Shed MEDS Data Safety Monitoring Board Report
-Closed Session-

A Randomized Controlled Trial To Deprescribe For Older Patients With Polypharmacy Transferred From The Hospital To Skilled Nursing Facilities

NIH Grant Number: RO1AG053264

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Closed Session Report Summary

Recruitment & Participation Status: Figure and Tables

Enrollment Start Date: DD/MM/YYY

Data Analyzed: DD/MM/YYY – DD/MM/YYY

Report Submitted to DSMB: DD/MM/YYY

Figure 1a: Overall Study Status by Treatment Group

Data as of: DD/MM/YYY

Date of Report: DD/MM/YYY

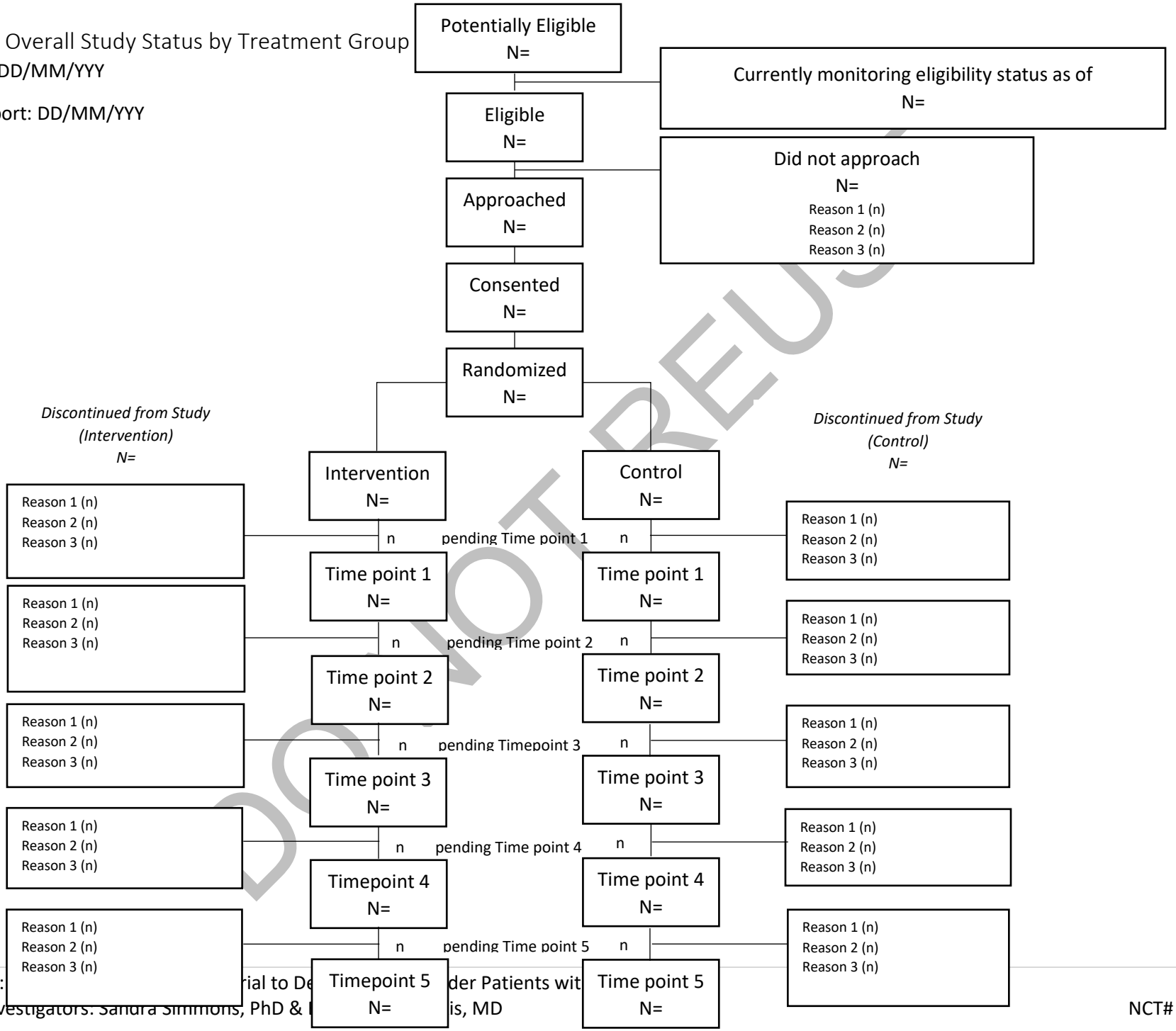
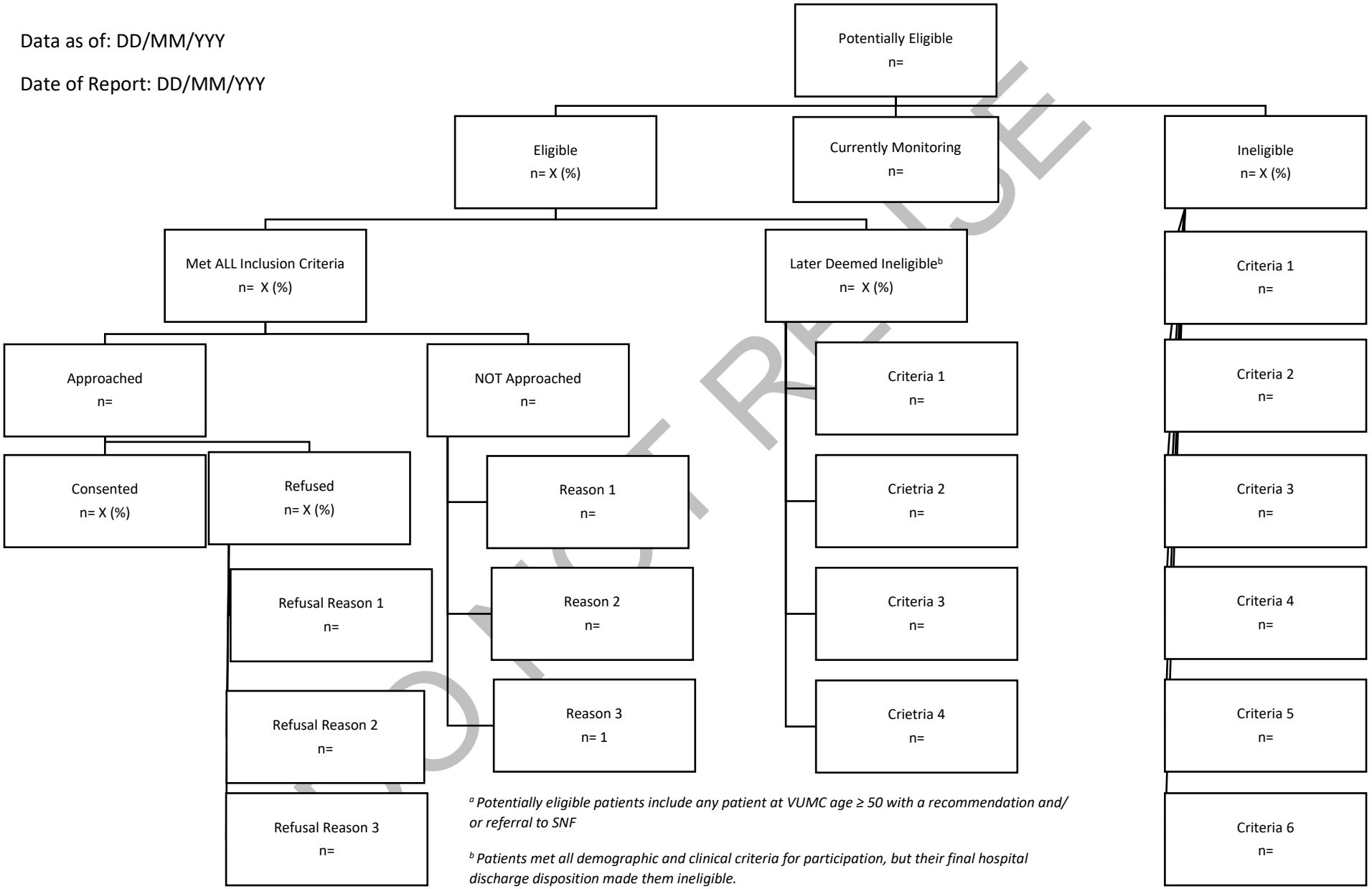


Figure 1b: Eligibility Determination

Data as of: DD/MM/YYY

Date of Report: DD/MM/YYY



[a] *Potentially eligible patients include any patient at VUMC age ≥ 50 with a recommendation and/ or referral to SNF*

