PITON Global

EXECUTIVE WHITE PAPER · WP-65

BIOTECH & LIFE SCIENCES · PHILIPPINES

# The source-verified standard: the executive economics of biotech and life-sciences support outsourcing to the Philippines.

An analysis of why records processed is a volume vanity metric, how source-data verification and GxP compliance — never processing throughput — decide the true cost of a life-sciences support operation once un-verified data, query storms, protocol deviations, and inspection findings are counted, and the vendor-selection discipline that keeps the data source-true and the study inspection-ready.


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**ABOUT THIS SERIES — VOLUME 65**

Every life-sciences support proposal is priced per record or per hour, because activity is easy to count. This volume is about the only outcome a sponsor's submission and inspection posture actually depends on: the data verified back to its source, coded to standard, and kept inspection-ready — so a filing is not delayed by query storms and an audit finds a clean trail. The gap between processing a record and verifying it to source is where un-clean data and inspection 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 life-sciences support capacity for three decades, and learned that the fast operation that processes every record and cannot trace it back to source is the most expensive one a sponsor can hire — because un-verified data is a query storm at CRO rates, a protocol deviation, and an inspection finding that can hold a submission. His standing question ignores the throughput report: of the records you processed, how many were verified to source, coded to standard, and inspection-ready? Applied at PITON-Global, that question is what clients get on every life-sciences sourcing decision — personally, with no account layer in between.

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## Ralf Ellspermann

Chief Strategy Officer

Ralf has spent twenty-five years running Philippine life-sciences support floors, and he judges a team by its source-verification rate and inspection history, not its records-per-day: whether the data ties back to source and survives an audit, or piles up as open queries. The compliance contract in Section 3 codifies what he learned rebuilding teams that processed data fast and left the source behind. He now reads life-sciences providers the way he once ran them — from the query log and the inspection findings 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 life-sciences team's real source-verification rate and inspection history rather than its records-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

**-58%**
Fully-loaded cost per source-verified, compliant record vs. US onshore

**99.5%+**
Source-verification accuracy on vetted teams, up from 90–95%

**-64%**
Reduction in open-query volume on vetted teams

**6.3×**
First-year ROI, reconstructed case (Section 6)

A life-sciences support engagement is bought on the price per record and paid for on the data it cannot trace to source. The vendor reports hundreds of thousands of records processed at a fraction of the onshore cost; the sponsor finds the data points that do not tie back to the source document, the query storm that erupts at database lock, the protocol deviations nobody flagged, and the inspection finding that holds a submission while the clock on exclusivity runs. The operation hit its records-processed number and the sponsor inherited a query backlog, a data-integrity problem, and inspection exposure it did not price. The gap between processing a record and verifying it to source is where the real cost of cheap life-sciences support hides, because an un-verified record is not throughput delivered — it is a query, a deviation, or a finding waiting to surface.

The Philippines — English-language, with a deep science- and health-literate talent pool and a mature GxP-aligned support base — is where life-sciences support is delivered with the most source-verification discipline, because that pool can run the source-data verification, standards coding, and inspection-ready documentation that data integrity demands. Five findings:

1. **Records processed is the industry's most flattering number.** Any team can key a value into an EDC. Vetted teams are measured on outcome: source-verification accuracy, query rate, and inspection readiness. Weak providers quote a low per-record price the sponsor repays in query storms, deviations, and findings. Section 2 shows the gap.

2. **The source-verified, standards-coded record, not the fast key, is the product.** A record a regulator accepts comes from verifying it against the source document, coding it to MedDRA/WHODrug and the protocol, and documenting it to survive inspection — not from clearing an entry queue. Teams that verify to source lock clean; teams that key loosely generate the queries that delay the lock.

3. **Un-clean data cuts both ways — delay and exposure.** Data that does not tie to source delays database lock and submission; data coded wrong distorts the safety and efficacy read and can surface in an inspection. Vetted teams hold source-verification above 99.5% precisely because both tails cost — the timeline lost and the finding raised.

4. **The query storm and the finding, not the keystroke, are what cost.** A record processed wrong costs the query resolution at CRO rates, the timeline slip against exclusivity, and the inspection exposure — many times the per-record saving. Teams that verify to source cut queries and de-risk the filing, and that protected timeline — not the offshore rate alone — is where the case study's return is built.

5. **Contract on the source-verified record, not the processed one.** The contracting failure of life-sciences support is paying per record and hoping the data ties to source. Vetted deals price against source-verification floors, query-rate ceilings, and inspection-readiness standards, making data integrity the team's problem, which is where it belongs.

The intended reader is a head of clinical operations, data management, or pharmacovigilance, or a COO buying life-sciences support per record and paying for it in query storms, deviations, and inspection findings. Sections 2–4 separate the teams that verify to source from the teams that process volume; Sections 5–7, the method and the proof.

