

## Location:

Parexel International GmbH

Am Bahnhof Westend 11

D-14059 Berlin

-> Building 11

## Time and Date:

March 6th 2019

Start: 9:30 a.m.

End: approx. 5 p.m.

Details about the Meeting Location, Team Dinner, Tipps for Travel and Accomodation and the Agenda topics: [Agenda 28th DACH UN Meeting](#)

Time	Topic	Who
9:30	Registration	
10:00	01 Welcome and introduction to Parexel	Jens Fischer Kurt Hellstern
10:10	02 CDISC Proof of Concept: Evolving our standards towards end to end automation	Peter Van Reusel
10:55	Discussion	
11:10	Break	
11:30	03 End-to-End in my Company Don't we all pursue a step by step approach? How far are we on this way? Experience exchange	All - Petra, Michael, Chantal, Torsten, (Anja), (Markus) (Bitte max auf 1 oder 2 Slides)
12:30	Lunch and Get-Together	
13:30	04 An update on CDISC SHARE and how to use it	Frederik Malfait
14:30	Medical Informatics Initiative (MII): Core Data Set as Basis for Recruitment for Clinical Trials in Germany's University Hospitals	Christian Gulden (i.A. TMF)
15:00	Break	
15:30	05 <del>CDISC Primer</del> (Agreed to be rescheduled in the meeting due to time constraints) Working Group Homepage: <a href="https://www.phusewiki.org/wiki/index.php?title=CDISC_Implementation_Primer">https://www.phusewiki.org/wiki/index.php?title=CDISC_Implementation_Primer</a>  CDISC related PhUSE working groups	<del>Beate Hentze</del>  Hasan Kantarci
16:00	06 Regulatory Updates /FDA Technical Conformance Guide	Marion Friebel
16:15	07 CDISC User Group Discussion <ul style="list-style-type: none"><li>• Overview SDTM IG 3.3 Updates</li><li>• Annotated CRF Working Group update</li><li>• Feedback: How is the GUN Wiki doing?</li><li>• Topics of interest</li><li>• Next meeting / Meeting / Closing remarks</li></ul>	All – Petra Markus Stoll Markus Stoll
17:00	Meeting end	

## Presentations:

20190306\_CDISC GUN 02 - CDISC360 - CDISC - PvReusel.pptx

20190306\_CDISC GUN 03 - E2E-01 - PAREXEL - ReinPetra.pptx

20190306\_CDISC GUN 03 - E2E-02 - Roche -MWalter.pptx  
20190306\_CDISC GUN 03 - E2E-03 - Profil - Chantal.ppt  
20190306\_CDISC GUN 04 - CDISC Share Update - FMalfait.pptx  
20190306\_CDISC GUN 04 - MII\_Patient\_Recruitment - TMF - CGulden.pptx  
20190306\_CDISC GUN 05 - PhUSE WG Update 01 - CDISC Implementation Primer Project - BHientsch.pptx  
20190306\_CDISC GUN 06 - TechConfGuide Updt - PAREXEL - MFriebel.pptx  
20190306\_CDISC GUN 07 - UN-Discussion-01 - PAREXEL - OccurrenceFlagsInADAE - JReiher.pptx  
20190306\_CDISC GUN 07 - UN-Discussion-02 - PAREXEL - SDTMIG 3.3 Updates - PRein.pptx  
20190306\_CDISC GUN 07 - UN-Discussion-03 - aCRF-Subteam-Status and SDTM-Wiki - MStoll.pptx