Pharmacogenomics and Precision Oncology: Beyond NGS

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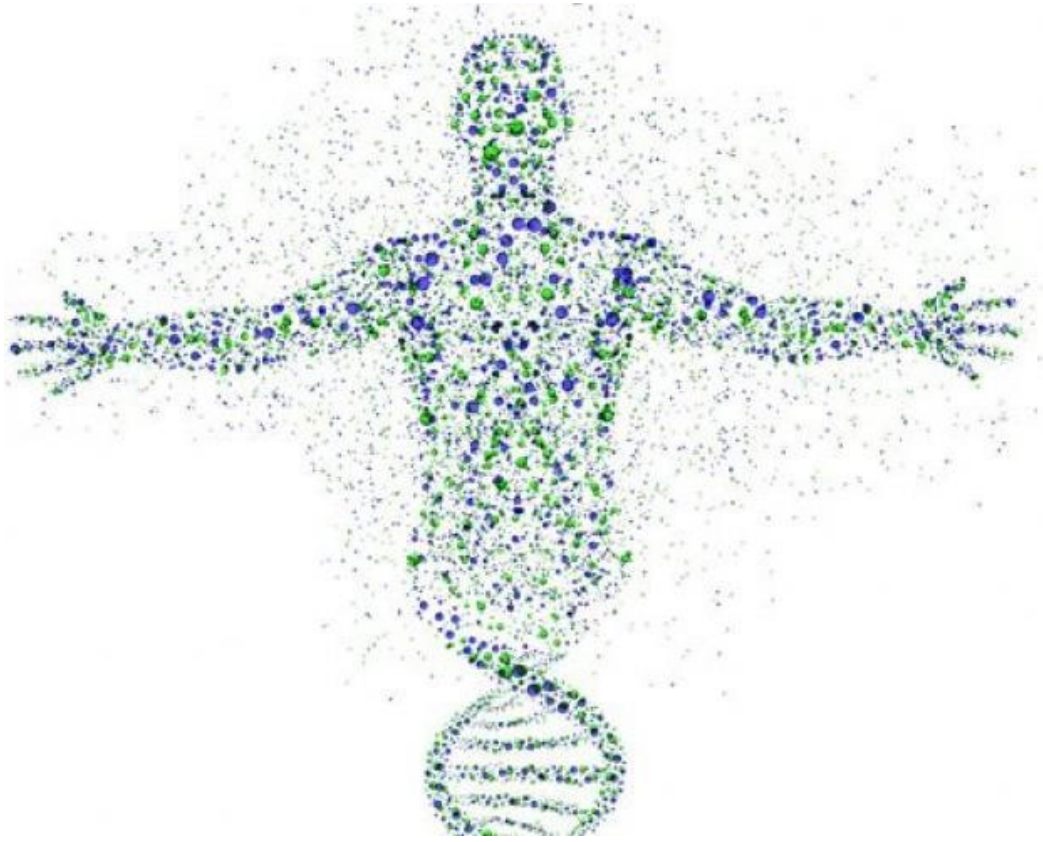
Ochsner Health

Disclosures

Consulting	AstraZeneca, Strata Oncology, Dispersol
Speakers Bureaus	AstraZeneca, Merck, BMS, Astellas, Eisai, Janssen, SeaGen , Exelixis

Agenda

- Overview
- NGS and Cancer: Just the Beginning
- Pharmacogenomics
- MRD Testing
- MCED Screening Tests
- Advocacy in Precision Medicine
- The Future



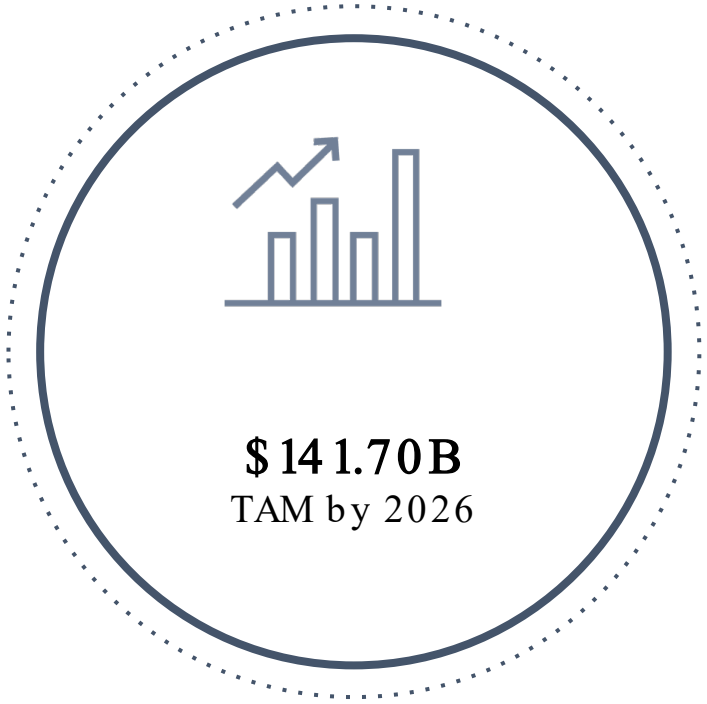
Precision Medicine Overview

What is Precision Medicine?

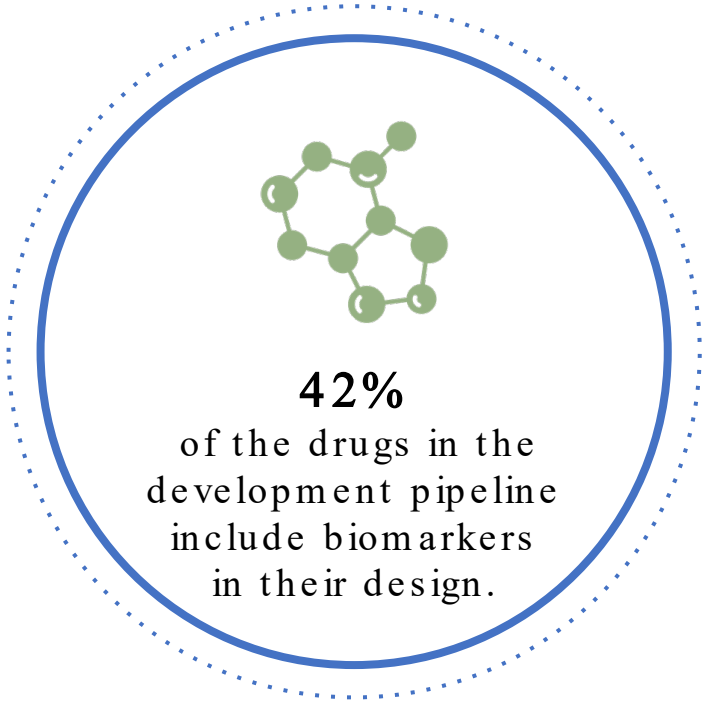
- Undercovers the underlying molecular alterations that drive health and disease
- Tailors health care on an individual patient level
- Most rapidly involving field in medicine, having a bigger impact each and every week.

No field in medicine will be untouched by this revolution.

Precision Medicine Market Overview



$141.70B
TAM by 2026



42%
of the drugs in the development pipeline include biomarkers in their design.

10
new precision medicine diagnostic tests daily

What is Precision Medicine?

Risk Assessment

- Hereditary screening for risk stratification
- Population based screening

Diagnosis

- Multi-cancer early detection (MCED)
- Rapid whole genome sequencing (WGS) in neonates and others
- Early detect of disease

Treatment

- Pharmacogenomics (PGx)
- Next-generation sequencing (NGS)
- Single gene-drug pairs

Getting the best medicine to each individual patient at the right time and the right dose based on advanced molecular and genomic technologies.

The Challenge of Precision Oncology

- Sequencing is only ONE step in the process!
  - Patient identification
  - Order entry
  - Bioinformatics
  - Interpretation
  - Report generation
  - EMR integration
  - Data mining/AI
  - Workflow automation
  - Clinical decision support
  - Access to treatment
  - Feedback loop

Meeting the Challenge

- Most institutions build a lab first, then address clinical integration, workflow, and patient access.

- At Ochsner, we have flipped this paradigm, building a precision medicine team, EMR and workflow integration, and access solutions first.

Integrating Precision Oncology

- Moved NGS ordering early in the process– at time of pathologic diagnosis before pt referred to oncology clinic
- Ochsner was first to fully integrate NGS into Epic genomics module end-to-end from ordering to automated reporting of results as discrete, searchable variables.
- Built a State-wide Virtual Molecular Tumor Board to assist physicians in interpreting NGS results.

Healthcare IT News

Global Edition Precision Medicine

Ochsner integrates precision medicine capabilities within Epic EHR

Clinicians can now order tests and access discrete biomarkers within the patient's electronic health record, rather than rely on PDF-based genetic testing results.

By Mike Miliard | August 31, 2022 | 10:32 AM

Team Driven Precision Medicine

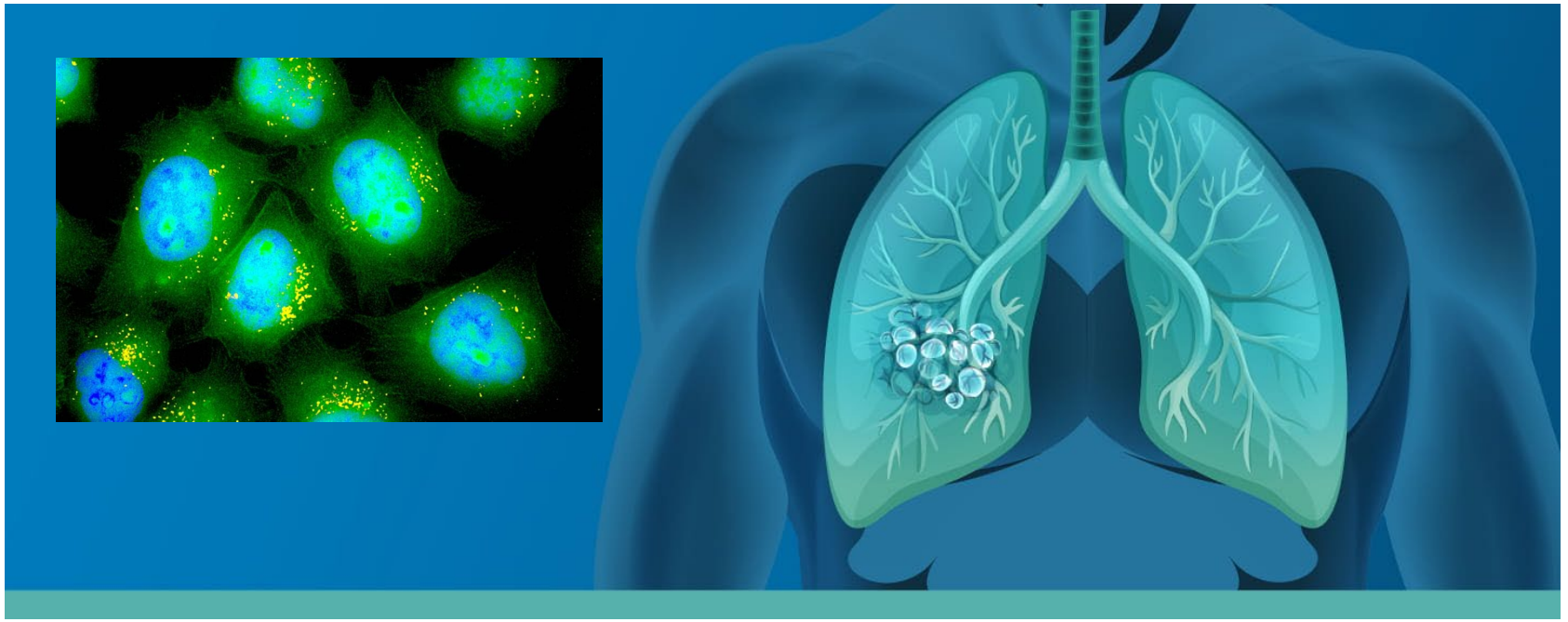
- Created a NEW team around precision medicine:
  - Medical Director of Precision Medicine
  - AVP of Precision Medicine
  - Lead Pharmacogenomics PharmD
  - Lead Genetic Counselor – Building Master's Degree Program with Xavier Univ
  - Precision Medicine RN Educator
  - Precision Medicine RN Navigator (for Positive Test Results)
  - Full-time on-site NGS coordination
- Created NEW committees and workgroups, including:
  - Precision Medicine Executive Steering Committee
  - Precision Oncology Steering Committee
  - Somatic Testing Committee
  - Precision Medicine Lab workgroup
  - Precision Medicine Care Variation Subcommittee
  - Pharmacogenomics P&T Subcommittee
  - Include regular meetings with CEO of Service Lines, CAO, and other Executive Leaders

