**Core Committee Call: 1 September, 2023, Noon US ET**

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| **Core Committee Members** | **Advisors** |
| Chair: Munish Mehra | Jerry Schindler |
| Stats Vice Chair/Communications Lead: Stephen Corson | Advisor: Bill Wang |
| DS Vice Chair: Michael Elashaoff | Advisor: Steve Wilson |
| Secretariat: Philip He | Advisor: Faisal Khan |
| Reg Chair (China): Jingjing Ye | Advisor: Freda Cooner |
| Education/VJC: Li Wang | Advisor: Joan Buenconsejo |
| Mem/Social: Yeh-Fong Chen | Advisor: Ruthie Davi |
|  | Advisor: Brenda Crowe |
|  | Advisor: Greg Ball |
|  | Advisor: Jon Haddad |
|  | Advisor: Susan Wang |
|  | Advisor: Matt Baldwin |

**AGENDA**

1. VJC on Pediatric Therapeutic Development on 8th September 10:30 AM to Noon EST – [For more information click here](https://www.linkedin.com/posts/dia-statistics-and-data-science-52922a1ab_innovations-in-pediatric-therapeutics-development-activity-7099292067670962176-Hnhq/): - **Stephen Corson, Li Wang**
2. Implementing Estimands in CDISC – PHUSE effort – **Matt Baldwin**
3. ASAPprocess Webinar 3 – Overall Safety Assessment – AE Grouping for Assessment of Safety Topics of Interest - 14 September 15:00 – 16:30 (BST) 10:00 – 11:30 (EDT) <https://advance.phuse.global/pages/viewpage.action?pageId=80806060> - **Gregg Ball**
4. DIA 2024 Global Annual Meeting Call for Abstracts went out on 2nd of August – Abstracts are for Sessions only and due by 14th September. Our **Statistics Track was renamed Statistics & Data Sciences Track** to align with our community. See email below for types of abstracts and how to submit – PLEASE SUBMIT ABSTRACTS AND ENCOURAGE OTHERS WHO YOU KNOW ARE GOOD PRESENTERS/ORGANIZERS TO DO SO TOO. For 2023 we did not get enough good abstracts – **Munish Mehra, Susan Wang, Mike Elashaoff (Track chairs) in addition to Pallavi Kalyani-Mishra, FDA**



Would be good to see examples. Phil will send link to Fouda’s book of examples.

1. AI/ML Webinar Series Plans – **Phil He**

Waiting for PHUSE kickoff meeting. Will plan a seminar later this year.

1. Action Items from past meeting - **Munish**
   1. Writeup of Stats Data Sc. Community for BSWG Newsletter – Munish – Draft circulated to Matt, Joan, Stephen and Freda for feedback
   2. Invite additional member to join Stats and Data Sc. Core Commmitee as backups for key roles – All/Munish
2. ASA BioPharma - 27-29 September in Rockville, MD <https://ww2.amstat.org/meetings/biop/2023/> - **Munish**
3. Yeh-Fong, Munish (most likely), Jerry, Phil, Matt (Maybe for dinner), Faisal (maybe for dinner)
4. Social Committee update (Should we plan something on 28th September during ASA BioPharm? – **Yeh Fong -**
5. Updates from Other Core Committee members – All
6. Any other items for discussion – All

**Other Committee Members:**

Mem/Social Comm Guest: Isaac Fwemba

Mem/Social Comm Guest: Helen Li

Mem/Social Comm Guest: Pradeep Dass

Education Comm Guest: Feifan Zhang

Education Comm Guest: Zhuoran Wu

Education Comm Guest: Nicole Li

Education Comm Guest: Yute Wu

Education Comm Guest: Doug Milikien

**See Minutes below for summary from 1st September and earlier meetings including 7th July meeting. Meeting on 4th August only had few individuals attend where we shared our experience from the 2023 June Annual meeting held in Boston which we all felt was a successful meeting.**

**ACTION ITEM**

Munish confirmed in Charter and based on recommendations from other Core committee members will invite Xiaotian to join Core Committee and help as Li's backup for VJC & Educational Committee

