



## AUGUST 13, 2024

Pancreatic Cancer-Global Clinical Trial Landscape (2024)

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Did you

know?

## **PANCREATIC CANCER (PC)** GLOBAL CLINICAL TRIAL LANDSCAPE (2024)

Asia had the highest incidence cases and accounted for nearly 45% of the global incidence cases of PC

**Europe** had the **second highest incidence**, with over 146,000 cases

**North- America** had **more than 67,000 cases**, followed by rest of the world (ROW)

PANCREATIC CANCER







The PC treatment market offers **diverse products** by companies including **Astellas Pharma Inc., Bristol Myers Squibb Co. and GemVax & Kael Co. Ltd** 



Multiple ongoing **Phase III trials** demonstrate continued efforts to enhance PC treatment **through antibody, small molecule, and protein** 

## PANCREATIC CANCER TRIAL CONTRIBUTIONS

LEADING CAUSE OF CANCER MORTALITY

Hh

Countries like **United States, Mainland China, Australia, Spain, and South Korea** emerged as **top locations** for conducting trials

Asia-Pacific showed faster recruitment durations and patient recruitment rates ASIA-PACIFIC & EUROPE

ROW

**38%** NORTH AMERICA

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## 1. EPIDEMIOLOGY

#### Introduction

Pancreatic cancer (PC) is known to be one of the most fatal gastrointestinal cancers (1). Worldwide, PC ranks twelfth in terms of total cancer incidence and sixth in cancer-related deaths (2). Pancreatic Ductal Adenocarcinoma (PDAC) is the most common subtype, comprising about 90% of cases, while Pancreatic Neuroendocrine Tumors account for the remaining 10%. PC occurs more frequently in elderly people aged 65 and above, with males reporting greater incidences of PC than females. According to GLOBOCAN 2022, there were over 240,000 PC cases reported in females with an ASIR (age-standardized incidence rate) of 4 per 100,000 population, and close to 270,000 PC cases in males with an ASIR of 5.5 per 100,000 population (2). Although the exact etiology of PC is unknown, risk factors include age, gender, ethnicity, family history, food and lifestyle choices, pancreatitis, obesity, and infections (1). PC has a poor prognosis, and the 5-year survival rate is between 2%-10%, with slight disparities between developed and developing countries (1). PC patients are treated with targeted therapy, immunotherapy, and microbial therapy in addition to surgery, chemotherapy, radiation, and palliative care (3). This disease report provides a detailed overview of the global PC clinical trial landscape and PC burden in different locations across the globe.

#### Epidemiology

Globally, PC accounted for nearly 511,000 new cases and 467,400 deaths in 2022. The global ASRs (Age Standardized Rates) of incidence and mortality for PC were 4.7 and 4.2 per 100,000 population respectively. This overview highlights the incidence and prevalence of PC across various regions and locations based on the data provided by GLOBOCAN 2022.

Asia led in PC incidence, with approximately 232,500 reported cases, and accounted for nearly 45% of the global PC cases in 2022. China alone contributed over 118,600 cases. Following this, Japan and India also reported higher incidences with over 47,600 and 13,600 cases, respectively. Japan had the highest ASIR rate of 9.7 per 100,000 population. Countries like Singapore, South Korea, the Philippines, Malaysia, and Thailand showed varying ASIRs, ranging from 7.6 to 2.0 per 100,000 population.

Europe reported approximately 146,400 PC cases, with an ASIR of 8 per 100,000 population, indicating a significant but comparatively lower burden than in Asia. Germany, France, Italy, and the United Kingdom reported between 21,000 and 11,000 cases. Spain and Poland have comparatively lower incidences, highlighting the diverse epidemiological landscapes across Europe.

The North American region had over 67,000 cases with the United States alone reporting around 60,000 cases with an ASIR of 8.5 per 100,000 population. Canada reported nearly 6,900 cases with an ASIR of 7.5 per 100,000 population.

Latin America and the Caribbean reported nearly 41,000 cases of PC, with Brazil leading in this region with 14,600 cases. The region's incidence rate was 4.7 per 100,000 population, showing a considerable but relatively lower burden compared to other locations.

Africa reported around 18,900 PC cases in 2022, grappling with limitations in health infrastructure that might have hindered efforts to combat the disease. South Africa led in the region with more than 2,700 cases and reported a global incidence rate of 5.2 per 100,000 population.

Oceania reported the lowest numbers with over 4,800 PC cases, with an ASIR of 6.2 per 100,000 population. Australia and New Zealand contributed to the regional burden, reinforcing the need for targeted initiatives and healthcare improvement.

