

AL-SHIFA RESEARCH CENTRE

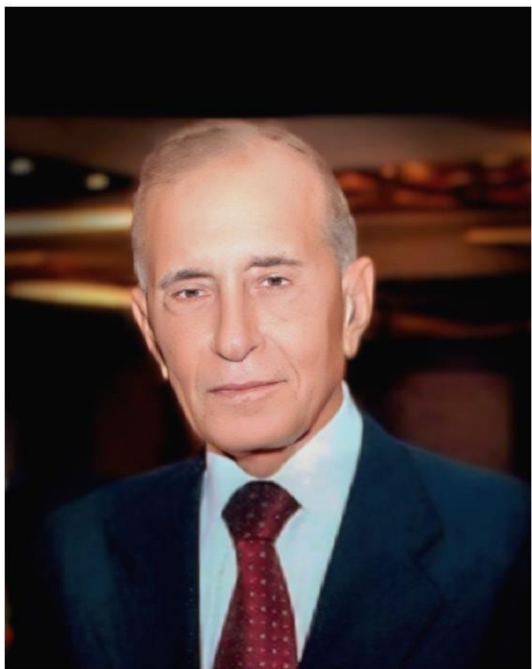


Table of Contents

About Us	05
Al-Shifa Research Centre	06
Clinical Trial Site	08
International Clinical Trials	09
Projects with WHO	18
CTS Services	22
Clinical Research Organization	24
Organogram / CRO Services	25
Collaborators of Al-Shifa Research Centre	26
Certifications of Al-Shifa Research Centre	27
Research Reports	28
Publications	29
The Core Team	30
ASRC Team	31



AL-SHIFA TRUST EYE HOSPITAL



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

Founder President



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

Current President



AL-SHIFA TRUST

Al-Shifa Trust was founded in 1985. It is a charitable, non-governmental, and non-political organization. The ex-officio Patron-in-Chief of the Trust is the President of Pakistan. The Board of Trustees comprises retired armed forces personnel, business leaders, government officials, and professionals from various fields.

The Trust aims to prevent and control blindness by providing high-quality, affordable, accessible, and sustainable eye care services. It is also committed to developing human resources through the training of ophthalmologists, nurses, and paramedical staff, raising public awareness about eye diseases through community outreach activities, and promoting ophthalmic research by establishing and supporting research facilities.

Al-Shifa Trust envisions being recognized as a leading eye care institution providing comprehensive primary, secondary, and tertiary ophthalmic care. It strives to continuously improve the quality of its services while expanding community outreach programs to serve underprivileged populations.

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.



Mission

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



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.

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.

