GCC RWE OPERATIONAL SERIES

PAPER 1 OF 3

An Operational Playbook for GCC Real-World Evidence Registries

The GCC Registry Readiness Model — a five-pillar operational framework for real-world evidence submissions, derived from a multi-country Asia-Pacific RWE program published across the Journal of Clinical Oncology, Annals of Oncology, and Liver Cancer, and translated for the Gulf's regulatory environment.

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Executive Summary

Across the Gulf Cooperation Council, a decade of health-data investment is converging into a regulatory reality. Regional pharmacoeconomic, drug safety, and reimbursement bodies now require **locally generated, registry-grade real-world evidence** to support marketing authorization, health technology assessment, and formulary access decisions. Extrapolated foreign RWE — the workaround sponsors have relied on since the region's first pricing negotiations — no longer satisfies the evidentiary threshold. What replaces it is a submission regime in which the presence, quality, and governance of a GCC-native registry is the price of entry.

The frameworks issued to date are precise, deliberate, and well-scoped. They define with clarity *what* fit-for-purpose real-world data must be: reliable, relevant, complete, and provenance-traceable. What they leave to the operational community — appropriately — is the *how*. How to build a registry that meets those criteria from the region's existing data assets: Malaffi in Abu Dhabi, Nabidh in Dubai, Riayati across the Northern Emirates, and the Saudi Cancer Registry. How to satisfy overlapping jurisdictional requirements — the UAE and Saudi Personal Data Protection Laws, emirate-level ethics oversight, and Gulf Health Council reliance mechanisms — within a single, coherent registry design. How to translate a defined evidentiary standard into repeatable operational practice.

I offer this paper as one contribution to that translation work. The Model is a practitioner-derived operational framework, grounded in a peer-reviewed multi-country RWE track record and translated for the Gulf's regulatory environment.

The blueprint I present is derived from the **AHCC08 multi-country real-world evidence program in hepatocellular carcinoma**, which I led operationally across IQVIA Asia-Pacific and Kantar Health. The registry's methodology and findings have been reported through a peer-reviewed evidence trail spanning 2017–2023, from *JCO* at ASCO Annual Meeting 2018, *JCO* at ASCO GI 2019, and additional peer-reviewed reports at ESMO Asia 2020 and ISPOR Asia-Pacific 2020 — culminating in the registry's definitive primary-endpoint manuscript, *Real-World Data on the Diagnosis, Treatment, and Management of Hepatocellular Carcinoma in the Asia-Pacific: The INSIGHT Study* (Sim et al., *Liver Cancer*, 2023), reporting on 2,533 patients across 33 sites in nine countries. Translated for the GCC's specific data landscape, regulatory architecture, and evidentiary standards, that operational experience yields the **GCC Registry Readiness Model** — five pillars, fifteen success criteria, and five measurable key performance indicators:

1. **Governance & Data Rights**
2. **Data Architecture & Interoperability**
3. **Quality Systems & Source Verification**
4. **Regulatory & Evidentiary Alignment**

5. **Sustainability & Publication Discipline**

The rest of this paper unpacks each pillar, applies the Model to three scenarios drawn from the region's evolving submission environment, and closes with a ninety-day sponsor-actionable sprint that translates the Model into concrete registry-launch preparation. The core argument of this paper, stated plainly: the constraint on GCC real-world evidence submissions is not data availability. Malaffi, Nabidh, Riayati, and the Saudi Cancer Registry hold submission-grade data today. The constraint is registry-governance discipline — the operational architecture that turns those data assets into evidence a regulator will accept.

Scope, Methodology, and Keywords

Scope. This paper presents an operational framework — the *GCC Registry Readiness Model* — for building submission-ready real-world evidence registries under the regulatory frameworks issued by the Saudi Food and Drug Authority, the Department of Health – Abu Dhabi, the Ministry of Health and Prevention (UAE), the Dubai Health Authority, and the Gulf Health Council between 2023 and 2025. The Model consists of five pillars, fifteen success criteria, and five measurable key performance indicators.

Methodology. The Model is derived from the author's operational leadership of a multi-country Asia-Pacific real-world evidence program (2017–2023) reported through the peer-reviewed evidence trail cited in Sections 1 and 3, translated for the Gulf's regulatory, data-infrastructure, and jurisdictional environment. It is a practitioner-derived framework, not a Delphi consensus, systematic literature review, or multi-stakeholder task-force output.

Keywords. real-world evidence · patient registries · GCC · SFDA · Malaffi · Nabidh · Riayati · Saudi Cancer Registry · registry governance · regulatory operations · UAE PDPL · Saudi PDPL · ICH E9(R1)

Section 1 — The Regulatory Moment

1. The Regulatory Moment

Three regulatory currents in the Gulf are converging in real time, and their intersection is producing a submission environment materially different from the one sponsors optimized for a decade ago.

The first current is the codification of real-world evidence as a formal regulatory input. Within the Kingdom of Saudi Arabia, the national drug authority's new framework on real-world data and real-world evidence establishes an evidentiary bar that names — with unusual specificity — what fit-for-purpose data must look like: accurate longitudinal capture, sufficient sample size, consistent treatment definitions, adequate covariate coverage, and rigorous bias-mitigation methodology. Within the United Arab Emirates, the health authority in Abu Dhabi has issued a parallel guideline that structures data quality around five explicit domains — reliability, relevance, fit-for-purpose determination, quality assurance, and provenance. Complementing both, the Abu Dhabi health technology assessment guideline released in mid-2025 now requires locally generated real-world evidence to support cost-effectiveness and budget-impact submissions, with an explicit cost-per-outcome threshold indexed to national economic output.

The second current is federal consolidation. The UAE is moving toward a unified federal drug regulator with authority over marketing authorization and post-market surveillance, closing the coordination gap that once existed between emirate-level health authorities and the federal ministry. For sponsors, this consolidation collapses what were previously two or three parallel submission tracks into a single, more demanding one. Registries designed to support only emirate-level reimbursement decisions will not, going forward, be sufficient to support federal marketing authorization or safety commitments.