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| **Minutes** | | |
| **VJC & Educational Committee (Li Wang)** | **From 1 Sept 2023 Minutes**  83 people registered as of today for Pediatric Therapeutic Development  – [For more information click here](https://www.linkedin.com/posts/dia-statistics-and-data-science-52922a1ab_innovations-in-pediatric-therapeutics-development-activity-7099292067670962176-Hnhq/) | |
| **Implementation of Estimands (Matt Baldwin)** | Two sub teams 1 for data collection and tabulation who are done. Sub team 2 is for analysis and reporting. First draft for internal PHUSE team review on 5th Sept. For wider group it will come out Q4. It’s a 30 to 40 page document. Have had posters at Conferences. Uses an example on MDD (Major Depressive Disorder) that was published. CSS is in Maryland in September. CDISC interchange is in October in VA (DC area) | |
| **PSAP and ASAPprocess Webinar Series** (Gregg Ball) | **1st September Meeting**  Over 200 attendees on 1st meeting and over 100 on second. Expect over 100 on one on 14th. The upcoming session will include FMQ’s and will build to next one which will be on using interactive safety graphics for regulatory decision making. Leveraging technology.  **7th July 2023 Meeting:**  Greg indicated the first session on 15th June was very well attended and there was a lot of interest at the Global Annual meeting last week. Excellent participation and leadership from FDA and industry. Next webinar is 13th July. See below for more details.  **From 2 June 2023 Meeting:**  **Links for Series and registering for first webinar**  <https://advance.phuse.global/display/WEL/Safety+Analytics+Webinar+Series%3A+Interdisciplinary+Safety+Evaluation+for+Learning+and+Decision-making>  <https://advance.phuse.global/display/WEL/Scientific+Evaluation+of+Safety+Data+and+Aggregate+Safety+Assessment+Planning+for+IND+Safety+Reporting>  Gregg provided an update on below which is organized and promoted by PHUSE, ASA and DIA using PHUSE’s platform. KoLs from industry, regulatory aagencies etc. representing Stats, Clinical, PV, etc.    **From 5 May 2023 Minutes:**  Interdisciplinary Safety Evaluation for Learning and Decision making  The webinar series is being co-promoted by ASA Biopharm, DIA Communities, and PHUSE. We should be able to start promoting the whole series this Friday. And we will promote each webinar a month or so before each event (with an abstract). Below will use PHUSE for registration and organizing the meetings etc.  **Final Schedule:**  • June 15; 10:00-11:30 ET: Scientific Evaluation of Safety Data and Aggregate Safety Assessment Planning for IND Safety Reporting  o Greg Ball (ASAPprocess), Brian Waterhouse (Merck), Barbara Hendrickson (University of Chicago), and Jacqueline Corrigan-Curay (FDA)  • July 13; 10:00 – 11:30 ET: Overall Safety Assessment – Standard Safety Tables and Figures  o Mary Nilsson (Lilly) Jim Buchanan (Covilance), and Veronica Pei (FDA)  • September 14; 10:00-11:30 ET: AE Groupings for Assessment of Safety Topics of Interest  o Mac Gordon (Janssen), Peg Fletcher (MedAssessment), and Scott Proestel (FDA)  • October 12; 10:00-11:30 ET: Interactive Safety Graphics for Regulatory Decision making  o Jeremy Wildfire (Gilead), Emma Jones (Veramed), and Mat Soukup (FDA)  • November 16; 10:00-10:45 ET: Education for Executives  Greg Ball (ASAPprocess), Sheila Mahoney (LifeSciHub), Barbara Hendrickson (University of Chicago), and Jacqueline Corrigan-Curay (FDA) | |
| Global Annual Meeting Update | **7th July 2023 Meeting:**  Greg, Jerry, Joan, Matt, Michael, Stephen, Munish attended:  It was a great multi-disciplinary meeting with lots on AI/ML (Part hype and part real. Traditional statistical methods using Bayesian, Regression, Modelling called AI when it’s not. Likely will see more on Large Language Models and Generative AI’s in future meetings), Pt Engagement, Diversity, Decentralized trials. Over 6000 attendees. Mix of new and old exhibitors. Not as many large exhibitors – some large companies like Oracle, IBM and large CROs were not there. There were signs in front of booths for first time exhibitors and those exhibiting 10+, 20+ years. There were also buttons for attendees to indicate 10+, 20+ year members.  Quality of sessions on Estimands was mixed. A small number of people doing great work. Many people don’t have a clue. We briefly discussed Estimands for safety. Division by division discussion on Estimands are taking place at FDA.  