



CLINICAL TRIAL LANDSCAPE OF DIABETES (TYPE 2) IN ASIA-PACIFIC

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EPIDEMIOLOGY OVERVIEW

Background

The prevalence of metabolic diseases such as type 2 diabetes has increased significantly in recent years worldwide. Diabetes, which is endemic in most Western countries, is now seeing a surge in developing nations across Asia due to aging, urbanization, and changing dietary habits. It is estimated that about 80% of the people with diabetes now reside in developing countries, and mortality rates due to diabetes are higher in the Asia-Pacific compared to the rest of the world.

A review of the epidemiology of diabetes globally shows developed regions of Asia have a higher prevalence of the disease than in Europe and North America. More than 60% of people with diabetes live in Asia, with almost one-half in China and India combined. Hong Kong and Singapore have the highest prevalence of diabetes in the world, affecting 12% and 11% of their population respectively [1].

Disease Prevalence

Type 2 diabetes impacted approximately 470 million people worldwide in 2017, with the number expected to climb to 700 million (representing about 10% of the adult population) by 2045. Between 1990 and 2017, the global incidence of diabetes has doubled, with the ASIR (age-standardized incidence rate) increasing from 234 per 100,000 people in 1990 to 285 per 100,000 in 2017. The global prevalence of diabetes increased by +130%, from 211 million in 1990 to 476 million in 2017, with the ASPR (age-standardized prevalence rate) increasing from about 4,700 to around 6,000 [2]. In 2017, type 2 diabetes affected about 6%, 15% and 22% of people aged 15–49, 50–69, and over 70 respectively [3].

Diabetes alone is responsible for about 1 million deaths per year, making it the ninth leading cause of death worldwide. In low-income countries, there are alarming tendencies of increased prevalence as well due to evolving dietary habits [4].

In the IDF (International Diabetes Federation) South-East Asia (SEA) region, 88 million individuals (aged between 20 and 79 years) had diabetes in 2019. Of these, India alone accounted for nearly 90% of the cases. By 2045, this number is expected to rise to 153 million for the SEA region. Because of their vast populations, China (116 million), India (77 million), and the United States (31 million) continue to be the countries with the highest total number of people with diabetes [5]. Countries like Thailand and Malaysia also have significant diabetic population of 4.2 million and 3.6 million which is about 8% and 7% of the adult population respectively [6].

In South Korea, over 3.5 million patients were diagnosed with diabetes in 2019, about 9% of the adult population [7].

In New Zealand, close to 260,000 people had diabetes in 2019, which is about 8% of the adult population [8].

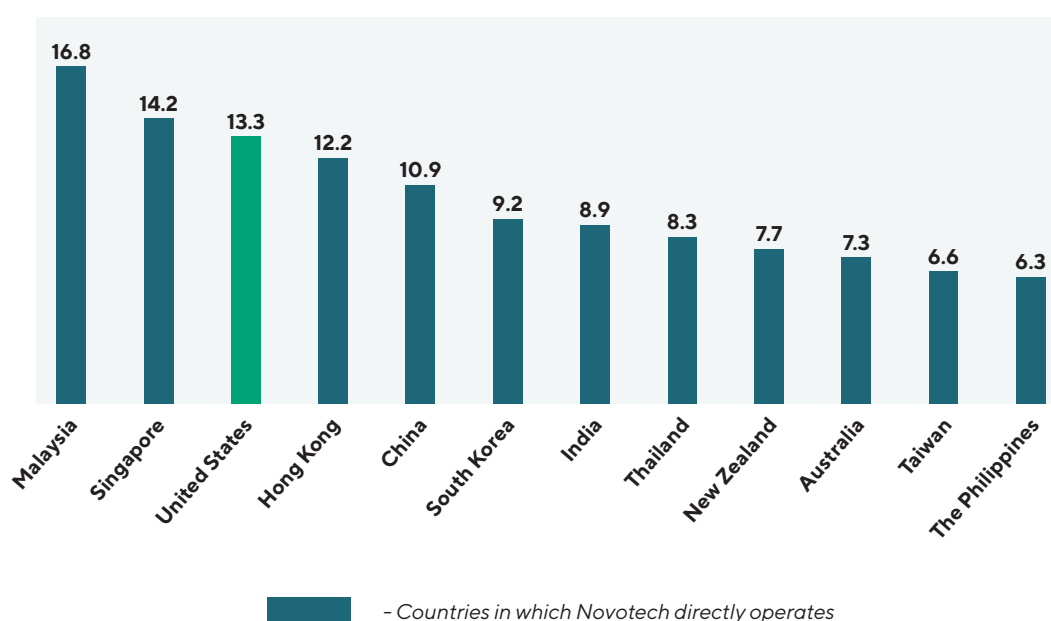
In Australia, over 1 million people had diabetes in 2019, which is about 7% of adult population [9].

