


**The Foundation for Science
and Technology**

**Debate on Lessons Learned
from the Response to the
Ebola Outbreak**

25 March, 2015
London

Lessons Learned

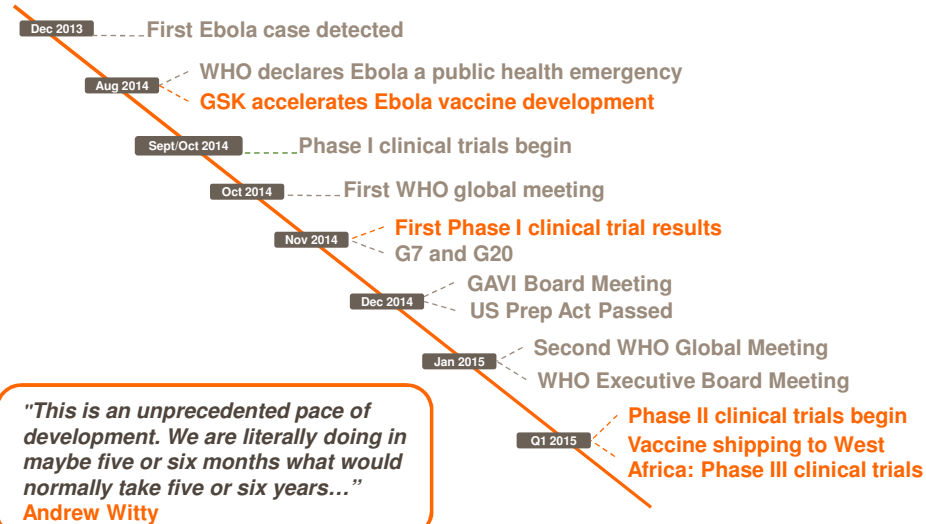


Chapter One

The Power of Partnership

2

Some Key Points So Far



The Power of Partnership



- As GSK has experienced with a number of its development programmes, strong partnerships make for good science, shared risks, and more efficient development of new medicines and vaccines
- By tapping into an existing network of scientists, investigators, funders, and advisors GSK was able to significantly accelerate the development program of its candidate vaccine
- With the help of WHO, we entered into constructive dialogues with regulators, government leaders, and NRAs to accelerate process development and manufacturing, to collect the clinical data needed to launch Phase 3, and to begin to define regulatory pathways that could lead to licensure of an Ebola vaccine in a timely manner

Accelerated development was only possible thanks to strong partnerships & collaborations



5

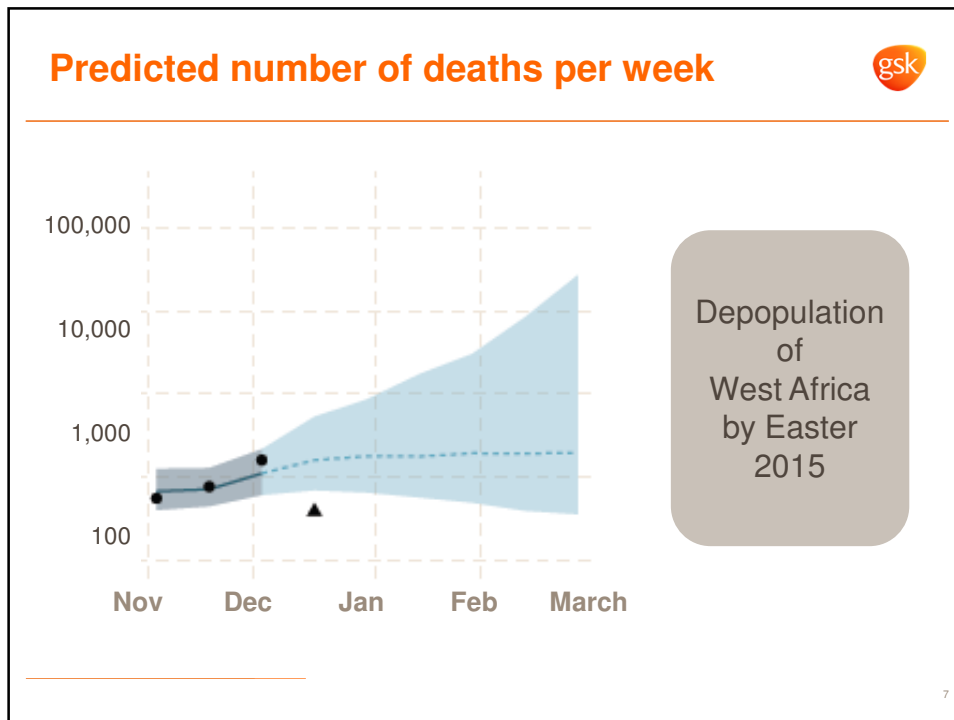
Lessons Learned



Chapter Two

The Problem with Predictions

6



- ### Problems with Predictions
1. Very effective for focusing the discussion, but perhaps not optimal for rational decision-making and planning
 2. Did such scenario predictions contribute to a sense of desperation which blocked normal scientific debate, especially around study designs?
 3. Case in point: negative views on the ability to implement randomized controlled trials, despite generally aligned ethical perspectives
- A small number '8' is in the bottom right corner.

