|  |  |  |  |
| --- | --- | --- | --- |
| **Site number** |  | **Study Name** | REMAP-CAP |
| **Site name** |  | **Protocol number**  | NCT02735707 |
| **PI name** |  | **Sponsor** | UMCU |
|  |  | **Note to File number** |  |

**1a What is the scope of the issue**

 [ ]  A single participant

 Complete section 1b, (local) Investigator to sign, original to be filed in
 ISF, copy to be filed in TMF

 [ ]  Multiple participants or general conduct at a single site

 Complete section 1b, (local) Investigator to sign, original to be filed in
 ISF, copy to be filed in TMF

 [ ]  Multiple sites or study management

 Complete section 1c, Central Principal Investigator to sign, to be filed in TMF

 [ ]  Other

**1b Participant(s) number:**

**1c Site numbers:**

|  |
| --- |
| **2 Description of the issue**  |
| **Date discovered:       Date occurred:** |

|  |
| --- |
| **3 Action Taken** |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **NAME, POSITION** | **DATE** | **SIGNATURE** |
| **Author Note to File form** |  |  |  |
| **Principal Investi-gator** |  |  |  |