

# Implementation of a Multi-Cancer Early Detection Test Using a Centralized Model Within a Multi-State Health System

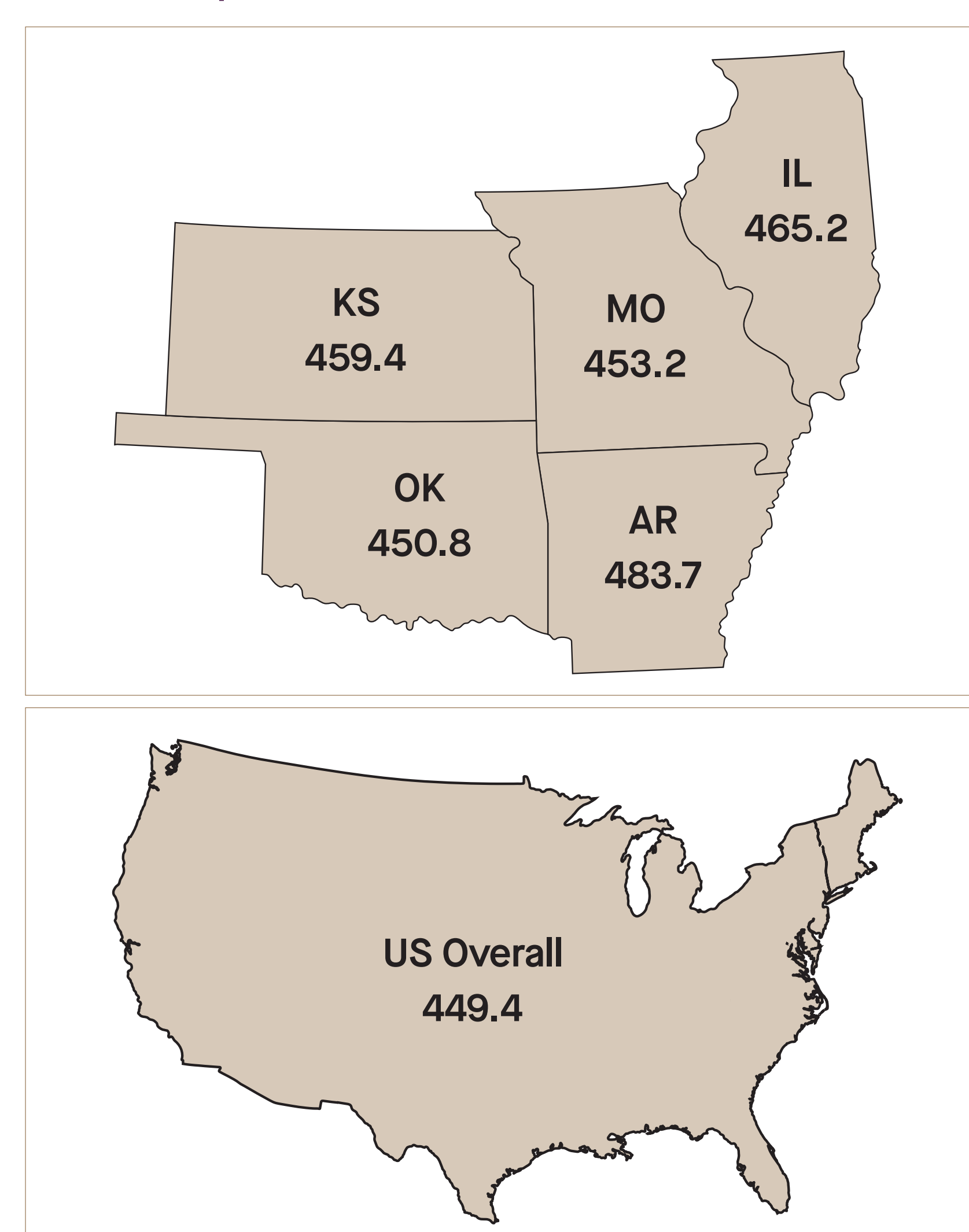
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## INTRODUCTION

