**Trial title:**  **Short title:**

**Date and version number of protocol:**  **Chief investigator at Máxima:**
**Responsible PI (or Co-PI/Junior PI) at Máxima:**  **Coordinating investigator (when outside Máxima):**  **Sponsor:**  **Contact person at external sponsor:**  **Date of completing form:**
**Intake for grant-application: yes / no**\*

**SUMMARY:**

1. **What is the objective of the trial (max. 5 lines)?**

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1. **What patient group is the target group for this trial?**

[ ] Hemato-oncology[ ] Solid tumours[ ] Neuro-oncology[ ] SCT[ ] LATER (long-term survivors of childhood cancer)[ ] All paediatric oncology

1. **Type of study:**

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|  [ ]  Observational (incl. diagnostic testing) *If observational;* [ ]  *Prospective* [ ]  *Retrospective* [ ] Intervention not involving drug trial[ ] Intervention with drugs[ ] Intervention with medical device(s) |
| Explanation:  |
| Research phase:[ ] Pilot study[ ] Phase **I** [ ] Phase **II** [ ] Phase **III** [ ] Phase **IV**

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 [ ] Other, please specify |

1. **Duration**

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| Total study duration:  |
| Inclusion period:  |
| Expected first inclusion at Máxima:  |
| Expected last inclusion at Máxima:  |
| Expected total inclusion at Máxima:  |

1. **Is this a multicentre trial?**  [ ]  **Yes** [ ]  **No**

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| If so, how many centres worldwide:  |
| If so, how many centres in Europe:  |
| If so, how many centres in the Netherlands:  |

1. **Please indicate whether each of the following items applies:**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Yes | No |
|  | Are there obligations under the Dutch Medical Research (Human Subjects) Act (WMO)? Please explain if necessary. |  |  |
|  | In the case of a drug trial, please explain whether trial medication is used or medication from a commercial source. |  |  |
|  | Are liquid biopsies being collected or used? |  |  |
|  | Are *contracts* required? If so, please explain what parties contracts are required with. |  |  |
|  | Is *monitoring* required? If so, please explain (monitoring plan, who will monitor etc.). |  |  |

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| Item: | Explanation: |
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1. **Has METC approval already been obtained for this protocol somewhere in the Netherlands?***If METC approval has already been obtained, please attach the METC approval letter with this form.*

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**PATIENT:**

1. **What is the burden on the patient (e.g. questionnaire, duration of questionnaire, extra outpatient visits, extra blood samples, extra diagnostic tests etc.)?**

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1. **Is the burden proportionate to the knowledge gained as a result of the trial?** [ ]  **Yes** [ ]  **No***Give reasons for your answer.*

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**FUNDING:**

1. **What is the plan for funding (budget and funding organisation)?**

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1. **Has the use of staff at the Trial and Data Center (TDC) been taken into consideration in the funding (see also question 14)?**

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**APPROVAL WITHIN UNIT:**

1. **Has the trial been discussed with and approved by the unit head and the relevant PIs at the Máxima?** *If so, please attach the approval letter from the unit head with this form.*

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**TDC AND STATISTICS:**

1. **Who has provided statistical/methodological support?**

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1. **Please indicate whether each of the following items applies:**

*If so, please state how much/in what way*

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| --- | --- | --- | --- |
|  |  | Yes | No |
|  | Is the TDC expected to create and maintain a database?*If not, please explain.* |  |  |
|  | Is *trial management* required? |  |  |
|  | Is *local data management* required? |  |  |
|  | Are *research nurses* needed? |  |  |
|  | Is the *pharmacy* needed? |  |  |
|  | Is *statistical support* required? |  |  |
|  | Are any *special procedures* required? *Such as coding and central review scans, PK/PD, PAT revision, other central lab etc.* |  |  |

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| Item: | Explanation: |
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1. **Will any human tissue be stored in a BIOBANK?** [ ]  **Yes** [ ]  **No**

*If so, please explain which “biobank”, what tissue, coding, duration of storage:*

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**\* For grant-applications the grant application form of the grant provider, including protocol summary, budget proposal and (if applicable) additional funding is sufficient.**

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| --- |
| **Please email the fully completed intake form to** **scicom@prinsesmaximacentrum.nl****with approval from unit head and PI(s) involved and the following documents:****Protocol, Patient Information forms and consent declarations and Funding plan.** |

**External links for more information**:
 [**http://www.ccmo.nl**](http://www.ccmo.nl)[**http://www.ccmo.nl/nl/standaardonderzoeksdossier-2**](http://www.ccmo.nl/nl/standaardonderzoeksdossier-2)