ICBio®
Excellence in Biosciences

ICBio
Pharmacovigilance Solutions

Safety First
Driving Pharmacovigilance Excellence

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ICBio Pharmacovigilance Solutions

Safety First Driving Pharmacovigilance Excellence

ICBio Excellence in Biosciences

About Us

ICBio is an independent full-service Contract Research Organization (CRO), based in Bengaluru, INDIA established in 2008, specialized in delivering high-quality, end-to-end clinical research solutions like Bioavailability / Bioequivalence Studies, Clinical Trials Phase I – IV, Medical Writing, pharmacovigilance and clinical safety services to pharmaceuticals, cosmetics, medical devices, and nutraceutical companies.

BA/BE study in Healthy subjects & Patient Population, Phase I / First in Human dose,

Clinical Trials Phase –II to IV,

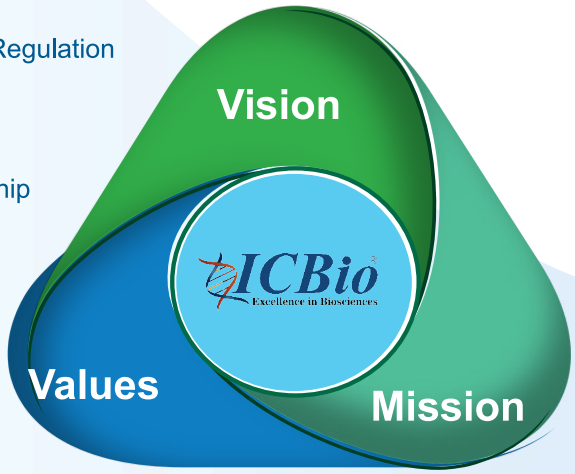
Biometric Services- Clinical Data Management, Statistical Programming Biostatistics Medical Writing

Pharmacovigilance

Connecting services across the product lifecycle

To be a trusted **one-stop destination** for our clients delivering end-to-end services throughout the product lifecycle, with a commitment of patient safety.

- Quality with Excellence
- Patient-Centric Approach
- Commitment to Client and Regulation
- Innovation with Continuous Improvement
- Empowerment and Ownership
- Honesty and Integrity



By embracing a growth mindset and through unwavering commitment and dedication to excellence, we aim to create impactful changes for our clients and patients, ultimately transforming lives worldwide in the healthcare industry.

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ICBio- Experience Expertise Global Reach

Global
56
countries around the globe

70 Plus Staff members

16+
years of experience

7+
Physicians

80+
Satisfied clients

500+
trials supported

7
Accreditation and certification

20+
Therapeutic areas

- Drugs
- Vaccines
- Combination Products
- Biologics
- Biosimilars
- Medical Devices
- Cell and gene therapy products Advanced therapy medicinal products

Tailored Solutions

- Full Service — All CRO capabilities
- Functional Service Provider — Per the given requirements
- Consulting Services

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Why ICBio As Partner

Cost Effective

Single partner Convenience

Tailored personalized solutions

Quality and Compliance with excellence KPI & SLA Driven

Subject matter Experts for each Process (Industry Experts)

Scalability (In- House PV training Programs)

Technology Automation Support

Addressing Your Staffing Needs

01

Easy access to candidates for recruitment In house -PV training institute

02

Efficient and effective training -Process Specific models for onboarding 15 + experience PV Subjetct Matter Experts (SMEs)

03

Flexible pricing models Unit based, FTE,Hourly

04

Flexible bench staff model /Weekend Comp Off and Overtime Options additional requirement

