Join us for a special HIV Vaccine Awareness Day webinar.

Just What is Discovery Medicine?

And What Does it Mean for HIV Vaccine Research?

THE CHOICE AGENDA

HIV prevention research - a new forum for advocacy on the latest

Date: **May 16, 2024**

Time: **9AM – 10:30AM ET**

Welcome – thank you for joining us today.

AVAC

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THE CHOICE AGENDA

HIV prevention research – a new forum for advocacy on the latest

avac.org/project/choice-agenda

Today’s playlist

Teka
Malumz on Decks

Water
Tyla and Travis Scott

BLACKBIRD
Beyoncé, Tanner Adell, Brittney Spencer

DÁKITI
Bad Bunny and Jhayco

Sability
Ayra Starr

DJ JIMBERLY


Over 2300 individuals from 40+ countries are subscribed to The Choice Agenda global discussion list.
Subscribe

Speakers

Dr. Sandhya Vasan, Henry M. Jackson Foundation for the Advancement of Military Medicine, U.S. Military HIV Research Program

Dr. Cathy Slack, HIV AIDS Vaccines Ethics Group

Dr. Betty Mwesigwa, Makerere University Walter Reed Project

Tian Johnson, BRILLIANT HIV Vaccine Discovery Consortium

Moderators

Stacey Hannah, AVAC

Louis Shackelford, HIV Vaccine Trials Network (HVTN) & COVID-19 Prevention Network (CoVPN)

Experimental Medicine in the context of HIV Vaccine Development

Sandhya Vasan, MD

Vice President, HJF Global Infectious Diseases

Director, HJF Component of the US Military HIV Research Program

16 May 2024

WRAIR
Walter Reed Army Institute of Research
MILITARY HIV RESEARCH PROGRAM

Outline of Talk

1. Background on Clinical Trial Development
2. What is Experimental Medicine
3. Examples of Experimental Medicine Development Trials

How are vaccines developed?

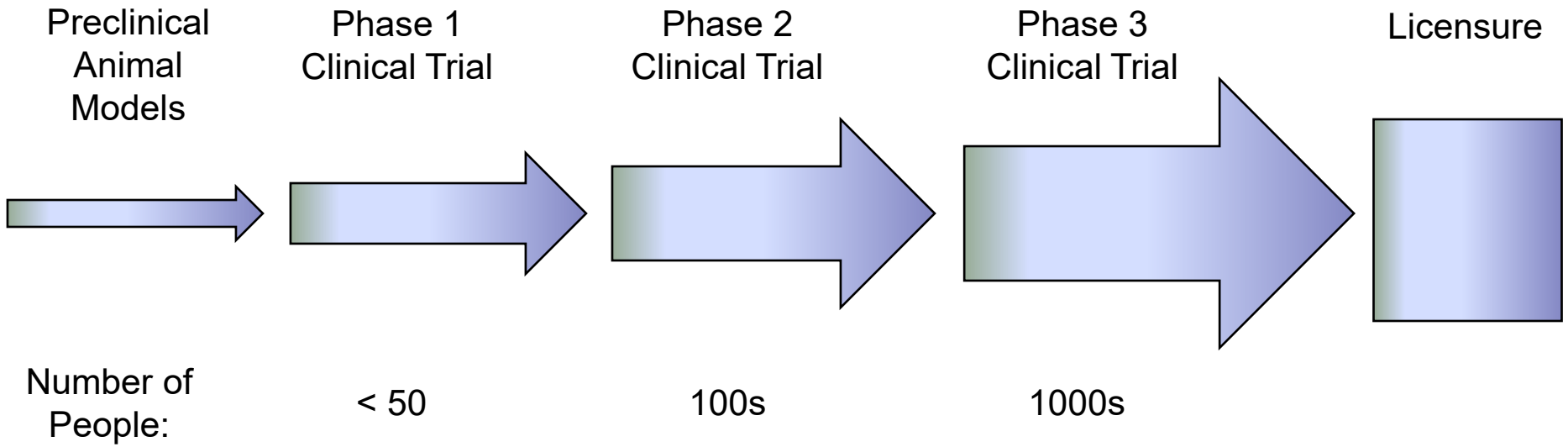
Screening and testing in the lab

Testing in animals

Testing in clinical trials

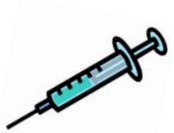
FDA approval for use in people

Vaccine Clinical Trials

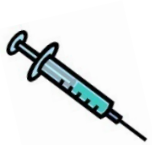


How do we test whether a vaccine works?

Healthy people who have some risk of getting HIV infection



Vaccine



Placebo

Random assignment

Counsel **ALL** participants to avoid HIV infection

Follow both groups to count HIV infection rate

HIV Vaccine and Antibody Efficacy Trials to Date

AVAC Advocacy. Access. Equity.

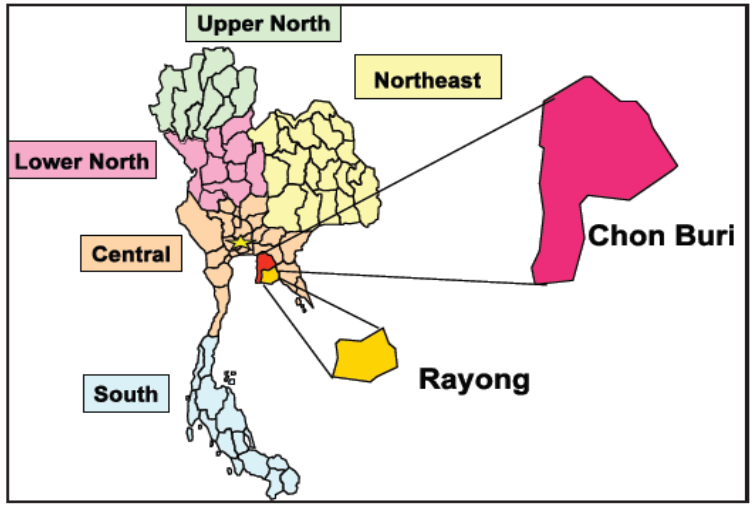
April 2024

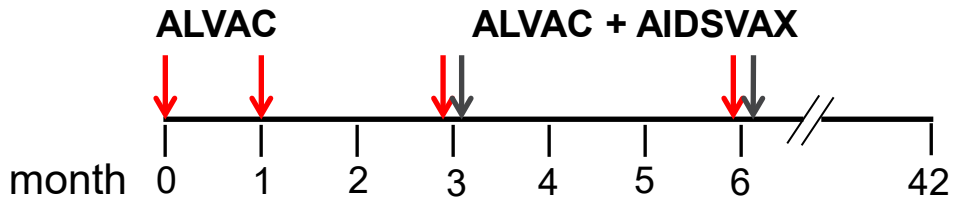
Over 20 years and 12 trials, only two positive signals have been observed.

Year End	2003	2003	2007	2007	**2009**	2013	2020	2021	**2021**	2023	2024
Trial, Product/ Clade	**VAX004**, AIDSVAX B/B	**VAX003**, AIDSVAX, B/E	**STEP**, MRK-Ad5, B	**Phambili**, MRK-Ad5, B	**Thai Prime-Boost/RV 144**, ALVAC-AIDSVAX, B/E	**HVTN 505**, DNA+Ad5, A/B/C	**Uhambo/ HVTN 702**, ALVAC/gp120 MF59 boost	**Imbokodo/ HVTN705**, Ad26 Mosaic/gp140 clade C boost	**AMP Studies**, VRC01 monoclonal antibody	**Mosaico/ HVTN706**, Ad26 Mosaic/gp140 mosaic boost	**PrEPVacc**, DNA-HIV-PT123 (clade C) with AIDSVAX, B/E or with MVA A/E, CN54gp140
Location	Canada, Netherlands, Puerto Rico, US	Thailand	Australia, Brazil, Canada, Dominican Republic, Haiti, Jamaica, Peru, Puerto Rico, US	South Africa	Thailand	US	South Africa	Malawi, Mozambique, South Africa, Zambia, Zimbabwe	Botswana, Brazil, Kenya, Malawi, Mozambique, Peru, South Africa, Switzerland, Tanzania, US, Zimbabwe	Argentina, Brazil, Italy, Mexico, Peru, Poland, Puerto Rico, Spain, United States	South Africa, Tanzania, Uganda
Number of Trial Participants	**5,417**	**2,546**	**3,000**	**801**	**16,402**	**2,500**	**5,400**	**2,600**	**1,924** **2,699**	**3,900**	**1,512**
Result		No effect	Stopped early for futility; potential increased HIV risk among Ad5-seropositive, uncircumcised men	Immunizations halted based on STEP result	**Modest effect (31.2%)**	Stopped early for futility; vaccine regimen did not prevenat HIV infection nor reduce viral load	Stopped early for futility	No efficacy	Did not reduce risk overall, but VRC01 **did reduce risk of acquisition in small subset of HIV strains** classified as "highly sensitive" to VRC01	No efficacy	Stopped early for futility

