Biopharmaceutical Landscape: Challenges and Opportunities

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Lessons Observed

✓ Collaboration Challenges
✓ Coordination Challenges
✓ Capacity Constraints
✓ Communication Failures
✓ Countermeasure Challenges
✓ Capability Deficits

CDC Anthrax Response After Action Reviews
Lessons Observed

- Collaboration Challenges
- Coordination Challenges
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SARS After Action Reviews
Lessons Observed

- Collaboration Challenges
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H1N1 Influenza After Action Reviews
Western Africa Ebola After Action Reviews

Déjà vu all over again…and again…and again…

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The Biopreparedness Paradox

✓ Human, animal, and plant pathogens capable of causing significant local, regional, and global humanitarian, geopolitical, and economic damage are emerging and/or re-emerging at an alarming rate.

✓ Our scientific capabilities are also advancing at unprecedented speed, and we have the potential to solve some of the most vexing threats in innovative ways that were unimaginable even a decade ago.

✓ Despite this potential, our global biopreparedness remains alarmingly inadequate and our health security remains at risk. Multi-national, multi-disciplinary, multi-lateral, and pan-sectoral sustained efforts are critical to break the cycle of crisis and complacency.
“Sustainability is not just about securing predictable financial resources. It is also about strengthening health systems while fighting disease, and using the extraordinary opportunities provided by disease programs to deliver other health benefits. It is about training and empowering the health workforce. It is about drawing on the experience of the private sector to help us innovate and measure risk and results.”

Ban Ki-moon
Former Secretary-General of the United Nations
Case Study 1: Ebola Virus Disease in West Africa 2014-16
Largest Outbreak in History with Devastating Local and Global Impact
V920 Ebola Zaire Vaccine (Erbevo) Partnerships

NewLink Genetics Announces Merck Has Begun Rolling Submission of Licensure Application for Ebola vaccine V920 (rVSVΔG-ZEBOV-GP) to U.S. Food and Drug Administration

In 2014 the Company entered into a license agreement with Merck to develop, manufacture and commercialize NewLink Genetics’ Ebola vaccine candidate

Public Health Agency of Canada

Agence de la santé publique du Canada
Catalyzed in the Crucible of Crisis: A Diverse and Dynamic Global Collaboration

<table>
<thead>
<tr>
<th>African governments, researchers and volunteers</th>
<th>Global public health entities</th>
<th>Governments of Canada, United States, Europe</th>
<th>Field response and service organizations</th>
<th>Universities</th>
<th>Private sector companies</th>
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- BARDA
- Bill & Melinda Gates Foundation
- CDC
- CEPI
- FDA
- Gavi
- International Federation of Red Cross and Red Crescent Societies
- LSE
- MEDECINS SANS FRONTIERES
- Doctors Without Borders
- NewLink Genetics
- NIH
- Public Health Agency of Canada
- Wellcome Trust
- World Health Organization
Rapid Clinical Trial Evaluation Across 10 Countries

**Phase 1 - HUG**
Geneva, Switzerland

**Phase 1 - KEMRI**
Kilifi, Kenya

**Phase 1 - CERMEL**
+ University of Tübingen
Lambarene, Gabon

**Phase 1 - WRAIR**
Silver Springs, MD, USA

**Phase 1 - NIH**
Bethesda, MD, USA

**Phase 1 - CCV**
Halifax, Nova Scotia, Canada

**Phase 1 - NewLink**
8 cities in USA

**Phase 1 - University Medical Center Hamburg + Clinical Trial Center North**
Hamburg, Germany

**Phase 2/3 - Liberia-NIH Partnership**
Liberia (PREVAIL PN009)

**Phase 2/3 - CDC + Sierra Leone Medical School**
Sierra Leone (PN011)

**Phase 3 - WHO + Norwegian Institute of Public Health + Health Canada + MSF**
Guinea (PN010)

**Phase 3 - Merck**
Multiple sites in the USA, Canada, Spain (PN012)

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Multiple sites in the USA, Canada, Spain (PN012)
Efficacy and effectiveness of an rVSV-vectored vaccine in preventing Ebola virus disease: final results from the Guinea ring vaccination, open-label, cluster-randomised trial (Ebola Ça Suffit!)

