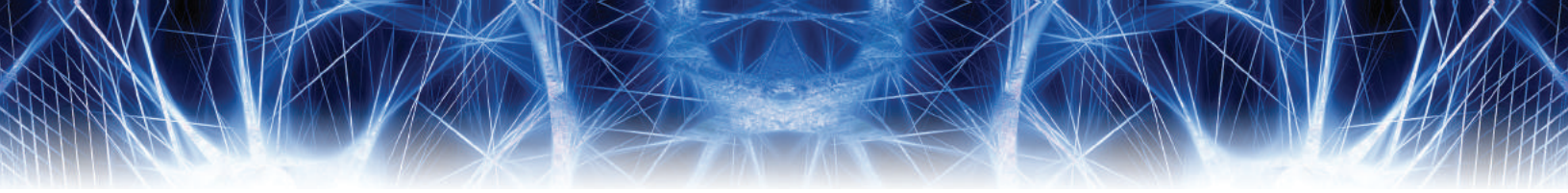
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

OFFICE OF CYBER INFRASTRUCTURE AND COMPUTATIONAL BIOLOGY

2017 ANNUAL REPORT



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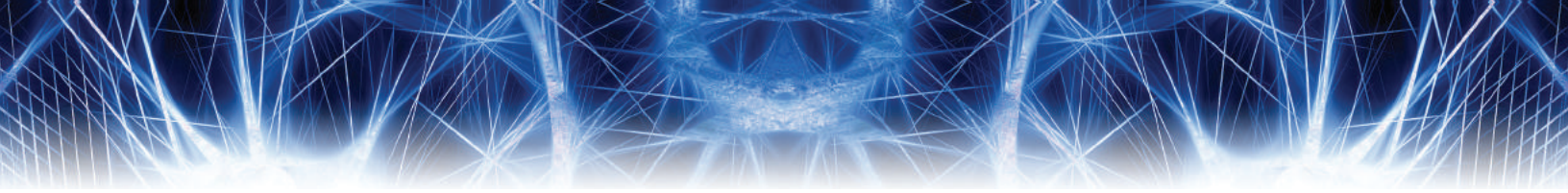


LETTER FROM

MICHAEL TARTAKOVSKY

NIAID Chief Information Officer
Director, OCICB

I'd like to welcome you to the 2017 OCICB Annual Report. The intent is to convey the work that we are doing here for NIAID with the hope that it will spur new and innovative ideas for how we, as an Institute, can utilize informatics and information technology to foster scientific discovery. This year's report is focused on the projects that had the broadest reach. I would like to highlight our work with the staff in the Tuberculosis Research Section of the NIAID Division of Intramural Research (DIR) Laboratory of Clinical Infectious Diseases. We provided an innovative technological infrastructure to support the large-scale PREDICT TB initiative. This is a global multi-site clinical protocol that explores the potential to reduce the treatment regimen for drug-sensitive TB patients.

The Department of Health and Human Services (HHS) issued a policy that required the NIH to encrypt all personally identifiable information data and storage media, which increased the complexity of the entire storage infrastructure. This resulted in updates and revisions to multiple storage systems within a short timeframe. We enabled encryption throughout the enterprise, adding an additional level of protection for the Institute.

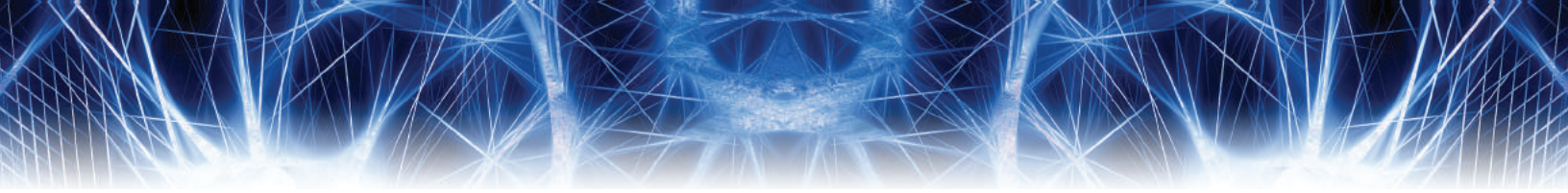
To advance NIAID intramural research, we collaborated with DIR to build the Genomic Research Integration System (GRIS), a web application that works with vast amounts of clinical and genomic data generated by translational genomics studies. GRIS capitalizes on resources generated from the NIAID Central Sequencing Initiative that aims to obtain whole exome sequences on all incoming NIAID patients.

We expanded usage of the Clinical Research Management System (CRMS), which supports scientific, administrative, and regulatory functions for NIAID-sponsored clinical research. Comprised of 27 modules, the system supports the management of external clinical research activities across the Institute.

And at the Rocky Mountain Laboratories, we upgraded the existing network fiber optic cabling and signal pathways to increase bandwidth and redundancy between buildings, providing additional pathways to expand the fiber backbone.

These projects represent just 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

In last year's CTO update, I discussed how OCICB is approaching the process of innovation. This time, I would like to review some of the most innovative solutions that OCICB delivered in 2017. Note that this is only a partial list. Because OCICB is a sizeable IT and informatics organization with broad responsibilities and a large operational component, there were too many exciting projects to include them all. Below, in no particular order, are four non-incremental innovative achievements that caught my attention.

Monarch. For several years, OCICB has been moving slowly but surely—mostly through the international program—into the cloud. We occasionally utilized SaaS cloud capabilities but focused typically on AWS-based IaaS. We moved to the next level with the introduction of Monarch. Our Office of Engineering Branch (OEB) designed, developed and implemented an enterprise-level capability to deliver services to NIAID, NIH, and the public. Monarch includes important aspects of development and operations, known as "DevOps." It incorporates modern technologies such as Docker and stays true to OCICB's IT security policies, all while providing a new way to deliver services and meet the spirit and the letter of the Cloud First federal initiative. Change management activities for Monarch were well planned out and seminars on Monarch helped to create momentum and a core group of the technology champions. You can read more about Monarch in the "Infrastructure and Service-Related Projects" section of this report.

Contract Planning and Execution (CPE). NIAID awards over $1B in multi-year research and development contracts annually. It has been a huge challenge to keep track of the related financials and execution activities. Government acquisitions are complex. Until now, amid diverse types of options and modifications, it was difficult to see how well NIAID was performing against the target because the target itself was hard to define. Recently, OCICB was approached by the Division of Microbiology and Infectious Disease (DMID) (for whom we developed successful informatics solutions in the past) to help them with such tracking. In close collaboration with DMID and after many years of trying, we were able to finally come up with a viable design. Since then, CPE has been successfully rolled out not only to DMID, but also to the Division of AIDS (DAIDS) and the Division of Allergy, Immunology, and Transplantation (DAIT). You can read more about CPE in the "Custom Software Development: Extramural Research" section of this report.

TB Portals. Tuberculosis (TB) plays a major role in the NIAID research agenda and for a good reason. In 2015, there were an estimated 10.4 million new TB cases worldwide, and 1.4 million estimated deaths. Drug-resistant TB cases are on the rise resulting in more adverse events from the treatment, and longer treatment regimens (up to two years) with expensive antibiotics. The TB Portals program is an international consortium of physicians, radiologists, and microbiologists from countries with a heavy burden of drug-resistant tuberculosis who are working with data scientists and information technology professionals. Together, we built the TB Portals, a repository of socioeconomic and geographic, clinical, laboratory, radiological, and genomic data from patient cases of drug-resistant tuberculosis backed by shareable, physical samples. Azerbaijan, Belarus, Georgia, Moldova, Romania, China, and South Africa are contributing to the TB Portals, with India, Congo, and Kazakhstan joining soon. The TB portals are supported by research laboratories in the United States of America, Germany and Spain. This system addresses the fact that certain critical-for-research TB data is unavailable in the US, and the only way to discover such priceless data is to engage with countries experiencing a high burden of multi-drug-resistant tuberculosis. At the core of the program, there is the data exploration portal called DePOT developed in Amazon Web Services using .Net, SAS and Qlick technologies. Data and knowledge generated from this project enabled publications in *Science Translational Medicine, Nature Genetics and Journal of Clinical Microbiology*. Feel free to learn more and explore the data on your own by visiting https://tbportals.niaid.nih.gov.

Upgrade to cloud-based email and to Office 365 cloud services. As you have probably noticed, your email has been migrated to the Microsoft SaaS cloud-based solution. With many ben-

efits and significant cost savings, this migration was a complex, multi-step joint effort between OCICB and NIH's Center of Information Technology (CIT), that required significant upgrades to the NIAID computing environment. As part of this migration, OneDrive will soon be available to all NIAID staff, allowing for easier access to your documents. You can read more about this project in the "Infrastructure and Service Related Projects" section of this report.

NIAID CTO Technological Innovation Lectures

Innovative ideas, of course, come from people who are intellectually stimulated. As CTO, I sponsor lectures throughout the year on current technology trends and advances. This encourages people to broaden their horizons and learn about concepts outside of their regular knowledge domains. This past year, nine lectures 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 lectures were presented this fiscal year:

Cloud adoption US Government Exploratory Discussion presented by Dr. Merrick Watchorn, Cloud Security Solutions Architect with SAIC, September 21, 2016.

Internet2 and RADII presented by Dr. Charles Schmitt of Renaissance Computing Institute (RENCI), October 27, 2016.

Human-Computer Interaction presented by Dr. Ben Shneiderman, Distinguished University Professor in the Department of Computer Science, University of Maryland, December 7, 2016.

Modern Mobile Apps Development Approaches, presented by Aaron Druck, Senior Architect and Engineering Lead at Deloitte, February 22, 2017.

Rugged DevOps – Bridging the Gap, presented by Mrs. Nancy Stetson, CSRA on March 30, 2017.

Interactive Visual Discovery in Event Analytics, presented by Ben Shneiderman, University of Maryland, Professor, Department of Computer Science, Member, Institute for Advanced Computer Studies, on April 26, 2017.

Exponential forces – Blockchain, presented by Mark White, Principal at Deloitte Consulting Innovation Office, May 15, 2017.

Clinical Data Management with i2b2 presented by Dongkyu Kim, Ph.D., Children's National Hospital, June 14, 2017.

8K Brain Tour: Interactive 3D visualization of terabyte-sized nanoscale brain images at 8K resolution presented by Dr. Yosuke Bando, Toshiba Corporation, and Ms. Mika Kanaya, Senior Producer at NHK (Japan Broadcasting Corporation) stationed in Boston as a researcher-in-residence at MIT Media Lab, August 16, 2017.

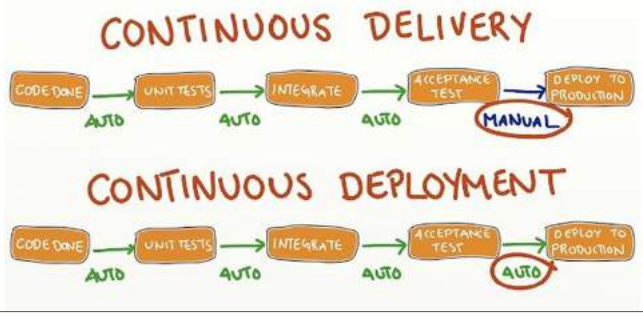
Infrastructure and Service-Related Projects

Monarch

The Monarch custom platform-as-a-service was established to improve OCICB's development capabilities and to provision infrastructure services using a faster, more secure and efficient methodology. This platform enables developers and researchers to consume infrastructure services in an automated and repeatable way. It reduces software deployment errors, supports zero-downtime application upgrades, and identifies security vulnerabilities so they may be remediated before they reach production or public-facing web sites.

Self-Service/API-Driven operations eliminate the "waiter/waitress" and allow developers to consume infrastructure services in a "buffet-style" setting. Instead of having systems delivered by a "waiter/waitress," developers can can help themselves as-needed to the services that have been supplied.

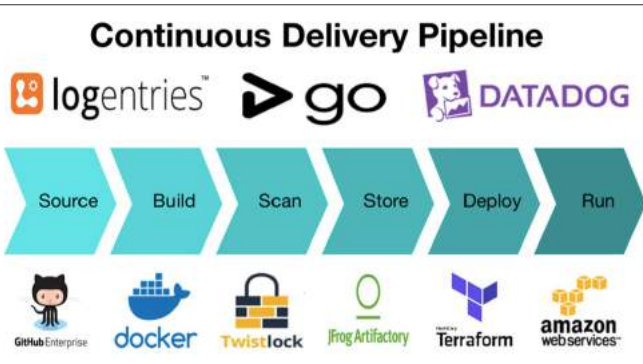
Launching Monarch satisfied a major objective for OCICB by establishing a supported environment with a public cloud provider, expanding NIAID Information Technology (IT) services and capabilities while addressing the Cloud First federal initiative. It shrinks the divide between development and operations teams, accelerating the delivery of custom applications to end users. Systems engineers can automatically deploy configured infrastructure services, and developers and researchers can deploy custom applications in a supported framework using continuous-integration and continuous-deployment pipelines. Researchers can develop custom bioinformatics applications or web sites and eliminate potential bottlenecks in the application and infrastructure life cycle.



Continuous Integration merges development with testing, allowing developers to build code collaboratively, submit it to a master branch, and check for issues. This allows developers to not only build their code, but also test their code in any environment type and as often as possible to catch bugs early in the applications development lifecycle. Continuous Deployment allows for automated delivery to production.

Since the deployment of Monarch, systems engineers have focused on hosting mainly Linux-based applications due to the progress made by the open-source community in the adoption of innovative technologies, such as Docker for hosting micro-services in containers. OCICB is working to integrate support for applications built using Microsoft services into the platform by early 2018.

It is essential to ensure the platform is secure. Anticipated for release in early 2018, an application scanning tool integrated into continuous deployment and integration pipelines will flag known security vulnerabilities within the application stack prior to deploying code to production. Monarch will be used to facilitate the Authorization to Operate (ATO) process for new applications, which will inherit the platform's security controls. This will reduce the time it takes to complete paperwork and implement compensating controls.



Continuous Delivery Pipeline.

Encryption

The U.S. Department of Health and Human Services (HHS) issued an updated Standard for Encryption of Computing Devices and Information Policy (HHS-OCIO-2016-0005) in December 2016. It required the NIH to encrypt all personally identifiable information data and storage media. To achieve this, encryption had to be enabled throughout the enterprise. Numerous hardware and software upgrades were accomplished. Older storage systems incapable or inadequate for supporting native encryption (dynamic Domain Name Systems, Metro2, Metro1, FAS19, FAS20) were retired. New storage arrays—both on order or scheduled for purchase—were upgraded to support native encryption. Adding an encryption layer increased the complexity of the entire storage infrastructure and required extensive testing. The testing, performed over several months, provided the information necessary to implement data-at-rest encryption across several petabytes of storage within NIAID's three data centers.

The Infinidat storage arrays were the first to be completed, without issue. These arrays support database backups and application environments, including ImmPort, Tenable, and Varonis. Then, the daunting process of encrypting department and user shares—a total of nearly two Petabytes of data—began. The work was divided into four carefully coordinated phases, each spanning about two weeks. Each phase required late nights and close monitoring to ensure users were not negatively affected. The project was completed without issue in September, several months ahead of the required deadline.

The completed encryption project provides an additional level of protection and saves approximately one hundred thousand dollars in maintenance costs per year. This is achieved by the ability to return used hard drives to the manufacture for warranty repair.

Windows Server Configuration and Security Improvements

Improved security and configuration management of the large Windows Server portfolio addressed the increased complexity of NIAID's hosting requirements as well as the constantly changing cybersecurity landscape. Efforts were focused on configuration management, automated processes, and adaptability.

Implementing advanced configuration management tooling laid the foundation for these enhancements. All managed Windows Servers now fall under a unified configuration management suite of tools, allowing for the rapid analysis of the environment and deployment of both new functionality and software updates. Although this functionality is not new, using a single tool platform allows for a more unified and reliable approach. The tool suite adds extensibility to new features, including the use of advanced, cloud-based monitoring, and process automation. There is a significant reduction in time spent performing manual tasks. More importantly, there is consistent system management and a quick response for required process changes. NIAID Windows Server systems are guaranteed to feature the same base configuration, and process updates are implemented immediately.

New security threats and vulnerabilities are swiftly addressed. Changes are rapidly validated against testing and software development environments to ensure minimal staff impact, then quickly delivered to production environments thus minimizing risk. One example of this work in action includes supported Transport Layer Security cipher suites. In response to the deprecation of outdated cipher suites, OCICB developed a revised management structure for Windows Server systems, allowing for a consistent cipher suite list to be updated and applied as needed, including testing applications in development systems. This management structure will also be used for updated systems in other areas.

NIAID Lab Support

Bench scientists know that the preservation and reliability of test samples is essential for data integrity. A slight variation in temperature or loss of power could be devastating, depending on the sensitivity of the specimen. To solve this problem, OCICB implemented customized Rees systems which monitor and detect abnormalities in freezer temperatures. Rees software logs the temperatures of the freezer and determines if a threshold, set by the lab, was reached. OCICB included a notification system with an interactive voice-response system to ensure issues are easily identified and quickly resolved. It alerts technicians and allows for remote troubleshooting and resolution. From a technical perspective, the installation required updating the applications individually, working with the vendor, and implementing an application server. The Rees monitoring project was completed in numerous labs on the Bethesda campus, Fishers Lane, and at the Integrated Research Facility (IRF) on Fort Detrick.

In addition to good sample integrity, the accuracy of lab results relies on the ability to perform analysis. Aperio, a digital pathology slide scanner produced by Leica, is a valuable tool for scanning and analyzing pathology slides. Abnormalities can be identified and flagged after analysis. OCICB installed Aperio and developed a solution for storing a digital slide repository of the images and slides of tissue samples. There were obstacles which made finding a solution challenging, as each image has the potential to use one half gigabyte of storage space. The scanners run on a scientific Virtual Local Area Network (VLAN), which brings increased security and access obstacles. It took expertise in database administration, enterprise storage, networking, and security to overcome these challenges.

Microsoft Office 2016 Migration

Microsoft Office applications are part of the core NIAID workstation configuration for both Mac and Windows, totaling approximately 8,500 endpoints. Users and researchers rely on this productivity suite for fundamental business and research needs. As Microsoft updates their products, our environment changes in concert. In preparation for NIH's transition of mail services to Office 365, NIAID management made a strategic decision to migrate personal computers (PCs) and Macintoshes (Macs), from Office 2011 for Mac and Office 2013 for Windows, to the Office 2016 productivity suite. This migration better positioned OCICB to support NIAID users while also providing the latest tools.

OCICB engineers developed a migration plan to seamlessly and silently deploy and install Office 2016 on both Mac and Windows endpoints. Users were given the option of installing the software suite themselves via a self-service tool. Over the course of a few weeks, Office 2016 was rolled out to users, with instructions on how to use the new suite.

NIAID Conference Room Technology Modernization

OCICB began a conference room technology upgrade program to achieve three primary goals: modernization, a consistent user experience, and improved supportability. A design standard developed to achieve these goals ensured that all room upgrades meet usage requirements while adhering to a technological specification. Prior to this upgrade program, the configuration and technology implementation of each room varied widely due to different procurement approaches and refresh cycles. Responsibility for room upgrades was often up to NIAID divisions, resulting in inconsistent specifications.

The technology plan for the new conference rooms incorporates NIAID's modern communication and collaboration systems. The primary technical capability for each new room design focuses on PC-based conferencing. The move to systems such as Skype for Business, WebEx, and GoToMeeting resulted in lower costs, greater flexibility, and in many cases, offers more capabilities than previous solutions. Although the use of traditional video teleconferencing (VTC) systems is less prevalent than in the past, these tools are still important for many external collaborations, especially international partnerships. To minimize cost while also maintaining comprehensive functionality, usage data was reviewed to select ideal locations for continued VTC support. Traditional VTC capabilities were implemented only where appropriate, while all other systems were designed for future expansion if needed.

Standardizing key components across all room designs resulted in a consistent user experience. The room control systems run multiple system components in the form of a touch panel that is now consistent in all rooms. All NIAID users from any building in the Montgomery County region will encounter the same interface; reducing training needs and decreasing meeting start time and setup needs. This same user experience will be replicated at remote locations in Frederick, MD and Hamilton, MT as the project expands to those sites.

This standardization makes it easier to support the hardware and software. Training requirements for users and technicians were reduced, resulting in the development of a single set of training materials. In addition, the use of a standard set of hardware devices has allowed for the creation of a spare parts depot, reducing room downtime. Spare parts can be used if the original equipment is out for repair.

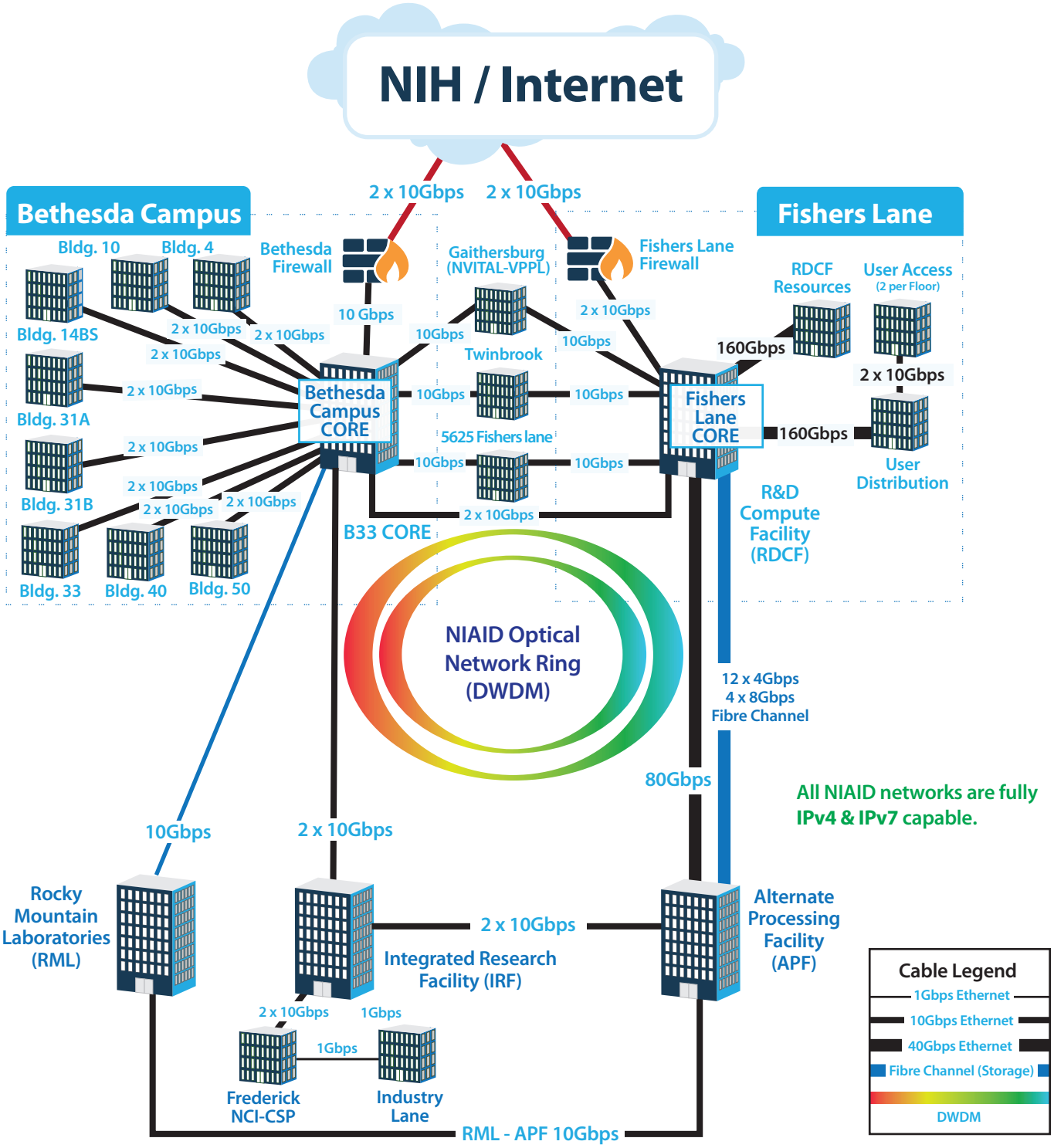
Remote Windows Endpoint Management

OCICB set out to provide full remote management capabilities for Windows-based endpoints, or computers--similar to the goal reached with Macs in FY2016. This accomplishment provides the ability to deploy software, updates, configuration settings and perform inventory of laptops, desktops, and mobile endpoints that might only connect via the internet without requiring a virtual private network (VPN).

Engineers migrated the Windows endpoint management platform, Microsoft System Center Configuration Manager, to Current Branch, which is the latest version. This migration positioned us to take advantage of upcoming changes in the operating system (Windows 10), productivity software (Office 2016/Office 365), and other management capabilities. However, this effort also required OCICB and Center for Information Technology (CIT) resources to implement on-premises technology utilizing Microsoft Enterprise public key infrastructure, which allows the secure management of internet-only connected computers. Through this implementation, NIAID was one of the first to utilize this type of set-up in a production environment.

Today, more than 6,000 Windows endpoints are managed by System Center Configuration Manager, including almost 2,200 mobile devices, including laptops and hybrids. Providing secure mobile devices and access to software and support is key to empowering users and researchers to do their work and meet the mission of NIAID.

NIAID Enterprise Network



NIAID's Enterprise Network Diagram as of August 2017.

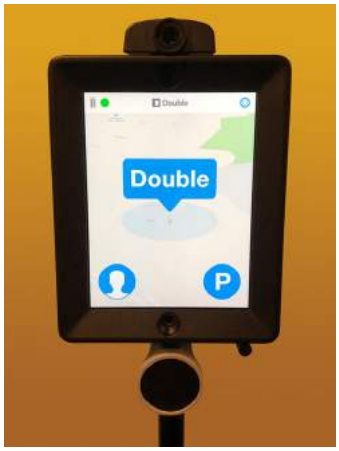
The NIAID DWDM Network and the Addition of MetroCluster-4 Services

The NIAID inter-campus network is composed of a highly scalable, redundant optical networking ring consisting of several nodes using dense wave division multiplexing (DWDM) technology at its core. To keep pace with the exponential storage growth requirements demanded by NIAID users and the associated research communities, new DWDM Fiber Channel services were deployed in 2017. OCICB worked closely with the DWDM vendor to activate the additional channel capacity and storage infrastructure between NIAID's primary and alternate compute facilities with minimal interruption.

