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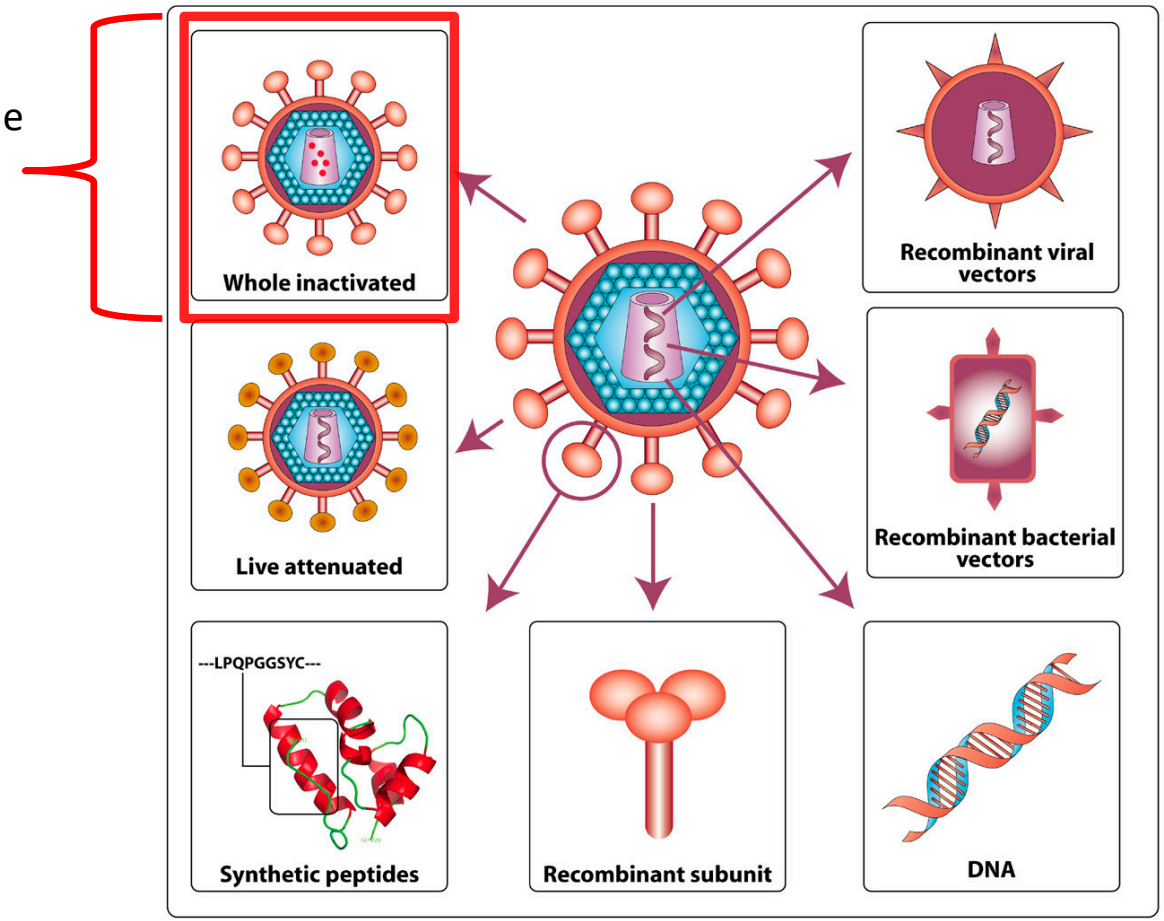
COVID-19 Vaccine:
Clinical Trials and Tribulations

Dr. Raches Ella
Project Lead SARS-CoV-2 Vaccines

Types of Vaccines

Whole Inactivated

- Conventional and Safe Vaccine
- Used in Pregnancy
- In use for Decades
- Vaccines
  - Polio
  - Pertussis
  - S. Flu
  - Rabies
  - Japanese Encephalitis



VERO CELL MANUFACTURING PLATFORM

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Developed several inactivated Vero cell derived vaccines which are proven, time-tested and long-lasting. A few include:

