Terumo Europe N.V. Grants and Donations Protocol Evaluation Form

***Please complete all fields in full written English, sign and submit to Medical Affairs Interventional Oncology @*** ***IO.IIS\_Management@terumo-europe.com***

|  |  |
| --- | --- |
| Study Title |  |
| Study Product |  |
| Principal Investigator |  |
| Contact Details |  |
| Institution |  |

|  |  |
| --- | --- |
| Target Study Population |  |
| Study Rationale |  |
| Treatment schedule |  |
| Primary Objective |  |
| Secondary Objective |  |
|  |  |

|  |  |
| --- | --- |
| Statistical analysis |  |
| Expected Outcomes |  |

|  |  |
| --- | --- |
| Number of patients |  |
| Follow up |  |
| Inclusion period |  |
| Overall study duration |  |
| Regulatory status |  |
| Inclusion criteria |  |
| Exclusion criteria |  |

Disclaimer:

Grants shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of Terumo products or services

Support requested:

I affirm that the grant will only be used for the described purpose. The research to be conducted will comply with the Helsinki Good Clinical Practice and otherwise stated regulatory requirements

Name, date and signature:

*To be completed by applicant*

*ANTICIPATED COSTS (if need be please add items)*

*Item (single or multicenter)Internal or External Planning & Startup*

*Insurance*

*Regulatory Submissions/Fees Ethics Submissions Investigator & Site Fees*

*Product amount of cost if known Study Monitoring & Management Data management & Statistics Statistical Analysis*

*Medical Writing*

*Other Costs*

*Cost (€)*

*SEE ATTACHED DETAILED BUDGET*

*TOTAL COSTS AND SUPPORT REQUESTED(€)*

*COST BREAKDOWN Continued*


# Estimated Scheduling Budget requested (current year)

*Estimated Scheduling of Costs vs Budgets*

# Year 1 Year 2 Year 3 Year 4

*Please note that the research milestones will also determine the payment milestones*

***Review Comments***