NIAID's latest storage environment, MetroCluster-4, is now utilizing double the amount of bandwidth per DWDM channel compared to the previous solution (an upgrade of four to eight Gbps per channel), while it continues to leverage all the existing built-in network redundancy and resiliency afforded by the overall DWDM network. One of the many technological advantages provided by NIAID's DWDM network is the ability to efficiently add new services (Ethernet and/or Fiber Channel), to meet the continuously growing storage and bandwidth needs of all NIAID users. This added flexibility has allowed NIAID greater control over the process of activating new network services and applications while delivering more cost-effective bandwidth where it is most critical. The DWDM network is architected to meet both short-term and long-term researching needs of the immediate NIAID user community by being adaptable to continually-changing network demands, while showcasing the Institute as a networking innovator within the overall NIH community.

Emerging Technologies – Robotics

Meet Double: The Robot Expanding How NIAID Communicates



A close up of the Double telepresence robot's iPad display and webcam.

One of the latest advances in virtual communication and collaboration is the use of telepresence robots. A telepresence robot is a remote-controlled, wheeled device with a screen and wireless internet connectivity. These robots are designed to enhance telecommuting and teleconferencing in a business environment. While in use, a live video of a remote person is displayed, making it look and seem as if that person is in the room. This new, more personal way to interact virtually has been used in countless scenarios, including in workplaces and schools; robots have allowed employees whose disabilities or locations prevent them from traveling to have a physical presence in the office and enabled students who are unable to attend classes due to illness to learn and interact with their classmates.

About NIAID's Telepresence Robots

When the need for a telepresence robot arose at NIAID, OCICB researched telepresence options and found *Double* to be the perfect solution. Double isn't the only telepresence robot out there, but it was chosen for NIAID based on its security specifications and its use of an iPad, which can be used with or without the full body of the robot. In an interview with Aaron Leavey, we learn more about NIAID's newest collaborative devices.

NIAID currently owns two telepresence robots. The first will support a remote NIAID employee who serves dual roles—one as a project lead who supervises three technical staff members and the other as a VRC Lab manager who requires daily contact with 16 employees; frequent travel between the United States and London, England is necessary for each of these roles. Challenges with this arrangement include the cost of travel and the demanding challenge of being in two places at one time. Therefore, procuring a telepresence robot was the perfect solution for this dilemma. The goal for this telepresence robot is to increase efficiency by enabling this employee to interact with her laboratory staff at will "unconstrained by timing and availability of conference facilities" and to save government resources by freeing the additional IT staff, who had to physically walk around the lab with an iPad so that the remote employee could see the experiments and perform her lab management duties.

The second robot is used for market and outreach and for troubleshooting. Since Double supports visitor's passes, NIAID users can request control for an allotted timeframe using a timed link. When the time's up, the link simply expires. Double can also be used in group settings. Instead of sending a large group of employees to a remote or difficult location, the robot can be driven by one person, while others observe.

While telepresence robots may be pricey, they are a cost-effective solution for NIAID since they save on travel costs and fees. The expectation for each of these robots is that the return on investment will be high.

Aaron Leavey and Gurpreet Singh provide an overview and demonstration of Double Robot's features, including the iPad display, arm and wheeled base.

What are Double's features?

Double consists of a wheeled base integrated with an iPad at the end of a movable arm. The iPad, or the display for one's face, comes equipped with a camera and audio kit. Double is all mobile and seamless; with no cords or wires. Double takes a while to get used to, but it becomes surprisingly easy to operate with time. When Double moves, it is steady and quiet. When it is idle, it rocks back and forth. While not in use, it can be docked in the charging station or stored in a safe space.

Double is guided using a computer, iPhone, or additional iPad. To connect to and operate the robot, sign in to the required website using a Web browser (Google Chrome or Firefox) on a computer or through the iPhone operating system app on the iPhone or iPad. The robot is controlled using the arrows and keys on the keyboard (while using the web browser) or the navigation buttons (using the App). The arm can be raised or lowered to control Double's height; it moves fastest when at its lowest height. There is even a camera button to capture the experience.

Due to its superior security specs, Double was approved by NIAID's Information Security Officer. Video and audio are encrypted with 128-bit AES end-to-end; encryption goes directly from the robot to the driver without being stored or recorded.

When asked, Aaron shared that it wasn't hard to assemble the robots. While NIAID's telepresence robots have only been around for a couple of months, the consensus is that this interactive approach will positively improve remote working situations.

Desktop and Laptop Upgrades

Windows XP Upgrade and Clean-up

With Windows XP at end-of-life (EOL), and Microsoft no longer providing security updates or technical support, OCICB made a concerted effort to upgrade computers running Windows XP to modern Windows operating systems, such as Windows 7 or Windows 10. Based on OCICB research, including input from NIAID's scientific community and scientific software developers and vendors, the Windows XP computers to be upgraded were determined. Windows XP computers that were not tied to legacy scientific software could upgrade to Windows 7 or Windows 10. Windows XP computers that were tied to legacy scientific software and thus unable to be upgraded were isolated on the NIAID network. OCICB upgraded 139 computers to a modern version of Windows that is supported by Microsoft with security updates and technical support. During the Windows XP upgrade, a process for identifying and documenting scientific equipment dependencies on older and EOL operating system was implemented.

Windows 10 Deployment

In February 2017, OCICB began deploying all new desktop and laptop computers with Windows 10 operating systems. With Windows 10, users can expect an enhanced desktop experience. The new system's tools range from virtual desktops to improved high dots per inch monitor support, better storage management tools and easy file version recovery. The underlying code has been optimized so it boots faster, especially with the solid-state-drive hard drive included in all of NIAID's standard Windows computers. Windows 10 is inherently more secure than Windows 7 with Microsoft's Defender antivirus software and Windows firewall. Native security protection is offered by Windows 10's Unified Extensible Firmware Interface Forum Secure Boot, SmartScreen filter and Windows Hello. Windows 10 also offers print to PDF natively; hovering over a window lets you scroll the window, rather than the in-focus program. With Windows 10, per-monitor display scaling eliminates visual peculiarities with multiple monitor setups. In FY2017, over 1000 computers were upgraded to Windows 10.

Apple Operating System 10.11 Deployment

OCICB upgraded the operating system on approximately 2,479 Apple computers in preparation for an Office 2016 upgrade and to mitigate current and future security vulnerabilities. Apple OS 10.11 provides faster and more responsive performance. It switches applications twice as fast as Apple's previous operating system and opens a PDF four times faster. The new operating system also offers these enhancements: the ability to re-size and move the Spotlight window, write queries in natural language, as well as built-in application enhancements. Mission management improvements included Mission Control, which separates all windows rather than overlapping them, and Split View, allowing users to run two full-screen applications side-by-side.

NIAID-Wide Office 365 (Cloud Services) Upgrade

Under an Office of Management and Budget (OMB) mandate and after evaluating results from a pilot test group, OCICB determined that upgrading to Office 2016 before beginning the Office 365 upgrade was important. Upgrading 2,479 Apple computers to the new Apple operating systems was also necessary for this institute-wide goal. OCICB also upgraded 7,508 computers to the Office 2016 mail client. OCICB then coordinated the migration of 5,256 e-mail boxes to Office 365, ensuring compliance with OMB's mandate to move e-mail to the cloud and thus enabling new functionality and collaboration capabilities. The advantages to Office 365 in the NIAID environment include:

- Larger mailbox sizes
- Constant access to data and e-mail
- No maintenance of data, websites or servers
- The ability to keep data safe using the continuous compliance built-in security
- Synchronized e-mail, calendar, and contacts
- Consistent costs
- Discontinued management of licensing for various Office versions

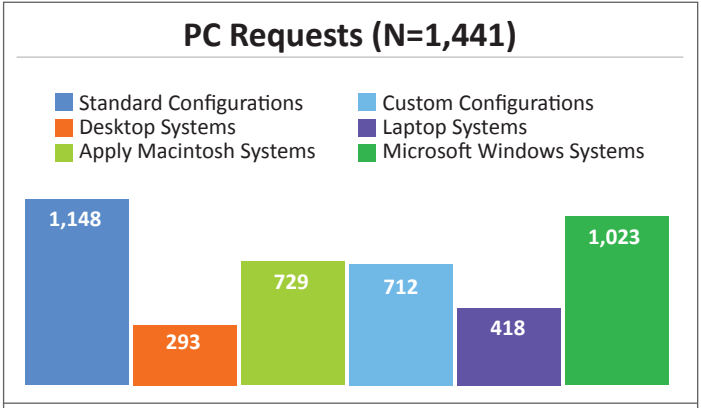
OCICB Pro-actively Managed Desktop and Laptop Security Vulnerabilities

For 2017, OCICB made great strides in proactively managing desktop and laptop security vulnerabilities, reducing a backlog of previously documented vulnerabilities through a real-time remediation process. OCICB manually remediated over 500 computer desktop and laptop vulnerabilities, including the rapid remediation of the WannaCry ransomware attack of May 2017 and the Petya ransomware attack of June 2017, thus preventing the spread of ransomware to NIAID computers. OCICB also took a proactive stance on computer security with the development of a process for identifying and documenting NIAID scientific equipment that have dependencies on older and EOL operating systems. This process allows OCICB to mitigate current and future vulnerabilities. To close the gap on vulnerabilities in NIAID's Linux environment and improve support for the Intramural community, OCICB established a Linux Workstation Support Team.

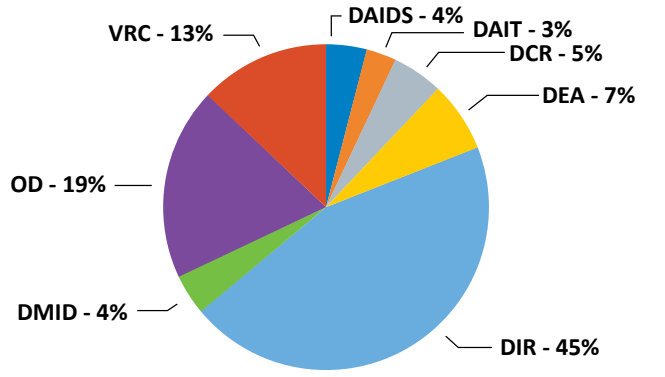
NIAID's Computer Acquisition, Configuration and Distribution Program

NIAID's Centralized Computer Acquisition, Configuration, and Distribution Program ensures that computer security configurations comply with NIH directive. It streamlines computer purchases, provides a standard configuration for NIAID computer hardware and improves property management with more accurate procurement and inventory status data. Effective October 16, 2015, OMB signed into effect Memorandum M-16-02, Category Management Policy 15-1: Improving the Acquisition and Management of Common Information Technology: Desktops and Laptops, which further defines how the Government is required to buy computers. Memorandum M-16-02 defines hardware specifications and procurement vehicles to buy computers. To meet compliance, a designated computer must be procured under the Government-Wide Strategic Solutions (GSS) program. In 2017, Federal computer purchases must meet a goal of 60% compliance and in 2018, Federal computer purchases must meet a goal of 75% compliance. In FY2017, OCICB exceeded the compliance goal; 82% of OCICB's computer purchases were GSS compliant.

In FY2017, NIAID's Centralized Computer Acquisition, Configuration, and Distribution Program procured, imaged, delivered and installed 1,441 new computer systems to NIAID scientific and administrative staff. On average, OCICB deployed the NIAID standard configuration computers within 4.9 business days.

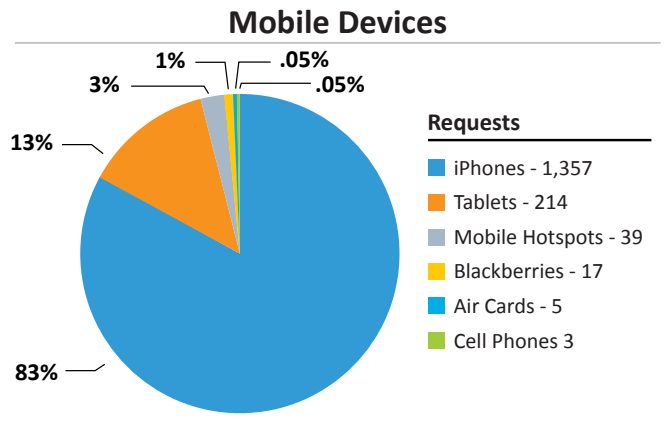


In addition to new computers, OCICB decommissioned and surplused 1,730 old systems.



Of 1,441 PC requests, the above chart shows the percentage of requests from each division.

Mobile Device Management



Of 1,635 mobile devices, the above chart shows the percentage of requests for each type of device.

Central Service Desk

OCICB provides technical and tactical cyber technologies management and technical support for NIAID biomedical research and administrative communities. The Central Service Desk (CSD) offers a single point of contact for assistance with information technology-related issues, including remote and desk-side support.

OCICB Service Desk and Desktop Support technicians processed 71,021 requests for assistance, including:

- Answering over 7,100 phone calls
- Responding to over 50,800 email tickets
- Providing support through Instant Message/Skype over 600 requests
- Helping over 12,490 walkups and other requests

A snapshot of the requests processed by OCICB's Service Desk and Desktop Support technicians.

Problems that require specialized knowledge are passed to the appropriate team, i.e., Desk-Side Support, Workstation Procurement, IT Service Management, Mobile Telecommunications Devices, Video Conferencing, or Training.

In addition to working on major IT projects, OCICB continued to improve the service delivery model by:

- Implementing problem management solutions to better track tickets.
- Creating an infrastructure for better reporting.
- Implementing a software asset management dashboard.
- Continually upgrading our internal knowledge article solutions.

OCICB created a reporting infrastructure to help make data-driven decisions based on real-time data. This infrastructure was the foundation for the OCICB Ten-Day Dashboard and supports the Business Intelligence Asset Management dashboard. The dynamic reporting functionality supports software and license management, allowing OCICB to make contractual decisions based on timely data.

In Remedyforce, a self-service capability for IT teams was developed to streamline the process for requesting VLAN changes, Java version exemptions, and access requests. This capability will be expanded to end-users over the next year. The process for adding new teams to Remedyforce was refined, reducing onboarding time from weeks to hours. The newly implemented Remedyforce Problem Management module improves reporting for major problems and upgrades (e.g. Office 2016, Office 365). Finally, to assist the international sites, a separate module to handle proactive and reactive problems was implemented in Remedyforce. The implemented process to streamline problem creation resulted in less duplication and manual effort.

The Service Desk created and updated KnowledgeBase articles that provide information for the Service Desk and desk-side support techs supporting customers: 62 new and 288 updated

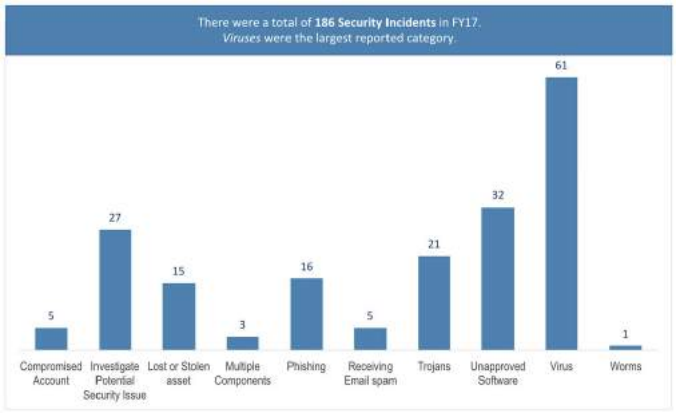
articles. In the future, KnowledgeBase articles will provide the foundation for self-service for NIAID staff.

Security Incidents

The Federal Information Security Modernization Act of 2014 (FISMA) defines "incident" as "an occurrence that (A) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (B) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies." FISMA requires federal Executive Branch civilian agencies to notify and consult with United States Computer Emergency Readiness Team (US-CERT) regarding information security incidents involving their information and information systems; whether managed by a federal agency, contractor, or another source. It is vital that an organization and the stakeholders understand the basic differences between a security event and a security incident. While an event includes any occurrence on a system or a network, (i.e. a user logging on to a system, or two systems communicating), an adverse event has a negative consequence and it is labeled as an incident. Examples include system crashes, network packet floods, unauthorized use of system privileges, unauthorized access to sensitive data, and execution of malicious code that destroys data.

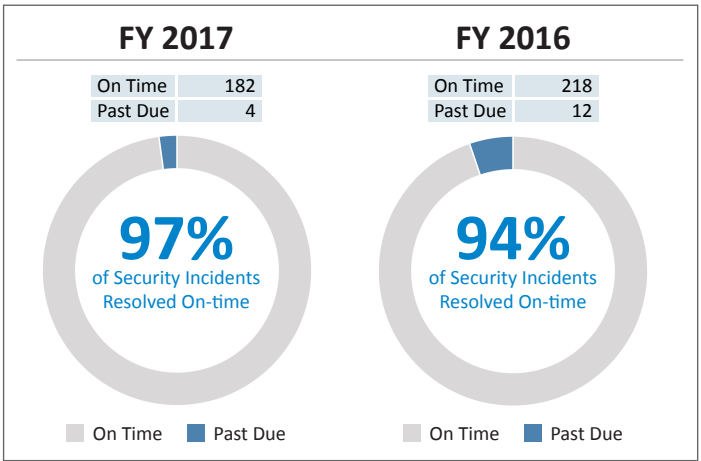
NIAID's Cyber Security Program works with NIH to identify, report, and handle security incidents as mandated by US-CERT. The identified incidents are categorized as per US-CERT's guidelines and then triaged into a specific subcategory and priority as per NIAID's requirements before being assigned to an operational team. All the incidents have a resolution target and follow a precise path towards a resolution as defined Incident Response Workflow in the Incident Response and Handling Guide.

During FY2017, NIAID handled 186 incidents. Seven Ransomware incidents were deemed of the highest priority and they were resolved successfully on time. Ransomware is a malicious software that holds user's files and digital devices hostage and demands the user a ransom amount to release their files and impacted devices. It has been a prominent threat to organizations worldwide and it continues to be one. **97%** of all the incidents were resolved on time during FY2017 as compared to **94%** in FY2016. All security incidents have a designated priority level ranging from 1 (most critical) to 4 (less critical) and they are required to be resolved in four, eight, 20 or 40 hours respectively.

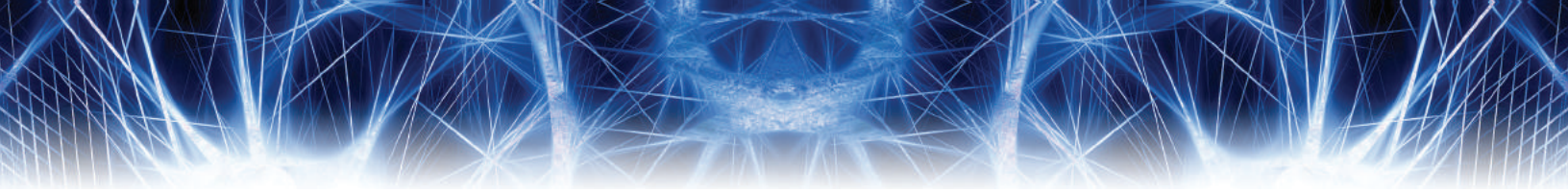


There was a total of 186 Security Incidents in FY2017. Viruses were the largest reported category.

Percentage of Security Incidents Resolved On-Time



The number of on-time and past due security incidents in FY2017 versus FY2016.



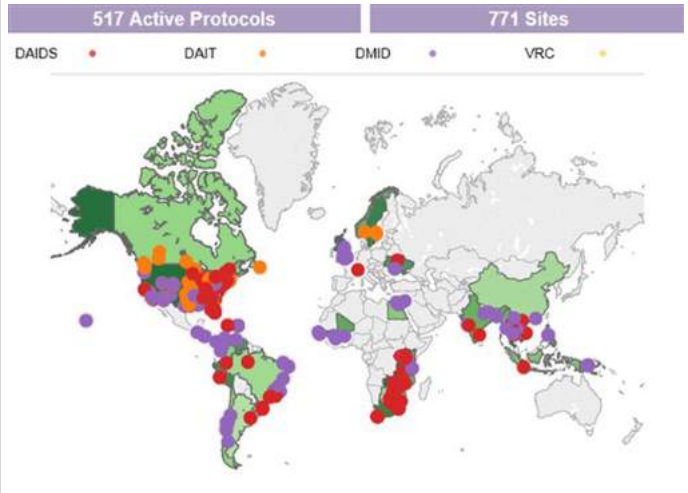
NIAID Clinical Research Management System

The NIAID Clinical Research Management System (CRMS) supports the scientific, administrative, and regulatory functions of the NIAID sponsored clinical research. Comprised of 27 components, the system supports the management of clinical research activities for the Division of AIDS (DAIDS), Division of Microbiology and Infectious Diseases (DMID), Division of Allergy, Immunology, and Transplantation (DAIT), and the Vaccine Research Center (VRC).

Learning Early About Peanut Allergy (LEAP) is just one of the study protocols tracked in CRMS. This randomized clinical trial involving more than 600 infants showed that the introduction of peanuts early in life significantly lowered the risk of developing a peanut allergy by the age of five. These findings generated a great deal of news in the press and were featured in *The New England Journal of Medicine* (vol. 372:803-813). This demonstrates the importance of the research that is facilitated by NIAID and by CRMS.

CRMS enhances NIAID's clinical research information management capacity by providing innovative data collection systems, management tools, processes, and communication methods. NIAID staff can rapidly search for and retrieve study data and information to support oversight and decision-making.

The system currently supports 517 active protocols spanning 771 clinical research sites in 45 countries.



Active Protocols across DAIDS, DAIT, DMID, and VRC.

CRMS data, including the number of users in the system, study participants, protocols, and adverse events, are listed in the summary data table.

Data Category	Amount of Data Retrieved	
	Between Oct 2016 - Sep 2017	TOTALS
Users	661	6,114
Protocols (including versions)	1,602	12,622
Protocol Review Requests	110	289
Study Participants	15,221	270,781
Organizations in Master Contact (i.e., Biopharmaceutical companies, Contract Research Organization, etc.)	146	3,057
Clinical Research Sites	78	3,095
People in Master Contact (e.g., Investigator, Study Coordinator)	6,557	23,285
Investigational New Drug applications (INDs)	155	1,041
Study Products (including drugs, vaccines, etc. used in clinical trials)	658	1,440
Expedited/Serious Adverse Events	1,263	17,329
Protocol Registrations/Site Essential Regulatory Document Submissions	2,774	26,641
Site Visits	1,708	15,219
Web Service Calls	**1,732,519**	**6,854,068**

High-Level Summary of NIAID CRMS Data.

NIAID CRMS Interaction with Other Systems

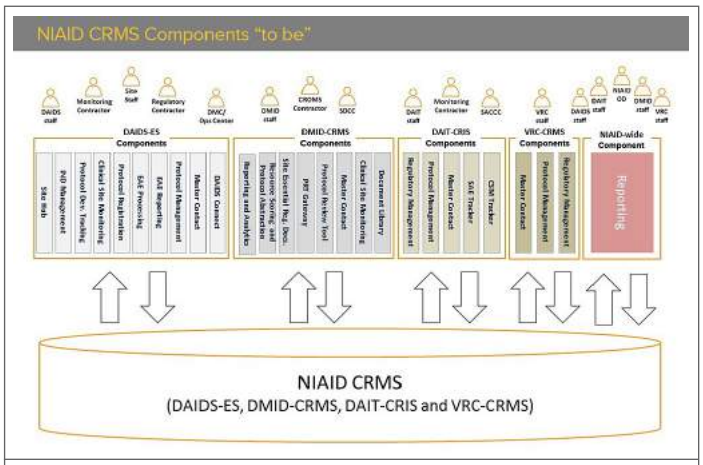
NIAID CRMS interactions with other NIH and NIAID systems.

In support of NIAID clinical research activities, NIAID CRMS collaborates with the following NIH/NIAID systems:

- **Electronic Research Administration (eRA) Inclusion Management System:** Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2 requires the inclusion of women and minority groups in clinical research. NIAID CRMS exchanges inclusion enrollment data with eRA Inclusion Management System for DMID protocols to assist NIH to comply with the federal law.
- **NIAID Central Database – Grants:** The Grants interface was established with the NIAID Central database to make IMPAC II grants data available to NIAID staff to facilitate resource scoring, and reporting on protocols associated with the grants.
- **National Library of Medicine (NLM) – PubMed:** With NIAID CRMS, users can interface with NLM's PubMed to obtain publication information based on grants; this allows DAIT to assess the impact of the research funded through various extramural clinical research programs.
- **ClinicalTrials.gov Registration:** NIAID CRMS exchanges protocol data with ClinicalTrials.gov to facilitate protocol registration.
- **Office for Human Research Protections:** This interface was established with the Office for Human Research Protections to determine expiry of Federalwide Assurance for DAIDS clinical research sites. Through the Federalwide Assurance, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 Code of Federal Regulations part 46. If the Federalwide Assurance expires, the institution must halt all clinical research activities that are sponsored or funded by NIAID.

Key Accomplishments:

- NIAID-wide reporting capability, which provides a comprehensive overview of the research portfolio
- Ability for DAIDS staff to collaborate and take actions on required tasks such as IND review, and serious adverse event assessment
- Newly-enabled Resource Scoring and Protocol Abstraction reporting for DMID
- Two major releases and five minor releases providing additional functionality for NIAID sites and collaborators



NIAID CRMS Components: An integrated view of NIAID CRMS including the operational modules for each Division.

The following list includes an overview of all operational components included in NIAID CRMS:

- **Adverse Experience Processing:** Supports and enables the processing and tracking of SAEs for DAIDS-sponsored studies; this components interfaces with the Adverse Experience Reporting component to receive expedited adverse events (EAE) electronically.
- **Adverse Experience Reporting:** Used for expedited reporting of adverse events in DAIDS-sponsored clinical trials.
- **Clinical Site Monitoring (CSM):** Provides a platform for DAIDS and DMID that serves as the information source for site monitoring activities.
- **Clinical Site Monitoring Tracker (CSM Tracker):** Manages key parameters that describe the performance of a site utilizing a common set of elements, and to translate the information across projects to analyze overall site performance.
- **DAIDS Connect:** Provides a framework for a common access point to the suite of products automating clinical

research and other related business processes.

