

# Diabetes Clinical Trials: India & the Gulf Region

As the prevalence of diabetes grows at an alarming rate worldwide, and especially within developing economies, all initiatives with the potential to impede this growth are being considered and implemented in the affected countries. While prevention, detection and management form the cornerstones of most national diabetes programmes, a large number of clinicians and affected patients are now looking at clinical trials as an opportunity to have early access to new treatment modalities for the effective management of their condition.

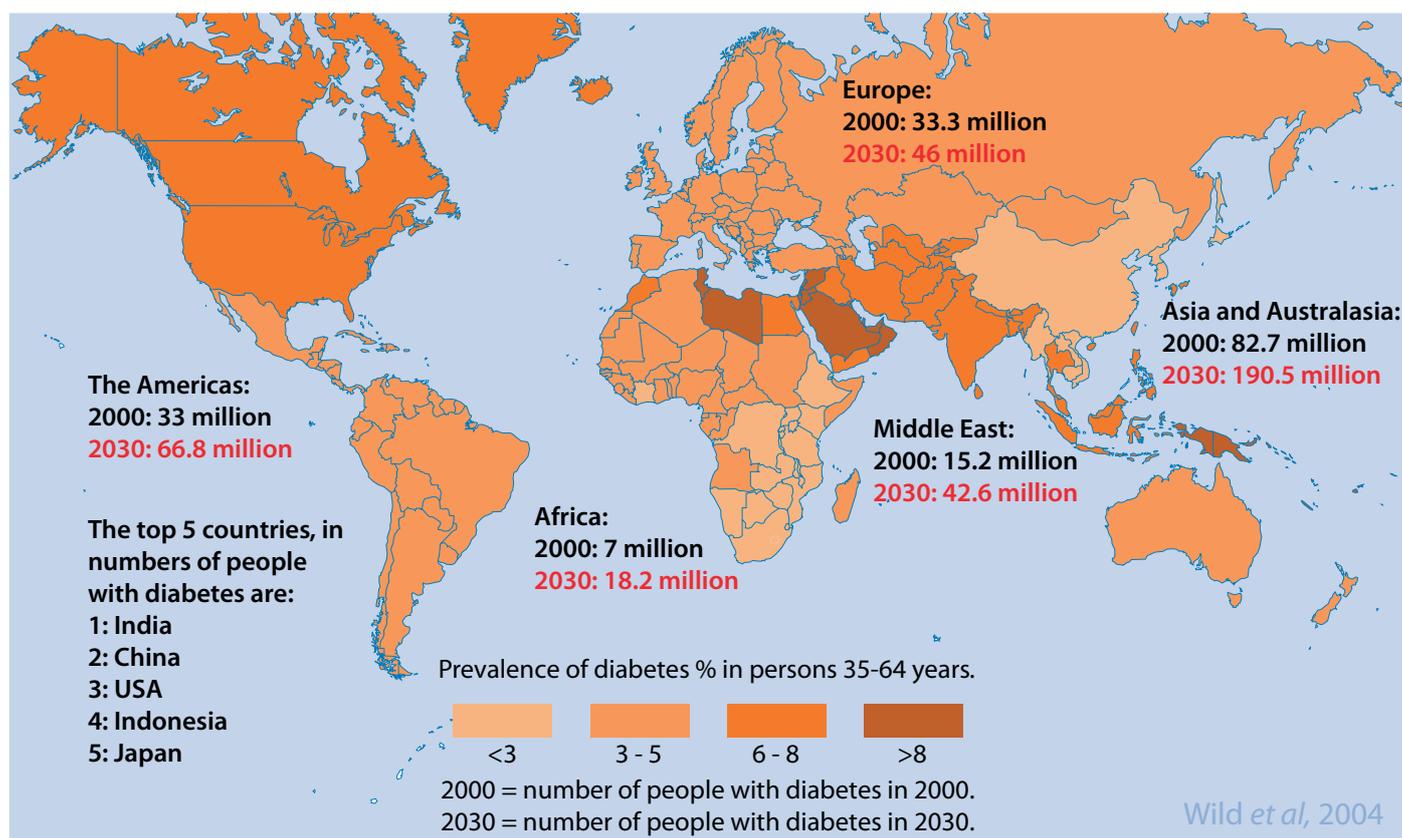
India and the Gulf countries are two regions of growing concern due to their significant morbidity. While India has for several years been listed as one of the countries having the highest number of diabetic patients, the prevalence of diabetes in the Gulf countries has been significant, with more than 8% of the adult population affected. These statistics have made both regions important as destinations for the conduct of clinical trials in diabetes patients.

