

Implementing Quality Standards for Clinical Studies to Support FDA PMTA and MRTPA Tobacco Product Applications

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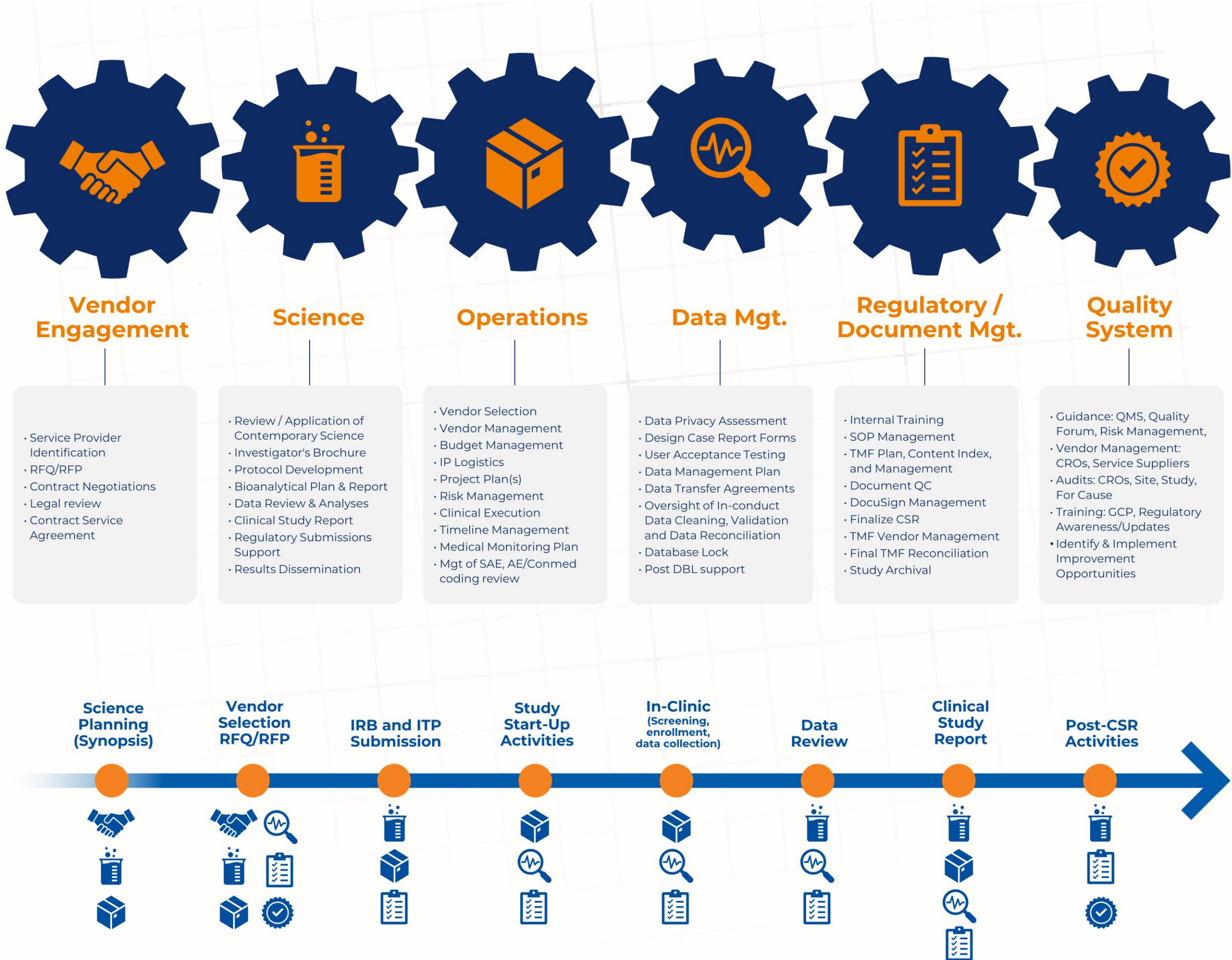
Background

Clinical research plays a critical role in evaluating the safety, efficacy and public health implications of consumer products, including those in the tobacco and nicotine sector. The emergence of new tobacco and nicotine delivery systems such as heated tobacco products (HTPs), vapor devices and oral nicotine pouches has led to the need for well-designed, ethically-conducted scientific research and a heightened demand for transparency and methodological rigor in any research related to tobacco and nicotine products. Consequently, the need for clinical research to evaluate both the risks and potential harm reduction claims associated with these products has become a focus of worldwide regulatory control activities.

Quality management in clinical research is designed to ensure that studies are conducted in accordance with ethical standards, regulatory requirements, and scientific best practices. Core components include quality assurance (QA), quality control (QC), and continuous quality improvement. In the absence of formal quality program guidance established specifically for clinical testing of tobacco products, the ICH GCP (Good Clinical Practice) guidelines provide a unified standard for the design, conduct, recording and reporting of clinical trials involving human participants. In the context of tobacco research, implementing robust quality management is especially critical to mitigate conflicts of interest, enhance data integrity, and promote public trust.

This presentation provides one example of a quality management program that has been implemented to support conduct of clinical studies for tobacco product premarket tobacco product application (PMTA)⁴ and modified risk tobacco product application MRTPA⁵ submissions to the US FDA.

Process



Why it Matters?

While GCP standards are not currently mandated for clinical research assessments of tobacco products for US FDA/CTP Submissions, our business upholds the level of quality prescribed within relevant regulatory guidelines, including the following:

- Quality Management & Standard Operating Procedures (SOPs): to ensure compliance with scientific and regulatory guidelines and standards related to validated study design & methods, ethical conduct, data reliability, scientific integrity and participant safety in clinical research trials.^{1,2}
- Data Standards & Metadata: to comply with the format of Clinical Data Interchange Standards Consortium (CDISC) foundational standards and the Tobacco Implementation Guide (TIG)³ which outlines standardized data formats and terminology for tobacco-related studies, improving transparency and interoperability.
- Trial Master File (TMF) Management: to document every aspect of the trial, from study personnel training/qualification records to protocol approvals, data management and informed consent forms.

Conclusion

Implementing a robust quality system to support clinical research studies is essential for ensuring data integrity, regulatory compliance, and participant safety. A well-structured quality framework not only enhances the credibility and reproducibility of research outcomes but also fosters operational efficiency, risk mitigation, and continuous improvement, ultimately accelerating the delivery of safe and effective health interventions to the public

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References

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- PMTA Final Rule <https://www.fda.gov/media/94052/download>
- MRTPA Guidance <https://www.fda.gov/media/83300/download>



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