# Friends of Cancer Research: A Blueprint for Breakthrough – Charting the Course for Precision Medicine

September 2017

FOCR's annual Blueprint for Breakthrough forum focused this year on enabling the development, approval, and uptake of novel cancer diagnostics. A diverse group of stakeholders from pharma, diagnostics companies, academia, non-profits, and regulatory agencies came together to discuss the challenges and develop recommendations.

| 3 Panel Discussions: | Establishing Analytical Standards & Identifying Critical Performance Characteristics | Streamlining Modifications to Diagnostic Tests | Driving Uptake of High Quality Precision Medicine Tools |
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| **Panelists** | Dara Aisner: *UC Denver*<br>Rasika Kalamegham: *Genentech*<br>Lisa McShane: *NCI*<br>Jason Merker: *Stanford*<br>Reena Philip: *FDA*<br>Erasmus Schneider: *NY Dept of Health* | Elizabeth Mansfield: *Grail*<br>Gideon Blumenthal: *FDA*<br>Keith Flaherty: *MGH*<br>David Kaufman: *Merck* | Kate Rawson: *Prevision Policy*<br>Joseph Chin: *CMS*<br>Andrea Ferris: *Lungevity*<br>Zach Hornby: *Ignyta*<br>A. John Iafrate: *MGH*<br>Michael Pellini: *Foundation Medicine*<br>Jeffrey Shuren: *FDA* |
| **Key issue** | **Can the development of novel Dx tests be expedited by setting standards for performance/ evaluation?** | **Can the regulatory approval process be streamlined to facilitate continued refinement of Dx tests?** | **Can adoption of novel Dx tests be accelerated by overcoming economic and educational hurdles?** |
| **Proposed next steps** | • Establish standardized reference materials, e.g., isogenic cell lines<br>• FDA to host collaborative meetings to establish baseline performance standards for Dx test & labs<br>− Continue to raise bar in the future<br>• Increase transparency by publishing performance data for Dx tests & labs<br>− Outline assay risks & steps to mitigate<br>• Accredit Dx labs that meet certain standards & inspection metrics<br>− Precedents set by CAP, NY state, et al. | • Potentially eliminate need for FDA Dx approval thru accreditation process<br>• Develop expedited pathway to update Dx label (or in the future, accreditation): a "pre-specification" plan:<br>1. Company pre-specifies anticipated updates (e.g., from ongoing clinical trial)<br>2. If pre-specified results are met, a streamlined update process is enacted | • Establish comprehensive payer policy, perhaps driven by Congress<br>• Build precision med evidence base:<br>− Additional prospective trials (like MATCH) showing clinical utility of NGS over SoC genotyping<br>− Registries to collect real-world data about Dx test performance<br>− Shared NGS database generated by multiple parties; aggregated data can build the story<br>− Simplified & harmonized reporting of test results |