# Oct 7, 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** |
| Outline | Recent and Upcoming Calendar (Matt)  Liaison Committee (Matt)  Education Committee (Jon)  Social/Membership Committee (Susan/Yeh-Fong)  Community Metrics as of Sep 2022 (Matt) |
| 2023 Global Annual Meeting abstract deadline | Changed from Thu, Oct 6 to Tue, Oct 11 |
| Pre-market Safety Assessment and FMQ Coding Scheme and TEAE | * Standardized safety tables and figures * FDA Medical Queries (FMQs) – new term to become familiar with, based on MedDRA preferred terms, used for labeling? * We should consider how to interact with this from our DIA community’s perspective * EMQs (EMA) and PMQs (Japan) coming? 😊 * Concept of beginning to end safety aggregation/monitoring created the ecosystem to operationalize what FDA just released * Encouraged to review for any tables and figures output, not just safety * Public comments are being submitted |

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| Recent and Upcoming Calendar (Matt) | Mon to Wed, Sep 19-21, 2022: **CONFERENCE (Multidisciplinary)** – PHUSE CSS [Silver Spring, MD]   * Liaison(s): ??? * Attendees: Greg, Steve Wilson * Notes: FDA draft guidance coming up in safety: standard tables, FMQ medical queries for AE grouping * Feedback:   + Vaishali had a keynote on safety graphics (again at CDISC interchange)   + AEGIS (AE grouping in safety) new project team, goes along closely with FMQs (Nov 7 webinar, details below)   + Estimands WG, Lori VanMeter, more awareness than feedback   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, Munish * Feedback: Ruthie presented on externals controls (hematology focus), late on last day, still good audience, good questions/engagement, FDA members on panel, labeling, decision making [session was Yeh-Fong’s idea] * RWE/RWD is a hot topic, liaise with Jon for education webinar in early 2023 (Yutei Wu (sp?) at FDA) * Quite a bit on estimands   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) * Feedback: session went well, good engagement with audience, there are some ASAP brave champions   Fri, Oct 7, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt share community metrics   Wed to Thu, Oct 26-27, 2022: **CONFERENCE (Multidisciplinary) -** CDISC US Interchange [Austin, TX]   * Liaison: Matt * Attendees: Matt * Notes: important annual meeting for data standards, will consider relevant info for this community   Thu to Fri, Nov 3-4, 2022: **CONFERENCE (Multidisciplinary) -** DIA Master Protocols and Complex Innovative Design [Tysons Corner, VA]   * Liaison: Susan * Attendees: * Notes: Susan not present, no one else had comments   Tue to Thu, Nov 8-10, 2022: **CONFERENCE (Data Science) -** R/Pharma Conference [virtual?]   * Liaison: Jerry * Attendees: * Notes: Jerry not present, Matt has reached out via email for more info   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.   + Cost was lowered (after Matt’s feedback? 😊)   + Any idea on attendee count?   + One pending session is close to finalizing   + Unique aspects, more interactive on Day 2   + Identify and discuss common themes and problems that can be collectively solved   + Speakers from pharma, tech, regulatory   + Titles of sessions are in a question format   + Email from Joan on Monday, please share with colleagues, not just for data scientists, good for statisticians also, we’ll post on LinkedIn also   Thu to Sun, Dec 8-11, 2022: **CONFERENCE (Multidisciplinary) -** DIA China Annual Meeting [Suzhou, China]   * 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. |
| FULL Annual Calendar | Two options:   1. [Google Drive link](https://docs.google.com/spreadsheets/d/1ZOwey1Xoimk1kVZ50og5UEaVf9BBDOAO/edit#gid=535291124) 2. Excel version: |

