

End-to-End Traceability from Protocol Development to Submission

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ABSTRACT /INTRODUCTION

To ensure end-to-end traceability of our collected data by use of standard terminology from protocol development to submission a new tool and process for trial set-up has been developed at Novo Nordisk A/S. This new process also supports use of standard terminology in the definition of CDISC trial design datasets and trial summary parameters.

A custom built repository for our trial metadata and controlled terminology called Metadata Management Application (MMA) in our Clinical Data Warehouse (CDW) is used when setting up a trial during protocol development. Reports generated from the MMA have been developed to ensure consistent use of standard terminologies in trial protocols from the very beginning and throughout the life cycle of the trial.

The aim of this presentation is to present the new process for trial set-up in the MMA and how we have applied end-to-end traceability.

GETTING IT RIGHT FROM PROTOCOL DEVELOPMENT TO SUBMISSION

An overview of the trial setup process of the protocol development phase is shown in Figure 1. Global standard teams maintain and ensure consistent use of the global standards (CDISC and sponsor defined standards) across projects. Within each project a Project Standard Team (PST) select and control project standards and ensure adherence to these. Changes to standards or requests for trial specific use of a standard have to be approved by the PST.

The trial team is provided with a project specific schedule of activities which is controlled by the PST. The visit of schedule includes all the assessments (topic codes) and activities to be conducted during a trial. The trial team will select the relevant assessments and request trial specific codes to the PST, if needed. The trial programmer will create a trial specific report named the protocol metadata document (PMD) which is an Excel report downloaded from the metadata repository containing the visit of schedule along with information needed for the SDTM trial design data set including the CDISC trial summary parameters.

It will be an iterative process finalising the trial specific PMD between the programmer and the trial team.

When the trial team agree it is final the programmer will download the visit of schedule in a word format that can be copied into the protocol. The PMD will be QC'ed against the protocol to ensure what is in our metadata repository is aligned with the protocol. The PMD will be archived in order for other areas to use the information for creation of case report forms (CRFs), Lab specifications etc.

