AACI Association of American Cancer Institutes

Innovating Cancer Genetics Programs: From Pharmacogenomics to Longitudinal Prevention

PCLI WEBINAR SERIES

Moderator: Jason Fleming, MD
Speakers: Sara Pirzadeh-Miller, MS, CGC; Rachel Wooldridge, MD; and Christine Hong, PharmD, MBA, BCOP

September 15, 2026 • 1:00-2:00 pm ET

Cancer Genetics Program Innovations: From Pharmacogenomics to Longitudinal Prevention

Sara Pirzadeh-Miller, MS, CGC
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UT Southwestern
Medical Center

Simmons Cancer Center Dallas

Children's Med Ctr Plano

Simmons Cancer Center FW

UTSW Cancer Genetics Clinics

Children's Med Ctr Dallas

Parkland Health (safety net)

JPS Health (safety net)

Cancer Genetics: Current and future health system impact

Pharmacogenomics (PGx) workflow: building system-wide infrastructure

Family history of cancer screening automation: SCC and primary care

Analyzing DSR: replicating our method in prenatal and cardiology

GCPC: High growth preventative oncology model

MCED testing: future of cancer screening across populations with GC leadership

Driving the GC profession pipeline: cancer genetics GCs leading new Masters in GC program

Pharmacogenomic case: DPD deficiency

5-FU and Capecitabine commonly in gastrointestinal, head & neck, breast, and other cancers

Dihydropyrimidine dehydrogenase (DPD) break down fluoropyrimidine chemotherapy

Approximately 3%–8% of individuals carry at least one clinically significant DPYD variant

DPD deficiency can result in severe or life-threatening treatment toxicity.

2.3% Treatment-related mortality in variant carriers vs. 0.1% in the general population receiving fluoropyrimidine therapy.

2–4 fold increased risk with standard-dose 5-FU

DPYD requirement labeling update

10/2025 FDA Labeling Update:
Black box warning added to Xeloda (capecitabine) recommending DPYD testing

2/2026 FDA Labeling Update:
Fluorouracil (5-FU) recommending DPYD testing

NCCN guidelines recommend DPYD genotyping before treatment initiation across multiple GI cancers

Problem & Aim Statement

Problem

- DPYD gene testing is not integrated into the standard clinical workflow. EMR-based PGx decision support does not exist to assist HCPs.
- This gap delays identification of patients with DPYD variants, increases the risk of fluorouracil-related toxicity.

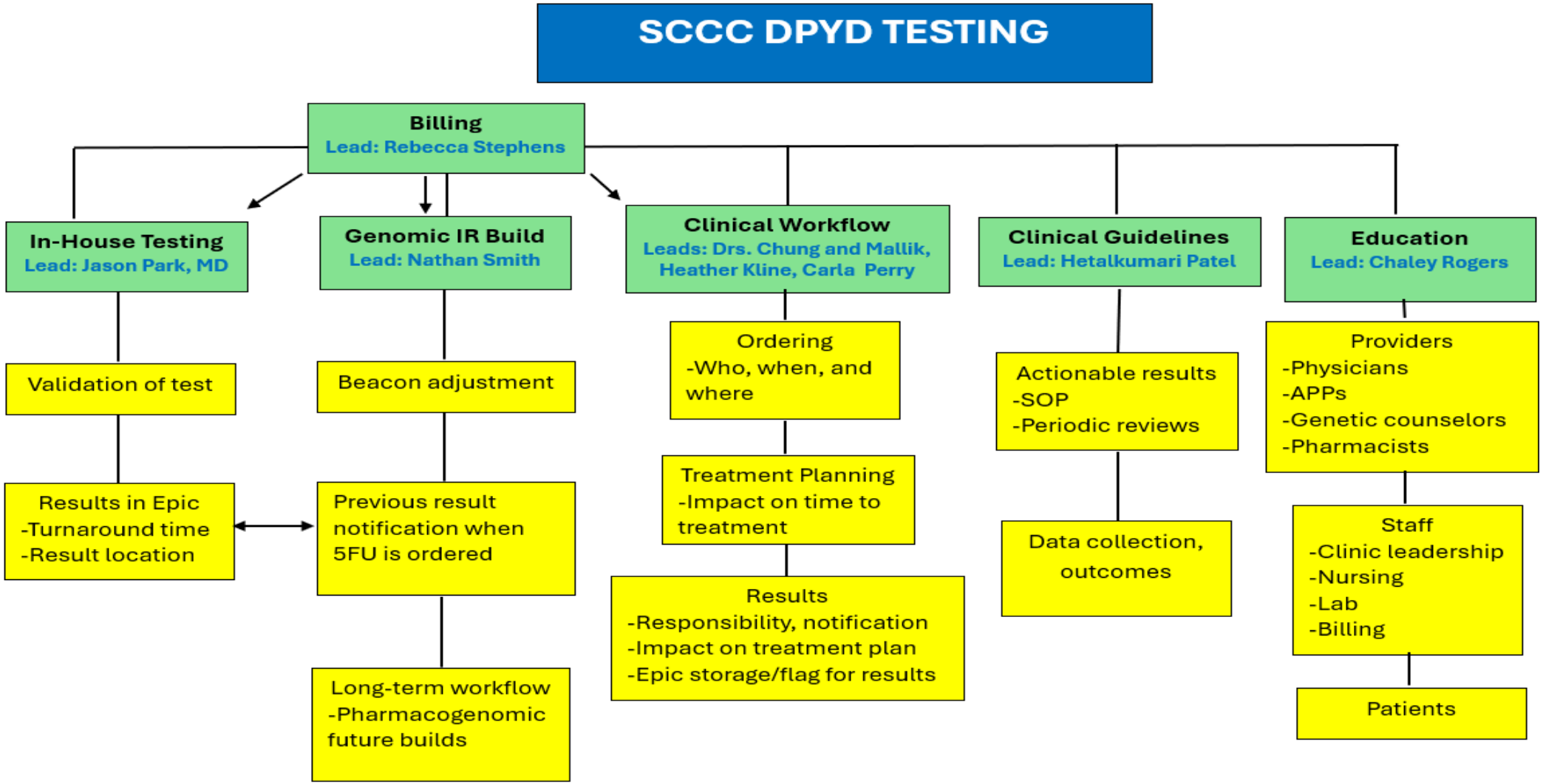
AIM

- Improve DPYD testing compliance to from 10% to **greater than 80%** before treatment initiation by December 2026

Key Performance Metrics

- Total Number of new capecitabine and 5-FU start monthly (distinct)
- Total in-house DPYD ordered vs. external orders
- Total number of test performed and results
- Number DPYD tests ordered prior to chemo day 1
- DPYD order to result Turnaround Time trends
- Reimbursement and Denials

DPYD Testing Initiative Workgroups



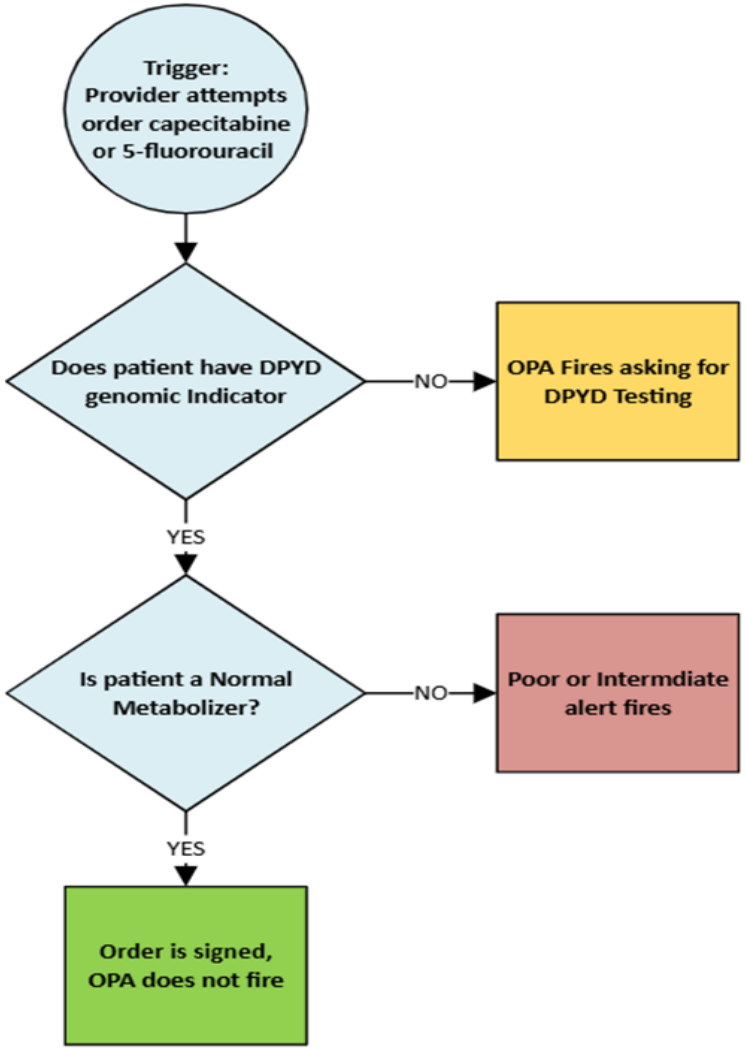
In-House DPYD Testing Progress

- Previous DPYD testing at UT Southwestern was an external “send out” lab, with results taking 7-10 + days.

