| Non Serious Adverse Drug Reactions Report | | | | | | | | |
|--|---------------------------------------|--------------------------------------|---------------------------------|----------------------------|------------------------------------|---------------------------|--|--|
| Start Date:2016-04-1 | 9 End Date:2016-04-2 | 0 | | | • | | | |
| 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 d | ate of batch : | | Batch number : | ber: | | | | |
| 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 | | | |
| | | 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:Moderate OHSS patients, improved canceled after embryo transfer. | | | | | | | | |
| Subject received concomitant medications: | | | | | | | | |
| Does the subject hav | re any relevant past or | present medical cond | itions:Yes | | | | | |
| Condition | | | Start Date | Related to study condition | Ongoing | | | |
| salpingemphrxis,lalad | ce peritoneoscope | | | Uk-Jul-2014 | Not on treatment/medicatio n | | | |

19-APR-16

NA/EMR700623-541/C02-0002

| Non Se | rious Adv | erse Drug | Reactions | s Report | | |
|---------------------------------|--|--|---|--|--|--|
| | | | | • | | |
| Investigator :NA | | Country of Investigator :China | SiteNo:C02 | | | |
| Subject Initials :L-Z | DOB :09/04/1981 | Sex:Female | Race:Asian | Height:156cm | Weight:53.0kg | |
| date of batch : | • | Batch number : | ' | | | |
| Start Date | | Dose | Change in Dose | Dose | | |
| 05/13/2015 | | 150 | | | | |
| Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | | |
| 05/30/2015 | 06/05/2015 | | Related | Moderate | | |
| | | Other action taken | Outcome | AE Special Interest | AE dose limiting toxicity | |
| None(Othervalue:) Not applicab | | Led to study termination | Resolved | | | |
| Moderate OHSS occurs | canceled embryo trans | sfer, OHSS improveme | ent | · | I | |
| ncomitant medications: | | | | | | |
| ave any relevant past or | present medical cond | litions:No | | | | |
| Condition | | | Start Date | Related to study condition | Ongoing | |
| | Investigator :NA Investigator :NA Subject Initials :L-Z date of batch : Start Date 05/13/2015 Start Date 05/30/2015 | Investigator :NA Subject Initials :L-Z DOB :09/04/1981 date of batch : Start Date 05/13/2015 Start Date End Date 05/30/2015 Action Taken with Study Treatment Not applicable Investigator :NA Bubject Initials :L-Z DOB :09/04/1981 DOB :09/04/1981 DOB :09/04/1981 DOB :09/04/1981 DOB :09/04/1981 DOB :09/04/1981 | Investigator :NA Investigator :NA Subject Initials :L-Z DOB :09/04/1981 Sex:Female date of batch : Start Date Dose 05/13/2015 Start Date End Date Time related to study treatment 05/30/2015 Action Taken with Study Treatment Not applicable Led to study termination Investigator :China Sex:Female Time related to study treatment Other action taken Led to study termination | Investigator :NA Country of Investigator :China Subject Initials :L-Z DOB :09/04/1981 Sex:Female Race:Asian date of batch : Start Date Dose Change in Dose O5/13/2015 Start Date End Date Time related to study treatment O5/30/2015 Action Taken with Study Treatment Not applicable Led to study termination Country of Investigator :China Race:Asian Race:Asian Change in Dose Led to study drug Related Outcome Change in Dose Change in Dose | Investigator :NA Country of Investigator :China Subject Initials :L-Z DOB :09/04/1981 Sex:Female Race:Asian Height:156cm date of batch : Batch number : Start Date Dose Change in Dose O5/13/2015 Investigator :China Sex:Female Race:Asian Height:156cm Change in Dose Change in Dose O5/13/2015 Start Date End Date Time related to study drug Severity drug O5/30/2015 Related Moderate Action Taken with Study Treatment Not applicable Led to study termination Coderate OHSS occurs canceled embryo transfer, OHSS improvement Incomitant medications: Inve any relevant past or present medical conditions:No | |

19-APR-16

NA/EMR700623-541/C02-0034

| Non Serious Adverse Drug Reactions Report | | | | | | | |
|---|-------------------------|--------------------------------------|---------------------------------|------------------------------|-----------------------------|---------------------------|--|
| Start Date:2016-04-1 | 9 End Date:2016-04-2 | 0 | | | | | |
| 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 da | ate 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 | | |
| | | Action Taken with Study Treatment | Other action taken | Outcome | AE Special Interest | AE dose limiting toxicity | |
| None(Othervalue:) Not app | | Not applicable | Led to study termination | Resolved | | | |
| Event Description:Mo | oderate OHSS patients | , improved canceled at | fter embryo transfer. | | | | |
| Subject received cond | comitant medications: | | | | | | |
| Does the subject have | e any relevant past or | present medical condit | tions:Yes | | | | |
| Condition | | | | Start Date | Related to study condition | Ongoing | |
| Laparoscopic tubal ed | ctopic pregnancy at the | e right side of the wind | Uk-Unk-2005 | Not on treatment/medicatio n | | | |
| Under the right fallopian tube ectopic pregnancy laparoscopic surgery | | | | Uk-Unk-2007 | Not on treatment/medication | | |

19-APR-16 NA/EMR700623-541/C02-0043

| | Non Se | rious Adv | erse Drug | Reactions | s Report | | |
|---|---------------------------------------|--------------------------------------|---------------------------------|-------------------------|------------------------------|---------------------------|--|
| Start Date:2016-04- | -19 End Date:2016-04-2 | 0 | | | | | |
| Study :EMR700623-541 | Investigator :NA | | Country of Investigator :China | SiteNo:C02 | | | |
| Subject No :C02-0045 | Subject Initials :H-T DOB :09/08/1983 | | Sex:Female | Race:Asian | Height:158cm | Weight:57.5kg | |
| First administration | date of batch : | • | Batch number : | : | | | |
| Study Drug | Start Date | | Dose | Change in Dose | nange in Dose | | |
| Gonal-f New Pen Stimulation Treatment | 05/13/2015 | | 250 | | | | |
| 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 | | |
| | | 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:M | oderate OHSS occurs o | canceled embryo trans | sfer, OHSS improveme | nt | <u>'</u> | | |
| Subject received co | ncomitant medications: | | | | | | |
| Does the subject ha | ave any relevant past or | present medical cond | litions:Yes | | | | |
| Condition | | | | Start Date | Related to study condition | Ongoing | |
| Hysteroscopic polypectomy | | | | Uk-Aug-2014 | Not on treatment/medicatio n | | |
| | | | | • | • | 19-APR-16 | |

19-APR-16

NA/EMR700623-541/C02-0045

| | Non Se | rious Adv | erse Drug | Reactions | s Report | | |
|---|---------------------------------------|--------------------------------------|---------------------------------|-------------------------|----------------------------|---------------------------|--|
| Start Date:2016-04- | -19 End Date:2016-04-2 | 0 | | | • | | |
| 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 | se | | |
| 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 | | |
| | | Action Taken with Study Treatment | Other action taken | Outcome | AE Special Interest | AE dose limiting toxicity | |
| None(Othervalue:) Not ap | | Not applicable | Led to study termination | Resolved | | | |
| Event Description:N | Noderate OHSS patients | , improved canceled a | after embryo transfer. | | <u>.</u> | | |
| Subject received co | ncomitant medications: | | | | | | |
| Does the subject ha | ave any relevant past or | present medical cond | litions:No | | | | |
| Condition | | | | Start Date | Related to study condition | Ongoing | |

19-APR-16 NA/EMR700623-541/C02-0046