

Clinical Study Bladder Cancer

Background

The health care industry lacks methods to select the optimal treatment for individual cancer patients. 12 million new cancer cases are diagnosed every year, and the majority of these need medical treatment. 8 million of these patients will eventually die from their disease. Part of the reason why current treatments fail to provide long-term survival is that only a minority of the patients respond to the given treatment (Figure 1). Patients that respond robustly to first line treatment, on the other hand, have excellent 5-year survival. Furthermore, with more than 200

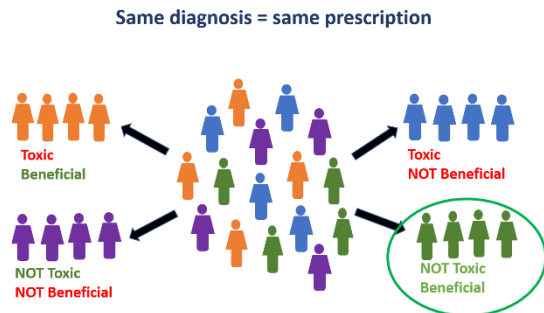


Figure 1. Patients exhibit unexplained heterogeneous responses to cancer treatments with only a minor part that get right treatment immediately

different cancer drugs on the market, and a multitude of other treatment options (i.e. surgery, radiation therapy, etc), patients that do would not respond to current 1st line treatment may likely benefit from an alternative drug or procedure. There are, however, no methods that can predict individual response to many different types of medical treatment, and therefore no means of identifying and prioritizing non-responding patients to alternative, and often expensive, medical treatments (and if so, which one) or immediate surgery if this is an option in the specific tumor type.

BioReperia ZTX[®] platform

The ZTX[®] platform directly measure the tumor-killing capabilities of anti-cancer drugs on patient tumors in a similar microenvironment as in the patient.

BioReperia provides an analysis on how efficient different cancer treatments are in inhibiting tumor growth and metastatic ability on the patient's own cells in vivo. The analysis is based on our proprietary Zebrafish Tumor Xenograft (ZTX[®]) platform. We create a solid microtumor with metastases from a patient's own tumor cells in a zebrafish embryo. By treating the embryos with the drugs that are available for the specific diagnosis, we can provide precision medicine data. We can thereby provide the oncologist with in vivo data on how each specific patient will respond to the different treatment options on the market. The platform has more than 90% accuracy when predicting responses and cuts time for a cancer treatment cycle from 3-6 months to 5 days.

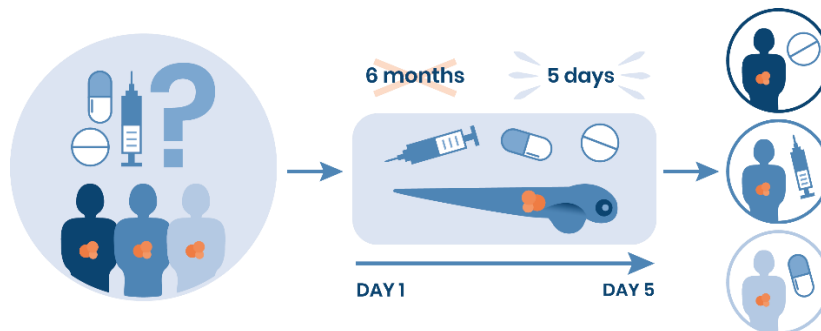


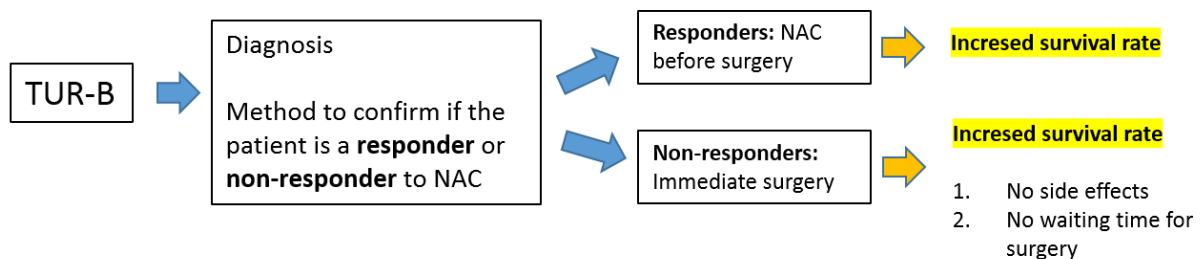
Figure 2. The ZTX[®]-platform cuts time from in the process of finding the right treatment to the right cancer patient from 6 months to 5 days.

Clinical Study Bladder Cancer

Ongoing clinical study Bladder cancer

The current treatment plan for patients with muscle invasive bladder cancer starts with performing TUR-B on all patients. Neoadjuvant treatment with Cisplatin-containing combination treatments (GC or MVAC) is then started and continued for 3-4 months followed by a total cystectomy (surgical removal of the bladder).

However, only 35% of the patients are responders to this neoadjuvant treatment, meaning that 65% of the patients undergo ineffective treatment for 4-6 months before cystectomy or other treatment and have much-lowered survival rate. These patients need to be identified immediately after TUR-B to get the cystectomy performed at once, not after 4-6 months of non-effective cisplatin treatment. Today there are no methods to identify these patients.



Together with world leading experts in the bladder cancer field, BioReperia is conducting a clinical study where cells obtained from the TUR-B is tested for cisplatin responsiveness in the ZTX® platform. To evaluate the efficacy of the ZTX® model, the data from the ZTX® model is cross correlated to the patient's response observed in the clinics, i.e. if there is any tumor present in the bladder, lymph nodes and metastatic sites at the time for cystectomy.

Study outcome for bladder cancer:

- Generate data on responsiveness on bladder cancer cells to cisplatin in the ZTX® platform and compare with the clinical outcome in the patient
- Correlate the results from the ZTX® platform to the 5-year survival rate of cisplatin responders and non-responders