

Overview of Renal and Bladder
cancer landscape in Asia
– 2019 update



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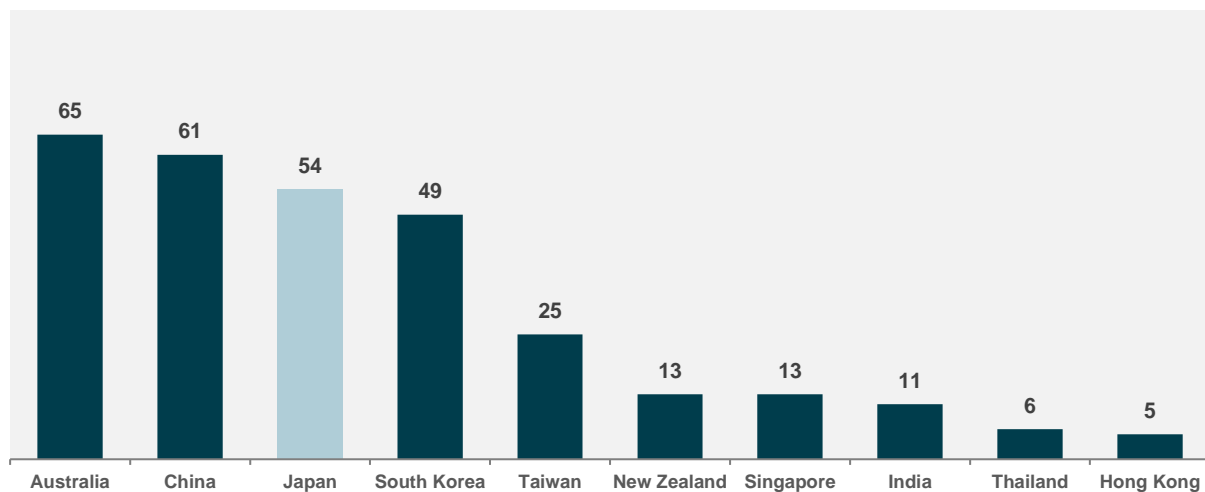
1. Clinical landscape in Asia-Pacific

The incidence of urological cancer has increased consistently in the recent years globally. Bladder cancer has become the ninth most common cancer worldwide, with over 400,000 new cases diagnosed each year. A majority of all bladder cancer cases occur in men in the less developed regions of the world due to environmental factors and smoking habits.

The morbidity and mortality of renal cell carcinoma (RCC) vary widely by geography, with increasing incidence in most countries overall. RCC has been showed to be significantly associated with chronic hepatitis infection, particularly in younger HBV-infected men. With the Asia Pacific region representing three quarters of chronic HBV patients worldwide, this relationship may explain the increase in the number of cases observed in the region, and why many small and mid-sized biopharma choose Asia as a destination for their trials.

Biopharma companies initiated 489 trials in renal and bladder cancer between 2016 and 2018, about 35% of which (169/489) involved a country from Asia. Australia, China, Japan and South Korea were the most frequently involved countries.

Top 10 countries in Asia-Pacific by the number of renal and bladder studies initiated by biopharma companies between 2016 and 2018.



Countries in which Novotech directly operates

Source: GlobalData

2. Recruitment and data from Novotech network

Feasibility, Standard of Care, and Multi-Disciplinary Treatment Centers

Information collected through Novotech study feasibility assessments found many investigators believed there were unmet clinical needs in the region.

In most countries in the region, diagnosis of RCC is routinely performed through various tumor marker and imaging tests, while diagnosis of bladder cancer mostly relies on fluorescence, narrow-band imaging cystoscopy with biopsy, intravenous urogram or retrograde pyelogram.

In renal cancer patients, the standard of care includes nephron-sparing surgery (T1a), laparoscopic radical nephrectomy (T1b), and open radical nephrectomy (T2). In countries such as Taiwan, South Korea, and India, the standard of care relies on a combination therapy with sunitinib or pazaponib (1st line), everolimus or nivolumab (2nd line), cabozantinib or axitinib (3rd line), and axitinib or everolimus (4th line). In non-muscle invasive bladder cancer, patients receive transurethral resection of bladder tumor, along with bacillus calmette-guerin, and mitomycin-C intravesical instillation. In muscle invasive bladder cancer patients, a combination therapy (methotrexate, vinblastine, adriamycin and cisplatin), radical cystectomy, synchronous chemoradiation or radical radiotherapy are the standards of care.

