

Accelerating access to Ebola vaccines

From research to large-scale use

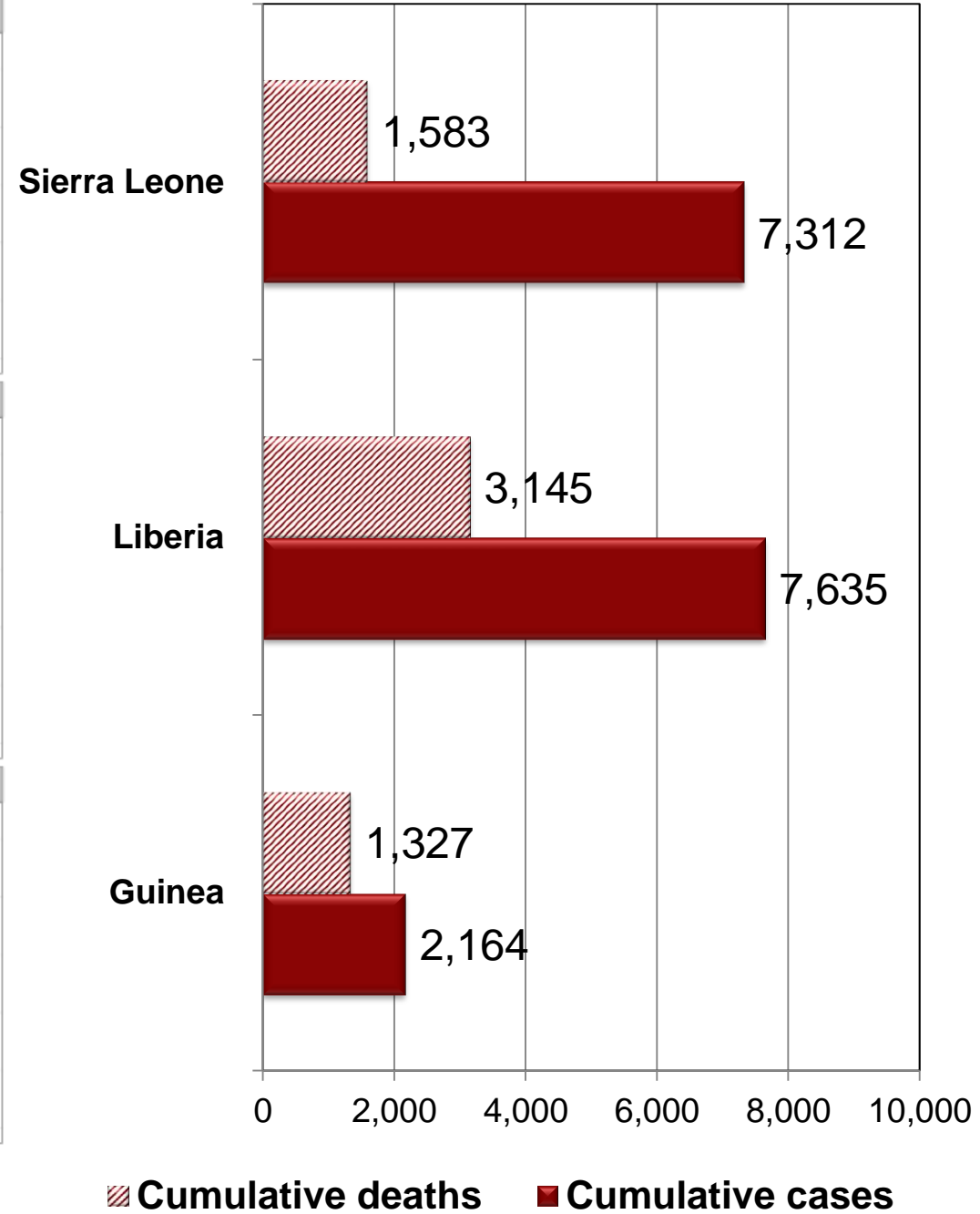
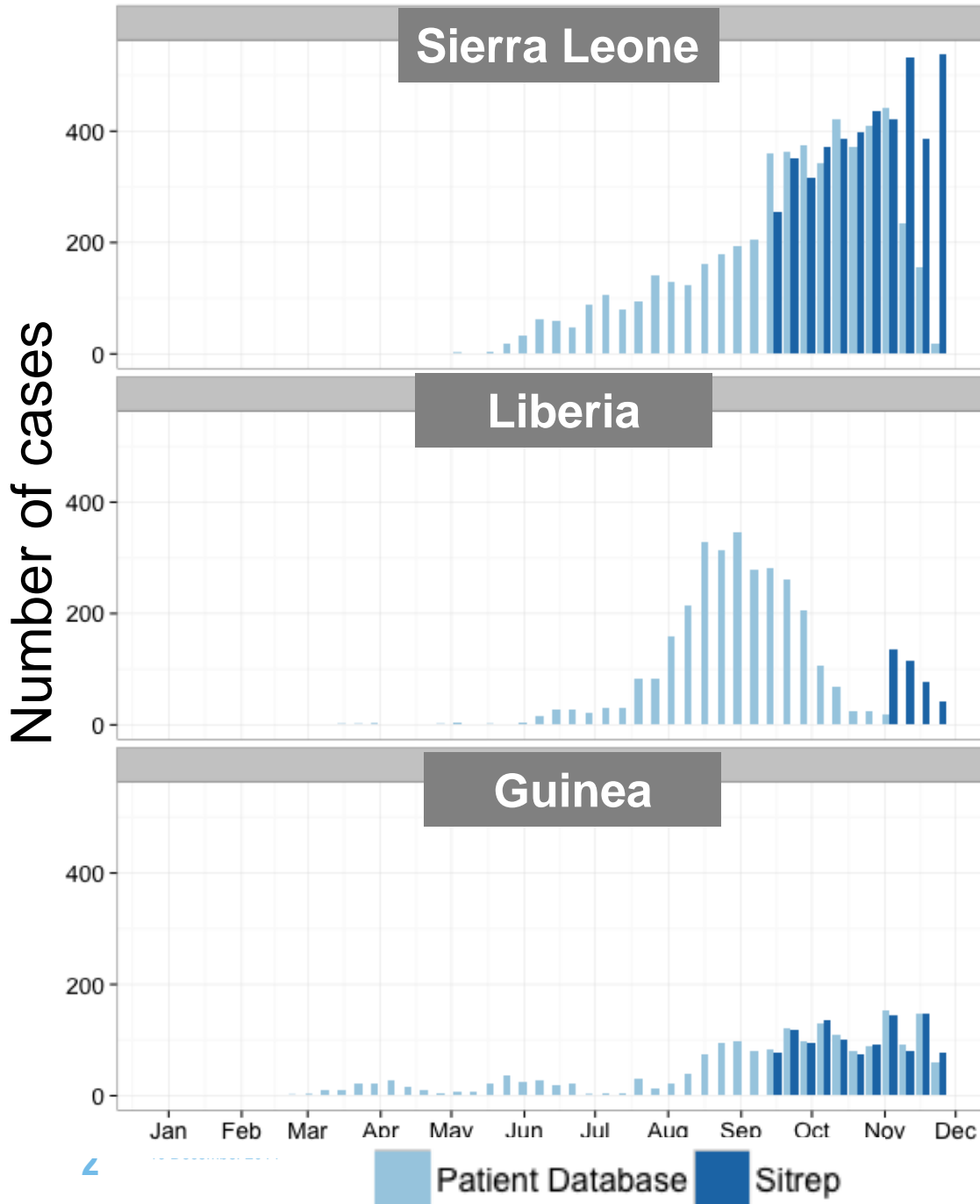
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