

115966 – PREFER

Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle

WP4 – Recommendations

Operational Guidance (D4.4)

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Operational Guidance

Patients' preferences are a growing topic of interest, and stakeholders (e.g. regulators, payers, industry, and patient organizations) have called for greater involvement of patients in drug development lifecycle. The objective of PREFER is to guide industry, regulatory authorities and HTA bodies and reimbursement agencies on how patient preferences can be assessed and used to inform medical product decision making by developing expert and evidence-based recommendations.

Along with the PREFER Recommendations, PREFER has developed operational guidance and training material to further assist in a patient preference study. The operational guidance consists of templates to utilize in the development and execution of a patient preference study. These templates are described below. The training material are listed on Zenodo (<https://doi.org/10.5281/zenodo.6397609>).

Templates

PREFER developed the templates relevant to preference studies for use to inform medical product decision making. These templates may be useful in the development and execution of a patient preference study and would be used in parallel with the PREFER recommendations. Users should also consider any local procedures, policies or regulations when developing documents for a patient preference study. The available templates for use or as a guide are listed below.

Title	Location
Protocol	https://doi.org/10.5281/zenodo.6400506
Protocol Synopsis	https://doi.org/10.5281/zenodo.6400496
Statistical Analysis Plan (SAP)	https://doi.org/10.5281/zenodo.6400511
Data Management Plan (DMP)	https://doi.org/10.5281/zenodo.6400415
Informed Consent Form	https://doi.org/10.5281/zenodo.6400437
Invitation to Participate	https://doi.org/10.5281/zenodo.6400445
Participant Information Sheet	https://doi.org/10.5281/zenodo.6400458
Study Report	https://doi.org/10.5281/zenodo.6400517
Plain Language Summary	https://doi.org/10.5281/zenodo.6415348