Research integrated in the response to Sudan ebolavirus outbreak in Uganda

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R&D Blueprint for epidemics
WHO Emergency programme
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World Health Organization

R&DBlueprint
Powering research to prevent epidemics

In May 2015, the Sixty-Eighth World Health Assembly

"…welcomed the development of a blueprint, in consultation with Member States and relevant stakeholders, for accelerating research and development in epidemics or health emergency situations where there are no, or insufficient, preventive, and curative solutions, taking into account other relevant work streams within WHO"[1].

R&DBlueprint

Powering research
to prevent epidemics

Our Vision

A world where diagnostics, medicines and vaccines are available to prevent and respond to epidemics across the world

Our Mission

We aim to achieve our vision by coordinating and accelerating global research work to:

Target diseases that threaten humanity

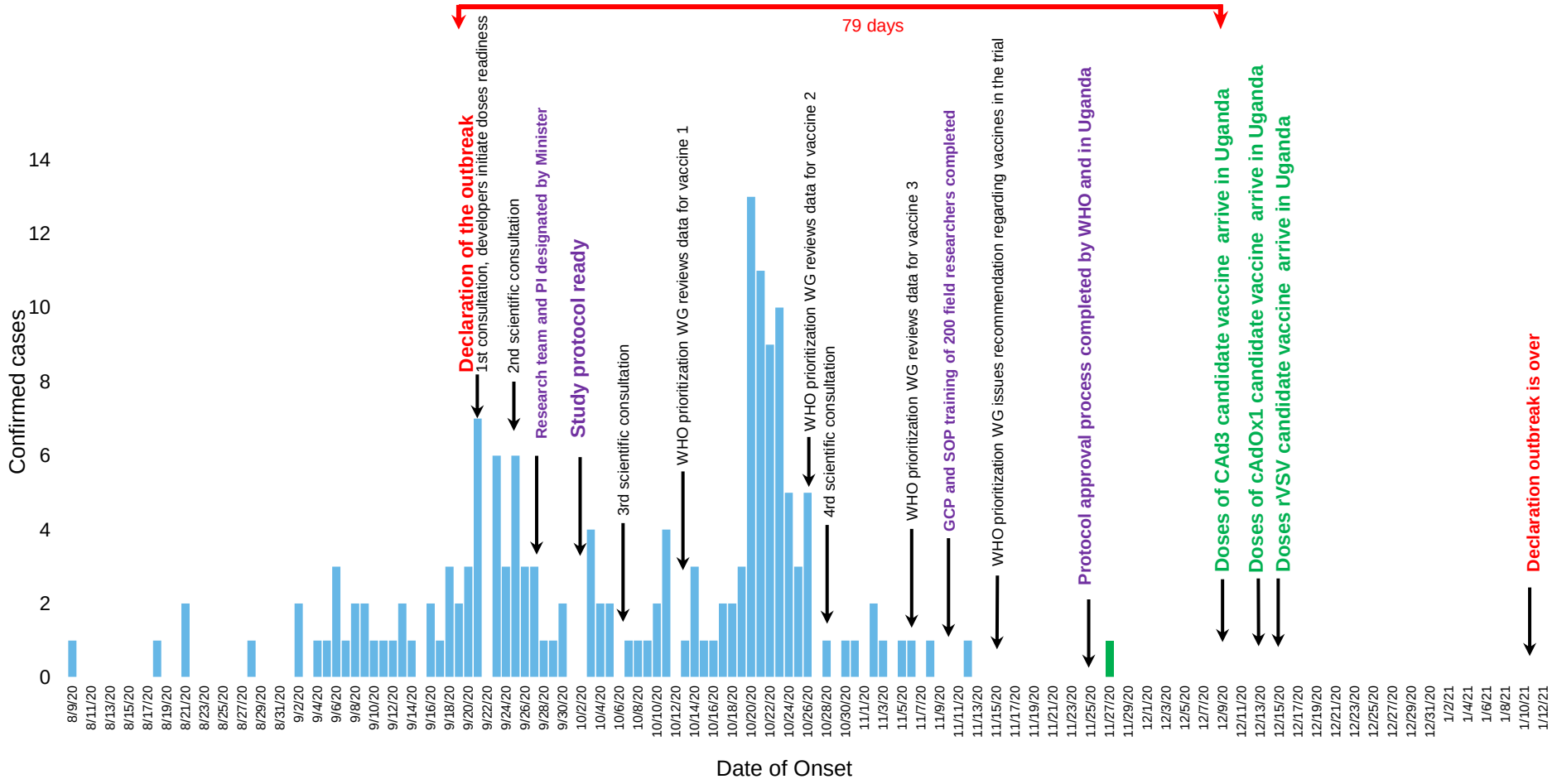
Develop diagnostics, medicines and vaccines faster

Respond to outbreaks, integrate research in the response, preventing epidemics

What did we have on Sep 20, 2022?

