

Non Serious Adverse Drug Reactions Report

Start Date:2015-09-10 End Date:2015-09-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo :C02		
Subject No :C02-0010	Subject Initials :Y-H	DOB :10/18/1985	Sex :Female	Race :Asian	Height :153cm	Weight :47.0kg
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	Causality to study drug	Severity	
OHSS	05/29/2015	06/02/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Concomitant medication**(Other value:)		Not applicable	Led to study termination	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions :No						
Condition				Start Date	Related to study condition	Ongoing

15-SEP-15

NA/EMR700623-541/C02-0010

Non Serious Adverse Drug Reactions Report

Start Date:2015-09-10 End Date:2015-09-17

Study :EMR700623-541	Investigator :Ying Zhong		Country of Investigator :China	SiteNo :C05		
Subject No :C05-0001	Subject Initials :XFZ	DOB :01/21/1988	Sex :Female	Race :Asian	Height :159cm	Weight :50kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose		Change in Dose		
Gonal-f New Pen Stimulation Treatment	08/01/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	08/16/2015	08/18/2015		Related	Severe	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Concomitant medication **	Resolved		
Event description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions: Yes						
Condition				Start Date	Related to study condition	Ongoing
oophorocystectomy				UK-Jul-2013	Not on treatment/medication	
salpingoplasty				UK-Feb-2014	Not on treatment/medication	
salpingitis after previous tubal occlusion				UK-Feb-2014	Not on treatment/medication	Ongoing

16-SEP-15

Ying Zhong/EMR700623-541/C05-0001