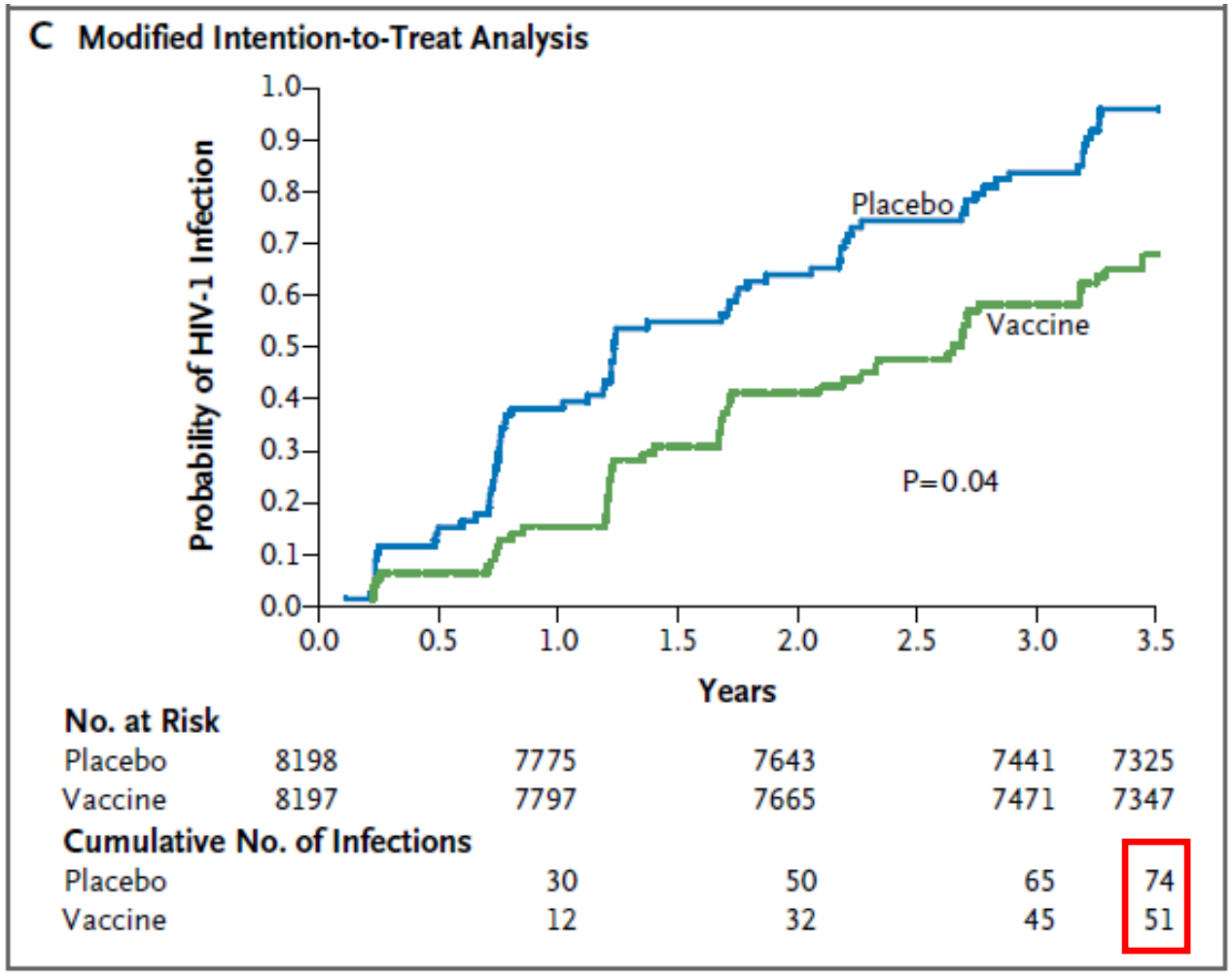
RV144 - Participants

- Men and women ages 18-30
- Heterosexual, at “community risk”
- 8,197 randomized to receive vaccine regimen, 8,198 received placebo





RV144 – Trial Results

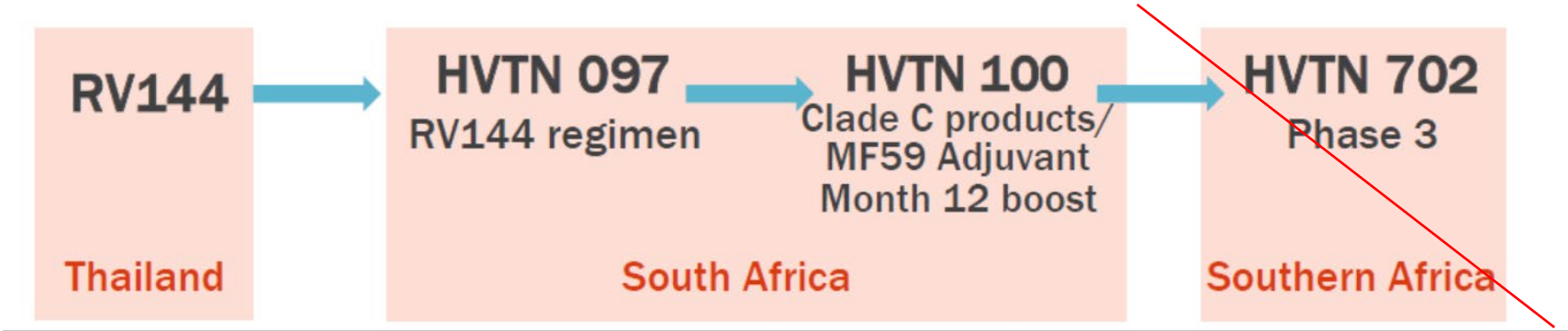


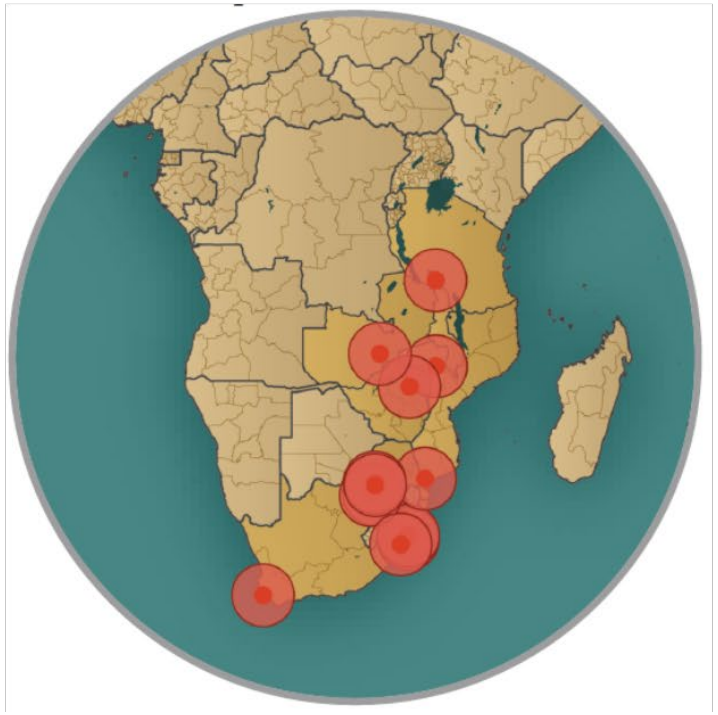
Efficacy: 31.2%

Rerks-Ngarm *et al.* NEJM 2009

Moving to Africa: HVTN702 Efficacy Trial

Feb 2020: No efficacy





Gray et al STM 2019
Bekker et al Lancet 2018
Bekker NEJM 2021

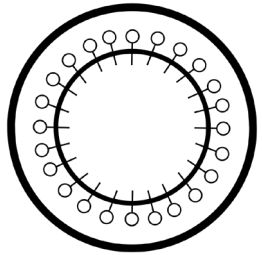
HIV VACCINE TRIALS NETWORK

Bill and Melinda Gates Foundation
DAIDS/NIAID
GSK, Novartis
Sanofi-Pasteur
Republic of South Africa Medical Research Council
US Military HIV Research Program

