Non Serious Adverse Drug Reactions Report

Start Date:2015-08-28	End Date:2015-08-31						
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:43kg	
First administration date of batch :			Batch number :				
Study Drug	Start Date		Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	06/26/2015		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:					•	•	
Subject received conco	mitant medications:						
Does the subject have	any relevant past or pr	esent medical conditio	ns: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 reso	ection because of Ectopic	pregnancy	UK-Oct-2011	Not on treatment/medication			

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Start Date:2015-08-28 End Date:2015-08-31

Start Date.2015-06-26	Liiu Date.2013-06-31						
Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01			
Subject No :k01-040	Subject Initials :LBH	DOB : 03/05/1985	Sex:Female	Race:Asian	Height:164cm	Weight:61kg	
First administration date of batch :			Batch number :				
Study Drug	Start Date		Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	04/06/2015		225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity		
OHSS	04/15/2015	04/30/2015		Related	Mild		
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
None(Othervalue:)		Dose not changed	Led to study termination	Resolved			
Event Description:							
Subject received conco	mitant medications:						
Does the subject have	any relevant past or pr	esent medical conditio	ns:No				
Condition				Start Date	Related to study condition	Ongoing	

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