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CURRICULUM VITAE

Kirsten Elizabeth Lyke, M.D. Associate Professor of Medicine Head - Immunoparasitology Unit University of Maryland School of Medicine

DATE: April 11, 2016

CONTACT INFORMATION

Division of Malaria Research/Center for Vaccine Development University of Maryland School of Medicine Institute for Global Health Head – Immunoparasitology Unit 685 W. Baltimore St., HSF II, Rm. 480 Baltimore, MD 21201

Tel. (410) 706-2493/0462 Fax: (410) 706-1204 E-mail: <u>Klyke@medicine.umaryland.edu</u> Foreign languages: Proficient in French

EDUCATION

1988 B.A. Cornell University College of Arts and Sciences

(Biology/Physiology/Anatomy) Ithaca, New York

Graduated with Honors and Distinction

1992 M.D. Georgetown University School of Medicine

Washington, D.C.

Graduated with Honors and AOA

POST GRADUATE EDUCATION AND TRAINING

Internship & Residency

1992-1995 Internal Medicine

Duke University Medical Center

Durham, North Carolina

Fellowships

1998-2002 Clinical Infectious Diseases Fellow

Division of Infectious Diseases

The Johns Hopkins Medical Institutions

1999-2002 Research Fellow

Malaria Section/Immunology Laboratory

Center for Vaccine Development

University of Maryland School of Medicine

Other Academic Fellowships

1990-1992 Research Associate

Department of Surgery and Transplantation Georgetown University School of Medicine

Washington, DC

1994 Research Fellow in Tropical Diseases

Division of Infectious Disease, HIV/AIDs

Muhimbili Medical Center, Dar es Salaam, Tanzania

1995 Research Fellow in Tropical Diseases

Division of Infectious Diseases, Tuberculosis Universidadé dos Espirito Santos, Vitoria, Brazil

CERTIFICATION

1995-2005 Diplomate, American Board of Internal Medicine

2010-2020 Diplomate, American Board of Internal Medicine

Infectious Diseases

2005 Good Clinical Practices for Clinical Investigators

2006 Good Manufacturing Practices for Clinical Investigators

MEDICAL LICENSURES

1995-1998 Arizona, Inactive 1998-Present Maryland, Active

MILITARY SERVICE

1995 Coordinator, Gulf War Syndrome Clinic

Sheppard AFB, TX

1995-1997 Chief, Medical-Surgical Intensive Care Unit

Sheppard AFB, TX

1995-1998 Major, United States Air Force, 82 MDS

Sheppard AFB, TX

1995-1998 Coordinator, HIV/AIDs and Infection Control Officer

Sheppard AFB, TX

1996-1998 Chief, Department of Internal Medicine

Sheppard AFB, TX

1996-1998 Chief, Division of Cardio-Pulmonary

Sheppard AFB, TX

EMPLOYMENT HISTORY

Academic Appointments:

2002-2010 Assistant Professor of Medicine

Division of Geographic Medicine, Department of Medicine and Malaria Section, Center for Vaccine Development

University of Maryland School of Medicine

2010-Present Associate Professor of Medicine

Division of Geographic Medicine, Department of Medicine

and Malaria Section, Center for Vaccine Development

Head – Immunoparasitology Unit

University of Maryland School of Medicine

2014 – present Co-Investigator, Ndirande Research Clinic, NIH DAIDS-ES 10822, Clinical trial of

trimethoprim-sulfamethoxazole or chloroquine in adults on ART

Other Employment:

1992 Healthcare Provider, Philippine Processing Refugee Camp

United Nations High Commissioner for Refugees

Bataan and Palawan, Philippines

1994 Staff Physician/Research Assistant:

Muhimbili Hospital Dar es Salaam, Tanzania

1995 Attending, Department of Internal Medicine

Cape Fear Memorial Hospital, North Carolina

1995 Staff Physician/Research Assistant:

Universidade de Espirito Santo, Vitoria, Brazil

1995-1998 Major, United States Air Force, Department of Internal Medicine

Sheppards AFB Hospital, Wichita Falls, TX

1998-present Medical Consultant, Himalayan Healthcare

Tipling, Nepal

PROFESSIONAL MEMBERSHIPS

1999-present American Society of Tropical Medicine & Hygiene

1999-present Infectious Diseases Society of America

HONORS AND AWARDS

1988 Honors in Neurobiology, Distinction in all Subjects

Order of Omega, Mortar Board Society, Cornell University, Ithaca, New York

1992 Alpha Omega Alpha Society, Sarah E. Stewart Award,

Janet M. Glasgow Award for academics and leadership,

Georgetown University School of Medicine

1995 Duke Young Investigator Award: Multi-drug resistant tuberculosis: Outbreak analysis in

Vitoria, Brazil

2005 Michael Scheld's Top 10 Most Influential Infectious Diseases articles for 2002. Annual

Review of Infectious Diseases-New York City, NY (See Peer Reviewed article reference

No. 4)

2006 National Foundation for Infectious Diseases/Sanofi Pasteur Advanced Vaccinology Course

Travel Grant. Annecy, France

2007-2012 Doris Duke Clinical Scientist Development Award

CLINICAL ACTIVITIES

Clinical expertise - Board Certified Infectious Disease specialist with clinical research interests in tropical medicine and parasitology, immunologic response/epidemiology of malaria and schistosomiasis, malaria vaccine trials.

1995-1997 Chief - Medical-Surgical Intensive Care Unit

Duties: Weekly staff meeting – 2 hours weekly, 12 months annually

Invasive central line insertion -5-10 per week Swan-Ganz catheter management -2 per week

Ventilator management – 4 per week Arterial line insertion – 2-4 per week

1995-1998 General Internal Medicine – Chief of Internal Medicine and Cardio-Pulmonary Department

Duties: Call every 3rd night – Clinical duty hours 60-80 hours/week

Electrocardiograph reading – 30-50 per week Pulmonary function test interpretation – 10 per week

Flexible sigmoidoscopies/Colonoscopies – 8 referrals per week/8-10 hour per week

Exercise tread mill testing, Sestimibe testing, Stress Thallium testing – 8 referrals per week/8-

10 hours/week

Bone Marrow Biopsies – 5 per year

University of Maryland Medical Center

2002-present Infectious disease clinical service attending

1-2 residents, 1 fellow, 1-2 students 8-10 hours/day, 6-12 weeks/year

2002-2014 Infectious diseases attending in Traveler's Clinic – Redwood Building

4-5 hours/day, 1 clinic per month

Baltimore VA Medical Center

2002-present Clinical attending in HIV outpatient clinical services weekly

4 hours/weekly, 12 months per year

2002-present Infectious diseases clinical service attending

1-2 residents, 1 fellow, 1-2 students 8-10 hours/day, 6-12 weeks/year

ADMINISTRATIVE SERVICE

Institutional Service

Sheppard AFB, Texas

1995-1998 Medical Deployment Representative

48 hour weekend training sessions/four times annually. Periodic unannounced drills – 2-4

hour sessions

1997 JCAHO Infection Control Committee

1 hour weekly, 12 months annually

1996-1998 Representative, Pharmacy and Therapeutics Committee

3 hours bi-monthly, 12 months annually

University of Maryland School of Medicine

Internal Safety Monitor - Evaluation of IMVAMUNE® Smallpox Vaccine with Respect to 2007-2008

Safety and Optimization of Immune Responses by Administration Timing and Subsequent Boost with Dryvax® Smallpox Vaccine in Vaccinia-Naïve Adults. DMID: 06-0012

Internal Safety Monitor - A Randomized, Double- Blinded, Placebo-Controlled, Phase I Safety 2008-Present

> And Immunogenicity Study In Healthy Subjects Of Detoxified J5 Core Glycolipid/Group B Meningococcal Outer Membrane Protein Vaccine For Gram Negative Bacterial Sepsis Administered With and without Synthetic Cpg Oligonucleotide 7909 Adjuvant. DMID: 04-

