Case Study

US-UK Phase II clinical trial support

Challenge

Support for timely approval of a Phase II clinical trial in the US and UK

- Required assistance in IND authoring, eCTD publishing and FDA Agent activities for submission to FDA.
- Alongside support in authoring of IMPD and local documentation required for submission to MHRA.

Solution

Appointment of a project lead to manage project co-ordination

- Prepared IND Module 1 documents and provided eCTD support for IND submission.
- Authored IMPD and local documentation for submission to MHRA.
- Conducted direct US and UK competent authority communication.
- Local submission platforms utilized.
- Maintenance activities including handling of substantial amendments, as required.

Outcome

All tasks delivered within defined time frame

- IND templates could be utilized for future submissions.
- 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.