



CLINICAL TRIAL REPORT

A Phase III Randomized Double Blinded
Plasebo - Controlled Clinical Trial of ZF2001
at Al-Shifa Research Center,
Al-Shifa Trust Eye Hospital
Rawalpindi



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ABOUT US

Al-Shifa Trust Eye Hospital

Al-Shifa Trust was established with the aim of prevention and control of blindness by providing standard and sustainable eye care services which are accessible and affordable to all regardless of gender, race, color, or religion. Its essential components would be hospital based tertiary eye care services, community-oriented prevention of blindness program, need based human resource development, promotion of basic and applied research in ophthalmology and development of appropriate and affordable technology



Al-Shifa Trust Eye Hospital

Al-Shifa Trust was established in 1985. It is a non-governmental, non-political, charitable organization. President of Pakistan is the ex-officio Patron-in-Chief of the trust. The board of trustees comprises of retired service men, businessmen, bureaucrats, and professionals. The aims and objectives of the trust are the prevention and control of blindness by providing standard and sustainable eye care services which are accessible and affordable, human resource development through training of doctors, nurses, and paramedics, creating awareness about eye diseases in general public through camping activities and to establish facilities for research in ophthalmology.

AL-SHIFA

RESEARCH CENTER



Al-Shifa Research Center

Research has been an integral part of Al-Shifa's mandate since its inception. Al-Shifa Center was established in September 2017 in Al-Shifa Trust Eye Hospital, PIO. Al-Shifa Research Center also prepares an annual research report covering the diverse array of all research activities done by the faculty, students, and trainees of Al-Shifa

Research Center To Clinical Trial Site



Earlier in the year the site was visited by Drug Regulatory Authority of Pakistan (DRAP) and was upgraded to clinical Trial site. This was a recognition of the research potentials at Al-Shifa and permission was granted to run all phases of clinical trial at our site. Later, DRAP recommended this site to a Chinese company Ahnui Longcom Biopharmaceuticals for conducting their phase III clinical Trial of Covid 19 Vaccines.



COVID-19 TRIALS IN PAKISTAN

In February 2021, it began the Phase III human trial of another China-made vaccine, named, ZF2001 amid alarms of the third wave of COVID-19 after successful completion of one-dose Ad5-nCoV vaccine trial, produced by CanSino Biologicals which tested over 18,000 volunteers across the country from September to January, 2021

Al-Shifa Trust and Anhui Longcom Biopharmaceuticals

Al-Shifa Trust Eye Hospital began the ZF2001 trial on 5th April, 2021 after signing an agreement with Chinese company Anhui Longcom Biopharmaceuticals. It was the last clinical trial site in Pakistan to sign the agreement





Zf2001, trade-named ZIFIVAX or ZF-UZ-VAC-2001, is an adjuvanted protein subunit COVID-19 vaccine that has been co-developed by Anhui Zhifei Longcom Biologic Pharmacy Co. Ltd, and the Institute of microbiology of the Chinese Academy of Sciences.

Anhui Biopharmaceutical, a company with its presence in biological product industry since 2002, officially presented its proposal to the Pakistani Embassy in Beijing asking for third phase trial to join healthy competition among foreign firms which won emergency use authentication in Pakistan.

The vaccine candidate had been in Phase III trials with 29,000 participants internationally in China, Ecuador, Malaysia, Pakistan, and Uzbekistan. As per official target, around 10,000 volunteers had to be recruited as trial participants in Pakistan receiving three shots of ZF2001 in 10 dedicated centers including University of Health Science (UHS), PIMS National Defense Hospital, Center Park Hospital, Avicenna Hospital, Aziz Fatima Hospital, Indus Hospital and Al-Shifa Trust Eye Hospital Rawalpindi



OUR VISION

To be the center of excellence for conducting world class and creative bio medical research activities to enhance the knowledge base and contribute towards improving the health care system and social advancement for the people of Pakistan.



OUR MISSION

To emphasize rigorous research fundamentals while stimulating innovation and providing the highest quality research facilities in

AIMS & OBJECTIVE

- Work in coordination with head of departments to identify areas of research.
- Provide operational support to the institutions research activities/program and to play a central role in facilitating the research outcome.
- Enhance the capacity building of the trainees and students in academic research.
- Facilitating the faculty /postgraduate Students to apply for research grants to HEC and other donor agencies.
- Find and explore the collaborations with national and international organizations.
- Establish and implement appropriate procedures and guidelines for monitoring research progress.



1st TARGET

Al-Shifa site was the first out of eight clinical trial sites to achieve its target for COVID-19 vaccine ZF2001. The First agreement was the completion of first dose vaccination of 1000 volunteers in three months. The target for screening and enrolment of volunteers was met in minimal time while strictly adhering to all the international protocols and standards of the Clinical Trial. Quality of the trial was being supervised by the sponsor supervisor and Clinical Research Organization (CRO) DRK Pharma Solutions.





