

Executive Summary

Conducting clinical trials in Europe is not a new concept for global pharmaceutical companies, but in which country to hold their individual and particular trial can sometimes be the subject of much deliberation. Where do the authorities welcome Phase I studies? Where is patient recruitment particularly straightforward and yet provides high-quality data? Which country has fast approval timelines at the local and country levels? Where are investigators particularly eager to become involved in clinical trials? Where is healthcare wanting and are patients readily available to participate in trials? These and other questions are part of any deliberation when choosing a particular country or countries within Europe to hold a trial.

Europe holds a unique position: it has the advantage of offering not only well-established clinical trial markets in countries that have a long history of conducting clinical trials but also many promising emerging markets that are new to the clinical trial arena. Further, Europe offers markets that have yet to introduce the concept of clinical trials into their legislative and health care structures. Within this spectrum, a majority of European countries fall under the European Union umbrella and adhere, with some variation, to its guidelines and legislation concerning the conduct of clinical trials.

European Clinical Trial Site Options: An Insider's Analysis answers many of the questions companies may have about holding their clinical trials in any country in Europe. In addition, the legislation processes in the European Area are discussed, along with comparisons to the United States. Russia with some CIS members, although geographically only partially within the definition of Europe adopted for this report, have been included. A standardized template is used throughout the report to describe the advantages, opportunities, background, regulatory framework, fees, challenges and other important information associated with conducting clinical trial studies in all 44 countries covered in this

report. The information provided has been assembled from discussions with clinical trial professionals based in many of these countries and thus provides a value-added “insider’s” perspective on the actual situation with each country.

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