ROTAVAC®
ORAL ROTAVIRUS VACCINE 116E, LIVE ATTENUATED

JENVAC®
PURIFIED, INACTIVATED JAPANESE ENCEPHALITIS VACCINE

INDIRAB®
PURIFIED, INACTIVATED RABIES VACCINE

ONGOING VACCINE CANDIDATE USING VERO CELL PLATFORM

- CHIKUNGUNYA
- ZIKA
- sIPV
- BBV152*

*COVAXIN

~25 CLINICAL STUDIES

~300,000 SUBJECTS

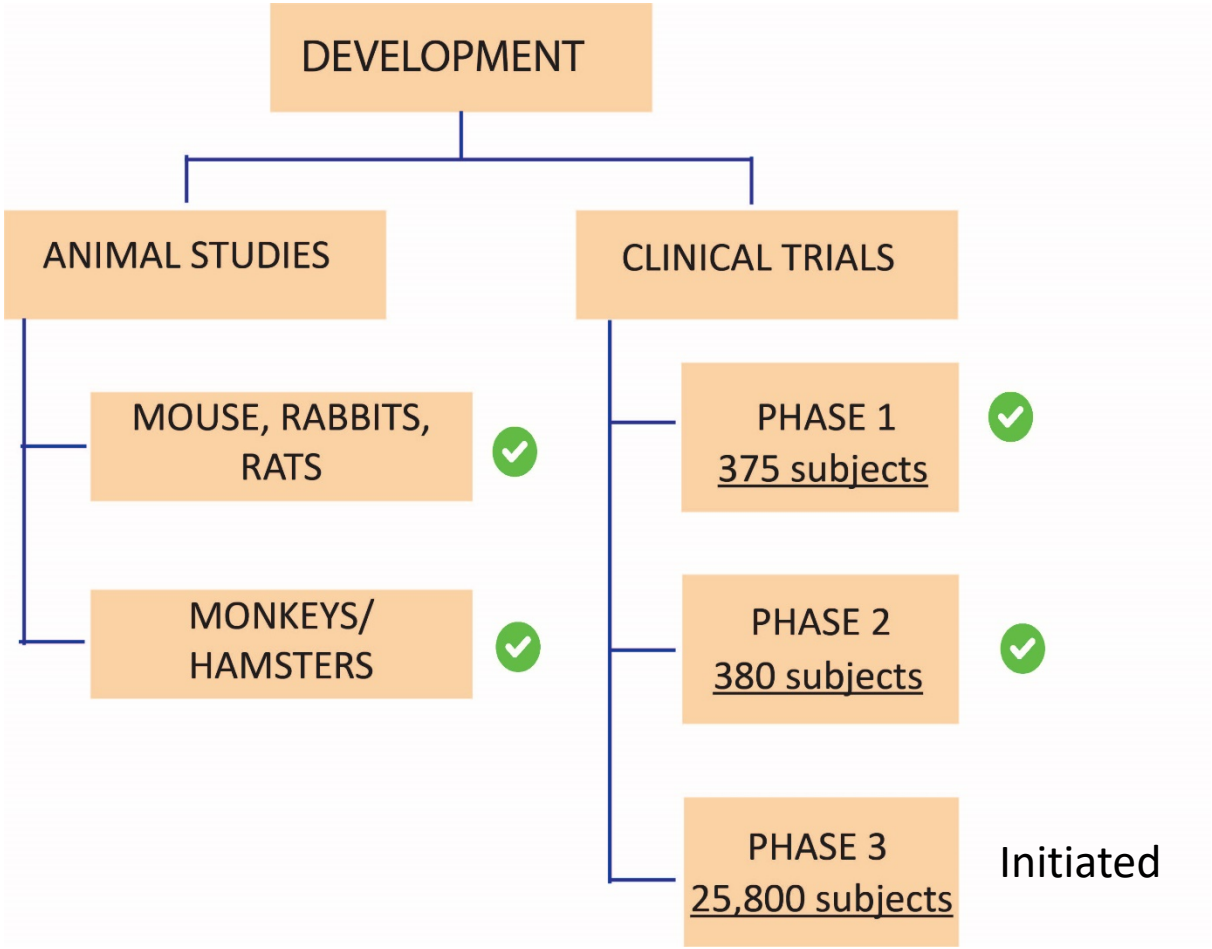
15 YEARS EXCELLENT CLINICAL TRIAL SAFETY