The third current is the region-wide adoption of reliance mechanisms. Gulf Health Council pathways and bilateral recognition agreements now enable a well-designed regional evidence package to accelerate access across multiple jurisdictions from a single dossier — provided the underlying data meets the highest jurisdictional standard. The corollary is uncompromising: the *weakest* registry design in a regional evidence package sets the ceiling for the entire submission.

These three currents converge on a single operational conclusion. The GCC has moved, in the span of eighteen months, from a market in which foreign real-world evidence could be repurposed to a market in which locally generated, registry-grade, provenance-traceable evidence is the entry criterion. The frameworks are precise about the standard. They are, appropriately, silent about the operational path.

That path already exists — in the peer-reviewed record.

The **AHCC08 multi-country real-world evidence program in hepatocellular carcinoma**, executed under the operational leadership of the author across IQVIA Asia-Pacific and Kantar Health, was designed against precisely the evidentiary criteria the region's new frameworks now codify: multi-country data harmonization, longitudinal endpoint validation, prospectively defined estimands, transparent bias-mitigation methodology, and a peer-reviewed publication trail spanning 2017–2023, from *JCO* at the ASCO Annual Meeting 2018, *JCO* at ASCO GI 2019, and additional peer-reviewed reports at ESMO Asia 2020 and ISPOR Asia-Pacific 2020. The evidence trail culminates in the registry's definitive primary-endpoint publication, Sim et al., *Real-World Data on the Diagnosis, Treatment, and Management of Hepatocellular Carcinoma in the Asia-Pacific: The INSIGHT Study* (*Liver Cancer*, 2023), reporting on 2,533 patients enrolled across 33 sites in nine countries. The registry's operational architecture is not proposed here as a theoretical model. It is proposed as the reference implementation — an artifact that has already been through submission-grade scrutiny, in multiple jurisdictions, across multiple regulatory tracks, and against a peer-reviewed evidentiary bar.

The remainder of this paper translates that reference implementation into the GCC context. Section 2 examines why direct transplantation of Western or Asian registry blueprints fails in the region's specific data, population, and jurisdictional environment. Section 3 unpacks the AHCC08 architecture itself, including three candid limitations that GCC registries should design around. Section 4 introduces the GCC Registry Readiness Model. Sections 5 and 6 apply the Model to concrete scenarios and to a ninety-day sponsor-actionable sprint.

Section 2 — Why Global Blueprints Fail in the GCC

2. Why Global Blueprints Fail in the GCC

Registry design frameworks developed in the United States, the European Union, and East Asia are competent, mature, and — when transplanted directly into the Gulf — insufficient. The insufficiency is not a matter of rigor; the imported frameworks are frequently more rigorous than what the region's own guidelines require. The insufficiency is structural. Three assumptions embedded in Western and Asian registry blueprints break at the GCC's specific data, population, and jurisdictional geometry. Sponsors who miss these three breakage points will build technically correct registries that fail their intended regulatory purpose.

2.1 Assumption One: Single-Payer, Single-System Data Provenance

Frameworks such as the FDA's real-world evidence program guidance, the EMA's registry-based studies guideline, and the AHRQ-endorsed Gliklich & Leavy criteria assume a data environment in which most patients are captured within one dominant payer's records or one dominant national health system. The GCC does not have that data environment.

Abu Dhabi's health information exchange, Malaffi, integrates providers under the emirate's health authority. Dubai's Nabidh does the same under Dubai's health authority. Riayati — the National Unified Medical Record operated by the federal Ministry of Health and Prevention — serves as the national integration layer. In January 2023, the three platforms were formally interlinked, enabling federated access across emirates: Riayati holds records for 9.5 million patients across more than 3,000 medical facilities, and integration extended access to Malaffi's 1.4 billion additional health records from 2,500 healthcare organizations. Saudi Arabia's national health data infrastructure — anchored by the Saudi Cancer Registry and the Ministry of Health's Sehhaty and Wasfaty platforms — operates on parallel but distinct architecture.

Integration at the exchange layer is not the same as harmonization at the semantic layer. A patient's oncology record extracted from Malaffi, Nabidh, and Riayati now flows through the same technical pipes; it does not yet resolve to a single, consistent set of clinical terms, code systems, or endpoint definitions. Registry designs that treat the UAE HIE as a single unified analytic source — and Saudi data as its equivalent counterpart — will discover the harmonization gap only at analysis, when it is prohibitively expensive to fix.

2.2 Assumption Two: Stable, Monolingual, Ancestry-Homogeneous Populations

The second embedded assumption is demographic. Most global registry frameworks were designed for populations that are relatively residentially stable, documented in a single clinical language, and — for

purposes of pharmacogenomic analysis — reasonably homogeneous in ancestral background. The GCC's population is none of the three.

Expatriate residents constitute approximately **88% of the UAE's population** and **44.4% of Saudi Arabia's** (GASTAT Population Estimates 2024; UAE Wikipedia demographic summary). Longitudinal follow-up in registries that assume patients remain in-country for the full observation window will produce differential loss-to-follow-up that is not missing-at-random and cannot be corrected with standard multiple imputation. Clinical documentation is routinely bilingual — Arabic and English — with the balance shifting depending on the provider, the tertiary care setting, and the encounter type. Common data models developed in monolingual clinical environments (OMOP's concept mapping, Sentinel's data dictionaries) do not natively accommodate the bilingual terminology reconciliation required to harmonize a GCC oncology dataset.

Ancestry is the third dimension. National consanguinity rates in the region produce a rare-variant landscape genuinely different from the populations on which most Western pharmacogenomic reference frameworks were built. Per the Centre for Arab Genomic Studies, Saudi Arabia's overall consanguinity rate is estimated at **52–58%**, with certain areas reaching 80%. The Emirati rate is comparable at approximately **50.5%** (Al-Gazali et al., cited in CAGS). Two operationally significant genomic consequences follow: **the estimated percentage of disease-causing founder variants in the Saudi population is 42%**, and among the autosomal recessive disorders reported in Saudi Arabia (which themselves account for 81% of all monogenic disease), **97% are homozygous** (Monies et al., *Human Genetics*, 2017, cited in CAGS Chapter 3). The Emirati population's Catalogue for Transmission Genetics in Arabs has documented 665 distinct genetic conditions and 1,365 gene mutations, close to 20% of which are absent from international genetic databases. Registries designed against non-Arab pharmacogenomic reference panels will misclassify variants of clinical significance, especially in oncology contexts where somatic-versus-germline calling depends on population-appropriate reference data.

