# June 3, 2022

**Attendees:**

Chair: Matt Baldwin

Stats Vice Chair: Stephen Corson

DS Vice Chair: Faisal Khan

Comm Lead: Stephen Corson

Secretariat: Philip He

Reg Chair (China): Jingjing Ye Reg Chair (Europe): Jürgen Kübler

Advisor: Jerry Schindler

Advisor: Bill Wang

Advisor: Steve Wilson

Advisor: Greg Ball

Advisor: Freda Cooner

Advisor: Ram Tiwari

Advisor: Joan Buenconsejo

Advisor: Ruthie Davi

Advisor: Brenda Crowe

Liaison: Munish Mehra

Education: Jon Haddad

Education (VJC): Susan Wang

Mem/Social: Yeh-Fong Chen

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| **Agenda** | **Minutes** |
| Stats & Data Science Community Resources are updated (Matt) | Virtual tour given by Stephen on 06May  <https://communities.diaglobal.org/group/jcmcCXpJZ2neJApah/admin/home>  Organized structures in the community page: hot topics, knowledge base, etc. Currently, the hot topics are inspired by the priority topics for the Global Annual Meeting Statistics Track.  ~~06May Action Item: All please browse the folders and provide any suggestions to Matt & Stephen by May 20~~~~th~~~~.~~ COMPLETE  03Jun Action Item: Stephen to announce the updates to our Community Resources to the Stats & DS community in June.  Stephen: to announce; files will be mirrored to google docs to avoid losing content if DIA changes community platforms again |

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| Recent and Upcoming Calendar (Matt) | Fri, Jun 3: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt check committee member email lists (Freda left Amgen and joined Arcutis: [fcooner@arcutis.com](mailto:fcooner@arcutis.com)) congrats!      * Matt share community metrics (not available from Luke Zimmer yet)   Sun to Wed, Jun 12-15: **CONFERENCE (Statistics) -** PSI (Europe) [Gothenburg, Sweden]   * Liaison: Jurgen? Stephen? Susan? * Stephen is a PSI member and will pass along info from colleagues that attend the conference.   <https://www.efspi.org/>    May Newsletter    If you want to learn more about the Oncology Estimand ESIG, please check out our webpage www.oncoestimand.org or our latest newsletter.  <https://www.psiweb.org/>  Sun to Thu, Jun 19-23: **CONFERENCE (Multidisciplinary) -** DIA Global Annual Meeting (Chicago, IL)   * Liaisons: Greg, Munish, Freda, Susan * Community Zone on Tuesday, June 21st from 12:00 - 1:15 PM * Attendees: Greg, Munish, Stephen   Munish has a short course and Stephen organized a session.  Joan mentioned a Content Hub that can lead to (or is displaying) collaboration on the topic of meaningful change for endpoints.  [Considerations for Establishing Meaningful Change for Digital Endpoints Derived From DHT Drug Development Tools](https://sched.co/10egA) (June 22, 3:15-3:45pm CT)  Sun to Wed, Jun 19-22: **CONFERENCE (Statistics) -** International Chinese Statistical Association (ICSA) Applied Statistics Symposium [University of Florida, Gainesville]   * Liaison: Susan?   Fri, Jul 1: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt check committee member email lists |

