# CMHS Clinical Trial Unit

*Advancing clinical and translational research from the College of Medicine and Health Sciences, UAE University*

College of Medicine and Health Sciences · United Arab Emirates University · Al Ain, UAE

## Overview

The CMHS Clinical Trial Unit (CTU) is the research coordination centre of the College of Medicine and Health Sciences at UAE University. Established in 2026, the CTU serves as the institutional hub for investigator-initiated trials, industry-partnered studies, and computational health research across Al Ain.

We provide end-to-end research support: from study design and biostatistics through ethics submission, data management, and publication. Our embedded collaborative model with healthcare facilities allows us to conduct participant-facing research at clinical sites while maintaining full academic governance and financial control within the University.

Whether you are a CMHS faculty member with a research question, a SEHA / healthcare-facility clinician seeking methodological support, or an industry sponsor looking for a qualified site in the Gulf region, the CTU is your starting point.

### What sets the CTU apart

**Data-driven research.** Our Computational and Data Trial Hub conducts retrospective data analysis, AI model validation, and translational research from day one — turning clinical data into publications, grant applications, and evidence that improves patient care in the UAE.

**Collaborative clinical trials.** Through our embedded partnership, we design and execute clinical trials at regional healthcare facilities. CMHS provides the academic engine; our hospital partners provide the clinical environment.

**International standards.** We operate to Good Clinical Practice (GCP) and Department of Health (DOH) standards, with a structured pathway to FDA site recognition through our international CRO partnership programme.

## About the CTU

### Our model

The CMHS CTU operates on an **Embedded Collaborative Model**. Unlike traditional hospital-based trial units, the CTU is anchored within the University while clinical delivery is conducted through our hospital partners. This structure allows CMHS to retain full academic control over research grants, publications, and intellectual property while accessing clinical infrastructure, patient populations, and electronic health records at partner hospitals.

### The dual-track strategy

The CTU operates two parallel workstreams:

- **Track A — Computational and Data Trial Hub.** Retrospective data analysis, AI clinical-reasoning model validation, synthetic data generation, and health-informatics research. This track requires no clinical space and produces academic output immediately.
- **Track B — Clinical Trial Pipeline.** Prospective observational and interventional studies conducted at healthcare facilities, expanding from off-peak sessions to a permanent Translational Research Hub.

### Data Sciences and Retrospective Research Hub

The CTU houses a Secure Data Enclave for processing de-identified electronic-health-record data. Our computational research programme includes:

- Retrospective cohort studies using Al Ain region clinical data
- Validation of locally developed clinical-reasoning AI models
- Synthetic data generation for research and education
- Health informatics and clinical decision-support research
- Collaborative data-science projects with CMHS departments

### Accreditation and quality pathway

The CTU is pursuing a structured accreditation pathway to establish CMHS as a recognised international clinical trial site:

- **DOH compliance.** All studies operate under Department of Health Abu Dhabi regulatory requirements.
- **GCP certification.** CTU staff are trained to ICH-GCP E6(R2) standards through our international CRO partnership programme.
- **ClinicalTrials.gov.** The CTU targets registration of its first trial within Year 1 of operations.

### Leadership

**CTU Lead:** Dr. Adnan Agha, Assistant Professor of Internal Medicine, CMHS; Consultant Endocrinologist, Tawam Hospital.

**Steering Committee:** to be announced.

## For Investigators

The CTU exists to help CMHS faculty and affiliated researchers turn clinical questions into well-designed, funded, and published studies. Whether you have a fully developed protocol or an early-stage research idea, we provide the methodological and operational support to move it forward.

### What the CTU provides

- **Study design and protocol development.** From concept through to a submission-ready protocol, including power calculations, endpoint selection, and randomisation strategy.
- **Biostatistical support.** Statistical analysis plans, interim analyses, and final data analysis for publications and regulatory submissions.
- **Ethics and regulatory submissions.** Preparation and submission of applications to the Al Ain HREC for clinical studies, including amendments and annual renewals.
- **Data management.** Electronic data capture, case-report-form design, data quality control, and secure storage in the CMHS Data Enclave.
- **EHR data extraction.** For approved retrospective studies, credentialed staff extract de-identified data from the hospital electronic-health-record system under strict Data Use Agreements.
- **Grant application support.** Budget development, methodology sections, and data-management plans for DOH, UPAR, and international funding applications.
- **Clinical space access.** Through our arrangement with health facilities, we can secure space for participant-facing research activities.
- **AI and computational research.** Validation of clinical-reasoning models, synthetic data generation, and health-informatics projects through the Data Hub.

### How to submit a study

- **Step 1.** Contact the CTU at ctu@uaeu.ac.ae with a brief description of your research question, study type (retrospective, observational, interventional), and estimated timeline.
- **Step 2.** The CTU Lead will schedule a feasibility meeting to discuss design, resource requirements, and the most appropriate ethics pathway.
- **Step 3.** For studies requiring clinical space at partner healthcare facilities, the CTU will facilitate the MoU process, credentialing, and site logistics.
- **Step 4.** For grant-funded studies, the CTU overhead levy (10–15%) is included in the grant budget to sustain CTU operations.