2.3 Assumption Three: Single Ethics and Data-Protection Jurisdiction

The third breakage point is legal. Global frameworks assume a registry sponsor navigates one national ethics regime, one data protection statute, and one cross-border data-transfer authority. A GCC registry sponsor navigates several, in parallel, for the same patient cohort — emirate-level ethics committees, federal ministry oversight, the Saudi National Committee of Bioethics, and two distinct Personal Data Protection Laws with meaningfully different cross-border transfer provisions. Registry designs built on a single-jurisdiction data-use agreement template will discover, mid-study, that they have executed a document that cannot lawfully authorize the data flow the analysis plan requires.

2.4 Implication

These three breakage points are not defects in the imported frameworks. They are defects in transplantation. The GCC's data, demographic, and legal geometry demands a registry architecture that

is structurally adapted at every layer — governance, data model, quality system, regulatory alignment, and long-term sustainability. That adaptation is what the GCC Registry Readiness Model, introduced in Section 4, provides.

Section 3 first examines the reference implementation from which the Model is derived.

Section 2 — Evidentiary Sources for Key Statistics

Claim	Verified value	Primary source
UAE HIE integration date	31 January 2023 (Arab Health 2023)	MoHAP announcement
Riayati coverage	1.9B records, 9.5M patients, 3,057 facilities	MoHAP announcement (same)
Malaffi records	1.4B records, 2,500 organizations	MoHAP announcement (same)
UAE expatriate share	~88%	Multiple sources including Wikipedia demographic summary; Khaleej Times NBS reporting
Saudi expatriate share	44.4% (2024, 15.67M of 35.29M)	GASTAT Population Estimates 2024 (official)
Saudi consanguinity rate	52–58% (up to 80% rural)	CAGS Chapter 3 (citations 9–11: Al-Abdulkareem 1998, Al-Owain 2012, El-Hazmi 1995)
UAE consanguinity rate	~50.5%	CAGS Chapter 3
Saudi founder-variant percentage	42%	CAGS Chapter 3, citing Monies et al. *Hum Genet* 2017;136(8):921–39
Saudi AR disorder homozygosity	97% (of the 81% AR share of monogenic disease)	CAGS Chapter 3, citing Monies et al. 2017
Emirati CTGA records	665 conditions, 1,365 mutations, ~20% not in international databases	CAGS March 2023 report

Section 3 — An Executed RWE Operational Architecture

3.1 The lineage from which this Model was derived

Every argument this paper makes about registry discipline can be traced to a single operational lineage: a multi-country real-world evidence program executed across Asia-Pacific between 2017 and 2023 under the author's operational leadership in successive roles as **Head of Real World Evidence at IQVIA Asia-Pacific** and **Vice President at Kantar Health**. The program is cited here not for its therapeutic finding — the clinical readouts belong to the investigators — but because it is where the operational architecture of a submission-ready RWE registry was designed, executed, closed out, and published.

The verified peer-reviewed record includes an ASCO 2018 abstract in *Journal of Clinical Oncology* covering an initial two-country cohort of 174 patients; an ASCO Gastrointestinal Cancers Symposium 2019 abstract reporting a sixteen-author manuscript on 657 patients; the ESMO Asia Congress 2020 Poster 166P — a real-world burden analysis across Hong Kong, Singapore, and Thailand, presented at the congress and published in the *Annals of Oncology* supplement (Chow PKH, …, **Gilliam Y**, et al.); and — as the definitive primary-endpoint manuscript — Sim et al., *Liver Cancer* 2023, reporting outcomes on 2,533 patients across 33 sites in nine countries under NCT03233360. The program's health-economic outputs were disseminated separately at ISPOR Asia-Pacific 2020 (Abstract PCN11).

We open with this record for one reason: regulators in the Gulf are now asking sponsors to demonstrate exactly the operational capability this program produced — and the operational choices that made those publications possible are not intuitive. They were, in nearly every instance, made **before Site 1 opened**. That timing is the entire argument of this paper.

3.2 Five things this program got right

1. Governance was written before enrollment, not after. Publication authorship, data-access rights, adjudication authority, and cross-country data-sharing conventions were fixed in a governance charter signed by every participating institution prior to first patient in. The nine-country footprint reported at primary-endpoint publication could not have been closed retrospectively; consent language, institutional review board harmonization, and cross-border transfer permissions all had to be aligned upfront. When the regulatory landscape shifted mid-program, the governance charter absorbed the change without renegotiation.

2. Common data model decisions were locked pre-enrollment. Variable definitions, coding standards (MedDRA, WHO-DD, ICD-10-CM), and outcome adjudication logic were agreed across all sites before the first case-report form was deployed. This is the single decision that most often determines whether a registry can be pooled at all, and it is the one most global blueprints defer. This program did not defer it.

3. Longitudinal follow-up was engineered for mobile populations. Loss-to-follow-up in Asia-Pacific cohorts is not a data-cleaning problem; it is an operational-design problem. Patient re-contact protocols, national-registry cross-linkage permissions, and vital-status verification pathways were built into the protocol, not layered on later. This is the capability GCC registries — operating in populations with 44–88% expatriate composition — will need to replicate, and it is the capability that global CRO templates most often lack.

4. Real-time quality dashboards, not quarterly reports. Site-level query rates, protocol deviation trends, source-data-verification burn-down, and enrollment velocity were surfaced to the operations lead in real time, not in retrospective quarterly summaries. The consequence: quality problems were addressed while they were still cheap to fix. We have since generalized this operational layer under the working name **Oncowave** — a real-time RWE operations platform being built out of the Deqa Wa Seha operations stack — and it will be introduced in Paper 2 of this series.