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SECTION 02

## The volume mirage: records processed versus source-verified, compliant records

Figure 1 follows one study's records through the verification gates that separate a clean, lockable database from a pile of processed entries. The records-processed number is identical in spirit to a chatbot's containment rate — a figure engineered to look like output while un-verified data, open queries, and inspection exposure accumulate underneath.

FIG. 1 — ONE STUDY'S RECORDS THROUGH THE VERIFICATION GATES


Weak provider bills 100% "processed" — but 21% never reach inspection-ready, surfacing as queries at database lock.

Vetted team holds >99.5% through every gate — the database locks clean and the trail survives inspection.

Gate pass-rates from a composite pre-engagement operation reviewed in diligence; vetted-team parameters from PITON-Global life-sciences engagements, 2025–26.

The economics follow the last gate, not the first. Everything that fails to reach inspection-ready comes back as a query at database lock, a deviation to document, or a finding to remediate — each at a multiple of the per-record price, and each against a submission clock where weeks of delay can cost a quarter of peak-year sales. A low per-record price that cannot pass the source gate is not a saving; it is timeline risk and inspection exposure, deferred to the worst possible moment. The source-verification audit — SDV accuracy, query rate, inspection readiness — is the cheapest due-diligence instrument in this paper.

SECTION 03

## The compliance contract: verify to source, code to standard, keep it inspection-ready

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

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

### VERIFY TO SOURCE

Every data point is checked against the source document under the SDV plan, discrepancies are raised as queries and resolved to source, and nothing is accepted on assumption. The record is made source-true at entry, so the database locks clean rather than erupting in queries later.

### CODE TO STANDARD

Adverse events, medications, and medical history are coded to MedDRA, WHODrug, and the protocol's conventions, consistently and to current versions, with an ambiguous term escalated to medical review rather than guessed. The safety and efficacy read rests on coding that is right and uniform.

### KEEP IT INSPECTION-READY

The audit trail, deviation log, and documentation are kept current to GCP/GxP and 21 CFR Part 11 so an inspector finds a clean, complete record — with a data-integrity report the sponsor can read. Inspection-ready is a study that survives an audit without a scramble, which is the only outcome a submission actually feels.

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### THE SOURCE-VERIFIED RECORD

99.5%+ SOURCE-VERIFIED | CODED TO STANDARD | INSPECTION-READY

Data ties to source, coding is right and uniform, and the trail is inspection-ready — so queries fall, the database locks on time, and an audit finds a clean study. The operation gets cheaper per source-verified record and de-risks the submission at the same time, which is the entire promise of outsourcing life-sciences support to people who measure source verification, not records processed.

Operating parameters from PITON-Global life-sciences engagements, 2025–26. Support operates under sponsor/CRO oversight and applicable GxP; nothing here substitutes for the sponsor's regulatory accountability.

In diligence, the contract is tested from the source document's side: pull processed records and re-verify a sample against source to measure true SDV accuracy; audit the coding against the dictionaries; review the query log and any past inspection findings. 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 source verification, not records processed.

SECTION 04

# Cost and performance: cost-per-source-verified-record economics and benchmarks

TABLE 1 — FULLY-LOADED COST PER SOURCE-VERIFIED, COMPLIANT RECORD: THREE OPERATING MODELS (2026)

| OPERATING MODEL | COST / RECORD | VS. US BASELINE |
|---|---|---|
| US onshore in-house / CRO data team | $4.10 | baseline |
| Low-cost offshore data mill (per-record) | $2.80 | −32% |
| **Vetted Manila team — source-verified, compliant** | $1.72 | −58% |

Basis: PITON-Global engagement pricing 2025–26; cost per source-verified, compliant record = fully-loaded operating cost divided by records verified to source, coded to standard, and inspection-ready (un-verified and re-worked records excluded); the data mill looks cheap per record but query storms, deviations, and inspection remediation lift its true cost per compliant record; US comparator fully-loaded in-house/CRO cost.

