Scaling Digital Health Globally: Navigating National Pathways for Patient Access

DIGITAL MEDICINE SOCIETY

International Digital Health **Regulatory Pathways**

WEBINAR

Tuesday, November 19

10 am - 11 am ET

RECORDINGS POSTED HERE

Housekeeping

- Today's session is being recorded

  Slides and recording will be available on DiMe's webinar page after the session

- To ask a question during the webinar, please **type your question** into the chat box

- Transcription of the webinar is not permitted by participants; transcription tools will be removed

Agenda

- Welcome and background
- Project resource overview
- *Panel discussion*: Impact of multi-market strategies on patient care and DHT commercial viability
- *Panel discussion*: Pace of global regulatory changes and DHT clinical evidence requirements
- Next steps
- Closing remarks

DiMe convenes stakeholders to take action to fix the problems in our complex field

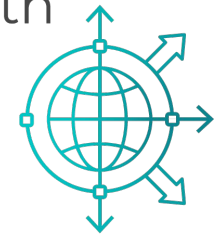
OUR MISSION:

To advance the safe, effective, and equitable use of digital approaches to **redefine healthcare** and **improve lives**

OUR VISION:

Better health powered by digital innovation

International Digital Health **Regulatory Pathways**



Assess global patient access pathways across Asia Pacific, Europe, and North America to scale digital health technologies (DHT)

Project partners

abbvie
ABHI
ANDHealth
APACMed
COMPLEAR HEALTH
DGG Deutsche Gesellschaft für Gesundheitstelematik
d-health consulting
DIGITAL THERAPEUTICS ALLIANCE
embecta
empatica
Google
Harvard-MIT Center for Regulatory Science
HPI Hasso Plattner Institut
HUMA
LUCA
MCRA
S3 Connected Health
SDA Bocconi School of Management
Spitzenverband Digitale Gesundheitsversorgung

Existing reality: Uncertainty inhibits growth

Market by market

Multi-market approaches are critical to delivering DHTs to patients globally at scale.

Yet, taking a country by country approach can be **inefficient** for developers and quickly drain resources.

Case by case

When every decision maker determines what good looks like, there are vastly **differing expectations** for developers.

This lack of alignment **hinders the adoption** and scale of DHTs within and across jurisdictions.

Inequitable access

While few pharmaceuticals take a single market approach, DHTs are encountering a more limited set of market opportunities.

DHT **scalability** and equitable patient access are therefore **limited**.

Aim: Enable greater DHT scalability and patient access

Inform overall business strategy	• Developers must incorporate regulatory strategy into overall business strategy. This includes considering all steps and requirements for regulatory authorization, product assessment, pricing and reimbursement, and patient access in each target market.
Equip to navigate evolving regulatory landscapes	• With new legislation and regulation being added monthly across global settings, developers require essential tools to compare and navigate the evolving, complex regulatory environments in key markets.
Identify clinical evidence efficiencies	• By identifying efficiencies in clinical evidence requirements, developers can streamline their global go-to-market strategies and bring DHT products to market more quickly and efficiently.

International Digital Health **Regulatory Pathways**

Research

Research and analysis of national pathways and clinical evidence requirements in eight global markets

KOL interviews and focus groups

Conducted interviews with key opinion leaders (KOLs) and subject matter experts (SMEs) in each jurisdiction

Expert workshop

Convened regulators, regulatory experts, and DHT developers to clarify the transferability of clinical evidence across national jurisdictions

Synthesis and resource development

Navigate global digital health regulatory pathways

Navigating global pathways to scale digital health technologies (DHTs) is complex. These resources are designed to help you with actionable insights to understand and compare regulatory environments across Asia Pacific, Europe, and North America. With country-specific guides, step-by-step flowcharts, and supporting resources, you'll be equipped to **streamline your go-to-market strategies** and bring your digital health innovations to patients worldwide **faster** and more **efficiently**.