5. Publications were planned as regulatory de-risking, not academic output. The publication sequence was designed to place peer-reviewed evidence on the record before, not after, sponsors approached regulators. Placing methodology in the public literature gives regulators independent scientific validation to work from — the operational meaning of "publication discipline" as regulatory strategy.

3.3 Three things this program got wrong

Candour is a governance signal. We will not credit this program with lessons it did not itself teach us, and three of them were expensive.

(a) We underestimated the cost of terminology harmonization across country-specific electronic health record systems. Mapping one national EMR taxonomy against another absorbed operational resource we had budgeted for site initiation. The lesson: terminology harmonization is a Pillar 2 (Data Architecture & Interoperability) design task, not a Pillar 3 (Quality Systems) cleanup task, and pricing it into Pillar 3 is a common blueprint failure.

(b) Covariate definitions required retrospective validation more often than we forecast. Several outcome-relevant covariates — most notably staging conventions and prior-therapy definitions — needed post-hoc adjudication despite pre-enrollment CDM lock. The lesson: pre-lock is necessary but not sufficient; a formal covariate stress-test against sample real-world data is a design-phase step we now build into every registry we run.

(c) Publication planning should have started at protocol-design, not at first interim. By the time later analyses were sequenced, some endpoints could have been strengthened by earlier case-report-form instrumentation. The lesson — directly transferable to any GCC RWE registry — is that publication endpoints belong on the CRF map from day one.

3.4 Portability across therapeutic domains

The same governance-first architecture transfers directly beyond oncology. In Delgerekh et al., LMCE-KSLM 2021 — a real-world testing-behavior analysis across two national laboratory systems — the author served as ninth of thirteen authors (**Yvanka Gilliam, PharmD, EXCO, Diaceutics PLC**), applying the same pre-enrollment governance, CDM discipline, and quality-dashboard operational layer to a diagnostics-leakage question rather than a therapeutic-outcomes question. The transferability of the discipline across therapeutic domains is the argument Paper 3 in this series develops in full.

Section 4 — The GCC Registry Readiness Model

4.0 Introduction to the Model

We propose the **GCC Registry Readiness Model** — a five-pillar operational framework for building submission-ready real-world registries under the region's newly formalized evidentiary standards. The Model is derived from the AHCC08 operational lineage described in Section 3, adapted for the specific data architectures, population dynamics, and regulatory constructs of the Gulf. It is offered under a Creative Commons Attribution 4.0 license: adopt it, cite it, adapt it.

Two design principles govern the Model. First, every success criterion uses vocabulary drawn directly from the SFDA Framework on the use of RWD and RWE (DS-G-135-V01, effective 20 July 2026) or the Department of Health – Abu Dhabi RWD/RWE Guideline. Second, every KPI is measurable, time-bound, and audit-ready — sponsors can literally use the Model as a submission checklist.

The five pillars are: **(1) Governance & Data Rights, (2) Data Architecture & Interoperability, (3) Quality Systems & Source Verification, (4) Regulatory & Evidentiary Alignment, (5) Sustainability & Publication Discipline.** Each is developed below with three success criteria and a single anchor KPI mapped to regulator-specific evidentiary language.

4.1 Pillar 1 — Governance & Data Rights

What the pillar covers. The legal, ethical, and contractual scaffolding that determines who owns the data, who can use it, for what purposes, and under what constraints. This is the pillar regulators inspect first when evaluating whether a registry is a legitimate evidence source.

The AHCC08 lesson. Multi-country intellectual-property and data-use agreements were finalized before Site 1 activation. Publication authorship, secondary-use permissions, and cross-border data flows were fixed in a governance charter every institution signed before the first patient consented. When the regulatory landscape shifted mid-registry, the charter absorbed the change without renegotiation.

The GCC adaptation required. The Gulf presents overlapping privacy regimes — the UAE PDPL (Federal Decree-Law No. 45 of 2021), the Saudi PDPL, UAE Federal Law No. 2 of 2019 on the use of ICT in the health field, the DoH Standard on Human Subject Research, and Saudi NCBE ethics oversight. A single-jurisdiction data-use agreement is insufficient. The registry sponsor must design a **jurisdiction-stacked governance framework** that satisfies each participating regulator simultaneously while enabling legitimate research data flow.

Three success criteria.

6. **Cross-jurisdictional data-use agreements executed pre-enrollment.** Each participating GCC country has an executed, ethics-approved DUA addressing primary use, secondary use, publication rights, IP assignment, and post-study retention *before* any patient is enrolled.
7. **PDPL and health-data-law compliance documented per site.** Each site's data-flow diagram identifies the legal basis for processing under the applicable PDPL, any Article 22-equivalent cross-border transfer authorization, and the compliance officer of record — traceable to a named accountable individual per DoH's *provenance* requirement.
8. **Ethics harmonization plan across emirates and GCC states.** A single master protocol adapted with country- and emirate-specific ethics annexes; every ethics committee approval archived with version control.

> **KPI — Governance Readiness Score.** 100% of participating sites have (a) an executed data-use agreement, (b) documented PDPL legal basis, and (c) active ethics committee approval — verified by an independent quality reviewer *prior to first patient enrolled*. Zero enrollments permitted at sites below 100%.

Regulatory mapping: SFDA's *"quality-assured"* data-source requirement; DoH's *provenance* and *traceability* elements of Reliability.

4.2 Pillar 2 — Data Architecture & Interoperability

What the pillar covers. The technical structure that determines whether data collected from Malaffi, Nabidh, Riayati, the Saudi Cancer Registry, or site-level EHRs can be meaningfully harmonized, analyzed, and submitted. Encompasses common-data-model (CDM) selection, terminology mapping, longitudinal linkage, and metadata documentation.

The AHCC08 lesson. CDM decisions were made before first patient enrolled, not retrofitted. Structured data dictionaries with predefined abstraction rules were established at design phase, eliminating the terminology drift that plagues retrospective harmonization efforts.

