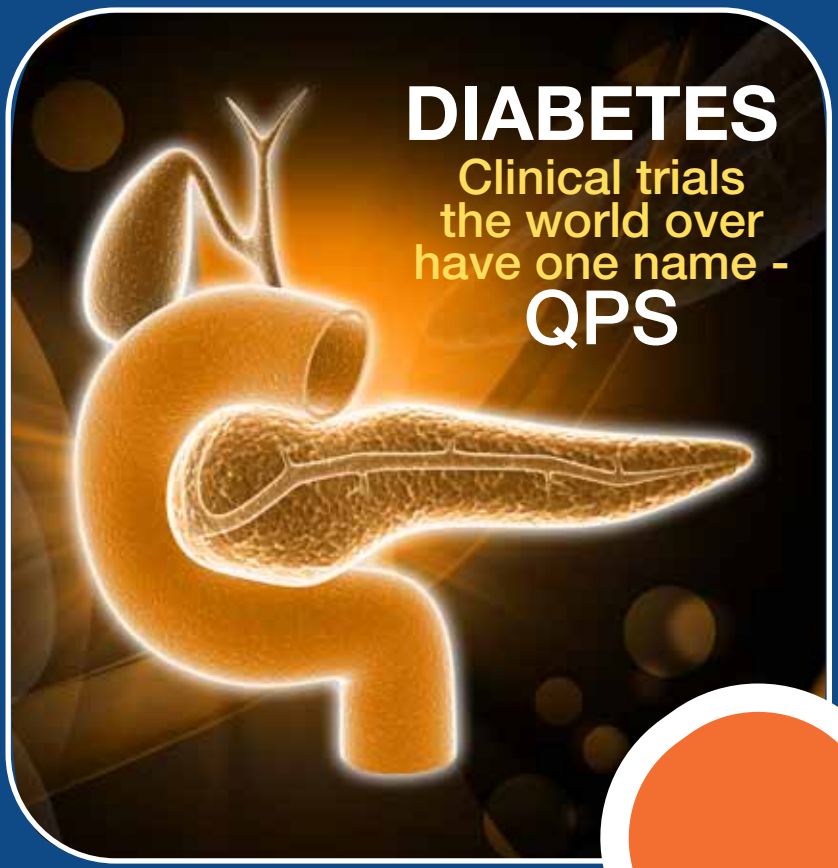


Patient recruitment

Co-morbidities

CV end points

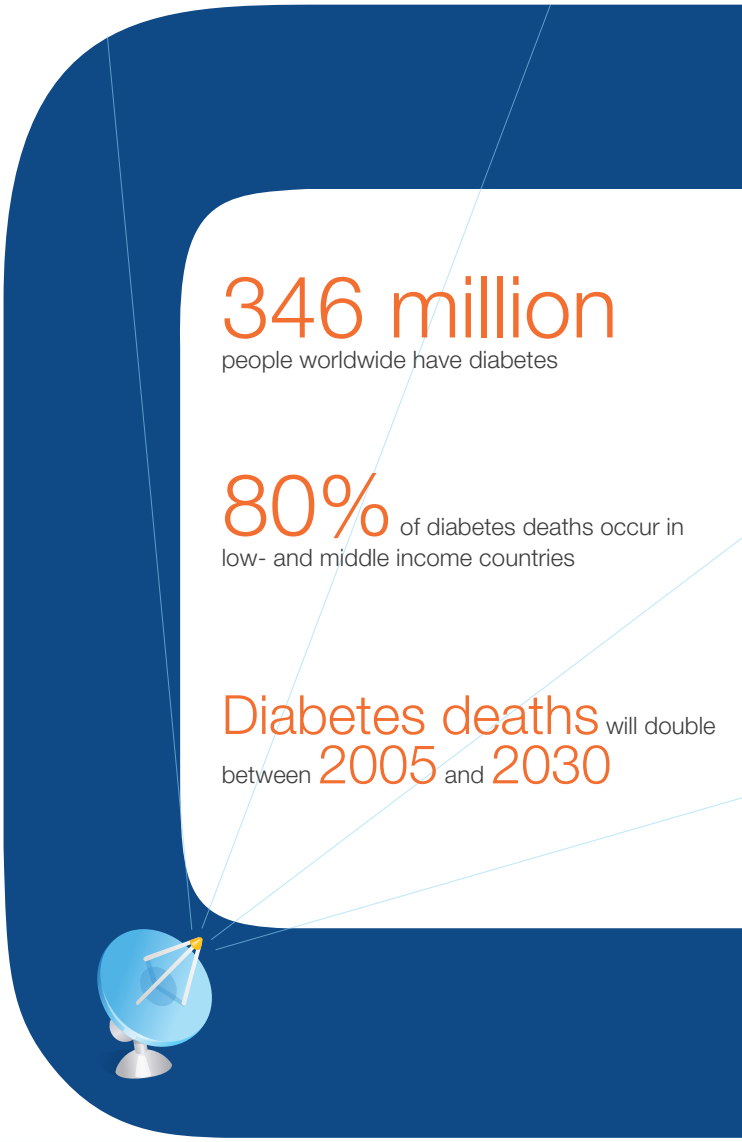
Protocols

QPS

helps you navigate

THE GLOBAL FOOTPRINT OF TYPE 2 DIABETES MELLITUS (T2DM)