Over the next 25 years, predictions indicate that PC instances will continue to rise, perhaps exceeding 998,600 new cases per year by 2050 (over 95.4% increase since 2022). The huge disparities in incidence rates among the various locations highlight the need for customized prevention and treatment strategies globally. (2)

Non-Hispanic Africans have higher incidence rates than non-Hispanic Europeans due to factors like smoking, diabetes, and obesity. Even with lifestyle adjustments, non-Hispanic Africans have a 20% higher risk, likely due to biological factors like slower carcinogen metabolism and increased K-RAS mutations. Asians have lower PDAC rates and higher survival, possibly due to lower smoking and obesity rates and genetic factors like lower SPARC expression. Common mutations include BRCA2, PALB2, ATM, and CDKN2A. Even without a family history, 5-8% of PDAC patients carry predisposing mutations, highlighting the importance of multigene panel testing. (4)



#### Figure 1: Regional Distribution of Pancreatic Cancer

Source: GLOBOCAN2022

#### Table 1: Global Incidence and Prevalence of PC, by regions (2022).

| Pogions                         | Incidence |             |                   |  |
|---------------------------------|-----------|-------------|-------------------|--|
| Regions                         | Cases     | ASR (World) | 5-year prevalence |  |
| World                           | 510,992   | 4.9         | 337,872           |  |
| Asia                            | 232,537   | 3.6         | 213,982           |  |
| Europe                          | 146,477   | 8.0         | 123,249           |  |
| Northern America                | 67,089    | 8.5         | 59,433            |  |
| Latin America and the Caribbean | 41,032    | 4.6         | 38,225            |  |
| Africa                          | 18,993    | 2.4         | 22,590            |  |
| Oceania                         | 4,864     | 6.2         | 4,000             |  |

Source: GLOBOCAN 2022

#### Table 2: Global Incidence and Prevalence of PC, in selected locations (2022).

| Leastions     | Incidence |             |                   |  |
|---------------|-----------|-------------|-------------------|--|
|               | Cases     | ASR (World) | 5-year prevalence |  |
| World         | 510,992   | 4.7         | 337,872           |  |
| China         | 118,672   | 4.4         | 111,752           |  |
| United States | 60,127    | 8.5         | 53,607            |  |
| Japan         | 47,627    | 9.7         | 32,262            |  |
| Germany       | 21,869    | 8.7         | 16,629            |  |
| Russia        | 21,842    | 7.7         | 21,496            |  |
| France        | 15,895    | 9.4         | 12,882            |  |
| Italy         | 15,710    | 7.9         | 11,570            |  |
| Brazil        | 14,670    | 4.7         | 13,766            |  |
| India         | 13,661    | 0.9         | 16,056            |  |

| United Kingdom  | 11,351 | 6.6 | 9,066 |
|-----------------|--------|-----|-------|
| South Korea     | 8,891  | 4.6 | 8,040 |
| Spain           | 8,823  | 7.5 | 7,625 |
| Canada          | 6,939  | 7.5 | 5,826 |
| Poland          | 5,881  | 6.7 | 5,135 |
| Australia       | 3,988  | 6.9 | 3,264 |
| Philippines     | 4,045  | 4.0 | 4,338 |
| The Netherlands | 3,490  | 8.1 | 2,596 |
| Thailand        | 3,314  | 2.5 | 3,248 |
| South Africa    | 2,779  | 5.2 | 3,112 |
| Nigeria         | 1,344  | 1.3 | 1,625 |
| Malaysia        | 1,014  | 2.7 | 1,182 |
| Singapore       | 923    | 7.6 | 872   |
| New Zealand     | 661    | 6.0 | 544   |



Source: GLOBOCAN 2022

## 2. STANDARD OF CARE

The sections below discuss PC treatment guidelines and other insights from the National Comprehensive Cancer Network (NCCN), the European Society for Medical Oncology (ESMO), and the Japan Pancreas Society.

#### NCCN Guideline Version 2.2024

The NCCN Guideline 2024, provides essential recommendations for PC across different stages. The table below outlines preferred and other recommended regimens for systemic therapy. These evidence-based guidelines aid clinicians in tailoring treatment strategies for optimal patient outcomes. (5)

#### Table 3: Recommendations on PC, NCCN Guideline Version 3.2024.

| Disease stage/Therapy<br>Type | Regimen  | Notes  |  |
|-------------------------------|--|--|--|
| Neoadjuvant Therapy           | -  | Limited evidence: practices vary with chemotherapy and radiation usage. Clinical trial encouraged. |  |
| Adjuvant Therapy              | - Modified FOLFIRINOX (ECOG 0–1)   | Specific regimens are recommended.   |  |
| Locally Advanced Disease      | - FOLFIRINOX or modified FOLFIRINOX<br>- Gemcitabine + nab-paclitaxel  | For patients with ECOG 0–1.  |  |
| Metastatic Disease            | <ul> <li>FOLFIRINOX</li> <li>Gemcitabine + nab-paclitaxel</li> <li>Gemcitabine + erlotinib</li> <li>Gemcitabine + cisplatin (for BRCA/<br/>PALB2 mutations)</li> </ul> | For first-line therapy.  |  |
| Maintenance Therapy           | -  | For patients without disease progression after 4–6 months of chemotherapy.                         |  |
|                               | - PARP inhibitors  | For patients with BRCA1/2 or PALB2 mutations.  |  |
|                               | - Liposomal irinotecan + fluorouracil/<br>leucovorin   | For patients who have received gemcitabine-based therapy.  |  |
|                               | - Fluoropyrimidine-based therapy   |  |  |
| Subsequent Therapy            | - Pembrolizumab  | For patients who have received gemcitabine-based therapy.  |  |
|                               | - NTRK inhibitors (larotrectinib,<br>entrectinib)  | For patients with NTRK gene fusion positive.   |  |
|                               | - Dabrafenib + trametinib  | For patients with BRAF V600E mutation positive.  |  |

