

Task	How CEBU can assist
Study design ↓	<ul style="list-style-type: none"> <li>clarification/definition of research question(s)</li> <li>clarification/definition of the primary and secondary objectives</li> <li>advice on an appropriate study design</li> <li>advice on the best outcome measures</li> <li>calculation(s) of the sample size</li> </ul>
Protocol development ↓	<ul style="list-style-type: none"> <li>assistance in drafting the protocol</li> <li>writing and/or checking over the definition of outcome measures, the sample size calculation and the statistical analysis section</li> </ul> <p>The protocol is the key document describing all aspects of the design and conduct of the trial, and drafting a protocol is often more complex than anticipated.</p>
Statistical analysis plan/ dummy tables ↓	<ul style="list-style-type: none"> <li>production of statistical analysis plan and dummy tables</li> </ul> <p>Particularly for large RCTs it is useful to produce a detailed document outlining the statistical analysis including the populations of interest, and how drop outs and protocol violations are going to be handled.</p> <p>It is also useful to generate a list or dummy version of the tables that will be required for the final analysis</p>
Development of Case Record Forms (CRFs) ↓	<ul style="list-style-type: none"> <li>assistance with the design of CRFs</li> </ul> <p>Designing the best CRFs can be more complex than anticipated. CEBU assistance will help to ensure that all the required data are collected, and the data are collected in a way that they can be analysed efficiently.</p>
Generation of random allocation sequence ↓	<p>CEBU can generate the random allocation sequence and supply</p> <ul style="list-style-type: none"> <li>randomisation envelopes, or</li> <li>randomisation lists (for blinded drug studies), or</li> <li>web-based randomisation</li> </ul>
Trial manual development ↓	<p>The trial manual is a document with clear instructions on how the day-to-day running of the trial will work, starting from when the patient comes in, to the eligibility checklist, the randomisation process, the data collection, and what happens to the forms once they have been completed.</p>
Regular Trial Management Group meetings ↓	<ul style="list-style-type: none"> <li>attendance at Trial Management Group meetings</li> </ul> <p>As with all research, things never go to plan. There will inevitably be problems that will arise during the life-time of the trial. These problems can impact on the quality of your trial and the quality of the data that are collected. Regular meetings which include the biostatistician can help minimise the impact.</p>
Database design ↓	<ul style="list-style-type: none"> <li>advice on choice of database software</li> <li>advice on database design</li> <li>database setup, including basic and more complex cross-variable checks</li> </ul>
Data entry ↓	<p>CEBU has a Data Capture/Entry Service (charges apply)</p>
Data checking/ data cleaning ↓	<ul style="list-style-type: none"> <li>systematic checking of data (using Stata statistics software) to find inconsistencies /mistakes in the data.</li> </ul> <p>It is important to get the data as clean (with as few errors) as possible prior to analysis. This can be time-consuming particularly for large trials.</p> <p>Data cleaning must be done before each DMC report (if any), and again before the final data analysis</p>
Interim / DMC reports ↓	<ul style="list-style-type: none"> <li>preparation of confidential interim reports for the Data Monitoring Committee</li> <li>includes data checking/cleaning (see above)</li> </ul> <p>To ensure trial rigour, it is important that the clinical investigators remain blinded to the results until the end of the trial.</p>
Final data analysis ↓	<ul style="list-style-type: none"> <li>analysis of data, production of study report (includes data checking/cleaning, see above)</li> <li>advice on analysis of data (if researchers carrying out their own data analysis)</li> </ul>
Publication(s)	<ul style="list-style-type: none"> <li>assistance with writing the publication, especially the statistical methods and interpretation of the study results.</li> </ul> <p>This will often warrant co-authorship of research papers</p>