A new by invitation session of round tables with 3 structured posters with steps to follow to identify challenges and problems, distill to a few that should be solved, who all should be involved, what are impediments, how can DIA facilitate solving. Gregg attended one. Munish attended one on AI/ML and another on ALS. The latter was very helpful and included Head of Neurology from MGH, representatives from C-Path, Sponsors with approved and products in development for ALS. DIA will follow-up with next steps. Book on AI/ML applications in drug development:  <https://www.taylorfrancis.com/chapters/edit/10.1201/9781003107323-6/ai-ml-medical-research-drug-development-amir-nikooienejad-haoda-fu>  There were sessions on Pt Engagement – good attendance by patients  PSAP ASAP sessions went very well FDA industry session on Standard Safety Tables and FMQs  Stats Round Table led by Joan and supported by Greg, Stephen and Munish went very well with over 90 people in attendance.  Susan mentioned complexity of dealing with safety for rare diseases with small datasets. There is a conference on Rare Diseases Statistics in October in NJ. See details in email below.    PHUSE has expanded from just software to broader collaboration across industry, regulators, etc. <https://phuse.global/> has on their website “The Global Healthcare Data Science Community - Sharing ideas, tools and standards around data, statistical and reporting technologies”  PhRMA (Previously PMA) does not seem as active.  DIA, PHUSE, SCDM, ASA-BioPharm all allow FDA industry exchange of learnings.  **2nd June 2023 Meeting:**  **Munish:** There was a cancellation on the person chairing the session on AI/ML in the Stats track. **Michael Elashoff** stepped in and has organized the session.  **Stephen:** Interpreting Statistical Concepts for Non-Statisticians and Half day course.  **Joan** will holding a round Table on Demystifying Statistical Concepts  **Gregg:** Has a couple of sessions. With Mack Gordon on going from PSAP to ASAP. Another session on operationalizing the Standard Safety TFs and FMQs. Also has a round table after the session. Another session on AI in Safety that Gregg will chair. FDA is partnering with industry on FMQs. It is not a guidance so no requirement, but how FDA is looking at it. Good to look at it. Document is informational for industry. It can become part of labeling discussion. Document should be considered for ISS. Hard part is coming up definitions. FMQ’s came up because SMQ’s were inadequate. Each company has their own versions so useful to see what is FDA seeing across submissions. Scott and Veronica are right people and in DIA sessions. They will also be presenting in the Webinar series. Knowledge of safety planning is important. Developing points to consider in implementing FMQs.  **Matt:**  *Real-World Data Standards and Protocol Designs for Information Exchange and Data Flow*: [https://sched.co/1H1WB [sched.co]](https://sched.co/1H1WB%20%5bsched.co%5d)  **Matt/Munish:** Estimands. Survey on CDISC implementation of Estimands, Intercurrent Events as part of ICH E9R1 (PHUSE effort)  Marion will present details of implementation  Jon is working on implementation in safety and RWD (bias control) – Jon will share link. | |
| Core Committee Meetings Going Forward | **From 2 June 2023 Meeting:**  DIA will open the meetings going forward  **Ankur updated meeting in DIA’s platform. It was set at 1 PM on first Friday.**  Below are useful links on Communities Platform to view quick start guide and for your settings to receive notifications from DIA (Default due to GDPR and limiting PII is for not getting any notifications)  **Quick Start Guide:** [**https://communities.diaglobal.org/viewdocument/dia-community-quick-start-guide-1?CommunityKey=6f5d66a7-a0b8-4ecb-82e9-01847c313bfd&tab=librarydocuments**](https://communities.diaglobal.org/viewdocument/dia-community-quick-start-guide-1?CommunityKey=6f5d66a7-a0b8-4ecb-82e9-01847c313bfd&tab=librarydocuments)  **Setting your Notifications -** [**https://communities.diaglobal.org/profile/myaccount/my-settings?section=subscriptions**](https://communities.diaglobal.org/profile/myaccount/my-settings?section=subscriptions) | |
| DIA Global Inspire Award | **From 2 June 2023 Meeting:**  The Committee congratulated Stephen on being recognized at receiving the Global Inspire Award. There will be a dinner (paid) at annual meeting to recognize Stephen. | |
| Success Stories in AI/ML in Pharma Industry – Phil He | **From 2 June 2023 Minutes:**  Munish connected Phil with Katie Warren at PHUSE  **FDA recently published a concept paper on AI/ML**  **It has a long list of items**  For more details see: <https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-machine-learning-aiml-drug-development>  **From 5 May 2023 Minutes:**  Plan one session this year – For AI/ML Matt asked who is our audience? What will be the involvement outside DIA? What is the overall strategy of what our community is trying to target? Phil indicated that the audience will be cross-functional and not Stats. Munish indicated we should share role of Statisticians in use of AI/ML and tools that have emerged (GPT) in drug development. Phil indicated that it is important to show real examples that have helped in drug development. Lilly has been working in this area including handling digital Biomarkers. AZ has advances in images. Faisal used to be at AZ. Can check with Faisal and Joan. Joan is organizing a conference. Susan indicated her company has also worked on digital biomarkers. Did proof of clinical principle. Data privacy. Copyrighting issues. Can think of use cases and test on dummy cases. Proprietary data can be used outside of companies. | |
