

SUSAR Line Listing (Blinded)

Report Criteria :

Initial/FU Receipt Date Period :	Jan 1, 1900 12:00 AM - Dec 9, 2020 12:00 AM
Project ID :	R10933-10987-COV, R10933-10987-COV-CU, R10933-10987-COV-UOO/RECOVERY
Study ID :	R10933-10987-COV-2066-PHASE2, R10933-10987-COV-2069, R10933-10987-HV-2093, R10933-10987-COV-2066-PHASE1-PARTA, R10933-10987-COV-2067-PHASE1-PARTA, R10933-10987-COV-2067-PHASE1-PARTB, R10933-10987-COV-2067-PHASE2, R10933-10987-COV-2066-PHASE1-PARTB
Product Name :	
Reporting Destination :	
<i>Includes cases with observe study types : Interventional, Interventional IIS and Non Company Sponsored Studies</i>	
<i>Excludes invalid and deleted cases and cases with follow-up version justification = Non-Medically Significant Follow-up</i>	

Product(s) :

Report generated on : 9-Dec-2020 9:48:15 AM

Case Number	Country Of Occurrence	Study ID	Patient Number	Patient Gender	Patient Age (in Years)	Product Name (Blinded)	Event Verbatim	MedDRA PT	Reporter Causality	Company Causality	Event Seriousness	Product-Event Listedness IB	SUSAR?
2020-80783	UNITED STATES	R10933-10987-COV-2067-PHASE2	840025-004	Male	71	REGN10933-10987, REGN10989 OR PLACEBO	ADVERSE MEDICATION REACTION-DIAPHORESIS	Hyperhidrosis	Related	Related	Serious	Unlisted	Yes
2020-80783	UNITED STATES	R10933-10987-COV-2067-PHASE2	840025-004	Male	71	REGN10933-10987, REGN10989 OR PLACEBO	Adverse medication reaction-decreased responsiveness	Hyporesponsive to stimuli	Related	Related	Serious	Unlisted	Yes
2020-80783	UNITED STATES	R10933-10987-COV-2067-PHASE2	840025-004	Male	71	REGN10933-10987, REGN10989 OR PLACEBO	Adverse medication reaction-nausea	Nausea	Related	Related	Serious	Unlisted	Yes
2020-80783	UNITED STATES	R10933-10987-COV-2067-PHASE2	840025-004	Male	71	REGN10933-10987, REGN10989 OR PLACEBO	adverse medication reaction-vomitting	Vomiting	Related	Related	Serious	Unlisted	Yes
2020-84745	UNITED STATES	R10933-10987-COV-2066-PHASE2	840037-015	Male	84	REGN10933-10987 OR PLACEBO	ENCEPHALOPATHY	Encephalopathy	Related	Related	Serious	Unlisted	Yes
2020-84745	UNITED STATES	R10933-10987-COV-2066-PHASE2	840037-015	Male	84	REGN10933-10987 OR PLACEBO	RESPIRATORY FAILURE DUE TO COVID19 WITH MULTIORGANISM VAP	COVID-19	Not Related	Not Related	Serious	Unlisted	No
2020-84745	UNITED STATES	R10933-10987-COV-2066-PHASE2	840037-015	Male	84	REGN10933-10987 OR PLACEBO	Severe rigors	Chills	Related	Related	Serious	Unlisted	Yes
2020-85397	UNITED STATES	R10933-10987-COV-2066-PHASE2	840037-017	Male	43	REGN10933-10987 OR PLACEBO	DYSPHAGIA	Dysphagia	Not Related	Not Related	Serious	Unlisted	No
2020-85397	UNITED STATES	R10933-10987-COV-2066-PHASE2	840037-017	Male	43	REGN10933-10987 OR PLACEBO	POSITIVE CULTURES	Culture positive	Not Related	Not Related	Serious	Unlisted	No
2020-85397	UNITED STATES	R10933-10987-COV-2066-PHASE2	840037-017	Male	43	REGN10933-10987 OR PLACEBO	RIGORS	Chills	Related	Related	Serious	Unlisted	Yes