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| **Education Committee** | |
| Collaborate with PHUSE? (Munish) | Action Item (Feb 4): Munish to follow up with Michael Rimler   * Team for years, with code (Git Hub repository)   15Apr2022: Yes, Munish has a call next week, though unclear if this is for Git Hub repository or estimands topic  Did the above happen?  Yes, we can close out this topic  Collaboration is in individual level. |
| Upcoming Webinars  As of Jun 3: 1/6 complete for 2022 | **2022 Webinars:**  Thu, Feb 24: 11:00am – 12:30pm ET: **WEBINAR -** Clinical Reporting in R: An evolving landscape (~179 attendees) – Jon  Clinical Reporting in R: An evolving landscape - Slides and Recording available here:  <https://communities.diaglobal.org/post/CmBs7cEdvgbwXW48T>  Education Ideas:  - dose finding (VJC and PSI), old concepts (dose concentration curve) still working with biologics?  Hot topics: RWD/RWE, decentralized clinical trials, discuss newly released guidance documents. There is a guidance that just came out on benefit risk.  New potential education committee member:  Doug Milikien, Principal Consulting Biostatistician, Accudata Solutions, Inc. Matt chatted with Doug last week and it seems Doug is motivated and has a lot ideas. He could potentially take over the education committee lead from Jon, which Jon is fine to hand off.  “I’m especially interested in events/webinars that collaborate with other functional areas such as Regulatory, ClinOps, and Legal that have an impact on statistical practice. (Example: there is some draft legislation that would allow some kinds of hearing aids to be sold OTC. If that legislation passes, it would blow the lid off of a very profitable Rx-based hearing aid industry that many people simply can’t afford because they are not covered by Medicare and create a market for OTC devices, which will need clinical trials.  There are some interesting statistical issues that brings up about use patterns and missing data and what constitutes “safe”. )  Secondly, building a community or “safe place” for sharing among small-company corporate statisticians who may be the only statistician in their company. How can they find mentors?...learn to be an advocate for good scientific practice?..etc.    Back in the early-to-mid 90’s (before the world wide web), I created an Applied Biostatistics branch within the San Fran chapter of the ASA.  I would get speakers among working statisticians on very practical and topical matters to benefit us worker-bee statisticians in industry, not just the academic. I set up a ListServ and we had our own Career Day at CSU Hayward, now CSU East Bay.    More recently, in 2017-2019, I was an officer in the No Cal chapter of the Assoc. for Clinical Research Professionals.  I created a topics survey to poll chapter members on what topics they would like to see at (in-person) seminars, and then built a 4x/year speaker program to support that by finding and inviting speakers from across the country, making sure the content complied with ACRP non-commercial guidelines, etc., distributing and collecting feedback forms and summarizing for the speaker and chapter Executive Committee.”  06May2022:   * DIA Community Safety webinars (note, we need to formally invite the speakers from the FDA – like we did last year)   + Using BDRIBS to Support the Decision to Refer an Event to a Safety Assessment Committee for Unblinded Evaluation     - Brian Waterhouse (Merck)     - Barbara Hendrickson (AbbVie)     - Jacqueline Corrigan-Curay (FDA)     - November 1 at 10-11:30 EST   + Interactive Safety Graphics     - Jeremy Wildfire (Gilead)     - Jim Buchanan (Covilance)     - Paul (Skip) Hayashi (FDA)     - 27 October at 10-11:30 EST   15Apr2022:  Munish: set up a call next week; Estimand topic. Jonathon Siegel (oncology safety Estimand). Templates protocol and SAP are available (clinical question, objectives) on Transcelerate’s website that can be freely downloaded from: <https://www.transceleratebiopharmainc.com/assets/clinical-content-reuse-solutions/>  Several groups are targeting on standards. **Munish would like to set up an estimands WG**. Bill Wang (safety Estimand). Therapeutic difference is recognized for Estimand framework consideration. DIA missing data WG (EU colleagues), led by Michael Kelly. PSI/SPI; NASH (liver disease). EFSPI.org.  Stat & DS Community Planner below (as of May 9, 2022): |
| Virtual Journal Club (VJC)  As of Jun 3: 1/3 complete for 2022 (Susan) | **2022 Webinars:**  Tue, Mar 1: 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)  planning a VJC for late July to early August, depending the availability of the presenters. The topics is on predicting individual effect for survival data. |

