TriTiCon

Data and Outputs Delivery Checklist

About this document

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1 Introduction

The actual data-sets and generated outputs (Tables, Listings, Figures) are of course key deliverables from data management and programming, but you need more than that. Documentation of the data, actual program code and logs/traceability are required as well. There are two main regulatory drivers behind these requirements.

1) Submission requirements – There are specific requirements for how data and documentation is submitted, and it is strongly recommended that you get it right from the start, and that you get these deliverables in place as early as possible.
2) Traceability and re-create requirements – You must be able to provide evidence on how a specific result, table, figure or listing was created (which program, which data, by whom, when etc.), and you need to be able to re-crate them (re-runt eh process and get the same result). This applies for submitted data and results, but also for other use of the data such as DMC/DSMB evaluations and periodic safety updates.

Even if you do not intend to submit a specific trial, the overhead is limited, and these deliverables ensures you can use/reference the data from the trial in the future – and plans can change. Therefore, there is also a strong business benefit in getting this in place for all trials -from the beginning.

Phone +45 52 19 31 99 |Mail: info@triticom.com

TriTiCon | Sandvejen 30 | DK 2665, Vallensbæk Strand | Denmark

2 Delivery Checklist

This checklist is written primarily for companies sourcing the generation of trial data and outputs to a vendor and need to ensure they receive the required deliverables to (Post trial / post contract) be ready for submission, due diligence and inspection (independent of the vendor or with help of another vendor). However, it can also be used as input to processes (SOPs) for internally run trials.

Note that this is not a submission checklist. The deliverables below will provide the fundamental trial data-related submission components, but for a submission additional and specific requirements apply. (Recommended reading: FDAs *STUDY DATA TECHNICAL CONFORMANCE GUIDE*, https://www.fda.gov/media/88173/download)

Delivery	Description
Blank CRF (pdf-format)	CRFs (Data Entry Screens) documenting the screens used for data entry. Requirements/submission notes: Note that you must be able to document changes/versions, and exactly which version of each page that was used for each patient.
Raw-data (data-sets, most common as SAS data-sets)	Raw-data ("original data as collected") and associated documentation of how the data is structured, which options that was allowed, data-format (numeric, date, text etc.). Requirements/submission notes: Not required for submission, but often beneficial for documenting the complete link from collected value to results and outputs (which is required).
Raw-data annotated CRF (pdf-format)	CRFs (data entry screens), marked with annotations of where in the data structure (table and variable) the data from each CRF-field is stored.
Patient CRFs (pdf-format)	Patient data CRFs in pdf-format, including user/date/time-stamps, query-history and audit trail. Requirements/submission notes: CRFs for "patients of special interest" (typically patients with SAEs or AEs defined in the protocol as "of special interest") is expected to be submitted as patient CRFs in addition to the SDTM and ADAM data.
SDTM data (SAS XPT format)	Data in CDISC SDTM compliant format. It is common and practical to deliver ongoing data in SAS format instead of XPT-files, as the former is easier to use. However, it is strongly recommended to get a submission-ready package as a final delivery (rather than converting and changing later to make the datasets submission ready). Requirements/submission notes: Very specific requirements regarding structure, content, naming and more. Ref: www.CDISC.org.

SDTM define.xml (xml-format with associated style sheet)	SDTM define file (and associated style sheet), describing the structure of the SDTM data. Requirements/submission notes: Very specific requirements regarding structure, hyperlinks, content, naming and more. Ref: CDISC.org.
SDTM Reviewers Guide (cSDRG) (Xml-format)	Reviewers Guide (cSDRG) – Readme file with key comments about the data. These can be known issues in the data or comments on how the data is derived and structured, in order for a reviewer to understand the data correctly and efficiently. Expected as part of submission, but also useful for other future understanding and use of the data. Requirements/submission notes: Required in submissions. It is recommended to follow recommendations from Phuse (www.phusewiki.org)
SDTM Annotated CRF	CRFs (data entry screens), marked with annotations of where in the data structure (table and variable) the data from each CRF-field is found in the SDTM data.
ADaM data (SAS XPT format)	Data in CDISC ADaM compliant format. It is common and practical to deliver ongoing data in SAS format instead of XPT-files, as the former is easier to use. However, it is strongly recommended to get a submission-ready package as a final delivery (rather than converting and changing later to make the datasets submission ready). Requirements/submission notes: Requirements regarding structure, content, naming and more. Ref: CDISC.org.
ADaM define.xml (xml-format with associated style sheet)	ADaM define file (and associated style sheet), describing the structure of the ADaM data as well as derivation-rules. Requirements/submission notes: Very specific requirements regarding structure, hyperlinks, content, naming and more. Ref: www.CDISC.org.
ADaM Reviewers Guide (cSDRG) (Xml-format)	Reviewers Guide (cSDRG)– Readme file with key comments about the data. These can be known issues in the data or comments on how the data is derived and structured, in order for a reviewer to understand the data correctly and efficiently. Expected as part of submission, but also useful for other future understanding and use of the data. Requirements/submission notes: Required in submissions. It is recommended to follow recommendations from Phuse (www.phusewiki.org)
Outputs (Results, Tables, Listings, Figures).	The outputs are of course most often part of a statistical or integrated report, where they are archived and potentially submitted. However, it is also beneficial to get and store

(As part of report in pdf, and/or as stand-alone in pdf, rtf or similar)	them separately for future reference and use, and to support of traceability (See also "Logs and evidence" below). Requirements/submission notes: Included (as relevant) in submission as part of reports in pdf-format.
Programs (Most commonly SAS programs)	Versioned, final programs and associated validation documentation (specifications, test documentation) should be submitted together with your data and outputs. Further, they required to be able to show traceability and re-create results and outputs. There is of course also a business benefit to have these programs for future reference and re-use In practice, this is a slightly outdated requirement, as programs today are most often environment-dependent, referencing libraries, macros or other settings, or even fully native to the environment they were created in, and cannot be run outside of this specific platform. That said, most programs can be "read and understood", to allow traceability and reuse of parts of the code and logics. Requirements/submission notes: Should be included in submission.
Logs and evidence (Various formats, but signed/locked or with other evidence for when they were generated, by whom and for not being modified since)	As traceability and to support re-creation of results and outputs, you need to have logs (manual or system logs) and other documents linking output or result back through programs, program executions and to data. It must be clear line of sight, for which program that was used, on which data, when and by whom, to generate a certain output). In theory you should be able to re-produce all results and outputs, although as mentioned above this is practically difficult to achieve without modifications as the programs most often is dependent on the environment.

Note: Pdf's should be formatted according to submission requirements (font, margins, bookmarks).