

PLACIDE study

Research number:

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Patient initials:

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vers 4: 17th March 2009

Patient's age:

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Clinical diagnosis

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Start date IMP

		/			/		
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Date of onset of SAE

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Date of end of SAE

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Describe SAE – what has happened?

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What is the most likely cause of this event (e.g. UTI, post-op complication)?

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ICD10 code

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Did the SAE require intervention? Yes – 1; No-2

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If Yes, describe intervention:

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Study preparation discontinued? Yes – 1; No - 2

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Final outcome regarding SAE

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(Full recovery -1; on-going disability/impairment – 2; died – 3)

Severity criteria (enter either Y or N – complete all boxes)

Life threatening

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Significant disability

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Hospitalisation/ prolongation

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Congenital anomaly/birth defect

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Important Medical Event

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Death

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Form completed by (initials):

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Pass form to Trial Manager to complete the following:

Reported to:

MHRA

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MREC

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R&D

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Date added to SAE database:

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