



SOFIVA GENOMICS



Stock Code 6615

Investor Conference

2024 / 12 / 18

Chairman
Yi-Ning Su, MD. Ph.D

Disclaimer

All statements for investors contain information that represent, other than historical facts, SOFIVA's plans and forward-looking statements are based upon management's current assumptions.

Environmental changes and other important factors could cause actual results to differ materially from those expressed in our statements.

Investors should carefully consider the investment objectives and risks before investing.

SOFIVA - The Dual Operating Strategy

Maternal Fetal Medicine

Precision Cancer Medicine

Genetic Screening Category	Servicing Specialty	Target
Reproductive	IVF Center	IVF Embryo Screening
Prenatal	OB-GYN	Pre-pregnant couples Pregnant couples
Newborn	Pediatrics, Neonatology	Child Newborn
Cancer	Cancer-related Specialty	All Target Audience (Pre-Cancer & Patient)
Rare Disease	Genetics-related Specialty	All Target Audience
Precision Medicine	Treatment-related Specialty	All Target Audience

Protecting Life and Health with 6 Core Testing Services



Preconception

About 50,000 Cycles per Year



Gestation

About 130,000 People per Year



Neonatal

About 130,000 People per Year



Healthy

About 120,000 New Cancer Cases per Year

Cancer Patient

Reproductive

Prenatal

Newborn

Cancer

Precision Medicine

Rare Disease

Maternal Fatal Medicine and Precision Cancer Medicine One Stop Service

Reproductive

- PGT-M
- PGT-A
- niPGT-A

Rare Diseases

- Hearing Loss Genetic Test v1.0/v2.0/v3.0
- Achondroplasia
- Osteogenesis Imperfecta
- Duchenne Muscular Dystrophy
- Wilson's Disease
- Marfan Syndrome
- Whole Exon Sequencing Genetic Testing

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Prenatal

- NIPS
- Array
- Karyotyping
- Carrier Scan
- SMA Genetic Testing-SMN gene
- Fragile X Genetic Testing-FMR1 gene
- Thalassaemia Genetic Testing-HBA,HBB gene
- Folate Metabolism Genetic Testing-MTHFR gene

Cancer

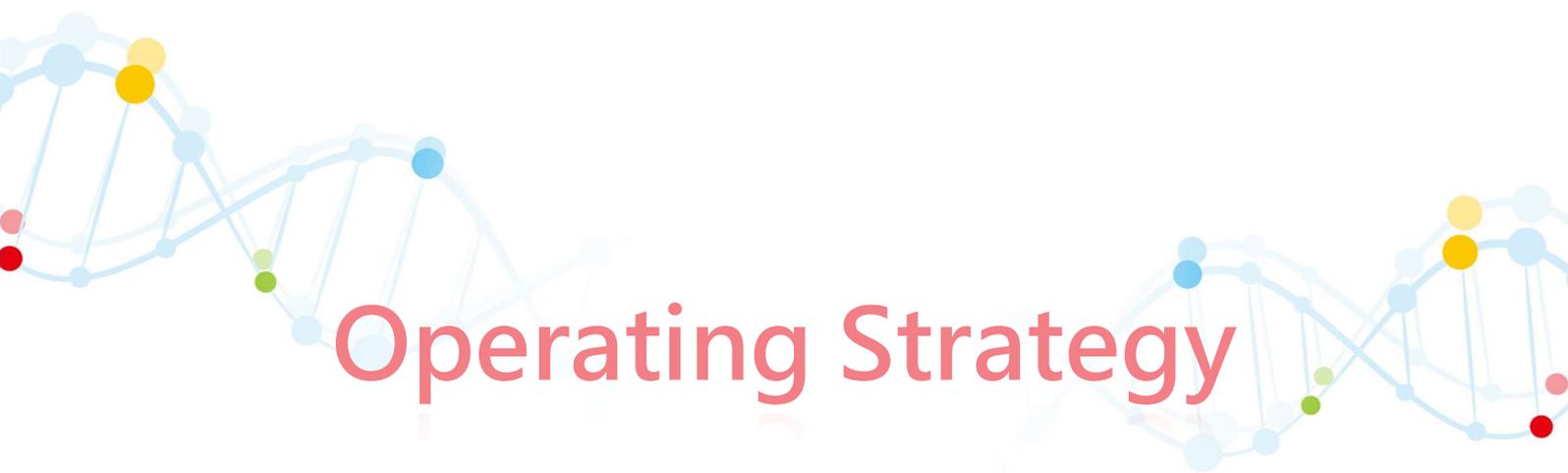
- Cancer Monitor
- Cancer Scan v1.0/v2.0
- Cancer Risk v1.0/v2.0
- HPV Screening

Newborn

- Baby Scan
- Hearing Loss Genetic Screening
- CCHS Genetic Screening
- Congenital CMV Infection Screening
- Atopic Dermatitis Genetic Screening -FLG gene

Precision Medicine

- HRD Status
- CGP Genetic Test
- BRCA1/2 Genetic Testing
- Endometrial Cancer Genetic Subtypes
- Prostate Cancer Genetic Testing

