CLINICAL PATHWAYS CONGRESS

CANCER CARE BUSINESS EXCHANGE

September 5–6, 2025
Westin Copley Place
Boston, MA

OFFICIAL CONGRESS PARTNER

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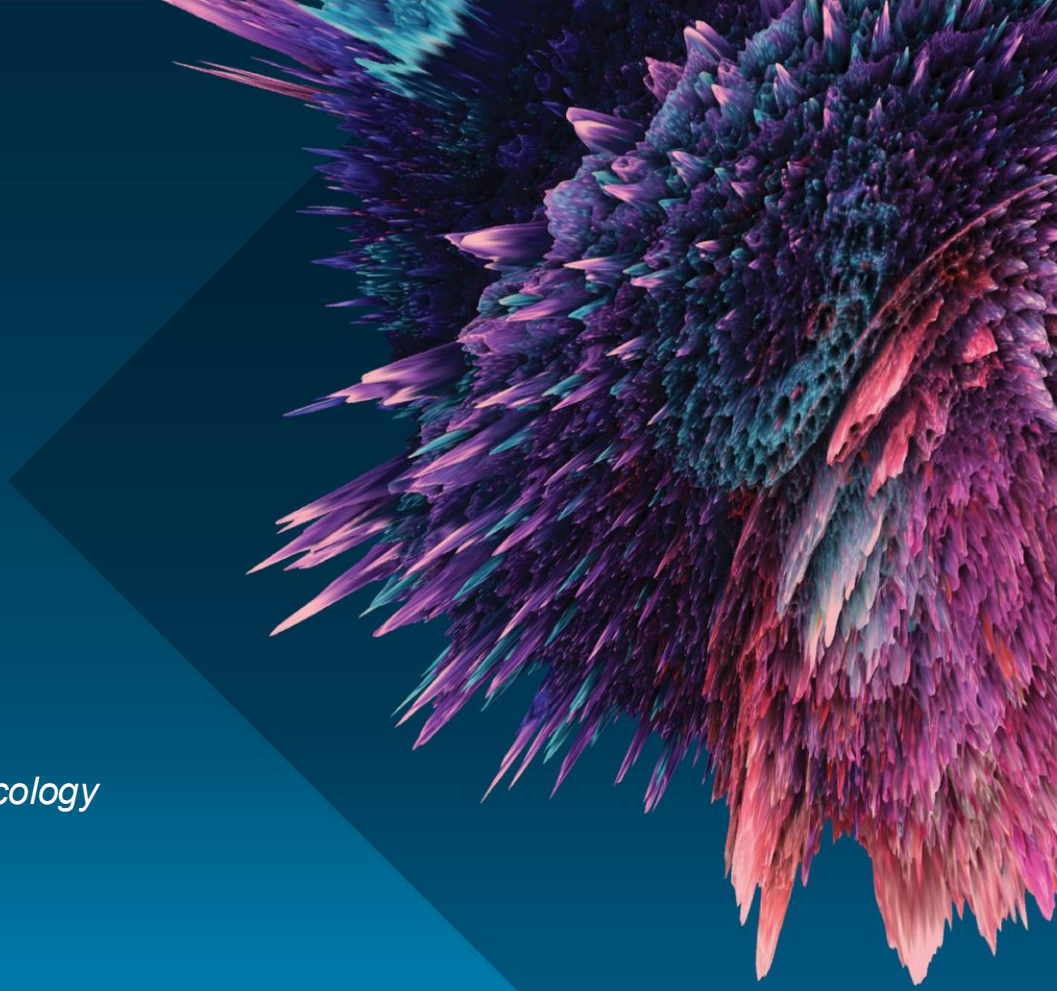
Optimizing Solid Tumor Care: The Role of Biomarkers in Clinical Pathways

Manish A. Shah, MD FASCO

Bartlett Family Professor of Gastrointestinal Oncology
Chief, Solid Tumor Program
New York-Presbyterian/ Weill Cornell Medicine



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Disclosures

- **Manish A. Shah, MD FASCO:** Consultant – JAZZ Pharmaceutical, Revolution Medicine; research/grant support – Bristol Meyers Squibb, MERCK, Oncolys Biopharma

Learning Objectives

- Describe evolving evidence-based guidelines for comprehensive biomarker testing across solid tumors and their implications for precision oncology and clinical pathways
- Integrate genetic testing, pathology, biomarkers (diagnostic, prognostic, predictive), and imaging into multidisciplinary care pathways for solid tumors—prioritizing accessibility across all practice settings, especially in community and rural areas
- Foster multidisciplinary collaboration to standardize biomarker use in clinical pathways throughout all stages of disease, ensuring equitable access and personalized treatment strategies in patients diagnosed with solid tumors

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The Role of Biomarkers and Precision Medicine in Solid Tumor Care

Case Study

- A 42-year-old woman with an undifferentiated pleomorphic sarcoma presents for consultation
- She is a banker, but hasn't worked for the past 6 months
- She has shortness of breath, and progressive weakness
- Her prior treatment has been
  - (1) Epirubicin, isofosfamide, and doxorubicin, and
  - (2) Sorafenib

Case Study

- You review her records and order imaging
- It shows her lungs are nearly replaced with large bilobar lung lesions

Case Study

- You review her records and order imaging
- It shows her lungs are nearly replaced with large bilobar lung lesions
- She is referred to precision oncology and undergoes tumor sequencing
  - What are the platforms?
  - What are you looking for?

Case Study

- Tumor sequencing reveals a LMNA-NTRK1 fusion!
- Why is this biomarker important?

Overview of Biomarker-Directed Therapy

- Precision medicine has rapidly evolved over the last 25 years
- Over 100 FDA-approved drugs require biomarker testing
- Understanding biomarker testing platforms and limitations is critical to appropriate application of novel therapeutics
- Prognostic vs predictive?
  - Are they mutually exclusive?

FDA = Food and Drug Administration.

Prognostic vs Predictive

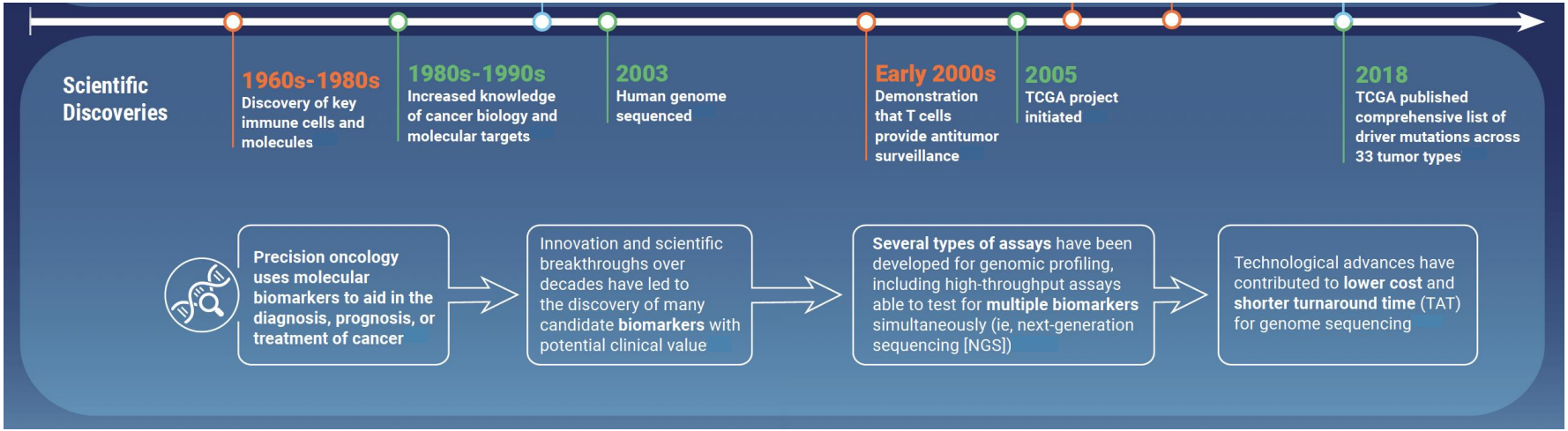
- Prognostic biomarker → disease related
  - Course of the disease irrespective of the treatment
  - Liver cancers with a high AFP → poor survival

- Predictive biomarker → drug related
  - Tells you the likelihood of a treatment working
  - Trastuzumab works better in tumors that are HER2 IHC 3+

AFP = alpha-fetoprotein; IHC = immunohistochemistry.

FDA-NIH Biomarker Working Group. BEST (Biomarkers, EndpointS, and other Tools) Resource [Internet]. Accessed September 2, 2025. https://www.ncbi.nlm.nih.gov/books/NBK402284/.

