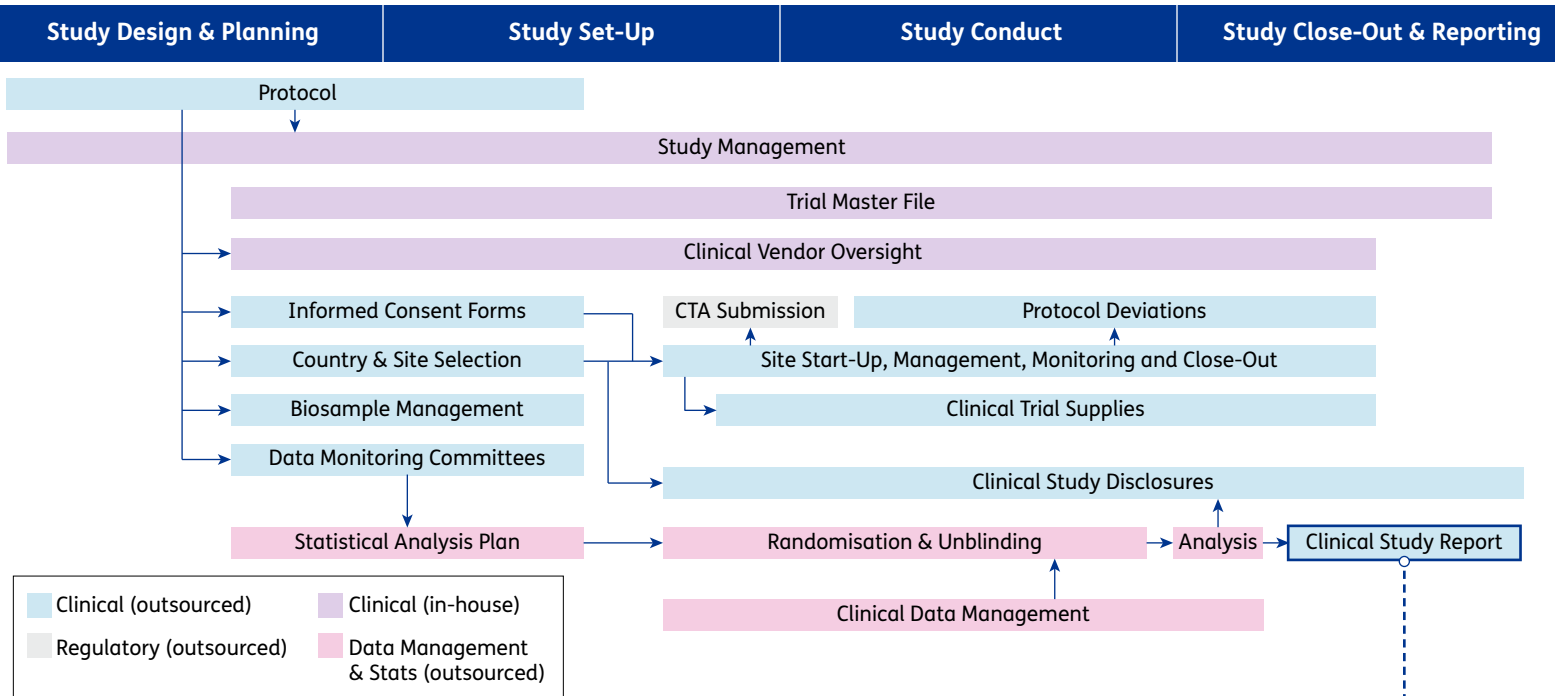


This visual shows some of the key processes we helped to simplify & bring in line with our client's strategic outsourcing partnership.



Clinical Trial Processes



Clinical Study Report

For each of the processes in scope we defined how our client would drive oversight of the E2E process in line with GCP principles and the agreement with the CRO partner. See an example of Clinical Study Report here:

We then used this to develop a simple SOP, set of templates, Work Instructions and Learning.

1.0 Write and review Clinical study report

CRO with IN-HOUSE oversight

1.1 Create CSR shell

CRO

1.2 Write, review and revise first draft of CSR

IN-HOUSE CRO

1.3 Review and revise second draft of CSR

2.0 Approve CSR

IN-HOUSE

2.1 Approve CSR

3.0 Publish CSR

CRO with IN-HOUSE oversight

3.1 Publish CSR