Source: NCCN Guidelines for PC (Version 2.2024); URL: https://www.nccn.org/professionals/physician\_gls/pdf/pancreatic.pdf

Note: This table provides a high-level overview. Please refer to the full NCCN guidelines for complete and up-to-date information

#### ESMO guidelines, 2023

In addition to NCCN, the European Society for Medical Oncology (ESMO) publishes clinical practice guidelines to guide treatment decisions for PC. The figure below summarizes the ESMO recommendations for PC. (6)

| Disease Stage Treatment Approach   |   | Therapies  |
|------------------------------------|---|--|
| Resectable Neoadjuvant<br>Adjuvant |   | - Clinical trial<br>- mFOLFIRINOX (ECOG PS 0-1)<br>- Gemcitabine + Capecitabine (ECOG PS 2, age >75, frail)          |
| Borderline Resectable              | Induction Therapy<br>Surgical Exploration | - FOLFIRINOX + CHT<br>- GN + CHT<br>- If fit and non-progressive, aim for R0 resection                               |
|                                    | Chemotherapy                              | - FOLFIRINOX<br>- GN   |
| Locally Advanced                   | Maintenance Therapy                       | - PARP inhibitors (BRCA1/2 or PALB2 mutations)   |
|                                    | Continuation                              | - Continue medical treatment or discuss surgery if downstaging occurs  |
|                                    | First Line                                | - FOLFIRINOX (ECOG PS 0-1, bilirubin < 1.5x ULN)<br>- GN<br>- Gemcitabine (ECOG PS 2)                                |
| Advanced PC                        | Second Line                               | - GN<br>- Gemcitabine<br>- Nanoliposomal Irinotecan + 5-FU-LV<br>- Alternatives: mFOLFOX6, OFF                       |
|                                    | Symptom-directed Care                     | - For ECOG PS 3-4  |
| Precision Medicine in Meta-        | First Line                                | - Maintenance Olaparib (BRCA mutations)<br>- Pembrolizumab (MSI-H/dMMR)<br>- Larotrectinib/Entrectinib (NTRK fusion) |
|                                    | Second Line                               | - Rechallenge with CHT (BRCA mutations)  |

#### Table 4: Systemic treatment for PC, ESMO 2023.

Source: ESMO Clinical Practice Guideline, URL: https://www.annalsofoncology.org/article/S0923-7534(23)00824-4/fulltext#secsectitle0100

Note: FOLFIRINOX: leucovorin-5-fluorouracil-irinotecan-oxaliplatin; GN: gemcitabine-nab-paclitaxel; LV: leucovorin; MDTB: multidisciplinary tumour board; mFOLFIRINOX: modified leucovorin-5-fluorouracil-irinotecan-oxaliplatin; PC: pancreatic cancer

. This table provides a high-level overview. Please refer to the full ESMO guidelines for complete and up-to-date information.

#### Japan Pancreas Society Guidelines, 2022

The table given below reflects the Japan Pancreas Society Practice Guidelines for PC treatment, established in 2022. (7)

