

## Notes to users.

The bootstrap report contains a front page and four sections.

### Front page.

Name of data file, date, time, random seed (for the Mersenne Twister algorithms used to generate uniform integers), bootstraps per sample size, and PQ status.

Re. PQ status:

Internally the executable that performs the bootstrap also imports the FDA dataset from the Budesonide draft guidance (<https://www.fda.gov/downloads/Drugs/.../Guidances/UCM319977.pdf>) and processes it with the internal evaluation function that is used by the bootstrap algorithm. From the FDA dataset, results for “Sigma R”, “HEta1” and “HEta2” are calculated. They are compared to FDA’s own output and the executable is considered PQ’ed if the results match. This is done every time the executable is used.

“PQ metric 4” is the number of data lines actually in a data set at a random (determined at run time) sample size.

The PQ status, generally “PASS”, is shown on the front page (it is only “PASS” if all the four aforementioned metrics have correspondence with FDA’s output).

### Section 1: Graph of power vs. sample size.

Note that this is shown as units per batch, not units in total (or units in total per treatment). In FDA’s own dataset we have N=10 units per batch at which we get less than 50% power.

### Section 2: Sample sizes and power.

Tabulation of the data used to generate section 1.

### Section 3: Input data.

A table of the user input. Note that in the demo report the table is populated with rows of “1.234” in the column for X which is  $\ln(\text{measurement})$ .

### Section 4: Settings script.

A script with settings for bootstraps, random number seed, and data file is used to start the executable’s bootstrapping loops. The script is shown in the report and determines the content in all sections. Some lines will be self-explanatory; a line containing “CPB=12 Run.” means that the executable will be generating a data point for a sample of 12 units per batch.