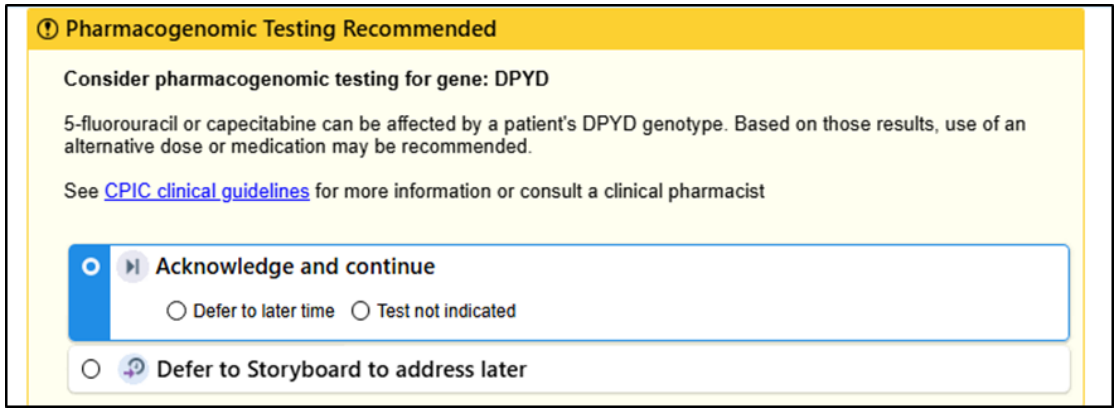
- UT Southwestern DPYD testing began on April 8, 2026
  - Turnaround time improvement
  - 3.7 calendar days; 2.5 working days

- Billing/reimbursement
  - Prior authorization plan
  - Correct code selection is key

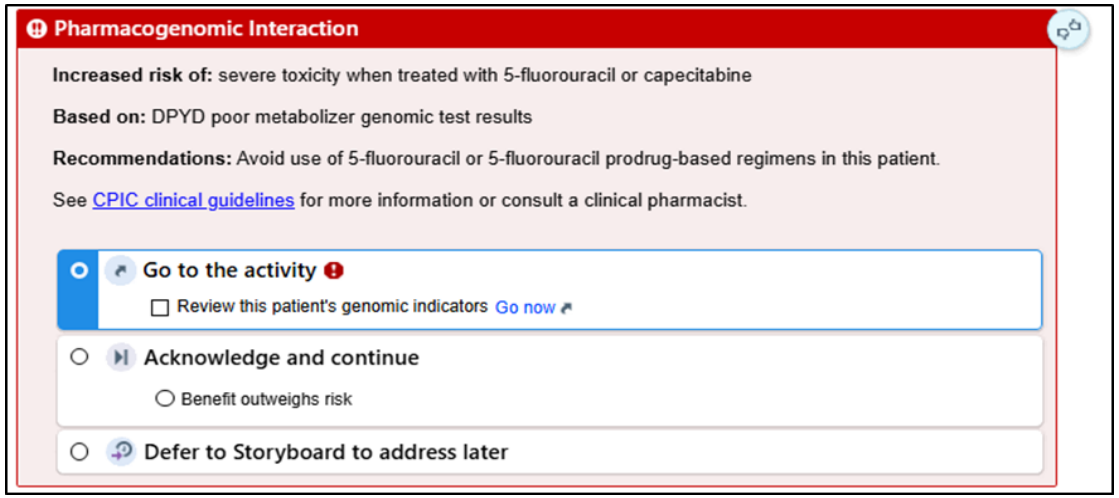
EHR Order Pattern Advisory



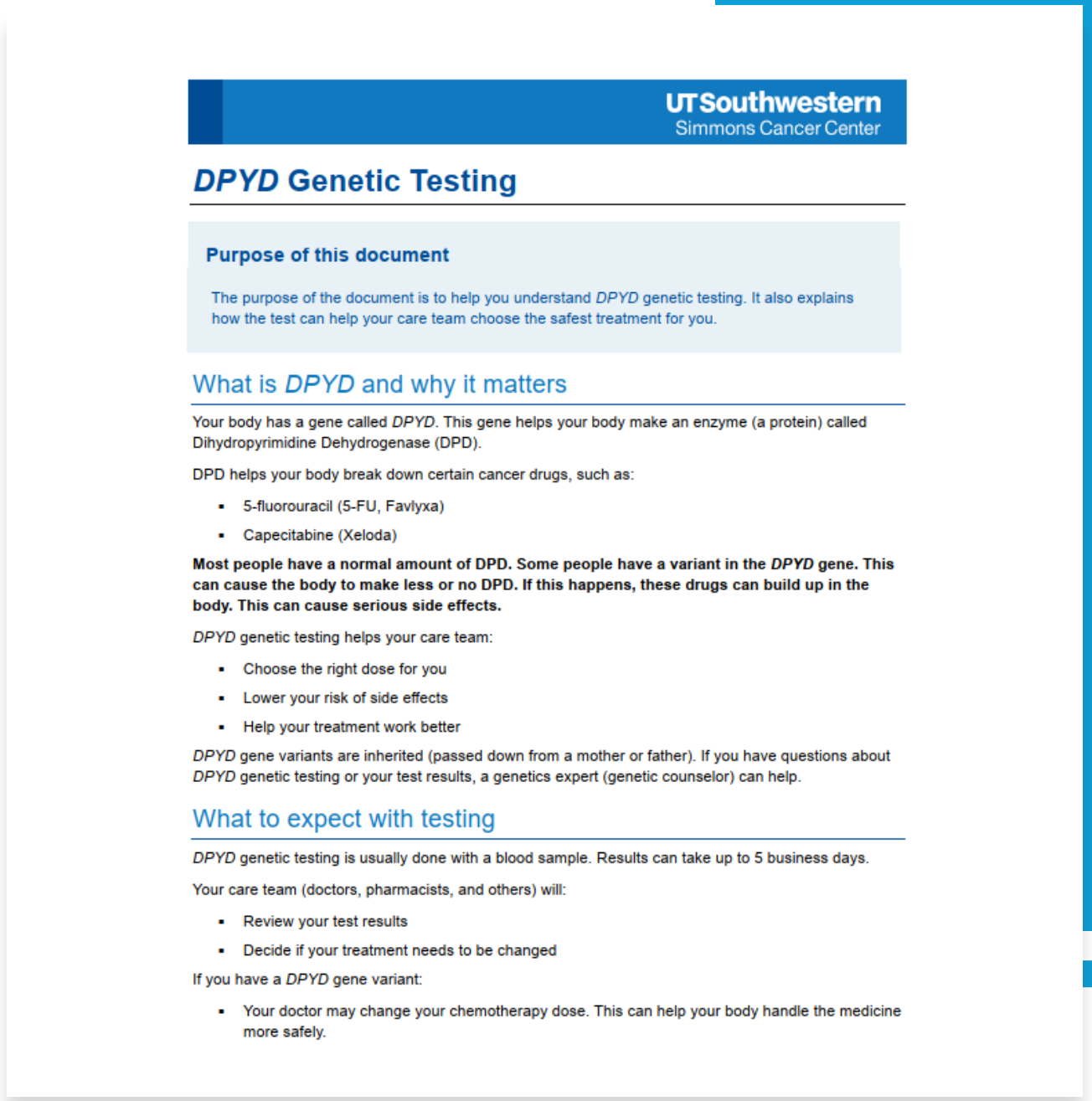
No DPYD result on file → OPA asks for testing



Poor/reduced metabolizer → OPA fires with dosing guidance



Patient education



UTSouthwestern
Simmons Cancer Center

DPYD Genetic Testing

Purpose of this document

The purpose of the document is to help you understand *DPYD* genetic testing. It also explains how the test can help your care team choose the safest treatment for you.

What is *DPYD* and why it matters

Your body has a gene called *DPYD*. This gene helps your body make an enzyme (a protein) called Dihydropyrimidine Dehydrogenase (DPD).

DPD helps your body break down certain cancer drugs, such as:

- 5-fluorouracil (5-FU, Favlyxa)
- Capecitabine (Xeloda)

Most people have a normal amount of DPD. Some people have a variant in the *DPYD* gene. This can cause the body to make less or no DPD. If this happens, these drugs can build up in the body. This can cause serious side effects.

DPYD genetic testing helps your care team:

- Choose the right dose for you
- Lower your risk of side effects
- Help your treatment work better

DPYD gene variants are inherited (passed down from a mother or father). If you have questions about *DPYD* genetic testing or your test results, a genetics expert (genetic counselor) can help.

What to expect with testing

DPYD genetic testing is usually done with a blood sample. Results can take up to 5 business days.

