FRIENDS OF CANCER RESEARCH

Annual Meeting

Panel 3

Data Generation (and Review Considerations) for Use of a Companion Diagnostic for a Group of Oncology Therapeutic Products

#FriendsAM19

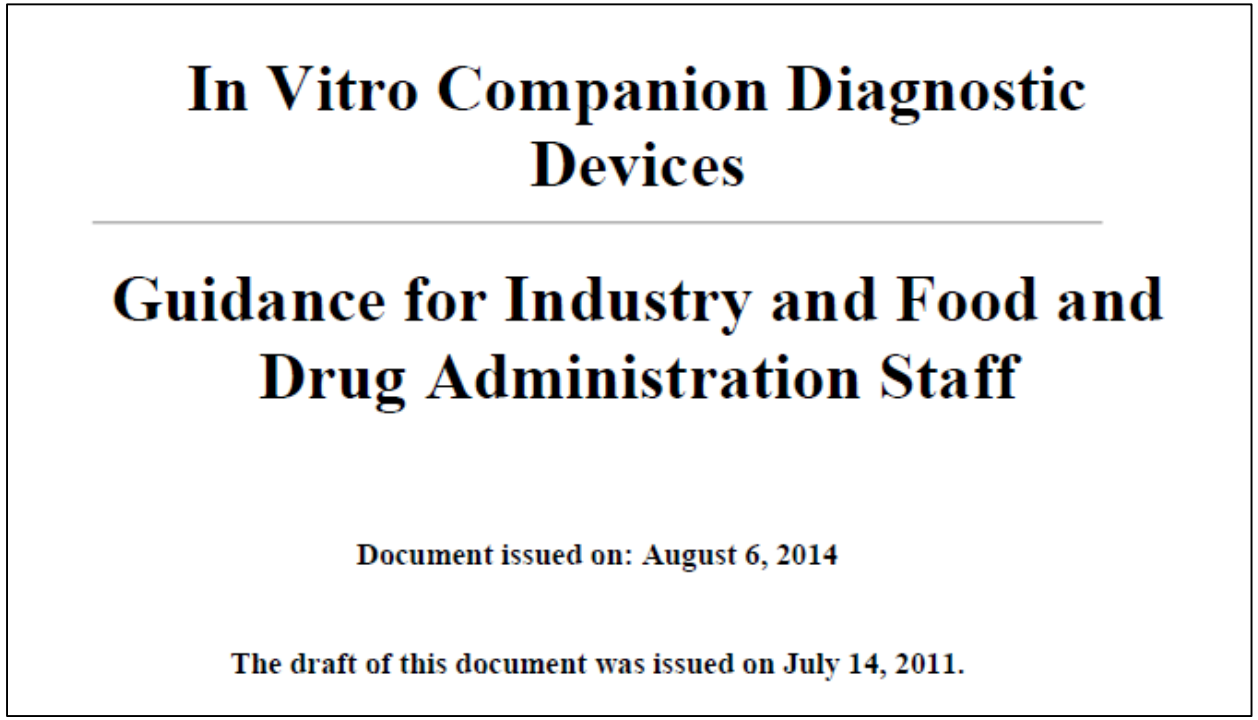
Password: FOCR2019

Panel 3 Participants

Moderator: Steffan Ho, Pfizer

- Andrea Ferris, LUNGevity
- David Hyman, Memorial Sloan Kettering Cancer Center
- Lynne McBride, Thermo Fisher Scientific
- Preeti Narayan, FDA
- Reena Philip, FDA
- Lakshman Ramamurthy, GlaxoSmithKline

Data Generation (and Review Considerations) for Use of a Companion Diagnostic for a Group of Oncology Therapeutic Products



In Vitro Companion Diagnostic Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: August 6, 2014

The draft of this document was issued on July 14, 2011.

