## Form: Collection of ADR information.

M	Δ	CL	.≡	0	D.	>
ш	ш		ш			ш

ADVERSE EVENT REPORT Page 1 of 2														
PATIENT INFORMATION:														
Patient initials:								Date:						
COUNTRY:														
REPORT T	YPE:		Initial [	☐ Follow-	up									
DATE OF BIRTH	Α	AGE	RACE	SEX	(		HEIC	НТ	WEIG	НТ	ONSE DATE		RE DA	COVERY
DD/MM/YYY	Y			וח	Male								D/MM/YYYY	
					Female					-				
4 D T T D D G D			2222		remaie									
ADVERSE ADVERSE					d:	:c	-:1-1-)		Cariana					
ADVERSE	EVENI	1(3)11	MEDICAL	TERMS (	nagnosis	, ii poss	sible)		Seriousness criteria Check all appropriate to event					
Description	of arran								_		_			
Description	oi eveii	ıı.							∐ Pati	ient di	ed			
									☐ Involved or prolonged inpatient hospitalization					
									☐ Involved persistent or significant disability					
									or incapacity					
									Life-threatening Congenital anomaly/birth defect					
									Other significant medical events					
									-					
HISTORY :							TEST / I	4 BOD	ATODX	/ EINII	DINGS	(antar only	, tho	so findings
		VANT	MEDICAL	<b>ШСТ∩Р</b> У	. (a.g. aa				RATORY FINDINGS (enter only those findings AE diagnosis or course description)					
PATIENT'S existing	medical		ions such as											
experien	ces)													
SUSPECT DRUG INFORMATION:														
Product Name Manufactu Batch/lot Expiry Dose Route of Fre								Frequ	equency Therapy dates Indication					
Brand	Gei	neric	rer	number	date		use		-	(from				
name	Nai									DD/MM	I/YYYY	DD/MM/YY	YY	

## Form: Collection of ADR information.

П	Δ	CI	E	0	D	2
ш	ш		Ш	ш	ш	111

ADVERSE EVENT REPORT Page 2 of 2

CONCOMITA	NT DRUGS		1						
DRUG NAME(S)		DOSE	THERA		Y DATES (To)	REASON FOR USE			
Brand name	Generic Name		DD/MM/YYY		DD/MM/YYYY				
ACTION TAK	EN WITH SUSI	PECT DRUG (m	ark all as ap	propriate	2)				
☐ No Action	Taken		Withdrawn			☐ Treatment taken			
Did Reaction D	Disappear After S	Stopping of Drug	??	Did Rea	action Reappeared Aft	er Restarting of Drug?			
Yes		Applicable		Yes					
	_			<u> </u>					
OUTCOME O	F THE PATIEN	T/AE							
Completely		Date of ecovery:	DD/MM/YYYY		Condition still present and unchanged				
Recovered	with sequelae				Condition deteriorated				
Condition i	improving				☐ Death Autopsy: ☐ No ☐ Yes				
ASSESSMENT	Γ OF CAUSALI	TY							
Probab	le [	Possible	t Related Unknown						
REPORTER'S	S INFORMATI	ON:							
NAME, ADDR REPORTE		ONE NUMBER	AND EMAI	L OF	DATE OF THIS REPORT DD/MM/YYYY				
					☐ HCP ☐ CONSUMER ☐ OTHER				
					Signature:				
					Senders Contact details:				
					USA Direct Line: 1-855-926-3384 (Time 09:00 AM To 05:00 PM CDT From Monday To Friday)				
					USA Toll Free: 1-888-943-3210 (This is a voice message service. We will respond to voice mail within 24 hours from Monday to Friday, 9 am to 5 pm CDT)				
					Email: safety@macleodspharma.com				