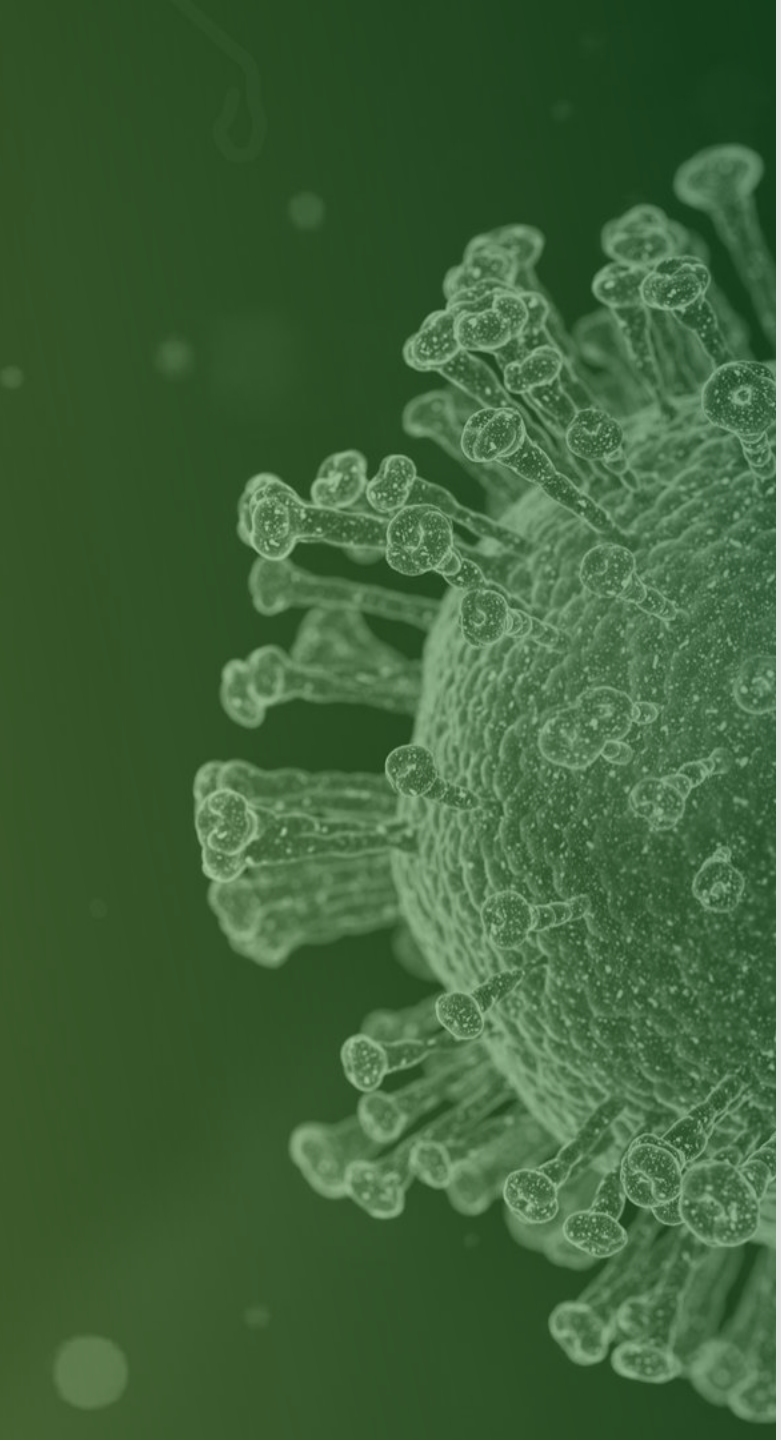


MVC-COV1901 VACCINE UPDATES

Why do we need a pan-sarbecovirus vaccine?

