



THE AGA KHAN UNIVERSITY

CTU 2025 HIGHLIGHTS

Advancing Clinical Research with Impact



Growth • Quality • Collaboration • Patient Impact

Clinical Trials Unit
Aga Khan University

MESSAGE FROM THE DIRECTOR, CLINICAL TRIALS UNIT



As I reflect on 2025, I am filled with gratitude and pride for what we accomplished together at the Clinical Trials Unit of The Aga Khan University. This year brought many defining moments, hosting the Clinical Trials Summit of Pakistan, where all stakeholders came together with a shared purpose of strengthening our research ecosystem.

We were also deeply honoured to be designated as a WHO Collaborating Centre for Clinical Trials, the first in the Eastern Mediterranean Region. Joining the WHO Global Clinical Trials Forum and continuing our contribution to the Technical Advisory Group further affirmed our growing role on the global stage.

Operationally, crossing 10,000 participant visits across 17 studies was a milestone made possible only through our hard work, resilience, and belief in our mission. I want to personally thank each member of the CTU team, as well as our collaborators, sponsors, and volunteers, for being the driving force behind our progress.

As we move into 2026, I look forward to building on this momentum together towards a stronger and more vibrant clinical research landscape for Pakistan.

Dr. Saeed Hamid
Director, Clinical Trials Unit

AKU LEADERSHIP SUPPORT

Continued strategic guidance from AKU leadership



The President of AKU, Dr. Sulaiman Shahabuddin, visited CTU in 2025, expressing keen interest in its work and reaffirming institutional support for its future growth.



The Clinical Trials Unit had the privilege of hosting the newly appointed Dean of the Medical College, Dr Karim Damji, AKU, during his first weeks in office, highlighting early leadership engagement and collaboration.

*Visits by the President, Dean, and Vice Provost (Research), Dr Salim Virani
Strong institutional commitment to advancing clinical research*

DRAP VISITS TO CTU



Dr. Obaidullah, Chief Executive Officer, DRAP; Dr. Akhtar Abbas Khan, Director of Pharmacy Services & Chair Clinical Studies Committee, DRAP; Dr. Saif Ur Rehman Khattak, Additional Director DRAP Karachi; Dr. Saeed S. Hamid, Director CTU; and Ms. Saharish Nazar, Manager CTU, Aga Khan University, during a meeting to strengthen collaboration on clinical studies and regulatory oversight.



Officials from the Drug Regulatory Authority of Pakistan (DRAP), including Dr Abdullah Diyo, Dr Mahvash Ansari, and Dr Shafqat Hussain Danish, Deputy Director (Clinical Research), DRAP, visited CTU for the license renewal inspection



Mr Abdul Rasool Shaikh, Additional Director/In-Charge, DRAP, Karachi. Mr Abdul Waheed, Deputy Director, DRAP Karachi. Dr Shafqat Hussain Danish, Deputy Director (Clinical Research), DRAP, visited CTU for the GCP Inspection

QUALITY & REGULATORY OVERSIGHT 2025

04 DRAP GCP Inspections
Flammingo • Hecolin • GCSF •
COPCOV

02 Sponsor Audits
ECLIPSE I • Hecolin

03 ERB Audits
ASPIRE-AF • BCD-248 • BCD-
264

01 DRAP License
Renewal Inspection

09 DRAP IP Reconciliation Audits

HIGHLIGHTS

CLINICAL TRIALS SUMMIT OF PAKISTAN 2025



The Clinical Trials Summit of Pakistan 2025 marked a significant milestone for the CTU, bringing together national and global stakeholders to advance a unified, patient-centred clinical trials ecosystem in Pakistan.

[\(Access the summit final report here\)](#)

The Clinical Trials Summit of Pakistan 2025 closed as a powerful national platform driving collaboration to advance clinical research. 6

INTERNATIONAL CLINICAL TRIALS DAY 2025

Celebrated the science and ethics of clinical trials



CTU celebrated International Clinical Trials Day 2025 with study teams, investigators, and CRO partners, recognising the purpose-driven work behind clinical research and patient impact.