Visit: [International Regulatory Pathways]

Resources launching today

Nation-specific resources:

- ✓ National Companion Guide
- ✓ RegPath Flowchart
- ✓ Patient Access Snapshot
- ✓ Library of Digital Health Regulations

- Australia
- China
- England
- France
- Germany
- Japan
- South Korea
- United States

Additional resources:

- ✓ **npj Digital Medicine Comment**: *Core elements of national policy for digital health technology evidence and access*
- ✓ **How-to Guide for DHT developers**: Navigating emerging global AI/ML regulations
- ✓ **Case studies**: Big Health | Empatica | Huma | Luca Healthcare | Oviva | WELT

National policy “full-stack”

npj | digital medicine

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Comment | Open access | Published: 13 August 2024

Core elements of national policy for digital health technology evidence and access

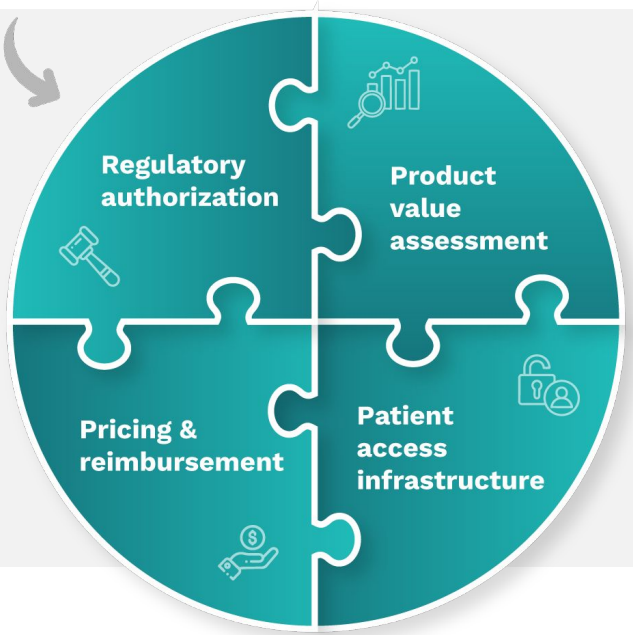
Megan Coder, Lacey McBride & Samantha McClenahan

npj Digital Medicine **7**, Article number: 212 (2024) | Cite this article

491 Accesses | **1** Altmetric | Metrics

Digital health technologies (DHT) offer the ability to deliver personalized care, lower barriers to access, and positively impact health outcomes. However, DHT utilization is impacted by insufficient market access pathways. A policy “full-stack”—including regulatory authorization, product value assessment, pricing and reimbursement, and patient access infrastructure—offers a framework for DHT integration into national healthcare ecosystems. Consistent clinical evidence requirements across national jurisdictions will further increase DHT scalability.

Components of a national policy “full-stack”:



Source: Nature

National Companion Guides

Asia Pacific

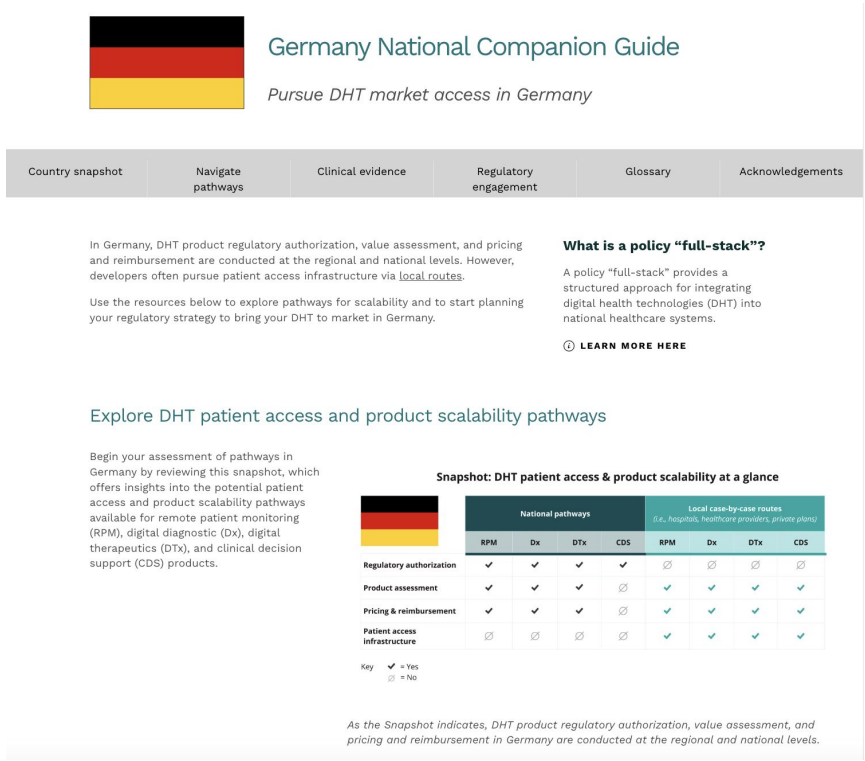
- Australia
- China
- Japan
- South Korea

