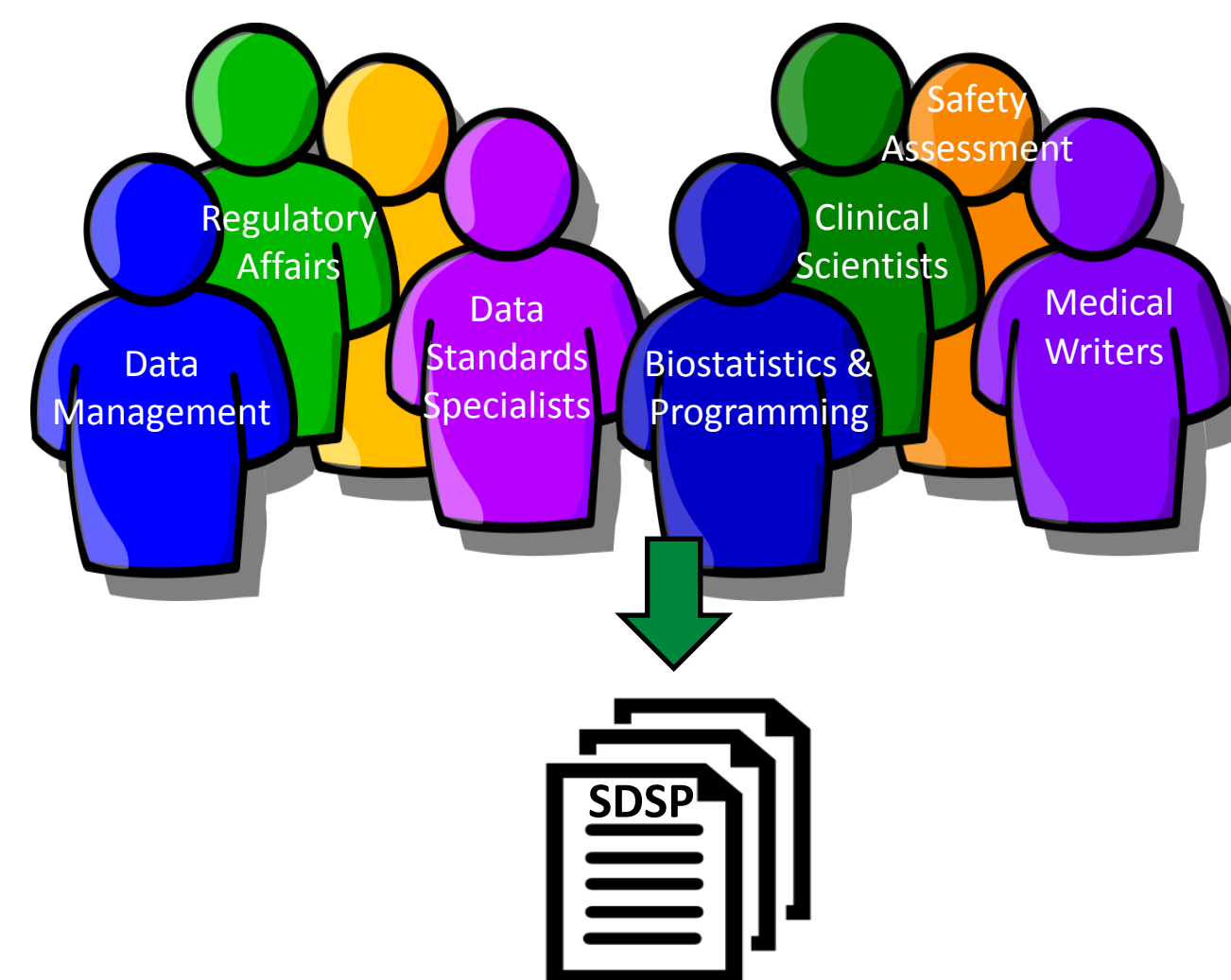


Touchpoints for the Study Data Standardization Plan (SDSP)