ADVANCING CLINICAL RESEARCH THROUGH QUALITY AND COLLABORATION




Oncology experts from hospitals across Karachi convened at the Clinical Trials Unit to exchange insights and explore collaborative approaches to strengthening cancer research in Pakistan.

POWERED BY PURPOSE

Celebrating the people advancing patient-centred clinical research

GLOBAL ENGAGEMENT – WHO

AKU Clinical Trials Unit Designated as WHO Collaborating Centre for Clinical Trials (2025–2029)

	World Health Organization	<i>WHO CC Global Database</i>
Reference number:	PAK-29	
Institution name:	Clinical Trials Unit Aga Khan University	
Region:	EMRO	
Phone:	+92 21 3486 2330 +92 21 3486 2303	
Website:	https://http://https://www.aku.edu/Pages/home.aspx	
Title of WHO CC:	WHO Collaborating Centre for Clinical Trials	
Head(s) of WHO CC:	Saeed Hamid saeed.hamid@aku.edu Saharish Nazar saharish.nazar@aku.edu	
<hr/>		
Dates of designation:	09 Dec 2025 - 08 Dec 2029	
<hr/>		
General Scope:	<ol style="list-style-type: none">1. Support the WHO in strengthening the capacities of countries to conduct clinical trials that meet relevant regulations and standards of quality.2. Support the WHO in enhancing the Clinical Trials Unit (CTU) maturity framework for countries in the region.3. Support the WHO in knowledge translation, identifying priority areas for multi-centre randomized controlled trials and capacity development on WHO guidance for best practices for clinical trials.	

The Clinical Trials Unit at Aga Khan University has been officially designated as a World Health Organisation Collaborating Centre for Clinical Trials for 2025–2029, recognising its leadership in strengthening national and regional capacity for high-quality, ethical clinical trials, advancing CTU maturity frameworks, and supporting multi-centre research aligned with global best practices.

[View a video message](#)

Global Clinical Trials Forum(GCTF)

Global Clinical Trials Forum

AKU- Pakistan member of WHO Global Clinical Trials Forum

- **WHA 75.8 calls for actions to strengthening clinical trials**
An ecosystem with sustained capacities in all regions to address the burden of disease through well-designed and well-implemented clinical trials, that meet the needs of populations, and gain from efficiencies and innovations, to be brought to bear in the clinical trials field by 2030.

Capacity Efficiency Innovation





Current list of GCTF members

The Global Clinical Trials Forum (GCTF) unites a diverse community of partners committed to strengthening clinical trial ecosystems worldwide. Members include governments, regulatory authorities, research institutions, funders, civil society organizations, and patient groups. Together, they bring expertise and perspectives that help advance the WHO Guidance for Best Practices for Clinical Trials and the Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS).

Current members include:

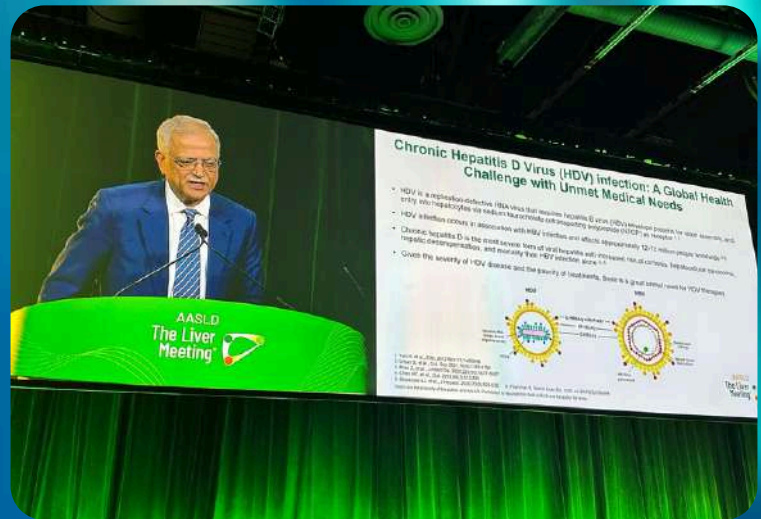


In 2025, AKU became a member of the WHO Global Clinical Trial Forum. Membership in the WHO-supported GCTF, aligned with WHA Resolution 75.8, reflects its commitment to building sustainable national and regional capacity for high-quality clinical trials.