- Cancer is the second leading cause of death in the US<sup>1</sup>
- Currently, the United States Preventive Services Task Force (USPSTF) recommends screening for only 5 cancers (breast, cervical, colorectal, lung [high-risk], prostate [individualized basis]),<sup>2-6</sup> but ~70% of cancer-related deaths are from cancers without recommended screening<sup>7</sup>
- A multi-cancer early detection (MCED) test is available as a complement to existing single-cancer screening tests and as a screening option for cancers that do not have USPSTF-recommended or other screening<sup>8-10</sup>
- This MCED test detects a shared cancer signal from abnormal methylation patterns of tumor cell-free DNA in blood using a targeted methylation assay and machine learning algorithm
- When a cancer signal is detected, a "cancer signal detected" result (positive result) is reported with 1 or 2 cancer signal origin (CSO) predictions
- The Mercy Health System (headquartered in St. Louis, MO) includes 44 acute and specialty hospitals with over 4,000 integrated providers and 44,000 employees in 5 states (MO, KS, AR, OK, IL)
- Notably, from 2015-2019, the incidence rate of cancer in each of these 5 states was higher than that of the overall US population (Figure 1),<sup>11</sup> thereby highlighting the need for improved early cancer detection strategies in these states

Figure 1. Average Annual Cancer Incidence Rate per 100,000 (2015-2019), Age Adjusted to the 2000 US Standard Population<sup>11</sup>



- Given the novelty of the MCED test technology, the Mercy Health System implemented a unique model of centralized MCED test implementation with the goal of standardizing the pretest and posttest patient experience within the health system

## OBJECTIVE

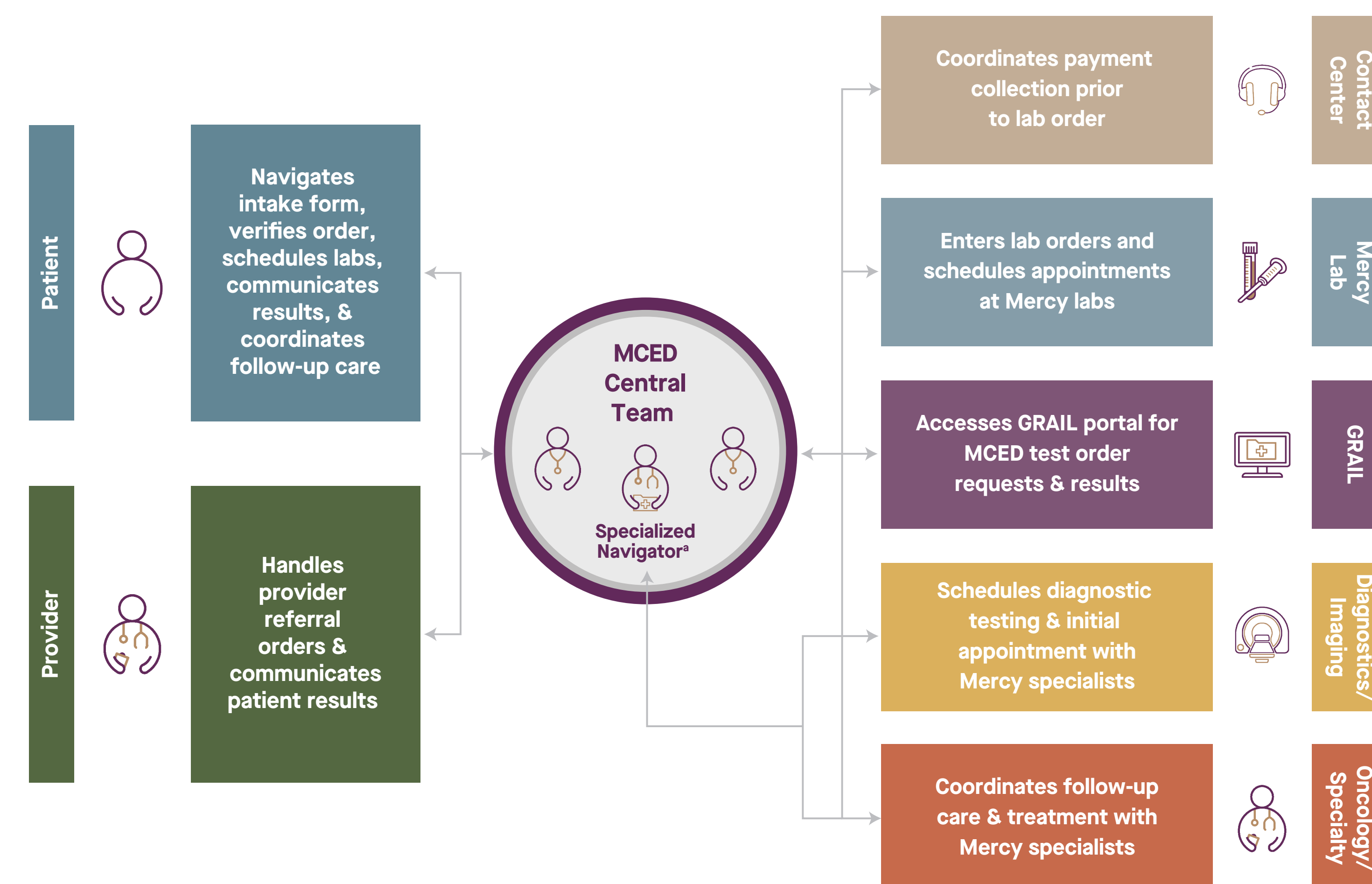
- We present a model of centralized MCED test implementation within the Mercy Health System, a multi-state health system