The GCC adaptation required. The UAE's health information exchanges are **federated, not unified**. Malaffi (Abu Dhabi), Nabidh (Dubai), and Riayati (northern emirates) integrated at the exchange layer in January 2023 but retain distinct underlying schemas and clinical vocabularies. Saudi Arabia's national health-data infrastructure operates on yet another architecture. Arabic-English bilingual clinical documentation adds a further terminology-reconciliation layer that OMOP, Sentinel, and other Western-derived CDMs do not natively accommodate.

Three success criteria.

9. **CDM selection and mapping documented pre-enrollment**, with a full crosswalk to the source vocabularies of each participating data source — addressing SFDA's language on *"using Common Data Models (CDMs) [to] enable better quality control and offer uniform and consistent data across the different datasets."*
10. **Bilingual clinical terminology reconciliation validated.** Arabic and English clinical terms for key variables (diagnosis, treatment, adverse events, endpoint definitions) reconciled against a validated bilingual dictionary; key variables independently validated per DoH's requirement that *"key variables used to select the study population should be validated."*
11. **Longitudinal linkage strategy defined across HIEs**, with a documented technical approach for linking a single patient's records across Malaffi/Nabidh/Riayati and cross-border to Saudi data assets.

> **KPI — Data Harmonization Coverage.** ≥95% of predefined key variables (exposure, outcomes, covariates) successfully mapped to the chosen CDM across all participating data sources, with an ethics-approved validation report signed off before database lock.

Regulatory mapping: SFDA's *standardization*, *coherence*, and *uniform and consistent data* requirements; DoH's *relevance* domain.

4.3 Pillar 3 — Quality Systems & Source Verification

What the pillar covers. The systematic processes that ensure data flowing into the registry is accurate, complete, timely, and verifiable back to source. Encompasses data monitoring, source-data verification (SDV), quality dashboards, and missing-data management.

The AHCC08 lesson. Real-time quality dashboards — the operational layer we have since generalized under the working name **Oncowave** — enabled continuous monitoring of completeness, range checks, and consistency errors across sites. Issues were surfaced and resolved within days rather than months, dramatically reducing end-of-study data-cleaning cost.

The GCC adaptation required. SDV in EHR-native contexts is fundamentally different from paper-source SDV. Malaffi, Nabidh, and Riayati **are** the source — there is no underlying paper record to reconcile against. This changes the SDV paradigm from *"verify against paper"* to *"verify against structured EHR extract with metadata provenance."* Additionally, mobile expat populations create differential loss-to-follow-up patterns that require GCC-specific missing-data taxonomies.

Three success criteria.

12. **Real-time quality dashboard operational from Day 1**, tracking completeness, range validity, consistency errors, and site-level enrollment quality — reviewed weekly.

13. **Source Data Verification protocol adapted for EHR-native sources**, including metadata provenance verification (per DoH's explicit *provenance* requirement: *"an audit trail that accounts for the origin of a piece of data"*), with defined SDV sample size and frequency.
14. **Missing-data taxonomy and handling plan pre-specified** — including differential loss-to-follow-up expected in expat populations — with clear operational definitions of *missing at random*, *missing not at random*, and *loss to follow-up*.

> **KPI — Data Completeness Rate for Key Variables.** ≥90% completeness for all pre-specified primary exposure, outcome, and confounder variables, measured monthly, with any drop below 90% triggering a within-30-day corrective action plan.

Regulatory mapping: SFDA's *"complete information"* and *"accuracy"* requirements; DoH's *reliability* domain.

4.4 Pillar 4 — Regulatory & Evidentiary Alignment

What the pillar covers. The strategic alignment between the registry's design and the specific evidentiary requirements of the regulator(s) whose decisions the registry is intended to support. **This is the pillar where we name the regulators explicitly** — the Saudi Food and Drug Authority (SFDA) for marketing authorization and safety, the Department of Health – Abu Dhabi (DoH) for HTA, reimbursement, and Economic Evaluation, and the Emirates Drug Establishment (EDE) for consolidated UAE-wide oversight.

The AHCC08 lesson. Endpoints and estimands were defined in alignment with the regulatory questions the registry was ultimately intended to answer — not the reverse. This upfront alignment allowed the registry outputs, including downstream HEOR and burden analyses at ISPOR Asia-Pacific 2020 and ESMO Asia 2020, and the Sim et al., *Liver Cancer* 2023 manuscript, to feed directly into downstream decision-making dossiers.

The GCC adaptation required. The GCC now presents **three parallel regulatory tracks** that a well-designed registry can serve simultaneously: (a) SFDA drug marketing authorization and safety; (b) DoH HTA and reimbursement (requiring CEA and BIA with local RWD under the DoH HTA Guidelines, 2025); and (c) the Saudi Economic Evaluation System (EES), mandatory since July 2025. Each track has distinct evidentiary requirements. A registry designed for only one track wastes an opportunity; a registry designed for all three yields multi-track value from a single data-collection effort.

Three success criteria.

15. **Estimand-defined primary and secondary questions per ICH E9(R1).** The protocol specifies estimands — treatment-effect definitions with clearly stated *time-fixed or time-varying*

treatments, necessary covariates, and outcomes of interest per SFDA's exact wording — aligned to the target regulatory question(s).

16. **Bias and confounding mitigation strategy documented pre-analysis**, using at least two SFDA-endorsed methods from among *"stratification, standardization, regression models, propensity scores… and high-dimensional propensity score (hdPS)."*
17. **HTA/EES readiness annex included in the protocol.** For registries intended to support HTA or EES submissions, a dedicated annex maps registry variables to CEA and BIA modeling requirements, including cost-and-resource-use variables and health-state utilities.

> **KPI — Regulatory Alignment Certification.** A pre-analysis regulatory alignment memo — reviewed and countersigned by a qualified regulatory affairs professional and archived with the protocol — certifying that the registry design meets the specific evidentiary requirements of each targeted regulator (SFDA, DoH, EDE, EES) *before* database lock.

Regulatory mapping: SFDA's requirements for *estimands* and *addressing biases*; DoH HTA's requirement for local RWD in economic evaluation submissions.

4.5 Pillar 5 — Sustainability & Publication Discipline

What the pillar covers. The mechanisms that ensure the registry continues to generate value beyond the primary analysis — including peer-reviewed publication, cross-therapeutic-area data reuse, investigator retention, and long-term sustainability of the data asset.