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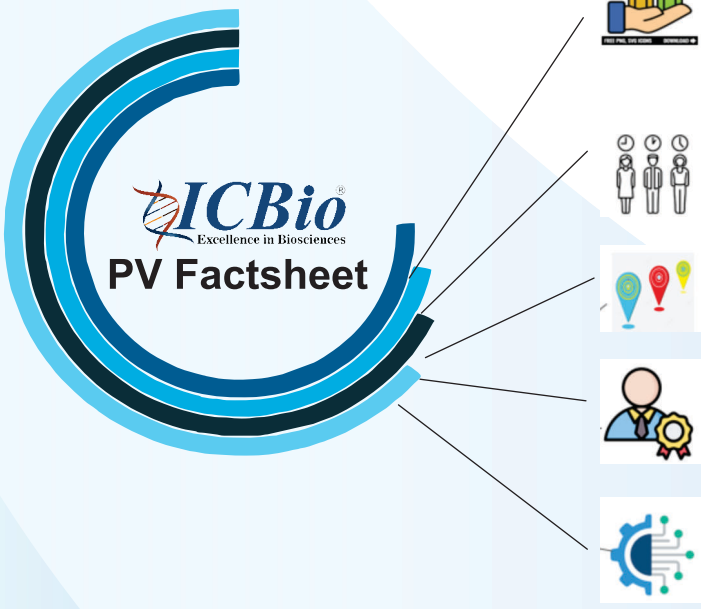
Pharmacovigilance Services Offering

- Individual Case Safety Report (ICSR) Services
- Aggregate Reports Services
- Signal And Risk Management Services
- Literature Screening and Review
- Risk Management Plan (RMP) development.
- QPPV Services
- Pharmacovigilance System Master File (PSMF)
- PV Consulting and Additional Support

ICBio PV Fact Sheet



15+ clients
24000 + ICSR cases - anually
100+ Aggregate reports (PSUR/PBRER/DSUR etc.)
Signal Detection for 50+ products
70000+ Literature Review

20 FTE supporting PV activities
80% of employee HCPs and 20% Physicians

Company Footprint
India-Benglaru (Head Office)/ Mumabi / New Delhi
Global - Australia / LATAM / Kazakhstan

Expertise
15 years of collective experience in PV
in house speciallzed PV Training programs

Technology Infrastructure
Safety Database / supporting end to end ICSRs
Literature search and review
Automation

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Individual Case Safety Report (ICSR)

Introducing our Individual Case Safety Report (ICSR) Services: Ensuring comprehensive and accurate reporting of adverse events for enhanced pharmacovigilance and patient safety. ICBio's ICSR safety team has extensive experience in providing end to end ICSR services and managing various databases, such as ArisG, Argus, AERS/FAERS, and Clinevo Safety.

Case Intake, Receipt & Triage

All Sources (Clinical trials/ Registries/ Spontaneous AE/SAEs Literature/ HA . Activities include Case validity Duplicate Check Reconciliation/ acknowledgment/ Follow Up

Case Processing and Narrative Writing

Data Entry /Coding
Narrative Writing
Analysis of Similar Events

Medical Review and Quality Review

100 % QC of the Cases
Medical assessment
Completing analysis of similar events Medical Cohesiveness Completing causality assessment and evaluating listedness / expectedness of the reported AE

Distribution & Regulatory Submission

Ensuring timely submission of ICSRS to relevant stakeholders (HAs/Sponsors/ LPs/E2B/EV web/)
Follow Up activities

15+ Clients **24000 +** ICSR cases- annually **20 FTE** supporting PV activities

Pharmacovigilance Safety Database Support

ICBIO provides a fully managed and well-maintained pharmacovigilance safety database services (hosting,servers, implementation, upgradation, maintenance, and support) with **Clinevo.**

* Fully validated Clinevo Safety system octp 2.0 in place at ICBio
* Fully compliant to EMA and FDA.
* Compliant with 21 CFR Part 11
* Facilitates quick case processing with auto narratives functionality
* Capable of generating all the regulatory reports (i.e. MedWatch, CIOMS, E2B XMLs [R2] & [R3] reports)
* Enables quick process flow and report generation.
* Assurance on data security and integrity
* Complete Access Control System is in place
* 24x7 user support available for any technical issues

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Aggregate Reports

ICBio, provide reliable and efficient pharmacovigilance aggregate reporting services. We understand the substantial responsibility and effort involved in preparing pre-approval and post-marketing aggregate reports.