- **Document Library:** Enables DMID-CRMS users to search and access monitoring and regulatory documents.
- **Investigational New Drug Application Management (IND Management):** As the central repository for all submissions tendered by the DAIDS to the Food and Drug Administration (FDA), it enables users to track and monitor progress of application processing and submissions.
- **Master Contact:** A centralized repository for organizations and key personnel participating in clinical research, such as investigators, participating institutions, laboratories, agencies, pharmaceutical sponsors, manufacturers, etc. Provides ability to update Master Contact with updates originating from Clinical Site Monitoring request for service.
- **Protocol Development Tracking:** Tracks DAIDS protocol development activities through identified milestones and facilitates a protocol development workflow. Also provides functionality to facilitate the development of clinical agreements that can accompany the protocol development process.
- **Protocol Management:** A centralized system to support scientific and administrative information needs for clinical research programs.
- **Protocol Registration:** A unified centralized system that serves as the official information source for Protocol Registration activities involving registering a Clinical Research Site to a protocol.
- **Protocol Review Tool (PRT):** Provides ability to assign subject matter experts to more than one role for protocol review and sign-off.
- **Regulatory Management:** Tracks and manages key regulatory application information and associated submissions and interactions with health authorities for VRC and DAIT.
- **Reporting and Analytics:** Provides an ability to build, save, modify, and execute custom reports and/or export the result set to Microsoft Excel.
- **Resource Scoring and Protocol Abstraction (RSPA):** Provides ability to perform resource scoring and protocol information abstraction for DMID protocols.
- **Serious Adverse Event Tracker (SAE Tracker):** Tracks the processing of 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.
- **Site Essential Regulatory Documents (SERD):** Provides ability to designate sites and administrative organizations to protocols and ability for DMID sites to submit essential regulatory documents for review by DMID.
- **Site Hub:** Supports verification of adherence to Good Clinical Practice/Human Subject Protection training and tracks site population characteristics.

Each of the above modules is used by at least one of the NIAID Divisions; details follow.

DAIDS ENTERPRISE SYSTEM (DAIDS-ES)

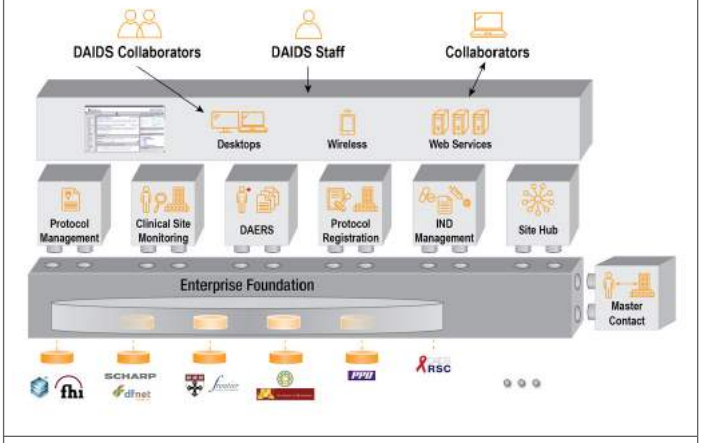
DAIDS-ES supports scientific, administrative, and regulatory needs related to the DAIDS research agenda on human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS) vaccine, prevention, and therapeutics research. Initial development began in 2003; new components and enhancements have been implemented since then.

The DAIDS-ES consists of the following ten components: DAIDS Connect, Master Contact, Protocol Management, Adverse Experience Reporting, Adverse Experience Processing, Protocol Registration, Clinical Site Monitoring, Protocol Development Tracking, Investigational New Drug Application Management, and Site Hub.

DAIDS-ES has 5,281 users in 35 countries. In addition to DAIDS staff, it is extensively utilized by DAIDS collaborators (such as the Regulatory Support Center and data management centers) and clinical research sites for clinical research activities sponsored or supported by DAIDS.

Key Accomplishments:

- Piloting of electronic distribution of Investigator's brochures (IB) for clinical research sites, operations centers, and DAIDS staff. Currently, IB documents are sent to sites via FedEx. This has caused regulatory compliance issues as the site leader may not be available to receive the documents and take necessary actions, or acknowledge the receipt of the IB documents. Electronic distribution facilitates faster distribution, easy access and availability of IBs ensuring patient safety.
- Ability for DAIDS staff to collaborate, share and take required actions on outstanding activities such as SAE assessment, IND review, etc.
- Ability to generate summary of site monitoring activities and site monitoring report through Clinical Site Monitoring module
- Ability to support monitoring of protocols using targeted source document verification monitoring paradigm. Targeted source document verification allows a risk-based monitoring strategy allowing reduced source data verification coverage without compromising data quality and process compliance.
- Ability to monitor and track observations related to protocol signature pages
- Ability to track study design based on the monitoring needs for trials
- Through data exchange, data for 2,338 EAEs were exchanged with network data management centers
- Performed daily update of accrual data for 174 protocols through data exchange for protocols managed through the network data management centers



DAIDS-ES Logical Diagram.

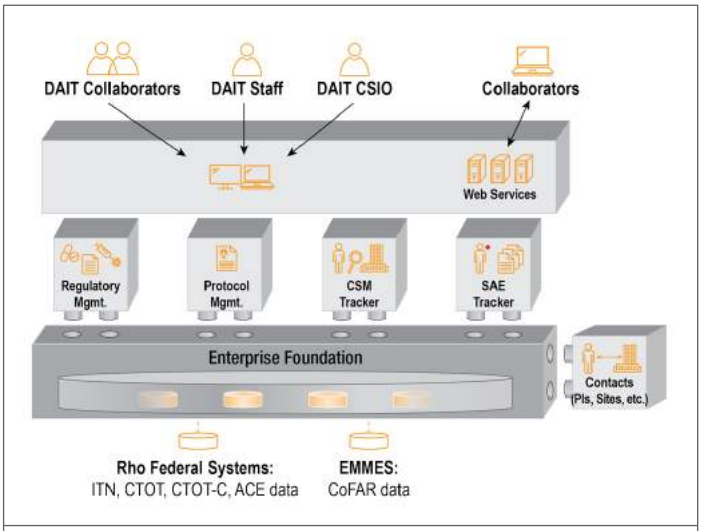
DAIT CLINICAL RESEARCH INFORMATION SYSTEM (DAIT-CRIS)

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 has been operational since March 2013. Developed as an integrated solution, it provides 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 comprised of five components: Protocol Management, Serious Adverse Event Tracker, Clinical Site Monitoring Tracker, Master Contact, and Regulatory Management.

Key Accomplishments:

- Established interface with NIAID central database to make DAIT grants data from IMPAC II available to DAIT staff, to support reporting and review of distribution of protocols by study phase and grant award
- Created interface with NLM PubMed to obtain publication information based on grants to understand the impact of DAIT-funded clinical research
- Developed ability to track queries between Statistical and Clinical Coordinating Center (SACCC) and medical monitor related to SAE assessments
- Established ability to generate Protocols by Data and Safety Monitoring Board oversight categories which provides DAIT with a tool for managing the protocols for which various levels of DSMB oversight is required
- Operationalized the data exchange of study status, site study team information for protocols with SACCC
- Abstracted and released 33 protocols and 86 protocol amendments prioritized by DAIT
- Exchanged data for 603 SAE case reports with DAIT SACCC (through data exchange)
- Performed daily update of accrual data for 76 protocols through data exchange for protocols managed through SACCC



DAIT-CRIS Logical Diagram.

DMID CLINICAL RESEARCH MANAGEMENT SYSTEM (DMID-CRMS)

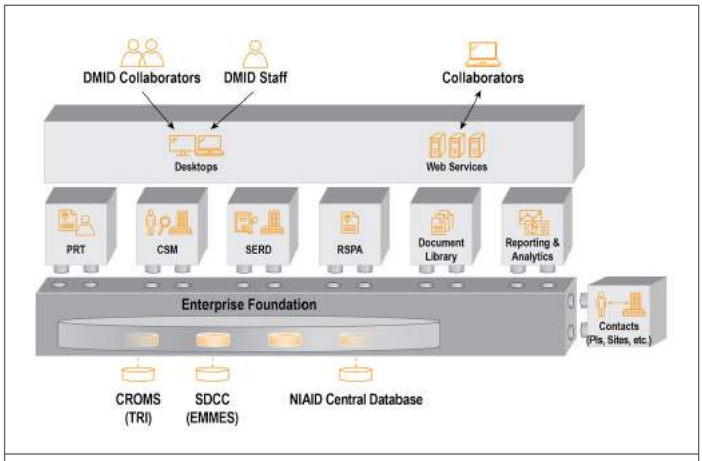
DMID supports a comprehensive extramural research program focused on the prevention and control of diseases caused by virtually all infectious agents (except for HIV). This includes basic research, such as studies of microbial biology and physiology; applied research, including the development of medical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

DMID-CRMS has helped automate DMID business functions, management, and oversight responsibilities; and is comprised of eight components: Clinical Site Monitoring, Document Library Master, Contact Site, Essential Regulatory Documents, Protocol Review Tool, PRT Gateway Resource, Scoring and Protocol Abstraction, and Reporting and Analytics.

Key Accomplishments:

- Developed and deployed Reporting and Analytics module
- Updated DMID-CRMS to support Final rule for FDAAA801 and NIH policy on Clinical Trial Reporting
- Updated DMID-CRMS to support Final NIH policy on the use

of a Single Institutional Review Board for multi-site research
- Updated DMID-CRMS to support NIH policy on Funding Opportunity Announcements for clinical trials
- Updated inclusion data exchange to conform with NIH Inclusion Management System requirements
- Updated accrual data daily for 45 protocols through the Statistical and Data Coordinating Center (SDCC)



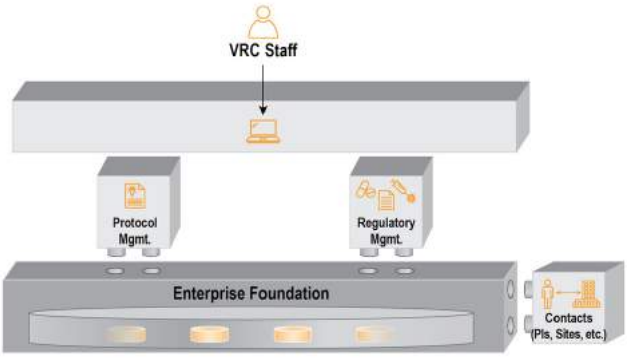
DMID-CRMS Logical Diagram.

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 conducts a comprehensive program of research on the NIH intramural campus and works with scientists in academic, clinical, and industrial laboratories through a program of national and international collaborations. 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.

To support its mission, VRC identified a need for an integrated system across clinical and regulatory functions. In addition, as vaccines developed by VRC are also utilized on DAIDS sponsored clinical trials, VRC identified the need for a centralized view and access to both VRC and DAIDS sponsored INDs using VRC interventions.

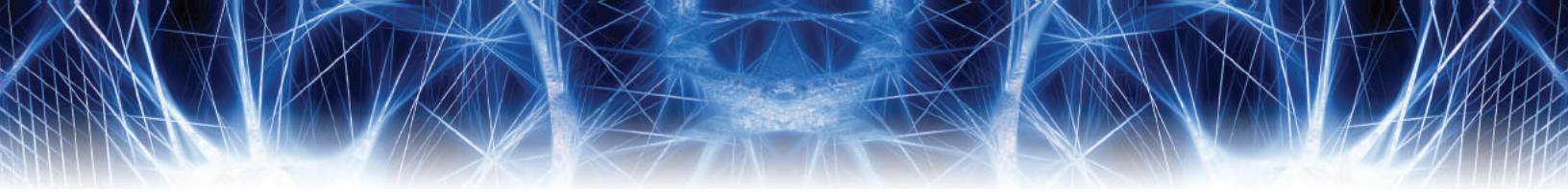
To support these needs, VRC implemented the VRC-CRMS, which are currently comprised of three components: Regulatory Management, Protocol Management, and Master Contact.



VRC-CRMS Logical Diagram.

Key Accomplishments:

- Provided ability to track clinical agreements and generate a customizable listing of the clinical agreements
- Provided ability to track study site locations
- Provided ability to associate and track electronic Common Technical Document (eCTD) for a pre-IND application
- Established framework for VRC data management centers to exchange accrual data for VRC protocols
- Abstracted 43 VRC protocols and 18 INDs in VRC-CRMS



Custom Software Development

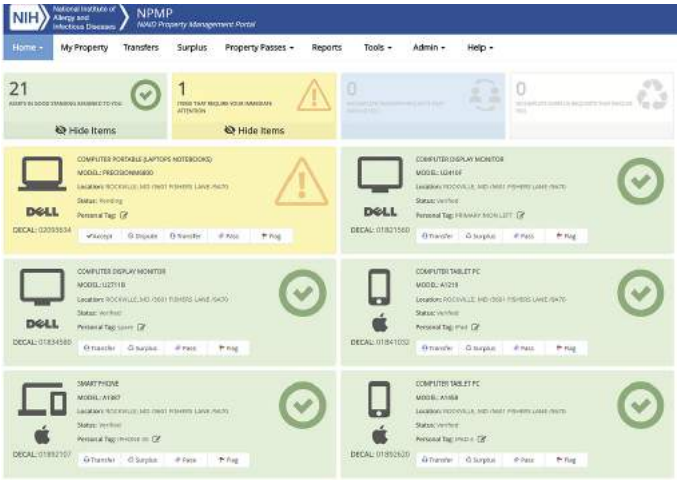
Custom software development is organized into the following lines of business programs: Administrative, Contracts Management, International, Grants Management, Human Capital Systems, Scientific Reporting, Extramural, and Financial Systems.

ADMINISTRATIVE SYSTEMS

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

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 updated email module and support for other NIH Institutes and Centers (ICs).



NIAID Property Portal Home Screen.

P-CARD Audit

P-Card Audit is an online tool that allows the NIAID procurement auditors to analyze purchase card transactions with the goal of identifying potential fraud, waste and abuse. Data that is entered is analyzed and visualized in the P-Card Risk Dashboard. This year, the application was opened for NIH OD and may be customized for use by other ICs.

P-CARD Audit Dashboard.

CONTRACTS MANAGEMENT

The Contract Management program provides system development and operation support for contract management requirements. The systems automate contract management, funds tracking, and reporting, streamlining the entire contract acquisition and funding process life cycle. Association and analysis of contracts information with major finan¬cial systems is another critical program responsibility.

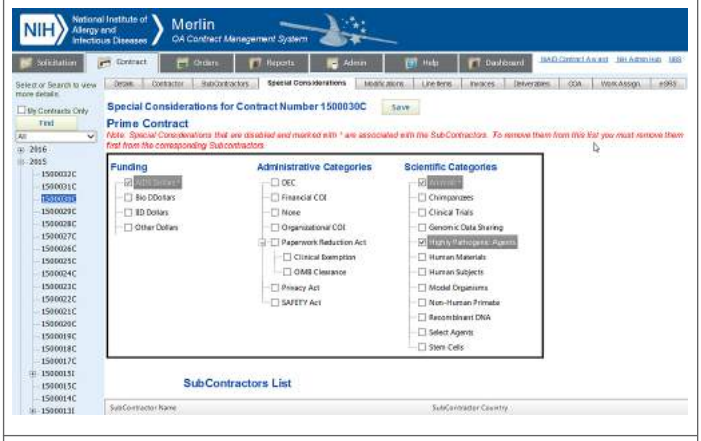
Significant upgrades were made to the following systems.

MERLIN

The Office of Acquisitions uses MERLIN to manage the Division of Extramural Activities (DEA) Contracts Acquisition Life Cycle. It provides real-time budget data by analyzing records contained in disparate systems against contracts data. In addition to behind the scenes technical improvements and routine maintenance work, significant enhancements include:

- Supplied the Vaccine Translational Research Branch Proj-

ects Practice Community with the ability to view the total award, remaining and "status of funds" information about their contracts from the DAIDS SharePoint site.
- Provided several custom views for the Portal site.
- Implemented Merlin and Contract Planning and Execution (CPE) integration; providing Contract Planning and Execution with contract/order data.
- Implemented Merlin and the Research Initiative Management System (RIMS) integration on non-research and development (non-R&D) initiative and solicitation.



Merlin – Special Considerations Selection Screen.

EXTRAMURAL RESEARCH

The Extramural Research Program provides custom applications developed for the DMID, the DAIDS and the DAIT divisions. Most of the systems automate processes to manage research requests and contract procurement and maintenance. The systems integrate with Electronic Document Records Management System (EDRMS) for workflow and document storage and archiving. The following system was a major enhancement for this year.

Contract Planning and Execution

The CPE application provides a common platform for Program, Office of Acquisition, and Administrative Office staff to plan, review and execute contract funding. This solution improves coordination across various offices involved in the contract funding process and promotes productivity transparency and accountability. It enables enhanced control over the contract funding process by establishing approval workflows that allow Contract Officer Representatives (COR's) and management in each division to review and approve the funding before the band Administrative Office review and approve.

The enhancements included integration of the approval process in and EDRMS workflow which provides the following benefits:

- Allows users to review and approve documents using electronic signatures in the required approval order, increasing efficiency and supporting telework
- Upon completion of the workflow process, approved documents are immediately available in a secure, access controlled repository.
- Provides tracking and reporting tools for the workflow processes; average step completion times, outstanding workflows by individual/groups, etc.
- Tasks are automatically assigned to individuals or groups, who receive emails notifying them to speed the processing of time-sensitive documents.
- A process history is maintained for audit trail purposes.
- Provides accountability and insight into document review process thus promoting transparency across the organization; helps supervisors track assignment status ("who, where, and when").

Contract Portfolio for Fiscal Year 2017

Obligations	$103,955,569.27	281
Reviews & Approvals	$ 1,458,695.00	1
Planned Actions	$ 27,818,033.72	241
Grand Total	$133,232,297.99	523

Summary Screen for Contract Portfolio by Fiscal Year.

FINANCIAL SYSTEMS AND GRANTS MANAGEMENT

Managing and tracking the NIAID budget across the years, from budget formulation to execution and reconciliation, is essential to report on the work of the Institute to various constituencies, including Congress. This is an intricate set of activities involving all 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 to manage the NIAID budget from initial planning to close the books.

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

These tools provide complementary 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, the Information for Management, Planning, Analysis, and Coordination System, version two (IMPACII), and NPARS. Significant collaboration and involvement with the Budget Office was necessary to establish the FY2017 operation budget, track expenditures and data reconciliation effort to close budget books.

Enhancements this year include:

- Opened Checkbook for FY2017 for budget operation by integrating initiative planning data to the execution year and establishing budget pools for commitment base.
- Provided various reporting solutions with data analysis dashboards that allow coordination, transparency, and accountability between Divisions and Grants Management and Budget office to manage the NIAID budget portfolio.

The following reports were incorporated or revised:

- **Common Account Number (CAN) Reconciliation:** The CAN Reconciliation report allows the Office of Financial Management (OFM) reconcile expenditures by comparing total NIAID expenditures (released, committed and awarded amounts) with IMPACII data. It provides users the ability to quickly filter down to applications, which are present in only one source or another or to grant applications that have a dollar difference between both data sets
- **Budget Mechanism:** Budget Mechanism categorizes NIAID budget portfolio into major categories including Research Grants, Research Centers, Other Research, Training Awards, Intramural Research, Research Management and Support (administrative costs for running NIAID) and several other smaller categories and shows all available funds, expenditures and balances for each category and provides drill down capability to the grant level transactions.
- **Soft Close:** Soft Close Report provides complete fund control capability (soft close) for the NIAID budget by providing a complete picture of available funds and expenditures at any given point of time. It simulates effective coordination between divisions and budget manage the NIAID budget portfolio.
- **Special Projects (Zika, CARB, EOY, AIDS Special Projects):** Allows Budget Office to monitor and track spending on special funds.
- **End of Year Report:** Allows Budget Office and Divisions to manage and track end of year expenditures and end of year grants that are in pipeline providing actual and projected expenditures.
- **Paid/Unpaid List:** Paid/Unpaid list report compares NIAID and IMPACII data sets to track grants and supplements that are released using NIAID grants management systems but have not been awarded in IMPACII. This report is heavily used during the end of year and it servers and allows open communication between Budget and Grant management to close the budget books for the Fiscal Year.

NIAID Budget Realignment System

This application automates the creation, submission, and approval of realignment requests to authorize budget transfers between NIAID initiatives across missions, divisions, and fiscal years. It integrates the realignment of funds with the Research Initiative Budget System (RIBS) and Checkbook.

System features include the following:

- Users can consolidate realignment requests spanning divisions and missions for multiple fiscal years into one request.
- Allows divisions to link grants to the request destination initiative.
- Notifies Office of Mission Integration and Financial Management and the Resource Planning and Mission Integration Branch when requests are received for approval or rejection.
- Notifies divisions when Resource Planning and Mission Integration Branch (RPMIB) and Office of Mission Integration and Financial Management (OMIFM) their requests are approved or denied.
- Provides flexibility between on the approval process between OMIFM and RPMIB, as both offices are required to approve it.
- Integrates requests with RIBS and Checkbook to reflect available initiative funds.

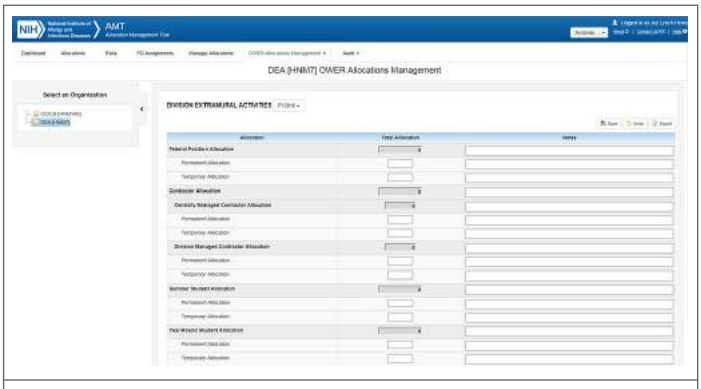
This year, the NIAID Budget Realignment system became the system of record to track contract realignments along with initiatives to prepare and manage NIAID fund realignments across multiple divisions. This provides transparency of budget dataflow in the organization by reflecting ongoing increases and decreases in budget allowance.

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 are discussed below.

Allocation Management Tool (AMT)

The Office of Workforce Effectiveness and Resources tracks official position allocations for the institute. An important aspect of this process is ensuring that NIAID does not exceed its official allocations ceiling. This tool compares staff information within NIAID's Workforce Management System against the official position allocations. Administrative and supervisory personnel can now easily track their position and slot allocations.



Input page used to manage the official center, division, and official allocations, to ensure operation within ceilings.

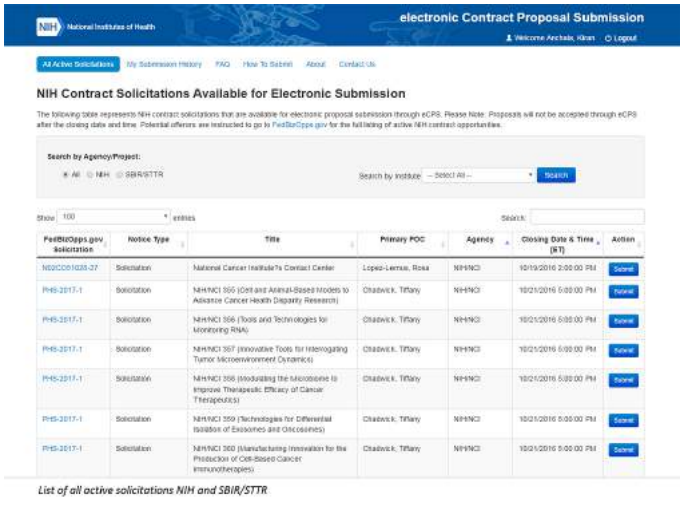
RECEIPT AND REVIEW PROGRAM

Contracts managed by the federal government must follow strict processes to ensure that taxpayer dollars are expended responsibly and that a level playing field is present for all potential vendors. It is essential that sensitive proposal information is not compromised. By provisioning the electronic receipt and review of contract proposals, the Receipt and Review Program decreases the risk of compromise and increases the productivity of Scientific Review Officers, Contracting Officer Representatives, and acquisition staff. It saves money by reducing work and document distribution costs. This program develops applications that are used internally and across the NIH, the Centers for Disease Control, and the Substance Abuse and Mental Health Services Administration.

Electronic Contract Proposal Submission

This component is part of NIAID's integrated, secure system for the electronic submission, capture, tracking, and review of research and development (R&D) contract proposals. Electronic Contract Proposal Submission (eCPS) consists of two systems; an external system which is used by vendors to self-register and submit contract proposals, and an internal system used to review and manage the proposals received. In addition to being selected as an NIH-wide enterprise application, the following objectives were achieved:

- The following ICs all successfully received proposals though eCPS in 2017: National Cancer Institute (NCI), National Institute on Alcohol Abuse and Alcoholism (NIAAA), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke (NINDS), NLM, Office of Research Facilities (ORF), Office of Research Services (ORS), Substance Abuse and Mental Health Services Administration (SAMHSA).
- Successfully received proposals for 2017 NIH and the Centers for Disease Control and Prevention's (CDC's) Small Business Innovation Research (SBIR) program that allows small business to submit electronic proposals across multiple ICs to encourage scientific and technical innovation.



Electric Contract Proposal Submission.

Electronic Reviewer Support System

This secure web-based application supports online reviewer collaboration by making meeting-specific information and resources, such as documents, notes, etc., available to potential reviewers within the NIH, nationally and internationally.

Electronic Reviewer Support System.

RESEARCH PLANNING PROGRAM

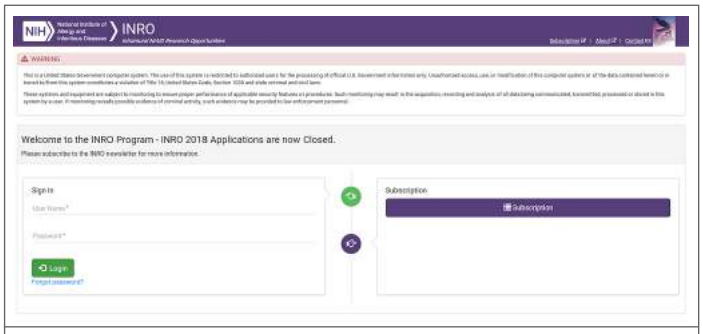
One of OCICB's goals is to ensure that decision-making regarding NIAID's research opportunities is based on accurate, timely, appropriate, and usable information and analysis by way of carefully developed software solutions. Research management systems (RMS) provide support and workflows for developing, planning, approving and reviewing the R&D process. These systems deliver meaningful views of research initiatives so that recommendations and funding decisions can be made. They are also the basis for grants and contracts management post-award sys¬tems.

Intramural NIAID Research Opportunities Application

The Office of Training and Diversity (OTD) offers the Intramural NIAID Research Opportunities (INRO) program which identifies talented students from populations underrepresented in the biomedical sciences. The program seeks out students who are interested in exploring research career opportunities in allergy, immunology, and infectious diseases and brings them to the NIH Bethesda Campus. While here, they spend four days with some of the Institute's premier researchers. The INRO application is used by students to apply for a slot in the program.

