

Non Serious Adverse Drug Reactions Report

Start Date:2016-09-12 End Date:2016-09-13

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0201	Subject Initials :J-L	DOB :12/15/1990	Sex:Female	Race:Asian	Height:168cm	Weight:65kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	09/07/2015	125				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	09/24/2015	10/02/2015		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 occurs canceled embryo transfer, OHSS improvement						
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: bilateral tubal occlusion	Uk-Unk-2012	Not on treatment/medication				

12-SEP-16

NA/EMR700623-541/C02-0201

Non Serious Adverse Drug Reactions Report

Start Date:2016-09-12 End Date:2016-09-13

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C04		
Subject No :C04-0171	Subject Initials :SHL	DOB :08/17/1987	Sex:Female	Race:Asian	Height:154cm	Weight:40kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	09/29/2015	300				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	10/03/2015	10/10/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose reduced	None	Resolved		
Event Description:none						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

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