

Document Title

Project Requirement Specification

Sponsor: Parexel International Ltd (UK)

Project: D3741C00003 (800226)

# Project Requirement Specification for Parexel International Ltd (UK) **Trial D3741C00003** **(ERT 800226)**

Protocol Version: Final 12 Feb 2015



**ERT**

*Getting It Done. Right.*

Internal

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## 1. Study Information

### Study Details:

A Randomized, Double Blind, Chronic Dosing (14 Days), Placebo Controlled, Incomplete Block Crossover, Multi center Study to Assess Efficacy and Safety of Three Dose Levels of AZD7594, Given Once Daily by Inhalation, in Patients With Mild to Moderate Asthma

Compound	Account Type	Population	Phase
AZD7594	Prospective	Adult	IIA

### Estimates:

Study Start	Study End	Study Duration	First Equipment at Site Date
22-MAY-2015	06-APR-2016	10 Months, 15 Days	27-APR-2015
Number of Sites	Screened Subjects	Enrolled Subjects	Approval Required for Equipment Shipment
9	384	48	Yes

### Products:

Product Name	Product Counts
AM3GSM Patient	180
ECG on MSCv2.x	0
ELI-150	9
MasterScope v2.0	9
NIOX Mino	9

### Services:

Service Name	Service Counts
BTR White List	1680
ECG Procedures	4143
Local Support	2
OR Spirometry Proficiency	25
QA including FAX to site	1680
Translations	2
Data Cleaning	Y
International Support	Y
Investigator Training	Y
Monitor Training	Y

### Data Types & Workflow:

Data Type	Analysis Methodology	Source	Source Document Return	Default Turnaround Time (TAT)
ECG	Measurement: Manual Adjudication (Global Median Beat) Interpretation: Cardiologist	Digital	XML	72 HR
Forced Spirometry	BTR QC	-	-	48 HR
FeNO	Not applicable	-	-	-

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**Project: D3741C00003 (800226)**

## **1. Study Information**

Data Type	Analysis Methodology	Source	Source Document Return	Default Turnaround Time (TAT)
COA - AM	Not applicable Not applicable Not applicable	-	-	-

## 2. Contact Information

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### 3. System Access

Accessibility to the individual functionalities is defined as follows:

Functionality	Monitor	Investigator	Auditor	Technical Support	-
<b>Visit</b>					
Define new patient		X			
Search patient	X	X	X	X	
View patient details	X	X	X	X	
Change patient demographics		X			
View and activate visit routines		X			
Print reports	X	X	X	X	
Change patient ID		X			
<b>Calibration</b>					
Enter ambient condition		X			
Calibration		X			
Calibration Check		X			
Linearity Check		X			
Calibration Log	X	X	X	X	
Calibration Check Log	X	X	X	X	
Linearity Check Log	X	X	X	X	
<b>Tools</b>					
Create backup	X	X		X	
View system info	X	X	X	X	
Transfer Data	X	X		X	
Add or change user	X			X	
Print audit trail	X		X	X	
Change settings for data transfer	X	X		X	
Restore from backup	X	X		X	
Change date and time settings	X			X	
Update software	X	X		X	
Print data correction form	X	X			
Import or Export Users				X	

### **3. System Access**

Functionality	Monitor	Investigator	Auditor	Technical Support	-
<b>Other</b>					
Enable/Disable Remote Support	X	X	X	X	

Note:

1) Users are only able to add other users with the same security level or lower. E.g.: Site Administrators are able to add Investigators and Site Administrators. Monitors are able to add Investigators, Site Administrators, Auditors and Monitors.

2) Users are only allowed to perform system recovery from backup media after receiving password from ERT Helpdesk. Recovery is password protected for all Monitors, Investigators and Site Administrators. This function will not be password protected for technical support.

## 4. Vocabulary

### 4.1 Dosing

ERT Terminology	Sponsor Terminology
Medication 01	Salbutamol
Medication 02	Study Drug

### 4.2 Visit Type

ERT Terminology	Sponsor Terminology
Inclusion	Inclusion
Proficiency	Proficiency
Randomization	Randomization
Run In	Run In
Treatment	Treatment

### 4.3 Additional Type

ERT Terminology	Sponsor Terminology
Site	Site
Subject	Patient

## 5. Site Information and Patient Demographics

The power-on password is MSCCT.

### 5.1 Investigator Information

Name	Description and Settings	Additional Information
Investigator	String	-
Center Number (d151633)	Number Range, [Min 4, Max 4], Range 0001-9999	Comments: Min 0001, Max 9999

### 5.2 Demographic Information

Name	Description and Settings	Additional Information
Year of Birth (d154244)	Birth Year, yyyy Required [ECG]	-
Patient Number (d151628)	Number Range, [Min 7, Max 7], Range 0001001-9999999, Site ID as Prefix Critical [ECG, Forced Spirometry, FeNO, COA - AM]	Comments: Patient Number must be between 001 to 999
Ethnicity (d151629)	Ethnicity Required [Forced Spirometry, FeNO, COA - AM]	Selected Ethnicities: African American Caucasian North East Asian Other South East Asian
Gender (d152246)	Gender Required [ECG, Forced Spirometry, FeNO, COA - AM]	Comments: Female or male
Height (d151624)	Numeric Required [Forced Spirometry] Optional [FeNO, COA - AM]  Min [cm]      Max [cm] Hard rule: 90      230  Min [inches]      Max [inches] Hard rule: 35.4      90.6	Calculate Predicted Value Once  Comments: Height must be between 90.0 cm and 230.0 cm
Age (d151625)	Numeric Required [Forced Spirometry] Optional [FeNO, COA - AM]  Min [yr]      Max [yr] Hard rule: 18.00      75.99	Calculate Predicted Value Once  Comments: must be between 18.00 and 75.99

### 5.3 Transmittal Information

Name	Description and Settings	Additional Information
Visit Schedule	String	-

## 5. Site Information and Patient Demographics

Name	Description and Settings	Additional Information
Collection Date (d151631)	Non-Future Date, dd-MMM-yyyy Required [ECG, Forced Spirometry, FeNO, COA - AM]	-
Collection Time (d151632)	Time, 24Hour Required [ECG, Forced Spirometry, FeNO, COA - AM]	-
Visit Label (d151626)	String, [Min 0, Max 15]	-

## 6. Master Visit Schedule

### 6.1 Basic Configuration

**Rename Original Visit after Reschedule:** Yes

**Visit label:** V1.0, V1.1, V1.2, V2, V3.0, V3.1, VUN1

**Allow Unscheduled visit on the same day with Scheduled visit:**  before Scheduled Visit  after Scheduled Visit

### 6.2 Visit Schedule

Visit Name	Phase/Period	Visit Interval	Visit Window				Visit can be skipped	Visit can be rescheduled
			Hard-	Soft-	Soft+	Hard+		
V1 (v728955)	Inclusion	-	-	-	-	-	No	Yes
V2 (v728956)	Run In	V1 +14d	-	0d	14d	-	No	Yes
V3 (v728957)	Randomization	V2 +21d	-	2d	9d	-	No	Yes
V4 (v728958)	Treatment	V3 +7d	-	2d	2d	-	Yes	Yes
V5 (v728959)	Treatment	V3 +14d	-	1d	1d	-	No	Yes
V6 (v728960)	Treatment	V5 +21d	-	1d	1d	-	No	Yes
V7 (v728961)	Treatment	V6 +7d	-	2d	2d	-	Yes	Yes
V8 (v728962)	Treatment	V6 +14d	-	1d	1d	-	No	Yes
V9 (v728963)	Treatment	V8 +21d	-	1d	1d	-	No	Yes
V10 (v728964)	Treatment	V9 +7d	-	2d	2d	-	Yes	Yes
V11 (v728965)	Treatment	V9 +14d	-	1d	1d	-	No	Yes
VUNR (v728966)	Run In	After V1 Before V3	-	-	-	-	-	-
VUNT (v728967)	Treatment	After V3	-	-	-	-	-	-
VPROF (v728968)	Proficiency	-	-	-	-	-	-	-
VET (v738148)	Termination	After V3	-	-	-	-	-	-

### 6.3 Visit Properties

Visit Name	Visit Time Window				Visit Duration	Reschedule			Reschedule Window			
	Hard-	Soft-	Soft+	Hard+		Max #	After Compl.	Duration	Hard-	Soft-	Soft+	Hard+
V1 (v728955)	-	6:00	11:00	-	1d	2	Yes	1d	-	-	-	-
V2 (v728956)	-	6:00	11:00	-	1d	1	Yes	1d	-	-	-	-
V3 (v728957)	-	6:00	11:00	-	1d	1	No	1d	-	-	-	-
V4 (v728958)	-	6:00	11:00	-	1d	1	Yes	1d	-	-	-	-
V5 (v728959)	-	6:00	11:00	-	1d	1	No	1d	-	-	-	-
V6 (v728960)	-	6:00	11:00	-	1d	1	No	1d	-	-	-	-
V7 (v728961)	-	6:00	11:00	-	1d	1	Yes	1d	-	-	-	-
V8 (v728962)	-	6:00	11:00	-	1d	1	No	1d	-	-	-	-
V9 (v728963)	-	6:00	11:00	-	1d	1	No	1d	-	-	-	-

## 6. Master Visit Schedule

### 6.3 Visit Properties

Visit Name	Visit Time Window				Visit Duration	Reschedule			Reschedule Window			
	Hard-	Soft-	Soft+	Hard+		Max #	After Compl.	Duration	Hard-	Soft-	Soft+	Hard+
V10 (v728964)	-	6:00	11:00	-	1d	1	Yes	1d	-	-	-	-
V11 (v728965)	-	6:00	11:00	-	1d	1	No	1d	-	-	-	-

Note: Visit Time Windows are displayed in 24-hour format.

### 6.4 Visit Comments

Visit Name	Investigator Comment	Sponsor Comment
VET (v738148)	Early Termination Visit	

## 7. Visit Tasks

### 7.1 Visit Task Mapping

The following table represents all actions which will be performed for each visit:

Task Name	V1 Inclusion	V2 Run In	V3 Randomization	V4 Treatment	V5 Treatment	V6 Treatment	V7 Treatment
Pre PFT (t5263)	X						
Post PFT (t5264)	X						
PFT (t5304)		X					
Pre PFT -60min (t5265)			X	X	X	X	X
Pre PFT -30min (t5266)			X	X	X	X	X
Additonal Pre PFT (t5298)						X	
Serial Measurements (t5267)			X			X	
Optional PFT (t5268)	X	X	X	X	X	X	X
Proficiency PFT (t5269)							
FeNO (t5270)	X	X	X	X	X	X	X
Optional FeNO (t5271)	X	X	X	X	X	X	X
AM Dispense (t5272)	X						
AM Download (t5273)		X	X	X	X	X	X
ACQ-5 Download (t5274)	X						
Optional AM Download (t5275)		X	X	X	X	X	X
AM Close (t5276)			X	X	X	X	X
AM Reprogram (t5278)		X	X		X	X	
Salbutamol Dosing (t5279)	X						
Study Drug Dosing (t5280)			X	X		X	X
Medication washout check (t5281)	X	X	X	X	X	X	X
Medication washout not met (t5282)	X	X	X	X	X	X	X
Inclusion (t5283)	X						
Randomization (t5285)			X				
FeNO device ready to use (t5288)	X	X		X	X	X	X
FeNO to be skipped (t5303)	X	X		X	X	X	X
Reversibility Not Met (t5289)	X						
Variability too high (t5301)						X	
Variability too high 2 (t5305)						X	
Variability still too high (t5302)						X	
Patients on ICS_LABA	X						

**7. Visit Tasks**

Task Name	V1 Inclusion	V2 Run In	V3 Randomization	V4 Treatment	V5 Treatment	V6 Treatment	V7 Treatment
(t5342)							
Task Name	V8 Treatment	V9 Treatment	V10 Treatment	V11 Treatment	VUNR Run In	VUNT Treatment	VPROF Proficiency
Pre PFT (t5263)							
Post PFT (t5264)							
PFT (t5304)							
Pre PFT -60min (t5265)	X	X	X	X			
Pre PFT -30min (t5266)	X	X	X	X			
Additonal Pre PFT (t5298)		X					
Serial Measurements (t5267)		X					
Optional PFT (t5268)	X	X	X	X	X	X	
Proficiency PFT (t5269)							X
FeNO (t5270)	X	X	X	X			
Optional FeNO (t5271)	X	X	X	X	X	X	
AM Dispense (t5272)							
AM Download (t5273)	X	X	X	X			
ACQ-5 Download (t5274)							
Optional AM Download (t5275)	X	X	X	X	X	X	
AM Close (t5276)	X	X	X	X			
AM Reprogram (t5278)	X	X					
Salbutamol Dosing (t5279)					X		
Study Drug Dosing (t5280)		X	X			X	
Medication washout check (t5281)	X	X	X	X	X	X	
Medication washout not met (t5282)	X	X	X	X	X	X	
Inclusion (t5283)							
Randomization (t5285)							
FeNO device ready to use (t5288)	X	X	X	X			
FeNO to be skipped (t5303)	X	X	X	X			
Reversibility Not Met (t5289)							
Variability too high (t5301)		X					
Variability too high 2 (t5305)		X					
Variability still too high (t5302)		X					

## 7. Visit Tasks

Task Name	V8 Treatment	V9 Treatment	V10 Treatment	V11 Treatment	VUNR Run In	VUNT Treatment	VPROF Proficiency
Patients on ICS_LABA (t5342)							
Task Name	VET Termination						
Pre PFT (t5263)							
Post PFT (t5264)							
PFT (t5304)							
Pre PFT -60min (t5265)							
Pre PFT -30min (t5266)							
Additonal Pre PFT (t5298)							
Serial Measurements (t5267)							
Optional PFT (t5268)							
Proficiency PFT (t5269)							
FeNO (t5270)							
Optional FeNO (t5271)							
AM Dispense (t5272)							
AM Download (t5273)	X						
ACQ-5 Download (t5274)							
Optional AM Download (t5275)							
AM Close (t5276)	X						
AM Reprogram (t5278)							
Salbutamol Dosing (t5279)							
Study Drug Dosing (t5280)							
Medication washout check (t5281)							
Medication washout not met (t5282)							
Inclusion (t5283)							
Randomization (t5285)							
FeNO device ready to use (t5288)							
FeNO to be skipped (t5303)							
Reversibility Not Met (t5289)							
Variabilty too high (t5301)							
Variability too high 2 (t5305)							
Variability still too high (t5302)							

## 7. Visit Tasks

Task Name	VET Termination						
Patients on ICS_LABA (t5342)							

### 7.2 Visit Task Properties - PFT

Task / Sub-Task Name	Task Type	Spirometry Type	Position for Test	Anchor to task start	Show report	Optional
Pre PFT (t5263)	Forced Spirometry	PRE	Sitting	Yes	No	No
Post PFT (t5264)	Forced Spirometry	POST	Sitting	Yes	No	No
PFT (t5304)	Forced Spirometry	PRE	Sitting	Yes	No	No
Pre PFT -60min (t5265)	Forced Spirometry	PRE	Sitting	Yes	No	No
Pre PFT -30min (t5266)	Forced Spirometry	PRE	Sitting	Yes	No	No
Additonal Pre PFT (t5298)	Forced Spirometry	PRE	Sitting	Yes	No	No
Serial Measurements (t5267) / Post PFT 10 min (s5026)	Forced Spirometry	POST	Sitting	Yes	No	No
Serial Measurements (t5267) / Post PFT 30 min (s5027)	Forced Spirometry	POST	Sitting	Yes	No	No
Serial Measurements (t5267) / Post PFT 1 h (s5028)	Forced Spirometry	POST	Sitting	Yes	No	No
Optional PFT (t5268)	Forced Spirometry	PRE	Sitting	Yes	No	No
Proficiency PFT (t5269)	Forced Spirometry	PRE	Sitting	Yes	No	No

## 7. Visit Tasks

### 7.3 Visit Task Properties - Other

Task / Sub-Task Name	Task Type	Optional	Help Text
Post PFT (t5264)	Forced Spirometry	No	Measurement should be started 15 min after Salbutamol dosing.
Pre PFT -30min (t5266)	Forced Spirometry	No	Measurement should be started 30 min after the start of the Pre PFT -60 min measurement.
Serial Measurements (t5267) / Post PFT 10 min (s5026)	Forced Spirometry	No	Measurement should be started 10 min after study drug administration.
Serial Measurements (t5267) / Post PFT 30 min (s5027)	Forced Spirometry	No	Measurement should be started 30 min after study drug administration.
Serial Measurements (t5267) / Post PFT 1 h (s5028)	Forced Spirometry	No	Measurement should be started 1 h after study drug administration.
FeNO (t5270)	FeNO Measurement	No	-
Optional FeNO (t5271)	FeNO Measurement	Yes	-
AM Dispense (t5272)	Dispense AM	No	-
AM Download (t5273)	Download AM	No	-
ACQ-5 Download (t5274)	Download AM	No	-
Optional AM Download (t5275)	Download AM	No	-
AM Close (t5276)	Close AM	No	-
AM Reprogram (t5278)	Reprogram AM	No	-
Salbutamol Dosing (t5279)	Form	No	-
Study Drug Dosing (t5280)	Form	No	Study drug should be administered 60 min after the start of the Pre PFT -60 min measurement.
Medication washout check (t5281)	Form	No	-
Medication washout not met (t5282)	Form	No	-
Inclusion (t5283)	Form	No	-
Randomization (t5285)	Form	No	-
FeNO device ready to use (t5288)	Form	No	-
FeNO to be skipped (t5303)	Form	No	-
Reversibility Not Met (t5289)	Form	No	-
Variability too high (t5301)	Form	No	-
Variability too high 2 (t5305)	Form	No	-
Variability still too high (t5302)	Form	No	-
Patients on ICS_LABA (t5342)	Form	No	-

### 7.4 Visit Task Properties - Serial Measurements

## 7. Visit Tasks

### 7.4 Visit Task Properties - Serial Measurements

**Serial Measurement:** Serial Measurements

The following table represents all actions and their timing related to serial measurements:

Seq	Sub-Task Name / Task Type	Timepoint	Timepoint Offset	Lower Extended Time Window	Lower Target Time Window	Upper Target Time Window	Upper Extended Time Window
10	Post PFT 10 min (s5026) Forced Spirometry		+10min	-5min	-	+5min	+10min
20	Post PFT 30 min (s5027) Forced Spirometry		+30min	-10min	-5min	+5min	+15min
30	Post PFT 1 h (s5028) Forced Spirometry		+60min	-15min	-5min	+5min	+60min

Note: For the -Soft, +Soft and -Hard time windows the timing rules are inclusive; the +Hard timing rule is exclusive.

## 8. Visit Workflow

### 8.1 V1

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
V1_Reversibility (R5204)	Rule	No	-	-
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
V1_Inclusion_Question_Rule (R5214)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
V1 Skip AM Dispense (R5268)	Rule	No	-	-
Asthma_Safety_exclusion (R5269)	Rule	No	-	-
Pre PFT (t5263)	Task	-	No	No
Post PFT (t5264)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Dispense (t5272)	Task	-	No	No
ACQ-5 Download (t5274)	Task	-	No	No
Salbutamol Dosing (t5279)	Task	-	No	No
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes
Inclusion (t5283)	Task	-	Yes	No
FeNO device ready to use (t5288)	Task	-	No	No
Reversibility Not Met (t5289)	Task	-	No	Yes
FeNO to be skipped (t5303)	Task	-	No	Yes
Patients on ICS_LABA (t5342)	Task	-	No	Yes

## 8. Visit Workflow

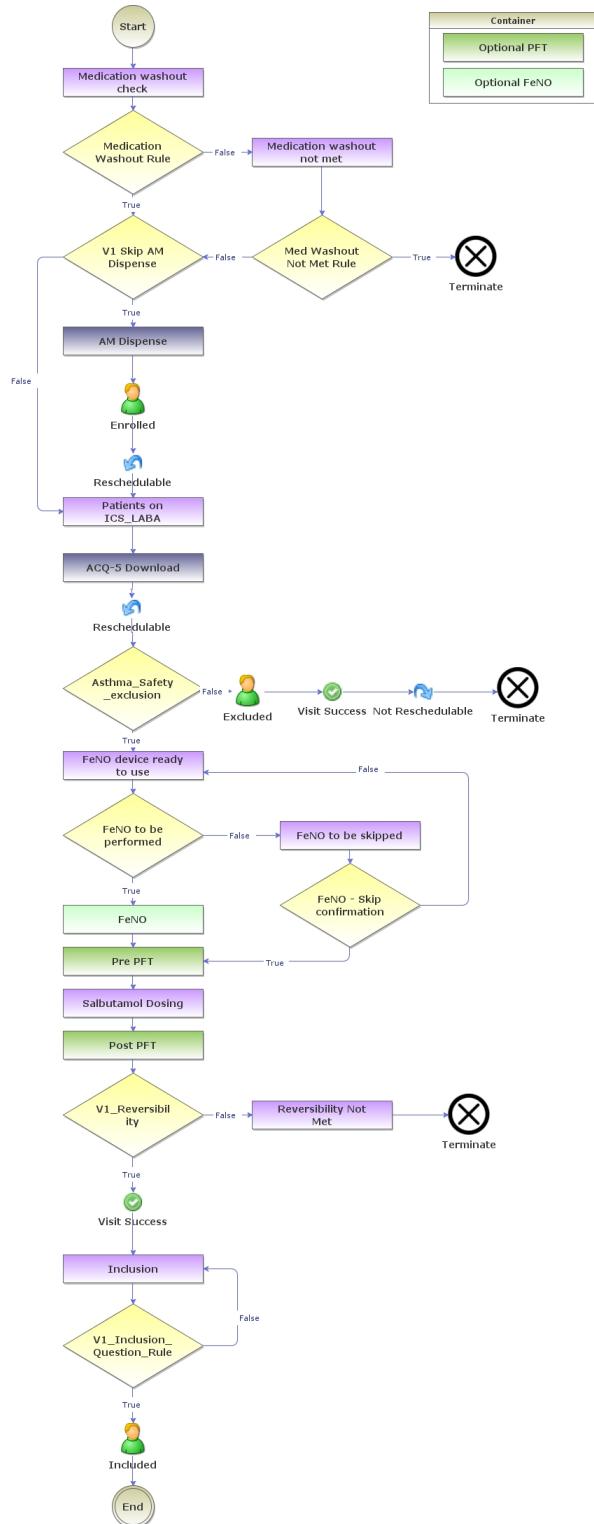
### 8.1 V1

#### Timing Rules

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Post PFT (t5264)	Current Visit	Salbutamol Dosing	15 min	5 min	0 min	15 min	105 min

## 8. Visit Workflow

### 8.1 V1



## 8. Visit Workflow

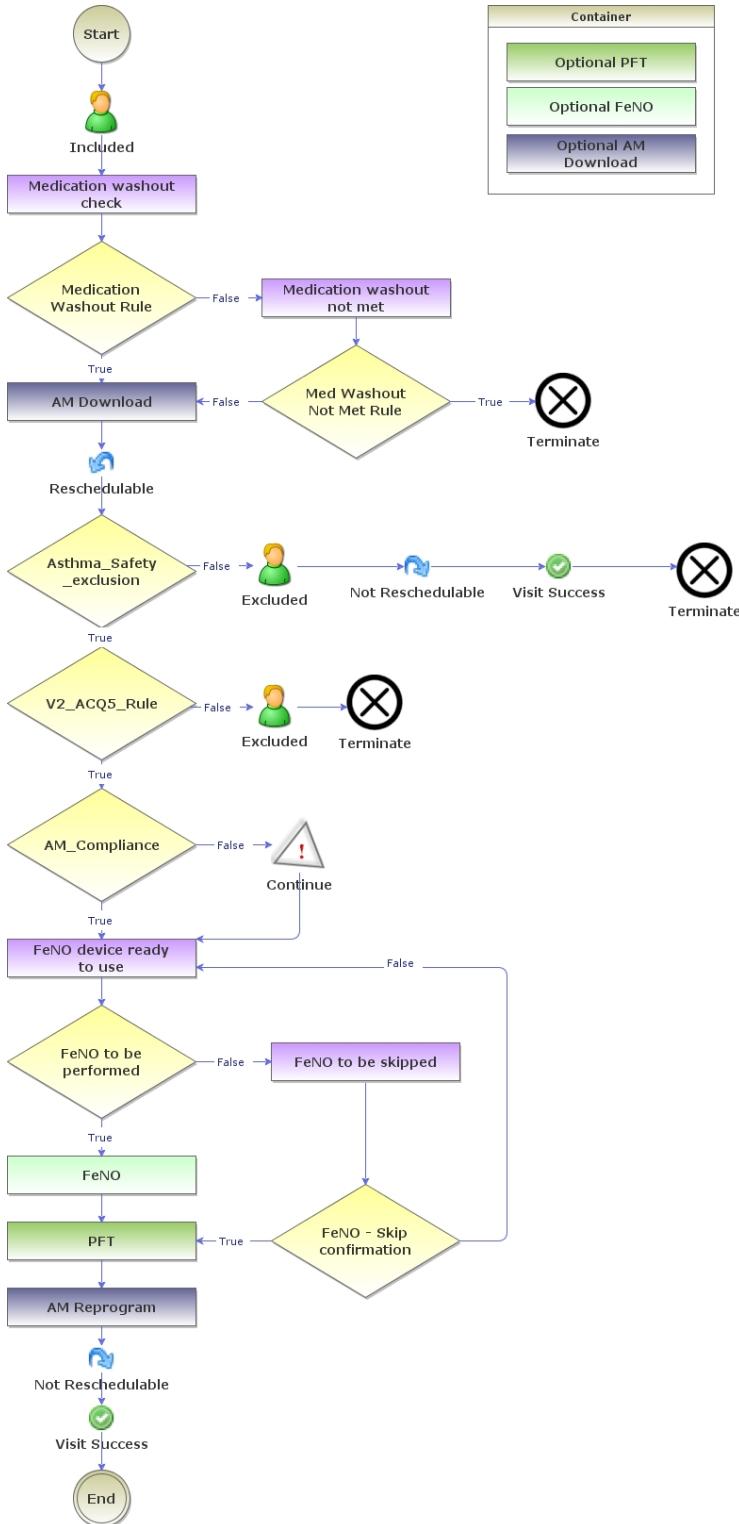
### 8.2 V2

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
V2_ACQ5_Rule (R5244)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
Asthma_Safety_exclusion (R5269)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Reprogram (t5278)	Task	-	No	Yes
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes
FeNO device ready to use (t5288)	Task	-	No	Yes
FeNO to be skipped (t5303)	Task	-	No	Yes
PFT (t5304)	Task	-	No	No

## 8. Visit Workflow

### 8.2 V2



## 8. Visit Workflow

### 8.3 V3

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
V3_Predicted_FEV1_average (R5209)	Rule	No	-	-
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
V3_Randomization_Question_Rule (R5216)	Rule	No	-	-
V3_FeNO (R5227)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
V3_Asthma_Safety_exclusion (R5324)	Rule	No	-	-
Pre PFT -60min (t5265)	Task	-	No	No
Pre PFT -30min (t5266)	Task	-	No	No
Serial Measurements (t5267)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Close (t5276)	Task	-	No	No
AM Reprogram (t5278)	Task	-	Yes	Yes
Study Drug Dosing (t5280)	Task	-	No	No
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes
Randomization (t5285)	Task	-	No	No

