RDCG CASE STUDY: Using our CTMS system to administer an adjudication process across multiple adjudicators, thousands of patients and over 200,000 documents

Situation:

During previous clinical trials, patient data was copied and mailed to each adjudicator for review. This process works with small numbers but when several adjudicators are reviewing hundreds of thousands of pages from thousands of patients, this process and recording the outcome can be a logistical challenge. A procedure was required to manage the documents and the adjudicator review efficiently and cost-effectively and to document all patients' data were adjudicated.

Challenges:

The main challenge was to get all the patient data, including source documents and eCRF data to each adjudicator and get their decision in an efficient manner. Since there were multiple adjudicators in several different locations, we had to ensure that all adjudicators reviewed all the patients and each adjudicator received the same data on each patient. With data coming in throughout the trial, there needed to be a tracking system to know which patient data were complete and ready for adjudication.

The collection, tracking, and management of the large number of patient CRFs and source documents from 11 investigator sites needed to be organized and monitored to ensure all documents were received, and properly adjudicated. This study enrolled over 3500 patients and there were over 200,000 documents to review.

The adjudicator decisions needed to be tracked to ensure all patients were reviewed by all adjudicators and to determine that the adjudication was complete for each patient. The decisions needed to be compiled for data analysis for the study report.

RDCG Actions:

After Research Dynamics learned that the previous study's adjudicator review process was to mail the data to the adjudicators to obtain their decisions, RDCG was concerned with the poor logistics of this method. RDCG recommended that the process be administered and coordinated through our web-based CTMS system (Clinical Conductor Enterprise) using the system's "data documents" function. Using the CTMS system, all patient CRF data and de-identified relevant source data were uploaded by the 11 sites into the system. RDCG monitors reviewed the uploaded data to ensure document accuracy and completeness. When each patient's data were complete and monitored, the patients file was noted as "ready for adjudication" and made available to each adjudicator through the CTMS system. Their review triggered a status update so we knew exactly which patients were reviewed by which adjudicator. Their decisions were entered into the eCRFS with the other study data. There was a defined work flow in the CTMS system so that the documents are uploaded, reviewed, finalized, and adjudicated in a consistent manner. The work flow and status updates were automated so the status was changed at each stage of the process.

Result:

The electronic collection, tracking, review, and storage of patient data and documents for adjudication through the CTMS system was more efficient, easier to use, and less expensive than sending paper copies or emailing copies of the data to the adjudicators. The CTMS system also provided a tracking system so the status of any patient's data review could be immediately known and reported.

There were 5 key results:
- Adjudication status known: The adjudication process became an established work flow with status updates so the status of the adjudication for each patient could be reviewed and reported at any time.
- Review documents always available anywhere: The adjudicators, being busy physicians, could access the data at any time (even when traveling) through the web based CTMS system so they did not need to handle paper copies.
- Time and cost savings: Using the CTMS system saved time and money over the paper/email process.
- Status tracking: The CTMS was able to track the process and provide dates of each status so we could prepare status reports by date, and adjudicator.
- Track when reviews are delayed: By tracking the adjudication process by each adjudicator, we could remind them when their reviews need to be completed.

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