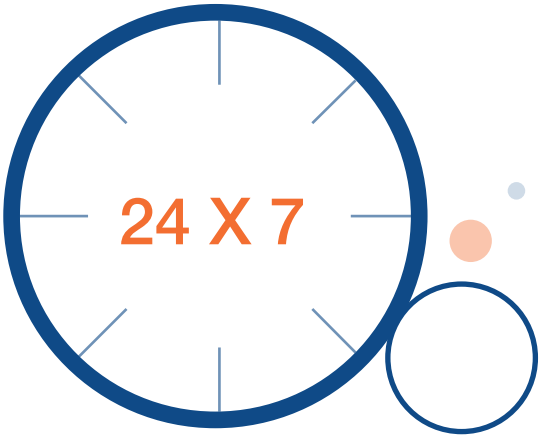
- According to the World Health Organization in 2001, 346 million people worldwide had T2DM.
- WHO projects that T2DM deaths will double between 2005 and 2030.
- More than 80% of T2DM deaths occur in low- and middle income countries.
- T2DM affects more than 20 million people in the U.S. and is the leading cause of kidney failure, blindness and non-traumatic amputations. It is also associated with a 2 to 4-fold increase in cardiovascular (CV) death.



CURRENT CHALLENGES

This chronic nature of T2DM necessitates multiple drug therapy over time and carries a number of co-morbid conditions such as obesity, renal disease, hypertension and heart disease. Furthermore, the rising prevalence of T2DM covers a widening age range.

The potential for some agents to increase the risk of cardiovascular events has led to substantial changes in regulatory requirements for new anti-diabetic therapies. For new T2DM clinical programs in the planning stage, the US FDA has recommended establishment of an independent CV endpoints committee for prospective adjudication of all Phase II and III trials. Events of interest should include CV death, MI, and stroke, and can also include hospitalization for acute coronary syndrome, urgent revascularization procedures, and other endpoints. Patient populations should comprise those at higher risk for a CV event (having suffered a longer duration of T2DM, elderly and/or exhibiting renal impairment). Studies are to be designed and conducted such that a meta-analysis (MA) can be performed, and a protocol describing the statistical methods to be used for the proposed MA should be submitted to the FDA. The future of T2DM drug development is therefore tied to large clinical programs engaged in the investigation of prospective CV outcome data. Future trials and programs that are currently underway, have prescribed CV outcomes, some with the objective of showing CV benefits, and will necessitate the gathering of more data in diverse T2DM populations to uncover more comparative efficacy and safety data.



WHY CHOOSE QPS?

Knowledge and Experience = Expertise

Our well-trained staff work together to produce high-quality studies. QPS has a strong history of supporting clinical research with new T2DM medications in Asia, Europe and the United States. We have the know-how to take your compound from the initial planning process to the collection of clinical evidence to registration. Our experience can reduce your time-to-market and minimize your costs. QPS will plan your clinical study from start to finish, putting the right team and protocol in place to make certain your trial runs smoothly.

SPEEDY PATIENT RECRUITMENT

Faster patient recruitment is one of the most important success factors for a clinical trial. QPS ensures a speedy patient recruitment through profound knowledge of efficient study conduct in multiple countries, innovative patient recruitment strategies, and close links with academia, SMOs, and specialist networks. QPS has a large worldwide database of investigators to ensure a high patient enrollment rate selected based on strict eligibility criteria. A specialized team of QPS works 24/7 to offer solutions that increase patient enrollment rates.

EXPERIENCED INVESTIGATORS

QPS knows the importance of working closely with our principal investigators to ensure that your studies are recruited on time and with qualified subjects. The strong relationships we forge with the investigators who conduct your clinical trials promote the performance of quality studies. We take pride in the fact that the skills of the most experienced investigators are applied to every clinical trial QPS conducts.

QPS FOR YOUR NEXT T2DM TRIAL

Whether you need clinical trials of small molecules, biologics, immunotherapies or other medications, QPS has the experience and resources to handle your trials and get your product to market.

Choose QPS for your next T2DM trial! Should you want to discuss your questions in more detail with one of our experts, please contact us directly at: info@qps.com

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1. http://www.who.int/mediacentre/factsheets/fs312/en/
2. Zannad F et al. Diabetes clinical trials: helped or hindered by the current shift in regulatory requirements? Eur Heart J. 2012 May;33(9):1049-57.

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