Quick Reference Guide

Digital Health Standards Foundations

Contents

About this Quick Reference Guide

This Quick Reference Guide (QRG) summarises the key concepts, tables and reference information from the Digital Health Standards Foundations course. Use it to refresh your understanding during knowledge checks and the final case study, or as an ongoing reference while working with Digital Health Standards.

Topic: What is a Standard and Why Standards Matter

Definition

A standard is a formally developed and endorsed specification, often a document, dataset, or technical framework, developed by accredited organisations. It defines processes, criteria, or methodologies to ensure the safety, reliability and interoperability of digital health solutions. Standards are built through consensus, bringing together industry, government, clinicians and consumers so no single interest dominates.

Standards vs Legislation, Policy and Guidelines

Type	Description	Example
Standard	Agreed minimum expectations for safety and quality, developed through consensus. Can be referenced by regulators and mandated through contracts or accreditation.	SNOMED CT-AU for clinical terminology
Legislation	Law made by Parliament. Legally enforceable with penalties for non-compliance.	Privacy Act 1988; My Health Record Act 2012
Policy	Authoritative organisational or government directives that set mandatory requirements within a jurisdiction or service, but are not laws.	A health department's data governance policy
Guidelines	Evidence-based recommendations to support good practice and clinical decision-making. Advisory rather than mandatory.	Clinical practice guidelines for diabetes management

Who Develops Standards?

Level	Description	Examples
International	Develop standards used globally	ISO, HL7 International, SNOMED International
Regional	Develop standards for specific	European Committee for

	regions or groups of countries	Standardisation (CEN)
National	Develop or adapt standards for a specific country	Standards Australia

Why Digital Health Standards Matter

Benefit	What it means in practice
Interoperability	Systems speak a common language, enabling data exchange across providers and settings
Safety and Quality	Reduce medical errors by ensuring information is accurate, complete and understood system-wide
Consistency and Reliability	Digital health systems behave predictably; information arrives in the expected format and is interpretable
Innovation and Scalability	Stable foundation for developers to build new applications that integrate with existing infrastructure without custom work
Market Confidence	Prevents vendor lock-in; organisations can switch vendors without losing data or rebuilding integrations
Public Trust	Demonstrates that health systems are designed with safety, privacy and quality in mind
Regulatory Alignment	TGA, ACSQHC and privacy regulators reference standards in their requirements; compliance provides evidence of meeting regulatory obligations

Key Message: Standards are like investments in critical infrastructure. They require upfront effort but deliver long-term value through interoperability, safety and market efficiency.

Topic: Key SDOs and How Standards Work Together

International SDOs

Organisation	Focus	Key standards / relevance
ISO	Broad international standards including health informatics (ISO/TC 215)	ISO 27799 (health information security); ISO 13606 (EHR communication)
HL7 International	Messaging, document exchange, APIs for health information	HL7 V2 (messaging); HL7 CDA (clinical documents); HL7 FHIR (APIs — modern standard of choice)
SNOMED International	World's most comprehensive clinical terminology	SNOMED CT-AU (Australian extension); used in My Health Record and clinical systems
IHE	Integration profiles showing how to use existing standards together (not an SDO)	Consumer administration, medical imaging and pharmacy profiles
IEC	Safety and performance standards for medical devices and equipment	IEC 60601 (medical electrical equipment safety); IEC 62304 (medical device software lifecycle)
GS1	Supply chain identification and traceability for healthcare products	GTIN for product identification; barcodes/RFID for tracking medical supplies
openEHR Foundation	Open standards for EHR information models and archetype-based data structures	openEHR archetypes; used by several Australian state health services

Australian Standards Landscape

Organisation	Type	Role in digital health
Standards Australia	SDO	Australia's peak non-government standards body; publishes AS/AS ISO standards; represents Australia internationally
Australian Digital Health Agency	National infrastructure	Defines conformance requirements for My Health Record; manages NCTS; develops Australian FHIR

(the Agency)		implementation guides; publishes National Healthcare Interoperability Plan
Department of Health and Aged Care	Policy & funding	Strategic oversight of national digital health programs; funds standards development and implementation
HL7 Australia	SDO affiliate	Develops AU Base and AU Core FHIR implementation guides; represents Australian interests in HL7 International
ACSQHC	Safety & quality	References digital health standards in NSQHS Standards; member of the Agency's Standards Advisory Group
TGA	Regulation	Regulates medical devices including software; ISO/IEC standards compliance can form part of conformance evidence

Key Message: The Agency and the Department are not SDOs, they implement, fund and govern the use of standards in Australia.