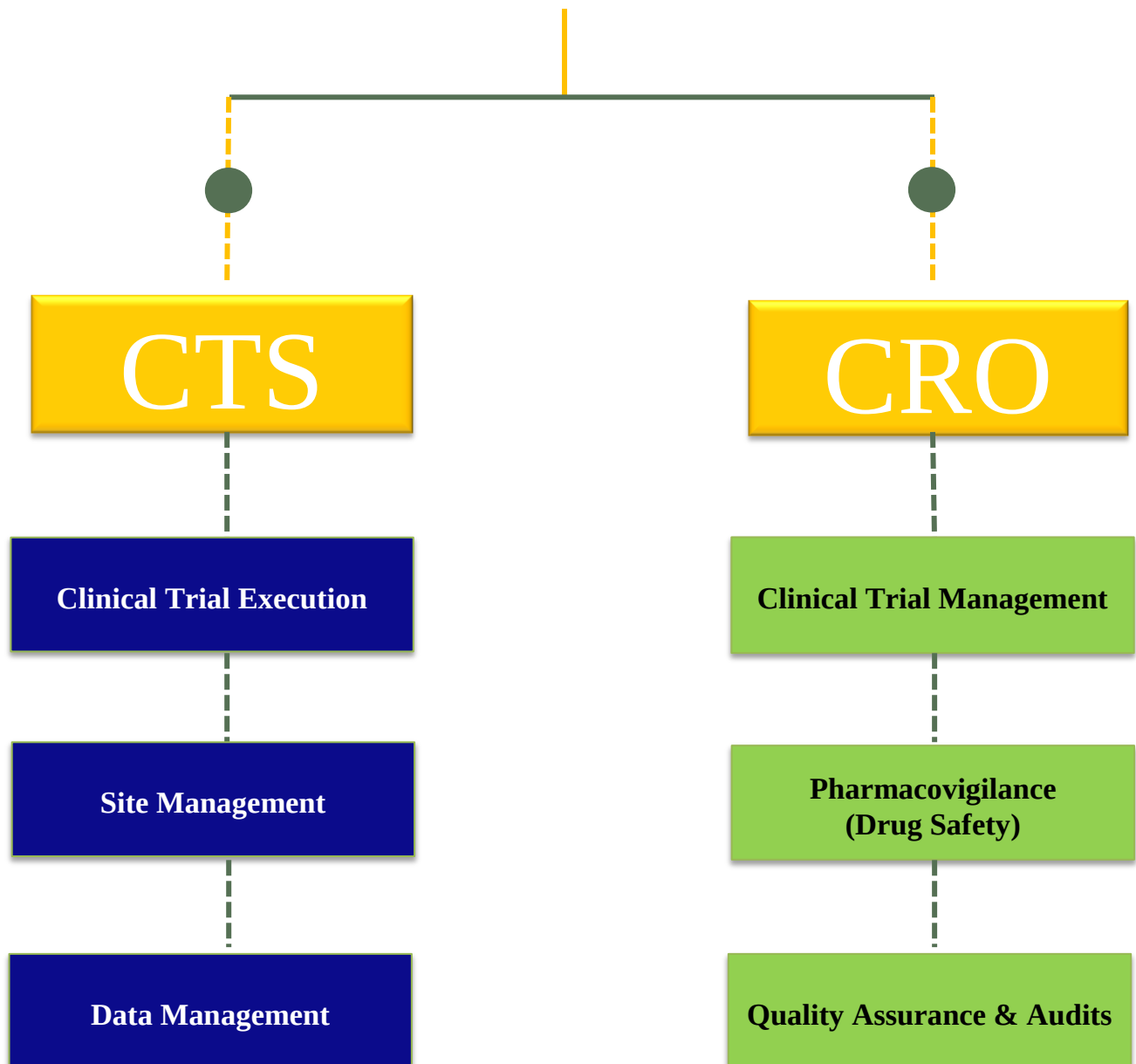
④

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.

AL-SHIFA RESEARCH CENTRE



CLINICAL TRIAL SITE

Approved in 2021

IRB & Regulatory Submission and Documentation

Phase II – IV Clinical Trial Execution

IP Management, Disposal of Samples & IP

Protocol Review

AE & SAE Reporting

Budgeting & Subject Insurance

Government of Pakistan
Ministry of National Health Services
Regulation & Coordination
Drug Regulatory Authority of Pakistan

Serial No. 0000

Form - V License No: CTS-0044

License to act as Clinical Trial Site

M/s Al-Shifa Trust Research Center is hereby licensed to act as Clinical Trial Site, the premises situated at Al-Shifa Trust Eye Hospital, Jhelum Road, Rawalpindi.

2. This license shall be subject to the following and in addition to the conditions as specified under Rule 04:-

- The license shall be valid for the period of three years from the date of issue unless earlier suspended or cancelled.
- The licensee shall maintain the conditions of GCP and GLP.
- Minimum safety standards shall be observed by the licensee.
- License holder shall develop Protocols or SOPs for the conduct of studies or trials and get formal approval from the DRAP.
- License holder shall maintain adequate arrangement for storage of the study material as per protocol of the study.

3. Name of approved expert staff: Brig (R) Rizwan Ullah Asghar.

Date of issue: 16 February 2021.

Secretary (CSC)

Chairman (CSC)

Page 1 of 2

Approved as Clinical Trial Site by DRAP
th
16 February 2021

F.No.16-39/2023-CSC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Pharmacy Services Division

Islamabad, 03rd March, 2023.

✓ Brig (R) Rizwan Ullah Asghar,
Executive Director,
M/s Al-Shifa Trust Eye Hospital,
Jhelum Road,
Rawalpindi.

Subject: APPLICATION FOR APPROVAL OF CLINICAL TRIAL SITE SITUATED AT PAKISTAN INSTITUTE OF OPHTHALMOLOGY, AL-SHIFA TRUST EYE HOSPITAL RAWALPINDI FOR PHASE I, II & IV. F.No.15-17/2022-DD (PS)

Dear Sir,

I am directed to refer your application on the subject cited above. The subject matter was placed before Clinical Studies Committee (CSC) in its 39th meeting held on 28th February, 2023. The CSC after detailed deliberations and discussion decided the case as under:

The CSC in pursuance of the recommendations of the inspection panel & in the light of discussions/deliberations unanimously decided to approve the site of M/s Al-Shifa Trust Eye Hospital, Jhelum Road, Rawalpindi for Phase-I, II and IV Clinical Trials except their PK/PD parts, which would be the responsibility of Sponsor, under the Bio-Study Rules, 2017.

Further, it was decided that, approval to act as Clinical Trial Site for Phase-I, II & IV will be incorporated in previously issued licence (CTS-0044) for Phase-III with same validity as already approved.

(SHAFQAT HUSAIN DANISH)
Assistant Director (PS)
(On behalf of Secretary CSC)

Copy to:
i. F.No.15-17/2022-DD (PS).