Progress in Precision Oncology Has Accelerated!

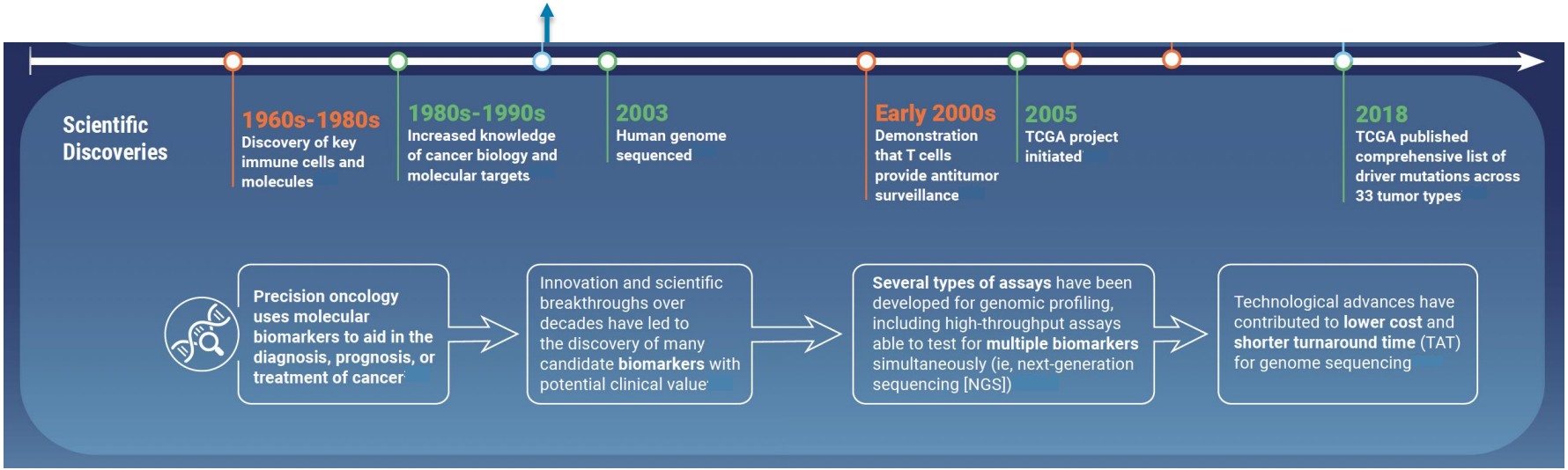


TCGA = The Cancer Genome Atlas Project.
Precision Medicine. *Molecular Diagnostics in Personalized Cancer Care.* Novartis; 2022.

Progress in Precision Oncology Has Accelerated!

But it is not a new concept

Trastuzumab approved for BC in 1998



BC = breast cancer.

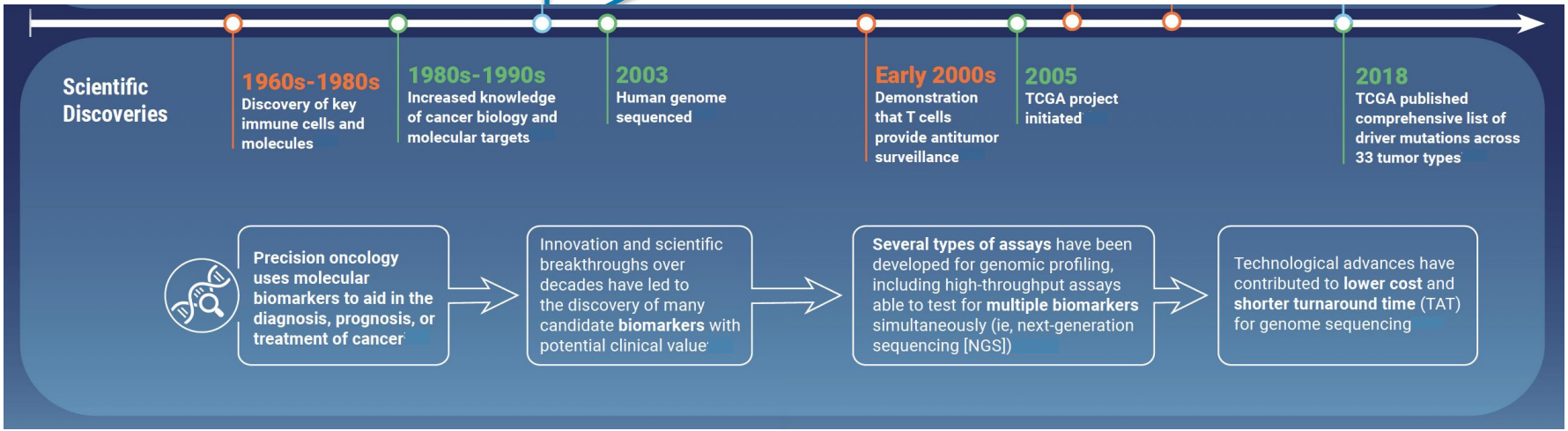
Dawood S, et al. *J Clin Oncol*. 2010;28(1):92-98. Precision Medicine. *Molecular Diagnostics in Personalized Cancer Care.* Novartis; 2022.

Progress in Precision Oncology Has Accelerated!

But it is not a new concept

Trastuzumab approved for BC in 1998

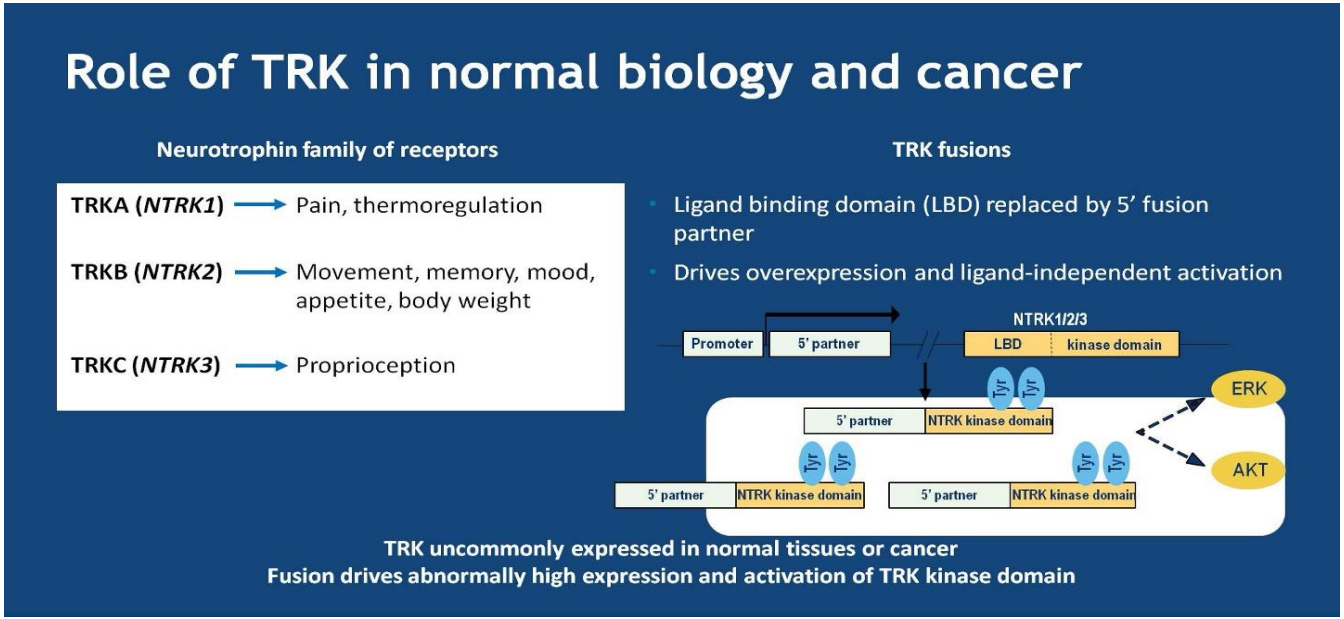
Imatinib approved for GIST in 2002



GIST = gastrointestinal stromal tumor.

Dagher R, et al. *Clin Cancer Res.* 2002;8(10):3034-3038. Precision Medicine. *Molecular Diagnostics in Personalized Cancer Care.* Novartis; 2022.

NTRK Fusions: One of the Few Tissue Agnostic Targets in Precision Oncology



TRK = tropomyosin receptor kinase.
Cocco E, et al. *Nat Rev Clin Oncol*. 2018;15(12):731-747.