In the Philippines, the prevalence of diabetes, was about 6% in adults in 2019 [10].

Table 1: Prevalence of diabetes in adults in a selection of locations, 2019 [11]

Locations	Total adult population	Total cases of diabetes in adults
China	1,065,411,600	116,446,900
India	859,956,100	77,005,600
US	233,505,400	30,987,900
Thailand	51,475,200	4,284,900
The Philippines	63,265,700	3,993,300
South Korea	40,123,300	3,689,400
Malaysia	21,711,800	3,652,600
Australia	17,740,200	1,288,300
Taiwan	18,523,400	1,228,800
Hong Kong	5,915,000	723,400
Singapore	4,512,200	640,400
New Zealand	3,362,100	259,800

Figure 1: Prevalence (%) of diabetes in population aged between 20-79, in a selection of locations, 2019 [11]



STANDARD OF CARE

The treatment of type 2 diabetes entails consumption of nutritious foods, exercise on a regular basis, weight loss, diabetes medication or insulin therapy, and regular monitoring of blood sugar levels. These methods aid the patient in maintaining a normal blood sugar level, which will help avoid or delay complications.

Standard medical treatments for type 2 diabetes include the following [12].

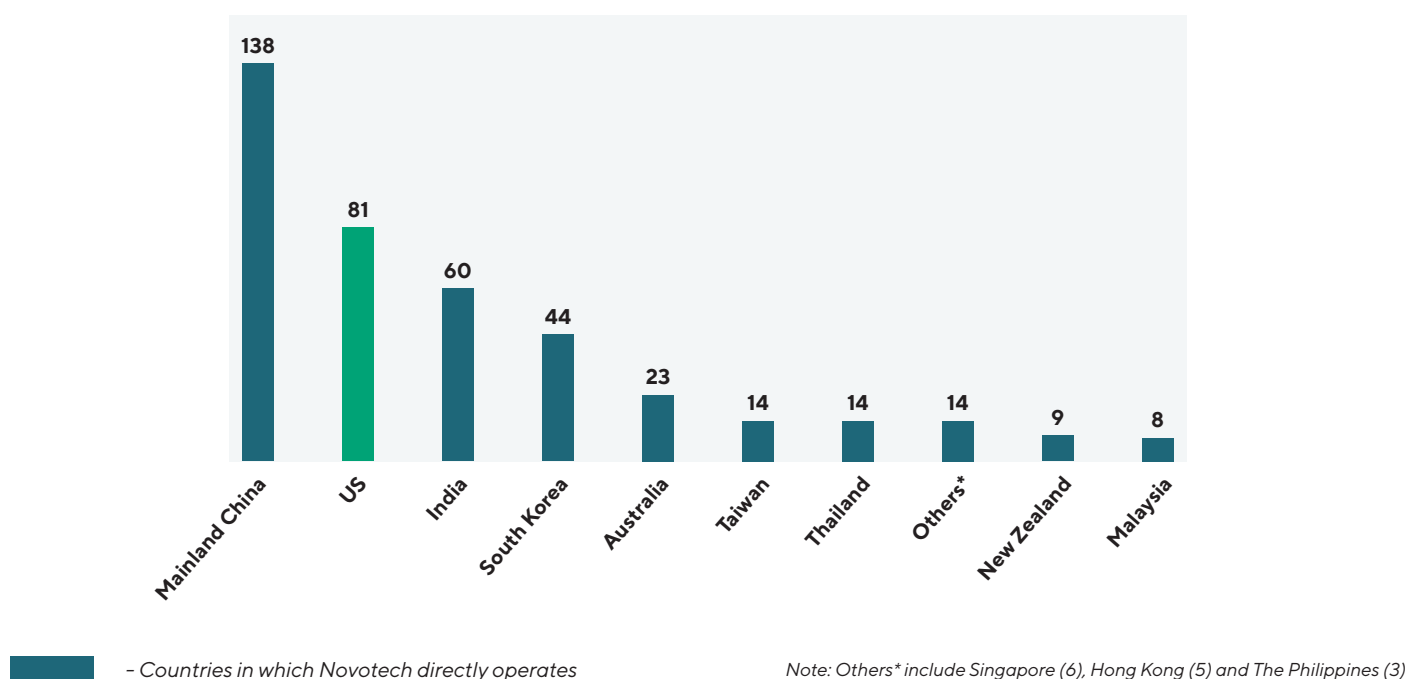
Drug/Therapy Type	Description
Metformin	This is usually the first medicine recommended. It works by reducing glucose synthesis in the liver and increasing insulin sensitivity, allowing the body to use insulin more effectively. Examples are Fortamet and Glumetza.
Sulfonylureas	These drugs aid in the production of more insulin in the body. Examples are Glyburide (DiaBeta, Glynase), glipizide (Glucotrol), and glimepiride (Amaryl).
Glinides	These drugs increase the amount of insulin secreted by the pancreas. They work faster than sulfonylureas and have a shorter duration of action in the body. Examples include repaglinide and nateglinide.
Thiazolidinediones	These medications increase the sensitivity of the body's tissues to insulin. Examples include rosiglitazone (Avandia) and pioglitazone (Actos).
DPP-4 inhibitors	These drugs aid in the reduction of blood sugar levels. However, their effect is minimal. Examples include sitagliptin (Januvia), saxagliptin (Onglyza) and linagliptin (Tradjenta).
