Rapid Response Platforms for COVID-19 Vaccine

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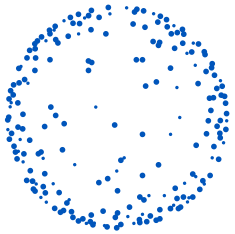
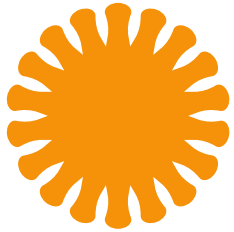
Dr. Melanie Saville, Director of Vaccine R&D, CEPI

February 2021

CEPI's strategic portfolio targets

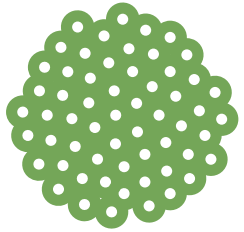


Lassa

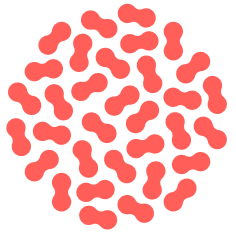


MERS-CoV

Nipah



Rift Valley Fever



Chikungunya

Disease X

Advance at least one vaccine for each pathogen through phase IIa and stockpile within five years of funding

Support activities enabling late stage development, prequalification and access

Advance through phase I multiple rapid response platforms with potential to significantly improve speed of vaccine development against multiple pathogens

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Acting fast and early

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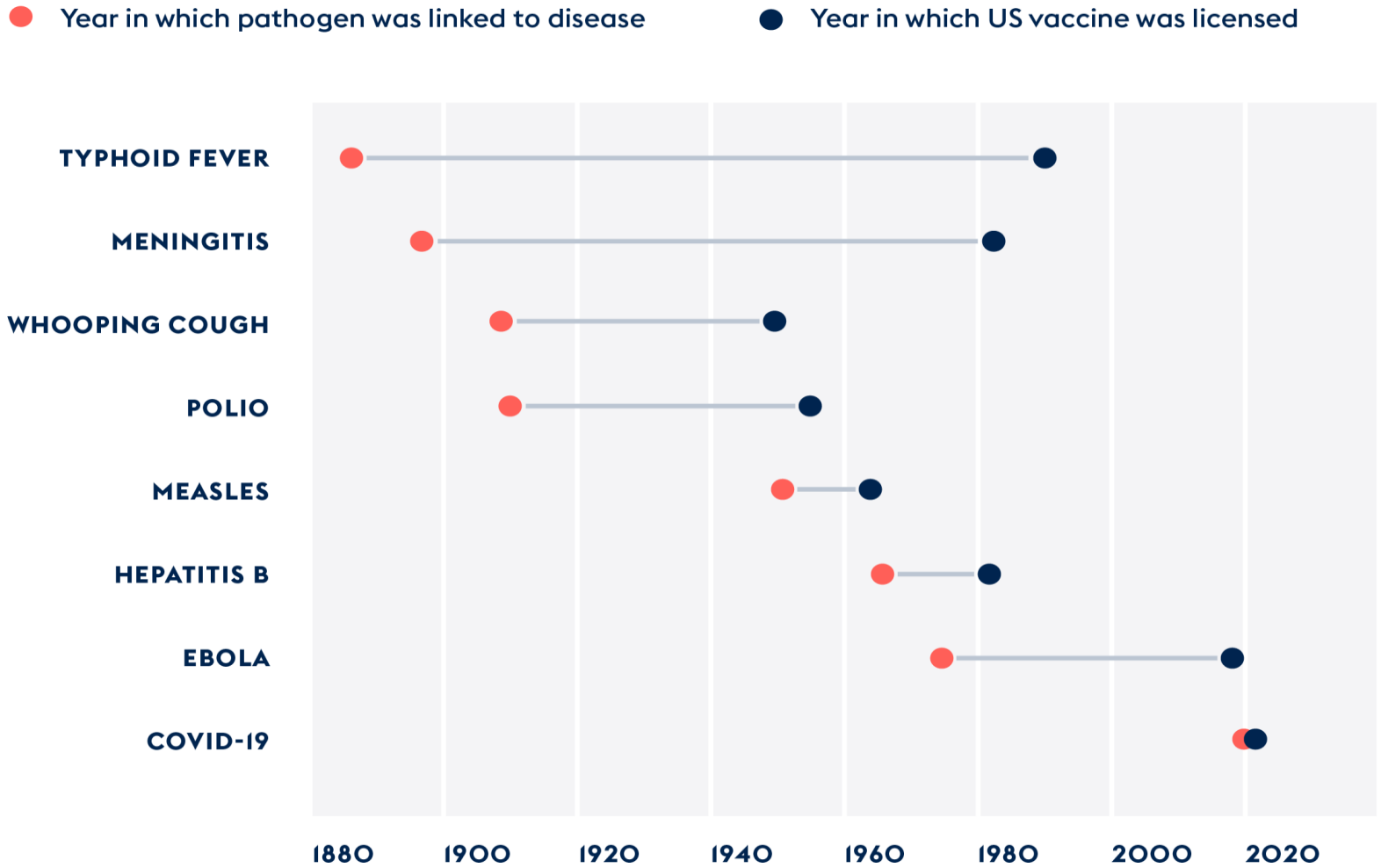
Rapid progress in vaccine innovation