~300 MILLION DOSES SUPPLIED FROM VERO MANUFACTURING PLATFORM | EXCELLENT POST MARKETING SAFETY RECORD

BBV 152 : BSL3 PRODUCTION FACILITY

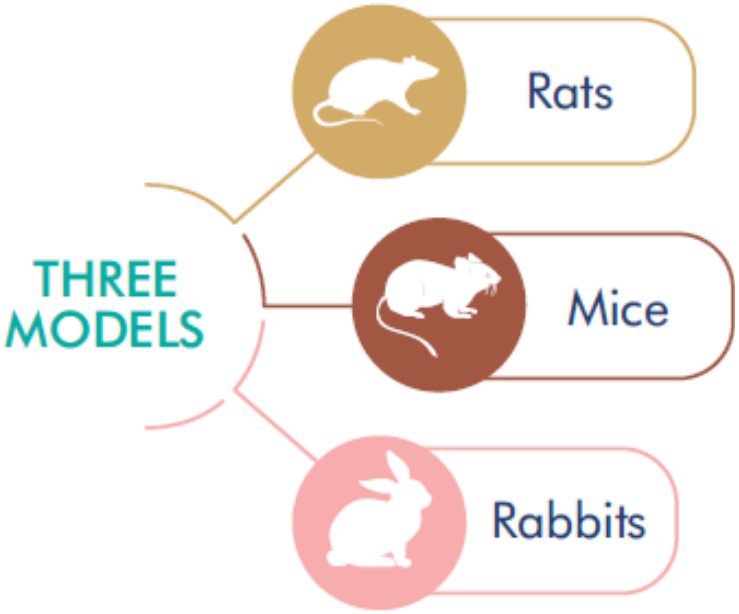
- Designed and constructed during 2017 – 2019
- Facility audited by ICMR technical team 2019
- Designed for large scale manufacturing and testing