## THIS CENTRALIZED MODEL ALLOWED FOR EFFICIENT IMPLEMENTATION OF THE MCED TEST AND IS AN EXAMPLE OF HOW A HEALTHCARE SYSTEM CAN INCORPORATE AND SCALE THE IMPLEMENTATION OF THE MCED TEST INTO CLINICAL PRACTICE

### Centralized Model Design

- From November 2021 to July 2022, clinical and operational leadership within the Mercy Health System created an MCED test implementation plan for their health system
- A model with centralized navigation was developed such that patients and providers contacted a single team (MCED Central Team) within the Mercy Precision Medicine Division using telemedicine to order an MCED test and navigate processes (Figure 2)

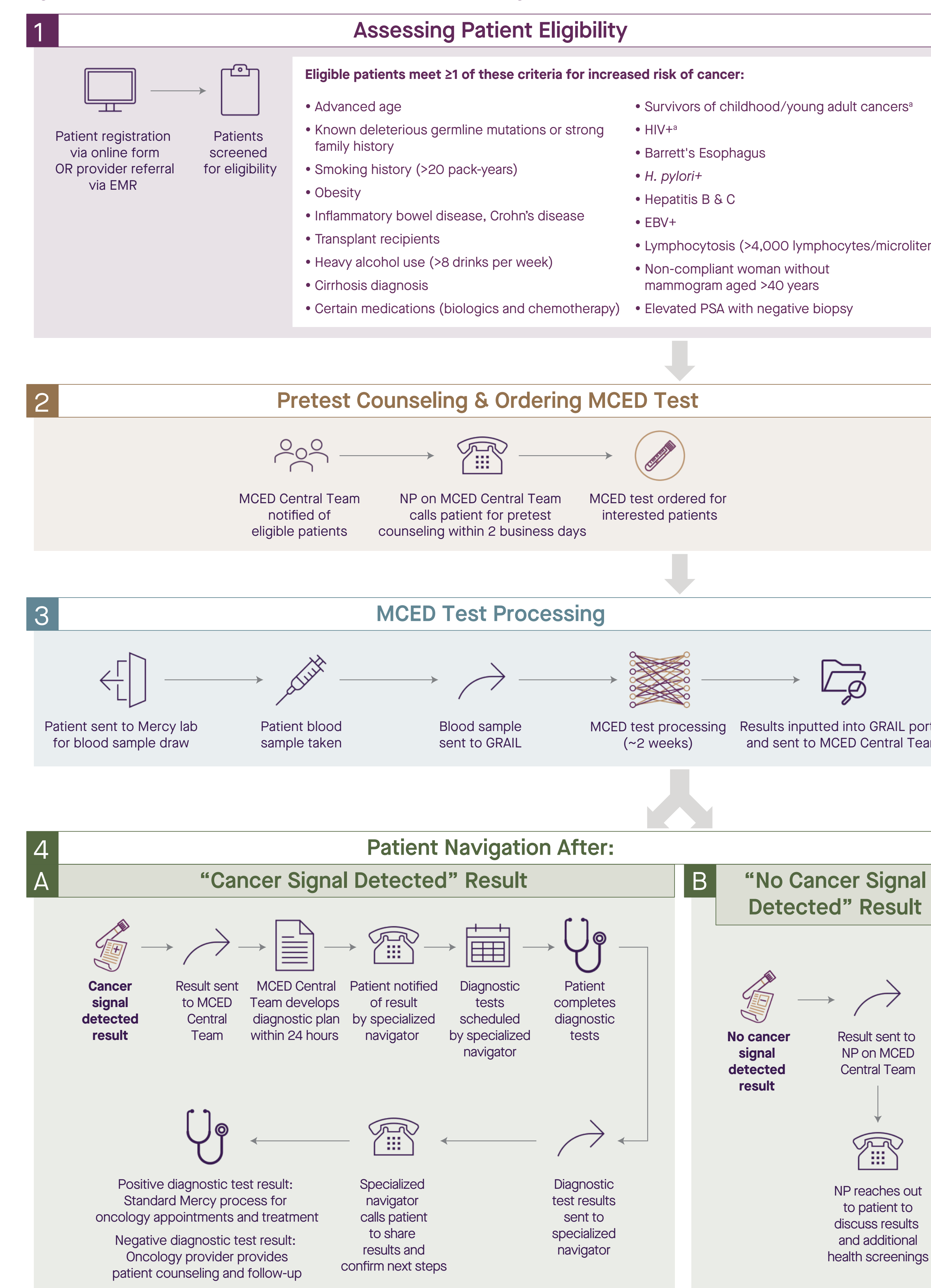
Figure 2. Role of the MCED Central Team



\*Hand-off if the MCED test result is cancer signal detected and specialized navigator is available in community specialty.

- In this model, access to MCED testing commences in 2 ways (Figure 3):
  - Providers within the health system submit a referral to the MCED Central Team through the electronic medical record (EMR) system
  - Patients register through an online form
- Patients are screened for MCED test eligibility via prespecified criteria
  - The eligibility criteria were determined by a review of published cancer risk factors followed by a process of consensus opinion by oncologic specialties
- Eligible patients are then contacted by a nurse practitioner (NP) on the MCED Central Team for pretest counseling within 2 business days
- If the patients are still interested after counseling, an MCED test is ordered
- Patients go to 1 of 11 Mercy labs to have their blood drawn for the MCED test
- Patients with a cancer signal detected test result are directed to a specialized navigator (NP) within the MCED Central Team who helps schedule diagnostic testing and initial appointments with specialists for the patients; the navigator also coordinates follow-up care and treatment within the health system