For information pp.
Perfected
Good development
Full done
Director Research 10/3/23

SEEN
✓
10/3/23

Upgraded to Generalized Clinical Trial Site
rd
3 March 2023

F.No.16-51/2024-CSC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Pharmacy Services Division

Islamabad, 31st October 2024.

✓ Brig (R) Rizwan Ullah Asghar,
Executive Director, M/s Al-Shifa Research Center,
Al-Shifa Trust Eye Hospital, Jhelum Road,
Rawalpindi.

Subject: APPLICATION FOR RENEWAL OF LICENSE TO ACT AS CTS FOR PHASE I, II AND IV FROM AL-SHIFA TRUST EYE HOSPITAL RAWALPINDI F.No.15-17/2022-CTS.

Please refer to your application dated 19th December 2023 on the subject cited above. Your application was placed before the Clinical Studies Committee (CSC) in its 51st meeting held on 24th October, 2024. The Committee after deliberation decided the case as under:

"The CSC after deliberation and on recommendation of panel of experts, decided to grant the license to act as clinical trial site for Phase II (except their PK/PD parts which will be responsibility of the Sponsor), III & IV clinical trials to "M/s Al-Shifa Research Center, Al-Shifa Trust Eye Hospital, Jhelum Road Rawalpindi."

2. The signed license on "Form-V" will be issued separately.

(MALIK MUHAMMAD ASAD)
Secretary CSC / Deputy Director (CT-Lic.)
Pharmacy Services Division-DRAP.

Copy to:
i. F.No.15-17/2022-CTS
ii. F.No.16-51/2024-CSC.
iii. Master folder.

License Renewed for Clinical Trial Site
st
31 October 2024

INTERNATIONAL CLINICAL TRIALS

List of international clinical trials encompassing both therapeutic and preventive interventions conducted at Al-Shifa Research Centre since 2021.

Area	Indication	Sponsor	Year	Phase	Status	Enrollment Duration	Subjects Screened	Subjects Enrolled
Immunology	COVID-19	Anhuei Zhefei Longcom Pharmaceutical	2021	III	Completed	3 Months	3840	2700
Immunology	Influenza	CSL Seqirus	2022	III	Completed	2 Months	191	188
Ophthalmology	Wet AMD	Alvotech Swiss AG	2022	III	Completed	8 Months	66	24
Immunology	COVID-19 Booster	AIM Vaccine Co., Ltd	2023	III	Completed	15 Days	2356	2000
Immunology	Rabies	Yisheng Biopharma	2023	III	Ongoing	1 Month	1004	889
Pediatrics	Malnutrition	Bill & Melinda Gates Medical Research Institute	2024	III	Completed	4 Months	17	15
Infectious Dis.	COVID-19	Atea Pharmaceuticals, inc.	2024	III	Completed	3 Months	250	5
Immunology	Rabies (Pre Exposure)	Sinovac (Chengdu) Biotech Co., Ltd.	2026	III	Ongoing	10 Days	415	390
Immunology	Rabies (Post Exposure)	Sinovac (Chengdu) Biotech Co., Ltd.	2026	III	Ongoing	10 Days	427	390

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

[Efficacy and Safety of the RBD-Dimer-Based Covid-19 Vaccine ZF2001 in Adults. N Engl J Med. 2022 Jun 2;386\(22\):2097-2111. doi: 10.1056/NEJMoa2202261. Epub 2022 May 4.](#)

Project Achievement



3,840

Subjects Screened

2,700

Highest Number
Enrolled

447

Highest Number
Elderly Enrolled

98%

Highest Follow-up
rate



Study Title: A Phase III, Randomized, Observer-blind, and 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

Project Achievement



188

Highest Number of
Subjects Enrolled

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

Dear V130_14 Investigators and Study Team,

We have enrolled 458 subjects as of today.

We would 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 **18th 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

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

Project Achievement



66

Highest Subjects
Screened

24

Top Recruiting Site
Worldwide

11

Highest PK-Sub study
Subjects



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.

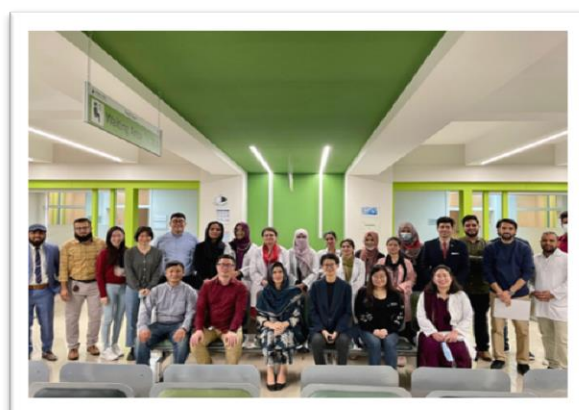
Project Achievement



2,356
Subjects Screened

2,000
Subjects Enrolled

15 Days
Recruitment Duration



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, US

[Impact of Bifidobacterium infantis supplementation on growth, health outcomes, and gut microbiome features in underweight infants from Pakistan. Front. Nutr. 13:1783141. doi: 10.3389/fnut.2026.1783141](#)

Project Achievement

17

Subjects Screened

15

Highest Number
Enrolled

4 Months

Recruitment Duration



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. USA

Project Achievement

250

Subjects Screened

5

Subjects Enrolled

3 Months

Recruitment Duration

Study Title: A phase III, Randomized, Comparator-Controlled, Double-Blind, Multi-center 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.

