

全球泛癌筛查行业发展情况

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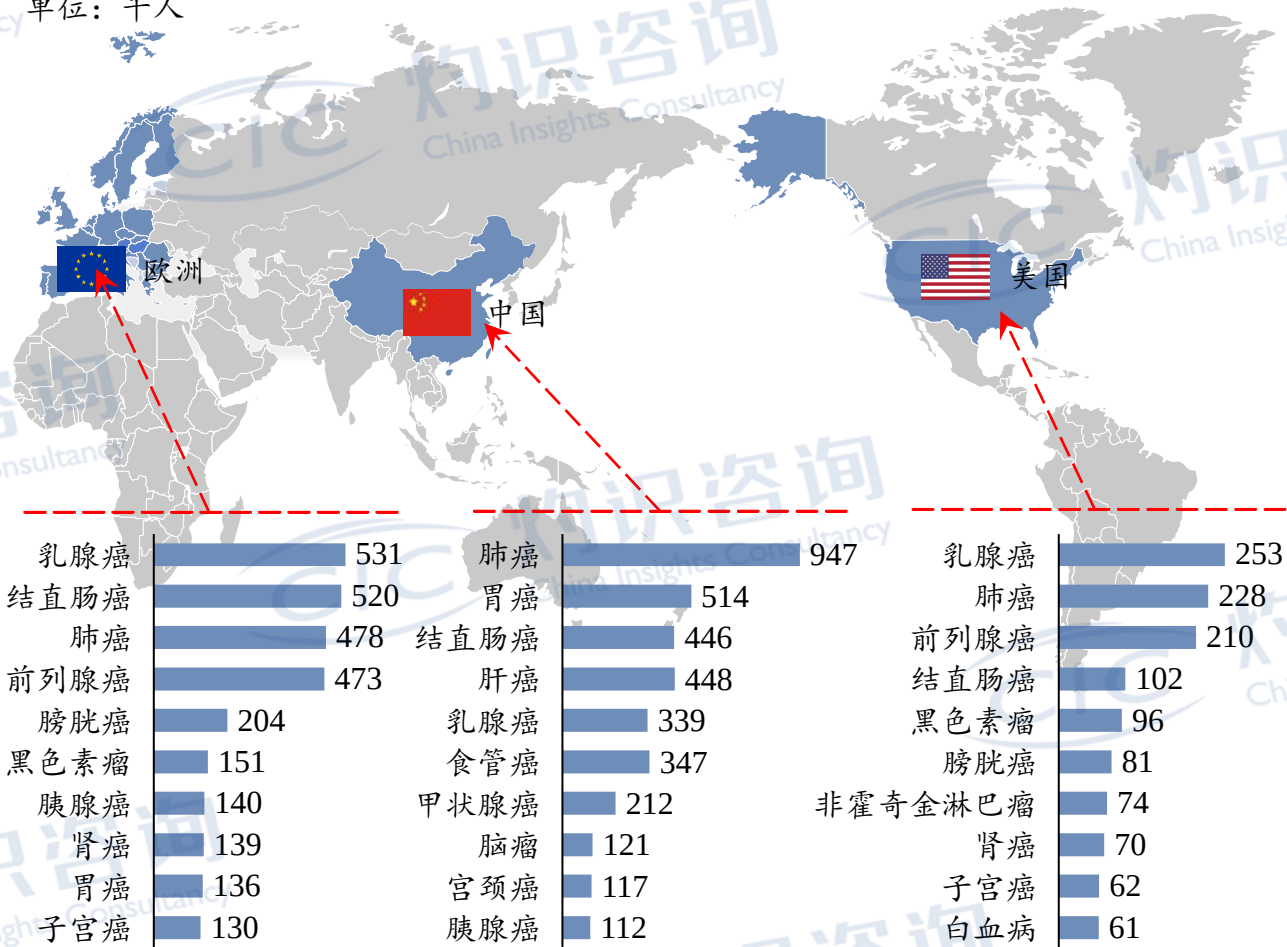
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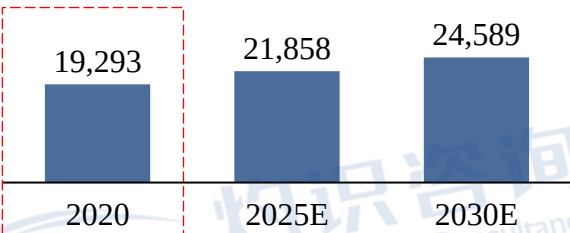
全球癌症流行病学

