

CMRPD CLINICAL RESEARCH SEMINAR SERIES

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CMRPD Summer Trainee Seminar Series *Clinical Research Management – What Does It Entail?*

Beth Baseler, CMRPD Director

C. K. Osborne, Clinical Project Manager IV

June 2022



DEPARTMENT OF HEALTH AND HUMAN SERVICES • National Institutes of Health • National Cancer Institute

Frederick National Laboratory is a Federally Funded Research and Development Center operated by Leidos Biomedical Research, Inc., for the National Cancer Institute



CMRPD Summer Trainee Seminar Series



- Session # 1: Clinical Research Management
 - What Does It Entail?
- Session # 2: Clinical Trials 101
 - What You Need to Know
- Session # 3: Project Management 101
 - Introduction to Project Management Fundamentals for Clinical Research Professionals
- Sessions # 4 & 5: Launching & Managing a Clinical Research Study
 - Two Sessions
- Session # 6: Breaking the Outbreak
 - Facilitating Good Participatory Practices in Clinical Research through Social Mobilization and Community Engagement
- Session # 7: My Tumor Is Not Your Tumor
 - Precision Medicine Initiatives to Tailor Treatment Approaches

Leidos Biomedical Research Leadership of the Frederick National Laboratory for Cancer Research

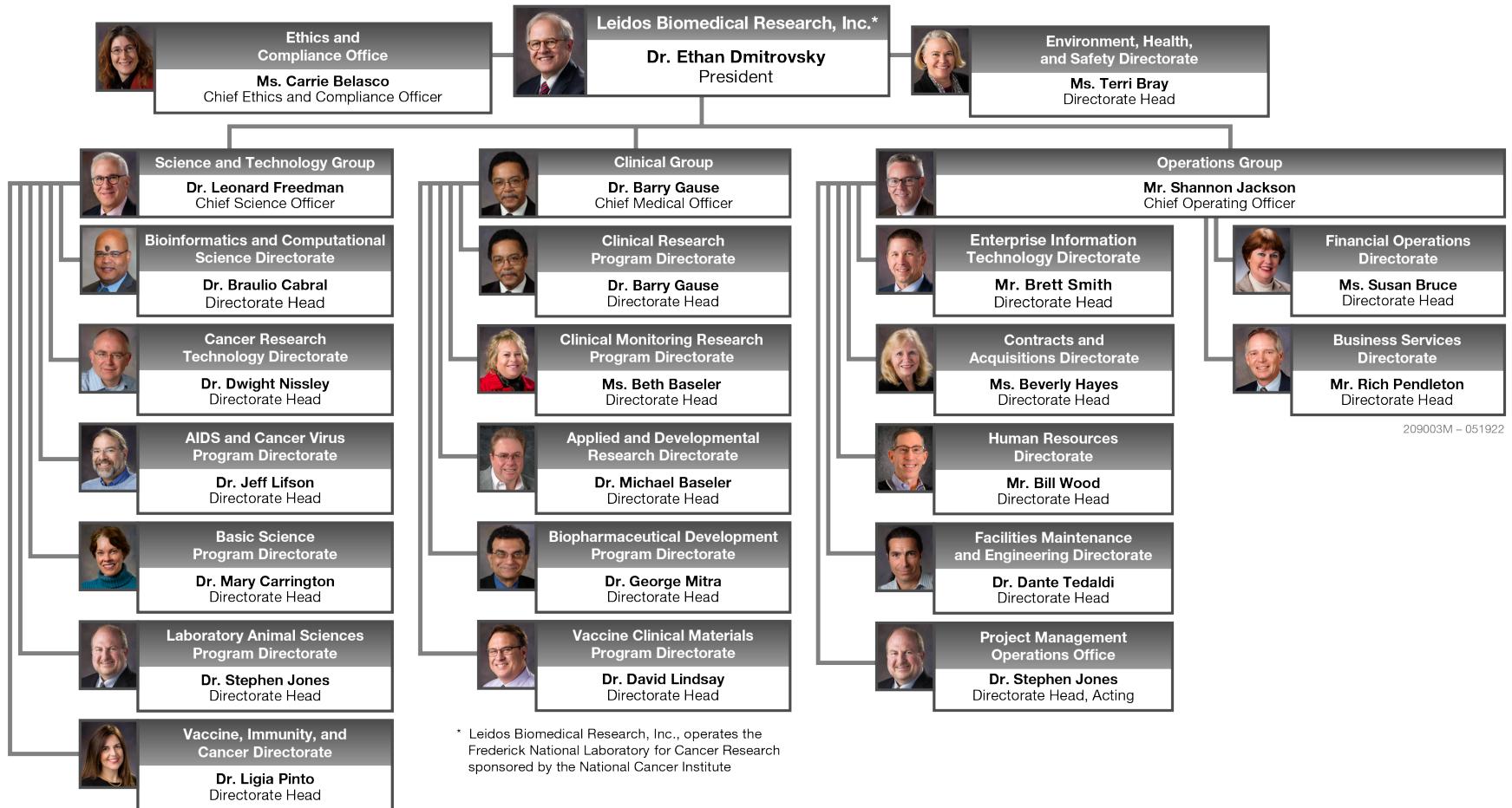


Table of Acronyms



Acronym	Definition	Acronym	Definition
CMRPD	Clinical Monitoring Research Program Directorate	IRB	Institutional Review Board
DRC	Democratic Republic of the Congo	MOU	Memorandum of Understanding
DSMB	Data Safety Monitoring Board	NIAID	National Institute of Allergy and Infectious Diseases
ETU	Ebola Treatment Unit	NIH	National Institutes of Health
EVD	Ebola Virus Disease	PAHO	Pan American Health Organization
FDA	U.S. Food & Drug Administration	PALM	PAmoja TuLinde Maisha (Swahili)
FNL	Frederick National Laboratory for Cancer Research	PREVAIL	Partnership for Research on Vaccines and Infectious Diseases in Liberia
ICH GCP	International Conference on Harmonisation Good Clinical Practice	SMC	Social Mobilization Committee
IDIQ	Indefinite Delivery Indefinite Quantity	WHO	World Health Organization

Agenda



- **Introduction**
- **Clinical Monitoring Research Program Directorate (CMRPD)**
- **Overview of how FNL's CMRPD facilitates strategic support to clinical research responses – our support services**
- **CMRPD's experience, comprehensive clinical trials operations and project management services in advancing NIH's mission and goals**
 - **Case Study: 2014 - 2016 Ebola outbreak and the FNL emergency clinical research response to support NIAID and global health....subsequent 2018-2022 Ebola outbreaks in the Democratic Republic of the Congo (DRC)**

Frederick National Laboratory for Cancer Research



- Mission
 - Provide a unique national resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer, AIDS/HIV, infectious diseases, and emerging health challenges
- Capabilities
 - Conduct basic, translational, preclinical, applied research and development, and clinical research
 - Support hypothesis-driven research and collaborative studies, spanning genetics, genomics, proteomics, biomedical computing, laboratory animal sciences, and clinical operations
 - Respond to emerging health threats, mobilize resources, and address disease outbreaks
 - Offer dedicated support to customer/government-sponsored initiatives, and monitor and support human clinical trials in the U.S. and at international locations

CMRPD Mission and Vision



- Mission
 - Facilitate strategic support of clinical research programs by providing comprehensive clinical trials operations and program/project management services to advance NIH's mission
 - Vision
 - Be the premier strategic global solution provider for the NIH clinical research enterprise, comprehensively handling project needs from concept to cure
 - Facilitate the conduct of >600* global clinical studies per year
- (* including SARS CoV-2)



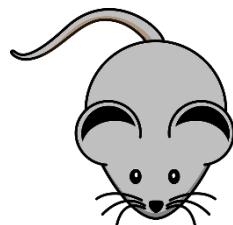
***“Basic science is the foundation for clinical research.
Treating patients directly is more like building a house on
that foundation.” S. Sankella, March 13, 2017***



Translational Research



Bench (Laboratory)



Outcomes obtained in the “Laboratory”
are applied to the “Clinical Site.”

