Smart sourcing strategy in pharmacovigilance

A Blue paper on pharmacovigilance partner selection

SCIFORMIX

Introduction

Strategic outsourcing is a multi-dimensional activity. Planning the outsourcing and implementing it requires sponsors to consider both the macro and the micro pictures. The macro picture includes sponsor's own growth strategy and attitude towards risk associated with outsourcing the process and the micro picture, includes tactical details of how the process will be supported by an outsourced partner.

Clients usually outsource to (a) augment capacity, (b) to rationalize cost or (c) to introduce rigor into their processes and bring them in line with industry benchmarks.

Typical approach towards Pharmacovigilance outsourcing is overwhelmingly tactical, largely due to organizational culture of risk aversion, perceived 'sacredness' of data and lack of sourcing experience and capability. However, on the contrary, for a process such as Pharmacovigilance, which is knowledge-based and is governed by stringent regulatory norms and compliances, it is especially important to take a long term strategic view of sourcing imperatives.

Sourcing strategy varies based on what, when and how the sponsor would want to out source. A series of decisions, related to choice of a pilot or a permanent contract, approach of migration to steady state, vendor management, KPIs (quality, cost, time) and success measures, have to be made. Partner selection is a vital step in the chain of decisions that leads to strategic outsourcing.

This paper discusses our proprietary model which we have used to help our clients out source their Pharmacovigilance operations smartly, primarily by choosing the pharmacovigilance partner smartly.

Sciformix' Framework for Outsourcing of Pharmacovigilance Operations

We have experience of managing Pharmacovigilance operations for the past 3 years and processing literature, spontaneous, regulatory, medico-legal and clinical trial cases for over 800 products originating from over 120 countries.

Based on this experience, along with our participation in industry benchmarking forums focused on Pharmacovigilance operations, we have developed a proprietary model and framework that facilitates choice of the right approach to Pharmacovigilance outsourcing and is consistent with the client's strategic objectives.

We have used this model to help our clients identify the right fit and to determine the extent and volume of scale-up, thus leading to a successful outcome of their outsourcing initiative. Many processes that we have transitioned offshore based on this model are currently in steady state and we continue to evolve this model based on the lessons that we learn from each such transition.

Our partner assessment model has been discussed in various industry group meetings and the basis of the model has been validated by practitioners of Pharmacovigilance from US and Europe.

Our assessment framework provides a roadmap to outsourcing PV operations based on maturity of the current in-house process and provides recommendations on partner selection model customized to the specific needs of our clients' product vigilance process. As a second step, our model provides quantitative measures of process transition and key milestones to ensure a successful outcome.

Partner Assessment Model©

Our framework involves an assessment of the overall pharmacovigilance processes, across three broad categories of service providers: Global CROs, Regional CROs and Large IT companies that offer BPO capabilities. Assessment is performed against six different criteria.

The six assessment criteria are:

- Operational Capability
- Regulatory Compliance
- Technology
- Team
- Process Maturity
- Business Factors

Figure 1 shows the outcome of an assessment we conducted for one of our clients. Based on publicly available data, each category was rated across the three different types of service providers considered and Sciformix, and the ratings were compared with the industry benchmarks. The client used this information to formulate their sourcing strategy and Sciformix was awarded the engagement to support their PV operations from our delivery center in Pune, India.

