ICBio Pharmacovigilance (PV) Solutions

Safety First

Driving Pharmacovigilance Excellence

www.icbiocro.com

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About us

ICBio is an independent full-service Contract Research Organization (CRO), based in Bengaluru ,INDIA established in 2008 providing comprehensive, quality & integrated and end to end clinical research solutions; specialized in providing Bioavailability / Bioequivalence Studies, Clinical Trials Phase I – IV, pharmacovigilance and clinical safety services.

Phase I

First in Human dose

BA/BE study

(Healthy subjects & Patient Population)

Clinical Trials

Phase –II to IV

Biometric Services

Clinical Data Management,

Statistical Programming

Biostatistics

Medical Writing

Pharmacovigilance

Connecting services across the product lifecycle

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Our Identity: Who We Are ?

- 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

Safety First Driving Pharmacovigilance Excellence

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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

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Pharmacovigilance Service Offerings

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

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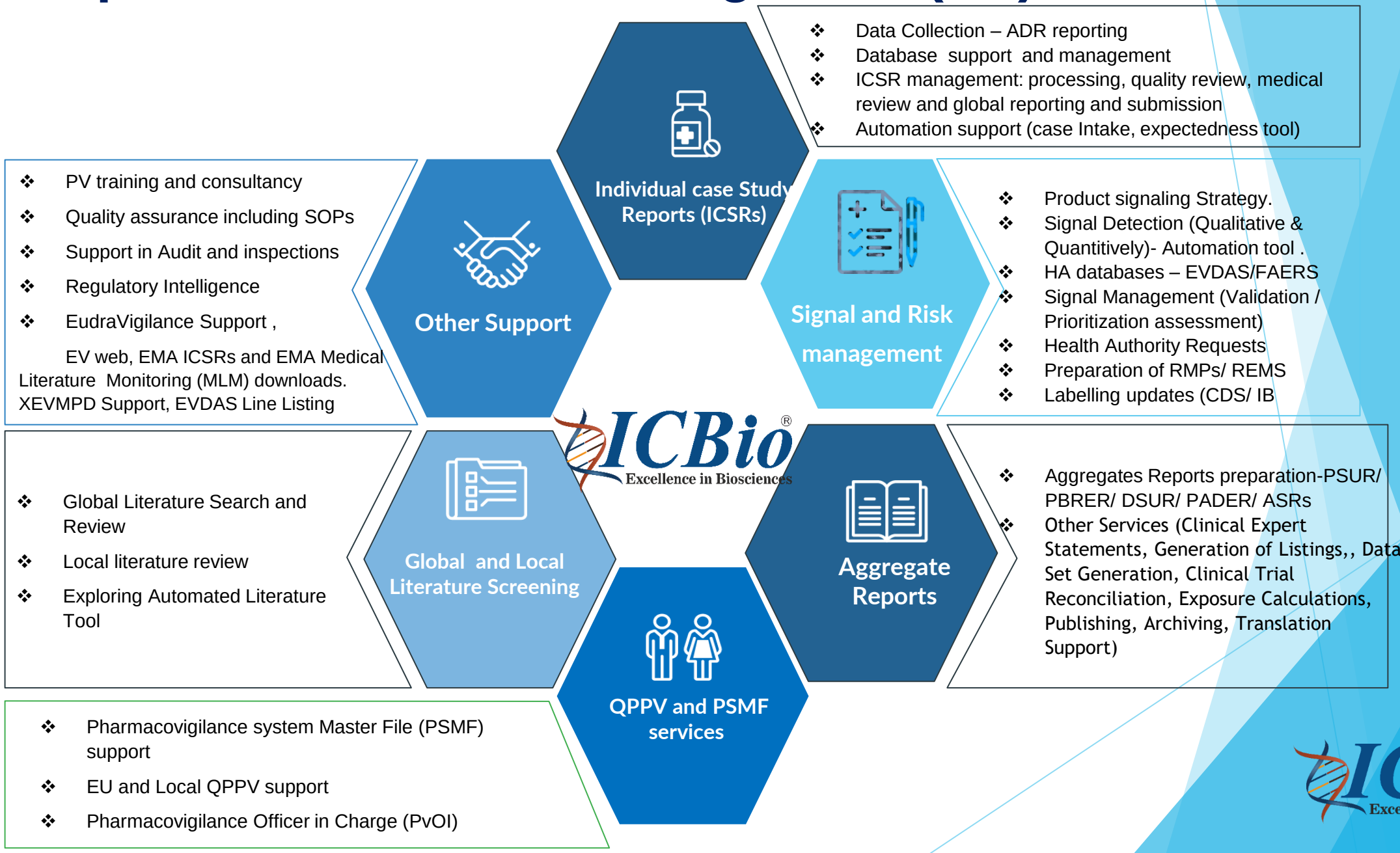
Comprehensive Pharmacovigilance (PV) Solutions



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ICBio PV -Fact Sheet

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PV Factsheet

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 specialized PV Training programs

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

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Why ICBio ?