Project Achievement

1004

Subjects Screened

889

Subjects Enrolled

15 Days

Recruitment Duration

741

Top recruiting Site
Globally for Group 2



Study Title: Immunogenicity and Safety of a Rabies Vaccine (Serum-free Vero cell), Freeze-dried in Comparison with Verorab (R), in a Post-Exposure Prophylaxis Regimen in Healthy Populations Aged ≥ 1 years: A Randomized, Double-Blind, Active-controlled Phase III Clinical Trial

Sponsor: Sinovac (Chengdu) Biotech Co., Ltd

Status: Ongoing

427

Subjects Screened

390

Highest Number
Enrolled

10 Days

Recruitment Duration



Study Title: Immunogenicity and Safety of a Rabies Vaccine (Serum-free Vero cell), Freeze-dried in Comparison with Verorab (R), in a Pre-Exposure Prophylaxis Regimen in Healthy Populations Aged ≥ 1 years: A Randomized, Double-Blind, Active-controlled Phase III Clinical Trial

Sponsor: Sinovac (Chengdu) Biotech Co., Ltd

Status: Ongoing

415

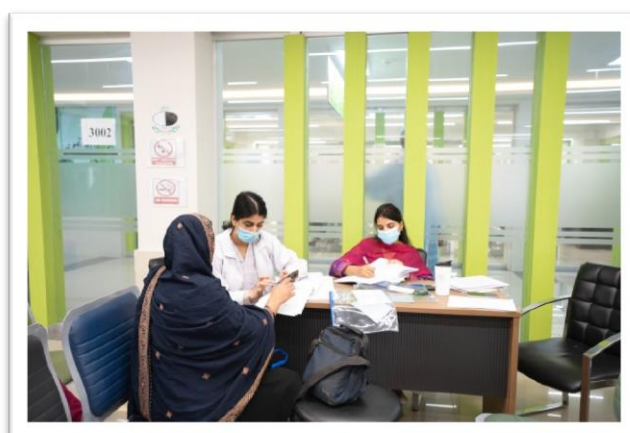
Subjects Screened

390

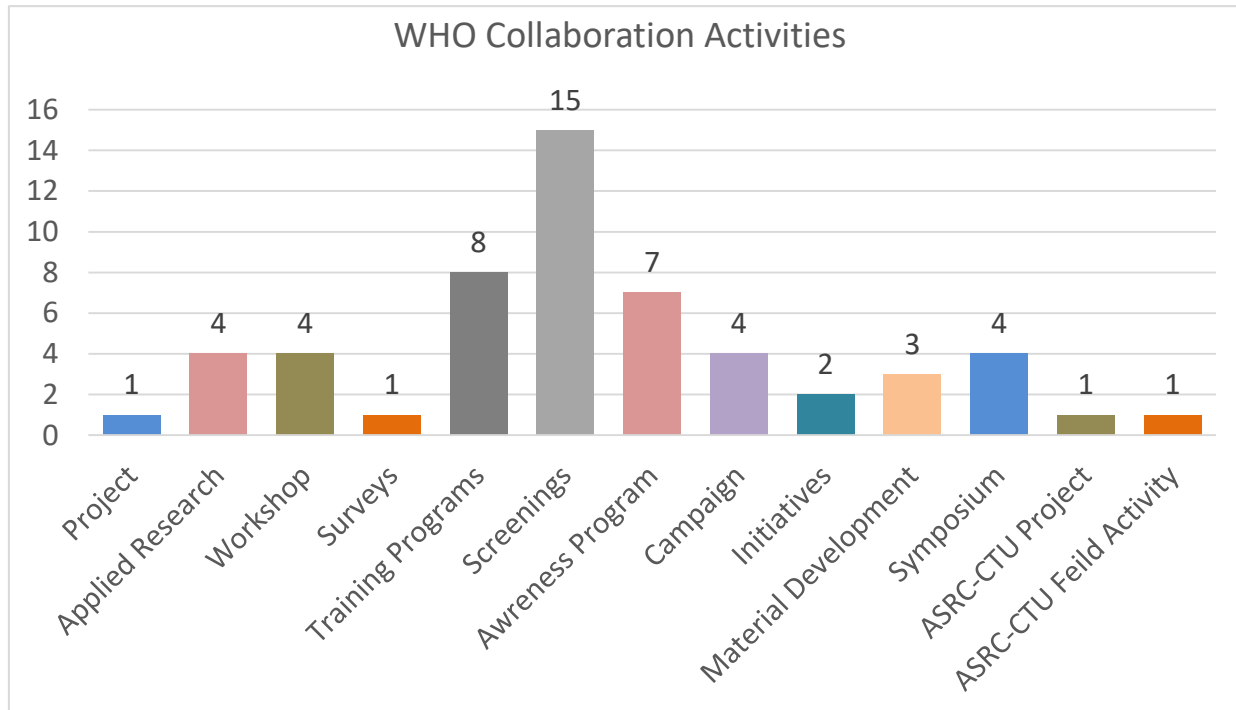
Highest Number
Enrolled

10 Days

Recruitment Duration



PROJECTS WITH WHO



Our institution **Al-Shifa Trust Eye Hospital** was a WHO collaboration centre since 1993 till 2016 for the prevention of blindness and has been actively engaged in a total of approximately 58 activities. **Al-Shifa Research Centre and Clinical Trial Unit** has undertaken six activities with WHO, including one project in 2021 and one field activity in 2022. The Centre also participated in the WHO Expert Consultation on Strengthening National Capacity for the Conduct of Randomized Trials (25–26 June 2024), the Meeting with WHO on Seeking Collaboration as a WHO Collaborating Centre (10 March 2025), and the National Consultation for Dissemination of Pakistan’s Bacterial and Fungal Priority Pathogen List (9–10 and 30 July 2025).

1. A project by WHO to evaluate the preparedness of public health facilities in Islamabad Capital Territory and Rawalpindi, Pakistan. 2020 – 2021.

Evaluating the Hospital Preparedness for Emergencies using WHO Hospital Safety Index Tool. Pak J Med Sci. 2025 Mar;41(3):676-681. doi: 10.12669/pjms.41.3.10875. PMID: 40103868; PMCID: PMC11911768. <https://www.pjms.org.pk/index.php/pjms/article/view/10875>

General Objective:

To develop a national strategy /approach to enhance hospital and Emergency Medical Service (EMS) provider preparedness for CBRN events involving the minimum requirements to meet IHR-CBRN preparedness recommendations in hospitals of Islamabad Capital Territory and Rawalpindi by using WHO Hospital Safety Index evaluation forms.