**TABLE 2 — LIFE-SCIENCES SUPPORT BENCHMARKS, VETTED VS. BASELINE (2025-26)**

| METRIC | VETTED TOP TIER | BASELINE | EXECUTIVE READING |
|---|---|---|---|
| **Source-verification accuracy** | **99.5%+** | 90–95% | The only data number the filing follows |
| **Open queries per 1,000 records** | **<6** | 18–30 | Locks clean, or a storm at lock |
| **Coding consistency (MedDRA/WHODrug)** | **99%+** | 88–94% | Uniform, or a distorted safety read |
| **Time-to-database-lock vs. baseline** | **–41%** | baseline | On the exclusivity clock, or behind it |
| **Inspection findings (data-integrity)** | **Zero critical** | 1–3 / study | Clean trail, or a remediation |

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

The strategic read: the data mill's –32% per record is a false economy — query storms, deviations, and inspection remediation lift its true cost per compliant record far above the per-record gap, and a submission delayed against exclusivity is a cost no rate recovers. The vetted Manila team's –58% is real because it is measured where the value is: the record verified to source, coded to standard, inspection-ready. Buy on records processed and you buy the right column of Figure 1; buy on cost-per-source-verified-record and you buy data integrity — the same discipline every volume in this series keeps arriving at from a different door.

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SECTION 05

## Sourcing discipline: the 7-Step Vendor Vetting Framework, applied to life sciences

Life-sciences diligence adds one hard requirement to every step: a per-record price is real only when the source-verification accuracy behind it survives a re-check against source documents. The funnel below is representative of a 30–70-seat clinical-data / pharmacovigilance search.

**FIG. 3 — THE 7-STEP FRAMEWORK AS A LIFE-SCIENCES FUNNEL**

| | STEP | WHAT IT ELIMINATES IN A LIFE-SCIENCES SEARCH | FIELD REMAINING |
|---|---|---|---|
| 1 | **Requirements definition** | Throughput-first scoping: fixes the source-verification floor, the query-rate ceiling, the coding-consistency target, and the inspection-readiness standard the operation must meet by study type | 1,000+ |
| 2 | **Market mapping** | Data mills: operations that bill records and treat queries and findings as the client's problem, and generalist floors with no GxP or clinical-data depth | ~40 |
| 3 | **Capability screening** | Teams without the machinery: GxP-trained staff, audited SDV history, MedDRA/WHODrug coding and medical-review workflow, and coverage across your therapeutic areas and EDC systems | ~11 |
| 4 | **Compliance & security audit** | Weak governance: 21 CFR Part 11 and GDPR/HIPAA controls, subject-data protection, access controls on EDC/safety systems, audit-trail integrity, SOC 2 scope covering the life-sciences stack | ~7 |
| 5 | **Operational diligence** | The re-verify: re-check a sample of processed records against source for true SDV accuracy; audit coding and the query log; interview on how they handle a source discrepancy or an ambiguous AE term | 4–6 |
| 6 | **Competitive RFP & negotiation** | Per-record pricing: finalists bid against source-verification floors, query-rate ceilings, and inspection-readiness standards — all carrying credits for records that come back un-verified | 2–3 |
| 7 | **Transition & launch governance** | Cold start: the team calibrates against your protocol, EDC, and coding conventions on a sample before it touches live study data, with the SDV floor certified before steady state, PITON-Global embedded buyer-side | 1 |

Field-remaining counts represent a 30–70-seat clinical-data / pharmacovigilance search, PITON-Global engagements 2024–26.

The standing guarantees hold: **vendor neutrality** — PITON-Global operates no data floors, verifies no records, and takes no placement economics, so the shortlist reflects audited source-verification 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 source verification: a 54-seat clinical-data rebuild, reconstructed

Engagement BT-076 is a US biotech and its CRO — processing roughly 2,600,000 clinical-data records a year across a multi-study portfolio — that had offshored clinical-data support to a per-record vendor. The record price was excellent; the data integrity was not: source-verification accuracy sat near 92%, queries piled up toward every database lock, coding was inconsistent across studies, and a sponsor audit had flagged data-integrity gaps. The head of data management wanted the arbitrage without the query storms and the inspection exposure. Identifying details are anonymized under NDA.

**SELECTION (WEEKS 0–8, RE-VERIFIES)**

Requirements fixed a 99.5% source-verification floor, a query-rate ceiling, and a coding-consistency target, with a mandatory SDV and medical-review workflow. Mapping produced 40 claimants; the machinery screen — GxP-trained staff, audited SDV history, coding workflow, therapeutic and EDC coverage — left 11; the Part-11-and-security audit left 7. Blind re-verifies of processed records against source shortlisted 5. A Manila team won priced against source verification and inspection readiness, with a re-verify written into the reporting spec.

**TRANSITION (MONTHS 2–7, CALIBRATED FIRST)**

The team calibrated against the sponsor's protocols, EDC, and coding conventions on sample data before touching live study data; the SDV floor was certified in month 3. The verify-and-medical-review loop fed calibration from day one. By month 7 source-verification reached 99.6%, open queries fell 64%, coding consistency hit 99%, and time-to-lock dropped 41%. PITON-Global chaired the data-integrity review board to steady state.

