

Overview of hepatocellular
carcinoma and bile duct
malignancies landscape in Asia
– 2019 update



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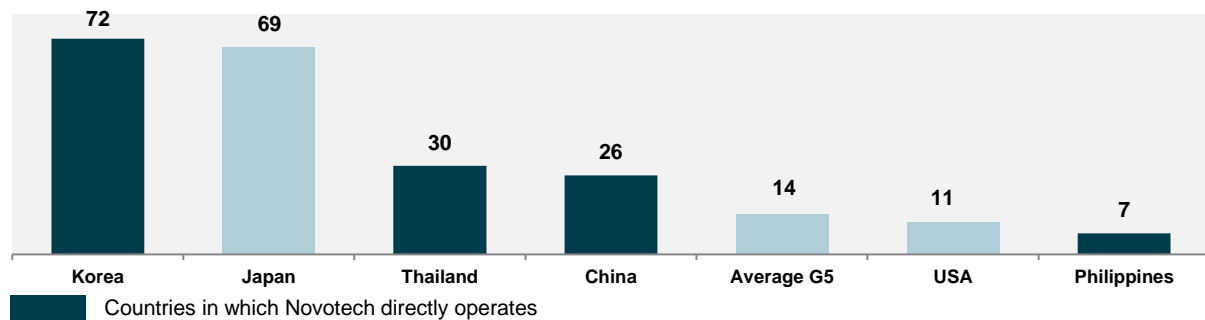
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1. Clinical landscape in Asia-Pacific

Epidemiology and clinical activity

Hepatocellular carcinoma (HCC) and bile duct malignancies are highly prevalent in Asia, especially in South Korea and in Japan where the prevalence rate is about 5 times higher than in Western countries. Chronic viral hepatitis infections as well as fatty liver diseases (NASH in particular), which are endemic in this part of the world, are known to markedly increase the risk of developing HCC and explain the high rates observed in Asia.

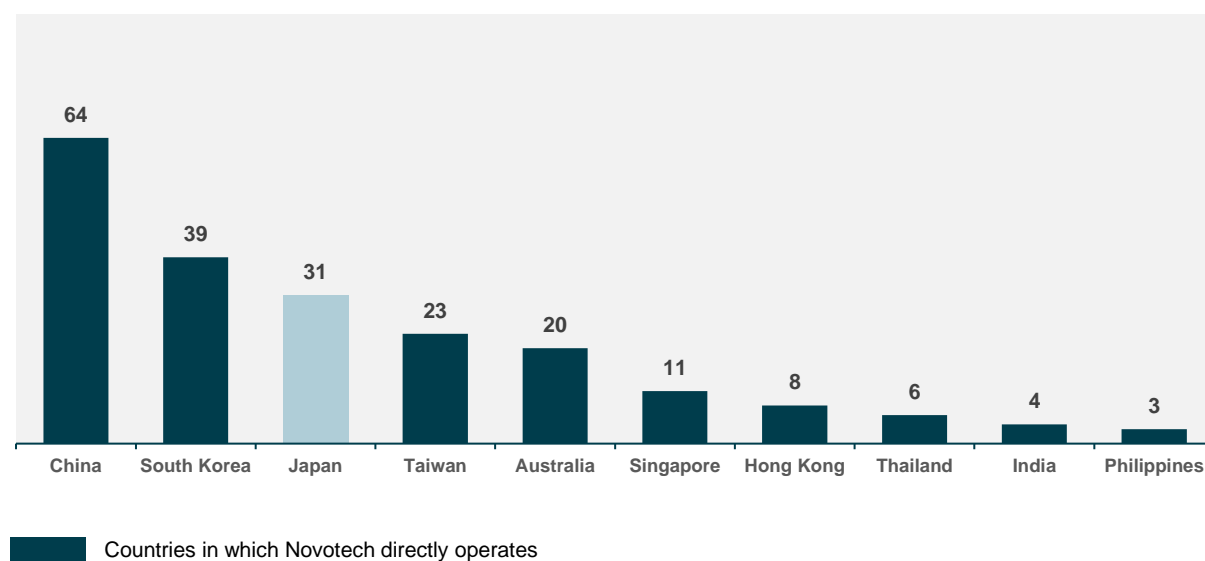
Prevalence rate of HCC and bile duct malignancies (per 100,000) in a selection of Western and Asian countries



Source: IPD. Kumar V, Fausto N, Abbas A, eds. (2015). *Robbins & Cotran Pathologic Basis of Disease (9th ed.)*. Saunders. pp. 870–873. ISBN 978-1455726134.

