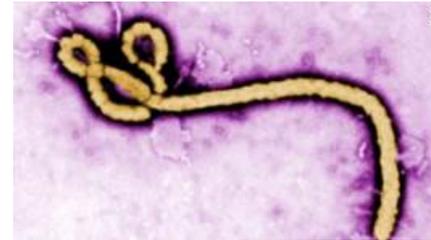
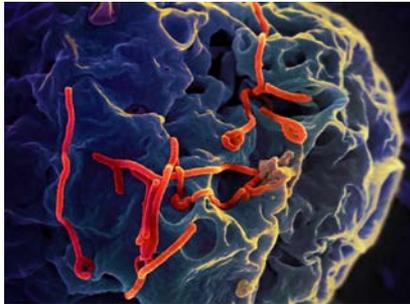




ASPR
ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE



EBOLA UPDATE

Gary L. Disbrow, Ph.D.
Director, CBRN Division
October 2016

Resilient People. Healthy Communities. A Nation Prepared.

The Worst Ebola Outbreak On Record

Total Cases	Confirmed Cases	Deaths
28,652	15,261	11,325

Table above includes 513 deaths of healthcare and frontline workers



Ebola is both an EID and a material threat to the United States



Development and Evaluation of Ebola MCMs Has Been a Coordinated Effort

■ Development

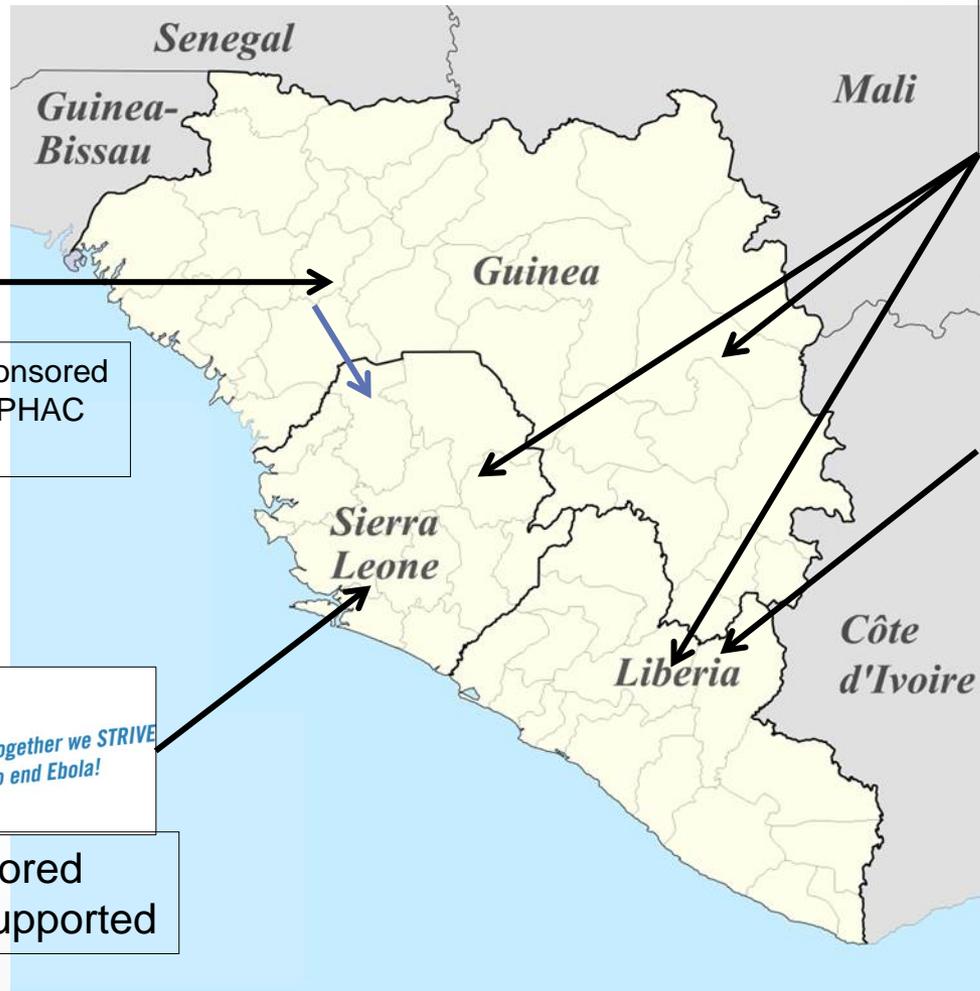
- NIH
- DoD
- BARDA
- FDA
- PHAC
- Industry partners

