Data Set Name: dataset_concert_hf_final_data.sas7bdat

Num	Variable	Type	Len	Format	Label
1	CONCERTID	Char	12		Randomized subject ID
2	RZTHERAPY	Num	8	BEST.	Randomized Treatment Assignment (1=MSCs+CPCs, 2=MSCs, 3=CPCs, 4=Placebo)
3	TREATMENTRECEIVED	Num	8	BEST.	Actual treatment received by patient (1=MSCs+CPCs, 2=MSCs, 3=CPCs, 4=Placebo, 5=Not treated)
4	GENDER	Num	8	BEST.	Subject's gender (Male =1, Female=2)
5	HISPANIC	Num	8	BEST.	Subject is of Hispanic ethnicity (self reported 1=yes, 2=no, 99=not reported)
6	WHITERACE	Num	8	BEST.	Subject is of White race (self reported, 0=no, 1=yes)
7	PACIFICISLANDERRACE	Num	8	BEST.	Subject is of Pacific Islander race (self reported, 0=no, 1=yes)
8	AMERICANINDIANRACE	Num	8	BEST.	Subject is of American Indian race (self reported, 0=no, 1=yes)
9	SCREENINGLVEF	Num	8	BEST.	Left ventricular ejection fraction (assessed via MRI) at initial screening
10	AGE	Num	8	BEST.	Age in years at the time of consent
11	DIABETES	Num	8	BEST.	Subject has a history of Diabetes (self reported, 1=yes, 2=no, 99=not reported)
12	HYPERTENSION	Num	8	BEST.	Subject has a history of Hypertension (self reported, 1=yes, 2=no, 99=not reported)
13	HYPERLIPIDEMIA	Num	8	BEST.	Subject has a history of Hyperlipidemia (self reported, 1=yes, 2=no, 99=not reported)
14	HYPERCHOLESTEROLEMIA	Num	8	BEST.	Subject has a history of Hypercholesterolemia (self reported, 1=yes, 2=no, 99=not reported)
15	HYPERTRIGLYCERIDEMIA	Num	8	BEST.	Subject has a history of Hypertriglyceridemia (self reported, 1=yes, 2=no, 99=not reported)
16	BMI	Num	8	BEST.	Body Mass Index at baseline (kg/m^2)
17	SMOKING	Num	8	BEST.	Subject has a history of smoking (self reported, 1=never, 2=previous, 3=current)
18	SMOKINGYEARS	Num	8	BEST.	Years smoked
19	SMOKINGPACKSPERDAY	Num	8	BEST.	Number of packs per day
20	MI	Num	8	BEST.	Subject has a history of Myocardial Infarction (self reported, 1=yes, 2=no)
21	MISPECIFY	Num	8	BEST.	Number of myocardial infarctions
22	MILOCATION	Num	8	BEST.	Specific location of most recent myocardial infarction (1=STEMI, 2=NSTEMI, 99=Unknown)
23	MITYPE	Num	8	BEST.	Specifc location (1=Anterior, 2=Non anterior, 99=Unknown)
24	ATRIALFIBRILLATION	Num	8	BEST.	Subject has a history of Atrial fibrillation (self reported, 1=yes, 2=no)
25	VENTRIARRHYTHM	Num	8	BEST.	Subject has a history of Ventricular arrhythmias (self reported, 1=yes, 2=no, 99=not reported)
26	VALVULARHEARTDISEASE	Num	8	BEST.	Subject has a history of Valvular heart disease (self reported, 1=yes, 2=no)
27	PERIVASCUDISEASE	Num	8	BEST.	Subject has a history of Peripheral vascular disease (self reported, 1=yes, 2=no)
28	VALVEREPAIR	Num	8	BEST.	Subject has a history of Valvular repair (self reported, 1=yes, 2=no)

Num	Variable	Type	Len	Format	Label
29	VALVEREPLACE	Num	8	BEST.	Subject has a history of Valvular replace (self reported, 1=yes, 2=no)
30	HEARTRATE	Num	8	BEST.	Subject's heart rate at baseline [beats per minute]
31	BLOODPRESSURESBP	Num	8	BEST.	Subject's systolic blood pressure recorded at baseline [mmHg]
32	BLOODPRESSUREDBP	Num	8	BEST.	Subject's diastolic blood pressure recorded at baseline [mmHg]
