Integrating Discrete Genomic Data with an EHR Improves Patient Care, Provider Satisfaction, and Program Metrics
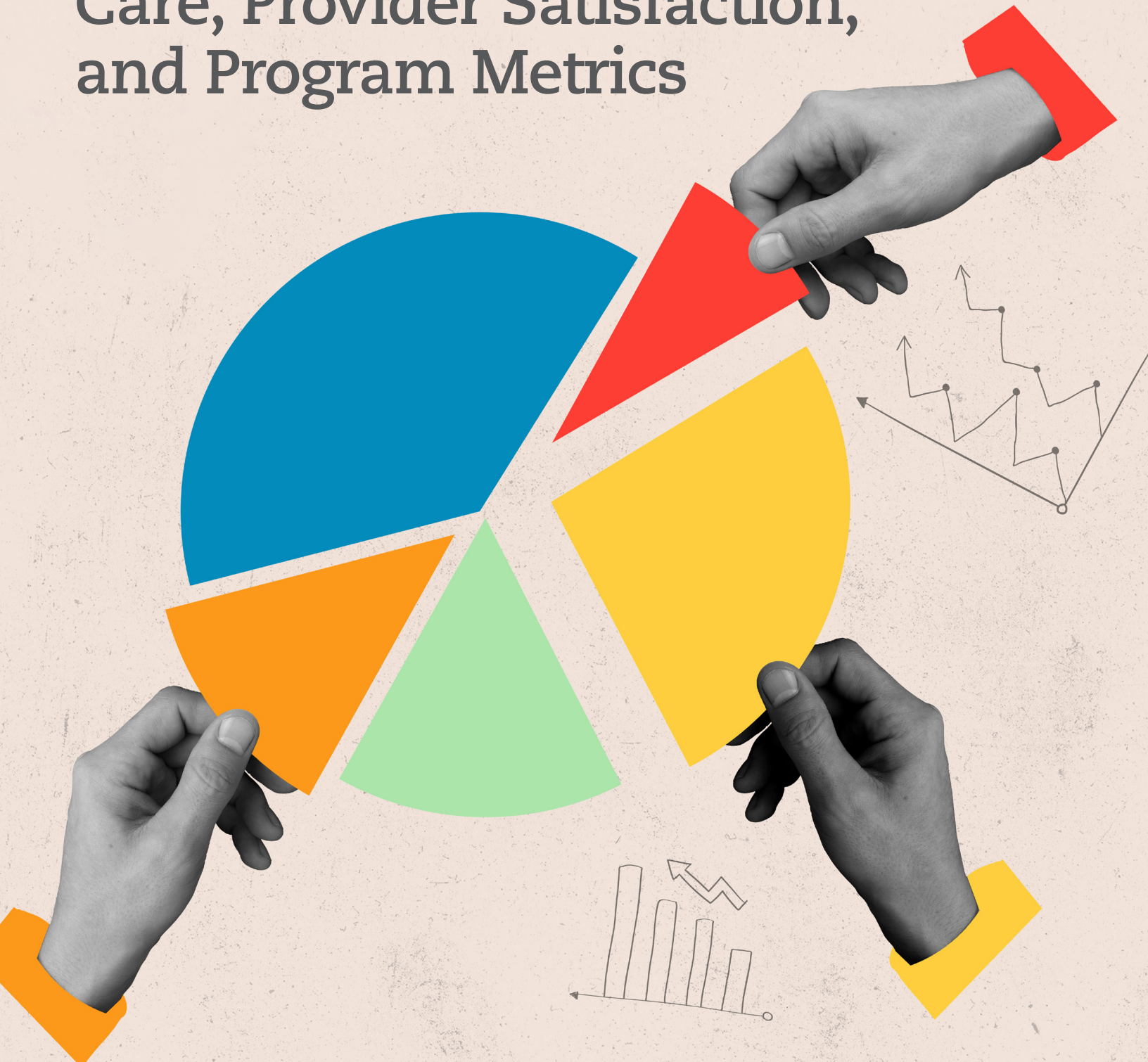
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As the use of genomic tumor profiling to guide personalized therapy increases, the volume of clinical data applied to complex clinical decision-making also increases.[1] The adoption of broad clinical tumor profiling presents many challenges for medical oncologists and a need to present actionable genomic data efficiently to assist with therapy decisions.[2] With the rapid growth of genomically targeted agents, some have advocated for universal tumor profiling.[3] Broader biomarker testing with more than 600 data points requires technical solutions in the electronic health record (EHR) to streamline clinical workflow.

