Structuring Asia-Pacific Digital Therapeutics Regulatory Data within the OMOP Common Data Model

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Abstract

Digital therapeutics (DTx) are rapidly expanding across Asia-Pacific, yet regulatory frameworks remain fragmented, inconsistent, and non-computable. This limits cross-country evidence generation, HTA alignment, and reimbursement decisions. We conducted a scoping review across five APAC jurisdictions and identified key regulatory variables governing approval pathways, evidence requirements, and reimbursement status. Based on these findings, we developed the first structured regulatory metadata layer for the OMOP Common Data Model. Embedding regulatory context into OMOP-CDM enables cross-country analytics, supports RWE-driven HTA, and strengthens digital-health governance for AI-enabled DTx.

Background

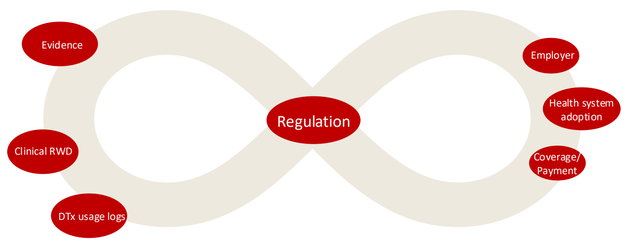
APAC DTx policies are fragmented and non-standardized

APAC countries remain highly heterogeneous in digital health maturity, regulatory infrastructure, and data interoperability.

OMOP-CDM for Unified DTx Evaluation

The udatake of DTx the adoption of OMOP-CDM adoption in APAC offers a timely opportunity to harmonise regulatory evaluation and real-world effectiveness studies.

Cross-country RWE → HTA → Payment circle



To enable regional evidence synthesis and policy comparability, DTx regulatory data must be represented in a structured, computable form that integrates with RWD/RWE.

Highlights

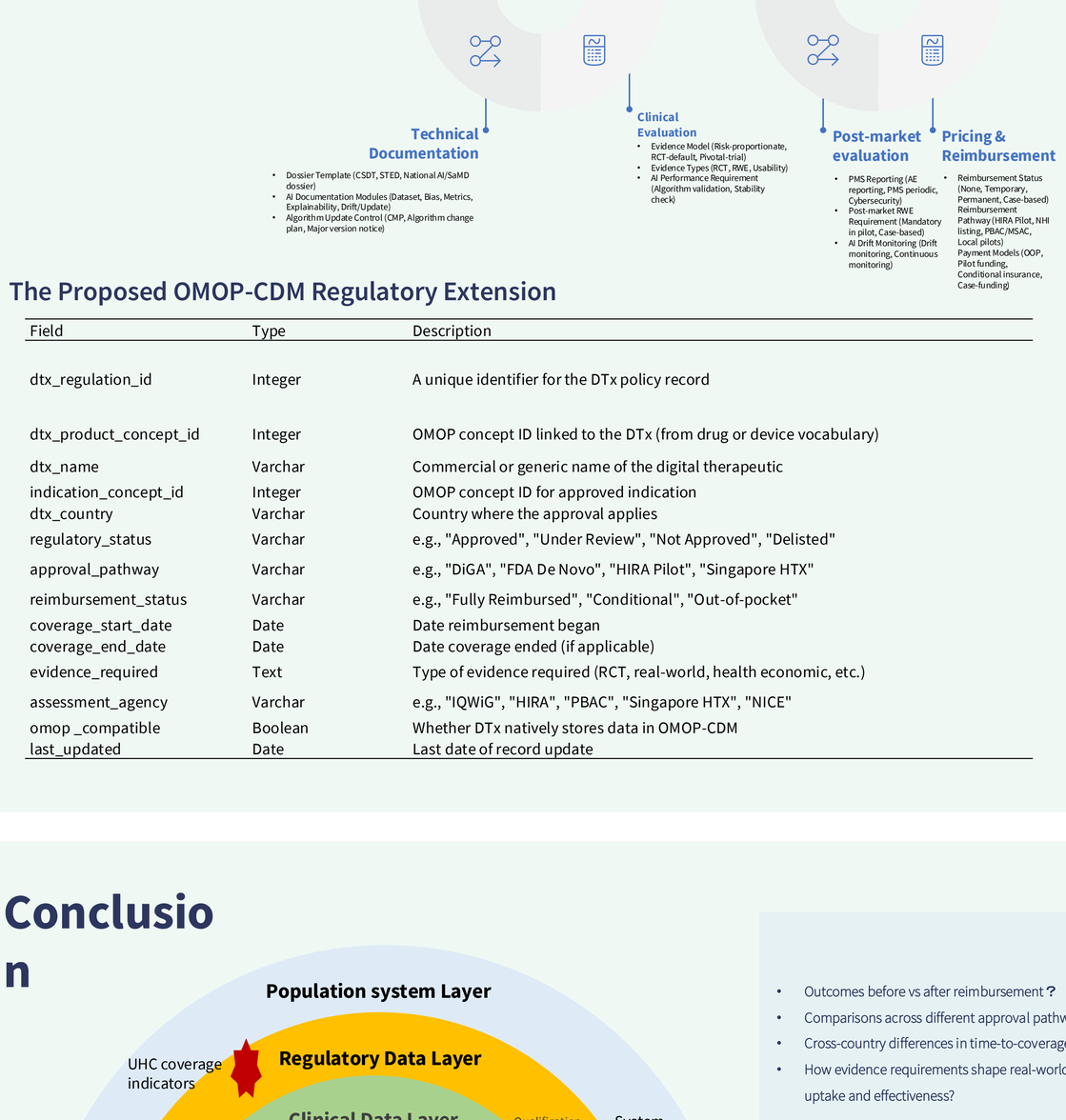
- First structured representation of APAC DTx regulatory data in OMOP-CDM
- Enables cross-country evidence generation and comparative HTA for DTx
- Links clinical RWE with regulatory decisions and reimbursement pathway