Data source: Our World in Data

Jan – April 2020: Ignition Funding

31 Dec – 10 Jan

Cases of pneumonia-like virus emerging in China

CEPI monitor situation, speak to vax developers

Identified as new coronavirus

CEPI had already funded platforms in MERS and Disease X

23 Jan

CEPI announces vaccine partnerships against novel coronavirus

Inovio

Moderna

Uni. of Queensland

31 Jan

CEPI announces additional vaccine partnership

CureVac

Ongoing monitoring of situation

3-11 Feb

Launch Call for Proposals for novel coronavirus vaccines

CEPI collaborates with GSK for adjuvant technology

Disease named COVID-19

Feb

CEPI makes urgent call for $2 billion funding to support COVID-19 vaccine programmes

Governments provided financial contributions

16 Mar CEPI-supported Moderna enters Phase I trials

Mar-Apr

Additional vaccine partnerships

Novavax

Uni. of Oxford

Uni. of Hong Kong

IP/ Themis

Clover

8 Apr - 5 COVID-19 vaccines in clinical development

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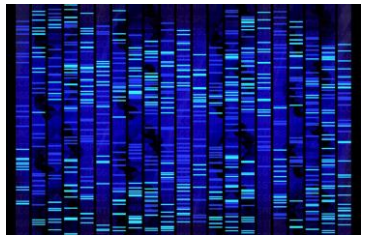
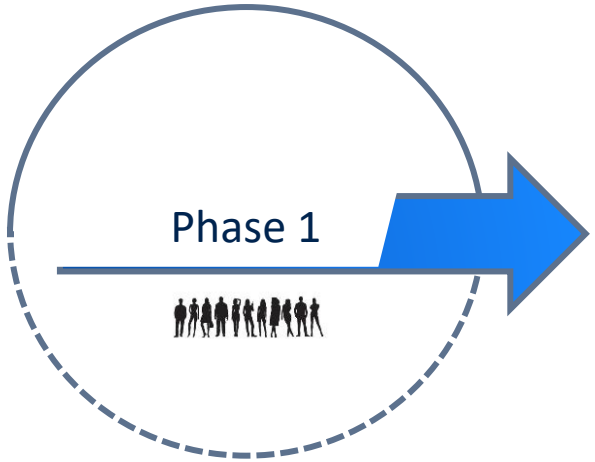
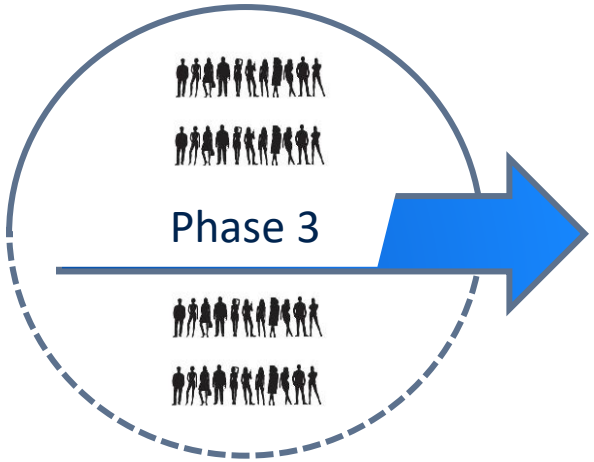
mRNA/LNP platforms demonstrated the speed of these technologies can be applied to address rapid responses against COVID

