**P-342 Rapidly designed data capture in a rapidly evolving global pandemic, lessons to be learnt**

Marianna Nodale, [mn348@medschl.cam.ac.uk](mailto:mn348@medschl.cam.ac.uk)

Simon Bond, [simon.bond@addenbrookes.nhs](mailto:simon.bond@addenbrookes.nhs)

Cambridge Clinical Trials Unit, Cambridge, United Kingdom

The design of a well-thought, comprehensive, yet nimble and focused Case Report Form (CRF) can greatly affect a study success. CRF designing requires enormous planning and attention to minute detail. Neither conditions were facilitated by the emergence of a global pandemic in 2020 requiring a hastily set up clinical trial investigating potential life-saving treatments.

The clinically-driven, rapidly-designed, resulting CRF met several challenges in its implementation that greatly affected the speed, accuracy and reporting of the clinical trial. All aspects of data collection, management, quality control and ultimate analysis were severely hampered by the following avoidable pitfalls in CRF design:

* Usage of a composite primary endpoint whose determination required cross-validation of several sources
* Duplication of data sources
* Collection of elaborate and/or unimportant clinical data
* Usage of clinically novel or clinically uncommon outcomes
* Poor connectivity of related parts of the CRF and lack of a clear hierarchical structure differentiating crucial data points vs potentially useful clinical information
* Persistent confusion of terms (i.e. “discharge” and “study termination”)
* Usage of daily patient status questions regarding safety vs detailed safety reporting
* Lack of foresight in understanding the disease follow-up (discharge from hospital & long term outcomes)
* Poor implementation of a “discharge” visit option
* Poorly designed “Termination of treatment form”
* Misuse of the End of Study form
* Lack of tools to quickly identify crucial missing data in real time

Given the adaptive design of the trial and the rapidly evolving pandemic, additional challenges were met in having to reactively adapt the CRF to accommodate new arms of the study. The added uncertainty of a hugely variable and unpredictable rate of recruitment made the retrospective quality control of the data very demanding and ultimately inefficient.

We will present a series of examples of improvements and mitigations, where greater input from experienced statisticians and/or data managers at design stage could have improved the CRF, streamlined the data acquisition and ultimately relieved pressures on the clinical staff conducting the trial under very challenging circumstances.

We argue that the challenges presented by a global pandemic demanded a nimbler and more focused data acquisition process and such lessons would be beneficial for clinical trials at large.