全球主要地区前十大肿瘤类型及发病人数（2020年）

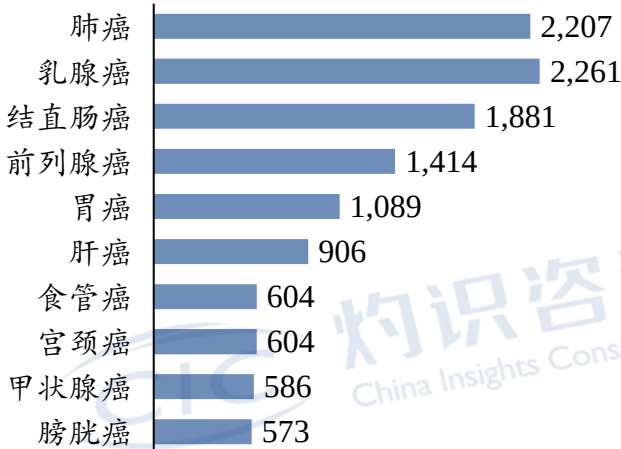
单位：千人



全球肿瘤发病人数（千人）

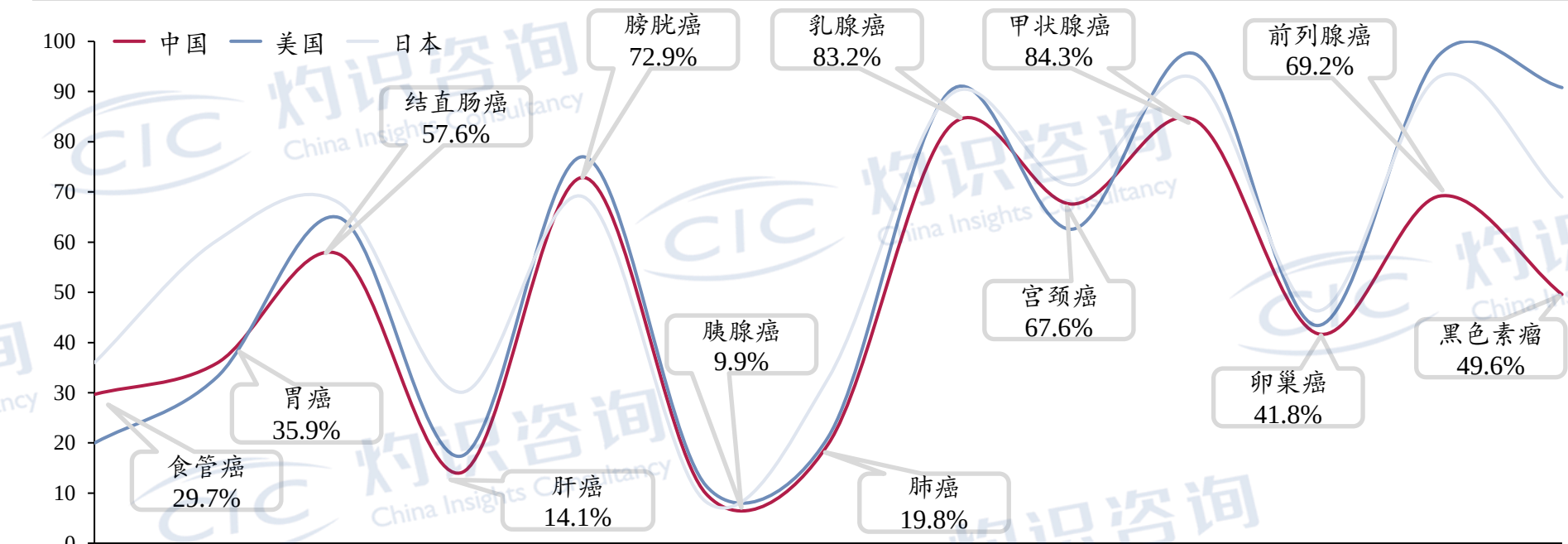


前十大肿瘤发病人数



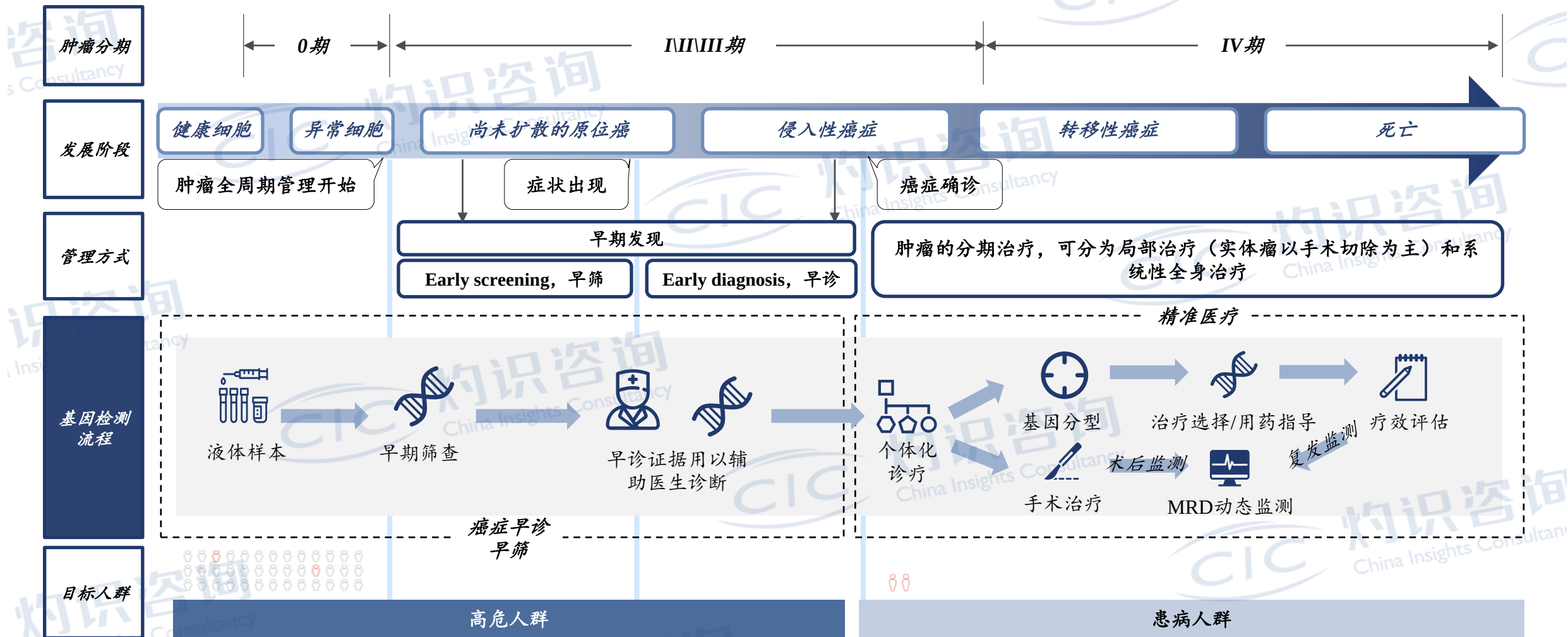
三大主要国家癌症五年生存率的对比

中、美、日癌症五年生存率对比



	食管癌	胃癌	结直肠癌	肝癌	膀胱癌	胰腺癌	肺癌	乳腺癌	宫颈癌	甲状腺癌	卵巢癌	前列腺癌	黑色素瘤
中国	29.7%	35.9%	57.6%	14.1%	72.9%	9.9%	19.8%	83.2%	67.6%	84.3%	41.8%	69.2%	49.6%
美国	20.0%	33.1%	64.9%	17.4%	77.0%	11.5%	21.2%	90.2%	62.6%	97.5%	43.4%	97.4%	90.8%
日本	36.0%	60.3%	67.8%	30.1%	69.0%	8.3%	32.9%	89.4%	71.4%	92.6%	46.3%	93.0%	69.0%

