

Details zu Anfahrt unter der Agenda im Dokument: [27th German CDISC UN Agenda_2018-08-17.pdf](#)

Details zum Meeting am Vorabend und Unterkunft: [CDISC Ludwigshafen Hotelauswahl und Vorabend.pdf](#)

Presentations:

[27th DACH CDISC UN Meeting Presentations.zip](#)

Agenda - 27th German CDISC User Network Meeting

(Version 2018-08-17)

Date:	25. September 2018	
Location:	AbbVie Deutschland GmbH & Co. KG Knollstrasse 50 67061 Ludwigshafen Bau 71 / Raum 301	Kontakt: Anja Kreis anja.kreis[at]abbvie.com Admin: Martina Berroth martina.berroth[at]abbvie.com
Time	Topic	Who
9:30	Registration	All
10:00	Welcome and introduction to AbbVie	Anja Kreis Kurt Hellstern
10:10	ISS – Integrated Analysis (integration where, how – experiences gained within a project)	Petra Rein
10:40	ISS – Metadata Handling in Define.xml	Judith Köppert
11:10	Break	
11:30	Discussion: Define.xml Process	Sabine Erbslöh, Susanne Bracht
12:30	Lunch and Get-Together	
13:30	Use of MDR/SHARE (set-up, integration with SHARE, how is it used, benefits, user feedback)	Michael Walter, Anja Kreis
14:15	An update on CDISC SHARE and how to use it	Frederick Malfait
15:00	Break	
15:30	Update to the FDA Technical Conformance Guide Discussion: Collection of Protocol Deviations (eCRF, external File, Derived) which deviations belong where (SDTM/ADaM) Converting original results using UCUM webservice Other topics to come along	Marion Friebel Dennis May Nicola Tambascia All
16:15	CDISC User Group Discussion • Annotated CRF Working Group update • Going Live with the new GUN Wiki • Break-out sessions to be planned for the next Meeting? • CDISC News / Regulatory Updates • Topics of interest • Next meeting / Meeting / Closing remarks	All Markus Stoll Markus Stoll
17:00	Meeting end	

