NOVOTECH
The Asia Pacific CRO

Breast Cancer landscape in Asia-Pacific

2021

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1. Epidemiology overview and Clinical activity

Breast cancer is the most frequent cancer, impacting 2.1 million patients each year, and causes the greatest number of cancer-related deaths. Each year, over 500,000 patients die from breast cancer – about 15% of all cancer deaths.

Breast cancer is the most common cancer affecting Australian patients, with about 20,000 new diagnosis each year. It is estimated that approximately 80% of new cases of Breast cancer will develop in patients aged 50 or above. The five-year relative survival rate for patients diagnosed with Breast cancer in 2011-2015 was 91%. Breast cancer accounts for 14% of all cancer deaths in Australian patients and is currently the second leading cause of cancer death in Australian patients after lung cancer.[1] Breast cancer is the most common form of cancer to affect New Zealand patients - every year more than 3,000 patients will be diagnosed. Māori patients are more likely to be diagnosed with Breast cancer than non-Māori patients and more likely to die from the disease. Every year, more than 650 patients die from Breast cancer in New Zealand.[2]

Breast cancer has the highest incidence of all female cancers in Thailand, with an age-standardized rate (ASR) of 29 cases per 100,000 person-years and is estimated to reach 37 in the next decade and the incidence in elderly females tend to be higher than the middle-aged females. The northeast has the lowest incidence of breast cancer, with an ASR of 19 cases per 100,000 per year, compared to the northern, central, and southern regions, with ASRs of 32, 34 and 27 cases per 100,000 PY respectively.[3]

About 35 patients out of 100,000 were diagnosed with Breast cancer between 2012 and 2016 in Malaysia. It accounted for 31% of total female cancers with the age-adjusted incidence of 47/100,000. [4] The Philippines has the highest prevalence of Breast cancer in Asia, and the 9th highest in the world. Risk of Breast cancer has increased from 1 in 22 to 1 in 8 over the years. It accounts for 30% of all cancer cases.

In Singapore, close to 2,000 patients are diagnosed with Breast cancer, and over 400 die from the disease each year. The incidence of Breast cancer tripled from 24 per 100,000 person-years in 1975 to 1979 to 65 per 100,000 person-years in 2010 to 2014.[6]
In South Korea, about 30,000 new cases are diagnosed each year which represents about 20% of all cancer cases in the country.

In Taiwan, Breast cancer is the most common cancer, with an age standardized incidence rate (ASIR) of 71 per 100,000 persons in 2014. The ASIR has gradually increased over the past several years, with an incremental annual change of 4 per 100,000. Despite the increased incidence, the 5-year mortality rate has not significantly changed (5% in 1997 and 4% in 2008). The 5-year relative survival rate of Breast cancer in Taiwan stands at just over 20%. [8,9]

Breast cancer is also the most frequently diagnosed cancer in Chinese patients, with about 300,000 new cases diagnosed each year. The age-standardized incidence rate per 100,000 people by the Chinese stand population was 1.4 times as high in urban areas as in rural areas (36 vs. 26 cases per 100,000 people). The incidence rates were 50 per 100,000 and 17 per 100,000 in 2004–2008 for urban and rural areas, which showed an increase from 30 per 100,000 and 7 per 100,000 in 1989–1993, respectively. China has the highest prevalence of breast cancer, estimated at over 1 million cases. [10,11]

In Hong Kong, Breast cancer accounts for about a third of all new cancers in females, with about 5,000 new cases diagnosed each year. The age-standardised incidence rate was 68 per 100,000 standard population. Breast cancer accounts for just over 10% of all cancer deaths in females in Hong Kong.[12]

In India, Breast cancer represent about 30% of all new cancers diagnosed each year. Over 150,000 news cases are diagnosed each year across the country. [13]