Clinicians have faced several barriers to adopting genomic-driven care for patients with cancer, including as follows:

- Use of third-party portals outside of the EHR working environment to place orders
- Unreliable and inconsistent workflows
- Potential for inequitable distribution of tumor profiling
- Difficulty accessing genomic data in real time during clinical encounters
- Time-consuming processes to measure testing utilization and outcomes.

Although the implementation of discrete data fields in the EHR is a crucial step in overcoming some of these challenges, EHR integration requires time and resources to complete and maintain. Health systems must consider the return on investment for EHR integration, including software updates and staffing. By integrating ordering and resulting of genomic testing into the EHR, the time savings may offset some of these expenses. Data from a University of Pennsylvania study demonstrated that ordering and resulting for genetic tests after an EHR integration saved approximately 10 minutes per test order.[4] Compounded annually by the number of tests ordered and resulted, this can lead to compounded savings in personnel time. This article describes additional benefits of having an integrated EHR.

TriHealth at a Glance

TriHealth is a community-based teaching hospital with multiple locations across various specialties in Cincinnati, Ohio. TriHealth has 4 acute-care hospitals, 1 short-stay hospital, and 800 adult beds. TriHealth includes 140 locations across the greater Cincinnati region

> TriHealth's information services and precision medicine teams have collaboratively built innovative clinical decision support and leveraged discrete genomic elements to design, build, and customize multiple tools.

and 1600 medical staff with more than 12,000 team members. The Precision Medicine Institute, led by a dyad medical oncologist and genetic counselor director, includes 14 genetic counselors with several unique roles such as precision oncology lead and precision medicine test coordinator. Precision Oncology also is led by a dyad medical oncologist and genetic counselor. The precision medicine team supports the TriHealth Cancer & Blood Institute, which includes 20 medical hematologist oncologists, 4 gynecology oncologists, 3 surgical oncologists, 3 breast surgeons, 5 radiation oncologists, and 16 advanced practitioners (clinical nurse practitioners and physician assistants). In 2019, the Precision Medicine Institute received internal grant funding from 2 local foundations (bi3 and Good Samaritan Foundation) to support a system-wide precision medicine program to incorporate genetic information into standard of care.

EHR Integration

TriHealth adopted Epic as its electronic health record in 2010. Most molecular testing is sent to outside labs, and there is very limited in-house biomarker testing. TriHealth's laboratory does not use the Epic Beaker module to integrate results. TriHealth was an early Epic EHR integration partner in precision oncology, with its first complete integration in 2020. TriHealth and its first partner lab completed point-to-point HL7 bidirectional integration of results and orders in 4 months on December 15, 2020. A conversion of historical data dating back to February 2019 was completed in June 2021.

