Public CMC Statistics European Network Version 10

CMC Statistics Network EuropeEFSPI SIG





CMC Statistical Network

Europe

"We are CMC Statisticians, working in Europe for pharmaceutical companies and CROs active in R&D, and we seek to collaborate and exchange in any precompetitive topic of our field."



This is what we want ...

... facilitate technical exchange in any precompetitive topic of our field.

... be seen as point of contact for EMA etc. for CMC stats related guidelines, solicit and corroborate feedback from members.

- CMC Statistical Network
 Europe
 ... encourage discussion on current
 good practice for design, computing.
- ... encourage discussion on current good practice for design, computing, evaluation, and reporting in the CMC space.
- ... create a platform for the community of European CMC statisticians.

CMC Statistics Network Europe ...so far



- Formed a steering team (Chair <u>Kevin.R.Lief@gsk.com</u>)
- Affiliated to EFSPI as a special interest group
- Created SIG website
 (https://www.psiweb.org/sigs-special-interest-groups/cmc-statistical-network-europe)
- Welcomed members
 - Do not have to be a member of EFSPI or PSI to join

Kevin Lief, GSK; Beate Presser, Boehringer-Ingelheim; Martin Otava, J&J; Christian Schmid, Roche; Jens Lamerz.



CMC Statistics Network Europe ... Current Activities



Submitted abstract to potentially present at 4th listen & learn focus group meeting of the EMA
 Quality Innovation Group

- Creating a CMC Stats Community of Practice for greater visibility
 - Planning for webinars
 - Looking to publish whitepapers/articles on hot topics

Kevin Lief, GSK; Beate Presser, Boehringer-Ingelheim; Martin Otava, J&J; Christian Schmid, Roche.

Please reach out to us