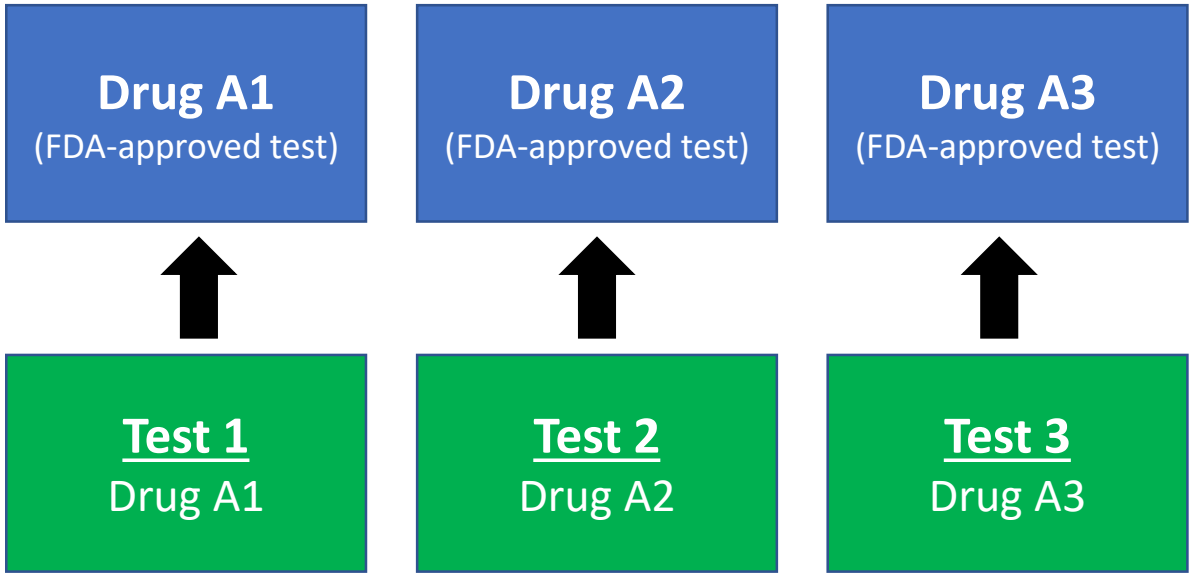
"The labeling for an in vitro diagnostic device is required to specify the intended use of the diagnostic device (21 CFR 809.10(a)(2)). Therefore, an IVD companion diagnostic device that is intended for use with a therapeutic product must specify the therapeutic product(s) for which it has been approved or cleared for use.

In some cases, if evidence is sufficient to conclude that the IVD companion diagnostic device is appropriate for use with a class of therapeutic products, the intended use/indications for use should name the therapeutic class, rather than each specific product within the class."

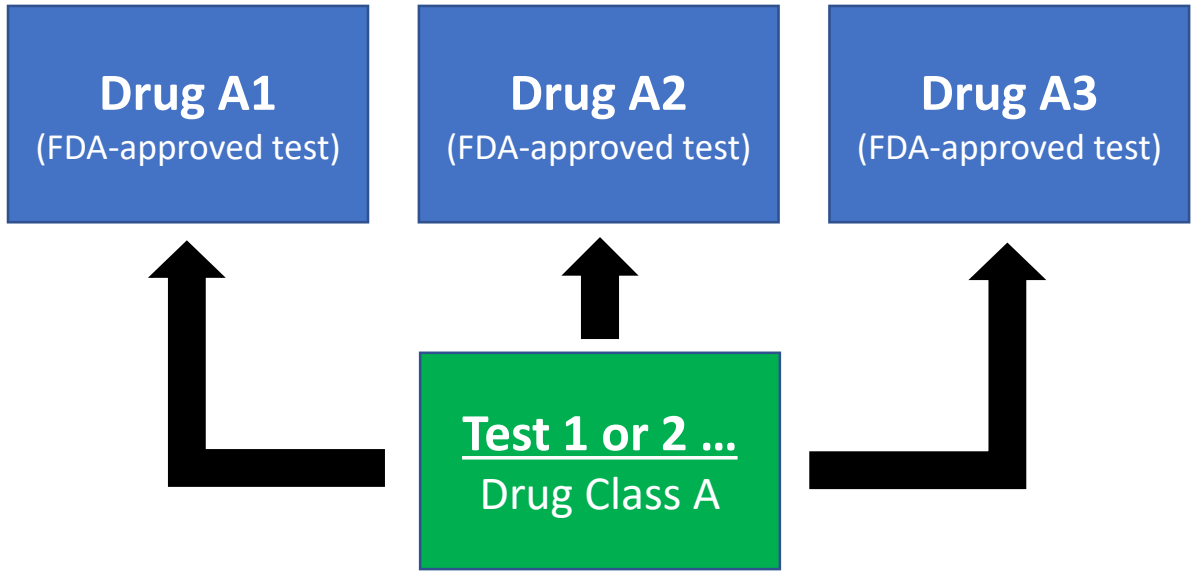
"The specific group or class of oncology therapeutic products would be identified for this purpose based on sufficient and consistent clinical experience with the therapeutics with the same approved indications, including mutation(s) and disease, for which a companion diagnostic could potentially be labeled (as discussed in this document)."