33	NYHACLASS	Num	8	BEST.	Subject's New York Heart Association Classification at baseline (class 2=2, class 3=3)
34	CCSCLASS	Num	8	BEST.	Canadian Classification of Angina (class 1=1, class 2=2, class 3=3, class 4=4) (note: reported only if history of angina within 6 months prior to baseline)
35	HXANGINA	Num	8	BEST.	Subjects has a history of angina in the last 6 months at baseling (self reported, 1=yes, 2=no)
36	ICD	Num	8	BEST.	Subject has an implantable cardiac device (1=yes, 2=no)
37	SUBJECTICD	Num	8	BEST.	Type of ICD implanted (1 Pacemaker only, 2 ICD only, 3 Pacemaker plus ICD, 4 Biventricular pacing, alone (CRT-P), 5 Biventricular pacing, with ICD (CRT-D))
38	MRI_CONDITIONAL	Num	8	BEST.	Device was MRI conditional (0=no, 1=yes, 2=not enough info to determine)
39	HEMORRHAGICSTROKE	Num	8	BEST.	Subject reported history at baseline of hemorrhagic stroke (1=yes, 2=no)
40	ISCHEMICSTROKE	Num	8	BEST.	Subject reported history at baseline of ischemic stroke (1=yes, 2=no)
41	TIAS	Num	8	BEST.	Subject reported history at baseline of transischemic attacks (1=yes, 2=no, 99=not reported)
42	ASYMPCAROTIDDISEASE	Num	8	BEST.	Subject reported history at baseline of asymptomatic carotid disease (1=yes, 2=no, 99=not reported)
43	CABG	Num	8	BEST.	Subject reported history at baseline of coronary bypass graft procedure (1=yes, 2=no)
44	PCI	Num	8	BEST.	Subject reported history at baselineof percutaneous coronary intervention (1=yes, 2=no)
45	HFHOSPITALIZATION	Num	8	BEST.	Hospitalized for HF in the 12mos prior to baseline (1=yes, 2=no)
46	HFEDVISITS	Num	8	BEST.	Visited the Emergency Department for Heart Failure in the 12mos prior to baseline (1=yes, 2=no)
47	ISCHEMICHFONGOING	Num	8	BEST.	Subject reported ongoing ischemic heart failure at baseline (1=yes, 2=no)
48	ISCHEMICHFVESSEL	Num	8	BEST.	Nature of the Ischemic Heart Failure (1=single vessel disease, 2=multivessel disease)
49	CADLEFTMAINDISEASE	Num	8	BEST.	Presence of Left Main Disease (1=yes, 2=no, 3=unknown)
50	CADLAD	Num	8	BEST.	Does left main disease include (1=proximal LAD involvement, 2=no proximal LAD involvemnt, 3=unknown)
51	HXTHYROIDDISEASE	Num	8	BEST.	Subject reported history at baseline of thyroid disease (1=yes, 2=no, 99=not reported)
52	HXLIVERDISEASE	Num	8	BEST.	Subject reported history at baseline of liver disease (1=yes, 2=no)
53	MALIGNANCY	Num	8	BEST.	Subject reported history at baseline of malignancy (1=yes, 2=no)
54	AUTOIMMUDISORDER	Num	8	BEST.	Subject reported history at baseline of autoimmune disorder (1=yes, 2=no)
55	ACE	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
56	ALDOSTERONE	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)

Num	Variable	Type	Len	Format	Label
57	ANGIOTENSIN	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
58	ANTIARRHYTHMICS	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
59	ANTICOAGULATION	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
60	ANTIDIABETICS	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
61	ANTIPLATELETS	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
