



Prepare Data and Mapping for Tx Datasets

AN UNRIVALLED COMBINATION OF SCIENCE AND PROFESSIONAL
CLINICAL CONDUCT.

WE DELIVER SOLUTIONS.

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Agenda

1 Fragestellungen

2 Aktuelle Implementierung bei Profil



Fragestellungen

■ Wer

- Verantwortung
- Ausführung
- Review/Approval

■ Wie

- Trial protocol
- Excel sheet
- eCRF basiert
- Other database frontend

Agenda

1 Fragestellungen

2 Aktuelle Implementierung bei Profil

Aktuelle Implementierung bei Profil -Wer?



Verantwortung

- Project Development
- Data Management

Ausführung

- Project Development
- Data Management
- Statistik

Review/Approval

- Principal Investigator (Coordinating Investigator)
- Sponsor
- Project Development
- Data Management
- Statistik

Aktuelle Implementierung bei Profil -Wie?



- ◆ Excel Datei (Abbild der Trial Design Domains)
 - ◆ Ausgefüllt vom Datenmanagement
(eindeutige Informationen aus dem Prüfplan)
- ◆ Word Datei
 - ◆ Ausgefüllt von Project Development und Statistik
 - ◆ Datenmanagement unterstützt und überträgt in Excel Datei
- ◆ Studiendatenbank
 - ◆ Import durch Datenmanagement

Aktuelle Implementierung bei Profil -Wie?



2 → Trial-Inclusion/Exclusion-Criteria-(TI)¶

→ Table is not applicable as length of all Inclusion/Exclusion criteria (including dosing day exclusion criteria and withdrawal criteria) is below or equal to 200 characters and no special characters are included¶

#¶	Protocol text¶	Text for SDTM (Shortened / without special characters)¶
Inclusion criteria.....¶ -NA¶		
INCL01¶	¶	¶
...¶	¶	¶
Exclusion criteria.....¶ -NA¶		
EXCL01¶	¶	¶
...¶	¶	¶
Dosing Day Exclusion criteria.....¶ -NA¶		
DDEXCL01¶	¶	¶
...¶	¶	¶
Withdrawal criteria.....¶ -NA¶		
WEXCL01¶	¶	¶
...¶	¶	¶

Aktuelle Implementierung bei Profil -Wie?



3 → Trial-Elements-(TE)

Element-Code	Description-of-Element	Rule-for-Start-of-Element	Rule-for-End-of-Element	Epoch
SCREEN	Screening	Informed consent	Admission to trial site at visit 2	SCREENING
RUNIN1	Run-in before randomisation	Admission to trial site at visit 2	Randomisation	SCREENING
RUNIN2	Run-in between randomisation and first trial drug administration	Randomisation	First trial drug administration	FIRST-TREATMENT
...
...
...

Aktuelle Implementierung bei Profil

-Wie?



4 → Trial-Summary-Information-(TS)

Trial-Summary-Parameter	Parameter-Value	Parameter-Code	Value	Reference-Terminology	Comment
Clinical-Study-Sponsor				DUNS	Code-to-be-obtained-from: https://www.upik.de/en/upik_suche.cgi
Trial-Indication				SNOMED-CT	Code-to-be-obtained-from: http://browser.ihtsdotools.org/
Diagnosis-Group-NA				SNOMED-CT	Code-to-be-obtained-from: http://browser.ihtsdotools.org/
Pharmacologic-Class				NDF-RT	Code-to-be-obtained-from: https://ncit.nci.nih.gov/ncitbrowser/pages/vocabulary.jsf?dictionary=NDFRT
Investigational-Therapy-or-Treatment				UNII	Code-to-be-obtained-from: https://fdasis.nlm.nih.gov/srs/
Comparative-Treatment-Name-NA				UNII	Code-to-be-obtained-from: https://fdasis.nlm.nih.gov/srs/
Added-on-to-Existing-Treatments	Yes-/No		Not applicable	Not applicable	Addon-is-defined-as: The-addition-of-a-therapeutic-product-to-the-existing-regimen-in-a-clinical-trial,-where-



Thank you very much!