COVID-19 sequence release



12th January 2020





		FSFV	FSFV	1st VE IA
9 weeks	❖ Moderna	→ March 16th	→ **July 27th**	→ **Nov 16th**
18 weeks	❖ Pfizer/BioNTech	→ May 14th	→ **July 27th**	→ **Nov 9th**
23 weeks	❖ Curveac	→ June 19th	→ **Dec 22nd**	
24 weeks	❖ Imperial	→ June 23rd		
25 weeks	❖ Walvax	→ June 29th		
31 weeks	❖ Arcturus	→ August 11th		

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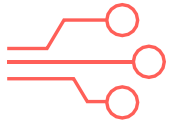
Today - 11 CEPI-supported vaccines

	DNA / mRNA			Viral vector			Protein		
COVID-19	**Inovio**	**Moderna**	**CureVac**	**Merck / Themis**	**AstraZeneca / Univ. Oxford**	**University of Hong Kong**	**Novavax**	**Clover BioPharma**	**Biological E**
Location	USA	USA	Germany	USA / Austria	UK	China	USA	China	India
Platform	DNA	mRNA	mRNA	Viral Vector	Viral Vector	Viral Vector	Protein	Protein	Protein
Antigen / Adjuvant	Full-length S protein	Full-length S protein	Full-length S protein	Full-length S protein	Full-length S protein	Receptor Binding Domain / AS03	Full-length S protein / saponin-based Matrix-M	Full-length S protein/AS03 or CPG1018	Monomer RBD /CpG-alum
Current phase	Phase II	Efficacy demonstrated Temporary approval granted by at least one Stringent Regulatory Authority	Phase II/III	Phase I	Efficacy demonstrated Temporary approval granted by at least one Stringent Regulatory Authority	Preclinical	Phase III Efficacy demonstrated	Phase I	Phase I

+ CEPI has also supported SK bioscience COVID-19 vaccine candidate as part of 'Wave 2' investments

