**EORTC protocol [number]**

**[Study title]**

**Statistical Analysis Plan (SAP)**

**[DRAFT/FINAL] version y.x**

**Date:**

**[DD MM YYYY]**

**🟅 Statistical Analysis Plan prepared by:**

[Name and title of study statistician]

**🟅 With the collaboration of:**

[Names and title of collaborators]

# Statistical considerations in the current protocol [version & date]

* Copy in this section the relevant sections from the study protocol, so that the reader of this SAP gets a clear understanding of the protocol context. **Please copy verbatim of relevant sections of the protocol**

## Trial Design

## Endpoints

## Statistical design and analysis plan

## Analysis methods

# Rationale for this SAP

* Indicate in this section the reason why a detailed SAP was needed for this study. The Rationale should justify the nature of the SAP:
* Clarification of the protocol SAP
* Change to the protocol SAP
* Additional SAP for an analysis/endpoint that was not in the protocol SAP
* Other, specify:

Depending on the type of SAP, the following section (section 3) will identify the elements that need, modification/clarification/change/

* IF purpose is “Clarification of the protocol SAP”

# Elements needing clarification

* IF purpose is “Change to the protocol SAP”

# Elements needing modification

* IF purpose is “Additional SAP for an analysis/endpoint that was not covered in the protocol SAP”, then section 3 may not be needed
* IF Purpose is “other” then section 3 should reflect the purpose of the SAP

# Trial objectives covered by this SAP

# Statistical Analysis plan

* Detail the SAP in this section. Structure it into primary analysis and sensitivity analysis for each endpoint. Specify methods clearly, so as to avoid needing further clarification of this SAP later on.