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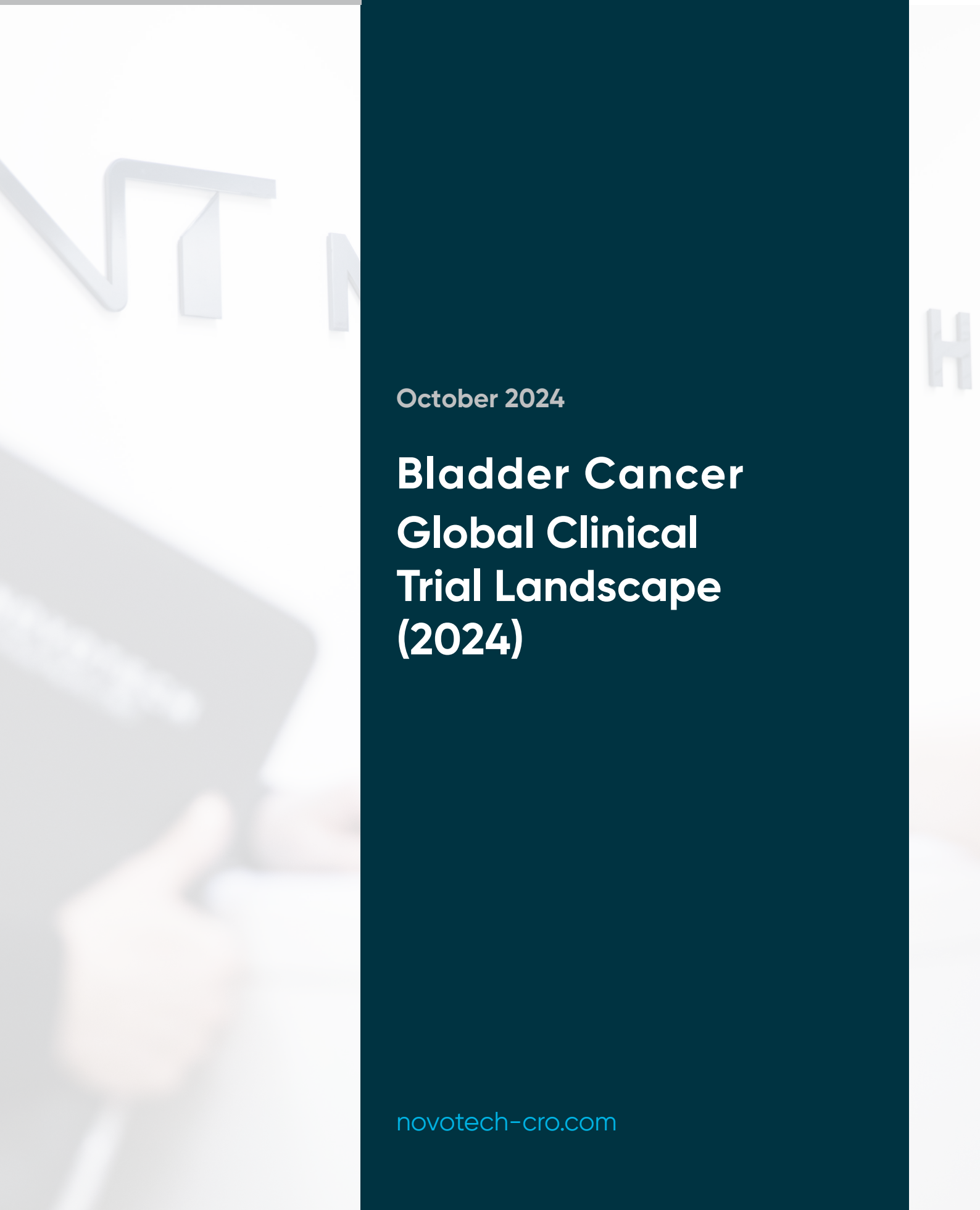


October 2024

Bladder Cancer Global Clinical Trial Landscape (2024)

novotech-cro.com

BLADDER CANCER
GLOBAL CLINICAL TRIAL LANDSCAPE (2024)

#DYK
Did you know?

BLADDER CANCER

9th
IN TOTAL CANCER INCIDENCE

13th
IN CANCER RELATED DEATHS

2022: GLOBALLY
614k
NEW CASES

Europe had the highest incidence cases, accounting for nearly 37% of the global cases.

Asia had the second highest incidence, with over 215,700 cases.

North America had more than 95,000 cases, followed by ROW.

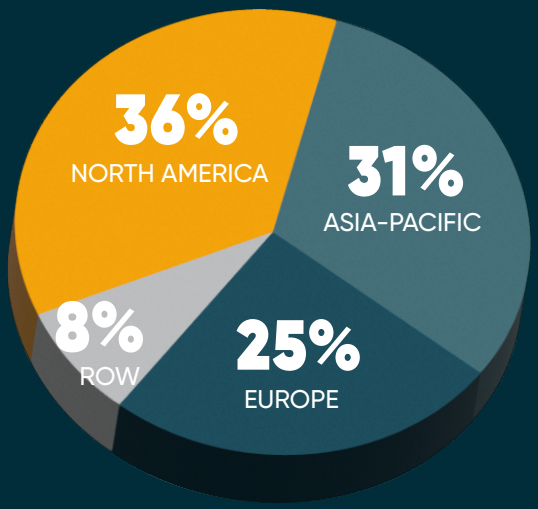
The bladder cancer treatment market offers diverse products by companies including **Alliance Pharma plc., AstraZeneca plc., Baxter International Inc., and Pfizer Inc**

Multiple ongoing Phase III trials demonstrate continued efforts to enhance bladder cancer treatment through **small molecule, oncolytic virus, and gene therapy**

BLADDER CANCER
TRIAL CONTRIBUTIONS

Countries like the **United States, Mainland China, Spain, France, the United Kingdom, Australia, and Italy** emerged as top locations for conducting trials

Asia-Pacific showed faster recruitment durations



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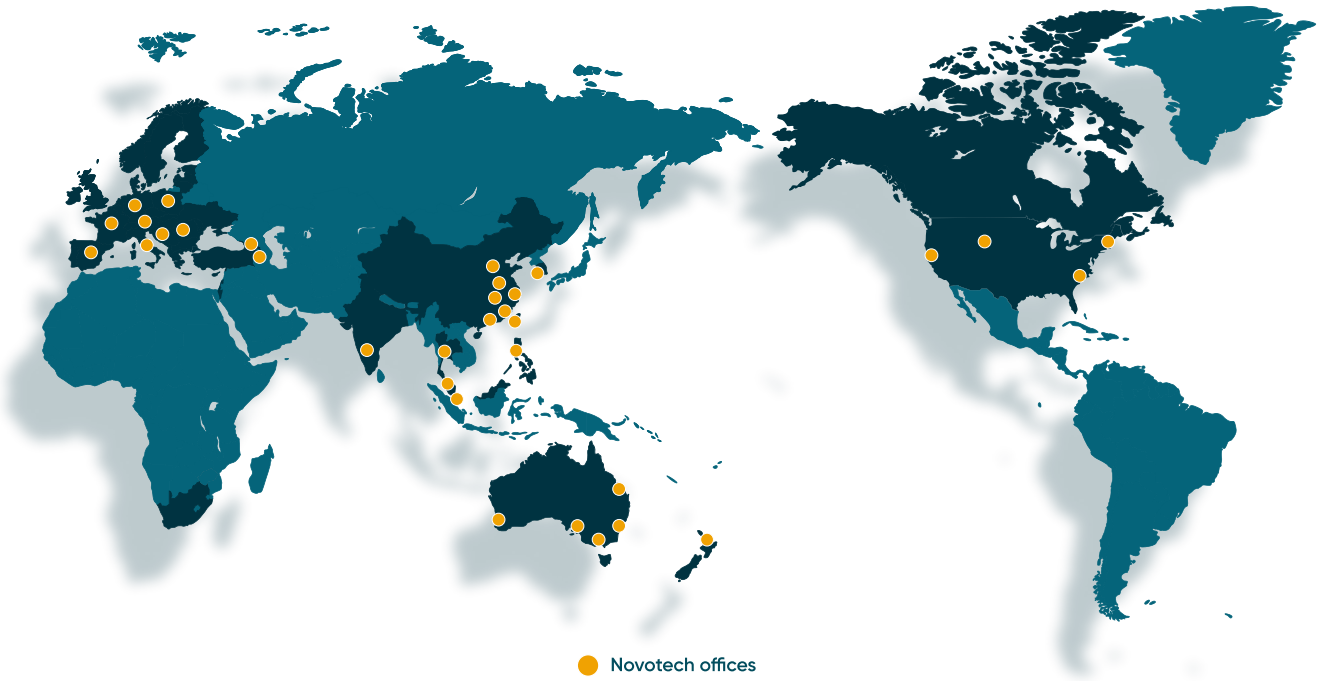


