV to discuss the study protocol, MOP, site SOPs, and screening and enrollment flow at the site. After that, CRA will have a discussion with RA and/or Laboratory Technician. CRA will also ask RA to role play in obtaining the ICF, screening and enrolling new subject, completing the study documents (Screening Log, Enrollment Log, SDW, CRF, Protocol Deviations, Serious Adverse Event Report) and all documents related to the Specimen Management (Specimen Log, Specimen Tracking Form, and Specimen Verification Chart). At the end of the visit, CRA will inform the investigator and site team about the site readiness using Site Preparation Checklist Report which previously has been completed and distributed to the site team by CRSS. Therefore, the investigator and site team should be aware of their status and what they should fulfill/complete for the site activation.

CRA will inform CRSS any deficiencies noted during SIV, so CRSS could assist the site and update the Site Preparation Checklist. Finally, the CRA will complete the SIV Report and SIV Follow-up Letter. They will then be submitted to the Chair of INA-RESPOND and sponsors (Louis Grue, Clinical Project Manager from Leidos Biomedical Research and Susan Vogel, Clinical Research Oversight Manager from NIAID) for review and approval. Once the documents have been approved, CRA will submit the final SIV Report to the Chair of INA-RESPOND and sponsors, and distribute the SIV Follow-up Letter to the investigator and site team. After all deficiencies are completed, the CRSS and the site Principal Investigator will sign the Site Preparation Checklist. The CRSS will request for site activation to the Chair of INA-RESPOND, sponsor and one of the protocol core team. After site meets all project requirements, site will be activated and may begin screening for the study.

Currently, CRAs are performing the SIVs for Tuberculosis Research of INA-RESPOND on Drug Resistance (TRIPOD) and a Prospective Observational Cohort Study on HIV Infection and Risk Related Coinfections/ Comorbidities in Indonesia (INA-PROACTIVE). Performing the SIV is crucial in the implementation of good Quality Management System in INA-RESPOND network. By conducting the SIV to check for site readiness, CRA will ensure that the investigator has adequate qualifications, resources, site team personnel, and facilities to conduct the clinical trial safely and properly. Therefore, all INA-RESPOND sites in the network will have an excellent foundation to begin conducting the INA-RESPOND studies.

Certificate of Confidentiality

We should be aware of the National Institutes of Health (NIH) policy for issuing Certificates of Confidentiality (CoC), effective 1 October 2017. NIH-funded research that is collecting or using identifiable, sensitive information is now automatically issued a CoC. These CoCs protect the privacy of subjects participating in federally funded research by limiting the disclosure of identifiable, sensitive information. Per NIH's policy, it is the responsibility of investigators to "inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy." This may be accomplished either by amending the current consent documents to include CoC language or by providing a supplemental information sheet with the CoC language until the consent form can be amended. Suggested language is available here: https://humansubjects.nih.gov/coc/suggested-consent-language. Further information regarding NIH's updated policy is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

THE FIRST WRITER and EDITOR

INA-RESPOND Newsletter

AUTHOR & EDITOR: WHEN LOVE AND HATE COLLIDE

BY: ALY DIANA

Relationship between an author and an editor is usually a bit complicated because they might not always agree with each other even though they need each other almost on every occasion. This complex association has too many details that often could not be described one by one. However, we could try to get closer to see the roles of each actor in general and how they work together.

A journal editor sounds like a CEO who also works as a salesperson of a company. The main role of a journal editor is to keep the high quality of a journal while promoting it as the best journal to publish in. As a salesperson, an editor should make sure that the journal becomes as famous as it could be. For the journal to be on the top chart, readers need to be able to easily locate papers of interest. Attempting to get the journal listed in as many databases as possible is one way to achieve this. At the same time, an editor depends on authors to submit quality papers of interest to readers. An editor welcomes papers that have originality and that are likely to be cited in other papers, which will increase the journal's impact factor.

As a CEO, an editor needs to encourage both new and established authors to submit articles; and set up a reliable panel of expert reviewers to maintain the quality of the journal. A high quality journal needs high quality articles, which basically come from good authors. Consequently, an editor also has a responsibility to increase the author pool through personal and professional connections. It is also an editor's responsibility to ensure that the journal has sufficient articles in their editorial system to be published in all their issues per year. By the end of the day, an editor has that supreme power to accept or reject articles for publication.

On the other hand, authors' primary goal is to have their paper read by many readers and cited by other authors. Authors want their manuscript to be accepted by a journal listed in high-profile databases and one with a high impact factor. The higher the impact factor is, the greater the possibility of the article to be cited is.

From a brief story above, it's clear that editors and authors depend on each other to manage the business, and off course, to spread good science. When we are invited to write for a particular journal, we might have more to say than usual. However, in most cases editor has the final say. As any other relationships, understanding these roles and what we are would be very beneficial.

Closing remark: Sometimes we do not always appreciate reviews and recommendations from an editor, but knowing responsibilities of an editor might help us to understand the actual intent behind an editor's actions or decisions.

References:

Karen Holland, Derrick Duncombe, Elizabeth Dyas, and Wim Meester, 2014. The Role of an Editor. https://www.elsevier.com/__data/assets/pdf_file/0005/95117/SC_FAQ-Role-of-an-Editor-22092014.pdf

INA-RESPOND website: www.ina-respond.net

INA-RESPOND Newsletter

The Indonesia Research Partnership on Infectious Disease newsletter is an internal bulletin of INA-RESPOND research network intended to disseminate information related to the network's studies, activities, and interests to all members of the network as well as its sponsors and related parties.

The INA-RESPOND newsletter welcomes all network members and stakeholders to contribute by submitting articles related to the network's studies and interests. Send your articles or subscribe to our latest newsletter by sending an email to INA.Secretariat@ina-respond.net