## INDIA

India is currently reported to have the highest number of diabetic patients in the world, with the International Diabetes Federation (IDF) reporting 50.8 million people suffering from the disease.

Government and non-government agencies, as well as corporate, are actively involved in campaigns that are based on community health intervention as well as education. In late 2008, the United Kingdom, acknowledging the increasing disease burden in the country, sent a delegation of experts in the field of diabetes to share expertise and collaborate with Indian institutions and companies. The last decade has seen the medical community actively developing infrastructure, resources and competencies for the management of diabetes. This has resulted in the establishment of a large number of specialised diabetes hospitals & clinics, which have helped patients to receive better care in the management of their condition. The significant morbidity, favourable regulatory reforms, and growing capabilities have all led to the inclusion of India in the clinical development plan of global pharmas targeting diabetes patients. From a couple of trials being conducted in the late 1990s, there are 28 diabetes clinical trials currently reported to be recruiting in India as per the US NIH trial registry.

These trials have not only established India as the preferred location for diabetes trials due to the recruitment potential, providing regulatory compliant data, but have also provided the patients participating in these trials with treatment options that are currently



unavailable to them at their pharmacies. The type of clinical trials that are being conducted have also progressively grown more complex, targeting the complications associated with the disease and reflecting the local clinical capabilities and expertise.

## THE GULF

The recent data reported in the Diabetes Atlas of the International Diabetes Federation estimates that diabetes in the Gulf population aged 20-79 years is between 10.8% and 14.4% (with the exception of Iran, where the estimates are reported to be lower at 6.1%). The highest prevalence has been reported in Bahrain (14.4%) followed by Saudi Arabia (13.6%). This epidemiology data makes this region relevant to the evaluation of drugs & devices in clinical trials.

While the infrastructure and medical expertise are not the same across the Gulf countries, UAE and Saudi Arabia are emerging as countries frequently included in the diabetes programmes of clinical development teams. Clinical trial regulations are evolving in the region and currently most countries do not require regulatory approval for the conduct of clinical trials, therefore approvals are primarily obtained from central or institutional ethics committees, while Phase I trials are not permitted.

The Gulf region has been involved in over 30 diabetes clinical trials in the last three years. These have included observation and mainly intervention (drug and device) trials. This emerging region shows a robust potential for the effective conduct of clinical trials due to the expanding availability of expertise, access to the large patient pool, regulatory agencies that are keen to build capabilities, and the active efforts of the pharmas and local CROs such as ClinTec International

in training and developing resources to manage these clinical trials. This is reflected in the increased number of diabetes trials, from five in 2007 to 15 in 2009, as reported in the US NIH trial registry.

## THE FUTURE

Diabetes has reached epidemic proportions in India, and as a result of increased life expectancy and urbanisation the number of diabetes patients is estimated to double within 20 years in the Gulf region based on WHO & IDF forecasts. While this burdens the healthcare system and would have economic repercussions, the clinical trial data emerging from these markets should help fuel the development of better products in the prevention, detection and management of diabetes in the years to come. ■



**Dr. Rabinder Buttar**, a highly successful British entrepreneur and the President, founder and CEO of ClinTec International. Dr. Buttar has a PhD Degree in Immunology, which she gained in 1988 from the University of Strathclyde, Scotland. Dr. Buttar served for four years on the Board of the Institute of Clinical Research (ICR UK), a key organisation for the education and development of clinical research professionals. Dr. Buttar is now an Honorary Fellow of ICR UK and a Fellow of the Royal Society of Medicine. Recently included in Real Business' List of Britain's 100 Most Entrepreneurial Women, Dr. Buttar is the recipient of a number of prestigious business awards, including the Business and Commercial Excellence Award for Northern Britain at the Lloyds TSB Jewel Awards 2008.

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