Security And Sustainability Forum
Convening Global Experts to Guide Decision Making

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GW Public Health

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AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.

Vaccine Manufacturing 101

Second in the Public Health Webinar Series

April 1, 2021

Kevin Yeskey, MD
Moderator
MDB's Senior Advisor for Emergency Public Health and former Principal Deputy Assistant Secretary to the HHS Assistant Secretary for Preparedness and Response

Alan Liss
Founder of GXP farma, LLC and FDA, Office of Counterterrorism and Emerging Threats

Amy Shurtleff
Senior Scientist in Preclinical Models at the Coalition for Epidemic Preparedness Innovations (CEPI)

Raafat Fahim
President of REFF Consulting and former Vice President of late-stage Development and Manufacturing at Sanofi-Pasteur

Wellington Sun
Senior Consultant, Vaxcellerant LLC and the former Head of Vaccine Strategy and Regulatory Affairs at Moderna Therapeutics.

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Public Health Webinar Series

Webinar 1: Public Health 101: How US Public Health Works – with APHA Executive Director, Georges Benjamin
Watch the video. https://vimeo.com/491848811

Webinar 2: Thursday April 1, 2021 - Vaccine Manufacturing 101, APHA, MDB, Milken Institute School

Webinar 3: Friday April 16, 2021 - Information, Data, and Tools to Support COVID-19 Vaccine Acceptance in Underserved Communities, APHA, MDB, Milken School Institute

Topics in planning include Emergency Public health, Global Environmental Health, Children's Health and others.

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Agenda

1. **Welcome:** Kevin Yeskey
2. **Introduction & Historical Context:** Alan Liss
3. **Panel Briefings**
   - Amy Shurtleff – Vaccine Pre-clinical Safety and Efficacy
   - Raafat Fahim – Vaccine Development and Manufacturing
   - Wellington Sun – Vaccine Authorization and Licensure
4. **Discussion with Audience Q + A:** *Use the box in the Go To Webinar window*
4. **Final Remarks –** Panel
5. **Closing –** Kevin Yeskey

Download the slides in the Go To Webinar window. Video will be posted shortly.

(Please Take the Brief Exit Survey. Add Questions to the GTW Window)

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Vaccine Manufacturing 101

April 1, 2021

Alan Liss, Ph.D.

GXP farma, LLC

Consulting and Mentoring

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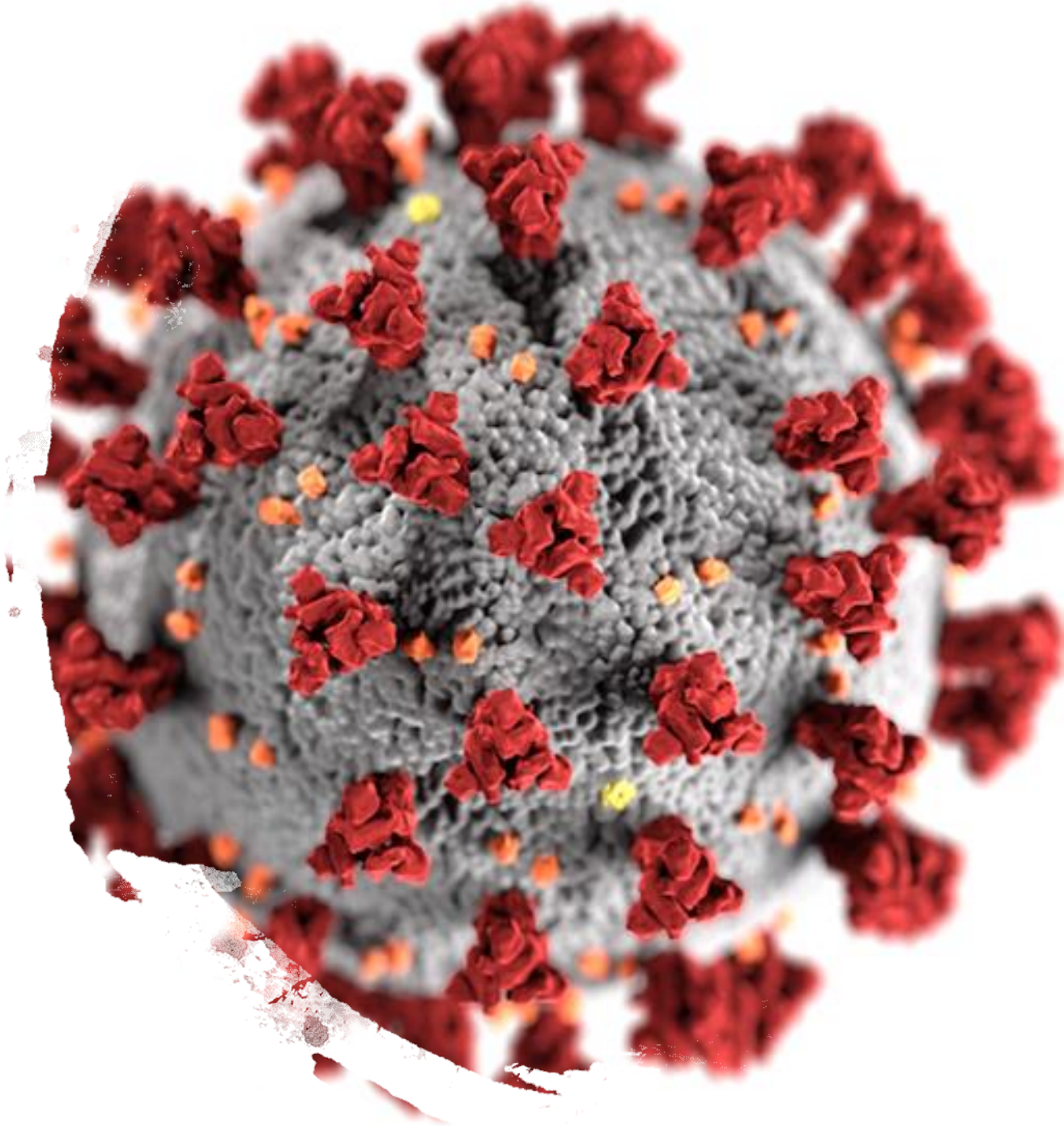
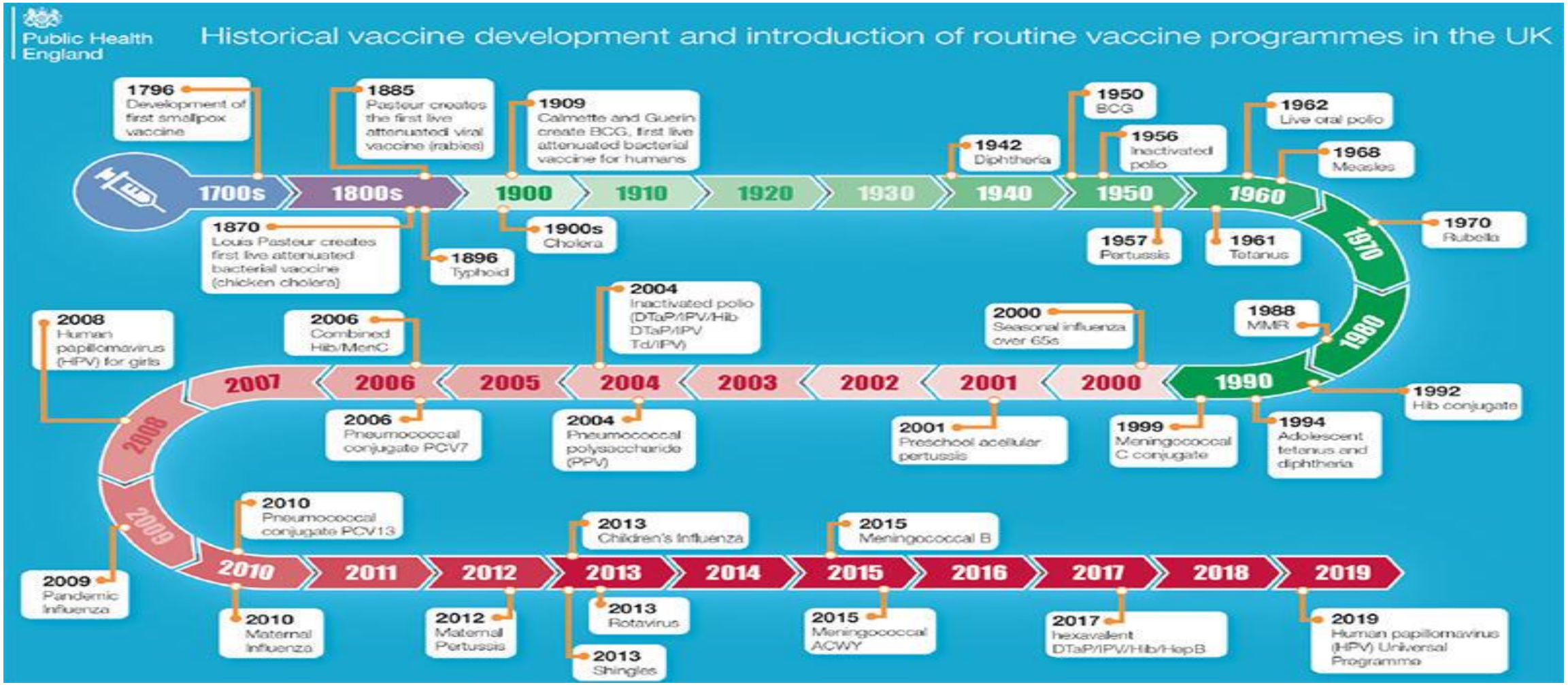
How Vaccines Work

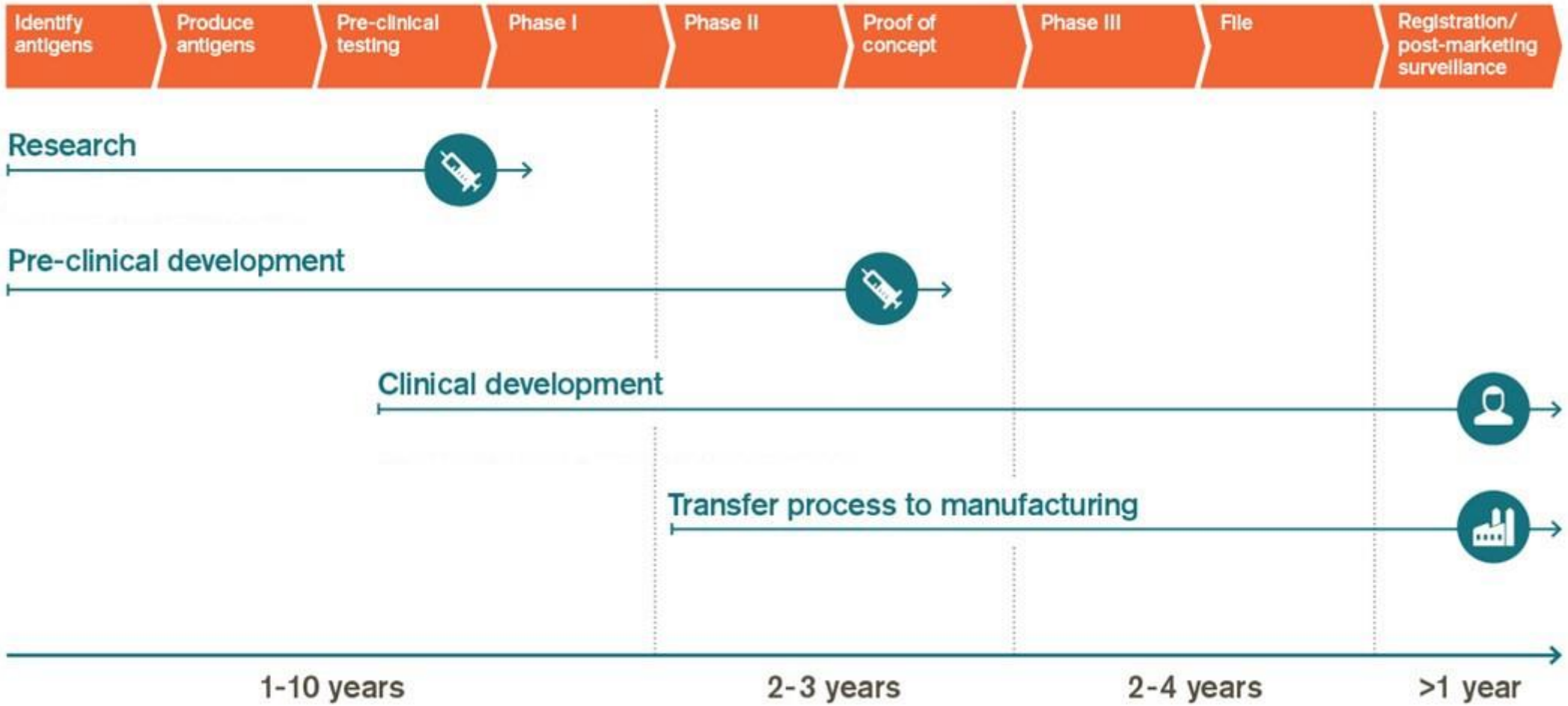
- Vaccines work by mimicking the infectious bacteria or viruses that cause disease. Vaccination stimulates the body's immune system to build up defenses against the infectious bacteria or virus (organism) without causing the disease. The parts of the infectious organism that the immune system recognizes are foreign to the body and are called antigens. Vaccination exposes the body to these antigens.
- Some vaccines contain weakened versions of a bacteria or virus, other vaccines contain only part of the bacteria or virus. Some vaccines contain only the genetic material for a specific protein and direct the body to produce a small amount of that protein. The body's immune system reacts defensively once it detects this protein.
- After vaccination, the immune system is prepared to respond quickly and forcefully when the body encounters the real disease-causing organism.



