SABIN VACCINE INSTITUTE

R&D KEY OPINION LEADER CONFERENCE

April 3, 2023
8:00 am – 5.00 pm ET
Marriott Marquis Hotel, Washington D.C.

Amy Finan

Chief Executive Officer
Sabin Vaccine Institute

Welcome

Dear colleagues and friends,

I am pleased to welcome you to Sabin's Key Opinion Leader conference today. This is the third forum in a series convening key scientific and regulatory leaders to consider actionable steps for filovirus vaccine research. The first two workshops laid the foundation for today's conference which should yield productive insights for creating more diverse and harmonized regulatory mechanisms for filovirus vaccine research and development.

This is our first hybrid meeting and we have a sizeable number of in-person attendees. We hope you take the opportunity to meet each other and identify ways to collaborate. These meetings are intended to fuel creative energy and innovation and help push forward our collective agenda to advance R&D for filovirus vaccines.

We at Sabin are deeply grateful to our funders and partners including those at BARDA and NIH. Their support enabled us to be the first organization to get our candidate vaccine for Ebola Sudan to Uganda last December and assist in the global outbreak response.

We are also thankful to our speakers and panelists who kindly agreed to be here to share their knowledge. Last but not least, we thank all of our participants here and online for contributing to what should be a robust discussion.

Thank you,

Amy Finan

Pathways to Licensure: Key Considerations for Filovirus Vaccine Development and Regulatory Harmonization

Note: All times are EST.

8:15–8:20 AM	**Welcome**	Courtney Finch (Sabin)
8:20–8:45 AM	**Keynote Address**	Betty Mwesigwa (MUWRP)

SESSION 1

8:45–9:00 AM	**Presentation:** Overview of filoviruses and filoviral disease	Courtney Finch (Sabin)
9:00–9:50 AM	**Short Presentations:** Case studies for development and licensure of vaccines	
	Licensing the first vaccine for an Indication under the FDA Animal Rule (10-12 min)	Mario Skiadopoulos (BARDA, CTR)
	Merck's Ebola vaccine development: A story of innovation and partnerships (10-12 min)	Beth-Ann Coller (Merck)
	Nonhuman primate to human immunobridging to infer the protective effect of Ad26.ZEBOV, MVA-BN-Filo (10-12 min)	Ramon Roozendaal (Janssen)
	Overview of Sabin's filoviruses countermeasure program: ChAd3-vectored vaccines against Marburg & Sudan viruses (10-12 min)	Katya Vert-Wong (Sabin)
9:50–10:05 AM	Q&A on presentations	**Moderator:** Ricardo Carrion Jr. (TXBIO)
10:05–10:20 AM	**Break**	
10:20–11:20 AM	**Panel Discussion:** Existing pathways to licensure and further discussion with Session 1 speakers	**Moderator:** Ricardo Carrion Jr (TXBIO) **Panelists:** Beth-Ann Coller (Merck), Ramon Roozendaal (Janssen), Mario Skiadopoulos (BARDA,CTR), Ekaterina Vert-Wong (Sabin)
11:20 – 12:20 PM	**BREAK/LUNCH**	

SESSION 2

12:20–1:20 PM	**Panel Discussion #1:** Prerequisites of vaccine acceptance, demand, and delivery	**Moderator:** Helen Rees (Wits RHI, University of Witwatersrand Johannesburg South Africa) **Panelists:** Anuradha Gupta (Sabin), Richard Kabanda (MoH, Uganda), Hannah Kibuuka (MUWRP), Stacey Knobler (Sabin), Lucy Mecca (MoH, Kenya)
1:20–2:20 PM	**Panel Discussion #2:** Lessons learned from COVID-19 about accelerated vaccine development and emergency use licensure; applicability to filoviruses	**Speaker:** Kimberly Taylor (NIAID/DMID/OBRRTR) **Panelists:** César Muñoz-Fontela (BNITM), Abdoul Habib Beavogui (UGANC), Brett Leav (Moderna), Sara Oliver (CDC), Carol Sabourin (BARDA, CTR), Tiziana Scarnà (Gavi), Nancy J. Sullivan (BU, NEIDL)
2:20–2:35 PM	**Break**	
2:35–2:55 PM	**Presentations:** Approaches to demonstrating the effectiveness of filovirus vaccines	Marion Gruber (IAVI)
	CEPI's 100-day mission and accelerating vaccine development	Adam Hacker (CEPI)
2:55–4:10 PM	**Panel Discussion #3:** Regulatory harmonization	**Moderator:** Adam Hacker (CEPI) **Panelists:** Marco Cavaleri (EMA), Delese Mimi Darko (FDA, Ghana) Mosoka Fallah (Africa CDC), Marion Gruber (IAVI), Daniel J. Kyabayinze (MoH, Uganda), Hilary Marston (FDA, USA), Allan Tindikahwa (PPD)
4:10 PM	**Closing Remarks**	

