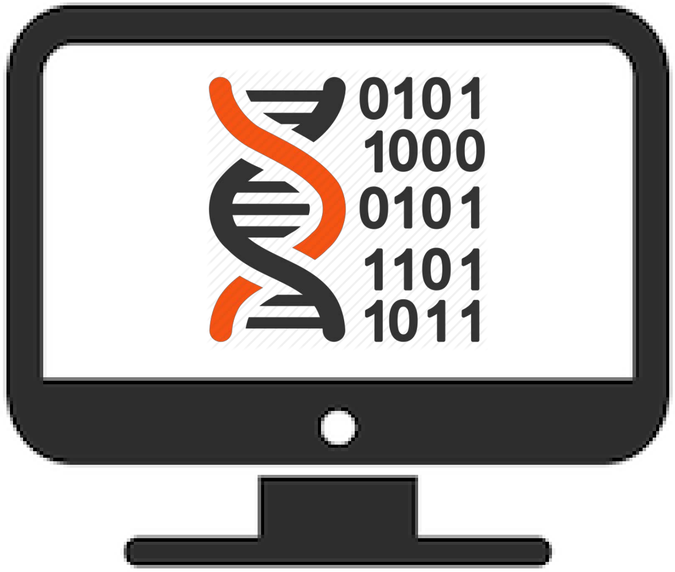
Workshop Wrap-Up



Computational Methods

- Diagnostic
- More Effective Treatment
- Safer Treatment
- Higher Value Care

Session 1: Overview

1. Insistence that computational technologies that interpret patient data interact with FDA and **test for clinical utility** in clinical studies.
2. Encourage **integration** of technologies and datasets for the purposes of validation and synergy.
3. Need for improved **training** of medical trainees to read –omics data to properly vet and value computational interpretations.

Moderator: Hedi Hricak

Session 2: Challenges

1. Need biomedical community-accepted criteria for deciding when a software product is ready for clinical practice, such as **well designed prospective trials**.
2. Deep learning by image analysis software **needs appropriate training and calibration**.
3. **Face validity** needs to be clear for purposes of understanding and acquiring drug approvals.
4. Need a process to **monitor ongoing performance** of deep learning technologies.
5. Can computational methods handle **heterogeneity within cancer**?
6. On focusing on individuals, don't forget about groups. **Homogeneity of data** is exclusive.
7. **Communicating** –omics, computational interpretation and risks to patients are challenged by the general public's low literacy, low numeracy, and theprobabilistic nature of data.

Moderator: Chris Cogle

Session 3: Data

1. Create **standards** for documenting reliability, quality and accuracy at the data source, dataset, and algorithm levels.
2. Power in sharing data among institutions.
3. Patient **data laws** are becoming more complex and changing requirements for informed consent.

Moderator: Amy Abernathy

Session 4: Methods

1. Method types: **statistical, algorithmic, heuristic**
2. Need **high quality data.**
3. Need for **computer code repositories**.
4. **Reproducibility** considerations are a key element in evaluating computational interpretation: **methods, results, inferential**.
5. FDA CDRH's approach to software as a medical device (SaMD) is investigating a **risk-based approach in determining appropriate regulatory pathways.**

Moderator: Constantine Gatsonis

Session 5: Clinical Structures

1. Need for accessible **expertise**.
   - Molecular tumor boards to facilitate treating physicians.
2. Need for support from **institution leadership**.
3. Technology **on** EHR, not necessarily within EHR.

Moderator: Mia Levy

Session 6: Roundtable

1. FDA process unclear
2. FDA process clear
3. Need for ongoing monitoring of software performance.
4. Need methods to assay methods.
5. Prospective clinical trials act as honest brokers.
6. Use of computational methods for prevention and early diagnosis.

Moderator: David Magnus

- Data
  - High quality
  - Inclusive of races & ethnicities
  - Need to change informed consent process
- Methods
  - Prospective clinical trials required to demonstrate clinical utility
  - Integration with other precision technologies
  - Face validity needs to be clear
  - Reproducibility needs to be assessed
  - Regulatory oversight needs more clarity
  - Computational systems need to be monitored on an ongoing basis.
- Clinical
  - Access to expertise to facilitate computer interpretation.
  - Education of clinicians to do their own vetting and validation of computer interpretation.

THANK YOU

- NCPF and NAM
- Planning Committee
- Moderators
- Speakers
- Audience
- NAM staff

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