

Acute Myeloid Leukemia landscape in Asia-Pacific

2021



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1. Epidemiology overview and Clinical activity

Acute myeloid leukemia (AML) is a malignant disease of hemopoietic stem cells or progenitors which is characterized as the differentiation arrest and aberrant proliferation of myeloid lineages. AML is the most common form of leukemia in adults, accounting for approximately a third of all leukemias worldwide. AML patients face the lowest survival rates of all leukemias. Only 1 in 4 adults with AML survive longer than five years after the diagnosis. In the United States, the average age of a patient with AML is about 67 years.[1]

Each year in Australia, more than 3,700 people are diagnosed with a form of leukaemia and it is the most common type of cancer diagnosed in young adults. About 1,400 of these cases are Acute Leukaemia, accounting for about 1% of cancer cases in Australia. About 1,100 people are diagnosed with Acute Myeloid Leukaemia each year. AML becomes more common with age and mostly occurs after 65. Overall AML is a rare disease, accounting for about 1% of all cancers diagnosed, at a rate of 3.7 per 100,000 of population. [2] AML is a relatively rare type of cancer, but it is the most common type of Acute Leukaemia diagnosed in adults in New Zealand.[3]

Accounting for 33% of all myeloid malignancies, AML was the most frequent in South Korea between 2008-2012. Five-year survival of patients stood at 30% between 2008-2012. Poor survival of patients with AML and high-risk MDS was more apparent in patients over 65 years old.[4] The incidence of AML is generally reported to be 3-5 per 100,000 per year but varies according to age. The 2-year overall survival (OS) rates of younger and elderly groups in Thai AML patients were merely 29% and 10%, respectively.[5]

There are 30,000 new cases of AML diagnosed in China annually and a five-year survival rate of below 20%. With an increasing life expectancy and aging population in China, the incidence of AML may rise significantly. The incidence of AML in Taiwan has increased from 1 to 2 per 100,000 between 2000 and 2008. [6]

The Philippines Cancer Society, for their “2015 Philippine Cancer Facts & Estimates” report, has said that around 5 individuals per 100,000 Filipinos will develop leukemia. The same report estimated that over 4,000 new cases were diagnosed each year. [7]

In India, the number of new cases of AML between 2010–2014 was 4 per 100,000 men and women per year. The number of deaths was 3 per 100,000 per year. AML is most frequently diagnosed among people aged 65–74 years. [8]

[1] AML factsheet by Pfizer

[2] Cancer Council Australia

[3] Leukaemia and Blood Cancer New Zealand

[4] Nationwide statistical analysis of myeloid malignancies in Korea: incidence and survival rate from 1999 to 2012

[5] The Development of Personalized Medicine: Acute Myeloid Leukemia as a Model

[6] Outcome and late effects among acute myeloid leukemia survivors: a nationwide population-based study

[7] Leukemia in The Philippines

[8] Clinical profile of acute myeloid leukemia in North India and utility of nontransplant measures in its management

Estimated incidence, mortality in 2020 and 5-year prevalence of Leukemia across APAC and the US

Country	New Cases		Deaths		5-year Prevalence	
	Number	ASR*	Number	ASR	Number	Proportions**
Australia	4,500	10.7	2,015	3.4	14,003	54.9
Greater China	85,404	5.1	61,694	3.3	2,141,752	16.7
India	48,419	3.6	35,392	2.6	127,493	9.21
Malaysia	1,905	6.3	1,481	4.4	6,113	18.9
New Zealand	691	8.8	449	4.2	2,141	44.4
Philippines	5,795	5.7	4,370	4.3	16,835	15.4
Singapore	648	8.9	306	3.1	2,142	36.6
South Korea	3,845	5.8	2,100	2.2	12,518	24.4
Thailand	4,577	5.4	3,308	3.4	12,747	18.3
United States	61,152	11.1	23,753	3.2	187,560	56.71

