Ultra-high Throughput Sequencing and Genomics in CDRH

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Genomics

- Sponsor interest primarily in context of companion diagnostic use
  - Selection, prediction, safety markers
- Array-based copy number variation
  - Developmental delay, mental retardation, etc
  - Conceptual difference in approach—look at everything and see if you find anything
  - OIVD has developed regulatory outline and shared with sponsors

Ultra-high Throughput Sequencing*

- Informal scientific meetings with manufacturers (Spring 2011)
- Public meeting (June 2011) to discuss analytical validation
- Several federal stakeholder meetings—FDA, NIH, CDC, others
- Ongoing interaction with Archon X-Prize

* Also called “next-gen sequencing”

UHTS

- Need for standard materials and protocols
  - Compare apples to apples
  - Understand analytical/informatics effects on results
  - CDRH in IAA with NIST to develop 2 human reference materials and 4-6 microbial RMs
    - Characterization as complete as possible
    - Materials under NIST “standard reference material” auspices
      - Certificate
      - Available to all
    - Data housed in federal database (NCBI?)
    - Analytics modules being set up on CDRH supercomputer for FDA-wide use (collaboration with CBER, CFSAN)

Ongoing Interest in Validation Models

- Highly Multiplex Testing* validation approach in development
  - Public meeting
  - Publication
- SEQC, MAQC activities with NCTR
- Internal development of statistical models for sensitivity testing

* primarily infectious disease