PITON Global

EXECUTIVE WHITE PAPER · WP-64

PHARMACOVIGILANCE & PHARMA SUPPORT · PHILIPPINES

The case-integrity standard: the executive economics of pharmacovigilance & pharma support outsourcing to the Philippines.

An analysis of why cases processed is a volume vanity metric, how case integrity and regulatory-reporting timeliness — never case throughput — decide the true cost of a safety operation once misclassified adverse events, missed reporting deadlines, coding errors, and audit findings are counted, and the vendor-selection discipline that gets every case complete, correct, and reported on time.

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ABOUT THIS SERIES — VOLUME 64

Every pharmacovigilance proposal is priced per case processed, because volume is easy to count. This volume is about the only outcome a drug-safety operation actually depends on and a cheap contract quietly trades away: the adverse-event case intaken complete, assessed and coded correctly, and reported to the regulator inside its deadline — audit-ready. The gap between processing a case and completing one that survives inspection is where missed deadlines, coding errors, and audit findings live. The full series lives at piton-global.com.

THE PITON-GLOBAL LEADERSHIP TEAM

About the authors

John Maczynski

Chief Executive Officer

John has bought pharmacovigilance capacity for three decades, and learned that the fast operation that processes every case and mis-assesses seriousness is the most expensive one a sponsor can hire — because a misclassified adverse event is a reporting failure, a missed deadline is a regulatory finding, and a botched inspection puts the marketing authorization itself at risk. His standing question ignores the cases-per-day report: of the cases you processed, how many were complete, correctly assessed, and reported inside the deadline — audit-ready? Applied at PITON-Global, that question is what clients get on every drug-safety sourcing decision — personally, with no account layer in between.

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Chief Strategy Officer

Ralf has spent twenty-five years running Philippine life-sciences support floors, and he judges a pharmacovigilance team by its case-quality score and on-time-reporting rate, not its cases-per-day: whether seriousness, causality, and coding were right and the case filed inside the clock, or logged and left to fail an inspection. The case contract in Section 3 codifies what he learned rebuilding teams that cleared cases fast and left the safety database non-compliant. He now reads pharmacovigilance providers the way he once ran them — from the audit-findings log and the late-report register backward.

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PITON Global

ABOUT PITON-GLOBAL

PITON-Global is a buyer-side advisory practice, Manila-based since 2001, that has never operated a delivery floor or taken a placement commission. Its stock-in-trade is knowing the Philippine provider market at the operating level — 1,000+ mapped operations, re-verified continuously, including each pharmacovigilance team's real case-quality score and on-time-reporting rate rather than its cases-per-day headline — and converting that knowledge into a shortlist of six to ten genuinely qualified partners per engagement. Buyers from Tripadvisor, Garmin, TSYS, HealthPartners, Yetipay, Workrise, and Norman Disney & Young have run their searches through the practice.

SECTION 01

Executive summary

-57%
Fully-loaded cost per compliant, audit-ready case vs. US onshore

99%+
Case-quality score on vetted teams, up from 86–93%

99.9%
On-time regulatory reporting (within deadline), vetted teams

6.2×
First-year ROI, reconstructed case (Section 6)

A pharmacovigilance engagement is bought on the price per case and paid for on the cases it gets wrong — and, at the extreme, on the inspection it fails. The vendor reports hundreds of thousands of cases processed at a fraction of the onshore cost; the sponsor finds the adverse events with seriousness mis-assessed, the causality calls that will not survive review, the MedDRA coding that drifts from the source, the expedited reports filed after the fifteen-day or seven-day clock, and a safety database that looks busy but would not pass an inspection. The operation cleared its queues and the sponsor inherited a compliance problem, a late-report register, and an audit exposure it never priced. The gap between processing a case and completing one that is compliant and audit-ready is where the real cost of cheap pharmacovigilance hides, because a mis-assessed or late case is not throughput delivered; it is a reporting failure, a regulatory finding, and — compounded — a risk to the product's standing.

