

Global Vaccine and Immunization Research Forum (GVIRF) 2023

Future Pandemic R&D Preparedness in Korea

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Acting Director, NIH Korea



National Institute of Infectious Diseases (NIID)
NIH Korea, KDCA





Long-term Pandemic R&D Preparedness in Korea

1) Therapeutics (mAb)

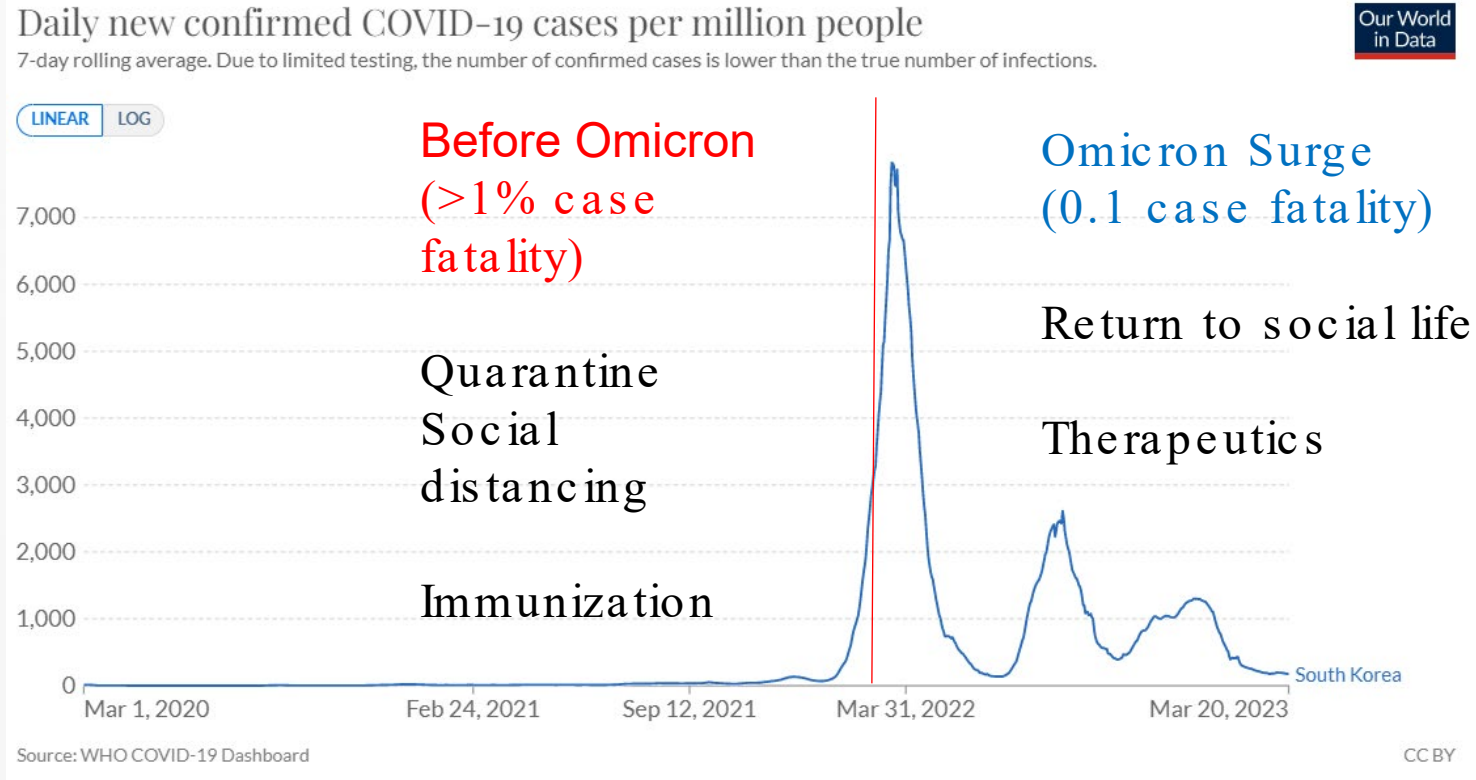
2) Vaccine

Change in Governance and Strategy : Pandemic Response



Korea Disease Control and Prevention Agency
National Institute of Health
National Institute of Infectious Diseases

Response to Pandemic crisis



Long-term Preparedness



MERS outbreak in Korea

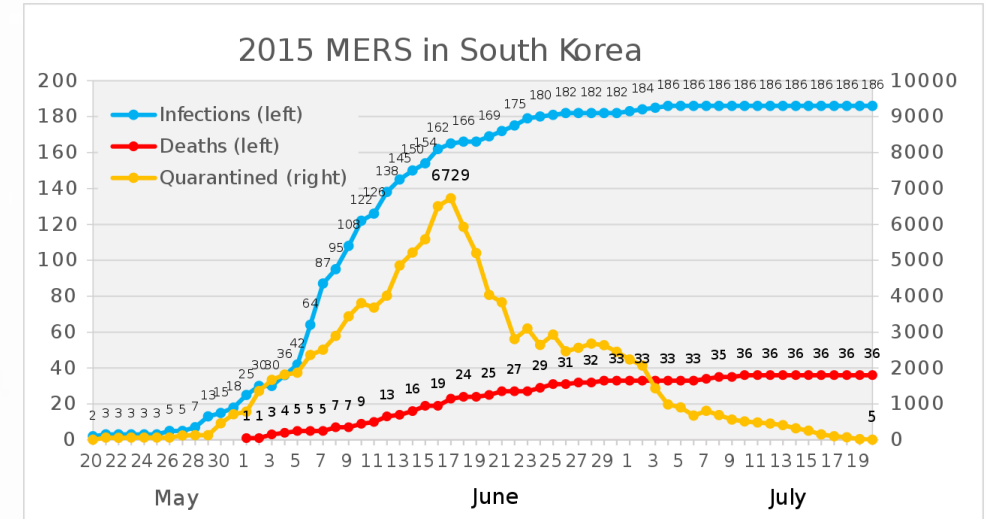
MERS (Middle-East Respiratory Syndrome) Outbreak in 2015 in Korea

