



A GLOBAL NGO NETWORK
FOR PRINCIPLED AND EFFECTIVE
HUMANITARIAN ACTION

Vaccines don't cure diseases.

They prevent them.

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NATIONAL INSTITUTE FOR HEALTH SCIENCES
ISLAMABAD PAK

COVID-19 VACCINES

SAMEE ULLAH – BIOINFORMATICIAN
NIH ISLAMABAD PAKISTAN

Get in touch!
sameeullah@bsqau.edu.pk

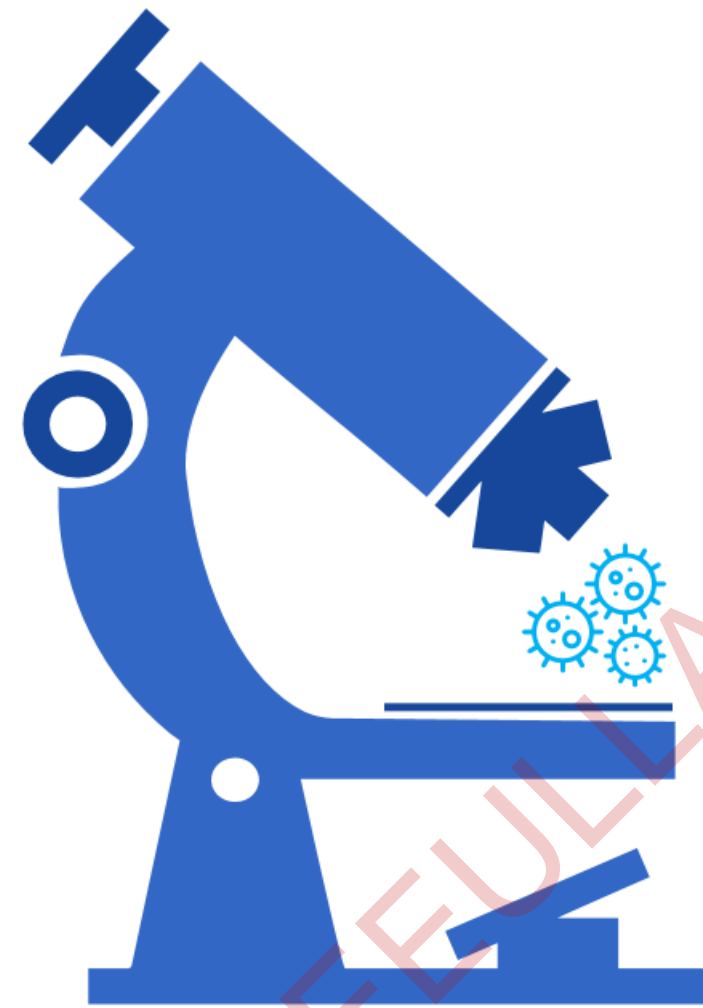
COVID-19 VACCINES

SAMEE ULLAH –BIOINFORMATICIAN
NIH ISLAMABAD PAKISTAN

Get in touch!

sameeullah@bs.qau.edu.pk

OUTLINES



1

Intro

What is a Vaccine?

2

Vaccine common components

What's inside Vaccines?

Approaches/Stages to Viral Vaccines developments

How vaccine works?

3

Leading SARS-CoV-2 Vaccine Candidates

Leading SARS-CoV-2 FDA approved Vaccines

Their methodology, Protocols & deciphering its technology

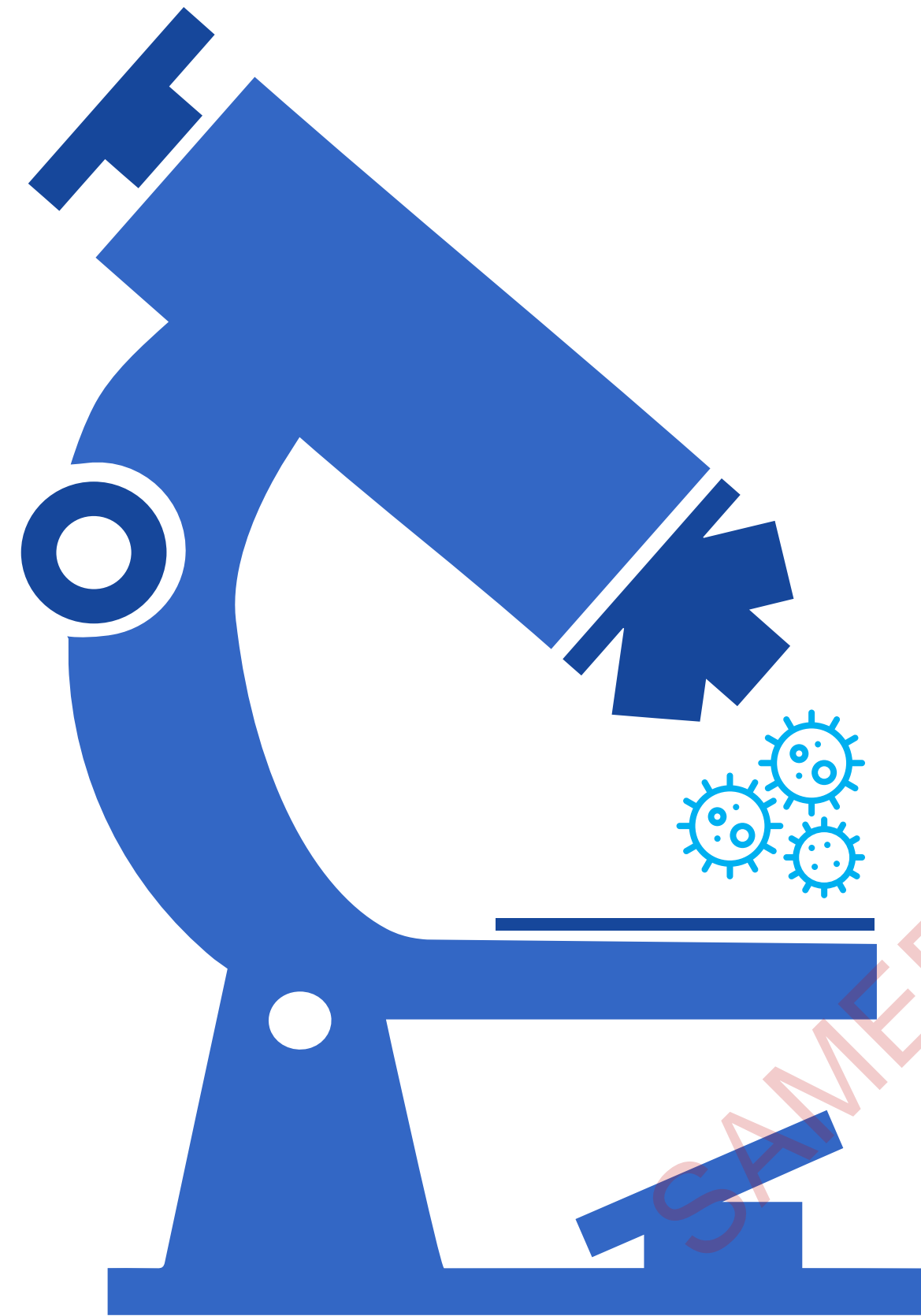
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SARS-CoV-2 Vaccines in Pakistan

The mind, institutes & efforts behind CanSinoBio now known as PAKVAC approved Vaccine



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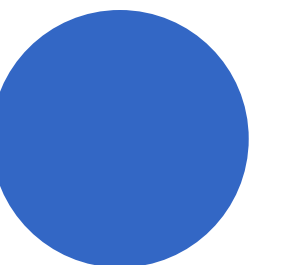
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What is a Vaccine???

Vaccines are products that produce immunity to a specific disease.

When you are immune to a disease, it means you are protected against that disease
(you can be exposed to it without becoming sick)



COVID-19 Vaccine updates 2021

265

vaccines in
development for
COVID-19.

9

different product
categories/platforms.

95

vaccines are in clinical
testing.

Update on 23-Aug-2021



COVID-19 VACCINE TRACKER

Rapidly evolving, check back often.

Last updated: August 23, 2021 9:04 PM PST

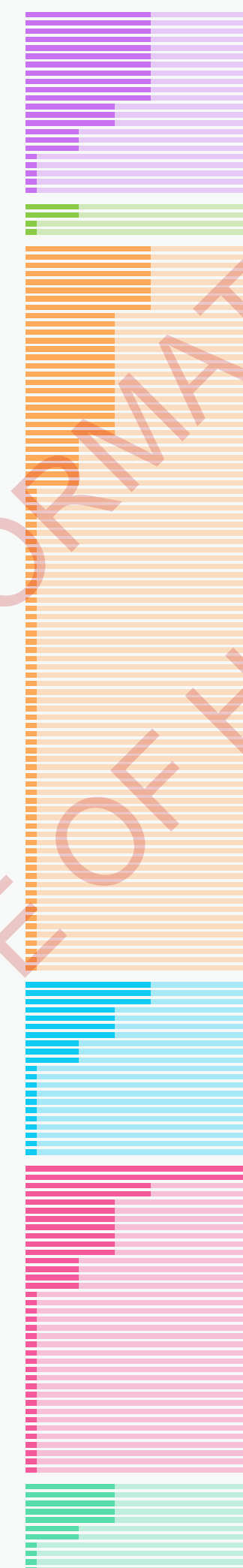
265 vaccines are in development.

95 are now in clinical testing.

18 are in use.

See which vaccines are in use—and the newest updates.

I II III RR AU



Leading Vaccines

- BioNTech/Pfizer
- Moderna
- Oxford/AstraZeneca
- Janssen Pharma
- Sinovac/Instituto Butantan
- Wuhan Inst./Sinopharm
- Beijing Inst./Sinopharm
- Gamaleya Research Inst.
- CanSino Biologics
- Novavax

VACCINES IN USE

> Key

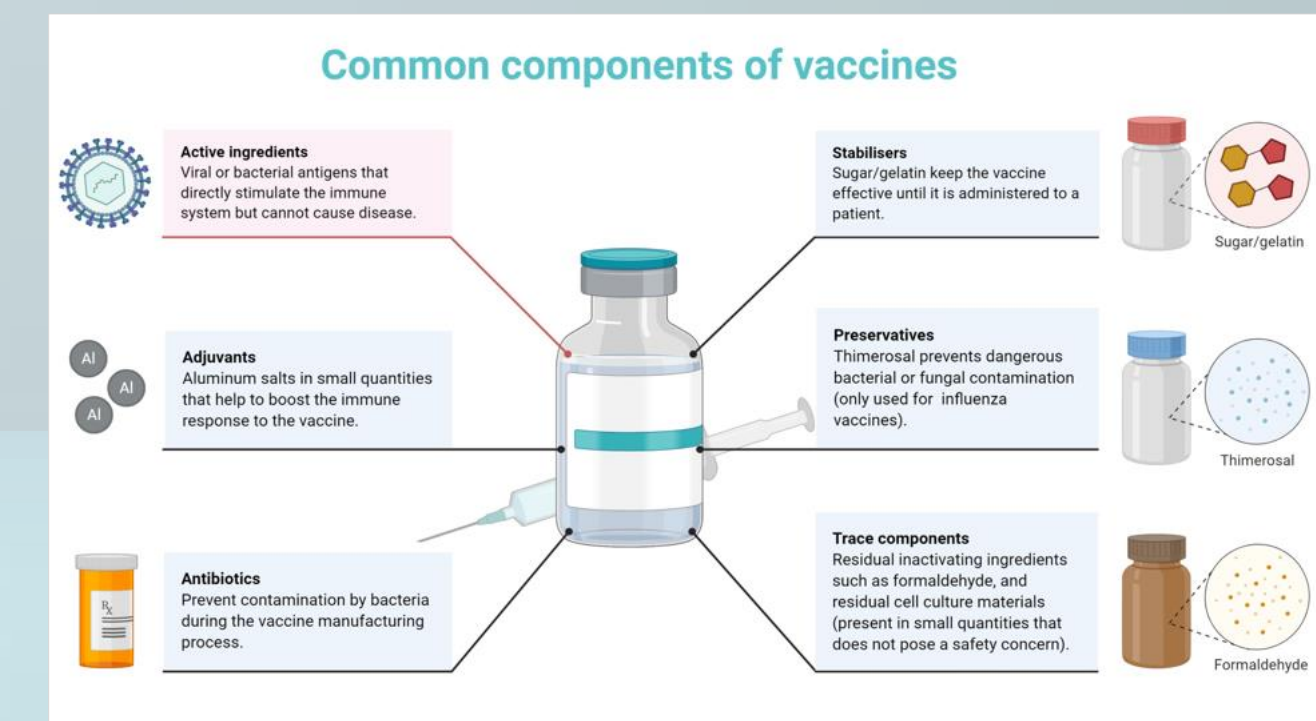
Update on 23-Aug-2021

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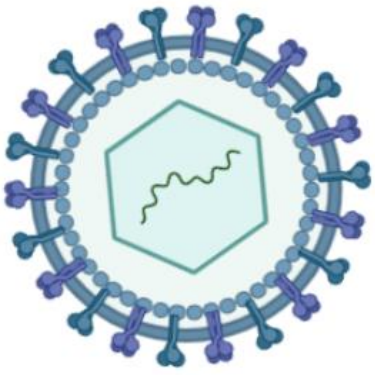


COMMON COMPONENTS of a VACCINE

What's inside a Vaccine?



Common components of vaccines



Active ingredients

Viral or bacterial antigens that directly stimulate the immune system but cannot cause disease.

