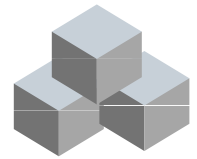


# Implementing a 'Press of a Button' Score-Based Treatment Path for Site Users



## Situation

A biopharmaceutical company had a Phase II study with 300 patients in 5 countries.

- At a key point in the study each patient's treatment path depended on a score calculated from data collected over the previous period.
- The treatment path decision needed to be rapid, accurate and made in real-time.
- To achieve maximum accuracy, the Sponsor did not want the calculation to be performed by the busy site staff.



## Challenge

Cmed needed to:

- Find a solution that would enforce a workflow to ensure the accuracy of the data used in the score calculation
- Provide a "press of a button" solution for users to make the correct treatment path decision
- Guarantee data traceability and integrity



## Solution

Cmed specializes in innovative technical solutions for our clients using encapsia (Cmed's proprietary eDC and analytics platform). By the time of initial database Go Live, Cmed:

- Implemented workflow controls to ensure and document entry and checking of the data required to calculate the relevant score.
- Programmed and validated "buttons": one to derive the score from individual data points comparing it to the baseline value, and a second one to determine the appropriate treatment path.
- Provided users at site with automated messages to confirm successful completion of calculations and treatment path decisions.



## Impact

Cmed provided:

- A user-friendly solution which minimised the impact on busy site staff
- An accurate and validated method for score calculation supporting timely, consistent treatment path decisions which the sponsor knew would stand up to regulatory scrutiny

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