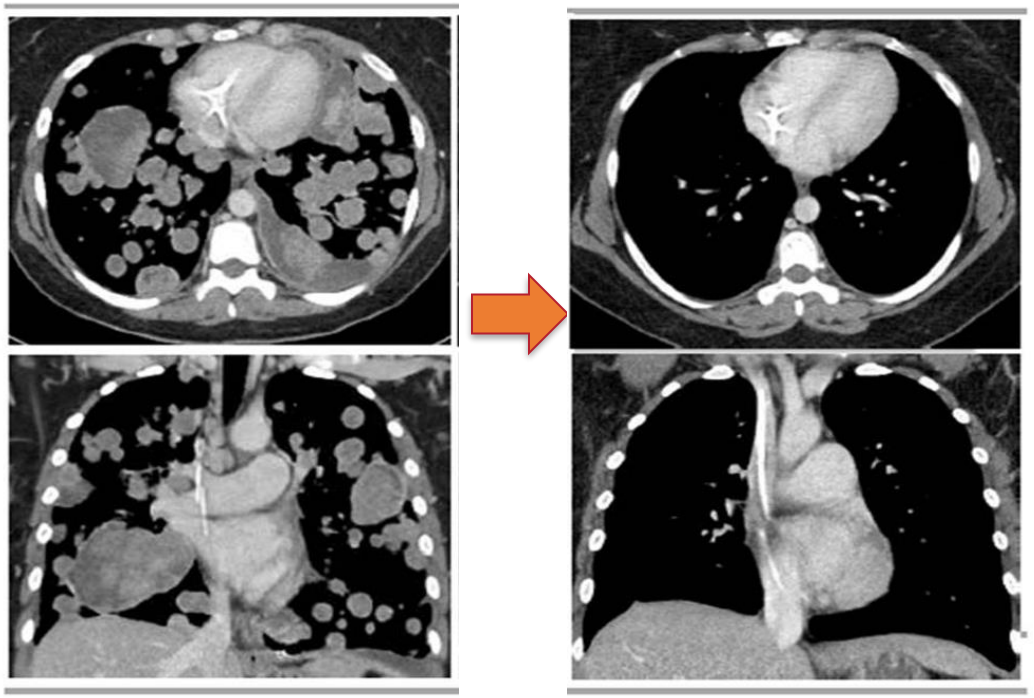
Targeting NTRK

- Larotrectinib
  - Approved in 2018 for adult and pediatric patients with solid tumors that harbor an NTRK gene fusion
  - Initial study of 55 patients
    - Objective response rate of 75%
- Entrectinib
  - Approved in 2019 for adult and pediatric patients above the age of 12 with solid tumors that harbor an NTRK fusion
  - Initial study of 54 patients
    - Objective response rate of 57%

Hagopian G, Nagasaka M. *Crit Rev Oncol Hematol*. 2024;194:104234.

Case Study

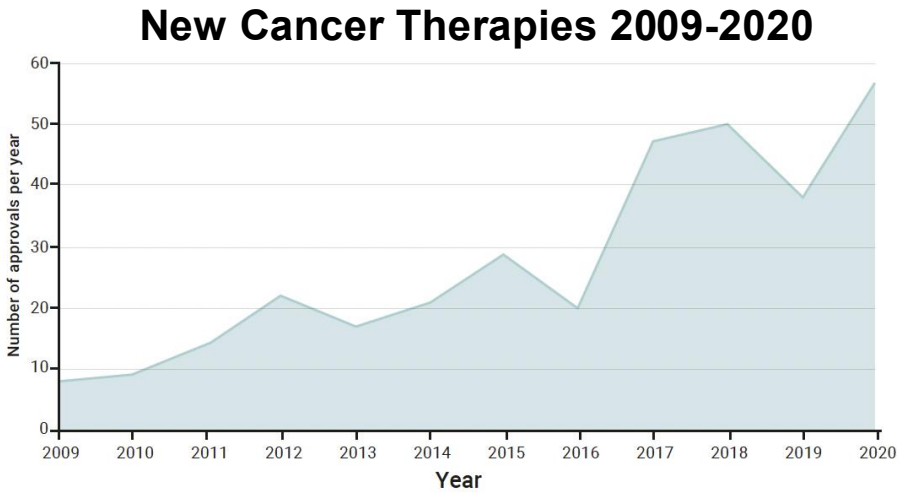
- Tumor sequencing reveals a LMNA-NTRK1 fusion!
- Why is this biomarker important?
- The patient received larotrectinib. 6 months later, you see the improvement in her lung metastases



Precision Medicine

- Initial successes in the late 1990s and early 2000s
  - … *it's relatively new*
- There has been a revolution in sequencing technology
- More and more drugs are available based on biomarkers discovered in the lab
- Successfully targeting a biomarker with precision oncology can change someone's life

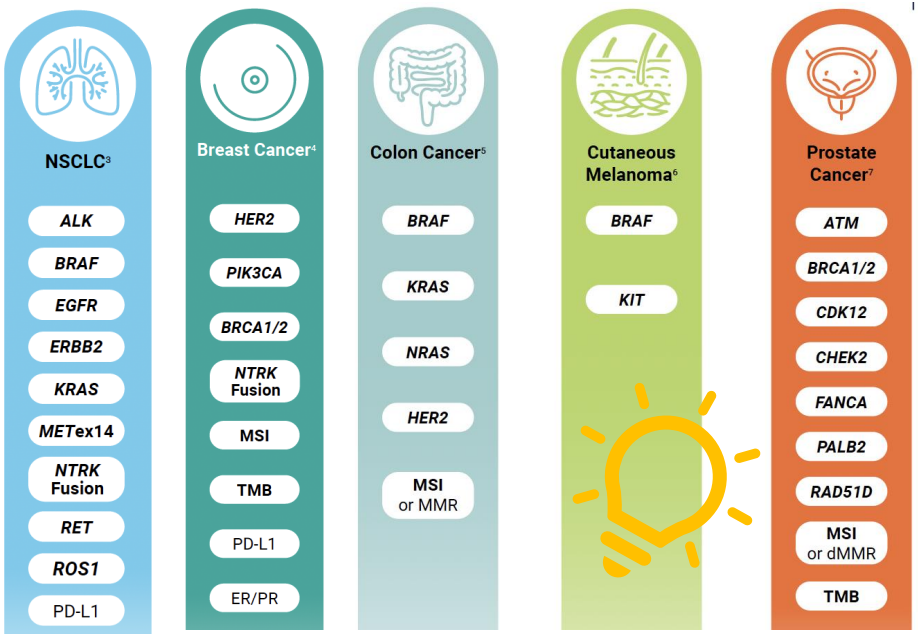
Accelerated Development of Precision Medicine



- Of the 332 approvals
  - >70 require biomarker testing
  - Over 28 cancer types

Olivier T, et al. *JAMA Netw Open*. 2021;4(12):e2138793. Chakravarty D, et al. *J Clin Oncol*. 2022;40(11):1231-1258.

Tumor-Specific Targets



NSCLC = non-small cell lung cancer.

Chakravarty D, et al. *J Clin Oncol*. 2022;40(11):1231-1258. Siegel RL, et al. *CA Cancer J Clin*. 2023;73(1):17-48.