The Philippines — English-fluent, with a deep, science-literate life-sciences talent pool and mature GVP-aligned safety operations — is where pharmacovigilance is delivered with the most case-integrity discipline, because that pool, properly trained and supervised, can run the complete intake, accurate medical assessment, and on-time regulatory reporting that a defensible safety database demands. Five findings:

1. **Cases processed is the industry's most flattering number.** Any floor can open a case and log it. Vetted teams are measured on outcome: case-quality score, coding accuracy, and on-time reporting. Weak providers quote a low per-case price the sponsor repays in coding errors, late reports, and audit findings. Section 2 shows the gap.

2. **The compliant, audit-ready case, not the processed one, is the product.** A case that protects the safety database comes from complete intake, accurate seriousness-and-causality assessment, correct coding, and on-time filing — not from clearing a queue. Teams that build case integrity pass inspection; teams that process loosely leave findings and late reports that cost far more than the case.

3. **The reporting clock is the one deadline that does not forgive.** A serious case has a fifteen-day expedited clock; certain cases, seven. Miss it and the failure is on the record regardless of how good the case is. Vetted teams hold on-time reporting at 99.9% precisely because a single late expedited report is a finding no efficiency can offset.

4. **Audit findings and rework, not the per-case rate, are what cost.** A case done wrong costs the rework, the corrective-and-preventive action, the late-report remediation, and the inspection exposure — many times the per-case saving. Teams that build case integrity keep the database inspection-ready, and that protected compliance standing — not the offshore rate alone — is where the case study's return is built.

5. **Contract on the compliant case, not the processed one.** The contracting failure of pharmacovigilance is paying per case and hoping quality and timeliness hold. Vetted deals price against case-quality floors, coding-accuracy targets, and a non-negotiable on-time-reporting standard, making case integrity the team's problem, which is where it belongs.

The intended reader is a head of pharmacovigilance, QPPV, or VP of drug safety at a sponsor or CRO buying case processing per case and paying for it in coding errors, late reports, and audit findings. Sections 2–4 separate the teams that build case integrity from the teams that clear cases; Sections 5–7, the method and the proof. This paper addresses operational sourcing, not medical or regulatory advice.

