

## Clarity's Medical Writers Help Pfizer Meet FDA Guidelines

### Challenge

Pfizer, one of the world's largest research-based pharmaceutical firms, needed assistance with its clinical studies documentation.

### Opportunity

After a new medicine is developed, it must undergo a clinical trial phase that is documented in accordance with U.S. Food and Drug Administration (FDA) guidelines. Pfizer's Clinical Communications Division needed to document its clinical studies, which were being prepared for submission by a specified deadline to the FDA. Clarity provided medical writers with relevant backgrounds in HIV and oncology research.

### Results

The medical writers developed templates for the clinical documentation that conformed to FDA guidelines. They also developed and reviewed content to ensure that it was presented accurately.



### Clarity enabled the client to:

- Produce scientifically sound reports in accordance with FDA guidelines.
- Meet the FDA's deadline for clinical studies documentation.



▶ Do you have critical projects to complete, but lack the necessary resources to get the job done? Contact us.