Methods

- **Conducted a scoping review of regulatory policies across five APAC countries (Japan, Korea, Singapore, China, Australia).**
- **Extracted regulatory variables related to qualification, classification, evidence requirements, registration, post-market rules, and reimbursement, and evaluated OMOP-CDM readiness.**
- **Mapped each variable to OMOP-CDM tables and domains to develop an extensible regulatory metadata layer.**

Results: OMOP Extension Model

Regulatory Variables Extracted Across 7 Stages of the DTx Lifecycle

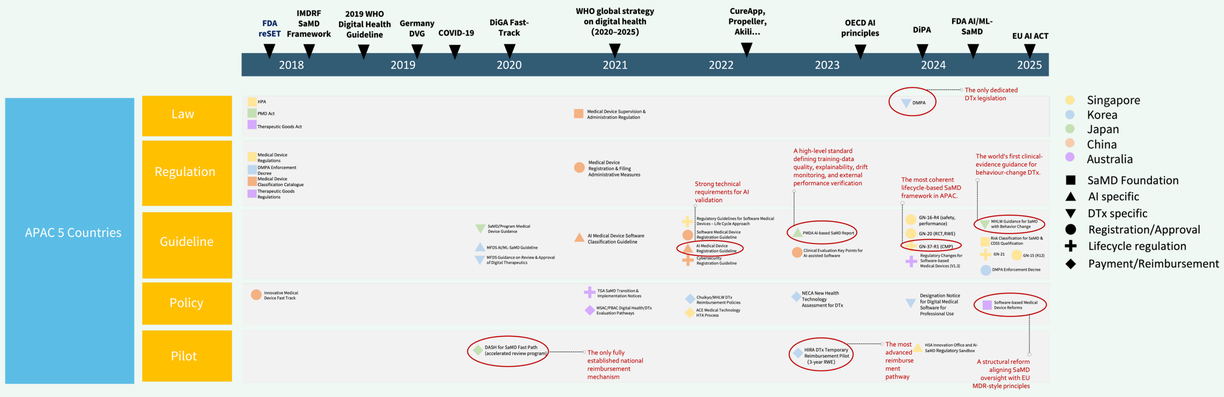


The Proposed OMOP-CDM Regulatory Extension

Field	Type	Description
dtx_regulation_id	Integer	A unique identifier for the DTx policy record
dtx_product_concept_id	Integer	OMOP concept ID linked to the DTx (from drug or device vocabulary)
dtx_name	Varchar	Commercial or generic name of the digital therapeutic
indication_concept_id	Integer	OMOP concept ID for approved indication
dtx_country	Varchar	Country where the approval applies
regulatory_status	Varchar	e.g., "Approved", "Under Review", "Not Approved", "Delisted"
approval_pathway	Varchar	e.g., "DiGA", "FDA De Novo", "HIRA Pilot", "Singapore HTX"
reimbursement_status	Varchar	e.g., "Fully Reimbursed", "Conditional", "Out-of-pocket"
coverage_start_date	Date	Date reimbursement began
coverage_end_date	Date	Date coverage ended (if applicable)
evidence_required	Text	Type of evidence required (RCT, real-world, health economic, etc.)
assessment_agency	Varchar	e.g., "IQWiG", "HIRA", "PBAC", "Singapore HTX", "NICE"
omop _compatible	Boolean	Whether DTx natively stores data in OMOP-CDM
last_updated	Date	Last date of record update

Results: Policy Landscape

DTx policies Landscape (40 documents, 2018-2025)



South Korea and Japan exhibit the only full-cycle DTx regulatory models with formal reimbursement; Singapore and Australia have advanced SaMD/AI governance but lack payment pathways; China has the largest expansion but limited DTx-specific structures.