#### Table 5: Recommendations of PC, Japan Pancreas Society Practice Guidelines, 2022.

| Stage of<br>Disease  | Patient<br>Type | Therapy Type                | Specific Therapies  |
|----------------------|-----------------|-----------------------------|---|
|                      | Non-elderly     | First-line<br>Chemotherapy  | <ul> <li>FOLFIRINOX therapy</li> <li>GEM + nab-PTX combination therapy</li> <li>GEM monotherapy</li> <li>S-1 monotherapy</li> </ul> |
|                      |                 | Second-line                 | After a GEM-containing regimen:<br>- FF + nano liposomal irinotecan combination therapy.<br>- Fluorouracil-containing regimen       |
|                      |                 |                             | After a fluorouracil-containing regimen:<br>- GEM-containing regimen  |
|                      |                 | Chemotherapy                | For MSI-H or TMB-H cases:<br>- Pembrolizumab monotherapy  |
| Locally<br>Advanced  |                 |                             | For NTRK gene fusion cases:<br>- Entrectinib monotherapy or larotrectinib monotherapy   |
| (UR-LA)              |                 | First-line<br>Chemotherapy  | - GEM + nab-PTX combination therapy<br>- GEM monotherapy<br>- S-1 monotherapy   |
|                      |                 | Second-line<br>Chemotherapy | After a GEM-containing regimen:<br>- FF + nanoliposomal irinotecan combination therapy<br>- Fluorouracil-containing regimen         |
|                      | Elderly         |                             | After a fluorouracil-containing regimen:<br>- GEM-containing regimen  |
|                      |                 |                             | For MSI-H or TMB-H cases:<br>- Pembrolizumab monotherapy  |
|                      |                 |                             | For NTRK gene fusion cases:<br>- Entrectinib monotherapy or larotrectinib monotherapy   |
|                      | Non-elderly     | First-line<br>Chemotherapy  | - FOLFIRINOX therapy<br>- GEM + nab-PTX combination therapy   |
|                      |                 |                             | When the above two treatments are not suitable:<br>- GEM monotherapy<br>- S-1 monotherapy   |
|                      |                 | Second-line<br>Chemotherapy | After a GEM-containing regimen:<br>- FF + nanoliposomal irinotecan combination therapy<br>- Fluorouracil-containing regimen         |
|                      |                 |                             | After a fluorouracil-containing regimen:<br>- GEM-containing regimen  |
|                      |                 |                             | For MSI-H or TMB-H cases:<br>- Pembrolizumab monotherapy  |
| Metastatic<br>(UR-M) |                 |                             | For NTRK gene fusion cases:<br>- Entrectinib monotherapy or larotrectinib monotherapy   |
|                      |                 | First-line<br>Chemotherapy  | - GEM + nab-PTX combination therapy<br>- GEM monotherapy<br>- S-1 monotherapy   |
|                      |                 | Second-line<br>Chemotherapy | After a GEM-containing regimen:<br>- FF + nanoliposomal irinotecan combination therapy<br>- Fluorouracil-containing regimen         |
|                      | Elderly         |                             | After a fluorouracil-containing regimen:<br>- GEM-containing regimen  |
|                      |                 |                             | For MSI-H or TMB-H cases:<br>-Pembrolizumab monotherapy   |
|                      |                 |                             | For NTRK gene fusion cases:<br>- Entrectinib monotherapy or larotrectinib monotherapy   |

Source Japan Pancreas Society Practice Guidelines, URL: Clinical Practice Guidelines for Pancreatic Cancer 2022 from the Japan Pancreas Society: a synopsis | International Journal of Clinical Oncology (springer.com) Note: This table provides a high-level overview. Please refer to the full Japan Pancreas Society Practice Guidelines for complete and up-to-date information.

## 3. GLOBAL CLINICAL TRIAL LANDSCAPE

Since 2019, the biotech and biopharma industry initiated over 2,000 PC clinical trials worldwide. North America and Asia-Pacific each contributed a similar share of trials, at 38% and 37% respectively, followed by Europe at 20%. The ROW contributed a moderate share of 5%. The United States had the highest trial share (88%) in North America, while Canada had 12%. Mainland China led the trial activity in Asia Pacific with a majority trial share of 43%, followed by Australia (17%) and South Korea (16%). Within Europe, Spain, France, the United Kingdom, and Italy, led the PC trials, showing the region's contribution to advancing research. Among the ROW countries, Israel led the trial activity followed by Iran and Chile. (Figure 3,4,5,6,7) (8)







Source: GlobalData, July 2024 Others- Asia Pacific: Hong Kong, India, New Zealand, Thailand, Malaysia, and Vietnam ROE: (excluding Russia) ROW: Includes Middle East and Africa and South and Central America The global landscape of PC trials reflects a strong focus on advancing research for novel therapeutics to effectively treat PC. Locations like the United States, Mainland China, Australia, Spain, and South Korea emerged as the top destinations for conducting trials. These trials reflect a consistent global effort towards PC research, though the intensity varies considerably across different countries and regions. (Figure 8). (8)



Locations where Novotech directly operates.

Others- Asia Pacific: Hong Kong, India, New Zealand, Thailand, Malaysia, and Vietnam ROE: (excluding Russia) ROW: Includes Middle East and Africa and South and Central America Source: GlobalData, July 2024

Moving on to trial phase trends, PC trials have shown advancements in various regions. North America, Asia-Pacific, and Europe mostly focus on early and mid-stage development, comprising Phase I and Phase II. ROW, on the other hand, participates to a lesser extent in different phases of the trials yet makes a moderate contribution to the overall global PC research. This suggests a potential difference in regional approaches to clinical research, possibly influenced by factors like funding availability, regulatory environments, and healthcare infrastructure. (Figures 9) (8)

Based on the trials by status, across Asia-Pacific, North America, Europe, and ROW, the number of ongoing trials exceeds that of completed ones. Ongoing PC trials outnumber completed studies due to the need for long-term follow-up to assess survival rates and delayed adverse reactions. The complexity of trials involving intricate therapy combinations, such as perioperative and multimodal treatments, necessitates longer completion times. Additionally, adaptive trial designs in oncology, which permit modifications based on interim results, further extend the duration of these trials. (Figures 10) (8)



Source: GlobalData, July 2024

Others include: Planned, Suspended, Terminated, Withdrawn

#### **Trial Density**

Despite its large population, the Asia-Pacific region has a clinical trial density that is six times lower than that of the US and about half that of Europe. (Figure 11). This underscores the urgent need for increased research and targeted medical interventions in these regions. The Asia-Pacific region's comparatively lower clinical trial involvement indicates the region's untapped research potential. With a vast patient population and unique genetic diversities, particularly in countries like China, and South Korea, this region presents a prime opportunity for groundbreaking clinical research and the development of tailored therapeutic interventions. (8)



