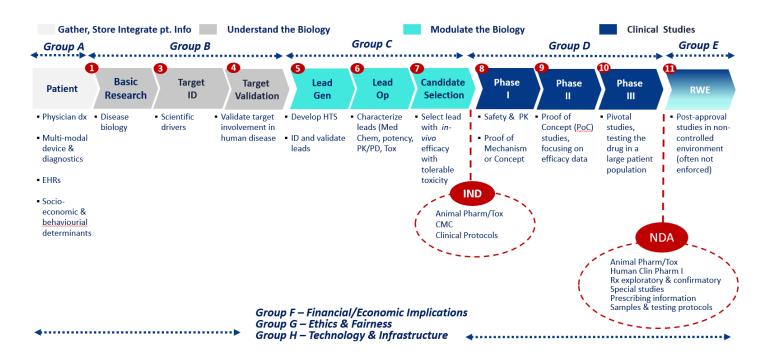


AAIH AI-Enabled Patient-Centric IND and NDA Series Inaugural Workshop v1.0

Al Enabled Drug Development Planning Session

8:00 - 8:40 AM	Registration & Coffee
8:40 - 9:00 AM	 AAIH Welcome Remarks & Workshop Framework (Annastasiah Mudiwa Mhaka) AAIH mission & purpose Today's principles, objectives and frameworks
9:00 - 10:15 AM	 Primer & Context Setting: Drug Development, AI/ML and Regulatory AI in Health Primer - terminology and use cases (Brandon Allgood) Setting common conceptual multi-stakeholder framework for the day (John Baldoni) Potential application of ML in drug development and regulation (Qi Liu)
10:15 - 10:30 AM	Coffee Break (Task-force Assignments)
10:30 - 10:40 AM	 Case Presentation Study #1: Scenario for Today (2019) (Esther Bleicher) Traditional diagnosis and treatment; consider CVD, (lung) cancer, rare disease Patient presents with well known patient symptoms, biology and drug development path
10:40 - 11:40 AM	Table Discussion with Focus on Questionnaire CPS #1
11:40 - 12:15 PM	3 Teams Report Out
12:15 - 12:30 PM	Grab Food for Working Lunch
12:30 - 12:40 PM	 Case Presentation Study #2: Scenario for Tomorrow (2024) (Sonia De Munari) Partially Al-enabled patient presentation and diagnosis; CVD, (lung) cancer, rare disease Patient presents with unclear biology and R&D challenges
12:40 - 1:40 PM	Table Discussion with Focus on Questionnaire CPS #2
1:40 - 2:20 PM	3 Teams Report Out
2:20 - 2:35 PM	Coffee Break
2:35 - 2:45 PM	 Case Presentation #3: Futuristic Scenario (2029) (Sonia De Munari) Al-enabled patient presentation and diagnosis; App notifies patient
2:45 - 3:15 PM	Table Discussion with focus on Questionnaire CPS #3
3:15 - 3:35 PM	2 Teams Report Out
3:35 - 3:45 PM	Coffee Break
3:45 - 4:00 PM	Moderator's Takeaways and Participating Qn List (Bill Martin)
4:00 - 5:15 PM	Interactive Panel Discussion (John Baldoni, Arnaub Chatterjee, Boris Hayete, Qi Lui)
5:15 - 5:30 PM	Closing Remarks and Key Next Steps
5:30 - 7:30 PM	Cocktails & Networking

AAIH TaskForce Framework: Integrated View of AI-Enabled Drug Development (IND & NDA)



Speaker Affiliations

Brandon Allgood, PhD

Chief Technology Officer, Numerate

Vice Chairman, AAIH

Esther Bleicher, JD, MPH

Executive Director, Regulatory Policy & Counsel, Integral Health

Boris Hayete, PhD

Senior Vice President, Precision Medicine, GNS Healthcare

> Sonia De Munari, PhD

Associate, Catenion

Annastasiah Mudiwa Mhaka, PhD

Co-Founder and Convenor, AAIH

John Baldoni, PhD

Chief Technology Officer, Integral Health

Founding Chairman, AAIH

Arnaub Chatterjee, MPA, MHA

Senior Vice President, Product & Ecosystem, Acorn AI - Medidata Solutions

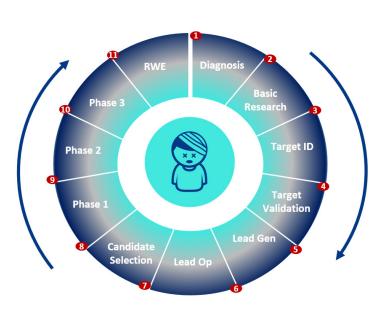
Qi Liu, PhD, MStat, FCP

Senior Science Advisor, Office of Clinical Pharmacology, CDER, FDA

Bill Martin, PhD

President and CEO, BlackThorn Therapeutics

Board of Directors; Committee Co-Chair, Federal Engagement and Regulatory Affairs, AAIH AAIH TaskForce Framework: *Imagining*AI-Enabled Patient-Centered, Continuous
Improvement Drug Development



Illustrative

