

Amendments/ Changes for Clinical Trial/ Medicinal Test

(Please use this form for each CTC subsequent submission during a clinical trial/ medicinal test)

Date of submission		For office acknowledgement stamp																						
CT cert no.																								
Ref. no.	PR/CT																							
Protocol no.																								
Protocol title																								
Trial site																								
Name of Certificate holder																								
<p>If the changes involve change of particulars on the Certificate, please submit the original CTC.</p> <p><input type="checkbox"/> Change of certificate holder/ address</p> <p><input type="checkbox"/> Change of principal investigator</p> <p><input type="checkbox"/> Change of study drug</p> <p><input type="checkbox"/> Change of trial site/ address</p> <p>Other amendments, please provide the EC approval/ acknowledgement:</p> <table style="width: 100%; border: none;"> <thead> <tr> <th style="width: 80%;"></th> <th style="width: 10%; text-align: center;">Yes</th> <th style="width: 10%; text-align: center;">No</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> Change of protocol title</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td><input type="checkbox"/> Amendment to protocol (please also provide summary of change)</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td><input type="checkbox"/> Amendment to consent form (please provide clean and track changes copies)</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td><input type="checkbox"/> Amendment to investigator's brochure (please also provide summary of change)</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td><input type="checkbox"/> Safety update</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td><input type="checkbox"/> Others (please specify):</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table> <p>This submission involves trial status report:</p> <p><input type="checkbox"/> Yearly progress report Date of the report _____</p> <p><input type="checkbox"/> Final report Date of the report _____</p>					Yes	No	<input type="checkbox"/> Change of protocol title	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Amendment to protocol (please also provide summary of change)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Amendment to consent form (please provide clean and track changes copies)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Amendment to investigator's brochure (please also provide summary of change)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Safety update	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Others (please specify):	<input type="checkbox"/>	<input type="checkbox"/>
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Reported by Signature: _____

Contact no.: _____

Signatory's name: _____

Date: _____