The TriHealth team that worked on this project included 2 Epic

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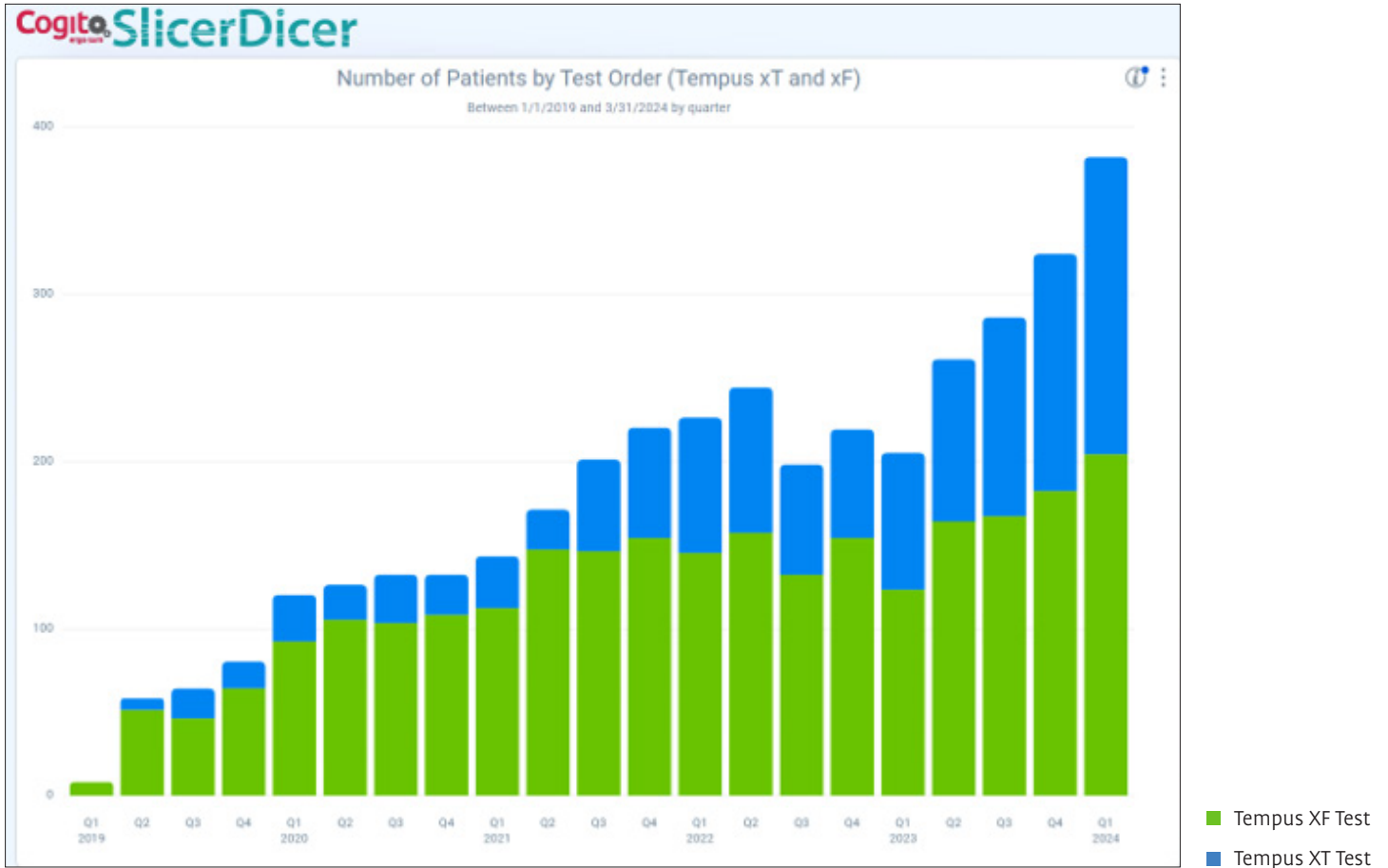It's the first-of-its-kind revenue intelligence solution that:

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Figure 1. Growth of Genomic Tumor Profile Testing Post EHR Integration

(*Continued from page 13*)

engineers, an Epic Bridges data integration engineer, a data analytics engineer, a project coordinator, and 2 genetic counselor champions. This was TriHealth's first genomic lab EHR integration; the team concurrently implemented the Epic Genomics Module. Since the initial integration, significant improvements have been accomplished in the speed of deployment, and several clinical and reporting applications have been developed. The TriHealth team has completed 6 additional HL7 integrations and 1 Aura integration with germline laboratories and continued to customize existing integrations to optimize the user experience. Subsequent integrations require only 1 Epic engineer.

At the time of this submission, TriHealth had 7 additional lab integrations in varying pipeline stages. Clinician uptake and benefits post integration have not been well-characterized in the literature. In this article, TriHealth demonstrates the benefits of integrated ordering and discrete results as they impact the clinical workforce and other departments across the health system.

Key Developments and Innovations

Since TriHealth's first somatic tumor profile integration using the Epic Genomics Module, there have been key developments and innovations in TriHealth's use of the Epic EHR, including as follows:

- Understanding best practices for efficient and seamless deployment of orderables
- Customizing the Epic ordering interface for ease and efficiency of use
- Adopting new test components as testing expands to include new types of results (examples include pharmacogenomics genes *DPYD* and *UGT1A1* for patients on relevant therapies) and how this expansion supports efficient adoption of new tests by oncologists
- Leveraging new discrete data for clinical care and decision-making; reliable genomic data in the EHR is used in clinic and clinician EHR tools to improve documentation accuracy and efficiency
- Automating referral for incidental germline patients to genetic counseling creates efficient and easier decision-making for oncologists

- Applying discrete results to track and report measurable precision oncology outcomes has increased self-service reporting efficiency for cancer program administrators
- Using discrete data to identify patients who may benefit from a newly approved therapy or meet inclusion and exclusion criteria for clinical trials.