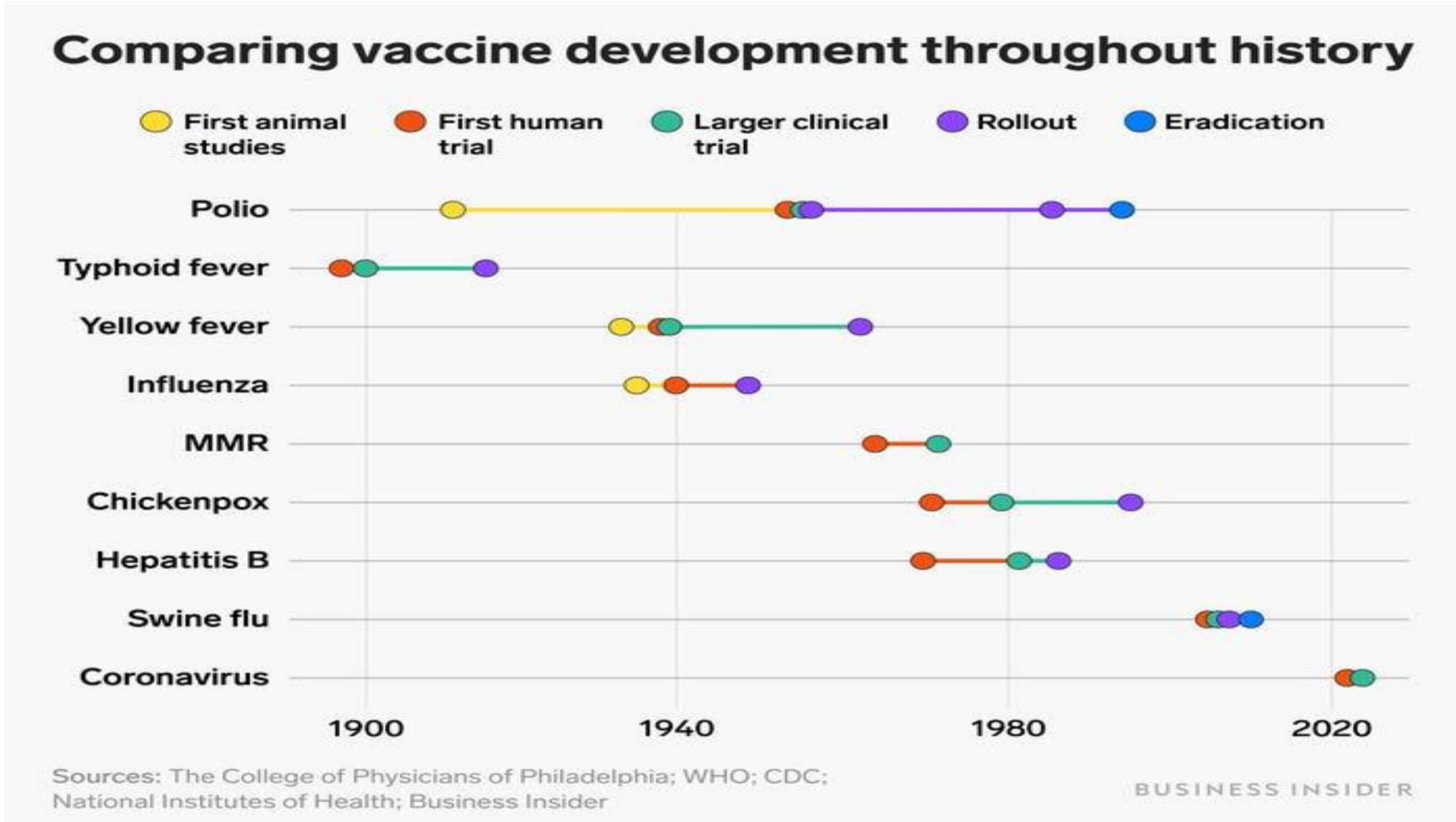
Vaccines continue to revolutionize our ability to maintain global public health quality. The development of novel vaccines is a long endeavor. It takes usually between 10 to 15 years to prevent diseases, save lives, and improve develop a novel vaccine, as well as establishing its quality, safety and efficacy.

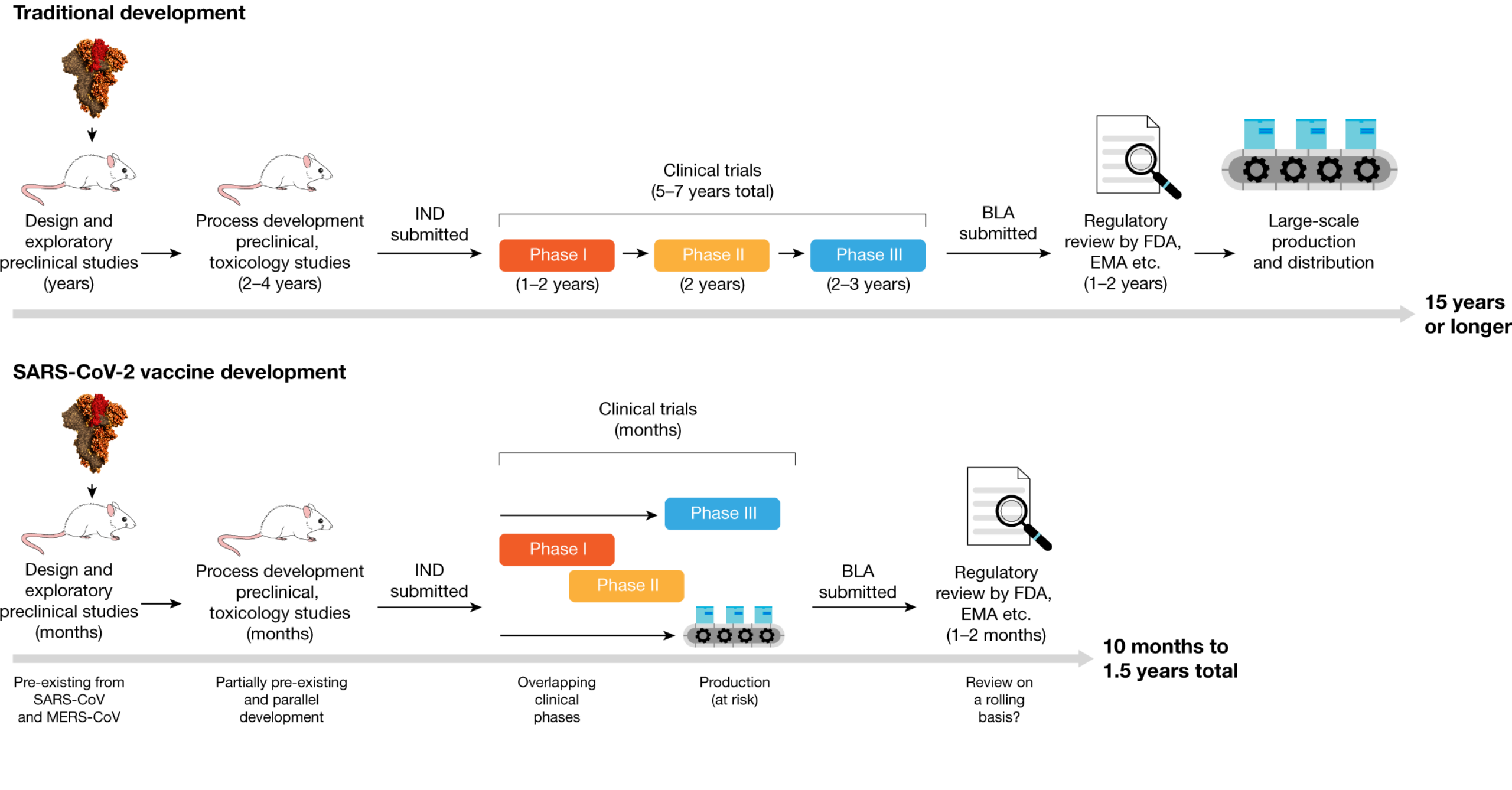


Vaccines research development cycle (industry average)

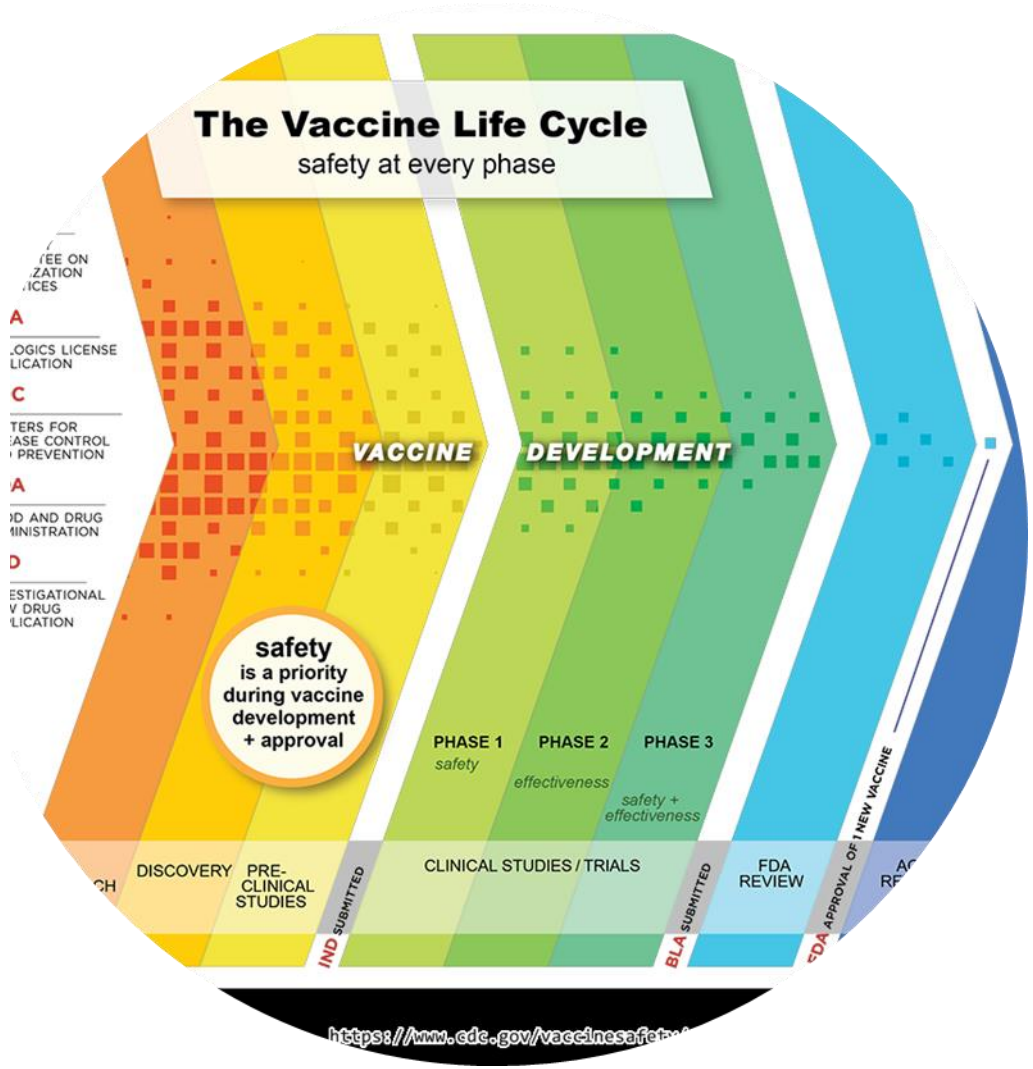


Source: ABPI


Comparing vaccine development throughout history
First animal studies
First human trial
Larger clinical trial
Rollout
Eradication
Polio
Typhoid fever
Yellow fever
Influenza
MMR
Chickenpox
Hepatitis B
Swine flu
Coronavirus
1900
1940
1980
2020
Sources: The College of Physicians of Philadelphia; WHO; CDC; National Institutes of Health; Business Insider
BUSINESS INSIDER

