



Check list for Submitting Requested Development Safety Update Reports (DSUR) in Electronic Format

Please complete and append the following checklist when submitting a DSUR.

Development Safety Update Reports (DSUR) Check List	Check all that Apply
Most recent Investigator's Brochure	
Cumulative Table of Important Regulatory Requests	
Summary Table of the Status of Ongoing and Completed Clinical Trials	
Cumulative Summary Tabulations of Demographic Data	
Line Listings of Serious Adverse Reactions	
Cumulative Summary Tabulation of Serious Adverse Events	
Cumulative Summary Tabulation of Serious Adverse Reactions	
List of subjects who died during the reporting period	
List of subjects who dropped out of clinical trials in association with an adverse event during the reporting period	
Significant Phase I protocol modifications	
Significant manufacturing changes	