Cost Effective

Single partner Convenience

Across Product lifecycle

Tailored personalized solutions

Flexibility/Dedicated Project Teams

Scalability

In house PV trainings Programs

Quality and Compliance

KPI & SLA Driven

Technology / Automation Support

Global Reach

Strong Customer Base

Subject matter experts Each Process

(Industry Experts)

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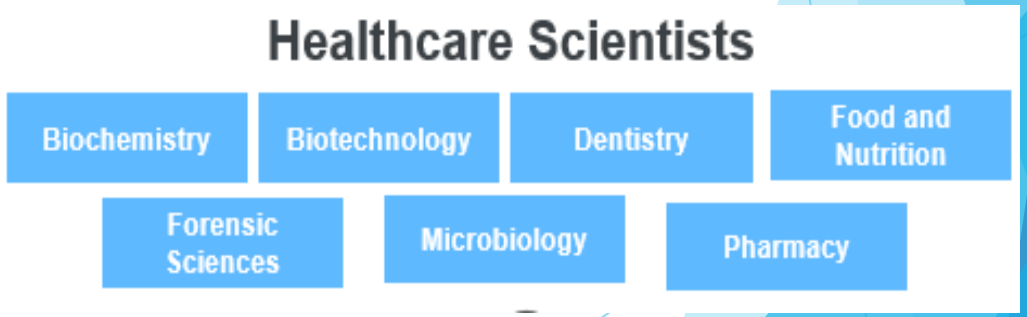
Technical expertise of our PV staff

- 08 Physicians
- 12 Pharmacists
- 02 Dentists
- 30 Life scientists
- 25+ Others

Each of our scientists has a university degree in pharmacy, life sciences, or dentistry

Senior	5 to 8 Years
Mid-level	4 to 5 Years
Junior	0 to 2 Years
Project Management	8 to 25 Years



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Individual Case Safety Report (ICSR)

Case Intake, Receipt & Triage

All Sources (Clinical trials/ Registries/ Spontaneous AE/SAEs Literature/ HA .

Activities include

Case validity

Duplicate Check

Reconciliation/ acknowledgement/ 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

Submission

Distribution & Regulatory

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

Follow Up activities

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Clinevo- Safety Database

- 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

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.

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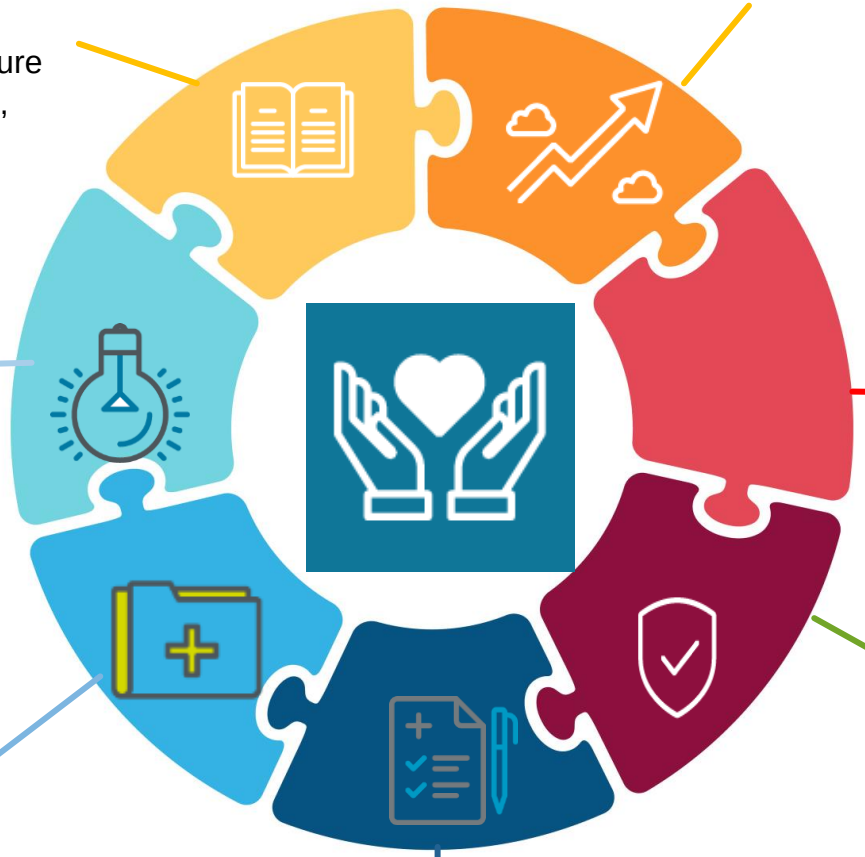
Signal And Risk Management

Global and local literature screening

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

Signal Detection

- All sources (safety database/literature /clinical database etc)
- Qualitative and Quantitative Analysis
- HA database (EVDAS and FAERS)
- Trend Analysis
- Manual and Automated



Health Authority Questions

- Response preparation for Health Authority Responses / Request to Questions

Signal Validation and Prioritization

- in-depth review and medical assessment of safety data for validating signal
- 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

