

## Non Serious Adverse Drug Reactions Report

Start Date:2015-08-24 End Date:2015-08-28

<b>Study</b> :EMR700623-541	<b>Investigator</b> :Fei Gong		<b>Country of Investigator</b> :China	<b>SiteNo</b> :C01		
<b>Subject No</b> :C01-0001	<b>Subject Initials</b> :TTW	<b>DOB</b> :05/13/1988	<b>Sex</b> :Female	<b>Race</b> :Asian	<b>Height</b> :157cm	<b>Weight</b> :41.5kg
<b>First administration date of batch</b> :			<b>Batch number</b> :			
<b>Study Drug</b>	<b>Start Date</b>		<b>Dose</b>	<b>Change in Dose</b>		
Gonal-f New Pen Stimulation Treatment	05/16/2015		113			
<b>Adverse Event</b>	<b>Start Date</b>	<b>End Date</b>	<b>Time related to study treatment</b>	<b>Causality to study drug</b>	<b>Severity</b>	
OHSS	06/06/2015	06/16/2015		Related	Moderate	
<b>Causality Factors</b>		<b>Action Taken with Study Treatment</b>	<b>Other action taken</b>	<b>Outcome</b>	<b>AE Special Interest</b>	<b>AE dose limiting toxicity</b>
None(Othervalue:)		Not applicable	Concomitant procedure**	Resolved		
Event Description:						
Subject received concomitant medications:						
<b>Does the subject have any relevant past or present medical conditions</b> :Yes						
<b>Condition</b>				<b>Start Date</b>	<b>Related to study condition</b>	<b>Ongoing</b>
Bilateral fallopian tube obstruction				04/11/2014	Not on treatment/medication	Ongoing

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Fei Gong/EMR700623-541/C01-0001

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<b>Subject No</b> :C01-0068		<b>Subject Initials</b> :X-S	<b>DOB</b> :04/16/1989	<b>Sex</b> :Female	<b>Race</b> :Asian	<b>Height</b> :160cm	<b>Weight</b> :43kg
<b>First administration date of batch</b> :				<b>Batch number</b> :			
<b>Study Drug</b>		<b>Start Date</b>		<b>Dose</b>		<b>Change in Dose</b>	
Gonal-f New Pen Stimulation Treatment		06/26/2015		150			
<b>Adverse Event</b>		<b>Start Date</b>	<b>End Date</b>	<b>Time related to study treatment</b>	<b>Causality to study drug</b>	<b>Severity</b>	
OHSS		07/23/2015	08/04/2015		Related	Severe	
<b>Causality Factors</b>			<b>Action Taken with Study Treatment</b>	<b>Other action taken</b>	<b>Outcome</b>	<b>AE Special Interest</b>	<b>AE dose limiting toxicity</b>
None(Othervalue:)			Not applicable	Concomitant procedure**	Resolved		
<b>Event description:</b>							
Subject received concomitant medications:							
<b>Does the subject have any relevant past or present medical conditions:</b> Yes							
<b>Condition</b>					<b>Start Date</b>	<b>Related to study condition</b>	<b>Ongoing</b>
The left Hydrosalpinx and adhesions,less patency.Right fallopian tube partially blocked					03/22/2014	Not on treatment/medication	Ongoing
right fallopian tube resection because of Ectopic pregnancy					UK-Oct-2011	Not on treatment/medication	

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Fei Gong/EMR700623-541/C01-0068

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<b>Study</b> :EMR700623-541		<b>Investigator</b> :NA		<b>Country of Investigator</b> :Korea		<b>SiteNo</b> :K01	
<b>Subject No</b> :k01-035	<b>Subject Initials</b> :PSS	<b>DOB</b> :01/19/1983	<b>Sex</b> :Female	<b>Race</b> :Asian	<b>Height</b> :161cm	<b>Weight</b> :56kg	
<b>First administration date of batch</b> :			<b>Batch number</b> :				
<b>Study Drug</b>	<b>Start Date</b>		<b>Dose</b>	<b>Change in Dose</b>			
Gonal-f New Pen Stimulation Treatment	03/11/2015		225				
<b>Adverse Event</b>	<b>Start Date</b>	<b>End Date</b>	<b>Time related to study treatment</b>	<b>Causality to study drug</b>	<b>Severity</b>		
OHSS	03/23/2015	04/21/2015		Related	Mild		
<b>Causality Factors</b>		<b>Action Taken with Study Treatment</b>	<b>Other action taken</b>	<b>Outcome</b>	<b>AE Special Interest</b>	<b>AE dose limiting toxicity</b>	
None(Othervalue:)		Dose not changed	Led to study termination	Resolved			
<b>Event description:</b>							
Subject received concomitant medications:							
<b>Does the subject have any relevant past or present medical conditions</b> :No							
<b>Condition</b>				<b>Start Date</b>	<b>Related to study condition</b>	<b>Ongoing</b>	

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NA/EMR700623-541/k01-035

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

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NA/EMR700623-541/k01-040

