NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

OFFICE OF CYBER INFRASTRUCTURE AND COMPUTATIONAL BIOLOGY

2016 ANNUAL REPORT

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OFFICE OF CYBER INFRASTRUCTURE AND COMPUTATIONAL BIOLOGY

LETTER FROM

MICHAEL TARTAKOVSKY

NIAID Chief Information Officer
Director, OCICB

Welcome to the 2016 fiscal year edition of the annual report for the Office of Cyber Infrastructure and Computational Biology. I've spent many years overseeing technology in support of the mission of this institute, and every year brings unique challenges and opportunities; this year was no different. As always, we strive to maintain and support the National Institute of Allergy and Infectious Diseases (NIAID) infrastructure and the people who work here. We provide technology support services, as well as user support. We also work with the scientific community to support their research projects; I would like to highlight just a few of our successes.

NIAID and the Republic of Mali, University of Sciences, Techniques, and Technology of Bamako (USTTB), established an international partnership to address the issue of reliable access to local bioinformatics tools, infrastructure, and computational biology training in a region deeply affected by emerging and reemerging diseases. This public-private-partnership was established to receive in-kind donations from private partners to build, deliver, install, and maintain a small high-performance computing device in Africa that provides sustainable bioinformatics capabilities. In conjunction with this effort, OCICB developed a program to run bioinformatics workshops at international sites, using re-purposed laptops from NIH surplus. This year, we strengthened the relationship by providing instruction to the students in the Master's program.

OCICB also worked with the Rakai Health Sciences Program in Uganda and the Johns Hopkins University to establish a unified database that integrates more than 20 years of community-based HIV/AIDS research into one centralized repository. This vast store of longitudinal data captured through the peak of the HIV epidemic was collected in 120-plus disparate files, using an unsupported legacy database technology. As time went on it became difficult to retrieve, interpret, and validate this data. OCICB established a sustainable platform that allows for reproducible research and improves the retrieval time of analytic datasets for the global HIV/AIDS research community.

OCICB instituted a novel microbiome data analysis platform that leverages cloud computing for improved consistency, centralization, and collaboration. This platform simplifies microbiome data analysis to make it accessible to more researchers and to facilitate discovery in this growing field. It provides the microbiome research community with no-cost access to core system functionality in order to run analysis pipelines and interact with microbiome data.

These projects represent some of our efforts, but they have one thing in common. They move the scientific agenda of NIAID forward. We are always looking for opportunities to partner with the NIAID research community to support efforts to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. If you have an idea for a project, please don't hesitate to contact me.

Michael Tartakovsky
NIAID Chief Information Officer
OCICB Director

Chief Technology Officer Update

Innovation is defined as the act or process of introducing new ideas, devices, or methods. At OCICB, we believe that innovation is essential in order to improve our technological environment, add value to our contributions, and find new ways to provide better service to our customers. A spirit and culture of innovation is essential in a technology and research driven environment, which is why NIAID leadership made a commitment to fostering innovation by establishing the position of Chief Technology Officer (CTO) within OCICB.

What is the best way to build innovation into the culture? What does that look like in an organization? What form should it take? Some organizations create a *CTO-managed team* charged with innovation. But OCICB management determined that this was not the best approach; it would take innovators out of the branches and isolate them. Further, it signals that only specific people can be innovators, which is not the case; everyone is capable of having innovative ideas. A CTO managed team would also create competition between the team and the branches, and complicate the process of transitioning projects from Research and Development (R&D) to operations and maintenance.

A far better approach is to empower innovation within the organization as a whole. How is this achieved? Should innovation be competition-based? A powerful argument against this idea is the concern that it would lead to an environment where there would be few winners, with decisions based on subjective rather than objective information. It could also filter out many ideas that could improve the operations and organization.

The answer is to enable every member of OCICB to act as an innovator, creating an open environment where ideas can be shared and discussed freely. The CTO functions as a senior technical advisor, working with the programs rather than being outside them. Anyone can bring their ideas to the CTO. Written proposals aren't necessary; individuals can schedule face-to-face meetings with the CTO, who set aside time on his calendar every Wednesday for this purpose.

When the CTO supports an idea, he will champion it with the CIO and branch chiefs. This process is known as "CTO as an Idea Advocate." It's an employee-driven innovation process that has already resulted in successfully generating and implementing new ideas.

New ideas, of course, come from people who are intellectually stimulated. The CTO sponsors lectures throughout the year on current technology trends and advances. He encourages people to broaden their horizons and learn about concepts outside of their regular knowledge domains. Six lectures this past year were presented by prominent individuals from industry and government. It was a chance for NIAID and OCICB staff to hear from experts, and gain the benefit of learning how they think about things.

The following NIAID CTO Technological Innovation Lectures were presented this fiscal year:

- **Creating an Information Ecosystem for Precision Medicine**, presented by John Quackenbush, Cofounder and CEO and Mr. Mick Correll, CTO and COO of Genospace, October 9, 2015.
- **Application Containers**, Mr. Jason Ingram, Cloud Solution Architect at Microsoft, November 18, 2015.
- **Scalable Bioinformatics Approaches to Drive Translational and Integrative Research in the Era of Big Data,** Dr. Subha Madhavan, Director of the Innovation Center for Biomedical Informatics at the Georgetown University Medical Center and Associate Professor of Oncology, February 17, 2016.
- **Graph Databases and Neo4J**, Bill Carden Account Manager, and Dave Fauth, Pre-sales Engineer, with Neo Technology, May 25, 2016.
- **Emerging Trends in Software Development and UI/UX design frameworks**, Mr. Tim Young, Principal with Deloitte consulting LLP, June 30, 2016.
- **Cloud Adoption by US Government Exploratory Discussion**, Dr. Merrick S. Watchorn, Cloud Security Solutions Architect with SAIC, September 21, 2016.

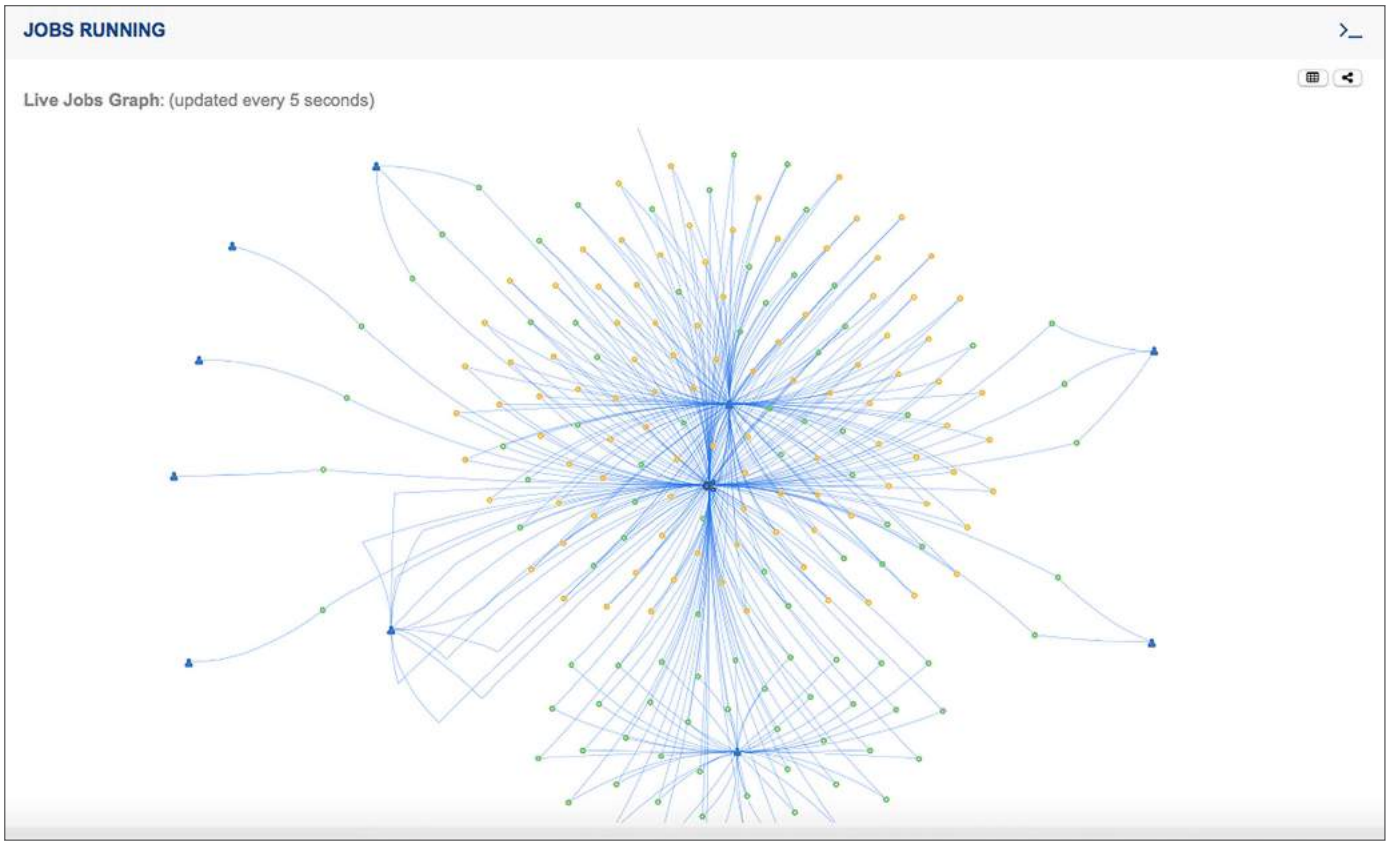
Infrastructure and Service Related Projects

LOCUS

In 2009, the NIAID intramural scientific community acquired several genomic sequencing machines. The initial project to store 200+ terabytes (TB) of sequencing information quickly grew, driven by the need to analyze the data using a wide range of bioinformatics applications from a growing number of users from the Division of Intramural Research (DIR).

A centralized and dedicated high-performance cluster (HPC) for scientific computing was clearly needed. The resulting NIAID HPC included the ROCKS cluster to simplify the deployment and management of the compute nodes, as well as the operating system (a variant of Red Hat Linux 5) and all the tools and applications required. Sun Grid Engine (SGE) was chosen as the workload manager and scheduler, and would become the primary tool for users. On the storage side, a DDN S2A9900 was purchased with a mixture of 15k and 7.2k hard drives, and a decision was made to front-end this storage with two servers running IBM's General Parallel File System (GPFS), which ensured greater performance and scalability. Initially, all of the nodes were communicating over gigabit Ethernet.

Increased requirements for data storage, compute nodes, and the number of users and applications required numerous upgrades. Ten-gigabit Ethernet was required for the GPFS servers, and four additional servers were needed to cope with cluster-wide bandwidth concerns. File system migration and consolidation was implemented to manage the uneven spikes in data growth. A newer, faster storage system (DDN's SFA12K-40) was purchased and integrated, along with solid-state storage devices that use integrated circuit assemblies as memory, to persistently



LOCUS Live Jobs Graph depicts running jobs on LOCUS.

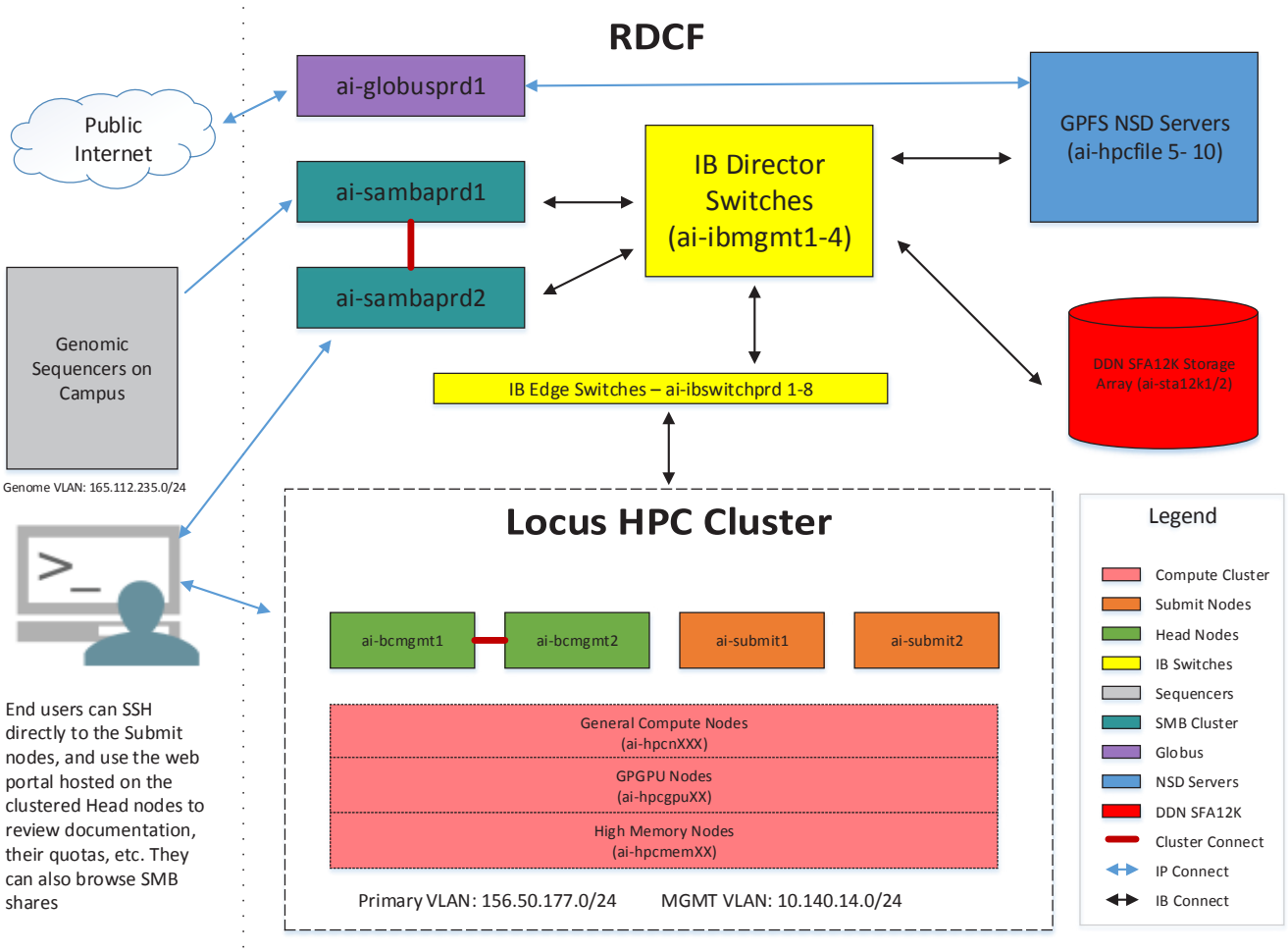
store data. These devices speed up both data and metadata operations. User training and clear, centralized documentation was added. The constant challenge of a power- and space-constrained datacenter was recently resolved when NIAID migrated to a new, primary compute facility at Fishers Lane.

The demand for more compute resources continues to grow. OCICB launched LOCUS, a new HPC cluster, to address issues with graphic processing units (GPU) and to facilitate data-collaboration and data-sharing. Locus utilizes 56 gigabit FDR InfiniBand – 14Gb/s data rate per lane computer-networking communications standard – for all intra-cluster communication to provide both higher bandwidth and lower latency. New Dell C6220 servers roughly double the number of Central Processing Unit (CPU) cores and increase available memory by approximately 700 percent. Fifty-six new general-purpose computing on graphics processing unit (GPGPU) servers were added that use NVIDIA's K80 Tesla GPU accelerators, to tackle a high volume of molecular dynamic work, specifically using AceMD. Bright Computing's Cluster Manager replaced ROCKS, as it provides similar, but more extensive, capabilities in conjunction with PUPPET for maintaining updated and consistent server builds. Univa Grid Engine (UGE) replaced Sun Grid Engine (SGE), which is no longer updated regularly from the vendor. GLOBUS, a service for high-speed data transfer and collaboration with HPC clusters and scientific institutes around the world, is now available via a self-service portal.

The custom user-support portal provides a knowledge base, FAQs, dynamic user-specific information about quotas, jobs, and lab shares for the 250-plus applications hosted on the cluster. Locus also uses NIH Active Directory authentication rather than local Lightweight Directory Access Protocol (LDAP) accounts to simplify password management for users. Environment modules make maintaining multiple version of compilers, libraries and applications for individual cluster users easier. EasyBuild, a software build and installation framework, efficiently manages applications.

Close to 100,000 jobs were successfully completed in the first four months that Locus was in production. Computational Structural Biologists indicated that, using a single K80 GPU, they can process 150 nsec/day for a 29K atom system (25mer peptide) and 20.4 nsec/day for a 238K atom system (HIV-1 gp120 trimer). That's fast.

Looking ahead, plans call for expanding the Locus file-system storage by adding roughly 800TB of usable storage space, bringing the total available storage to roughly two Petabytes (PB). Upgrades to the IBM Spectrum Scale file-system, cluster-management and scheduler software will be completed to ensure the cluster is running current, stable, feature-rich releases. OCICB is researching efficient and scalable methods to burst into the public cloud when sudden increases in demand for Locus resources occur, or when planned research projects require more resources than normally available. Solutions may incorporate new bioinformatics tools, such as JupyterHub, Apache Spark, and RStudio are being implemented. Finally, OCICB is focusing on identifying a technical offering to support data reproducibility using Locus. Pipelines and the genomic tools and algorithms used to analyze data must be both scientifically sound and reproducible. This will ease challenges inherent in sharing and reproducing computational analysis of high-throughput data.



Depiction of Locus cluster devices and configuration.

BACKUPS AND STORAGE ARRAY REFRESH

OCICB implemented a number of solutions to reduce the time required to back up the Institute's data. Previously, it took several days to back up parts of our enterprise storage. Shortening this timeframe was critical, given the continuing growth of NIAID's electronic data and the need to secure it.

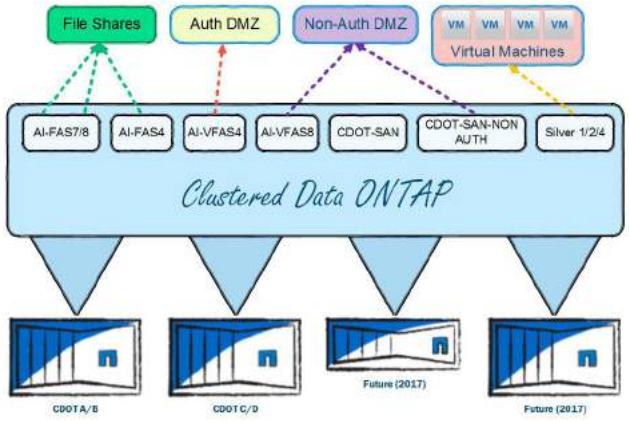
OCICB conducted a detailed analysis of over 1,200 individual jobs that run every day across the NIAID enterprise. Based on the results, a number of incremental changes were executed over several months that redistributed storage and backup resources.

A new Infinidat array replaced an aging and failing storage array, providing sufficient current and future capacity to support the increasing demands for reliable backups. All Microsoft SQL server backups were re-architected to leverage lower-cost storage; this change had the added benefit of reducing the processor requirement within the virtual environment as well as recovering several TB of tier one storage. The internal disk volumes were rebalanced to reduce larger data stores to more manageable sizes, enabling more frequent but smaller backups, thereby reducing any single job. Backups were distributed across an entire calendar month to remove resource bottlenecks within the backup and storage environments.

This initiative reduced the overall impact backups have on the environment, improved performance, and decreased backup times so significantly that all backups now take less than 24 hours.

Data is currently being migrated from older arrays at the Alternative Processing Facility (APF) and the Research and Development Computing Facility (RDCF) using six new high-end NetApp controllers and 3100TB of additional storage. This work will continue into FY17, when OCICB will begin replacing production

controllers within the RDCF. Once complete, the new NetApp infrastructure will operate on the latest and fastest hardware while running within a clustered storage environment, providing additional flexibility to NIAID's storage and backup systems. The integration of this new equipment is ongoing and the entire project duration will span more than two years.

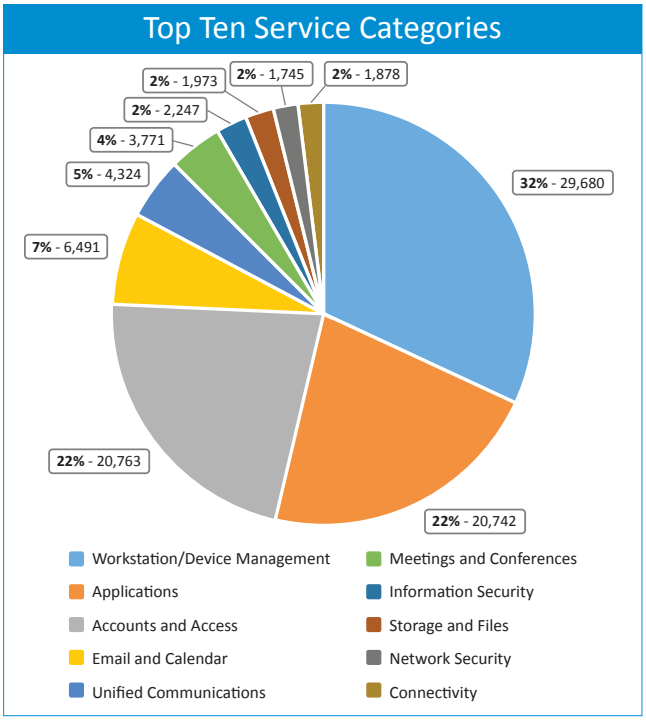


Architectural view of NIAID's RDCF CDOT infrastructure.

CUSTOMER SUPPORT

OCICB embarked on several projects to improve the integrity, reliability, and consistency of the desktop computing environment. We worked closely with customers to upgrade older and unsupported operating systems and applications, remediate security vulnerabilities, and upgrade hardware in anticipation of FY17 system requirements.

An automated call distribution (ACD) technology was implemented for the Central Service Desk (CSD) that integrates Skype for Business with Service Desk processes. It helps better manage call flow, ensure that calls are automatically routed to the next available agent, and balances the workload. The advanced analytics provided by the system monitor calling patterns and agent availability to dynamically adjust staffing to best meet customer needs.



Breakdown of the top ten types of help desk requests, categorized by the root reason for the call.

MOBILE TELECOMMUNICATION DEVICE MANAGEMENT

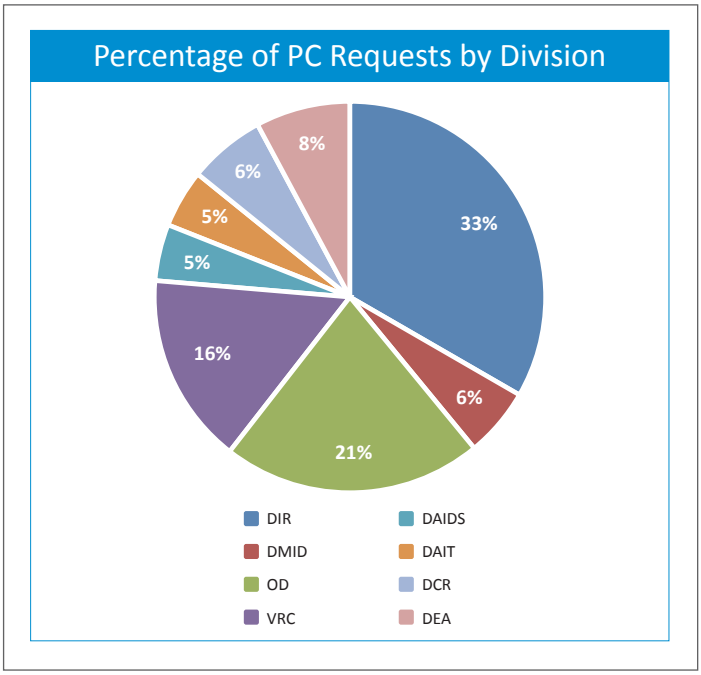
Mobile telecommunications devices (MTD) (e.g., cellular phone, BlackBerry, iPhone, Personal Digital Assistant [PDA], smartphone, iPad, tablet, and mobile broadband device) are essential for today's workforce. Mobile devices have diverse uses; sending and receiving email, storing documents, delivering presentations, and remotely accessing data. Despite the many benefits, there is also a downside. The devices may be lost or stolen, presenting potential security risks.

The MTD program was transitioned to OCICB in early FY15. In May of 2015, the Resource Planning and Evaluations Working Group (RPEWG) recommended standardizing MTDs to the iPhone. All eligible devices incapable of supporting the day-to-day work requirements of the NIAID community were replaced. Approximately 620 mobile devices were upgraded to the iPhone 6 and 450 Blackberry users converted to the iPhone. This transition provides greater mobile productivity, more collaborative communications and more cost-effective mobile solutions. Currently, 1,547 mobile devices across three separate service providers are managed by OCICB.

PERSONAL COMPUTER PROCUREMENT PROGRAM

OCICB acquires, configures, and distributes all NIAID computers. The process begins when a new acquisition request is entered into the Administrative Management Budget Information System (AMBIS). Once approved, the number of days it takes to deliver and install standard and custom personal computer (PC) orders are tracked. The customer experience and trends are analyzed to identify potential bottlenecks in the PC procurement process. A customized funding dashboard provides NIAID divisional Administrative Officers with information on their PC requests. They can review funds expended on equipment purchases and to-date PC budget status. Requesters, end users and accountable users can also track the status of their PC requests.

This year, OCICB received 1,280 PC requests; approximately 106 per month. New customized scripting tools streamline and automate the backup process when transitioning from an old machine to a new PC for both Apple and Windows platforms.



CAMPUS CONFERENCE ROOM REDESIGN

OCICB maintains a large number of audio-visual (AV) systems in conference rooms across NIAID. In order to better support new technologies and allow for seamless collaboration between on-site and remote meeting participants, OCICB engineers spent much of FY16 visiting sites, collecting usage information, and developing new designs for the Bethesda main campus conference rooms.

More than 20 conference rooms and team rooms were selected. The existing systems did not support use of the room speakers and microphones with the room PCs, preventing the use of PC-based conferencing tools. Detailed room measurements were recorded, and local staff were interviewed to determine how the rooms are most commonly used. Usage metrics available from backend systems were collected to better understand requirements.

The resulting new designs feature fully-integrated systems, enabling the use of many popular communication and collaboration tools with central control from a touch screen panel. The cornerstone of these updated AV systems is an industry-wide shift to PC-based conference and collaboration systems, such as Skype for Business, GoToMeeting, and WebEx.

Conference room control systems will provide multiple inputs and display devices (Liquid-Crystal Displays [LCDs] and/or projectors) and, in some cases, integration with lighting and automatic shades. Team rooms will feature a single display with the option for multiple inputs, including a room PC and individual laptops; switching between these sources will be handled automatically.

Implementation of the new room designs has begun, and will continue through FY17, based on room schedule availability, equipment availability, and prioritization of rooms based on need.

VIDEO TELECONFERENCING AND TEAM ROOMS GROUP

OCICB refined and improved the Fishers Lane conference rooms based on end-user feedback about their experiences. Changes to control systems within Fishers Lane resulted in an improved experience, making it easier to set up teleconferencing sessions. Customer feedback will continue to inform conference room design decisions. Training on how to use the equipment is available for all NIAID staff. OCICB will build on the foundation of the user-friendly technology already available and continue to improve the user-experience across all NIAID facilities.

FISHERS LANE RESOURCE LIBRARY AUDIO AND CONTROL SYSTEM UPGRADES

The Fishers Lane resource libraries support collaborative remote working sessions and presentations using video tele-conferencing (VTC) and PC-based conferencing (Skype for Business, GoToMeeting, etc.). Feedback from the NIAID user community identified issues with the spaces, specifically poor audio quality and the lack of user-friendly systems in these rooms. To rectify this, OCICB recently completed an upgrade of the audio and control systems.

The table-mounted microphones were the source of the audio quality issues, transmitting rustling papers, tapping pens, vibrating cellular phones, etc., which muffled participants' voices and made it challenging for remote attendees to hear clearly. A successful pilot, implemented in the 5C100 resource library, was rolled out building-wide. The new setup dramatically improves sound quality and microphone coverage by replacing table-mounted microphones with three ceiling-suspended microphone units. Each new unit contains three independent microphones, which increased the number of microphones per room from one per table to nine per room. Because the microphones are suspended from the ceiling, speakers' voices are more clearly transmitted from anywhere in the room, while table noise is reduced. Increased microphone coverage is supported by new digital signal processors installed in each room.

The touch-panel control system was redesigned, using the existing panels as the base. A cleaner interface was introduced and some common functions were brought to the forefront of the panel to increase user-friendliness. Most notably, outgoing phone calls can be placed directly from the touch-panel without logging into the PC. Unlike the Polycom phones, the new system uses the speakers and microphones installed in the room for phone call audio. This greatly improves the call clarity and collaborative experience for both local and remote participants. The system defaults to the most common room configuration (both LCD displays presenting the room PC). Alternative configurations are easy to set up from the control panel, saving time and establishing consistency in all libraries. A clearly-labeled "mute" button on the touch-panel controls the room microphones, replacing the table-mounted "mute" buttons. The wall-mounted control panel near the door displays the room's microphone status for all local participants to see.

LYNC/SKYPE FOR BUSINESS CONTACT CENTER IMPLEMENTATION

Lync/Skype for Business provides basic calling-tree functionality through a feature called Response Groups; however, several NIAID groups required a more robust call center solution, akin to those used by help desks at support organizations. This type of solution, referred to as a "contact center," allows for specific routing of calls based on interactive responses from callers, resulting in a more efficient process for resolving calls.

