



آغا خان یونیورسٹی

THE AGA KHAN UNIVERSITY

Clinical Trials Unit
celebrates

Clinical Trials Awareness Week

CLINICAL TRIALS IN A NUTSHELL

An ethically and scientifically sound, detailed clinical trial protocol with clear objectives, endpoints and design.

Realistic patient recruitment volumes & timelines. (evidence shows only 30% of patient population participates in a trial). Strong statistical component is required and the calculated sample size based on the power of the study.

Informed Consent (English, Urdu and or any other languages as required). Developed in easy language and communicated regularly to the patient / subject.

Appropriate drug management (from procurement to incineration, drug monitoring and accountability).

A realistic trial budget

Approvals (Ethics Review Committee (ERC), National Bioethics Committee (NBC), Institutional, Grant Checklist).

Contracts and agreements (Clinical Trial Agreement and financial).

Data! Data! Data! Accurate & appropriate.

Protocol compliance. Effective and Efficient system of auditing, monitoring and tracking in place.

Maintain patients rights (informed consent, safety, ethics, risk benefit ratio), protocol compliance, adverse / serious events monitoring / management / and reporting.

A GCP trained study team of Investigators, Study Coordinators, Pharmacist, Statistician, Data Collectors.

Don't forget, annual renewal of ERC approval for trial, 6 monthly trial reporting. and to archive for 15 years

Thank you all for joining us this week and supporting our efforts.