Best Practices and Measurable Outcomes With EHR Integration

TriHealth's information services and precision medicine teams have collaboratively built innovative clinical decision support and leveraged discrete genomic elements to design, build, and customize multiple tools. These include best practice alerts, as well as sophisticated

Figure 2a. Multiple Genomic Tests in 1 Epic View of Variant Results Report

Figure 2b. Genomic Orders Filter Showing All Tests in 1 View

clinical trial matching algorithms. TriHealth has demonstrated how genomic integration (ie, having all integrated genomics in 1 location, the EHR) led to streamlined workflow, reduction in time to access results, and efficiency in clinical decisions. EHR integration has empowered this community cancer program to become an informatics leader. The benefits of discrete variants, genomic smart phrases (Epic's note-writing tools), the use of the EHR to identify patients with specific biomarkers, and the ability to consider patients for research are described below. Specifically, an integrated EHR helped TriHealth achieve innovations and customizations in 11 key areas.

Testing Volume Increases

Precision oncology tumor genomic testing through the EHR order interface correlates with increased testing volume. After its December 15 EHR integration go-live date, tumor profile tests at TriHealth increased by 46% from 2020 to 2021 and by 20% from 2021 to 2022. Although volume data are not complete for 2023, TriHealth did add 12 new precision oncology tests in FY2023 (Figure 1).

Orders and Results Time Savings

EHR integration correlates with a reduction in time to enter orders and find results in the Epic EHR. Based on the University of Pennsylvania study, which found 10 minutes saved on average per test post integration, and the volume of testing,[4] TriHealth calculated the hours saved in the first year. Somatic tumor profile testing at 1000 tests/year equated to 167 FTE hours/year. Germline testing at 1500 tests per year equated to 250 FTE hours/year. Taking into consideration the 3 completed integrations and 7 integrations in the pipeline, the time savings for 10 integrated labs compounded annually can be used to make the case for investment in EHR integration and return on investment. Bottom line: Spending less time on routine ordering and resulting allows clinicians to spend more time patient bedside.

Reliable Location of Results

Integrated resulting allows for the structured report (in PDF format) to easily be found in the patient's chart (lab tab) upon completion. A genomic order filter in Epic will efficiently pull up all genomic tests (eg, somatic, germline, pharmacogenomic). Integrated resulting eliminates the need for staff to scan reports to the media tab (a part of the Epic EHR) and confusing or inconsistent file names. When integrated with multiple labs, the genomic variant page in the Epic Genomics Module allows clinicians to visualize results from multiple sources on a single variant page (Figures 2a and 2b). Updates and customizations occur post integration and require dedicated time from the Information Systems team after the system goes live. Examples include new testing components added by the laboratory (eg, homologous recombination deficiency, *DPYD* pharmacogenomic, tumor of origin).

Smart Phrases for Clinical Documentation

Discrete variants in the EHR allow deployment of customized smart phrases (note-writing tools that are a feature of the Epic EHR) to document genomic results in the clinic note. The ability to place genomic results efficiently and intentionally in the Epic workflow—without the need for an outside portal—reduces documentation time and errors. Reliable results allow clinicians to confidently review results with patients at the point of care during encounters. Figures 3a–3d illustrate customized smart phrases; examples include PD-L1, full tumor profile results from solid tumor biopsy and liquid biopsy tests simultaneously, and relevant biomarker-driven therapy.

Systemwide Visibility of Orders and Results

Order and result information in the Epic EHR is accessible to all clinicians systemwide, including pathologists and radiologists. In the past, with individual portal access, only the ordering clinician