| Additional Topics | **2nd June 2023 Meeting:**  An additional good publication on Estimands was recently published in TIRS and is open access. See: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10224760/>  Matt is active in PHUSE [Implementation of Estimands (ICH E9 (R1)) using Data Standards](https://advance.phuse.global/display/WEL/Implementation+of+Estimands+%28ICH+E9+%28R1%29%29+using+Data+Standards) project team that will expand on estimands 1 and 3 of the above paper for implementing in data standards. This will be an end to end (protocol, CRFs, SDTM, cSDRG, SAP, ADaM, ADRG) example in a white paper that will be out for public review by the end of 2023Q3. | |
| Update on Core Committee members and Open Positions | **From 5 May 2023 Minutes:**  Munish requested other Core Committee members to volunteer for the Vice Chair role or suggest others. Munish will also be reaching out to other DIA members to join Core Committee in this or other roles  Freda spoke to Meghann about a separate Zoom account for BSWG. BSWG and IDSWG will be a separate Community channel and will require individuals to be DIA members. Since many WG members are not DIA members, this will be challenging. DIA Zoom account calls can’t be used for non-DIA members. Still being worked out. Some things require DIA membership and not others. Was more flexible in the past. Zoom allows anyone with link to participate. Communities page is only accessible to DIA members. Additional roles with capabilities being developed by DIA.  **From 3 May 2023 and prior minutes:**  Ram and Juergen decided not to continue on the core committee.  Faisal will continue as an Advisor.  Vice Chair to back up Chair and help with Core group on logistics, Agenda, Minutes. The Stat Vice Chair position is open  Data Sciences Vice Chair is also open. Looking for someone who can strategically set direction, bring in speakers etc. for application of AI/ML in medical product development. Munish has spoken to Ruthie and there may be someone who is interested. Barbara and Mike Elashaoff (Former FDA Statisticians) – Data Scientists, especially Mike. [Munish will invite them both to attend next core committee meeting].  VJC is within Education Committee. Jon is looking for a successor. Need someone by September. Susan will discuss with Jon and see if combining the two may be an easier way to manage both. | |
| DIA Communities platform to Higher Logic - All | **From 5 May 2023 Minutes:**  Stephen had a call with Ankur and updated the group that all DIA community calls and presentations etc. will be setup by DIA personnel to be compliant with Zoom policies. Previous sharing of Zoom accounts was in violation of Zoom policies and will not be used any more. Everything will be setup as a Zoom meeting and not as a Zoom Webinar. A Form needs to be filled out. No host needed is. Munish indicated that DIA is updating back end of website so Form will eventually be competed online. The new Zoom policy starts next month and over past months and this month Ankur has met with Community Chairs etc. Attendance at Webinars will be only for DIA members. Individuals will need to register for meetings. DIA will allow topic of broad interest to be open to non-members. Ankur, who reports to Meghann who reports to Katie can be reached to help out. He has been very responsive and helpful. Matt indicated that it was unclear if Community presentations and other content will be put in DIA NOW. DIA NOW basic is free to all members. Materials from conferences is only available to paid DIA NOW membership. Munish will check with Ankur on plan for putting community content in DIA NOW. It would be great to add content from Community presentations. Stephen is managing our content as backup on a Google drive.  **From 3 May 2023 and prior minutes:**  Open House planned by DIA  Some issues with getting notifications and emails from DIA. Not everyone is receiving so planned webinars may be impacted.  Open House for CLC members was held.  Additional are planned for anyone.  We can also invite Ankur to do demo for our Community for 30 min at next meeting. [Munish will follow-up with Ankur and Meghann. Check when open house is for anyone to attend.]  Update on migration to the new DIA Communities platform to Higher Logic (which was the one DIA used prior to Tradewing). [Munish will follow-up with Ankur and Meghan on giving Admin rights to select Core committee leaders and when this will be enabled by].  Contact: Meghann Hartnett | Senior Manager, Digital Solutions, DIA - [meghann.hartnett@diaglobal.org](mailto:meghann.hartnett@diaglobal.org)  Munish offers to orient anyone around the community website if anyone is interested. Please send a message to Munish if interested. | |