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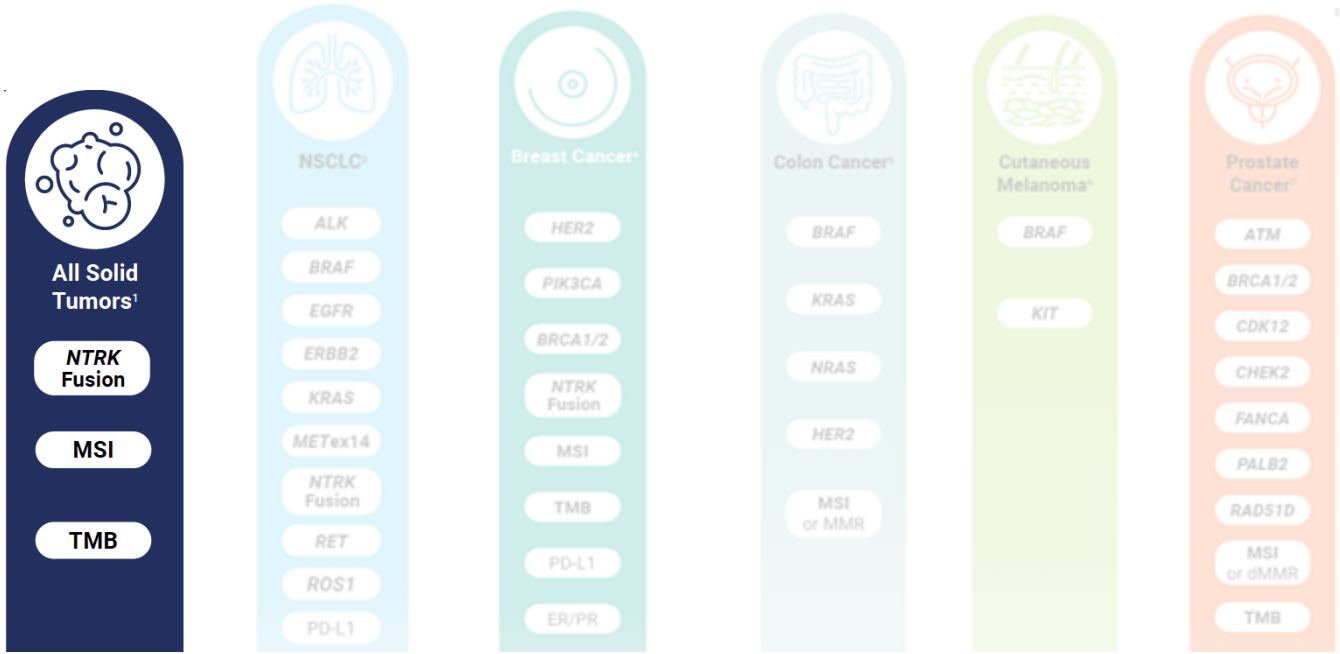
Tumor-Agnostic Targets



MSI = microsatellite instability-high; TMB = tumor mutation burden.

Chakravarty D, et al. *J Clin Oncol*. 2022;40(11):1231-1258. Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.4.2025, NSCLC V.8.2025, Colon Cancer V.4.2025, Prostate Cancer V.2.2025, Melanoma: Cutaneous V.2.2025, © National Comprehensive Cancer Network, Inc.2025. All rights reserved. Accessed August 18, 2025. To view the most recent and complete version of the guidelines, go online to NCCN.org.

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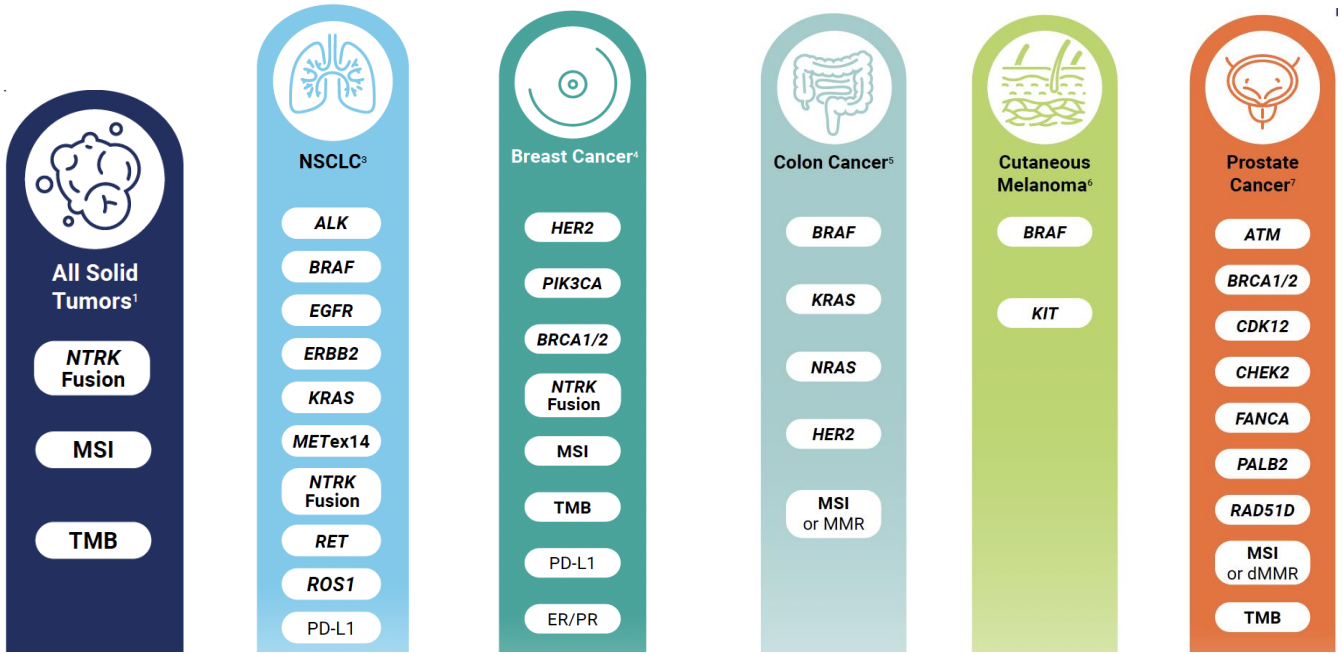
NCCN Guidelines: Understanding Biomarkers Critical across Solid Tumors



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Growing Number of Guideline-Recommended Biomarkers in Multiple Cancer Types

Cancer Type	Targetable Alterations																							
	EGFR mt	*ALK fusion*	*ROS1 fusion*	*BRAF mt*	*ERBB2 (HER2) amp*	*ERBB2 (HER2) mt*	*RET fusion*	*RET mt*	*MET amp & ex 14 skip*	*NTRK fusion*	*MSI high*	*BRCA1/2 g*	*BRCA1/2 somatic*	*KRAS mt exons 2,3,4*	*NRAS mt exons 2,3,4*	*NRAS mt*	*PIK3CA mt*	*KIT mt*	*PALB2*	*NRG1^*	*PDGFRA mt*	*FGFR3 mt*	*FGFR2/3 fusions*	*AR mt*	*IDH1 mt*
NSCLC†	✓	✓	✓	✓	✓	✓	✓		✓	✓				✓											
Colorectal†				✓	✓					✓	✓			✓	✓										
Breast†					✓					✓	✓	✓					✓								
Pancreatic†		✓	✓	✓		✓				✓	✓	✓	✓	✓					✓	✓					
Prostate†											✓	✓	✓						✓						
Ovarian										✓	✓	✓	✓												
Endometrial					✓					✓	✓														
Esophageal Esophagogastric†					✓					✓	✓														
Gastric†					✓					✓	✓														
Cervical										✓	✓														
Cholangiocarcinoma				✓						✓	✓												✓		✓
Melanoma†		✓	✓	✓						✓						✓		✓							
GIST				✓						✓											✓				
Head & Neck					✓					✓														✓	
Bladder																						✓	✓		
Thyroid				✓				✓		✓															
Small bowel										✓	✓														

- ASCO recommendation as of February 2022
  - Multigene panel–based genomic testing should be used whenever more than one genomic biomarker is linked to a regulatory agency–approved therapy
- †NCCN guidelines suggest that liquid biopsy may be considered for these cancer types under certain conditions, such as when patients are unable to undergo a traditional biopsy or tissue is insufficient for complete testing, upon relapse or progression depending

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FDA Targeted Therapy Approvals: Immunotherapy (July 2024 – June 2025)

Target	Drug	Disease Indication (succinct)	Year
PD-1	Dostarlimab-gxly	Primary advanced or recurrent endometrial cancer with chemotherapy (1L)	2024
PD-1	Pembrolizumab + pemetrexed + platinum chemotherapy	Metastatic malignant pleural mesothelioma (1L)	2024
PD-1 + CTLA-4	Nivolumab + ipilimumab	Metastatic hepatocellular carcinoma (1L)	2025
PD-1	Penpulimab-kcqx	Recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (1L)	2025
PD-1	Retifanlimab-dlwr ± carboplatin + paclitaxel	Squamous cell carcinoma of the anal canal (1L combo; single agent after platinum)	2025
PD-1	Pembrolizumab (perioperative regimen)	Neoadjuvant + adjuvant therapy for resectable HNSCC (PD-L1 positive)	2025

HNSCC = head and neck squamous cell carcinoma.

Drugs@FDA: FDA-Approved Drugs. Accessed August 18, 2025. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-expands-endometrial-cancer-indication-dostarlimab-gxly-chemotherapy; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nivolumab-ipilimumab-unresectable-or-metastatic-hepatocellular-carcinoma; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-penpulimab-kcqx-non-keratinizing-nasopharyngeal-carcinoma; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-retifanlimab-dlwr-carboplatin-and-paclitaxel-and-single-agent-squamous-cell-carcinoma; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-darolutamide-metastatic-castration-sensitive-prostate-cancer.