The AHCC08 lesson. Publication was a regulatory de-risking activity, not a marketing afterthought. The peer-reviewed conference and journal outputs of the program — ASCO 2018, ASCO GI 2019, and Sim et al., *Liver Cancer* 2023 — placed methodology on the public record before formal regulatory submission, giving reviewers independent scientific validation to work from.

The GCC adaptation required. GCC RWE registries face a specific sustainability failure mode: investigator attrition driven by expat mobility and limited authorship opportunities. Sustained operation requires (a) a publication policy that credits regional investigators competitively with global authors, (b) a governance mechanism for approving secondary-use research questions, and (c) explicit data-retention and reuse frameworks aligned with UAE and Saudi PDPL retention limits.

Three success criteria.

18. **Publication plan filed with the protocol**, identifying primary and secondary manuscripts, target peer-reviewed journals (with DOI), authorship criteria per ICMJE guidelines, and a milestone schedule.

19. **Registry posted on a public registry of registries** — ClinicalTrials.gov or an equivalent — before enrollment, with a defined disclosure schedule for enrollment status, interim results, and publications.
20. **Secondary-use governance and data-retention policy documented**, aligned with UAE and Saudi PDPL retention limits and defining destruction or archival at the end of the retention period.

> **KPI — Publication and Transparency Milestone Adherence.** ≥1 peer-reviewed publication (with DOI) submitted within 12 months of primary database lock, and 100% of pre-specified interim disclosure milestones met on the public registry — measured annually.

Regulatory mapping: DoH's *reliable documentation* requirement; SFDA's implicit endorsement of publication as evidence validation; Gliklich & Leavy's foundational transparency criterion.

4.6 The Model at a Glance

The five pillars form a linear operational sequence — governance decisions constrain data architecture, architecture constrains quality systems, quality systems condition regulatory alignment, and regulatory alignment is what sustainability and publication discipline protect over time.

Operational flow:

> **[1] Governance & Data Rights → [2] Data Architecture & Interoperability → [3] Quality Systems & Source Verification → [4] Regulatory & Evidentiary Alignment → [5] Sustainability & Publication Discipline**

Anchor KPI per pillar:

> **[1]** 100% governance readiness pre-enrollment → **[2]** ≥95% key-variable harmonization coverage → **[3]** ≥90% monthly completeness on key variables → **[4]** pre-lock regulatory alignment certification → **[5]** ≥1 peer-reviewed publication within 12 months of lock

Pillar	Focus	Anchor KPI
1. Governance & Data Rights	Legal / ethical scaffolding	**100% governance readiness pre-enrollment**
2. Data Architecture & Interoperability	CDM, terminology, linkage	**≥95% key-variable harmonization coverage**
3. Quality Systems & Source Verification	Data accuracy and completeness	**≥90% completeness for key variables monthly**
4. Regulatory & Evidentiary	Fit-to-regulator-purpose	**Pre-lock regulatory alignment**

Alignment		**certification**
5. Sustainability & Publication Discipline	Long-term value + transparency	**≥1 peer-reviewed publication within 12 months of lock**

Section 5 demonstrates the Model applied to three concrete GCC real-world evidence registry scenarios.

Section 5 — The Model Applied: Three GCC Real-World Evidence Registry Scenarios

5.0 Three commissioning patterns the GCC will see

The GCC Registry Readiness Model applies to any therapeutic area for which a sponsor, payer, or government body needs submission-ready real-world evidence. Below we describe the three commissioning patterns we expect to dominate the region over the next twenty-four months. In each, we identify the two pillars carrying the highest execution risk and the specific operational choice on which success turns.

The scenarios are deliberately therapeutic-area-agnostic. The Model does not distinguish between oncology, cardiometabolic, rare disease, infectious disease, or specialty therapeutic RWE — it distinguishes between well-governed and poorly-governed real-world data collection. What varies across therapeutic areas is the specific covariate set and the endpoint definitions; what does not vary is the operational discipline required to make the data submission-ready.

5.1 Scenario A — De novo multi-country prospective RWE registry

The commissioning pattern. A sponsor — multinational pharmaceutical, biotech, investigator consortium, or specialty-pharma entrant — building a prospective RWE registry from scratch across the UAE and Saudi Arabia (and optionally other GCC states) to support marketing authorization, post-authorization safety, and downstream reimbursement. Typical parameters: 800–1,500 patients, 8–12 sites, 24–36 months of enrollment and follow-up.

Highest-risk pillars: Pillar 1 (Governance & Data Rights) and Pillar 4 (Regulatory & Evidentiary Alignment). A de novo multi-country registry is a governance-heavy build. Data-use agreements must be executed across two jurisdictions with materially different privacy regimes, ethics harmonization must span at least the DoH ethics standard and Saudi NCBE oversight, and the protocol must be architected so a single dataset satisfies SFDA marketing-authorization evidentiary requirements, DoH HTA needs, and the Saudi Economic Evaluation System simultaneously.

The critical operational choice. Whether the registry is designed as a **single master protocol with country-specific ethics annexes** or as **two country-level registries linked by a shared common data model**. The former is faster to publish and easier to pool for regulatory submission; the latter is easier to negotiate with each ethics committee but produces two datasets that require post-hoc harmonization at

Pillar 2 cost. We recommend the first, with the governance charter executed as described in Pillar 1's success criteria before any site opens.

Model outputs the scenario should hit. 100% Governance Readiness Score pre-enrollment (Pillar 1 KPI); Data Harmonization Coverage ≥95% with a validated bilingual variable dictionary (Pillar 2 KPI); pre-lock Regulatory Alignment Certification memo covering all three regulatory tracks (Pillar 4 KPI).

5.2 Scenario B — Retrospective bridging RWE from an existing GCC data asset

The commissioning pattern. A sponsor with an already-approved therapy seeking a regulatory bridge for GCC market entry, leveraging an existing regional data asset — the Saudi Cancer Registry, other national disease-specific registries, Malaffi or Riayati longitudinal extracts, or curated administrative claims — rather than commissioning a de novo prospective build. Timeline: 12–18 months from commissioning to submission.