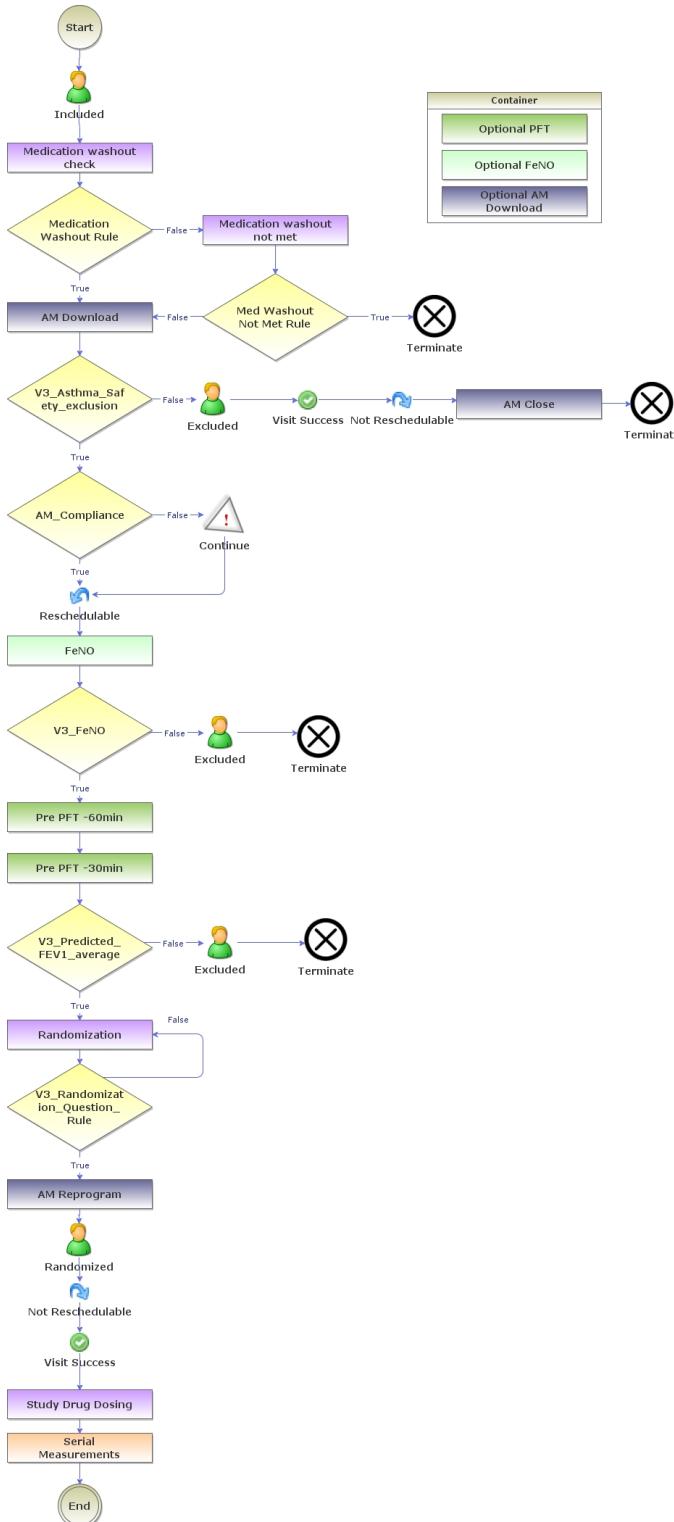
#### Timing Rules

**8. Visit Workflow****8.3 V3**

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Pre PFT -30min (t5266)	Current Visit	Pre PFT -60min	30 min	15 min	-	30 min	-
Serial Measurements (t5267)	Current Visit	Study Drug Dosing	-	-	-	-	-
Study Drug Dosing (t5280)	Current Visit	Pre PFT -60min	60 min	-	-	-	-

## 8. Visit Workflow

### 8.3 V3



## 8. Visit Workflow

### 8.4 V4

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
Asthma_Safety_Withdraw (R5272)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
Pre PFT -60min (t5265)	Task	-	No	No
Pre PFT -30min (t5266)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Close (t5276)	Task	-	No	No
Study Drug Dosing (t5280)	Task	-	No	Yes
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes
FeNO device ready to use (t5288)	Task	-	No	Yes
FeNO to be skipped (t5303)	Task	-	No	Yes

#### Timing Rules

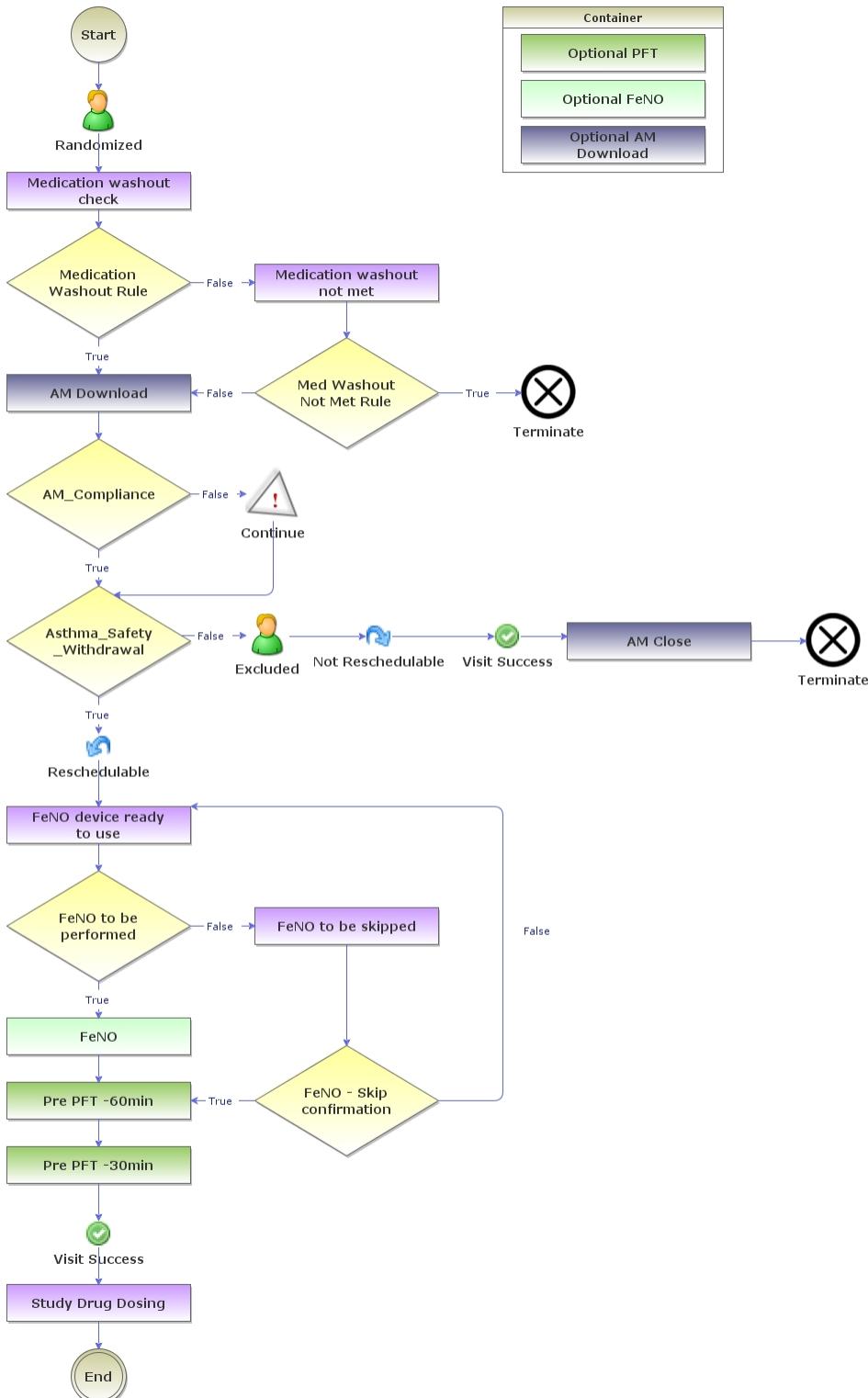
Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Pre PFT -30min (t5266)	Current Visit	Pre PFT -60min	30 min	15 min	-	30 min	-

**8. Visit Workflow****8.4 V4**

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Study Drug Dosing (t5280)	Current Visit	Pre PFT -60min	60 min	-	-	-	-

## 8. Visit Workflow

### 8.4 V4



## 8. Visit Workflow

### 8.5 V5

#### Visit Task Properties

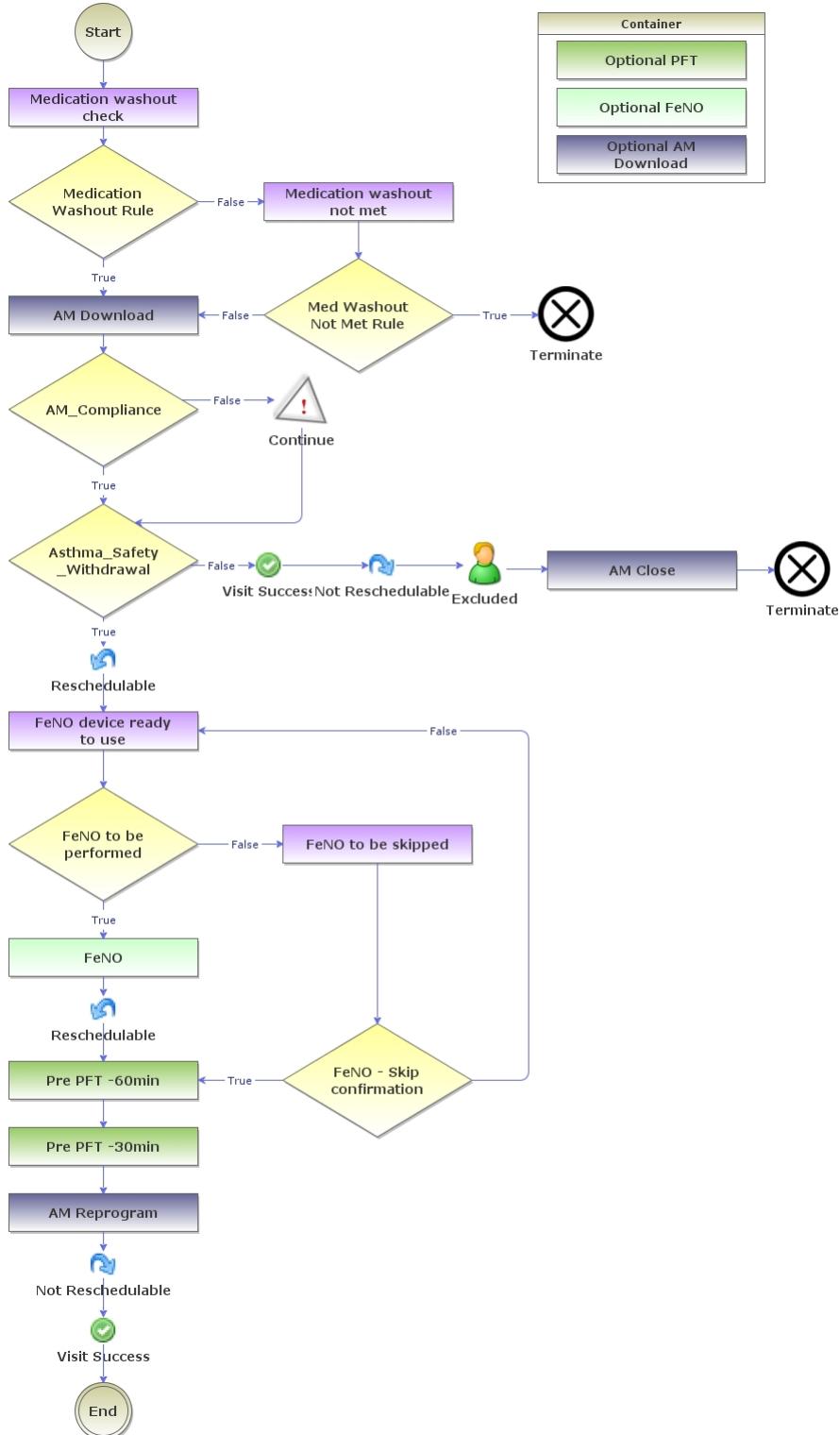
Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
Asthma_Safety_Withdraw (R5272)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
Pre PFT -60min (t5265)	Task	-	No	No
Pre PFT -30min (t5266)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Close (t5276)	Task	-	No	No
AM Reprogram (t5278)	Task	-	Yes	Yes
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes
FeNO device ready to use (t5288)	Task	-	No	Yes
FeNO to be skipped (t5303)	Task	-	No	No

#### Timing Rules

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Pre PFT -30min (t5266)	Current Visit	Pre PFT -60min	30 min	15 min	-	30 min	-

## 8. Visit Workflow

### 8.5 V5



## 8. Visit Workflow

### 8.6 V6

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
V6_Variability_V6_and_V3 (R5235)	Rule	No	-	-
V6_Variability_V6_V3_Add_PFT (R5236)	Rule	No	-	-
V6_Variability_V6_30m_V3_rule (R5241)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
ACQ5_Rule_Withdrawal_SR (R5273)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
Pre PFT -60min (t5265)	Task	-	No	No
Pre PFT -30min (t5266)	Task	-	No	No
Serial Measurements (t5267)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Close (t5276)	Task	-	No	No
AM Reprogram (t5278)	Task	-	No	No
Study Drug Dosing (t5280)	Task	-	No	No
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes

**8. Visit Workflow****8.6 V6**

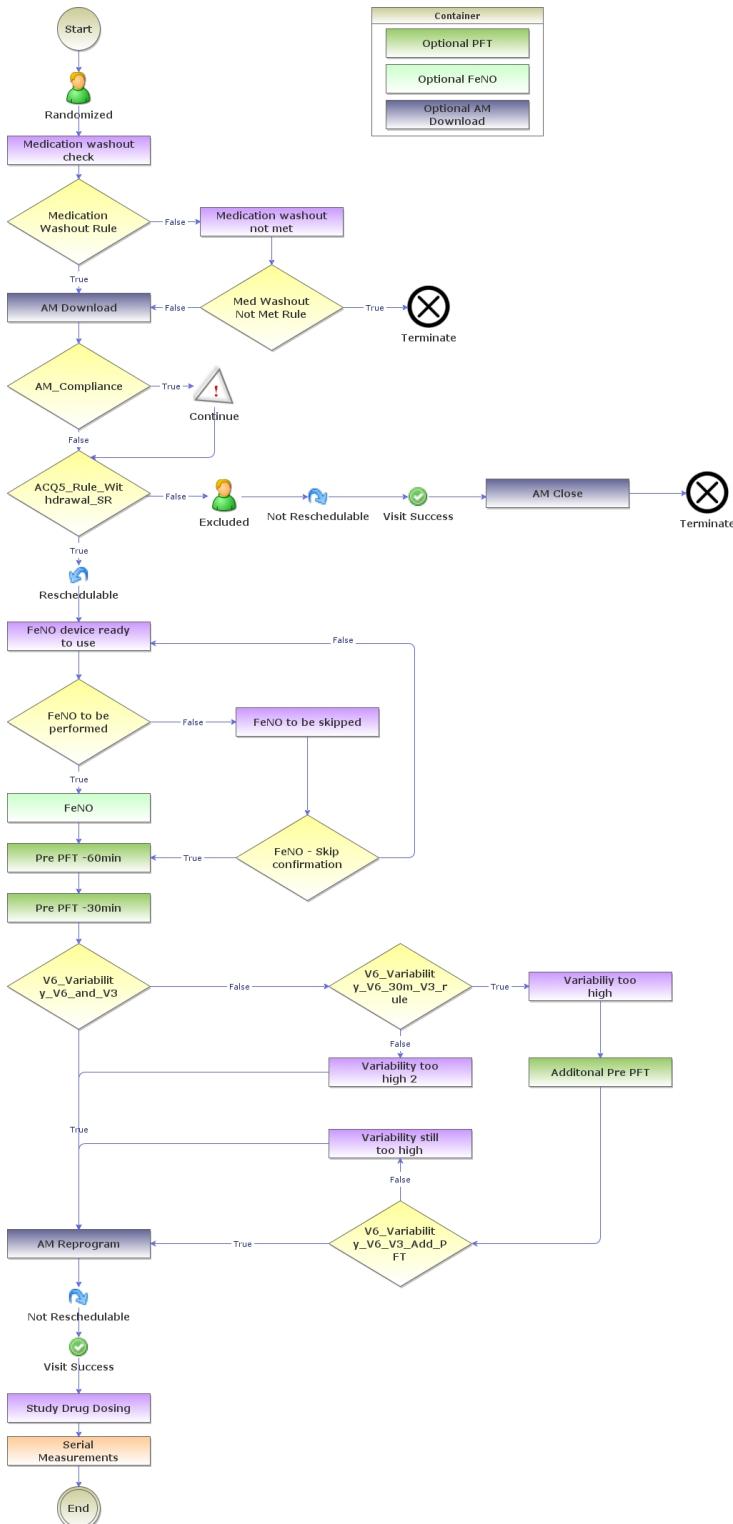
Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
FeNO device ready to use (t5288)	Task	-	No	No
Additonal Pre PFT (t5298)	Task	-	No	No
Variabiliy too high (t5301)	Task	-	No	Yes
Variability still too high (t5302)	Task	-	No	Yes
FeNO to be skipped (t5303)	Task	-	No	Yes
Variability too high 2 (t5305)	Task	-	No	Yes

**Timing Rules**

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Pre PFT -30min (t5266)	Current Visit	Pre PFT -60min	30 min	15 min	-	30 min	-
Serial Measurements (t5267)	Current Visit	Study Drug Dosing	-	-	-	-	-
Study Drug Dosing (t5280)	Current Visit	Pre PFT -60min	60 min	-	-	-	-
Additonal Pre PFT (t5298)	Current Visit	Pre PFT -30min	30 min	15 min	-	30 min	-

## 8. Visit Workflow

### 8.6 V6



## 8. Visit Workflow

### 8.7 V7

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
Asthma_Safety_Withdraw (R5272)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
Pre PFT -60min (t5265)	Task	-	No	No
Pre PFT -30min (t5266)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Close (t5276)	Task	-	No	No
Study Drug Dosing (t5280)	Task	-	No	Yes
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes
FeNO device ready to use (t5288)	Task	-	No	No
FeNO to be skipped (t5303)	Task	-	No	Yes

#### Timing Rules

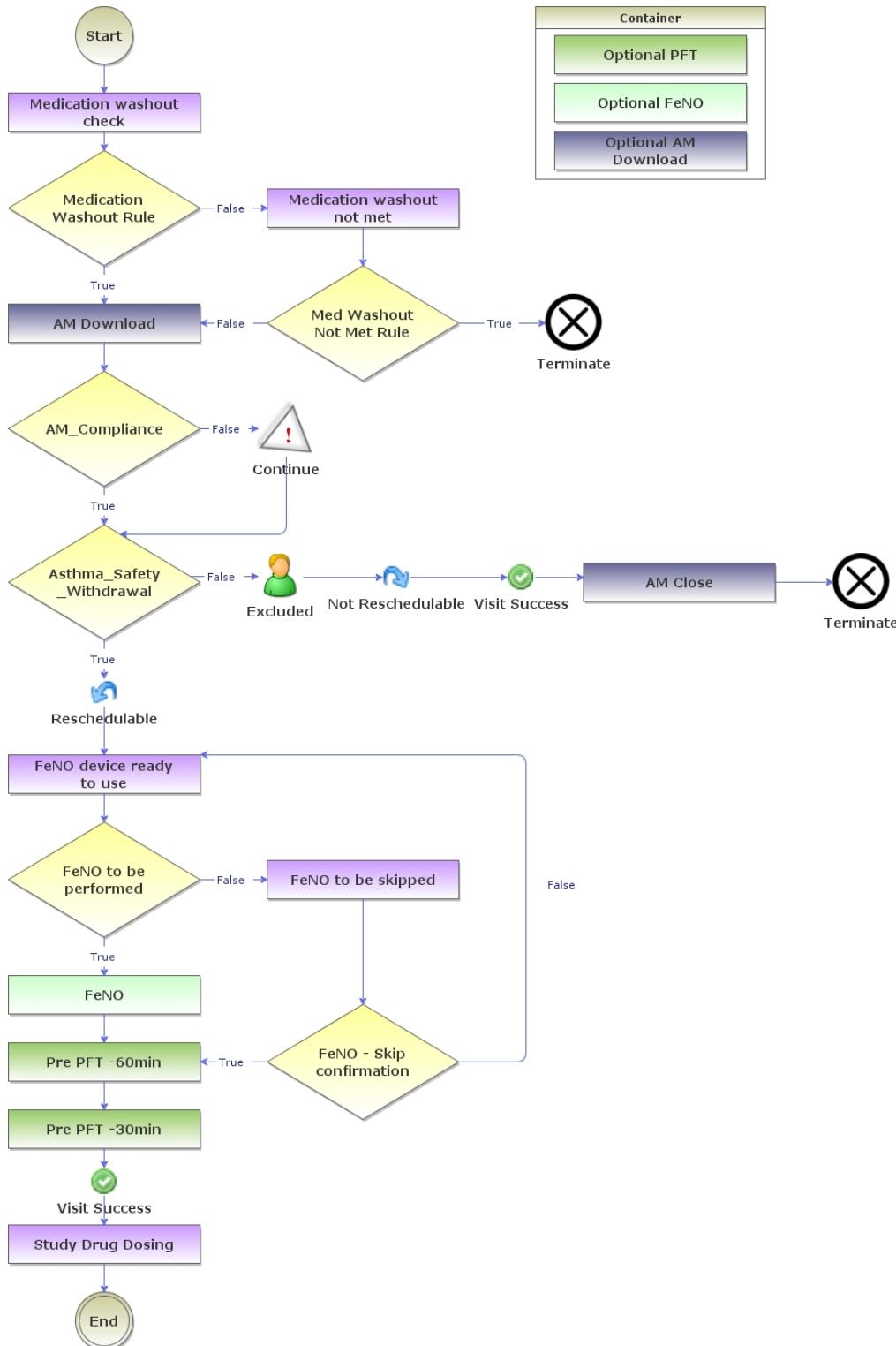
Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Pre PFT -30min (t5266)	Current Visit	Pre PFT -60min	30 min	15 min	-	30 min	-

**8. Visit Workflow****8.7 V7**

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Study Drug Dosing (t5280)	Current Visit	Pre PFT -60min	60 min	-	-	-	-

## 8. Visit Workflow

### 8.7 V7



## 8. Visit Workflow

### 8.8 V8

#### Visit Task Properties

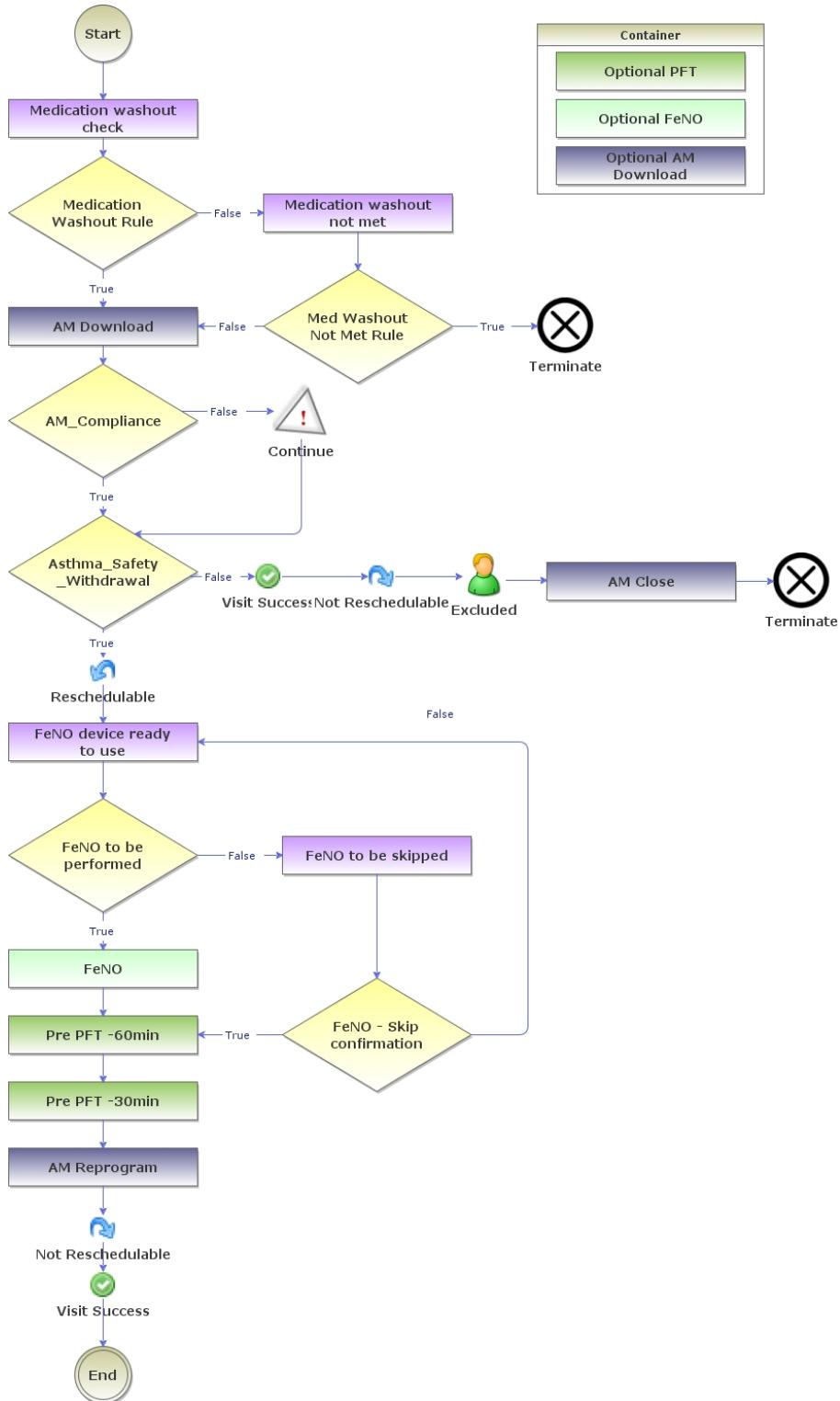
Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
Asthma_Safety_Withdraw (R5272)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
Pre PFT -60min (t5265)	Task	-	No	No
Pre PFT -30min (t5266)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Close (t5276)	Task	-	No	No
AM Reprogram (t5278)	Task	-	Yes	Yes
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes
FeNO device ready to use (t5288)	Task	-	No	Yes
FeNO to be skipped (t5303)	Task	-	No	Yes

#### Timing Rules

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Pre PFT -30min (t5266)	Current Visit	Pre PFT -60min	30 min	15 min	-	30 min	-

## 8. Visit Workflow

### 8.8 V8



## 8. Visit Workflow

### 8.9 V9

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
V9_Variability_V9_and_V3 (R5237)	Rule	No	-	-
V9_Variability_V9_V3_Add_PFT (R5238)	Rule	No	-	-
V9_Variability_V9_30m_V3_rule (R5242)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
Asthma_Safety_Withdraw (R5272)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
Pre PFT -60min (t5265)	Task	-	No	No
Pre PFT -30min (t5266)	Task	-	No	No
Serial Measurements (t5267)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Close (t5276)	Task	-	No	No
AM Reprogram (t5278)	Task	-	No	No
Study Drug Dosing (t5280)	Task	-	No	No
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes

**8. Visit Workflow****8.9 V9**

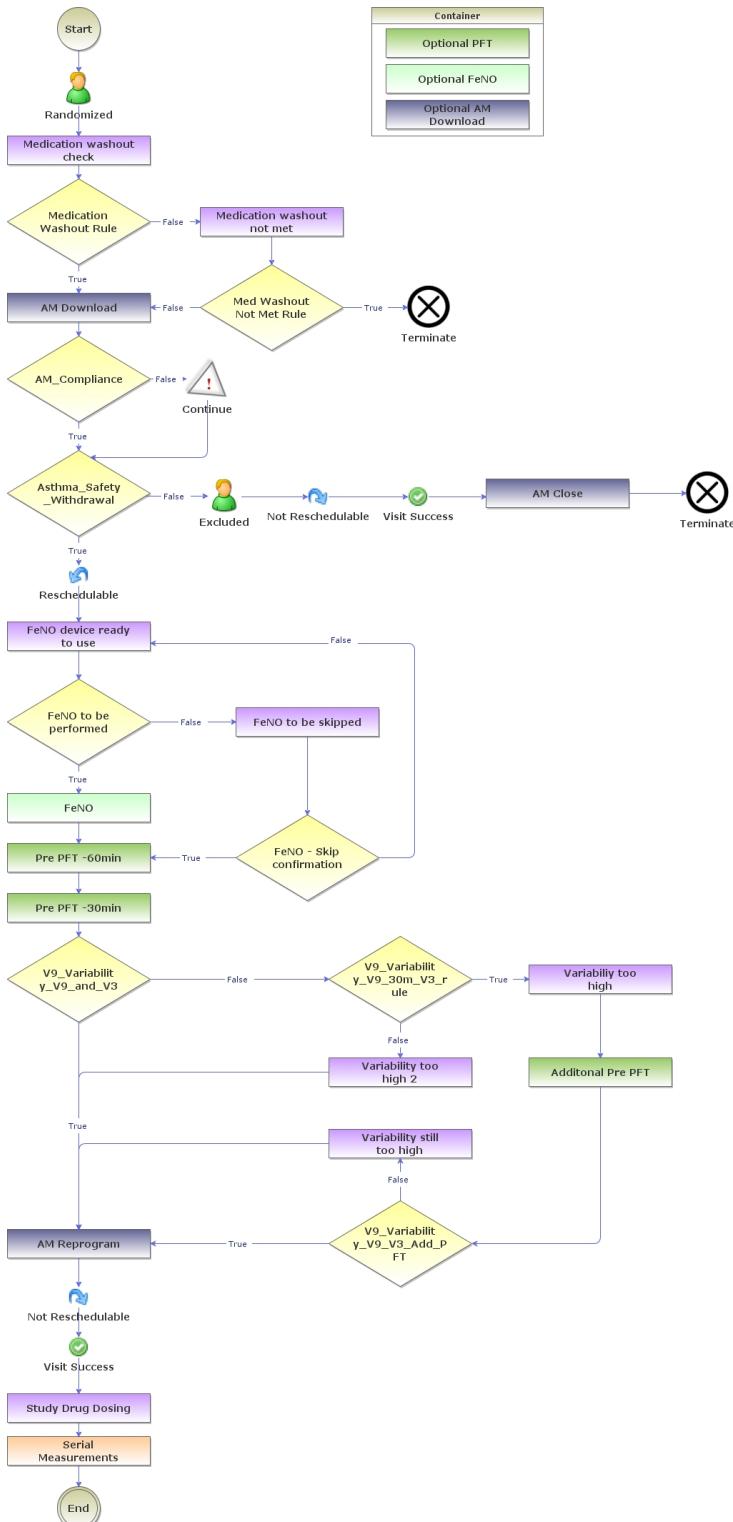
Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
FeNO device ready to use (t5288)	Task	-	No	Yes
Additonal Pre PFT (t5298)	Task	-	No	No
Variabiliy too high (t5301)	Task	-	No	Yes
Variability still too high (t5302)	Task	-	No	Yes
FeNO to be skipped (t5303)	Task	-	No	Yes
Variability too high 2 (t5305)	Task	-	No	Yes

**Timing Rules**

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Pre PFT -30min (t5266)	Current Visit	Pre PFT -60min	30 min	15 min	-	30 min	-
Serial Measurements (t5267)	Current Visit	Study Drug Dosing	-	-	-	-	-
Study Drug Dosing (t5280)	Current Visit	Pre PFT -60min	60 min	-	-	-	-
Additonal Pre PFT (t5298)	Current Visit	Pre PFT -30min	30 min	15 min	-	30 min	-

## **8. Visit Workflow**

8.9 V9



## 8. Visit Workflow

### 8.10 V10

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
Asthma_Safety_Withdraw (R5272)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
Pre PFT -60min (t5265)	Task	-	No	No
Pre PFT -30min (t5266)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Close (t5276)	Task	-	No	No
Study Drug Dosing (t5280)	Task	-	No	Yes
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes
FeNO device ready to use (t5288)	Task	-	No	Yes
FeNO to be skipped (t5303)	Task	-	No	Yes

#### Timing Rules

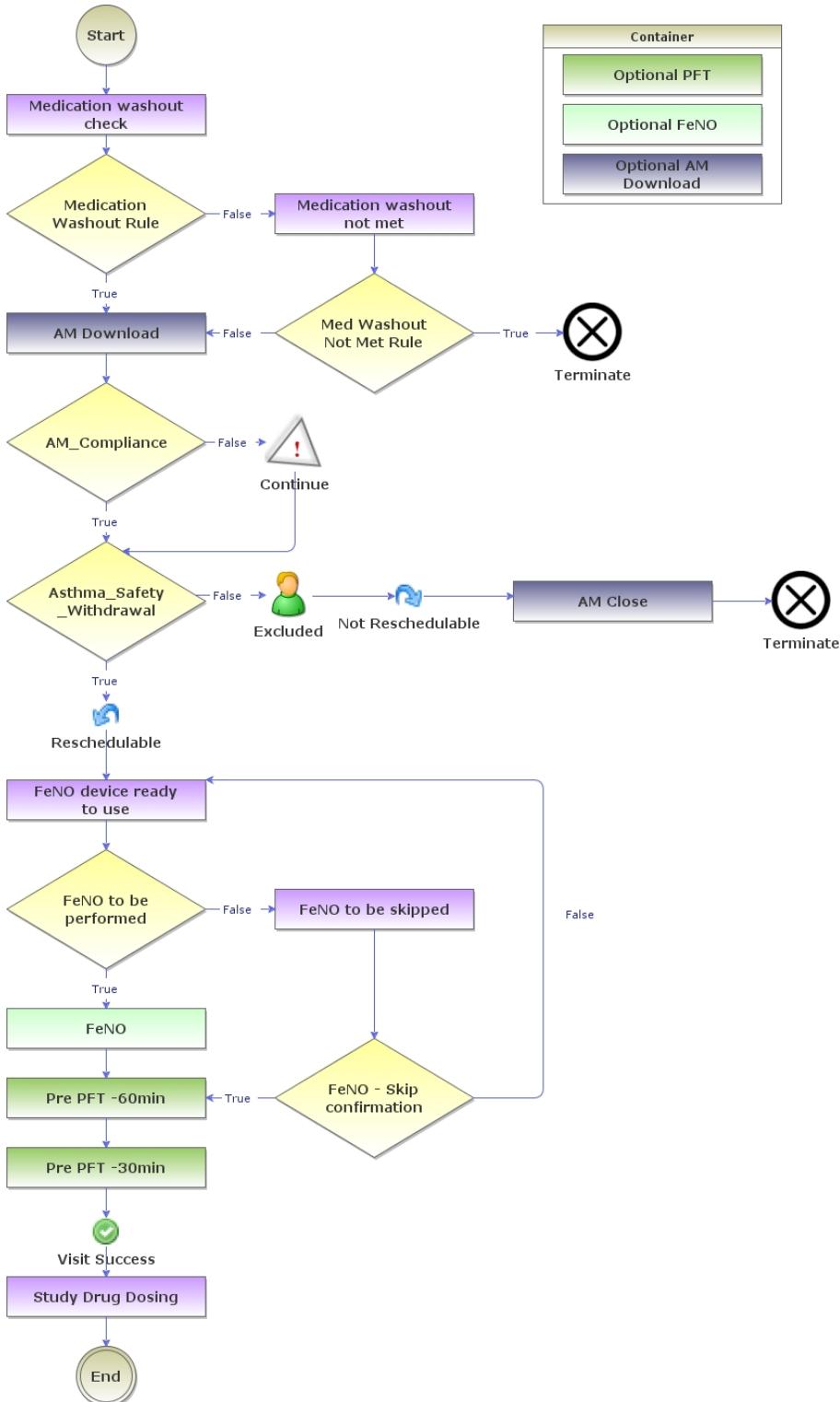
Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Pre PFT -30min (t5266)	Current Visit	Pre PFT -60min	30 min	15 min	-	30 min	-

**8. Visit Workflow****8.10 V10**

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Study Drug Dosing (t5280)	Current Visit	Pre PFT -60min	60 min	-	-	-	-

## 8. Visit Workflow

### 8.10 V10



## 8. Visit Workflow

### 8.11 V11

#### Visit Task Properties

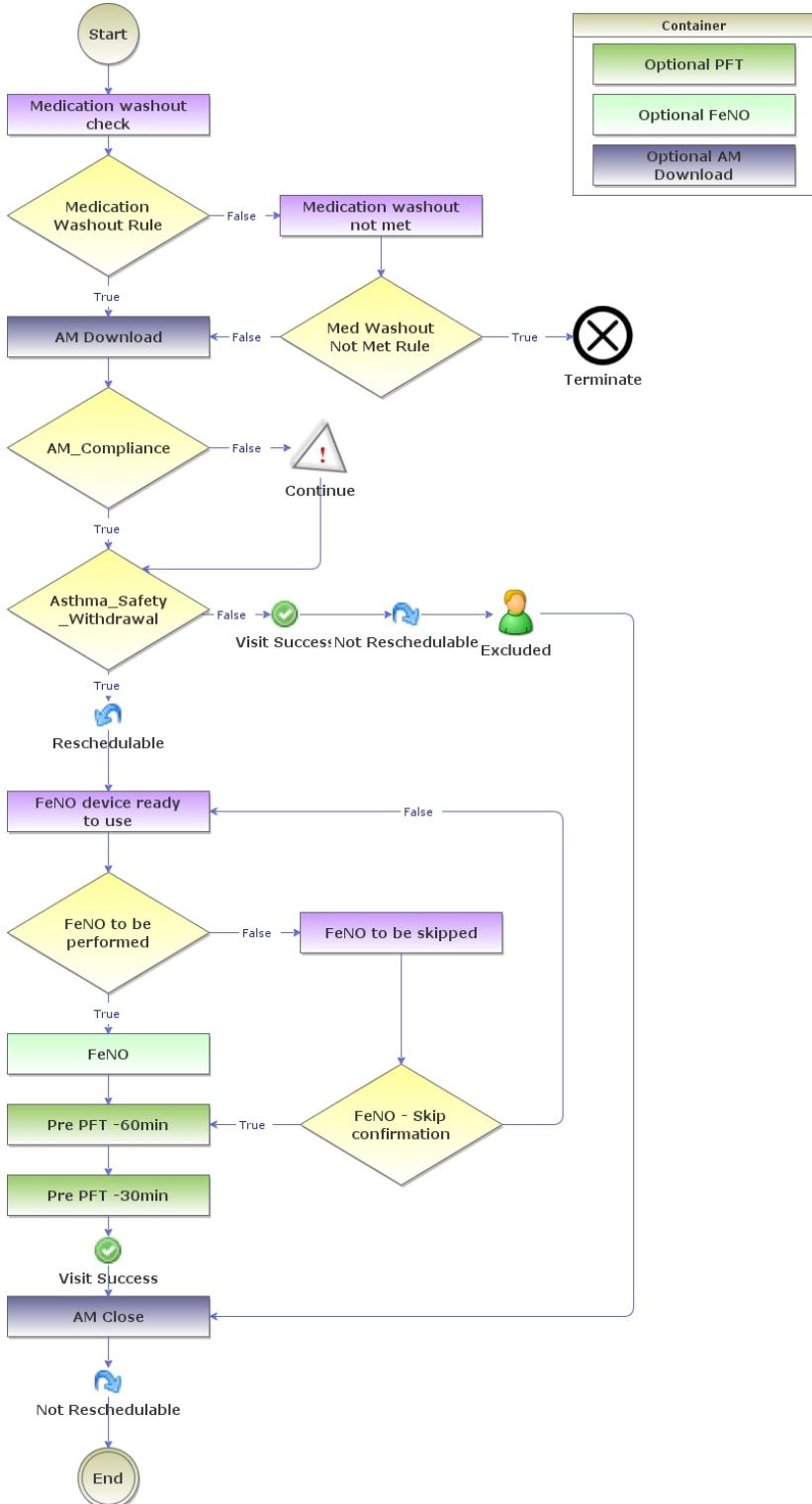
Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
FeNO to be performed (R5221)	Rule	No	-	-
FeNO - Skip confirmation (R5247)	Rule	No	-	-
Asthma_Safety_Withdraw (R5272)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
Pre PFT -60min (t5265)	Task	-	No	No
Pre PFT -30min (t5266)	Task	-	No	No
Optional PFT (t5268)	Task	-	No	No
FeNO (t5270)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
AM Download (t5273)	Task	-	No	Yes
Optional AM Download (t5275)	Task	-	No	No
AM Close (t5276)	Task	-	Yes	No
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes
FeNO device ready to use (t5288)	Task	-	No	Yes
FeNO to be skipped (t5303)	Task	-	No	Yes

#### Timing Rules

Task	Reference Visit	Reference Task	Interval	Hard-	Soft-	Soft+	Hard+
Pre PFT -30min (t5266)	Current Visit	Pre PFT -60min	30 min	15 min	-	30 min	-

## 8. Visit Workflow

### 8.11 V11



## 8. Visit Workflow

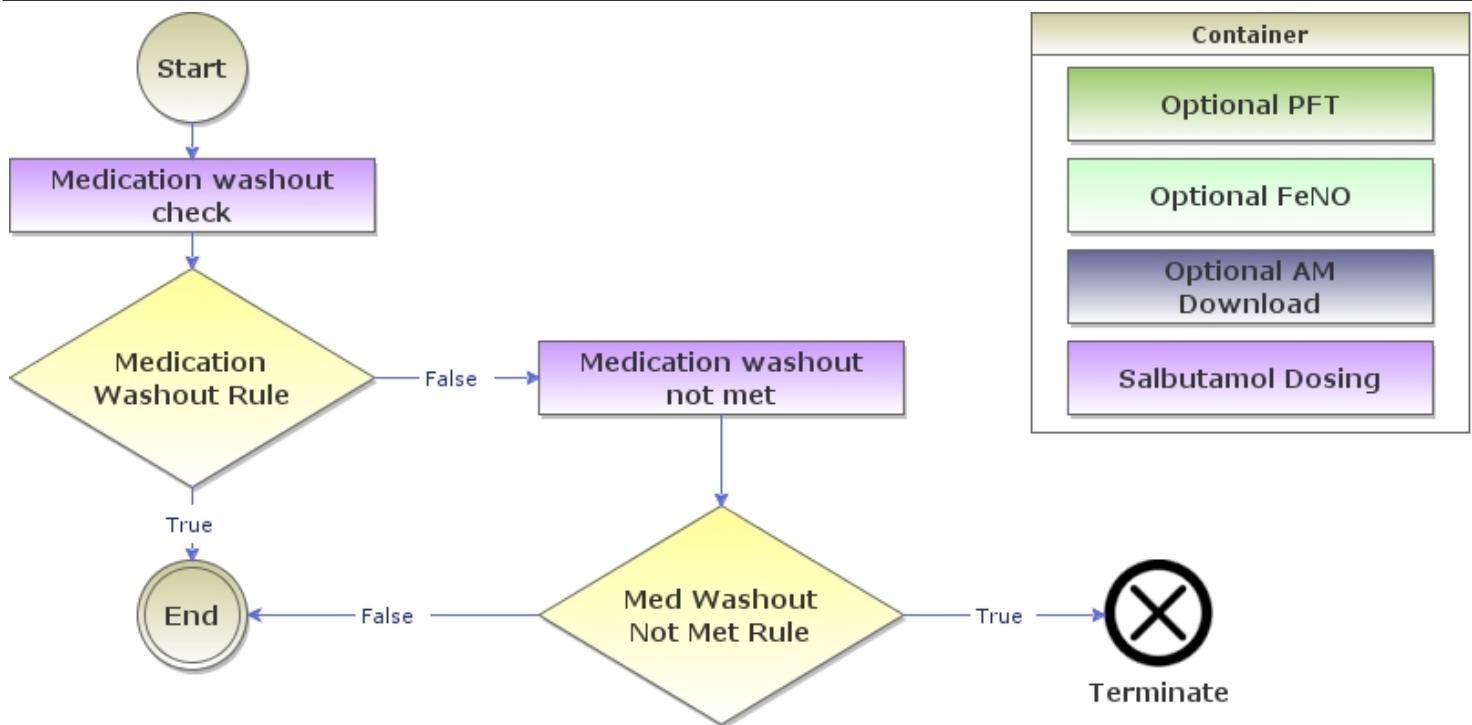
### 8.12 VUNR

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
Optional PFT (t5268)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
Optional AM Download (t5275)	Task	-	No	No
Salbutamol Dosing (t5279)	Task	-	No	No
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes

## 8. Visit Workflow

### 8.12 VUNR



## 8. Visit Workflow

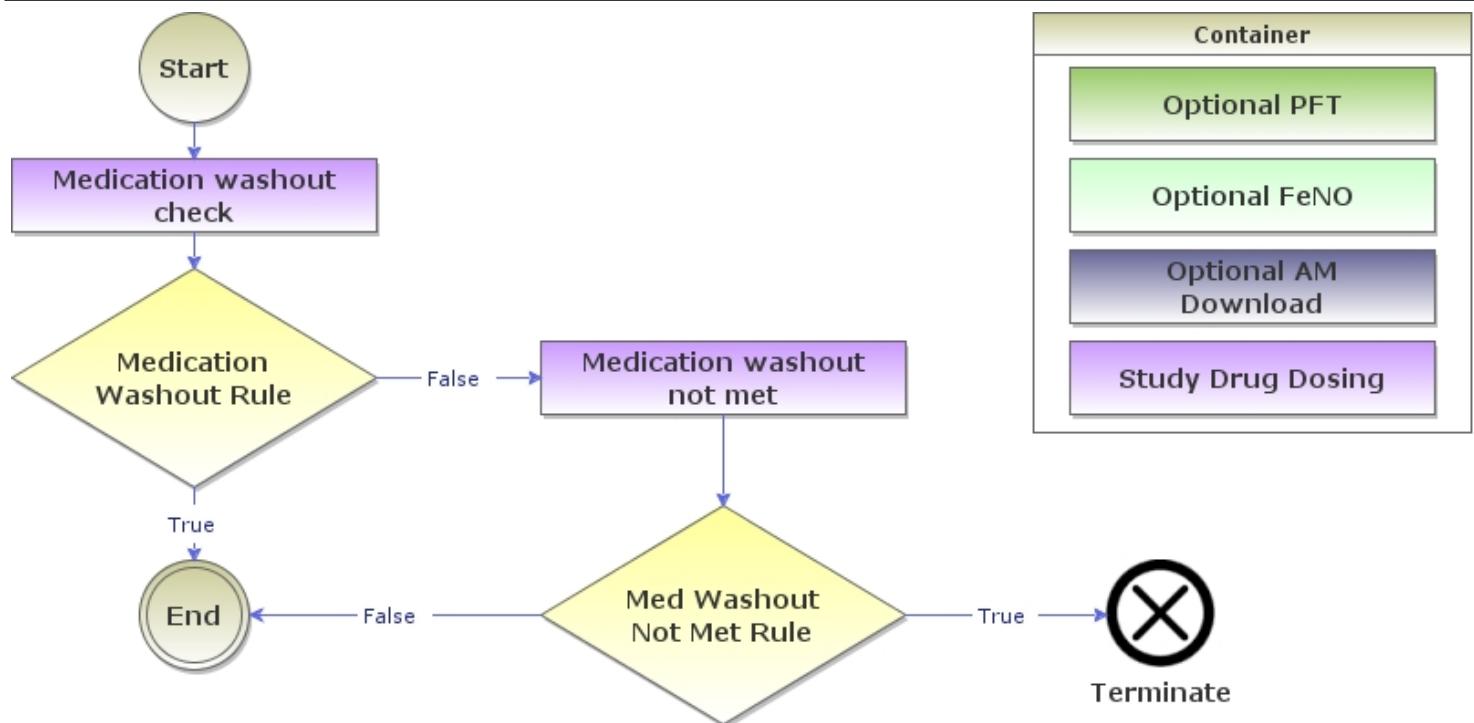
### 8.13 VUNT

#### Visit Task Properties

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Medication Washout Rule (R5212)	Rule	No	-	-
Med Washout Not Met Rule (R5213)	Rule	No	-	-
Optional PFT (t5268)	Task	-	No	No
Optional FeNO (t5271)	Task	-	No	No
Optional AM Download (t5275)	Task	-	No	No
Study Drug Dosing (t5280)	Task	-	No	No
Medication washout check (t5281)	Task	-	No	Yes
Medication washout not met (t5282)	Task	-	No	Yes

## 8. Visit Workflow

### 8.13 VUNT

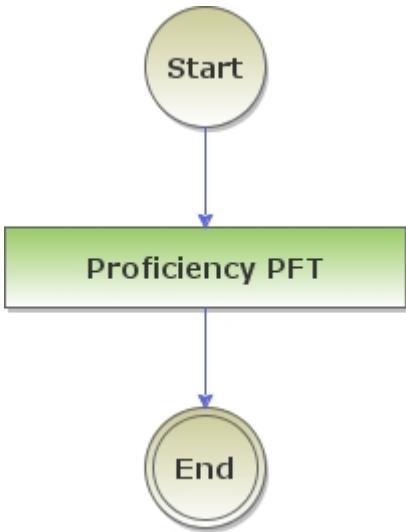


## **8. Visit Workflow**

### **8.14 VPROF**

#### **Visit Task Properties**

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Proficiency PFT (t5269)	Task	-	No	No



## **8. Visit Workflow**

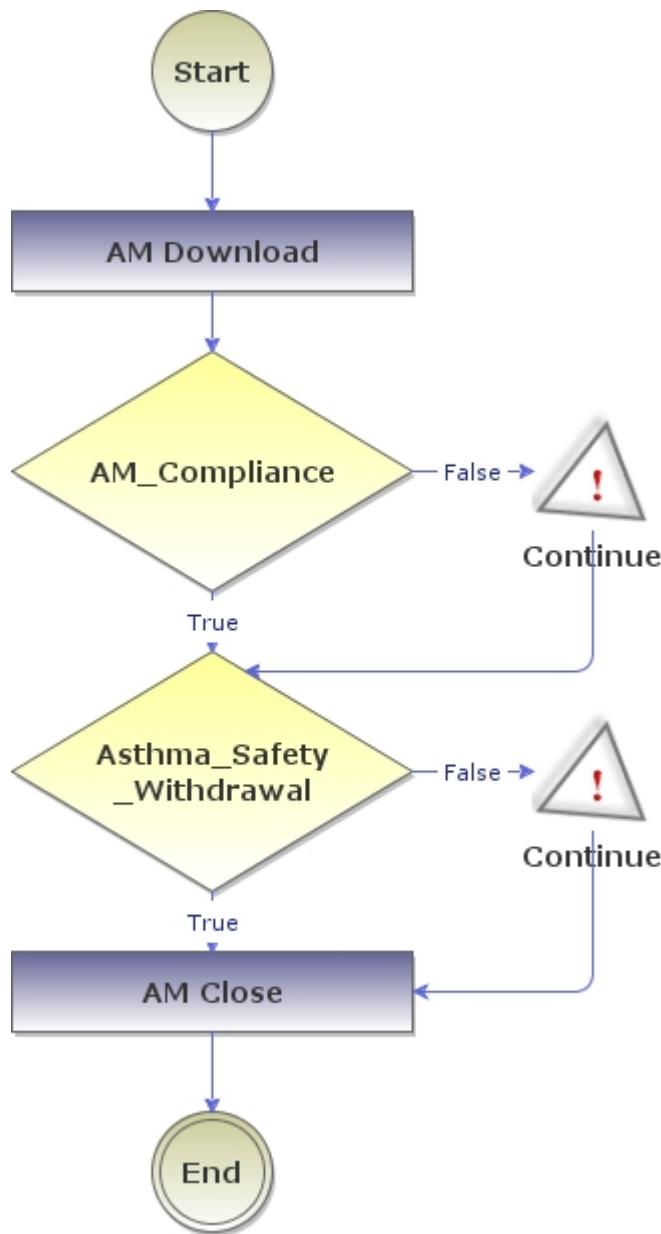
### **8.15 VET**

#### **Visit Task Properties**

Visit Action	Type	Show Result Message	Show task on the next day	Auto start this task
Asthma_Safety_Withdrawal (R5272)	Rule	No	-	-
AM_Compliance (R5276)	Rule	No	-	-
AM Download (t5273)	Task	-	No	Yes
AM Close (t5276)	Task	-	No	No

## 8. Visit Workflow

### 8.15 VET



## 9. Workflow Variables

### 9.1 Reversibilty\_mL (V5094)

The variable calculates the reversibility in mL between the Post PFT and the Pre PFT measurement at Visit 1. The following formula will be used for the calculation:

Reversibility [mL] = Post FEV1 - Pre FEV1

**System:** Backend, MSCCT

**Function:** StudyMathLibrary.ReversibilityInMilliliter

**Rounding:** No decimals

**Used on:** V1

**Parameters:**

**Name:** reversibilityBase

**Type:** Input

**Target:** Relative Task/Pre PFT

**Source:** FEV1

**Name:** compared

**Type:** Input

**Target:** Relative Task/Post PFT

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Inclusion/V1

## 9. Workflow Variables

### 9.2 Reversibility\_percent (V5093)

The variable calculates the reversibility in percent between the Post PFT and the Pre PFT measurement at Visit 1. The following formula will be used for the calculation:

$$\text{Reversibility [%]} = [(\text{Post FEV1} - \text{Pre FEV1}) / \text{Pre FEV1}] * 100.$$

**System:** Backend, MSCCT

**Function:** StudyMathLibrary.ReversibilityInPercent

**Rounding:** 2 decimals

**Used on:** V1

**Parameters:**

**Name:** reversibilityBase

**Type:** Input

**Target:** Relative Task/Pre PFT

**Source:** FEV1

**Name:** compared

**Type:** Input

**Target:** Relative Task/Post PFT

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Inclusion/V1

### 9.3 V3\_PrePFT\_60min\_Precent\_Predicted (V5096)

The variable calculates the percentage of predicted of FEV1 at the selected timepoint.

**System:** MSCCT

**Function:** StudyMathLibrary.PercentOfPredicted

**Rounding:** 2 decimals

**Used on:** V3

**Parameters:**

**Name:** compared

**Type:** Input

**Target:** Relative Task/Pre PFT -60min

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

## 9. Workflow Variables

### 9.4 V3\_PrePFT\_30min\_Precent\_Predicted (V5095)

The variable calculates the percentage of predicted of FEV1 at the selected timepoint.

**System:** MSCCT

**Function:** StudyMathLibrary.PercentOfPredicted

**Rounding:** 2 decimals

**Used on:** V3

**Parameters:**

**Name:** compared

**Type:** Input

**Target:** Relative Task/Pre PFT -30min

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

## 9. Workflow Variables

### 9.5 AM\_DownloadCompliance (V5097)

A scheduled session is considered to be compliant if a complete set of answers and at least 2 PEF measurements are available. The AM3 compliance is defined as the ratio [Number of compliant sessions] / [Number of expected sessions] since the last download at a scheduled visit in percent. In the case V1 was rescheduled, the compliance must be calculated from the dispense day. The AM3 Compliance is calculated precisely and then rounded to the nearest integer. The AM3 compliance is printed on the AM3 data report: Compliance with use of AM3: n%

**System:** MSCCT

**Function:** ComplianceFunctions.StandardCompliance

**Rounding:** No decimals

**Used on:** V10, V11, V2, V3, V4, V5, V6, V7, V8, V9, VET, VUNR, VUNT

**Parameters:**

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V10

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V11

**Name:** result

**Type:** Output

**Target:** Visit/Run In/V2

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V4

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V5

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V7

## 9. Workflow Variables

### 9.5 AM\_DownloadCompliance (V5097)

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V8

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

**Name:** result

**Type:** Output

**Target:** Visit/Termination/VET

**Name:** result

**Type:** Output

**Target:** Visit/Run In/VUNR

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/VUNT

## 9. Workflow Variables

### 9.6 AM\_QuestionAlert1 (V5103)

The variable detects if the AM3 has triggered an alarm because the patient entered  $\geq 12$  puffs (Rescue\_Medication\_Alert\_12\_puffs) on at least 3 consecutive days (Rescue\_Medication\_Alert\_Consecutive\_Days).