Professional Engagements, Quality & Learning

Dr. Saeed Hamid Presents Landmark Hepatitis Delta Trial at AASLD

A major milestone for Pakistan in Hepatitis Delta research—Dr. Saeed Hamid presented promising Phase II clinical trial results on HDV at AASLD, highlighting a potential breakthrough for a disease with limited treatment options and showcasing Pakistan's growing impact in global clinical research.



Advancing Learning in Metabolic Liver Disease



Clinical Trials Unit hosted Dr. Zobair M. Younossi, a world-renowned liver disease expert, for an educational session on MASLD in LMICs, strengthening clinical knowledge exchange and reinforcing CTU's commitment to continuous learning and capacity building.

*Learning, collaboration, and excellence—driving meaningful impact in
2025 and beyond.*

CTU Representation at ICSPA-2025



November, 2025 – Ms. Saharish Nazar represented the Clinical Trials Unit (CTU), Aga Khan University, at an invited panelist at the Conference on Sustainable Practices in Pharmaceutical Advancements, organized by Jinnah University for Women (JUW).

Participation in the 2nd National PPIE Collaborators' Meeting



May 24, 2025 – Ms. Saharish Nazar, Dr. Fariha Ayaz, Dr. Saadia Birjees, and Nida-e-Zehra attended the 2nd National PPIE Collaborators' Meeting, arranged by Ziauddin University.

6th International Medical Research Conference



May, 2025– Dr. Saeed Hamid at the 6th International Medical Research Conference (IMRC), organized by the Health Research Advisory Board (HealthRAB) and supported by Getz Pharma.

Representation at The Global Clinical Trial Forum



April, 2025 – Dr. Saeed Hamid (extreme left, second row from the bottom) represented Aga Khan University at the 2nd Global Clinical Trial Forum.

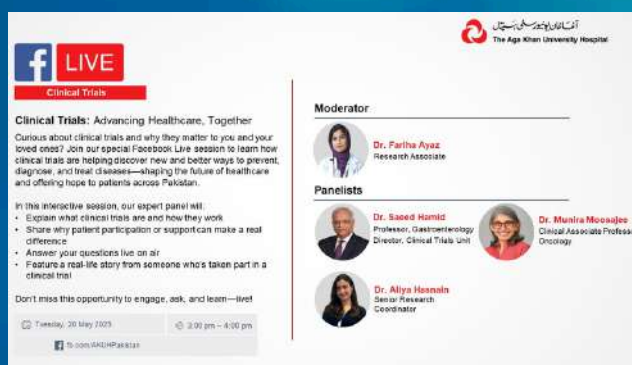


Regional Research Leadership at WHO EMRO 2025

October, 2025– Dr. Saeed Hamid represented Pakistan and the Aga Khan University at the WHO EMRO 2025 meeting to establish regional research networks for multi-country clinical studies in the Eastern Mediterranean Region.

Knowledge Exchange & Capacity Building

Educational workshops, CMEs, and training sessions were conducted throughout 2025, strengthening skills across clinical research teams. Interactive learning initiatives, including the Clinical Trials Day 2025 quiz and live YouTube educational sessions, supported engagement, awareness, and continuous professional development.