Figure 3. An Overview of the Centralized Model Design

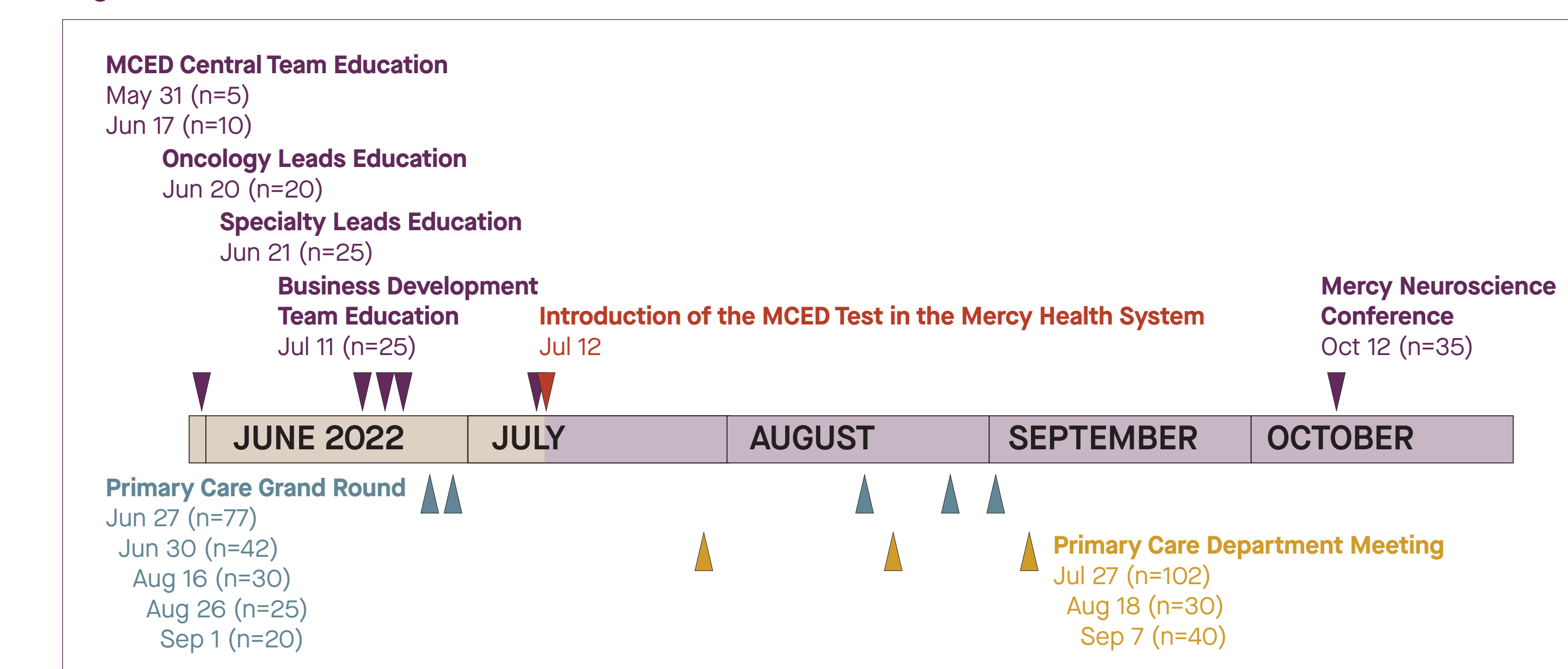


\*Additional consideration needed. EBV, Epstein-Barr virus; HIV, human immunodeficiency virus; PSA, prostate-specific antigen.

### Medical Education

- In the 2 months prior to and 3 months after introduction of the MCED test in the Mercy Health System (July 12, 2022), 14 medical education sessions were held for various groups within the health system, including the MCED Central Team, leaders of subspecialty departments, and primary care providers, to inform on the MCED test and the MCED test implementation plan (Figure 4)
- The sessions highlighted the benefits of the MCED test, the science behind the MCED test, the performance features of the MCED test, how to interpret MCED test results, and examples of potential diagnostic evaluations based on predicted CSO
- Over 400 individuals were educated across these sessions

Figure 4. Timeline of Medical Education Sessions

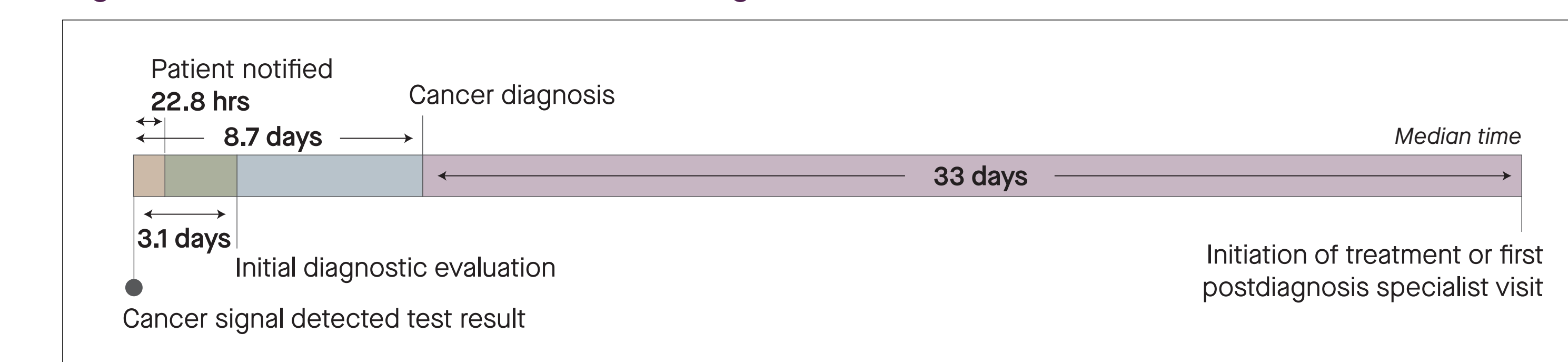


Note: (n=x) denotes the number of individuals educated at the session.

### Analytics

- Early analytics show that from MCED test introduction (July 12, 2022) to January 31, 2023, there were 3,777 total referrals (2,931 patient, 846 provider) that led to 925 MCED test orders
  - Of the ordered tests, 6 had a cancer signal detected test result
- Median time from a cancer signal detected test result to patient notification of test result was 22.8 hours, to initial diagnostic evaluation was 3.1 days, and to a cancer diagnosis was 8.7 days (Figure 5)
- Median time from cancer diagnosis to initiation of treatment or first postdiagnosis specialist visit was 33 days (Figure 5)

Figure 5. Timeline of Events After Cancer Signal Detected Test Result



## CONCLUSIONS

- The model presented is an example of how a healthcare system can incorporate and scale the implementation of an MCED test into clinical practice
- The centralized model allowed for efficient time to diagnosis and treatment or triage of eligible-risk patients using an MCED test

- Notably, systematic and timely education of all involved stakeholders was critical for the smooth functioning of the model
- Additional follow-up on the centralized model can help inform areas of improvement for future implementation of an MCED test into a healthcare system

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## Disclosures

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