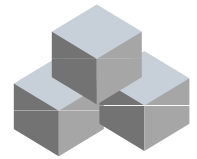


# Combining A Phase I Study With An Ongoing Observational Study

Cmed's Data & Analytics team demonstrated their commitment to providing flexible and innovative solutions to meet the requirements of complex clinical trial situations



## Situation

A biopharmaceutical company had an ongoing observational study with 120 patients in 5 sites. As the team started to plan their first Phase I study they realised that they wanted to align the data structures from both studies.

The observational study had been initiated in Openclinica but this was not a suitable solution for the sponsor. The preference was to adopt encapsia (Cmed's proprietary EDC and analytics platform) to take advantage of its advanced analytical capability.



## Challenge

Cmed needed to provide an encapsia database to:

- Incorporate data for existing patients from the OpenClinica database whilst minimizing impact on the sites and ensuring complete data integrity
- Capture and manage prospective data from existing patients
- Capture and manage all data from new patients



## Solution

Cmed specializes in innovative technical solutions for sponsors.

By applying previous experience of rescue approaches for clinical data, Cmed:

- Built an encapsia database to meet needs for all prospective data
- Worked closely with the client to appropriately map existing data to encapsia and agree comprehensive rules for handling non-standard situations
- Used fully validated functionality within encapsia using bespoke requirements to import data extracted from OpenClinica, initially to a test environment and then to the live database



## Impact

Cmed provided:

- An efficient transfer of data with just days between data being extracted from OpenClinica and available in encapsia
- A user-friendly solution which minimized the impact on busy site staff, avoiding re-entry of data and allowing easy prospective data collection
- An accurate and validated transfer of data which the sponsor knew would stand up to regulatory scrutiny

*Data science and analytics solutions to fit your needs perfectly*

