The EORTC New Drug Development Office (NDDO)

C.K. van Kalken, director

The general co-ordination and local organization of the series of NCI-EORTC Symposia on New Drugs in Cancer Therapy is one of the responsibilities of the EORTC New Drug Development Office (NDDO). The NDDO is the scientific office of a unique European network which has been established to take a leading role in the preclinical and (early) clinical development of new anticancer drugs.

Drug Development

The field of anticancer drug development is facing some unprecedented alterations, changing the research landscape entirely. Increasing pressure on governmental and charity budgets forces academic institutions and other research driven organizations to redefine their priorities. At the same time, price cuts and a series of mergers have reduced R&D budgets in the pharmaceutical industry. This has resulted in more carefully designed drug development programs and strategic alliances with specialized research organizations and institutions.

Simultaneously, due to recent advances in basic research and new methods for drug discovery, the number and variety of innovative anticancer drugs is higher than ever. The prospect of achieving significant improvement in treatment is therefore more promising than the decades of conventional chemotherapy behind us.

European Gateway

During the last decade, many parties have discovered the NDDO as their gateway to European drug development. At present, 35 compounds, including cytotoxic compounds, vaccines, signal transduction inhibitors, anti-sense oligonucleotides and others are in different stages of late pre-clinical and early clinical development through the NDDO.

The NDDO is responsible for data management and monitoring of early clinical trials carried out within the Early Clinical Studies Group (ECSG) and the Biological Therapeutics Development Group (BTDG) of the EORTC. The ECSG is an established network of 50 oncology centers from all over Europe and Israel. The ECSG is known for its high quality of clinical trials and has built an impressive track record.

The BTDG, which was established only in 1994, focuses on the organization of preclinical and clinical research on anticancer therapy with biologically active agents.

Future Aims

It is the goal of the NDDO to minimize the development time of a new drug while meeting the highest regulatory and scientific standards. Through the EORTC network and the commitment of the NDDO, the logistics for optimal development of new anticancer agents are clearly present in Europe.

Collaboration

Over the past years the NDDO has been implementing and disseminating its basic philosophy, that fast-track, high-quality development of more specific new anticancer agents is not only in the interest of cancer patients but also in the interest of those who are professionally involved with the problem of cancer. This concept is enjoying an increasing awareness and interest.

In 1986, an agreement was signed between the US National Cancer Institute (NCI), the Cancer Research Campaign (CRC) in the United Kingdom and the EORTC to establish an intercontinental network for drug development. This agreement was updated in 1995 and due to acceptance of the Standard Operating Procedures (SOP's) of the NDDO by the FDA, global regulatory affairs related to the preclinical and clinical data of the EORTC are greatly facilitated.

The NDDO provides companies and organizations with an attractive infrastructure for drug development. Through the NDDO in vitro and in vivo experimental studies, formulation and toxicology studies, as well as extensively monitored phase I and early phase II clinical studies, can be conducted in a highly efficient and transparent development program.
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