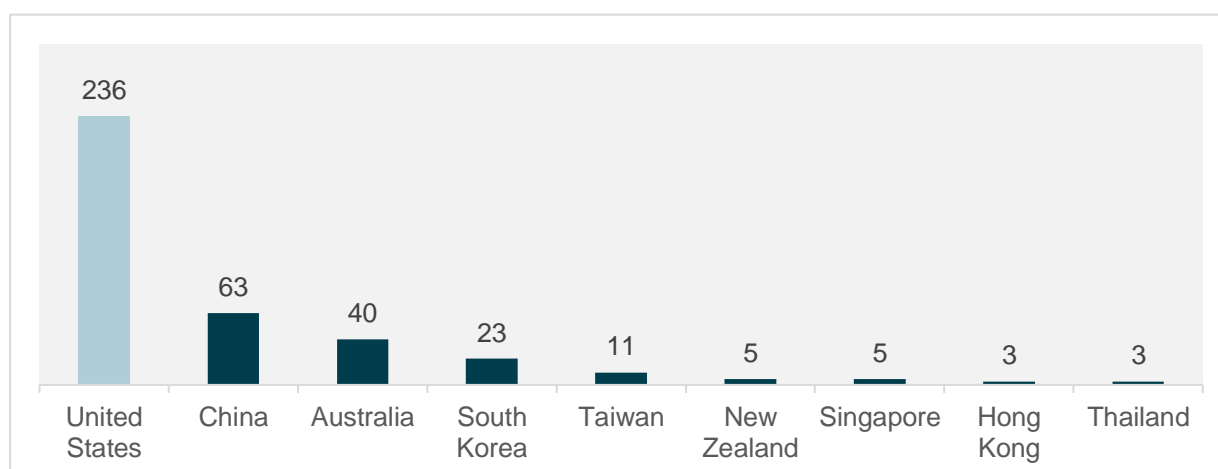
*Age standardized rate per 100,000

**Proportions per 100,000

Source - Cancer Today by WHO

Biopharma companies initiated over 450 trials in Acute Myeloid Leukemia since 2018, a fourth of which involved the Asia-Pacific region. China, Australia and South Korea were the most frequently involved countries with fewer competing trials compared to the US.

Top countries in Asia-Pacific in relation to the number of AML studies initiated by Biopharma companies between 2018-2020.

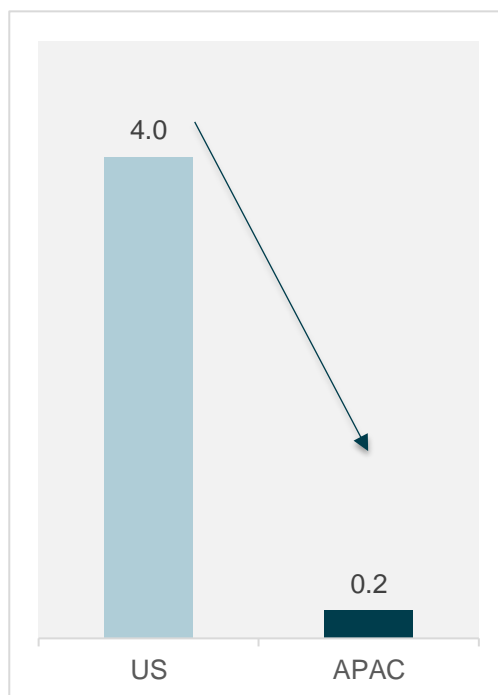


Countries in which Novotech directly operates

Source – GlobalData [Accessed 12th January 2021]

Lower Trial density (US vs. APAC)

Number of recruiting sites for industry-initiated AML trials per million of urban population in selected Asia-Pacific countries, 2020-2021.