**System:** MSCCT

**Function:** AmAlert.QuestionAlert1

**Rounding:** No decimals

**Used on:** V1, V10, V11, V2, V3, V4, V5, V6, V7, V8, V9, VET, VUNR, VUNT

#### Parameters:

**Name:** alertName

**Type:** Input

**Constant:** Rescue Medication usage alert

**Name:** description

**Type:** Input

**Constant:** Daily rescue use of  $\geq 12$  puffs of Salbutamol for  $\geq 3$  consecutive days.

**Name:** shortName

**Type:** Input

**Constant:** QA1

**Name:** refValName

**Type:** Input

**Constant:** Rescue\_Medication\_Alert\_12\_puffs;Rescue\_Medication\_Alert\_Consecutive\_Days

**Name:** relatedQuestions

**Type:** Input

**Constant:** MQ2;EQ2

**Name:** result

**Type:** Output

**Target:** Visit/Inclusion/V1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V10

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V11

**Name:** result

**Type:** Output

**Target:** Visit/Run In/V2

## 9. Workflow Variables

### 9.6 AM\_QuestionAlert1 (V5103)

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V4

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V5

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V7

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V8

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

**Name:** result

**Type:** Output

**Target:** Visit/Termination/VET

**Name:** result

**Type:** Output

**Target:** Visit/Run In/VUNR

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/VUNT

## 9. Workflow Variables

### 9.7 AM\_QuestionAlert1\_triggered (V5107)

The variable defines the threshold when a warning message will be displayed on the MasterScope.  
Threshold for question alert 1 = 1.

**System:** MSCCT

**Function:** StandardWarnings.MoreThanXAlertsSinceLastScheduledVisit

**Rounding:** No decimals

**Used on:** V1, V10, V11, V2, V3, V4, V5, V6, V7, V8, V9, VET, VUNR, VUNT

#### Parameters:

**Name:** param1

**Type:** Input

**Constant:** AM\_QuestionAlert1

**Name:** param2

**Type:** Input

**Constant:** 0

**Name:** param3

**Type:** Input

**Constant:** TO BE FILLED

**Name:** result

**Type:** Output

**Target:** Visit/Inclusion/V1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V10

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V11

**Name:** result

**Type:** Output

**Target:** Visit/Run In/V2

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V4

## 9. Workflow Variables

### 9.7 AM\_QuestionAlert1\_triggered (V5107)

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V5

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V7

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V8

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

**Name:** result

**Type:** Output

**Target:** Visit/Termination/VET

**Name:** result

**Type:** Output

**Target:** Visit/Run In/VUNR

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/VUNT

## 9. Workflow Variables

### 9.8 Rescue\_Medication\_Alert\_Puffs\_Per\_Day (V5104)

The variable determines the threshold for the number of puffs of rescue medication which will trigger the alarm on the AM3.

Daily rescue use [puffs] = (Sum of puffs per day of the last 7 days of the Run-In Period) / 7.

**System:** MSCCT

**Function:** ReferenceValueEvaluation.MeanDailySumScoreLastDays

**Rounding:** No decimals

**Used on:** V3

**Parameters:**

**Name:** refValName

**Type:** Input

**Constant:** Rescue Medication Mean Usage [puffs]

**Name:** dataType

**Type:** Input

**Constant:** INTEGER

**Name:** editable

**Type:** Input

**Constant:** TRUE

**Name:** from

**Type:** Input

**Constant:** 0

**Name:** to

**Type:** Input

**Constant:** 9999

**Name:** preceedingCountOfDays

**Type:** Input

**Constant:** 7

**Name:** includeDownloadDay

**Type:** Input

**Constant:** TRUE

**Name:** questionIds

**Type:** Input

**Constant:** MQ3;EQ2

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

## 9. Workflow Variables

### 9.9 Rescue\_Medication\_Alert\_Consecutive\_Days (V5105)

The variable determines the threshold for the number of consecutive days (3 or more days) of rescue medication usage which will trigger the alarm on the AM3.

**System:** MSCCT

**Function:** ReferenceValueEvaluation.Static

**Rounding:** No decimals

**Used on:** V1, V3

#### Parameters:

**Name:** refValName

**Type:** Input

**Constant:** Rescue Medication Threshold - consecutive days [days]

**Name:** staticValue

**Type:** Input

**Constant:** 3

**Name:** dataType

**Type:** Input

**Constant:** INTEGER

**Name:** editable

**Type:** Input

**Constant:** FALSE

**Name:** from

**Type:** Input

**Constant:** 3

**Name:** to

**Type:** Input

**Constant:** 3

**Name:** result

**Type:** Output

**Target:** Visit/Inclusion/V1

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

## 9. Workflow Variables

### 9.10 Rescue\_Medication\_Alert\_12\_puffs (V5106)

The variable determines the threshold for the maximum number of puffs (12 puffs).

**System:** MSCCT

**Function:** ReferenceValueEvaluation.Static

**Rounding:** No decimals

**Used on:** V1, V3

**Parameters:**

**Name:** refValName

**Type:** Input

**Constant:** Rescue Medication Threshold - Maximum puffs

**Name:** staticValue

**Type:** Input

**Constant:** 12

**Name:** dataType

**Type:** Input

**Constant:** INTEGER

**Name:** editable

**Type:** Input

**Constant:** FALSE

**Name:** from

**Type:** Input

**Constant:** 12

**Name:** to

**Type:** Input

**Constant:** 12

**Name:** result

**Type:** Output

**Target:** Visit/Inclusion/V1

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

## 9. Workflow Variables

### 9.11 V3\_Average\_Pre\_FEV1 (V5108)

Variable calculates the average FEV1 of the Pre PFT -60 min and Pre PFT -30 min measurement.

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "Mean FEV1 [L] = x.xx".

**System:** MSCCT

**Function:** StudyMathLibrary.Mean

**Rounding:** 2 decimals

**Used on:** V3

**Parameters:**

**Name:** first

**Type:** Input

**Target:** Relative Task/Pre PFT -60min

**Source:** FEV1

**Name:** second

**Type:** Input

**Target:** Relative Task/Pre PFT -30min

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

## 9. Workflow Variables

### 9.12 V6\_Average\_Pre\_FEV1 (V5109)

Variable calculates the average FEV1 of the Pre PFT -60 min and Pre PFT -30 min measurement.

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "Mean FEV1 [L] = x.xx".

**System:** MSCCT

**Function:** StudyMathLibrary.Mean

**Rounding:** 2 decimals

**Used on:** V6

**Parameters:**

**Name:** first

**Type:** Input

**Target:** Relative Task/Pre PFT -60min

**Source:** FEV1

**Name:** second

**Type:** Input

**Target:** Relative Task/Pre PFT -30min

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

## 9. Workflow Variables

### 9.13 V6\_Average\_Pre\_FEV1\_Repeat (V5111)

Variable calculates the average FEV1 of the Pre PFT -30 min and Additional Pre PFT measurement.

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "Mean FEV1 [L] = x.xx (Pre PFT -30 min and Add. PFT)".

**System:** MSCCT

**Function:** StudyMathLibrary.Mean

**Rounding:** 2 decimals

**Used on:** V6

**Parameters:**

**Name:** first

**Type:** Input

**Target:** Relative Task/Pre PFT -30min

**Source:** FEV1

**Name:** second

**Type:** Input

**Target:** Relative Task/Additonal Pre PFT

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

## 9. Workflow Variables

### 9.14 V9\_Average\_Pre\_FEV1 (V5110)

Variable calculates the average FEV1 of the Pre PFT -60 min and Pre PFT -30 min measurement.

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "Mean FEV1 [L] = x.xx".

**System:** MSCCT

**Function:** StudyMathLibrary.Mean

**Rounding:** 2 decimals

**Used on:** V9

**Parameters:**

**Name:** first

**Type:** Input

**Target:** Relative Task/Pre PFT -60min

**Source:** FEV1

**Name:** second

**Type:** Input

**Target:** Relative Task/Pre PFT -30min

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

## 9. Workflow Variables

### 9.15 V9\_Average\_Pre\_FEV1\_Repeat (V5112)

Variable calculates the average FEV1 of the Pre PFT -30 min and Additional Pre PFT measurement.

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "Mean FEV1 [L] = x.xx (Pre PFT -30 min and Add. PFT)".

**System:** MSCCT

**Function:** StudyMathLibrary.Mean

**Rounding:** 2 decimals

**Used on:** V9

**Parameters:**

**Name:** first

**Type:** Input

**Target:** Relative Task/Pre PFT -30min

**Source:** FEV1

**Name:** second

**Type:** Input

**Target:** Relative Task/Additonal Pre PFT

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

## 9. Workflow Variables

### 9.16 Variability\_V6\_V3 (V5113)

The variable calculates the variability between the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V6 and the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V3.

Variability [%] = [(Average FEV1 of Pre PFT -60 min and -30 min at V6) - (Average FEV1 of Pre PFT -60 min and -30 min at V3)] / (Average FEV1 of Pre PFT -60 min and -30 min at V3).

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "FEV1 Variability [%] = xx.xx".

**System:** MSCCT

**Function:** StudyMathLibrary.Variability

**Rounding:** 2 decimals

**Used on:** V6

#### Parameters:

**Name:** variabilityBase

**Type:** Input

**Target:** Visit/Randomization/V3

**Source:** V3\_Average\_Pre\_FEV1

**Name:** compared

**Type:** Input

**Target:** Current Visit

**Source:** V6\_Average\_Pre\_FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

## 9. Workflow Variables

### 9.17 Variability\_V6\_30min\_V3 (V5120)

The variable calculates the variability between the average of the Pre PFT -30 min at V6 and the average of the two Pre PFT measurements at V3.

Variability [%] = [(FEV1 of Pre PFT -30 min at V6) - (Average FEV1 of Pre PFT -60 min and -30 min at V3)] / Average FEV1 of Pre PFT -60 min and -30 min at V3).

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "FEV1 Variability [%] = xx.xx (Pre PFT -30 min only)".

**System:** MSCCT

**Function:** StudyMathLibrary.Variability

**Rounding:** 2 decimals

**Used on:** V6

#### Parameters:

**Name:** variabilityBase

**Type:** Input

**Target:** Visit/Randomization/V3

**Source:** V3\_Average\_Pre\_FEV1

**Name:** compared

**Type:** Input

**Target:** Relative Task/Pre PFT -30min

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

## 9. Workflow Variables

### 9.18 Variability\_V6\_V3\_Additional\_PFT (V5114)

The variable calculates the variability between the average of the Pre PFT -30 min and Additional Pre PFT measurement at V6 and the average of the two Pre PFT measurements at V3.

Variability [%] = [(Average FEV1 of Pre PFT -30 min and Add. PFT min at V6) - (Average FEV1 of Pre PFT -60 min and -30 min at V3)] / Average FEV1 of Pre PFT -60 min and -30 min at V3).

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "FEV1 Variability [%] = xx.xx (Pre PFT -30 min and Add. PFT)".

**System:** MSCCT

**Function:** StudyMathLibrary.Variability

**Rounding:** 2 decimals

**Used on:** V6

**Parameters:**

**Name:** variabilityBase

**Type:** Input

**Target:** Visit/Randomization/V3

**Source:** V3\_Average\_Pre\_FEV1

**Name:** compared

**Type:** Input

**Target:** Current Visit

**Source:** V6\_Average\_Pre\_FEV1\_Repeat

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

## 9. Workflow Variables

### 9.19 Variability\_V9\_V3 (V5115)

The variable calculates the variability between the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V9 and the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V3.

Variability [%] = [(Average FEV1 of Pre PFT -60 min and -30 min at V9) - (Average FEV1 of Pre PFT -60 min and -30 min at V3)] / (Average FEV1 of Pre PFT -60 min and -30 min at V3).

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "FEV1 Variability [%] = xx.xx".

**System:** MSCCT

**Function:** StudyMathLibrary.Variability

**Rounding:** 2 decimals

**Used on:** V9

**Parameters:**

**Name:** variabilityBase

**Type:** Input

**Target:** Visit/Randomization/V3

**Source:** V3\_Average\_Pre\_FEV1

**Name:** compared

**Type:** Input

**Target:** Current Visit

**Source:** V9\_Average\_Pre\_FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

## 9. Workflow Variables

### 9.20 Variability\_V9\_30min\_V3 (V5121)

The variable calculates the variability between the Pre PFT -30 min at V9 and the average of the two Pre PFT measurements at V3.

Variability [%] = [(FEV1 of Pre PFT -30 min at V9) - (Average FEV1 of Pre PFT -60 min and -30 min at V3)] / Average FEV1 of Pre PFT -60 min and -30 min at V3).

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "Mean FEV1 [L] = x.xx (Pre PFT -30 min only)".

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "FEV1 Variability [%] = xx.xx (Pre PFT -30 min only)".

**System:** MSCCT

**Function:** StudyMathLibrary.Variability

**Rounding:** 2 decimals

**Used on:** V9

**Parameters:**

**Name:** variabilityBase

**Type:** Input

**Target:** Visit/Randomization/V3

**Source:** V3\_Average\_Pre\_FEV1

**Name:** compared

**Type:** Input

**Target:** Relative Task/Pre PFT -30min

**Source:** FEV1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

## 9. Workflow Variables

### 9.21 Variability\_V9\_V3\_Additional\_PFT (V5116)

The variable calculates the variability between the average of the Pre PFT -30 min and Additional Pre PFT measurement at V9 and the average of the two Pre PFT measurements at V3.

Variability [%] = [(Average FEV1 of Pre PFT -30 min and Add. PFT min at V9) - (Average FEV1 of Pre PFT -60 min and -30 min at V3)] / Average FEV1 of Pre PFT -60 min and -30 min at V3).

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "FEV1 Variability [%] = xx.xx (Pre PFT -30 min and Add. PFT)".

**System:** MSCCT

**Function:** StudyMathLibrary.Variability

**Rounding:** 2 decimals

**Used on:** V9

**Parameters:**

**Name:** variabilityBase

**Type:** Input

**Target:** Visit/Randomization/V3

**Source:** V3\_Average\_Pre\_FEV1

**Name:** compared

**Type:** Input

**Target:** Current Visit

**Source:** V9\_Average\_Pre\_FEV1\_Repeat

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

## 9. Workflow Variables

### 9.22 PEF\_Stability\_Limit (V5117)

The variable calculates the PEF stability limit for the Treatment and Follow-up Period. The stability limit will be calculated as 70% of the mean value of all available best morning PEF values obtained in morning sessions from the last 7 days of the Run-In Period (Visit day included).

**System:** MSCCT

**Function:** ReferenceValueEvaluation.MeasurementMeanLastDays

**Rounding:** 1 decimal

**Used on:** V3

**Parameters:**

**Name:** sessionType

**Type:** Input

**Constant:** MorningSession

**Name:** lastDays

**Type:** Input

**Constant:** TRUE

**Name:** questionConditions

**Type:** Input

**Constant:** MQ1>=0

**Name:** requiredNumberOfValidManeuvers

**Type:** Input

**Constant:** 1

**Name:** refValName

**Type:** Input

**Constant:** PEF Stability Limit

**Name:** dataType

**Type:** Input

**Constant:** DECIMAL(1)

**Name:** editable

**Type:** Input

**Constant:** TRUE

**Name:** calcType

**Type:** Input

**Constant:** MAXIMUM

**Name:** from

**Type:** Input

**Constant:** 0

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## 9. Workflow Variables

### 9.22 PEF\_Stability\_Limit (V5117)

**Name:** scaleFactor

**Type:** Input

**Constant:** 0.7

**Name:** to

**Type:** Input

**Constant:** 9999

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

## 9. Workflow Variables

### 9.23 AM\_MeasurementAlert1 (V5118)

The variable detects if the AM3 has triggered an alarm because the best morning PEF has dropped below the PEF Stability Limit on at least 3 consecutive days after randomization.

**System:** MSCCT

**Function:** AmAlert.MeasurementAlert1

**Rounding:** No decimals

**Used on:** V10, V11, V4, V5, V6, V7, V8, V9, VET, VUNT

**Parameters:**

**Name:** alertName

**Type:** Input

**Constant:** PEF below stability limit

**Name:** description

**Type:** Input

**Constant:** PEF below stability limit

**Name:** shortName

**Type:** Input

**Constant:** MA1

**Name:** refValName

**Type:** Input

**Constant:** PEF\_Stability\_Limit

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V10

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V11

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V4

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V5

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

## 9. Workflow Variables

### 9.23 AM\_MeasurementAlert1 (V5118)

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V7

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V8

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

**Name:** result

**Type:** Output

**Target:** Visit/Termination/VET

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/VUNT

## 9. Workflow Variables

### 9.24 AM\_MeasurementAlert1\_triggered (V5119)

The variable defines the threshold when a warning message will be displayed on the MasterScope.

Threshold for measurement alert 1 = 1.

**System:** MSCCT

**Function:** StandardWarnings.MoreThanXAlertsSinceLastScheduledVisit

**Rounding:** No decimals

**Used on:** V10, V11, V4, V5, V6, V7, V8, V9, VET, VUNT

**Parameters:**

**Name:** param1

**Type:** Input

**Constant:** AM\_MeasurementAlert1

**Name:** param2

**Type:** Input

**Constant:** 0

**Name:** param3

**Type:** Input

**Constant:** The patient experienced a significant drop of PEF for at least 3 consecutive days. Please check withdrawal criterion has been met.

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V10

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V11

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V4

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V5

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

## 9. Workflow Variables

### 9.24 AM\_MeasurementAlert1\_triggered (V5119)

Name: result

Type: Output

Target: Visit/Treatment/V7

Name: result

Type: Output

Target: Visit/Treatment/V8

Name: result

Type: Output

Target: Visit/Treatment/V9

Name: result

Type: Output

Target: Visit/Termination/VET

Name: result

Type: Output

Target: Visit/Treatment/VUNT

## 9. Workflow Variables

### 9.25 ACQ5\_Score (V5123)

Variable calculates the ACQ5 score of the downloaded ACQ5 questionnaire. Only the ACQ5 questionnaire of the download day will be taken into account.

The assessed value will be displayed on the visit summary screen as well as on the AM3 report as "ACQ5 Score = x.x".

**System:** MSCCT

**Function:** MedicationCompliance.AcqScoreDownloadDay

**Rounding:** 1 decimal

**Used on:** V1, V10, V11, V2, V3, V4, V5, V6, V7, V8, V9, VET, VUNR, VUNT

**Parameters:**

**Name:** questionIds

**Type:** Input

**Constant:** ACQ5\_Q1;ACQ5\_Q2;ACQ5\_Q3;ACQ5\_Q4;ACQ5\_Q5

**Name:** result

**Type:** Output

**Target:** Visit/Inclusion/V1

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V10

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V11

**Name:** result

**Type:** Output

**Target:** Visit/Run In/V2

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V4

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V5

## 9. Workflow Variables

### 9.25 ACQ5\_Score (V5123)

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V7

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V8

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

**Name:** result

**Type:** Output

**Target:** Visit/Termination/VET

**Name:** result

**Type:** Output

**Target:** Visit/Run In/VUNR

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/VUNT

### 9.26 AM\_Dispensed (V5129)

Variable checks if AM has been dispensed at V1.

**System:** MSCCT

**Function:** AMLibrary.AmIsDispensedForSubjectMethodDef

**Rounding:** No decimals

**Used on:** V1

#### Parameters:

**Name:** alias1

**Type:** Input

**Name:** result

**Type:** Output

**Target:** Visit/Inclusion/V1

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## 9. Workflow Variables

### 9.27 AM\_QuestionAlert2 (V5130)

The variable detects if the AM3 has triggered an alarm because the patient entered  $\geq 8$  puffs over baseline usage (Rescue\_Medication\_Alert\_Puffs\_Per\_Day) on at least 3 consecutive days (Rescue\_Medication\_Alert\_Consecutive\_Days).

**System:** MSCCT

**Function:** AmAlert.QuestionAlert2

**Rounding:** No decimals

**Used on:** V10, V11, V4, V5, V6, V7, V8, V9, VET, VUNT

**Parameters:**

**Name:** alertName

**Type:** Input

**Constant:** Rescue Medication usage alert

**Name:** description

**Type:** Input

**Constant:** Daily rescue use of 8 or more puffs over baseline use on  $\geq 3$  consecutive days.

**Name:** shortName

**Type:** Input

**Constant:** QA2

**Name:** refValName

**Type:** Input

**Constant:** Rescue\_Medication\_Alert\_Puffs\_Per\_Day;Rescue\_Medication\_Alert\_Consecutive\_Days

**Name:** relatedQuestions

**Type:** Input

**Constant:** MQ2;EQ2

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V10

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V11

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V4

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V5

## 9. Workflow Variables

### 9.27 AM\_QuestionAlert2 (V5130)

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V7

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V8

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

**Name:** result

**Type:** Output

**Target:** Visit/Termination/VET

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/VUNT

## 9. Workflow Variables

### 9.28 AM\_QuestionAlert2\_triggered (V5131)

The variable defines the threshold when a warning message will be displayed on the MasterScope. Threshold for measurement alert 1 = 1.

**System:** MSCCT

**Function:** StandardWarnings.MoreThanXAlertsSinceLastScheduledVisit

**Rounding:** No decimals

**Used on:** V10, V11, V4, V5, V6, V7, V8, V9, VET, VUNT

**Parameters:**

**Name:** param1

**Type:** Input

**Constant:** AM\_QuestionAlert2

**Name:** param2

**Type:** Input

**Constant:** 0

**Name:** param3

**Type:** Input

**Constant:** TO BE FILLED

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V10

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V11

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V4

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V5

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V6

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V7

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## 9. Workflow Variables

### 9.28 AM\_QuestionAlert2\_triggered (V5131)

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V8

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V9

**Name:** result

**Type:** Output

**Target:** Visit/Termination/VET

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/VUNT

### 9.29 V3\_PrePFT\_Precent\_Predicted\_Mean (V5138)

Variable calculates the average %predicted FEV1 of the Pre PFT -60 min and Pre PFT -30 min measurement.

The assessed value will be displayed on the visit summary screen as well as on the PFT report as "Mean %predFEV1 [%] = xx.xx".

**System:** MSCCT

**Function:** StudyMathLibrary.Mean

**Rounding:** 2 decimals

**Used on:** V3

#### Parameters:

**Name:** first

**Type:** Input

**Target:** Current Visit

**Source:** V3\_PrePFT\_60min\_Precent\_Predicted

**Name:** second

**Type:** Input

**Target:** Current Visit

**Source:** V3\_PrePFT\_30min\_Precent\_Predicted

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

## 9. Workflow Variables

### 9.30 V1\_V3\_AM\_Compliance (V5161)

Variable will detect the AM compliance during the entire Run-In Period (V1 to V3).

The assessed value will be displayed on the visit summary screen as well as on the AM3 report as "AM3 Run-In Compliance [%] = xx".

**System:** MSCCT

**Function:** MedicationCompliance.ComplianceSinceSpecificPrecedingVisit

**Rounding:** No decimals

**Used on:** V3

**Parameters:**

**Name:** precedingVisitOids

**Type:** Input

**Constant:** SE\_VISIT\_V1

**Name:** result

**Type:** Output

**Target:** Visit/Randomization/V3

## 9. Workflow Variables

### 9.31 Study\_medication\_compliance\_TP1 (V5122)

The study medication compliance will be calculated for MQ5 for all periods. Study medication compliance is defined as:

$$(\text{TOTAL NUMBER OF ADMINISTERED DOSES}) / (\text{TOTAL NUMBER OF SCHEDULED DOSES}) * 100 = \% \text{ OF ADMINISTERED DRUG.}$$

The expected dose for a visit day is 2.

The starting point for the study medication compliance is the first day of treatment period 1 (V3) until the last day of the treatment period 1 (V5).

Clinic visit days will be not taken into account for the medication compliance calculation. For missing answers due to missing sessions, an answer of 0 puffs will be taken into account. The compliance will be calculated precisely and then be rounded to the nearest integer.

The study medication compliance will be printed on the AM3 data report: "Study medication compliance: n%."

**System:** MSCCT

**Function:** MedicationCompliance.SessionDosingComplianceSinceSpecificPrecedingVisit

**Rounding:** No decimals

**Used on:** V4, V5, VET, VUNT

**Parameters:**

**Name:** sessionDoseInhalerQuestion

**Type:** Input

**Constant:** MQ5

**Name:** expectedDosingPerSession

**Type:** Input

**Constant:** 2

**Name:** includeDownloadDaySession

**Type:** Input

**Constant:** False

**Name:** includeLastVisitDaySession

**Type:** Input

**Constant:** False

**Name:** omitBetweenScheduledDownloadDays

**Type:** Input

**Constant:** True

**Name:** precedingVisitOids

**Type:** Input

**Constant:** SE\_VISIT\_V3

**Name:** result

**Type:** Output

**Target:** Visit/Treatment/V4

## 9. Workflow Variables

### 9.31 Study\_medication\_compliance\_TP1 (V5122)

Name: result

Type: Output

Target: Visit/Treatment/V5

Name: result

Type: Output

Target: Visit/Termination/VET

Name: result

Type: Output

Target: Visit/Treatment/VUNT

## 9. Workflow Variables

### 9.32 Study\_medication\_compliance\_TP2 (V5172)

The study medication compliance will be calculated for MQ5 for all periods.

Study medication compliance is defined as: (TOTAL NUMBER OF ADMINISTERED DOSES) / (TOTAL NUMBER OF SCHEDULED DOSES) \* 100 = % OF ADMINISTERED DRUG.

The expected dose for a visit day is 2.

The starting point for the study medication compliance is the first day of treatment period 2 (V6) until the last day of the treatment period 2 (V8). Clinic visit days will be not taken into account for the medication compliance calculation.

For missing answers due to missing sessions, an answer of 0 puffs will be taken into account.

The compliance will be calculated precisely and then be rounded to the nearest integer. The study medication compliance will be printed on the AM3 data report: "Study medication compliance: n%."

**System:** MSCCT

**Function:** MedicationCompliance.SessionDosingComplianceSinceSpecificPrecedingVisit

**Rounding:** No decimals

**Used on:** V7, V8, VET, VUNT

**Parameters:**

**Name:** sessionDoseInhalerQuestion

**Type:** Input

**Constant:** MQ5

**Name:** expectedDosingPerSession

**Type:** Input

**Constant:** 2

**Name:** includeDownloadDaySession

**Type:** Input

**Constant:** False

**Name:** includeLastVisitDaySession

**Type:** Input

**Constant:** False

**Name:** omitBetweenScheduledDownloadDays

**Type:** Input

**Constant:** False

**Name:** precedingVisitOids

**Type:** Input

**Constant:** SE\_VISIT\_V6

## 9. Workflow Variables

### 9.32 Study\_medication\_compliance\_TP2 (V5172)

Name: result

Type: Output

Target: Visit/Treatment/V7

Name: result

Type: Output

Target: Visit/Treatment/V8

Name: result

Type: Output

Target: Visit/Termination/VET

Name: result

Type: Output

Target: Visit/Treatment/VUNT

## 9. Workflow Variables

### 9.33 Study\_medication\_compliance\_TP3 (V5173)

The study medication compliance will be calculated for MQ5 for all periods.

Study medication compliance is defined as: (TOTAL NUMBER OF ADMINISTERED DOSES) / (TOTAL NUMBER OF SCHEDULED DOSES) \* 100 = % OF ADMINISTERED DRUG.

The expected dose for a visit day is 2.

The starting point for the study medication compliance is the first day of treatment period 3 (V9) until the last day of the treatment period 3 (V11). Clinic visit days will be not taken into account for the medication compliance calculation.

For missing answers due to missing sessions, an answer of 0 puffs will be taken into account.

The compliance will be calculated precisely and then be rounded to the nearest integer. The study medication compliance will be printed on the AM3 data report: "Study medication compliance: n%."