- ☒ A WHO **R&D roadmap** for filoviruses - AFIRM
- ☒ 5 **candidate vaccines**, 2 of them with Phase 1 data, and an additional one later
- ☒ Vaccine **developers committed** to speed up availability of GMP doses
- ☒ **MOH Uganda and Makerere University** poised to prepare rapidly for the trial
- ☒ A draft **protocol** to evaluate candidate vaccines
- ☒ **Global partners** ready to provide prompt financial support
- ☒ An independent **WHO Working Group for vaccine prioritization**
- ☒ A WHO **legal framework** and WHO insurance and liability arrangements
- ☒ An open global **scientific forum** to discuss research priorities

Confirmed cases of SUVD and key vaccine trial milestones



A global collaborative effort accelerated many key actions

0 **Outbreak declared**

1 Open scientific consultation process initiated/ Preparation of GMP doses initiated

3 Ugandan PI and team initiate preparations for the trial, with support from WHO trial RCT experts

13 Protocol and SOPs ready and submission for approval initiated

23 Vaccine prioritization data submission initiated and review process started

51 Trial team trained on GCP and on protocol SOPs - 200 field researchers; DSMC and TSC established

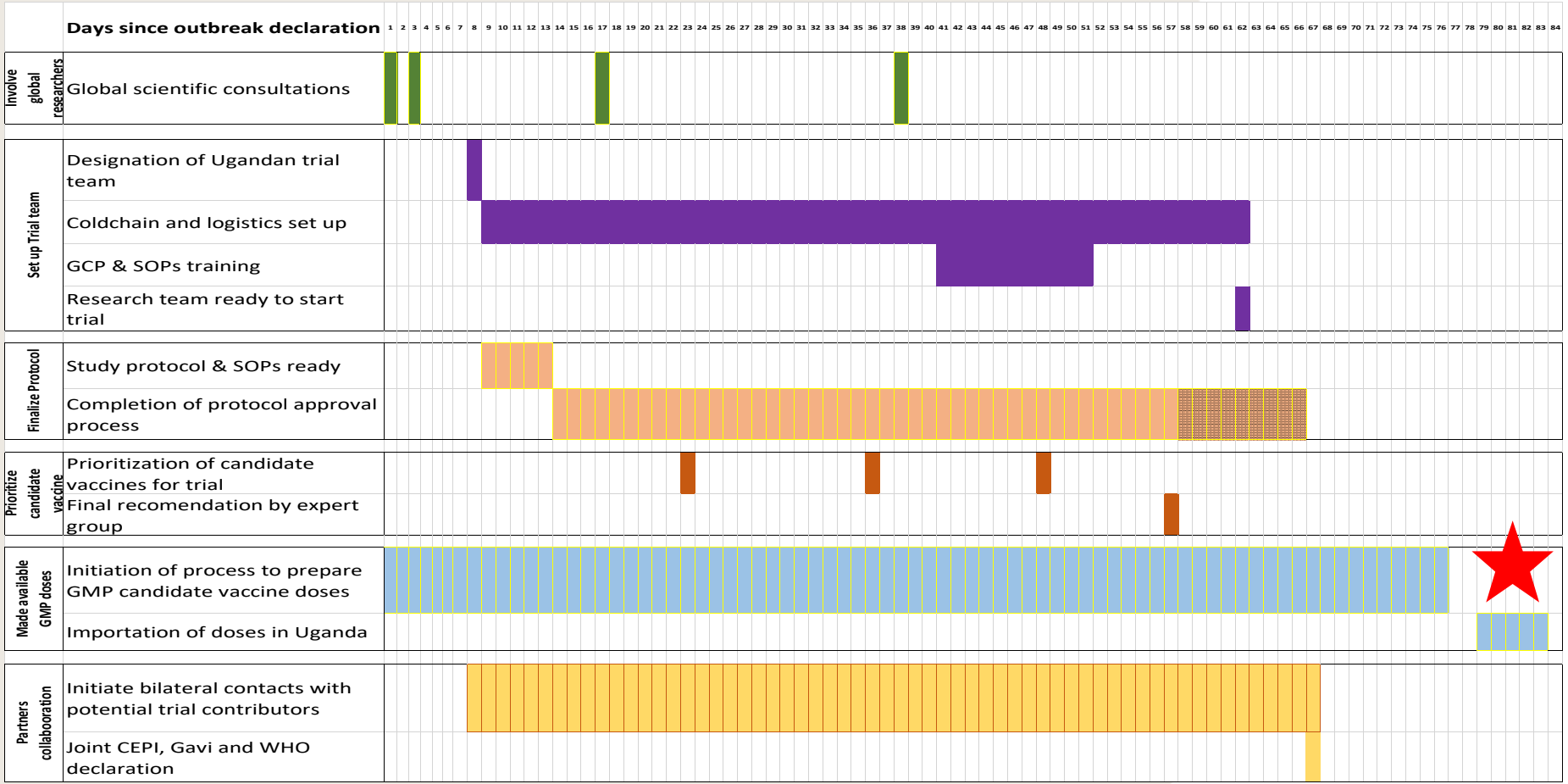
66 Protocol approval process completed at WHO and in Uganda

