Case Study

# Multi-country Phase III clinical trial support

## Challenge

Market specific CTA applications for a multi-country EU Phase III clinical trial

- Assistance required to review core documentation.
- Authoring of local documentation for country specific submissions.
- Assistance with competent authority and ethics committee communication.
- Support with handling of substantial amendments to competent authorities and ethics committees, as required.

## Solution

Appoint a project leader to manage project co-ordination

- Reviewed, provided and prepared local documentation by PharmaLex employees.
- Submitted competent authority and ethics committee packages and tracked to approval.
- Supported preparation and submission of substantial amendments through to approval.

## Outcome

All tasks delivered within defined timeframe

- Minimal requests for further information received as country specific packages were provided.
- Local expertise from PharmaLex employees allowed efficient management of the clinical trial from authorization to completion.