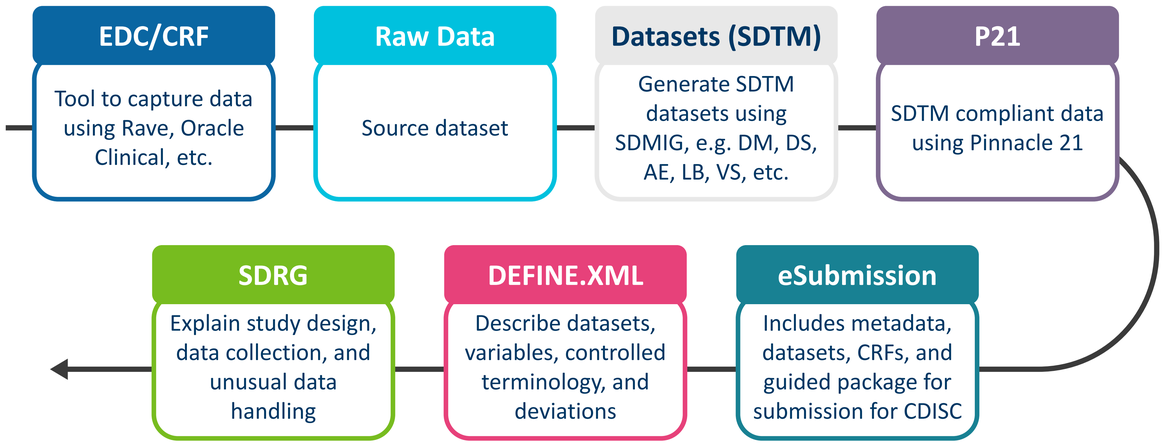
Creating a Clinical Trial Data Package for Regulatory Submission

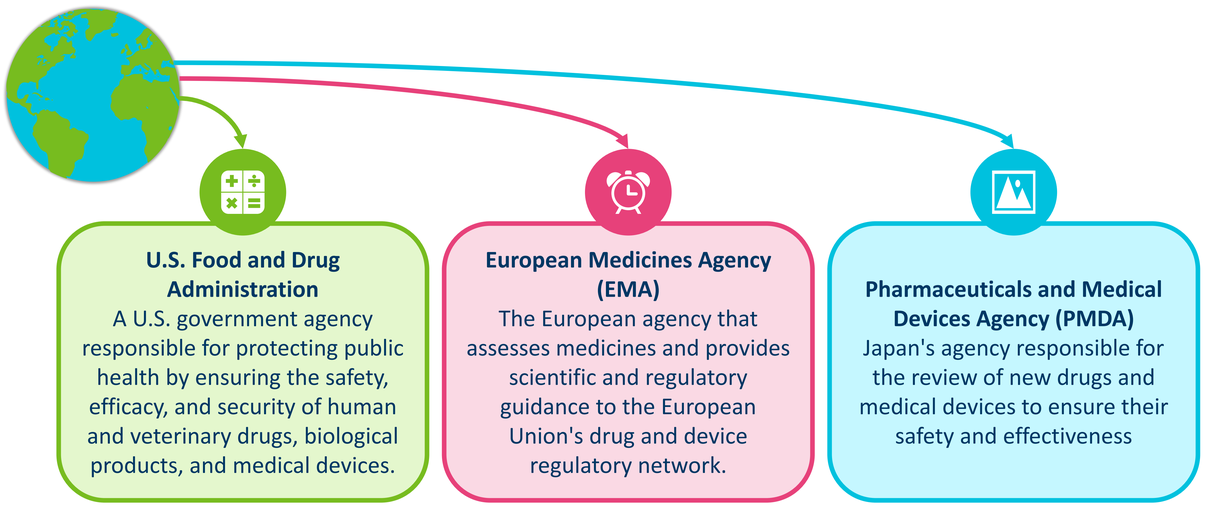
Background

Regulatory agencies increasingly require standardized clinical trial data submissions. Standardization enables consistent metadata definitions, improved traceability, and streamlined downstream datasets. The CDISC SDTM provides a framework to ensure consistency, transparency, and interoperability across studies. The resulting SDTM package provides a clear, well-organized representation of collected study data for efficient review and analysis. In essence, SDTM e-submission is the bridge between clinical trial data and regulatory approval, ensuring that data is standardized, validated, and review-ready.

1. Process Overview

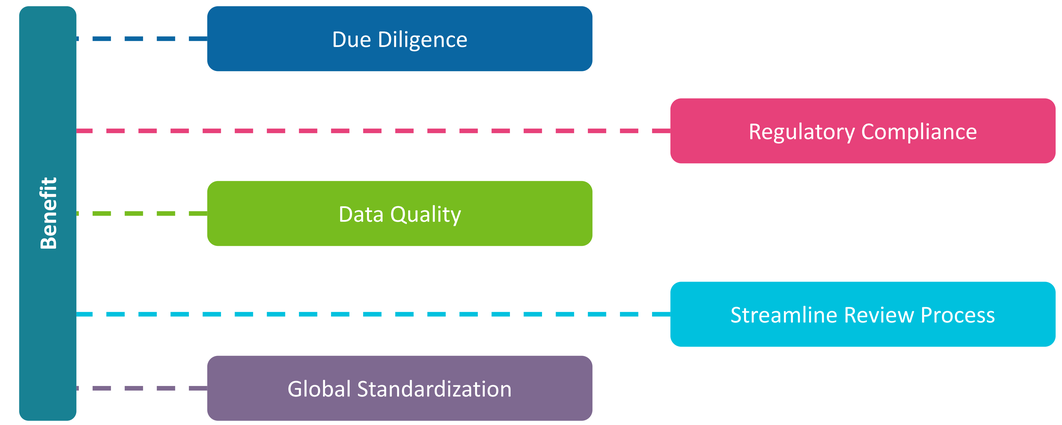


2. Regulatory Agencies



3. Lessons Learnt

Benefit



Key Takeaways

- Data quality is important for efficient submission. Provide valid explanations for issues in SDRG.
- For blinded trials, ensure unblinding is accurately done. An overall P21 validation score of a minimum 90% or more should be achieved on the final run.
- Check all tabulation data provided have dataset and variable labels and that they are consistent if referenced within the Define and cSDRG files.
- Check for references of intermediate datasets or external files (*.xls, *.doc) within the RGs and associated define files to ensure such files are documented according to our guidance.

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