Lessons Learned



Chapter Three

The Perils of Promises

9

The Perils of Promises



Leaked documents reveal behind-the-scenes
Ebola vaccine issues **SCIENCEINSIDER** 23 Oct 2014

GSK Manufacturing Capacity

Production line		Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15	Nov-15	Dec-15
1	Purified bulk		24000		24000	30000	35,000	35,000	35,000	35,000	35,000	35,000	35,000	Maintenance	35,000	35,000	35,000
	Released				24000	24000*	30000**	0	35,000	35,000	35,000	35,000	35,000	35,000	35,000	0	35,000
2	Purified bulk			Purchase	IO/OQ		35,000	35,000	35,000	35,000	35,000	35,000	35,000	Maintenance	35,000	35,000	35,000
	Released						35,000	35,000	35,000	35,000	35,000	35,000	35,000	35,000	35,000	0	35,000
3	Purified bulk						80,000	80,000	80,000	80,000	80,000	40,000	Maintenance	320,000	320,000	320,000	320,000
	Released							80,000	80,000	80,000	80,000	80,000	80,000	40,000	0	320,000	320,000
5	Purified bulk						80,000	80,000	80,000	80,000	80,000	40,000	Maintenance	320,000	320,000	320,000	320,000
	Released							80,000	80,000	80,000	80,000	80,000	80,000	40,000	0	320,000	320,000
5	Purified bulk						80,000	80,000	80,000	80,000	40,000	Maintenance	320,000	320,000	320,000	320,000	
	Released									80,000	80,000	80,000	40,000	0	320,000	320,000	
	Total PB																
	Total Released		0	0	24,000	24000*	30000**	0	230,000	230,000	310,000	310,000	310,000	190,000	70,000	960,000	1,030,000

* At risk, will be released in January if filled by Jan. 9th, 2015
** At risk, will be released in February if filled by Feb. 6th, 2015

Several analyses laid out the complex regulatory and liability issues. The U.K. government argued that "there is a need to provide some form of relief of liability for the producers and distributors of the vaccines"

10

The Perils of Promises



1. High level talks were held with governments on the issue of loss mitigation, not only due to resources diverted to fight Ebola, but also for indemnification against claims that might be brought by trial participants, given the very early stage of the Ebola program
2. GSK continues to invest without a concrete mitigation plan and has had to acquire expensive supplementary trial insurance using its own resources
3. The US stepped up with the PREP act - It is essential that government provide the incentives to ensure that industry continues to step up in future emergencies

11

Lessons Learned



Chapter Four

Policy and Perception

12

Policy and Perception



- There was a collective failure of global governance as the scale and the nature of this humanitarian crisis unfolded
- By being fully focused on the traditional pillars of case identification, case isolation and contact tracing, the wrong signals were sent to industry – consider what more could have been done if we had a six month head start
- Stronger surveillance and detection systems coupled with better global coordination and decision-making could go a long way to being better prepared for the next PHEIC

13

Lessons Learned



Chapter Five

Prepare or Perish

14

Prepare or Perish



- Over the last decade the world has encountered a series of global health emergencies for which we were unprepared H5N1, SARS, H1N1, MERS, Ebola,...what will the next one be?
- All of these threats have a common theme – zoonotic diseases that jump from animal reservoirs to humans – there are many more that we know about and certainly some that we don't – and we are not prepared to respond to them
- We have a major opportunity to make a substantial change because of the focus created by Ebola, but it will take vision, political leadership, and a rethinking of how we address this class of infectious disease threats. We must seize this opportunity.

15

Prepare or Perish



- Create a global institution dedicated to surveillance and basic research on agreed prioritized emerging disease threats
- Create dedicated R&D units embedded in an industrial setting to focus on developing drugs, vaccines and diagnostics for priority pathogens
- Establish mid-scale manufacturing capacity for lower volume stockpiles, a network of manufacturing capacity across the world for mass production, and create a payment system to ensure that supplies are available when and where they are needed
- Create a legal framework for indemnification, agree an acceptable clinical development approach that can work under outbreak conditions (ethical framework, capacity in developing countries), and new regulatory pathways for approval of the tools the world will need to respond adequately to future emerging diseases

16