GLP-1 receptor agonists	These are injectable drugs that aid in the reduction of blood sugar levels by slowing digestion. Examples include exenatide (Byetta, Bydureon), liraglutide (Saxenda, Victoza) and semaglutide (Rybelsus, Ozempic).
SGLT2 inhibitors	By preventing glucose from returning to the bloodstream, these drugs alter the blood-filtering processes of the kidneys. Glucose is excreted in the urine as a result. These medications may lower the risk of heart attack and stroke in those who are at high risk for both. Examples include canagliflozin (Invokana), dapagliflozin (Farxiga) and empagliflozin (Jardiance).
Insulin therapy	Insulin therapy is required for certain patients with type 2 diabetes. Once used as a therapy of last resort, insulin is now being administered sooner if blood sugar objectives aren't met with lifestyle changes and other medications.
Weight-loss surgery	Weight-loss surgery alters the shape and function of the digestive system, thereby aiding in weight loss and the management of type 2 diabetes and other obesity-related conditions.

With the rising prevalence of type 2 diabetes, particularly in developing countries, it is important to investigate how to manage it within the constraints of the available resources. While international standards are comprehensive and scientifically sound, they may not be applicable for regions such as Asia, Latin America, or Africa, where epidemiology, patient phenotypes, cultural norms, and socioeconomic position differ from those in the United States and Europe. Although glycaemic control and the reduction of micro- and macrovascular outcomes are still important parts of treatment, access and cost are major limiting factors; thus, in low-resource settings, a pragmatic approach is required. Newer medicines, such as sodium-glucose cotransporter 2 inhibitors and glucagon-like peptide 1 receptor agonists, are more expensive and have limited availability, even though they could be beneficial to individuals with insulin resistance and cardiovascular problems. As a result, more accessible second-line therapies with long-established efficacy and cost, such as sulfonylureas, in the management of type 2 diabetes are required. This is especially true in developing or resource-constrained nations [13].

