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Israel has increasingly become an important centre for conducting multinational clinical trials, with major pharmaceutical companies sponsoring trials in the country's many academic and medical facilities. With high-quality medical professionals and leading academics, in addition to a diverse population base and a modernized regulatory environment, Israel is an attractive venue for conducting clinical research.

Companies that wish to sponsor a clinical trial in Israel must be mindful of a number of international and domestic legal and regulatory requirements. The planning, approval, conduct, recording and reporting of a clinical trial in Israel must be done in compliance with: (1) the principles articulated in the Helsinki Declaration of the World Medical Association, (2) the Israeli Public Health Regulations (Clinical Trials in Human Subjects), 1980 passed pursuant to the Israeli Public Health Ordinance, 1940, including all subsequent additions and amendments thereto, (3) the Israeli Ministry of Health Guidelines entitled Clinical Trials and Human Subjects, implemented pursuant to the foregoing Regulations, (4) the Genetic Information Law, 2000, (5) the provisions of the current Harmonized Tripartite Guidelines for Good Clinical Practice (ICH-GCP E6), and (6) other regulations and guidelines published periodically by the Ministry of Health.

In particular, the Clinical Trials and Human Subjects Guidelines of the Israeli Ministry of Health provide detailed directives concerning the method of submission, approval and inspection of clinical trials and clinical research in human subjects, and define the requirements for conducting and supervising them. In addition, the Guidelines set out, among other provisions, the requirements for labelling, storing and supplying investigational products, reporting obligations should adverse events occur during a clinical trial, insurance obligations and the sponsor's obligation to continue to provide investigational products after the clinical trial is completed in certain cases.

Compliance with these requirements is intended to protect the rights, safety and well being of the participants in the trial, and ensure that the information obtained from the study is reliable.

In light of the regulatory environment, any entity considering sponsoring a clinical trial in Israel, whether with an academic institution or a hospital, is well advised to consult with local counsel before starting the trial.

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