Europe

- England
- France
- Germany

North America

- United States



Germany National Companion Guide

Pursue DHT market access in Germany

Country snapshot | Navigate pathways | Clinical evidence | Regulatory engagement | Glossary | Acknowledgements

In Germany, DHT product regulatory authorization, value assessment, and pricing and reimbursement are conducted at the regional and national levels. However, developers often pursue patient access infrastructure via local routes.

Use the resources below to explore pathways for scalability and to start planning your regulatory strategy to bring your DHT to market in Germany.

What is a policy "full-stack"?

A policy "full-stack" provides a structured approach for integrating digital health technologies (DHT) into national healthcare systems.

LEARN MORE HERE

Explore DHT patient access and product scalability pathways

Begin your assessment of pathways in Germany by reviewing this snapshot, which offers insights into the potential patient access and product scalability pathways available for remote patient monitoring (RPM), digital diagnostic (Dx), digital therapeutics (DTx), and clinical decision support (CDS) products.

Snapshot: DHT patient access & product scalability at a glance

	National pathways				Local case-by-case routes (i.e., hospitals, healthcare providers, private plans)			
	RPM	Dx	DTx	CDS	RPM	Dx	DTx	CDS
Regulatory authorization	✓	✓	✓	✓	∅	∅	∅	∅
Product assessment	✓	✓	✓	∅	✓	✓	✓	✓
Pricing & reimbursement	✓	✓	✓	∅	✓	✓	✓	✓
Patient access infrastructure	∅	∅	∅	∅	✓	✓	✓	✓

Key ✓ = Yes ∅ = No

As the Snapshot indicates, DHT product regulatory authorization, value assessment, and pricing and reimbursement in Germany are conducted at the regional and national levels.

Source: Germany National Companion Guide

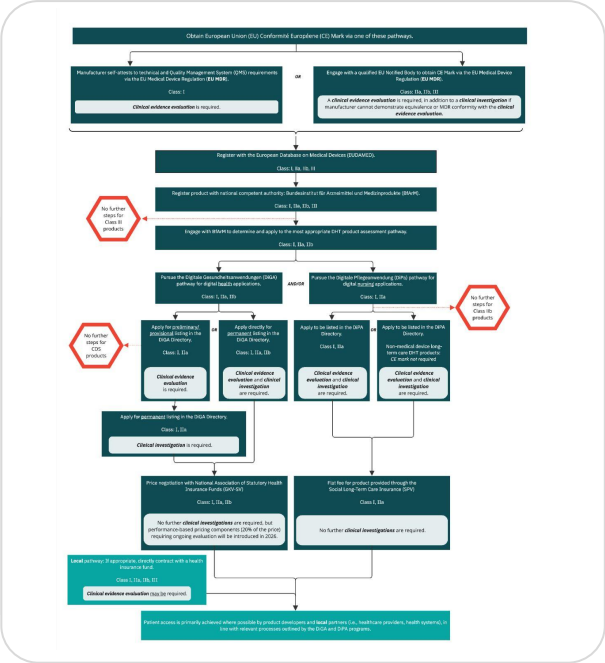
Regulatory & product assessment pathways

Snapshot: DHT patient access & product scalability at a glance

	National pathways				Local case-by-case routes *(i.e., hospitals, healthcare providers, private plans)*			
	RPM	Dx	DTx	CDS	RPM	Dx	DTx	CDS
Regulatory authorization	✔	✔	✔	✔	∅	∅	∅	∅
Product assessment	✔	✔	✔	∅	✔	✔	✔	✔
Pricing & reimbursement	✔	✔	✔	∅	✔	✔	✔	✔
Patient access infrastructure	∅	∅	∅	∅	✔	✔	✔	✔

Key ✔ = Yes
∅ = No

Snapshots offer insights into potential patient access and product scalability pathways for DHTs.



Flowcharts guide developers through key steps in national DHT patient access pathways.