Adjuvants

Aluminum salts in small quantities that help to boost the immune response to the vaccine.

Antibiotics

Prevent contamination by bacteria during the vaccine manufacturing process.

Stabilisers

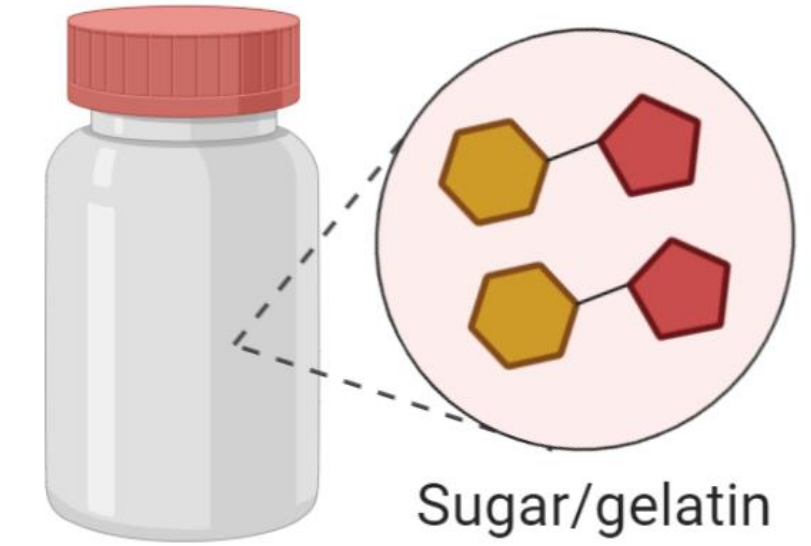
Sugar/gelatin keep the vaccine effective until it is administered to a patient.

Preservatives

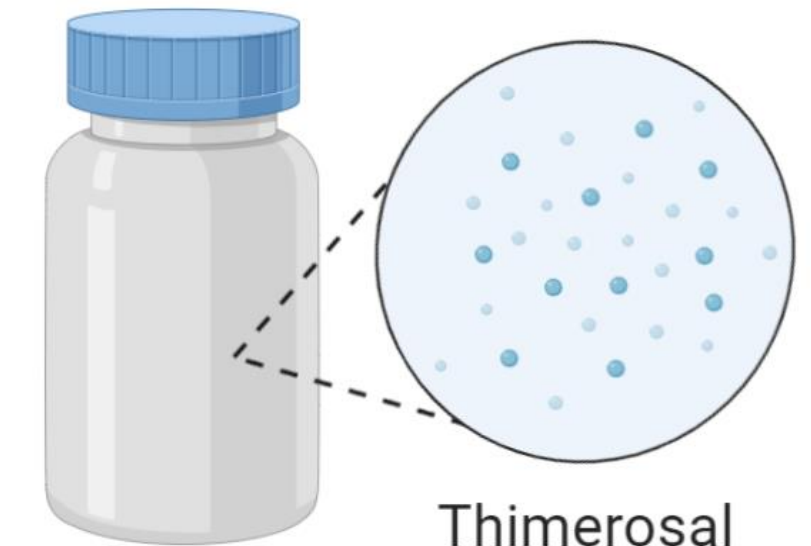
Thimerosal prevents dangerous bacterial or fungal contamination (only used for influenza vaccines).

Trace components

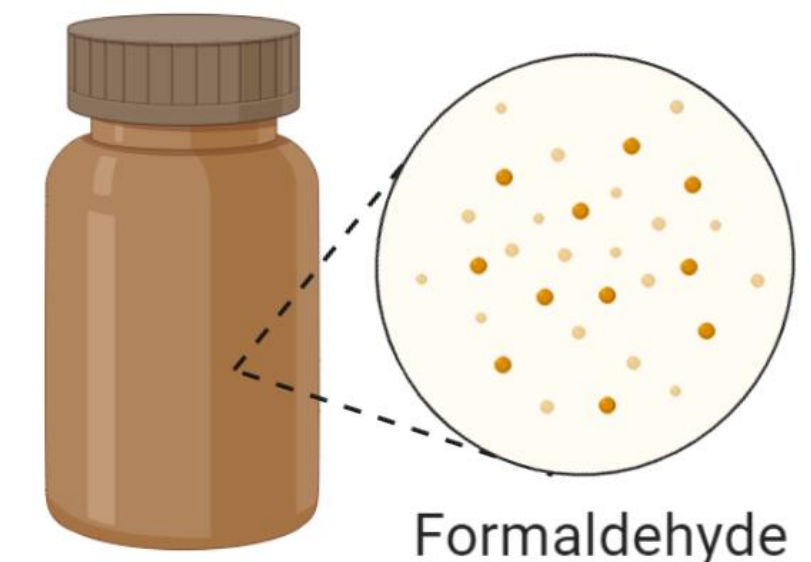
Residual inactivating ingredients such as formaldehyde, and residual cell culture materials (present in small quantities that does not pose a safety concern).



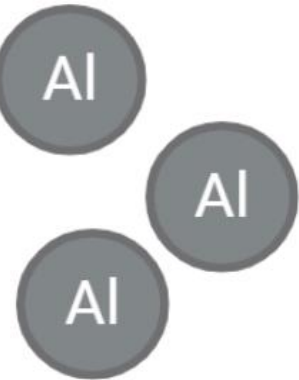
Sugar/gelatin



Thimerosal

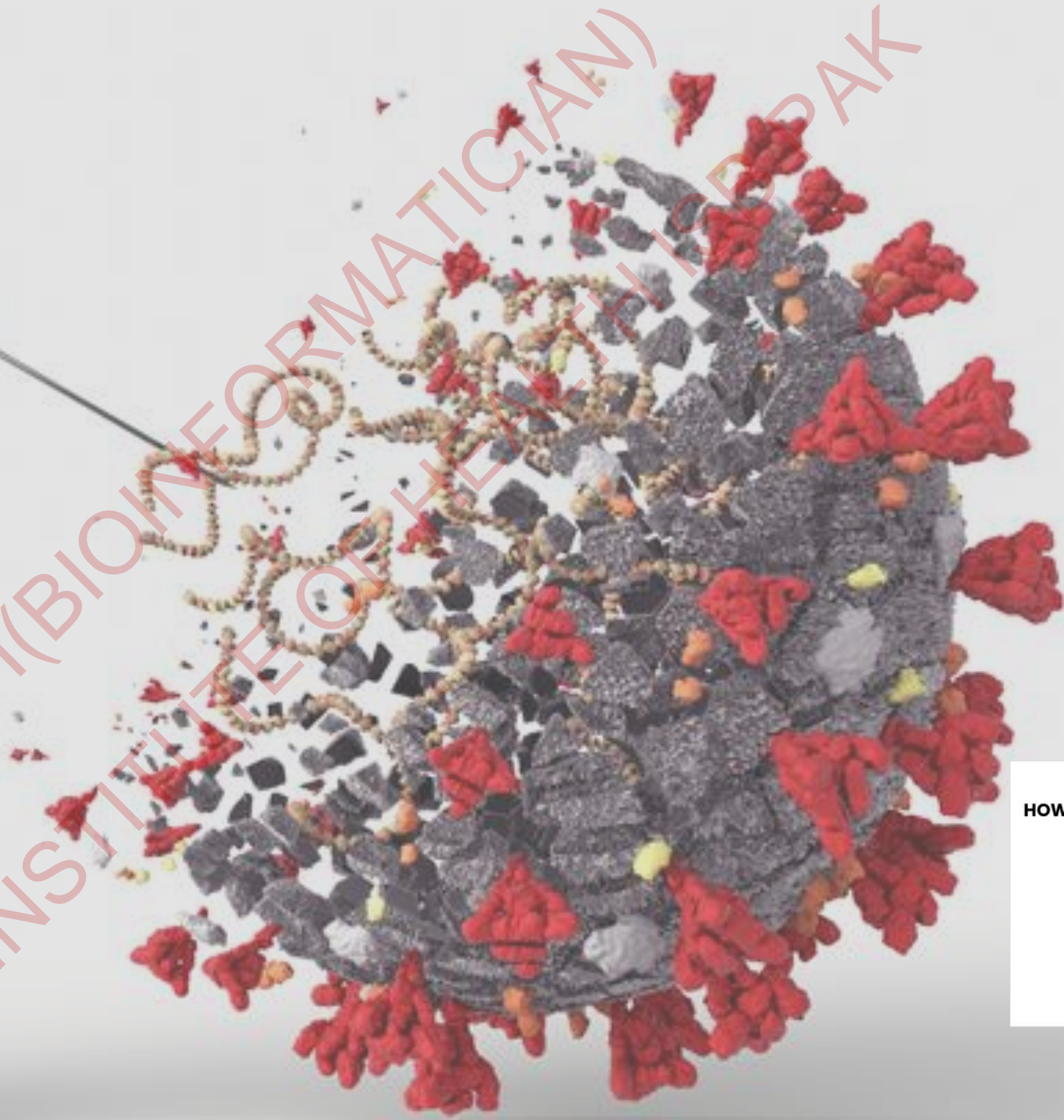


Formaldehyde



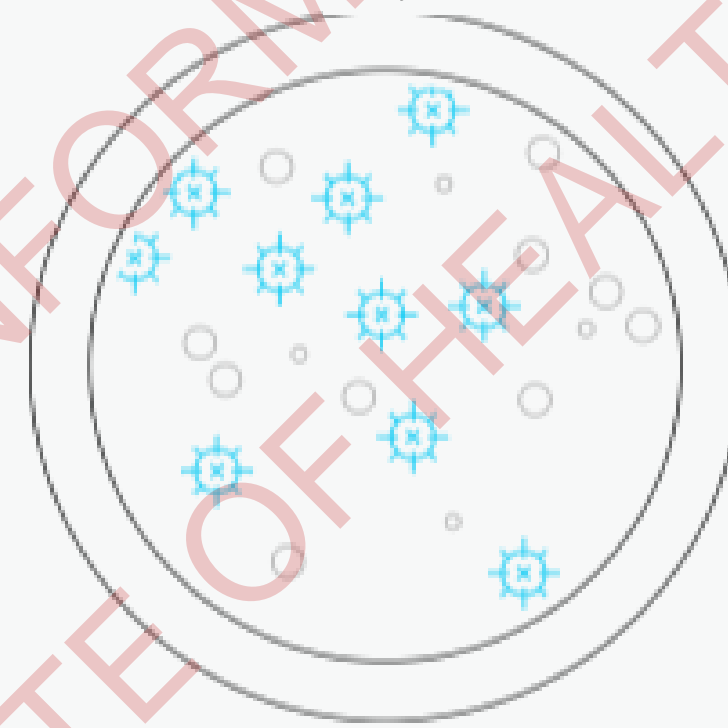
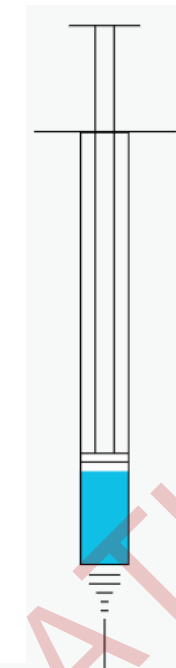
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How a Vaccine Works?



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PHILIPPAK

HOW Vaccines Work?



WEAK GERMS
INJECTED

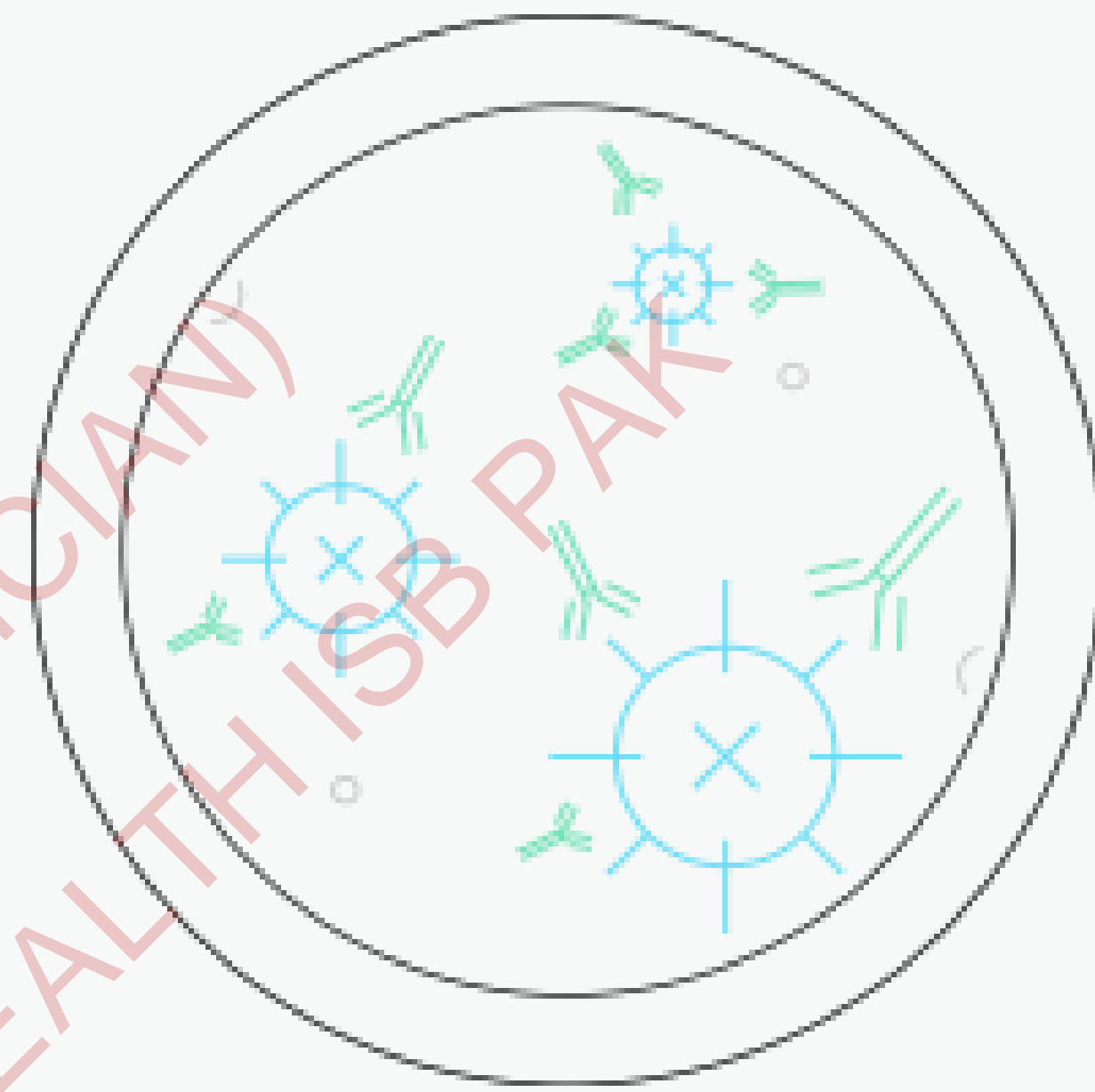
Vaccines contain the same germs that cause the disease, either killed or weakened, or they contain genetic instructions that code for the disease.



