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| **SITE & REPORT INFORMATION** | Kirby Protocol Number: VHCRP1510 EDURACT Number:  Pharma Protocol Number : MSD\_MISP 56015 (If applicable)  (If applicable)  To: Kirby Institute, VHCRP Fax No: +61 2 9385 9214  To: Merck worldwide product safety Fax No: +1 215 993 1220  Pages:     Initial Report  Follow-up report Date of report: Click here to enter a date.  Principal Investigator’s Name:       Reported By:  Site Phone Number:       Site Fax No: |

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| **PATIENT** | Subject ID Number:       Subject date of birth: Click here to enter a date.  Date site became aware of the SAE: Click here to enter a date.  Patient Gender:  Male Height:       (cms) Weight:       (kgs)  Female  Transgender  Unknown |

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| **INVESTIGATOR SIGN-OFF** | INVESTIGATOR SIGN-OFF:  I verify that the information contained in this SAE is accurate and compatible with the source documents.  Investigator Name (Please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Note: SAE form can be submitted without the investigator signature but must be signed and resubmitted once signature is complete. |

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| **KIRBY** | Received date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Received By: ­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **SAE INFORMATION** | SAE DETAILS:  Event Onset Date: Click here to enter a date.  Severity:  Mild  Moderate  Severe  Life Threatening   |  |  | | --- | --- | | Investigator Narrative: describe the event , suspected causes and timing | | | Include:  Signs & Symptoms  Investigations  Course of Events  Timings  Treatment for SAE  Suspected Causes  Concomitant medicines  Concurrent conditions  Other Comments |  |  |  |  |  | | --- | --- | --- | | Drug: Elbasvir/grazoprevir | Drug: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Drug: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Causality:  Not related  Unlikely  Possibly  Probably | Causality:  Not related  Unlikely  Possibly  Probably | Causality:  Not related  Unlikely  Possibly  Probably | | Action Taken:  Drug withdrawn  Drug interrupted  Dose reduced  Dose increased  Dose not changed  Unknown  Not applicable | Action Taken:  Drug withdrawn  Drug interrupted  Dose reduced  Dose increased  Dose not changed  Unknown  Not applicable | Action Taken:  Drug withdrawn  Drug interrupted  Dose reduced  Dose increased  Dose not changed  Unknown  Not applicable | |

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| **SAE INFORMATION CONTINUED** | |  |  |  | | --- | --- | --- | | SAE Outcome:  Recovered/Resolved  Recovery date: Click here to enter a date.  Recovered with sequalae  Recovering/Resolving  Not recovered/not resolved  Fatal (complete death details)  Unknown | SAE Outcome:  Recovered/Resolved  Recovery date: Click here to enter a date.  Recovered with sequalae  Recovering/Resolving  Not recovered/not resolved  Fatal (complete death details)  Unknown | SAE Outcome:  Recovered/Resolved  Recovery date: Click here to enter a date.  Recovered with sequalae  Recovering/Resolving  Not recovered/not resolved  Fatal (complete death details)  Unknown | | SAE Seriousness Category:  Death (complete death details)  Hospitalisation Required  Prolonged Hospitalisation  Life Threatening  Persistent/Significant disability  Congenital anomaly/birth defect  Cancer  Overdose  Other medically important condition  Pregnancy (if applicable) | SAE Seriousness Category:  Death (complete death details)  Hospitalisation Required  Prolonged Hospitalisation  Life Threatening  Persistent/Significant disability  Congenital anomaly/birth defect  Cancer  Overdose  Other medically important condition  Pregnancy (if applicable) | SAE Seriousness Category:  Death (complete death details)  Hospitalisation Required  Prolonged Hospitalisation  Life Threatening  Persistent/Significant disability  Congenital anomaly/birth defect  Cancer  Overdose  Other medically important condition  Pregnancy (if applicable) | | Study Drug Dosing: Elbasvir/grazoprevir  Start Date: Click here to enter a date.  Stop Date*:* Click here to enter a date.  Dose: 100/50  Unit: mg  Frequency: Once daily  Route: Orally  Batch/Lot No.: | Study Drug Dosing:  Start Date*:* Click here to enter a date.  Stop Date*:* Click here to enter a date.  Dose:  Unit:  Frequency:  Route:  Batch/Lot No.: | Study Drug Dosing:  Start Date*:* Click here to enter a date.  Stop Date*:* Click here to enter a date.  Dose:  Unit:  Frequency:  Route:  Batch/Lot No.: | |

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| **DEATH** | DEATH DETAILS  Date of Death*:* Click here to enter a date.  Autopsy Performed?:  No  Yes (if yes, attach a copy of report if available) |