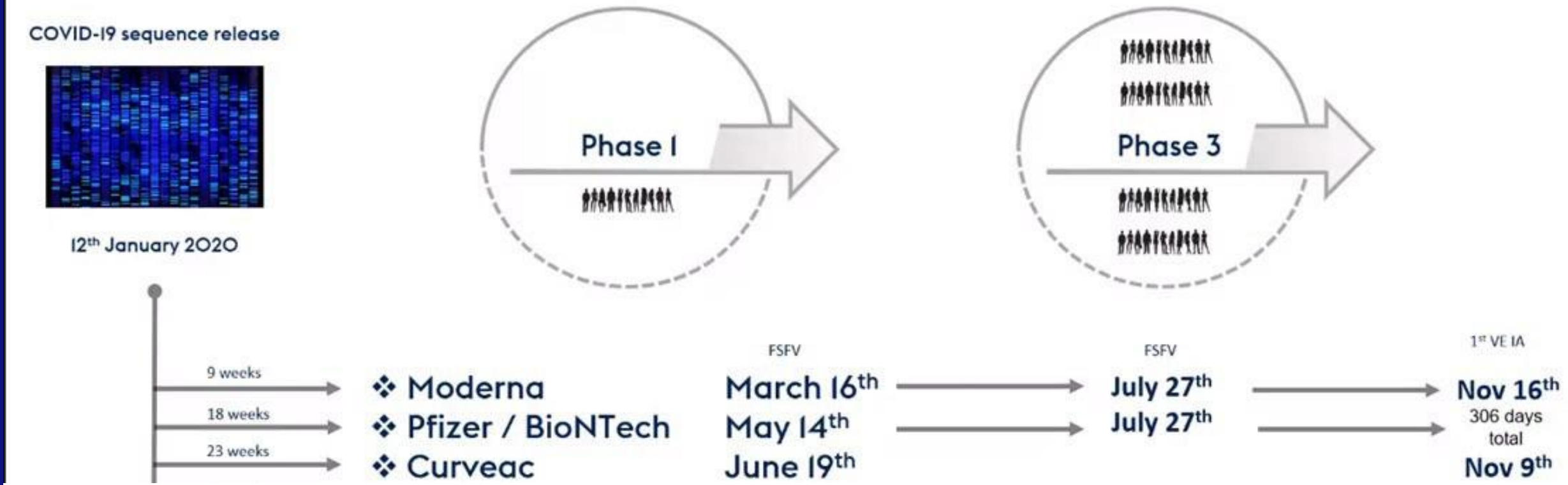

Traditional development
Design and exploratory preclinical studies (years)
Process development preclinical, toxicology studies (2–4 years)
IND submitted
Clinical trials (5–7 years total)
Phase I
(1–2 years)
Phase II
(2 years)
Phase III
(2–3 years)
BLA submitted
Regulatory review by FDA, EMA etc. (1–2 years)
Large-scale production and distribution
15 years or longer
SARS-CoV-2 vaccine development
Design and exploratory preclinical studies (months)
Process development preclinical, toxicology studies (months)
IND submitted
Clinical trials (months)
Phase III
Phase I
Phase II
BLA submitted
Regulatory review by FDA, EMA etc. (1–2 months)
10 months to 1.5 years total
Pre-existing from SARS-CoV and MERS-CoV
Partially pre-existing and parallel development
Overlapping clinical phases
Production (at risk)
Review on a rolling basis?

Vaccines continue to revolutionize our ability to maintain global public health quality. The development of novel vaccines is a long endeavor. It takes usually between 10 to 15 years to prevent diseases, save lives, and improve develop a novel vaccine, as well as establishing its quality, safety and efficacy.



Preclinical approaches to quickly find safe and effective vaccines against COVID-19

Amy C. Shurtleff, PhD
Senior Scientist, Preclinical Models
CEPI

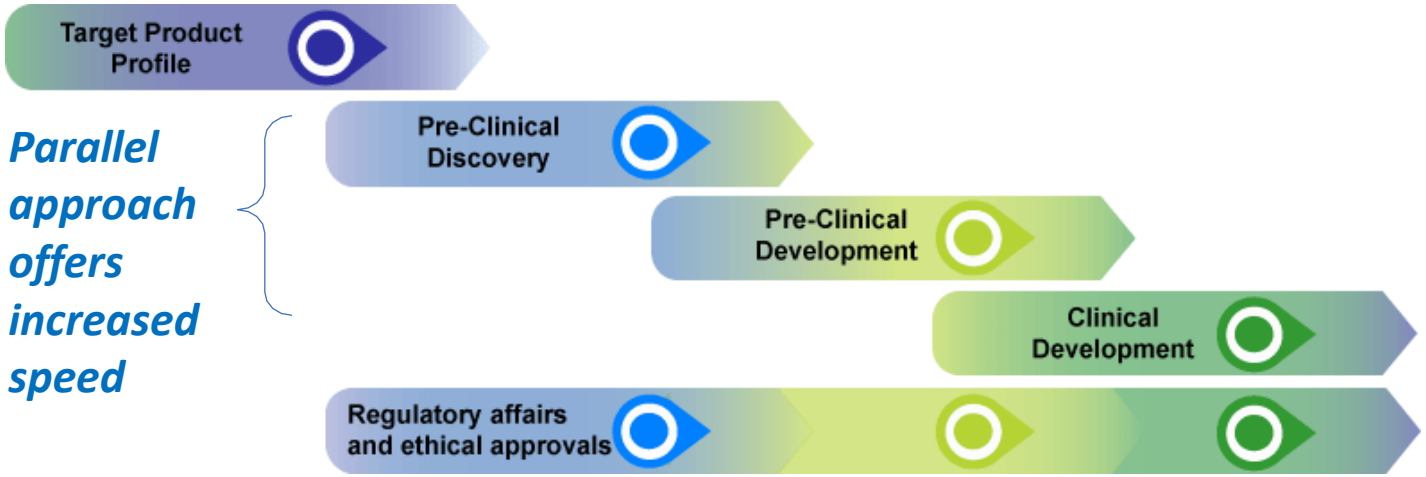


New speeds of vaccine development never seen before

What previously took 10-20 years has been done in about 300 days

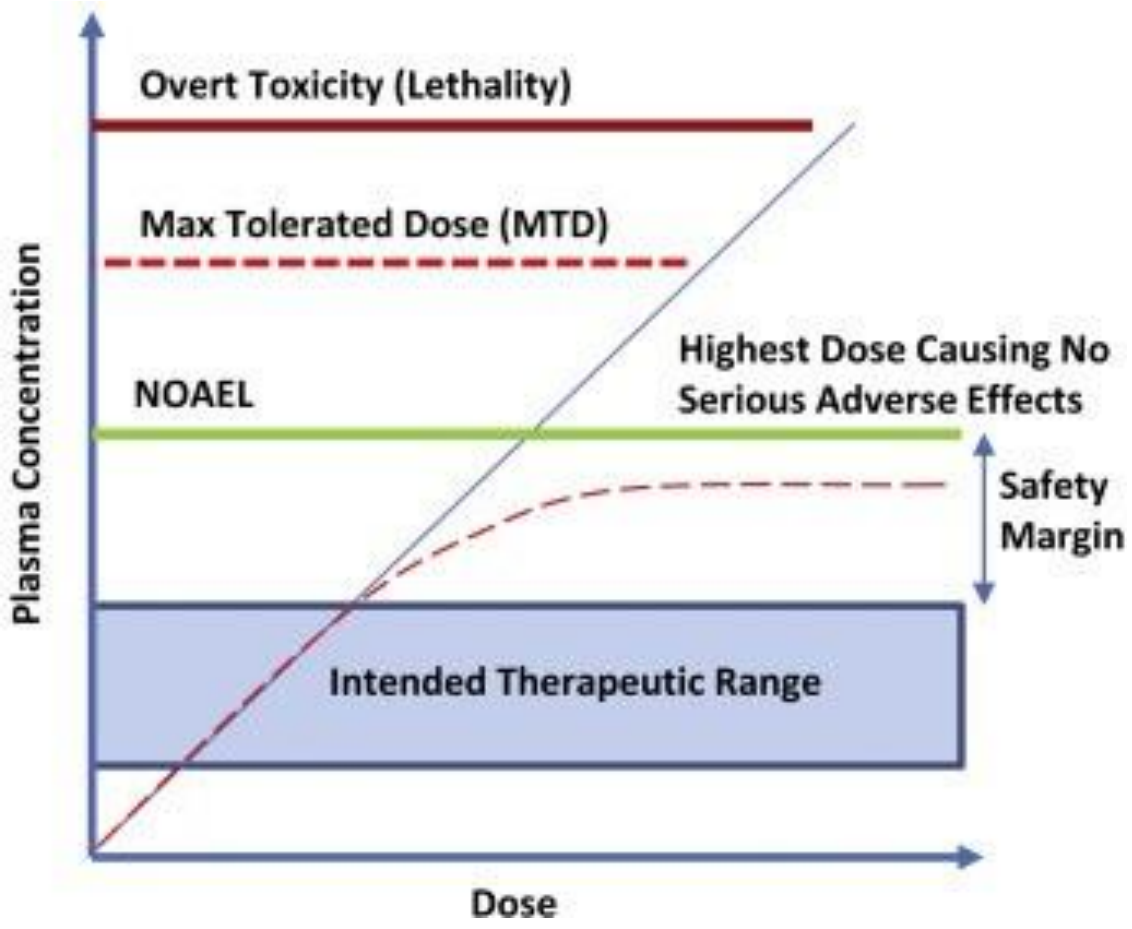
How do early vaccine discovery efforts work?

https://www.vaccinedevelopment.org.uk/index.html



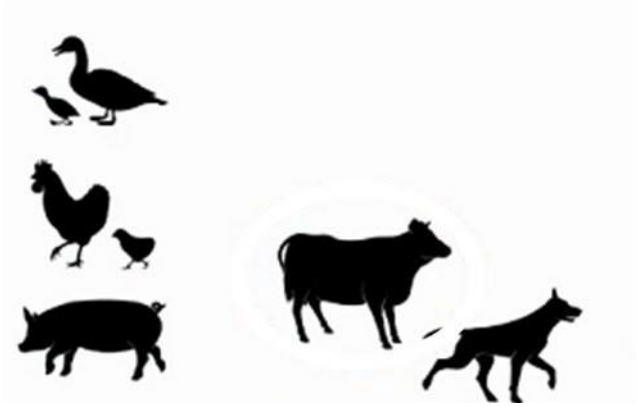
- **Preclinical discovery studies** prove safety, immunogenicity and efficacy in lab animal models
  - Mice, hamsters, rabbits
  - Larger species
- Safety: dose ranges, dose frequency, any toxic tissue effects/pathology, lack of integration into cellular genetic material, teratogenesis, mutagenesis
- Immunogenicity: humoral and cellular immune responses, antibody binding assays (ELISA), virus neutralizing assays (antibody based blockage of virus *in vitro* assay)
- Efficacy: blocks disease or viral growth in animal model of infection
- Speed: studies can be done in parallel, **shaves off time *not safety***

Safety studies evaluate doses above human level



- Dose multiple times at increased dose levels (0 mcg vs 1, 10, 100, 1000 mcg etc)
  - Look for changes in body weight, appetite, appearance, health
- Dose multiple times at high dose levels
  - 100 mcg or 1000 mcg
  - Look for same
- Concept of n+1
  - *dose 1 + dose 2 + dose 3 at 100 mcg or more*
  - Data must show safety in animals given 1 dose more than what is planned for humans
  - Planned human dose might be 2 doses of 30 mcg or 100 mcg

