

## Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :Fei Gong	Country of Investigator :China	SiteNo:C01			
Subject No :C01-0001	Subject Initials :TTW	DOB :05/13/1988	Sex:Female	Race:Asian	Height:157cm	Weight:3050g
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/16/2015	112.5				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/06/2015	06/15/2015		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:Nausea, vomiting, yellow urine with less volume, chest pelvic effusion,ascites puncture 10-Jun-2015,2200ml;ascites puncture 15-Jun-2015,2900ml;						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition	Start Date	Related to study condition	Ongoing			
Bilateral fallopian tube obstruction	04/11/2014	Not on treatment/medication	Ongoing			

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Fei Gong/EMR700623-541/C01-0001

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

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/medicatio n	Ongoing	
right fallopian tube resection because of Ectopic pregnancy			UK-Oct-2011	Not on treatment/medicatio n		

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Fei Gong/EMR700623-541/C01-0068

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

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: <b>Abdominal distension, Nausea, yellow urine with less volume, chest pelvic effusion,ascites puncture 12-Oct-2015,2500ml</b>						
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

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Fei Gong/EMR700623-541/C01-0158

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0002	Subject Initials :LLL	DOB :02/12/1987	Sex:Female	Race:Asian	Height:158cm	Weight:50.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/08/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/25/2015	06/03/2015		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: <b>Moderate OHSS patients, improved canceled after embryo transfer.</b>						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
salpingemphrxis,lalace peritoneoscope				Uk-Jul-2014	Not on treatment/medication	

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NA/EMR700623-541/C02-0002

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0118	Subject Initials :MLF	DOB :08/03/1984	Sex:Female	Race:Asian	Height:160cm	Weight:55.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/21/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/07/2015	06/12/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description: <b>Moderate OHSS occurs canceled embryo transfer, OHSS improvement</b>						
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 obstruction				Uk-Unk-2007	Not on treatment/medication	
Laparoscopic pelvic sticky points, bilateral ovarian drilling				Uk-Unk-2007	Not on treatment/medication	
Cervical biopsy showing inflammation				Uk-Unk-2015	Not on treatment/medication	

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NA/EMR700623-541/C02-0118

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C04			
Subject No :C04-0087	Subject Initials :HZD	DOB :08/04/1983	Sex:Female	Race:Asian	Height:161cm	Weight:60kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	06/26/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	07/07/2015	07/21/2015		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:Yes						
Condition				Start Date	Related to study condition	Ongoing
spontaneous abortion				01/05/2010	Not on treatment/medication	
spontaneous abortion				05/18/2012	Not on treatment/medication	

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NA/EMR700623-541/C04-0087

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

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	09/30/2015	10/09/2015		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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NA/EMR700623-541/C04-0171

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

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:)		Not applicable	None	Resolved		
Event Description:Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd						
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/medicatio n	
salpingoplasty				UK-Feb-2014	Not on treatment/medicatio n	
salpingitis after previous tubal occlusion				UK-Feb-2014	Not on treatment/medicatio n	Ongoing

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Ying  
Zhong/EMR700623-541/C05-0001



# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :Ying Zhong	Country of Investigator :China	SiteNo:C05			
Subject No :C05-0010	Subject Initials :Q-Z	DOB :01/31/1990	Sex:Female	Race:Asian	Height:159cm	Weight:45kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/02/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	08/17/2015	08/24/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Disease under study**,Protocol procedure**,Concomitant medication**(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:abdominal distention;nausea Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 17-Aug-2015 / 27-Aug-2015						
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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Ying  
Zhong/EMR700623-541/C05-0010

