Real World Data and Evidence

At Emmes, the goal of our RWD and RWE experts is to enhance your evidence generation by leveraging a wide spectrum of validated, contemporaneous, real-world data sources, to support the entire drug lifecycle including hypothesis generation, clinical-development as well as post market evidence generation requirements.

Real world evidence on patient outcomes in addition to experiential data have become an integral part for regulatory submissions in vaccines, epilepsy, migraine or Crohn's disease. Additionally, biomarkers, subgroups, and other response predictor models derived from trial or real-world data offert more informed guidance on therapeutic effectiveness, trial designs and can be used to mitigate study risks.

From rare disease study recruitment to control-arm data acquisition, post market commitments and innovative study designs to understand the patients journey, our RWE/RWD team can partner with you in expanding access to comprehensive sources to enhance your studies, registries and other evidence generation needs.

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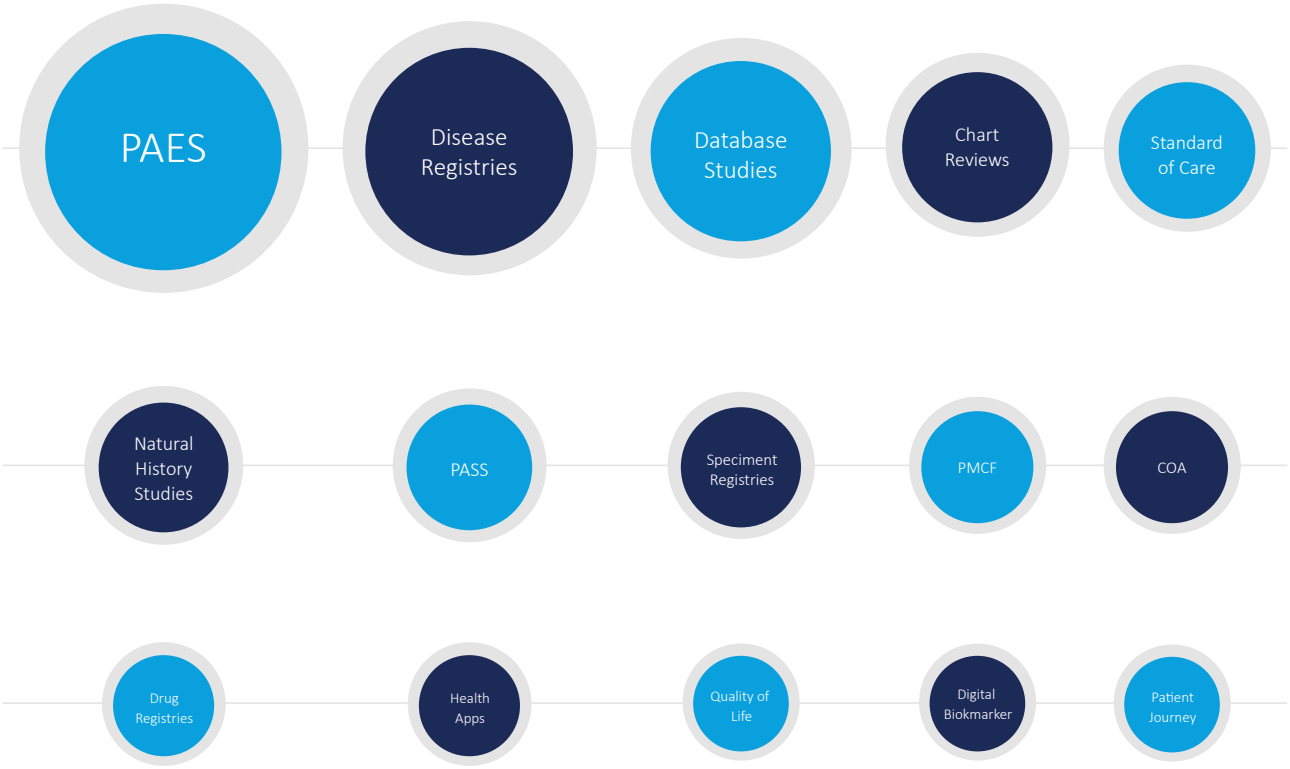
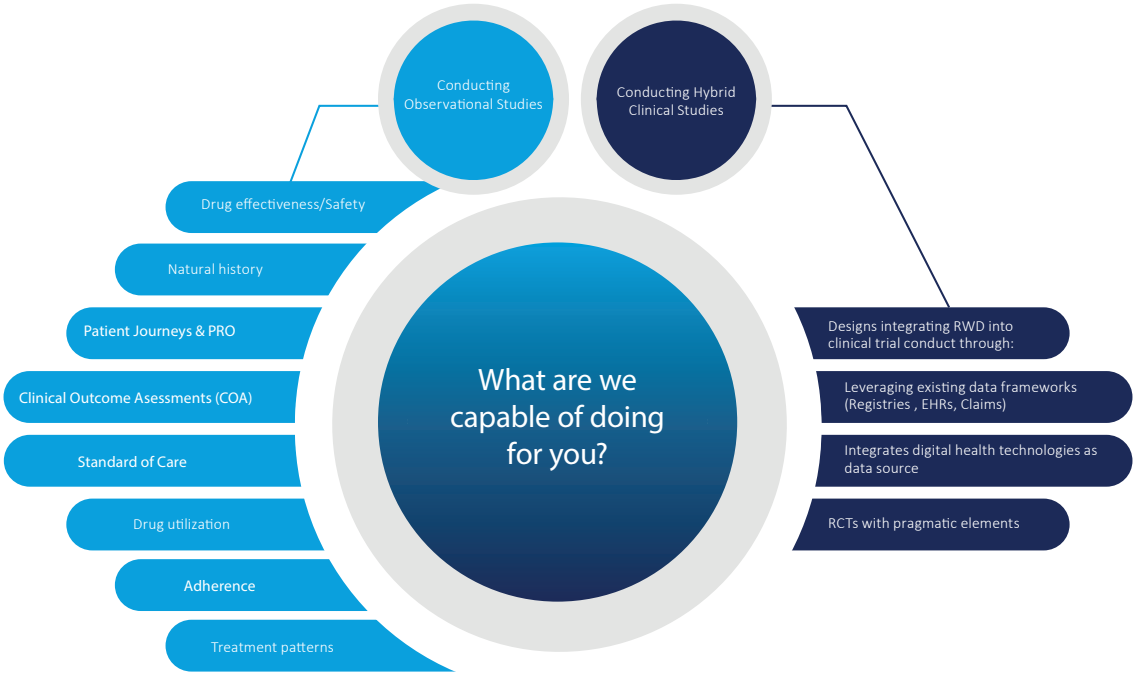
Emmes RWE Experience for the last 10 years



