Regulatory Framework for Digital Therapeutics in APAC

	US	EU	S. Korea	Japan	China	Taiwan	India	Indonesia	Singapore	Australia
Regulatory Agency	FDA	European Commission	MFDS	PMDA	NMPA	TFDA	CDSCO	NADFC	HSA	TGA
DTx Regulation	Class II 510(k) or De Novo	Class IIa, IIb	Class II	Mostly Class II	Class II	Class II	Class C	Class C	Class B	Class IIa, IIb
Pre-submission	Yes	No	Emerging	Yes	No	No	No	No	Yes	Yes
Approval Timeline	9-12 months	2 years	6-8 months	12 months	6 months	10-12 months	6-9 months	4 months	3-4 months	4-6 months
Alternate Pathways	Wellness; Exempt; Enforcement Discretion	Class I	Class I	Exempt	Class I	Consumer Health	Consumer Health	Consumer Health	Class A (exempt)	Excluded, Class I
DTx Clinical Data Requirements	Sham-controlled RCT generally required	RCT generally required	RCT generally required	RCT generally required for novel devices	Clinical evaluation required; RCT may be required	Clinical data generally required	Clinical data generally required	Clinical data generally required	Clinical data generally required	Clinical data generally required; RCT for novel devices
Clinical Data Portability	Must be relevant to US demographics and SOC; Must follow GCP	Must demonstrate state of the art Must follow GCP	Foreign clinical data may be accepted if relevant to Korean population	Clinical data must be obtained on Japanese population	Foreign clinical data can support local data	US and EU clinical data accepted	Foreign clinical data accepted	Foreign clinical data accepted	US, EU, Canada, Japan, Australia clinical data may be accepted	US, EU, Canada, Japan, Singapore clinical data may be accepted
Government Reimbursement	Limited / emerging; additional data typically required	Yes / emerging depending on market; additional data required	Emerging	Yes; Same data may potentially be used	No	No	No	No	No	Emerging; depends on therapeutic area
International Standards										
IMDRF Framework	✓	✓	✓	✓	✓		✓		✓	✓
IEC 62304 - SDLC	✓	✓	✓	✓	✓		✓			✓
ISO 13485 - QMS		✓	✓	✓	✓	✓	✓	✓		✓
ISO 14971 – Risk Management	✓	✓	✓	✓			✓			✓

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