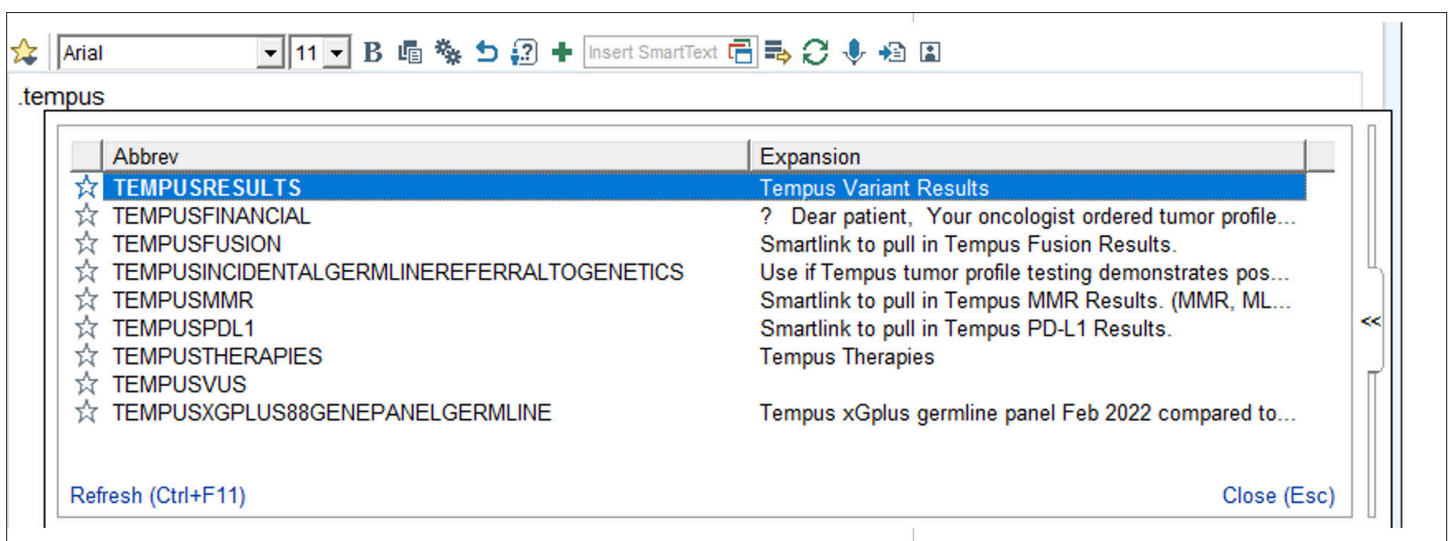Figure 3a. Use of Epic Smart Phrases in Clinic Note to Document Genomic Results

Figure 3b. Use of Epic Smart Phrases in Clinic Note to Document Genomic Results

Test Info:
Tempus xT Tumor Genomic Profile (600+ somatic panel & paired germline)
Result Date:
Specimen Source:
Pathology Case #:TriHealth Laboratories - Cincinnati - Pathology
SN21-6737

Tempus xF Tumor Genomic Profile
Result Date:
Specimen Source: Peripheral Blood
Pathology Case #:

Genomic Variants
Somatic (Potentially Actionable and Biologically Relevant):
There are no somatic variants associated with this patient.

xF Liquid Biopsy (Pathogenic/Likely Pathogenic):
PIK3CA   p.M1043I - c.3129G>A Missense variant (exon 20) - GOF   0.001

CDKN2A   p.D74N - c.220G>A Missense variant - LOF   0.009

Germline (Pathogenic/Likely Pathogenic):
No pathogenic variants were found in the limited set of genes that are
reported.

Other Tempus results:
Lab Results

Component	Value	Date/Time
MSI	Not detected	

Tempus Therapies:
Therapy 1

Component	Value	Date
Gene	PIK3CA	
Agent	Alpelisib	
Association	response	
Evidence Status	Clinical research	
Evidence Type	therapeutic	
FDA Approved	Yes	
On Label	No	

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Figure 3c. Use of Epic Smart Phrases in Clinic Note to Document Genomic Results

PD-L1 Results:

Tumor Proportion Score

Date	Value	Ref Range	Status
	20	%	

Combined Positive Score

Date	Value	Ref Range	Status
	20		

Figure 3d. Use of Epic Smart Phrases in Clinic Note to Document Genomic Results

Tempus Therapies:
Therapy 1

Component	Value	Date
Gene	PIK3CA	
Agent	Alpelisib	
Association	response	
Evidence Status	Clinical research	
Evidence Type	therapeutic	
FDA Approved	Yes	
On Label	No	
Tissue	Solid Tumors	
Variant	p.M1043I	
Pubmed ID	29401002	
Pubmed URL	https://www.ncbi.nlm.nih.gov/pubmed/29401002	

Figure 4. Universal Tumor Profile Genomic Order Page

Cancer Genetic Tumor Profile ✔ Accept

☑ Disease Evaluation

☑ Tempus Tumor Profile

☑ ❶ Tempus Order Selection

☐ Tempus xT Tumor Genomic Profile (600+ somatic panel & paired germline)
☐ Tempus xF Tumor Genomic Profile (Liquid biopsy)
☐ Blood draw - Tempus (check this box EVERYTIME to confirm that you are sending blood sample) ■
Routine, Back Office, Expected: Today, Expires: 1 Year, Blood draw can be sent for xT Tumor Normal and xF Liquid Biopsy tests - choose your Tempus Order selection above which MUST be included with Blood Draw order. If collecting this blood sample at a draw site, please call Genetic Lab Coordinator at 513-853-2253 for information on what to collect.