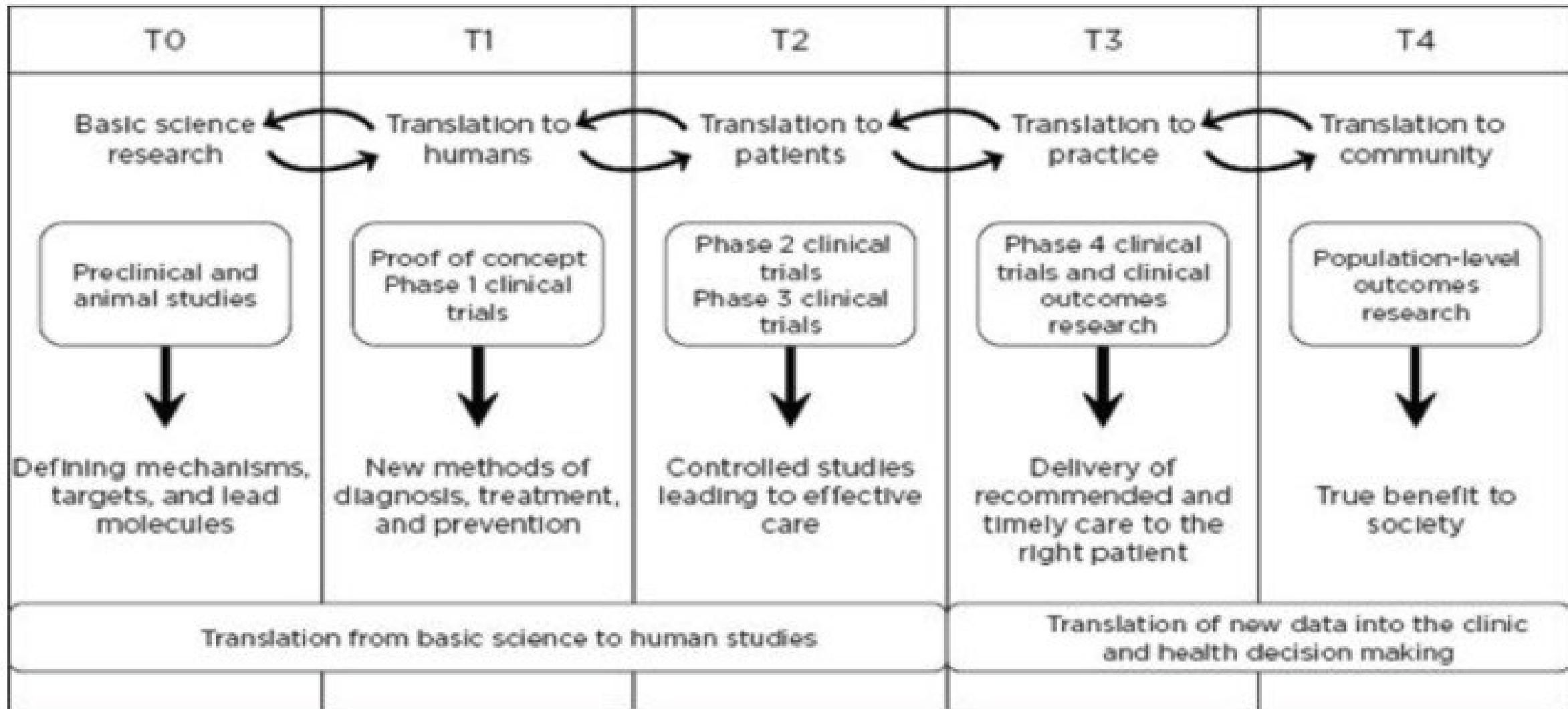


Results found at the “Clinical Site”
are studied in the “Laboratory.”



Bedside
(Clinical Site)

Operational Phases of Translational Research



Clinical Trials: Research using human volunteers (“participants”) intended to add to medical knowledge



Two Main Types

Interventional Studies

- Participants receive specific interventions according to the investigator's research plan or protocol
- Interventions may be medical products (e.g., drugs or devices), procedures, or participants behavior changes (e.g., diet)
- May compare a new medical approach to a standard one, to a placebo that contains no active ingredients, or to no intervention
- May compare already available interventions to each other

When a new product or approach is being studied, it is usually unknown whether it will be helpful, harmful, or no different than available alternatives (including no intervention). Investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.

Observational Studies

- Investigators assess health outcomes in groups of participants according to a research plan or protocol
- Participants may receive interventions, which can include medical products, or procedures as part of their routine medical care
- Participants not assigned specific interventions by the investigator (as in a clinical trial)

Clinical Research Management (Clinical Operations Management)



- Focuses on the operational and management of systems and processes in the conduct of clinical trials to ensure:
 - Safe and effective trials
 - Compliance with federal regulations, ICH GCP E6 guidelines, and host country regulations (if applicable)
 - Protection of human subjects
 - High-quality data is produced
- Includes procedures that support participant safety, protocol compliance, data quality, efficient study completion, data sharing, and timely publication and dissemination of results
- Oversees, coordinates, and facilitates clinical research implementation by providing tools, training and resources to ensure compliance with applicable human subjects' regulations, standards, policies, and Good Clinical Practices (GCP)



Comprehensive Clinical Research Support

Customer Support Services / Areas of Expertise

Clinical Monitoring Research Program Directorate Support Services



**Frederick National Laboratory
for Cancer Research**

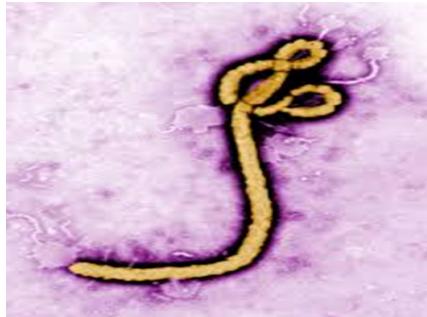


CMRPD's experience, comprehensive clinical trials operations and project management services in advancing NIH's mission and goals

Case Study: 2014 - 2016 Ebola Outbreak



FNL's emergency clinical research response to support NIAID and global health



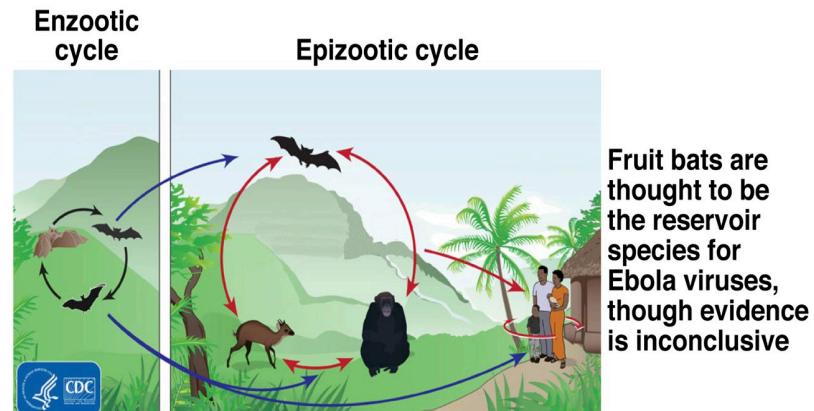
Background and History



Ebola Virus Disease (EVD)

