Companion Diagnostics: An Evolving Paradigm

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Companion Diagnostic Policy

• Approval of a test if it is essential for the safe and effective use of a therapeutic product

- Policy articulated formally 2011
- CoDx for ~11 drug indications
- Successful approach
Evolution of In Vitro Diagnostics

• New technologies
  – Multiple simultaneous measurements
  – Mostly nucleic acid based
  – Model already in use (early adopters)

• FDA tracking technology
Changes in Policy?

• Multiplex ability
  – Given a cancer type (e.g., NSCLC)
  – Measure all or most markers of interest
    • One test
    • One sample
    • Many results

• Appropriate policy moving forward?
Questions that Need Answers

• What do we need to know about the test
  – Tumor heterogeneity?
  – Test sensitivity vs probable response?
  – Primary vs metastatic disease?

• What do we need to know about biology
  – Spectrum of mutations vs response?
  – Rare mutations vs response? (VUS/path)
Finally

• What we know we don’t know
• What we don’t know we don’t know
• Time for answers?