Pathogen: MERS-CoV

Infected Patients: 186

Death: 38

Case fatality rate 20%

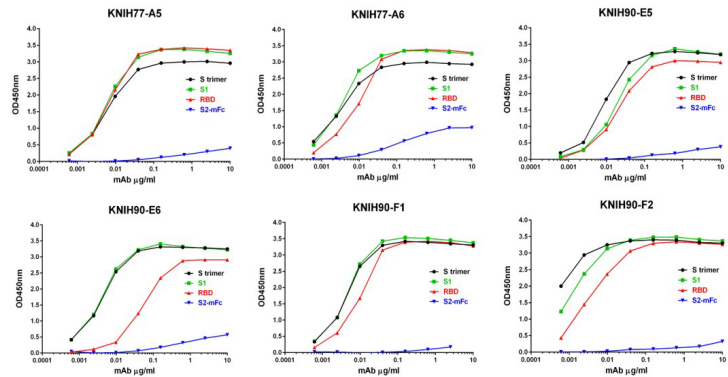


- => Establishment of 3T (testing, tracing, and treating) strategy
- Preparation of Negative Isolating Rooms
- Increase in R&D funding for EIDs

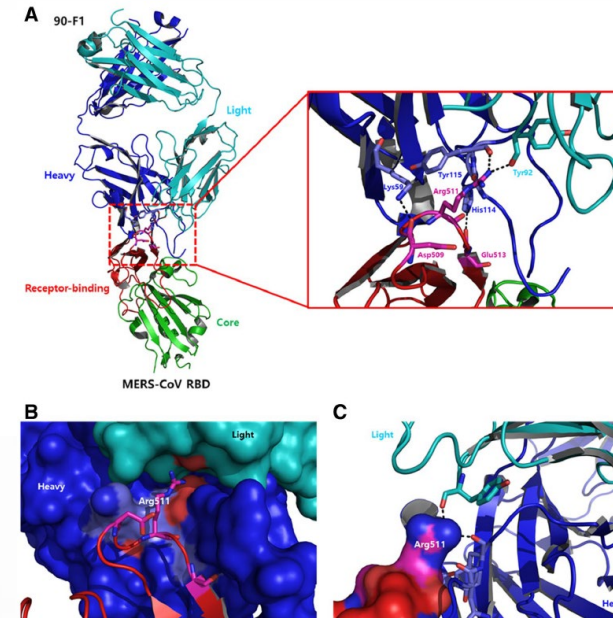
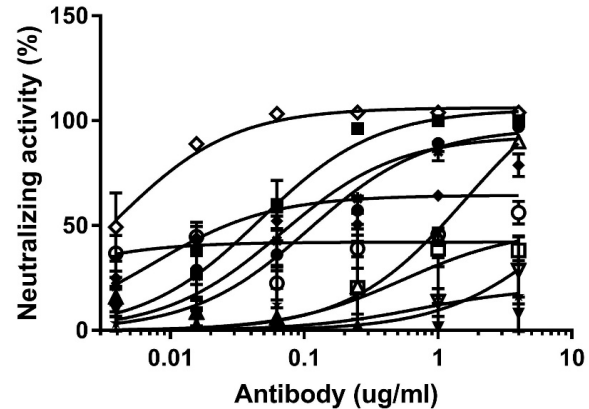
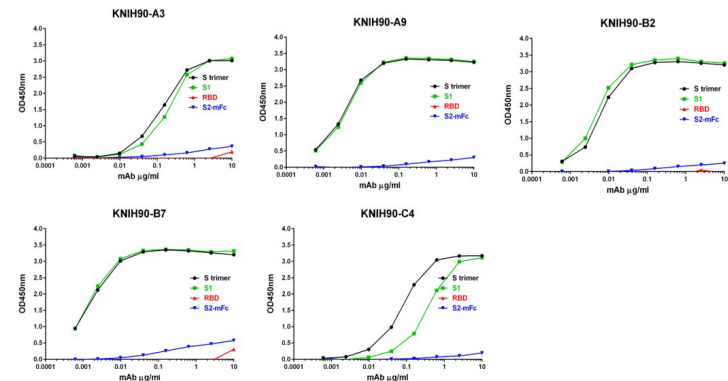
mAb for MERS: KNIH-NIAID VRC co-operation from 2016



RBD



S1



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CONFIRMATION NO. 2123

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Date Mailed: 03/20/2023

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Power of Attorney: None

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This application is a DIV of 10/641,580 02/24/2020 ABN
which is a 371 of PCT/KR2018/009754 08/23/2018

Foreign Applications (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see <http://www.uspto.gov> for more information.)
REPUBLIC OF KOREA 10-2017-010636 08/23/2017 No Access Code Provided

page 1 of 4

PLoS ONE 15(5) 2020

Scientific Reports, 2022, 12:1260

Binding Abs (11)

Neutralizing Abs (6)

Pre-clinical studies
joint patent (KNIH-90F1) :
NIAID-NIID

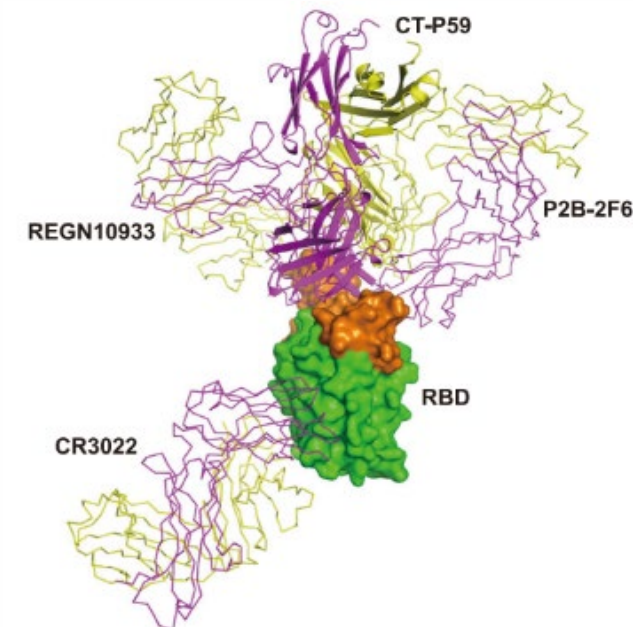
mAb for Covid-19 : NIID-Celltrion co-operation

Joint patent : NIID – Celltrion Pharm.