In conjunction with the move to Microsoft Lync/Skype for Business, OCICB engineers deployed Clarity Connect, a contact center solution. The NIAID Information Technology (IT) Service Desk was the first group to move to Clarity Connect. It offers extensive metrics and reporting capabilities, allowing for call centers to ensure that they are delivering appropriate levels of service. Call center agents can be active from any location, ensuring no disruptions to service during inclement weather or other office closures. This system has been deployed in a high availability configuration, making use of both the NIAID RDCF and the NIAID APF.

NIAID COLLABORATION PLATFORM UPGRADED TO MICROSOFT SHAREPOINT 2013

OCICB provides a collaboration environment for NIAID and research collaborators from institutes and universities around the world. Microsoft SharePoint is one of the most popular collaboration tools and requires careful management. OCICB migrated to SharePoint 2013 in FY16 to provide a more efficient and reliable platform. This version includes enhancements such as easier drag-and-drop capabilities, simpler content sharing, and general user interface improvements that foster increased productivity and adoption.

The enhanced search engine leverages a mechanism called Continuous Crawl. This enables a faster crawl of new or updated content, while ensuring that search results are relevant. A separate set of servers was configured to provide browser-based file viewing and editing services for Office files to support Microsoft Office web applications. The Office Web Apps Server works with products and services that support the Web App Open Platform Interface Protocol (WOPI). People can view and edit documents as they would in Microsoft Word, for example, without downloading them. Separating this Office Web App Server from the SharePoint servers makes the system more versatile and accessible. For instance, multiple SharePoint farms can connect to the same Office Web Apps servers. As a result, the SharePoint farms can be isolated from the Office Web Apps platform for more efficient patching.

REMOTE MAC MANAGEMENT

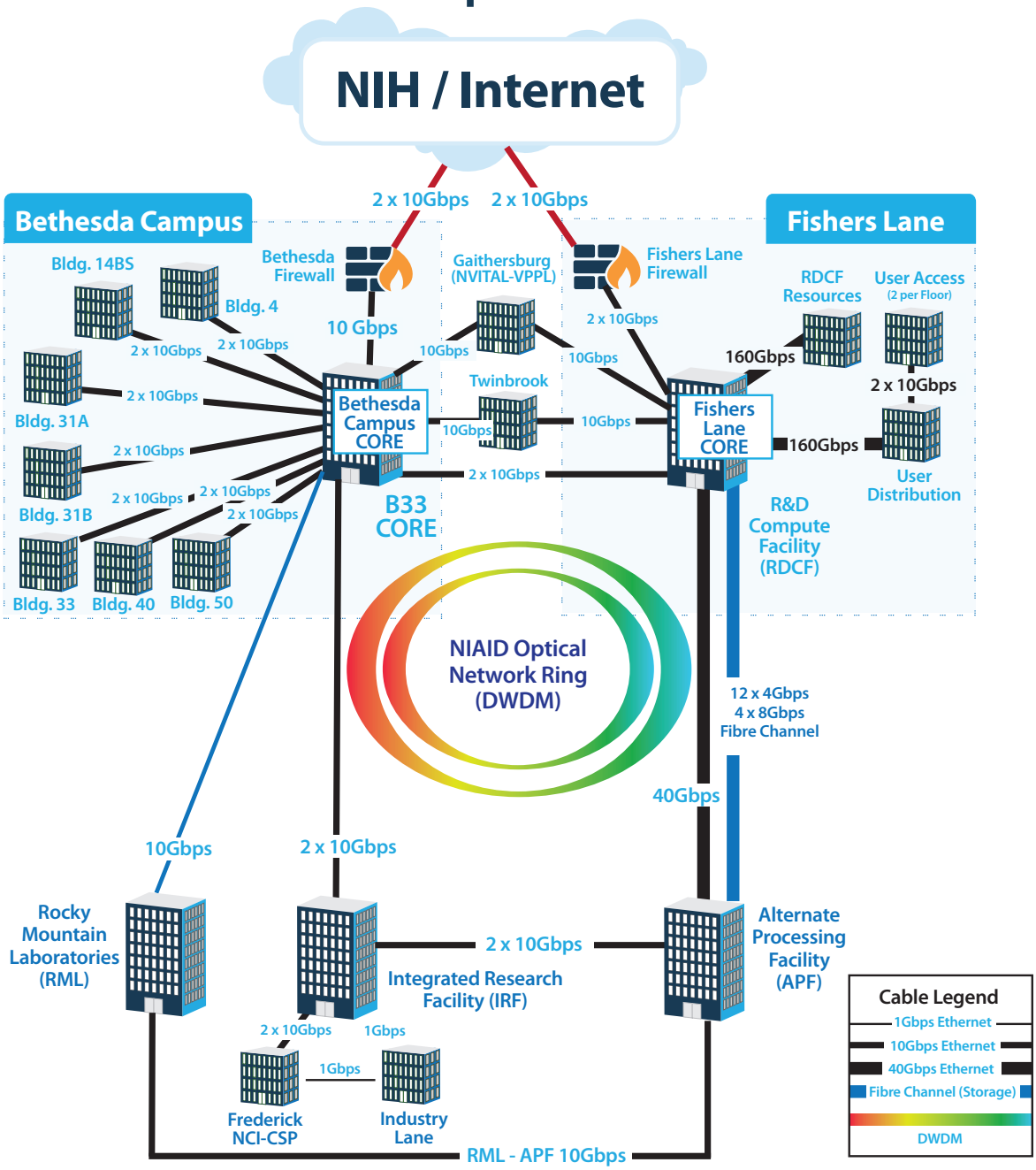
Improving the infrastructure of the NIAID Mac management system was a high priority in FY16. Remote users can now receive access to essential software, even without a direct NIAID network connection (on-premises Local Area Network (LAN) or Wireless (Wi-Fi); Virtual Private Network (VPN)). The Remote Mac Management project addressed critical questions surrounding how to ensure that all Macs are properly managed, the right software and services are available to users, and the software and inventory data for Macs in the environment is accurate, regardless of their location.

Macs connected primarily to the Internet, and only occasionally to the NIH/NIAID network, were a key focus. The requirements and considerations for extending management capabilities to these Macs were explored, focusing on network server and Mac client security. For instance, this project required that NIAID Mac computers within the NIH/NIAID network were properly enrolled in the system.

With the infrastructure in place, the only step left was ensuring that enrolled Macs would automatically check-in to the management system server. OCICB validated that enrolled Macs successfully received software deployments and could access self-service to download and install software. When the system went live, it was unclear how many Macs might be picked up as a result of this new capability. An additional 200 plus Macs were added to the inventory within a couple of weeks.

Today, there are nearly 1,400 Mac laptops in the NIAID environment that can be successfully inventoried, managed, and provided with end-user self-service capabilities, using only an Internet connection. Organizational benefits include better software management, improved hardware inventory, and increased device security.

NIAID Enterprise Network



The NIAID network is composed of switches, routers, and fiber optic lines that connect staff to NIAID, NIH and Internet resources. Within each building, workstations are connected to one switch on each floor or wing within the building, which is then connected to a pair of distribution switches that connect to the redundant core of our network, which in turn, connect to the dark fiber ring between NIAID buildings and campuses. The core networking infrastructure at NIAID was implemented with redundant components (duplicate cables, fiber optic lines, switches, etc.) and battery backup units to ensure that the network is fault tolerant. This level of fault tolerant design has resulted in a network up time of more than 99.92% percent (this number includes scheduled and partial outages). The NIAID inter-campus network, connecting Fishers Lane, the Bethesda campus, the IRF and the APF, is composed of a highly scalable, redundant optical networking ring consisting of several nodes using Dense Wave Division Multiplexing (DWDM) technology at its core. It provides a regional fiber optic network that allows researchers to access and share critical data residing in remote data centers at extremely high bandwidth rates with minimal latency and supports the synchronous replication of data to the APF for Continuity of Operation.

Training Seminars and Outreach Initiatives

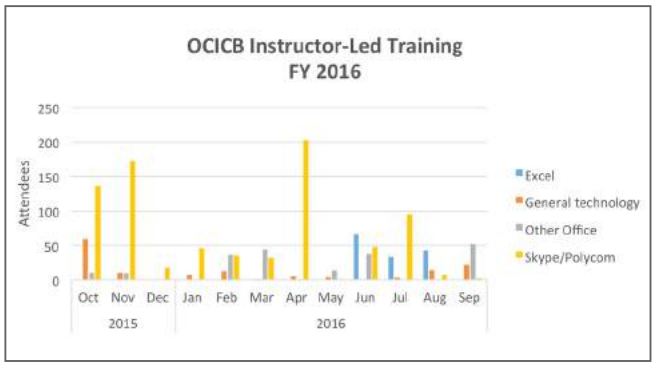
IN-HOUSE NIAID-BASED TRAINING

OCICB provides training support for various IT projects and initiatives to the internal NIAID workforce. Materials are designed in-house and disseminated in person and in classes. Three major projects were launched: an eLearning Initiative, Walk-In Workshops and Skype for Business classes.

The main function of eLearning is to provide learning on-demand. People unable to attend training in-person, as well as those who only want to learn a specific subsection of content, can take advantage of eLearning training modules at their convenience. These modules also serve as a great resource and refresher to people who previously attended training.

Walk-In Workshops take place in the Fishers Lane lobby to promote new technologies available in the NIAID environment. People learn how to incorporate these technologies into their daily work environment. OCICB promotes training and learning opportunities within NIAID that people may not know about. For example, currently there are three different Skype for Business Training sessions that offer focused content: *Quick Start with Skype for Business and Polycom, Skype for Business Basics, and Managing Skype Meetings*. Three separate walk-in workshops specific to Skype occurred; *Introducing Skype for Business, Whiteboards & Polling, and Effective Q&A*.

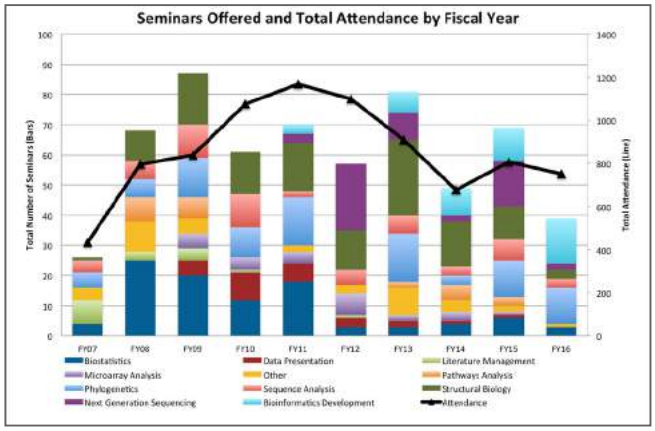
More than 170 in-person and blended classes reached 1,358 attendees. Topics ranged from general technology such as unified communications to conference room technology, and a concentration on Microsoft Excel and other Microsoft Office applications. Follow-up surveys indicate that 100% of the respondents would recommend the class to their coworkers and 99% believed that all of the class objectives were successfully met.



In FY16, staff attended OCICB Instructor-led trainings on various subjects including Excel, General Technology, Skype/Polycom, and other Office applications.

The http://ocicbtraining.niaid.nih.gov site, is a training resource for NIAID staff members. It provides class schedules, user guides, quick reference cards, and tips. During FY16, the site received 7,628 page views from 1,167 sessions.

SCIENTIFIC SEMINARS & OUTREACH INITIATIVES



OCICB offers seminars and workshops led by staff computational biologists on a variety of bioinformatics and biocomputing tools. Seminar topics range from introductory lectures to more advanced, hands-on workshops. Thirty-nine seminars were presented during FY16.

Good Clinical Data Management Practices and Datafax

February 23-26, 2015
Chennai, India

Over the past 15 years, regulatory agencies have published regulations that govern data management. The Food and Drug Administration (FDA) in the U.S. published the 21 CFR part 11 regulations as a guide to proper clinical data management. These standards set guidelines for research and support teams to maintain the integrity of data collected.

As part of a National Institute for Research in Tuberculosis (NIRT) and NIH collaboration, a support team travelled to Chennai to conduct training on "Good Clinical Data Management Practices (GCDMP) and DataFax." The four-day training was presented by Michael Holdsworth and Cindy Lassnoff, members of the OCICB International Support team.

The training provided a basic overview of these regulations and a summary of the industry standard known as GCDMP, which was developed and published by a non-profit international organization called the Society for Clinical Data Managers (SCDM). GCDMP has become the gold standard for clinical research data management.

The training also focused on DataFax – a data management software being used for the NIH collaboration studies. DataFax is a comprehensive data management solution that provides intuitive internet ready tools allowing researchers to set up databases and administer, enter, process, clean, report and export their data from anywhere in the world. DataFax is adaptable and a true hybrid system since it allows for paper-based or electronic studies. Together, DataFax and the OCICB International Support team offers a fully validated and efficient means for data management.

Cindy Lassnoff and Michael Holdsworth with the students participating in the workshop.

SUPPORT FOR THE USTTB MASTER'S DEGREE IN BIOINFORMATICS

In April 2015, the University of Science, Technique and Technologies of Bamako (USTTB) began offering a Master's in Bioinformatics – the first in francophone Africa. The program integrates biology with mathematics and computer sciences, and builds on the research opportunities established between NIAID and USTTB. The OCICB team provided extensive support for the program, and the telelearning center built as part of the African Centers of Excellence in Bioinformatics (ACE) initiative provides advanced communication infrastructure for remote learning.

Building on work done in FY15, OCICB increased commitment to the program, providing full instruction for the *Molecular Modeling and Sequencing & Data Analysis Techniques* classes, and supplemental webinars for the *Evolutionary Phylogenetics* and *Bioinformatics Programming* courses. To facilitate this effort, OCICB developed a syllabus, provided twice-a-week sessions in two-hour intervals, supplied homework assignments and final exams, and hosted meetings with USTTB instructors.

During the third semester, OCICB offered instruction for the Metabolomics and *In Silico* Analysis course via the University of Alabama at Birmingham (UAB). OCICB scheduled the sessions between UAB and the USTTB telelearning center, provided WebEx test/walk-through sessions to all UAB instructors, ensured the availability of video recordings, and liaised between the UAB faculty and the USTTB faculty.

Clinical Data Interchange Standards Consortium (CDISC) Training

October 23-26, 2015
Rockville, Maryland

OCICB hosted an open CDISC training session on data management. Spanning four days, the sessions covered various CDISC standards and data management aspects. The first two days covered study data tabulation models (SDTM), the standard specification for submitting data to the FDA. Day three covered Clinical Data Acquisition Standards Harmonization (CDASH), the standard for common clinical data collection research with an emphasis on using these standards when designing Case Report Forms (CRF). The final day focused on Analysis Data Models (ADaM) for collected data and statistical analysis. This introductory training reviewed the significance of following established standards and provided guidance on applying them to data collection, reporting and CRF development. Participants received certificates of attendance for each course.

The onsite training in 5601 Fishers Lane lasted a week and covered the three components of CDISC- CDASH, SDTM, and ADaM. Attendees came from OCICB, DCR and DIR.

Transforming Your Science: Innovations with 3-D Printing

October 22–23, 2015
Research Triangle Park, North Carolina

The National Institute of Environmental Health Sciences (NIEHS) hosted "Transforming Your Science: Innovations with 3-D Printing," an event intended to introduce NIEHS researchers to 3D printing and ultimately generate momentum for a 3D printing program on-site at NIEHS' campus in Raleigh, NC. NIEHS reached out to OCICB for expertise in 3D modeling and printing, and Dr. Meghan Coakley helped NIEHS to organize the event. Dr. Darrell Hurt presented on "3D Printing for Scientific Discovery," where he explained the workflows and development processes that led to the NIH 3D Print Exchange, and the vast potential for 3D printing technology to impact science and medicine. Dr. Phil Cruz and James Tyrwhitt-Drake provided training to NIEHS staff on 3D modeling and 3D printing of biological molecules. The event was featured in the NIEHS December 2015 newsletter, which touted NIAID's contributions and accomplishments in the field.

International Tuberculosis Portals Workshop

December 8–9, 2015
Tbilisi, Georgia

The International Tuberculosis Portals Program was initiated and spearheaded by OCICB. This collaborative effort focuses on the better understanding and treatment of multidrug-resistant forms of tuberculosis (MDR-TB) and improving diagnostics and outcomes for TB patients with MDR-TB.

The 2015 International Tuberculosis Portals meeting brought together researchers and clinicians to discuss research and treatment challenges related to MDR-TB, and to identify new and improved methods for using information technologies to address those challenges.

Highlights of the meeting were the establishment of the International Tuberculosis Portals Consortium and the formation of a multinational Steering Committee. Representatives of the Steering Committee have been working with NIAID to guide future international research and development directions in MDR-TB.

Clinical Data Management Training

January 25-29, 2016
Dhaka, Bangladesh

The NIAID DIR, Laboratory of Infectious Diseases (LID) initiated a new clinical trial for a potential Dengue vaccine (TV005) protocol in Bangladesh, which assesses the safety and immunogenicity of the dengue fever vaccine test product. The protocol is sponsored by the Office of Clinical Research Policy and Regulatory Operations (OCRPRO), Division of Clinical Research (DCR), NIAID, and the NIH with Dr. Stephen Whitehead (NIAID/LID) as the Scientific Investigator.

Dengue viruses are now the leading arbovirus infection globally, with over two billion persons at risk of infection and continually expanding affected regions. The first dengue fever outbreak in Bangladesh occurred in 2000, and the burden of dengue disease in this area has continued since then. A dengue vaccine has not yet been tested on the Indian subcontinent, despite large populations at risk for infection. In Dhaka, a densely populated

city of 12-20 million inhabitants, antibody testing demonstrates that 80% of the population (9.6-16 million persons) has been exposed to this virus. This study is very similar to another ongoing LID protocol in Bangkok, Thailand (called TV00X) - which is assessing safety and immunogenicity of a very similar dengue vaccine product. Together, these protocols will provide important information for licensing submissions to the FDA.

OCICB's Clinical Research Data and Biostatistics Subject Matter Expert, Kevin Newell, conducted a preliminary DataFax and clinical research data management training. The host institution for this protocol, the International Centre for Diarrheal Disease Research, Bangladesh (ICDDR,B), is a highly experienced clinical research, training, clinical services, and humanitarian organization which employs over 5,000 staff members. The center focuses on communicable diseases affecting children and adolescents, addressing neonatal, infant and childhood mortality, as well as infectious diseases including gastrointestinal parasites and rotaviruses associated with poverty within urban Dhaka and throughout rural Bangladesh.

The event was highly successful. Although new to DataFax, the data management team has extensive experience conducting clinical trials and long-term observational research cohorts with web-based electronic data capture systems. The local team has a rigorous standardized approach to clinical research data management, ensuring high quality data for the upcoming study. The OCICB DataFax team will continue ongoing mentoring and capacity building for the local users throughout the lifetime of this protocol.

The site team will work in close collaboration under the guidance of the University of Vermont study team, with direction by the protocol principal investigator, Dr. Beth Kirkpatrick. The planned implementation date for the Dengue in Dhaka protocol was March 27, 2016.

DataFax and FrameMaker Training
January 25--February 2, 2016
Kampala, Uganda

OCICB conducted a workshop on GCDMP, DataFax (including database setup, and data entry and management), CRF design, and using Adobe FrameMaker to create CRFs. Approximately 20 study coordinators, data managers, and DataFax support staff from the Infectious Diseases Institute (IDI), the Rakai Health Sciences Program (RHSP), and the Fred Hutchinson Cancer Research Center (FHCRC) attended the workshop.

Michael Holdsworth and Cindy Lassnoff with their students in Kampala, Uganda- the OCICB duo for data management training that includes how to use CDMS systems and CRF design to improve data quality.

Sequencing and Data Analysis in Bioinformatics Workshop
February 9–13, 2016
Chennai, India

An OCICB team provided instruction in sequencing techniques, microbiome analysis, biostatistics, and imaging to support tuberculosis research at the NIAID International Center for Excellence in Research (ICER) and NIRT. In preparation for the workshop, OCICB sent registered attendees an online survey to gain a better understanding of their current knowledge levels, and to target presentations toward their backgrounds.
Five OCICB staff provided fifteen workshop sessions:

- Working with Sequences in UGENE
- Unix Basics
- Scripting, and Cluster Computing
- Mapping and De-novo Assembly
- ChIP-seq Theory and Hands-on Analysis Using Useq
- Comparison of ChIP-seq Tools and Hands-on Peak Finding Using MACS
- Function Prediction
- Introduction to R and Statistical Analysis with R
- NGS Data Analysis in the Context of Biological Networks
- Microbiome Data Analysis and Microbial Ecology
- Variant Calling and Exome Analysis
- Using QIIME and Mothur Pipelines with Microbiome Data
- R for NGS Data Analysis
- RNA-seq Data Analysis

- Interactive Visualization Using Chimera

On the final day, participants were asked to complete a survey rating the instruction experience, materials, and topics chosen. The team received very positive ratings, as well as constructive feedback for how to improve future events.

Dr. Mariam Quiñones teaches a session on microbiome analysis at the Sequencing and Data Analysis in Bioinformatics Workshop held in Chennai, India.

Specimen Tracking and Inventory Management Training

February 17, 2016
Chennai, India

OCICB provides the FreezerPro specimen tracking and inventory management system as a freezer specimen tracking service for international collaborations that manage biobanks and track compounds. As part of NIRT and NIAID collaboration, Jaskiran Singh, Clinical Data Architect, conducted a FreezerPro workshop at NIRT. The workshop had approximately 31 attendees including data managers, study coordinators, lab technicians and clinicians from various Indian Council of Medical Research (ICMR), NIRT and ICER facilities, HIV/AIDS labs and other organizations. The training provided users with hands-on experience with the application.

OCICB International Data Architect and the students from the Specimen Management workshop at the ICER in Chennai, India.

Dashboards for Active Clinical Studies

February 18, 2016
Chennai, India

Jaskiran Singh spoke on "Building Clinical Data Warehouses Using Standard Data Models and Open Source Software for Active studies." The presentation focused on an initiative related to the development of dashboards for clinical studies and the extensive foundation work needed.

Students at the OCICB International Seminar on how to build data warehouses for active clinical trials to ensure regulatory compliance-National Institute for Research in Tuberculosis, Chennai, India.

3D Modeling & Printing of Tissue and Organs

March 10, 2016
Silver Spring, Maryland

The 19th US-Japan Cellular and Gene Therapy Conference is jointly supported by the FDA and the Japanese Ministry of Education, Culture, Sports, Science and Technology, under the US-Japan Cooperative Research Program. The goal was to exchange

ideas on cutting edge areas of biomedical research and enhance opportunities for collaborations among scientists from the US and Japan. The theme for 2016 was 3D Modeling and Printing of Tissues and Organs. Dr. Coakley gave a presentation titled "3D Printing in the Sciences: Past, Present, and Future Horizons," introducing the NIH 3D Print Exchange, along with an overview of the value of 3D printing in science, barriers to adoption, technological challenges, issues pertaining to ethics and the lack of standards, how the field has evolved over time, and where it is headed.

NIH Pi Day Poster Presentation

March 14, 2016
Bethesda, Maryland

Activities for the NIH-hosted second annual Pi Day celebration included a data center tour, lightning talks, poster presentations, a data science seminar series, and a workshop on reproducible research. OCICB's Dr. Mariam Quiñones presented a poster on Nephele during the poster presentation held on the Foundation for Advanced Education in the Sciences (FAES) Terrace.

USA Science & Engineering Festival

April 15–17, 2016
Washington, DC

The biennial USA Science and Engineering Festival showcases all facets of Science, Technology, Engineering and Math (STEM), with a focus on engaging America's youth by providing a compelling, exciting, and educational festival. Over 400,000 people attended this event. In 2014, NIAID partnered with the Eunice Kennedy Shriver National Institutes of Child Health and Human Development (NICHD) to organize the NIH 3D Print Exchange exhibit. Following on that success, NIAID hosted its own booth in the NIH pavilion for the first time in 2016. Visitors to the booth engaged with a wide range of 3D-printed models of viruses and infectious disease-related molecules. Over two dozen NIAID intramural researchers and subject matter experts volunteered for the event, guiding visitors with hands-on activities that demonstrated concepts about DNA and protein structure, viral assembly and immune response, antibody production and vaccination. The NIAID booth was organized by OCICB in partnership with the NIAID Office of Communications and Government Relations (OCGR).

Advancing TB Research: An Exploration of Opportunities

April 23–24, 2016
Mumbai, India

Based on the success of the Chennai workshop, the OCICB team was asked to participate in another training event. The P.D. Hinduja Hospital and Medical Research Center, in association with the NIAID Division of Acquired Immunodeficiency Syndrome (DAIDS), hosted a workshop "Advancing TB Research: An Exploration of Opportunities." Attendees included TB researchers, pulmonologists, infectious disease specialists, physicians, microbiologists, and bioinformaticians. The workshop provided comprehensive information on diagnostic modalities for TB diagnosis and drug resistance testing. A two-day training on microarray and next generation sequencing (NGS) was held in parallel. Maarten Leerkes, OCICB's genome analysis specialist, traveled to Mumbai to present the Microarray and NGS training. The sessions were a mix of lecture and hands-on components. OCICB received positive responses from the attendees.

Dr. Maarten Leerkes presents on Microarray, DNA-, and RNA-seq analysis at the Workshop on Advancing TB Research: An Exploration of Opportunities in Mumbai, India.

Building Evidence for 3D Printing Applications in Medicine

May 19–20, 2016
Orlando, Florida

The "Building Evidence for 3D Printing in Medicine" workshop was co-located with RAPID 2016 and organized by Science

Management Engineering (SME). Dr. Coakley was invited to participate in the workshop, which gathered together leaders in the medical community and additive manufacturing. Participants discussed clinical studies, shared best practices, and identified effective research methodologies, focused on the goal of allowing more patients worldwide to benefit from the personalized approach enabled by 3D printing. The event was also the kick-off to SME's Medical Additive Manufacturing 3D Printing Workgroup, during which Dr. Coakley represented the NIH 3D Print Exchange. An important outcome of this engagement is that the NIH 3D Print Exchange will be used as a central database to share 3D models derived from patient medical imaging data. In turn, OCICB will draw on the expertise of the more than 50 member group to inform further development of the Exchange.

2016 Clinical Data Management User Group (CDMUG) Conference

June 15, 2016
Rockville, Maryland

OCICB supplies DataFax to the NIAID international research community. OCICB supports the community with specialized data management expertise, knowledge of best practices, and industry experience with the tool. This expertise is shared in training sessions and workshops like the NIH CDMUG workshop that covered the following topics:

- Moving to CDISC/SDTM compliant modules within DataFax 2014.1.1
- Demonstrating medical coding using fully-loaded MedDRA dictionaries
- Implementation of post-production database changes
- Development of dynamic ("smart") patient casebooks
- User authorization database
- Project Harmony dashboards
- Monitoring database quality issues during project initiation

Making Health: Inspiring Innovative Solutions for Research and Clinical Care

June 21, 2016
Bethesda, Maryland

NIAID partnered with the NIH Office of the Director and the HHS IDEA Lab to host a special symposium as part of the National Week of Making. This White House initiative celebrates the ingenuity and creativity of a diverse community of inventors in the Maker Movement, which encourages innovation through a new class of technologies, like 3D printing. The goal of the event was to raise awareness on how everyone - researchers, clinicians, and patients alike - can improve their health and the health of others through Making and innovation. Susannah Fox, HHS CTO, was the keynote speaker for the event, which also featured short presentations and a panel discussion with staff from several NIH institutes and centers (ICs) and the Walter Reed National Military Medical Center (WRNMMC). The event also advances the HHS Invent Health Initiative, born out of the HHS IDEA Lab, which seeks to empower inventors both inside and outside government to create tools for better living and better clinical care.

Capitol Hill Maker Faire

June 21, 2016
Washington, DC

Dr. Coakley represented the NIH, along with presenters from the National Institute of Standards and Technology (NIST), National Aeronautics and Space Administration (NASA), Department of Education (DoED), National Education Association (NEA), National Science Foundation (NSF), and more, on a panel titled "The Federal Government & Making: Five Minute Lightning Talks by Agency Partners." The panel was part of the second annual Capitol Hill Maker Faire, a hands-on, interactive event for members of Congress, their staff, families, and Capitol Hill visitors. The meeting explores the movement driven by hobbyists, tinkerers, crafters and innovators that is changing the face of informal learning at community institutions and is breathing new life and innovation into the American economy. The NIH 3D Print Exchange exhibited 3D prints and information at the evening reception.

Freezer Management User Group Meeting

June 22, 2016
Bethesda, Maryland

An NIH campus-based workshop reviewed the specimen tracking and inventory management application, FreezerPro, for frozen sample management. Michael Duvenhage presented an overview of the biochemical and compound management system. He also discussed modes of importing data into FreezerPro. Subsequently, Kathy Pomeroy gave a demonstration on the new FreezerPro version 7 interface. Several labs located near the NIH main campus attended the session via GoToMeeting and participants had great questions and discussions thereafter.

NIH Safety, Health, and Wellness Day
June 22, 2016
Bethesda, Maryland

Every year, NIH hosts an event featuring health screenings, safety and health promotion events, nutrition demonstrations, Cardiopulmonary resuscitation (CPR) training demonstrations, food trucks, and more. The different ICs take turns co-sponsoring the event. This year, NIAID was the co-sponsor. OCICB was invited to attend to promote the 3D Print Exchange and Nephele microbiome analysis platform. Karlynn Noble and James Tyrwhitt-Drake spoke to booth visitors about the increase in knowledge regarding the microbiome and how it affects human health, as well as how 3D printing is changing the surgical landscape.

Karlynn Noble meets with Dr. Fauci, NIAID Director, at the NIH Safety, Health, and Wellness displays, co-sponsored by NIAID.