■ Evaluation

- NIH
- DoD
- CDC/OID/NCIRD
- FDA
- BARDA
- WHO
- NGOs
- Industry partners
- Liberia, Sierra Leone, and Guinea regulatory authorities



Three, Large, Phase II/III Vaccine Trials and One Therapeutic Trial



Campagne Ebola Ça Suffit

MSF, WHO, and Guinea Govt. Sponsored
WHO, WT, MSF, RC of Norway, PHAC Supported



CDC Sponsored
CDC/BARDA Supported

Prevail II
NIH Sponsored
and Supported



NIH Sponsored
and Supported



Ebola Vaccines

■ Profectus BioSciences

- Recombinant vesicular stomatitis virus (rVSV) vectored monovalent vaccine against Ebola-Zaire
 - Currently in Phase I and program will transition to DoD

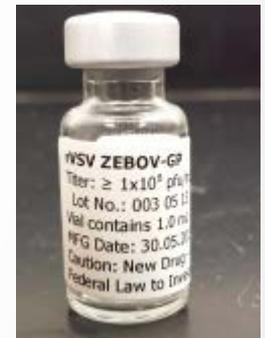


■ NewLink/Merck

- Recombinant vesicular stomatitis virus vectored monovalent vaccine against Ebola
 - Has been evaluated in Phase II/III studies in Liberia, Sierra Leone and Guinea

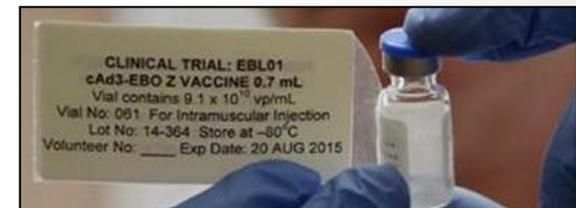
■ GlaxoSmithKline

- Chimp Ad3 vectored monovalent vaccine against Ebola
 - One of the first Ebola vaccines to enter clinical trials
 - Has been evaluated in a Phase II/III study in Liberia



■ Crucell/Bavarian Nordic

- HuAd26 prime with MVA trivalent, heterologous boost
 - Has been evaluated in Phase I study – Oxford
 - Multiple Phase II studies



Ebola Therapeutics

■ Mapp Bio

- Developing a cocktail of chimeric monoclonal antibodies (ZMapp)
 - Has been evaluated in a Phase II/III efficacy trial (PREVAIL II)
 - Trial was halted – trend toward efficacy but failed to meet endpoints



■ Regeneron

- Developing a cocktail of fully human monoclonal antibodies
 - Currently in Phase I



■ BioCryst

- Developing a small molecule drug (BCX4430) – potential broad spectrum
 - Currently in Phase I



■ Genentech/Emergent (CIADM)

- Developing a cocktail of humanized ZMapp clones in CHO cells
 - Currently being evaluated in non-clinical studies

■ BARDA supported small-scale efforts with Medicago and Fraunhofer



Expanded Access Protocol

- BARDA is working with Mapp Bio and our International partners to maintain access to ZMapp
- Mapp Bio has established an EAP in Guinea, Sierra Leon, and Liberia
 - Provides continued access to ZMapp, supply chain and storage control of the product, and additional safety and effectiveness data collection
 - Provides a clinical site, potential mobile units, and potential air transportation for 3 years
- The EAP has also been established at the 10 Ebola treatment centers in the US and the NIH hospital