Phase III Clinical Trial Completed in Dec 2020.

Regdanvimab (Reckirona): K-FDA approval in **Feb 2021**.
EMA approval in Nov 2021.

More than **60,000 COVID-19 patients**
were treated with regdanvimab in Korea in 2021.



ARTICLE

<https://doi.org/10.1038/s41467-020-20602-5>

OPEN



A therapeutic neutralizing antibody targeting receptor binding domain of SARS-CoV-2 spike protein

Cheolmin Kim^{1,11}, Dong-Kyun Ryu^{1,11}, Jihun Lee^{1,11}, Young-Il Kim^{2,11}, Ji-Min Seo¹, Yeon-Gil Kim³, Jae-Hee Jeong³, Minsoo Kim¹, Jong-In Kim¹, Pankyeom Kim¹, Jin Soo Bae¹, Eun Yeong Shim¹, Min Seob Lee¹, Man Su Kim¹, Hanmi Noh¹, Geun-Soo Park¹, Jae Sang Park¹, Dain Son¹, Yongjin An¹, Jeong No Lee¹, Ki-Sung Kwon¹, Joo-Yeon Lee⁴, Hansaem Lee⁴, Jeong-Sun Yang⁴, Kyung-Chang Kim⁴, Sung Soon Kim⁴, Hye-Min Woo⁴, Jun-Won Kim⁴, Man-Seong Park⁵, Kwang-Min Yu², Se-Mi Kim², Eun-Ha Kim², Su-Jin Park^{2,10}, Seong Tae Jeong⁶, Chi Ho Yu⁶, Youngjo Song⁶, Se Hun Gu⁶, Hanseul Oh⁷, Bon-Sang Koo⁷, Jung Joo Hong⁷, Choong-Min Ryu⁸, Wan Beom Park⁹, Myoung-don Oh⁹, Young Ki Choi^{2,8} & Soo-Young Lee^{1,8}

[Nat Commun.](#) 2021; 12: 288.

Longterm R&D Pandemic Preparedness: Therapeutics

Plan to be announced on April 2023

	Pre-pandemic	Pandemic	Post-Pandemic
Mission	Preparedness (Infrastructure, Networks)	Response (Vaccine preparation)	Immunologic analysis (for vaccination strategy)
Strategy	Library of candidate therapeutics for possible pathogens Platform development Pre-clinical study	Pre-clinical study Large-scale Production Clinical Trial	Cohort F/U Efficacy f/u for Variants

Response in Pandemic Period

Track	Pre-clinical	Clinical Trial Phase I/II	Phase III Large scale production	FDA approval	Total	Platform
1	30 Days	Done	70 Days	<40 D	100D	mAb Antivirals
2	50Days	30 Days	120Days	<40 D	200D	mAb

Track1: known pathogens
Track2: novel pathogens

Lesson from mAb development for Covid-19



Korea Disease Control and Prevention Agency
National Institute of Health
National Institute of Infectious Diseases



1) Prepare **before pandemic**

- Importance of Pre-existing R&D Co-operation
- Clinical Trial Network
- Vx/mAb Candidate Discovery

2) Consider **variants** from the early stage of development

- Combination of mAb from the initiation (Cocktail)

Pre-pandemic period: Vx/mAb Candidate Discovery



Korea Disease Control and Prevention Agency
National Institute of Health
National Institute of Infectious Diseases



Korea PREMISE project

Serum collection from Infected host
Discovery of neutralizing Ab
Vaccine candidate discovery
Vaccine candidate library operation
Production of mAb and vaccines for
preclinical study and clinical trial



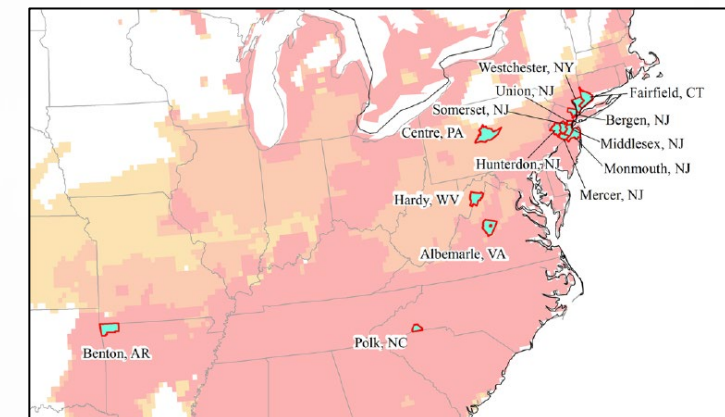
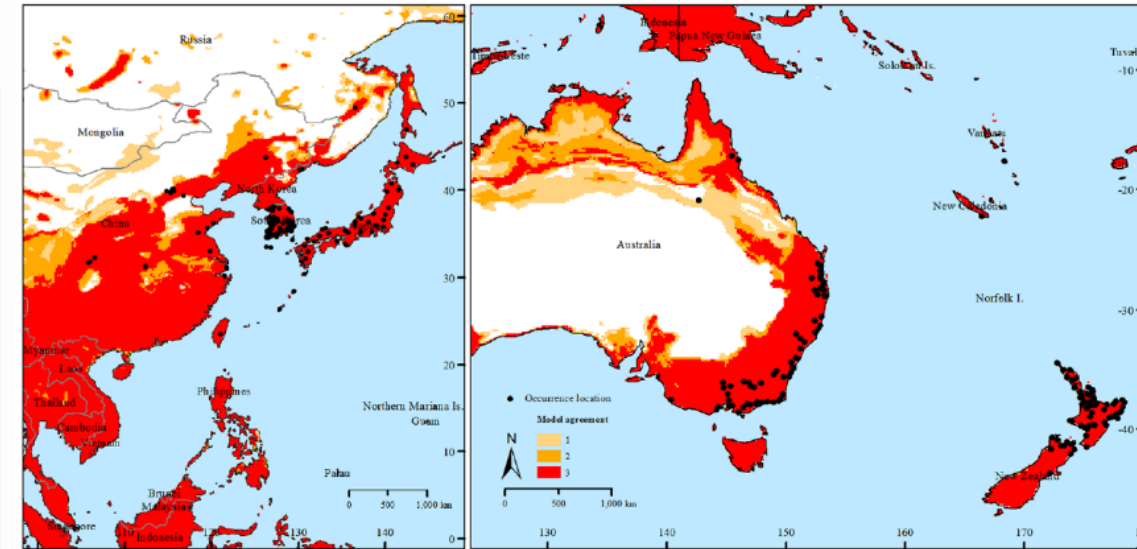
Pandemic Response Repository
through Microbial and Immune Surveillance and Epidemiology