Bladder and Renal cancer patient enrolment estimates (patient/site/year) in a selection of countries where Novotech operates

Country	RCC - Patient recruitment (p/s/m)	Bladder cancer - Patient recruitment (p/s/m)	Government Reimbursement of Nivolumab / Sunitinib
Australia	0.4	0.9	N
South Korea	0.3	0.4	Y
Taiwan	0.4	0.4	Y
The Philippines	0.3	0.3	-
Malaysia	-	-	-
New Zealand	0.15	2.4	N
Singapore	0.3	1.9	N
Hong Kong	0.3	0.3	N

Key Opinion Leaders in Renal and Bladder Cancer

Prof. YUNG JUE BANG

Seoul National University Hospital – SOUTH KOREA

Prof. Bang is Professor of Medical Oncology, President of Biomedical Research Institute and Director of Clinical Trials Center of Seoul National University Hospital. He is the co-author of over 200 publications including in *The Lancet* and *The New England Journal of Medicine*. He was involved in over 130 clinical studies including 13 in renal and bladder cancer for Roche, MSD, AstraZeneca, Eli Lilly, Curis, Debiopharm, and MacroGenics. He is the Chief Scientific Officer of In2Gen.



Prof. KIM DONG WAN

Seoul National University Hospital - SOUTH KOREA

Prof. Kim is Professor of Medical Oncology at Seoul National University Hospital. He is Steering Committee Member at Singapore Clinical Research Institute. He is the co-author of over 200 publications. He was involved in over 80 clinical studies including 5 in renal and bladder cancer for Pfizer, Novartis, Bayer, EMD, MedImmune, MethylGene, and TP-Therapeutics.

Prof. JIN JIE

Peking University First Hospital – CHINA

Prof. Jin is Professor and Director at Institute of Urology, Peking University First Hospital in China. Prof. Jin is a specialist in male genitourinary system diseases. He is the co-author of over 100 publications. He was involved in over 23 clinical studies including 10 in Renal and Bladder cancer for BMS, Johnson & Johnson, Roche, AnewPharma, BeiGene Co, Patheon, and Ono Pharmaceuticals.



Prof. SCOTT ANDREW

Ludwig Cancer Institute – AUSTRALIA

Prof. Scott is Professor at Ludwig Cancer Institute, and Head of Tumor Targeting Laboratory, Olivia Newton-John Cancer Research Institute. Prof. Scott is Board member of the Australian Nuclear Science and Technology Organization. He is the co-author of over 80 publications. He was involved in over 33 clinical studies including 6 in renal and bladder cancer for Abbott, Atara Biotherapeutics, and Humanigen.

Prof. SU WU CHOU

National Cheng Kung University Hospital - TAIWAN

Prof. Su is Professor and Director at Department of Internal Medicine at National Cheng Kung University Hospital in Taiwan. He is the co-author of 100 publications. He was involved in over 78 clinical studies including 8 in renal and bladder cancer for Roche, BMS, AstraZeneca, Boehringer Ingelheim, Hutchinson MediPharma, Ignyta, SciClone pharma, and Takeda.



3. Novotech Overview

Novotech is internationally recognized as the leading regional full-service contract research organization (CRO) in the Asia Pacific region. Novotech provides clinical development services across all therapeutic areas and has been instrumental in the success of hundreds of Phase I - IV clinical trials.



Full service CRO with on-the-ground operations in Australia, New Zealand, India, South Korea, Taiwan, Thailand, Malaysia and Singapore, the Philippines, Hong Kong and China.

600+ full-time employees

Best in class technology solutions including CTMS (Oracle Siebel), eDC (Medidata Rave, Oracle Inform), eTMF (SureClinical) and Safety (Oracle Argus)

Extensive therapeutic area experience handling clinical studies with biopharma companies across all phases of clinical trials

Managed APAC component of pivotal trials for multiple FDA, EMA registered products since 2001

Established in 1996, with head office in Sydney, Australia

Recipient of the 2019 Frost & Sullivan **Asia Pacific Biotech CRO Company of the Year** award for the 4th consecutive year.

Full service CRO



Services

Registered product experience

Novotech has successfully managed the APAC component of over 20 FDA and EMA registered compounds and devices. This speaks to the quality of the data generated from Novotech sites across the region and to our experience working on large pivotal studies for US and EU based biotech.

Abraxane (breast, lung, and pancreatic cancer)	Nerlynx (HER2-positive breast cancer)
Cellegesic (hemorrhoids)	Nothera (orthostatic hypertension)
Depodur (post-operative pain)	Ocaliva (primary biliary cirrhosis)
Firazyr (hereditary angioedema)	Solaraze (actinic and solar keratosis)
Galafold (Fabry's disease)	Tarceva (NSCLC and pancreatic cancer)
GC Flu H5N1 Multi Injection (influenza)	Vimpat (partial-onset seizures)
Hismanal (allergic rhinitis)	Xiaflex (Dupuytren's and Peyronie's contracture)
Istodax (T-cell lymphomas)	Xtandi (prostate cancer)
Levact (chronic lymphocytic leukemia)	Zilretta (osteoarthritic knee pain)
Lucentis (wet AMD)	Zurampic (gout)
Metvix PDT (skin cancer)	Zytiga (prostate cancer)

Novotech people expertise and experience

Novotech has many of the most experienced professionals in the industry.

Average years of Novotech staff experience

