

Non Serious Adverse Drug Reactions Report

Start Date:2016-07-14 End Date:2016-07-15

Study :EMR700623-541	Investigator :Fei Gong	Country of Investigator :China	SiteNo:C01			
Subject No :C01-0068	Subject Initials :X-S	DOB :04/16/1989	Sex:Female	Race:Asian	Height:160cm	Weight:2500g
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	06/27/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	07/23/2015	08/04/2015		Related	Severe	
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 23Jul2015,1000ml; 27Jul2015,2100ml; 30Jul2015,2500ml; 04Aug2015,2000ml ;						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition	Start Date	Related to study condition	Ongoing			
The left Hydrosalpinx and adhesions,less patency.Right fallopian tube partially blocked	03/22/2014	Not on treatment/medication	Ongoing			
right fallopian tube resection because of Ectopic pregnancy	UK-Oct-2011	Not on treatment/medication				

15-JUL-16

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