# Aug 5, 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** |
| DIA Quarterly Community Leadership Council (CLC) Meeting – Notes from Jul 15th (Matt/Faisal) | 1) They’ll be sending out check-ins on community working groups for an update on status, how active, they are etc.  There’s over 80 Working Groups and they’d like to clean out the inactive ones.  2) They are focusing heavily on increasing active members in Communities.  Currently about 3K active members  3) As a way to drive membership, DIA is running Webinar series (also eligible for CE), which are complimentary for and only available to DIA members.  The first 4 or 5 are all centered around Ukraine, covering Regulatory issues, Good Clinical Practice in a war zone, how to run clinical trials, ethical issues, etc.  Here is the link:  [DIA - DIA Direct Webinars (diaglobal.org)](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.diaglobal.org%2Fen%2Fcourse-listing%2Fwebinar%2Flisting%2Fdirect%3Futm_source%3Ddb&data=05%7C01%7Cmbaldw01%40amgen.com%7Cc496e469be6a43b7efe708da667c6322%7C4b4266a6136841afad5a59eb634f7ad8%7C0%7C0%7C637934981672181919%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Fyh9PvGfp6yTBsjDf5LIP4ks6XgLBA5lBP7ZtriRtHw%3D&reserved=0)  Munish: adjust price according membership level? Being discussed. $275  4) Lot of focus on Digital Membership benefits, mentoring, newsletters, etc.  There is also a special focus on a DIA Learning Library.  5) There is a new search tool that’s been launched on the DIA website. Search for presentations, publications. Check out the new search tool and feedback.  6) DIA is hosting a [virtual Career Fair](https://www.diaglobal.org/en/resources/career-center) in Oct 2022.  Looking for employers to sign up and job seekers will be able to register in late Aug/Sept.  7) Interesting feedback from the Regulatory Affairs committee.  They’ve been doing webinars on how to navigate the Chinese landscape, and been hardly getting any US/non-Chinese attendees.  Some discussion on how DIA can help drive attendance. They maybe lack of knowledge for who to invite. Think of bridges communications.  7.1) Offer to include publicity on events in the DIA comms (eg Breakfast briefing that’s sent by email).  FMK Comment: Who is our group’s link to this?  Publicity/Liaison/Chair?  8) Long discussion on zoom issues accessing DIA webinars, etc, especially from India/China, etc.  Zoom security issues are challenging the various Working Groups holding events.  20 min spent just discussing the Regulatory Affairs Community, so didn’t discuss any other group (including us). Largest group in DIA 1200+ members. |
| Charter with redlines updated on Aug 2, needs team final review by Aug 5 (Matt) | Any charter content to discuss?  01Jul Action Item: **Munish** will check whether a Microsoft Teams account can be created by DIA for community use. DIA is evaluating teams and will share more when available. Will move to a new section of the agenda for topics being monitored. |
| Follow up from PSI Conference (Matt) | 05Aug Action Item: Topics about estimands, R, might be useful to refresh our community on content we have on these topics. **Stephen?**  Yeh-Fong: PRO, benefit-risk, Yeh-Fong joined the external control.  PHUSE estimands in data science? How much RWE needs to conform CDISC standards? Sufficient evidence to justify the use of RWE; the advantage of CDISC standards is for easier understanding. |

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| Recent and Upcoming Calendar (Matt) | Thu to Sun, Jul 21-24, 2022: **CONFERENCE (Multidisciplinary) -** DIA China Annual Meeting [Suzhou, China]   * Liaison: Jingjing * The DIA China Annual Meeting is now set to happen in October (dates TBD) 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 (dates TBD) in the DIA China Annual Meeting.   Fri, Aug 5, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Liaison committee updates - Matt * Regional chair updates – Jurgen, Jingjing   Probably removing the formal Europe regional chair and moving Jurgen to a liaison CONFIRMED  Sat to Thu, Aug 6-11, 2022: **CONFERENCE (Statistics) -** JSM [Washington, DC]   * Liaison: Freda   Regular registration is done. FDA can attend in person since it is in DC. Cost is $500-$600.  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 * May consider a connection   Mon to Wed, Sep 19-21, 2022: CONFERENCE (Multidisciplinary) – PHUSE CSS [Silver Spring, MD]   * Liaisons: ???   Tue to Thu, Sep 20-22, 2022: **CONFERENCE (Statistics) -** ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop [Rockville, MD]   * Liaisons: Freda, Jingjing   PHUSE CSS conf same time |