CTU Staff Capacity Building



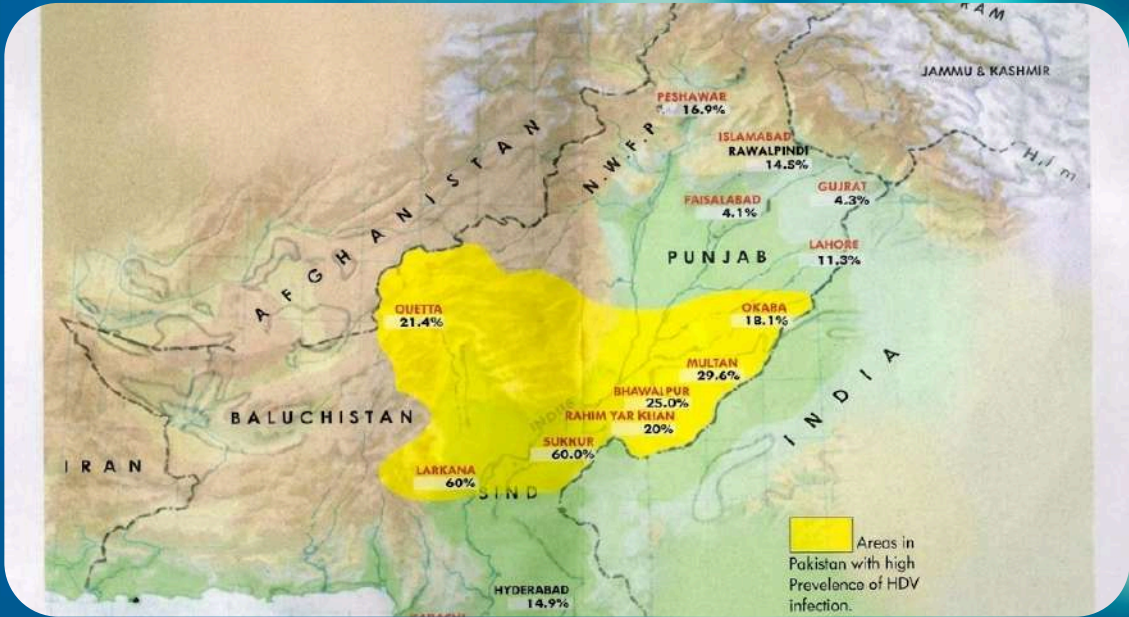
All CTU staff have received ACRP (Association of Clinical Research Professionals) membership and have been enrolled for the ACRP certification exam.

Together, these engagements reflect CTU's continued commitment to excellence, collaboration, and lifelong learning in clinical research.

HEPATITIS DELTA PROGRAM

Pakistan: Leading Innovation in Hepatitis Delta Research

 PRINCIPAL INVESTIGATOR: **Dr. Saeed Hamid**



Pakistan has one of the largest populations of Hepatitis Delta Virus (HDV) patients globally, with the highest prevalence in Sindh and Balochistan, making local clinical research critical for global impact.

04 New Trials Initiated

Strengthening access to innovative HDV therapies in high-burden regions.

Regulatory Progress in Pakistan

One trial medication is advancing through regulatory review with the Drug Regulatory Authority of Pakistan (DRAP).

FDA Breakthrough Recognition

Several investigational therapies evaluated within these trials have received FDA Breakthrough Therapy designation.

Active HDV Clinical Trials

THE ECLIPSE PROGRAM (Vir Biotechnology)

ECLIPSE 1

Evaluating combination therapeutic strategies aimed at improving viral suppression and clinical outcomes

ECLIPSE 3

A comparative study assessing emerging treatment approaches against current standards of care

THE AZURE PROGRAM (Bluejay Therapeutics)