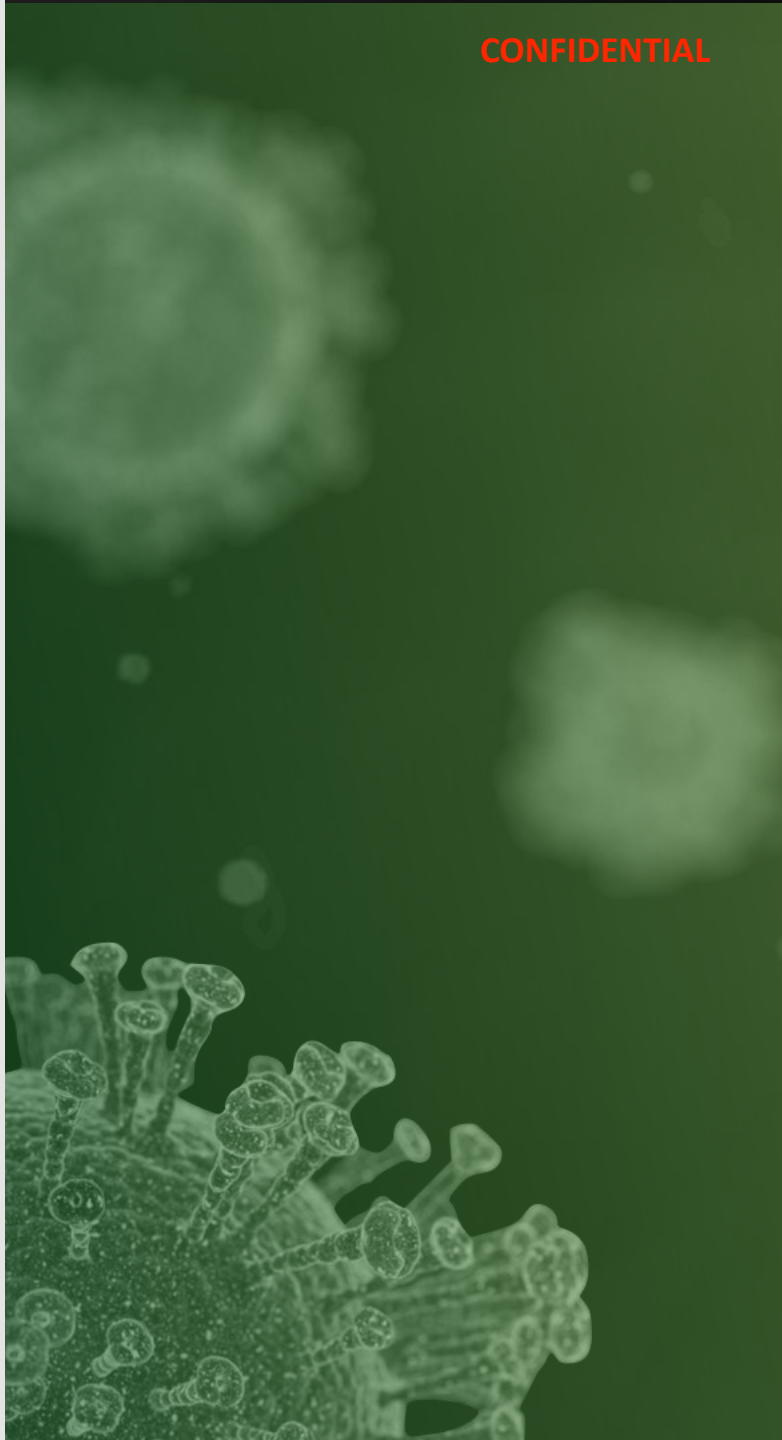
WHO R&D Blueprint Meeting

28 January 2022

Allen Lien M.D. DrPH

Vice President, International and Governmental Affairs

MEDIGEN VACCINE BIOLOGICS CORP



COVID-19

OUTLINE OF PRESENTATION

1. A booster dose of MVC-COV1901
2. A booster dose of MVC-COV1901 Beta-based vaccine in hamsters
3. MVC-COV1901 Beta-based vaccine timeline
4. Opportunity to demonstrate Efficacy in Previously Infected Population

