



ISPE RWE Task Force (Co-leads: Wei Zhou (Merck) /Helga Gardarsdottir (Utrecht University); FDA CDER liaison (Mike Blum))

Subgroup	Title	Co-leads	Short description
#1	RWE and regulatory decision-making	Cindy Girman (CERobs)/Karolina Sundell Andersson (Astrazeneca)	Develop feedback, papers and workshops on regulatory RWE guidelines and papers, including use of 'fit-for purpose' methods for regulatory decisions
#2	RWE and Real-World Data Sources	Annie McNeill (Abbvie)/Kenneth Man (University College London)	Outreach/collaboration with big data vendors (could involve Database SIG); Develop and/or align methods development efforts among other RWE Working Groups for database evaluation
#3	RWE in Oncology	Donna Rivera (NCI)/Deborah Layton (IQVIA)	Collaborate with national and international organizations, professional societies, and relevant RWD stakeholders to facilitate the exchange of ideas, represent the goals of ISPE, support alignment across groups on emerging analytic methods, and advance the development of strategies for optimal use of RWE in the oncology therapeutic area
#4	RWE Statistical Methods	Jeremy Rassen (Aetion)/Rolf Groenwold (Leiden University)	Develop statistical methods related to RWE, evaluating existing methods of "fit for purpose" of RWE
#5	Collaboration with DIA	Arnold Chan (National Taiwan University)/Patrice Verpillat (Merck KGaA)	Collaborate with DIA on RWE, including global and regional meetings

#6	Collaboration with Duke Margolis	David Miller (UCB)/Christina Mack (IQVIA)	Collaborate with Duke Margolis on white papers, workshops, and policies related to RWE. Ensure ISPE presence
#7	RWE reproducibility and transparency and collaboration with ISPOR	Shirley Wang (Harvard Medical School)/Anton Pottegård (University of Southern Denmark)	Collaborate with ISPOR and other organizations on efforts related to transparent reporting and reproducibility of RWE. Currently partnering with ISPOR, Duke Margolis, and the National Pharmaceutical Council on a RWE Transparency Initiative. Collaborate with ISPOR on white papers, workshops and policies on other topics related to RWE.
#8	RWE website content	Meredith Smith (Alexion)/Rachel Sobel (UBC)	ISPE website development related to RWE, in collaboration with "Publication Committee"
#9	RWE methods training	Christopher Rentsch (London School of Hygiene&Tropical Medicine)/Joshua Gagne (Harvard medical School)	Promote training in RWE methods to ISPE and non-ISPE members and key external stakeholders, in collaboration with the Education Committee
#10	RWE manuscripts development	Mehmet Burcu (Merck)/Darren Toh (Harvard Medical School)	Develop manuscripts on methods, data quality, and other issues related to RWE, with target journals beyond PDS and potentially in collaboration with other professional societies
#11	RWE and Device	Mary Beth Ritchey (RTI Health Solutions)/Daniel Prieto-Alhambra (University of Oxford)	Outreach and collaboration with the medical device ecosystem related to RWE. Develop manuscripts and training related to RWE for medical devices.