Strategizing /Authoring/ preparation / Quality review/ Formatting/ publishing
Comprehensive analysis all 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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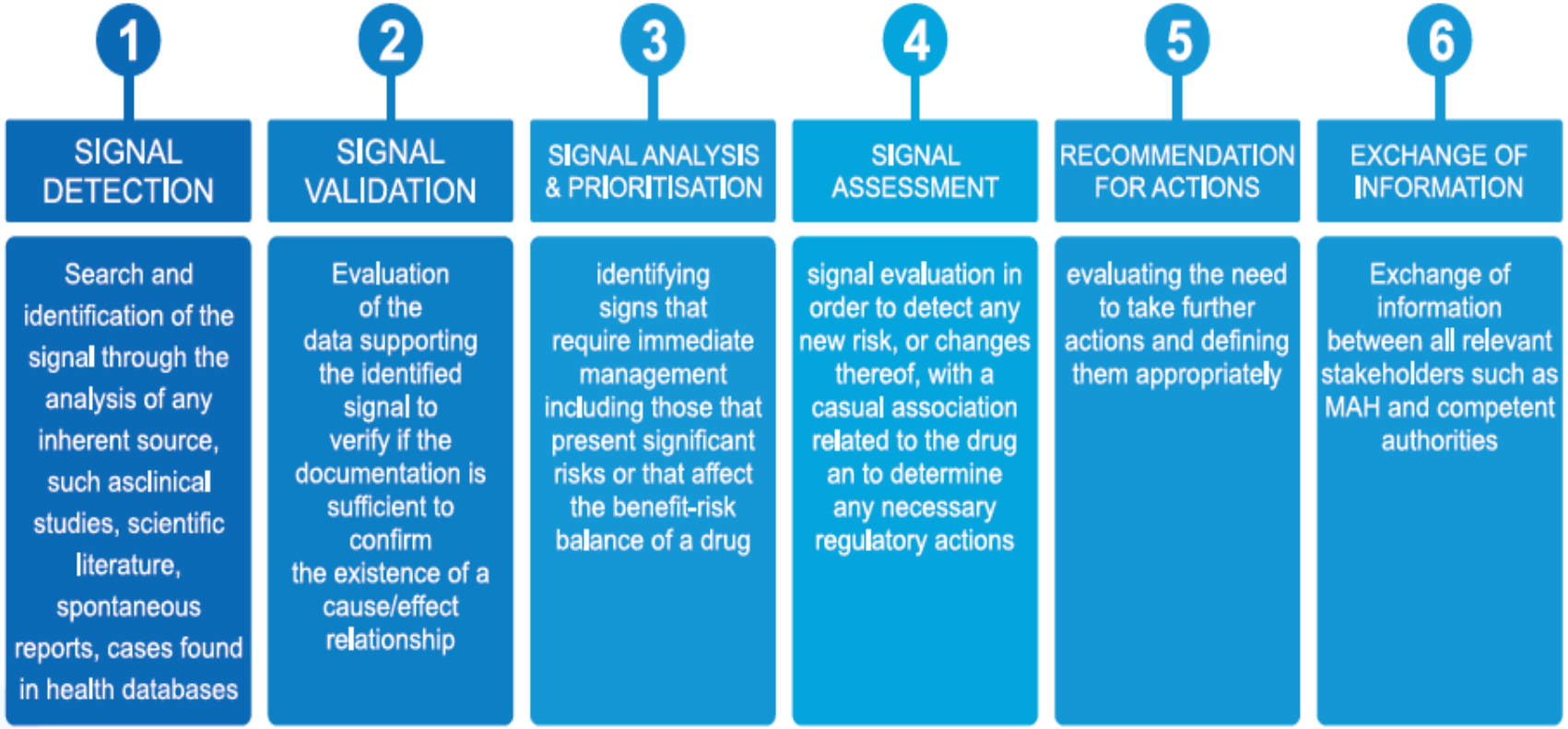
Signal Management Overview



