



**VAXART VAAST® Platform
Pandemic Vaccines**

World Vaccine Congress

James F. Cummings, MD

April 01, 2026

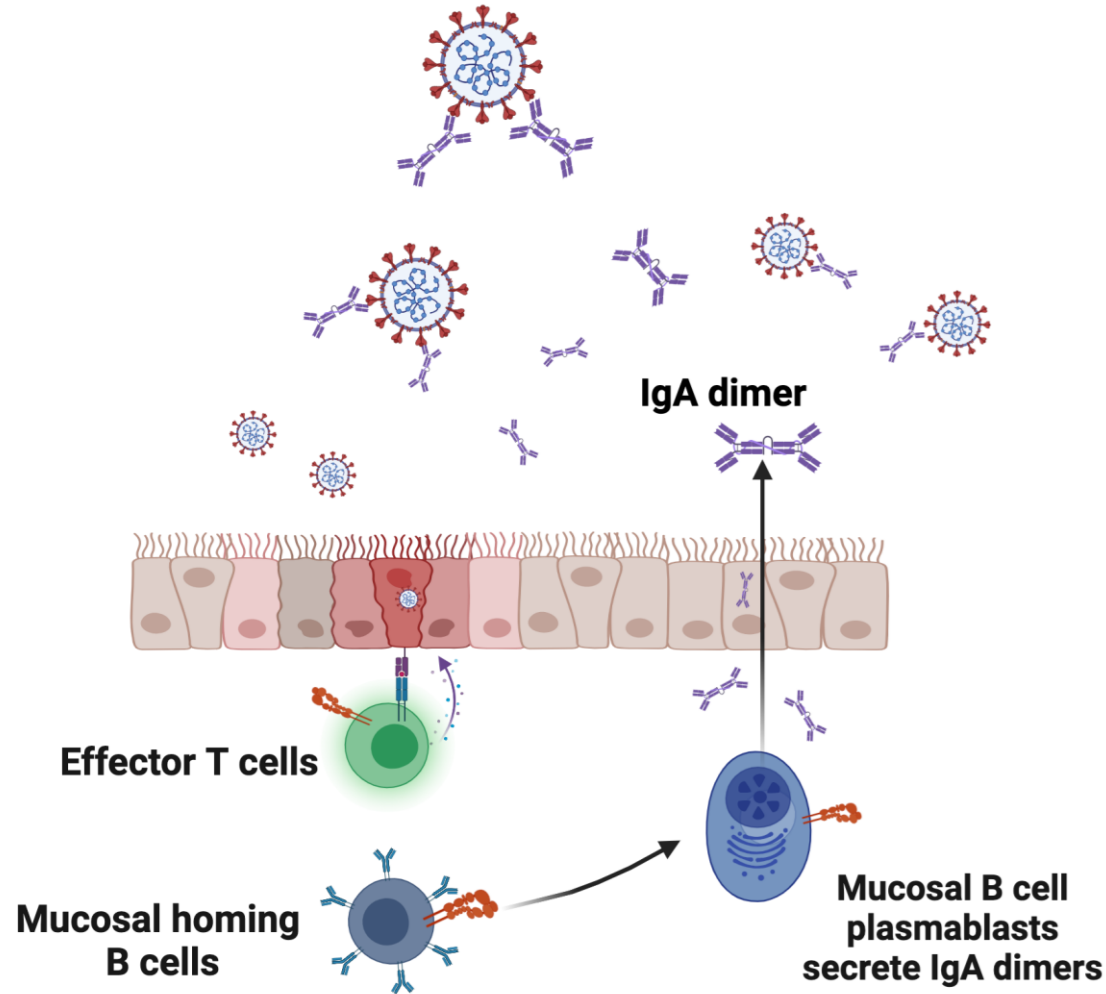


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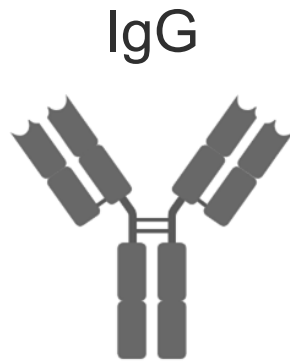
Most Pathogens Invade Through A Mucosal Surface

Mucosal Vaccination Can Promote Mucosal Antibodies At The Surface



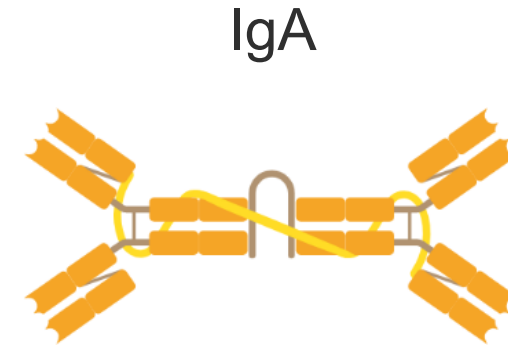
Dimer IgA Has Shown Greater Cross-reactivity Compared To IgG

ANTIBODY CROSS-REACTIVITY: IgG VS. IgA



Characteristics:

- Major antibody isotype induced systemically
- Binding affinity is significantly reduced when challenged with variants
- Has shown poor cross-reactivity with respect to known variants^{1,2}



Characteristics:

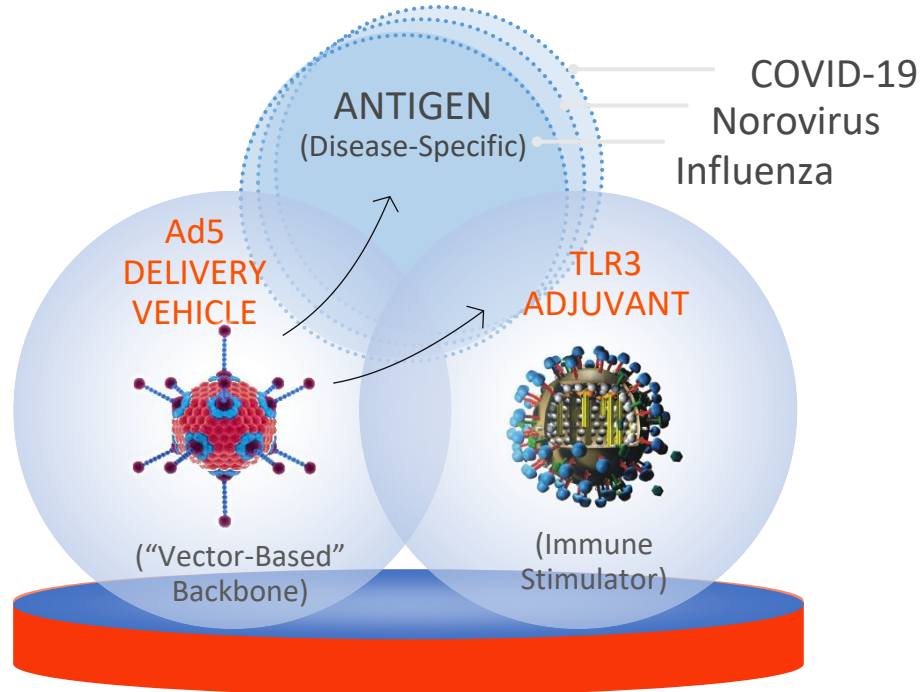
- Predominantly present in the mucosal tissues
- Shown to have greater cross-reactivity against both SARS-CoV-2¹ and Influenza² variants

Source: 1. [Ejemel, et al, Nature, 2020](#); 2. [Muramatsu, et al, PLOS, 2014](#).

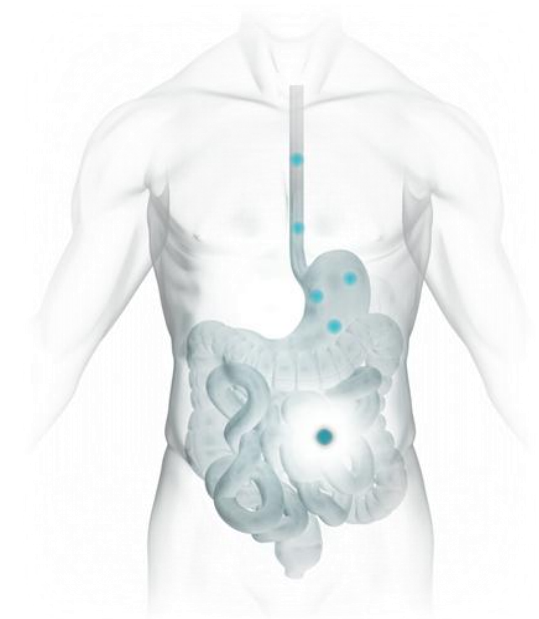
Vaxart Solution: Intestinal Delivery + Targeted Immune Activation: Non-replicating Vector With Molecular Adjuvant

Key issues to solve:

1. Replicating oral vaccines do not work well in the developing world
2. Protein delivered to the intestine is treated like food



