Precision Medicine with AI: Integrating Imaging with Multimodal Data (PRIMED-AI)

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Council of Councils
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NIH National Institutes of Health
Office of Strategic Coordination–The Common Fund

OSC (Common Fund) – PRIMED-AI

Concept Clearance: New Common Fund Program

Title: Precision Medicine with AI: Integrating Imaging with Multimodal Data

Objective: To catalyze the development & adoption of innovative AI-based clinical decision support tools that integrate clinical imaging with multimodal health data to enable reliable, cost-effective, accessible, and sustainable precision medicine workflows for diagnosis, treatment, and quality of care.

Sub-goal 1: Imaging and multimodal data integration

Sub-goal 2: AI algorithm and tool development

Sub-goal 3: Clinical implementation

Sub-goal 4: Building trust and coordination

Program Duration: 5 years

Funds Available and Anticipated Number of Awards: ~$25M per year (FY27–31)

~90 meritorious awards (over five years, contingent upon availability of funds)

Council Action: Vote for approval of the concept for PRIMED-AI

PRIMED-AI Working Group

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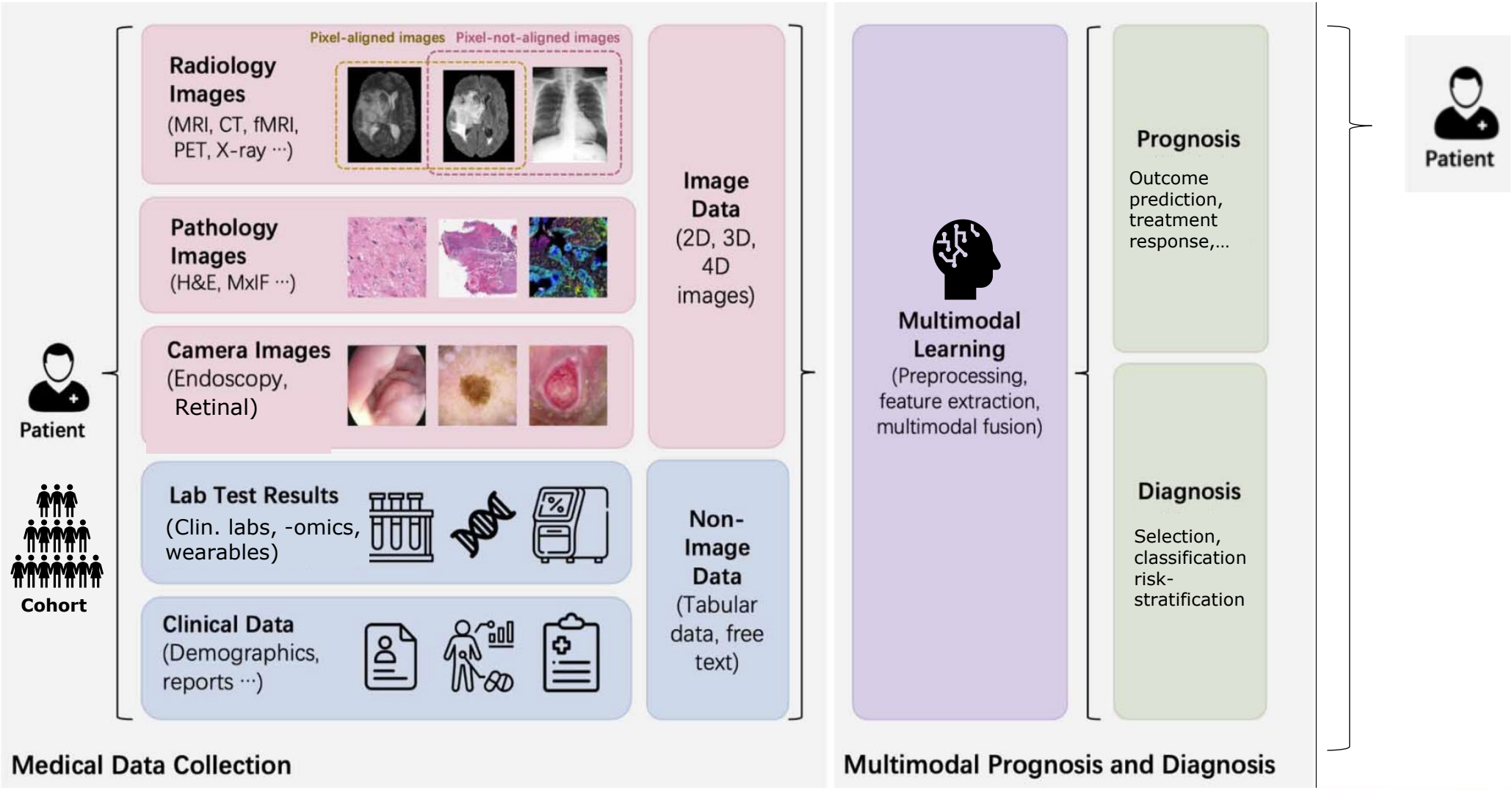
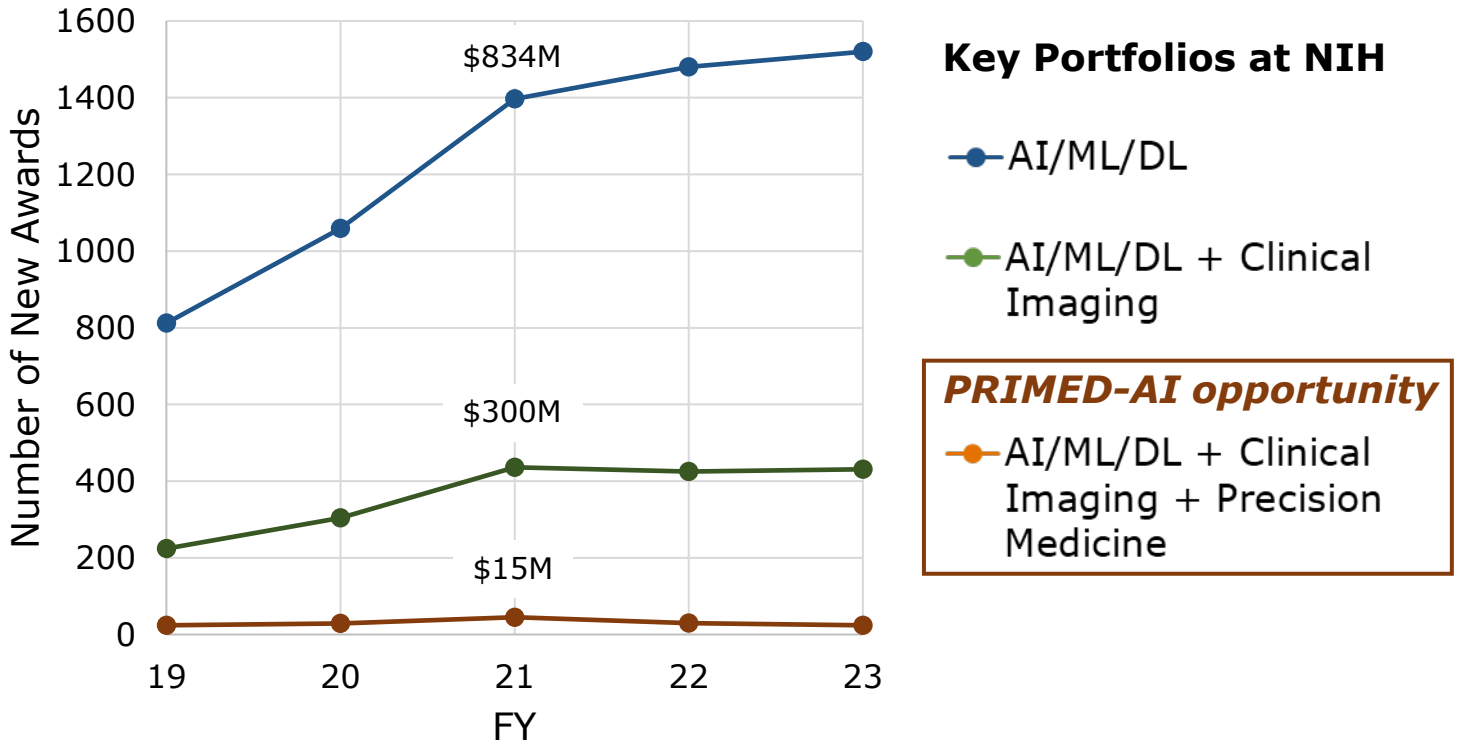
Gap: Integrating Imaging with Multimodal Data



