Data Protection & Privacy Decision Flow

Operationalizing privacy is challenging, but there are clear steps you can take to devise an operational policy that supports your business goals. The following decision flow can bring clarity and order to the process of sharing individual patient data.

Start

This is the trigger to your process. You are here because you have a new reason or place to share data, or there's a material change (process, regulatory, etc.) that affects something you are doing today.

1 Data Environment

Define business cases and determine the environment(s) that will enable your data sharing use case. For example, where will you share your data? Are there cross-border considerations (such as patients from different countries)?

Determines

2 Regulatory Environment

Which data protection and privacy regulations apply (e.g., GDPR, HIPAA)? If more than one regulatory framework applies, which one will govern?

Informs

3 Lawful Processing

Do you have the grounds for processing patient data within the applicable regulatory framework? For example, do you have appropriate patient consent for secondary research use or other legal basis under the regulation?

Informs

4 Data Classification

How will the protected data be classified to meet your use case aims and fulfill any regulatory requirements? For example, at the end of the process, do you consider the patient data to be anonymized, de-identified, or pseudonymized?

Informs

5 Privacy Methodology

Which privacy-protecting methodology will you employ to meet your business goal *and* satisfy your regulatory environment? Examples include rules-based anonymization (qualitative risk assessment) and risk-based anonymization (quantitative risk assessment).

Determines

6 Operational Considerations

How will you execute? What internal and external resources will you need? Are the right processes in place to manage risk and support your initiative?

Success

The result is a data protection approach that supports your use cases and responsibly protects patient privacy.

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