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| **Liaison Committee** | |
| 2022 plans  (Matt) | Matt will meet with the liaison committee on Aug 8th to get moving on some initiatives. Also sent invite to entire 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 |
| Regional Chair updates  (Matt) | DIA China Statistics Community (July 1 update)  Two DIA Statistics seminars: May 13 on combination therapy study design in cancer drug development and June 12 on Treatment efficacy evaluation in precision medicine.  ~~A request: they asked us to help organize a seminar in August on statistics in drug development topics. 1.5 hour, will be Friday afternoon/evening time US and China Saturday morning time. Two speakers each 30 min and Q&A 30 min. Highly preferred Chinese-speaking speakers. If the topic is timely and great, English-speaking speaker is fine. I am wondering what the committee is thinking. My two proposals can be: 1) FDA aggregate safety review/Benefit-risk evaluation; 2) Clinical Trial Diversity Plan.~~    ~~01Jul Action Item: Please let Jingjing know what the committee thinks and any proposed speakers?~~ Deadline is passed, Jingjing is moving ahead  DIA Europe Statistics Community  (Feb 4 update)  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?  (Jul 1 update)  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 |
| 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  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 Jun 28: 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:  *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)     - 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   Dec 2022: Digital tools/Meaningful Change (COA/PRO) – Joan  Stat & DS Community Planner below (as of June 27, 2022):    01Jul Action Item: Jon will discuss with the Education Committee about review of presenter slides to make sure they are not promotional.  Greg has 2 sessions in safety. |
| Virtual Journal Club (VJC)  As of Aug 2: 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 Jun 28: 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?  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. |

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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. |

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| FULL Annual Calendar | Fri, Aug 5, 2022: 12:00-1:00pm ET: **MEETING -** Core Committee   * Liaison committee updates - Matt * 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   Sat to Mon, Sep 17-19, 2022: **CONFERENCE (Statistics & Data Science)** - Quantitative Science Forum [Nanjing, China]   * Liaison: Jingjing   Mon to Wed, Sep 19-21, 2022: CONFERENCE (Multidisciplinary) – PHUSE CSS [Silver Spring, MD]   * Liaisons: ???   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 - Matt * 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*   Fri, Feb 3, 2023: 12:00-1:00pm ET: **MEETING -** Core Committee   * Liaison committee updates - Matt * Regional chair updates – Jurgen, Jingjing   Mon to Wed, Feb 6-8, 2023: **CONFERENCE (Safety & PV) -** DIA Global Pharmacovigilance and Risk Management Strategies Conference [virtual?]   * Liaison: Greg   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 - Matt * 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   Fri, Jun 2, 2023: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt check committee member email lists   Sun to Wed, <TBD>, 2023: **CONFERENCE (Statistics) -** PSI (Europe) [<TBD>]   * Liaison: Jurgen? Stephen? Susan?   Sun to Thu, Jun 25-29, 2023: **CONFERENCE (Multidisciplinary) -** DIA Global Annual Meeting (Boston, MA)   * Liaisons: Greg, Munish, Freda, Susan   Fri, Jul 7, 2023: 12:00-1:00pm ET: **MEETING -** Core Committee   * Matt check committee member email lists * Matt share community metrics   Thu to Sun, <TBD>, 2023: **CONFERENCE (Multidisciplinary) -** DIA China Annual Meeting [<TBD>]   * Liaison: Jingjing |