

Case Study

When FDA Feedback Puts Your RWE Timeline at Risk

How Worldwide Flex FSP rapidly developed a regulatory-compliant protocol and helped a sponsor move forward with confidence.

The Challenge

A mid-sized pharmaceutical company urgently needed to respond to FDA feedback related to a product label expansion. The immediate requirement was a full protocol for a non-interventional retrospective study in a rare endocrine disorder.

The Solution

- ✓ **Built for rapid regulatory alignment**
Worldwide centered delivery on quality content, effective communication, and agile execution.
- ✓ **Applied recognized standards**
The team used the EnCePP checklist to align the protocol with global research writing standards.
- ✓ **Simplified review**
The study synopsis, schematic, and schedule of assessments were streamlined to make supplementary-material review more efficient.
- ✓ **Resolved questions quickly**
Cross-functional subject matter experts addressed sponsor concerns within one business day.
- ✓ **Covered governance needs**
The team prepared a customized no objection letter focused on data privacy and data governance.
- ✓ **Delivered at speed**
Worldwide delivered a draft regulatory-compliant protocol within three days.

Why This Matters

If urgent regulatory feedback requires you to redesign or realign an RWE study, every review cycle can affect your ability to start on schedule. You need a partner who can translate feedback into a compliant protocol quickly, resolve issues without creating more oversight, and keep cross-functional contributors aligned.

Outcome

**3 DAYS**

Draft regulatory-compliant protocol delivered

**Just Over 1 Month**

Protocol development and regulatory alignment completed

**Ahead of schedule**

Study start enabled by rapid protocol realignment

The sponsor gained confidence in the team's ability to deliver independently, reducing the oversight burden. Streamlined communication and efficient writing also saved time for the project manager and subject matter experts.