TITLE

SISAQOL: Establishing international standards in the analysis of patient-reported outcomes and health-related quality of life data in cancer clinical trials

Funding source: Innovative Medicines Initiative, 18th call 2019 ((13470)IMI2)

Participation: Montse Ferrer (Member of the Scientific Advisory Board)

Duration: 2021-2024

SUMMARY OF PROJECT

Measuring and quantifying how a patient feels or functions during treatment is an important endpoint in cancer clinical trials. It is generally accepted that the collection of PRO data in cancer clinical trials allows the inclusion of the patient's voice in the risk-benefit assessment of therapies. However, no standards exist on how to analyse, interpret or report health-related quality of life (HRQOL) and other patient-reported outcomes (PROs). This initiative wants to pursue efforts in addressing the urgent need for standardization, by setting clear and validated standards that are tailored to and endorsed by all relevant stakeholders. With a strong international and multi-stakeholder Consortium, the initiative aims at finding consensus on suitable methods to analyse valid PRO objectives in cancer randomized clinical trials (RCTs) and ways to communicate these PRO findings in a standardized way that is understandable to all. To achieve this aim, SISAQOL-IMI will identify valid PRO research objectives and match these with appropriate statistical methods for PRO analysis in cancer RCTs. Translation to the estimands framework will be provided. Furthermore, the possibility of extending these recommendations to single-arm trial designs will be explored. Recommendations on clinically meaningful change for PRO instruments, as well as design considerations and ways for assessing quality of collected PRO data will be developed, and tools and templates for presentation and visualization of PRO findings freely made available. Strong emphasis is put on continuous collaboration with patient advocacy representatives throughout the project. Increased interpretability, adoption and full use of PRO outcomes for all stakeholders is expected by providing consensusbased and validated recommendations and communication tools for PRO data, ultimately resulting in better communication and shared decision making, improved outcomes, treatment satisfaction and care.