CSN Clinical Related Documents for eCTD Formatting BARDA Held INDs

Document type	Description
Protocol	CSN Starting point template available • BARDA_CSN_Clinical Study Protocol Phase II-III_2021-12-07_v1.0_20Dec2021
Informed consent	No starting point template. Document(s) should be submission ready: • BARDA's Document QC Guide • PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am)
Investigator's Brochure	BARDA will provide starting point template *Note: for IB's already available from a manufacturer, IB to be requested from manufacturer in eCTD format. If not, CSN contractor to format so submission ready.*
Package Insert (as applicable)	BARDA will provide starting point template *Note: package inserts to be requested from manufacturer in eCTD format. If not, CSN contractor to format so submission ready.*
1572(s)	No starting point template. FDA Form. Document(s) should be submission ready: • BARDA's Document QC Guide • PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am)
Financial disclosure 3454 or 3455	No starting point template. FDA Form. Document(s) should be submission ready: • BARDA's Document QC Guide • PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am)
CV PI(s)	No starting point template. Document(s) should be submission ready: • BARDA's Document QC Guide • PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am)
IRB approval(s)	No starting point template. Document(s) should be submission ready: • BARDA's Document QC Guide • PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am)

Document type	Description
Annual IND Report	BARDA will provide starting point template *Note: Same starting point template provided previously to some CROs for Bsafe and H7 protocol*
Statistical Analysis Plan	BARDA will provide starting point template *Note: Same starting point template provided previously to some CROs for Bsafe and H7 protocol*
Interim Analysis Reports as applicable	No starting point template. Document(s) should be submission ready: • BARDA's Document QC Guide • PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am)
IND safety reports	No starting point template. Document(s) should be submission ready: • BARDA's Document QC Guide • PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am)
Module 5 Literature references	Will vary by submission. No starting point template. Documents should be submission ready: • Ensure documents are 8.5x11, avoid using scanned literature references when possible and only include one bookmark per lit reference. • Format for bookmark should be Author Last Name First name initial, year of publication and Title. • BARDA's Document QC Guide • PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am)
Clinical Study Report	BARDA will provide starting point template *Note: Same starting point template provided previously to some CROs for Bsafe and H7 protocol*
Case report forms	No starting point template. Documents should be submission ready: • BARDA's Document QC Guide • PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am) *Note: extremely bookmark and link intensive*
datasets	CDISC SDTM & ADaM: Define files (XML, PDF), Reviewer Guide, Transport files Annotated CRFs

Notes:

- *Will be protocol specific. Early in protocol development for BARDA held IND's, the Project Coordination Team (PCT) will meet and a build list will be prepared.*
- *BARDA Starting point templates for other Modules and documents available and will be provided as needed for any given protocol specific submission.*

References

- (multiple) https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd (accessed 16Aug21 9:49am)
- PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS (September 2016 v4.1) https://www.fda.gov/files/drugs/published/Portable-Document-Format-Specifications.pdf (accessed 16Aug21 8:42am)
- BARDA's Document QC Guide (undated)