Consistent Testing Terminology
Use Cases Workshop

March 11, 2021
Consistent Testing Terminology Working Group

### Patient Advocacy Groups
- BE the Match
- CancerCare
- Cancer Support Community
- CLL Society
- Colorectal Cancer Alliance
- Fight Colorectal Cancer
- Force
- ICAN
- Leukemia & Lymphoma Society
- The Life Raft Group
- Lymphoma Research Foundation
- Living Beyond Breast Cancer
- Lubecan
- Lungevity
- NLCRT
- Pancreatic Cancer Action Network
- Prostate Cancer Foundation
- PMC
- OCRA
- Sharsheret
- Susan G. Komen

### Professional Societies
- ACCC
- AMP
- Advanced Practitioner Society for Hematology and Oncology
- ASCP
- National Society of Genetic Counselors
- IASLC
- International Association for the Study of Lung Cancer

### Industry Partners
- AbbVie
- Amgen
- AstraZeneca
- Bayer
- Blueprint Medicines
- Boehringer Ingelheim
- Bristol Myers Squibb
- CARIS Life Sciences
- Daiichi-Sankyo
- Elevation Oncology
- Lilly
- Foundation Medicine
- Genentech
- GSK
- Integrated Oncology
- Myriad
- Novartis
- NeoGenomics
- Pfizer
- PGDx
- Takeda
- Thermo Fisher Scientific
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 deaths\(^1\)

• Many individuals with CRC have genomic mutations, such as KRAS, BRAF V600e, and MSI-H.
  • BRAF mutations account for approximately 10% of CRC\(^2\)
  • KRAS mutations account for approximately 30-50% of CRC\(^3\)
  • Microsatellite Instability- High CRC makes up about 15% of CRC cases\(^4\)

• 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 testing\(^5\), 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\(\text{c.1799 [p.V600]}\)]) 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.