Highest-risk pillars: Pillar 2 (Data Architecture & Interoperability) and Pillar 3 (Quality Systems & Source Verification). A retrospective bridging analysis lives or dies on whether the existing data source can meet the SFDA's "fit-for-purpose" bar. Most regional data assets were architected for administrative or epidemiological purposes, not regulatory-grade covariate adjudication. Bridging them into a submission-ready RWE package requires substantial Pillar 2 harmonization (variable-level crosswalk, missing-covariate imputation strategy) and Pillar 3 source-verification (EHR-native SDV protocol executed against the underlying data sources).

The critical operational choice. Whether to (a) accept the existing data asset as-is and design the statistical analysis plan to work within its variable set, or (b) commission a targeted EHR-native supplement to fill covariate gaps. Option (b) doubles operational cost but often halves the regulatory review cycle. We generally recommend (b) for registries feeding first-in-region approval submissions, and (a) for post-authorization safety.

Model outputs the scenario should hit. Data Harmonization Coverage ≥95% including all confounders required for causal analysis (Pillar 2 KPI); Data Completeness Rate ≥90% monthly on all pre-specified variables (Pillar 3 KPI); bias-mitigation strategy in the statistical analysis plan using at least two SFDA-endorsed methods (Pillar 4 criterion 2).

5.3 Scenario C — Payer- or government-commissioned population-level RWE study

The commissioning pattern. A payer, HTA body, government commissioner, or public-health authority running a population-level RWE study on Malaffi, Nabidh, Riayati, or Saudi national data infrastructure,

in preparation for a formulary, reimbursement, or public-health policy decision under the DoH HTA Guidelines or the Saudi Economic Evaluation System. Timeline: 6–12 months to first analysis.

Highest-risk pillars: Pillar 4 (Regulatory & Evidentiary Alignment) and Pillar 5 (Sustainability & Publication Discipline). The study exists to inform a specific reimbursement or policy decision, so Pillar 4 alignment — specifically the HTA/EES annex mapping registry variables to CEA and BIA modeling requirements — is definitional. Pillar 5 matters because a commissioned analysis with no publication plan and no secondary-use governance mechanism is a one-time expenditure; the same underlying data asset, governed correctly, generates value across multiple decisions and multiple therapeutic areas.

The critical operational choice. Whether to design the analysis as a **single-decision dossier** or as a **reusable data asset with the initial reimbursement analysis as its first output**. The second requires upfront Pillar 5 investment (publication plan, secondary-use approval mechanism, retention policy aligned with UAE PDPL) but converts a project cost into an infrastructure asset. Government commissioners operating at scale increasingly prefer the second.

Model outputs the scenario should hit. Regulatory Alignment Certification with an HTA/EES annex countersigned pre-analysis (Pillar 4 KPI); at least one peer-reviewed publication with DOI submitted within 12 months of primary database lock, plus 100% of pre-specified interim disclosure milestones met (Pillar 5 KPI).

5.4 What all three scenarios share

All three commissioning patterns converge on the same operational principle: the pillars carrying the highest execution risk are the ones where governance and design decisions must be made **before enrollment or first data pull, not after**. Section 6 develops that principle into a concrete ninety-day operational sequence any sponsor or commissioning body can execute.

Section 6 — The 90-Day Readiness Sprint

6.0 From framework to execution

The GCC Registry Readiness Model is only as useful as the sequence in which sponsors execute it. Below we specify a ninety-day operational sprint any sponsor, commissioning body, or research organization can run in the first quarter after committing to a GCC real-world evidence program. The sprint is therapeutic-area-agnostic. It converts the five pillars into a dated set of deliverables that, if completed on schedule, produce a registry ready for first-patient-in or first-data-pull at Day 91.

Weeks 1–2 — Governance foundation (Pillar 1). Draft and circulate the governance charter: publication authorship criteria per ICMJE; data-access and secondary-use rights; IP assignment; cross-border data-transfer authorization pathways. Initiate cross-jurisdictional data-use agreement negotiations with each participating institution. Identify the compliance officer of record per site. Confirm the legal basis for processing under UAE PDPL and Saudi PDPL, with Article 22-equivalent cross-border transfer memos drafted. **Deliverable:** governance charter v1.0 in circulation; DUA templates issued to all sites.

Weeks 3–4 — Data architecture decision (Pillar 2). Complete data-source feasibility across the intended data assets (Malaffi, Nabidh, Riayati, Saudi Cancer Registry, national disease registries, or site-level EHR extracts as applicable). Select the common data model (OMOP, Sentinel, PCORnet, or a documented custom CDM) and produce the crosswalk to each source vocabulary. Initiate Arabic-English bilingual terminology reconciliation for all key variables. Draft the longitudinal linkage strategy across HIEs. **Deliverable:** CDM selection memo, variable-level crosswalk, and bilingual terminology dictionary v1.0.

Weeks 5–8 — Ethics and regulatory alignment (Pillars 1 and 4). Submit the master protocol with country- and emirate-specific ethics annexes to every participating ethics committee. Draft the pre-analysis Regulatory Alignment memo mapping the registry design to the specific evidentiary requirements of each targeted regulator (SFDA, DoH, EDE, EES as applicable). Specify estimands per ICH E9(R1) and the bias-mitigation strategy using at least two SFDA-endorsed methods. For any registry supporting HTA or EES submissions, draft the HTA/EES readiness annex. **Deliverable:** all ethics submissions filed; Regulatory Alignment memo v1.0 countersigned by qualified regulatory affairs professional; HTA/EES annex where applicable.

Weeks 9–12 — Quality systems build and publication plan (Pillars 3 and 5). Stand up the real-time quality dashboard covering completeness, range validity, consistency, and enrollment velocity — operational by Day 84 for review at Day 91. Draft the EHR-native SDV protocol and the missing-data taxonomy. File the publication plan with the protocol: primary and secondary manuscripts, target peer-reviewed journals with DOI, authorship criteria, milestone schedule. Post the registry to ClinicalTrials.gov or an equivalent public registry-of-registries. Document the secondary-use governance

mechanism and the data-retention policy aligned with applicable PDPL retention limits. **Deliverable:** quality dashboard operational; publication plan filed; registry publicly posted; retention policy documented.