AZURE 1

Assessing a high-potency monoclonal antibody approach for HDV management

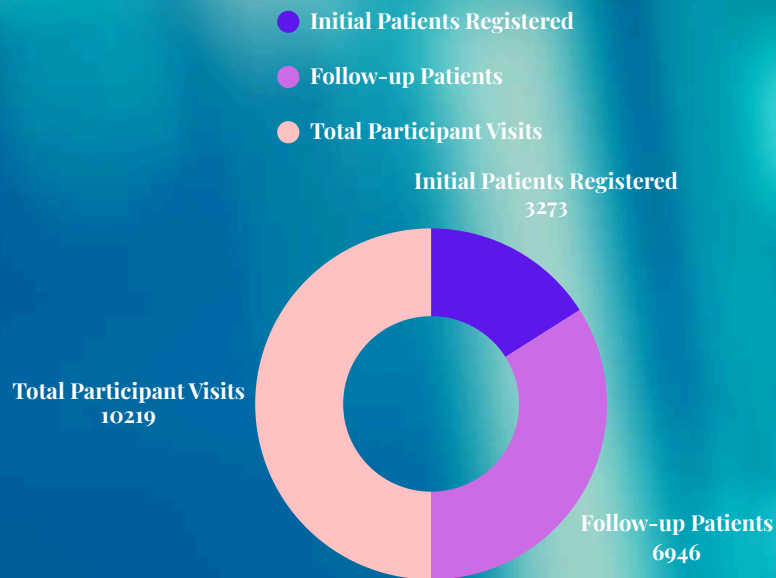
AZURE 4

Focused on long-term safety and effectiveness across HDV genotypes prevalent in Pakistan.

These trials ensure that patients from high-burden regions are represented in global research, contributing evidence that informs future international treatment strategies for Hepatitis Delta.

2025 AT A GLANCE

PATIENT IMPACT – 2025



12

New Studies
Initiated

17

Active Ongoing
Studies

10,219

Total Research
Participants Visits
to CTU

18,622

IPs dispensed by
CTU Pharmacy

6,000

Blood samples shipped
by CTU Laboratory

Every number represents a patient, a family, and a contribution to science.

HIGH-ENROLLMENT STUDIES HOSTED IN 2025

HECOLIN



2,358

Participants

MOMCARE



736

Participants

TEPHINET



424

Participants

RABIES



120

Participants

Thousands of participants were enrolled, multiple studies reached completion, and several progressed through follow-up phases

TRIALS RECRUITING

A Global, Randomized, Open-label, Multicenter, Phase 2b/3 Trial Evaluating BJT-778 vs Delayed Treatment for the Treatment of Chronic Hepatitis Delta Infection (AZURE-1)
[NCT06907290](#)

PI: Dr Saeed S. Hamid

Study Coordinator: Shaheryaar Shiraz



An Evaluation of Bemnifosbuvir-Ruzasvir (BEM/RZR) Versus Sofosbuvir-Velpatasvir (SOF/VEL) for the Treatment of Chronic Hepatitis C Virus (HCV) Infection in a Phase 3 Randomized, Controlled, Open-label Study

[NCT06868264](#)

PI: Dr. Saeed S. Hamid

Study Coordinator: Dr. Aliya Hasnain



A Randomized, Open-label, Multicenter, Phase 2b Trial Evaluating Brelovitug vs Delayed Treatment for the Treatment of Chronic Hepatitis Delta Infection (AZURE-4)
[NCT07298330](#)

PI: Dr Saeed S. Hamid

Study Coordinator: Shaheryaar Shiraz



Comparative Evaluation of KA6 X-Ray Handheld Camera Versus Conventional X-ray to support the diagnosis of Pulmonary Tuberculosis (TB) through Chest X-ray: A Cross sectional, Crossover Study

PI: Dr. Muhammad Irfan

Study Coordinator:

Dr. Fariha Ayaz



"MOM-CARE" – A Phase III Double-Blind, Adaptive Randomized Trial of Antenatal MMSPlus Versus UNIMAPP MMS and Postnatal MMSPlus Versus UNIMAPP MMS or IFA to Improve Infant Birth Outcomes and Growth at 6 Months

[NCT07029282](#)

PI: Dr Fyezah Jehan

Anticoagulation for Stroke Prevention In patients with Recent Episodes of Perioperative Atrial Fibrillation after noncardiac surgery – The ASPIRE-AF trial