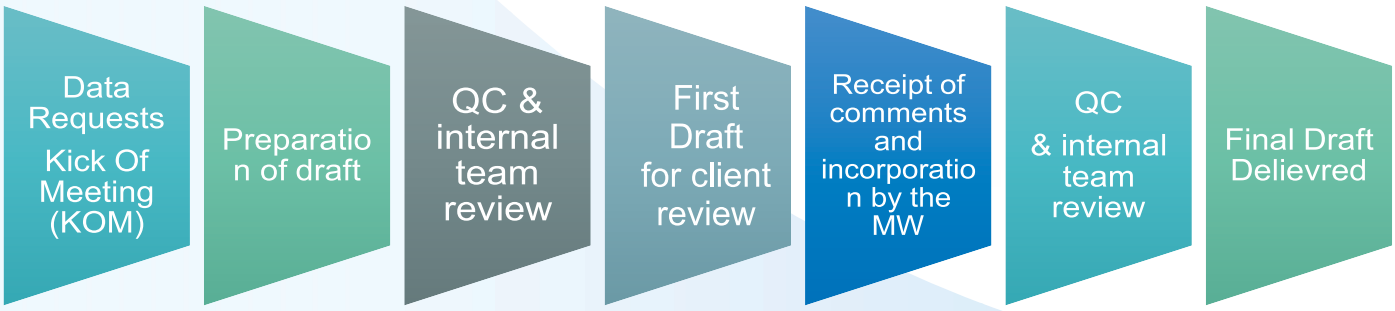
The ICBio medical writing team can support you in the scheduling, alignment, and preparation/ submission of all types of aggregate reports.

Stand-alone or End-to-end Services

* Period Benefit-Risk Evaluation Report (PBRER) and Periodic Safety Update Report (PSUR)
* Development Safety Update Report (DSUR)
* Periodic Adverse Drug Experience Report (PADER)
* Risk Management Plans (RMP)/REMS
* Periodic Adverse Drug Experience Report (PADER)
* ACO
* Health Authority (HA) Requests
* Canada Annual Summary reports
* PSUR Addendum reports, PSUR Line Listings Reports
* SUSAR reports (six monthly)
* Clinical Overviews / Ad-hoc reports, special projects, review of lit & listings,
* Other services (Clinical Expert Statements, Generation of Listings for Aggregate Reports, call for information, Data set Generation,
* Clinical trial Reconciliation, Exposure Calculations, Publishing, Archiving, Translation support.
* Independent Quality Review & Quality Assurance.

For all the reports above, we help determine strategy, review, and analyze data/literature/signals, provide guidance, review, and implement comments.

Aggregate Workflow



Aggregate Experience

20+ Medical Writer

100 + reports

Regulatory compliance **-100%**

Quality meeting/exceeding client expectations

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Signal & Risk Management Services

At ICBio we understand that signal management is crucial in pharmacovigilance for drug safety and patient health protection. The primary goal is to detect new risks or changes in the safety profile of drugs, Thorough analysis and accurate evaluation of data are emphasized throughout the signal management process.

