

THE PATHFINDER STUDY

GRAIL

Assessment of the Implementation of GRAIL's Multi-Cancer Early Detection Test Into Clinical Practice

The PATHFINDER Study is an interventional, multi-center study that evaluated GRAIL's multi-cancer early detection (MCED) blood test Galleri®. The study marked the first time the MCED test was used to return results to healthcare providers and participants to help guide appropriate diagnostic workup.

Study Design

Study Type: Prospective Interventional
Primary Purpose: Screening



Study Arm:

- Cohort A: Adults 50 years of age and older with additional risk (~56% of participants enrolled)**
- Cohort B: Adults 50 years of age and older without additional risk (~44% of participants enrolled)**

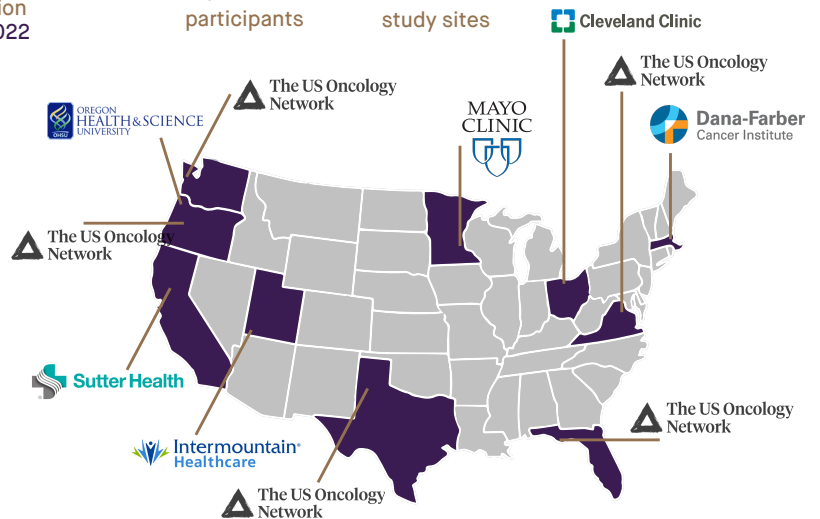


Intervention:

Multi-Cancer Early Detection Test
Blood collection and multi-cancer early detection testing with return of results.

Who Participated in the Study

6,629 participants 11 study sites



Interim Study Findings

The interim PATHFINDER results, using an earlier version of Galleri, demonstrate performance in a clinical setting and support findings from previous studies. The interim results demonstrate that Galleri can detect multiple types of cancer, including in early stages, with high positive predictive value, and can determine where in the body the cancer signal is located with high accuracy. PATHFINDER participants will continue to be followed for 12 months, with final results expected in the first half of 2022.

29 cancers detected across 13 types, including:

- Breast
- Colon or rectum
- Head and neck
- Liver & bile duct
- Lung
- Lymphoid Leukemia
- Lymphoma
- Ovary
- Pancreas
- Plasma cell Neoplasm
- Prostate
- Small intestine
- Waldenstrom macroglobulinemia

96.3%

accuracy in predicting the first or second cancer signal origin

44.6%

positive predictive value, or the likelihood that a person has cancer when a positive test result is returned

High satisfaction rate among PATHFINDER participants* was recorded (n=6618):

97% Satisfied, Very or Extremely Satisfied with the multi-cancer early detection test

Participant* attitudes indicate continued adherence toward recommended screenings (n=6159):

96% were Likely or Very Likely to follow healthcare provider's cancer screening recommendations

*Refers to participants who completed the questionnaire.

The interim analysis identified four study-related adverse events (two related to mild anxiety before the test, one related to mild anxiety about the blood draw, and one related to mild bruising).