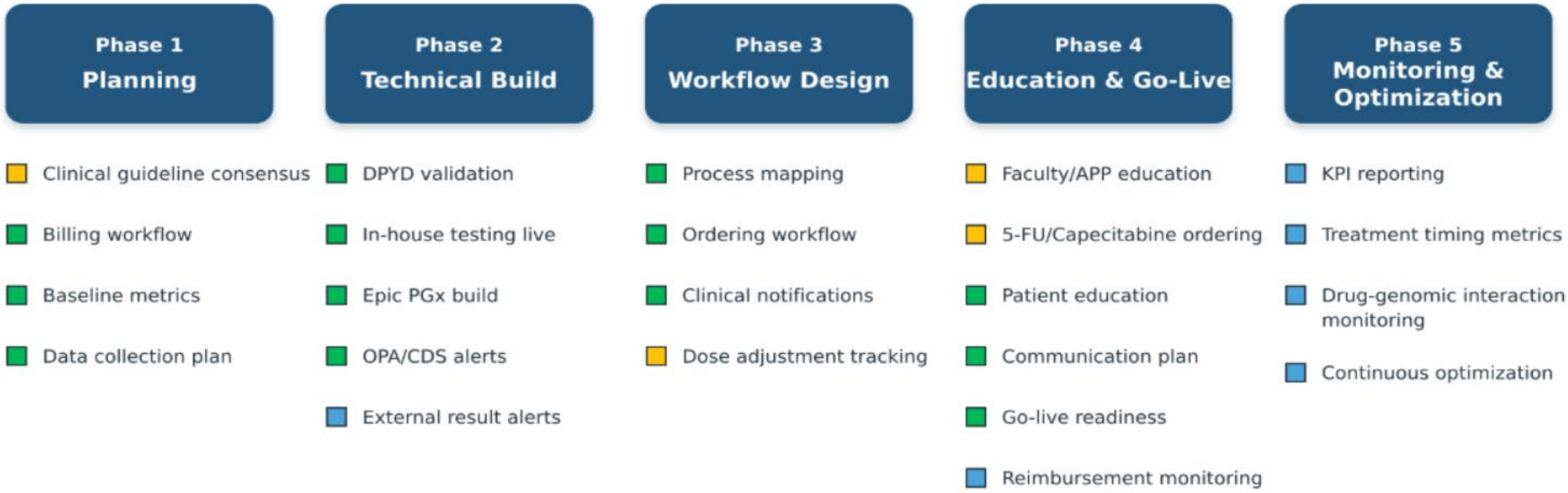
Your care team (doctors, pharmacists, and others) will:

- Review your test results
- Decide if your treatment needs to be changed

If you have a *DPYD* gene variant:

- Your doctor may change your chemotherapy dose. This can help your body handle the medicine more safely.