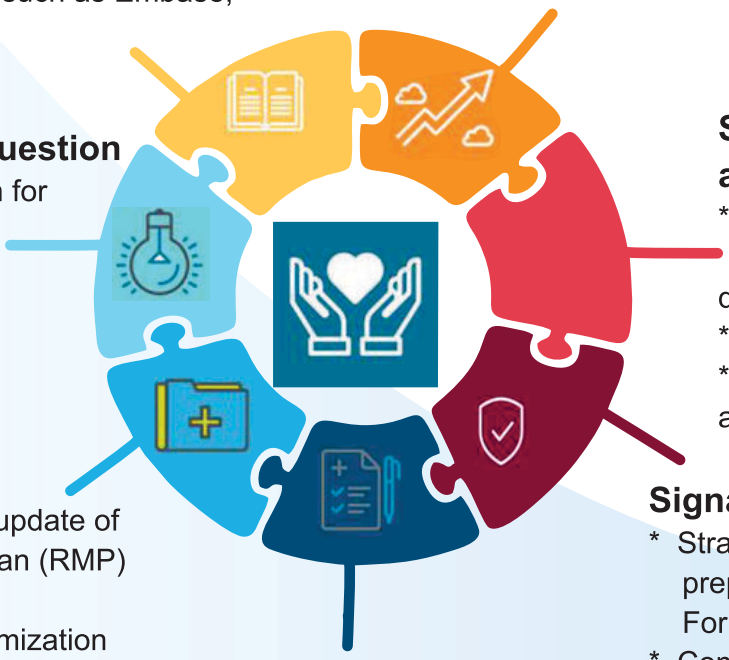
* ICBio has a team of subject matter experts with over 16 years of experience
* A well-trained team conducts comprehensive analysis to detect early signals and its management
* Customized pharmacovigilance signal detection plans and monitoring processes are developed
* Regular internal reviews ensure regulatory compliance for ICBio & signal management services

Signal Detection

* All sources
* Qualitative and Quantitative Analysis
* HA database (EVDAS and FAERS)
* Trend Analysis
* Manual and Automated

Global and local literature screening

* End-to end literature search and review
* Expertise in handling various literature search databases such as Embase, PubMed,



Health Authority Question

* Response preparation for Health Authority Request to Questions

Signal Validation and Prioritization

* in-depth and medical assessment of safety data for validating
* Support of AI
* Single case analysis or aggregate review

Risk Management

Supports creation and update of

* Risk Management Plan (RMP) REMS
* Supporting Risk minimization activities

Signal Assessment Reports

* Stratregizing / Authoring / preparation / Quality / review Formatting / publishing
* Comprehensive analysis aa sources (Safety/literature/ clinical/RA databases/epi etc)

Recommendation for Action and Exchange of Information

* Label updates
* Sharing of information to relevant stakeholders (RA / Licensing partners)

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Signal Management Process Overview

1	2	3	4	5	6
SIGNAL DETECTION	SIGNAL VALIDATION	SIGNAL ANALYSIS & PRIORITISATION	SIGNAL ASSESSMENT	RECOMMENDATION FOR ACTIONS	EXCHANGE OF INFORMATION
Search and identification of the signal through the analysis of any inherent source, such asclinical studies, scientific literature, spontaneous reports, cases found in health databases	Evaluation of the data supporting the identified signal to verify if the documentation is sufficient to confirm the existence of a cause/effect relationship	identifying signs that require immediate management including those that present significant risks or that affect the benefit-risk balance of a drug	signal evaluation in order to detect any new risk, or changes thereof, with a casual association related to the drug an to determine any necessary regulatory actions	evaluating the need to take further actions and defining them appropriately	Exchange of information between all relevant stakeholders such as MAH and competent authorities

Experience

50 +
Signal Detection for products.

70000 +
Literature Review

40 + Signal assessment reports and HA request.

Signal Detection Activities Scope

At ICBio we understand that signal detection and management is a customized process that varies for different products and safety organizations. With our expertise and experience, we offer support for all signal detection (SD) activities across the lifecycle of a product.

- Signal Detection/Review Plan
- Qualitative signal detection using a case-by-case analysis.
- Quantitative signal detection using disproportionality analysis.
- Listings- AESIs, pediatric, elderly, pregnancy, LOE, off-label, med error, mortality
- FAERS/ VAERS- Vigibase
- EMA EVDAS Review
- Literature review
- Event analyses and issue workups

Labelling Document support

Our Labelling Update Services are designed to provide comprehensive support to pharmaceutical companies in keeping their product labelling current, informative, and compliant.

Our Labelling Support Services

Label Assessment : We conduct comprehensive reviews of your product labels,identifying any discrepancies, outdated information, or regulatory gaps.