Kevan Simms
AVP Precision Medicine

Mark Kirkiskis
Lead PGx PharmD

Abby Labit
PMed RN Educator

NGS and Cancer



Next Generation Tumor Sequencing

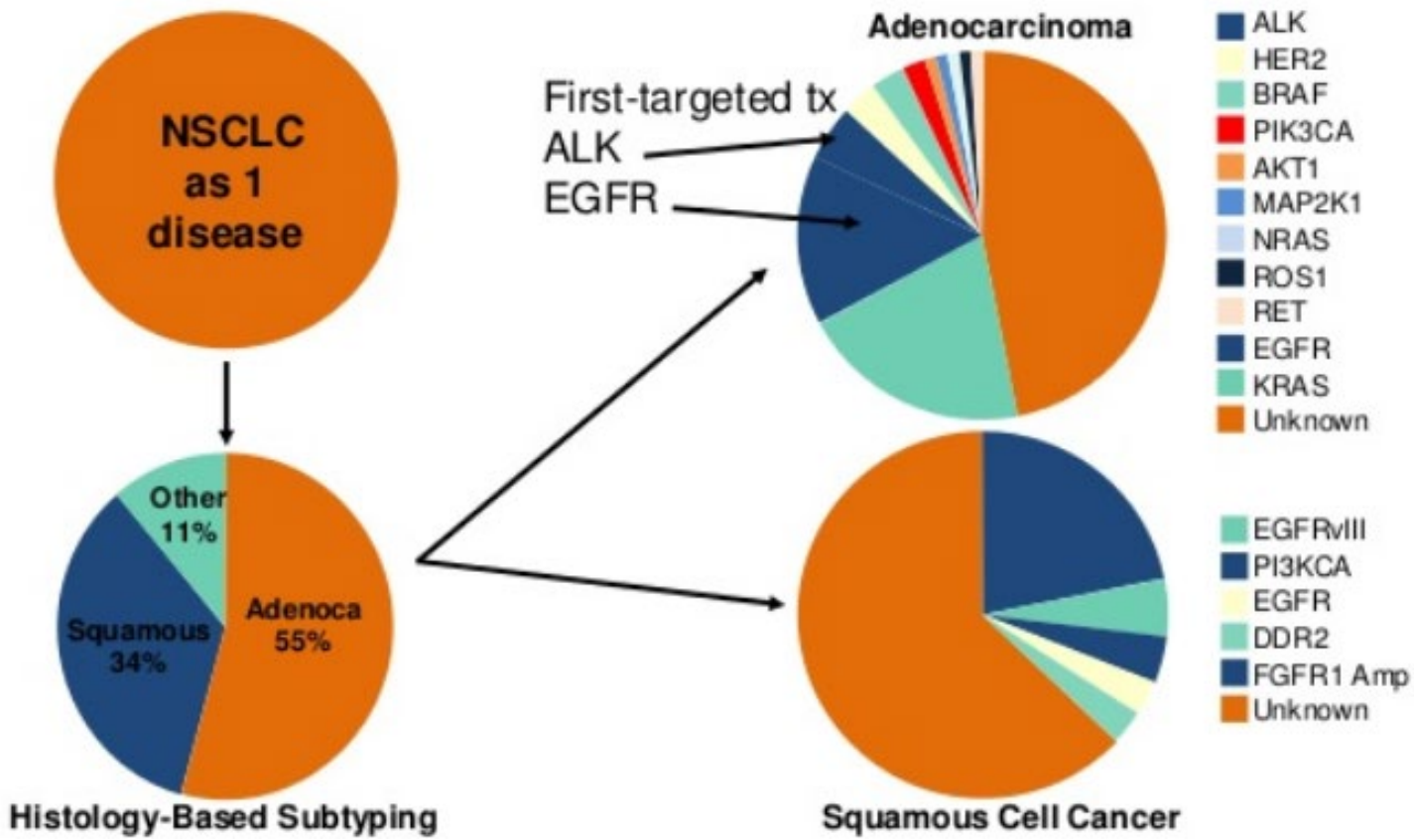
- One very important tool for precision medicine in cancer.
- Allows for testing hundreds of gene mutations from a single tissue sample or even from naked tumor DNA found in serum or urine.
- Provides the most personalized therapy options available.
- Studies have shown that the NGS is reliable and often finds actionable mutations at a higher rate the ordinary methods
- Costs are dropping drastically ~ $1-2k
- Allow for stratification to clinical trials

Patient Selection is KEY

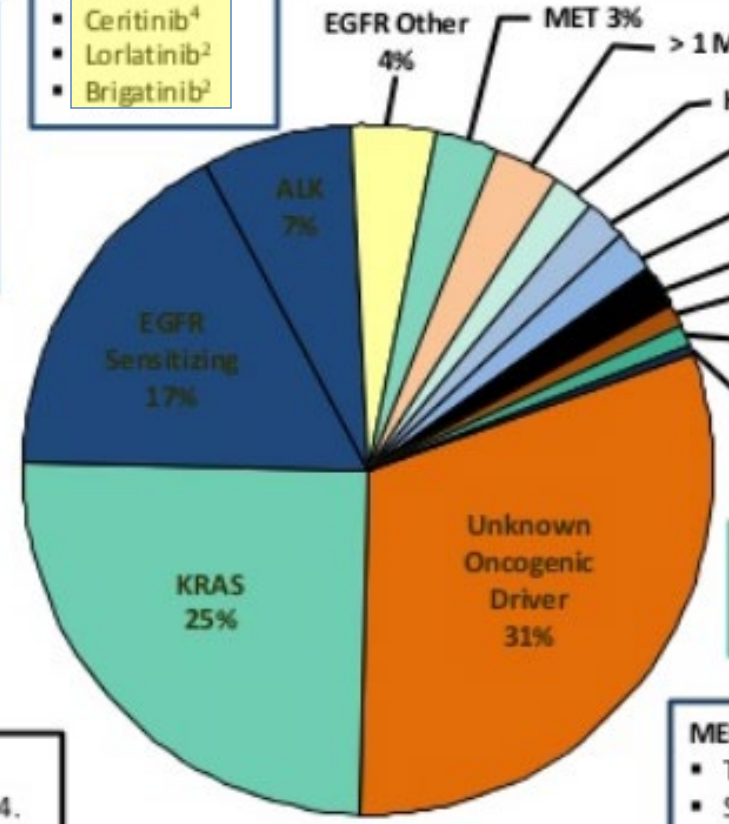
- Testing EVERY patient for EVERY actionable mutations is recommended PRIOR to beginning systemic therapy.

- Setting up systems to automate and integrate testing into workflows is essential.

NSCLC Evolution: From Single Disease to Many Molecularly Defined Subsets



Targeted Therapy for Adenocarcinoma



Exon 20 Ins
- Amivantimab
- Mobocertinib

MET
- Capmatinib

HER2
- Trastuzumab emtansine[3]
- Afatinib[2]
- Dacomitinib[2]

ALK
- Crizotinib[4]
- Alectinib[4]
- Ceritinib[4]
- Lorlatinib[2]
- Brigatinib[2]

ROS1
- Crizotinib
- Entrectinib
- Lorlatinib
- DS-6051b[1]

EGFR Sensitizing
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PIK3CA
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- PQR 309[1]

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MEK1
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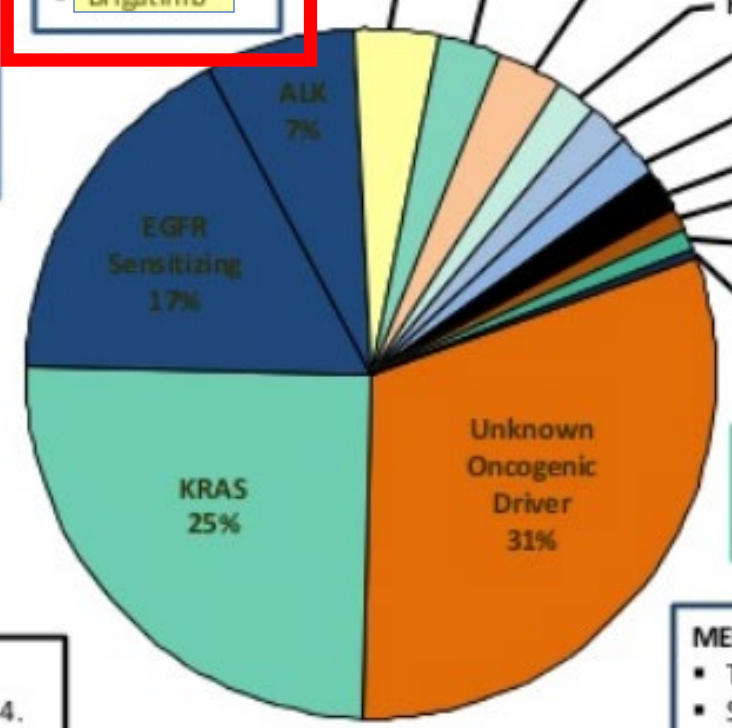
- Selumetinib[3]
- Cobimetinib[1]

Key

1. Phase I
2. Phase II
3. Phase III 4. Approved

Tsao AS, et al. J Thorac Oncol. 2016;11:613-638.

Targeted Therapy for Adenocarcinoma



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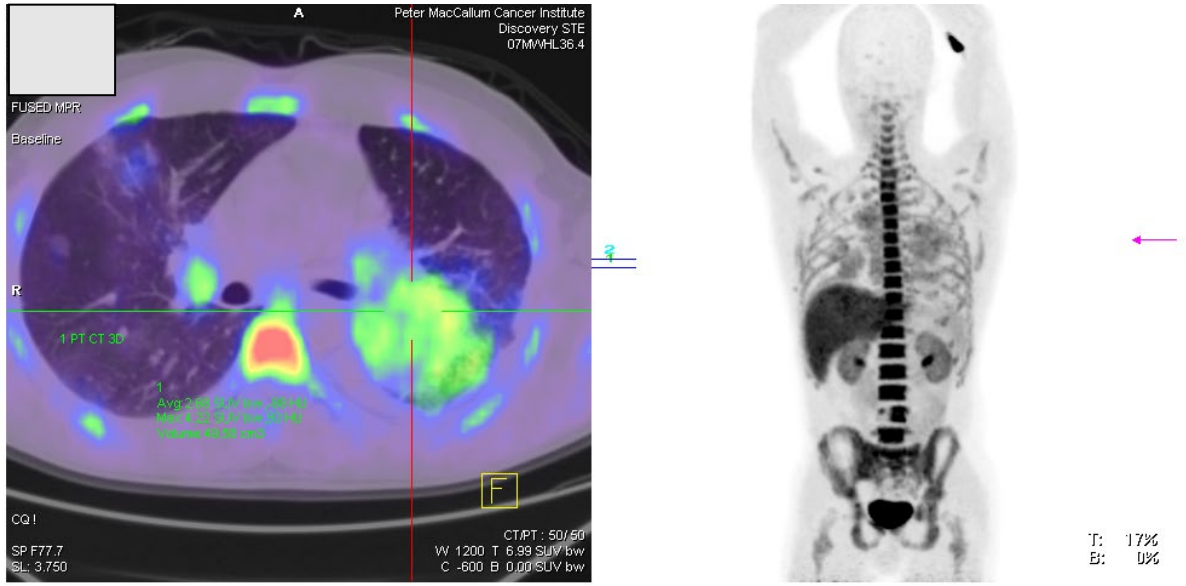
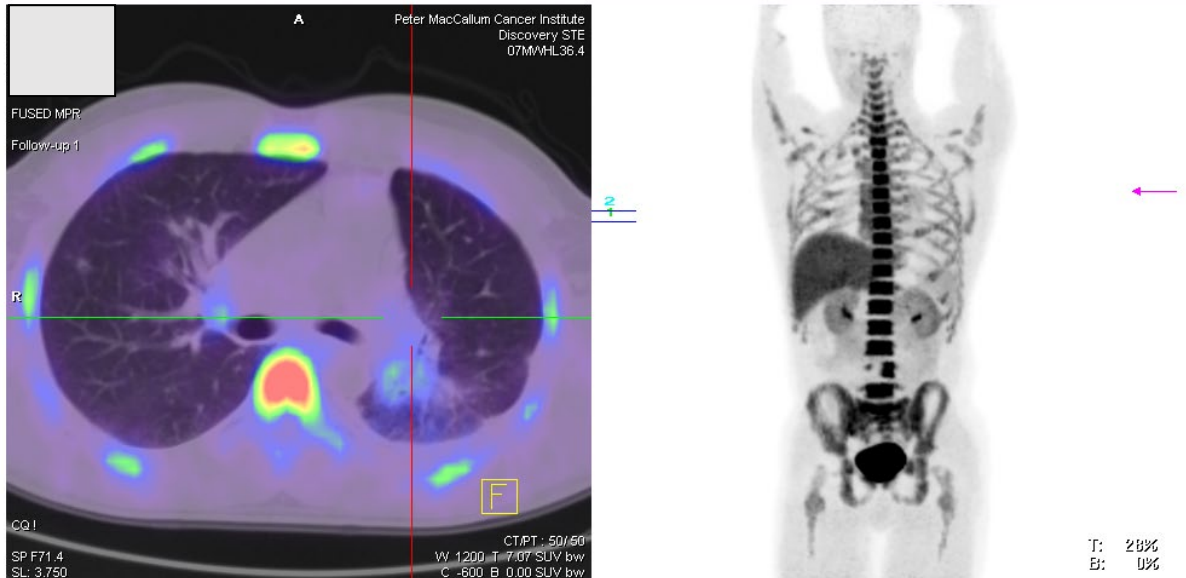
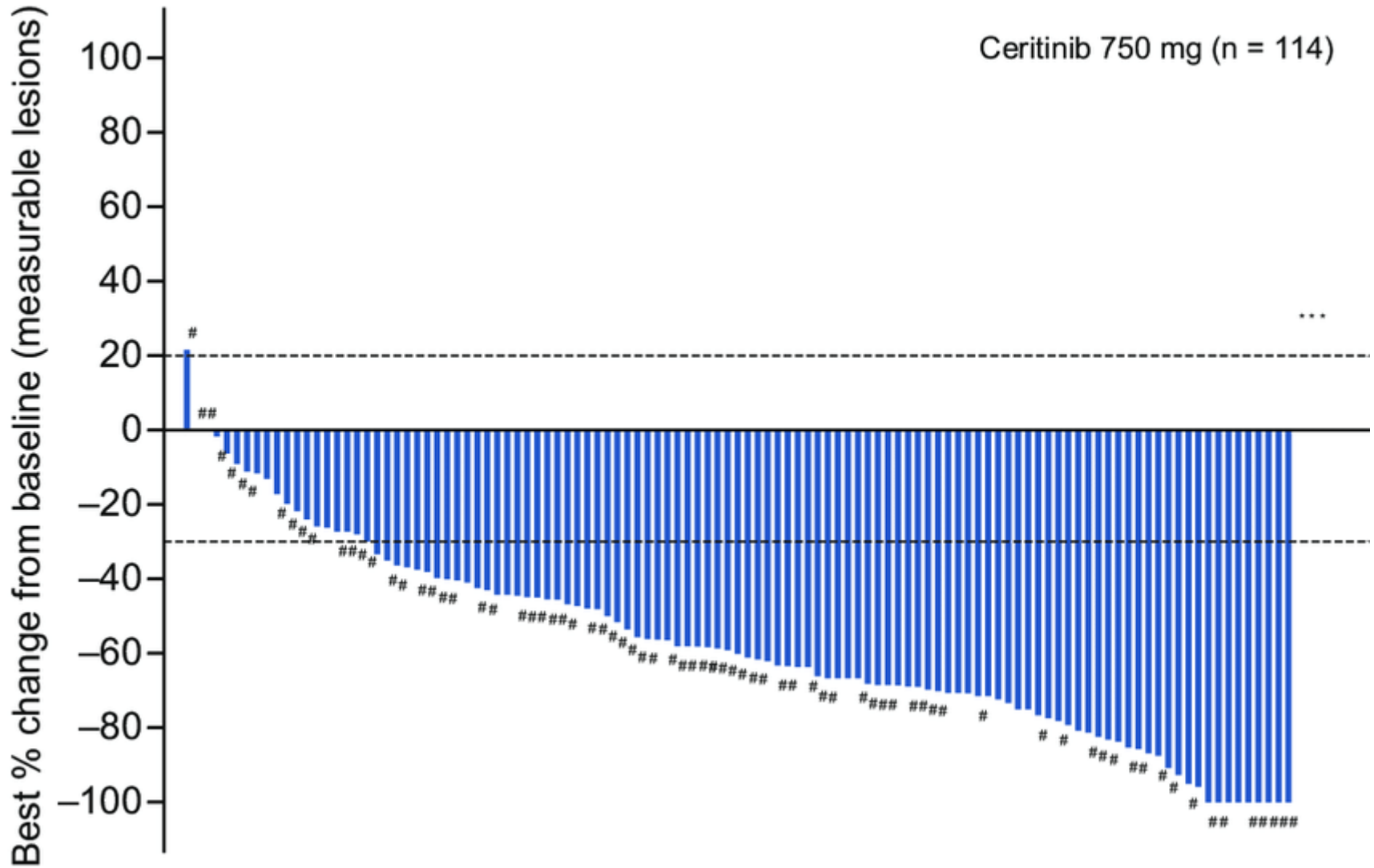
43 yo Male Never Smoker with Stage IV NSCLC Positive for EML4-ALK