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then...

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ANTIBODIES
CREATED

They stimulate your
immune system to produce
antibodies, as if you were
exposed to the germ.



Finally...



IMMUNITY
DEVELOPED

After getting vaccinated,
one develops immunity to
that disease without having
to get it first.



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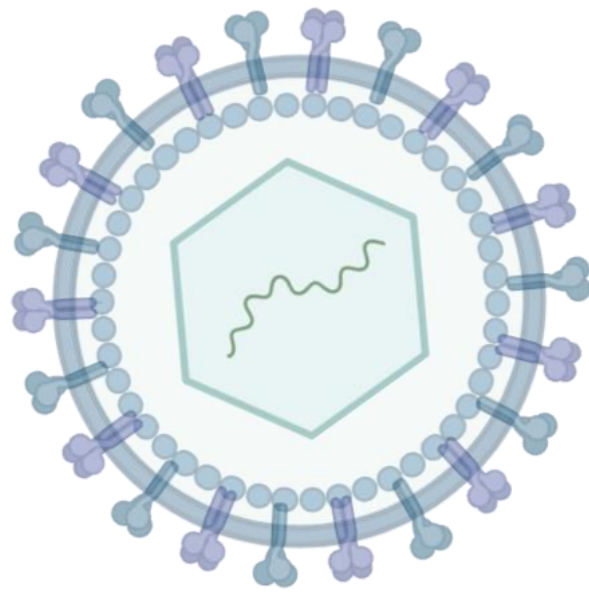
A hand wearing a blue nitrile glove is shown holding a small glass vial with a metal cap. The vial has a white label with blue text that reads "CORONAVIRUS COVID-19 VACCINE" and "10 Doses". Below this, smaller text says "Store at temperature not exceeding 30°C (86°F) and protected from direct sunlight." In the background, a row of similar vials is visible, slightly out of focus. The entire scene is set against a light, neutral background.

Approaches to Vaccine Development

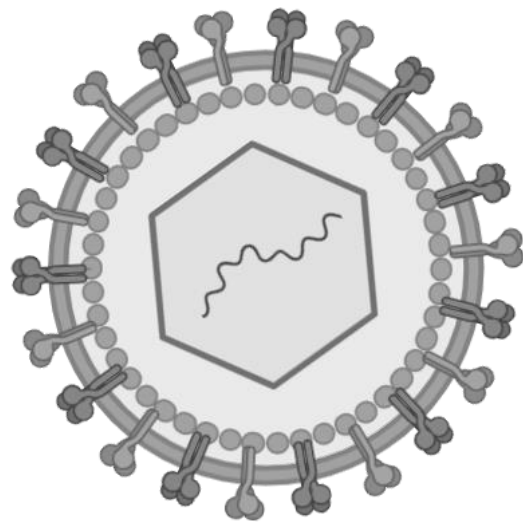
SAMEEL (PHARMACOLOGICAL/BIOINFORMATICIAN)
NATIONAL INSTITUTE OF HEALTH ISB PAK

Approaches to Viral Vaccine Development

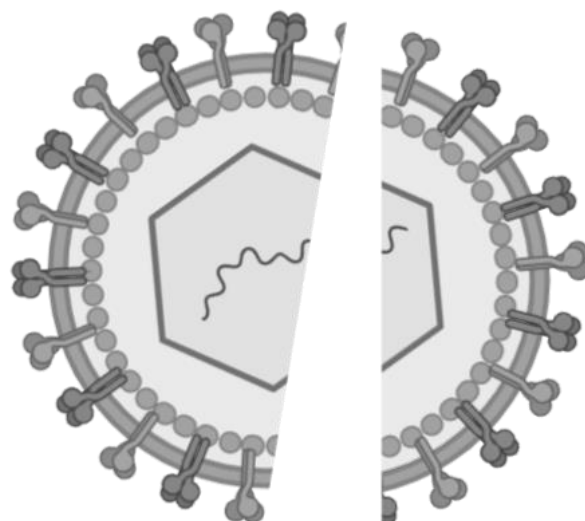
a. Live attenuated



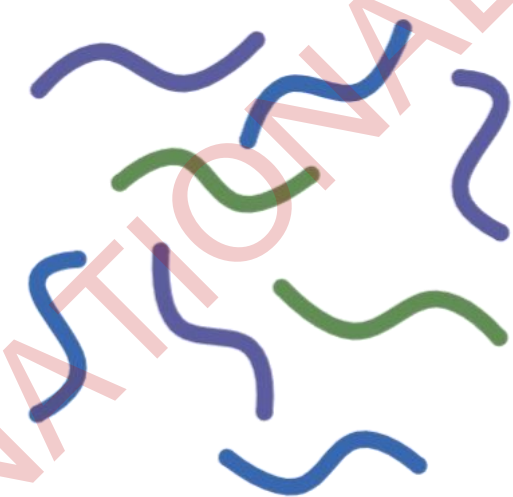
b. Whole inactivated



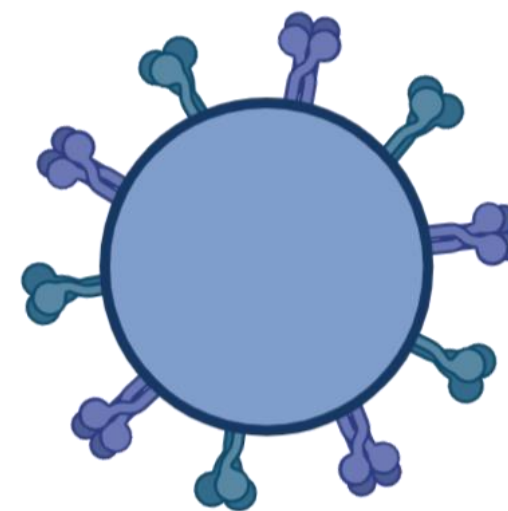
c. Split inactivated



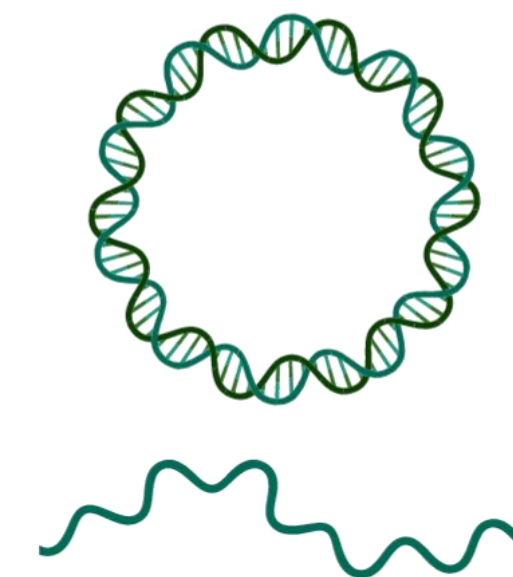
d. Synthetic peptides



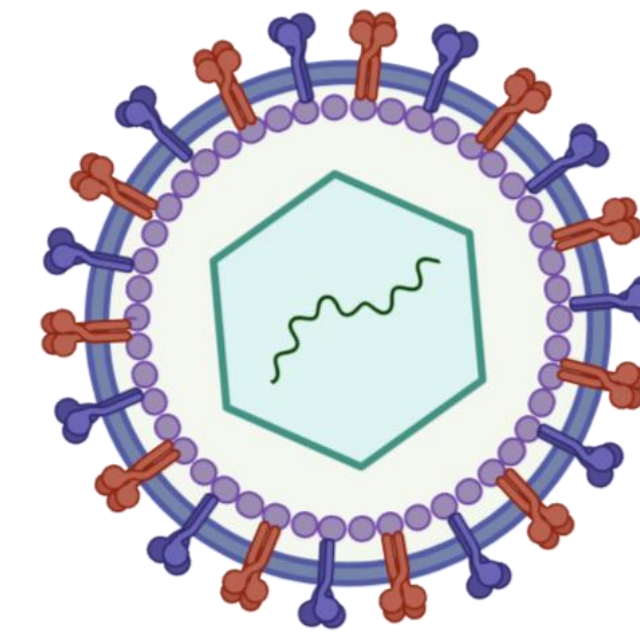
e. Virus-like particles



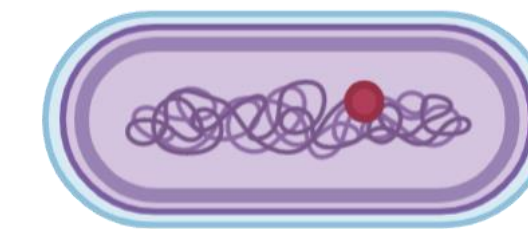
f. DNA or RNA



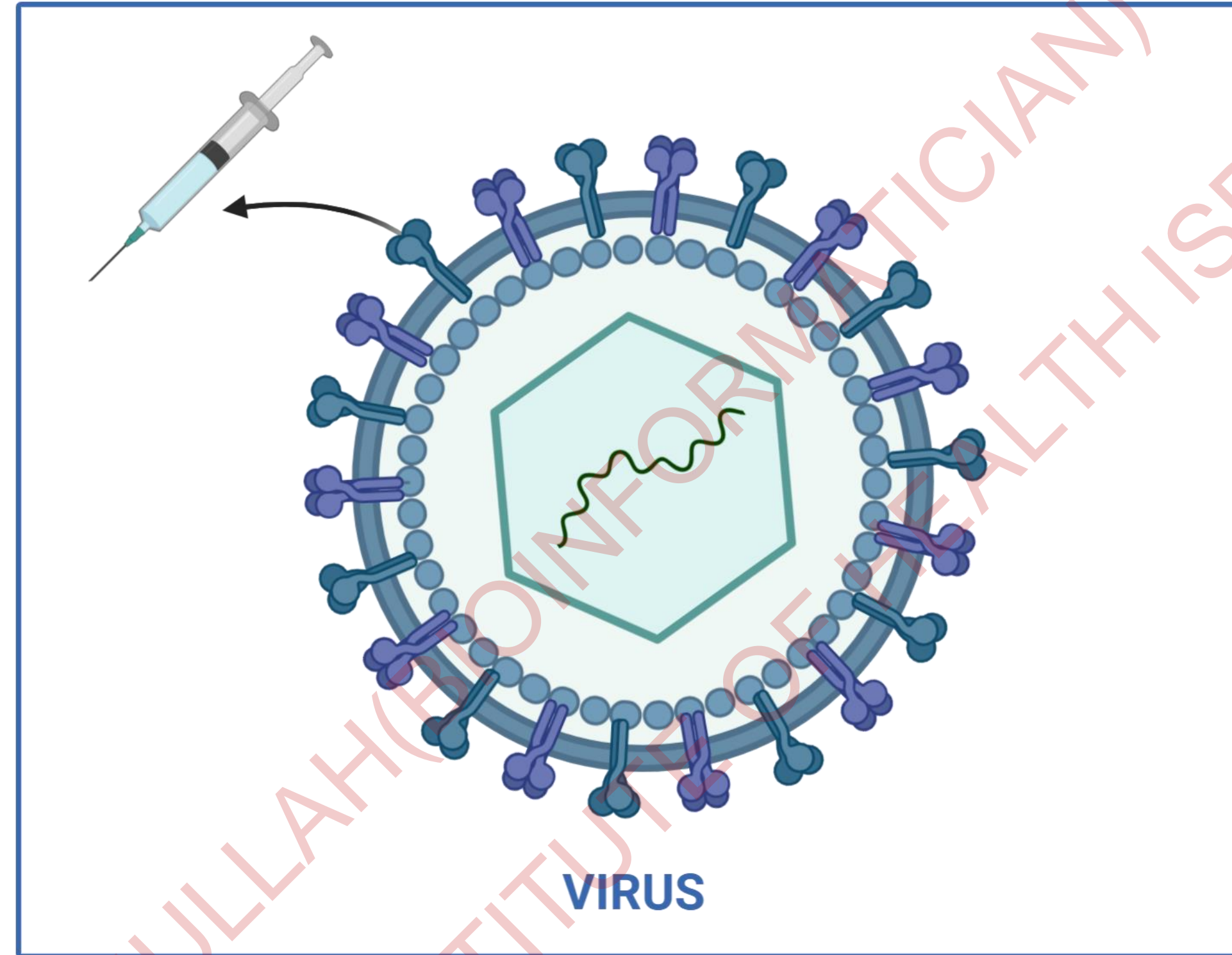
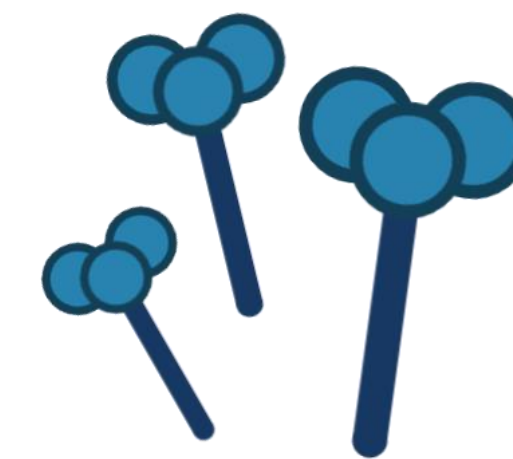
i. Recombinant viral vectors



