

Strategies for writing the ADRG

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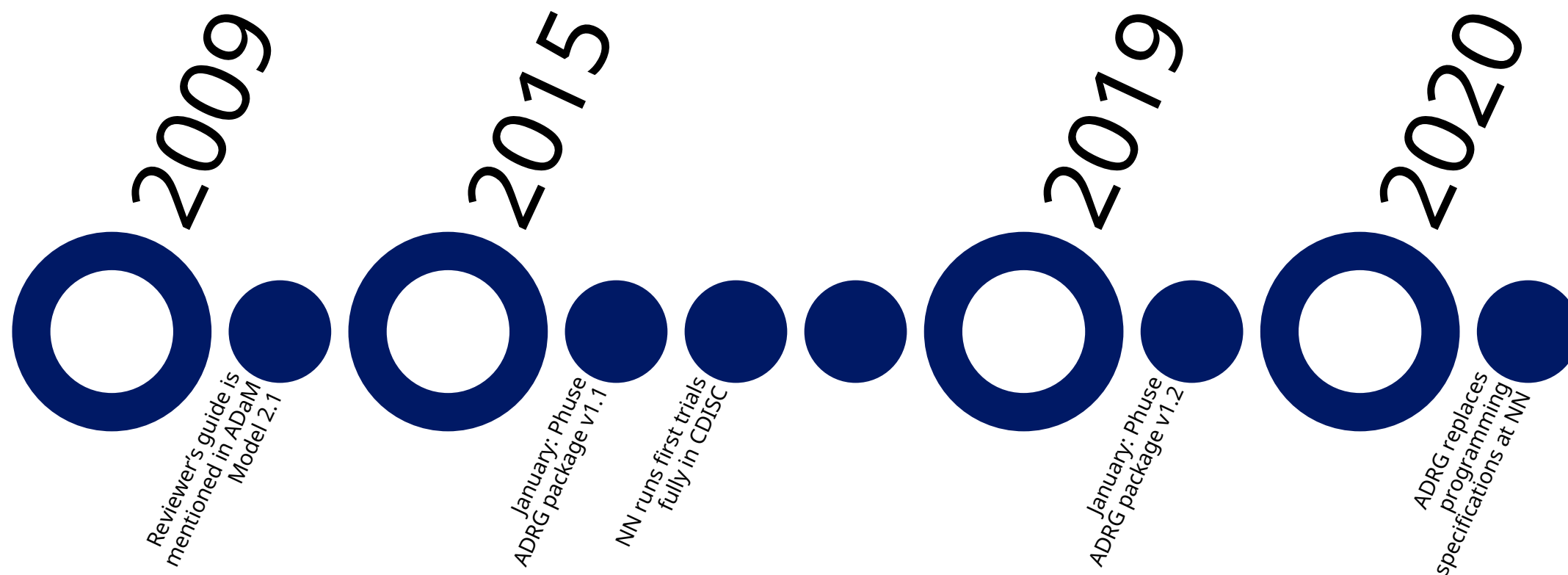
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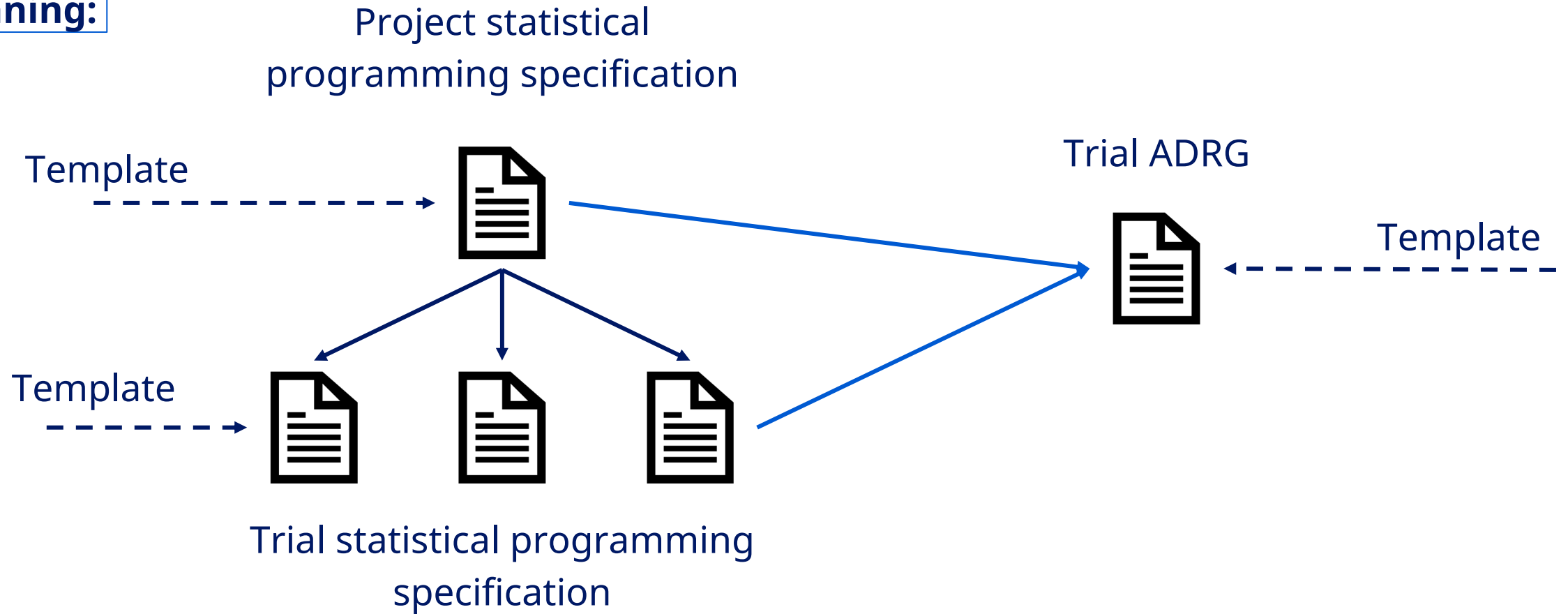
- # Agenda
1. ADRG beginnings
 2. The ADRG process at Novo Nordisk
 3. The ADRG standard Novo Nordisk
 4. Take away messages