Making Health: An Interactive Celebration of How Tinkering, Technology and Design Tools are Transforming Health Care
June 23, 2016
Washington, DC

As a follow up to the "Making Health" symposium at NIH, NIAID, the NIH OD, and the HHS IDEA Lab co-hosted with MedStar Health a showcase of healthcare solutions from practitioners, patients, designers, engineers, entrepreneurs, and other tinkerers who are creating healthcare solutions by transforming an idea from a quick sketch to a working prototype. Making Health was open to anyone interested in learning how the democratization of technology has led to the maker movement in health care (See James Fallows article in The Atlantic: Why the Maker Movement Matters). The focus was primarily on creating physical objects to help people live more independently, in better health, and with greater dignity. Over 275 visitors attended the event, which featured an exhibit from NIAID's 3D Print Exchange, and a short presentation from Dr. Coakley.

The Challenge of Attribution or "View Source" for 3D Printed Objects, Singularity University
June 29, 2016
Mountain View, California

The Creative Commons organization, in partnership with Shapeways, gathered together at the Singularity University on NASA's Ames campus in Mountain View, CA for a one-day workshop to address when attribution, or "view source," matters in 3D printing. Attendees included intellectual property and policy experts, representatives from 3D repositories and 3D printer manufacturers, and leaders in the field of 3D modeling and design. The group discussed the role of Creative Commons licenses in a field rich with data and designs both restricted and not restricted by copyright. Dr. Coakley was invited to explain the ways that NIAID is addressing attribution and licensing of 3D models shared and created via the NIH 3D Print Exchange. She also presented on the technical aspects of 3D data formats and the potential to create a new data standard that would incorporate metadata within the 3D object.

Web3D 2016 & SIGGRAPH 2016
July 22–29, 2016
Anaheim, California

Web3D 2016, the 21st International Conference on 3D Web Technology, was hosted by the Web3D Consortium and co-located with SIGGRAPH 2016. OCICB staff attended both events, held at the Anaheim Convention Center. Dr. Hurt was a General Co-Chair for the Web3D conference and Dr. Coakley was a Workshop Co-Chair. At the Web3D Consortium Townhall Meeting, Dr. Hurt and Dr. Coakley each gave presentations on 3D modeling workflows, and capturing metadata for digital 3D objects, respectively. Dr. Coakley hosted a workshop at Web3D 2016, "Application of 3D Technologies in Medicine," with collaborators from Jump Training Simulation and Education Center (Peoria, IL) and the Veterans Affairs Hospital at the University of Washington (Seattle, WA), and presented on similar topics at a Birds-of-a-Feather meeting at SIGGRAPH. Dr. Coakley also exhibited 3D prints and 3D modeling workflows at the Web3D Consortium's booth in the SIGGRAPH 2016 exhibit hall.

Worldcomp '16
July 25–28, 2016
Las Vegas, Nevada

Worldcomp provides a unique platform for a diverse community to hold a coordinated research meeting in the different fields of computer science, computer engineering, and applied computing. Dr. Octavio Juarez-Espinosa presented a software prototype created to improve the user queries of the NIAID Tuberculosis Portals database.

Octavio Juarez-Espinosa presents his poster at WorldComp 2016.

2016 NIH Research Festival Exhibits and Posters
September 14–16, 2016
Bethesda, Maryland

OCICB actively promotes the use of bioinformatics tools and techniques, and highlights its collaborations and development projects by presenting scientific posters at the NIH Research Festival. OCICB also participates in the Special Exhibits for Intramural Researchers.

Five posters were presented at the festival. They highlighted antibiotic resistance in Belarus, a comparative study for classifying radiology images of TB patients, similarity-ordered heat maps, the design and fabrication of biomolecular models using extrusion 3D printing, and a framework to address challenges in the application of standards to metadata collected from microbiome studies.

Scientific Collaborations and Initiatives

MALARIA AND VACCINE RESPONSES (MENACTRA) (15-I-N197)

Primary Collaborator and Affiliation: Dr. Sara Healy (DIR/LMIV)

Location: Mali, Bancoumana and neighboring villages

Research Objective: A Longitudinal clinical study of adults who have or have not received antimalarial treatment prior to scheduled vaccination with Menactra. Primary objective of the study was to compare the proportion of PD1+ CD4 T cells among all T cells in vaccine immune responses in adults that have or have not received antimalarials prior to Menactra vaccination.

CASE CONTROL STUDY OF CEREBRAL MALARIA IN MALI (DMID # 14-0042)

Primary Collaborator and Affiliation: Dr. Mahamadou Thera (Mali ICER)

Location: Mali, Districts of Bandiagara, Bankass, or Bamako

Research Objective: Protocol to determine the association between risk of cerebral malaria and seroreactivity to the contemporaneous predominantly expressed infecting PfEMP1. Determine the predominantly expressed infecting PfEMP1 in cerebral malaria cases and the two control groups.

SMC-AZ TRIAL

Primary Collaborator and Affiliation: Dr. Daniel Chandramohan & Dr. Brian Greenwood (London School of Tropical Medicine and Hygiene), Dr. Alassane Dicko (Mali ICER), LMIV

Location: Dande district in Burkina Faso and in Bougouni district in Mali

Research Objective: A trial of seasonal malaria chemoprevention plus Azithromycin in African children with the primary objective to measure incidence of the combination of death or hospital admission for at least 24 hours, not due to trauma, or for elective surgery during the intervention period.

SPUTUM PHARMACOKINETICS OF TB DRUGS AND BACTERIAL DRUG RESISTANCE (SPUTUM PK) (15-I-0187)

Primary Collaborator and Affiliation: Dr. Clifton Barry (DIR/LCID/TRS)

Location: Zhengzhou, Henan Province (China) and NIH Clinical Center (US)

Research Objective: Protocol to investigate the sputum pharmacokinetics of TB drugs and Bacterial Drug Resistance with the primary objective to determine the concentration of TB drugs in plasma and sputum over time.

TACT IN PF MALARIA IN CAMBODIA (TRACII) (16-I-N023)

Primary Collaborator and Affiliation: Dr. Rick Fairhurst (DIR/LMVR)

Location: Pursat, Cambodia; Preah Vihear, Cambodia; Ratanakiri, Cambodia

Research Objective: A multi-center, open-label randomized trial to assess the efficacy, safety and tolerability of Triple Artemisinin-based Combination Therapies (TACTs) compared to Artemisinin-based Combination Therapies (ACTs) in uncomplicated falciparum malaria and to map the geographical spread of artemisinin and partner drug resistance.

ARTEMETHER-LUMEFANTRINE FOR PF MALARIA IN MALI (AL RESISTANCE) (16-I-N033)

Primary Collaborator and Affiliation: Dr. Rick Fairhurst (DIR/LMVR)

Location: Kenieroba, Mali

Research Objective: Artemether-lumefantrine resistance monitoring in children with uncomplicated Plasmodium falciparum malaria in Mali. The primary object of the study is to monitor

for potentially AL-resistant parasites in those infections that do not meet the definition of an adequate clinical and parasitological response (ACPR), and to estimate the treatment failure rate.

PFSPZ - DOSE ESCALATION (16-I-N004)

Primary Collaborator and Affiliation: Dr. Sara Healy (DIR/LMIV)

Location: Doneguebougou, Mali

Research Objective: Dose Escalating and Randomized, Placebo-Controlled, Double-Blind Study to Assess Safety, Immunogenicity, and Protective Efficacy of Radiation Attenuated Plasmodium falciparum NF54 Sporozoites (PfSPZ Vaccine) in Healthy African Adults in Mali.

MARKERS OF T CELL SUPPRESSION COHORT (15-I-N163)

Primary Collaborator and Affiliation: Dr. Michal Fried (DIR/LMIV)

Location: Ouelessebougou, Mali

Research Objective: Markers of T cell Suppression: Associations with Malaria Infection and Antimalarial Treatment in Malian Children. Protocol has the primary objective to investigate the effect of blood stage malaria on T cell suppression and vaccine responses. Describe markers of T cell suppression in children who have or have not received antimalarial treatment.

NEXGEN EBA (15-I-N070)

Primary Collaborator and Affiliation: Dr. Clifton Barry (DIR/LCID/TRS)

Location: Cape Town, South Africa

Research Objective: Radiologic and Immunologic Biomarkers to Enhance Early Bactericidal Activity Measurements of Sterilizing Drug Activity in Tuberculosis. Primary objective is to learn the effect of different anti-TB drugs on microbiological, radiographic and immunologic markers in people with TB.

TV005 (PR-15097)

Primary Collaborator and Affiliation: Dr. Rashidul Haque (the Centre for Vaccine Sciences, International Centre for Diarrhoeal Disease Research, Bangladesh) and Dr. Steve Whitehead (DIR/LID)

Location: Dhaka, Bangladesh

Research Objective: Phase II, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Immunogenicity of the Recombinant Live Attenuated Tetravalent Dengue Virus Vaccine Admixture TV005 (TetraVax-DV TV005) in Healthy Adults, Adolescents, and Children in Dhaka, Bangladesh.

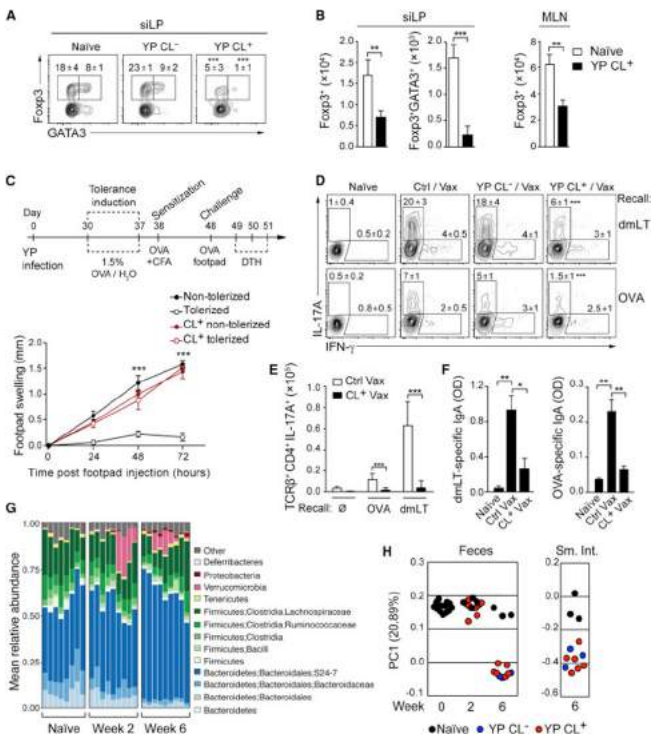
MICROBIOTA-DEPENDENT SEQUELAE OF ACUTE INFECTION COMPROMISE TISSUE-SPECIFIC IMMUNITY

Primary Collaborator and Affiliation: Dr. Yasmine Belkaid, NIAID, Laboratory of Parasitic Diseases

Research Objective: To identify associations between defined infectious agents and the initiation of chronic disease based on the hypothesis that infections are initiating factors for inflammatory disorders.

A single acute infection can have dramatic and long-term consequences for tissue-specific immunity. Following clearance of Yersinia pseudotuberculosis, sustained inflammation and associated lymphatic leakage in the mesenteric adipose tissue deviates migratory dendritic cells to the adipose compartment, thereby preventing their accumulation in the mesenteric lymph node. As a consequence, canonical mucosal immune functions, including tolerance and protective immunity, are persistently compromised. Post-resolution of infection, signals derived from the microbiota maintain inflammatory mesentery remodeling and consequently, transient ablation of the microbiota restores mucosal immunity. OCICB's Computational Molecular Biology Specialist completed the 16S data analysis.

Research Outcomes: Persistent disruption of communication between tissues and the immune system following clearance of an acute infection represents an inflection point beyond which tissue homeostasis and immunity is compromised for the long-term.



Infection-Induced Mesenteric Lymphadenopathy Is Associated with Disruption of Mucosal Immunity

(A and B) Naive or 4-week infected C57BL/6 (CD45.2) mice were transferred with CD45.1+Rag1−/− OT-II TCR transgenic T cells (CD45.1), fed ovalbumin (OVA) in the drinking water, and cells from the siLP and MLNs were isolated. (A) Representative flow cytometric contour plots of Foxp3 and GATA3 expression by OT-II T cells isolated from the siLP of naive and infected mice with or without lymphadenopathy (YP CL+ and YP CL−, respectively). Numbers represent the mean percentage within the gate (±SEM) of all samples in this experiment. (B) Numbers of OTII Foxp3+ and OT-II Foxp3+GATA3+ T cells in the siLP and MLN.

(C) Top: scheme for induction of oral tolerance. CFA, complete Freund's adjuvant. Bottom: footpad swelling was measured in the feet of sensitized mice after challenge with OVA.

(D–F) Naive, YP CL− and YP CL+ mice were immunized orally with OVA and double mutant heat labile toxin (dmLT). (D and E) Seven days after immunization, lymphocytes were isolated from the siLP and stimulated in vitro with DCs pulsed with dmLT or OVA to measure T cell responses. (D) Flow cytometric contour plots show representative populations of antigen-specific IFN-γ and IL-17A-producing CD4+ T cells from naive, vaccinated (Ctrl/Vax), or Y. pseudotuberculosis-infected vaccinated (YP CL+/−/Vax) mice. Numbers in plots represent the mean frequency of cells within the adjacent gate (±SEM) of all samples within this experiment. (E) Numbers of IL-17A-producing CD4+ T cells from (D). (F) Measurement of dmLT and OVA-specific fecal IgA by ELISA. OD, optical density.

(G) Bar graphs showing the fraction of the fecal microbiota represented by individual operational taxonomic units (OTUs) identified by 16S bacterial gene sequencing at the time points indicated.

*(H) Principal coordinate analysis of 16S gene sequencing data derived from fecal and small intestinal samples (weighted UniFrac). All experiments, except (G) and (H), are representative of three to five separate experiments containing five control mice and five to ten infected mice per group. All graphs show the mean ± SEM. *p < 0.05, **p < 0.005, ***p < 0.0005 (Student's t test).*

ANALYSIS OF MULTI-DOMAIN PROTEIN DYNAMICS

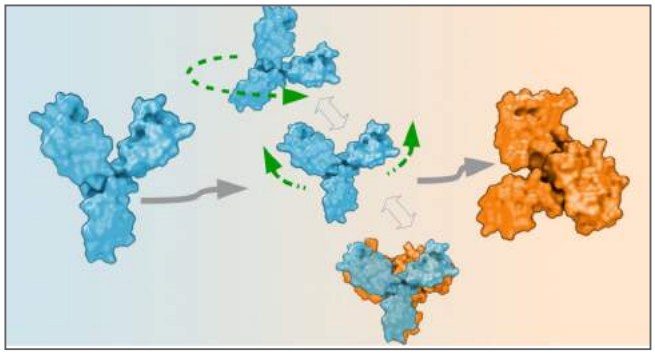
Primary Collaborator and Affiliation: Professor Carol B. Post, Medicinal Chemistry and Molecular Pharmacology, Purdue University

Research Objective: Proteins with a modular architecture of multiple domains connected by linkers often exhibit diversity in the relative positions of domains, while the domain tertiary structure remains unchanged. The biological function of these modular proteins, or the regulation of their activity, depends on the variation in domain orientation and separation. The objective was to understand the functional behavior of modular proteins by carefully characterizing the interdomain motion and correlated fluctuations of multidomain systems. Molecular dynamics (MD) simulations provide a powerful approach to study these motions in atomic detail. Nevertheless, the common procedure for analyzing fluctuations from MD simulations after rigid-body alignment fails for multidomain proteins greatly overestimates correlated positional fluctuations in the presence of relative domain motion.

Expressing the atomic motions of a multidomain protein as a combination of displacement within the domain reference frame and motion of the relative domains correctly separates the internal motions allowing a useful description of correlated fluctuations. The methodology of separating the domain fluctuations and local fluctuations by application to the tandem SH2 domains of human Syk protein kinase and by characterizing an effect of phosphorylation on the dynamics is illustrated. Correlated motions are assessed from a distance covariance rather than the more common vector-coordinate covariance. The approach makes it possible to calculate the proper correlations in fluctuations internal to a domain as well as between domains.

Research Outcomes: Effective analysis of the motion of modular, multidomain proteins includes the separation of domain motions from the total atomic displacements and a rigid-body rotation and translation of individual domains in addition to the

typical overall alignment of the whole molecule extracts relative domain dynamics from local fluctuations internal to each domain. The approach enables characterization of the conformational states of multidomain proteins following a description of domain motions and local fluctuation magnitudes to relate structure and function. Functional changes in dynamics of multidomain proteins due to factors such as effector binding or phosphorylation can be effectively assessed from MD simulations with this two alignment approach. In particular, accurate estimation of LF will allow identification of possible allosteric pathways as traced from correlated fluctuations of residues in multidomain proteins. The approach was illustrated by application to the Syk tSH2 to examine the change in dynamics upon phosphorylation of Tyr-131. This chemical modification regulates the association of Syk with membrane immunoreceptors. Differences in domain–domain motion and Cα covariance were detected between the unphosphorylated and phosphorylated forms of the Syk tSH2. Efforts are underway with more extensive sampling to understand how concerted motions internal to linker A influence, or not, the coupling of the two SH2 domains of Syk tyrosine kinase and the effects of Tyr131 phosphorylation.



Expressing the atomic motions of a multidomain protein as a combination of displacement within the domain reference frame and motion of the relative domains correctly separates the internal motions to allow a useful description of correlated fluctuations.

DBAASP V.2: AN ENHANCED DATABASE OF ANTIMICROBIAL ACTIVITY AND STRUCTURE OF PEPTIDES

Primary Collaborator and Affiliation: Malak Pirtkhalava, Ivane Beritashvili Center of Experimental Biomedicine, Tbiisi, Georgia

Research Objective: To increase interest in Antimicrobial peptides (AMPs)—anti-infectives that may represent a novel and untapped class of biotherapeutics—encouraging the faster discovery of new peptides (natural and synthetic).

Research Outcomes: A new version of the Database of Antimicrobial Activity and Structure of Peptides (DBAASPv.2, which is freely accessible at http://dbaasp.org) was developed as part of this collaboration. This iteration of the database reports chemical structures and empirically-determined activities (MICs, IC50, etc.) against more than 4200 specific target microbes for more than 2000 ribosomal, 80 non-ribosomal and 5700 synthetic peptides. Of these, the vast majority are monomeric, but nearly 200 of these peptides are found as homo- or heterodimers. More than 6100 of the peptides are linear, but about 515 are cyclic and more than 1300 have other intra-chain covalent bonds. More than half of the entries in the database were added after the resource was initially described, which reflects the recent sharp uptick of interest in AMPs. New features of DBAASPv.2 include: (i) user-friendly utilities and reporting functions, (ii) a 'Ranking Search' function to query the database by target species and return a ranked list of peptides with activity against that target and (iii) structural descriptions of the peptides derived from empirical data or calculated by MD simulations. The three-dimensional structural data are critical components for understanding structure–activity relationships and for design of new antimicrobial drugs. More than 300 high-throughput MD simulations were created specifically for inclusion in DBAASP. The resulting structures are described in the database by novel trajectory analysis plots and movies. Another 200+ DBAASP entries have links to the Protein DataBank. All of the structures are easily visualized directly in the web browser.

UTR INTRONS, ANTISENSE RNA AND DIFFERENTIALLY SPLICED TRANSCRIPTS BETWEEN PLASMODIUM YOELII SUBSPECIES

Primary Collaborator and Affiliation: Xin-zhuan Su, Ph.D., NIAID, Laboratory of Malaria and Vector Research

Research Objective: The rodent malaria parasite Plasmodium yoelii is an important animal model for studying host-parasite interaction and molecular basis of malaria pathogenesis. Although a draft genome of P. yoelii YM is available and RNA sequencing (RNA-seq) data for several rodent malaria species (RMP) were reported recently, variations in coding regions and structure of mRNA transcript are likely present between different parasite strains or subspecies. Sequencing cDNA libraries from additional parasite strains subspecies will help improve the gene models and genome annotation.

The objective was to initiate and perform discovery driven research of UTR introns and differentially spliced introns between P. yoelii subspecies. This raises interesting questions on the potential role of these introns in regulating gene expression and evolution of malaria parasites, and avenues for molecular targeting.

OCICB's Genome Analysis Specialist did the alignments, gave an overview of splicing types, validated statistics of splice site distributions, used IGV to filter bam files by intron positions based on parsing annotation files and created automated IGV shots, helped write and interpret the meaning and functional ramifications of the splicing on the disease phenotype, and helped edit the manuscript based on the rebutting the reviewer's comments to help get the paper published.

Research Outcomes: The detection of a large number of UTR introns should raise attention to the potential regulatory roles of these largely ignored introns and the molecular mechanisms of gene expression regulation by UTR introns in general. Analysis of genetic variations should consider the large numbers of alternatively spliced transcripts in a parasite and the differentially-spliced forms between parasite strains or subspecies. This study proposes novel avenues for molecular targeting of regulatory pathways.

NANOPORE SEQUENCING AS A RAPIDLY DEPLOYABLE EBOLA OUTBREAK TOOL

Primary Collaborator and Affiliation: Dr. Thomas Hoenen, Laboratory of Virology

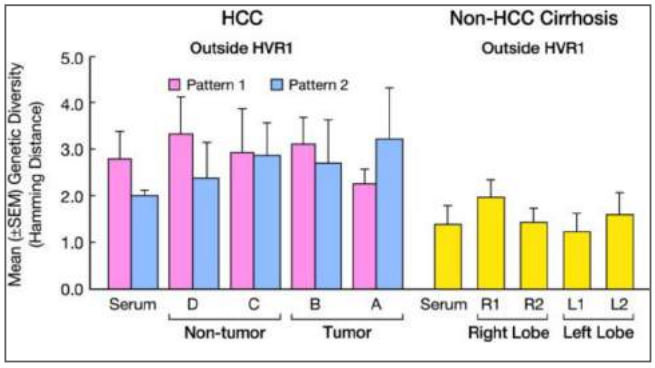
Research Objective: Rapid sequencing of RNA/DNA from pathogen samples obtained during disease outbreaks provides critical scientific and public health information. The objective was to address the existing rapid sequencing challenges with exporting samples to laboratories and establishing conventional sequencers in remote outbreak regions.

Research Outcomes: A novel, pocket-sized nanopore sequencer at a field diagnostic laboratory in Liberia was successfully used during the recent Ebola virus outbreak.

DIMINISHED VIRAL REPLICATION AND COMPARTMENTALIZATION OF HEPATITIS C VIRUS IN HEPATOCELLULAR CARCINOMA TISSUE

Research Objective: To conduct a comprehensive study of serum and multiple liver specimens from patients with hepatocellular carcinoma (HCC) who underwent liver transplantation. A sharp and significant decrease in hepatitis C virus (HCV RNA) was found in the tumor compared with surrounding nontumorous tissues, but no differences were found in multiple areas of control non-HCC cirrhotic livers. HCV genetic diversity was significantly higher in livers containing HCC compared with control non-HCC cirrhotic livers. The genetic diversity and compartmentalization analysis calculations in this work were performed by the OCICB phylogenetics specialist.

Research Outcome: Tracking of individual variants demonstrated changes in the viral population between tumorous and nontumorous areas, the extent of which correlated with the decline in HCV RNA, suggesting HCV compartmentalization within the tumor. In contrast, compartmentalization was not observed between nontumorous areas and serum, or in controls between different areas of the cirrhotic liver or between liver and serum.



Genetic diversity of the HCV quasispecies within the E1/E2 region outside the HVR1 in serum and multiple liver areas of patients with HCC and controls with non-HCC cirrhosis. Genetic diversity (distance among variants) within the viral quasispecies, as measured by mean Hamming distance, in serum and liver of HCC patients and controls. HCC patients were divided according to the drop in intrahepatic HCV RNA as pattern 1 (<2 logs; patients 1–5) or pattern 2 (>2 logs; patients 6–8). Patient numbers are the same as in Fig. 1 E and F. Data represent the mean ± SEM of the results obtained from all patients within each group. The difference was significant when the livers of patients with non-HCC cirrhosis were compared both with the tumorous tissue (P = 0.002) and with the surrounding nontumorous tissue (P = 0.0035) of HCC patients.

INTERACTION OF TAPBPR, A TAPASIN HOMOLOG, WITH MHC-I MOLECULES PROMOTES PEPTIDE EDITING

Primary Collaborator and Affiliation: David Margulies, M.D., Ph.D.

Research Objective: To better define the interaction of the tapisan-related protein (TAPBPR) with the major histocompatibility complex (MHC) class I molecules which present high-affinity peptides at the cell surface to T cells. OCICB's computational structural biology specialist constructed a homology model of TAPBPR based on the tapisan protein, dock it to MHC-1 and perform molecular dynamics to better refine the interaction of the complex.

Research Outcomes: Amino acids on MHC-1 and TAPBPR that are likely to interact were discovered. These residues can be selected for further scrutiny at the bench.

MAPPING AND MODELING OF A STRAIN-SPECIFIC EPITOPE IN THE NORWALK VIRUS CAPSID INNER SHELL

Primary Collaborator and Affiliation: Kim Green, Ph.D., NIAID, LID

Research Objective: To determine the epitope on the Norwalk virus inner shell protein defined by the antibody MAb NV10 and its specific interaction with the antibody. The homology modeling of the S and P domain of the Norwalk virus inner shell protein was performed as well as the Mab NV10 antibody followed by using Rosetta to perform protein-protein docking experiments.

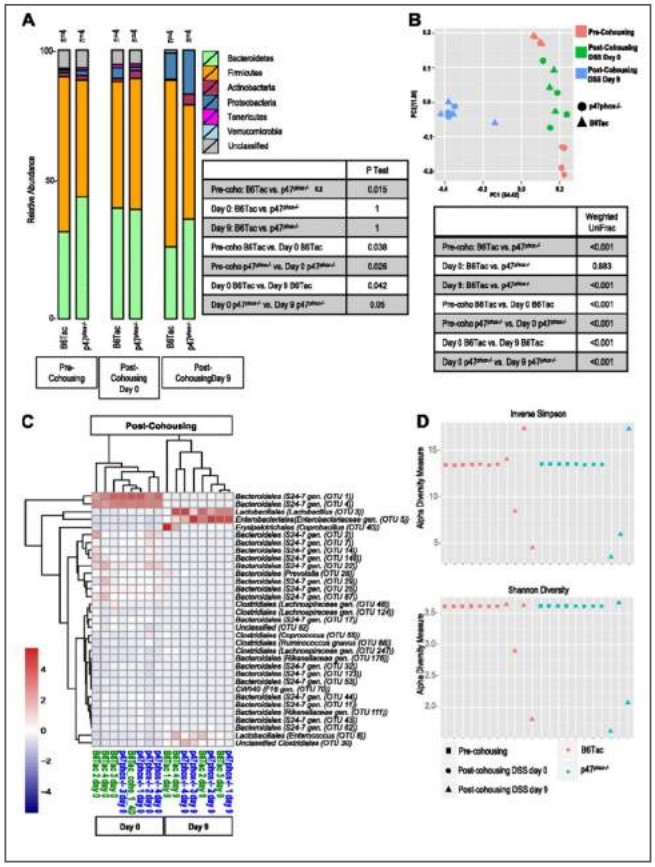
Research Outcomes: Docking experiments provided some important directions for future research and narrowed down the conformation of a linear peptide that defines the epitope.

COLITIS SUSCEPTIBILITY IN P47PHOX−/− MICE IS MEDIATED BY THE MICROBIOME

Primary Collaborator and Affiliation: Dr. Steven Holland, NIAID, Laboratory of Clinical Infectious Diseases

Research Objective: Chronic granulomatous disease (CGD) is caused by defects in nicotinamide adenine dinucleotide phosphate oxidase 2 (NOX2) complex subunits (gp91phox (a.k.a. Nox2), p47phox, p67phox, p22phox, p40phox) leading to reduced phagocyte-derived reactive oxygen species production. Recognizing that almost half of patients with CGD develop inflammatory bowel disease, the objective was to explore the involvement of the intestinal microbiome in relation to this predisposing immunodeficiency in mice. Although CGD mice do not spontaneously develop colitis, p47phox−/− mice have increased susceptibility to dextran sodium sulfate colitis in association with a distinct colonic transcript and microbiome signature. Neither restoring NOX2 reactive oxygen species production nor normalizing the microbiome using cohoused adult p47phox−/− with B6Tac (wild type) mice reversed this phenotype. However, breeding p47phox+/− mice and standardizing the microflora between littermate p47phox−/− and B6Tac mice from birth significantly reduced dextran sodium sulfate colitis susceptibility in p47phox−/−mice. Similarly decreased colitis susceptibility was found in littermate p47phox−/− and B6Tac mice treated with Citrobacter rodentium. OCICB's Computational Molecular Biology Specialist performed the microbiome data processing, analysis, and visualization.

Research Outcomes: Findings suggest that the microbiome signature established at birth may play a bigger role than phagocyte-derived reactive oxygen species in mediating colitis susceptibility in CGD mice. These data further support bacteria-related disease in CGD colitis.



