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DRS

DATA REDUCTION SYSTEMS

NEWS RELEASE

*DRS' quick response to an FDA-required inspection of a critical
RNAi therapeutic orphan drug study at the Mayo Clinic... Helps
advance vital research while expanding its own TMF customer base.*

UNION, NJ – July 20, 2018– A world-renowned research-based pharmaceutical company today announced they have engaged Data Reduction Systems (DRS) to manage and oversee this comprehensive TMF project which involves the scanning of a large volume of paper TMF documents, Quality Assurance (QA) and the certification of TMF study records involving an RNAi therapeutic class of medicines for the treatment of patients facing a limited number of options.

Major factors for DRS' selection to head up the TMF portion of this critically important TMF project included...

- DRS' vast experience acquired in the paper TMF space over the years
- A well-earned reputation for exceptional customer service
- A full support team of highly skilled professionals with years of Document Management experience
- The ability to respond quickly to the on-site project with equipment and resources
- With a very short timeline, the confidence instilled by DRS being ready to go within 48 hours

Project Outline...

- Assist in the QA of clinical study records in order to get Orphan Drug Designation from the FDA.
- Scanning of paper files and certification of the records
- Working with staff at the Mayo Clinic where the records were maintained
- Ability to identify items through the QA process that needed corrective action
- Certify copies of all records for eventual inspection by the FDA

About The Study – Orphan drugs are commonly defined by the FDA as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the United States.

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.

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Data Reduction Systems. Expanding the potential. Fulfilling the promise.