OTD asked OCICB to improve and modernize the user interface and take advantage of available technology to better match the methods students are now using to access and enter their information. They also wanted to streamline the student application review and administration process. In response, OCICB provided:

- New user interface, system architecture re-design and technology upgrade to enhance usability and system functionalities.
- Streamlined selection process that automates the complete workflow system.
- Easier student information interface that allows for multiple line entry, possibly table entry with a single upload and save function.
- Real Time Tracking Page to see Assignment loading sheet, Audit Trail, University Wise-head count, evaluation progress, and Milestone timeline.
- Improved Email notification system to seamlessly connect students, references, sponsors and program administrators.



INRO – Student Login Page.

Pharmacy International Establishment (PHIESTA)

The DAIDS Pharmaceutical Affairs Branch (PAB), part of the Office of Clinical Site Oversight, determines pharmacy requirements based on study protocols and provides oversight of the clinical site pharmacies. The PHIESTA web application was developed as their primary pharmacy database to maintain key information regarding individual site pharmacies. PAB staff can enter, update and query relevant site pharmacy information.

Major tasks implemented in FY 17 include:

- Implemented the custom query.
- Enabled multi-document upload for site visits
- Stored documents in Live link EDRMS
- Enabled keyword search of documents

PHIESTA – Clinical Research Site (CRS) List Page.

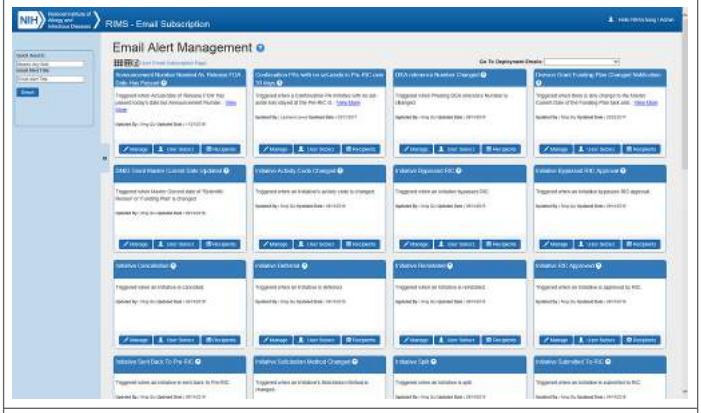
Research Initiative Management System

This system captures the relevant data needed to create, record, and monitor initiatives from concept to publication to award. Integrated components, or 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.

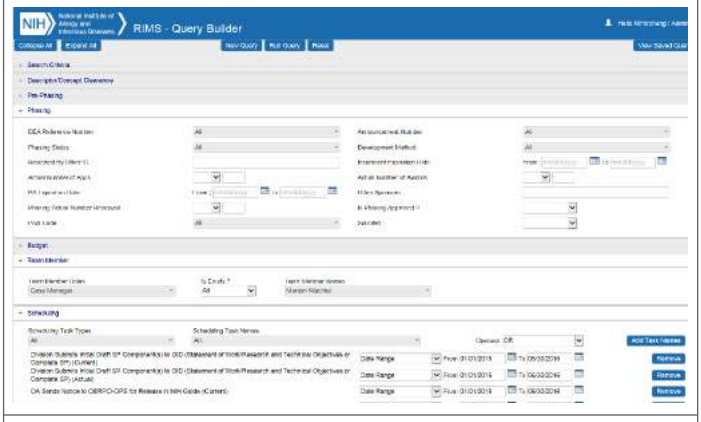
RIMS is secure and permission-based. All users must be registered with a specific assigned role. Privileges within the various modules are based on these user roles. These privileges are also highly dependent on the development stage of the initiative. RIMS is an integrated solution accessible from the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

Enhancements include:

- Non-R&D initiatives are included in RIMS. This involved coordinating multiple revisions across multiple modules. It also passes non-R&D initiatives to Merlin, the ERDMS RIMS Portal, and RIBS.
- Added a "Manage Email Alerts" module so that Office of Initiative Development Administrators can manage out-going email alerts; registered users can receive email alerts based on their individual preferences
- Division Coordinators are no longer restricted to creating initiatives for their own divisions; they can create Initiatives for multiple divisions.



RIMS – Email Alert Management.



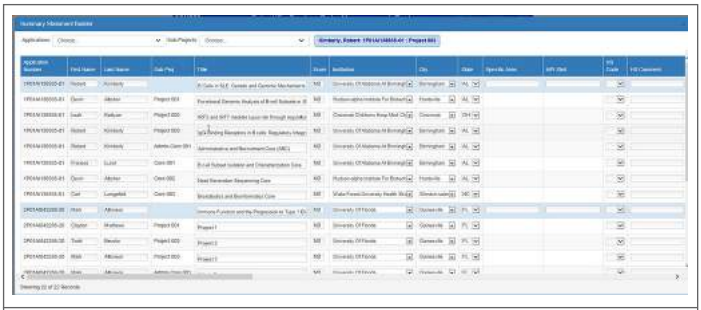
RIMS - Query Builder.

Scientific Review Data Management System

The Scientific Review Program peer review process is an integral part of the NIAID funding process. The Scientific Review Data Management System 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/ 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 con¬sistent and stable usage.

Enhancements include:

- Implemented an extractor to find critiques and strengths from the pre-summary statement in Word and save each critique and strength into the database.
- Created a builder to upload IMPACII application data required for the Final Summary Statement.
- Produced Final Summary Statement for single, charter and multi-project reviews.



Scientific Review Data Management System – Summary Statement Builder.

SCIENTIFIC REPORTING

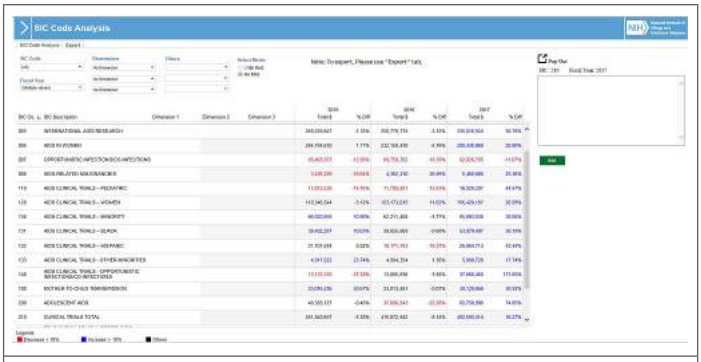
In support of the Institute's scientific coding and reporting database, and suite of applications for the Institute's requirements to report funding by areas of scientific research, the Scientific Reporting Program improved overall user experience by implementing enhancements to the Scientific Coding and Referral System (SCORS); Scientific Information Request System (SIR); NIAID Budget and Science Reports; and Multicenter AIDS Cohort Study database. New projects include:

Manual Categorization System

OCICB's Scientific Reporting Program has been heavily involved in assisting with efforts to coordinate NIAID coding systems with the new NIH-wide Research, Condition, and Disease Categorization (RCDC), known as the Manual Categorization System (MCS). The Program has been working closely with NIH's RCDC and Office of AIDS Research to advise and request enhancements based on clients' unique needs and our expertise in AIDS coding. OCICB has started downloading MCS data tables, and created complex discrepancy reports, to compare our Internal Coding data to that in MCS. Users can now export the report on-demand from our scientific report menus.

Special Interest Category and Strategic Plan Code Dashboards

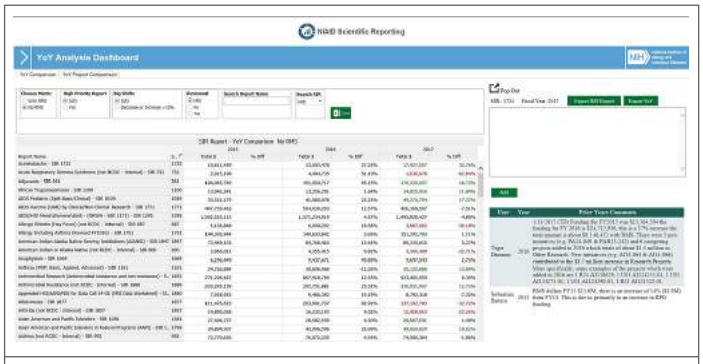
The Special Interest Category (SIC) and Strategic Plan Code (Plan) Dashboards were created to provide a flexible tool to analyze current and prior year NIAID spending per SIC/Plan code. These dashboards combine functionality from the tool Tableau, as well as a custom web-based section which allows users to enter and create and maintain comments. The flexibility includes options for dynamic dimensions showing breakouts by Project, CAN, Budget Mechanism, etc., as well as other types of scientific coding. Users can choose metrics for dollars with or without the RMS.



Analysis screen showing total dollars for SIC's by Fiscal Year.

Year Over Year Dashboard

The Year Over Year Dashboard was created as a joint vehicle for RPAB and the NIAID Budget Office to analyze the current year's dollars per scientific report against that of the prior years, and to share individual comments. It is especially important to use this tool, prior to freezing Fiscal Year reports, to flag and be prepared to explain large dollar decreases. This dashboard combines functionality from the tool Tableau, as well as a custom web-based section which allows users to create and maintain comments. Available dynamic metric choices include displaying dollars with or without the RMS, "Big shifts," "High priority-only", or reports flagged as RPAB-reviewed. The dashboard provides users with a choice of multiple export options.



Year Over Year Analysis Dashboard.

ANALYTICS

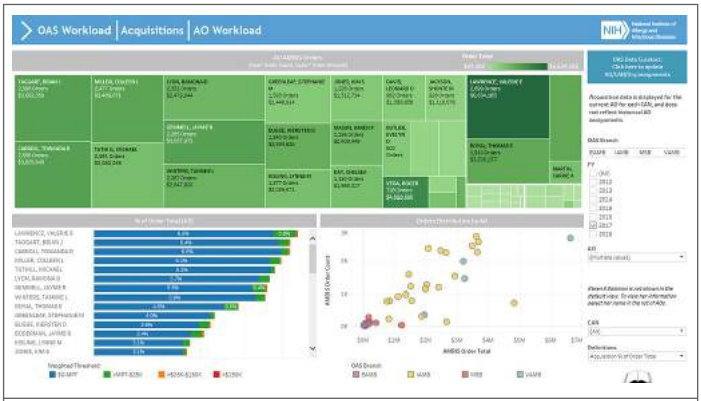
Business analytics provide a broad array of data visualizations and analysis dashboards for financial, administrative, scientific, and clinical programs. Data-driven decisions at all levels of the Institute are facilitated by providing task-based operational dashboards and sophisticated budget analysis 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 Factbook

Each fiscal year, NIAID publishes a Fact Book to report on the IC's annual Congressional appropriation spend. In previous years, the Fact Book was a PDF generated in a desktop publishing tool with data gathered from spreadsheets—a time intensive and error-prone process. For the FY2016 report, OCICB worked with data owners to develop a database sourced from authoritative systems to automate a significant portion of the Fact Book creation, improve data quality, and promote consistency in year-over-year reporting. The team also created a reproducible PDF report template that will significantly reduce the development time for future year Fact Books. For FY2017,

the focus will go beyond automation efforts to deliver an online interactive version of the Fact Book as a series of more innovative data visualizations.

Workload Dashboard for Office of Administrative Services



OAS Workload Dashboard.

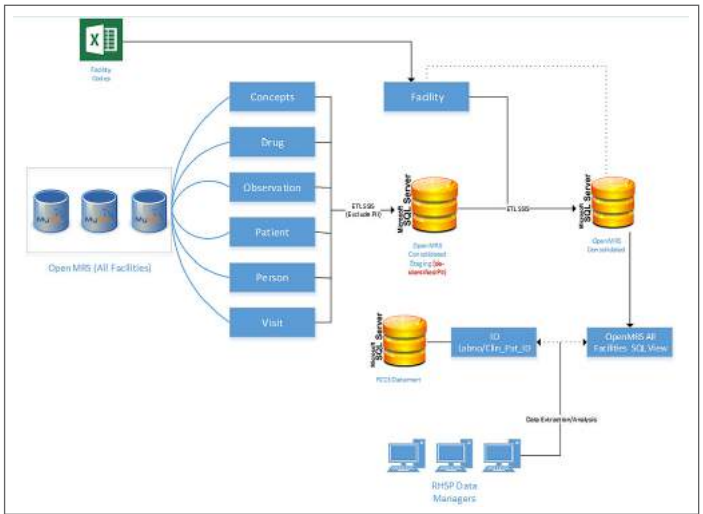
The Office of Administrative Services (OAS) Workload Dashboard was developed to visualize the acquisitions, travel and human resources (HR) activities by the responsible administrative officer (AO) to support resource allocation and strategic planning. The OAS workload dashboard provides insights and information to facilitate executive decision making in adjusting and balancing AOs workload and resource allocations.

Clinical Research Support

OCICB supported numerous efforts around clinical data management and analytics. Below are details from a sample of projects in which OCICB worked with clinical stakeholders to develop methods to consolidate data from various resources, transform and load the data into an integrated model, and provide the capability to report against the information.

Uganda Rakai Health Services Sciences Program OpenMRS Data Consolidation Effort

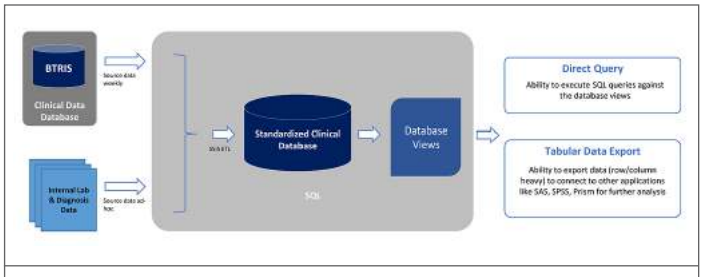
Rakai Health Sciences Program (RHSP) has numerous remote facilities where HIV treatment and care services are provided and data is captured on standalone OpenMRS systems. The OpenMRS data mart leverages Microsoft Structured Query Language (SQL) Server to consolidate OpenMRS data from 20 remote facilities into a single location. The merged database allows RHSP team members and data managers to extract data from multiple facilities with ease in a timely and efficient manner. Also, it enables linkage with the existing RHSP Data mart which contains survey and census data. By using the standard query templates, users can extract demographics information, clinical outcomes, follow up records, and regimen information for researchers. This process saves the data managers and researchers a significant amount of time and provide more accurate results the prior methods.



System Diagram showing the data flow for OpenMRS data.

Laboratory of Parasitic Diseases Helminth Immunology Section Data Consolidation Effort

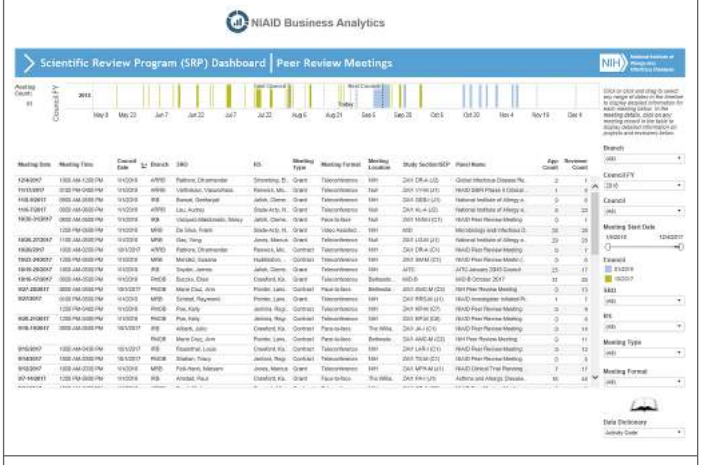
Built on the Microsoft SQL Server platform, the Laboratory of Parasitic Diseases (LPD), Helminth Immunology Section, Clinical Data Mart enable scientists and researchers to analyze LPD HIS research data in a centralized location. The data mart leverages a standard study data tabulation models (SDTM) and Biomedical Research Integrated Domain Group (BRIDG 4.0) compliant data model to consolidate HIS data from multiple sources, such as the Biomedical Translational Research Information System and Excel. Users can query the consolidated database views to create cohorts based on demographics, observation, medical history, and diagnosis. They can then export that data for analysis.



System Diagram showing the operational data flow of LPD Clinical Data for Research.

Scientific Review Program Dashboard

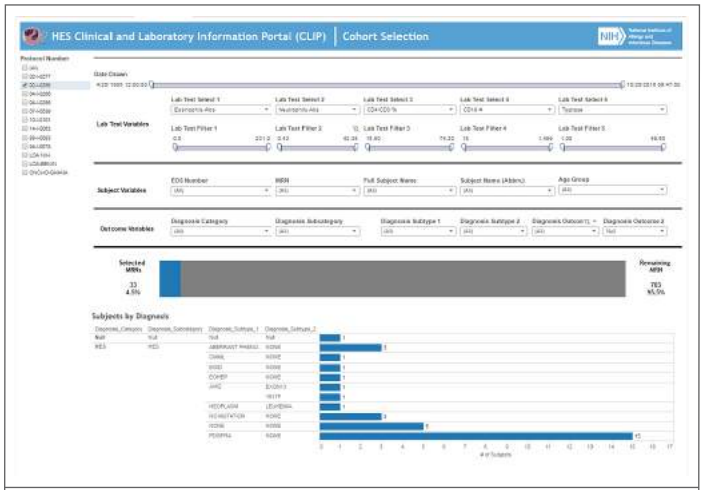
This dashboard provides an intuitive graphic interface that permits users to review meeting data for grant and contract applications, summary statements, scheduled review meetings, and program meeting trends. Data can be filtered by Branch, Council Date, Meeting Start Date, Scientific Review Officer, RS, Activity Code, or Summary Statement and Scoring Status. Users can analyze program level meeting information over time, and workload distribution. The dashboard is leveraged to gain better insights into pending activities at the aggregate and individual panel levels. It is also used to demonstrate the depth, variety, and the number of reviews that are conducted by the organization.



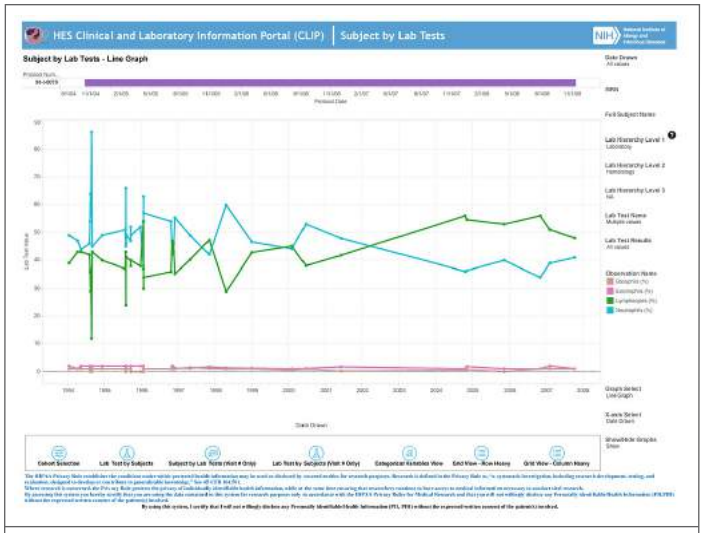
Dashboard showing peer review meetings along with details like # of applications and reviewers.

Clinical and Laboratory Information Portal

The Clinical and Laboratory Information Portal (CLIP) is a knowledge information platform where data from disparate sources is consolidated into a single location and curated for visualization-assisted discovery. Clinical and lab data are mapped and loaded to a standardized data model that is compatible with current biomedical and clinical standards, including Clinical Data Interchange Standards Consortium (CDISC) and BRIDG 4.0 standards. Users interface with the data through interactive Tableau visualization dashboards that support automated data loads. Users can create and save cohorts by filtering data parameters, visualize lab results by a patient or a group of patients, and export tabular views to Excel for further analysis. In addition to using CLIP for exploratory data analysis, researchers save time due to the user-friendly interface that lets them quickly and easily access their data used for conference posters and journal publications.



Users can select a cohort using filters on clinical and laboratory parameters and can view lab test results by subjects or groups of subjects.



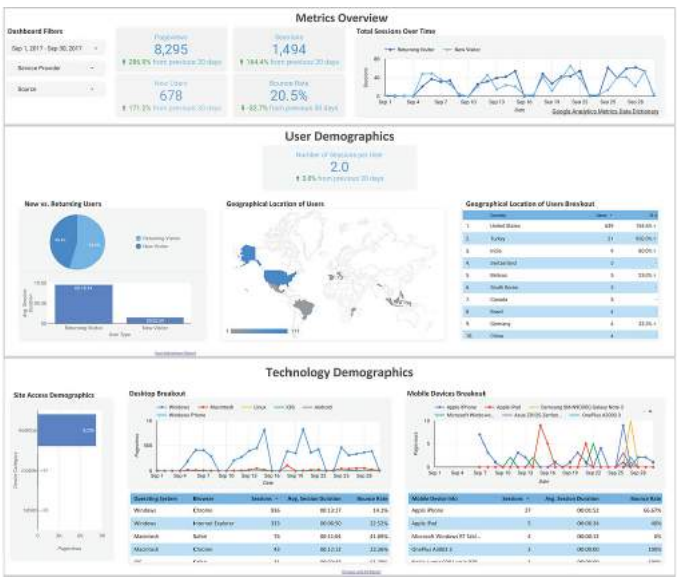
Users can select a cohort using filters on clinical and laboratory parameters and can view lab test results by subjects or groups of subjects.

Customer Analytics

To provide insight into customer interactions with NIAID web applications, the customer analytics initiative implements web analytics software in external and internal applications. Usage data is tracked using Google Tag Manager and Google Analytics, a tag management and web analytics tool suite that collects, processes and reports on customer website usage data. OCICB provides and analyzes the usage data to improve KPIs around customer retention and engagement, identifying bottlenecks in current application workflows that hinder the user experience. Data is further used to conduct technical segmentation, analyze user flow, and identify web acquisition traffic sources to ensure that applications are reaching their intended audience. Dashboards created in Google Data Studio, a web visualization and dashboard tool, pro-

vide insight into customer interactions to inform IT-management decisions and proactively identify and resolve application issues.

Self-Service Analytics and Joint Analytics and Metrics Sessions

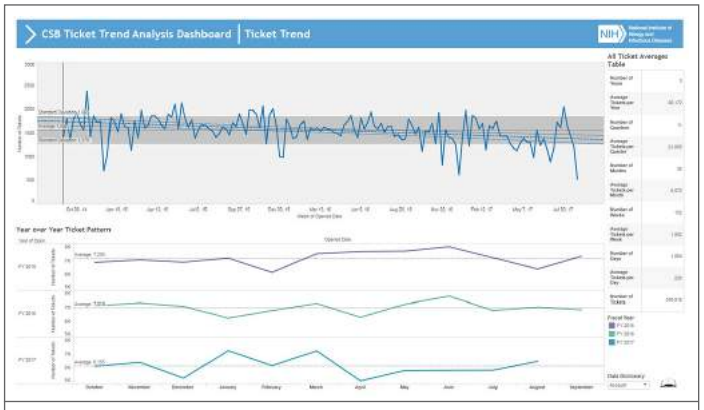


Joint Analytics and Metrics sessions (JAMS).

A self-service approach is employed to provide analytics to the institute. OCICB provides developer licenses and services to automate data feeds, test data and visualizations, clean up and rework visualizations, and publish the solution to production. OCICB uses Joint Analytics and Metrics sessions, or "JAMS," with NIAID clients to solve their analytic needs. There are several variations of JAMS, but the basic intent is to work closely with end users to visualize data in real-time, employing an agile methodology. Below are some examples of self-service applications that were developed by analytic end users with minimal assistance from OCICB.

CSB Ticket Trend Dashboard

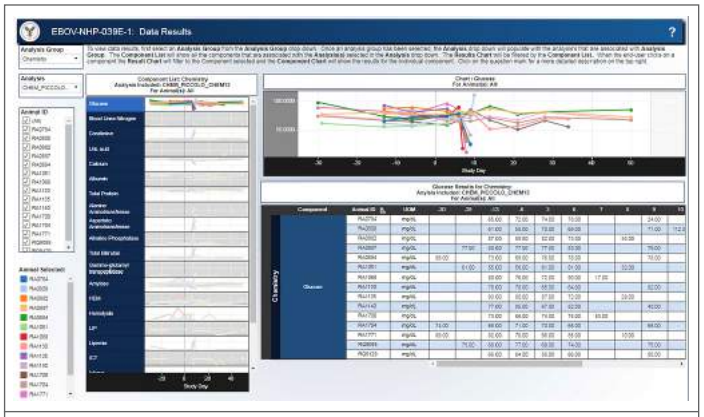
The CSB Ticket Trends Dashboard allows users to visualize NIAID Help Desk ticket trends. The service ticket data from Remedyforce is presented by ticket status, ticket category, incident type, divisions, building, and clients. The data is presented in meaningful graphic formats to easily reveal trends and workload distribution. The dashboard is integrated into a unified reporting layer for easy access and enhanced user experience.



Joint Analytics and Metrics sessions (JAMS).

IRF Data Browsers

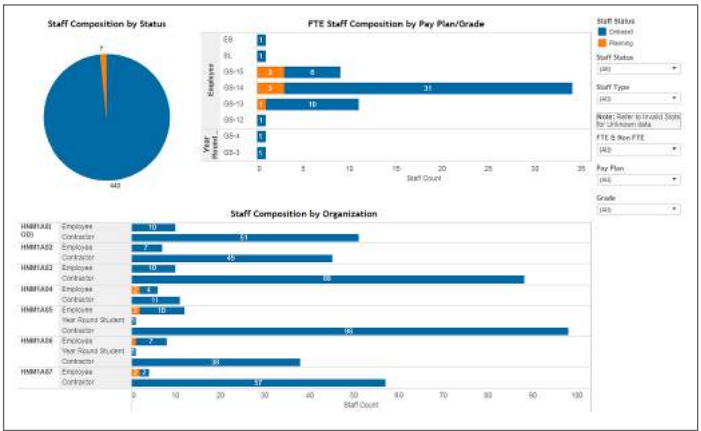
IRF researchers can analyze their laboratory and assay data from a centralized location. OCICB created a data repository on the Microsoft SQL Server platform that lets self-service analysts build specialized dashboards and reports.



Dashboard showing analysis of laboratory assay results for experiments at the IRF.

SEB Human Capital AMT Dashboard

The AMT Dashboard allows users to visualize OCICB full-time equivalent staff composition by pay grade and organization. Users are able to seamlessly navigate between the custom .NET application and the Tableau dashboard.