1. EPIDEMIOLOGY

Disease background

Bladder cancer ranks as the ninth most common cancer globally in terms of incidence and the thirteenth in mortality. Urothelial carcinoma (UC) is the most common histologic subtype, with other subtypes including squamous cell bladder cancer, sarcoma, adenocarcinoma, and small cell bladder. Most urothelial carcinomas (UC) are non-muscle invasive bladder cancer (NMIBC), remaining within the bladder's inner lining. Muscle-invasive bladder cancer (MIBC) extends into the bladder wall muscle, making it more likely to spread and harder to treat.

While both men and women can develop bladder cancer, men are at a higher risk, making it the sixth most common type of cancer among men. [1,2] Several risk factors influence its development, including age, gender, smoking, and exposure to occupational and environmental toxins.

The five-year relative survival rates for bladder cancer are 97% for carcinoma in situ, 71% for localized cancer, 39% for regional cancer, and 8% for metastatic cancer.[3] Despite improvements in survival rates due to advances in early detection, robotic surgery, and immunotherapy, bladder cancer continues to be a significant and increasing contributor to the global cancer burden.

This disease report provides a detailed overview of the global bladder cancer clinical trial landscape and bladder cancer burden in different locations across the globe.

Epidemiology

Globally, bladder cancer accounted for nearly 614,000 new cases and 220,600 deaths in 2022. The global ASRs (Age-Standardized Rates) of incidence and mortality for bladder cancer were 5.6 and 1.8 per 100,000 population respectively. This overview highlights the incidence and prevalence of bladder cancer across various regions and locations based on 2022 data from GLOBOCAN.

Europe led in bladder cancer incidence, with around 224,000 reported cases, accounting for approximately 37% of the global disease burden. Italy, Germany, the United Kingdom, Spain, and France contributed significantly to this number, with 34,500, 29,000, 23,600, 21,400, and 19,700 cases reported respectively. Additionally, Spain, Italy, and the United Kingdom had some of the highest global Age-Standardized Incidence Rates (ASIR), with rates of 19.3, 18.1, and 13.4 per 100,000 people, respectively, indicating a high prevalence of bladder cancer relative to their population age structures.

Asia reported approximately 215,700 cases and accounted for 35% of the global bladder cancer cases. China alone contributed to over 92,800 cases. Japan and India reported incidences with over 34,568 and 22,500 cases respectively with an ASIR of 7.0 and 1.6 respectively per 100,000 population. Following this, countries like South Korea, Singapore, Thailand, Malaysia, and the Philippines showed varying ASIRs, ranging from 4.9 to 2.1 per 100,000 population.

The North American region had over 95,000 bladder cancer cases with the United States alone reporting around 80,400 cases with an ASIR of 10.5 per 100,000 population. Canada and Mexico reported nearly 15,000 and 3,800 cases with an ASIR of 15.6 and 2.5 per 100,000 population respectively.

Africa reported approximately 37,000 bladder cancer cases, with an ASIR of 4.7 per 100,000 population. South Africa led in this region with more than 2,100 cases and reported the highest ASIR of 4.1 per 100,000 population.

Latin America and the Caribbean reported nearly 35,000 cases of bladder cancer, with an ASIR of 4.0 per 100,000 population. Brazil led in this region with 17,000 cases.

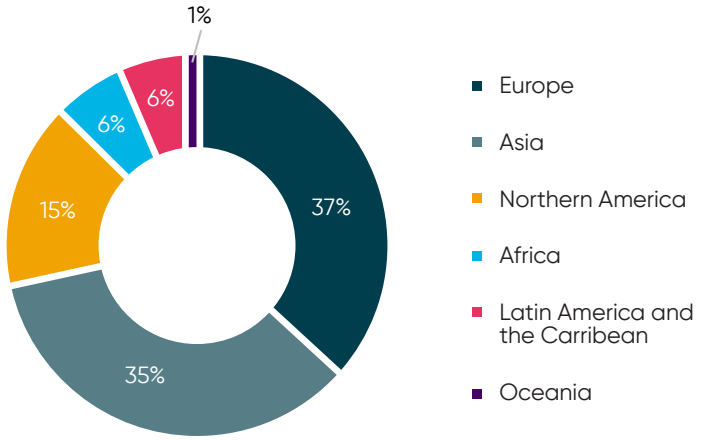
Oceania reported the lowest numbers with over 5,300 bladder cancer cases, with an ASIR of 6.60 per 100,000 population. Australia and New Zealand contributed to the regional burden, reinforcing the need for targeted initiatives and healthcare improvement.

Over the next 25 years, predictions indicate that bladder cancer instances will continue to rise, perhaps exceeding 1,200,000 new cases per year by 2050 (over 100% increase since 2022). The huge disparities in incidence rates among the various locations highlight the need for customized prevention and treatment strategies across the globe. [4]

Ethnic disparities in bladder cancer are clear, with both Caucasians and African Americans experiencing lung and bone as primary sites of metastasis. However, African Americans have higher metastasis rates, particularly in these areas. Contributing factors include occupational exposure, tumor biology, healthcare access, and genetics. More research is needed to fully understand racial differences in metastatic patterns and outcomes. [5]

Regarding gene mutations, several DNA repair genes, such as ERCC2, ATM, and BRCA1, are more frequently mutated in high-grade NMIBC and MIBC. ERCC2, a key component of the nucleotide excision repair pathway, has been associated with improved survival in MIBC patients with mutations receiving cisplatin-based chemotherapy. Additionally, ERCC2 polymorphisms may reduce bladder cancer risk, particularly in older individuals and smokers, though further research is needed to confirm these findings. [6]

Figure 1: Regional Distribution of Bladder Cancer Cases



Source: GLOBOCAN 2022

Table 1: Global Incidence and Prevalence of Bladder Cancer, by region (2022).