2nd TARGET

After meeting the first target of vaccinating 1000 volunteers for the trial in a record time with quality and proficiency Chinese Company Anhui requested Al-Shifa to enter another agreement for the enrolment of further 1000 volunteers for the trial. This agreement was settled after having an inhouse consensus and negotiations with the sponsor. This target was achieved in yet another record-breaking time frames. This created an inspiration for the other sites and their representatives came and visited our site to see the functioning for us site to replicate the model at their sites for achieving the targets. Our site was thoroughly appreciated for the speed and quality by the Chinese Country Head and their Head Office in China

3rd TARGET

After hitting the 2nd target of enrolling 1000 subjects, the Chinese required us to enter into another agreement with them for further enrollment of 700 subjects. This was again negotiated with the Chinese Company and after reaching an inhouse consensus the agreement was made with the sponsors. This was the most challenging target since we had to capture 250 elderlies because the Chinese could not get elderly from other sites and our site was the one which was getting on an average of 10 elderlies daily. But again, we channelized our energies and started targeting elderlies from the nursing homes and from our acquaintances. It was a surprise to everyone when even elderlies were also captured in a month's time period while the rest of the sites were still struggling with their first targets, we met all our three targets.





TRIAL AUDIT

Based on the excellent quality of clinical trial conducted at our site, Al-Shifa was nominated for a third-party audit and audit by the Drug Regulatory Authority of Chinese government. All three audits were carried out at Al-Shifa trial site data both and appreciated, while trial report writing is being carried out for submission to World Health Organization (WHO).

SUBJECT REVIEWS



“

M. NAWAZ

The Doctors were very helpful throughout the trial at every visit, always willing to answer my questions and resolve my queries

”

“

FARAH NAZ

I would like to appreciate the management of this trial How they managed such large a number of subjects so successfully giving each subject time and attention and solving queries

”

“

ASTER

My experience with this trial was very satisfying I had no major side effects from the vaccine. I recommend everyone to get vaccinated and be a responsible citizen

”

“

SIDRA ABBAS

I liked the fact that all the staff was so welcoming and how I was properly examined by the doctors before receiving the vaccination and I was observed post vaccination and explained when I would have to visit again

”

“

WILLIAM JOSEPH

I got into an accident during the trial, the doctors stayed in touch with my surgeon and followed up with my case until I was discharged

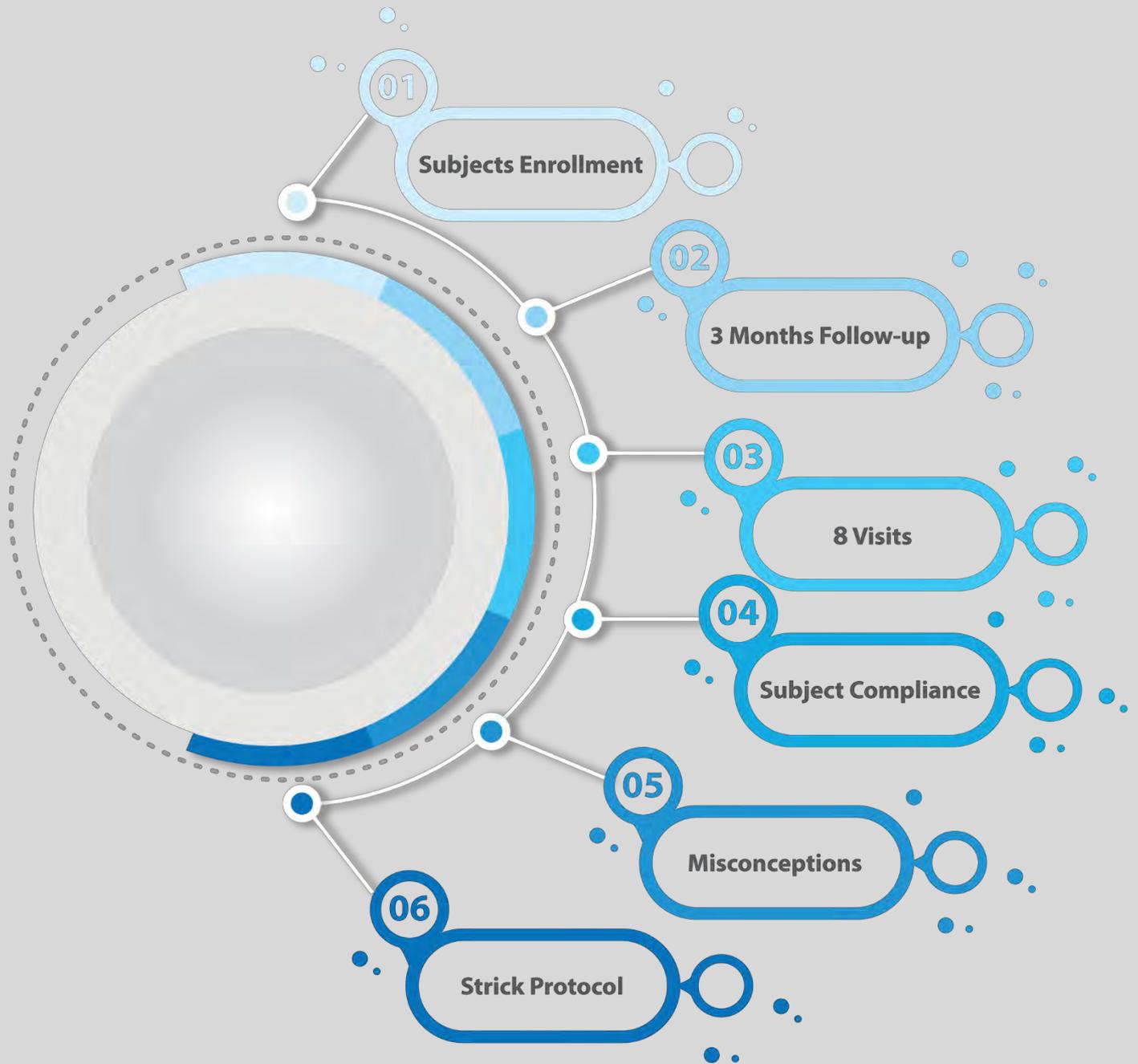
”