"… a specific group or class of oncology therapeutic products are those approved for the same indications, including the same mutation(s) and the same disease for which clinical evidence has been developed with at least one device for the same specimen type for each therapeutic product."

Multiple therapeutics of the same class each with a different companion diagnostic test



A companion diagnostic test(s) appropriate for use with a specific group or class of therapeutic products



FDA Approved CDx	Same-in-Class Therapeutic Products EGFR inhibitors indicated for the treatment of EGFR-positive metastatic NSCLC (matrix: FFPE tumor tissue; analyte: DNA)				
	Gefitinib	**Erlotinib**	**Afatinib**	**Osimertinib**	**Dacomitinib**
Not Applicable	**Rx** 5/2003	**Rx** 11/2004			
Therascreen EGFR RGQ PCR Kit [PCR]	**Rx** 7/2015 **Dx** 7/2015		**Rx** 7/2013 **Dx** 7/2013		**Rx** 9/2018 **Dx** 9/2018
Cobas EGFR Mutation Test V2 [PCR]	**Rx** 7/2015 **Dx** 9/2015	**Rx** 5/2013 **Dx** 7/2013		**Rx** 11/2015 **Dx** 11/2015%*	
Oncomine Dx Target Test [NGS]	**Dx** 7/2017				
FoundationOne CDx [NGS]	**Dx** 11/2017	**Dx** 11/2017	**Dx** 11/2017	**Dx** 11/2017% **Dx** 7/2019	

% T790M only; *8/2018 label extended to include plasma

FDA Approved CDx	Same-in-Class Therapeutic Products ALK inhibitors indicated for the treatment of ALK-positive metastatic NSCLC (matrix: FFPE tumor tissue; analyte: variable)				
	Crizotinib	**Ceritinib**	**Alectinib**	**Brigatinib**	**Lorlatinib**
Not Applicable		**Rx** 4/2014[1]	**Rx** 12/2015[1]	**Rx** 4/2017[1]	**Rx** 11/2018[2]
Vysis ALK Break Apart FISH Probe Kit [FISH]	**Rx** 08/2011 **Dx** 08/2011				
VENTANA ALK (D5F3) CDx Assay [IHC]	**Dx** 09/2015	**Rx** 5/2017 **Dx** 5/2017	**Rx** 11/2017 **Dx** 11/2017		
FoundationOne CDx [NGS]	**Dx** 11/2017	**Dx** 11/2017	**Dx** 11/2017		

[1] Accelerated pproval for the treatment of patients with ALK-positive metastatic NSCLC who have progressed on or are intolerant to crizotinib
[2] Accelerated pproval for patients whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or alectinib as the first ALK inhibitor therapy for metastatic disease; or ceritinib as the first ALK inhibitor therapy for metastatic disease

FDA Approved CDx	Same-in-Class Therapeutic Products PARP inhibitors in advanced ovarian cancer[1]		
	Olaparib	**Rucaparib**	**Niraparib**
Not Applicable			**Rx** 3/2017 (maint)
BRCAnalysis CDx[2] [PCR, Sanger seq] Matrix: whole blood	**Rx** 12/2014 **Dx** 12/2014	**Dx** 10/2018	**Dx** 3/2017
	Dx 12/2018 (maint)		**Dx** 1/2018 (maint)
FoundationFocus CDxBRCA Assay [NGS] Matrix: FFPE tumor tissue		**Rx** 12/2016 **Dx** 12/2016	
		Dx 4/2018 (LOH[3])	
FoundationOne CDx [NGS] Matrix: FFPE tumor tissue	**Dx** 7/2019	**Dx** 11/2017	

[1] recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer

[2] intended for the qualitative detection and classification of variants in the protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes using genomic DNA obtained from whole blood specimens collected in EDTA. Single nucleotide variants and small insertions and deletions (indels) are identified by polymerase chain reaction (PCR) and Sanger sequencing. Large deletions and duplications in BRCA1 and BRCA2 are detected using multiplex PCR. Results of the test are used as an aid in identifying ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants

[3] Positive homologous recombination deficiency (HRD) status defined as tBRCA-positive or LOH high

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