62	ASPIRIN	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
63	BETABLOCKERS	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
64	CCBS	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes) [Calcium channel blockers]
65	DIURECTICS	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
66	ENTRESTO	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
67	HYDRALAZINE	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
68	INSULIN	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
69	IVABRADINE	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
70	NITRATES	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
71	STATINS	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
72	PCSK9INHIBITORS	Num	8	BEST.	Subject taking medication in this drug class at baseline (0=no, 1=yes)
73	BMASUCCESS	Num	8	BEST.	Subject's bone marrow aspiration procedure was successful (0=no, 1=yes, 2= did not advance from randomization to harvest visit; note: 6 pts did not advance)
74	EMBSUCCESS	Num	8	BEST.	Subject's endomyocardial biopsy procedure was successful (0=no, 1=yes, 2=did not advance from randomization to harvest visit; note: EMB only applies to those randomized to receive MSCs+CPCs or CPCs)
75	RECVDPROD	Num	8	BEST.	Subject received study product injections (0=no, 1=yes)
76	TOTALINJECTIONS	Num	8	BEST.	Total number of injections received (min=0, max=15)
77	TOTALVOLUME	Num	8	BEST.	Total fluid volume injected (min=0, max=6 ml)
78	_6MATTEND	Num	8	BEST.	Subject attended 6 Month follow up visit (0=no, 1=yes)
79	_12MATTEND	Num	8	BEST.	Subject attended 12 Month follow up visit (0=no, 1=yes)
80	CE_DEATH	Num	8	BEST.	Clinical endpoint of death criteria was met (0=no, 1=yes). Endpoint adjudication definitions supplied with BioLINCC submission.
81	CE_HSPLZ_HF	Num	8	BEST.	Clinical endpoint of hospitalization for heart failure criteria was met (0=no, 1=yes). Endpoint adjudication definitions supplied with BioLINCC submission.
82	CE_HF_EXACER	Num	8	BEST.	Clinical endpoint of heart failure exacerbation (non-hospitalization) was met (0=no, 1=yes). Endpoint adjudication definitions supplied with BioLINCC submission.
83	CE_NFSTROKE	Num	8	BEST.	Clinical endpoint of non-fatal stroke criteria was met (0=no, 1=yes). Endpoint adjudication definitions supplied with BioLINCC submission.
84	CE_NFMI	Num	8	BEST.	Clinical endpoint of non-fatal myocardial infarction criteria was met (0=no, 1=yes). Endpoint adjudication definitions supplied with BioLINCC submission.
85	CE_CAR	Num	8	BEST.	Clinical endpoint of coronary artery revascularization criteria was met (0=no, 1=yes). Endpoint adjudication definitions supplied with BioLINCC submission.

Num	Variable	Type	Len	Format	Label
86	CE_VT_VF	Num	8	BEST.	Clinical endpoint of ventricular tachycardia/fibrillation criteria was met (0=no, 1=yes). Endpoint adjudication definitions supplied with BioLINCC submission.
87	CE_PT	Num	8	BEST.	Clinical endpoint of pericardial tamponade criteria was met (0=no, 1=yes). Endpoint adjudication definitions supplied with BioLINCC submission.