h. Recombinant bacterial vectors



g. Recombinant subunits





Stages to Vaccine Development

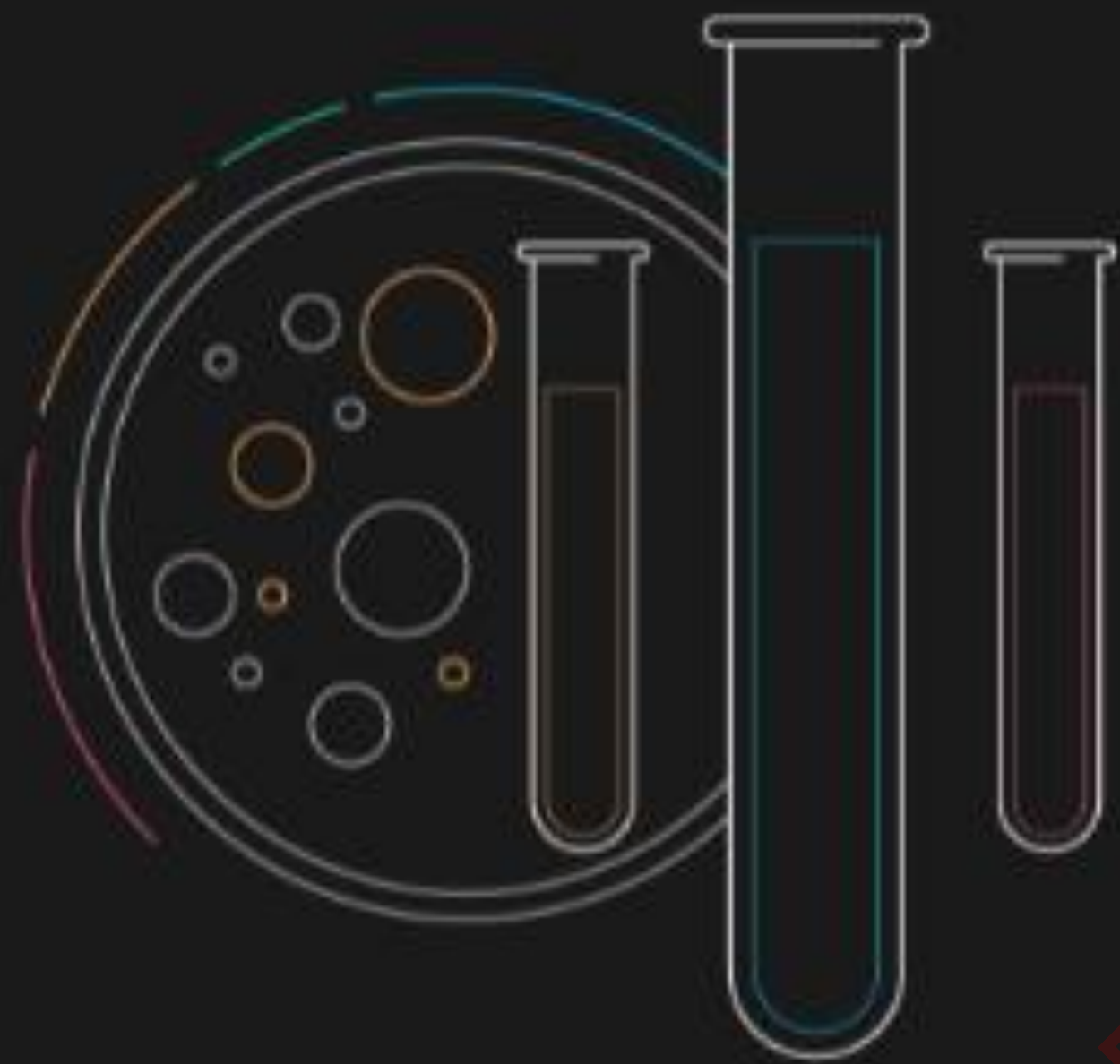
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STAGES OF DEVELOPMENT

After pre-clinical studies are completed, the multiple phases of the clinical trial process test whether new vaccines are safe and effective before going public—culminating in a regulatory review. Phase IV is post-approval and monitors real-world effectiveness.

This process usually takes approximately 10 years, but governments and industry are fast-tracking these vaccines while maintaining safety and efficacy standards.

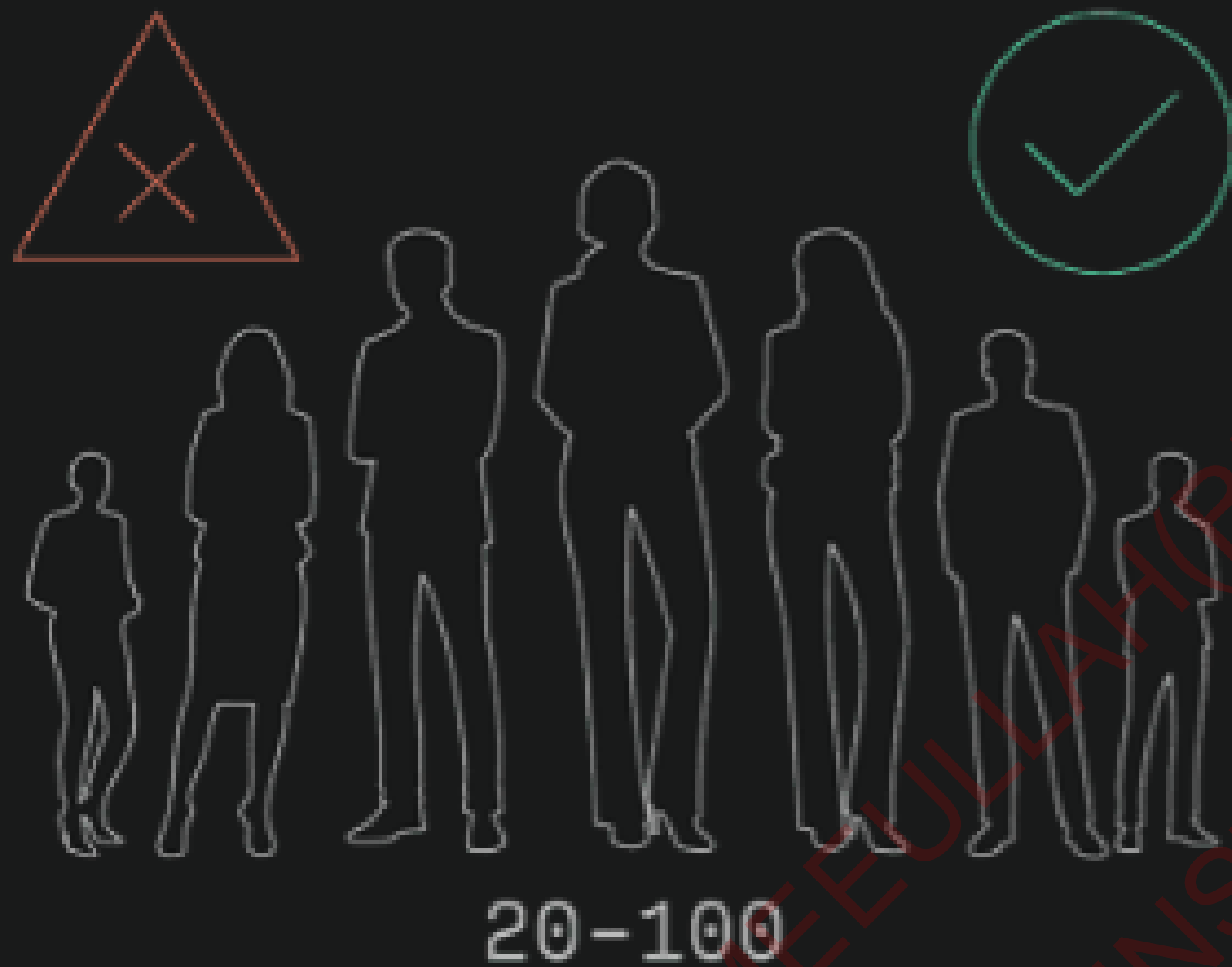
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PRE

PRE-CLINICAL PHASE

- Collects data to support feasibility and safety
- Involves iterative non-human testing
- Evaluates toxic and pharmacological effects
- Normally occurs before human testing can begin



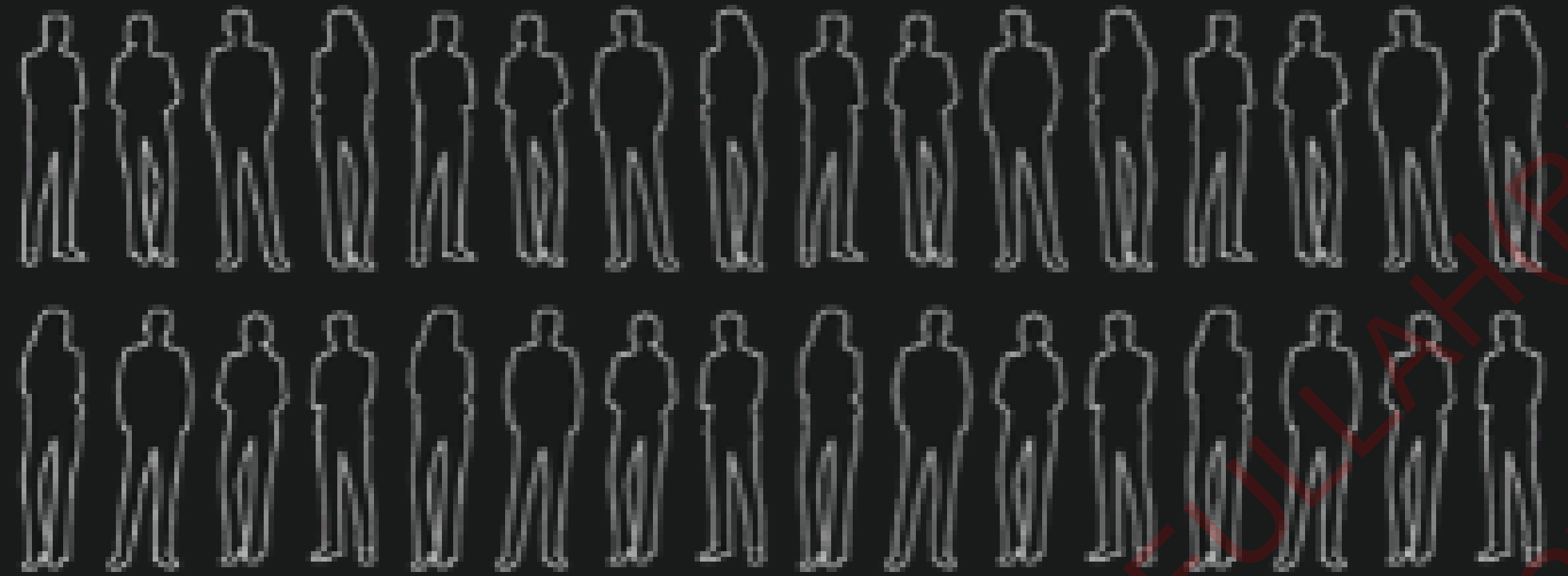
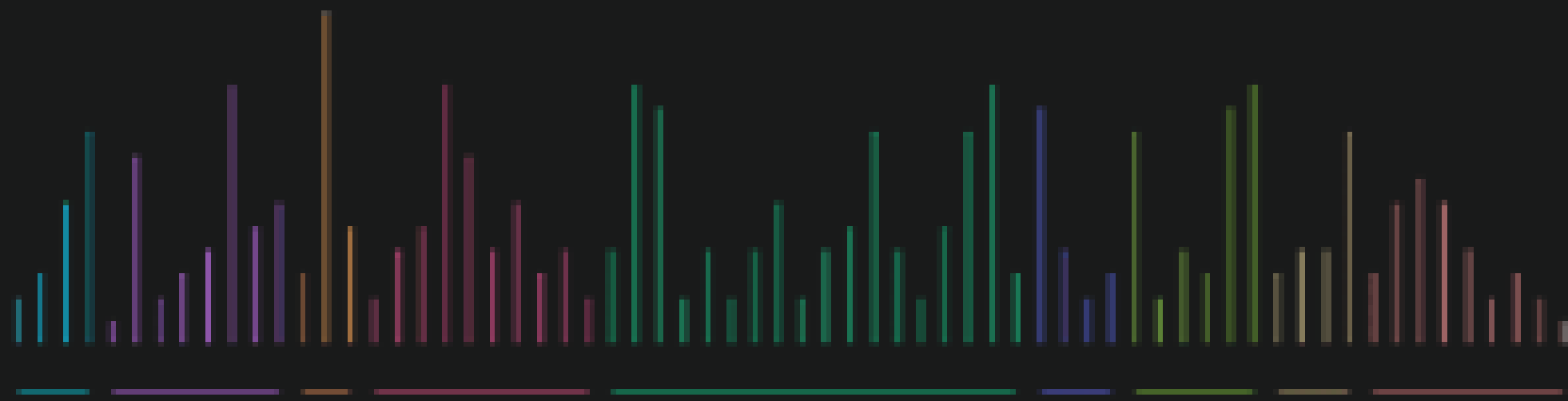
I

