Non Serious Adverse Drug Reactions Report

Start Date:2016-06-03 End Date:2016-06-06

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:001		
Subject No :001-0009	Subject Initials :	DOB :08/08/1960	Sex:Female	Race:Caucasian	Height:160(cm)	Weight:65(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	12/22/2014	44	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	12/22/2014	44	
Visit 1/ Baseline (Day 1)	12/22/2014	44	
Visit 4 (Month 9)	12/22/2014	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
injection site inflammation	12/22/2014			Suspected	Mild

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	None	Ongoing		

Event description:

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
persistent flu-like symptoms	12/22/2014	UK-unk-2014		Suspected	Mild

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	None	Resolved		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
acetaminophen	Uk-Feb-2015		Uk-Feb-2015	500	mg	per day

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
hypertension			Yes
dyslipidemia			Yes
acute bronchitis			No