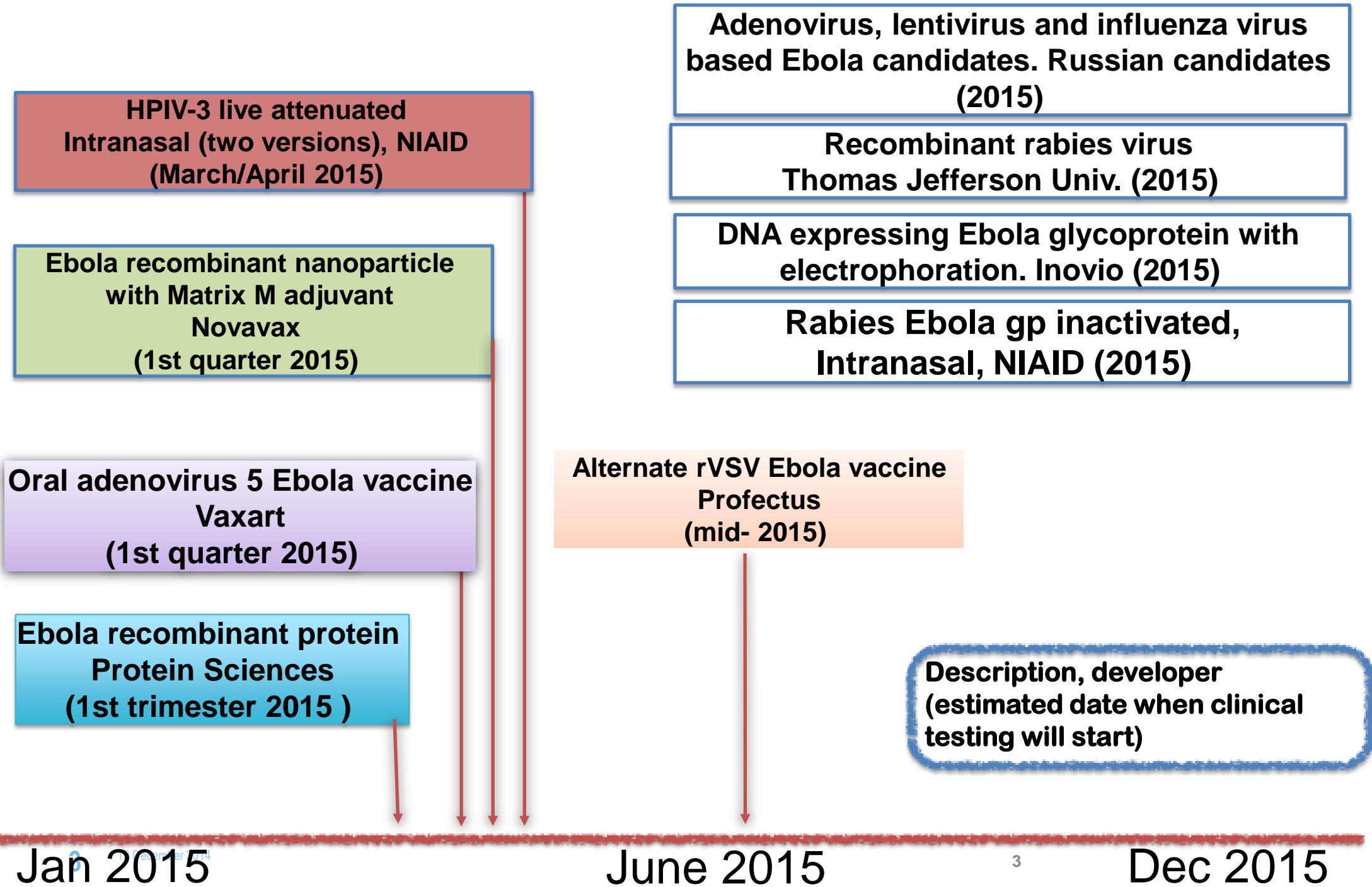
**World Health
Organization**