Specific Objectives:

1. To develop a standard national tool to evaluate hospital preparedness involving Emergency Departments (ED) as well as EMS providers' readiness for CBRN events in Pakistan.
2. To evaluate the preparedness of public health facilities in Islamabad Capital Territory and Rawalpindi, Pakistan, for managing (potential) CBRN events and the challenges in implementation of an organized command system during such an emergency.
3. To identify the gaps and challenges operating at these health facilities that inhibits the mounting of an effective response in such situations.

2. Post Evaluation Campaign field activity for Lot Quality Assessment Sampling (LQAS) as a part of Polio Eradication Program after National Immunization Day (NID). May 2022 – June 2022

156Union Councils
Screened**1560**

Subjects Screened

7 Days

Duration

29

Teams



3. Expert consultation on strengthening national capacity for the conduct of randomized controlled trials and large-scale studies. 25 – 26 June 2024

General Objective:

WHO in jointly with National Human Rights Commission and Drug Regulatory Authority of Pakistan organized an expert consultation to enhance national capacity for Randomized Controlled Trials & Large-Scale studies to share experiences among health experts on robust evaluation of several therapeutics to reduce mortality

4. Meeting with WHO for Seeking Collaboration as a WHO Collaborating Centre CTU. 10th March 2025

General Objective:

A meeting was held with the World Health Organization (WHO) to discuss the establishment of a Collaborating Clinical Trial Centre aimed at strengthening Pakistan's capacity in conducting high-quality, GCP-compliant clinical research.

5. National Consultation for Dissemination of Pakistan's Bacterial and Fungal Priority Pathogen List (PPL). 09-10 July 2025

Director Research (Member of the Expert Advisory Group) attended the physical meeting of WHO on National Consultation on Dissemination of Pakistan's Bacterial and Fungal Priority Pathogen List (PPL)

30 July 2025 Director Research (Member of the Expert Advisory Group) attended the WHO meeting through a virtual session

General Objective:

The objective of the meeting was to present and disseminate Pakistan's National Priority Pathogen List, including the development process for translating the PPL into action, outlining priority interventions, and a way forward.