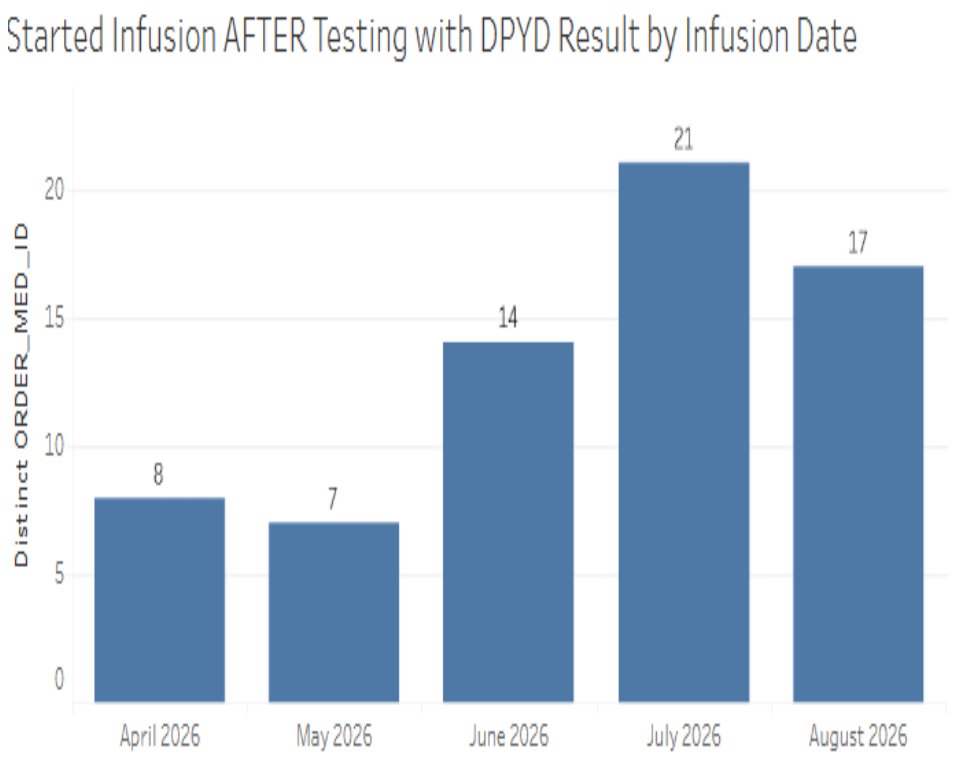
Project Plan as of 9/1/26

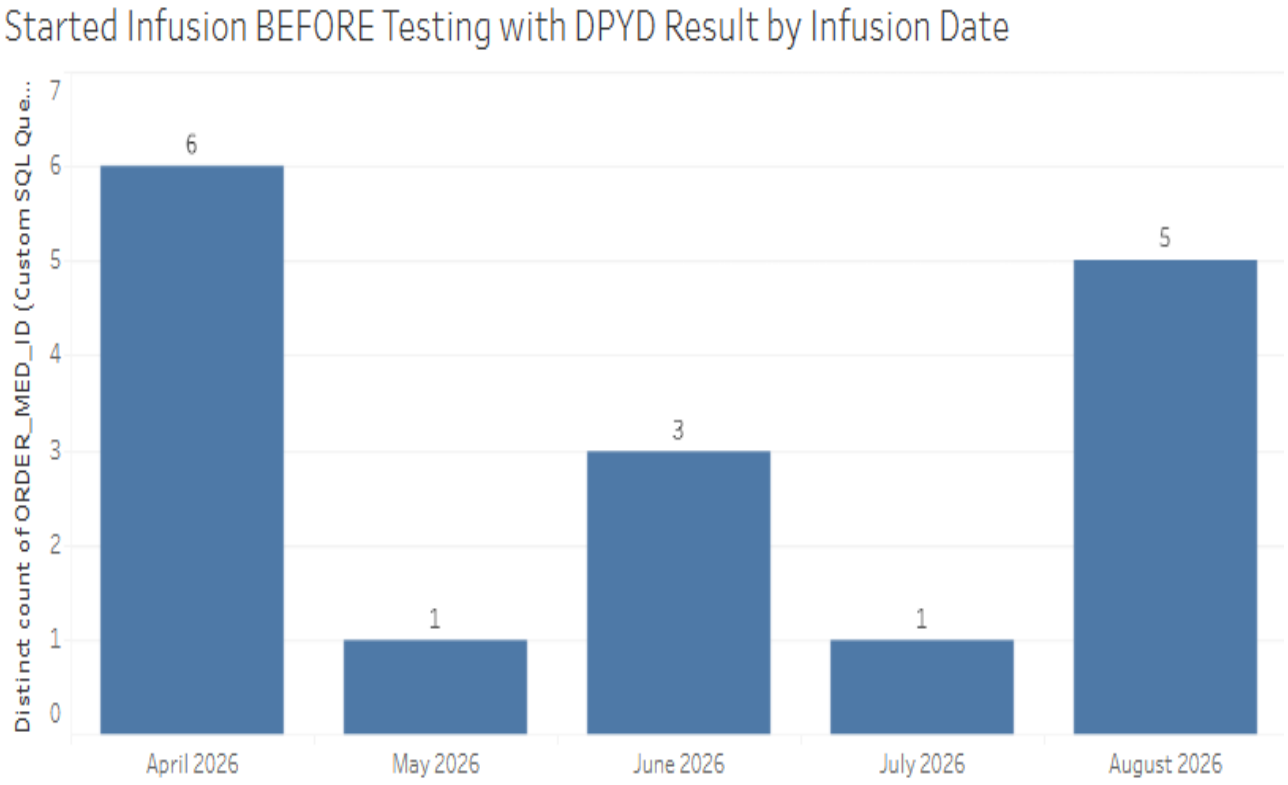


Status Legend

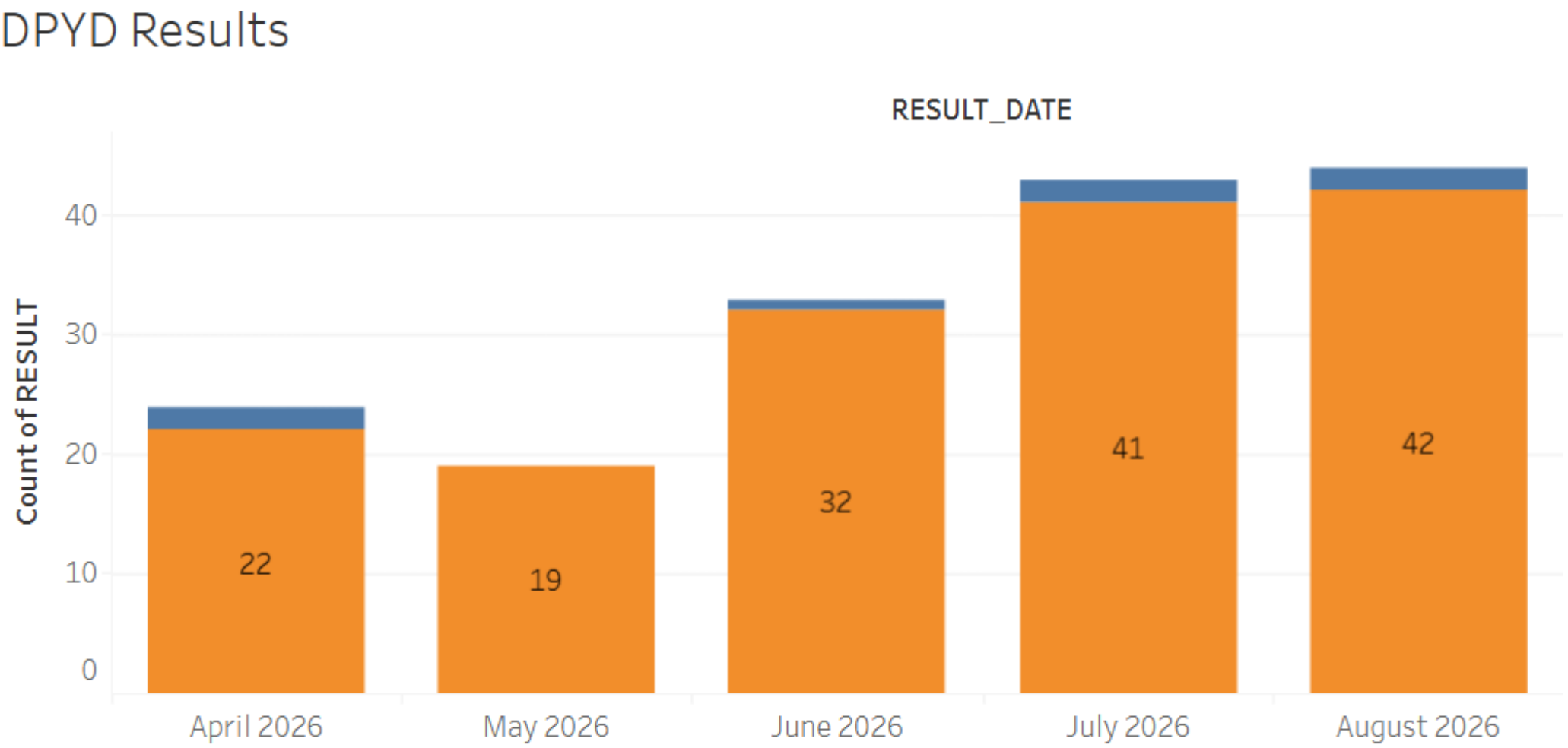
- Complete
- In Progress
- Ongoing

DPYD program build: preliminary outcomes

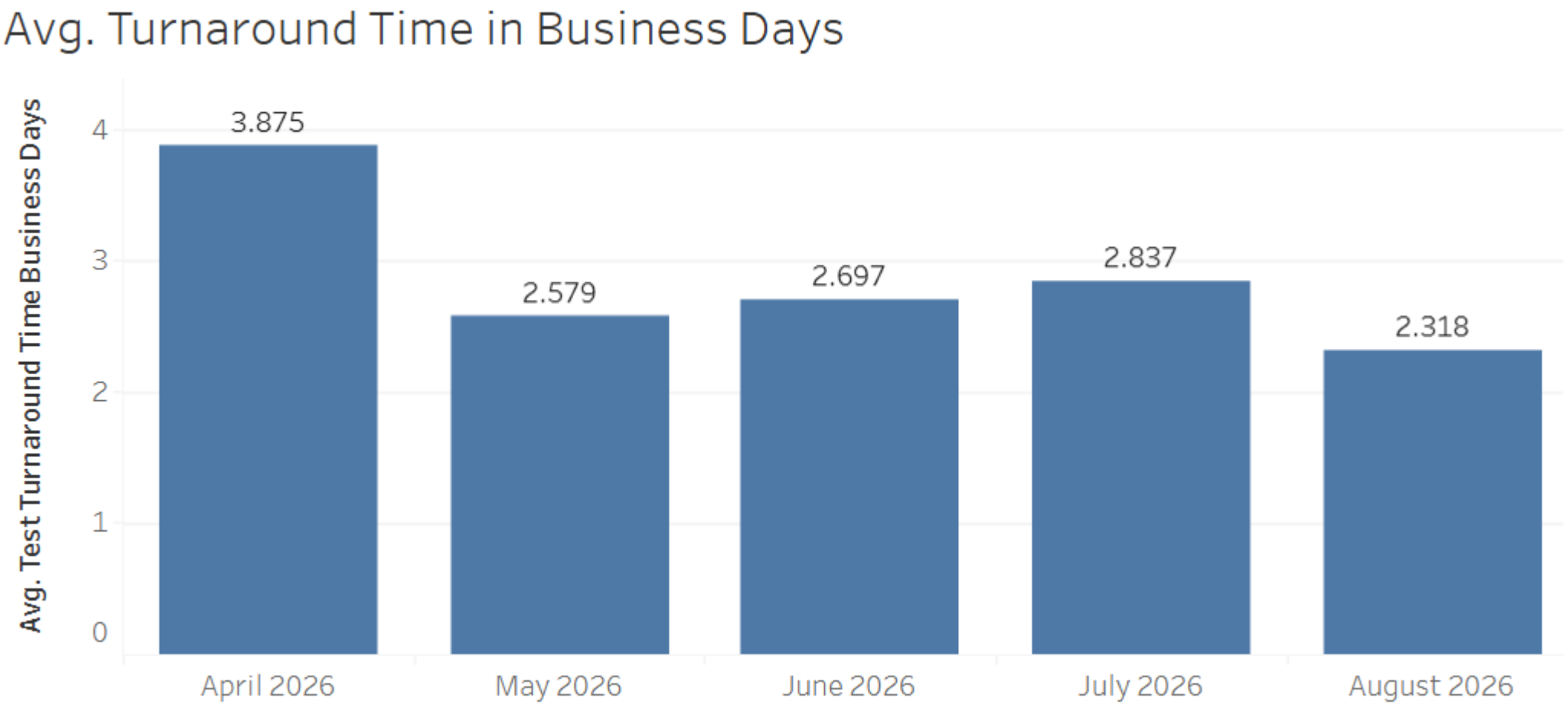




Result: Total Testing Completed (April – Aug 2026)



Result: Average Turnaround Time Order to Result



Where are we going next?

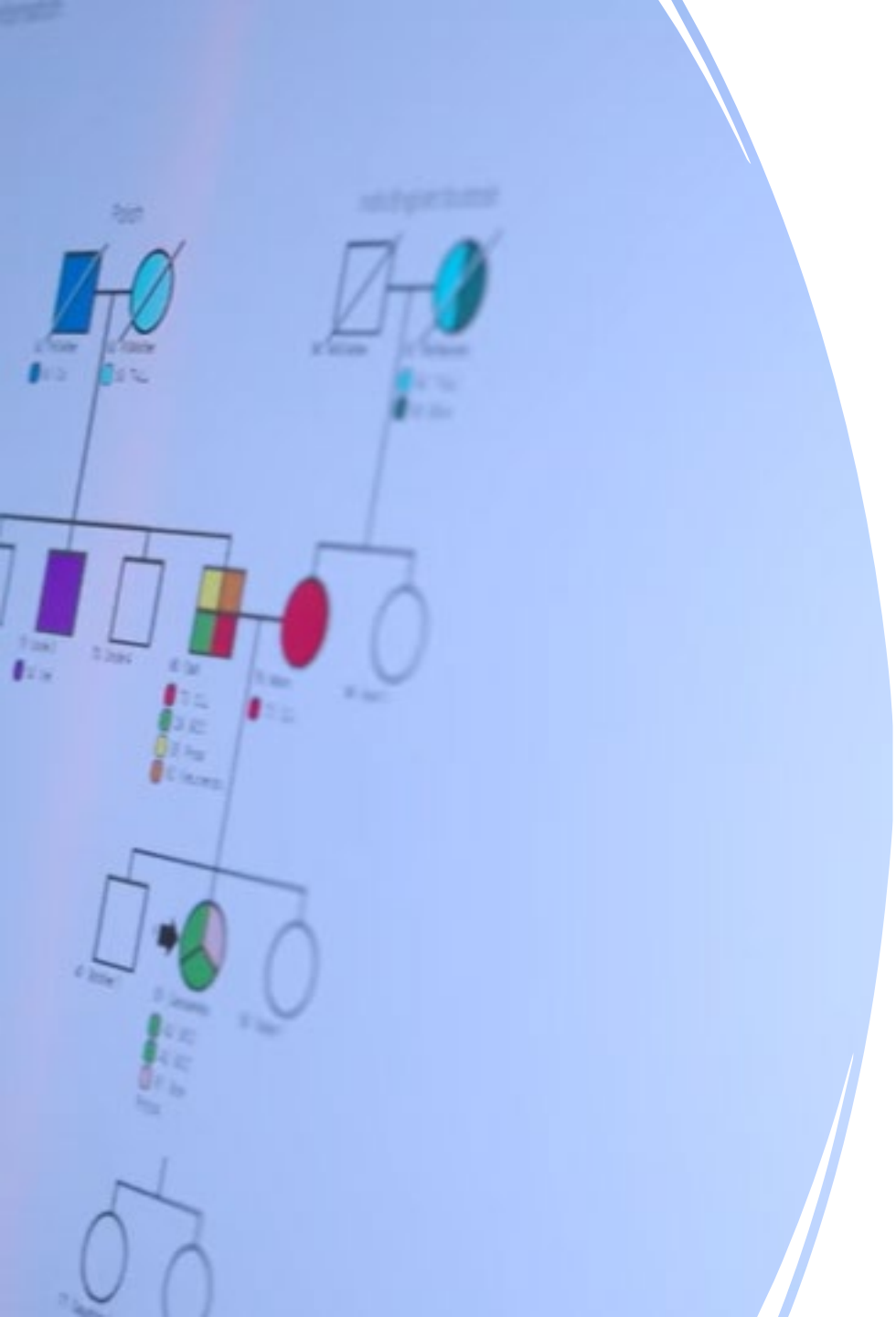
Upcoming NCCN conference submission

Adding PGx indication in oncology

UGT1A1 exploration

Assess PGx infrastructure for health system – future discussions

Cardiology, neurology, etc



Genetic Cancer Prevention Clinic

NCI 2023

"Precision Prevention – it can end cancer as we know it by preventing suffering and death for those at risk and helping those not at risk avoid unnecessary tests and therapy."