[b] *Patients met all demographic and clinical criteria for participation, but their final hospital discharge disposition made them ineligible.*

Figure 2: Target v. Actual Enrollment

Data as of: DD/MM/YYYY

Date of report: DD/MM/YYYY

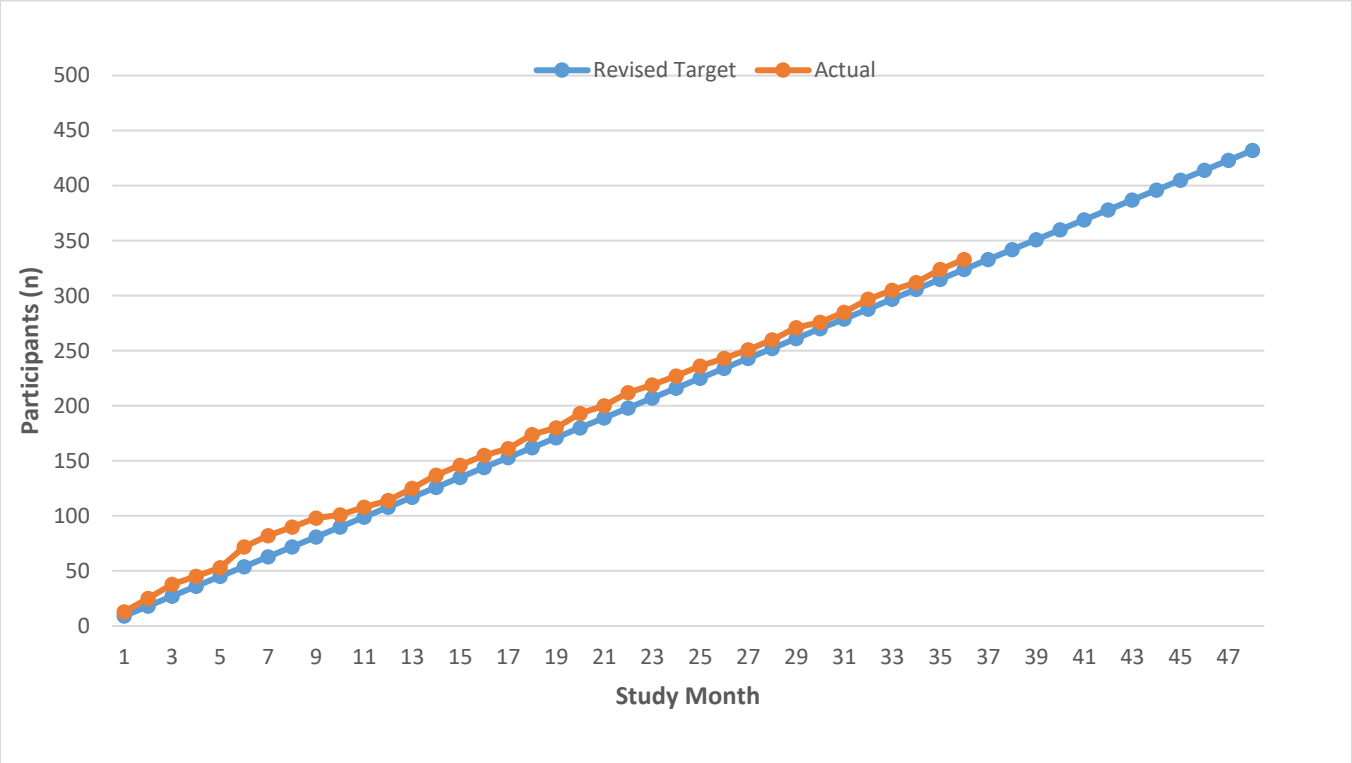


Table 1: Demographic & Key Baseline Characteristics by Group

Characteristics	Intervention N (%)	Control N (%)	Total N (%)
Total Enrolled			
Gender			
Male			
Female			
Ethnicity			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race			
American Indian/ Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
Caucasian (White)			
More than one race			
Unknown or Not Reported			
Age			
Mean			
Standard Deviation			
Median			
Minimum			
Maximum			
Interquartile Range			
Protocol Specific Measures			

Table 2: Overall Completion Rates for Interview Measures & Primary Outcome by Study Phase

Measures	Baseline N= X (%)	Time Point A N= X (%)	Follow-up		
			Time Point B N= X (%)	Time Point C N= X (%)	Time Point D N= X (%)

Safety Assessments: Tables and Listings

For Tables 3a-4d: The hazard ratio (and 95% CI) are computed using Cox proportional hazards regression in the recurrent events (frailty) configuration, as described in the project manual.