SFTS: no Tx, no Vx despite 14 years after discovery



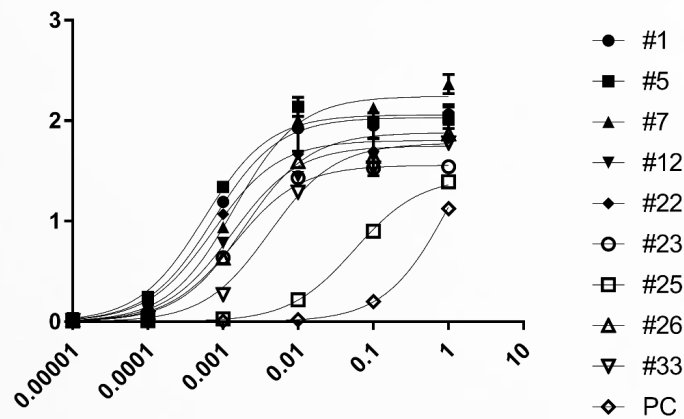
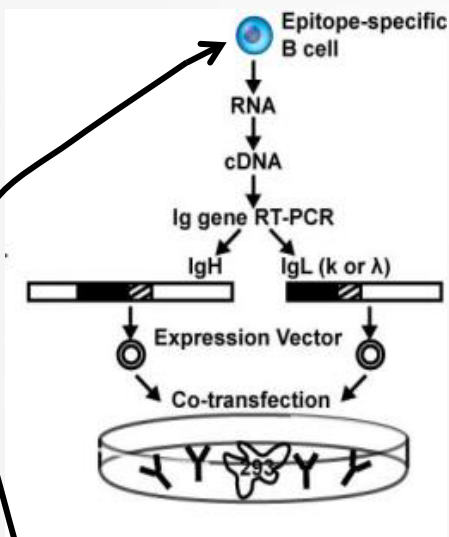
- SFTS was first reported in China in 2009, Japan and Korea in 2012.
- Vietnam (2019), Taiwan (2020)
- Fatality (7~27%) from 2010 to 2018

2010~2018	China	Japan	South Korea
SFTS cases	11,995	396	866
Annual incidence/10 ⁵	0.1	0.04	0.19
No. of deaths	881	107	173
Fatality rate (%)	7.34	27.02	19.98
Age median	62 (52-70)	74 (5-96)	65 (64-66)
% of female cases	53.15	51.52	50.35
Major epidemic seasons	May-July	May-July	July, September-October

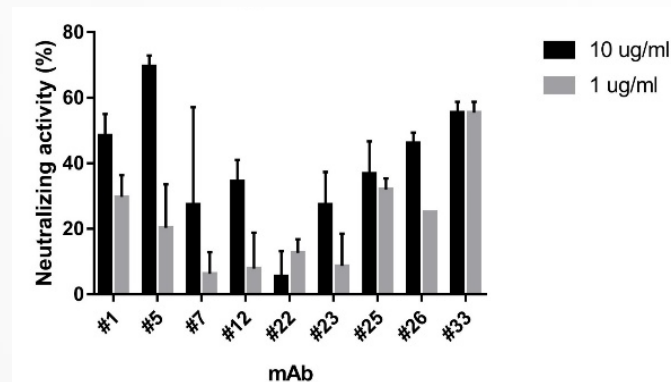
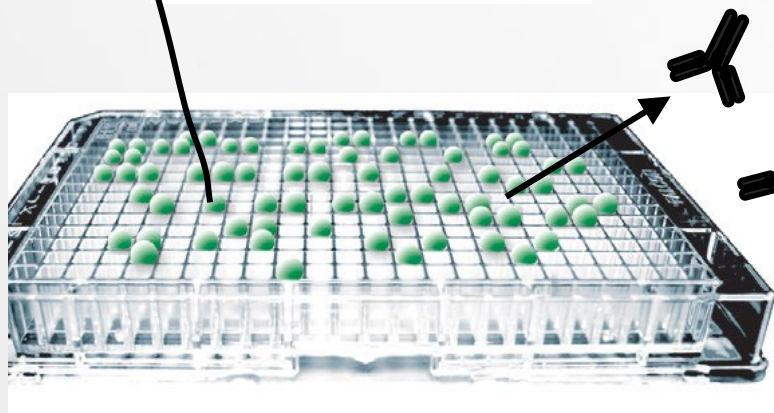


Cause: tick-born virus named *Dabie bandavirus*
 Family *Phenuiviridae*, Order *Bunyavirales*

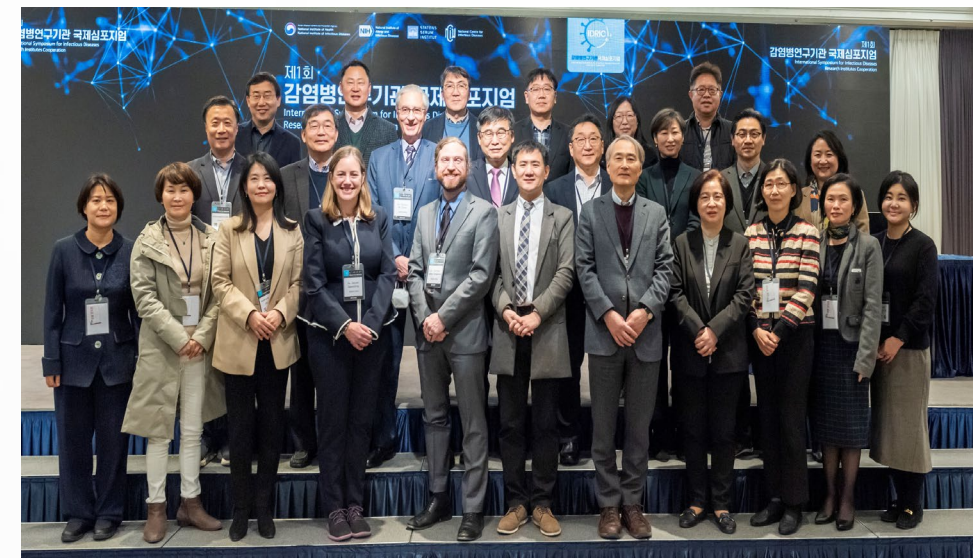
mAb for SFTSV : NIID-NIAID co-operation



1st LOI for expanding co-operations
Between NIAID and NIID
(April 2022)



