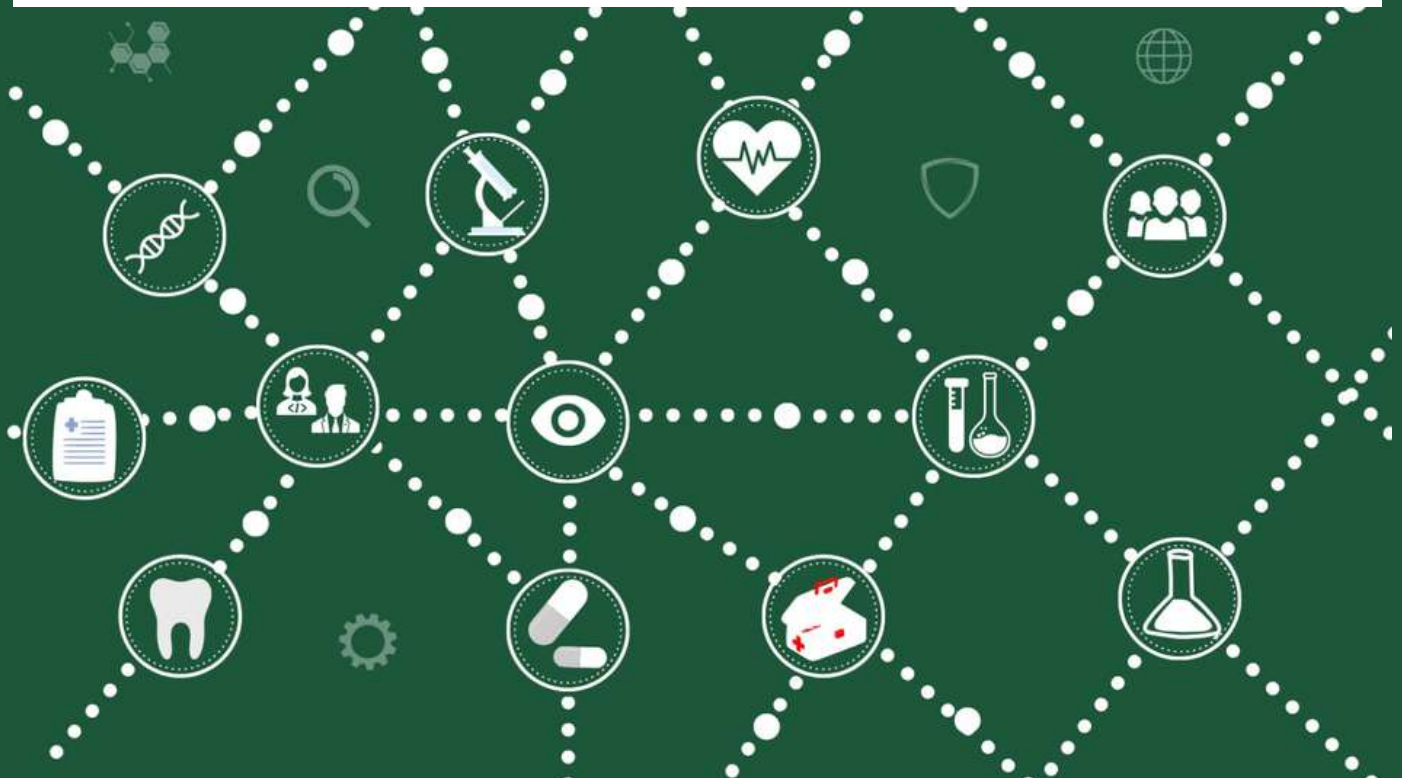
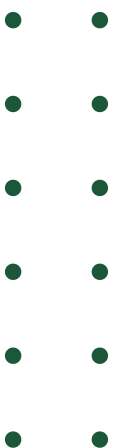


Al-Shifa Clinical Trials Report



Prepared By:

Al-Shifa Research Centre - **ASRC**





AL-SHIFA TRUST EYE HOSPITAL



**LT-GEN (RETD)
JAHANDAD KHAN**
Founder President



**MAJ-GEN (RETD)
REHMAT KHAN**
Current President

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About Us

Al-Shifa History

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.