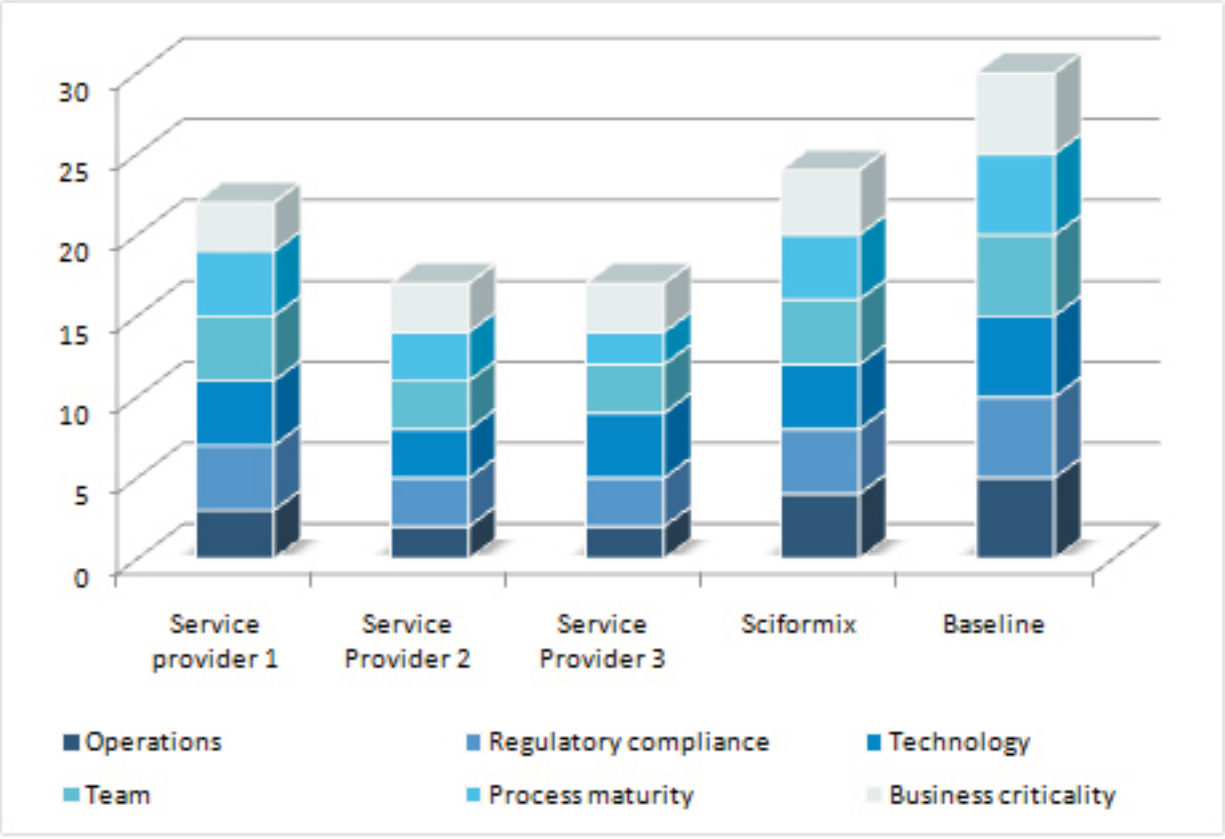


Figure 1: Example outcome of an assessment conducted for one of our clients prior to executing their outsourcing initiative

Each of the criteria utilized in the model includes 3 to 10 factors. Operational capability, one of the criteria considered, addresses factors like number of global sites/hubs for the PV team, competence to perform varied tasks associated within Pharmacovigilance like literature search & review, periodic reporting, CCDS/label update and signal detection. Process maturity on the other hand evaluates standardization within the process being followed at the provider, employee productivity, employee training etc.

- We employ our proprietary Product Vigilance Process Maturity Model© to assess the overall process as it is currently executed with our client, and its comparison vis-à-vis industry benchmarks. The assessment is performed against six different criteria, each of which is supported by multiple assessment factors. Five of the six criteria are related to the critical components of case processing-

- Case Receipt
- Triage (Seriousness/Expectedness)
- Case Content
- Medical Review
- Follow-up

The sixth one is about Capacity Management. This assessment helps our client(s) evaluate their processes against the industry baseline for case processing operations and helps identify next steps in maturing their processes and in outsourcing.

The key outcome of this assessment is a recommendation for the optimal choice of partner organization for the execution of an outsourcing initiative in the context of managing the associated risk.

Outsourcing Approaches

We apply our Partner Assessment Model© and Product Vigilance Process Maturity Model© in the context of the client's approach to outsourcing. Our insightful and customized application of our tools helps our clients make and implement the right decisions.

Risk-based approach

If opting for a risk based approach to outsourcing, a sponsor might want to lower the risk by selecting low complexity activities, products or case types to be externally sourced. The first step is to clearly determine what can be considered as "low risk" from both the product portfolio and process complexity perspective.

While this approach might safeguard perceived 'sacred cow' in the short term, if one of the objectives for the initiative is to rationalize overall case costs, this approach may not provide the most optimal solution. For example, if the client organization's current operational model is to have a single person handle a case from cradle to grave, the process may not be amenable, without some re-engineering, to be handled in a structured manner with an outsourced partner.