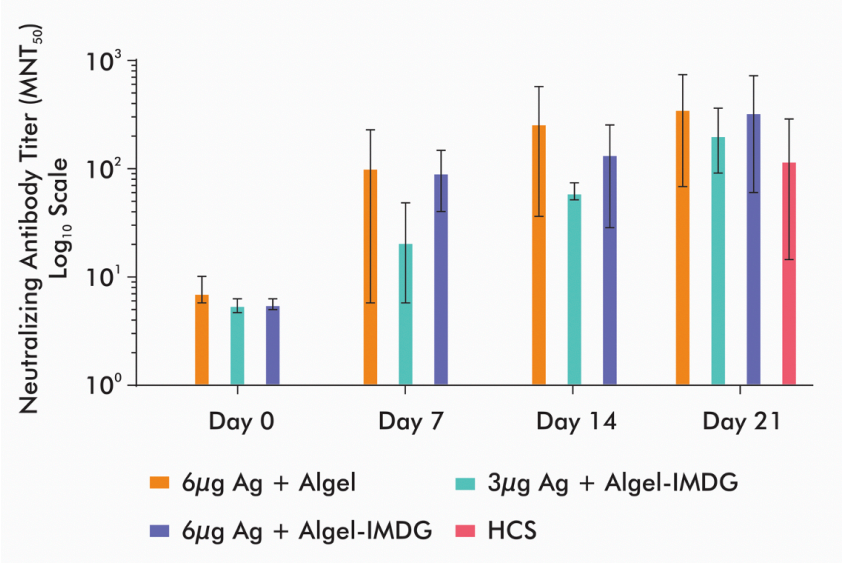
COVAXIN™ PROGRESS

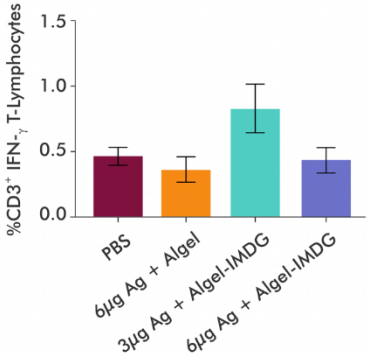


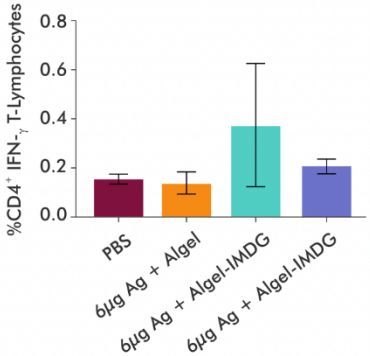
BBV152
PRECLINICAL PROFILE

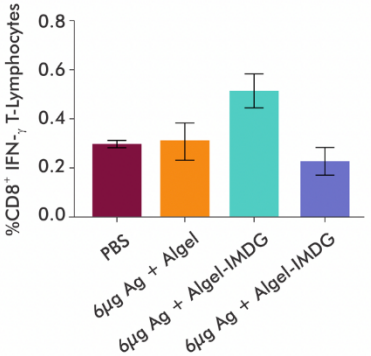
STUDY DESIGN











NON-HUMAN PRIMATES & HAMSTER STUDIES

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Preclinical Evaluation of Live Viral Challenge Studies

icmr
INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

NIV
NATIONAL INSTITUTE OF VIROLOGY

TWO BBV152 PAPERS
(UNDERGOING PEER-REVIEW)

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ARTICLE *General Microbiology* *Vaccine Development*

Remarkable immunogenicity and protective efficacy of BBV152, an inactivated SARS-CoV-2 vaccine in rhesus macaques

Pragya Yadav, Raches Ella, Sanjay Kumar, Dilip Patil, Sreelekshmy Mohandas, Anita Shete, Gaurav Bhati, Gajanan Sapkal, Himanshu Kaushal, Savita Patil, Rajlaxmi Jain, Gururaj Rao Deshpande, Nivedita Gupta, Kshitij Agarwal, Mangesh Gokhale, Basavaraj Mathapati, Siddhanath Metkari, Chandrashekhar Mote, Dimpal Nyayanit, Deepak Patil, Sai Prasad B S, Annasaheb Suryawanshi, Manoj Kadam, Abhimanyu Kumar, Sachin Daigude, Sanjay Gopale, Triparna Majumdar, Deepak Mali, Prasad Sarkale, Shreekant Baradkar, Pranita Gawande, Yash Joshi, Sidharam Fulari, Hitesh Dighe, Sharda Sharma, Rashmi Gunjikar, Abhinendra Kumar, Kaumudi Kalele, V K Srinivas, Krishna Mohan, Raman Gangakhedkar, Krishna Ella, Priya Abraham, Samiran Panda, Balram Bhargava

DOI: 10.21203/rs.3.rs-65715/v1 Download PDF

nature research

RESEARCH ARTICLE *Vaccine Development*

Immunogenicity and protective efficacy of BBV152: a whole virion inactivated SARS CoV-2 vaccine in the Syrian hamster model

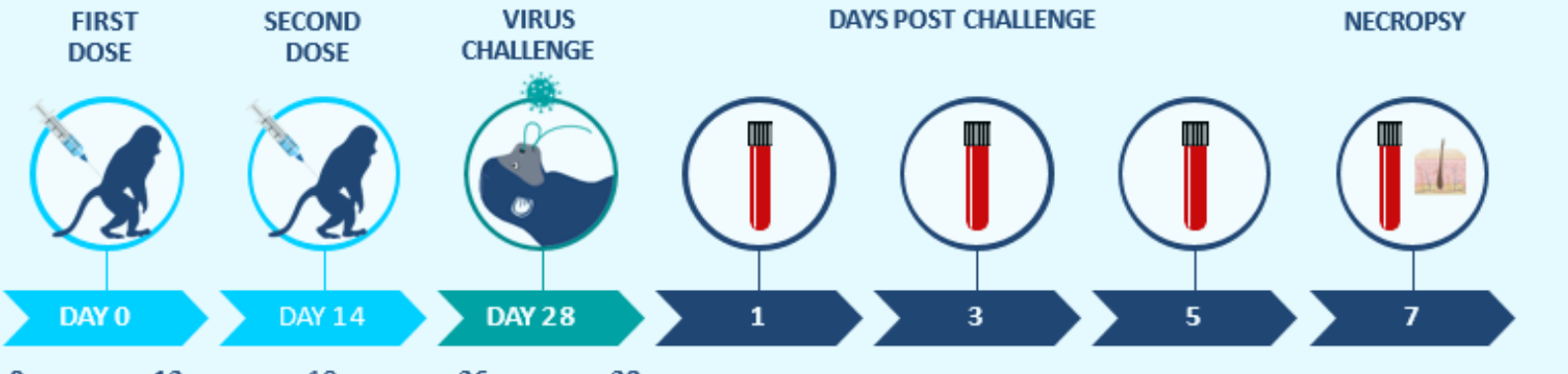
Sreelekshmy Mohandas, Pragya D Yadav, Anita Shete, Priya Abraham, Krishna Mohan, Gajanan Sapkal, Chandrashekhar Mote, Dimpal Nyayanit, Nivedita Gupta, V K Srinivas, Manoj Kadam, Abhimanyu Kumar, Rajlaxmi Jain, Triparna Majumdar, Gururaj Deshpande, Savita Patil, Prasad Sarkale, Deepak Patil, Raches Ella, Sai D Prasad, Sharda Sharma, Krishna M Ella, Samiran Panda, Balram Bhargava