Al-Shifa Research Centre

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

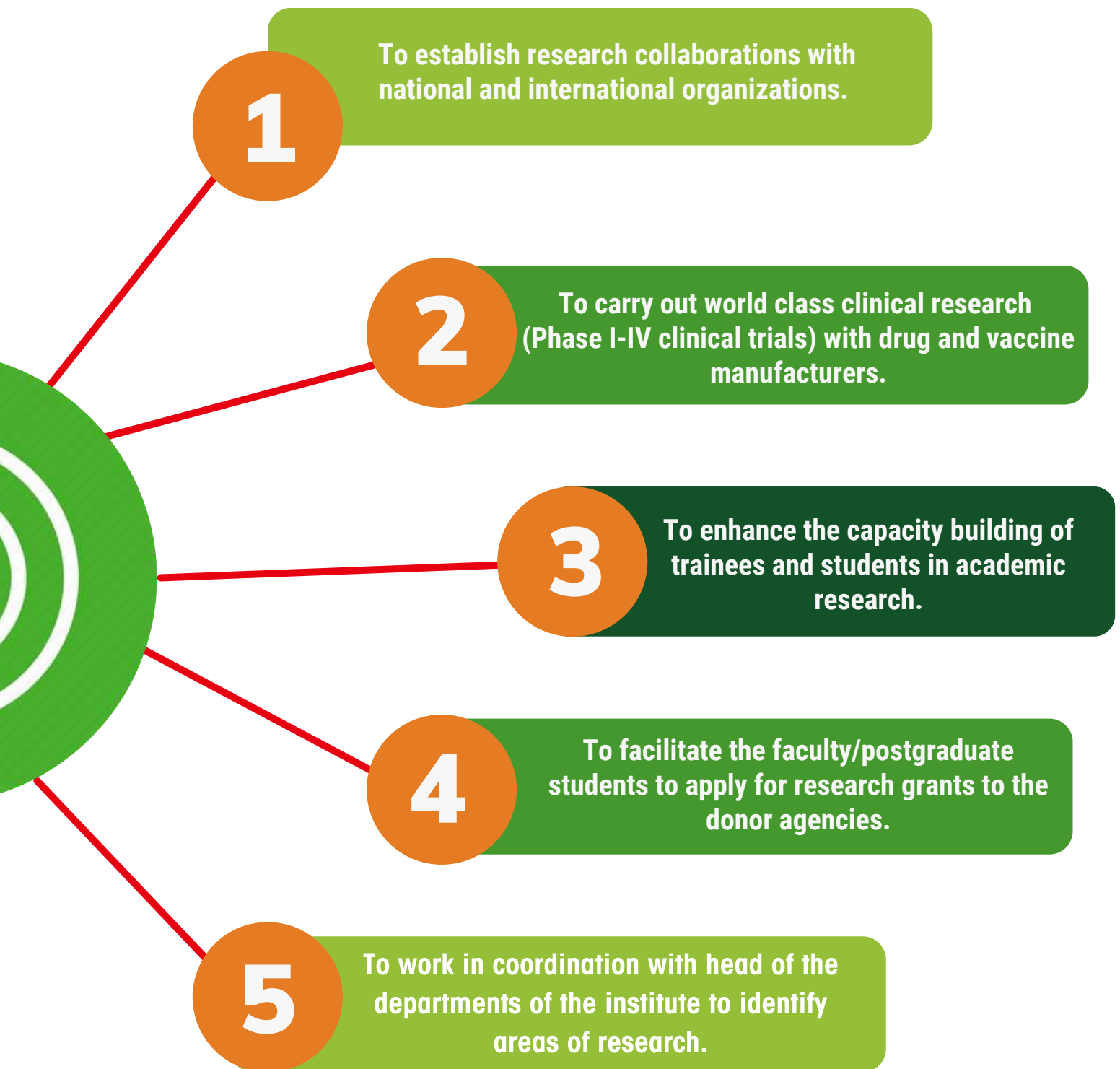
To be the centre of excellence for conducting world-class and creative bio-medical research activities to enhance the knowledge base and contribute towards improving the health care system and social advancement for the people of Pakistan.

