

Vaccines - Road of development & regulatory sights to keep safety & efficacy as front burner priority

RAK Medical & Health Sciences University
UAE, Thursday March 4, 2021
2.00 – 2.45 pm UAE time
<https://www.rakmhsu.ac.ae/upcoming-cme>



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CEO, Centre for Quality Sciences



Essential References for Lecture

1. US-FDA Portal on Developing and Manufacturing Drugs Including Biologics, <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/developing-and-manufacturing-drugs-including-biologics>
2. Virology, transmission, and pathogenesis of SARS-CoV-2 BMJ 2020; 371 doi: <https://doi.org/10.1136/bmj.m3862> (Published 23 October 2020)
3. WHO good manufacturing practices for biological products Replacement of Annex 1 of WHO Technical Report Series, No. 822
4. Vaccines and Related Biological Products Advisory Committee Meeting, US-FDA, December 10, 2020
5. Safety and Immunogenicity Study of 2019-nCoV Vaccine (mRNA-1273) for Prophylaxis of SARS-CoV-2 Infection (COVID-19) - ClinicalTrials.gov Identifier: NCT04283461
6. Microbiology, Michael J. Pleczar.

Disclaimer

It reflects the views and understanding of presenter & may not represent the views or policies of organization or association to which speaker has or had ties. These views are constructed purely in the boundary of science. Speaker's educational, training, professional services background helped to create the today's learning objectives

9

Learning Outcomes

- 1 - What is immunity and how it is acquired?
- 2 - How infection intervenes in the acquiring of immunity?
- 3 - How vaccine picks up the same pathway of infection in acquiring immunity?

9

Learning Outcomes

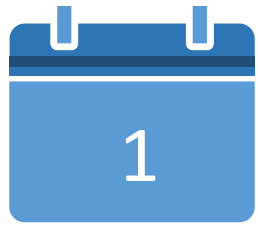
- 4 - How advancement of molecular biology influence in the development of vaccine?
- 5 - What are the safety concerns with vaccines?
- 6 - What are the efficacy expectations with vaccines?

9

Learning Outcomes

- 7 - What are the quality questions with vaccine manufacturing?
- 8 - What is the Post marketing Surveillance & Pharmacovigilance of Vaccines?
- 9 - How causality analysis is done in case of Adverse Events Followed by Immunization?

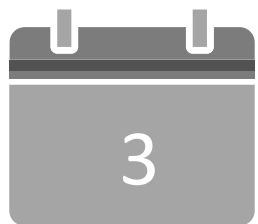
Lets move one by one to catch the today's learning objectives



Biology and Vaccine



Healthcare and Vaccine



Development Strategies of Vaccine



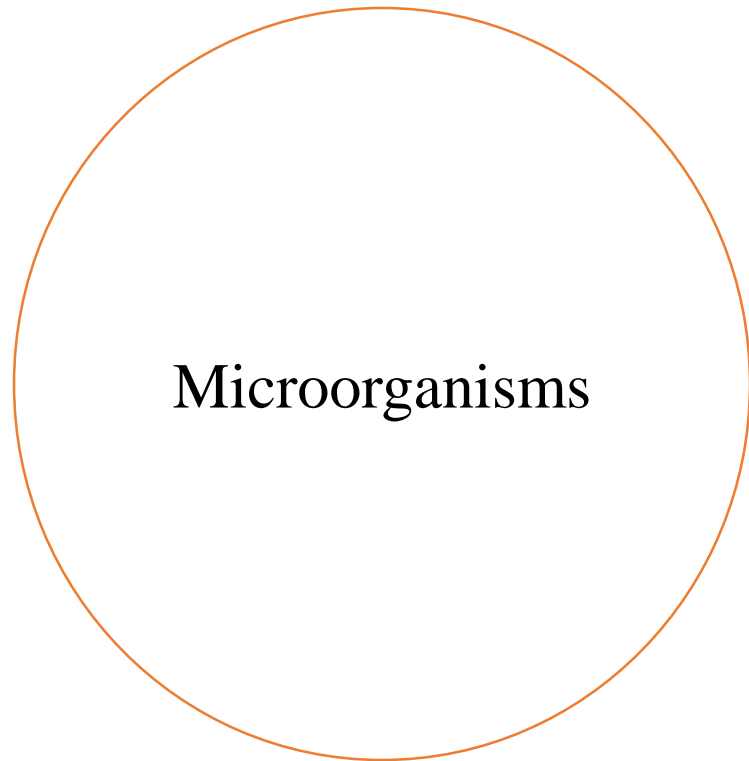
Vaccine and Clinical Trials



Vaccine Application Reviews



Vaccine Post marketing affairs



Protozoa (Amoeba, Malaria, ...)

Fungi

Bacteria

Virus

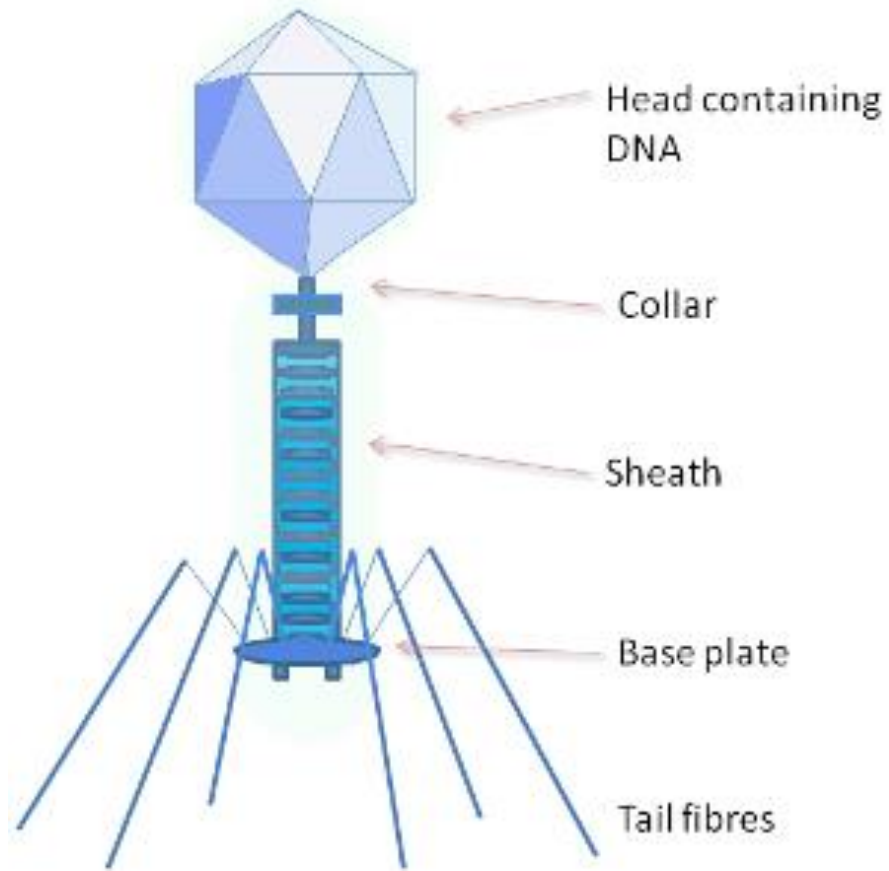


< 10um - Red blood cell

< 5 um - Bacteria

100 nm - Virus

< 5 nm - Lipid



200 nm long & 80 - 100 nm wide
Range is 20 – 400 nm length

nm ... um ... mm



Pox



Ebola

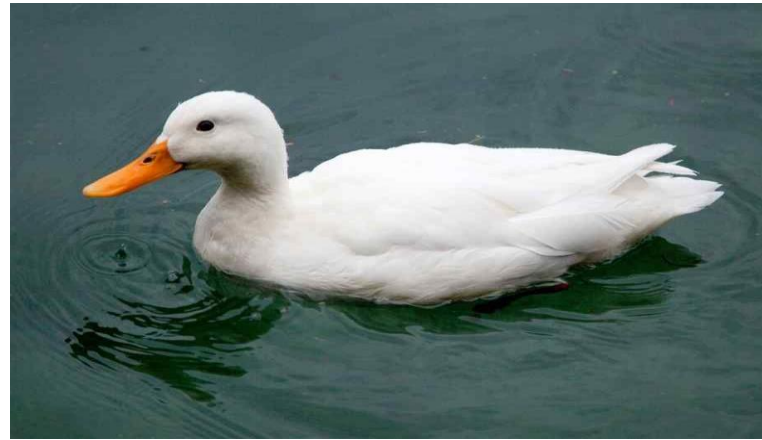


Rabies



...

