Increased Success of Drug Development by Using the Chemotherapy Resistance Assay (CTR-Test®) in Clinical Trials to Identify the Susceptible Patient Population

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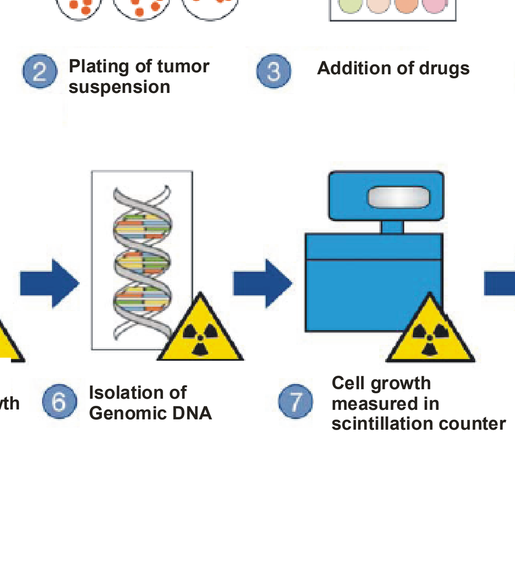
Summary:

. Unsuccessful clinical trials are the most expensive and latest obstacle in drug development.
. The success of clinical trials can be significantly increased by using diagnostics to identify the patient susceptible for the drug.
. The CTR-Test® is a Personalized Cancer Cytometrics technology.
. With this assay all drugs, which act directly onto the target cells, can be tested and assessed.
. The technology was developed for validating the activity of chemotherapeutic drugs onto tumor cells.
. The cells are received from cancer patients in a viable and fresh status and are directly analyzed. The test results are available after 6-9 days after setting up the assay.
. 19 clinical trials exist, which show the performance of the technology.
. The CTR-Test® is offered exclusively by TherapySelect.
. Clinical Trials can be supported worldwide.

Overview of CTR-Test®:

. CTR-Test® is a diagnostic tool for identifying ineffective drugs for a particular patient before therapy.
. Resistance against a drug can be identified with high probability (95%).
. CTR-Test® can be used for all solid tumor entities (e.g. Ovarian CA, Mamma CA, Lung CA, Colon CA).
. Alive tumor cells are needed. Solid tumor samples can be gained by surgery. Malignant liquids (e.g. ascites or pleural effusions) can be used alternatively.
. The technology is validated by numerous publications. This includes 18 clinical trials with more than 2.100 patients and 10 addtional studies with tumor samples of more than 19.700 patients.
. CTR-Test® is currently used in Germany for all solid tumor entites in particular
- when no standard guidelines exist,
- when different equal therapy options exist,
- when primary tumor is unknown or
- when patient|s condition does not enable standard therapy.

Logistic chain of CTR-Test®:

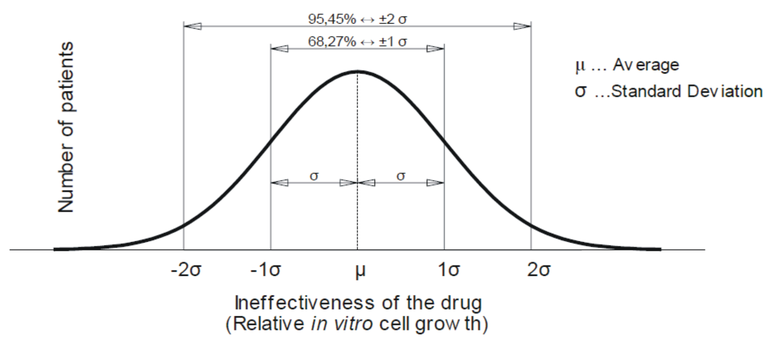


Principle of CTR-Test®:

How to interpret the results of CTR-Test®?

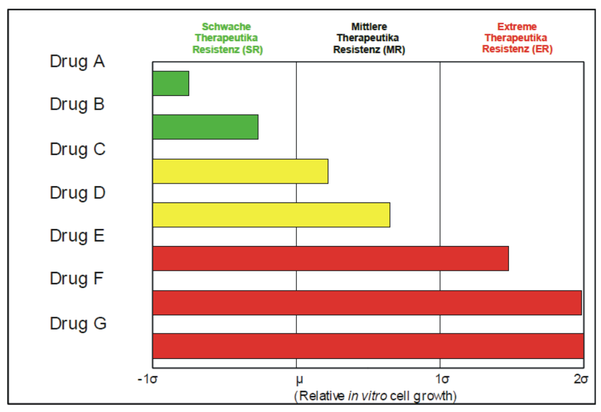
The Chemotherapy Resistance Assay (CTR-Test®) identifies for every patient individually ineffective drugs with high accuracy already before the beginning of a therapy . The therefore required living cells are treated in our laboratory with the drugs chosen by the respective physician. Every single drug has been tested with a statistically significant number of patients which allows to identify a curve of distribution in order to demonstrate the ineffectiveness of the respective drug:

Standard distribution of a drug effect



The test result mirrors the ineffectiveness of each drug as shown in a bar diagram. For the classification of the ineffectiveness distinction is made between the following three categories:

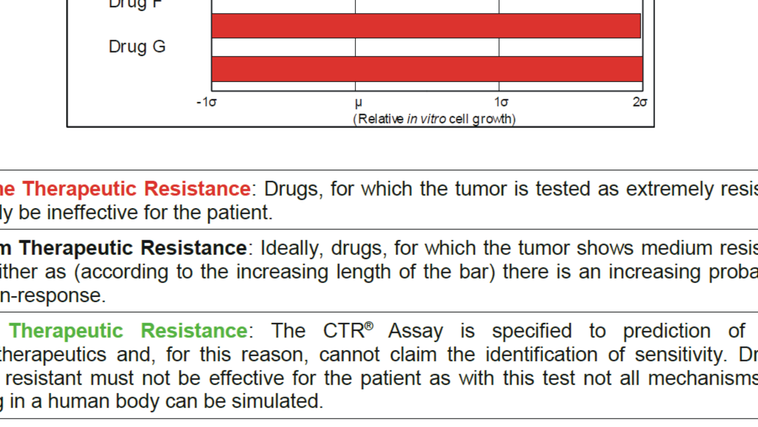
Test result



ER	**Extreme Therapeutic Resistance**: Drugs, for which the tumor is tested as extremely resistant, will most probably be ineffective for the patient.
MR	**Medium Therapeutic Resistance**: Ideally, drugs, for which the tumor shows medium resistance, are not used either as (according to the increasing length of the bar) there is an increasing probability for an *in vivo* non-response.
SR	**Slight Therapeutic Resistance**: The CTR® Assay is specified to prediction of resistance of chemotherapeutics and, for this reason, cannot claim the identification of sensitivity. Drugs tested as slightly resistant must not be effective for the patient as with this test not all mechanisms of resistance existing in a human body can be simulated.

Business opportunity with CTR-Test®:

Identification of susceptible patient population (example)



Holloway et al. (2002) Gynecologic Oncology 87(1):8-16

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