Developing next-generation HIV vaccine concepts

Immunogen Design

Platform



Adjuvant

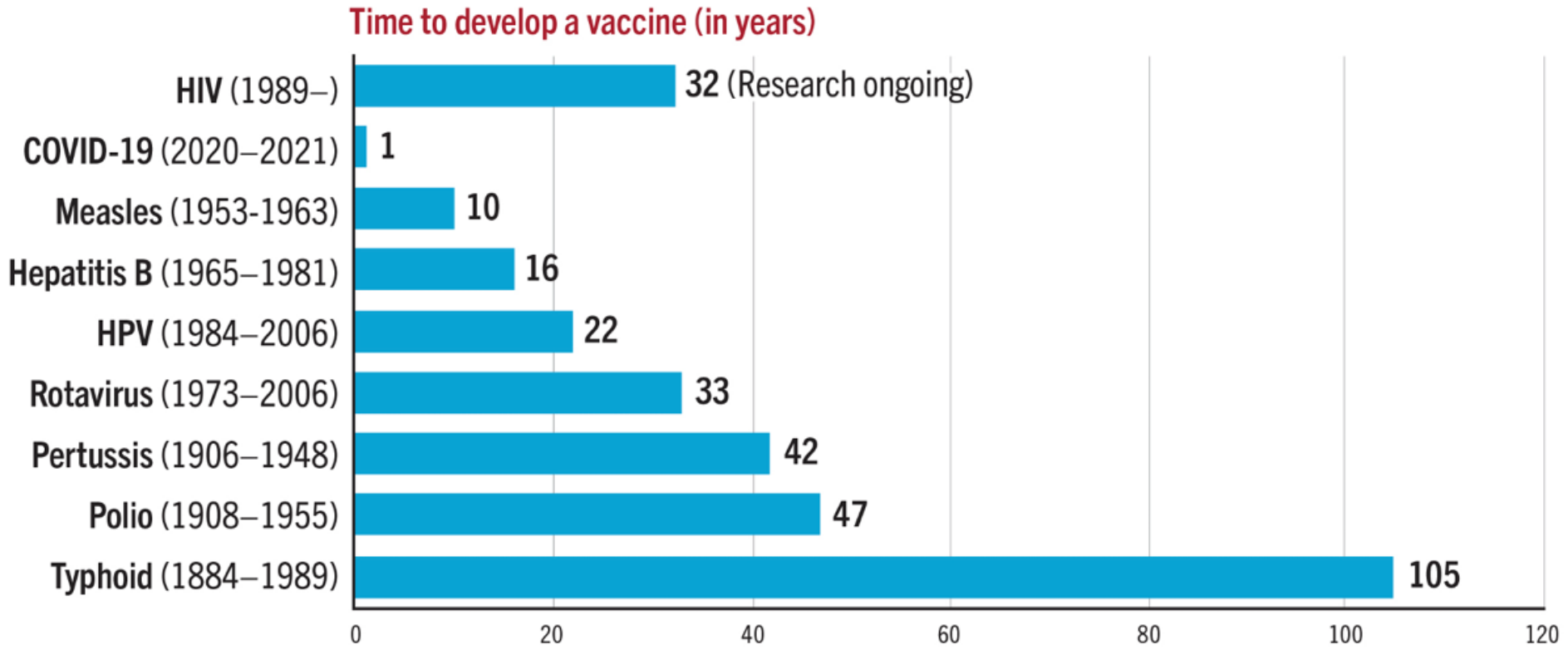
Dosing

Boosting

But how can we make this development go faster?

Vaccine Development in History

Time to Develop a Vaccine: Duration between discovery of microbiologic cause of selected infectious diseases and development of a vaccine



AVAC
25 Years and Counting

Outline of Talk

1. Background on Clinical Trial Development
2. What is Experimental Medicine
3. Examples of Experimental Medicine Development Trials

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https://avac.org/wp-content/uploads/2023/05/EMVTtrials_may2023.pdf

vaccines

MDPI

Conference Report

Experimental Medicine for HIV Vaccine Research and Development

Holly Prudden [1,*,†], Roger Tatoud [2,†], Cathy Slack [3], Robin Shattock [4], Pervin Anklesaria [5], Linda-Gail Bekker [6] and Susan Buchbinder [7,8]

2023

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† These authors contributed equally to this work.

IAS International AIDS Society

HIV VACCINE TRIALS NETWORK

"Clinical investigations of multiple immunogens undertaken to generate or test a scientific **hypothesis** rather than that advances vaccine development and discovery rather than testing a specific **product** being designed to move into later phase trials"

	Traditional Phase I	Experimental Medicine Phase I
Purpose of the trial	Product development	Scientific information
Next step	Hopefully Phase II	Improve vaccine design / Phase I
Number of Volunteers	~20-100	Defined by scientific question
Use of Controls / Placebo	Yes	Potentially No
Duration (months)	~12-18 months	Usually <12 months
Laboratory monitoring of volunteer	Safety / mostly regular immunogenicity	Safety / mostly special assays
Preclinical (animal) evaluation	Extensive (up to protection)	Limited / generic for platform (safety)
Vaccine Manufacturing	Scalable product (reproducibility)	Pilot / small scale lot
Product characterization	Suitable for Ph3 trials; long term stability	Description of product (qualified assays); purity, potency, stability
Regulatory	IND / IMPD	IND / IMPD
Ethics	IRB approval; involves large communities	IRB approval; involves individuals
Industrial partner	Highly desirable	Desirable, but not essential

Experimental Trials

Benefits

- Smaller trials can move more quickly
- Early validation of new concepts
- More reliable than animal models
- Maintain the same standards of ethical review and safety

Considerations

- Requires the same stringency of manufacturing product standards, which is important for safety, but takes time
- Ethical review is not expedited for these trials
- Participants must understand these products may have no direct benefit to themselves
- May involve more extensive visits and sample collection (e.g. tissue biopsies)

Outline of Talk

1. Background on Clinical Trial Development
2. What is Experimental Medicine
3. Examples of Experimental Medicine Development Trials
    - Rapidvax
    - Multiple Founder Virus

RV591 (Rapidvax)

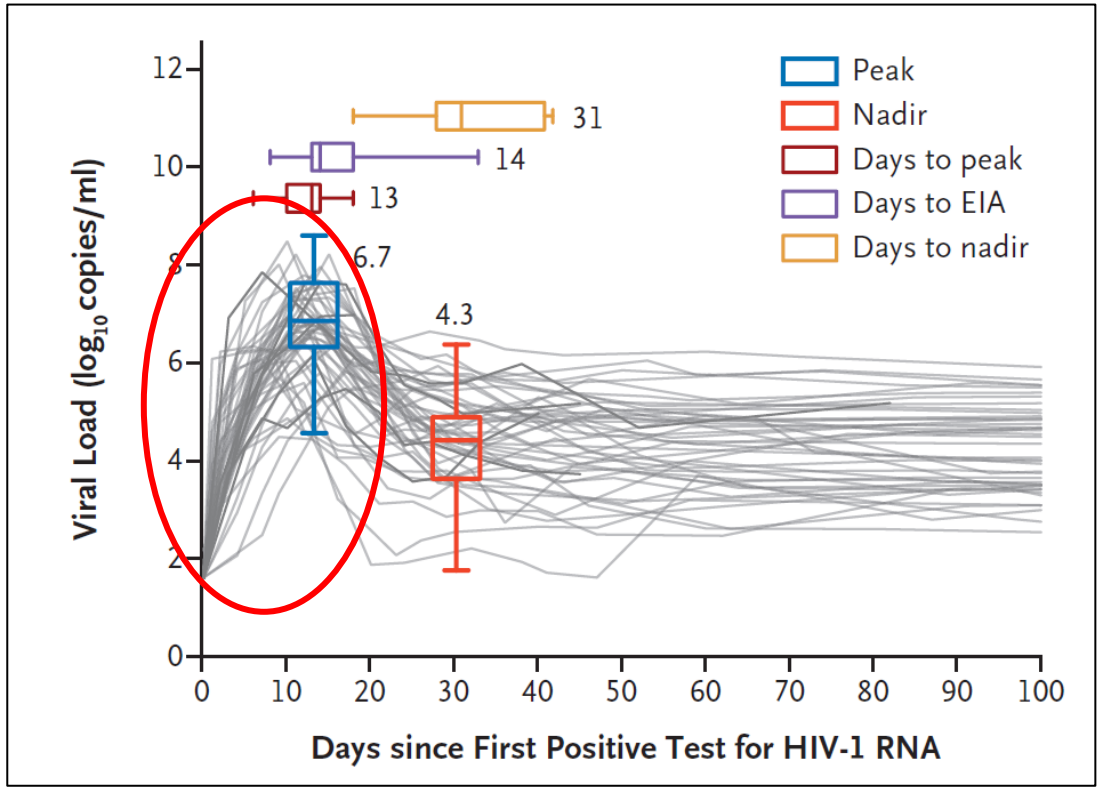
Antigen Delivery Optimization: Learning from Acute Infection

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

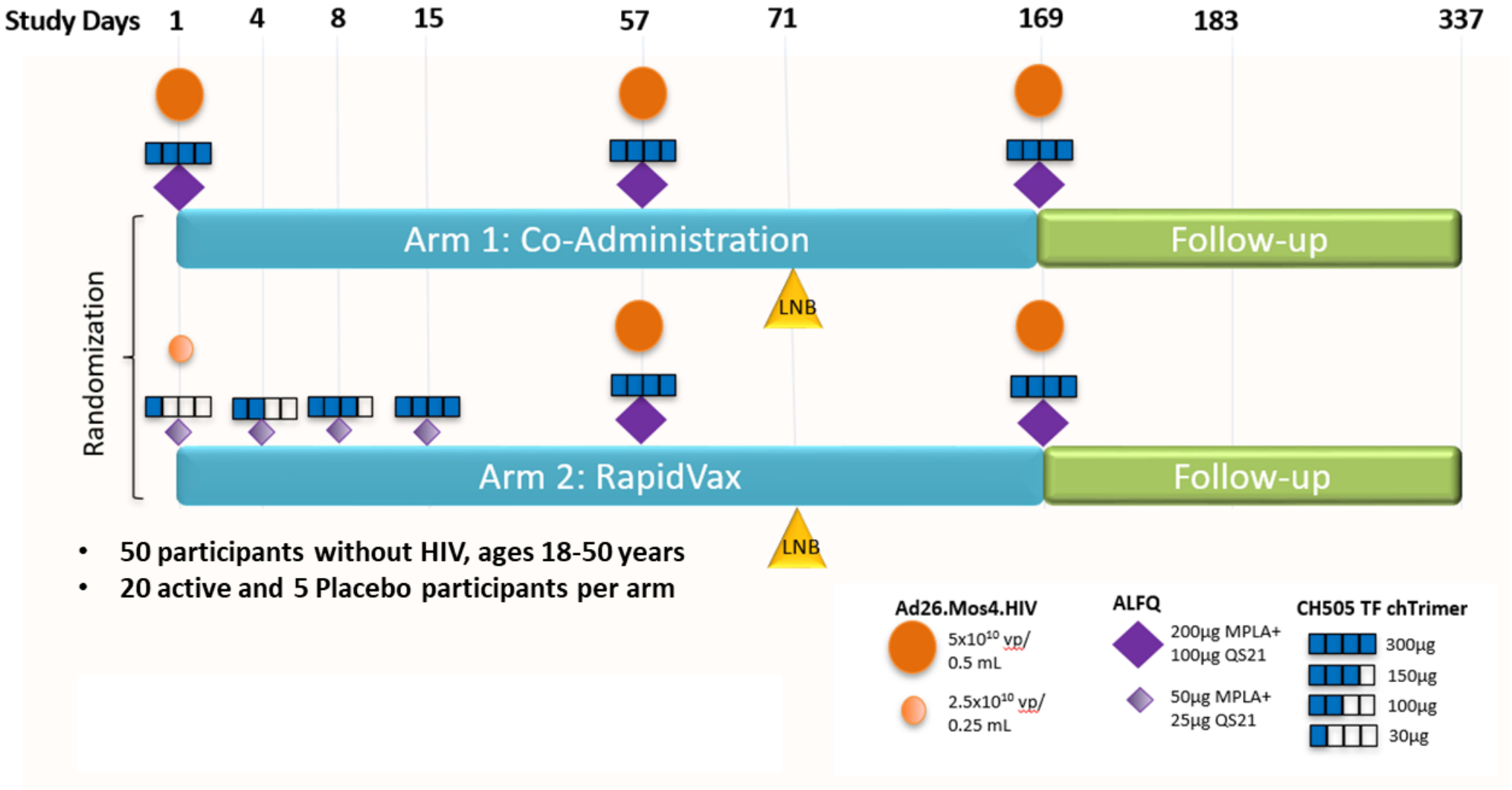
Prospective Study of Acute HIV-1 Infection in Adults in East Africa and Thailand

