# Clinical Drug Development in Emerging Markets



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## CHALLENGES AND OPPORTUNITIES

The involvement of emerging markets in clinical drug development has escalated in recent years. This has provided opportunities for drug development companies, such as increased access to patient populations for clinical trial activities and to the corresponding markets. If emerging countries are becoming involved more and earlier in the clinical trial programme, more clinical data will be gathered in these regions, and will thus facilitate better characterisation of drug handling in the local populations. This

should provide the regulatory agencies with greater assurance during the drug review and approval process.

This has been coupled, however, with infrastructure challenges. For example, there may be limited regulatory capability to manage the increased demand and to have the expertise to handle new and evolving processes of clinical trial applications and all the subsequent regulatory involvement in the drug development process. As drug development is new to many of these countries, investigator site capability may be limited, and the local culture may further inhibit the application of the protocol-defined processes for running a clinical trial to GCP standards.

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## WHAT ARE EMERGING MARKETS?

The precise definition of emerging markets may vary depending on your perspective, but the term can be broadly defined as nations in the process of rapid economic growth. In some cases, the growth rates of these countries has increased such that the standard of living has been raised for many in their populations, and thus created new markets for consumer products and services. In addition, many of these countries have large, lowcost and increasingly educated labour pools, to give these markets competitive advantage in many fields of production and information technology.

The number of countries described as emerging markets has grown over the years and of course will depend on how the term is defined. Approximately 10 years ago, the term "BRIC" was used to represent Brazil, Russia, India and China. However, other countries are now considered as emerging and may include, for example, other South American countries such as Chile and Peru. Asian countries such as Korea and Taiwan, as well as some Eastern European, Middle Eastern and other countries.

#### IN THIS SPECIAL SECTION

The articles covering this special topic will review some aspects of the practicalities of clinical drug development. As this special topic is extensive, it will

be reviewed over two editions of the Global Forum. The Asia Pacific region will be a focus in Part 1. Specifically, there will be a review of fora for collaboration of regulatory agencies and other bodies such as the World Health Organisation (WHO) to address issues emerging in the global drug development environment. We also hear about the innovative approach of co-locating regulatory agencies and science parks. In addition, there are overviews of practical experiences in the regulatory review process and the establishment of investigator sites. •

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