

Paper ###-2019 (if SAS author, use SAS###-2019 or SAS####-2019)

Stay Ahead of the Curve: How to implement New FDA Recommendation Study Data Standardization Plan (SDSP) in your organization?

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ABSTRACT

The Study Data Standardization Plan (SDSP) is a living document and assists FDA in identifying potential data standardization issues early in the development program. As the Food and Drug Administration (FDA) has already started asking some sponsors to provide a SDSP, it may not be that long until this new FDA recommendation becomes new FDA requirement. Initial recommendations have been provided through a PHUSE sponsored limited duration team. We have taken these recommendations and expanded the tools and process necessary to help the sponsor implement the SDSP within their organization We will go through step by step process to implement SDSP in your organization. This paper will focus on: SDSP background, Sponsor benefits to implement SDSP, Development of SDSP project charter, Stakeholder analysis, RACI, Overall SDSP process and timelines, Pilot project selection for SDSP implementation and Long-term implementation.

INTRODUCTION

SDSP BACKGROUND

SPONSOR BENEFITS TO IMPLEMENT SDSP

DEVELOPMENT OF SDSP PROJECT CHARTER

STAKEHOLDER ANALYSIS

DEVELOPMENT OF RACI

OVERALL SDSP PROCESS AND TIMELINES

PILOT PROJECT SELECTION

LONG TERMS IMPLEMENTATION

CONCLUSION

REFERENCES

ACKNOWLEDGMENTS

CONTACT INFORMATION