88	LVEF_B	Num	8	BEST.	Left ventricular ejection fraction (assessed via MRI) at baseline [within 30 days of study product injection]
89	LVEF_6	Num	8	BEST.	Left ventricular ejection fraction (assessed via MRI) at 6 Months post injection
90	LVEF_12	Num	8	BEST.	Left ventricular ejection fraction (assessed via MRI) at 12 Months post injection
91	HARPGLOBALCIRCST_B	Num	8	BEST.	Global circumferential strain (assessed via MRI) at baseline
92	HARPGLOBALCIRCST_6	Num	8	BEST.	Global circumferential strain (assessed via MRI) at 6 Months post injection
93	HARPGLOBALCIRCST_12	Num	8	BEST.	Global circumferential strain (assessed via MRI) at 12 Months post injection
94	HARPGLOBALLONGST_B	Num	8	BEST.	Regional longitudinal strain (assessed via MRI) at baseline
95	HARPGLOBALLONGST_6	Num	8	BEST.	Regional longitudinal strain (assessed via MRI) at 6 Months post injection
96	HARPGLOBALLONGST_12	Num	8	BEST.	Regional longitudinal strain (assessed via MRI) at 12 Months post injection
97	LVEDVI_B	Num	8	BEST.	Left ventricular end diastolic volume index (assessed via MRI) at baseline (note indices are volumes normed by body surface area)
98	LVEDVI_6	Num	8	BEST.	Left ventricular end diastolic volume index (assessed via MRI) at 6 Months post injection
99	LVEDVI_12	Num	8	BEST.	Left ventricular end diastolic volume index (assessed via MRI) at 12 Months post injection
100	LVESVI_B	Num	8	BEST.	Left ventricular end systolic volume index (assessed via MRI) at baseline (note indices are volumes normed by body surface area)
101	LVESVI_6	Num	8	BEST.	Left ventricular end systolic volume index (assessed via MRI) at 6 Months post injection
102	LVESVI_12	Num	8	BEST.	Left ventricular end systolic volume index (assessed via MRI) at 12 Months post injection
103	SPHERICITYINDEX_B	Num	8	BEST.	Left ventricular Sphericity Index (assessed via MRI) at baseline (note sphericity index is the ratio of the long and short axis measurements of the left ventricle)
104	SPHERICITYINDEX_6	Num	8	BEST.	Left ventricular Sphericity Index (assessed via MRI) at 6 Months post injection
105	SPHERICITYINDEX_12	Num	8	BEST.	Left ventricular Sphericity Index (assessed via MRI) at 12 Months post injection
106	SCARSIZEPER_B	Num	8	BEST.	Scar size percent (percentage of mass assessed via MRI DEMRI) at baseline
107	SCARSIZEPER_6	Num	8	BEST.	Scar size percent (percentage of mass assessed via MRI DEMRI) at 6 Months post injection
108	SCARSIZEPER_12	Num	8	BEST.	Scar size percent (percentage of mass assessed via MRI DEMRI) at 12 Months post injection

Num	Variable	Type	Len	Format	Label
109	SCARTISSUEMASS_B	Num	8	BEST.	Scar tissue mass ([in grams] assessed via MRI DEMRI) at baseline
110	SCARTISSUEMASS_6	Num	8	BEST.	Scar tissue mass ([in grams] assessed via MRI DEMRI) at 6 Months post injection
111	SCARTISSUEMASS_12	Num	8	BEST.	Scar tissue mass ([in grams] assessed via MRI DEMRI) at 12 Months post injection
112	VIABLEMASS_B	Num	8	BEST.	Viable tissue mass ([in grams] assessed via MRI DEMRI) at baseline
113	VIABLEMASS_6	Num	8	BEST.	Viable tissue mass ([in grams] assessed via MRI DEMRI) at 6 Months post injection
114	VIABLEMASS_12	Num	8	BEST.	Viable tissue mass ([in grams] assessed via MRI DEMRI) at 12 Months post injection
115	VIABLEMASSPER_B	Num	8	BEST.	Viable tissue mass percent (percentage of mass assessed via MRI DEMRI) at baseline
116	VIABLEMASSPER_6	Num	8	BEST.	Viable tissue mass percent (percentage of mass assessed via MRI DEMRI) at 6 Months post injection
117	VIABLEMASSPER_12	Num	8	BEST.	Viable tissue mass percent (percentage of mass assessed via MRI DEMRI) at 12 Months post injection