| Invitation to contribute to Guest Column of DIA BSWG Newsletter – Freda | **From 5 May 2023 Minutes:**  Freda has been in communication with DIA and indicated BSWG will not work under DIA due to restrictions from DIA. For IDSWG (Innovative Design) Munish needs to check with person who chairs the group.  **From 3 May 2023 and prior minutes:**  Next newsletter in April. After than next newsletter will be in Oct/Nov.  Input to be provided in March.  Action Item: Munish to write an introduction to the community and send Freda – Past due    Not recognized as a DIA Community. Being a Community has different requirements than being a WG.  Develop newsletter every 3 to 6 months  May have more than 2 newsletters this year  Each newsletter has a guest column  Extended invitation to this community and other organizations to write something on collaborations with BSWG. Organize conferences and workshops. Have a lot of collaborations. Or can introduce our community to BSWG.  Find someone early in their career to write something.  [Munish will write something to introduce our community]  Jerry – How do we connect BSWG and other WG’s  WG’s used to be a subset of Communities. Now they tend to be separate. | |
| Recent and Upcoming Calendar | **From 5 May 2023 Minutes:**  Since Matt is transitioning from his role we need to find someone else to update the calendar. Matt maintains on a Google Drive.  Need new volunteer to manage calendar – Matt used to keep 3 months ahead and 6 month in the past  **From 3 May 2023 and prior minutes:**  UPCOMING CONFERENCES:  Statistics:  ENAR Spring Meeting [Sun to Wed, Mar 19-22, 2023, Nashville, TN]  Eastern North American Region - International Biometric Society  <https://www.enar.org/meetings/spring2022/>  Jon plans to attend ENAR meeting  DIA/FDA Biostatistics Industry and Regulator Forum [Wed to Fri, Mar 29-31, 2023, virtual]  <https://www.diaglobal.org/en/conference-listing/meetings/2023/03/biostatistics-industry-and-regulator-forum>  Forum is virtual. Agenda is very strong. Jerry and Li are on organizing committee. Recommend others to attend. Was decided by DIA a year in advance.  Duke-Industry Statistics Symposium [Wed to Fri, Mar 29-31, 2023, virtual]  Empower Clinical Development by Harnessing Data from Diverse Sources  [sites.duke.edu/diss/register](http://sites.duke.edu/diss/register)  Duke symposium is virtual. Yeh-Fong (RWD) and Freda on organizing committee. Ruthie will speak in Yeh-Fong’s session  ICSA in June – Li on Board of Directors  DIA Global Annual Meeting June 25 to 29 in Boston  **Multidisciplinary:**  PHUSE US Connect [Sun to Wed, Mar 5-8, 2023, Orlando, FL]<https://www.phuse-events.org/attend/frontend/reg/thome.csp?pageID=9346&eventID=18&CSPCHD=000004000000gGpPyA5nzHsJ4RwH035c5lz1ejT3ltlQDHOHVr>  Matt is on two PHUSE teams and created recordings that will be available on demand for conferences attendees. Data standards governance and Implementing Estimands in CDISC.  DIA Europe [Wed to Fri, Mar 22-24, 2023, Basel, Switzerland]  <https://www.diaglobal.org/Flagship/DIA-Europe-2023>  Data Sciences Conference - Jingjing, Pritibha, Ruthie and Joan are still pursuing potential Data Science Conference. Still under discussion. Discussed with New England Statistics Society. Have a data sciences day that has been around for 5 years. Hoping to modify Agenda from last year. Will be hybrid.  DIA Community on CDM. How does that fit into Data Sciences. We should consider collaborating with them. DIA Japan DM meeting will be end of February (in-person with some virtual). CDM has put together a panel on RWD/RWE and use of MedDRA. Steve will share information. Mary Banach chairs DIA CDM Community. They are active. Meets regularly. Need a Data Sc. Vice Chair to set the vision. [Matt will see what can be done through liaison] | |
