Ensuring Registry Data Relevance and Reliability for Regulatory Use

Data Governance and Integrity

- Have a data dictionary that contains information about data elements, their definitions, ranges, allowable values, data standards and terminologies used.
- Missing or inconsistent data should be minimised, and specific processes need to be defined to assess data consistency, accuracy, and completeness periodically.
- Loss to follow-up (losing touch with registry participants) should be minimised and specific processes need to be defined for this.
- Routine descriptive statistical analyses should be performed to detect the extent of any missing data, inconsistent data, outliers, and loss to follow-up.
- All queries into missing or inconsistent data and resolutions or any data modifications need to be documented with the date, time, modification and reason for the changes, and the original data needs to be preserved.
- If registry data is linked with another data repository (such as EHR, an other registry or other). It is important that the same participant in both data sources is being correctly identified and linked, and appropriate testing is in place to make sure that data is being linked correctly.
- It should be possible to verify any data that comes from external sources against the source data.
- If data is moved from one system or format to another, it should be confirmed that the data has not been modified in any way. Any errors and corrective steps taken have to be documented.

Data fit for purpose

- The registry may or may not be suitable for use in drug development – it depends on multiple factors, such as population enrolled, which data was collected, and how registry datasets were created, maintained, curated, and linked to other datasets.
- The registry may also have been created for one purpose and may not be appropriate for another.

Security and privacy

- The electronic system used to hold data, such the as registry platform, has to be validated and conform to 21 CRF Part 11.
- Privacy and security controls need to be in place.
- The institutional review board (IRB) should be consulted.
- There should be informed consent to use the data for the intended purpose.

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- Procedures and processes should be in place to govern the registry, provide education and training of registry staff, and ensure appropriateness and quality of the data.
- Regulators should be able to assess the data quality and review all processes, procedures, and documentation.

FDA guidance, 'Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products-, is available at: https://www.fda.gov/media/154449/download

This resource is brought to you by the Best Data Practices for Rare Disease Patient Foundations and Researchers Working Group Project.