CLINICAL PHASE

- Small study of healthy people
- Evaluates safety and immune response at different doses
- Typically takes 1-2 years, but for COVID-19 trials, expected to take 3 months

II

CLINICAL PHASE



100-300

- **Studies 100s of people**
- **Further evaluates safety, assesses efficacy, and informs optimal dose and vaccine schedule**
- **Typically takes 2-3 years, but for COVID-19 trials, expected to take 8 months**



III

CLINICAL PHASE

- Studies 1000s of people
- Further evaluates safety and efficacy
- Typically takes 2-4 years, but for COVID-19 trials, may be combined with Phase II

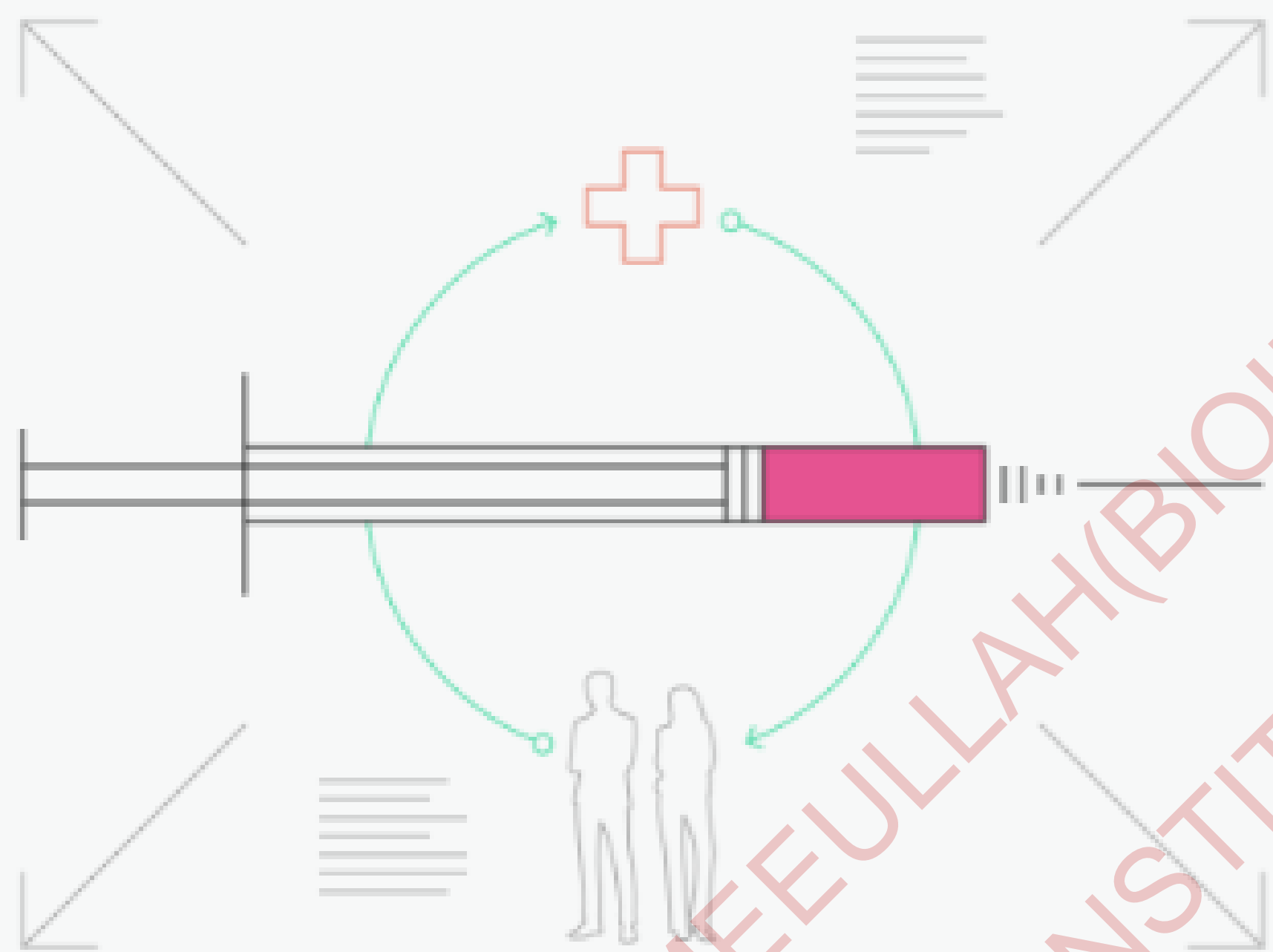
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RR

REGULATORY REVIEW

- Government agency reviews trial data and licensing application information before authorization
- Can happen while manufacturing has started
- Typically takes 1-2 years, but for COVID-19, expedited to take a few months



IV

CLINICAL PHASE

- Post-approval studies that monitor effectiveness in real-world conditions
- Testing begins after vaccine has been released to public

Leading COVID-19 Vaccine candidates

Three of them

Published their FULL protocols...



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Three of them

Published their FULL protocols...

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A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19

Sponsor Name: AstraZeneca AB
Legal Registered Address: 151 85 Södertälje, Sweden
Regulatory Agency Identifier Number(s): IND number 23522



A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

Study Sponsor: BioNTech
Study Conducted By: Pfizer
Study Intervention Number: PF-07302048
US IND Number: RNA-Based COVID-19 Vaccines
EudraCT Number: 19736
Protocol Number: 2020-002641-42
Phase: C4591001
Short Title: A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals



CLINICAL STUDY PROTOCOL

Protocol Title: A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older
Protocol Number: mRNA-1273-P301
Sponsor Name: ModernaTX, Inc.
Legal Registered Address: 200 Technology Square
Cambridge, MA 02139
Sponsor Contact and Medical Monitor: Tal Zaks, MD, PhD, Chief Medical Officer
ModernaTX, Inc.
200 Technology Square, Cambridge, MA 02139
Telephone: 1-617-209-5906
e-mail: Tal.Zaks@modernatx.com
Regulatory Agency Identifier Number(s): IND: 19745
Amendment Number: 3
Date of Amendment 3: 20 Aug 2020
Date of Amendment 2: 31 Jul 2020

TITLE PAGE

A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19

Sponsor Name: AstraZeneca AB

Legal Registered Address: 151 85 Södertälje, Sweden

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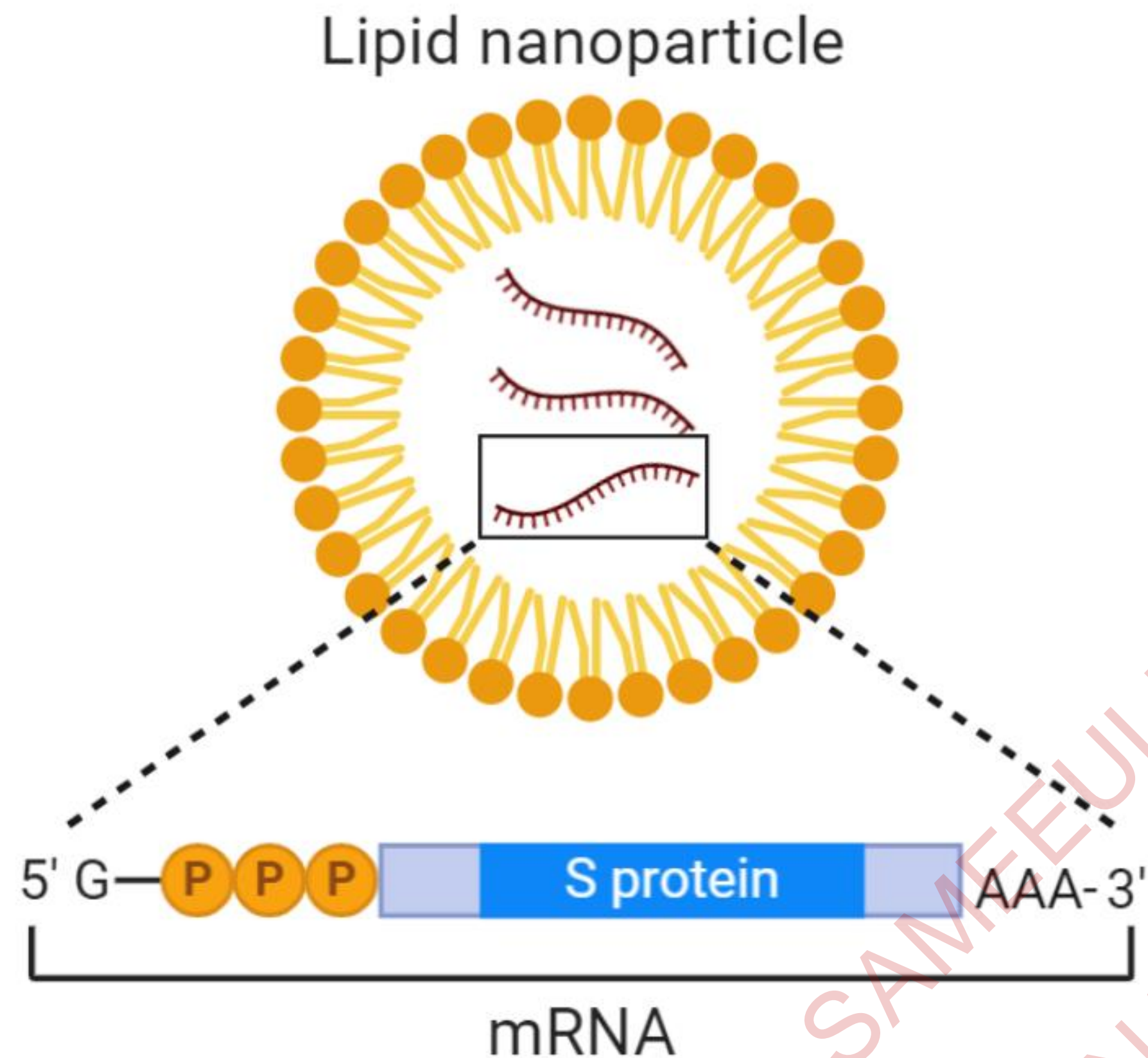
Regulatory Agency Identifier Number(s): IND: 19745

Amendment Number: 3

Date of Amendment 3: 20 Aug 2020

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Moderna (mRNA-1273)



Platform: LNP-encapsulated mRNA encoding S protein.