6. National Consultation for Dissemination of Pakistan's Bacterial and Fungal Priority Pathogen List (PPL). 11-13 November 2025

Director Research (Member of the Expert Advisory Group) attended the physical meeting of WHO on National Consultation on Dissemination of Pakistan's Bacterial and Fungal Priority Pathogen List (PPL)

General Objective:

The objective of the meeting was to present and disseminate Pakistan's National Priority Pathogen List, including the development process for translating the PPL into action, outlining priority interventions, and a way forward

CTS SERVICES



STATE-OF-THE-ART Infrastructure



4 Clinical Trial Sites



Hospitable Environment



Home Health AIDES



Protocols, Reports Writing & Publications



Data Collection & Analysis



Investigational Drug Management



PK Analysis



Clinical Trial Execution



Expert Clinicians



Dedicated Staff



Health Care Report

CTS SERVICES



Lab Tests



Clinical Pharmacy



Patient Care



Data Storage



IT Facility



Data Management



Power Backups



House Calls



Telehealth



Biological Sample
Storage and
Management



Network Facilities



Ethics Review
Committee

CLINICAL RESEARCH ORGANIZATION

Scientific Research Solution established
in 2025

Site selection, monitoring, and
coordination

Preparation and submission of
regulatory documents

Timeline, budgeting and cross-
functional coordination

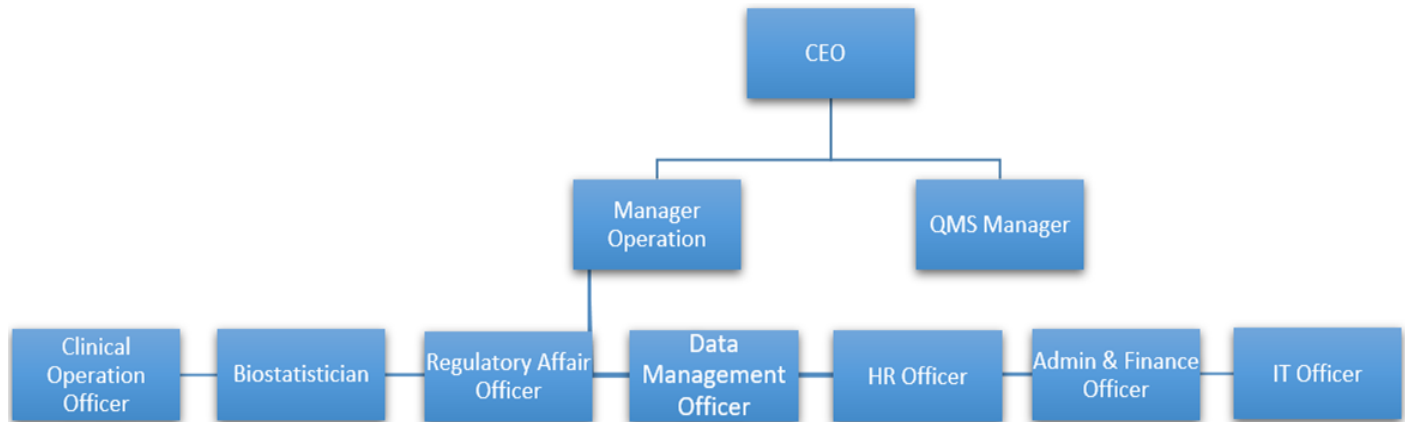
End-to-end management of clinical trials
(Phase I – IV)

License for CRO
07th November 2025

CORE PRINCIPLES

- Scientific integrity in all research activities
- Strict adherence to ICH-GCP, local, and international regulations
- Uncompromising focus on patient safety and rights
- Commitment to high-quality, reproducible, and auditable results
- Transparent, client-focused communication and collaboration

ORGANOGRAM



CRO SERVICES

- **Clinical Trial Management**
 - End-to-end management of clinical trials (Phase I–IV)
 - Site selection, monitoring, and coordination
- **Regulatory Affairs**
 - Preparation and submission of regulatory documents
 - Liaising with regulatory agencies.
- **Data Management & Biostatistics**
 - Database design, validation, and data entry
 - Statistical analysis and reporting
- **Pharmacovigilance (Drug Safety)**
 - Adverse event monitoring and reporting
 - Risk management and safety signal detection
- **Quality Assurance & Audits**
 - GCP (Good Clinical Practice) compliance
 - Internal and external audits, SOP development
- **Project Management**
 - Timelines, budgeting, and cross-functional coordination
 - Communication between sponsors and study sites
- **Site Management & Patient Recruitment**
 - Site feasibility, investigator training
 - Recruitment strategy and retention planning