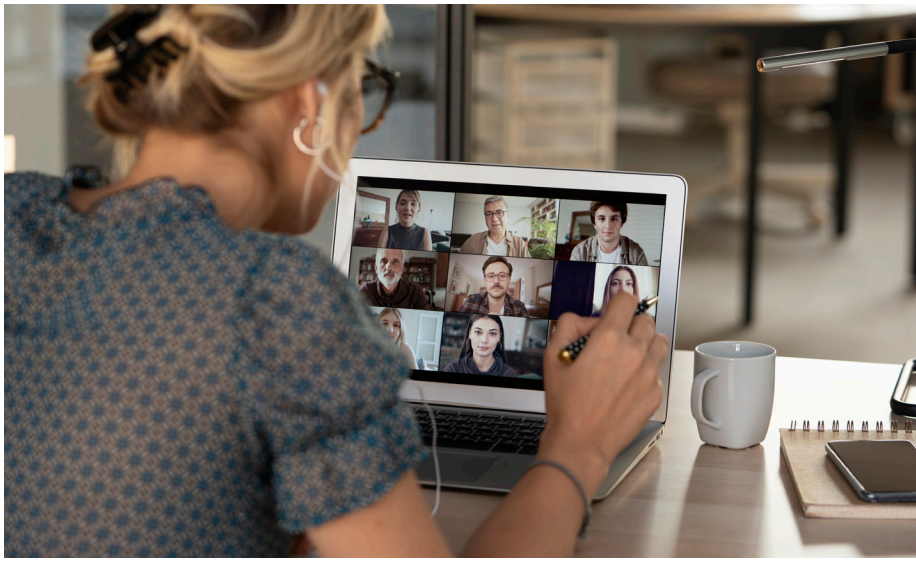
Sabin's Vaccine R&D Program

Our R&D strategy focuses on developing new vaccines and improving existing vaccines for infectious diseases that lack commercial value.

Sabin is advancing vaccine candidates against diseases caused by Marburg virus and the Sudan strain of the Ebola virus using the ChAd3 platform. Our work builds on prior non-clinical and clinical research by the National Institute of Allergy and Infectious Diseases' Vaccine Research Center and GSK. Marburg and Sudan are among the world's most dangerous viruses, causing hemorrhagic fever and resulting in the deaths of approximately half the people infected.

As recently as last year, we saw both Marburg and Sudan outbreaks. Preventive measures are essential to protect people against these deadly emerging infectious diseases and head off future epidemics. Sabin was actively involved in the Sudan ebolavirus global outbreak response in 2022 and was the first organization to deliver its ChAd3-SUDV vaccine to Uganda.

No approved vaccines exist to protect against either Sudan or Marburg virus diseases.



Synopsis: KOL Workshop 1, May 2021

The first KOL workshop was a virtual meeting held on May 6, 2021. It brought together regulatory and filovirus experts from multiple agencies in the U.S. and abroad including key African stakeholders. The meeting "KOL Blue Ribbon Panel: Regulatory Harmonization and Pathways to Licensure" sought to establish an understanding of viable regulatory pathways for candidate vaccines in the absence of human efficacy data and how these pathways differ from a traditional licensure pathway, where human efficacy data is attainable.

Synopsis: KOL Workshop 2, Oct. 2021

The second workshop "KOL Blue Ribbon Panel: Immune Correlates of Filovirus Protection at the Human-Animal Interface, a Pathway to Licensure" was a virtual meeting held on October 18, 2021. The meeting once again brought together filovirus and regulatory experts from multiple agencies and around the globe. This workshop focused on the concepts of immune correlates of protection and immunobridging as they relate to potential licensing of vaccine candidates in the absence of human efficacy data — when obtaining human efficacy data is unfeasible or unethical. Discussions focused on key scientific components such as what constitutes a sufficiently well-characterized animal model in which to perform the animal efficacy studies (to be used to gather the animal data package required for immunobridging) as well as what defines an immune correlate(s) of protection with which to bridge from the animal to human data as well as the inherent challenges of immunobridging.