Best animal models showing disease/ prevention of disease by vaccination



Hamster, NHP
hACE2 transgenic mouse

Less susceptible

More susceptible

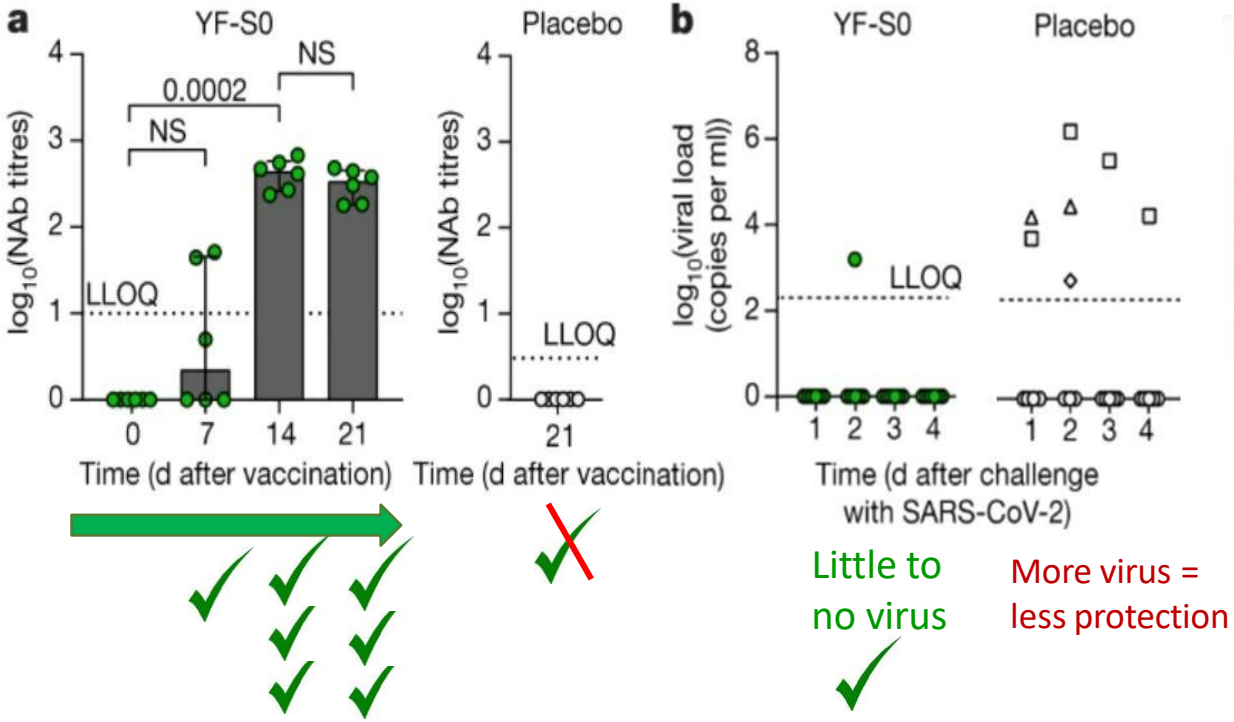
Generally suitable species for lab investigations,
laboratory reagents to perform immune function analyses

Virus genome detection
Seroconversion - antibodies
Transmission

Clinical signs of disease

Early efficacy studies show solid protection from disease in vaccinated animals

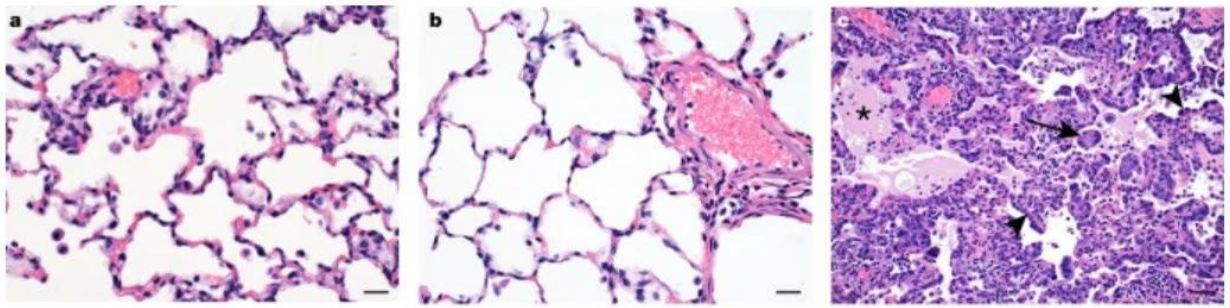
Fig. 3: Immunogenicity and protective efficacy in cynomolgus macaques.



Published reference:
Dallmeier K et al., Nature 590, 320-325 (2021), YFV vaccine construct expressing SARS-CoV-2 S protein

Infected lung tissue from…

Fig. 4: Histological changes in lungs of rhesus macaques on 7 d.p.i.



…1 dose of vaccine, protection

…2 doses of vaccine, clear protection, clear air space in lungs

…unvaccinated control animals show COVID-19 pneumonia

Published reference:
Van Doremalen, N et al., Nature 586, 578-582 (2020), Oxford/AZ adenovirus vaccine construct expressing SARS-CoV-2 S protein

Respiratory imaging shows similarities between human and animal disease

Chest CT scanning is a sensitive, accurate and rapid diagnostic tool

Human patient CT images

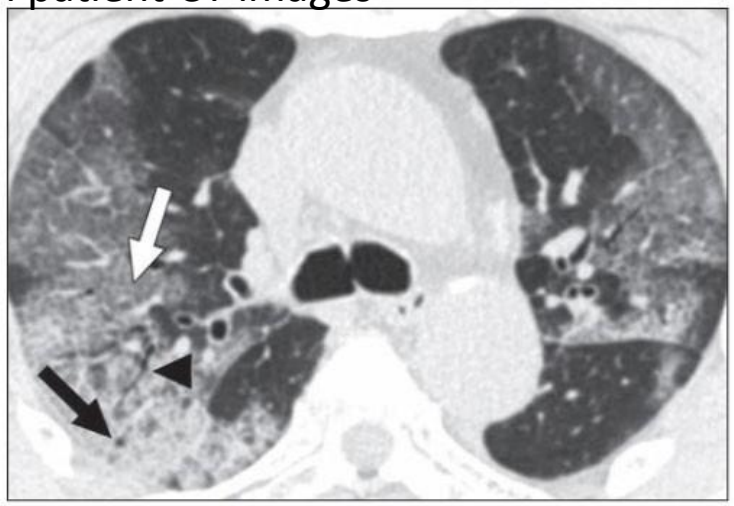


Fig. 2—77-year-old woman with coronavirus disease (COVID-19). Transverse CT scan shows multiple ground-glass opacities and consolidation with thickened intralobular and interlobular septum (*white arrow*). Air bronchogram sign (*arrowhead*) and air trapping (*black arrow*) are present.

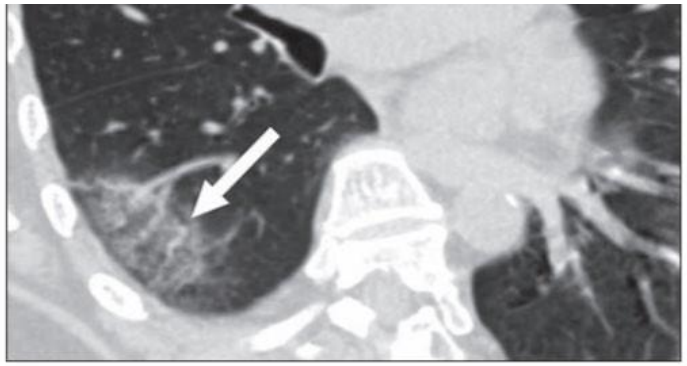
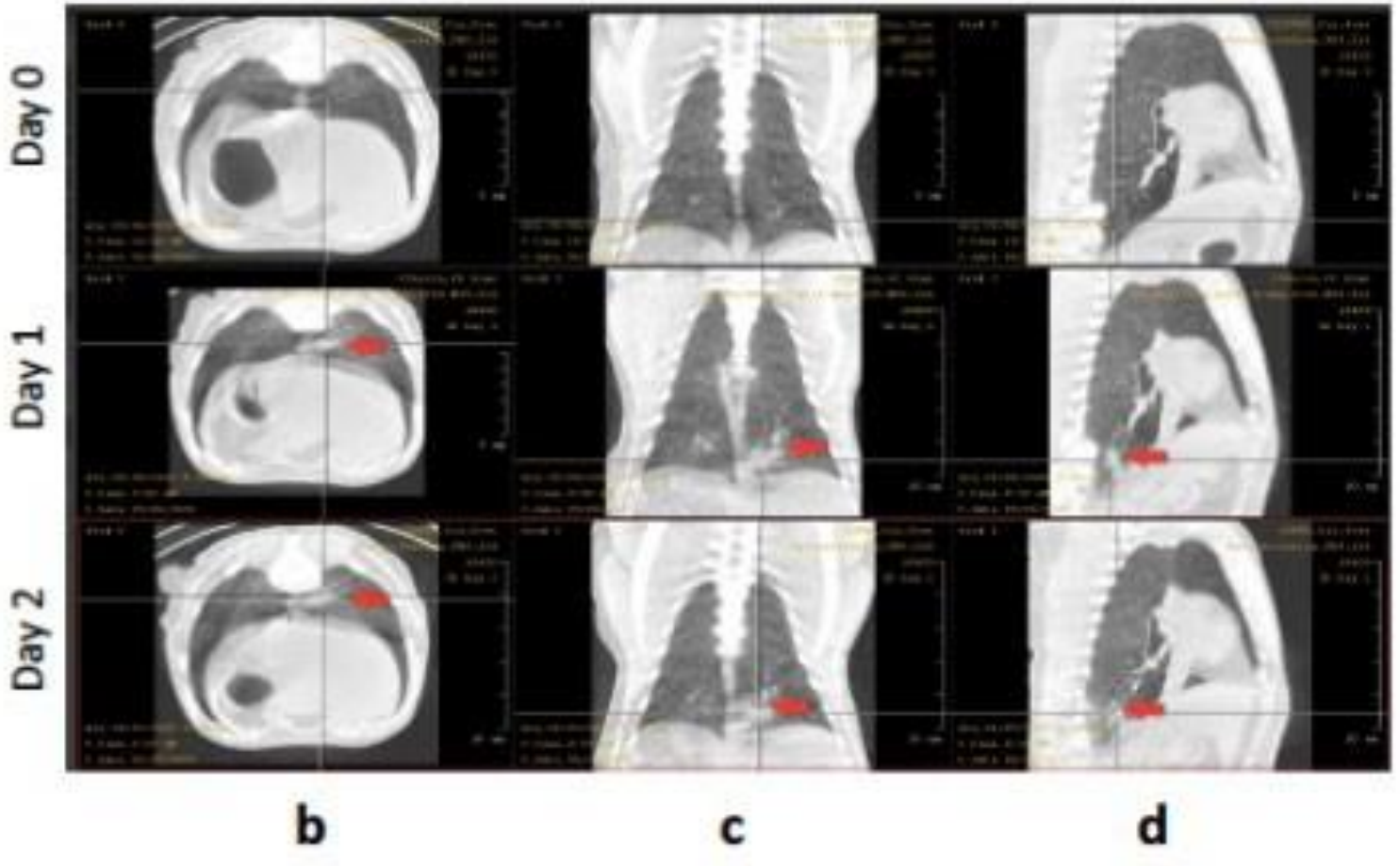


Fig. 3—61-year-old woman with coronavirus disease (COVID-19). Oblique transverse CT image shows ground-glass opacities with vascular enlargement (*arrow*).