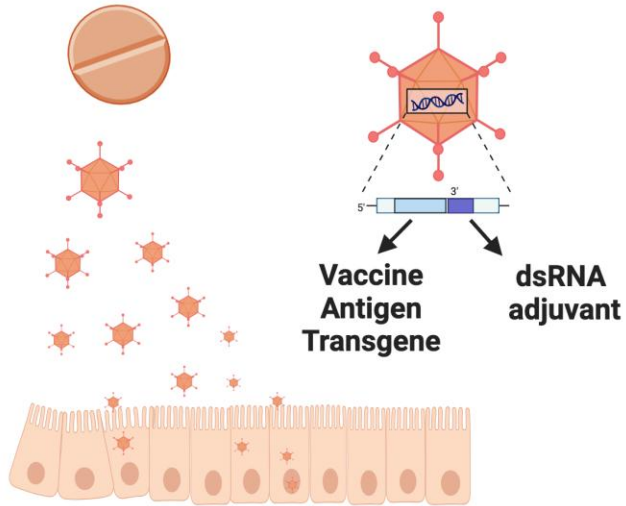
Room-temperature stable
enteric-coated tablets



VAAST™: Vector-Adjuvant-Antigen Standardized Technology

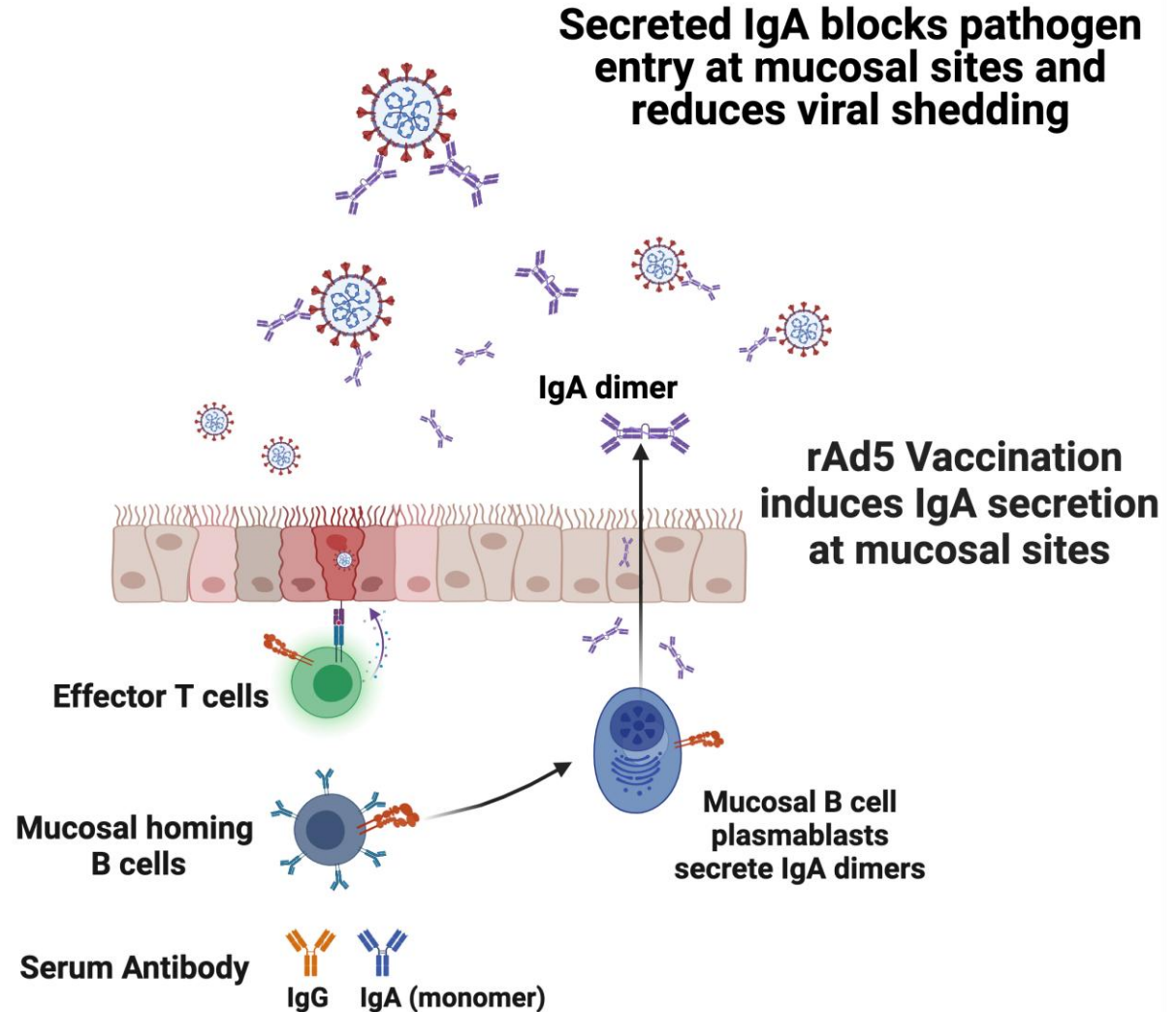
Vaxart Vaccine Proposed Mechanism : Make IgA – Block Infection

Oral rAd5 Vaccine Tablet



Delivered to Small Intestine (Ileum)

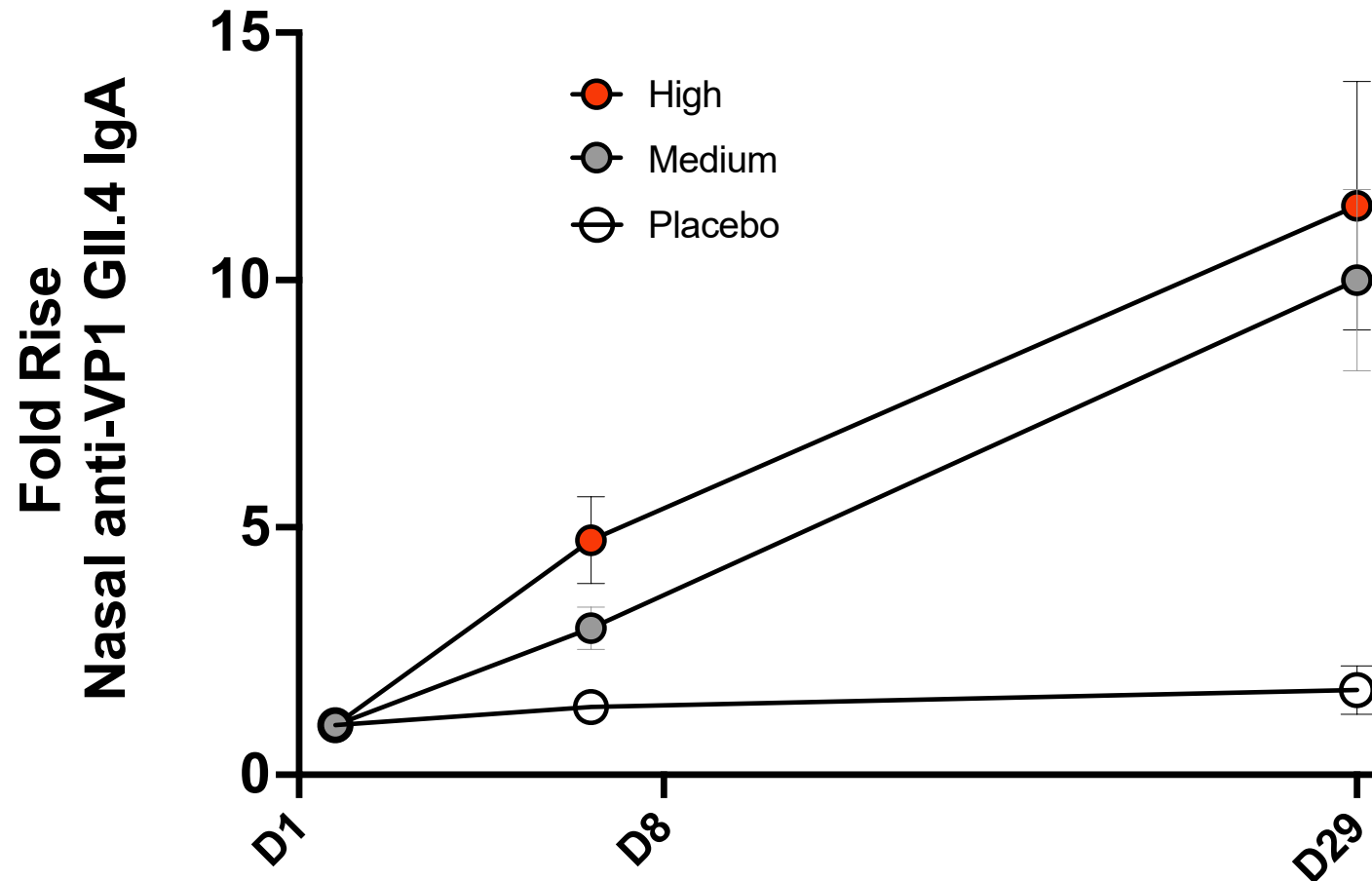
Vaccination generates systemic and mucosal immune responses