Genetic Cancer Prevention Clinic (GCPC)

Creation of a centralized clinic to direct medical care for those with a hereditary predisposition to cancer

Purpose: Prevent and Reduce Cancer Incidence

- Longitudinal cancer risk reduction
- Promotion of cascade testing
- Clinical research

UT Southwestern
Harold C. Simmons
Comprehensive Cancer Center

NCI
Designated
Comprehensive
Cancer Center

NCCN
National
Comprehensive
Cancer
Network®
Member Institution

GCPC: Overview

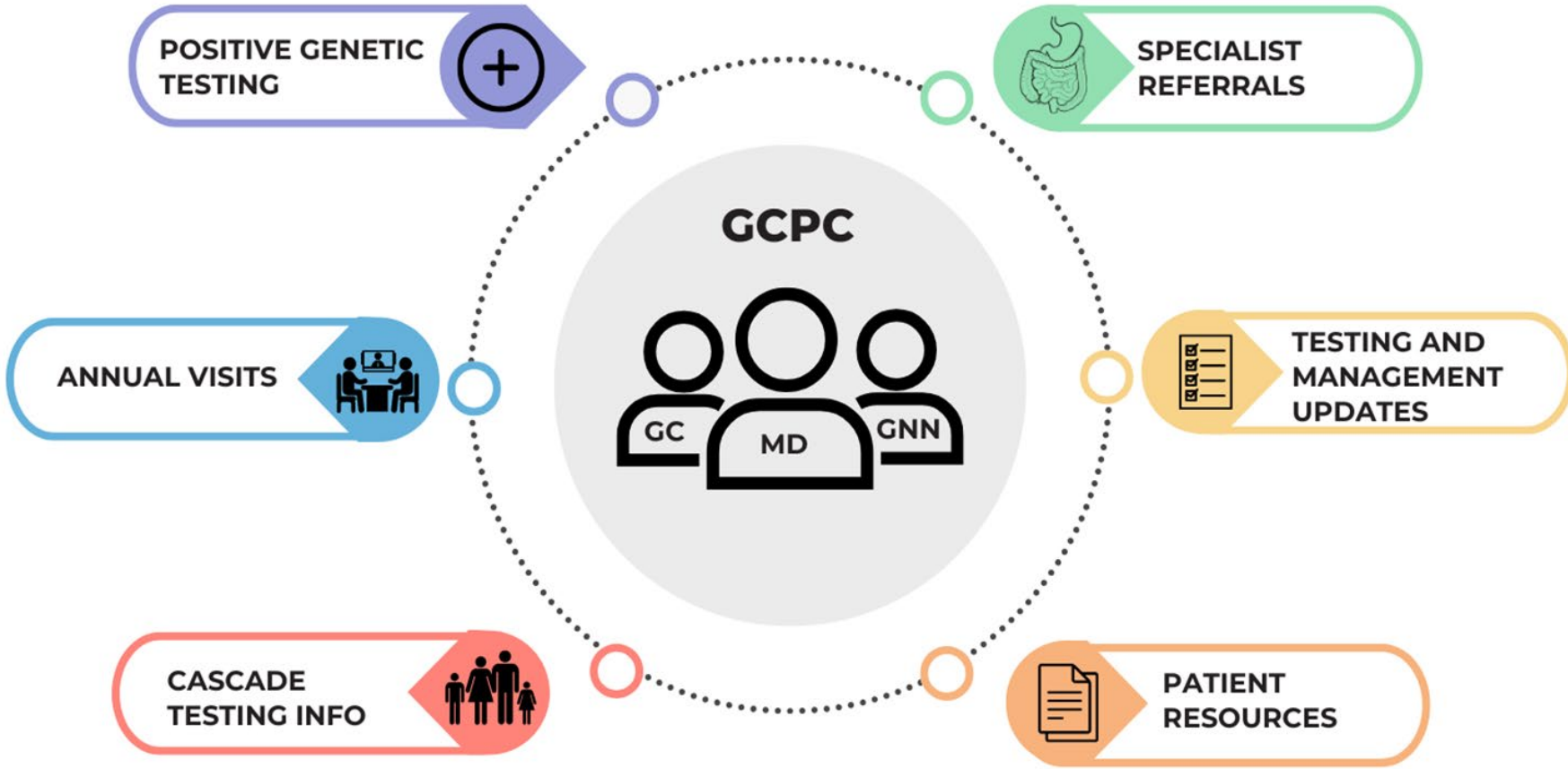
Clinical program and research interface

Multidisciplinary clinical team

- Team of MDs (including Medical Director), Advanced Practice Providers; Genetic Nurse Navigator (GNN); Genetic Counselors, Social Workers.
- Other personnel: Patient Access Specialist and a future dedicated research coordinator
- Availability for referral to all Cancer Center resources

Important definitions

- Does not replace a disease site clinic
  - Example: breast cancer risk management needs goes to high-risk breast clinic
- 'Quarterback' for patients with hereditary cancer syndromes (2 or more lifetime elevated cancer risks)
  - Coordination, navigation, management review touchpoint to ensure ALL risks covered
  - Added focus on family and cascade testing education
  - Offer clinical trial participation


POSITIVE GENETIC TESTING
SPECIALIST REFERRALS
GCPC
GC
MD
GNN
ANNUAL VISITS
TESTING AND MANAGEMENT UPDATES
CASCADE TESTING INFO
PATIENT RESOURCES

GCPC: Making the Case

- Destination clinic – external high-risk individuals will come for care and stay within institution.
- At-risk relatives: expanding familial risk identification through cascade testing
- Direct (visit) and indirect (downstream) revenue
- Differentiator service line for SCCC
- Provider satisfaction: significant reduction in referral entry and coordination of highly complex patients with (at times) frequently changing recommendations for surveillance

GCPC: Multi-Disciplinary Clinic flow map

GC

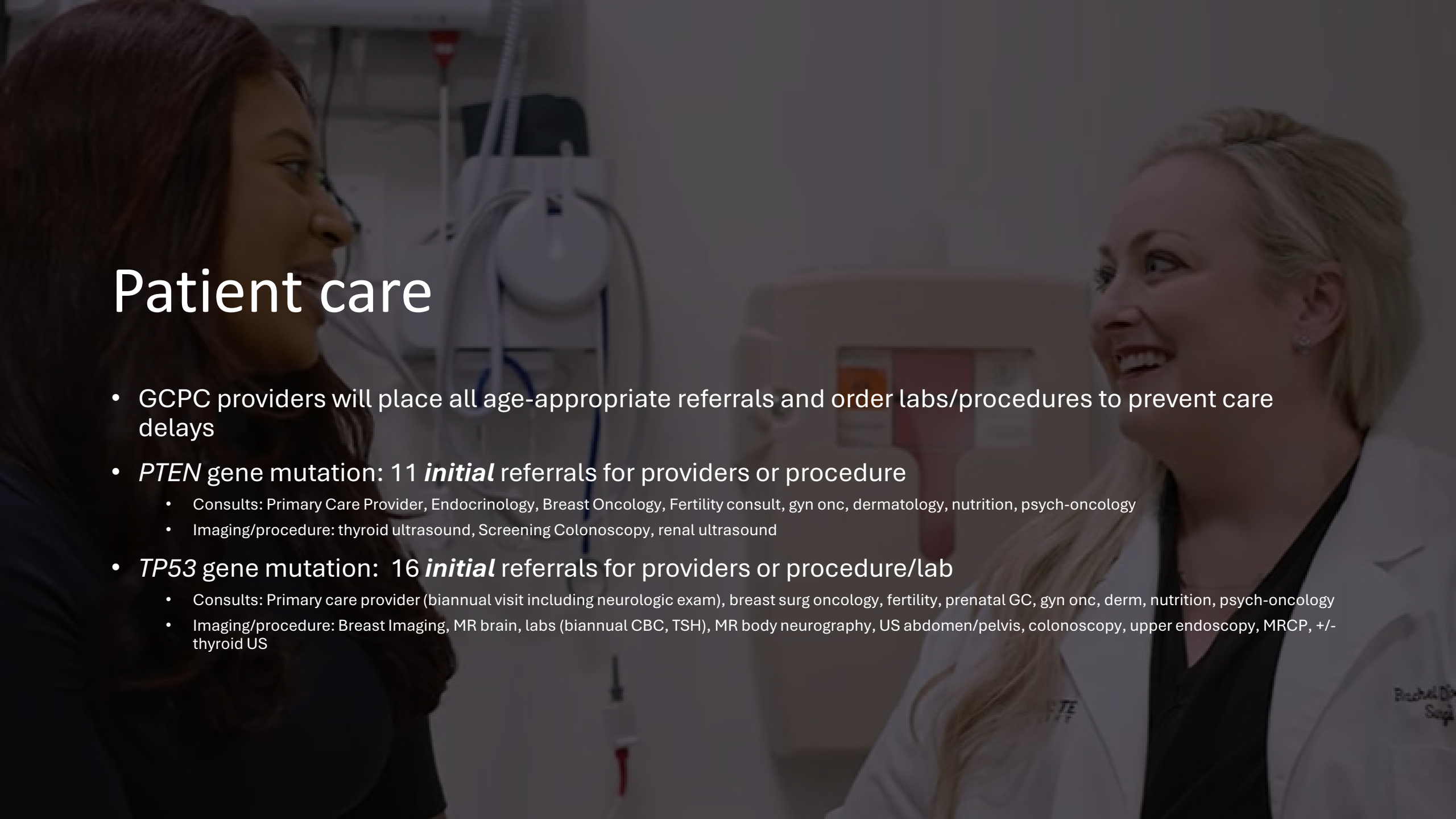
Prior: Medical Assistant vitals; RN medication reconciliation; standard clinic check in protocol/procedures
Review family history updates; genetic info and cascade testing questions.
Evaluate updated testing needs if applicable. Typical length: 25 minutes.

APP/MD

Mutation specific directed physical exam.
Review management recommendations/overall progress on compliance.
Referrals to appropriate providers, education on risk reduction. Typical length: 25 minutes.