Regions	Incidence		
	Number	ASR (World)	5-year prevalence
World	614,298	5.60	1,950,315
Europe	224,777	12.00	758,094
Asia	215,755	3.40	643,459
Northern America	95,546	11.00	327,816
Africa	37,064	4.70	97,605
Latin America and the Caribbean	35,791	4.00	105,577
Oceania	5,365	6.60	17,764

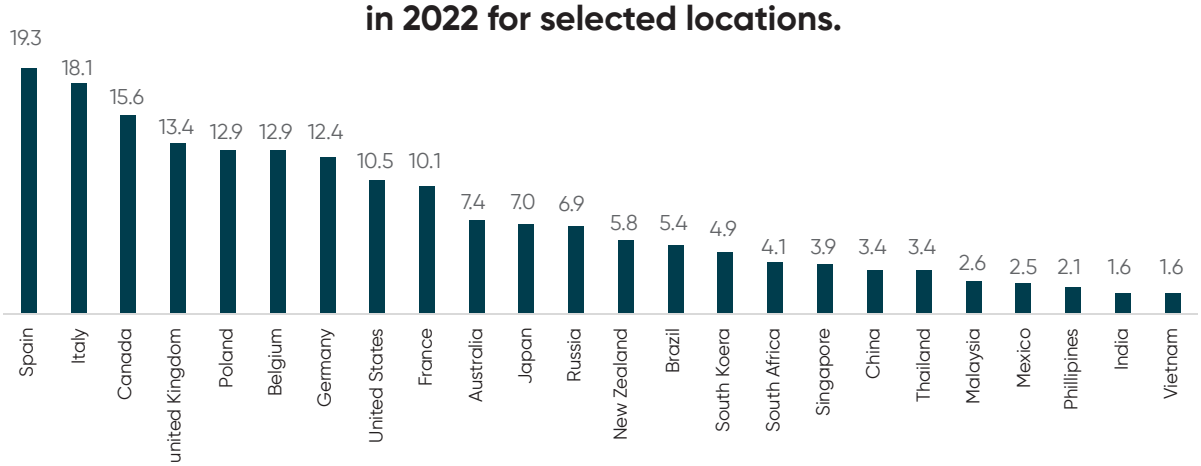
Source: GLOBOCAN 2022

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

Regions	Incidence		
	Number	ASR (World)	5-year prevalence
World	614,298	5.6	1,950,315
China	92,883	3.4	276,102
United States	80,404	10.5	276,091
Italy	34,580	18.1	112,637
Japan	34,568	7.0	107,730
Germany	29,035	12.4	102,053
United Kingdom	23,643	13.4	79,763
India	22,548	1.6	60,083
Spain	21,418	19.3	75,358
France	19,733	10.1	63,459
Russia	19,352	6.9	64,848
Brazil	17,028	5.4	49,665
Canada	15,111	15.6	51,725
Poland	11,992	12.9	40,208
South Korea	5,909	4.9	20,855
Thailand	4,596	3.4	13,825
Australia	4,454	7.4	15,178
Belgium	3,821	12.9	13,171
Mexico	3,814	2.5	11,680
South Africa	2,148	4.1	6,139
Philippines	2,094	2.1	6,160
Vietnam	1,972	1.6	5,785
Malaysia	964	2.6	2,988
New Zealand	662	5.8	1,950
Singapore	465	3.9	1,713

Source: GLOBOCAN 2022

Figure 2: Incidence rate for Bladder Cancer per 100,000 people in 2022 for selected locations.



Source: GLOBOCAN 2022

2. STANDARD OF CARE

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

NCCN Guideline Version 4.2024

The NCCN Guideline 2024 provides essential recommendations for bladder cancer 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. [7]

Table 3: Recommendations on Bladder Cancer, NCCN Guideline Version 4.2024.

Treatment Line	Preferred Regimens	Other Recommended Regimens	Special Considerations
Neoadjuvant Chemotherapy	DDMVAC with growth factor support	Gemcitabine and cisplatin	Preferred over adjuvant therapy for better evidence-based outcomes
Adjuvant Chemotherapy	DDMVAC with growth factor support (if no prior neoadjuvant therapy)	Gemcitabine and cisplatin	Nivolumab recommended after prior platinum-based neoadjuvant therapy
First-Line for Metastatic Disease	Cisplatin-base (GC or ddMVAC)	Gemcitabine and carboplatin	Pembrolizumab plus enfortumab vedotin for cisplatin-ineligible patients
Maintenance Therapy	Avelumab for patients with stable disease after first-line chemotherapy		Nivolumab can be used as maintenance, if part of the first-line therapy
Second-Line Therapy	Enfortumab vedotin	Erdafitinib (FGFR3 genetic alterations)	Sacituzumab govitecan, checkpoint inhibitors, or combination chemotherapy

Source: NCCN Guidelines for bladder cancer (Version 4.2024); URL: https://www.nccn.org/professionals/physician_gls/pdf/bladder.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

The European Society for Medical Oncology (ESMO) publishes clinical practice guidelines to guide treatment decisions for bladder cancer. The figure below summarizes the ESMO recommendations for bladder cancer: [8]

Table 4: Systemic treatment for Bladder Cancer, ESMO 2023

Treatment Line	Preferred Regimens	Alternative Regimens	Special Considerations
Neoadjuvant Therapy	Cisplatin-based chemotherapy	Gemcitabine + cisplatin	Preferred over adjuvant therapy for better evidence-based outcomes
Adjuvant Therapy	Cisplatin-based chemotherapy (for patients not receiving neoadjuvant therapy)	None	Debate exists on its survival benefit; some evidence of improved disease-free survival (DFS)

First-Line for Metastatic Disease	Enfortumab vedotin-pembrolizuma (3)	Carboplatin + gemcitabine for cisplatin-ineligible patients	PD-L1-positive patients may receive pembrolizumab or atezolizumab
	Nivolumab-gemcitabine-cisplatin (3)		
Maintenance Therapy	Avelumab for patients with stable disease after platinum-based chemotherapy		Started within 10 weeks after chemotherapy completion
Second-Line Therapy	Pembrolizumab for disease progression post-chemotherapy	Enfortumab vedotin, erdafitinib (FGFR mutation), atezolizumab	Enfortumab vedotin recommended in cisplatin-ineligible or PD-L1 positive patients
Third-Line Therapy	Enfortumab vedotin	Taxanes (paclitaxel, docetaxel), vinflunine	For patients relapsing after immunotherapy and chemotherapy
Targeted Therapies	Erdafitinib for FGFR-altered tumors	Taxanes (paclitaxel, docetaxel), vinflunine	FDA-approved for FGFR2/3-altered metastatic urothelial carcinoma

Source: https://www.annalsofoncology.org/action/showPdf?pii=S0923-7534%2824%2900075-9; https://www.esmo.org/guidelines/guidelines-by-topic/esmo-clinical-practice-guidelines-genitourinary-cancers/clinical-practice-guideline-bladder-cancer

Asia-specific guidelines for bladder cancer

In the Asian region, there are no distinct, universally adopted guidelines specifically tailored for bladder cancer management. Instead, healthcare providers in Asia predominantly follow the NCCN guidelines, which offer comprehensive, evidence-based recommendations for the treatment of bladder cancer. These guidelines provide a robust framework that ensures patients receive standardized care based on the latest research and clinical practices. By adhering to the NCCN guidelines, clinicians in Asia ensure that their patients benefit from internationally recognized protocols and the highest standards of care.