癌症筛查在全球人群中的意义：癌症早期发现与诊断对于癌症治疗在公共卫生经济学上的意义远大于开发针对晚期癌症的特异性药物



资料来源：WHO，灼识咨询

绝大多数的癌症患者，在癌症初诊的时候都太晚

>80%

癌症患者在没有任何被临床指南推荐的癌症筛查就已经死亡

>86%

癌症患者并非经过临床指南推荐的癌症筛查发现癌症

~4X

癌症患者在早期发现可以获得的生存率提升

主要的单癌症筛查手段

目前主流癌症筛查手段包括但不限于：胃肠镜、乳腺癌钼靶检测，粪便DNA甲基化、肝癌彩超及AFP、肺癌LDCT等不同方法学下的多重检测方法



单癌症筛查的优劣势

- 对于部分癌症筛查方法已经获得了较好的临床试验数据
- 基于目前复杂冗长且方法学多样的筛查手段，新增加一个全新方法学的癌症筛查，更少的健康人会接受更加麻烦的筛查流程
- 由于每个不同检查均有独立的假阳性率，完全按照要求进行各类癌症的筛查会进一步放大假阳性率对于健康人群的影响

泛癌筛查的优劣势

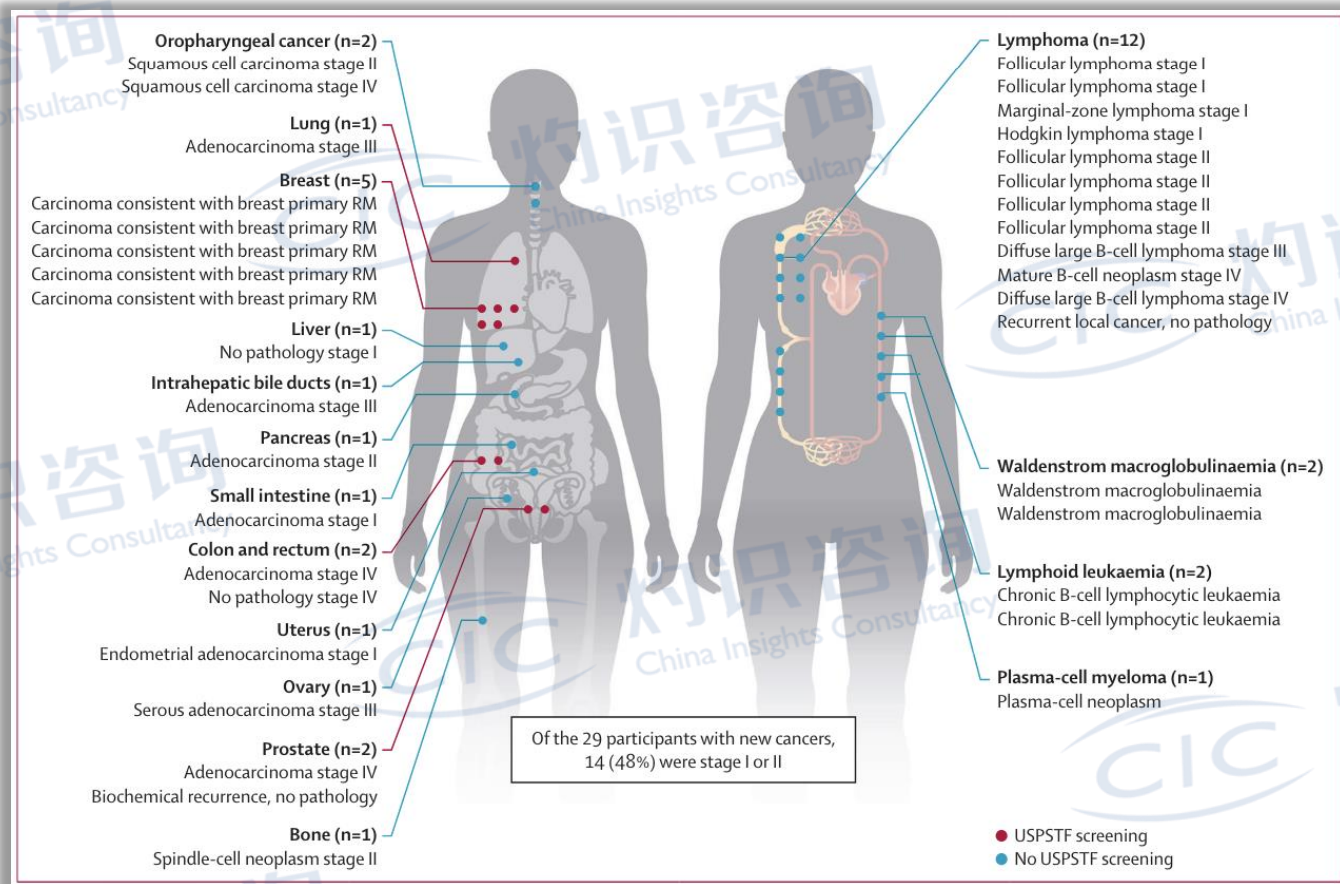
- 单一方法学检测手段可以极大的提升健康人群筛查的依从性
- 基于单独的假阳性率可进一步帮助普及癌症筛查
- 缺乏阳性后精准定远癌症病原位置的方法，需要进一步进行各类检查
- 临床试验成本巨大，进行长期临床获益验证的试验成本为天文数字，获批路径难

