propharma

CASE STUDY

Rapid Safety Database Implementation: Achieving Global Compliance in Just Four Weeks

> "We are excited to be partnered with you and your team at ProPharma!"

Challenge

A mid-sized U.S. pharmaceutical company required the **rapid implementation of a global safety database** to support four affiliate partners, 4,000 legacy safety cases, four product families, and two active clinical trials.

Approximately 50% of the **cases were over 20 years old** and documented only in CIOMS format.

The project had an **aggressive timeline of just four weeks** to achieve Go Live.

Solution

ProPharma configured a safety database to accommodate all case types and product lines.

Tailored methodologies were applied for each partner's data, including CIOMS/MedWatch conversions to XML, XML imports, and manual data entry.

A **comprehensive data transition plan and Safety Management Plans were developed.**

Results

- All legacy data tested, validated, and loaded successfully
- **Production database** launched on time
- Team fully trained to manage active clinical trials
- **Met the Go Live milestone** within the required four-week timeline.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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