

## Case Study #3: Clear, Actionable, Communication

### SITUATION

Accudata Solutions was hired by a mid-size pharmaceutical company to provide analysis support of an ongoing registry study to Medical Affairs. The already-approved treatment was an analgesic drug delivered by a pump. These analysis reports were source material for manuscripts and abstracts for professional publications and conference presentations.



### ISSUE

Through a history of company acquisitions, the company that originally developed the drug was three companies removed from the client company that now owned the drug. A fourth company manufactured the pump. Therefore, there was a knowledge gap among the personnel of the client company as to how the pump delivered the medication. This gap led to poor understanding of the drug dosing information.

### PROBLEM IDENTIFIED

Through persistent questioning of Medical Affairs staff, Medical Science Liaisons, and even representatives of the pump manufacturer, Accudata Solutions began to understand how exactly the pump delivered the medication and discovered that the Case Report Form capturing drug dosing was inadequate. For the previous year-and-a-half, dose levels had been systematically underreported.

### ACCUDATA SOLUTIONS ACTION

- Clearly communicated the problem to the Medical Monitor and Medical Science Liaisons
- Laid out multiple paths of resolution
- Took a leadership role in communicating with the CRO in charge of both site management and data management, including the preparation of revised training materials and CRF instructions for monitors and site personnel

### CLIENT BENEFIT

The Medical Monitor imposed a six-month moratorium on any scientific presentations or abstracts from the registry study results until an investigation and retraining at each investigator site had completed. By preventing the dissemination of study results based on incorrect data, Accudata Solutions prevented damage to the company's reputation resulting from the retraction of erroneous scientific conclusions.