MJ Research

MISSION

Being
the reference
for quality
and proficiency
for all CRO
related activities.

QUALITY

VISION

To offer quality
without compromise
in monitoring,
pharmacovigilance,
investigator
and site selection,
to professionals involved
in clinical research
and product development.

PROFICIENCY

EXPERT MEDICAL SERVICES

Quality assessment of clinical trial proposals.

Investigator selection: contacts and practice profile.

Selected medical advice on product development.

Standard Operating Procedures (SOP).

MONITORING

Partnership in “Investigator Meetings”, allowing knowledge of issues related to clinical trials and professional contacts with investigators.

Evaluation of potential centers assessing their capacity to run clinical trials.

Checklist of required documents such as: FDA 1572, HPB 3005, investigator’s C.V., informed consent forms, IRB (Ethics Committee), laboratory accreditation(s), investigator’s brochure etc…

Site Visits:

- Protocol presentation to the clinical research team
- Ensure delivery of clinical supplies to site
- Periodic monitoring following GCP guidelines:
  - Source document verification
  - Clinical supplies accountability and return
- Shadow monitoring in French sites
- Follow-up with amendment applications
- Closeout.

PHARMACOVIGILANCE

General management *of all*

Adverse Events *or*

Drug Reactions *including :*

Quality control of adverse event and/or drug reaction reports by interaction with investigators or reporters

Notification to investigators of serious, unexpected and related adverse events according to Regulatory Authorities.

Periodic Safety Update Reports (PSURs - ICH - E2C) by medical experts

Counseling on all aspects of pharmacovigilance activities

Management of adverse event or drug reaction reports from study sites

Management of all post marketing drug reactions

Response to TPP(HPB), FDA or EMEA (Europe) regulations in reporting adverse drug reactions

Annual reporting of adverse drug reaction data

Emergency counseling by medical experts (if required)

Preparation for Audits