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FDA Targeted Therapy Approvals: TKIs/ ADCs (July 2024 – June 2025)

Target	Drug	Disease Indication (succinct)	Year
EGFR/MET (bispecific)	Amivantamab-vmjw + carboplatin + pemetrexed	Metastatic NSCLC with EGFR exon 19 del or L858R after EGFR TKI	2024
EGFR	Osimertinib	Unresectable stage III EGFRm NSCLC following chemoradiation (no progression)	2024
RET	Selpercatinib	Advanced/metastatic medullary thyroid cancer with RET mutation (adult & pediatric ≥2y)	2024
PI3Kα	Inavolisib + palbociclib + fulvestrant	Endocrine-resistant, PIK3CA-mutated HR+, HER2– locally advanced or metastatic breast cancer	2024
CLDN18.2	Zolbetuximab-clzb + fluoropyrimidine + platinum	First-line HER2–, CLDN18.2+ gastric/GEJ adenocarcinoma	2024

TKI = tyrosine kinase inhibitor; ADC = antibody–drug conjugates.

FDA. Accessed August 18, 2025. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-amivantamab-vmjw-carboplatin-and-pemetrexed-non-small-cell-lung-cancer-egfr-exon-19; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-osimertinib-locally-advanced-unresectable-stage-iii-non-small-cell-lung-cancer; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-selpercatinib-medullary-thyroid-cancer-ret-mutation; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-inavolisib-palbociclib-and-fulvestrant-endocrine-resistant-pik3ca-mutated-hr-positive; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-zolbetuximab-clzb-chemotherapy-gastric-or-gastroesophageal-junction-adenocarcinoma

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FDA Targeted Therapy Approvals: TKIs/ ADCs (July 2024 – June 2025)

Target	Drug	Disease Indication (succinct)	Year
KRAS G12C + EGFR	Sotorasib + panitumumab	KRAS G12C-mutated metastatic colorectal cancer after prior therapy	2025
RAF/MEK clamp + FAK inhibitor	Avutometinib + defactinib	KRAS-mutated recurrent low-grade serous ovarian cancer after prior therapy (accelerated)	2025
c-Met (ADC)	Telisotuzumab vedotin-tllv	NSCLC, non-squamous with high c-Met protein overexpression (after prior systemic therapy)	2025
HIF-2α	Belzutifan	Pheochromocytoma or paraganglioma (≥12y), unresectable, locally advanced or metastatic	2025
ROS1	Taletrectinib	Locally advanced or metastatic ROS1-positive NSCLC (adults)	2025

FDA. Accessed August 18, 2025. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-sotorasib-panitumumab-kras-g12c-mutated-colorectal-cancer; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-combination-avutometinib-and-defactinib-kras-mutated-recurrent-low; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-telisotuzumab-vedotin-tllv-nsclc-high-c-met-protein-overexpression; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-belzutifan-pheochromocytoma-or-paraganglioma; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-taletrectinib-ros1-positive-non-small-cell-lung-cancer

Key Learning Points

- Biomarkers can be prognostic (ie. good vs bad outcome)
- Biomarkers can be predictive (ie. selection for drug) – this is the main topic today

- Biomarker testing for precision oncology is still relatively new
- Pace of drug development based on biomarkers is nearly exponential
- It will be nearly impossible for keep up and provide state-of-the-art care

- NCCN: Liquid biopsy is an option for certain cancer types if patient unable to undergo a traditional biopsy or tissue is insufficient for complete testing
- ASCO: Multigene panel-based genomic testing is suggested if more than one genomic biomarker is linked to an agency-approved therapy

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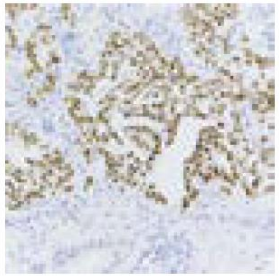
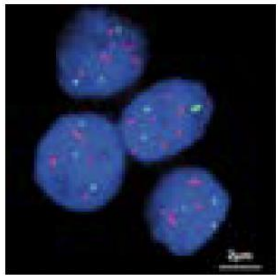
Biomarker Testing Methods

Precision Oncology Methods

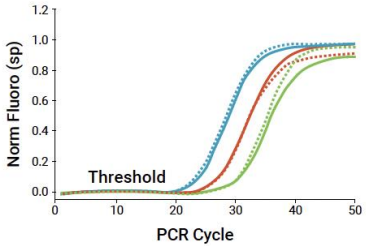
IHC



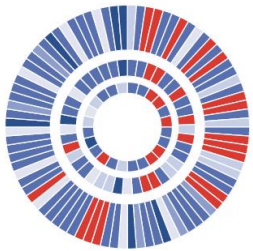
FISH



RT-PCR



NGS

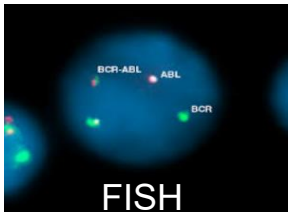


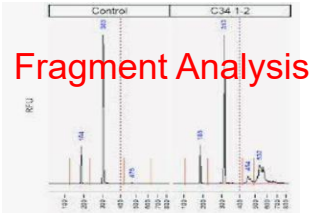
- Biomarker testing
  - No one platform is perfect for every test
  - Knowledge of the limits and expectations of the different platforms is critical

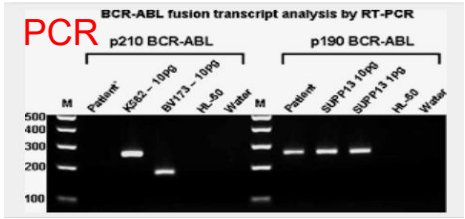
FISH = fluorescence in situ hybridization; RT-PCR = reverse transcription-polymerase chain reaction; NGS = next-generation sequencing.
Chakravarty D, et al. *J Clin Oncol*. 2022;40(11):1231-1258

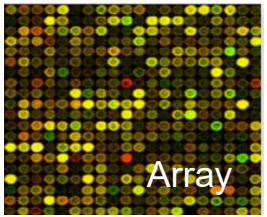
Biomarker Testing Techniques in NSCLC

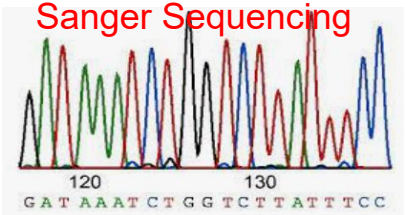
	ACTIONABLE BIOMARKERS									EMERGING BIOMARKERS		
	EGFR	*ALK*	*ROS1*	*BRAF*	*RET*	*NTRK 1/2/3*	*MET*ex14	*KRAS*	PD-L1	TMB	*MET*amp	HER2
NCCN Recommended	PCR NGS	FISH IHC NGS	FISH IHC NGS	PCR NGS	FISH IHC NGS	FISH IHC NGS	NGS	PCR NGS	IHC	NGS	FISH NGS	PCR NGS











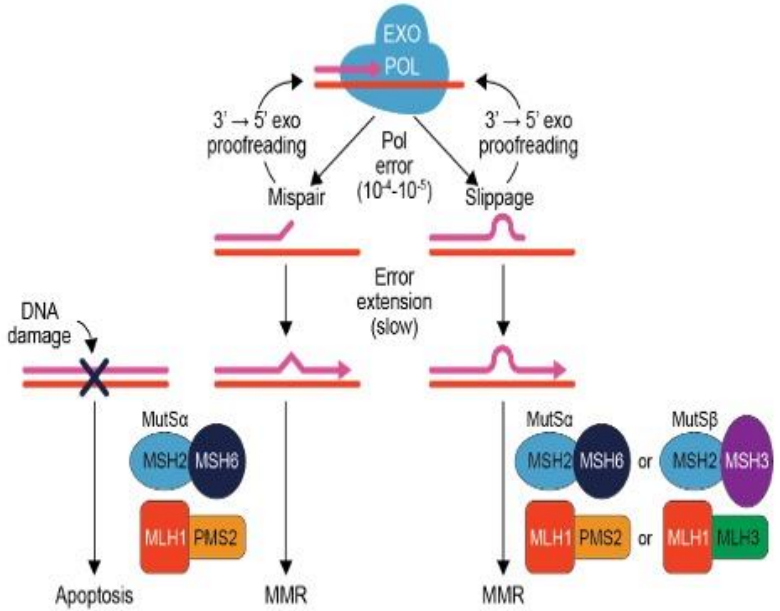
Mitsudomi T, et al. *J Thorac Oncol*. 2023;18(4):436-446.

