File Review Sample Size Calculator

Use sample size parameters to calculate an ideal sample size for File Reviews created from a particular template.

Sample size parameters include the following:

- **Z Score** – The Z Score represents your desired level of confidence in the sample size as an adequate representation of the study as a whole. For example, a confidence level of 95% indicates that in repeated File Reviews, the sample size will mimic the entire population 95% of the time. You can find a complete list of Z scores at http://www.z-table.com. Commonly used Z-scores include 1.28 (90% confidence), 1.64 (95% confidence), and 2.32 (99% confidence).
- **Estimated Percentage of Valid Documents** – The estimated percentage of valid documents is an estimate of Study Items that typically pass review without issue. This is the benchmark for measuring how accurately the sample size mimics the population. For example, an estimation of 70% indicates that you expect approximately 70% of the sampling to be valid documents. This value is usually based on previous review statistics. eTMF automatically uses an estimate of 50% if no value is available.
- **Margin of Error** – The Margin of Error is the amount of error you can tolerate in the sample size. For example, a 3% Margin of Error indicates that you can tolerate only a 3% deviation in the sample size results from the results of the entire population. A smaller Margin of Error generally produces a larger sample size in relation to the population and more accurate results.

For example, suppose you specify a 95% confidence level (Z

Score of 1.64), a 50% estimate of valid documents, and a 3% Margin of Error. This means that in repeated File Reviews, the sampling should contain between 47 and 53% valid documents, 95% of the time.

To specify sample size parameters while defining a File Review Template:

1. Select “Sample Size Parameters” on the Create File Review Template screen. The Sample Size Parameters screen is displayed.
2. On the Sample Size Parameters screen, select “Yes” in the **Use Sample Size Parameters**
3. In the **Z Score** field, enter the z score that represents the level of confidence you want in the sample size. Acceptable values range between -4.0 and 4.0.
4. (Optional) Enter an estimated percentage of valid documents in your study(ies). Acceptable values range between 0.0 and 100.0 (for example, enter “70” to specify 70% valid documents). If no value is entered, eTMF uses 50%.
5. In the **Margin of Error** field, enter the percentage of error you can tolerate in the sample size. Acceptable values are greater than 0.0 and less than or equal to 100.0.
6. Select “Save.”

The system calculates the sample size when the template is used to create a File Review within a specific study. The calculation is shown below:

*Sample size = z^2 * (p * (1 – p)) / ME^2 , where*

- z = Z Score
- p = Estimation population of valid documents/100
- ME = Margin of Error/100

Once the calculated sample size has been determined, the

system divides the sample size by the total number of Study Items in the study to produce a percentage.

Both the calculated percentage and the fixed percentage from the template are displayed on the screen. The system automatically uses the higher of the two percentages; however, you can override this value if needed. See Create a New File Review for more information.

If the sample size is larger than the number of Study Items in the study, all Study Items that meet other conditions for inclusion will be included as Review Items.