3. GLOBAL CLINICAL TRIAL LANDSCAPE

Since 2019, the biotech and biopharma industry initiated over 1,500 bladder cancer clinical trials worldwide. North America led with a trial share of 36%, followed by Asia-Pacific (31%), Europe (25%) and the ROW (8%). The United States led the trial activity in North America with a majority trial share of 79%, while in Asia-Pacific, Mainland China accounted for the largest share of trials (32%). Within Europe, Spain, France, the United Kingdom, and Italy, led the bladder cancer trials, showing the region's contribution to advancing research. Among the ROW countries, Israel led the trial activity followed by Argentina. [9] (Figure 3,4,5,6,7)

Figure 3: Bladder Cancer trials % share by region

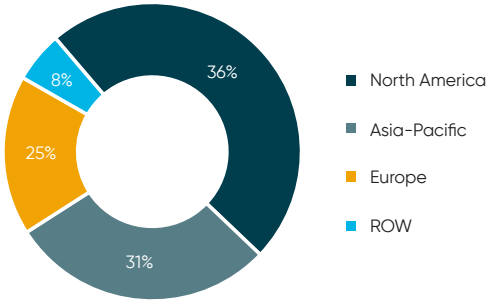


Figure 4: North America-Bladder Cancer trials % share

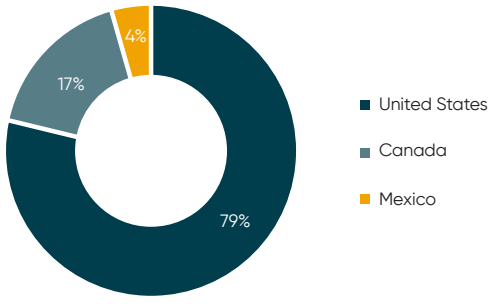


Figure 5: Asia Pacific-Bladder Cancer trials % share

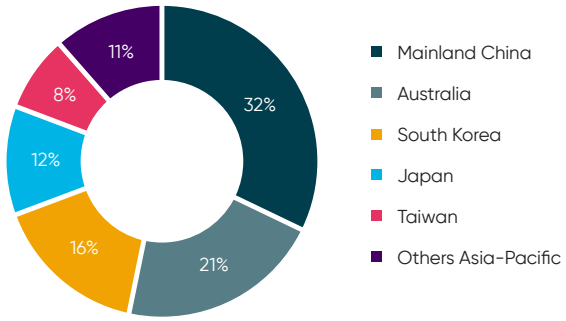


Figure 6: Europe-Bladder Cancer trials % share

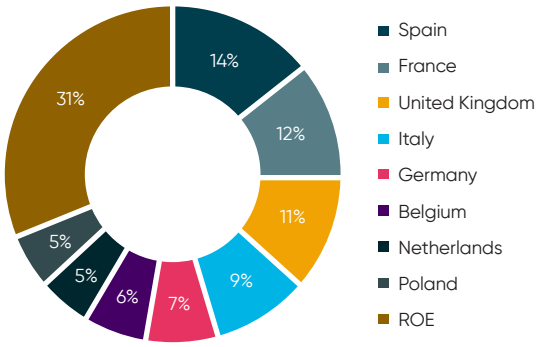
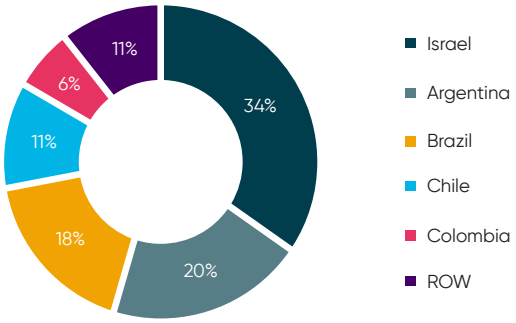


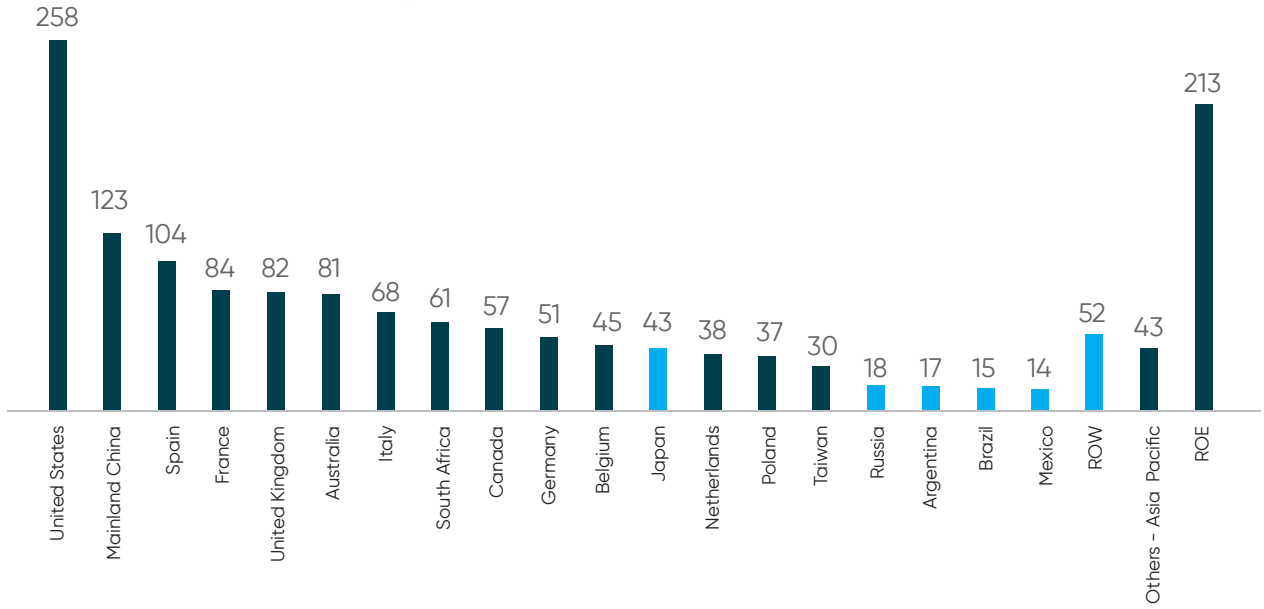
Figure 7: Middle East and Africa-Bladder Cancer trials % share



Source: GlobalData, September 2024
Others- Asia Pacific: Singapore, India, Thailand, Hong Kong, New Zealand, Malaysia, Philippines, Vietnam.
ROE: Denmark, Greece, Russia, Turkey, Czech Republic, Hungary, Austria, Ukraine, Portugal, Romania, Switzerland, Ireland, Sweden, Serbia, Bulgaria, Georgia, Finland, Norway, Estonia, Latvia, Croatia, Slovakia, Cyprus, Lithuania, Moldova. ROW: Includes Middle East and Africa and South and Central America

The global landscape of bladder cancer trials reflects a strong focus on advancing research for novel therapeutics to effectively treat bladder cancer. Locations like the United States, Mainland China, Spain, France, the United Kingdom, Australia, and Italy emerged as the top destinations for conducting trials. These trials reflect a consistent global effort towards bladder cancer research, though the intensity varies considerably across different countries and regions. (Figure 8) [9]

Figure 8: Number of Industry-initiated Bladder Cancer Trials by Global Locations, since 2019



Locations where Novotech directly operates.