Merlin L. Robb, M.D., Leigh A. Eller, Ph.D., Hannah Kibuuka, M.B., Ch.B., Kathleen Rono, M.B., Ch.B., Lucas Maganga, M.B., Ch.B., Sorachai Nitayaphan, M.D., Eugene Kroon, M.D., Fred K. Sawe, M.B., Ch.B., Samuel Sinei, M.B., Ch.B., Somchai Sriplienchan, M.D., Linda L. Jagodzinski, Ph.D., Jennifer Malia, Dr.Ph., Mark Manak, Ph.D., Mark S. de Souza, Ph.D., Sodsai Tovanabutra, Ph.D., Eric Sanders-Buell, B.S., Morgane Rolland, Ph.D., Julie Dorsey-Spitz, B.S., Michael A. Eller, Ph.D., Mark Milazzo, B.A., Qun Li, M.Sc., Andrew Lewandowski, Ph.D., Hao Wu, Ph.D., Edith Swann, Ph.D., Robert J. O'Connell, M.D., Sheila Peel, Ph.D., Peter Dawson, Ph.D., Jerome H. Kim, M.D., and Nelson L. Michael, M.D., Ph.D., for the RV 217 Study Team*



Pauthner et al Immunity 2015; Tam et al PNAS 2016; Cirelli et al Cell 2019

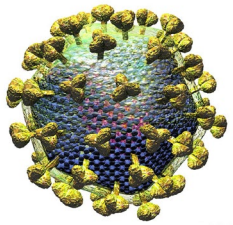
RV591 RapidVax Study Schema

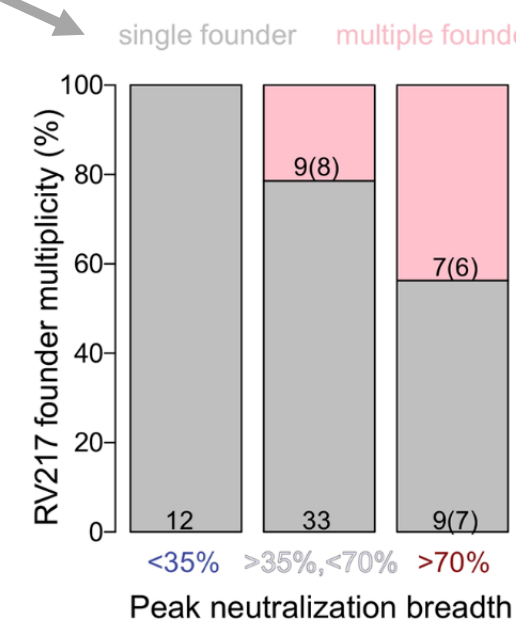


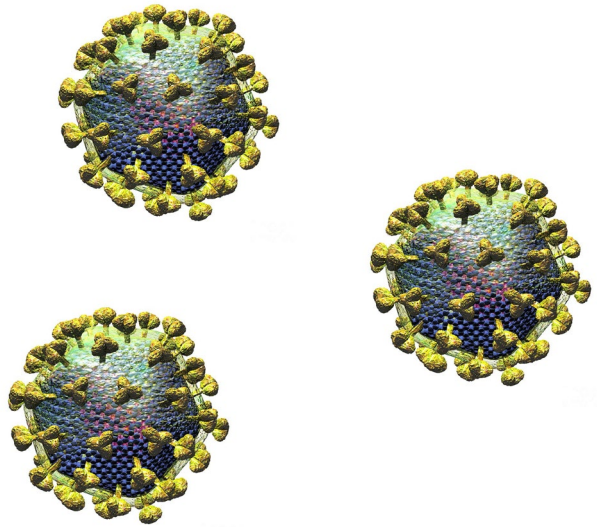
Multiple Founder Viruses

Most people who acquire HIV start with a single strain, or “founder” virus

A few people start with more than one “founder” virus strains



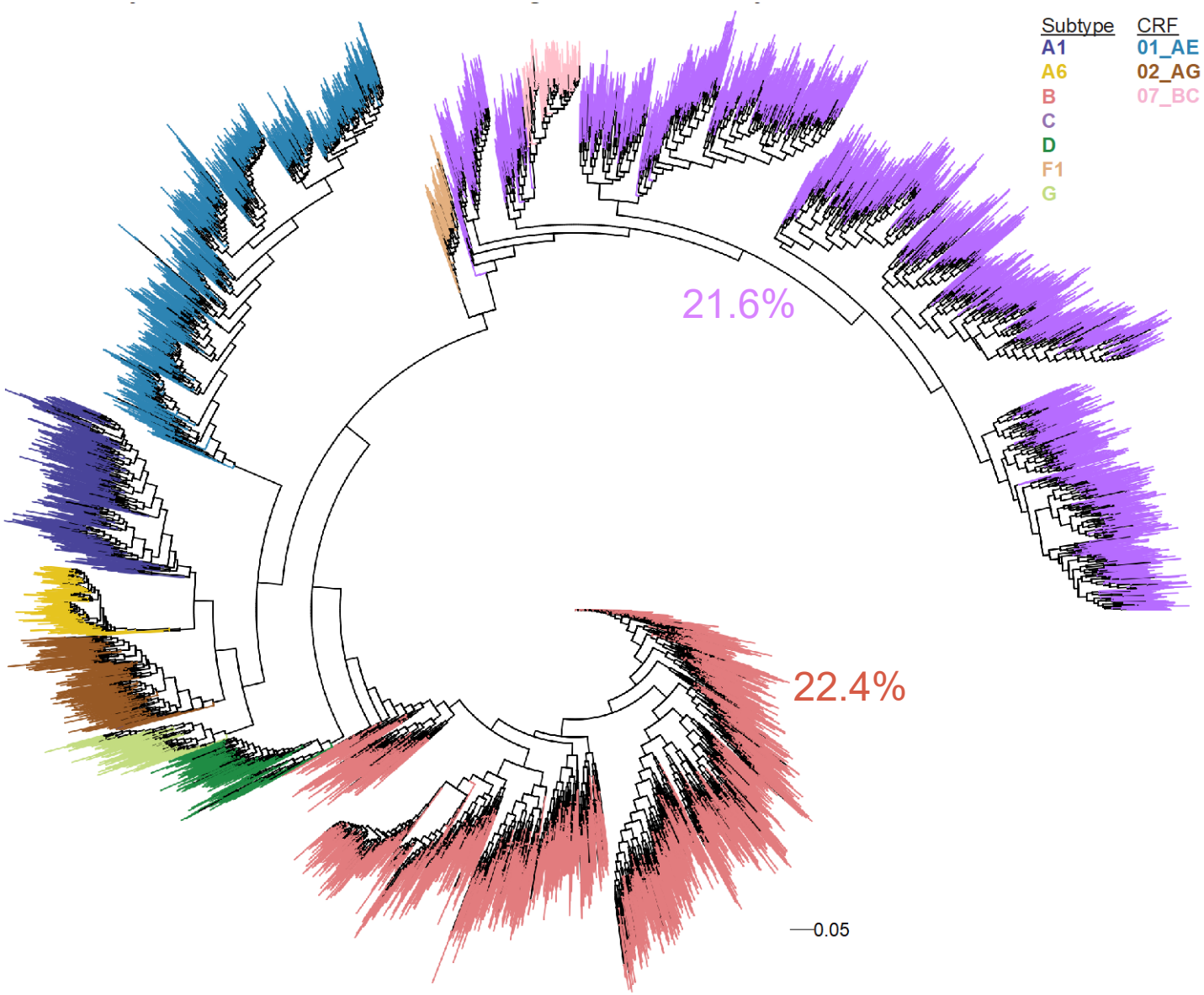




People with multiple founder viruses make broader neutralizing antibodies

Rolland et al., *PLoS Path*, 2020

HIV strains across the globe are HIGHLY diverse



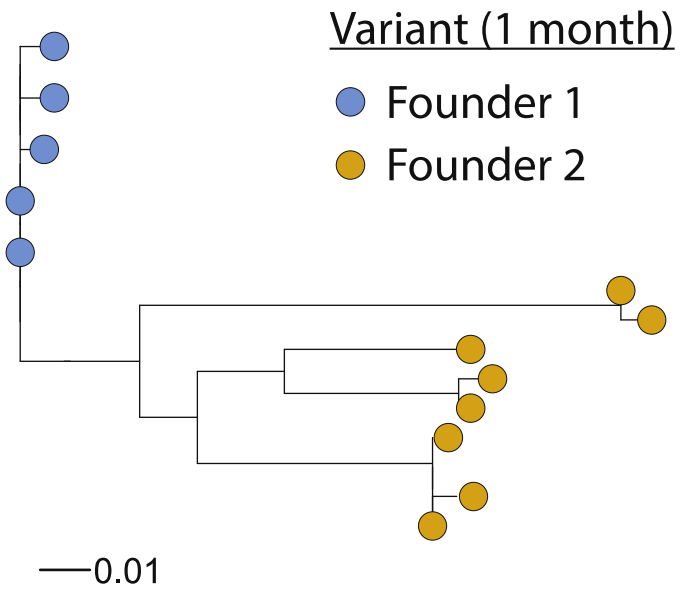
But…

The diversity WITHIN a single person is much smaller

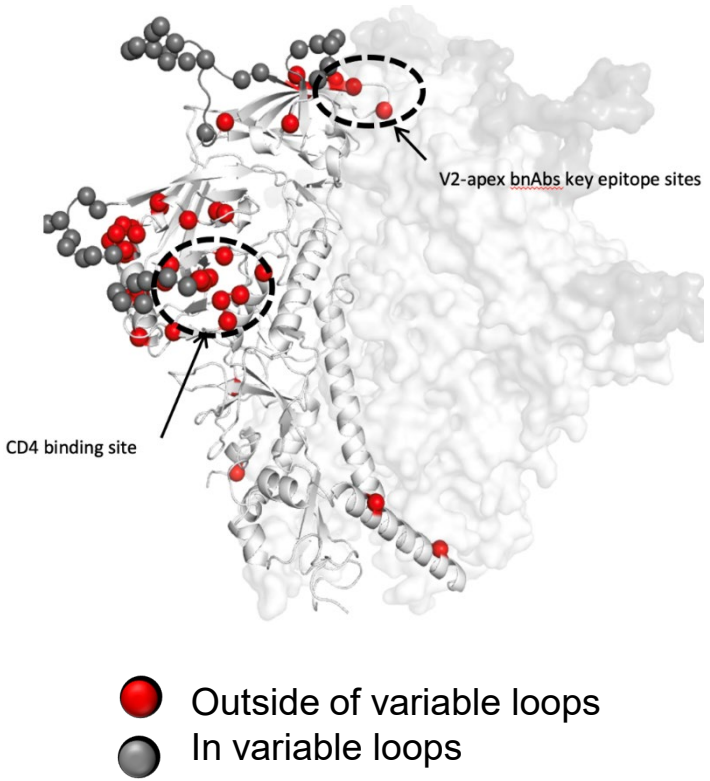
Lewitus, Li, Rolland, *mBio*, 2024

“Multiple Founder Variant” Immunogen Design

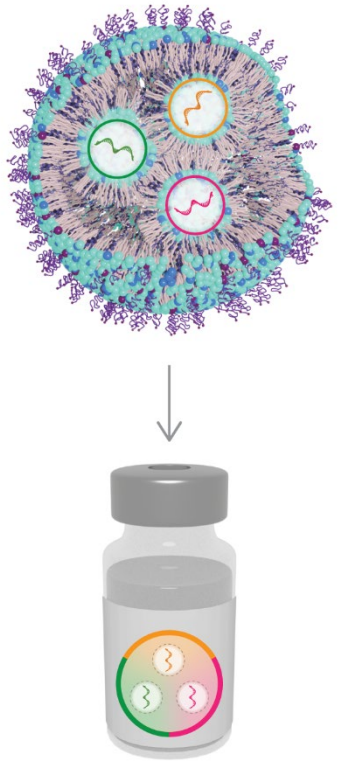
1 Sequences from a participant who acquired multiple “founder” HIV variants at the same time



2 Optimize these sequences to maximize immune responses



3 Combine sequences into a single vaccine



Lewitus et al., *PLoS Path*, 2022

Robust Community Engagement Remains KEY for the Success of Experimental Medicine Trials

MUWRP Site Team

Community Education & Dialogue

Community Advisory Board

Lobbying to streamline and harmonize regulatory procedures (while maintaining participant safety)

Acknowledgements… It takes a global village!

All Study Participants

Community Advisory Boards

WRAIR Military HIV Research Program

WRAIR Armed Forces Research Institute of Medical Sciences

Royal Thai Army, Armed Forces Research Institute of Medical Sciences

Mahidol University

Thai Ministry of Public Health

BIOPHICS

The EMMES Corporation

SCHARP, Fred Hutchinson Cancer Research Center

Henry M. Jackson Foundation (HJF)

WRAIR Africa Clinical Research Centre, Kericho Kenya

Makerere University-Walter Reed Project

Sanofi Pasteur

Global Solutions for Infectious Diseases

Duke University

Janssen Pharmaceuticals

Division of AIDS, National Institute of Allergy and Infectious Diseases, NIH

