Investigator Initiated Research
Serious Adverse Event Report Form

For Pfizer internal use only

AER Number	Date Reported to Pfizer

Write all dates as DD/MMM/YYYY

X 5		
PROTOCOL / STUDY I.D.	CENTER I.D	SUBJECT I.D. / RANDOMIZATION #

Zeile füllt BiKeR aus!

Protocol Title: ***Langzeitdokumentation der Anwendung von Etanercept / MTX bei im Kindesalter erkrankten Patienten mit chronischer Arthritis – Biker***

☒ **Initial Report** ☐ **Follow Up Report** **Country where event occurred:** Germany

Patient Data PAT.CODE Date of Birth Race ☐ White ☐ Black ☐ Asian ☐ Other

☐ Male ☐ Female Weight ☐ lb ☒ kg Height ☐ in ☒ cm

If patient has died: Date of Death Cause of Death Determined by Autopsy ☐ Y ☐ N

Patient History ***Provide relevant medical history below or include copy of the Medical History case report form page. Include other illnesses present at time of event, previous study emergent adverse events, and pre-existing medical conditions. If additional space is necessary, use further copies of this page.***

☐ Check box if a copy of Medical History page of the case report form is included with this report

Disease (specify)	Onset Date	Stop Date	Check box if Ongoing	Pertinent Details ***Include surgical procedures and dates***
			☒	
			☐	
			☐	
			☐	

Study Drug, Formulation, Route	*Check box if Pfizer Drug*	Dose	Units	Frequency	Start Date	Stop Date	Check box if Ongoing
Etanercept	☒						☐
	☐						☐
	☐						☐
	☐						☐
	☐						☐

Concomitant Drugs ☐ None ☐ Unknown ***List below concomitant drugs taken within 2 weeks before the event onset or include copy of Concomitant Drugs case report form page. Exclude all drugs only administered more than two weeks before the event, and any drug used to treat the event or taken after event onset. If additional space is necessary, use further copies of this page.***

☐ Check box if a copy of Concomitant Drugs page of the case report form is included with this report

Drug Name (Trade and Generic)	Reason for Use	Route	Start Date	Stop Date	Check box if Ongoing
					☐
					☐
					☐
					☐
					☐

Relevant Tests ***List only relevant confirmatory test results for event(s), for example, from blood tests, diagnostic imaging. If additional space is necessary, use further copies of this page.***

Test	Date	Result	Units	Normal Range Low	Normal Range High	Comments

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SERIOUS ADVERSE EVENTS (if more than 2, use additional copies of this page)
Specify diagnosis if known, rather than symptoms or signs

Serious Adverse Event Term ____________________

Onset Date: ____________

Status at date of report or at death:
☐ Recovered }
☐ Recovered with sequelae} Date of Recovery: ____________
☐ Recovering
☐ Not Recovered
☐ Unknown

Seriousness Criteria (Check all that apply):
☐ Resulted in death
☐ Life-threatening
☐ Hospitalization/Prolongation of hospitalization
☐ Persistent/Significant disability/Incapacity
☐ Congenital anomaly/Birth defect
☐ Important medical event

Is there a reasonable possibility that the event is related to Study Drug (specify):
____________________ ☐ **Yes** ☐ **No**
____________________ ☐ **Yes** ☐ **No**

If related to a Concomitant Drug, specify: ____________________

Study Drug Action Due to Event (specify drug name):

____________	____________
☐ Withdrawn (temporarily or permanently, or delayed)	☐ Withdrawn (temporarily or permanently, or delayed)
☐ Dose reduced	☐ Dose reduced
☐ Dose increased	☐ Dose increased
☐ Dose not changed	☐ Dose not changed
☐ Unknown	☐ Unknown
☐ Not applicable	☐ Not applicable

Serious Adverse Event Term ____________________

Onset Date: ____________

Status at date of report or at death:
☐ Recovered }
☐ Recovered with sequelae} Date of Recovery: ____________
☐ Recovering
☐ Not Recovered
☐ Unknown

Seriousness Criteria (Check all that apply):
☐ Resulted in death
☐ Life-threatening
☐ Hospitalization/Prolongation of hospitalization
☐ Persistent/Significant disability/Incapacity
☐ Congenital anomaly/Birth defect
☐ Important medical event

Is there a reasonable possibility that the event is related to Study Drug (specify):
____________________ ☐ **Yes** ☐ **No**
____________________ ☐ **Yes** ☐ **No**

If related to a Concomitant Drug, specify: ____________________

Study Drug Action Due to Event (specify drug name):

____________	____________
☐ Withdrawn (temporarily or permanently, or delayed)	☐ Withdrawn (temporarily or permanently, or delayed)
☐ Dose reduced	☐ Dose reduced
☐ Dose increased	☐ Dose increased
☐ Dose not changed	☐ Dose not changed
☐ Unknown	☐ Unknown
☐ Not applicable	☐ Not applicable

Event Narrative ***Provide any information regarding the circumstances, sequence, diagnosis and treatment of the event(s) not otherwise reported on this form. If additional space is necessary, use further copies of this page.***

Reporter Comments:

Study Site Reporter BIKER-Register

Investigator's name (onsite) ____________________
Name / City

Telephone ____________ Fax ____________ Date / Signature