Table 3a: Overall Incidence of All Cause Adverse Events and Serious Adverse Events by Study Arm

	Intervention Group (N, Y person months)					**Control Group (N, Y person months)**					**Hazard Ratio [hr (95%CI)]**
		Events per person					Events per person				
	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	
Emergency Room Visit											
Hospitalization											
Death											
Other[ł]											
Overall Adverse Events*											
Serious Adverse Events**											

**Note that the Overall Adverse Event columns (1 event and >1 event) may not add up because a participant could have more than one type of event, so overall for the "Overall Event' they could be included in the >1 event cell.*

***Serious Adverse Event (SAE) is any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires prolonged or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, is another condition which investigators judge to represent significant hazards.*

[ł]*During this reporting period "Other" in both the groups were ICU transfers during the hospital phase*

Table 3b: Overall Incidence of All Cause Adverse Events and Serious Adverse Events by Study Arm: Hospital Phase

	Intervention Group (N, Y person months)					**Control Group (N, Y person months)**					**Hazard Ratio [hr (95%CI)]**
		Events per person					Events per person				
	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	
Emergency Room Visit											
Hospitalization											
Death											
Other[ŧ]											
Overall Adverse Events*											
Serious Adverse Events**											

**Note that the Overall Adverse Event columns (1 event and >1 event) may not add up because a participant could have more than one type of event, so overall for the "Overall Event' they could be included in the >1 event cell.*

***Serious Adverse Event (SAE) is any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires prolonged or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, is another condition which investigators judge to represent significant hazards.*

[ŧ]*During this reporting period "Other" in both the groups were ICU transfers during the hospital phase*

Table 3c: Overall Incidence of All Cause Adverse Events and Serious Adverse Events by Study Arm: SNF Phase

	Intervention Group (N, Y person months)					**Control Group (N, Y person months)**					**Hazard Ratio [hr (95%CI)]**
		Events per person					Events per person				
	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	
Emergency Room Visit											
Hospitalization											
Death											
Other[ŧ]											
Overall Adverse Events*											
Serious Adverse Events**											

**Note that the Overall Adverse Event columns (1 event and >1 event) may not add up because a participant could have more than one type of event, so overall for the "Overall Event' they could be included in the >1 event cell.*

***Serious Adverse Event (SAE) is any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires prolonged or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, is another condition which investigators judge to represent significant hazards.*

[ŧ]*During this reporting period "Other" in both the groups were ICU transfers during the hospital phase*

Table 3d: Overall Incidence of All Cause Adverse Events and Serious Adverse Events by Study Arm: Follow-Up Phase

	Intervention Group (N, Y person months)					**Control Group (N, Y person months)**					**Hazard Ratio [hr (95%CI)]**
		Events per person					Events per person				
	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	
Emergency Room Visit											
Hospitalization											
Death											
Other[ŧ]											
Overall Adverse Events*											
Serious Adverse Events**											

**Note that the Overall Adverse Event columns (1 event and >1 event) may not add up because a participant could have more than one type of event, so overall for the "Overall Event' they could be included in the >1 event cell.*

***Serious Adverse Event (SAE) is any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires prolonged or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, is another condition which investigators judge to represent significant hazards.*

[ŧ]*During this reporting period "Other" in both the groups were ICU transfers during the hospital phase*

Table 4a: Type of Adverse Events by Study Arm

	Intervention Group (N, Y person months)					**Control Group (N, Y person months)**					**Hazard Ratio [hr (95%CI)]**
		Events per person					Events per person				
	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	
Drug Related Adverse Event											
Potentially due to drug withdrawal											

- *Drug Related Adverse Events may be due to a single drug or a combination of drugs and actions i.e., more than one drug is involved, and each drug could have a different action (added, dose increased, stopped, dose decrease, no change).*

- *Withdrawal of Drug is defined as stopping or dose reduction. The adverse event was categorized as potentially related to drug withdrawal if the blinded adjudicator attributed the event due to the stopping or reduction of one or more drugs.*