086

2009-Present Internal Safety Monitor - Comparison of the Safety and Immunogenicity of Lyophilized

IMVAMUNE® (1x108TCID50) versus Liquid Formulation IMVAMUNE® (1x108 TCID50)

Administered by the Subcutaneous Route and a Lower Dose Liquid Formulation IMVAMUNE® (2x107 TCID50) Administered by the Intradermal Route in Healthy

Vaccinia- Naïve Individuals

2010 Internal Safety Monitor - Phase I Randomized Study of the Safety, Dose Escalation, and

> Immunogenicity of Adjuvanted Influenza A/Anhui/05 Boosting in Subjects Previously Immunized with One or Two Doses of A/Vietnam/1203/04 or in Unprimed Individuals and

Compared to Placebo. DMID: 08-0013

2010-Present Internal Safety Monitor - Phase 1 Study to Determine the Safety and Immunogenicity of an

Oral ETEC Candidate Vaccine, Attenuated, Recombinant Double Mutant Heat-Labile Toxin

(dmLT) from Enterotoxigenic Escherichia coli. DMID: 09-0066

2011-Present University of Maryland School of Medicine K leadership Conference. Transitioning to

Independence: A Professional Development Symposium on Leadership for UMB Career

Development Awardees. Panelist.: August 18, 2011 – 0.75 hour contact

University of Maryland School of Medicine Council Meeting Faculty Presentation. Standing 2012

on the Precipice of a Malaria Vaccine: Updates from the trenches on the whole organism Pf

sporozoite approach. December 19, 2012. 0.15-hour contact

Division of Geographic Medicine, Center for Vaccine Development

2010-Present Chair, Committee on the Issues of Women Physicians and Scientists in Academic Medicine

August 2011 Author, Type II Insectary Master File BB-6441 at the U.S. Food and Drug Administration

(FDA) Plasmodium falciparum Laboratory Components of a Malaria Challenge Model Used

to Test Candidate Vaccines in Healthy Adult Volunteers.

University of Maryland Medical Center

2006-2015 Residency Selection Committee-University of Maryland Medical Center

3-6 hours weekly/4-6 months annually

Local and National Service

2002-Present Reviewer: Human Immunology Project Consortium, Infection and Immunity, Journal of

Infectious Diseases, American Journal of Tropical Medicine and Hygiene, Journal of

Epidemiology, Annals of Internal Medicine, Vaccine, PLoS ONE, PLoS Medicine, PLoS NTD,

and European Journal of Clinical Investigation.

2005-2006	Safety Monitoring Committee - Pfs25H/Pvs25H/ISA51-Phase I Study of the Safety and Immunogenicity of PpPfs25/ISA51 and ScPvs25/ISA51: Transmission Blocking Vaccines for <i>Plasmodium falciparum</i> and <i>Plasmodium vivax</i> Malaria-The Johns Hopkins University
2006-2007	Safety Monitoring Committee - Phase I/IIa double-blind, randomized study of the safety, immunogenicity and preliminary efficacy after primary sporozoite challenge of FMP2.1/AS01B and FMP2.1/AS02A candidate malaria vaccines administered intramuscularly at months 0, 1, and 2 in healthy malaria-naïve adults living in the United States- WRAIR/PATH
2007	Safety Monitoring Committee - Phase 1 Study of the Safety, Reactogenicity and Immunogenicity of AMA1-C1/ISA720: A Blood Stage Vaccine for <i>Plasmodium falciparum</i> -DMID
2007-2008	Safety Monitoring Committee - Pharmacokinetic Issues in the Use of Moxifloxacin plus Rifapentine, The Johns Hopkins University, DMID 06-0050
2007-2009	Vaccine Advisory Committee – Sanaria, Inc. Metabolically active, replication-deficient whole organism malaria vaccines
2007-2009	Consultant – Vaccine Distribution Working Group, Sanaria Phase II SBIR AI058499 4 hours contact every 3 months
2008-2011	Clinical Development Planning Committee – Sanaria, Inc. Radiation-Attenuated PfSPZ vaccine
2008	Safety Monitoring Committee - A Randomized, Double-Blinded, Controlled, Phase I, Study of the Safety, Reactogenicity, and Immunogenicity of Intramuscular Inactivated Influenza A/H5N1 Vaccine Given Alone or with AS03 in Healthy Adults. DMID: 07-0081
2008	Safety Monitoring Committee - A Randomized, Double-Blinded, Phase I/II Study of the Safety, Reactogenicity, and Immunogenicity of an Inactivated Influenza Vaccine Derived from A/H5N1/Indonesia/05/05 (clade 2) in Healthy Adults and Elderly Who Participated in a Previous A/H5N1/Vietnam/1203/2004 (clade1) Vaccine Study. DMID: 07-0022
2008-present	Safety Monitoring Committee - A Randomized, Double- Blinded, Placebo-Controlled, Phase I Safety and Immunogenicity Study In Healthy Subjects Of Detoxified J5 Core Glycolipid/Group B Meningococcal Outer Membrane Protein Vaccine For Gram Negative Bacterial Sepsis Administered With And Without Synthetic Cpg Oligonucleotide 7909 Adjuvant. DMID: 04-086
2009	Consultant – Meningococcal Advisory Group – The Hilton, Baltimore, Maryland 8 contact hours/year
2010-Present	Safety Monitoring Committee - Phase 1 Trial of a Live Oral Salmonella enterica Serovar Paratyphi A Vaccine Harboring Mutations in guaBA and clpX. DMID: 09-0020
2010-Present	Independent Safety Monitor - Phase 1 Study to Determine the Safety and Immunogenicity of an Oral ETEC Candidate Vaccine, Attenuated, Recombinant Double Mutant Heat- Labile Toxin (dmLT) from Enterotoxigenic Escherichia coli. DMID: 09-0066
2010-Present	Safety Monitoring Committee and Independent Safety Monitor – Mix and Match Study: A Randomized, Double-Blinded, Controlled, Phase I Study in Healthy Adults to Assess the Safety, Reactogenicity, and Immunogenicity of Intramuscular Subvirion Inactivated Monovalent Influenza A/H5N1 Virus Vaccine Administered at Different Dose Levels Given

	With and Without MF59 Adjuvant and A Randomized, Double-Blinded, Controlled, Phase I Study in Healthy Adults to Assess the Safety, Reactogenicity, and Immunogenicity of Intramuscular Subvirion Inactivated Monovalent Influenza A/H5N1 Virus Vaccine Administered at Different Dose Levels Given With and Without AS03 Adjuvant. DMID: 10-0016 and 10-0017
2011-present	Chairman – Safety Monitoring Committee - Open Label Phase 1 Study in Malaria Naïve Adults of the Safety and Immunogenicity of Pfs25-EPA/Alhydrogel®, a Transmission Blocking Vaccine Against <i>Plasmodium falciparum</i> . NIAID-NIH
2011-present	Safety Monitoring Committee - Phase 1 Study of the Safety and Immunogenicity of <i>Na</i> -GST-1/Alhydrogel® with or without GLA-AF in Brazilian Adults. The Sabin Institute at The George Washington University Medical School- SVI-10-01.
2012-2013	Safety Monitoring Committee - A Randomized, Double-Blinded, Controlled, Phase I Study in Healthy Adults to Assess the Safety, Reactogenicity, and Immunogenicity of Intramuscular Subvirion Inactivated Monovalent Influenza A/H5N1 Virus Vaccine Administered With and Without AS03 Adjuvant: Standard and Systems Biology Analyses. NIAID/DMID 10-0074.
2012-Present	Data Safety and Monitoring Board - A Pilot Study of the Immune Repertome* NIH/PIPB.
2012-2013	Safety Monitoring Committee - A Phase 1 Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of the Vaccine Candidates LEISH-F3 + GLA-SE, LEISH-F3 + MPL-SE, and LEISH-F3 + SE in Healthy Adult Subjects. DMID 11-0031.
2013-2014	Internal Safety Monitor - Phase II, Randomized, Open-Label Study to Evaluate the Safety and Immunogenicity of IMVAMUNE® Using Three Immunization Schedules and Two Modes of Delivery. DMID 11-0021.
2014	Internal Safety Monitor - Human Experimental Challenge with Enterotoxigenic <i>Escherichia coli</i> (ETEC) strain H10407, which is serotype O78:H11 and expresses colonization factor I antigen (CFA/I) and both heat-labile enterotoxin (LT) and heat-stable enterotoxin (ST). Sponsor: Center for Vaccine Development, University of Maryland School of Medicine, <i>E. coli</i> CVD 28000.
2014-Present	Safety Monitoring Committee (Chair): Phase I Study of the Safety, Reactogenicity, and Immunogenicity of Sm-TSP-2/Alhydrogel® for Intestinal Schistosomiasis in HealthyAdults. DMID 13-0009.
2015	Safety Monitoring Committee (Chair): Phase I Study of the Safety and Immunogenicity of <i>Na</i> -APR-1 (M74)/Alhydrogel® Co-Administered with <i>Na</i> -GST-1/Alhydrogel® in Brazilian