On the other hand, if the current process is reasonably de-constructed, it may allow easier transition of perceived "low risk" activities such as case entry, MedDRA coding and safety narrative writing in order to build confidence with the outsourced partner and yet meet cost rationalization objectives.

Deconstructed process approach

A deconstructed process approach allows individual steps within a process to be separately outsourced. For example, it would make it possible to retain case intake and submissions internally or to outsource it separately, and include case entry, coding etc. in the central sourcing strategy.

However, the sponsor would be required to invest significant time and effort upfront in standardization of the process and the hand-offs across various partners. In the longer term, the primary role of the sponsor will be to manage the hand-offs between various sourced partners.

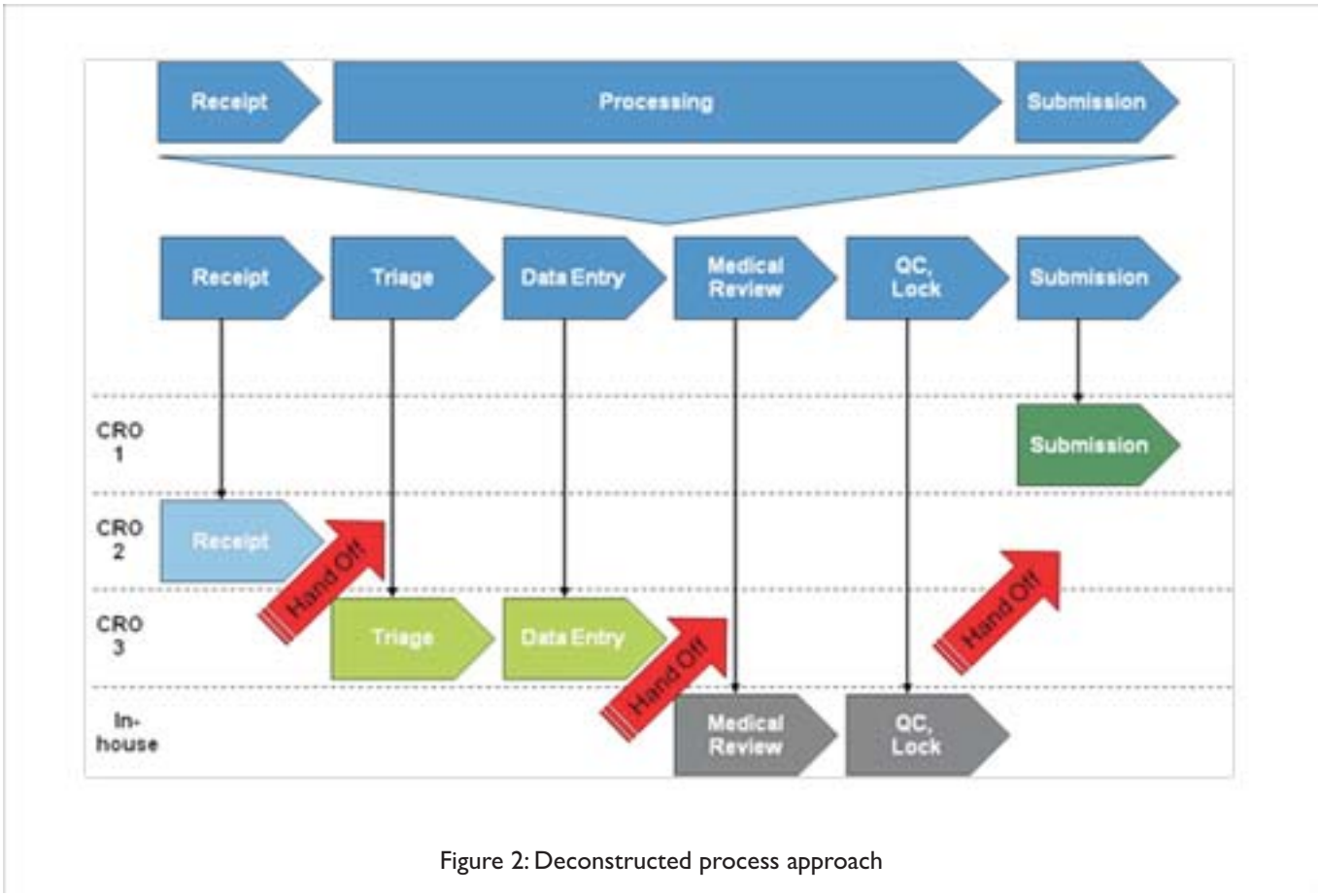


Figure 2: Deconstructed process approach

Figure 1 shows how a deconstructed process works across multiple providers. The biggest challenge in this approach is to arrive at the most optimum level of deconstruction to ensure effective management of hand-offs between various partners.