Speed



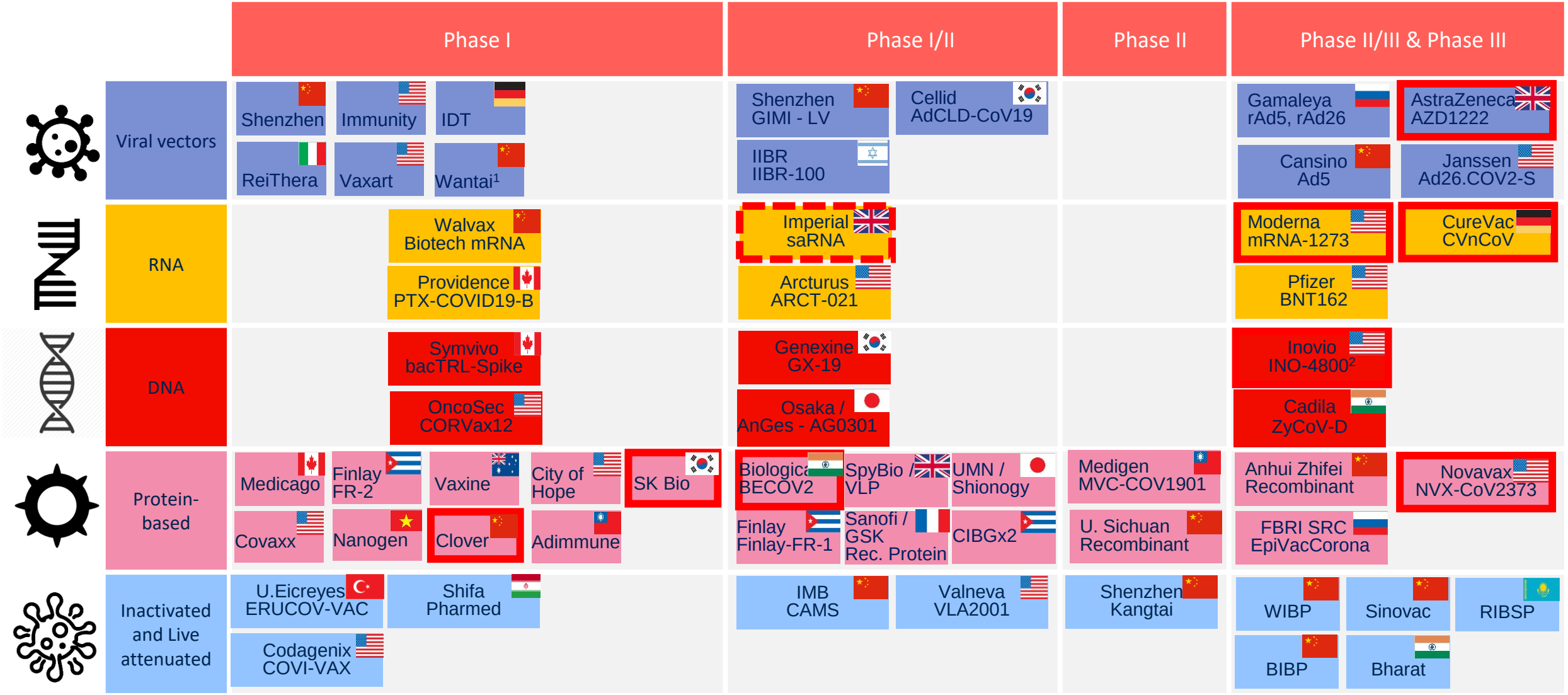
Scale

Access

Date: February 2021

World wide vaccine landscape; clinical trial status.

CEPI-funded



[1] *U.HK programme distinct from CEPI-funded programme*
[2] *Phase III segment remains partial clinical hold by FDA*

Lessons from rapid response platforms (mRNA)