Cohousing homogenizes the intestinal microbiota between p47phox−/− and B6Tac mice. (A) Relative abundances of 7 major phyla taxonomies in p47phox−/− and B6Tac mice pre-cohousing and post-cohousing (DSS days 0 and 9) are shown. p values from P tests were used to indicate whether the samples from B6Tac and p47phox−/− mice pre-cohousing, on DSS day 0, and DSS day 9, have the same community structure. (B) PCoA and p values from weighted UniFrac analyses of p47phox−/− and B6Tac mice pre-cohousing and post-cohousing (DSS days 0 and 9) are shown. (C) Heat map depicting average relative abundance by LEfSe of bacterial genera in fecal samples from p47phox−/− and B6Tac mice post-cohousing (DSS day 0 and DSS day 9). (D) Alpha diversity was measured in p47phox−/− and B6Tac mice pre- and post-cohousing (DSS days 0 and 9) by inverse Simpson and Shannon diversity. Gen. classified as distinct but unnamed genus in Greengenes reference database, sp. designates a distinct species in Greengenes reference database

PREDICTION OF HOMOPROTEIN AND HETERO-PROTEIN COMPLEXES BY PROTEIN DOCKING AND TEMPLATE-BASED MODELING: A CASP-CAPRI EXPERIMENT

Primary Collaborator and Affiliation: Prof. Daisuke Kihara, Computer Science, Purdue University, West Lafayette, IN

Research Objective: To present the results for CAPRI Round 30, the first joint CASP-CAPRI collaboration experiment, between experts from the protein structure prediction and protein–protein docking communities. The targets included mostly homodimers, a few homotetramers, and two heterodimers, and comprised protein chains that could readily be modeled using templates from the Protein Data Bank (PDB). In total, over 9500 models were assessed against the 3D structures of the corresponding target complexes. Results show that the prediction of homodimer assemblies by homology modeling techniques and docking calculations is quite successful for targets featuring large enough subunit interfaces to represent stable associations. Targets with ambiguous or inaccurate oligomeric state assignments, often featuring crystal contact-sized interfaces, represented a confounding factor. For those, a much poorer prediction performance was achieved, while nonetheless often providing helpful clues on the correct oligomeric state of the protein. The prediction performance was very poor for genuine tetrameric targets, where the inaccuracy of the homology-built subunit models and the smaller pair-wise interfaces severely limited the ability to derive the correct assembly mode. Analysis revealed that docking procedures tend to perform better than standard homology modeling techniques and that highly accurate models of the protein components are not always required to identify their association modes with acceptable accuracy. OCICB's computational biology specialist participated in CASP-CAPRI 2014 experiment along with Prof. Kihara's group.

Research Outcomes: The 25 targets of this round represented a subset of the targets submitted for the CASP11 prediction season of the summer of 2014. In line with the main focus of CASP, the majority of these targets were single protein chains, forming mostly homodimers, and a few homotetramers. Only two of the targets were heterodimers, similar to the staple targets in previous CAPRI rounds. Unlike in most previous CAPRI rounds both subunit structures and their association modes had to be modeled for all the targets. Since the docking or assembly modeling performance may crucially depend on the accuracy of the models of individual subunits, the targets chosen for this experiment were proteins deemed to be readily modeled using templates from the PDB. Interestingly, templates were used mainly to model the structures of individual subunits, to limit the sampling space of docking solution or to filter such these solutions. Only a few groups carried out template-based docking for the majority of the targets, and two of those ranked amongst the top performers, indicating the potential in this relatively recent modeling strategy.

RODENT ADAPTED FILOVIRUSES AND THE MOLECULAR BASIS OF PATHOGENESIS

Primary Collaborator and Affiliation: Hideki Ebihara, Ph.D.

Research Objective: To determine how mutations in the Ebola VP24 and NP proteins affect binding to one another and how these two proteins might interact. OCICB's computational structural biology specialist generated homology models of VP24 and NP and indicated how these two proteins interact with one another.

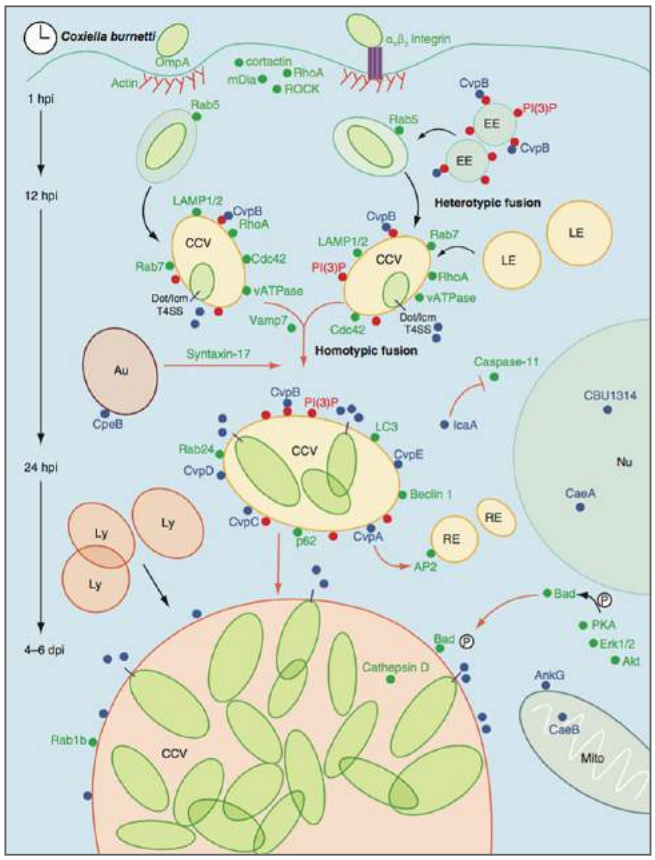
Research Outcomes: VP24 and NP appear to be major virulence factors for Ebola viruses in rodents. Characterization of mutations and understanding the molecular mechanisms that lead to the acquisition of virulence, can increase understanding of the pathogenic processes that underlie filovirus disease in humans.

RIGHT ON Q: GENETICS BEGIN TO UNRAVEL *COXIELLA BURNETII* HOST CELL INTERACTIONS

Primary Collaborator and Affiliation: Dr. Robert Heinzen, NIAID, Laboratory of Intracellular Parasites

Research Objective: To determine how newly developed genetic tools can be used to further understand the biology of *Coxiella burnetii*. OCICB's Computational Biology Specialist provided a comparative genomics approach to the genetic differences in the known exported proteins in several clinical isolates of *Coxiella burnetii*.

Research Outcomes: The comparative genomics results of the exported proteins showed that there is a higher rate of disruption of the exported proteins in those strains that are more virulent to the host. These indicate that potential roles of these exported proteins are to inhibit or reduce the host immune response.



Steps in Coxiella infection and Coxiella-containing vacuole formation and host cell processes potentially modulated by Coxiella effector proteins. Coxiella internalization is facilitated by the rearrangement of the host actin cytoskeleton, mediated by the actin-binding proteins cortactin and mDia and requiring the activation of the small GTP-ases RhoA and ROCK. The Coxiella invasin OmpA mediates bacterial internalization by nonprofessional phagocytes, whereas internalization by macrophages requires interaction with cell surface αVβ3 integrins.

IMMUNOPHENOTYPIC AND ULTRASTRUCTURAL ANALYSIS OF MAST CELLS IN HERMANSKY-PUDLAK SYNDROME TYPE-1: A POSSIBLE CONNECTION TO PULMONARY FIBROSIS

Primary Collaborator and Affiliation: Dr. Dean Darrel Metcalfe, M.D., NIAID, Laboratory of Allergic Diseases

Research Objective: Exploratory bioinformatics analyses of microarray data indicated a possible connection to pulmonary fibrosis based on functional analyses. Initially, the objectives were to develop a research hypothesis and to generate research eventually revealing that mast cells containing mutations in HPS-1 gene are directly responsible for laying down ECM. The Research objective evolved into finding evidence of a direct role of mast cells in the fibrogenesis process, based on observation of cell behavior in culture.

OCICB's genome analysis specialist executed the bioinformatics for the initial hypothesis to generate research. The generated hypothesis is that mast cells containing mutations in HPS-1 gene are directly responsible for laying down ECM independently, where interactions with fibroblasts served a signaling function, similar to cancer cells that manipulate the environment. Follow up experiments were designed based on the bioinformatics functional analyses and were a spin off from network analyses.

Research Outcomes: Consistent with the bioinformatics findings, cultured HPS-1 HuMCs appeared activated as evidenced by surface activation marker expression; a decrease in mediator content and impaired releasibility. The near-normalization of constitutive cytokine and matrix release following rescue by HPS1 transduction of HPM cells suggested that HPS-1 HuMCs may contribute directly to pulmonary fibrosis alongside fibroblasts and constituted a target for therapeutic intervention.

Software Development Projects and Initiatives

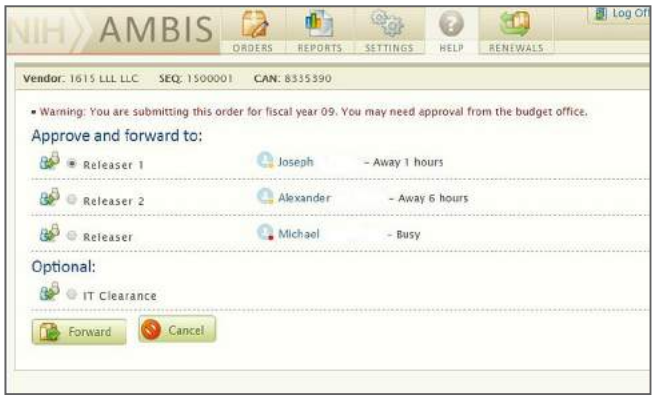
Custom development is organized into program and enterprise-wide projects. Targeted program areas focus on Administrative, Contracts Management, Extramural Research, Financial Systems and Grants Management, Human Capital Systems, Receipt and Review, Research Planning, Scientific Support, and Scientific Reporting. Enterprise-wide programs include Business Analytics, Collaborative Technologies, and the Electronic Document Records Management System (EDRMS).

ADMINISTRATIVE SYSTEMS

The Administrative Program provides systems development support ranging from procurement management systems, property management systems, and scientific administrative support systems.

Acquisition Management and Budget Information System

The Acquisitions Management and Operations Branch (AMOB) oversees the official purchasing of all NIAID-related items. The Acquisition Management and Budget Information System (AMBIS) serves as the primary requisitioning and purchase order system for all NIAID purchases. This year AMBIS was integrated with Skype to display the current status of every user on an order approval chain. Users can now initiate conversations directly from AMBIS.



AMBIS forward screen showing user Skype status of releasers

NIAID Property Management Portal

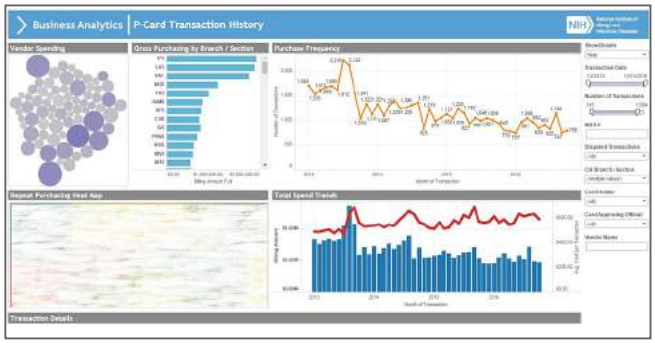
The NIAID Property Management Portal supplements Sunflower, the NIH Enterprise Property System. The portal improves data integrity and accountability by providing people with a way to monitor government property and equipment assigned to them, and identify and correct invalid data contained within Sunflower. Workflows allow people to reassign equipment or kick off a workflow that decommissions outdated or broken property. The portal improves communications and helps establish accountability for governmental resources. Enhancements include a new delegation workflow, a streamlined property pass module, and improved Mobile features.

NPMP 3.0 Home Screen showing all property assigned to user and status of property

P-CARD Audit

This tool helps NIAID procurement auditors analyze purchase card transactions with the goal of identifying potential fraud waste and abuse. Data is analyzed and visualized in the P-Card Risk Dashboard.

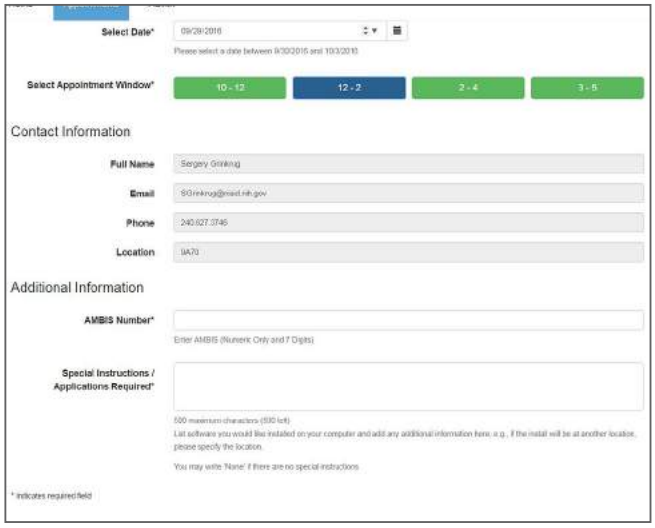
Custom development is organized into program and enterprise-wide projects. Targeted program areas focus on Administrative, Contracts Management, Extramural Research, Financial Systems and Grants Management, Human Capital Systems, Receipt and Review, Research Planning, Scientific Support, and Scientific Reporting. Enterprise-wide programs include Business Analytics, Collaborative Technologies, and the EDRMS.



P-Card Audit Dashboard showing purchase card transaction history

Workstation Procurement Team Scheduler

The Workstation Procurement Team Scheduler streamlines the process of delivering new PCs to the NIAID community by providing the ability to schedule installation appointments based on the availability and location of technicians.



New appointment scheduling screen for deliverying PCs to users

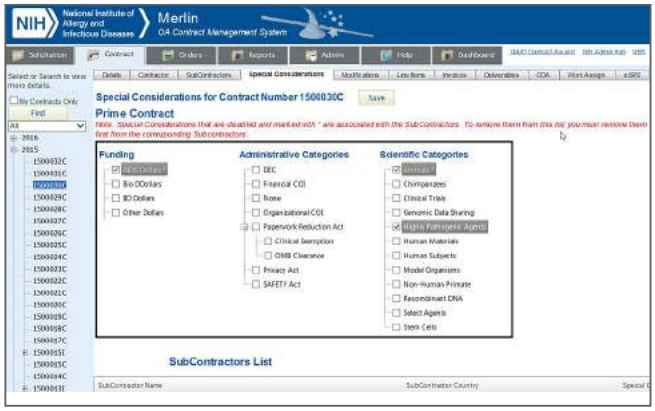
CONTRACTS MANAGEMENT

The Contract Management program provides system development and operation support for NIAID's contract management requirements. The systems enable the automation of process for managing contracts, tracking funds and providing reports to streamline the entire life cycle of the contracts' acquisition and funding process. Association and analysis of contracts information with major financial systems is another critical responsibility of the program. The following system had major enhancements this year.

MERLIN

Merlin allows the Office of Acquisitions (OA) to manage the Division of Extramural Activities (DEA) Contracts Acquisition Life Cycle. It provides real-time budget data to Intramural and Extramural divisions by analyzing records contained in disparate systems against contracts data. Improvements this year include:

- Provided integration solution to Research Initiative Management System (RIMS) OMNIBus Solicitation and allowed for the mapping of the award details back to the individual Business Associate Agreement.
- New functionality to automatically add IDIQ Orders using nVision Data together with email reminder.
- Displayed electronic Subcontracting Reporting System (eSRS) historical actions of subcontractor submissions for each contract by enabling upload of eSRS data on spreadsheet to Merlin by OA admin.



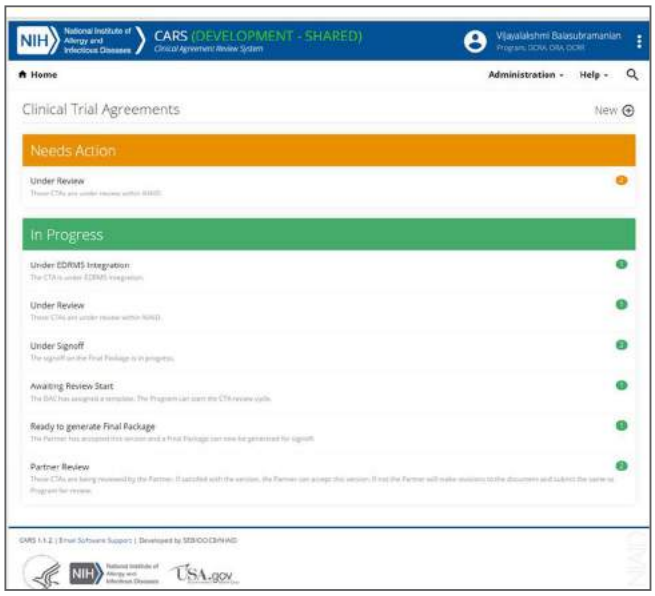
Merlin - Special considerations selection screen

EXTRAMURAL RESEARCH

The Extramural Research Program provides custom applications developed for the Division of Microbiology and Infectious Diseases (DMID). Most of these systems automate complex workflows to help DMID manage important documents and associated procurements as they make their way through the review, editing and approval process. The systems integrate with the NIAID EDRMS for workflow and document storage and archiving. The systems also include external partners in the workflows in order to provide a complete solution. The following system had major enhancements this year.

Clinical Agreement Review System (CARS)

The CARS application version 1.1 was deployed in FY2016. This web application allows the Clinical division in DMID to create, review, finalize and maintain their clinical trial agreements electronically. This increases productivity and allows real-time collaboration within a review team, making the process more effective.



CARS system showing status of clinical trial agreements

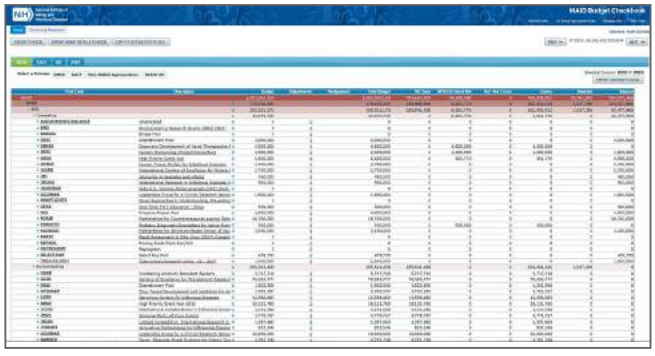
FINANCIAL SYSTEMS AND GRANTS MANAGEMENT

Managing and tracking the NIAID budget across the years, from budget formulation to execution and reconciliation, is essential in order to report on the work of the Institute to various constituencies, including Congress. This is an intricate set of activities involving all of the divisions, and numerous complex financial workflow processes. Multiple financial systems are used by the budget office to track the flow of money across all missions, divisions and mechanisms in order to manage the NIAID budget from initial planning to closing the books.

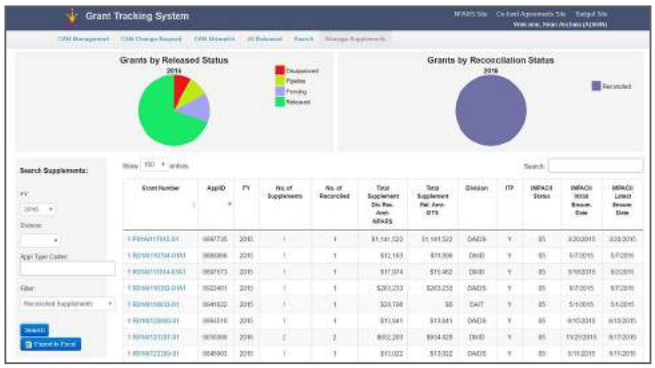
Checkbook, Grant Tracking System, and the NIAID Planning and Reporting System

These tools provide complimentary and yet distinct functionality for the Institute. The NIAID budget office uses Checkbook to oversee the current budget for all initiatives and projects across all missions, divisions and mechanisms. The Grant Tracking System (GTS) is used by the NIAID budget office to manage, monitor and keep track of grants that are released for award funding, and managing non-competing applications. NIAID Divisions, the DEA, the Budget Office, and the Grant management office use the NIAID Planning and Reporting System (NPARS) to administer competing grants, supplements and associated release amounts. Together, the systems offer a three-way comparison and reconciliation between data in the NIH Business System (NBS), the Information for Management, Planning, Analysis, and Coordination System, version two (IMPACII), and NPARS. Enhancements this year include:

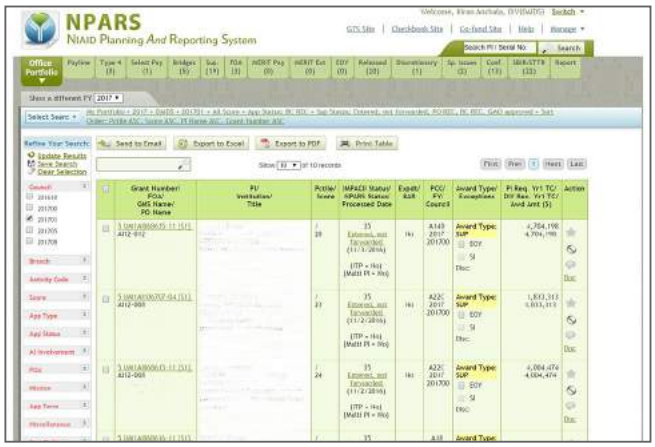
- Opened Checkbook for FY16 for budget operation by integrating initiative planning data to the execution year and establishing budget pools for commitment base.
- Integrated GTS actuals with Checkbook to provide real-time transactions and balances; provided data reconciliation grant views to compare with IMPACII NIAID and NBS datasets.
- Played a major role in improving business process by integrating financial systems from budget formulation to execution and reconciliation of grants which ensures transparency and accountability.
- Significant collaboration and involvement with Budget Office to establish the FY16 operation budget, track expenditures and data reconciliation effort to close budget books.
- Provided Solution to have complete fund control capability (soft close) for the NIAID budget. This solution simulates effective coordination between divisions and Budget office to manage the NIAID budget portfolio by providing a complete picture of available funds and expenditures at any given point of time.



Checkbook screen showing data for managing and tracking execution budget and expenditures across all missions and divisions



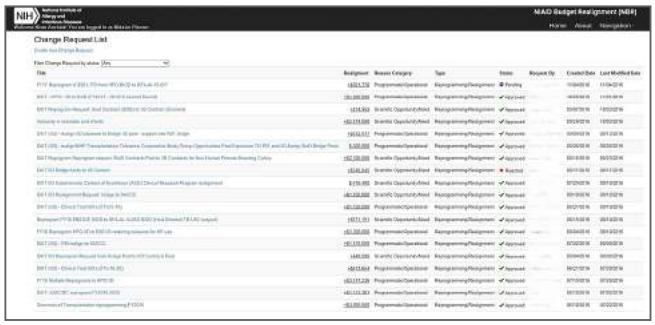
Supplement reconciliation interface used to manage and reconcile supplements



Office portfolio tab listing all grants by Council by Division

NIAID Budget Realignment System

NIAID Budget Realignment system has become the system of record this year to prepare and manage NIAID fund realignments across multiple divisions providing transparency of budget data flow in the organization by reflecting ongoing increases and decreases to the budget allowance. This system eliminates the cumbersome paper request and approval process and centralizes the data.

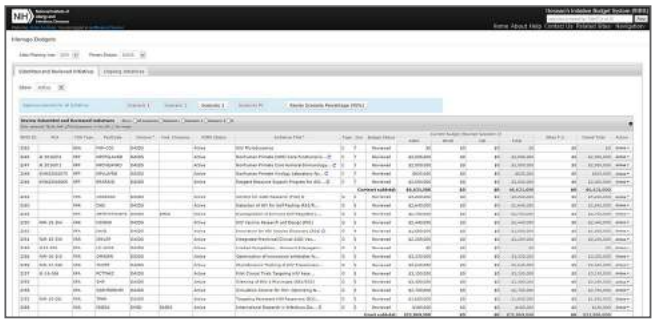


Reaglignment requests screen that lists all budget realignment requests by status

Research Initiative Budget System (RIBS)

RIBS allows the Mission Planning, Divisions and Budget Office to track and review the initiative planning budget across NIAID. It enables enhanced control over the research initiative budget planning and management processes by establishing workflows, tracking expiring initiatives, modeling and finalizing various budget scenarios, capturing detailed budget change request information and tracking historical changes to all budget data. Enhancements this year include:

- Developed a solution to plan budgets based funding source and budget pools with the ability to view and track funds given to and received from the other divisions
- Initiated creation/association of budget pools for each funding source, integrated with Checkbook for real-time initiative budget planning



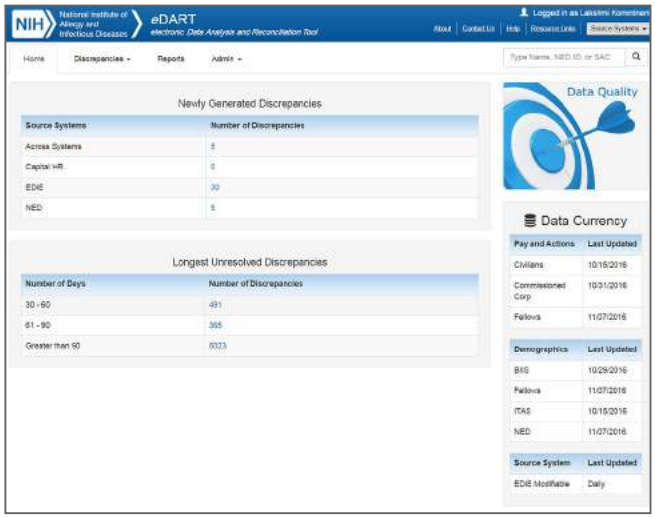
Management budgets screen that lists all submitted and reviewed initiatives and budgets by division and FY across all missions

HUMAN CAPITAL SYSTEMS

The Human Capital Systems Program supports NIAID business operations with systems aligned to the business needs of the workforce. Systems with major enhancements this year include:

Electronic Data Analysis and Reconciliation Tool

The electronic Data Analysis and Reconciliation Tool (eDART) provides NIAID administrative staff with the ability to identify, track, and manage discrepancies from NIH and NIAID human capital systems in an effort to support NIAID's data quality initiative. Managers use it to monitor, report on, and view discrepancy metrics for their program area. The tool's primary focus is to identify key discrepancies within various business systems such as Capital HR, COPPS, EDiE, FPS, and NED, as they occur. Then staff can resolve issues within the source system in a timely manner to ensure data quality.



eDART home page showing newly generated discrepancies and longest unresolved discrepancies, as well as currency of data

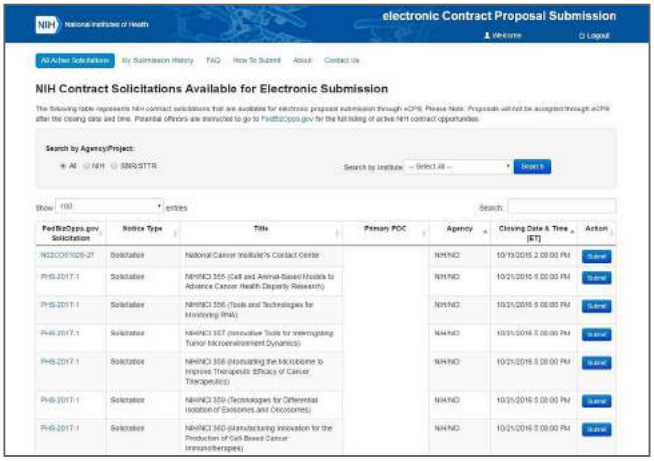
RECEIPT AND REVIEW PROGRAM

These applications support the electronic receipt and review of contract proposals, decreasing the risk of compromising sensitive proposal information. They increase the productivity of Scientific Review Officer's (SRO's), Contracting Officer Representative's (COR's), and acquisition staff, and reduce costs associated with effort level and document distribution. This program develops applications that are used internally at NIAID and externally across the NIH, the Centers for Disease Control (CDC), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Electronic Contract Proposal Submission

The electronic Contract Proposal Submission (eCPS) system is a component of NIAID's integrated, secure system for the electronic submission, capture, tracking and review of NIAID Research and Development contract proposals. ECPS consists of two systems; an external system which is used by NIAID vendors for self-registering and submitting contract proposals, and an internal system used to review and manage the proposals received. This year eCPS was selected as an NIH wide enterprise application. The following objectives were achieved this year:

- NIAID now receives and reviews all research proposals electronically.
- The NIH/CDC SBIR program allows small business to submit electronic proposals across multiple institute centers to encourage scientific and technical innovation.
- Rolled out consolidated single eCPS site NIH wide that provides login using multiple options (i.e. NIHEXT, eRA Common's, Federated/Open ID authentication, etc.) to reduce the requirement for multiple user accounts.
- Provided detailed audit trails and activity logs to provide visibility into the user activity to help with user support and troubleshooting.
- Provided support to all Institutes that use eCPS.



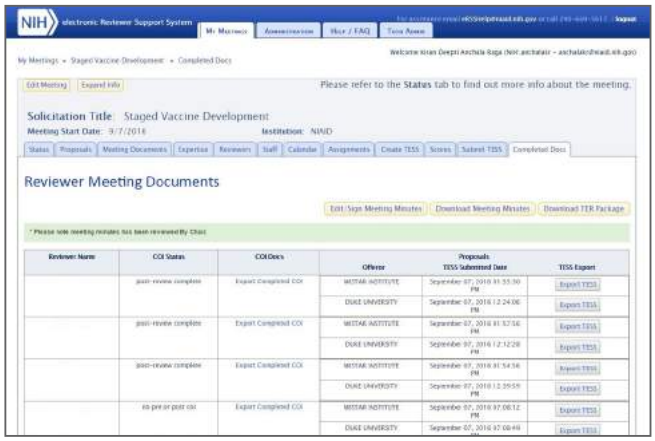
List of NIH contract soliciations available for electronic submission

Electronic Reviewer Support System

The electronic Reviewer Support System (eRSS) is NIAID's secure web-based application that supports online reviewer collaborations by making meeting-specific information and resources

such as documents and notes available to potential reviewers within the NIH, nationally and internationally. This year eRSS was selected as an NIH-wide enterprise application. Additional achievement this year include:

- Developed an automated Technical Evaluation Report (TER) compilation tool; it creates a complete TER package that includes: pre/post conflict of interest certifications forms for reviewers and staff with electronic signatures, completed technical evaluation forms from reviewers, concatenated reviewer critiques, meeting minutes, technical proposals and special issue codes.
- Provided support to the Institutes that use eRSS: NIAID, NCI, NCATS, NCAMS, NINDS, NLM and NIAAA.