DOI: 10.21203/rs.3.rs-76768/v1 Download PDF

CellPress

1. NON-HUMAN PRIMATE – STUDY DESIGN

- A 2-dose vaccination regimen of inactivated SARS-CoV-2 vaccine candidates was administered in 20 rhesus macaques (divided into four groups equally).
- One group was administered with placebo while three groups were immunized with 3 different vaccine candidates at 0 and 14 days. All the macaques were exposed to viral challenge 14 days after the 2nd dose.



TWO-DOSE VACCINATION REGIMEN

Group-I (Placebo-Phosphate buffer saline)

Group-II (6µg + Adjuvant-A)

Group-III (3µg + Adjuvant-B)

Group-IV (6µg + Adjuvant-B)

All the monkeys were challenged with SARS-CoV-2 14 days after the 2nd dose

Collection of blood, nasal swab, throat swab, rectal swab, bronchoalveolar lavage fluid, urine, stool specimens and acquisition of chest X-rays.

Pictures shown are for illustration purpose only

LOAD OF COVID-19 SUBGENOMIC VIRAL RNA DETECTION IN RESPIRATORY TRACT SPECIMENS

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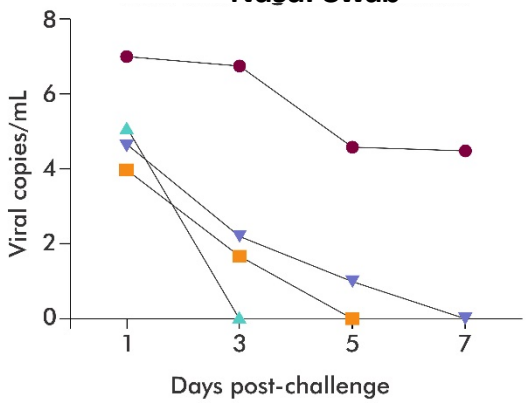
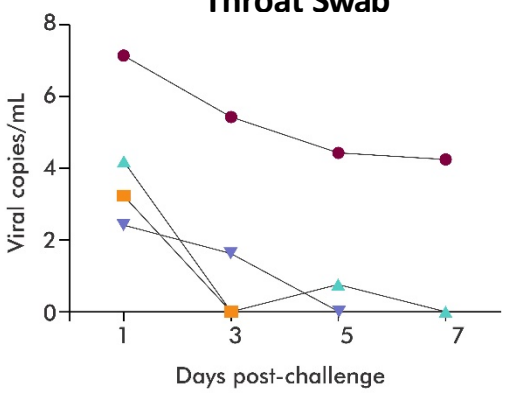
Upper airway protection