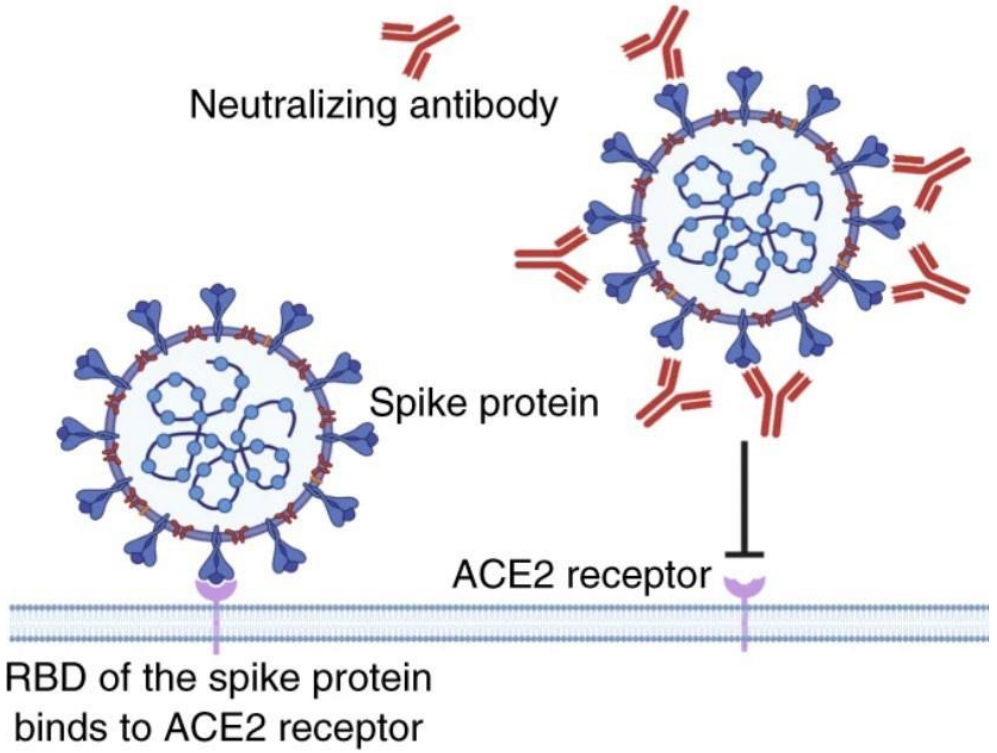
Published reference:
Li Y and Xia L. AJR: 214, June 2020

NHP CT images

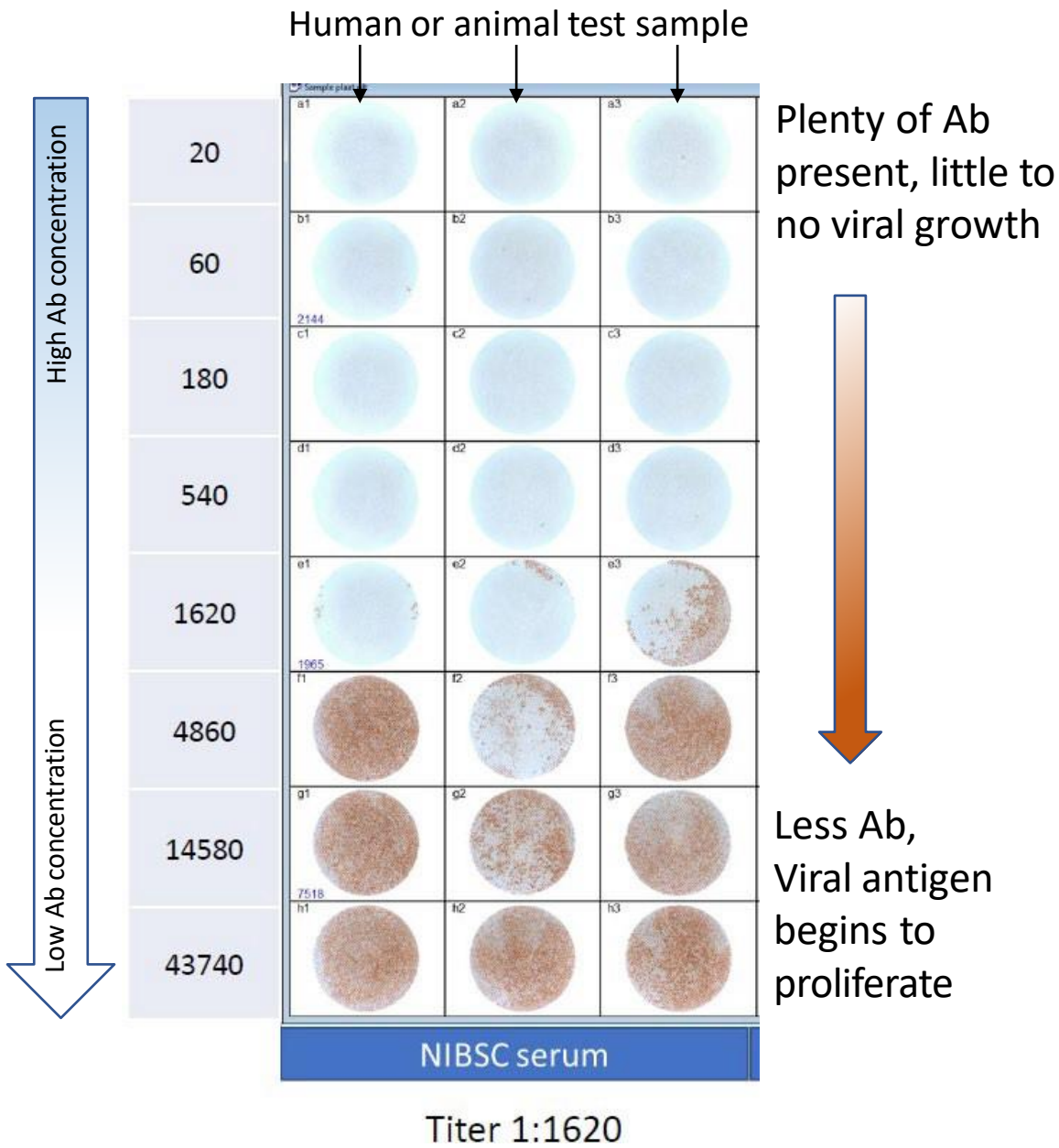


Pre-print reference:
Singh DK et al., https://doi.org/10.1101/2020.06.05.136481

Immunology assays – neutralizing antibodies block virus entry into cells



Live virus is used at BSL-3
Pseudotyped virus at BSL-2



https://www.nature.com/articles/s41587-020-0631-z

Vaccine development can be safely accelerated, if activities are done in concert

Safety studies were not sacrified in the rapid development of COVID-19 vaccines

- *Studies performed in parallel cut time off development process*

Lab animal studies are beneficial for selecting safe and effective doses of vaccines for humans

Looking for patterns of benefit we want to see in people

- *High antibody response, little to no virus replication, clear lungs in imaging studies*

During preclinical work, vaccine manufacturing and regulatory evaluation of data also happening in parallel; speeds up vaccine development time.

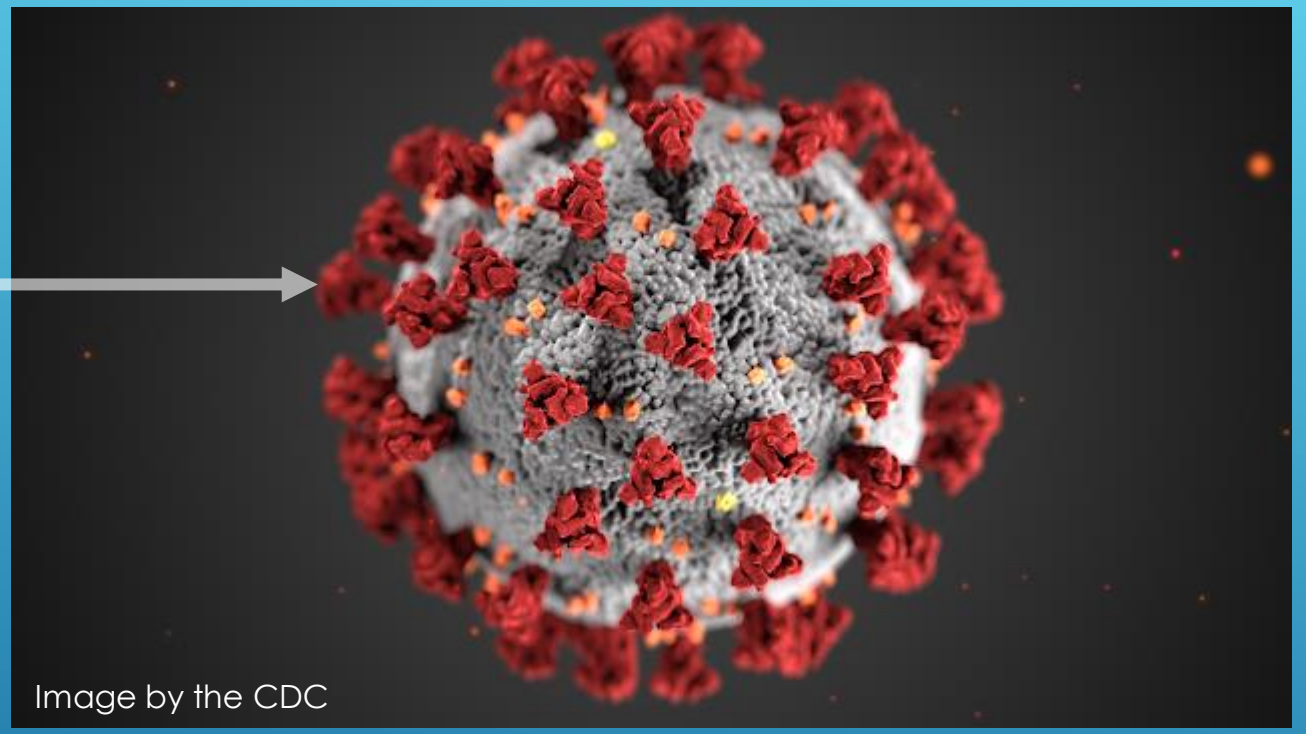
COVID-19 VACCINES..

DEVELOPMENT AND MANUFACTURING

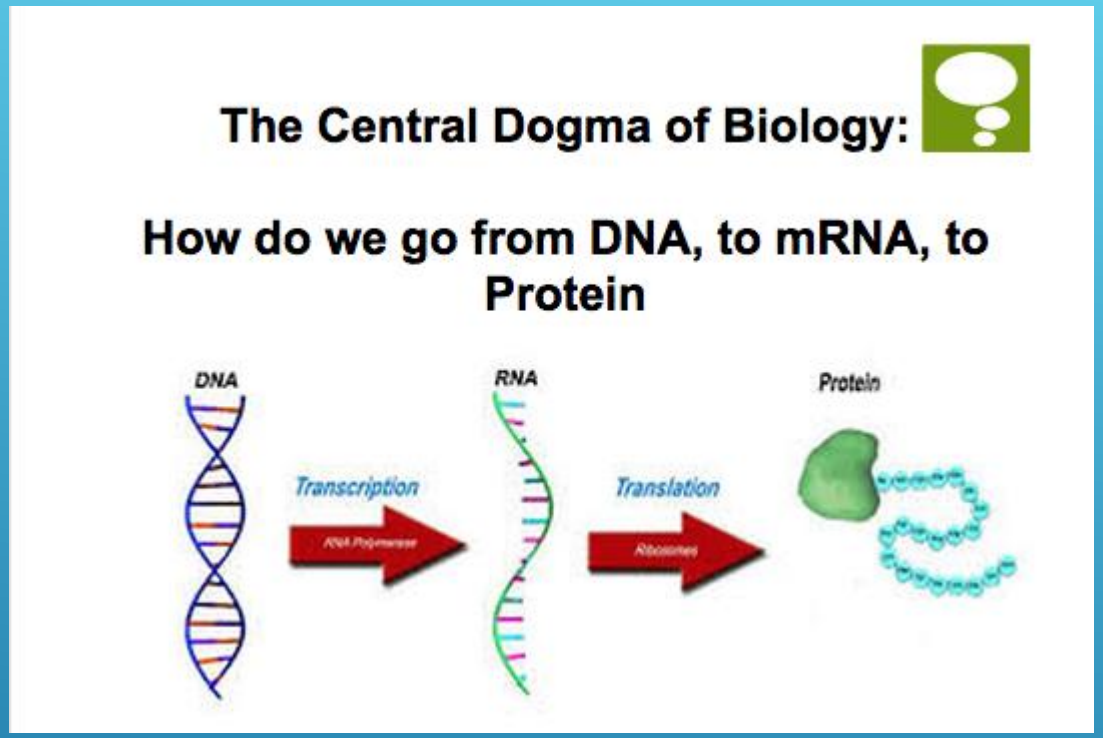
Raafat Fahim, Ph.D.