68 **Onset of last SUDV confirmed case**

74 Contributors met and confirmed their pledges to collaborate and support the trial

79 First candidate vaccine doses arrive in Uganda. The remaining two arrived withing days

A global collaborative effort accelerated many actions

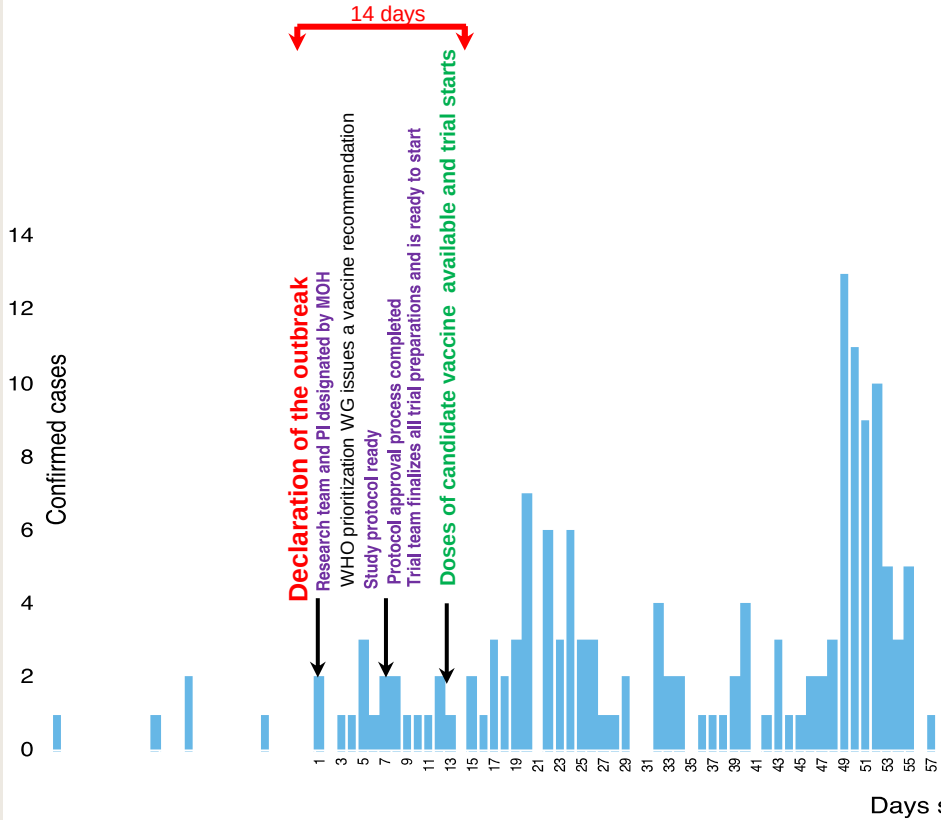


Candidate vaccines: doses ready to use for trial or deployment*

Doses in 2023	cAd3	cAdOx1	VSV
In Uganda	1,096	2,000	2,200
With developer/ manufacturer	Nearly 10,000	70,000	Nearly 95,000
Additional doses	Several thousands	Several hundred thousands	Several thousands

* Preliminary estimates subject to changes

What if we address key vaccine research milestones before the next outbreak?



