

SAE Reconciliation Checklist
<Study Title>

Patient ID:

SAE No:

Adverse Event		Match	Result		Follow up Query
eCRF data	SAE Report		OK	Query	OK
Description SAE	SAE diagnosis	Consistent			
Patient number	Patient number	Exact			
Patient Initials	Patient Initials	Exact			
Date of birth or Age	Age	Consistent			
Onset Date	Date of event onset	Exact			
Stop Date	Date Event Recovered	Exact			
Severity	Severity	Exact			
Relation to the study drug	Relationship to study drug	Exact			
Outcome	Outcome of the event	Consistent			
Action taken	Action taken by Investigator	Consistent			
Treatment assigned	Study Drug Information	Exact			
Date of Study Med intake	Date of Study Drug intake	Exact			
Concom. Med.	Concomitant Drug Information	All drugs present on the SAE Report form should be present in the eCRF but not vice versa.			
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SAE Reconciled and all discrepancies closed?

Signature:

Date: