

## Expert CRO Harmony Clinical Research adopts BSI's eTMF to scale up its clinical trial operations

**The Belgian-based company has chosen BSI's eClinical platform for its comprehensiveness and flexibility**

**Baden, Switzerland, April 8, 2024** – BSI Life Sciences announces Harmony Clinical Research (HarmonyCR) as the latest client to adopt its cloud-based electronic Trial Master File (eTMF).

Founded in 2012 and headquartered in Belgium, HarmonyCR is an expert CRO. They cover the full spectrum of clinical research services. This includes medical writing, regulatory, project management, site management, data management, statistics, pharmacovigilance, and medical monitoring.

HarmonyCR delivers these services to pharmaceutical, biotech, nutritional, and medical device companies, CROs, academic organizations, and governmental institutions. Additionally, HarmonyCR offers staffing services on a flexible basis and in various outsourcing scenarios.

While on the lookout for a comprehensive eTMF tool to support its expanding operations, the company was referred to the eClinical platform of BSI Life Sciences. "Just after the first demo, we became immediately convinced of the capabilities and advantages of BSI eTMF," recalls Tom Van Paepegem, co-founder and CEO of HarmonyCR. "The software is highly scalable and perfectly tailored to support our growing customer base, both in Europe and overseas," he continues.

Available as either a standalone product or integrated in BSI's all-encompassing Clinical Trial Management System (BSI CTMS), BSI eTMF offers more than simple regulatory document management. It enables CROs and Sponsors to plan and execute hundreds of end-to-end clinical trials in a single place. Included in the solution is a module to track milestones and activities, as well as a personal dashboard that notifies users of upcoming due dates.

"BSI's eTMF has been a game changer for us," comments Marike Van Dongen, Clinical Operations Manager at HarmonyCR. "Not only does it come with placeholders and reminders for regulatory artifacts, but it also allows users to create document plans for the different trials or types of trials, and even customize the TMF index. This means the software can be configured to fulfill the needs and preferences of all our clients, supporting virtually any study phase and design," she adds.

The eClinical solution is delivered fully validated by BSI and complies with all applicable regulatory requirements of the countries where it is marketed, including ICH-GCP E6, EU GMP Annex 11, and 21 CFR Part 11.

For BSI's Community Manager of Life Sciences Jan Nielsen, the adoption of BSI eTMF by HarmonyCR is more evidence of the product development strategy's success. In his words, BSI "focuses on developing flexible, modular eClinical solutions that cater well to all CROs and Sponsors, regardless of their size and location. By choosing our eTMF, HarmonyCR will have the opportunity to upgrade to a full-scale Clinical Trial Management System at any point in time if they so wish, without needing to migrate any data."

Nielsen continues: "We are excited for the collaboration with this renowned CRO and are proud to welcome them to our global community of eTMF and CTMS users and ambassadors."

HarmonyCR has already benefited from a 2-day product training session for system administrators and key-users and is expected to go live with BSI eTMF in spring 2024.

### Media contact details

Charlotte Malz, +41 (0)58 255 97 33  
[charlotte.malz@bsi-software.com](mailto:charlotte.malz@bsi-software.com)

**BSI Business Systems Integration AG**  
Täfernweg 1, 5405 Baden  
Switzerland  
[www.bsi-lifesciences.com](http://www.bsi-lifesciences.com)

+32 9 324 11 70  
[info@harmony-cr.com](mailto:info@harmony-cr.com)

**Harmony Clinical Research BV**  
Brusselsesteenweg 159, 9090 Melle,  
Belgium  
[www.harmony-cr.com](http://www.harmony-cr.com)

### About HarmonyCR

Founded in 2012 as a clinical CRO, HarmonyCR covers the full spectrum of clinical research services, including medical writing, regulatory, project management, site management, data management, statistics, pharmacovigilance, and medical monitoring. These services can be offered as a full package or as stand-alone services, depending on the client's needs. Additionally, HarmonyCR also offers staffing services on a flexible basis and in various outsourcing scenarios.

While having a track record of clinical studies in all phases, HarmonyCR specializes in early phase (I and II) and vaccine trials.

Their customer base includes pharmaceutical, biotech, nutritional, and medical device companies, CROs, academic organizations, and governmental institutions.

For more information, please visit: [www.harmony-cr.com](http://www.harmony-cr.com)

### About BSI Life Sciences

BSI Life Sciences offers smart eClinical software for CTMS, eTMF and more. BSI makes life science software for people – and has done so for 27+ 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!

For more information, please visit: [www.bsi-lifesciences.com](http://www.bsi-lifesciences.com)