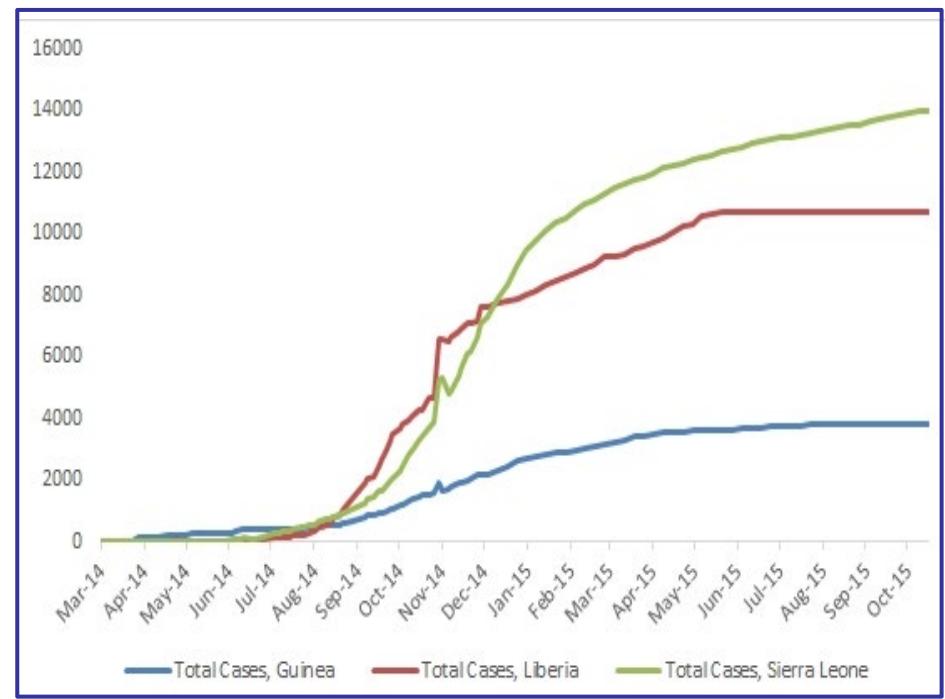
- Prototypic hemorrhagic fever caused by infection with one of the six Ebola filovirus strains
- Zoonotic infection
- Spread by droplet transmission- found in blood, saliva, sweat, sputum, stool, semen, and urine

Theoretical Ebola Transmission Cycle



2014-2016 West African Outbreak

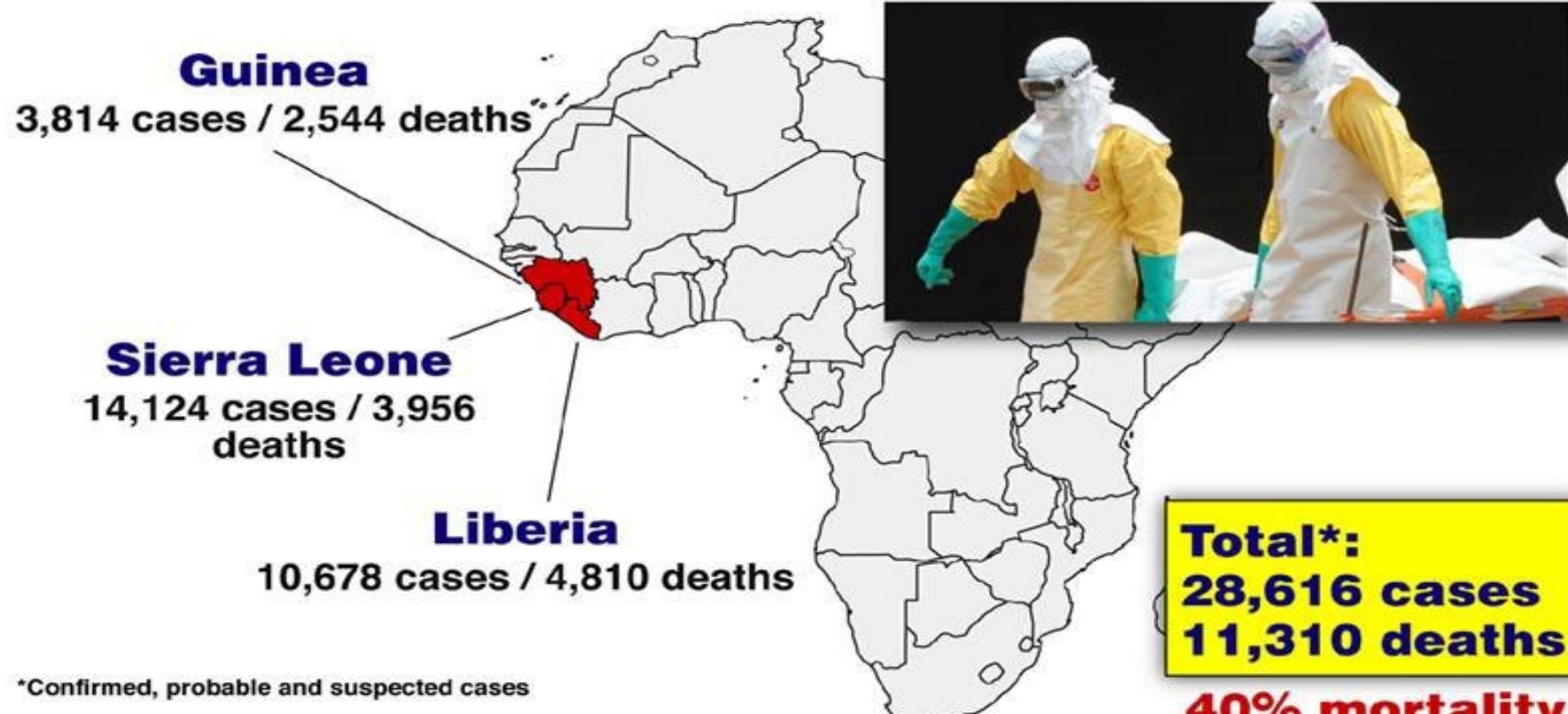
- Single introduction in Guinea
- Index case: 18 month old child, thought to be playing with bats or secretions
- Child died December 2013



2014 – 2016 Ebola Outbreak in West Africa



Reported Ebola Virus Disease Cases in Guinea, Liberia, and Sierra Leone, 2014-2016



HC Lane/NIAID

News Headlines – The Threat of Ebola



Daily Observer



WORLD NEWS AUGUST 7, 2014 / 5:00 PM / 5 YEARS AGO

Exclusive: Liberia health system collapsing as Ebola spreads



'Ebola a Serious Threat to Liberia's National Existence'

Webmaster Admin - September 10, 2014

Madam President Members of the Council SRSR Langren Ambassador Marten Grunditz Ladies and Gentlemen It is a privilege for me to participate, for the second time, in a meeting...

Ebola Task Force Unit Flees Tense Crowd

Webmaster Admin - September 25, 2014

An Ebola task force unit (ETFU) which arrived in the Caldwell community, north of Monrovia last Monday to remove a corps abandoned the body...



The long-term cure for Ebola: An investment in health systems

Webmaster Admin - October 21, 2014

As the Ebola nightmare continues in Liberia and as we battle to contain the epidemic, it is important to look beyond the immediate crisis....

Troubling Reality

As of October 26, 2014: 28,528 cases 11,298 deaths



- Research has not yet demonstrated a safe and effective Ebola therapy
- No potential vaccine efficacy known
- No licensed products
- Need to seize upon learning opportunities



Ethical considerations of experimental interventions in the Ebola outbreak
Annette Rid, Ezekiel J Emanuel *Lancet* 2014; 384: 1896–99 Published Online August 21, 2014

2014 News Headlines: Randomized Clinical Trials Controversy



THE WALL STREET JOURNAL.