CLINICAL TRIAL LANDSCAPE

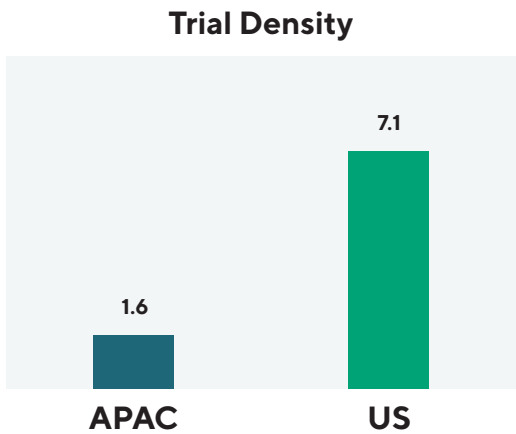
Biopharma companies have initiated over 500 clinical trials in Type 2 Diabetes since 2018, with the Asia Pacific region involved in a majority of the trials. Clinical trials in the Asia-Pacific predominantly involve Mainland China, India, South Korea, and Australia with fewer competing trials compared to the US. (Figure 2).

Figure 2: Top countries in the Asia-Pacific based on the number of studies in Type 2 Diabetes initiated by Biopharma companies since 2018 [14].



Due to its large population and lower volume of studies, the Asia-Pacific region has lower competing trial risk with a trial density about four times lower than the US (Figure 3).

Figure 3. Comparison of the trial density* for industry-sponsored Type 2 Diabetes clinical trials in the US and Asia-Pacific [14]



**Trial density is the number of recruiting sites for industry-initiated trials per million urban population*

Trials running in the Asia-Pacific region since 2018, show recruitment durations about 20% shorter than trials in the US (Figure 4). In addition, these trials in the Asia-Pacific region recruit, on average, three times faster than the US (7.2 and 2.5 patients per site per month respectively) (Figure 5).

Figure 4. Comparison of mean patient enrolment duration (in months) for Type 2 Diabetes clinical trials in the US and Asia-Pacific since 2018 [14]

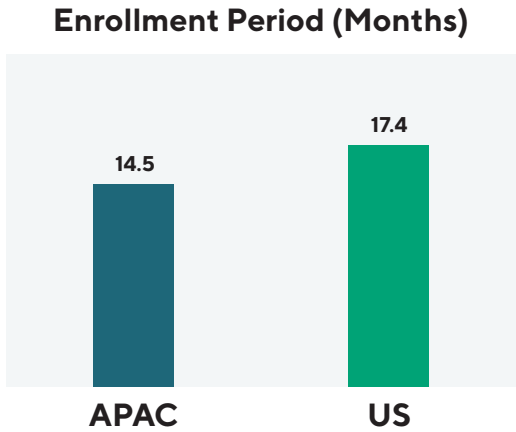
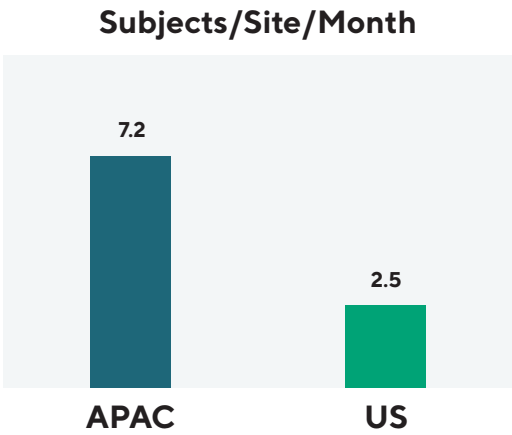