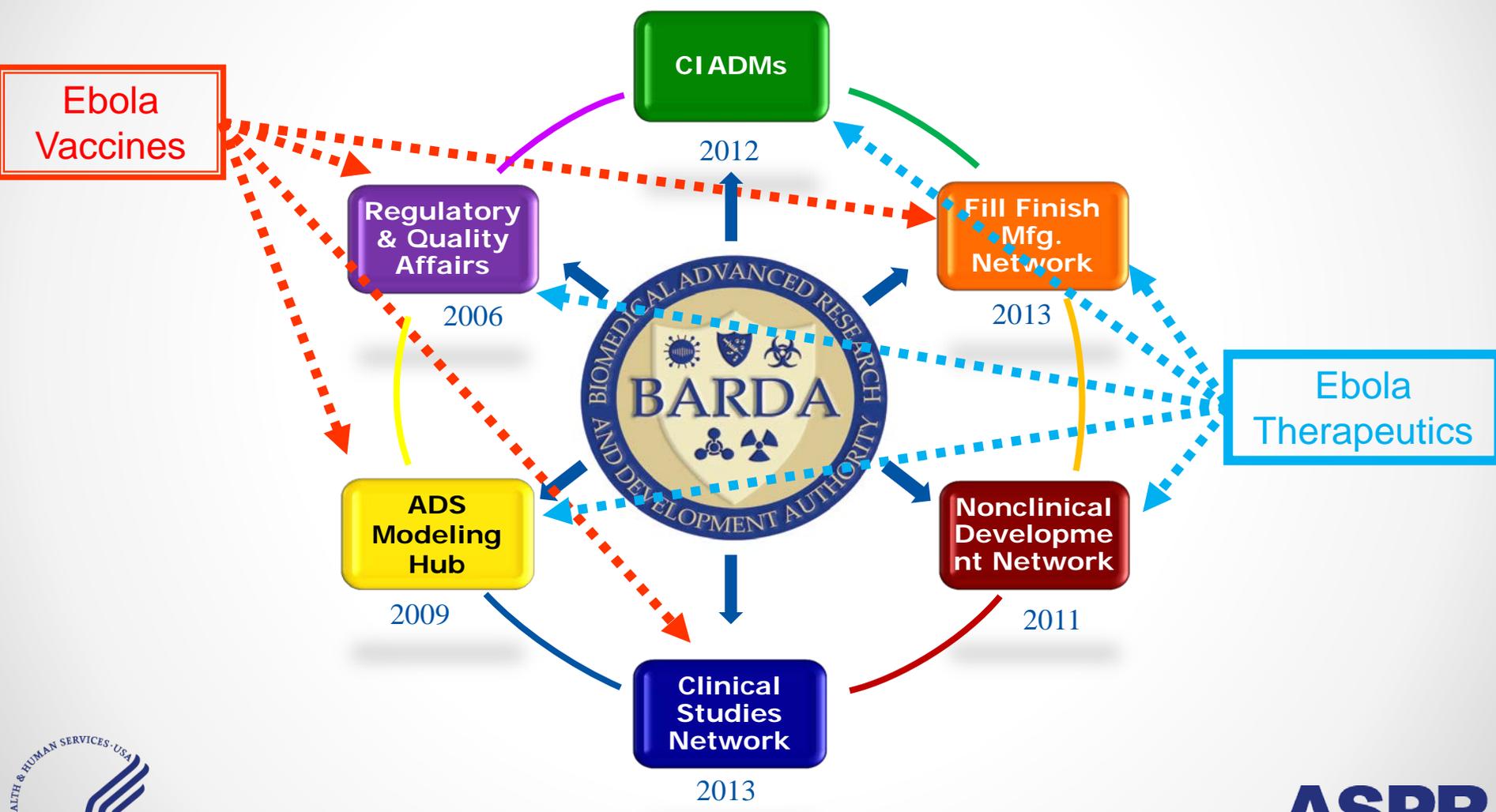
Ebola Diagnostics

- Several diagnostics have received EUA
- BARDA is supporting OraSure for the development of a rapid, POC, diagnostic
 - Has EUA status
 - Utilizes blood or oral fluid
 - Quick – point of care, lateral flow
 - BARDA will support
 - Assay design/improvement
 - Process and product validation
 - Analytical and functional testing
 - Clinical trial to support 510(k) clearance



OraSure Technologies

BARDA's National Countermeasure Response Infrastructure



What's Next?

- Potential efficacy of one vaccine candidate
 - Data still needs to be reviewed by regulatory agencies
- Trend in benefit for ZMapp
- How will regulatory authorities license vaccines and therapeutics in the absence of definitive or sufficient efficacy data?
 - Animal rule
 - Accelerated approval pathway
- BARDA will continue to support development of vaccines and therapeutics
 - Need to finish the job and support licensure and approval
- Remaining questions:
 - How many vaccines and therapeutics to support?
 - What data is necessary to support potential procurement under PBS for EUA?
 - What is the regulatory path for the products?

