# Sep 2, 2022

**Attendees:**

Chair: Matt Baldwin

Stats Vice Chair: Munish Mehra

DS Vice Chair: Faisal Khan

Comm Lead: Stephen Corson

Secretariat: Philip He

Reg Chair (China): Jingjing Ye

Liaison: Matt Baldwin

Europe Liaison: Jürgen Kübler

Education: Jon Haddad

Education (VJC): Susan Wang

Mem/Social: Yeh-Fong Chen

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

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| **Agenda** | **Minutes** |
| [placeholder for leading topics] | [placeholder for leading topics] |

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| Recent and Upcoming Calendar (Matt) | Sat to Thu, Aug 6-11, 2022: **CONFERENCE (Statistics) -** JSM [Washington, DC]   * Liaison: Freda * Attendees: Philip, Ruthie, Yeh-Fong, Freda, Faisal, Munish * Feedback: first in-person conference, academia, estimands, training materials   Fri, Sep 2, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt share community metrics   Sat to Mon, Sep 17-19, 2022: **CONFERENCE (Statistics & Data Science)** - Quantitative Science Forum [Nanjing, China]   * Liaison: Jingjing * Attendees: * Notes: skipped since Jingjing was not present   Mon to Wed, Sep 19-21, 2022: **CONFERENCE (Multidisciplinary)** – PHUSE CSS [Silver Spring, MD]   * Liaison(s): ??? * Attendees: Greg, Steve Wilson, Munish * Notes: FDA draft guidance coming up in safety: standard tables, FMQ medical queries for AE grouping   Tue to Thu, Sep 20-22, 2022: **CONFERENCE (Statistics) -** ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop [Rockville, MD]   * Liaisons: Freda, Jingjing * Attendees: Philip, Yeh-Fong, Freda, Joan, Ruthie * Notes:   Tue to Wed, Oct 4-5, 2022: CONFERENCE (Safety & PV) - World Drug Safety Congress Americas [Boston, MA]   * Liaison: Greg * Attendees: Greg * Notes: Organized a session in aggregated safety reporting, ASAP (or AgSAP at Merck)   Thu to Sun, Oct 13-16, 2022: **CONFERENCE (Multidisciplinary) -** DIA China Annual Meeting [Suzhou, China]   * Liaison: Jingjing * The DIA China Annual Meeting is now set to happen Oct 13-16 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. * DIA China will host a Pediatric Drug Development Forum in October in the DIA China Annual Meeting.   Mon to Tue, Nov 14-15, 2022: **CONFERENCE (Data Science) -** DIA Data Science Conference [virtual]   * Liaisons: Joan, Steve, Ruthie * Attendees: * Notes: Steve & Ruthie are involved with a session of Data Science in Regulatory Agency. 8 sessions (for entire conference?); one is on data science careers. We should continue staying in the loop of conference content development process, as well as how it informs us on the overlap/relationship between statistics and data science. |
| FULL Annual Calendar | Embedded Excel file below for now, considering where to place centrally for access by core committee and liaison committee, potentially Google Drive or Box folder.    This will replace the FULL Annual Calendar section at the end of the agenda/minutes, to avoid having calendar details in more than one location. |

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| **Liaison Committee** | |
| 2022 plans  (Matt) | Matt has met with the liaison committee on Aug 8th to get moving on some initiatives. Also had a few join from the larger community.  15Aug Update: Had 10+ in attendance, good discussion, Matt is pulling together feedback for liaison activity, including where liaison committee members are already involved and interested  Next steps TBD, but likely will meet in Sep to discuss where to focus our efforts first on liaison activity, although we have a growing list of potential organizations and conferences/meetings to liaise with. We have our own space on Tradewing, like the core committee, to collaborate. |
| Regional Chair updates  (Matt) | DIA China Statistics Community  DIA Europe Statistics Community  We can strongly consider partnering with EFSPI instead of fighting to resurrect DIA Stats in Europe  EFSPI June Newsletter (July is not available as of Aug 15)    7th EFSPI Regulatory Statistics Workshop  14th – 15th September 2022  Face-to-face meeting in Basel, Switzerland    Partnerships with European statistical organizations like PSI and EFSPI is being explored |
| 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)  Wiki is open and won’t lose.  Munish, Matt, and Matt’s colleague (Steve Pearce) from Amgen met in July to discuss.  05Aug: Nothing to report yet  Action Item (Apr 15): Steve will work with Yeh-Fong to determine if there is a content sharing platform that will work for FDA  Any progress?  05Aug: Nothing to report yet  Knowledge Sharing:   * Matt brought up this topic as something he has been considering recently, how it happens within an organization, across our industry. * Yeh-Fong suggests a Wiki page, which FDA uses. Matt will consider, since Munish is looking this direction for the guidance repository. Is there more we can add to a community Wiki for knowledge sharing purposes? * (Optional) Action Item (02Sep)   Here is a 45 min Knowledge Cast (by Enterprise Knowledge) podcast episode titled [Bryan Yee – Director of Knowledge Management at Amgen](https://open.spotify.com/episode/2lgABKLYxv1aGHoHLMpDdx?si=UUBM6UI4Qvq9eLjXlzvTMQ&nd=1)   * + Matt fully realizes he is biased since Amgen is his company, but trying to be as impartial as possible, he believes it is good information for everyone to consider.   + Episode Description:   “Enterprise Knowledge CEO Zach Wahl speaks with Bryan Yee, Director of Knowledge Management at Amgen, one of the world’s largest biotechnology companies. Bryan has been at Amgen for over 16 years and has served as the Director of Knowledge Management since 2019. His team is focused on tapping into the collective genius of drug developers, with a specific focus on fostering a culture of psychological safety and leveraging data science to reduce the friction of knowledge sharing and discovery.”  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? |