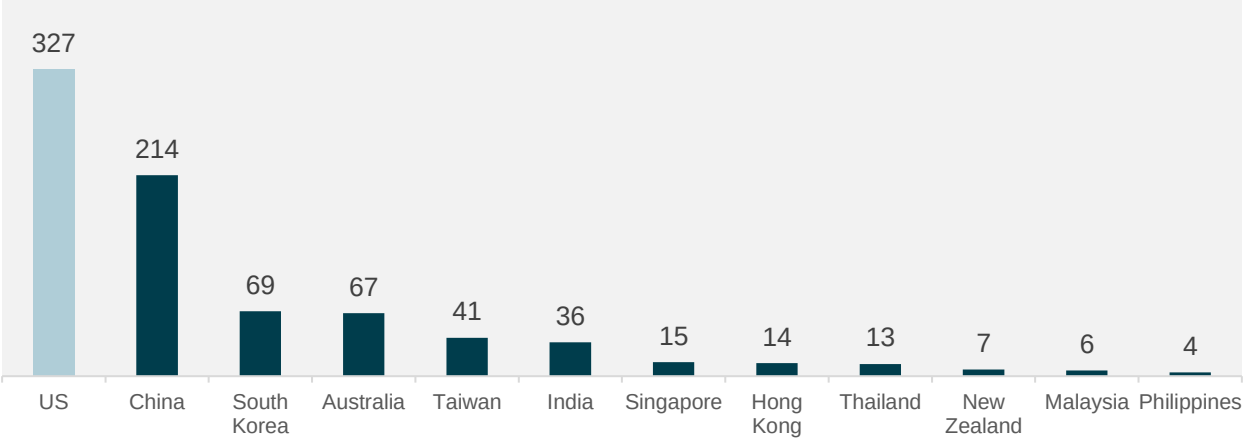
Incidence and mortality and 5-year prevalence of Breast cancer in a selection of locations (2020)

	New Cases		Deaths		5-year Prevalence	
Country	Number	ASR*	Number	ASR	Number	Proportions**
Australia	19,617	96.0	3,132	11.7	84,199	657.7
Greater China	416,371	39.1	117,174	10.0	1,390,095	197.0
India	178,361	25.8	90,408	13.3	459,271	69.3
Malaysia	8,418	49.3	3,503	20.7	29,453	187.2
New Zealand	3,660	93.0	660	14.1	15,403	628.2
Philippines	27,163	52.7	9,926	19.3	85,206	156.2
Singapore	3,662	77.9	921	17.8	15,306	549.0
South Korea	25,814	64.2	3,009	6.4	86,672	338.5
Thailand	22,158	37.8	8,266	12.7	76,440	213.3
United States	253,465	90.3	42,617	12.4	1,070,703	640.3

**Age standardized rate per 100,000*
***Proportions per 100,000*
Source - Cancer Today by WHO

Biopharma companies initiated close to 900 trials in Breast cancer between 2019-2020, about 40% of which involved the Asia-Pacific region. China, South Korea and Australia were the most frequently involved locations with fewer competing trials compared to the US.

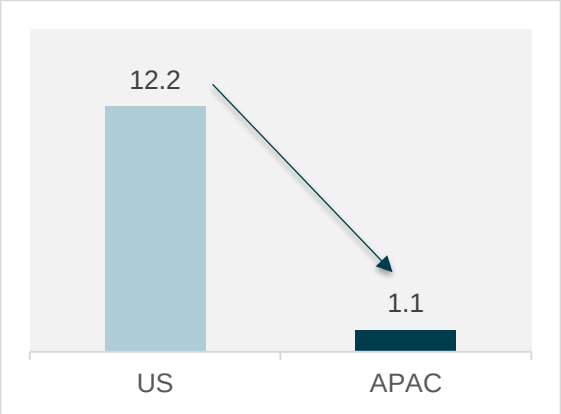
Top locations in Asia-Pacific in relation to the number of Breast cancer Studies initiated by Biopharma Companies between 2019-2020.