hjf GLOBAL INFECTIOUS DISEASES

This work was supported by a cooperative agreement (W81XWH-18-2-0040) between the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and the U.S. Department of Defense (DoD).

What does the shift to Discovery Medicine HIV vaccine trials mean for current ethics guidance?

Catherine Slack, Siyabonga Thabethe & Abigail Wilkinson
Coalition to Accelerate and Support Prevention Research
16 May 2024

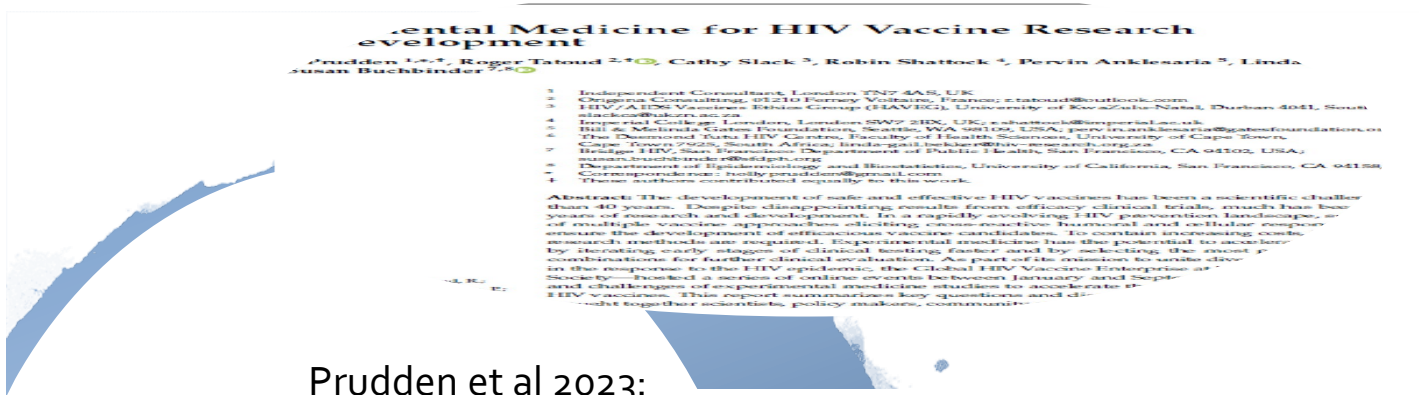
To be ethical a study should:

1. Explore a question of relevance to a health problem (**social value**) using methods that will yield valid, reliable results (**scientific validity**)
2. Select participants fairly -for scientific reasons; to minimize risks to participants; to ensure that risks are spread across populations that stand to benefit (**fair selection**)
3. Ensure that potential risks of study procedures/interventions to participants are sufficiently minimized and sufficiently outweighed by potential benefits to participants OR by societal knowledge gains (**favorable risk-benefit ratio**)
4. Ensure respect for enrolled participants (prevention, care, payment, access to results) (**ongoing respect**)
5. Ensure that stakeholders are appropriately engaged (**meaningful stakeholder engagement**)
6. Ensure informed, voluntary consent from participants (**informed consent**)
7. Be reviewed by a competent REC (**independent ethics review**)

What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research

Ezekiel J. Emanuel, David Wendler, Jack Killen, and Christine Grady

Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, National Institutes of Health, Bethesda, Maryland


ental Medicine for HIV Vaccine Research
evelopment

Prudden et al 2023:

- CABS, community stakeholders and participants will need to appreciate the central purpose of such trials, requiring tailored explanations
- The risk-benefit ratio of such trials will need careful communication i.e. that the intervention will not have potential individual benefit but may rather have social value in terms of societal knowledge gains
- The purpose of such trials will need to be highlighted in consent forms and discussions to "offset any potential misunderstanding that the study intervention may confer direct health-related benefits to participants or even that the study goal is to move products through a pipeline towards introduction in vulnerable communities" (p. 5)
- Study teams must elicit perspectives and opinions of community stakeholders
- Advocates will need to be engaged to solicit and be responsive to their inputs
- Countries not accustomed to engaging in early phase trials may be involved
- RECs may benefit from cross-REC communication to harmonize any concerns they identify

