Office Of Clinical Site Oversight
National Institute of Allergy and Infectious Diseases (NIAID)

MOB Report

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ORGANIZATION INFO

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THE FEDS

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Use of Electronic Informed Consent

Technology plays a critical role in clinical trials operations. While we need to align our business practices to incorporate electronic technology, we must also remain compliant with regulatory guidelines and regulations that govern electronic source data capture and electronic Informed Consent Form (eICF).

In an effort to modernize clinical trial technology, and in response to the clinical research community's interest in the use of electronic media to enhance the ICF process, the Food and Drug Administration (FDA) published a draft document detailing the agency's current thinking on the use of eICF.

Prior to this, in 2013 the FDA published a guidance document on Electronic Source Data in Clinical Investigations. In response, clinical research sites are continuing to develop processes to shape their clinical research operations and maintain compliance with 21CFR part 11. While some sites may face challenges with implementing and operationalizing eSource data, sites should be aware of the current thinking on eICF.

The informed consent process is the initial and critical step in recruiting participants to a clinical trial and it is imperative that we ensure that participants are adequately informed about the purpose of the trial, the risks, benefits and more importantly their rights and safety. The purpose of informed consent is ultimately to ensure that the rights, safety and well-being of study participants are protected. With the potential implementation of eICF, we face the question **'Does eICF provide the same level of protection for participant rights and well-being?'**

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Use of Electronic Informed Consent, cont.

To respond to this question and address potential issues with eICF, the FDA recommends that at a minimum, Institutional Review Boards (IRBs), Ethics Committee(s) (ECs) and investigators should consider the following areas when using eICFs;

- Participant Identity Confirmation
- Data Privacy and Security
- Electronic Interactive Process: Questions and Answers
- Participant Data Integrity

Above all, FDA notes that eICF must still contain all of the elements of informed consent currently required by FDA regulations.

For details on the draft eICF guidance, please access the draft document by clicking the following hyperlink: **Electronic Informed Consent in Clinical Investigations.**

Regulations, Policies & SOPs

The Division of AIDS has updated the policy on **Requirements for On-Site Monitoring** (PDF) to be effective 07 August 2015. It can be accessed by clicking the above hyperlink.

The major changes are;

- Updates to meet 508 compliance and guidelines
- Updates to include the DAIDS risk-based approach, which is applicable to the frequency, duration and intensity of monitoring activities

NIAID: Development, Maintenance and Operation of an integrated Clinical Research Management System (NCRMS): Version 1.0 release planned for September 2015

The System Formerly Known As The DAIDS-ES.

The Divisions at NIAID, Division of AIDS (DAIDS), Division of Allergy, Immunology and Transplantation (DAIT), and Division of Microbiology and Infectious Diseases (DMID), are working to enhance their current clinical research information management (CRMS) capacity through the development of innovative data collection systems, management tools, processes, and communication methods. The development of these tools, methods, and systems as a whole is termed the NIAID Clinical Research Management System (NIAID CRMS). This system was previously known as the DAIDS Enterprise System (DAIDS-ES).

The goal is to support the management of clinical research funded by DAIDS, DMID, DAIT, and by the Vaccine Research Center (VRC). This will assist staff in the clinical research programs by providing extensive information capabilities, such as the ability to rapidly search and retrieve study data and details to support oversight and decision making. The NIAID CRMS is composed of multiple integrated modules developed by the extramural Divisions to support their business operations. The DAIDS developed a set of components, collectively called the DAIDS-ES. More recently, DMID and DAIT developed their systems, the DMID-CRMS and the DAIT Clinical Research Information System (DAIT-CRIS).

These systems are operated and supported under the NIAID Office of Cyber Infrastructure and Computational Biology (OCICB), Clinical and Medical Informatics Program (CMIP) Management.

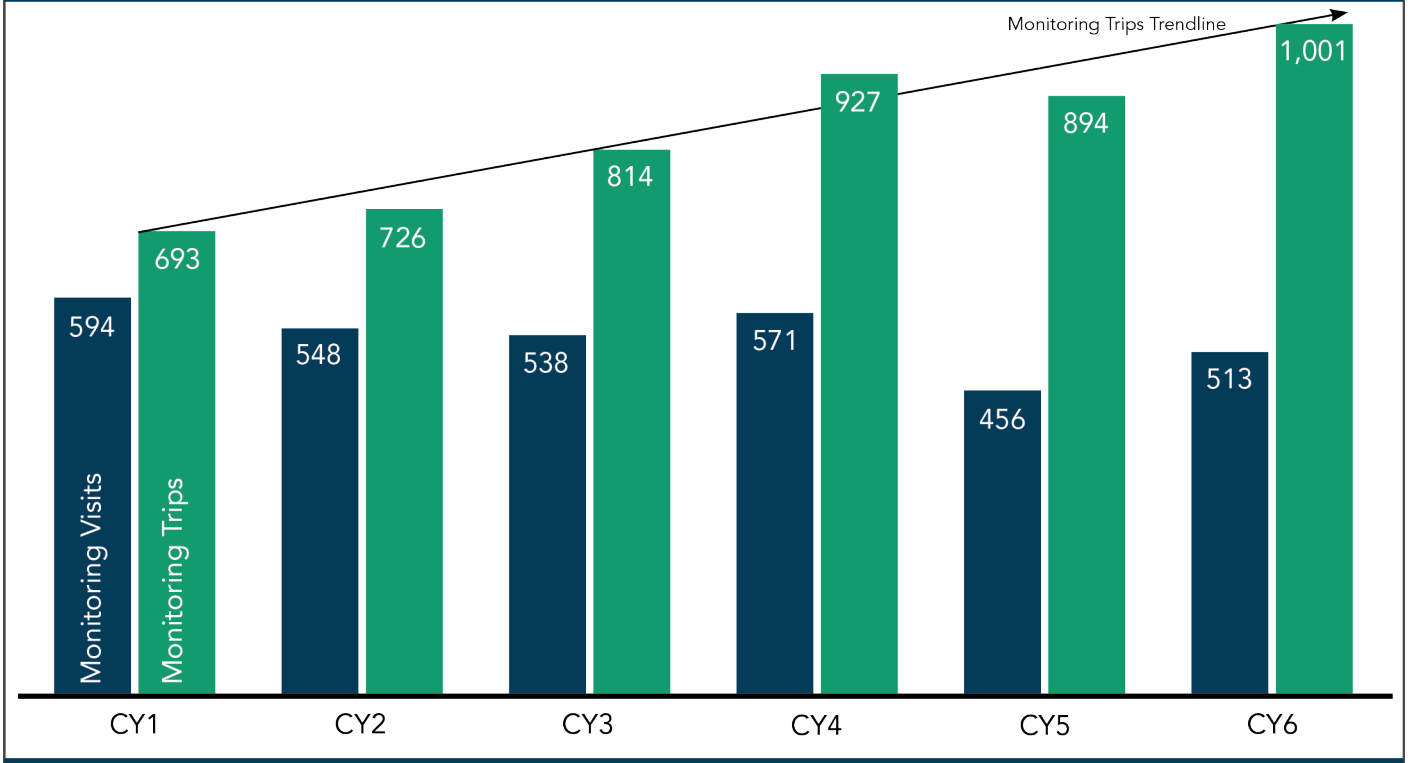
NIAID's objective is to continue developing, maintaining, and operating a unified/integrated Clinical Research Management System (N-CRMS) that supports the unique data and clinical research process needs of NIAID's Divisions and Offices. Version 1.0 of this integrated system is planned for September 2015.