COVID-19

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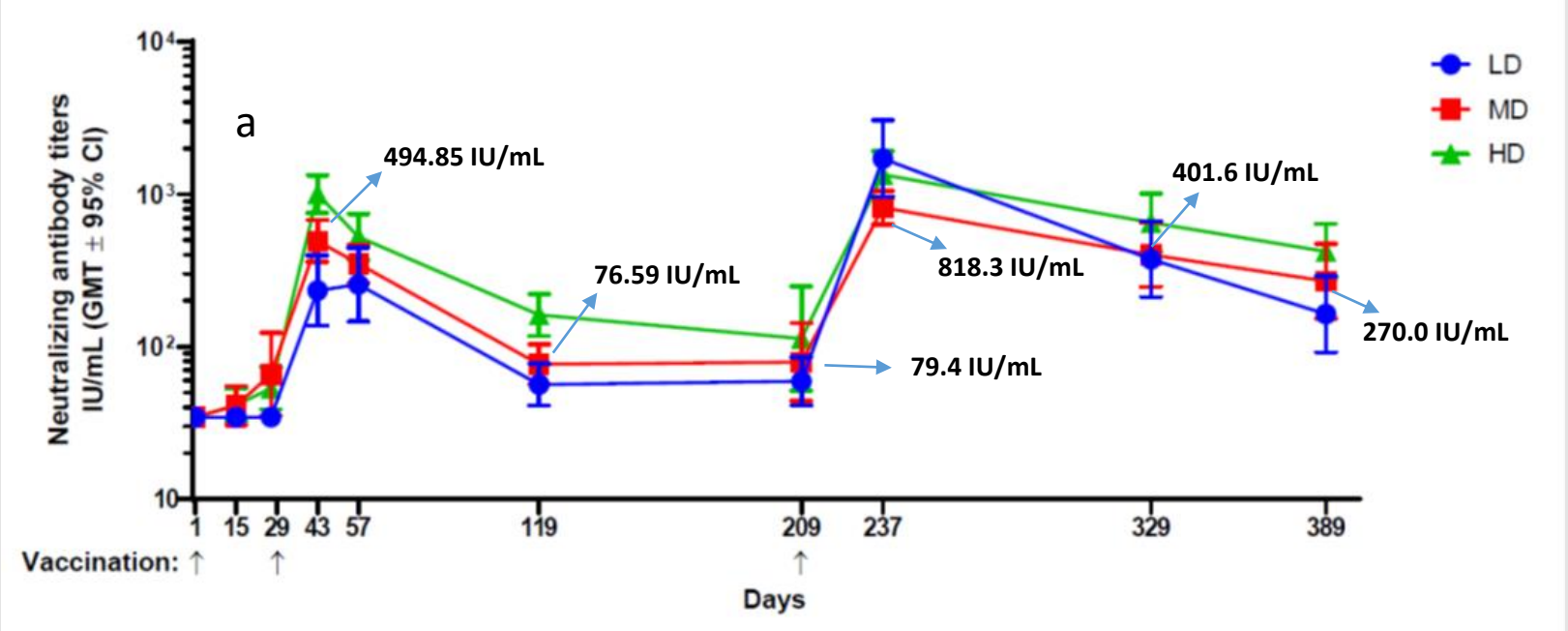
Durability of immune response to MVC-COV1901 six months after the booster

- Neutralizing antibodies declined by **84%** within 6 months after 2 doses
- Neutralizing antibodies declined by **67%** within 6 months after the booster
- *Half-life of NT was 12 days (11-14) after 2nd dose and 44 days (31-76) after booster dose.