International Service

2015

2006-Present Associate Editor: PLoS Neglected Tropical Diseases

http://ntds.plosjms.org

Adults. DMID 15-0012.

2009 Consultant, World Health Organization Initiative for Vaccine Research, Scientific Forum

Progress and Challenges with Whole-Organism Malaria Vaccines

11/21/2009 Chair; Malaria – Regulation of Cellular Immunity in Malaria, Session 131, American Society

(FLSC) Institute of Human Virology's HIV monoclonal antibody vaccine.

Data Safety Monitoring Board (Medical Monitor): Phase 1 study of full-length, single chain

of Tropical Medicine and Hygiene, Washington, DC

3/8/2009-present Consultant, World Health Organization Consortium for the Optimization of Clinical

Challenge Trials for Evaluation of Candidate Blood Stage Malaria Vaccines

6/23-25/2011 Consultant – European Malaria Vaccine Development Authority (EMVDA) – Pf Sporozoite

Challenge Workshop. Sponsor: The Radboud University Nijmegen Medical Centre.

Amsterdam, The Netherlands

3/11-3/12/2013 Consultant – The Bill and Melinda Gates Foundation – Schistosomiasis Eradication Working

Group, Seattle, WA.

2014-Present Data Safety Monitoring Board: Identification of pre-erythrocytic target antigens induced by P.

falciparum sporozoite immunization under chemoprophylaxis" (BMGF1). Radboud

University Nijmegen Medical Center.

TEACHING SERVICE

Clinical and Laboratory Teaching

Duke University Medical Institutions

1993 Medical Grand Rounds, HIV diagnostics

Muhimbili Medical Center Dar es Salaam, Tanzania 1 hour/week, 3 months

1994-1995 Greenfield Rounds – Duke University Medical Center – Weekly duties include discussing a

pertinent case to internal medicine residents 90 minutes per week/3 months per year

1995 Medical Grand Rounds, Chagas Disease – Duke University Medical Center

2 contact hours annually

1995 Weekly Friday didactic lecturer: Dept. of Internal Medicine

Cape Fear Memorial Hospital - Weekly guest attending. Duties include rounding with

residents and weekly didactic lectures 5 hours/week, 3 months annually

Sheppard AFB Hospital

1996 Advanced Electrocardiograph Interpretation

Course Organizer/Lecturer 8 hours daily/2 days per year

1995-1998 Organizer/Lecturer: Weekly Medical Grand Rounds Series

4 internal medicine attendings/8 Family practice attendings

1 hour per week/12 months per year

1997 Lecturer, Advanced Cardiac Life Support

8 hours daily/3 days per year

University of Maryland School of Medicine

1999-2004 Mentor in immunology to Drs. Yacouba Cissoko and Lassana Sangare, Bandiagara, Mali

20-80 hrs/week contact for 3-4 months annually

2001-2004	Mentor in immunology to Dr. Charles Arama, Bandiagara, Mali 20-80 hours/week contact for 3 weeks annually
2001-2009	Mentor in immunology to Drs. Issa Diarra and Modibo Dao, Bandiagara, Mali 20-80 hours/week contact for 3-4 months annually
2006-2009	Mentor and collaborator in Immunology to Dr. Bourema Kouriba, Bamako, Mali 24 hours contact annually
2007-2008	Mentor in Immunology to Dr. Amadou Niangaly, Bandiagara, Mali 20-80 hours/week contact for 2 months annually
2009-2011	Mentor and collaborator in Immunology to Dr. Wilson Mandela, Blantyre, Malawi –T regulatory cell induction with malaria 8 hours contact annually
2010-2012	Immunology Laboratory supervisor for Samuel Pan MD, Resident in Internal Medicine, University of Maryland School of Medicine 3-5 hours contact weekly during twice yearly rotations
2010-2014	Mentor and collaborator in Immunology to Andrea Berry, MD, Baltimore, MD – Antibody avidity associated with FMP2.1/ASO2 $_{\rm A}$ malaria vaccine candidate 24 hours contact annually

University of Maryland Medical Center

1999-2009 Laboratory supervisor for immunologic studies – Bandiagara, Mali and Bamako, Mali

Duties include processing sample, organizing and documenting samples, immunologic assays, and creation of standard operating procedures, shipping and receipt of samples from the field

to UMMS 5-20 hours/week

2003-present Infectious diseases fellows' didactic conference-Helminth infections and flukes

1 hour contact annually

2004-present Infectious diseases fellows didactic conference-Hemorrhagic Fevers

1 hour contact annually

2014-present Laboratory Project leader for immunologic studies - Ndirande Blantyre Malaria Project in

Blantyre, Malawi. Duties include optimization of an exhaustion panel to assess immunologic

exhaustion in Malawian adults co-infected with HIV and malaria.

Student Teaching

University of Maryland School of Medicine

2000-2005 Mentor for Fogarty students in tropical medicine in Mali, West Africa

Duties include mentoring in field studies, immunology assay instruction, parasitology

didactics, database and case report form entry

40 hours contact annually

2000-Present Mentor for Immunology for Dr. Yacouba Cissoko, MSc student in Immunology and

Infections, Mali West Africa

2000-present Small group leader for Host Defenses and Infectious Diseases- MSPR 520 24 medical students 3 hours contact annually Medical student mentor: Veronique Nussenblat 2002-2006 4 hours contact annually 2002-present Small group leader for parasitology laboratory block Course: Host Defenses and Infectious Diseases- Parasitology - MSPR 520 24 medical students 3-6 hours contact annually 2004-2008 Medical Student mentor: Adriana Jones 2 hours contact annually 2006 Immunology Laboratory supervisor for Kavita Gandhi, PhD candidate, Division of **Epidemiology** 3-5 hours contact weekly for 2 months 2006-2008 Mentor for Doris Duke students in tropical medicine in Mali, West Africa, and for immunology at the CVD 8-10 hours contact annually 2007 Immunology Laboratory supervisor for Steve Bowen, PhD candidate, Division of Microbiology and Immunology 5 hours weekly for 2 months 2007-present University of Maryland School of Medicine Lecturer – Helminth infection, Cestodes and trematodes 1 hour contact annually 2008-present University of Maryland School of Medicine Vaccinology Course Lecturer – Helminth/Tropical Diseases Vaccines 1 hour contact annually Immunology Laboratory supervisor for Eric Gotlieb, Masters candidate, University of 2010-2011 Maryland School of Medicine 3-5 hours weekly during clinical rotation 2010-2013 Mentor and thesis committee member in Immunology to Dr. Monica McArthur, Baltimore, MD – Differential immune responses to Salmonella enterica serovar Typhi (S. Typhi) in volunteers immunized with Ty21a 5-10 hours contact annually 2011-2013 Mentor and Post-doctoral advisor in Immunology to Dr. Shawna Graves, Baltimore, MD – Differential immunologic responses to AMA-1/AS02b vaccine in Malian children aged 1-6 vears of age. 2-5 hours contact weekly 2013-Present Mentor and Thesis committee member in Immunology to Sarah Boudova, Baltimore, MD -Determining the relationship between in utero malaria antigen exposure and development of immune tolerance versus sensitization. 2-5 hours contact weekly when in-country. 2016-Present Mentor and Thesis committee member in Molecular Epidemiology to Kara Moser

Genomic epidemiology of the malaria parasite *Plasmodium falciparum*: Implications for whole-organism malaria vaccine development 2-5 hours contact four times per year.