(1) EMPIRICAL RESEARCH

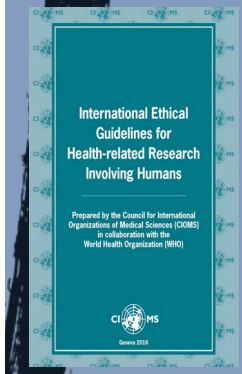
- Planned for submission at SA MRC HREC
  - *Aims*: To explore perceived complexities and opportunities
  - *Methods*: In depth interviews
  - *Outcomes*: Better understanding of degree to which guidelines address perceived complexities

Cathy Slack cathymayslack@gmail.com

(2) REVIEW OF GUIDELINES

E.g. Researchers should:

- Ensure that trial participants are provided opportunities to learn trial results before they are announced publicly (GPP 2011 3.15)
- Inform participants and governments (…) (ideally) of research results before others (UNAIDS 2021 gp 14)
- Disseminate progress updates and results to study participants, national authorities, local communities (as) a priority (..) before or contemporaneously with international dissemination (UNAIDS 2021 gp 14)
- Make every effort, in cooperation with government and other relevant stakeholders, to make available as soon as possible (…) knowledge generated, for the *population or community* in which the research is carried out (CIOMS 2016 gp2)
- Recognize 'there may be legal requirements that affect the timing and methods for public announcement of a trial closure' (GPP 2011 3.5)



(3) RESOURCE DEVELOPMENT

For advocates

1. *To raise awareness with community stakeholders (educational role)*
2. *To make inputs to documents/processes (advisory role)*
3. *To hold researchers accountable (watchdog role)*

Page **1** of **5**

Using International Ethics Guidelines to Inform Advocacy Efforts: A CASPR Resource on Early Phase Clinical Trials

Part 1: Introduction

HIV vaccine candidates tested in the Uhambo, Imbokodo/Mosaico and PrEPVacc clinical trials did not show any efficacy signal. As a result, the HIV vaccine field has gone back to the drawing board, with researchers testing out alternative approaches, many aimed at inducing anti-HIV broadly neutralizing antibodies (bnAbs). These approaches include the HVTN Discovery Medicine studies (i.e. 031,302) and the IAVI Goo suite of studies, which are testing germline-targeting antigens.

Similarly, research on *passive immunization* with bnAbs (where pre-existing bnAbs are injected or infused) is now planning or evaluating combination bNAbs in studies among adults and infants, building on results from the AMP studies to test "combo bnAbs".

In addition, *ARV-based prevention* has been rejuvenated by the MATRIX project's suite of products that includes vaginal inserts, films, rings, and subcutaneous implants, all undergoing clinical research in the US and East and Southern Africa. These MATRIX studies will evaluate safety, tolerability, and acceptability of the various products.

The above research areas will all include, if not rely on, 'early phase' clinical trials.

Most early phase clinical trials are *Phase 1 trials* which aim to explore the safety of individual products, enroll small numbers of participants with a low likelihood of acquiring HIV, take place over a moderate timeframe, involve intensive laboratory monitoring, and the tested products have typically undergone animal evaluation (Prudden et al., 2023).

Some phase 1 trials are "*first in human*" trials, designed using preclinical animal and laboratory results.

Some phase 1 trials reflect a "*Discovery Medicine*" or "*Experimental Medicine*" approach where the aim is to generate scientific insights rather than aiming to test a specific product on a path toward licensure, which is the more traditional approach in phase 1 (Prudden et al., 2023). The DM approach is being used in the HIV vaccine field currently.

Some early phase trials might be *Phase 0* trials. They share common features with Phase 1 studies (with some exceptions). These aim to explore the pharmacokinetic–pharmacodynamic relationships of new drugs in humans (Kummar et al., 2008). New drugs are given in very small 'microdoses' (Kimmelman, 2007) to a handful of participants. It is not clear yet which products in the prevention field might adopt phase 0 trials.

Advocates in the CASPR coalition and beyond are well-placed to shape the conduct of early phase clinical trials in Africa.

Aims and audience

- This resource aims to highlight international ethics recommendations and support advocates to ground their practices in international ethics guidance around early phase trials, where this would be helpful.
- Other stakeholders, e.g. researchers, Research Ethics Committees, and Community Advisory Board members, may also find the resource useful.

Cathy Slack cathymayslack@gmail.com

Thank You!!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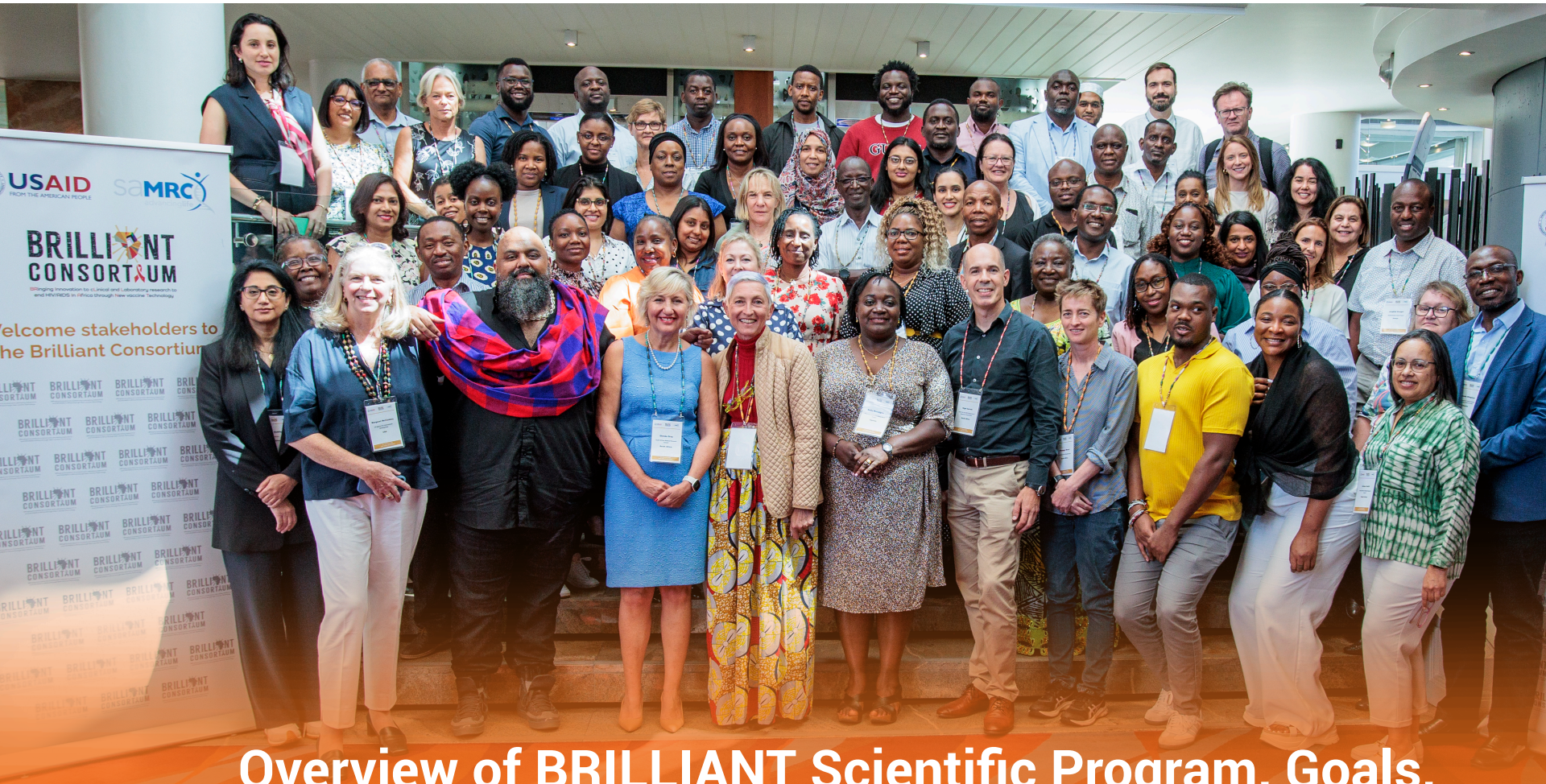