\*Trial density is the number of recruiting trial sites for industry-initiated trials per million urban population Source: GlobalData, July 2024

#### Patient Recruitment Landscape

Since 2019, clinical trials for PC have shown regional variations in recruitment metrics. The enrolment period data shows regional differences in clinical trial recruitment. Europe has the longest median trial duration at 27.12 months, followed by the US at 18.77, and Asia-Pacific with the shortest at 12.37 months. Additionally, the Asia-Pacific region achieved a higher median recruitment rate of 0.73 subjects per site per month, significantly outpacing the US rate of 0.29 and Europe rate of 0.20. This suggests that single-country trials running in Asia-Pacific since 2019 showcase the region's effectiveness in clinical trial initiatives and the ample availability of patient populations for such trials. (Figure 12,13). (8)



Source: GlobalData, July 2024

#### Growth trends of PC trials in Asia-Pacific, North America, and Europe (2014-2023)

Over the period from 2014 to 2023, the Asia-Pacific region experienced the highest increase in trial activity with a Compound Annual Growth Rate (CAGR) of 14.7%. North America followed with 5.1%, displaying a progressive trend in trial activity and Europe showed a steady and moderate growth rate at 0.2%. In contrast, the growth in ROW has declined by -5%. This trend suggests Asia-Pacific's progress in this field and a favorable research environment, while other regions also show sustained trial activity in PC. (Figure 14). (8)



Source: GlobalData, July 2024

## 4. DRUG DEVELOPMENT LANDSCAPE

Across the spectrum of PC drug development by phase, there are about 164 drugs in preclinical stages, 25 in research, and 91 in Phase I trials. Additionally, 142 drugs are in Phase II, 29 in Phase III, and 11 are already in the market, reflecting a progressive landscape of PC treatments. (Figure 15) (8)



Source: Biocentury, July 2024

Among the marketed drugs by diverse mechanisms of action (MOA), Ribonucleoside Diphosphate Reductase Large Subunit Inhibitor, DNA Synthesis Inhibitor, and Thymidylate Synthase Inhibitor dominate the landscape, followed by Epidermal Growth Factor Receptor ERB1 Inhibitor, and Serine/Threonine Protein Kinase mTOR Inhibitor. In addition, other enzyme inhibitors such as Somatostatin Receptor Type 2 Agonist, Somatostatin Receptor Type 5 Agonist, DNA Topoisomerase I Inhibitor, DNA Helicase Inhibitor, and Tubulin Inhibitor, and a few others contribute to the varied drug MOA. (Figure 16)

Additionally, in the ongoing Phase III trials of PC drugs, Programmed Cell Death 1 Ligand 1 Inhibitor, Fibroblast Growth Factor Receptor 3 Antagonist, CCN Family Member 2 Inhibitor, DNA Topoisomerase I Inhibitor, and a few other MOAs. The diverse MOA observed in marketed drugs for PC underscore the complexity and tailored nature of drug development, offering promising avenues for personalized treatment approaches in disease management. (Figure 17) (8)



Source: GlobalData, June 2024

## 5. FUNDING LANDSCAPE

#### Public and NGO funding initiatives

Public and NGO (such as Pancreatic Cancer Action Network) funding initiatives are transforming the landscape of PC treatment accessibility. Regional investments by government bodies are being made to expand access to innovative therapies and improve the quality of care for affected individuals. (Figure 18) These efforts not only alleviate financial burdens but also actively work to improve patient outcomes and address unmet medical needs in the fight against PC. (9–11)

#### Figure 18: Public funding initiatives for PC.

#### Pancreatic Cancer Action Network:

The Pancreatic Cancer Action Network provides grants for basic, translational, and clinical research focused on PC. Since 2003, they have awarded 236 grants to 217 scientists across 78 institutions, amounting to a total projected research investment of approximately \$208 million.

#### Pancreatic Cancer Action Network and National Cancer Institute:

The Pancreatic Cancer Action Network has played a cruicial role in boosting federal research funding for PC. They contributed to increasing National Cancer Institute (NCI) funding from \$17 million in 1999 to over \$203 million in 2021.

#### **National Cancer Institute:**

The NCI offers substantial funding for PC research through a range of grants and programs, supporting basic, clinical, and translational research focused on understanding and treating pancreatic cancer.

#### World Pancreatic Cancer Coalition:

The World Pancreatic Cancer Coalition unites organizations globally to increase awareness and fund research for PC. Their collaborative efforts aim to improve patient outcomes and support research initiatives.

#### Pancreatic Cancer Research:

The Pancreatic Cancer Research organization funds projects specifically targeting PC, with the goal of improving early detection, treatment, and survival rates.