mRNA—messenger RNA

Comprised of LNP (lipid nano-particle)
Encodes S-spike protein SARS-CoV-2

ORGANIZATIONS

Moderna, NIAID, Biomedical Advanced Research and Development

COUNTRIES INVOLVED

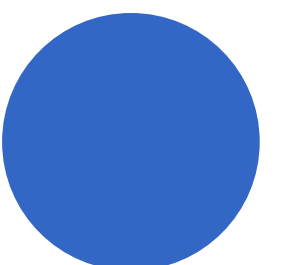
USA

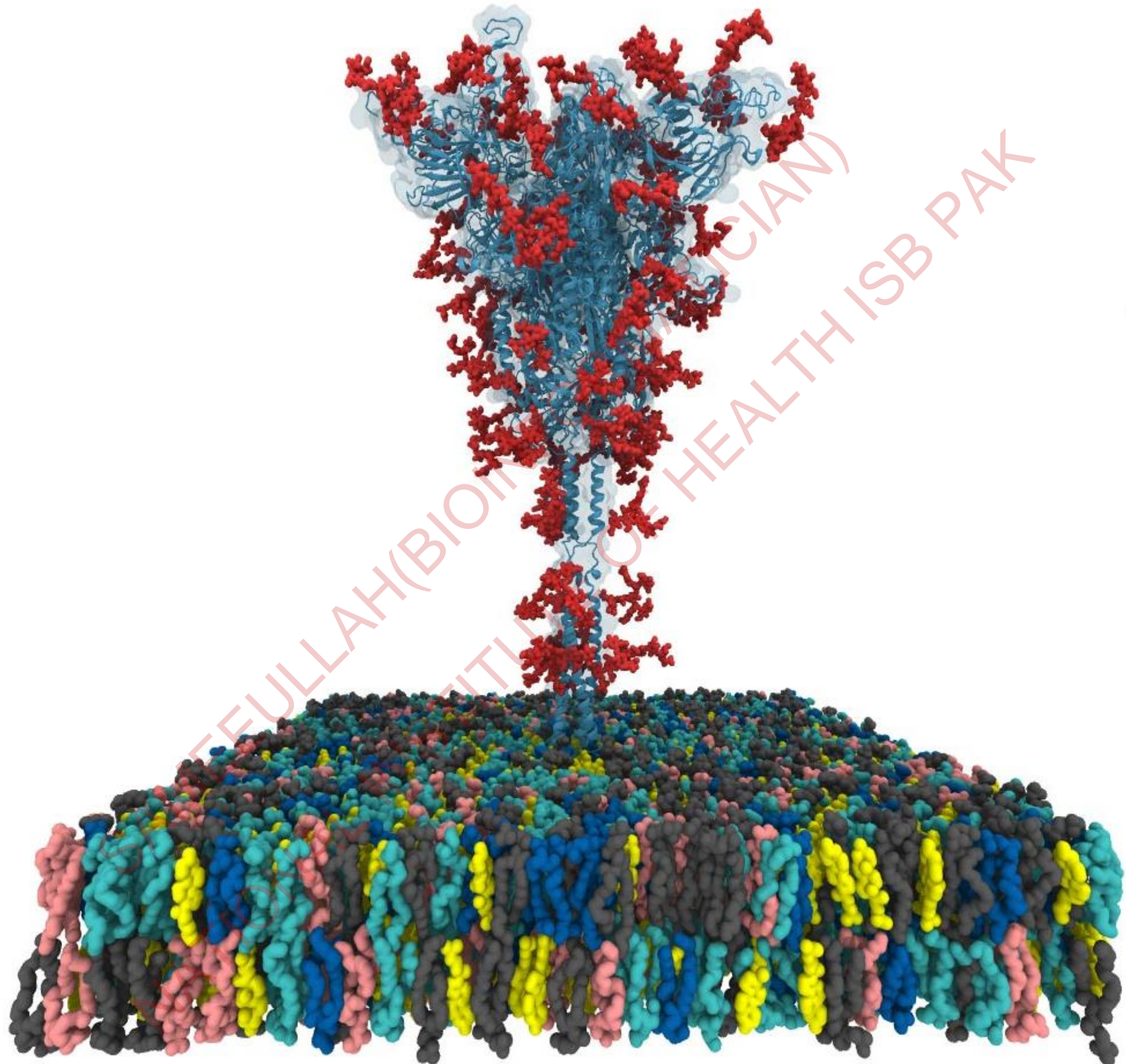
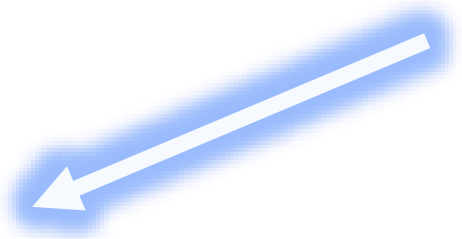
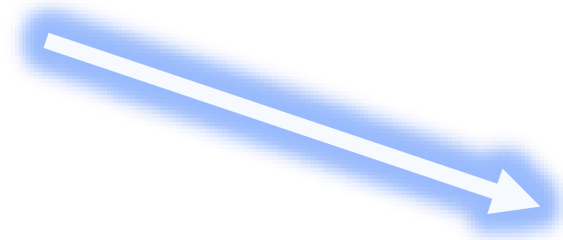
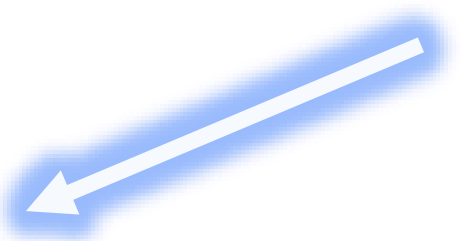
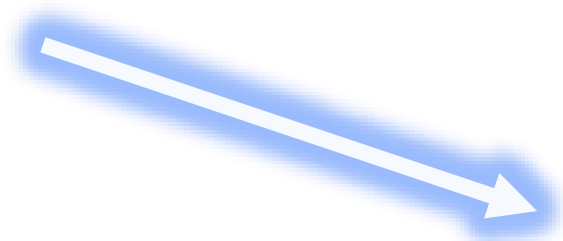
TRIALS PARTICIPANTS

Phase 1: 105

Phase 2: 600

Phase 3: 30,000







University of Oxford & AstraZeneca
(AZD1222, formerly ChAdOx1 nCoV-19)

Non-replicating viral vector Attenuated Adeno-Virus

ORGANIZATIONS

- University of Oxford/AstraZeneca

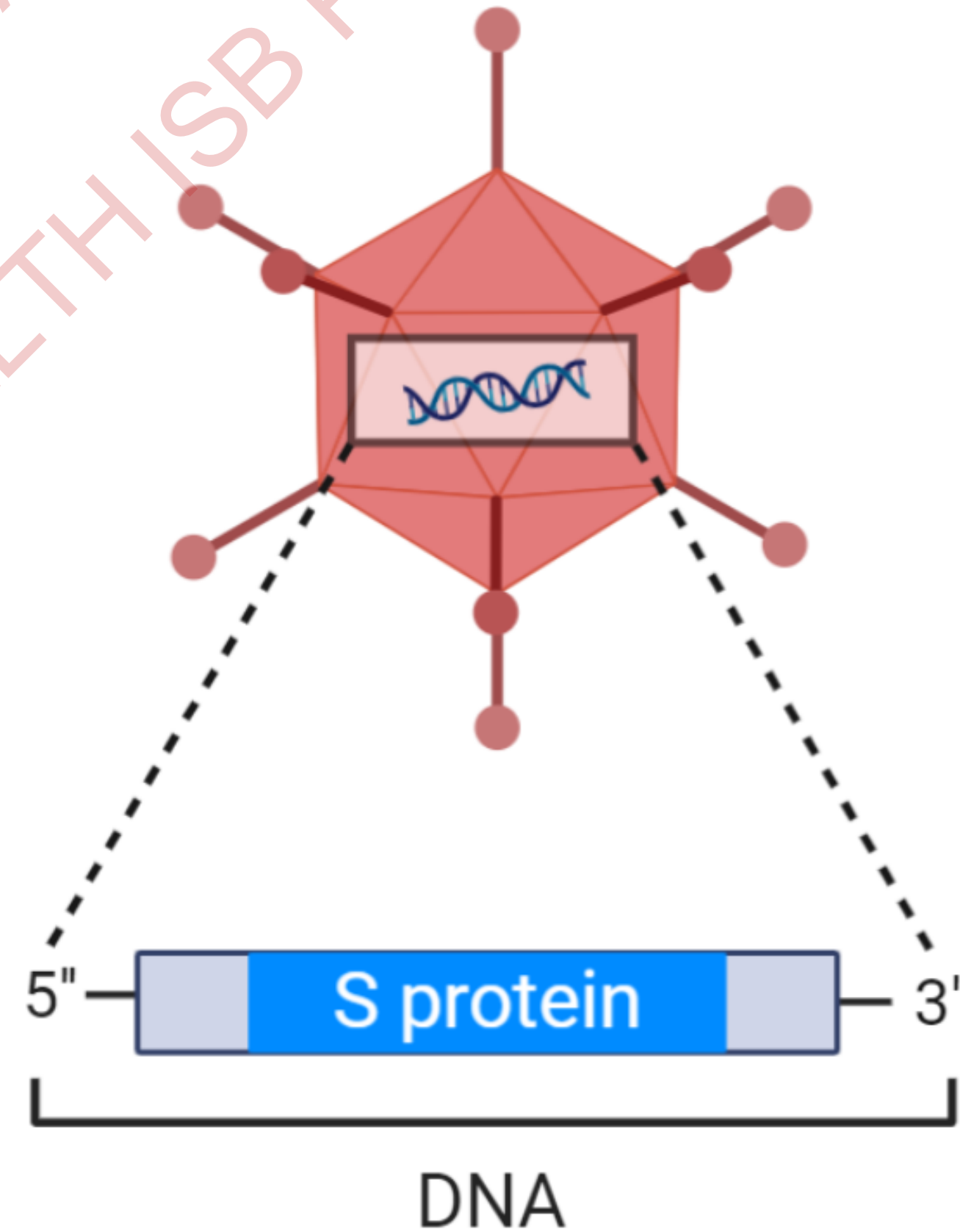
COUNTRIES INVOLVED

UK

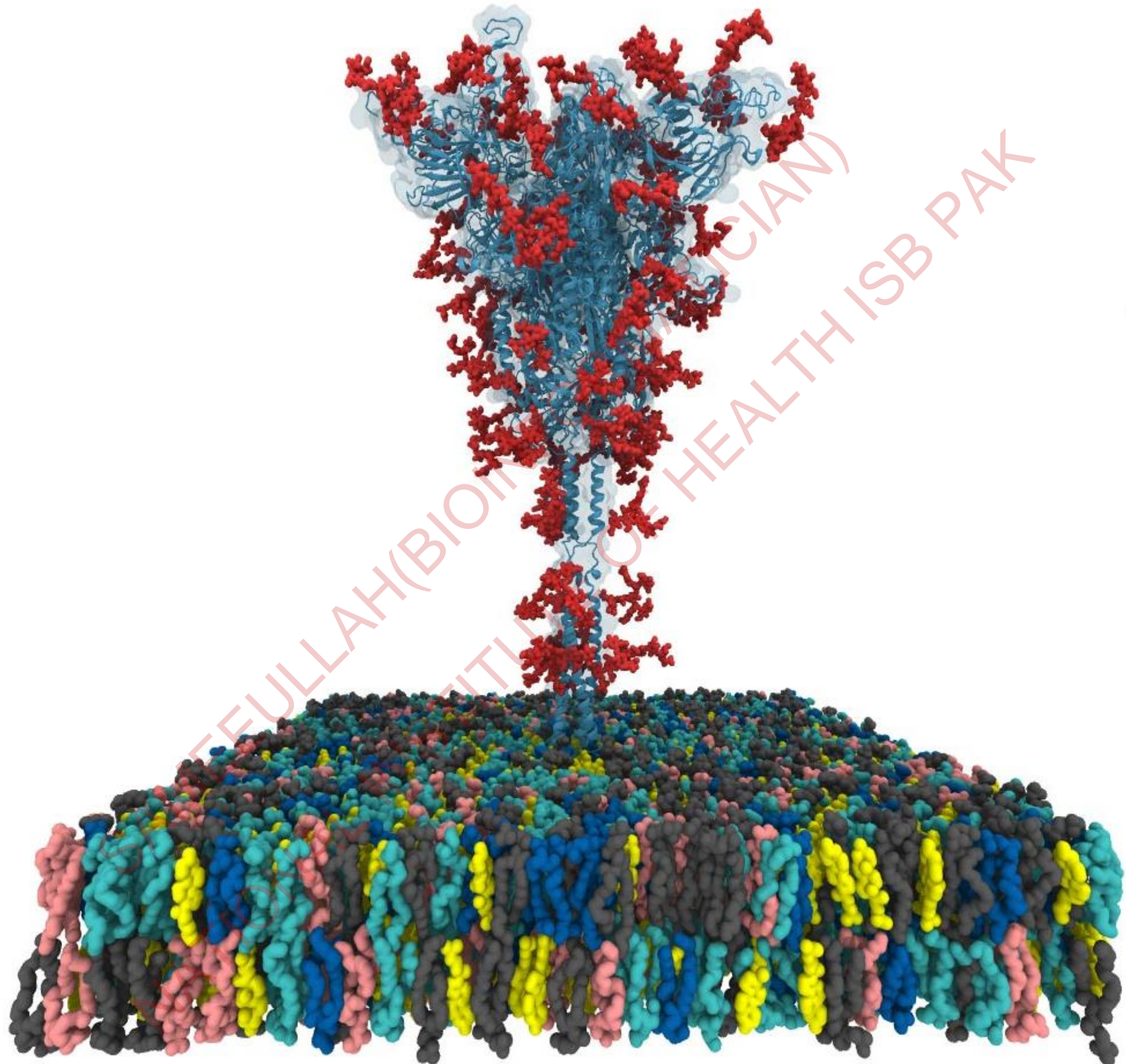
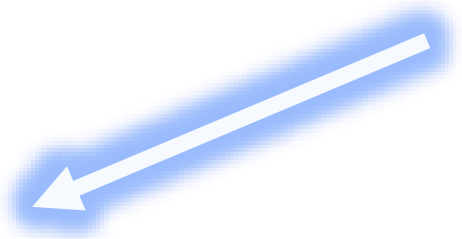
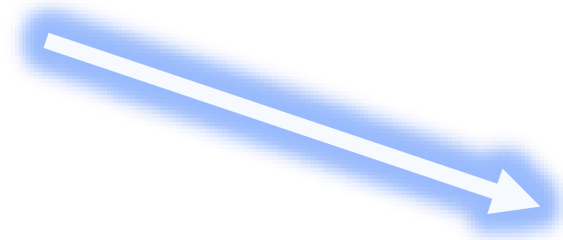
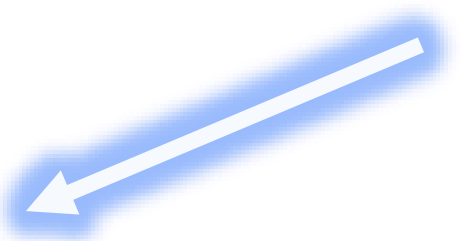
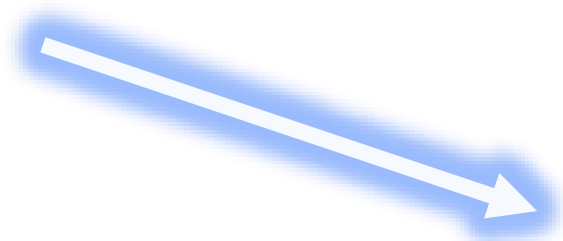
TRIALS PARTICIPANTS

