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Biomarkers, Companion Diagnostics and Enabling Technologies and Services for Personalized Medicine

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Biomarker/IVD Development Philosophy

- Biomarker discovery is a crucial component of the drug development process
 - Biomarker team formed at the earliest phase of drug development (initial focus PD assessment)
 - Keep the end in mind: ultimate goal is the identification and development of clinically relevant assays
- Technology agnostic
 - Match the simplest assay to the target/question
 - Protein, RNA, and DNA approaches all utilized
- Biomarker→IVD-Companion Diagnostic (CoDx)
 - Technologies continue to evolve – partner with leaders in field
 - Aim to deliver therapeutics globally, so must the IVD-CoDx

Get the Right Drug to the Right Patient at the Right Time

Current and Future State

- *Current:* Each targeted therapy has its own IVD-CoDx
- *Future:* Patient management will require multiple IVD-CoDx to determine therapy eligibility
- Each IVD-CoDx likely run on a different platform, and may not be available in same lab
- How can this diagnostic information be most efficiently delivered?
 - Use of technology(s) that encompasses multiple IVDs
 - Ongoing monitoring of disease state at molecular level
 - Starts with appropriate consent for banked tissue

What if the data already existed?

Challenges and Opportunities

- Technology improvements & increased understanding of pathobiology will transform patient treatment
- Regulatory authorities globally are increasing diagnostic requirements but value-added reimbursement is challenging
- Tests in addition to those approved will be used
- Payers - via comparative effectiveness research – will continue to monitor therapeutic efficacy claims
- Need to consider the lifecycle of the biomarker measurement (incl. the IVD-CoDx) with therapeutic
 - External Quality Assurance programs?