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| **Education Committee** | |
| Upcoming Webinars  As of Aug 31: 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.  2023 ideas:  Joan shared the following from memory, since she is on the Education Committee:  Oncology dose optimization, external control borrowing, clinically meaningful change, quite a few topics, decentralized trials, CovID19 lessons learned  Yeh-Fong added:  multi-regional trials, especially from the perspective of submissions to various regulatory agencies with various requirements, can this be harmonized better?  *Jurgen:*  Patient Preference  here is the link to the IMI-PREFER website: [https://imi-prefer.eu/](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fimi-prefer.eu%2F&data=05%7C01%7Cmbaldw01%40amgen.com%7Cd25d461cb1b047f5e8a808da5b82985e%7C4b4266a6136841afad5a59eb634f7ad8%7C0%7C0%7C637922913876649115%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=fvodXw7QFOoEtSWRGPR%2FvWQqWUhKiK1b7SSuYLHHVZo%3D&reserved=0)  I also attached a Pink Sheet article on the recent EMA Methods Qualification and its expected impact.  *Matt:*  RWE Submission Approaches Before RWD Standards Exist    [https://www.psiweb.org/vod/item/psi-rwd-sig-webinar-real-world-evidence-submission---a-case-study-in-lung-transplantation#video\_692324223](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.psiweb.org%2Fvod%2Fitem%2Fpsi-rwd-sig-webinar-real-world-evidence-submission---a-case-study-in-lung-transplantation%23video_692324223&data=05%7C01%7Cmbaldw01%40amgen.com%7C2821123911e44d29d3c908da5b84b5f9%7C4b4266a6136841afad5a59eb634f7ad8%7C0%7C0%7C637922923097714469%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=E1o0bulGspOrhkRhoCmTAcX9hSetS5Olk0IDEJWOT7I%3D&reserved=0)  This submission was completely based on RWD, no clinical trial data collected, used R code, didn't fully comply with CDISC (though it was CDISC-like in some ways), and the product was approved. The sponsor, RWD vendor, and FDA statistical reviewer all give their insights on this case study. I think more will be following after this precedent.  05Aug Action Item: Jon to follow up with Matt for consideration of a session on RWD data standards  *Munish:*   * There seems to be interest in my presentation at link below I did at PHUSE in 2020 and did again at the DIA Annual meeting this year with Stephen.   <https://www.lexjansen.com/phuse-us/2020/dv/DV07_ppt.pdf>   * The DIA MW and CR communities are interested in a cross-functional discussion around it. * If you think Stats would be interested take a look and see who would be interested in providing input during the discussion. * I was intending this to be a discussion around slides and suggestions of alternatives rather than presenting and saying this is the way to do it.   Consideration of easy summary of data by utilizing graphics. Consider safety graphics WG? QT prolongation graphics; exposure-adjusted AE graphics; ECG display.  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)     - 1 December at 10-11:30 EST   + Interactive Safety Graphics     - Jeremy Wildfire (Gilead)     - Jim Buchanan (Covilance)     - Paul (Skip) Hayashi (FDA)     - 7 November at 10-11:30 EST   Dec 2022: Digital tools/Meaningful Change (COA/PRO) – Joan  Stat & DS Community Planner below (as of Sep 2, 2022):    Matt has provided an updated speaker planner above from Jon. Open to see the list of planned topics for 2023. |
| Virtual Journal Club (VJC)  As of Aug 31: 2/3 complete for 2022 (Susan, Yeh-Fong) | **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)  Wed, July 27, 10:30am-12:00pm EST  Topic: The Predictive Individual Effect for Survival Data and Patient Centricity  Slides link: <https://communities.diaglobal.org/post/838yiApw3SDr9A7BA>  Recording link: <https://communities.diaglobal.org/virtualEvent/jPTQwznGMmpkBqZtt> |

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| **Membership/Social Committee** | |
| 2022 plans  As of Aug 31: 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.  Community Dinner – Tue, Sep 20th, 6-9pm ET, Washington DC (Silver Spring / Rockville, MD area), location TBD  This has been announced to our community, and Greg has shared with other select CSS attendees.  **Action Item (Sep 2):** **Yeh-Fong** will prepare a short survey to determine type of food is preferred, and possible activities.  Faisal recommends [Busboys and Poets](https://www.busboysandpoets.com/) (click link for website)  Current RSVP as of Sep 2:  Matt Baldwin  Munish Mehra  Phil He  Greg Ball  Ram Tiwari  Yeh-Fong Chen  Mac Gordon (Janssen) |

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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?  DIA membership:  In July 2022, Munish talked with Barbara Lopez Kunz (DIA Global Chief Executive) recently about DIA membership reduction, such as partnerships with other organizations and discounts for some countries in Latin America or Asia.  PHUSE is free to members, with costs covered by industry companies. Steve explained that FDA can collaborate in DIA because it is not paid for by industry companies.  In June/July 2022, Munish has checked whether a Microsoft Teams account can be created by DIA for community use. DIA is evaluating teams and will share more when available. |

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| **Community Metrics** | |
| As of July 01, 2022 | Communities Enrollment (as of May 2022):   * 1362 in Regulatory Affairs * 947 in Clinical Research * 877 in Clinical Safety & Pharmacovigilance * 663 in Project Management * 646 in Medical Writing * 590 in Patient Engagement * 509 in Statistics & Data Science * 508 in Study Endpoints * 377 in Real World Evidence * 371 in Digital Acceleration * 280 in Clinical Data Management * 225 in Bayesian Scientific Working Group   Perhaps the recent boost is due to Global Annual Meeting registrations in April and May, and more Data Scientists selected our community to join. |