Non Serious Adverse Drug Reactions Report

Start Date:2016-03-18 End Date:2016-03-21

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:002		
Subject No :002-0002	Subject Initials :	DOB :08/13/1955	Sex:Male	Race:Caucasian	Height:180(cm)	Weight:84(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	02/16/2015	8	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	02/16/2015	8	
Visit 1/ Baseline (Day 1)	02/16/2015	8	
Visit 4 (Month 9)	02/16/2015	8	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
Injection site inflammation	11/11/2015			Suspected	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Drug withdrawn	Led to study termination	Ongoing		

Event description:

Subject received concomitant medications

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency

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

Condition	Start Date	Related to study condition	Ongoing
Blood hypertension			Yes
Cardiac ischemic heart disease			Yes
Diabetes mellitus type 2			Yes
Benign prostatic hyperplasia			Yes