Non Serious Adverse Drug Reactions Report

Start Date:2016-03-15 End Date:2016-03-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0126	Subject Initials :RCM	DOB :01/09/1989	Sex:Female	Race:Asian	Height:165cm	Weight:60.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/21/2015	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:

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: the right fallopian tube obstruction, poor uterine shape	Uk-Unk-2013	Not on treatment/medication	
Hysteroscopy: uterine spindle-shaped, single horn.	Uk-Unk-2014	Not on treatment/medication	

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Start Date:2016-03-15 End Date:2016-03-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0134	Subject Initials :QYL	DOB :06/17/1986	Sex:Female	Race:Asian	Height:155cm	Weight:47.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/22/2015	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
Laparotomy: pelvic abscess incision and drainage, the right accessories cystectomy	Uk-Unk-2009	Not on treatment/medication	
Hysteroscopy normal uterine shape	Uk-Unk-2013	Not on treatment/medication	
Hysteroscopic curettage	Uk-Unk-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-03-15 End Date:2016-03-17

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:62kg
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 **,Led to study termination	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	