[NCT03968393](#)

PI: Dr. Yawer Saeed

Study Coordinator: Dr. Saadia Birjees



Validation of OvaPrint™ cell-free DNA Methylation Liquid Biopsy in women with Adnexal Masses

PI: Dr. Aliya B. Aziz

Study Coordinator: Dr. Fariha Ayaz



HIP Fracture Accelerated Surgical Treatment And Care track 2 (HIP ATTACK-2) Trial

[NCT04743765](#)

PI: Dr. Masood Umer

Study Coordinator: Zoya Walani



A Double-Blind, Randomized Clinical Study of the Efficacy and Safety of Monotherapy with BCD-264 and Darzalex® in Subjects with Relapsed and Refractory Multiple Myeloma

[NCT06296121](#)

PI: Dr. Munira Moosajee

Study Coordinator: Zoya Walani



TRIALS RECRUITMENTS COMPLETED

ECLIPSE 1: A Phase 3 Randomized, Open-Label Study to Evaluate the Efficacy and Safety of Tobeivart +Elebsiran Combination Therapy in Participants with Chronic HDV Infection

[NCT06903338](#)

PI: Dr Saeed S. Hamid

Study Coordinator: Dr Osama Afzal



An Open-Label Clinical Study of the Efficacy and Safety of BCD-248 in Patients With Relapsed/Refractory Multiple Myeloma (FLAMMINGO)

[NCT06668792](#)

PI: Dr. Natasha Ali

Study Coordinator: Zoya Walani



ECLIPSE 3: A Phase 2b Randomized, Open-Label Study to Evaluate the Efficacy and Safety of Tobeivart+Elebsiran Combination Therapy versus Bulevirtide in Participants with Chronic HDV Infection (ECLIPSE 3)

[NCT07142811](#)

PI: Dr. Saeed S. Hamid

Study Coordinator: Dr. Osama Afzal



Immunogenicity and Safety of two dosages of Rabies Vaccine (Serum-free Vero Cell), Freeze-dried in Comparison with. Verorab®, in a Simulated Post-exposure Prophylaxis Regimen in Healthy Adults: A Randomized, Double-Blind, Active-controlled Phase II Clinical Trial.

[NCT07055893](#)

PI: Dr Ali Faisal Saleem

Sub I: Dr Zaubina Kazi



To Explore the Transmission Dynamics of HDV Infection and Health Related Quality of Life Assessment in Selected Rural Communities of Sindh, Pakistan.

PI: Dr. Saeed S. Hameed

Study Coordinator: Dr Huzefa Ahmed



A Phase II, Randomized, Multicenter, Observer-blinded, Active Controlled Trial to Evaluate the Safety and Immunogenicity of Hecolin® in Healthy Pregnant Women between Gestational Age 14-34 weeks and Non-Pregnant Women of 18 years of age and above

[NCT05808166](#)

PI: Dr. Imran Nisar



International
Vaccine
Institute

TRIALS COMPLETED IN 2025

Prevalence of weight related complications across Diverse Weight Classifications – A large cross-sectional study in India, Pakistan, Philippines and Vietnam

PI: Dr. Amna Subhan

Study Coordinator: Dr. Paras Shahzad



Therapy for Hepatitis C Virus (HCV) in Primary Treatment Failure in Pakistan

[NCT05248919](#)

PI: Dr Saeed S. Hamid

Study Coordinator: Dr Aliya Hasnain



A Prospective Study for the Collection of Whole Blood Samples to Support the Development and Validation of In Vitro Diagnostic Tests for Dengue

[NCT07203183](#)

PI: Dr. Nosheen Nasir

Study Coordinator: Nida e Zehra



Abbott

CTU BEYOND THE WORKPLACE

World Pharmacist's Day



Marking Pharmacy Day with colleagues to recognize the vital role of pharmacy teams in safe, high-quality clinical research and patient care.

