

**Serious Adverse Event [SAE] / Unanticipated Problem [UAP]
Source Document Coversheet**



Study ID:

SAE

UAP

SAE / UAP Description (e.g., *pneumonia*)

Site Name:

Initial submission

Follow-up submission

Date (MM/DD/YYYY):

Number of pages (including coversheet):

Records included: (check)

Laboratory reports, specify:

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All identifying information must be concealed.***