



### Meeting the Unique Requirements of Post-Approval Studies

Post-approval studies can be very large, and are often conducted by prescribing physicians rather than seasoned investigators. Bioclinica's Program Coordinating Center (PCC) ensures that:

- > Site management strategies are tailored to meet the needs of research-naïve physicians as well as experienced clinical research sites.
- > Prescribing physicians receive the remote monitoring and support necessary to enhance their engagement and compliance with established protocols throughout the course of the study.
- > All participants in the study have access to PCC staff members for swift response to any questions or concerns.

### Exclusively Focused on Coordinating and Supporting Participating Sites

Our experienced Post-Approval Research team develops and implements customized strategies for each drug, specifically structured for the needs of post-approval research. At Bioclinica, we enhance the management of post-approval studies with our **Program Coordinating Center (PCC)**.

- > Validated SOPs developed expressly for post-approval studies
- > Staff located globally to ensure real-time support in local languages
- > Execution of site management strategies tailored to meet the needs of physicians, from seasoned clinical research sites to research-naïve physicians
- > Remote monitoring that leverages post-approval-specific technology
- > Customized study reports that integrate multiple discrete data sets to help you analyze data and gain clarity
- > Maintains confidential patient data in compliance with country and state laws and regulations (HIPAA, FDA, EMA, etc.)