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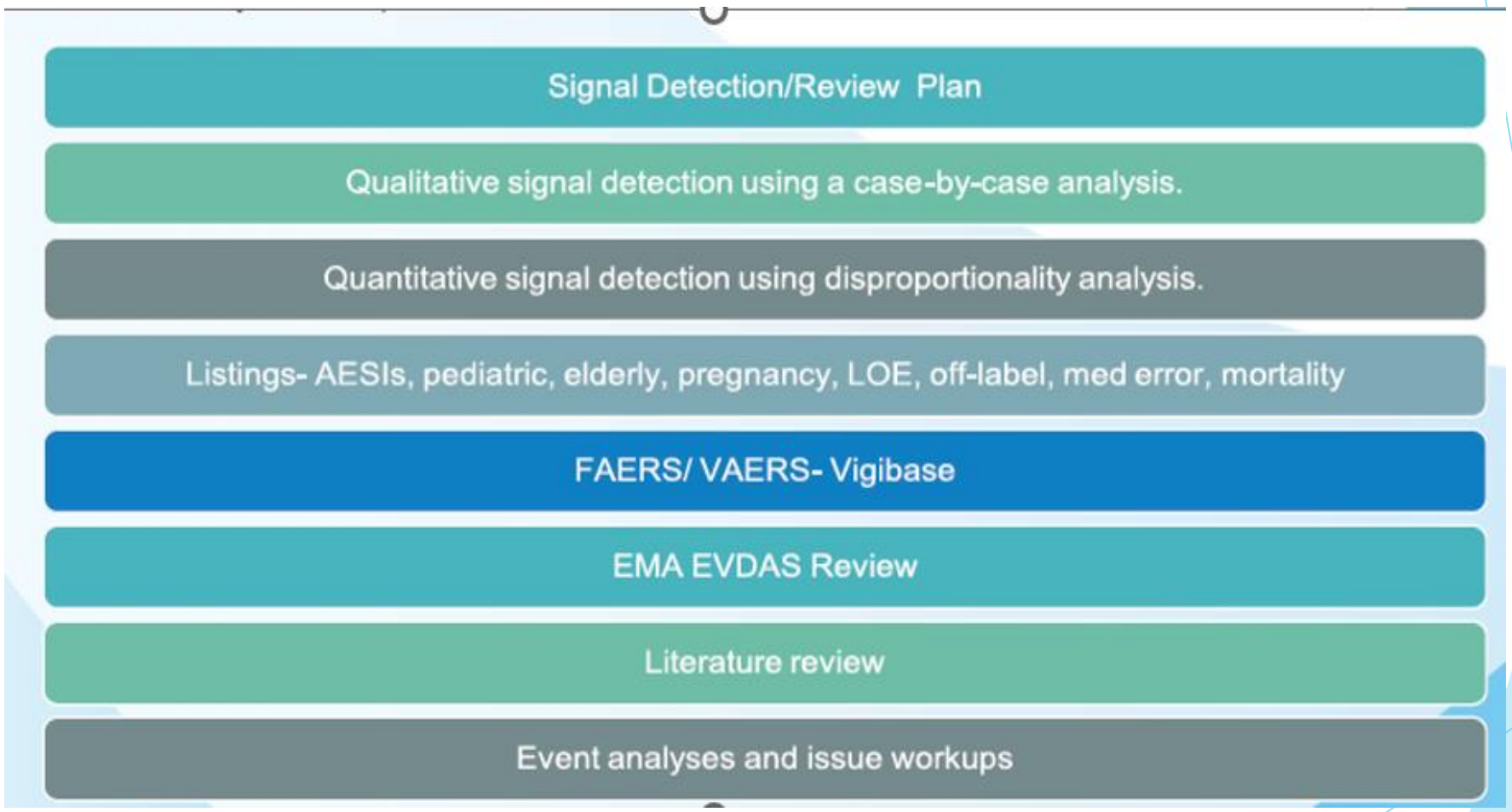
Signal Detection Activities



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Labelling 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

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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

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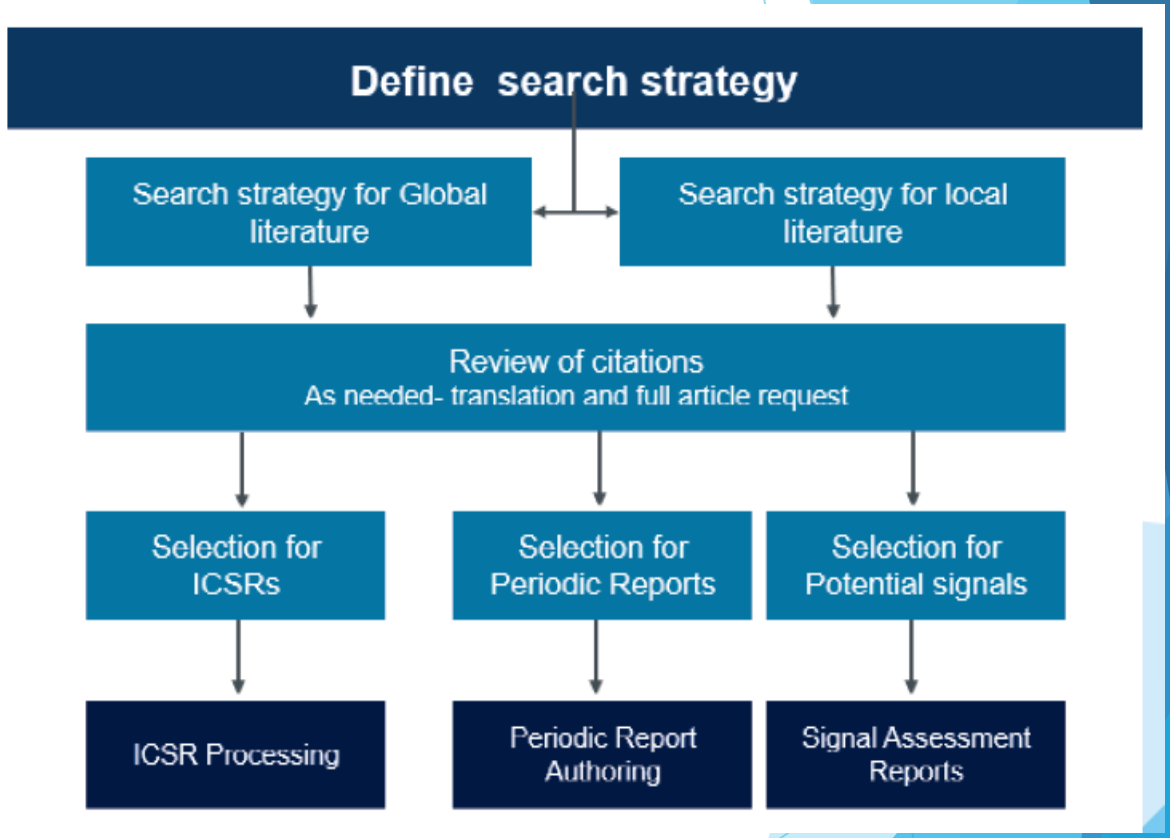
Literature –Scope Of Activities