Key Opinion Leaders Conference Speakers and Panelists, April 2023

Name	Affiliation	Title
Abdoul Habib Beavogui	University Gamal Abdel Nasser, Conakry, Guinea	Head of Parasitology and Mycology department, Public Health, University Gamal Abdel Nasser; Director of the Maferinyah National Research and Training Center; Senior Scientific Director of Guinea and NIH-USA Partnership on clinical research (PREGUI) in Guinea
Ricardo Carrion Jr.	Texas Biomedical Research Institute (TXBIO)	Professor and Director of Maximum Containment Contract Research and Co-lead of the Disease Intervention and Prevention Program
Marco Cavaleri	European Medicines Agency (EMA)	Head of Office, Health Threats and Vaccines Strategy
Delese Mimi Darko	Food and Drugs Authority, Ghana	Chief Executive Officer
Mosoka P. Fallah	Africa Centers for Disease Control and Prevention	Program Manager, Saving Lives and Livelihoods Initiative
Courtney Finch	Sabin Vaccine Institute	Director of Pre-Clinical, Research and Development
Beth Ann Coller	Merck	Executive Director Global Clinical Development
Marion Gruber	International AIDS Vaccine Initiative (IAVI)	Vice President for Public Health and Regulatory Science
Anuradha Gupta	Sabin Vaccine Institute	President, Global Immunization
Adam Hacker	Coalition for Epidemic Preparedness Innovations (CEPI)	Director and Head of Global Regulatory Affairs
Richard Kabanda	Ministry of Health (MoH), Uganda	Acting Commissioner Health Services - Health Promotion, Education and Communication
Hannah Kibuuka	Makerere University Walter Reed Project (MUWRP)	Executive Director
Stacey Knobler	Sabin Vaccine Institute	Vice President, Vaccine Innovation & Global Immunization
Daniel Kyabayinze	Ministry of Health (MoH), Uganda	Director of Health Services, Public Health

Brett Leav	Moderna	Executive Director of Clinical Development for Public Health Vaccines
Hilary Marston	Food and Drug Administration, USA	Chief Medical Officer
Lucy Mecca	Ministry of Health (MoH), Kenya	Head, National Vaccines and Immunization Program
César Muñoz Fontela	Bernhard Nocht Institute for Tropical Medicine (BNITM); World Health Organization (WHO)	Head of Research Group; Chairman, WHO COVID-19 Animal Models Ad-Hoc Expert Group, WHO R&D Blueprint Team
Betty Mwesugwa	Makerere Unviersity Walter Reed Project (MUWRP)	Deputy Executive Director
Sara Oliver	Centers for Disease Control (CDC), USA	Lead for the COVID-19 vaccines ACIP Work Group and Medical Officer in the National Center for Immunizations and Respiratory Diseases (NCIRD)
Helen Rees	Wits RHI, University of Witwatersrand Johannesburg, South Africa	Executive Director Wits RHI; Chair, World Health Organisation, AFRO Region Immunization Technical Advisory Group; Co-Director of the Wits African Leadership in Vaccinology Expertise Flagship programme, University of Witwatersrand; Board Chair, South African Health Products Regulatory Authority
Ramon Roozendaal	Janssen Vaccines and Prevention B.V.	Scientific Director
Carol Sabourin	Biomedical Advanced Research and Development Authority (BARDA)/Tunnell Government Services	Senior Biological Nonclinical SME
Tiziana Scarnà	Gavi, the Vaccine Alliance	Senior Manager
Mario Skiadopoulos	Biomedical Advanced Research and Development Authority (BARDA)/Tunnell Government Services	Preclinical Drug Development SME
Nancy J. Sullivan	Boston University (BU), National Emerging Infectious Diseases Laboratories (NEIDL)	Director, Boston University's National Emerging Infectious Diseases Laboratories (NEIDL)
Kimberly Taylor	Vaccines, Office of Biodefense, Research Resources and Translational Research, Division of Microbiology and Infectious Diseases National Institutes of Allergy and Infectious Diseases (NIAID/DMID/OBRRTR)	Senior Scientific Officer, Concept Acceleration Program
Allan Tindikahwa	Pharmaceutical Product Development (PPD)	Principal Regulatory Specialist
Ekaterina Vert-Wong	Sabin Vaccine Institute	Vice President, Portfolio & Alliance Management, Research and Development