☐ Tempus Refresh Request
Please include the original Epic order number that you would like refreshed by Tempus.

☐ Guardant 360
☐ Oncotype DX Breast Recurrence Score Report (Exact Sciences)
Back Office, This order is not integrated with Exact Sciences. Precision Medicine (PM) Test Coordinator will place order in external lab portal. When result is available PM Test Coordinator will import into Epic.

☐ Breast Cancer Index (Biotheranostics)
Back Office, This order is not integrated with Biotheranostics. Precision Medicine (PM) Test Coordinator will place order in external lab portal. When result is available PM Test Coordinator will import into Epic.

☐ Tumor Add On - Individual Tests (Neogenomics)
☐ Other Diagnostic Tests Not Otherwise Listed

☐ Disease Monitoring

❶ Next Required ✔ Accept

(*Continued from page 17*)

had access to orders and results, or other clinicians needed to rely on results in the scanned media tab. The ability to review orders facilitates multidisciplinary teamwork. For example, pharmacists now have access to tumor profile results needed for prior authorization for personalized therapies. Interventional radiologists and pulmonologists need access to ensure adequate biopsy tissue for next generation sequencing (NGS), and pathologists need access to ensure tumor content for testing. Broader awareness of tissue that is intended for tumor profiling has contributed to reduced instances of quality and/or quantity not sufficient (QNS) and

turnaround time (TAT) while eliminating access barriers. From 2019 to 2022, the TriHealth QNS rate decreased from 25% to 10%; TAT decreased from 27 days to 9 days.

Consistent Workflow for Integrated and Nonintegrated Tests

TriHealth created a single universal starting place in Epic (eg, "tumor profile") for all genomic tumor profiling orders. The initial order starts with the options "disease evaluation," "disease monitoring," and "cancer screening." Disease evaluation includes all solid tissue and liquid biopsy tests that identify biomarkers for therapy and clinical trials. Disease monitoring includes circulating tumor DNA (ctDNA) or liquid biopsy testing that monitors for effects of therapy, signs of residual disease, recurrence, or resistance. Cancer screening includes blood-based multicancer early detection (MCED), which was included because it relies on ctDNA in the blood. The universal order includes integrated and nonintegrated labs because TriHealth uses a "shell" order for nonintegrated tests. In those cases, the precision medicine test coordinator uses information provided by the

ordering clinician in an Epic shell order to transcribe the order into the outside lab portal. For the clinician, the process is seamless, and when tests are eventually built as an integrated test there is minimal change to workflow for the ordering provider. This allows the Epic team to build new integrations while maintaining a consistent workflow for clinicians. Figure 4 illustrates the universal tumor profile genomic order page with decision-tree logic and tests at various stages in the integration pipeline.

Support of Social Determinants of Health Measures

Since discrete data from somatic tumor profile or germline testing can be combined with other patient data in Epic and connected based on medical record number, reporting measurable outcomes related to social determinants of health is possible using SlicerDicer, a feature of the Epic EHR. The precision oncology lead and other administrators can harness discrete genomic results in a self-service manner, increasing efficiency in reporting. Since discrete variants from integrated testing labs feed reports in real time, reporting updates are also available in

Figure 5a. Epic Self-Service Reporting Workbench to Identify Patients With New Incidental Germline Mutation

Figure 5b. Output From Reporting Workbench for Daily Identification of New Incidental Germline Mutation (Deidentified)

Variant Name	REF 1114 Date	Gene	Significance	Assessment	MRN	Patient	Ordering Provider	Display Name
c.		CDH1	Likely pathogenic	Detected			Kuritzky, Benjamin	Tempus xT Tumor Genomic Profile (600+ somatic panel & paired germline)
p. variant	2/13/2024	MSH2	Pathogenic	Detected			Draper, David James	Tempus xT Tumor Genomic Profile
p. variant	2/10/2024	MSH6	Likely pathogenic	Detected			Budde, Leanne S.	Tempus xT Tumor Genomic Profile
p.	5/22/2023	PMS2	Pathogenic	Detected			Maher, James F	Tempus xT Tumor Genomic Profile
p. LOF	1/26/2024	ATM	Likely pathogenic	Detected			Parchman, Andrew J	Tempus xT Tumor Genomic Profile
p. c. frameshift_variant	2/13/2024	CDH1	Likely pathogenic	Detected			Crane, Edward J	Tempus xT Tumor Genomic Profile
p. LOF	10/31/2023	CDKN2A	Pathogenic	Detected			Kuritzky, Benjamin	Tempus xT Tumor Genomic Profile
p. LOF	1/22/2024	APC	Pathogenic	Detected			Shatavi, Seerin Viviane	Tempus xT Tumor Genomic Profile