GRAIL

癌症覆盖	测试方法	阳性预测值PPV%	假阳性率%
多癌症	Galleri血液检测	43.1	0.5
前列腺癌	血液检测	30.0	10.4
宫颈癌	HPV检测	19.0	7.4
肺癌	LDCT	3.8	12.8
乳腺癌	钼靶检测	4.4	11.1
结直肠癌	FIT	1.2	1.3

1 (i) PPV: CA: A Cancer Journal for Clinicians, March 2010, and (ii) False Positive Rate: Annals of Family Medicine, May 2009.
Prostate screening is an USPSTF grade C.
2 (i) PPV: International Journal of Cancer, May 2019, and (ii) False Positive Rate: JAMA, August 2018
3 (i) PPV: New England Journal of Medicine, May 2013, and (ii) False Positive Rate: Annals of Internal Medicine, April 2015
4 Source for PPV and False Positive Rate: Radiology. 2017; 283(1): 49-58.
5 PPV and False Positive Rate: Abdominal Radiology, August 2016

Pathfinder临床试验的整体性数据总结



在入组后 12 个月内，121 名参与者中诊断出 122 种癌症，其中，35 例（29%）为 MCED 检测到癌症信号，38 例（31%）为根据 USPSTF 指南等筛查检测到，其余 48 例（40%）则是通过临床检测到。在 35 例真阳性患者中，24/35 例（69%）属于额外风险队列，28/35 例（80%）患有新发癌症，6/35 例（17%）患有复发性癌症，1/35 例（3%）患有两种癌症，共计 36 例癌症（19 例实体瘤和 17 例血液学恶性肿瘤）。在真阳性患者的新发癌症中，29 种癌症中有 14 种（48%）为 I-II 期：6 种实体瘤和 8 种血液学恶性肿瘤，并且 97% 在第一次或第二次 MCED 检测后就得到了正确的 CSO 预测。

综上，MCED 检测的总体阳性预测值为 38%，阴性预测值为 98.6%，特异性为 99.1%，并且经过优化后，其特异性可以达到 99.5%，阳性预测值提升至 43.1%。

