



PRESS RELEASE

DEBIOPHARM LEVERAGES RISKLICK'S AI-POWERED SOLUTION TO IMPROVE PROTOCOL DEVELOPMENT EFFICENCY

Successful completion of milestone in pilot phase with Risklick's Protocol Al™ applied to Debiopharm's oncology research protocol creation process

Lausanne and Basel, Switzerland, October 16, 2025 – Risklick AG, a Swiss MedTech company specializing in Al-driven solutions for clinical trial protocol development, and Debiopharm, a privately-owned, Swiss-based biopharmaceutical company focused on curing cancer and infectious diseases, today announced the successful completion of a key milestone within their pilot project agreement.

This initial phase focused on the **proof-of-concept** of Risklick's **Protocol AI™** software within Debiopharm's clinical development operations. This successful completion confirms the system's potential to **generate a robust clinical protocol** within a structured environment. Implementation of this Al-based tool is anticipated to enhance the speed and quality of clinical trial protocol design.

One of the primary challenges in clinical trial protocol design for oncology studies is the complexity and time-consuming nature of the process. Protocols must be meticulously detailed, encompassing everything from patient eligibility and dosing schedules to complex endpoints like progression-free survival and overall survival. The process is often manual and fragmented, relying on a patchwork of legacy documents and templates, which can lead to inconsistencies and delays. This is further complicated by the rapid pace of innovation in cancer research, as protocols need to be constantly updated to reflect the latest scientific findings and regulatory requirements. This manual, document-based approach is often a bottleneck, hindering the efficient launch of new oncology trials within set timelines, ultimately delaying access to potential life-saving treatments for patients.

Risklick's end-to-end software is designed to help companies shorten clinical timelines by enabling experts to rapidly design and develop high-quality protocols and study plans. Debiopharm's team, including in-house clinical scientists and medical writers, dedicated time to thoroughly test the solution by **creating** a new-generation clinical protocol. This intensive **pilot testing confirmed the software's anticipated outcomes**: assessing data-driven design, properly implementing the Debiopharm protocol template in Protocol AI, and using the tool's structured authoring to generate a clinical protocol in a seamless manner.

By embracing this AI-powered protocol authoring tool, Debiopharm is taking a strategic step to embed machine learning into its research processes. Integrating such tools will enable faster development of the initial protocol draft by using a more collaborative and controlled environment and a data-driven generation of the trial design. This allows Debiopharm to refocus resources on high-value scientific work and accelerate the delivery of new treatments to patients.

"The successful completion of this initial proof-of-concept phase is a key step forward for our clinical development team," said Hans Cruz, Medical Writer & Clinical Scientist Group Head at Debiopharm. "The efficiency gains are now clearly visible and will allow us to streamline our protocol development efforts." Our next milestone is already underway: developing the subsequent oncology protocol with Protocol AI™.

"This successful milestone with Debiopharm demonstrates the transformative potential of Protocol AI to revolutionize clinical trial protocol design and development, making the process more efficient and improving the quality of trial protocols. The collaboration with Debiopharm's forward-thinking team has validated the solution's potential. We are now expanding this success to collaborations with other pharmaceutical companies" Poorya Amini, CEO of Risklick

About Risklick

Risklick is a Swiss MedTech company specializing in Al-driven solutions for clinical trial protocol development. The company partners with global pharmaceutical and biotech organizations to accelerate innovation in oncology and infectious diseases by providing advanced tools for protocol design, data-driven study planning, and operational efficiency. Risklick's flagship platform, Protocol Al™, empowers clinical teams to streamline processes and bring new therapies to patients faster. Headquartered in Bern, Switzerland, Risklick is committed to advancing digital transformation in clinical research.

More information on the website: www.risklick.ch

Follow us on LinkedIn: https://www.linkedin.com/company/risklick/

Debiopharm's commitment to patients

Debiopharm aims to develop innovative therapies that target high unmet medical needs primarily in oncology and bacterial infections. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy, and then hand stewardship to large pharmaceutical commercialization partners to maximize patient access globally.

Visit us: www.debiopharm.com/drug-development/

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