How International Standards Are Used in Australia

Approach	Description	Example
Direct Adoption	International standard used as-is, without modification	HL7 FHIR R4 — used directly for many implementations
Adoption with Extension	International standard adopted with additional Australian content added	SNOMED CT-AU — SNOMED CT International + Australian Medicines Terminology (AMT), Australian places and concepts
Localisation	International standard adapted with Australian implementation guidance and requirements	AU Base and AU Core — FHIR implementation guides specifying Australian identifiers (Medicare, IHI), terminologies (SNOMED CT-AU, AMT) and privacy requirements

SDO Focus Areas: What Each Type of Standard Does

Focus Area	What it does	Key standards
Information Exchange & Messaging	Defines how information is packaged, transmitted and received between systems	HL7 V2 (very high adoption — messaging); HL7 CDA (moderate — clinical documents); HL7 FHIR (growing rapidly — APIs & granular data)
Clinical Terminology & Coding	Defines codes and terms for recording clinical information with consistent meaning (semantic interoperability)	SNOMED CT-AU; AMT; LOINC; ICD-10-AM
Privacy, Security & Data Governance	Defines requirements for protecting health information and managing data responsibly	ISO 27001/27799; Privacy Act 1988 & APPs; Australian Government ISM; Notifiable Data Breaches scheme

Key Message: No single standard does everything. Standards work together, terminology for shared meaning, messaging for exchange, information models for coordinated use.

Topic: Key Stages in Standards Development

The Seven Stages of Standards Development

All major SDOs follow similar processes, though terminology differs. The following is based on the ISO model — the most widely accepted across SDOs.

Stage	What happens	Timeframe
1. Proposal	A need for a new standard or revision is identified. Proposal submitted outlining scope, rationale, benefits and stakeholder support.	Weeks to months
2. Drafting	Working groups formed to develop the initial draft. Involves research, analysis of current practice and collaborative writing.	Months to years
3. Committee Review	Draft reviewed by a broader technical committee. Members provide feedback, raise concerns and suggest improvements.	Several months
4. Public Consultation	Draft released publicly for broader stakeholder review. Anyone can provide feedback — healthcare organisations, vendors, clinicians, consumers, government.	30–90 days
5. Balloting / Voting	After feedback is incorporated, formal voting occurs. A supermajority is typically required. Negative votes must be addressed with documented rationale.	Weeks to months
6. Approval	Standard receives final approval from the SDO's governance body. Remaining objections resolved before publication.	Weeks to months
7. Publication & Maintenance	Standard published and enters a maintenance cycle. Minor issues addressed via errata/amendments; significant changes require full revision.	Reviewed every 2–5 years

Key Roles in Standards Development

Role	Who they are	Responsibilities
Governance Bodies	Committees/working groups with balanced representation from industry, clinical, government, consumers, academia and vendors	Review and approve proposals; oversee drafting; vote on standards progression; resolve disagreements
SDO Secretariat	Process support staff provided by the SDO	Manage the development process; schedule meetings and consultations; maintain documentation; coordinate between stakeholder groups
Subject Matter Experts	Clinical experts, informaticians, software developers, privacy specialists, implementation experts	Draft standard content; provide technical input; review drafts for accuracy and implementability
Reviewers / Public Commentators	Any stakeholder: healthcare providers, vendors, consumer advocates, researchers, government agencies	Review drafts during public consultation; submit comments; propose improvements or alternative approaches

How Consensus is Achieved

Mechanism	How it works
Discussion and Review	Structured committee/working group discussions where members review drafts, raise issues and work collaboratively to resolve them
Public Consultation & Comment Resolution	All comments documented, reviewed and addressed. Committee must explain how each comment was resolved — incorporated, rejected with rationale, or addressed through alternative changes
Formal Voting / Balloting	ISO requires: ≥66% approval from voting members AND ≤25% negative votes. Negative votes require rationale and must be considered before final approval.
Escalation	When disagreements can't be resolved: appeals to a higher governance body, independent expert review, mediation, or minority position documentation

Key Message: Standards are living documents. Always ask vendors: which version are they implementing, when was it published, and what is their plan to keep pace with standard evolution?

Topic: How Standards Enable Interoperability and Connected Care

What is Interoperability?

Interoperability is the ability to move information easily between people, organisations and systems — enabling a connected healthcare system that shares health information securely and safely.

Layer	What it means
Layer 1: Between organisations	Sharing information between organisations — hospital to GP, GP to specialist
Layer 2: Within an organisation	Sharing information between systems within an organisation — clinical system to admin system, department to department
Layer 3: At the point of care	Information available to clinicians and consumers when and where they need it

Three Types of Standards — The Common Language of Health

Type	What it does	Australian examples
Standards for Shared Meaning (Semantic interoperability)	Define codes and terms so everyone understands clinical information the same way	SNOMED CT-AU (diagnoses, procedures, findings); AMT (medicines); LOINC (pathology & observations); ICD-10-AM (hospital diagnoses & procedures)
Standards for Information Exchange (Technical interoperability)	Define how information is packaged, transmitted and received between systems	HL7 FHIR; HL7 CDA; HL7 V2
Standards for Coordinated Use (Structural interoperability)	Define how information is modelled, stored and structured for long-term use and reuse	openEHR archetypes; IHE integration profiles; ISO information models

Key Message: Standards create the common language that enables health systems to communicate. They also support population health, disease surveillance and research through standardised coded data.