The Johns Hopkins School of Medicine

1998-1999 Small group leader for infectious diseases topics with medical students

30 medical students 6-9 contact hours annually

1999-2002 Immunology and Epidemiology of *Plasmodium falciparum* malaria: Infectious Diseases

Grand Rounds

2 contact hours/annually

GRANT AND CONTRACT SUPPORT

Active

8/1/2013-7/31/2016 Miriam Laufer, M.D. –PI – (Lyke, Kirsten E. Immunologic Project Leader – up to 10%

Mass cytometry analysis of T and B cell immune exhaustion in response to chronic malaria infection in HIV co-infected Malawian adults. Ndirande Blantyre Malaria Project.

Total: Direct - \$274,000

2/1/2014 - 1/31/2017 Kirsten E. Lyke, M.D. – PI – 40%

HHSN272201000049I

NIH – VRC 500/314 – Malaria CVD 24000 - A Phase 1, Open-Label, Clinical Trial with Experimental Controlled Human Malaria Infections (CHMI) to Evaluate Safety and Durability of Protection Following Intravenous and Intramuscular Administration of PfSPZ

Vaccine in Malaria-Naive Adults.

vaccine ili iviaiaria-narve Adurts.

Direct and Indirect: \$997,507 Option A: \$332,374 Option B: \$351,883

4/1/2014-3/30/2019 Claire Fraser, PhD, PI - Institute of Genome Sciences, (Kirsten E. Lyke, M.D., - Malaria Immunology Project 4 Leader – 20%)

Initiational of the state of th

Host, Pathogen, and the Microbiome: Determinants of Infectious Disease Outcome AI13-09 Impact of parasitic diseases on public health; challenges to drug and vaccine development specific to parasites; contribution to be had from parasite genomics resources; recent advances in parasite genomics.

2/27/2015-1/31/2017 Kirsten E. Lyke, M.D. - PI - 18%, HHSN272201000049I

NIH – VRC 500/208 – Ebola CVD 2000 - A Phase 1/1b Open-Label Clinical Trial to Evaluate Dose, Safety and Immunogenicity of a Recombinant Modified Vaccinia Virus Ankara Ebola Vaccine, VRC-EBOMVA079-00-VP (MVA-EbolaZ), Administered Alone or as a Boost to cAd3-Ebola Vaccines in Healthy Adults

Direct and Indirect: \$266,960

3/31/2015-3/30/2020 Kirsten E. Lyke, M.D. - Sub-contract site PI - 15%, R01-AI-110852

NIH — Malaria CVD 27000 – Primary PI; Kim Williamson, USUSH, Repetitive Plasmodium falciparum (Pf) Malaria of the NF54 strain Controlled Human Challenge Infection (CHMI) Study in Malaria-Naïve Adults

Direct and Indirect: \$1,860,601

5/17/2015-5/16/2020 Kirsten E. Lyke, M.D. -Clinical PI, AID-OAA-C-15-0007

USAID- MVDP SOL-OAA-13-000091- Lead Site: Leidos, Inc.- Proof of Concept Malaria

Vaccine Development Program. Consortium: Leidos, UMB, Emory University

Direct and Indirect: \$23,756,66,960

10/1/2015-4/30/2017 Kirsten E. Lyke, M.D. –PI – 30%

Office of the Surgeon General, Department of the Army – DPIV-025 – Dengue CVD 2000 - A Phase 1/2, Randomized, Observer-blind Study of Varying Injection Schedules of a Tetravalent Dengue Virus Purified Inactivated Vaccine (TDENV-PIV) with AS03B Adjuvant and Placebo in Healthy Adults in the US Direct and Indirect: \$951,083

10/1/2015-4/30/2017 Kirsten E. Lyke, M.D. -PI, JW148430

Joint Warfighter Medical Research Program, Advanced Medical Development Program, Military Infectious Diseases Research Program – Warfighter II – Malaria CVD 26000 - Phase 2 Development of the PfSPZ Vaccine to Protect the Warfighter from Malaria Direct and Indirect: \$2,181,000

10/1/2015 -9/30/2020 Kirsten E. Lyke, M.D. -PI, NIAID-LMIV-NIHAO2015023

Laboratory of Malaria Immunology and Vaccinology Contract - Operation of a Facility Testing Malaria Vaccines in Adult Human Subjects

Pending:

Autumn 2016 Kirsten E. Lyke, M.D. – PI, Alopexx

A randomized, open-label, parallel-control clinical trial to assess the efficacy of F598, an antipoly N-acetyl glucosamine (PNAG) monoclonal antibody, in preventing controlled human malaria infection (CHMI) in healthy subjects.

Autumn 2016 Kirsten E. Lyke, M.D. – PI, HHSN272201000049I

NIH – VRC 500/315 – Malaria CVD 28000. A Phase 1, Open-Label, Clinical Trial with Heterologous NFc135.10 Experimental Controlled Human Malaria Infections (CHMI) to Evaluate Safety and Durability of Protection Following Direct Venous Inoculation of heterologous PfSPZ Vaccine in Malaria-Naive Adults

Completed

1998-2005 Co-investigator 100% - Christopher V. Plowe, M.D., M.P.H. – P.I.

NIH N01-AI85346. Malaria: Clinical research and trial preparation sites in endemic areas. Case control study of severe malaria clinical and laboratory supervisor. Bandiagara lab supervisor.

Total direct costs \$9,022,744.

2002-2005 P.I. 75%

NIAID K23 Award (K23-AI49203).

Immunologic interaction of chronic schistosomiasis and acute falciparum malaria.

Total direct costs \$424,730 DMID #02-028

2005-2006 University of Maryland School of Medicine Intramural Grant – 0%

Immunologic assessment of cell mediated immunity induced by recombinant AMA-1 vaccine FMP2.1 adjuvanted with GlaxoSmithKline Biologicals' ASO2A in adults naturally exposed

to malaria

Total direct costs \$14,934

9/1/05-6/30/10 Christopher V. Plowe, M.D., M.P.H. – P.I.

(Aim 2, Project 2 Lead Investigator – Kirsten E. Lyke- 10% effort)

NIH - International Collaboration on Infectious Diseases Research (ICIDR) - U01AI065683-

06. Genetic diversity and protective immunity to malaria infection and disease

Direct: \$3,811,298

2006-2008 Co-investigator 25% - Christopher V. Plowe, M.D., M.P.H. - P.I.

US Army Medical Research & Material Command X81XWH-06-1-0427

Double blind randomized controlled Phase I trial to evaluate the safety and immunogenicity

> of WRAIRs MSP1 candidate malaria vaccine (FMP1) adjuvanted in GlaxoSmithKline Biologicals AS02A vs. Rabies vaccine in semi-immune adults in Bandiagara, Mali

Total direct costs \$527.527

Kirsten E. Lyke, P.I. 10% 2006-2008

Protein Sciences, Inc.

Comparison of the Immunogenicity, Safety and Reactogenicity of FluBlØkTM, Trivalent Recombinant Baculovirus-Expressed Hemagglutinin Influenza Vaccine, to a Licensed Egg-

grown Influenza Vaccine in Ambulatory Elderly Adults.

