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*For immediate Release*

## **Datafarm releases S-Cubed CRT v3.0 to support clinical data submission requirements from the FDA following the CDISC standards**

*-S-Cubed CRT v3.0 helps ensure sponsor organizations are meeting the CDISC standards for the creation of the clinical data for FDA submission that include define.xml and SAS transport files-*

**Marlborough, MA September 1, 2009** —**Datafarm Inc.**, a world leading provider of high performance electronic regulatory submission solutions for the life sciences industry, today announced the release of S-Cubed<sup>®</sup> CRT v3.0 to help ensure sponsor organizations are compliant with the FDA requirements for clinical data submission, and following CDISC standards when preparing the Case Report Tabulations (CRTs) or the datasets sections of a regulatory submission to the FDA.

CDISC (Clinical Data Interchange Standards Consortium) is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. In order to increase the level of automation and improve the efficiency of the regulatory review process for new drugs, the FDA announced specifications for dataset data definitions using CDISC SDTM standards and requires that all study data must be delivered in an electronic format - even if the marketing application is in paper format.

S-Cubed<sup>®</sup> CRT v3.0 automatically creates the entire CRT section of an electronic submission along with the define.xml (or define.pdf for legacy data) file, SAS transport files and other related components along with necessary navigational functionalities such as hyperlinks and bookmarks. S-Cubed CRT then verifies and reports on whether or not the included datasets and variables are in compliance with the CDISC SDTM (Submission Data Tabulation Model).

## Datafarm releases S-Cubed CRT v3.0 to enable compliance with FDA and CDISC standards for Clinical Data submission

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“As a CDISC Registered Solution Provider, we are very pleased to provide our customers with the latest technology in automation and compliance for creating CDISC-compliant CRTs for electronic submissions,” said George Waidell, VP of Product Strategy at Datafarm. “The release of S-Cubed CRT v3.0 is the latest testament to our commitment to help customers navigate the ever-changing regulatory landscape.”

For more information on Datafarm’s CDISC standard based solutions please visit:

<http://www.datafarminc.com/Solutions-CRT.aspx>

### **About Datafarm Inc.**

Established in 1997, Datafarm is a world leader in high performance electronic regulatory submission solutions for the life sciences industry. Datafarm’s open, modular technologies and professional services experts enable life sciences companies to meet the strict standards of regulatory authorities across the world, helping them achieve quality, accuracy, and compliance to efficiently deliver regulatory reports and submissions.

Datafarm has helped hundreds of sponsor companies compress the regulatory submissions approval process, improving speed to market, cost control and productivity in order to achieve their ultimate goal of ensuring patients’ and physicians’ timely access to new drugs.

As a total solutions provider, Datafarm employs some of the industry’s pioneers in document-based software development as well as world renowned life sciences regulatory specialists who proactively work with customers and business partners to drive new initiatives and maintain a market lead approach to development and services. Headquartered in Marlborough, Massachusetts, US, Datafarm has regional offices in California in the US, UK, France, and India. Information about Datafarm's products and services can be found at [www.datafarminc.com](http://www.datafarminc.com).

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