118	PEAK_V02ML_KG_MIN_B	Num	8	BEST.	Maximal Oxygen Consumption (Peak VO2) at baseline
119	PEAK_V02ML_KG_MIN_6	Num	8	BEST.	Maximal Oxygen Consumption (Peak VO2) at 6 Months post injection
120	PEAK_V02ML_KG_MIN_12	Num	8	BEST.	Maximal Oxygen Consumption (Peak VO2) at 12 Months post injection
121	DISTANCEWALKED_B	Num	8	BEST.	Six Minute Walk Test Distance Walked (in meters) at baseline (two tests per visit [separated by 30 minutes]; the average of the two tests used for analysis)
122	DISTANCEWALKED_6	Num	8	BEST.	Six Minute Walk Test Distance Walked (in meters) at 6 Months post injection
123	DISTANCEWALKED_12	Num	8	BEST.	Six Minute Walk Test Distance Walked (in meters) at 12 Months post injection
124	SUMMARYSCORE_B	Num	8	BEST.	Minnesota Living with Heart Failure Questionnaire Summary Score at baseline (min score=0, max= 105; lower scores indicative of better outcomes)
125	SUMMARYSCORE_6	Num	8	BEST.	Minnesota Living with Heart Failure Questionnaire Summary Score at 6 Months post injection
126	SUMMARYSCORE_12	Num	8	BEST.	Minnesota Living with Heart Failure Questionnaire Summary Score at 12 Months post injection
127	PROBNP_B	Num	8	BEST.	NT-proBNP value at baseline
128	PROBNP_6	Num	8	BEST.	NT-proBNP value at 6 Months post injection
129	PROBNP_12	Num	8	BEST.	NT-proBNP value at 12 Months post injection
130	LPROBNP_B	Num	8	BEST.	Transformed value (using log transformation) of NT-proBNP value at baseline
131	LPROBNP_6	Num	8	BEST.	Transformed value (using log transformation) of NT-proBNP value at 6 Months post injection
132	LPROBNP_12	Num	8	BEST.	Transformed value (using log transformation) of NT-proBNP value at 12 Months post injection
133	CONSENTDAYS	Num	8		Number of days from randomization to date of study consent
134	PRODDAYS	Num	8		Number of days from randomization to date of study product injection
135	DEATH_DAYS	Num	8		Number of days from randomization to date of death

Num	Variable	Type	Len	Format	Label
136	HSPLZ_DAYS1	Num	8		Number of days from randomization to date of first heart failure hospitalization
137	HSPLZ_DAYS2	Num	8		Number of days from randomization to date of second heart failure hospitalization
138	HSPLZ_DAYS3	Num	8		Number of days from randomization to date of third heart failure hospitalization
139	HSPLZ_DAYS4	Num	8		Number of days from randomization to date of fourth heart failure hospitalization
140	HSPLZ_DAYS5	Num	8		Number of days from randomization to date of fifth heart failure hospitalization
141	EXACER_DAYS	Num	8		Number of days from randomization to date of heart failure exacerbation
142	NFSTR_DAYS	Num	8		Number of days from randomization to date of non-fatal stroke
143	NFMI_DAYS	Num	8		Number of days from randomization to date of non-fatal myocardial infarction
144	CAR_DAYS	Num	8		Number of days from randomization to date of coronary artery revascularlization
145	VT_VF_DAYS1	Num	8		Number of days from randomization to date of ventricular tachycardia/fibrillation event 1
146	VT_VF_DAYS2	Num	8		Number of days from randomization to date of ventricular tachycardia/fibrillation event 2
147	PT_DAYS	Num	8		Number of days from randomization to date of pericardial tamponade event
148	MIDAYSRECENT	Num	8		Number of days from randomization to date of most recent myocardial infarction
149	IMPLANTDAYS	Num	8		Number of days from randomization to date of device implantation
150	MIDAYSRECENT_FLG	Num	8		Flag: only year was reported for date of most recent myocardial infarction
151	IMPLANTDAYS_FLG	Num	8		Flag: only year was reported for date of device implantation
152	OTHRACEG	Num	8		Subject is African American, Asian, or race not otherwise noted above (self reported, 0=no, 1=yes)