Dashboard showing OCICB FTE staff composition by status, pay grade, and organization.

DASHBOARDS

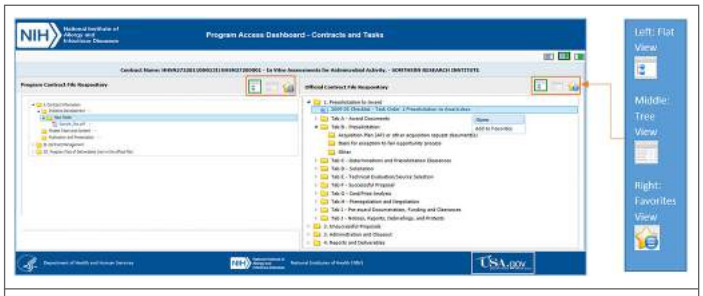
NIAID Program Contract Repository for DAITS and DAIT

This system gives CORS and program staff easy access to official contract files by leveraging the existing DEA Office of Acquisition Official Contract Repository. Key contract related information was available only via physical paper files - not easily searchable, no central access, lack of transparency, duplication, all leading to manual processes. As a result, program staff had to make both physical and electronic copies of contract documents to administer and oversee contracts.

This web-based solution is intuitive and user-friendly. The 'Program' section allows the program staff to work on relevant documents with the ability to easily view and access all official contract documents on the same screen. Previously, the Program staff had to hunt and peck because the files were duplicated in multiple locations. The site features:

- Web interface with on-demand access so designated staff can access all official contract documents without having to request them from Office of Acquisition
- Supervisors can monitor contract activities and step in as required.
- Transparent Central location and a standardized template-driven folder structure ensures an overall reduction in 'paper' documentation and duplication of documents (staff and official files)
- The system maintains an audit trail (more secure than paper file access).

After the successful implementation of the Program Contract Repository for DMID, the next phase focused on the rollout to DAIDS and DAIT.

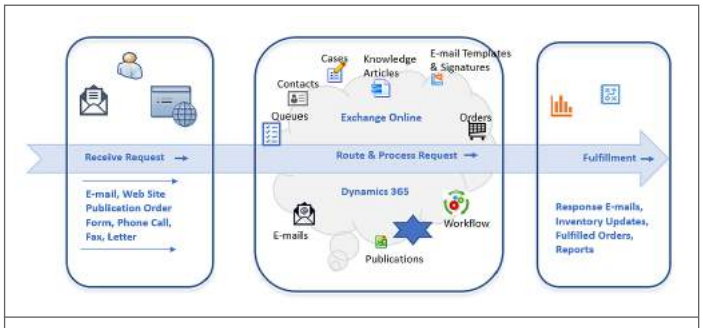


Program Contract Repository Dashboard.

OD OCGR Public Inquiry System

Every year, OCGR receives hundreds of inquiries from a broad constituency. OCGR must ensure that every request receives a response, whether the inquiry comes from senators seeking information on funding outcomes, advocates interested in specific research agendas, or private citizens requesting health care information. Their previous system for tracking and managing inquiries was hosted by a subcontractor.

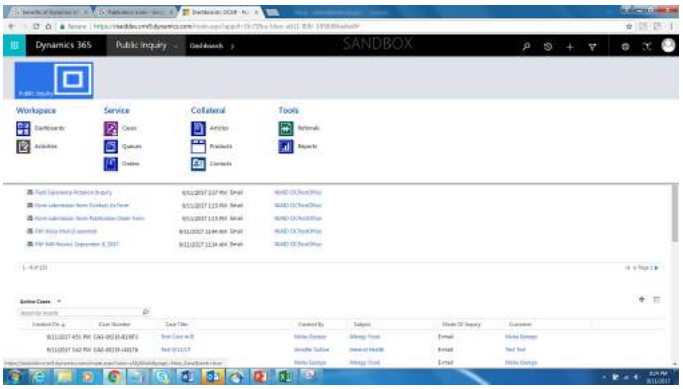
The Public Inquiry System is used to track and record inquiries received via e-mail, phone, fax, and letters. It provides tools that help generate responses, such as knowledge articles and standard response templates. It helps OCGR securely manage the NIAID publication inventory and fulfill order requests.



A high-level view of the Public Inquiry CRM System.

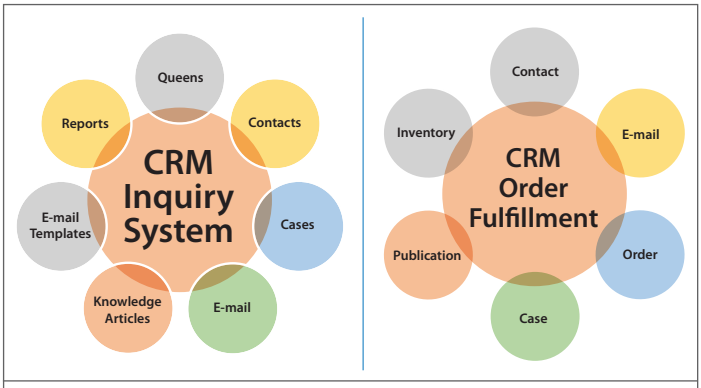
High Level Public Inquiry CRM System

The old system was developed in Microsoft CRM 2011. The new system was internally developed on the latest Dynamics 365 online environment hosted by Microsoft. Data from the old system was migrated to the online CRM system.



A view of the OCGR Public Inquiry Application.

The system has two major components; Public Inquiry, and Order Fulfillment. The Public Inquiry component tracks public requests to completion. The Order Fulfillment component allows order requests to be tracked and fulfilled against existing Publications. The system also maintains the publication inventory.



Public Inquiry Components and Order Fullfillment Components.

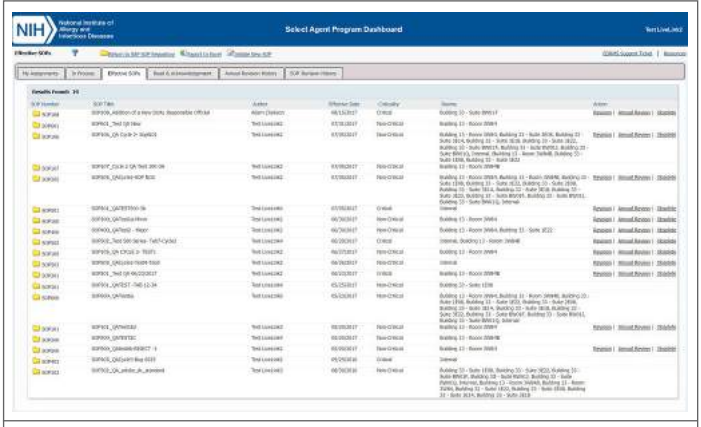
Benefits of the system include:

- Efficiently tracks all Public Inquiries and responses
- Allows for efficient order fulfillment and publication inventory management
- Creation of customer, case and order database
- Efficient response creation based on knowledge articles for technical inquiries
- Adherence to strict standards when creating responses by using email templates
- Easy assignment and monitoring of work via in-built queues which are tightly integrated with Outlook
- CRM Outlook client seamlessly track e-mails in the system
- Seamless access - Users no longer must log-in to sub-contractor system to access the CRM System
- The data is managed securely within the NIAID environment and e-mails do not have to re-sent to contractor email system
- Advance reporting and searching capabilities
- Reports based on Beats
- High security levels
- Advanced automatized back-up policies
- FedRAMP certified system managed and hosted by Microsoft

ORS-Select Agent Program SOP Management

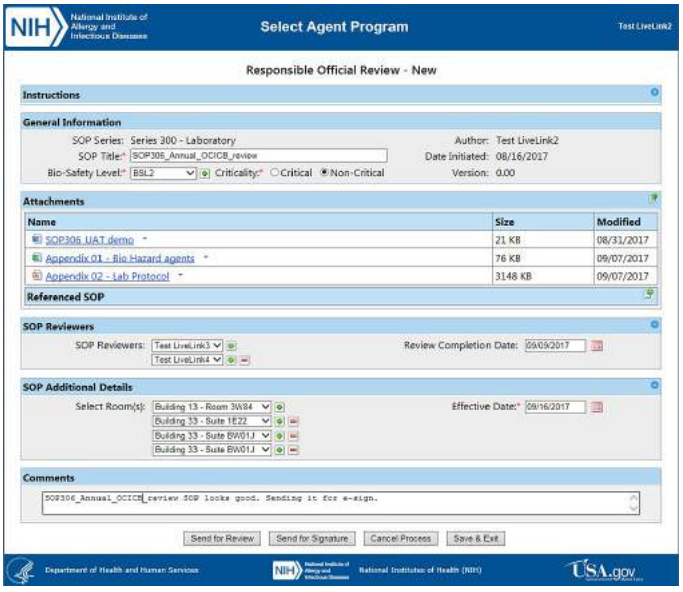
The Select Agent Program (SAP) within the Bio-Risk Management Branch (within the Division of Occupational Health and Safety in ORS) facilitates NIH research utilizing select agents and toxins. These biological agents and toxins have been determined by the Federal SAP to pose a severe threat to human and animal health, to plant health, or to animal and plant products. The NIH SAP registers participants in the Federal SAP; and provides initial and annual training as well as any necessary supplemental training related to a specific agent, toxin or biohazard level.

Launched in August 2017, the SAP Standard Operating Procedure (SOP) Management Application is a content management solution which provides organized storage, access control, automation of approval processes for newly crafted standard operating procedures, and their subsequent revisions and annual reviews. It includes dashboard reports for annual CDC audit requirements. And of course, it enables quick and secure access to the latest applicable SOPs. OCICB worked with business representatives from the NIH ORS SAP and NIAID's Division of Intramural Research (DIR) to leverage existing infrastructure to develop this content management solution.

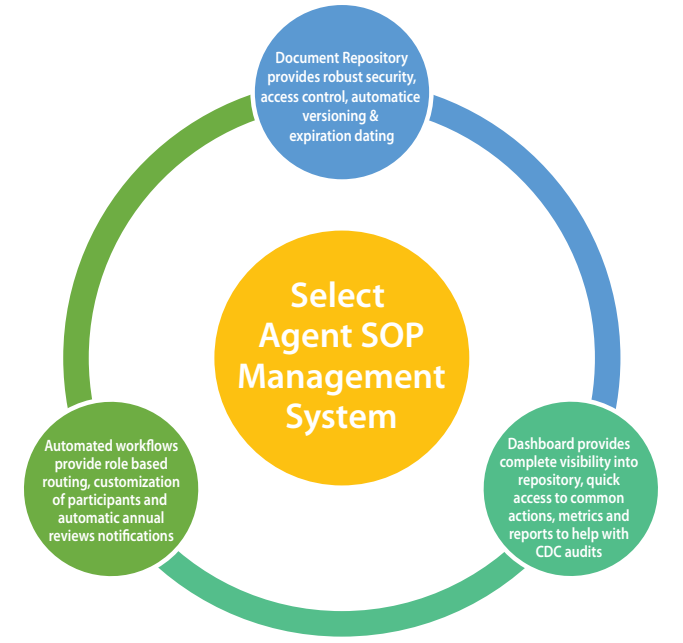


Dashboard ensures visibility into repository and quick links to Revision/Annual Review.

Select Agent Program SOP approval process flow.



Intuitive web interface for each step of SOP approval/revision workflows.



Major benefits of the Select Agent Program SOP Management.

This solution addresses three core objectives:

1. Secure electronic document repository for SOP's
2. Automate new approval, revision and annual review workflows
3. Dashboard that provides a complete picture of the repository

The system provides the following major benefits:

- Document repository provides automated versioning, efficient means to search for and retrieve specific documents, robust security, and access controls that manage role-based user access to sensitive documents; and protect against inadvertent access, edits or deletion.
- Automatic expiration dating of all printed versions of SOPs to assure end user-only access; and the ability to refer to latest SOPs.
- Electronic signatures to ensure the authenticity, integrity, signer non-repudiation, and when appropriate, the confidentiality of electronic records.
- Workflows that allow for customization of participants and role-based routing to meet variable business requirements.
- Automatic notification process for scheduled annual review due dates.
- Dashboard provides a central location to access SOPs and initiate revisions, annual reviews, and obsolete SOPs.
- Read and Acknowledgement Report provides the ability to view information on Read and Acknowledgement metrics data for SOP approvals.
- Annual Revision History Report provides visibility on upcoming annual review due dates and annual review completion data from the prior three years for a given SOP.
- SOP Revision History Report provides full revision history for a given SOP life-cycle to help with annual CDC inspection.

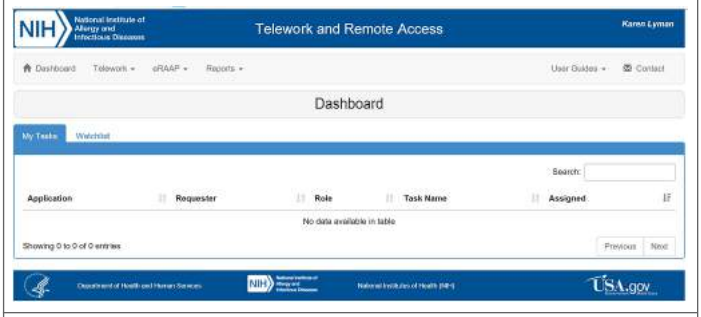
Telework and Remote Access Approval System

NIAID employees that want to work remotely must have an electronic Remote Access Agreement in place. The web-based Telework and Remote Access Approval System replaced two systems; the Telework system and the electronic Remote Access Authorization Process (eRAAP) application. A unified portal, it allows NIAID employees and contractors to initiate both requests from one location and provides a status update throughout the approval process.

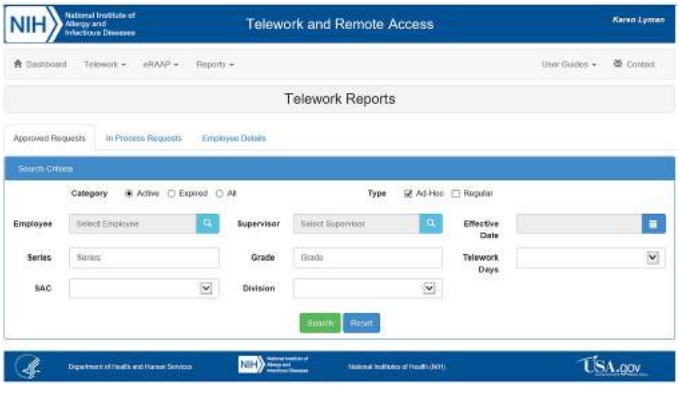
Although the topics are closely related – you can't telework without remote access – the telework and eRAAP workflows were built separately. They have their own landing pages and use different technologies. People needed to visit two different sites to manage their requests. After requesting and receiving approval for telework, you were required to initiate a separate request for remote access. Supervisors approved multiple requests in differing formats, and OCICB had to manage two systems and data sources.

That is why a unified portal was created. The Telework and Remote Access Approval System allows NIAID employees and contractors to initiate requests from one location. The different approving roles in the system can approve requests in a standardized manner. The new system incorporates efficiencies and improvements including:

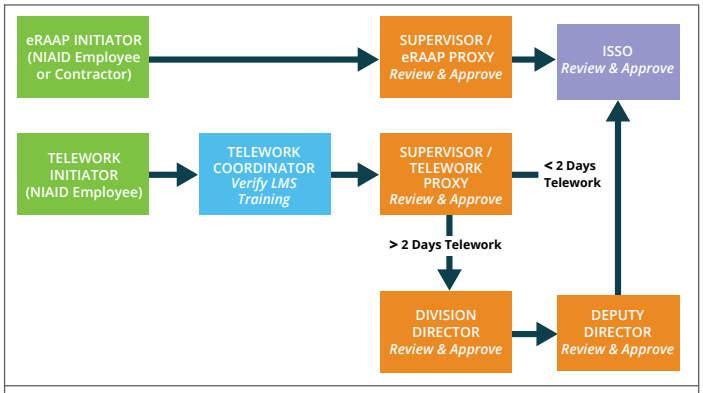
- Telework and eRAAP requests are combined into ONE approval process for NIAID Employees.
- Reporting implemented to track approved, pending, or expired requests.
- Division Director and Deputy Director approvals are included in the workflow when requesting more than two days per week of telework.
- Dashboard and assignments landing page lists pending requests for the current user and/or for their direct reports.
- Implementation of standardized integration with the NIAID Employee Assignment Registry to facilitate Supervisor Proxies.
- Integration with NIH CIT Training to verify completion of training requirements as a condition for submitting for approval.
- Migrated all data from the last two years into the new system.
- Synchronized expiration dates for telework and remote access.



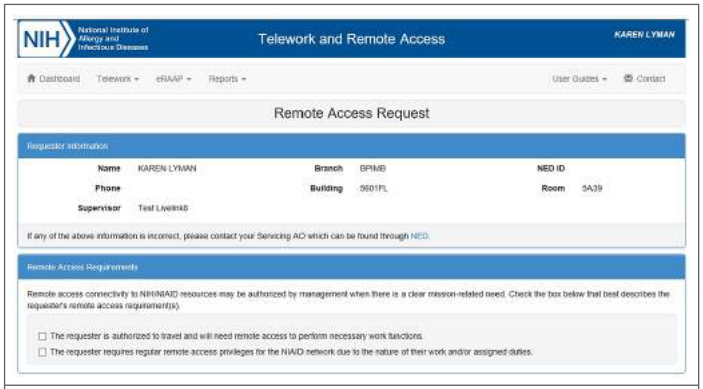
Telework and Remote Access home page with Telework and eRAAP access and one unified application.



Telework Reports with ability to search for approved and in-process requests and employee details.



Workflow diagram for the Telework and eRAAP processes.



Remote Access Request form without 'Telework' justification.

DAIDS Learning Portal

DAIDS offers online training courses for external partners, clinical researchers, grantees, and collaborators via a web-based system. Training courses include Clinical Best Practices, Human Subject Protection, Clinical Site Monitoring, Quality Management, and a host of other subject areas. The system allows sites to assign, track, and monitor the completion of required training for DAIDS-supported and/or sponsored clinical research sites. It hosts approximately 66 courses and is used by more than 5,000 users at 200 sites throughout the world. The system is comprised of two primary components: a front-end portal for end users access and navigate the system and a backend Learning Management System (LMS) in which course are housed and delivered.

The DAIDS Learning Portal (DLP) is the primary entry point for end users. The DLP is constructed in Drupal and includes a search-engine, course overviews with links to the individual courses and syllabi in the back-end, and a variety of resource links and material. The DLP was constructed by Westat, Inc. under a Clinical Research Support System (CRSS) contract using the HHS Enterprise Performance Life Cycle (EPLC) methodology. The DLP uses both standard and custom Drupal templates and options. Search, single sign-on, user profile, and links to the

backend were constructed using heavily customized Drupal functionality. It was in production since November 2012.

DAIDS and OCICB collaborated to bring the DLP site into NIAID's data center. Primarily, this change was to allow DAIDS to focus their CRSS contract effort on scientific and regulatory work. Increasingly, the Institute is insourcing IT functions from support and R&D contracts to OCICB to realize cost-savings, increase control, and meet IT security and regulatory requirements.

The process of migrating the DLP site was complex. OCICB developers familiarized themselves with the DLP code and configuration. Mirroring the previous configuration was challenging, but hard work paid off and the transition went smoothly.

DCR Good Clinical Practices Learning Center

Good Clinical Practice (GCP) is the standard for monitoring clinical trial performance to provide assurance that the data and reported results are credible and accurate; and that the rights, integrity, and confidentiality of trial subjects are protected. NIAID operates the GCP Learning Center (https://gcplearningcenter.niaid.nih.gov), a free resource for NIAID's staff, partners, and the public. It provides GCP training and offers certification for learners. The GCP Learning Center has become the de-facto training resource for the NIH community.

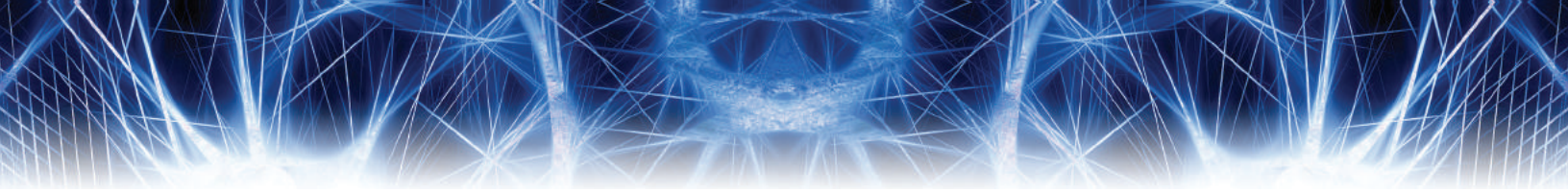
The original GCP Learning Center was custom software built on top of Microsoft SharePoint. Changes to the course content required a software developer to implement. Learning Management System features and activities, like quizzes and certificates, were developed specifically for the system. In 2017, the Division of Clinical Research (DCR) and OCICB decided to replatform the GCP Learning Center to the open-source Moodle Learning Management System. Moodle provides content updates, learning activities, and many other features out-of-the-box. Implementing the GCP training in Moodle required little software development. DCR course administrators can update and manage the course content without support from OCICB.

DAIDS VRP Portal

The DAIDS Vaccine Research Program (VRP) portfolio spans three areas of programmatic focus: Pre-clinical Research/Discovery, Translational Research, and Clinical Research. The mission of the VRP is to develop a safe and efficacious vaccine to prevent HIV infection.

VRP staff periodically collect and summarize information about their scientific portfolio in slide decks that are used by senior executives for presentations, and as source material for other documents and reports. Much of this information is currently maintained in a OneNote notebook that is accessible to users on an as-needed basis. Although the information is primarily used within NIAID, it is of interest and value to constituencies outside of the Institute.

DAIDS and OCICB collaborated on the VRP Landscape (https://vrplandscape.niaid.nih.gov) to permit access by interested parties to the VRP portfolio. VRP has a richer and more current portfolio and provides NIAID executives and scientists with an easily-accessible source for quality and current reference material. OCICB worked closely with DAIDS to customize the open-source Drupal platform to create a web-based, interactive research portfolio.



Training Initiatives

IN-HOUSE NIAID TRAINING

OCICB provides training support for IT projects and initiatives to the internal NIAID workforce. Materials are designed in-house and disseminated in person and online. This year there was a strong training focus on three major initiatives: eLearning, Office 2016, and Office 365.

eLearning provides interactive, self-paced on-demand content for the NIAID community. Those who are unable to attend training in-person, and people who only want to learn a specific subsection of content, can take advantage of the eLearning training modules at their convenience. The modules also serve as a great resource and refresher to people who previously attended a training. In addition to these readily-accessible eLearning modules, OCICB training worked with groups to develop event-focused eLearning solutions like the OAS Visioning event.

This past year OCICB worked with a number of groups to design and develop eLearning. Completed efforts include modules on the electronic Data and Reconciliation Tool (eDART), electronic Performance Management Appraisal Program (ePMAP), and Navigating OCICB. The ePMAP module caught the attention of the National Cancer Institute and Human Resources and Services Administration (HRSA) and both have requested to leverage it.

Current projects include an orientation for new DCR residents, Navigating DEA, Phishing, NIAID Property Management Portal (NPMP), and the Personnel Action Request Information System. With a focus on engaging and inventive content, compelling instructional design, and appealing look and feel, the eLearning initiative continues to expand across multiple groups and projects at NIAID.

Both the Office 2016 upgrade and Office 365 Mail Migration projects involved training to increase awareness, presenting how these changes will affect users, demonstrating the new technology, and providing hands-on guidance. The training team offered information sessions, desk-side training, quick reference cards, and classroom trainings to help aid in the success of these major projects.

Through September 1st, more than 251 in-person and blended classes reached 1,252 attendees. Topics ranged from general technology such as unified communications to conference room technology, Office 2016 and Office 365 upgrades, with a concentration on Microsoft Excel and other Microsoft Office applications.

Office 365 Training

To facilitate the move to Office 365, OCICB delivered instructor-led demonstration sessions on and off campus. The presentation highlighted anticipated changes to the Office workspace and included overviews of the timeframes, new features, and where to go for more help. Staff were given an overview of what would be different after the move, such as cloud features including a larger mailbox (100GB), access to webmail, and the availability of online archives.

The following resources are available:

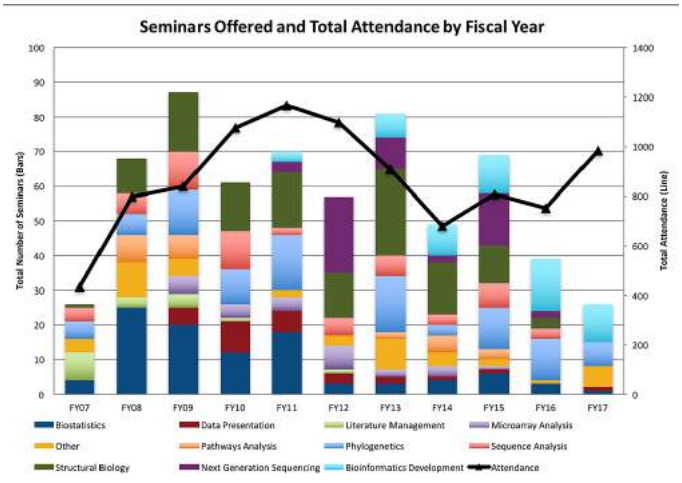
- Tri-fold brochure highlighting important information
- Frequently Asked Question document
- Mac-specific changes handout
- Step-by step instructions for mobile email setup

IT Training

OCICB provided IT training in a range of formats to best meet the needs of NIAID staff:

- 251 classroom sessions
- Four virtual sessions
- Six blended classroom and virtual sessions
- Five lobby sessions
- 175 individual deskside training sessions

In addition, OCICB developed three new on-demand online courses (eDART, ePMAP, and Navigating OCICB) that NIAID staff can access 24 hours a day, 365 days a year.



OCICB provided scientific software training to 1,255 NIAID staff on 22 topic areas.

Go to http://ocicbtraining.niaid.nih.gov site for information on IT training course. You will find class schedules, user guides, quick reference cards, and tips. During FY2017 Fiscal year, the site received 9,043 Page Views from 2,499 sessions.

External Training Events

DataFax User Group (DFUG) Meeting
September 27- 29, 2017
Orlando, Florida

The DFNet hosted the annual DataFax User Group (DFUG) Meeting. Three members represented the OCICB International Support Team: Kanwaldeep Bajwa, Neshen Moodley and Jaskiran Singh. The organizers invited the OCICB International Services Team to deliver two presentations: "Uploading REDCap source data to DataFax" and "Automating the flow of Clinical Data from DataFax to a visualization tool and data warehouse environment." Jaskiran Singh and Neshen Moodley presented on behalf of OCICB.