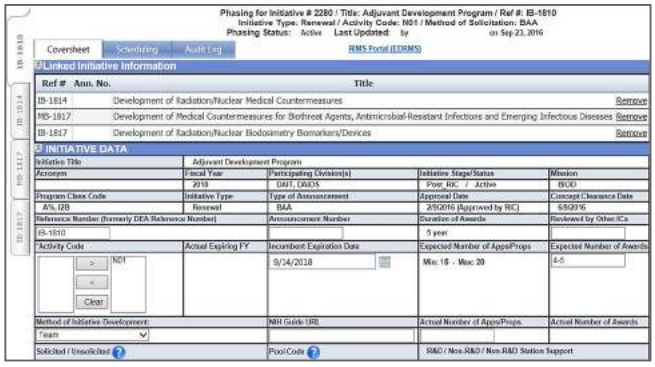
List of all reviewer meeting documents for a specific solicitation

RESEARCH PLANNING PROGRAM

One of OCICB's goals is to ensure that decision-making regarding NIAID's research opportunities is based on accurate, timely, appropriate, and usable information and analyses by way of carefully developed software solutions. Research management systems provide support and workflows for developing, planning, approving and reviewing the research and development process. These systems deliver meaningful views of research initiatives so that recommendations and funding decisions can be made. They form the basis of other electronic post-award systems pertaining to grants and contracts management.

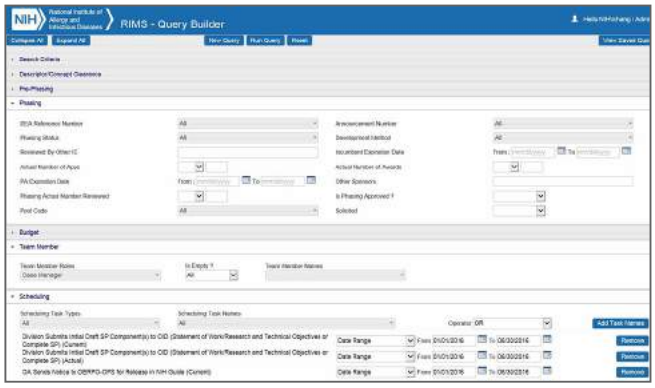
Research Initiative Management System

RIMS captures all relevant data required to create, record, and monitor initiatives from concept to publication to award. Integrated components, also known as modules, make up this suite of tools built to support the Institute's scientific, administrative, and budgetary processes related to initiative planning, development and execution.



Coversheet screen allowing RIMS users to link OMNIBus initiatives together

RIMS is secure and permission-based. All users must be registered with a system-specific role. Privileges within the various modules are based on these user roles. Privileges are also highly dependent on the development stage of the initiative. RIMS is an integrated solution accessible from the NIAID Intranet.

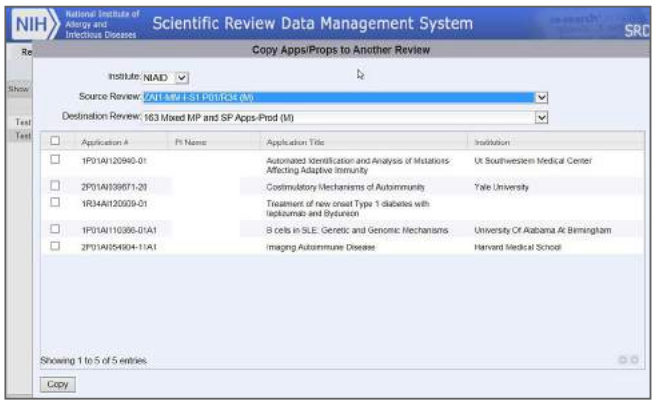


Query builder screen showing filtering by phasing, team member, and scheduling

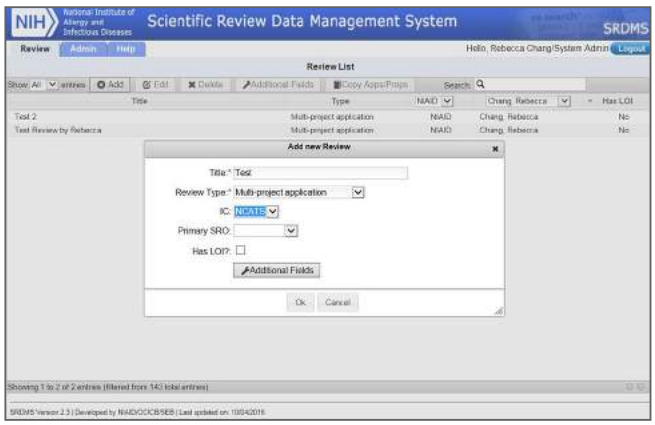
Scientific Review Data Management System

The SRP peer review process is an integral part of the NIAID funding process. The Scientific Review Data Management System (SRDMS) is an administrative review one-stop-shop that complements IMPAC II. It is used to collect application and proposal-specific data, automate the administrative review and maximize efficiency by facilitating complex data analysis and reporting related to the major review phases. Since its initial release in March 2014, approximately 100 reviews have been created and processed within the system, demonstrating consistent and stable usage. The multi-project review type was

expanded to incorporate multi-component (large/complex) application data and reporting.



SRDMS allows users the ability to copy muplitple Apps/Props to another review



Users are able to create review for other ICs

SCIENTIFIC REPORTING

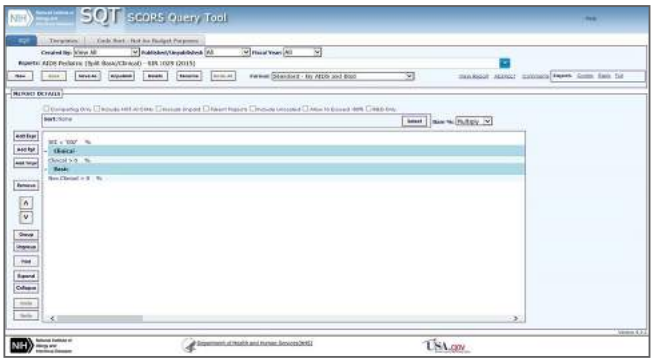
NIAID maintains a suite of applications that support scientific coding report funding by areas of scientific research. Upgrades this year include:

- Enhanced the Multicenter AIDS Cohort Study (MACS) Database
- Updated and enhanced the Budget and Science Report Menus
- Improved user experience by implementing enhancements to the Scientific Coding and Referral System (SCORS)
- Enhanced the SCORS Extended Systems (SES)
- Updated the Scientific Information Request System (SIR)

SCORS Query Tool

The SCORS Query Tool (SQT) helps users develop complex queries against the MACS scientific coding database and to create reports based on the criteria. Major enhancements include:

- Provided the ability for users to build reports with three-level sub-reports
- Added ability to add user-defined templates to a query, as a primary sort
- Added name-only option for 2nd level sub-reports
- Redesigned the query window functionality, to allow users to insert sub-reports much more easily
- 72% of the FY2015 and 2016 PTD reports in our Science & Budget Reports menu were created in SQT (up from 61% in 2014)



SQT SCORS query tool report details

SCIENTIFIC SUPPORT SYSTEMS

METAGENOTE

Microbiome samples should be annotated with consistent use of variables and vocabulary terms as described in the Genomics Standards Consortium standards to facilitate reproducibility and cross-study comparisons. However, many researchers find the manual annotation process cumbersome. In collaboration with the NIAID Microbiome Program, OCICB is designing METEGENOTE, a powerful yet simple web annotation system to apply standardized metadata and provide uniform data submissions to the National Center for Biotechnology Information. The system will minimize the learning curve needed to properly apply ontology and standards, while maximizing the possibility of extracting knowledge from data analysis derived from integrating multiple studies.

DBAASP v.2

http://dbaasp.org

DBAASP provides informational and analytical resources to facilitate the development of antimicrobial compounds with high therapeutic index. In version 2.0, an additional 350 molecular dynamics calculations were added, with another 20 in the pipeline. Heat maps from molecular dynamics simulations were analyzed to try to identify possible correlation with peptide activity.

Deployment of a LIMS platform solution for VRC Next Generation Sequencing Lab

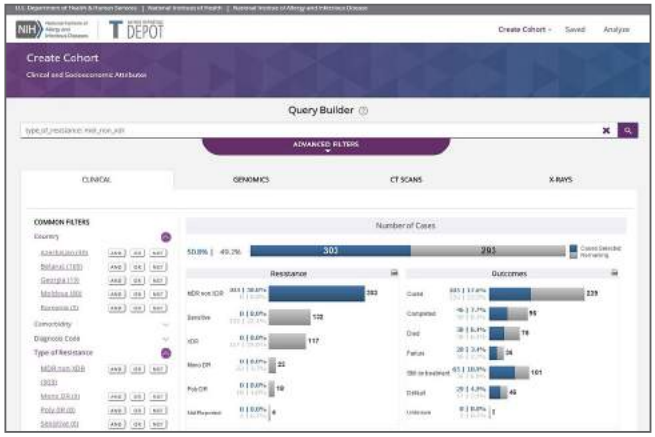
OCICB partnered with the Vaccine Research Center (VRC) Next Generation Sequencing Lab to select and implement a Laboratory Information Management System (LIMS) solution to manage samples, reagents, and experiments related to Next Generation Sequencing. The selected LIMS provides a platform solution that enables OCICB to extend the solution to other VRC and NIAID research groups. The OCICB team is currently working on the Core LIMS deployment and configuration to the VRC NGS lab's needs. OCICB team members are receiving the training they need to build and deliver LIMS solutions to NIAID laboratories using the Core LIMS platform solution.

BUSINESS ANALYTICS

Business analytics provide a broad array of data visualizations and analysis dashboards for financial, administrative, scientific, and clinical programs. Data-driven decisions at all levels of the Institute are facilitated by providing task-based operational dashboards and sophisticated budget analysis tools. It is used to integrate and modernize historical clinical data, providing management analysis tools, and a customizable "self-service" analytics environment that may be tailored to individual programmatic requirements.

NIAID M/XDR TB Portals DEPOT

OCICB launched the Amazon Cloud-based multiple and extensively drug resistant data exploration portal (M/XDR-TB DEPot). This public portal allows researchers to exchange, visualize, and analyze information from tuberculosis resources, including country-specific TB portals, to assist in the multi-factor analysis of rare, unusual, atypical, most dangerous MXDR-TB cases. Researchers and physicians can create, save, and analyze multiple cohorts of patients that have drug resistant tuberculosis. An international consortium of physicians contributed de-identified tuberculosis patient data to common public database that NIAID supports. The web application allows users to quickly identify important patterns in disease factors and develop new clinical trial hypotheses.



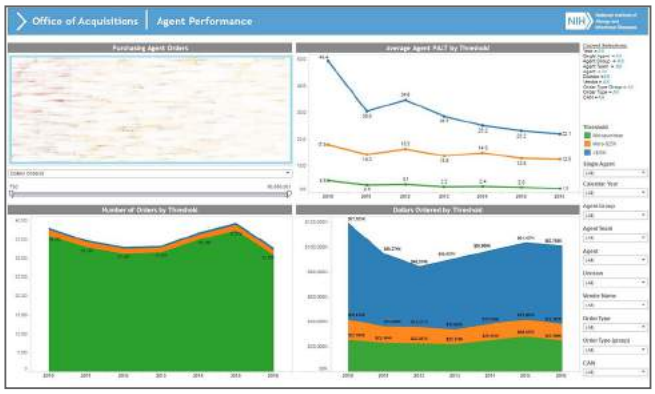
Query builder page showing advanced filtering. The site is publicly available at: https://depot.tbportals.niaid.nih.gov/.

IT Asset Management Dashboard

The IT Asset Management Analytics tool is used to track software licenses across NIAID machines. It determines what licenses have not been or are no longer in use. Unused licenses may be removed or reassigned to conserve costs. It also enables OCICB and NIAID IT leadership to track software usage by users. This ultimately helps NIAID IT with budget savings as well as other important budgetary and executive decisions.

Office of Acquisitions Performance Dashboard

Purchasing agent activity from 2010 to today shows trends by dollar thresholds (micro-purchases, micro-purchases up to $25k, and over $25k), the number and dollars ordered, the time it took for an agent to place an order, and year-to-date agent order activity. This dashboard allows management to make decisions on workload allocation.

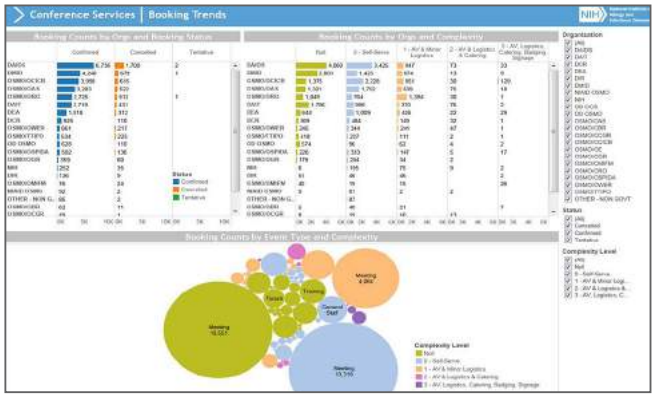


Dashboard homepage showing agent performance metrics

Facilities Management Dashboard

The Facilities Management tool enables OWS leadership to track and analyze conference room booking trends along various dimensions in order to more effectively level resources. Some meeting and conference rooms and resources are over-utilized, while others are under-utilized. Using the dashboard, OWS leadership can analyze facility utilization trends (square foot/person) in order to more effectively design and allocate space.

The Facilities Management tool tracks escalated tickets and complaints in order to identify and improve low performing areas and ensure that tickets are resolved in a timely manner. It helps with the management of AV and other logistical support functions to ensure availability. Leadership can track trends (e.g. a room is too hot, a chair is broken, etc.) in order to strategically address recurring issues.

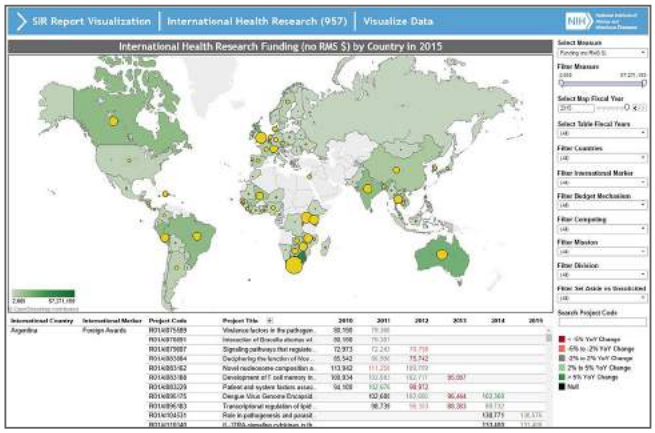


Dashboard homepage showing booking trends for conference services

Scientific Information Requests Visualizations

SIR reports are maintained in a number of reporting categories: Immunology, International, Tuberculosis, Emerging Infectious Diseases/Pathogens, and Antimicrobial Research. OCICB identified 1703 reports that are frequently used and developed a standard dashboard to visualize these SIR reports. The reports were previously downloadable in Excel or PDF formats, but were available one Fiscal Year at a time. This limitation doesn't exist in the SIR Visualization dashboards.

It provides trends for "reported" data over multiple fiscal years and enable detailed analysis across multiple scientific dimensions. OCICB worked with the Science Reporting team to integrate dashboards with the existing NIAID Budget and Science Reports site. Now, when users search for a report in SciRpt that is also available for visualization, a button will be enabled to indicate this. The button will open the SIR Visualization dashboard enabling the user to view and interact with multiple years of data to quickly identify trends and perform analysis. Additional SIR Visualization dashboards will be developed for more reports as the user base grows and other high interest reports are identified.

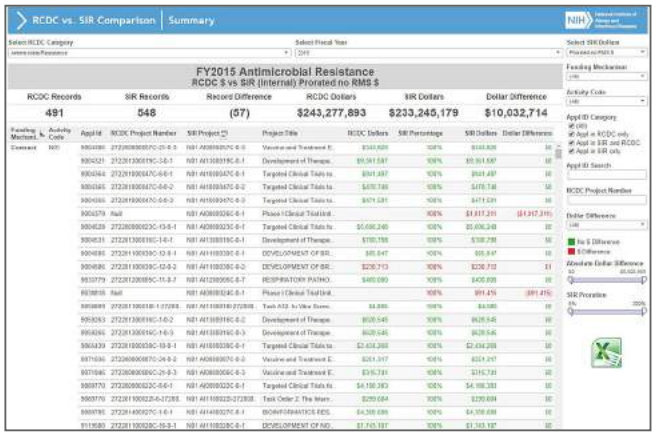


SIR Visualization for international health research funding by country by year

Research, Condition, and Disease Categorization vs. Scientific Information Requests Comparison Dashboard

The Research, Condition, and Disease Categorization (RCDC) vs. Scientific Information Requests Comparison Dashboard was developed to allow analysts to compare the dollars awarded within a specific RCDC category against the dollars awarded to the correlated internal science and budget report in any given fiscal year. This dashboard shows the comparison at the application level and enables the user to quickly filter down to applications which are present in only one source or another, or to applications which have a dollar difference greater than

zero. The dashboard also allows users to compare data from each source for a given application outside of the scope of the selected report. The current version of the dashboard allows users to choose between two RCDC Categories and two available fiscal years for comparison but will continue to expand to include additional categories and fiscal years.



Comparison summary analysis for FY2015 Antimicrobial Resistance

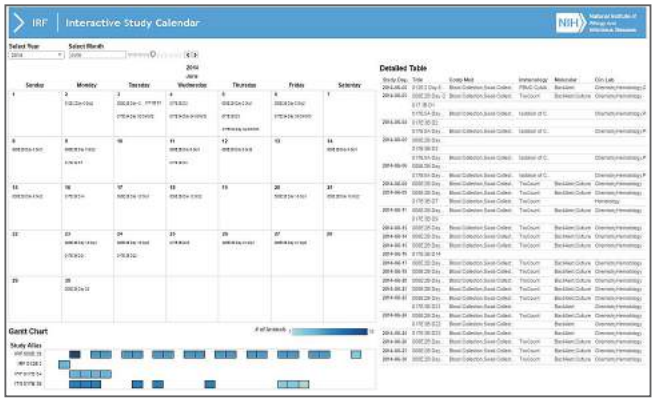
Intramural Administrative Management Branch Workload Dashboard

To help the Intramural Administrative Management Branch (IAMB) with decision-making, resource allocation and strategic planning, OCICB developed 'workload dashboards' that show the Acquisitions, Travel and HR details by Administrative Officer (AO).

Dashboard showing workload by AO, Total Trips, Weighted Workload Distribution, Total Transfer Counts by AO, and AO Workload by Staff Type

Integrated Research Facility Interactive Study Calendar Dashboard

The Integrated Research Facility (IRF) Interactive Study Calendar Dashboard provides insight into all the lab studies being scheduled for experimental testing within the IRF. This dashboard allows users at IRF to plan for incoming studies and coordinate on-going studies in the pipeline more effectively and more efficiently.



Dashboard showing interactive study calendar with GanTT Chart and detailed table

COLLABORATIVE TECHNOLOGIES

OCICB uses portal technologies to enhance communication and collaboration endeavors across the Institute. These technologies serve as the backbones for the NIAID internet and intranets, and provide a single platform with a unified taxonomy and common navigational elements. The platform can be deployed in a myriad of circumstances to facilitate organizational communications.

NIAID Conference Support (Respond)

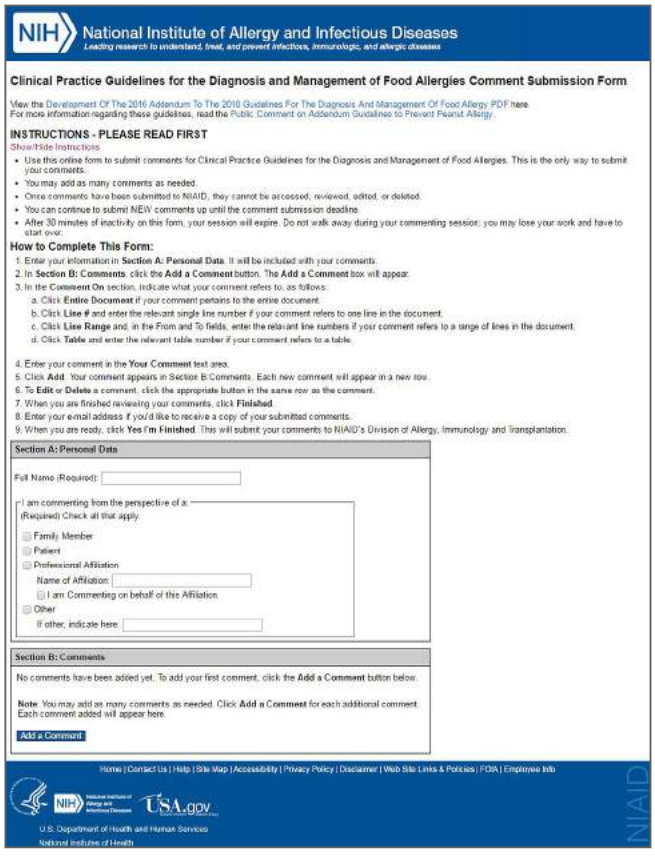
OCICB provides conference site development for NIAID conference planners. This year, there were 21 requests in support of NIAID conferences. Conferences organized using this site include:

- 2016 Bioinformatics Festival Virtual Clinical Trials: Modernizing Comparative Studies Workshop in Bethesda, Maryland
- International Tuberculosis Portals Consortium in Minsk, Belarus
- NIAID Grants Day Workshop in Stockholm, Sweden
- U.S. – Japan Cooperative Medical Sciences Program presents 50th Anniversary Celebration in Bethesda, Maryland

- Sequencing and Data Analysis in Bioinformatics Workshop, Chennai, India
- Standardizing MERS-CoV Animal Models: Current Status and the Path to Clinical Trials for Vaccines and Therapeutics
- Cures for Chronic Hepatitis B, Metabolism and Pathogens Symposium, in Hamilton, Montana
- 2016 Exploring Opportunities for Arbovirus Research Collaboration in Havana, Cuba
- NIAID Post Award Grants Policy and Management Training in Toronto, Canada.

Food Allergy Public Comments Form (Respond)

OCICB built a web form to allow the public to provide detailed feedback about NIAID's research related to food allergies, in reference to the text and data in a published PDF document.



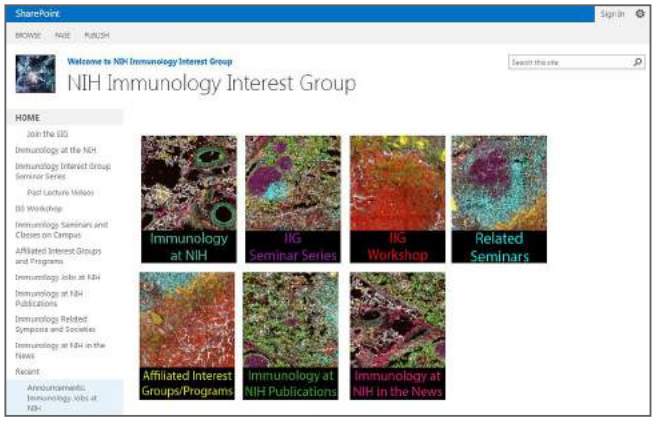
Food Allergy public comments input form page

Google Tag Manager and A/B Testing (Internet & Inside)

The Google Tag Manager was implemented to consolidate the websites' third-party tools for analytics, site surveys, and other purposes. This will aid in NIAID's compliance with the federal Digital Analytics Program, as well as help streamline use of analytics tools across NIAID's multiple web properties. Additionally, A/B Testing Tools were added to assist in development of content strategy.

Immunology Interest Group Collaboration Site

The NIH Immunology Interest Group (IIG) website was upgraded to create a new site on the outward facing SharePoint servers that reflects the thinking of the current IIG Board and that can be easily maintained by the IIG themselves. The IIG is very active, has weekly meetings and includes external members from research intuitions and scientists from commercial organizations. The site supports the collaboration mission of NIAID scientists and laboratories. Specifically, the site is used to publish documents, announcements, and a directory of interest group members.



NIH Immunology Interest Group collaboration site

ELECTRONIC DOCUMENT AND RECORDS MANAGEMENT SYSTEM

The EDRMS Program:

- helps individuals, teams, branches, and divisions manage their high-value documents and content
- provides process improvement solutions to scientific, clinical, and administrative programs
- supports institute-wide regulatory requirements and records management needs

EDRMS document repositories are vastly superior to manag-

ing documents on network drives or in Outlook. In addition to full-text searching capabilities, EDRMS can establish metadata (tags) on documents that allow database-style content querying. All EDRMS documents are automatically versioned, and the system keeps an audit trail of all actions (views, changes, deletes) to meet regulatory and Federal records management requirements. We work with programs and offices to clean up and restructure documents with an improved taxonomy and security model to facilitate this process.

EDRMS Workflows automate an organization's business processes, ensuring that the process is repeatable and consistent. We help business units re-engineer and optimize their processes to improve transparency, eliminating guesswork about what step comes next. This increases accountability because business administrators can now monitor the status of the workflow via a web page. Manual processes that used to take days can be electronically routed and completed in a matter of minutes or hours. Workflows also provide reports on how long steps take to complete, durations for the overall process, and number of workflows initiated for a given period.

NIAID eCTD System

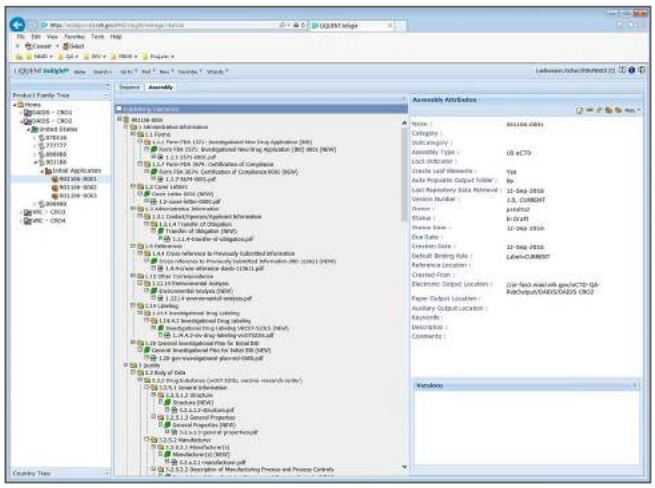
The FDA mandated the use of electronic Common Technical Documents (eCTDs) for all Investigational New Drug applications (INDs) beginning in 2017. This requires significant changes to the processes and tools used by sponsor regulatory groups. Representatives from DAIDS, the VRC, and OCICB formed a team to evaluate options for NIAID to prepare for the mandate well in advance of the expected deadline.

The team's efforts culminated in the acquisition and installation of an eCTD product suite. This system provides all the tools needed to assemble, review, and validate eCTD submissions. It is also integrated with NIAID's existing validated content management system, which provides a secure repository for the storage of all sponsor documents used in submissions. In addition to directly supporting the preparation of eCTDs, this repository will simplify and streamline contract research organization (CRO) turnovers since information will no longer need to be transferred, reorganized, and reviewed when CRO contracts are re-competed.

New operational standard operating procedures (SOPs) and processes will be used by NIAID and its CROs to prepare and manage IND submissions in accordance with FDA and NIAID regulatory requirements.

Although DAIDS and the VRC are the initial users of the System, it was constructed to support any other interested NIAID sponsors. Additionally, both the eCTD tools and the document repository are accessible to external CROs who will continue to perform most of the actual submission assembly and management tasks.

Within OCICB, the EDRMS program had lead responsibility for development of the System. Representatives from DAIDS and the VRC regulatory affairs groups provided subject matter expertise and were responsible for development of new business processes, SOPs, and coordination with CROs and the FDA.



eCTD Submission Assembly screen

PARIS

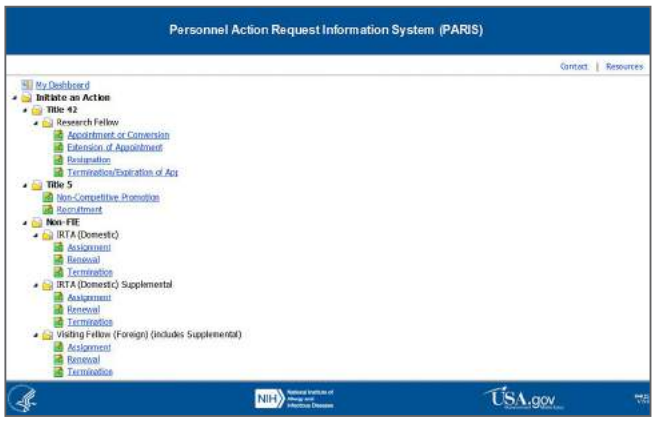
The Personnel Action Request Information System (PARIS) was launched in early 2014. It provided assistance with the Title 42 Research Fellow appointment and conversion process, and with personnel actions for the DIR and the VRC. This fiscal year, the following three workflows were added:

1. Title 5 Non-Competitive Temporary and Career Ladder promotion actions across all NIAID divisions
2. Automation of assignments, renewals and terminations for seven different types of Visiting Fellow and Intramural Research Training Award positions; these processes are associated with a variety of actions and positions requiring complex document packages.
3. Automation Title 5 recruitment actions across all NIAID divisions.