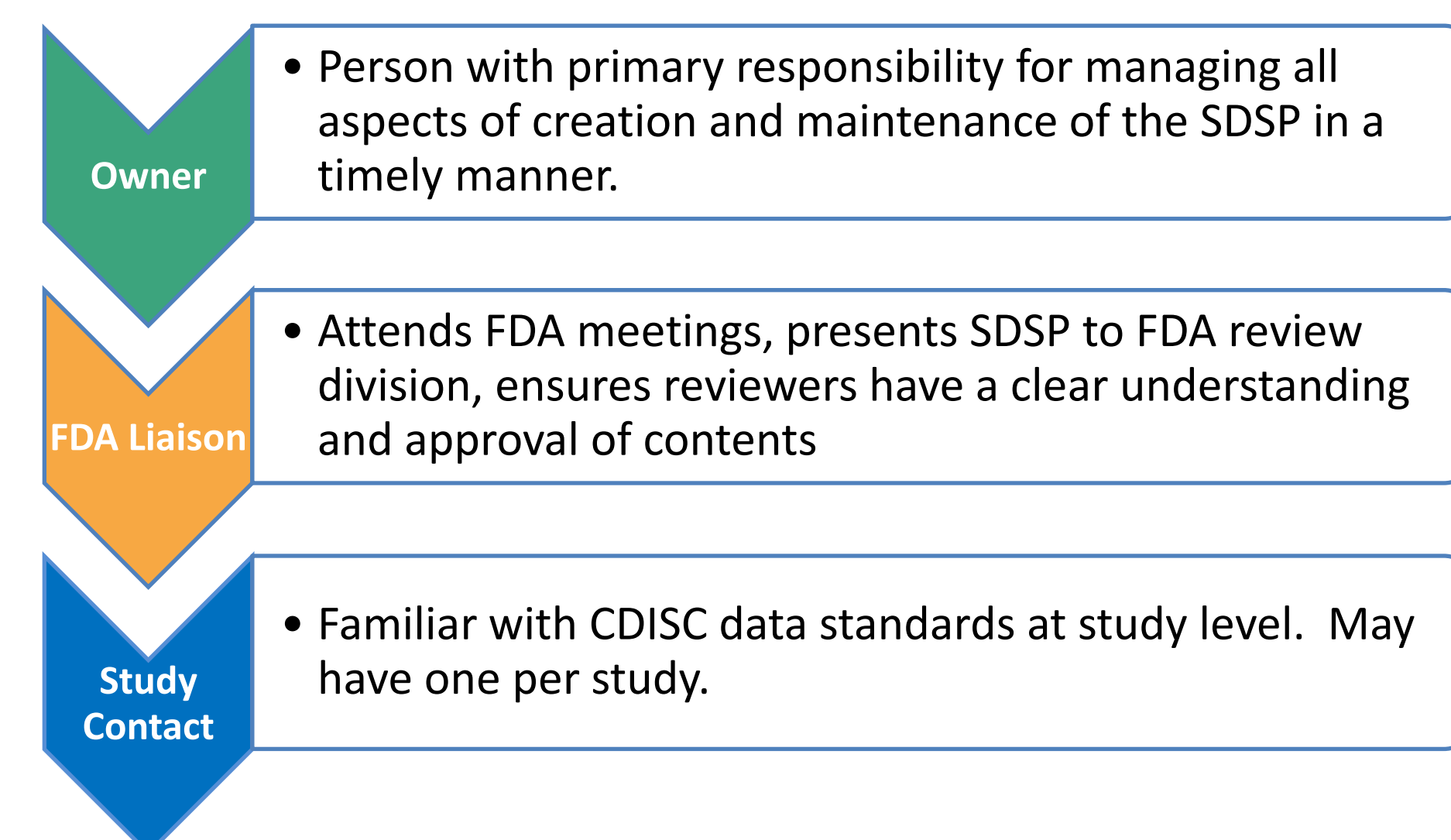
Abstract

The SDSP is intended to aid in the conversation with the FDA when submitting a program. It seems like a very straightforward document template which can easily be filled in by the study team. However, on closer analysis it has numerous places where the study team needs to reach out to its full membership including programming, regulatory, study statistician and drug program decision-maker.