Jaskiran Singh, OCICB, presenting at the 2017 annual DataFax Users Group (DFUG) conference in Orlando, Florida.

Society of Clinical Data Managers (SCDM) Conference
September 24- 27, 2017
Orlando, Florida

Jaskiran Singh presented, "Adopting CDASH and SDTM for Clinical Trials and Dashboards." It describes the process of creating an integrated solution that uses globally accepted CDISC CDASH standards. The presentation provided an overview of Clinical Data lifecycle from building case report forms (CRF) using CDASH, to mapping clinical database source systems into standard data model by adopting SDTM standards and using extraction, transformation, and loading, to creating dashboards.

(From Left to Right) Nick Moodley, Jaskiran Singh and Kanwal Bajwa attending the 2017 Annual SCDM Conference.

FMUG (Freezer Management User Group) Conference 2017
June 14, 2017
Rockville, Maryland

OCICB hosted the FMUG conference, which was attended by NIAID Data Managers and laboratory team members from Laboratory of Clinical Infectious Diseases.

CDMUG (Clinical Data Management User Group) Conference 2017
June 7, 2017
Rockville, Maryland

OCICB hosted the annual CDMUG meeting in the new Fishers Lane facility. Presentations and discussions included topics related to Good Clinical Data Management Practice (GCDMP), database compatibility with Clinical Data Interchange Standards Consortium (CDISC) standards, and best practices and future developments for the DataFax and REDCap CDM platforms. Attendees included data managers from the Laboratory of Malaria Immunology and Vaccinology (LMIV), Laboratory of Clinical Infectious Diseases (LCID), Laboratory of Malaria and Vector Research (LMVR), and Laboratory of Immunogenetics (LIG).

Presenters and Attendees at IBRSP's CDMUG Meeting.

CDISC SDTM Theory and Application Training Event
June 1-2, 2017
Rockville, Maryland

CDISC SDTM Theory and Application trainings were provided for OCICB, DIR, DCR, and DMID.

Bioinformatic Server Configuration Management Training
April 2017-Present
On-line

This course, presented by Jimmy Anthony Gerard Griffin, was developed for the NIAID International Centre for Excellence in Research and FNIH Public-private-partnership, the African Centre of Excellence in Bioinformatics Research.

CDASH Implementation Training Event
May 31, 2017
Rockville, Maryland

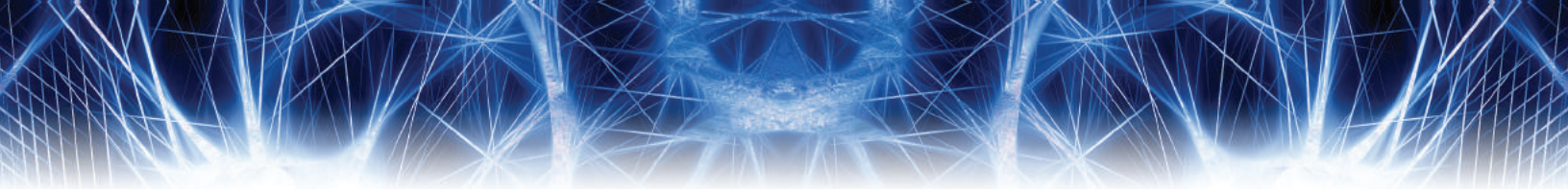
CDASH Implementation training was provided for OCICB, DIR, DCR, and DMID.

Internship Training for INA-RESPOND
April 2017
Kalisizo and Entebbe, Uganda

OCICB staff provided INA-RESPOND training to technical support staff from Jakarta, Indonesia at the NIAID ICER facilities.

Virtual Research Organization Workshop
March 13-24, 2017
Cincinnati, Ohio

Matthew Economou presented, "Deploying and Maintaining Federated Identity Management Services" and, "Deploying and Maintaining Virtual Research Environments" on behalf of OCICB.



Scientific Collaborations and Initiatives

GENOMIC Research Integration System

Vast amounts of clinical and genomic data are generated in translational genomics studies conducted by the NIAID Clinical Genomics Program (CGP) at the NIAID DIR. The collaborative CGP includes 16 laboratories working to better understand, diagnose, and treat disorders of the immune system in concert with clinical agents.

The Genomic Research Integration System (GRIS) web application will enable meaningful and synergistic use of clinical genomics data generated on NIAID-wide protocols. This will be especially helpful to capitale on resources generated from the NIAID Central Sequencing Initiative which aims to obtain whole exome sequences on all incoming NIAID patients. The portal was developed in close collaboration with CGP stakeholders, including DIR Director Steve Holland, M.D., Joshua Milner, M.D., and Michael Lenardo, M.D., as well as the team supporting the NIAID Clinical Research Information Management System and the Biospecimen Inventory System. The technical approach was guided by the FAIR principles to make data Findable, Accessible, Interoperable, and Reusable.

GRIS developers customized and linked Phenotips®, a free open source clinical database tool, and Seqr, a genetic analysis tool to enable researchers to traverse phenotypic and genotypic data. GRIS provides automated, streamlined data capture from disparate systems and paper-based records, reducing costs and errors associated with manual data entry. Data access and sharing workflows are optimized to promote maximum data usage while protecting patient privacy and confidentiality. Role-based authorization and authentication via NIH login credentials, coupled with secure data storage and transfer, enables quick access to relevant data for all aspects of the clinical study lifecycle. Users can quickly document, view, and download patient relationships. The research team can quickly search and retrieve data and produce reports for research administrators.

GRIS provides seamless access to powerful integrated clinical genomic computational tools. Analysis methods and parameters are logged so the results can be understood more transparently. The use of standardized vocabularies allows researchers to query and retrieve data from all the studies in GRIS, increasing the statistical analysis power, making discoveries otherwise not possible using data from individual studies.

Outreach to promote reuse of the tool includes tutorials and hands-on training. GRIS was presented at scientific meetings and workshops.

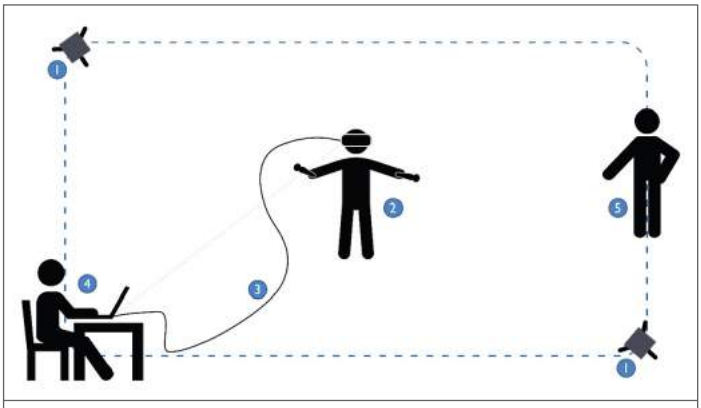
Integrating Virtual Reality

Virtual reality (VR) combines a computer-generated environment with wearable hardware in the form of a head-mounted display to create an immersive, interactive experience. A user can view the virtual world in all directions and interact with virtual features. While VR has traditionally been used in gaming and entertainment, new and diverse applications are now emerging. Structural biology depends upon the process of understanding the complex three-dimensional (3D) structures of biomolecules. VR environments provide viewpoints and stereoscopic depth information that cannot be grasped with a traditional stereo-3D view on a 2D display. The HTC Vive VR headset used at NIAID is a fully immersive virtual environment compatible with the UCSF ChimeraX molecular visualization application (https://www.rbvi.ucsf.edu/chimerax/).

In the virtual environment, scientists can explore their molecule of interest in ways similar to how they might interact with a physical object or environment. Inexperienced users adapt to navigating the space and manipulating the molecules with hand controllers in one or two minutes. Moving through the virtual space involves physical movement, either walking or "pulling" oneself through the space, which serves to reinforce the researcher's comprehension by overlaying a spatial component to the mental map of the molecule.

Feedback from researchers was overwhelmingly positive. This includes not only the personal experience of being in VR, but more importantly, its utility for scientific discovery. Testers reported improved understanding of the structure and the relationships between specific structural features.

Dan Sackett, an investigator from NICHD, compared the experience of approaching a drug binding pocket to exploring the inner recesses of a cave, calling it "molecular spelunking." Three additional researchers who are highly familiar with the same molecule were presented with it in VR. Each person independently identified the same previously unobserved (and unreported before VR) drug binding pocket.



Set-up of the HTC Vive virtual reality environment for NIAID.

Dr. Michelle Crank (left; NIAID/VRC) explores a molecule in VR with UCSF ChimeraX, while James Tyrwhitt-Drake (right; NIAID/OCICB/BCBB, alumnus) explains to onlookers at the NIAID VRC during a virtual reality open house event.

Working with BARDA's CAVE2 Visualization Environment

In January 2017, OCICB was invited to use the HHS Biomedical Advanced Research and Development Authority's (BARDA) Visualization Hub, which contains a cave automatic virtual environment (CAVE). This next-generation, large-scale "visualization" is more appropriate here than "VR". Located in the Thomas P. O'Neill Jr. Federal Building, it provides 72 panels of 66m+ pixels for an immersive 360-degree stereo capability.

OCICB's objective was to experiment with CAVE2 capabilities that could support NIAID- and NIH-wide research. OCICB provided software resources, data, and a list of use cases and justifications for the resource. In September, OCICB supported a demonstration by then-Secretary of Health and Human Services (HHS), Tom Price, to a congressional delegation, which displayed the benefits of this high-tech environment.

NIAID researchers collaborate in the CAVE2 (Cave Automatic Virtual Environment), a resource provided by the HHS Assistant Secretary for Preparedness and Response.

Highlights

TEDMED 2016: What if we could bring abstract scientific into the physical, tangible world?

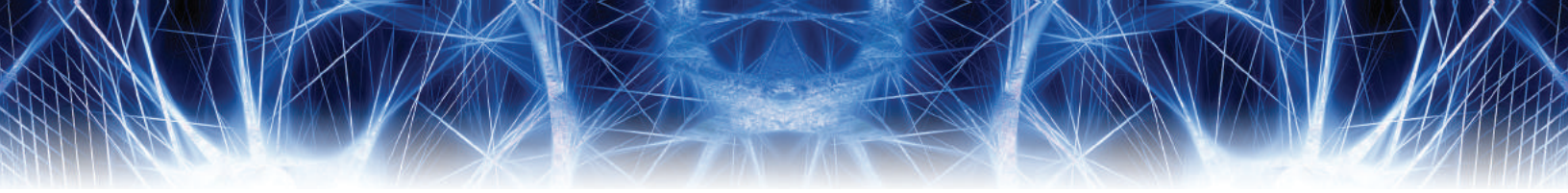
Dr. Meghan McCarthy presents as a Hive Innovator at TEDMED 2016.

At TEDMED 2016, the NIH 3D Print Exchange was featured during a two-minute talk given by OCICB's Meghan Coakley McCarthy. In keeping with the conference's "What If?" theme, the talk titled "*3D Printing Technology – What if we could bring abstract scientific concepts into the physical tangible world*," covered various uses of 3D Printing Technology.

3D Printing Technology allows for fabrication of complex objects that would generally be impractical, expensive or impossible to create using traditional manufacturing methods. Through the NIH 3D Print Exchange, 3D Printing Technology is being used to study anatomy and structures, build physical models of biomolecules, including deoxyribonucleic acid (DNA) and proteins, as well as to create and share scientifically accurate 3D representations of patient's organs with specialists all over the world; including surgeons who can now place

their hands and their instruments exactly where they will go before they even make an incision.

This technology is providing valuable insights into health and disease, diagnosis and treatment plans as well as patient understanding. Models are being used in hospitals, laboratories, and schools around the world to rapidly create 3D objects related to bioscience and medicine at relatively low costs. McCarthy explained that the NIH 3D Print Exchange's library of biomedical and scientific models provides an "amazing opportunity to advance learning, to accelerate research discoveries, and to improve patient care." She encouraged viewers to look beyond making things and discover the possibilities for making lives better.



International Program and Project Initiatives

The Predict Tuberculosis Protocol

Is it possible to reduce the drug regimen for tuberculosis (TB) from six to four months? That is the question the TB Research Section of the NIAID DIR Laboratory of Clinical Infectious Diseases is investigating by means of a clinical protocol exploring the potential to reduce the treatment regimen for drug-sensitive TB patients. Primary investigator Clifton Barry III, Ph.D., notes that while past trials have consistently cured 80-85% of patients after four months of therapy, the standard of care is to treat all patients for six months to avoid relapse that occurs in a small subset of patients. Why some patients have a higher probability of relapse is not completely understood. *Using Biomarkers to Predict TB Treatment Duration (Predict TB)* will test the hypothesis that a combination of radiographic characteristics at baseline, the rate of change of these features at one month, and markers of residual bacterial load at the end of treatment will identify which TB patients are cured following four months of standard treatment.

DCR provides multi-disciplinary support to NIAID's domestic and international research programs, including intramural clinical research management, regulatory oversight services, and statistical research and consultation. OCICB worked closely with DCR and DIR to integrate systems and services to support *Predict TB*. Key to this endeavor is the new platform – The NIAID VRE – built to provide a solution for international collaborations involving researchers from many institutions.

Most staff contributing to the PredictTB protocol in South Africa are employees, students, or faculty at the University of Cape Town or at Stellenbosch University. Both universities are part of the South African trust federation SAFIRE. This made it easy to add them to the NIAID VRE. The VRE lets researchers from federated sites use their existing organizational credentials to log into the Document Management system in the SharePoint server operated out of Bethesda.

In addition to working with the Identity and Access Management staff for the South African Federation, University of Cape Town, and Stellenbosch University, OCICB is working to support researcher identities and credentials for scientists working in China. They have credentials for OCICB systems, and testing is underway to integrate credentials from the Chinese Research and Education federation as well as commercial providers such as Weibo and Ali Baba. These options are important to ensure that scientists in China have a local provider of identity and credentials for collaboration.

Once researchers log into the NIAID VRE they can access DataFax, a clinical data management system (CDMS) OCICB offers as a managed service. CDMSs are specialized systems that manage the collection of data for a clinical trial or protocol. They provide data collection tools that integrate quality checks during the data collection process (front-end data quality checks) and post-process (back-end data quality checks). Clinical research teams can screen data at the point of entry for typological mistakes, logical errors, and protocol deviations. CDMSs also provide tools for coding adverse events and medications using dictionaries such as Medical Dictionary for Regulatory Activities and World Health Organization Drug Dictionary.

DataFax uses a hybrid approach, enabling data capture in both paper and electronic formats. The Predict TB protocol is planned for five sites in the South African Cape Town region, and four sites in China, around the city of Zhengzhou in Henan Province. Study clinicians at these TB treatment clinics will screen patients to see if they meet the eligibility criteria for protocol enrollment. Initial data will be collected on paper Case Report Forms (CRFs) for those TB patients who meet the inclusion parameters. The forms are available in English and Chinese at the sites around Zhengzhou and in English at the South African sites.

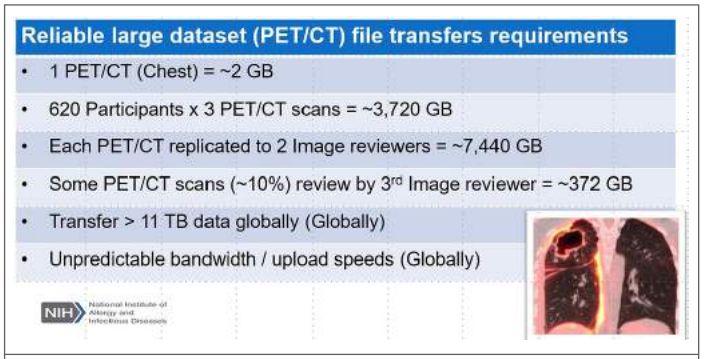
Eligible participants who join the study receive a Positron Emission Tomography/Computed Tomography (PET/CT) scan. The images, initially stored on optical disk or flash drives, are uploaded via the Aspera Drive client to the server located in the NIAID Data Center. Simultaneously, the study staff complete the CRFs that contain demographic information, clinical observations, and lab data, including the GeneXpert information.

The Digital Imaging and Communications in Medicine (DICOM) medical imaging standard for handling, storing, printing, and transmitting information is used to ensure that the radiological technicians obtain identical three-dimensional images. DICOM includes a file format definition and a network communications protocol. Like the image files taken by digital cameras and mobile phones, the file metadata includes information about the camera (PET scan). When a new set of image files is uploaded, the system extracts the settings to a text file that is imported into DataFax. This starts the edit check which triggers alerts if incorrect machine settings are identified.

Acquisition Date	20160407
AcquisitionTime	154131.907
DaysSinceFirstScan	0
InstitutionName	<Full Institution Name>
Modality	PT
PathPatientName	PD_13005_W0
PathScanNo	S36980
PatientID	143288090
PatientName	NG 019
PatientWeight	54
PixelSpacing	4\4
RadionuclideTotalDose	186400000
RadiopharmaceuticalStartTime	143700
ReconstructionMethod	3D-RAMLA
ScanDate	20160407
ScanRelPath	PD_13005_W0/S36980/
SeriesDescription	[PREVIEW] Total Body
SliceThickness	4
TimeSinceRPInjectionHHMMSS	01:04:31
TimeSinceRPInjectionInSecs	3871.907
VoxelSize	4x4x4
VoxelVolMM3	64

The above figure shows an example of the information contained in the DICOM metadata.)

Investigators asked OCICB to build image review randomization within DataFax for PET/CT images to minimize subjectivity in the reading of medical images. The randomization algorithm uses the CRF to assign each image set to two reviewers. A micro-service copies the image files from the primary image upload repository to the reviewers' folders. The Aspera Drive Client application uses User Datagram Protocol- a connectionless transfer protocol - that efficiently and quickly moves large data sets over the internet. Rich event logs and an audit trail comply with Good Data Management Practices for research data involving human participants.



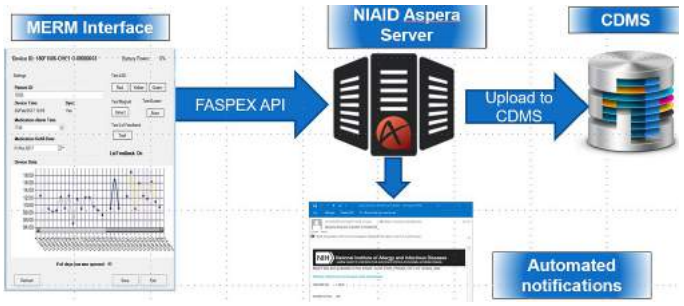
The figure above shows requirements for image review randomization within DataFax.

The CDMS notifies clinicians via email when they are assigned an image to review and score. The MIM imaging application provides 3D images to review. They can measure the pathology of the TB and record their observations. If the two randomized readers do not agree then the image is assigned to a third clinician to break the tied result.

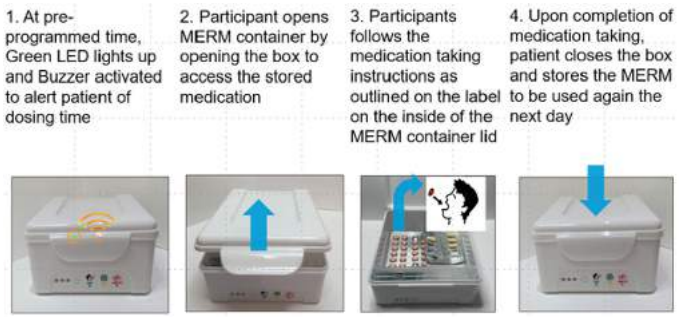
Clinicians use a single license server running as an instance in the Amazon EC2 Cloud. This lets them use the software they can connect to the internet. They can easily change laptops without having to return to central help desks for additional support and installations. This is an important feature in a study that is truly global in nature and operation.

One of the most difficult aspects of TB treatment is ensuring that patients take their medication daily and on-time. Failure to follow the regimen can lead to the cultivation of drug-resistant TB bacteria strains. The increasing prevalence of drug-resistant pathogens is a major concern to public health officials around the world. One method often used to improve drug adherence/compliance is a system known as Direct Observed Therapy. A health worker physically visits patients daily to observe them taking the medicine. Variations such as using mobile phones with cameras or clinic visits everyday exist, but are difficult and expensive.

Some PredictTB site investigators designed an alternative. Participants receive a thirty-day supply of drugs in a specialized Medication Event Reminder Monitor (MERM) box, built by Wisepill Technologies, a South African firm. The box issues audible and visual alarms every 24 hours to remind the participants to take their medication. When the MERM box is opened, it records the time and date. This information is stored until the box returns to the clinic for refill, where the data is downloaded into the clinic computer. Tuberculosis Research Section (TBRS) asked OCICB to optimize the MERM box interface. OCICB simplified it and added a line graph so the site can immediately see if the participant missed days. OCICB also automated uploading the output file to the NIAID Aspera server, providing an auditable treatment regimen record. The file can be imported into the study database.



The above diagram displays process of how the MERM container records patients opening/closing box for medication and how the information is stored and uploaded for researchers.



A view of the MERM Container.

At the sixteen-week visit, the site collects and uploads the adherence data, performs the third PET/CT scan of the lungs, collects additional laboratory data from GeneXpert, and refills the MERM box. DataFax integrates the data into a randomization algorithm to assign the patient to a treatment arm. One person will complete treatment immediately while another may continue through the standard 24-month regimen.

Implementing a simultaneous quality control system in parallel with the DataFax edit checks and manual data reviews was necessitated by the protocol complexity. OCICB built a server running the "R" Software environment for statistical computing. This open source software package, licensed under the GNU General Public License, is increasingly used by academic statisticians as a powerful and affordable alternative to commercially licensed products. DCR statisticians are using R Studio with a development server to build and test the code. It is then saved to a GitHub repository; the production R server pulls the updated code from the repository and implements it into the existing data flow. The input data for the statistical quality control comes from automated dumps of the data from DataFax using Cron and leverages the Aspera client on the R server to pull the flat files uploaded from the MERM boxes as well as the DICOM metadata.

The statistical program outputs include graphical and text files that need must be readily available to the study team. OCICB implemented an automated system to upload the R server output to the VRE SharePoint in the Amazon Cloud. This distribution method allows the study coordinators to keep site-specific information in locations that are available only to that site's staff.

PredictTB Space SharePoint Site

DCR faces multiple challenges intrinsic to international collaborative research. Study information and documents were distributed via email, and the lack of a single, centralized source of study information made it difficult for team members to locate current information. English is not the primary language for some study team members, presenting communication challenges.

OCICB worked with representatives of DCR's Biostatistics and Research Branch to develop PredictTB Space, a collaborative SharePoint site. The site fosters collaboration and was designed with cross-language considerations. Major features include:

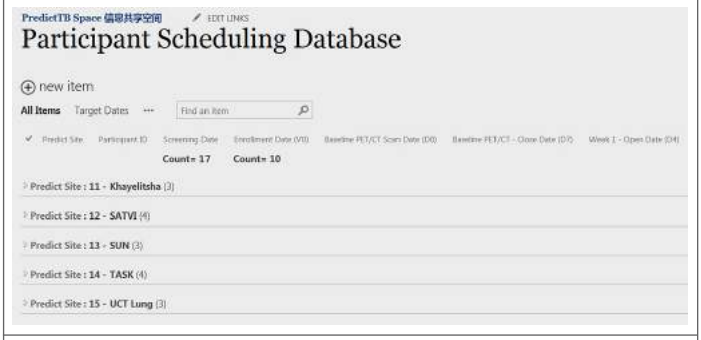
Unrestricted Document Libraries*	Restricted Document Libraries	Lists	Other Features
•Protocol •Case report forms •Operations manual •Investigator binder •Compilation of frequently-asked questions •Meeting minutes	•Study-wide and site-specific data reports •Imaging data reports •Open Data Safety and Monitoring Board (DSMB) reports	•Calendar of important study dates •Study participant visit scheduling database •Action item list for study team members •Study team member roster and contact info	•Navigational links in English (primary) and Chinese (secondary) •Option to display SharePoint menu functions in other languages •Useful links, such as email listservs for clinical site contacts

** Some documents are available in English and Chinese versions.*

Major features of the PredictTB Space SharePoint site.

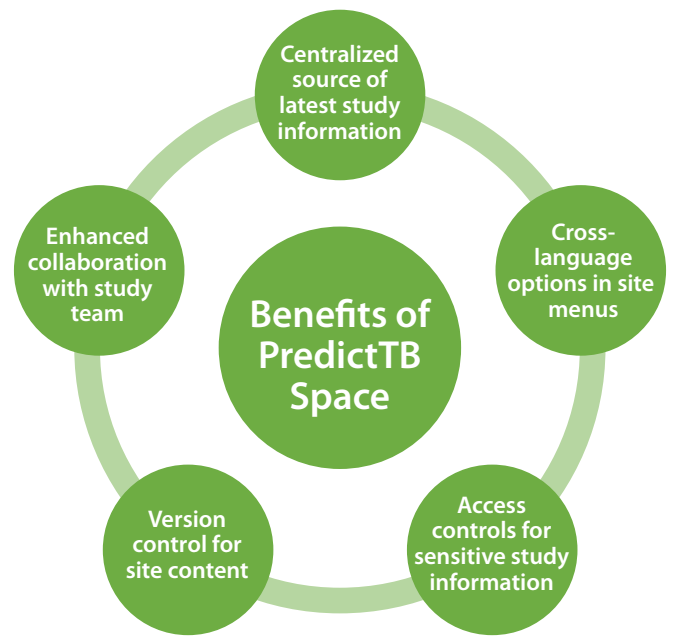
PredictTB Space home page, with navigational links in English and Chinese.

PredictTB Space SharePoint menu options (Chinese).



PredictTB Space Participant Scheduling Database, which automatically calculates visits dates based on enrollment date.

PredictTB Space addresses two challenges inherent to international collaborative research: dissemination of information to and fostering collaboration with geographically-dispersed study team members. PredictTB Space serves as a central, authoritative source of information for the PredictTB study.



Benefits of the PredictTB Space SharePoint site.

Study team members rely on the site for the most up-to-date study information, ranging from the latest protocol version to the study participants' targeted clinic site visit dates. Study team members can also access the email listserv section of the site, and with a single click, generate an email to a group of users, such as the PredictTB investigators.

