BSI Life Sciences and SMART-TRIAL Unite to Deliver First European eClinical Suite for Medical Devices

BSI Life Sciences, a specialist in CTMS and eTMF, and SMART-TRIAL, provider of industry-leading EDC, announce a strategic partnership to provide a comprehensive, streamlined MedTech eClinical suite.

MOUNTAIN LAKES, NEW JERSEY, March 2, 2021 – **With EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) deadlines looming, BSI Life Sciences and SMART-TRIAL have teamed up to offer an all-in-one, interoperable solution for medical device and diagnostics companies revising their clinical data strategy to ensure compliance and maximize resources.**

The MedTech eClinical Suite from BSI Life Sciences and SMART-TRIAL ensures simplified and compliant clinical data gathering and management through advanced oversight of clinical trials (CTMS), efficient study documentation (eTMF), and verified capture of clinical data (EDC).

"By bringing together our two experienced, best-in-class companies, we become the first European-based eClinical software suite specifically tailored to the MedTech industry," explains Jan Nielsen, Community Manager, Life Sciences at BSI. "We're very pleased to be partnering with SMART-TRIAL on this flexible, unique, and much-needed solution."

Medical device manufacturers are in complete control of their studies and clinical data with the BSI Life Sciences and SMART-TRIAL MedTech eClinical Suite.

"Clinical teams are under pressure to deliver more evidence than ever before. This requires thorough control and oversight of every single activity that produces clinical data," says Jon Bergsteinsson, VP of Global Business Development at SMART-TRIAL. "The partnership between SMART-TRIAL and BSI Life Sciences is designed to help MedTech companies streamline their clinical operation to simplify the path towards MDR and IVDR compliance."

Key features and benefits of the BSI Life Sciences and SMART-TRIAL MedTech eClinical Suite include:
- Validated software with compliance templates

- MedTech industry know-how and experience

- European data protection

- Simplified system management

- Seamless system integration

For more information or to request a product demonstration, visit www.bsi-lifesciences.com.

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About BSI
BSI Life Sciences – Software that fits your organization like your favorite pair of jeans. BSI CTMS with integrated eTMF is the efficient and comprehensive solution for clinical trials management. What's more, there are innovative applications such as the BSI CX automation and digitalization platform and BSI CRM, one of the leading omni-channel platforms on the market with smart industry solutions for retail, banking, health, and insurance. And, always present: a 360° view of all data and authentic full service from A to Z.

More than 130,000 users profit from our software daily around the globe. Behind it stands the work and dedication of 350 engineers and project managers in Germany, Switzerland, USA, and anywhere else you need us to be.

About SMART-TRIAL
SMART-TRIAL helps MedTech clinical teams comply with regulations on clinical evidence by simplifying the collection and management of data. Tailor-made for MedTech, SMART-TRIAL offers a do-it-yourself electronic data capture for clinical investigations, clinical performance studies, PMCF, and PMPF activities, including registries, surveys, and case-series.

SMART-TRIAL is built to empower clinical teams to be their best, and in full control of their data, without compromising on features, design, or compliance.