Pretreatment



After 1 cycle


Ceritinib 750 mg (n = 114)
Best % change from baseline (measurable lesions)
100
80
60
40
20
0
–20
–40
–60
–80
–100

No-Cost Next Generation Sequencing of Advanced Cancer Patients within the Strata Precision Oncology Network Supports Clinical Trial Enrollment

Marc A. Matrana[1], Scott A. Tomlins[2], Kat Kwiatkowski[2], Khalis H. Mitchell[2], J. Marie Suga[3], E. Claire Dees[4], Mark E. Burkard[5], Jamil Khatri[6], Malek M. Safa[7], Eddy Yang[8], Benjamin Parsons[9], Alex R. Menter[10], Michael A. Thompson[11], Anneliese O. Gonzalez[12], Timothy Robert Wassenaar[13], Dan Rhodes[2]

[1]Ochsner Clinic Foundation, New Orleans, LA; [2]Strata Oncology, Ann Arbor, MI; [3]Kaiser Permanente, Vallejo, CA; [4]The University of North Carolina at Chapel Hill, Chapel Hill, NC; [5]University of Wisconsin Carbone Cancer Center, Madison, WI; [6]Christiana Care Health System, Newark, DE; [7]Kettering Cancer Center,Kettering, OH ; [8]University of Alabama at Birmingham, Birmingham, AL; [9]Gundersen Health System, La Crosse, WI; [10]Kaiser Permanente , Denver, CO; [11]Advocate Aurora Health, Milwaukee, WI; [12]The University of Texas, Houston, TX; [13]ProHealth Care Regional Cancer Center, Waukesha, WI

Background

Recent approvals for tumor agnostic precision therapies have expanded therapeutic options for patients, however, widespread integration of systematized next generation sequencing (NGS) to support continued drug development is hindered by numerous barriers.

The Strata Trial provides no-cost NGS to advanced cancer patients across the Strata Precision Oncology Network™ of 21 academic institutions and clinical cancer centers (Figure 1). This observational study is designed to evaluate the proportion of patients available for targeted therapy clinical trials and to assess the feasibility of using a large-scale NGS screening program to match patients for eligibility assessments (Clinical trial information: NCT03061305).

Aims

- Provide comprehensive tumor sequencing and trial matching for 100,000 advanced cancer patients
- Accelerate enrollment of partnered precision medicine clinical trials
- Catalyze new studies for patients harboring other targetable alterations

Objectives

Primary Objective

- To evaluate the proportion of subjects with genetic alterations targeted by approved or investigational therapies

Secondary Objectives

- To evaluate the proportion of subjects whose targeted genetic sequencing affected treatment selection and/or clinical trial enrollment
- To demonstrate the feasibility of a broad-based screening study of subjects utilizing molecular profiling and disseminating the results for relevant therapeutic protocols

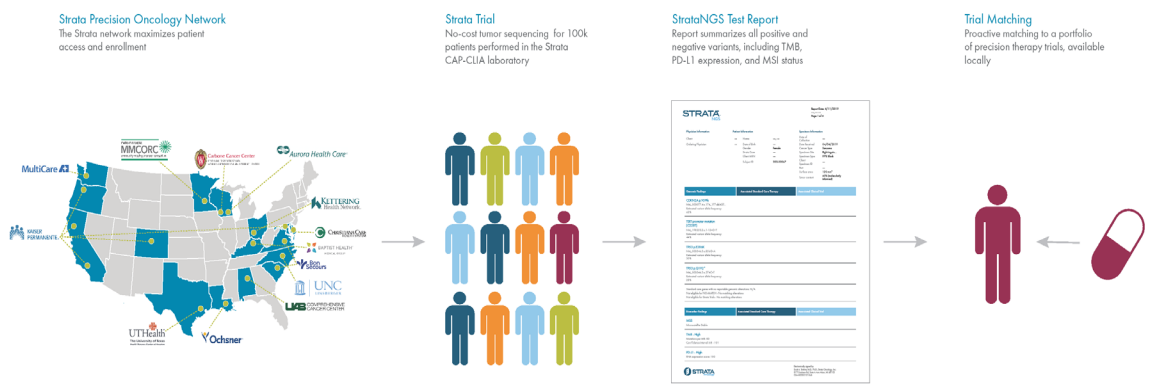
Exploratory Objective

- To determine the frequency of genetic alterations in subjects and explore potential relationships among genetic alterations and disease progression or treatment response

Methods

No-cost NGS testing is provided to a network of partnered centers within the Strata Precision Oncology Network. The archival FFPE tissue is submitted for NGS to Strata Oncology, a CLIA/CAP certified and NCI-MATCH accredited lab. The StrataNGS™ assay sequences DNA and RNA, and simultaneously assesses all classes of actionable genomic alterations including gene mutations, small insertions and deletions, copy number changes, and gene fusions in 500 cancer-related genes. Immunotherapy biomarkers include tumor mutational burden (TMB), PD-L1 expression, and microsatellite instability (MSI) status. MSI is determined via the number of length variant alleles observed in NGS sequencing data at several microsatellite loci. Test reports presented to the clinician include all positive and negative variants detected, and information about potential matching therapeutic protocols.

Figure 1. Schema

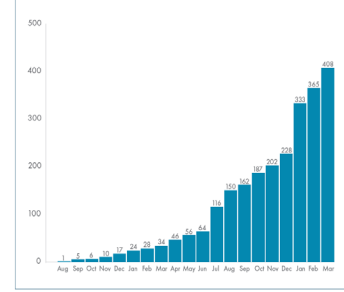


1. Patients with advanced or metastatic cancer are eligible for testing. An archival FFPE tumor sample is shipped to the Strata Oncology CAP-certified, CLIA approved laboratory for no-cost tumor sequencing.
2. A clinical report detailing tumor mutations and if applicable, a matching clinical trial, is returned to the provider in <10 d.
3. For patients with a matching trial, the provider screens the patient for additional eligibility criteria and may consent and enroll the patient on the protocol.

Discussion

Through the implementation of streamlined consent methods, electronic medical record queries, and high throughput laboratory testing at no cost to patients, we demonstrate that scaled precision oncology is feasible across a diverse network of healthcare systems when paired with access to relevant clinical trials. Since the Strata Trial protocol encourages physicians to enroll and test subjects early to support improved decision making, it is not surprising that almost 70% of subjects are still being followed for potential enrollment into clinical trials. To date, 15% of patients that matched to locally available Strata-partnered therapeutic trials have been enrolled. The median time-to-enrollment from match to receipt of therapy was 6 months, with several patients enrolling 12+ months following identification. Since 89% of the matched patients were identified within 1 year of this analysis, and time to progression must be considered to accurately assess how many patients will eventually enroll, additional follow-up time is needed to better understand screen failure rates and clinical trial enrollment timelines. (Figure 8 – histogram) When assessing patients identified at least 1 year prior to this analysis, 35% of patients matched to locally available Strata-partnered trials have enrolled.

Figure 8. Strata-partnered Trial Matches by Month (cumulative)



Conclusions

- StrataNGS is capable of sequencing samples otherwise rejected by other available tests with short turnaround time to support eligibility assessment for targeted therapies
  - 52.4% of specimens received and successfully sequenced by Strata were < 25mm²
  - StrataNGS minimum specimen size requirement = 2mm²
- Additional follow-up time is required to assess eligibility of patients recently matched to Strata-partnered therapeutic trials.

Results

StrataNGS Test Performance

Across the network of 17 active centers, specimens from 11334/12013 (94.3%) patients were successfully tested. 394 specimens were received with a quantity not sufficient for sequencing (QNS rate 3.3%). Median surface area of received FFPE tumor samples was 20mm² (interquartile range 8-90mm²), and the median turnaround time from sample receipt to report was 6 business days. (Figure 2; Figure 3).

Figure 2. Real-world Samples Received by Tumor Surface Area

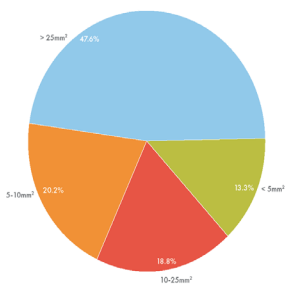


Figure 3. Turnaround Time (business days)

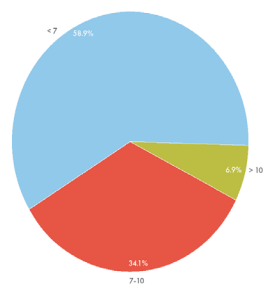
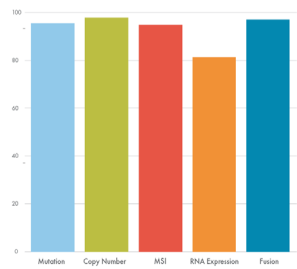


Figure 4. Success Rate by Alteration Type



Clinical Actionability

3600 (31.7%) patients had highly actionable alterations, defined as alterations associated with within cancer type FDA approved or NCCN guideline recommended therapies (1485 patients), NCI-MATCH trial arms (1636 patients), Strata-partnered therapeutic trials(408 patients), or specific alteration-matched FDA approved therapies in patients with cancers of unknown primary (71 patients). (Figure 5; Figure 6) Of the 1636 patients matched to an NCI-MATCH trial arm, 15 enrolled. Of the 408 patients matched to one of nine Strata-partnered clinical trials, 118 (29%) were screen failures, while 290 (71%) have either enrolled or are being actively followed for enrollment upon progression. (Figure 7).

Figure 5. Clinical Actionability

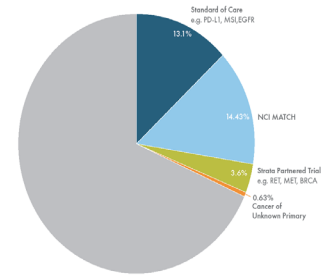


Figure 6. Distribution of Strata Partnered Trial Matches

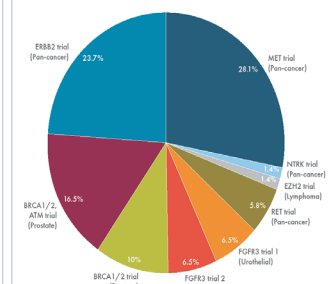
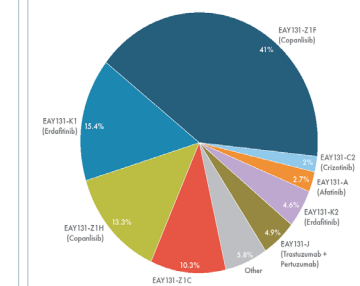


Figure 7. Distribution of NCI MATCH Eligible Patients



Implementation of no-cost, universal next generation sequencing for patients with advanced solid tumors and lymphomas: The Ochsner Experience

Erin Pierce, MSN,APRN,FNP-C, Marc Matrana, MD, MSc, FACP, Danial Johnson, MD, Christina Robinson
Hematology and Medical Oncology, Ochsner Medical Center, New Orleans, LA

Background

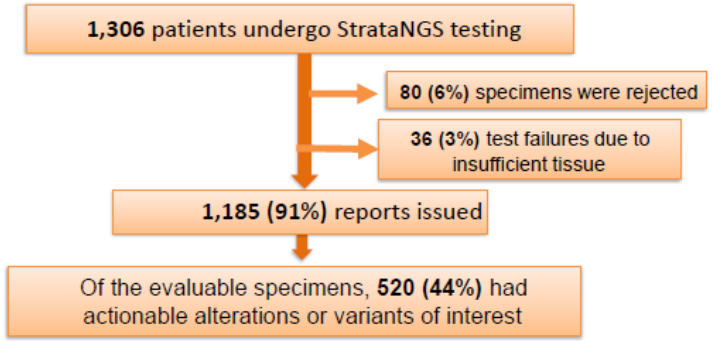
Next generation sequencing (NGS) allows for simultaneous testing for hundreds of gene mutations in a single, small tumor specimen. NGS has become an invaluable application to identify somatic driver mutations with therapeutic importance. One challenge of NGS is access, as testing is expensive and often not covered by insurance. In collaboration with Strata Oncology, Ochsner Health is offering all patients with advanced cancers genetic profiling of their tumor through an observational trial using a customized NGS panel at no charge. Here we compile the results of this trial and explore the benefits of NGS testing in this setting.

Methods

Data from patients enrolled in the Strata Trial from November 2017 through December 2019 at Ochsner Health was collected retrospectively. All adult patients diagnosed with a locally advanced or metastatic solid tumor/lymphoma, or any stage pancreatic cancer, glioblastoma, or rare tumors were eligible. FFPE blocks or unstained slides were sent to Strata for DNA and RNA extraction and profiling using a 429-gene assay to detect mutations, microsatellite instability, tumor mutational burden, and PD-L1. A multidisciplinary molecular tumor board was formed to interpret data.

Results

1,306 patients have undergone StrataNGS testing, with 1,185 reports issued. 80 (6%) specimens were rejected and there were 36 (3%) test failures due to insufficient tissue. Of the evaluable specimens, 520 (44%) had actionable alterations or variants of interest. Due to StrataNGS testing at Ochsner Health, 78 (7%) patients have been matched to clinical trials and 3 enrolled to Strata Oncology trials. Turnaround time averaged 10 days.