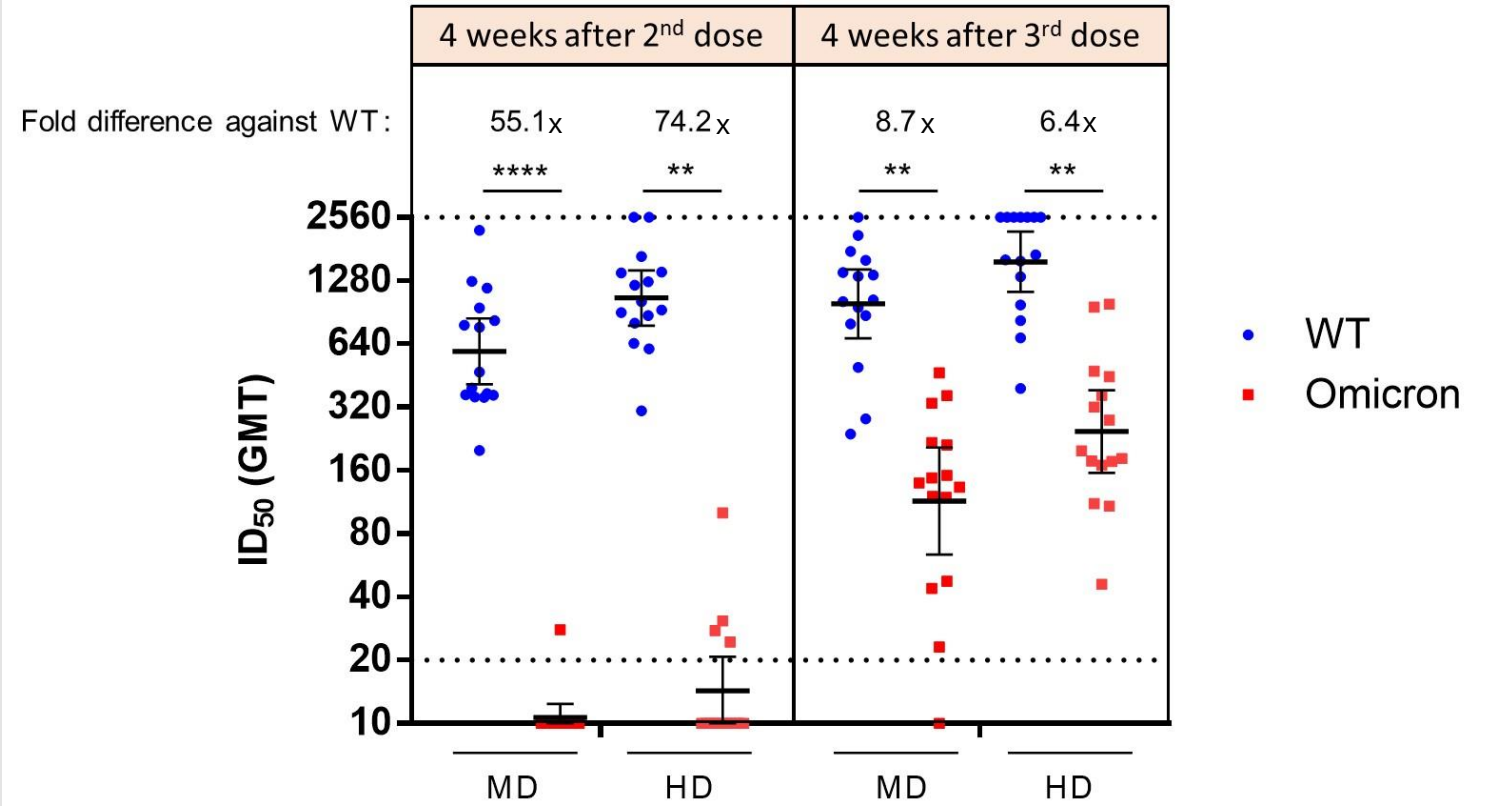


*Exponential decay estimated with mixed linear models

Research available in part at medRxiv: https://www.medrxiv.org/content/10.1101/2021.12.01.21267115v2

3 doses of MVC-COV1901 in adults provide cross-reactivity against Omicron

- Adults immunized with 2 (Day 57) or 3 (Day 237) doses of mid-dose (15 µg) or high-dose (25 µg) MVC-COV1901
- Both dose groups demonstrated cross-reactivity to Omicron



Research available in part at medRxiv: https://www.medrxiv.org/content/10.1101/2021.12.01.21267115v2

