

Consistent Testing Terminology Use Cases Workshop

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Consistent Testing Terminology Working Group

PATIENT ADVOCACY GROUPS



PROFESSIONAL SOCIETIES



INDUSTRY PARTNERS



Use Case – Colorectal Cancer

Developed by Reese Garcia, Fight CRC

Use Case: Colorectal Cancer (CRC)

Presenter: Fight Colorectal Cancer

- The ACS predicts that there will be nearly 150,000 new cases of colorectal cancer in 2021, accounting for almost 53,000 deaths¹
- Many individuals with CRC have genomic mutations, such as KRAS, BRAF V600e, and MSI-H.
 - BRAF mutations account for approximately 10% of CRC²
 - KRAS mutations account for approximately 30-50% of CRC³
 - Microsatellite Instability- High CRC makes up about 15% of CRC cases⁴
- Most CRC tumors are sporadic (70-80%), approximately 20% are hereditary.⁴

Use Case: Colorectal Cancer

- Biomarker testing is critical to guiding treatment decisions in CRC.
 - The American Society for Clinical Pathology (ASCP), College of American Pathologists (CAP), Association for Molecular Pathology (AMP), and American Society of Clinical Oncology (ASCO) recommend biomarker testing⁵, including but not limited to:
 - Patients with CRC who are being considered for anti-epidermal growth factor receptor (EGFR) therapy must receive *RAS* mutational testing
 - *BRAF* p.V600 (*BRAF* c.1799 [p.V600]) position mutational analysis should be performed in CRC tissue in selected patients for prognostic stratification.
 - Clinicians should order mismatch repair status testing in patients with CRC to identify patients at high risk for Lynch syndrome and/or for prognostic stratification.
- Biomarker testing can also be used to determine clinical trial eligibility. For example, many CRC trials are currently investigating targeted therapy for those with MSS CRC, *BRAF* mutations, and *KRAS* mutations.
- Biomarker testing can provide prognostic value (in Stage II CRC, those with MSI-H tumors have increased overall survival, *BRAF* mutations have bad prognostic in metastatic setting)⁴

Use Case: Colorectal Cancer

- Guidelines developed by ACSP, CAP, AMP, and ASCO recommend:
 - *BRAF* p.V600 mutational analysis should be performed in deficient mismatch repair (dMMR) tumors with loss of *MLH1* to evaluate for Lynch syndrome risk. Presence of a *BRAF* mutation strongly favors a sporadic pathogenesis. The absence of *BRAF* mutation does not exclude risk of Lynch syndrome.
 - Clinicians should order mismatch repair status testing in patients with CRC to identify patients at high risk for Lynch syndrome and/or for prognostic stratification.

Use Case: Colorectal Cancer

- Fight CRC developed the Biomarked campaign in 2017 when it was clear that few resources existed for patients with CRC on biomarkers
- Focus groups were held with patient communities to determine wording, terminology, content, and look and feel
- After findings from the CTTWG were released, Fight CRC audited materials (print and web) to understand if educational resources were consistent with CTTWG's recommendations.
 - The large majority of resources utilized “biomarker testing” and “genetic testing” or “germline testing”
- In the Fall of 2021, Fight CRC will be revamping Biomarker resources and will host additional focus groups and update web and print wording to align with CTTWG recommendations.
 - i.e. update “genetic testing” to include “for an inherited cancer risk”
- Fight CRC continuously updates resources as new biomarker testing recommendations arise

Use Case: Colorectal Cancer

- Consistent testing terminology hasn't been implemented fully across the colorectal cancer space.
 - Many patients still have confusion with terms such as somatic testing, tumor testing, genetic, and germline testing.
- Continuing to implement consistent terms across various stakeholders groups, including providers, patients, patient organizations, regulatory agencies, laboratories, industry partners, and academia.
- There are still nuances in terminology across disease states
- Integrating comprehensive biomarker testing terms and the necessity of these panels into communications and materials

Use Case: Colorectal Cancer

- Leverage patient advocacy groups to introduce terms and encourage the disease type community to do the same.
- Create simple, effective communication to educate the provider and patient community on terminology, alongside the recommended testing types for each disease state, and the benefit of testing.