Personalized Medicine—View from OIVD

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What is Personalized Medicine at FDA?

- a model for taking into account a patient's particular genetic, genomic, or proteomic constitution to deliver treatments that are as safe and as effective for that patient as possible
- Effective mechanisms for oversight of medical products used to personalize treatment

Diagnostics in Personalized Medicine

- The success of personalized medicine depends on safe and effective diagnostics
  - Select patients for therapy
  - Identify responders/non-responders
  - Identify patients at high risk for adverse events
  - Select dose for safety/efficacy

Regulatory Challenges in Personalized Medicine

- Different regulatory pathways
  - Regulatory requirements for devices and drugs are different
  - Laws not written with personalized medicine focus
  - Drug labeling changes could change device risk profile
- Regulatory processes for co-review of diagnostics and therapeutics
  - Need to establish policies
  - Current approach has led to inconsistencies

Personalized Medicine in CDRH

- Organization of PM in Center for Devices
  - Personalized medicine will depend on devices
    - Classify disease
    - Stratify population
    - Avoid adverse events
    - Dose choices

Personalized Medicine in CDRH-OIVD

- OIVD
  - Regulation of in vitro diagnostic devices (clinical laboratory tests)
    - Immunology/hematology/pathology
    - Chemistry/toxicology
    - Bacteriology/virology
  - Policies and procedures for regulation and review

Personalized Medicine Staff

- CDRH cross-cutting personalized medicine staff
  - Three full-time staff (mainly policy and process)
  - 5 reviewers in various review divisions (mainly scientific reviews)
  - Personalized medicine staff currently performing multiple functions
    - Premarket review
    - Postmarket support
    - Compliance
    - Policy, process issues

OIVD Personalized Medicine activities

- Policies
  - Guidances, regulatory approaches
- Science
  - Analytical and clinical issues
    - What's the same, what's different
- Outreach
  - What OIVD is doing
- Intercenter coordination
  - Co-reviews
  - Balance of regulation
  - Labeling issues

Goals

- Establish clear(er) path for IVD tests used in PM
- Help to establish clear(er) path for codevelopment
- Provide helpful technical guidance
- Contact point for PM issues