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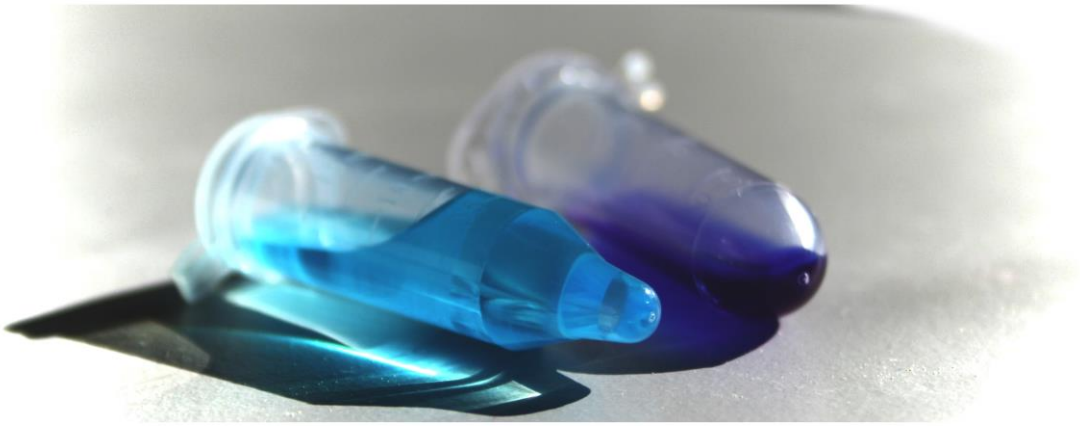

Metabolomics and NMR applied to in vivo studies

Metabolomics can accurately describe the physiology of a cell or organism, as it identifies and quantifies small metabolic products of a biological system. There are two principal approaches to determining the metabolic state of an organism - mass spectrometry (MS) and nuclear magnetic resonance (NMR) spectroscopy.

In collaboration with our partners we can offer state of the art NMR metabolomic analysis in all in vivo studies. We provide a metabolomic analysis of in vivo study samples that substantially increase the quantity and quality of data from a single study in a time and cost efficient manner.

The advantages of NMR metabolomics are high reproducibility, a wide range over which the results are quantitative, is very well suited for compound identification, can be used for tracing metabolic pathways, is non-destructive and has a proven track record of translating in vitro results to in vivo applications.

To improve the efficacy of the drug development process, it is necessary to obtain maximum information from each animal study. There are various ways to achieve this goal, such as metabolomic profiling of biological fluids and various organ tissues, disease metabolomics finger-printing and identification of metabolomics cancer markers. Additionally, a metabolomic profile allows an analysis of the treatment effect with a new drug candidate at the molecular level both in the healthy and tumor tissue.

Toxicology studies can greatly benefit from metabolomic data. As there is a correlation between extracellular metabolites and the intracellular situation, analysis of metabolomic profiles of either body fluid samples or organs can provide information on organ specific toxicity and an insight into a drug‘s mode of action. An added benefit is that body fluid sampling is non-invasive, therefore a large quantity of data can be obtained during the course of a toxicology study and not only at the study end-point.

Metabolomics are also very useful in the field of drug development with the potential to identify and validate novel therapeutic targets, creating alternative screening protocols, helping in the selection of cancer metabolite biomarkers, disease fingerprinting and identifying metabolite signatures for the drug efficacy mechanism of action.

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Experiment summary example

Application of NMR metabolomics to drug candidate in vivo testing

Example 1 – Drug effect/toxicity

Study request

You would like to test the potential toxicity and/or effect of a newly developed drug candidate.

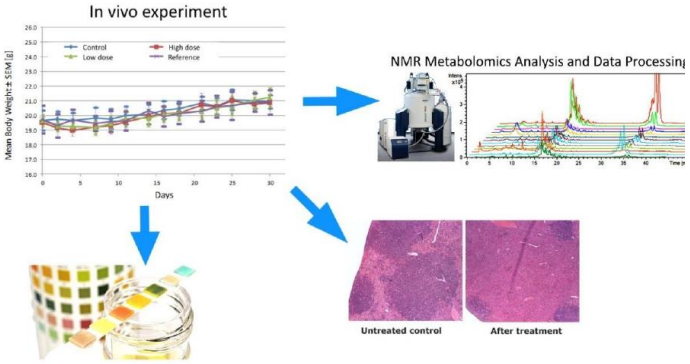
Study setup

We can design a protocol to monitor the toxic effect of the compound on the whole organism and specific organs during and at the study end-point.

A study would consists of a minimum of three groups of animals – control (non-treated), low dose and high dose group. The number of animals in each group depends on the estimated compound toxicity at tested doses in order to obtain statistically significant results.

Results

At defined time-points body fluids are collected which are then used to establish metabolomic profiles. At the end of the study histopathology samples are analysed, biochemical blood analysis is performed and blood and organ metabolomic profiles are established.



Example 2 – Drug efficacy

Study request

You would like to test the efficacy of a newly developed drug candidate.

Study setup

We can design a protocol to determine the compound efficacy in an appropriate model. We will assist with the animal model selection, based on the putative mode of action and expected effect.

Generally, the study consists of three animal groups: negative control (non-treated) group, tested compound group and a reference compound (positive control) group. The number of animals in each group is defined by the efficacy of the reference compound to assure statistically significant results.

Results

The common read-outs collected during the study are Total Body Weight, Tumor Volume, Tumor Growth Delay, Mean Survival Time.

At defined time-points body fluids are collected which are then used to establish metabolomic profiles.

At the study pre-defined end-point is prepared pathology report, analysed metabolomic profiles of selected organs and tumors, histopathology samples and performed biochemistry blood analysis.