Locations in which Novotech directly operates
Source – GlobalData [Accessed 13th January 2021]

Lower Trial density (US vs. APAC)

Number of recruiting sites for industry-initiated Breast cancer trials per million of urban population in selected Asia-Pacific countries (2020)



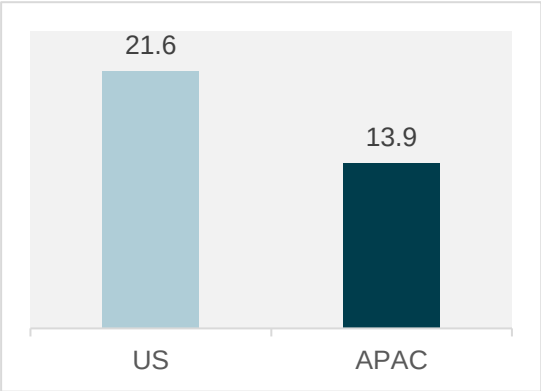
Source – ClinicalTrials.gov [Accessed 13th January 2021]

Recruitment Analysis

Asia-Pacific region shows faster enrolment periods and higher recruitment rates when compared to the US.

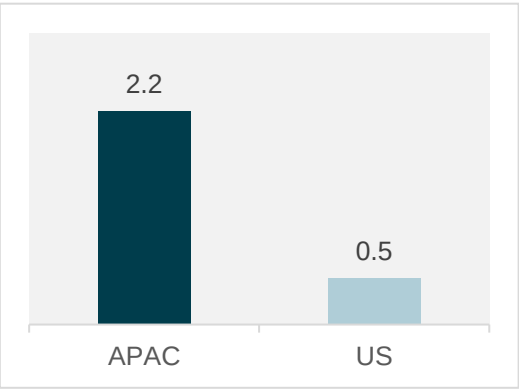
Faster Trial Enrolment

Mean enrolment duration (in months) for industry sponsored Breast cancer trials in the Asia-Pacific and the US, initiated between 2018-2020.



Higher Recruitment Rate

Median recruitment rate (subject/site/month) for industry sponsored breast cancer trials in the Asia-Pacific and the US, initiated between 2018-2020.



Source – GlobalData [Accessed 13th January 2021]

2. Standard of Care

Standard treatment for breast cancer includes:

Treatment Option	Types

Radiation	• External beam radiation
	  ▪ Whole breast radiation
	  ▪ Accelerated partial breast irradiation - Intraoperative radiation therapy (IORT), 3D-conformal radiotherapy (3D-CRT), Intensity-modulated radiotherapy (IMRT)
	  ▪ Chest wall radiation
	  ▪ Lymph node radiation
	• Brachytherapy
	  ▪ Intracavitary brachytherapy
	  ▪ Interstitial brachytherapy

Chemotherapy	• Adjuvant and neoadjuvant chemotherapy
	  ▪ Anthracyclines, such as doxorubicin and epirubicin
	  ▪ Taxanes, such as paclitaxel and docetaxel
	  ▪ 5-fluorouracil (5-FU) or capecitabine
	  ▪ Cyclophosphamide
	  ▪ Carboplatin

Hormone Therapy	• Selective Estrogen Receptor Modulator (SERM) – Tamoxifen, Toremifene • Selective Estrogen Receptor Degrader (SERD) – Fulvestrant • Aromatase inhibitors (AIs) – Letrozole, Anastrozole, Exemestane

Targeted Therapy	• For HER2-positive breast cancer
	  ▪ Monoclonal antibodies – Trastuzumab, Pertuzumab, Margetuximab
	  ▪ Antibody-drug conjugates – Ado-trastuzumab emtansine, Fam-trastuzumab deruxtecan
	  ▪ Kinase inhibitors – Lapatinib, Neratinib, Tucatinib
	• For hormone receptor-positive breast cancer
	  ▪ CDK4/6 inhibitors – Palbociclib, Ribociclib, Abemaciclib
	  ▪ mTOR inhibitor – Everolimus
	  ▪ PI3K inhibitor – Alpelisib
	• For breast cancer with BRCA gene mutations – Olaparib, Talazoparib
	• For triple-negative breast cancer
	  ▪ Anitbody-drug conjugate – Sacituzumab govitecan

Immunotherapy	• Immune checkpoint inhibitors
	  ▪ PD-1 inhibitor – Pembrolizumab
	  ▪ PD-L1 inhibitor – Atezolizumab

Surgery	• Breast-conserving surgery - only the part of the breast containing the cancer is removed. • Mastectomy - the entire breast is removed, including all of the breast tissue and sometimes other nearby tissues.

