

**The Cancer Human Biobank (caHUB) Biospecimen-Based  
Reference Sets for Drug-Diagnostic Co-development  
Workshop (OBBR / NCI)**

***Real-World Rx-CDx Learnings***

**David M Jackson PhD**

Senior Director, Companion Diagnostic Partnerships  
QIAGEN Manchester  
*david.jackson@qiagen.com*

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## Contemporaneous approval of drug and diagnostic

- FDA states +/- 2 weeks for NDA / PMA
- FDA states no NDA approval without PMA-approved IVD

## Diagnostic is available for trial participants

- Not just any assay but a standardized test
- If used for inclusion/exclusion, must approach CDRH for IDE

## Collaborative commercialization

- Companion products have obvious co-selling attributes
- Companion products *may* have dissimilar sales points



# Co-Development of Rx/CDx

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## Requirements

- Equal risk to that of the therapy
- Class III device
- PMA
- Prospective trial

## The “System”

- “Sample” uniformity
  - [ Sample collection >>to>> Diagnostic “call” ]
  - Sample type specific
  - Sample handling protocol
- “Hardware” uniformity
  - Tissue recovery
  - Analyte isolation
  - Sample interrogation
  - Instrument/s
- “Software” uniformity
  - Interpretive software
  - Algorithms

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## Validation

- Biomarker – correlation with disease / dysfunction
- Analytical – correlation with reality
- Clinical – correlation with clinical outcome

## Concordance

- LDT (+/- RUO) or IUO
- ...against FDA's "gold standard"
- ...against the "market ready" version (system!)

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## Issues

- Acquisition
- Preservation
- Annotation
- Consent

## Company A

- Archived centrally
- Handled on protocol
- Fully consented
- NA recovered
- Validated LDT
- Most blocks available

## Company B

- Archived poorly
- Handled poorly
- Some consented
- NA recovered
- Multiple LDTs
- Few blocks available

## Uniformity

- Technology
- Protocol

## Harmony

- CLIA – CAP – CDRH
- RX – Dx – CDx

## Parity

- LDT - MDT