“

M. AKRAM

I was impressed by the follow-up calls that I used to get post vaccination and how the doctors were just a call away and I could easily ask and clear my doubts if I had any

”



CHALLENGES

STRATEGIES

Active Community awareness

01

Personally, visiting the communities

02

Subjects were thoroughly facilitated by Al-Shifa by Provision of conveyance & hospitality

03

Highly motivated and dedicated Team work

04

Site used to be open from morning 7:00 AM till evening 7:00 PM to facilitate the subjects

05

Site was even open during lockdown days and National holidays

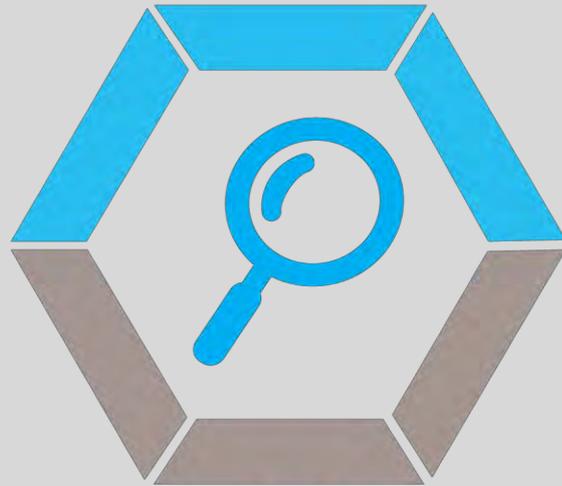
06

ACHIEVEMENTS

2700
Highest Number of
Subjects vaccinated



3840
Total Number of
Subjects Screened



477
Highest Number of
Elderly vaccinated



98%
Highest Subjects
Follow-up Rate



THE TEAM



Dr. Ume Sughra
Principal Investigator



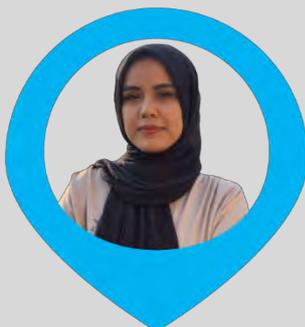
Dr. Marriam Suleman
Trial Manager
Co-Principal Investigator



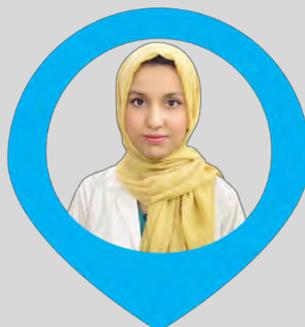
Dr. Asmaa Riaz
Trial Manager
Co-Principal Investigator



