Sojar

Sojar Research Services Pvt. Ltd.

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Our Mission...

Our mission to provide Pharmacovigilance services with exceptional quality and follow through on our promises..

At SOJAR, we provide comprehensive pharmacovigilance services to help pharma and biopharma companies to support and streamline their challenges, strengthen work efficiency and improve quality with on time delivery. We support to achieve 100% regulatory compliance, process efficiency with our cost-effective PV solutions.

We also have flexible and customized operational model utilizing experience, knowledgeable and well-trained global PV associates allow us to deliver on even toughest challenges.

We have strong QMS (Quality Management System) and business continuity plan to deliver the uninterrupted quality services to all our clients.

For more info please access ***https://www.sojarresearch.com/***

Sojar

How we do it?

1. Need Analysis

We meet you and/ or your team to understand your Pharmacovigilance & Drug Safety needs

2. Process development and mapping

Our pharmacovigilance experts meticulously plan and organize a process that defines your regulatory needs and provide you with all the required information to smoothen out your pharmacovigilance activities as per updated regulatory guidelines

3. Setting up an operational guidelines

We establish PSMF/PvMF, SOP's and other operational guidelines to help drug safety and pharmacovigilance team to have clear and consistent guidelines to follow so that all your operations stay completely compliant

4. Day to day PV operations & continuous regulatory intelligence

We provide end-to-end case processing (ICSR), aggregate reports like; PSUR, PBRER, DSUR, RMP, and regulatory intelligence services for ever updating regulatory guidelines.

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Post Marketing Vigilance Services...

Post Marketing Pharmacovigilance Services...

- PV System and SOP's
- Pharmacovigilance System Master File (PSMF)
- ICSR end to end case processing
- ICSR Collection services 24/7
- Aggregate Reporting
- Local Literature search
- Global Literature search
- Regulatory Intelligence in PV
- SDEA Services
- PV Services for distributors
- Medical information and call center (MICC)
- Medical Device Service Support

Technology and Databases we use..

Availability of Drug Safety Databases

Oracle Argus Safety

Sojar also provides in-house hosting of Oracle Argus Safety via Tech subcontractor

Argus is world-class database, widely used by top pharma and biotech companies worldwide

PV Edge

PV Edge Safety is a cloud-based, easy-to-use, regulatory Compliant, end to end Pharmacovigilance / Drug safety system that provides PV Intake, Case processing, Analytics and Submissions

Clinevo Safety

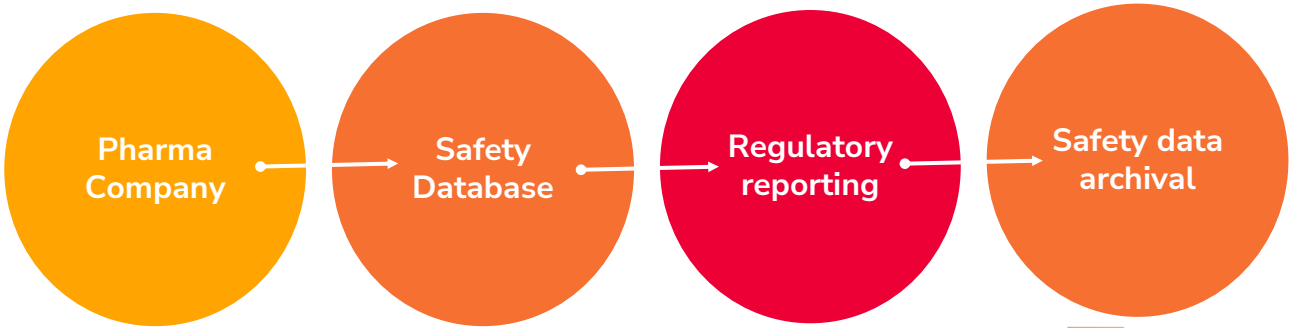
Clinevo Safety is a cloud-based, easy-to-use, regulatory Compliant, end to end Pharmacovigilance / Drug safety system provides PV Intake, Case processing, Analytics, Submissions /AS2 gateway capabilities under one platform.

User-friendly and can be accessed with internet / intranet using Chrome and Firefox browsers

Safety Database Implementation..

