

Non Serious Adverse Drug Reactions Report

Start Date:2015-10-22 End Date:2015-10-29

Study :EMR700623-541		Investigator :NA		Country of Investigator :China		SiteNo :C02	
Subject No :C02-0008		Subject Initials :R-H		DOB :02/06/1993		Sex :Female	
				Race :Asian		Height :158cm	
						Weight :51.0kg	
First administration date of batch :				Batch number :			
Study Drug		Start Date		Dose		Change in Dose	
Gonal-f New Pen Stimulation Treatment		05/11/2015		150			
Adverse Event		Start Date		End Date		Time related to study treatment	
OHSS		05/27/2015		06/05/2015		Related	
						Severity	
						Moderate	
Causality Factors		Action Taken with Study Treatment		Other action taken		Outcome	
None(Othervalue:)		Not applicable		Led to study termination		Resolved	
Event description :Moderate OHSS patients, improved canceled after embryo transfer.							
Subject received concomitant medications:							
Does the subject have any relevant past or present medical conditions :Yes							
Condition				Start Date		Related to study condition	
laparoscope hydrotubation				Uk-Unk-2013		Not on treatment/medication	

29-OCT-15

NA/EMR700623-541/C02-0008

Non Serious Adverse Drug Reactions Report

Start Date:2015-10-22 End Date:2015-10-29

Study :EMR700623-541		Investigator :NA		Country of Investigator :China		SiteNo :C02	
Subject No :C02-0124		Subject Initials :Y-C	DOB :07/17/1982	Sex :Female	Race :Asian	Height :150cm	Weight :48.5kg
First administration date of batch :				Batch number :			
Study Drug		Start Date		Dose		Change in Dose	
Gonal-f New Pen Stimulation Treatment		05/21/2015		225			
Adverse Event		Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS		06/07/2015	06/12/2015		Related	Moderate	
Causality Factors			Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)			Not applicable	Led to study termination	Resolved		
Event description :Moderate OHSS patients, improved canceled after embryo transfer.							
Subject received concomitant medications:							
Does the subject have any relevant past or present medical conditions :Yes							
Condition					Start Date	Related to study condition	Ongoing
HSG: the left fallopian tube obstruction and hydrocephalus right salpingitis					Uk-Unk-2013	Not on treatment/medication	
Hysteroscopy normal					Uk-Mar-2015	Not on treatment/medication	

28-OCT-15

NA/EMR700623-541/C02-0124