Phase 1/2: 3102

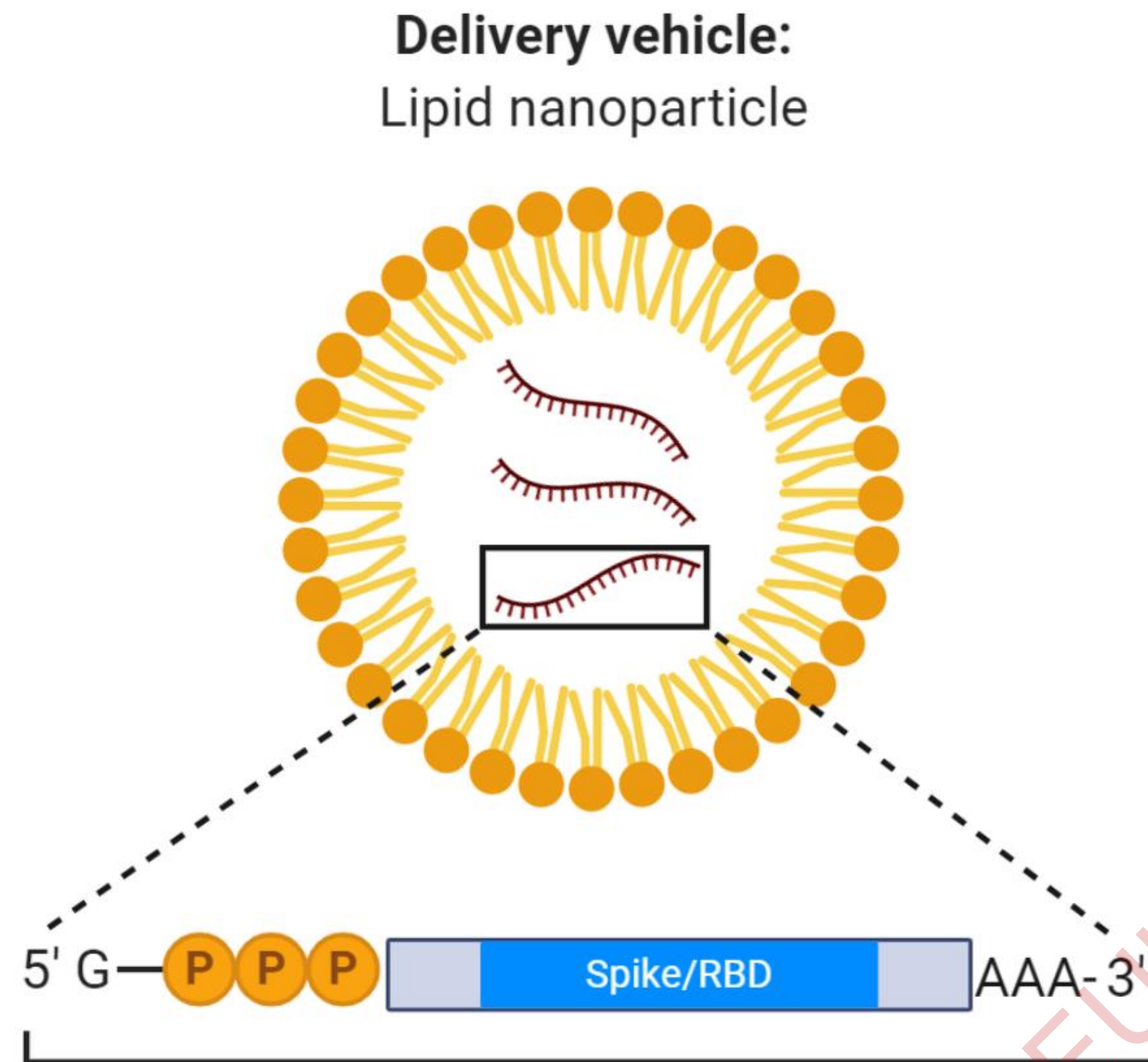
Phase 3: 35,100



Platform: Engineered AZD1222 adenovirus capable of producing the spike (S) protein of SARS-CoV-2.



BioNTech (BNT162: a1, b1, b2, c2)



Nucleoside modified RNA (modRNA)
Uridine containing mRNA (uRNA)
Self-amplifying mRNA (saRNA)

Comprised of **LNP (lipid nano-particle)**

2-modRNA (Nucleoside modified)
1-uRNA (Uridine containing mRNA)
1-saRNA (self-amplifying mRNA)

ORGANIZATIONS

Biontech SE, Pfizer, Shanghai Fosun Pharmaceutical Development Co, Ltd.

COUNTRIES INVOLVED

Germany, Global

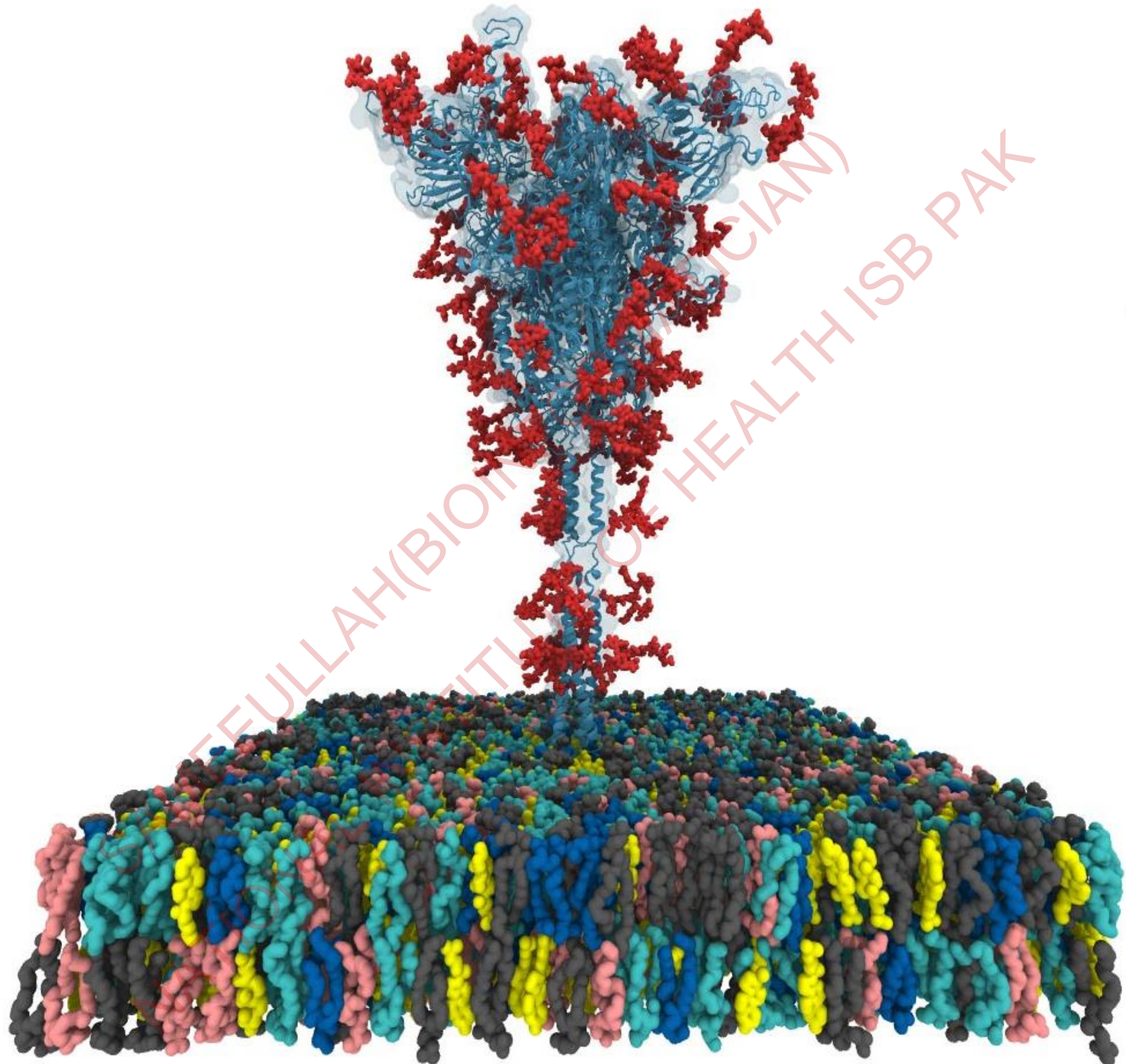
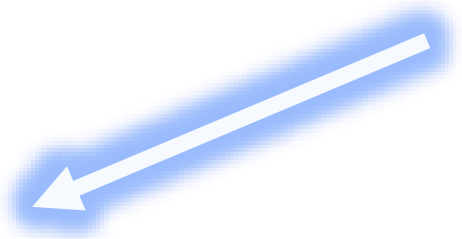
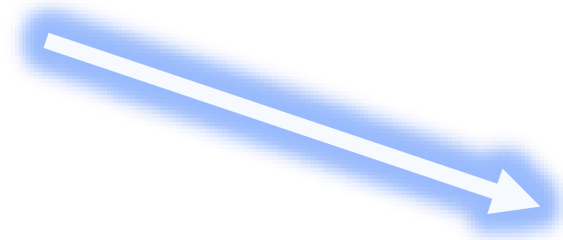
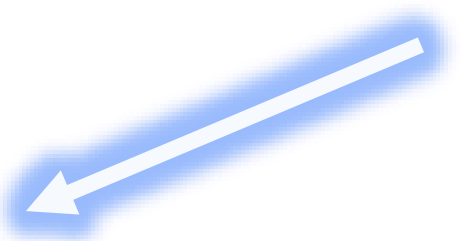
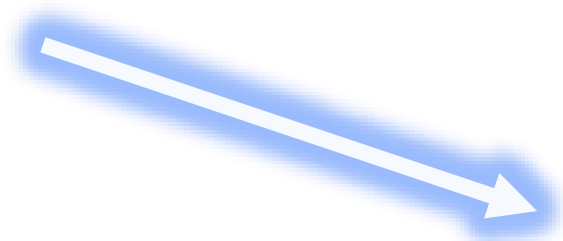
TRIALS PARTICIPANTS

Phase 1: 288

Phase 2: 764

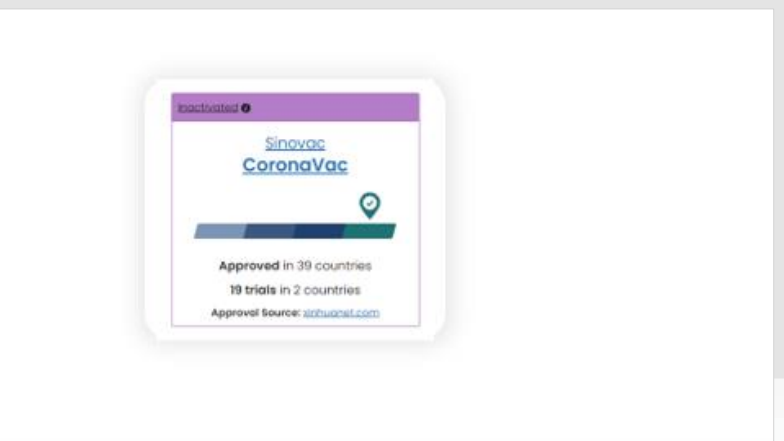
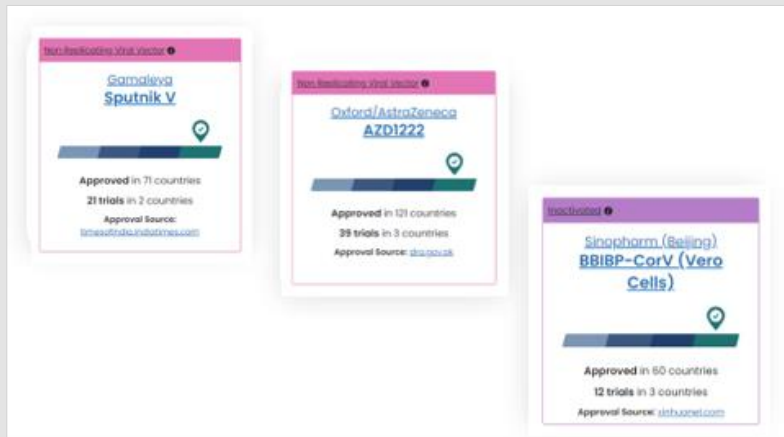
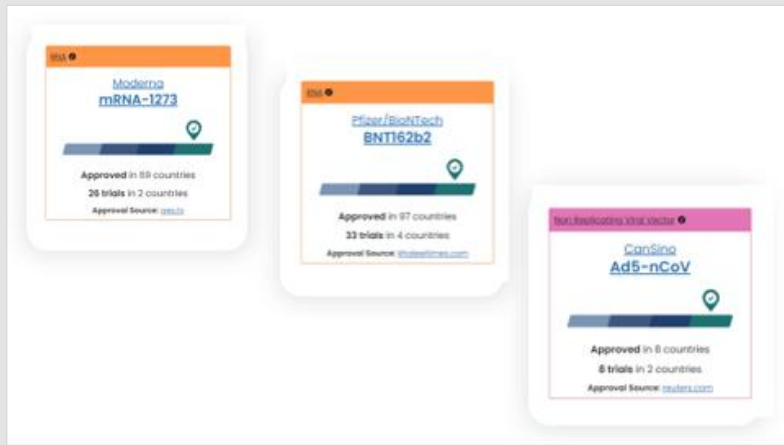
Phase 3: 29,481

Platform: Four individual LNP-encapsulated mRNA vaccines (2 modRNA, 1uRNA, 1 saRNA) encoding Spike protein or Receptor Binding Domain (RBD).



