

## Overview of Lung cancer landscape in Asia (2019 update)



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# 1. Clinical landscape in Asia-Pacific

## Epidemiology overview and Clinical activity

Lung cancer is one of the most common malignancies in the world, representing about 1.6 million cases annually and over 10% of all new cancers.

The most well-known risk factor for lung cancer is cigarette smoking which has become endemic in Asia. Hence the prevalence of the disease in Asia has dramatically increased in the past years reaching over 720,000 patients in the countries where Novotech operates. The prognosis in Asian patients is more favourable than in Western population partially due to a higher frequency of EGFR mutations.

*Estimated incidence of Lung cancer in a selection of countries (Source IPD)*

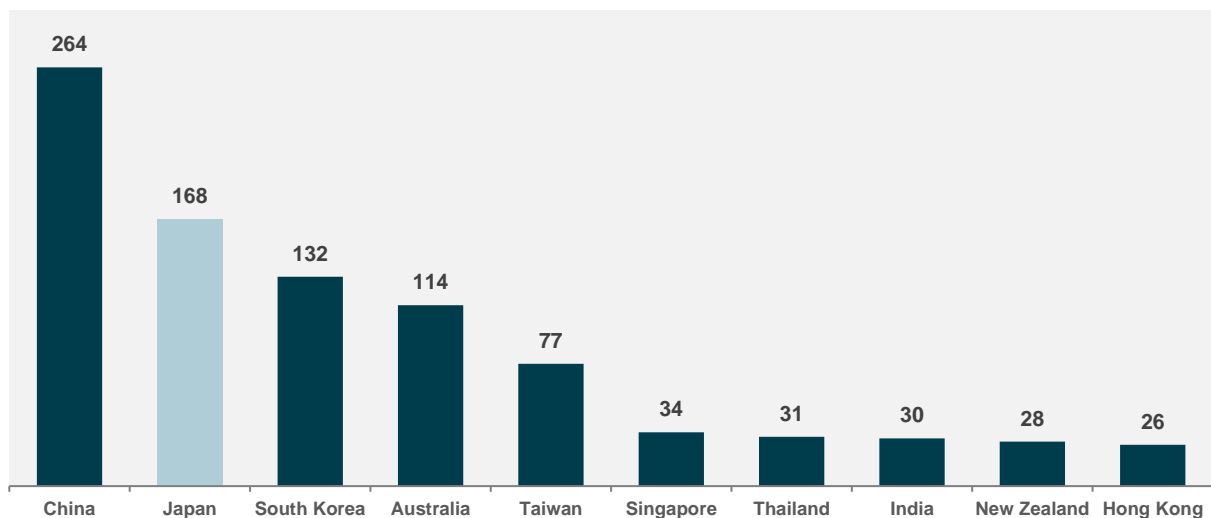
Region/Country	Incidence rate (per 100,000)
United States	68
Hong Kong	64
China	53
Australia	44
Worldwide	27
South Korea	27
Thailand	21
The Philippines	19

Sources: *Diagnosis and Management of Lung Cancer, 3rd ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2013 May; 143(5 Suppl): e1S–e29S.*

*EGFR mutation incidence in non-small-cell lung cancer of adenocarcinoma histology: a systematic review and global map by ethnicity. Am J Cancer Res 2015;5(9):2892-2911.*

Biopharma companies initiated 1,219 trials in lung cancer between 2016 and 2018, 47% of which (574/1,219) involved a country from Asia Pacific. China, Japan, South Korea and Australia were the most frequently involved countries.

*Top 10 countries in Asia Pacific in relation to the number of lung cancer studies initiated by biopharma companies between 2016 and 2018.*



Countries in which Novotech directly operates

Source: GlobalData

## 2. Recruitment and data from Novotech network

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

In most countries in the region, the diagnosis of lung cancer is routinely performed through sputum cytology, tissue biopsy, bronchoscopy, and imaging. Standard of care within the major multi-disciplinary treatment clinics is PD-1 and PD-L1 inhibitors such as nivolumab, pembrolizumab (1<sup>st</sup> line and 2<sup>nd</sup> line Non-small cell lung carcinoma), and pemetrexed.

In Taiwan, South Korea, India and New Zealand patients diagnosed with locally advanced and metastatic non-small cell lung carcinoma, and disease progression after platinum-based combination chemotherapy (cisplatin-etoposide + EBRT, carbo-pac, tarceva, vinorelbine, carbo-gem, avastin etc), are treated with atezolizumab.

Small-cell lung carcinoma patients are treated with radiation therapy, and prophylactic cranial irradiation to prevent brain metastases. Limited scale and extensive scale small-cell lung carcinoma are treated with a combination therapy of CAV and PEI regimen. Wedge resection, segmental resection, lobectomy, and pneumonectomy is the common surgical standard of care.