We take care of end-to-end safety database implementation including but not limited to the below activities;

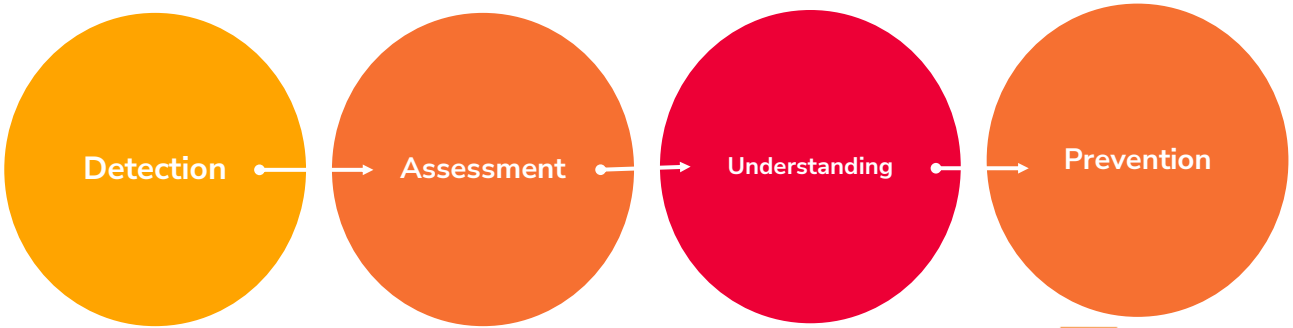
1. User configuration/User access management
2. Products and License configuration/Combination products (Drug and Device)
3. Study configuration
4. Expediting reporting rule configuration
5. License partner configuration
6. E2b profile configuration
7. Adhoc reports via SQL /PSUR report line listing



End-to-end case processing...

We provide end to end case processing services including collection of data from local/global sites and further as per below workflow;

1. Safety Mailbox handling/MICC
2. Triaging/Book in
3. Case processing/data entry
4. ICSR Quality review
5. ICSR Medical review by the MBBS Physician
6. Follow up activity
7. ICSR Submission



Aggregate report writing..

We are well-versed in below aggregate report writing and have been providing ongoing support for both generic and new molecules/Innovators

Types of Aggregate Reports

- ✓ Medical Device Report (MDR) Procedure
- ✓ PSUR (Periodic Update Safety Report)
- ✓ PBRER (Periodic Benefit Risk Evaluation Report)
- ✓ PADER (Periodic Adverse Drug Experience Report)
- ✓ DSUR (Development Safety Update Report)
- ✓ ADCO (Addendum of clinical overview)
- ✓ RMP (Risk Management Plan)
- ✓ SSR (Safety summary report)
- ✓ Product quality complaint reports
- ✓ Post marketing surveillance reports
- ✓ HHE (Health Hazard Evaluations) reports

Other Pharmacovigilance Services at Sojar..

Other Pharmacovigilance Services at Sojar

1. Qualified Person for PV (QPPV)
2. Local Person for PV (LPPV)
3. Reconciliation of partner cases
4. XEVMPD management
5. Regulatory letter/queries responses
6. Medical device summary support
7. Product quality complaint report
8. Signal Management
9. Audit and inspection readiness support

Our current engagements..

- **We are catering Pharmacovigilance services to US based Pharmaceutical companies**

  (FTE services for ICSR case processing on Argus, Medical review and Medical writing)

- **Delivering average 100 ICSRs per day for EU based client**

- **We provide industry-standard application implementation and support to one of the top Japanese company subsidiary based in India**
- **Multiple discussions are in the pipeline offering end-to-end PV service...**

Our Expert Team..

Our leadership team

Leadership team is seassoned with 15+ years experience in management and delivery of Drug Safety and Pharmacovigilance activities for big pharma, biopharma, CRO, BPO and KPO companies.

Worked on across the theraputic areas like

1. Oncology
2. Neurology
3. Cardiology
4. Gynecology
5. Respiratory
6. Ophthalmology
7. Cell and Gene Therapy
8. Immunology and Dermatology

Our Management team

Management team of Sojar is quick and proactive

Our management provide 24/7 x 365 days support in project management activities

Team take care of project update and real time delivery of tasks. Our management team take care of all the communication with clients and contractors.

We provide industry standard solutions to the clients to ease of drug development to meet regulatory compliance.