Source – [ClinicalTrials.gov](https://clinicaltrials.gov) [Accessed 12th January 2021]

2. Standard of Care

Standard treatment for Acute Myeloid Leukemia includes:

Treatment Option	Types
Chemotherapy	<ul style="list-style-type: none"> • Anthracyclines – Daunorubicin, Idarubicin, Mitoxantrone • Anti-metabolites – Cytarabine, Cladribine, Fludarabine • Hypomethylating Agents – Decitabine, Azacitidine
Targeted therapy	<ul style="list-style-type: none"> • CD33 surface protein – Gemtuzumab • Core Binding Factor (CBF) – Gemtuzumab in combination with Daunorubicin, Cytarabine • FLT3 inhibitors – Midostaurin or Gilteritinib is used to treat AML with FLT3-ITD and FLT3-TKD gene mutations. Sorafenib with Azacitidine or Decitabine is used to treat AML with FLT3-ITD mutation. • IDH inhibitors – Ivosidenib, Enasidenib • BCL-2 inhibitor – Venetoclax • Hedgehog pathway inhibitor – Glasdegib
Stem Cell Transplant	<ul style="list-style-type: none"> • Autologous transplant of one's own stem cells. • Allogenic transplant of stem cells from a healthy donor.

Source – NCCN guidelines for patients – Ovarian Cancer 2020 edition

3. Key Opinion Leaders in Acute Myeloid Leukemia

A/Prof. ANDREW WEI

Alfred Hospital – AUSTRALIA

A/Prof Andrew Wei is a haematologist and the head of leukemia research at The Alfred hospital. He has been the AML disease group chairperson for ALLG since 2009 and has led multiple nationwide cooperative group studies as chief investigator. A/Prof Wei is an executive member of the ALLG Scientific Advisory Committee, and a member of the National Medical and Scientific Advisory Committee of the Leukemia Foundation of Australia. He sits on the International Steering Committee for Celgene, providing expert advice on AML.



Prof. PETER BROWETT

University of Auckland – NEW ZEALAND

Prof. Browett is a Consultant Haematologist at the Auckland City Hospital, and Professor of Pathology at the University of Auckland. He is co-director of the Leukaemia and Blood Cancer Research Unit, with interest in blood cancer genomics, biomarkers in leukaemia, and the monitoring of measurable residual disease. Peter is also the clinical director of the Auckland Regional Tissue Bank, and Grafton Clinical Genomics. He has co-authored over 100 publications in journals including *Clin Cancer Res*, *Br J Haematol*, *Eur J Haematol*.

Dr. MICHELLE POON

National University Cancer Institute Singapore (NCIS NUH) – SINGAPORE

Dr. Poon is a senior consultant at the Dept. of Haematology-Oncology at NCIS NUH. Her research interests include use of novel clinical therapies to manage acute lymphoblastic leukemia and lymphoma and hematopoietic stem cell transplantation in adults with haematological diseases. She has co-authored over 40 publications in journals such as *New England Journal of Medicine* and *International Journal of Haematology*.



Prof. SUNG-SOO YOON

Seoul National University – SOUTH KOREA

Prof. Sung-Soo Yoon is a Professor and Director of the Centre for Hematologic Malignancies at the Seoul National University. He is a key member of the International Cancer Genome Consortium (ICGC), formed to reveal 50 cancer genomes. He has the experience of working on over 40 haematology clinical trials.

Prof. XIAO JUN HUANG

Peking University People's Hospital – CHINA

Prof. Xiao Jun Huang is Professor of Medicine and Haematology and the Peking University Institute of Haematology. He was the first president of the Asia Pacific Haematology Consortium. Prof. Huang focuses on the clinical and experimental fields of haematology and hematopoietic stem cell transplantation (HSCT). He is the co-author of over 100 publications and engaged in 80 early phase clinical studies in haematological cancers.



4. Novotech Overview

Novotech is internationally recognized as the leading regional full-service 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 was established in 1996, with offices in 11 locations across the region, and site partnerships with major health institutions.

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/>