**System:** MSCCT

**Function:** MedicationCompliance.SessionDosingComplianceSinceSpecificPrecedingVisit

**Rounding:** No decimals

**Used on:** V10, V11, VET, VUNT

**Parameters:**

**Name:** sessionDoseInhalerQuestion

**Type:** Input

**Constant:** MQ5

**Name:** expectedDosingPerSession

**Type:** Input

**Constant:** 2

**Name:** includeDownloadDaySession

**Type:** Input

**Constant:** False

**Name:** includeLastVisitDaySession

**Type:** Input

**Constant:** False

**Name:** omitBetweenScheduledDownloadDays

**Type:** Input

**Constant:** True

**Name:** precedingVisitOids

**Type:** Input

**Constant:** SE\_VISIT\_V9

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## 9. Workflow Variables

### 9.33 Study\_medication\_compliance\_TP3 (V5173)

Name: result

Type: Output

Target: Visit/Treatment/V10

Name: result

Type: Output

Target: Visit/Treatment/V11

Name: result

Type: Output

Target: Visit/Termination/VET

Name: result

Type: Output

Target: Visit/Treatment/VUNT

## 10. Workflow Rules

### 10.1 V1\_Reversibility\_in\_Percent\_SR (R5203)

The rule detects if the FEV1 reversibility is greater or equal to 12.00% at V1.

Reversibility [%] = [(Post FEV1 - Pre FEV1) / Pre FEV1] \* 100

**Visit(s):** V1

**System:** Backend, MSCCT

**Action:** Inclusion

**Type:** Soft

**Expression:** [Forced Spirometry] [Current Visit] Reversibility\_percent >= 12

**Variables:** Reversibility\_percent

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is True:** FEV1 reversibility is >= 12.00%.

**Message if condition is False:** FEV1 reversibility must be >= 12.00%.

### 10.2 V1\_Reversibility\_in\_mL\_SR (R5232)

The rule detects if the FEV1 reversibility is greater or equal to 200 mL at V1. Reversibility [mL] = Post FEV1 - Pre FEV1

**Visit(s):** V1

**System:** Backend, MSCCT

**Action:** Inclusion

**Type:** Soft

**Expression:** [Current Visit] Reversibilty\_mL >= 200

**Variables:** Reversibilty\_mL

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is True:** FEV1 reversibility is >= 200 mL.

**Message if condition is False:** FEV1 reversibility must be >= 200 mL.

## 10. Workflow Rules

### 10.3 V1\_Reversibility (R5204)

The rule determines if sub rules (V1\_Reversibility\_in\_percent\_SR and V1\_Reversibility\_in\_mL\_SR ; FEV1 reversibility >=12% and 200 mL) have been met and adds a overall message to the resulting message.

**Visit(s):** V1

**System:** Backend, MSCCT

**Action:** Inclusion

**Type:** Soft

**Expression:** [Forced Spirometry] [Sub Rules] V1\_Reversibility\_in\_Percent\_SR = true AND [Forced Spirometry] [Sub Rules] V1\_Reversibility\_in\_mL\_SR = true

**Treat Undefined as True:** No

**Message if condition is True:** The patient meets the reversibility inclusion criterion based on the Pre and Post PFT measurements, because:

**Message if condition is False:** The patient does not meet the reversibility inclusion criterion based on the Pre and Post PFT measurements, because:

### 10.4 V1\_Inclusion\_Question\_Rule (R5214)

The rule detects the answer to the "Inclusion" question. If the question is answered with "Yes" the patient can continue, if the answer is "No" the workflow returns to the "Inclusion" step.

**Visit(s):** V1

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Hard

**Expression:** [Relative Task/Inclusion] YESNO.YES = true

**Treat Undefined as True:** No

### 10.5 V2\_ACQ5\_Rule (R5244)

The rule determines if sub rule (ACQ5\_Rule\_SR) has been met and adds a overall message to the resulting message.

**Visit(s):** V2

**System:** Backend, MSCCT

**Action:** Inclusion

**Type:** Hard

**Expression:** [COA - AM] [Sub Rules] V2\_ACQ5\_Rule\_SR = true

**Treat Undefined as True:** No

**Message if condition is True:** The patient meets ACQ inclusion criteria, because:

**Message if condition is False:** The patient does not meet ACQ inclusion criteria, because:

## 10. Workflow Rules

### 10.6 V2\_ACQ5\_Rule\_SR (R5243)

The rule checks if the ACQ5 value is <= 1.5.

**Visit(s):** V2

**System:** Backend, MSCCT

**Action:** Inclusion

**Type:** Hard

**Expression:** [Current Visit] ACQ5\_Score <= 1.5

**Variables:** ACQ5\_Score

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is True:** ACQ5 score is <= 1.5.

**Message if condition is False:** ACQ5 score should be <= 1.5.

### 10.7 V3\_Predicted\_FEV1\_average (R5209)

The rule determines if sub rule (V3\_Predicted\_FEV1\_average\_SR, %predicted FEV1 >= 40.00% and <= 85.00%) has been met and adds a head line to the resulting message.

**Visit(s):** V3

**System:** Backend, MSCCT

**Action:** Randomization

**Type:** Hard

**Expression:** [Forced Spirometry] [Sub Rules] V3\_Predicted\_FEV1\_average\_SR = true

**Treat Undefined as True:** No

**Message if condition is True:** The patient meets inclusion criterion for the Pre PFT measurements, because:

**Message if condition is False:** The patient does not meet inclusion criterion for the Pre PFT measurements, because:

## 10. Workflow Rules

### 10.8 V3\_Predicted\_FEV1\_average\_SR (R5207)

The rule determines if the average FEV1 percent predicted of the Pre PFT -60 min and -30 min measurement is between  $\geq 40.00\%$  and  $\leq 85.00\%$ .

**Visit(s):** V3

**System:** Backend, MSCCT

**Action:** Randomization

**Type:** Hard

**Expression:** [Forced Spirometry] [Current Visit] V3\_PrePFT\_Precent\_Predicted\_Mean  $\geq 40.00$  AND [Forced Spirometry] [Current Visit] V3\_PrePFT\_Precent\_Predicted\_Mean  $\leq 85.00$

**Variables:** V3\_PrePFT\_Precent\_Predicted\_Mean

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is True:** Average Percent Predicted FEV1 is within  $\geq 40.00\%$  and  $\leq 85.00\%$  of the predicted value.

**Message if condition is False:** Average Percent Predicted FEV1 is either  $< 40.00\%$  or  $> 85.00\%$  of the predicted value.

### 10.9 V3\_Randomization\_Question\_Rule (R5216)

The rule detects the answer to the "Randomization" question. If the question is answered with "Yes" the patient can continue, if the answer is "No" the workflow returns to the "Randomization" step.

**Visit(s):** V3

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Soft

**Expression:** [Relative Task/Randomization] YESNO.YES = true

**Treat Undefined as True:** No

### 10.10 V3\_FeNO (R5227)

The rule determines if sub rule (V3\_FeNO\_SR) has been met and adds a overall message to the resulting message.

**Visit(s):** V3

**System:** Backend, MSCCT

**Action:** Randomization

**Type:** Hard

**Expression:** [FeNO] [Sub Rules] V3\_FeNO\_SR = true

**Treat Undefined as True:** No

**Message if condition is True:** The patient meets randomization criterion for the FeNO measurement, because:

**Message if condition is False:** The patient does not meet randomization criterion for the FeNO measurement, because:

## 10. Workflow Rules

### 10.11 V3\_FeNO\_SR (R5226)

The rule detects if the FeNO value is >= 25 ppb.

**Visit(s):** V3

**System:** Backend, MSCCT

**Action:** Inclusion

**Type:** Hard

**Expression:** [FeNO] [Relative Task/FeNO] FeNO >= 25

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is True:** FeNO is >= 25 ppb.

**Message if condition is False:** FeNO must be >= 25 ppb.

### 10.12 Medication Washout Rule (R5212)

The rule detects the answer to the "Medication Washout" question. If the question is answered with "Yes" the patient can continue, if the answer is "No" the workflow returns to the starting point.

**Visit(s):** V1, V10, V11, V2, V3, V4, V5, V6, V7, V8, V9, VUNR, VUNT

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Soft

**Expression:** [Forced Spirometry] [Relative Task/Medication\_washout\_check] NOYES.NO = true

**Treat Undefined as True:** No

### 10.13 Med Washout Not Met Rule (R5213)

If the "Medication Washout" question has been answered with "No", the "Medication Washout Not Met" message will be displayed. By clicking on "Continue" the patient can continue anyway, if the answer is "No" the workflow returns to the starting point.

**Visit(s):** V1, V10, V11, V2, V3, V4, V5, V6, V7, V8, V9, VUNR, VUNT

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Soft

**Expression:** [Relative Task/Medication\_washout\_not\_met] CONTINUECANCEL.CANCEL = true

**Treat Undefined as True:** No

## 10. Workflow Rules

### 10.14 V6\_Variability\_V6\_and\_V3 (R5235)

The rule identifies if the variability between the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V6 and the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V3 is within 20.00%.

**Visit(s):** V6

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Hard

**Expression:** [Forced Spirometry] [Current Visit] Variability\_V6\_V3 <= 20.00 AND [Forced Spirometry] [Current Visit] Variability\_V6\_V3 >= -20.00

**Variables:** Variability\_V6\_V3

**Treat Undefined as True:** No

### 10.15 V6\_Variability\_V6\_30m\_V3\_rule (R5241)

The rule identifies if the variability between Pre PFT -30 min at V6 and the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V3 is within 20.00%.

**Visit(s):** V6

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Hard

**Expression:** [Forced Spirometry] [Current Visit] Variability\_V6\_30min\_V3 <= 20.00 AND [Forced Spirometry] [Current Visit] Variability\_V6\_30min\_V3 >= -20.00

**Variables:** Variability\_V6\_30min\_V3

**Treat Undefined as True:** No

### 10.16 V6\_Variability\_V6\_V3\_Add\_PFT (R5236)

The rule identifies if the variability between the average of the Pre PFT -30 min and Additional Pre PFT measurement at V6 and the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V3 is within 20.00%.

**Visit(s):** V6

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Hard

**Expression:** [Forced Spirometry] [Current Visit] Variability\_V6\_V3\_Additional\_PFT <= 20.00 AND [Forced Spirometry] [Current Visit] Variability\_V6\_V3\_Additional\_PFT >= -20.00

**Variables:** Variability\_V6\_V3\_Additional\_PFT

**Treat Undefined as True:** No

## 10. Workflow Rules

### 10.17 V9\_Variability\_V9\_and\_V3 (R5237)

The rule identifies if the variability between the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V9 and the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V3 is within 20.00%.

**Visit(s):** V9

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Hard

**Expression:** [Forced Spirometry] [Current Visit] Variability\_V9\_V3 <= 20.00 AND [Forced Spirometry] [Current Visit] Variability\_V9\_V3 >= -20.00

**Variables:** Variability\_V9\_V3

**Treat Undefined as True:** No

### 10.18 V9\_Variability\_V9\_30m\_V3\_rule (R5242)

The rule identifies if the variability between Pre PFT -30 min at V9 and the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V3 is within 20.00%.

**Visit(s):** V9

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Hard

**Expression:** [Forced Spirometry] [Current Visit] Variability\_V9\_30min\_V3 <= 20.00 AND [Forced Spirometry] [Current Visit] Variability\_V9\_30min\_V3 >= -20.00

**Variables:** Variability\_V9\_30min\_V3

**Treat Undefined as True:** No

### 10.19 V9\_Variability\_V9\_V3\_Add\_PFT (R5238)

The rule identifies if the variability between the average of the Pre PFT -30 min and Additional Pre PFT measurement at V9 and the average of the Pre PFT -60 min and Pre PFT -30 min measurement at V3 is within 20.00%.

**Visit(s):** V9

**System:** Backend, MSCCT

**Action:** Alert

**Type:** Hard

**Expression:** [Forced Spirometry] [Current Visit] Variability\_V9\_V3\_Additional\_PFT <= 20.00 AND [Forced Spirometry] [Current Visit] Variability\_V9\_V3\_Additional\_PFT >= -20.00

**Variables:** Variability\_V9\_V3\_Additional\_PFT

**Treat Undefined as True:** No

## 10. Workflow Rules

### 10.20 FeNO to be performed (R5221)

The rule checks if the answer to the FeNO device ready to use message. If the user presses Yes, the FeNO measurement will be offered, if No is pressed the FeNO measurement will be skipped.

**Visit(s):** V1, V10, V11, V2, V4, V5, V6, V7, V8, V9

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Soft

**Expression:** [FeNO] [Relative Task/FeNO\_device\_ready\_to\_use] YESNO.YES = true

**Treat Undefined as True:** No

### 10.21 FeNO - Skip confirmation (R5247)

The rule checks the answer to the "FeNo to be skipped" message. If the user presses continue, the FeNO measurement will be finally skipped, if Cancel is pressed the workflow will jump back to the "FeNO device ready" to use message.

**Visit(s):** V1, V10, V11, V2, V4, V5, V6, V7, V8, V9

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Hard

**Expression:** [FeNO] [All Tasks/FeNO\_to\_be\_skipped] CONTINUECANCEL.CONTINUE = true

**Treat Undefined as True:** No

### 10.22 V1 Skip AM Dispense (R5268)

If V1 has been rescheduled, AM3 Dispense will be skipped.

**Visit(s):** V1

**System:** Backend, MSCCT

**Action:** Dialog

**Type:** Hard

**Expression:** [COA - AM] [Current Visit] AM\_Dispensed = false

**Variables:** AM\_Dispensed

**Treat Undefined as True:** No

## 10. Workflow Rules

### 10.23 Asthma\_Safety\_exclusion (R5269)

The rule determines if sub rules (ACQ5\_Rule\_Exclusion\_SR and Rescue\_Use\_exclusion\_SR) have been met and adds a overall message to the resulting message.

**Visit(s):** V2, VUNR

**System:** Backend, MSCCT

**Action:** Exclusion

**Type:** Hard

**Expression:** [COA - AM] [Sub Rules] Rescue\_Use\_exclusion\_SR = true AND [COA - AM] [Sub Rules] ACQ5\_Rule\_Exclusion\_SR = true

**Treat Undefined as True:** No

**Message if condition is False:** The patient meets the exclusion criterion, because:

### 10.24 ACQ5\_Rule\_Exclusion\_SR (R5270)

Rule checks if the ACQ5 Score is 3.0 or greater. If score is  $\geq 3.0$ , a exclusion message will be displayed.

**Visit(s):** V1, V2, V3, VUNR

**System:** Backend, MSCCT

**Action:** Exclusion

**Type:** Hard

**Expression:** [COA - AM] [Current Visit] ACQ5\_Score < 3.0

**Variables:** ACQ5\_Score

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is False:** ACQ Score is  $\geq 3.0$ .

### 10.25 Rescue\_Use\_exclusion\_SR (R5271)

Rule checks if the daily rescue use was  $\geq 12$  puffs for  $\geq 3$  consecutive days since the last scheduled visit.

**Visit(s):** V1, V2, V3, VUNR

**System:** Backend, MSCCT

**Action:** Exclusion

**Type:** Hard

**Expression:** [COA - AM] [Current Visit] AM\_QuestionAlert1\_triggered = false

**Variables:** AM\_QuestionAlert1\_triggered

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is False:** Daily rescue use of  $\geq 12$  puffs for  $\geq 3$  consecutive days.

## 10. Workflow Rules

### 10.26 Asthma\_Safety\_Withdrawal (R5272)

The rule determines if sub rules (ACQ5\_Rule\_Withdrawal\_SR; Rescue\_Use\_withdrawal\_SR; PEF\_Drop\_Withdrawal\_SR) have been met and adds a overall message to the resulting message.

**Visit(s):** V10, V11, V4, V5, V6, V7, V8, V9, VET, VUNT

**System:** Backend, MSCCT

**Action:** Exclusion

**Type:** Hard

**Expression:** [COA - AM] [Sub Rules] ACQ5\_Rule\_Withdrawal\_SR = true AND [COA - AM] [Sub Rules] PEF\_Drop\_Withdrawal\_SR = true AND [COA - AM] [Sub Rules] Rescue\_Use\_withdrawal\_SR = true

**Treat Undefined as True:** No

**Message if condition is False:** The patient meets the asthma safety withdrawal criterion, because:

### 10.27 ACQ5\_Rule\_Withdrawal\_SR (R5273)

Rule checks if the ACQ5 Score is 3.0 or greater. If score is  $\geq 3.0$ , a withdrawal message will be displayed.

**Visit(s):** V10, V11, V4, V5, V6, V7, V8, V9, VET, VUNT

**System:** Backend, MSCCT

**Action:** Withdrawal

**Type:** Hard

**Expression:** [COA - AM] [Current Visit] ACQ5\_Score < 3.0

**Variables:** ACQ5\_Score

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is False:** ACQ Score is  $\geq 3.0$ . The patient needs to be withdrawal from the study.

### 10.28 Rescue\_Use\_withdrawal\_SR (R5274)

Rule checks if the daily rescue use was either  $\geq 12$  puffs for  $\geq 3$  consecutive days and/or  $> 8$  puffs over baseline for  $\geq 3$  consecutive days since the last scheduled visit.

**Visit(s):** V10, V11, V4, V5, V6, V7, V8, V9, VET, VUNT

**System:** Backend, MSCCT

**Action:** Withdrawal

**Type:** Hard

**Expression:** [COA - AM] [Current Visit] AM\_QuestionAlert1\_triggered = false AND [COA - AM] [Current Visit] AM\_QuestionAlert2\_triggered = false

**Variables:** AM\_QuestionAlert1\_triggered, AM\_QuestionAlert2\_triggered

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is False:** Daily rescue use of  $\geq 8$  puffs of salbutamol above baseline use and/or  $\geq 12$  puffs for  $\geq 3$  consecutive days.

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## 10. Workflow Rules

### 10.29 PEF\_Drop\_Withdrawal\_SR (R5275)

Rule checks if the morning PEF has dropped below threshold for >= 3 consecutive days.

**Visit(s):** V10, V11, V4, V5, V6, V7, V8, V9, VET, VUNT

**System:** Backend, MSCCT

**Action:** Withdrawal

**Type:** Hard

**Expression:** [COA - AM] [Current Visit] AM\_MeasurementAlert1\_triggered = false

**Variables:** AM\_MeasurementAlert1\_triggered

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is False:** Drop of morning PEF of >=30% from baseline for >=3 consecutive days.

### 10.30 AM\_Compliance (R5276)

Rule checks if the AM compliance is >= 80%.

**Visit(s):** V10, V11, V2, V3, V4, V5, V6, V7, V8, V9, VET, VUNR, VUNT

**System:** Backend, MSCCT

**Action:** Alert

**Type:** Soft

**Expression:** [Current Visit] AM\_DownloadCompliance >= 80

**Variables:** AM\_DownloadCompliance

**Treat Undefined as True:** No

**Message if condition is False:** AM3 compliance is < 80%. Please remind the patient to use the AM3 twice daily.

### 10.31 V3\_Asthma\_Safety\_exclusion (R5324)

The rule determines if sub rules (ACQ5\_Rule\_Exclusion\_SR and Rescue\_Use\_exclusion\_SR;V3\_Compliance\_SR) have been met and adds a overall message to the resulting message.

**Visit(s):** V3

**System:** Backend, MSCCT

**Action:** Exclusion

**Type:** Hard

**Expression:** [COA - AM] [Sub Rules] ACQ5\_Rule\_Exclusion\_SR = true AND [COA - AM] [Sub Rules] Rescue\_Use\_exclusion\_SR = true AND [COA - AM] [Sub Rules] V3\_AM\_Compliance\_SR = true

**Treat Undefined as True:** No

**Message if condition is False:** The patient meets the exclusion criterion, because:

## 10. Workflow Rules

### 10.32 V3\_AM\_Compliance\_SR (R5325)

Rule checks if the AM compliance is  $\geq 80\%$  during the entire Run-In period.

**Visit(s):** V3

**System:** Backend, MSCCT

**Action:** Exclusion

**Type:** Hard

**Expression:** [COA - AM] [Current Visit] V1\_V3\_AM\_Compliance  $\geq 80$

**Variables:** V1\_V3\_AM\_Compliance

**Subrule:** Yes

**Treat Undefined as True:** No

**Message if condition is False:** AM Compliance during the entire Run-In period is below 80%.



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## 11. Message Designer

### 11.1 Message Box: FeNO device ready to use (M5404)

Description: FeNO device ready to use.  
 Header: FeNO device ready to use  
 Icon: Question  
 Body: Is the FeNO device ready for the measurement?  
 Help Text: Press [Yes] to perform the FeNO measurement now.

Press [No] to skip the FeNO measurement.

Used on: V1, V2, V4, V5, V6, V7, V8, V9, V10, V11

**Button: Yes**

**Button: No**

### 11.2 Message Box: FeNO to be skipped (M5436)

Description: FeNO to be skipped  
 Header: FeNO to be skipped  
 Icon: Warning  
 Body: You are about to skip the FeNO measurement for today. If you confirm the skipping now, no FeNO measurement will be possible for today.  
 Help Text: Press [Continue] to skip the FeNo measurement.

Press [Cancel] to abort.

Used on: V1, V2, V4, V5, V6, V7, V8, V9, V10, V11

**Button: Continue**

**Button: Cancel**

### 11.3 Message Box: Inclusion (M5411)

Description: Confirmation of Inclusion.  
 Header: Patient Inclusion  
 Icon: Question  
 Body: Do you want to include patient E\${path:'[PAT SUBJECTID]' } into the study?  
 Help Text: Press [Yes] to include the patient.

Press [No] to abort inclusion

Used on: V1

**Button: Yes**

**Button: No**

## 11. Message Designer

### 11.4 Message Box: Medication washout check (M5409)

Description: Medication washout check.  
 Header: Medication washout check  
 Icon: Question  
 Body: Has the patient used Rescue Medication/Salbutamol within the last 6 hours?  
 Help Text: Click [No] to confirm that the patient did not take any Rescue Medication/ Salbutamol.  
 Click [Yes] if Rescue Medication/Salbutamol has been taken within the last 6 hours  
 Used on: V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, VUNR, VUNT

**Button: No**

**Button: Yes**

### 11.5 Message Box: Medication washout not met (M5410)

Description: Medication washout not met.  
 Header: Medication washout not met  
 Icon: Question  
 Body: Patient has taken Rescue Medication/Salbutamol within the last 6 hours.  
 Before proceeding with the patient's visit, please confirm that you want to continue.  
 Help Text: Please press [Continue] to confirm and start the visit.  
 Press [Cancel] to abort the visit.  
 Used on: V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, VUNR, VUNT

**Button: Continue**

**Button: Cancel**

### 11.6 Message Box: Patients on ICS LABA (M5490)

Description: Message will check if the patient is still on ICS/LABA at V1.  
 Header: Patients on ICS/LABA  
 Body: If the patient has taken ICS/LABA within the last 48 hours, please reschedule the visit to allow a washout time of 48 hours.  
 If no ICS/LABA within the last 48 hours, please continue with the visit today.  
 Help Text: Press [OK] to confirm  
 Used on: V1

**Button: OK**

## 11. Message Designer

### 11.7 Message Box: Randomization (M5402)

Description: After clicking the randomization icon.

Header: Patient Randomization

Icon: Question

Body: Do you want to randomize patient E\${path:'[PAT SUBJECTID]'} into the study?

Help Text: Press [Yes] to randomize the patient.

Press [No] to abort randomization.

Used on: V3

**Button: Yes**

**Button: No**

### 11.8 Message Box: Reversibility Not Met (M5401)

Description: Message will be displayed directly after the Post PFT measurement, if the Reversibility criterion has not been met.

Header: Reversibility Not Met

Body: The patient did not meet the reversibility inclusion criterion today.

To include the patient into the study, the reversibility test needs to be repeated.

Therefore please reschedule V1 and repeat the visit within one week or screen fail the patient.

Help Text: Press [OK] to confirm.

Used on: V1

**Button: OK**

### 11.9 Dosing Dialog: Salbutamol Dosing (M5399)

Description: At V1, VUN in Screening, for Dosing Salbutamol

Header: Salbutamol Dosing

Body: Please enter the time of Salbutamol dosing

Help Text: Press [now] once you are ready to administer the dose.

Used on: V1, VUNR

**Dosing: Salbutamol**

Must occur after measurement: Yes

### 11.10 Dosing Dialog: Study Drug Dosing (M5406)

Description: Study Drug Dosing

Header: Study Drug Dosing

Body: Enter the time of study drug dosing

Help Text: Press [now] once you are ready to administer the dose.

Used on: V3, V4, V6, V7, V9, V10, VUNT

**Dosing: Study Drug**

Must occur after measurement: Yes



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## 11. Message Designer

### 11.11 Message Box: Variability still too high (M5434)

Description: Variability still too high!

Header: Variability still too high!

Body: Variability of the average FEV1 between the current visit and V3 is still > 20.00%.

Please reschedule the visit within a week

or

if the visit had been rescheduled to high variability already once, please continue with the patient.

Help Text: Press [OK] to confirm.

Used on: V6, V9

**Button: OK**

### 11.12 Message Box: Variability too high 2 (M5437)

Description: Variability too high 2

Header: Variability too high!

Body: Variability of the average FEV1 between the current visit and V3 is > 20.00%.

Please reschedule the visit within a week

or

if the visit had been rescheduled to high variability already once, please continue with the patient.

Help Text: Press [OK] to confirm.

Used on: V6, V9

**Button: OK**

### 11.13 Message Box: Variability too high (M5435)

Description: Variability too high!

Header: Variability too high!

Body: Variability of the average FEV1 between the current visit and V3 is > 20.00%. Please perform the additional PFT measurement (next workflow step) to meet the variability criterion.

Help Text: Press [OK] to confirm

Used on: V6, V9

**Button: OK**

## 12. Cardiac Safety

### 12.1 ECG Analysis

Data Type: ECG

Measurement Requirement	Measurement Order			RR Specification	QT Method	Beat Finding Method	Display Mode
	First	Second	Third				



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## 12. Cardiac Safety

### 12.1 ECG Analysis

Data Type: ECG

Measurement Requirement	Measurement Order			RR Specification	QT Method	Beat Finding Method	Display Mode
	First	Second	Third				
-	-	-	-	-	-	-	Superimposed

**Measurement Items:**

Group	Category	Item	Number of beats
Measured Items	Individual	HR,GL	-
	Individual	RR,GL	-
	Individual	PR,GL	-
	Individual	QRS,GL	-
	Individual	QT,GL	-
Derived Items	Individual	QTcB,GL	-
	Individual	QTcF,GL	-

### 12.2 Quality Assurance Process

Data Type: ECG

**QA Selection:**

- Random 2% of all ECGs processed for this protocol.

