PMCF: Data Quality Challenges & Best Practices

Growing appetite/need of Health Authorities and Notified Bodies for patient data, for performance or safety reasons, is a challenge for manufacturers, both operationally and budgets wise. Companies with high-risk devices got these covered to some extent, but a vast majority of the manufacturers perform PMCF only when Residual risks are to be justified or HA/NB raises safety concerns. With EU MDR and other regulations, PMCF to be performed for the other reasons as well going forward. “Old methods” of running PMCF may pose data quality challenges which we discuss in this article.

Data quality problems occur in 3 scenarios: a) Data Collection methods b) Data Processing and c) Measurement procedures. Despite the differences in setting and the sources of the errors, the end result will be the same, inaccurate data.

Reality of Errors

Errors occur naturally by physical means and human fallibility. Some errors cannot be prevented or even detected, for instance, a patient who deliberately provides an inaccurate answer on a questionnaire or a measurement that is in range but due to calibration drift or measurement error. In a recent study, up to 8% of patients could not recall historical items and up to 30% gave different answers on repeat questioning.

Even with clinician observation, reading test results, or interpreting images, human error and variability remain as factors. While measurements and processes capable of achieving the desired levels of quality are often planned and implemented, constant efforts coupled with vigilance must continuously be applied to maintain them.

Defining Data Quality

The Institute of Medicine (IOM) defines quality data as “data strong enough to support conclusions and interpretations equivalent to those derived from error-free data”. Applying the IOM definition requires a priori knowledge of how a statistical analysis for decision making behaves in the presence of data errors. For this reason, in clinical/patient data capture, it is most appropriate that a data manager and statistician set the acceptance criterion for data quality.

Data quality is “Multi-dimensional”. In patient/clinical area, the dimensions most commonly considered are reliability, validity, accuracy, and completeness. Reliability and validity address the underlying concept being measured, i.e., is this question a reliable and valid measure of pain-free walking? Accuracy is important with respect to and intrinsic to the data value itself. For example, does the blood pressure 130/70 represent the patient’s true BP at the time of measurement? That is, is it correct? And completeness is a property of a set of data values; i.e., are all the data there?

Although accuracy and completeness historically have been emphasized in the clinical areas, multiple dimensions ultimately affect and determine the usefulness of data. Each individual dimension describes an element of quality that is necessary but usually not sufficient for data to be useful for their intended purpose. As we begin to see an increase in secondary uses of patient data, the need for fundamental dimensions of data quality will become a necessary data itself. When maintained as metadata, can be used to assess the quality for primary and secondary uses.

Some real-time examples

Below are a few of the data quality issues that we come across often in PMCF projects.

- **Missing data:** It was observed that for many patients, the values were not captured in full for certain variables. This will impact proper analysis and conclusion of study results.
- **Different data formats:** The score variables were captured differently in data. Few scores were captured in percentages (for example, 34 %, 50 %. etc.) and some scores were captured as characters (for example, ‘Minimal’, ‘Mild’, ‘Severe’, ‘2 out of 10’, ‘No score collected’). These should have been captured in a standard format as per requirement.
- **Special characters:** Some values were captured as special characters (for example, ‘-’), which will hamper data analysis at the end.
- **Study deviation/violation:** Few subjects were included in study outside the specified age range of 18 - 70 years (for example, subjects with age of 71, 78 and 80 years were enrolled).
- **Expected data missing:** As per the protocol, all mandatory data must be collected in the form. For example, as per protocol, BMI should be less than 40 for the subjects. However, BMI data itself was missing in the data and hence the eligibility could not be evaluated.
- **Different Date/Month formats:** Another issue was with ‘Timeframe’ variable having the responses like 2 weeks, 6 months, 1 year, 09/09/2019, ‘-’ etc.

Best Practices

Gathering high-quality, reliable and statistically sound data is the goal for every PMCF project; and effective data management is essential to ensuring accurate data collection, entry, reports and validation. Some of the below fundamental elements of quality data management can both improve your manufacturer’s data management standards and get more mileage of the data.

1. ‘Fit for Purpose’

Several clinical and data professional societies advice companies to establish standard practices that produce ‘fit for purpose’ data sets, i.e., quality data. Fit for purpose methodologies implies that data quality improves when the data collected becomes more targeted to the study/project objectives. Eliminating non-critical data points lowers risk during endpoint analysis and minimizes the effort required to verify non-critical data. To ensure fit for purpose data, companies must clearly define critical data points and standardize their collection and monitoring processes. Guidance in these areas can improve clinical data integrity and reduce the variability of data quality among individuals and teams involved.

2. Identify critical data points

Critical data points are identified at the very beginning of the study process. To do this, you must determine what data you need to measure to answer the scientific question your study originates from. What is the quantitative definition of your end goal?

This fundamental part of the study process may seem fairly straightforward. However, issues often arise when non-critical data is collected for additional purposes, such as patient safety and/or exploratory analysis. Though important in many respects, ensuring these data meet quality standards requires considerable effort for the data management team. In addition to identifying more targeted data points, standard operating procedures (SOPs) can help reduce some of the time and effort for the teams when working with large amounts of data, and ultimately improve overall data quality.

3. Detailed standard operating procedures (SOPs)

Fewer errors in data collection and reporting means less time spent investigating the cause and correcting the problem. Developing thorough SOPs can help increase the accuracy of data collection by clearly outlining organizational practices and role-specific responsibilities. This specificity helps get all involved staff on the same page, reduces the risk for error in data collection and can make it easier to pinpoint the cause if and when errors occur.

4. Get digital

With cloud technology advancing rapidly, data capture electronically is much cheaper than most manufacturers think. Keep it simple with simpler tools and the cost of the tool will pay for itself in efficiency gains and quality improvement. If an electronic system is not possible or cost-prohibitive, use an excel with pre-defined macros and rules built-in to avoid data-entry mistakes by sites or your field teams. The best systems should be easy-to-use and intuitive for all members, and ultimately reduce the potential for error when reporting into the system.

5. Data Correction guidelines

For retrospective studies, if any irregular/missing/inconsistent data error occurs, Self Evident Corrections (SEC) or Universal Ruling Guidelines (URG) procedures can be implemented to resolve the data issues and approval from QA teams can be taken for all those data modifications.

"The time to repair the roof is when the sun is shining." -- John F. Kennedy, former U.S. President

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