| Liaison Committee  (Matt) | **From 5 May 2023 Minutes:**  Matt will be transitioning out of liaison committee and possibly phasing out by end of year. He is not in a statistician role but in standards. Has had frustrations with DIA since communities don’t seem to be a priority. Working with PHUSE for blogs and knowledge sharing is much easier. There is no cost to join and participant with PHUSE. One just needs to email them and they add you to Teams and you can join various working groups.  If DIA liaison committee is to continue Matt indicated we need to find someone else. Munish will check with Madhurima and Chava if they want to lead.  For below spreadsheet see link from older version of minutes. Can copy calendar to here.    **From 3 May 2023 and prior minutes:**  The liaison committee last met on Feb 22nd to continue developing a **quarterly liaison newsletter**, first edition expected Mar 2023. Latest draft of content is below.    DIA China Statistics Community (Any updates from Jingjing?)  It is about time to propose Feb seminar topics and speakers for the Widen the Horizon and Go Forward Together in Statistics & Data Science series (jointly sponsored by DIA China stat and DIA stat & Data Science Community). Jingjing has not put much thoughts into the topics yet and would like to hear input.  Joined seminar on clinical trials diversity, a joint event with FDA colleagues, 2000+ attendees, Mark presented. Plan to have seminar series Q6W. Call for ideas for the seminar topics. Feel free to connect to Jingjing; e.g., safety graphics, etc. | |
| **Education Committee –**  Upcoming Webinars  **Virtual Journal Club (VJC) - Li** | **From 5 May 2023 Minutes:**   * Success Stories in AI/ML – Update from Phil He – Plan one session this year – For AI/ML Matt asked who is our audience? What will be the involvement outside DIA? What is the overall strategy of what our community is trying to target? Phil indicated that the audience will be cross-functional and not Stats. Munish indicated we should share role of Statisticians in use of AI/ML and tools that have emerged (GPT) in drug development. Phil indicated that it is important to show real examples that have helped in drug development. Lilly has been working in this area including handling digital Biomarkers. AZ has advances in images. Faisal used to be at AZ. Can check with Faisal and Joan. Joan is organizing a conference. Susan indicated her company has also worked on digital biomarkers. Did proof of clinical principle. Data privacy. Copyrighting issues. Can think of use cases and test on dummy cases. Proprietary data can be used outside of companies.     Jon, Li and Susan met twice. They have a good plan for the Education Committee – Seminars in April, May, June, Sept., Oct. – Speakers from FDA and Industry being confirmed. Will have one VJC on 10 August by Tom Fleming and Robert Nelson on Pediatric Drug Development. After that will discuss merging. Li has a spreadsheet. Li will clean and send to Munish to embed here. Susan will send spreadsheet of VJC past meetings that will be embedded here  Education Committee and VJC met and have been merged with Jon, Susan and Yeh-Fong transitioning leadership to Li who has been involved with VJC over the last 10 years  **From 3 May 2023 and prior minutes:**  **2023 Webinars:**  Webinar in Fall  April 13 Webinar on RWD/External Controls  Sue Jane Wang speak on preparing for Advisory Committee  Greg will have one or more on Safety including the FDA FMQ/Standard Tables – Series of 5 Webinars – Jacqueline Corrigan on first session on aggregate safety – kickoff will be a big meeting – 2 hrs. Brian Waterhouse and Barbara Hendrickson – 2nd one will be on Safety Assessment – Mary Nelson from PHUSE and Veronica –– Jointly with DIA, ASA and PHUSE – Discuss with stake holders based on who has biggest platform  Post meeting update email from Gregg    Doug Milken has re-engaged with the Educational subcommittee – Being a Statistician in a small company with only 1 and 2 – Munish responded positively on it including role and skills required of Statisticians – Jon and Munish to discuss  **2023 VJC Webinars Planned**  VJC is planning 3 meetings this year.  Thu, Jan 12, 2023, 10-11:30am ET  Topic: Biomarker Adaptive Designs (joint with PSI)  Registration Link: <https://diaglobal.zoom.us/webinar/register/WN_iL56FKmZSUSfpfy-e0OOpQ>  181 registered as of Jan 4, 2023  Chris S at DIA is coordinating a Global Forum article about VJC with Susan Wang.  Stat & DS Community Planner below as of 2 Feb 2023 from Jon    From 6January2023 Meeting minutes: When possible suggest using DIA Webinar(instead of Zoom) since it has more functionality and one can ask people to register etc. Bayesian WG KOLs (Freda) meet the 3rd Friday each month so we should not schedule anything at that time. Freda will also ask DIA for a separate Zoom account since this activity is not officially sponsored by the Stats & DS Community.  Topics discussed at 6Jan2023 call for education sessions, VJC, manuscripts, etc.   * Rare disease – Jon suggested new materials beyond what is in CID and use of Bayesian analysis. Susan suggested there is a lot more interaction between Stats and clinical due to the small sample sizes, understanding natural history, etc. – Advantage of DIA being cross-functional and making it convenient to collaborate with clinical and other functions. DIA annual meeting has a session on this topic Susan is organizing. A summary of what will be covered at this could be presented in May and/or a more detailed presentation in July/August after the annual meeting * Use of synthetic controls * Patient reported outcomes is still an important topic – Yeh-Fong * Data science (Jerry) – ML; R has a increasing toolbox; Most companies are working on efforts involving ML. Statistical methods used in ML (Munish). ChatGPT has had a lot of recent publicity and will increase use of ML/AI. Use of data lakes. * Full Regulatory submissions in R – Many companies are working on it - Lilly, Amgen, Novartis, Merck, Roche…. * Decentralized clinical trials; Craig Lipset; Frank Rockhold GSK; * RWE/RWD, RWE in Pivotal Oncology Trials, RWD/RWE, decentralized clinical trials, discuss newly released guidance documents - IQVIA Nancy Dreyer; * Pragmatic clinical trials / Large Simple Trials (LSTs) Dr. Leonard Sacks at FDA. * FDA medical queries (FMQ); safety standards; safety estimands – Greg agreed to present – will coordinate with Jon * Important to share Case studies and not just speak theoretically (Steve) * Consider an interest for a whitepaper if interested on any of the above topics * Preparing for Ad Comm Meetings * Benefit risk guidance * Dose finding (VJC and PSI), old concepts (dose concentration curve) still working with biologics? * Joan: Oncology dose optimization * External control borrowing * Meaningful Chane (Clinically meaningful change) * CovID19 lessons learned * Yeh-Fong: Multi-regional trials, especially from the perspective of submissions to various regulatory agencies with various requirements, can this be harmonized better   **2022 WEBINARS FROM OUR COMMUNITY:**  [DIA Statistics & Data Science Community Library](https://communities.diaglobal.org/communities/community-home/librarydocuments?communitykey=e8cc6d91-23c5-4211-b15b-d7d766fb7298&LibraryFolderKey=&DefaultView=)- We have many years of content available to DIA members.  **Digital Health Technology and Meaningful Change: A joint DIA Webinar: Digital Health Technology and Meaningful Change**  Thu, Dec 8, 2022: 11am-12:30pm ET  Attendees unknown since hosted by Study Endpoints Community  DIA Statistics & Data Science Community Library: [Slides](https://communities.diaglobal.org/viewdocument/digital-health-technology-and-meani-1?CommunityKey=e8cc6d91-23c5-4211-b15b-d7d766fb7298&tab=librarydocuments) and [Recording](https://communities.diaglobal.org/viewdocument/digital-health-technology-and-meani?CommunityKey=e8cc6d91-23c5-4211-b15b-d7d766fb7298&tab=librarydocuments)  **Using BDRIBS to Support the Decision to Refer an Event to a Safety Assessment Committee for Unblinded Evaluation**  Thu, Dec 1, 2022: 10-11:30am ET  92 registered, 58 unique viewers  DIA Statistics & Data Science Community Library: [Slides and Recording](https://communities.diaglobal.org/viewdocument/bdribs?CommunityKey=e8cc6d91-23c5-4211-b15b-d7d766fb7298&tab=librarydocuments)  **Deep Mining Signal Detectors**  Tue, Nov 29, 2022: 10-11:30am ET  ~62 attendees  DIA Statistics & Data Science Community Library: [Slides](https://communities.diaglobal.org/viewdocument/deep-mining-safety-data-29nov2022-1?CommunityKey=e8cc6d91-23c5-4211-b15b-d7d766fb7298&tab=librarydocuments) and [Recording](https://communities.diaglobal.org/viewdocument/deep-mining-safety-data-29nov2022?CommunityKey=e8cc6d91-23c5-4211-b15b-d7d766fb7298&tab=librarydocuments)  **Beyond 1000’s of Tables, Figures and Listings (TFLs) – Envisioning the future of reviewing and summarizing clinical trial data and analyses**  Wed, Nov 16, 2022: 12-1pm ET  Attendees unknown since hosted by Medical Writing Community  DIA Medical Writing Community Library: [Slides](https://communities.diaglobal.org/communities/community-home/librarydocuments/viewdocument?DocumentKey=147712fe-f999-4029-a406-4ff8466a3c4d&CommunityKey=10fe3fc6-5e6a-4977-b253-8e6670058860&tab=librarydocuments&hlmlt=VT) and [Recording](https://communities.diaglobal.org/communities/community-home/librarydocuments/viewdocument?DocumentKey=67f52c5a-fde0-4c23-95e7-769279d3a278&CommunityKey=10fe3fc6-5e6a-4977-b253-8e6670058860&tab=librarydocuments&hlmlt=VT)  **Clinical Reporting in R: An evolving landscape**  Thu, Feb 24, 2022: 11:00am – 12:30pm ET  ~179 attendees  DIA Statistics & Data Science Community Library: [Slides](https://communities.diaglobal.org/communities/community-home/librarydocuments/viewdocument?DocumentKey=baada92f-c96f-4f5a-95e6-b7ab2469ee5e&CommunityKey=e8cc6d91-23c5-4211-b15b-d7d766fb7298&tab=librarydocuments) and [Recording](https://communities.diaglobal.org/communities/community-home/librarydocuments/viewdocument?DocumentKey=cfbe95e1-7594-49c6-9b7b-2c6eea5973a8&CommunityKey=e8cc6d91-23c5-4211-b15b-d7d766fb7298&tab=librarydocuments)    **2022 VJC Webinars:**  Wed, July 27, 2022, 10:30am-12:00pm ET  Topic: The Predictive Individual Effect for Survival Data and Patient Centricity  Recording Link and Slides available