Influenza



AIDS



Zika



Plants, Animals to humans
host virus

Influenza



AIDS



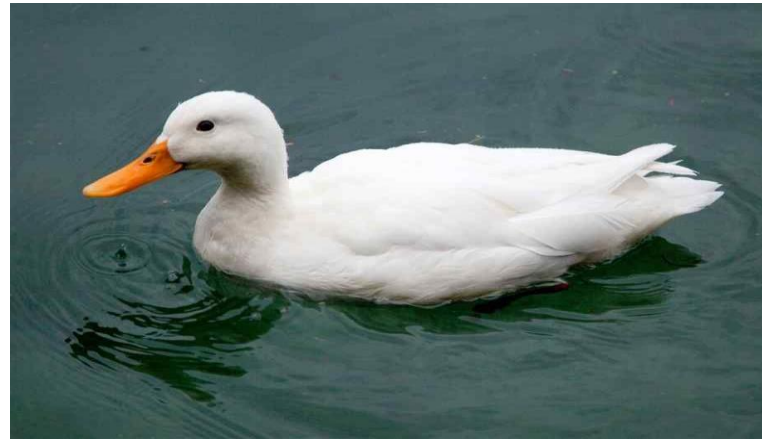
Zika



Plants, Animals to humans
host virus

Viruses are the obligate
parasites

Influenza



AIDS



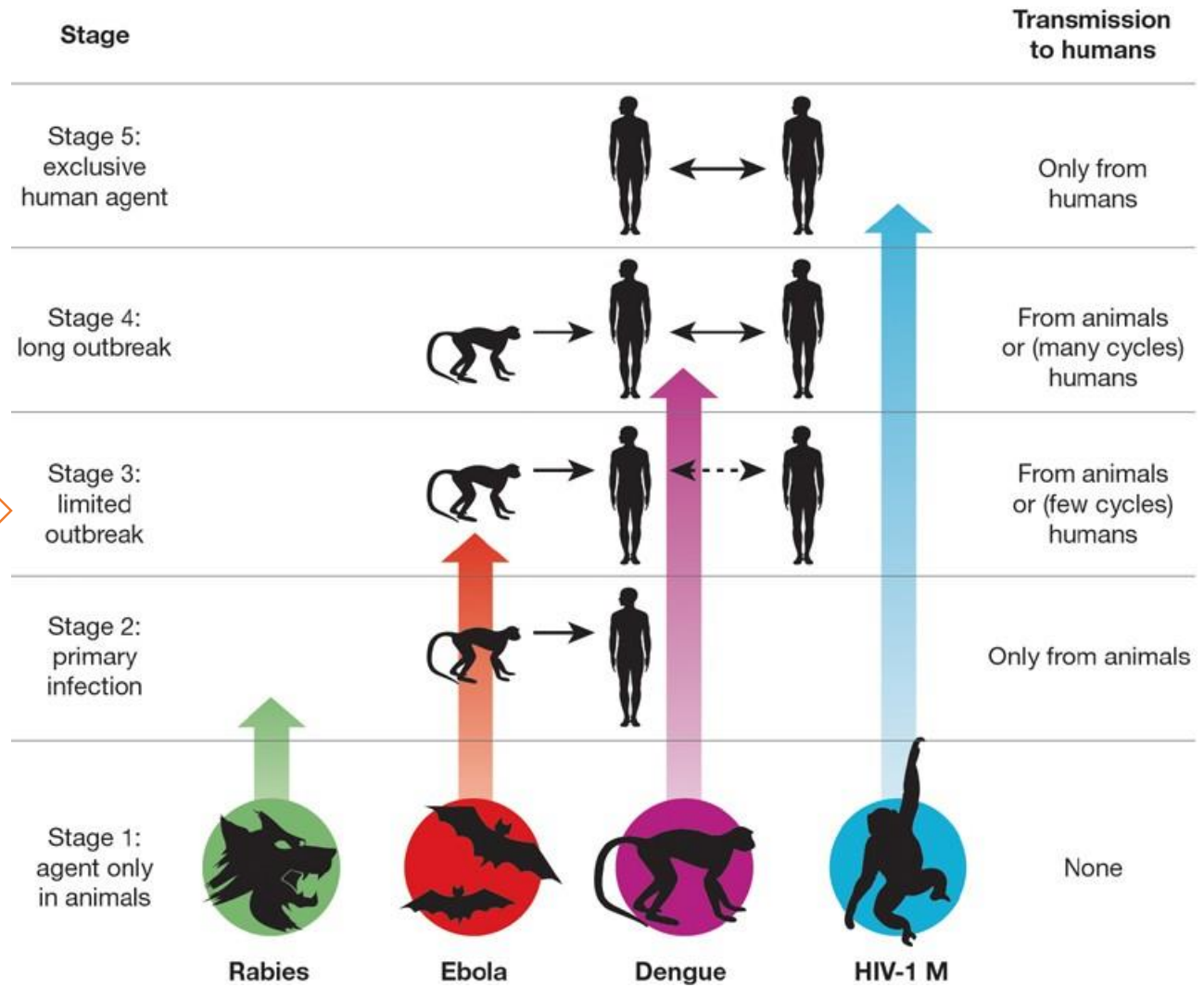
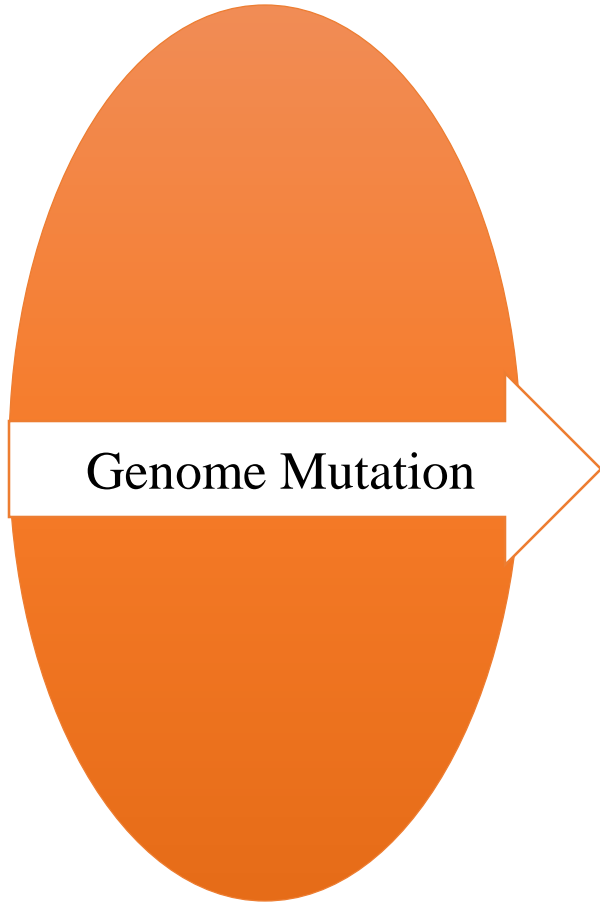
Zika