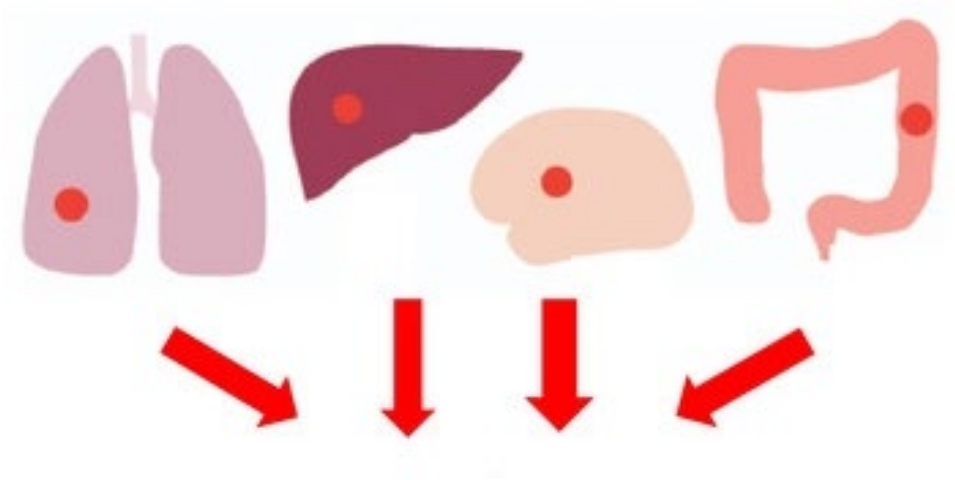
Conclusions

Through the Stata Trial, advanced cancer patients receive personalized medicine based on individual genomic information at no charge, which saves them thousands of dollars and performed in less time than commercial NGS testing. This allows for more precise, targeted therapies with higher efficacy and lower rates of potential side effects. A monthly multidisciplinary molecular tumor board led by Dr. Tong Yang was formed to help interpret this data.

Ochsner Health

Tumor Agnostic Precision Medicine

- Underlying driver mutations may be more important in defining some cancers than tissues of origin or type of cancer.



Common Type of Mutation

- Examples: NTRK, RET, TMB, MSI-H

Next Generation Sequencing - Challenges

- May provide information which is difficult to act upon:
  - Mutation for which no drug targets
  - Actionable drug pair which has not been studied in the tumor type tested
  - Difficult to distinguish driver vs passenger mutations
  - Must consider tumor heterogeneity and tumor evolution
  - Insurance issues

State-wide Molecular Tumor Board

- Currently held monthly with our molecular pathologists, physicians (surgeons, oncologists, etc.), LSU-Shreveport faculty, scientists from Strata NGS, fellows, research nurses, etc.

- We strongly welcome participation of any interested healthcare providers.

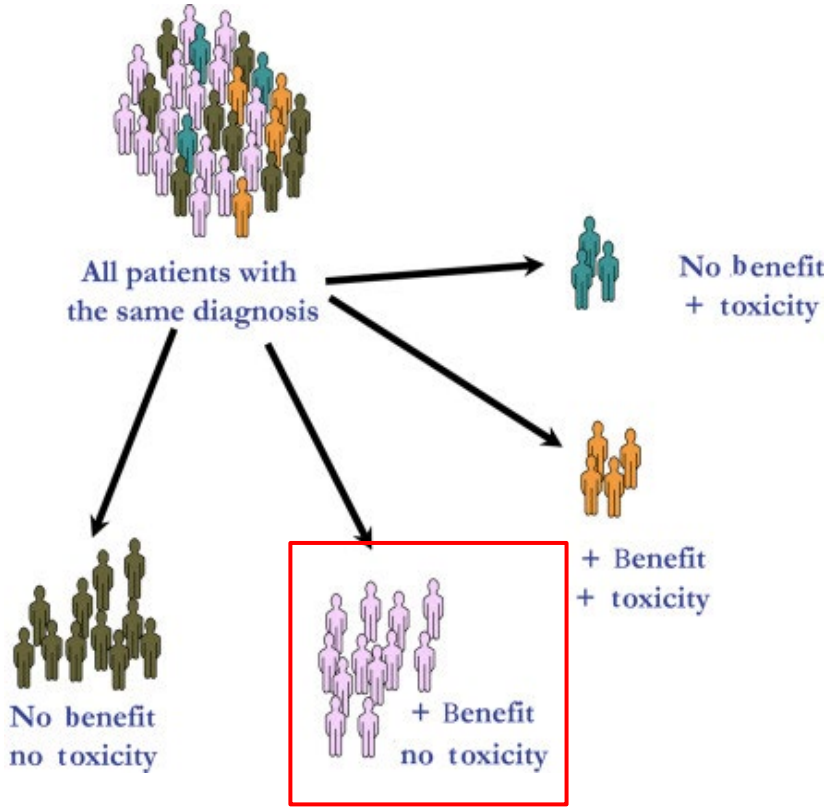
- E-mail Nicole Perry: nicole.perry@ochsner.org

Pharmacogenomics

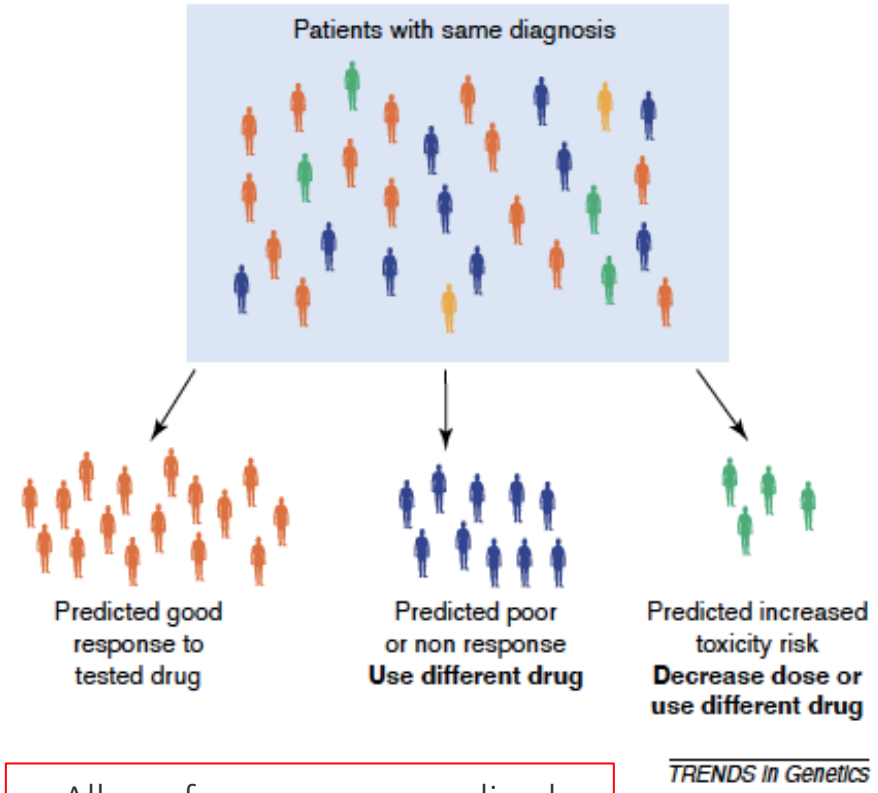
What is Pharmacogenomics (PGx)?

- For clinicians – using knowledge of genetic changes in metabolic enzymes, drug transporters, and drug receptors to guide medication selection
- For patients – understanding that changes in their DNA may affect the way the process or react to medication

Current State

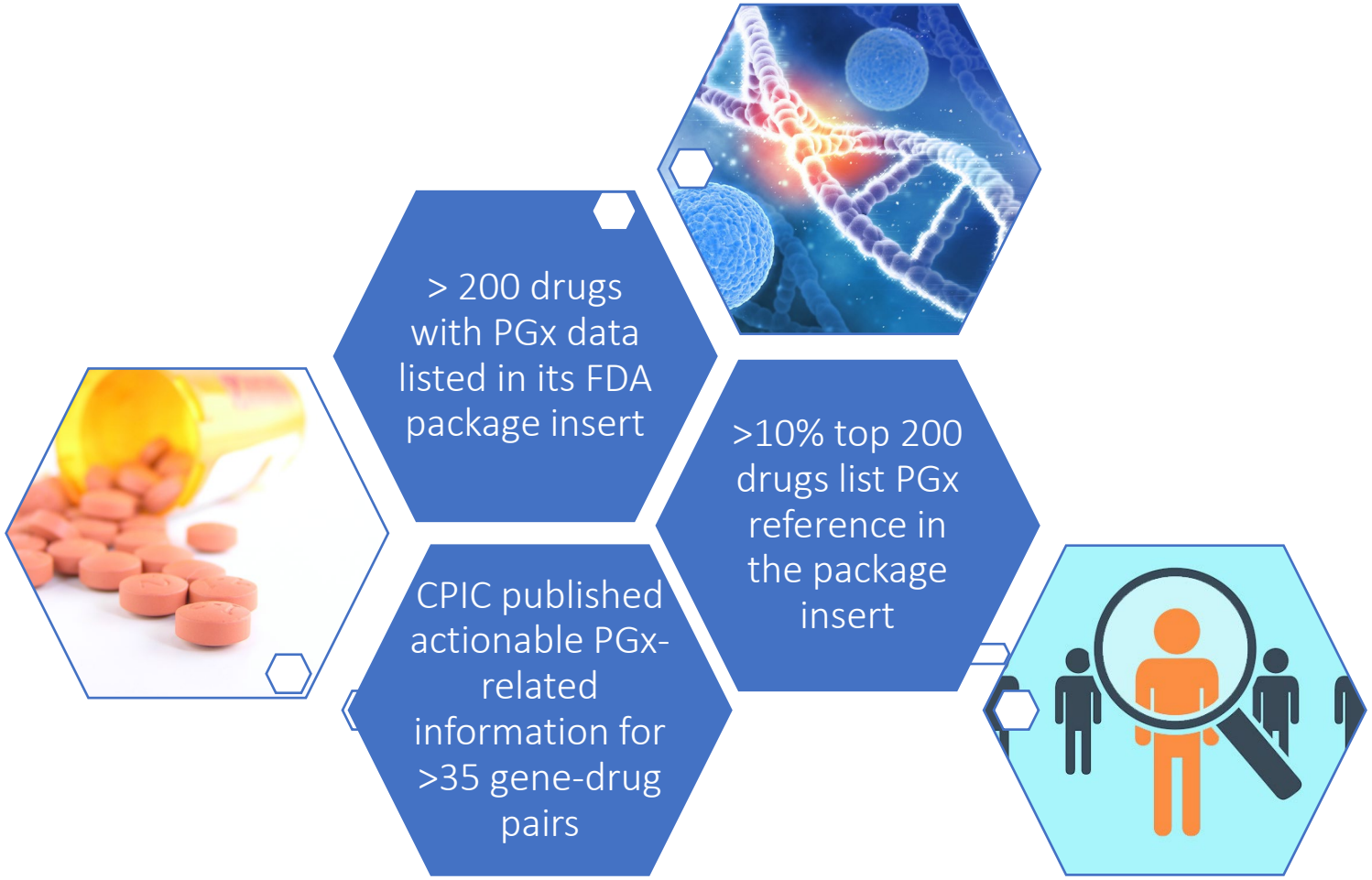


Future State



Allows for more personalized approach to drug utilization

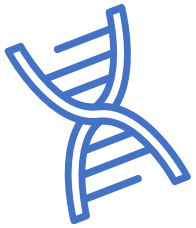
The Medications



Pharmacogenomics: Prevalence of Actionable Variants

99%

Patients carried at least ONE actionable pharmacogene variant



>50%

Of pharmacy population has been exposed to a drug affected by these variants

- Based on study performed on 7,769,359 US Veterans Health Administration (VHA) patients who use the VHA pharmacy services

Among the VHA pharmacy patients:

54.8% received at least 1 level A drug

15.3% received 2 drugs

11.7% received 3 or more

Therapeutic Areas

Current CPIC Guidelines for Drug-Gene Pairs

Cardiology
- Clopidogrel – *CYP2C19*
- Simvastatin – *SLCO1B1*
- Warfarin – *CYP2C9* and *VKORC1*

Infectious Disease
- Abacavir – HLA-B*57:01
- Atazanavir – *UGT1A1*
- PEG-interferon – *IL28B*
- Efavirenz - *CYP2B6*
- Voriconazole - *CYP2C19*
- AMGs - *MT-RNR1*

Neurology
- Carbamazepine – *HLA-B*15:02*
- Phenytoin – *CYP2C9, HLA-B*15:02*
- Atomoxetine - *CYP2D6*

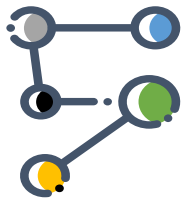
Oncology
- Thiopurines – *TPMT*
- Capecitabine/5-FU – *DPYD*
- Rasburicase – *G6PD*
- Tamoxifen - *CYP2D6*

Pain Management
- Codeine – *CYP2D6*
- Tramadol – *CYP2D6*
- Tricyclic antidepressants – *CYP2C19, CYP2D6*
- NSAIDS - *CYP2C9*

Psychiatry
- Tricyclic antidepressants – *CYP2C19, CYP2D6*
- Selective serotonin reuptake inhibitors– *CYP2C19, CYP2D6*

Rheumatology
- Thiopurines – *TPMT, NUDT15*
- Allopurinol – *HLA-B*58:01*

Solid Organ Transplant
- Tacrolimus – *CYP3A5*

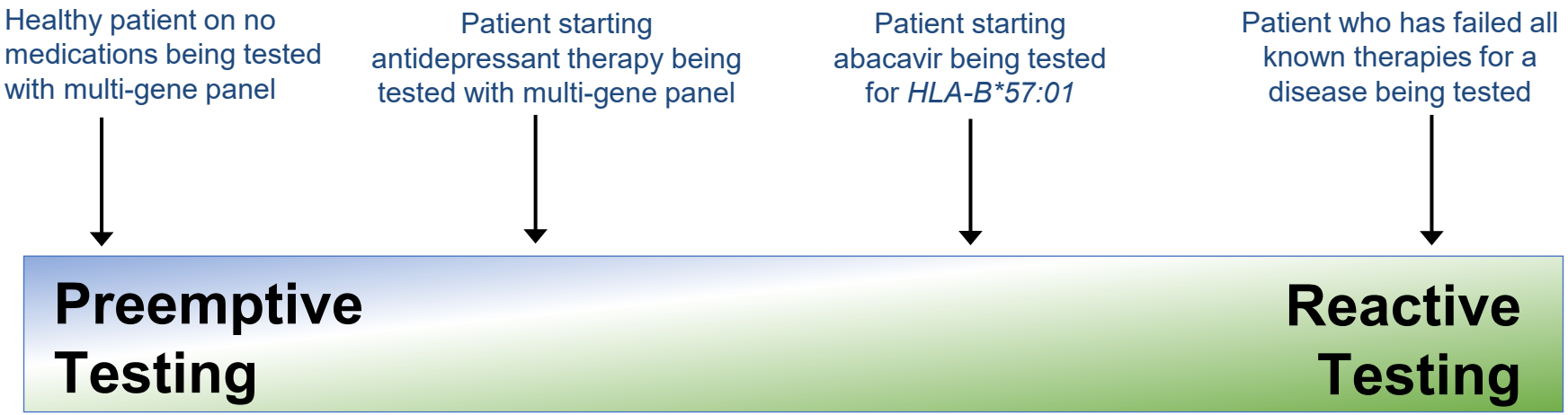


Respiratory
- Ivacaftor – CFTR

Other
- PPI – CYP2C19
- Ondansetron - CYP2D6
- Anesthesia - RYR1, CACNA1S

CPIC®
Clinical Pharmacogenetics Implementation Consortium

Timing of PGx test and change in value



Informative: results available when needed for future drug selection

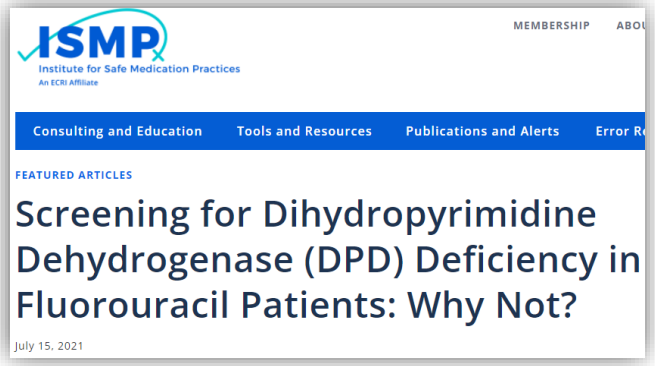
Directive: results guide best option from start of treatment

Preventative: results prevent use in patients with high risk of adverse events

Explanative: results explain medication failures after trial-and-error approach to medication selection

Required DPYD Testing at Ochsner

- Cost of Screening: Medicare/Medicaid Covered, Avg OOP <$90
- Delay in Therapy: ~5-day T-A-T
- Lack of Consensus on Dosing: CPIC Guidelines
- Decreased Efficacy in Cancer Treatment: PK studies
- NCCN does not endorse: BUT Acknowledges feasibility



Ochsner Experience:

- January 2020 – May 2021: 106 patients were tested for DPYD genetic variation in reaction to adverse events related to 5-fluorouracil or capecitabine therapy
- 11 patients tested positive for at least one mutation with clinically significant variation in drug metabolism
- 8 patients had potentially avoidable consequences if pre-emptively tested

Oregon Health System Settles Chemotherapy Death Lawsuit

July 16, 2022

Oregon Health System Settles Chemotherapy Death Lawsuit: Oregon Health & Science University ("OHSU") reportedly has agreed to pay $1 million to the widow of a cancer patient who allegedly died as a result of a toxic reaction to a chemotherapy drug due to a genetic variant that affects about 8% of the population. OHSU reportedly also agreed as part of the settlement that its oncologists will advise patients about the genetic variant before initiating the chemotherapy drug capecitabine.

CATEGORIES

Select Category

SEARCH ALL BLOGS BY WORD OR PHRASE

Search... SEARCH

HEALTHCARE & PHARMACEUTICALS FEBRUARY 15, 2021 / 5:26 PM / UPDATED 2 YEARS AGO

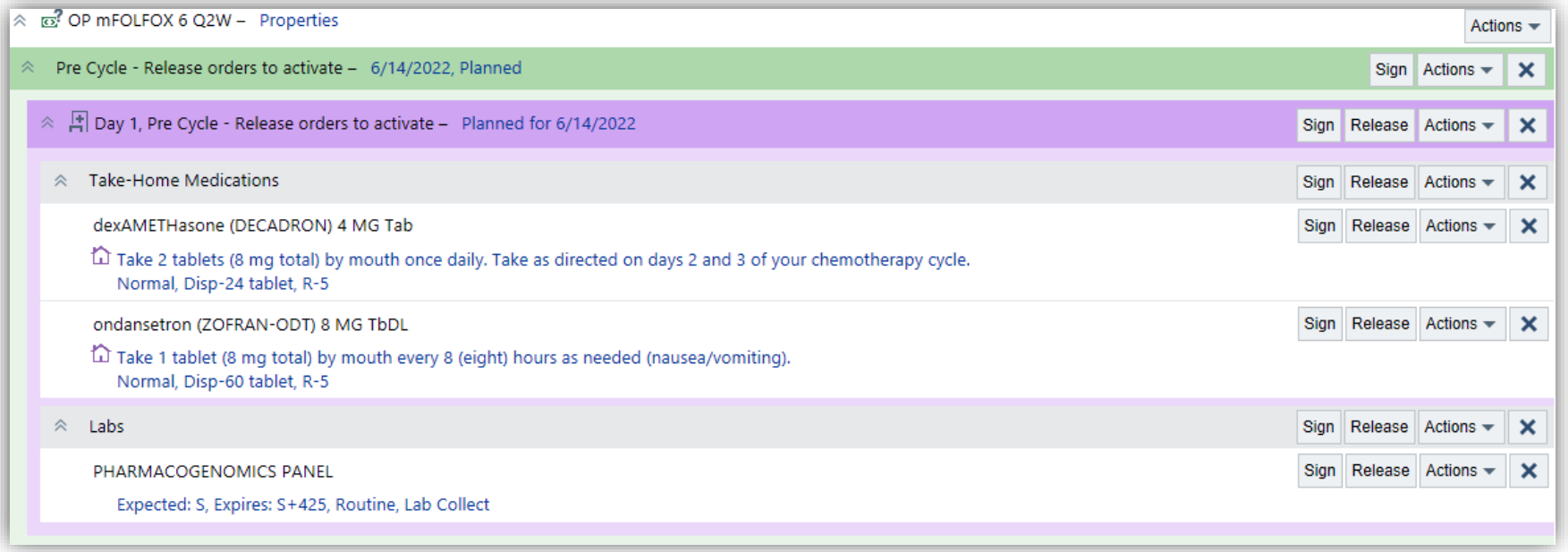
Bristol-Myers, Sanofi ordered to pay Hawaii $834 million over Plavix warning label

By Tina Bellon, Nate Raymond

2 MIN READ

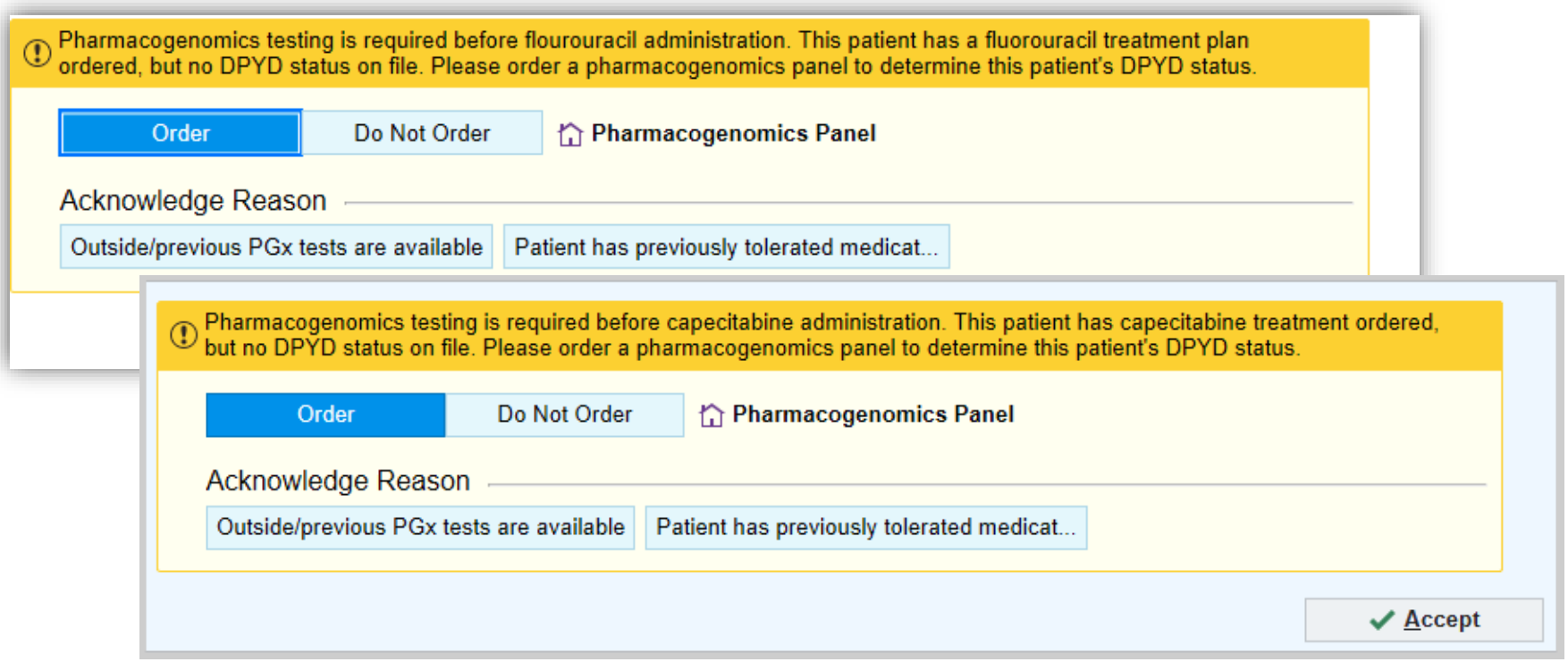
(Reuters) - A judge in Hawaii on Monday ordered Bristol-Myers Squibb Co and Sanofi SA to pay more than $834 million to the state for failing to warn non-white patients properly of health risks from its blood thinner Plavix.

PGx Pre-cycle Order



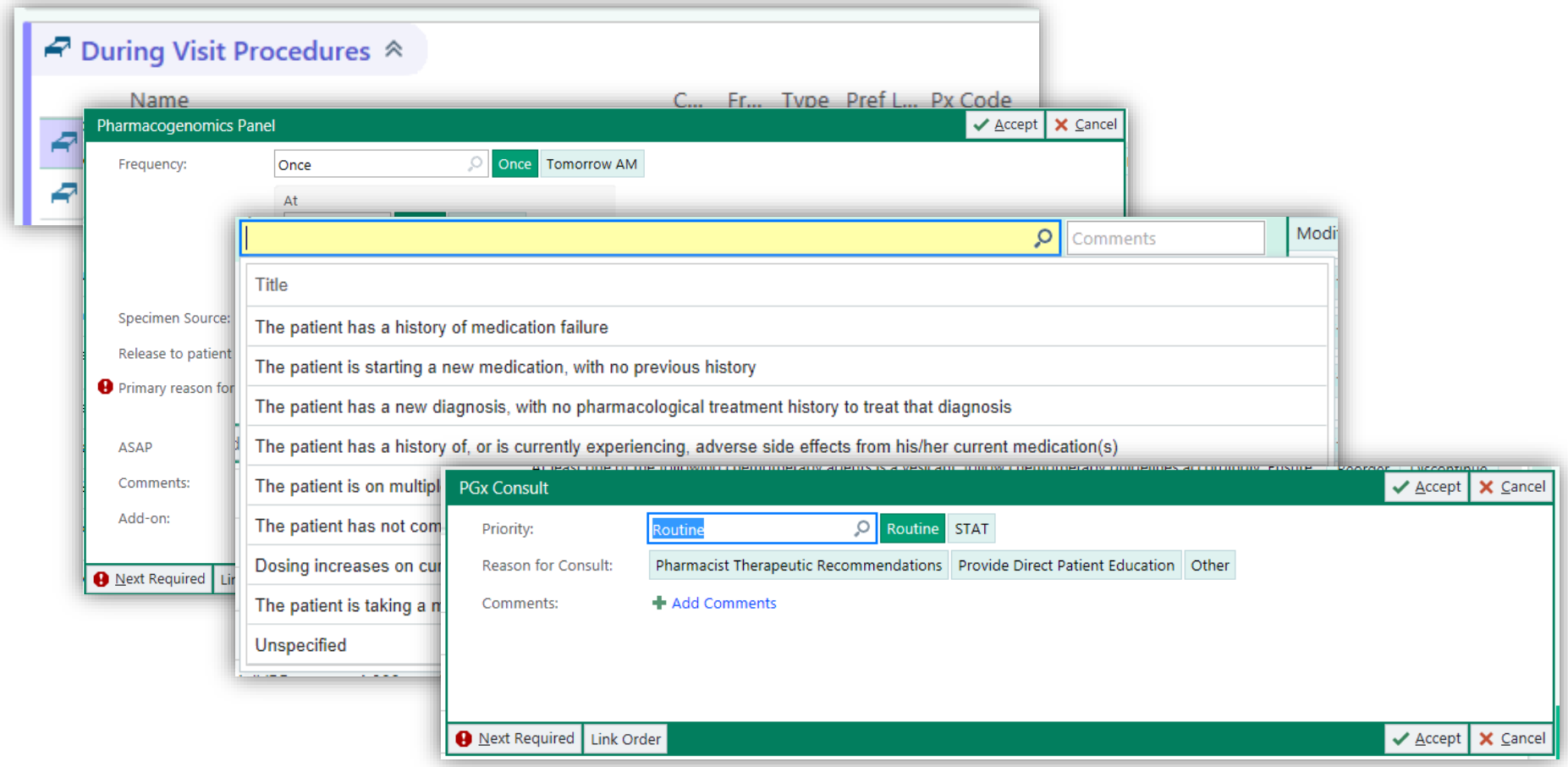
- Included in Pre-cycle orders if no PGx order has been placed
- Does NOT have to result to start therapy

DPYD BPA



- BPA will fire if:
  - Outside of the treatment plan
  - Skipped pre-cycle release (i.e., straight to Cycle 1 Day 1)