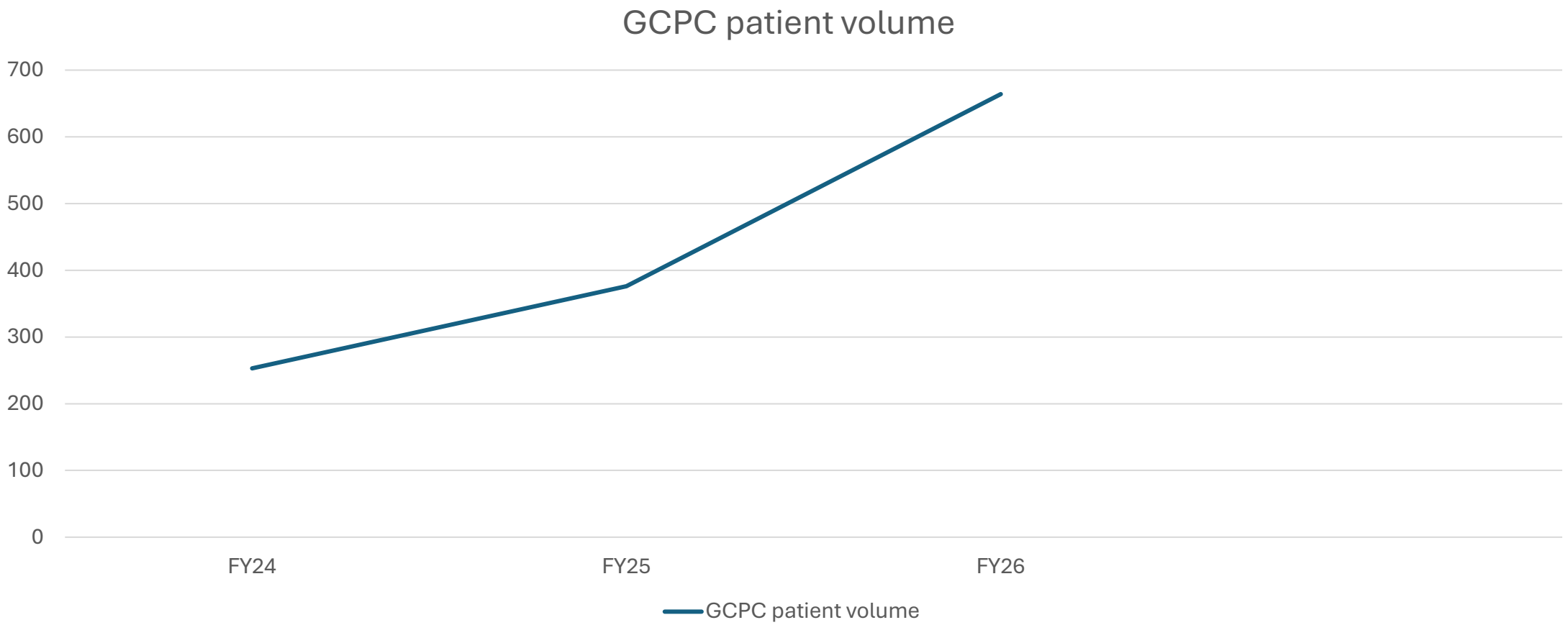
GNN

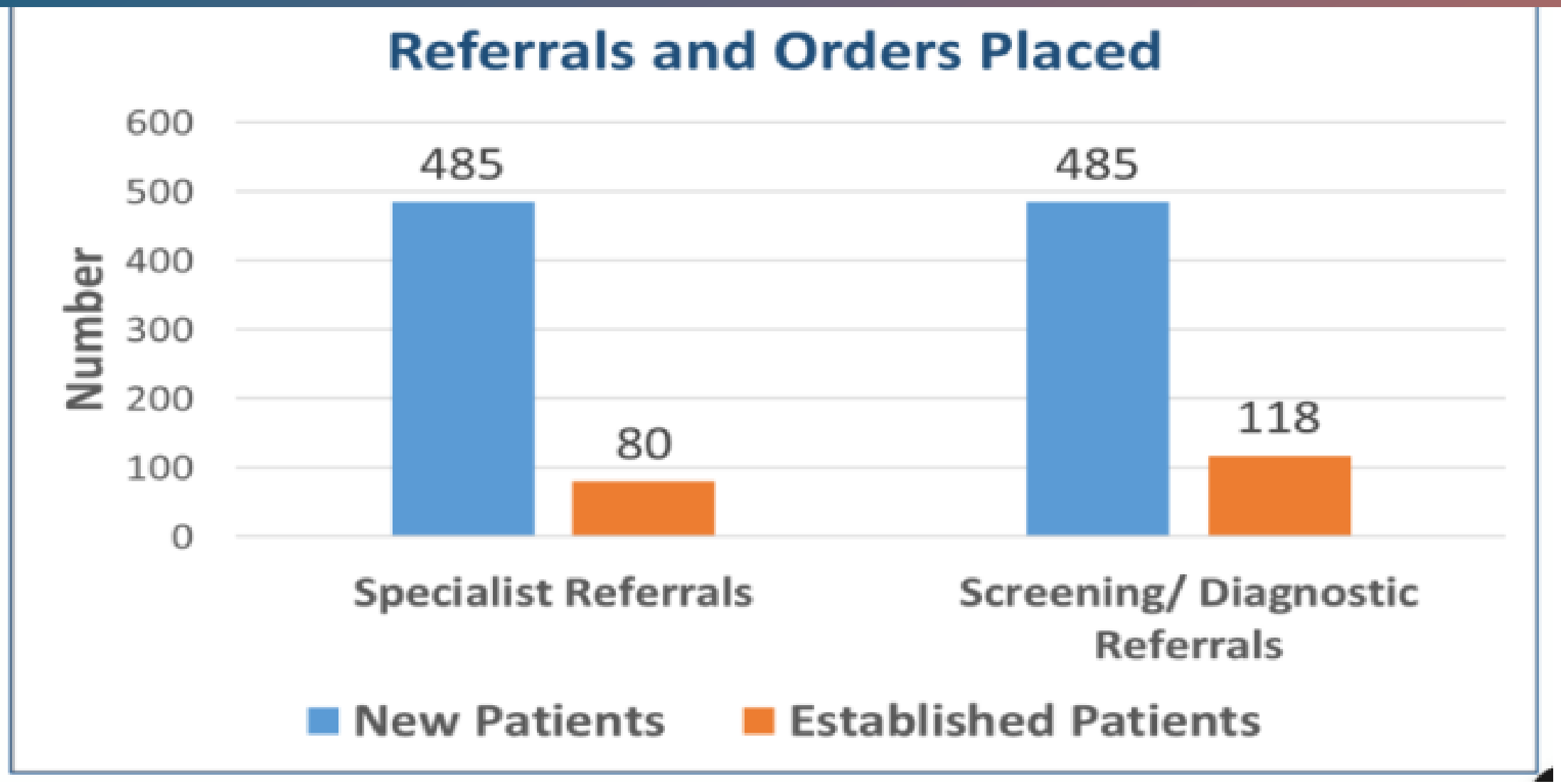
Review After Visit Summary and all recommendations.
Support resources including research opportunities.
Handoff to scheduling for next (annual) visit. Typical length: 10 minutes.



Patient care

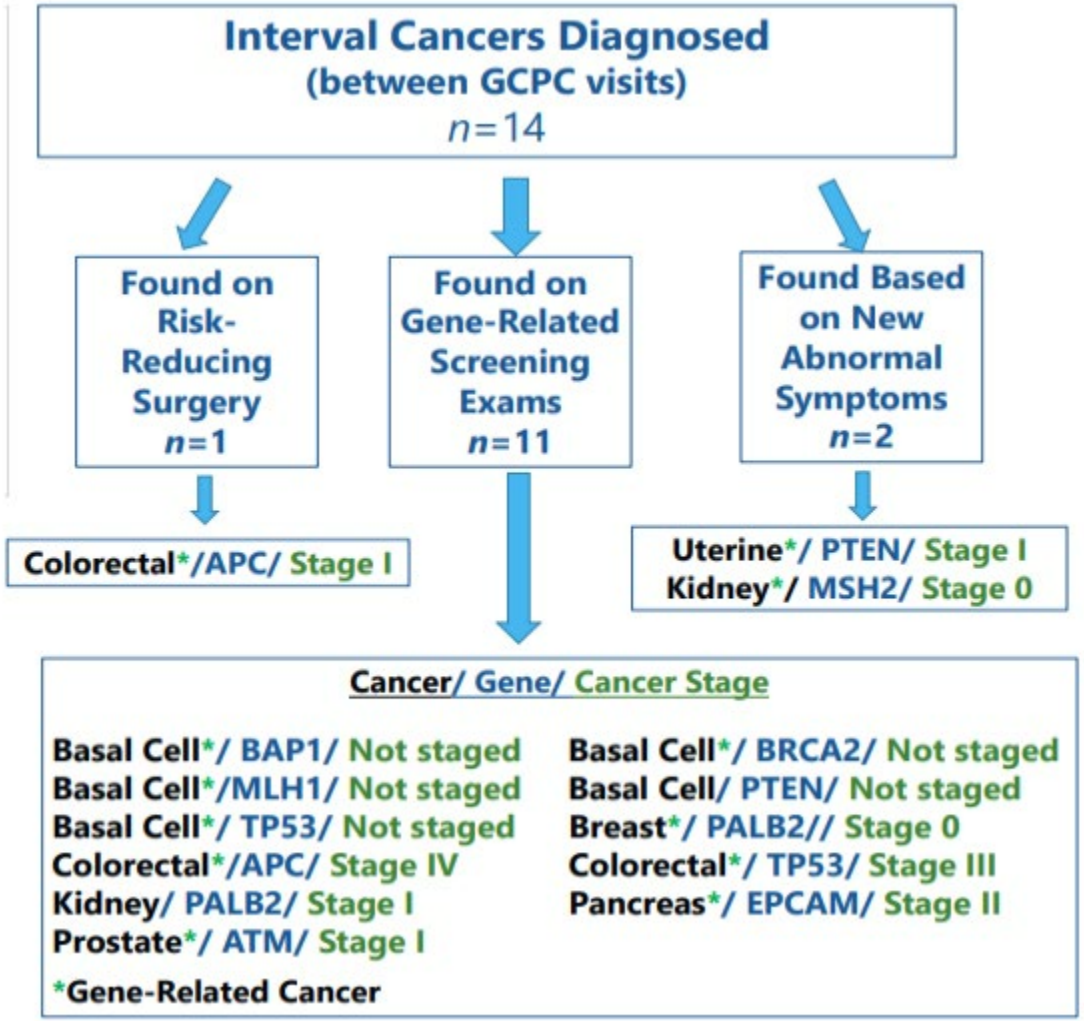
- GCPC providers will place all age-appropriate referrals and order labs/procedures to prevent care delays
- *PTEN* gene mutation: 11 ***initial*** referrals for providers or procedure
  - Consults: Primary Care Provider, Endocrinology, Breast Oncology, Fertility consult, gyn onc, dermatology, nutrition, psych-oncology
  - Imaging/procedure: thyroid ultrasound, Screening Colonoscopy, renal ultrasound
- *TP53* gene mutation: 16 ***initial*** referrals for providers or procedure/lab
  - Consults: Primary care provider (biannual visit including neurologic exam), breast surg oncology, fertility, prenatal GC, gyn onc, derm, nutrition, psych-oncology
  - Imaging/procedure: Breast Imaging, MR brain, labs (biannual CBC, TSH), MR body neurography, US abdomen/pelvis, colonoscopy, upper endoscopy, MRCP, +/- thyroid US