1st NIID-NIAID-NCID-SSI symposium (Feb 2023)



Organizing and Maintaining Clinical Trial Network



Korea Disease Control and Prevention Agency
National Institute of Health
National Institute of Infectious Diseases



NIAID ACTT trial : Korea SNUH/BSNUH

Participation in NIAID Clinical Network

- RECOVERY (Tb)
- STRIVE (Covid-19)

KONECT: COVID-19 clinical trial network
(Public Centers and Referral Centers)

K-COT-1: camostat for severe covid-19
28 University Hospitals

9:20 – 9:45am CDT

REC

STRIVE
ACTIV
INSIGHT018

Strategies and Treatments
for Respiratory Infections
and Viral Emergencies

Shionogi-217622 Trial
Jason Baker, MD

69

insight

The screenshot shows a video conference interface. On the left, there's a 'REC' indicator. The main area displays a slide with the 'STRIVE' logo and text. A small video window on the right shows a man speaking. The bottom of the slide includes the trial name 'Shionogi-217622 Trial', the speaker's name 'Jason Baker, MD', a slide number '69', and the 'insight' logo.

New Clinical Trial Center for Next-Pandemic



- Samsung Co. donated 0.7 B USD for Next Pandemic Preparedness (May 2021).
- 500 M USD : National Central Hospital for Infectious Diseases and Clinical Trial
- 200 M USD : Clinical Research Center of NIID and Research



Long-term Pandemic R&D Preparedness in Korea

1) Therapeutics

2) Vaccine

Longterm R&D Pandemic Preparedness: Vaccine



Korea Disease Control and Prevention Agency
National Institute of Health
National Institute of Infectious Diseases



Plan to be announced on April 2023

	Pre-pandemic	Pandemic	Post-Pandemic
Mission	Preparedness (Infrastructure, Networks)	Response (Vaccine preparation)	Immunologic analysis (for vaccination strategy)
Strategy	Vaccine Library for highly possible pathogens Platform development Pre-clinical study	Pre-clinical study Large-scale Production Clinical Trial	Vaccination Cohort F/U Real-world monitoring: efficacy/adverse reaction

Response in Pandemic Period



Korea Disease Control and Prevention Agency
National Institute of Health
National Institute of Infectious Diseases



Track	Pre-clinical	Clinical Trial Phase I/II	Phase III Large scale production	FDA approval	Total	Platform
1	30 Days	Done	70 Days	<40 D	100D	mRNA
2	40Days	60 Days	100Days	<40 D	200D	mRNA

Track1: known pathogens
Track2: novel pathogens

South Korea's first homegrown Covid-19 vaccine



- The Institute for Protein Design of the University of Washington
- GSK's AS03 adjuvant
- K-FDA approval in **June, 2022**
- COVID-19 Therapeutics made in Korea: Feb 2021 (13 months)
- COVID-19 Vaccines made in Korea: June 2022 (27 months)

MOHW-KDCA-Private Co-operation



'As Is'

VITAL-Korea
('20~'29; 10 yrs; 200M US\$)

Category	Key targets	Goal
Securing self-sufficiency of NIP vaccines	DTaP	Phase 2 clinical trial
	Japanese encephalitis	
	Hepatitis A	
	HPV	
Vaccines of global un-met need	SFTS	Phase 2 clinical trial
	Noroviral gastroenteritis	
	Next-generation Tuberculosis	
	HFMD	
	Universal Influenza	Phase 1 clinical trial
	Dengue Fever	Non-clinical
	RSV	
	Vaccine platform technologies for emerging viral diseases	Candidate
Vaccine enabling technology	Novel adjuvants	Proof of concept
	Vaccine delivery system	

'To Be'

K-Vaccine Hub
('22-'26; 5 yrs; 2B US\$)



- **Pandemic vaccines**
 - Speedy delivery platform
 - Universal vaccine
 - Vaccine libraries
- **Premium vaccines**
- **Enabling Technologies**

Platform: mRNA vaccine committee & funding

MOHW & KDCA (NIID) from 2021

National Project for the Platform Development of mRNA Vaccine Technology

Korea mRNA Vaccine Initiative (KmVAC)
for the preparedness of Emerging Infectious Diseases:

Field	Aim	Principal Invest.	Disease & tech.
Subjects for clinical trials to secure platform	Phase 2 clinical trial	ST PHARM	Mockup vaccine for universal coronavirus preparedness
		EYEGENE Inc.	Multivalent vaccine for universal coronavirus preparedness
Subjects for pre-clinical trials to enhance future technological development	IND of Preventive/Therapeutic Vaccine	Quratis	mRNA material for dual purposes of tuberculosis vaccine and therapeutics
	IND for clinical trial of novel mRNA antigens	IVI	mRNA vaccine candidate for Lassa fever preparedness
		NES Biotechnology	mRNA antigen with high stability for influenza vaccine
		QuadMedicine	Micronee type mRNA vaccine for coronavirus preparedness
		Chonbuk Univ.	mRNA vaccine candidate for SFTS preparedness
		RNAGENE	Pan-corona mRNA vaccine antigen technology
		Sogang Univ.	mRNA vaccine candidate for Zika virus infection



코로나19 치료제·백신개발
 범정부 실무추진위원회
 (mRNA 백신 전문위원회)
 - 1차 회의 안건 -

2021. 3. 9.