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QPPV , PSMF and PV Consulting Services

QPPV Services

EU and Local QPPV Support, Local Contact Person or National Contact Person for Pharmacovigilance

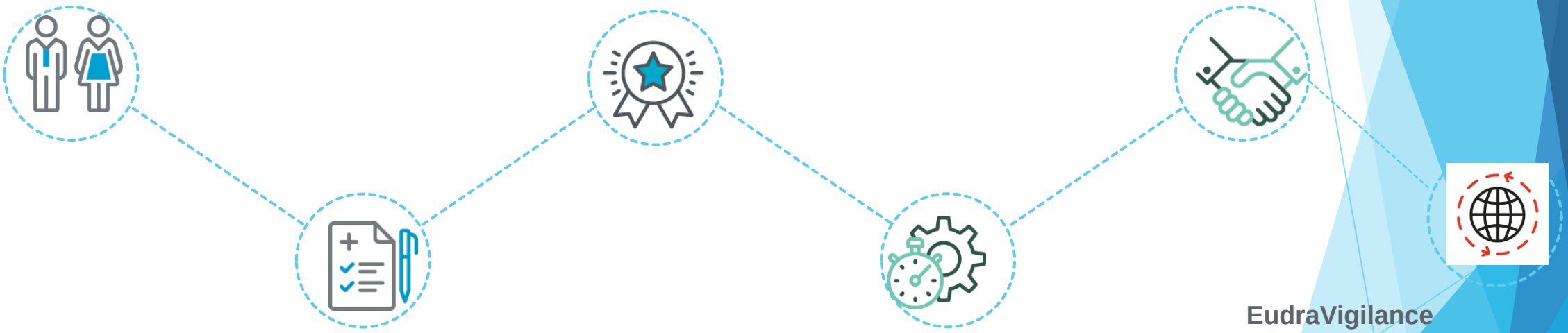
Support in Audit and inspections

Preparation, implementation of regulation, inspection readiness, Documentation Management

Regulatory intelligence

RI activities for current trends, regulatory updates, changes in the guidance's

Impact Assessment



PSMF Support

Global and Local PSMF solution

Country-wise national PSSF/PvSF, India: Pharmacovigilance System Master File (PvMF), EAEU countries: PSMF)

Establishment/ Setting up and maintenance PSMP Procedures

SOPs

Development /update and maintenance of process related SOPs

QMS – Support

EudraVigilance

EMA website, Handling EMA ICSRs and EMA Medical Literature Monitoring (MLM) downloads. Support for XEVMPD compliance, Extraction of EVDAS line listing for safety signals and benefit-risk analysis.

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QPPV Services

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

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PSMF activities

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 Services

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.

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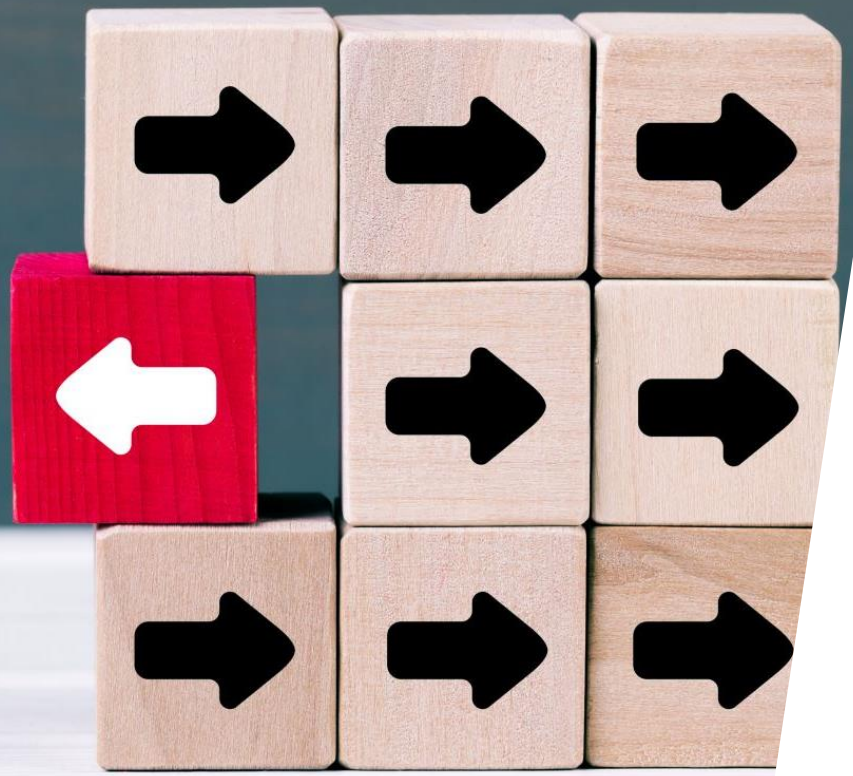