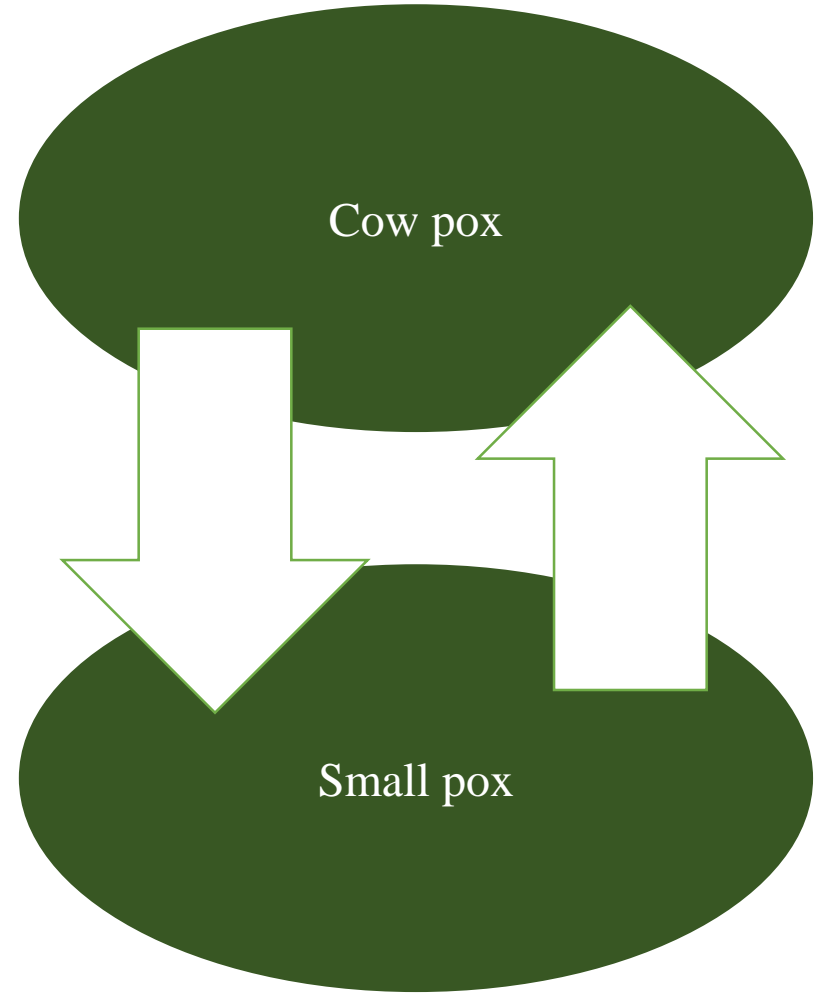
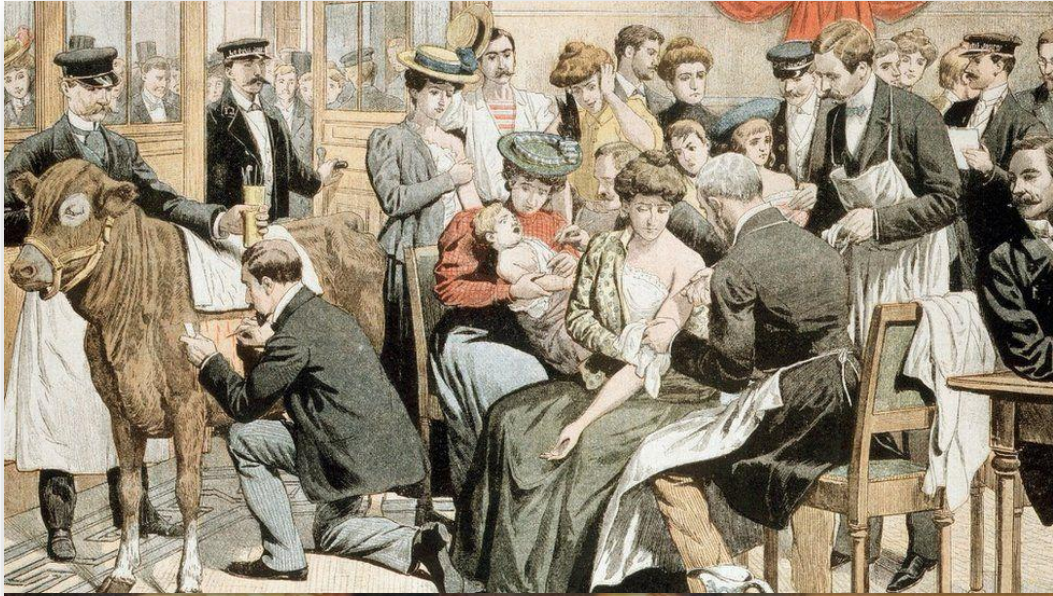