Ebola response roadmap: Situation report

3 December 2014



Ebola vaccines under Preclinical evaluation



Ebola vaccines under clinical evaluation in 2014

rVSV-ZEBOV

Recombinant vesicular stomatitis virus

It aims to induce EVD-specific immune responses.

NewLink Pharmaceuticals?Merck

ChAd3-ZEBOV

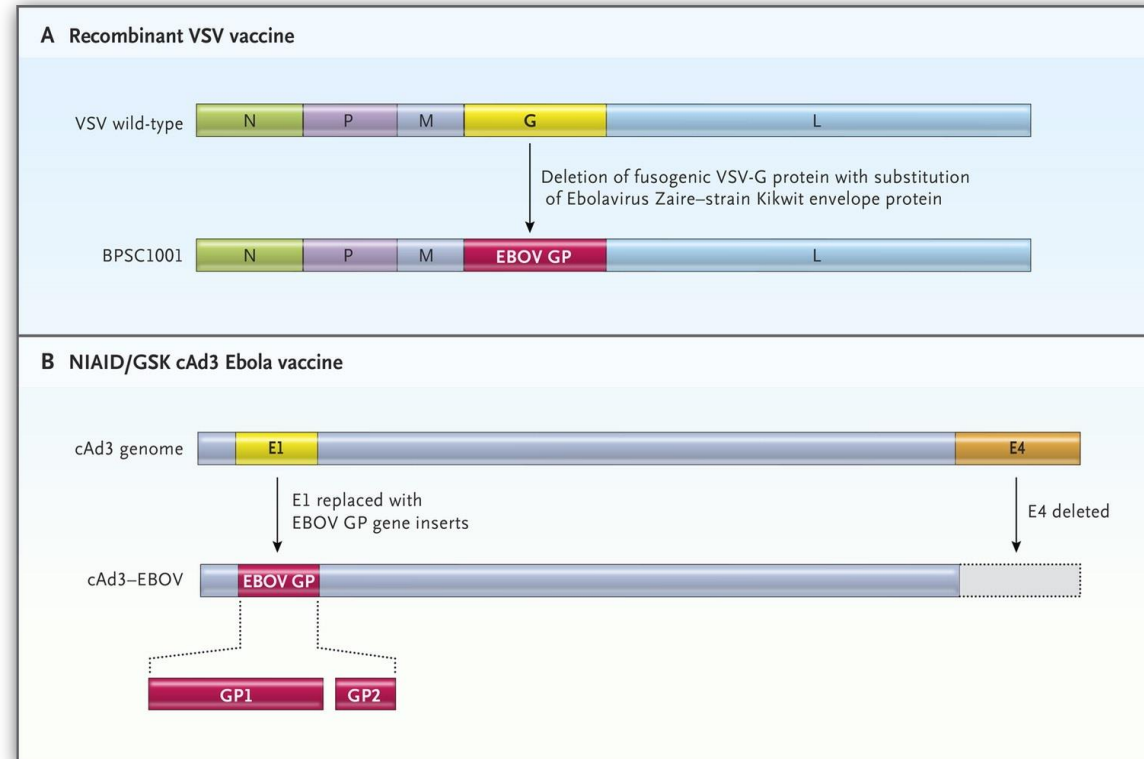
Chimpanzee adenovirus 3

It uses a chimpanzee adenovirus that does not grow, containing the gene for EVD surface protein.