Labelling Strategy : Our experts collaborate to develop a tailored labelling strategy that aligns with your portfolio and regulatory requirements. We assist in creating templates and guidance documents

Label comparisons and alignment

Labelling Life cycle Management : Our services cover all aspects of labelling life-cycle management, including initial product launches, updates, revisions, and in-market maintenance.

Regulatory Intelligence

Health Authority Responses

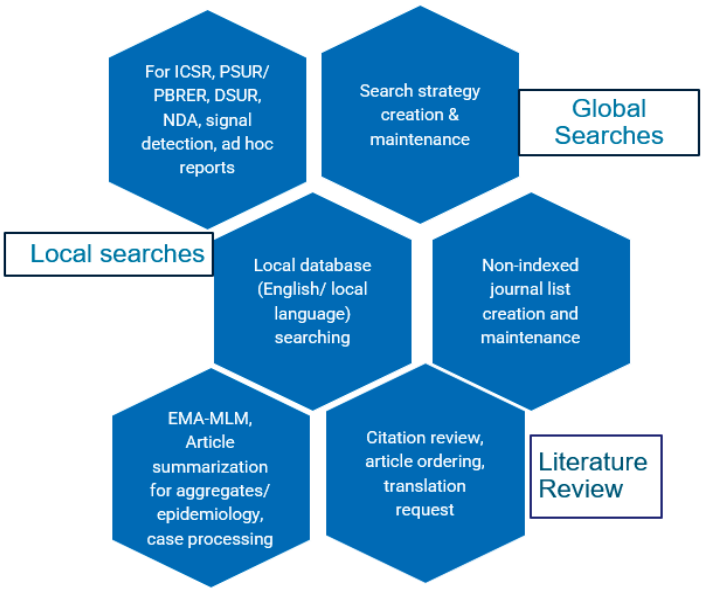
Scope Of HA requests	Safety data, preclinical research outcomes, clinical trial data, monitoring activities, regulatory documentation, submission requirements, and post-marketing commitments
Addressing the Request	Focused Data Analysis - single data source (/preclinical /safety/clinical/literature). Comprehensive analysis in the form of Signal Assessment/evaluation Report
Preparation of Response	Appropriate search and presentation strategy is decided to address the questions. Involvement of Relevant Stakeholders (Safety, regulatory, clinical, pre-clinical, RWD etc.)
Process	Formats–Response Letters /Data Analysis Reports / Safety assessment reports/ Scientific presentations or additional data etc. Relevant Review rounds are conducted, Sign off and Submission
Challenges	Compliance Management - Ad hoc nature, Communication and coordination

Literature Monitoring

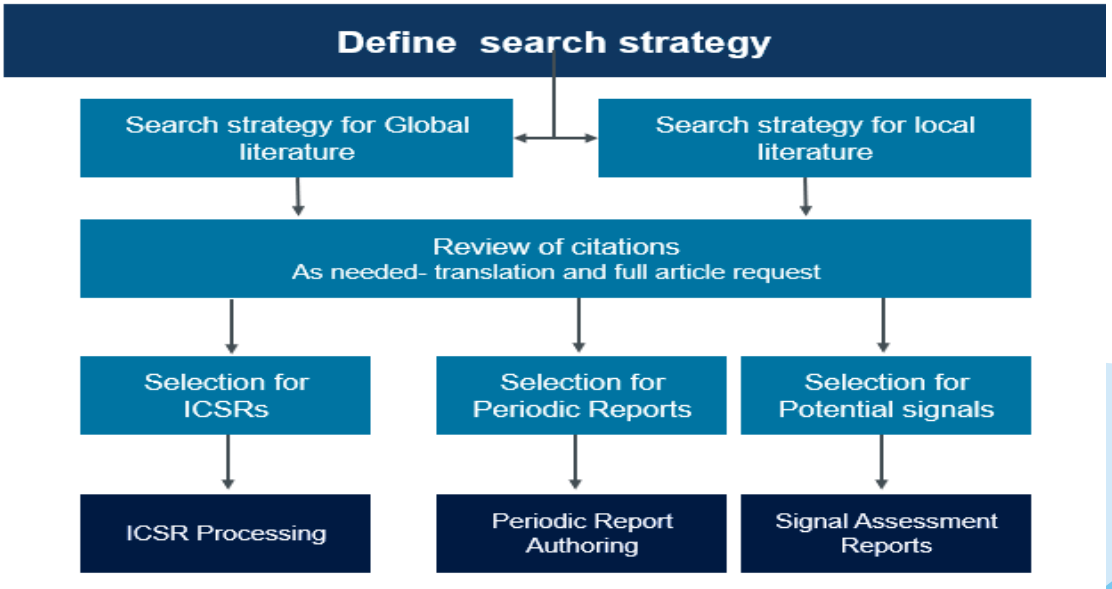
Ensuring constant vigilance across all levels.

