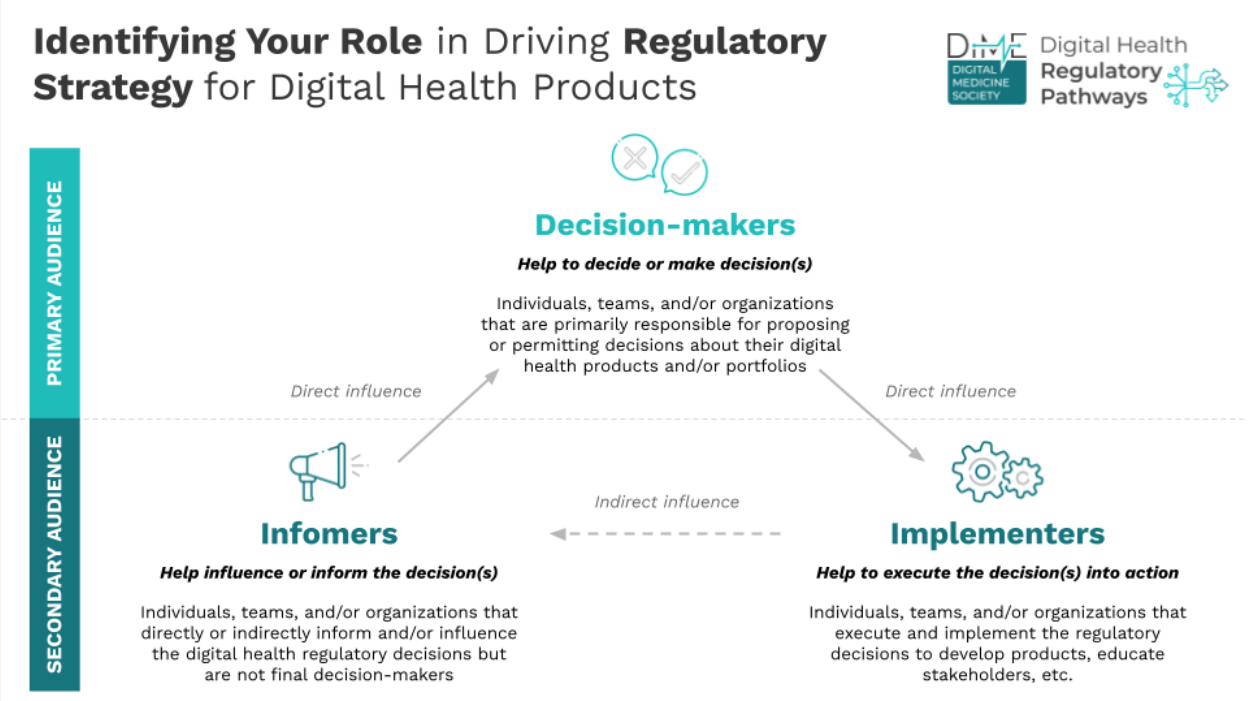
Identifying Your Role in driving **Regulatory Strategy** for Digital Health Products

Digital Health **Regulatory Pathways**

Which of the **three key stakeholder groups** driving regulatory strategies for digital health products do you best identify with?



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Stakeholder Archetypes

The archetype examples shared below are not job titles, but rather a way to help identify your role in the context of digital health regulations as part of your product development and deployment.

Decision-Makers | Primary Audience

Help to decide or make decision(s)

Individuals, teams, and/or organizations that are primarily responsible for proposing or permitting decisions about their digital health products and/or portfolios

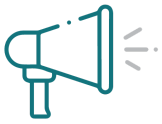
MUST READ RESOURCES

1. **Navigation tool**: DiMe's U.S. RegPath tool
2. **Decision Map**: Digital health product class
3. **Value guide** for digital health regulations
4. **Flowchart** of Digital Health Regulatory Pathways
5. **Regulatory Strategy Toolkit** for digital health products