Source - Treating Breast Cancer – American Cancer Society

3. Key Opinion Leaders in Breast Cancer

Prof. ARLENE CHAN

Hollywood Hospital – ***AUSTRALIA***

Prof. Chan is a professor at Curtin University and the Director of the Breast Clinic Trials Unit, at Hollywood Private Hospital. She has over 20 years of experience and has recruited nearly 1,200 patients to clinical trials. She has authored over 100 breast cancer publications in journals including *New England Journal of Medicine*, *Lancet Oncology and Journal of Clinical Oncology* and has been a reviewer for UK NHS and NHMRC grants.

Prof. SHERENE LOI

Peter MacCallum Cancer Institute – ***AUSTRALIA***

Prof. Loi is an oncologist at Peter Mac and Professor at the University of Melbourne. Her research focuses on novel target and immune therapies for Breast cancer. She leads the Breast Cancer Clinical Trials Unit at the Victorian Comprehensive Cancer Centre. She is an active member of the Breast Cancer Trials ANZ Group and holds an Endowed Chair from the National Breast Cancer Foundation. She has published over 180 peer-reviewed articles and is on the Scientific Committee for Breast Cancer for the ASCO.

A/Prof. YEN-SHEN LU

National Taiwan University Hospital – ***TAIWAN***

A/Prof. Yen Shen Lu is an Associate Professor and Division Chief of Medical Oncology at the National Taiwan University College of Medicine. His research focuses on targeted agents for metastatic Breast cancer. A/Prof Yen Shen Lu is an invited speaker at the Asia Oncology Summit and the Global Breast Cancer Conference. He has over 30 conference papers and over 60 articles to his credit in international journals, including *Lancet Oncology* and *Cancer Research*.

A/Prof. LEE SOO CHIN

National University Cancer Institute Singapore (NCIS) – ***SINGAPORE***

A/Prof Lee Soo Chin is the Head & Senior Consultant, Dept. of Haematology-Oncology, NCIS, Associate Professor and Senior PI at the Cancer Science Institute, Singapore. She specialises in Breast cancer and directs the Cancer Genetics program at the NCIS. She engaged in more than 40 trials and has co-authored over 150 publications in journals like *Lancet Oncology*, *Breast Cancer Research and Treatment* and *New England Journal of Medicine.*

Prof. PARK YEON HEE

Samsung Medical Center – ***SOUTH KOREA***

Prof. Park Yeon Hee is a Professor of Haematology-Oncology at the Sungkyunkwan University School of Medicine and Chair, Breast Cancer Centre, Samsung Medical Centre (SMC). She is a research leader of SMC breast cancer genomics studies with a focus on refractory breast cancer. She engaged in 80 global clinical trials and has authored over 150 papers including in *The Lancet*, *OncLive, Targeted Oncology and European Journal of Cancer*.

4. Novotech Overview

Novotech is internationally recognized as a leading regional contract research organization (CRO) in Asia-Pacific. Novotech has been instrumental in the success of over a thousand Phase I - IV clinical trials for biotechnology companies.

Novotech provides clinical development services across all clinical trial phases and therapeutic areas including: feasibility assessments; ethics committee and regulatory submissions, data management, statistical analysis, medical monitoring, safety services, central lab services, report write-up to ICH requirements, project and vendor management. Novotech obtained the ISO 27001 certification which is the best-known standard in the ISO family providing requirements for an Information Security Management System. Together with the ISO 9001 Quality Management system, Novotech aims at the highest IT security and quality standards for patients and biotechnology companies

https://novotech-cro.com/

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