ICBio offers a comprehensive Global and Local Literature Monitoring service, which is vital in any pharmacovigilance system. Literature provides invaluable early insights into safety issues and facilitates the capturing of ICSRs and aggregate reports.

Scope Of Activities



Literature Management Workflow

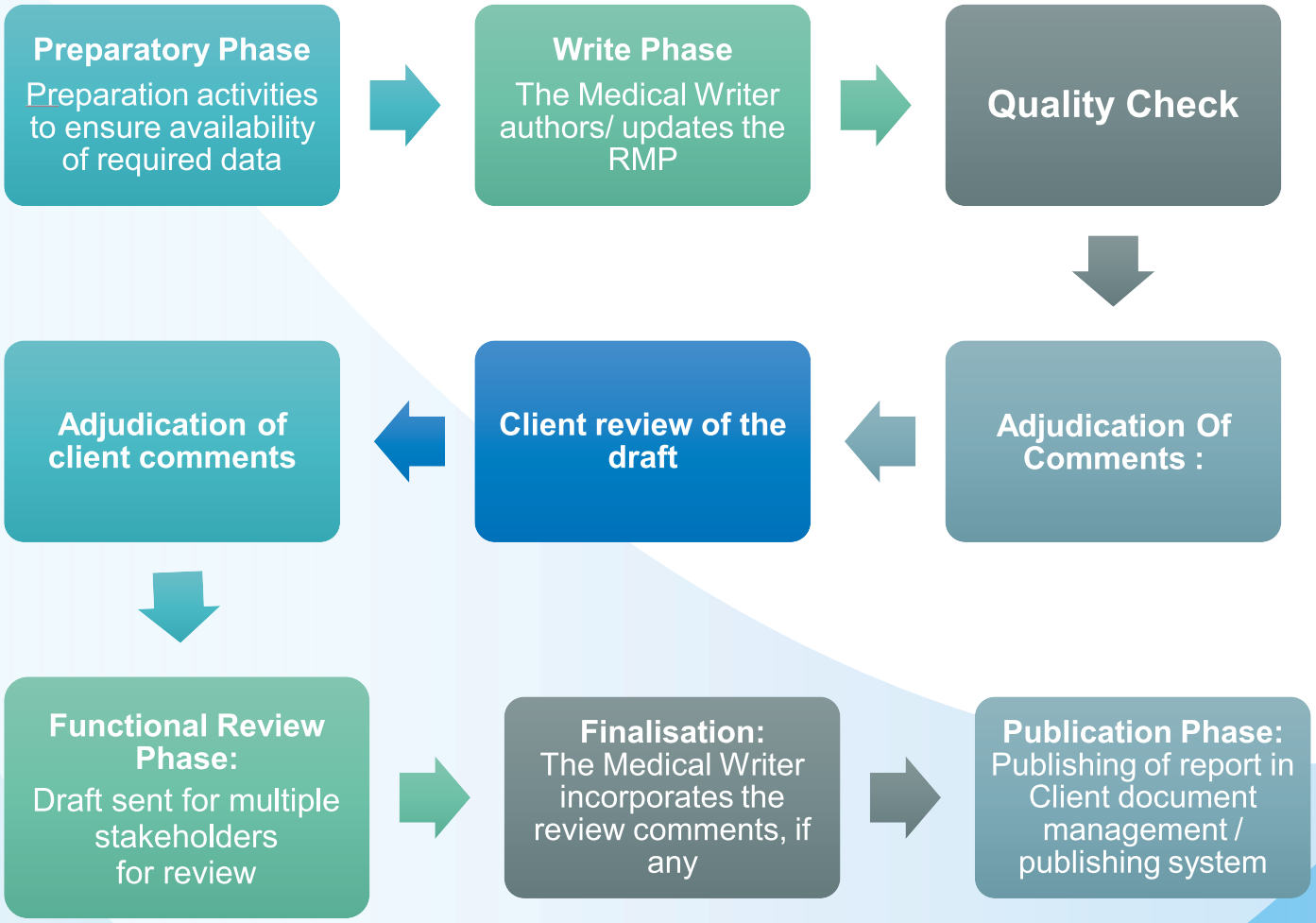


ICBio's Risk Management Support

Enhancing Patient Safety Through Comprehensive Strategies

With ICBio, you can trust that your risk management needs are in capable hands. We understand they differ in elements such as the implementation of risk management pharmacovigilance plans and the reporting-time requirements.

- ICBio can support sponsors in authoring and update of the Risk Management Plans (RMP) and Risk Evaluation and Mitigation Strategies (REMS) to support the marketing authorization applications.
- Our team of experts provides invaluable guidance through strategic advice, meticulous analysis, and proactive measures.
- We specialize in authoring and updating Risk Management Plans (RMP) and Risk Evaluation and Mitigation Strategies (REMS) to support marketing authorization applications, ensuring compliance with regulatory requirements.



QPPV Strategy – Dedicated QPPV Model

Explore how our QPPV services can support your pharmacovigilance requirements and enhance the safety and success of your products.

Reliable Oversight and Implementation

Our QPPV office ensures the smooth functioning of pharmacovigilance systems. They directly oversee implementation and maintenance of a strong pharmacovigilance system for sponsors.

* 24 Hour Contact Point
  QPPV serve as the 24/7 contact point for competent authorities.
* With backup QPPVs in place, we ensure uninterrupted support

Our QPPV plays a key role by

* Defining essential process requirements for compliance in pharmacovigilance.
* Serving as the intermediary between clients and competent authorities for safety-related issues
