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

**Background**: Clinical imaging plays a vital role in the prediction, diagnosis, treatment, and assessment of patient outcomes but it is often utilized in isolation from other health data during the development of AI-based clinical decision support tools. Current AI applications primarily use single imaging modalities such as radiological or retinal images. However, health is shaped by a variety of interconnected factors—clinical, social, biological, genetic, and environmental. Recent advances in artificial intelligence (AI) offer opportunities to combine imaging with a wider range of health data, promising improved diagnostic precision. The Precision Medicine with AI: Integrating Imaging with Multimodal Data (PRIMED-AI) program seeks to integrate clinical imaging with ancillary, multimodal, clinical data for developing innovative AI-powered clinical decision support tools for precision medicine. The PRIMED-AI initiative aims to tackle complex clinical challenges by fostering cross-disciplinary collaboration to create reliable, cost-effective, accessible, and sustainable AI solutions.

Rationale (based on both landscape analysis and external input):

- Health data are multimodal, yet AI systems in medicine have largely addressed narrow tasks.
- Opportunities exist to link data across scales; however, cohesive infrastructures with reliable, explainable, and validated methodologies are needed.
- Despite advances in AI-technology discovery, wider testing and implementation of clinical decision support tools are not yet optimized.
- Building trusting relationships between patients, clinicians and data scientists for AI-tools is important, but an organized framework for their development is needed.

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

**Scope:** We define clinical imaging as any FDA-approved imaging modality used in patient care, including radiologic (*e.g.*, X-ray, CT, MRI, NM), ophthalmologic (*e.g.*, OCT), endoscopic, laparoscopic, and dermatologic imaging. PRIMED-AI projects will include clinical imaging as the backbone in combination with any other multimodal health data type (*e.g.*, Electronic Health Record – clinical labs, cellular -omics, wearables). We anticipate projects will leverage multiscale data suited to address clinical needs through development of new precision medicine strategies and AI-clinical decision support tools.

# Proposed initiatives, staggered over 5 years:

- 1. *Playbook* of reliable yet flexible standardized frameworks fit for multiple use cases.
- 2. *Academic-Industrial Partnership (AIP)* for data inter-operability in a first phase, and algorithm development and performance testing in a second phase.
- 3. *Modular software tools* for focused needs to facilitate multimodal data integration, model robustness, and user interface design.
- 4. *Model to Clinic* to optimize AI models for broad clinical use. This initiative will include AI model building in a first phase and clinical testing in a second phase.
- 5. *Emergent Opportunity Revisions* to leverage new advances in clinical research, including ancillary trials, towards PRIMED-AI goals.
- 6. *Validation Center* for verification, validation, and uncertainty quantification of PRIMED-AI tools.
- 7. *Logistics Center* for program administration and evaluation, providing multidisciplinary teaming support, and engaging with stakeholder communities.
- 8. *Communication Curricula* for novel strategies to build trust & enhance communication between patients, clinicians, and data scientists.

### Deliverables:

PRIMED-AI deliverables will include the following: (1) Best practices for developing precision medicine tools that integrate imaging and multimodal data, (2) Innovative and reliable tools, and (3) Durable relationships between stakeholders to expand and sustain the field. PRIMED-AI data sharing criteria will be incorporated into each funding opportunity to balance pre-competitive collaboration, innovation, and incentives consistent with this program's clinical decision support tools-oriented deliverables.

Estimated Total Cost (\$M)	FY27	FY28	FY29	FY30	FY31	TOTAL
1 ••• Playbook (UG3)	2	2	-	1.2	1.2	6.4
2 •••• Academic-Industrial Partnerships (UG3-UH3)	3.6	3.6	2.4	2.4	2.4	14.4
3 •••• Modular Software Tools (R03)	-	1.5	1.5	1.5	1.5	6
4 💶 Model to Clinic (UG3-UH3)	7.5	7.5	12	12	12	51
5 •• Emergent Opportunity Revisions	-	4	4	4	4	16
6 • Validation Center (U54)	2.7	2.7	2.7	2.7	2.7	13.5
7 Logistics Center (U24)	0.75	1.75*	1.75*	1.75*	1.75*	7.75*
8 Communication Curricula (R25)	-	1.5	1.5	1.5	1.5	6
RMS – for NIH staff salary and travel	0.75	0.75	0.75	0.75	0.75	3.75
TOTAL	17.3	25.3	26.6	27.8	27.8	124.8

#### Budget: \$124.8 M over 5 years

RMS, Research Management and Support; \*includes funds for teaming pilot projects in FY28-FY31

Imaging-Multimodal Data Integration

Clinical Implementation

AI Algorithm and Tool Development

Building Trust & Coordination

# **Concept Planning Team:**

- Co-Chairs: Michael Chiang (NEI), Susan Gregurick (ODSS), Richard Hodes (NIA), Walter Koroshetz (NINDS), Bruce Tromberg (NIBIB)
- Coordinators: Sangeeta Bhargava (NEI), Michael Espey (NCI), Kris Kandarpa (NIBIB)
- Common Fund Staff: Sahana Kukke (Program Leader), Kaitlyn Browning (Strategic Planning, Evaluation, and Communication), David Dzamashvili (Operations)