SARS COV-2 VIRUS CAUSES COVID-19

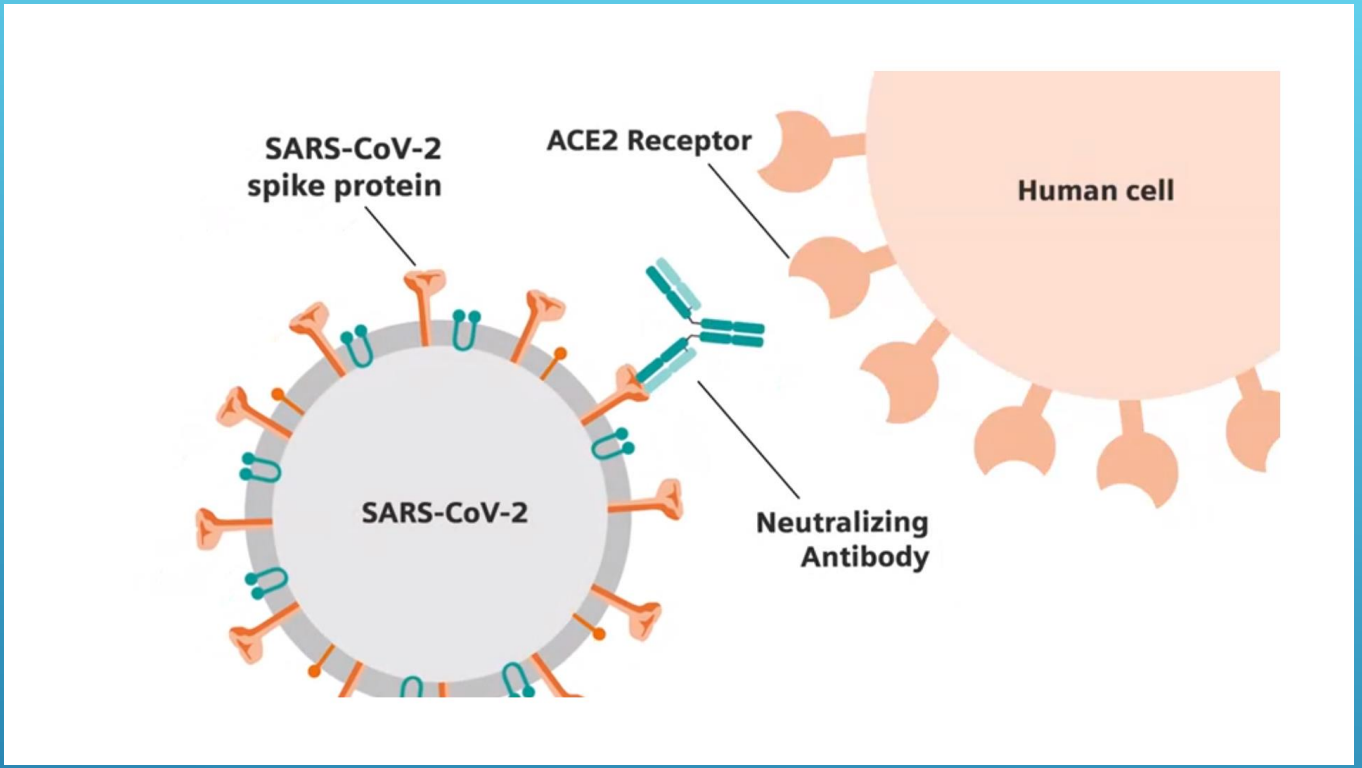
- Spike



The virus binds to special receptors on the cells through the Spike protein, enters and replicates in the cells



IMPORTANT BASIC BIOLOGY INFORMATION



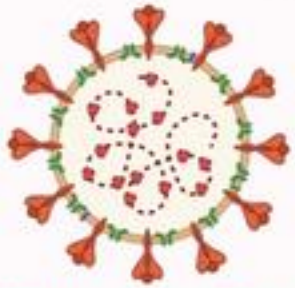
NEUTRALIZING ANTIBODIES PREVENT SARS-COV-2 FROM FUSING TO CELLS

HOW DO COVID-19 VACCINES WORK

- Covid-19 vaccines contain (or trigger the production in the body of) all or parts of the spike protein of the virus
- When injected, the vaccine provoke an immune response by training our bodies to recognize and produce specific antibodies to the spike protein
- If a vaccinated individual encounters the virus in the future, the antibodies bind and neutralize the spike protein and prevent the virus from attaching to the cells

a. Inactivated vaccines

Inactivated vaccines contain SARS-CoV-2 viruses that are chemically inactivated

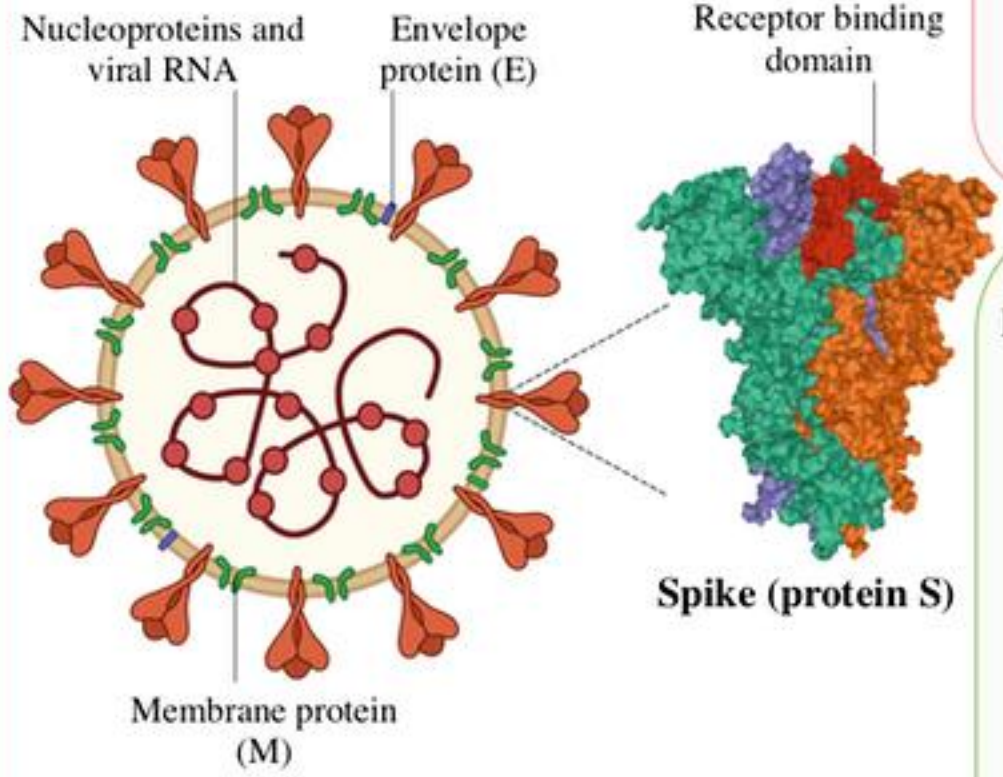


b. Recombinant proteins vaccines

Vaccines composed of recombinant spikes

Vaccines composed of receptor binding domain

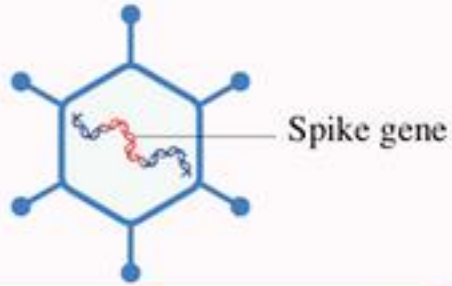
Virus-like particles are devoid of genetic material but display spikes, M and E proteins on their surface



SARS-CoV-2

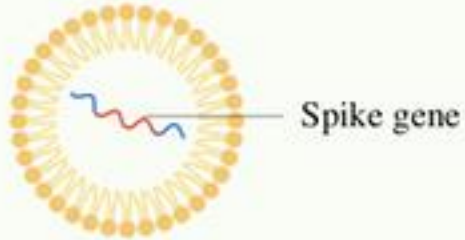
c. Viral vector vaccines

Viral vector vaccines contain another virus modified to express S protein



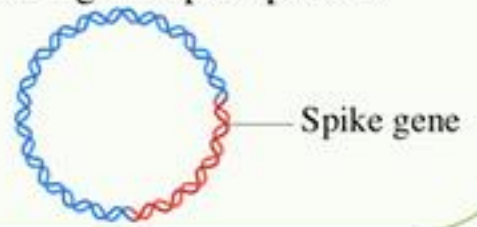
d. RNA vaccines

RNA vaccines consist of RNA packed in lipid nanoparticles



e. DNA vaccines

DNA vaccines contain a circular DNA encoding the spike protein



Generic Manufacturing Process

Thaw cells in T-flask

CellSTACKS

Spinner Flasks

Bioreactor

Harvest

Ultrafiltration 1

Treatment

Chromatography

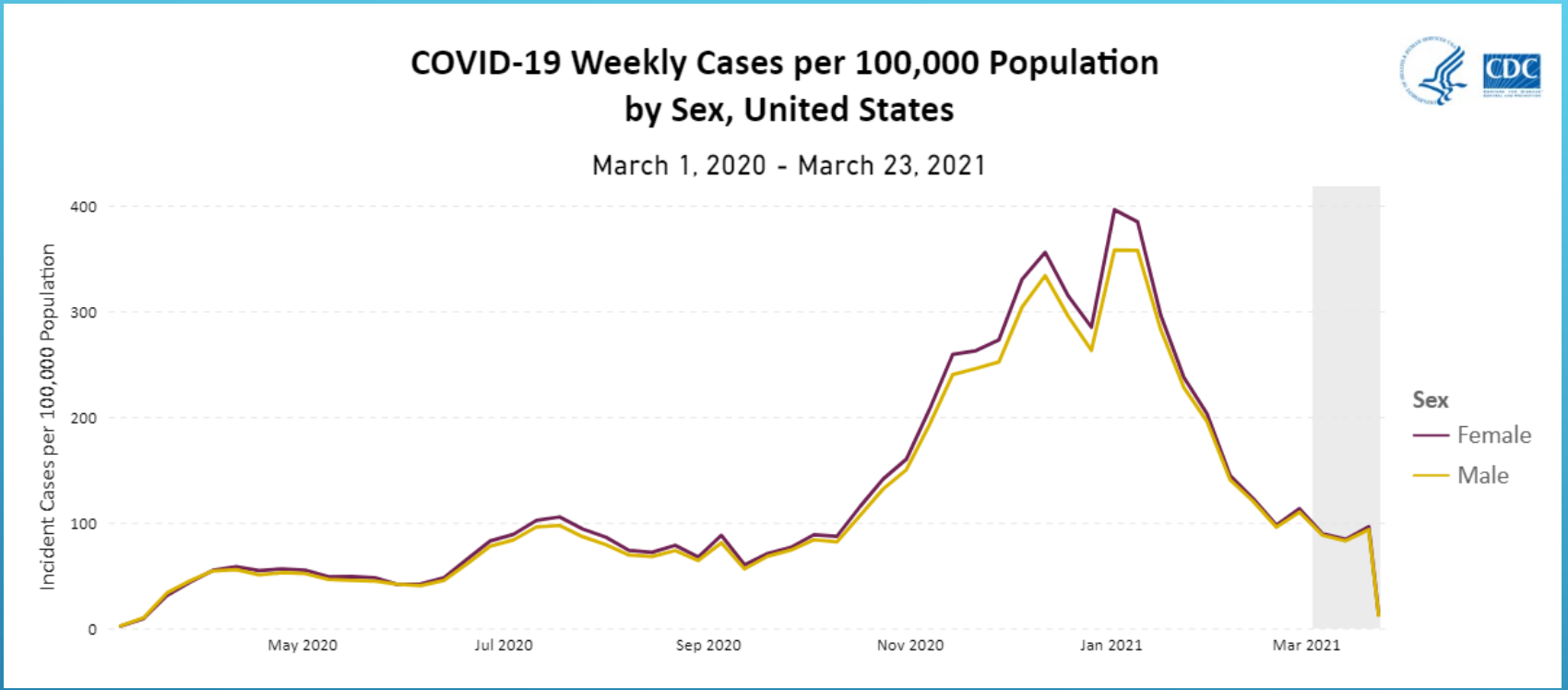
Ultrafiltration 2

Aliquot/Storage

Vaccine Production in highly Controlled Clean Rooms

Vaccine	Country	Technology	Licensure/ Status	Overall efficacy	Protection Against Hospital &Death	Safety
Pfizer (2 shots)	US/Germany	mRNA	Licensed	95% (published)	Yes	>50 M safely injected
Moderna (2 shots)	US	mRNA	Licensed	94.1% (published)	Yes	>50 M safely injected
Astra-Zeneca (2 shots)	UK	Chimp adeno (Viral vector)	Licensed outside USA	62% to 90% (published)	Yes	> 20 M safely injected
Johnson and Johnson (1 shot)	US	Adenovirus (viral vector)	Licensed	70%	Yes	>4 M safely injected
Novavax (2 shots)	US	Recombinant protein	Good data from UK/SA	89%	Yes	>50,000 safely injected
Sinopharm (2 shots)	China	Inactivated Virus	UAE, China, Egypt, other	76 to 85%	Yes	> 4 M safely injected
Sputnik V (2 shots)	Russia	Adenovirus (viral vector)	Licensed in Russia, others	91%	Yes	> 1 M safely injected

