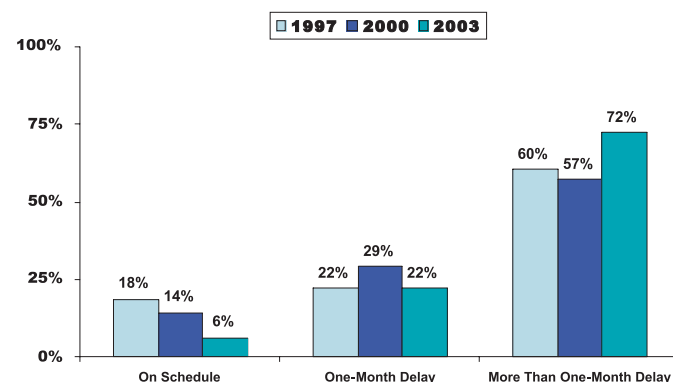


# Kendle International: Delivering Patient Access Solutions in Established and Emerging Regions

The ever-increasing demand for clinical study patients, coupled with the need for well-trained and motivated clinical research professionals, has caused some analysts to predict that up to 30 percent of all clinical trials and related activities worldwide will occur outside the United States and Western Europe by the end of the decade.

When you factor in the increasing need for biopharmaceutical companies to expedite their time to market, it's obvious why issues surrounding patient recruitment and retention are of paramount importance. With more than 90 percent of all trials in North America extending the enrollment period beyond the required project timeline and 72 percent of U.S. trials experiencing more than a one-month delay in completing enrollment (*CenterWatch*, March 2004), biopharmaceutical companies are looking increasingly to new geographies that provide access to untapped patient populations for the conduct of their clinical trials. As a result, clinical research is exploding in ascending regions such as Central Eastern Europe, Latin America and Asia — with the number of trials there accounting for 20-30 percent of all trials being conducted worldwide according to *CenterWatch*.

## Percentage of Trials Completing Enrollment



Source: CenterWatch surveys of 400+ U.S. investigative sites, July 2003.

*As one of the world's leading clinical research organizations (CROs), Kendle International Inc. has the global reach and local knowledge to deliver innovative and creative clinical development solutions while meeting the patient access needs of our customers in these emerging regions and other key geographies worldwide.*

## Global Patient Access Solutions for Your Clinical Trials

One of the strategies to address the need for new patient populations has been to “go where they aren't,” that is, focus patient recruitment in areas of the world that are trial naïve — that aren't currently engaged in large-scale clinical trial activity.

Ten years ago, the emerging market was Latin America. Five years ago, the virgin land was Central Eastern Europe. For the past few years, it's been India. When considering the various factors that lead clinical research organizations to conduct clinical trials in a new country or region, several are critical: adequate population bases from which to recruit, adherence to “Western” quality standards and motivated investigators and patients.

As shown in the following chart, India compares favorably on these factors with Latin America from the late 1990s and Central Eastern Europe from the turn of the century. The major advantage India offers is that more than twice as many people live there than the other two regions.



	Latin America	CEE	India
Population	490 million	400 million	1.0 billion
Adherence to GCP & ICH standards	Yes	Yes	Yes
Population Income	Low	Low	Low
Investigator & Patient Motivation	High	High	High

India also provides several other advantages for CROs. First, almost the entire population speaks English. Second, the IT infrastructure in India is, in a word, excellent. And third, there is a concentrated effort by the government to strengthen ICH-GCP compliance, thus improving the credibility of data.

India also provides access to patients with first world diseases, such as asthma, diabetes, hypertension, oncology, etc., as well as sub-tropical and third world diseases, including HIV, malaria and tuberculosis.

## Global Phase I-IV and Regulatory Consulting and Submission Capabilities

To succeed in Latin America, Central Eastern Europe, India or any other emerging region, a CRO needs not only to provide its clients a local presence and knowledge of the local regulatory environment, but also be able to deliver the entire spectrum of global clinical research services: from Phase I-Phase III clinical development to regulatory consulting and submission and all the way through late phase expertise (Phase IIIB/IV), thereby allowing marketing solutions to factor into decisions early in the drug development process.

Kendle International is structured to deliver this full spectrum of service offerings. We provide innovative and robust clinical development solutions — from first-in-man studies through market launch and surveillance — to help the world's biopharmaceutical companies maximize product life cycles and grow market share.

Our more than 1,700 associates worldwide are senior scientists and industry-experienced clinical development, regulatory and life cycle management professionals with a proven track record of success in delivering results for our customers, from project design through execution.

One of the ways we are responding to the patient access needs of our customers is by establishing offices in emerging geographic regions such as Latin America, Central Eastern Europe, China and now India. These areas provide our customers with access to new patient populations, thus lowering their overall recruitment costs and expediting the time it takes to complete a clinical trial. As the average life of a new drug's patent continues to decrease (from several years to several months), providing access to new patient populations has become a key priority for Kendle. This “global reach” that we provide our customers is also coupled with well-trained, in-country staff, allowing that “local knowledge” to manage the actual trials.

**Kendle**  
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