

# Agenda 30<sup>th</sup> Meeting

## German CDISC User Network

**Date:** 14. March 2023

**Location:** mainanalytics GmbH  
Otto-Volger Str. 3c  
65843 Sulzbach Ts.

**Kontakt:**  
[katrin.besch@mainanalytics.de](mailto:katrin.besch@mainanalytics.de)

Time	Topic	Who
9:30	Registration	All
10:00	Welcome and introduction to mainanalytics	Beate Hientzsch, Markus Stoll
10:10	Focus Session <ul style="list-style-type: none"> <li>• FDA CDISC Standards “requirements” in 2023               <ul style="list-style-type: none"> <li>○ Define-XML v2.1 - What’s New</li> <li>○ Technical Conformance Guide – Updates?</li> <li>○ SDTM-IG v3.3 / v3.4 - What’s New                   <ul style="list-style-type: none"> <li>▪ SV</li> <li>▪ LB/MB/IS</li> <li>▪ GF</li> <li>▪ xxx (more ?)</li> </ul> </li> </ul> </li> </ul>	Steffen Müller <b>Volunteer?</b>  <b>Volunteer?</b> <b>Volunteer?</b> <b>Volunteer?</b> <b>???</b>
11:15	Break	
11:30	Continue CDISC Standards discussion... <ul style="list-style-type: none"> <li>• FDA vs PMDA - Discussion</li> <li>• CDISC Outlook 2023               <ul style="list-style-type: none"> <li>○ Expected updates</li> </ul> </li> </ul>	All  All  <b>t.b.d.</b>
12:30	Lunch and Get-Together	
13:30	CDISC COSA Initiative <ul style="list-style-type: none"> <li>• COSA Introduction               <ul style="list-style-type: none"> <li>○ Tool Presentation</li> </ul> </li> </ul>	Markus <b>Volunteer(S)?</b>
14:15	DEUN UG TOI-Initiative - Tools of Interest Presentations <ul style="list-style-type: none"> <li>• Status + Outlook 2023</li> </ul>	Markus
14:30	CDISC Library for Dummies – First Steps <ul style="list-style-type: none"> <li>• Data Standard Browser</li> <li>• API Remote Access – How To</li> </ul>	<b>Volunteer</b> <b>Volunteer</b>
15:00	Break	
15:30	CDISC - Hidden Details <ul style="list-style-type: none"> <li>• COVID-TAUG               <ul style="list-style-type: none"> <li>○ SDTM</li> <li>○ ADaM Component</li> </ul> </li> <li>• CT Relationships</li> <li>• Dictionaries in define.xml               <ul style="list-style-type: none"> <li>○ Define CT</li> </ul> </li> <li>• LB domain History</li> </ul>	<b>Volunteer?</b> <b>Volunteer?</b>  <b>Volunteer?</b>  <b>Volunteer?</b>  <b>Volunteer?</b>

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16.15	CDISC User Group Discussion <ul style="list-style-type: none"><li>• Poll - Usergroup Steering Committee</li><li>• Topics of interest</li><li>• Next meeting / Meeting / Closing remarks</li></ul>	Markus Stoll and all
17:15	Meeting end	

## Anfahrt:

Sag Google Maps oder Deinem Navi:

Otto-Volger Straße 3c, 65843 Sulzbach (Taunus)

Oder nutze diesen Link (Google-Maps): <https://goo.gl/maps/aNaP9v94VMausUJh6>

## Parken

Bitte suchen Sie sich einen öffentlichen Parkplatz. Möglichkeiten finden Sie in den Straßen

- Otto-Volger-Straße
- Oberliederbacher Weg
- Im Haindell
- Am Limespark

## Anreise mit Bahn:

Nächster Halt – Sulzbach(Taunus) Bahnhof, von dort Fussweg ca. 900m (12-15 Minuten)



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## Hotelempfehlungen

### Sulzbach

Dorint

<https://hotel-frankfurt-sulzbach.dorint.com/de/>

Landhotel Sulzbacher Hof

<https://www.sulzbacher-hof.de/>

### Bad Soden

H+ Hotel

<https://www.h-hotels.com/de/hplus/hotels/hplus-hotel-bad-soden/hotel>

Hotel Rheinischer Hof

<http://rheinischer-hof.com/de/>

Milbor Hotel

<http://milbor-hotel-bad-soden.de/de/>

## Vorabend Event/Abendessen:

**ab ca. 18.30 t.b.updated**

## Anmeldung/Registrierung:

Per Email unter: [katrin.besch@mainanalytics.de](mailto:katrin.besch@mainanalytics.de)

Für Event "CDISC DEUN Usergroup Meeting"