Nasal Swab

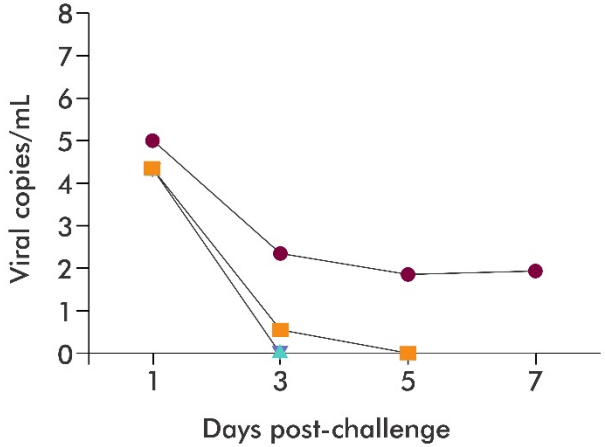


Throat Swab

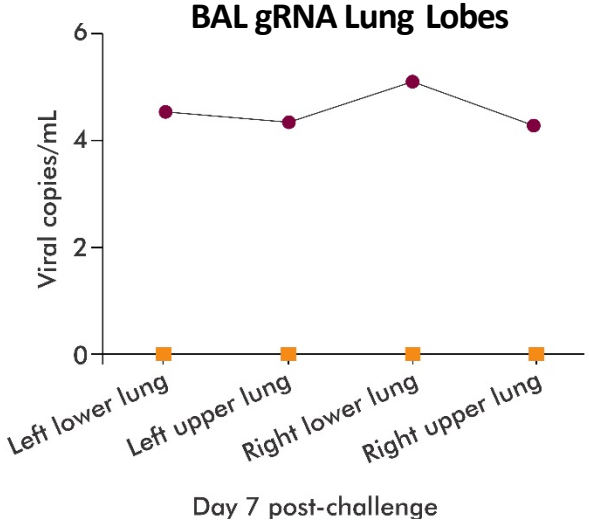


Lower airway protection

Bronchoalveolar lavage (BAL) gRNA

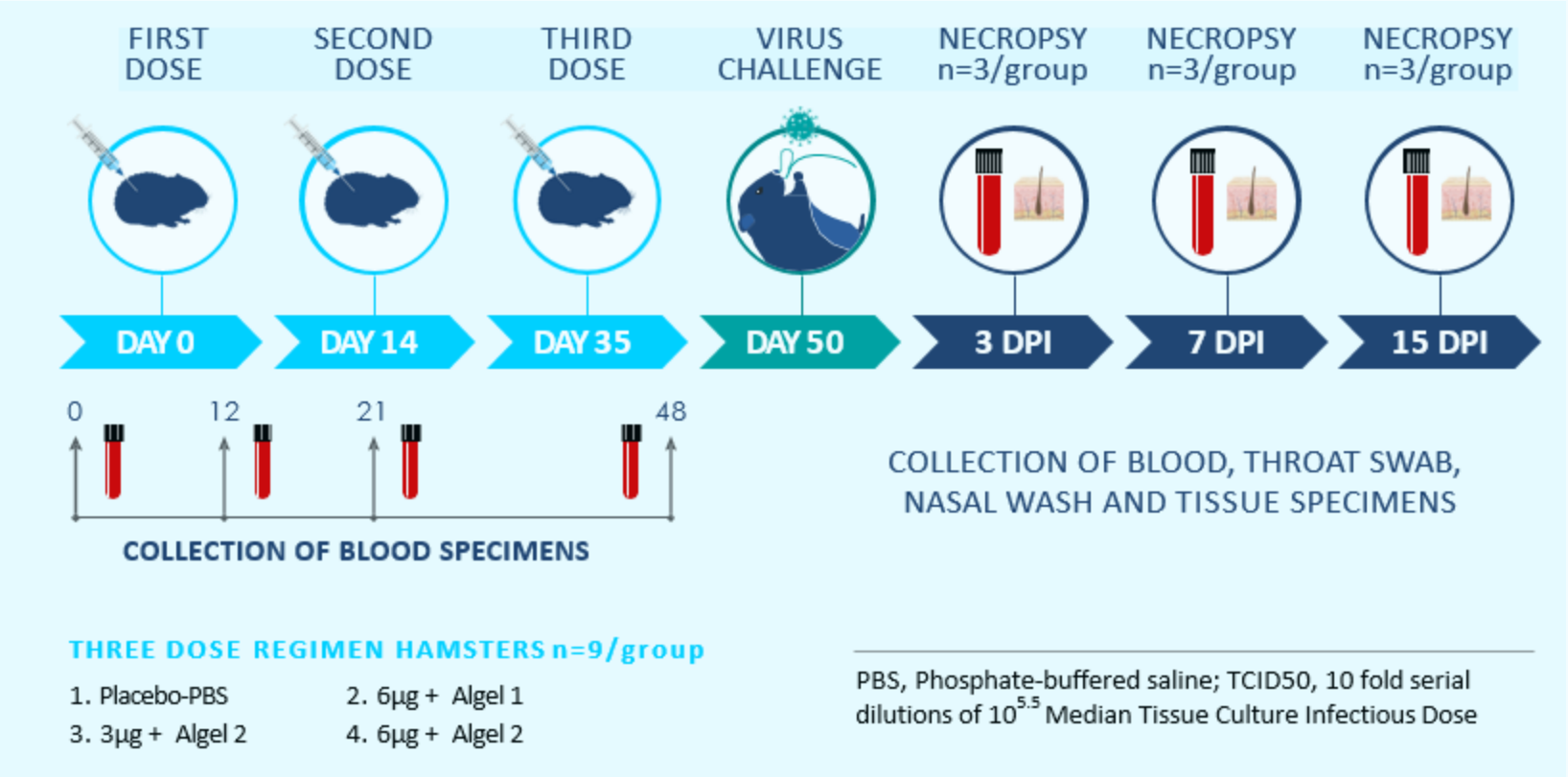


BAL gRNA Lung Lobes



2. HAMSTER CHALLENGE - STUDY DESIGN

- Thirty-six female Syrian hamsters were divided into four groups of 9 hamsters each. Each group were immunized with 0.1 ml of PBS/vaccine formulations intramuscularly on 0, 14, and 35 days.
- The immunized hamsters were challenged with 0.1 ml of 105.5 TCID50 SARS-CoV-2 virus intranasally on the 8th-week post-immunization (day 50).



