

Advancing Peri- and Post-Approval Research

Evidera's interventional study team has extensive experience in the design and execution of global, regional, and single country studies in the peri- and post-approval space. Our research generates impactful medical data through structured studies that build a larger body of evidence in support of a product or specific patient population to better inform appropriate clinical practice, enable optimal commercialization and market access, and address specific post-approval health authority requirements. All of our studies are conducted following Good Clinical Practice (GCP) and research principles, but at times do not require the same level of monitoring or lab collection since the research often follows the standard of care.

Evidera has developed global process standards and tactics that allow us to develop streamlined and cost-efficient programs that maximize data collection, monitoring, and quality while minimizing operational risk. Our focus is on targeting inclusion and exclusion criteria to ensure they are specific to the need of the research program and the specific patient population. Our team has deep country-level knowledge of ethical and regulatory requirements, patient privacy legislation, investigator grant policies, academic and site networks, patient associations, national health databases, and local healthcare systems that allows us to customize each project for successful execution.

We Can Help You

- Generate data to address peri- and post-approval evidence gaps
- Meet Health Authority requirements for post-marketing safety
- Optimize data flow to answer key asset / brand questions in a timely manner
- Inform appropriate clinical practice and product use, and ensure data are available to answer medical communication queries
- Enable optimal commercialization and market access
- Validate new dosing or models of administration
- Enhance exploratory analyses through innovative collaborations with scientific experts

Excellence in Study Design and Execution

- **Extensive experience** – Dedicated operations, regulatory, and global, clinical supply teams with experience across ~116,000 patients and ~15,000 sites globally in the past 5 years
- **Specialist medical affairs team** – Rapid study start-up and patient recruitment when working under an early engagement partnership model
- **Therapeutic area experts** – Capabilities across a wide range of indications, and ability to leverage PPD's network of clinicians and global operations professionals
- **Integrated partnership model** – Flexible and proactive operating and governance model customized to unique needs
- **Innovative methodologies** – Application of innovative methods (e.g., pragmatic studies) resulting in optimal study design, endpoint selection, and statistical analyses
- **Expertise in study design and protocol development** – All studies governed by a scientifically robust protocol that is reviewed and quality controlled by an in-house, industry-recognized research team

Interventional Study Offerings

- Phase IIIb / IV Studies
- Expanded Access / Compassionate Use Programs (EAP / CUP)
- Extended Access Programs (XAP) / Open Label Extension
- Post-Marketing Commitments
- Lactation / Placental Transfer Studies
- Pragmatic / Adaptive Trials
- Investigator Sponsored / Initiated Trials (IST / IIT)

Case Study: Compassionate Use Program (CUP) - Rapid Drug Delivery to Patients in Need

Situation

- Client required a global program to provide treatment to patients with a serious influenza infection
- Program needed to span 38 countries across North America, Latin America, Europe, the Middle East, Africa, and Asia Pacific and accept treatment requests from thousands of patients

Key Challenges

- Patient demand varied based on the influenza season within different countries
- 24 to 48 hour shipment of drug from patient approval
- Meeting the approval requirements from a variety of regulatory agencies across multiple countries

A Two-Fold Approach

Sponsor-Dedicated Program Pathway

- Provided first-line contact and acted as a resource for physicians requesting treatment
- Streamlined physician drug request process
- Handled follow-up for any missing treatment / shipping information
- Initiated and coordinated drug shipments to physicians

Drug Depots in Countries with High Demand

- Allowed for expedited shipment of drug within specified high-demand countries

Outcome

- Provided over 3,100 patient treatments from more than 2,800 physician requests
- Our streamlined request process decreased time from physician request to shipment of drug allowing for 24 to 48 hour turnaround

Impact

- Consolidated point of contact for treatment requests
- Flexible program process easily allows for ramp up / ramp down
- Minimal time delay in triggering shipments
- Ability to handle requests from various countries regardless of demand