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| **Liaison Committee** | |
| 2022 plans  (Matt) | Plan to meet in Oct to discuss a quarterly liaison newsletter, but first need to develop the structure and type of content. |
| Regional Chair updates  (Matt) | DIA China Statistics Community  QSF (quantitative statistics forum) celebrated the 10th event on 9/17-9/19 in Nanjing. It was quite a success. The website is:  [https://www.icsa.org/2022-dia-china-quantitative-science-forum-september-17-19-2022/](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.icsa.org%2F2022-dia-china-quantitative-science-forum-september-17-19-2022%2F&data=05%7C01%7Cmbaldw01%40amgen.com%7Ce29899b6a309449f7ce408da9fbcc775%7C4b4266a6136841afad5a59eb634f7ad8%7C0%7C0%7C637997930390535369%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=yFx%2FVR7g6uhy8%2BBb1A%2FrApYnEs6EMaFQvwLRGjuqaTk%3D&reserved=0)  [https://www.bagevent.com/event/8207025](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.bagevent.com%2Fevent%2F8207025&data=05%7C01%7Cmbaldw01%40amgen.com%7Ce29899b6a309449f7ce408da9fbcc775%7C4b4266a6136841afad5a59eb634f7ad8%7C0%7C0%7C637997930390535369%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=48VOh4XYjzAFamigDIonix6bSlJW54BIiIibwZMN3xQ%3D&reserved=0)  Several of the DIA US statistics and data sciences members participated in the session as panels or speakers.  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 September Newsletter    EFSPI Summer Newsletter    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.  Susan knows the EFSPI president very well, (who is the global head for biostatistics and data sciences in BI, whom she reports to as the global head for biostatistics and data sciences for Inflammation). She wonders if it will be a good idea to invite the EFSPI president to talk to us about EFSPI in one of our meetings. Liaison only? Core only? Liaison and Core only? All community meeting?  Wonderful Wednesdays – EFSPI work on graphics  **~~Action Item: Matt~~** ~~to invite liaison committee and EFSPI president to next Nov core meeting, or schedule another meeting if that time slot does not work~~ RESOLVED  13Oct Follow Up: Justine, EFSPI president, will come to Dec 2nd core committee meeting |
| 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  Can we turn this effort into a white paper? |

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| **Education Committee** | |
| Upcoming Webinars  As of Oct 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.  2023 ideas:  02Sep:  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?  Munish has an idea to expand on his presentation from 2020 in a cross-community webinar. The presentation is called [Visualizing Clinical Trial Design and Results in 20 Graphical Displays – Achieving 20-20 in 2020](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.lexjansen.com%2Fphuse-us%2F2020%2Fdv%2FDV07_ppt.pdf&data=05%7C01%7Cmbaldw01%40amgen.com%7Cfab9dfa40f444912dc6d08daa2de5d14%7C4b4266a6136841afad5a59eb634f7ad8%7C0%7C0%7C638001373340514783%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=kLY1hTIgvAOsTnrt4lwI4PDSutyuezWl%2F2AphsaE5i4%3D&reserved=0), and can be viewed at the link provided. See theemail thread for the cross-community discussion and brainstorming so far.    Medical Writing will probably lead this webinar, other communities like ours will support  Probably presenters: Jeremy Wildfire, Bodo, Vaishali, Zach (sp?) at Lilly  Aiming for mid Nov  06May2022:   * DIA Community Safety webinars (note, we need to formally invite the speakers from the FDA – like we did last year)   + Interactive Safety Graphics     - Jeremy Wildfire (Gilead)     - Jim Buchanan (Covilance)     - Paul (Skip) Hayashi (FDA)     - 7 November at 10-11:30 EST     - Planning status update? Announce soon?     - We will advertise outside DIA walls     - **~~Action Item:~~** **~~Greg~~** ~~will send presenter emails to Stephen~~ RESOLVED   + 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     - **Action Item:** **Greg** will send this announcement to Stephen   Dec 2022 Digital tools/Meaningful Change (COA/PRO) – Joan  Stat & DS Community Planner below (as of Oct 3, 2022):    03Oct speaker planner above from Jon. Open to see the list of remaining topics in 2022 and planned topics for 2023.  Plan for Jon’s successor?  Considering Feifan, Joan is also a possibility  Training someone in 2023  **~~Action Item:~~** **~~Matt~~** ~~to replace Nelson with Yute Wu in education committee member list~~ RESOLVED |
| Virtual Journal Club (VJC)  As of Oct 3: 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>  Planning the last VJC for this year to take place late (Nov?) or early December. ~~The topic is on “Study Design Considerations for a Biomarker Driven Phase 3 Trial”.~~ Hopefully we can finalize the speakers and discussants soon.  planning a joint meeting with PSI on the topic of Biomarker Adaptive Designs |

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| **Membership/Social Committee** | |
| 2022 plans  As of Oct 3: 2/2 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 took place on Tue, Sep 20th, 6-8pm ET, Rock Bottom Restaurant & Brewery (Bethesda, MD)  Attendees:  Matt Baldwin  Munish Mehra  Phil He  Greg Ball  Yeh-Fong Chen  Joan Buenconsejo  Mac Gordon (Janssen)  Carl DiCasoli (Sunovion)  Richard Payne (Lilly)  Saurabh Mukhopadhyay (Abbvie)  Sarabdeep Singh (FDA)  Sutan Wu (Daiichi Sankyo)  Helen Li (SDC Clinical)  Huan Wang (FDA) |

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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 Oct 3, 2022 | 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. |