



Lessons from Rapid COVID-19 Vaccine Development

Session on Equitable Scientific Collaborations, Partnerships, and Coordination Within the US

Workshop on Applying Lessons Learned from COVID-19

Research and Development to Future Epidemics

Washington, DC 7 December 2022

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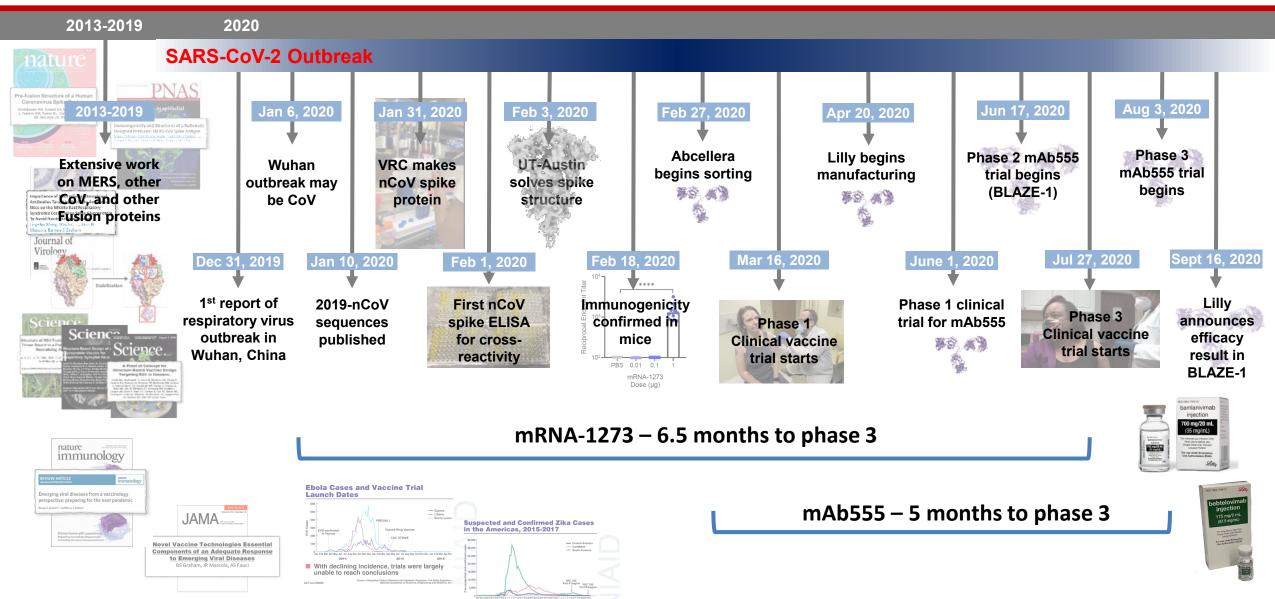
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COVID-19 VACCINE & MAB DEVELOPMENT



Readiness for COVID-19 and its Consequences

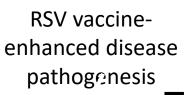


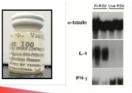


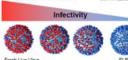
HIV-1 vaccine development













Prior responses to PHEIC and interagency coordination





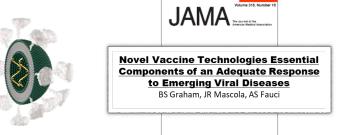




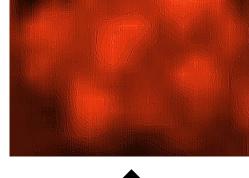


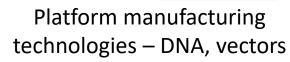






Precision vaccinology including structure-based vaccine design and protein engineering for **RSV** and CoV







