REPORTING, ASSESSMENT AND CLOSE OUT OF TEMPERATURE EXCURSIONS

SECTION 1 : REPORT (All excursions)	
Protocol N°/Trial No (as applicable):	
Site name:	
Product:	Packaging Batch N°:
Defined storage conditions: °C Defined transport conditions: °C (Presentation)	Kit N°: Quantity of product affected:
Deviation occurred during: ☐ Transport ☐ Storage (Sponsor) ☐ Storage (Clinical trial site)	**Apparent Cause:** ☐ Refrigerator, cold room, air-conditioning problems ☐ Power failure ☐ Other: *please report in Comments/ Emergency Action Taken*
Description of Deviation: Date: Temperature: Duration:	**Documentation attached:** ☐ No ☐ Yes (please list):
Comments / Emergency Action Taken:	
Person reporting the deviation Date: Name/ Position: Signature:	

SECTION 2 – ASSESSMENT (All excursions)	
Assessment Visual Appearance: ☐ Container contents ☐ Primary packaging ☐ Secondary packaging	**Data Assessment:** ☐ Available stability data
Result of Assessment by Delegate: ☐ Allowed Temperature Excursion - material can be confirmed for clinical use ☐ Critical Temperature Excursion - requires Assessment/ Investigation and release by QP	
Comments:	
Person performing assessment: Date: Name/ Position: Signature:	