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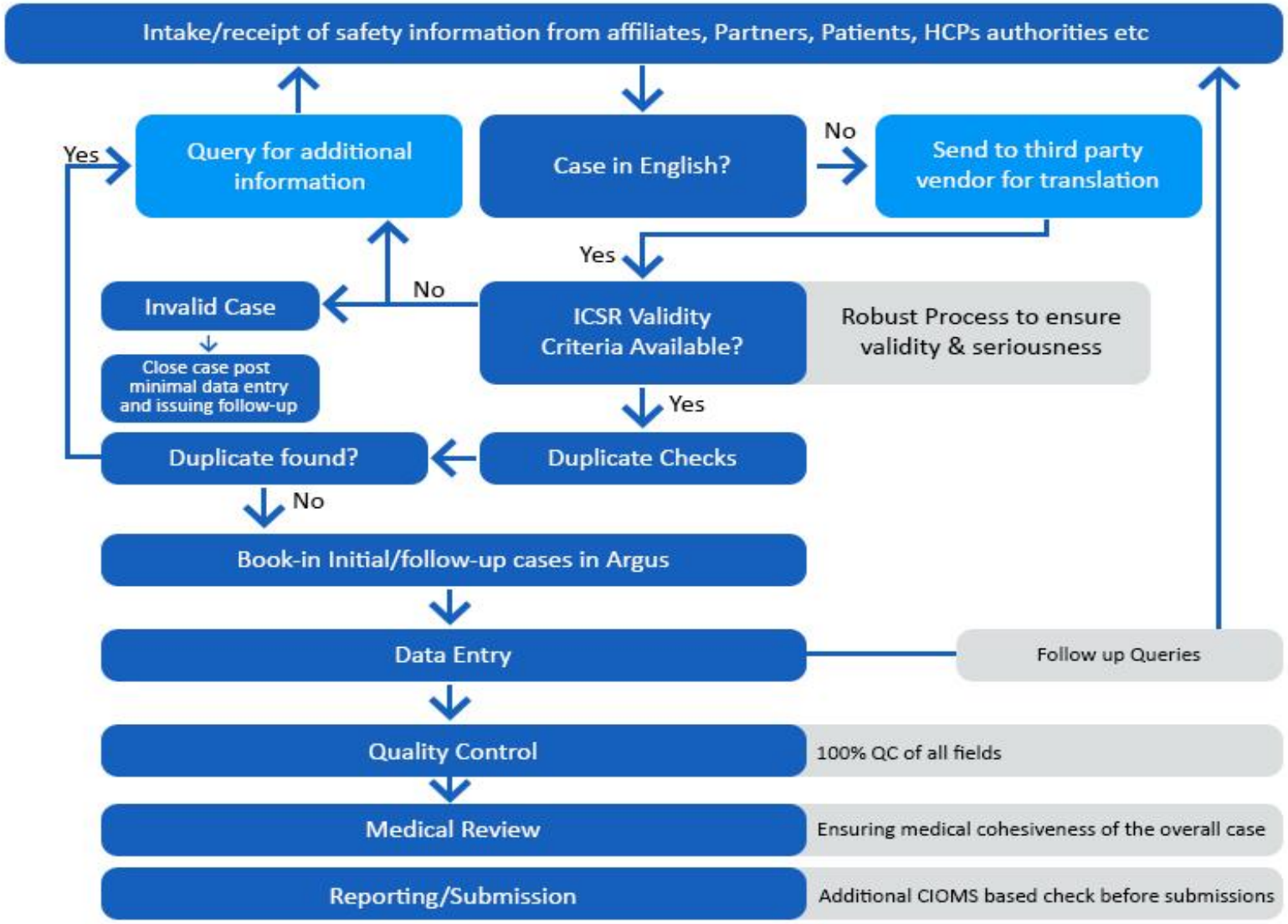
Process Workflows