Regulatory Development Stages for DTx

Phase 1 (2018-2019) Legal identity formation

Global regulators first established the regulatory identity of DTx and AI-enabled software, clarifying their status as medical technologies. This phase focused on foundational definitions, risk classification, and boundary-setting between wellness apps, CDSS, and SaMD.

Phase 2 (2020-2021) Acceleration

Driven by COVID-19 and rapid digital adoption, countries introduced expedited pathways, temporary flexibilities, and early payment pilots to enable real-world use of DTx despite immature regulatory structures. This period is characterized by pragmatic experimentation, partial relaxation of evidence requirements, and the emergence of first-generation AI-SaMD principles without yet achieving full lifecycle control.

Phase 3 (2022-2023) Structuring

Regulatory systems consolidated into coherent, end-to-end frameworks, integrating DTx qualification, SaMD documentation, AI technical standards, clinical evidence requirements, and PMS expectations. Evidence governance became more explicit—from RCT standards to RWE integration—while AI oversight evolved from static pre-market checks to lifecycle-based management.

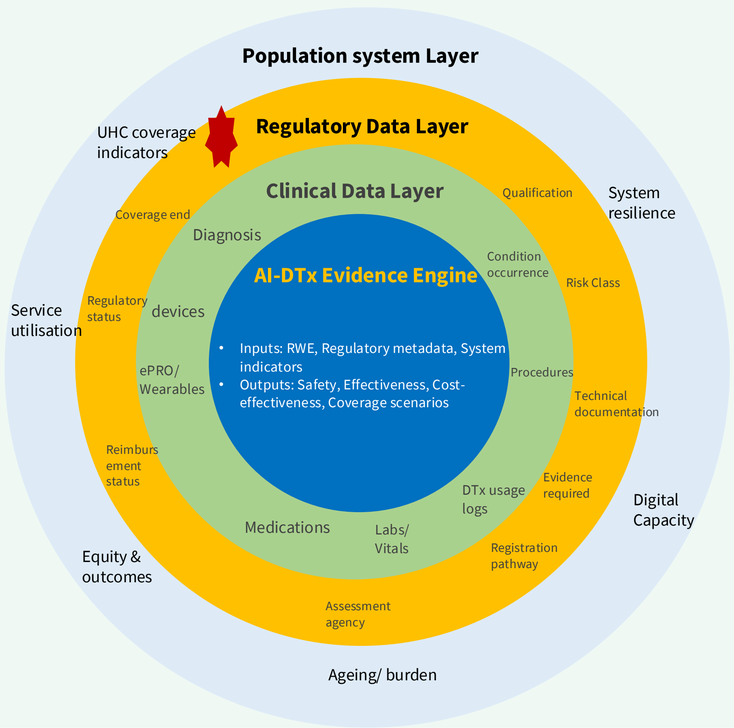
Phase 4 (2024-2025) Institutionalization

AI-DTx became embedded within routine regulatory and reimbursement architectures. Countries established predictable approval-to-payment pathways, and adopted continuous real-world performance monitoring. DTx shifted from "innovation exceptions" to stable health-system components, supported by emerging efforts toward interoperable, computable regulatory data for cross-country evidence translation.

APAC DTx Products Approvals

Korea	Japan	Singapore	Australia	China
8 DTx Reimbursement: Pilot Somzz (2023); WELT-I (2023); VIVID Brain (2023); EasyBreath (2023); Acryl-D01 (2024); Sori-Clear (2024); Anzeilex (2024); Cogthera (2024)	5 DTx Reimbursement: Yes CureApp SC (2020); CureApp HT (2022); SUSMED CBT-i (2023); ENDEAVORRIDE (2025); CureApp Alcohol DTx (2025)	8 DTx Reimbursement: No reSET (2020, prescription DTx for SUD)	1 DTx Reimbursement: No TALi Train / ReadyAttentionGo (2023, cognitive training SaMD)	235 DTx Reimbursement: No Domain: Neurology, Ophthalmology, Mental health, Others

Conclusion



- Outcomes before vs after reimbursement？
- Comparisons across different approval pathways？
- Cross-country differences in time-to-coverage？
- How evidence requirements shape real-world uptake and effectiveness?

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The concentric model integrates clinical RWD (OMOP-CDM), regulatory metadata, and population-system indicators, enabling consistent generation of safety, effectiveness, cost-effectiveness, and reimbursement-readiness evidence. This unified infrastructure supports lifecycle-based oversight, accelerates HTA processes, and enables cross-country translation of AI-DTx evidence.

Implication

Extending OMOP-CDM with computable regulatory metadata enables the platform to support lifecycle evaluation of DTx and AI-DTx. This unified structure allows cross-country comparisons of access, adherence, and real-world effectiveness, strengthens HTA, and informs equitable reimbursement in APAC.

Next Step:
(1) pilot the regulatory table in at least one OMOP site; (2) populate it for 3–5 DTx products, and (3) run exemplar analyses — such as reimbursement-linked outcome studies or cross-country time-to-coverage comparisons.