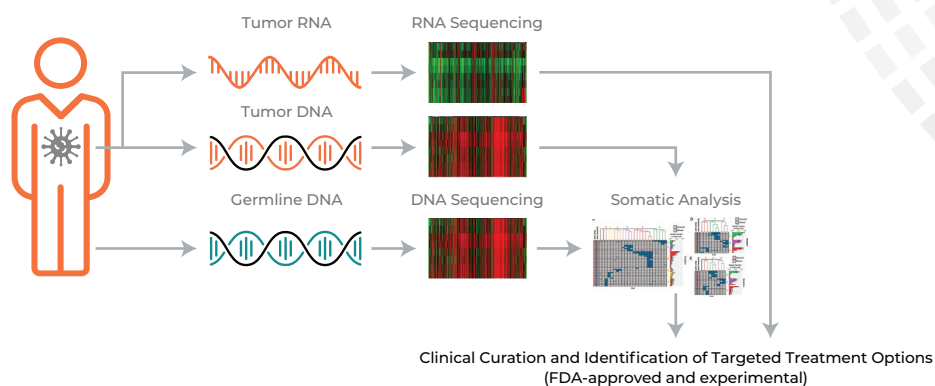


# Complete The Genomic Picture By Including DNA+RNA To Obtain The Most Actionable Insights For Therapy Selection

The OncoExTra® test is an **ultra-comprehensive genomic profiling assay** that incorporates tumor whole-exome (DNA) and whole-transcriptome\* (RNA) sequencing with paired tumor-normal analysis to identify alterations biomarkers in individuals diagnosed with advanced cancers. Findings are mapped to a knowledgebase of FDA-approved targeted treatment options as well as relevant clinical trial options.



**WES (DNA)** - Allows for comprehensive analysis of all protein-coding genes in a sample.

**WTS (RNA)** - Allows the identification of transcript variants and fusion genes that may be undetectable through conventional CGP tests which only employ DNA analysis.



## Comprehensive Without Compromise

- The OncoExTra test interrogates ~20,000 genes.<sup>3</sup>
- IO signatures including tumor mutational burden (TMB) and microsatellite instability (MSI).
- 15 optional immunohistochemistry (IHC) stains† including PD-L1 (SP142, 22C3, SP263) and MMR (Mismatch Repair) proteins.
- Patient-matched tumor-normal sample to rule out benign variants.<sup>3</sup>



## All About Actionability

- Reports clinically actionable mutations, copy number alterations, transcript variants/fusions through DNA and RNA analyses.
- FDA-approved therapies and clinical trial options based on the patient's results are also reported.
- In a clinical utilization study, at least one clinically actionable variant was identified in 83.9% of reports (1267/1509).<sup>3</sup>

According to one estimate, 20% of cancer morbidity occurs in tumors driven by translocations and gene fusions. Many of these alterations are actionable and may be missed by panel-based tests and WES alone.<sup>1,2</sup>

## Case Study: OncoExTra<sup>®</sup> detects fusion event in NSCLC

- A **64-Year-old- male** former smoker with a 50-pack year history presented to his primary physician with a 2-month history of fatigue, shortness of breath and unintentional weight loss.
- The patient previously had been offered lung cancer screening with a low dose CT scan of the chest but refused.
- A chest x-ray was ordered, and a **suspicious nodule was noted in the left lung upper lobe**. A CT of the chest demonstrated multiple nodules throughout both lungs suspicious for malignancy.
- CT guided lung biopsy **confirmed adenocarcinoma** consistent with pulmonary origin. PET/CT was completed and in addition to the lung lesions, 2 hypermetabolic hepatic lesions were also noted.
- The OncoExTra test** was performed on the biopsy. It was discovered the **patient harbored ROS1 fusion**.
- Tyrosine Kinase Therapy was initiated** and after **3 months repeat imaging demonstrated stable disease** throughout the chest and abdomen.

This case study is for educational purposes only and is not clinical, diagnostic, or treatment advice for any particular patient. Results and outcomes may vary. Providers should use their clinical judgment and experience when deciding how to diagnose or treat patients. Exact Sciences does not recommend or endorse any particular course of treatment or medical choice.