- ✓ Enhanced surveillance and earlier lab confirmation
- ✓ More data to support decisions on: Prioritization, Regulatory, Deployment Future policy
- ✓ Trial ready platform - Protocol and conditional approvals available, logistics, national research teams trained on protocol & SOPs
- ✓ Data available for WHO prioritization expert group
- ✓ Doses of candidate vaccine(s) **in vials**

Since 2016, during Zaire EVD outbreaks, ring vaccination – under approved protocol & with ICF – was initiated within a few days of an outbreak being declared

Our challenge is not to prepare to respond to pandemics. Our challenge is to timely detect and respond to outbreaks (with research integrated in response) thus avoiding they expand to become a PHEIC or pandemic.

Preparing for the inevitable

Current priority pathogens to guide our collective efforts

	Generic methodology	CCHF	Ebola/ Marburg	Lassa Fever	MERS CoV/ SARS	Nipa and other Hepav	Rift Valley fever	Zika	Plague	Pathogen X	COVID-19	Monkeypox	Sudan ebolavirus
R&D Roadmap													
TPP vaccines													
TPP therapeutics													
TPP diagnostics													
Regulatory pathways													
Vaccine trial design													
Therapeutics trial design													
Decision tree for trial design													
Trial simulator													
Innovative analysis approach													
Good Participatory Practice guidelines and tools													

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Preparing for the inevitable and faster

We need advanced **strategic** investments

- Ready to go **trial platforms and protocols** in countries at risk
- Doses of GMP **candidate vaccines in vials** available (& funded)
- **More data on candidate vaccines to support decisions & prioritization** (safety, immunogenicity, other)
- Anticipatory **regulatory and ethics pre-approvals,** to inform trial designs, expanded use and/or deployment of vaccines, and import and export processes
- **Flexible funding** to be able to initiate trials promptly without inappropriate deliberations on scientific issues by donors or recipients
- Additional **strategic investment** in candidate development and evaluation

Previously agreed prioritization of candidate vaccines

Previously agreed trial platforms and simple protocols

Funded investigational vaccines already in internationally transferable vials

Previously agreed WHO insurance providing appropriate liability and compensation framework

Previously agreed funding

Rapid start of studies integrated into initial outbreak responses
Future deployment if efficacious

Thank you!

The Ministry of Health in Uganda and the Ugandan researchers: Prof B Kirenga at Makerere University's Lung Institute and Prof Pontiano Kaleebu at MRC Uganda whom with supported from WHO researchers, adjusted the protocols, trained about 200 researchers, set up the equipment needed and the processes for the the trial in record time.

The candidate vaccines developers and funders of **cAd3** (Sabin Vaccine Institute and the US BARDA and NIH), **cAdOx1** (Univ of Oxford, Jenner Institute, the UK GOV and the Serum Institute of India) and **rVSV SUVD** (IAVI, MSD and US BARDA and NIH) produced, tested and put into vials in record time (79 days!) sufficient doses of the candidate vaccines for the trial and beyond. This is faster than what was achieved during the COVID pandemic.

Several global partners including: Government of Canada, CEPI, European Union HERA and WHO allocated funds to facilitate the trial implementation. Others: Gavi, UNICEF, UKHSA, WT offered support

Scientists contributing to the expert committees: WHO prioritization Committee, the Trial Steering Group and the DSMC and the hundreds of experts who supported all the research efforts.