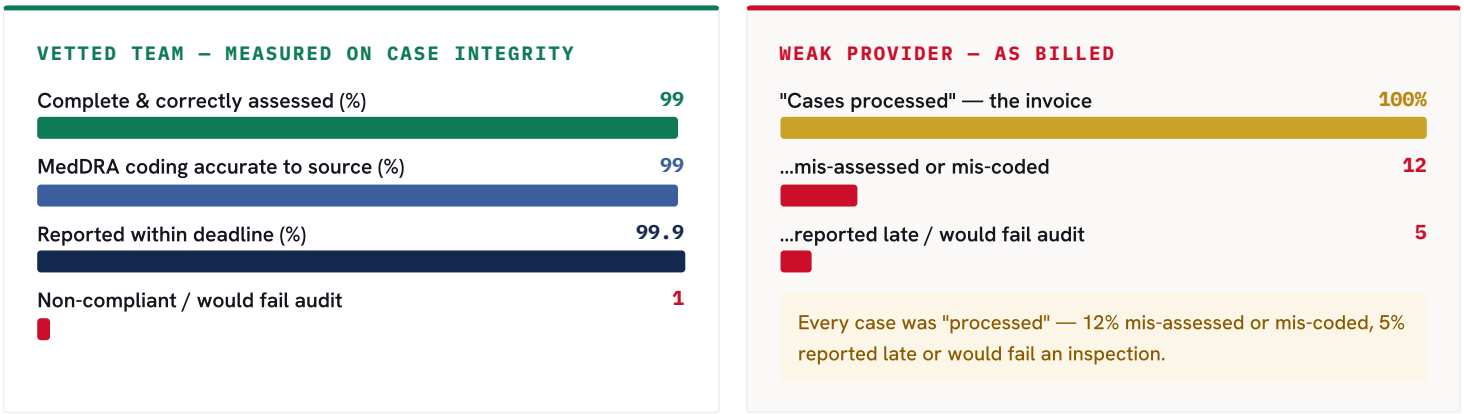
SECTION 02

The volume mirage: cases processed versus compliant, audit-

ready cases

Figure 1 shows one month of a sponsor's adverse-event cases two ways: as the cases-processed report a weak vendor bills, and as the case-integrity reality the QC review, the reporting clock, and the inspection experience. The cases-processed number is engineered to look like output while coding errors, late reports, and audit findings accumulate underneath.

FIG. 1 — ONE MONTH OF CASES: CASE-INTEGRITY QUALITY VS. REPORTED VOLUME



Left: PITON-Global engagement instrumentation, 2025–26, case quality and timeliness audited. Right: composite of pre-engagement vendor reporting reviewed in diligence.

The economics follow the case integrity and the clock, not the case count. On the left, ninety-nine percent of cases are complete and correctly assessed and 99.9 percent are reported inside the deadline, so the safety database survives inspection; on the right, a cheap per-case price mis-assesses or mis-codes twelve percent and files five late, paying in coding rework, late-report remediation, and audit findings at once. A low per-case price that leaves cases non-compliant is not a saving; it is a remediation bill and an inspection exposure the sponsor carries. The case-integrity audit — case-quality score, coding accuracy, on-time reporting — is the cheapest due-diligence instrument in this paper.

SECTION 03

The case contract: intake it complete, assess it accurately, report it on time

Figure 2 lays out the three clauses of a working pharmacovigilance contract — the machinery a floor read verifies before any per-case price is believed.

FIG. 2 — THE CASE CONTRACT, AS OPERATED ON VETTED TEAMS

INTAKE IT COMPLETE

Every adverse-event report — the four minimum criteria and beyond — is captured complete from the source, with follow-up raised for missing information rather than a case closed on a gap. The case is made complete at intake, so assessment and reporting rest on a full record and the clock starts clean.

ASSESS IT ACCURATELY

Seriousness, expectedness, and causality are assessed to the sponsor's conventions, MedDRA coding is applied accurately to the source, and the narrative is written to standard — with medical review where required and a QC check before the case is locked. The assessment is made correct before the report goes out, so it holds on review.

REPORT IT ON TIME

Expedited and periodic reports are submitted to each authority inside the regulatory clock, tracked against the deadline, and evidenced in an audit-ready trail — with a compliance report the sponsor can read. On-time reporting is the outcome the inspector and the safety database both feel, and the one the clock will not forgive.

↓ yields ↓

THE COMPLIANT, AUDIT-READY CASE

99%+ CASE QUALITY | 99.9% ON-TIME | INSPECTION-READY

Cases are intaken complete, assessed and coded accurately, and reported inside the clock — so coding errors and late reports disappear and the safety database survives inspection. The operation gets cheaper per compliant case and more defensible at the same time, which is the entire promise of outsourcing pharmacovigilance to people who measure case integrity, not cases processed.

Operating parameters from PITON-Global pharmacovigilance engagements, 2025–26. Case processing is operated to each sponsor's SOPs and applicable GVP standards under sponsor oversight.

In diligence, the contract is tested from the inspector's side: pull processed cases and re-review a sample for seriousness, causality, and coding accuracy against the source; audit the late-report register against the reporting clock; and stress-test the audit trail as an inspector would — because a floor that files one expedited report late fails the whole engagement, whatever its throughput stats say. Perhaps one team in ten survives it cleanly. Steps 3 and 5 of the framework exist to find that one before the contract does — because everything in Table 3 of Section 6 depends on compliant, audit-ready cases, not cases processed.