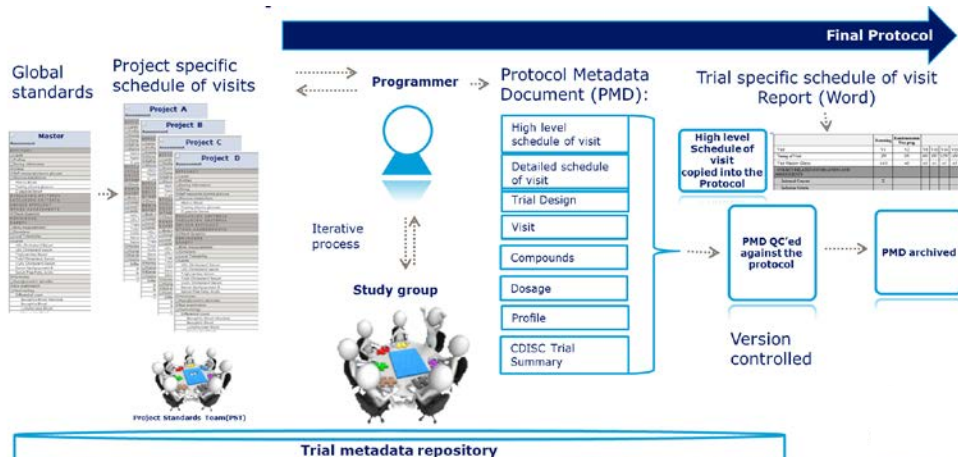
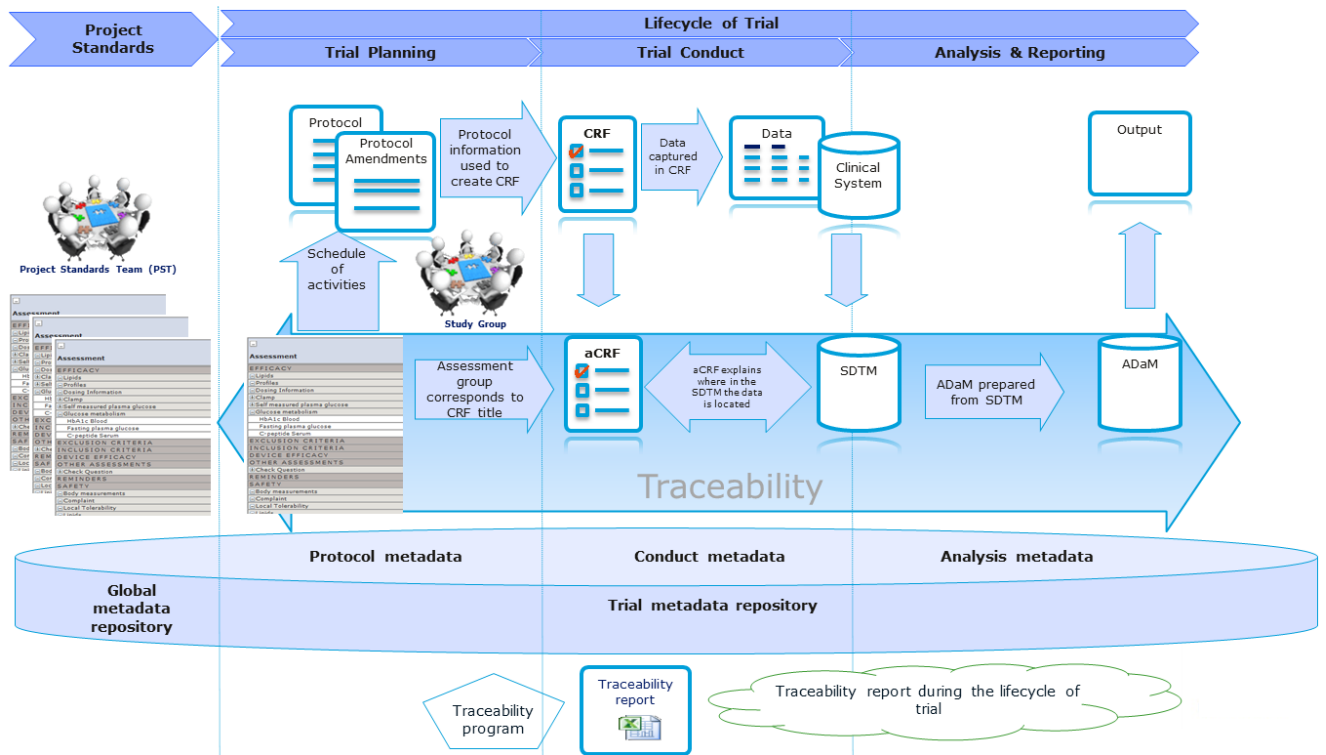


Figure 1: Overall process for setting up a trial in the trial metadata repository during the protocol development

REPORTS SUPPORTING TRIAL SET-UP PROCESS



METADATA REPOSITORY

Standards in MDR	Trial Setup in MDR
<ul style="list-style-type: none"> • CDISC CT • SDTM master model • Sponsor concepts and labels, link to CDISC CT • Sponsor defined CT submission values • Project standards • Trial setup reports and templates 	<ul style="list-style-type: none"> • Select SDTM and CDISC CT version • Select project standard • Define trial metadata for trial design and trial summary parameters • Add trial specific assessments • Manage changes • Run trial setup reports

MDR: Metadata Repository, CT: Controlled Terminology

CONCLUSION/LEARNINGS

- Getting it right from the beginning is possible and save time downstream
- Reports supporting end-to-end traceability helps bridging the communication gaps across skill area
- Development and maintenance of standards is key
- Processes for control of standards is needed
- Challenging to introduce a MDR system and reports for use of standards, compare to traditional document centric solutions
- Do not underestimate the effort for support and change management

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