

SUSAR Line Listing (Blinded)

Report Criteria :

Initial/FU Receipt Date Period :	Mar 9, 2021 12:00 AM - Jun 9, 2021 12:00 AM
Project ID :	
Study ID :	
Product Name :	CASIRIVIMAB AND IMDEVIMAB, Placebo (REGN10933-10987)
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>	

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?
2020-94760	UNITED STATES	R10933-10987-COV-2066-PHASE2	840104-012	Male	55	REGN10933-10987 OR PLACEBO	SYSTEMIC INFLAMMATORY RESPONSE	Systemic inflammatory response syndrome	Related	Related	Serious	Unlisted	Yes
2020-94760	UNITED STATES	R10933-10987-COV-2066-PHASE2	840104-012	Male	55	REGN10933-10987 OR PLACEBO	WORSENING RESPIRATORY FAILURE	Respiratory failure	Not Related	Not Related	Serious	Unlisted	No
2021-11631	UNITED STATES	R10933-10987-COV-2066-PHASE2	840045-097	Male	88	REGN10933-10987 OR PLACEBO	HYPOXIA	Hypoxia	Related	Not Related	Serious	Unlisted	Yes
2021-18151	UNITED STATES	R10933-10987-COV-2066-PHASE2	840088-148	Male	71	REGN10933-10987 OR PLACEBO	TACHYCARDIA	Tachycardia	Related	Related	Serious	Unlisted	Yes
2021-29550	BRAZIL	R10933-10987-COV-2066-PHASE2	076008-011	Male	69	REGN10933-10987 OR PLACEBO	SECONDARY BACTERIAL INFECTION	Bacterial infection	Related	Not Related	Serious	Unlisted	Yes
2021-35296	UNITED STATES	R10933-10987-COV-2066-PHASE2	840003-049	Female	62	REGN10933-10987 OR PLACEBO	PRURITIS	Pruritus	Related	Related	Serious	Unlisted	Yes
2021-35800	UNITED STATES	R10933-10987-COV-2066-PHASE2	840016-022	Male	46	REGN10933-10987 OR PLACEBO	HYPOXIA	Hypoxia	Related	Not Related	Serious	Unlisted	Yes
2021-39969	BRAZIL	R10933-10987-COV-2066-PHASE2	076008-015	Female	69	REGN10933-10987 OR PLACEBO	SECONDARY BACTERIAL INFECTION	Bacterial infection	Related	Not Related	Serious	Unlisted	Yes
2021-39969	BRAZIL	R10933-10987-COV-2066-PHASE2	076008-015	Female	69	REGN10933-10987 OR PLACEBO	WORSENING OF COVID-19 INFECTION	COVID-19	Not Related	Not Related	Serious	Unlisted	No
2021-43819	UNITED STATES	R10933-10987-COV-2067-PHASE3	840102-176	Male	24	REGN10933-10987 OR PLACEBO	ANAPHYLAXIS (NEBULIZER TREATMENT OR STUDY DRUG)	Anaphylactic reaction	Related	Related	Serious	Unlisted	Yes

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.