



SAE REPORT FORM

ERC PROFILE	ERC REFERENCE no: _____ Principal Investigator: _____ Contact no: _____ Protocol Title: _____ _____																														
SUBJECT INFO	Subject clinical: _____ Date of Birth: __/__/__ Gender: _____ Date enrolled: __/__/__ <small>Day Month Year Day Month Year</small>																														
SAE DESCRIPTION	<table border="0"> <tr> <td>SAE Diagnosis: _____</td> <td>Category:</td> <td>Savarity</td> </tr> <tr> <td>_____ [] death</td> <td>[] desability in capacity</td> <td>[] Mild</td> </tr> <tr> <td>Date of Experience: __/__/__</td> <td>[] life threathening</td> <td>[] Moderate</td> </tr> <tr> <td></td> <td>[] congrental anomaly birth defect</td> <td>[] Severate</td> </tr> <tr> <td>End of Experience: __/__/__</td> <td>[] important medical event</td> <td>Relationship to Study</td> </tr> <tr> <td></td> <td>[] hospitalization- initial prolonged</td> <td>[] Unrelated</td> </tr> <tr> <td>Date of Awareness: __/__/__</td> <td>[] required intervention to prevent</td> <td>[] Unlikely</td> </tr> <tr> <td></td> <td>permanent impairment</td> <td>[] Possibly</td> </tr> <tr> <td></td> <td>[] other: _____</td> <td>[] Definitely</td> </tr> <tr> <td colspan="2">Investigator's Narrative Report: : (Pls. write legibly and provide attachements if necessary)</td> <td>Expectedness: [] Expected [] Unexpected</td> </tr> </table>	SAE Diagnosis: _____	Category:	Savarity	_____ [] death	[] desability in capacity	[] Mild	Date of Experience: __/__/__	[] life threathening	[] Moderate		[] congrental anomaly birth defect	[] Severate	End of Experience: __/__/__	[] important medical event	Relationship to Study		[] hospitalization- initial prolonged	[] Unrelated	Date of Awareness: __/__/__	[] required intervention to prevent	[] Unlikely		permanent impairment	[] Possibly		[] other: _____	[] Definitely	Investigator's Narrative Report: : (Pls. write legibly and provide attachements if necessary)		Expectedness: [] Expected [] Unexpected
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REPORTING	Type of Report: <input type="checkbox"/> Initial Report <input type="checkbox"/> Follow-up Report 2 <input type="checkbox"/> Final Report <input type="checkbox"/> Response to NOA <i>Outcome</i> On going Complete Recovery FatalDeath Cause of Death: _____ Designation: _____ _____ Recovered w/ sequelae (for ERC only) _____ Received by: _____ _____ (Signature over printed name)																														