We understand the importance of applying ethical and quality standards to real-world data curation and analysis. Our dedicated team of data managers, data scientist and biostatisticians identify, mitigate and account for bias that could negatively impact inference from your studies involving RWD – for both drug and medical device development.



Some of the key highlights of our services include:

- Dedicated operating model for prospective Non-interventional studies (NIS)
- EDC systems tailored to NIS requirements (including the ability to harness the capabilities of eAdvantage)
- Global full-service capabilities
- Bioinformatics services- supporting data curation and validation as well as advanced analytics
- Flexible and innovative in approach we are ready to incorporate health apps and combine existing products
- Very flexible/customizable for novel approaches (showcased in our client testimonial below) – we build the solution around your ideas – at a competitive rate.

10 Years
We have provided RWD/E services for 10 years

200+
RWE studies

43
Across 43 countries

19+
Therapeutic Areas

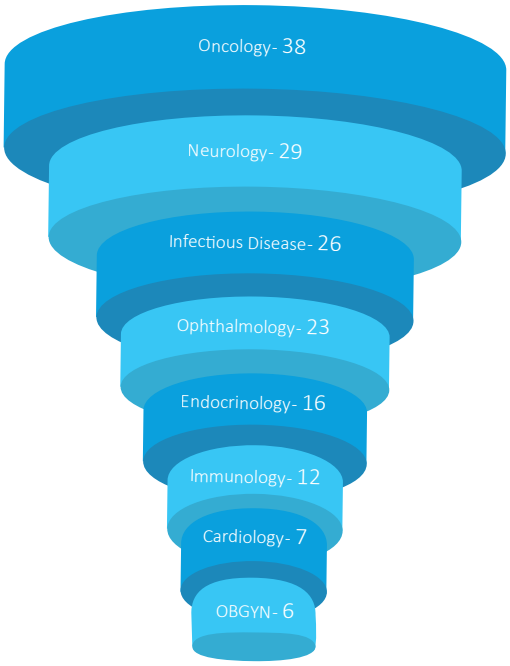
What clients say about our RWE Teams

> Sponsor: We are impressed with the team's flexibility, professionalism, an "can-do attitude" (and therefore committed to working with Emmes in a follow up study.

> Sponsor: "We appreciate the team's "fantastic support" and "trusted collaboration" which has led to an excellent outcome."

Aside from several large registries Emmes has also been supporting 2 large pediatric initiatives in the US, the Best Pharmaceuticals for Children Act (BPCA) as well as the North American Pediatric Renal Trials Cooperative Study (NAPRTCS)

Most Common Therapeutic Areas



Best Pharmaceuticals for Children Act (BPCA) Data Coordinating Center

> Through the BPCA contract, Emmes' has supported more than **44** studies, evaluating **128** drugs and obtaining labeling updates from the FDA for **14** drugs and **2** devices.

Historically, as much as 80% of all drugs prescribed for children in the US have lacked adequate labeling for pediatric use because they were never tested in children. The BPCA aims to rectify this public health challenge by ensuring that new medicines and other therapeutics are tested in children, as appropriate, and by developing evidence-based improvements in pediatric labeling for drugs and other therapeutics that were approved before United States law made provisions for mandatory pediatric testing. This will therefore improve the safety and efficacy of the drug substance for the affected population.

Leading the Data Coordinating Center Emmes has played a key role in the translation of quality pediatric research into scientifically supported evidence that allow the FDA to improve pediatric labeling.

North American Pediatric Renal Trials Cooperative Study (NAPRTCS)

The North American Pediatric Renal Trials Cooperative Study (NAPRTCS) assesses both short-term and long-term outcomes in pediatric patients who have received renal transplants, patients receiving dialysis, and patients with pre-end stage chronic kidney disease. This study encompasses over **100 treatment centers** in the United States and Canada.

As the Statistical and Data Coordinating Center, Emmes has continuously supported this research effort since its founding in 1987. Emmes provides statistical analysis, reporting, and data capture services, as well as support to all participating centers.

> Emmes has supported or authored an excess of **300** publications and abstracts regarding this project

Over **12,000** children with renal transplants have been registered, **>8,100** children have been enrolled in the Dialysis Registry, and almost **8,300** children have been registered with pre-end stage chronic kidney disease.

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For additional information on our services, please visit
www.emmes.com/real-world-data-and-real-world-evidence