|  |  |  |  |
| --- | --- | --- | --- |
| **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** |  |  |  |