Biomarker Testing

- Some biomarkers can have multiple testing strategies
- For example,
  - *ALK*, *ROS*, *EGFR* (for lung cancer) → NGS sequencing, FISH, IHC
  - Mismatch repair for immunotherapy → IHC, PCR

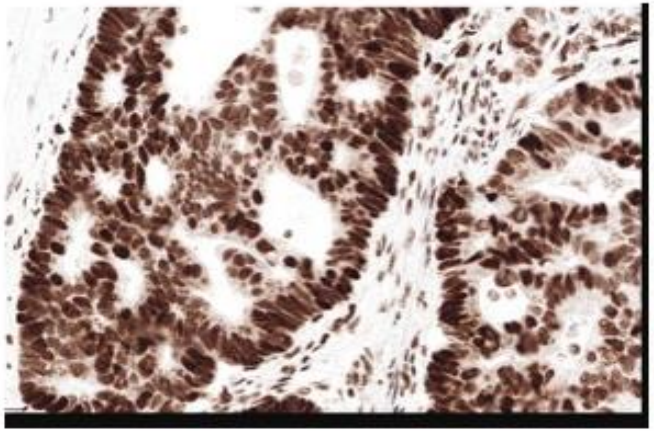
EGFR = epidermal growth factor receptor.

Mismatch Repair: A Biomarker for Immunotherapy

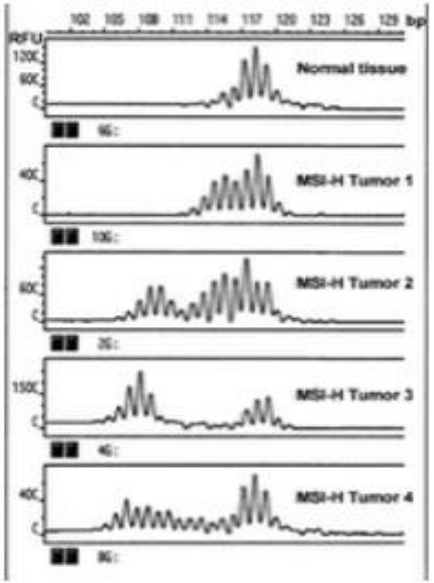


Mismatch Repair Testing Strategies

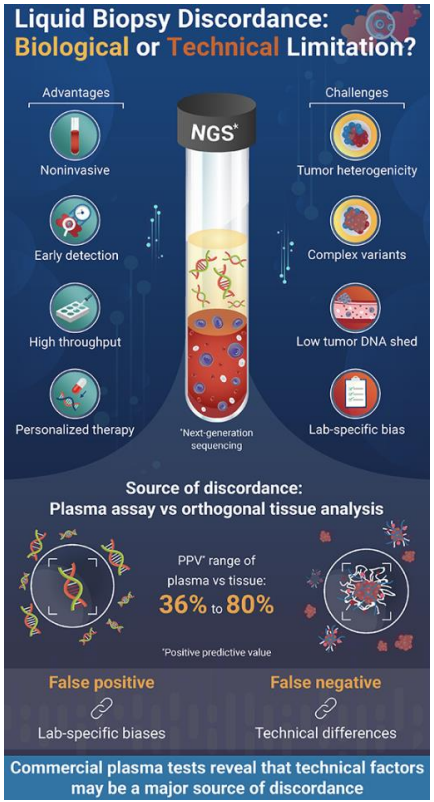
Immunohistochemistry



Microsatellite Instability



Vikas P, et al. *J Clin Oncol*. 2023;41(10):1943-1948. Dietmaier W, Hofstädter F. *Lab Invest*. 2001;81(10):1453-1456.



Liquid Biopsy

- Identify circulating tumor DNA
  - Tumor specific mutations
  - Tumor heterogeneity
  - Both prognostic and predictive
- Identify circulating tumor cells
  - Prognostic for survival (breast, colon, prostate)
  - Predictive of response (ER resistance, breast)
  - Predictive of response (AR, prostate)

- False positives/ negatives?
- Tumor shedding varies

ER = estrogen receptor; AR = androgen receptor.
Paweletz CP, et al. *JCO Precis Oncol*. 2019;3:1-3.

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Integrating/Refining Biomarker Testing in Clinical Pathways

Biomarker Testing: Multistep Process

Patient's genome

Sample (i.e., biomarker)

Genome sequencing/ testing (i.e., NGS)

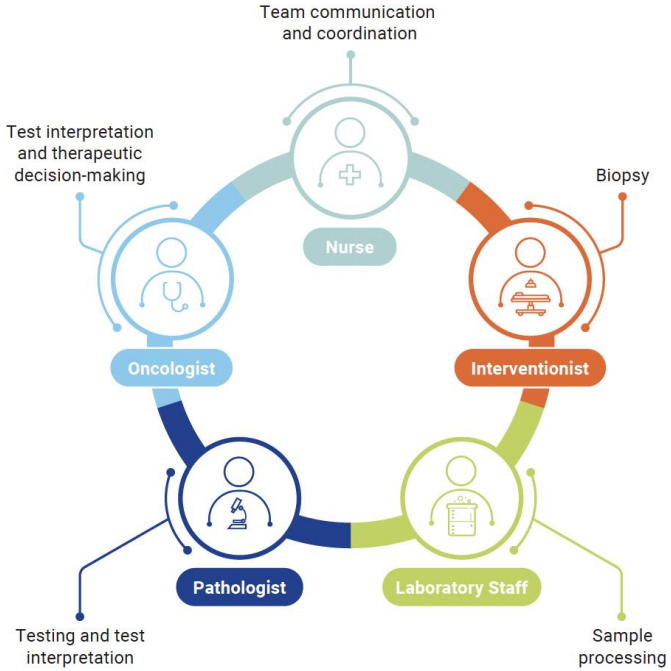
Genome analysis

Pharmacogenetic interpretation

Precision medicine application (diagnostic, treatment, prediction, prevention)

Biomarker Testing: Multistep Process

- Not as simple as ordering a blood test
- Requires a team
- Need to understand what tissue/ how much/ what type of biopsy, etc.



Economic Considerations

- Costs are expected to increase exponentially!
- Precision oncology means that we select the right drug for the right target
- Most targets are rare – so few patients will receive the drug

Economic Considerations

- Costs are expected to increase exponentially!

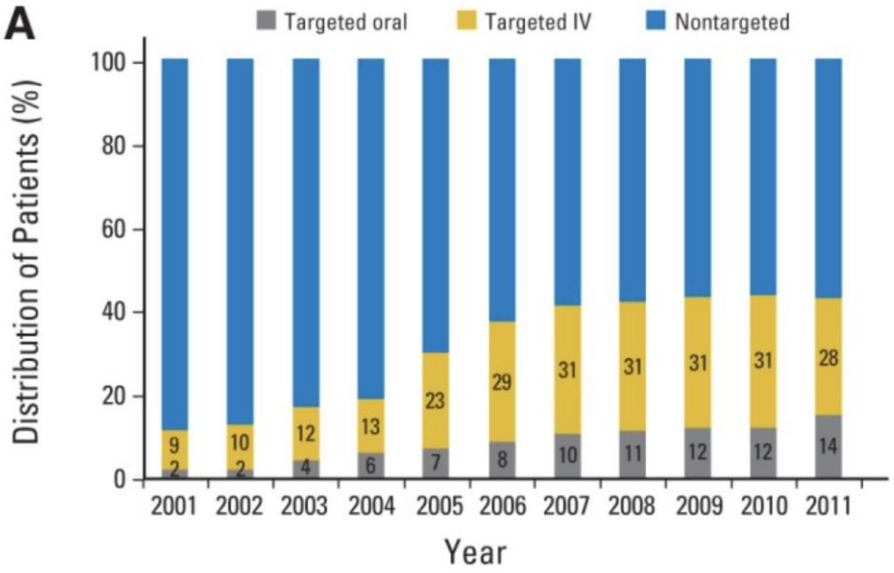
- Drug development costs increase
  - Biomarker validation
  - Increasingly rare population
  - Longer time to identify and enroll patients

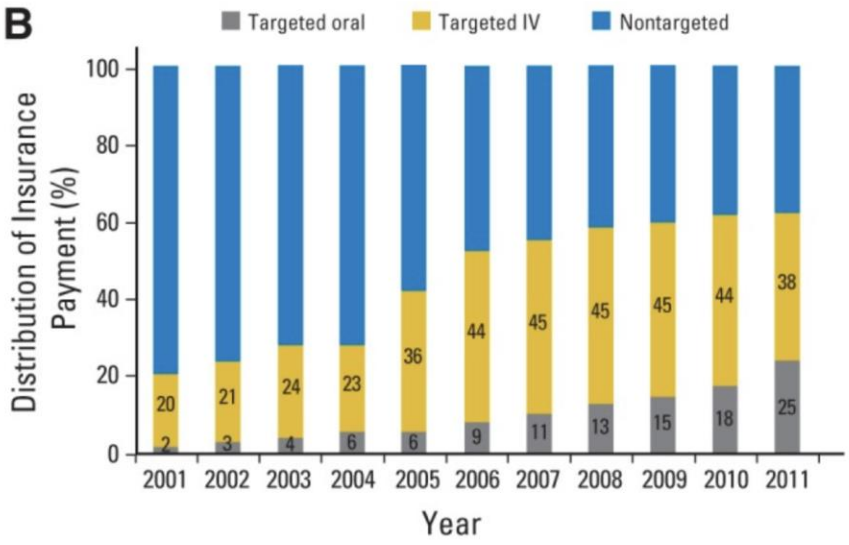
  - Approvals require companion diagnostic testing

  - Assay validation and incorporation across pathology labs

Economic Considerations

- Costs of targeted therapy disproportionately increase





Shih YC, et al. *J Clin Oncol*. 2015;33(19):2190-2196.

