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DSG AND OPKO HEALTH ENTER INTO ENTERPRISE LICENSING AGREEMENT FOR FULLY INTEGRATED EDC, IWRS, SAFETY, AND TRIAL MANAGEMENT SOLUTION
—OPKO Health to build and configure integrated data capture and drug safety systems—

MALVERN, Pa., November 4, 2014 — OPKO Health, Inc., a multinational pharmaceutical & diagnostics company, has selected DSG’s eCaseLink integrated suite for self-building of harmonized electronic data capture (EDC), IWRS, drug safety event capture and case reporting, and CTMS systems. DSG’s team will support the OPKO team and their Site users 24 x 365.

DSG’s [Drug Safety](#), a comprehensive adverse event management system developed by DSG as part of an integrated suite including EDC, IWRS, and CTMS, streamlines the safety recording, reporting process, data entry on Serious Adverse Events (SAEs), storing associated documents facilitating the generation and tracking of queries. Features include integration with other regulatory and management systems, ICH E2B compliance, and generating FDA 3500A MedWatch and CIOMS forms, exporting data as required. Sponsors configure the system to accommodate unique workflows and procedures more efficiently.

DSG’s flagship EDC software, [eCaseLink™](#), in continuous use since 1999, provides system builders with an intuitive tool, DSG Designer, enabling unlimited quantities of cross-visit edits on eCRFs without compromising system performance, a proprietary technology unique to DSG. Other helpful features include risk-based monitoring, 3rd-party system data integration, module for managing local lab Normals, integrated MedDRA/WHO drug auto-interactive encoder, ad-hoc reporting, SAS datasets on demand, patient profiles, protocol deviations, image upload and management, unlimited auto-emails, auto-population between eCRFs, Innovation Award-winning IWRS and also Data Management dashboard, integrated training modules, with round-the-clock support from DSG, one of the industry’s oldest and most experienced EDC providers.

“We are very pleased to be working with OPKO Health,” said Tony Varano, CEO of DSG, Inc, “and are excited to partner with and support such an experienced and talented multinational team with our technology.”

About DSG

DSG, Inc. supports clinical data capture and management with a proprietary, organically integrated suite of award-winning user-friendly technology solutions, including flagship

eCaseLink™ EDC, ePRO, IWRS, Drug Safety, and CTMS. Since 1992, DSG has successfully supported thousands of clinical trials for over 400 companies and 25,000 sites across 90 countries, headquartered in Malvern, Pa., with additional offices in the U.S. and Asia: www.dsg-us.com.

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