Human monoclonal antibody discovery



Pre-existing public-private and academic partnerships



Prototype Pathogen Approach for Pandemic Preparedness and Response

VRC Coronavirus Collaborations

Clinical Trials Networks







Antibody Discovery



Vaccine Research Center



Basic Research



Pandemic Preparedness

基亞疫苗生物製劑股份有限公司 MEDIGEN VACCINE BIOLOGICS CO





Virus replication & evolution

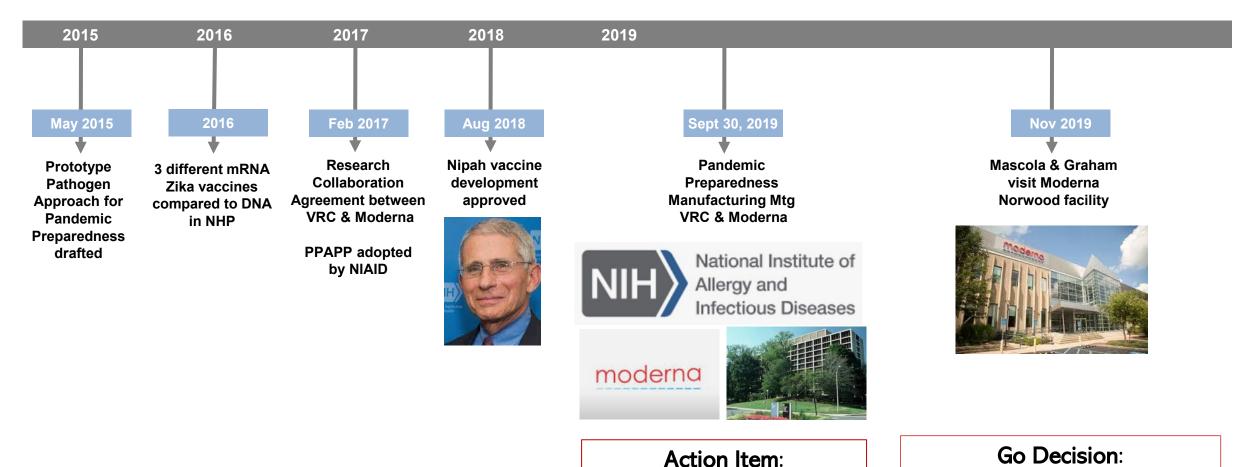


Animal models & molecular biology



Structural Biology

Pandemic Preparedness Demonstration Project



Pandemic response demonstration project

Use small-batch manufacturing for Phase 1

Government Coordination & Collaboration

2002 SARS

2002 WNV

2005 Avian influenza

2006 ASPR/BARDA

2009 Swine influenza

2011 Chikungunya

2012 MERS

2014 Ebola

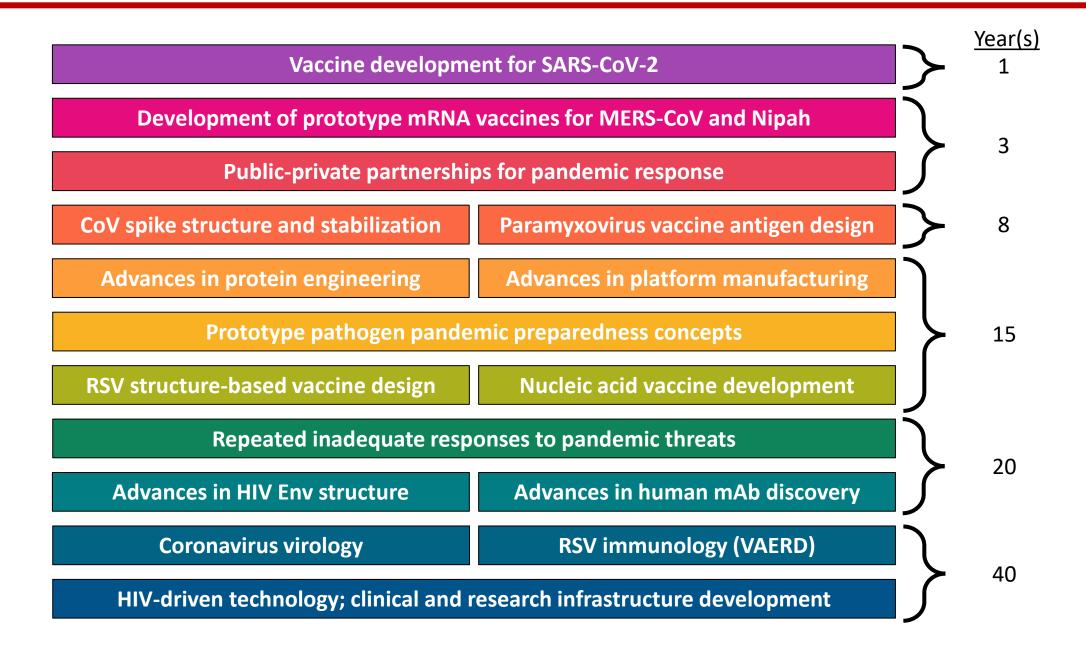
2016 Zika - ZLG

2020 SARS-CoV-2 - OWS

NIAID OD: Trial Design Scientific Support NIAID DIR & Diplomatic FDA CBER DCR: Relations Regulatory Vaccine and Oversight and Assav Assay Consultations Development Biostatistics NCATS: NIAID DAIDS: Scientific Advice Site Establishment Phase 2b Operations Project Management **VRC** Zika Vaccine **Development NIAID DMID:** DOD WRAIR: Assay Lab/Assay Collaboration Support Protocol Pharmacy tracking Consultation Support CDC BARDA Epidemiology and ASPR support **US Dept of State** Embassy/Site/Cou ntry Support

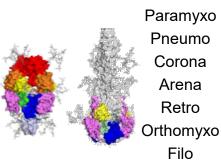
2022 H-CORE - HHS Coordination Operations and Response Element

Foundation for rapid COVID-19 vaccine development



Prototype Pathogen Approach for Pandemic Preparedness

Class I



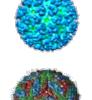
Core Functions

Sequencing/synthesis

Protein production Structure/Antigen design Antigen display/delivery Animal modeling Pathogenesis and organ-specific immunology B cell biology/serology T cell biology/flow cytometry Single cell analysis Computational biology **Bioinformatics** Process development Pilot manufacturing

Class II

Toga Matona Flavi/hepatitis C Bunyavirales order Hanta Nairo Phenui



Develop vaccines for ~30 prototype viruses through phase 1

~120 viruses from 26

families known to infect

humans with potential for

increased human-to-human

transmission and virulence

Develop vaccine candidates (& reagents) for other ~90 through animal testing

Non-enveloped

Picorna (EV-D68) Polyoma Papilloma Calici Astro

Reo

Hepe



Class III and others



Pox Rhabdo Hepadna (Arterivirus)

Herpes Phase I clinical trials

Adeno Parvo

Graham & Sullivan. Nature Immunology 2018