GALLERI良好数据下隐藏的担忧：在检测到癌症信号的那些人中，92 人中的 35 人（38%）被诊断患有癌症（真阳性），57 人（62%）没有癌症诊断（假阳性）

COMPLETED

Assessment of the Implementation of an Investigational Multi-Cancer Early Detection Test Into Clinical Practice

ClinicalTrials.gov ID NCT04241796

Sponsor GRAIL, LLC

Information provided by GRAIL, LLC (Responsible Party)

Last Update Posted 2022-10-25

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Study Overview

Brief Summary

PATHFINDER is a prospective, multi-center study in which approximately 6,200 participants will be enrolled. An investigational multi-cancer early detection test, developed by GRAIL, will be ordered by and results returned to a study investigator. In cases with a "signal detected" test result (with a predicted or indeterminate tissue of origin (TOO)), the diagnostic work-up will not be dictated by the protocol, but will instead be coordinated by the ordering and treating medical team at the enrolling sites based on the participant's clinical condition, recommendations by each institution's clinical practices, and in consultation with the study investigator and interdisciplinary care team, as necessary. Additionally, [Show more](#)

Official Title

The PATHFINDER Study: Assessment of the Implementation of an Investigational Multi-Cancer Early Detection Test Into Clinical Practice

Conditions

Cancer

Intervention / Treatment

Device: Multi-Cancer Early Detection Test

Other Study ID Numbers

GRAIL-007

Study Start (Actual)

2019-12-12

Primary Completion (Actual)

2021-12-01

Study Completion (Actual)

2022-01-05

Enrollment (Actual)

6662

Study Type

Interventional

Phase

Not Applicable

Blood-based tests for multicancer early detection (PATHFINDER): a prospective cohort study

Deb Schrag, Tomasz M Beer, Charles H McDonnell III, Lincoln Nadauld, Christina A Dilaveri, Robert Reid, Catherine R Marinac, Karen C Chung, Margarita Lopatin, Eric T Fung, Eric A Klein

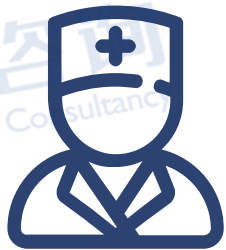
Summary

Background Multicancer early detection (MCED) blood tests can detect a cancer signal from circulating cell-free DNA (cfDNA). PATHFINDER was a prospective cohort study investigating the feasibility of MCED testing for cancer screening.

Methods In this prospective cohort study done in oncology and primary care outpatient clinics at seven US health networks, a convenience sample of adults aged 50 years or older without signs or symptoms of cancer consented to MCED testing. We collected blood, analysed cfDNA, and returned results to participants' doctors. If a methylation signature indicative of cancer was detected, predicted cancer signal origin(s) informed diagnostic assessment. The primary outcome was time to, and extent of, diagnostic testing required to confirm the presence or absence of cancer. This trial is registered at ClinicalTrials.gov, NCT04241796, and is completed.

Findings Between Dec 12, 2019, and Dec 4, 2020, we recruited 6662 participants. 4204 (63.5%) of 6621 participants with analysable results were women, 2417 (36.5%) were men, and 6071 (91.7%) were White. A cancer signal was detected in 92 (1.4%) of 6621 participants with analysable results. 35 (38%) participants were diagnosed with cancer (true positives) and 57 (62%) had no cancer diagnosis (false positives). Excluding two participants whose diagnostic assessments began before MCED test results were reported, median time to diagnostic resolution was 79 days (IQR 37–219): 57 days (33–143) in true-positive and 162 days (44–248) in false-positive participants. Most participants had both laboratory tests (26 [79%] of 33 with true-positive results and 50 [88%] of 57 with false-positive results) and imaging (30 [91%] of 33 with true-positive results and 53 [93%] of 57 with false-positive results). Fewer procedures were done in participants with false-positive results (17 [30%] of 57) than true-positive results (27 [82%] of 33) and few had surgery (one with a false-positive result and three with a true-positive result).