## 12. Cardiac Safety

### 12.3 Quality Control Parameters and Ranges

**Data Type:** ECG

**QC Selection:**

- Random 100% of all good quality ECGs processed in EXPERT across all studies at ERT;
- All ECG tracings showing other than good quality;
- All IDM outliers (as identified in the table below); and
- Annotations on 100% of the ECGs are confirmed by the cardiologist in EXPERT

**Changes Compared with Previous ECGs:** 100% (if applicable)

## 12. Cardiac Safety

### 12.4 ECG Measurement Exclusion Alerts

**Data Type:** ECG

Alerts:

Category	Item	Demography	Visit Condition	Normal Range	Logic	Compare Range	Percentage Range	Variance Threshold
Globals	PR_GL	All	On Screen	High: 240				
Globals	QTcF_GL	All	On Screen	High: 449				

## 12.5 Cardiology Review Items

**Data Type:** ECG

**Overall evaluation:** Normal, Abnormal, Unable to Evaluate

Evaluation Items:

Category	Review Items		
Rhythm	Artificial Pacemaker Ectopic Supraventricular Rhythm Junctional Tachycardia Supraventricular Tachycardia Other	Atrial Fibrillation Idioventricular Rhythm Sinus Pauses Sinus Tachycardia	Atrial Flutter Junctional Rhythm Sinus Bradycardia Ventricular Fibrillation
Ectopy	Atrial Premature Complexes Frequent Ventricular Premature Complexes (>2)	Frequent Atrial Premature Complexes (>3) Non-sustained Ventricular Tachycardia	Ventricular Premature Complexes Other
Conduction	2:1 AV Block Complete Heart Block Incomplete Right Bundle Branch Block Left Bundle Branch Block Right Bundle Branch Block	AV Mobitz I First Degree AV Block Intraventricular Conduction Defect Left Posterior Hemiblock Wolff-Parkinson-White	AV Mobitz II Incomplete Left Bundle Branch Block Left Anterior Hemiblock Prolonged QTc Other
ST Segment	Depressed	Elevated	Other
T Waves	Biphasic Other	Flat	Inverted
U Waves	Abnormal	Other	
Myocardial Infarction	Lateral MI 1, L, V5, V6 High Lateral MI 1, AVL Antero Lateral MI V3-V6	Septal MI V1, V2, (V3) Inferior MI (2), 3, F Antero Septal MI V1-V4	Extensive Anterior MI 1, L, V1-V6 Anterior MI V3, V4 Other

## 12. Cardiac Safety

### 12.5 Cardiology Review Items

Data Type: ECG

Evaluation Items:

Category	Review Items		
Morphology	Left Atrial Abnormality	Left Ventricular Hypertrophy	Low Voltage
	Right Atrial Abnormality	Right Ventricular Hypertrophy	Other

Review Rules:

Interpretation	Category	Review Item	Rule Logic	Demography
Abnormal	Rhythm	Sinus Bradycardia	(HR_GL < 41) AND (PR_GL is Not Null)	-
-	Rhythm	Sinus Bradycardia	(HR_GL < 50) AND (PR_GL is Not Null)	-
-	Rhythm	Sinus Tachycardia	(HR_GL > 100) AND (PR_GL is Not Null)	-
Abnormal	Rhythm	Sinus Tachycardia	(HR_GL > 119) AND (PR_GL is Not Null)	-
Abnormal	Rhythm	Any	PR_GL is Null	-
Abnormal	Conduction	First Degree AV Block	PR_GL > 200	-
Abnormal	Conduction	Prolonged QTc	QTcB_GL > 500	-
Abnormal	Conduction	Prolonged QTc	QTcF_GL > 500	-
Abnormal	Conduction	Any	QRS_GL > 109	-

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Data Type:** ECG

**Measurement Comparator:** One group for all

**Allow repeat visit:** Yes

**Allow replacement visit:** Yes

**Visit sequence checking:** Yes

**Requeue on comparator event:** Yes

**Minimum number of transmittals for QTc mean:** 1

**Visit Schedule:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Type	Visit Option	TAT	Visit Comparators	Demography / Timeframe
10	SCREENING/ECG A	S/A	Screen	Required	72 HR	Mean	-
20	SCREENING/ECG B	S/B	Screen	Required	72 HR	Mean	-
30	SCREENING/ECG C	S/C	Screen	Required	72 HR	Mean	-
40	VISIT 3/PREDOSE ECG A	3/PA	Treatment	Required	72 HR	-	-
50	VISIT 3/PREDOSE ECG B	3/PB	Treatment	Required	72 HR	-	-
60	VISIT 3/PREDOSE ECG C	3/PC	Treatment	Required	72 HR	-	-
70	VISIT 3/30 MIN POSTDOSE ECG A	3/30A	Treatment	Required	72 HR	-	-
80	VISIT 3/30 MIN POSTDOSE ECG B	3/30B	Treatment	Required	72 HR	-	-
90	VISIT 3/30 MIN POSTDOSE ECG C	3/30C	Treatment	Required	72 HR	-	-
100	VISIT 3/1 HOUR POSTDOSE ECG A	3/1A	Treatment	Required	72 HR	-	-
110	VISIT 3/1 HOUR POSTDOSE ECG B	3/1B	Treatment	Required	72 HR	-	-
120	VISIT 3/1 HOUR POSTDOSE ECG C	3/1C	Treatment	Required	72 HR	-	-
130	VISIT 3/2 HOUR POSTDOSE ECG A	3/2A	Treatment	Required	72 HR	-	-
140	VISIT 3/2 HOUR POSTDOSE ECG B	3/2B	Treatment	Required	72 HR	-	-
150	VISIT 3/2 HOUR POSTDOSE ECG C	3/2C	Treatment	Required	72 HR	-	-
160	VISIT 3/4 HOUR POSTDOSE ECG A	3/4A	Treatment	Required	72 HR	-	-
170	VISIT 3/4 HOUR POSTDOSE ECG B	3/4B	Treatment	Required	72 HR	-	-

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Visit Schedule:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Type	Visit Option	TAT	Visit Comparators	Demography / Timeframe
180	VISIT 3/4 HOUR POSTDOSE ECG C	3/4C	Treatment	Required	72 HR	-	-
190	VISIT 4/PREDOSE ECG A	4/PA	Treatment	Required	72 HR	-	-
200	VISIT 4/PREDOSE ECG B	4/PB	Treatment	Required	72 HR	-	-
210	VISIT 4/PREDOSE ECG C	4/PC	Treatment	Required	72 HR	-	-
220	VISIT 4/1 HOUR POSTDOSE ECG A	4/1A	Treatment	Required	72 HR	-	-
230	VISIT 4/1 HOUR POSTDOSE ECG B	4/1B	Treatment	Required	72 HR	-	-
240	VISIT 4/1 HOUR POSTDOSE ECG C	4/1C	Treatment	Required	72 HR	-	-
250	VISIT 5/PREDOSE ECG A	5/PA	Treatment	Required	72 HR	-	-
260	VISIT 5/PREDOSE ECG B	5/PB	Treatment	Required	72 HR	-	-
270	VISIT 5/PREDOSE ECG C	5/PC	Treatment	Required	72 HR	-	-
280	VISIT 5/30 MIN POSTDOSE ECG A	5/30A	Treatment	Required	72 HR	-	-
290	VISIT 5/30 MIN POSTDOSE ECG B	5/30B	Treatment	Required	72 HR	-	-
300	VISIT 5/30 MIN POSTDOSE ECG C	5/30C	Treatment	Required	72 HR	-	-
310	VISIT 5/1 HOUR POSTDOSE ECG A	5/1A	Treatment	Required	72 HR	-	-
320	VISIT 5/1 HOUR POSTDOSE ECG B	5/1B	Treatment	Required	72 HR	-	-
330	VISIT 5/1 HOUR POSTDOSE ECG C	5/1C	Treatment	Required	72 HR	-	-
340	VISIT 5/2 HOUR POSTDOSE ECG A	5/2A	Treatment	Required	72 HR	-	-
350	VISIT 5/2 HOUR POSTDOSE ECG B	5/2B	Treatment	Required	72 HR	-	-
360	VISIT 5/2 HOUR POSTDOSE ECG C	5/2C	Treatment	Required	72 HR	-	-
370	VISIT 5/4 HOUR POSTDOSE ECG A	5/4A	Treatment	Required	72 HR	-	-
380	VISIT 5/4 HOUR POSTDOSE ECG B	5/4B	Treatment	Required	72 HR	-	-
390	VISIT 5/4 HOUR POSTDOSE ECG C	5/4C	Treatment	Required	72 HR	-	-

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Visit Schedule:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Type	Visit Option	TAT	Visit Comparators	Demography / Timeframe
400	VISIT 5/8 HOUR POSTDOSE ECG A	5/8A	Treatment	Required	72 HR	-	-
410	VISIT 5/8 HOUR POSTDOSE ECG B	5/8B	Treatment	Required	72 HR	-	-
420	VISIT 5/8 HOUR POSTDOSE ECG C	5/8C	Treatment	Required	72 HR	-	-
430	VISIT 5/12 HOUR POSTDOSE ECG A	5/12A	Treatment	Required	72 HR	-	-
440	VISIT 5/12 HOUR POSTDOSE ECG B	5/12B	Treatment	Required	72 HR	-	-
450	VISIT 5/12 HOUR POSTDOSE ECG C	5/12C	Treatment	Required	72 HR	-	-
460	VISIT 5/24 HOUR POSTDOSE ECG A	5/24A	Treatment	Required	72 HR	-	-
470	VISIT 5/24 HOUR POSTDOSE ECG B	5/24B	Treatment	Required	72 HR	-	-
480	VISIT 5/24 HOUR POSTDOSE ECG C	5/24C	Treatment	Required	72 HR	-	-
490	VISIT 6/PREDOSE ECG A	6/PA	Treatment	Required	72 HR	-	-
500	VISIT 6/PREDOSE ECG B	6/PB	Treatment	Required	72 HR	-	-
510	VISIT 6/PREDOSE ECG C	6/PC	Treatment	Required	72 HR	-	-
520	VISIT 6/30 MIN POSTDOSE ECG A	6/30A	Treatment	Required	72 HR	-	-
530	VISIT 6/30 MIN POSTDOSE ECG B	6/30B	Treatment	Required	72 HR	-	-
540	VISIT 6/30 MIN POSTDOSE ECG C	6/30C	Treatment	Required	72 HR	-	-
550	VISIT 6/1 HOUR POSTDOSE ECG A	6/1A	Treatment	Required	72 HR	-	-
560	VISIT 6/1 HOUR POSTDOSE ECG B	6/1B	Treatment	Required	72 HR	-	-
570	VISIT 6/1 HOUR POSTDOSE ECG C	6/1C	Treatment	Required	72 HR	-	-
580	VISIT 6/2 HOUR POSTDOSE ECG A	6/2A	Treatment	Required	72 HR	-	-
590	VISIT 6/2 HOUR POSTDOSE ECG B	6/2B	Treatment	Required	72 HR	-	-
600	VISIT 6/2 HOUR POSTDOSE ECG C	6/2C	Treatment	Required	72 HR	-	-

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Visit Schedule:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Type	Visit Option	TAT	Visit Comparators	Demography / Timeframe
610	VISIT 6/4 HOUR POSTDOSE ECG A	6/4A	Treatment	Required	72 HR	-	-
620	VISIT 6/4 HOUR POSTDOSE ECG B	6/4B	Treatment	Required	72 HR	-	-
630	VISIT 6/4 HOUR POSTDOSE ECG C	6/4C	Treatment	Required	72 HR	-	-
640	VISIT 7/PREDOSE ECG A	7/PA	Treatment	Required	72 HR	-	-
650	VISIT 7/PREDOSE ECG B	7/PB	Treatment	Required	72 HR	-	-
660	VISIT 7/PREDOSE ECG C	7/PC	Treatment	Required	72 HR	-	-
670	VISIT 7/1 HOUR POSTDOSE ECG A	7/1A	Treatment	Required	72 HR	-	-
680	VISIT 7/1 HOUR POSTDOSE ECG B	7/1B	Treatment	Required	72 HR	-	-
690	VISIT 7/1 HOUR POSTDOSE ECG C	7/1C	Treatment	Required	72 HR	-	-
700	VISIT 8/PREDOSE ECG A	8/PA	Treatment	Required	72 HR	-	-
710	VISIT 8/PREDOSE ECG B	8/PB	Treatment	Required	72 HR	-	-
720	VISIT 8/PREDOSE ECG C	8/PC	Treatment	Required	72 HR	-	-
730	VISIT 8/30 MIN POSTDOSE ECG A	8/30A	Treatment	Required	72 HR	-	-
740	VISIT 8/30 MIN POSTDOSE ECG B	8/30B	Treatment	Required	72 HR	-	-
750	VISIT 8/30 MIN POSTDOSE ECG C	8/30C	Treatment	Required	72 HR	-	-
760	VISIT 8/1 HOUR POSTDOSE ECG A	8/1A	Treatment	Required	72 HR	-	-
770	VISIT 8/1 HOUR POSTDOSE ECG B	8/1B	Treatment	Required	72 HR	-	-
780	VISIT 8/1 HOUR POSTDOSE ECG C	8/1C	Treatment	Required	72 HR	-	-
790	VISIT 8/2 HOUR POSTDOSE ECG A	8/2A	Treatment	Required	72 HR	-	-
800	VISIT 8/2 HOUR POSTDOSE ECG B	8/2B	Treatment	Required	72 HR	-	-
810	VISIT 8/2 HOUR POSTDOSE ECG C	8/2C	Treatment	Required	72 HR	-	-
820	VISIT 8/4 HOUR POSTDOSE ECG A	8/4A	Treatment	Required	72 HR	-	-

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Visit Schedule:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Type	Visit Option	TAT	Visit Comparators	Demography / Timeframe
830	VISIT 8/4 HOUR POSTDOSE ECG B	8/4B	Treatment	Required	72 HR	-	-
840	VISIT 8/4 HOUR POSTDOSE ECG C	8/4C	Treatment	Required	72 HR	-	-
850	VISIT 8/8 HOUR POSTDOSE ECG A	8/8A	Treatment	Required	72 HR	-	-
860	VISIT 8/8 HOUR POSTDOSE ECG B	8/8B	Treatment	Required	72 HR	-	-
870	VISIT 8/8 HOUR POSTDOSE ECG C	8/8C	Treatment	Required	72 HR	-	-
880	VISIT 8/12 HOUR POSTDOSE ECG A	8/12A	Treatment	Required	72 HR	-	-
890	VISIT 8/12 HOUR POSTDOSE ECG B	8/12B	Treatment	Required	72 HR	-	-
900	VISIT 8/12 HOUR POSTDOSE ECG C	8/12C	Treatment	Required	72 HR	-	-
910	VISIT 8/24 HOUR POSTDOSE ECG A	8/24A	Treatment	Required	72 HR	-	-
920	VISIT 8/24 HOUR POSTDOSE ECG B	8/24B	Treatment	Required	72 HR	-	-
930	VISIT 8/24 HOUR POSTDOSE ECG C	8/24C	Treatment	Required	72 HR	-	-
940	VISIT 9/PREDOSE ECG A	9/PA	Treatment	Required	72 HR	-	-
950	VISIT 9/PREDOSE ECG B	9/PB	Treatment	Required	72 HR	-	-
960	VISIT 9/PREDOSE ECG C	9/PC	Treatment	Required	72 HR	-	-
970	VISIT 9/30 MIN POSTDOSE ECG A	9/30A	Treatment	Required	72 HR	-	-
980	VISIT 9/30 MIN POSTDOSE ECG B	9/30B	Treatment	Required	72 HR	-	-
990	VISIT 9/30 MIN POSTDOSE ECG C	9/30C	Treatment	Required	72 HR	-	-
1000	VISIT 9/1 HOUR POSTDOSE ECG A	9/1A	Treatment	Required	72 HR	-	-
1010	VISIT 9/1 HOUR POSTDOSE ECG B	9/1B	Treatment	Required	72 HR	-	-
1020	VISIT 9/1 HOUR POSTDOSE ECG C	9/1C	Treatment	Required	72 HR	-	-
1030	VISIT 9/2 HOUR POSTDOSE ECG A	9/2A	Treatment	Required	72 HR	-	-

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Visit Schedule:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Type	Visit Option	TAT	Visit Comparators	Demography / Timeframe
1040	VISIT 9/2 HOUR POSTDOSE ECG B	9/2B	Treatment	Required	72 HR	-	-
1050	VISIT 9/2 HOUR POSTDOSE ECG C	9/2C	Treatment	Required	72 HR	-	-
1060	VISIT 9/4 HOUR POSTDOSE ECG A	9/4A	Treatment	Required	72 HR	-	-
1070	VISIT 9/4 HOUR POSTDOSE ECG B	9/4B	Treatment	Required	72 HR	-	-
1080	VISIT 9/4 HOUR POSTDOSE ECG C	9/4C	Treatment	Required	72 HR	-	-
1090	VISIT 10/PREDOSE ECG A	10/PA	Treatment	Required	72 HR	-	-
1100	VISIT 10/PREDOSE ECG B	10/PB	Treatment	Required	72 HR	-	-
1110	VISIT 10/PREDOSE ECG C	10/PC	Treatment	Required	72 HR	-	-
1120	VISIT 10/1 HOUR POSTDOSE ECG A	10/1A	Treatment	Required	72 HR	-	-
1130	VISIT 10/1 HOUR POSTDOSE ECG B	10/1B	Treatment	Required	72 HR	-	-
1140	VISIT 10/1 HOUR POSTDOSE ECG C	10/1C	Treatment	Required	72 HR	-	-
1150	VISIT 11/PREDOSE ECG A	11/PA	Treatment	Required	72 HR	-	-
1160	VISIT 11/PREDOSE ECG B	11/PB	Treatment	Required	72 HR	-	-
1170	VISIT 11/PREDOSE ECG C	11/PC	Treatment	Required	72 HR	-	-
1180	VISIT 11/30 MIN POSTDOSE ECG A	11/30A	Treatment	Required	72 HR	-	-
1190	VISIT 11/30 MIN POSTDOSE ECG B	11/30B	Treatment	Required	72 HR	-	-
1200	VISIT 11/30 MIN POSTDOSE ECG C	11/30C	Treatment	Required	72 HR	-	-
1210	VISIT 11/1 HOUR POSTDOSE ECG A	11/1A	Treatment	Required	72 HR	-	-
1220	VISIT 11/1 HOUR POSTDOSE ECG B	11/1B	Treatment	Required	72 HR	-	-
1230	VISIT 11/1 HOUR POSTDOSE ECG C	11/1C	Treatment	Required	72 HR	-	-
1240	VISIT 11/2 HOUR POSTDOSE ECG A	11/2A	Treatment	Required	72 HR	-	-
1250	VISIT 11/2 HOUR POSTDOSE ECG B	11/2B	Treatment	Required	72 HR	-	-

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Visit Schedule:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Type	Visit Option	TAT	Visit Comparators	Demography / Timeframe
1260	VISIT 11/2 HOUR POSTDOSE ECG C	11/2C	Treatment	Required	72 HR	-	-
1270	VISIT 11/4 HOUR POSTDOSE ECG A	11/4A	Treatment	Required	72 HR	-	-
1280	VISIT 11/4 HOUR POSTDOSE ECG B	11/4B	Treatment	Required	72 HR	-	-
1290	VISIT 11/4 HOUR POSTDOSE ECG C	11/4C	Treatment	Required	72 HR	-	-
1300	VISIT 11/8 HOUR POSTDOSE ECG A	11/8A	Treatment	Required	72 HR	-	-
1310	VISIT 11/8 HOUR POSTDOSE ECG B	11/8B	Treatment	Required	72 HR	-	-
1320	VISIT 11/8 HOUR POSTDOSE ECG C	11/8C	Treatment	Required	72 HR	-	-
1330	VISIT 11/12 HOUR POSTDOSE ECG A	11/12A	Treatment	Required	72 HR	-	-
1340	VISIT 11/12 HOUR POSTDOSE ECG B	11/12B	Treatment	Required	72 HR	-	-
1350	VISIT 11/12 HOUR POSTDOSE ECG C	11/12C	Treatment	Required	72 HR	-	-
1360	VISIT 11/24 HOUR POSTDOSE ECG A	11/24A	Treatment	Required	72 HR	-	-
1370	VISIT 11/24 HOUR POSTDOSE ECG B	11/24B	Treatment	Required	72 HR	-	-
1380	VISIT 11/24 HOUR POSTDOSE ECG C	11/24C	Treatment	Required	72 HR	-	-
1390	VISIT 12	12	Followup	Required	72 HR	-	-
9910	UNSCHEDULED ECG A	UA	Unknown	Optional	72 HR	-	-
9920	UNSCHEDULED ECG B	UB	Unknown	Optional	72 HR	-	-
9930	UNSCHEDULED ECG C	UC	Unknown	Optional	72 HR	-	-

**Alternative Visit Tracks:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Tracks
10	SCREENING/ECG A	S/A	1, 2
20	SCREENING/ECG B	S/B	1, 2
30	SCREENING/ECG C	S/C	1, 2

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Alternative Visit Tracks:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Tracks
40	VISIT 3/PREDOSE ECG A	3/PA	1, 2
50	VISIT 3/PREDOSE ECG B	3/PB	1, 2
60	VISIT 3/PREDOSE ECG C	3/PC	1, 2
70	VISIT 3/30 MIN POSTDOSE ECG A	3/30A	2
80	VISIT 3/30 MIN POSTDOSE ECG B	3/30B	2
90	VISIT 3/30 MIN POSTDOSE ECG C	3/30C	2
100	VISIT 3/1 HOUR POSTDOSE ECG A	3/1A	1, 2
110	VISIT 3/1 HOUR POSTDOSE ECG B	3/1B	1, 2
120	VISIT 3/1 HOUR POSTDOSE ECG C	3/1C	1, 2
130	VISIT 3/2 HOUR POSTDOSE ECG A	3/2A	2
140	VISIT 3/2 HOUR POSTDOSE ECG B	3/2B	2
150	VISIT 3/2 HOUR POSTDOSE ECG C	3/2C	2
160	VISIT 3/4 HOUR POSTDOSE ECG A	3/4A	2
170	VISIT 3/4 HOUR POSTDOSE ECG B	3/4B	2
180	VISIT 3/4 HOUR POSTDOSE ECG C	3/4C	2
190	VISIT 4/PREDOSE ECG A	4/PA	1
200	VISIT 4/PREDOSE ECG B	4/PB	1
210	VISIT 4/PREDOSE ECG C	4/PC	1
220	VISIT 4/1 HOUR POSTDOSE ECG A	4/1A	1
230	VISIT 4/1 HOUR POSTDOSE ECG B	4/1B	1
240	VISIT 4/1 HOUR POSTDOSE ECG C	4/1C	1
250	VISIT 5/PREDOSE ECG A	5/PA	2
260	VISIT 5/PREDOSE ECG B	5/PB	2

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Alternative Visit Tracks:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Tracks
270	VISIT 5/PREDOSE ECG C	5/PC	2
280	VISIT 5/30 MIN POSTDOSE ECG A	5/30A	2
290	VISIT 5/30 MIN POSTDOSE ECG B	5/30B	2
300	VISIT 5/30 MIN POSTDOSE ECG C	5/30C	2
310	VISIT 5/1 HOUR POSTDOSE ECG A	5/1A	2
320	VISIT 5/1 HOUR POSTDOSE ECG B	5/1B	2
330	VISIT 5/1 HOUR POSTDOSE ECG C	5/1C	2
340	VISIT 5/2 HOUR POSTDOSE ECG A	5/2A	2
350	VISIT 5/2 HOUR POSTDOSE ECG B	5/2B	2
360	VISIT 5/2 HOUR POSTDOSE ECG C	5/2C	2
370	VISIT 5/4 HOUR POSTDOSE ECG A	5/4A	2
380	VISIT 5/4 HOUR POSTDOSE ECG B	5/4B	2
390	VISIT 5/4 HOUR POSTDOSE ECG C	5/4C	2
400	VISIT 5/8 HOUR POSTDOSE ECG A	5/8A	2
410	VISIT 5/8 HOUR POSTDOSE ECG B	5/8B	2
420	VISIT 5/8 HOUR POSTDOSE ECG C	5/8C	2
430	VISIT 5/12 HOUR POSTDOSE ECG A	5/12A	2
440	VISIT 5/12 HOUR POSTDOSE ECG B	5/12B	2
450	VISIT 5/12 HOUR POSTDOSE ECG C	5/12C	2
460	VISIT 5/24 HOUR POSTDOSE ECG A	5/24A	2
470	VISIT 5/24 HOUR POSTDOSE ECG B	5/24B	2

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Alternative Visit Tracks:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Tracks
480	VISIT 5/24 HOUR POSTDOSE ECG C	5/24C	2
490	VISIT 6/PREDOSE ECG A	6/PA	1, 2
500	VISIT 6/PREDOSE ECG B	6/PB	1, 2
510	VISIT 6/PREDOSE ECG C	6/PC	1, 2
520	VISIT 6/30 MIN POSTDOSE ECG A	6/30A	2
530	VISIT 6/30 MIN POSTDOSE ECG B	6/30B	2
540	VISIT 6/30 MIN POSTDOSE ECG C	6/30C	2
550	VISIT 6/1 HOUR POSTDOSE ECG A	6/1A	1, 2
560	VISIT 6/1 HOUR POSTDOSE ECG B	6/1B	1, 2
570	VISIT 6/1 HOUR POSTDOSE ECG C	6/1C	1, 2
580	VISIT 6/2 HOUR POSTDOSE ECG A	6/2A	2
590	VISIT 6/2 HOUR POSTDOSE ECG B	6/2B	2
600	VISIT 6/2 HOUR POSTDOSE ECG C	6/2C	2
610	VISIT 6/4 HOUR POSTDOSE ECG A	6/4A	2
620	VISIT 6/4 HOUR POSTDOSE ECG B	6/4B	2
630	VISIT 6/4 HOUR POSTDOSE ECG C	6/4C	2
640	VISIT 7/PREDOSE ECG A	7/PA	1
650	VISIT 7/PREDOSE ECG B	7/PB	1
660	VISIT 7/PREDOSE ECG C	7/PC	1
670	VISIT 7/1 HOUR POSTDOSE ECG A	7/1A	1
680	VISIT 7/1 HOUR POSTDOSE ECG B	7/1B	1
690	VISIT 7/1 HOUR POSTDOSE ECG C	7/1C	1
700	VISIT 8/PREDOSE ECG A	8/PA	2

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Alternative Visit Tracks:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Tracks
710	VISIT 8/PREDOSE ECG B	8/PB	2
720	VISIT 8/PREDOSE ECG C	8/PC	2
730	VISIT 8/30 MIN POSTDOSE ECG A	8/30A	2
740	VISIT 8/30 MIN POSTDOSE ECG B	8/30B	2
750	VISIT 8/30 MIN POSTDOSE ECG C	8/30C	2
760	VISIT 8/1 HOUR POSTDOSE ECG A	8/1A	2
770	VISIT 8/1 HOUR POSTDOSE ECG B	8/1B	2
780	VISIT 8/1 HOUR POSTDOSE ECG C	8/1C	2
790	VISIT 8/2 HOUR POSTDOSE ECG A	8/2A	2
800	VISIT 8/2 HOUR POSTDOSE ECG B	8/2B	2
810	VISIT 8/2 HOUR POSTDOSE ECG C	8/2C	2
820	VISIT 8/4 HOUR POSTDOSE ECG A	8/4A	2
830	VISIT 8/4 HOUR POSTDOSE ECG B	8/4B	2
840	VISIT 8/4 HOUR POSTDOSE ECG C	8/4C	2
850	VISIT 8/8 HOUR POSTDOSE ECG A	8/8A	2
860	VISIT 8/8 HOUR POSTDOSE ECG B	8/8B	2
870	VISIT 8/8 HOUR POSTDOSE ECG C	8/8C	2
880	VISIT 8/12 HOUR POSTDOSE ECG A	8/12A	2
890	VISIT 8/12 HOUR POSTDOSE ECG B	8/12B	2
900	VISIT 8/12 HOUR POSTDOSE ECG C	8/12C	2
910	VISIT 8/24 HOUR POSTDOSE ECG A	8/24A	2
920	VISIT 8/24 HOUR POSTDOSE ECG B	8/24B	2

## 12. Cardiac Safety

### 12.6 Visit Schedules

**Alternative Visit Tracks:**

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Tracks
930	VISIT 8/24 HOUR POSTDOSE ECG C	8/24C	2
940	VISIT 9/PREDOSE ECG A	9/PA	1, 2
950	VISIT 9/PREDOSE ECG B	9/PB	1, 2
960	VISIT 9/PREDOSE ECG C	9/PC	1, 2
970	VISIT 9/30 MIN POSTDOSE ECG A	9/30A	2
980	VISIT 9/30 MIN POSTDOSE ECG B	9/30B	2
990	VISIT 9/30 MIN POSTDOSE ECG C	9/30C	2
1000	VISIT 9/1 HOUR POSTDOSE ECG A	9/1A	1, 2
1010	VISIT 9/1 HOUR POSTDOSE ECG B	9/1B	1, 2
1020	VISIT 9/1 HOUR POSTDOSE ECG C	9/1C	1, 2
1030	VISIT 9/2 HOUR POSTDOSE ECG A	9/2A	2
1040	VISIT 9/2 HOUR POSTDOSE ECG B	9/2B	2
1050	VISIT 9/2 HOUR POSTDOSE ECG C	9/2C	2
1060	VISIT 9/4 HOUR POSTDOSE ECG A	9/4A	2
1070	VISIT 9/4 HOUR POSTDOSE ECG B	9/4B	2
1080	VISIT 9/4 HOUR POSTDOSE ECG C	9/4C	2
1090	VISIT 10/PREDOSE ECG A	10/PA	1
1100	VISIT 10/PREDOSE ECG B	10/PB	1
1110	VISIT 10/PREDOSE ECG C	10/PC	1
1120	VISIT 10/1 HOUR POSTDOSE ECG A	10/1A	1
1130	VISIT 10/1 HOUR POSTDOSE ECG B	10/1B	1
1140	VISIT 10/1 HOUR POSTDOSE ECG C	10/1C	1
1150	VISIT 11/PREDOSE ECG A	11/PA	2

## 12. Cardiac Safety

### 12.6 Visit Schedules

#### Alternative Visit Tracks:

Seq	Visit / Timepoint Name	Visit Abbreviation	Visit Tracks
1160	VISIT 11/PREDOSE ECG B	11/PB	2
1170	VISIT 11/PREDOSE ECG C	11/PC	2
1180	VISIT 11/30 MIN POSTDOSE ECG A	11/30A	2
1190	VISIT 11/30 MIN POSTDOSE ECG B	11/30B	2
1200	VISIT 11/30 MIN POSTDOSE ECG C	11/30C	2
1210	VISIT 11/1 HOUR POSTDOSE ECG A	11/1A	2
1220	VISIT 11/1 HOUR POSTDOSE ECG B	11/1B	2
1230	VISIT 11/1 HOUR POSTDOSE ECG C	11/1C	2
1240	VISIT 11/2 HOUR POSTDOSE ECG A	11/2A	2
1250	VISIT 11/2 HOUR POSTDOSE ECG B	11/2B	2
1260	VISIT 11/2 HOUR POSTDOSE ECG C	11/2C	2
1270	VISIT 11/4 HOUR POSTDOSE ECG A	11/4A	2
1280	VISIT 11/4 HOUR POSTDOSE ECG B	11/4B	2
1290	VISIT 11/4 HOUR POSTDOSE ECG C	11/4C	2
1300	VISIT 11/8 HOUR POSTDOSE ECG A	11/8A	2
1310	VISIT 11/8 HOUR POSTDOSE ECG B	11/8B	2
1320	VISIT 11/8 HOUR POSTDOSE ECG C	11/8C	2
1330	VISIT 11/12 HOUR POSTDOSE ECG A	11/12A	2
1340	VISIT 11/12 HOUR POSTDOSE ECG B	11/12B	2
1350	VISIT 11/12 HOUR POSTDOSE ECG C	11/12C	2
1360	VISIT 11/24 HOUR POSTDOSE ECG A	11/24A	2
1370	VISIT 11/24 HOUR POSTDOSE ECG B	11/24B	2

## **12. Cardiac Safety**

### **12.6 Visit Schedules**

**Alternative Visit Tracks:**

<b>Seq</b>	<b>Visit / Timepoint Name</b>	<b>Visit Abbreviation</b>	<b>Visit Tracks</b>
1380	VISIT 11/24 HOUR POSTDOSE ECG C	11/24C	2
1390	VISIT 12	12	1, 2

## 13. Spirometry

### 13.1 Forced Spirometry

#### 13.1.1 Parameters

FEV1 Variation Threshold will not be used.

