

# **SDTM aCRF Guideline Team**

## **Status Summary**

# aCRF Guideline Team – Status Summary

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- aCRF Subteam Setup
- Collaboration + Approach
- Current Status

# aCRF Guideline Status – Team Setup

2017-06-02	Kick-Off Meeting
➤	Wahl Organisator und Stellvertreter
➤	Grundlegende Ziele
➤	Nächsten Schritte
➤	<b>Homework</b> - Quellensuche

Team	
Christina Paul (Grünenthal)	Petra Rein (Parexel)
Eva Bervar (Bayer)	Stefan Bordasch
Markus Stoll* (Merck KGaA)	Steffi Sturm** (HMS Analytical)
Michael Schmitz (Bayer)	Torsten Petsching (Böhringer-I.)
Nicola Tambascia (Clinipace)	Walter Stöttner (Roche Diagnostics)

(\*Organisator und \*\*Stellvertreter)

# aCRF Guideline Status – Approach

## 2017-07-07 - 1<sup>st</sup> Arbeitsmeeting

- Auswertung Quellenliste
- Nächsten Schritte
- **Homework** – Quellenanalyse + Summary

## Dursuchte Quellen

FDA	EMA
PhUSE	ODM-XML
CDISC	TMF
PMDA	Other existing Guidelines

# aCRF Guideline Status

2017-08-25 - 2<sup>nd</sup> Arbeitsmeeting

➤ **Diskussion: Inhalt, Struktur, Gliederung**

➤ **Homework – Consolidation**

## Contents

1. Purpose
2. Glossary
3. Prerequisites / Requirements
4. Format
  - PDF Format
  - Color coding, format
  - Page Numbering
  - Naming Conventions
5. Bookmarks
6. TOC

## 7. Annotations

- General Assumptions
- Domain Level
  - Location of annotations
  - CAT, --SCAT
- Element Level
  - Date / Time fields
  - TESTCD
  - SUPP-
  - GRPID
  - SPID, --TPT, --SPDC1
  - Ongoing
  - NOT SUBMITTED
  - Annotations
  - MedDRA Coding
  - OTHER
  - Not Done / --REASND
  - Prespecified Events

## Controlled Terminology

- FINDINGS ABOUT
- RELREC
- Questionnaires
- External Data

## 8. Ongoing Trials

## 9. Special Cases

- Update Process
- Versioning
- Legacy Data

## 10. Tumor Domains

## 11. Version History

# aCRF Guideline Status – Feedback Session

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**FAQ's...**

**Inhalte die Fehlen?**

**Erwartungen?**

**Anregungen, Tipps, weitere Quellen?**

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# Thank You

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