



**WORKSHOP ON BIOSPECIMEN
REFERENCE SETS AND DRUG-
DIAGNOSTIC CO-DEVELOPMENT:**

**PERSPECTIVES FROM AN INDUSTRY
PATHOLOGIST**

**Myla Lai-Goldman, MD
Personalized Science, LLC
January 21, 2011**

BACKGROUND

- Anatomic and Clinical Pathologist
- 18 years at LabCorp
- 2 years as a founder of Personalized Science, LLC
- 1 year as CEO of CancerGuide Diagnostics
- Adjunct Professor of Pathology at UNC- CH

PATHOLOGIST

- Assay quality begins with quality samples
 - Pre-analytic, Analytic and Post-analytic variables
 - Whether an assay that's already onboard, or an assay that's being developed, the quality of the sample or biospecimen is the starting point
 - Garbage in, garbage out.....

REFERENCE LABORATORY PERSPECTIVE

- In general, not basic research, but translation, test development and validation
- Both FDA-cleared and Laboratory Developed Tests
- Each new test project has a determined budget
 - Opportunity
 - Market size
 - Reimbursement
 - Requirements
 - Development
 - Regulatory
 - Sample
- Biospecimen barriers can be high
 - Disease prevalence
 - Ovarian cancer – low prevalence disease
 - Sample type
 - Paired fresh/frozen tissue and FFPE

DIAGNOSTICS CONSULTANT

- Innovation is important for the future of healthcare
- Single test or single platform start-ups
- Limited budget
- Rely on data integrity of licensed technology
- Require multiple, well-characterized sample sets for a single product

CO-DEVELOPMENT

- Depends on stage of co-development
 - May require single tumor type or multiple
- Example:
 - Tentative genomic signature
 - Investigate number of tumor types to determine which ones have the highest % of tumors with a related expression profile
 - Archival FFPE blocks of primary tumors compared to metastatic disease for the same patients to see what changes occur
 - Interested in common, as well as rare tumor types

ACADEMIC RESEARCH

- Funding to collect high quality specimens and associated data in clinical trials is a challenge
 - More funding for treatment trials ... not enough support for the correlative lab studies
 - CTEP and NCI-NIH have too little funding earmarked for assay development and validation
 - Need a funding mechanism with review groups composed of practicing molecular pathologists and other experienced laboratorians

CLOSING THOUGHTS

- Process of discovering/translating/validating new tests requires multiple validations
 - Repeat validations with independent samples
- NCI efforts are critical, but not enough
 - Remain significant barriers to translation until we do better in standardizing the collection, preservations, and storage of real-time patient samples