Organizing Committee Members

Ricardo Carrion Jr, Texas Biomedical Research Institute (TXBIO)

William Dowling, Coalition for Epidemic Preparedness Innovations (CEPI)

Courtney Finch, Sabin Vaccine Institute

Adam Hacker, Coalition for Epidemic Preparedness Innovations (CEPI)

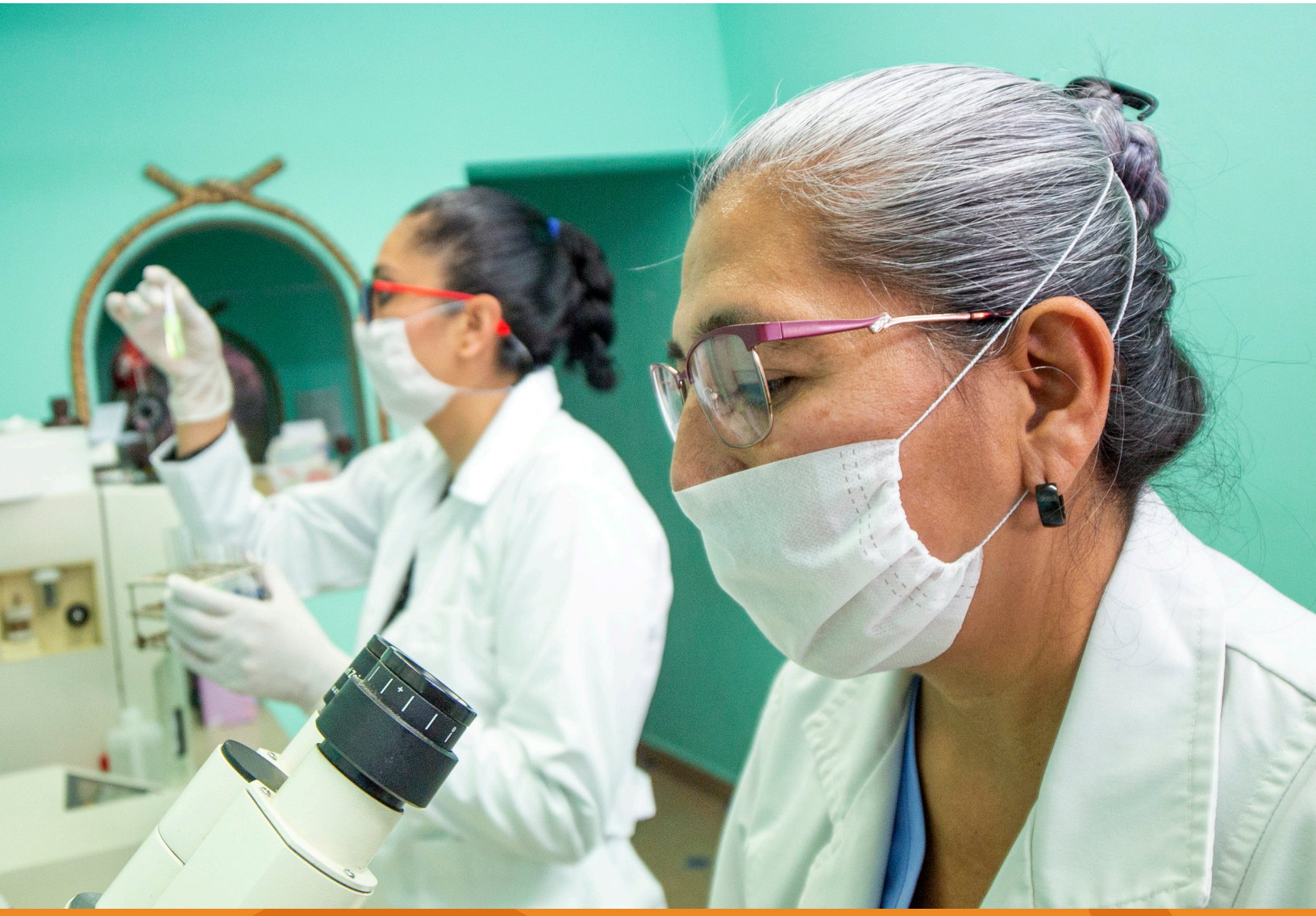
Jocelyn Jakubik, Sabin Vaccine Institute