Plants, Animals to humans
host virus

Viruses are the obligate
parasites

They cannot grow on non-
living thing

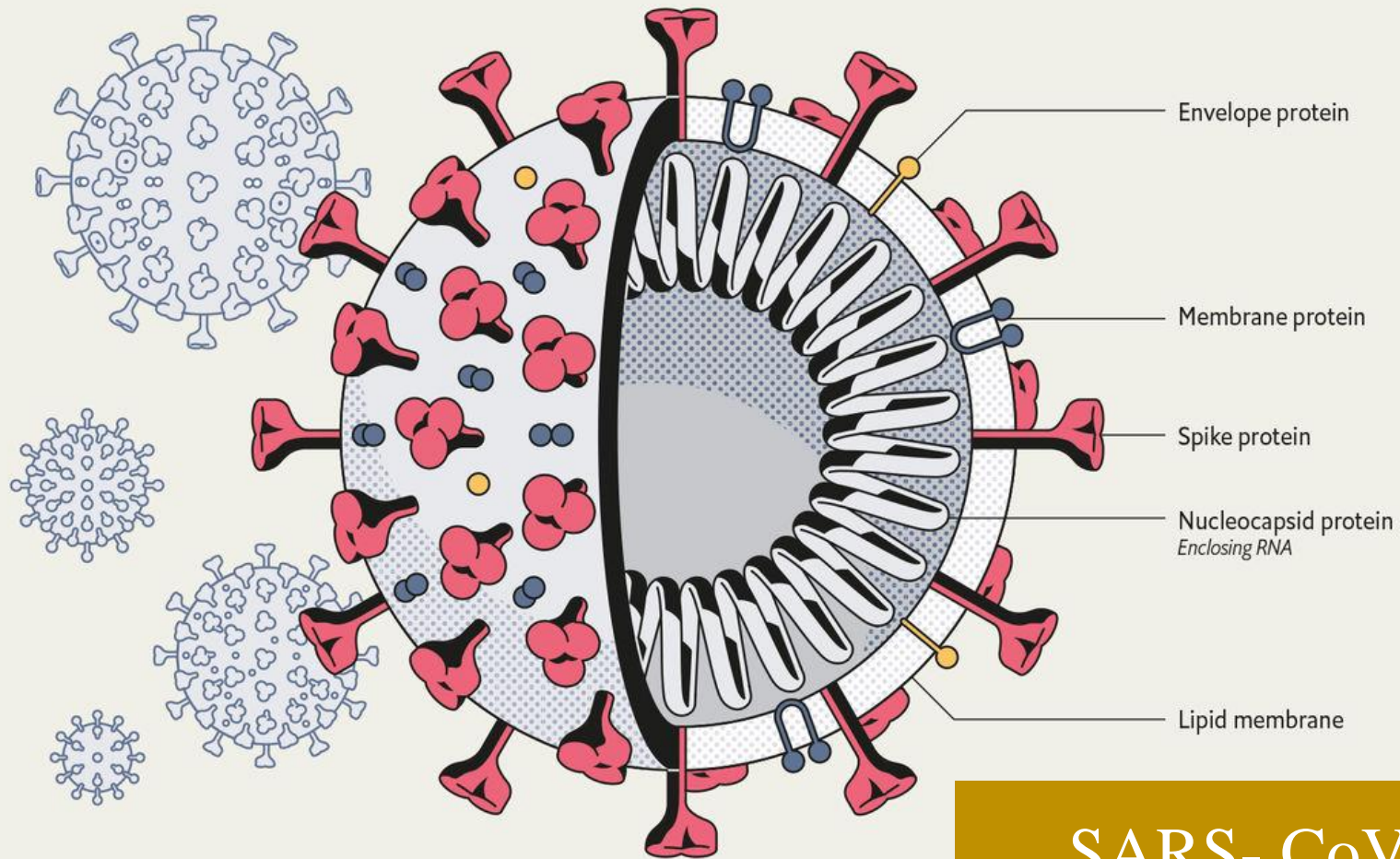




1796

Pathogenicity

Immunogenicity



SARS- CoV-2



Diagnostic kit

Therapeutic

Preventive

Antigen testing

Diagnostic kit

Therapeutic

Preventive

Antibody testing

Antiviral (Chemical) Drugs

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graph TD; A[Antiviral (Chemical) Drugs] --> B[Diagnostic kit]; A --> C[Therapeutic]; A --> D[Preventive]; C --> E[Monoclonal Antibodies & Serum Therapies];
```

Diagnostic kit

Therapeutic

Preventive

Monoclonal Antibodies & Serum Therapies

