STAIR IX

Companion Diagnostics: CDER Perspective

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Bethesda, MD

Disclaimer

The views expressed in this presentation are those of the speaker, and are not an official statement of the Food and Drug Administration.

Companion diagnostic device (CoDx)

- Provides information that is essential for the safe and effective use of the corresponding therapeutic product

In Vitro Companion Diagnostic Devices, August 6, 2014
http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm262327.pdf

When is a CoDx essential?

- When it is essential to:
  - Identify patients most likely to benefit
  - Identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with the therapeutic product

In Vitro Companion Diagnostic Devices, August 6, 2014
http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm262327.pdf

When is a CoDx essential?

- When it is essential to:
  - Monitor response to treatment with the therapeutic product for the purpose of adjusting treatment to achieve safety and/or effectiveness, e.g. dose, dosing schedule or discontinuation
  - Identify patients for whom treatment has been shown to be safe and effective (insufficient information about the safety and effectiveness in any other population).

In Vitro Companion Diagnostic Devices, August 6, 2014
http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm262327.pdf

Approval/Clearance of the CoDx

- Under jurisdiction of CDRH
- Must be properly validated and meet the standards for safety and effectiveness (PMA) or substantial equivalence (510(k)) for the use indicated in the label for the therapeutic product.

Specific Performance characteristics of the CoDx

- Accuracy
- Precision
- Specificity
- Sensitivity
- Additional depending on the test/technology

CFR 809.10(b)(12)

Risks of inadequate performance

- Adverse reaction to the therapeutic product
- Failure to realize benefit from an alternate therapeutic product

CoDx in a clinical trial

- Is it investigational?
- Is it a significant risk device?
- Information about the planned use of an IVD companion diagnostic device and its use in clinical trials should be included in an investigational submission.

Early development of a CoDx

- FDA strongly encourages sponsors considering developing the products discussed in this guidance to request a meeting with both relevant device and therapeutic product review divisions as early in development as possible.

Guidance documents

- In Vitro Companion Diagnostic Devices, August 6, 2014
  http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm262327.pdf
- Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products *DRAFT GUIDANCE,* December 2012
  http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm332181.pdf

Questions?