Event Categorisation Flow Chart – email rgosponsor@le.ac.uk

Adverse Event

Does it meet seriousness criteria?

If Yes

SAE

Is it Device-Product related?

If Yes

ADE

Is it anticipated?

If Yes

Anticipated SADE

If No

SADE

If No

AE

Is it Device-Product related?

If Yes

Unexpected Serious Adverse Device Effect

If NO

If Yes

Is it Device-Product related?

If Yes

Anticipated SADE

If No

If No

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