WORLD | AFRICA

Disputes Emerge on African Ebola Drug Trials

With outbreak waning, researchers debate ethics of testing on patients without rigorous controls

The New York Times
Nonrandomized Trials Could Minimize Deaths of Ebola in West Africa

UPDATED DECEMBER 2, 2014, 10:54 AM

The New York Times

Don't Ignore Established Research Ethics When Treating Ebola

UPDATED DECEMBER 2, 2014, 10:54 AM

Initial Ebola Outbreak Involvement



The Initial NIH Ebola Response

AUGUST 2014



Walter Gwenigale, Liberia MoHSW:
...I am writing to ask your assistance in developing collaboration between your department and my ministry to conduct clinical research on promising therapeutics for Ebola Virus Disease and vaccines for its prevention...

OCTOBER 2014



Sylvia M. Burwell, HHS Sec.:
...HHS would be pleased to initiate U.S.-Liberia planning for collaborative Ebola research by sending a scientific team for direct discussions as soon as possible...

Why is clinical research critical in an outbreak setting?

- Reduce the number of deaths in current and future outbreaks
 - Characterize disease pathophysiology
 - Optimize clinical management
 - Efficiently, rigorously assess the safety and efficacy of putative countermeasures
- Accelerate the end of the current outbreak and prevent future outbreaks
- Provide information on optimal use of treatment and prevention products once licensed



FNL's Strategic Role



- Develop, manage, and oversee a portfolio of clinical research studies in regions of the world where emerging and re-emerging viral hemorrhagic fever and other infectious diseases are prevalent
- Provide scientific, technical and clinical leadership and expertise
- Procure necessary goods and services (subcontracting, materials and supplies, capital equipment, consultants)
- Manage logistics (export control, warehousing, inventory management, shipping, travel)
- Provide clinical research management, including clinical trial operations, clinical trial management, regulatory affairs, pharmacovigilance, protocol navigation, and medical writing
- Oversee clinical laboratory and research operations

FNL's Strategic Role



- Informatics and data management
- Biostatistical analysis and reporting
- Clinical project and program management
- Risk management
- Health and safety
- Specialized technical training and professional development
- Strategic and operational planning
- Quality assurance
- Safety and protection and FNL volunteers

Setting in Liberia in October 2014



- Limited infrastructure
 - Reconstruction following 2 civil wars
 - Poor electricity and roads
- Over 250 people in ETUs
- Schools and businesses closed
- Health care facilities avoided
- Cultural disruptions
- Community concerns/confusion about vaccine study
- National curfews

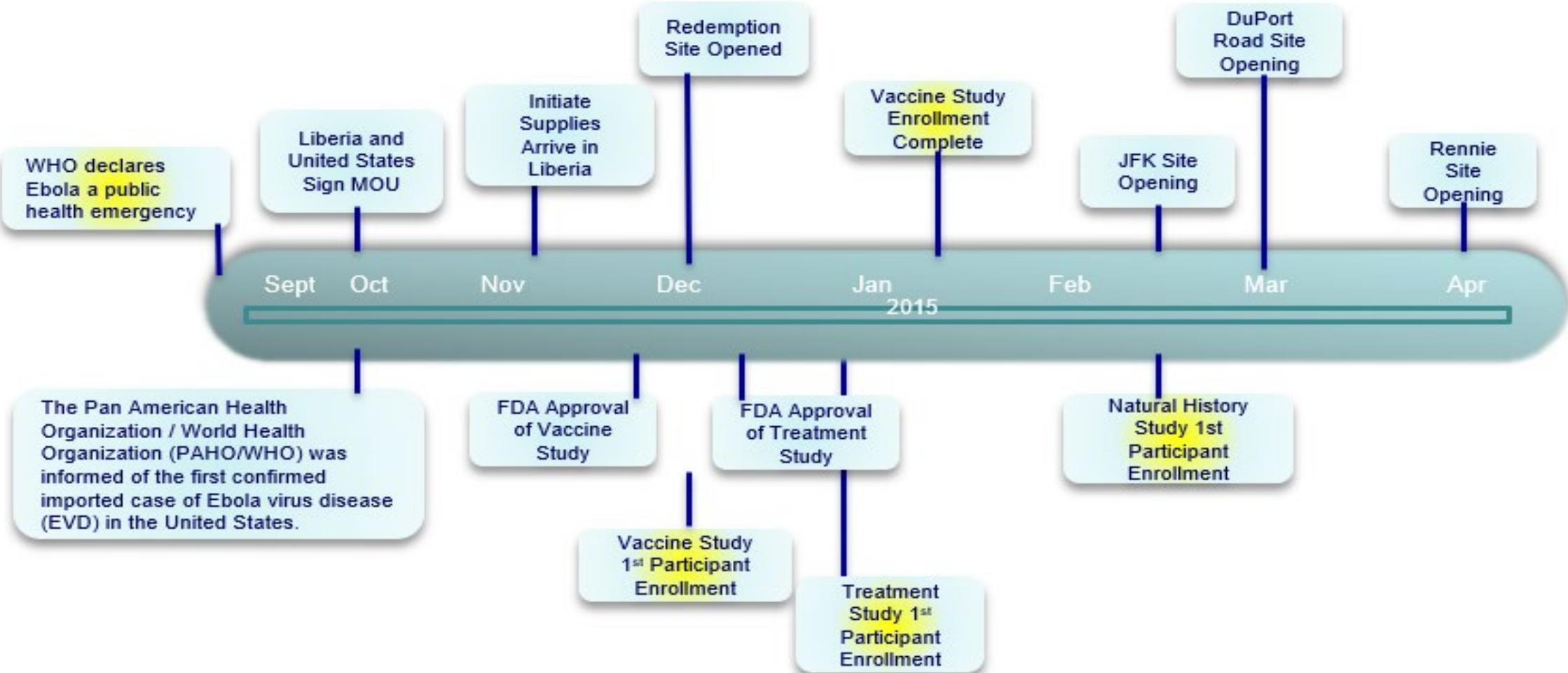


PREVAIL Timeline



- **Planning for PREVAIL Study**
 - FNL approved to commence support: October 27, 2014
 - Advance planning team visit to Liberia: October 27- 31, 2014
 - December 13 - 14, 2014: US – Liberia Joint Clinical Research Program technical team meeting
- **Outcome – consensus to proceed**
 - Initiation of PREVAIL study: February 2, 2015
 - Unprecedented time to initiation of study
 - Average time to initiate a study of this magnitude is 18+ months
 - Record time of 3 - 5 months

Ebola Response – PREVAIL 1



October - December 2014



- Agreement with Liberian investigators on randomized study design (December 2014)
- Identification of sites in and around Monrovia to which vaccine could be quickly transported
- Identification of a single site for renovation for Phase 2 vaccine study – Redemption Hospital
- Renovation of space on US Old Embassy Compound for pharmacy, data management, and supply center
- Establishment of subcontracts and procurement mechanisms
- Deployment of FNL staff (volunteer basis)
- Development of risk management strategies
- Establishment of communication plan



January 2015



- Social mobilization strategies and communications initiated
- Vaccine shipments to Liberia
- Laboratory renovated and qualified
- Formation and initial meeting of Data Safety Monitoring Board (DSMB)
- Dose of vaccines established (different fill volumes for syringes required design change)
- Supplies and laboratory/pharmacy equipment shipments to Liberia
- Protocol submitted to NIH and Liberian IRB (approvals obtained within 2 weeks)
- Hiring and training of Liberian staff
- Renovation of pharmacy and data management center completed



It Takes a Village



- Contributing FNL directorates and programs
 - Clinical Research Directorate
 - Clinical Monitoring Research Program Directorate
 - Applied Developmental Research Directorate
 - Contracts and Acquisition Directorate
 - Human Resources Directorate
 - Facilities Maintenance and Engineering Directorate
 - Financial Operations Directorate
 - Environmental, Health and Safety Directorate
 - Vaccine Clinical Materials Program Directorate
 - Project Management Operations Directorate
- Leidos Corporate



Frederick National Laboratory for Cancer Research

Pharmacy Center, Old Embassy Compound



Frederick National Laboratory for Cancer Research

Site: Redemption



Redemption Hospital - Before and After Renovations
New Kru Town, Monrovia January 5 - 25, 2015



Vaccine Shipment, Double Blind Labeling, and Administration



Opening Ceremony Redemption Hospital (February 1, 2015)



Vaccine Study Begins



Associated Press

February 2, 2015

Ebola Vaccines Testing Starts in Liberia

- Phase II/III trial; goal is 27,000 volunteers
- cAd3-EBOZ vs. rVSV-EBOV vs. placebo



PREVAIL

Areas of Contribution to Liberia



Infrastructure



Education/Training



Participant Benefits



Community Benefits



**Support Goals
of Liberia**

The NEW ENGLAND JOURNAL of MEDICINE

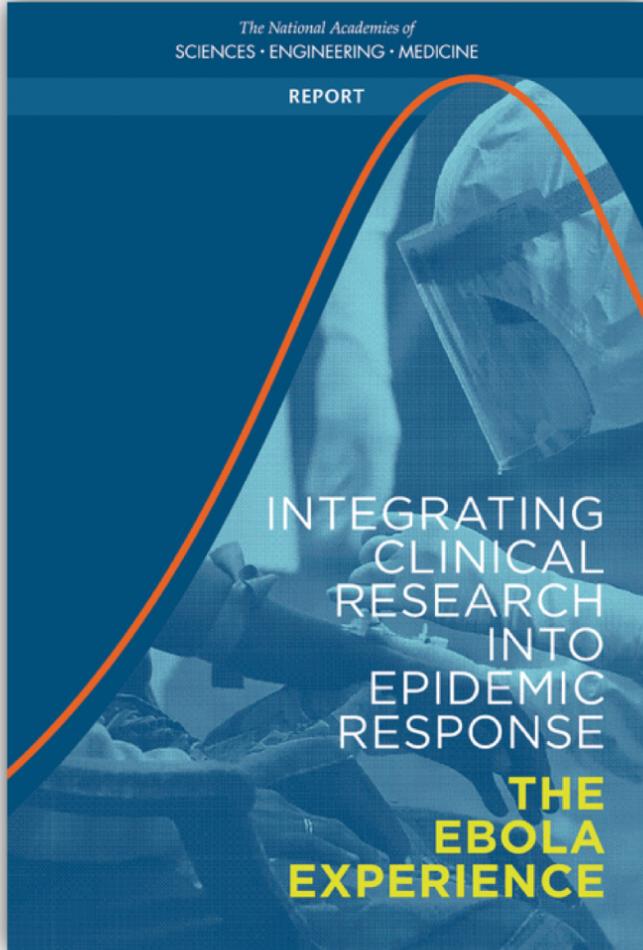
ORIGINAL ARTICLE

Phase 2 Placebo-Controlled Trial of Two Vaccines to Prevent Ebola in Liberia

S.B. Kennedy, F. Bolay, M. Kieh, G. Grandits, M. Badio, R. Ballou, R. Eckes, M. Feinberg, D. Follmann, B. Grund, S. Gupta, L. Hensley, E. Higgs, K. Janosko, M. Johnson, F. Kateh, J. Logue, J. Marchand, T. Monath, M. Nason, T. Nyenswah, F. Roman, E. Stavale, J. Wolfson, J.D. Neaton, and H.C. Lane,
for the PREVAIL I Study Group*

New Knowledge

National Academies Report Released April 12, 2017



- The core principles of science and ethics in conducting clinical research do not and should not change in the midst of an epidemic.
- The randomized controlled trial is ethical and the most appropriate study design to use because it is the most efficient and reliable way to determine whether an investigational treatment or vaccine is safe and effective.
- Clinical research studies must have
 - Scientific and social value
 - Respect for and engagement with people in affected communities
 - Post-trial access to any investigational agent that proves effective

Subsequent Ebola Outbreaks 2018 – 2022

The Democratic Republic of the Congo



New Challenge: Ebola Outbreak in a War Zone

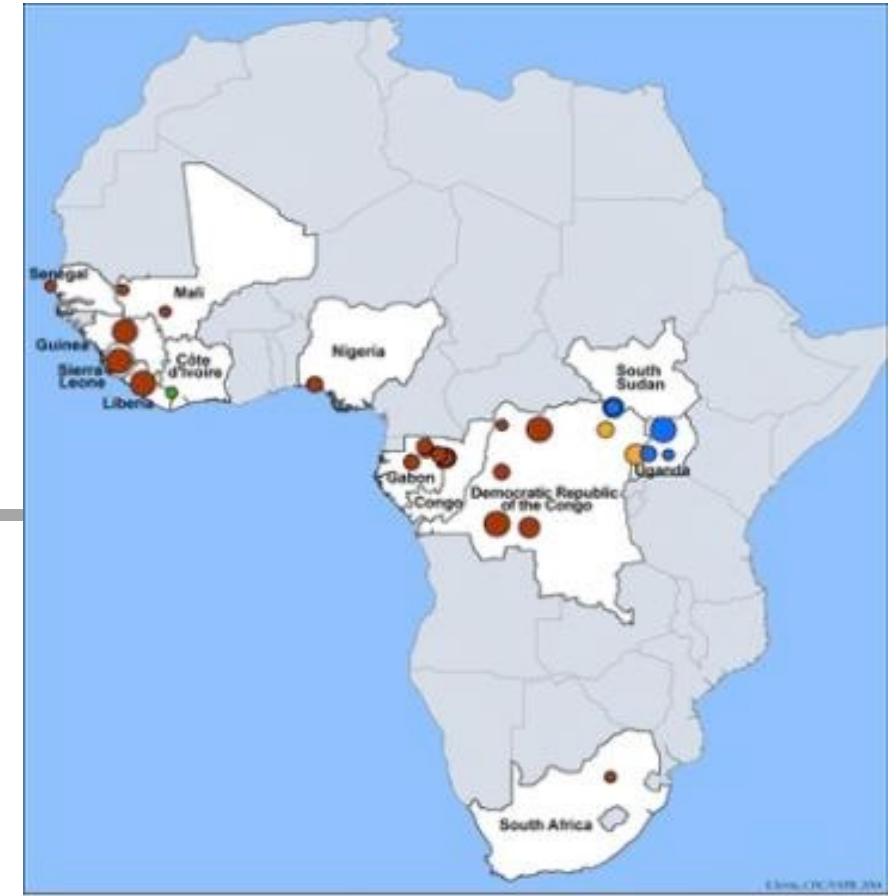




Photo from Fischer et al., Shifting the Paradigm, NEJM 2019

- 67% case fatality rate
- No approved treatments for Ebola
- Supportive care measures: adequate volume resuscitation, electrolyte monitoring and replacement, administration of supplemental oxygen