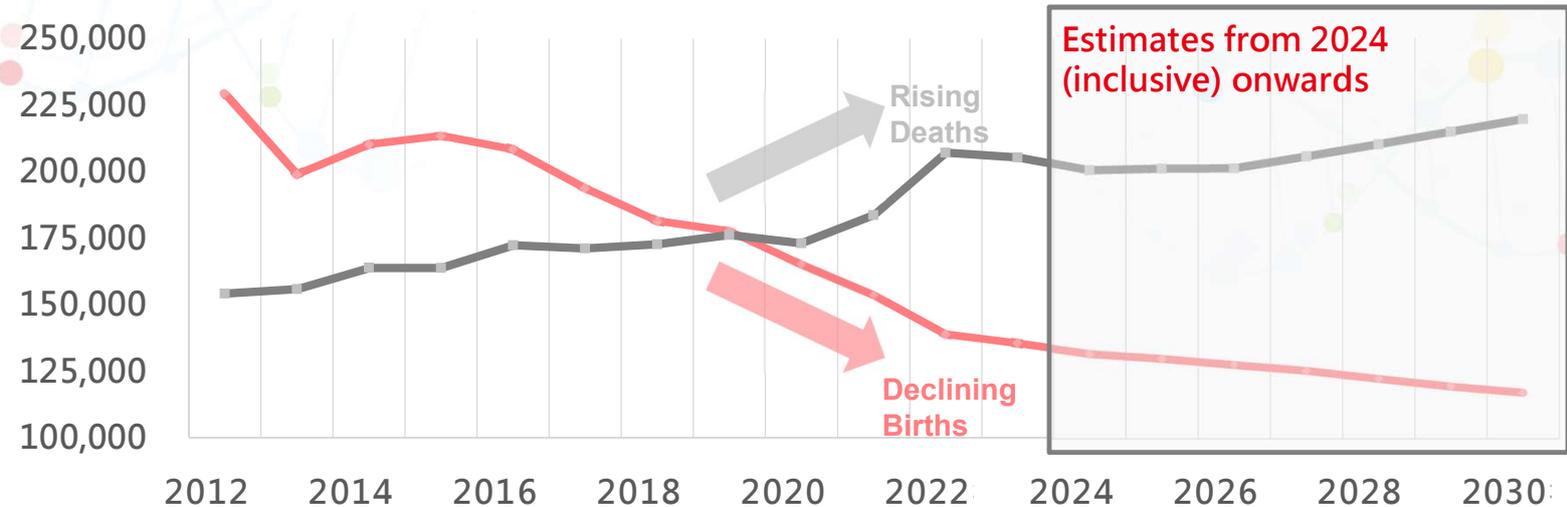


Operating Strategy

The Impact of Declining Birth Rates

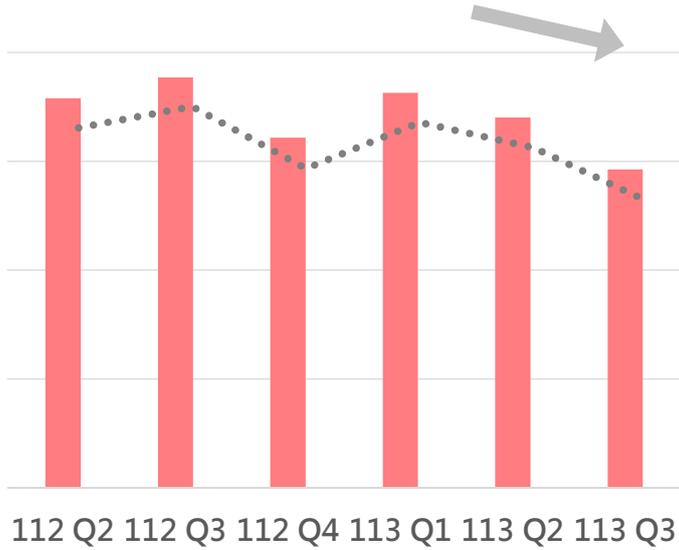
NUMBER OF BIRTHS AND DEATHS

- Number of Births
- Number of Deaths

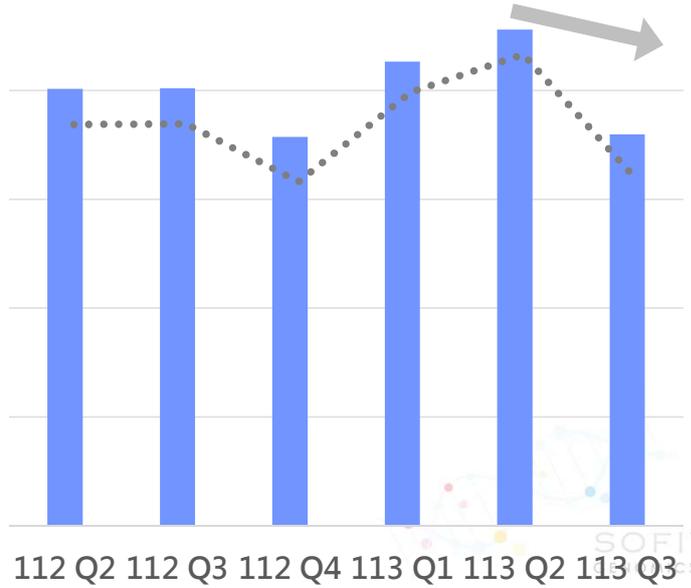


Impact of Declining Birth Rates on Revenue

Reproductive
PGT-A+PGT-M



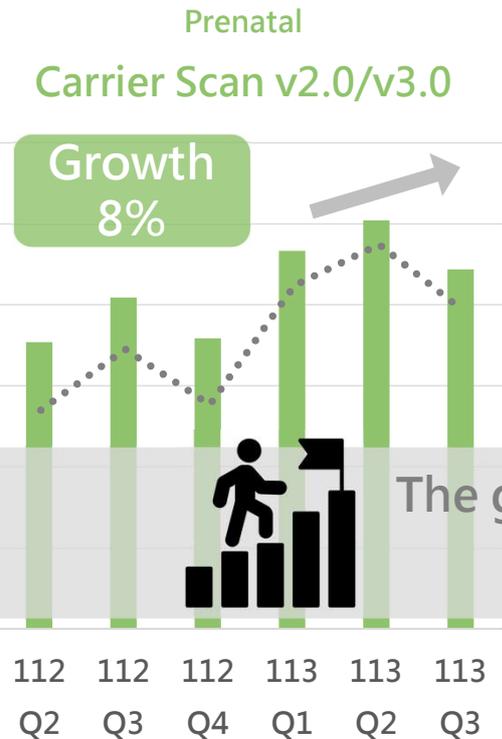
Prenatal
NIPS v2.0/v3.0



113Q3 compared to 112Q3

Focus on Advancing High-Level Projects on Revenue

113Q3 compared to 112Q3



The goal is to boost revenue per capita from testing.
We will refine market direction and promotion.

Cancer Products Aligned with Clinical Requirements

1. Clinical Institutions

Partner Institutions: Over 190 Hospitals and Clinics



品項	基因數	檢體	特色	適用科別
1 子宮內膜癌基因分型	6	組織+血液	市場獨家; 子宮內膜癌治療	婦科
2 癌監控基因檢測-膽管癌	13	組織 or 血液	膽管癌: FDA用藥+ 臨床試驗用藥	消化
3 癌監控基因檢測-泌尿道上皮癌	13	組織 or 血液	泌尿道上皮癌: FDA用藥+ 臨床試驗用藥	泌尿
4 癌監控基因檢測-肺癌	26	組織 or 血液	肺癌: FDA用藥+ 臨床試驗用藥	胸腔
5 癌監控基因檢測-乳癌	26	組織 or 血液	乳癌: FDA用藥+ 臨床試驗用藥	乳外
6 癌監控基因檢測-大腸癌	26	組織 or 血液	大腸癌: FDA用藥+ 臨床試驗用藥	直外