Table 4b: Type of Adverse Events by Study Arm: Hospital Phase

	Intervention Group (N, Y person months)					**Control Group (N, Y person months)**					**Hazard Ratio [hr (95%CI)]**
		Events per person					Events per person				
	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	
Drug Related Adverse Event											
Potentially due to drug withdrawal											

- *Drug Related Adverse Events may be due to a single drug or a combination of drugs and actions i.e., more than one drug is involved, and each drug could have a different action (added, dose increased, stopped, dose decrease, no change).*

- *Withdrawal of Drug is defined as stopping or dose reduction. The adverse event was categorized as potentially related to drug withdrawal if the blinded adjudicator attributed the event due to the stopping or reduction of one or more drugs.*

Table 4c: Type of Adverse Events by Study Arm: SNF Phase

	Intervention Group (N, Y person months)					Control Group (N, Y person months)					Hazard Ratio [hr (95%CI)]
		Events per person					Events per person				
	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	
Drug Related Adverse Event											
Potentially due to drug withdrawal											

- *Drug Related Adverse Events may be due to a single drug or a combination of drugs and actions i.e., more than one drug is involved, and each drug could have a different action (added, dose increased, stopped, dose decrease, no change).*

- *Withdrawal of Drug is defined as stopping or dose reduction. The adverse event was categorized as potentially related to drug withdrawal if the blinded adjudicator attributed the event due to the stopping or reduction of one or more drugs.*

Table 4d: Type of Adverse Events by Study Arm: Follow-Up Phase

	Intervention Group (N, Y person months)					Control Group (N, Y person months)					Hazard Ratio [hr (95%CI)]
		Events per person					Events per person				
	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	Total Number of Events	No event (n)	1 event (n)	>1 event (n)	Total events per person month (rate)	
Drug Related Adverse Event											
Potentially due to drug withdrawal											

- *Drug Related Adverse Events may be due to a single drug or a combination of drugs and actions i.e., more than one drug is involved, and each drug could have a different action (added, dose increased, stopped, dose decrease, no change).*

- *Withdrawal of Drug is defined as stopping or dose reduction. The adverse event was categorized as potentially related to drug withdrawal if the blinded adjudicator attributed the event due to the stopping or reduction of one or more drugs.*

Listing 1: Serious Adverse Events (including deaths) sorted by Group & Study ID

Study ID/ Treatment Group	Study Phase	Days since Randomization	Onset Date	Stop Date	SAE Type	MedDRA SOC *Preferred Term*	Drug(s) Involved & Drug Action Preceding the Event*	Description of SAE	Outcome**
INTERVENTION GROUP									
CONTROL GROUP									

*Drug Actions Involved:

Added- Medication is new or restarted
D/C- Medication discontinued/ stopped
Dose ↓- Dose Reduced
Dose ↑- Dose Increased
PRN- Status changed from Scheduled to PRN (or vice versa)
N Δ- No Change (medication was involved but the medication status remained the same prior to the event)
N/A- Event is not medication related

** Outcomes:

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present- no treatment
Residual effect(s) present- being treated
Subject died

Listing 2: Deaths by Group and Study ID

Treatment Group	Study ID	Study Phase	Days since Randomization	Relatedness	Cause of Death
Intervention Group					
Control Group					

Listing 3: Adverse Events (excludes SAEs) sorted by Group and Study ID

Study ID/ Treatment Group	Days Since Randomization	AE Type	MedDRA SOC *Preferred Term*	Symptom	Drug(s) Involved*	Outcome**
Intervention Group						
Control Group						

*Drug Actions Involved:

Added- Medication is new or restarted
D/C- Medication discontinued/ stopped
Dose ↓- Dose Reduced
Dose ↑- Dose Increased
PRN- Status changed from Scheduled to PRN (or vice versa)
N Δ- No Change (medication was involved but the medication status remained the same prior to the event)
N/A- Event is not medication related

**Outcomes:

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present- no treatment
Residual effect(s) present- being treated
Subject died

Listing 4: Intervention Group Events Potentially Related to the Study- Event Details (includes SAEs)

Study ID	Study Phase	Drug(s) Involved & Drug Action Preceding the Event[i]	Naranjo Score for Involved Drug(s)	Source of Medication Change	Description of Adverse Event	Can the event be attributed to intervention? Rationale

Listing 5: Protocol Violations

Treatment Group	Participant ID	Study Phase	Description of Violation	Actions Taken in Response to Protocol Violation