Since pharmacovigilance is a time sensitive process, a poorly deconstructed and inefficiently handled process manifests itself in late submissions. For example, if the case intake and case processing activities are handled by two different providers, managing follow-up calls becomes very critical. In our experience, for spontaneous AEs, when the process reaches steady state, approximately 30% of the cases reported to the call center require active follow up. If the follow up activity is handled by a different provider, chances of calls being dropped is higher, leading to poor case quality and lower timeline compliance.

The sponsor in this case ends up spending an inordinate amount of time reconciling processes across two different providers and we have operational data to substantiate such findings. Our tools incorporate this learning and it manifests in the form of the weights that we assign to various factors for the evaluation criteria while developing an optimal sourcing model for our clients.

The Sciformix Approach to Benchmarking and Transition

We have developed a series of measurable and quantifiable metrics which enable us to compare our client's processes against industry benchmarks and best practices.

Product Vigilance Transition Index© provides a recommendation which we flesh out collaboratively with the client team along 5 defined dimensions.

One of the other key outcomes of this assessment is a recommendation for the optimal pace of execution of an outsourcing initiative in the context of managing the associated risk. This is quantitatively captured in the Safety Transition Index©.

Index	Client Status
1-3	Client's process and operations are not ready to be outsourced. Recommended steps are to introduce rigor in the existing process through better definition of roles and responsibilities, baseline existing operations for productivity (# cases/ FTE per day) and Quality (% critical, major and minor errors) and re-engineering of existing processes.

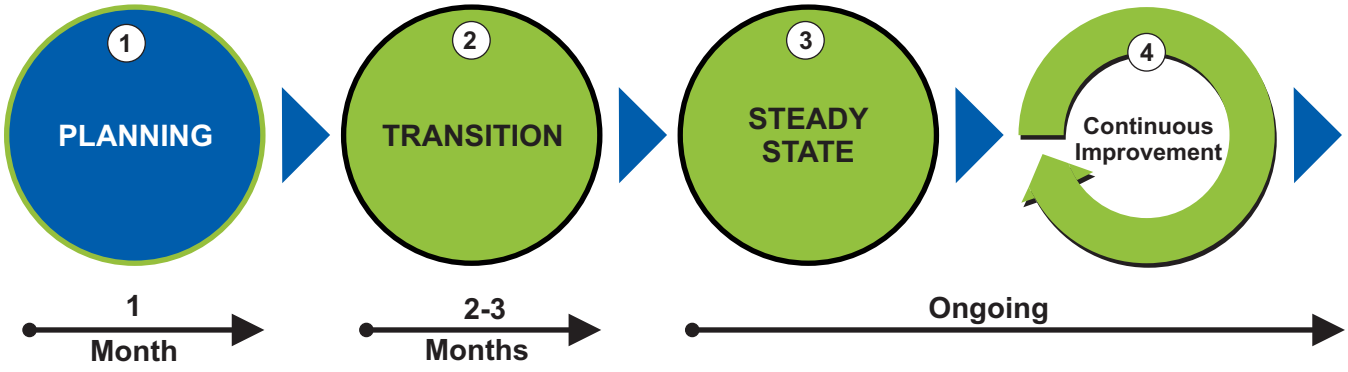
Index	Client Status
4 - 7	Parts of the client's process are mature to be supported from an outsourced provider. Understand hand-offs and dependencies between what is retained and what can be supported from an external provider, what level of oversight is required to ensure continuity in operations, mitigation factors for commonly encountered risks (e.g., definition of Day 0) for activities considered for outsourcing. Better defined parts of the process which are not as mature (e.g., safety data exchange agreements, updating CCDS, centralizing product registry information across geographies) and baseline these activities.
8 - 10	Client's process is mature to be supported by an external provider. Create expected Service Level Agreements based on current baseline, formalize the rate of outsourcing activity (how much work to be supported by an outsourced provider and how soon), evaluate portfolio segmentation, perform prod-uct risk categorization and develop a 3-5 year projection for an outsourced operation.

