

CHALLENGER



SOLVER



MDR-PREP

IT driven QMS-tool for MDR compliance of early-stage medical device development

Innobuyer collaborated with public institutions (challengers) to identify their unmet innovation needs and select suitable SMEs (solvers) to address them. The matched teams co-created pilot solutions over a 10-month period. Following successful pilots, challengers received support from Innobuyer and experts to design simplified ToR. Each project was backed by €100,000 in financial support—€41,500 for the challenger and €58,500 for the solver.

THE NEED

TU Delft, an academic institution engaged in medical device development, faced significant **challenges in complying with regulatory standards**, specifically the Medical Device Regulation. Early-stage research projects required assistance in structuring and managing necessary documentation. Researchers and students needed accessible, basic compliance tools throughout their project lifecycle. The primary need was a system to streamline compliance processes, reduce administrative burdens, and enhance user experience while integrating seamlessly with existing systems. Affected groups include faculty, researchers, and students involved in medical device development

THE IMPACT

The pilot programme provided critical insights into QMS Lite's practical implementation. Key insights validated that **AI-enhanced features reduce effort and time for regulatory review**, and structured data management minimizes duplication. User feedback validated the need for an intuitive UI and integrated training. Complear gained a deeper understanding of academic institutions' needs, influencing customization and highlighting the need for continuous user engagement. TU Delft gained insights into compliance challenges and digital solutions' potential. Although the real-life pilot was delayed, extensive user feedback collection was effective, and there is a strong commitment from stakeholders to continue work in 2025.

THE SOLUTION

Complear, developed QMS Lite, a streamlined version of their electronic Quality Management System (eQMS) and electronic Technical Documentation (eTD) platform. This solution is specifically tailored for early-stage research projects in academic settings. It aims to simplify and enhance documentation and compliance using structured tools and integrating advanced technologies like Large Language Models (LLMs) for smart content suggestions. The solution's modular design allows for flexibility and scalability. Based on stakeholder feedback, the user interface was enhanced, training materials were expanded, and features for different product phases and collaboration were adjusted



THESE INNOVATIVE PROCUREMENT PROJECTS ALLOW CO-DESIGN SOLUTIONS THAT LEVERAGE BOTH ORGANIZATIONS' KNOWLEDGE AND CAPABILITIES, BRIDGING THE GAP TO UNMET MARKET NEEDS WITHOUT REINVENTING THE WHEEL. FOR COMPLEAR, THIS IS AN OPPORTUNITY TO EXPLORE A NEW MARKET SEGMENT AND OPEN THE DOOR TO CREATING AN OFFERING THAT CAN SERVE MULTIPLE RESEARCH ORGANIZATIONS IN MULTIPLE COUNTRIES. FOR TU Delft, THIS IS AN OPPORTUNITY TO ACCESS A TAILORED SOLUTION TO THEIR NEEDS IN SPECIAL CONDITIONS WHILE BENEFITING FROM THE SCALE OF A SOLUTION USED BY A WIDER GROUP OF SIMILAR ORGANIZATIONS.