* Providing clients with regular feedback on critical aspects of their pharmacovigilance system

Local QPPV Requirements

Pharmacovigilance System Master File (PSMF)

We are here to support you in navigating the complexities of PSMF requirements, ensuring your global compliance with pharmacovigilance regulations.

Our services includes: -

* Establishment and maintenance of the PSMF
* Setting up PSMF procedures
* Third-party expert PSMF review and gap analysis
* Template transfer of existing PSMF
* Timely revision of PSMF to reflect significant changes in the pharmacovigilance system

Maintenance of both core EU-PSMF local PSMF(s) and Rest of World (RoW)

* GCC nations (Arab nations): Country-wise national PSSF/PvSF
* India: Pharmacovigilance System Master File (PvMF)
* EAEU countries: PSMF

Our PSMF process is designed to be robust, and risk proportionate. We have established standard operating procedures, defined templates, and checklists to ensure data accuracy and completeness, in full compliance with relevant regulatory requirements.

PV Consulting And Additional Support

EudraVigilance Support

* ICSR submissions through EMA gateway and EVWEB.
* Handling EMA ICSRs and EMA Medical Literature Monitoring (MLM) downloads.
* Support for Article 57 (XEVMPD) compliance, including DMP/AMP submission and MAH/QPPV contact information and updates.
* Download electronic Reaction Monitoring Reports (eRMRs)
* Extraction of EVDAS line listing for safety signals and benefit-risk analysis

Regulatory Intelligence

* Pharmacovigilance consulting services on regulations for individual countries.
* Region-wise product-specific (drugs, device, or biologics) guidance and Pharmacovigilance consultancy.
* Country-specific regional ICSR and aggregate reporting timelines and requirements.
* Local representation (QPPV, NPPV, etc.) and post-marketing authorization information

