**Summary Attachment for EudraCT**

| Name of Sponsor/Company:  EORTC | Individual study Table Referring to Part of the Dossier | *(For National Authority Use Only)* |
| --- | --- | --- |
| Name of the finished product | Volume: |  |
| Name of Active Ingredient | Page |  |
| Title of the Study |  | |
| Investigators & Study Centers | *List here the investigators with their institution name and address and preferably with the number of patients they entered in the study.*  *This information is readily available from IT tools* | |
| Publication (reference) | *List here any existing reference for the presentation of the study results. If the final publication is not yet out, please list here any abstracts or formal presentations with the statement*  *The overall study data have not been published yet, however, publications about part of the data are: …* | |
| Objective(s) | *The following parts are available from the Study Protocol Summary* | |
| Methodology |  | |
| Number of patients  Number planed (Statistical design)  Number analyzed |  | |
| Diagnosis and main criteria for inclusion |  | |
| Treatment  Test product, dose and mode of administration (batch number if applicable) |  | |
| Duration of treatment |  | |
| Reference therapy, dose and mode of administration (batch number if applicable) |  | |
| Criteria for evaluation |  | |
| Efficacy |  | |
| Safety |  | |
| Statistical methods |  | |
| Summary of Results  Efficacy Results | *The contents of this section should be prepared on the basis of the section “Summary of Results” from the Final Analysis Report. It may however be less extensive than that chapter from the FAR study summary.* | |
| Safety Results |  | |
| Conclusions |  | |
| Date of Report | *Should be the date of the FAR* | |