Our team

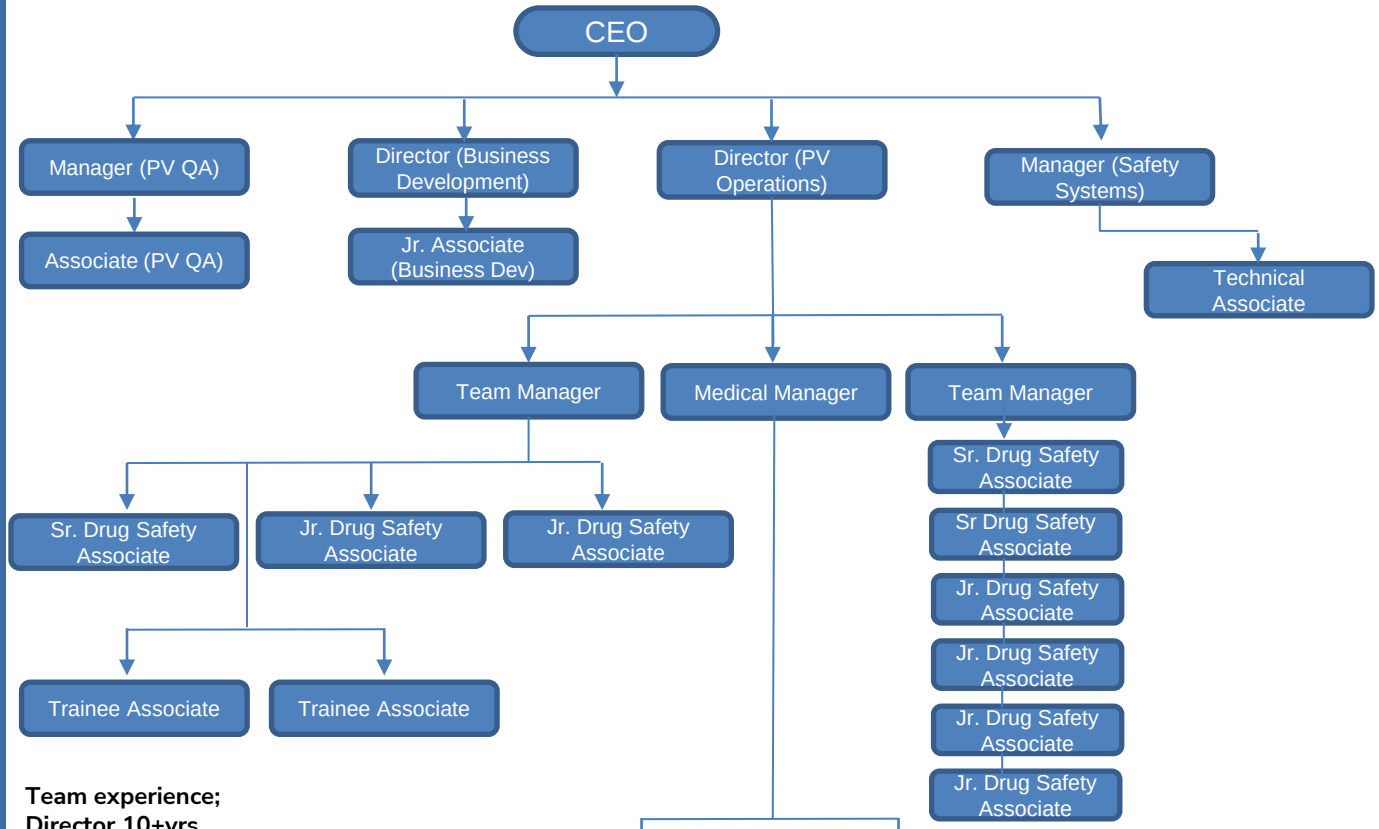
Our team works **24/7 x 365 days.**

Team is highly experienced keeping eye on gender equality

We provide attractive compensation with added incentives on the basis of productivity and quality.

Our team is highly motivated to deliver the tasks on time without deviations.