COVID-19

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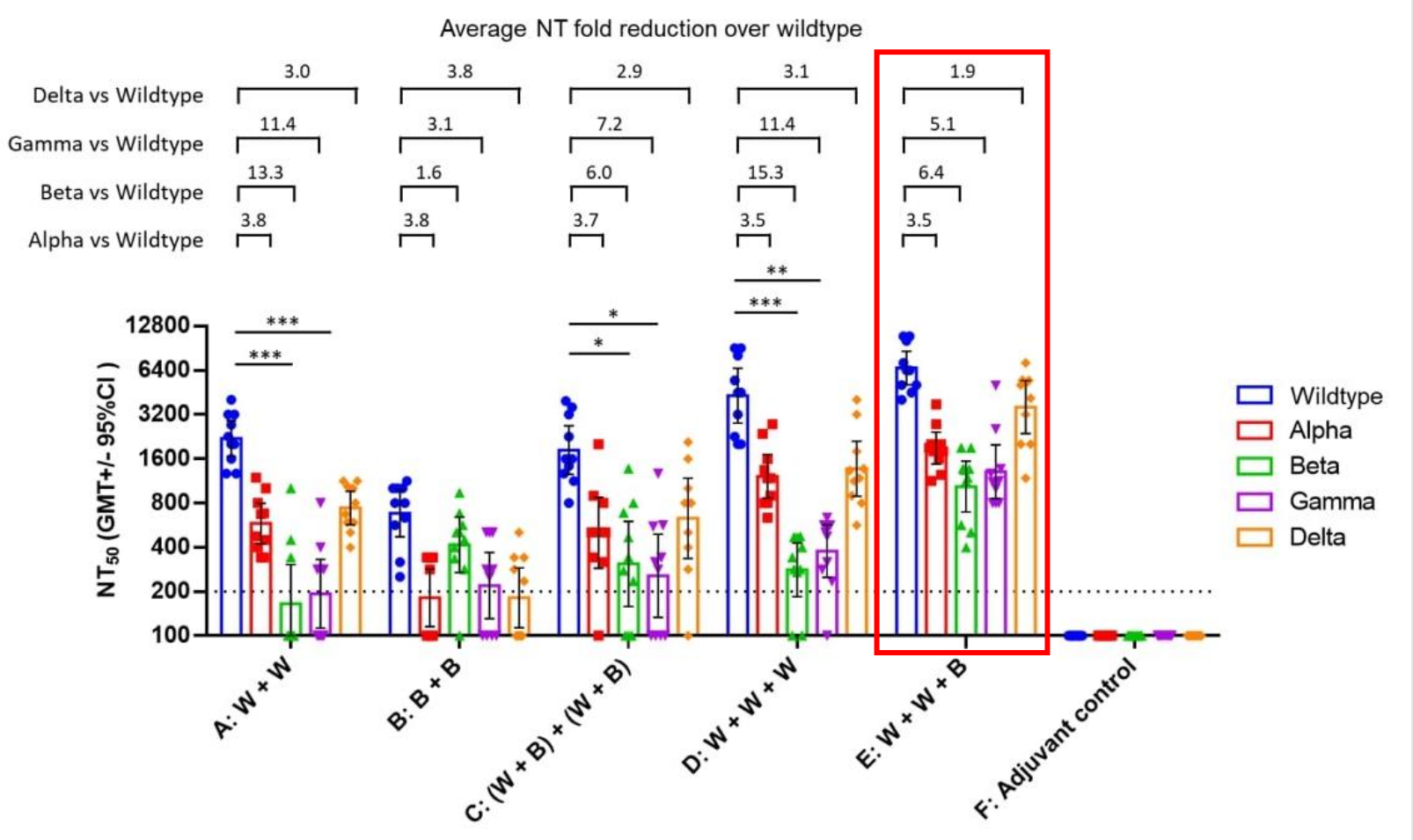
A booster dose of beta-based vaccine offers broad coverage against variants of concern (VoC)

