

# Study Design Guidelines

While there are many things to consider when initiating a study, ultimately there are two basic principles behind every successful metabolomics study — **good study design and adequate power**.

## STUDY DESIGN

### Spectrum of groups or treatments

To ensure that the salient “cause and effect” metabolic changes are detected, experiments should ideally have a spectrum of either timepoints, doses, or phenotypic/ disease severity. A good rule of thumb is to collect samples at time-points/ doses/exposures that induce mild, moderate, and severe experimental effects (e.g., observed effect, phenotype, or endpoint assay).

### Controls

Though it may sound obvious, make sure you are prepared to have every variable in your study accompanied by a control. It is recommended that you only include variables that can be tested with proper controls.

Cell Based Study	Time Point 1	Time Point 2
Vehicle Control	5	5
Drug Dose 1	5	5
Drug Does 2	5	5
Small Animal Study	Chow	High Fat Diet
Wild Type	10	10
Knock Out	10	10
Over Express	10	10
Human Studies	Male	Female
Control	30	30
Case	30	30

## STUDY POWER

Adequate study power is central to uncovering statistically significant results. Even an otherwise well-designed study can produce ambiguous results if it is not sufficiently powered.

**An appropriately powered study has enough samples to overcome biological variation, process variation and other factors (such as collection site differences).**

Sample Type	Samples per group
Cell Lines <sup>1</sup>	4-7
Small Animal <sup>1</sup>	6-10
Large Animal <sup>1</sup>	8-15
Human <sup>1</sup>	25-40+

<sup>1</sup> Isogenic and inbred genetic models typically require fewer samples than human studies.

### Fewer samples may be needed if:

- ▶ Using multiple time points for cells in culture
- ▶ Using multiple drug concentrations
- ▶ Taking repeated samples from the same individual
- ▶ Treatment effects are expected to be dramatic (toxicological studies)

### More samples may be needed if:

- ▶ Using a mixed population (mixed gender, fasting status, or a wide-ranging BMI)
- ▶ Samples are derived from multiple sites
- ▶ Samples are derived using multiple protocols
- ▶ Treatment effects are expected to be subtle (diet and exercise studies)

## Sample Quantity

Metabolon has worked with nearly 400 different sample types including some with various challenges and quantity limitations. Please refer to the Sample Submission Guide for GDP & CLP and/or the Sample Submission Guide for Microbiome Solutions for detailed sample guidance. Consult with your Metabolon representative if you have a sample type(s) or amount that falls outside these guidelines so we can discuss potential solutions. Sample guidance for each Targeted Panel can be found at [Metabolon.com](https://www.metabolon.com) or by request.

**Samples in this project are intended for** (check all that apply)

**Global Discovery Panel** (untargeted metabolomics)

**Complex Lipids Targeted Panel**

**Other Targeted Panel** (please specify in Purpose section below)

**Custom Targeted Panel**

**Microbiome Panel** (metabolomics)

**Metagenomics Sequencing**

16S

Shotgun

## STUDY INFORMATION & OBJECTIVES

**Client Name & Organization:**

**Project Title**

**Purpose** *If applicable, include specific targeted panels of interest, depth of metagenomics shotgun sequencing, etc.*

**Experimental Design** *please define abbreviations*

**Interpretation Focus** *i.e. key biological areas of interest*

## SAMPLE INFORMATION

**Sample Type** *i.e. plasma, cells, tissue/type, etc., Please indicate which analysis each sample type is intended for (if multiple selected above).*

**Sample Source (organism, cell type, etc.)**

**Sample Biosafety Level** *Do your samples include a known pathogen? Have they been screened for pathogens?*

**Sample Total** *(Total # of samples per analysis)*

**Amount of Each Sample**

*See Sample Submission Guides referenced above.  
Consult your Metabolon representative with  
any questions.*

**ESTIMATED Sample & Funding Availability (dates)****Sample Disposal**

*Option to return any remaining sample/s with \$1,500 domestic (United States & Canada) and \$3,000 World Courier packing/shipping fee.  
Must communicate request before/with sample delivery.*

**Are you interested in return of any remaining sample** **Y** **N**

**Data Merging** *Will merging data with a previous or future dataset be needed?* **Y** **N**

*If merging with a previous dataset, please provide project code.*

**STUDY INFORMATION & OBJECTIVES** *For projects with Metagenomics Sequencing, please list as separate line item(s) and indicate 'metagenomics' in DESCRIPTION field.*

GROUP	GROUP NAME	# OF SAMPLES	DESCRIPTION	STATISTICAL COMPARISONS* (OPTIONAL)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

*\*For Global Discovery or Microbiome Panel projects, please indicate the relevant fold changes of interest for statistical analysis. For example, if group A is the control, group B is drug X level 1, and group C is drug X level 2, the fold changes of interest are: B/A, and C/A and optionally, C/B. All other panels and Metagenomics data do not include statistical analysis, but this can be requested.*

**STANDARD PROTOCOL DEVIATIONS** (Metabolon Representative)

*Please describe any deviations from standard protocol here.*

**ADDITIONAL COMMENTS**

*Please include additional comments here.*

**STUDY/CLIENT CONTACT**
**Study Contact:**
**Title:**
**Institution/Company:**
**Department/Division:**
**Mailing Address:**
**City:**
**State/Province:**
**Post Code:**
**Country:**
**Telephone:**
**Mobile:**
**Email:**
**Additional Contacts:**
**Accounts Payable, Purchasing, or Admin Email & Phone:**
**Sample Contact Name:**
**Sample Contact Email & Phone:**
**Other Contact Names for Data Delivery/Receipt:**
**Other Contacts Email & Phone:**