



Development of an Ebola Rapid Diagnostic Test

Robert F. Garry, PhD

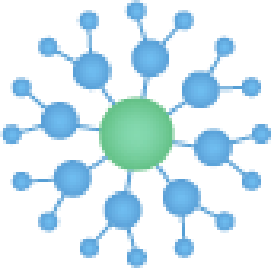
Professor of Microbiology and Immunology

Tulane University School of Medicine

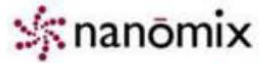
For the

VIRAL HEMORRHAGIC FEVER

CONSORTIUM (vhfc.org)



VIRAL HEMORRHAGIC FEVER CONSORTIUM



VHFC.org

Lassa fever program at Kenema Government Hospital

Important site for Lassa fever research by CDC and others



May Chu, Dan Bausch, others refurbish Lassa Laboratory



Introduction of ReLASV lateral flow immunoassays

1960s
1970s and 1980s

1993

2005

2008

2010

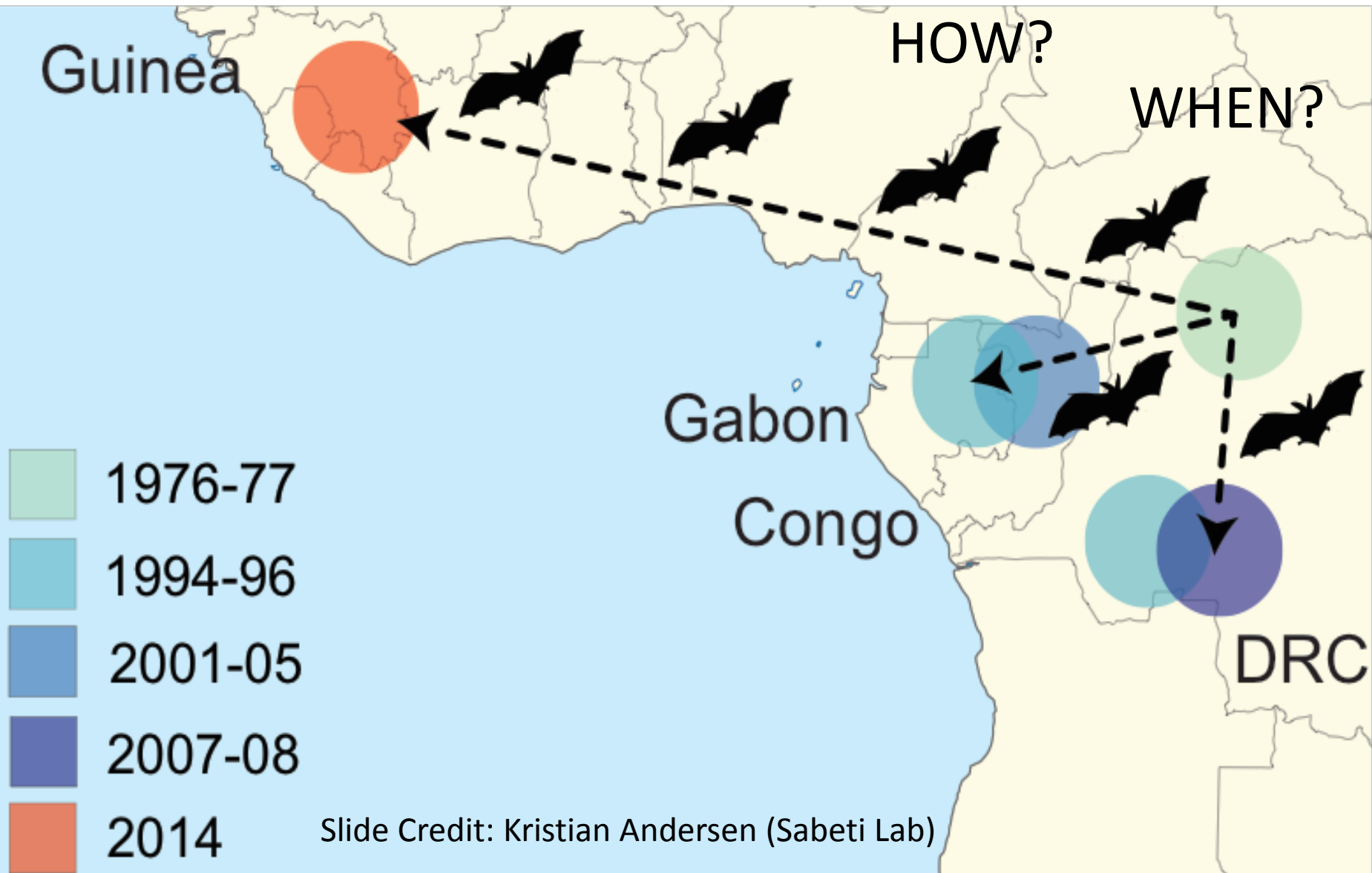
Blood Diamonds civil conflict forces suspension of Lassa program