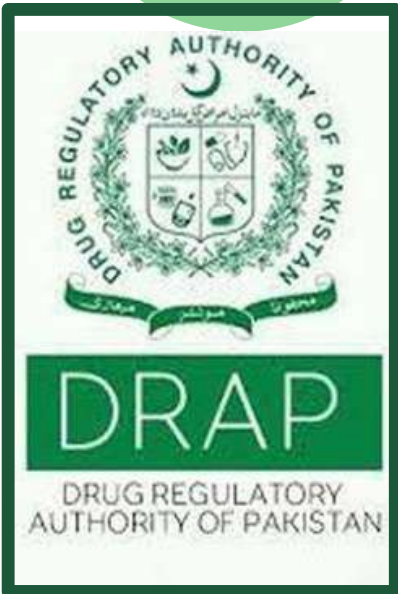
Our Mission

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



Aims & Objectives







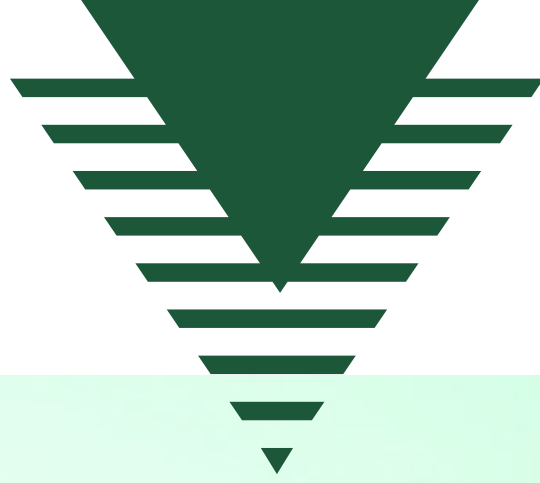
Approved as Clinical Trial Site by DRAP

Issue Date: 16th February 2021



Upgraded to Generalized Clinical Trial Site

Issue Date: 3rd March 2023



CLINICAL TRIALS AT ASRC



1



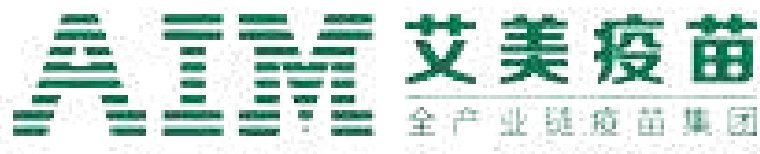
2



3



4



5

BILL & MELINDA
GATES *foundation*

6



7





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 Administrated in Healthy Subjects aged 6 Months through 47 Months.



SPONSOR
Seqirus Inc./Seqirus
UK Limited

Principal Investigator
Prof. Dr. Ume Sughra



INITIATION
16th November 2022



STATUS
Ongoing



TRIAL ACHIEVEMENTS

“
188
”

“
**Highest number of
subjects vaccinated**
”

TRIAL ACHIEVEMENTS

CSL

V130_14 Weekly updates for NH2022/23 Investigators and Study Team-week 7-

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:



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

Country/Site #	PI Name	Enrolment vs. Target	Target enrolment	Actual enrolled
Pakistan			398	125
58601	Dr Sughra	100%	80	80
58602	Dr Khan	5%	60	3
58604	Dr Fatima	5%	100	5
58605	Dr Zareen	25%	100	25
58607	Dr Zaman	21%	58	12



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).



SPONSOR
Alvotech Swiss AG
Principal Investigator:
Prof. Dr. Ume Sughra



INITIATION
30th December 2022



STATUS
Ongoing



TRIAL ACHIEVEMENTS



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

CONTENTS

Introduction	1
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Recruitment status	2
Efficacy analysis	3

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 irides)
- 20 subjects are enrolled on the PK sub study
- 5 DSMBs 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.

TRIAL ACHIEVEMENTS

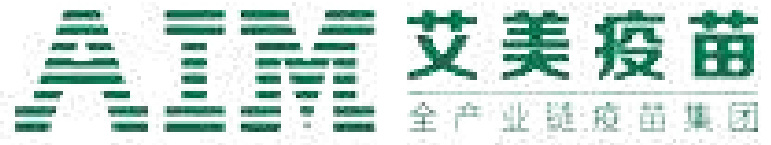


RECRUITMENT STATUS

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.

Congratulation 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) **Dr Kristine Baumane** (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.



