Personalized Medicine and the FDA

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Context

- "Personalized medicine" must fit into the framework of "safe and effective"
- Applies to drugs, devices, biologics
  - Often multiple centers engaged in decision-making
- Traditional model not going away

Considerations

- Decisions usually made at population level
- What is right for public health
  - Often tension between access and quality
- Possible risks weighed against possible benefits
- Practice of medicine uneven

IVDs

- Products must be:
  - Reasonably free of technically incorrect results
    - Fairly rigorous demonstration of accuracy, precision, reproducibility
    - Ability to manufacture a specified product
  - Reasonably predictive of clinical condition
    - “reasonable” varies across unmet need, severity of harm possibly incurred, how results are used

FDA's Needs

- Align regulatory processes between centers
  - SOPs, guidance, formal/informal interactions
- Provide clarity to stakeholders
  - Guidance, public engagement
- Manage increasingly complex issues
  - Applications of WGS to devices, drugs, etc.

Personalized Medicine Activities

- Personalized Medicine Staff, OIVD
- Intercenter connections
  - companion Dx consults—large increase in volume
  - Biomarker qualifications
- Guidance preparation
  - Companion Dx—near term draft publication
  - Codevelopment—longer term, but underway
- Address novel technologies
  - Cytoarrays
  - WGS
  - CDS/mobile apps