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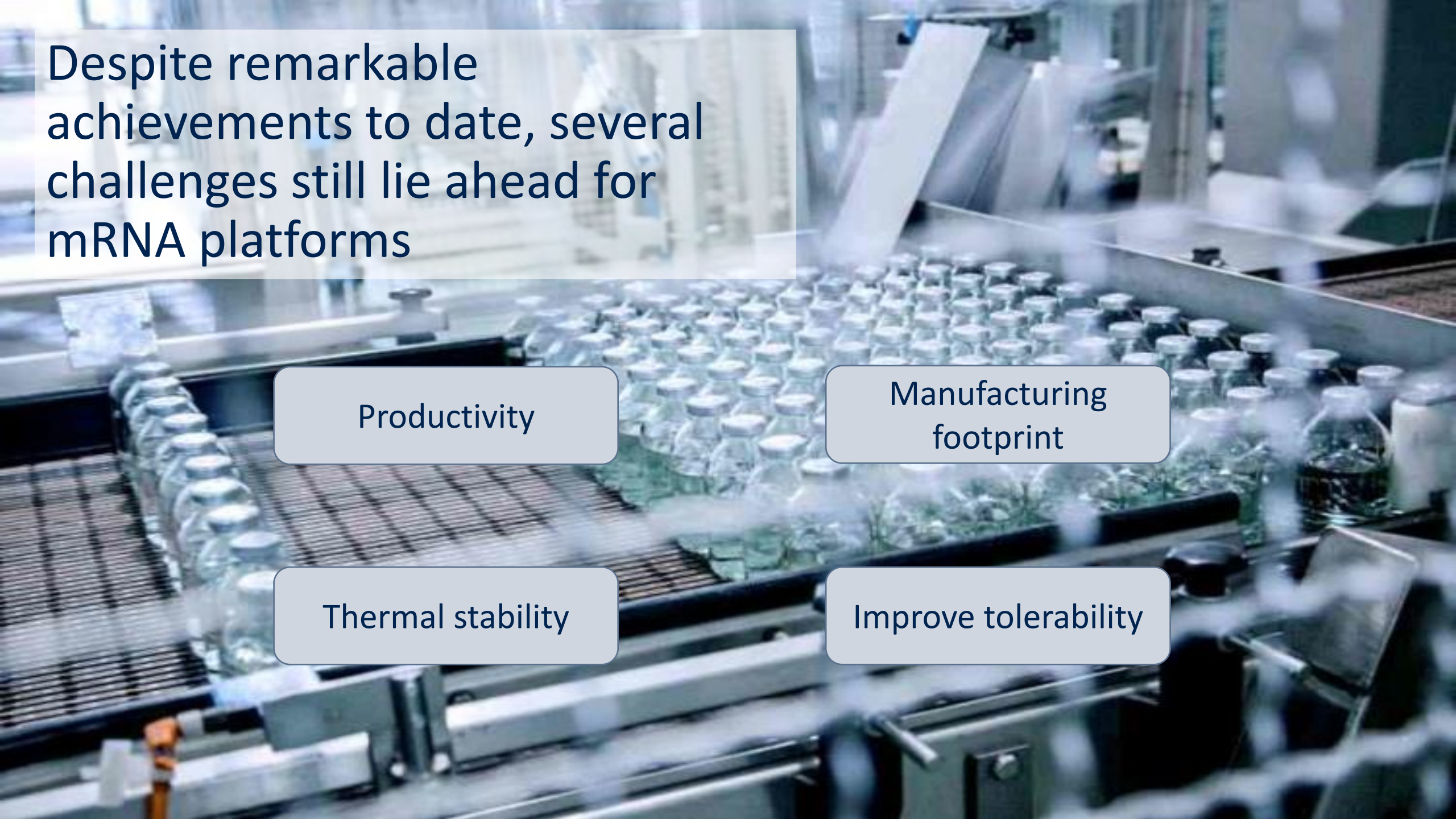
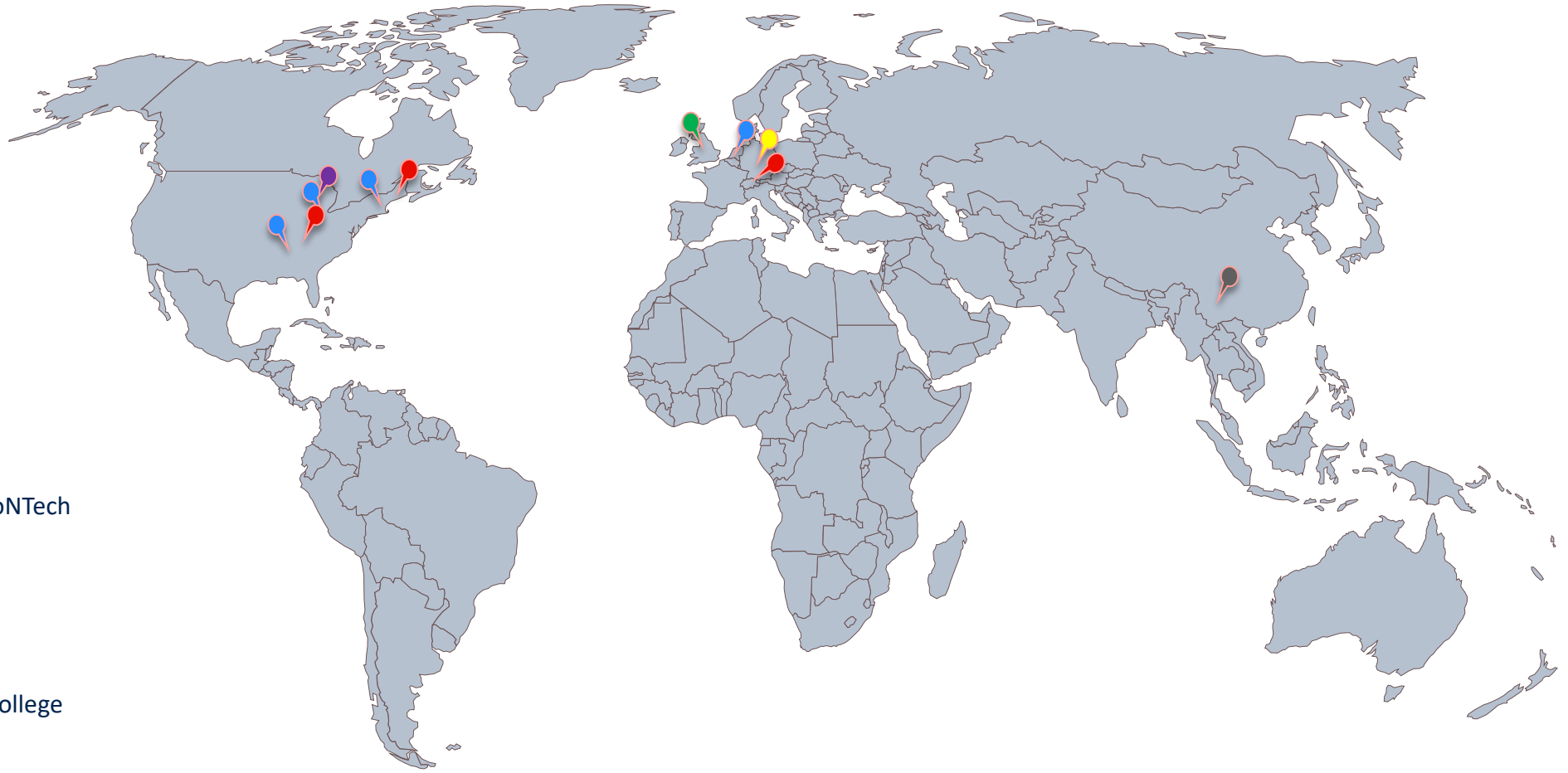