ADRG Beginnings



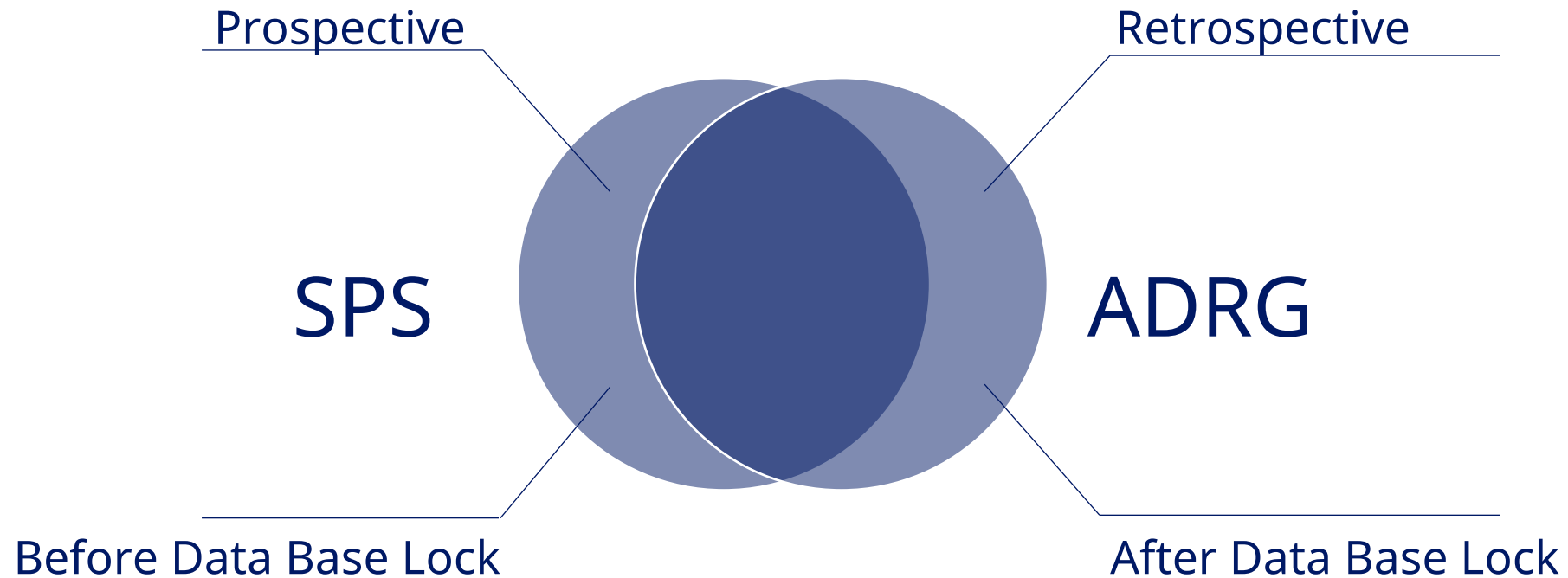
The ADRG process at Novo Nordisk

