

## 115966 – PREFER

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

#### WP4 – Recommendations

#### Operational Guidance (D4.4)

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## Document History

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V1.0	30 03 2022	

## 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	<a href="https://doi.org/10.5281/zenodo.6400506">https://doi.org/10.5281/zenodo.6400506</a>
Protocol Synopsis	<a href="https://doi.org/10.5281/zenodo.6400496">https://doi.org/10.5281/zenodo.6400496</a>
Statistical Analysis Plan (SAP)	<a href="https://doi.org/10.5281/zenodo.6400511">https://doi.org/10.5281/zenodo.6400511</a>
Data Management Plan (DMP)	<a href="https://doi.org/10.5281/zenodo.6400415">https://doi.org/10.5281/zenodo.6400415</a>
Informed Consent Form	<a href="https://doi.org/10.5281/zenodo.6400437">https://doi.org/10.5281/zenodo.6400437</a>
Invitation to Participate	<a href="https://doi.org/10.5281/zenodo.6400445">https://doi.org/10.5281/zenodo.6400445</a>
Participant Information Sheet	<a href="https://doi.org/10.5281/zenodo.6400458">https://doi.org/10.5281/zenodo.6400458</a>
Study Report	<a href="https://doi.org/10.5281/zenodo.6400517">https://doi.org/10.5281/zenodo.6400517</a>
Plain Language Summary	<a href="https://doi.org/10.5281/zenodo.6400474">https://doi.org/10.5281/zenodo.6400474</a>