Non Serious Adverse Drug Reactions Report

Start Date:2016-02-03 End Date:2016-02-22

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:

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	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-03 End Date:2016-02-22

Study :EMR700623-541	**Investigator :**NA		**Country of Investigator :China**	**SiteNo:**C02		
Subject No :C02-0011	**Subject Initials :**P-X	**DOB :**12/07/1994	**Sex:**Female	**Race:**Asian	**Height:**160cm	**Weight:**60.0kg
First administration date of batch :			**Batch number :**			

Study Drug	**Start Date**	**Dose**	**Change in Dose**
Gonal-f New Pen Stimulation Treatment	05/11/2015	150	

Adverse Event	**Start Date**	**End Date**	**Time related to study treatment**	**Causality to study drug**	**Severity**
OHSS	05/27/2015	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**
ectopic pregnancy Salping ectomy	Uk-Unk-2013	On treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-03 End Date:2016-02-22

Study :EMR700623-541	**Investigator :**NA		**Country of Investigator :China**	**SiteNo:**C02		
Subject No :C02-0023	**Subject Initials :**JYF	**DOB :**11/10/1981	**Sex:**Female	**Race:**Asian	**Height:**163cm	**Weight:**70.0kg
First administration date of batch :			**Batch number :**			

Study Drug	**Start Date**	**Dose**	**Change in Dose**
Gonal-f New Pen Stimulation Treatment	05/12/2015	300	

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**
Hysteroscopy Salpingemphraxis	Uk-Mar-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-03 End Date:2016-02-22

Study :EMR700623-541	**Investigator :**NA		**Country of Investigator :China**	**SiteNo:**C02		
Subject No :C02-0026	**Subject Initials :**HCJ	**DOB :**07/07/1993	**Sex:**Female	**Race:**Asian	**Height:**161cm	**Weight:**53.0kg
First administration date of batch :			**Batch number :**			

Study Drug	**Start Date**	**Dose**	**Change in Dose**
Gonal-f New Pen Stimulation Treatment	05/12/2015	200	

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**
Laparotomy with left tubal ectopic pregnancy resection	Uk-Unk-2011	Not on treatment/medication	
Under ectopic pregnancy laparoscopic conservative surgery	Uk-Unk-2012	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-03 End Date:2016-02-22

Study :EMR700623-541	**Investigator :**NA		**Country of Investigator :China**	**SiteNo:**C02		
Subject No :C02-0029	**Subject Initials :**XLX	**DOB :**06/08/1981	**Sex:**Female	**Race:**Asian	**Height:**158cm	**Weight:**70.0kg
First administration date of batch :			**Batch number :**			

Study Drug	**Start Date**	**Dose**	**Change in Dose**
Gonal-f New Pen Stimulation Treatment	05/12/2015	250	

Adverse Event	**Start Date**	**End Date**	**Time related to study treatment**	**Causality to study drug**	**Severity**
OHSS	06/01/2015	06/07/2015		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**
Pelvic mass laparoscopic pelvic surgery sticky points, bilateral tubal ostomy, left ovarian drilling, tubal.	Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-02-03 End Date:2016-02-22

Study :EMR700623-541	**Investigator :**NA		**Country of Investigator :China**	**SiteNo:**C02		
Subject No :C02-0034	**Subject Initials :**L-Z	**DOB :**09/04/1981	**Sex:**Female	**Race:**Asian	**Height:**156cm	**Weight:**53.0kg
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	05/30/2015	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:2016-02-03 End Date:2016-02-22

Study :EMR200136_583	**Investigator :**NA		**Country of Investigator :Romania**	**SiteNo:**006		
Subject No :006-0005	**Subject Initials :**	**DOB :**08/28/1965	**Sex:**Female	**Race:**Caucasian	**Height:**165(cm)	**Weight:**70(kg)
First administration date of batch :			**Batch number :**			

Study Drug	**Start Date**	**Dose**	**Change in Dose**
Visit 2 (Month 3)	03/11/2015	8	
Visit 1/ Baseline (Day 1)	03/11/2015	8	
Visit 4 (Month 9)	03/11/2015	8	

Adverse Event	**Start Date**	**End Date**	**Time related to study treatment**	**Causality to study drug**	**Severity**
increased liver enzimes	06/11/2015			Suspected	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	Ongoing		

Event description:

Subject received concomitant medications:Yes

Name of medication	**Start Date**	**Ongoing**	**End Date**	**Dose**	**Unit**	**Frequency**
desloratadinum	08/22/2015		09/09/2015	5	miligrams	qd
liv 52	08/22/2015	Yes		275	miligrams	qd

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

Condition	**Start Date**	**Related to study condition**	**Ongoing**
thrombophilia			Yes
arterial hipertension			Yes
peripheral artheriopathy			Yes