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541		Investigator :Ying Zhong		Country of Investigator :China		SiteNo:C05	
Subject No :C05-0013		Subject Initials :L-L	DOB :06/12/1986	Sex:Female	Race:Asian	Height:159cm	Weight:54.5kg
First administration date of batch :				Batch number :			
Study Drug		Start Date		Dose		Change in Dose	
Gonal-f New Pen Stimulation Treatment		08/02/2015		150			
Adverse Event		Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS		08/18/2015	08/20/2015		Related	Moderate	
Causality Factors			Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Disease under study**,Protocol procedure**,Concomitant medication**(Othervalue:)			Dose not changed	Led to study termination	Resolved		
Event Description:abdominal distention;nausea ,ascites,Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 18-Aug-2015 / 20-Aug-2015							
Subject received concomitant medications:							
Does the subject have any relevant past or present medical conditions:Yes							
Condition				Start Date		Related to study condition	Ongoing
ampullary pregnancy				UK-Unk-2010		Not on treatment/medication	
ampullary pregnancy				UK-Unk-2012		Not on treatment/medication	
ampullary pregnancy				UK-Unk-2013		Not on treatment/medication	
salpingocatheterism				UK-Unk-2013		Not on treatment/medication	

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Ying  
Zhong/EMR700623-541/C05-0013

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :Ying Zhong	Country of Investigator :China	SiteNo:C05			
Subject No :C05-0021	Subject Initials :FYZ	DOB :08/28/1990	Sex:Female	Race:Asian	Height:150cm	Weight:45kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/04/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	08/19/2015	08/21/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Protocol procedure**,Concomitant medication**(Othervalue:)		Not applicable	None	Resolved		
Event Description:abdominal distention;Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 19-Aug-2015 / 21-Aug-2015						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
salpingocatheterism				UK-Unk-2012	Not on treatment/medicatio n	

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Ying  
Zhong/EMR700623-541/C05-0021

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :Ying Zhong	Country of Investigator :China	SiteNo:C05			
Subject No :C05-0041	Subject Initials :W-Y	DOB :07/03/1981	Sex:Female	Race:Asian	Height:153cm	Weight:55kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/08/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	08/23/2015	08/25/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Protocol procedure**,Concomitant medication**(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:abdominal distention;Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 21-Aug-2015 / 25-Aug-2015						
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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Ying  
Zhong/EMR700623-541/C05-0041

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :Ying Zhong	Country of Investigator :China	SiteNo:C05		
Subject No :C05-0056	Subject Initials :X-P	DOB :06/14/1983	Sex:Female	Race:Asian	Height:158cm Weight:46kg
First administration date of batch :			Batch number :		
Study Drug	Start Date	Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	08/13/2015	150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	08/27/2015	08/29/2015		Related	Mild
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest AE dose limiting toxicity
Protocol procedure**,Concomitant medication**(Othervalue:)		Not applicable	Led to study termination	Resolved	
Event Description:abdominal distention;nausea ;ascites;Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 17-Aug-2015 / 27-Aug-2015					
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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Ying  
Zhong/EMR700623-541/C05-0056

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541		Investigator :Ying Zhong		Country of Investigator :China		SiteNo:C05	
Subject No :C05-0068		Subject Initials :YPL	DOB :12/07/1985	Sex:Female	Race:Asian	Height:160cm	Weight:50kg
First administration date of batch :				Batch number :			
Study Drug		Start Date		Dose		Change in Dose	
Gonal-f New Pen Stimulation Treatment		08/15/2015		225			
Adverse Event		Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS		08/27/2015	08/29/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
Protocol procedure**,Concomitant medication**(Othervalue:)		Dose not changed	Led to study termination	Resolved			
Event Description:abdominal distention;nausea ;ascites;Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 17-Aug-2015 / 27-Aug-2015							
Subject received concomitant medications:							
Does the subject have any relevant past or present medical conditions:Yes							
Condition				Start Date		Related to study condition	Ongoing
Fallopian tube repair anaplasty				UK-Unk-2010		Not on treatment/medication	

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Ying  
Zhong/EMR700623-541/C05-0068

