Delegation log

**Protocol: Empirical Meropenem versus Piperacillin/Tazobactam for Adult patients with Sepsis (EMPRESS) trial.**

**EU CT Number: 2023-509703-33-00**

**Site: *Insert name of department and/or hospital***

**Investigator: *Insert name***

**Description key for delegation log:**

|  |  |  |  |
| --- | --- | --- | --- |
| **A** | **Screening of patients, assessment of inclusion and exclusion criteria and perform randomisation.** | **E** | **Identify events and side effects (SAR/SUSAR)** |
| **B** | **Inform and acquire consent from the legal guardian, relatives and the participant** | **F** | **Evaluate events and side effects (SAR/SUSAR) for possible causality with the investigational drug** |
| **C** | **Register and edit data in eCRF** | **G** | **Educate personnel** |
| **D** | **Report SAR and SUSAR to sponsor** |  |  |

**I *insert name* hereby delegate the following tasks to EMPRESS trial personnel. In addition, I declare with signature that the following personnel are informed and trained in the relevant trial specific tasks:**

**The EMPRESS trial personnel declare with signature that their e-mail address will be used for EMPRESS newsletters and to personalise a user for the eCRF.**

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| --- | --- | --- | --- | --- | --- |
| **Trial personnel** | **Trial tasks**  **(Descrip-tion key)** | **Dated signature of personnel accepting delegated tasks** | **Local investigator’s dated signature for delegation** | **Date of trial involvement (start)** | **Date of trial involvement (end)** |
| Name:  Title:  E-mail: |  |  |  |  |  |
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| Name:  Title:  E-mail: |  |  |  |  |  |
| Name:  Title:  E-mail: |  |  |  |  |  |

**Local investigator’s signature at the end of the trial**

Date: \_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_