Adapted from Prog. Biomed. Eng. 2023, 5 022001

NIH Landscape Analysis

Slow growth for new projects in PRIMED-AI space at NIH



Landscape Summary Report

- Interest, investment, and expertise exist, but are siloed
- Infrastructure and capacity are rapidly building, but lack any cohesive structure
- There are opportunities for new *federal and non-federal* partnerships that could make this initiative powerful
- Opportunity for NIH investment to meet increasing demands for patient benefit

External Input for PRIMED-AI

Public RFI: NOT-RM-24-011, RFI Summary Report

Strategic Planning Workshop: 1,050 participants

1. Imaging and Multimodal Data Integration

- Include multimodal data types, open-source platforms, **standardized protocols**.
- **Address variations** in image acquisition, high integration costs, data harmonization complexities.

2. AI Algorithm and Tool Development

- Harmonize data and **interoperable platforms**, integrate **datasets consisting of multiple types of data** with associated context.
- **Address scientific bias**, protect privacy, **promote dissemination and commercialization.**

3. Clinical Implementation

- Collect and include high-quality datasets.
- Use **federated learning** to maintain **patient privacy**.

4. Building Trust and Coordination

- **Collaborate** among partners with different expertise, **outreach/education** for wide-reaching data collection. include **data quality** committees.

Filling Unmet Needs

- Integrate and interpret **multimodal** sets of health data using AI
- Advance and promote AI-driven Precision Medicine for all Americans
- Build cohesive infrastructures to link data **across scales**
- Accelerate implementation of **clinical decision support tools** for Precision Medicine
- Develop **trusting relationships** between patients, clinicians, and data scientists

NOFOs Address **four iterative** sub-goals

Imaging-Multimodal Data Integration

Facilitate access and integration of clinical images and multimodal data

AI Algorithm and Tool Development

Develop and iterate on AI-based algorithms and tools to support clinical diagnosis, management, and prediction

Clinical Implementation

Test PRIMED-AI clinical decision support tools to catalyze new precision medicine approaches

Building Trust & Coordination

Coordinate activities to ensure program and community cohesion, adaptability, scientific validation & rigor, and operational transparency

PRIMED-AI NOFO Ecosystem

Data   **Models**   **Clinic** 

Playbook of **standardized frameworks** fit for multiple use cases, responsible AI objectives and needs, while being flexible

Academic-Industrial Partnership (*AIP*) Phase 1 for data inter-operability; Phase 2 for algorithm development and performance testing

Modular Software Tools for focused needs to facilitate multi-modal data integration, model robustness, and user interface design

*Model to Clinic** — Optimization of AI models for **broad clinical use**. Phase 1 for AI tool development; Phase 2 for clinical testing

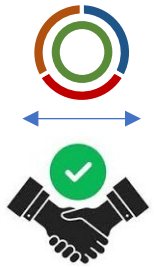
Emergent Opportunity Revisions — **Leverage new advances** in clinical research towards PRIMED-AI goals including ancillary trials

Trust

Validation Center for **verification, validation, and uncertainty quantification** of PRIMED-AI tools; promoting reproducibility

Logistics Center for program **administration** and **evaluation**, provide **teaming support**, and **engage** with stakeholder communities

Communication Curricula, novel strategies to **build trust & enhance communication** between data scientists, clinicians, and patients



Clinical Testing of PRIMED-AI Tools *Model to Clinic NOFO*

NOFO Phase 1 (tool development) | NOFO Phase 2 (*e.g.*, ancillary clinical testing)

Leverage externally supported clinical study 1

Leverage externally supported clinical study 2, 3…

Data

- Repositories: Imaging & MMD
- Retrospective clinical trial data
- Integrated and Interoperable

Models

- **Built to address defined clinical problem**
- Development & training
- Milestones for Phase 2 transition (go/no-go funnel)

- NOFO Phase 2 ancillary clinical testing: addition of PRIMED-AI secondary objectives to test models in prospective clinical studies with relevant patients and non-PRIMED-AI primary objectives

Clinic

- **Real-world** AI-model performance testing
- **Iteration**, optimize CDS tool
- Preparation for regulatory/implementation

