



## Late-Phase Services

### Global Planning & Services for Post-Approval Success

PRA's Late-Phase Services group supports global and regional Post-Approval studies. Late-Phase Services assists sponsors with the Post-Marketing process by planning and conducting Safety-Surveillance studies, Large Simple Trials (LSTs), Registries, Retrospective Studies and Restricted Access Programs. The international management team has many years experience managing late-phase studies ranging in size from 60 patients to 18,000 patients. The Late-Phase Services operational team is supported by industry-leading strategic, scientific, medical, and epidemiological experts.

We recognize our sponsors' prescribers are of the utmost importance, therefore, we provide customer service through our global multilingual Study Coordinating Center. With a focus on scientific endpoints, our goal is to provide rapid study start-up, swift high-quality data collection, and precise benefit and risk analysis.

Our team conducts and manages Post-Approval studies with simplicity in mind, using streamlined data capture methods such as web-based EDC and ePROs. Case Report Forms (CRFs) and surveys are developed to allow for easy data collection – as well as proactive edit checks that focus on safety and the study endpoints. Our innovative study-branded investigator kit, with its reduced prescriber paperwork, speeds the start-up processes.

#### PRA's Late-Phase Services:

- Safety Surveillance/Post-Authorization Safety Studies (PASS)
- Large Simple Trials (LSTs)
- Disease/Product/Pregnancy Registries
- Restricted Access Programs
- Retrospective Studies

#### In addition, PRA Late-Phase Services also offers:

##### Post-Marketing Research Training

- Provides an overview of the global Post-Marketing environment, research trends, study design options, execution and operational considerations

##### Post-Marketing Study Designs

- Our Late-Phase Services group will work with your team to identify the organization's Post-Approval research goals, interpret regulatory commitments, develop various study designs and create a protocol synopsis to meet your internal and external needs.



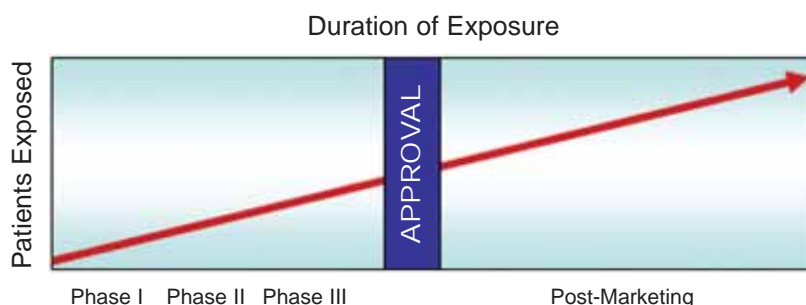
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# Phase IV—An Integral Stage of Drug Development



Number and types of patients taking a product post-approval can vary greatly from those studied in the earlier phase clinical trials. Length of exposure can be significantly greater as well. Post-marketing studies help to identify trends and signals in large “real-life” populations.

## Tools for Post-Approval Study Success:

- Scientific, streamlined protocol writing to support study endpoints
- Critical thinking to minimize risk and increase benefit
- Experienced international Late-Phase project management
- Global multilingual Study Coordinating Center to ease physician administrative burden
- Current understanding of evolving regional and local Post-Approval requirements
- Rapid study start-up supported by innovative study materials
- Active participant follow-up to support long-term retention
- Electronic, paper and hybrid data capture methods
- Flexible resourcing for evolving project needs

Our group utilizes a unique global team of Site Management Associates (SMAs), Lead CRAs and oversight by Late-Phase experienced Project Managers and Project Directors. This global group is responsible for the collection and processing of initial and ongoing essential documents, as well as oversight of the clinical operations and monitoring activities. Our operational model allows us to effectively manage both small and large Post-Marketing programs.

## PRA's Therapeutic Expertise

Since 2004, PRA has managed more than 150 Late Phase studies and related services in the following areas:

Cardiovascular	CNS/Neurology/Psychiatry	Women's Health
Oncology/Hematology	Respiratory/Allergy	Gastrointestinal
Endocrinology	Infectious Diseases	Ophthalmology

## PRA Phase IV Success Stories

### Gastrointestinal Registry — 21 Countries, 500 sites / 3,000 participants — 5+ years

INTERNATIONAL COORDINATION—PRA worked with the sponsor to identify the product approval timelines for each country and planned country activations accordingly. The team reached out to each country's regulatory agency to confirm the current regulations for non-interventional programs according to Volume 9A. We worked with the sites that participated in the Phase III open label to roll-over as many patients from that program as possible into the Registry. The management team worked with the sponsor to align country affiliate expectations to ensure a streamlined and highly productive global project team.

### Epilepsy Phase IV Trial — US Only, 425 sites / 500 patients — 2 years

COLLABORATION & COACHING—PRA worked with the sponsor to develop and manage a difficult program. The study was transitioned mid-way through the program to PRA from another CRO. Most of the 425 sites were research naïve and participants included both adult and pediatric epilepsy patients. The project team mentored the sites in essential document requirements, informed consent procedures, data collection methods and safety event reporting. This resulted in faster site activations and subsequent boosts in participant enrollment. Throughout the study, the management team seamlessly coordinated all study activities from data capture, site monitoring and successful study lock.

### GERD Limited Access Program — US Only, 4,526 sites / 16,726 patients — 8 years

ACCESS & SUPPORT—PRA and the sponsor partnered to make an effective GERD treatment available to patients who have no other way to obtain the drug, while monitoring each patient carefully for safety. The product was approved, but soon after was associated with an increased risk of heart attack and subsequently removed from the market for further research. PRA has successfully managed the data collection for eight years using a call center in conjunction with IVRS. Working with research naïve sites, PRA helped a large number of physicians progressively increase their safety data submissions and timeliness through the course of the program.

## PRA INTERNATIONAL

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