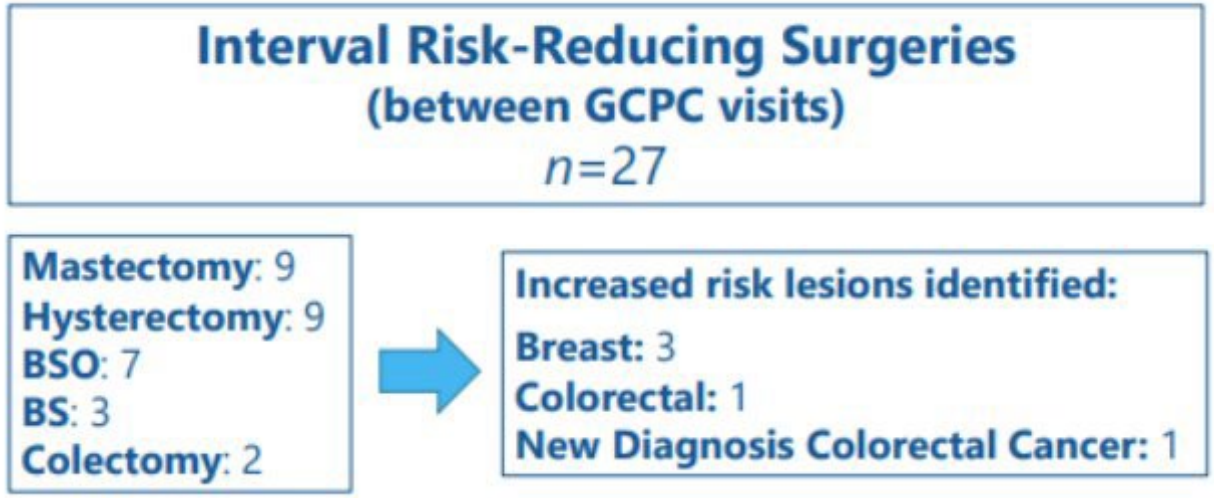

GCPC patient volume
700
600
500
400
300
200
100
0
FY24
FY25
FY26
GCPC patient volume



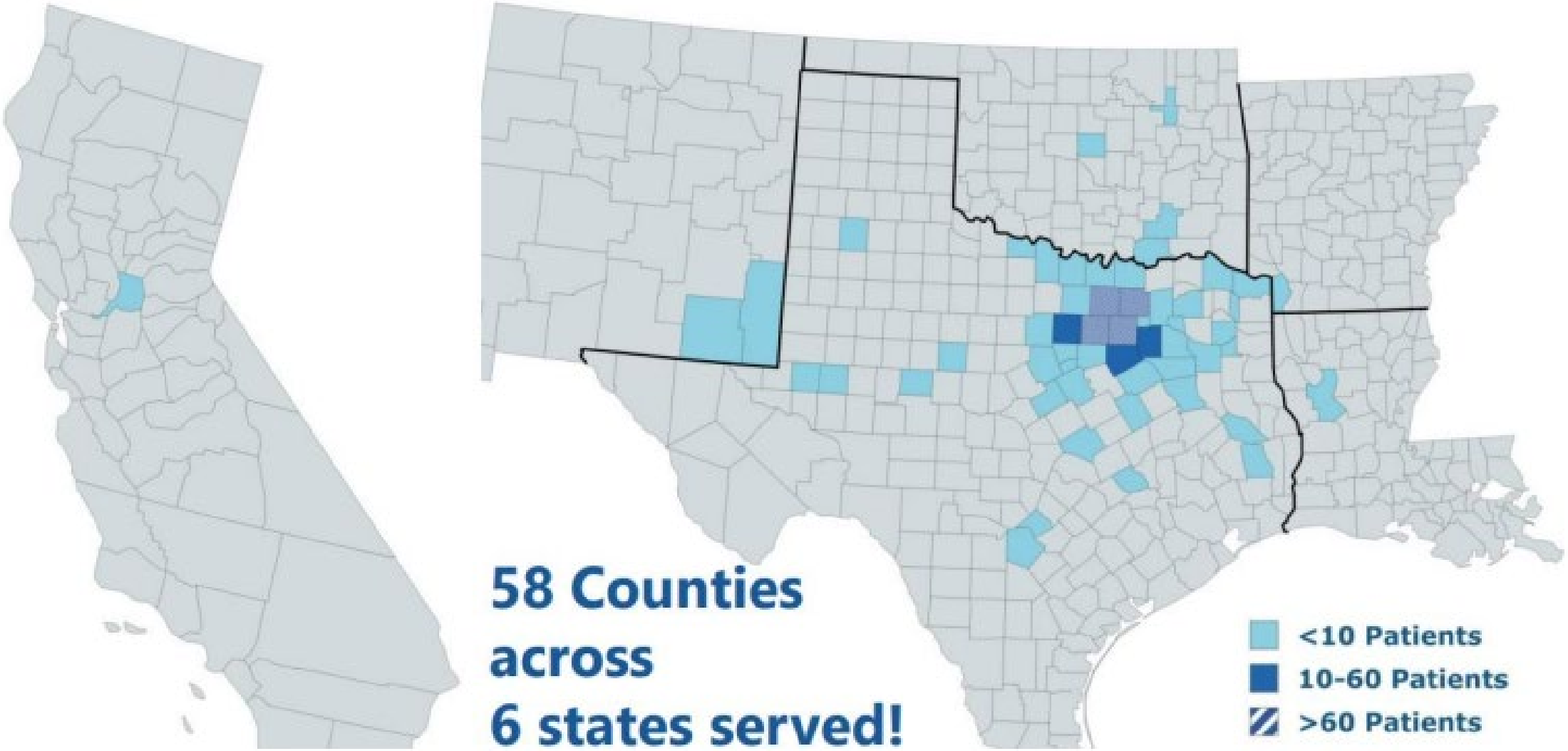
36-month experience of specialist orders and screening/diagnostic referrals placed for new and established patients, impacting downstream institutional activity and revenue.

Preliminary preventative outcomes





States and Counties Served



Downstream Revenue Generated by Patients With Hereditary Cancer in the Multigene Panel Testing Era

Caitlin B. Mauer Hall, MA, MS, CGC[1]; Brian D. Reys, MS, CGC[2]; Amber P. Gemmell, MS, CGC[2]; Connor L. Campbell, BBA[3]; and Sara M. Pirzadeh-Miller, MS, CGC[2]