Biopharma companies initiated 304 trials in hepatocellular carcinoma between 2016 and 2018, about 45% of which (137/304) involved a country from Asia. China, South Korea, Japan and Taiwan were the most frequently involved countries.

Top 10 countries in Asia Pacific in relation to the number of hepatocellular carcinoma studies initiated by Biopharma companies between 2016 and 2018



Source: GlobalData

Key opinion leaders in hepatology and oncology

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. Prof 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.



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 involved 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.

Prof RONNIE POON

Hong Kong Integrated Oncology Center – HONG KONG

Ronnie Poon is Honorary Clinical Professor at the Li Ka Shing Faculty of Medicine, Hong Kong, and has been involved in about 50 clinical trials on both first-in-human testing and pivotal studies. He collaborated with major pharmaceutical and biotech companies such as Novartis, Bayer, Amgen, and GSK and was involved on 8 studies with Novartis alone. Professor Poon has been actively involved in academic research as well and is the co-author of over 300 scientific publications including in the *J Clin Oncol* and *Cancer Cell*.



DR LIM HO YEONG

Samsung Medical Center – SOUTH KOREA

Dr Lim is the co-author of over 50 scientific publications and was involved in almost a hundred clinical trials including for Sanofi, Pfizer, Eli Lilly, Amgen, Transgene, PharmAbcine and Merck. Dr Lim is a Research Fellow from Johns Hopkins University Oncology Center and is an active member of several academic societies including the American Society of Clinical Oncology and the American Association for Cancer Research.

DR YOON-KOO KANG

ASAN Medical Center – SOUTH KOREA

Dr Kang is Assistant Professor at UUCM AMC and a Research Fellow in Medicine Branch from the National Cancer Institute. Dr Kang is one the most active clinical investigators in South Korea. He is the co-author of over 200 scientific publications and was involved in over 140 clinical studies in numerous Oncology indications and with a specific focus on digestive cancers (gastric, esophageal and HCC). He is currently involved on ongoing pivotal studies with BMS, LSK, Ono and Sanofi.



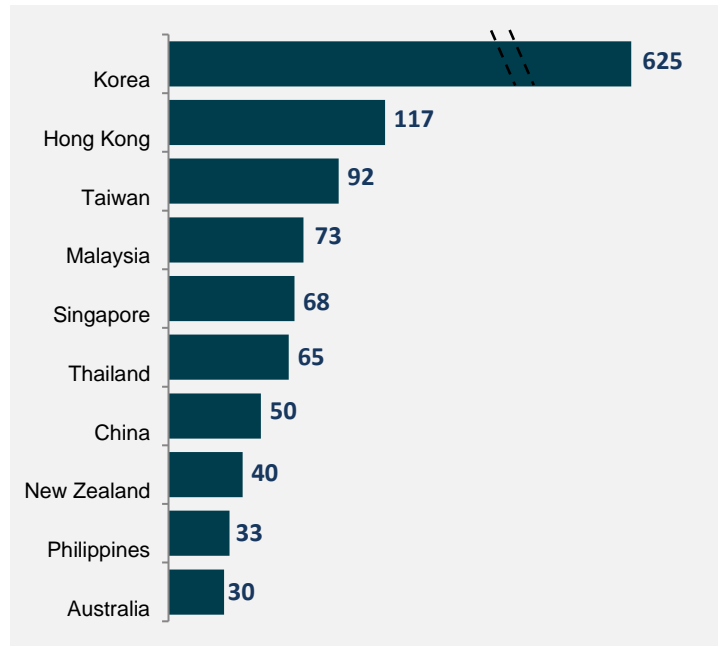
2. Recruitment and data from Novotech network

Information collected through various study feasibility assessments confirmed the great interest from a number of investigators to engage in HCC trials.

As expected based on the epidemiology landscape, sites in South Korea have the highest number of patients with unresectable HCC (between 500 to 1,500 patients per year depending on the site). A significant number of patients was also reported from sites in Hong Kong (between 125-250 patients per year), and Taiwan (45-300 patients per year).

For a majority of these patients, the treatment for a locally advanced disease relied on surgery, transarterial chemoembolization procedure (TACE) and ablative therapy. The table on the right displays the estimated average number of HCC patients being treated through TACE in each of the key Asian countries based on a sample of investigators (n=30).

Estimated average number of hepatocellular carcinoma patients receiving TACE from a sample of Asia-based clinical investigators (n=30)



TOTAL Average 119 patients/year

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 3rd 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)

Novotech people expertise and experience

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

Average years of Novotech staff experience