Despite remarkable achievements to date, several challenges still lie ahead for mRNA platforms
Productivity
Manufacturing footprint
Thermal stability
Improve tolerability

Limited footprint for mRNA manufacturing capabilities globally



- Pfizer / BioNTech
- Moderna
- Curevac
- Walvax
- Imperial College
- Arcturus

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Current thermal stability claims for mRNA formulations

	Moderna[1]	Pfizer/BioNTech[2]	Curvevac	Imperial[3]	Arcturus[4]	Walvax
Shipment	-20^{0}C (up to 6 mo)	-70^{0}C	Not disclosed	-70^{0}C or 2-8^{0}C	Lyophilized DP being tested at 2-8^{0}C & RT	Not disclosed
Post-thawing	2-8^{0}C (up to 30 days) RT (up to 12 hrs)	2-8^{0}C (up to 5 days)	2-8^{0}C (up to 3mo)	2-8^{0}C (data up to 3months available)		Not disclosed

Note: Several claims have yet to provide supportive data

1: Moderna R&D Day September 17th 2020
2: Pfizer investor call September 15th 2020
3: Personal communication with Prof R Shattock at Imperial
4: Personal communication with Sean Sullivan at Arcturus

The need for global equitable access

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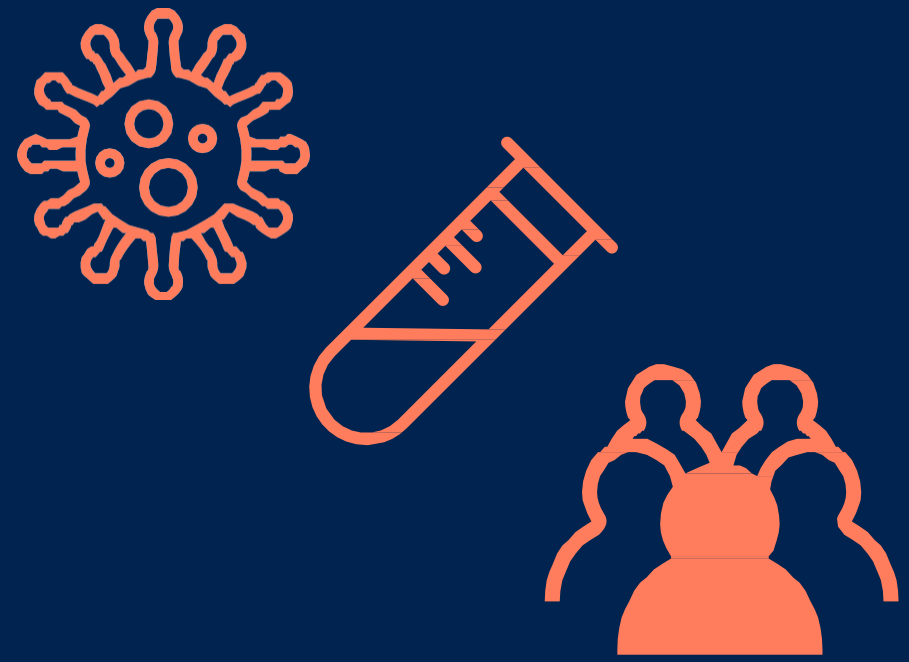
A global crisis requires a global solution

Even if a safe and effective vaccine were developed, how would it be manufactured and delivered to the billions around the world?

The Access to COVID-19 Tools (ACT) Accelerator was established as a global solution to accelerate the development, production and deployment of **vaccines** **diagnostics** and **therapeutics**.

By acting **now**, we will save millions of lives and protect the livelihoods of billions more.



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COVAX

COVAX launched to end the acute phase of the pandemic by the end of 2021.

Co-led by CEPI, Gavi, WHO. Partners include UNICEF, World Bank, civil society organisations, and others.

COVAX on track to deliver on aim to develop, manufacture and enable global equitable access **to 2 billion doses of COVID-19 vaccine**.

190 participating economies – 92 LMICs.

First right of refusal to potentially **over 1 billion CEPI-supported COVID-19 vaccine** doses.

Delivery in first half of 2021, anticipated to begin Q1 contingent with regulatory approvals and countries' readiness for delivery.

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Building on rapid response platforms for the future