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :Ying Zhong	Country of Investigator :China	SiteNo:C05		
Subject No :C05-0117	Subject Initials :Y-L	DOB :04/16/1982	Sex:Female	Race:Asian	Height:165cm Weight:48kg
First administration date of batch :			Batch number :		
Study Drug	Start Date	Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	08/23/2015	225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/08/2015	09/10/2015		Related	Mild
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest AE dose limiting toxicity
Protocol procedure**,Concomitant medication**(Othervalue:)		Dose reduced	Led to study termination	Resolved	
Event Description:abdominal distention;ascites;Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 19-Aug-2015 / 21-Aug-2015					
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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Ying  
Zhong/EMR700623-541/C05-0117

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541		Investigator :Ying Zhong		Country of Investigator :China		SiteNo:C05	
Subject No :C05-0141		Subject Initials :XHZ	DOB :04/14/1987	Sex:Female	Race:Asian	Height:158cm	Weight:48kg
First administration date of batch :				Batch number :			
Study Drug		Start Date		Dose		Change in Dose	
Gonal-f New Pen Stimulation Treatment		08/29/2015		150			
Adverse Event		Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS		09/12/2015	09/14/2015		Related	Moderate	
Causality Factors			Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Protocol procedure**,Concomitant medication**(Othervalue:)			Dose not changed	Led to study termination	Resolved		
Event Description:abdominal distention;nausea ;ascites;Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 17-Aug-2015 / 27-Aug-2015							
Subject received concomitant medications:							
Does the subject have any relevant past or present medical conditions:Yes							
Condition				Start Date		Related to study condition	Ongoing
Fallopian tube repair anaplasty				UK-Unk-2009		Not on treatment/medication	

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Ying  
Zhong/EMR700623-541/C05-0141



# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :NA	Country of Investigator :Korea	SiteNo:K01			
Subject No :k01-0059	Subject Initials :LKH	DOB :08/05/1981	Sex:Female	Race:Asian	Height:153cm Weight:74g	
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	06/02/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/13/2015	07/02/2015		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	None	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

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NA/EMR700623-541/k01-0059

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :NA	Country of Investigator :Korea	SiteNo:K01			
Subject No :k01-035	Subject Initials :PSS	DOB :01/19/1983	Sex:Female	Race:Asian	Height:161cm	Weight:56g
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	03/11/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	03/23/2015	04/21/2015		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	None	Resolved		
Event Description: <span style="color: red;">no additional data</span>						
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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NA/EMR700623-541/k01-035

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :NA	Country of Investigator :Korea	SiteNo:K01			
Subject No :k01-036	Subject Initials :JSY	DOB :07/28/1981	Sex:Female	Race:Asian	Height:162cm	Weight:54g
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	03/13/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	03/24/2015	04/07/2015		Related	Moderate	
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:No						
Condition	Start Date	Related to study condition	Ongoing			

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NA/EMR700623-541/k01-036

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

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:61g
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	None	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

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NA/EMR700623-541/k01-040

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :NA	Country of Investigator :Korea	SiteNo:K01			
Subject No :k01-049	Subject Initials :PGR	DOB :02/20/1983	Sex:Female	Race:Asian	Height:168cm	Weight:62g
First administration date of batch :		Batch number :				
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/02/2015	300				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/13/2015	05/29/2015		Related	Mild	
Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
None(Othervalue:)	Not applicable	Concomitant medication **	Resolved			
Event Description:albumin treatment and resloved						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition	Start Date	Related to study condition	Ongoing			
laparoscopic ovary cystectomy	UK-UNK-2004	Not on treatment/medication				

19-AUG-16

NA/EMR700623-541/k01-049

# Non Serious Adverse Drug Reactions Report

Start Date:2016-08-19 End Date:2016-08-20

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-050	Subject Initials :KHG	DOB :04/22/1984	Sex:Female	Race:Asian	Height:150cm	Weight:46g
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/03/2015		300			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/14/2015	05/29/2015		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 concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
ovary cystectomy				UK-Jan-2014	Not on treatment/medication	

19-AUG-16

NA/EMR700623-541/k01-050

