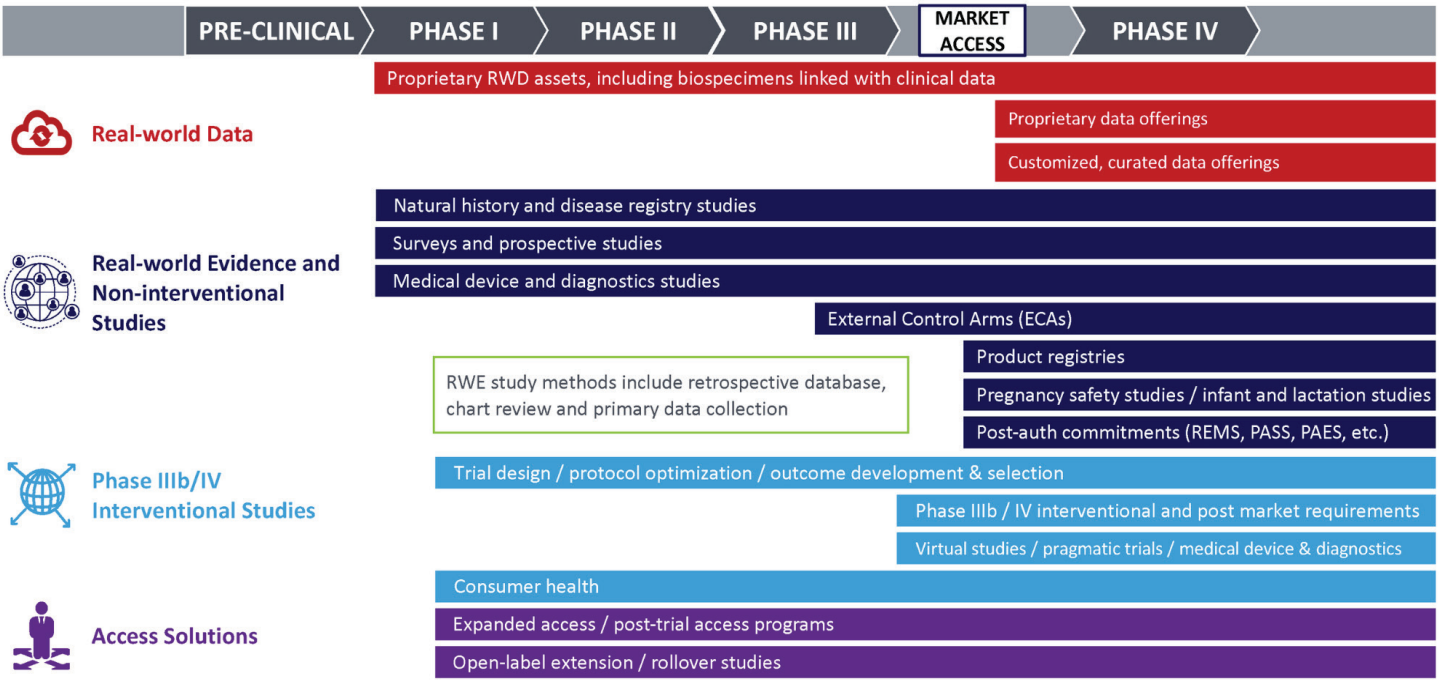
Evidera | PPD | COREVITAS®
Part of Thermo Fisher Scientific

Real-world evidence for real-life insights

Our industry-leading solutions, backed by a multi-disciplinary team of scientific experts, provide integrated real-world data and evidence, strategic consulting, scientific expertise, and global operational capabilities across the product development and commercialization life cycle.



Our solutions are shaped by our deep understanding of challenging client needs

Real-World Evidence and Non-Interventional Studies: Putting pharmacoepidemiology into practice

Our real-world evidence (RWE) team has the breadth and depth to support a full spectrum of RWE offerings, spanning the product development lifecycle from early development to post-marketing requirements. Close collaboration between our science and operations teams allows us to customize our approach based on a client's needs, and employ innovative study design driven by epidemiology, statistics, strategy, and data science expertise.

We offer a unique suite of registry solutions and studies, including single sponsor, independent, retrospective, and hybrid models, tailored to suit each client's needs. We help clients understand how their product works in the real world, collecting robust clinical data from providers and patients, including active safety and effectiveness assessments, utilizing patient- and physician-reported outcomes, quality of life, and health care resource utilization metrics. These data can be linked and combined with other data sources to meet complex research needs.

Come and speak with our experts

Epidemiology and Scientific Affairs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Patient Research and Inclusion

Our clients are partnering with us to address the latest questions in patient-centered research (PCR):

- What does the FDA's fourth PFDD guidance mean for my outcome strategy?
- When is it optimal to conduct exit interviews?
- What does the FDA's benefit-risk assessment guidance mean for use of patient preference data?
- Does NICE's methods guide mean I should use vignette studies to estimate patient and caregiver health state utility?

