
# Clinical Trial Unit

## Central Park Teaching Hospital

A Project of Health & Education Foundation

**Participant Safety at Core**

**Advancing Medical Innovation**

**Committed to Global Standards**

# Central Park Teaching Hospital

INTRODUCTION

- A project of Health & Education Foundation, which is a not-for-profit organization.
- A tertiary care hospital with all the major medical and surgical specialties – draining an area of 50 KM.
- 600 bedded hospital, with 20 bedded Emergency department and 25 bedded Intensive Care Unit.
- 24/7 Emergency services.
- Registered with Punjab Healthcare Commission.

Accident & Emergency

Medical ICU


Ambulance Services

## Clinical Departments

- Internal Medicine
- General Surgery
- Critical Care Unit *(MICU, SICU, NICU)*
- Accident & Emergency
- Radiology
- Pathology
- Cardiology
- Cardiac Surgery
- Anesthesiology
- Pediatrics
- Orthopedics
- Pulmonology
- Dermatology
- Nephrology
- Neurology
- Ophthalmology
- Otorhinolaryngology
- Gastroenterology
- Rheumatology
- Urology
- Obstetrics & Gynecology
- Oncology
- Clinical Trial Unit

**All above mentioned departments are fully equipped and functional**

# Equipment

- CT Scan
- X-Ray
- Ultrasound
- Ventilators
- Bi-PAP
- C-PAP
- Echocardiograph
- ECG
- Defibrillator
- Portable X-Ray
- Laryngoscope
- Suction Machine
- Fiber-optic-esophagoscope/gastroscope
- Cystoscopes
- Bronchoscope
- Otoscope
- Ophthalmoscope
- Retinoscope
- Nebulizer
- Cardiac Monitor

# CPTH LABORATORY

## Department of Pathology

Central Park Teaching Hospital houses a fully equipped in-house Pathology Lab, ensuring accurate and timely diagnostic services. The lab conducts a wide range of blood tests and cultures, supporting effective diagnosis and treatment. With modern equipment and skilled professionals, it plays a vital role in delivering reliable healthcare services to patients.


# Introduction to Clinical Trials Unit

- Established in 2021, the Clinical Trials Unit (CTU) at Central Park Teaching Hospital is dedicated to delivering high-quality, ethical, and patient-centered clinical research.
- Participant safety remains our highest priority, with all processes designed to ensure the protection, dignity, and well-being of study volunteers.
- The CTU operates from a state-of-the-art, purpose-built facility, designed to provide a dedicated research environment. This allows participants to be managed separately from routine hospital settings, minimizing exposure to hospital-acquired infections while maintaining immediate access to full emergency medical services when required.
- Our unit is supported by a highly experienced and dedicated multidisciplinary team, with a proven track record of successfully conducting multiple international Phase II, III, and IV clinical trials.
- The facility is fully equipped with modern infrastructure and equipment, enabling efficient and compliant trial conduct across a range of therapeutic areas.
- All operations are governed by comprehensive Standard Operating Procedures (SOPs), regularly updated in accordance with ICH-GCP E6 (R3) guidelines.
- The CTU is committed to expanding its capabilities and is actively seeking opportunities to conduct Phase I–IV clinical trials, contributing to advancements in medical science and improved patient care.
- The unit operates in full compliance with ICH-GCP standards, ensuring the highest levels of quality and regulatory adherence.
- We adhere strictly to Good Documentation Practices, following ALCOA+ principles to ensure data integrity, accuracy, and traceability.