\$102,374

2007-2008 Kirsten E. Lyke, P.I. 10%

NIH - VTEU N01 AI25461- VTEU PI: Myron Levine

A Phase I/II study of the Safety and Immunogenicity of a Recombinant Human Parvovirus

B19 Vaccine (on clinical hold)

\$314,500

10/1/07-8/30/10 Kirsten Lyke, M.D. – P.I. - 15.5%

Safety, Tolerability, and Protective Efficacy of a Non-replicating, Metabolically Active

Plasmodium falciparum Sporozoite Vaccine (Pf SPZ Vaccine) Administered

Subcutaneously to Malaria-Naïve Adult Healthy Volunteers. Contract: MVI-PATH: Bill and Melinda Gates Foundation

Pre-Award: \$133,662, Core Award: \$723,187 (add on award total: \$1,119,226)

11/1/2010 -Kirsten E. Lvke, M.D. – PI – 20%

5/9/12 Pre-award - Safety, immunogenicity and efficacy against malaria in the sporozoite challenge

model of one dose of circumsporozoite antigen expressing recombinant adenovirus 35

followed by two doses of RTS, S/AS01_B in healthy malaria-naïve adults.

Contract: MVI-PATH: Bill and Melinda Gates Foundation

Direct: \$84,458.

8/1/2007-7/31/2012 Kirsten Lyke, M.D. –PI – 30%

Doris Duke Clinical Scientist Development Award: Schistosoma-mediated resistance to

malaria

Direct: \$405,000

11/1/2007-11/6/12 Kirsten Lyke, M.D. –PI – 2.5% (**Investigator-Derived** Protocol)

> An interventional *Plasmodium falciparum* malaria challenge model utilizing the NF54 strain of parasite transmitted by aseptic A. stephensi mosquitoes to healthy malaria-naïve adult

volunteers (11/8/09-11/6/11).

NIH - VTEU N01-AI-25461. VTEU PI: Karen Kotloff

Direct: \$658,438.

8/1/2008-7/31/2013 Kirsten Lyke, M.D. –PI – 30%

Immunologic determinants of schistosoma-mediated resistance to malaria in humans

NIH 1R01AI067954

Total: Direct and Indirect: \$1,114,270

9/1/2010-6/30/2015 Christopher V. Plowe, M.D., M.P.H. – P.I.

(Immunology Lead Investigator – Kirsten E. Lyke- 4% effort)

International Collaboration on Infectious Diseases Research (ICIDR) - U01AI065683-06.

Genetic diversity and protective immunity to malaria infection and disease

Direct: \$3,811,298

7/19/2011-10/31/14 Kirsten Lyke, M.D. –PI – 35%

A randomized interventional malaria challenge study of intradermally-administered, infectious (replication-intact), cryopreserved *Plasmodium falciparum* sporozoites (PFSPZ Challenge) in healthy malaria-naïve adults aged 18-50 years DMID- 11-0027 NIH - VTEU N01-AI-25461. *VTEU PI: Karen Kotloff* Direct: \$358,000.

9/10/2014–9/30/2015 Kirsten Lyke, M.D. –PI – 35%, HHSN272201000049I

NIH – VRC 500/207 – Ebola CVD 1000 - A Phase 1/1b, Open-Label, Dose-Escalation Clinical Trial to Evaluate the Safety, Tolerability and Immunogenicity of the Ebola Chimpanzee Adenovirus Vector Vaccines, VRC-EBOADC069-00-VP (cAd3-EBO) and VRC-EBOADC076-00-VP (cAd3-EBOZ), in Healthy Adults – Multicenter trial Direct and Indirect: \$378.056

PUBLICATIONS

Peer-reviewed journal articles

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- 8. Lazaro AM, Burdett L, Cao K, Machan C, Husted L, Lyke KE, Doumbo OK, Ng J, Hartzman RJ, Plowe CV, Sztein MB, Fernandez-Vina MA. HLA-B-Cw-DRB1-DQA1-DQB1 haplotypes diversity in Mali population. *Hum Immunol*, 2003; Oct;64(10 Suppl):S135.
- 9. **Lyke, KE**, Dicko A, Kone A, Coulibaly D, Guindo A, Cissoko Y, Traoré K, Plowe CV, and Doumbo OK. Incidence of severe *Plasmodium falciparum* malaria as a primary endpoint for vaccine efficacy trials in Bandiagara, Mali. *Vaccine* 2004; 22: 3169-3174.
- 10. **Lyke KE,** Burges R, Cissoko Y, Sangare L, Dao M, Diarra I, Kone A, Harley R, Plowe CV, Doumbo OK and Sztein MB. Serum levels of pro-inflammatory cytokines interleukin-1 beta, IL-6, IL-8, IL-10, Tumor necrosis factor-alpha and IL-12p70 in Malian children with severe *Plasmodium falciparum* malaria and uncomplicated malaria or healthy controls. *Infect Immun* 2004; 72:5630-37.
- 11. Moulds JM, Thomas BJ, Doumbo O, Diallo DA, **Lyke K**, Plowe CV, Birmingham D. Identification of the Kn^a/Kn Polymorphism and a Method for Knops Genotyping. Transfusion 2004; 44(2):164-9.
- 12. Cao K, Moormann AM, **Lyke KE**, Masaberg C, Doumbo OK, Ng J, Hartzman RJ, Plowe CV, Sztein MB, Fernández-Viña MA. Differentiation between African populations is evidenced by the diversity of alleles and haplotypes of HLA class I loci. *Tissue Antigens*. 2004; 63: 293-325.
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- 15. Deans AM, **Lyke KE**, Thera MA, Plowe CV, Kone A, Doumbo OK, Kai O, Marsh K, Mackinnon MJ, Raza A, Rowe JA. Low multiplication rates of African *Plasmodium falciparum* isolates and lack of association of multiplication rate and red blood cell selectivity with malaria *Am J Trop Med Hyg*. 2006; Apr;74(4):554-63.
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- 17. Thera MA, Sehdev PS, Coulibaly D, Traore K, Garba MN, Cissoko Y, Kone A, Dicko A, Beayogui AH, Djimde AA, **Lyke KE**, Diallo DA, Doumbo OK, Plowe CV. Impact of trimethoprim-sulfamethoxazole prophylaxis on falciparum malaria infection and disease. *J Infect Dis*. 2005; Nov 15;192(10):1823-9.
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- 22. Arman A, Raza A, Tempest LJ, **Lyke KE**, Thera MA, Abdoulaye Koné, Plowe CV, Doumbo OK, and JA. Platelet-mediated clumping of *Plasmodium falciparum* infected erythrocytes is associated with high parasitaemia but not severe clinical manifestations of malaria in African children. *Am J Trop Med Hyg*. 2007; Nov; 77(5):943-946.
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- 30. **Lyke KE,** Laurens M, Adams M, Billingsley P, Richman A, Loyevsky M, Chakravarty S, Plowe CV, Sim KL, Edelman RE, Hoffman S. *Plasmodium falciparum* Malaria Challenge by the Bite of Aseptic Anopheles stephensi Mosquitoes: Results of a Randomized Infectivity Trial. *PLoS ONE* 2010; Oct 21;5(10):e13490. http://dx.plos.org/10.1371/journal.pone.0013490.
- 31. **Lyke KE**, Fernández-Viña MA, Cao K, Hollenbach J, Coulibaly D, Kone AK, Ando Guindo⁵, Burdett LA, Hartzman RJ, Wahl AR, Hildebrand WH, Doumbo OK, Plowe CV, and Sztein MB. Association of HLA Alleles with *Plasmodium falciparum* Severity in Malian Children. *Tissue Antigens*, 2011 77(6):562–571.
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- 48. Progress with *Plasmodium falciparum* sporozoite (PfSPZ)-based malaria vaccines. Richie TL, Billingsley PF, Sim BK, James ER, Chakravarty S, Epstein JE, Lyke KE, Mordmüller B, Alonso P, Duffy PE, Doumbo OK, Sauerwein RW, Tanner M, Abdulla S, Kremsner PG, Seder RA, Hoffman SL. Vaccine. 2015 Dec 22;33(52):7452-61. doi: 10.1016/j.vaccine.2015.09.096. Epub 2015 Nov 27.
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year and immune correlates following PfSPZ vaccination. Nat Med. Accepted for publication Apr 10, 2016.