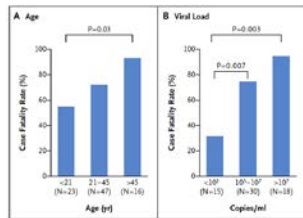
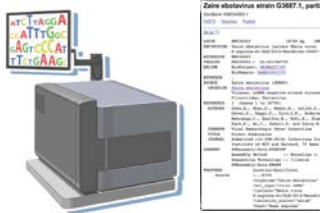
Establishment of recombinant Lassa ELISA diagnostics



Ebola came to us



Leading Insights and Response



- **Established Ebola Diagnostics at Kenema**
 - Performing Surveillance in March and April
 - Immediately identifying first case in hospital
- **Sequenced Ebola Genomes**
 - Rapidly making data public for 99 Ebola genomes
 - Publication in *Science* 2014
- **Provided Clinical Data**
 - Rapidly making data public from 100 patients
 - Publication in *NEJM* 2014
- **Developed Rapid Diagnostic Test**
 - 15-minute Ebola diagnostic test
 - First RDT to obtain WHO and FDA approval

Quantitative reverse transcriptase polymerase Chain reaction versus lateral flow immunoassay

| Assay | qPCR | LFI-RDT |
|-------------------------|---|--|
| Sample collection | Venipuncture, Skilled | Fingerstick, Minimal training |
| Time to result | 1-5 days | 15 minutes |
| Assay performance | Skilled | Minimal training |
| Laboratory requirements | Electrical power qPCR machine, centrifuge, etc., Skilled technicians | No power required, No laboratory equipment required, Minimal training |

ReEBOV™ Rapid Test



Matt Boisen
Corgenix
Tulane
Biomedical Sciences
Program

Later flow immunoassay



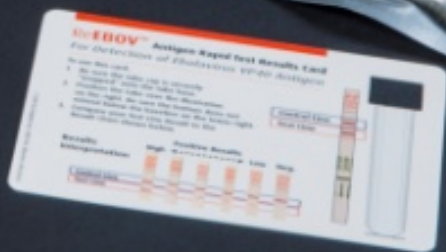
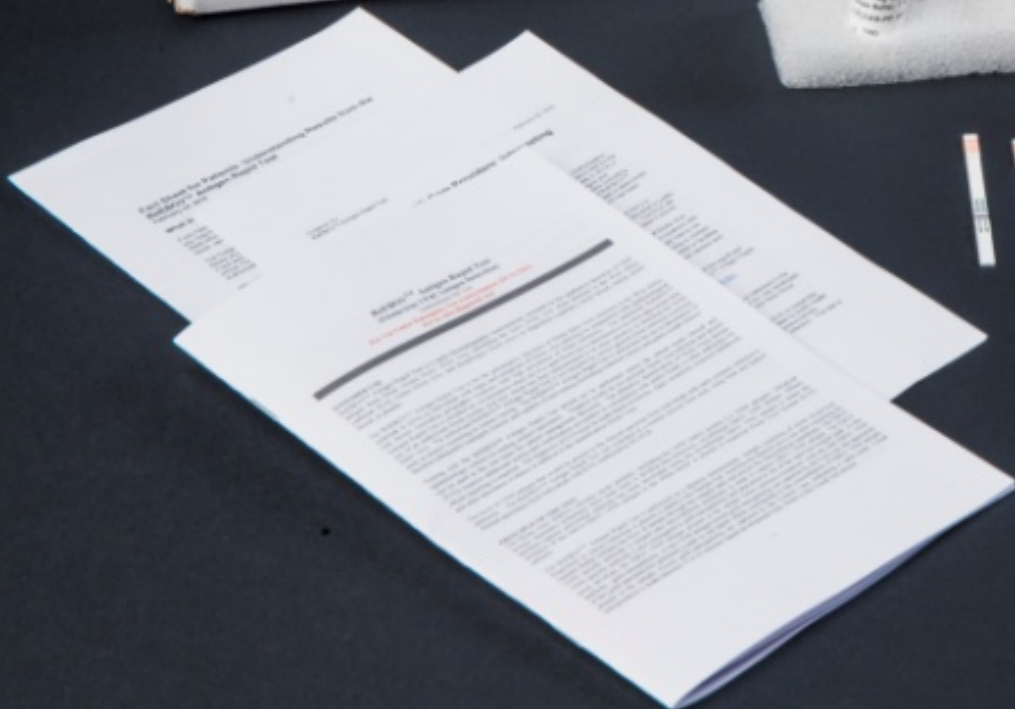
Erica Saphire
Zach Bornholdt



Luis Branco



Bob Cross



ReEBOV Antigen Rapid Test Kit (Corgenix)