GSK/NIAID

Ad26/Ad35/MVA

Johnson and Johnson Crucell



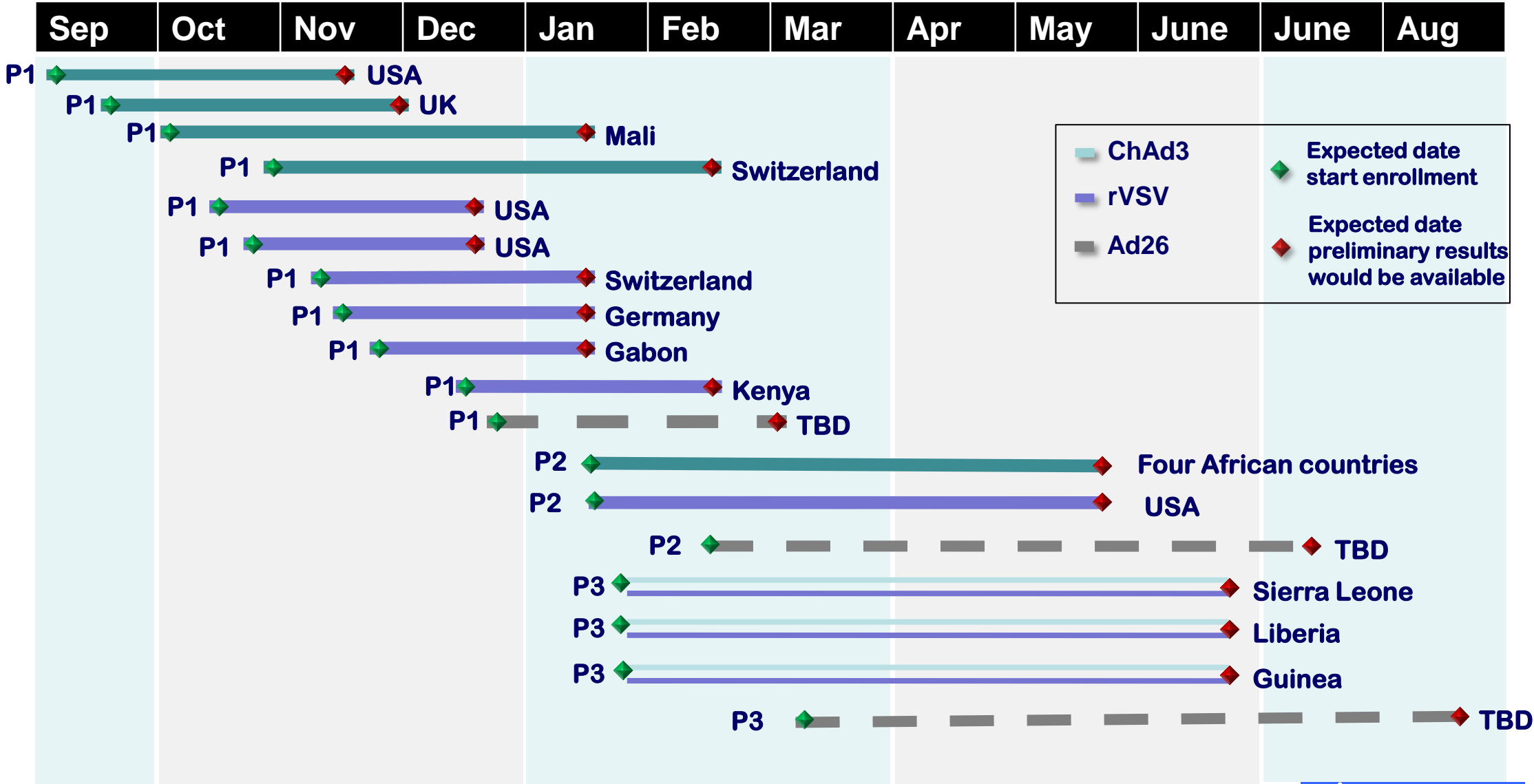
Kanopathipillai R et al. N Engl J Med 2014. DOI: 10.1056/NEJMp1412166