7 HRD檢測	28	組織+血液	在台灣已收案1000多案例	婦科/乳外/泌尿
13 癌風險-大腸癌基因檢測			可用液體 全球第一	
14 癌風險-婦癌基因檢測				
15 癌風險基因檢測 v1.0	67	組織 or 血液	各癌別	全科別
16 癌風險基因檢測 v2.0	151	組織 or 血液	各癌別	
17 癌監控基因檢測 v2.2	197	組織+血液	全方位: FDA用藥+ 復發相關基因	
18 癌監控基因檢測 v3.0	249	組織+血液	全方位: FDA用藥+ 臨床試驗用藥+ 復發相關基因	

Multiple Products

Multiple Sample Types

Unique Testing Features

Wide Range of Applicable Specialties



Cancer Products Compliant with Government Policies

2. NGS Genetic Laboratory - Accredited Laboratory Operations

Compliant with the Qualifications and Standards of the Regulations on Special Medical Techniques

衛生福利部食品藥物管理署
精準醫療分子檢測實驗室列冊登錄資料

機構名稱：慧智基因醫學檢驗所(地址：臺北市中正區寶慶路27號6樓・8樓)
機構負責人：連鈺萍
實驗室名稱：慧智基因醫學檢驗所(地址：臺北市中正區寶慶路27號)

實驗室負責人
列冊登錄編號
列冊有效期間
列冊範圍：

項次	內容
1	癌症
2	癌症
3	癌症

2. 基因數：249 (附表1)

LDTs Registration

財團法人台灣醫學會
Taiwan Accreditation Foundation
認證證書
(證書編號：L-1962-210011)

茲證明
慧智基因醫學檢驗所
慧智基因醫學實驗室
台北市中正區寶慶路27號(6樓・8樓)
為本會認證之實驗室

證 照 號：ISO 15189：2012
證 照 編 號：4982
新 證 照 日 期：一百一十二年三月二十八日
證 照 有 效 期 間：一百一十二年三月二十八日至一百一十五年三月二十一日止