Sub Clinical Infection

Diagnostic kit

Therapeutic

Preventive

Immunization



Diagnostic



Critical to know

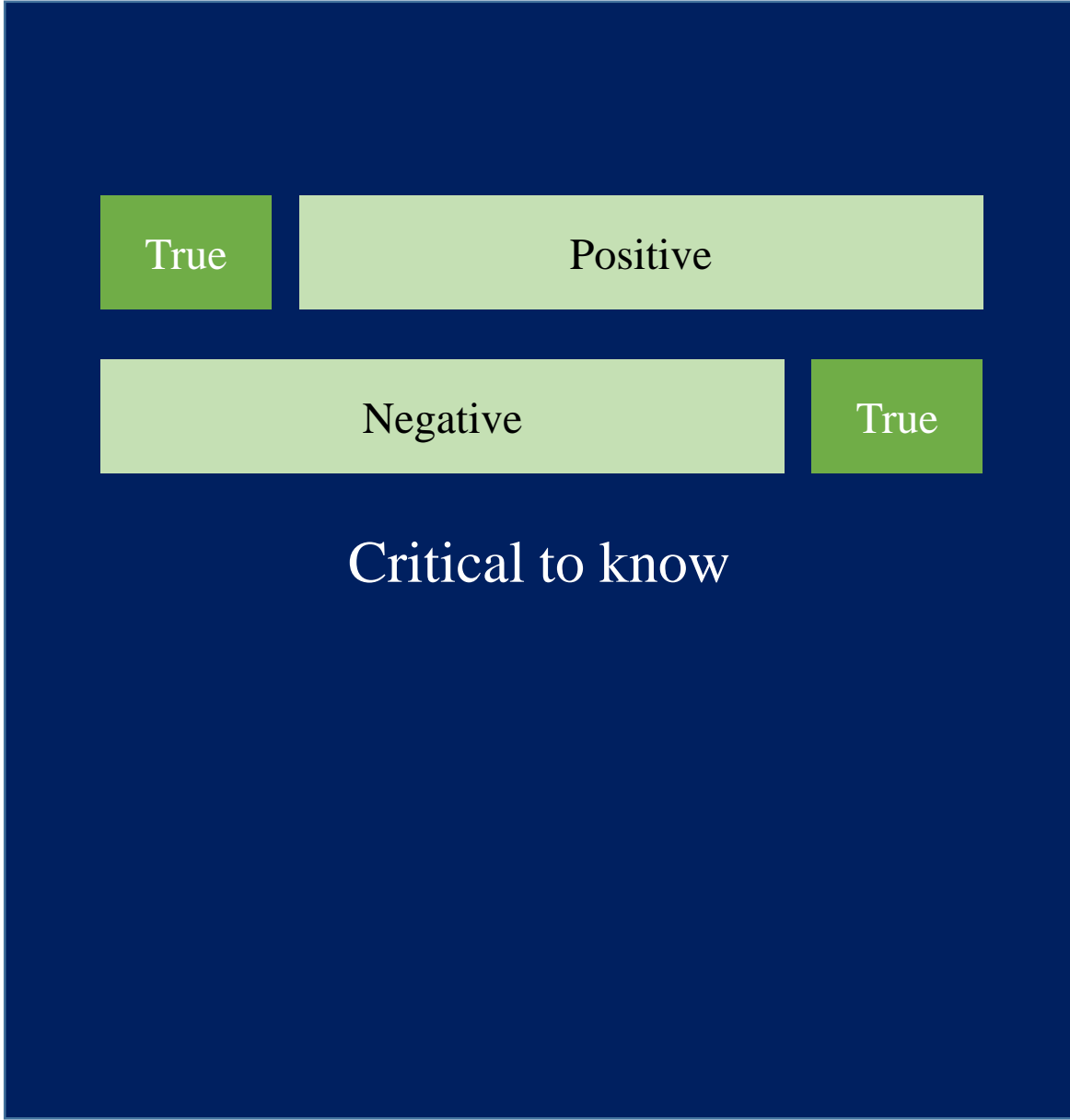
Diagnostic

True

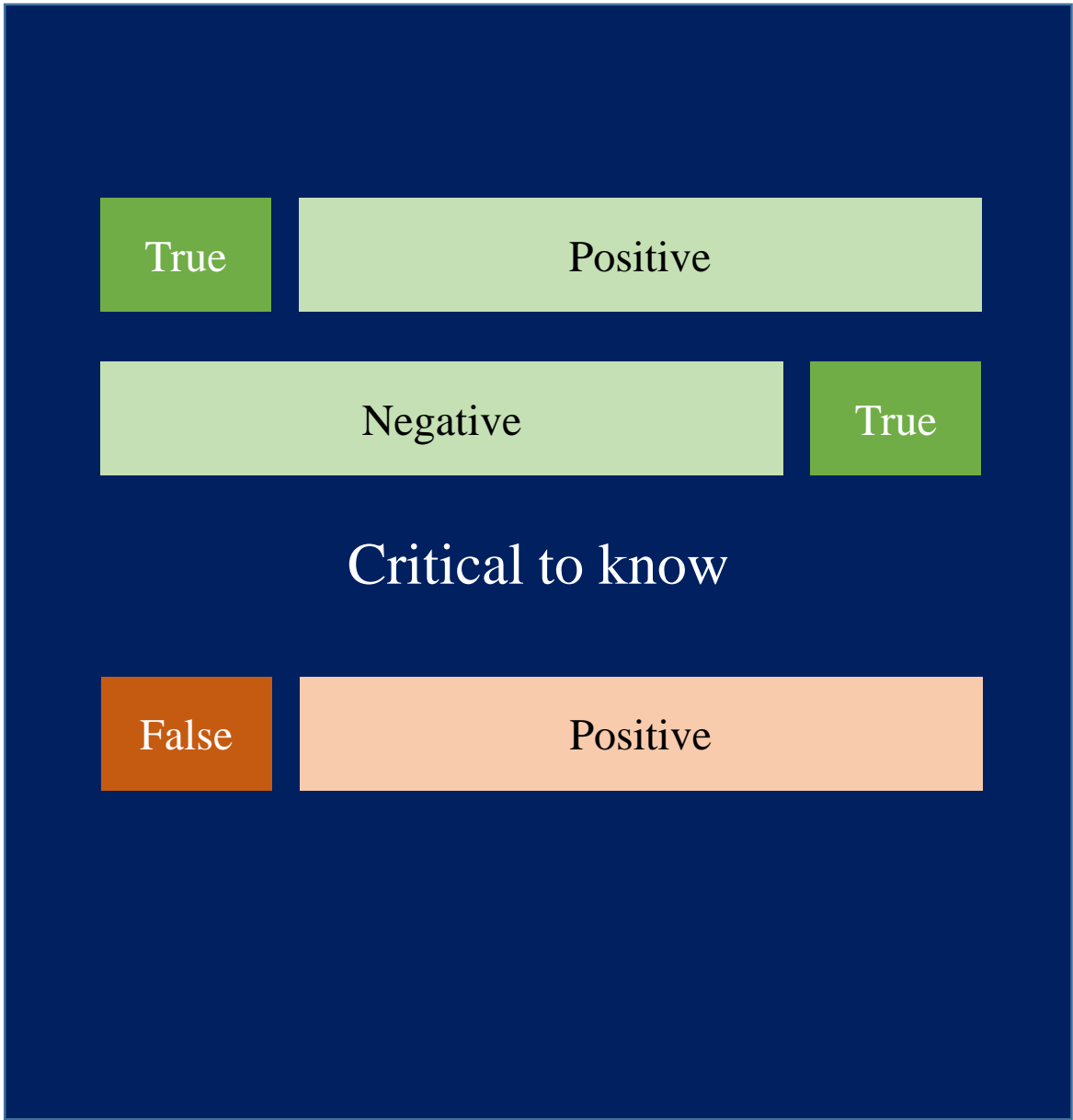
Positive

Critical to know

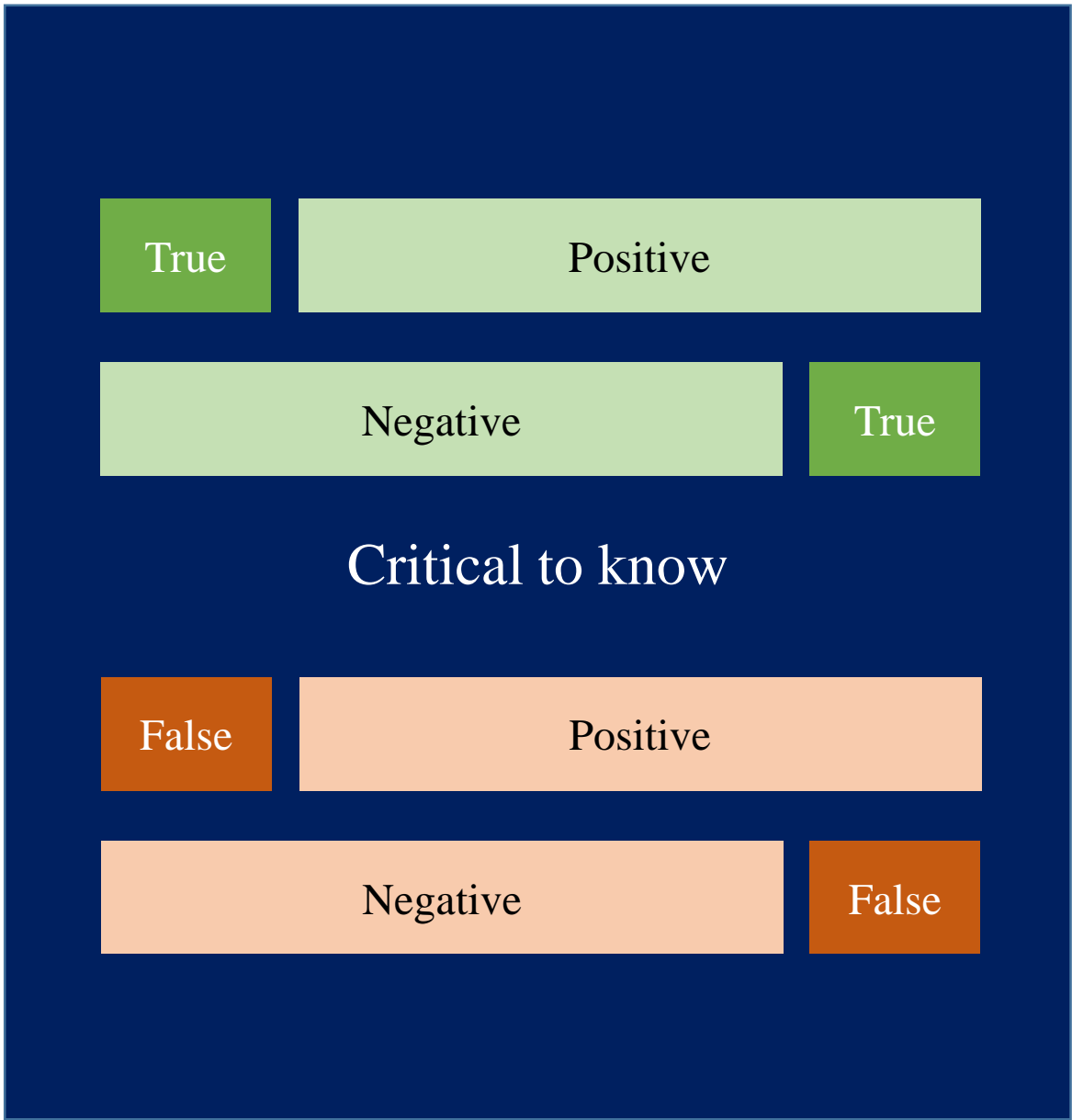
Diagnostic



Diagnostic



Diagnostic



Antiviral (Chemical) Drugs

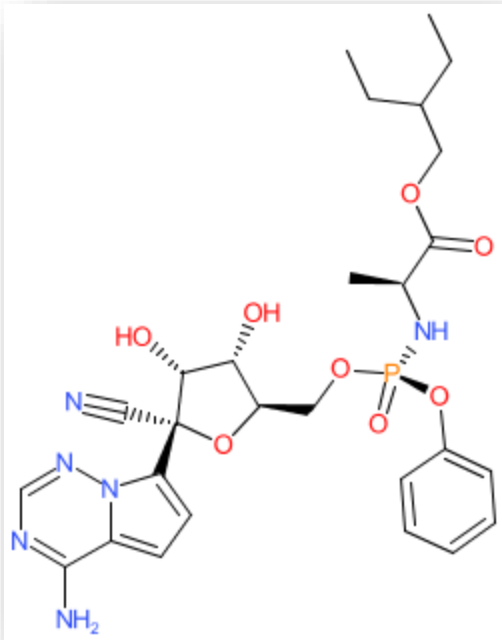
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graph TD; A[Antiviral (Chemical) Drugs] --> B[Diagnostic kit]; A --> C[Therapeutic]; A --> D[Preventive]; C --> E[Monoclonal Antibodies & Serum Therapies];
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Diagnostic kit

