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Post Marketing Clinical Follow (PMCF) is a continuous process to assess and analyze clinical data pertaining to device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

Usually device studies are used to acknowledge the information to a manufacturer mainly on the below points:

Thus, a PMCF on medical device would be considered as successful if both

- To approve the safety and performance of the device throughout its expected lifetime.
- To find out the previously unknown side-effects and to track the identified side-effects.
- To identify and analyze emergent risks on the basis of authentic evidence.
- To ensure the continuous acceptability of the benefit/risk ratio.
- To identify possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct
- To evaluate the safety and effectiveness of the device in the population expected to be indicated.

the safety and effectiveness endpoints are met throughout the expected lifetime of the medical device.

In order to conduct a PMCF study on medical device, manufacturer should use scientifically justified sample size for a study. There are several key factors involved in the sample size calculation. This white paper outlines the factors to be considered for sample size calculation for planning a study.

Since there are different statistical methods available for determining right sample size, manufacturer should select an appropriate method depending upon type of device and the objective sought. At this stage, an experienced satistician's help may be sought for the selection of the most appropriate method for sample size calculation. Taking the **study objective** and the **primary endpoints into consideration,** a statistician will select a right method considering several input parameters. For insance, one of the parameters Statistician would like to know is the expected outcome (e.g. number of failure of devices over a period of time, say, for next 5 years) from the proposed study. Usually, the answer from the manufacturer would be that a small proportion (say, 5%) of devices would be failed or malfunctioned during the study period.

The next question from the statistician would be about the **expected precision** of the estimate. This could be assessed from manufacturer's past experience or any other published study performed by other manufacturers. Anther parameter needed is the **expected drop-out** rate for the proposed study. Manufacturer would provide this figure from their past experience..

Let us assume that the objective of the study is to estimate the proportion of failure of devices from the study.. Then the below formula can be used for estimating the sample size.

$$n=[Z2 * P (1-P)] / d2$$

where P is the expected proportion of failure rate; d is expected precision and if we assume 95% confidence interval, then Z = 1.96.

Further, if we assume that a drop-out rate of x%, then the sample size adjusted for drop-out rate would be

$$n´ = [n/ (100-x)]*100$$

As an illustration, if P = 5%, d=1% and 95% confidence interval; then the sample size would be

$$n = [(1.96)2 * 0.05 (1-0.05)] / (0.01)2$$
$$= [3.8416 * 0.05 *0.95]/ 0.0001 = 1824.76$$

Now by adjusting for the drop-out rate of, say 25%, the adjusted sample size would be

$$n´ = [1824.76 / (100-25)]*100$$
$$= 2433.01 = 2433$$

As per the above calculation, we need to recruit about 2433 subjects into the study. However, the next key question will be about the availability of subjects for that study. Once again, statistician should initiate a discussion with manufacturer about the availability of subjects and study duration. For example, in order to recruit 2433 subjects into the study, manufacturer should select large number of sites leading to much higher budgets. Hence the statistician can prepare other sample size options with different inputs so that an appropriate suitable sample size can be decided by statistician and the manufacturer.

Please reach out to MakroCare statisticians for any additional questions on Sample sizes for your studies

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