Others- Asia Pacific: Singapore, India, Thailand, Hong Kong, New Zealand, Malaysia, Philippines, Vietnam.
ROE: Russia excluded.
ROW: Includes Middle East and Africa and South and Central America
Source: GlobalData, September 2024

Moving on to trial phase trends, bladder cancer studies have shown advancements across various regions. North America, Asia-Pacific, and Europe primarily concentrate on early and mid-stage development, mainly in Phase I and Phase II trials. In contrast, the rest of the world (ROW) is less involved across various trial phases but still contributes moderately to global bladder cancer research. This suggests regional differences in clinical research, possibly influenced by factors like funding availability, regulatory environments, and healthcare infrastructure. (Figure 9) [9]

Based on the trials by status, across North America, Asia-Pacific, Europe, and ROW, the number of ongoing trials exceeds that of completed ones. This could be attributed to the need for extended follow-up periods to evaluate long-term survival outcomes and monitor delayed adverse effects. The treatment of bladder cancer is rapidly advancing with the development of new therapies, such as precision medicine, immunotherapy, and combination therapies. Ongoing clinical trials are important to assess the efficacy and safety of these emerging treatments. (Figure 10) [9]

Figure 9: Trials by phase and regions since 2019

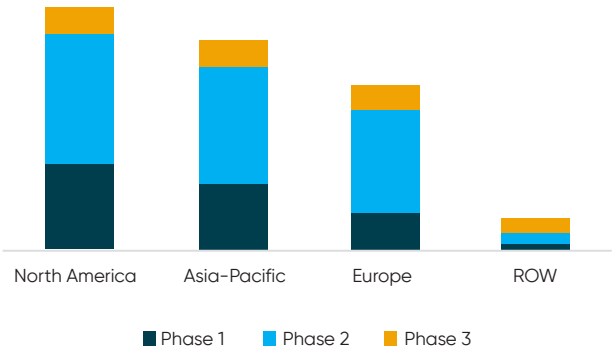
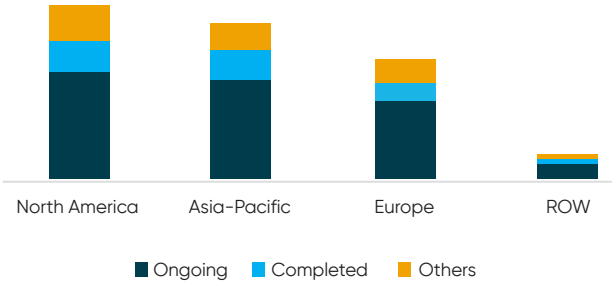


Figure 10: Trials by status and regions since 2019

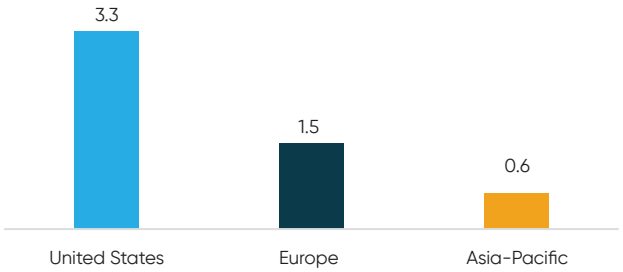


Source: GlobalData, September 2024
Others include: Planned, Suspended, Terminated, Withdrawn

Trial Density

Despite its large population, the Asia-Pacific region has a clinical trial density that is five times lower than that of the US and about half that of Europe. (Figure 11). This highlights the need for scaling up research efforts and more targeted medical interventions in the region. With a vast patient population and unique genetic diversities, particularly in countries like China, Australia, and South Korea, this region presents a prime opportunity for groundbreaking clinical research and the development of personalized therapeutic interventions. [9]

Figure 11: Trial density* for industry-sponsored Bladder Cancer.



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

Patient Recruitment Landscape

Since 2019, clinical trials for bladder cancer have exhibited regional differences in recruitment metrics. Data shows that Europe has the longest median trial duration at 34.05 months, while the US has the shortest at 16.25 months. Europe also achieved a higher median rate of 1.32 subjects per site per month, compared to 0.29 in the US region. Europe's higher subjects per site per month are due to multi-country trials, providing access to a larger patient population and experienced trial sites. Efficient research infrastructure, fewer competing trials than the US, and the highest disease incidence help sustain faster and more consistent recruitment compared to the US and Asia-Pacific regions. (Figure 12,13) [9]

Figure 12: Enrolment Period (months), since 2019

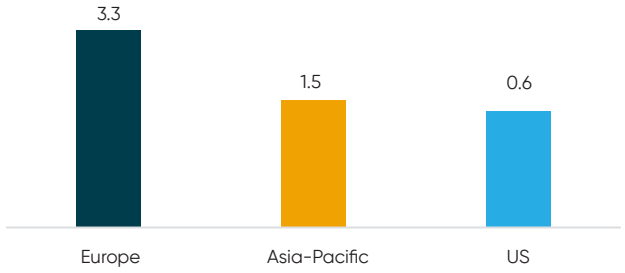
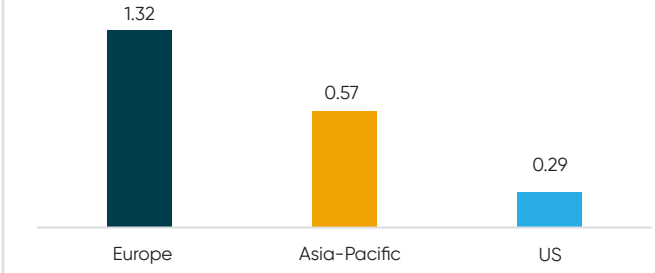


Figure 13: Subjects/Site/Month, since 2019.

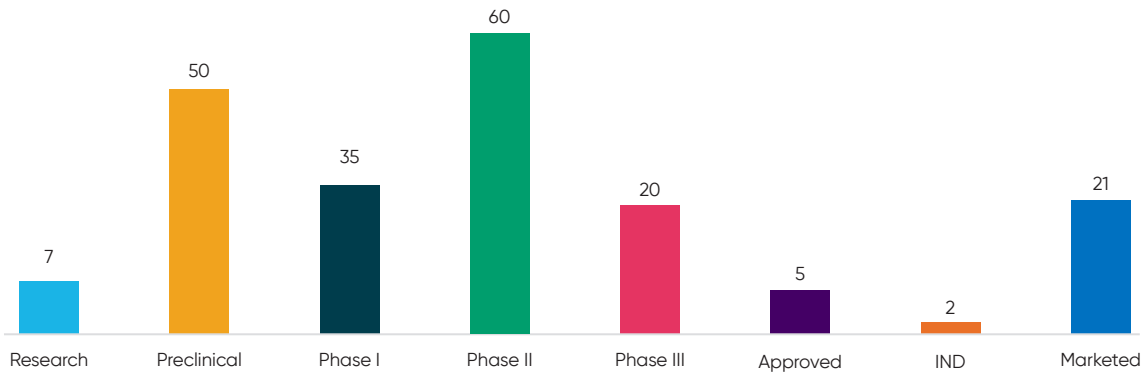


Source: GlobalData, September 2024

4. DRUG DEVELOPMENT LANDSCAPE

Coming to the bladder cancer drug development pipeline, there are seven drug candidates in research, 50 in preclinical stage, and 35 in Phase I trials. Phase II has the most drug candidates numbering 60 drugs, while there are 20 in Phase III, and 21 which are already in the market. These trends reflect a progressive landscape of bladder cancer drug research and development. (Figure 14) [9]

Figure 14: No. of products by phase of development



Source: Biocentury, September 2024

Among the marketed drugs by diverse mechanisms of action (MOA), DNA Synthesis Inhibitor, and Dihydrofolate Reductase Inhibitor dominate the landscape, followed by Ribonucleoside Diphosphate Reductase Large Subunit Inhibitor, DNA Synthesis Inhibitor and DNA Helicase Inhibitor. In addition, other enzyme inhibitors such as Thymidylate Synthase Inhibitor, DNA Topoisomerase II Inhibitor, Programmed Cell Death Protein 1 Antagonist, Tubulin Inhibitor, DNA Topoisomerase I Inhibitor, and a few others contribute to the varied drug MOA. (Figure 15) [9]

Additionally, in the ongoing Phase III trials of bladder cancer drugs, Programmed Cell Death Protein 1 Antagonist dominates the MOA, followed by Programmed Cell Death 1 Ligand 1 Inhibitor, Cytotoxic T Lymphocyte Protein 4 Antagonist, Fibroblast Growth Factor Receptor 1 Inhibitor, and a few other MOAs. The diverse MOAs observed in marketed drugs for bladder cancer emphasizes the complexity and individualized nature of drug development, offering promising avenues for personalized treatment approaches in disease management. (Figure 16) [9]