Book Chapters and Policy Initiatives:

- 1. Sack DA, **Lyke KE**, McLaughlin C, Suwan V. Resistance of selected bacterial diarrheal diseases: shigellosis, cholera and campylobacteriosis. Microbiological and epidemiological mechanisms and implications for policy. USAID Drug Resistance Policy Initiative: AMR Members Initiative. March 2000.
- 2. **Lyke KE.** The Johns Hopkins Women in Medicine: Profile of Terry Shapiro, MD, PhD. Edited: Rebecca Ashkenazy, The Mary Elizabeth Garrett Fund. http://www.medicalarchives.jhmi.edu/garrett/acknowledgments.htm
- 3. Cao K, **Lyke K**, Masaberg C, Doumbo O, Ng J, Hartzman R, Plowe C, Sztein M & Fernández-Viña M. Distribution and association of alleles at the HLA class I-A, B and C loci in a Malian population. In: "HLA 2002. Immunobiology of the Human MHC". Hansen, J. and Dupont, B., Editors. Seattle, WA. May 12-22, 2002. IHWG Press, Seattle, WA.

Abstracts (peer-reviewed):

- 1. **K.E. Lyke**, O Obasanjo, M. O'Brien, M. Williams, R. Chotani, T.M. Perl. Ventriculitis Complicating Intra-Ventricular Catheter (IVC) in Adult Neurosurgical Patients. The Johns Hopkins Medical Institutions, Baltimore, Maryland. Society of Health Care and Epidemiology: Presentation/Abstract No. 320 April 19, 1999.
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- 7. Sehdev PS, Thera MA, Coulibaly D, Traore K, Cissoko Y, Kone A, Guindo A, Sangaré L, Coulibaly S, Dicko A, **Lyke KE**, Diallo DA, Doumbo OK, Plowe CV. Effect of trimethoprim-sulfamethoxazole prophylaxis on the incidence of malaria disease, clinical antifolate resistance, and infection in Bandiagara, Mali. American Society of Tropical Medicine & Hygiene: Presentation No. 361. November 13, 2001.
- 8. **Lyke KE**, Burges R, Cissoko Y, Sangare L, Kone A, Fernandez-Vina M, Plowe C, Doumbo O, and Sztein MB. Interferon-gamma (IFN-γ) production and proliferation of HLA-A*3 restricted peripheral blood mononuclear cells (PBMC) derived from Malian children with severe or uncomplicated *P. falciparum* malaria and healthy controls after antigenic stimulation with HLA-A3-restricted malaria peptide pools. Malaria's Challenge: From Infants to Genomics in Vaccines. Keystone, Colorado, March 3-8, 2002.
- 9. **Lyke KE**, Burges R, Cissoko Y, Sangare L, Dao M, Diarra I, Kone A, Harley R, Plowe C, Doumbo O, and Sztein MB Serum levels of pro-inflammatory cytokines Interleukin-1 beta, IL-6, IL-8, IL-10, Tumor necrosis factor-alpha, and IL-12p70 in specimens derived from matched Malian children with severe or uncomplicated *P. falciparum* malaria and healthy controls. Center for Vaccine Development, University of

Maryland, Baltimore, MD, Malaria Research and Training Center, Bandiagara Malaria Project, University of Bamako, Bamako, Mali. American Society of Tropical Medicine & Hygiene: Presentation No. 433, December 5, 2003.

- 10. Cissoko Y, Daou M, Lyke KE, Dicko A, Diarra I, Kone, A, Guindo A, Traore K, Krishnegowda G, Thera MA, Diallo DA, Doumbo O, Plowe C, Gowda DC and Sztein MB. Serum antibody levels to glycosylphosphatidylinositols (GPIs) in specimens derived from matched Malian children with severe or uncomplicated *P. falciparum* malaria and healthy controls. Malaria Research and Training Center, Bandiagara Malaria Project, University of Bamako, Bamako, Mali, Center for Vaccine Development, University of Maryland, Baltimore, MD, Department of Biochemistry and Molecular Biology, Pennsylvania State University College of Medicine, Hershey, PA. American Society of Tropical Medicine & Hygiene: Presentation No. 831, December 7, 2003
- 11. Koné A, Dicko A, **Lyke KE**, Coulibaly D, Traoré K Guindo A, Cissoko Y, Dao M, Diarra I, Dakouo B, Thera MA, Diallo DA, Plowe CV, and Doumbo O. Clinical presentations and risk factors of death from severe malaria in Bandiagara, Mali. Malaria Research and Training Center, Department of Epidemiology of Parasitic Diseases, Faculty of Medicine Pharmacy and Odonto-Stomatology, University of Mali, Bamako, Mali, Center for Vaccine Development, University of Maryland, Baltimore, MD. American Society of Tropical Medicine & Hygiene: Poster No. 1470, December 2003
- Dicko A, Coulibaly D, Guindo A, Kone A, Traore K, Thera MA, Lyke KE, Diallo DA, Doumbo O, Plowe CV Stable incidence of clinical malaria in three consecutive years in Bandiagara, Mali: Implication for malaria vaccine trials. Malaria Research and Training Center, Faculty of Medicine Pharmacy and Odonto-Stomatology, University of Mali, Bamako, Mali, Center for Vaccine Development, University of Maryland, Baltimore, MD. American Society of Tropical Medicine & Hygiene: Poster No. 332, December 5, 2003
- 13. Kone A, Dicko A, **Lyke KE**, Traore K, Coulibaly D, Guindo A, Cissoko Y, Dao M, Diarra I, Dakouo B, Thera MA, Diallo DA, Plowe CV, and Doumbo O. Clinical presentation and risk factors for death from severe falciparum malaria in Bandiagara, Mali. Malaria Research and Training Center, Faculty of Medicine Pharmacy and Odonto-Stomatology, University of Mali, Bamako, Mali, Center for Vaccine Development, University of Maryland, Baltimore, MD. American Society of Tropical Medicine & Hygiene: Poster No. 284, December 5, 2003.
- 14. Moulds JM, Diallo DA, Doumbo OK, Coulibaly D, Lyke K, Plowe C. Reinvestigation of the Direct Coomb's Test in Malaria Patients: Lack of Correlation. Dept. of Microbiology & Immunology, Drexel University College of Medicine, Philadelphia, PA, Dept. of Hematology, University of Bamako, Bamako, Mali, MRTC, University of Bamako, Bamako, Mali, MRTC, University of Bamako, Mali, CVD, University of Mayland School of Medicine, Baltimore, MD, CVD, University of Maryland School of Medicine, Baltimore, MD. American Society of Tropical Medicine & Hygiene: Poster No. 676, December 6, 2003.
- 15. Deans AM, **Lyke K**, Plowe C, Doumbo O, The Bandiagara Malaria Project, Marsh K, and Rowe A. Institute of Cell, Animal and Population Biology, Ashworth Laboratories, University of Edinburgh, West Mains Rd, Edinburgh EH9 3JT, UK. Severe malaria in Africa and *Plasmodium falciparum* multiplication rates. Molecular Approaches to Malaria, Lorne, Australia, Feb 1-5, 2004.
- 16. **Lyke KE,** Dicko A, Sangare L, Kone A, Coulibaly D, Guindo A, Traore K, Dra M, Diarra I, Dabo A, Sztein MB, Plowe CV, and Doumbo OK. Association of protection against acute *Plasmodium falciparum* infection in Malian children with concomitant *Schistosoma haematobium*. American Society of Tropical Medicine & Hygiene: Oral presentation 24, Miami, FL, November 8, 2004.
- 17. **Lyke KE**^{1*}, Fernández-Viňa MA^{2*}, Cissoko Y³, Coulibaly D³, Kone AK³, Guindo A³, Doumbo OK³, Plowe, CV¹, Sztein MB¹. Association of HLA alleles with *P. falciparum* severity in Malian children with severe malaria matched to uncomplicated malaria or healthy controls. ¹Center for Vaccine Development, University of Maryland School of Medicine, Baltimore, Maryland, ²C.W. Bill Young DoD Marrow Program, Naval Medical Research Center, Georgetown University, Kensington, MD, and ³Malaria Research and Training Center, University of Bamako, Bamako, Mali. *Contributed equally to the study. Multilateral Initiative in Malaria (Yaounde, Cameroon, November 17, 2005).
- 18. Traoré K, Coulibaly, D, Guindo A, Kone, A, Thera MA, Dicko A, Sagara I, Diawara SI, Diarra I, Dao M, Cissoko Y, **Lyke KE**, Diallo DA, Plowe CV and Doumbo OK. Dynamics of *P. falciparum* sensitivity to chloroquine (CQ) and sulfadoxine-pyrimethamine (SP) during 7 years (1997-2003) of sentinel site surveillance in Bandiagara, Mali. Poster 885. International Medicine and Health in the Tropics Congress, Marseilles, France, September 11-15, 2005.

