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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** | | | | | | | | | |
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| 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 | | | |
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| **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 | | | | | | | | | |
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| **OUTCOME:** | | | | | | | | | |
| Add Text | | | | | | | | | |
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| **DECISION:** | | | | | | | | | |
| Add Text | | | | | | | | | |
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| Signature Over Printed Name / Date and Time | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR** | | | | | | | | | |