ARCHETYPES

- C-Suite/Executive leader at a small startup making commercial decisions based on regulations that apply to their products.
- Venture Capitalists (VCs) making decisions to invest in a company based on their regulatory strategy.
- Head of strategy at a digital health company using regulatory strategy as a differentiator for market positioning.
- Product chief within an industry with regulatory information evaluating and planning for new product development for portfolio strategy and management.
- Technical/product founder of a digital health startup making a decision about what features/functionality to build into their product that may impact decisions about the regulatory pathways.
- Healthcare grant-making organization (non-VC) making decisions to invest in the company based on the organization's regulatory strategy.
- Head of regulatory affairs at a life science company charged with assigning resources to support product development.
- R&D executive at a MedTech device company developing the company's first digital device with limited regulatory experience in digital health.
- Executive or product team lead developing the company's first Digital Health Technology (DHT) that could be regulated as an FDA medical device.
- Digital health startup executive making commercial decisions for product capabilities in the health, wellness, and consumer health market.
- Life science organization product team lead developing DHTs and/or partnering a DHT for use with a drug product in a commercial use or clinical trial setting.
- Teams or organizations with limited experience developing combinational (drug+device) products, software-based medical products, etc.
- Research groups and academic organizations interested in developing digital health products.

Informers | Secondary Audience



Help influence or inform the decision(s)

Individuals, teams, and/or organizations that directly or indirectly inform and/or influence digital health regulatory decisions but are not final decision-makers

MUST READ RESOURCES

1. **DiMe's Library** of digital health regulations
2. **Flowchart** of Digital Health Regulatory Pathways
3. Digital health **pathways toolkit**
4. **Guide** for digital health product classification
5. **Value guide** for digital health regulations

ARCHETYPES

- Legal and regulatory teams at an organization in a specific focus area (medtech, tech, life science, etc.) advising top leadership in support of regulatory decisions.
- Digital health project management teams at an organization that inform other teams about regulatory proceedings for their products.
- Trade associations and professional societies influencing regulatory decisions.
- Non-FDA federal agencies in the US [e.g., The Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), The Office of the National Coordinator for Health Information Technology (ONC), etc.] that maintain awareness of various FDA regulatory paths a digital health innovator may pursue.
- Regulatory consultants both in and outside of the US that advise medtech and digital health companies on US regulatory strategy.
- Academic research organizations and think tanks conducting research on improving evidence generation that meets the needs of regulatory decision-makers.
- Patient groups influencing product development strategies (e.g. product format, functions, etc.) in early phase development.

Implementers | Secondary Audience

Help to execute decision(s) into action

Individuals, teams, and/or organizations that execute and implement the regulatory decisions to develop products, educate stakeholders, etc

MUST READ RESOURCES

1. **Flowchart** of Digital Health Regulatory Pathways
2. **Toolkit** for interacting with US regulators
3. Digital health **pathways toolkit**
4. **Guide** for digital health product categorization
5. **5-Step Approach** to Classifying your Digital Health Product in the US

ARCHETYPES

- Product development teams at medtech industry organizations executing regulatory decisions to build new products.
- Software engineer at a small, early-stage startup upgrading tech capabilities based on regulatory controls and decisions shared by their product executive leads.
- Health system partnering with a new digital health vendor and evaluating whether the vendor's digital health product is regulated (and more).
- Investors mentoring and advising portfolio companies about commercialization plans based on a company's product and regulatory strategy.
- Accelerators and incubators guiding early-stage organizations at the beginning of their product development cycles.
- Regulatory consultants both in and outside of the US supporting medtech and digital health companies with regulatory applications in the US.
- Regulatory team at a company with a specific focus area (medtech, tech, life science, etc.) responsible for developing regulatory strategy and managing regulatory submissions.
- Quality assurance and quality control leads at companies with specific focus areas (tech, life sciences, digital health, etc.) responsible for the development of a product in accordance with applicable regulatory status (e.g., design controls, etc.).
- National Institutes of Health (NIH) sponsors of extramural research to help guide grantmaking and funded device development programs.
- Contract Research Organizations (CROs) implementing research programs and advising on regulatory issues across the product and device development lifecycle.
- Clinicians making evidence-based clinical decisions using regulated and non-regulated digital health products.

Access DiMe's Digital Health Regulatory Pathway Resources

Identify your regulatory pathway

Build your regulatory strategy

Interact with regulators