Problem:
Novella was contracted to perform Clinical and Data Management services on a randomized, double-blind, multi-center, international oncology study with over 1,000 patients. Initially, Novella used patient profiles that were provided by the sponsor for data cleaning. However, the sponsor-provided profiles from a third party vendor proved too difficult to use. It quickly became apparent Novella needed to improve the data review process by creating new patient profiles according to its specifications. The Patient Profiles product offered a flexible, on-demand solution to produce the patient profiles, at a significant cost savings and with a much faster deployment time compared to other systems.

Importance:
Data quality and study conduct are important to the success of a clinical trial. Poor data quality can increase the variability in key endpoints, making it more difficult to find statistically significant differences between treatment arms.

Study conduct is important for several reasons:

- To ensure the treatment is properly administered to maximize the efficacy and minimize side effects of the study drug.
- To ensure that only the protocol-specified population of patients is enrolled in the study.
- To minimize site-to-site differences that may raise concerns during FDA review.

Relevant Technologies/Products Used on the Project:
Patient Profiles is a clinical trial software solution developed specifically for creating individual patient profiles. It does not require programming knowledge. The software provides easy setup for reading data and creating standard profiles, the flexibility to adapt to the specifics of each trial’s data, changing data types and formats, deriving new variables, and transposing long, skinny data structures. Clinical data become accessible by non-technical staff, avoiding the review of traditional lengthy and inflexible printed data listings. Patient Profiles’ software provides quick access to readable, visual data, which makes data review faster and more consistent. Patient Profiles’ software was used to create all of the patient profiles used by Novella for data review.

Key Results:
Patient Profiles was used to generate individual tabular/graphical reports for each patient, integrating data from three disparate electronic systems: the EDC system, the IWRS system, and a central laboratory. A team of 12 Novella data reviewers were convened and trained on how to use the patient profiles for data review. The Novella data review team requested patient profiles each week based on priority and upcoming site visits. One Novella team member was responsible for generating new PDF files for the Novella data review team. To generate the PDFs, the Novella team member simply “pointed” the Patient Profiles software to a Novella network directory where the clinical data files for the study resided.
Armed with modified patient profiles, the Novella team was able to review and clean the data for approximately 900 patients in about four months, falling well within the established clinical timeline, and a notable improvement from the first 100 patients, which took about four months as well.

In addition to improving the overall workflow and throughput for the data review, the Patient Profile outputs enabled the Novella data review team to identify trends indicating issues with certain data items. As with any study, there were some unexpected study conduct issues at a few sites that could not have been foreseen. These were related to: under-reporting of Adverse Events in some countries and the trending of laboratory values. With the data displayed in a consistent format from patient to patient, the profiles helped the review team uncover these issues. Novella CRAs then re-trained site staff on how to complete those data items according to the eCRF Completion Guidelines at the next scheduled monitoring visit.

The initial Patient Profile software license fees and the cost of creating the design file were significantly lower than what the typical specification/program/validation process would have entailed. From the time the patient profile specification document was complete until the Novella data review team began using the profiles was 4 weeks. The drag-and-drop design features of the Patient Profile software allowed the Novella data review team to see a draft profile within a week. Online review meetings were organized where the Novella data review team worked with Patient Profiles in a rapid-application-design (“RAD”) fashion to tweak and finalize the patient profile. Once the patient profiles were finalized, it was simple and easy for Novella to run the profiles on-demand without utilizing internal programming resources.

**Broader Impact on the Community / Industry:**
Patient Profiles’ impact on the industry will be to enable companies to find errors and trends within sites earlier in the data review process. The patient profiles are also helpful for streamlining the preparation of AE narratives, profiles for DSMB meetings, and dossiers for adjudication committees.

The innovative Timeline feature, which is unique to Patient Profiles’ software, is instrumental to the idea of visualizing the patient’s time on study. It was especially important in this project because it helped the Novella team to identify the under-reporting of Adverse Events in certain countries. In short, it allows users to overlay multiple variables on a timeline and graphically display the patient’s time on study. Variables such as Adverse Events, Concomitant Medications, study drug dosing, and clinic visits, for example, can be overlaid on a timeline so the reviewer can get an immediate understanding of what has happened to the patient while on study. In addition, Flags, Headers, and Data Highlighting within timelines and tables can quickly draw attention to values outside of normal ranges, serious events, dose limiting toxicities, and other important data points.

Patient Profiles’ 21 CFR Part 11 compliant software is easy to program, flexible, inexpensive to deploy, and feature-rich. The software does not require any additional software to operate and is able to incorporate data from most of the common clinical data sources, such as Excel files, SAS data sets, and EDC systems.