Topic: Real-World Examples of Standards in Australian Digital Health

My Health Record

Australia's most visible standards-based digital health infrastructure — one of the largest national health record systems in the world, with most GPs, pharmacies and public hospitals registered.

Function	Standards used
Clinical documents	HL7 CDA (document structure); SNOMED CT-AU (clinical concepts); AMT (medications); LOINC (pathology observations)
Medication information	AMT (all medication coding); HL7 FHIR (prescription exchange); SNOMED CT-AU (indications and reactions)
Consumer identity & security	IHI (individual healthcare identifier); HPII (healthcare provider — individual); HPIO (healthcare provider — organisation)
System access & integration	HL7 FHIR APIs; OAuth2 and SMART on FHIR (authentication)

NCTS — National Clinical Terminology Service

Managed by the Agency. Australia's authoritative source for clinical terminologies — the shared national infrastructure enabling semantic interoperability.

What NCTS provides	Detail
SNOMED CT-AU	International SNOMED CT + Australian Medicines Terminology (AMT) + Australian-specific concepts. Updated twice yearly. Required for My Health Record.
Supporting terminologies	LOINC (pathology & observations); ICD-10-AM (hospital coding); PBS codes; Medicare codes; professional role codes
Reference sets / Value sets	Curated subsets specifying which codes to use for specific purposes (e.g., GP problem list, medicines subset for e-prescribing). SNOMED CT-AU contains 400,000+ concepts — reference sets make implementation practical.
Tools for	Terminology browser (healthterminologies.gov.au); terminology

implementers	server (real-time code lookup); mapping tables (e.g., SNOMED CT-AU ↔ ICD-10-AM); implementation guidance

Secure Messaging

Component	Standards and detail
Message standards	HL7 CDA or FHIR (referral letters); HL7 V2 or FHIR (pathology results); SNOMED CT-AU and AMT (coded clinical content)
Security & identity	TLS/SSL (encryption in transit); HPII and HPIO (provider addressing); PKI certificates or modern authentication standards
eReferrals (next evolution)	Built on HL7 FHIR and SNOMED CT-AU; enables structured referral data, workflow management, direct booking and feedback loops to referring providers

Electronic Prescribing: A Standards Success Story

Component	Standards and detail
Core standard	HL7 FHIR — prescription data structure and exchange between prescribers, dispensers and the Active Script List. Now available across Australia.
Medication coding	AMT — ensures medications coded consistently across every system in the workflow
Provider identity	HI Service (HPII / HPIO) — uniquely identifies prescribing clinician and dispensing pharmacy

Benefits of Standards Implementation

Benefit	What it looks like in practice
National Consistency	A consumer can move from QLD to VIC and their My Health Record remains accessible. COVID-19 vaccination tracking works because all jurisdictions use SNOMED CT-AU.
Vendor Neutrality and Choice	Organisations using openEHR can switch clinical system vendors without migrating data structures. Open standards prevent vendor lock-in.
Innovation Enablement	FHIR APIs allow innovative apps to integrate with My Health Record without custom integration with every health service.

Clinical Safety and Quality	Standardised medication coding (AMT) reduces prescribing errors; standardised consumer identification (IHI) prevents treatment of the wrong person.
Efficiency and Reduced Duplication	Discharge summaries sent electronically; pathology results flow directly into clinical systems; medication histories available via My Health Record.

Implementation Challenges

Challenge	Why it happens	Mitigation strategies
Fragmented systems and data silos	Systems implemented at different times; organisational boundaries; legacy systems not designed for data exchange	Incremental implementation; health information exchanges as hubs; clear governance on mandatory standards
Inconsistent and voluntary adoption	Most Australian standards are voluntary, not mandated; competing priorities; wait and see approach	Procurement requirements mandating standards; government funding tied to compliance; early adopter success stories
Vendor capability varies	Small vendors lack development resources; standards evolve faster than product cycles; compliance claims not always verified	Specify exact standard versions in procurement; require proof of compliance (testing/certification); pilot before full rollout
Workforce digital literacy gaps	Digital health literacy not consistently in health professional education; standards seem abstract; time pressure in clinical settings	Training and education; workflow redesign to make structured data entry easier; clinical champions; start with high-frequency codes

Key Message: These challenges do not mean standards are not worth implementing — they mean implementation needs realistic planning, adequate resourcing and sustained commitment.