

PointCross Life Sciences and Smithers Avanza forge strategic partnership for SEND solutions

For biopharma companies, this collaboration will streamline the flow of high quality CDISC SEND standardized data for regulatory submissions required by the FDA and to serve sponsor R&D needs

Silver Spring, MD, November 9th, 2015

[PointCross Life Sciences](#) and [Smithers Avanza](#) announced today that they have entered into a partnership to provide SEND solutions to their Toxicology Services clients. PointCross will apply its technology and expertise to reduce the costs and time needed to prepare high quality SEND data from toxicology studies conducted by Smithers Avanza and other providers. Complete e-data packages fit for FDA review will be supplied to sponsor clients for compliance with the U.S. FDA's upcoming regulatory mandate.

The two parties will also offer biopharma companies value-added services to reduce costs and apply standardized data for better R&D decisions. These services include defining study data specifications prior to initiation, delivering interim data for sponsor study monitoring, and reviewing standardized data using ToxVision™, the data browser utilized at the FDA. The two companies will also partner to deliver data from safety pharmacology and reproductive toxicology studies, and hold data in a repository to offer analytics services across studies and species.

“With the binding guidance from the FDA set to start in December 2016, the industry has a very short time frame to implement solutions and processes that ensure compliance” said Dr. Shree Nath, VP of Business Development at PointCross Life Sciences. “We are excited about partnering with Smithers Avanza to help pharma companies comply with the new submission requirements, and apply standardized study data to reduce costs and cycle time for R&D decisions.”

Dr. Michael Dorato, Executive Vice President at Smithers Avanza, said “Smithers Avanza continues to invest in strategies that advance our regulatory compliance and reporting capabilities while supporting our commitment to scientific excellence. By partnering with PointCross Life Sciences, we are in a position to offer clients high value solutions that meet their regulatory SEND submission and review needs.”

About PointCross Life Sciences

PointCross Life Sciences provides the life sciences industry with data management, analytics and visualization solutions that reduce risks, improve data quality, shorten time to market, and generate better insights from R&D and regulatory data. We are a strategic solution provider to the FDA and to several major biopharma companies.

PointCross was recognized in 2013 as one of [Gartner's Cool Vendors in Life Sciences](#).

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About Smithers Avanza

Smithers Avanza is a contract research organization (CRO) supporting the pharmaceutical, agrochemical, and chemical industries. Our scientists have expertise in large molecule bioanalysis, assay development, validation and sample analysis at our GLP- and GCP-compliant and CLIA registered laboratory. We offer preclinical toxicology and vaccine testing at our AAALAC accredited facilities.

Smithers Avanza Toxicology Services Division supports pharmaceutical and agrochemical development through the identification of safety and/or efficacy outcomes. Studies are conducted across multiple species. Our key expertise includes single dose to two-year general toxicology studies, vaccine safety testing, toxicokinetics, and infusion studies.

Smithers Avanza Bioanalytical Services Division supports the development of biologics and vaccines from discovery through phase IV, with expertise that includes bioassays and high sensitivity assays. The services focus primarily on development, validation and sample analysis for PK/TK, ADA, bioassays and biomarker assays.