Therapeutic

Preventive

Monoclonal Antibodies & Serum Therapies



Sub Clinical Infection

Diagnostic kit

Therapeutic

Preventive

Immunization

CoVid-19 Vaccine Approaches

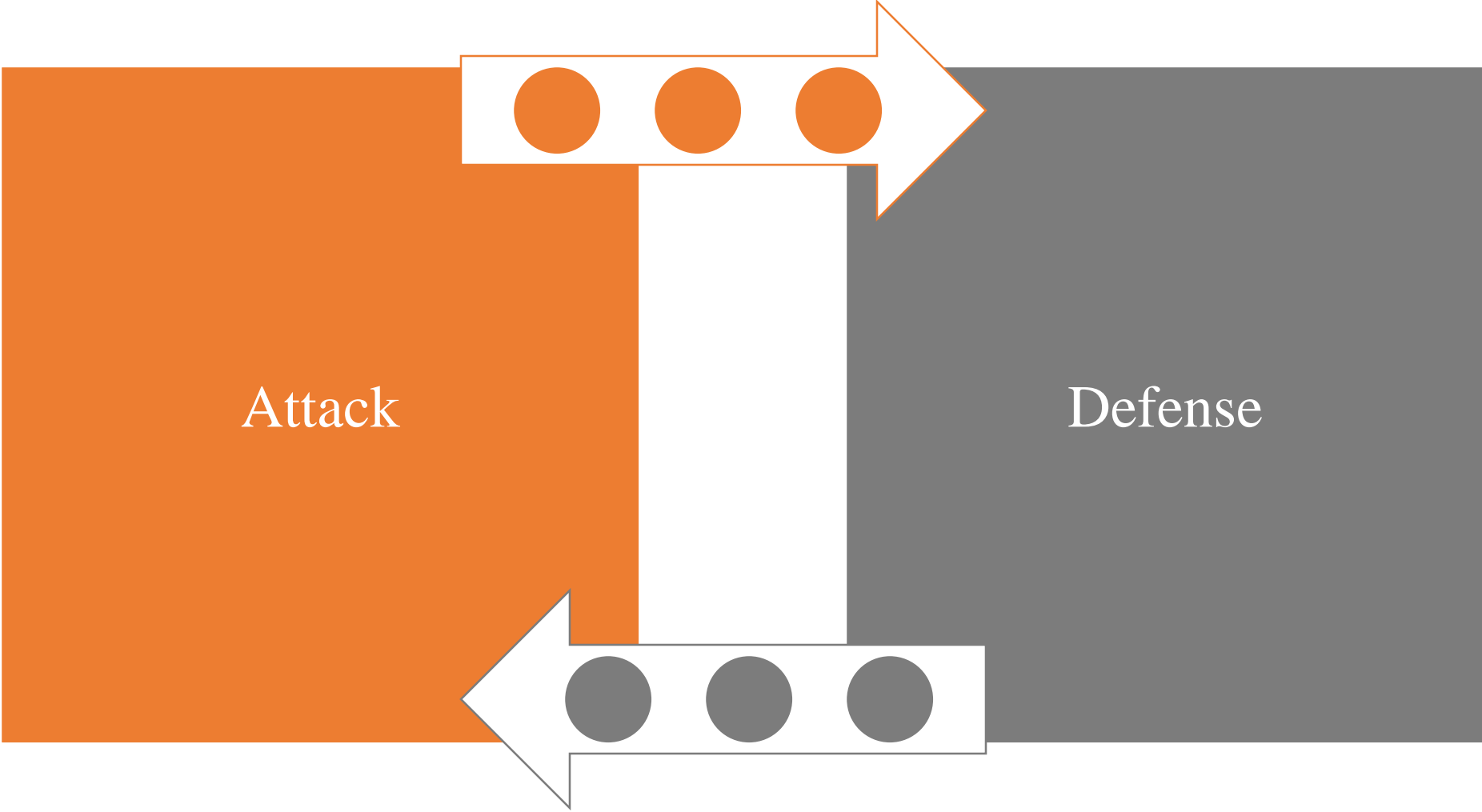
Inactivated &
Live Attenuated
Vaccine

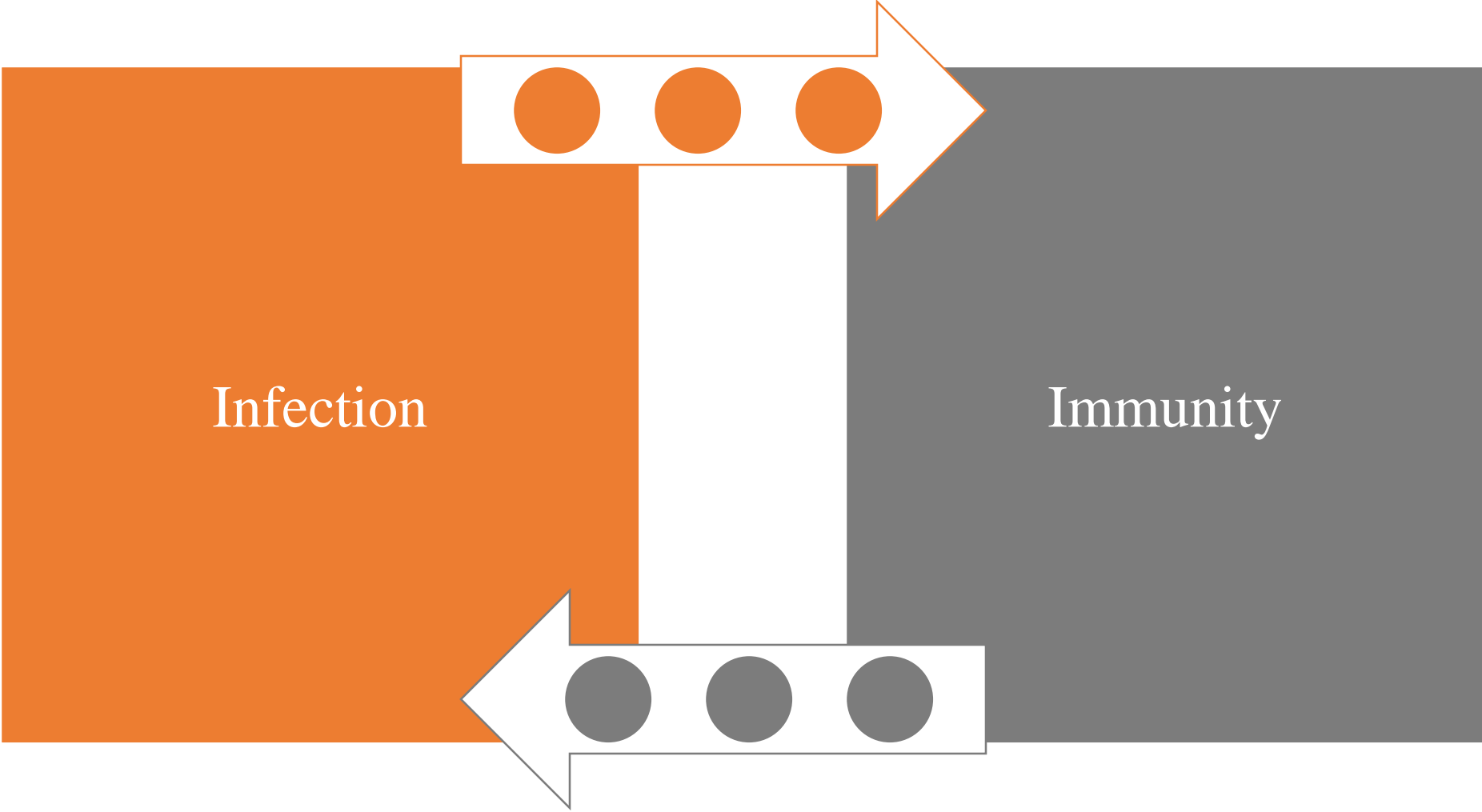
Genetic (DNA or
RNA) Vaccine

Viral Vector
Vaccine

Protein Based
Vaccine

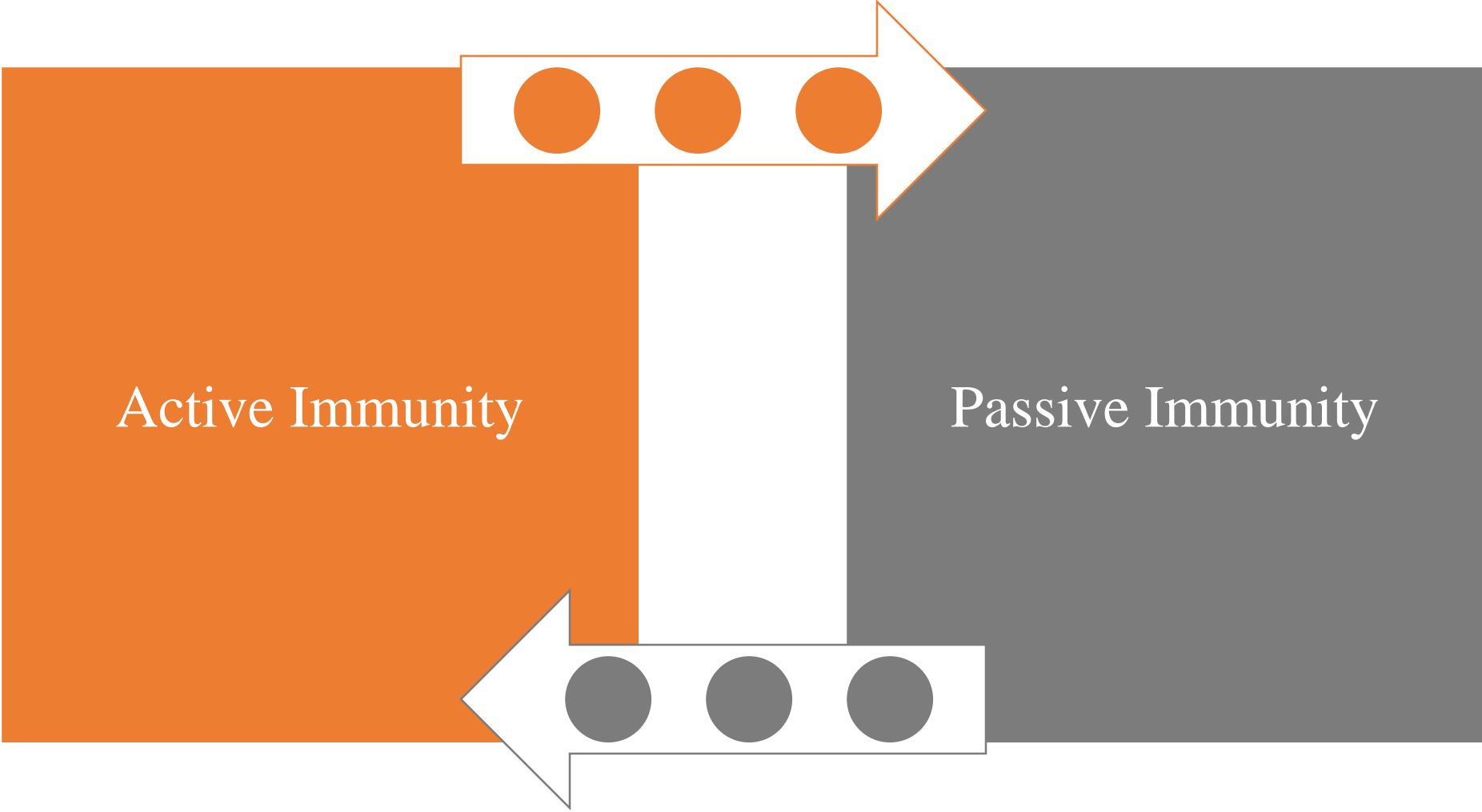


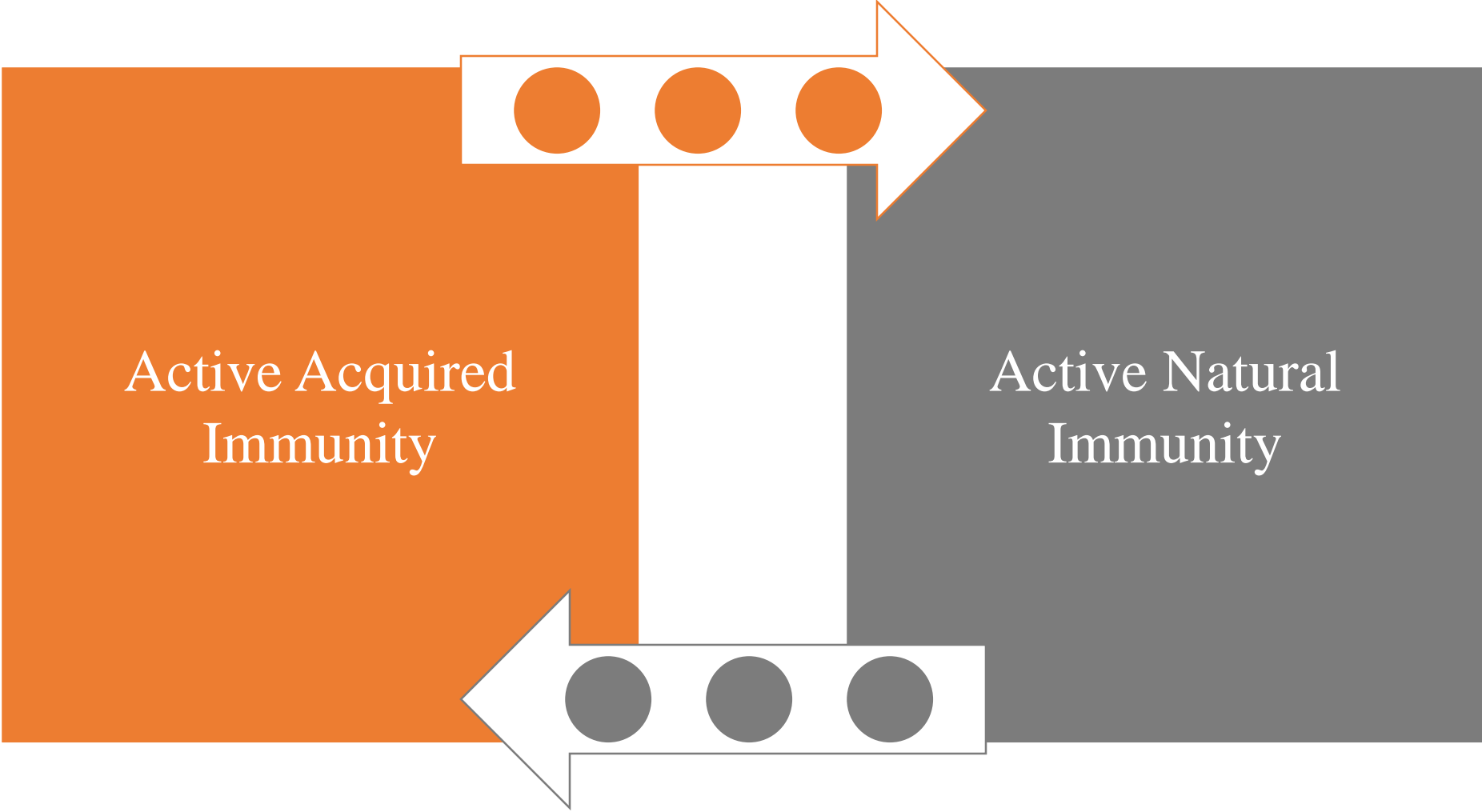


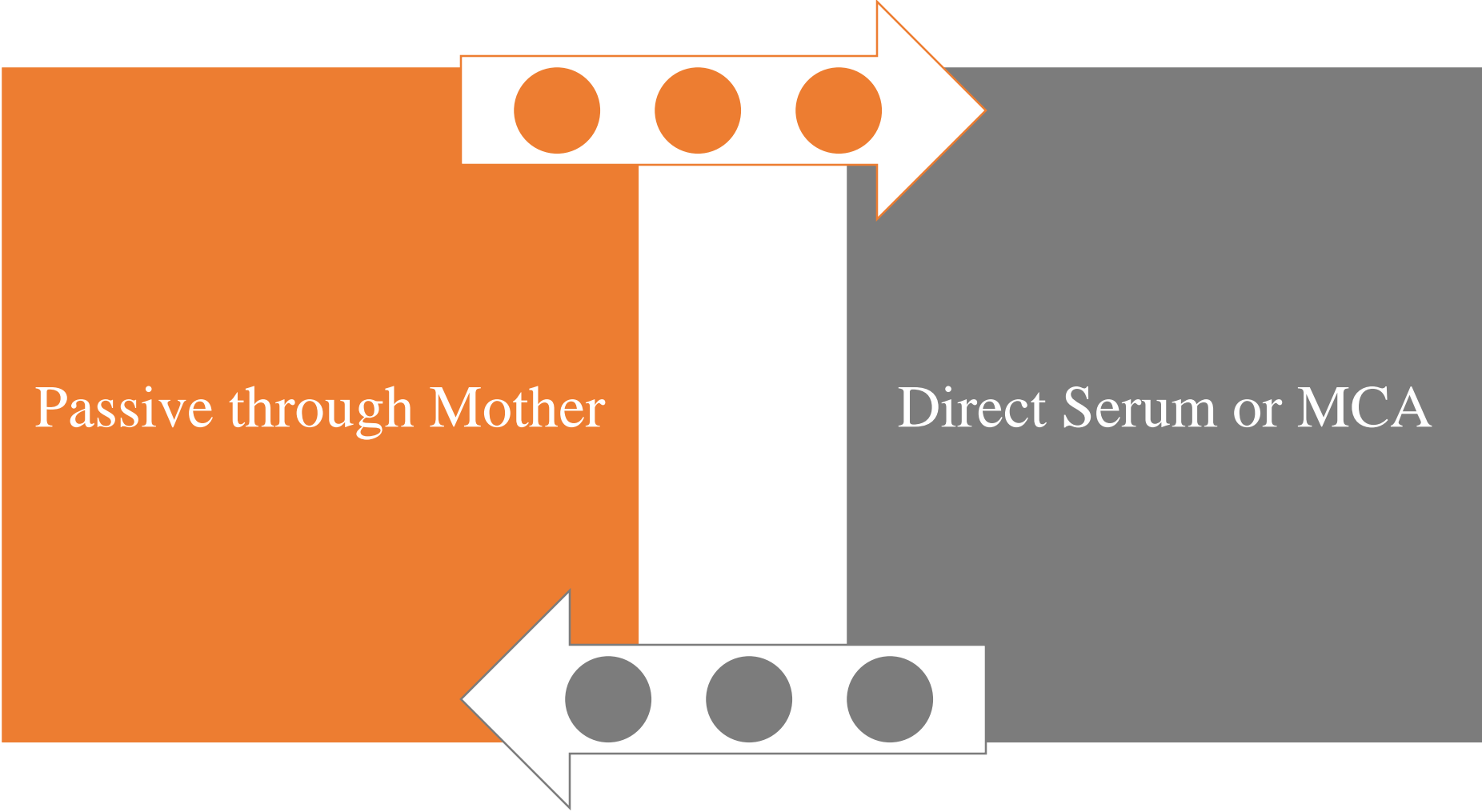


Infection

Immunity





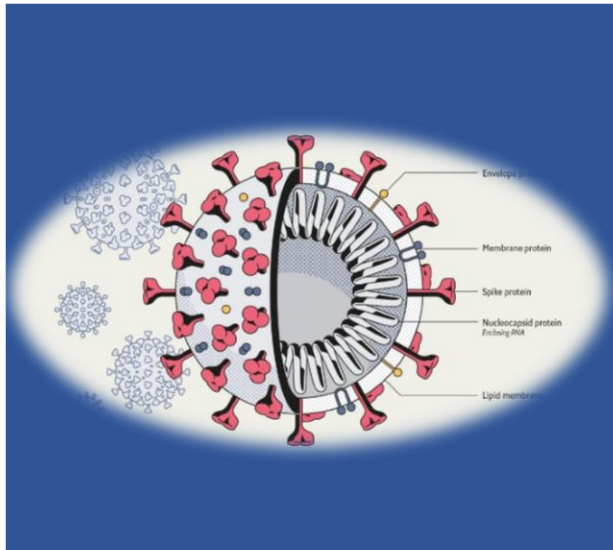


Passive through Mother

Direct Serum or MCA

Hypersensitivity





Smallest in size

