Al-Shifa Clinical Trials Report

Prepared By:
Al-Shifa Research Centre - ASRC
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Al-Shifa Trust was founded in 1985. It is a charitable, non-governmental, and non-political organisation. The trust's ex-officio Patron-In-Chief is the President of Pakistan. The trustee board is made up of former service members as well as businesspeople, government officials, and professions. The trust's aims and objectives include preventing and controlling blindness by providing high-quality, affordable, accessible, and sustainable eye care services, developing human resources by training physicians, nurses, and paramedics, raising awareness of eye diseases among the general public through outdoor activities, and establishing facilities for ophthalmology research.
Research has been an integral part of Al-Shifa’s mandate since its inception. Al-Shifa Research Centre was established in September 2017 at Al-Shifa Trust Eye Hospital. Al-Shifa Research Centre also prepares an annual research report and clinical trials report covering the diverse array of all research activities done by the faculty, students, and trainees of Al-Shifa.
Our Vision

To be the centre 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 the institution.
Aims & Objectives

1. To establish research collaborations with national and international organizations.

2. To carry out world class clinical research (Phase I-IV clinical trials) with drug and vaccine manufacturers.

3. To enhance the capacity building of trainees and students in academic research.

4. To facilitate the faculty/postgraduate students to apply for research grants to the donor agencies.

5. To work in coordination with head of the departments of the institute to identify areas of research.
Approved as Clinical Trial Site by DRAP

Issue Date: 16th February 2021

Upgraded to Generalized Clinical Trial Site

Issue Date: 3rd March 2023
CLINICAL TRIALS AT ASRC
1. STUDY TITLE:
A Phase III Randomized, Double-blind, Placebo-controlled Clinical Trial in 18 Years of Age and Above to Determine the Safety and Efficacy of ZF2001, a Recombinant Novel Coronavirus Vaccine (CHO cell) for Prevention of COVID-19.

SPONSOR
Anhui Zhifei Longcom Biopharmaceutical Co., Ltd China

Principal Investigator:
Prof. Dr. Ume Sughra

STATUS
Closed Out
2. STUDY TITLE:

A Phase III, Randomized, Observer-blind, Multicenter Study to Evaluate the Efficacy, Immunogenicity and Safety of Seqirus’ Cell-Based Quadrivalent Subunit Influenza Virus Vaccine (QIVc) Compared to a Non-Influenza Vaccine when Administered in Healthy Subjects aged 6 Months through 47 Months.
Highest number of subjects vaccinated

188
Dear V130_14 Investigators and Study Team,

We have enrolled 468 subjects as of today. We should like to highlight our top enrolling sites last week:

Dr Sughra 58601, Al Shifa Research Centre
Dr Zareen 58605, Avicenna
Dr Grigore 64202, Spitalul Municipal Caracal

Thank you very much for getting us closer to our enrollment goal of 1000 subjects by 16th of December 2022! In the interest of our subjects’ safety, we encourage you to schedule the randomization visits as early as possible to get ahead of questions regarding enrollment, do reach out to your assigned IQVIA CRA.

The target enrollment breakdown per site can be found below for your convenience.
3. STUDY TITLE:
A Randomized, Double-masked, Parallel-group, Multicenter Clinical Study to Evaluate the Efficacy and Safety of AVT06 Compared with EU-Eylea® in Subjects with Neovascular (wet) Age-related Macular Degeneration (ALVOEYE).
INTRODUCTION

Dear ALVOEYE Study Team!

Please find in this newsletter the update of patient recruitment and study status, but also important points about the critical analysis on primary endpoint. Please do not hesitate to discuss with your CRA related issues and we will do our best to find a suitable solution.

Thank you for your contributions to the ALVOEYE Study

MESSAGE FROM GLOBAL STUDY TEAM

We are very pleased to inform you on our achievements for as of 31-Jul-2023!

- 338 subjects have been enrolled & dosed (46.9% with light index)
- 20 subjects are enrolled on the PK sub study
- 5 DISMIs have been conducted, last meeting occurred on 27-Jun-23, and recommendation was “study may continue without modifications”.

Thank you very much for all your contributions to make this happening!

Enrolment: Although we have seen a slow-down in screening in the last couple of months the SF rate has improved significantly. Thank you for your efforts with the pre-screening). Enrolment on the PK sub-study is also behind expected. We appreciate an extra last effort during Aug and beg September to achieve the enrolment goals!

Study recruitment Status

- 748 subjects screened (987 expected in total)
- 341 subjects randomized (444 expected in total)
- 20 subjects in PK sub-study (40 expected)
- 332 subjects evaluable (398 expected in total)

To achieve the enrolment target, we expect to randomize approximately 103 additional subjects.
RECRUITMENT STATUS

As of 31-Mar-2023, 427 patients have been screened and 175 patients have been randomized & dosed. Among them, only 16 subjects are participating to the PK sub-study.