The cross-language options available on the site also improves usability for study team members whose primary language is not English. Study team members can use the secondary navigational links in Chinese, or configure their preferences to display the SharePoint menu options in a different language.

OCICB Biothermic Service

Throughout the course of the Predict TB study, clinicians collect biological samples from participants at all nine sites. Due to restrictions on the export and transport of biological samples in some countries, the collaboration will store most of them in -80C Freezers in the local country.

OCICIB operates temperature monitoring and alerting systems globally that maintain a log of the temperature data from the specimen freezers so that monitors and investigators can review the quality of the samples. The OCICB Biothermic service also sends SMS text messages to local staff in the event of a temperature deviation. This is a critical component for international research that protects the significant NIH investment in collecting and characterizing these samples.

An ancillary system allows collaborators to track samples. Researchers record the freezer and location within that freezer of any given sample. Both tools are compliant with the FDA 21 Code of Federal Regulations (CFR) Part 11 standard.

Over the next five years, tens of thousands of PET/CT DICOM files will be uploaded to the NIAID servers. Thousands of CRFs will be sent, text files transferred, and specimens documented. Supporting the use of the data and results from this study will require continuous monitoring of this suite of tools. If the results of the trial recommend a change in the treatment regimens, the Institute must have a complete set of records for global health professionals to use to validate the results.

INA Respond

Since 2011, DCR has conducted clinical research with the Indonesian Ministry of Health. Known as project INA-RESPOND, research focuses on infectious diseases specified by the Ministry of Health of the Republic Indonesia. The list includes Malaria, Avian Influenza, Dengue, AIDS (HIV), TB, and other neglected infectious diseases.

One challenge in conducting research in Indonesia is adhering to the "Ministerial Decree number 657/Menkes/PER/8/2009," which prohibits the shipment of research specimens, biological materials, and research data/information out of Indonesia. To accommodate this, OCICB worked with the INA-RESPOND program to build a robust cyberinfrastructure. In FY2016, OCICB helped bridge the research program from its dependence on the previous contractor to a new clinical system. This effort required extensive training of the technical support staff and the conversion of many edit checks for validating clinical

data from the statistical language "R" into OpenClinica native edit checks.

OCICB performed several tests of the disaster recovery plan for the document management system, now fully migrated to SharePoint and running in a collocation center in Jakarta. OCICB also worked with the staff in Jakarta to program new studies into the OpenClinica Data Management System to support a new protocol INA102, which is a large study of TB patients in Indonesia and will be that country's first protocol that is part of the international Division of AIDS global network TB-RePORT. This collaborative network to advance TB biomarker research includes research at sites in Brazil, South Africa, India, and now Indonesia.

To support the growing cyberinfrastructure needs of the site OCICB also worked with the INA-RESPOND team to implement an Information Technology Service Management system to ensure that service requests and incidents have the proper tracking and documentation.

REDCap Server Deployment into VREs

OCICB deployed five new Remote Data Capture (REDCap) servers into the International VRE in 2017. Vanderbilt University received funding from the NIH National Center for Advancing Translational Sciences to develop this application. It facilitates the collection of clinical research data through both web browsers and mobile devices such as tablets and smartphones. The licensing model allows non-profit, government, or academic research programs who are members of the consortium to install and use it free of charge. OCICB joined the consortium on behalf of the NIAID intramural program and has begun using the system to support mobile data collection when protocols use tablets, particularly in remote areas where it is not possible to connect to the server due to a lack of infrastructure.

One distinct advantage of the REDCap system is that it supports federated logons which allowed OCICB International to easily integrate the servers into the Virtual Research Environments. This allows study managers to collect collaborating users from many institutions into a group that can work together in the collection, validation, and analysis of data. The VRE also provides a platform that supports the collection and retention of rich audit trails to ensure aspects of data provenance throughout the data validation process.

In the coming year, OCICB will be replacing the tablet-based data collection tool used for nearly six years as a mobile source data collection system for clinical research in field studies. REDCap offers the rare combination of a scalable licensing model with the offline data collection tool that is rare in the field of clinical data management systems. The offline capability combines the security of encrypted data transfers from tablet to server with audit trails and encryption of the data on the devices. Nearly all the protocols that the OCICB international clinical data support team hosts have source data included in the collection forms, the CRF. Because OCICB staff may not know which fields are source and which are copies of source as well as the potential for form designers to include participant identifiable information in a local study the regulatory team determined that the best model keeps the source data in the country and at the collaborating site whenever possible. The implementation of REDCap following this model includes a server at each International Center for Excellence in Research (ICER) has a server as well as two in the Amazon Cloud.

Connecting and UCRC

NIAID launched a new collaboration at the Mali ICER, the University Clinical Research Center (UCRC), which will manage and coordinate clinical trials and protocols for NIAID and other sponsors working with the Malian Ministries of Health and Higher Education. Located on the grounds of the National Hospital, adjacent to the Faculty of Medicine, OCICB provided organizational support and oversight to wire the new network and connect it to the ICER data center.

The NIH, the French National Institute of Health and Medical Research (INSERM), and the London School of Hygiene and Tropical Medicine (LSHTM), in collaboration with health authorities in Guinea, Mali, and Liberia, are launching a large clinical trial of candidate Ebola vaccines under the aegis of the Partnership for Research on Ebola VACcination (PREVAC) international consortium. A key requirement of the PREVAC Vaccine trial is to directly collect data from the laboratory equipment into a central database. Then the data is uploaded to the data management centers in France and at the University of Minnesota. OCICB added a microwave circuit from the ICER data center to the laboratories and office of the Center for Vaccine Development in Bamako. This 12-kilometer wireless connection allows the two computers connected to analysis equipment to save the data directly to servers in the data center.

OCICB extended the Biothermic service to the UCRC to monitor the temperature of the freezers, refrigerators, and incubators. This service alerts Malian staff in the event of a temperature fluctuation in units housing tissue samples, drugs, or vaccines. The temperature data and monitoring use an FDA-compliant system to ensure proper audit trails and access controls. These are critical for clinical trials and difficult to manage in regions with serious infrastructure challenges like those encountered in Mali, where power systems and maintenance standards are unpredictable.

Educational Roaming – Eduroam

All three ICERs are now connected with the educational roaming service (Eduroam), operated by the European Union for academic educational staff and researchers. OCICB worked with Géant, the EU academic research and education network organization, to extend this service to the ICERs in Mali, Uganda, and India. Eduroam is a global Wi-Fi network supported by thousands of universities, research institutions, and educational organizations to provide secure internet access for traveling students and faculty. This is an extremely valuable service for biomedical researchers who travel frequently to institutions. Many countries have restrictions on giving free unauthenticated internet access. This lack of easy access to the internet and to one another's research tools can be a substantial impediment.

However, when OCICB began the effort to extend the Eduroam networks to the ICERs there were serious challenges. None of the National Research and Education Networks (NRENs) had the infrastructure to support the service and lacked experience operating the RADIUS systems required. OCICB worked with Géant in the Netherlands and with all three national NRENs to provide this service, becoming the first customers in both Uganda and Mali. OCICB recently obtained access for the Indian ICER, allowing visiting researchers to access the internet using their own credentials. Because all the users identify themselves through their RADIUS logons it is possible to identify users who abuse the privilege and restrict their use or escalate to their home institution if necessary.

Uganda ICER in Research collaborating with RENU

Major upgrades to the OCICB managed Data Center and WAN for the Ugandan ICER greatly improved the ability to conduct research in these remote locations. The ICER in Uganda is geographically distributed, which provides a challenge. The primary site is in Kalisizo, a remote village located in the Rakai Province about a three-hour drive from the capital city of Kampala. The main offices are in Entebbe on the campus of the Uganda Virus Research Institute, which hosts other collaborative efforts such as the Medical Research Council of the London School of Tropical Medicine and Hygiene, the International AIDS Vaccine Initiative, and the US Center for Disease Control and Prevention. The ICER also works closely with the Infectious Diseases Institute at the Makerere University located in Kampala.

OCICB and the NIH have been working with the Research and Education Network of Uganda (RENU) since it was founded. RENU is a non-profit corporation operated for the institutions of higher education in Uganda and is a founding partner in UbuntuNET, the regional association of NRENs that have built an impressive collaborative network of fiber throughout East Africa. Together, OCICB and RENU deliver a reliable and high throughput data backbone between the Ugandan research sites.

OCICB worked with RENU to establish their Trust Federation and support for Eduroam. As one of the first trust federations in Africa, RENU is providing scientists, faculty, and students the ability to collaborate with other institutions, as well as to build services for local researchers. These scientists can now access the NIAID VRE platform to work with NIH research tools using identity providers at their own institutions. Using Eduroam, the ICER collaborators (and other academics in Uganda) can visit thousands of academic and research institutions in almost 100 countries and access secure fully encrypted Wi-Fi through this global network, which is operated by the European Research and Education Network association, Géant.

RENU provides the internet connection for the Uganda ICER at cost to its stakeholders and passes on the savings as bandwidth prices drop through increased capacity. The internet connection for the ICER sites increased from 20 Mbps this year to 27 Mbps, an increase in capacity of 10,500% in the ten years since OCICB connected the laboratories and offices via a satellite network. The inter-site connections between Kalisizo-Entebbe-Kampala increased from 100 Mbps to one Gbps. These dramatic improvements improve communications between the three sites through voice, video, and exchanges of data sets. The increased throughput makes it easier for the OCICB Business Analytics team to connect to the infrastructure in the village of Kalisizo from Fishers Lane to build the Uganda Data Mart that includes 25 years of health and demographic data on the Rakai cohort used for NIH sponsored clinical trials and research.

In 2017, OCICB installed new hypervisor servers to improve system availability for the Rakai district and a new effort that extends to the islands in Lake Victoria. The data center has new Power Distribution Units (PDUs) that can be remotely managed and have a higher wattage to allow the increased load of new equipment such as enterprise storage, servers, and network switches. Remote sites like the Kalisizo data center provide huge challenges. Utility power is not reliable and there are often problems with delivery of diesel fuel and the automatic transfer switches that fail the electrical power between the national utility grid and the local generators. The new PDUs allow OCICB to connect securely to the power delivery system from remote locations and observe power consumption, or cut electrical delivery completely to shut down systems. This is particularly useful when there are emergencies and local staff are unavailable.

A new backup inter-site circuit between the Kalisizo field site and data center with the Entebbe ICER offices circuit uses dark fiber and has significantly more bandwidth. It provides access to resources such as the Uganda ICER data mart when the RENU circuit is offline. OCICB added a new solar-powered emergency power system to the Entebbe campus offices that serves all or-

ganizations hosted by the UVRI and acts as the internet gateway for the Kalisizo and Kampala remote sites. The solar batteries will operate during electrical utility or generator failures. Massive quantities of patient data from the nearly thirty years that the site has been conducting research in the Rakai district are stored at the site. This personally identifiable data must be available for local health workers to use to treat residents who participated in the research over this extended period. This regulatory and ethical requirement makes it critical for the ICER to continue to maintain the local infrastructure.

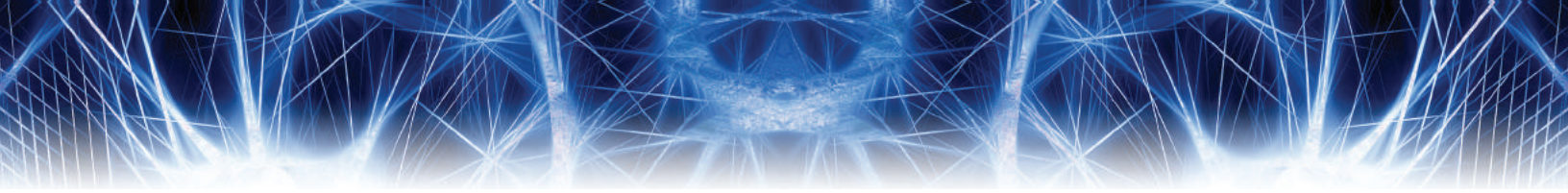
India Cyclone

The winter season in Chennai often begins with cyclones off the Bay of Bengal, and on December 12, 2016, for the second year in a row, the India ICER located in Chennai experienced catastrophic events as a result. The most intense tropical cyclone of the season was Vardah. This severe cyclonic storm struck Chennai causing a data center shutdown and an extended internet outage.

OCICB established a persistent VPN tunnel to a virtual private cloud in the Amazon Web Services data center in Dublin, Ireland where a copy of the Active Directory forest can operate. NIAID staff and their local collaborators are thus able to access their ICER email in the cloud during extended periods when the data center is offline. In addition, OCICB installed an out of band access system that allows remote administrators to connect over mobile data networks to the data center. They can switch off systems that might be causing the data center to overheat and shut them down. Remote management keeps people safe; Chennai staff don't need to take unnecessary risks in storms and floods to shut down the infrastructure.

VRE platform

This year, OCICB completed development of the most important component of the VRE platform, the SaToSa Proxy - https://github.com/SUNET/SATOSA. It allows the VRE to proxy between the research services that are the blocks within the NIAID platform and the global academic and research identity providers through the NREN Trust Federations. Not only does SaToSa allow security assertion markup language (SAML)-to-SAML proxying, it also supports SAML-To-OpenID Connect (OIDC) and OIDC-To- SAML. This provisions the NIAID collaboration platform for planned changes to the trust federations that will move to supporting OIDC instead of SAML-only authentication. The use of the proxy for all interactions with the VRE means that NIAID can now support institutions and countries where user confidentiality is particularly important. Those institutions use an authentication attribute that does not reveal the identity of the collaborator or researcher to the service by providing a different persistent identity for each service. Because NIAID presents its services through the proxy, users can access services for bioinformatics, data management, specimen management, and other research tools without requiring the scientist to create new identities every time. The effort to develop the SaToSa proxy is a collaborative open source project between the Swedish National Research and Education Network, SUNET, the NIH, and the Dutch NREN, SURFNet.



Rocky Mountain Laboratories Program And Project Initiatives

RML Consolidated Computational Research Facility (The Final Leg)

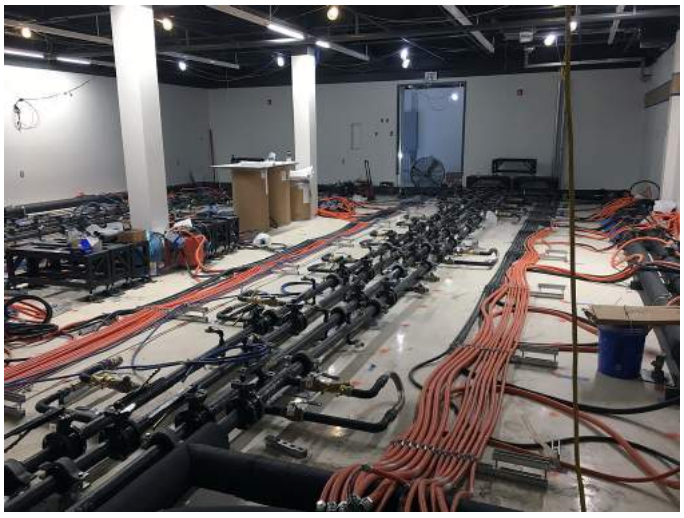
The third and final phase of NIAID's Network Consolidation Plan included merging multiple server rooms into the Rocky Mountain Laboratories (RML) Consolidated Computational Research Facility (CCRF). The original server room, constructed in the 1980s, was not large enough to support today's compute infrastructure needs. Back then, RML's campus needs were met with just a small footprint; including the use of "thick Ethernet" cabling, minimal computer connections and a small number of servers. Improvements in the late 1990s included upgrading to new network switches and cabling to support standard Ethernet connectivity; however, the need for additional servers and an enterprise backup solution caused issues with space constrictions.

In the early 2000s, the RML campus and it's cyber requirements grew was constructed. An additional compute space was allocated, mainly to support the new facility. The IRF grew, with the formation of several core facility groups—including Genomics, Microscopy, and Visual Medical Arts—and the addition of a new laboratory group. The resultant explosion in the need for multiple clustered compute platforms and servers and for large data storage arrays quickly consumed the empty space and taxed the power and cooling infrastructure of the compute space.

After years of researching options and locations, the construction of the CCRF began in 2017. The new space is separated into three areas with different functions: Entry/Staging area, Burn-in room, and main computational space. The Entry/Staging area will allow equipment to be brought in from the elements for unpackaging. This will keep packing materials, dirt, and dust away from the next area, which is the Burn-in room. In the Burn-in room, equipment will be configured and tested to ensure it operates properly before being installed into a cabinet in the main computational space. Since the air pressure in the computational area will be positive in relation to the burn-in and staging areas, the computational space will be a cleaner environment.

This project required special considerations for two reasons: the new space was previously an office and there is an active lab directly overhead. Advanced water damage and leak mitigation measures include new vinyl flooring in the lab space above with coved bases to contain any major fluid leaks, strategically-placed drip pans, and leak detectors that are connected to the Building Automation System to alert facilities staff about leaks.

Cooling for the computational room is provided by in-row coolers, which use liquid that is supplied at a constant temperature to provide chilled air. This liquid is supplied through a system of pipes and valves located under a raised floor, originating from several large chillers outside the building which provide redundant cooling to the space. To protect this space from liquid leaks, floor drains were installed. Also, an epoxy floor coating was installed on the floor and extended six inches up the walls in case of a large leak. Leak detectors were placed under the raised floor to alert the facilities staff of an issue using the Building Automation System.

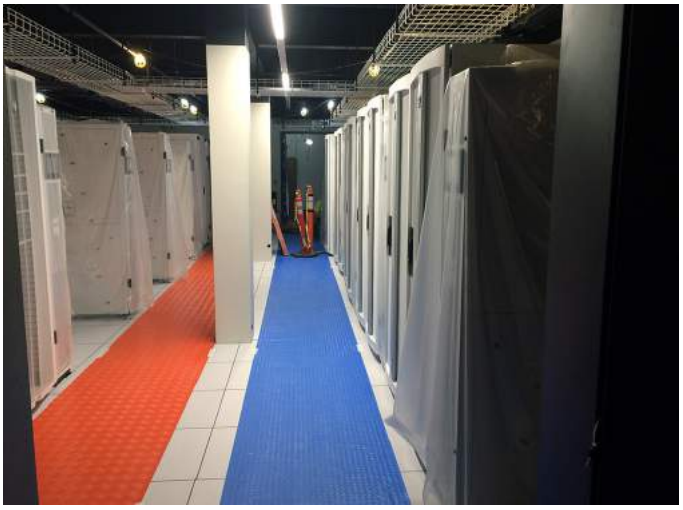


View of the power and cooling infrastructure that resides under the raised floor in the CCRF.

Lighting plays a big role in the overall function of the space. Light-emitting diode (LED) lights contain energy costs and provide a bright working area. All walls, flooring, and equipment cabinets are white. Although black computer cabinets are typically the standard, white cabinets reflect about 80% of the light while black cabinets only reflect about 5%. White cabinets save energy by requiring less lighting and allow for a better experience while working inside the cabinet.

During the ongoing construction phase, OCICB has been configuring the 24 Cisco Network switches that will be placed in the

CCRF. RML and Bethesda staff meet weekly to work on the migration plan; the move is tentatively scheduled for Q1 of CY18.



Here the raised floor is installed and computer cabinets are being placed in the CCRF.

An epoxy coating was applied to the CCRF concrete floor for protection in the unlikely event of a large leak.

RML High Performance Computing (The End of Supercomputers)

The arrival of the first Silicon Graphics (SGI) UV100 supercomputer in 2010 started RML's education in managing and maintaining large memory system computers. In 2010, "large Memory" amounted to 512 GB of RAM, an amount of random-access memory (RAM) that at the time, no standard computer server could provide; and which RML soon found limiting. In 2011, the RAM was expanded to one TB in the SGI. For the next four years, RML researchers learned to manage and make the most of the one TB of RAM, which allowed the loading of entire databases into memory or the assembly of large genomes in reasonable time frames. By 2013, one TB proved inadequate, and the four-year-old central processing units (CPUs) were showing their age. A new acquisition resulted in a SGI UV2000 supercomputer with four TB of RAM and four times the number of cores. This supercomputer proved pivotal in defining and understanding the functional computational requirements for the majority of RML's bioinformatics jobs and tools. Over the next two years, as RML users and system administrators collaborated to understand and modify bioinformatics packages to make the most of the UV2000's capacity; they realized that while four TB of RAM supported multiple simultaneous users, it was beyond what a single user would need for any given large memory task. It was determined by early 2017, that three TB would sufficiently support any single large memory task for the next three to five years.

RML's first foray into supercomputers coincided with users reaching the practical RAM limits of 2010-era commodity servers, which typically provided 256 GB of RAM. Going beyond those limits required a decision to either move to common off-the-shelf cluster computing or invest in large scale non-uniform memory access (NUMA) supercomputers. NUMA architectures provided separate memory to each processor, thus increasing performance. Both paths offered large memory space with trade-offs. From a purely hardware standpoint, commercial-off-the-shelf (COTS) clustering was cheaper—it used COTS components, but exacted a high cost in performance as well as in administrative and software support. On the other hand, large scale NUMA supercomputers were anything but cheap due to custom-built integrated chips and systems buses which provided non-uniform memory access to terabytes of RAM. An advantage of the supercomputer's additional upfront cost was its performance and ease of running available bioinformatics tools unmodified. Over the computer's lifetime, this cost paid itself back many-fold in reduced programming and administrative costs.

However, now the advantage of supercomputers over COTS servers has shrunk, given the existence of high performance computing (HPC). New CPU architecture dramatically increased core counts and with improved memory buses, it is now possible to provision dozens of computational cores and access terabytes of RAM without supercomputers and their often-pricey hardware and software contracts.

Over the past year, OCICB has closely tutored and assisted young post-baccalaureate and doctoral students in the use of the high-performance environment, its UNIX operating systems, and the wide range of computational tools in support of their explorations into genome, microscopy, and molecular data sets. Each user interaction has been a journey of discovery; exploring new territories of learning and understanding together. It can be particularly challenging for users to not only learn a completely new computational environment, but to also begin evaluating their data using the wide range of

computational tools available. The highly-interactive nature of RML's HPC environment and the close support of the HPC administrators provides novice users an excellent introduction to the full breadth and depth of UNIX tools to enhance their computational skillsets.

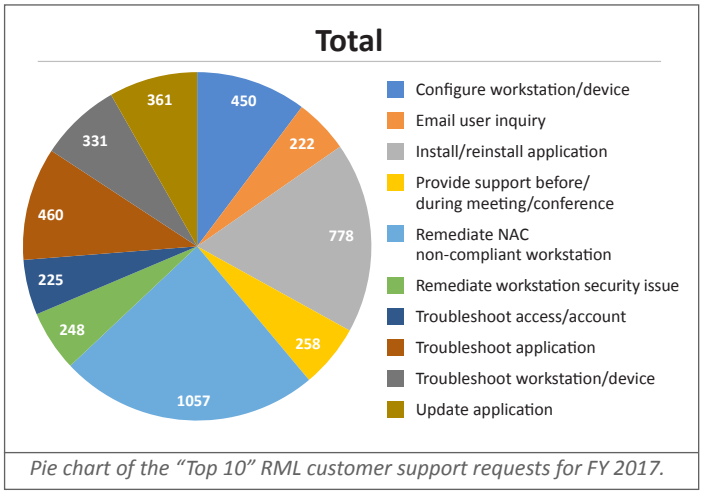
RML Fiber Optic and Signal Pathway Project (The Data Runs Through It)

The original RML fiber optic backbone is comprised of multiple multimode fiber segments between the various buildings. The light propagation properties of multimode fiber, as well as the light source used for multimode fiber communications, create distance limitations. This makes it a challenge in some buildings and instances to locate a connection route that is within the distance limitation of the multimode fiber.

An opportunity to upgrade existing network fiber optic cabling and signal pathways occurred in early 2017. Working with the General Services Administration (GSA), a contract was released to a Montana 8a construction firm. New single mode fiber cables were installed in 19 data closet locations to provide enhanced connectivity between network switches and buildings to support research equipment. The additional single mode fiber allows for increased bandwidth and redundancy between buildings and better positions the infrastructure for future projects requiring fiber connectivity. Underground signal ducts—strategically installed around the campuses perimeter — provide redundant pathways for expanding the fiber backbone, rerouting existing fiber to address a future vivarium site, and offer connectivity for future growth. This fast-track project was completed in three months, meeting the GSA deadlines and ultimately providing significant enhancements to the RML fiber infrastructure.

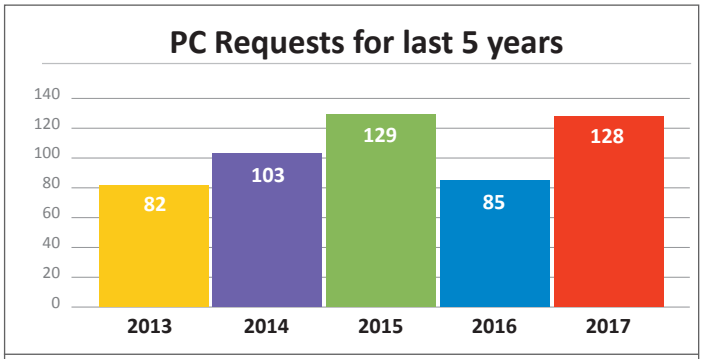
RML Desktop Support (We Aim To Please)

The desktop support function provides staff support and is an essential part of the technical support structure. Technicians troubleshoot and repair computer hardware and software issues. As we all are aware, computer security is a number one priority; OCICB technicians are on the front lines to ensure NIAID computer security guidelines are met. RML desktop support responded to over 6,500 requests for assistance during FY2017. Many of these requests were resolved within a 24-hour work period.



Pie chart of the "Top 10" RML customer support requests for FY 2017.

The RML desktop support team deployed over 460 Polycom Voice over Internet Protocol (VoIP) phones, and assisted users with the setup of voicemail. Following the "go live" date, they responded to general operations and integration with Skype for Business help requests. Prior to NIAID's email migration to Office 365, the team provided support for the Office 2016 upgrades of Windows and Mac computers, which also entailed removing instances of Office 2013 on Mac systems. OCICB configured 128 RML computers through the NIAID PC request program. Of these 128 systems, 103 were Windows computers from RML's inventory pool, three were from Bethesda's inventory pool, and 22 were custom configured computers.



Graph of RML PC request for the past 5 years.

Unified Communications (Is this the party to whom I am speaking?)

For many years, RML managed its telephone infrastructure using an Avaya Private Branch Exchange (PBX) system. In December 2016, OCICB executed the final piece of the NIAID Lync Unified Communication infrastructure by deploying the Polycom VoIP phones to the current 465 phone accounts. Moving to the NIAID Lync Unified Communications platform offered several advantages, including the ability to collaborate through online meetings,

and the options of screen sharing and video conferencing using desktop web cameras. The time-saving name searches in the Skype for Business desktop console enable calls to other enterprise users; looking up phone numbers from manually updated electronic files or hard copy lists is no longer necessary.