ISO15189

連鈺萍
中華民國一十二年四月一日

Pathological Slides

Biological Analysis

Report Consultation

Report Discussion



Cancer Products Compliant with NGS Health Insurance Coverage

3. NGS Genetic Testing Laboratory and Testing Compliant with NGS Health Insurance Coverage

Over Ten Types of Tests

1

納入健保給付

14 Types Solid Tumors

5 Types Hematologic Cancers

健保
1
輸卵管癌/原發性膽胰癌*攝護腺癌*胰臟癌*NTRK基因融合
實
泌
不
B細胞淋巴瘤(BCL)*及T或NK細胞血癌與
淋巴癌(NKTL)*

① NGS 檢測給付以檢測結果有對應「具藥標的標靶藥物」且「效果明確之癌別及檢測基因」為優先
② 7大類癌症*專家共識建議採單基因檢測



Compliant with Health Insurance Coverage Criteria for Various Cancer Types

BRCA1/2 Genetic Testing

Coverage of \$10,000 TWD

Small Panel ≤100 genes

Coverage of \$20,000 TWD

Large Panel > 100 genes

Coverage of \$30,000 TWD

可再次檢測(不包含癌症轉移)
② NGS 檢測結果須上傳至健保署, 未來有新標靶藥物納入健保給付, 不需重新檢測, 可直接比對資料庫, 把握用藥黃金期, 提升治療效益及降低民眾經濟負擔



Current Status of Cancer Product Review

次世代基因定序檢測實驗室審查慢 醫事司：改電子化

2024-10-21 03:48 聯合報 / 記者沈龍元 / 台北報導

+ 腫瘤



「次世代基因定序檢測」(NGS)上路後,可望讓晚期癌友獲得精準治療,但成效卻不如預期,一位不具名腫瘤科醫師表示,部分關鍵在於實驗室開發檢測(LDTs)核准速度太慢,建議明文規定適當審查期限,讓醫療院所掌握完成時間。

義大癌治療醫院副院長饒坤銘表示,NGS採「事前報備、事後審查」制度,一旦癌友血液上,

The Laboratory Review Process is Experiencing Delays

饒坤銘表示,就院方來說,右並非做體取疵,造成做測後無法找到突變基因,應算有雙檢測。除非是檢體瑕疵,無法完成檢測才給予退費,醫院應先與病人說明溝通。建議健保署盤點NGS審查、收費、退費等流程,使其更為流暢,並讓更多醫院加入檢測,才能提高服務量能,「不要讓病人想做,卻沒得做」。

衛報

衛福部醫事司副司長劉玉菁指出,實驗室開發檢測(LDT)送審個案均已審查完畢,僅剩八一件,仍有四二八四件待審。為加速審查作業,已要求院所「日後醫療設備為醫療院所採電子化,節省人工審查及書面往來時間,期望送檢案件儘速完成審查。

Testing Items Awaiting Simplified Review

NGS給付累計842件、肺癌最多 台大癌醫院長曝有1限制

2024-11-16 10:50 聯合報 / 記者林琮恩 / 台北即時報導

+ 肺癌



As of Now, Only 842 Applications Have Been Approved

第一,其次為卵巢/輸卵管/腹膜癌共155件,其次為肝癌/膽管癌63件,胰臟癌16件,甲狀腺癌12件,小於100基因的「小套組」247件, BRCA 1/2基因檢測為最多,共432件。