ICSR processing workflow



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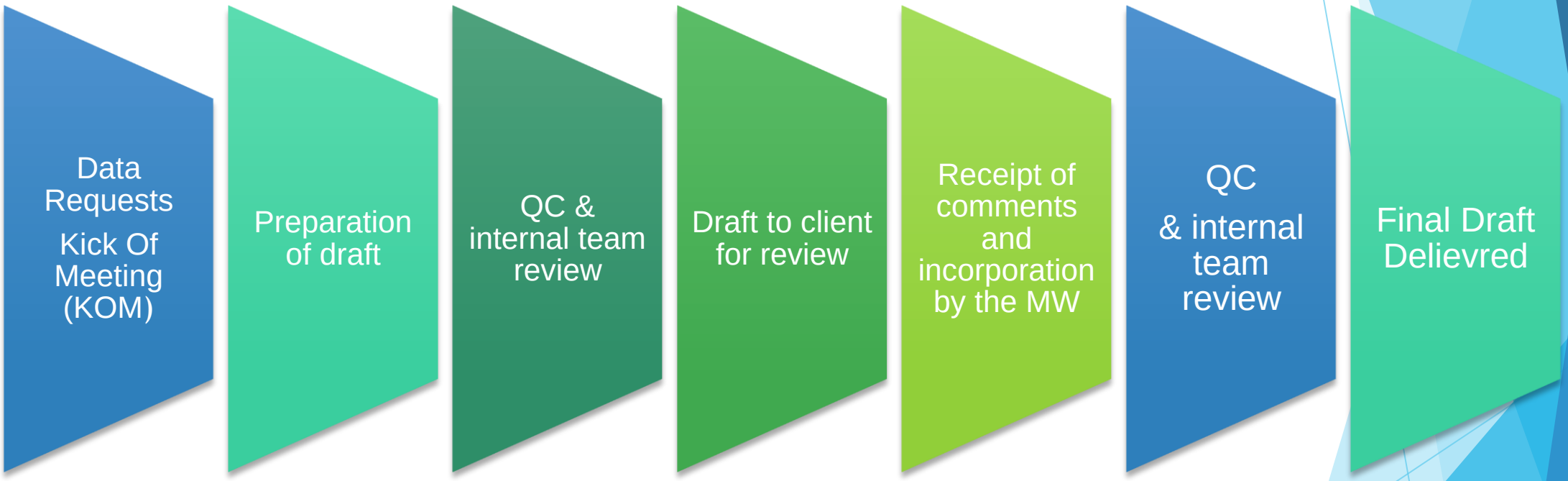
Aggregate reports– Document writing



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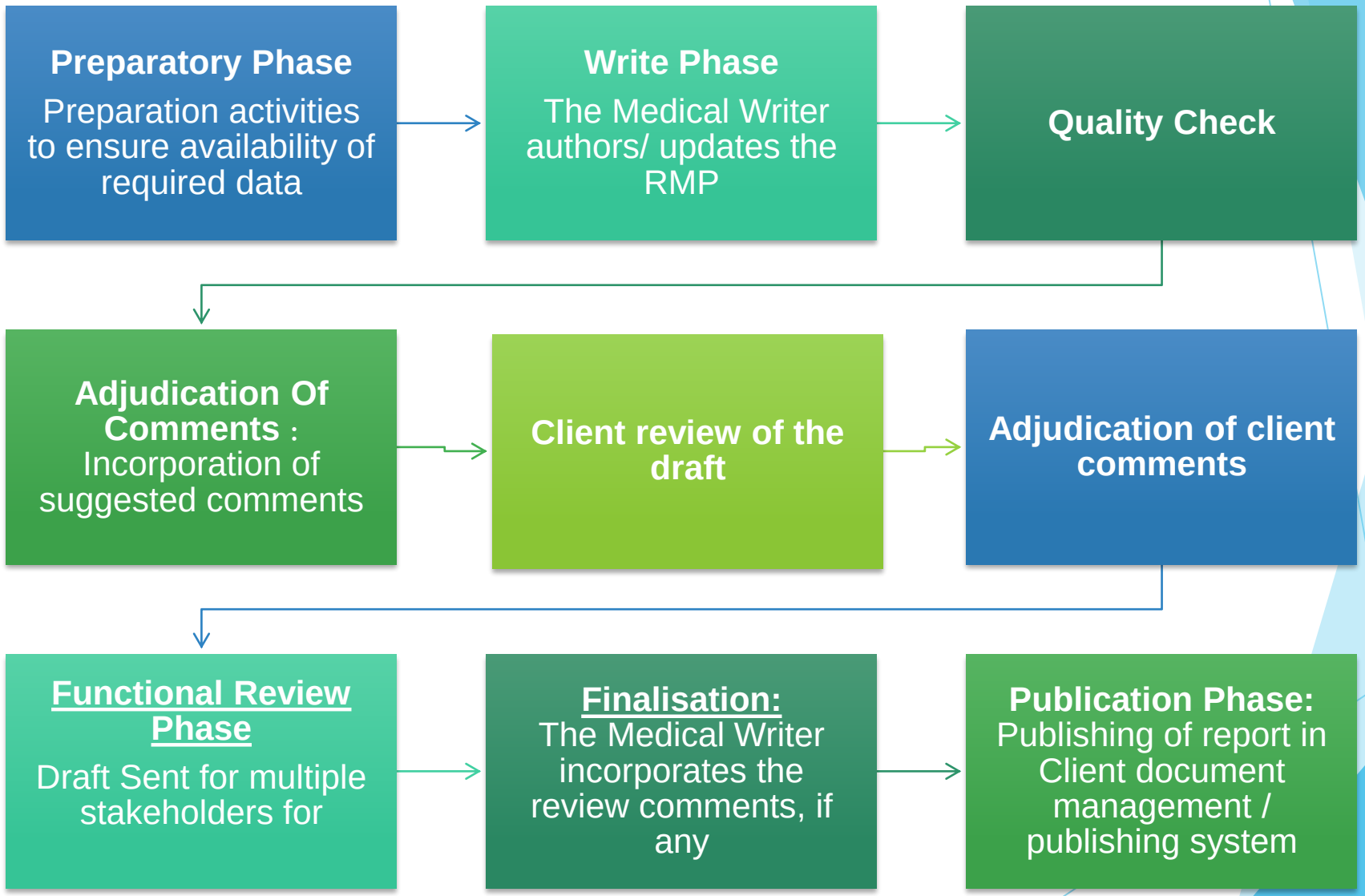
RMP Authoring – Workflow



