



FDA Update

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Our Mission

Getting safe and efficacious drugs and devices to market as quickly as possible...



... while ensuring that drugs and devices currently on the market remain safe and efficacious

Helping the public get science-based accurate information about drugs and medical devices needed to improve health



Organizational Initiative

- Senior Genomics Advisor in the Office of the Chief Scientist – Liz Mansfield on detail

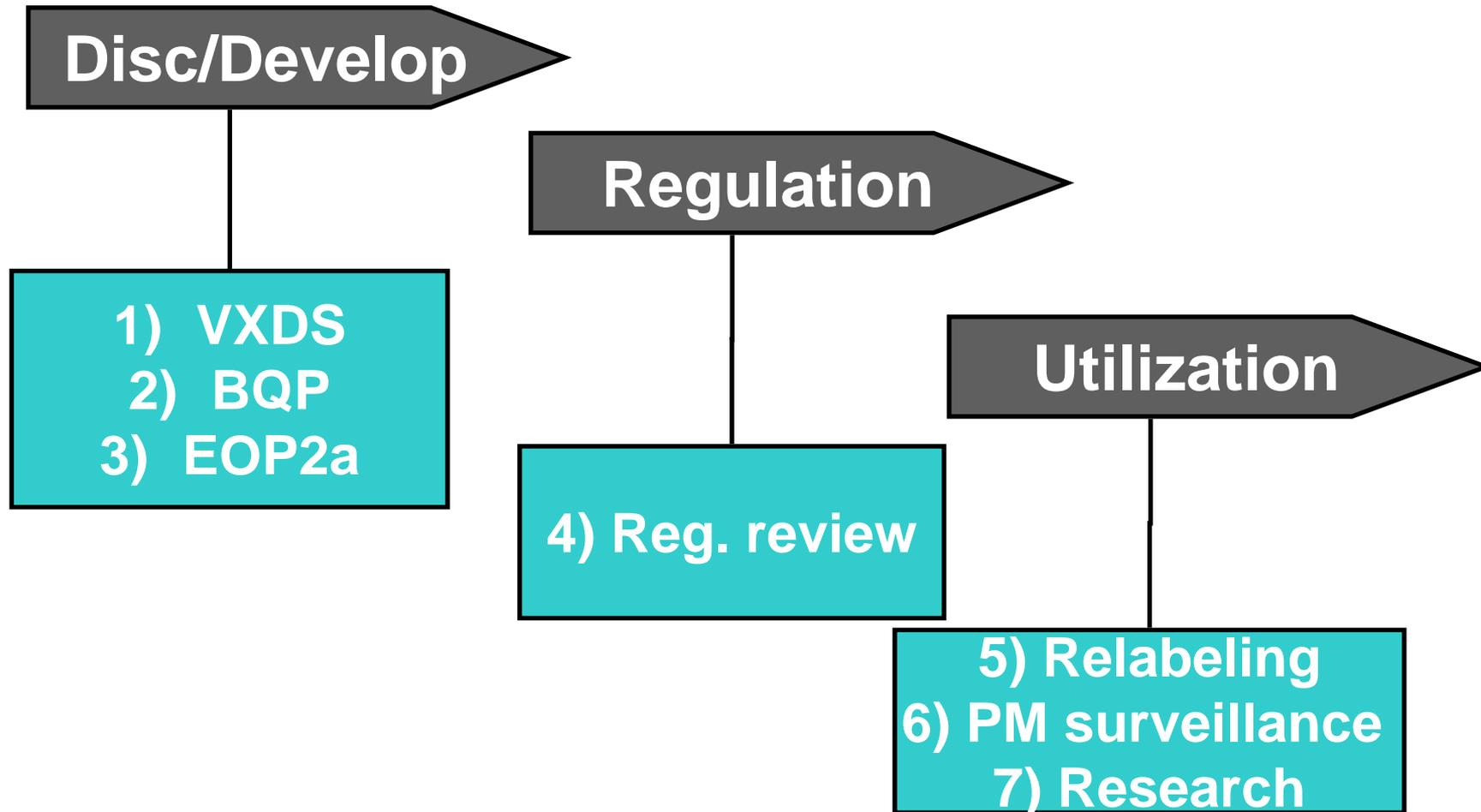


Agencies Genomics Programs

- National Center for Toxicological Research (NCTR)
- Office of Clinical Pharmacology (OCP)
- Office of In Vitro Diagnostics (OIVD)

OCP Genomics Activities

The DDRU Continuum





Organizational Change - OIVD

- Steve Gutman – Retired
- Don St.Pierre – Acting Office Director
- Creation of Personalized Medicine Staff



Guidances

- IVD MIA – under review
- Migration Studies
- Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA



Notable New Clearances

- rRT-PCR Flu Panel test – a CDC Test to Detect Human Influenza



Notable Panel Meetings

- Advisory panel meeting on Fujirebio Diagnostics Inc. HE4 Enzyme Immunoassay and Risk of Ovarian Malignancy Algorithm™ (ROMA™)
- ODAC panel meeting on K-RAS testing



Postmarket Actions

- Warning letter to LabCorp for OvaSure
- Test removed from market



Critical Path Programs

- Genomics – interactions with NCI including EDRN, SPORE, PACCT, BRN and with CDC (EGGAP)



Cancer Biomarker Consortium– AACR, FDA, NCI

- Biorepositories
- Bioinformatics
- Bioassay validation
- Data sharing



IOTF

- Molecular diagnostics—proteomics project underway to define data and review requirements
- Biospecimens—collaboration with NCI to raise awareness, generate data
- PGx group



Regulation of Laboratory Developed Test

- Genentech Petition under review