15 YEARS OF EXCELLENCE IN RESEARCH

cliantha research

Pharmacovigilance Services

Scope

- Medicinal Products
- Medical Devices
- Human Vaccines
- Cosmetic Products
- Herbal Products
- Veterinary Products

PSMF
Spontaneous Reports
Literature Monitoring
XEVMPD
Science & Integrity
Medical Inquiry
CIOMS
PSUR
Signal Management
Regulatory Responses
Product Labels
PSUR
RMP
PHARMACOVIGILANCE
PASS
Patient Safety
QPPV
PBRER
Clinical Trials
DSUR
PADER
ICSRs
REMS
MedWatch
E2B XMLs

Regulatory

FDA | European Medicines Agency | MHRA | CDSCO | Health Canada | Australia TGA

PV Service Offerings

Medical Information Management System

- Patient Support Call Center
- Medical Inquiry Handling
- Categorizing Inquiries & Responding
- Inquiry Close Out

Clinical Trial Safety Monitoring

- SAE Processing & Reporting
- Safety Listing Review
- Clinical Safety Meetings
- DSUR

Post Marketing PV Services

- ICSR Processing
- Literature Monitoring
- Aggregate Reporting
- RMP, REMS
- PSMF, XEVMPD
- Product Label, CCDS

PV Support Services

- Auditing & Inspection Support
- E-Training System
- Quality Management System
- Document Support
- Consultation

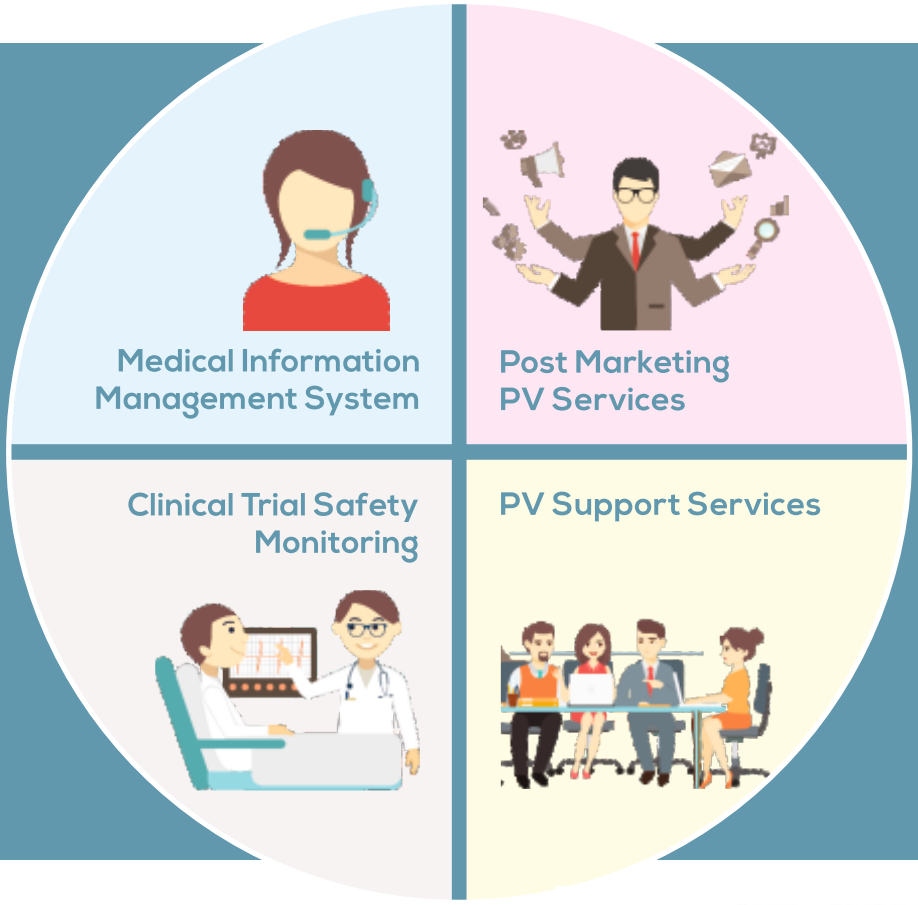
- Double Layer Quality Review Process
- Literature Support by Medically Qualified Persons
- ICSR Triaging by Medically Qualified Persons
- Continuous Process Improvement with more than 50 SOPs
- Flexible and Customer Centric Approach
- Objectively designed KPIs
- Strong Regulatory Intelligence System

15 YEARS OF EXCELLENCE IN RESEARCH

cliantha research

Pharmacovigilance Services

Wherever you want to partner, we are close by...



ePSMF

Safety System Master File - Mandatory requirement in majority of countries including all major regulatory authorities like EMEA, MHRA, DCGI, TGA, CIS, MENA etc. Also accredited as

PSMF	Pharmacovigilance System Master File
PVMF	Pharmacovigilance Master File
PSSF	Pharmacovigilance Sub System File

Salient Features

- Accessible over Cloud for QPPV, Sponsor
- One click solution for your entire PV system
- Version control management
- Role & right specific system
- Audit trail
- Easy access for auditors and inspectors
- Customizable electronic content filing plans
- Interoperable Archives
- Save time, save money & increase visibility