Figure 15: % Share of Marketed Bladder Cancer Drugs by Mechanism of Action

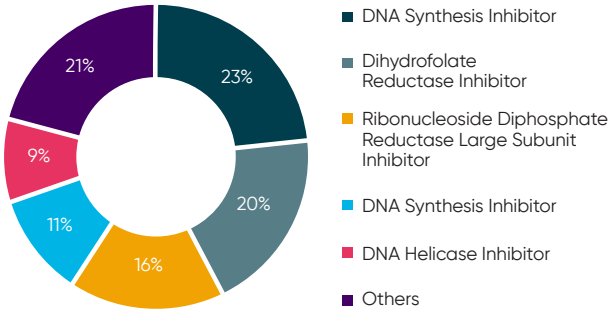
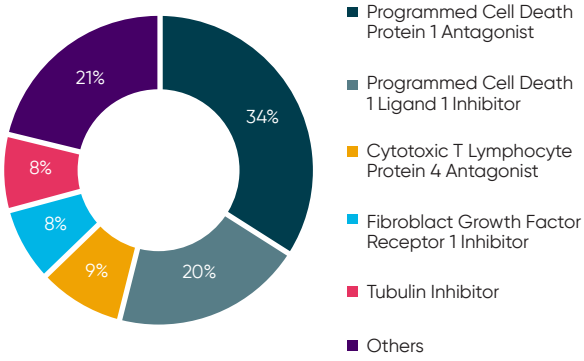


Figure 16: % Share of Phase III Bladder Cancer Drugs by Mechanism of Action



Source: GlobalData, September 2024

5. FUNDING LANDSCAPE

Public and NGO funding initiatives

Public and NGO funding initiatives for bladder cancer have significantly increased, focusing on enhancing vaccination (Bacillus Calmette-Guerin (BCG) vaccine), screening, and treatment efforts worldwide. Major organizations like the Bladder Cancer Advocacy Network (BCAN), and the American Cancer Society (ACS), have committed major resources to improve healthcare infrastructure and raise awareness about early detection. These efforts aim to reduce the global burden of bladder cancer, particularly in low and middle-income countries, ensuring more people have access to life-saving treatment. (Figure 17) [10], [11], [12]

Figure 17: Public and NGO funding initiatives for Bladder Cancer.

The **NCI** funds research on bladder cancer through several programs, including the Bladder Specialized Program of Research Excellence (SPORE). The NCI also has funding opportunities for research on the biology and underlying mechanisms of bladder cancer.

Bladder Cancer Advocacy Network (BCAN) is one of the leading nonprofit organizations funding bladder cancer research. BCAN offers multiple research grants, including their Bladder Cancer Research Innovation Award and other annual awards that provide over $500,000 in grants each year

Cancer Care provides comprehensive support for individuals with bladder cancer, offering financial assistance of up to $4,000, along with counselling, support groups, educational workshops, and publications.

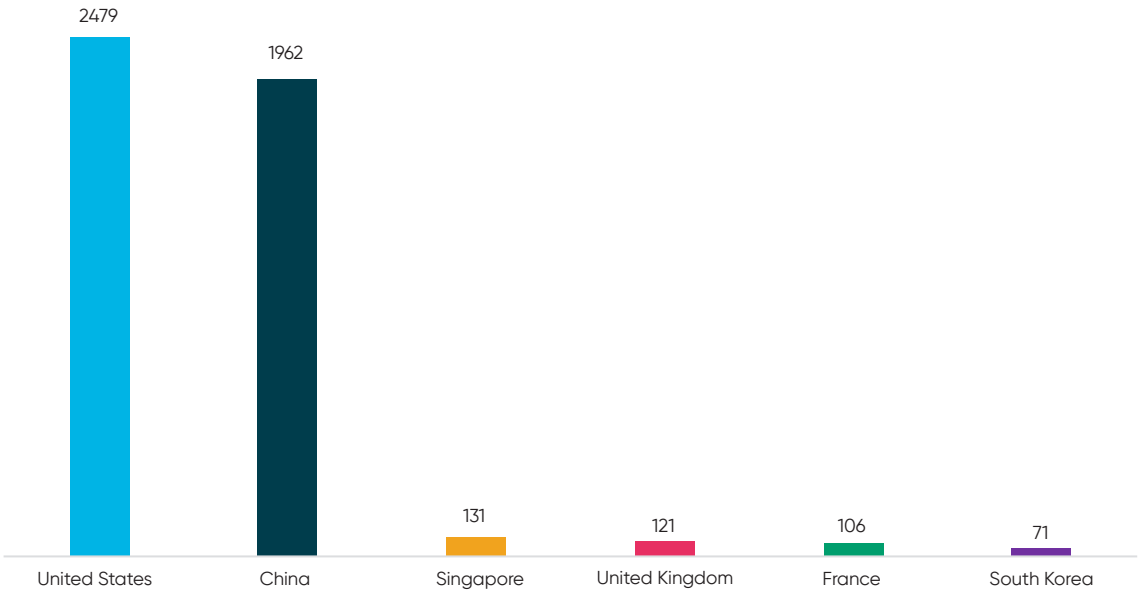
The American Cancer Society (ACS) plays an important role as a key stakeholder in funding bladder cancer research. While bladder cancer currently receives less than 1% of federal funding compared to other cancers, their efforts help ensure that research in this area continues, offering hope for increased focus and future advancements.

Source: https://www.cancercare.org/co_payment_fundings/bladder-cancer; https://bcan.org/; https://www.cancer.org/; https://www.nih.gov/.

Venture Capital Funding

Between 2019 and 2023, venture capital funding by locations shows that the United States experienced an influx of venture capital, with investments of $2.4 billion, followed by China with $1.9 billion. Countries such as Singapore, the United Kingdom, France, and South Korea contributed to venture funding, although to a lesser extent, with investments ranging from $131 million to $70 million. These investments reflect a global effort for advancing bladder cancer research and development. (Figure 18) The top firms that received venture funding for bladder cancer include Zhuhai Beihai Biotech Co. Ltd., Shorla Oncology, Iambic Therapeutics Inc., and Deka Biosciences Inc. [9]

Figure 18: Venture capital funding (US$M) for Bladder Cancer, 2019-2023



Source: GlobalData, September 2024

Moving on to funding by rounds of financing, bladder cancer research and development has secured funding in Series B and C rounds from 2019 to 2023, driven by advancements in immunotherapies, targeted therapies, and combination therapies. These rounds are higher because they fund companies at a more advanced stage, where promising treatments are closer to commercialization, reducing risk and increasing potential returns. (Figure 19) [9]

Based on the stage of development, over 60% of funding supported the preclinical, Phase II, and Phase I 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 20). [9]

Figure 19: Average Deals Share % by Round of Financing

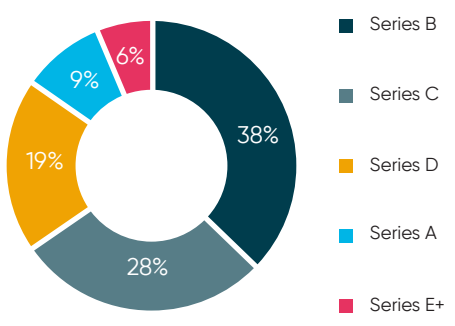
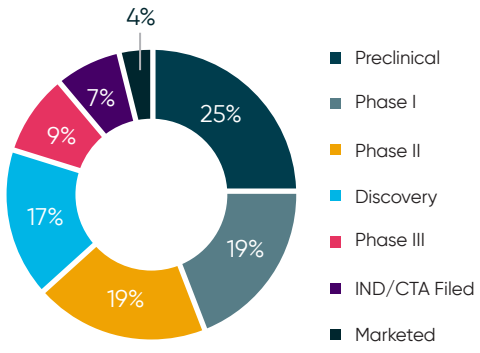


