FDA Update

AMDM IVD Focus Meeting

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MDUFA III

Key Points of MDUFA III

- Shared Outcome Goal – Total Time
  - Fewer extensions, fewer cycles
- No Submission Left Behind
- Refuse to Accept policy
- Substantive Interaction goals
- PMAs separated: panel vs no panel

Submission Type		MDUFA III (2013-2017) - all in FDA Days except Average Total Time				
		FY13	FY14	FY15	FY16	FY17
510(k)s	Performance Goal	91% in 90 days	93% in 90 days	95% in 90 days	95% in 90 days	95% in 90 days
	Interaction Goal	65% in 60 days	75% in 60 days	85% in 60 days	95% in 60 days	95% in 60 days
	Average Total Time (shared)	**135 days**	**135 days**	**130 days**	**130 days**	**124 days**
Original PMAs & Panel Track Supplements (including Expedited)	Performance Goal (no panel mtg)	70% in 180 days	80% in 180 days	80% in 180 days	90% in 180 days	90% in 180 days
	Performance Goal (with panel mtg)	50% in 320 days	70% in 320 days	80% in 320 days	80% in 320 days	90% in 320 days
	Interaction	65% in 90 days	75% in 90 days	85% in 90 days	95% in 90 days	95% in 90 days
	Average Total Time (shared)	**395 days**	**395 days**	**390 days**	**390 days**	**385 days**
180 Day PMA Supplements	Performance Goal	85% in 180 days	90% in 180 days	90% in 180 days	95% in 180 days	95% in 180 days
	Interaction	65% in 90 days	75% in 90 days	85% in 90 days	95% in 90 days	95% in 90 days
Real Time PMA Supplements	Performance Goal	90% in 90 days	90% in 90 days	95% in 90 days	95% in 90 days	95% in 90 days
CLIA Waiver Applications	Dual CLIA/510(k)	90% in 210 days				
	CLIA (no panel)	95% in 180 days				
	CLIA (with panel)	95% in 330 days				

MDUFA III status

- Quarterly reports
  - google – mdufma reports
  - Everything you wanted to know, but were afraid to ask
- So far all looks good….

CLIA Categorizations

Year	2008	2009	2010	2011	2012	2013
High Complexity	110	183	194	267	149	181
Moderate Complexity	1246	1223	891	2498	1258	532
Waived	389	401	714	420	505	557

PMA Approvals

- Roche's cobas® EGFR Mutation Test
  - Aid in selecting patients with NSCLC for whom Tarceva® (erlotinib) is indicated.
- bioMérieux's THxID™ BRAF Kit
  - Aid in selecting melanoma patients for treatment with dabrafenib [Tafinlar®] and for treatment with trametinib [Mekinist ™]

PMA Approvals

- Abbott's RealTi*m*e HCV Genotype II
  - Aid in the management of HCV-infected individuals and in guiding the selection of therapeutic treatment indicated for genotypes 1, 1a, 1b, and 2-5
- Qiagen's therascreen® EGFR RGQ PCR Kit
  - To select patients with NSCLC for whom GILOTRIF™ (afatinib) is indicated

De Novo classifications

- Roche's COBAS INTEGRA 800 Tina-quant HbA1cDx Gen.2
  - This test is to be used as an aid in diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes

De Novo classifications

- CDC's Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS
  - To detect and measure the concentration of specific organophosphate metabolites in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning

De Novo classifications

- Abbott's Vysis EGR1 FISH Probe Kit
  - The Vysis EGR1 FISH Probe Kit – SC assay results characterize bone marrow specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted by a qualified pathologist or cytogeneticist. This device is not intended for high-risk uses such as selecting therapy, predicting therapeutic response or disease screening. The use of this product for diagnosis, monitoring or risk assessment has not been established.

De Novo classifications

- Cepheid's Xpert® MTB/RIF Assay
  - The Xpert® MTB/RIF Assay, performed on the GeneXpert® Instrument Systems, is a qualitative, nested real-time polymerase chain reaction (PCR) *in vitro* diagnostic test for the detection of *Mycobacterium tuberculosis* complex DNA in raw sputum or concentrated sediments prepared from induced or expectorated sputum. In specimens where *Mycobacterium tuberculosis* complex (MTB-complex) is detected, the Xpert MTB/RIF Assay also detects the rifampin-resistance associated mutations of the *rpoB* gene

Guidances

- Special Controls : Norovirus Serological Reagents
- Special Controls : Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens
- Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications
- The Pre-Submission Program and Meetings with FDA Staff (draft)

Guidances

- Humanitarian Use Device (HUD) Designations
- Types of Communication During the Review of Medical Device Submissions
- Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia burgdorferi
- Molecular Diagnostic Instruments with Combined Functions

Guidances

- Assay Migration Studies for In Vitro Diagnostic Devices
- FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens

Guidances

- eCopy Program for Medical Device Submissions
- Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies
- Mobile Medical Applications
- Global Unique Device Identification Database (GUDID)

Notable Panel Meetings

- Classification Panel, April 25, 2013
  - Methotrexate Test Systems
  - PCP Test Systems
  - Isoniazid Test Strips

Notable Panel Meetings

- Flu up-classification, June 13, 2013
  - Minimum performance criteria that should be required for clearance of the rapid influenza detection devices
  - Appropriate reference method to be used for evaluation of clinical performance
  - Annual post-market reactivity testing of device performance due to the continuous genetic changes of seasonal influenza viruses and, how to communicate the ability of previously cleared rapid influenza detection devices to detect novel influenza virus strains
  - Testing when a new influenza strain with a potential to become a public health emergency emerges.

Notable Workshops

- Clinical Flow Cytometry in Hematologic Malignancies, February 25-26, 2013
- Diabetes Technology Society's meeting on performance of glucose meters, May 21, 2013

Re-Org info

- OIR – approx 270 people with All Rad Health and Mammography
- DPOM (Division of Program Operations and Management)
  - This is the new policy group
  - One team for program management
  - One team for program operations

Helpful Contacts

- Policy/Process Questions
  - PMA (Kelly Wilkicki, kelly.wilkicki@fda.hhs.gov)
  - 510k (Sara Aguel, sara.aguel@fda.hhs.gov) or (Brendan O'Leary, brendan.oleary@fda.hhs.gov, while Sara is on maternity leave)
  - IDE/Q-Subs (Elizabeth Hillebrenner, elizabeth.hillebrenner@fda.hhs.gov)

Thanks