### For clinicians

If you are a clinician within an academic / clinical healthcare facility with a research idea that would benefit from methodological and biostatistical support, the CTU offers the **Academic Barter System**. We provide study design, statistical analysis, data management, and publication support for your investigator-initiated trials. In return, the study utilises clinical space within your facility and CMHS faculty are designated as Co-Principal Investigators. Contact us to discuss a collaboration.

## For Industry and CRO Partners

The CMHS Clinical Trial Unit offers a qualified clinical trial site in the Al Ain region of Abu Dhabi, UAE, with access to a diverse patient population through the partner hospital network. We welcome enquiries from pharmaceutical companies, medical-device manufacturers, CROs, and biotech firms seeking trial sites in the Gulf region.

### Site capabilities

- **Clinical access.** Participant-facing research conducted at agreed health facilities.
- **Patient population.** Access to the Al Ain regional population (approx. 750,000) across endocrinology, metabolic liver disease, cardiometabolic disorders, internal medicine, and general primary care.
- **Data infrastructure.** Electronic-health-record access for screening and eligibility; electronic data capture; Secure Data Enclave for local data processing.
- **Quality systems.** SOPs aligned with ICH-GCP E6(R2); risk-based monitoring; digital Trial Master File; structured reporting.
- **Regulatory.** DOH Abu Dhabi ethics pathway via the Al Ain HREC.
- **Staff.** GCP-trained clinical research coordinators, biostatistician, data manager, and regulatory support.

### Therapeutic areas of interest

- Endocrinology and diabetes (Type 1 and Type 2)
- Metabolic liver disease (MASLD / MAFLD)
- Cardiometabolic disorders
- Obesity and GLP-1 receptor agonist studies
- Clinical AI and digital-health validation
- General internal medicine

### CRO partnership model

The CTU maintains an active partnership programme with international CROs. If you are a CRO seeking to expand your Gulf-region site network, we offer:

- **Site development.** A qualified academic site with university governance, trained staff, and established hospital access.
- **Regulatory navigation.** Local expertise in DOH Abu Dhabi regulatory requirements and ethics-submission pathways.
- **Academic value.** University-affiliated sites add academic credibility and publication potential to a sponsor's trial portfolio.
- **Flexible engagement.** We work under CRO-managed protocols, sponsor-managed protocols, or collaborative arrangements.

### How to place a trial

For site-feasibility enquiries, study placement, or partnership discussions, contact us at ctu@uaeu.ac.ae with the following information:

- Protocol synopsis or study summary
- Therapeutic area and phase
- Estimated patient population and enrolment target
- Anticipated timeline

The CTU Lead will respond within five business days with an initial feasibility assessment.

## Our Services

The CTU provides centralised research support across the full trial lifecycle. All services are available to CMHS faculty, to partner healthcare-facility clinicians through the Academic Barter System, and to external sponsors through fee-for-service arrangements.

| Service | What we provide |
|---|---|
| **Study design & protocol development** | Concept refinement, study-design selection, protocol writing, power and sample-size calculations, endpoint selection, randomisation strategy, and feasibility assessment. |
| **Biostatistics** | Statistical analysis plans, interim analyses, final data analysis, figure and table generation for manuscripts, and statistical review for grant applications. |
| **Data management** | Database design, electronic case-report-form development, data quality control and cleaning, data-lock procedures, and secure archival. |
| **Regulatory & ethics support** | Ethics applications (Al Ain HREC), DOH regulatory submissions, protocol amendments, annual renewals, and clinical-trial-agreement review. |
| **Clinical operations** | Site qualification, patient screening and recruitment support, informed-consent management, specimen-collection coordination, and monitoring-visit preparation. |
| **EHR data extraction** | De-identified data extraction from the electronic-health-record system under approved Data Use Agreements, with secure transfer to CMHS servers. |

| Service | What we provide |
|---|---|
| **AI & computational research** | Clinical-reasoning model validation, synthetic data generation, natural-language processing on clinical text, and health-informatics pipeline development using the Secure Data Enclave. |
| **Grant support** | Methodology sections, data-management plans, budget development, and letters of support for DOH, UPAR, EDCTP, and international funding applications. |
| **Quality assurance** | Risk-based monitoring, central statistical monitoring, site audits, protocol-deviation tracking, and inspection-readiness preparation. |

To discuss your project or request a specific service, contact us at ctu@uaeu.ac.ae.

## Contact

We welcome enquiries from CMHS faculty, clinicians, industry sponsors, and CRO partners. For general enquiries or to discuss a research project, please use the details below.

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| **Email** | ctu@uaeu.ac.ae |
| **Location** | CMHS Clinical Trial Unit, College of Medicine and Health Sciences, United Arab Emirates University, Al Ain, Abu Dhabi, UAE |
| **General enquiries** | Response within 3 business days |
| **Trial feasibility assessments** | Response within 5-7 business days |
| **Ethics-submission support** | Response within 5-7 business days |