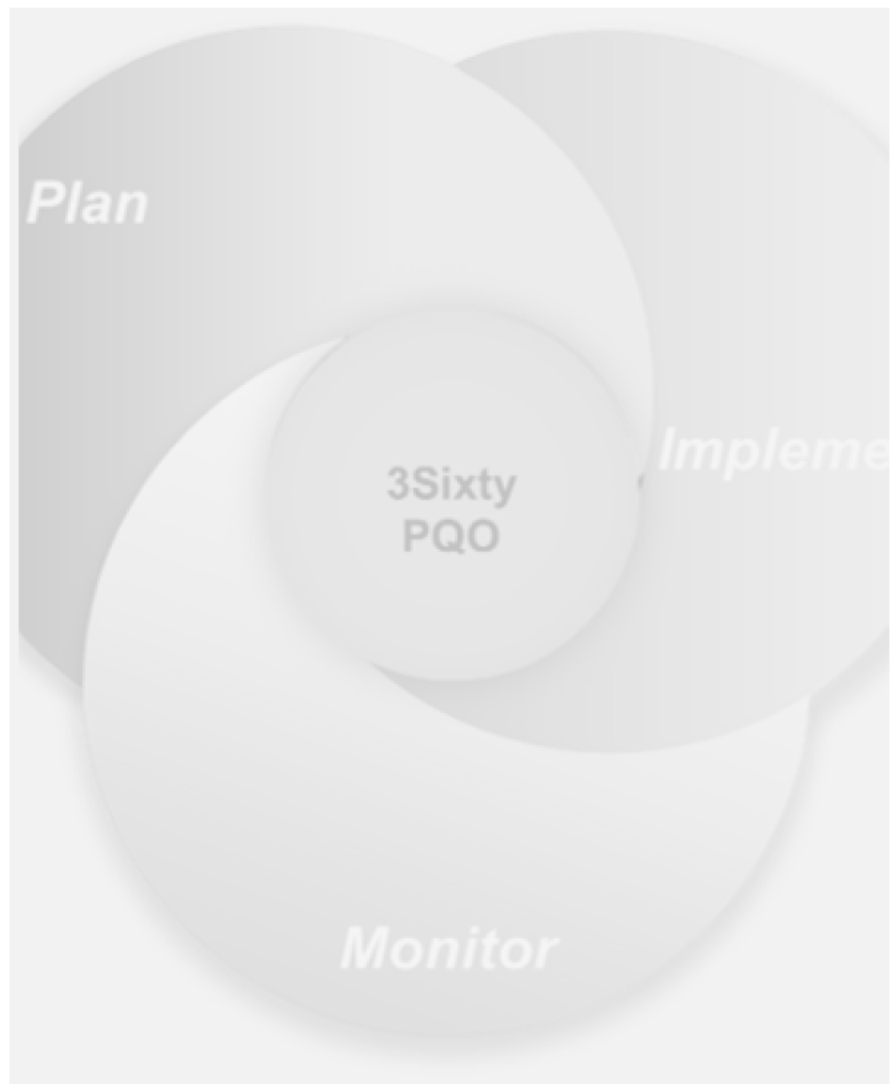


# Clinical Operations Optimization



## The Challenge

Pharmaceutical company was pursuing exclusivity for a pediatric indication.

## Our Approach

Embedded into company, using and improving internal processes, enhanced internal & external team communications, optimized investigator & site engagement, and strengthened CRA training & support.

## Value Added

Fully enrolled two studies six months ahead of schedule. Enrollment completed so rapidly that only 50% of sites had time to be initiated.

## Specifics

- ✓ Led global project teams & inspection-readiness.
- ✓ Created program plans, timelines, tracking, metrics, dashboards.
- ✓ Drafted communications & relevant protocol sections.
- ✓ Supervised EDC database development & deployment.
- ✓ Led planning & execution: IMs, CRA training.
- ✓ Engaged/managed vendors, CROs, and Clinical Research Associates.