Information about clinical study programs

What is a clinical study?

Clinical studies are conducted to provide evidence for scientific theories and improve the medical treatment of patients. A clinical study is an examination of new medication or treatment methods with test persons or patients in the course of a drug approval to test the safety and efficacy of a product.

Under what circumstances could I consider participating in a clinical study?

Clearly structured treatment guidelines exist for most diseases in which scientifically validated knowledge is applied for the optimal treatment of patients. This is also the case for treatment of cancer.
The guidelines contain treatment methods which optimally suit most treatment situations and they are therefore primarily considered when making a treatment decision.
In certain situations or advanced disease stages, where regularly available treatment options are not feasible or no longer effective, participation in a clinical trial can be taken into consideration.
The most important contact person for a patient is always his or her treating physician who is best able to assess the patient and his or her disease.

How can I participate in a clinical study and where can I get information about ongoing clinical trials?

If you or a member of your family is interested in participating in a clinical study, please talk to your treating physician about your intentions and ask for advice. Your treating physician will be able to answer your questions and to refer you to a clinical study center.

Who is competent to decide whether a study participation is feasible or not?

Only the investigating physician at a clinical study center (mostly specialized departments in university medical hospitals) where clinical studies are conducted is competent to decide which patients fulfill the necessary requirements to participate in a clinical study.

What are "Clinical study centers"?

The location where clinical studies are conducted is called a clinical study center. These are mostly universities. Only the investigating physicians in theses study centers have the scientific competence to decide which patients qualify for a study participation. The decision is taken according to the rules in the relevant study protocols and according to the individual characteristics of the patient´s disease and the criteria which apply to in- or exclude participants from a specific study.

What does a clinical study protocol define?

The study protocol defines the conditions under which a patient is accepted for participation in a study. Further, it describes in detail the process of a clinical study. Criteria about the different requirements for a patient such as the disease stage, co-medication and coexisting diseases are determined in these protocols. Only patients who exactly fulfill the requirements of the study protocol are allowed to participate in the respective clinical trial.

How can I contact clinical study centers?

At http://clinicaltrials.gov you have the ability to "Search for Studies" using for example an indication or a company name. The website provides a list of all clinical studies that correspond with your search criteria.
The clinical study centers, that conduct studies in many different indications, are listed under „see Contacts and Locations" for the respective study.

Which clinical studies is BioNTech currently conducting?

BioNTech is currently conducting phase I clinical trials in malignant melanoma. A clinical study in the indication breast cancer (Triple Negative Breast Cancer (TNBC) – a very particular form of breast cancer) is planned.

What does "Phase I" mean?

In a phase I clinical trial we test tolerability and safety of a product. Phase I is an early stage phase and does not provide information or evidence about the efficacy of the product which is under development. To test the efficacy further clinical studies are required (Phase II- and Phase III-studies).

Who can I contact if I am interested in participating in a clinical study?

If you are interested in participating in a clinical study, please directly contact the clinical study centers that are listed under the respective study at http://clinicaltrials.gov. BioNTech is not allowed to choose study participants as this falls under the exclusive competence of the physicians at the respective clinical study centers.

Is BioNTech planning studies in other cancer types/indications?

As BioNTech´s programs are at a very early stage of development we are currently unable to provide information regarding the extension of clinical studies to other (cancer) indications.

How long will it take until BioNTech brings its first cancer treatment to market?

The clinical development of a cancer treatment requires different development stages in which the safety and efficacy of new medical products are tested. It takes several years from the start of the first clinical trial until the product is approved and can be launched on the market. We are currently unable to provide concrete timings for when our products will be available on the market.

We would kindly like to ask for your understanding that BioNTech staff are not allowed to provide information about a potential study participation or to give any form of advice.

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