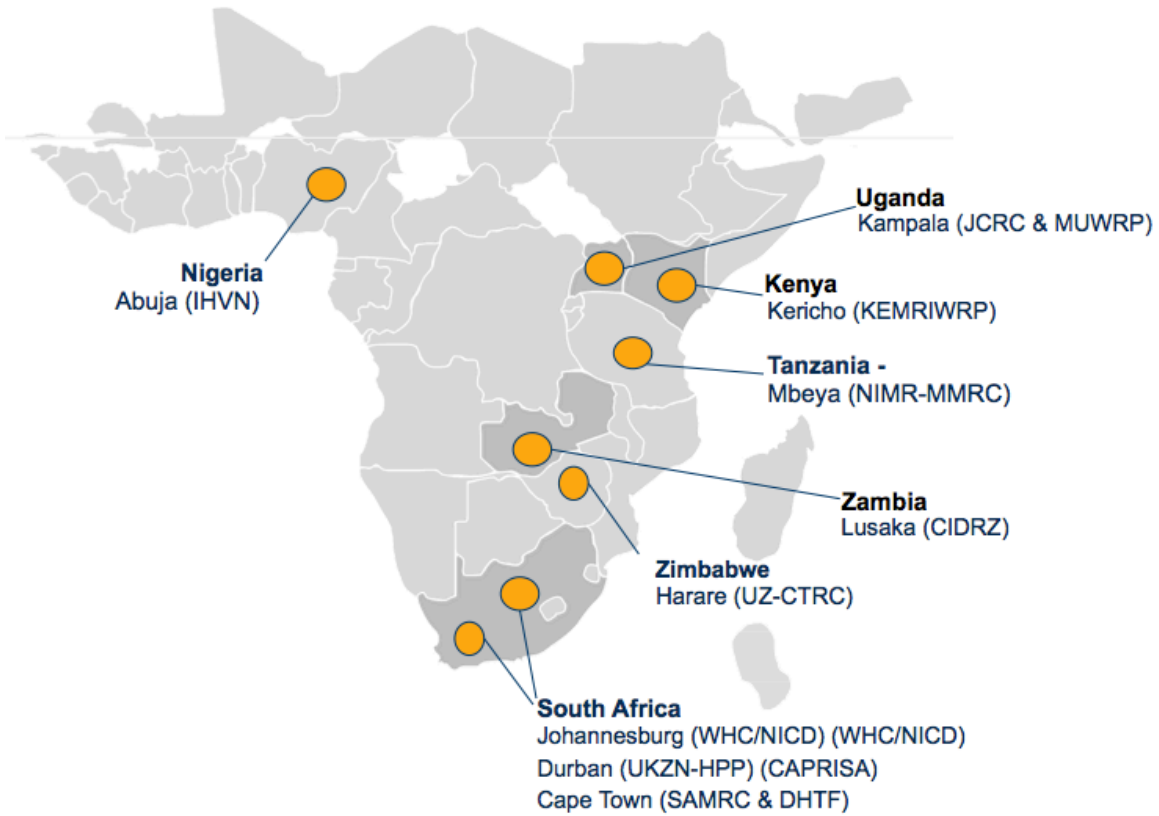
Overview of BRILLIANT Scientific Program, Goals, Linking to Discovery Medicine Concepts - 16 May 2024

DR. BETTY MWESIGWA
MUWRP Deputy Executive Director | BRILLIANT Co-PI

MISSION

To harness and catalyze African scientists to contribute to an African-led effective HIV vaccine

BRILLIANT CONSORTIUM



- Led predominantly by African women scientists & comprise a multi-disciplinary team
- Overall objective is to evaluate HIV vaccine candidates emanating from our continent.
- ***"First in Africa"*** (FIA) clinical development with existing immunogens, and HIV Vaccine Discovery medicine
- Rapidly evaluate "*African*" immunogens by doing discovery and pre-clinical evaluation utilizing mRNA technology evolving on our continent.

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DEFINITIONS

- **TO DISCOVER:** Find unexpectedly or during a search. Or to bring to light.
- **DISCOVERY MEDICINE** involves identifying and characterizing molecules (particles) with the potential to safely modulate (modify) disease, with a goal to bring products that can improve the lives of patients (vaccines, medicines etc).
- It is a lengthy and resource intensive process, that requires close cooperation across multiple disciplines.

OBJECTIVES

1. **COMMUNITY PROGRAM**: Partner with civil society to advance ***African-led*** HIV vaccine discovery science.
2. **CLINICAL PROGRAM:** Design and implement innovative, early-stage clinical trials using an HIV vaccine discovery approach ***to improve immunogenicity*** and hasten the development of an effective broadly neutralizing antibody (bnAb) inducing HIV vaccine regimen.
3. **LABORATORY PROGRAM**: Undertake comprehensive safety, immunologic and genomic investigations to assess B-cell, T-cell, and additional humoral/cell-mediated immune responses to HIV immunogens, as well as the effect of virus and host genetics to inform HIV vaccine design.
4. **DISCOVERY/PRECLINICAL PROGRAM:** Develop innovative ***preclinical*** HIV vaccine concepts.
5. **COLLABORATION AND CAPACITY AUGMENTATION:** Fully utilize and strengthen systems of collaborations for HIV vaccine research in Sub-Saharan Africa (SSA) and increase opportunities to advance the careers of promising SSA scientists.

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SCIENTIFIC STRATEGY

Overall Immunogen Design and Vaccine Development Strategy is a two-stage approach:

1. Using immunogens previously tested in humans, but “First in Africa” (FIA) to ***advance the science fast***, while testing out and strengthening our research infrastructure.

   Vaccine responses may differ across populations with lower responses seen in LMICs so may not base immunogenicity on studies just done in HICs

2. Integrating our own African immunogens into the clinical development pipeline, after preclinical evaluation utilizing a ***validated mRNA vaccine platform to advance immunogens into the clinic***

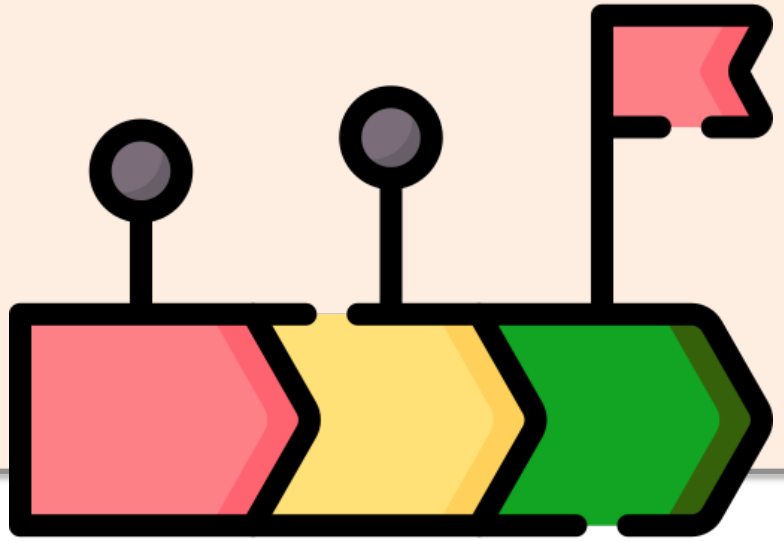
BRILLIANT – 001: YEAR 1/2

A phase 1 HIV vaccine discovery trial to evaluate the safety and immunogenicity of 426c.Mod.Core-C4b and BG505 GT1.1 immunogens in prime-boost combinations with 3M-052-AF/ Alum adjuvant in HIV negative adults

Group	No.	Prime 1 (day 0)	Prime 2 (08 weeks)	Boost 1 (24 weeks)	Boost 2 (40 weeks)
1	8/2 Active/ placebo	426c Core NP + 3M-052-AF/ Alum	426c Core NP + 3M-052-AF/ Alum	BG505 GT1.1+ 3M-052-AF/ Alum	BG505 GT1.1+ 3M-052-AF/ Alum
2	8/2	426c Core NP + 3M-052-AF/ Alum	426c Core NP + 3M-052-AF/ Alum	BG505 GT1.1+ 426c Core NP + 3M-052-AF/ Alum	BG505 GT1.1+ 426c Core NP + 3M-052-AF/ Alum
3	8/2	BG505 GT1.1+ 426c Core NP + 3M-052-AF/ Alum	BG505 GT1.1 + 426c Core NP + 3M-052-A/ Alum	BG505 GT1.1+ 426c Core NP + 3M-052-AF/ Alum	BG505 GT1.1+ 426c Core NP + 3M-052-AF/ Alum
Total	**30 (24 vaccine, 6 placebo)**				

IMMUNOGEN DESIGN & PRECLINICAL TESTING

- Develop first generation BRILLIANT immunogens for evaluation
- Increase capacity to develop mRNA vaccine candidates for preclinical & clinical evaluation
- Establish collaboration with MHRP to adapt the multiple founder virus (MFV) concept for African clades
- Establish collaboration with University of Amsterdam to support development of new SOSIP trimers
- Evaluation of env and gag sequences from recent break-through infections to inform vaccine design
- Exploratory program for immunogen and platform optimization



COLLABORATION WITH UNIVERSITY OF AMSTERDAM TO SUPPORT TECHNOLOGY TRANSFER OF SOSIP TRIMER DESIGN

- Lead by Cissy Cityo's team at JCRC
- Screen local samples for bNAb activity, generate envelope sequences as the basis of SOSIP trimers with support from Rogier Sanders and Marit van Gils' teams at UMC Amsterdam
- Will diversify pipeline of characterised envelope trimers to feed into immunogen design

COLLABORATION WITH MHRP TO DEVELOP THE MULTIPLE FOUNDER VIRUS (MFV) CONCEPT

- Lead by Betty Mwesigwa's team at MUWRP
- Leveraging long-standing collaboration with MHRP and several years of work from Morgane Rolland and colleagues which suggest that MFV may be associated with increased breadth
- Currently focussed on subtype B, with willingness to collaborate on under-represented African clades

PLOS PATHOGENS

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

HIV-1 infections with multiple founders associate with the development of neutralization breadth