Cancer Product Response Strategies

Slow Review Process

Establish a Dedicated Team to Handle the Process



Accelerate Data Processing

Monitor the Review Process Speed



Health Insurance Coverage for NGS

Focus on Key Tests Covered by Health Insurance for NGS

Breast Cancer

Ovarian Cancer

Lung Cancer

Pancreatic Cancer

Cholangiocarcinoma

Prostate Cancer

BRCA

HRD

CGP

MSI

Series of Lung Cancer Tests

Series of Cancer Monitor

Testing Items Awaiting Simplified Review

In Response to the High Demand for Health Insurance Coverage of NGS

In Response to the Demand for Health Insurance Coverage of Medications

Strengthen Cross-Industry Alliances

Focus on Key Tests Covered by Health Insurance for Medications

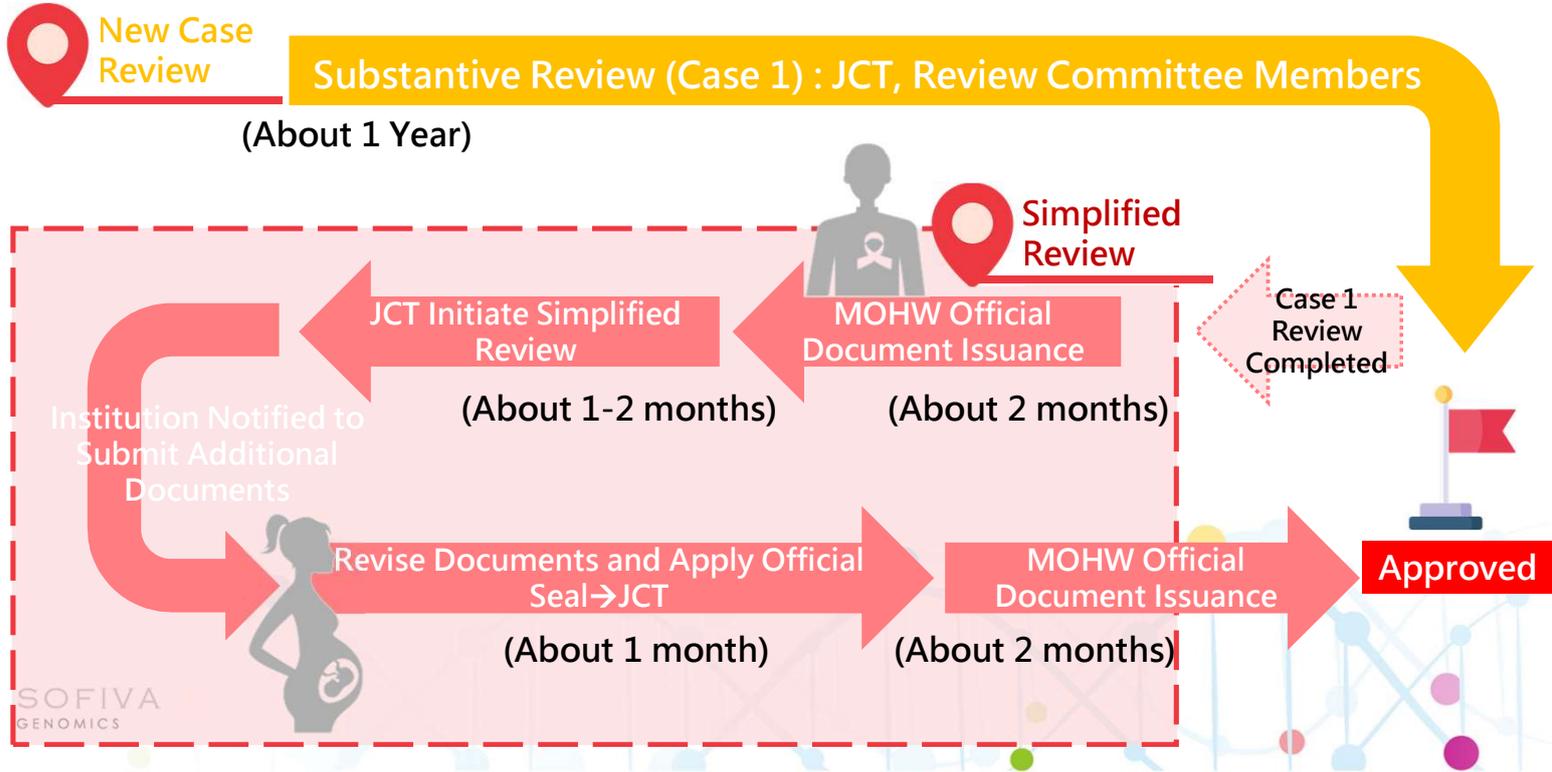
Pharmaceutical Partners



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Review Process and Progress





Strategic Expansion into the Health Check-up Market

Cancer: The Leading Cause of Death

Top 10 Cancer Causes of Death

In 2021, 120,000 New Cancer Cases (Published in 2023)
In 2023, 50,000 Cancer Deaths (Published in 2024)

Lung
Cancer

Liver
Cancer

Colorectal
Cancer

Breast
Cancer

Prostate
Cancer

Early Cancer Screening Reduces Mortality Risk by up to 70%
MOHW to Increase Early Cancer Screening Budget in 2025
(from 2.8 Billion to 6.8 Billion)

Oral
Cancer

Pancreatic
Cancer

Stomach
Cancer

Esophageal
Cancer

Ovarian
Cancer

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Source: MOHW, Department of Statistics

Strengthen the National Cancer Prevention and Control Program

早期癌篩、新藥基金、精準醫療 目標2030年癌死降三分之一

2024-11-29 02:40 聯合報 / 記者周佑政、廖靜清、賴明岫 / 台北報導

+ 健保

分享 1 分享



Enhance Early Cancer Screening



Provide Coverage for Cancer Genetic Testing



Increase Cancer New Drug Fund by Billions

2024 新清境 國家希望工程

健康台灣

強化國家癌症防治計畫

目標

2030年癌症標準化死亡率降低1/3

癌症治療三箭

- 1 提升早期癌症篩檢
- 2 聚焦基因檢測與精準醫療
- 3 建立百億癌症新藥基金

衛生福利部 常務次長 周志浩 報告人



Reduce Cancer Mortality Rate by One-Third by 2030

總統府健康台灣推動委員會第二次會議昨天登場，衛福部提出「強化癌症防治策略」報告。圖／擷取自總統府YT頻道

Health Check-up Market Size



衛生福利部國民健康署
Health Promotion Administration, Ministry of Health and Welfare

Utilization Rate of
Preventive Health
Services Among
Taiwanese Adults

40-64yrs

Utilized Population
Qualified Individuals Tested

3,035,023

72.2%

843,280

>65yrs

Utilized Population
Qualified Individuals Tested

4,085,793

74.2%

1,054,877

25.8%

40-64yrs	Ages 40-64: Eligible for Screening Every 3 Years
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Qualified Individuals Tested 3,035,023

Utilized Population 843,280

Service Utilization Rate 27.8%

>65yrs	Ages 65 and Above: Eligible for One Screening per Year
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Qualified Individuals Tested 4,085,793