##### Basic Configuration

Changeability of the Valid State of the Trials: Enable Smart Controls, Change State

Show Animation: Hide animation irrespective of configuration

Show QC Trial Dialog: Yes

Show Plateau Bar Graph: Yes

Best Expiration Definition: Effort with highest sum of FVC+FEV1

Best Inspiration Definition: Effort with highest sum of FVCin+PIF/10

FEV1 Variation Threshold: 300 mL

Number of Trials: 8

Wait Mode Allowed: No

Min. Wait time between efforts: 0 sec.

##### OTR Selection:

Reselect auto-deselected trials: No

Comment for Reselection Needed: No

Comment for Deselection Needed: Yes

Joint selection/deselection of in- and expiration: Yes

Only last performed effort can be selected/de-selected: No

##### Configuration

The following parameters will be displayed in the Spirometry viewer and printed on the report.

Long Name	Short Name	Description and Settings	Rounding
FEV1	FEV1	FEV 1 Unit: [L] Test result: Highest	Rounded to 2 decimal places
FVC	FVC	FVC Unit: [L] Test result: Highest	Rounded to 2 decimal places
FEV1/FVC	FEV1/FVC	FEV1/FVC Unit: [%] Test result: Best FEV1/Best FVC	Rounded to 0 decimal places

## 13. Spirometry

### 13.1 Forced Spirometry

#### 13.1.1 Parameters

##### Configuration

Long Name	Short Name	Description and Settings	Rounding
MMEF	MMEF	MMEF Unit: [L/s] Test result: Highest	Rounded to 2 decimal places

Values for percentage of predicted will be rounded to 2 decimal places.

#### 13.1.2 Predicted Values

**Extrapolation method:** Extrapolate outside of range (age, height)

Age Range	From (yrs)	To (yrs)	Parameter	Author	Race	Calculation	Corr. Factor Female	Corr. Factor Male
age range	18	76	25-75	GLI2012	African American	GLI2012 African American	1	1
					Caucasian	GLI2012 Caucasian	1	1
					North East Asian	GLI2012 North East Asian	1	1
					Other	GLI2012 Other	1	1
					South East Asian	GLI2012 South East Asian	1	1
	FEV1	GLI2012	GLI2012	GLI2012	African American	GLI2012 African American	1	1
					Caucasian	GLI2012 Caucasian	1	1
					North East Asian	GLI2012 North East Asian	1	1
					Other	GLI2012 Other	1	1
					South East Asian	GLI2012 South East Asian	1	1
	FVC	GLI2012	GLI2012	GLI2012	African American	GLI2012 African American	1	1
					Caucasian	GLI2012 Caucasian	1	1
					North East Asian	GLI2012 North East Asian	1	1
					Other	GLI2012 Other	1	1

## 13. Spirometry

### 13.1 Forced Spirometry

#### 13.1.2 Predicted Values

Age Range	From (yrs)	To (yrs)	Parameter	Author	Race	Calculation	Corr. Factor Female	Corr. Factor Male
age range	18	76	FVC	GLI2012	South East Asian	GLI2012 South East Asian	1	1

Note: The predicted values will be calculated for the age valid when the first spirometry measurement is done. Even if a patient has a birthday during the study, the predicted values do not change. If a patient's demographics (date of birth (if applicable), age, gender, race or height) change after the first spirometry measurement was carried out, the predicted values are recalculated for all measurements.

#### 13.1.3 Error Codes

Error Code	Error Display Text	Traffic Light / Error Dialog	QC Message
A	No repeatability; Less than 3 accepted forced measurements	Show in Error Dlg. Incl. Traffic Light	-
B	FEV1 repeatability is unacceptable	Show in Error Dlg. Incl. Traffic Light	-
C	FVC repeatability is unacceptable	Show in Error Dlg. Incl. Traffic Light	-
D	Expiration time was too short (< 6 sec or < 3 sec if age < 10 years)	Yes/No dialog to accept or hide trial	Expiration time was too short (< 6 sec or < 3 sec if age < 10 years), FVC might be underestimated. => Expiration has to be performed for a longer time, please try to coach the patient to exhale for longer.
E	No plateau was detected at the end of the expiration	Yes/No dialog to accept or hide trial	No plateau was detected at the end of the expiration, FVC might be underestimated. => Expiration has to be continued until a plateau is reached.
F	Back extrapolation volume was too large	Show only OK to hide trial	Back extrapolated volume was too large (5% of FVC or 150 ml, whichever is greater), FEV1 might be underestimated. => Forced expiration has to start without hesitation, please try to coach the patient to exhale without hesitation.
H	Late peak flow detected	Show only OK to hide trial	Late peak flow was detected, possibly indicating a poor effort. => Forced expiration has to start without hesitation.
I	Coughing was detected in the first part of the expiration	Show only OK to hide trial	Coughing was detected in the first part of the expiration, FEV1 might be effected. => The effort was automatically deselected. Please review this effort.

Error Criteria	Method	Absolute/%	FVC Limit Low	Absolute/% Low
Repeatability of PEF	ATS/ERS 2005 - Diff. Highest/Second: <=670 ml			
Repeatability of FEV1	ATS/ERS 2005 - Diff. Highest/Second : <=150 mL / FVC<1000mL: <= 100 mL			

## 13. Spirometry

### 13.1 Forced Spirometry

#### 13.1.3 Error Codes

Error Criteria	Method	Absolute/%	FVC Limit Low	Absolute/% Low
Repeatability of FVC	ATS/ERS 2005 - Diff. Highest/Second : <=150 mL / FVC<1000mL: <= 100 mL			
Expiration Time	ATS/ERS 2005 Expiration time >= 6 seconds (>=3 seconds if age < 10)			
Plateau	ATS/ERS 2005 - Volume change last 1 second: <= 25 mL			
Back Extrapolation	ATS/ERS 2005 - Extrapolated Volume: <= 5% of FVC or <= 150 mL			
Time to peak	Time PEF > 120			

## 14. FeNO

**Quality Check:** Recommended On Each Visit Day

**Measurement Mode:** 10 seconds

**Parameter:** FeNO

**Rounding Rule:** No decimals



**ERT**

*Getting It Done. Right.*

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## 15. COA

### 15.1 COA Study Configuration

**Subject Rollover:** No      **Site Visibility:** Responses, Scores, Alerts  
**Set Subject PIN**    No      **Prompt Text Display:** Full  
**Close Visits:**       No      **Report Open Queries:** No

### 15.2 COA - AM Configuration

**Allow Default Answers:** Yes

**Device Type:** AM3 GSM

**Languages:** English (USEN)

**Module:** PXL\_800226

Position	Question Name	Question	Answers
1	MQ1	Please record your Daytime Asthma Symptoms:	Single Select: 0 = I have no asthma symptoms 1 = I am aware of my asthma symptoms but I can easily tolerate the symptoms 2 = My asthma is causing me enough discomfort to cause problems with normal activities (or with sleep) 3 = I am unable to do my normal activities (or to sleep) because of my asthma
2	MQ2	Did your asthma cause you to wake up last night?	Single Select: 0 = No 1 = Yes
3	MQ3	How many inhalations of salbutamol did you take during last night (last diary entry)?	Range: 0 .. 99 puff(s)
4	MQ4	How many puffs of study medication you did inhale?	Range: 0 .. 30 puff(s)
5	MQ5	How many capsules of study medication did you inhale?	Range: 0 .. 30 puff(s)
6	EQ1	Please record your Daytime Asthma Symptoms	Single Select: 0 = I have no asthma symptoms 1 = I am aware of my asthma symptoms but I can easily tolerate the symptoms 2 = My asthma is causing me enough discomfort to cause problems with normal activities (or with sleep) 3 = I am unable to do your normal activities (or to sleep) because of my asthma
7	EQ2	How many inhalations of salbutamol did you take since this morning (last diary entry). Do not include any inhalations that you might have been given at the clinic visit.	Range: 0 .. 99 puff(s)
8	EQ3	How many puffs of study medication did you inhale?	Range: 0 .. 30 puff(s)

**15. COA****15.2 COA - AM Configuration**

Position	Question Name	Question	Answers
9	ACQ5_Q1	On average, during the past week, how often were you woken by your asthma during the night?	Single Select: 0 = Never 1 = Hardly ever 2 = A few times 3 = Several times 4 = Many times 5 = A great many times 6 = Unable to sleep because of asthma
10	ACQ5_Q2	On average, during the past week, how bad were your asthma symptoms when you woke up in the morning?	Single Select: 0 = No symptoms 1 = Very mild symptoms 2 = Slightly limited 3 = Moderately limited 4 = Very limited 5 = Extremely limited 6 = Totally limited
11	ACQ5_Q3	In general, during the past week, how limited were you in your activities because of your asthma?	Single Select: 0 = Not limited at all 1 = Very slightly limited 2 = Slightly limited 3 = Moderately limited 4 = Very limited 5 = Extremely limited 6 = Totally limited
12	ACQ5_Q4	In general, during the past week, how much shortness of breath did you experience because of your asthma?	Single Select: 0 = None 1 = A very little 2 = A little 3 = A moderate amount 4 = Quite a lot 5 = A great deal 6 = A very great deal
13	ACQ5_Q5	In general, during the past week, how much of the time did you wheeze?	Single Select: 0 = Not at all 1 = Hardly any of the time 2 = A little of the time 3 = A moderate amount of the time 4 = A lot of the time 5 = Most of the time 6 = All the time
14	ACQ5_SCORE	ACQ5_Score	

**Module:** DYN\_800226\_DailySessionInitials**Module:** DYN\_800226\_DownloadInitials**Session Name:** MorningSession**Min. # of Valid Maneuvers:** 3

	Internal		Confidential
	Generated on: 06-MAR-2015 10:17:25		Version: 1.00

**15. COA****15.2 COA - AM Configuration****Prompts:**

Question	eDiary Compliance
MQ1	Yes
MQ2	Yes
MQ3	Yes
MQ4	Yes
MQ5	Yes

**Session Name:** EveningSession**Min. # of Valid Maneuvers:** 3**Prompts:**

Question	eDiary Compliance
EQ1	Yes
EQ2	Yes
EQ3	Yes

**Session Name:** AdditionalSession**Prompts:**

Question	eDiary Compliance
ACQ5_Q1	No
ACQ5_Q2	No
ACQ5_Q3	No
ACQ5_Q4	No
ACQ5_Q5	No
ACQ5_SCORE	No

**15. COA****15.2 COA - AM Configuration**

Epoch	AM State	Converted to at 02:00 AM	Morning available	Evening available	Note
Enroll					
Enter Enroll	1	2		X	
During Enroll	2	2	X	X	
During Enroll Scheduled Visit	3	2		X	State will not used in this study
Leave Enroll	4	2		X	
Run-in					
Enter Run-in	5	6		X	
During Run-in	6	6	X	X	
During Run-in Scheduled Visit	7	6		X	State will not used in this study
Leave Run-in	8	6		X	
Treatment					
Enter Treatment	9	10		X	
During Treatment	10	10	X	X	
During Treatment Scheduled Visit	11	10		X	
Leave Treatment	12	10		X	
Washout					
Enter Washout	13	14		X	
During Washout	14	14	X	X	
During Washout Scheduled Visit	15	14		X	
Leave Washout	16	14		X	

## 15. COA

### 15.2 COA - AM Configuration

#### REMINDER SCREENS

Screen	Possible answers	Default	Routines to be started, next step
Do you want to change an answer?	Yes		Display 1 <sup>st</sup> question of appropriate questionnaire with last answer pre-selected
	No	x	Message: Now, please perform your peak expiratory flows PEF readings

Screen	Possible answers	Routines to be started, next step
Do not take Salbutamol prior to attending the clinic!	OK	Reminder only at visit days
Take your AM3 device with you to your clinic!	OK	Reminder only at visit days during Run-in and Wash-out except V2
Do not take your study medication prior to attending the clinic!	OK	Reminder only at visit days during Wash-out and Treatment
Please take all used and unused drugs and inhalers and your AM3 device with you to your clinic!	OK	Reminder only at visit days (all periods)
Please take your study medication now and don't forget to answer the next question!	OK	Reminder only at non-visit days during Treatment

#### ALERT SCREENS

Screen
Rescue medication use is high! Please contact your study doctor!
PEF too low! Please contact your study doctor!

#### CUSTOMIZED TIME OUT

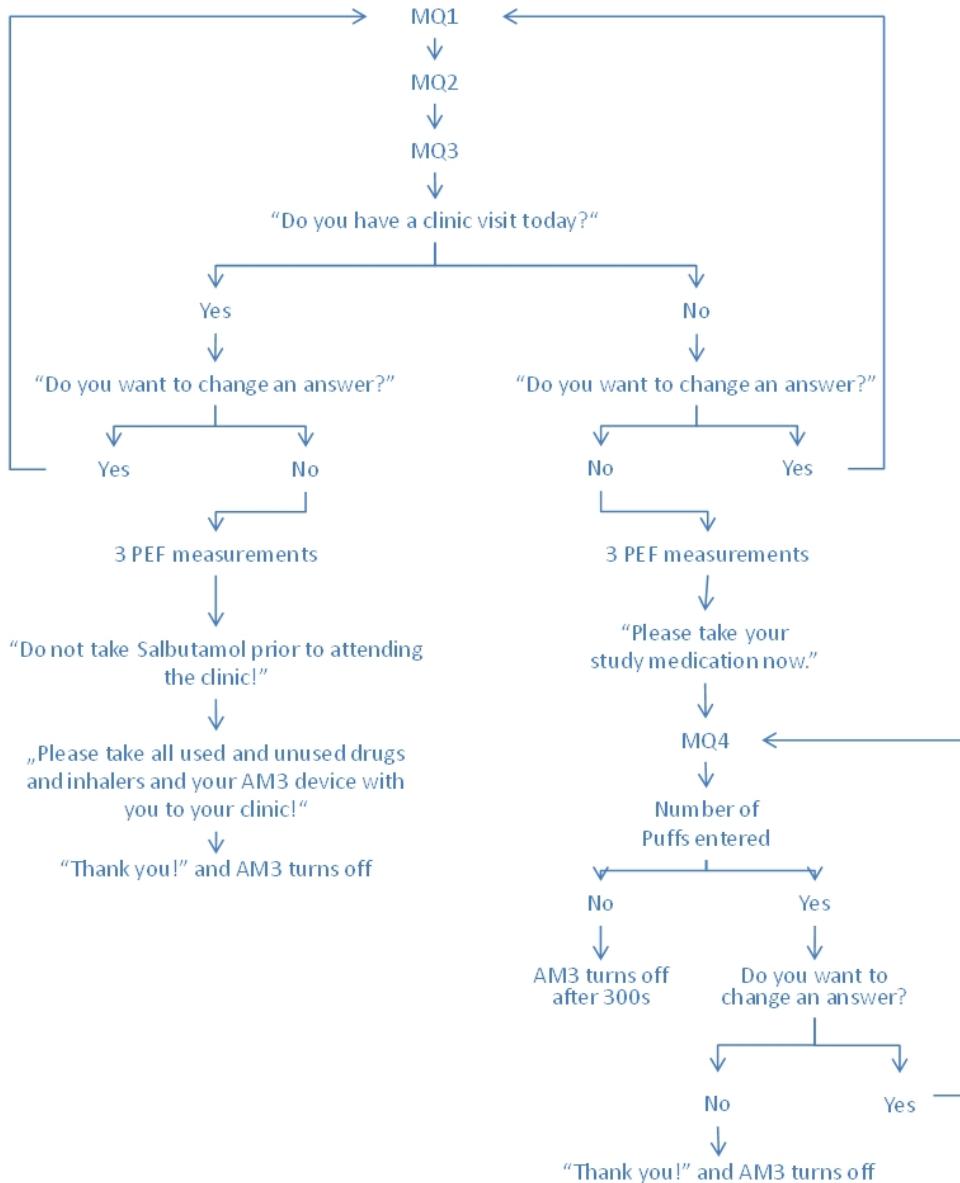
For the study the following time outs are defined:

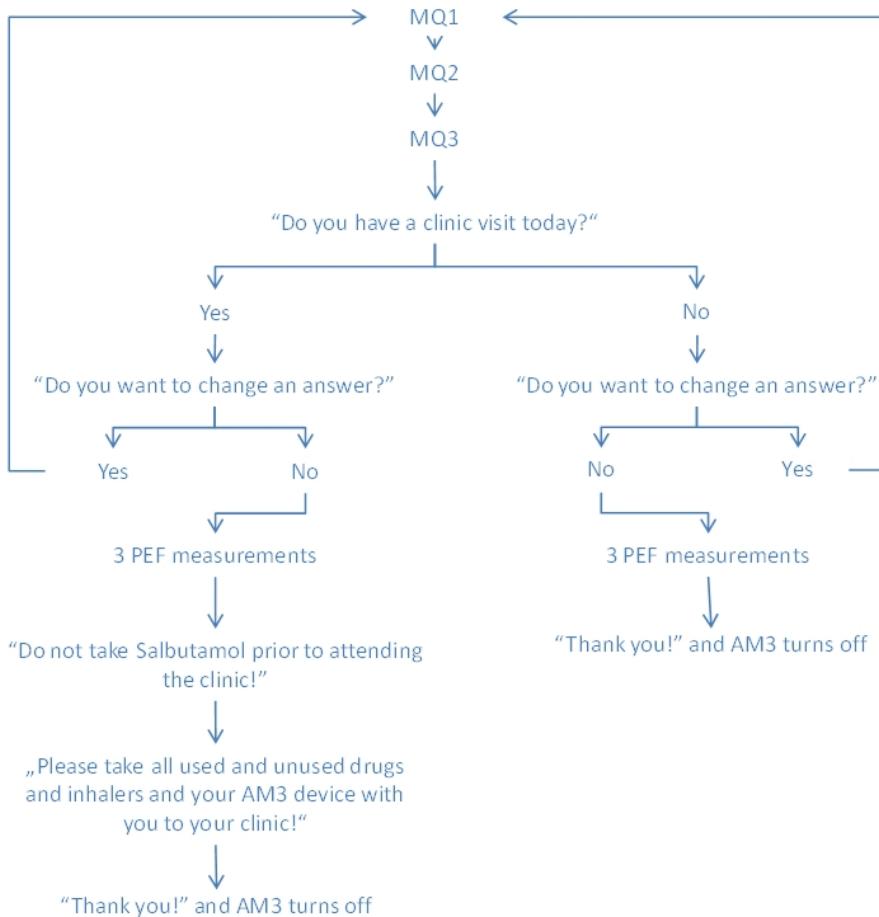
Screen	Possible answers
MQ4 (Enroll (before V2))	300 seconds
MQ5 (Treatment Phase)	300 seconds
EQ4 (Treatment Phase)	300 seconds

15. COA

## 15.2 COA - AM Configuration

## MORNING QUESTIONNAIRE WORKFLOW DURING ENROLL PERIOD (BEFORE V2)

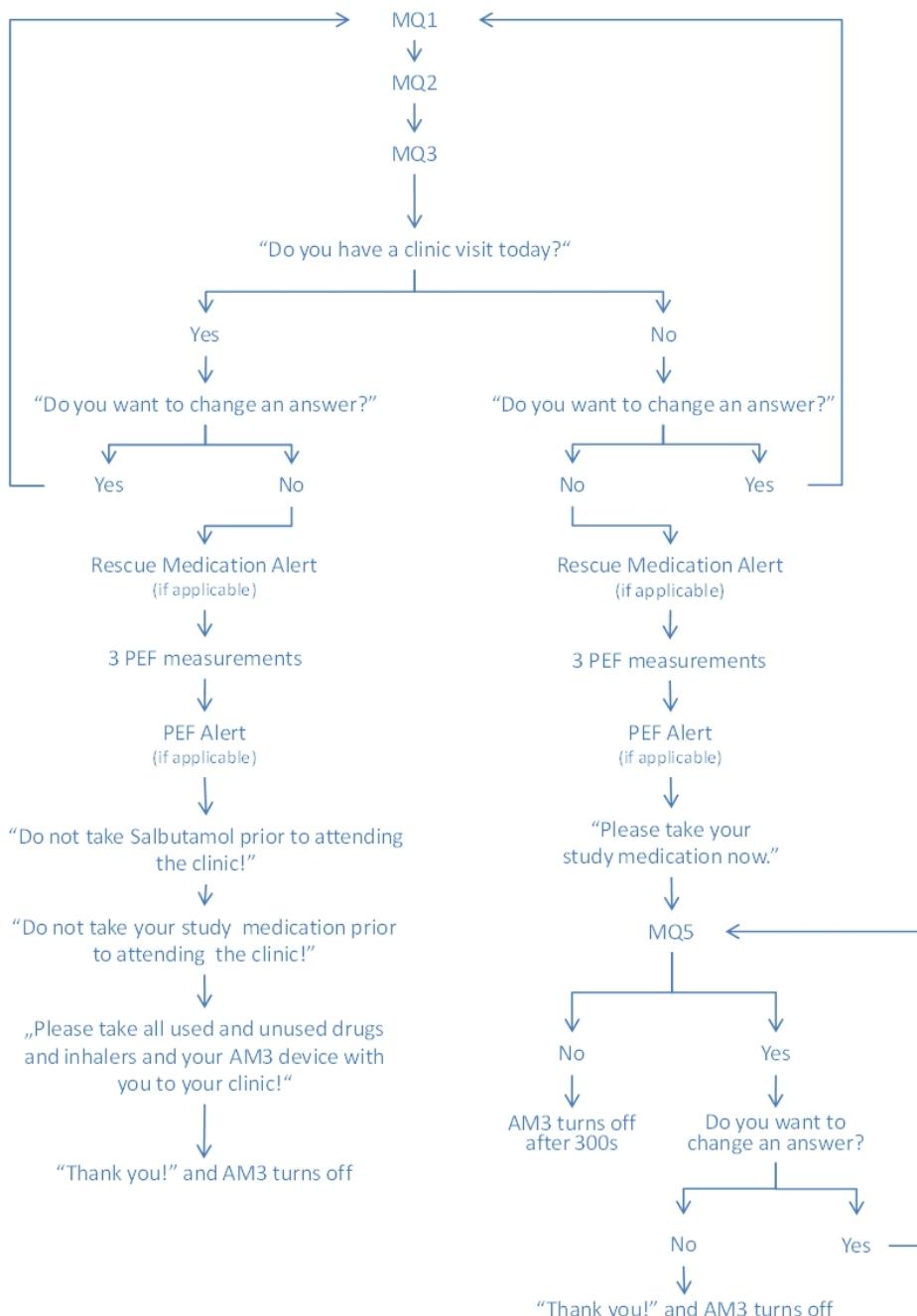


**15. COA****15.2 COA - AM Configuration****MORNING QUESTIONNAIRE WORKFLOW DURING RUN-IN AFTER V2 AND BEFORE V3**

15. COA

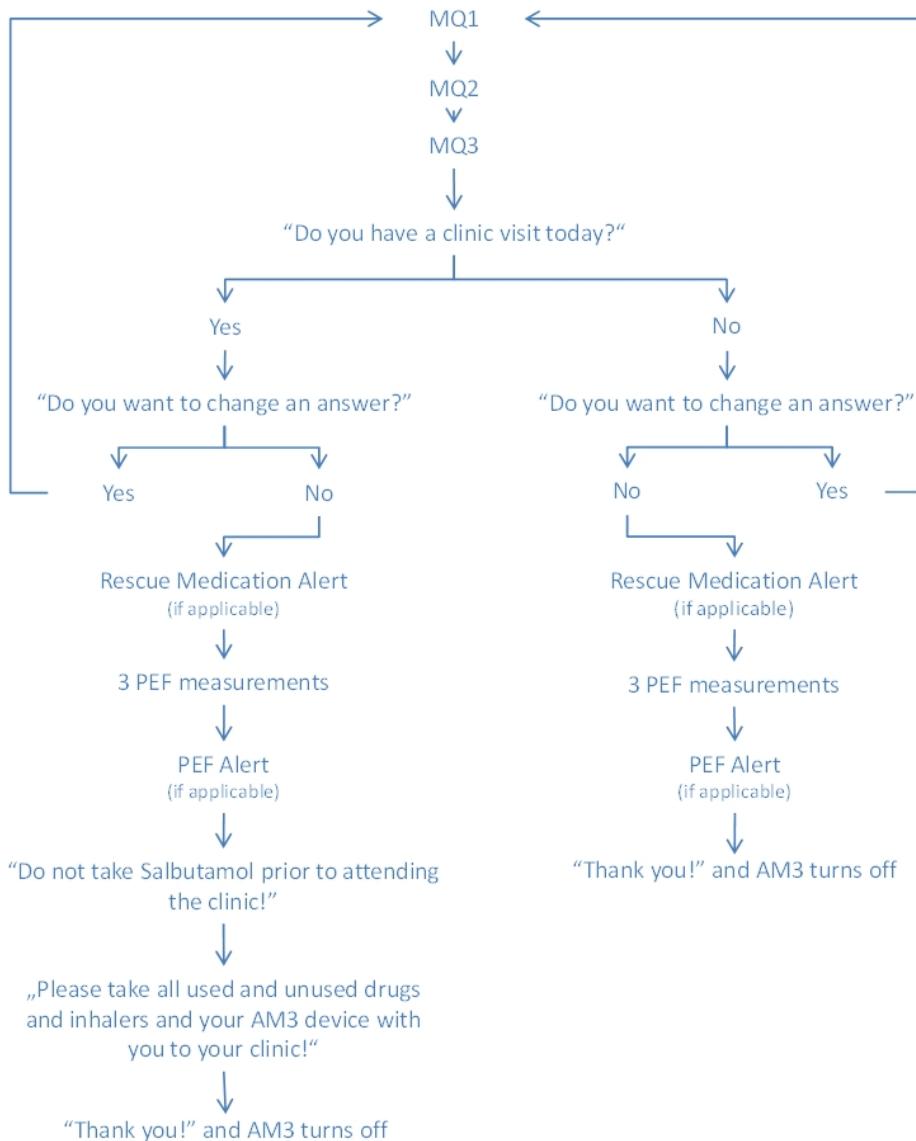
## 15.2 COA - AM Configuration

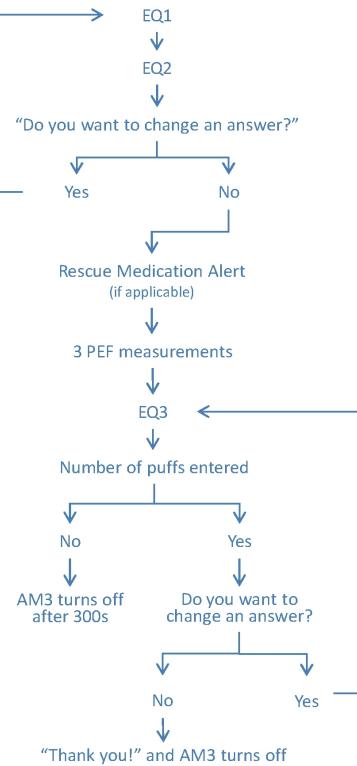
## MORNING QUESTIONNAIRE WORKFLOW (TREATMENT) (AFTER V3 AND BEFORE V5), (AFTER V6 AND BEFORE V8) AND (AFTER V9 AND BEFORE V11)