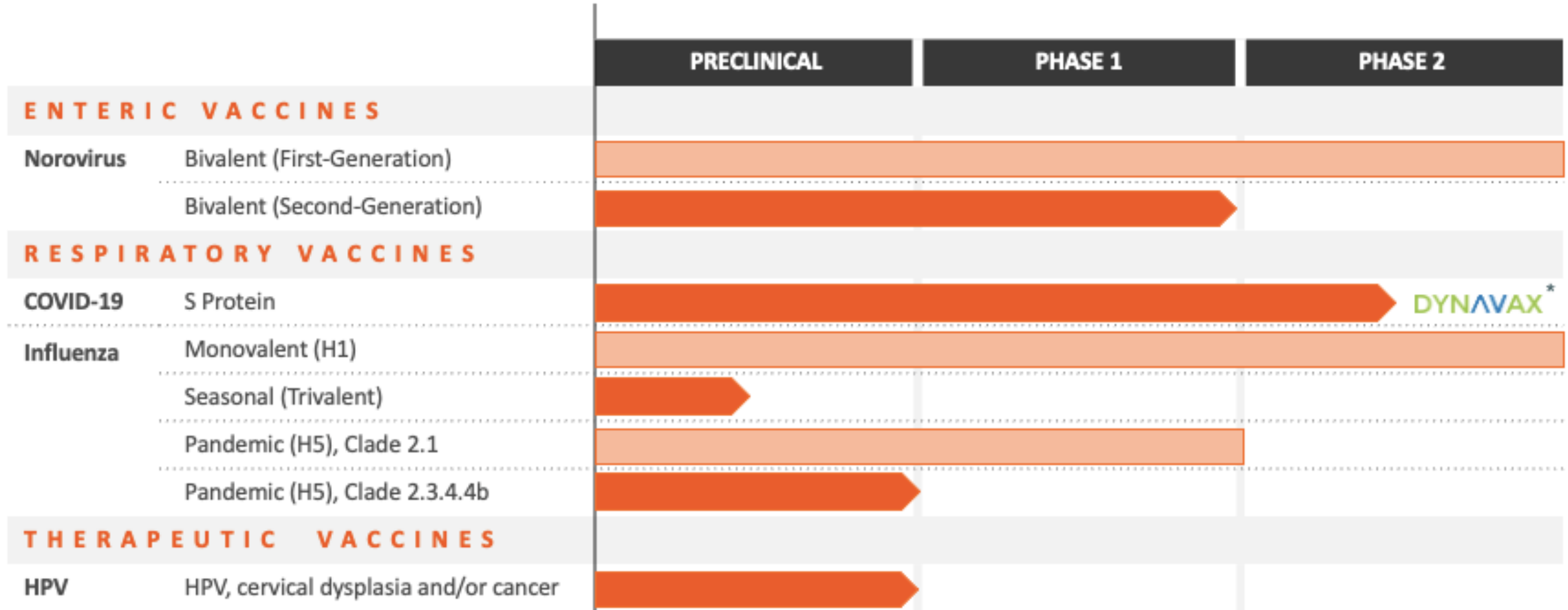
Distal As Well As Local Mucosal IgA By Oral Tablet Vaccination In Humans

Oral tablet vaccine for norovirus makes norovirus specific antibodies in the nose

Norovirus Specific IgA



Multiple Promising Clinical Stage Programs



* Sanofi announced on February 10, 2026, that it had completed its acquisition of Dynavax Technologies Corporation

Pandemic Platform

Respiratory Diseases

- Influenza
- COVID



Influenza Vaccine Candidates

Human Influenza Challenge Study: Challenge After 90 Days

- A single dose administration of one of the following:

Arm 1	VXA-A1.1 oral vaccine + placebo IM injection	(n=60+extra)
Arm 2	QIV injection + oral placebo tablet	(n=60+extra)
Arm 3	Placebo IM injection + oral placebo tablet	(n=30+extra)

- Subjects with baseline HAI titers ≤ 10
- Challenge post randomization after Day 90 (up to 120 days)
 - A wild-type influenza A/Ca/2009/pH1N1 strain was administered to subjects in all treatment groups
 - Virus was propagated on eggs, 3 passages, before use as a challenge virus
- Primary endpoint
 - Number and % of subjects protected against A/CA/2009/pH1N1 challenge by VXA-A1.1 compared to QIV and placebo

Liebowitz, et al, *Lancet ID*, 2020

Favorable Safety and Tolerability Profile

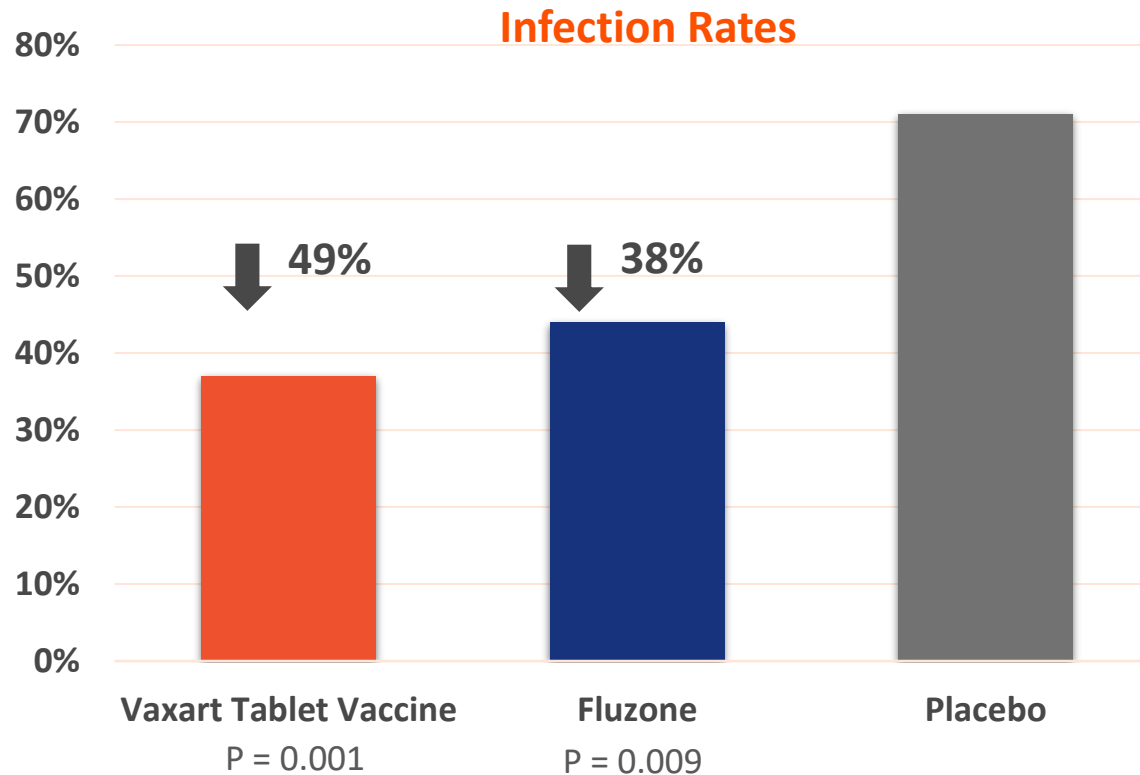
Solicited Symptom	Placebo (n=36)	VXA-A1.1 (n=70)	QIV (n=72)
Number of Subjects with Solicited Symptom TEAEs	15 (42%)	20 (29%)	26 (36%)
General Disorders and Nervous System Disorders			
Malaise/Fatigue	5 (14%)	3 (4%)	5 (7%)
Headache	7 (19%)	5 (7%)	6 (8%)
Myalgia/body aches	1 (3%)	1 (1%)	0
Fever	0	2 (3%)	0
Gastrointestinal Disorders			
Diarrhea	5 (14%)	4 (6%)	0
Abdominal Pain	1 (3%)	0	1 (1%)
Nausea	1 (3%)	4 (6%)	3 (4%)
Vomiting	0	0	1 (1%)
Local Symptoms			
Pain at injection site	1 (2.8%)	2 (2.9%)	10 (13.9%)
Tenderness at injection site	1 (2.8%)	3 (4.3%)	19 (26.4%)

Liebowitz, et al, *Lancet ID*, 2020

Demonstration Of Efficacy – Respiratory Virus Challenge In Humans

Oral Vaccine Candidate protected against influenza infection as well as market leading injected vaccine after influenza challenge

Reduced Infection Rates Trending Superior to Fluzone



- Both vaccines protected against illness and infection
- Oral Vaccine had a different correlate of protection

Infection defined by subjects shedding virus 36 hours after challenge.
Jason Asher, BARDA

Machine Learning Results: IgA Antibody Secreting Cells (ASC) Was The Most Important Immune Parameter To Predict Protection From Oral Immunization

- Random Forest Analysis – builds hundreds of decision trees on random slices of the data, then combines their predictions through majority vote or averaging
 - IgA ASC most important immunological feature for protection against shedding for the Oral Vaccine
 - HAI most important feature for protection against shedding for the QIV vaccine
- Clearly, it takes a very potent serum response to equal the response to a few mucosal homing cells

Oral Vaccine – Most Important Feature (IgA ASC)

IgA ASC Count per 1e6	Predicted Protection Rate
2.3	50%
55.4	75%
108.4	90%
144.5	95%