Utilized Population 1,054,877

Service Utilization Rate 25.8%

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Source : Executive Yuan Gender Equality Committee; National Health Insurance Administration, 2022 Adult Preventive Health Services Payment Data File; Ministry of the Interior Population Statistics (Year-End Population)

Health Checkup Market : Product Expansion



Preconception



Female



Male



Elderly

Available for All
Specialties: Access to
Preconception Screening
with Seamless Referral
After Screening

In Line with Regular Health
Insurance Screenings, Early
Screening for Women's
Cancers is Crucial

In Line with Regular Health
Insurance Screenings, Early
Screening for Men's
Cancers is Crucial

Health Management for
the Elderly Population:
Focus on Cancer, Aging,
and Dementia

Comprehensive and Precise Health

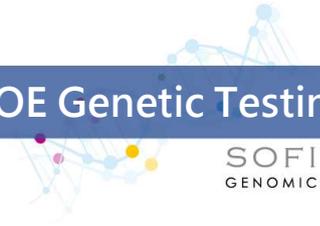


Carrier Scan

Cancer Scan

Cancer Risk

APOE Genetic Testing



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The world's top medical journals NEJM

NIPS / NIPT

cfDNA Result

Unable to Analyze Chromosomal Aneuploidy

Failure Report



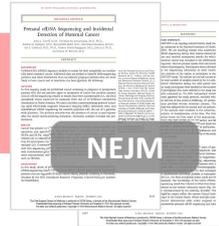
Suspected Maternal Cancer

No Cancer Symptoms in the Pregnant Woman

52 People With Cancer

48.6%

107 People Unable to Analyze



NEJM

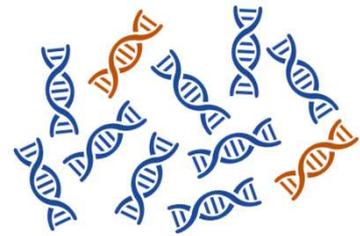
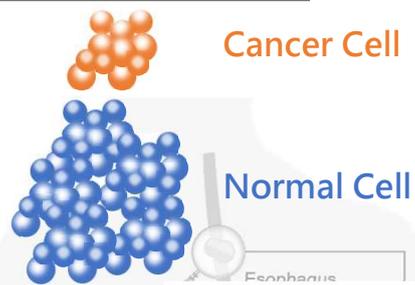


Strategic Expansion into the Health Check-up Market

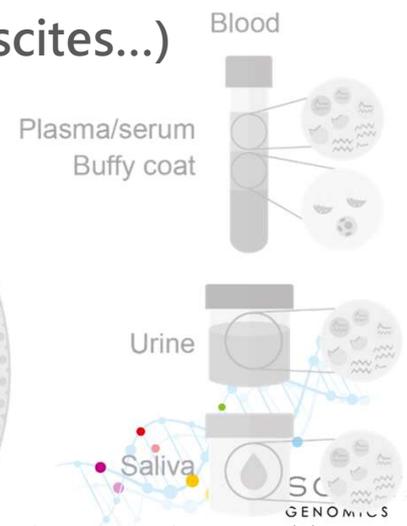
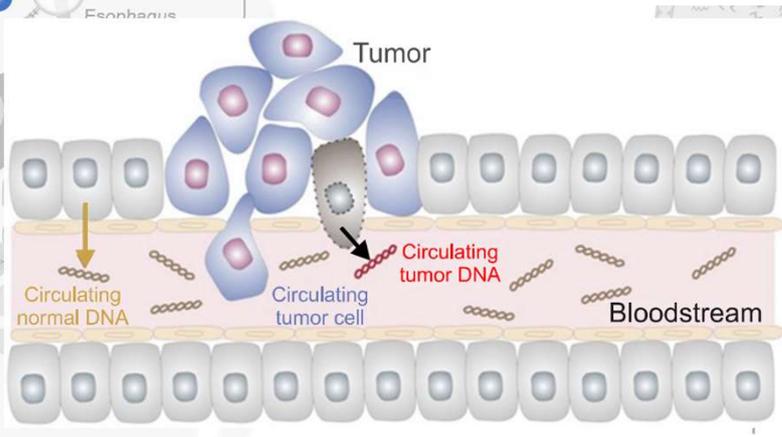
Cancer Scan *Liquid Biopsy*

Cancer Screening

What is Liquid Biopsy? Circulating Tumor DNA (ctDNA)

