

RESPONSE TO FDA ON INFORMATION REQUEST#45 RECEIVED ON JANUARY 13, 2022

The Sponsor acknowledges comments on INFORMATION REQUEST#45 dated 13 JANUARY 2022 in **(BOLD)**

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Clinical IR – Safety Data Study P301

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. We have the following clinical request for additional information:

ITEM 1:

For mRNA-1273 and placebo recipients in Part A who reported PT of chest pain, chest discomfort, myocardial infarction within 28 days of any vaccination, please provide the following information in a table and arrange rows by Dose 1 or 2 and ascending order of day of onset from most recent vaccination:

Group	Sex	Age	MedDR APT	Onset after Dose 1 or 2	Day of onset after most recent vaccination	Resolution	Grade	Serious	Other risk factors	Causality as assessed by the investigator
mRNA				Dose 1						
mRNA				Dose 2						
Placebo				Dose 1						
Placebo				Dose 2						

Sponsor Response:

Please see the table below for mRNA-1273 and placebo recipients in Part A who reported PT of chest pain, chest discomfort, myocardial infarction within 28 days of any vaccination by dose.

Group	Sex	Age	MedDRA PT	Onset After Dose 1 or 2	Day of Onset After Most Recent Vaccination	Resolution	Grade	Serious	Other Risk Factors	Causality as Assessed by the Investigator
mRNA-1273	F	60	Chest pain	1	7	RECOVERED/RESOLVED	SEVERE	Y	Medical Hx: Diabetes, heartburn, hiatal hernia, hyperlipidemia, history of transient ischemic attack, PTSD, anxiety and depression	NOT RELATED
mRNA-1273	M	42	Chest discomfort	1	10	RECOVERED/RESOLVED	MILD	N	Medical Hx: Anxiety, asthma, GERD, Hypertension, Obesity, Panic attacks	NOT RELATED
mRNA-1273	F	63	Chest pain	1	15	RECOVERED/RESOLVED	MODERATE	N	Medical Hx: Hypertension	NOT RELATED
mRNA-1273	M	56	Chest pain	1	12	RECOVERING/RESOLVING	MILD	N	None	NOT RELATED
mRNA-1273	M	62	Myocardial infarction	1	13	RECOVERED/RESOLVED WITH SEQUELAE		Y	Medical Hx: History of Atrial septic defect, coronary artery disease with calcified lesion, Hx of DVT left leg, heart murmur, hyperlipidemia, hypertension, irregular heart rhythm,	NOT RELATED
mRNA-1273	M	59	Chest discomfort	1	6	RECOVERED/RESOLVED	MODERATE	N	None	NOT RELATED
mRNA-1273	M	28	Chest pain	1	4	RECOVERED/RESOLVED	MILD	N	Medical Hx: Left chest pain with unknown non-cardiac etiology	NOT RELATED
mRNA-1273	F	21	Chest discomfort	1	9	RECOVERED/RESOLVED	MODERATE	N	Medical Hx: Anxiety, asthma, severe obesity	NOT RELATED
mRNA-1273	M	39	Chest pain	1	12	RECOVERED/RESOLVED	MODERATE	N	None	NOT RELATED
mRNA-1273	M	42	Chest pain	1	13	RECOVERED/RESOLVED	MODERATE	N	Medical Hx: Acid reflux, pain in chest when eats greasy food	NOT RELATED
mRNA-1273	M	76	Chest discomfort	1	11	RECOVERED/RESOLVED	MODERATE	N	Medical Hx: High cholesterol, Type II diabetes	NOT RELATED

Group	Sex	Age	MedDRA PT	Onset After Dose 1 or 2	Day of Onset After Most Recent Vaccination	Resolution	Grade	Serious	Other Risk Factors	Causality as Assessed by the Investigator
Placebo	F	64*	Chest pain	1	11	RECOVERED/RESOLVED	SEVERE	N	Medical Hx: Atrial fibrillation, cardiac ablation, GERD, post-menopausal	NOT RELATED
Placebo	F	64*	Chest pain	1	23	RECOVERED/RESOLVED		Y	Medical Hx: Afibrillation, cardiac ablation, GERD, post-menopausal	NOT RELATED
Placebo	F	60	Chest discomfort	1	6	RECOVERED/RESOLVED	MILD	N	Medical Hx: Hypercholesterolemia, hypertension, Hx of myocardial infarction, post-menopausal, stent placement	RELATED
Placebo	M	46	Myocardial infarction	1	26	RECOVERED/RESOLVED		Y	Medical Hx: Hypercholesterolemia, acid reflux,	NOT RELATED
Placebo	F	64	Chest discomfort	1	19	RECOVERED/RESOLVED	MILD	N	Medical Hx: Asthma, post-menopausal	NOT RELATED
Placebo	M	71	Chest discomfort	1	2	RECOVERED/RESOLVED	MILD	N	Medical Hx: Hyperlipidemia, hypertension, obesity, peripheral vascular disease, Type II diabetes	NOT RELATED
Placebo	M	71	Chest pain	1	3	RECOVERED/RESOLVED	MILD	N	Medical Hx: Hypertension	NOT RELATED
Placebo	M	54	Chest discomfort	1	11	RECOVERED/RESOLVED	MILD	N	Medical Hx: Type II diabetes, hyperlipidemia, hypertension, obesity	NOT RELATED

*One placebo subject had two events of chest pain reported as chest pain etiology undetermined and atypical chest pain.