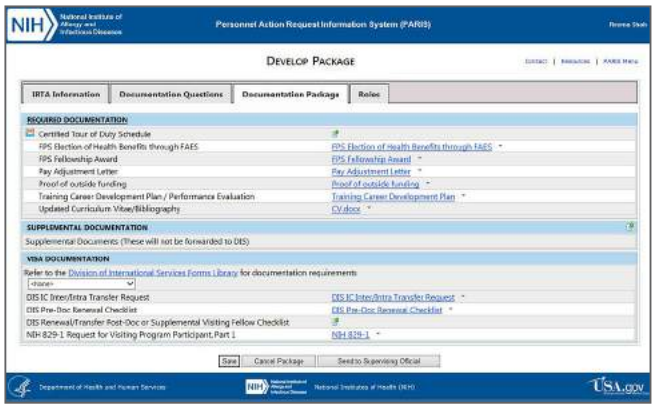
PARIS supports streamlined role-based processes provides consistency across the divisions. The system includes a "smart form," which assists users by identifying documentation required to complete a specific HR action. The system interfaces with the NIAID Organizational Hierarchy to automatically extract all roles for the action based on standard administrative codes and action type and intelligently builds the signature sheet for the Package

and determines the routing for electronic signatures.

The system addresses two NIAID priorities: process harmonization across divisions and automation of HR actions. The system's documentation rules engine, based on the approved and streamlined SOPs, assists the Initiator in building the documentation package easily and consistently for different actions. The reviewing and approving official's actions are enabled using a standardized interface. The combined PARIS Dashboard ensures complete visibility into all actions and provides an overview of all actions and their current status. The HR Actions document repository stores all action related documentation in a centralized and secured location and provides access to only the roles involved in the process.



PARIS landing page showing initate and action by type



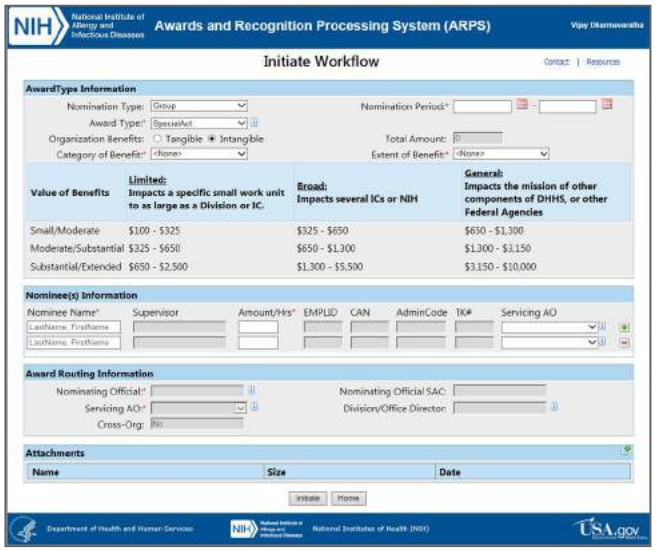
PARIS Documentation Collection Interface based on Position Type and Type of Action

ARPS 2.0

The Awards Recognition Processing System (ARPS), facilitates users to nominate NIAID Employees for various NIH Awards such as Special Act, Time Off and QSIs. The application automates routing of the nomination within NIAID to reviewers and approvers as per guidelines of the NIH Delegations of Authority, and sends the completed awards to the Office of Human Resources at NIH.

ARPS uses newer Content Server 10 technologies for faster processing with an innovative more streamlined workflow. It also has added the complex functionality of Group Awards and Cross Organizational Awards. The addition of Group Awards now enables NIAID nominators to list multiple nominees in one award, and Cross Organizational Awards will permit nominators to choose nominees from different SACs. Improved reports will inform workflow participants on the status of their workflow as well as be able to quickly search and retrieve awards based on multiple criteria such as status of the workflow, nominees and nominators.

The ARPS workflow is used extensively by nominators in NIAID during the peak nomination periods with an average of around 300 to 400 awards per fiscal year.



ARPS 2.0 Nominee initate workflow screen

RML ACUC ASPs Repository and Workflow

All research at NIH involving animals must adhere to a specific set of laws, rules, guidelines, regulations, and policies affecting the use of animals. The NIAID RML Animal Care and Use Committee (ACUC) oversees the animal program, facilities and procedures, including the key functions of reviewing and approving requests to use animals in research under Animal Study Proposals (ASP) for the five labs at Rocky Mountain Laboratories (RML). The ASP form is a required document, mandated by federal regulations, that describes and justifies in detail the use of animals in experiments.

OCICB worked with the RML ACUC Coordinator to set up the RML ASP Repository and migrate the metadata and documents related to more than 200 ASPs to provide a consistent structure and easily searchable and maintainable metadata. The RML ACUC Dashboard provides an easy and convenient means to search for and retrieve specific ASPs and perform various actions based on roles. The project also provided a streamlined workflow for routing a new ASP for scientific review, preview, ACUC review and finalization, and automated the annual review process and addendum creation process. The electronic RML Repository and ASP Management system overcomes the issues associated with the manual management of ASPs, and shall provide RML with various benefits such as:

- Easy means to create new ASPs, Addendums and Annual Reviews from standard templates
- Standardized Review & Approval process for new ASPs & Addendums
- Robust security and access controls that manage user access to ASPs and protect against inadvertent deletion
- Electronic Signatures
- Reducing the work load of ACUC Coordinator
- Easy means to select & manage the reviewers for all ASPs for a ACUC Meeting

Application of metadata input screen

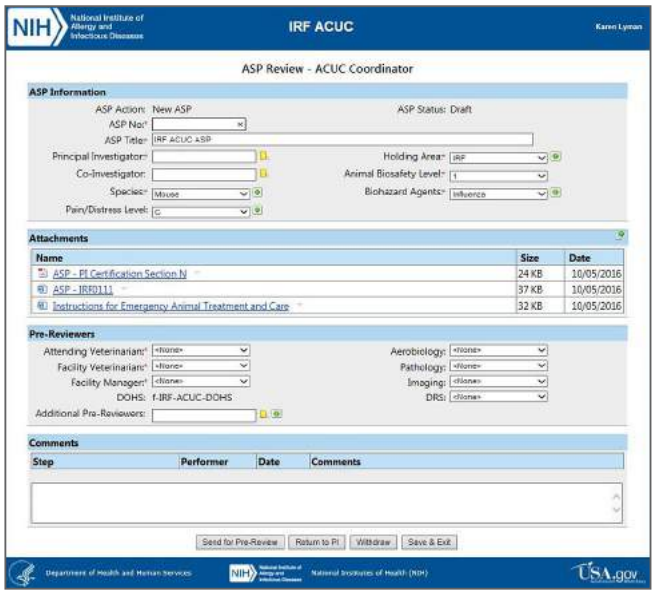
DCR IRF ACUC Workflow and Repository

The NIAID DCR ACUC is a federally mandated committee, appointed by the NIAID Scientific Director, which ensures the care and use of animals is appropriate, humane, and in accordance with animal welfare regulations.

The NIAID DCR ACUC required a document management system/ workflow in order to gain efficiencies in the ACUC ASP creation, review, and approval process. The existing process involved email and hardcopy distributions of draft ASPs. Management of the process was difficult due to the number of people involved and the fact that different groups of people were involved with different ASPs. Additionally, approved ASPs usually go through several Amendments, Annual Reviews, and triennial Renewals. All of these steps were handled and tracked manually.

OCICB worked with the IRF to automate their ASP workflow and document management processes. The resulting project provides these features:

- Streamlined routing and approval process for new ASPs, Amendments, Annual Reviews, and Renewals
- A single repository to store ASPs and all related documents
- Security and access controls
- Electronic Signatures
- Development and application of metadata for ASP document content
- Scientific merit review by the IRF Scientific Director
- Ability to post documents critical to the ACUC meetings
- Dashboard enabling metadata searches of ASPs



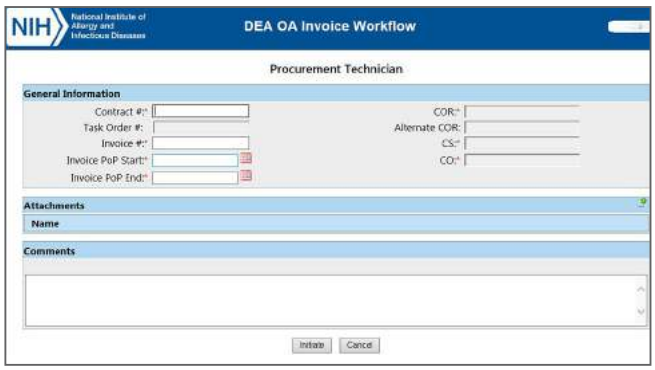
ASP review ACUC Coordinator review screen

OA Invoice Workflow

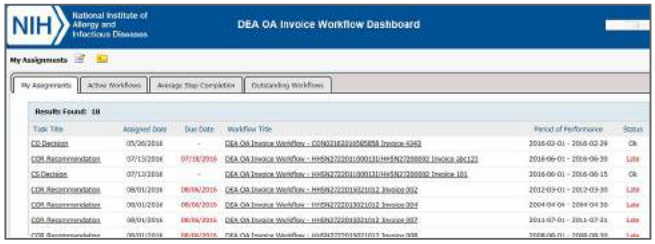
The NIAID OA maintains official contract files within an EDRMS repository. The Federal Acquisition Regulation as well as the HHS Acquisition Regulation prescribe the content for these files, and require that invoices be included.

Previously, invoices were routed through a SharePoint workflow and, once the workflow was complete, the invoice was manually loaded into the Official Contract File. OA desired a reliable workflow to eliminated pen-to-paper signatures and reduce processing steps. The goals of the new Invoice Workflow included:

- Provide a reliable method to review and approve invoices.
- Eliminate manual processing steps.
- Provide a standard naming convention for invoices.
- Deliver status and tracking reports for invoices.
- Offer role based metrics for performance.



Procurement Technician initate workflow screen

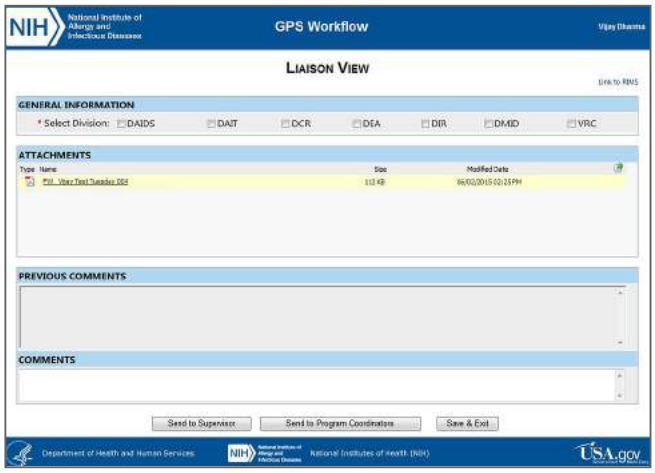


DEA OA Invoice worklow dashboard showing status of workflows

NIAID FOA Participation Portal

The DEA receives Funding Opportunity Announcements (FOA) from the NIH Guide Publishing System. The NIAID Liaison emails the announcements to the various divisions within NIAID to determine if they are interested in participating. If the divisions are interested, a reply is sent back to the Liaison and the FOA is sent to the Executive Committee meeting. This process was automated using OpenText Content Server workflow technology. The resulting workflow enables:

- Ability to easily track the workflow progress.
- Easily identify which division will participate.
- The results of the Executive Committee meeting will be immediately available.
- Emails and related documentation are automatically archived in the repository.



ASP review ACUC Coordinator review screen

IT Policy Management System (ITPMS)

The OCICB Program Management Branch (PMB) is responsible for developing, implementing, and reviewing OCICB and NIAID level policies to ensure that they conform to technology-related Federal laws, regulations, and policies. PMB also performs strategic planning, analyzes resources, enhances the professional development of staff through in-service training, monitors investments, performs quality assessments on projects and programs, and manages acquisitions.

Prior to ITPMS, policies were manually reviewed and were difficult to track during the review process. The completed policies were difficult to locate because they were stored in multiple locations. To address these deficiencies, the ITPMS system provides the following features:

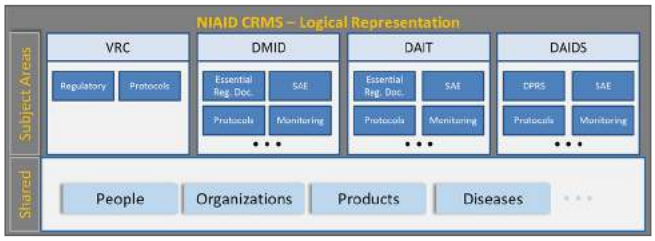
- A centralized repository to store all policies and procedures.
- Ease of access to the repository by way of an intuitive interface.
- Convenient means to search and retrieve specific documents based on topic area.
- An automated review workflow which reduces the time to review and sign policies.
- Ability to monitor and manage documents during the review process.
- A digital signature interface to ease the process of electronically signing approved policies.

EDRMS Digital Signature Application (DigiSign) Interface signature input screen

Clinical Research Support Systems

The NIAID Clinical Research Management System (CRMS) supports the scientific, administrative, and regulatory components of the Institute's research agenda (e.g. clinical site monitoring and protocol lifecycle tracking). It is comprised of a number of components, including the DAIDS Enterprise System (DAIDS-ES), DMID Clinical Research Management System (DMID-CRMS), DAIT Clinical Research Information System (DAIT-CRIS) and the VRC Clinical Research Management System (VRC-CRMS).

NIAID CRMS facilitates the management of internal and external NIAID-funded clinical research programs. It enhances the NIAID clinical research information management capacity by providing innovative data collection systems, management tools, processes, and communication methods. Staff can rapidly search for and retrieve study data and information to support oversight and decision-making.



NIAID-CRMS Logical Representation

OCICB deployed two major system releases and two minor releases during the past fiscal year. Two new NIAID CRMS modules were released on September 12, 2016:

1. Site Hub: Facilitates tracking of Good Clinical Practice/Human Subject Protection training and population characteristics for DAIDS sites.
2. Resource Scoring and Protocol Abstraction: Enables resource scoring and management of protocols sponsored or supported by DMID.

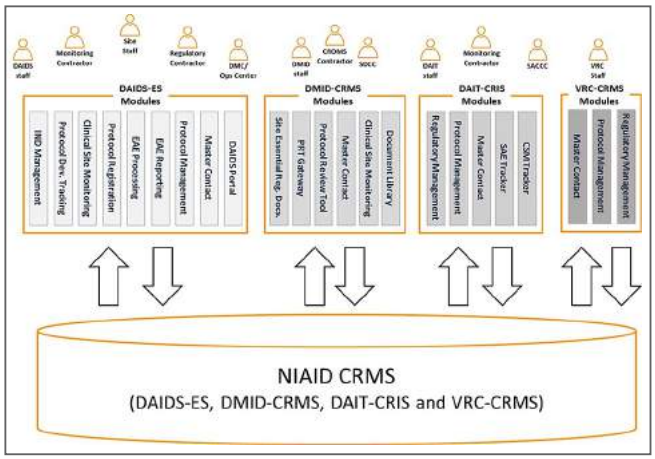
A summary of data generated in NIAID CRMS in the past contract year is included below.

Summary of NIAID-CRMS Data

Data Category	Created Between 9/26/15 - 9/25/16	TOTALS
Users	664	5,642
Protocols (including versions)	1,536	11,179
Protocol Review Requests	117	221
Participants	19,345	255,672
Organizations in Master Contact (i.e., Biopharmaceutical companies, Contract Research Organization, etc.)	212	4,572
Clinical Research Sites	144	3,030
People in Master Contact (e.g., Investigator, Study Coordinator)	2,623	18,850
Investigational New Drug Submissions	235	893
Study Products (including drugs, vaccines, etc. used in clinical trials)	366	1,225
Expedited/Serious Adverse Events (SAE)	1,890	16,251
Protocol Registrations/Site Essential Regulatory Document Submissions	2,410	24,257
Site Visits	2,603	14,373
Web Service Calls	**1,608,540**	**5,115,863**

KEY ACCOMPLISHMENTS

- Updated 25 applications across four divisions
- Released Site Hub for DAIDS and Resource Scoring and Protocol Abstraction for DMID
- Provided ability to register DAIT protocols with ClinicalTrials.gov
- Established interface with National Library of Medicine (NLM) PubMed
- Established interface with NIAID Central database to make grants data from IMPAC II available in NIAID CRMS
- Implemented HTTP Strict Transport Security (HSTS) enhancement in NIAID CRMS web application and report servers
- Updated Transport Layer Security (TLS) certificates on NIAID CRMS application servers



NIAID CRMS Components. This diagram provides an integrated view of NIAID CRMS with the operational modules for each of the NIAID divisions.

DAIDS ENTERPRISE SYSTEM (DAIDS-ES)

DAIDS-ES supports scientific, administrative, and regulatory needs related to the DAIDS research agenda on HIV/AIDS vaccine, prevention, and therapeutics research. Initial development began in 2003 with multiple subsequent new components and enhancements. This is the most mature of the NIAID-CRMS components and serves as the foundation for the other systems.

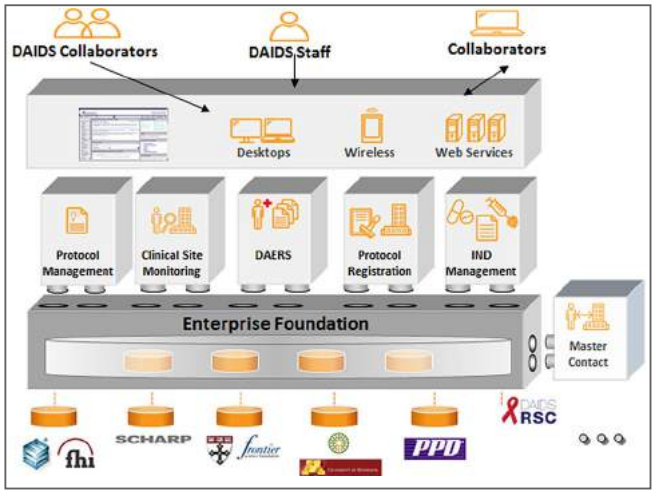
The DAIDS-ES consists of ten discrete components:

- **DAIDS Portal:** The framework for a common access point to the suite of products automating clinical research and other related business processes.
- **Master Contact:** Centralized system for stakeholders engaged in clinical research, such as investigators, participating institutions, laboratories, agencies, pharmaceutical sponsors, manufacturers, etc.
- **Protocol Management:** Supports end-to-end clinical trials processes, including protocol development, registration, conduct, accrual, oversight, site monitoring, tracking and closeout.
- **Protocol Registration:** Provides a unified centralized system that serves as the official information source for Protocol Registration activities involving registering a Clinical Research Site (CRS) to a protocol.
- **Protocol Development Tracking:** Provides tracking of protocol development activities through identified milestones, facilitates a protocol development workflow, and provides functionality to facilitate the development of clinical agreements that may accompany the protocol development process.
- **Investigational New Drug Application Management:** This is the central repository for all submissions tendered by the DAIDS to the Food and Drug Administration (FDA) and it enables users to track and monitor progress of application processing and submissions.
- **Clinical Site Monitoring:** Provides a unified platform that serves as the official information source for site monitoring activities.
- **Adverse Experience Reporting:** Used for expedited reporting of adverse events in DAIDS-sponsored clinical trials.
- **Adverse Experience Processing:** Supports and enables the processing and tracking of SAEs for the DAIDS-sponsored studies; this component interfaces with the Adverse Experience Reporting (AER) component to receive Expedited Adverse Events (EAE) electronically.
- **Site Hub:** Supports verification of adherence to Good Clinical Practice/Human Subject Protection (GCP/HSP) training and tracks site population characteristics.

DAIDS-ES has 3,579 users in 22 countries. In addition to DAIDS staff, collaborators (Regulatory Support Center, Data Management Centers, etc.) and clinical research sites sponsored or supported by the division also use the system.

KEY ACCOMPLISHMENTS

- Released site hub module for use by DAIDS clinical trials units and clinical research sites to support verification of adherence to GCP/HSP and track site population characteristics.
- DAIDS Regulatory Support Center can now apply Medical Dictionary for Regulatory Activities (MedDRA) coding to clinically significant adverse events in addition to the primary adverse event.
- Clinical trial agreement special handling requirements are accessible based on intervention, manufacturer, and/or supplier when processing EAE.
- Site monitoring visit reports are generated through the Clinical Site Monitoring module.
- AIDS Clinical Trials Group (ACTG) laboratory sciences group can access protocol registration information to facilitate final lab approval when a site initiates submission in NIAID CRMS.
- Exchanged data for 907 EAE with network data management centers.
- Performed daily update of accrual data for 97 protocols through data exchange for protocols managed through the network data management centers (DMC).



DAIDS-ES Logical Diagram. This schematic provides a high-level overview of DAIDS-ES.

DAIT CLINICAL RESEARCH INFORMATION SYSTEM (DAIT-CRIS)

DAIT promotes and supports a broad range of basic, pre-clinical, and clinical research to enhance the understanding of protective immunity, and the causes and mechanisms that lead to the development of immunologic diseases. This knowledge informs the development of improved diagnostic tests, more effective approaches to treatment, and, ultimately, the prevention of immune-mediated diseases.

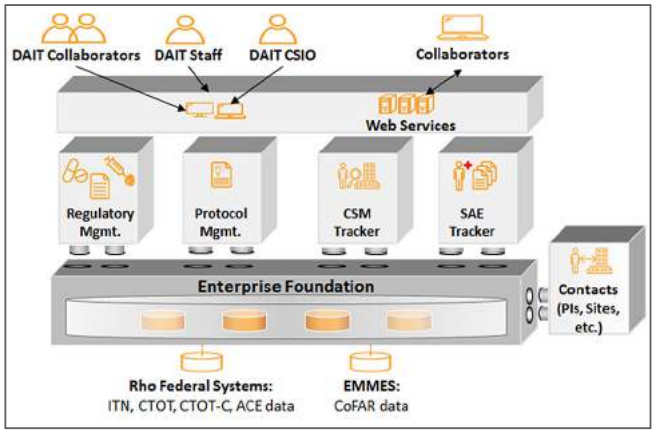
DAIT-CRIS was developed as an integrated solution to provide DAIT staff with the ability to capture, manage, share, and access study, site and safety related information across consortia from a centralized repository. DAIT-CRIS is presently comprised of five components:

- **Protocol Management:** Centralized system supporting scientific and administrative information needs for DAIT clinical research programs.
- **Serious Adverse Event Tracker:** Track the processing of serious adverse event (SAE) reports from initial submission to final disposition. Access SAEs across all DAIT clinical trials and networks and facilitate reporting and analysis related to SAE submissions.
- **Clinical Site Monitoring Tracker:** Manage key parameters that describe the performance of a site utilizing a common set of elements, and translate the information across projects to analyze overall site performance.
- **Master Contact:** Centralized repository of organizations and key personnel participating in DAIT clinical research.
- **Regulatory Management:** Track and manage key information for regulatory applications associated with DAIT studies.

DAIT prioritized change requests for Protocol Management (PM), SAE Tracker and Regulatory Management (RM). The DAIT Clinical Study Information Office (CSIO) supported abstracting and populating DAIT prioritized protocols within this system.

KEY ACCOMPLISHMENTS

- Interface with National Library of Medicine (NLM) PubMed populates Publication information in DAIT CRIS
- Supports Clinicaltrials.gov protocol registration
- Provides notifications to DAIT staff of upcoming Primary Completion and Basic Results Submission
- Tracks accrual data for non-consortia studies
- Tracks allergen related interventions
- Tracks archival of regulatory application information
- Restricts viewing of 'confidential' regulatory documents
- Provides notification to Statistical and Clinical Coordinating Center (SACCC) if DAIT assessment differs from Investigator/SACCC assessment
- Provides access to key data to facilitate review/approval process for SACCC and DAIT staff (e.g., protocol, safety management plan, adverse event grading information)
- Abstracted and released 31 protocols prioritized by DAIT in production
- Through data exchange, data for 984 SAE Case reports was exchanged with DAIT SACCC contractor systems
- Updated accrual data daily for 101 protocols via data exchange for protocols managed by SACCC



DAIT-CRIS Logical Diagram. This schematic provides a high-level overview of the DAIT-CRIS.

DMID CLINICAL RESEARCH MANAGEMENT SYSTEM (DMID-CRMS)

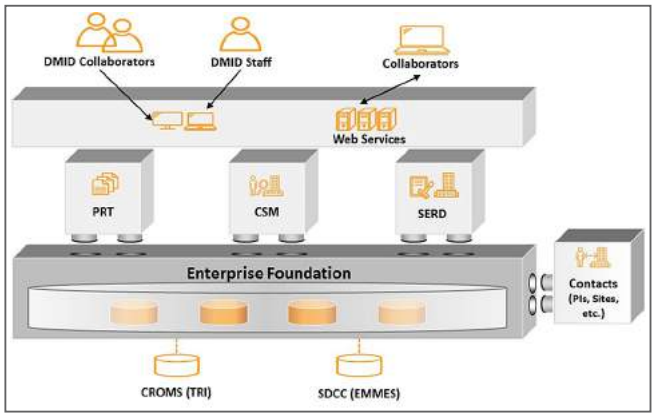
DMID supports a comprehensive extramural research program focused on the prevention and control of diseases caused by virtually all infectious agents (with the exception of HIV). This includes basic research, such as studies of microbial biology and physiology; applied research, including the development of medical diagnostics, therapeutics and vaccines; and clinical trials to evaluate experimental drugs and vaccines. Based on DMID business priorities and needs, the first component to be developed as part of the DMID-CRMS system was clinical site monitoring.

DMID-CRMS supports business functions, management, and oversight responsibilities; DMID-CRMS is comprised of six components:

- **Clinical Site Monitoring:** Generates reports to assist with resource planning for site monitoring visits and allows the monitor to submit closeout visit-related materials afterwards
- **Document Library:** Users can search and access monitoring and regulatory documents
- **Master Contact:** Centralized repository of organizations and key personnel participating in DMID clinical research. Master Contacts are updated with information originating from Clinical Site Monitoring requests for service.
- **Site Essential Regulatory Documents:** Provides ability to designate sites and administrative organizations to protocols and ability for DMID sites to submit essential regulatory documents for review by DMID.
- **Protocol Review Tool:** Subject matter experts may be assigned to more than one role for protocol review and sign-off.
- **Resource Scoring and Protocol Abstraction:** Resource scoring and protocol information abstraction is available for DMID protocols.

KEY ACCOMPLISHMENTS

- Developed and deployed Resource Scoring and Protocol Abstraction module
- Developed and deployed a data exchange to submit inclusion enrollment data to the NIH Inclusion Management System
- Established an interface with the NIAID Central database to make DMID grants data from IMPAC II available to DMID staff for resource scoring
- Supported scheduling and post-visit activities for 503 site visits through the clinical site monitoring module
- Exchanged data for 1,110 protocols with Clinical Research Operations and Management Support (CROMS) contractor systems
- Updated accrual data daily for 45 protocols through the Statistical and Data Coordinating Center (SDCC)

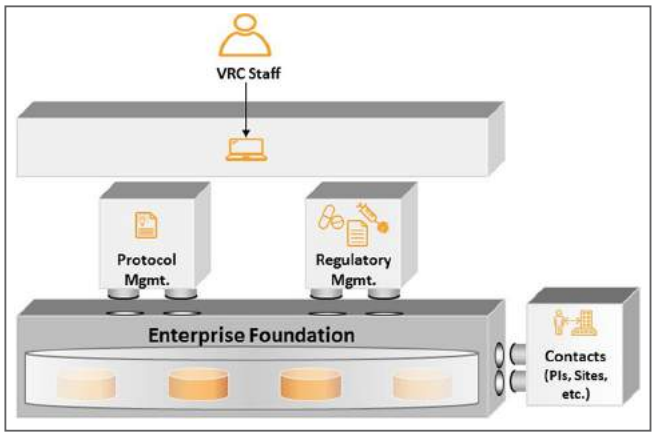


DMID-CRMS Logical Diagram. This schematic provides a high-level overview of the system.

VRC CLINICAL RESEARCH MANAGEMENT SYSTEM (VRC-CRMS)

The VRC mission is to conduct research that facilitates the development of effective vaccines for human disease, primarily focused on the development of vaccines for AIDS. VRC oversees a comprehensive program of research on the NIH intramural campus and has national and international collaborations with scientists in academic, clinical, and industrial laboratories. The VRC collaborates with industry on the development, testing, and marketing of vaccines. It focuses on the development of new methodologies and training opportunities to benefit all HIV vaccine researchers. VRC-CRMS is currently comprised of three components:

- **Regulatory Management:** VRC staff can centrally access regulatory application information and associated submissions, interactions with health authorities.
- **Master Contact:** a centralized repository of organizations and key personnel participating in VRC clinical research.
- **PM:** provide VRC staff the ability to track key protocol information and documents for protocols managed and/or supported by VRC.



VRC-CRMS Logical Diagram. This figure provides a high-level overview of the VRC-CRMS.

KEY ACCOMPLISHMENTS

- Provided access to DAIDS protocols when the protocol is associated with VRC products.
- Ability to search and view DAIDS INDs and associated submission documents with VRC-CRMS when the IND is associated with VRC products.
- Means to associate and track Electronic Common Technical Document (eCTD) submissions for a regulatory application.
- Ability to track accrual data for non-network protocols.
- Customized listing of regulatory applications and associated interactions and documents.
- Populated VRC-CRMS with 36 protocols and 17 INDs.

International Program and Project Initiatives

RAPID DEPLOYMENT OF COMPUTERS FOR WORKSHOPS

OCICB developed a program to run bioinformatics workshops at international sites. Re-purposed laptops from NIH surplus are imaged using a customized Linux installation. The laptops can be remotely updated using a combination of SaltStack and GitHUB. The SaltStack platform - or Salt - is a Python-based open-source configuration management software and remote execution engine. Supporting the "Infrastructure as Code" approach to deployment and cloud management, OCICB integrates Salt with GitHUB to allow configuration management from an easily accessible platform. New versions of computational bioscience tools can be deployed to laptops around the world using this system. OCICB is moving towards using this technology for configuration management of all the international servers, data analytics servers, and ACE bioinformatics platforms.