real time. Once the cohort of patients with tumor profile testing is defined in Epic SlicerDicer, patient lists are easily exported and analyzed. In July 2023, the TriHealth precision oncology team demonstrated that tumor profiling for disease evaluation performed between January 1, 2021, and June 30, 2023, had no statistically significant differences when analyzed by social determinants of health (race and zip code of residence).

Building of Reporting Dashboards
Continuous updating of discrete data allows real time dashboards to be built for reporting to cancer program leadership. TriHealth uses several reporting dashboards in Tableau that are fed by Epic-integrated discrete data. These include standard reports used for cancer program quality measures. Examples include dashboards that show use of tumor profile volume by test, orders for germline and pharmacogenomic tests, and clinician ordering patterns. Epic also offers reporting workbench dashboards.

Identification of Patient Cohorts by Specific Genetic Result or Specimen Source
Epic's discrete variant data allows identification of patients with prior genomic profile results that can be matched with updated therapy or new clinical trials. Partnering with a tumor profile lab, TriHealth is piloting a concept to update reports with new FDA-approved therapies based on original tumor mutations. For example, when the FDA approved therapy for patients with non–small cell lung cancer with somatic KRAS G12C mutation, the precision oncology lead was able to run a report to identify patients in Epic who met the criteria and

alert their clinicians to the possibility of an update in therapy. This reporting capability is used repeatedly when new markers are identified. Other examples include identifying postmenopausal patients with metastatic breast cancer with ESR1 somatic mutations for new therapy or finding patients with ovarian cancer with specific biomarkers for a new research study.

Identification of Patients With New Incidental Germline Mutations
TriHealth's precision oncology program has a goal to ensure that patients with an incidental germline mutation on tumor profiling are referred to genetic counseling for confirmatory testing so they can be offered family cascade testing. Previously, the precision oncology lead reviewed every tumor profile report to identify these patients, and the volume of testing eventually outpaced the ability to review. With lab integration and genomics module implementation, TriHealth now runs a daily report in Epic to identify new incidental germline patients. This automated process requires approximately 2 minutes, consistently and efficiently identifying patients with new pathogenic or likely pathogenic germline mutations among the 65 genes reported by the tumor profile lab. Figure 5a shows the build in the Epic reporting workbench, and Figure 5b shows an example of report output with patient identifiers removed.

Epic Decision Support Tools
Implementation of the Epic Genomics Module and discrete genomic variants in the EHR delivers new opportunities for clinical decision

Figure 6a. BRCA2 Genomic Indicator and Best Practice Advisories for Referral to Gynecology Oncology and Genetic Counseling

Figure 6b. Care Gap Logic for Newly Identified BRCA Germline Mutation Carrier to Include Breast MRI

support. Discrete variants can automatically trigger genomic indicators, patient-level alerts indicating genetic factors that should be considered during patient care. In the current Epic environment, new potential incidental germline mutations will not fire a genomic indicator, but a pathogenic variant on confirmatory germline test will fire for any genes with built genomic indicators. A genomic indicator will fire downstream best practice alerts and care gaps in the Epic EHR. This includes indicators created for 26 cancer genes and rule-based triggers that incorporate patient sex, age, family history, and completed procedures. The TriHealth team built best practice alerts to address care gaps for actionable germline mutations with National Comprehensive Cancer Network guidelines. Care gap logic is used to trigger clinical follow-up items for patients with specific indicators. An example is a referral for breast MRI in a patient with a newly identified germline BRCA2 mutation. Best practice alerts are also employed to drive clinical workflows and guide patient care. In addition, the team created patient-facing content in MyChart that provides additional information and resources about positive germline results. An example is "referral to genetic counselor" for confirmatory germline testing when incidental germline result occurs. Figures 6a and 6b include visualizations of active best practice advisories and care gap logic in the TriHealth Epic EHR. The precision medicine team continues to build reporting tools that measure uptake of genetic counseling referrals, breast MRI, and downstream revenue.

