

Higher Quality. Lower Costs.  
Faster Results.

# India



## Fast-Track Your Trials with Our Local Expertise

As the first and largest full-service global CRO in India, Quintiles offers an unbeatable combination of local experience, quick patient access, high-quality results and low costs. India has a large, high-density population. Efficient access to broad patient populations with common and special disease profiles delivers rapid recruitment.

Our well-established site network and investigator relationships – built over a decade – aid in appropriate site / investigator selection and assure faster study start-ups. Plus, high patient compliance ensures low drop-out rates and better data quality.

India also offers less competition for recruiting patients (when compared to Western countries) and a similar level of professional skills. Of course, Quintiles' superiorly-trained investigators adhere to ICH-GCP guidelines and the highest ethical standards. Let Quintiles be your ally in unlocking the tremendous potential for your clinical development as you navigate *the New Health* landscape emerging in India.

*Are you ready to take advantage of the enormous potential of this growing market?*

*We're ready to be your ally.*

## Quality Data

- > Data capture and management complies with FDA and EMA (formerly known as EMEA) requirements
- > Over 95% of Quintiles India studies have supported submissions in the US and EU
- > Quintiles India adheres to Quintiles' high-quality, global standard operating procedures and conforms to ICH-GCP requirements

## Operational and Delivery Excellence

- > Quintiles is the first and largest full-service global CRO in India, offering fully integrated services for Phase II–IV studies
- > We have managed complex global programs over the last 12 years across all key therapeutic areas
- > Solid relationships with the leading medical centers and experienced English-speaking investigators
- > Client-focused Project Managers, with pharmacy and life sciences backgrounds; national coverage and low staff turnover
- > Skilled, proactive, multilingual CRAs, with wide therapeutic area expertise, maintain good site relationships through frequent interactions
- > Our world-class, full-service Data Management Center located in Bangalore is the largest Quintiles DM unit and provides centralized services for trials conducted in India and worldwide; also offer Biostats services
- > ECG core laboratories in Mumbai and Bangalore provide 24/7/365 digital ECG reading services to sites across the globe
- > Our wholly owned CAP-accredited Central Laboratory in Mumbai is a key component of the Quintiles global central lab network

## Assurance of Quality:

- > India's first ever US FDA site inspection was performed on a Quintiles-monitored study
- > Quintiles is the only CRO in India monitoring sites that have faced multiple US FDA inspections
- > US FDA has inspected 9 Quintiles-managed sites conducting 5 studies within Oncology, Psychiatry and Infectious Diseases
- > No 483s were ever issued to Quintiles during any inspection

## Key Facts

### Regional

- > Population of over 1.1B people, 340M in cities
- > Urbanization, higher disposable income and sedentary lifestyles are prompting increased incidence of Western-style diseases
- > Urban areas have a well-established healthcare infrastructure and Standard of Care comparable with developed countries
- > Over 675,000 English-speaking, computer literate physicians practice Western-style medicine
- > Wide usage of English; no need to translate study documents except patient-related documents such as ICFs, patient diaries, etc.
- > All sites work with ICH-GCP-compliant Ethics Committees
- > The Ethics Committee and Drug Controller General of India (DCGI) approval processes run in parallel

### Quintiles

- > Local presence since 1997
- > First and largest full-service global CRO in India
- > Extensive national coverage from offices located in four major cities – Ahmedabad, Bangalore, Mumbai and New Delhi
- > Highly trained team with global exposure and local knowledge

## State-of-the-Art Technology

- > Quintiles' industry-leading experience (more than 550 EDC studies globally) and availability of high-speed Internet across India provides the ability to conduct EDC studies successfully
- > 24/7 communications: Study updates and patient recruitment data uploaded to a secure Project Communication Internet Site so you can rapidly access information and make smart decisions

## The Resources to Deliver on Your Objectives

- > Highly trained staff – all adhering to globally consistent SOPs – ensure high-quality standards are met
- > Customer-centric, proactive study teams offer flexibility and ensure smooth conduct of your clinical trials
- > Single point of contact for customers facilitates rapid communication and early issue identification and resolution
- > Global and regional study management and project management offered from India
- > Stringent site selection ensures better output and quality of data

### Global Laboratory Expertise Locally: Mumbai

- > Leverage the largest wholly-owned and CAP-accredited central laboratory network to deliver clean, reliable and comparable data
- > Extensive scientific expertise to augment your internal capabilities and ensure quality from sample collection to data delivery
- > A large validated test menu with assay development capabilities to validate and test commercially available biomarkers and manage technical transfers
- > Offering laboratory services since 2006 and regional presence since 1997, our experience enables us to be your ally throughout the entire clinical trial process, working with you to make your clinical trial as easy and worry free as possible

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