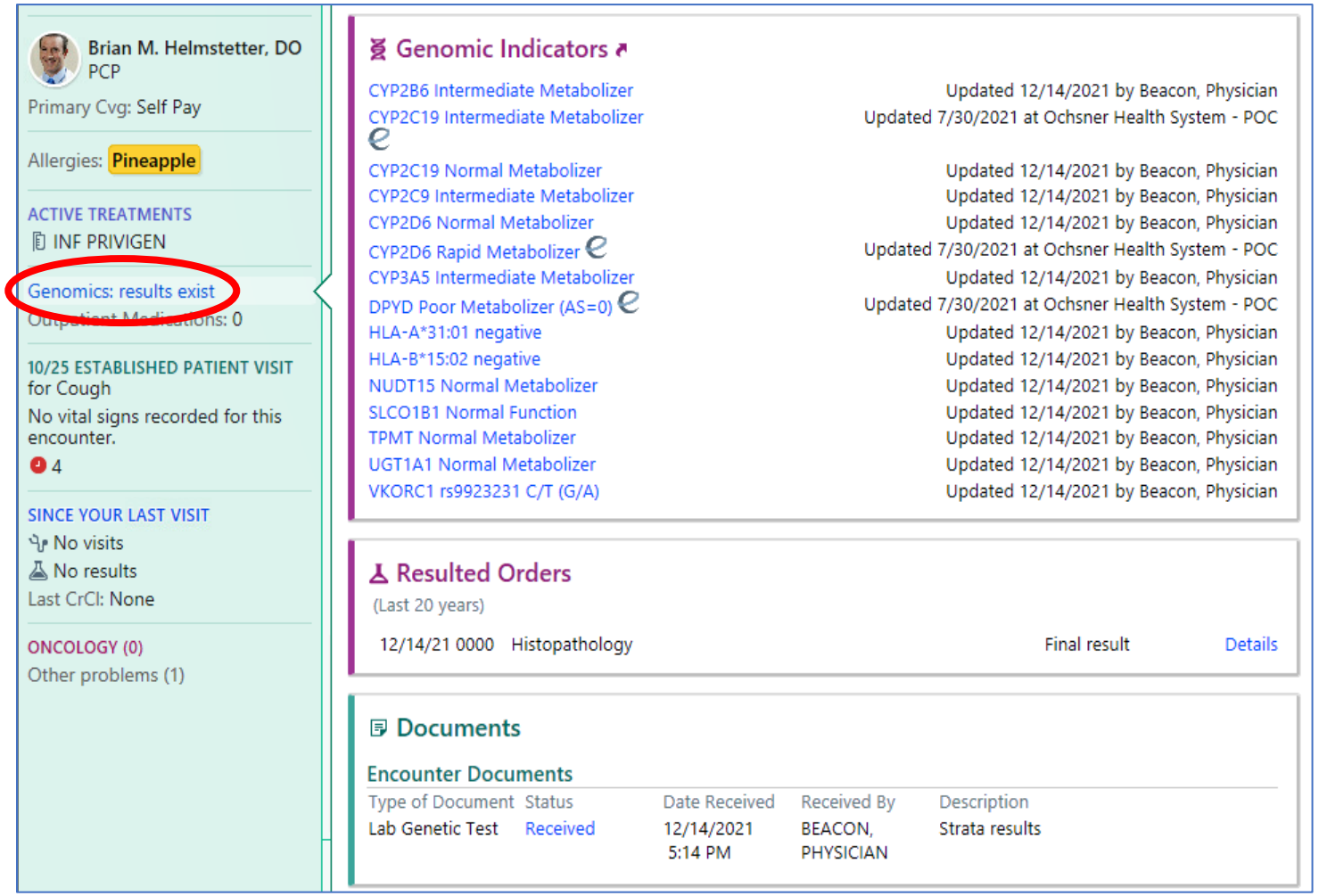
Ordering PGx



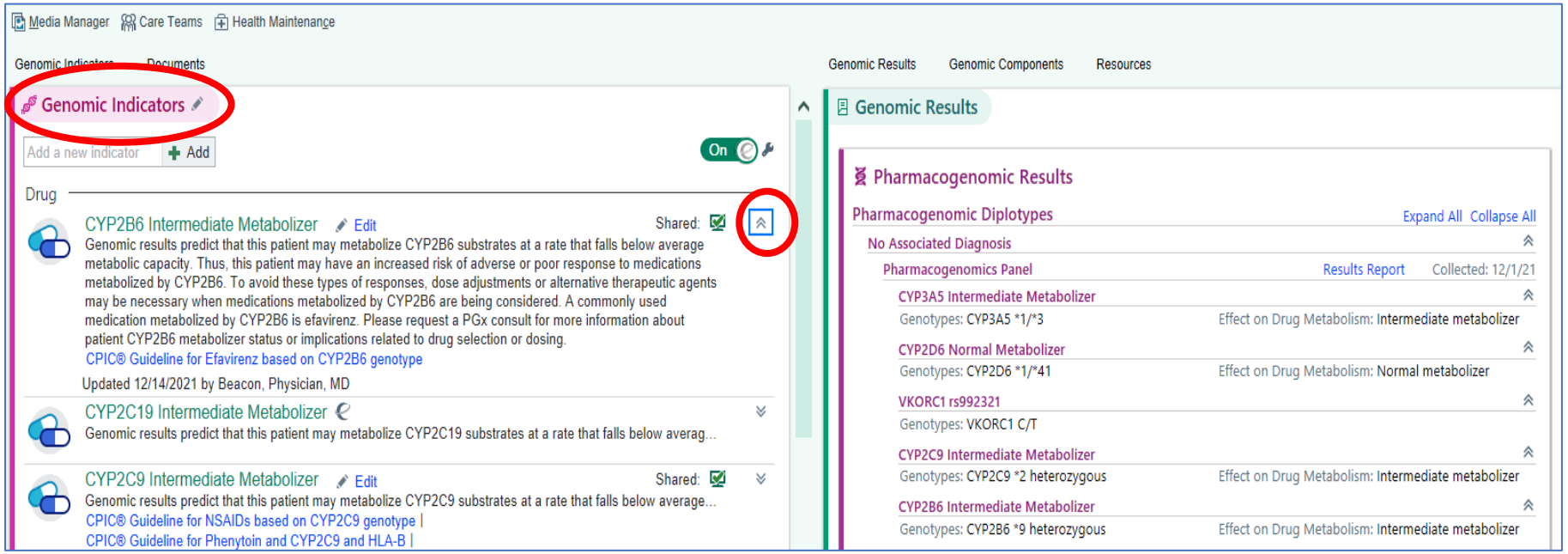
PGx Results – Storyboard

If the patient has genomic results, link appears in STORYBOARD for pharmacy and oncology staff.

Hover and see Gene and Phenotype.



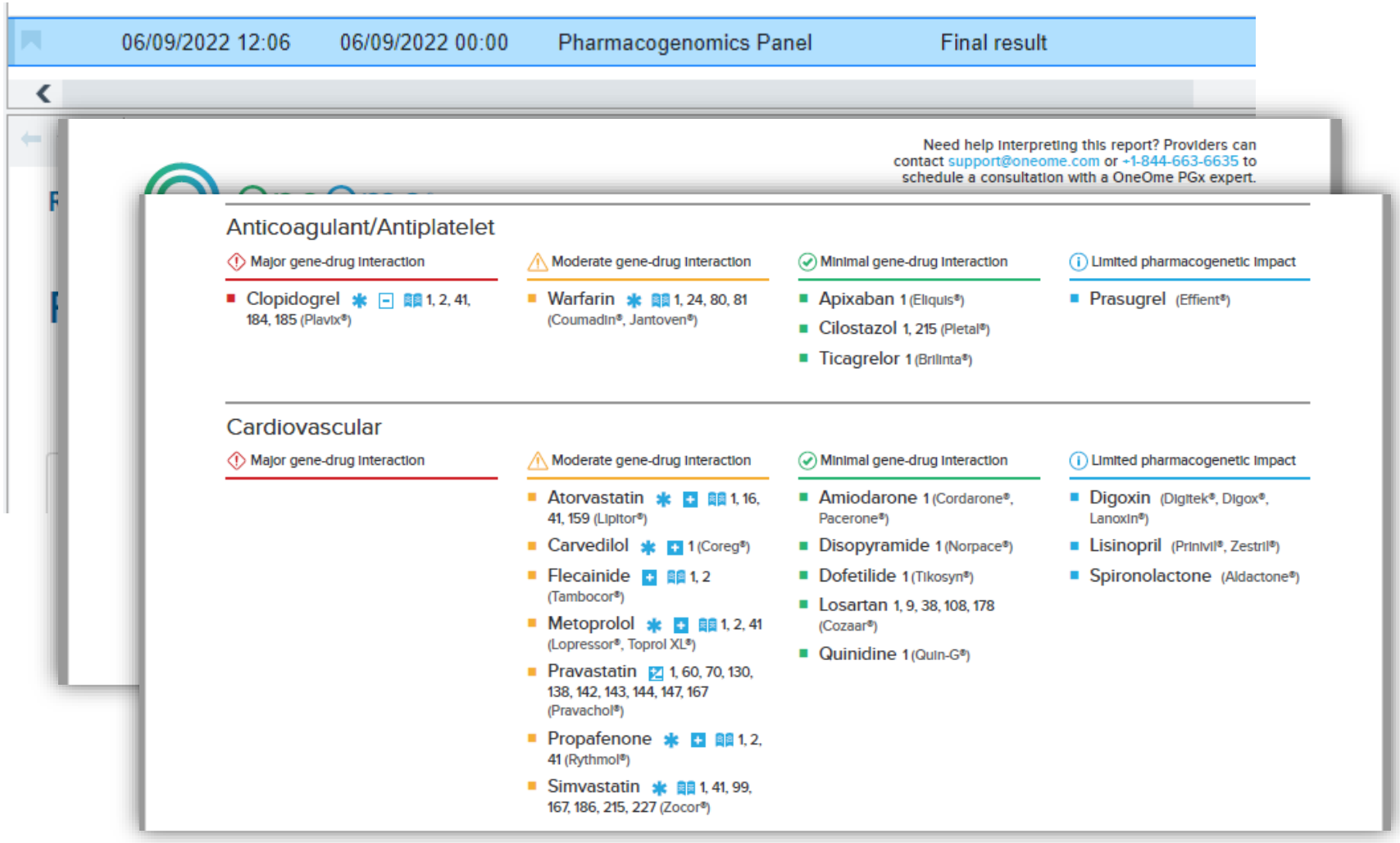
PGx Results – Genomic Indicators



Click into Genomic Indicators:
Includes link to CPIC Guidelines for specific medications.

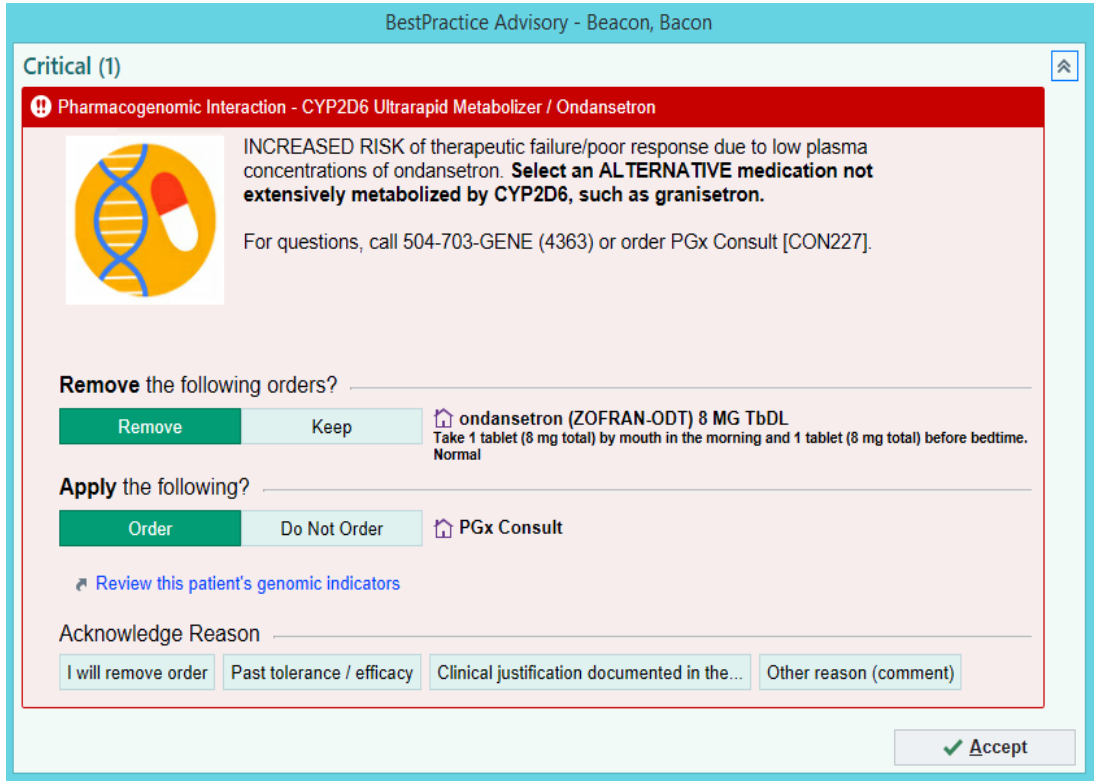
Right Side Panel: See phenotype and genotype

Link to Results PDF



BPA Alerts: Critical Interaction Interruptive Alerts

Any drug-gene-phenotype interaction with a PGx contradiction for use or recommendation to dose reduce related to the following:



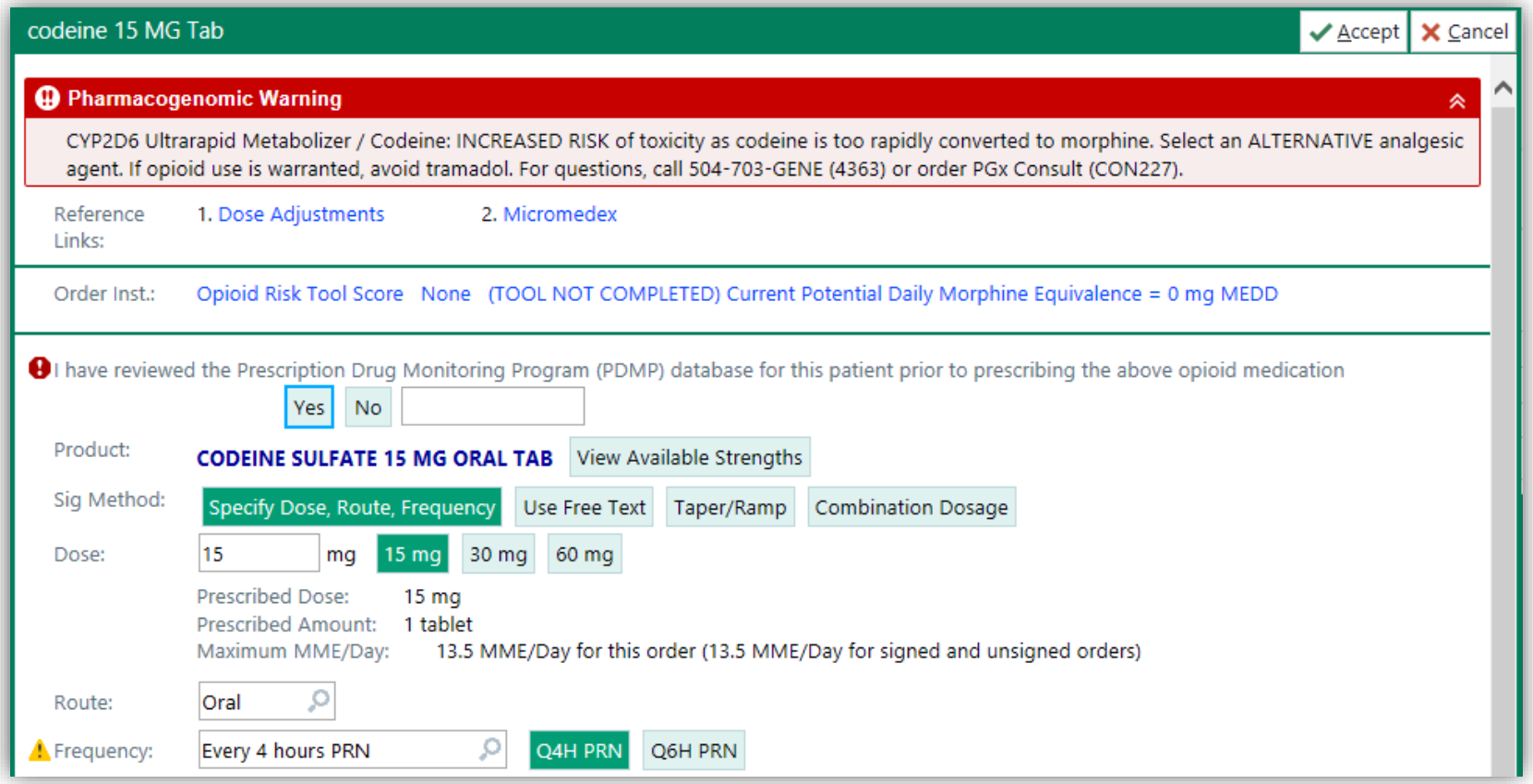
- Risk of SJS, TEN, other SCAR
- Risk of severe neutropenia, thrombocytopenia, myelosuppression
- PGx-related black box warning
- Treatment failures => risk of uncontrolled pain, vomiting, fungal infection or organ rejection

- Risk of acute hemolytic anemia
- Increased risk of other SAEs: severe respiratory depression, hepatotoxicity, QT events, visual disturbances
- PGx label contraindication and on FDA Table of Pharmacogenetic Associations

Inline Alert – Significant Interactions

Drug-gene-phenotype interactions with PGx recommendations to:

- Avoid use
  - Select alternate treatment to decrease risk of adverse events or treatment failure
- Reduce dose
  - Dose reduce to offset increased risk of adverse events due to predicted increases in drug plasma concentrations



PGx Support

- Epic Clinical Decision Support tools available – Providers DO NOT have to be proactive
- Pharmacy PGx Consult is available
  - Epic: PharmacoGENOMICS Consult Order (CON227)
- Or Contact Info:
  - Phone: (504) 703-GENE (4363)
  - Email: PGx@Ochnser.org

Employee Health Plan 2023

- PGx Testing for covered for Ochsner employees with Behavioral Health diagnoses

Studies in Behavioral Health:

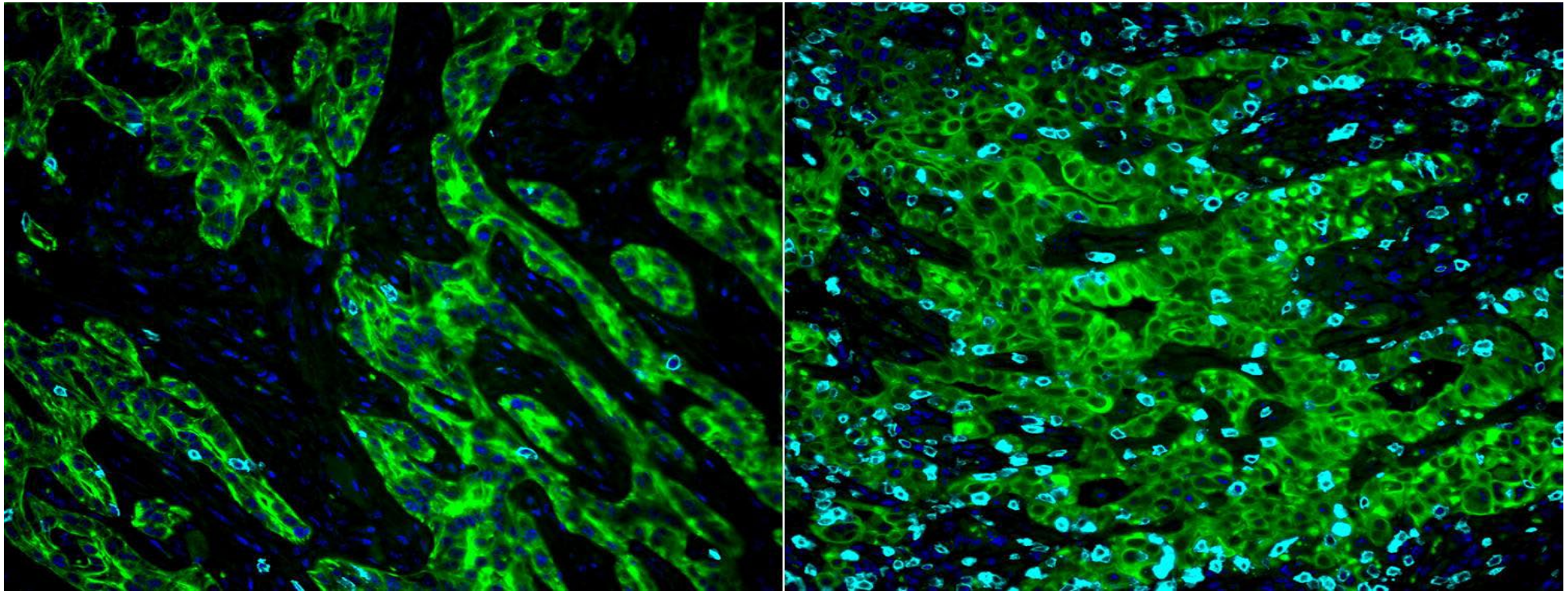
- Increased adherence and decreased cost in outpatients
- Higher cost of care in extreme metabolizers
- PGx testing reduces the cost
- Increased health care utilization and time away from work in patients treated with non-optimal medication

Psychiatry

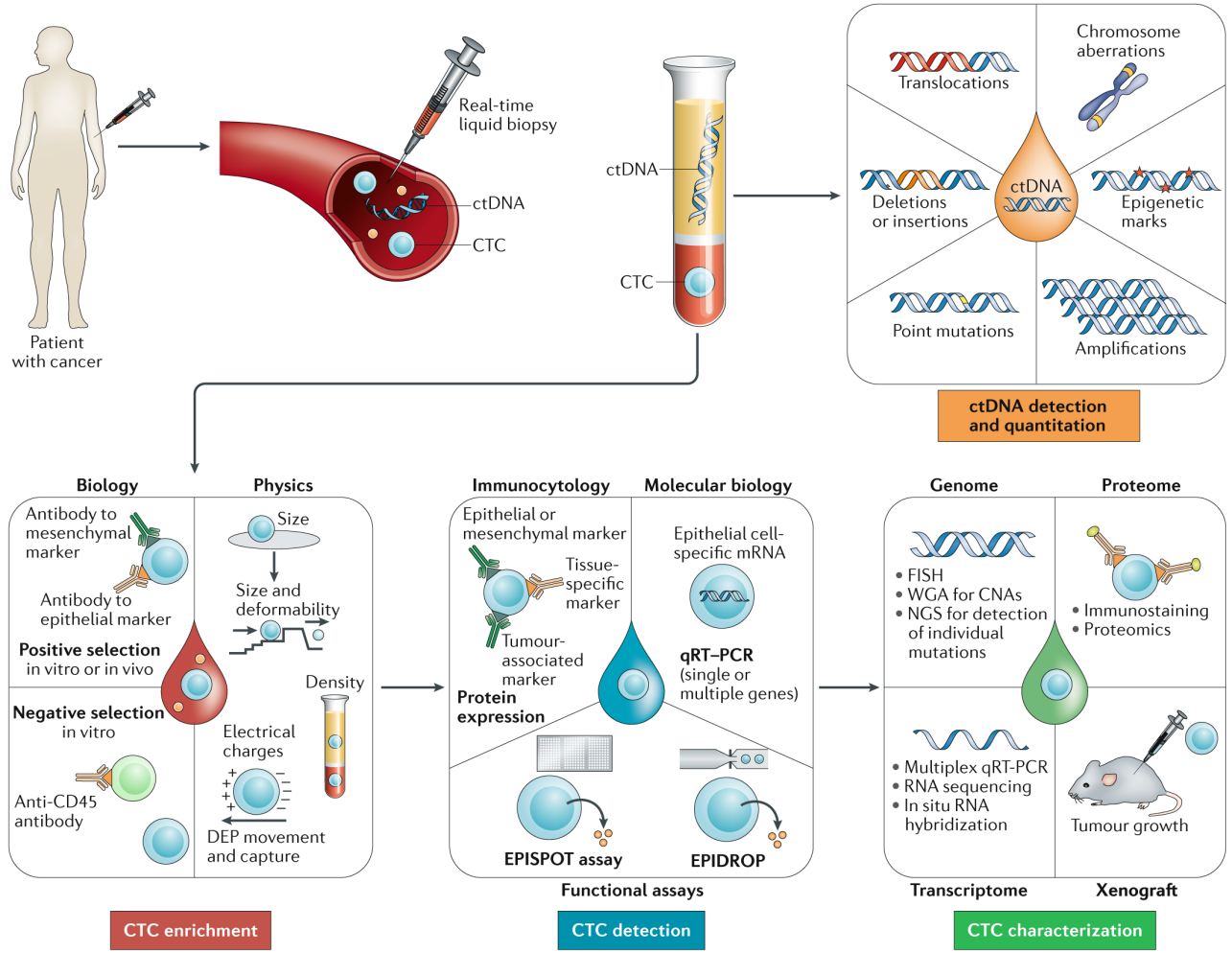
- Tricyclic antidepressants – *CYP2C19, CYP2D6*
- Selective serotonin reuptake inhibitors– *CYP2C19, CYP2D6*

Fagerness J. Am J Manag Care. 2014; 20(5):e146-56.
Herbild L. Basic Clin Pharmacol Toxicol. 2013;(4):266-72.
Winner J. Transl Psychiatry. 2013 Mar 19;3:e242.

Minimal Residual Disease Testing



MRD in Solid Tumors



MRD for Recurrence Monitoring

- Commercially available (Natera, etc.), but limited clinical studies to guide clinical decisions with positive tests (i.e., start therapy, etc.).

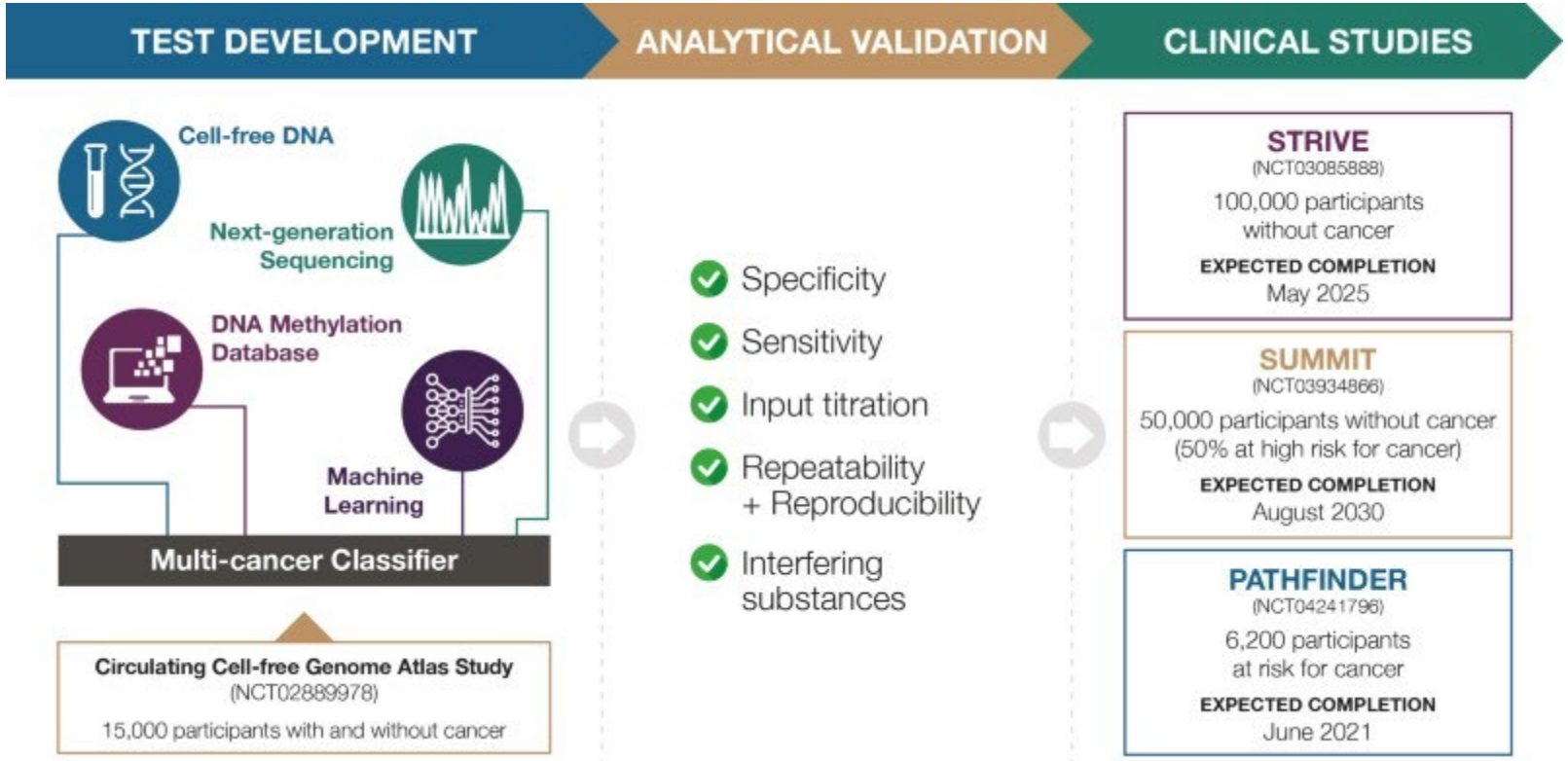
- Strata Sentinel Trial enrolling at Ochsner in this space.