*Patient enrolment estimates (patient/site/y), and key MDT clinics in a selection of countries in lung cancer*

Country	Recruitment (p/s/y)	Standard of Care (1 <sup>st</sup> and 2 <sup>nd</sup> line)	Government Reimbursement
Australia	20	Carbo/Gem +/- pemetrexed, often followed by nivolumab and docetaxel	Y (Nivolumab and Atezolizumab)
New Zealand	40	Carbo/Gem followed by single agent chemotherapy and docetaxel	N
Thailand	40	Platinum compounds in combination with TKI (if EGFR+) followed by docetaxel	N
Taiwan	10	Target therapy for EGF+, alimta in association with cisplatin for EGFR-, followed by alimta and cisplatin for EGFR+ or taxotere for EGFR	Y (Pembrolizumab)
Hong Kong	6-8	1st line: Pemetrexed/cisplatin or carboplatin +/- bevacizumab 2nd and 3rd line: Gemcitabine or docetaxel	N
Malaysia	10	Alimta in association with platinum compounds followed by taxotere	N
Singapore	120	Platinum compounds followed by nivolumab, pembrolizumab and docetaxel	N
South Korea	50	Pemetrexed in combination with cisplatin followed with TKI and docetaxel	Y
India	12-15	Platinum compounds in combination with paclitaxel followed by cisplatin and gemcitabine	N
Philippines	20-25	Pemetrexed in combination with cisplatin and TKI (EGFR+), followed by combination paclitaxel and carboplatin	Y

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## Key opinion leaders in lung cancer

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### **Prof. DAE HO LEE**

*Asan Medical Center – SOUTH KOREA*

Prof. Lee is Associate Professor of Oncology at the Asan Medical Center (S. Korea). He served as Guest Researcher at the National Institutes of Health, and as a Board member for the American Society of Clinical Oncology. He is the co-author of over 100 publications and he participated to 85 clinical studies, including 40 in lung cancer, for Roche, AstraZeneca, Eli Lilly, Novartis, Samyang Bio, Astex Therapeutics, and Chong Kun Dang Pharmaceutical.



### **Dr. MOK SHU KAM TONY**

*Chinese University of Hong Kong – HONG KONG*

Dr. Mok is Chairman of the Department of Clinical Oncology at the Chinese University of Hong Kong, and serves on the Board of Director at the American Society of Clinical Oncology. He participated in over 90 clinical studies, including 69 in lung cancer, for Roche, Boehringer Ingelheim, BMS, AstraZeneca, ImmvaRx, AVEO Bio, Ono Pharma, and Xcovery.

### **Dr. HUANG CHENG**

*Fujian Provincial Cancer Hospital – CHINA*

Dr. Cheng is Chief Physician and Director of Department of Oncology at the Fujian Medical University. Dr. Cheng is Director of Fujian Provincial Cancer Chemotherapy Quality Control Center in China. He is the co-author of over 100 scientific publications. He was involved in 59 clinical studies, including 44 in Lung cancer, for Amoytop Biotech, Jiangsu Hengrui Medicine BeiGene, and Betta Pharmaceuticals.



### **Prof. YANG JAMES CHIH HSIN**

*National Taiwan University Hospital – TAIWAN*

Prof. Yang is the Director of the Graduate Institute of Oncology at the National Taiwan University. He served on the editorial board of *Annals of Oncology* and *Lung Cancer Journals* and is the current associate editor of the *Journal of Thoracic Oncology* and *Nature Scientific Report*. He is the co-author of over 100 scientific publications and he was involved in over 80 clinical studies, including 65 in lung cancer for AstraZeneca, Novartis, Eli Lilly, Incyte Corporation, BMS, Takeda, and Hutchinson MediPharma.

### **Prof. KIM SANG WE**

*Asan Medical Center – SOUTH KOREA*

Prof. Kim is Professor of Oncology at the Asan Medical Center (S. Korea). He is member of the Korean Association of Lung Cancer. He is the co-author of over 100 publications and he participated in over 100 clinical studies, including 71 in lung cancer, for AstraZeneca, Novartis, and MedImmune.



### 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 4<sup>th</sup> 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)

Cellegesic (hemorrhoids)  
 Depodur (post-operative pain)  
 Firazyr (hereditary angioedema)  
 Galafold (Fabry's disease)  
 GC Flu H5N1 Multi Injection (influenza)  
 Hismanal (allergic rhinitis)  
 Istodax (T-cell lymphomas)  
 Levact (chronic lymphocytic leukemia)  
 Lucentis (wet AMD)  
 Metvix PDT (skin cancer)

Nerlynx (HER2-positive breast cancer)  
 Northera (orthostatic hypertension)  
 Ocaliva (primary biliary cirrhosis)  
 Solaraze (actinic and solar keratosis)

### Tarceva (NSCLC and pancreatic cancer)

Vimpat (partial-onset seizures)  
 Xiaflex (Dupuytren's and Peyronie's contracture)  
 Xtandi (prostate cancer)  
 Zilretta (osteoarthritic knee pain)  
 Zurampic (gout)  
 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

#### Clinical

**Project Managers:** 13.3 years  
**SCRAs:** 10.2 years  
**CRAs:** 6 years

#### Data management

**Director:** 15.5 years  
**CDMs:** 10.8 years  
**CDAs:** 4 years

#### Biostatistics

**Biostatisticians:** 12 years  
**Programmers:** 9.7 years

#### Medical and safety

**Director:** 21 years  
**Medical Monitors:** 25 years  
**Safety Associates:** 3.6 years



