Clinico-Genomic Data

From Memorial Sloan Kettering Cancer Center

When patients look to you for answers, look to us for insights. Solving today's most complex health challenges starts with putting the right data insights in the hands of the right people. At Memorial Sloan Kettering Cancer Center (MSK), we are leading the field of specialty oncology data and insights.

MSK's robust data combines de-identified longitudinal clinical information and genomic data from MSK's comprehensive genomic profiling tests for both solid tumors and hematologic malignancies.

MSK CLINICO-GENOMIC DATA IN BRIEF:

- Structured genomic records from 56,500+ consented* cases, with an additional ~1,150 consented* cases tested each month, including basic clinical annotation
- Comprises all prevalent cancer types, as well as rare cancers
- Clinically relevant and actionable biomarkers represented
- Includes somatic and germline results from matched tumor-normal sequencing

- Planned integration with clinical outcomes and drug response
- Near real-time updates with greater clinical and genomic detail than publicly available
- This data has been used to power 900 clinical trials at MSK, where our record of regulatory success includes 11 FDA-approved therapies based upon MSK innovation.

*Patients have consented to their data being used in research

Memorial Sloan Kettering Cancer Center

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BUILT ON MSK'S SEQUENCING AND ASSAY DEVELOPMENT EXPERTISE:

- MSK-IMPACT®: Solid tumor Comprehensive Genomic Profiling (CGP) test, run on >50,000 MSK consented* cases to date (latest test version run on 505 genes)
- MSK-IMPACT®-Heme: An IMPACT test for Hematologic malignancies run on >5,000 MSK consented* cases to date (latest version run on 468 leukemia & lymphoma genes)
- MSK-ACCESS℠: Liquid biopsy test of 129 genes, run on almost 4,000 MSK consented* cases since launch in 2019

All assays involve paired tumor/normal sequencing to distinguish somatic mutations from inherited variants and clonal hematopoiesis.

MSK DE-IDENTIFIED CLINICO-GENOMIC DATA:

CLINICAL DATA*

- Cancer type and primary tumor site
- Sample type (primary, metastasis, or cell-free DNA)
- Demographics (where not-identifiable) — self-reported ethnicity, race, sex, age
- Survival status and time since sequencing
- Additional clinical elements depending on tumor type

  *Additional data fields may be available for curation

GENOMIC DATA

- Somatic mutations, including silent and off-target variants, and variant allele frequencies
- Rearrangements/fusions in select genes
- Gene level, copy number calls (amplifications and deletions), and genome-wide segmented copy number
- Tumor mutation burden and microsatellite instability status
- Germline (pathogenic) variants for cancer predisposition genes

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PROVIDING VALUABLE INSIGHTS FOR RESEARCH PURPOSES ACROSS MULTIPLE CANCER SUBSPECIALTIES — EXAMPLES INCLUDE:

Select Cancer Types	Case Counts*
Non-Small Cell Lung Cancer	6,693
Breast Cancer	6,255
Colorectal Cancer	4,589
Prostate Cancer	3,375
Pancreatic Cancer	3,350
Endometrial Cancer	2,652
Soft Tissue Sarcoma	2,359
Ovarian Cancer	2,266
Bladder Cancer	2,186
Mature B-Cell Neoplasms	2,161
Glioma	2,155
Melanoma	2,018
Esophagogastric Cancer	1,853
Cancer of Unknown Primary	1,745
Hepatobiliary Cancer	1,520
Renal Cell Carcinoma	1,215

*Case counts as of March 24, 2022

CANCER RESEARCH EXAMPLES INCLUDE:

- Identify high-value biomarker targets
- Prioritize and validate targets
- Expand clinical indications for therapies
- Optimize clinical trial design
- Identify markers relevant for companion diagnostics
- Develop synthetic clinical trial control arms

WHY PARTNER WITH MSK:

- Single-sourced data from leading cancer-focused institution
- Longitudinal, de-identified clinical data
- Expansive population of consented* cases
- Linked genomic data from various platforms, time horizons, samples
- Inclusive of rare cancer types
- Ability to provide data for custom use cases and solutions
- Potential to include OncoKB℠** and/or hotspot annotations

  **A portion of MSK's Oncology Knowledge Base (OncoKB℠) has been recognized by the FDA as a source of valid scientific evidence for level 2 (clinical significance) and level 3 (potential clinical significance) biomarkers. Under the FDA's database recognition program, test developers can use these data to support the clinical validity of tumor-profiling tests in premarket submissions.