Source: Pancreatic Cancer Action Network announces \$34 million in grants | Philanthropy news | PND (philanthropynewsdigest. org), PANCREATIC CANCER ACTION NETWORK (PANCAN) AWARDS MORE THAN \$10.5 MILLION OF INNOVATIVE RESEARCH GRANTS, MARKING LARGEST-EVER SINGLE YEAR INVESTMENT AND BRINGING THE ORGANIZATION'S TOTAL RESEARCH INVESTMENT LAST YEAR TO \$25 MILLION (prnewswire.com), Research Grants Program - Pancreatic Cancer Action Network (pancan.org).

#### **Venture Capital Funding**

Between 2019 and 2023, Venture Capital funding by locations show that China experienced an influx of venture capital, with investments of \$3.87 billion, followed by United States with \$3.18 billion. Countries such as Switzerland, France, the United Kingdom, and South Korea also contributed to venture funding, although to a lesser extent, with investments ranging from \$458 million to \$87 million. These investments reflect a global effort to advance PC research and development. (Figure 19) The top firms that received venture funding for PC include Kanaph Therapeutics Inc, CytosinLab Therapeutics Co Ltd, Netris Pharma SAS, and Bicara Therapeutics Inc.



Source: GlobalData, July 2024

Moving on to funding by rounds of financing, PC research and development have secured funding in Series C and Series B rounds from 2019 to 2023, highlighting investor interest and promising advances in treatment strategies. (Figures 20)

Based on the stage of development, over 60% of funding supported the Preclinical, Phase I, and Phase II stages, with a slight decline in investment during the discovery phase. In contrast, Phase III, IND/CTA Filed, and Marketed stages received smaller shares, reflecting the reduced need for external investment as the drug advances towards commercialization. (Figure 21). (8)



Source: GlobalData, July 2024

## 6. EVOLVING THERAPEUTIC STRATEGIES

PC research has seen significant advancements in recent years, offering new hope for patients and their families. Current treatments like neoadjuvant chemotherapy and innovative RAS-directed therapies are improving patient outcomes. Immunotherapy and stroma-modifying drugs are also showing promise in clinical trials. Additionally, new chemotherapy combinations, such as NALIRIFOX, have been approved for use. Looking ahead, the future of PC treatment appears promising, with advancements in personalized medicine, early detection methods, and targeted biological therapies on the horizon. Comprehensive treatment approaches combining surgery, chemotherapy, radiation, and novel therapies are expected to further enhance survival rates and quality of life for patients. (Figure 22) (12–15)

#### Figure 22: Emerging therapeutic strategies and Future Prospects in PC Treatment.

| Emerging therapeutic strategies   | Future Prospects  |
|---|---|
| <b>Neoadjuvant Chemotherapy:</b> This approach<br>involves administering chemotherapy before<br>surgery to shrink the tumor, making it easier to<br>remove and potentially improving outcomes.              | <b>Personalized Medicine:</b> Advances in genetic testing<br>and molecular profiling are paving the way for<br>personalized treatment plans tailored to each<br>patient's unique cancer profile.        |
| <b>RA S-Directed Therapies:</b> Researchers are developing drugs targeting mutant forms of the RAS gene, which is altered in over 90% of pancreatic cancers.  | <b>Early Detection:</b> Improved imaging techniques and liquid biopsies using circulating biomarkers are enhancing early detection capabilities.  |
| <b>Immunotherapy:</b> Treatments like pembrolizumab<br>and immune checkpoint inhibitors are being tested<br>to boost the body's immune response against<br>cancer cells.                                    | <b>Comprehensive Treatment Approaches:</b> Combining surgery, chemotherapy, radiation, and novel therapies to address both local and systematic disease is showing promise in improving survival rates. |
| <b>Stroma-Modifying Drugs:</b> These drugs aim to alter the tumor microenvironment, making it less conductive for cancer growth.  |   |
| <b>New Chemotherapy:</b> The FDA recently approved<br>NALIRIFOX, a combination of liposomal irinotecan,<br>5-FU/leucovorin, and oxaliplatin, as a first-line<br>treatment for metastatic pancreatic cancer. |   |
| <b>Biological Therapies:</b> Researchers are focusing on developing targeted biological therapies (such as vaccines) that specifically attack pancreatic cancer cells while sparing healthy tissues.        |   |

Source: https://www.cancer.gov/types/pancreatic/research, Cancers | Special Issue : Recent Advances in Diagnosis and Treatment of Pancreatic Cancer (mdpi.com), People with pancreatic cancer are living longer, thanks to improved approaches - Mayo Clinic Comprehensive Cancer Center Blog, FDA Approves New First-line Treatment Option for Metastatic Pancreatic Cancer - Pancreatic Cancer Action Network (pancan.org)

In conclusion, the recent therapeutic strategies in PC have evolved, improving patient outcomes. Advances in immunotherapy and personalized medicine offer hope for individuals battling this disease. Collaborations among researchers and biotech industries along with associated costs, and long-term effects are crucial for exploring these innovative therapies and technologies to improve PC care.

