



INVEST FOR
PROGRESS 

Mental Health Social Impact Collaborative

FDA DIGITAL HEALTH ADVISORY COMMITTEE

NOVEMBER 6, 2025

Invest for Progress Overview



Rebecca Messing Haigler MPH, MBA
Senior Vice President



Morgan Bailie, MPH
Policy Director

- The Invest for Progress Collaborative brings together leading behavioral health investors and their portfolio companies, which provide critical mental health and substance use treatment services to communities across the U.S.
- Through regional convenings and focused innovation topics, Invest for Progress is engaging private sector companies in refining and scaling existing models of behavioral health care to create an investment transformation framework that ensures patients have access to the care they need.
- Invest for Progress identifies reimbursement gaps and care delivery needs to help advance new payment models and improve outcomes for behavioral health.

BH Innovation Considerations

- FDA has an opportunity to assume key leadership role in guiding the safe and effective deployment of GenAI in Mental Health
 - 24% of U.S. adults use LLMs for mental health support. Based on recent Stanford pre-print study; conservative adjustments suggest this is about 13-17M people nationwide
 - Many opportunities exist to deploy GenAI innovation at a time when patients are experiencing significant access barriers to mental health providers
- Need for understanding of innovative mental health solutions balancing pursuit of SAMD process vs defaulting to a wellness pathway
- Behavioral Health Conditions are highly co-morbid across Mild to Moderate, Depression, Anxiety Disorders, Serious Mental Illness and Substance Use Disorders
- MD prescribing authority is different in Behavioral Health, as many patients receive care from Therapists – PhDs, LCSWs, LMFTs, etc.

FDA Oversight & a clear Regulatory Framework is necessary

To advance generative-AI innovation in behavioral health & Safeguard patients

■ **Clinical Evidence Considerations**

- Validated behavioral health symptom measures (e.g. PhQ-9, GAD 7, MADRS, etc)
- Functional behavioral health outcomes (WHO-DAS, FAST, RAS, SDS, SF36/SF12)
- Patient & Caregiver motivational outcomes (e.g. Brief Inventory of Thriving)

■ **Post Market Real world Digital Mental Health registries should also include:**

- Longitudinal patient outcomes (number of crisis episodes, ED visits, return to work/school) over 6 and 12 months

■ **Important note:** BH providers did not receive Meaningful Use funding for EHRs and data infrastructure for outcomes tracking is still in development

- Post market registry requirements could accelerate definitions for BH therapeutic safety and efficacy

Recommendations to FDA DHAC

- Establish a **formal framework** to define, evaluate, and validate “**mental health efficacy**” for generative AI-enabled tools by integrating *clinical outcome metrics, user safety benchmarks, and AI-specific performance standards*
 - Opportunity to drive alignment across agencies (CMS, ASTP/ONC, NIMH, SAMSHA) on adverse outcomes, longitudinal endpoints and real-world data collection
- Create a unified, **federally supported registry** to monitor real-world safety and efficacy of digital tools used in mental healthcare
 - Collaborate with BH providers, health systems, developers, EHR vendors, researchers and digital therapeutic companies akin to other disease registry programs
 - Align with CMS to establish data-sharing channels to inform national coverage determinations and quality measures
- Create a **SaMD subcategory** for regulatory guidance on **Gen AI in Therapeutic Contexts**, clearly defining if it is for Rx , OTC, and/or wellness (with or without a clinician):
 - What constitutes “dynamic learning” requiring re-validation,
 - When model updates trigger new regulatory submissions and a clear timeframe to do so,
 - How developers must monitor **drift, bias, and safety** over time.

Thank you

CONTACT:

MBAILIE@HEALTHSPERIEN.COM