Independent model testing in coordination with *Validation Center*

PRIMED-AI NOFO Ecosystem

Budget Estimates	Total Cost (over 5 years)
Playbook (UG3) (8 awards)	**$6.4 M**
Academic-Industrial Partnerships (UG3-UH3) (6 awards)	**$14.4 M**
Modular Software Tools (R03) (40 awards)	**$6 M**
Model to Clinic (UG3-UH3) (10 awards)	**$51 M**
Emergent Opportunity Revisions (16 awards)	**$16 M**
Scientific Validation Center (U54) (1 award)	**$13.5 M**
Logistics Center (U24) (1 award)	**$7.75 M***
Communication Curricula (R25) (10 awards)	**$6 M**
TOTAL	**$121 M**

* includes funds for teaming pilot projects

PRIMED-AI Deliverables

Best practices for precision medicine through integration of imaging and multimodal data

- Playbook – multimodal data & algorithm management, model validation
- Comparative analysis of data integration methods
- Clinical impact assessments of multimodal data type combinations
- Standardized parameters and metrics to inform AI predictive models

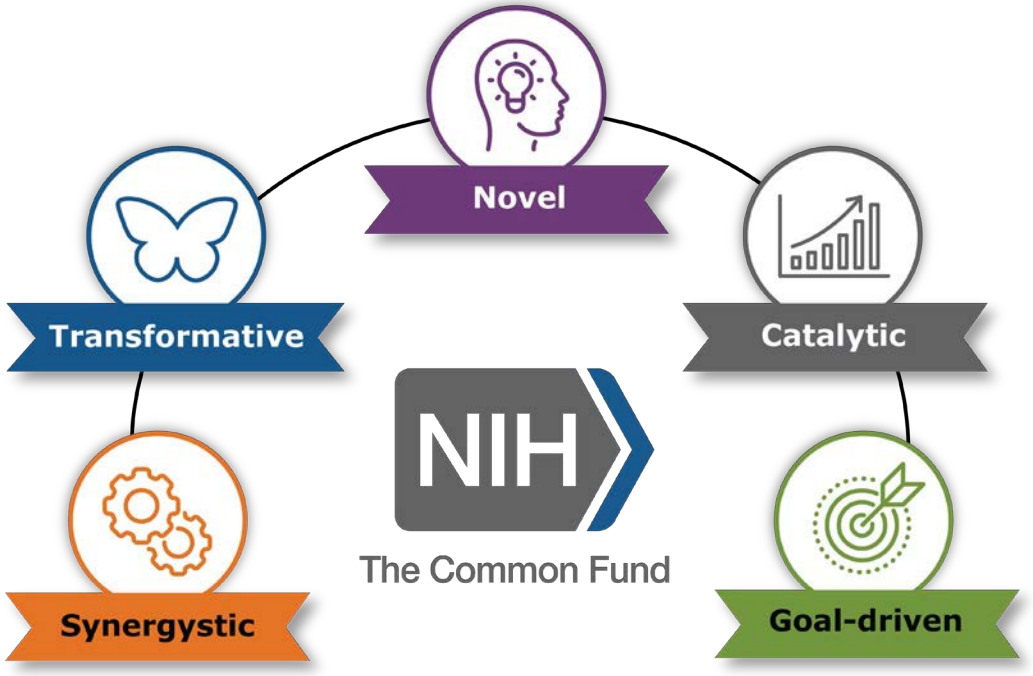
Innovative and reliable tools

- Clinical Decision Support tools for rapid bench-to-bedside deployment
- Modular software tools to address critical gaps in the data → models → clinic pipeline
- Pre-commercialization verification and validation to support scientific rigor

Durable relationships to expand and sustain the field

- Curricula to build trust and enhance communication between stakeholders
- Outreach to scientific-clinical community and public

PRIMED-AI Take-Home Points



- AI-supported translational impact for patients
- Seeds culture change in clinical practice
- Enables Precision Medicine strategies at scale
- Fosters cross-platform validation
- Integrates input from all stakeholders
- Accelerates use of multi-scale digital biomarkers

