

Non Serious Adverse Drug Reactions Report

Start Date:2016-07-25 End Date:2016-07-26

Study :EMR700623-541	Investigator :Fei Gong	Country of Investigator :China	SiteNo:C01			
Subject No :C01-0158	Subject Initials :T-Y	DOB :06/17/1983	Sex:Female	Race:Asian	Height:163cm	Weight:3300g
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	09/16/2015	112.5				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	10/12/2015	10/12/2015		Related	Moderate	
Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
None(Othervalue:)	Not applicable	Concomitant procedure**	Resolved			
Event Description: Abdominal distension, Nausea, yellow urine with less volume, chest pelvic effusion,ascites puncture 12-Oct-2015,2500ml						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition	Start Date	Related to study condition	Ongoing			
right fallopian tube is less patency,left fallopian tube is obstruction	06/04/2015	Not on treatment/medication	Ongoing			
Endometrial polyps hyperplasia	08/24/2015	Not on treatment/medication	Ongoing			

26-JUL-16

Fei Gong/EMR700623-541/C01-0158