SECTION 04

Cost and performance: cost-per-compliant-case economics and benchmarks

TABLE 1 — FULLY-LOADED COST PER COMPLIANT, AUDIT-READY CASE: THREE OPERATING MODELS (2026)

OPERATING MODEL	COST / CASE	VS. US BASELINE
US onshore in-house safety team	$62.00	baseline
Low-cost offshore case mill (per-case)	$42.00	−32%
Vetted Manila team — complete, accurate, on-time	$26.66	−57%

Basis: PITON-Global engagement pricing 2025–26; cost per compliant, audit-ready case = fully-loaded operating cost divided by cases completed accurately and reported on time (mis-assessed, mis-coded, and late excluded); the case mill looks cheap per case but coding rework, late-report remediation, and audit findings lift its true cost per compliant case; US comparator fully-loaded in-house cost. Case mix spans ICSRs of varying complexity.

TABLE 2 — PHARMACOVIGILANCE BENCHMARKS, VETTED VS. BASELINE (2025–26)

METRIC	VETTED TOP TIER	BASELINE	EXECUTIVE READING
Case-quality score	**99%+**	86–93%	The only PV number inspection follows
On-time regulatory reporting	**99.9%**	94–98%	Inside the clock, or a finding
MedDRA coding accuracy	**99%+**	88–94%	Coded to source, or drift
Case rework rate vs. baseline	**–62%**	baseline	"Assess it accurately" — held or not
Audit / inspection findings	**Zero critical**	recurring	Inspection-ready, or exposed

Source: PITON-Global pharmacovigilance engagement data 2025–26; baseline = typical pre-engagement operations billed on cases processed.

The strategic read: the case mill's –32% per case is a false economy — coding rework, late-report remediation, and audit findings lift its true cost per compliant case far above the per-case gap, and a critical inspection finding is a cost no rate recovers. The vetted Manila team's –57% is real because it is measured where the value is: the case complete, correctly assessed, and reported inside the clock. Buy on cases processed and you buy the right column of Figure 1; buy on cost-per-compliant-case and you buy case integrity — the same discipline every volume in this series keeps arriving at from a different door.

SECTION 05

Sourcing discipline: the 7-Step Vendor Vetting Framework, applied to pharmacovigilance

Pharmacovigilance diligence adds two hard requirements to every step: a per-case price is real only when the case-quality score behind it survives a re-review against the source, and only when the on-time-reporting record behind it survives a late-report audit against the regulatory clock. The funnel below is representative of a 50–120-seat drug-safety search.

FIG. 3 — THE 7-STEP FRAMEWORK AS A PHARMACOVIGILANCE FUNNEL

	STEP	WHAT IT ELIMINATES IN A PV SEARCH	FIELD REMAINING
1	**Requirements definition**	Throughput-first scoping: fixes the case-quality floor, the coding-accuracy target, and the non-negotiable on-time-reporting standard by case type and authority	1,000+
2	**Market mapping**	Case mills: operations that bill case volume and treat coding errors and late reports as the client's problem, and generalist floors with no GVP, medical-assessment, or safety-database depth	~44
3	**Capability screening**	Teams without the machinery: science-literate case processors, medical review, audited case-quality history, MedDRA and safety-database (Argus/ARISg) proficiency, and coverage across your case types	~12
4	**Compliance & security audit**	Weak governance: patient-data protection, GVP/21 CFR alignment, inspection-readiness, access controls on the safety database, business continuity, SOC 2 scope covering the PV stack	~7
5	**Operational diligence**	The case-integrity read: re-review a case sample for seriousness, causality, and coding against source; audit the late-report register against the clock; interview on a complex causality call and a follow-up-driven case	4–6
6	**Competitive RFP & negotiation**	Per-case pricing: finalists bid against case-quality floors, coding-accuracy targets, and the on-time-reporting standard — all carrying credits for non-compliant cases and any late expedited report	2–3
7	**Transition & launch governance**	Cold cutover: the team calibrates against your SOPs, conventions, and safety database on a sample before it owns live case flow, with the case-quality floor and on-time reporting certified before steady state, PITON-Global embedded buyer-side	1

Field-remaining counts represent a 50–120-seat pharmacovigilance search, PITON-Global engagements 2024–26.

