

DATE:

## **PHARMACOVIGILANCE SERVICES**

**Cloud based, E2b(R2)/(R3) complaint database  
with integrated  
Automated Literature Module and Signal Detection  
Using Artificial Intelligence**

**Submitted To**

This project will be undertaken across five core phases:

**Phase 1: PLANNING - Project start up activities**

- Establishing an organogram
- Identifying & defining Roles & Responsibilities (Job descriptions)
- Developing Standard Operating Procedures & Work Instructions
- PSMF or Drug Safety System
- Preparation of Risk Management Plan

**Phase 2: PHARMACOVIGILANCE SET UP (INITIAL/ANNUAL) COST**

The fee for various requirements for Pharmacovigilance set up as per the European Pharmacovigilance guidelines are as follows:

**Table 2.1:** One time and annual maintenance cost (To be finalized as per client requirement)

Activities	First Time (EURO)	Annual Maintenance (EURO)
Safety Database Configuration Implementation & Validation	5500	1250
Literature monitoring setup- Configuration of search criteria in literature data base for <b>each set of 10 brands</b>	120	NA
MedDRA and WHO DD subscription	900	Depending on new subscription from MedDRA and WHO DD
Preparation of Client specific SOPs & Work Instruction (Per Doc)	100	100 for each revision required
Preparation of Pharmacovigilance System Master File (PSMF)	1200	180
Training of client employees	900	250
Record Management	600	250
<b>Optional Services</b>		
<b>MICC installation and One time Setup cost</b>	4800	
<ul style="list-style-type: none"> <li>• For 100 cases</li> <li>• For 250 cases</li> <li>• For 500 cases</li> </ul>		4800PA/ 500 PM 6500PA/ 650 PM 8500PA/ 800 PM

Activities		First Time (EURO)	Annual Maintenance (EURO)
Preparation of Risk Management Plan (per document)	For India & ROW	1200	NA
	For EU/USFDA	1800	NA
<b>XEVMPD- For EU region only, if required</b>		420	NIL
Update for <b>each brand</b> in XEVMPD		25	NIL
EVWEB registration (Required for EU market)- <b>Optional</b>		600	NA
Submission Gateway (per gateway)		1800	NA
Data Migration		Depends on amount of data	
Clinical Trail Database One Time Setup			Per Study/Month
• EDC		4800	600
• CTMS		4800	700

### Phase 3: REAL TIME PV ACTIVITIES

#### Collection of ADR, Case Processing and Reporting

Collection of ADRs is to be done in the through **MICC** or from patients/relatives/ medical and paramedical staff and Clinical Trials followed by Processing of ICSRs and Expedited Reporting. The cost of each activity is as follows:

**Table 3.1:** Fee for ADR collection through MICC (If required)

Activities	Fee (EURO)
<b>For up to 100 cases Per Month</b>	500/ Month
<b>For up to 250 cases Per Month</b>	650/ Month
<b>For up to 500 cases Per Month</b>	800/ Month

**Table 3.2:** Fee for ADR collection through literature monitoring, **charged on monthly basis Mandatory activities**

Activities	Fee (EURO)
1) Weekly Searches through mail alert, random searches, duplicate check, tracking, repository and over all data collation from literature databases	5/articles

Activities	Fee (EURO)
2) Literature evaluation of articles, obtained in step 1, for valid and invalid cases	

Note: Articles to be purchased for identified valid cases will be charged separately as per actuals.

**Table 3.3:** Fee for processing and reporting of ADRs collected from **all applicable sources (Call Centre/ Literature Monitoring/ Clinical Trials/ Health Authority/ Business Partner)**

Activities	Fee (EURO)
Clinical Trail Cases	90/Case
Serious ICSRs - Case processing and reporting from all sources	75/Case
Non-Serious ICSRs - Case processing and reporting from all sources	60/Case

#### Phase 4: AGGREGATE REPORTING

PSURs, PBRER, PADER etc. will be done as per regulatory requirements on annually/biannually/quarterly bases

**Table 4.1:** Step 1- Screening of literature for ICSRs per **molecule through monthly reconciliation**

S. No.	Activity type	Activities	Fee (EURO)
1	Core	1) Screening, collection of cases from literature databases for <b>each Brand</b> 2) Identification of valid and invalid cases for cases collected in step 1	5/articles
2	Core	Serious ICSRs - Case processing from all sources (Cost/case)	75/Case
3	Core	Non-Serious ICSRs - Case processing from all sources (Cost/case)	60/Case

**Table 4.2:** Step 2- Preparation of periodic reports/updates

Sr. No	Activity type	Preparation/compilation of AGGREGATE REPORTS	First Report (EURO)	Subsequent Reports (EURO)
1	Core	PSUR (per document)* for Indian and ROW markets	850	600

Sr. No	Activity type	Preparation/compilation of AGGREGATE REPORTS	First Report (EURO)	Subsequent Reports (EURO)
2	Core	PBRER/PADER (per document) *	3000	1800

## Phase 5: RISK MANAGEMENT ACTIVITIES

**Table 5.1** Signal Detection

Activities	Fee (EURO)
Signal Management and Reporting per brand annually as and when required	1400

## Phase 6: QPPV services

In order to perform the above activities, services of following key personnel will be billed to the sponsor.

**Table 6.1:** Fee for QPPV personals

Description	Fixed Cost/Month (EURO)
QPPV Fee	To be discussed as per requirement

## INVOICE SCHEDULE

The below is a proposed invoicing schedule, for which we will be happy to discuss alternative options.

**Table 7.1: Invoice schedule for one time cost**

Invoice	Percent (%)	Invoice Point	Estimated Invoice Date
1	60%	Upon contract signature	TBD
2	40%	Upon set up of PV system	TBD

**Table 7.2: Invoice schedule for monthly variable cost**

Invoice	Percent (%)	Invoice Point	Estimated Invoice Date
1	100%	End of the month	8 <sup>th</sup> of every month

Taxes as applicable would be charged extra.

**For Indivirtus Healthcare Services Pvt. Ltd.**

Indivirtus Healthcare Services (P) Ltd.  
  
 Director

(Dr. Upendra K Jain)