## 7. SWOT ANALYSIS

This SWOT analysis section focuses on evaluating strengths, weaknesses, opportunities, and threats in the PC treatment landscape. It systematically assesses internal and external factors, helping healthcare professionals optimize treatment strategies, address challenges, capitalize on opportunities, and enhance care for individuals with PC. (12,13,16,17)

|   | STRENGTHS T  | WEAKNESSES 🕁  |
|---|--|---|
| • | <ul> <li>Development of new therapies: Targeted therapies and immunotherapies are showing promise in specific patient populations.</li> <li>Research Funding: Increased funding and grants for PC research.</li> <li>Innovative Treatment Approaches: Development of new therapies, such as RAS-directed treatments and immunotherapies, shows promise in improving patient outcomes.</li> </ul> | <ul> <li>Late diagnosis: PC is often diagnosed at an advanced stage, limiting treatment options.</li> <li>Low Survival Rates: PC has one of the lowest survival rates among cancers, with a five-year survival rate of around 10%.</li> <li>Lack of early detection biomarkers: Reliable biomarkers for early detection are still under development.</li> </ul> |
|   | OPPORTUNITIES  | THREATS   |
| • | Advancements in Personalized Medicine: Precision medicine and genetic profiling offer opportunities  | Stringent Regulations: Strict regulatory  |

| • | Increased funding for research: Growing awareness | • |
|---|---|---|
|   | of the disease may lead to increased funding for  |   |
|   | research and development.                         |   |

for personalized treatment plans, potentially

improving efficacy and outcomes.

## **High Treatment Costs:** The cost of advanced treatments and therapies can be prohibitive, limiting access for many patients.

treatments are developed and approved.

requirements can limit the speed at which new PC

#### ANALYSIS SUMMARY

While current treatments manage symptoms and extend lives, they have limitations and side effects. Emerging techniques, such as personalized medicine, offer hope for the future. Challenges include late diagnosis, low survival rates, and lack of early detection biomarkers. However, advancements in new therapies present opportunities to improve outcomes in PC management.

Source: https://www.cancer.org/cancer/types/pancreatic-cancer/about/new-research.html, https://www.cancer.org/ cancer/types/pancreatic-cancer/about/key-statistics.html, https://www.cancer.gov/types/pancreatic/researc, https:// www.mdpi.com/journal/cancers/special\_issues/Advances\_Diagnosis\_Treatment\_Pancreatic

## 8. APPENDIX

- The market for PC treatment is diverse, featuring products from companies like Astellas Pharma Inc., Bristol Myers Squibb Co., Sun Pharma Advanced Research Company Ltd., and GemVax & Kael Co. Ltd.
- These companies have developed various therapeutic modalities targeting different aspects of PC, such as small molecule, peptide, and drug/device combination.
- The majority of these products have already reached the market, indicating a significant advancement in PC treatment options.
- Multiple ongoing Phase III trials by AB Science S.A., FibroGen Inc. and Merck & Co. Inc. demonstrate continued efforts to enhance PC treatment through antibody, small molecule, and protein.
- Overall, these developments reflect a comprehensive approach by pharmaceutical companies to address the complexities of PC and improve patient outcomes.

#### Table 6: Drug Development: Recently Marketed and Phase III Trials Overview.

| Company Name<br>(Originator)                               | Product Name  | Targets   | Therapeutic<br>Modalities  | Phase of<br>Development |
|--|---|---|----------------------------|-------------------------|
| Astellas Pharma Inc.                                       | Tarceva, erlotinib<br>(R1415, RG115, CP-<br>358,774, OSI-774)       | Epidermal growth factor receptor<br>(EGFR) (ErbB1) (HER1)   | Small molecule             | Marketed                |
| Bristol Myers Squibb<br>Co.                                | Abraxane,<br>nab-paclitaxel<br>(ABI-007)                            | Tubulin   | Small molecule             | Marketed                |
| Debiopharm Group   | Eloxatin, Elplat,<br>Dacotin, Dacplat,<br>oxaliplatin               | DNA   | Small molecule             | Marketed                |
| Eli Lilly and Co.  | Gemzar,<br>gemcitabine  | DNA polymerase; Ribonucleotide reductase  | Small molecule             | Marketed                |
| GemVax & Kael Co.<br>Ltd.                                  | Riavax,<br>tertomotide HCI<br>(GV1001)                              | Telomerase reverse transcriptase<br>(TERT)  | Peptide                    | Marketed                |
| Ipsen Group  | Onivyde, irino-<br>tecan (nal-IRI,<br>MM-398, PEP02,<br>SHP673)     | Topoisomerase I (TOP1)  | Small molecule             | Marketed                |
| Pfizer Inc.  | Sutent, sunitinib<br>(SU11248)                                      | Platelet derived growth factor<br>receptor (PDGFR); Vascular endotheli-<br>al growth factor (VEGF) receptor | Small molecule             | Marketed                |
| Simcere Pharma-<br>ceutical Group Ltd.                     | Sinofuan  | Undisclosed   | Drug/device<br>combination | Marketed                |
| Sun Pharma<br>Advanced Research<br>Company Ltd.<br>(SPARC) | Bevetex,<br>paclitaxel<br>(taclantis)                               | Tubulin   | Small molecule             | Marketed                |
| Taiho<br>Pharmaceutical Co.<br>Ltd.                        | Teysuno, tegafur/<br>gimeracil/oteracil<br>potassium (S-1,<br>TS-1) | Dihydropyrimidine dehydrogenase   | Combination                | Marketed                |
| Yakult Honsha Co.<br>Ltd.                                  | Campto, Camp-<br>tosar, irinotecan                                  | Topoisomerase I (TOP1)  | Small molecule             | Marketed                |
| AB Science S.A.  | Alsitek, Masiviera,<br>masitinib (ma-<br>sican, masipro,<br>AB1010) | Stem cell factor (SCF) receptor<br>tyrosine kinase (c-Kit) (KIT) (CD117)                                    | Small molecule             | Phase III               |
| Cancer Advances<br>Inc.                                    | Insegia (G17DT)   | Cholecystokinin B receptor (CCKBR)<br>(CCK2R)   |                            | Phase III               |