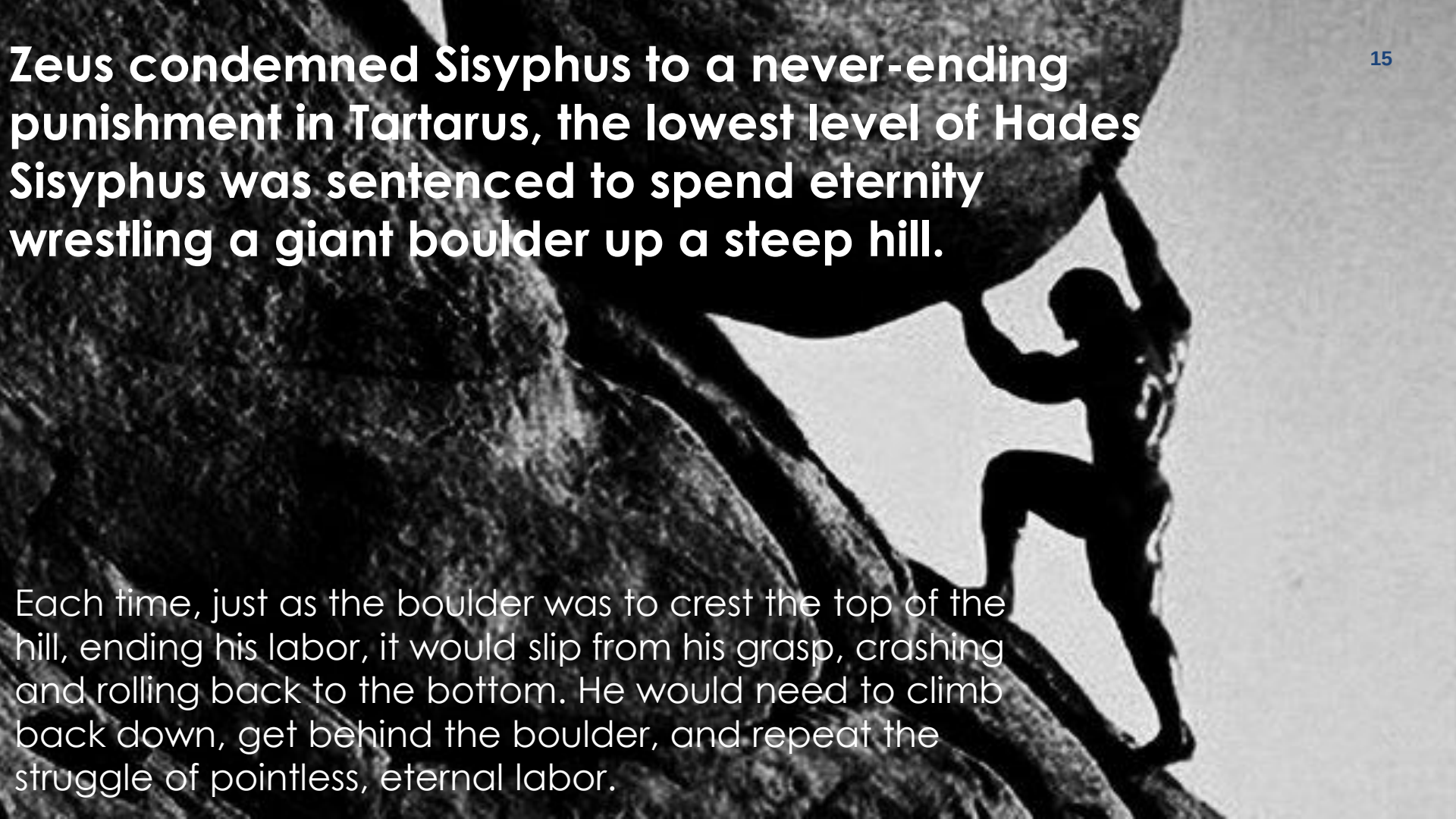
The WHO colleagues in Uganda, the African Regional Office and Geneva.

"We have demonstrated that we can do it much faster, much quicker, with the country at the center, with ethics, with all issues being properly dealt with.

We can go fast without cutting any corners.

And we can do that even faster if we invest in the sort of the countermeasures platforms that we need for the pathogens that we've identified as being important".

Mike Ryan



Zeus condemned Sisyphus to a never-ending punishment in Tartarus, the lowest level of Hades Sisyphus was sentenced to spend eternity wrestling a giant boulder up a steep hill.

Each time, just as the boulder was to crest the top of the hill, ending his labor, it would slip from his grasp, crashing and rolling back to the bottom. He would need to climb back down, get behind the boulder, and repeat the struggle of pointless, eternal labor.