Beginning:



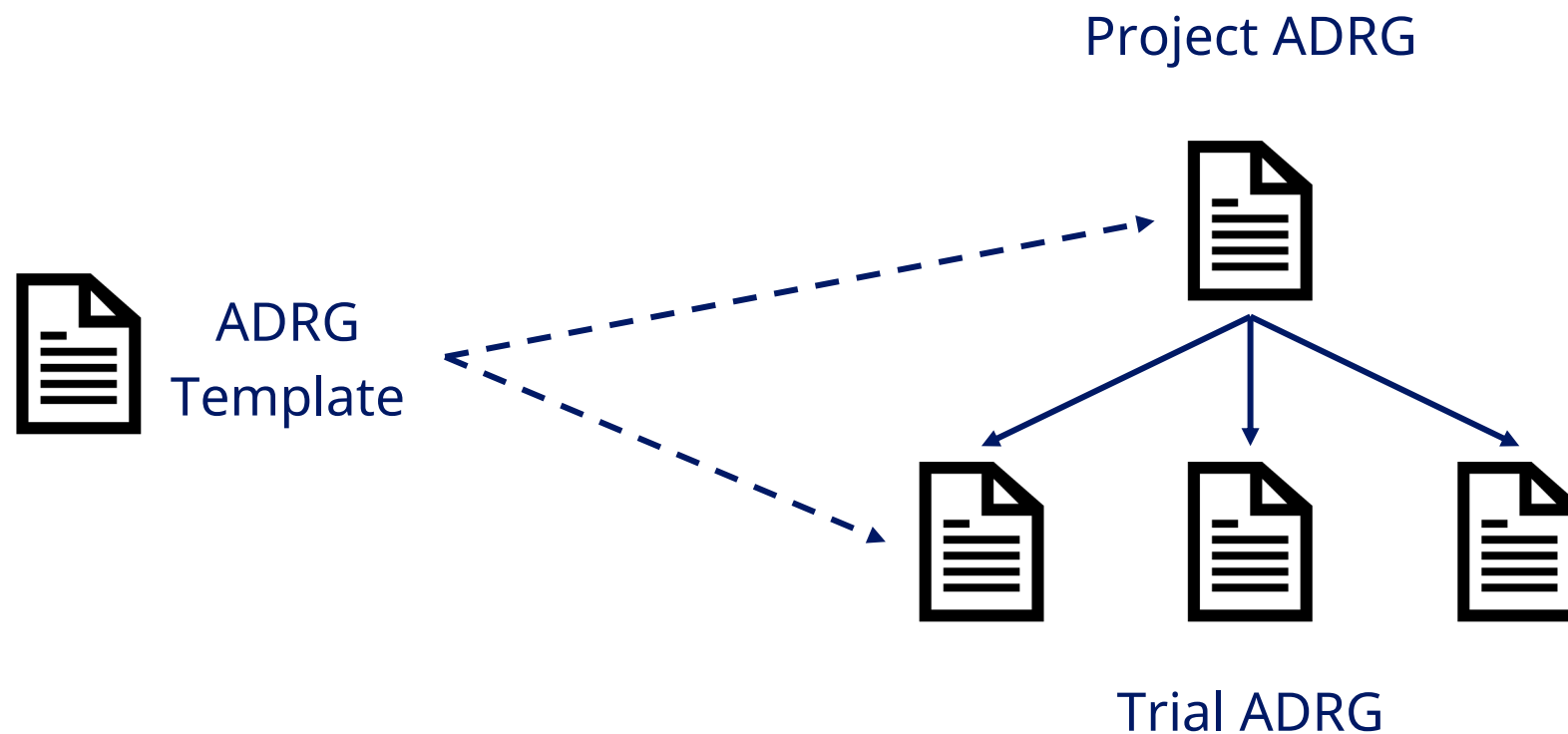
The ADRG process at Novo Nordisk

Beginning:



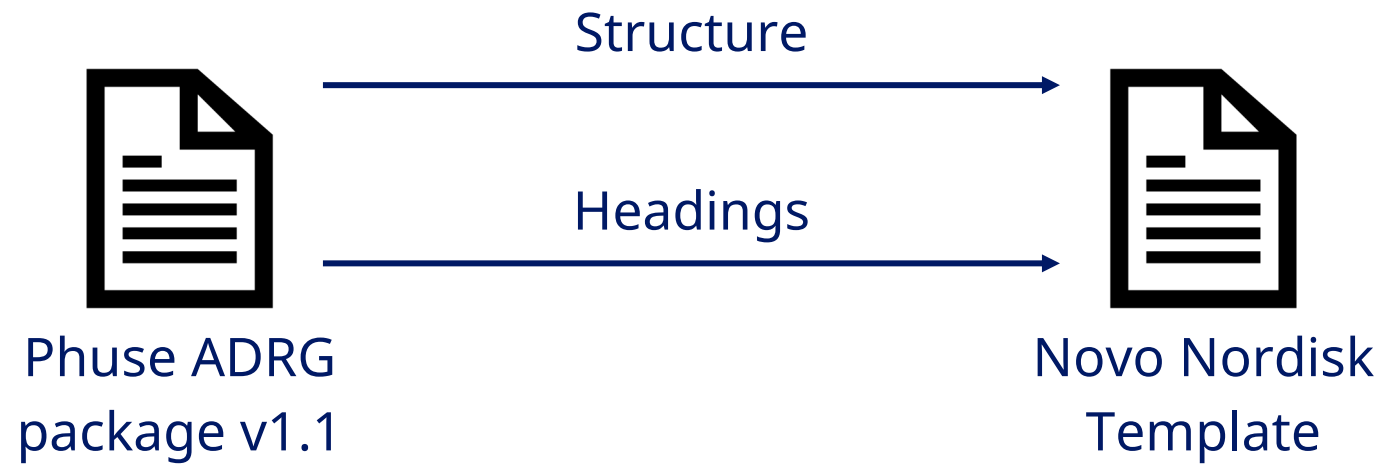
The ADRG process at Novo Nordisk

Now:



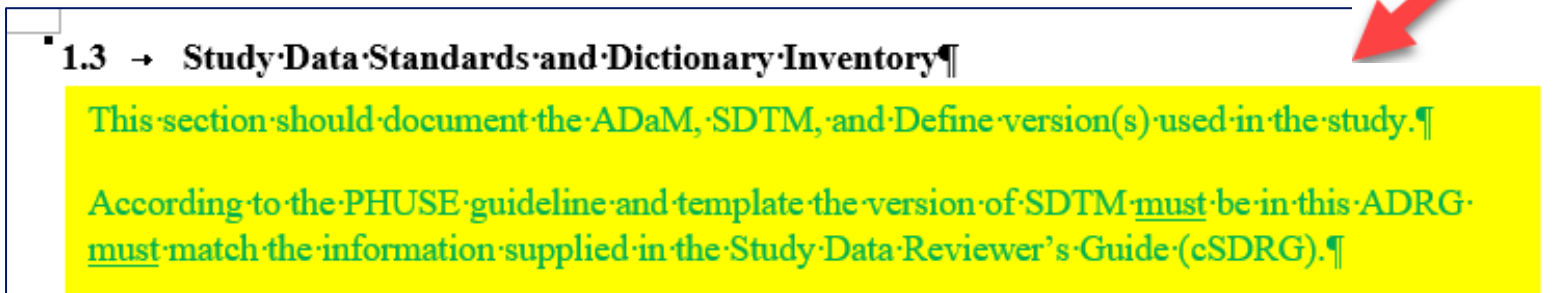
The ADRG standard at Novo Nordisk

- Governed by internal template



The ADRG standard at Novo Nordisk

- The template setup:
 - Mandatory
 - Trial/therapeutic area specific
 - Guidance
 - Specification ADRG guidance



