

Protocol Deviation and Unanticipated problems Form

Study title:

EC Refs:

N° Eudract-CT:

Principal Investigator:

Date (dd-mmm-yyy)	Subject number	Non compliance (NC) / Deviation (Dev) / Violation (Viol) / Unanticipated problem (Unantip P) Please specify	Related to (if applicable)	Description and comments ACTION TAKEN	RESOLVED yes or no
.....-.....-20.....		<input type="checkbox"/> NC <input type="checkbox"/> Dev <input type="checkbox"/> Viol <input type="checkbox"/> Unantip P	<input type="checkbox"/> drug <input type="checkbox"/> protocol <input type="checkbox"/> Excl/incl <input type="checkbox"/> NA		
.....-.....-20.....		<input type="checkbox"/> NC <input type="checkbox"/> Dev <input type="checkbox"/> Viol <input type="checkbox"/> Unantip P	<input type="checkbox"/> drug <input type="checkbox"/> protocol <input type="checkbox"/> Excl/incl <input type="checkbox"/> NA		
.....-.....-20.....		<input type="checkbox"/> NC <input type="checkbox"/> Dev <input type="checkbox"/> Viol <input type="checkbox"/> Unantip P	<input type="checkbox"/> drug <input type="checkbox"/> protocol <input type="checkbox"/> Excl/incl <input type="checkbox"/> NA		
.....-.....-20.....		<input type="checkbox"/> NC <input type="checkbox"/> Dev <input type="checkbox"/> Viol <input type="checkbox"/> Unantip P	<input type="checkbox"/> drug <input type="checkbox"/> protocol <input type="checkbox"/> Excl/incl <input type="checkbox"/> NA		

Principal Investigator : Signature :

Date :

Evaluation by the Ethics Committee: No feed back Feed back Plenary session

Name :

Signature :

Date :-.....-20.....