Source: Germany National Companion Guide

Navigating emerging global AI regulations: How-to guide for DHT developers

How to stay informed	Suggested actions
Register for agency and organization email listservs	Subscribe to receive the latest updates directly from regulatory agencies and relevant organizations.
Monitor federal and international regulatory dockets	Regularly check platforms like Regulations.gov in the U.S. and international counterparts to keep up with proposed changes.
Follow agency and regulatory body social media accounts	Engage with real-time updates and insights by following agencies on platforms like LinkedIn and official news feeds.
Provide formal comments on legislative and regulatory proposals	Actively participate by submitting comments during open consultation periods to influence policy development.
Engage with industry groups and regulatory consortia	Join associations and societies with AI/ML-focused work groups that work directly with regulatory bodies to stay informed on collective insights and guidance.
Attend relevant conferences and regulatory webinars	Gain deeper insights by attending events where regulatory updates and trends are discussed by industry and policy experts.
Engage with the academic and legal research community on evolving AI/ML policies	Keep up to date through research papers and journals that analyze regulatory changes and predict future trends.

Source: AI How-to Guide

Case studies: See how others have done it

Explore **real-world examples** of companies successfully **navigating regulatory landscapes**, offering **insights** into market entry strategies and effective evidence generation.

Big Health Cross-jurisdictional recognition	empatica Utilizing US Data in Europe	HUMA Clinical evidence transferability
LUCA Conducting clinical trials in China	Oviva Leveraging UK data in Germany	WELT Navigating clinical trial comparators

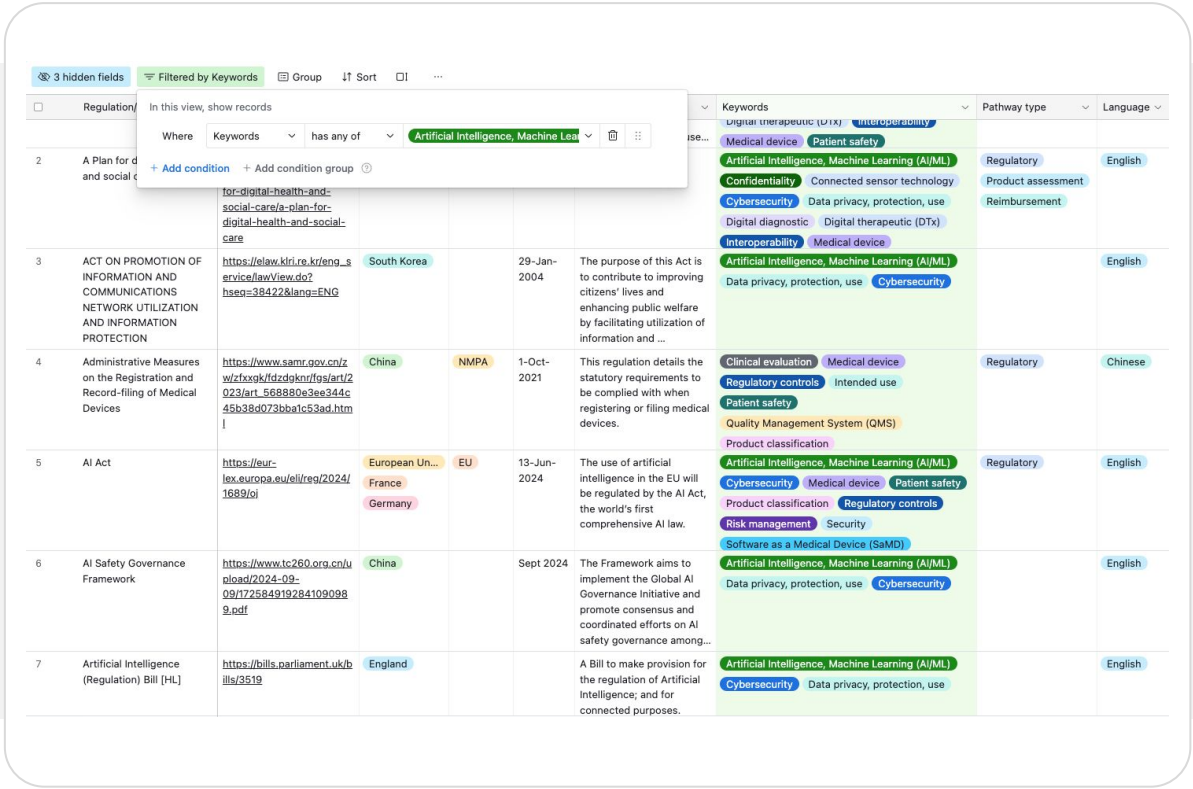
Library of Digital Health Regulations

Publication topics include, but are not limited to:

- Regulations
- AI/ML
- Cybersecurity
- Interoperability
- Labeling
- Patient safety

Jurisdictions currently include:

Australia | China | England | European Union (EU) | France | Germany | Japan | South Korea | United States (US)



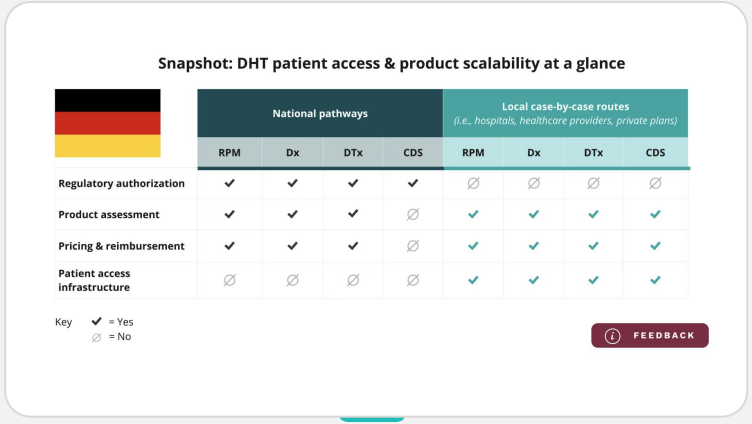
	Regulation/						Keywords	Pathway type	Language
							Medical device, Patient safety		
2	A Plan for d... and social c...	for-digital-health-and-social-care/a-plan-for-digital-health-and-social-care					Artificial Intelligence, Machine Learning (AI/ML), Confidentiality, Connected sensor technology, Cybersecurity, Data privacy, protection, use, Digital diagnostic, Digital therapeutic (DTx), Interoperability, Medical device	Regulatory, Product assessment, Reimbursement	English
3	ACT ON PROMOTION OF INFORMATION AND COMMUNICATIONS NETWORK UTILIZATION AND INFORMATION PROTECTION	https://elaw.klri.re.kr/eng_service/lawView.do?hseq=38422&lang=ENG	South Korea		29-Jan-2004	The purpose of this Act is to contribute to improving citizens' lives and enhancing public welfare by facilitating utilization of information and ...	Artificial Intelligence, Machine Learning (AI/ML), Data privacy, protection, use, Cybersecurity		English
4	Administrative Measures on the Registration and Record-filing of Medical Devices	https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/fgs/art/2023/art_568880e3ee344c45b38d073bba1c53ad.html	China	NMPA	1-Oct-2021	This regulation details the statutory requirements to be complied with when registering or filing medical devices.	Clinical evaluation, Medical device, Regulatory controls, Intended use, Patient safety, Quality Management System (QMS), Product classification	Regulatory	Chinese
5	AI Act	https://eur-lex.europa.eu/eli/reg/2024/1689/oj	European Un..., France, Germany	EU	13-Jun-2024	The use of artificial intelligence in the EU will be regulated by the AI Act, the world's first comprehensive AI law.	Artificial Intelligence, Machine Learning (AI/ML), Cybersecurity, Medical device, Patient safety, Product classification, Regulatory controls, Risk management, Security, Software as a Medical Device (SaMD)	Regulatory	English
6	AI Safety Governance Framework	https://www.tc260.org.cn/upload/2024-09-09/1725849192841090989.pdf	China		Sept 2024	The Framework aims to implement the Global AI Governance Initiative and promote consensus and coordinated efforts on AI safety governance among...	Artificial Intelligence, Machine Learning (AI/ML), Data privacy, protection, use, Cybersecurity		English
7	Artificial Intelligence (Regulation) Bill [HL]	https://bills.parliament.uk/bills/3519	England			A Bill to make provision for the regulation of Artificial Intelligence; and for connected purposes.	Artificial Intelligence, Machine Learning (AI/ML), Cybersecurity, Data privacy, protection, use		English