W+W+B induced the broadest breadth of coverage against the VoCs



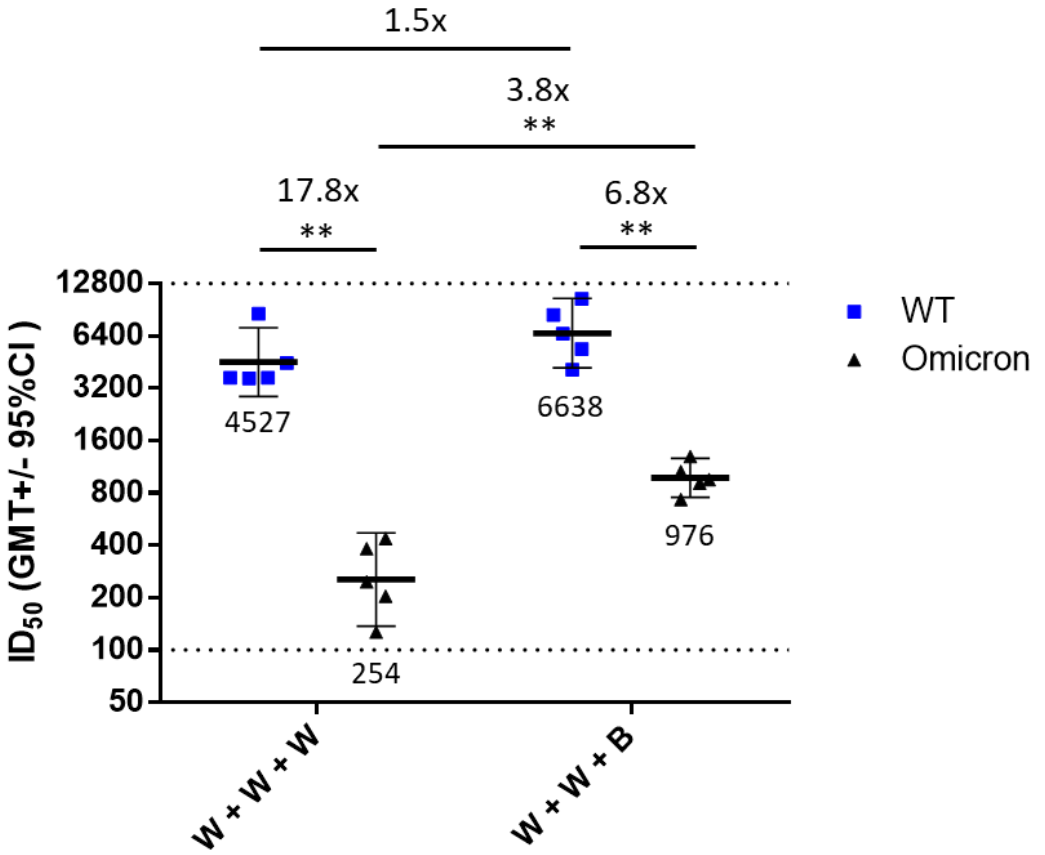
MEDIGEN VACCINE BIOLOGICS CORP

Research available in part at bioRxiv: https://www.biorxiv.org/content/10.1101/2021.09.29.462344v3

A booster dose of beta-based vaccine in hamsters provides cross-reactivity against Omicron

- Hamsters immunized with
  - 3 doses of Wildtype S-2P (W+W+W)

    or
  - 2 doses of Wildtype S-2P and 3rd dose of Beta S-2P (W+W+B)



Unpaired Mann-Whitney U test
* = p < 0.05, ** = p < 0.01, *** = p < 0.001, **** = p < 0.0001

MEDIGEN VACCINE BIOLOGICS CORP

Research available in part at bioRxiv: https://www.biorxiv.org/content/10.1101/2021.09.29.462344v3

COVID-19

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3. **MVC-COV1901 Beta-based varian vaccine timeline**
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MVC-COV1901 Beta-based vaccine development timeline

		Year	2021												2022															
		Month	October				November				December				January				February				March				April			
		Week	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Master Cell Bank (MCB)	MCB banking																													
	MCB testing - MVC																													
	MCB testing-mycoplasma																													
	*MCB characterization (I)																													
	**MCB characterization (II)																													
	***MCB characterization (III) @CRL																													
Development	#UBH Test (I)																													
	UBH Test (II) - TEM																													
	DS characterization (peptide mapping, N glycan , IEF)																													
	DS characterization (CD, disulfide bond)																													
	Viral Clearance Study																													
Good Manufacturing Process (GMP) Production	50L GMP production-upstream																													
	50L GMP production-downstream																													
	DS release tests																													
	DP Filling&Inspection-15 mcg																													
	DP Filling&Inspection- 25mcg																													
	DP release test (sterilty & Ag content)																													
	DP release test(immunogenicity)																													

- MCB has been established with some characterization remaining
- Development and GMP Production to be finished by Q1 of 2022

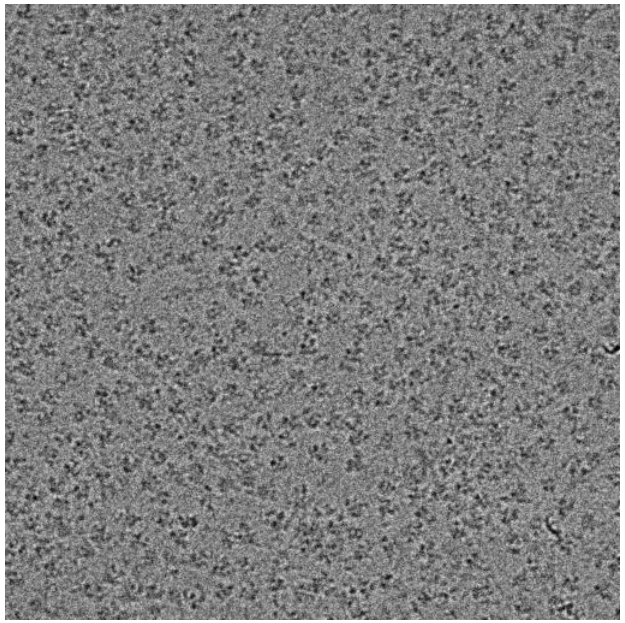
*MCB characterization (I): Sterility, mycoplasma(Indicator cell culture), Retroviral infectivity,TEM Thin Section, Specific Virus Detection, HAP test, BPyV

**MCB characterization (II): Identity, Mycoplasma(Direst culture), In vitro/In vivo adventitious virus test, PERT, Bovie virus detection