Organizational chart for Drug Safety

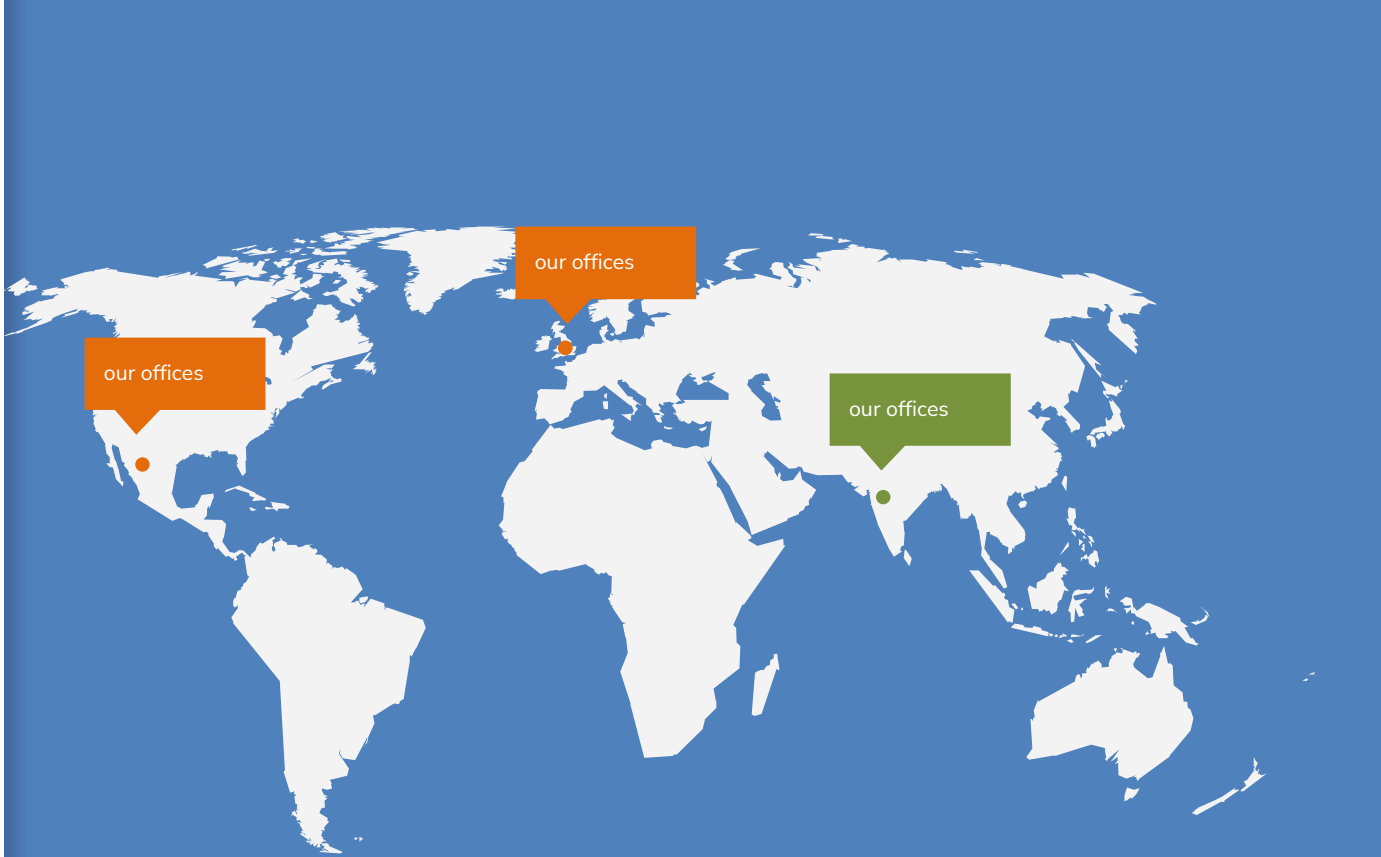


Team experience;
Director 10+yrs
Team Manager 7+yrs
Sr. Drug Safety Associate 5+yrs
Jr. Drug Safety Associate 3+yrs
Trainee Associate 0-3yrs
MBBS Physician for Medical reviewer 3+yrs

Our offices..

Our **Pune-Hinjewadi** office is operational with full of its capacity, our **UK-London** and **Mexico-Mexico City** offices will start in its operation soon..

Pune-Hinjewadi (India): 201-Creative's Orchid, Punawale-Hinjewadi Link Road, Near Lotus Business School, Pune (411033).



Let’s Make Something Awesome Together!!

Thank you…!

Looking forward to connect via;

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