NETWORK EVALUATION IN JAKARTA FOR THE INA-RESPOND PROGRAM

The DCR requested assistance transitioning their research collaboration site in Indonesia to a new network management provider. The collaboration between DCR and the Indonesian National Institute of Health, Research, and Development (NIHRD) has been underway for nearly seven years. The program develops and runs clinical investigations and provides clinical protocols management services via the NIHRD in Jakarta. Services provided include data management expertise and cyberinfrastructure support.

The initial data management and supporting infrastructure groundwork was completed by Social and Scientific Systems (SSS), a Clinical Research Organization. SSS provided Open Clinica as the clinical data management system and an SSS custom-built electronic document management system built on Oracle technology. However, SSS did not have the requisite experience to provide systems that collaborating institutions can use and support independently. A more experienced provider was needed.

DCR implemented a timetable to end reliance on SSS and transition to the new team. OCICB sent two specialists to Indonesia to conduct an initial survey and capability evaluation; one focused on the cyberinfrastructure, the other on data management capabilities. The resulting transition strategy and priorities focused on three primary areas: data management, cyberinfrastructure transition, and maintaining customer support during the transition.

Project highlights include:

- Revised and updated SOPs, workplace guidelines, and the manual of operations.
- Replaced the custom electronic data management system SharePoint and SQL servers at the Jakarta co-location hosting facility.
- Successfully migrated more than 80,000 documents to the new document management system with all of requisite security restrictions.
- Set up new Open Clinica servers so that site data managers can test modifications to existing protocols and develop data collection and validation tools.

The billing and payment system used to compensate clinical sites was written in the open source statistical application "R" and required conversion to PHP in order to work with Open Clinica. This challenging project will continue at a reduced level of effort into the coming year, with disaster recovery planning and testing as well as preparations for a large clinical study to begin in early 2017.

Between the 17th and 27th of March 2016, Brian Moyer and Michael Holdsworth visited the INA-RESPOND offices in Jakarta, Indonesia to perform an IT and Data Management evaluation.

Between the 5th and 28th of June 2016, Michael Holdsworth returned to Jakarta, Indonesia to help transition IT & Data Management activities from SSS Clinical Research Organization to INA-RESPOND.

SPECIMEN MANAGEMENT FOR INTERNATIONAL SCIENTIFIC COLLABORATIONS

Researchers in remote locations can now access a specimen management service using a web browser. Based on FreezerPro, it allows them to catalog, characterize, and record the freezer location of specimens and other compounds. Field researchers can print custom labels for their vials before placing them in the freezers, refrigerators, and cryogenic storage systems. The labels have barcodes, so scanners may be used to inventory storage systems and identify samples and compounds quickly. The service also tracks specimen shipments from field sites to sequencing and analysis labs, back to the NIH, or to third party laboratories.

LIG Lab team and IBRSP FreezerPro team after training.

Brian Moyer and Michael Duvenhage leading the Biospecimen and FreezerPro Workshop for the UCRC Team.

SATELLITE UPLINK UPGRADE - MALI

The last of four major field sites in Mali received a satellite uplink upgrade. At one time OCICB operated a satellite network using a C-band uplink that used nine 12-foot diameter antennas in five sub-Saharan African countries. The C-band network was costly in terms of bandwidth and operations; therefore the sites were transitioned to the Ku-band.

The Ku-band provides connectivity to the sites for nearly the same cost as one site using the C-Band. This technology uses smaller antennas, only one meter in diameter, and uses lower cost bandwidth that provides greater competition and coverage around the world. The Mali sites use this systems for primary and/or emergency backup connections. The Bancoumana, Mali site was the last one using the C-band technology.

DFNET AUDIT

NIAID uses DataFax, from DF/Net based in Seattle, Washington, for all interventional clinical protocols and many non-interventional clinical investigations as well. DF/Net provides DataFax at a significant discount to academic researchers who often have limited budgets. Clinical trials software must adhere to a regulatory framework of internationally accepted industry standards and US government regulations which require external audits every two years.

At a DataFax Users Group meeting NIAID committed to work with other organizations to perform a customer audit of DF/Net. The audit allows customers to document that the software is compliant with FDA regulations in design and that the development and support of the software ensures continued compliance. A member of OCICB, along with two other cus-

tomers, visited the software development offices of DF/Net in Hamilton, Ontario for two days in October of 2015. The audit process included documentation reviews, process inspections, and interviews with DF/Net staff members regarding:

- Overall quality management
- Personnel qualification and training
- Software development methodology
- Supplier and sub-contractor management
- Project management
- Quality control processes
- Quality assurance processes
- Merger management
- Security
- Disaster Preparedness
- Physical server and file rooms
- Financial stability
- Outcomes from other audits and regulatory inspections
- Follow-up from previous DFUG vendor audits

The resulting audit report detailed 12 minor findings and the audit team released the documentation to the user group by email. In October of 2016 at the next user group meeting in Durban, South Africa the findings will be presented formally.

INFORMATION TECHNOLOGY SERVICE MANAGEMENT TOOL

A legacy ticketing system supporting daily operations, hosting services, and applications for international research collaborations was replaced with Remedyforce, a full-featured IT Service Management (ITSM) tool. This Software-as-a-Service tool is hosted by Salesforce.com, a cloud services company. It was configured to meet the needs of the international collaborative research sites in Mali, Uganda, and India. Research site-based support staff can easily access the ITSM system using their local credentials to open, update, and close tickets.

The system permits categorizing tickets as service requests or incidents, providing statistics for help desk support and infrastructure operations. OCICB implemented a regional approach to queues so that operations in Mali and Cameroon are captured in the West Africa queue supported by our francophone service desk in Mali, while support in East Africa is based at the Uganda ICER Service Desk. The Asia service desk in India supports operations in China, India, and Indonesia, with significant help from the infrastructure team in Uganda. For those applications and services supported globally from the NIAID DMZ or Amazon Web Services there is a Global Queue which enables tracking of non-geographically specific support services. Incidents or service requests often require more extensive effort to resolve than the three-day target service level allows. Problem management lets us convert complicated tickets or groups of tickets into a problem that can be tracked over time. This is particularly important for efforts that require logistical support; i.e. procuring hardware in the US that is shipped to international sites. Change Management was implemented, making it easier for our staff to track their own activities and to escalate tickets between one another in different technical specialties across multiple timezones.

VIRTUAL RESEARCH ORGANIZATION (VRO) PLATFORM ROLLOUT

Researchers collaborate globally with multiple institutions and increasingly write software and design new technologies in partnership with universities, private institutions, and companies. A collaboration platform needs to be able to fit into this quickly changing environment and make it easier for scientists use their preferred tools. NIAID is supporting a vision of the Virtual Research Organization as a flexible collaboration platform to meet the needs of modern science.

OCICB built a platform to support collaborations between scientists using their existing institutional credentials. Initial efforts targeted collaborations based at the NIAID ICER in Mali and Uganda. The platform is expanding to support international virtual organizations worldwide, with researchers in China, South Africa, the United Kingdom, and France.

OCICB worked with partners from the:

- NIH Center for Information Technology (CIT) IAM team.
- US Academic Trust and Identity Federation, InCommon, operated by the Internet2, a member-owned advanced technology community founded by the nation's leading higher education institutions.
- Research and Education FEDerations group (REFEDS), the umbrella organization that guides eduGAIN.

EduGAIN is the meta-federation allowing the global network of trust federations to interact with each other, enabling access to services between academic organizations and service providers in more than 40 countries.

Technologies new to OCICB are used in the academic trust and identity vertical throughout the higher education community.

These include:

Shibboleth: A single sign-on system for computer networks and

the Internet. It allows people to sign in using just one identity to various systems run by federations of different organizations or institutions.

COmanage: A tool that creates a local identity that maps to the institutional federated identity for access controls. Multiple institutional credential sets and identities can be mapped to this identifier so that scientists can maintain their collaboration when they change institutions or roles.

Microsoft ADFS: The sole commercial software in this platform, it links identities from the collaboration platform to Microsoft products such as SharePoint.

Grouper: An enterprise access management system designed for the highly distributed management environment and heterogeneous information technology environment common to universities and research institutions.

The NIH sponsored the two NIAID African ICERs located in Mali and Uganda into InCommon as sponsored Identity Providers (IdPs). OCICB installed Shibboleth based SAML Identity Providers for the two African ICERS as a preliminary step in building the virtual organizations. InCommon exported these two IdPs into the global meta-federation, eduGAIN so that they were able to access the global community of service providers and other institutions of higher learning and research. NIH exported the metadata for two Shibboleth based Service Providers (SP) and Microsoft ADFS servers at each of the ICERs that linked to SharePoint servers.

This topology allowed collaborations to span the ICERs using COmanage, operating in the Amazon Web Services (AWS) Cloud, as the central management platform. It also allows scientists to quickly upload data to the local server at LAN speeds, and collaborators can download from the site using their own institutional credentials; they do not require accounts in the local Mali Active Directory.

NETWORK EVALUATION AND OPTIMIZATION IN CAMEROON

Doctors Thomas Nutman and Amy Klion from the Laboratory of Parasitic Diseases requested assistance with internet connectivity issues at their collaborative research site in Yaoundé, Cameroon.

This site is the center of a clinical protocol sponsored by the Bill and Melinda Gates Foundation to help field clinicians quickly diagnose Loa Filariasis. The trial will screen 30,000 participants over the course of several years. Study clinicians use iPhones equipped with small microscopes to collect seven-second videos of blood samples obtained from study participants. At the end of each day, the videos are uploaded from the mobile devices to AWS, and a video analysis application is used to make a diagnosis.

The internet connection at the laboratories was insufficient to handle the video uploads. A team from the US and Mali visited the Yaoundé site and deployed an integrated system developed by OCICB to optimize network connectivity at remote research sites which lack access to reliable technical support. The system uses cloud managed antivirus, patch management, routers, and wireless access points. Improved service from the internet service provider was also negotiated.

Sidy Soumare evaluating line site for potential methods of microwave wireless connectivity for the NIAID collaborating partner, Centre de Recherche sur les Filarioses & Autres Maladies Tropicales (CRFILMT).

Network backbone for Centre de Recherche sur les Filarioses & Autres Maladies Tropicales (CRFILMT)

CLINICAL DATA MANAGEMENT SYSTEM RANDOMIZATION TOOL

OCICB developed a fixed randomization solution (sequential allocation, also allowing stratification) that integrates with the clinical data management system (CDMS) and complies with regulatory requirements while also leveraging the benefits offered by Interactive Voice/Web Response Systems (IVRS/IWRS). The solution maps to the established randomization process and runs within the workflows of the CDMS itself, providing participant randomization based on both inclusion and protocol criteria.

The system protects the randomization tables from unintended user access, change control testing, and ensures that it meets the regulatory requirements. In addition, the design can accommodate blinded randomization schemas, patient eligibility checks, data consistency checks, 'system' access control, and protection of the data post randomization.

The IBRSP randomization solution maps the digital process of randomization to the regulatory framework such as GCP and 21 CFR Part 11, and includes user authentication, audit trails, and reporting tools. It will accommodate the collection of randomization data as part of the CDMS ensuring that the workflow is contained within the same system. It thereby simplifies the randomization process, reducing interfaces between multiple systems and ensures a more streamlined and easily validated solution.

REDCAP SERVER PROJECT FOR MOBILE DATA COLLECTION

A pilot project, in collaboration with DCR, has been ongoing for several years using tablets and smartphones (also known as multi-functional devices, or MFDs) for data collection in remote locations. The objective is to collect data for clinical trials and non-interventional protocols using MFDs in remote locations while maintaining full compliance with GCDMP and the FDA 21CFR part 11, and with ethical and regulatory guidance from the NIAID DCR Office of Clinical Research Policy and Regulatory Operations (OCRPRO).

There were two simultaneous urgent requests for mobile data capture in FY16.

The Laboratory of Malaria Immunology and Vaccinology has a number of studies running in the Ouelessebougou area outside of Bamako, Mali. They needed a census of all study participants but previous efforts using tablets experienced synchronization issues. They requested a solution that would enable offline data collection using the same Android tablets; the data collected included identifiable source data.

OCICB installed two instances of the mSource, one in the Mali ICER data center and one in the AWS Cloud. Study source data, often containing names, birthdates, and addresses, resides at the clinical site in the country of origin. The tablets in the field collect data and upload it to the ICER Data Center. The data is then de-identified and exported into the OCICB CDMS where it can be used by the several protocols operating from the Malian cohort.

The Laboratory of Parasitic Diseases planned to conduct an interventional clinical trial in Cameroon that would test the effectiveness of the Novartis drug Imatinib against the Loa Loa parasite, which causes the loaiasis condition. OCICB was testing REDCap (Research Electronic Data Capture) as a possible replacement for the current mSource solution, with promising early results.

The Imatinib Study was intended to precede an observational Bill and Melinda Gates Foundation study which uses video microscopy to identify Loa Loa infections in the same cohort in Yaoundé, Cameroon. However, NIAID lacked server infrastructure in Cameroon. OCICB established a two server model based in the AWS cloud. One server will contain source data for studies in countries that lack infrastructure and therefore allow data to reside

outside of national borders. The other server model will be used for non-source data collections. Unfortunately, after strenuous efforts to meet an aggressive timeline, regulators in Cameroon cancelled the study. However, on a positive note, investigators are exploring using the same protocol in another country.

REDCap promises to be a useful tool for mobile and web browser based electronic data collection. Forms management is easier than many other solutions tested and the tool is relatively simple to deploy. It will be integrated into the Virtual Organization suite of tools for international research collaborations over the course of the next year. It is free for use by members of the consortium and its development and support is sponsored by the NIH and NCRR.

CLINICAL DATA INTERCHANGE STANDARDS APPLIED TO A CLINICAL DATA WAREHOUSE

OCICB provides clinical research data management tools for almost 100 active protocols. A number of them are interventional clinical trials but most are longer running, observational or natural history investigations that require continuous management and oversight by scientific investigators and their study coordinators to ensure the data is accurate and consistent.

The Clinical Data Warehouse (CDW) project provides a standardized database to house data from multiple research protocols that reside in study-specific databases on other CDMS, LIMS, or picture archiving and communication systems used in medical imaging technology. The Extract-Transform-Load (ETL) process from the CDMS consolidates the data and standardizes the format to populate the warehouse. The ETL process maps the data using the CDISC standards and loads it into the warehouse, which is based upon the Study Data Tabulation Model (SDTM).

Our clinical data warehouse provides data managers, study coordinators, investigators and sponsors with a central standardized electronic system for analyzing and monitoring study progress. It has user access and security mechanisms to make sure that unauthorized individuals cannot access study data. Research staff interact directly with the warehouse and can customize data queries to understand and make informed decisions for the ongoing health and safety of research participants. The use of the SDTM data model also affords effective archiving, data exchange and interchange with other systems, and promotes efficient development of study reports to the FDA or other regulatory authorities.

Data warehouses consolidate data from multiple data sources in a consistent way, even when the operational data is formatted, stored and maintained in many different ways. This approach affords the separation of decision support functions from data collection and data quality management systems. It also enables internationally recognized common data standards for data exchange, integration, and regulatory reporting.

Research organizations and publishers increasingly require that investigators release or share data using publically accessible repositories, such as clinicaltrials.gov, that are based on diverse data models. The SDTM-based warehouse will simplify publication to these public repositories and make data sharing more efficient. SDTM warehouses facilitate building standard data visualizations and clinical study reports. The increasing use of standards also reduces training required for data managers and visualization designers because of widespread access to workshops and existing SDTM resources.

For academic research communities in low- to middle-income countries that operate with limited budgets, use of open-source systems provides a low cost solution. The warehouse solution leverages widely accepted open-source tools to provide a model that other institutions can use without additional licensing costs. The OCICB clinical data warehouse uses the following open-source tools.

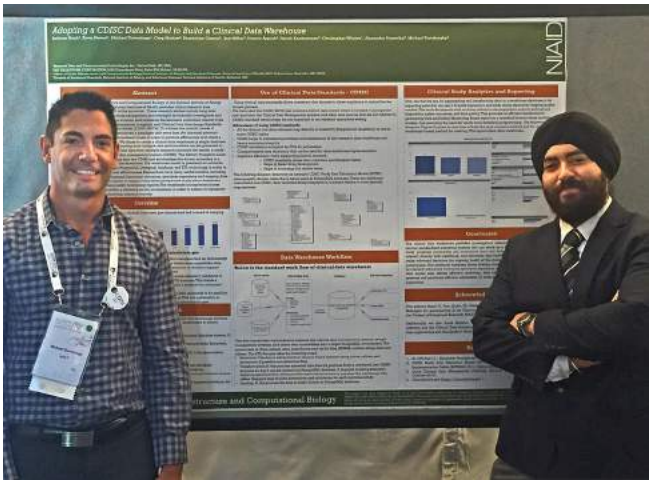
- PostgreSQL database: PostgreSQL is a powerful open-source object-relational database system. It runs on all major operating systems, including Linux and UNIX.
- Pentaho data integration: Pentaho open-source community edition delivers powerful ETL capabilities.
- Red Hat Enterprise Linux 6.7: the open-source version is freely available as CentOS 7 and is virtually identical in capabilities and features.

The CDW serves as a standard starting place to layer specialized analytics and reporting tools such as data visualization applications and centralized study reporting. This includes clinical study reports such as those related to demographics summaries, enrollment trends, patient safety outcomes and accrual and disposition as well as page counts and data quality indicators. CDW provides a standard system for creating data and safety monitoring board (DSMB) reports, reducing the need for sophisticated statistical programming skills to produce customized reports on a study-to-study basis.

Standard vocabularies for clinical research data provide a consistent data format to streamline the review process for data managers, clinical team members, statistical analysts and regulators. It promotes patient safety through the standardized model during trials by reducing the possibility of confusion and ensuring that trial results can be analyzed accurately. Standards are also important since they facilitate aggregation of data to improve signal detection and drug safety.

The data warehouse strategy to meet CDISC compliance has proven to be an efficient centralized solution that affords us to

meet the FDA submissions requirement for multiple protocols, and in addition has the benefit of structuring research data into a standardized relational database format. From this substrate, multiple useful downstream analytic business lines can be deployed to support the various requirements and goals of the clinical researchers we support.



Winning SCDM Poster presented by Jaskiran Singh.

Rocky Mountain Laboratories Program And Project Initiatives

Network Restructuring

Twenty-four new network closet switches were deployed, replacing end-of-lifecycle hardware, in an effort that spanned from late FY15 to early FY16. Because this project impacted all RML personnel, OCICB worked closely with the RML community to reduce service interruptions. The results of this project will provide network stability for years to come.

Additional 10GB paths were provided to the RML Research Technologies Branch (RTB) Genomics Lab desktop computers, enabling the bioinformatics team to analyze data on their local systems.

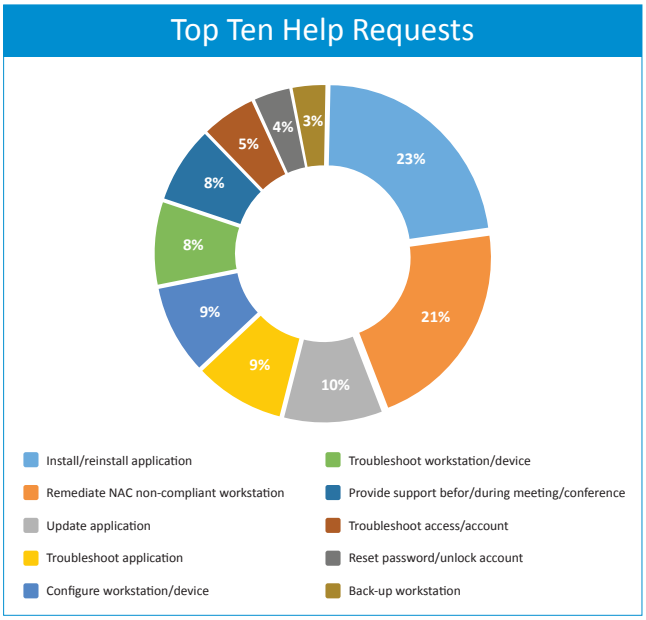
The RML network consisted of one single subnet that served all network devices. This meant that these devices were at risk if a network interruption or malware incident occurred. With the upcoming Lync deployment, the network needed to be broken down into multiple networks. Emergency 911 calls must provide location information; a single campus network would not provide this. OCICB engineers determined how to create multiple networks based on the buildings. RML now has 44 user equipment networks which allow for precise management, as well as greater location accuracy for emergency purposes. As part of this process, new Dynamic Host Configuration Protocol (DHCP) scopes were established for all the buildings. All computers then had to receive new IP addresses from the newly established IP ranges. All printers were manually reconfigured and isolated onto their own network.

VoIP Phone System Pre-deployment Preparation

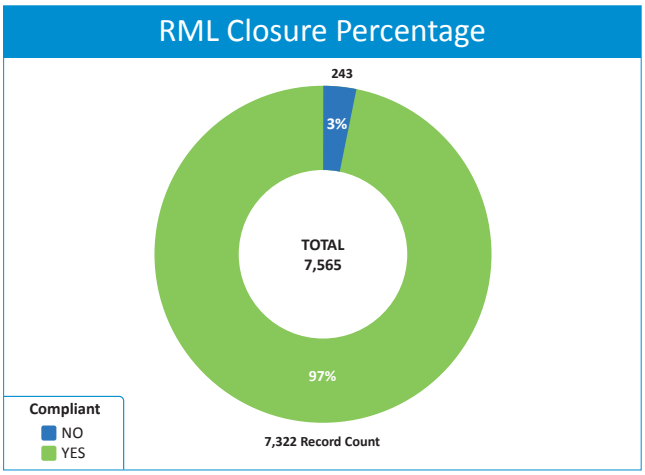
OCICB documented and prepared 600 phone lines at RML for the switchover from the current telephone system to the NIAID Lync Unified Communications infrastructure. In order to remain operational should a disruption occur between the RML and Bethesda campuses, a survivable branch appliance (SBA) was installed. This will allow IP-based phones, faxes, and emergency communications to continue to operate during an outage between campuses. The RML Security Control Center (SCC) is required to record all incoming calls, therefore plans call for the installation of multiple servers capable of meeting this need. A failover system located in Bethesda is in testing to provide redundancy.

RML Desktop Support

Technical assistance is an essential RML support component. In FY16, the desktop support team processed over 7600 requests for assistance. Of those requests, desktop support technicians were able attain a closure rate of three days or less 97% of the time; the majority of requests were resolved on the same day.



Top 10 RML help requests by Category.



Percentage of RML Tickets closed on time

The preponderance of support requests were due to application installs or network access control (NAC) compliance remediation. Thirty percent of the requests were to install or troubleshoot application issues, and 21% were to remediate NAC non-compliant workstations.

Projects completed this year include:

1. Upgraded Windows XP operating systems to Windows 7
2. Upgraded Mac personal computers to OS 10.11.x
3. Continued remediating NAC compliance issues.
4. Prepared IAMB and AMOB PCs for an upcoming NBS upgrade that requires newer versions of Java.
5. Remediated System Center Configuration Manager (SCCM) client issues. SCCM facilitates the management of client computers across the NIAID computer network. It is used to deploy new or updated software and install security updates. It also facilitates imaging new computers with a standard configuration for system uniformity.
6. Developing a new VPN SOP for teleworkers. Some personnel require cellular hotspots to perform their telework duties. The SOP provides guidance to telework employees that use this option.

RML Consolidated Computational Research Facility

In the third phase of NIAID's Network Consolidation Plan, the contract to build a Consolidated Computational Research Facility (CCRF) was awarded. This project entails renovating existing spaces in RML's Building 31 to create a 2500 square feet space for the RML compute infrastructure. Multiple RML server rooms will be combined on the first floor into space previously occupied by IAMB and Visual Medical Arts (VMA). The CCRF will feature a modular design that will allow flexibility and provide the needed redundancy in power and cooling for future expansion.

The two existing server rooms are now full, with limited-to-no room for expansion. Data storage capacity trends which currently average six TB per month are expected to increase to over ten TB per month in the next year due to an increased need for computational analysis.

In order to free up space for the CCRF, additional remodeling projects in three buildings were required. OCICB was involved in the network and telecom portions of these renovations, to ensure sufficient connectivity in office spaces to meet the needs of the occupants. These projects were completed in September and OCICB facilitated moving administrative staff into these spaces.

The project has an expected completion date in mid-summer 2017.

Security Control Center ICS 201

The addition of an RML Emergency Manager introduced new documentation requirements. The Incident Command System (ICS) 201 form is crucial for multi-jurisdictional incidents; it is used to brief arriving resources. OCICB leveraged work done last year for the NIH Police Logging Application to update the Police database and create a pre-formatted merge document. The Emergency Manager can print out a current ICS 201 form for arriving personnel. This process has proven successful during several training events held in coordination with RML First Responders, regional HazMat, Public Health, local law enforcement, NIH Police, and the Federal Bureau of Investigation.

Media Lab Supply Center

The RML Media Lab is a Life Technologies supply center serving the scientific community. A decision was made to use the RML Stockroom platform to manage inventory for the Media Lab in order to reduce cost. The result is an online real-time inventory and price list with product and user management, purchase and credit functions, and a full suite of reports including Excel exports that are sent to IAMB.

Research Technologies Section Project Tracking (Gateway)

The RTB and the RML Research Technologies Section (RTS) track core projects from initiation onward; however pre-project requests and workflows with relevant meta-data, samples, and technological considerations were being handled by the individual RTS groups. The new RTS Gateway application provides a centralized user-friendly interface for documenting and track-

ing these items, along with group specific sections for more relevant individualized data. A common RTS identifier is used in addition to the group identifiers to facilitate tracking samples as they progress across the four RTS groups as well as for administrative auditing purposes.

High Performance Computing

Infrastructure Changes

RML HPC reached a milestone this year with the retirement of the 600 TB EonStor iSCSI data store. Configured as two 300 TB mirrored arrays, the Eonstor infrastructure provided a critical bandage for the RML HPC infrastructure at a time when our computational resources and users engagement with them were growing more quickly than had been anticipated. Thanks to the EonStor, the storage requirements of our computational clients were met while we simultaneously installed and configured the Data Direct Network's infrastructure that now replaces it.

Spacewalk Repository

Another milestone was reached this year with the deployment and configuration of the Open Source repository management suite: Spacewalk. The application, which is the upstream model for RedHat Inc.'s Satellite, provides an atomic administration of software bug fixes, security updates, and enhancements, and equally important, reduces network traffic over the outbound network links. All RedHat and CentOS hosts now pull software updates directly from the local RML spacewalk infrastructure, rather than reaching out to public mirrors, reducing bandwidth usage by terabytes.

Splunk

Usage of the Splunk data-mining application has increased for day-to-day real time HPC servers logging. Effective real-time parsing of thousands of log messages for error and threshold events has proven key in detecting hardware and software anomalies before they manifest themselves as system failures and downtime.

ERGO2

A decade-long relationship between RTB and Igenbio Inc. recently entered a new phase, with the delivery and installation of the ERGO (v2) System biology informatics toolkit for comparative genomics. Widely used by RTB's NIAID customer base, the Ergo (v1) web application is beginning to show its age since its deployment nearly 10 years ago. The new ERGO (v2) application was installed, configured, tested, and presented to a representative sample of RML users over a three-day period.

A Prototype Method For Functional Clustering Of Protein Sequences

Current methods of sequence analysis rely heavily on sequence alignment. While this may be correlated to biological function, it is not always an accurate determinate of biologically functional similarity. Given the small size of viral genomes, every amino acid is important for protein function. Small differences between amino acid sequences can result in drastically different disease outcomes. Researchers in the RML Laboratory of Virology (LV) identified a previously described method, known as the Resonant Recognition Model (RRM), which measures physicochemical attributes of biomolecules in an attempt to more accurately cluster amino acid sequences based on biological function.

Members of the NIAID Laboratory of Virology were interested in employing an adaptation of the RRM in their analysis of viral pathogenicity determinates. RML LV scientists and OCICB staff collaborated to develop an adaptation of the RRM method in the R programming language.

Aerial view of the Rocky Mountain Laboratories Campus, Hamilton, Montana

Organizational Overview

BIOINFORMATICS AND COMPUTATIONAL BIOSCIENCES BRANCH (BCBB)

BCBB drives innovation in biomedical informatics at NIAID for global health clinicians and researchers by fostering a pipeline of products, platforms, and solutions. The BCBB partners with clients in the research process by applying bioinformatics and computational biology methods to generate new hypotheses and data, analyze existing data, and ultimately elevate the use of these methods and resources throughout the NIH. While BCBB services and resources are tailored to meet the needs of the NIAID intramural and extramural research communities, the branch regularly engages in formal collaborations with other NIH Institutes.

The BCBB staff consists of an integrated team of computational biology specialists, bioinformatics software developers, and operations support staff, which includes project managers, business and infrastructure analysts, and communications and design specialists. Each BCBB project is completed with input from a specialized team that contributes interdisciplinary expertise.

CLINICAL AND MEDICAL INFORMATICS PROGRAM (CMIP)

CMIP was chartered to promote the use of tailored information technology and business computing solutions that advance the NIAID mission. The branch provides planning, acquisition, execution, and support for information resources to enhance clinical research and medical health care practices. Strategic IT planning and project oversight for the NIAID CRMS, coordinating initiatives across NIAID, developing business cases, ensuring compliance with the HHS Enterprise Performance Life Cycle and NIH policies, and managing projects costing over $10 million annually are the purview of this branch.

