Working Party:

Title of the study:

**Study Assumptions**

Study type:  Survey

Retrospective without additional data collection

Retrospective with additional data collection

Prospective without additional data collection

Prospective with additional data collection

Number of eligible sites:

Expected number of responding sites:

Total number of variables included in the survey *or* study-specific variables (‘MED-C’):

*In case it’s* ***NOT*** *a survey, please complete the next questions:*

Expected number of included patients:

Total number of core & extended variables:

Percentage of incompleteness of core & extended variables:

Use of Study Manager tool (for MED-C data collection):  Yes

No

Statistical analysis type:

Small study (i.e. less than approximately 100 patients, which means less extensive analyses)

Large standard study (i.e. with usual outcomes such as Overall survival, Progression free survival, Engraftment, standard analyses, etc.)

Large non-standard study with more extensive analyses that are known in advance, interactions, new scores, new analysis methods

Manuscript contribution by statistician:  normal

substantial

primarily responsible

**Time Investment Estimation**

**To be filled in by the Working Party (WP) Study Coordinator/Data Manager and Statistician.**

The time investment estimation gives an indication of the hours the WP Study Coordinator/Data Manager (SC/DM) and Statistician (Stat) are expected to invest in the study once the study protocol has been accepted (i.e. not including the feasibility, protocol completion/submission and selection phase). This is important to determine whether the WP has enough resources available to conduct the study. Please note that this estimation gives no information on the overall time needed for study completion, as this is also dependent on other factors such as centre response time.

|  |  |  |
| --- | --- | --- |
| **Task:** | **Estimated hours:** | |
| **SC/DM** | **Stat** |
| **Development of data collection form** |  |  |
| **Data entry** |  |  |
| **Data check (including additional queries)** |  |  |
| **Data file preparation** |  |  |
| **Statistical analysis** |  |  |
| **Manuscript** |  |  |
| **Study coordination** |  |  |
| **Total time investment:** |  |  |

**Study Timeline Estimation**

**To be filled in by the WP Study Coordinator/Data Manager and Statistician.**

The study timeline estimation gives an indication of the number of months required from the actual start of study preparation to study completion. It does not include the protocol submission and selection phase, nor any time between protocol acceptance and the WP being able to start study preparation.

|  |  |
| --- | --- |
| **Phase:** | **Estimated months:** |
| **Preparation (development of data collection forms/ database)** |  |
| **Active data collection (entry, additional queries, check)** |  |
| **Analysing (datafile preparation, statistical analysis)** |  |
| **Manuscript (writing, review, submission/revision)** |  |
| **Total study timeline:** |  |