We partner with our clients to design a PCR strategy that optimizes rapid patient insights, patient partnering, product strategy and regulatory-quality patient-experience data to increase chances of market success for products

Speak with our experts

Meredith Smith
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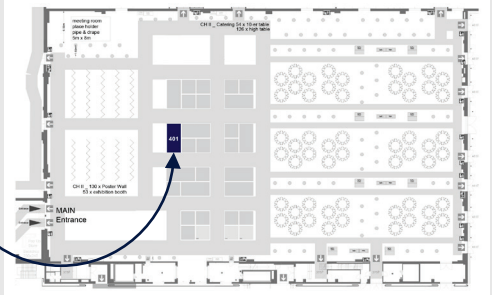
Market Access Regulation Changes

The Inflation Reduction Act (IRA) and the EU Health Technology Assessment (HTA) Regulation bring about major changes in the US and EU access landscape that require early and strategic preparation to ensure an optimal evidence package to demonstrate value. Generation of RWE can be a useful tool in addressing the challenges arising from these new access policies and prepare for stakeholder discussions.

Our strategic consultants focus on navigating the changes brought about by the IRA and the HTA Regulation and on preparing clients to plan and prepare for the new landscape in the US and the EU, thanks to our unique combination of technical expertise and strategy consulting.

Scan the QR code for additional presentations at ICPE 2024

Stop by our booth, **401**, to speak with us about any of our solutions!



Real-World Data

With the proliferation in real-world data (RWD) across the globe, our clients are often unsure which RWD are optimal to generate the real-world evidence needed to meet their objectives.

We guide our clients on RWD identification and selection to optimize research needs. Proprietary data sources, experience with 100+ global data sources, advanced technologies and expert data scientists provide the insights our clients need to inform decision-making.

Speak with our experts and ask about our data!

- Optimized utilization of available datasets and comprehensive analysis and study solutions
- Proprietary CorEvitas registry data on 100k patients in Derm, Rheum (US/Japan), GI and Neuro immune-mediated diseases
- Retina specialty EMR data on 2.5M patients from 350 retina ophthalmologists' panel
- Provider Insights: Real-time prescribing data from 2.2 million global health care providers (HCPs) showing treatment pattern and sequence, patient profiling, and trends in prescribing
- Partnership with ConcertAI for curated data on 7M+ oncology patients combined with our methodological expertise

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Complex Reimbursement Hurdles

Reimbursement hurdles in HTA countries are higher and more complex than ever before. Our clients value our expertise in HEOR strategy and in developing fit-for-purpose tools for successful submissions. These tools include robust evidence synthesis and indirect treatment comparisons, as well as advanced statistical analyses of trial data—all presented within the value-focused narrative of the submission dossier.

Our global team of consultants bring their extensive experience in economic modeling, HTA-compliant literature reviews, complex statistical analyses, and market access communications to each of our client partnerships, ensuring each client has a strong HEOR strategy and is prepared for reimbursement discussions with a sound evidence package

Saturday, August 24

Pre-conference Skills Course: 9:00am – 12:30pm

1. Risk Minimization and Communication: Scientific Approaches and Case Studies for Designing and Evaluating Interventions for the Safe Use of Medicines (Meredith Smith)

Monday, August 26

Poster Session A: 8:00am – 6:00pm

1. Synthesized learnings and considerations from global historical cohort studies via retrospective chart review in oncology. (Neil Brett, Laura Sayegh, Mariam Selvage, Celena Kent, Marielle Bassel)

2. Adjuvant, 1L and 2L treatment patterns were described within metastatic non-small cell lung cancer (mNSCLC) patient populations across EU4, UK and USA during the years 2022 and 2023.
(Delphine Saragoussi, Ivana Sestak, Elvira Gomez, Kacy Emeanuru)

3. Safety Results of Post-Marketing Surveillance Studies of B/F/TAF in China and South Korea.
(Javier Cid-Ruzafa, Harmony Omeife)

Tuesday, August 27

Oral Presentation Session 3: 8:00am – 9:30am

1. Performance of entropy balancing and covariate balancing propensity score methods for controlling confounding under challenging real-world conditions in observational studies: a simulation study.
(Michael Singleton, Oksana Pugach, Melissa Eliot, Robert R. McLean, Adam Sima, Heather Litman)

2. Development of the Reporting recommendations Intended for pharmaceutical risk Minimization Evaluation Studies-Standards for Reporting of Implementation Studies Extension (RIMES-SE). (Meredith Smith)