PALM: Pamoja TuLinde Maisha



**Swahili for
“Together, Save
Lives”**



November 2018: Initiation of Randomized Controlled Trial



- “Multi-center, Multi-outbreak, Randomized, Controlled Safety and Efficacy Study of Investigational Therapeutics for the Treatment of Patients with Ebola Virus Disease”
- DRC Principal Investigator:
 - Jean-Jacques Muyember-Tamfum, MD, PhD Director-General, DRC National Institute for Biomedical Research
- U.S Principal Investigator:
 - Richard Davey, Jr., MD Clinical Research Section, NIAID



Randomized Controlled Trial



- PALM 1 Study:
 - Zmapp (triple monoclonal antibody agent): chosen as the control based on data from PREVAIL II trial
 - Remdesivir (GS-5734) (nucleotide analogue RNA polymerase inhibitor)
 - REGN3470-3479 (co-formulated mixture of three human IgG1 monoclonal antibodies)
 - mAb114 (a single human monoclonal antibody derived from an Ebola survivor)



Primary outcome: 28 day mortality

Concept : August 8, 2018

Study Start: November 20, 2018



PALM Study Challenge: Site Activation



Site opened

Criteria:

- One site at the time (based on the outbreak general dynamic)
- NGO approval
- Completion of site assessment list requirements

Current sites location:

- Beni
- Butembo
- Katwa
- Mangina

PALM Study Challenge: Workflow Activities

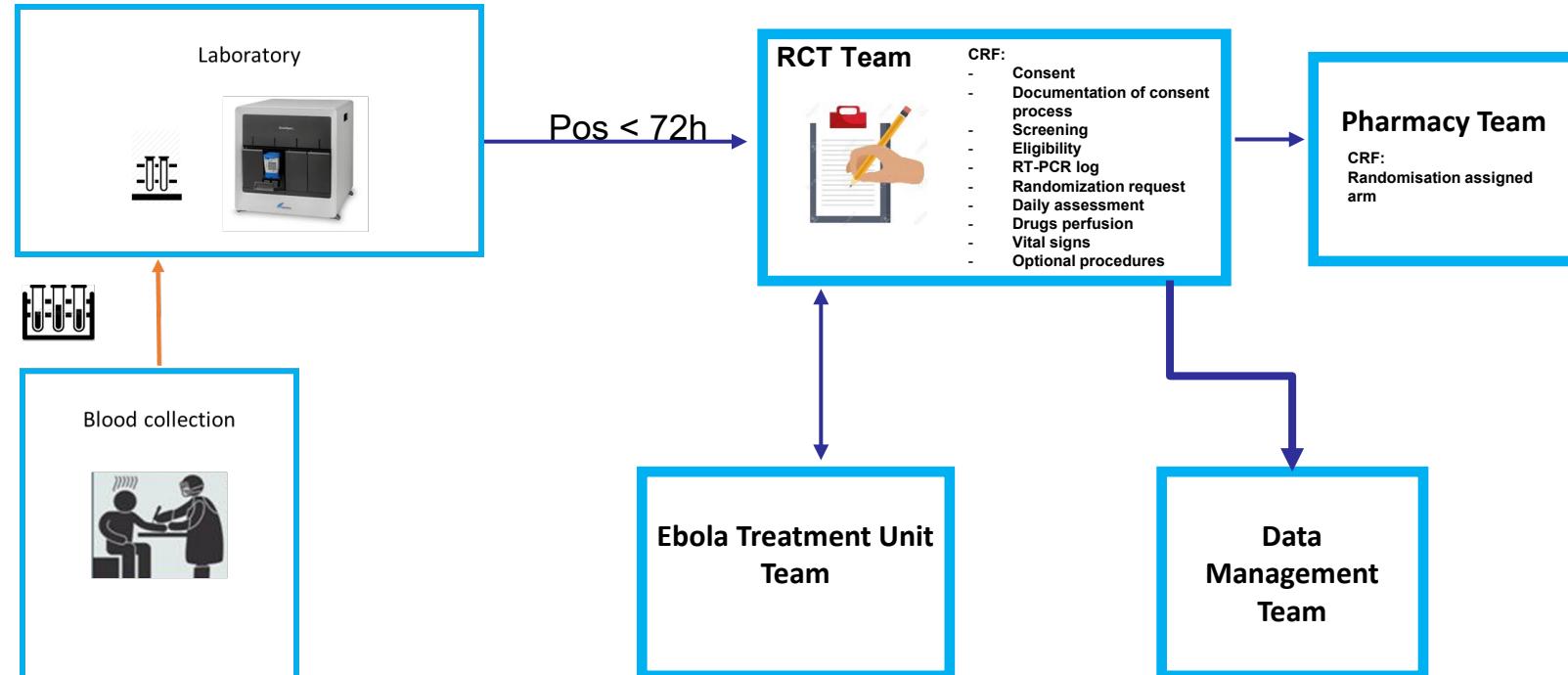
PALM vs. ETU



Workflow process:

Workflow:

- Fluid system
- No overlap
- Clear communication



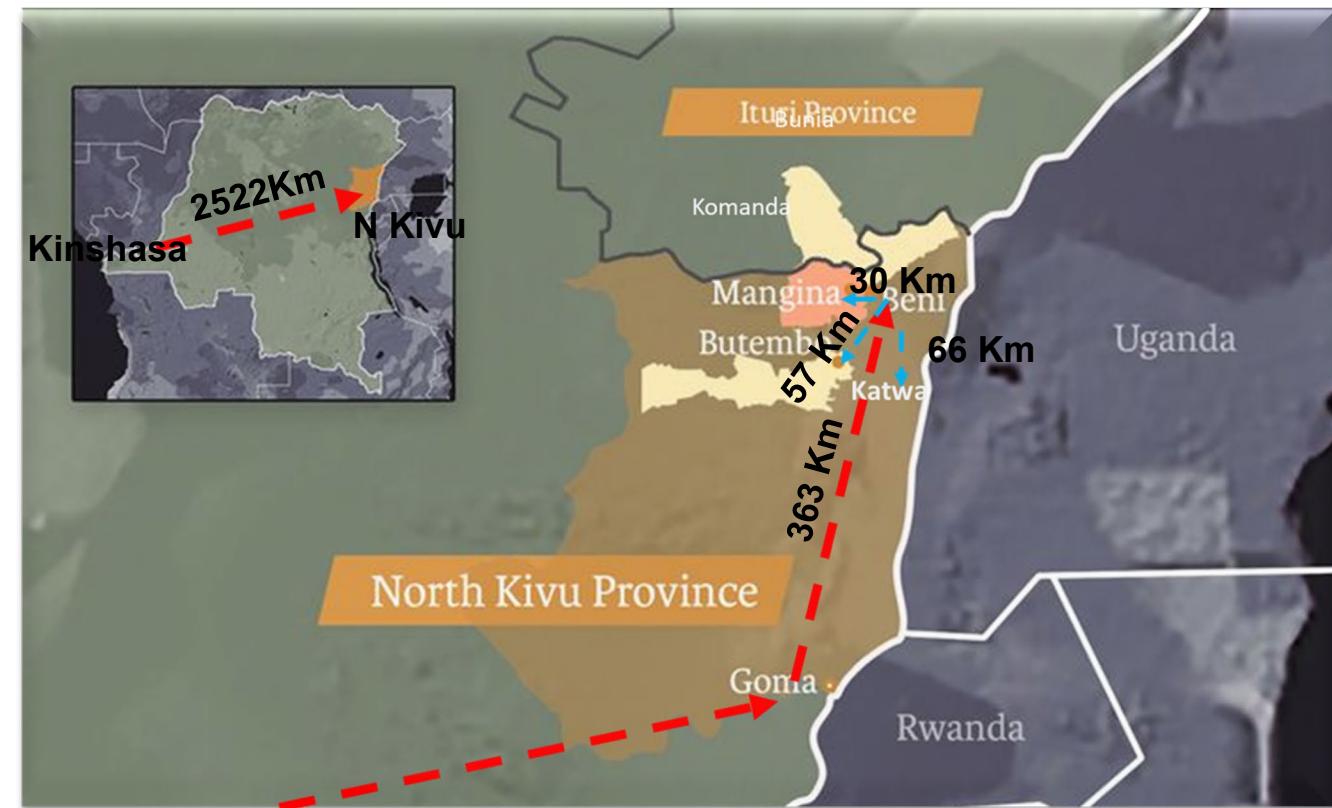
PALM Study Challenge: Circuit of Investigational Products