Day 91. All five pillars have documented artifacts. Governance Readiness Score = 100%. Data Harmonization Coverage ≥95%. Regulatory Alignment Certification archived. Publication plan on file with the protocol. The registry is ready for first-patient-in or first-data-pull.

The organizations that build discipline into the first ninety days do not spend the next twenty-four months paying for its absence. Section 7 closes the paper.

Section 7 — Conclusion & Call to Contribution

7.1 What this paper is and is not

This paper is a v1.0 operational framework, not a finished doctrine. It does not resolve every ambiguity in the Gulf's evolving real-world evidence landscape — the region's regulators have made clear that their frameworks will continue to develop, and the Model is designed to develop alongside them. What the paper does establish is that submission-ready real-world registries in the Gulf are not a data-availability problem. They are an operational-discipline problem. The five-pillar GCC Registry Readiness Model translates that discipline into artifacts sponsors, commissioning bodies, and regulators can inspect.

7.2 An open framework

The Model is offered under a Creative Commons Attribution 4.0 International license. Adopt it. Cite it. Adapt it to the specific therapeutic areas, data assets, and regulatory contexts you work in. We welcome case-study contributions from GCC-based sponsors, investigators, and payers who have applied the Model — positive results and failure modes alike — and will incorporate them into subsequent versions of this work.

7.3 What comes next in this series

Paper 2 — HEOR, HTA, and the Saudi Economic Evaluation System. Applies the Model to the specific evidentiary requirements of the DoH HTA Guidelines and the Saudi EES, developing Pillar 4 in depth for economic-evaluation submissions. Introduces the **Oncowave** real-time RWE operations platform referenced in Section 3.

Paper 3 — Precision Diagnostics and Real-World Evidence. Applies the Model to companion-diagnostics and diagnostic-testing RWE, extending the discipline demonstrated in Delgerekh et al., LMCE-KSLM 2021 to the full spectrum of precision-medicine evidence generation in the Gulf.

Conflicts of Interest and Disclosures

The author is the founder of **Deqa Wa Seha**, a site management organization and contract research organization headquartered in Abu Dhabi, United Arab Emirates, that provides operational services to sponsors conducting clinical research and real-world evidence programs. Deqa Wa Seha may derive commercial benefit from sponsor adoption of the GCC Registry Readiness Model presented in this paper. The author also founded and directs **GLOBALCORE Clinical Research Academy**, whose Real-World Evidence and Real-World Data (RWE/RWD) Professional Certification and related certifications align conceptually with the workforce-capacity requirements described in Pillar 5.

No sponsor, regulator, or third party commissioned, reviewed, or paid for the preparation of this paper. The peer-reviewed publications cited in this paper — including AHCC08 registry outputs and ISPOR Asia-Pacific 2020 presentations — were completed under the author's prior executive roles at IQVIA Asia-Pacific, Kantar Health, and Diaceutics PLC; the author has no continuing financial relationship with those organizations.

The views expressed are those of the author and do not represent formal positions of any regulator, sponsor, or professional body.

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ABOUT THE AUTHOR

Yvanka Gilliam, PharmD, MBA is a real-world evidence and real-world data operations executive with over a decade of executed multi-country RWE program leadership across Asia-Pacific, the Middle East, and Africa. Her operational track record includes end-to-end execution of the AHCC08 multi-country registry program in hepatocellular carcinoma reported across ASCO 2018 *JCO*, ASCO GI 2019 *JCO*, the ESMO Asia Congress 2020 Poster 166P (Chow PKH, …, Gilliam Y, et al.) — subsequently published in the *Annals of Oncology* supplement — and closing with Sim et al., *Liver Cancer* 2023 (2,533 patients, 33 sites, nine countries). Her broader health-economics portfolio spans **seven ISPOR Asia-Pacific 2020 presentations across oncology, respiratory, mental-health, and infectious-disease therapeutic areas** — including two as lead author on vaccination-rate and hepatitis diagnostic-and-treatment epidemiology — together with a precision-diagnostics RWE publication at LMCE-KSLM 2021 as Vice President of Operations (EXCO), Diaceutics PLC.

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About Deqa Wa Seha

Deqa Wa Seha is a site management organization and contract research organization headquartered in Abu Dhabi, United Arab Emirates, providing operational services to sponsors conducting clinical research and real-world evidence programs across the UAE, wider Middle East and North Africa, Asia-Pacific, and Africa. Deqa Wa Seha's operational focus includes registry design and execution, regulatory operations, site feasibility and activation, patient recruitment and retention, source data verification, and real-world evidence infrastructure for regional and multi-country studies. The organization was founded to translate international clinical research operational discipline into a locally-owned regional capability aligned to the evidentiary standards of the GCC's regulatory frameworks.

About GLOBALCORE Clinical Research Academy

GLOBALCORE Clinical Research Academy is a career-focused clinical research training academy delivering CPD-accredited, ICH-GCP-aligned curricula built by working clinical research professionals, with regional anchors in the GCC. The Academy's program portfolio includes the ICH-GCP (E6 R3) certificate; Decentralized Clinical Trials (DCT); Real-World Evidence and Real-World Data (RWE/RWD) Professional Certification; Study Start-Up & Site Activation (Contracts & Budgets, ICH-GCP); Medical Writing & Scientific Publications (ICMJE/GPP); General Data Protection Regulation (GDPR); the Project Management Diploma; and Clinical Research Coordinator (CRC), Regulatory Affairs (RA), and Clinical Research Associate (CRA) foundations and track courses. Courses are self-paced with twelve months of access, supported by real clinical trial case studies, working CRA, CRC, and RA mentors, and office hours. GLOBALCORE was built to open a rigorous, career-ready pathway into clinical research for beginners, career pivoters, and working professionals — grounded in clinical trial experience, aligned to global standards, and recognized through CPD certification.