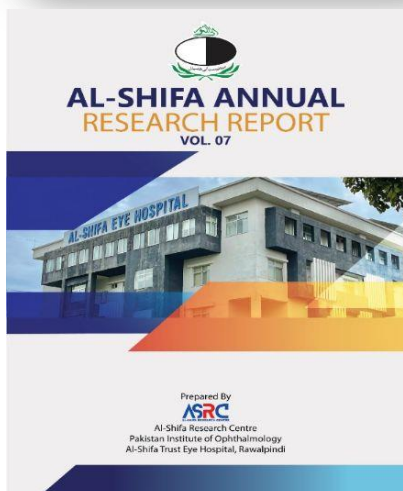
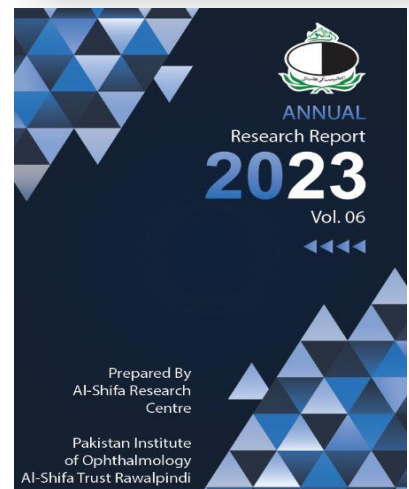
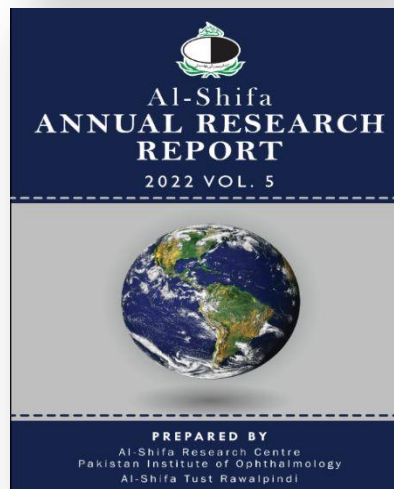
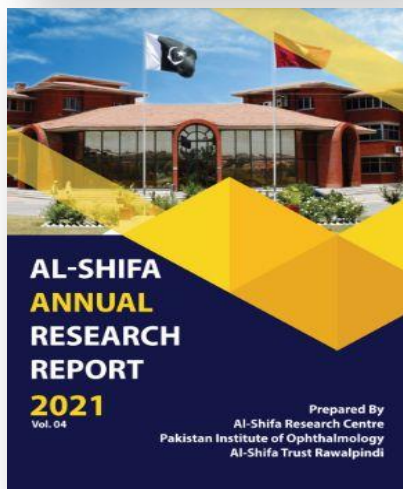
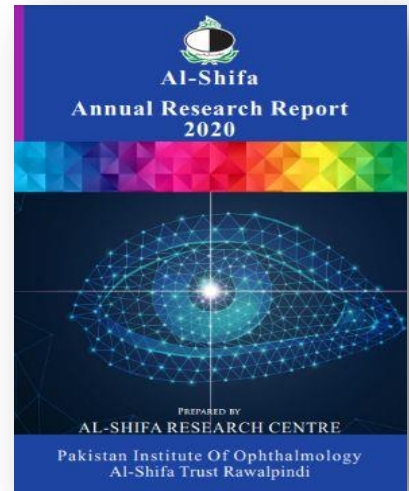
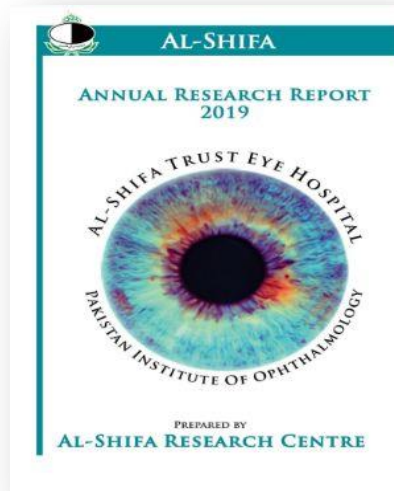
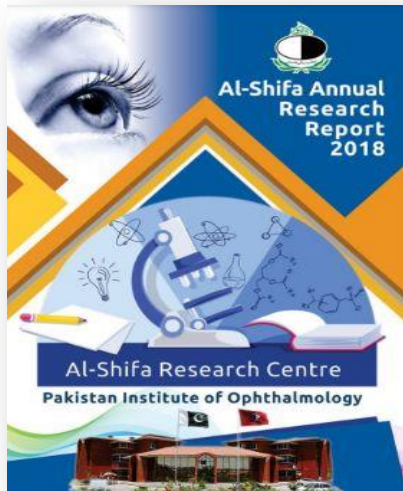
COLLABORATORS OF AL-SHIFA RESEARCH CENTRE