2020-86335	ROMANIA	R10933-10987-COV-2067-PHASE2	642001-056	Male	68	REGN10933-10987, REGN10989 OR PLACEBO	FEBRILE SYNDROME	Pyrexia	Not Related	Related	Serious	Unlisted	Yes
2020-86793	UNITED STATES	R10933-10987-COV-2066-PHASE2	840021-006	Female	69	REGN10933-10987 OR PLACEBO	WORSENING HYPOXIA	Hypoxia	Related	Not Related	Serious	Unlisted	Yes
2020-87567	UNITED STATES	R10933-10987-COV-2066-PHASE2	840016-004	Female	95	REGN10933-10987 OR PLACEBO	ACUTE HYPOXEMIC RESPIRATORY FAILURE	Acute respiratory failure	Related	Not Related	Serious	Unlisted	Yes
2020-88058	UNITED STATES	R10933-10987-COV-2066-PHASE2	840081-008	Male	63	REGN10933-10987 OR PLACEBO	ANAPHYLACTIC REACTION	Anaphylactic reaction	Related	Related	Serious	Unlisted	Yes
2020-88058	UNITED STATES	R10933-10987-COV-2066-PHASE2	840081-008	Male	63	REGN10933-10987 OR PLACEBO	EDEMA	Oedema	Not Related	Not Related	Non-Serious	Unlisted	No
2020-88092	UNITED STATES	R10933-10987-COV-2066-PHASE2	840063-013	Female	68	REGN10933-10987 OR PLACEBO	WORSENING HYPOXIA	Hypoxia	Related	Not Related	Serious	Unlisted	Yes
2020-88833	UNITED STATES	R10933-10987-COV-2066-PHASE2	840068-003	Male	84	REGN10933-10987 OR PLACEBO	HYPERKALEMIA	Hyperkalaemia	Related	Related	Serious	Unlisted	Yes
2020-89955	UNITED STATES	R10933-10987-COV-2067-PHASE2	840077-081	Male	51	REGN10933-10987, REGN10989 OR PLACEBO	HIGH FEVER	Pyrexia	Not Reported	Not Related	Serious	Unlisted	Yes
2020-89955	UNITED STATES	R10933-10987-COV-2067-PHASE2	840077-081	Male	51	REGN10933-10987, REGN10989 OR PLACEBO	HYPOXIA	Hypoxia	Not Reported	Not Related	Serious	Unlisted	Yes
2020-90799	UNITED STATES	R10933-10987-COV-2067-PHASE2	840019-004	Female	23	REGN10933-10987, REGN10989 OR PLACEBO	Elevated PTT	Activated partial thromboplastin time prolonged	Related	Not Related	Serious	Unlisted	Yes
2020-92088	UNITED STATES	R10933-10987-COV-2066-PHASE2	840021-008	Male	74	REGN10933-10987 OR PLACEBO	WORSENING OF RESPIRATORY STATUS	Respiratory disorder	Not Related	Not Related	Serious	Unlisted	No
2020-92088	UNITED STATES	R10933-10987-COV-2066-PHASE2	840021-008	Male	74	REGN10933-10987 OR PLACEBO	WORSENING OF RESPIRATORY STATUS	Respiratory disorder	Related	Not Related	Serious	Unlisted	Yes

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Glossary/Logic

- a) The search is based on most current data in Argus on the date of the report is generated.
- b) Based on the search criteria, the report includes cases where at least one event met the SUSAR criteria (Event is serious , unexpected and related to the suspect drug by either investigator or company)
- c) For identified SUSAR cases, all reported events are presented. Including events that do not meet SUSAR criteria
- d) Each row represents a unique combination of suspect products and events.
- e) Use the column 'SUSAR' to filter events that are considered SUSARs.
- f) Report excludes invalid cases.