Source: Library of Digital Health Regulations

Dynamic ecosystem necessitates ongoing community engagement

DiMe invites insights on:

- Novel or updated national pathways
- Revised regulations or guidances
- New DHT developments within any country



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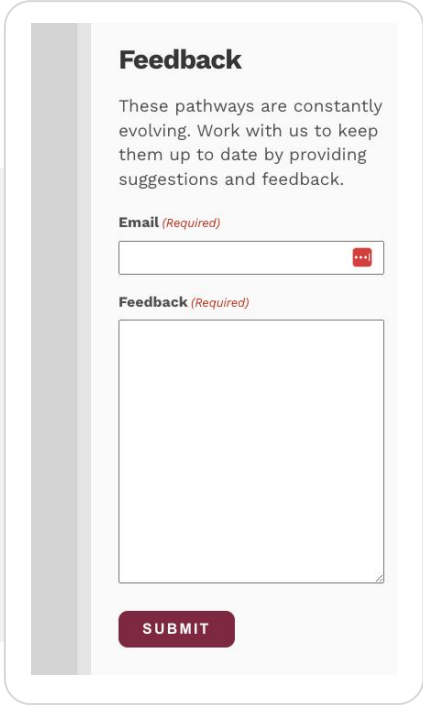
Pricing & reimbursement	✓	✓	✓	∅	✓	✓	✓	✓
Patient access infrastructure	∅	∅	∅	∅	✓	✓	✓	✓

Key ✓ = Yes ∅ = No

FEEDBACK



Feedback

These pathways are constantly evolving. Work with us to keep them up to date by providing suggestions and feedback.

Email *(Required)*

Feedback *(Required)*

SUBMIT

Scaling Digital Health Globally: Navigating National Pathways for Patient Access

Panel discussion: Impact of multi-market strategies on patient care and DHT commercial viability

DIGITAL MEDICINE SOCIETY

Brian Flatley
VP Consulting Services
S3 Connected Health

Shani Frenkel
Regulatory Affairs
Google Health

Marisa Kaup
Taskforce Lead for European & International Topics
Spitzenverband Digitale Gesundheitsversorgung

Moderator:
Lacey McBride
Project Management Lead
Digital Medicine Society (DiMe)

Scaling Digital Health Globally: Navigating National Pathways for Patient Access

Panel discussion: Pace of global regulatory changes and DHT clinical evidence requirements

DIGITAL MEDICINE SOCIETY

Miguel Amador
Partner and Chief Innovation Officer
Complear

Jeroen Bergmann
Professor, Head of Dept of Technology and Innovation
University of Southern Denmark / University of Oxford

Francesco Petracca
Research Assistant at CeRGAS Bocconi
Università Bocconi

Moderator:
Megan Coder
VP Product & Policy
Digital Medicine Society (DiMe)

Drive increasing globalization and impact of DHTs

Don’t see your country listed?

Partner with DiMe to add your country to the IRP resources and position your country as a leader in digital health innovation.

New resources launch on December 10!

DATACC by DiME

Validating
Novel Digital
Clinical Measures

Join us to learn more about the framework and simulation toolkit and how they can support your work in validating and developing novel digital clinical measures.

Free DiMe webinar
Tuesday
December 10
11 a.m. ET
Scan to register

Scaling Digital Health

Join us for our upcoming **Scaling Digital Health** project to support the continued development, adoption, and scale of digital health capabilities within pharmaceutical and biotech organizations

Visit the project page

Start the DiMe Seal process today!

Differentiate your products with the DiMe Seal

Together, we can advance our ecosystem to a point where digital innovations are synonymous with quality and trustworthiness, delivering on their promise to patients and providers.

Scan to visit dimesociety.org/dime-seal for more details.

Scaling Digital Health Globally: Navigating National Pathways for Patient Access

Closing remarks

Jennifer Goldsack
Chief Executive Officer
Digital Medicine Society (DiMe)

DIGITAL MEDICINE SOCIETY

19 Nov 2024 | Virtual

THANK YOU

Megan Coder | megan.coder@dimesociety.org

Lacey McBride | lacey.mcbride@dimesociety.org

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www.dimesociety.org

www.linkedin.com/company/dime-society

https://dimesociety.slack.com