Clinical Trials were performed at different times during the pandemic



Timeframe of Moderna trial

Timeframe of Pfizer trial

Timeframe of JnJ trial

Plus emergence of variances

…Which makes comparison of trial data difficult

HOW DID COMPANIES DEVELOP THE COVID-19 VACCINES VERY QUICKLY

- Not starting from scratch. SARS COV-2 is the third Corona virus evolving in the past 20 years (SARS, MERS)
- Technology has improved significantly and Spike sequence deciphered quickly
- Accelerated administration
- Significant funding. There are approximately 350 Covid-19 vaccines being developed with tens of billions of dollars granted
- Parallel activities: research, development and manufacturing but same care and thoroughness. Manufacturing of commercial vaccines started right after phase I/IIa trials
- Large number of infected people in multiple countries which significantly reduced efficacy timelines. This reduced efficacy outcomes by almost 10 folds
- Accelerated, prioritized and concurrent (rolling) regulatory review. The same meticulous review but using significantly more reviewers
- Note that several vaccines had setbacks (Sanofi/GSK, Merck and CSL) which will delay or terminate their development confirming that important vaccine development activities were not ignored

The New Variants Of Concern and the current Vaccines

- So far there are four significant Variants Of Concern:
  - UK: all vaccines tested seems to protect against this variant
  - SA: Moderna, Pfizer, JnJ, AZ and Novavax, seems to partially protect against this variant:
    - Likely other vaccines partially protect as well
    - Vaccines tested thus far against the SA variant, seem to protect against hospitalization and death
  - Brazil: Similar to the SA variant
  - California: not enough information, yet
- It is likely that there are other variants not yet discovered
- It is most likely there will be in the future; viruses mutate frequently, most mutations don't change the virus much but some make the virus more transmissible or more deadly
- So far it seems that the current vaccines are protective (at least) against hospitalization and death of all variants
- If new variants emerge that escape the vaccine, we will need to produce new vaccines. However, development of new vaccines this time around would take even less time

COVID-19 Vaccine Development

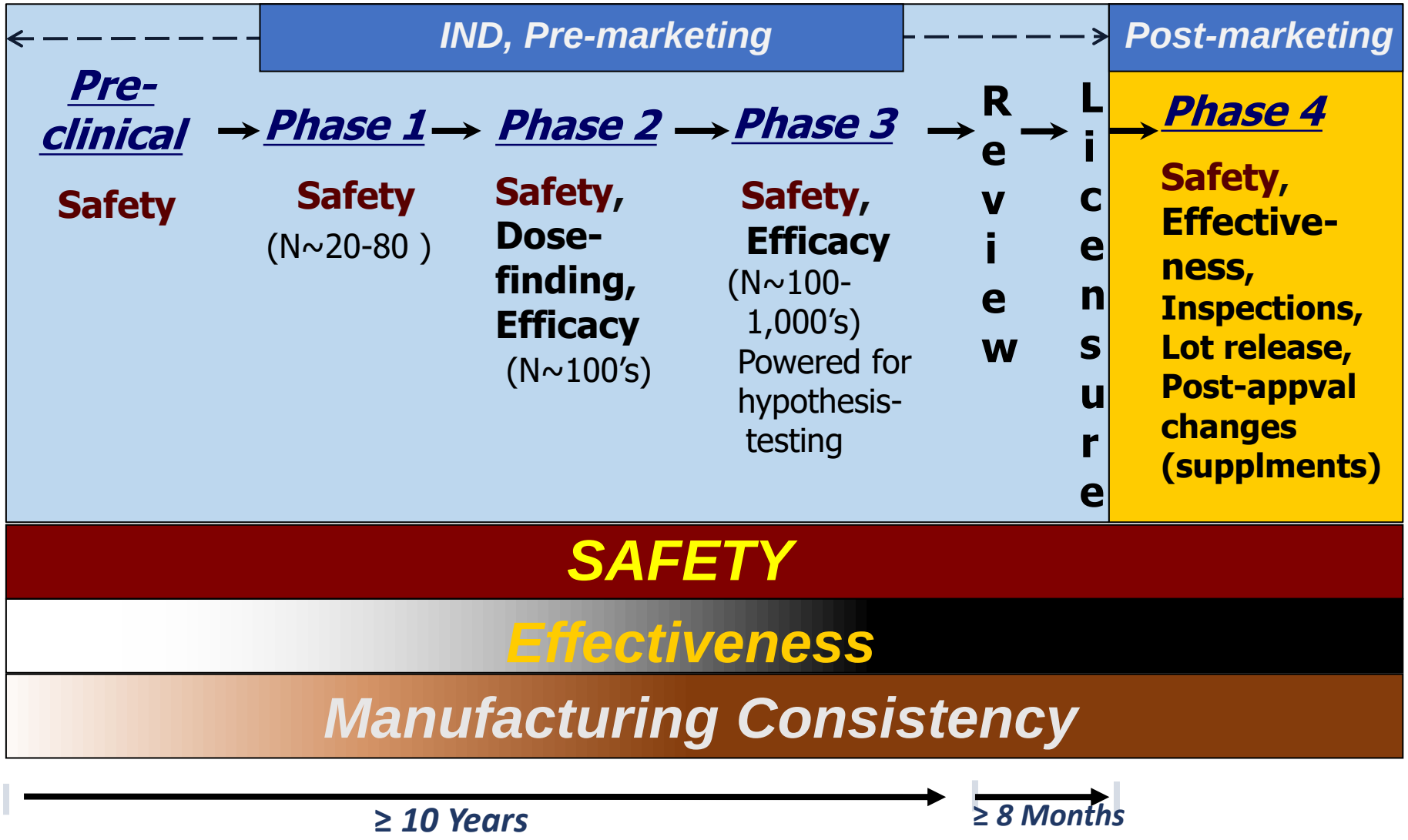
Vaccine Authorization and Licensure

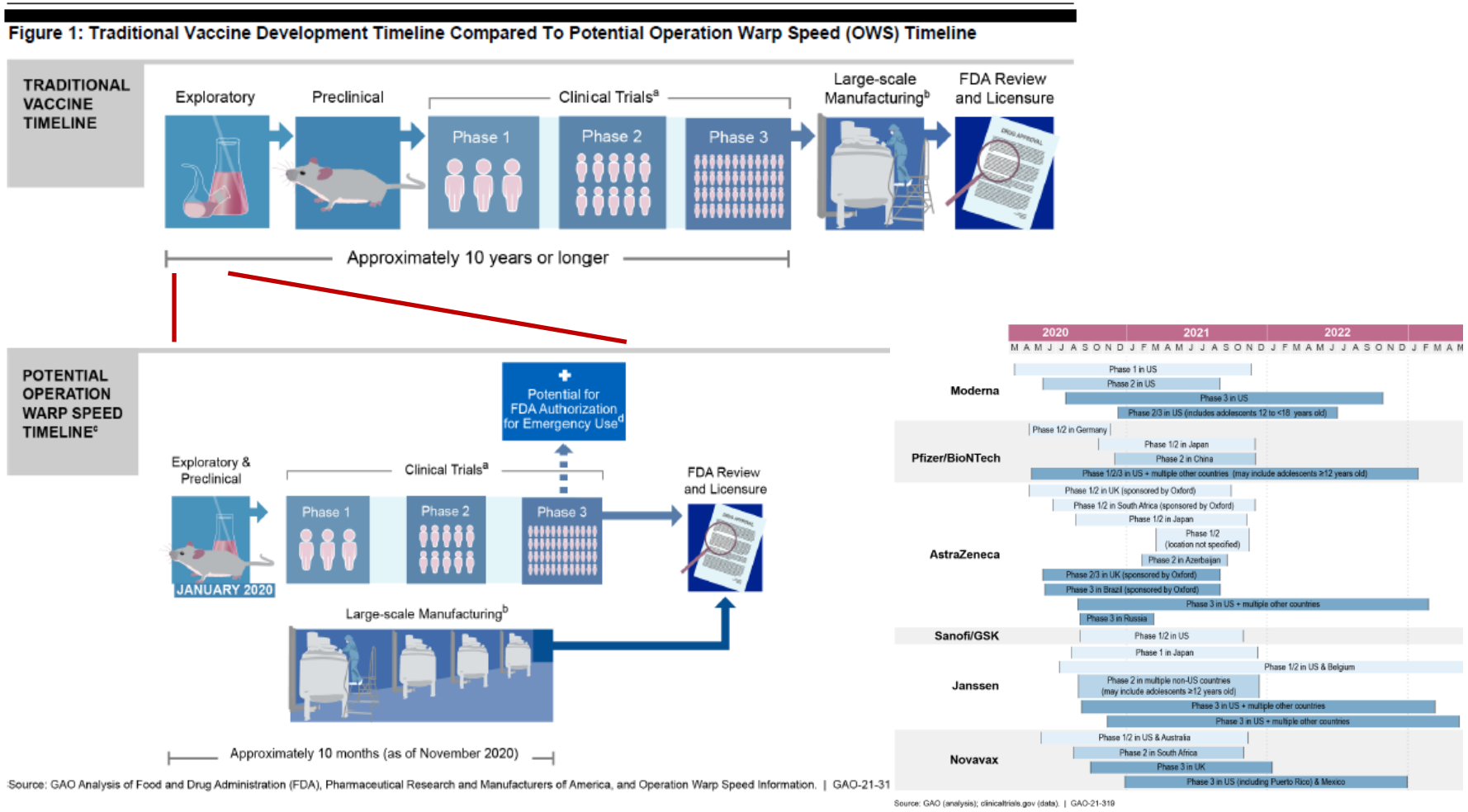
Vaccine Manufacturing 101
April 1, 2021

Wellington Sun, M.D.
Vaxcellerant LLC

The opinions expressed in this presentation are those of the Speaker only and do not necessarily represent positions of any of his current or past organizations.