**Targetable mutations and associated therapies**

**TMB & MSI Status**

**High Interest Biomarkers**

oncoExTra<sup>®</sup>

**EXACT SCIENCES**

Report Date: MM/DD/YYYY

Patient: [Name]	Collecting Clinic: [Name]	Medical Center: [Name]	<b>Results Snapshot</b>
Sex at Birth: [Gender]	Specimen Type: [Type]	FFPE Block: [Status]	Pathway Signature: DNA/RNA-IHC Actionable Targets: 5    IHC Tested: 1 TMB Intermediate    PD-L1: See Below MSI: Stable    Clinical Trials: Yes
DOB: [Date]	Specimen Site: [Site]	Lung	
Medical Record #: [ID]	Tumor Collection Date: [Date]	MM/DD/YYYY	
Client Accession #: [ID]	Normal Collection Date: [Date]	MM/DD/YYYY	
Ordering Physician: [Name]	Sample Physician: [Name]	Received Date: [Date]	MM/DD/YYYY

Diagnosis: Lung Cancer

KEY BIOMARKERS	FDA-APPROVED DRUGS for patient's cancer <sup>†</sup>	FDA-APPROVED DRUGS for another cancer <sup>†</sup>	DRUGS PREDICTED NON-BENEFICIAL/REDUCED BENEFIT	POTENTIAL CLINICAL TRIALS
	<b>TUMOR GENOMIC ALTERATIONS</b>			
AN10A (S224P*)				Yes
CD74ROS1 (Fusion)	crizotinib, entrectinib	cabozantinib, cefitinib, lorlatinib		Yes
NF1 (C609*)		bravonitinib, everolimus, temozolomide, trametinib		Yes
TSP3 (H95T)				Yes
<b>TUMOR MUTATION BURDEN (TMB)</b>				
INTERMEDIATE (8.7mut/Mb)				No
<b>MICROSATELLITE STATUS (MSI)</b>				
STABLE				No
<b>IHC RESULTS</b>				
PD-L1 (22C3): Low	atezolizumab, durvalumab, nivolumab, nivolumab + ipilimumab, pembrolizumab	dostarlimab-gly		

**HIGH INTEREST BIOMARKERS**

As part of the OncoExTra test, key biomarkers relevant to the patient's tumor type have been assessed: NTRK1, NTRK2, NTRK3, BCL2, BRCA1, ALK, EGFR, ERBB2, KRAS, MEK, ROS1, PD-L1. If clinically pertinent events in these biomarkers have been identified, the biomarker(s) will appear within the 'Key Biomarker Findings' section of the report. If biomarkers from this list do not appear, clinically pertinent events have not been identified or fell outside of the OncoExTra reporting thresholds (please see Disclaimer Limitations information).

<sup>†</sup>The prescribing information for the FDA-approved therapeutic option may not include the associated Key Biomarker.

**Snapshot of Key Findings**

**Clinical Trial Options**

**IHC Results<sup>†</sup>**

To Learn More: [OncoExTra.com](https://OncoExTra.com) | To Order: [OncoExTra.com/order](https://OncoExTra.com/order)



**References:** 1. Drenner, Basu CD, Goodman LJ, et al. The value of comprehensive genomic sequencing to maximize the identification of clinically actionable alterations in advanced cancer patients: a case series. *Oncotarget*. 2021; 12:1836-1847. 2. Nikanjam M, Okamura R, Barkauskas DA, Kurzrock R. Targeting fusions for improved outcomes in oncology treatment. *Cancer*. 2020;126:1315-1321. 3. White T, Szelinger S, LoBello J, et al. Analytic validation and clinical utilization of the comprehensive genomic profiling test, Oncotarget 2021;12: 726-739

**Disclaimer:** The OncoExTra test is not a FDA cleared or approved IVD device or companion diagnostic for the referenced biomarkers and FDA approved therapies.

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OncoExTra has been validated according to the guidelines set forth by the New York State Department of Health. Whole exome (DNA) events have been validated to include point mutations, indels, and copy number alterations, as well as MSI analysis and TMB calculation. Whole transcriptome (RNA) has been validated to report on select fusion genes and special transcripts.

<sup>†</sup>IHC testing not currently available in New York State

OncoExTra is a registered trademark of Genomic Health, Inc., a wholly-owned subsidiary of Exact Sciences Corporation. Exact Sciences is a registered trademark of Exact Sciences Corporation.