1.3 → Study Data Standards and Dictionary Inventory¶

This section should document the ADaM, SDTM, and Define version(s) used in the study.¶

According to the PHUSE guideline and template the version of SDTM must be in this ADRG. must match the information supplied in the Study Data Reviewer's Guide (cSDRG).¶

Guidance Text

The ADRG standard at Novo Nordisk

- Readability
 - Technical writing courses
 - Bullet questions



Phuse completion guideline

corresponds directly to the ADRG Template. **Note: Certain ADRG Sections include a series of questions intended to aid FDA Reviewers. Provide complete answers to all questions. Do not delete the primary questions from the final document.**



Phuse completion guideline

3.1 Comparison of SDTM and ADaM Content

- Are data for screen failures, including data for run-in screening (for example, SDTM values of ARMCD='SCRNFAIL', or 'NOTASSGN') included in ADaM datasets?

<insert text here>

- Are data taken from an ongoing study?

<insert text here>



Novo Nordisk Template

▪ 3.1 → Comparison of SDTM and ADaM Content ¶

The following bulleted questions must be addressed: ¶

- → Are data for screen failures, including data for run-in screening (for example, SDTM values of ARMCD='SCRNFAIL', or 'NOTASSGN') included in ADaM datasets? ¶
- → Are data taken from an ongoing study? If yes then describe the data cut and any issues that might influence record selection from SDTM to ADaM and refer to section 4.1. ¶

- Text examples
 - Reference points for language
 - Tried to cover more than one situation where possible

Example 1: Parallel group trial design relevant for many phase 3 trials and some phase 1 trials

The values of ARM and ACTARM in SDTM correspond to the values of TRT01P and TRT01A in ADSL. The planned (randomised) treatment is used for analyses based on the full analysis set, while the actual treatment is used for analyses based on the safety analysis set.

Example 2: Cross-over design

The values of ARM in SDTM correspond to ADSL.TRTSEQP as illustrated in [Table 2-1](#). All analyses are based on actual treatment at the time of observation (TRTA).

3.5.4 Record selection

Table 3-4 Record ineligibility reasons

Ineligibility reason (ANELREA)	Rationale
<i>Fasting requirement not fulfilled</i>	<i>For some parameters, the assessment was planned to be taken in a fasting state. If this was not the case, the value is not included in the analysis.</i>
<i>Baseline measurement after date of first trial product</i>	<i>Applies to baseline values only. If obtained after the date of the first trial product dose, baseline values are not included in the analysis.</i>
<i>Not the first value</i>	<i>If more than one valid value is recorded for the same parameter at a visit, only the first valid value is used in analysis. Other recorded values from the particular visit are omitted from analysis and ANELFL – Analysis Flag is set to missing.</i>
<i>Not the last value</i>	<i>If more than one valid value is recorded for the same parameter at a visit, the latest valid value is used in analysis. Other recorded values are omitted from analysis.</i>

Novo Nordisk defined content

3.6 Imputation/Derivation Methods

Table 3-5 *Common imputation of partial dates and time applicable to multiple datasets*

Dataset	Variable	Imputation convention/rule
<i>ADBLDDET, ADBLDEPI</i>	<i>AENDTM</i>	<i>If bleed end date and time are missing:</i> <i>End date is imputed to 3 days after time of last treatment of bleed dose and indicated by AENDTF = "Y"</i> <i>If end time is missing, the end time is imputed to "23:59:00" with AENTMF = "H"</i>
<i>ADLB, ADVS, ADPE</i>	<i>ADT</i>	<i>If partial or missing date the date will be replaced with the actual visit date of the visit associated with the record. This is indicated by ADTF = "Y".</i>

Novo Nordisk defined content

Take Away Messages

- Own it – create your own template
- Integrate the work into your processes
- Educate your programmers in the art of technical writing

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