Logistics support for Investigational Products

Shipment support:

- Ensure coordination with charter
 - Ensure communication between teams
 - Ensure shipment tracking
- Cold chain maintenance:**
- Ensure temperature monitoring
 - Ensure cold panel change



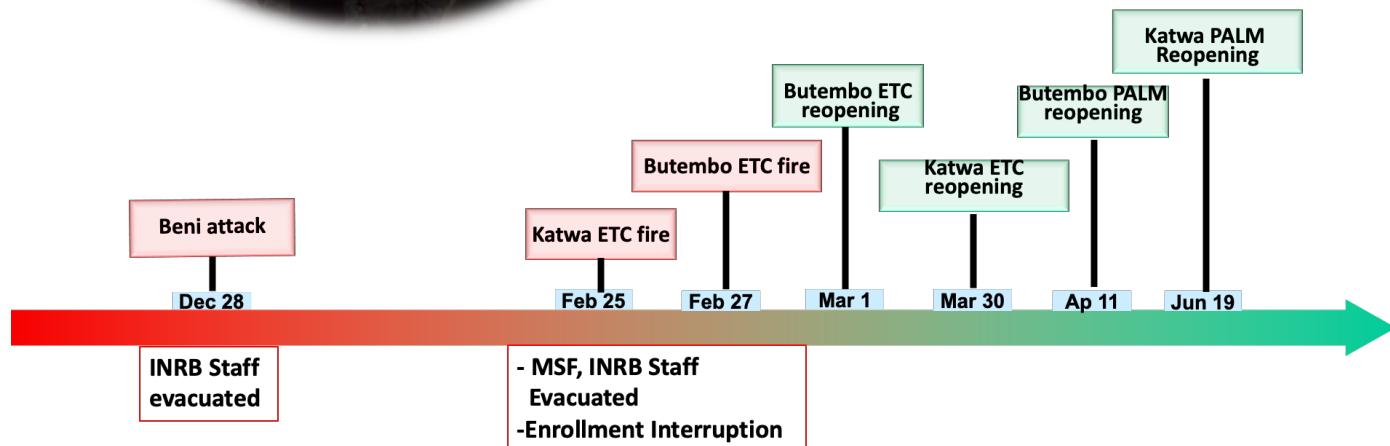
PALM Study Challenge: Security and Community Mistrust



Butembo ETU fire



Katwa ETU fire



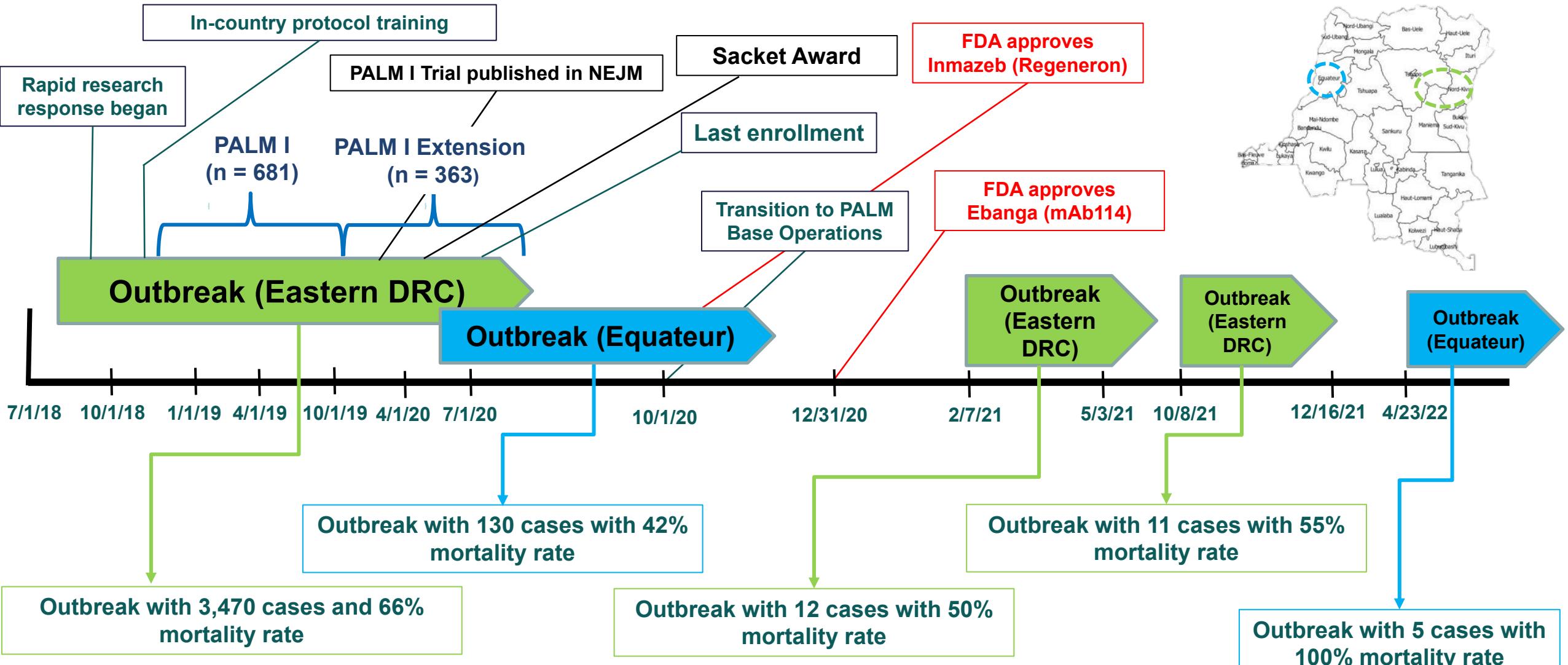
Community mistrust: generated a massive movement of violence

- Study team was assaulted several times
- 2 ETUs burned (Katwa and Butembo)
- Destruction of PALM study equipment and infrastructure
- Negative impact on enrollment accrual: interruption
- Staffs and patients' lives were endangered

Strategies:

- SMC worked on community engagement
- Recruitment of more local staffs in the study team

DRC and Course of Latest Ebola Virus Outbreaks



PALM I Research Support Accomplishments



- Ebola clinical trial supported by FNL received Sacket “**Trial of the Year**” award
- Investigational Drugs Reduce Risk of Death from Ebola Virus Disease (*NIAID News Release; 11/27/2019*)
- Continuation and sustainability of clinical research work: bi-directional knowledge sharing among research partners
- Establishment of trust, clinical research infrastructure, and sustainable collaboration
- Well published in high-impact journals and widely presented at various conferences.
- Both MAb114 and REGN-EB3 were superior to ZMapp in reducing mortality from EVD (*Mulangu et al, 2019*)