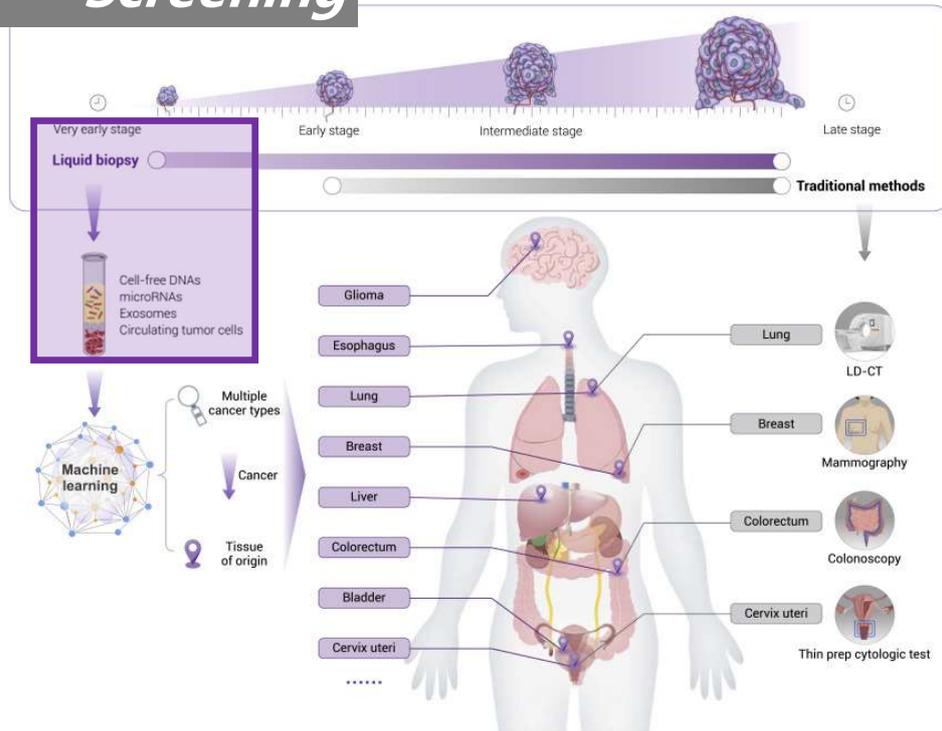


Blood (Urine/Ascites...)



Cancer Screening

The Advantages of Using ctDNA) for Cancer Screening



Liquid Biopsy

- Can detect early-stage cancer
- Can provide information on multiple types of cancer simultaneously
- A simple blood draw is sufficient
- Provide genetic information about the tumor

Traditional Cancer Screening

- Less sensitive
- Targets only one type of cancer at a time
- Some cancers do not have suitable detection methods
- Mostly invasive testing
- Cannot provide genetic information about the tumor

The Innovation 3(4): 100259, July 12, 2022



SOFIVA Blood Testing

Genetic Mutations + Cancer Screening + Cancer Recurrence

Healthy Individual

Diagnosis

Surgery (Treatment)

Hereditary Genetic Testing

Family Genetic Testing



Blood

Liquid Biopsy

ctDNA

Hereditary Genetic Testing

Family Genetic Testing



Blood

Liquid Biopsy

Target Therapy



ctDNA

Early Detection

Early Screening



ctDNA

1. Target Therapy
2. Cancer Monitor

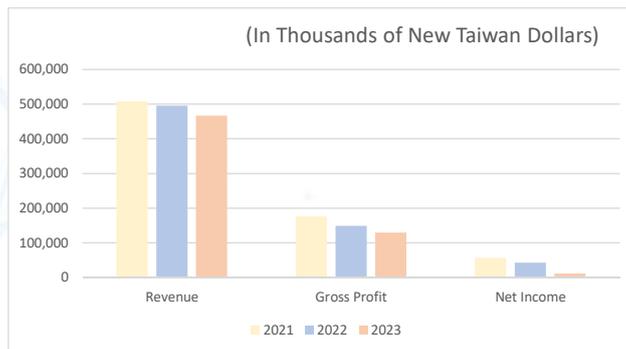
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Operating Performance

Operational Performance

Statements of Comprehensive Income of last 3 years



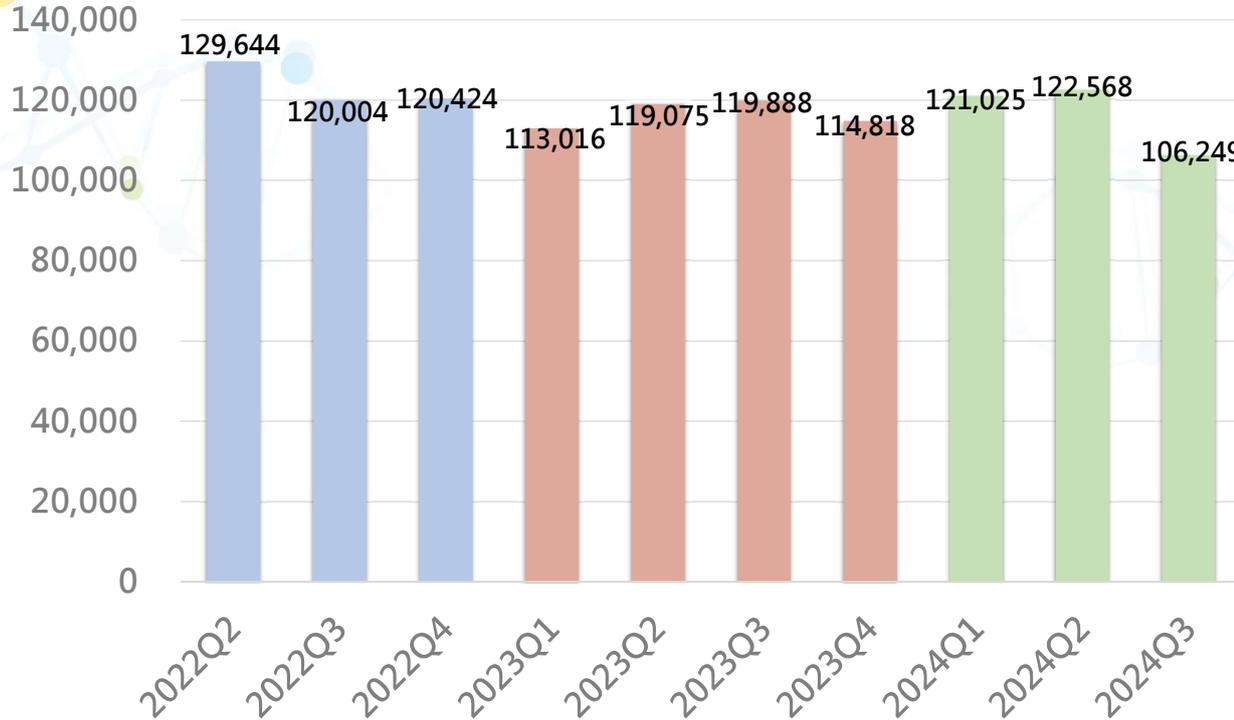
(In Thousands of New Taiwan Dollars)

