

## Case Study #2 Expert Representation to Regulatory Agencies Leading to Product Approval



### SITUATION

Accudata Solutions was hired by Therasense to provide comprehensive biometrics support to the planning and analysis of a pivotal clinical trial leading to a PMA submission of a Continuous Glucose Monitoring System intended for diabetics.

### ISSUE

The product's innovative commercial and regulatory goal was to get approval as a *substitute* for finger-stick testing of blood glucose. This goal was more far-reaching and commercially rewarding than previous glucose monitors approved only as a *supplement* to finger-stick testing.

### DILEMMA

Since previous continuous glucose monitors were only approved as supplements to traditional finger-stick blood glucose testing, the burden of quantitative evidence demonstrating accuracy was relatively low. Historically, the FDA had only required *descriptive* information when comparing accuracy of the investigational monitor to the gold standard of glucose measurement (YSI Laboratories).

On the other hand, a regulatory claim of *substitutability* required a higher burden of accuracy, but as a novel technology, the FDA had no clear direction as to how high that burden should be.

### ACCUDATA SOLUTIONS ACTION

After conferring internally with client's device engineers, clinicians, and regulatory personnel, Accudata Solutions proposed and negotiated with the FDA for a primary endpoint of an acceptable difference between blood glucose measured by the investigational monitor and companion measurements made by the gold-standard instrument.

Accudata Solutions then designed and produced analysis outputs that fit that analysis strategy, leading to a successful PMA.

### CLIENT BENEFIT

The Therasense Freestyle Navigator™ was the first continuous glucose monitor approved and sold as a replacement for finger-stick glucose testing. Shortly after approval, Therasense was sold to Abbott Labs in 2004 for \$1.2 billion. Abbott Diabetes Care was created from the merger of this technology with Abbott's existing glucose technology.