

STALICLA's go-live with BSI eTMF sets the new standard for implementation of eClinical solutions at startups and SMEs

The Swiss based drug discovery biopharmaceutical company STALICLA SA went live with BSI's electronic trial master file solution in December 2021, less than two months after implementation kick-off.

BADEN, SWITZERLAND, April 22, 2022 – When looking for an eTMF to support STALICLA's expanding pipeline for neurodevelopment disorders, Head of Clinical Operations Dr. Eric Painbeni had clear goals in mind: the eTMF solution should be easy to use, fast to roll out and affordable for a rapidly growing biopharmaceutical company. 'When we first heard of BSI Life Sciences, we quickly realized that the product they were offering was perfectly tailored for STALICLA. BSI eTMF doesn't require a team of IT specialists on the client's end and can be easily maintained by a Clinical Trial Manager', said Dr. Painbeni.

STALICLA's Drug Development Unit based in Geneva, Switzerland, opted for the standard BSI eTMF configuration, which comes with a pre-defined set of modules and utilizes the industry-standard DIA TMF Reference Model. 'I was very impressed by how fast and smooth the process was. After a 1.5-day introductory workshop I already felt confident using the system. The team at BSI also showed a lot of flexibility when we asked them to configure a couple more user roles on top of the standard set-up we purchased', continued Dr. Painbeni.

For Jan Nielsen, Community Manager Life Sciences at BSI, the successful rollout at STALICLA should pave the way for the implementation of the BSI eTMF standard solution at other startups and SMEs: 'The smooth onboarding of STALICLA proves that electronic trial master files are not just for Big Pharma, but for small and medium size organizations too. At BSI Life Sciences we strive to tailor our digital solutions to our customers to make sure they can achieve their research goals, regardless of the scale of their operations'. Mr. Nielsen also added, 'We are honored to work with a Swiss clinical biopharmaceutical company and look forward to continuing our partnership with Dr. Painbeni's team'.

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About STALICLA

STALICLA is a Swiss clinical stage biopharmaceutical company leading omics-based precision medicine development for patients with neurodevelopmental disorders (NDDs). Lynn Durham, its CEO and Founder, has initiated a paradigm shift in the NDD drug discovery space by pioneering the creation of the first NDD specific precision medicine discovery platform, DEPI (Databased Endophenotyping Patient Identification). STALICLA's DEPI technology is the first platform specifically developed to enable precision medicine in complex NDDs. The platform integrates clinical, metabolomics, whole-genome and RNA sequencing and its advanced HC match module to pair patient biological signatures with drug candidates. Leveraging its platform, STALICLA has already: i) identified 2 ASD subgroups and their corresponding treatments, STP1 and STP2; ii) Proven in independent clinical observational studies thepclinical and biological validity of these subgroups; iii) established specificity of STP1 and STP2 as tailored treatment for their respective subgroup of patients; and iv) completed Phase 1b for STP1 lead asset. www.stalicla.com

About BSI Life Sciences

BSI offers smart eClinical software for CTMS, eTMF and more. BSI makes life science software for people – and has done so for 25+ years. BSI's software solutions made in Switzerland, Germany, USA and anywhere else clients need them to be, are innovative and user-friendly. They focus resources on staying ahead of the trends and delivering functional, compliant, and affordable eClinical software. In this way, BSI helps its customers continuously optimize and accelerate the clinical development process. And that's what they love! www.bsi-lifesciences.com