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| **THE MEDICAL CITY** |
| Ortigas Avenue, Pasig City, Philippines |
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| **INSTITUTIONAL REVIEW BOARD** |
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| **SERIOUS ADVERSE EVENTS (SAE) AND SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION (SUSAR) REPORT FORM** |
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| **PROTOCOL INFORMATION** |
|  |
| Protocol Title: | Protocol Title |
| IRB Registry No.: | IRB Registry Number | Protocol No.: | Protocol Number |
| Principal Investigator: | Principal Investigator | Field of Study: | Field of Study |
| Date Submitted: | Enter Date | Sponsor: | Sponsor |
|  |  |  |  |
|  |
| **REPORT INFORMATION** |
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| Date Submitted to Sponsor: | Enter Date | Route of Administration: | Add Text |
| Patient Initials: | Add Text | Manufacturer Information: | Add Text |
| Date of Birth: | Add Text | Mfr. Control Number: | Add Text |
| Reaction Onset: | Add Text | Date Received by Mfr.: | Add Text |
| Study Drug: | Add Text | Report Source: | Add Text |
| Suspected Drug: | Add Text |  |  |
| Daily Dose: | Add Text | Concomitant Drug | Date of Administration |
| Indication for Use: | Add Text |  |  |
| Therapy Dates: | Add Text |
| Therapy Durations: | Add Text |
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| **NATURE OF THE REACTION OBSERVED:** |
| Add Text |
|  |
|  |
| **OUTCOME:** |
| Add Text |
|  |
|  |
| **DECISION:** |
| Add Text |
|  |
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|  |  |  |  |  |
| Signature Over Printed Name / Date and Time |
| **PRINCIPAL INVESTIGATOR** |