

Same Time. Another Season. Gateway to Africa.

South Africa is in the same time zone as Europe, but the seasons are reversed and patients are eager to participate in trials with experienced investigators.

Clinical trials in South Africa can be a blessing to patients as well as a boon to sponsors. First, they provide access to sophisticated care for a large portion of the population that generally receives only basic medical services and many who have not received previous treatment. At the same time, islands of excellence for clinical research have been in place for more than 15 years. Faster patient recruitment could mean earlier trial completion. And Quintiles strictly adheres to FDA and EMEA regulations, ICHGCP guidelines and local regulatory guidelines for all trials conducted in South Africa.

POPULATION AND DISEASE PREVALENCE

South Africa has a population of 47 million, which is increasing by nearly a half million people each year. There is a high prevalence of cardiovascular diseases, diabetes, hypertension, psychotic disorders, cancer, respiratory infections, tuberculosis, malaria and other infectious diseases. HIV/AIDS is increasing, and other sexually transmitted diseases are also on the rise.



LOCAL PRESENCE SINCE 1990

Quintiles provides fully integrated services for Phase I-IV studies, as well as local central laboratory services and a registered pharmacy for clinical trial supplies storage and distribution. Our South African data group delivers traditional and electronic data management services with world class quality and adherence to global standards, and is frequently selected to handle data management assignments for trials worldwide.

Our track record in South Africa is particularly important, since conducting trials here involves ►



some unusual challenges. For example, South Africa has eleven official languages. Knowledge of local culture and customs is essential. And Quintiles has developed innovative methods to facilitate patient enrollment follow-up and communication – largely through mobile phones – in remote rural areas.

All this has made Quintiles the leader in South Africa's growing pharmaceutical product development industry. We have performed more than **300** studies at **2,000** sites, involving almost **37,000** patients.

SEASONED INVESTIGATORS WHO ADHERE TO ICH-GCP, FDA, EMEA, AND LOCAL REGULATORY STANDARDS

Quintiles has ready access to more than 3,400 investigators in all therapeutic areas, and we routinely conduct studies for US drug registration. We have made a commitment to develop new investigator sites in South Africa in all therapeutic areas and have recently expanded this commitment into Africa, especially East Africa. Our study site coordinators facilitate investigator and site training in all aspects of clinical trials, and assist with patient identification and recruitment.

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OPERATIONAL ADVANTAGES

Investigator fees and infrastructure costs are low, and the number of patients per site is much higher than in US or European studies. This is especially true for emerging countries – the rest of Africa. This leads to efficiencies in both patient recruitment and site monitoring. In addition, rapid recruitment leads to overall shorter study timelines – and lower costs.

FIRST CHOICE INSTEAD OF LAST RESORT: THE SOUTH AFRICAN ADVANTAGE AT A GLANCE

- > Population: 47 million, increasing by about half a million a year
- > Disease prevalence: HIV/AIDS, other sexually transmitted diseases, cardiovascular diseases, diabetes, hypertension, psychological disorders, cancer, respiratory infections, tuberculosis and malaria
- > FDA, ICH-GCP and local regulatory quality standards followed in all Quintiles trials
- > Rapid recruitment through relationships with 1000+ investigators in all therapeutic areas
- > Operational efficiencies: Lower initial costs and major time savings
- > Proven track record dealing with local customs and remote areas
- > Gateway to Africa



QUINTILES®

The Development Group of
Quintiles Transnational