

Publishable Summary

The overarching goal of the DARE project is to equip the Italian Ministry of Health and the National Health Service (NHS) with efficient, effective, and innovative technologies. This transition is geared towards revolutionizing the healthcare landscape to better serve our communities' needs. As a part of this endeavor, Spoke 3 WP1 assumes a critical role in evaluating the quality and appropriateness of proposed pilots. This task involves a rigorous assessment of several key elements, including study design, sample size justification, statistical analysis plan, and outcomes evaluation. Our role aligns with the DARE project's objective of implementing innovative technologies and advancing prevention strategies, with the ultimate aim of improving health outcomes.

Our first duty lies in evaluating study design, which is fundamental to the success of any pilot study. We are tasked with ensuring that the design adequately addresses the research question, reduces bias and confounding, and maximizes validity (Porta, 2008). Furthermore, it is our responsibility to ensure the appropriateness of the sample size. An adequate sample size provides sufficient statistical power, controls for random error, and enhances the credibility and generalizability of the findings (Charan & Biswas, 2013).

In addition, we scrutinize the statistical analysis plan. A robust plan strengthens the validity of a study and ensures the proper interpretation of results (Gelman et al., 2013). Moreover, we will encourage pilots to apply statistical methodologies that can handle deviations from the protocols since we are aware that the research process is not always linear, which should be accounted for in the statistical plan. Finally, we evaluate outcomes, focusing on their appropriateness, validity, and sensitivity to changes in the factors under investigation (Haber et al., 2021).

At WP1, we collaborate closely with various DARE consortium partners to develop a comprehensive list of indicators. These will be instrumental in assessing the utility and implementability of innovative technologies within the framework of pilot studies. We use two frameworks for this purpose: the GRADE Evidence to Decision (EtD) framework for partners implementing clinical studies (Alonso-Coello et al., 2016) and the Predictive Clinical Model framework for partners creating predictive clinical models using artificial intelligence, machine learning, and deep learning.

In sum, our mission at WP1 of Spoke 3 is to ensure the rigorous, scientific, and ethical conduct of pilot studies, all with the aim of advancing the objectives of the broader DARE project.