

## Study design

Asses two lead compounds and various indications in one study design

## Case study



### The objective

The sponsor has an antibody platform technology with two lead compounds. They sought data on the on- and off-target binding of both compounds across various solid tumor types to determine which compound and indication(s) to move forward with in future trials.

### The solution

The clinical team worked together with the sponsor and surgical oncologists at the clinical site to identify the most suitable indications for the trial, considering target expression in different indications and ease of recruitment per tumor type. In parallel, the project manager was in contact with the regulatory bodies to ensure the adaptive study design with two compounds can be submitted as one clinical trial.

### What we delivered

TRACER designed an adaptive basket trial for the sponsor that runs both compounds in parallel in one clinical trial. In a basket trial, you include multiple indications or diseases. This way the sponsor was able to assess the safety, pharmacokinetics and biodistribution of the two compounds in seven target indications. The sponsor selected one lead compound and two main targets to move into their Phase 1 study.

### Our contributions

TRACER's expertise in adaptive clinical study designs allowed the sponsor to answer and evaluate multiple research questions in one regulatory submission. Delivered:

- Adaptive study design
- Full CTA package
- In patient PK/BD data
- Compound evaluation
- Selection of target indications

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