Pharmacovigilance Audits and Training

* Comprehensive support in pharmacovigilance training and audits, helping with plans, findings, programs, and recommendations..
* Aligning your processes and products with quality, information security, compliance, and regulatory requirements, including GVP/GCP guidelines.
* Our services help you maintain compliance with policies, plans, procedures, and laws, complying with evolving regulatory requirements

SOP writing and Training Servies

* Our authoring services catering to diverse area of PV services including process, information technology, quality management review and clinical research SOPs.
* Support provided for preparation, review and change management.

Quality Management System

The Quality System is part of the Pharmacovigilance System and consists of its own structures and processes.

* Managing quality, regulatory, and information security at the organization level
* Providing quality compliance services and ensuring compliance with applicable guidelines and legislations of the USFDA, EU, MHLW, ICH-GCP, 21 CFR Part 11, PIC/S, GAMP 5, HIPAA, CSV standards, data transfer content standards, ISO 27001, and 9001 Standards
* CAPA Management- Plans CAPA, triages CARs, and performs RCA.

Quality Management

Process/ Documents

Project specific Training Plans

Client's or ICBio SOPs clearly defining workflows and responsibilities

Formalized QC checklists

Planning document to capture key decisions, data responsibilities and timings

Timeline Compliance

100 % regulatory submission timelines

Others:

Kick-off meeting on time

First draft sent on time

QC comments addressed on time

Quality Compliance

Client or ICBio Specific KPIs

Quality parameters:

Scoring based with threshold criteria

KPI data shared at regular intervals: monthly/quarterly

Training management At ICBio

To ensure competency and appropriate qulification of the personnel to achieve the required qualit of the PV processes

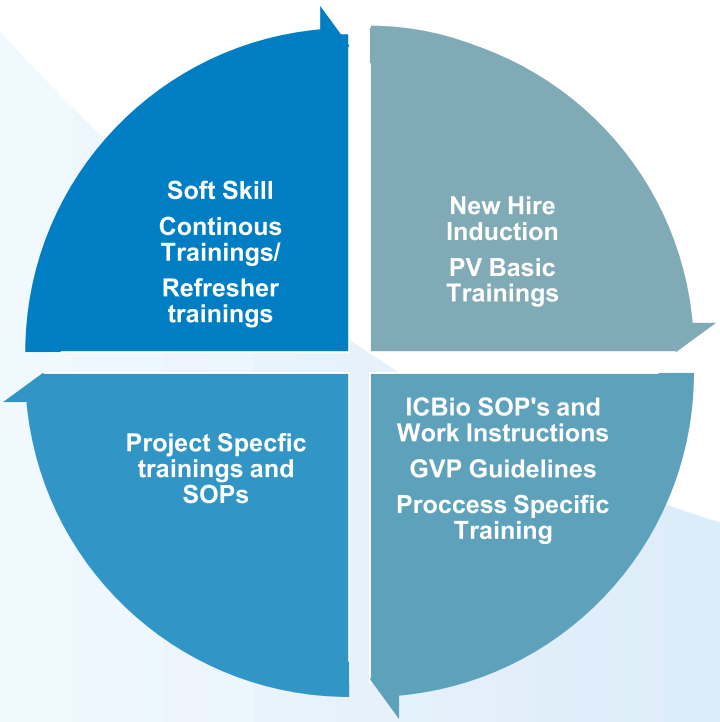
To provide basic and continuous training to all personnel involved in performing PV activities according to their job Descriptions

To document the competencies of the personnel by archiving training plans and records

To ensure continuous improvement of relevant skills, scientific progress and professional development of the personnel to enable appropriate understanding of relevant PV requirements and experience for assigned tasks and responsibilites

To checks training results for the appropriate level of understanding for the assigned task and responsibilities

To ensure adequate training for personnel with no specific PV tasks and responsibilities



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Please feel free to reach out to us
We look forward to assisting you

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