Contact: Keith Westrich
Data Reduction Systems
Phone: (908) 622.9240
Email: keithw@drscorp.com

1323 Burnet Avenue
Union, NJ 07083
www.drscorp.com

NEWS RELEASE

Alzheimer's-Focused Clinical Study Benefits from DRS Risk-Based Review of Trial Master File

Global healthcare company turns to Data Reduction Systems to restore TMF integrity

UNION, NJ – October 21, 2016 -- During a mock audit of their TMF content, a prominent international biopharmaceutical company discovered an alarmingly high number of duplicate, misfiled and missing documents. Naming convention inconsistencies were also in evidence throughout the file. The study manager was surprised by the outcome since the TMF had been managed all along by two independent CRO partners. But with a regulatory inspection fast approaching, the company's priority was obviously to solve the eTMF problem now and deal with the *"reason-why-it-happened"* problem later. So they immediately called DRS for TMF remediation assistance.

Facing a short timeline, the DRS Professional Services team arrived within a few days. Armed with a comprehensive action plan for a Risk-Based Review of the entire TMF, the team went to work immediately. Their mission was clear: Partner with the client and their CROs to restore the TMF to the high quality level that regulatory inspectors have come to expect – no less! By doing so, TMF inspection readiness would be assured.

DRS then assisted the sponsor organization with the reporting and collection of missing documents and assisted with appropriate corrective measures activities on behalf of the client. DRS' master plan for a comprehensive audit included a thorough review of the TMF contents and a findings report that uncovered all missing or incorrect filings in time to have the CRO partners address the issues. DRS assisted the sponsor organization with the reporting and collection of missing documents and assisted with corrective action as well. Within a short period, the integrity of the TMF was restored.

About DRS

Founded in 1985, Data Reduction Systems (DRS) has long been at the forefront as a specialist in cross-industry information management technologies and services. Developed specifically for the life sciences, DRS eTMF OneSource is an integrated system of technologies and services for clinical studies departments. At the heart of the system is a single electronic Trial Master File repository that centralizes study documents from all locations into one, with a properly documented chain of custody, whether electronic or paper submission. While the DRS eTMF OneSource solution preserves high quality levels, it has also proven to be a more streamlined, time saving approach to the preparation and submission of regulatory documentation. This typically results in compressed study completion times, accelerated patent enrollments and bringing remedies more quickly to market for those patients in need.