Figure 20: Average deals share % across stage of development

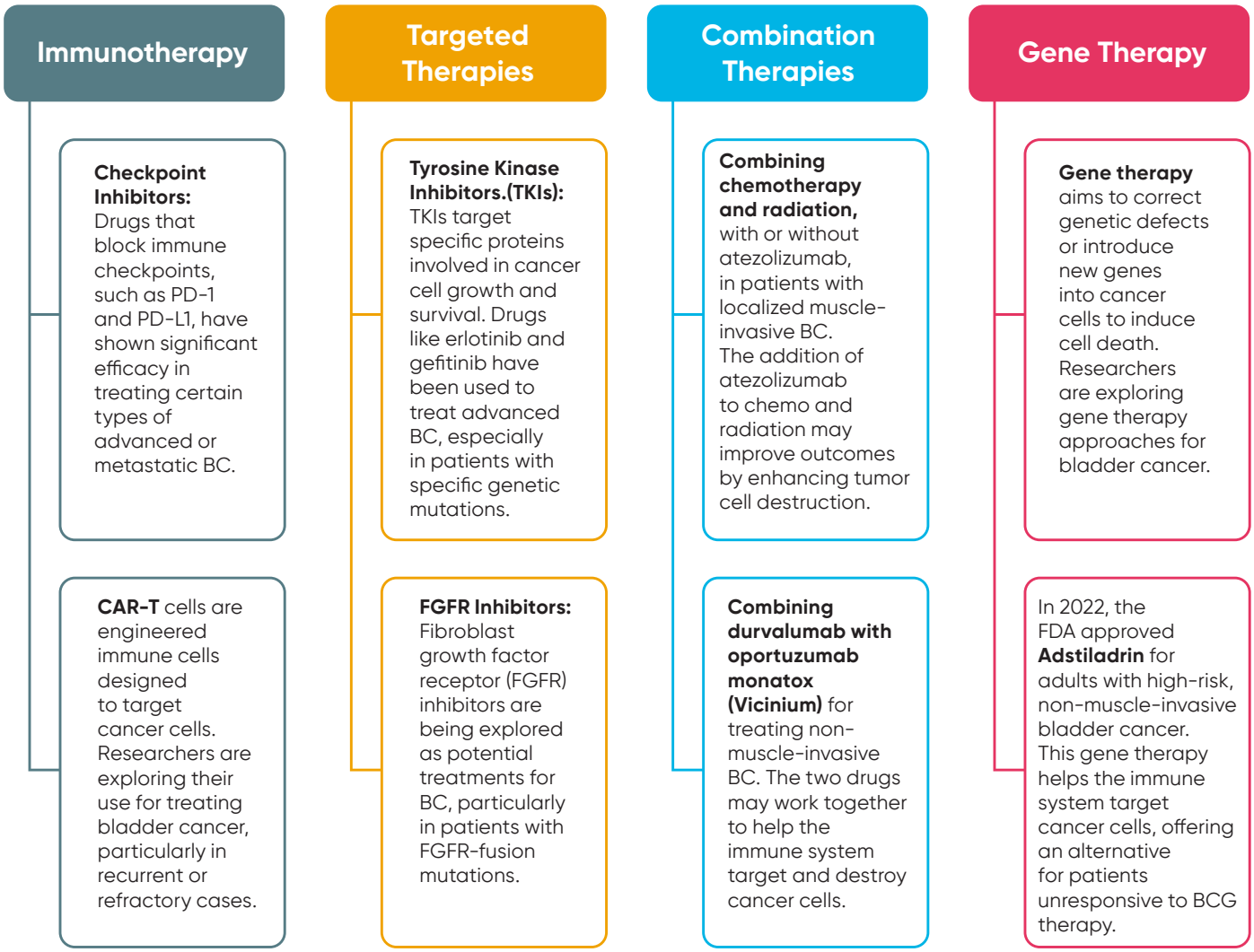


Source: GlobalData, September 2024

6. EVOLVING THERAPEUTIC STRATEGIES

The evolving therapeutic strategies in bladder cancer reflect significant advancements across multiple treatment modalities. These approaches aim to enhance patient outcomes, especially in cases resistant to traditional therapies. Immunotherapy, including checkpoint inhibitors and CAR-T cell modalities, offers promising results for advanced or metastatic bladder cancer. Targeted therapies, such as tyrosine kinase inhibitors and FGFR inhibitors, focus on disrupting specific cancer cell growth mechanisms. Combination therapies are exploring the synergistic effects of chemotherapy, radiation, and immunotherapy, while gene therapy seeks to address genetic defects by introducing new genes to target and eliminate cancer cells. These cutting-edge treatments represent a hopeful future for bladder cancer care. (Figure 21) [13,14,15,16,17]

Figure 21: Emerging therapeutic strategies and Future Prospects in Bladder Cancer Treatment.



Source: https://www.cancer.gov/types/bladder/research; 10.1093/annonc/mdz127; 10.3389/fimmu.2022.925985; 10.1056/NEJMoa1817323; 10.1038/s41523-018-0097-z.

In conclusion, evolving strategies in bladder cancer treatment are advancing prevention, detection, and personalized care. Innovations like immunotherapy, targeted therapies, combination therapies, and gene therapy offer hope for better outcomes, making bladder cancer more manageable and preventable.

7. SWOT ANALYSIS

This SWOT analysis section focuses on evaluating strengths, weaknesses, opportunities, and threats in the bladder cancer 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 bladder cancer. [18,19, 20]

STRENGTHS	WEAKNESSES
• **High Unmet Need:** Bladder cancer is a prevalent disease with a significant unmet medical need, particularly in advanced or metastatic stages, creating a strong demand for novel therapies. • **Targeted Therapies:** Targeted therapies, like FGFR and CDK4/6 inhibitors, offer more effective treatments for certain bladder cancer subtypes. • **Immunotherapy** approaches, including checkpoint inhibitors and CAR-T cells, show great promise in treating advanced bladder cancer.	• **Lack of Early Symptoms:** Bladder cancer often presents with subtle or non-specific symptoms, leading to delayed diagnosis. • **Limited Treatment Options for Advanced Disease:** Despite advancements, treatment options for advanced or metastatic bladder cancer remain limited, and outcomes can be challenging. • **Side Effects of Treatments:** Many bladder cancer treatments can have significant side effects, such as fatigue, nausea, and hair loss, impacting patients' quality of life.

OPPORTUNITIES	THREATS
• **Personalized Medicine:** Advances in genomics and molecular profiling can lead to more personalized treatment approaches based on individual patient characteristics. • **Combination Therapies:** Combining different treatment modalities, such as immunotherapy and targeted therapies, may offer synergistic benefits. • **Emerging Biomarkers:** The discovery and validation of novel biomarkers could open the door to more personalized and effective treatments, accelerating clinical trial success.	• **Rising Healthcare Costs:** Increasing costs of treatments, including novel therapies and advanced imaging techniques, can pose challenges for patients and healthcare systems. • **Regulatory Hurdles:** Delays in regulatory approval processes can slow the introduction of promising new therapies. • **Limited funding:** Aside from contributions by BCAN, ACS, Cancer Care, and NCI, limited funding hinders progress in advancing treatment and care.

ANALYSIS SUMMARY
Current treatments manage symptoms and extend lives, they have limitations and side effects. Emerging techniques, such as targeted therapies, immunotherapy, and combination therapies, offer hope for the future. Challenges include lack of funding, regulatory hurdles, and the high cost of treatment. However, advancements in new therapies present opportunities to improve outcomes in bladder cancer management.