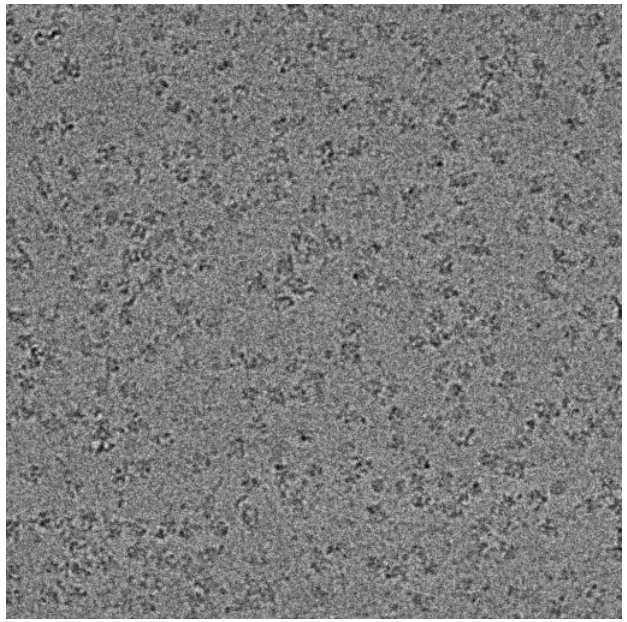
***MCB characterization (III): MAP, 9CFR, PCV-1/2 @CRL : Charles River Laboratories

#UBH Tests (I): Bioburden, Adventitious virus test, PERT, MMV-qPCR, Mycoplasma (qPCR)

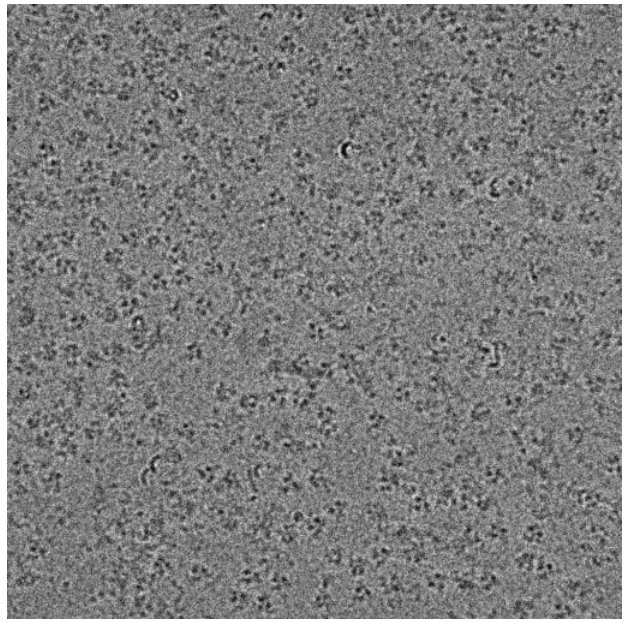
Cryo-EM screening results :