Poster Session B: 8:00am – 6:00pm

1. Vaccine Cohort Event Monitoring: Enhancement of Safety Data Collection.
(Sarah Rosen, David Hillman, Delphine Saragoussi)

2. A step-by-step guide for incorporating estimands in observational studies.
(Ivana Sestak, Maryse Kochoedo, Lindsey Radenbaugh, Yuliya Halchenko, Martin Ladouceur)
3. Understanding the utility of historical cohort studies via retrospective chart review studies in inflammatory bowel disease: A review of global studies.
(Neil Brett, Christian Betz, Lauren Gianchetti, Zaeem Khan, Daniela Castano, Gustav Schellack, Marielle Bassel)

4. Comparator cohort selection: a case study among review of prospective pregnancy registries for multiple sclerosis (MS) products. (Kristin Veley, Reem Masarwa, Rebecca Buus, Yuliya Halchenko, Caitlyn Blum)

5. Evaluation of digital data collection methods in a prospective pregnancy registry for a migraine product with both acute and preventive indications.
(Kristin Veley, MacDonald SC, Hardy JR, Huang Q, Ivans A, Norris CG, O'Donnell A, Yang R, Asomaning K)

6. Effectiveness of awareness/recruitment activities for pregnancy registries.
(Kristin Veley, Courtney G. Norris, Lindsey Radenbaugh, Fang-Yi Lin)

7. A hypothetical case study describing different intercurrent events in an observational prospective study: Differential interpretation of results.
(Ivana Sestak, Bree Newton, Yuliya Halchenko, Kathleen Shannon, Delphine Saragoussi)

Tuesday, August 27

8. Real-world data collection in medical device for regulatory submissions: Considerations in epidemiology. (Ronna Chan, Ken Butz, Christine Varner, Delphine Saragoussi)

9. Methodological considerations for the design and implementation of real-world vaccine-related studies in low-and middle-income countries. (Angela Carter, Annamaria Kiure, Sandra Okala, Sarah Rosen, Kat Downes, Delphine Saragoussi)

10. Systematic Definition Development of Variables of Interest for Studies Using Administrative Databases. (Mai Duong, Noami Berfeld, Mark Yates)

11. Using Large Language Models with Real-World Data to Support Regulatory Decision-Making for Medicinal Products: Are We on the Road to Regulatory Convergence or Chaos? (Meredith Smith)

Symposia & Workshop Session 3: 4:15pm – 5:45pm

1. Novel Individualized Therapeutics: Challenges and Opportunities for the Use of Real-World Evidence in Rare Diseases. (Delphine Saragoussi)
2. Why Real-World Evidence (RWE) Studies Need Implementation Research: The Value Proposition. (Meredith Smith)

Wednesday, August 28

Poster Session C: 8:00am – 6:00pm

1. Study Design Considerations for Real-world Observational Studies Supporting Pre-Approval Regulatory Decision-making in China. (Yufei Song, Lu Ban, Jiang Li, Ziyi Li, Alice Rouleau)

2. Retrospective chart review data collection to generate external comparator arm populations: Considerations and suggestions for reducing key biases. (Neil Brett, Fang-Yi Lin, Elizabeth Donahue, Marielle Bassel, Martin Ladouceur)

3. C&G therapy post-marketing commitments: review of designs, differences cell vs. gene therapy, EU vs. US, potentially other regions as well. (Sara Angleman, Alice Rouleau, Bethany Gibson, Elizabeth Donahue, Delphine Saragoussi)

4. A comparison of Regulatory Frameworks for real-world data (RWD) collection within Early Access Programs (EAP) in the US, EU and Japan. (Alice Rouleau, Janneke Luijken, Zaeem Khan, Yufei Song, Pedro Inacio, Emily Speas, Ivana Sestak)

5. Use of test-negative designs in pharmacoepidemiology: focus on vaccine effectiveness 2013-2023. (Delphine Saragoussi, Aurelien Mantonnier, Amanda Pulfer, Martin Ladouceur, Jack Ishak, Susan Oliveria)

6. Standardization of Coding Definitions for Sickle Cell Disease Complications: A Systematic Literature Review. (Firas Dabbous, Rajrupa Gosh, Surbhi Shah)

7. Estimation of period-based costs associated with individual chronic complications of rare inherited diseases, in the context of multimorbidity, using real-world data. (Caoimhe Rice, Jennifer Davidson, Sara Carvalho)

Symposia & Workshop Session 4: 10:30am – 12:00pm

1. Back to the Source: a Review of the Current State of Social Determinants of Health in European and US Real World Data Sources. (Syd Phillips)

2. Risk Minimization Programs for Teratogenic Drugs: How to Move from Art to Science. (Meredith Smith)