

Implementing a National Cancer Clinical Trials System for the 21st Century

Diagnostics Industry Perspective

Steven Shak, MD
Chief Medical Officer
Genomic Health, Inc.

Bringing Biomarkers Into Clinical Practice – Principles for Success

- Delivering what patients, physicians, regulators, and payors need
 - Most importantly, tests must be “Fit for Purpose” with evidence relevant to that specific patient population and its clinical utility
 - Consistent results across multiple well-designed studies, of varying design and purpose
 - Test must be shown to have value beyond traditional measures
- Technical innovation brought to standardized implementation
- Requires collaboration among stakeholders, people with technical and management skills, and sufficient funding to do it right

Exciting Time - Change Is Ongoing and More Change Is Urgently Needed

- Fund tumor block collection for every major study
- Across all disease groups, and for every disease group there is a need for “portfolio” strategy
- For every treatment in development there is a need for more “life-cycle planning” with a:
 - Strategy to establish effectiveness
 - Strategy to define the adverse effects
 - Strategy to obtain data on patient selection, including imaging/biomarkers/diagnostics
 - Strategy to obtain data on health economics, comparative effectiveness, and use in clinical practice
 - Strategy for funding, study management/implementation, and decision-making
- Better integrate our diagnostic and drug development efforts, informed by molecular insights, within and across our organizations