LOAD OF COVID-19 SUBGENOMIC VIRAL RNA DETECTION IN RESPIRATORY TRACT SPECIMENS

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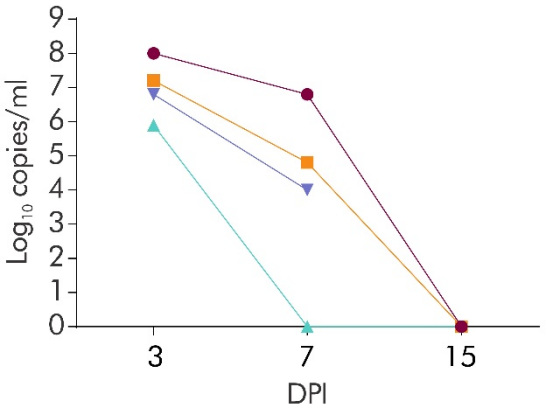
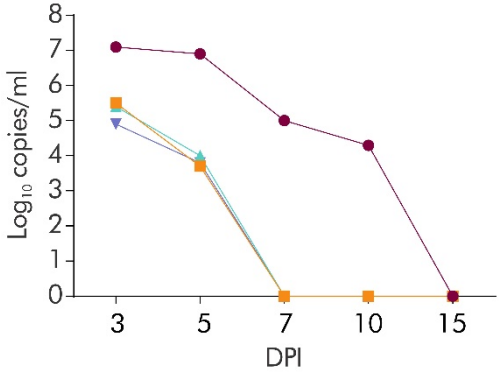
Upper airway protection

Nasal Wash gRNA

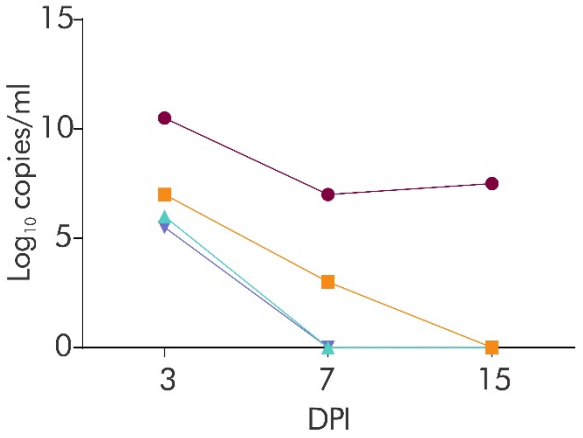


Throat Swab gRNA

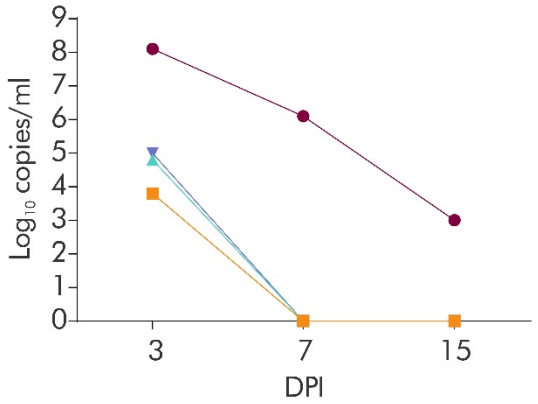


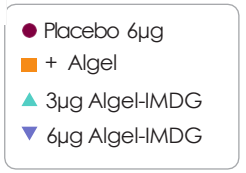
Lower airway protection

Lungs gRNA



Trachea gRNA





STATUS UPDATE & MILESTONES

PHASE I

IM study:

- ❑ Administered at 14 day interval
- ❑ 375 subjects.

