**LifeGuide Trial Setup Guide**

To set up a trial in LifeGuide, you'll need to submit a file which specifies how you want the trial to run. This trial must be in a certain format, as described in the next section. It contains a number of parts, some of which are optional. Although the order of these parts can be changed, it's recommended that you use the following order to avoid problems:

* Allocation method name
* Allocation method parameters (optional)
* Stratification (optional)
* Treatment arms
* Treatment arm weights/limits (optional)
* Default treatment group (optional)
* Attribute values
* Attribute weights (optional)

Each of these is described in more detail below.

**Allocation method name**

Currently the system supports three main methods of allocation:

* SimpleRandomisation
* BlockedRandomisation
* Minimisation

The choice of allocation method must be specified in the following way:

Method: <name>

For example:

Method: BlockedRandomisation

**Allocation parameters (optional)**

Some allocation methods need additional parameters (for example, blocked randomisation requires a block size). If the parameters used by a method aren't specified, some default values are used instead. These are specified in the following way:

<Parameter Name>: <Parameter Value>

For example:

Block size: 30

A full list of available parameters for each allocation method is included further down in this guide.

**Stratification (optional)**

If the trial needs to be stratified on any of the participant attributes, this needs to be specified in the following way:

Stratify: <attribute 1> <attribute 2> …

For example:

Stratify: gender age

**Treatment arms**

To set up the various groups the participant could be allocated to, you must specify the following:

Arms: <treatment1> <treatment2> ...

For example:

Arms: pill1 pill2 placebo

**Treatment arm weights/limits (optional)**

You may want participants to be allocated to treatment groups with a specific ratio. To do this, you must set weights on each arm (if you don't specify a treatment arm's weight, it defaults to 1). This is specified in the following way:

Weight: <treatment name> <weight>

For example, to ensure three times as many participants are assigned to a treatment:

Weight: pill1 3

You may also wish to limit the participants in a group. To do this, you use the following format:

Limit: <treatment> <limit>

For example, to put a cap of 200 participants for a given treatment arm:

Limit: placebo 200

**Default treatment group (optional)**

If you want a default treatment group, into which participants are allocated once all groups have reached a limit, you specify:

Default: <treatment name>

**Attribute values**

The system needs to know how to categorise a participant's answers to the trial's data gathering questions. If the user has to select from a number of options, the group should be specified in the file as:

Group: <attribute name> <number of options>

For example, a yes/no question about whether a user smokes may be defined as:

Group: smokes 2

If a user will be entering a raw value as a response, you will need to specify how to group these responses. To do this, you specify:

Group: <value name>

<list of ranges>

Each range must be either:

<[value]

>[value]

[value] to [value]

For example, if you wanted to use a participant's age, you might specify:

Group: age

<20

20 to 40

40 to 60

>60

**Attribute weights (optional)**

If you're using minimisation for allocation, you may want the process to give priority to balancing some attributes over others. To do this, you assign a greater weight to the attributes which should influence the balancing process more, using:

Priority: <attribute name> <weight>

For example:

Priority: age 2

**Custom Parameters**

As mentioned above, certain allocation methods have custom parameters. For blocked randomisation, you can specify the following (use the names as shown, with numeric values):

* Block size – the size of block to use when allocating participants. Defaults to 10.
* Delta – the possible variation in block size between each block (for more unpredictable randomisation). Defaults to 5, allowing block sizes to potentially be 5, 10 or 15 for any given block.

For minimisation, you may use:

* Certainty – the percentage chance to use minimisation to allocate (given as a decimal between 0 and 1, e.g. 0.5 gives a 50% chance). Adds unpredictability to the results to aid in allocation blinding. Defaults to 1, giving a fully deterministic allocation process.

**Complete Examples**

This is an example of what a full trial specification might look like for a basic trial, where one group has a participant limit:

Method: SimpleRandomisation

Arms: exercise, diet, control

Limit: control 200

Stratify: bmi, gender

Group: gender 2

Group: bmi

<27.5

>27.5

A trial in which you wish to have twice as many participants in one group, a specification might look like this:

Method: BlockedRandomisation

Block Size: 20

Delta: 4

Arms: arm1, arm2, arm3

Weight: arm1 2

Weight: arm2 1 # Optional, allocation weights default to 1 anyway

Weight: arm3 1 # Optional, allocation weights default to 1 anyway

Stratify: age, gender

Group: gender 3

Group: age

<20

20 to 50

>50

Minimisation allows assignment of priorities to attributes, to ensure certain attributes are given priority for balancing over others. For example, a trial where age MUST be balanced over groups, and gender would be nice to have balanced, a specification might look like:

Method: Minimisation

Certainty: 0.8

Arms: arm1, arm2

Stratify: age, gender

Priority: age 10

Priority: gender 1 # Optional, priorities default to 1 anyway

Group: gender 3

Group: age

<20

20 to 50

> 50