Sciformix transitions PV processes from its client's locations to its operational centers based on factors like client portfolio size, portfolio maturity and volumes. The approach depends on the ability for the client's team to expend focused time and effort and financial objectives of the sourcing and urgency in achieving them.

The approach could be one of the following:

Big BangApproach - The transition of operations is completed in one shot.

Wave approach - Processes is transitioned in multiple waves over a longer period of time and the approach would be product, function and geography specific.



	1 PLANNING	2 TRANSITION	3 STEADY STATE	4 Continuous Improvement
Goal	Formalize process to establish a robust pharmacovigilance infrastructure (people, processes and technologies)	Transition Processes and Roles and pilot the process	Execute processes in-scope consistent with the SLAs agreed.	Identify opportunities for improving process efficiency through process reengineering and IT intervention.
Key Activities	Current process review Current systems review Organization and people/ competencies review Redesign processes and develop detailed prerequisites (eg SOPs, training, systems, KPIs)	Redefine roles, responsibilities and authorities globally and locally to support vision and processes- redesign organizational model Contingency planning external environment changes	Initiate performance measurement Train off-shore resources Initiate communication/ change management program Create framework to enable continual process improvement in response to environmental changes	Initiate process audits to identify opportunities for process improvement Deploy process improvement methodologies to improve quality, productivity and reduce Turn Around Time Deploy IT tools like macros to reduce manual intervention and increase process efficiency

Figure 3: Sciformix Transition Approach

Key components of Steady State Operations:

Processes

➲ Operation in "predictable" mode: Processes will be well documented with all scenarios covered by work instructions

➲ Process executes seamlessly across functions and locations and Hand-offs between the client and Sciformix are well understood and smooth.

Volume

➲ Predictability and meeting SLAs

Quality

- Guaranteed compliance with regulatory requirements
- Robust QA and feedback mechanism
  - QA level reduces gradually to stabilize at ~10%. If quality levels are not met them QA level is successively increased.
- Quality and regulatory compliance, feedback mechanism

People

- Team is trained and certified on the processes

Continuous Improvement

Weekly global team review by selecting and discussing sample cases processed in the previous week

