02 Feb 2023 - Core Committee Meeting

01 December 2023   16:17

AGENDA

1. Update on items from the last meeting
   - Community charter updates — **Munish/Stephen**

2. Community plans for 2024

3. Conference discussion

4. Thanks to Matt Baldwin

Meeting Notes

Meeting started with an introduction of core committee to new members.

1. Charter
   Committee were reminded that the charter was out for comments following Stephen's updates to align with the new roles and the latest CLC guidance document
   Deadline for comments set for Feb 15, 2024 and if no comments are received by that date then the document will be finalized

2. Goals for 2024
   Munish discussed the 2024 goals document for the community
   The committee discussed the existence of working groups within DIA and recalled the changes to DIA policy that has lead to these working groups moving away from DIA

   Munish worked through the goals for the year and sought volunteers for presentation, webinar etc. Involved discussions on potential topics and speakers. The Community planning document for DIA was updated in real time and people to organize events were identified.

   Discussions on webinars vs community shared presentations

Shared Learning Presentations
Shared Learning Presentations are one of many tools Community leaders use to disseminate information to Community members. These presentations are an effective means of engaging Community members for discussion on discipline-specific issues.

Shared Learning Presentation Guidelines:
- Shared Learning Presentations are **not** training, workshops, or conferences/meetings. They cannot conflict with DIA educational programming delivered through the DIA conference or training course portfolio, implemented as part of DIA's mission.
- If a Shared Learning Presentation conflicts with DIA educational programs, the Community/Working Group will work with DIA staff to resolve the conflict, which could include rescheduling the Shared Learning Session, etc.
- Shared Learning Presentations should not exceed 90 minutes and should focus on the discussion of a topic, concentrating on questions and answers.
- A variation is to develop a Shared Learning topic around a journal article, creating a Journal Club session. The article is shared in advance with Community members on the Community platform so that they can read the article before the call. A presenter summarizes the journal article in a slide deck, and the presenter or a designated member then facilitates a group discussion on the content.
- Shared Learning Presentations are a DIA community member benefit. Participants must be DIA members. The Community must not open Shared Learning Presentations to non-DIA members.
- DIA and its Board of Directors places a high priority on maintaining a neutral forum for knowledge exchange. As such, it is critical that all Community events adhere to DIA's neutrality policy. DIA requires speaker presentations to be noncommercialized, objective, and fairly balanced. Company names, logos, or other images that may be considered as promotional in nature are not permitted to be included in Shared Learning Presentations. Speaker clothing and backgrounds may not carry logos or other company-specific emblems. Presenters are required to deliver their presentation in accordance with *DIA's Policy Concerning Promotion of Products and Services From the Podium* (see below). This can also be found in the CLC Library for reference.
- Presenters must utilize the DIA Communities PowerPoint Template for Shared Learning Sessions, or to alternatively use a generic, unbranded template. The DIA Communities PowerPoint Template can be found in the CLC Library.

Stephen Wilson noted that looking at our plans for 2024 would be ideal opportunities to collaborate with groups within DIA. An example of risk based monitoring was given. Further discussion was given to the need to seek opportunities with other DIA communities who can provide access to speakers.

Munish mentioned that the document that was updated will be tidied up to give DIA a high level summary of our activities.

3. Greg Ball mentioned the Pharma DS conference in march at the University of Connecticut
   PharmaDS 2024 : Home (nestat.org)

4. Stephen led a thank you to Matt Baldwin for all his help and support with DIA and the community.

CORE COMMITTEE
- ☑ Chair: Munish Mehra
- ☑ Stats Vice Chair/Communications Lead: Stephen Corson
- ☐ DS Vice Chair: Michael Elashaoff
- ☐ Secretariat: Philip He
- ☑ Reg Chair (China): Jingjing Ye
- ☑ Education/VJC: Li Wang (Qu Yongming)
- ☐ Liaison/Membership/Social: Yeh-Fong Chen
- ☑ Backup for Education/VJC: Xiaotian Chen
- ☑ Education/VJC: Qu Yongming
- ☑ New Member -Timothe Menard
- ☑ New Member Jie Shen

ADVISORS
- ☑ Jerry Schindler
- ☐ Bill Wang
- ☑ Steve Wilson
- ☐ Faisal Khan
- ☐ Freda Cooner
- ☐ Joan Buenconsejo
- ☐ Ruthie Davi
- ☐ Brenda Crowe
- ☑ Greg Ball
- ☐ Jon Haddad
- ☑ Matt Baldwin

Date	Core Committee Lead	Topic and Notes
4 Feb 2024	Greg Ball	Short Course "Aggregate Safety Assessment Planning Process" at PV meeting - To educate individuals to implement ASAP process across their organizations
28 Feb 2024, 10 AM ET	Li	Webinar or Understanding Estimands framework – Applications in multiple therapeutic areas (Annie)
4 or 5 additional Webinars	Li	Dates and Topics TBD (will also cover safety, Deep learning, ML, Visualization, Digital endpoint), Li to provide by end of the month
TBD	Yongming	Topic on decentralized clinical trials,
TBD	TBD	Data Sc. topic, Li (From Beigene)
TBD	TBD	Topic RWD, RWE – December registry guidance (has QBD)
March 2024	TBD	Topics from Pharma-DS Conf at UConn. https://phds.nestat.org/index.html
April 2024	Yeh-Fong to provide update	DISS – Duke Conf. https://sites.duke.edu/diss/ - Program is final. Can submit posters – Registration fee will be waived
May 2024	Those attending can provide update	DIA Regulatory-Industry workshop – Munish on program committee. Who else plans to attend? Munish can share key topics – This year Clinical Ops is added as a track
	TBD	FDA Stats Guidances for last two years – Covariates adjustments, etc.
	TBD	EMA HTA Guidances
	Yeh-Fong	Innovative designs and analyses for rare disease clinical trials – Bayesian designs
16-20 June 2024, San Diego	All	Munish is track chair (last year). Susan is also track chair and this is her last year. Pallavi from FDA is also a co-chair. We have 9 allotted slots. 1 Forum, 2 Workshops and 6 Sessions. https://www.diaglobal.org/en/flagship/dia-2024/program/schedule/agenda
	Timothe	TBC for the June Global Meeting, Possible panel discussion with EMA/FDA on AI
July 2024	Munish	Improving protocol design using Estimands – Summary of annual meeting short course - Cross functional (with CR, MW, PM)
Aug 2024	Stephen	Webinar on Study design considerations
Sept 2024	Timothe	Why data ethics matters to data scientists / data practitioners

From <https://phastar1-my.sharepoint.com/personal/stephen_corson_phastar_com/Documents/Attachments/Annual%20DIA%20Statistics%20and%20Data%20Sc.%20Community%20Core%20Committee%20Call%202%20Feb%202024%20Notes.docx>