CURELEADS

Local AE Reporting Form

To be used for adverse event (AE) reporting if Principal/MAH form or reporting portal not available

Send this form to CURELEADS PV team via email: adverseevent@cureleads.com

*** = Mandatory Fields**

1- General Information

Principal/MAH Name		***Product Name**	

2- Reporter

***Name (First/Last)**		***Phone / email**	
***Address/Country**		***Reported by HCP? (If no Clarify)**	☐ Yes ☐ No
***Oral Consent to contact HCP?**	☐ Yes ☐ No		

3- Patient

***Initials**		***Sex**		***Date of Birth or Age at onset or Age Group**	
***Oral Consent to contact Patient?** (If yes, please add patient contact details)	☐ Yes ☐ No				

4- Adverse Event

***Main Event**		***Date of Onset**	

AE description, signs & symptoms, possible causes, progression, treatments, relevant medical history, investigations

Serious Criteria ☐ None apply *or check all that apply*	☐ Death ☐ Life-Threatening ☐ Congenital Anomaly/ Birth Defect	☐ Inpatient/ Prolonged Hospitalization ☐ Persistent or Significant Disability / Incapacity ☐ Suspected transmission of infectious agent
Action Taken ☐ None ☐ Discontinued ☐ Dose changed specify:	Did event reoccur after drug was restarted? ☐ Yes ☐ No ☐ Unk Did event abate after drug was stopped or dose changed? ☐ Yes ☐ No ☐ Unk Corrective treatment was required, ☐ specify:	

***Outcome of Event*:**

☐ Recovered	Date of Resolution, if not available, event duration:	
☐ Recovered with sequelae:	Specify:	
☐ Recovering		
☐ Not Recovered		
☐ Unknown		
☐ Fatal	Specify date & cause of death.	Autopsy: ☐ Yes ☐ No ☐ Unk.

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5- CURELEADS Medication/Device involved

Trade/Brand name & or INN (strength & form)	Indication	Dosage/Unit/Freq/ amount	Route	Treatment Dates		Lot/Batch/ exp. date
				Start	**End or Duration**	

6-Concomitant drugs and medical history

CAD - First received Date:*	*Name: (First /Last)*	
CURELEADS LSR received Date:	*Name: (First /Last)*	
CURELEADS PV Ref. No.	*CURELEADS PTC Ref. No.*	*Principal/MAH PV Ref. No.*

*CAD = Contact Awareness Date