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| --- | --- | --- | --- | --- | --- | --- |
| Author | *Hélène François* | | Reviewer(s) | *Joëlle De Vriese* | Approved by | *Michel Toungouz* |
| Public | *🞏All 🞏 Investigators 🞏 Study Nurse 🞏 Study coordinator 🞏 Paramedics 🞏 Admin Staff* | | | | | |
| Document revision history / Changes-Revision Comment | |  | | | | |

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| --- |
| Protocol (Acronym):  Title:  Principal Investigator:  Erasme EC Reference number:  Leading EC:  EC approval date:  Date of report: |

The experiment didn’t start yet because:

The experiment started on …………………. (Initiation date or date of 1st "screening")

ο The experiment is performed according to the expected design:  YES  NO

* Expected patients number:
* Recruitment status on :(date)

* Patients on site :
  + - * Screened patients number:
      * Enrolled patients number:
      * Drop-out/withdrawal patients number:

+ reasons if known:

* + - * Number of patients having terminated the experiment according to the protocol:
* Total patients (multicentric research) :

ο The experiment is temporary stopped because of:  YES  NO

 adverse events (please specify) :

 technical or practical issues (please specify) :

 other (please specify) :

ο The experiment is terminated because of:  YES  NO

adverse events (please specify):

other (please specify)

limited number of recruited patients

according to the study design

* Are the observed adverse events and their severity in accordance with the information provided at time of initial submission?

YES

NO (please specify):

* If no DSUR (from the Sponsor) is provided, please provide a summary of adverse events and adverse outcomes experienced by participants, as well as a summary of unanticipated problems involving risks to participants or others.
* Please provide a summary of complaints received about the research.
* Please provide a summary of amendments and modifications submitted since last report.
* Please communicate any relevant recent literature or interim findings that could impact safety of participants.
* Please provide any relevant multi-center trial reports
* Is the risk/benefit balance, based on study results, still positive for the participants (according to PI’s opinion)?

YES

NO (please specify)

The Erasme Hospital EC has received, analyzed and approved the above information on (date) ………………