

## Care Communications Medical Chart Research Services

*Client name and condition withheld to ensure confidentiality.*

### CASE STUDY:

To procure the necessary medical record copies and abstract 225 valid cases of patients identified in claims data as having a connective tissue disorder.

Patients were assigned to one of three cohorts based upon prescription drug usage and the presence or absence of comorbid conditions associated with the study diagnosis.

Medical chart abstraction was performed to confirm the diagnosis, identify disease severity and exacerbations of the condition, and determine a claims-based definition of an exacerbation.

### CHALLENGES:

- To procure and abstract the appropriate sample of medical records according to protocol requirements in 10 weeks or less.
- To procure 300 medical record copies from specialty provider offices for patients who met study cohort requirements, with one cohort requiring procurement of medical charts from two providers per patient: both specialist and primary care physicians.
- To procure sampled patients' medical record copies for 6 months prior to a specified Index Date and 12 months after that same Index Date.
- To conduct a pilot study of 15 cases (5 from each cohort) and demonstrate agreement on seven key variables of at least 80% among abstractors or kappa of less than 0.5.
- To provide comprehensive and relevant data abstracted from "real world" clinical (medical chart) documentation in support of claims data validation to develop an improved algorithm for identifying cases with a diagnosis of the designated condition, to determine disease severity level parameters, and to develop claims-based disease exacerbation criteria.
- To ensure the integrity and quality (accuracy, reliability, and validity) of the data collected.
- To avoid a prolonged post-study data cleaning (data query resolution) process.

In addition to the above challenges, an unusually high invalid rate in one cohort resulted in the need to procure 30% more records than initially anticipated in order to meet study requirements for comprehensive data in that cohort. Invalid cases were those for which the designated diagnosis could not be confirmed or the date range of the medical record procured did not meet the protocol requirement.

## SOLUTION:

Care Communications, Inc. (*CARE*) was selected to procure and abstract medical record copies of patients identified as having the study-specific disorder of interest per ICD-9-CM diagnosis codes from claims data. In order to meet the challenges, *CARE*:

- Pre-tested the data collection tool through performance of a pilot in which 15 cases (five from each cohort) were abstracted and the required abstractor agreement rate and kappa were met.
- Recommended changes to the data collection tool and abstraction guidelines to ensure consistent interpretation of “real world” clinical documentation and to provide valid and reliable data for researcher analysis.
- Implemented *CARE*'s sophisticated ProcurementPlus(SM) methodology (a proprietary and customizable process) to ensure predictable medical chart procurement outcomes to meet study-specific goals.
- Procured the required number of medical record copies for each cohort specified in the study protocol and confirmed validity of the required sample for full abstraction.
- *CARE*'s project and operations management team coordinated efforts to procure the minimum necessary number of oversample records, ensuring compliance with the budget allocated for review of charts ultimately deemed ineligible for full abstraction per the study protocol.
- Resolved data queries throughout active procurement and clinical data abstraction phases of the study by establishing a rigorous question-and-answer process between *CARE* and researchers.
- Monitored production status and provided detailed weekly status reports, allowing *CARE*'s client to provide the study sponsor with up-to-date progress reports.

## RESULTS:

- Realized efficiencies in procurement that allowed study cohort quotas to be met within budgeted limits established for the review of charts in the available oversample population.
- Client review of pilot data proved abstractor agreement above the minimum threshold of 80%, and the required kappa was met.
- Maintained data quality by incorporating validation edits at the point of abstractor data entry as well as resolving abstraction questions throughout the pilot and production phases of abstraction – with complete and reliable data confirmed when no data queries were received following final database submission.
- Including time for *CARE*'s final data consistency and validation checks, the database was locked within 14 days of the last case being abstracted, allowing the client to meet further study timeline goals.

*For more information on Care Communications' medical research services or its many other health information management services, visit [carecommunications.com](http://carecommunications.com).*