The standing guarantees hold: **vendor neutrality** — PITON-Global operates no safety floors, processes no cases, and takes no placement economics, so the shortlist reflects audited case-integrity and timeliness performance, not inventory; **right-sizing** — teams for whom your operation is a flagship account. Six to ten genuinely qualified providers, delivered within 48–72 hours, free to the buyer, competing through a fully transparent, fair, comprehensive, and highly competitive RFP.

SECTION 06 · ANONYMIZED CASE STUDY

Re-basing the operation on case integrity: a 70-seat pharmacovigilance rebuild, reconstructed

Engagement PV-089 is a global pharma sponsor — processing roughly 180,000 adverse-event cases a year across marketed products and clinical programs — that had offshored case processing to a per-case mill. The case price was excellent; the integrity and timeliness were not: case-quality score sat near 89%, MedDRA coding drifted from source, expedited reports were occasionally filed late, and a recent inspection had raised findings on the safety database. The head of pharmacovigilance wanted the arbitrage without the coding rework and the inspection exposure. Identifying details are anonymized under NDA.

SELECTION (WEEKS 0–8, QUALITY + TIMELINESS READS)

Requirements fixed a 99% case-quality floor, a 99% coding-accuracy target, and a non-negotiable 99.9% on-time-reporting standard, with medical review and a QC lock. Mapping produced 44 claimants; the machinery screen — science-literate processors, medical review, audited case quality, MedDRA/safety-database proficiency — left 12; the GVP-compliance-and-security audit left 7. Case re-reviews and late-report audits shortlisted 5. A Manila team won priced against case quality and on-time reporting, with both written into the reporting spec.

TRANSITION (MONTHS 2–7, CALIBRATED FIRST)

The team calibrated against the sponsor's SOPs, conventions, and safety database on a sample before it owned live case flow; the case-quality floor and on-time reporting were certified in month 3, and the reporting-clock tracker ran from day one. The QC-and-medical-review loop fed processor coaching continuously. By month 7 case quality reached 99.2%, coding accuracy hit 99%, on-time reporting held at 99.9%, and case rework fell 62% with zero critical findings on the follow-up inspection. PITON-Global chaired the case-integrity review board to steady state.

TABLE 3 — PV-089 FIRST-YEAR VALUE BUILD-UP (US$)

VALUE COMPONENT	YEAR 1	BASIS
Labor arbitrage on the 70-seat operation	**$1.92M**	131.3k productive hrs × ($24.10 − $9.50)
Coding rework & case reprocessing removed	**$0.58M**	Rework eliminated by higher case quality
Inspection-finding & remediation exposure avoided	**$0.52M**	CAPA and late-report remediation removed
Cycle-time & QP capacity value	**$0.18M**	Faster case lock and reclaimed medical-review time
Gross value created	**$3.20M**	
Less: engagement & transition costs	**($0.52M)**	Calibration, QC-loop build, safety-database integration; advisory fee $0 (provider-paid model)
Net value ÷ cost = first-year ROI	**6.2×**	$3.20M ÷ $0.52M

Figures rounded; case-quality, coding, and timeliness effects audit-verified. Method in Methodology & notes.

Sixty percent arbitrage, forty percent from removed coding rework, avoided inspection remediation, and reclaimed medical-review capacity — a typical split for the series, earned because the operation was re-based on case integrity rather than case volume. Every line traces to a diligence step: the case-quality floor and on-time standard to Step 1, the integrity-and-timeliness pricing to Step 6, the QC-and-medical-review loop to Step 3's contract. The head of pharmacovigilance's line at the year-one review: "The case price barely moved. What moved is that the database holds up — and the inspection came back clean."

SECTION 07

The executive playbook: governance for the first 180 days

A pharmacovigilance transition succeeds when the team is measured and paid on case quality and on-time reporting — client in command throughout.