Obligate Parasite

Protein-Spike, Envelope, Membrane, Nucleic



ACE – 2 Cells

Cytokine Storm

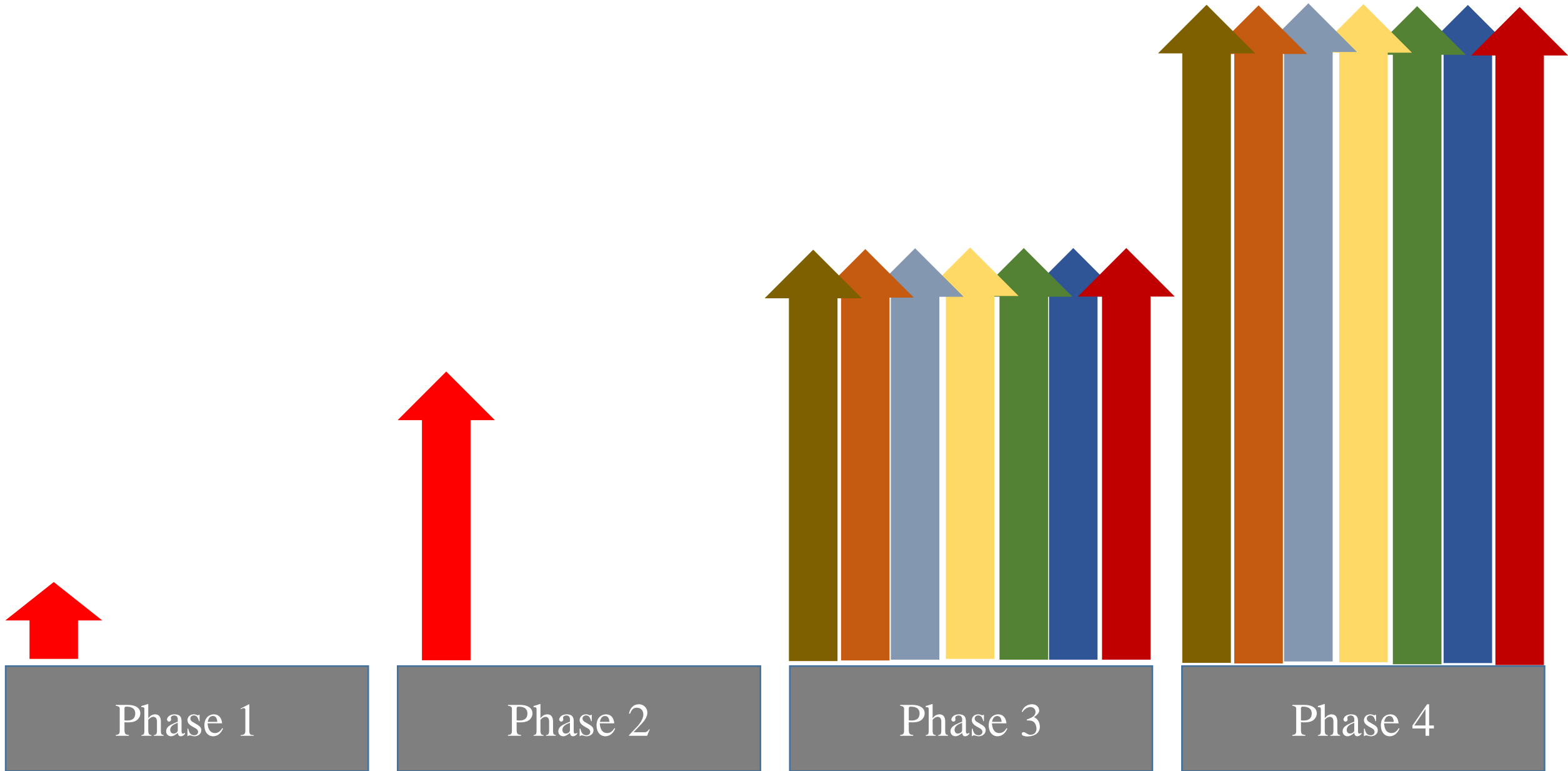
Dimer ... Clotting ... Diversity

Immunogenicity

Safety

Efficacy





Phase 1

Phase 2

Phase 3

Phase 4

No Vaccine

100% effective in preventing disease

100% safe in all vaccinated people

CoVid
Vaccine

If it is 50% efficient &

95% confidence interval of this 50% is about 20%

Temperature,
Efficacy & Integrity



What kind of safety checks are required at the covid vaccine manufacturing plant?


Consistency

Purity

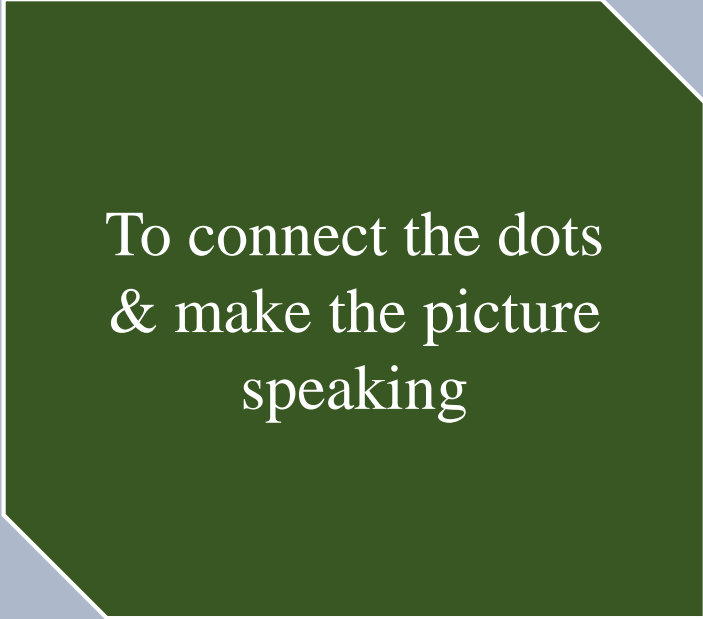
Potency

Transportation & Lot Release

What kind of safety checks are required at the covid vaccine manufacturing plant?



Let's have real time
observation &
evidences



To connect the dots
& make the picture
speaking



CoVid Discriminating

Geography

Races

Age

Diseases



We are Blind

CoVid Positive

CoVid R_0 Value

CoVid Transmission

CoVid Treatment



We are Blind

Children Transmission

Contact Transmission

Mask Efficiency

Lockdown Efficiency



We are Blind

Treatment Protocol

Actual Cause of Death

Local Data

Drug Usage



What we have to unlearn

What we have to verify

What we have to Prioritize

What we have to generate data

Aggressive to Unmask the Reason behind every Event

Thanks