Ebola vaccine research and anticipated development timelines

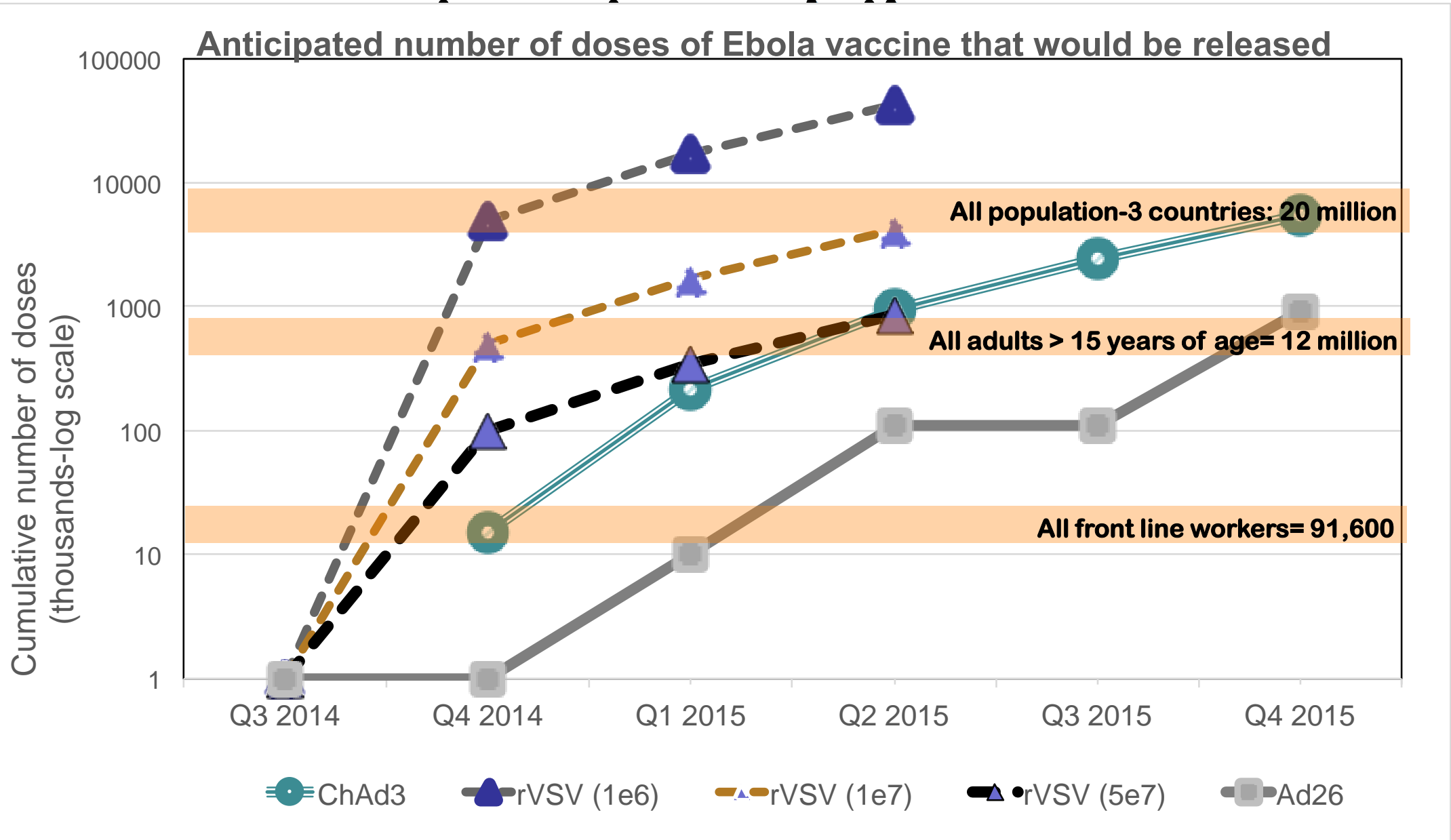
(information available to WHO as of Dec 8, 2014)

2014

2015



Matching vaccine supply to potential



Ebola vaccines: WHO Oversight

RESEARCH AND DEVELOPMENT PATHWAY

Strategic and Technical Advisory Committee on Experimental Ebola Therapeutics and Vaccines (STAC-EE): Review of development plan, expert opinion on protocol design, and interpretation of data emerging from trials

REGULATORY MATTERS

African Vaccine Regulators Forum (AVAREF): Review of IND application: Protocols, IB, Ethics and informant consent

WHO Advisory Committee on Regulatory Emergency Authorization of unlicensed Ebola Vaccines: Review of GMP, evidence on safety and efficacy, programmatic suitability. Time limited authorization for use

SAFETY AND RISK ASSESSMENT

WHO Ebola Vaccines Risk Assessment Group and WHO Global Advisory Committee on Vaccine Safety: Evaluation of safety data and opinion on potential risks and benefits.