Many Functional Groups



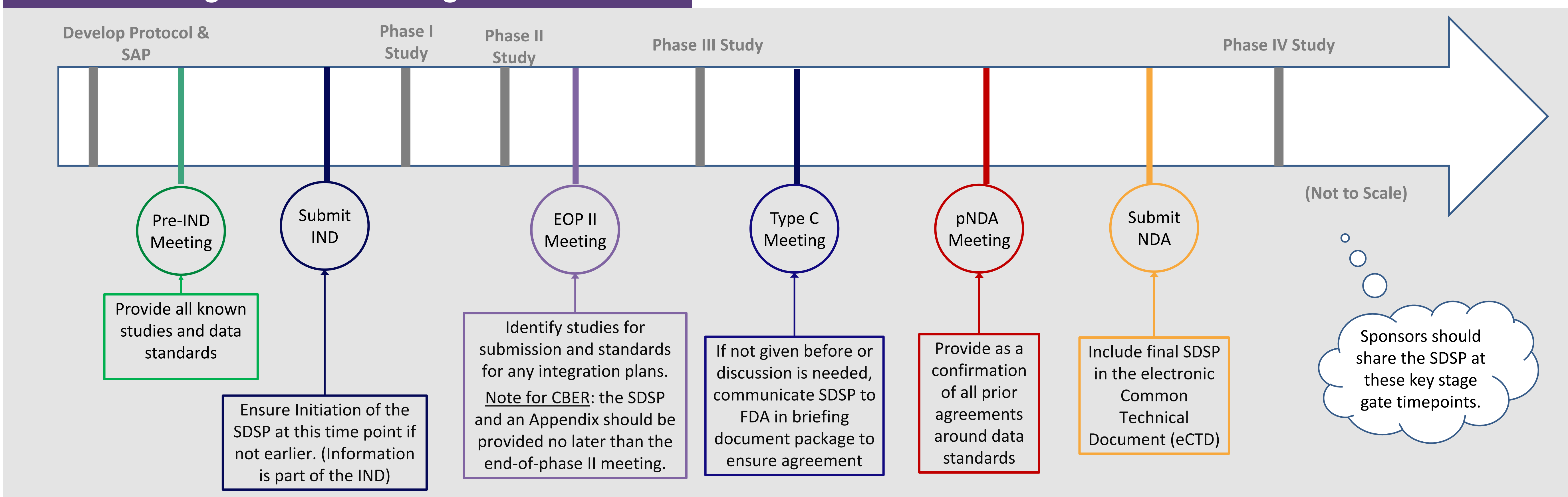
Suggested Roles



Considerations

- Depending on organizational needs, multiple individuals may contribute to or fill a given role (*colors are not indicative of role*)
- A Non-clinical Owner may start the SDSP and hand-off or coordinate with a Clinical Owner
- A Study Contact may interact with other subject matter experts (SMEs) to provide complete and accurate information
- An SDSP may have one or multiple studies, and a study may be present in one or more SDSPs (i.e. an ISS and an initial submission, or same study in different indications)
- Multiple SDSPs are permissible for a single compound in the event of multiple Indications (INDs)

Potential Stage Gates for Sharing SDSP with FDA



References

Study Data Standardization Plan (SDSP) Template (in MS Word) Version 1.0 TP001 16-Jan-2018 <https://www.phuse.eu/documents//sop/wp/phuse-wp002-sdsp-sponsor-implementation-guide-v1-8408.pdf>

Study Data Standardization Plan Completion Guidelines Version 1.0 WP001, 16-Jan-2018 <https://www.phuse.eu/documents//sop/wp/phuse-wp001-sdsp-completion-guideline-v1-8407.pdf>

SDSP Sponsor Implementation Guide, Version 1.0 WP002 16-Jan-2018
<https://www.phuse.eu/documents/sop/wp/phuse-wp002-sdsp-sponsor-implementation-guide-v1-8408.pdf>

Study Data Technical Conformance Guide
[<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>]

Data Standards Catalog
[<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>]

CBER SDSP Checklist Recommendations (SDSP CBER Appendix)
<https://www.fda.gov/downloads/BiologicsBloodVaccines/DevelopmentApprovalProcesses/UCM535589.docx>

Completion Guidelines

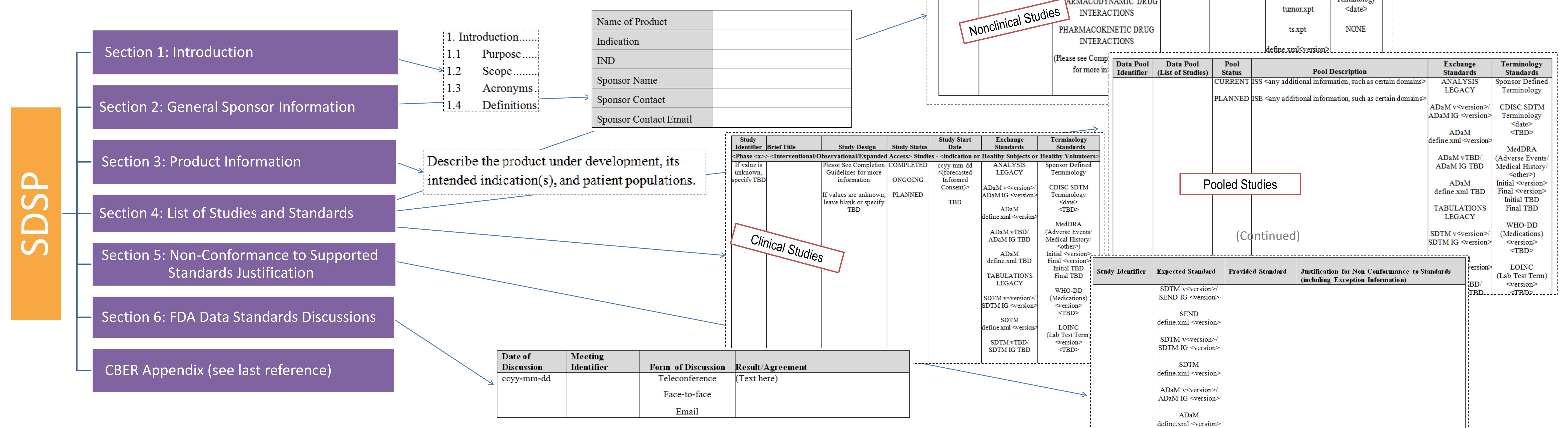
The SDSP Template by PhUSE provides a starting framework which is recommended by FDA. (Note: other formats may be used as long as all information is included.)

Each section has to be included in a Sponsor's SDSP. If values are unknown, leave blank or specify TBD. Then update as soon as new information becomes available.

Updates to the SDSP should not be communicated each time a study is started. The SDSP is a living document and version dates should correspond with communication to the FDA

The CBER appendix is only applicable for submissions to CBER and helps reviewers to understand the metadata for the study. It resembles an abbreviated version of an SDRG for SDTM

The final version has a statement in the cover letter describing the extent to which the latest version of the SDSP was executed



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