NKTIREC FORM 4.1B: STANDARD ADVERSE DRUG EVENT/S REPORT

Principal Investigator:	NKTI REC Protocol No.:	
Study Protocol Title:		
Name of the study drug/device	Report Date: dd/mm/yyyy ☐ Initial ☐ Follow-up Onset date: dd/mm/yyyy	
Sponsor:	Date of first use:	
Patient's Initial/Number:	Age:	☐ Male ☐ Female
Patient's Date of Birth: dd/mm/yyyy	Weight: kg	Height: cm
Relevant medical history and concurrent conditions:		

I. REACTION INFORMATION:

_____ (use CIOMS definition) List all relevant tests/ lab data:	Check all appropriate to adverse reaction: ☐ Patient died ☐ Involved or prolonged inpatient hospitalization ☐ Involved persistence or significant disability or incapacity ☐ Life threatening

II. SUSPECT DRUG/S INFORMATION:

Suspect drug/s (include generic name)		Did reaction abate after stopping drug? ☐ Yes ☐ No ☐ NA
Daily dose/s:	Routes of administration:	Did reaction appear after reintroduction? ☐ Yes ☐ No ☐ NA
Indication/s for use:		
Therapy date/s: (from/to)	Therapy duration:	
Is this reaction ☐ Unexpected ☐ Expected		
Treatment given for Adverse Event:		
Causality Assessment by Investigator (Using WHO-UMC Causality Assessment System) ☐ Certain ☐ Probable		

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☐ Possible ☐ Unlikely ☐ Unclassifiable
Outcome of reaction/event at the time of last observation: ☐ Recovered ☐ Recovering with sequelae ☐ Death ☐ Recovering ☐ Not recovering ☐ Unknown

III. CONCOMITANT DRUG/S AND HISTORY:

Concomitant drug/s and dates of administration (exclude drug used to treat reaction)
Other relevant history (e.g., diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER'S INFORMATION:

Name and address of manufacturer		
Manufacturer control no.		
Date received by manufacturer: dd/mm/yyyy	Report source ☐ Study ☐ Literature ☐ Health professional	
Date of this report: dd/mm/yyyy	Report type ☐ Initial ☐ Follow-up	

RECOMMENDED ACTION: (for NKTIREC only)

- ☐ TAKE NOTE AND NO FURTHER ACTION
- ☐ REQUEST INFORMATION: (indicate information)
- ☐ RECOMMEND FURTHER ACTION: (indicate action)
- ☐ REQUEST AMENDMENT TO THE PROTOCOL
- ☐ REQUEST AMENDMENT TO THE INFORMED CONSENT FORM
- ☐ SUSPEND OR TERMINATE THE STUDY
- ☐ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

PRIMARY REVIEWER	Signature	_____
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>

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