

Overview of Hepatitis B
landscape in Asia -
2019 update



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1.HBV trial landscape in APAC

Epidemiology overview and clinical activity in Asia

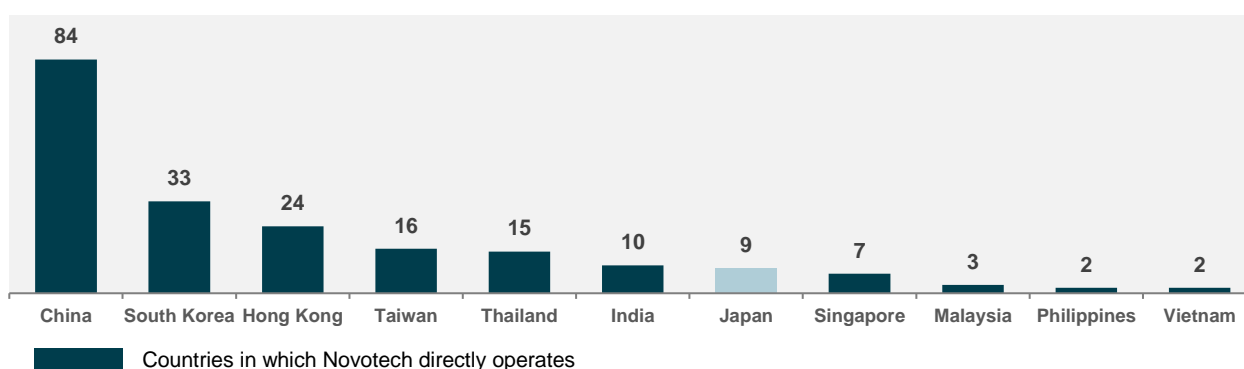
It is estimated that at least 2 billion people or one third of the world’s population have been infected with HBV. Approximately 240 million people or 6% of the world’s population are chronically infected. The Asia Pacific region represents three quarters of chronic HBV patients worldwide. Specifically, the Western Pacific region comprising of countries including China, Japan, South Korea, Philippines and Vietnam account for 50% of the worlds chronic HBV population. One third of liver cirrhosis cases and more than half of the HCC cases in the Asia region are attributable to HBV. The dominant risk factor for HCC in most areas of Asia Pacific is HBV. Prior to the implementation of the HBV vaccination program, the Asia Pacific region was divided into three categories in terms of prevalence. High prevalence (>8%) regions included mainland China, Hong Kong, Taiwan, Korea, Mongolia, Philippines, Thailand, Vietnam and the south pacific islands. Intermediate prevalence (2-8%) included central Asia, India, Indonesia, Malaysia and Singapore. Low prevalence (<2%) included Australia and New Zealand, though this has increased in recent years due to migration from high prevalence nations.

Country	Prevalence category	Estimated prevalence
Australia	Low (1-2%)	240 K – 489 K
China	High (7-8%)	98 M – 112 M
Hong Kong	High (7-8%)	515 K – 589 K
India	Intermediate (2-8%)	26 M – 80 M
Japan	High (7-8%)	8.9 M – 10.2 M
Malaysia	Intermediate (2-8%)	632 K – 253 K
New Zealand	Low (1-2%)	47 K – 94 K
Philippines	High (7-8%)	7.3 M – 8.4 M
Singapore	Intermediate (2-8%)	0.1 M – 0.5 M
South Korea	High (7-8%)	1.6 M – 1.9 M
Taiwan	High (7-8%)	1.6 M – 1.9 M
Thailand	High (7-8%)	4.8 M – 5.5 M

Source: S. K. Sarin, M. Kumar, G. K. Lau; *Asian-Pacific clinical practice guidelines on the management of hepatitis B: a 2015 update; Hepatol Int; 2016 Jan; 10(1)- 1-19*

Biopharma companies initiated 226 trials in HBV between 2016 and 2018, 76% of which (172/226) involved a country from Asia, with China, Korea, Hong Kong and Taiwan being the countries the most frequently involved.

Top 10 countries in Asia in the number of industry-funded HBV studies initiated between 2016 and 2018



Key hepatologists

Prof EDWARD GANE

Auckland Hospital – NEW ZEALAND

Edward Gane is Professor of Medicine at the University of Auckland, New Zealand and Chief Hepatologist, Transplant Physician and Deputy Director of the New Zealand Liver Transplant Unit at Auckland City Hospital. He is the co-author of over 100 publications including in *The Lancet* and *The New England Journal of Medicine* and serves on the editorial committee for several journals. Dr. Gane serves on the Executive Committee of the NZ Society of Gastroenterology and is a member of several international organizations including APASL, AASLD, ILCA and ILTS.



DR PISIT TANGKIJVANICH

King Chulalongkorn Memorial Hospital - THAILAND



Dr Pisit Chulalongkorn holds a Research Fellowship (Molecular hepatology) from the UCLA School of Medicine. He is the co-author of 70 scientific publications and has participated in 10 clinical trials, including pivotal studies, for major Pharmaceutical and Biotech companies and more specifically with Abivax, Arrowhead, Contravir and Gilead.

Prof MAN FUNG YUEN

Queen Mary Hospital – HONG KONG

Professor Man-Fung Yuen is the Chair Professor and Endowed Professor in Medicine of the Li Shu Fan Medical Foundation, the Chief of the Division of Gastroenterology and Hepatology and the Deputy Chief of Service of the Department of Medicine, Queen Mary Hospital, Hong Kong. He has participated in 50 clinical trials and is the author of over 170 scientific publications. Dr Yuen was mostly involved in late phase trials including pivotal studies and has extensive experience working with major Pharmaceutical and Biotech companies including Gilead, GSK, Roche, Alnylam and Inovio Pharmaceuticals.



Prof YOUNG-SUK LIM

Asan Medical Center – SOUTH KOREA



Young-Suk Lim is Professor University of Ulsan College of Medicine, South Korea, and head of the Asan clinical trial center. Professor Lim is co-author of over 150 scientific publications and was evolved in about 40 clinical trials, primarily for pivotal and phase IV trials. Professor Lim more specifically worked on both hepatitis and HCC trials for Gilead, BMS, AbbVie, GSK, Celltrion, Altimune, Roche or Ildong.

Source: Pubmed; Citeline

2. 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)	Northera (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)

Overview of staff experience

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

Average years of Novotech staff experience