코로나19 범정부 실무추진위원회
 mRNA백신 전문위원회

NIID supports domestic companies for pre-clinical trials



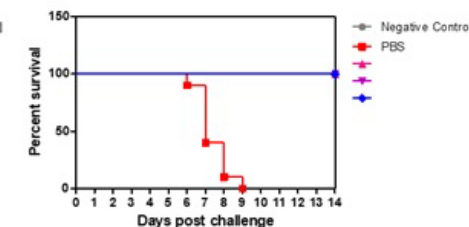
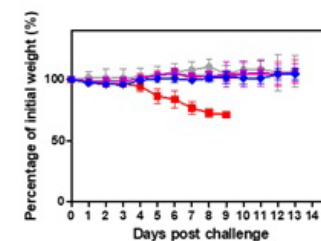
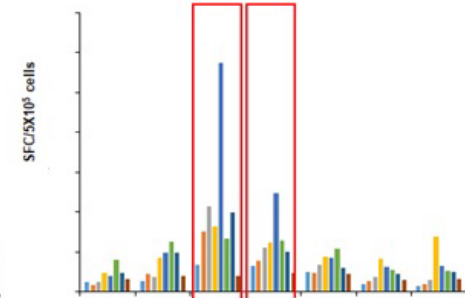
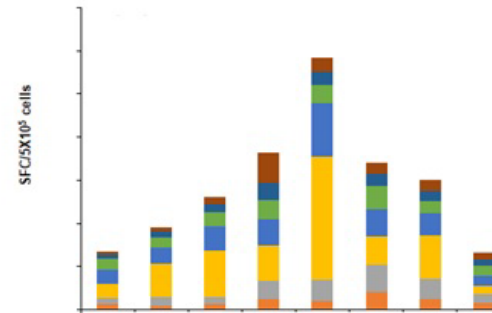
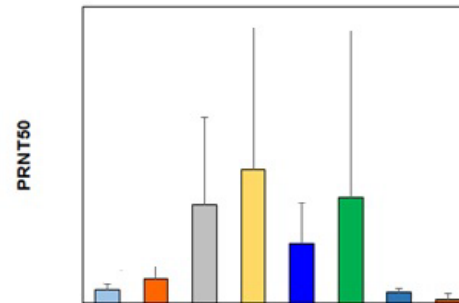
Vaccine Research Center

Built in 2020

(BL3/aBL3....BL4)

Intra- mural Research
Support for companies

 ST PHARM



mRNA vaccine development with Moderna: SFTS



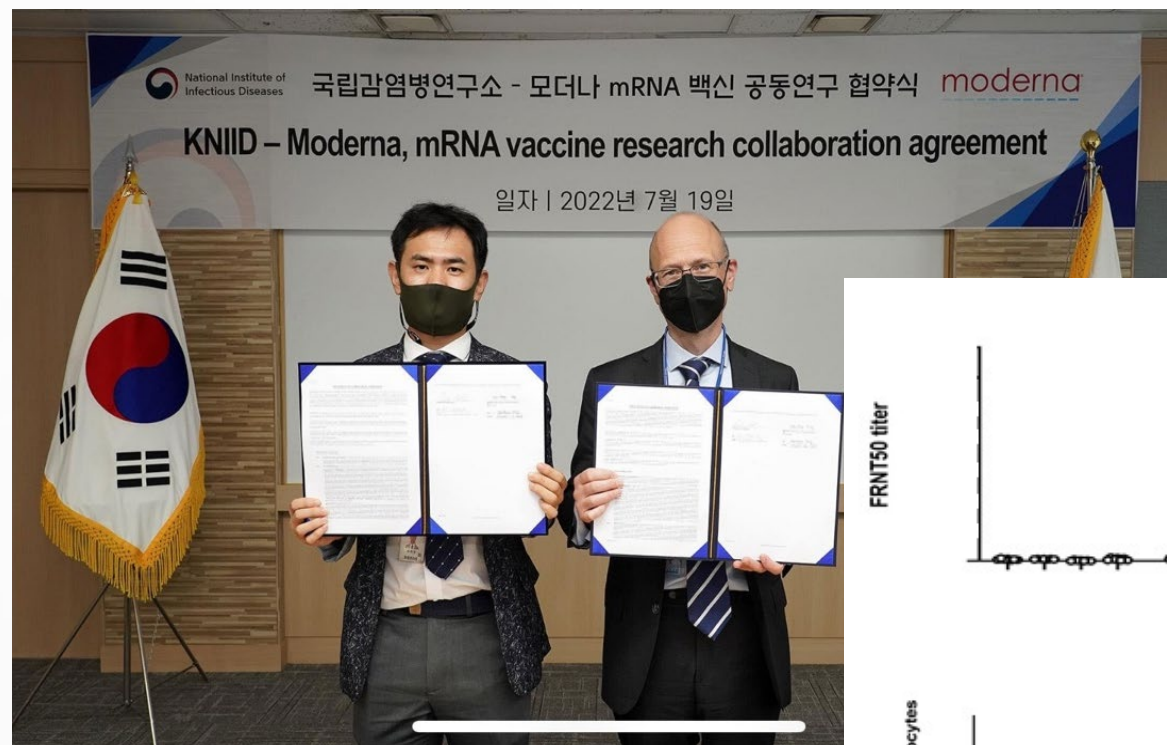
Korea Disease Control and Prevention Agency
National Institute of Health
National Institute of Infectious Diseases



