ALLIANCE FOR ARTIFICIAL INTELLIGENCE IN HEALTHCARE

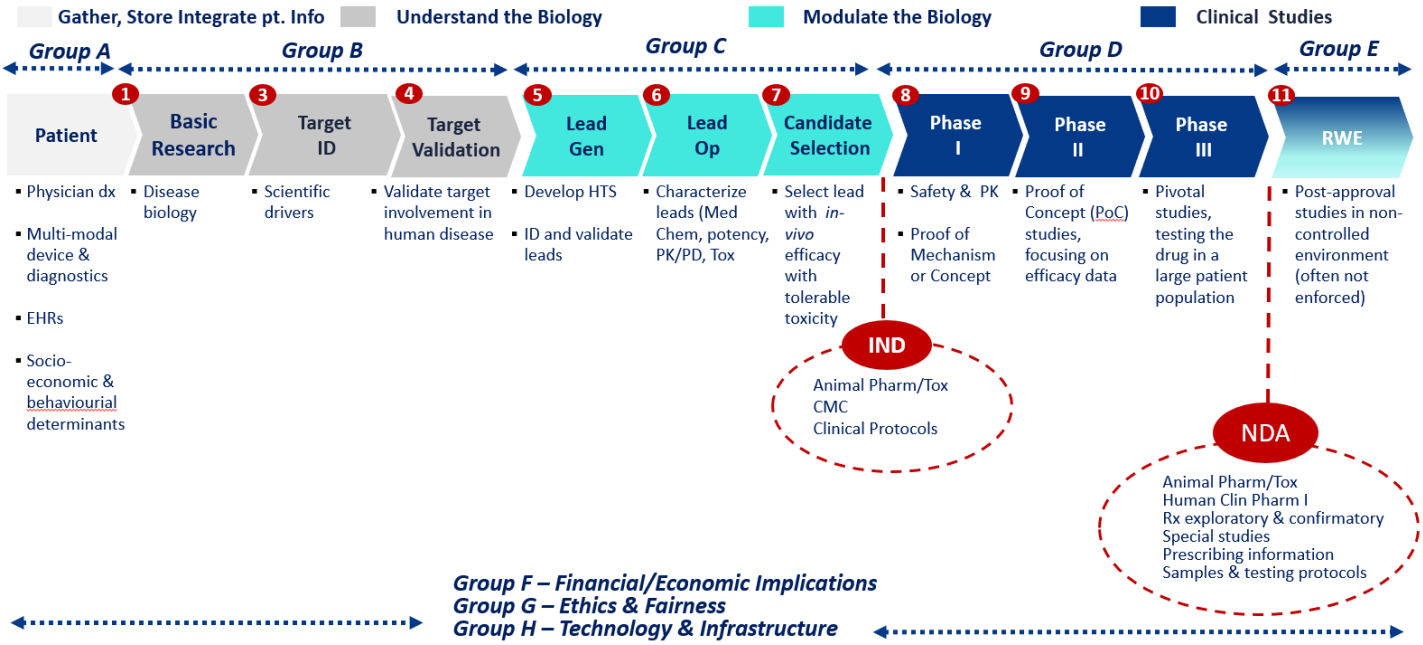
AAIH AI-Enabled Patient-Centric IND and NDA Series

Inaugural Workshop v1.0

AI 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 AI-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)* • AI-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,

Vice Chairman, AAIH

John Baldoni, PhD
Chief Technology Officer, Integral Health

Founding Chairman, AAIH

Esther Bleicher, JD, MPH
Executive Director, Regulatory Policy & Counsel, Integral Health

Arnaub Chatterjee, MPA, MHA
Senior Vice President, Product & Ecosystem, Acorn AI - Medidata Solutions

Boris Hayete, PhD
Senior Vice President, Precision Medicine, GNS Healthcare

Qi Liu, PhD, MStat, FCP
Senior Science Advisor, Office of Clinical Pharmacology, CDER, FDA

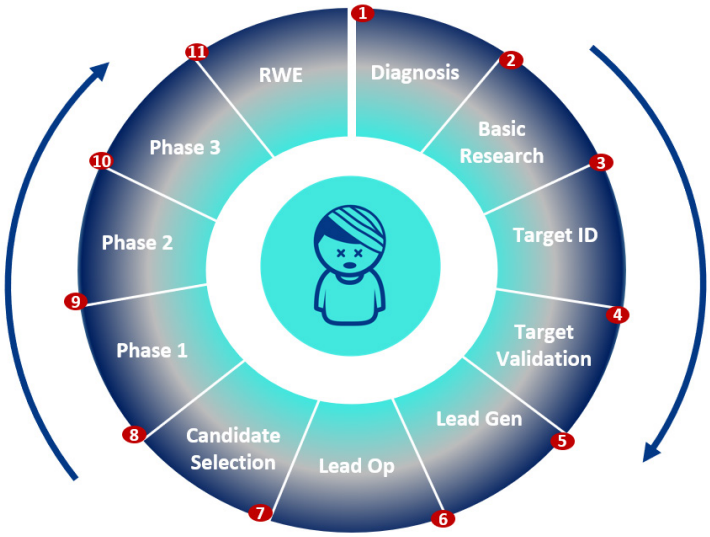
Sonia De Munari, PhD
Associate, Catenion