19. **Lyke, KE,** Daou M, Diarra I, Kone, A, Thera MA, Heppner G, Leach A, Doumbo, O, Plowe,C, and Sztein, MB. Cell mediated immunity elicited in semi-immune adults in Bandiagara, Mali after a Randomized controlled Phase I trial of WRAIR's AMA1 antigen adjuvanted in GlaxoSmithKline Biologicals' AS02A. American Society of Tropical Medicine & Hygiene: Poster presentation 24, Atlanta, GA, November 2006.

- 20. Takala SL, Coulibaly D, Thera MA, Dicko A, Smith DL, Guindo AB, Kone AK, Ouattara A, Djimde A, Sehdev P, **Lyke KE**, Diallo DA, Doumbo OK, and Plowe CV. Dynamics of *Plasmodium falciparum* MSP-1₁₉ genetic diversity at a malaria vaccine-testing site in Mali. American Society of Tropical Medicine & Hygiene: Poster presentation, Atlanta, GA, November 2006.
- 21. Epstein JE, **Lyke KE**, Regis D, Reyes S, Williams F, Mendoza-Silveiras J, Parekh F, Lee Sim K, Lemiale L, Edelman R, Richie TL, Hoffman SL. A Metabolically Active, Non-Replicating *Plasmodium falciparum* Sporozoite Vaccine: The First Phase 1/2a Clinical Trial and Beyond. Poster presentation: Malaria Vaccines for the World, Royal Society of Medicine, London, UK, Sept. 17-19, 2007.
- 22. **Lyke KE**, Dabo A, Arama C, Daou M, Diarra I, Plowe CV, Doumbo OK, and Sztein MB. Effects of Concomitant *Schistosoma Haematobium* Infection on the Intracellular Cytokine Levels and T Cell Memory Populations Elicited by Acute *Plasmodium Falciparum* Malaria Infection in Malian Children. American Society of Tropical Medicine & Hygiene: Oral presentation, Philadelphia, PA, November 5, 2007.
- Takala SL, Ouattara A., Coulibaly D, Thera MA, Dicko A, Guindo AB, Kone AK, Traore K, Djimde A, **Lyke KE**, Diallo DA, Doumbo OK, and Plowe CV Dynamics of polymorphism in apical membrane antigen 1 over three years at a vaccine-testing site in Mali. American Society of Tropical Medicine & Hygiene: Oral presentation, Philadelphia, PA, November 5, 2007.
- 24. **Lyke KE**, Dabo A, Arama C, Daou M, Diarra I, Plowe CV, Doumbo OK, and Sztein MB Effects of Concomitant *Schistosoma haematobium* Infection on the Immunologic Responses Elicited by Acute *Plasmodium falciparum* Malaria Infection in Malian Children. Doris Duke Charitable Foundation Annual Meeting, October 27, 2008, Abstract 2494
- 25. **Lyke KE**, Epstein JA, Richie T, James E, Lee KL, Hoffman S. A Phase 1/2A Trial of the Metabolically Active, Non-Replicating (Attenuated) *Plasmodium falciparum* Sporozoite (*Pf* SPZ) Vaccine. MALVAC Scientific Forum Meeting: Progress and Challenges with Whole Organism Malaria Vaccines for Endemic Countries, Le Président Méridien Hôtel, Dakar, Senegal, June 3, 2009
- 26. **Lyke KE,** Dabo A, Arama C, Daou M, Diarra I, Plowe CV, Doumbo OK, Sztein MB. Effects of Concomitant *Schistosoma haematobium* Infection on the T Regulatory Cell Response Elicited by Acute *Plasmodium falciparum* Malaria Infection in Malian Children. American Society of Tropical Medicine & Hygiene: Oral Presentation No. 744, November 21, 2009
- 27. Thera MA, Doumbo OK, Coulibaly C, Laurens MB, Kone A, Guindo A, Diallo DA, Traore K, Kouriba B, Diarra I, Dolo A, Niangaly A, Daou M, Sissoko M, Traore, D, Lyke KE, Takala S, Godeaux O, Thonnard J, Cohen J, Lanar D, Diggs C, Soisson L, Heppner DG, Plowe CV. Randomize, Controlled, Phase 2B Clinical Trial to Evaluate the Safety, Immunogenicity and Efficacy of WRAIR's AMA-1 Malaria Vaccine (FMP2.1) Adjuvanted with GSK Biologicals' AS02A vs. Rabies Vaccine in 1-6 Year Old Children in Bandiagara, Mali. American Society of Tropical Medicine & Hygiene: Oral Presentation No. 1074, November 22, 2009
- 28. **Lyke KE**, Laurens M, Adams M, Billingsley P, Richman A, Loyevsky M, Chakravarty S, Plowe CV, Sim KL, Edelman R, Hoffman S. A New Malaria Experimental Challenge System; Infection of Volunteers by the Bite of Aseptic *Anopheles Stephensi* Mosquitoes Infected with *Plasmodium falciparum* (NF54) sporozoites. American Society of Tropical Medicine & Hygiene: Oral Presentation No. 879, November 22, 2009.
- 29. Epstein JE, Lyke KE, Laurens MB, Reyes MS, Sedegah M, Tamminga C, Thomas N, Murphy J, Billingsley PF, James E, Gunasekera A, Richman A, Loyevsky M, Li T, Murshedkar T, Fedders C, Steinbeiss V, Bennet J, Richie N, Chakravarty S, Li M, Stafford R, Ahumada A, Steinbeiss M, Reyes A, Plowe CV, Smith K, Whitman T, Tucker K, Lemiale L, Taylor D, Ockenhouse C, Sim BKL, Edelman R, Richie TL, Hoffman SL. The First Phase 1 Trial of the Metabolically-active, Whole Organism Plasmodium falciparum sporozoite (PfSPZ) Vaccine. American Society of Tropical Medicine & Hygiene: Oral Presentation Abstract No. 807, November 5, 2010.
- 30. **Lyke KE**, Wang A, Dabo A, Arama C, Daou M, Diarra I, Dutta S, Angov E, Lanar DE, Plowe CV, Doumbo OK, Sztein MB. Antigen-specific B memory cell responses to *Plasmodium falciparum* Blood Stage Malaria Antigens and Schistosomal Antigens in Malian Children With and Without *Schistosoma haematobium*. American Society of Tropical Medicine & Hygiene: Oral Presentation Abstract No. 1288, November 7, 2010.

31. Thera MA, Doumbo OK, Coulibaly C, Laurens MB, Kone A, Guindo A, Diallo DA, Traore K, Kouriba B, Diarra I, Niangaly A, Dolo A, Daou M, Sissoko M, Sagara I, Sissoko M, Kouriba B, **Lyke KE**, Takala S, Godeaux O, Soisson L, Lanar D, Dutta S, House B, Heppner DG, Plowe CV. Extended safety, immunogenicity and efficacy of WRAIR's AMA-1 malaria vaccine (FMP2.1) adjuvanted in GSK Biologicals' AS02A in 1-6 year old children in Bandiagara, Mali. American Society of Tropical Medicine & Hygiene: Oral Presentation Abstract No. 161, November 6, 2010.