pH 7
1 mg/ml

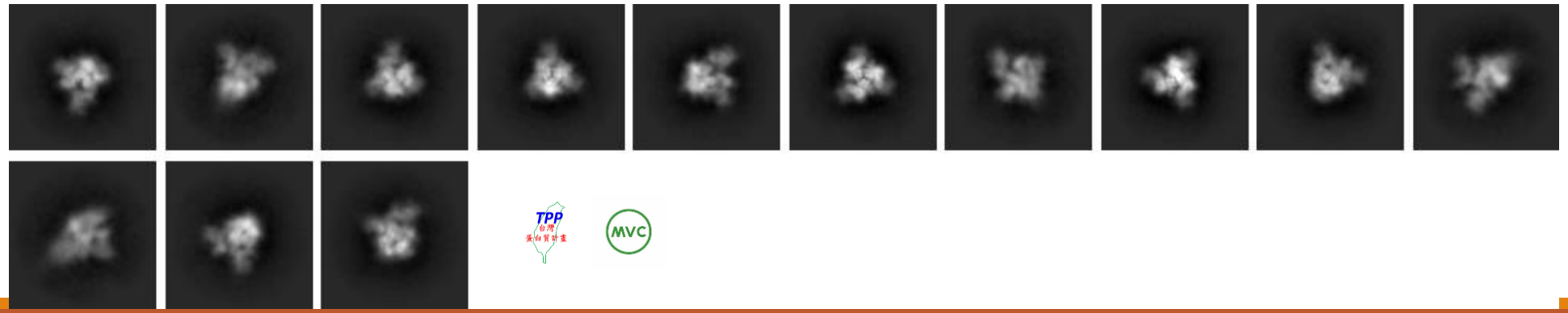


pH 7
0.5 mg/ml



pH 5.5
0.5 mg/ml

Collect overnight data



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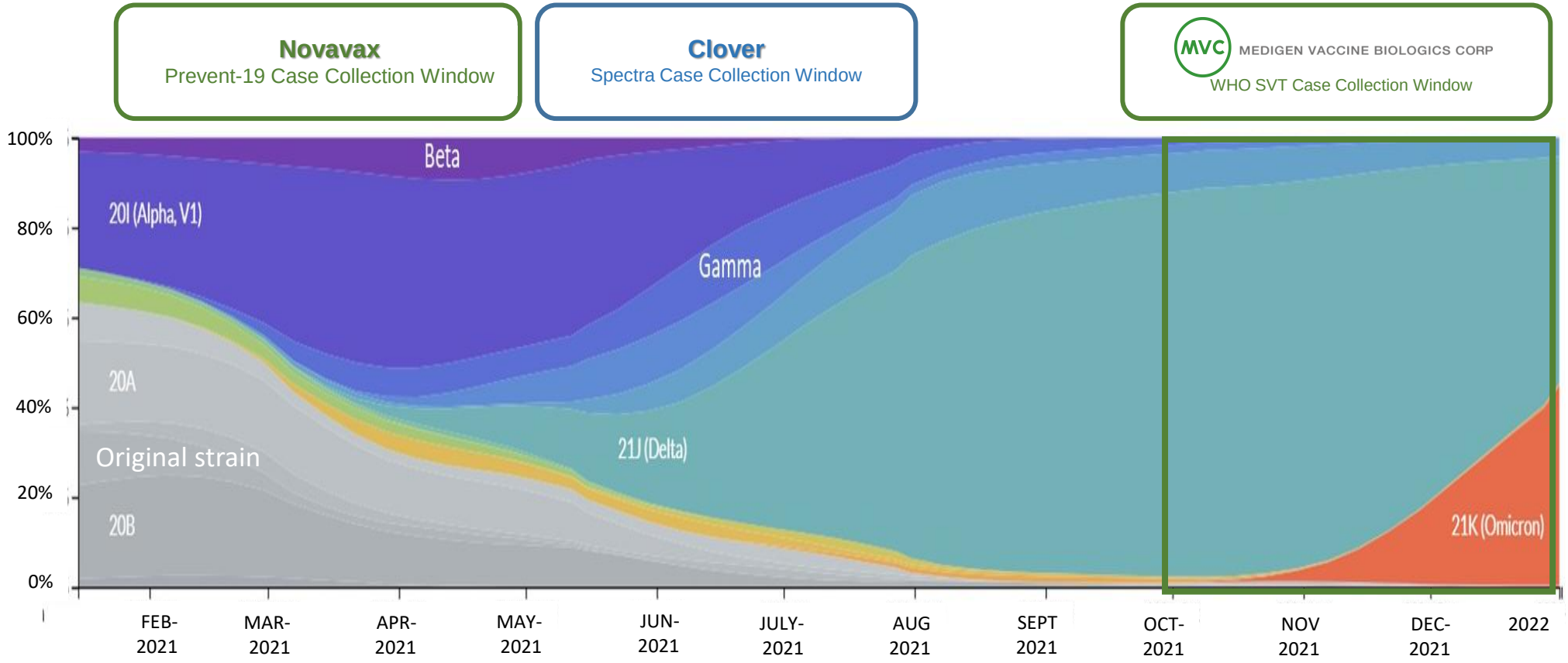
Phase III trials recruitment during the global spread of Variants of Concern

- Pfizer, AstraZeneca, Moderna and J&J recruited before Jan-2021: the original strain was predominant.
- MVC recruits from Oct-2021: Delta and Omicron are predominant.



Key takeaways

- A booster dose of MVC-COV1901 **increased cross-reactivity** against Omicron, and **increased the durability** of neutralizing antibody.
- In hamster model, MVC-COV1901 beta vaccine as booster dose increased breadth of coverage against **Wildtype, Alpha, Beta, Delta, and Gamma**.
- Compared to three doses of prototype vaccine, using beta vaccine as booster, the NT titer increased by **1.5 folds against Wildtype virus, 3.8 folds against Omicron**.
- Clinical trial using MVC-COV1901 beta vaccine as booster will start in Feb, 2022.
- **WHO Solidarity Vaccine Trials** allows MVC-COV1901 to demonstrate the vaccine efficacy against Omicron.