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| **Liaison Committee** | |
| Database/repository of guidances, need a name for this project/initiative? (Munish) | Timeline: by end of 2022, will need maintained going forward as well  - value add and unmet need in industry  - This will be our 1 main NEW contribution in 2022.  - Munish offers to lead, needs input on technical system to use (link to DIA website? Git Hub? Wiki? Ondrive? Box? Needs confirmation from FDA colleagues to access)  Action Item (Feb 4) – ALL share ideas of site hosting with Munish  Did the above happen? Munish received some suggestions and will work on the technical part. Matt will facilitate a conversation with IT guy and Munish. Onedrive and box are account-associated. Wiki is open and won’t lose.  15Apr2022: Munish received minimal feedback  Action Item: Steve will work with Yeh-Fong to determine if there is a content sharing platform that will work for FDA  Did the above happen?  04Mar2022: FDA has a website with all the guidance documents. The team discussed setting up a Wikipedia page for creating a custom list that includes a few other things besides the guidance documents.  15Apr2022: Is FDA website adequate to locate statistical guidance? Other regulatory agencies?  Can we turn this effort into a white paper? |
| Discuss keeping the Liaison Committee or not (Matt) | Munish isn’t convinced we need to keep this committee, but let’s discuss openly the various perspectives on formal or informal liaisons to other DIA Communities and conferences, as well as non-DIA organizations and conferences  15Apr2022: Munish – Liaison happens at topic level. Not straightforward in practice.  ~~06May Action Item: Matt will ask the core committee in May for any additional inputs and we decide on the look and feel of the liaison committee by our next meeting on June 3~~~~rd~~~~.~~ COMPLETE  Keep As Is (5)   * Greg * Munish (if someone steps up to lead, else Abandon) * Yeh-Fong * Joan (I believe there is really value in having a cross-community, or even cross-statistical organization liaison(s). I also believe the excerpt from the charter captured what the liaison(s) can support/accomplish, and not necessarily to do everything simultaneously. It could be incremental and fit for purpose.) * Matt   There are different levels of liaisons and involvements. Reviewed the Liaison committee in the charter. Easy to collaborate thru PHUSE. 50+ WGs. Need to recommend someone to lead the Liaison committee. Joan? Freda shared the experience in Bayesian WG how to reach out to authors for speakers based on recent publications. People can also volunteer to present in webinars.  PHUSE initiated a “community forum” (Greg Ball) which targets awareness of what’s going on in various communities (either inside or outside PHUSE). Groups come together to work on specific topics / objectives. Connect 2+ groups to facilitate talks. Eg, re-imagine safety submission. This could be a possible model for us to consider.  Keep But Modify (3)   * Stephen (simpler version, conferences only) * Ruthie (try to make success more achievable.  I wonder if we prioritize only a few groups that we would like to keep in touch with and remove the others for now, would help) * Phil (The current scope of the work is fine but suggest focusing on the items of our interest, i.e., to support our community’s objectives by seeking support from other communities. In addition, consider more “long-term” relationship strategy rather than transient. The benefit of having the liaison committee is additional resource to support the chair and achieving the objectives.)   Abandon (4)   * Faisal * Jon * Freda * Jingjing   Doesn’t Matter (1)   * Brenda   Remaining (7)   * Susan * Jurgen * Steve * Bill * Ram * Jerry   **03Jun Final Decision:** The voting is in favor of keeping a liaison committee in some form, so Matt willconsider the feedback and make a proposal before the next Core meeting. |
| Regional Chair updates, revisit previously shared info (Matt) | DIA China (in April)  1. Please see the upcoming DIA China 2022 Annual Conference Program    2. In Q1, DIA Statistics has organized a seminar discussing FDA review on BOIN design. They plan to have other seminar topics in the next few months. Typically seen 1000 participants.  3. Since May last year, the DIA statistics community has established a training series on clinical trial statistics (31 sessions). The recording is ongoing.  Can/should we partner more with China DIA Statistics Community?  Jingjing: Interested in perspectives of regulatory outside of China. May consider to partner with. She will pass along any opportunities to suggest speakers for China DIA Stats events.  DIA Europe (Feb 4) – not much is happening related to stats, DIA lost stats community, many/most turned to PSI, DIA Europe conference was hijacked by other disciplines, can our community take the lead to provide value in Europe (data science?), convince someone at EMA to join our efforts?  Action Item: ALL email DIA leadership about this pain point, Barbara Lopez Kunz (Global Chief Executive) [Barbara.Lopez.Kunz@diaglobal.org](mailto:Barbara.Lopez.Kunz@diaglobal.org)  Did the above happen?  Not sure, but we can strongly consider partnering with EFSPI instead of fighting to resurrect DIA Stats in Europe |

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| **Membership/Social Committee** | |
| 2022 plans  As of Jun 3: 1/2 events complete for 2022 (Yeh-Fong) | 2 Membership/Social events in 2022 – Yeh-Fong  Virtual Event took place on Wed, Apr 27th, 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. |

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| **Any Other Business** | |
| AOB | Transition to using Tradewing for video conferencing instead of Zoom (still bumps to smooth out as of Feb 2022, Matt is staying current with CLC team)  - Matt, Stephen  Where does Quantitative Pharmacometrics fit in DIA? |