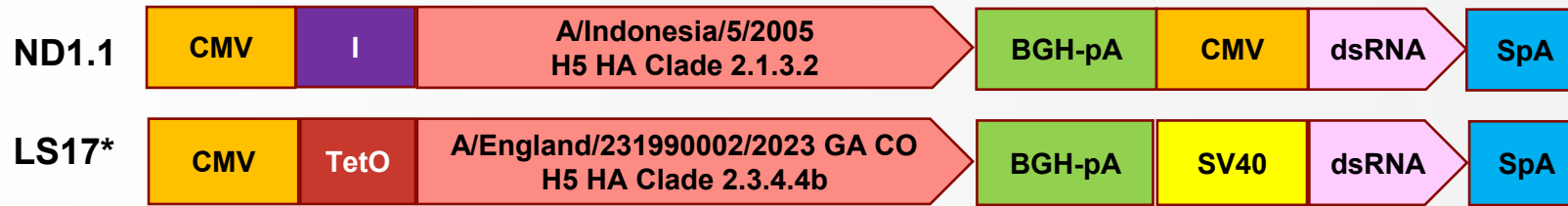
Injected vaccine – Most Important Feature (HAI)

HAI Titer- Day 30	HAI Titer – Day 90	Predicted Protection Rate
82	78	50%
416	269	75%
2100	931	90%
6311	2165	95%

H5 Pandemic Influenza

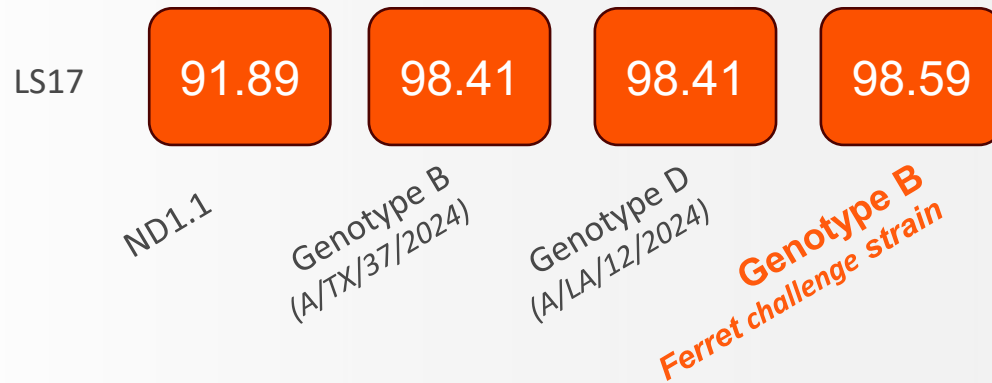
Next Generation H5 (LS17) Has 43% Higher Antigen Expression Level Compared To Old H5 Construct (ND1.1)

H5 constructs based on full length hemagglutinin from A/Indonesia/2005 (ND1.1) and A/England/2023 (LS17)

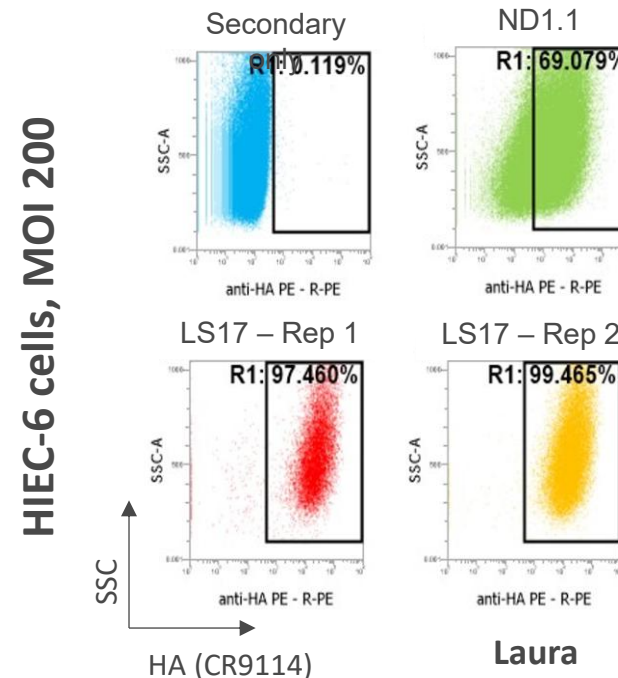


*Next gen H5 construct targeting current outbreak

LS17 HA protein similarity to strains from Clade 2.3.4.4b[^]



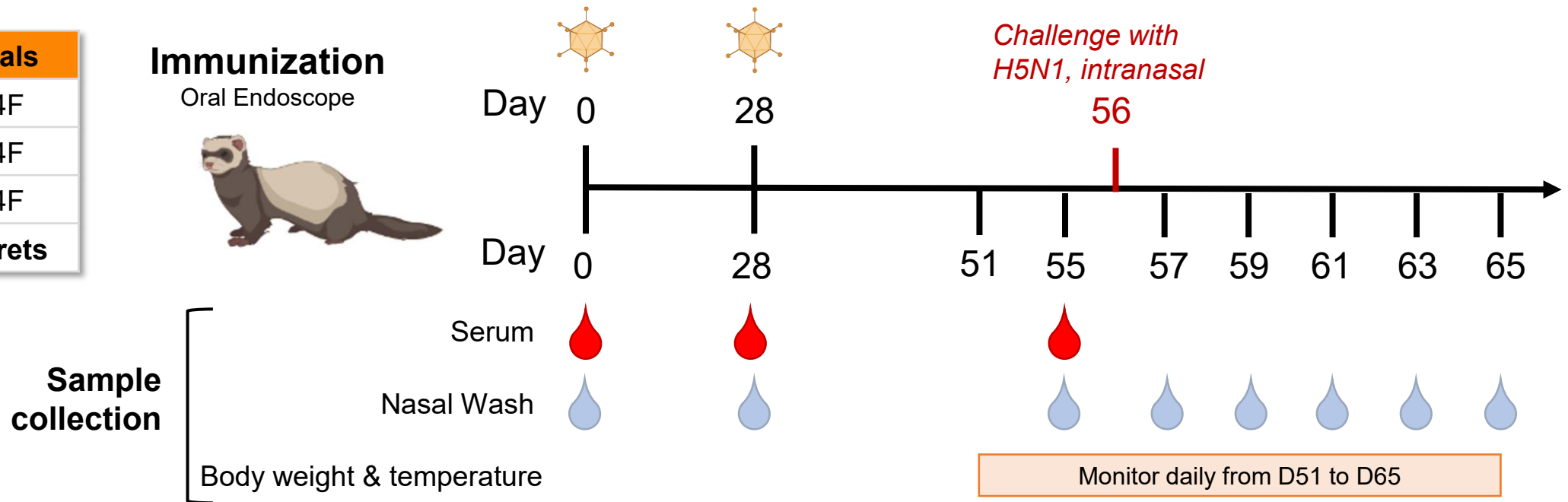
[^]Aligned with the Clustal Omega program, <https://www.uniprot.org/align>



- Clear population shift to the left
- **43% increase in expression**

Vaccination + Challenge Study To Evaluate LS17 Efficacy In Ferrets

Group	Animals
PBS	4M/4F
ND1.1	4M/4F
LS17	4M/4F
Total	24 ferrets



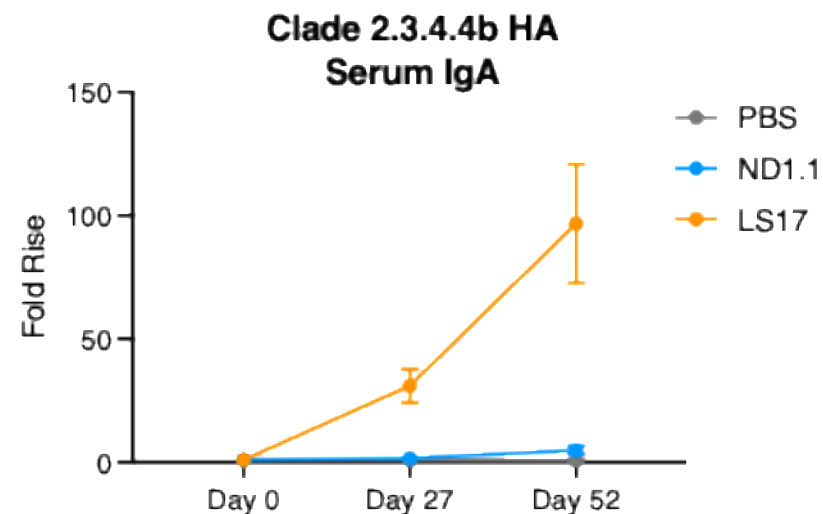
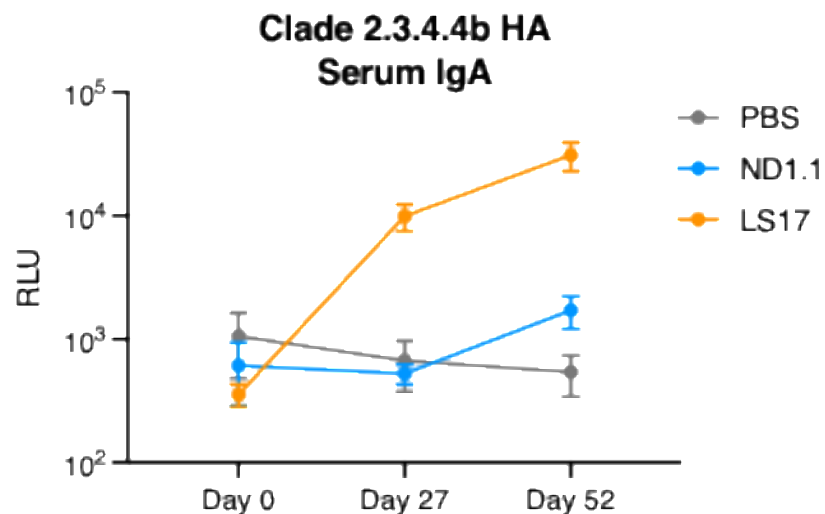
Immunization dose: 1e10 IU/animal, 8 ferrets per group (4M/4F) will be dosed on D0 and D28

