

## Care Communications Medical Chart Research Services

*Client name and condition withheld to ensure confidentiality.*

### CASE STUDY:

Procurement and abstraction of medical records of patients with an inflammatory auto-immune disorder of the central nervous system

### CHALLENGE:

To confirm identification of the disorder in claims data through validation of the algorithm used to select cases through ICD-9-CM diagnosis codes. Diagnosis of this condition is not always straightforward, and the patient may undergo an extensive work-up prior to determination of the diagnosis. The condition may be documented by health care providers in a variety of ways, including as an equivocal or “rule out” diagnosis that may actually be assigned an ICD-9-CM code for the condition, even if the patient is never ultimately diagnosed with the disorder.

In order to correctly identify and select a sample of patient records to review for this study, Care Communications, Inc. (CARE) was selected to procure the medical records of patients identified in the claims database in a sample that included patients identified with the disorder using only ICD-9-CM diagnosis codes as well as patients identified with the disorder using ICD-9-CM diagnosis codes in addition to disease modifying therapy. The purpose of this chart study was to verify the condition in subjects identified in claims data based solely on diagnosis codes.

Study timelines and goals:

- To procure and abstract the appropriate sample of medical records according to protocol requirements in 10 weeks or less.
- To procure medical record copies from specialty provider offices for patients who met study protocol requirements.
- To procure specific sampled patients’ medical record copies for 12 months prior to a specified Index Date and 12 months after that same Index Date.
- To provide comprehensive and relevant clinical documentation abstracted from “real world” medical charts to support researcher development of an improved algorithm for identifying cases with a valid diagnosis of the designated condition using claims data.
- 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.

### 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 study during which 10 cases were abstracted.
- 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 as specified in the study protocol and confirmed their validity 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:

- Procurement and abstraction were completed four weeks ahead of the project deadline.
- Realized efficiencies in procurement that allowed medical record abstraction quotas to be met within budgeted limits established for the review of charts in the available oversample population.
- 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 three days of the last case being abstracted.

#### TESTIMONIAL:

“CARE generated insightful, detailed, and careful questions throughout the pilot and the production phases of the study; the questions helped us refine our data collection tools and allowed us to provide timely feedback to our client. The quality of project management and data collection were excellent, and we really enjoyed working with your team.”

Project Manager, Clinical Research Client

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