Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0043	Subject Initials :F-H	DOB :03/13/1983	Sex:Female	Race:Asian	Height:164cm	Weight:54.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/13/2015	225	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/30/2015	06/05/2015		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:

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 tubal ectopic pregnancy at the right side of the window to take embryo	Uk-Unk-2005	Not on treatment/medication	
Under the right fallopian tube ectopic pregnancy laparoscopic surgery	Uk-Unk-2007	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0046	Subject Initials :Q-H	DOB :10/07/1985	Sex:Female	Race:Asian	Height:161cm	Weight:50.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/13/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/28/2015	06/05/2015		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:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0049	Subject Initials :HPT	DOB :09/16/1980	Sex:Female	Race:Asian	Height:155cm	Weight:50.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/14/2015	187.5	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/31/2015	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:

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 surgery appendicitis	Uk-Unk-2012	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0052	Subject Initials :YLL	DOB :02/07/1992	Sex:Female	Race:Asian	Height:165cm	Weight:54.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/14/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/30/2015	06/05/2015		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:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0053	Subject Initials :YND	DOB :04/13/1992	Sex:Female	Race:Asian	Height:155cm	Weight:45.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/14/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/30/2015	06/05/2015		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:

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 tubal colostomy, pelvic surgery sticky points.	Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0059	Subject Initials :J-L	DOB :12/23/1984	Sex:Female	Race:Asian	Height:155cm	Weight:50.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/14/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/31/2015	06/05/2015		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:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0062	Subject Initials :FQR	DOB :07/25/1983	Sex:Female	Race:Asian	Height:162cm	Weight:46.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/14/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/30/2015	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:

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
Hysteroscopic tubal inspection	Uk-May-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0071	Subject Initials :LLX	DOB :07/13/1987	Sex:Female	Race:Asian	Height:157cm	Weight:41.5kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/15/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/31/2015	06/05/2015		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:

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 pelvic sub sticky, sticky points left fallopian tube surgery.	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0115	Subject Initials :KJT	DOB :07/02/1988	Sex:Female	Race:Asian	Height:163cm	Weight:52.0kg
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	06/06/2015	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:

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 examination: bilateral tubal occlusion	Uk-Unk-2012	Not on treatment/medication	
Laparoscopy surgery: pelvic sticky points, bilateral tubal ostomy + right side mesosalpinx cyst removal.	Uk-May-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

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

01-MAR-16

Ying Zhong/EMR700623-541/C05-0010

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

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	

01-MAR-16

Ying Zhong/EMR700623-541/C05-0013

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

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:)	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 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/medication	

01-MAR-16

Ying Zhong/EMR700623-541/C05-0021

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

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	225	

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

01-MAR-16

Ying Zhong/EMR700623-541/C05-0041

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

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	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:No

Condition	Start Date	Related to study condition	Ongoing

01-MAR-16

Ying Zhong/EMR700623-541/C05-0056

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

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	

01-MAR-16

Ying Zhong/EMR700623-541/C05-0068

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

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	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 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

01-MAR-16

Ying Zhong/EMR700623-541/C05-0117

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

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	

01-MAR-16

Ying Zhong/EMR700623-541/C05-0141

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-26 End Date:2016-03-14

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:007		
Subject No :007-0007	Subject Initials :	DOB :08/01/1981	Sex:Female	Race:Caucasian	Height:163(cm)	Weight:60(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	06/05/2015	9	
Visit 3 (Month 6)	06/05/2015	9	
Visit 1/ Baseline (Day 1)	06/05/2015	9	
Visit 4 (Month 9)	06/05/2016	9	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
Adverse event	12/16/2015			Suspected	Mild

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Other(Othervalue:Rebif therapy)	Dose not changed	Concomitant medication	Ongoing		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Stilnox	06/02/2015	Yes		1	tb	QD
Alanerv	06/06/2015		11/30/2015	2	tb	BID
Acetaminophen	06/05/2015	Yes		500	mg	PRN
L-Thyroxin	Uk-Jan-2016	Yes		25	mcg	QD

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
Depression			Yes