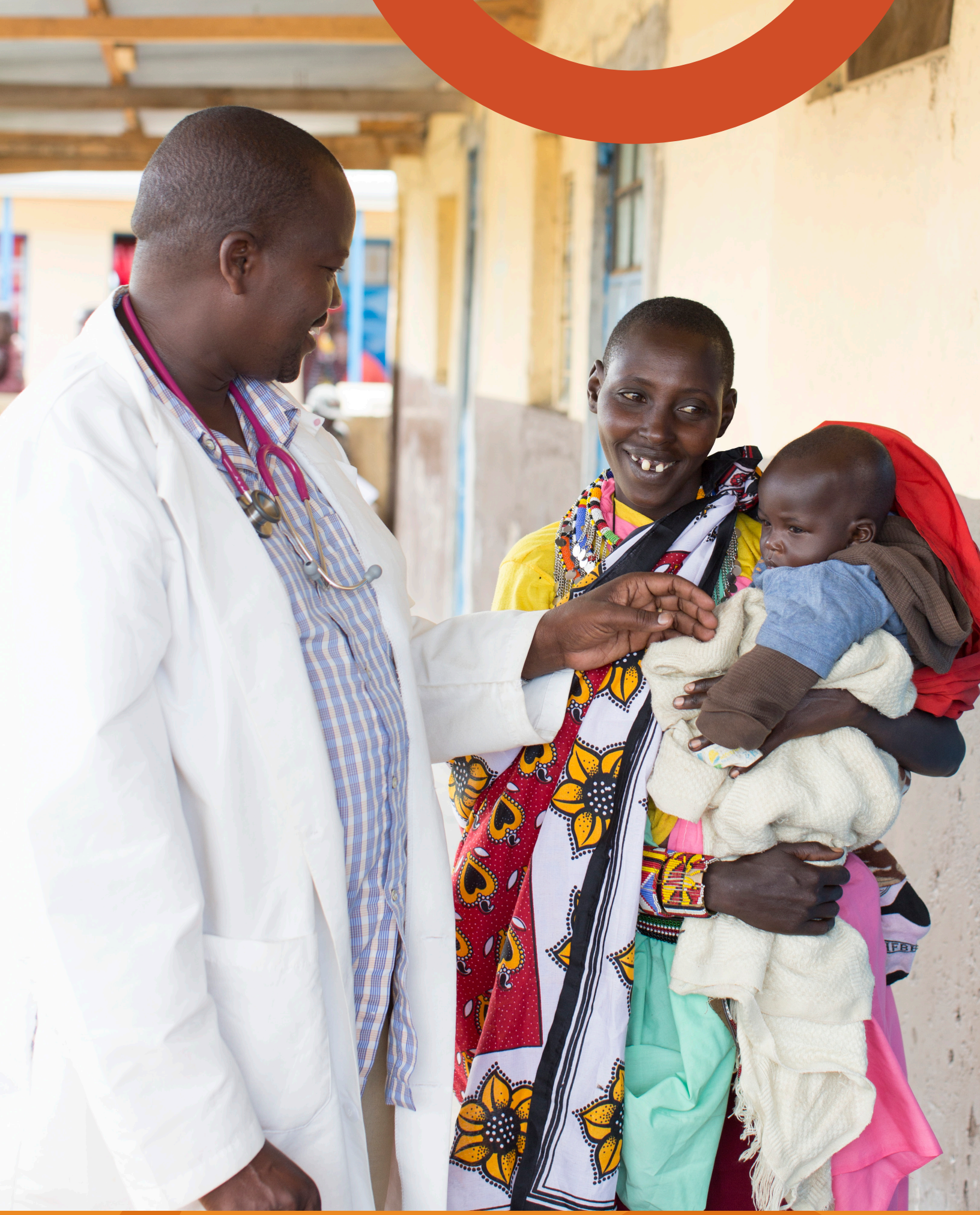
Thomas King, Sabin Vaccine Institute

Betty Mwesigwa, Makerere Unviersity Walter Reed Project (MUWRP)

Helen Ndagije, National Drug Authority, Uganda

Ekaterina Vert-Wong, Sabin Vaccine Institute





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