GCC RWE OPERATIONAL SERIES · PAPER 1 OF 3

Executive Summary

Companion to An Operational Playbook for GCC Real-World Evidence Registries · Paper 1 of 3

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Suggested citation. Gilliam Y. *Executive Summary — An Operational Playbook for GCC Real-World Evidence Registries.* GCC RWE Operational Series, Paper 1 of 3. Zenodo, August 2026. DOI: 10.5281/zenodo.22086631. CC BY 4.0.

*This Executive Summary is a companion document to **An Operational Playbook for GCC Real-World Evidence Registries** (Paper 1 of 3). Read it independently or as an on-ramp to the full paper.*

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.