Route: oral endoscopic delivery to the duodenum

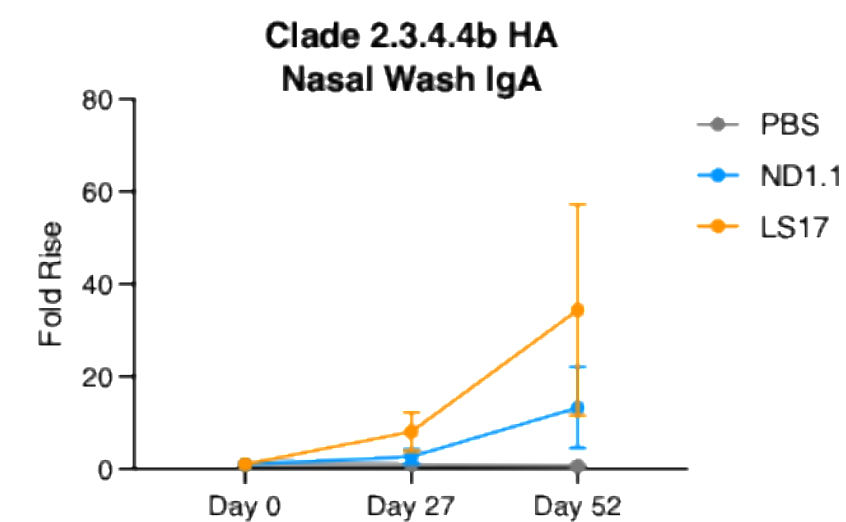
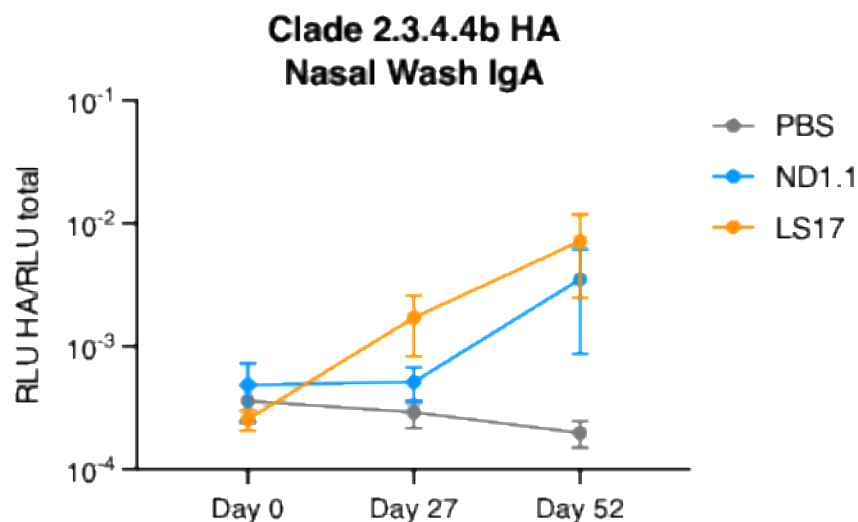
Challenge: all ferrets challenged with H5N1 (Clade 2.3.4.4b, Genotype B, strain A/dairy cow/Texas/24-008749-002-v/2024)

Ferrets Immunized With LS17 Have High Levels Of Anti-clade 2.3.4.4b IgA In Serum And Nasal Washes

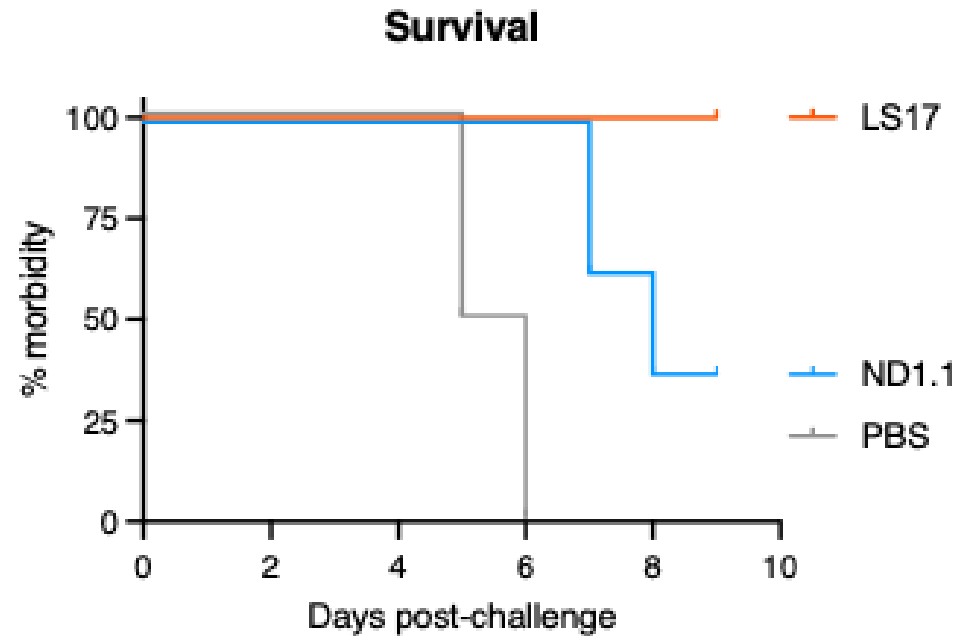
Serum



Nasal Wash



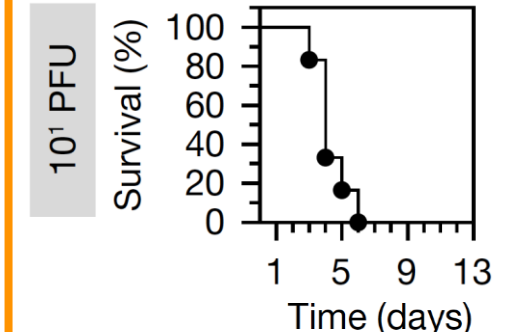
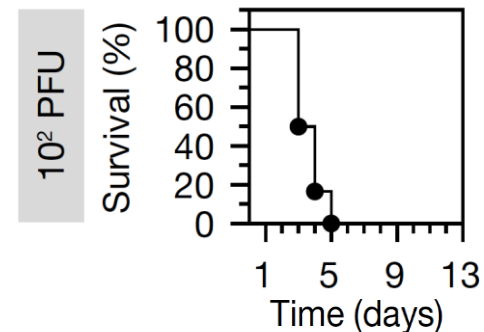
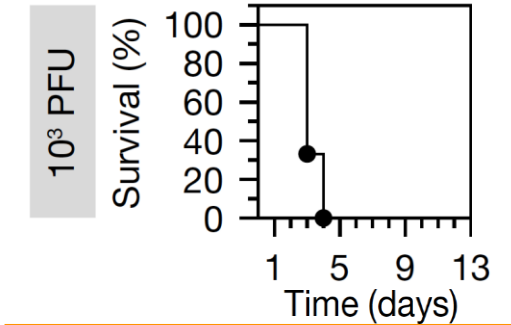
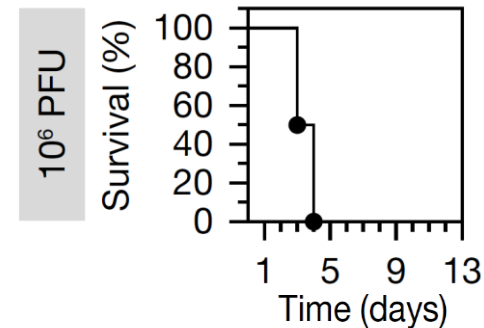
LS17 Protects Ferrets From Lethal Clade 2.3.4.4b HPAI Infection



Ferrets challenged with 1×10^5 TCID₅₀ of Clade 2.3.4.4b HPAI, Genotype B (A/dairy cow/Texas/24-008749-002-v/2024).

100% of LS17-immunized ferrets were protected from lethal infection.

