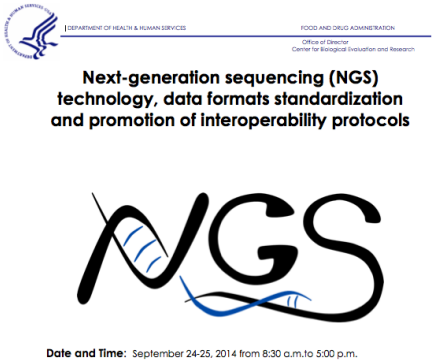
NGS & Standards

- Concerns over NGS standards
  - Includes bioinformatics
- IgDAWG is investigating these
  - http://igdawg.org
- Aim to develop standards and pilot these in the NGS workshop component
  - MIRING

FDA NGS Standards Workshop: Recap

- NGS standards (FDA Genomics Working Group, HL7, NCBI)
- Big data administration & computational infrastructure
  - (FDA/CBER/HIVE, NCI, NY Genome Center)
- Database development
  - (NCBI, Stanford, NCBI/Virus Genome Group)
- Biologics product evaluation
  - (FDA/CBER, UCSF, Sanofi Pasteur, Merck)
- Clinical biomarkers and personalized medicine
  - (VCUMC, Celera/Quest, MSKCC, UCSF)
- NGS sequencing devices and clinical applications
  - Panel - PacBio, Ion Torrent, Illumina, Complete Genomics
- Food safety and pathogen detection (FDA, NCBI, CDC)

- Nothing new from FDA in terms of regulations or even guidelines
  - They are gathering info from community
  - Some people complaining; others working on solutions

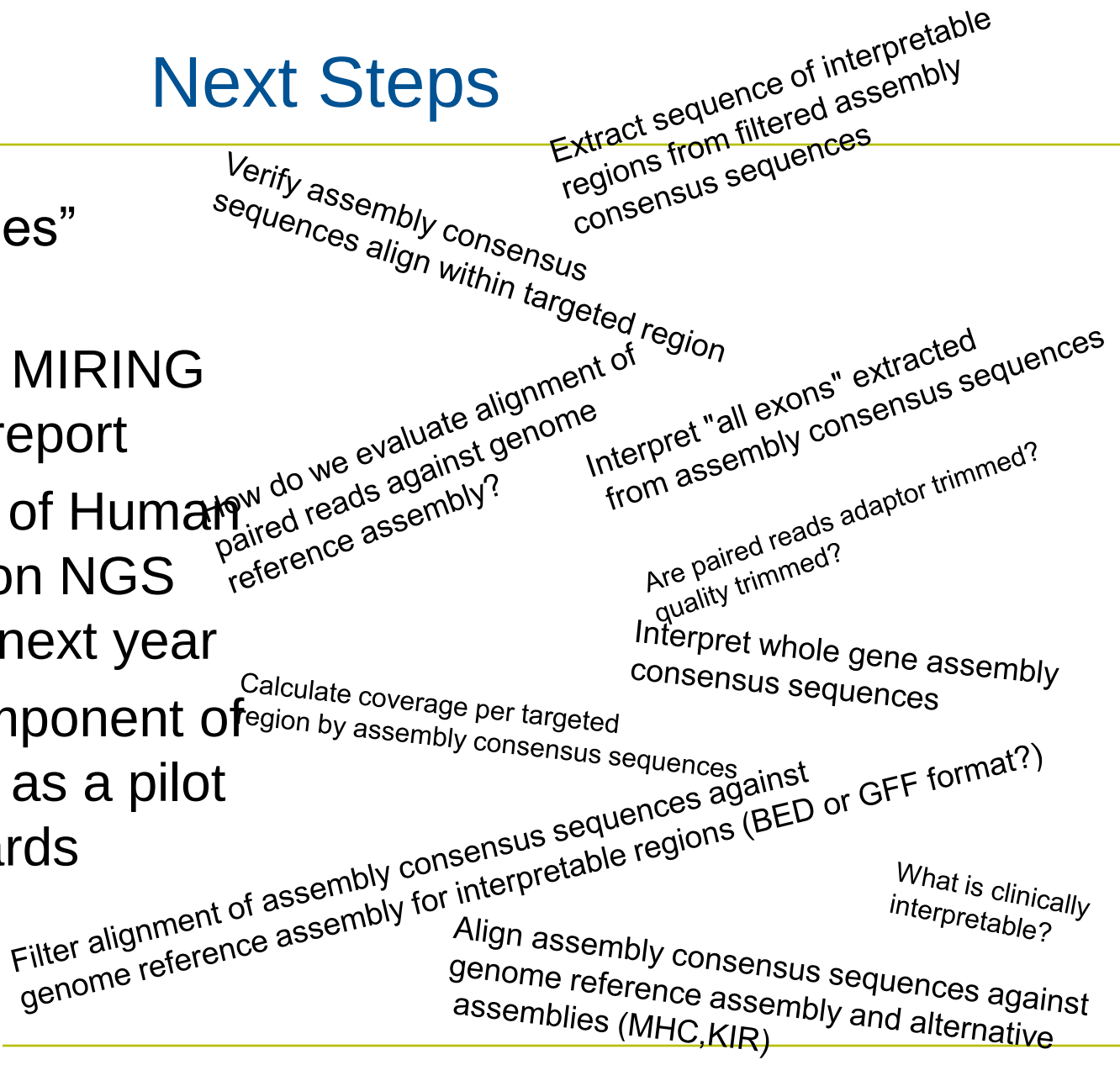


Data Standards Hackathon (DaSH) Recap

- MIRING revised substantially: reduced from 10 to 8 items
- HML:
  - released versions 0.9.4, 0.9.5, 0.9.6
  - incorporated MIRING features
  - HML messages created/processed by many
  - Implementation issues (performance, security)
- Addressed questions about GL String, GL Service, OIDs, GTR,
- Finalized specification for a Multiple-Allele Code Creation Service

Next Steps

- Address “issues” identified
- Publish HML, MIRING and meeting report
- Special issue of Human Immunology on NGS coming early next year
- Use NGS component of the workshop as a pilot for the standards



IDAWG
IMMUNOGENOMICS DATA ANALYSIS WORKING GROUP