# Completed Clinical Trials

| Sr. No. | Sponsor | Protocol | Indication | Medical Specialty | Type | Recruitment Target | Target Achieved |
|---|---|---|---|---|---|---|---|
| 1 | Anhui Zhifeilongcom Biopharmaceutical Co. LTD | ZF2001 | Primary Covid-19 Vaccine | Infectious Diseases | Vaccination Trial | 1000 | 1352 |
| 2 | Livzon Mabpharm Inc. | TG2102V01 | Covid-19 Booster Vaccine | Infectious Diseases | Vaccination Trial | 1000 | 2158 |
| 3 | Seqirus UK Ltd | V130_14 | Influenza Vaccine – Pediatric | Pediatric Infectious Diseases | Vaccination Trial | 58 | 86 |
| 4 | Shionogi | ACTIV-2d/A5407 | Covid Treatment | Infectious Diseases | Treatment Trial | 5 | 5 |
| 5 | Alvotech Swiss AG | AVT06-GL-C01 | Age Related Macular Degeneration | Ophthalmology | Treatment Trial | 2 | 1 |
| 6 | AIM Vaccine Co., Ltd.Ningbo Rongan Biological Pharmaceutical Co., Ltd.LiveRNA Therapeutics Inc. | LVRNA021-Ⅲ-01 | Primary Covid-19 Vaccine | Infectious Diseases | Vaccination Trial | 1000 | 1965 |
| 7 | Yisheng Biopharma Pte, Ltd | YS-002 | Rabies Vaccine | Infectious Diseases | Vaccination Trial | 500 | 950 |
| 8 | Seqirus UK Ltd | V201_03 | Influenza Vaccine - Adults | Infectious Diseases | Vaccination Trial | 200 | 219 |
| 9 | | PBMT | Pneumonia | Pulmonology | Treatment Trial | 6 | 6 |

# Ongoing Clinical Trials

| Sr. No. | Trial Name/Sponsor | Indication | Medical Specialty | Type | Recruitment Target | Target Achieved |
|---|---|---|---|---|---|---|
| 1 | Eclipse 1 | Hepatitis D | Gastroenterology | Treatment Trial | 4 | 8 |
| 2 | Eclipse 3 | Hepatitis D | Gastroenterology | Treatment Trial | 4 | 7 |
| 3 | AT01B-008 | Hepatitis C | Gastroenterology | Treatment Trial | 15 | 29 |