DOI https://doi.org/10.1200/OP.23.00817

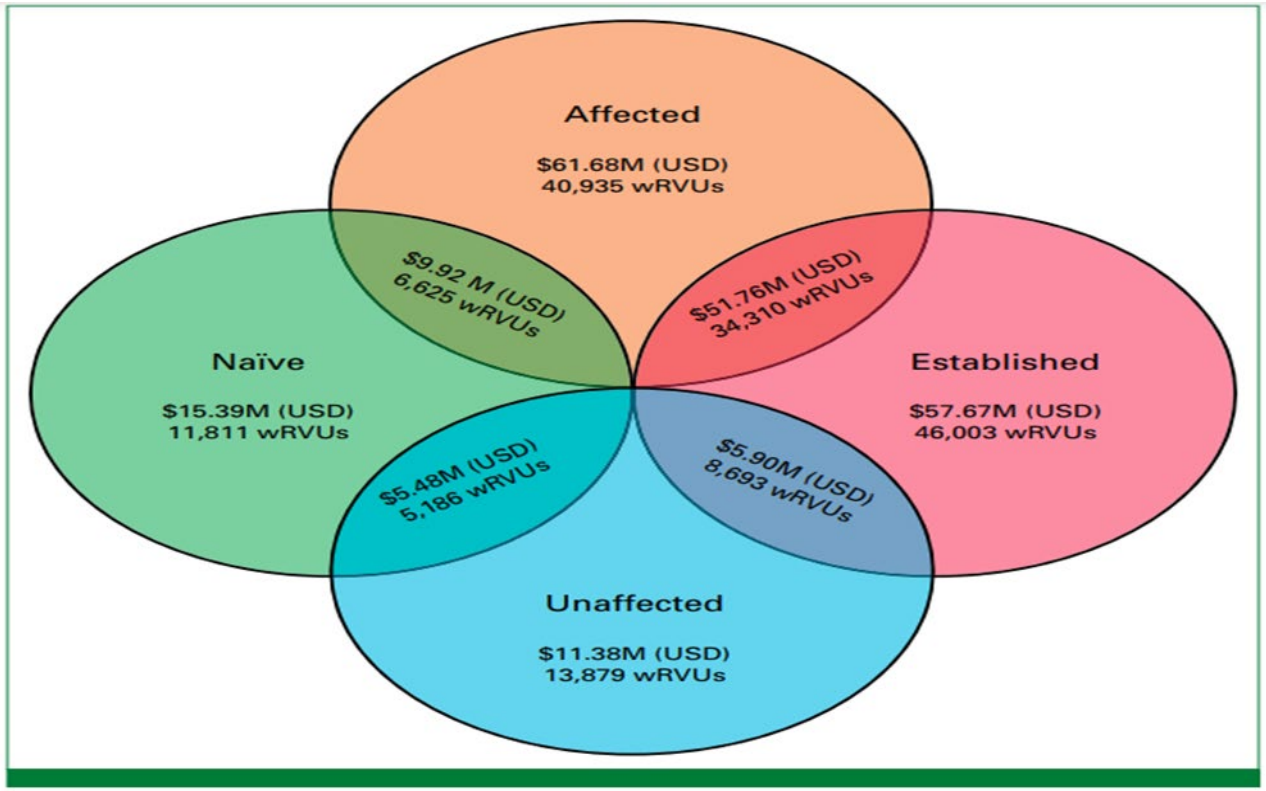


FIG 2. The total downstream revenue (in US dollars) and total wRVUs generated from each subgroup (affected, unaffected, established, and naïve) over the entire study period, as well as the cross-section from the overlapping populations. Affected/unaffected and naïve/established are mutually exclusive categories with no overlapping patients. M, million; USD, US dollars; wRVUs, work relative value units.

**DSR 2.0 paper = Analyzed DSR for genes on typical cancer panels over 11 years

1 FTE GC = 66 positive pts/y, $4.76M DSR/y

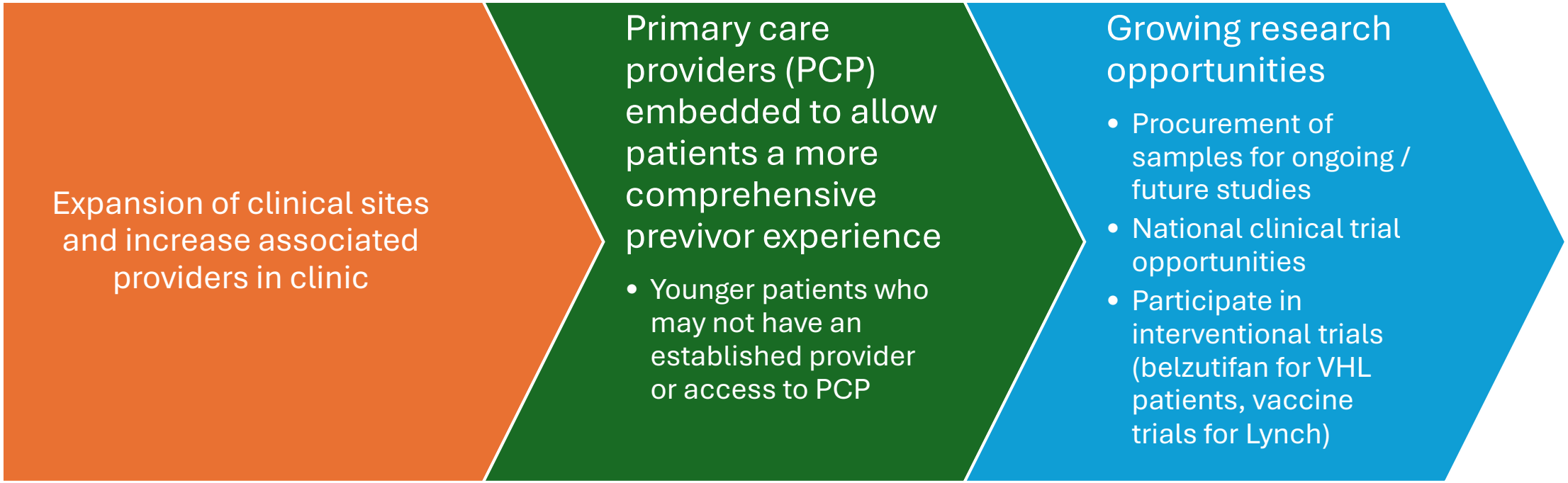
Patient feedback tells the story!

Patient Satisfaction Feedback

After attending my appointment at GCPC, …	Yes, Definitely	Yes, Somewhat
I feel empowered with increased knowledge to make healthcare decisions as it relates to my cancer risk.	100%	
I feel confident discussing genetic test results with family members.	92%	8%

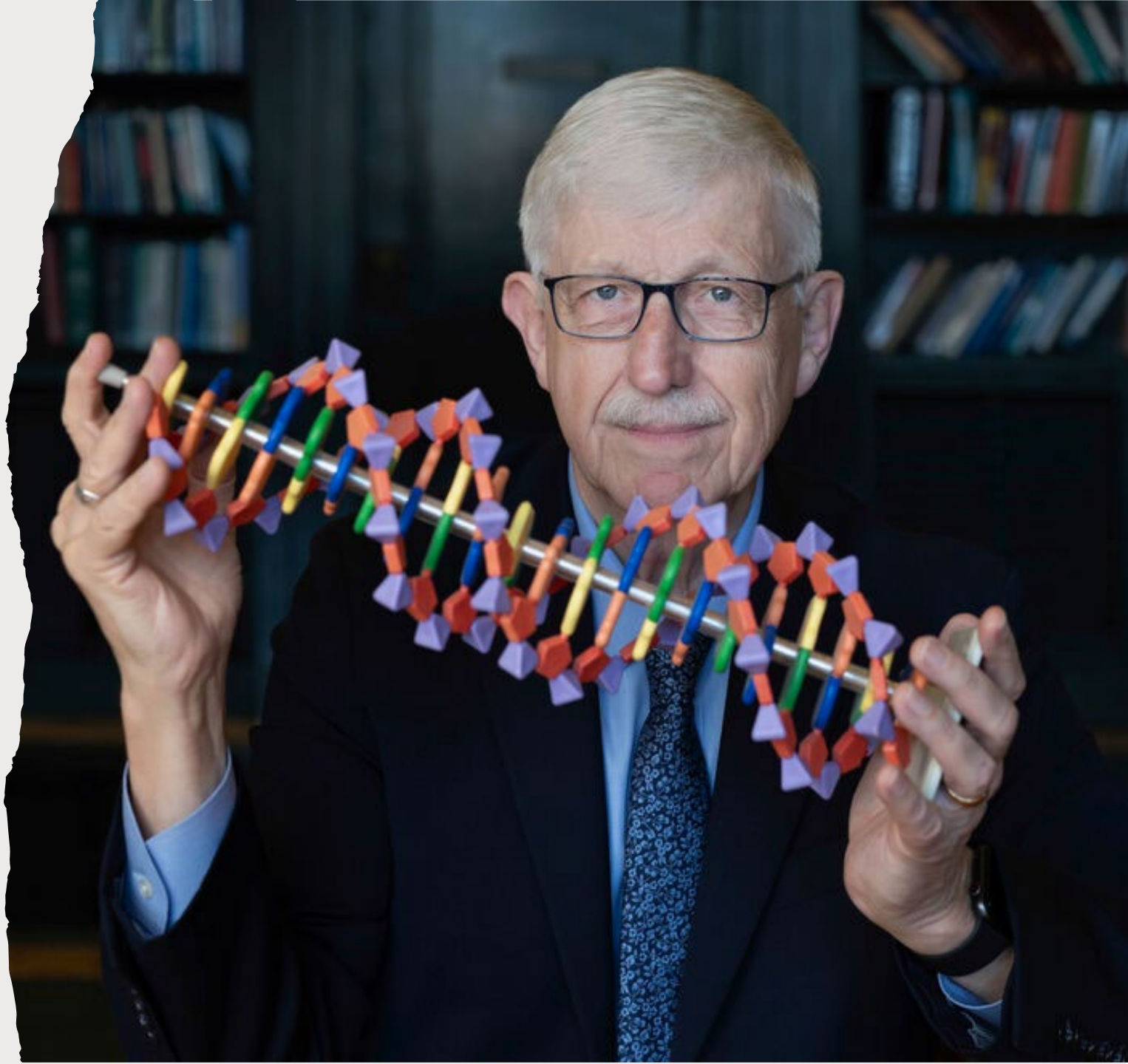
- "I am very impressed with this program, everyone is so knowledgeable and nice."
- "I am very glad to have found this clinic"
- "Excellent service from all staff.“
- "When you are first diagnosed,… your head goes to terrible places … once someone framed [it] in a different light, … *I took back the power.*"

Future Directions



‘Cancer is a disease of the genome.’

– Dr. Francis Collins



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Any Questions?

Thank you!