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SARS-CoV-2 Vaccines Approved for use in Pakistan



**PAKISTAN
STRONG!**

**FIGHT AGAINST COVID-19
CORONAVIRUS**

RNA ⓘ

Moderna
mRNA-1273



Approved in 69 countries
26 trials in 2 countries
Approval Source: geo.tv

RNA ⓘ

Pfizer/BioNTech
BNT162b2



Approved in 97 countries
33 trials in 4 countries
Approval Source: khaleejtimes.com

Non Replicating Viral Vector ⓘ

CanSino
Ad5-nCoV



Approved in 8 countries
8 trials in 2 countries
Approval Source: reuters.com

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Non Replicating Viral Vector ⓘ

Gamaleya Sputnik V



Approved in 71 countries

21 trials in 2 countries

Approval Source:

timesofindia.indiatimes.com

Non Replicating Viral Vector ⓘ

Oxford/AstraZeneca AZD1222



Approved in 121 countries

39 trials in 3 countries

Approval Source: dra.gov.pk

Inactivated ⓘ

Sinopharm (Beijing). BBIBP-CorV (Vero Cells).



Approved in 60 countries

12 trials in 3 countries

Approval Source: xinhuanet.com

Inactivated ⓘ

Sinovac
CoronaVac



Approved in 39 countries

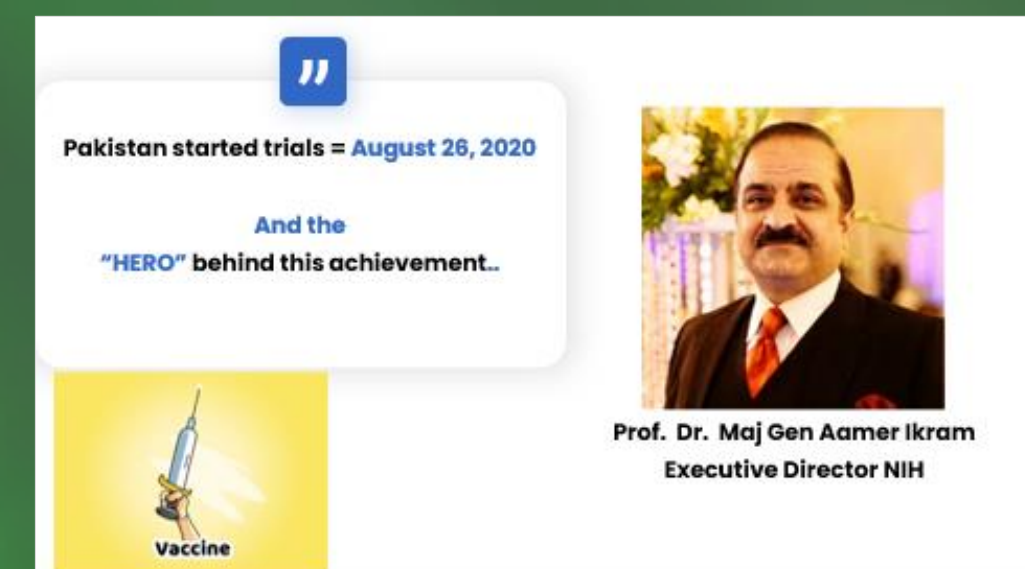
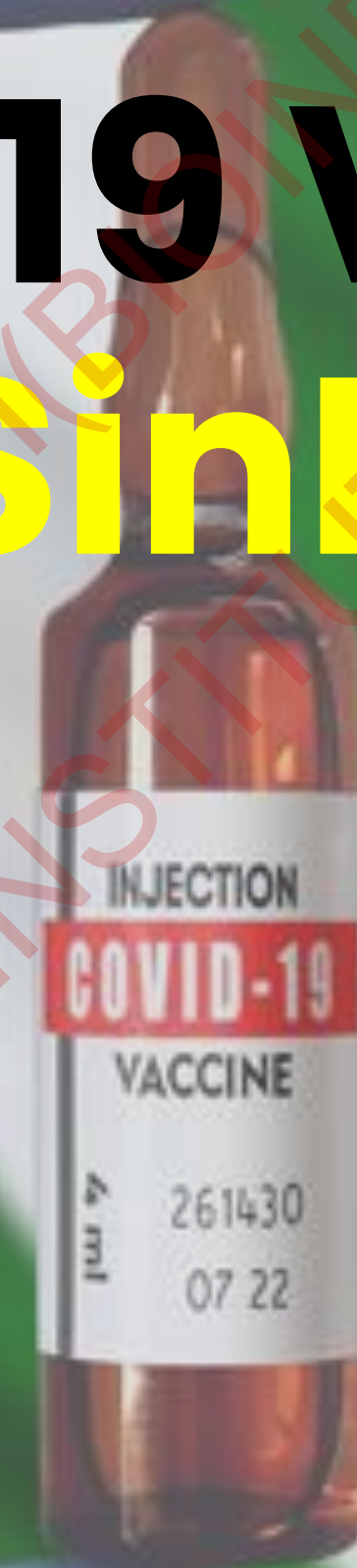
19 trials in 2 countries

Approval Source: xinhuanet.com

SAMEFULAH (BIOINFORMATICIAN)
NATIONAL INSTITUTE OF HEALTH ISB PAK

The FACE and Efforts of the HERO...

**behind COVID-19 Vaccine TRIALS in
Pakistan "CanSinBio now known as
PAKVAC"**





Ad5-nCoV

Adenovirus type 5 vector

Express S-spike proteins

“Trials participants were from Pakistan”

ORGANIZATIONS

CanSino Biologics Inc., Institute of Biotechnology,

COUNTRIES INVOLVED

China, Canada, Russia, **Pakistan**,

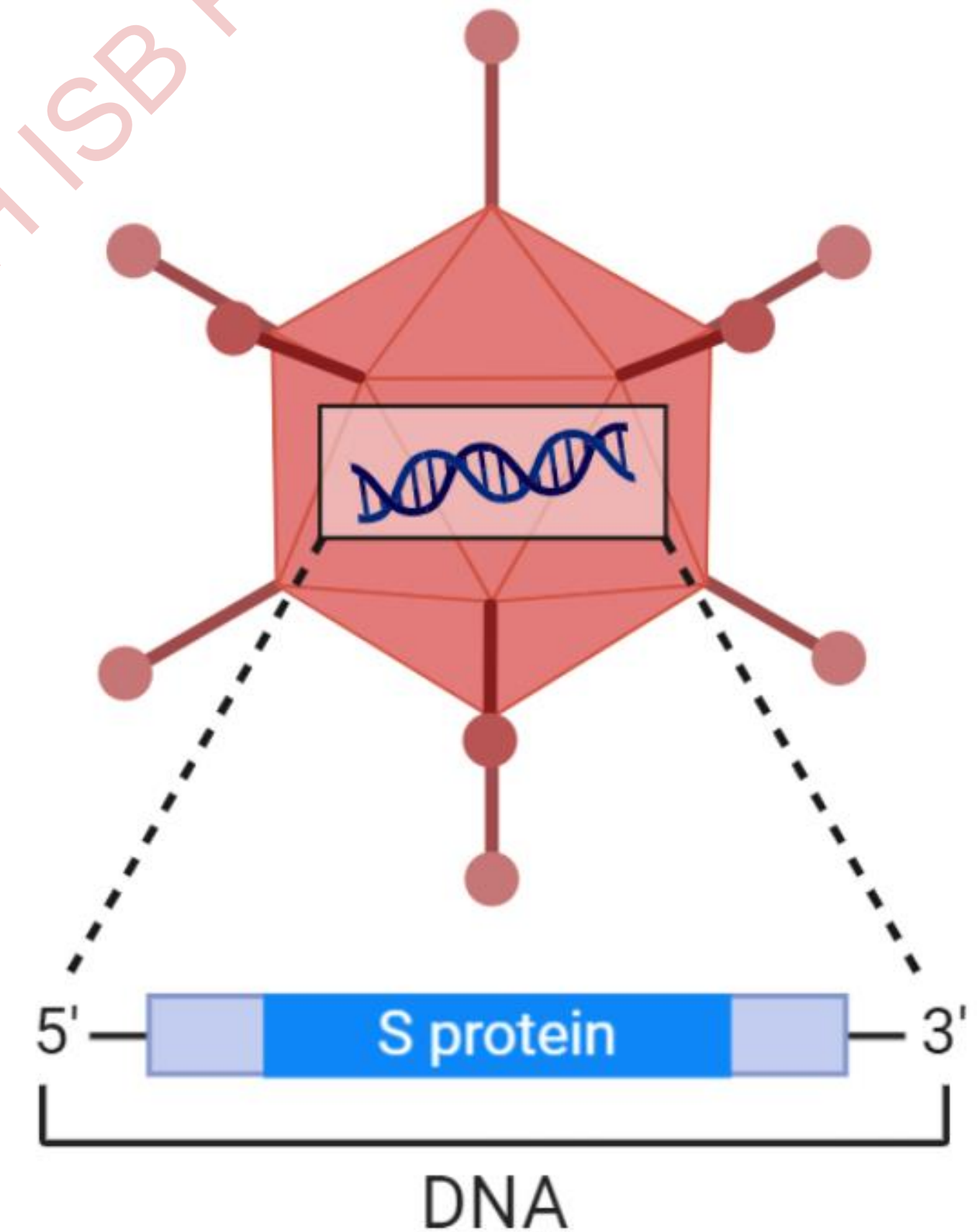
TRIALS PARTICIPANTS

Phase 1: 276

Phase 2: 989

Phase 3: 40,500

CanSino Biologics (Ad5-nCoV)

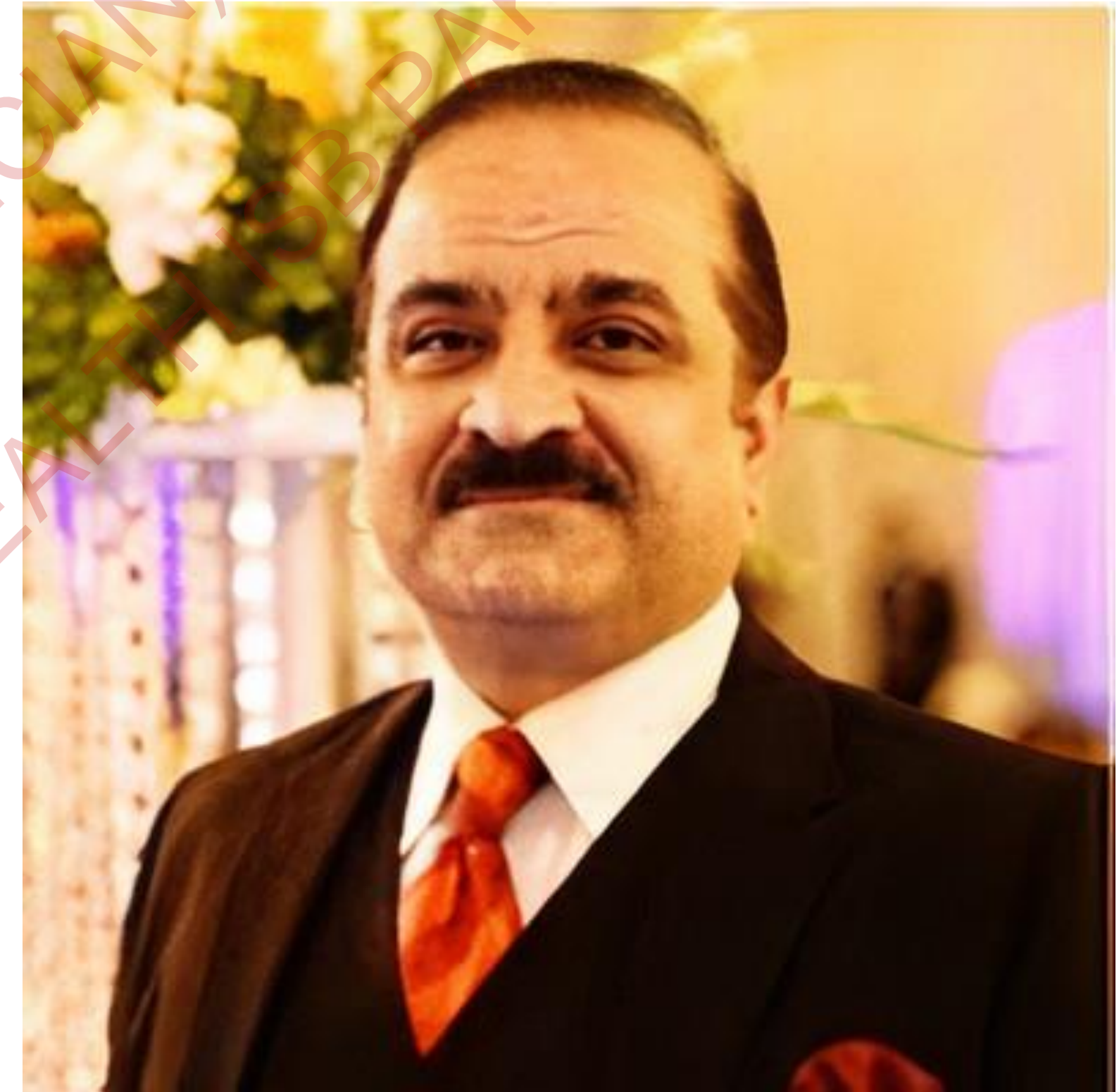


Platform: Adenovirus type 5 vector that expresses S protein.



Pakistan started trials = August 26, 2020

**And the
"HERO" behind this achievement..**



**Prof. Dr. Maj Gen Aamer Ikram
Executive Director NIH**



Thank You

COVID-19
coronavirus disease
vaccine





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