Case Study: HER2 Targeted Therapy

- Trastuzumab was approved in 1998 for the treatment of HER2 positive breast cancer

Dawood S, et al. *J Clin Oncol*. 2010;28(1):92-98.

Case Study: HER2 Targeted Therapy

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Bang YJ, et al. *Lancet*. 2010;376(9742):687-697. Dawood S, et al. *J Clin Oncol*. 2010;28(1):92-98.

Case Study: HER2 Targeted Therapy

- Trastuzumab was approved in 1998 for the treatment of HER2 positive breast cancer

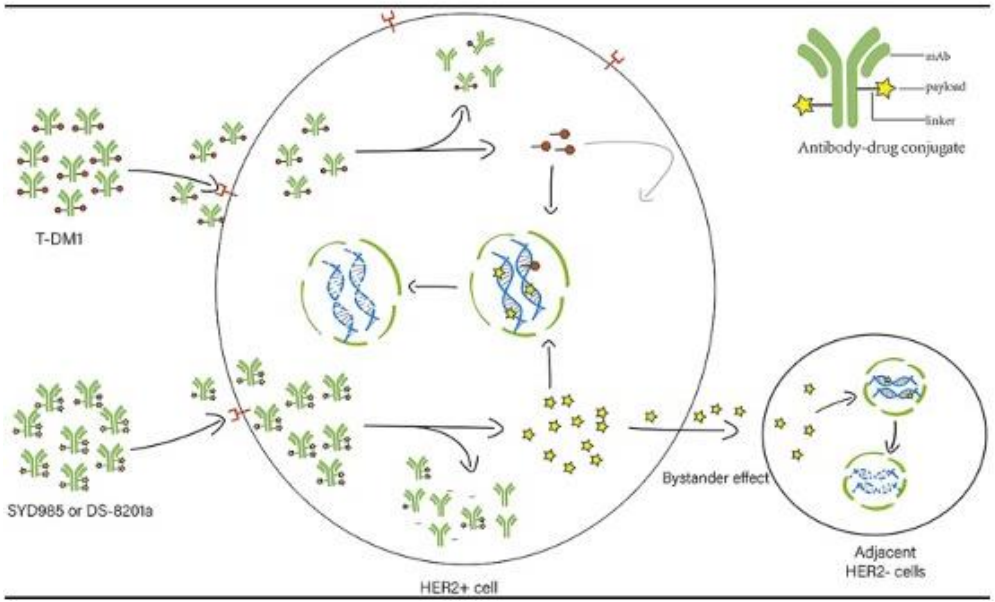
- 2010: Trastuzumab was approved for HER2 positive gastric cancer based on the ToGA trial

- 2011-2018: Drugs that target HER2 and are APPROVED in breast cancer were examined in HER2 positive gastric cancer
  - JACOB: Capecitabine/cisplatin/trastuzumab +/- pertuzumab (N = 780)
  - HELOISE: Capecitabine/cisplatin + 2 dose levels of trastuzumab (N = 400)
  - GATSBY: Paclitaxel vs T-DM1 (N = 412)

Bang YJ, et al. *Lancet*. 2010;376(9742):687-697. Dawood S, et al. *J Clin Oncol*. 2010;28(1):92-98. Tabernero J, et al. *Lancet Oncol*. 2018;19(10):1372-1384. Shah MA, et al. *J Clin Oncol*. 2017;35(22):2558-2567. Thuss-Patience PC, et al. *Lancet Oncol*. 2017;18(5):640-653.

Trastuzumab Deruxtecan

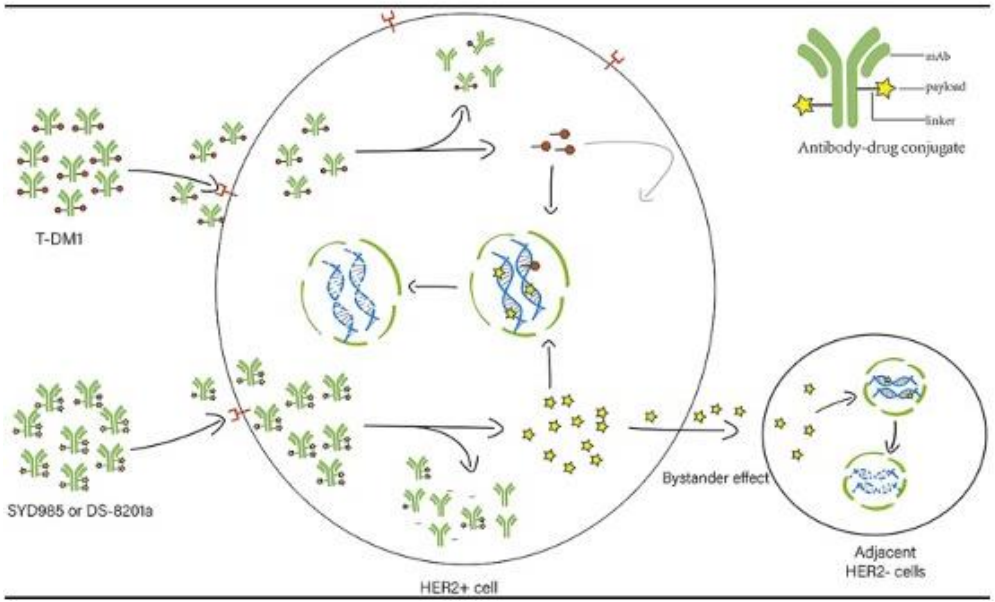
- Next generation drug targeting the same target
- Antibody drug conjugate
- Issues to consider
  - Linker between the payload and the Ab
  - DAR (drug to Ab ratio)



Shah MA. ***Lancet Oncol.*** **2017;18(11):1433-1434.**

Trastuzumab Deruxtecan

- Next generation drug targeting the same target
- Antibody drug conjugate
- Extends the approval of targeting HER2 in breast cancer
- Approved in gastric cancer
- Other GI cancers

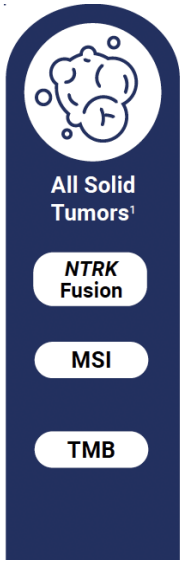


Shah MA. *Lancet Oncol*. 2017;18(11):1433-1434. Modi S, et al. *N Engl J Med*. 2022;387(1):9-20. Jones L, et al. *Cancer Treat Rev*. 2024;129:102789.

Regulatory/Quality Considerations

- Emergence and evolving field of precision medicine require novel policy framework that balances the needs of patients, industry, and science without impeding progress or limiting access

- Recent tumor agnostic FDA approvals



Regulatory/Quality Considerations

- FDA leads the way for regulatory aspects
  - 1996: Health Insurance Portability and Accountability Act (HIPAA) ensures that personal medical information stored, accessed, or processed adheres to privacy guidelines
  - 2015: PrecisionFDA was introduced – a cloud-based site for community research and development
  - 2020: FDA issued several guidance documents on manufacturing and clinical development of gene and cell-based therapeutic products
  - 2021: FDA updated guidelines on new products, like the development of antisense oligonucleotides

Novel Adaptive Design for Precision Oncology

- FDA Project Optimus --> use of patient data to improve toxicity assessment

- Utilize patient reported outcomes (PRO) within oncology trials
  - Could streamline drug development
  - Could reduce costs

Alger E, et al. *Res Involv Engagem*. 2024;10(1):63.