Ana Maria Henao-Restrepo, Anton Camacho, Ira M Longini, Conall H Watson, W John Edmunds, Matthias Egger, Miles W Carroll, Natalie E Dean, Ibrahima Diatta, Moussa Doumbia, Bertrand Draguez, Sophie Duraffour, Godwin Enwere, Rebecca Grais, Stephan Gunther, Pierre-Stéphane Gsell, Stefanie Hossmann, Sara Viksmoen Wadle, Mandy Kader Kondé, Sakaba Kéita, Souleymane Kone, Eewa Kuisma, Myron M Levine, Sema Mandal, Thomas Mauget, Gunnstein Norheim, Ximena Riveros, Aboubacar Soumah, Sven Trelle, Andrea S Vicari, John-Arne Rettingen*, Marie-Paule Kiery*

Lancet 2017; 389: 505–18 Published Online December 22, 2016
http://dx.doi.org/10.1016/S0140-6736(16)32621-6
Innovative and Collaborative Registration Pathway Employed

OBJECTIVE:
Make a safe, efficacious, high-quality vaccine available rapidly to the people who need it to prevent the incidence of Ebola Virus Disease caused by the Zaire strain.

European Medicines Agency (EMA) Approval

Review by EMA facilitated parallel review by WHO PQ team and collaborative review by AVAREF, thereby accelerating the approval process and enabling stockpile purchases by funders.

APPROVED 11-NOV-2019

World Health Organization (WHO) Prequalification (PQ)

WHO PQ team reviews in parallel with EMA. PQ allows vaccine purchase by United Nations procurement agencies, in addition to facilitating review of the dossier by AVAREF representatives.

PREQAXUALIFIED 12-NOV-2019

African Vaccine Regulatory Forum (AVAREF) Country Approvals

AVAREF representatives review in parallel with EMA and in collaboration with WHO to accelerate approval.

TARGET APPROVALS BY 10-FEB-2020
Roadmap to Accelerated Approval and Access

STANDARD PROCESS

Reference Country Approval ~12 months
WHO Prequalification ~12 months
Country Registration ~12 months ~36 Months

ACCELERATED PROCESS

Reference Country Approval ~9 months
WHO Prequalification ~9 months
Country Registration ~9 – 12 Months

ENABLERS TO SUCCESS

• MSD willingness to submit the same dossier in all countries
• EMA willingness to allow WHO and country representatives to join review process
• WHO/AVAREF identification of high risk countries
• WHO/AVAREF coordination of dossier distribution
• EMA/WHO/AVAREF consolidation of questions
• WHO/AVAREF coordination of review workshop
• EMA/WHO/AVAREF consolidation of GMP inspections
Local and Global Partners Supporting International Outbreak Response

Ebola Zaire Vaccine (Ervebo) helps support the international outbreak response in the DRC and neighboring countries...exceptional collaboration among governments, UN agencies, and above all, heroic frontline responders, community workers, and surviving patients who are providing care and comfort to others.

As of October 22, 2019
(numbers subject to change)

>245,000 doses donated and shipped to WHO by Merck

>240,000 individuals vaccinated by government and frontline workers *

* Source: World Health Organization Ebola Situation Reports; DRC Ministry of Health
Case Study 2: Antimicrobial Resistance (AMR)
Major Global Attention but Minor Global Investment

Headlines, but limited real progress

- Increasing government funding for “push” incentives (and exit of private venture capital)
- Improved visibility and recognition of role of industry
- Reimbursement reform proposed but not implemented in US and UK;

Challenging Environment:
- Dynamic political environment (elections, divided governments)
- Intense pressure on drug pricing and scrutiny of the pharmaceutical industry
- Low awareness and prioritization of AMR by governments
Worried Investors Abandoning Small Companies; Even Most Large Companies No Longer Supporting Antibiotic Pipelines

... and antibiotic-focused biotechs are failing

New innovative models to support research and market access are needed

FT
Financial Times

We ignore the disaster in the antibiotics market at our peril
Jeremy Farrar
Director
Wellcome

WIRED

THE RADICAL PLAN TO CHANGE HOW ANTIBIOTICS GET DEVELOPED

Forbes

Dr. Rick Bright

Building New Models To Support The Ailing Antibiotics Market
Our Collective Call to Action: 
*An International Community Standing Strong Together*

End the cycle of crisis and complacency…
Commit to continuous prevention, protection and resilience

- Respectful Partnerships, Meaningful Investments, and Innovative Market Models
- Joint Preparation for Collaborative Global Action in Response to Global Challenges to Challenges