DATE:

PHARMACOVIGILANCE SERVICES

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

Submitted To

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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 **each set of 10 brands**	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
Optional Services		
MICC installation and One time Setup cost	4800	
• **For 100 cases** • **For 250 cases** • **For 500 cases**		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
XEVMPD- **For EU region only, if required**		420	NIL
Update for **each brand** in XEVMPD		25	NIL
EVWEB registration (Required for EU market)- **Optional**		600	NA
Submission Gateway (per gateway)		1800	NA
Data Migration		Depends on amount of data	
Clinical Trail Database One Time Setup • EDC • CTMS		 4800 4800	Per Study/Month 600 700

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)
For up to 100 cases Per Month	500/ Month
For up to 250 cases Per Month	650/ Month
For up to 500 cases Per Month	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 **each Brand** 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	8th 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)