Figure 5. Comparison of mean patient recruitment rates (in subjects per site per month) for Type 2 Diabetes clinical trials in the US and Asia-Pacific since 2018 [14]



KEY OPINION LEADERS IN DIABETES MELLITUS

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Professor Gilfillan is Director at the Eastern Health Endocrinology & Diabetes centre at the Box Hill Hospital. Prof. Gilfillan is the co-author of over 10 publications, and he was involved in over 30 clinical studies including 25 trials in Obesity and Diabetes for Novo Nordisk, Verva, GeNeuro, Zafgen, AstraZeneca, Amgen, GSK, and Takeda.



Prof. PETER COLEMAN

Royal Melbourne Hospital (RMH) – AUSTRALIA

Professor Peter Colman is the head of the Royal Melbourne Hospital's Department of Diabetic and Endocrinology, where he is involved in diabetes clinical care. He is one of four ADDN (Australasian Diabetes Data Network) Principal Investigators and is involved in several clinical trials targeting type 1 diabetes prediction, prevention and novel treatments. He has been a TrialNet Investigator since the beginning, and he also oversees a Diabetes Clinical Research Unit at RMH, where he investigates innovative treatments for people with type 1 and type 2 diabetes.

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Professor Markovic is Director of the Department of Endocrinology at the Royal Prince Alfred Hospital in Sydney, and she is Professor at the Boden Institute of Obesity, Nutrition, Exercise and Eating Disorders at the University of Sydney. She is the co-author of over 25 publications including in Diabetes Care. She was involved in 4 clinical studies mostly in late phase trials in Obesity and Diabetes for AstraZeneca, Eli Lilly, Alkermes, and Zafgen.



Prof. RUSSELL SCOTT

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Professor Russell Scott is a physician at the Christchurch Hospital, New Zealand, where he is involved in the acute internal medicine service in his speciality areas of diabetes, endocrinology, metabolic diseases, and lipidology. His research interests are prevention and treatment of diabetes and lipid disorders in addition to clinical trials of new drugs in these therapeutic areas. He has been the Principal Investigator for more than 10 trials with sponsors such as Amgen Inc, Gilead Sciences Inc and Strongbridge Biopharma plc. Additionally, he has contributed to 12 book chapters and more than 200 articles till date.

Prof. KIM SOO KYUNG

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Professor Kyung is a Professor at the CHA Bundang Medical Center, and a member of the European Society of Endocrinology. He is the co-author of over 100 publications, including in *Diabetes Care* and was involved in 5 clinical studies in Obesity and Diabetes Mellitus for Novartis, Bayer, Karyopharm Therapeutics, and YiSheng Biopharma.



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Dr. Deshmukh is Head of the Department of Endocrinology, and Senior Diabetologist at Deenanath Mangeshkar Hospital and Deendayal Memorial Hospital in Pune, India. She is the co-author of 19 publications. She was involved in over 45 clinical studies including 4 late phase trials in Obesity and Diabetes for Biocon, MJ Biopharm, Novo Nordisk, Boehringer Ingelheim, and Eli Lilly.

Dr. WING SUN CHOW

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Dr. Sun Chow is a Professor at the University of Hong Kong and Secretary of the Hong Kong Society of Endocrinology. He is the co-author of over 30 publications, and he was involved in 7 clinical studies including 3 late phase trials in Obesity and Diabetes Mellitus for Bayer, MSD, and GSK.



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Professor Chow is Associate Professor at the Hong Kong Institute of Diabetes and Obesity. He currently serves as Consultant and Chief of Service of the Department of Medicine and Therapeutics at the Prince of Wales Hospital. He is the co-author of 40 publications including in *Diabetes Care* and was involved in over 30 clinical studies including 24 early and late phase trials in Obesity and Diabetes Mellitus for Novo Nordisk, Novartis, Merck, Ajinomoto, Kyorin Pharma, and Frosst Canada.



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