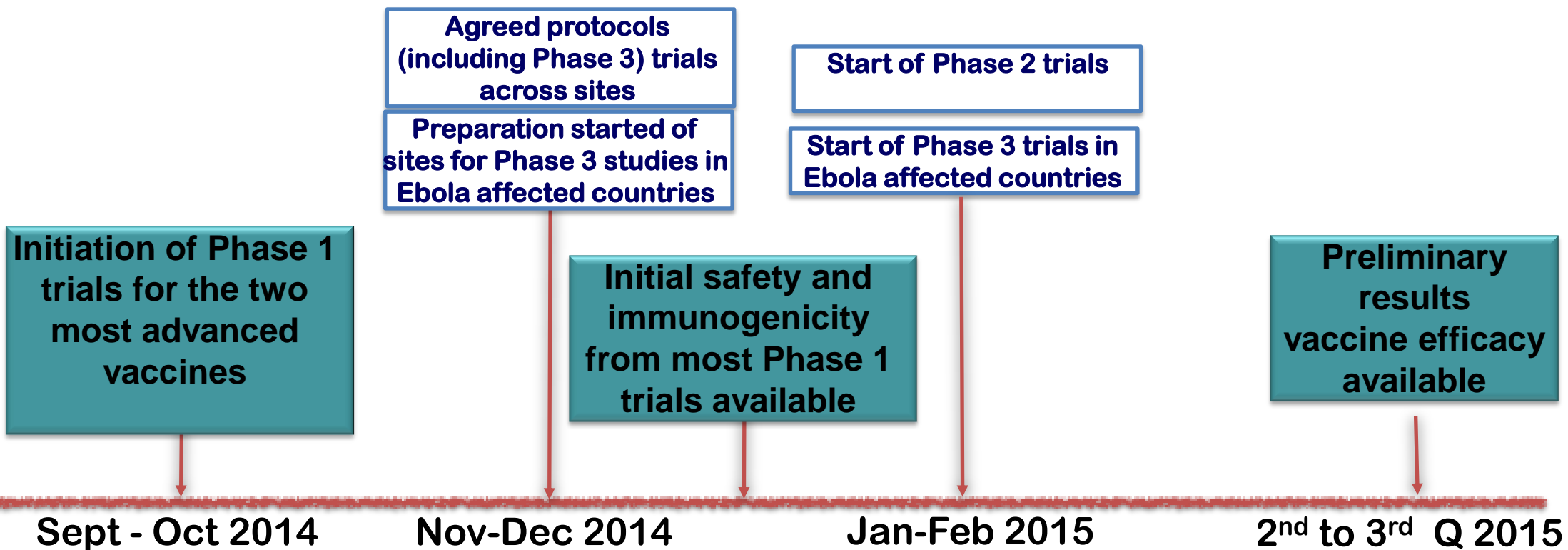
POLICY AND IMPLEMENTATION

Strategic Advisory Group of Experts (SAGE) : Review of evidence to inform policy considerations for large scale use, if appropriate

Task Force on Immunization (TFI): Operational implementation and monitoring in Africa

Ebola Vaccines - Key milestones

Planning for large-scale use including systems for vaccine financing, allocation and use.



3 concluding messages

1 Accelerated efforts are underway to evaluate a number of Ebola vaccines. Preliminary results anticipated:

- Phase 1 data: Dec 2014
- Phase 2 data: 1st Quarter 2015
- Phase 3 data: 2nd to 3rd Quarter 2015

2 Analysis of anticipated supply and potential target populations suggest that doses would match demand as follows:

- 1st Quarter 2015: Front line workers
- 3rd Quarter 2015: Adults (older than 15 years of age or geographic target areas strategies)
- 2nd to 4rd Quarter 2015: All populations in 3 worst affected Ebola countries

3 WHO has set in place the required oversight to ensure quality and compliance with ethical and regulatory matters, to develop policy recommendations and vaccine roll-out as appropriate

"The vaccine is not the magic bullet.

But when ready, they may be a good part of the effort to turn the tide of this epidemic."



Thank you