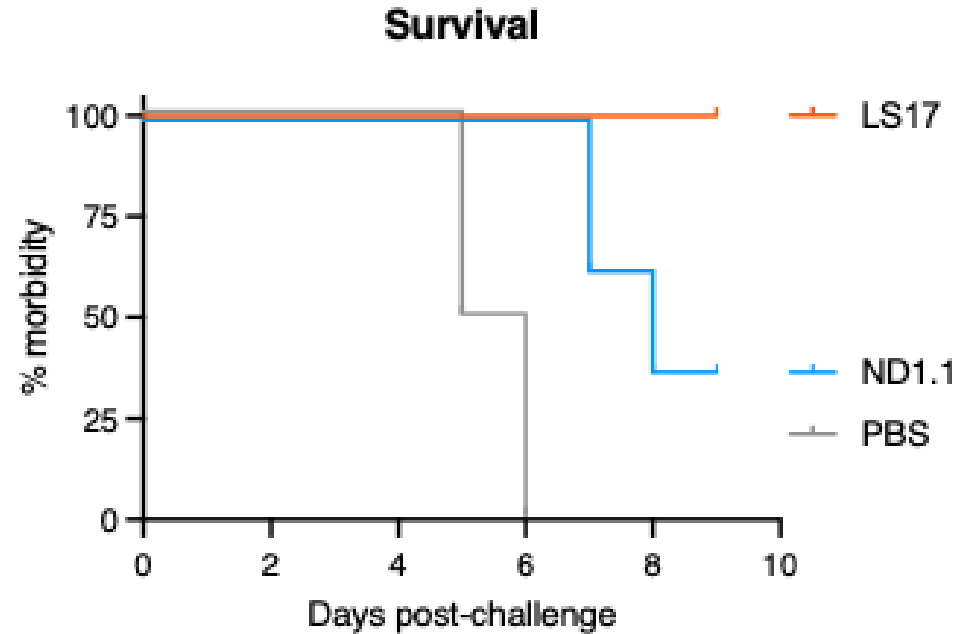
10 PFU of Clade 2.3.4.4b is lethal to ferrets



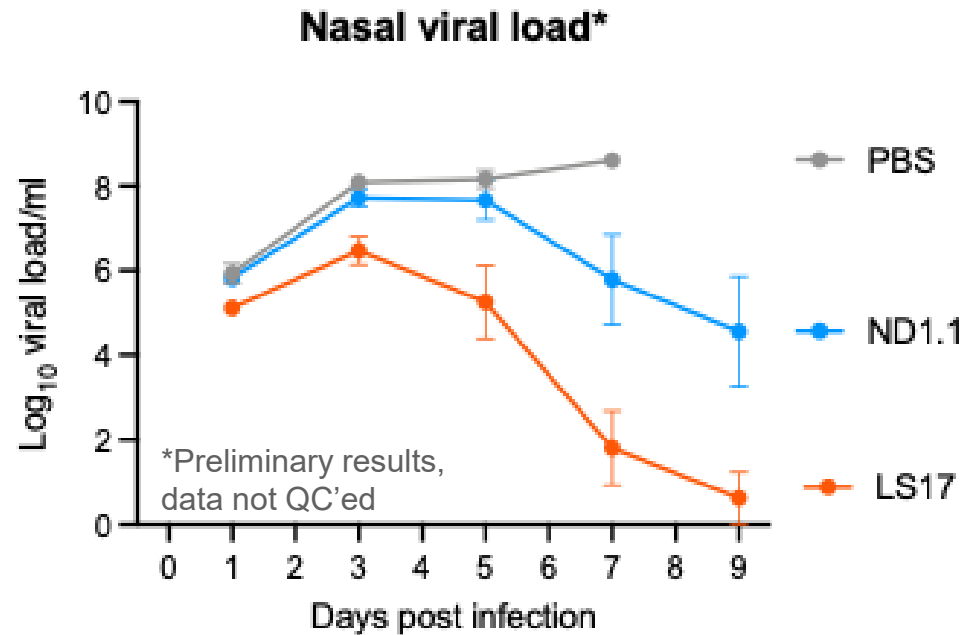
Naïve ferrets were challenge with the indicated PFU of Clade 2.3.4.4b, Genotype B (Strain A/Texas/37/2004).

Gu et al (2024) Nature (PMID:39467571)

LS17 Vaccinated Ferrets Also Have Reduced Viral Load In Nasal Washes



Ferrets challenged with 1×10^5 TCID₅₀ of Clade 2.3.4.4b HPAI, Genotype B (A/dairy cow/Texas/24-008749-002-v/2024).

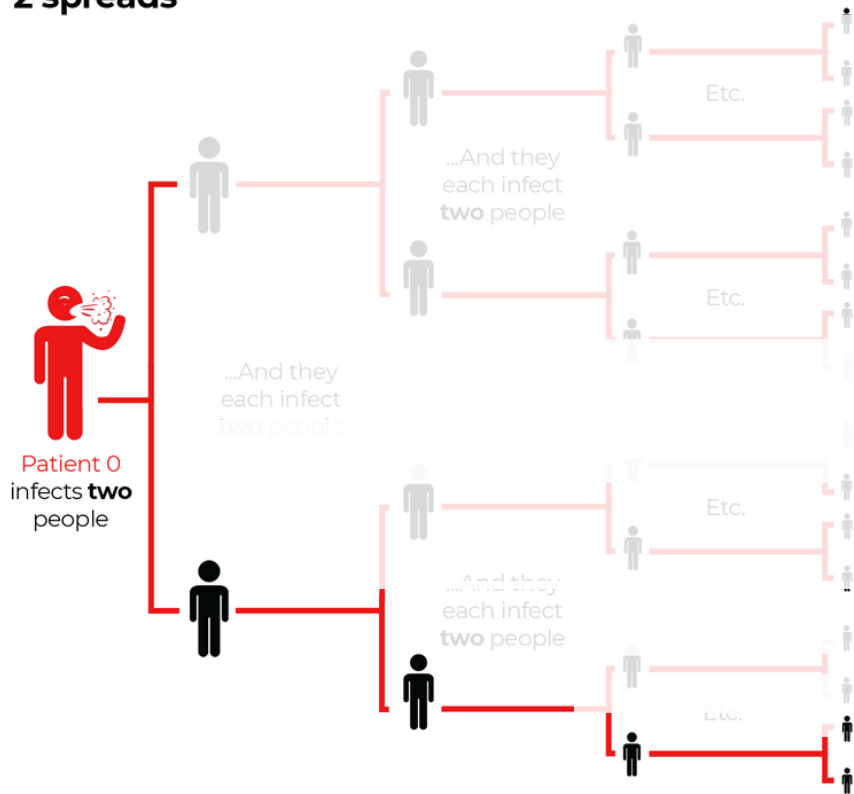


Over 2-log reduction in nasal wash viral load in LS17-immunized ferrets by Day 3.

DECREASE SHEDDING!
DECREASE TRANSMISSION?

A Reduction In Transmission May Significantly Impact Virus Spread

How a virus with a reproduction number (R0) of 2 spreads



Estimated R0 values for SARS-CoV-2 Variants Worldwide

Delta	$6 < R_0 < 7$
Omicron	$9.6 < R_0 < 14.61$

Liu, et al. *Journal of Travel Medicine*, 2022

Can mucosal vaccination lower the R0?

Mucosal Vaccination (rAD-S Wuhan) Protects Hamsters From Illness By SARS-CoV-2 And Reduces The Area Under The Curve (Shedding Vs Time)

Vaccine: rAd5-S (S only)