SPONSOR

Bill & Melinda Gates Medical
Research Institute

Country Principal Investigator:

Prof. Dr. Ume Sughra

STATUS

Ongoing



TRIAL ACHIEVEMENTS

1st Subject randomized globally at ASRC, Prof. Dr. Ume Sughra (Country PI)

CONSTELLATION Study: First Participant Randomized



Janie Parrino
dr_sughra@yahoo.com, + 7

6:27 PM



Dear Dr. Sughra,

On behalf of the CONSTELLATION 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

Janie Parrino, MD

Clinical Development Leader

**BILL & MELINDA GATES
MEDICAL RESEARCH
INSTITUTE**



 **Bill & Melinda Gates Medical Research Institute**
49,536 followers
3w • 

Infant malnutrition is a significant public health challenge that disproportionately impacts low- and middle-income countries. This article in [Contagion Live](#) highlights our Phase 3 clinical trial, the CONSTELLATION study, to evaluate the effect of B. infantis as a dietary supplement in underweight infants. The study enrolled its first patient in Pakistan this month. Learn more about our efforts to help address the significant burden of disease experienced by underweight infants: <https://lnkd.in/ebDdxW5e>





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



TRIAL ACHIEVEMENTS

1st Subject enrolled at ASRC among 5 sites of Pakistan, Prof. Dr. Ume Sughra (PI)

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**

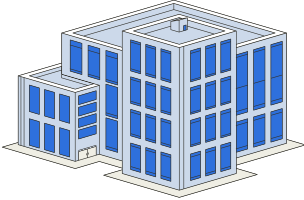
Country Principal Investigator:

Prof. Dr. Ume Sughra

Initiated



FACILITIES



STATE-OF-THE-ART
INFRASTRUCTURE



4 CLINICAL
TRIAL SITES



HOSPITABLE
ENVIRONMENT



CLINICAL
PHARMACY



MEDICAL
CHECKUPS



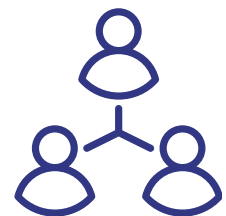
PATIENT CARE



LAB TESTS



EXPERT
CLINICIANS



DEDICATED
STAFF



NETWORK
FACILITIES



ETHICS REVIEW
COMMITTEE



TELEHEALTH

FACILITIES



HOME HEALTH AIDES



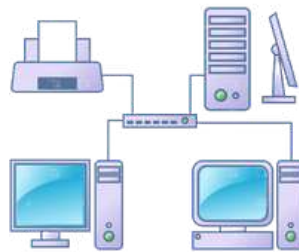
HEALTH CARE REPORT



DRUG STORAGE



BIOLOGICAL SAMPLE STORAGE & MANAGEMENT



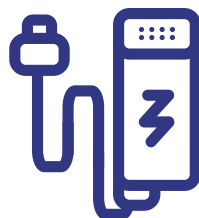
IT FACILITY



DATA MANAGEMENT



DATA STORAGE



POWER BACKUPS



HOUSE CALLS



FAST AND PRECISE SERVICES



EMERGENCY SERVICES



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

Team



Dr. Fatima Farahi
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



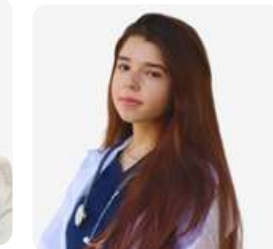
Dr. Naseem
Pharmacist



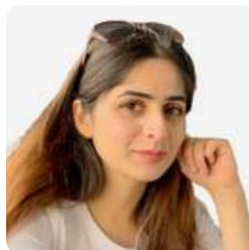
Dr. Aqsa Chaudhary
Research Officer



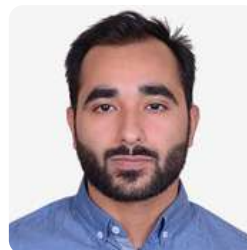
Dr. Urooj Arshad
Research Officer



Dr. Mahnoor
Research Officer



Dr. Momina Saeed
Research Officer



Dr. Khizar Abbas
Research Officer



Dr. Talia Mukhtar
Research Officer

ASRC



Dr. Noor Ul Huda
Research Officer



Dr. Noor Ul Ain
Research Officer



Ali Farahi
Site Coordinator



Saqib Minhas
Lab Technician



Rukhsana Saddique
Study Nurse



Saira Rehman
Accountant



Mazhra Saqib
Data Operator



Aneela Tariq
Data Operator



Sanam Parvez
Data Operator



Rehmat Ullah
Lab Technician



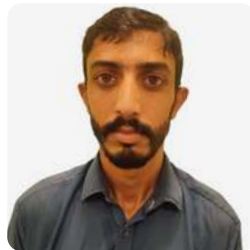
Zubair Hussain
Supporting Staff



Muhammad Jamal
Supporting Staff



Talha Qazi
Supporting Staff



Umer Masood
Supporting Staff



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

www.alshifaeye.org