The main goals of CMIP are:

- Increase efficiency and effectiveness of clinical research
- Strengthen safety and pharmacovigilance monitoring
- Improve data quality, integrity and stability
- Strengthen regulatory compliance and development of evidence-based clinical research policy
- Harmonize and standardize towards interoperability and eliminate redundancies
- Help accelerate the ability to capitalize on scientific opportunities
- Support cross-division reuse of software applications for greater returns on investments
- Allow for the retention of corporate knowledge
- Provide comprehensive, consistent, and lucid reporting for better regulatory compliance
- Provide “similar” experience to investigators across participating divisions

CMIP implemented plans to support greater awareness about branch operations through an increased availability of data, enhanced tools and communications to disseminate data, and to provide greater context and understanding about the meaning of data. Analytical reports are utilized to measure and improve service, program and project delivery performance. The use of clinical and medical informatics tools and methods in order to improve the effectiveness and efficiency of clinical and medical research within NIAID is actively promoted.

CUSTOMER SERVICES BRANCH (CSB)

CSB provides technical and tactical cyber technologies management and technical support for NIAID biomedical research and administrative communities. The Central Service Desk offers a single point of contact for assistance with information technology related issues, including remote and desk-side support. Problems that require specialized knowledge are passed to the appropriate team, i.e., Desk-Side Support, Workstation Procurement, IT Service Management, MTDs, Video Conferencing, and Training. CSB teams procure, configure and disseminate laptops and workstations, manage MTDs, support videoconferencing, and provide training on Skype for Business, Excel, and other commonly used applications.

The CSB team continually evaluates and integrates new ideas, processes, and technologies into its operations to ensure that NIAID receives the highest quality of service in the most expedient manner possible.

CYBER SECURITY PROGRAM (CSP)

CSP is responsible for protecting data, information and information resources from unauthorized access that might threaten the security of NIAID information technology resources. CSP accomplishes this through the development, implementation and maintenance of information security processes such as security risk assessments, secure technical architecture designs, vulnerability management, security governance, and business continuity and disaster recovery management. CSP is also responsible for oversight-oriented operational processes, such as incident management and response.

Security personnel work to ensure that NIAID adheres to federal information security laws, regulations and guidance. The branch is comprised of two main functional areas: Risk Management, and Oversight and Management. Risk Management is broken out into two sub functional areas: Digital Forensics and Incident Response, and Infrastructure Oversight. Oversight and Management is broken out into two areas: Governance and Compliance.

GLOBAL BIOMEDICAL RESEARCH SUPPORT PROGRAM (GBRSP)

Consisting of two arms, the Rocky Mountain Laboratories (RML) and the International Biomedical Research Support Program (IBRSP), GBRSP provides cyber and information technology and biomedical research support functions to diverse stakeholders around the globe.

ROCKY MOUNTATIN LABORATORIES

The RML team consists of specialists who provide on-site support and expertise to the Hamilton, Montana campus for a wide variety of technologies, including software training, desktop support for hardware and software issues, server administration, network infrastructure, enterprise storage and backup, telecommunications management and high performance computing. Collaborations with Bethesda-based OCICB branches provide an extension of services, technologies, and expertise to the RML facility, thus offering immediate local support and experience in conjunction with the in-depth knowledge available from all of the OCICB teams.

The Integrated Research Facility (IRF) located on the RML campus houses active Biosafety Level 4 (BSL4) containment laboratories. The nature of the research conducted in the BSL4 environment provides unique opportunities for close collaborations between GBRSP/RML and local scientific staff.

INTERNATIONAL BIOMEDICAL RESEARCH SUPPORT PROGRAM

The International Biomedical Research Support Program (IBRSP) has two teams; the first supports cyberinfrastructure for global research and the second manages data tools used by researchers for human clinical trials and translational research in remote regions. The cyberinfrastructure team consists of experienced computer technicians, network engineers, operations staff, and project managers who work in multiple regions around the world, including South America, West Africa, East Africa, South Asia and East Asia. This global group designs, integrates, installs, and provides ongoing operations support for data and communication solutions.

The clinical research support team operates a fully validated and 21 CFR Part 11 compliant environment for human translational research. A clinical data management system located in the NIAID data center supports international collaborative protocols, facilitating legacy paper data collection, electronic collection, and mobile devices. Our specimen and chemical compound-tracking tool helps research teams locate and label aliquots, drugs, and vaccines in freezers and cryogenic storage systems throughout the world. A temperature monitoring system covers the freezers, refrigerators, liquid nitrogen storage tanks, and incubators at the major collaboration sites in Mali, Uganda, India, and China. OCICB International offers a full suite of support services including training, mentoring, and operational management. Working closely with researchers and administrators, IBRSP specialists ensure that collaborative data and tissue samples obtained in resource-poor regions are safe, secure, accessible and compliant with applicable regulatory requirements.

The infrastructure team constructed satellite networks for field laboratories and clinics in Sub-Saharan Africa that lack other communication options, enabling electronic submission of clinical research data to remote data management systems. In addition to data access solutions, IBRSP delivers voice and video conferencing, email, and Web collaboration tools for centers located in low- to middle-income regions.

The IBRSP clinical support team collaborates with investigators, monitors, and regulatory teams, as well as data management staff, to select the best case report form delivery system, whether it be paper, electronic, mobile, or a combination of these options, depending on the geographic location, available infrastructure, and the protocol requirements. The program offers best practices for clinical data management, procedures and workflows including opportunities for standardization with the goal of providing clinicians, sponsors, and investigators the highest quality datasets.

OPERATIONS AND ENGINEERING BRANCH (OEB)

OEB architects, implements, maintains and supports NIAID infrastructure essential to meeting the complex computing requirements of the institute. They manage our high-speed network, the two NIAID computing facilities (the Research and Development Computing Facility and the APF), a storage and backup infrastructure capable of hosting over 5 Petabytes of storage, a server infrastructure composed of over 1,000 servers ranging from state-of-the-art virtual servers to legacy devices, the Unified Communications infrastructure that support the NIAID phones and video conferencing services, and the High Performance Computing environment. They also provide application hosting, database administration and workstation development services.

OEB has a constant focus on continuity of operations planning and on protecting the NIAID network and data produced by NIAID staff. Their security team proactively manages network firewalls, monitors network activity, and evaluates and deploys security measures. OEB operates the NIAID APF, a secondary computing facility that can host most of NIAID's critical applications and shared network drives, and which may be activated when the main NIAID computing facility is compromised. They ensure that data is replicated to the APF according to approved schedules and that the APF facility is ready to be activated at all times so that the impact of potential infrastructure disruptions on NIAID activities is alleviated.

PROGRAM MANAGEMENT BRANCH (PMB)

PMB provides OCICB with its technology management governance framework, ensuring that NIAID is compliant with federal technology-related laws, regulations, and policies. PMB leads and coordinates strategic and program planning and provides resource administration for OCICB. PMB team members plan, monitor, and evaluate OCICB programs, oversee information technology management contracts, monitor commitments, and ensure that business flows smoothly. PMB staff work closely with the Office of the Chief Information Officer to specify management metrics, and implement processes and procedures for OCICB. PMB also provides oversight for OCICB technology maintenance and licensing agreements.

PMB works to enhance the professional development of OCICB personnel by promoting and providing project management training opportunities. The branch provides the quality assurance component for programs and performance assessments. PMB also serves as the communications arm for the CIO's office, seeking to inform NIAID stakeholders of available OCICB resources.

SOFTWARE ENGINEERING BRANCH (SEB)

SEB delivers expert technical application development services for NIAID. Professional project managers guide software development teams that provide customized business specific solutions to automate and streamline Institute processes. Experienced designers and software engineers provide a vital asset to NIAID by creating easy-to-navigate user interfaces ensuring robust, responsive, and secure applications.

SEB project managers and analysts collaborate with NIAID customers to analyze and document guidelines and processes, identify workflows, and ascertain project requirements. This in-depth collaboration ensures the resulting software products meet the needs of the Institute. SEB utilizes a proven software development methodology and quality assurance process to manage project risk and produce high-quality solutions. Whether working with one-of-a-kind, highly customized applications or tailoring off-the-shelf commercial packages, SEB strives to ensure that all clients have the best solutions possible to meet programmatic needs.

Senior Staff Biographies

MICHAEL TARTAKOVSKY

NIAID CHIEF INFORMATION OFFICER
DIRECTOR, OCICB

Michael Tartakovsky is the NIAID Chief Information Officer and Director of OCICB. He provides strategic leadership and technical direction for the modern, secure, high-performance infrastructure that supports the NIAID biomedical research mission. Mr. Tartakovsky is a member of the NIAID Executive Committee, co-chair of the NIAID IT Investment Review Board, and is responsible for the NIAID IT Capital Planning and Investment Control process. He establishes and directs long-term goals, policies, and procedures for the NIAID technology infrastructure.

During the last 15 years, Mr. Tartakovsky has held progressively more responsible positions at the NIH. In addition to implementing new and expanding technologies at NIAID, Mr. Tartakovsky undertook the reorganization of the Office of Technology Information Systems that led to the formation of OCICB. He also established the NIAID OCICB Bioinformatics and Computational Bioscience Branch, articulating strategic collaborative goals and communications initiatives that emphasized the cutting-edge role of bioinformatics and computational sciences and technologies.

Mr. Tartakovsky holds a B.S. in Engineering from Azerbaijan Civil Engineering University and a Master's certificate in Project Management from George Washington University.

ALEX ROSENTHAL

CHIEF TECHNOLOGY OFFICER
DEPUTY DIRECTOR, OCICB

Alex Rosenthal has been leading information technology projects on behalf of the NIH since 1994, during which time he has received many awards and held various positions. In 2006, he became NIAID Deputy Chief Information Officer and the Deputy Director for OCICB. In 2013, to address the critical need to keep up with the rapidly changing cyber infrastructure landscape and to maintain NIAID technical excellence, Alex took on a new senior level role as the Chief Technology Officer. In this role, he manages a wide spectrum of bioinformatics, application development, IT security, and infrastructure activities.

Mr. Rosenthal had the distinction of being the first Director of the NIH CIT Division of Enterprise and Custom Applications (DECA), where he led development and support efforts for NIH software applications that included ITAS, the NIH Data warehouse, and NIH Login. Prior to joining CIT, he was the first branch chief for SEB, where he led development efforts for a number of Web applications some of which were used NIH-wide and some that were later adapted by IMPACII.

Mr. Rosenthal has an M.B.A. from Loyola University in Baltimore, a B.S. and an M.S. in Applied Mathematics from the Baku State University, and a Master's Certificate in Project Management from the George Washington University. He is a graduate of the NIH Senior Leadership Program delivered by the University of Maryland, School of Public Policy.

JOE CROGHAN

CHIEF, SOFTWARE
ENGINEERING BRANCH

Joe Croghan joined NIAID in July 2009 as the chief of the Software Engineering Branch (SEB) where he directs systems and software applications development. Since joining NIAID, Mr. Croghan has initiated the business intelligence program resulting in increased automation of NIAID's business processes. Under Mr. Croghan's direction, SEB has moved to an Agile development methodology resulting in a more responsive and flexible software development approach. Prior to joining NIAID, Mr. Croghan was Vice President of Client Operations at 5AM Solutions, where he managed programs that built systems for agencies such as the National Cancer Institute, the HHS Office of the National Coordinator for Health Information Technology, and the Translational Genomics Research Institute. He has extensive experience developing and managing software and technology at companies such as Booz Allen, Pricewaterhouse and Cysive.

Mr. Croghan holds a B.S. in Systems Engineering from the University of Virginia with a concentration in Management Information Systems, and an M.S. in Systems Engineering from the University of Virginia with a concentration in Operations Research. He also obtained an Executive Leadership Certificate from The American University School of Public Affairs.

KEN GROSSMAN

INFORMATION SECURITY OFFICER

Ken Grossman has worked in the information security field for more than 15 years and has been instrumental in various major security initiatives. He was a founding member of the Department of Homeland Security's National Cyber Security Division/ United States Computer Emergency Readiness Team (US-CERT). He joined OCICB in 2006 where he manages the NIAID Cyber Security Program. Ken oversees the handling and mitigation of NIAID information security events. He also ensures that NIAID adheres to Federal security policies and guidelines. He develops NIAID information security policies and training programs and is the liaison with the NIH and other Institutes security programs

Mr. Grossman has an M.S. in Computer Systems Management from the University of Maryland University College and a B.S. in Aerospace Engineering from Virginia Tech. His certifications include Certified|Chief Information Security Officer, Certified Information Systems Security Professional, Certified Information Security Manager, and Certified Ethical Hacker, and GIAIC Certified Incident Handler.

KIM KASSING

ASSISTANT DIRECTOR FOR TELECOMMUNICATION AND INFRASTRUCTURE RESEARCH

As a senior advisor to OCICB management, Kim provides expertise, guidance, and consultation on the development and integration of IT infrastructure and telecommunications technologies in support of the complex scientific and biomedical research conducted or sponsored by the Institute. Kim is also responsible for identifying, researching, and reviewing major infrastructure and telecommunications projects. He evaluates advances in technologies, anticipates future growth areas, and conducts expert technical reviews of complex IT infrastructure solutions needed to support basic, translational, pre-clinical, and clinical research. He works closely with OCICB senior staff in leading research on new products, product enhancements, and product redesign to align the product development function with the research goals of the Institute and recommend the adoption of new technologies.

Mr. Kassing cut his teeth in IT as a contractor serving the federal government, including NIH, during the eighties. He was one of the very first experts in network technologies. After deploying networks across much of the federal government, Mr. Kassing joined NIAID in 1991 where he managed a number of different IT functions before taking on his current role.

Mr. Kassing has a B.S. in Psychology from Guilford College. He has significant training and experience in information systems, including hardware, security, forensics, networking, switching, routing and operating systems.

CHARLIE STONE

PROGRAM DIRECTOR, CLINICAL AND MEDICAL INFORMATICS PROGRAM

Charlie Stone, a Health Science Administrator, is Director of the Clinical and Medical Informatics Program. He provides strategic IT planning, implementation, operations, and project oversight for the various divisional systems comprising the NIAID Clinical Research Management System. Prior to NIAID, Charlie served in both the FDA and the DHHS Office of the Assistant Secretary for Health (OASH). His last position was in the FDA Center for Drug Evaluation and Research's Office of Surveillance and Epidemiology as Associate Director for Post-Marketing Surveillance Systems. In this capacity, he served as the business Program Manager for the development and implementation of strategic plans for drug adverse events reporting.

Mr. Stone's career includes serving OASH as a software developer and systems analyst and in the FDA Center for Veterinary Medicine as the Director of Information Technology Services. In addition to positions in program management and information technology, Charlie was a Research Physiologist at the FDA. Charlie brings valuable experience in the areas of personnel management, contracting, budget execution, strategic planning, business case analysis, scientific research, business program management support, and computer systems operations, development and implementation to NIAID.

CHRIS WHALEN

PROGRAM LEAD, INTERNATIONAL BIOMEDICAL RESEARCH SUPPORT PROGRAM
RESEARCH DATA & COMMUNICATION TECHNOLOGIES CORPORATION

Chris Whalen has provided information technology and communication systems support for biomedical research at various national and international medical research facilities since 1995. Currently, he leads the OCICB International Biomedical Research Support Program (IBRSP). Mr. Whalen has an appreciation for the specialized IT needs of researchers in the field, and focuses on identifying, developing, and implementing IT infrastructure and service solutions to assist them. He began supporting research efforts in low- to middle-income countries in the late 1990's and has since focused much of his efforts on the NIAID International Centers for Excellence in Research in Mali, Uganda, and India. In recent years, his attention has been directed at meeting the data collection and validation needs of clinical researchers working in regions with poor infrastructure (including the use of mobile technologies) while also adhering to international standards and regulations, such as those of the FDA and the International Conference on Harmonization (ICH).

Mr. Whalen's IT experience ranges from network infrastructure, data storage, information life cycle management, electronic mail systems, directory services, and IT project management, to the IT Infrastructure Library (ITIL). He holds a B.A. in Economic Theory and an M.A. in Applied Economics from American University.

ARNE FLEISHER

CHIEF, OPERATIONS AND ENGINEERING BRANCH

Arne Fleisher has served as the Chief of the Operations Engineering Branch since 2012, leading an organization of over seventy engineers and administrators dedicated to the operation and support of the NIAID bio-computational infrastructure. He joined NIAID in 1999 as a LAN administrator, and quickly became responsible for supporting and building infrastructure systems. He became a federal employee in 2002. Over the next several years, he served as the team lead of each of the OEB technical teams and gained in-depth experience in the various infrastructure technologies used at NIAID. He was also involved in the design and implementation of seven NIAID data centers.

As the OEB Branch Chief, Mr. Fleisher spearheaded the implementation of server virtualization, managed print services, unified communications, and the initial implementation of high performance computing and its FY15 upgrade. He led the implementation of two new computing facilities, the Alternate Processing Facility in Ashburn, VA, and the Research and Development Compute Facility at Fishers Lane, and oversaw the implementation of networking for the Fishers Lane building. He oversees the NIAID cybersecurity program, and implemented the OEB Vulnerability Management Program to streamline the NIAID response to cyber threats. He currently leads the Applications Hosting, Database Administration, Enterprise Storage, High Performance Computing, Networking, Security, Windows Server and Workstation Development teams.

DARRELL HURT, PH.D.

CHIEF, BIOINFORMATICS AND COMPUTATIONAL BIOSCIENCES BRANCH

Darrell Hurt, Ph.D. is Chief of the Bioinformatics and Computational Biosciences Branch (BCBB). He has been associated with OCICB since early 2006. He currently leads a staff of over thirty multidisciplinary federal and contract staff consisting of computational biology specialists, bioinformatics software developers, business and infrastructure analysts, and communications professionals. His scientific expertise is primarily in computational structural biology – including protein folding, docking, and molecular dynamics – all of which require high-performance computing techniques. Dr. Hurt also has special expertise in 3D printing, visualization, and modeling. His efforts at the NIAID have been recognized by various awards at the HHS, NIH, NIAID, and OCICB levels.

Before working at the NIAID, Dr. Hurt did postdoctoral work at the NIDDK in lipid signaling and cell trafficking using X-ray crystallography with Dr. James Hurley (now at Stanford). His educational background includes a B.S. in chemistry (computational emphasis, physics minor) with Honors from Brigham Young University and a combined M.S./Ph.D. in chemistry (biophysical emphasis) from Cornell University under the mentorship of Dr. Jon Clardy (now at Harvard Med). His doctoral work was recognized with the Pauling Award from the American Crystallographic Association and his work has been published in numerous prestigious scientific journals.

CHRIS OHLANDT

CHIEF, CUSTOMER SERVICES BRANCH

Chris Ohlandt joined NIAID in November, 2015, bringing nearly 30 years of private sector and federal customer service experience. He administers a staff of over 80 federal and contractor IT support specialists. Mr. Ohlandt oversees a broad portfolio of customer service operations, including the Central Service Desk, Deskside Support, Audio Visual Technology Support, Training, Workstation Acquisition, Mobile Telephone Device Acquisition, Workstation Procurement and Mobile Technology consulting. Prior to joining NIAID, Mr. Ohlandt served as a senior advisor to the NIH CIO for cloud technologies. He was the Director of the NIH CIT Division of Customer Support for more than 15 years, and served as a senior advisor on customer service to the NIH CIO. He led the NIH DCRT Communications Technology Section and implemented the first local area network and desktop support program at the National Eye Institute. He also worked for Microsoft as an Architectural Engineer and Sr. Systems Engineer, and was a customer service representative and computer programmer for the Stamford Water Company.

Mr. Ohlandt is a recipient of the HHS Secretary's Award for Distinguished Service, a number of NIH and CIT Merit Awards, the NIH OD Director's Award, the DCRT Director's Award, and the Microsoft Outstanding Achievement Award. He is certified in ITIL Foundations and COBIT and is an alumnus of the NIH Senior Leadership program and the Federal Executive Institute.

KRISTI SCHMIDT

TEAM LEAD, RML

Since 2001, Kristi Schmidt has led the IT support group that provides hardware, software, telecommunications, videoconferencing, Unix/Linux, and high performance computing support to more than 400 research, administrative, and support personnel at the NIAID Rocky Mountain Laboratories in Hamilton, Montana. She also directs IT support of more than 25 buildings and over 780 network nodes on the RML campus and is involved with the IT components of the Integrated Research Facility and associated BSL4 high containment laboratories. She is extensively engaged in RML construction and renovation projects.

Ms. Schmidt's tenure at RML began in 1986 when she was involved in the installation of RML's original network infrastructure. She holds a two-year certificate in Business Data Processing from the University of Montana. While the courses provided the fundamentals of software programming and general computer hardware, Kristi obtained much of the knowledge and skills on the job through experience, additional training classes, troubleshooting, and the numerous construction/renovation activities that occur on the RML campus.

Publications

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Gabrielian, A., Engle, E., & Juarez-Espinosa, O. (2016, October). Comparative study for classification of radiology images for Tuberculosis patients. Poster session presented at 2016 NIH Research Festival, Bethesda, Maryland.

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Economou, M. & Flanagan, H. (2016, September). "VO in Reverse - Federation for Campuses without IT Infrastructure." Presentation at Advanced Campus Architecture and Middleware Planning un-conference at the Internet2 Technology Exchange, Miami, Florida, 28 September 2016

Economou, M., & Thia, J.M., Phillips, C. (2016, September). "Federating SharePoint to Support International Research." Presentation at Internet2 2016 Technology Exchange, Miami, Florida, 26 September 2016.

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Singh, J. (2016, September). "Adopting a CDISC Data Model to Build a Clinical Data Warehouse." Presented at CDISC International Interchange, Bethesda, Maryland, 28–29 Sep 2016.

Whalen, C., Basney, J., & Koranda, S. (2016, June). "A Word from Our Customers – Virtual Organizations and the Need for Attribute Release." Presentation at Research and Education FEDerations group (REFEDS) meeting, Prague, Czech Republic, 12 June 2016.

Whalen, C., & Flanagan, H. (2016, March). "Research and Collaborations: Virtual Organizations for Collaboration at a West African Research, enter." West and Central Africa Research and Education Networks annual meeting, Authentication, Access, and Identity Track, Dakar, Senegal, 14 -18 March 2016.

Whalen, C., Short, H. Beddoes, B. (2016 September). "The Realities of Collaborative Research: Integrating COTS Products into FIM Platforms." Presentation at Internet2 2016 Technology Exchange, Miami, Florida, 26 September 2016.

AWARDS

Singh, J. (2016). First place in Poster Presentation (Adopting a CDISC Data Model to Build a Clinical Data Warehouse) at SCDM (Society of Clinical Data Management) Annual Conference, San Diego, California, 11 –14 Sep 2016

Tartakovsky, M., Rosenthal, A., Huyen, Y., Hurt, D., Whalen, C., Gloss, S., Keita, A., Bergman, A., Mahdessian, G., Zagaria, V. (2016) NIH Director's Awards (African Centers of Excellence in Bioinformatics in Mali), 19 July 2016 Ruth L. Kirschstein Auditorium at the Natcher Conference Center.

Acronyms

Acronym	Meaning
A	
ACD	Automated Call Distribution
ACE	African Centers of Excellence in Bioinformatics
ACTG	AIDS Clinical Trials Group
ACUC	Animal Care and Use Committee
ADaM	Analysis Data Models
AER	Adverse Experience Reporting
AIDS	Acquired Immunodeficiency Syndrome
AMBIS	Administrative Management Budget Information System
AMOB	Acquisitions Management and Operations Branch
AO	Administrative Officer
APF	Alternative Processing Facility
ARPS	Awards Recognition Processing System
ASP	Animal Study Proposals
AV	Audio-Visual
C	
CCRF	Consolidated Computational Research Facility
CDASH	Clinical Data Acquisition Standards Harmonization
CDISC	Clinical Data Interchange Standards Consortium
CDMS	Clinical Data Management System
CDMUG	Clinical Data Management User Group
CDW	Clinical Data Warehouse
CEO	Chief Executive Office
CIO	Chief Information Officer
CIT	Center for Information Technology
COO	Chief Operating Officer
CPR	Cardiopulmonary Resuscitation
CPU	Central Processing Unit
CRF	Case Report Forms
CRMS	Clinical Research Management System
CRO	Contract Research Organization
CROMS	Clinical Research Operations and Management Support
CRS	Clinical Research Site
CSB	Customer Service Branch
CSD	Central Service Desk
CSIO	Clinical Study Information Office
CTO	Chief Technology Officer
D	
DAIDS	Division of Acquired Immunodeficiency Syndrome
DAIDS INDs	DAIDS Investigational New Drug
DAIDS-ES	DAIDS Enterprise System
DAIT-CRIS	DAIT Clinical Research Information System
DCR	Division of Clinical Research
DEA	Division of Extramural Activities
DIR	Division of Intramural Research
DMC	Data Management Centers
DMID	Division of Microbiology an Infectious Diseases
DMID-CRMS	DMID Clinical Research Management System
DoED	Department of Education
DPRS	DAIDS Protocol Registration System
DSMB	Data and Safety Monitoring Board
E	
EAE	Expedited Adverse Events
eCTD	Electronic Common Technical Document
EDRMS	Electronic Document Records Management System
eSRS	Electronic Subcontracting Reporting System
ETL	Extract, Transform, Load
F	
FAES	Foundation for Advanced Education in the Sciences
FAQs	Frequently Asked Questions
FDA	Food and Drug Administration
FDR	Fourteen Data Rate, 14Gb/s data rate per lane
FHCRC	Fred Hutchinson Cancer Research Center
FOA	Funding Opportunity Announcements
G	
GB	Gigabyte
GCDMP	Good Clinical Data Management Practices
GCP/HSP	Good Clinical Practice/Human Subject Protection
GPFS	IBM's General Parallel File System
GPGPU	General Purpose computing on Graphics Processing Unit
GPU	Graphic Processing Units
H	
HIV	Human Immunodeficiency Virus
HPC	High Performance Cluster
HSTS	HTTP Strict Transport Security
I	
IAM	Identity and Access Management
IAMB	Intramural Administrative Management Branch
IBRSP	The International Biomedical Research Support Program

ICDDR,B	International Centre for Diarrheal Disease Research, Bangladesh
ICER	International Center for Excellence in Research
ICMR	Indian Council of Medical Research
ICs	Institutes and Centers
ICS	Incident Command System
IDI	Infectious Diseases Institute
IdPs	Identity Providers
IIG	Immunology Interest Group
IMPAC II	Information for Management, Planning, Analysis, and Coordination System
IND	Investigational New Drug
IRF	Integrated Research Facility
IT	Information Technology
ITPMS	IT Policy Management System
ITSM	IT Service Management

L

LAN	Local Area Network
LCD	Liquid-Crystal Display
LDAP	Lightweight Directory Access Protocol
LID	Laboratory of Infectious Diseases
LIMS	Laboratory Information Management System
LLP	Limited Liability Partnership

M

MACS	Multicenter AIDS Cohort Study
MC	Master Contact
MDR-TB	Multidrug-Resistant Forms of Tuberculosis
MedDRA	Medical Dictionary for Regulatory Activities
MFD	Multi-Functional Devices
MTD	Mobile Telecommunitcations Devices

N

NAC	Network Access control
NASA	National Aeronautics and Space Administration
NBS	NIH Business System
NCBI	National Center for Biotechnology Information
NEA	National Education Association
NGS	Next Generation Sequencing
NIAID	National Institute of Allergy and Infectious Disease
NIAID-CRMS	NIAID Clinical Research Management System
NICHD	National Institute of Child Health and Human Development
NIEHS	National Institute of Environmental Health Sciences
NIRT	National Institute for Research in Tuberculosis
NIST	National Institute of Standards and Technology
NLM	National Library of Medicine
NPARS	NIAID Planning and Reporting System
NSF	National Science Foundation

O

OA	Office of Acquisitions
OCGR	Office of Communications and Government Relations
OCICB	Office of Cyber Infrastructure and Comutational Biology
OCRPRO	Office of Clinical Research Policy and Regulatory Operations
OD	Office of the Director

P

PARIS	Personnel Action Request Information System
PB	Petabyte
PC	Personal Computer
PDA	Personal Digital Assistant
PDB	Protein Data Bank
PM	Protocol Management
PMB	Program Management Branch

R

RCDC	Research, Condition and Disease Categorization
REDCap	Research Electronic Data Capture
RDCF	Research and Development Computing Facility
R&D	Research and Development
RHSP	Rakai Health Sciences Program
RM	Regulatory Management
RIMS	Research Initiative Management System
RML	Rocky Mountain Laboratories
RPEWG	Resource Planning and Evaluations Working Group
RTB	Research Technologies Branch
RTS	Research Technologies Section

S

SAC	Standard Administration Code
SACCC	Statistical and Clinical Coordinating Center
SAE	Serious Adverse Event
SAIC	Science Applications International Corporation
SAML	Security Assertion Markup Language
SCDM	Society for Clinical Data Managers
SCORS	Scientific Coding and Referral System
SDCC	Statistical and Data Coordinating Center
SDTM	study data tabulation models
SGE	SUN Grid Engine
siLP	small intestine lamina propria
SIR	Scientific Information Request System
SME	Science Management Engineering
SOP	Standard Operating Procedures
SQL	Structured Query Language
SRDMS	Scientific Review Data Management System
SSS	Social and Scientific Systems
STEM	Science, Technology, Engineering and Math

T

TB	Terabyte
TCR	T-cell receptor
TLS	Transport Layer Security

U

UAB	University of Alabama at Birmingham
UGE	UnivaGrid Engine
USTTB	University of Science, Technique and Technologies of Bamako

V

VMA	Visual Medical Arts
VPN	Virtual Private Network
VRC	Vaccine Research Center
VRC-CRMS	VRC Clinical Research Management System
VTC	Video teleconferencing

W

Wi-Fi	Wireless Internet through a wireless router
WOPI	Web App Open Platform Interface Protocol
WRNMMC	Walter Reed National Military Medical Center


NIH
National Institute of
Allergy and
Infectious Diseases
DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
U.S. Department of Health and Human Services
National Institutes of Health
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