# Publications

| Sr. No. | Sponsor | Protocol | | Publish Journal |
|---|---|---|---|---|
| 1 | Anhui Zhifeilongcom Biopharmaceutical Co. LTD | ZF2001 | Efficacy and Safety of the RBD-Dimer-Based Covid-19 Vaccine ZF2001 in Adults, The New England Journal of Medicine, June 2022 (listed as part of the ZF2001 Global Trial Group), N Engl J Med. 2022 Jun 2;386(22):2097-2111. doi: 10.1056/NEJMoa2202261. Epub 2022 May 4. PMID: 35507481; PMCID: PMC9127771. | The New England Journal of Medicine, June 2022 |
| 2 | Livzon Mabpharm Inc. | TG2102V01 | Wang XY, Mahmood SF, Jin F, Cheah WK, Ahmad M, Sohail MA, Ahmad W, Suppan VK, Sayeed MA, Luxmi S, Teo AH, Lee LY, Qi YY, Pei RJ, Deng W, Xu ZH, Yang JM, Zhang Y, Guan WX, Yu X. Efficacy of heterologous boosting against SARS-CoV-2 using a recombinant interferon-armed fusion protein vaccine (V-01): a randomized, double-blind and placebo-controlled phase III trial. Emerg Microbes Infect. 2022 Dec;11(1):1910-1919. doi: 10.1080/22221751.2022.2088406. | Taylor & Francis<br>- Emerging Microbes & Infections |
| 3 | Seqirus UK Ltd | V201_03 | de Looze F, Essink BJ, van Boxmeer J, Andrade C, de Rooij R, Casula D, Xing R, Tovar MP, Albano FR. Immunogenicity and safety of higher-dose cell-based adjuvanted quadrivalent influenza vaccines: Combined results of randomised, controlled dose-finding and dose-confirmation studies. Vaccine. 2026 Mar 18;79:128436. doi: 10.1016/j.vaccine.2026.128436. Epub ahead of print. PMID: 41855648. | Elsevier - Vaccine |
| 4 | Alvotech Swiss AG | AVT06-GL-C01 | Agostini, H., Baumane, K., Balčiūnienė, V. J., Ozols, K., Soni, R., Hamdi, S., … Berti, F. (2025). A randomized, double-masked parallel-group, multicenter clinical study evaluating the efficacy and safety of the biosimilar candidate AVT06 compared to the reference product aflibercept in participants with neovascular age-related macular degeneration. *Expert Opinion on Biological Therapy*, *25*(7), 773–787. https://doi.org/10.1080/14712598.2025.2519531 | Taylor & Francis |
| 5 | Seqirus UK Ltd | V130_14 | Poder A, Ong-Lim AL, Rivera Medina DM, Zaman K, Makedonska I, de Bruijn M, Matassa V, Fortanier AC, Heijnen E, Hohenboken M, Molrine DC. Efficacy, immunogenicity, and safety of a cell culture-derived quadrivalent influenza vaccine compared with a non-influenza vaccine in infants and children across five influenza seasons: a phase 3, multinational, observer-blind, randomised controlled trial. Lancet Child Adolesc Health. 2026 May;10(5):352-363. doi: 10.1016/S2352-4642(26)00009-X. | The Lancet – Child & Adolescent Health |
| 6 | Shionogi | ACTIV-2d/A5407 | Luetkemeyer AF, Chew KW, Lacey S, Hughes MD, Harrison LJ, Daar ES, Eron J, Fletcher CV, Greninger AL, Hessinger D, Li JZ, Mailhot D, Wohl D, Chayakulkeeree M, Mendoza JLA, Elistratova P, Makinde O, Morgan G, Portsmouth S, Uehara T, Smith D, Currier JS. Ensitrelvir for the Treatment of Nonhospitalized Adults with COVID-19: Results from the SCORPIO-HR, Phase 3, Randomized, Double-blind, Placebo-Controlled Trial. Clin Infect Dis. 2025 Jul 18;80(6):1235-1244. doi: 10.1093/cid/ciaf029. PMID: 39960062; PMCID: PMC12272848. | Oxford Academic-Clinical Infectious Diseases |

# Premises

Waiting Area


Reception Area


CTU Pharmacy


File Storage & Archiving


CTU Pharmacy

Secure Restricted Areas ensure safe handling and controlled access to sensitive Pharmacy and Archiving records. It maintains confidentiality, integrity, and organized storage of critical medical and administrative files.

# Premises


Key Procedure Rooms

## Participant Visit Flow

Key Procedure Rooms

- Informed Consent Room
- Physical Examination Room
- Phlebotomy & Sample Processing Room