| Cancer Advances<br>Inc.                        | Polyclonal<br>Antibody<br>Stimulator (PAS)   |   | Peptide                    | Phase III |
|--|--|---|----------------------------|-----------|
| Corcept<br>Therapeutics Inc.                   | relacorilant<br>(CORT125134)   | Glucocorticoid receptor (GCCR)<br>(NR3C1)   | Small molecule             | Phase III |
| Cornerstone<br>Pharmaceuticals<br>Inc.         | devimistat (CPI-<br>613, ONO-7912)   | Pyruvate dehydrogenase (PDH)  | Small molecule             | Phase III |
| FibroGen Inc.                                  | Pamrevlumab<br>(FG-3019)   | Connective tissue growth factor<br>(CTGF)   | Antibody                   | Phase III |
| Jiangsu Hengrui<br>Pharmaceuticals<br>Co. Ltd. | fluzoparib, fuzu-<br>loparib (HS10160,<br>SHR3162)   | Poly(ADP-ribose) polymerase-1 (PARP-<br>1); Poly(ADP-ribose) polymerase-2<br>(PARP-2)                     |                            | Phase III |
| Merck & Co. Inc.                               | PEG-IL-10,<br>pegilodeca-<br>kin (LY3500518,<br>AM0010)  | Interleukin-10 (IL-10) receptor (IL10RA)  | Protein                    | Phase III |
| Morvus Technology<br>Ltd.                      | Acelarin (MTL-007,<br>NUC-1031)  | Not available   | Small molecule             | Phase III |
| NanoCarrier Co. Ltd.                           | Nanoplatin (NC-<br>6004, cisplatin<br>micelles)  |   | Nanoparticle               | Phase III |
| Novartis AG                                    | Afinitor, Certican,<br>Votubia, Zor-<br>tress, everolimus<br>(RAD001)  | Mammalian target of rapamycin<br>(mTOR) (FRAP) (RAFT1)  | Small molecule             | Phase III |
| Novocure GmbH                                  | Tumor Treating<br>Fields (TTFields),<br>NovoTTF-100L   | Undisclosed   | Electromagnetic            | Phase III |
| Phaxiam<br>Therapeutics S.A.                   | Graspa,<br>eryaspase (ERY-<br>ASP, ERY001)   | Undisclosed   | Enzyme                     | Phase III |
| Pola Pharma Inc.                               | doranidazole   |   |                            | Phase III |
| RenovoRx Inc.                                  | RenovoGem  | DNA polymerase  | Drug/device<br>combination | Phase III |
| Roche  | Xeloda,<br>capecitabine<br>(R340, RG340)   | Thymidylate synthetase (TYMS)   | Small molecule             | Phase III |
| Shouyao Holdings<br>(Beijing) Co. Ltd.         | SY-707   | Anaplastic lymphoma kinase (ALK);<br>Focal adhesion kinase (FAK);<br>Insulin-like growth factor-1 (IGF-1) | Undisclosed /<br>Unknown   | Phase III |
| SynCore Biotechnol-<br>ogy Co. Ltd.            | EndoTAG-1 (SB05,<br>MBT-0206)  | Tubulin   | Small molecule             | Phase III |
| Takeda Pharmaceu-<br>tical Co. Ltd.            | Glufosfamide   | DNA   | Small molecule             | Phase III |
| Unicancer Group                                | mFOLFIRINOX  | Not available   |                            | Phase III |
| Wellstat Therapeu-<br>tics Corp.               | Xuriden (Brand),<br>Vistogard (Brand),<br>PN401 (Com-<br>pound #), viston-<br>uridine (Former),<br>uridine triacetate<br>(Generic), Xuriden<br>(Other), Vistogard<br>(Other) |   | Small molecule             | Phase III |
| Xoma Corp.                                     | NIS793   | Transforming growth factor (TGF) beta<br>1 (TGFB1)  | Antibody                   | Phase III |

Source: Biocentury, June 2024

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