泛癌筛查未来需要验证和解决的几大问题：论证泛癌筛查如何协助医生筛选和判断患者的患癌情况；论证是否进行大规模普及有利于总体性的提升人群的健康水平



“

在泛癌筛查检测结果为阳性之后，我到底该为患者做进一步的检查或治疗？

”



“

收到了泛癌筛查阳性检测报告，我到底该怎么办？去哪个医院科室看什么医生？

”



“

政府是否该把泛癌筛查纳入医保？这种筛查是否会引起过度医疗？

”

泛癌筛查依然需要以全面的临床数据验证作为基础，而泛癌筛查的本质却导致了相关的临床研究可能是医学历史上最为庞大、长期、复杂的研究项目，所需的资金也是海量的

An update on the ongoing NHS-Galleri trial

📅 29 May 2024 🧑‍⚕️ Professor Peter Johnson

Cancer

Based on data from the first year of the three-year [NHS-Galleri trial](#), NHS England has decided that it will wait to see final results, expected in 2026, before considering whether an NHS rollout of the Galleri multi cancer early detection test (the Multi Cancer Blood Test Programme, MCBT) should go ahead.

NHS England's commercial agreement with health technology company [GAIL in November 2020](#) positioned the NHS at the forefront of an exciting area of healthcare innovation, and the company's Galleri® test is now being subjected to one of the most rigorous investigations in any healthcare system worldwide. Over [140,000 people between the ages of 50 and 77 years have taken part](#) in what is the world's largest prospective trial of a multi cancer early detection blood test.

Using a blood sample taken from a patient, the Galleri test works by detecting a common signal among more than 50 cancer types, meaning that a cancer could be detected earlier – even before a patient experiences any symptoms.

The NHS-Galleri trial was designed with three consecutive years of screening, and it is vital to evaluate the primary objective and endpoints at the end of the study in 2026. The primary endpoint of the trial is an absolute reduction in the number of late stage (stage 3 and 4) cancers diagnosed, and cancer-specific mortality will also be analysed after five years of follow up.

Many successful cancer screening trials have failed to show a stage shift initially, and it is frequently observed that the first-year data will differ from the final trial results.

NHS England has reviewed preliminary data from the first year of the NHS-Galleri trial and did not find them compelling enough to justify proceeding straight away with a large-scale pilot programme of the test in NHS clinical practice, while we await the final results of the trial. Committing to accelerate implementation of the test in the NHS at scale would have been an exceptional step, requiring exceptional data after just one year, and while what we have seen is very promising, the data so far do not support moving at such a fast pace.

NHS为何在与Grail合作三年临床后坚持要求等待2026年后的最终结果？

泛癌症筛查的真正临床终点是什么？

➤ PPV? NPV? 灵敏度? 特异性?

还是：

➤ 提升全人群癌症的五年生存率

➤ 提升全人群癌症早期发现率

➤ 通过早期干预真正的降低癌症发病率

百亿美元的吞金兽，全球泛癌筛查领域需要的是坚持与全行业的团结



After more than two years of figuratively duking it out with U.S. and European antitrust enforcers – not to mention taking heat from activist investor Carl Ichan – San Diego, CA-based Illumina conceded the fight for Grail in December. Last week, at the annual J.P. Morgan Healthcare Conference, Illumina's top executives shared a bit more color about the pending divestiture.

Illumina CEO Jacob Thaysen said the company is working “very diligently to **resolve Grail as quickly as possible**,” with the goal of finalizing the terms by the end of the second quarter of 2024. He said the divestiture will either be in the form of a capital market transaction, or a third-party sale.



临床试验	入组人数	目标
CCGA	15,254	开发验证泛癌筛查
PATHFINDER	6,662	初步评估MCED
PATHFINDER2	35,000	注册临床
NHS-Galleri	142,321	大规模人群筛查注册临床
Galleri-Medicare	50,000	真实世界大人群筛查评估
SYMPLIFY	6,242	辅助诊断领域拓展
REFLECTION	17,000	真实世界应用评估
STRIVE	99,481	钼靶对标观察性试验
SUMMIT	13,035	肺癌高危人群观察性试验

资料来源：灼识咨询

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