Source: https://www.cancer.gov/; https://bcan.org/facing-bladder-cancer/bladder-cancer-treatment/

8. APPENDIX

- The market for bladder cancer treatment is diverse, featuring products from companies like Alliance Pharma plc., AstraZeneca plc., Baxter International Inc., and Pfizer Inc.
- These companies have developed various therapeutic modalities targeting different aspects of bladder cancer, such as biologic, antibody, small molecule, and antibody-drug conjugate.
- Multiple ongoing phase III trials by Bristol Myers Squibb Co., CG Oncology Inc., and Ferring Pharmaceuticals A/S demonstrate continued efforts to enhance bladder cancer treatment through small molecule, oncolytic virus, and gene therapy.
- Overall, these developments reflect a comprehensive approach by pharmaceutical companies to address the complexities of bladder cancer and improve patient outcomes. [9]

Table 5: Drug Development: Recently Marketed and Phase III Trials Overview.

Company Name (Originator)	Product Name	Targets	Therapeutic Modalities	Phase of Development
Alliance Pharma plc	Immucyst		Biologic	Marketed
AstraZeneca plc	Imfinzi, durvalumab (MEDI4736)	Programmed cell death 1 ligand 1 (PD-L1) (B7-H1) (CD274)	Antibody	Marketed
Baxter International Inc.	Holoxan, ifosfamide		Small molecule	Marketed
BeiGene Ltd.	Tevimbra, tislelizumab (BGB-A317, VDT482)	Programmed cell death 1 (PD-1) (PDCD1) (CD279)	Antibody	Marketed
Endo Inc.	Valstar, valrubicin (AD32, Valtaxin)	DNA	Small molecule	Marketed
Japan BCG Laboratory Ltd.	Immunobladder intravesical			Marketed
Merck & Co. Inc.	Keytruda, pembrolizumab (MK-3475, lambrolizumab)	Programmed cell death 1 (PD-1) (PDCD1) (CD279)	Antibody	Marketed
Merck KGaA	Bavencio, avelumab (MSB0010718C, PF-06834635)	Programmed cell death 1 ligand 1 (PD-L1) (B7-H1) (CD274)	Antibody	Marketed
Ono Pharmaceutical Co. Ltd.	Opdivo, nivolumab (BMS-936558, MDX-1106, ONO-4538)	Programmed cell death 1 (PD-1) (PDCD1) (CD279)	Antibody	Marketed
Otsuka Pharmaceutical Co. Ltd.	Balversa, erdafitinib (JNJ42756493)	Fibroblast growth factor (FGF) receptor (FGFR)	Small molecule	Marketed
Pfizer Inc.	Padcev, enfortumab vedotin-ejfv (ASG-22CE, ASG-22ME, asg-22m6e)	Nectin-4 (PRR4)	Antibody-drug conjugate	Marketed
Roche	Tecentriq, atezolizumab, Anti-PDL1 (RG7446, MPDL3280A)	Programmed cell death 1 ligand 1 (PD-L1) (B7-H1) (CD274)	Antibody	Marketed
Shanghai Junshi Biosciences Co. Ltd.	Loqtorzi, Tuoyi, toripalimab-tpzi (JS001)	Programmed cell death 1 (PD-1) (PDCD1) (CD279)	Antibody	Marketed
Speciality European Pharma Ltd.	Mitem, mitomycin		Small molecule	Marketed

UroGen Pharma Ltd.	Jelmyto, UGN-101 (mitogel)			Marketed
Bristol Myers Squibb Co.	linrodostat (BMS-986205, ONO-7701, f001287)	Indoleamine 2,3-dioxygenase 1 (IDO1)	Small molecule	Phase III
Bristol Myers Squibb Co.	Yervoy, ipilimumab (MDX-CTLA-4, MDX-010, BMS-734016)	Cytotoxic T-lymphocyte associated protein 4 (CTLA-4) (CTLA4) (CD152)	Antibody	Phase III
Carisma Therapeutics Inc.	Vicineum, Vicinium (VB4-845)	Epithelial cell adhesion molecule (EpCAM)	Antibody-drug conjugate	Phase III
CG Oncology Inc.	cretostimogene grenadenorepvec (CG0070)	Granulocyte macrophage colony-stimulating factor (GM-CSF) (CSF2)	Oncolytic virus	Phase III
Dr. Reddy's Laboratories Ltd.	CA-170 (AUPM-170)	V-region immunoglobulin-containing suppressor of T cell activation (VISTA); Programmed cell death 1 ligand 1 (PD-L1) (B7-H1) (CD274)	Small molecule	Phase III
Eli Lilly and Co.	Cyramza, ramucirumab (IMC-1121B, LY3009806)	Vascular endothelial growth factor (VEGF) receptor 2 (VEGFR-2) (KDR/Flk-1)	Antibody	Phase III
Ferring Pharmaceuticals A/S	rAd-IFN/Syn3		Gene therapy	Phase III
ImPact Biotech Ltd.	Tookad, padeliporfin di-potassium			Phase III
Jiangsu Yahong Meditech Co. Ltd. (Asieris Pharmaceuticals)	Vesique (APL-1202)	Methionine aminopeptidase 2 (MetAP2)	Enzyme	Phase III
Johnson & Johnson	cetrelimab (JNJ-63723283, JNJ-3283)	Programmed cell death 1 (PD-1) (PDCD1) (CD279)	Antibody	Phase III
Johnson & Johnson	Gemcitabine-releasing intravesical system, GemRIS (TAR-200, td-210)	Not applicable	Drug/device combination	Phase III
Nektar Therapeutics	bempegaldesleukin (NKTR-214)	Interleukin-2 (IL-2) receptor beta chain (IL2RB) (CD122)		Phase III
Novartis AG	bempegaldesleukin (NKTR-214)	Fibroblast growth factor (FGF) receptor (FGFR); Fibroblast growth factor (FGF) receptor 1 (FGFR1) (CD331); Fibroblast growth factor (FGF) receptor 2 (FGFR2) (KGFR) (CD332); Fibroblast growth factor (FGF) receptor 3 (FGFR3) (CD333)	Small molecule	Phase III
Pfizer Inc.	Truseltiq (infigratinib, BGJ398, BBP-831)	Cytotoxic T-lymphocyte associated protein 4 (CTLA-4) (CTLA4) (CD152)	Antibody	Phase III
Pfizer Inc.	Imjudo, tremelimumab (ticilimumab, CP-675, CP-675, CP-675206)	Programmed cell death 1 (PD-1) (PDCD1) (CD279)	Antibody	Phase III
UroGen Pharma Ltd.	UGN-102 (vesigel)			Phase III

Source: Biocentury, September 2024

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NOTE: GlobalData's Clinical Trials Intelligence gathers data from a mix of primary and secondary sources to offer comprehensive insights for stakeholders involved in drug development and clinical research. Primary research contributions include exclusive insights from journalists covering developments only available on the GlobalData platform. Secondary sources include over 100 clinical trials registries like ClinicalTrials.gov (Global), EudraCT/EUCTR (Europe), JAPIC/UMIN (Japan), CTRI (India), ChiCTR (China), and more, alongside company sources such as press releases, financial statements, SEC filings, investor presentations, and pipeline information from company webpages. Information is also sourced from over 200 scientific conferences like ASCO, investor conferences such as the Annual JP Morgan Healthcare Conference, regulatory authorities including the USFDA, EMA, UKMHRA, and academic publications from journals and PubMed. Supported by more than 100 dedicated researchers, GlobalData's platform is a vital resource for pharmaceutical companies, biotech firms, and other stakeholders, helping them stay updated on the latest trends and developments in the clinical trials landscape for better decision-making.

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