# The GCC's Real-World Evidence Moment

**A 2-Page Executive Brief** — Companion to *An Operational Playbook for GCC Real-World Evidence Registries*, Paper 1 of 3

## Why this brief, from this author, from this region

I am **Yvanka Gilliam, PharmD, MBA** — Founder & Chief Executive Officer of **Deqa Wa Seha**, a site management and contract research organization headquartered in Abu Dhabi, United Arab Emirates, operating across the UAE, wider MENA, Asia-Pacific, and Africa; and Founder of **GLOBALCORE Clinical Research Academy**, a clinical research training academy with regional anchors in the GCC.

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I built and led the operational architecture behind one of Asia-Pacific's largest multi-country oncology real-world evidence programs — a decade of registry work reported through the peer-reviewed evidence trail — *JCO* at ASCO 2018, ASCO GI 2019, ESMO Asia 2020, seven ISPOR Asia-Pacific 2020 presentations, and Sim et al., *Liver Cancer*, 2023 (2,533 patients, 33 sites, nine countries). I served previously as Vice President of Operations and Executive Committee member at Diaceutics PLC, Vice President at Kantar Health, and Head of Real World Evidence for IQVIA Asia-Pacific.

I am now based in the UAE. This paper series translates that operational track record into a framework the GCC's regulatory community can execute against.

## The submission regime has changed

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. Extrapolated foreign RWE — the workaround sponsors have relied on since the region's first pricing negotiations — no longer satisfies the evidentiary threshold.

The frameworks issued to date are precise 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**.

> **The primary 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.**

## The GCC Registry Readiness Model

Five operational pillars derived from the multi-country APAC real-world evidence program cited above, translated for the GCC's regulatory architecture. Each pillar carries three success criteria and one measurable KPI aligned to regional evidentiary standards.

| # | Pillar | Anchor KPI |
|---|---|---|
| 1 | **Governance & Data Rights** | 100% governance readiness pre-enrollment |
| 2 | **Data Architecture & Interoperability** | ≥95% key-variable harmonization coverage |
| 3 | **Quality Systems & Source Verification** | ≥90% completeness for key variables, monthly |
| 4 | **Regulatory & Evidentiary Alignment** | Pre-lock regulatory alignment certification |
| 5 | **Sustainability & Publication Discipline** | ≥1 peer-reviewed publication within 12 months of database lock |

## Who this is for

Regulators and health technology assessment bodies designing evidence review pathways for regional submissions. Sponsors and CROs commissioning GCC-native registries to support marketing authorization, pricing, and reimbursement.

Investigator networks and academic medical centers building the infrastructure to participate in regulatory-grade real-world evidence programs.

### What the full paper contains

The 28-page companion paper builds out the Model in operational detail: the reference architecture derived from the APAC program, the five pillars with fifteen success criteria and five KPIs, three commissioning scenarios likely to dominate the region over the next twenty-four months, and a 90-day readiness sprint any sponsor or investigator team can execute. Every claim is anchored to a primary regulatory source or a peer-reviewed publication.

### What comes next

**Paper 2 of 3 — publishing in three weeks** — extends the Model into health economics: how to design a GCC registry that produces submission-ready inputs for pharmacoeconomic and economic evaluation reviews on a single dataset.

**Paper 3 of 3 — publishing in six weeks** — extends the Model into precision diagnostics: how to build the real-world evidence trail that supports companion diagnostic reimbursement in emerging regulatory jurisdictions.

### Contact

Regulators, sponsors, and investigator teams working on GCC real-world evidence readiness are invited to open a conversation directly: **yvanka.gilliam@deqawaseha.ae**.

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