ID study:

- ❑ Administered in 24 subjects.

Status: Completed

PHASE II

IM study:

- ❑ Administered at a 28-day interval.
- ❑ Includes 380 subjects.
- ❑ Dose-1 has been administered.

ID study:

- ❑ Administered in 100 subjects.

Status: Initiated

PHASE III

- ❑ Scheduled to commence in October all over India around 25 centers
- ❑ Trial includes >25,000 subjects
- ❑ IM study with 2-dose vaccine regimen administered at a 28-day interval.

Status: To initiate

WHOLE-VIRION INACTIVATED SARS-CoV-2 VACCINE (BBV152) IN HEALTHY VOLUNTEERS - A PHASE 1 STUDY

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Phase 1 trial overview (NCT04471519)				
Protocol Title	Phase 1, double blind, multi-centre study of safety, reactogenicity, tolerability, and immunogenicity in 375 healthy volunteers.			
Study Groups	**Cohorts/ Vaccine Candidates**	**Age groups**	**Dosage (D0, D14)**	**Enrollment status**
	BBV152A	≥18 to ≤55 years	0.5 mL of Whole Virion Inactivated SARS-CoV-2 Vaccine	(Fully enrolled) 100
	BBV152B			(Fully enrolled) 100
	BBV152C			(Fully enrolled) 100
	Placebo		0.5 mL placebo	(Fully enrolled) 75
Population	Participants of either gender of age between ≥18 to ≤55 years.			
Study Endpoints	Safety (Mild AEs were noted within 2 hours after Dose 1. No immediate AEs were reported after Dose 2). Immunogenicity (e.g., neutralizing antibody titers are suggestive of protection)			
Study Duration	12-month follow up study after the last vaccine administration.			

PHASE 1 & 2: GEOGRAPHIC SPREAD

List of Hospitals Across India
All India Institute of Medical Sciences, Delhi
Rana Hospital and Trauma Center, Gorakhpur
All India Institute of Medical Sciences, Patna
Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak
Prakhar Hospital, Kanpur
Gillukar Multispeciality Hospital, Nagpur
Redkhar Hospital, Dhargalim VP
Jeevan Rekha Hospital, Belgaum
Institute of Medical Sciences and SUM Hospital, Bhubaneshwar
Nizam Institute of Medical Sciences Hospital, Hyderabad
SRM Hospital & Research Center, Chennai

A PHASE 2 STUDY SHOWING WHOLE-VIRION INACTIVATED SARS-CoV-2 VACCINE (BBV152) IN HEALTHY VOLUNTEERS

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Phase 2 trial overview (NCT04471519)				
Protocol Title	Phase 2, double blind, multi-centre study of safety, reactogenicity, tolerability, and immunogenicity in 380 healthy volunteers.			
Study Groups	**Cohorts/ Vaccine Candidates**	**Age groups**	**Dosage (D0, D28)**	**Enrollment status**
	BBV152A	≥12 to ≤65 years	0.5 mL	(Fully enrolled) 190
	BBV152B		0.5 mL	(Fully enrolled) 190
Population	Participants of either gender of age between ≥12 to ≤65 years.			
Study Endpoints	No immediate AEs occurred within 2 hrs after vaccination; there were no SAEs reported. Immunogenicity (e.g., neutralizing antibody titers are suggestive of protection)			
Study Duration	6-month study after the last vaccine administration.			

Phase 3 Efficacy Trial (n=26,000)

mint

Home >News >India >Covaxin update: Bharat Biotech gets nod from DCGI panel for Phase III trials

The human trials of Covaxin has begun at the All India Institute of Medical Sciences

Covaxin update: Bharat Biotech gets nod from DCGI panel for Phase III trials

THANK YOU