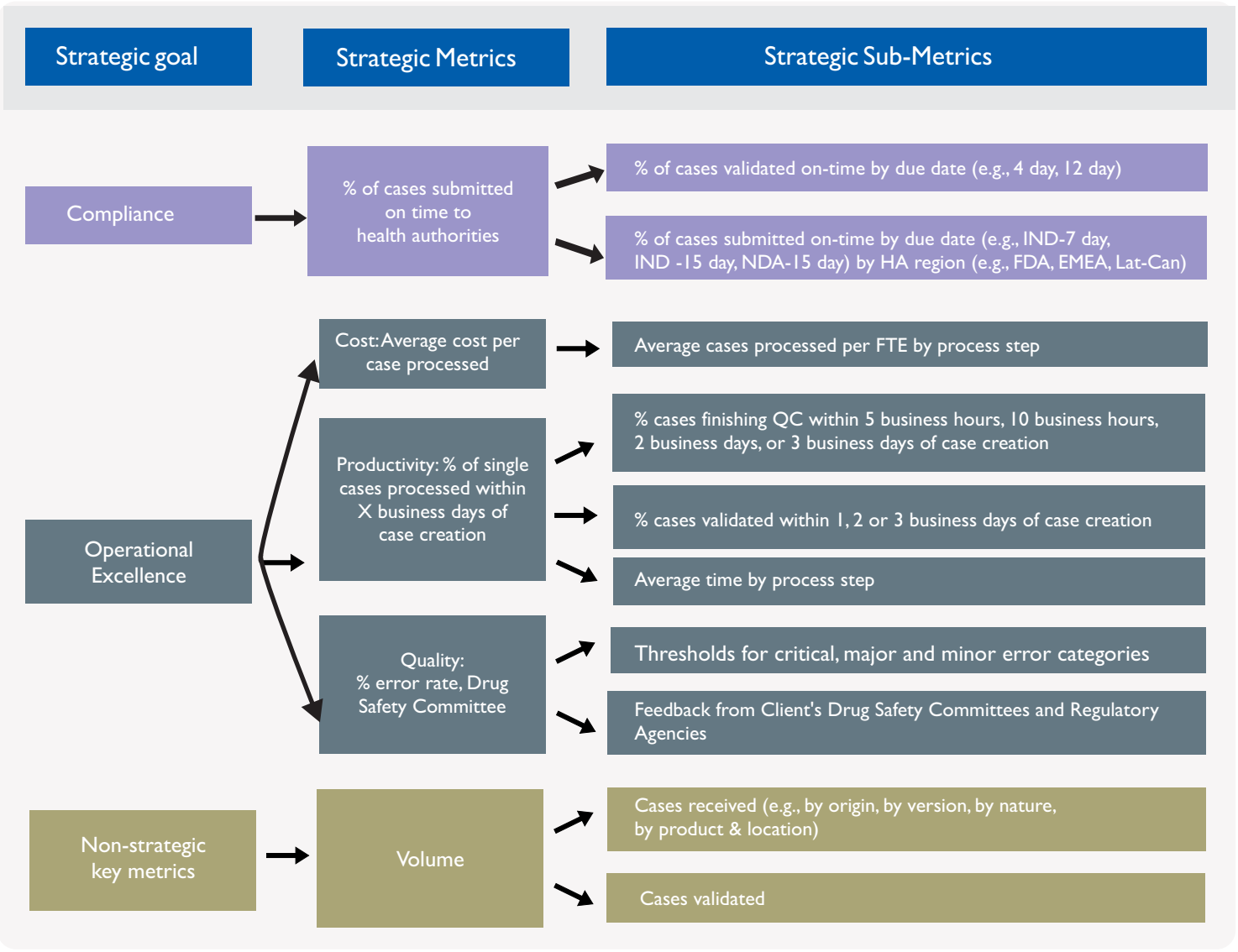


Figure 4 – Monitoring Process in Steady State

Metrics and SLAs

The table below is a representative set of steady state KPIs we use in our typical pharmacovigilance service engagements.

We work collaboratively with our clients to tailor these KPIs to their specific needs during the planning discussions at the beginning of the engagement.

SLA Category	KPI	Measurement	Target Service Level
Performance	TurnaroundTime	Submission to client by Day 3 for SAEs	100%
Quality	Error Rate	Percentage of critical or major errors detected per quarter	<2%
Timelines	Regulatory Compliance	Percentage of cases submitted on time to regulators	99%
Volume	Productivity	Number of SAEs reviewed or completed/data reviewer on a 4 week rolling average	99%

The Sciformix Advantage

Sciformix understands that PV processes are fundamentally different from processes like Data Capture and Discrepancy Management. Our experience of supporting global clients over the last three years has taught us how much more complex is case entry relative to CRF data entry. The process of triage, case entry and medical coding is a lot more complex and subjective. Further, label and causality assessment requires an understanding of the mechanism of action of the drugs that we support, something that our medical review and assessment teams have developed. Since we provide end-to-end support for Pharmacovigilance operations, we have a better understanding of how individual case assessments shape the aggregate analysis reported in a PSUR or a PADER, how EU RMPs and US REMS evaluate the overall risk of the product in the market and how case processing and aggregate report authoring activities enable effective management of overall risk-benefit balance for the products we support. Our approach balances process rigor, flexibility and adaptability to provide our clients with an optimal pharmacovigilance solution.

Sciformix has access to a team of experienced therapeutic area Key Opinion Leaders (KOLs) and Subject Matter Experts (SMEs) across our service delivery centers in India and US. Our delivery model provides us the ability to scale up or scale down depending upon the evolving needs of our client's product portfolio along with cost effective services delivery enabled by leveraging a globally distributed team.

Our proprietary tools and methodologies enable us to increase the probability of success of an outsourcing initiative for our clients by leveraging our experience, industry benchmarks and best practices in Pharmacovigilance operations.

Sciformix is a knowledge based global service provider for the Pharmaceutical and Biopharmaceutical industry.

We partner with our clients through the entire drug development cycle, to provide a full range of services from study design to post marketing services.

Our expertise lies in using scientific rigor to synthesize knowledge from the deluge of available information and using it, along with our understanding of the regulations, to help our clients make the right decision at the right time.

To get more details about our proprietary models, contact us at…..

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