SERVICES

MEDICAL AFFAIRS

“Committed to fulfill your pursuit of bringing hope and smile to the patients

At COD, our medical affairs team is quintessentially responsible for the development, writing, review and interpretation of standalone or end-to-end clinical documents for scientific accuracy and medical expert review to meet the regulatory compliance for proof concept studies, drug phase trials, medical device trials, drug-device combination trials, post-marketing commitment trials, academic clinical trials and patient based generic molecule studies.

Clinical Concept Development

- Extensive literature search
- Key enrollment criteria
- Type of studies and its design
- Objectives and endpoints
- Liasoning with KOLs

Medical Monitoring

- Medical inputs in clinical documents prepared by medical writers
- Medical inputs for sample size estimation
- Preparation and/or review of Medical Monitoring Plan (MMP)
- Preparation and/or review of Safety Management Plan (SMP)
- Eligibility review
- 24 x 7 availability for discussion & response to medical emergencies
- Review of serious adverse event/pregnancy cases
- Protocol deviation review and discussion
- Medical/Safety line listing review and discussion
- Medical coding review
- AESI review in a clinical trial
- Review of emergency unblinding request
- Development and delivery of CIOMS
- Analysis of similar events and its review

Medical Writing

- Investigator’s Brochures (IB)
- Clinical study protocols / clinical investigation plan
- Consent documents, patient scales, patient diary cards, etc.
- Comprehensive (ICH-E3 compliant) / Abbreviated / Synoptic clinical study reports
- Clinical Investigation Reports
- Clinical and non-clinical summaries and overviews of the common technical document (CTD)
- Briefing documents for various regulatory agencies

MEDICAL AFFAIRS

Why COD – Medical Affairs:

+10
Vaccine/drug development experience

+150
Clinical Study Protocols and associated pre-study documents (overall team experience)

+20
global clinical trial's medical monitoring experience as stand-alone projects to +5

+56000
Patients Medical Monitoring ongoing for 02 COVID-19 Global Clinical Trials

+80
Clinical Study Reports – ICH-E3 compliant (overall team experience)

+37
Years of cumulative Medical/Clinical experienced Medical Monitors

KOL Council

Industry veteran Medical experts across Therapeutic Areas

Qualified experts:

Medical Monitors
(M.D. – Pharmacology)
Medical Writers
(M.Pharm – Pharmacology)

Dynamic and professional medical monitors & medical writers with regulatory compliant orientation

COD® RESEARCH

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