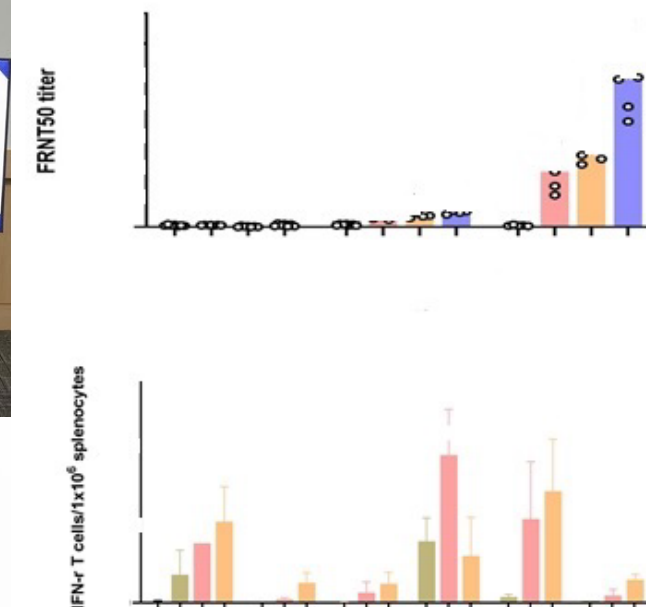
Ag design (NIID/Moderna)-> Vaccine Formulation (Moderna)-> Preclinical Trial (NIID)



2021 Boston, US



2022 Osong, Korea



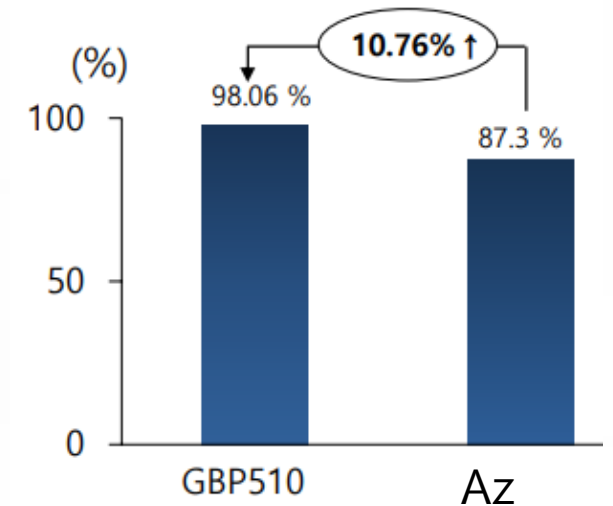
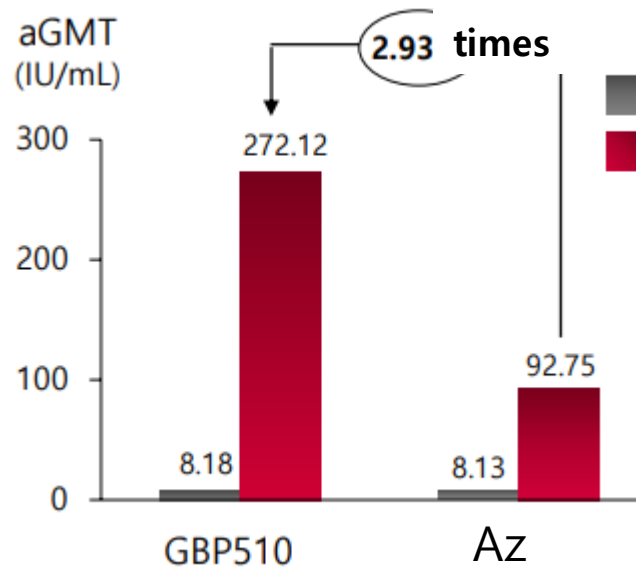
Support: Clinical Trial & Immunologic analyses

Skycovione Phase III Clinical Trial

Korea, Vietnam, Thailand, Philippine, Ukraine, New Zealand
4037 Participants

FRNT
80% NIID
20% IVI

GCLP certified



Skycovione: SK bioscience COVID-19 vaccine
partially CEPI-funded

Skycovione heterologous 3rd booster trial



Korea Disease Control and Prevention Agency
National Institute of Health
National Institute of Infectious Diseases

Sample Size

- 550

Country

- Korea

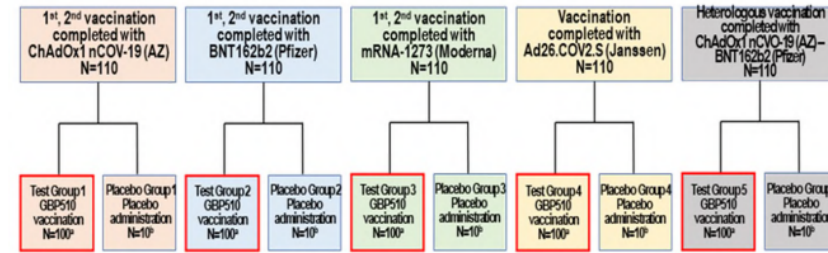
Evaluation

- Booster interval : at least 12 weeks
- Superiority of post-booster GMT / pre-booster GMT
- NAb, ECLIA, CMI
- VOC will also be analyzed

Progress/ Plan

- 2022.01 IND approval
- 2022.06 approximately 40% enrolled
- 2022.07 Interim result
- 2022.12 Key result

NIID-funded

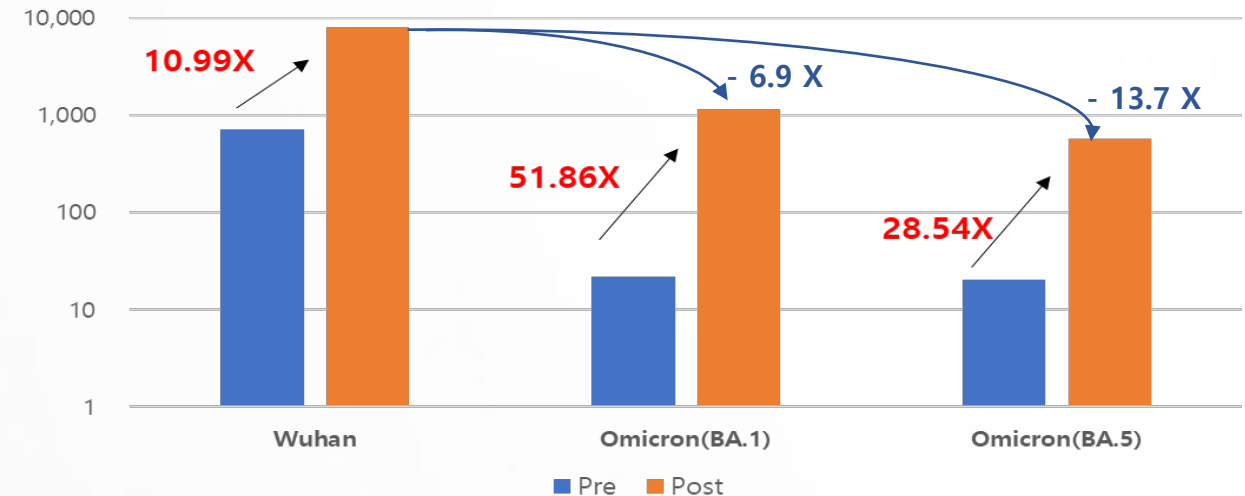


a: CMI assessment to be performed for approx. 20 out of 100 participants in each Test Group.
b: CMI assessment to be performed for approx. 2 out of 10 participants in each Placebo Group.

