Conduct of Clinical Research in the United Arab Emirates

Clinical research has been conducted for quite a long time now in the United Arab Emirates (UAE). There are three main regulatory bodies active here, and the approval process differs from each hospital ethics committee to the approval of the main regulatory authority. UAE has a local and expat population of approx 7m, with cardiovascular diseases and diabetes being prevalent. Many pharmaceutical companies and clinical research organisations (CROs) have shown an interest in conducting clinical trials in the Middle East and North Africa (MENA) region in different therapeutic areas.

Why consider UAE for clinical research:-

- Market with high potential
- Patient diversity
- Patient pools
- English competency fostered by US/UK presence (i.e., less need for translation)
- Regulatory guidelines and government policies aligned with global standards
- Favourable logistics

With three main regulatory authorities, the approval process differs between them.

- Ministry of Health (MOH)
- Dubai Health Authority (DHA)
- Health Authority of Abu Dhabi (HAAD) covering Abu Dhabi and Al Ain

MOH covers hospitals in Dubai, Sharjah, Fujairah and Ras Al Khaimah, namely Qassimi Hospital - Sharjah, Kuwaiti Hospital - Sharjah, Fujairah Hospital - Fujairah, RAK hospital - Ras Al Khaimah, Sheikh Khalifa Hospital - Ajman, Al Baraha Hospital - Dubai, Al Amal Hospital - Dubai.

The process is quite simple; the regulatory package includes the entire document list that can be obtained from the MOH. The clinical study is submitted by the investigator to the research ethics committee head in MOH, along with fourteen hard copies, one electronic copy and the submission fees. Official time required for the review and approval is 30-60 days.

DHA covers four hospitals, namely Dubai Hospital, Rashid Hospital, Latifa Hospital and Hatta Hospital along with several other clinics. Clinics which do not fall under the DHA can also apply for the conduct of clinical research. DHA has a central research ethics committee in charge of reviewing and approving study protocols in hospitals affiliated with DHA.

- In DHA, the investigator or the sponsor can submit the study package to the REC. All applications for ethical review must be submitted to the office of the medical research committee, by close of business on the relevant closing date. The closing dates for applications should normally be no earlier than 21 days and no later than 14 days prior to each MRC meeting. A fee will be charged for applications submitted for assessment by the MRC in the circumstances outlined in the MRC's fee policy. The fee policy shall be made available to applicants prior to submission of an application to the MRC. Applications will be reviewed and checked for their completeness by the MRC executive officer/secretary prior to their acceptance onto the agenda. Incomplete applications will be returned to the applicant. The MRC shall meet on a regular basis, which will normally be every six weeks.

HAAD covers the region of Abu Dhabi and Al Ain, with 14 authorised hospitals which can conduct human subject research[2].

- The procedure is the same for all hospitals that are authorised. Research proposals must be submitted to the facility research ethics committee. Research cannot be conducted at hospitals that have not been authorised by HAAD to conduct research. Clinical trials that involve drugs that have not yet been approved for use in UAE (investigational new drugs) must receive regulatory authorisation from MOH so that a drug import license can be issued. Other studies in Abu Dhabi that do not involve new drugs can be conducted after approval is received from the facility research ethics committee. An application for ethical review of a research proposal shall be made by the principal investigator for the clinical study. Applications shall be submitted to the REC coordinator using the facility REC application form. Every valid application shall receive a unique REC reference number. The REC must give an ethical opinion within 60 days upon receipt of a valid application by the REC coordinator. The REC shall hold meetings as required for the purposes of primary ethical review of new applications. A minimum of four meetings per year is recommended.[2]

Conclusion

Clinical research is on a roll currently and with many private hospitals and clinics showing keen interest, clinical research in UAE will be at its peak in a couple of years.

Reference

1. www.moh.gov.ae, Hospitals covered

2. Medical Research Section, Health Authority - Abu Dhabi

Adhiti Sharadkumar Soni, Clinart Fz LLC is currently working at Clinart looking into regulatory, training and marketing activities. She is also the Coordinator for the Gulf Chapter of Association of Clinical Research Professionals - ACRP
Email: adhiti.soni@clinart.net