# Observation Bay & IP Administration

Observation Bay


Emerygency Crash Trolley

Conference Room

## TemperatureControl & Confidentiality Measures

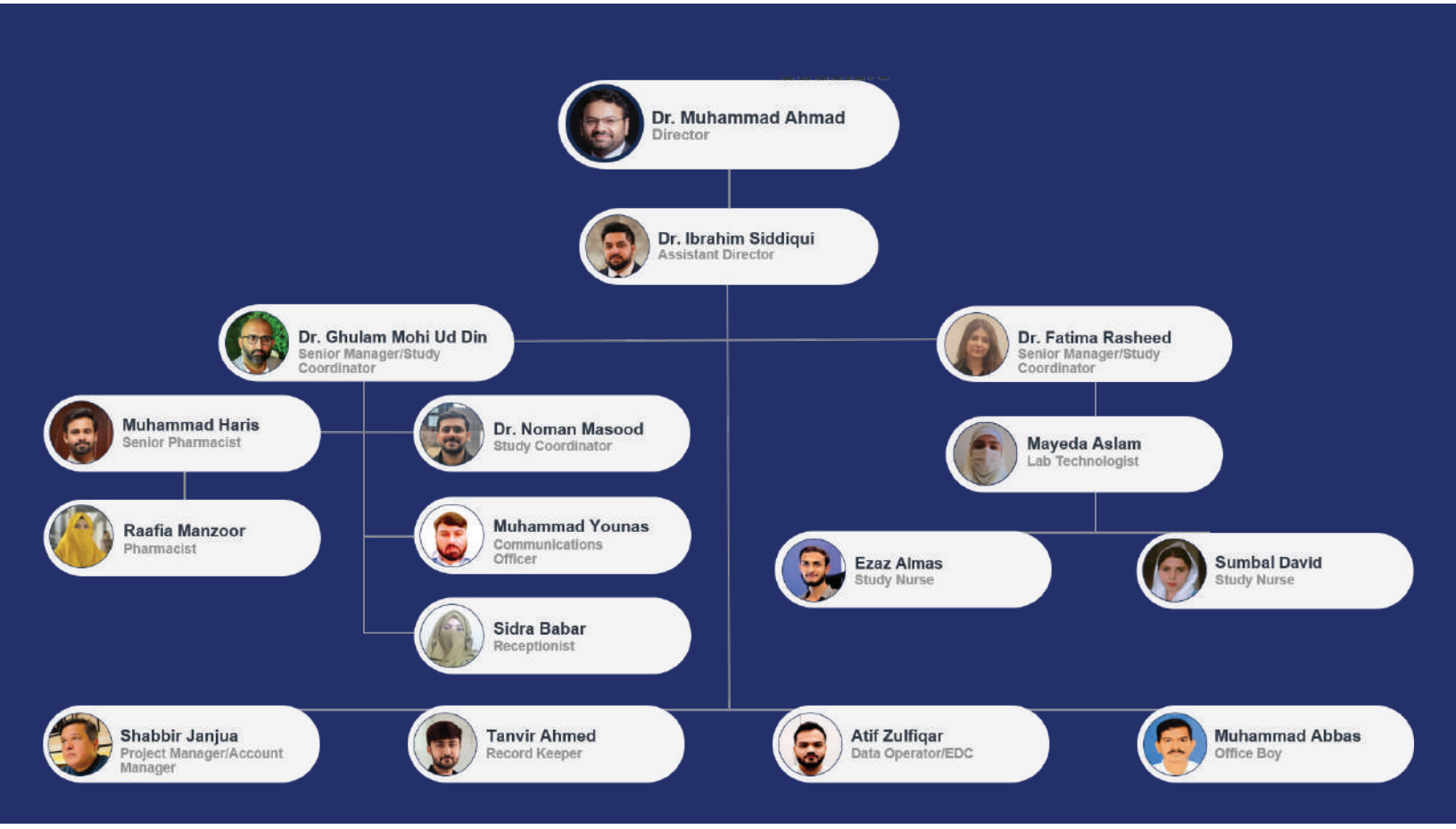


## Security &Safety Measures

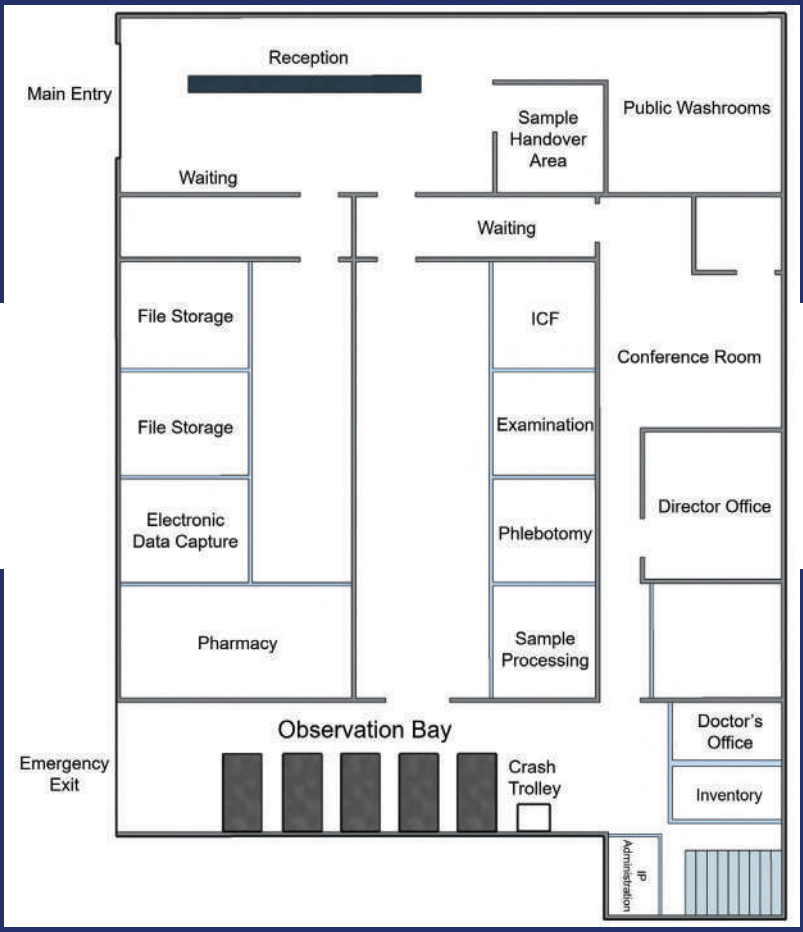
# Clinical Trial Unit – Structure

## Core Team

- Director Clinical Trial Unit
- Assistant Director Clinical Trial Unit
- Study Coordinator
- Pharmacist
- Lab Technologist
- Study Nurse
- Accountant / Project Manager
- Electronic Data Capture
- Telephone Operator / Follow-up
- Record Keeper / Office Boy



# Clinical Trial Unit Layout




# Clinical Trial Unit Equipment

**The unit is fully equipped with**

- 2° to 8° Refrigerators
- -20° to -40° Freezer
- -40° to -80° Freezer
- Centrifuge Machines
- Water-bath Machine
- Biosafety Cabinet
- Defibrillator
- Crash Trolley
- Height/Weight machine
- Nebulizer
- 12-lead ECG Machine
- Sphygmomanometer
- Lockable cabinets for archiving.
- Pediatric Equipment (such as infantometer)
- Cardiac Monitors
- Oxygen Concentrators
- Calibrated Thermometers/Infrared thermometers
- Wireless Data Loggers
- Suction Machine

**All equipment is regularly maintained & calibrated, with record & certifications available.**

# Core Processes & Capabilities

## Informed Consent Process (ICF)

- Dedicated private counselling room ensuring confidentiality and patient comfort
- Fully compliant with ICH-GCP R3 informed consent requirements
- Consent discussion conducted by qualified and trained medical personnel
- Use of ethics committee–approved ICF versions only
- Documentation of consent process, date/time, and personnel involved
- Provision for impartial witness (if required)

## Qualified Personnel & Training

- Experienced Principal Investigators and Sub-Investigators
- Dedicated study coordinators and research staff
- All staff trained in:
  - ICH-GCP R3 guidelines
  - Protocol-specific procedures
  - Safety reporting requirements
- Ongoing training logs and competency assessments maintained

## Data Integrity & Confidentiality

- Compliance with ALCOA+ principles
- Secure handling of source documents and electronic data
- Restricted access to subject-identifiable information
- Compliance with applicable data protection regulations

## Quality Assurance & Compliance

- SOP-driven processes across all study activities
- Regular internal audits and quality checks
- Readiness for:
  - Sponsor audits
  - Regulatory inspections
- Deviation management and CAPA (Corrective and Preventive Actions) processes in place