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| FULL Annual Calendar | Fri, Jun 3, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt check committee member email lists * Matt share community metrics   Sun to Wed, Jun 12-15, 2022: **CONFERENCE (Statistics) -** PSI (Europe) [Gothenburg, Sweden]   * Liaison: Jurgen?   Sun to Thu, Jun 19-23, 2022: **CONFERENCE (Multidisciplinary) -** DIA Global Annual Meeting (Chicago, IL)   * Liaisons: Greg, Munish, Freda, Susan * Attendees: Greg, Munish, Stephen   Sun to Wed, Jun 19-22, 2022: **CONFERENCE (Statistics) -** International Chinese Statistical Association (ICSA) Applied Statistics Symposium [University of Florida, Gainesville]   * Liaison: Susan?   Fri, Jul 1, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt check committee member email lists   Thu to Sun, Jul 21-24, 2022: **CONFERENCE (Multidisciplinary) -** DIA China Annual Meeting [Suzhou, China]   * Liaison: Jingjing   Fri, Aug 5, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Liaison committee updates - Munish * Regional chair updates – Jurgen, Jingjing   Sat to Thu, Aug 6-11, 2022: **CONFERENCE (Statistics) -** JSM [Washington, DC]   * Liaison: Freda   Fri, Sep 2, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt share community metrics   Tue to Thu, Sep 20-22, 2022: **CONFERENCE (Statistics) -** ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop [Rockville, MD]   * Liaisons: Freda, Jingjing   Thu to Fri, Oct 6-7, 2022: **CONFERENCE (Multidisciplinary) -** DIA Diversity, Equity, and Inclusion in the Drug Development Lifecycle Meeting [virtual]   * Liaison: Matt   Fri, Oct 7, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt check committee member email lists   Tue to Wed, Oct 4-5, 2022: **CONFERENCE (Safety & PV) -** World Drug Safety Congress Americas [Boston, MA]   * Liaison: Greg   Wed to Thu, Oct 26-27, 2022: **CONFERENCE (Multidisciplinary) -** CDISC US Interchange [Austin, TX]   * Liaison: Matt   Tue to Thu, Nov 8-10, 2022: **CONFERENCE (Data Science) -** R/Pharma Conference [virtual?]   * Liaison: Jerry * Website?   Thu to Fri, Nov 3-4, 2022: **CONFERENCE (Multidisciplinary) -** DIA Master Protocols and Complex Innovative Design [Tysons Corner, VA]   * Liaison: Susan   Fri, Nov 4, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Liaison committee updates - Munish * Regional chair updates – Jurgen, Jingjing * Working group updates – Greg, others?   Thu to Fri, Nov 10-11, 2022: **CONFERENCE (Multidisciplinary) -** DIA Real-World Evidence Conference [San Diego, CA]   * Liaison: ???   Mon to Tue, Nov 14-15, 2022: **CONFERENCE (Data Science) -** DIA Data Science Conference [virtual?]   * Liaisons: Joan, others   Fri, Dec 2, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt share community metrics * Munish completes pilot of database/repository of guidances   Sun to Tue, Dec 18-20, 2022: **CONFERENCE (Statistics) -** International Chinese Statistical Association (ICSA) International Conference [Chinese University of Hong Kong]   * Liaison: Susan   Fri, Jan 6, 2023: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt check committee member email lists   **~~Jan 6-10, 2022:~~ CONFERENCE (Statistics) -** International Indian Statistical Association (IISA) Virtual Mini Conference [virtual?]   * Liaison: Ram * *Cannot find 2023 information*   **~~January 24-26, 2022:~~** **CONFERENCE (Safety & PV) -** DIA Global Pharmacovigilance and Risk Management Strategies Conference [virtual?]   * Liaison: Greg * *Cannot find 2023 information*   Fri, Feb 3, 2023: 12:00-1:00pm ET: **MEETING -** Core Committee   * Liaison committee updates - Munish * Regional chair updates – Jurgen, Jingjing   Fri, Mar 3, 2023: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt share community metrics   Sun to Wed, Mar 19-22, 2023: **CONFERENCE (Statistics) -** ENAR Spring Meeting [Nashville, TN]   * Liaison: Jon   Wed to Fri, Mar 22-24, 2023: **CONFERENCE (Multidisciplinary) -** DIA Europe [Basel]   * Liaison: Jurgen?   Fri, Apr 7, 2023: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt check committee member email lists   Wed to Fri, <TBD>, 2023: **CONFERENCE (Statistics) -** DIA/FDA Biostatistics Industry and Regulator Forum [virtual?]   * Liaison: Brenda * *Cannot find 2023 information*   Sun to Wed, <TBD>, 2023: **CONFERENCE (Statistics) -** PHUSE US Connect [<TBD>]   * Liaison: Greg   Fri, May 5, 2023: 12:00-1:00pm ET: **MEETING -** Core Committee   * Liaison committee updates - Munish * Working group updates – Greg, others?   Sun to Wed, May 21-24, 2023: **CONFERENCE (Multidisciplinary) -** Annual Meeting of the Society for Clinical Trials [Baltimore, MD]   * Liaison: Greg |