	2021	2022	2023
Revenue	508,415	495,775	466,797
Gross Profit	176,813	148,988	129,908
Gross Profit (%)	34.78%	30.05%	27.83%
Operating Income	35,240	3,787	(15,882)
Total Non-Operating Income	28,453	43,562	24,785
Pre-Tax Income	63,693	47,349	8,903
Net Income	56,769	43,153	11,923
EPS	2.68	2.00	0.54

Revenue Trend : The Last 10 Quarters

(In Thousands of New Taiwan Dollars)

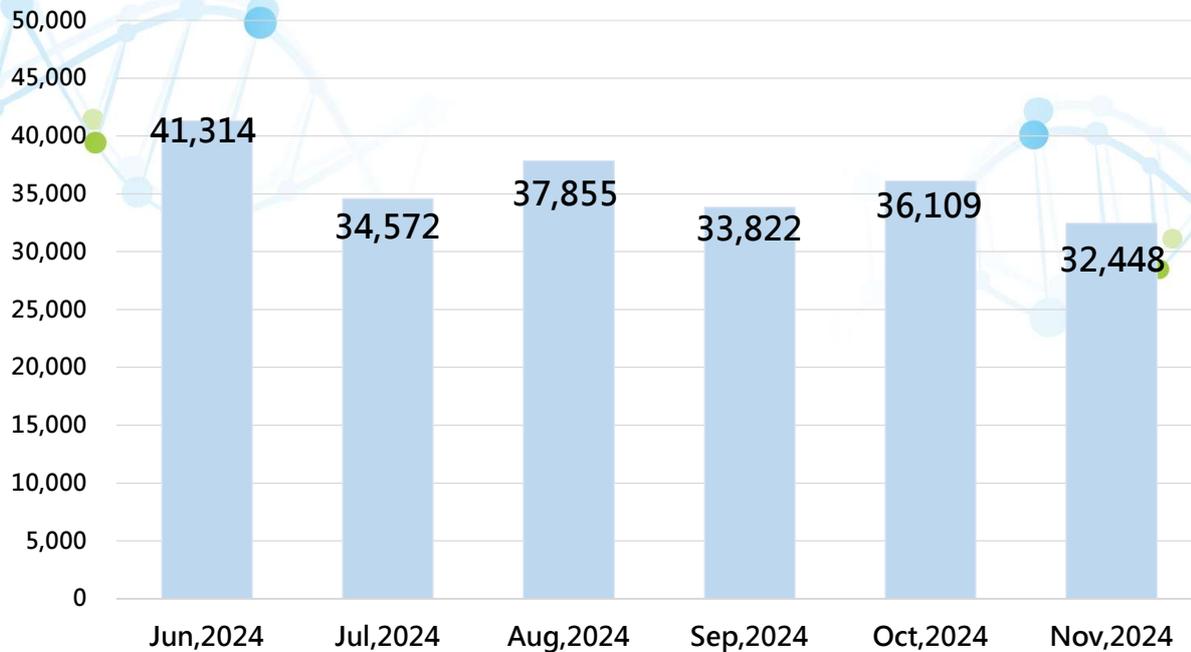
Revenues of Last 10 Quarters



Revenue Trend : The Last 6 Months

Revenues of Last 6 Months

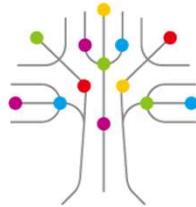
(In Thousands of New Taiwan Dollars)



Investment Performance

(In Thousands of New Taiwan Dollars)

DIANTHUS CO.,Ltd			
Statements of Comprehensive Income			
	2021	2022	2023
Sales Revenue	599,944	689,795	695,831
Comprehensive Income	171,767	253,022	142,929
Capital Stock	895,000	895,000	895,000
Investment from Sofiva	148,250	148,250	148,250
Shareholding Ratio of Sofiva	16.56%	16.56%	16.56%
Investment Income of Sofiva	31,047	41,902	23,671



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