

# CLINICAL TRIAL UNIT

"Research excellence for better healthcare"

www.zu.edu.pk ziauddin.ctu@zu.edu.pk +9221-35862937 ext 2359

## **About US**

Ziauddin University Clinical Trial Unit (CTU) is approved and recognized by the Drug Regulatory Authority of Pakistan (DRAP). The initiative of CTU is taken to establish a center of excellence committed to advancing the Ziauddin research mission. We are committed to developing systems and procedures that would enable us to conduct high-quality clinical trials, thereby enhancing access to drugs, and improving the health of individuals. Ultimately, it can enhance healthcare practices on a national and international scale.

#### **Mission**

To execute clinical trials effectively and competently in clinical research in line with the International Directives for Clinical Trial Research (Declaration of Helsinki, ICH, and GCP Guidelines).

#### **Vision**

The Clinical Trials Unit aims to conduct clinical trials that help Sponsors and collaborators to develop new medications and new indications for existing medications for a variety of disorders over a wide spectrum of clinical areas. At the same time, helping our patients and clinical trial participants discover new and effective therapies for their conditions where other existing therapies have been unsuccessful.

### **OUR GROUP OF HOSPITALS**

All our hospital sites are certified by ISO and Sindh Health Commission.

All our patient data is secured in EMR through a centralized database.

These hospitals are:

- Dr. Ziauddin Hospital, North Nazimabad Campus (319 Beds, Tertiary Care Hospital)
- Dr. Ziauddin Hospital, Clifton Campus (182 Beds, Tertiary Care Hospital)
- Dr. Ziauddin Cancer Hospital (27 Beds, Tertiary Care Hospital)
- Dr. Ziauddin Hospital KDLB, Keamari Campus (120 Beds, Tertiary Care Hospital)
- Dr. Ziauddin Memorial Hospital (25 Beds, Tertiary Care Hospital)
- Boat Basin Executive Clinics (22 Beds, Tertiary Care Hospital)
- Dr. Ziauddin Hospital Sukkur
- Zia Medical center Dubai, UAE

# **Ziauddin University**

Ziauddin University is HEC recognized, degree awarding institution which was founded in the memory of Sir Dr. Ziauddin Ahmad, and Ziauddin university faculty of Health Sciences is Nationally and Internationally recognized

The University Campuses are consist of:

- Ziauddin University, Clifton Campus
- Ziauddin University, North Campus
- Ziauddin University, Link-Road Campus
- Ziauddin University, Sukkur Campus
- Ziauddin University, Islamabad Campus (In progress)

# **Our Dedication**

We Ensure that trial personnel are supervised uniformly throughout trials and that all activities are performed following Good Clinical Practice guidelines. The CTU's trial management services greatly facilitate the completion of projects while maintaining patient safety and data integrity through quality control.

#### **Our Strengths**

- 1. Principal investigators have national and worldwide renown, high level of clinical experience, and academic distinction.
- 2. Investigators who are community-respected thought leaders in their respective fields who have conducted several national and international clinical studies.
- **3.** University hospital with a vast array of onsite professionals, encompassing the entire spectrum of medical and surgical specialties, pharmacy, neuropsychology, critical care, anesthesiology, Intensive care units, Emergency and etc
- 4. University is highly equipped with research facilities comprise of Multi-disciplinary laboratory-I, Multi-disciplinary laboratory-II and Multi-disciplinary laboratory-III Having Cell Culture Facility, Spectrophotometer Services, Nucleic Acid and Protein Estimation, Histopathology & High Resolution Imaging Facility, Bioinformatics Analysis, HPLC Facility, NGS, Sanger and isotope techniques etc
- 5. A facility including a reception area, specialized research pharmacy, physical exam rooms, samples collection room, monitor rooms, refrigerator and -20C, -80C freezers for storing temperature-sensitive material, data storage space, on-site laboratory, and computerized data management capacity.
- 6. Research personnel with substantial clinical trial experience and knowledge assist in timely protocol approval.
- Compliance with local and international regulatory requirements for paperwork and contracts
- 8. Regular meetings of the Institutional Review Board/Ethics Review Committee
- Quality Assurance checks to offer high-impact, high-quality clinical trials
- 10. Institutional assessment of clinical trial protocols
- 11. Good Clinical Practice-compliant facility & employees

## **Our Facilities and Services**

#### Clinical

- Equipped examination rooms, consultation rooms, Separate Consent room
  and assessment rooms
- · Infusion and cardiac monitoring
- Protocol-related specimen collection, processing, and handling; specimen collection restrooms
- Management of experimental products linked to protocols
- Dedicated space for investigators to work during research clinics
- · Common reception, check-in, and waiting area
- Nutrition support study subjects, approved access per protocol (fasting, long-stay)
- Safe Waste Disposal

#### **Equipment**

- Standard bed Units with oxygen, vacuum; infusion pumps, and vitals monitors
- 2 (-20C) & 1 (-80C) freezer
- On-site ECG tracing services and Cardiac monitoring capability
- Equipped and medically stocked emergency cart
- Audio and visual call system
- All clinical and consulting rooms are provided with a wireless Internet connection and secure Computers and computer systems.

#### **Administrative**

- Certified researchers, research nurses and CTU staff with extensive expertise
- A phlebotomy room with a separate lab processing section that includes refrigerated and non-refrigerated centrifuges.
- A drug preparation room with temperature-controlled storage
- Audio-conference facilities to facilitate collaborations
- workspaces for study coordinators
- Procedure room with four beds, an emergency trolley, and IV infusion supplies
- Secure Document/data storage room
- Data entry and data management services
- Support services printing, copying, and other
- Specialized monitoring area
- Hazard monitoring command center
- Fire emergency system (Fire Alarm, Fire extinguisher and Fire proof cabinets)

# DATA HANDLING PROCEDURES & COMPUTER VALIDATION

- Computer Networking is used for Data Handling
- Limited Access to the Data
- Dedicated Server
- Data Security

# **Projects by ZU CTU**

Project Name	Funder Name	Project title
ISARIC	University of Oxford/Wellcome Trust	(Enabling ISARIC Clinical Characterization Protocol (CCP) rollout in LMICs ISARIC)
MegaRox	MRINZ	The Mega Randomized Registry Trial Comparing Conservative vs. Liberal Oxygenation Targets (Mega-ROX)
Recovery	University of Oxford	Randomized Evaluation of COVID-19 Therapy ISRCTN: ISRCTN50189673 EU Clinical Trials Register: EudraCT 2020-001113-21 Clinical Trials.gov: NCT04381936 RECOVERY)
MM vs N95	McMaster University	Medical Masks versus N95 respirators to prevent 2019 Novel Coronavirus Disease (COVID-19 N95 Vs MM)
REMAP-CAP	Monash University	Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia including COVID 19 (REMAP CAP+ Pandemic) in Pakistan.
O2CoV2	WHO	Oxygen requirements and approaches to respiratory support in patients with COVID-19 in low- and middle-income countries: a WHO study
ACRON-HAI	National University of Singapore /Wellcome Trust	Clinically-Oriented Antimicrobial Resistance Surveillance Network for Healthcare-associated
ISARIC-EXT	University of Oxford/Wellcome Trust	Enabling ISARIC Clinical Characterization Protocol (CCP) roll out in LMICs
GenOMICC	University of Edinburgh	Conceptualizing & designing the study & for identification & collection of patient samples

Study Monitoring

Patient Safety

> Clinical Data Query Management

Clinical Study Statistical Analysis and CSR Project Management

Study Close-out; Archival and Data Transfer