Creating Educational Simulations of Clinical Research Management on Novel Electronic Platforms

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Introduction: Clinical research professionals are trained on cutting-edge technology and practical application of regulations and guidance. Clinical data management skills are a competency of clinical research professionals which allow for patient evaluation, patient data processing, and documentation of vital steps in the trial process. This project sought to improve the on-line educational environment by creating tailored regulatory-compliant CRFs within an industry approved electronic data capture system for a kinesthetic learning opportunity with the Master in Clinical Research Management (CRM) program students which will enable them to apply best practices learned in the classroom within the pharmaceutical industry.

Methods: Review of data management related Code of Federal Regulations guidance, the Clinical Data Interchange Standards Consortium case report form standards, and current CRF templates from public universities and National Institute of Health websites was performed. The CRFs were customized towards a Phase I/II oncology research protocol and then translated into electronic format within an electronic data capture system. User acceptance testing was performed by two experts in the field.

Results: Twenty-one CRFs were generated. Factors such as ease of use, versatility of data, nuances across visit days, and uniformity of forms were used in development. An instructional video was created for student reference. Twenty-two Spring 2021 CRM students will pilot this kinesthetic learning opportunity.

Conclusion: There is notable interest to expand the kinesthetic learning opportunity by including diverse study designs and therapeutic areas, and opportunities to link hands-on activities with other customizable clinical operation processes.