**TABLE 3 — BT-076 FIRST-YEAR VALUE BUILD-UP (US$)**

| VALUE COMPONENT | YEAR 1 | BASIS |
|---|---|---|
| Labor arbitrage on the 54-seat data operation | **$1.66M** | 101.3k productive hrs × ($26.30 − $9.90) |
| Query-storm & rework removed (source-verified) | **$0.74M** | CRO-rate query resolution avoided |
| Timeline value (faster database lock) | **$0.48M** | Exclusivity-clock value of −41% time-to-lock |
| Inspection & remediation exposure avoided | **$0.22M** | Finding-remediation and audit exposure removed |
| **Gross value created** | **$3.10M** | |
| Less: engagement & transition costs | **($0.49M)** | Calibration, medical-review-loop build, EDC/coding integration; advisory fee $0 (provider-paid model) |
| **Net value ÷ cost = first-year ROI** | **6.3×** | $3.10M ÷ $0.49M |

Figures rounded; SDV, query, and timeline effects audit-verified. Method in Methodology & notes.

Fifty-four percent arbitrage, forty-six percent from removed query storms, protected timeline, and avoided inspection exposure — a typical split for the series, earned because the operation was re-based on source verification rather than record volume. Every line traces to a diligence step: the SDV floor to Step 1, the source-verification-based pricing to Step 6, the SDV-and-medical-review workflow to Step 3's contract. The head of data management's line at the year-one review: "The record price barely moved. What moved is that the studies lock clean now — and the last audit found nothing to remediate."

SECTION 07

# The executive playbook: governance for the first 180 days

A life-sciences support transition succeeds when the team is measured and paid on source verification and inspection readiness — client in command throughout.

**DAYS 0–30**

**Define integrity, contract on it**

Set the source-verification floor, the query-rate ceiling, and the coding-consistency and inspection-readiness thresholds with data-management and QA leadership before launch, and document the SDV and medical-review workflow by study type. Contract against source verification and inspection readiness — never per record alone — with floors and ceilings carrying credits. Stand up the re-verify as the program's arbiter of truth.

**DAYS 30–90**

**Calibrate, prove the floor**

Calibrate the team against your protocols, EDC, and coding conventions on sample data before it touches live study data; certify the SDV floor and medical-review loop. Switch on the verify-and-review loop from day one. Publish the data-integrity dashboard: source-verification accuracy, open-query rate, coding consistency, time-to-lock, inspection readiness.

**DAYS 90–180**

**Run live data, certify steady state**

Route live study data to the team only after it holds the SDV floor and inspection-readiness standard, under sponsor/CRO oversight. Review the data-integrity board monthly with the query log and any audit findings on the table. Certify steady state on two months at floor including a database-lock cycle; hand over on documented criteria; keep the quarterly re-verify standing.

**THE FIVE FAILURE MODES WE ARE HIRED TO PREVENT**

Paying per record while data does not tie to source · keying values instead of verifying to source · coding inconsistently across studies · letting queries pile toward database lock · running live study data before source verification is proven. All five are settled at selection and contract.

The life-sciences argument, in one sentence: a processed record is activity and a source-verified one is a database that locks clean and a study that survives inspection, and a vetted Philippine team delivers −58% cost per source-verified record with 99.5%+ SDV accuracy, open queries cut by nearly two-thirds, and time-to-lock down 41% — for buyers who re-verify the data instead of counting records processed, and compete the finalists through a fully transparent, fair, comprehensive, and highly competitive RFP. Anyone can process a record. We make sure you buy the team whose data ties back to source.

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**METHODOLOGY & NOTES**

# How the numbers were built

**Source-verification and query figures** (Fig. 1, Table 2) derive from engagement instrumentation in PITON-Global life-sciences engagements, 2025–26. Source-verification accuracy and coding consistency are measured by re-checking processed records against source documents and the dictionaries; open-query rate, time-to-lock, and inspection findings are measured 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-source-verified-record figures** (Table 1) are fully loaded — wages, benefits and statutory charges, facilities, validated-system and EDC tooling, management and QA overhead including SDV reviewers and medical coders, attrition-driven recruiting — divided by records verified to source, coded to standard, and inspection-ready, with un-verified or re-worked records excluded from the denominator; US comparators reflect fully-loaded in-house/CRO cost on the same basis. A source-verified record ties to its source document, is coded to standard, and survives inspection.

**The case study** (BT-076) is anonymized under NDA; volumes and dates are generalized, figures rounded. SDV, query, and timeline effects are audit-verified; the timeline line reflects the exclusivity-clock value of a faster lock, and the inspection 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; source-verification and inspection performance re-verified May 2026). Life-sciences support operates under sponsor/CRO oversight and applicable GxP; nothing here substitutes for the sponsor's regulatory accountability. 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 record price survive a source-verification re-check?

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

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