



Personalized Medicine Update

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Medicine

OIR/CDRH

IVD Roundtable, Nov 18, 2014

Personnel

- New Personalized Medicine Staffer
 - Kate Donigan, to start Dec 2014
- Div. of Genetics and Molecular Pathology
 - Reena Philip, Division Director
 - Yun-Fu Hu
 - Donna Roscoe
 - ~29 reviewers/postmarket staff

Activities

- Companion Diagnostic reviews
- Consults to CDER, CBER
- Guidance documents
 - Codevelopment
 - NGS panels
 - Me-too Companion Diagnostics
 - Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices



Companion Dx Consults

- Continue to see year over year increases:
 - Consults from CDER/CBER
 - Presubmissions
 - NSR/SR decisions
 - Technical issues with test

NGS

- Continuing policy development around efficient ways to manage NGS regulation
 - Standards development
 - Materials
 - Analytical standard?
 - Database approaches
 - Informatics tools
 - Panel approaches