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Additional slides

PRIMED-AI Glossary

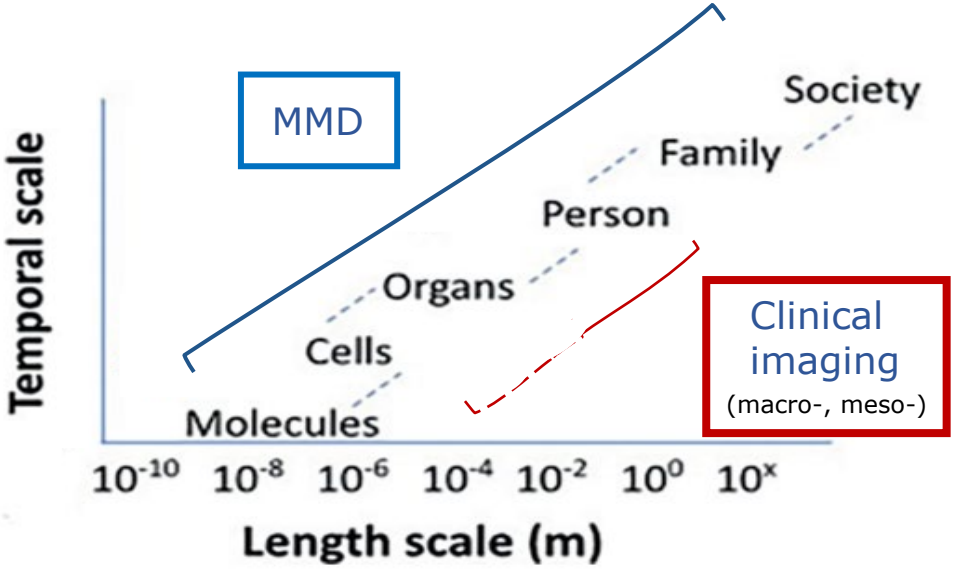
- **Clinical Imaging** is any FDA- approved imaging modality used in patient care, including radiologic (*e.g.,* X-ray, CT, MRI, NM), ophthalmologic *(e.g.,* OCT), endoscopic, and dermatologic imaging.

- **Multimodal** data sets may include multiple types of imaging (*e.g.,* CT, OCT, MRI etc.) and non-imaging health data (*e.g.,* electronic health records, EKG, medical reports, etc.).

- **Precision Medicine** is a healthcare approach that optimizes management based on a patient's individual characteristics, such as their health measures, genotype, phenotype, environment, and lifestyle.

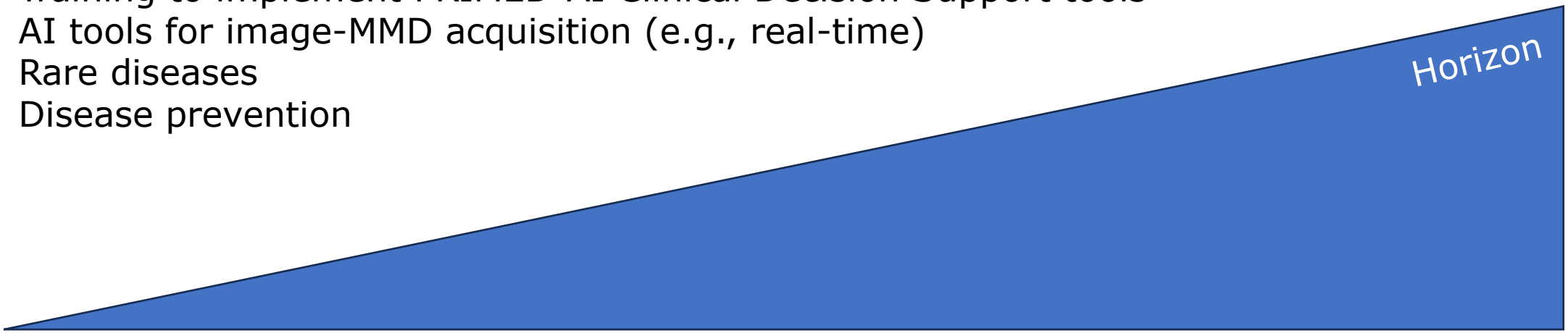
PRIMED-AI: Addressing multiple scales

Multi-scale data
(quantitative + qualitative)



Next steps for consideration

- Commercialization accelerator
- Regulatory alignment and implementation
- Clinical adoption of Clinical Decision Support tools
- Training to implement PRIMED-AI Clinical Decision Support tools
- AI tools for image-MMD acquisition (e.g., real-time)
- Rare diseases
- Disease prevention



Relationship between Bridge2AI and PRIMED-AI Common Fund Programs