Bill Martin, PhD
President and CEO, BlackThorn Therapeutics

Board of Directors; Committee Co-Chair, Federal Engagement and Regulatory Affairs, AAIH

Annastasiah Mudiwa Mhaka, PhD
Co-Founder and Convenor, AAIH

AAIH TaskForce Framework: *Imagining* AI-Enabled Patient-Centered, Continuous Improvement Drug Development



Illustrative

Case Study Questions

CASE STUDY PRESENTATION (CSP) #1 - TODAY (2019)

I. Start with B, C, and D, the core of drug development today: Answer with perspectives from B, C, D

a. What are the key hurdles for drug development in given use case *(CVD, (lung) cancer, rare disease)*?
b. How would AI/in silico tools help?
   1. What tools are available now that have been designed for:
      - B (be specific)
      - C (be specific)
      - D (be specific)
   2. Can any tools utilized in other stages of development be repurposed to fill holes?
   3. Can any tools created for other therapeutic areas be used here?
   4. Can any tools that are available but not yet used in drug development be useful here?

II. Discuss the roles of patients & real-world data: Answer with focus on expert perspectives from A, D, E

a. What are the key hurdles for drug development in given use case?
b. How can existing AI tools better utilize/improve on D, E in drug development?

For Patients consider:

- What AI tools are there to gain patient information, preferences, and facilitate engagement throughout drug development?

For Real World Data consider:

- What applicable AI tools are there?
- How would they improve post-market surveillance and generation of new hypotheses for R&D?

III. Thinking back on the conversation of the table, what are key issues related to F, G, and H? (Go through each one by one, tracking across A-E)

a. What issues are "hard" problems, and which are low-hanging fruit?
b. What issues must be resolved to enable the use of AI, e.g.,
   1. For supporting drug development, but not replacing traditional tools?
   2. For relying on AI tools to replace traditional tools in regulatory decision-making?

IV. What do AI tools do today better than traditional tools? What do traditional tools do better than AI tools today?

a. How could they support a determination that human subjects would not be exposed to an unreasonable and significant risk of illness or injury (i.e., IND)?
b. How could they contribute to substantial evidence of safety and effectiveness (i.e., NDA)?
c. How could they assist a regulatory assessment of the benefit and risk of a drug?

CASE STUDY PRESENTATION (CSP) #2 - TOMORROW (2024)

I. Start with B, C, and D, the core of drug development today: Answer with perspectives from B, C, D.

a. Generate hypotheses for how AI could intervene in each stage of development
b. How would future AI tools be better than existing AI and other tools? How would they improve drug development? What unresolved issues would they tackle?

II. Discuss the roles of patients & real-world data: Answer with perspectives from A, D, E.

For Patients consider:

a. How can AI tools be utilized to make drug development more patient centric? How could this improve drug development? For example:
    1. Identification of targets
    2. Outcomes based on real patient preferences
    3. Human subject engagement and retention
    4. Reduction in burden of participation
    5. Reliability of data

b. How could AI improve patient journey, e.g
    1. Diagnosis and identification treatment options, including appropriate clinical studies?
    2. Access to (diagnosis) and clinical studies?
    3. Satisfaction with participation in clinical studies?
    4. Others?

For Real World Data consider:

a. What AI tools are expected to arise?

b. How would they improve post-market surveillance and generation of new hypotheses for R&D?

c. What is the extent to which these new tools, coupled with tools discussed earlier, could shift the generation of clinical evidence from premarket to postmarket?

III. Thinking back on the conversation of the table and what was covered in CSP#1, what are key issues related to F, G, and H? (Go through each one by one, tracking across A-E)

a. What issues are "hard" problems, and which are low-hanging fruit?

b. What issues must be resolved to enable the broad use of AI (How far out are these tools)?

c. What issues must be resolved to enable the responsible use of AI?

d. What would AI tools in the near future do better than traditional tools?

e. What would traditional tools continue to do better?

f. How could AI tools in the future support a determination that human subjects would not be exposed to an unreasonable and significant risk of illness or injury (i.e., IND)?

g. How could they contribute to substantial evidence of safety and effectiveness (i.e., NDA)? How could they assist a regulatory assessment of the benefit and risk of a drug?

CASE STUDY PRESENTATION (CSP) #3 - FUTURE (2029)

I. Putting the entire process & key questions together, what is pie in the sky thinking for fully AI enabled scenario?

a. What would fully AI-enabled drug development look like, from patient presentation to postmarket? (A-F)

b. What would a demonstration of substantial evidence of safety and effectiveness (i.e., NDA) look like?

c. What would the regulatory assessment of the benefit and risk of a drug look like?

d. Are there any traditional tools that AI will never replace?