The Protocol was revised to increase the sample size of cohort 2, 3 of mRNA vaccine

Skycovione: SK bioscience COVID-19 vaccine partially CEPI-funded

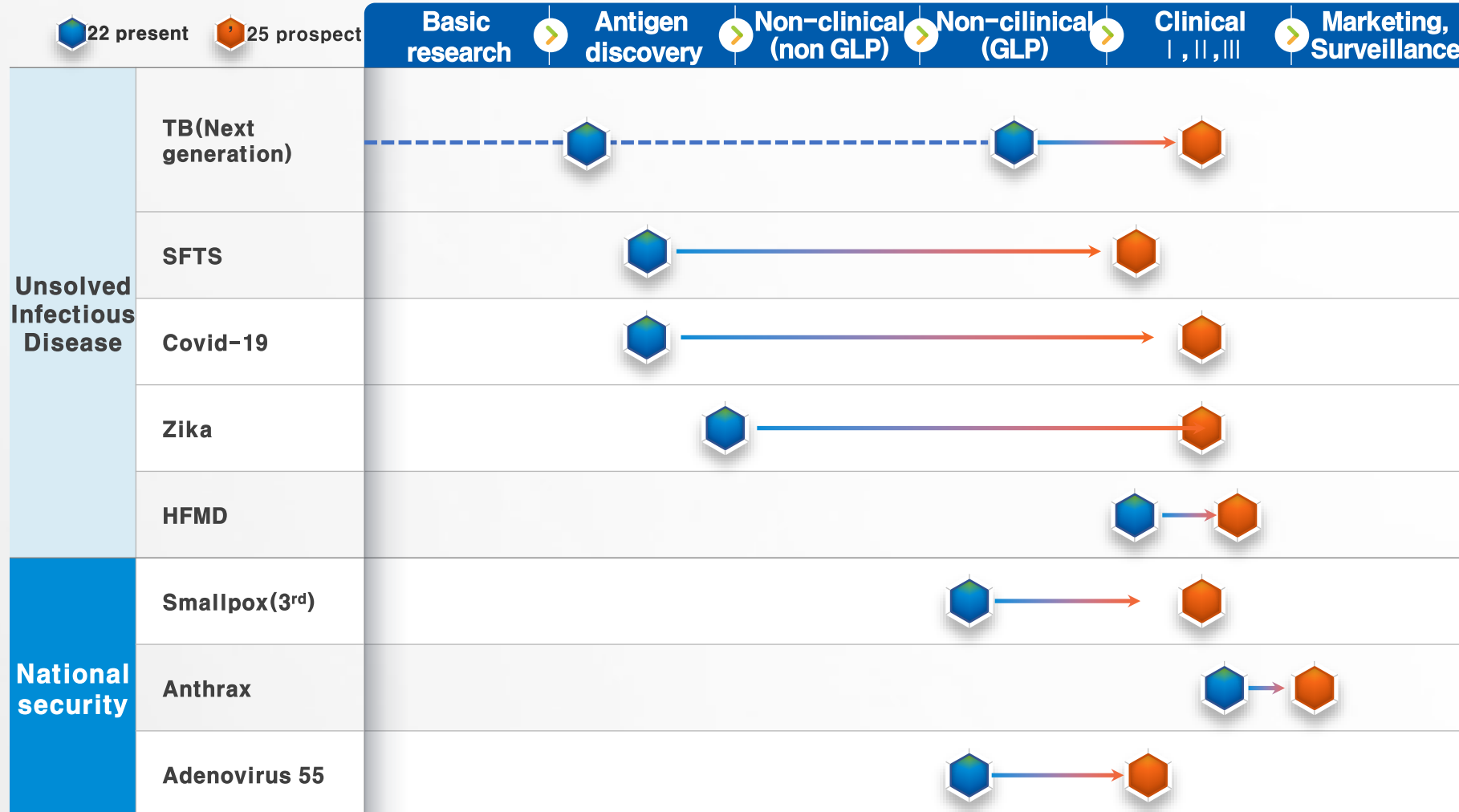
Heterologous Booster



Vaccines related to National Security

A randomized, double-blind, controlled clinical trial to evaluate the efficacy and safety of CJ-50300, a newly developed cell culture-derived smallpox vaccine, in healthy volunteers ☆

[Hee-Chang Jang^a](#), [Choong Jong Kim^a](#), [Kye Hyoung Kim^a](#), [Kwang-Hee Lee^b](#), [Young-Ho Byun^b](#), [Baik-Lin Seong^b](#), [Giulietta Saletti^c](#), [Cecil Czerkinsky^c](#), [Wan Beom Park^a](#), [Sang-Won Park^a](#), [Hong-Bin Kim^a](#), [Nam Joong Kim^a](#), [Myoung-don Oh^a](#)  



inno.N



Pre-pandemic period: Vx/mAb Candidate Discovery



Korea Disease Control and Prevention Agency
National Institute of Health
National Institute of Infectious Diseases



Korea PREMISE project

Serum collection from Infected host
Discovery of neutralizing Ab
Vaccine candidate discovery
Vaccine candidate library operation
Production of mAb and vaccines for
preclinical study and clinical trial



Pandemic Response Repository
through Microbial and Immune Surveillance and Epidemiology

International Cooperation: Funding

Cooperation with Global Funds

Korean companies have high investment value !



Respect! Thanks!

It means "respect" "thanks"
in sign language