New Year Breakfast at CTU



CTU marked the start of the New Year with a breakfast gathering, bringing teams together to reflect, reconnect, and begin the year with shared purpose.

AWAZ SE AAGHAZ (FROM VOICE TO AWARENESS)



The Clinical Trials Unit (CTU) participated in the 2nd National PPIE Summit, held on 1 November 2025 at Avari Towers, Karachi, marking an important step toward integrating patient voices into clinical research in Pakistan. The CTU was represented by Nida e Zehra, Dr. Saadia Birjees, and Dr. Fariha Ayaz.

GLOBAL REPRESENTATION: SRAI 2025



Mr. Atif Suleman represented the Clinical Trials Unit at the 2025 SRAI Annual Meeting in San Antonio, USA. He attended the Society of Research Administrators International (SRAI) meeting.

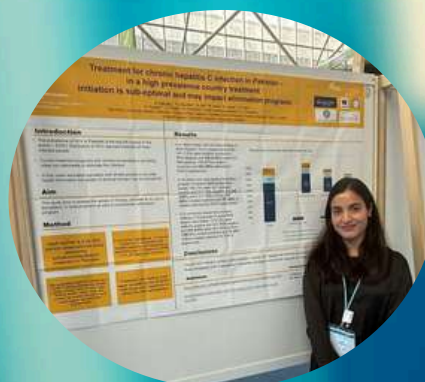
ADVANCING BREAST CANCER RESEARCH & AWARENESS



October is Pinktober ❤️

The Clinical Trials Unit (CTU) celebrated Pink October in recognition of Breast Cancer Awareness Month. Breast cancer continues to impact millions of women worldwide, yet research in this area remains significantly underfunded.

EASL CONGRESS 2025



Dr. Aliya Hasnain presented findings from HepFREEPak, an HCV elimination project funded by Queen Mary University of London at the EASL Congress 2025 in Amsterdam Netherlands May 7th, 2025

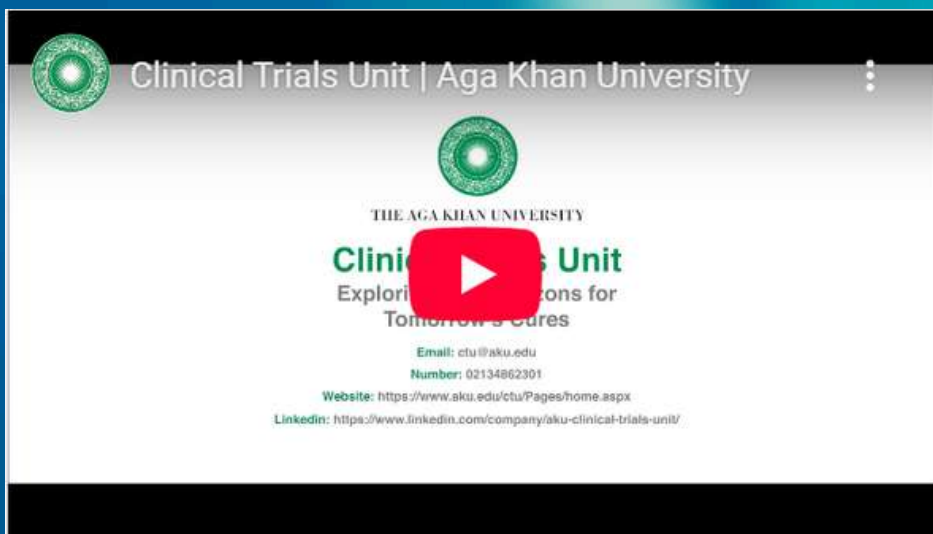
CTU ANNUAL DINNER 2025




An evening dedicated to celebrating teamwork, dedication, and shared achievements honouring the people who form the foundation of CTU's success.

THANK YOU


With gratitude for 2025, we look forward to the year ahead with optimism, purpose, and continued collaboration.




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Edited By: Fariha Ayaz

A year of growth, learning, and progress