MRD for Response Monitoring

- Emerging area for Precision Medicine, Strata trial will expand in 2023 to include this area.

Multi-Cancer Early Detection

Genomic Screening for Cancer



Multi-Cancer Early Detection: Blood-Based Screening

A

	Cancer	Non-cancer	Total
	2823	1254	4077
Test positive	1453	6	1459
Test negative	1370	1248	2618
	Sensitivity = 1453/2823 51.5% (49.6%-53.3%)	Specificity = 1248/1254 99.5% (99.0%-99.8%)	

Two-sided 95% Wilson confidence intervals were calculated.

B

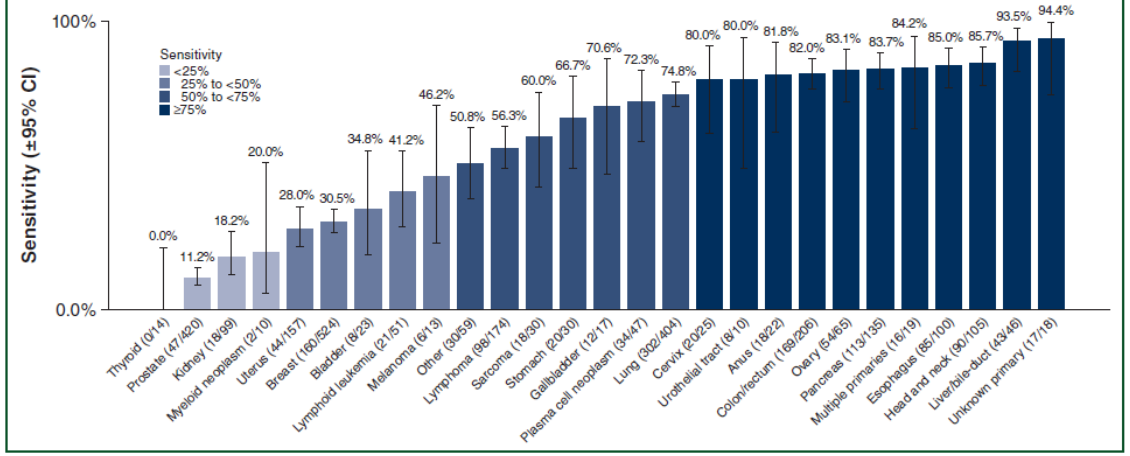


Figure 3. MCED test performance for cancer signal detection (A) overall sensitivity and specificity, (B) sensitivity by cancer class, and (C) sensitivity by stage in 12 pre-specified cancers.
(A) The 2 × 2 contingency table summarizes overall sensitivity and specificity. (B) Sensitivity (y-axis) by cancer class based on individual cancer classes (x-axis), including other, unknown primary, and multiple primaries. Cancer classes are ordered based on increasing sensitivity; bars indicate 95% CI. (C) Sensitivity by stage is depicted in each box for each of the 12 pre-specified cancer classes; bars indicate 95% CI.
CI, confidence interval; MCED, multi-cancer early detection.

C

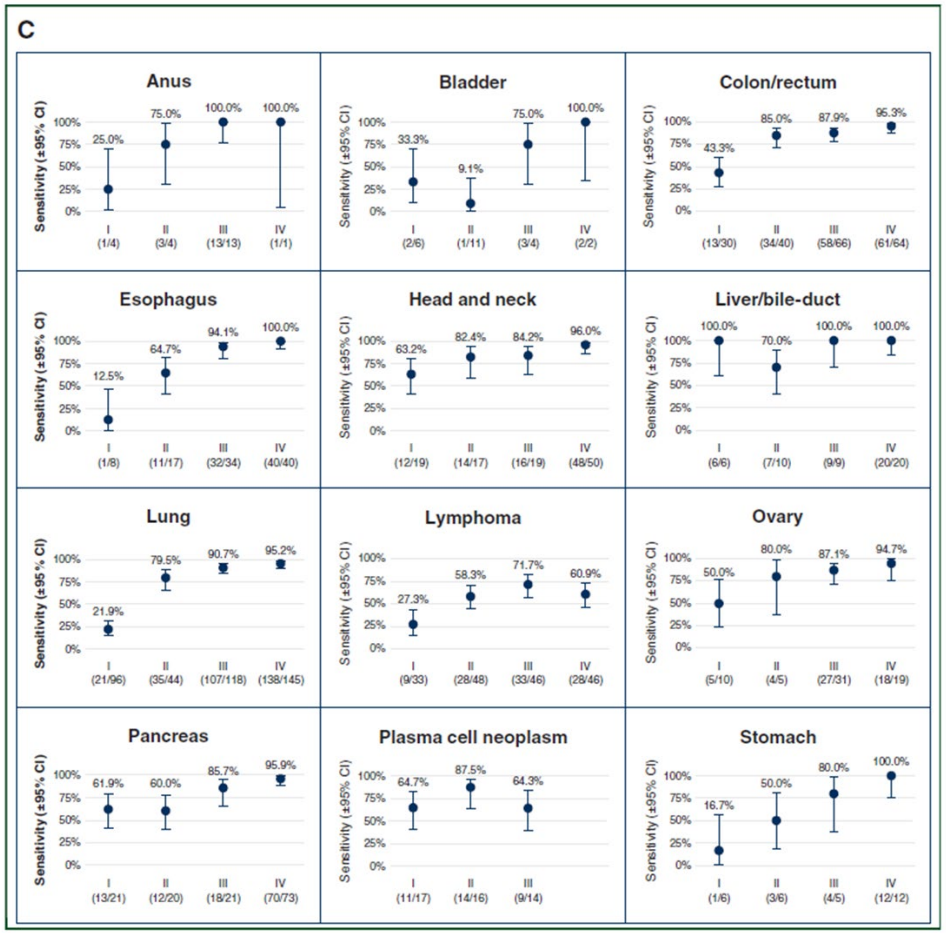


Figure 3. Continued.

MCED Projects

- Pathfinder2 Study – Grail
  - Enrolling 1,500 patients
- REFLECTION/Community Demonstration Project – Grail
  - Enrolling 7,500 diverse, underserved patients in our community health centers
  - Will enrich data with underrepresented minority patient samples
- DELFI Partnership
  - Two studies aimed at validating a blood-based screening test for lung cancer

Advocacy and Precision Medicine

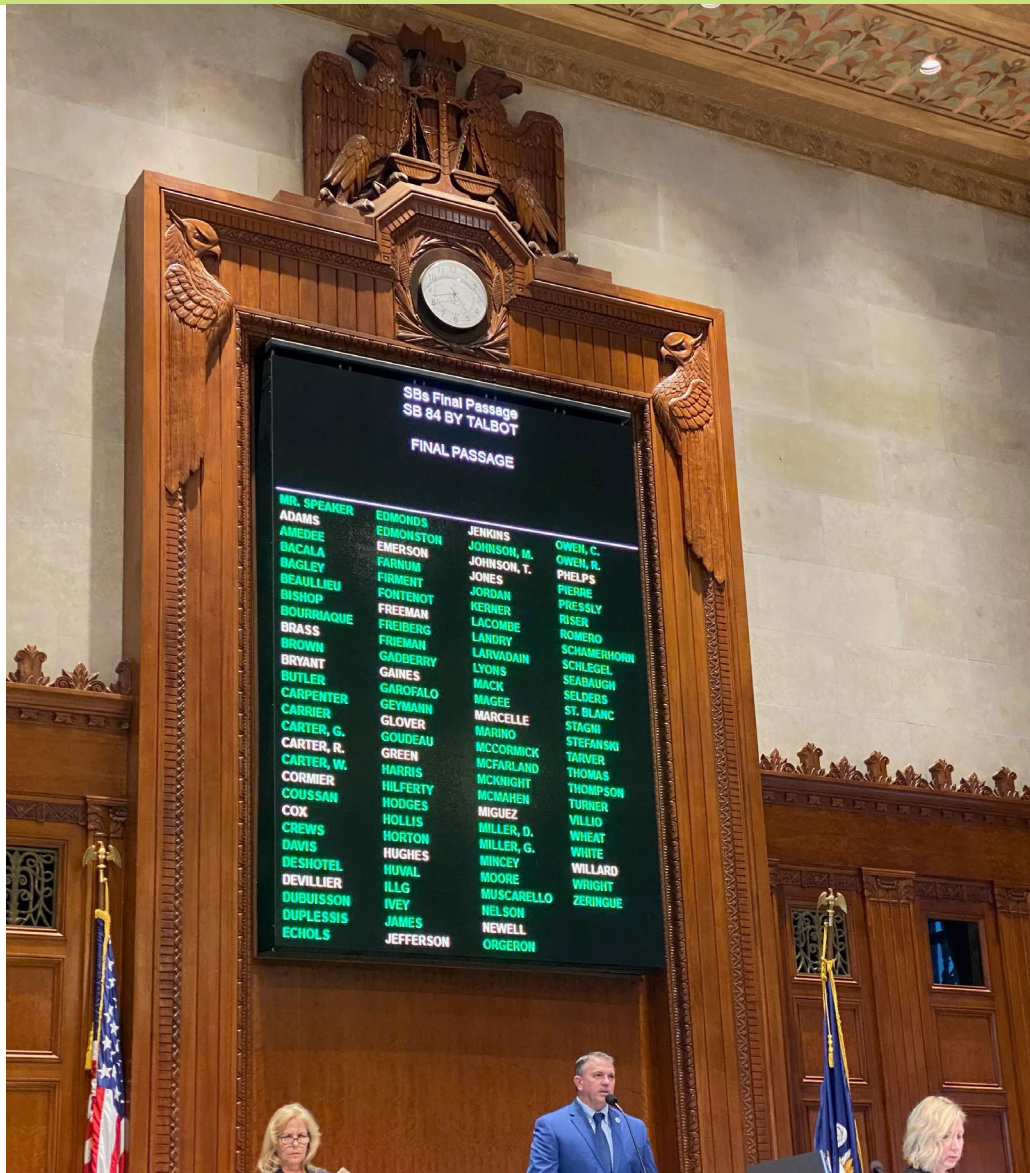
CAGLA Precision Medicine Legislative Advocacy

- SB 204 (2020)
  - Unanimously passed House and Senate, Signed into law
  - Mandated insurance coverage of precision medicine treatments for cancer patients

- Also in 2020, we amended LA revised statue 22:1044 mandating insurance coverage of phase 1 clinical trial patients with cancer

CAGLA Precision Medicine Legislative Advocacy

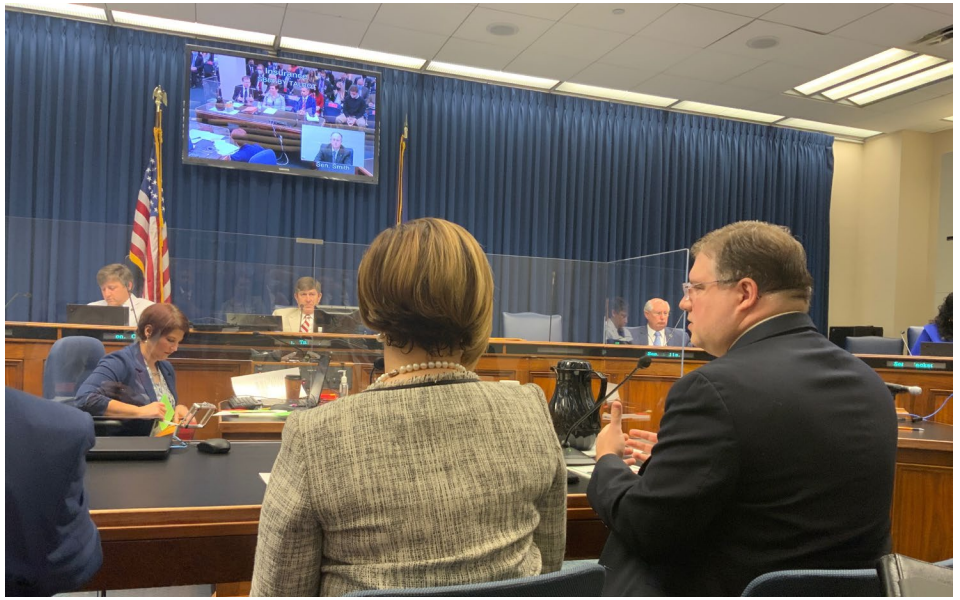
- SB 84 (2021) - now signed into law
  - Mandates insurance coverage of any/all genetic/genomic testing in cancer patients



CAGLA Precision Medicine Legislative Advocacy

- SB 118 (2022) – now signed into law
  - Mandates broad coverage for biomarker testing
- SB 146 (2022) – now signed into law
  - Strengthens our previous precision medicine treatment bill
- SB 154 (2022) – now singed into law (Act 501)
  - Mandates insurance and Medicaid coverage for WGS in NICU
- These bills are progressive and unprecedented and serve as examples for other state legislatures and national efforts

For more information: CAG-LA.org



The Future of Precision Medicine

- What Does the Future Hold?

  - Precision Medicine will transform every aspect of medical care
  - Adoption of new technologies (CRISPR, gene editing, etc), germline?
  - Greater integration of other “–omics”
  - Expansion of AI and advanced machine learning
  - Expanded access, lower prices
  - Better outcomes for patients

ANY QUESTIONS?