Reference: Mulangu et al, 2019; Ebola Treatment Research, NIAID site, 2019

Summary



- Many challenges and setbacks required innovative and creative solutions.
- Partnerships with Leidos Biomed Business Operations Directorates were critical to pivot rapidly.
- Follow GCP – studies and among stakeholders/implementing players
- Recognition that EVD response pushed clinical research teams to implement new procedures and technologies at an unprecedented speed
- Evaluate lessons learned – implement new tools in our Rapid Response Toolkit
- Possible to adapt processes to comply with regulatory and ethical frameworks at a previously unimagined speed
- The response to EVD left us better equipped with more tools to combat other emerging and re-emerging infectious diseases, such as the COVID-19 outbreak

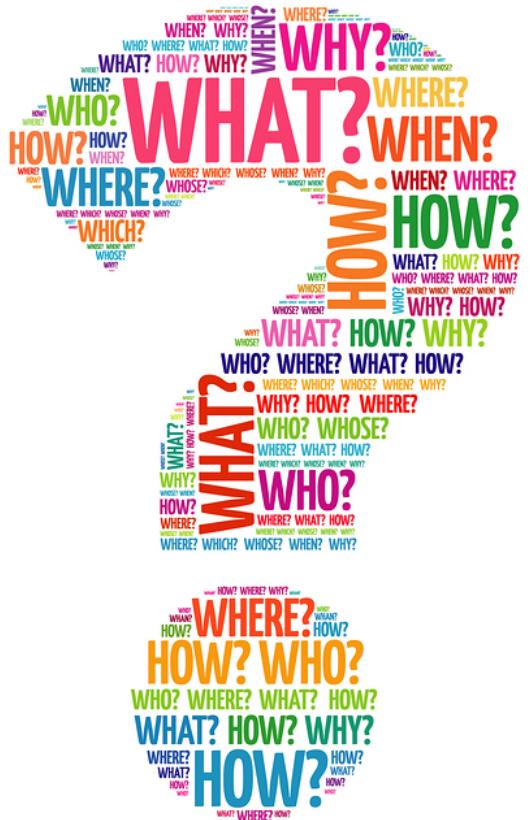


“A unique feature of international collaborative research is the degree to which economically more prosperous countries can enhance and encourage further collaboration by leaving the host community or country better off as a result.”

National Bioethics Advisory Commission. Executive Summary.
<https://bioethicsarchive.georgetown.edu/nbac/clinical/execsum.html>



Questions?



Next Seminar



- **Clinical Trials 101: What You Need to Know**
- Learn the basic ABCs of clinical trials, including key terms and processes, human subjects' protections and ethical considerations, costs/funding, and subject recruitment challenges and opportunities
- Presenter: Geoff Seidel
- **Thursday, June 23rd**

Seminar 1 Evaluation

Please use the link or QR code to provide an evaluation of this session.

<https://forms.office.com/g/iPuSjrqg9u>



Frederick National Laboratory for Cancer Research



References



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- Samuel Lopez (5/26/2020). FNL News; Ebola clinical trial supported by FNL receives “Trial of the Year” award. <https://frederick.cancer.gov/news/ebola-clinical-trial-supported-fnl-receives-trial-year-award>

CMRPPD's Service Offerings



Project & Program Management

Manage domestic, international, single and multi-site clinical research programs • Manage research subcontracts with clinical sites, CROs, consultants, and laboratory vendors • Manage CRADAs to support correlative science studies • Facilitate strategic support and provide comprehensive clinical trials operations and program/project management services • Organize and implement program management infrastructures • Provide rapid response to urgent clinical research initiatives • Support program evaluation and data analysis activities • Foster collaborations with internal and external organizations • Recruit and hire professionals • Provide programmatic guidance and support • Disseminate information

Clinical Trials Management

Facilitate and manage domestic and international clinical research studies and IND trials • Conduct pre-study site assessments, site initiation, monitoring and close-out visits • Provide training to site staff • Design, prepare, submit, distribute, and track essential study documents • Develop manuals of operation • Track study agents • Ensure compliance with research protocols, regulatory requirements, ICH/GCP guidelines, and applicable regulations • Prepare for FDA and drug-sponsored audits/inspections • Facilitate communication between clinical research sites and IND sponsor entities • Coordinate investigator meetings • Develop case report form (CRF) templates and load CRFs into databases • Ensure human subject protections and data integrity

Regulatory Affairs

Act as regulatory liaison with sponsors, FDA, regulatory bodies • Offer regulatory strategy and support to investigators • Prepare, submit, and maintain compliant regulatory applications (INDs, CTAs, IDEs, and DMFs) • Generate regulatory filings in eCTD format • Develop and submit requests (breakthrough therapy designations, regenerative medicine therapy designations) to FDA/regulatory authorities • Conduct regulatory review of protocols, informed consents, and other clinical documents • Provide cGMP guidance on product storage, shipping, labeling, and manufacturing issues

Protocol Navigation/Development & Protocol Coordination

Streamline clinical research protocol writing and approval processes • Edit and format clinical protocol documents, e.g., study concepts, SOPs, informed consent forms, amendments, publications • Function as liaisons between customers and review offices • Navigate investigators through regulatory and administrative requirements for protocol submission • Respond to IRB stipulations • Collect metric data, track milestone dates, and categorize IRB stipulations • Identify quality improvement opportunities • Facilitate clinical research start-up activities • Provide programmatic and logistical support for operation of clinical trials • Provide administrative coordination to support regulatory activities • Coordinate protocol review submissions

Administrative Management

Provide procurement and supply chain management for office and laboratory equipment, materials, and supplies • Coordinate events and meetings • Manage travel logistics • Plan conferences • Facilitate logistical support for pharmaceuticals and clinical research material shipments • Identify logistical quality improvement opportunities • Track government-furnished equipment • Establish and oversee equipment maintenance agreements • Provide building management and facility coordination • Support recruitment and hiring of human resources

Clinical Research Teams

Support NIH clinics and program initiatives • Provide clinical research care providers, e.g., MDs, PAs, NPs, CRNs • Provide medical imaging scientists, statisticians, bioinformatic analysts, clinical pharmacists, medical affairs scientists, and QA/QC managers and specialists • Support pre-clinical and clinical operations • Coordinate and perform clinical research protocol responsibilities related to research participants • Determine subject population availability, develop informed consents and screening materials, screen and recruit subjects, schedule visits, oversee study visits • Offer medical and technical writing services • Facilitate preparation of reports and publications

Clinical Safety Oversight

Promote protection of clinical trial participants • Perform protocol safety oversight • Review and process safety-related events for IND and IDE studies • Evaluate SAEs for safety signals and FDA reportability • Coordinate and manage DSMB, SMC, and ISM review meetings • Perform protocol safety reviews • Maintain safety compliance • Review safety data, unanticipated problems, and early study stop rules • Provide recommendations to study sites

Learning & Professional Development

Provide continuing education and customized training events to CMRPPD staff and government customers • Address required regulatory, technical, and professional skills competency • Conduct training needs assessments and respond to training needs • Offer eligible competency-based courses for continuing education units (CEUs) • Award IACET CEUs to eligible participants • Establish and maintain a pool of qualified trainers • Identify, develop and facilitate professional development opportunities • Maintain training records for all staff/ensure compliance with FDA/GCP regulations • Monitor quality and effectiveness metrics for all learning events • Facilitate new employee orientation

Clinical Data Management & Information Technology

Create and maintain clinical trial summary records • Manage clinicaltrials.gov protocol registration and results system for NCI-sponsored trials • Perform clinical data abstraction, curation, and management • Develop CRFs • Determine data management/IT requirements at clinical sites • Establish validated data flows • Provide data management training to sites • Support database locking and data archiving • Provide user support • Manage IT solutions • Support business continuity • Develop websites and databases • Customize enterprise applications • Provide lifecycle support • Provide document control services