Monitoring Metrics

Overview of Monitoring Visits and Trips to Date

Monitoring Trips and Visits (Contract Year 1 to Contract Year 6)

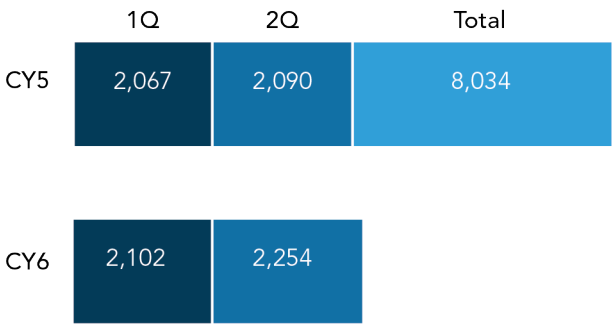
Over the last 6 years, OCSO has conducted a total of 3,220 Monitoring Visits and 5,055 Monitoring Trips. Monitoring Trips have increased throughout the past 6 contract years.



Monitoring Visits: Any time a monitor travels to a site to conduct monitoring.
Monitoring Trips: Includes the total number of monitors traveling to a site to conduct a site monitoring visit.

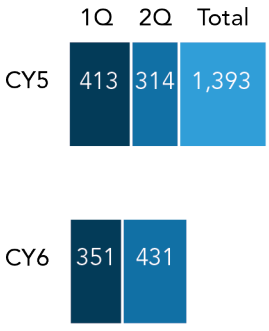
Record Review

CY5 (2014) and CY6 (2015) Quarter 1 and 2 Comparisons



Pharmacy Assesment

CY5 (2014) and CY6 (2015) Quarter 1 and 2 Comparisons



Monitor Spotlight – Bangkok, Thailand

Rapin with her Thailand Team

From left to right: Suchansa, Rapin, Salisa, Phorranee, and Sutadsawan.

About the Monitors:

Suchansa Sukhanantapong joined PPD in Oct 2007 as a Clinical Research Associate (CRA) for NIH-funded studies. She holds a Zoology degree from the University of Washington. She has monitored NIH-funded studies in Thailand and Cambodia and is now working on CSSM studies, commercial studies and other government studies. She enjoys traveling for monitoring visits and does not mind the constant packing for trips. She has been making annual trips to Chantaburi province in Thailand for durians, mangosteens and rambutans since 2008. She splits her free time between her husband who lives in Pattaya, the in-laws in Bangkok, her family and friends.

Rapin Own-On joined PPD in March 2006 as a CRA. She has a Bachelor's degree in Nursing and a Master's degree in Science (Public Health) from Mahidol University, Thailand. She has 12 years of clinical trial experience in various therapeutic areas and has been working on DAIDS sponsored trials for 9 years. In 3Q 2014, Rapin started the lead role as Clinical Site and Study Monitoring (CSSM) Functional Manager for DAIDS sponsored projects in the APAC region which includes Thailand, India, Australia, China, Vietnam, and Indonesia. She loves to spend her free time traveling. She likes dancing, singing Thai country songs, and yoga. She also loves to spend her weekends with her parents and family members.

Salisa Pohpeera joined PPD in January 2014 as a CRA. She graduated from Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand in 2012. She likes spending her free time with family and friends.

Phorranee Rananand joined PPD in October 2011 initially as a Research Assistant (RA). She was promoted to CRA in September 2013. She has a Bachelor's degree in Medical Technology and a Master's degree in Science (Major in Pharmacology) from Chulalongkorn University, Thailand. She likes spending her free time with family and her favorite activity is running.

Sutadsawan Chitsuksom joined PPD in January 2008 initially as a RA. She has been working as a CRA for 4 years for both commercial and government studies. She has a Bachelor's degree in Pharmacy from Faculty of Pharmacy, Srinakharinwirot University, Thailand. She enjoys running in the park near her house on the weekends. Sometimes, she runs in the park near PPD's office with colleagues after work.