# Core Processes & Capabilities

## Safety Monitoring & Emergency Preparedness

- Comprehensive safety reporting SOPs compliant with ICH-GCP R3
- Timely reporting of:
  - Adverse Events (AEs)
  - Serious Adverse Events (SAEs)
- 24/7 emergency medical support availability
- Established Code Blue protocol
- Fully equipped crash trolley including:
  - Defibrillator
  - Emergency Medications
- Immediate access to hospital emergency and ICU services
- Trained staff in Basic Life Support (BLS) / Advanced Cardiac Life Support (ACLS)

## Archiving & Document Management

- Dedicated archival facility for study documents
- Access-controlled (biometric/logged entry) to ensure confidentiality and traceability
- Storage in fire-resistant cabinets with safety measures
- Controlled temperature and humidity environment
- Defined document retention timelines per regulatory and sponsor requirements
- SOPs for secure retrieval, tracking, and destruction of records

## Temperature Monitoring & Cold Chain Management

- Centralized temperature monitoring system using validated wireless data loggers
- Real-time alerts for temperature excursions (SMS/email-based)
- Fully implemented Cold Chain SOPs for IMP and biological samples
- Dedicated clinical trial pharmacy and sample storage areas
- Storage capacity refrigerators (2–8°C), freezers (-20°C), ultra-low freezers (-80°C)
- Regular calibration, validation, and maintenance of equipment
- Backup power systems (generators/UPS) ensuring continuous temperature control
- Documented temperature logs and excursion management procedures

# Core Processes & Capabilities

## Investigational Product (IP) Management

- Secure, access-controlled Investigational Product storage areas
- IP accountability logs maintained (receipt, dispensing, return, destruction)
- Storage conditions maintained per protocol and label requirements
- Segregation of quarantined, dispensed, and returned products
- Compliance with Good Pharmacy Practices and sponsor requirements

## Logistics & Sample Handling

- SOPs for sample collection, processing, storage, and shipment
- Use of validated packaging and temperature-controlled transport (e.g., dry ice)
- Chain-of-custody documentation maintained
- Coordination with central laboratories and couriers
- IATA certified personnel for bio-hazardous sample packing and shipping

| Sr. No | SOP Number | SOP Title |
|---|---|---|
| 01 | SOP_101 | Writing SOPs |
| 02 | SOP_102 | Responsibilities of Research Team |
| 03 | SOP_103 | Clinical Study Conduct |
| 04 | SOP_104 | Recruitment and Screening |
| 05 | SOP_105 | Inform Consent Process |
| 06 | SOP_106 | IP Management |
| 07 | SOP_107 | Safety Information Management & Reporting |
| 08 | SOP_108 | Source Documentation |
| 09 | SOP_109 | Archiving Study Records |
| 10 | SOP_110 | Temperature Monitoring |
| 11 | SOP_111 | Randomization Blinding |
| 12 | SOP_112 | Blinded and Unblinded Staff |
| 13 | SOP_113 | Equipment Maintenance and Calibration |
| 14 | SOP_114 | Preparation of Injectable Medications |
| 15 | SOP_115 | Primary and Satellite Site |
| 16 | SOP_116 | Emergency Handling of Cases Related to Clinical Trial |
| 17 | SOP_117 | Specimen Collection and Management |
| 18 | SOP_118 | Cold Chain Management |
| 19 | SOP_120 | Study Visits |

# Accreditations, Affiliations & Regulatory Oversight

1495

UNIVERSITY OF ABERDEEN

Affiliatied with University of Aberdeen

Affiliatied with University of The Punjab

Licensed & Regulated by Drug Regulatory Authority of Pakistan

All studies are conducted under the supervision and approval of IRB Central Park Medical College

HEALTH & EDUCATION
FOUNDATION

https://www.cpth.pk
director.clinicaltrial@cpmc.edu.pk
irb@cpmc.edu.pk

042-34500003 (Ext. 2098)
Central Park Housing Scheme 31 Km,
Ferozepur Road, Lahore-Pakistan