- 32. Laurens MB, Thera MA, Coulibaly C, Kone A, Guindo A, Diallo DA, Traore K, Diarra I, Niangaly A, Dolo A, Daou M, Tolo Y, Sissoko M, Sissoko MS, Kouriba B, Lyke KE, Takala-Harrison S, Blackwelder WC, Wu Y, Godeaux O, Vekemans J, DuBois MC, Cohen J, Ballou WR, Thompson, D, Dube T, Lanar D, Dutta S, House B, Diggs C, Soisson L, Heppner DG, Doumbo OK, Plowe CV. Efficacy of AMA1 malaria vaccine FMP2.1/AS02_A against gametocytemia in 1-6 year old children in Bandiagara, Mali: implications for malaria elimination. American Society of Tropical Medicine & Hygiene: Abstract No. 590, November 6, 2010.
- 33. The Attenuated Sporozoite Vaccine Laboratory and Clinical Development Teams: Sanaria Inc., Rockville, MD, USA, Naval Medical Research Center, U.S. Military Malaria Vaccine Program, Silver Spring, MD, USA, Center for Vaccine Development, University of Maryland School of Medicine, Baltimore, MD, USA, Radboud University Nijmegen Medical Center, Nijmegen, the Netherlands, Leiden Malaria Research Group, LUMC, Leiden, the Netherlands, Columbia University Medical Center, New York, NY, USA, Protein Potential LLC, Rockville, MD, USA, Vaccine Research Center, NIAID, NIH, Bethesda, MD, USA. Progress Toward Development of an Attenuated Sporozoite Vaccine to Prevent and Eliminate Plasmodium falciparum Malaria. Phacilitate Vaccine Conference, January 24, 2011, Washington, DC.
- 34. **Lyke KE**, Fernández-Viňa MA, Cao K, Hollenbach J, Coulibaly D, Kone AK, Ando Guindo⁵, Burdett LA, Hartzman RJ, Wahl AR, Hildebrand WH, Doumbo OK, Plowe CV, and Sztein MB. Association of HLA Alleles with *Plasmodium falciparum* Severity in Malian Children. American Society of Tropical Medicine & Hygiene: Oral Presentation Abstract No. 6, December 5, 2011.
- 35. Laurens MB, Coulibaly D, Bergmann-Leitner ES, Angov E, Kone A, Guindo A, Diallo DA, Traore K, Traore I, Sissoko MS, Kouriba B, Lyke KE, Blackwelder W, Wu Y, Vekemans J, Cohen J, Ballou WR, Lanar DE, Dutta S, Diggs C, Soisson L, Heppner DG, Plowe CV, Doumbo OK, Thera MA. Strain-specific *Plasmodium falciparum* growth inhibition among Malian children immunized with the FMP2.1/ASO2A Vaccine. American Society of Tropical Medicine & Hygiene: Oral Presentation Abstract No. 952, December 6, 2011.
- 36. Hoffman SL, Epstein JL, Seder R, **Lyke KE**, Tanner M, Abdulla S, Sauerwein R. Adaptive clinical trials of three PfSPZ products for development of a whole sporozoite vaccine that prevents *Plasmodium falciparum* infection, disease and transmission. American Society of Tropical Medicine & Hygiene: Oral Presentation Abstract No. 956, December 6, 2011.
- 37. **Lyke KE**, Laurens MB, Plowe CV, Kim BLS, Hoffman SL. *Plasmodium falciparum* sporozoite Challenge (Intradermal administration of infectious cryopreserved Pf sporozoite). American Society of Tropical Medicine & Hygiene: Sanaria PfSPZ Symposium, November 13, 2012.
- 38. **Lyke KE**, Laurens MB, Adams M, Strauss K, Plowe CV. The University of Maryland Controlled human malaria infection (CHMI) quantitative polymerase chain reaction (qPCR) Experience. American Society of Tropical Medicine & Hygiene: Sanaria PfSPZ Symposium, November 13, 2012.
- 39. Berry AA, Gotlieb E, Kouriba B, Thera MA, Lanar DE, Dutta S, Heppner DG, Coulibaly D, Ouattara A, Niangaly A, Diggs C, Soisson L, Wu Y, Laurens MB, Sztein MB, Doumbo OK, Plowe CV, **Lyke KE**. Antibody subclass and avidity responses to AMA1 vaccine candidate FMP2.1/AS02A. American Society of Tropical Medicine & Hygiene: Oral Presentation Abstract No. 7, November 12, 2012.
- 40. Travassos MA, Coulibaly D, Laurens MB, Dembélé A, Tolo Y, Koné A, Traoré K, Niangaly A, Berry AA, Takala Harrison S, Kouriba B, **Lyke KE**, Diallo DA, Doumbo OK, Plowe CV and Thera MA. Incidence of malaria and anemia in children with Hemoglobin C trait: a longitudinal cohort study in Bandiagara, Mali. American Society of Tropical Medicine & Hygiene: Abstract No. 1335, November 14, 2012.

MAJOR INVITED SPEECHES

Local 2002

2005	University of Maryland School of Medicine, Clinical Pathology Conference (Medical Grand Rounds): "A 21 year old Guinean man with intermittent fever, splenomegaly and pancytopenia" - 1 hour contact
2009	University of Maryland School of Medicine, Grand Rounds Conference, "Back to the Future with Malaria Vaccines: Have We Come Full Circle?" November 4, 2009 – 1 hour contact
2010	University of Maryland, College Park, School of Public Health: Overview of Malaria and Malaria Vaccines – 3 hours contact
2010	University of Maryland Center for Vaccine Development, Frontiers of Vaccinology, "Whole Organism, Metabolically Active Pf Sporozoite Malaria Vaccine: Phase I/II first in human trial". December 7, 2010 – 0.5 hour contact.
2011	University of Maryland Infectious Diseases Review-Haitian Fellowship Attendees. "Malaria Review and Cestode and Trematode Review." August 28, 2011 – 2 hour contact
2012	Symposium on the Whole Sporozoite Vaccine Approach. "A randomized interventional malaria challenge study of intradermally-administered, infectious (replication-intact), cryopreserved <i>Plasmodium falciparum</i> sporozoites (PFSPZ Challenge) in healthy malarianaïve adults aged 18-50 years" November 13, 2012.
2013	University of Maryland School of Medicine, Grand Rounds Conference, "Standing on the Precipice of a Malaria Vaccine? (Updates from the trenches on the whole organism <i>Pf</i> sporozoite approach)" January 16, 2013 – 1 hour contact
2013	National Foundation of Infectious Diseases. Updates in Vaccinology – Symposium 2: Malaria Vaccines- Current and Future. "Whole organism, metabolically-active, Pf sporozoite vaccine approach." April 22, 2013
2015	American College of Physicians – Maryland – Symposium: The Ebola Crisis - Past, Present, Future. January 31, 2015 – 1 hour contact.
<u>International</u>	
11/17/2005	Multilateral Initiative in Malaria, Yaounde, Cameroon: "HLA and Malaria" 1 hour contact
5/15/2006	7 th Advanced Vaccinology Course, Annecy, France: "Association of protection against acute <i>Plasmodium falciparum</i> infection in Malian children with concomitant <i>Schistosoma haematobium</i> ." – 2 hours contact
6/3/2009	World Health Organization, MALVAC Scientific Forum Meeting, Dakar, Senegal: "Progress and Challenges with Whole Organism Malaria Vaccines for Endemic Countries" 1 hour contact
Fall 2010	University of Maryland Medicine Bulletin, Featured article, Making a Difference, Global Health. Vol. 95, No. 2, p. 11-16.
June 2011	European Malaria Vaccine Development Association (EMVDA) – "Progress and Rationale towards the PfSPZ Challenge". June 22, 2011 – 1 hour contact. Didactic round table June 22-23, 2011.