Eric Lewitus, Samantha M. Townsley, Yifan Li, Gina C. Donofrio, Bethany L. Dearlove, Hongjun Bai, Eric Sanders-Buell, Anne Marie O'Sullivan, Meera Bose, Hannah Kibuuka, Lucas Maganga, Sorachai Nitayaphan, Fredrick K. Sawe, Leigh Anne Eller, Nelson L. Michael, Victoria R. Polonis, Julie A. Ake, Sandhya Vasan, Merlin L. Robb, Sodsai Tovanabutra, Shelly J. Krebs, Morgane Rolland [view less]

Version 2 Published: March 18, 2022 • https://doi.org/10.1371/journal.ppat.1010369

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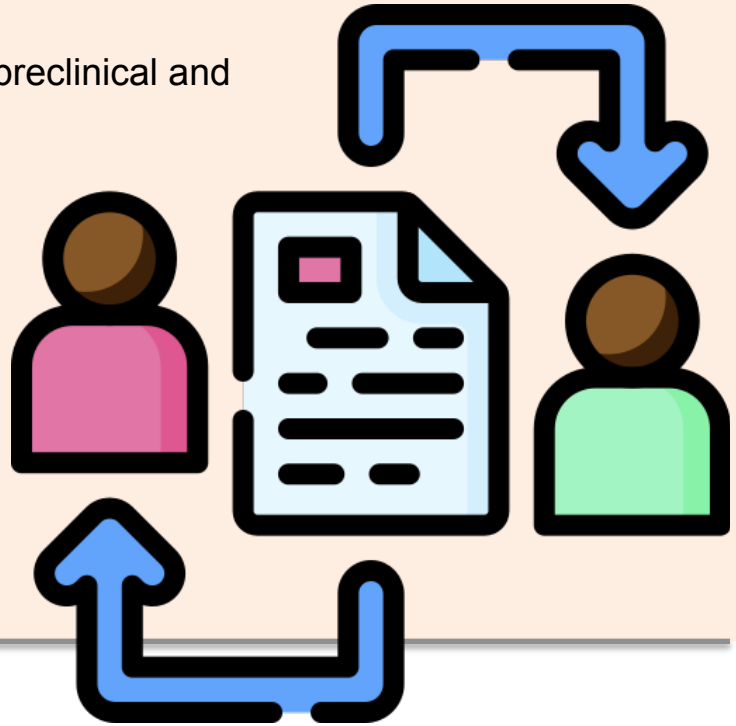
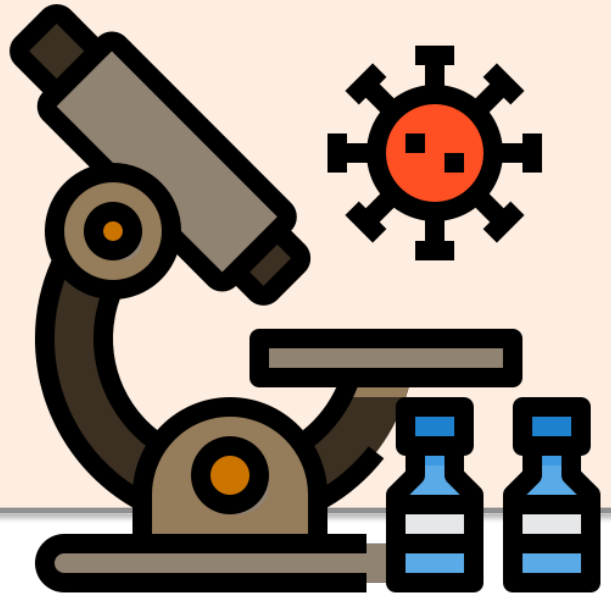
EXPLORATORY PROGRAM
(WHICH INCLUDES CAPACITY AUGMENTATION)

- Don’t want all our “eggs in the mRNA basket”
- Envelope protein boost candidates (stable, purified Env trimers and/or purified nanoparticles, e.g. using spycatcher technology)
- Develop self-amplifying RNA constructs
- Use of novel adjuvants from MHRP (ALF) and Afrigen, with protein vaccines
- Exploring novel vaccine delivery platforms
- Implementation of standardised assays across labs for preclinical and clinical programs



TECH TRANSFER AND IMPLEMENTATION OF ASSAYS

- Early transfer of B cell assays:
  - ✓ ELISA and pseudovirus neutralisation assays: preclinical and clinical
  - ✓ NICD/Moore lab to specific Consortium labs, including concordance study
- T cell preclinical assays – need to conduct concordance between preclinical labs so that vaccine candidates can be compared
- Establish B cell analytics, or work with others who have this pipeline
- Setting up regional capability for discovery medicine trials



AVAC/Choice Agenda Webinar - 16 May 2024

BRILLIANT Project – An Example of a Discovery Medicine-Focused HIV Vaccine Initiative with Community Engagement as a Cornerstone

Tian Johnson
Co-Principal Investigator (CEA) | African Alliance

KEY OBJECTIVES OF THE COMMUNITY ENGAGEMENT & ADVOCACY WORKSTREAM YEAR 1

1. Community Governance
2. Co-create an Advocacy Agenda
3. Communications for Discovery
4. Community Leadership of MEL

1.1 GOOD GOVERNANCE

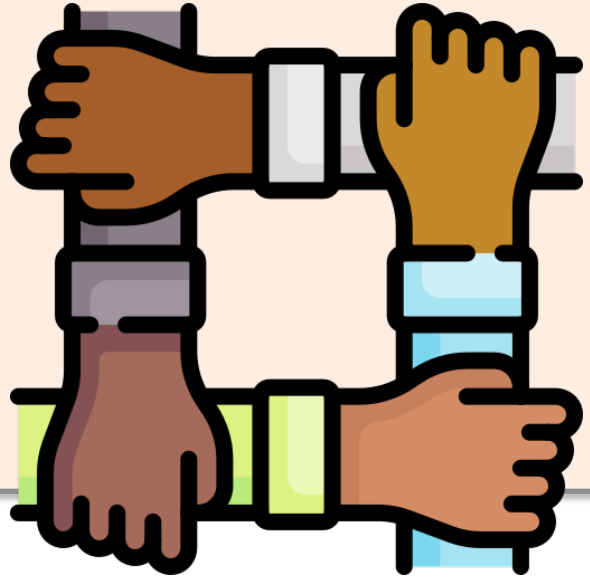
- Ensuring that effective good governance is implemented by:
  a. Monthly CEA Steering Committee Meetings;
  b. EXECO Meetings

1.2 ROLL OUT OF COMMUNITY ENGAGEMENT ACTIVITIES

a) Recruitment of CEA implementing partners across consortium countries (who meet pre-determined criteria detailed in a call for expression of interest).

b) Implementation and Technical Assistance meetings between AA and the national implementing partners.

c) Ensure that activists have the language, the technical understanding, and the historical context of vaccine research and development to enable meaningful engagement.



2.1 DEVELOPING AN ADVOCACY AGENDA FOR BRILLIANT

HOW?

a) Baseline assessments to co-create the tools and approaches.

b) Community engagement protocol

c) HIV vaccine discovery module (incorporating current work and lessons learnt from the HIV Cure agenda and CUREiculum)

d) Storytelling and Media Engagement module (incorporating current work and lessons learnt from PVA Africa subgrantees work)

2.2 CEA IMPLEMENTING PARTNERS ONBOARDING

- BRILLIANT CEA Implementation Partners Gathering

3. PRACTICE AND OVERSEE MEANINGFUL COMMUNITY ENGAGEMENT AND ADVOCACY TO SUPPORT THE OVERALL MISSION OF THE BRILLIANT CONSORTIUM

- Ongoing engagement with regional platforms such as SADC, AU, East African Community, ECOWAS, and the Economic Community of Central African States will be crucial in fostering support for HIV Vaccine Discovery.

4. COMMUNICATIONS FOR MEANINGFUL ENGAGEMENT

a) Newsletter (Shona, Portuguese, Pidgin, Nyanja, Swahili, Luganda);
b) Podcasts;
c) Consortium Op Eds;
d) National Op Eds;
e) Community radio drama;
f) Journal articles, publications, and presentations;
g) `Profile Consortium sites - including CABS.

4. TO UTILIZE EXISTING PARTICIPATORY STRATEGIES THROUGH MONITORING, LEARNING AND ADAPTATION OF APPROACH TO INFORM REFLECTIVE LEARNING

- Reflection meeting - to serve as an opportunity to reflect on progress and strategize for the remainder of the year.
- Annual internal accountability scorecard on measuring voice, visibility, and power within all structures of the consortium.
- Profile community engagement workstream in the BRILLIANT Consortium.


THANK YOU!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BRinging Innovation to cLinical and Laboratory research to
end HIV/AIDS in Africa through New vaccine Technology


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HIV VACCINE
TRIALS NETWORK


Scripps


AAHI


CAPRISA
CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA


NATIONAL INSTITUTE FOR MEDICAL RESEARCH


MUWRP
Makerere University Walter Reed Project


DESMOND TUTU
HEALTH FOUNDATION


University of Cape Town
Universiteit van Kaapstad
iYunivesithi yaseKapa


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KENYA MEDICAL RESEARCH INSTITUTE
KEMRI


AHRI
AFRICA
HEALTH
RESEARCH
INSTITUTE


BARC


African Alliance
Altahaluf al'Afriqiu
التحالف الأفريقي


NATIONAL INSTITUTE FOR
COMMUNICABLE DISEASES
Division of the National Health Laboratory Service


JCRC


Afrigen


International
Vaccine
Institute


UZ-CTRC


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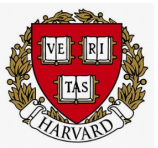
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