BIO PRO Baden-Württemberg GmbH

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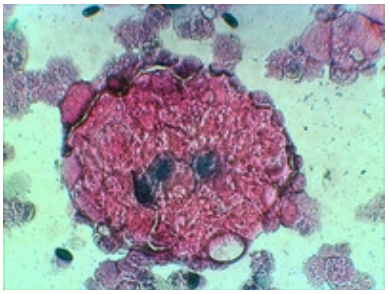
TherapySelect – identifying susceptibility to cancer therapy

TherapySelect Dr. Frank Kischkel is a small innovative biotechnology company based in Heidelberg, Germany, with a special focus on the development, validation and application of diagnostic tests for cancer patients. The company's proprietary CTR-Test® uses patients' cancer cells to determine the tumour's susceptibility to treatment with cytostatic drugs. This knowledge helps identify ineffective drugs prior to treatment as well as reduce adverse drug effects and costs.

Cancer is a very personal disease. Due to progress in genotyping and automated sequencing methods that have increased the speed and reduced the cost of genomic analyses, it has become clear that cancer cells harbour many genetic changes, and that these changes differ in patients who appear to have the same type of tumour. In the same way as every human individual has a specific fingerprint, i.e. genetic profile, so do tumours. On average, any given prescription drug works for half of those who take it. So how can a physician tell whether a patient belongs to one group or the other?

The chemotherapy resistance assay (CTR-Test®)



A three-dimensional tumour cell complex (spheroid) used for the CTR-Test®. (© TherapySelect)

Dr. Frank Kischkel has established TherapySelect in order to change this situation and increase the chances of a successful treatment outcome in cancer patients. TherapySelect has developed a chemotherapy resistance assay (CTR-Test®) which, as the company name suggests, enables a drug that has a high probability of treatment success to be selected.

The CTR-Test® is an in vitro test that uses living cancer cell samples from a patient and is carried out before the patient undergoes chemotherapy. The test identifies which drugs will be effective in treating the patient's tumour. Ineffective drugs can be excluded right from the start and the patient can be spared a therapy that is both ineffective as well as associated with potential severe adverse drug effects.

The exclusion of ineffective drugs helps reduce costs for the healthcare system. But most of all, the information provided by the test helps physicians to select drugs with a promising therapeutic outcome: The treating doctor is able to tailor a treatment regime to a person's unique cancer profile. Leading oncologists believe that the fight against cancer can only be won using diagnostic systems like the CTR-Test®, which determine a person's susceptibility to drugs and hence increase the chances of cure.

The efficiency of TherapySelect's CTR-Test® was validated with 32 drugs commonly used for the treatment of cancer, but its efficiency in identifying effective drugs will also soon be validated with targeted drugs.

CTR-Test® Chemotherapie-Resistenz-Test

CTR-Test®. (© TherapySelect)

The test has been validated with tamoxifen, a drug that is only effective in estrogen receptor-positive breast cancer patients. Numerous clinical studies showed that the test had a predictive power of 95% in terms of identifying a patient's resistance to tamoxifen treatment. The test requires around one gramme of vital tumour tissue or at least 250 ml of a malignant effusion. The result of the chemoresistance assay is available around six to nine days after delivery of the sample to

the company.

TherapySelect not only carries out its comprehensively validated CTR-Test®, but also distributes it to physicians and hospitals around the world. The company is currently undertaking a clinical predictor study funded by the German Ministry of Education and Research and aimed at assessing the effectiveness of new cytotoxic drugs for the treatment of patients with ovarian cancer. Recruitment of the patients was completed in January and initial results are expected by the end of 2014.

At present, the costs of the CTR-Test® are not reimbursed by German statutory health insurance. In order for drugs to be reimbursed, clinical studies need to be carried out in order to prove that the CTR®-Test is able to prolong patients' lives. This is a controversial issue, both in terms of science, medicine and politics and affects diagnostics producers in the field of regenerative medicine in general. TherapySelect is unable to finance such a study on its own and is interested in working with pharmaceutical companies. Its CTR-Test® is available worldwide as a diagnostic platform for the development of new products and for all phases of clinical development.

OncompassTM, a therapeutic information service based on molecular diagnostics

Dr. Frank Kischkel, managing director of TherapySelect, Heidelberg. (© TherapySelect)

In addition to the CTR-Test®, TherapySelect also markets Oncompass™, a genetic profiling service offered by the Hungarian molecular diagnostics company KPS. The service helps to find the most effective personalised anti-cancer therapy by profiling 58 oncogenes and determining their amplification in a patient's cancer cells using next generation sequencing methods. The services also include pharmacological information on more than 200 targeted anti-cancer drugs that are in clinical use or being tested in clinical trials and which are linked to these genes as well as information on which of the 200 drugs are likely to be effective or ineffective for a particular patient's tumour.

The Oncompass™ service has the big advantage that formalin-fixed and paraffin-embedded tumour tissue samples used for pathological investigations can be used. No additional tumour sample has to be prepared. Budapest KPS Kft has established a 100% subsidiary, KPS Diagnostics GmbH, in Heidelberg. It is managed by Dr. Frank Kischkel and its office is in the TherapySelect headquarters in Heidelberg. Kischkel also provides patient advice on the application and outcome of the company's diagnostic tests. As part of the Oncompass™ service, Kischkel also provides information about the effectiveness of new drugs that are still in clinical development, but which may be alternative therapy options for patients who are unresponsive to existing cancer drugs. Patients who opt for such an alternative are given information on participation in one of the ongoing clinical studies.

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A contribution from:

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More Information

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