Communication with Patients

Due to these genomic module and lab integrations, patients can see their reports, come to visits prepared, and receive fact sheets about their germline results. This feature in the Epic MyChart is called "My Genomic Profile." Based on the 21st Century Cares Act,[5] discrete integrated genomic results are shared with patients immediately. TriHealth embraced the concept that genetic information should be shared immediately with patients like other medical information. It has not proven to be harmful to patients or resulted in extra messages to the clinical team.

Lessons Learned

TriHealth has completed 6 point-to-point HL7 integrations. Many additional labs are in the pipeline for integration because of the tremendous value this offers clinicians, patients, and the health system. These are at various stages of build with a mix of HL7 and Aura. Through this work, the TriHealth team has become skilled in EHR integration. This experience allows the TriHealth team to carefully vet new partners in an environment where some third-party laboratories are more ready than others for EHR integration. Epic Aura integrations can be deployed with less effort than HL7 integrations, which require more time and experience. Although TriHealth is fortunate to have seasoned and committed integration champions, limited Information System resources can still present barriers.

When planning for initial EHR integration, include engineers with experience and strong backgrounds in lab, orders, ambulatory, and HL7 integrations. Collaboration and resource alignment between the clinical and technical teams early and often are crucial. TriHealth recommends the inclusion of genetic counselors from initial build to postintegration customizations, given their expertise in genetics and

genomics. TriHealth elected to concurrently implement the Epic Genomics Module in parallel with the first lab integration. Although the functions of the Epic Genomics Module exist without lab integration, TriHealth found that having a lab integration at the module go live allowed the team to fully benefit from genomic indicators that can drive clinical decision support.

The Epic Genomics Module features automated genomic indicators, best practice advisories, and health maintenance logic to help providers use actionable genetic information for patients at point of care. Genomic indicators are a key driver of the value of the Epic Genomics Module. Genetic results are now housed in a standardized location that is easy to find and connected to actions in the EHR. With discrete results in the Epic Genomics Module, TriHealth achieved the goal of integrated genomic results as part of standard patient care and clinical workflow. EHR integration of discrete genomic variant results can accelerate the application of personalized medicine and supports workflows using genetic and/or genomic information in routine patient care.

Consideration of the end user, clinician interface, and patient experience is important in the initial integration planning. Once live, TriHealth found it necessary to have an efficient method of providing clinician and patient feedback to the technical team. This allowed the teams to quickly incorporate feedback into real time workflow optimizations, a huge clinician satisfier. It is important to balance the benefits of presenting a clinical decision support alert to providers with the potential disruption to workflow and the extra time needed to read and select the decisions. For this reason, clinical decision support alerts are only presented if there is strong evidence for the recommendation and the alert changes a care recommendation, for example, the need to order an additional image or lab test. We do not use alerts with "softer" recommendations such as "monitor for" or "may consider." More research is needed to understand the needs of patients when reviewing discrete genomic results in MyChart. TriHealth has found that patients who review their genomic results prior to their next clinical encounter can consider questions ahead of the visit. However, these issues need to be assessed for a range of educational levels and those with fewer resources.

Reporting and measurable outcomes are made possible by discrete variants in the EHR, and Epic's reporting tool (SlicerDicer) is a valuable self-service analytic tool. Analysis supported by discrete variants allows the health system to understand its patient population in new ways. For example, uptake and outcomes data allow TriHealth to understand areas in our program with inconsistent performance (or outcomes) and then focus quality improvement efforts in these areas. This ensures that all patients benefit from a highly reliable process. Measurable outcomes allow TriHealth to identify patients who are overdue for procedures and consider targeted interventions. In addition, reporting in the EHR advances health equity in genomic testing and the ongoing evolution of reporting capabilities.

Previously, clinicians and administrative leaders relied solely on business intelligence teams for reports. Demand for reports was high, which meant there was a lag in receiving those reports. TriHealth decided to identify key clinical champions to learn how to to run reporting in SlicerDicer, a tool that allows clinical users to run many reports on their own (referred to as "self-service reports).

Nearly 3 years after the first EHR integration, the TriHealth team has found more downstream benefits of EHR integration than initially realized, including new partner opportunities due to the active integrations in place, identification of patient cohorts by biomarker with inclusion and exclusion criteria, increased matching to oncology research and trials, discovery of new ways to use self-service reporting tools, and partnerships that have developed secondary to EHR integration. ▢I

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