Vaccine Development





"To achieve great things, two things are needed: a plan, and not quite enough time." – *Leonard Bernstein*

Operation Warp Speed Vaccines

Vaccine	Company	Vaccine Ag/ Platform	R&D Funding	Doses Purchased	$/Dose
BNT162b2	Pfizer/ BioNTech	Spike/mRNA	$0	$1.95B (100M doses) and will buy 500M doses more	**$19.5**
mRNA-1273	Moderna	Spike/mRNA	$955M	$3.2B (200M doses)	**$16**
Ad26.COV2.S	Janssen	Spike/Replication-defective adenovirus 26 vector	$456M	$1B (100M doses) and will buy 200M doses more	**$10**
AZD1222	AstraZeneca	Spike/Replication-defective chimpanzee adenovirus vector	$1.2B	(300M doses)	**$3-4**
NVX-2373	Novavax	Spike/Recombinant protein with adjuvant	$1.6B	(100M doses)	**$16**
VAT01	Sanofi/GSK	Spike/Recombinant protein with adjuvant	$2B	(100M doses)	**$20**

As of December 2020

Authorized vaccine P3 case definitions and endpoints

	Case Definition	Primary Endpoint	Time Period	Age	Baseline serostatus
BNT162b2	1) ≥ 1 symptom/sign* *AND* 2) (+) NAAT within 4-days of symptomatic period	COVID-19 incidence per 1,000 person-years	≥ 7 days after Dose 2	≥ 16 y.o.	1) Seronegative *AND* 2) Seropositive and seronegative
mRNA-1273	1) ≥ 2 systemic symptoms/signs *OR* 2) ≥ 1 respiratory symptom(s)/sign(s) *AND* 3) (+) PCR	COVID-19 incidence	≥ 14 days after Dose 2	≥ 18 y.o.	Seronegative
Ad26.CoV2.S	1) ≥ 2 systemic symptoms/signs *OR* 2) ≥ 1 respiratory symptoms/signs, including DVT *AND* 3) (+) PCR or molecular test	Moderate-severe COVID-19 incidence	1) ≥ 14 days after Dose *And* 2) ≥ 28 days after Dose	≥ 18 y.o.	Seronegative

* Does not include pneumonia

Authorized vaccines' phase 3 baseline characteristics

	BNT162b2	*mRNA-1273*	*Ad26.CoV2.S*
Sites	Argentina, Brazil, South Africa, USA	USA	Argentina, Brazil, Chile, Columbia, Peru, Mexico, South Africa, USA
Demographics			
White	82.9%	79.2%	58.7%
Black or African-American	9.2%	10.3%	19.4%
Asian	4.2%	4.3%	3.4%
Am Indian/Alaskan Native	0.5%	0.7%	9.5%
Hawaii/Pacific Islander	0.3%	0.2%	0.3%
Age			
16-18 yo	0.4%	0%	0%
18-65 yo	78.2%	75.2%	80.5%
>65 yo	21.4%	24.8%	19.5%
EUA data cut-off date	Nov 14, 2020	Nov 21, 2020	Jan 22, 2021

From FDA VRBPAC briefing documents

Safety Profile - Findings from EUA Clinical Trials

Vaccine	N	Local	Systemic
Dose 1			
BNT162b2	**3K**	32% M-S pain	4% fever 27% meds
mRNA-1273	**15K**	3% S pain	1% fever 23% meds
Ad26.COV2.S	**3K**	0.4% S pain	13% fever 26% meds
Dose 2			
BNT162b2	**3K**	28% M-S pain	15% fever 45% meds
mRNA-1273	**15K**	4% S pain	17% fever 57% meds

L= mild, M=moderate, S =severe; AE=adverse event

Vaccine	Unsolicited AE	Serious AE
BNT162b2	Lymphadenopathy; Bell's palsy (4:0); Hypersensitivity (137:111)	Appendicitis (8:4)
mRNA-1273	Lymphadenopathy; Bell's palsy (3:1) Hypersensitivity (258:233)	Facial swelling (2:0) Bell's palsy (1)
Ad26.COV2.S	Tinnitus (6:0)	Thromboembolism (6:2)

Local and systemic adverse event rates generally lower in older age group all 3 vaccines.

"Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice."

Data from EUA Fact Sheets

Vaccine efficacy (VE)

$$VE\ (\%) = \left(1 - \frac{\text{Incidence of disease in vaccinated arm}}{\text{Incidence of disease in control arm}} \right) \times 100$$

Authorized vaccines' phase 3 efficacy

Primary Analyses

	N	Case Rate (%) Vaccine	Case Rate (%) Placebo	Efficacy (95% CI)	FDA Success Criteria Met
BNT162b2					
All ages	34,922	8/17,411 (0.05)	162/17,511 (0.93)	95.0% (90.3-97.6)	Yes
16-55 yo	19,852	5/9,897 (0.05)	114/9,955 (1.14)	95.6% (89.4-98.6)	NA
> 55 yo	15,043	3/7,500 (0.04)	48/7,543 (0.6)	93.7% (80.6-98.8)	NA
mRNA-1273					
All ages	27,817	5/13,934 (<0.1)	90/13,883 (0.6)	94.5% (86.5-97.8)	Yes
18-64 yo	20,791	5/10,407 (<0.1)	75/10,384 (0.7)	93.4% (83.7-97.3)	NA
≥ 65 yo	7,026	0/3,527 (0.0)	15/3,499 (0.4)	100%	NA
Ad26.CoV2.S					
All ages	39,058	116/19,514 (0.6)	348/19,544 (1.8)	66.9% (59.0-73.4)	Yes
18-59 yo	25,532	95/12,750 (0.7)	260/12,782 (2.0)	63.7% (53.9-71.6)	NA
≥ 60	13,526 13,340	21/6,764 (0.3) 14/6,689 (0.2)	88/6,762 (1.3) 41/6,651 (0.6)	76.3% (61.6-86.0) 66.2% (36.7-83.0)	NA

From FDA VRBPAC briefing documents

Vaccine efficacy vs *severe* disease from phase 3 trials

Secondary Analyses

	N	Case Rate % (Vaccine)	Case Rate % (Placebo)	Efficacy (95% CI)
BNT162b2 vs severe disease				
All ages	34,922	1/17,411	3/17511	66.4% (-124.8-96.3)
mRNA-1273 vs severe disease				
All ages	27,817	0/13,934	11/13,893	100%
Ad26.CoV2.S vs severe/critical disease				
All ages	39,058	14/19,514	60/19,544	76.7% (54.6-89.1)
18-59 yo	25,532	8/12,750	41/12,782	80.5% (57.8-92.1)
≥ 60 yo	13,526	6/6,764	19/6,762	68.5% (18.1-89.7)

From FDA VRBPAC briefing documents

Emergency Use Authorization vs Licensure

	EUA	Licensure
Disease/Condition	Only serious and life-threatening	All diseases/conditions
Duration	Only during declared public health emergency	In perpetuity
Currently available therapy	No approved alternatives for the indication	Other approved alternatives may be available for the same indication
Evidence of safety and efficacy	Can be only preliminary	Full final data
Good Manufacturing Practice	Can be partial preliminary data; some requirement can be waived	Full manufacturing quality data on commercial scale product
Risk/Benefit of Product	Positive balance with lower level of evidence – "may be effective"	Positive balance based on full review of final data – more certainty
FDA review	Weeks	8-12 Months
Distribution	Directed by U.S. Gov't based on exigency	Directed by Manufacturer based on market

From Authorized COVID-19 Vaccines to Licensure

- Submission of Biologic Licensing Application by manufacturer
- Efficacy at longer duration of follow-up
- Longer duration of follow-up of safety in trial participants
- Updated global safety data from use under authorizations and approvals
- CMC data on commercial scale manufacturing
- Completion of inspections of facilities and trial sites

Figure 13 Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

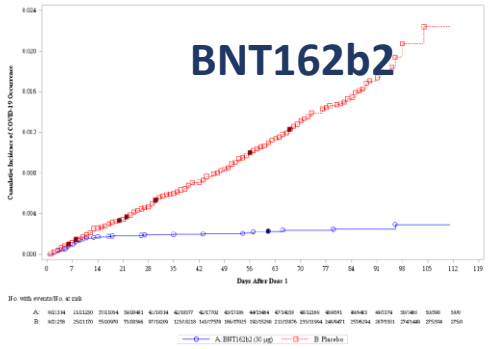


Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Randomization, mITT Set

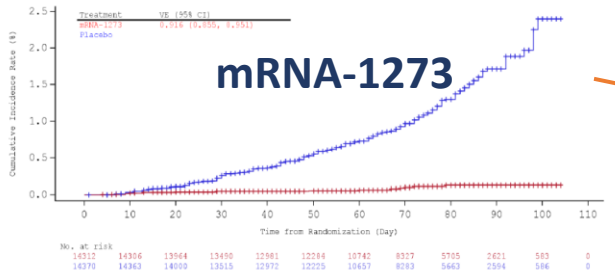
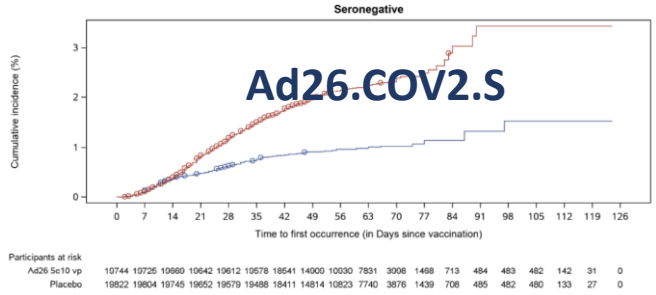
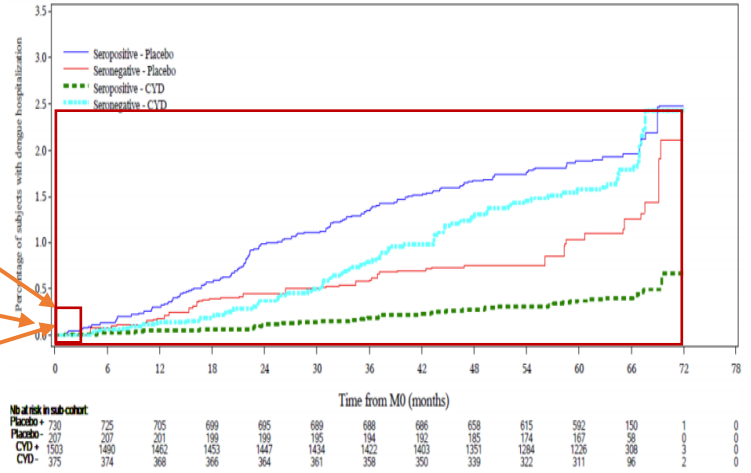


Figure 1. Cumulative Incidence Curve of Centrally Confirmed Moderate to Severe/Critical COVID-19 Cases With Onset at Least 1 Day After Vaccination, Full Analysis Set



Sanofi Pasteur, Inc. VRBPAC Briefing Document
Dengvaxia (Dengue Tetravalent Vaccine, Live)

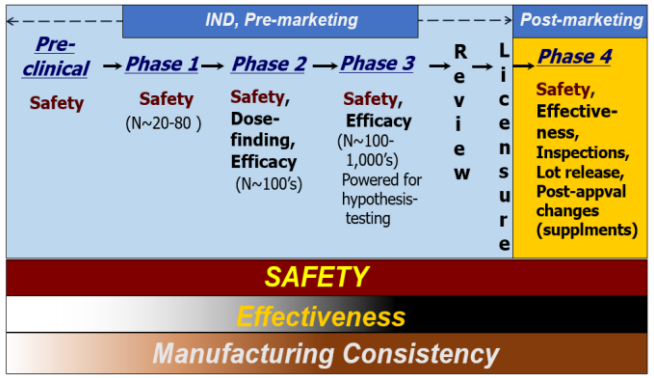
Figure 2. Kaplan-Meier Curve of time to dengue hospitalization from M0 in subjects aged 9 to 16 years at enrollment - serostatus classified by PRNT50 at baseline or NS1 (multiple imputation approach)



Source: Adapted from STN 125682/0 Clinical Overview, Figure 15.
Numbers at risk are average numbers from 10 iterations of multiple imputations.
Data pooled from CYD14, CYD15, and CYD23/57.

From FDA VRBPAC briefing documents

Manufacturing consistency



Biologics License Application Review Sections
CTD Module 1 Contents
CTD Module 2 Contents
CTD Module 3 Contents: Chemistry Manufacture Control
Drug Substance [3.2.S]
Drug Product (name, dosage form) [3.2.P]
Appendices [3.2.A]
Pre-Clinical Section [Module 4]
Clinical Section [Module 5]
Combination Products
Adjuvants

Biologic License Application

➢ *Module 3 CMC*

1. Drug Substance (DS)
   - Facilities registrations
   - Mfg process
   - Characterization DS (e.g. impurities)
   - Control (spec's for safety, identity, purity and potency)
   - Reference Standards
   - Stability
   - Container Closure
2. Drug Product (DP)
   - Pharmaceutical dev
   - Mfg process (control of critical steps and intermediates, validations, e.g. sterility, process changes and justifications)
   - Control of excipients
   - Control of DP (analytic procedures and validation, specification, batch analysis)
   - Reference standards
   - Stability (justifications of dating period, hold times, during shipping)
   - Container closure (e.g. L&E)
3. Appendices
   - Facilities and equipment (e.g. cleaning, HVAC, prevention of cross-contaminations)
   - Method validation package
   - Adventitious agents evaluation
   - Executed batch records
   - Comparability protocols
   - Lot release protocols

Summary

- Success of COVID-19 vaccines development unprecedented
- Data on safety and efficacy from RCT's supported use under EUA
- Additional requirements in moving from EUA to licensure
- Licensure is based on demonstration of safety, effectiveness and manufacturing consistency
- Problems with conducting comparative effectiveness based on different RCT's

The Week, Feb 12, 2021

Thank You

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