The hardware infrastructure devices were configured in Bethesda then shipped to RML. The equipment was installed throughout the campus. Additional work was required to switch over specialized devices such as elevator phones, various intercoms, as well as replace bells and strobes that are required in extremely noisy spaces such as the campus steam plant. Special phone side-cars were used to replace the older Avaya phone consoles for the Security Command Center (SCC). The SCC is part of RML's Security structure and is manned 24/7 and provides secure monitoring of the Campus and is the main point of contact in emergency situations.

Once the Polycom phone network update was completed, OCICB provided location information for E911 calls. Extensive call testing was conducted prior to switching to the new infrastructure to ensure local and regional dispatch centers would receive all necessary information, reducing response times in the event of an emergency. In addition to the new dedicated VoIP phone line and VoIP 911 line, multiple 10 Gig circuits are employed for connectivity to Bethesda in the event of a primary connection failure.

Due to phone circuit provider constraints, the cutover from the old Avaya system to the new Lync infrastructure was performed during business hours. Since the Polycom phones, analog converters and fax gateways were pre-deployed throughout RML, most of the new infrastructure was up and running within two hours. After a day and a half, all remaining issues were resolved.

Example of a portion of the wire infrastructure required for the RML Avaya PBX telephone infrastructure.

Preparing to deploy some of the 645 Polycom VoIP phones to RML users.

RML Library Project
(When the Going Gets Tough, the Tough Get a Librarian)

The first image: a view of the RML Library before the remodel project, viewed from the main entrance.;

The second image: a view of the RML Library after the remodel was completed as viewed from the main entrance. The new circulation desk is shown on the right.

Outside view of the RML Library bay window with View Dynamic glass panes. Here the glass is not tinted. Notice that the side of the building is in full shade.

The RML Library was constructed during renovations in the late 1990s. Although some updates, including the addition of study carols, a copier and computer refreshes occurred over the years, the space was due for remodeling and upgrades. The goal was to turn the approximately 3,862 square foot area into a space that would draw people in. The space was modernized to include new computer areas, a collaboration room, a reading room with a bay window and a view over the Bitterroot Mountains, as well as a conference room and a training room for video conferencing and presentations. Old network cabling was removed and replaced with new CAT6a cables.

The training room is configured with dual projectors and screens. The projectors use laser technology so there are no bulbs to burn out. The training room was designed to serve dual purposes: first, as a training space with room for seventeen people at movable tables, with access to wired network connections, power and wireless connectivity; and second, as a conference space with Wi-Fi that accommodates up to 42 people.

Several panels of self-tinting glass from View Dynamic Glass, which uses a proprietary electrochromic process, were installed to help control heat and glare from the sun. Tinting is achieved by converting the amount and direction of light shining on roof top sensors to an electrical signal that is then transmitted over an Ethernet cable to a control panel. This in turn processes the signal to lighten or darken the separate panes of glass. The tint of the glass can also be manually controlled using an iPod. The panels, located on the west side of the building in the reading room's bay windows, are exposed to the afternoon sun. Tinting the windows in the afternoon allows the reading room to remain cooler, resulting in energy cost savings and a glorious glare-free view of the mountains.

Outside view of the RML Library bay window with View Dynamic glass panes. Here the glass is in its fully tint stage. Notice the side of the building is in full sun.

Incident Command Area
(Where there is Smoke, there is Fire)

At the request of RML's Emergency Manager Roger Laferriere, OCICB established a central command post for the Incident Management Team from which they coordinate emergency procedures. OCICB provided connectivity for up to eight computer and phone connections. The system was designed to receive real-time video from the Security Command Center during training exercises, or during active campus incidents.

OCICB team members trained on the Incident Command System participated in incident drills and responded to actual incidents. In March of 2017, RML hosted a training exercise that simulated someone trying to take a dangerous pathogen from a laboratory area. Teams from RML, the Montana National Guard and the FBI participated in the exercise. After the mock suspect was apprehended and the area was secured, teams determined what steps need to be taken to decontaminate the exposed areas.

The decontamination area setup for a mock exercise.

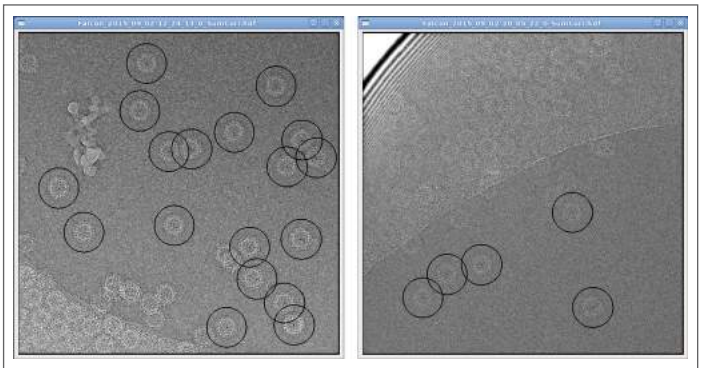
A Life Flight helicopter waits during an multi-agency active shooter drill.

Manned Incident Command Center during an active shooter exercise.

DeepPicker
(Not Your Average Picker)

Cryogenic electron microscopy (Cryo-EM) technology is used to determine protein complex structures at near atomic resolutions. The Cyro-EM analysis workflows identify single particles within high resolution micrographs captured using sophisticated RML EM cameras. Cryo-EM and HPC staff undertook an evaluation of the new DeepPicker methodology to help automate this very time-consuming, repetitive process.

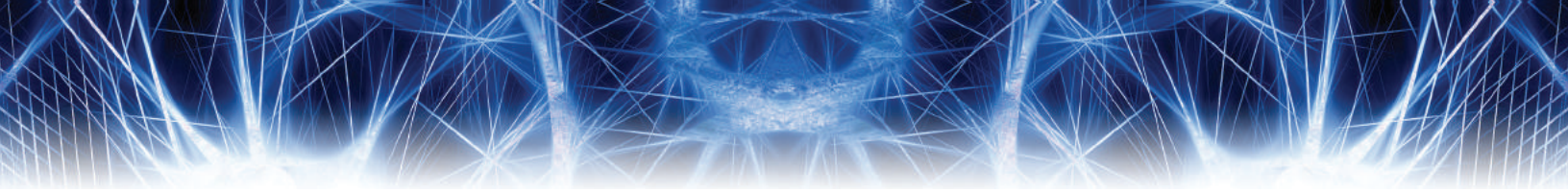
The DeepPicker framework is classified as a “deep learning” method, which is a type of artificial intelligence machine. Deep learning methods are capable of learning via unsupervised models that can effectively use unstructured input data, such as single particle images. As these approaches evolve and are refined, machine learning approaches leveraging the power of deep learning tools are proving to be valuable tools in structural molecular biology. DeepPicker is noteworthy in its ability to implement automated pipelines using highly efficient graphical processing unit (GPU) computer hardware, with Google’s TensorFlow machine learning software serving as the analysis foundation of the DeepPicker framework software. DeepPicker employs a novel training strategy to capture common features from previously analyzed micrographs. Several representative micrograph (images) used within a typical single-particle picking workflow are shown here, where interactively identified single-particles are circled.



The first image shows 18 candidate particles from a Norovirus virus-like particle (VLP) sample imaged on Titan Krios camera, captured using a Falcon II direct electron detector and post-processed using EMAN2 software for particle selection. The second image shows five candidate particles from a Norovirus VLP sample frozen in vitreous ice, imaged on a Titan Krios camera, alined with MotionCorr2, and post-processed with EMAN2 software for particle selection.

Although the results of RML’s initial workflow trials yielded only modest results, it provided the Cyro-EM and HPC team with valuable insights into the role of model ‘training’ requirements within a convoluted neural network approach, and ultimately how fuller automation of traditionally manual single-particle-picking can increase staff productivity. Lessons learned included the need to develop good local training data. RML had insufficient EM imagery that was qualified to build a custom implementation. Because of this, pre-calculated training models were used which ultimately yielded inferior results.

1 Cryogenic electron microscopy employs extremely low temperature operating environments, allowing the analysis of preserved specimens in their native state without the use of dyes or fixatives.



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.

Business Process and Information Management Branch (BPIMB)

Mission Statement
To develop and deliver high quality Electronic Content Management (ECM) and Business Process Management (BPM) solutions that increase effectiveness and efficiency for both internal and external NIAID collaborators.

Program Description
BPIMB project managers and analysts work closely with NIAID customers to analyze and document standards and processes, identify documents and content, and ascertain project requirements to ensure that resulting software products meet the needs of the Institute. BPIMB typically leverages defined methodologies and off-the-shelf commercial packages to produce high-quality solutions. By configuring and customizing these solutions as needed, BPIMB strives to ensure that all NIAID clients have the best solutions to meet programmatic needs.

Document Management
Document repositories and electronic management and control of storage and retrieval of document-based content

Workflow and Business Process Automation
Electronic automation of business process steps

Regulated Environment
Automates the sharing and management of controlled content in support of Clinical and Laboratory document management. Regulated environments will help Labs to comply with regulations such as GxP and 21CFR11.

Collaboration
Process and tools enabling synchronous and asynchronous communication (group calendars, lists, social media)

Web Content Management
Digital management, cataloguing, storage retrieval, and disribution of digital assets (images, audio, video, etc.)

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 Clinical Research Management System (N-CRMS), coordinating initiatives across NIAID, developing business cases, ensuring compliance with the HHS Enterprise Performance Life Cycle and NIH policies, and managing large projects costing several millions 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 (CSD) 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, Mobile Telecommunications Devices, Video Conferencing, and Training. CSB teams procure, configure and disseminate laptops and workstations, manage mobile telecommunications devices, 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, security audits of internal NIAID systems as well as external contracted systems, 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 Mountain Laboratories (RML)

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 (IBRSP)

The International Biomedical Research Support Program (IBRSP) has two primary objectives:

- Support the cyberinfrastructure for global research in remote regions and
- Provide software and computational tools, as a managed service, for translational research collaborations between the NIAID and international sites.

Experienced computer technicians, network engineers, operations staff, and project managers work in multiple regions around the world to support the cyberinfrastructure needed for modern biosciences. They provide hands-on, local, or time zone appropriate support from locations in the United States, West Africa, East Africa, South Asia, and East Asia. This glob-

ally distributed team designs, integrates, installs, and provides ongoing operations support for data and communication solutions. These systems, in collaboration with US and international scientific organizations, support the NIH mission of global research in emerging and re-emerging pathogens.

The translational research support team provides managed services including operating a validated, 21 CFR Part 11 compliant environment for human translational research. This virtual research organization (VRO) platform includes clinical data management systems that support international clinical protocols; protocols that support legacy paper data collection, electronic data collection, as well as data collection via mobile devices such as tablets and smartphones. The VRO suite also includes regulatory compliant specimen and chemical compound-tracking system allowing research teams to locate and label specimen aliquots, study drug and/or, vaccine, in freezers and cryogenic storage systems located throughout the world. It is also important and sometimes required by regulators that researchers ensure these specimens and study compounds are stored in temperatures that would retain specimen or compound integrity. Therefore, the service platform also includes a validated and compliant system for monitoring the temperature of the freezers, refrigerators, liquid nitrogen storage tanks, and incubators, that house the specimen or study compound, at the major collaboration centers in Mali, Uganda, India, and China. OCICB International Program offers a full suite of support services for these tools in the VRO and the centers that includes training, mentoring, and operational management. Working closely with researchers and administrators, IBRSP support staff ensure that collaborative data and tissue samples obtained in remote infrastructure-challenged regions of the world are safe, secure, accessible, and compliant with applicable regulatory requirements.

The infrastructure team has managed construction of satellite networks for field laboratories and clinics in Sub-Saharan Africa that lack other communication options, enabling the 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 translational and clinical research support team also plays an active role in working with the investigators, the monitors, and the regulatory teams, as well as investigators' data management staff to select the optimum delivery method of the CRF (case report form), i.e., 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. The team programs studies using CDISC standards for clinical research data and investigators allowing study managers to monitor the status of their studies and specimen collection through customizable dashboards, based on the study needs.

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 (RDCF) and the Alternate Processing Facility (APF), a storage and backup infrastructure capable of hosting over 12 Petabytes of storage, a server infrastructure composed of over 1,400 servers ranging from state-of-the-art virtual servers to legacy devices, the Unified Communications infrastructure that supports the NIAID phones and video-conferencing services, and the High-Performance Computing environment. They also provide application hosting, database administration and workstation development services. In addition, OEB architects and administers a custom platform-as-a-service offering providing automated delivery of immutable infrastructure through CI/CD pipelines, zero-downtime application deployments, and on-demand resource scaling.

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 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 manage-

ment 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
OCICB DIRECTOR

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.

MATT EISENBERG

ACTING CHIEF, BUSINESS PROCESS AND INFORMATION MANAGEMENT BRANCH

Matt Eisenberg joined NIAID in February of 2011 as the Electronic Document and Records Management System (EDRMS) Program Manager where he directed a team of developers and analysts to provide Document Management and Business Process Automation solutions to the Institue. Mr. Eisenberg led the expansion of the EDRMS program into a Enterprise resource and it's role in NIAID's Core Operating Environment. In late 2015, Mr. Eisenberg took over Program Management responsibilities for the Collaborative Technologies program, managing the Institute's portfolio of Web Content Management and Collaboration systems. Under Mr. Eisenberg's direction, the Collaborative Technologies program has shifted from a reactive, operations focused organization into a pro-active, software development team utilizing open-source technologies and Agile methodologies.

Prior to joining NIAID, Mr. Eisenberg was the Application Development and Support Branch Chief at the United States Peace Corps where he lead a team that developed smart-client software used by over 8000 Peace Corps Volunteers around the world. He has 20 years of experience in Software Development and Project Management in large and small for-profits, non-profits, and higher education settings.

Mr. Eisenberg holds a B.A. in Government and Politics from the University of Maryland with a concentration in International Relations and Conflict Resolution.

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.

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 including ensuring that security audits are performed on covered information systems. 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 GIAC Certified Incident Handler.

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.

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.

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, Linux, and high performance computing support to more than 400 research, administrative, and support personnel at the NIAID Rocky Mountain Laboratories (RML) in Hamilton, Montana. She also directs IT support of more than 25 buildings 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.

CHARLIE STONE
PROGRAM DIRECTOR, CLINICAL AND MEDICAL INFORMATICS PROGRAM (CMIP)

Charlie Stone, a Health Science Administrator, is Director of the Clinical and Medical Informatics Program (CMIP). He provides strategic IT planning, implementation, operations, and project oversight for the various divisional systems comprising the NIAID Clinical Research Management System (N-CRMS). Prior to NIAID, Charlie served in both the Food and Drug Administration (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 & COMMUNICTION 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.

Publications

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Moodley, N., Duvenhage, M., Bajwa, K., Gumne, P., Whalen, C., Moyer, B., Rosenthal, A., & Tartakovsky, M. (2017, September). *Fulfilling the needs of Researchers for an easy-to-use on- and offline data capturing system.* Poster session presented at the NIH Research Festival, Bethesda, Maryland, 13 September 2017.

Oler, A.J., Xirasagar, S., Li, Z., Cheng, X., Kaminsky, D., Similuk, M., Zhang, Y., Johnson, J., Hong, C., & Milner, J. (2017, May). NIAID Clinical Genomics Tools. Poster session presented at BioIT World Conference & Expo ‘17, Boston, Massachusetts.

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Duvenhage, M., (2017, September). Improving Drug Adherence using Electronic Monitoring Device. Presentation at SCDM (Society of Clinical Data Management) Annual Conference, Orlando, Florida, 24–27 September 2017.

Duvenhage, M., (2017, September). WTP?!? – What the Predict: How the NIAID tested and stretched the limitations of DataFax. Presentation at DFNet Research Annual Conference, Orlando, Florida, 27–29 September 2017.

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ACKNOWLEDGEMENT IN MANUSCRIPTS

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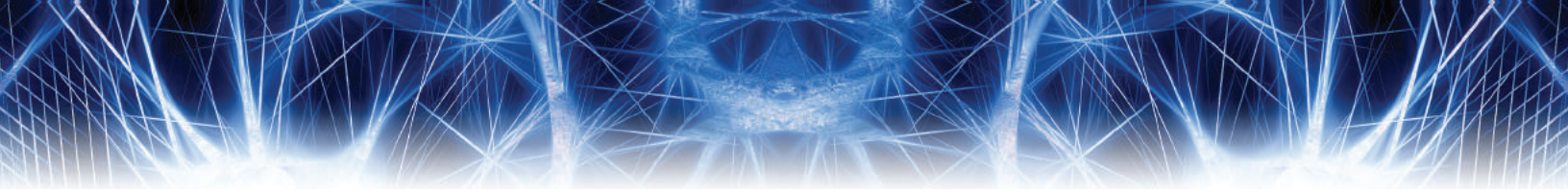


Acronyms

Acronym	Meaning
3D	Three-dimensional
A	
AIDS	Acquired Immunodeficiency Syndrome
AMT	Allocation Management Tool
ATO	Authorization to Operate
B	
BARDA	Biomedical Advanced Research and Development Authority
C	
CAN	Common Account Number
CCRF	Consolidated Computational Research Facility
CDC	Centers for Disease Control and Prevention
CDISC	Clinical Data Interchange Standards Consortium
CDMS	Clinical Data Management System
CDMUG	Clinical Data Management User Group
CGP	Clinical Genomics Program
CIO	Chief Information Officer
CIT	Center for Information Technology
CLIP	Clinical and Laboratory Information Portal
COR	Contract Officer Representative
COTS	Commercial-off-the-shelf
CPU	Central Processing Unit
CRF	Case Report Forms
CRMS	Clinical Research Management System
CRSS	Clinical Research Support System
Cryo-EM	Cryogenic Electron Microscopy
CSD	Central Service Desk
CSM	Clinical Site Monitoring
CTO	Chief Technology Officer
D	
DAIDS	Division of Acquired Immunodeficiency Syndrome
DAIDS IND	DAIDS Investigational New Drug
DAIDS-ES	DAIDS Enterprise System
DAIT	Division of Allergy, Immunology, and Transplantation
DAIT-CRIS	DAIT Clinical Research Information System
DCR	Division of Clinical Research
DEA	Division of Extramural Activities
DFUG	DataFax User Group
DICOM	Digital Imaging and Communications in Medicine
DIR	Division of Intramural Research
DLP	DAIDS Learning Portal
DMID	Division of Microbiology and Infectious Diseases
DMID-CRMS	DMID Clinical Research Management System
DNA	Deoxyribonucleic Acid
DWDM	Dense Wave Division Multiplexing
E	
EAE	Expedited Adverse Events
eCPS	Electronic Contract Proposal Submission
eCTD	Electronic Common Technical Document
eDART	Electronic Data and Reconciliation Tool
EDRMS	Electronic Document Records Management System
EOL	End-of-Life
EPLC	Enterprise Performance Life Cycle
ePMAP	Electronic Performance Management Appraisal Program
eRA	Electronic Research Administration
eRAAP	Electronic Remote Access Authorization Process
F	
FISMA	Federal Information Security Modernization Act
FMUG	Freezer Management User Group
FY	Fiscal Year
G	
GPU	Graphic Processing Units
GRIS	Genomic Research Integration System
GSA	General Services Administration
GTS	Grant Tracking System
H	
HHS	U.S. Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HPC	High Performance Cluster
HR	Human Resources
I	
IB	Investigator Brochure
ICER	International Center for Excellence in Research
ICs	Institutes and Centers
IMPAC II	Information for Management, Planning, Analysis, and Coordination System
IND	Investigational New Drug
INRO	Intramural NIAID Research Opportunities

IRF	Integrated Research Facility
ISRP	Infrastructure and Service-Related Projects
IT	Information Technology

J

JAMS	Joint Analytics and Metrics Sessions

K

KPI	Key Performance Indicators

L

LEAP	Learning Early About Peanut Allergy
LED	Light-emitting Diode
LMS	Learning Management System
LPD	Laboratory of Parasitic Diseases

M

Mac	Macintosh
MCS	Manual Categorization System
MERM	Medication Event Reminder Monitor
MTD	Mobile Telecommunitcations Devices

N

NAC	Network Access Control
NASA	National Aeronautics and Space Administration
NCI	National Cancer Institute
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Disease
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NLM	National Library of Medicine
NPARS	NIAID Planning and Reporting System
NREN	National Research and Education Networks
NUMA	Non-uniform Memory Access
NREN	National Research and Education Networks

O

OAS	Office of Administrative Services
OCICB	Office of Cyber Infrastructure and Computational Biology
OD	Office of the Director
OFM	Office of Financial Management
OIDC	OpenID Connect
OMB	Office of Management and Budget
OMIFM	Office of Mission Integration and Financial Management
ORF	Office of Research Facilities
ORS	Office of Research Services
OTD	Office of Training and Diversity

P

PAB	Pharmaceutical Affairs Branch
PBX	Private Branch Exchange
PC	Personal Computer
PDU	Power Distribution Unit
PET/CT	Positron Emission Tomography/Computed Tomography
PHIESTA	Pharmacy International Establishment
PREVAC	Partnership for Research on Ebola VACcination
PRT	Protocol Review Tool

R

R&D	Research and Development
RAM	Random-access Memory
RCDC	Research, Condition, and Disease Categorization
REDCap	Research Electronic Data Capture
RENU	Research and Education Network of Uganda
RHSP	Rakai Health Sciences Program
RIBS	Research Initiative Budget System
RIMS	Research Initiative Management System
RML	Rocky Mountain Laboratories
RMS	Regulatory Management System
RPAB	Referral and Program Analysis Branch
RPMIB	Resource Planning and Mission Integration Branch

S

SACCC	Statistical and Clinical Coordinating Center
SAE	Serious Adverse Event
SAMHSA	Substance Abuse and Mental Health Services Administration
SAML	Security Assertion Markup Language
SAP	Select Agent Program
SCC	Security Command Center
SCDM	Society of Clinical Data Managers
SCORS	Scientific Coding and Referral System
SDTM	Study Data Tabulation Models
SEB	Software Engineering Branch
SIC	Special Interest Category
SIR	Scientific Information Request System
SOP	Standard Operating Procedures
SQL	Structured Query Language
SRDMS	Scientific Review Data Management System
SRP	Scientific Review Program

T

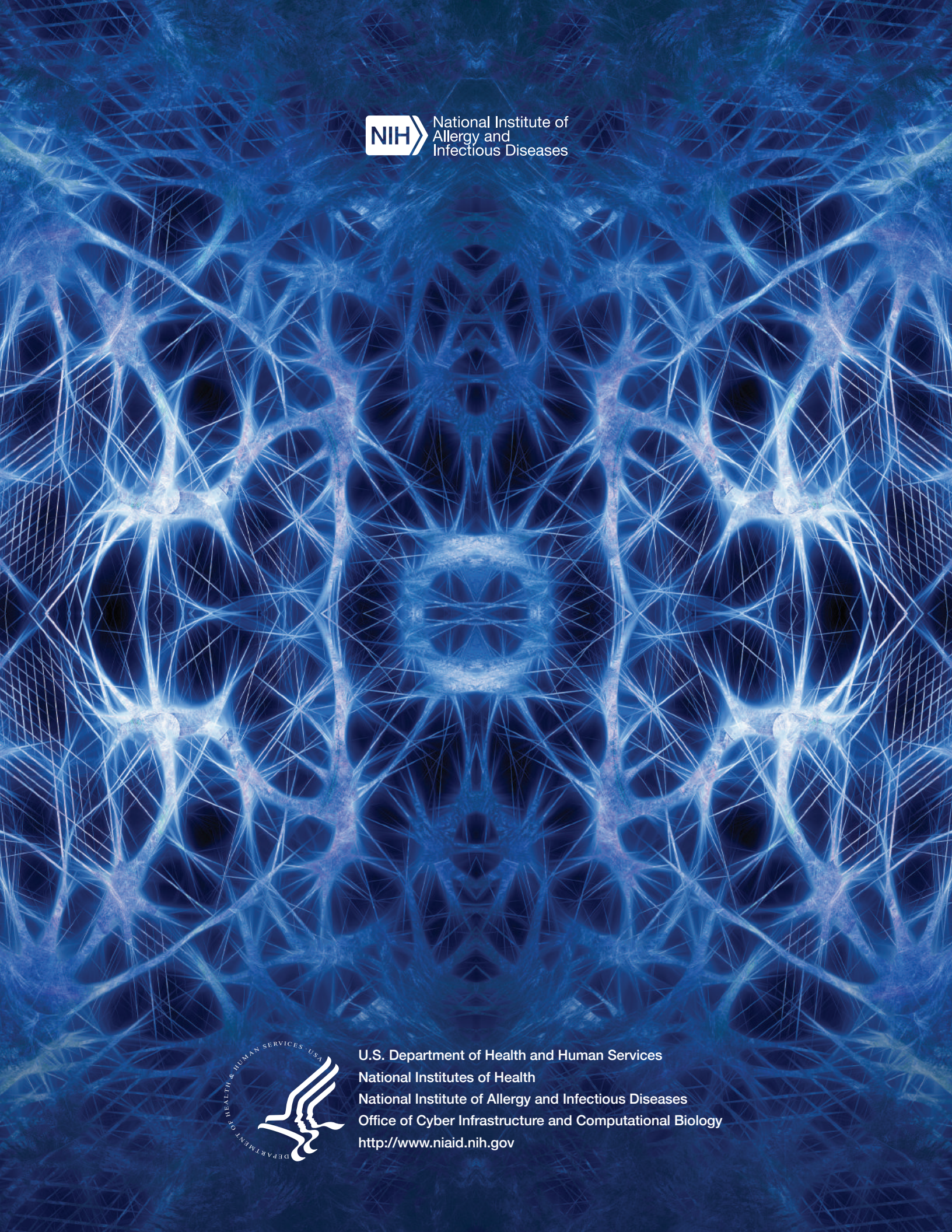
TB	Tuberculosis
TBRS	Tuberculosis Research Section

U

UCRC	University Clinical Research Center
US-CERT	United States Computer Emergency Readiness Team

V

VLAN	Virtual Local Area Network
VoIP	Voice over Internet Protocol
VPN	Virtual Private Network
VR	Virtual Reality
VRC	Vaccine Research Center
VRC-CRMS	VRC Clinical Research Management System
VRE	Virtual Reality Environment
VTC	Video Teleconferencing



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