CERTIFICATIONS OF AL-SHIFA RESEARCH CENTRE

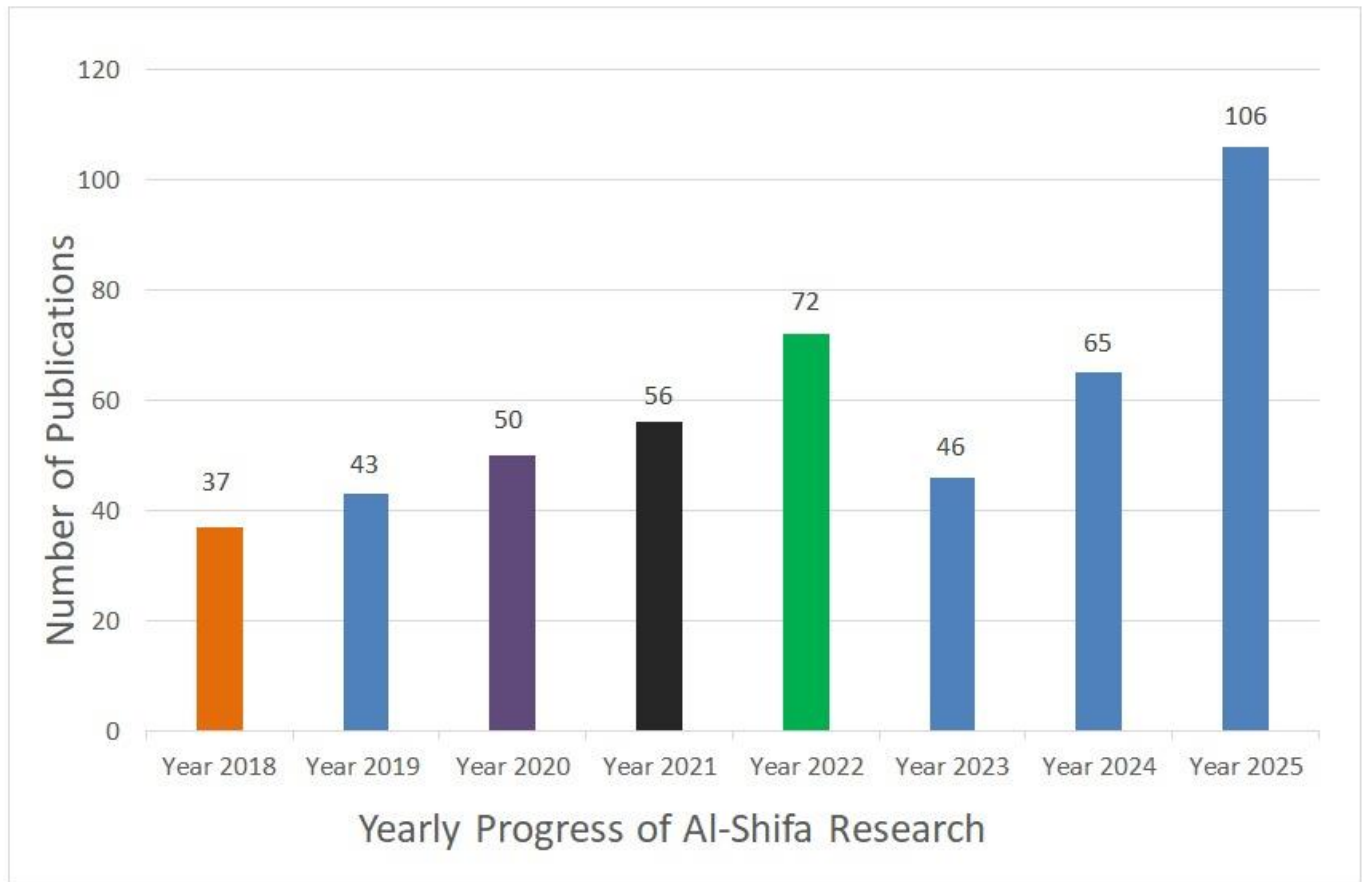


RESEARCH REPORTS



PUBLICATIONS

2018-2025



THE CORE TEAM



Prof. Dr. Ume Sughra
Director Research



Dr. Marriam Suleman
Senior Research Officer



Dr. Asmaa Riaz
Senior Research Officer

ASRC TEAM



Dr. Tahir Syam
Research Officer



Dr. Sabahat Tahir
Research Officer



Dr. Rishail Muzaffar
Research Officer



Dr. Ramsha Gondal
Research Officer



Dr. Chand
Research Officer



Dr. Shizrah Ashraf
Research Officer



Dr. Kainat Waqar
Research Officer



Dr. Naseem
Pharmacist



Dr. Nauman Ali Shah
Pharmacist



Aneela Tariq
Data Operator



Rukhsana Siddique
Staff Nurse



Saqib Minhas
Lab Technologists



Abdullah
Lab Technologists



Farooq Tahir
AM Finance



Waqas ul Hassan
AM Finance



Muhammad Jamal
Supporting Staff



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

www.alshifaeye.org/al-shifa-research-centre