upon request (due to Community platform change in Dec 2022)  Tue, Mar 1, 2022: 9:00 – 10:30am ET: **WEBINAR -** Clinical Trial Monitoring (~40 attendees) – Susan, Yeh-Fong  Clinical Trial Monitoring - Recording available here on Matt’s personal Dropbox account, unable to be posted to DIA Community and shared due to violations of neutrality:  [https://www.dropbox.com/sh/kf3imqv38oqgq7k/AADkTh7Cr2bCf4aEqTP4OJvpa?dl=0](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.dropbox.com%2Fsh%2Fkf3imqv38oqgq7k%2FAADkTh7Cr2bCf4aEqTP4OJvpa%3Fdl%3D0&data=04%7C01%7Cmbaldw01%40amgen.com%7C3eb25a54e77741ab2ed008d9fd1bf2d8%7C4b4266a6136841afad5a59eb634f7ad8%7C0%7C0%7C637819118744833104%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=6Rj8MXYprt4M1o0AFDHcsY8nlhlqg0qhEOSwDxxYkVg%3D&reserved=0)  **RECENT PAST CONFERENCES:**  Sun to Tue, Dec 18 - 20, 2022: **CONFERENCE (Statistics) -** International Chinese Statistical Association (ICSA) International Conference [Chinese University of Hong Kong]  Thu to Sun, Dec 8-11, 2022: **CONFERENCE (Multidisciplinary) -** DIA China Annual Meeting [~~Suzhou, China~~ virtual]   * Liaison: Jingjing   The DIA China Annual Meeting is now set to happen Dec 8-11 in person in Suzhou. Postponed from May. The [program](https://www.diaglobal.org/Tools/Content.aspx?type=eopdf&file=%2fproductfiles%2f9864107%2fen_22975_cam_program_ebook_en%2Epdf) is available. |
| Regional Chair updates  (Jingjing for China. Don’t have a rep for Europe) | Matt will include a regional section in the liaison newsletter. Chava had some info on New Zealand and Balaji for Singapore. African Medicines Agency (AMA) is being formed.  DIA China Statistics Community  It is about time to propose Feb seminar topics and speakers for the Widen the Horizon and Go Forward Together in Statistics & Data Science series (jointly sponsored by DIA China stat and DIA stat & Data Science Community). Jingjing has not put much thoughts into the topics yet and would like to hear input.  Joined seminar on clinical trials diversity, a joint event with FDA colleagues, 2000+ attendees, Mark presented. Plan to have seminar series Q6W. Call for ideas for the seminar topics. Feel free to connect to Jingjing; eg, safety graphics, etc  Europe Liaison Activity  EFSPI newsletters: <https://www.efspi.org/EFSPI/News/Newsletters.aspx?&WebsiteKey=0b28fec8-fcd6-4283-b360-0c689a893140&hkey=2c121403-0d2d-4ab9-9a82-fce10742c0b7>  EFSPI October Newsletter    Partnerships with European statistical organizations like PSI and EFSPI is being explored.  Google: Wonderful Wednesdays – EFSPI work on graphics  Time zone challenge in collaborating with the WGs there. A practical challenge is to engage with EU regulators, so the EU connection is helpful. PHUSE WGs have members in both US and EU.  Need to determine if the regional chairs are under a subcommittee (e.g. education or liaison) or report directly to core committee. |
| **TIRS Publications** | Update from Joan - Meaningful Change Digital Workstream 4 is in round 2 of review from TIRS journal. |
| **Membership/Social Committee**  2023 plans –  - Yeh-Fong | Community Dinner took place on Tue, Sep 20th, 2022, 6-8pm ET, Rock Bottom Restaurant & Brewery (Bethesda, MD)  Virtual Event took place on Wed, Apr 27th, 2022, 12-1pm ET. There were about 12 in attendance, 3-4 not from the core committee. Nice event, 12 people attended the event with some fun games. Hope to do another one later this year. |
| **Community Metrics**  As of Oct 3, 2022 (To be updated)  - Munish | Communities Enrollment (from May to Aug 2022):   * 1357 to 1495 in Regulatory Affairs * 945 to 1088 in Clinical Research * 876 to 983 in Clinical Safety & Pharmacovigilance * 662 to 749 in Project Management * 646 to 712 in Medical Writing * 587 to 657 in Patient Engagement * 507 to 616 in Statistics & Data Science * 505 to 569 in Study Endpoints * 370 to 475 in Digital Acceleration * 374 to 473 in Real World Evidence * 279 to 360 in Clinical Data Management * 223 to 263 in Bayesian Scientific Working Group   All Communities appear to have increased in size from May to Aug 2022. |
| Database/repository of guidances, need a name for this project/initiative? (Munish) | Timeline: by end of 2023, will need maintained going forward as well  - value add and unmet need in industry  - This will be our 1 main NEW contribution in 2023.  - Munish offers to lead, needs input on technical system to use (link to DIA website? Git Hub? Wiki? OneDrive? Box? Needs confirmation from FDA colleagues to access)  Wiki is open and won’t lose.  Munish, Matt, and Matt’s colleague (Steve Pearce) from Amgen met in July 2022 to discuss.  05Aug2022: Nothing to report yet  Action Item (Apr 15, 2022): Steve will work with Yeh-Fong to determine if there is a content sharing platform that will work for FDA  Can we turn this effort into a white paper? |