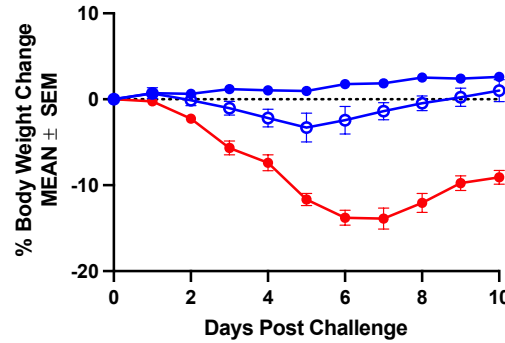
Vaccination



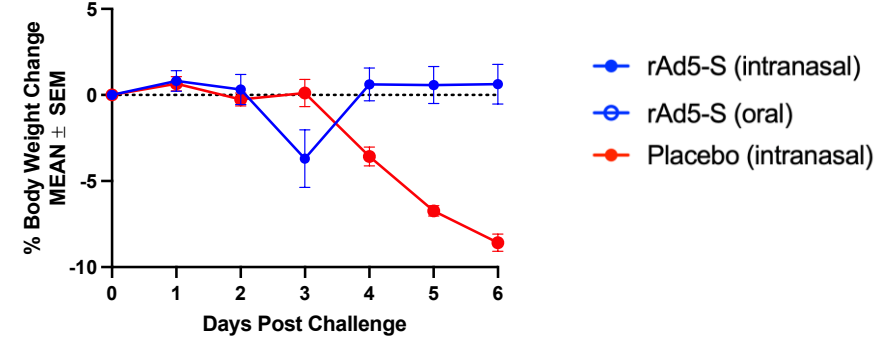
Challenge



Challenge: delta virus

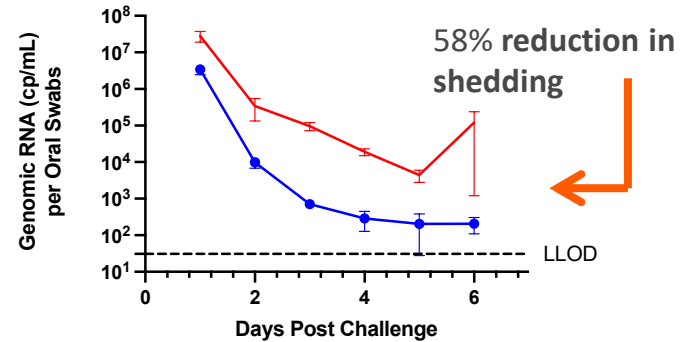
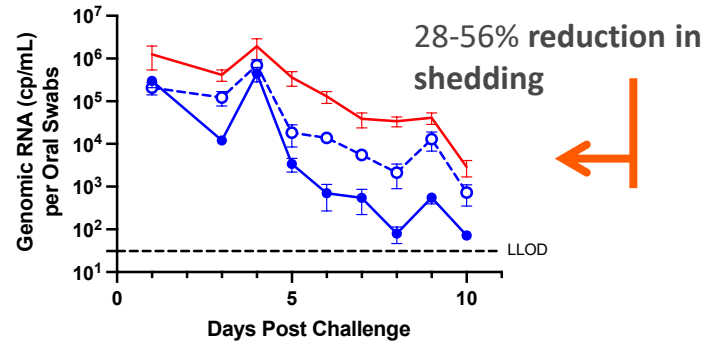


Challenge: omicron virus



Weight Loss

Shedding



Braun, et al, Frontiers in Immunology 2023

Vaccination elicited high levels of mucosal IgA and serum IgG in addition to protecting from disease

IgA Can Functionally Block Transmission

Generating a targeted immune response in the mucosa could reduce global disease

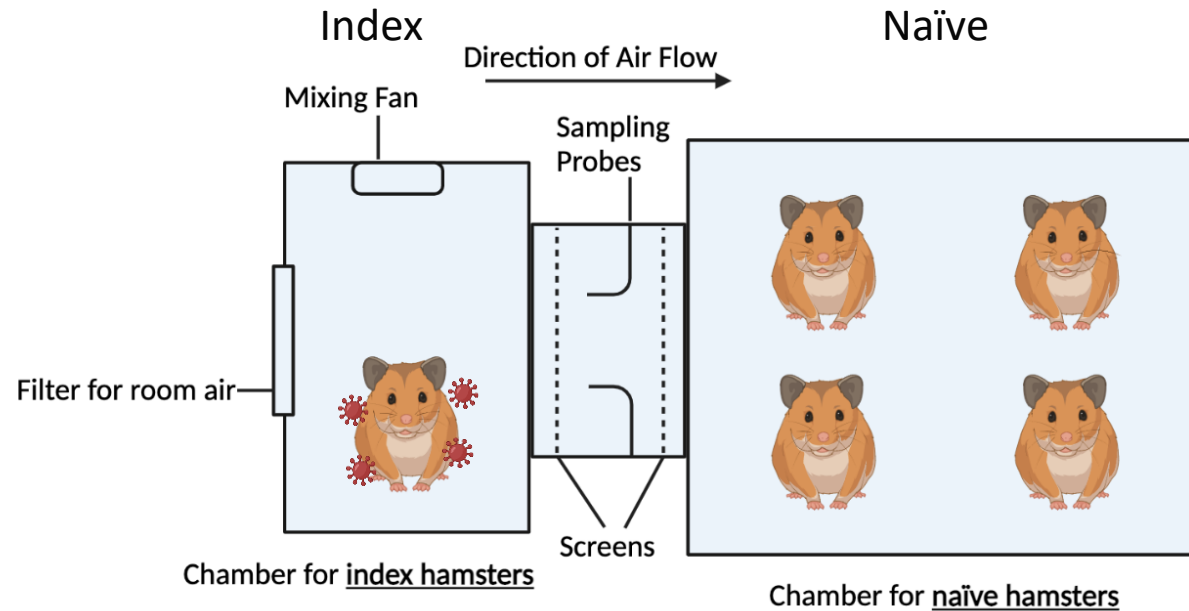
- Norovirus specific breast milk IgA can inhibit diarrhea disease in infants
 - Labayo, et al, EClinMed, 2020
- Studies with guinea pigs given IgA could be protected from transmission when in contact with infected animals
 - Seibert, et al, J. Virology, 2013
- We wanted to see if mucosal responses could block transmission in the other direction
 - Could a nasal mucosal response inhibit transmission to uninfected animals in a vaccine breakthrough – aerosol transmission model

Transmission Study: Model Vaccine Breakthrough To Naïve Subjects

- Goal: Evaluate whether mucosal vaccination blocks transmission and shedding better than an injected vaccine for aerosolized viruses
- Method: Vaccinate animals, give high dose of SARS-CoV-2 (create vaccine breakthrough), expose to vaccine naïve animals for 8 hours

Index animals vaccination groups:

- Vaxart Oral rAd-S
- Vaxart Intranasal rAd-S
- Intramuscular S protein
- Placebo (Oral)



Transmission Blocking: Viral And Disease Burden Is Decreased In Naïve Animals Exposed To Mucosally Vaccinated Animals With Breakthrough Infections

Index Animals
Vaccine Breakthrough

Naïve Animals
Unvaccinated

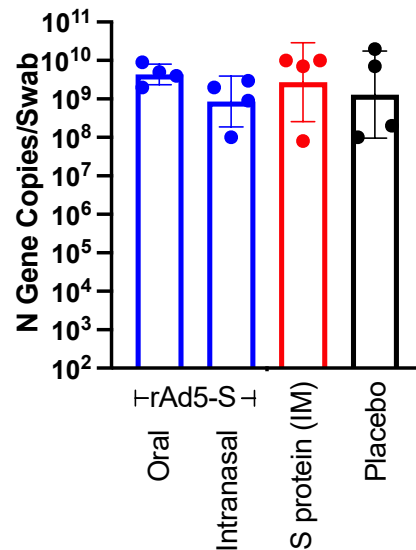
Naïve Animals
protected from illness 5 days after exposure



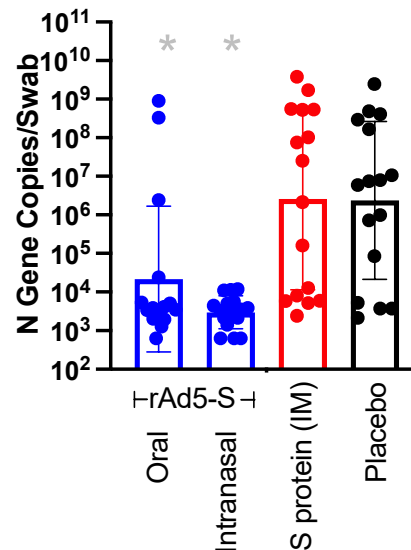
Aerosol exposure (8 hrs)



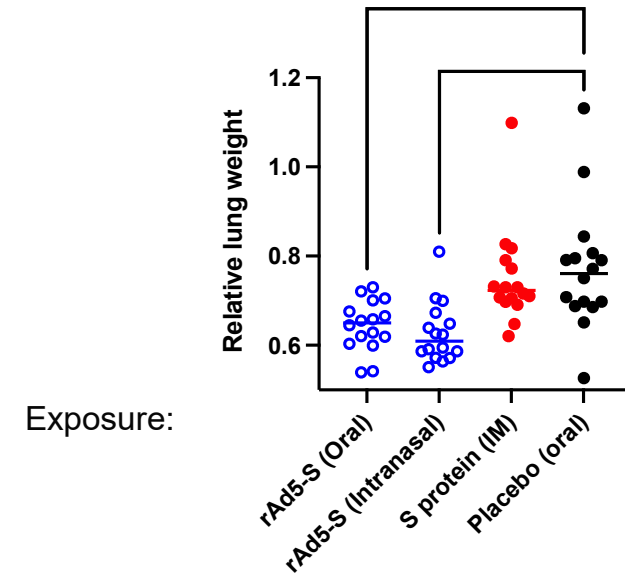
Day 1 post infection



Day 1 post exposure



Lung Weights as a
Percent of Body Weight



Langel et al, *Sci Translational Med*, 2022

* P < 0.012 by Fishers' Exact

Modeling: How Transmission Impacts Health Care

What is the effect on transmission blocking on infection?