DAYS 0–30

Define case integrity, contract on it

Set the case-quality floor, the coding-accuracy target, and the non-negotiable on-time-reporting standard with pharmacovigilance leadership before launch, and document the SOPs, conventions, and escalation path by case type and authority. Contract against case quality and on-time reporting — never per case alone — with floors carrying credits and any late expedited report a defined breach. Stand up the case re-review and the reporting-clock tracker as the program's arbiters of truth.

DAYS 30–90

Calibrate, prove the clock

Calibrate the team against your SOPs, conventions, and safety database on a sample before it owns live case flow; certify the case-quality floor and run the reporting-clock tracker to 99.9% on-time. Switch on the QC-and-medical-review loop from day one. Publish the PV dashboard: case-quality score, coding accuracy, on-time reporting, case rework, audit-finding trend.

DAYS 90–180

Own case flow, certify steady state

Hand live case flow to the team only after it holds the case-quality floor and the on-time-reporting standard. Review the board monthly with the late-report register and audit-finding trend on the table. Certify steady state on two months at floor including a signal or PSUR/PBRER cycle; hand over on documented criteria; keep the case re-review and reporting-clock audit standing.

THE FIVE FAILURE MODES WE ARE HIRED TO PREVENT

Paying per case while cases fail an audit · clearing cases instead of building case integrity · mis-assessing seriousness or drifting on coding · missing an expedited reporting deadline · owning live case flow before quality and timeliness are proven. All five are settled at selection and contract.

The pharmacovigilance argument, in one sentence: a processed case is activity and a compliant, audit-ready case is a safety database that survives inspection and a report filed inside the clock, and a vetted Philippine team delivers −57% cost per compliant case with a 99%+ case-quality score, 99.9% on-time reporting, and case rework cut by nearly two-thirds — for buyers who re-review case quality and audit the clock instead of counting cases processed, and compete the finalists through a fully transparent, fair, comprehensive, and highly competitive RFP. Anyone can process a case. We make sure you buy the team that gets the case right and files it on time.

METHODOLOGY & NOTES

How the numbers were built

Case-integrity and timeliness figures (Fig. 1, Table 2) derive from engagement instrumentation in PITON-Global pharmacovigilance engagements, 2025–26. Case-quality score and coding accuracy are measured by re-reviewing a case sample against the source; on-time reporting against the regulatory clock; case rework and audit-finding trend against the client's pre-engagement baseline. The weak-provider column is a composite of pre-engagement vendor reporting reviewed in diligence, shown for contrast.

Cost-per-compliant-case figures (Table 1) are fully loaded — wages, benefits and statutory charges, facilities, safety-database and technology tooling, management and QC overhead including medical reviewers, and attrition-driven recruiting — divided by cases completed accurately and reported on time, with mis-assessed, mis-coded, or late cases excluded from the denominator; US comparators reflect fully-loaded in-house cost on the same basis. A compliant, audit-ready case is complete, correctly assessed and coded, reported inside the clock, and defensible on inspection.

The case study (PV-089) is anonymized under NDA; volumes and dates are generalized, figures rounded. Case-quality, coding, and timeliness effects are audit-verified; the rework-removed line reflects eliminated reprocessing, and the exposure-avoided line is a conservative estimate. ROI = net first-year value ÷ all engagement-related client costs. PITON-Global's advisory fee is provider-paid and appears at $0 in the client cost base; neutrality safeguards are documented at piton-global.com.

Market context draws on IBPAP reporting and PITON-Global's proprietary provider mapping (1,000+ operations; case-integrity and timeliness performance re-verified May 2026). Case processing is operated to each sponsor's SOPs and applicable GVP standards under sponsor oversight; this paper addresses operational sourcing, not medical or regulatory advice. Estimates and projections are PITON-Global analysis and should be cited as such. The full series is available at piton-global.com.

Would your provider's case price survive a case-integrity audit?

Thirty minutes with John will tell you. Free to buyers, strictly vendor-neutral — a case-integrity-and-timeliness-verified shortlist within two to three business days.

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