Novel Adaptive Design for Precision Oncology

- FDA Project Optimus --> use of patient data to improve toxicity assessment

- Utilize patient reported outcomes (PRO) within oncology trials
  - Could streamline drug development
  - Could reduce costs

  - Requires the development of new reporting measures and metrics
    - PROM = PRO-Measure
    - PRO-CTCAE = PRO-Common Toxicity Criteria for Adverse Events
      - Patients report symptomatic toxicities via a questionnaire

Alger E, et al. *Res Involv Engagem*. 2024;10(1):63. Klutz PG. *ASCO Education Book*. 2016.

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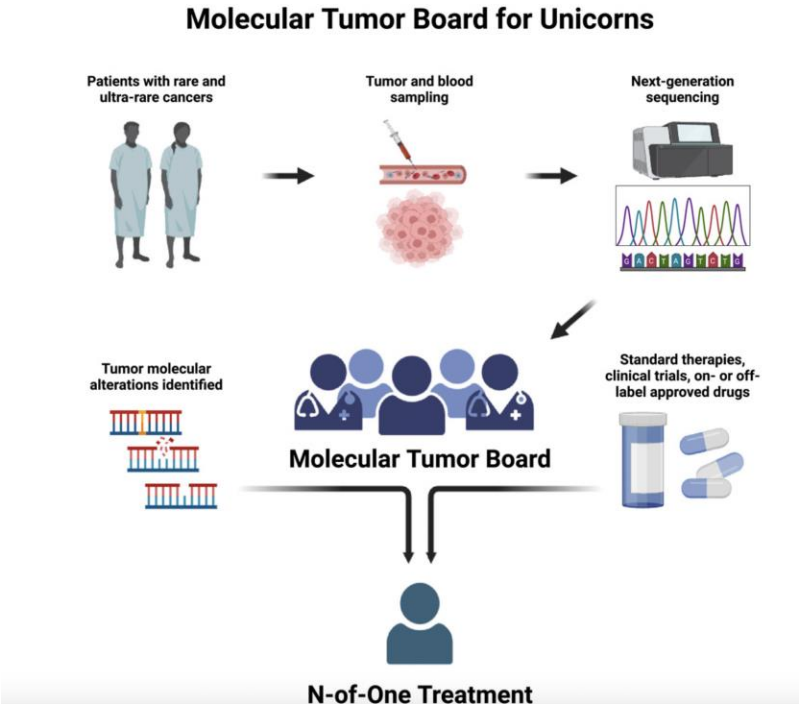
Molecular Tumor Boards

Molecular Tumor Boards

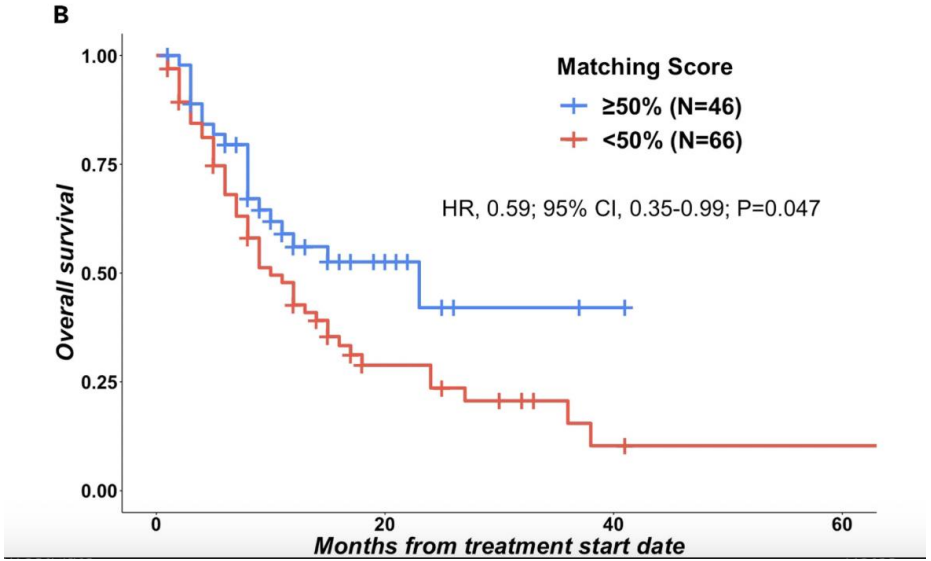


- Molecular tumor board
  - A multidisciplinary team that integrates molecular profiling to generate personalized treatment plans

Louie BH, et al. *iScience*. 2024;27(8):110465.

Impact on Clinical Decision Making

- A study of 112 patients with rare/ ultra-rare tumors
  - 41% received treatment with a high degree of matching with their molecular alteration
  - Patients who received targeted therapy had a better survival, higher response rate, and better outcomes



Louie BH, et al. *iScience*. 2024;27(8):110465.

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Understanding Barriers and Disparities in Biomarker Testing

Barriers to Precision Medicine

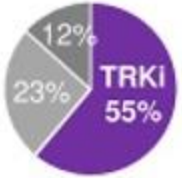
- Patient and clinician understanding of testing

- Time it takes to get the test
- Adequate tissue acquisition
- Insurance/cost

Biomarker Testing Not Always Done

- Another significant barrier to implementation of biomarkers

- 43-year-old woman diagnosed with pT4aN0 **colon cancer**; deferred chemotherapy; right lower quadrant mass later recurred, with carcinomatosis and ascites
- Cancer is dMMR/MSI-high, TMB-high, and *NTRK* fusion positive; pembrolizumab started but PD after 2 months; nivolumab/ipilimumab started but PD again after 2 months



N = 85; A6†
1.2020-1.2021

- 50-year-old nonsmoker with metastatic **lung adenocarcinoma**
- *EGFR/ALK/ROS1/BRAF* all negative, PD-L1 <1%; patient received carboplatin, pemetrexed, and pembrolizumab but PD
- NGS panel of original biopsy showed *NTRK* fusion

N = 591; A7†
2.2020-3.2021

dMMR = deficient mismatch repair.
Topping R, et al. *J Clin Oncol.* 2021;39(Suppl 28):abstr 229.

Patient Disparities and Considerations

- **Precision medicine** – initially believed to be an opportunity to overcome or address known healthcare disparities, because treatment is based purely on genetic or protein alterations

- But, disparities have grown
  - Insurance/ payment for testing
  - Mistrust in healthcare system (genetic testing)
  - Discordance in patient and clinician understanding on the importance of biomarker testing

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Technologies to Optimize Pathways and Biomarker Testing

Value Pathways

- Oncology clinical pathways integrated into electronic health record (EHR)
  - Treatment pathways highlight evidence-based treatment options
  - Based on efficacy, toxicity, financial impact to patient and payor
  - Refinement of NCCN Guidelines
  - Narrower list; 100% concordant
  - Includes incorporation of biomarkers relevant for decision making
  - Embedded in clinical decision support tool

Ginsburg A, et al. *J Clin Pathways*. 2020;6(9):38-41.

Clinical Management Technology

- Oncology decision support tool
- Integrated into provider's EHR and workflow
- Highlights up-to-date evidence-based treatment options at the point of care
  - Presents Value Pathways powered by NCCN and NCCN Guidelines
  - Keeps pace with personalized medicine and the use of diagnostic tests through automatic clinical updates
    - Prompts for relevant information, including biomarkers, to guide treatment options

Ginsburg A, et al. *J Clin Pathways*. 2020;6(9):38-41.

Clinical Decision Support Systems

- Integration of multi-modal data systems
  - Genomics and multi-omics data
  - Electronic health records
    - Including clinical history, laboratory data, and diagnostic imaging

Chen Z, et al. *Open Heart*. 2023;10(2):e002432.

Clinical Decision Support Systems

- Integration of multi-modal data systems
  - Genomics and multi-omics data
  - Electronic health records
    - Including clinical history, laboratory data, and diagnostic imaging
  - Opportunity for artificial intelligence
    - Review radiology and pathology
    - Integrate all the data together

Chen Z, et al. *Open Heart*. 2023;10(2):e002432. Wang L, et al. *Int J Med Sci*. 2023;20(1):79-86.

Key Learning Points

- Biomarker testing – many options, will need a strategy given limited tissue availability
- Economic considerations – the costs go up as the targets become more narrow, and the drugs get refined
- Regulatory advances to develop precision oncology – need for new approaches
- Barriers to widespread implementation include patient and physician understanding and implementation
- Pathways to support precision oncology – technology may be key

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Q&A Session