- Assuming an oral vaccine is 50% more effective against both any infection and transmission in the US for a COVID-19 vaccine:
 - 9,481,245 fewer infections
 - 37,100 fewer deaths
 - 1,932,727 fewer hospitalization days
 - 278,292 fewer ICU days¹

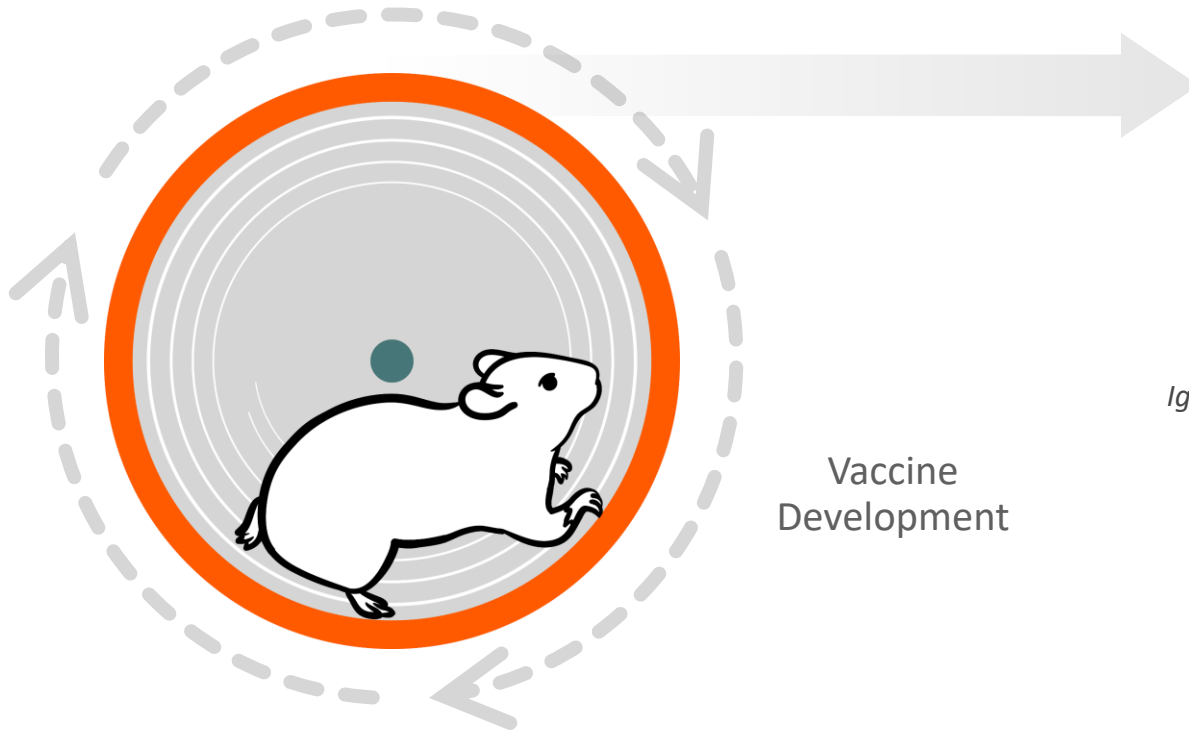
¹ Jeromie Ballreich PhD and Bryan Patenaude, ScD, BMC Public Health, 2022

COVID Vaccine Candidates

COVID Vaccine Development – Chasing Viruses As They Evolve Is Time Consuming

Rapid Emergence of New SARS-CoV-2 Strains

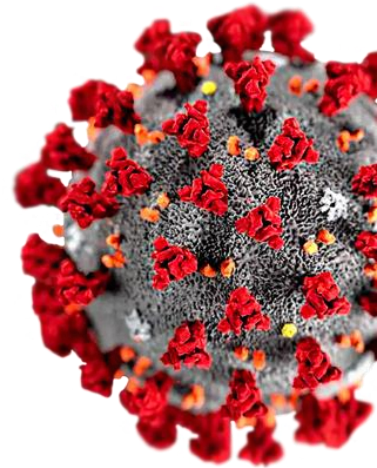
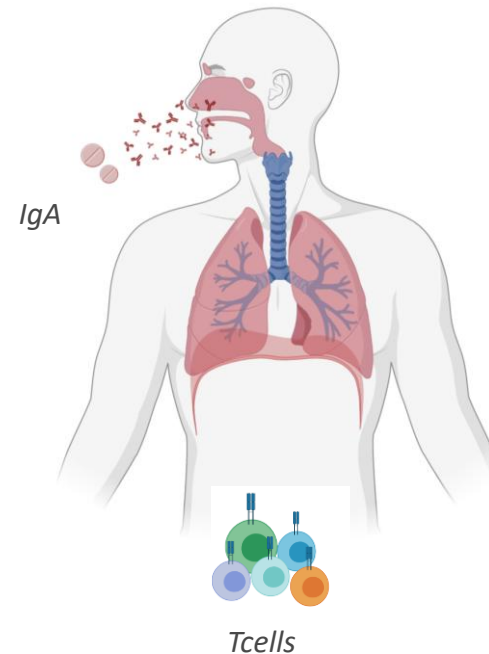
Distribution & Administration



Vaccine Development

Oral Tablet is different

- Cross-reactive immune responses which may lead to broader protection
- Tablets rather than injections

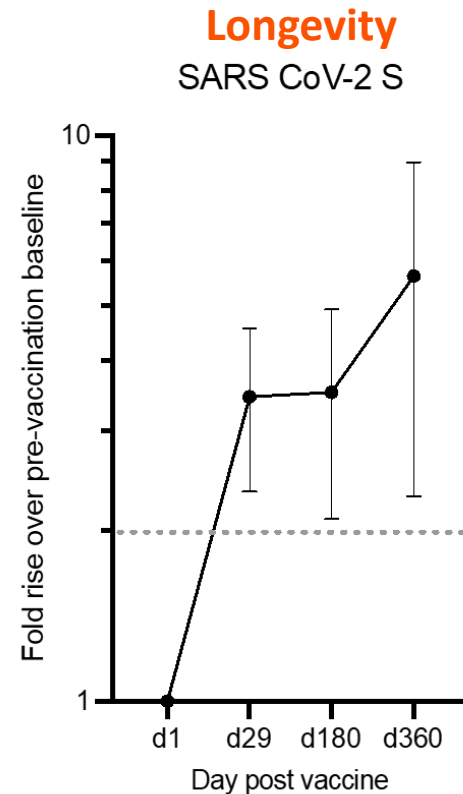
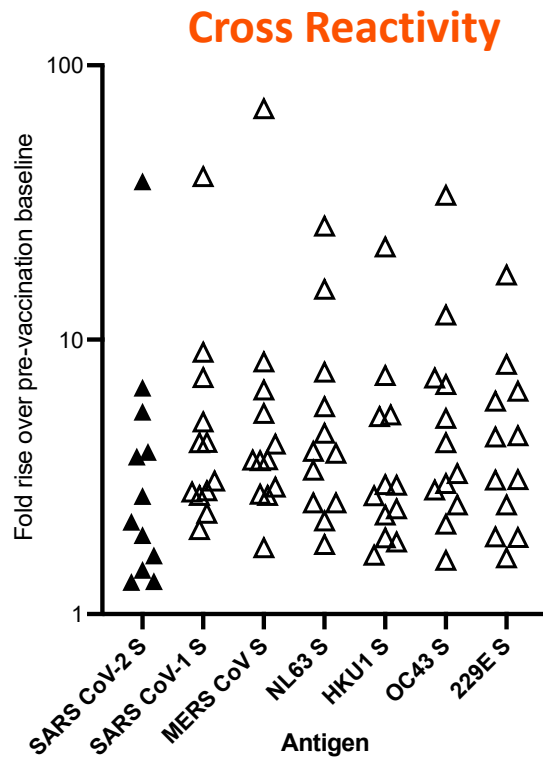


We are currently chasing the virus with vaccines like a hamster on a wheel

VXA-CoV2-1 Induces Cross-reactive And Long-Lasting Nasal IgA

- 46% of subjects had a 1.5 fold increase or better against SARS-CoV2-S which also induced increased antibody responses to every Coronavirus tested

Nasal IgA responses *highly cross reactive against all coronaviruses*



Langel, et al, Sci Translation Medicine, 2022

COVID-19 Vaccine Candidates In Humans

VXA-CoV2-1 (Expresses S+ N): phase I study

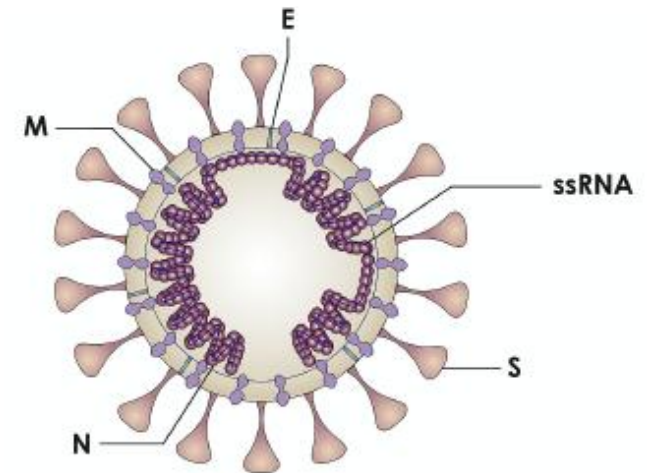
- Highly immunogenic on eliciting T cells and mucosal IgA
- **Made cross-reactive mucosal IgA**

VXA-CoV2-1.1-S (Expresses only S): phase II study

- Much higher serum antibody responses than the S&N version
- Boosted the mRNA vaccines
- **Made cross-reactive mucosal IgA**

VXA-CoV2-3.1 and VXA-CoV2-3.3 (Expresses only S): phase IIb study

- Comparative efficacy vs. mRNA
- Study In progress





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