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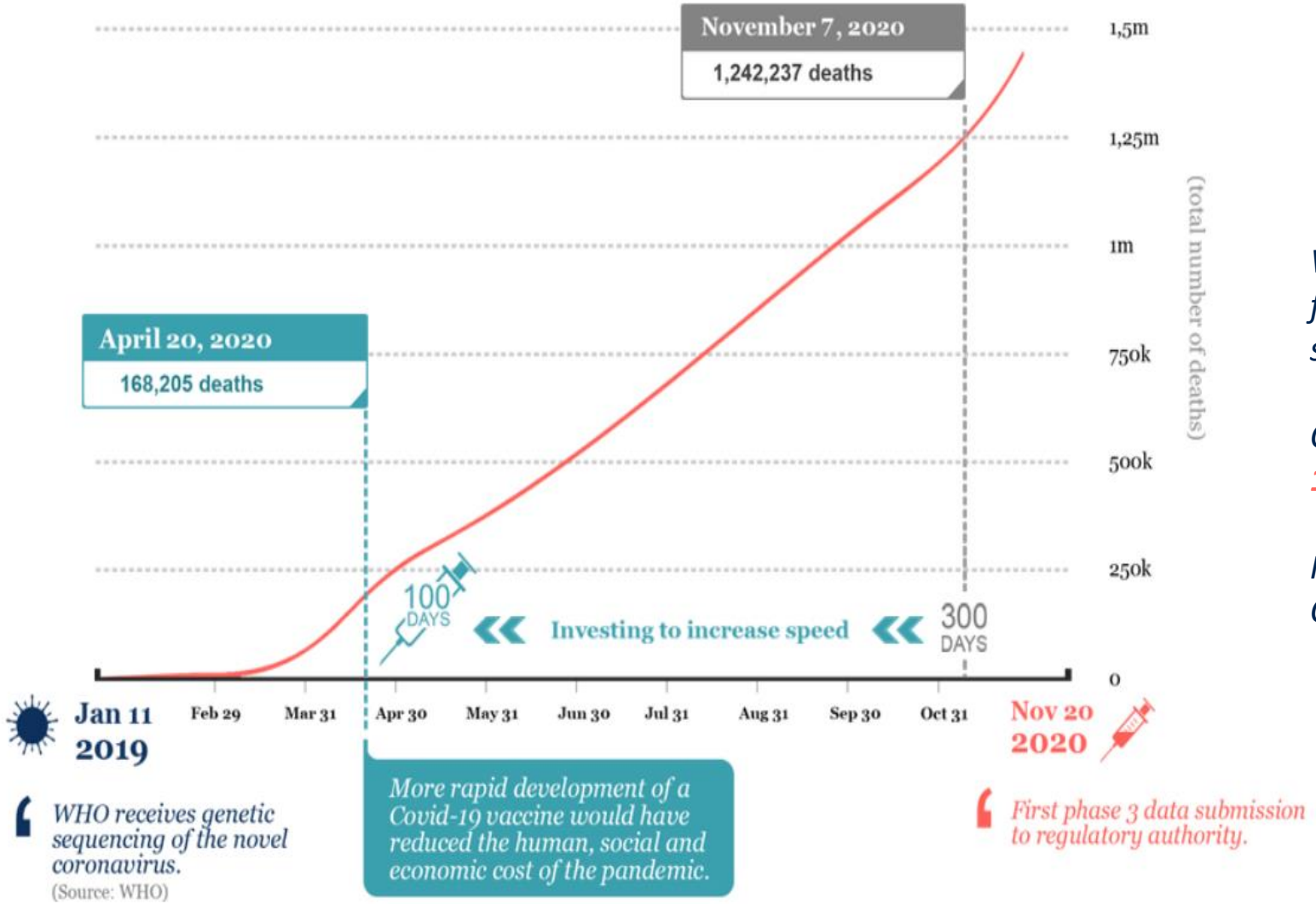
Speed is of the essence in outbreak response



*With COVID-19 it took about **300 days** from virus characterisation to submission of phase 3 data.*

*CEPI's aspiration is reduce this time to **100 days** for future outbreaks.*

*First test with **new variants** for COVID-19*

Looking to the future

COVID-19 provides an opportunity to think about how we systematically reduce the risk of naturally occurring threats

Trends are converging in a way that could make the world better prepared for the next pandemic:

- **Political will** to invest in health security
- **Revolution in vaccinology**, with multiple new platforms approved
- **Global desire** to reduce pandemic risk

Viruses are collective, transnational threats. They should be tackled collaboratively in future

- Develop global end-to-end global R&D system and financing model for preparedness and response
- COVAX can serve as a model

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