Quality management system

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

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ICBio Training Methodology

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

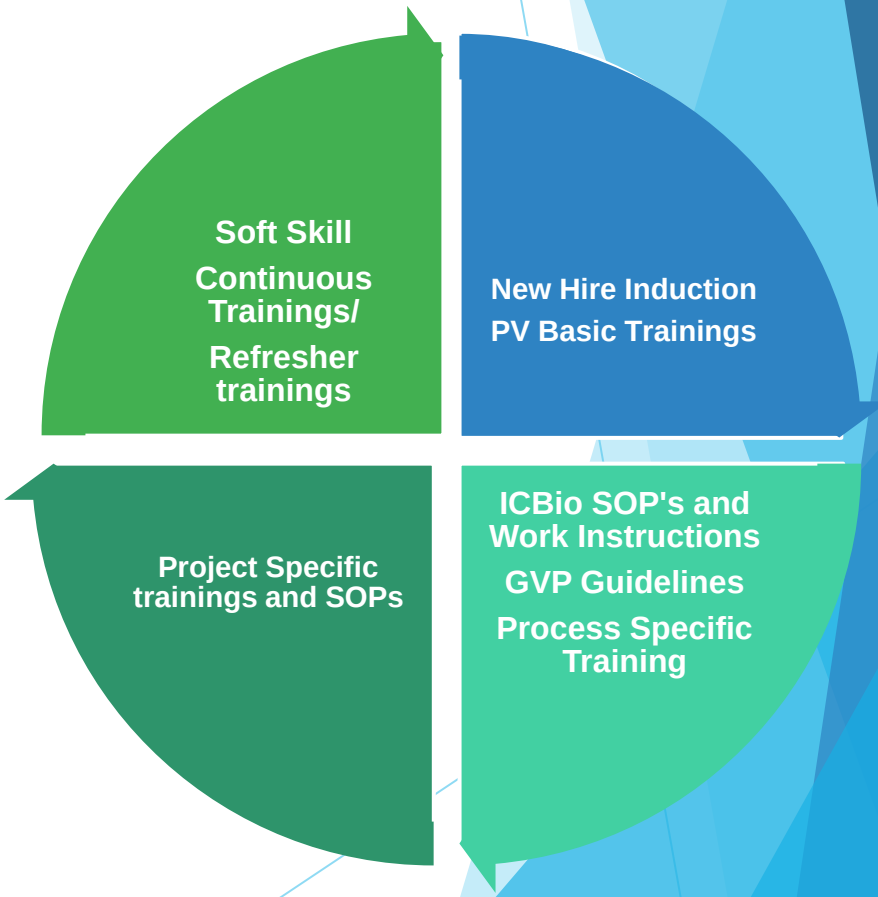
To provide basic and continuous training to all personnel involved in performing PV activities according to their job Descriptions

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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Delivery elements for success

- Team resourcing
- Transition approach and ramp-up
- Training and knowledge transfer
- IT connectivity and infrastructure planning
- Establishing operational processes
- Governance, quality management and key performance indicators
- Risk assessment and business continuity planning

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Future – Automation in PV

- PV advance analytics using Analytics database (PowerBI)
- Literature retrieval Automation
- Quality Check (QC) and Compliance trackers
- A common track wise program/database for ICSR's, Literature review, Aggregate reports and Signal detection for tracking the updates for timely completion of deliverables with in the TAT timelines.

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We look forward to assisting you, please feel free to reach out to us !

ICBio Clinical Research Pvt. Ltd.

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Connect With Us ……..

We look forward to assisting you, please feel free to reach out to us !

RFP Link

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