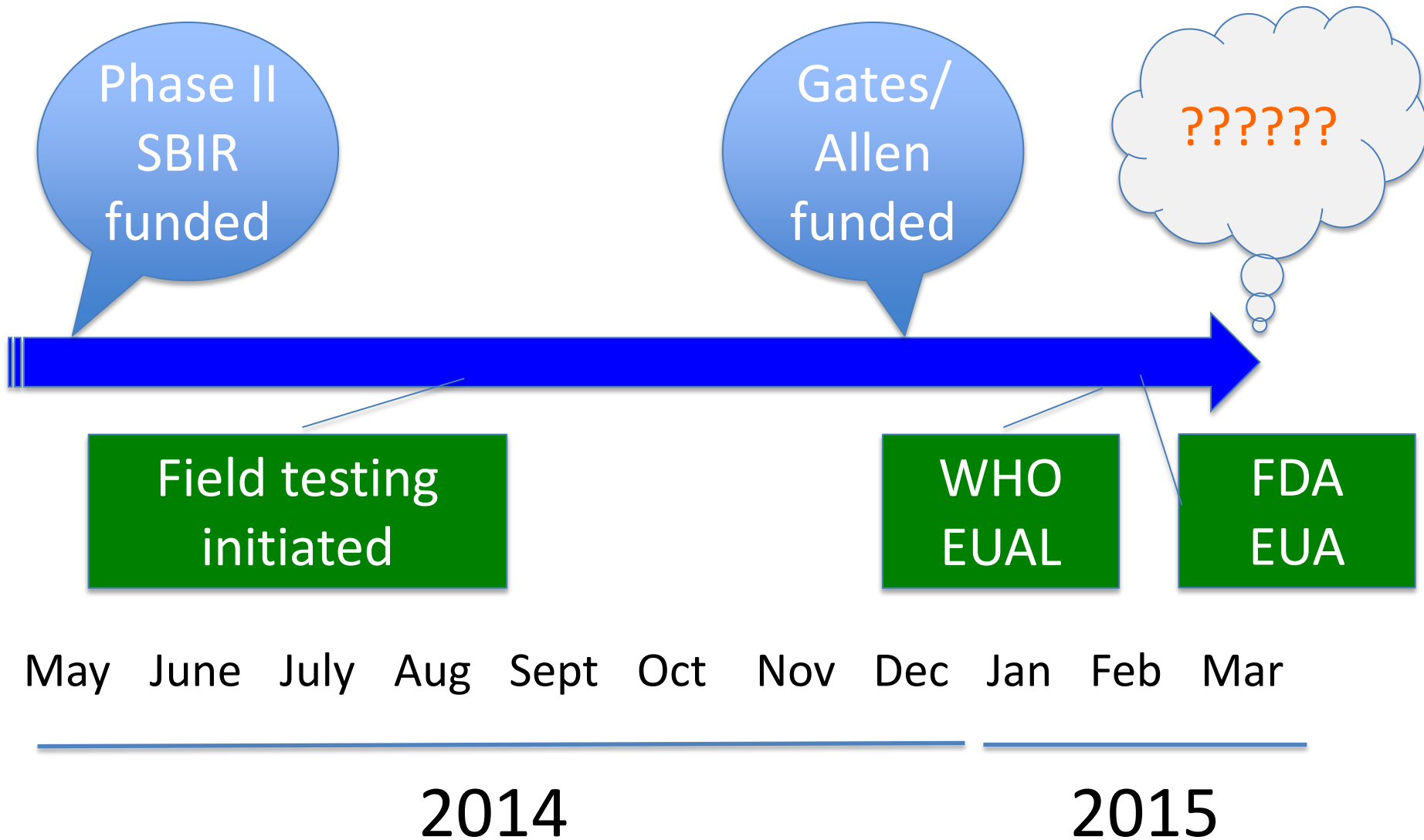


WHO Emergency Use
Authorization and
Listing (EUAL)
February 20, 2015



FDA Emergency use
authorization (EUA)
February 24, 2015

ReEBOV Rapid Test Timeline



Where does the money come from?



Robert Garry PI
James Robinson PI
Tulane

THE PAUL G. ALLEN
FAMILY foundation



Kelly Pitts, PI
Corgenix



WORLD
BANK
Christian Happi PI
Redeemers University
(Lagos)

H3Africa



USAID
FROM THE AMERICAN PEOPLE



National Institutes
of Health

Partnerships for Enhanced
Engagement in Research
(PEER) Health

Donald Grant PI Robert Garry sponsor
KGH Sierra Leone



Adam Smith
INTERNATIONAL

Lina Moses PI Tulane

Viral Hemorrhagic Fever
Immunotherapeutic Consortium

Erica Sapphire PI
Scripps



How do you get the product on the market?

The market for the product is:

- the Federal Government (stockpile)
- “Rich” African Nations (ex. Nigeria)
- Foundations (ex. Gates Foundation)



What do we need to do?

- Convince the USG of the need for stockpiling
- Convince relatively wealthy countries or foundations to buy or subsidize the product.

Can we implement “orphan drug”
incentives for bioterror/emerging
pathogen MCMs?