Dr. Rasikh Arif
Co-Principal Investigator



Dr. Fatima Farahi
Research Officer



Dr. Amna Shahid
Research Officer



Dr. Ali Zeb Khan
Research Officer



Ahsan Abid
Data Operator



Sidra Nawaz
Data Operator



Tayyaba Azim
Data Operator



Shazia Perveen
Staff Nurse



Rukhsana Saddique
Staff Nurse



Saira Kausar
Staff Nurse



Shazia Farooq
Staff Nurse



Saqib Minhas
Lab. Assistant



Zia Mehmood
Lab. Assistant



Saira Batool
Supporting Staff



Atiqa
Supporting Staff



M. Naseem
Supporting Staff



Umer Masood
Supporting Staff



Maryam Fatima
Supporting Staff



Nimra Anis
Supporting Staff

OVERVIEW OF THE TRIAL

Objective of the Trial

The Vaccine was to be given to thousands of people to check its efficacy and safety. The trial done to determine if the vaccine protects against the coronavirus. It had been proven to be safe in Phase I and Phase II



Total Visits for the trial:

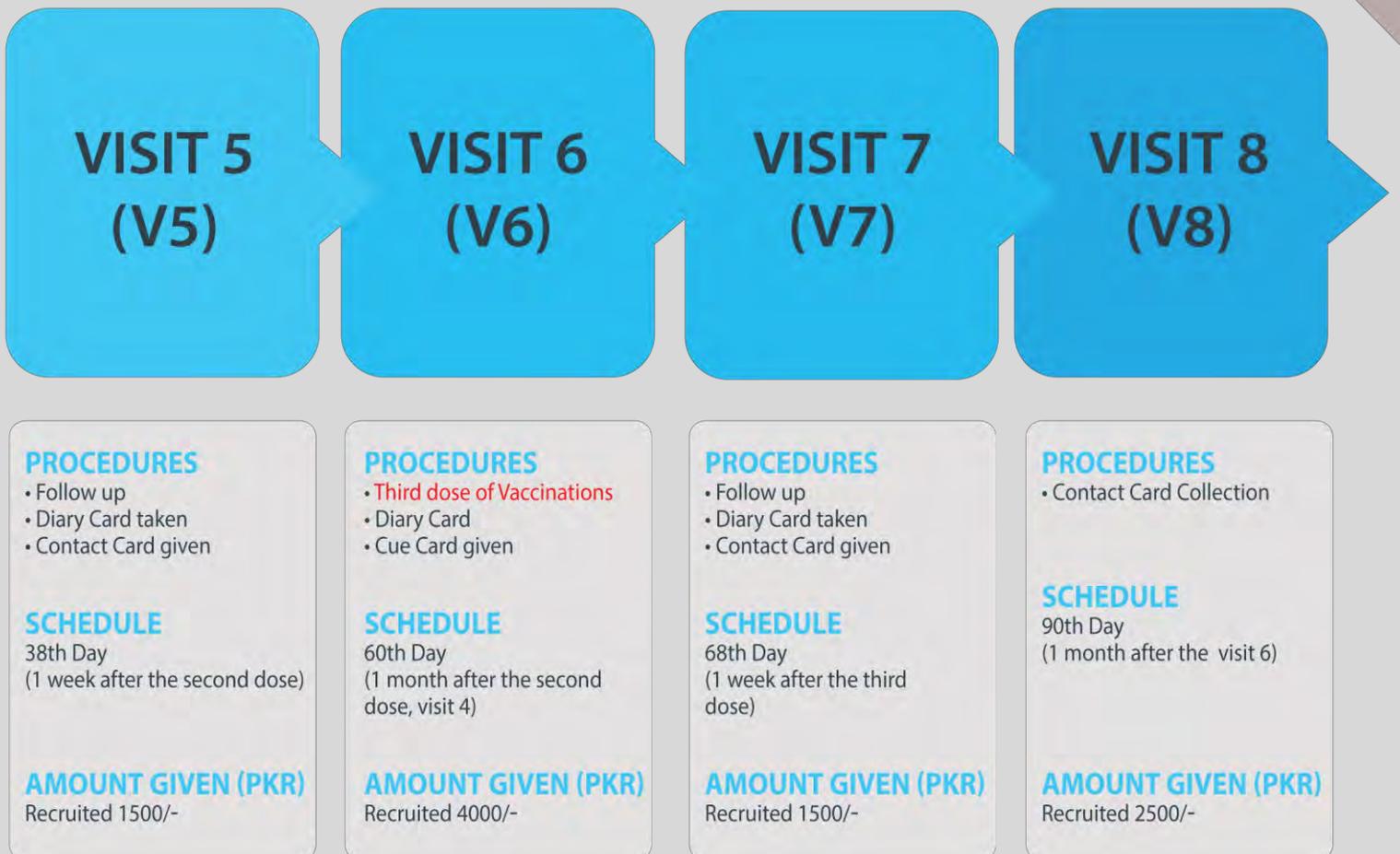
8 Visits

Total Amount Given to each Volunteer:

16000/-PKR

Total Duration:

3 Months (90 Days)





**Al-Shifa Research Center,
Al-Shifa Trust Eye Hospital,
Rawalpindi**

www.alshifaeye.org