Congratulations to Lithuania, Latvia and Pakistan, best countries with the higher recruitment rate above 0.9 subject/site/month.

Best recruiter sites with respectively 46 or 20 subjects screened and 15 or 14 subjects randomized, Dr Ume Sughra (Rawalpindi-Pakistan) and Dr Kristine Bauman (Riga-Latvia) and Dr Kaspars Ozols (Ventspils-Latvia).
4. STUDY TITLE:
A Multi-center, Randomized, Blinded, Placebo-controlled, Phase 3 Clinical Study to Evaluate the Efficacy, Safety And Immunogenicity of Sars-cov-2 Bivalent mRNA Vaccine (LVRNA021) as Booster In Participants aged 18 Years and Older Who Completed Primary/1 Booster Dose(s) Of SARS-Cov-2 Vaccination.

SPONSOR
AIM Vaccine Co., Ltd.
Ningbo Rongan Biological Pharmaceutical Co., Ltd.
LiveRNA Therapeutics Inc.

Principal Investigator:
Prof. Dr. Ume Sughra

Status
Ongoing
5. STUDY TITLE:
A Phase 3, randomized, double-blind, placebo-controlled study to evaluate the effect of Bi-26 (strain of Bifidobacterium longum, B. infantis) supplementation versus placebo on weight gain in underweight Infants.
1st Subject randomized globally at ASRC, Prof. Dr. Ume Sughra (Country PI)

CONSTITUTION Study: First Participant Randomized

Janie Parrino
dr.sughra@yahoo.com, +7

6:27 PM

Dear Dr. Sughra,

On behalf of the CONSTITUTION study team, I want to thank you and the staff at your site for all your efforts and congratulate you on randomizing the first participant into the study!

We sincerely appreciate your time, energy, and commitment and look forward to continued collaboration.

All my best,

Janie Parrino, MD
Clinical Development Leader

BILL & MELINDA GATES MEDICAL RESEARCH INSTITUTE
6. STUDY TITLE:
A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Bemnifosbuvir in High-Risk Outpatients with COVID-19

SPONSOR
Atea Pharmaceuticals, Inc.

Principal Investigator:
Prof. Dr. Ume Sughra

STATUS
Ongoing
Dear Dr. Sughra and team,

On behalf of the Sunrise-3 Study team, a sincere congratulations on enrolling your first subject in the AT-03A-017 COVID-19 trial! We greatly appreciate your entire study team’s dedication and efforts to this trial. We look forward to celebrating continued achievements with your site.

If you have any questions or require support, please do not hesitate to reach out to your CRA.

Kind Regards,
The AT-03A-017 Study Team
7. STUDY TITLE:
A phase III, Randomized, Comparator-Controlled, Double-Blind, Multicenter Study to Evaluate the Immunogenicity, Safety and Lot to Lot Consistency of Three Lots of a PIKA Rabies Vaccine (Vero cell) for human use, freeze-dried in Healthy Adults using a Post Exposure Prophylaxis schedule

SPONSOR
Yisheng Biopharma (Singapore) Pte, Ltd

Country Principal Investigator:
Prof. Dr. Ume Sughra
FACILITIES

STATE-OF-THE-ART INFRASTRUCTURE

4 CLINICAL TRIAL SITES

HOSPITABLE ENVIRONMENT

CLINICAL PHARMACY

MEDICAL CHECKUPS

PATIENT CARE

LAB TESTS

EXPERT CLINICIANS

DEDICATED STAFF

NETWORK FACILITIES

ETHICS REVIEW COMMITTEE

TELEHEALTH

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FACILITIES

HOME HEALTH AIDES

BIOLOGICAL SAMPLE STORAGE & MANAGEMENT

FAST AND PRECISE SERVICES

HEALTH CARE REPORT

IT FACILITY

EMERGENCY SERVICES

DRUG STORAGE

DATA MANAGEMENT

POWER BACKUPS

HOUSE CALLS

PROPER WASTE MANAGEMENT
THE CORE TEAM, ASRC

Prof. Dr. Ume Sughra
Director Research

Dr. Marriam Suleman
Senior Research Officer

Dr. Asmaa Riaz
Senior Research Officer
Dr. Aqsa Chaudhary
Research Officer

Dr. Amna Shahid
Research Officer

Dr. Rasikh Arif
Research Officer

Dr. Ali Zeb Khan
Research Officer

Dr. Khizraan Naseer
Research Officer

Dr. Hamza Rabbani
Research Officer

Dr. Azalfa Malik
Research Officer

Dr. Naseem
Pharmacist

Dr. Aqsa Chaudhary
Research Officer

Dr. Urooj Arshad
Research Officer

Dr. Mahnoor
Research Officer

Dr. Momina Saeed
Research Officer

Dr. Khizar Abbas
Research Officer

Dr. Talia Mukhtar
Research Officer