**15. COA****15.2 COA - AM Configuration**

**MORNING QUESTIONNAIRE WORKFLOW DURING WASH OUT  
(AFTER V5 AND BEFORE V6) AND (AFTER V8 AND BEFORE V9)**

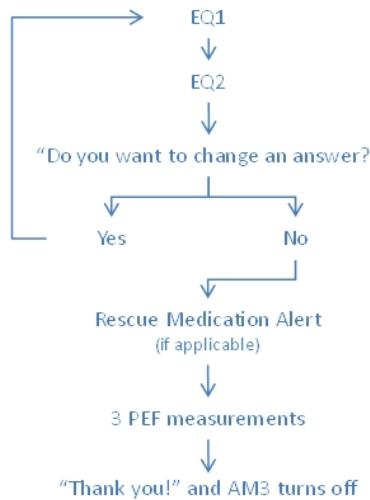


**15. COA****15.2 COA - AM Configuration****EVENING QUESTIONNAIRE WORKFLOW (ENROLL) BEFORE V2**

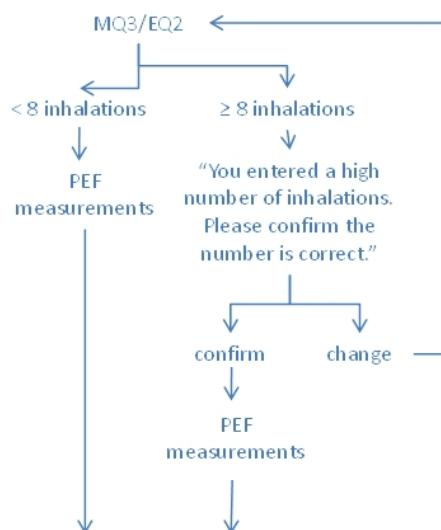
## 15. COA

### 15.2 COA - AM Configuration

**EVENING QUESTIONNAIRE WORKFLOW (RUN-IN) AFTER V2 AND BEFORE V3 AND  
(TREATMENT AND WASHOUT) (V3-V11)**



**MQ3/EQ2 HIGH SALBUTAMOL USAGE CONFIRMATION**



**15. COA****15.2 COA - AM Configuration**

**Session Name:** MorningSession (by Phase)

**Device Phases:** Enroll

**Question Alerts:** QAlert1

**Min. # of Valid Maneuvers:** 3

**Prompts:**

Question	eDiary Compliance
MQ1	Yes
MQ2	Yes
MQ3	Yes
MQ4	Yes

**Session Name:** MorningSession (by Phase)

**Device Phases:** Treatment

**Question Alerts:** QAlert1, QAlert2

**Measurement Alerts:** MAlert1

**Min. # of Valid Maneuvers:** 3

**Prompts:**

Question	eDiary Compliance
MQ1	Yes
MQ2	Yes
MQ3	Yes
MQ5	Yes

**Session Name:** MorningSession (by Phase)

**Device Phases:** Run-In

**Question Alerts:** QAlert1

**Min. # of Valid Maneuvers:** 3

**Prompts:**

Question	eDiary Compliance
MQ1	Yes
MQ2	Yes
MQ3	Yes

**Session Name:** MorningSession (by Phase)

**Device Phases:** Washout

**15. COA****15.2 COA - AM Configuration****Question Alerts:** QAlert1, QAlert2**Measurement Alerts:** MAlert1**Prompts:**

Question	eDiary Compliance
MQ1	Yes
MQ2	Yes
MQ3	Yes

**Session Name:** EveningSession (by Phase)**Device Phases:** Run-In**Question Alerts:** QAlert1**Min. # of Valid Maneuvers:** 3**Prompts:**

Question	eDiary Compliance
EQ1	Yes
EQ2	Yes

**Session Name:** EveningSession (by Phase)**Device Phases:** Enroll**Question Alerts:** QAlert1**Min. # of Valid Maneuvers:** 3**Prompts:**

Question	eDiary Compliance
EQ1	Yes
EQ2	Yes
EQ3	Yes

**Session Name:** EveningSession (by Phase)**Device Phases:** Treatment, Washout**Question Alerts:** QAlert1, QAlert2**Measurement Alerts:** MAlert1**Prompts:**

Question	eDiary Compliance
EQ1	Yes
EQ2	Yes

**15. COA****15.2 COA - AM Configuration**

**Session Name:** AdditionalSession (by Phase)

**Device Phases:** Enroll, Run-In, Treatment, Washout

**Prompts:**

Question	eDiary Compliance
ACQ5_Q1	No
ACQ5_Q2	No
ACQ5_Q3	No
ACQ5_Q4	No
ACQ5_Q5	No
ACQ5_SCORE	No

**Timeouts:**

Category	Timeout (sec)
At any stage of the workflow, except stages defined below	90
While displaying the "Thank you" screen	5
While waiting for a PEF measurement	20

**Device Labels:**

Device Type	Label	Description
Subject Device	D3741C00003 / 220707	D3741C00003 / 220707
Tutorial Device	D3741C00003 / 220707 Tutorial	D3741C00003 / 220707 Tutorial

**Measurement Parameters:**

Parameter Name	Unit	Format
PEF	[L/s]	3
PEF	[L/min]	3

**Device Phases:**

Phase	Name	Description	Patient States
01	Enroll	Enroll	Enrolled, Included
02	Run-In	Run-In	Included

**15. COA****15.2 COA - AM Configuration****Device Phases:**

Phase	Name	Description	Patient States
03	Treatment	Treatment	Randomized
04	Washout	Washout	Randomized

**15. COA****15.2 COA - AM Configuration****Visit Schedule**

- ACQ5 will be enabled via investigator password at visit start (3741) in investigator mode (started by pressing on the arrow up and OK icon).
- ACQ5 can only be done once per day.
- At any scheduled visit, prior to the AM download, there will be an ACQ5 Check. If the patient has not completed the ACQ5 on the day of the visit, the AM download will not be started. The user will be reminded that the patient needs to complete the ACQ5 questionnaire first and then start the ACQ check again. After patient completed the ACQ5 questionnaire, all AM3 data (ACQ5 and all recorded daily sessions) will be downloaded.
- The tutorial AM3 offers ACQ5 questionnaire by starting the AM3 in investigator mode. 4 digit pin is not necessary in tutorial AM mode.

**Schedule Name:** AM3**Schedule Description:** AM Schedule**Visit Schedule:**

Seq	Visit	Modules / Packages	Calc. From	Visit Type	Visit Window
10	V1		-	Inclusion	-

## 15. COA

### 15.2 COA - AM Configuration

#### Visit Schedule

Visit Schedule:

Seq	Visit	Modules / Packages	Calc. From	Visit Type	Visit Window
20	ANYTIME		-	Screen	-

**Name:** MorningSession

**From:** 02:00

**To:** 13:59

**Questionnaire Prefix:** MQ

**Sessions:** MorningSession

Alarm Name	Start	Duration	Type	Text
MorningAlarm1	9:00	-	-	-
MorningAlarm2	10:00	-	-	-

**Name:** EveningSession

**From:** 14:00

**To:** 23:59

**Questionnaire Prefix:** EQ

**Sessions:** EveningSession

Alarm Name	Start	Duration	Type	Text
EveningAlarm1	20:00	-	-	-
EveningAlarm2	21:00	-	-	-

**Name:** ACQ5Session

**From:** 00:00

**To:** 23:59

**Questionnaire Prefix:** ACQ5

**Sessions:** AdditionalSession

30	V2		-	Run In	-
40	V3		-	Randomization	-
50	V4		-	Treatment	-
60	V5		-	Treatment	-
70	V6		-	Treatment	-
80	V7		-	Treatment	-

**15. COA****15.2 COA - AM Configuration****Visit Schedule**

Visit Schedule:

Seq	Visit	Modules / Packages	Calc. From	Visit Type	Visit Window
90	V8		-	Treatment	-
100	V9		-	Treatment	-
110	V10		-	Treatment	-
120	V11		-	Treatment	-
9910	VUNR		-	Run In	-
9920	VUNT		-	Treatment	-
9930	VPROF		-	Proficiency	-
9940	VET		-	Termination	-

**16. Portal Access****16.1 MSP3 Portal****16.1.1 Portal Settings**

**Portal Version:** My Study Portal 3 v2

**Online Access:** Yes

**Navigation:** Clinical Data

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader  
MD5: 484A9D0CC067AC89557D01195FD7B4F0

Data Management

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary

## 16. Portal Access

### 16.1.1 Portal Settings

Navigation:

Data Management

My Portal  
(Initial Landing Page)

ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader

MD5: 484A9D0CC067AC89557D01195FD7B4F0

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Administrator, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader

MD5: 77BF09083455AF6F8ACAD797B05F1396

Site Qualification

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA

## 16. Portal Access

### 16.1.1 Portal Settings

Navigation:	Site Qualification	Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Administrator, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader MD5: 77BF09083455AF6F8ACAD797B05F1396
Study Permissions		Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader MD5: 484A9D0CC067AC89557D01195FD7B4F0
Study Reports		Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other

## 16. Portal Access

### 16.1.1 Portal Settings

**Navigation:** Study Reports

Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader

MD5: 484A9D0CC067AC89557D01195FD7B4F0

**Dashboard:** Announcements

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Administrator, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader

MD5: 77BF09083455AF6F8ACAD797B05F1396

Enrollment Graph

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1,

## 16. Portal Access

### 16.1.1 Portal Settings

Dashboard:

Enrollment Graph

HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader

MD5: 484A9D0CC067AC89557D01195FD7B4F0

Open DCRs

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader

MD5: 484A9D0CC067AC89557D01195FD7B4F0

Open Queries to Site

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer

## 16. Portal Access

### 16.1.1 Portal Settings

Dashboard:

Open Queries to Site

Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader

MD5: 484A9D0CC067AC89557D01195FD7B4F0

Reference Materials

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader

MD5: 484A9D0CC067AC89557D01195FD7B4F0

Study Metrics

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical

## 16. Portal Access

### 16.1.1 Portal Settings

Dashboard:	Study Metrics	Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader MD5: 484A9D0CC067AC89557D01195FD7B4F0
Visit Overview		Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader MD5: 484A9D0CC067AC89557D01195FD7B4F0

## 16. Portal Access

### 16.1.1 Portal Settings

**Permissions:** Answer Query

Roles: Customer Care Rep., Investigator, Other Site Contact, Portal Administrator, Primary Alert Receiver, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Study Coordinator  
MD5: CD36F7960BDFAE2DDBA20CFA2C38B0CB

New DCR button

Roles: Customer Care Rep., Investigator, Other Site Contact, Portal Administrator, Primary Alert Receiver, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Study Coordinator  
MD5: CD36F7960BDFAE2DDBA20CFA2C38B0CB

New Order Button

Roles: Customer Care Rep., Investigator, Investigator Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, Other Site Contact, Portal Administrator, Primary Alert Receiver, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Study Coordinator  
MD5: EF52589311020B984B1F57F25CD3E279

Request Removal button

Roles: AM, Auditor, CDMS Administrator, CRO Contact, CRO DCF Receiver, CRO Data Contact, CRO Data Receiver, CRO ECG Report Receiver, CRO or SMO Data Manager, CRO or SMO Medical Monitor, CRO or SMO Monitor, CRO or SMO Study Manager, CS Management, CSI, CSS, CSS Trainee, Cardiologist, Chief Cardiologist, Community Receiver, Customer Care Director, Customer Care Rep., DC, DC Location, DC Management, DM, Data Manager, Development, ECG Specialist, EXPeRT Administrator, Education, Finance, Global Study Manager, HolterOverreadLevel1, HolterOverreadLevel2, HolterOverreadLevelQA, Investigator, Investigator Monitor, Logistics Maintenance, Logistics Management, Logistics PA, Medical Monitor, Monitor, Monitor DCF Receiver, Monitor ECG Report Receiver, OPS Director, Online Reporting, Other Site Contact, PM DCF Receiver, Portal Administrator, Primary Alert Receiver, Primary Sponsor Contact, Primary ePRO Alert Receiver, Principal Investigator, Project Manager, Project Manager Director, QA Analysis, QA Analysis Adjudicator, QA Analyst, QA Manager, QA Review Adjudicator, QC Management, QC Specialist, Read-Only, Review Queue Read Only, Secondary Alert Receiver, Secondary ePRO Alert Receiver, Shipping Contact, Site Contact, Site DCF Receiver, Site ECG Report Receiver, Site Qualifier, SpirometryORLevel1, SpirometryORLevel2, SpirometryORLevel3, SpirometryORLevelQA1, SpirometryORLevelQA2, Sponsor Contact, Sponsor DCF Receiver, Sponsor Data Contact, Sponsor Data Receiver, Sponsor ECG Report Receiver, Sponsor ePRO Alert Receiver, Study Coordinator, Study Manager, Systems Analyst, Technical Support, TicketCreator, TicketReader  
MD5: 484A9D0CC067AC89557D01195FD7B4F0

**Reports:**

Abnormal ECGs Report

Roles: Default Portal Permissions

Comprehensive ECG Analysis Report

Roles: Default Portal Permissions

## **16. Portal Access**

### **16.1.1 Portal Settings**

Reports:	Comprehensive ECG Analysis Report (.csv)	Roles: Default Portal Permissions
	Contact Information Report	Roles: Default Portal Permissions
	Country Overview Report	Roles: Default Portal Permissions
	Data Correction Report	Roles: Default Portal Permissions
	Data Transfer Alert Report	Roles: Default Portal Permissions
	Data Transfer Tracking Report	Roles: Default Portal Permissions
	FEV1 Predicted Decrease Alert Report	Roles: Default Portal Permissions
	Investigator Information Report	Roles: Default Portal Permissions
	Investigator QC Report	Roles: Default Portal Permissions
	Missing Visits Report w/o Optional Visits	Roles: Default Portal Permissions
	Non-Proficient User Alert Report	Roles: Default Portal Permissions
	Predicted Reversibility Report	Roles: Default Portal Permissions
	QC Frequent Findings Report	Roles: Default Portal Permissions
	QC on QC Report	Roles: Default Portal Permissions
	Quality Alert Report	Roles: Default Portal Permissions
	Site Overview Report	Roles: Default Portal Permissions
	Site Status Report	Roles: Default Portal Permissions
	Software Update Alert Report	Roles: Default Portal Permissions
	Spirometry Alert Results Report	Roles: Default Portal Permissions
	Spirometry BTR Report	Roles: Default Portal Permissions
	Spirometry QC Findings Detail Report	Roles: Default Portal Permissions
	Spirometry QC Findings Summary Report	Roles: Default Portal Permissions
	Spirometry QC Grading Report	Roles: Default Portal Permissions
	Spirometry User Certification Report	Roles: Default Portal Permissions
	Study Monitoring Report	Roles: Default Portal Permissions
	Study Tracking Report	Roles: Default Portal Permissions
	Subject Demographic Changes	Roles: Default Portal Permissions
	Summary of Alerts Report	Roles: Default Portal Permissions
	Unresolved Queries over 14 days	Roles: Default Portal Permissions
	Unresolved Query Report	Roles: Default Portal Permissions
	Visit Tracking Report	Roles: Default Portal Permissions

Note: User Access to the reports available through My Study Portal is configured as either "Default Portal Permissions" or "Reports Section Permissions". The Default Portal Permission option allows all roles to view and generate the report as long as the role has access to the Reports Navigation button. The exception is for Site roles that do not have access to summary Cardiac Safety reports (if that service is included for the study). The Reports Section Permissions allows access to a report only for those roles specified in the Report Configuration section below.

### **16.1.2 Clinical Data**

## **Country View Columns:**

## 16. Portal Access

### 16.1.2 Clinical Data

<b>Country</b>	<b>Sites Total</b>	<b>Subjects Total</b>	<b>Subjects Enrolled</b>	<b>Subjects Included</b>
name of the country Filter: Yes	number of sites Filter: Yes	number of patients for the corresponding country Filter: Yes	Number of Subjects in State Enrolled (cumulated) Filter: Yes	Number of Subjects in State Included (cumulated) Filter: Yes
<b>Subjects Randomized</b>	<b>Subjects Treatment Completed</b>	<b>Subjects Finished</b>	<b>Subjects Withdrawal</b>	<b>Subjects Excluded</b>
Number of Subjects in State Randomized (cumulated) Filter: Yes	Number of Subjects in State TreatmentPeriodCompleted (cumulated) Filter: Yes	Number of Subjects in State Finished (non-cumulated) Filter: Yes	Number of Subjects in State EarlyTerminated (non-cumulated) Filter: Yes	Number of Subjects in State Excluded (non-cumulated) Filter: Yes
<b>QC Findings Forced</b>	<b>Open DCRs</b>	<b>Open Queries</b>	<b>AM3 Overall Compliance</b>	<b># of Subjects Who Received a Diary</b>
% of number of QC Findings for Spiro Filter: Yes	Number of open DCRs for all patients on any site of the appropriate country Filter: Yes	Number of open queries for all patients on any site of the appropriate country Filter: Yes	Overall Compliance Filter: Yes	Count total number of subjects per country with a training complete [3062] record Filter: Yes

**Site View Columns:**

<b>Site/Investigator</b>	<b>Subjects Total</b>	<b>Subjects Enrolled</b>	<b>Subjects Included</b>	<b>Subjects Randomized</b>
Site/PI Filter: Yes	Total number of patients for the corresponding site Filter: Yes	Number of Subjects in State Enrolled (cumulated) Filter: Yes	Number of Subjects in State Included (cumulated) Filter: Yes	Number of Subjects in State Randomized (cumulated) Filter: Yes
<b>Subjects Treatment Completed</b>	<b>Subjects Finished</b>	<b>Subjects Withdrawal</b>	<b>QC Findings Forced</b>	<b>Last Visit Date</b>
Number of Subjects in State TreatmentPeriodCompleted (cumulated) Filter: Yes	Number of Subjects in State Finished (non-cumulated) Filter: Yes	Number of Subjects in State EarlyTerminated (non-cumulated) Filter: Yes	% of number of QC Findings for Spiro Filter: Yes	Last Visit Date Filter: Yes
<b>Last Visit Name</b>	<b>Next planned Visit Date</b>	<b>Next planned Visit Name</b>	<b>Last Data Transfer</b>	<b>Open DCRs</b>
Last Visit Name Filter: Yes	the next scheduled visit of all patients on this site Filter: Yes	the next scheduled visit of all patients on this site Filter: Yes	Date and time of last data transfer from that site Filter: Yes	Number of open DCRs for all patients on the appropriate site Filter: Yes
<b>Open Queries</b>	<b>AM3 Overall Compliance</b>	<b># of Subjects Who Received a Diary</b>	-	-
Number of open queries for all patients on the appropriate site Filter: Yes	Overall Compliance Filter: Yes	Count total number of subjects per site with a training complete [3062] record Filter: Yes	-	-

## 16. Portal Access

### 16.1.2 Clinical Data

Subject View Columns:

Subject Number	Subject Status	QC Findings Forced	Last Visit Date	Next planned Visit Date
Patient Id Filter: Yes	Status of patient Filter: Yes	% of number of QC Findings for Spiro Filter: Yes	the last performed visit date of any patient on any site in the appropriate country Filter: Yes	the next scheduled visit for that patient Filter: Yes
Next planned Visit Name	Open DCRs	Last Visit Name	Open Queries	AM3 Overall Compliance
the next scheduled visit for that patient Filter: Yes	Number of open DCRs related to that patient Filter: Yes	the last performed visit name of any patient on any site in the appropriate country Filter: Yes	Number of open queries related to that patient Filter: Yes	Overall Compliance Filter: Yes
<b>Demographics</b>				
Showing all subject demographics which are configured as critical in date entry section of PD Filter: Yes	-	-	-	-

Visit View Columns:

Visit	Date and Time for Performed Action	Event	Operator	Event Detail 1
Visit Filter: Yes	Filter: Yes	Filter: Yes	Filter: Yes	Filter: Yes
Event Detail 2	Event Detail 3	Event Detail 4	-	-
Filter: Yes	Filter: Yes	Filter: Yes	-	-

## 17. Report Configuration

### 17.1 AM3 Alert Report

Contacts:

Contact Name	Schedule	Delivery Method	Condition	Data Type
Primary ePRO Alert Receiver	Immediately	E-mail Fax	AM3_ALERT_SCOR_MODULE/AM3_ALERT_SCOR/AM3_GSM_ALERT_RPT	COA
Sponsor ePRO Alert Receiver	Immediately	E-mail Fax	AM3_ALERT_SCOR_MODULE/AM3_ALERT_SCOR/AM3_GSM_ALERT_RPT	COA

### 17.2 AMx Data Report

Short Description: The purpose of the report is to list all AMx Questionnaires (questions and answers) and measurements per patient.

Long Description: Long description

Report Attributes: Show Customer Logo, Show Logo

Report Version: 1.0.8

Default File Name: AMx Data Report

Default Output Format: PDF

Data Group for AMx Report: Subject All

Time interval for alert reports: 14

Columns:	AMMeasurementAlert1 PatientData1	AMQuestionAlert1 Site#	AMQuestionAlert2
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Contacts:

Contact Name	Schedule	Delivery Method	Condition	Data Type
Primary ePRO Alert Receiver	Weekly: Sun Run time: 1 Start Date: End Date:	-	-	-
Project Manager	Weekly: Sun Run time: 1 Start Date: End Date:	-	-	-

### 17.3 Device Download Upload Tracking Report

Short Description: The purpose of the ePRO report is to list all devices which are related to subjects (e.g. AM3, VIAPen, VIAPad) including the assigned subject, the date of last download/upload and the used SW version.

Long Description: Long description

Report Attributes: Show Logo

Report Version: 1.0.8

Default File Name: Device Download Upload Tracking Report

Default Output Format: PDF

Data Group for AMx Report: Subject All

Time interval for alert reports: 14

## 17. Report Configuration

Columns:	AssignedSubject Country DeviceStatus LastUpload SWVersion	AssignedSubjectInUCS DeviceName InstallationDate PIFirstname Site#	BatteryRemoved DeviceSerialNo LastDownload PILastname SiteStatus
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### 17.4 ECG Analysis with Source Data

Contacts:

Contact Name	Schedule	Delivery Method	Condition	Data Type
Monitor	Immediately	E-mail	Clinical Alert Exclusion Alert	ECG
Site ECG Report Receiver	Immediately	E-mail	Clinical Alert Exclusion Alert	ECG
Sponsor ECG Report Receiver	Immediately	E-mail	Clinical Alert Exclusion Alert	ECG

### 17.5 PFT Analysis Report

Contacts:

Contact Name	Schedule	Delivery Method	Condition	Data Type
Principal Investigator	Immediately	E-mail Fax	Effort selection changed Unacceptable	-

Note: Attachments received via email will be password protected. The password to open the file will always be the recipient's email address in all lowercase letters without spaces.

## 18. Data Management

### 18.1 Data Validation

#### Data Revision Request Forms

Data Correction Requests (DCRs) are able to be submitted by the sites on My Study Portal. The purpose of this process is for sites to proactively notify ERT of any changes that are needed to the demography or visit data.

Electronic documentation of the request, and the requestor, are maintained at ERT. The electronic audit trail will indicate 'Site Response' as the reason for the change.

All changes from the source data (original report) or since the last report (subsequent reports) will be documented in the Remarks Section of the ECG Analysis Report.'

#### Master Lists

ERT will resolve queries, correct discrepancies and update subject identifiers using master patient and visit lists provided by Parexel.

Paper documentation is retained by ERT. The electronic audit trail will indicate 'Master List' as the reason for the change.

All changes from the source data (original report) or since the last report (subsequent reports) will be documented in the Remarks Section of the ECG Analysis Report.

#### Self Evident Corrections - Demographic

ERT may perform Self Evident Corrections (SECs) on demographic data without site contact in the following situations:

1. Adding leading zeros to subject and site numbers
2. Completing subject identifiers that require a set prefix, eg Site number, protocol number
3. Correcting format of subject identifiers by adding numbers, letter or punctuation based on study specific guidelines.
4. Correcting format of inconsistent subject identifiers based on previous ECGs received and processed (minimum two ECGs processed to SEC).

Paper documentation is retained by ERT. The electronic audit trail will indicate 'SEC' as the reason for the change.

All changes from the source data (original report) or since the last report (subsequent reports) will be documented in the Remarks Section of the ECG Analysis Report.

#### Self Evident Corrections -Visit Queries

ERT may perform Self Evident Corrections (SECs) on visit data to resolve improperly formatted, out-of-sequence or missing visit queries when:

1. A minimum of one (1) visit for the subject can be identified using the study/subject/visit tracking reports
2. The current visit falls into the visit schedule based on the protocol and actual collection date and time
3. Proper visit can be determined from previous visit(s) and/or visit schedule
4. Correcting a visit that is clearly identified in the Visit Schedule, eg V1 = 1
5. If an unlabeled or unrecognized ECG is received and the visit can not be SECed, the ECG will be processed as UNSCHEDULED
6. If duplicate ECGs are received; the first ECG labeled with Visit and subsequent ECGs will be Marked Repeat

Paper documentation is retained by ERT. The electronic audit trail will indicate 'SEC' as the reason for the change.

All changes from the source data (original report) or since the last report (subsequent reports) will be documented in the Remarks Section of the ECG Analysis Report.

#### ECG Inactivations

## 18. Data Management

### 18.1 Data Validation

ERT has the ability to deactivate (i.e. 'turn-off') an ECG in ERT's database.

Investigational sites will be permitted to request deactivations of ECGs from ERT's database.

ECGs will be deactivated if:

1. Site or sponsor confirmed that data was transmitted to ERT for a patient that was not enrolled in the study
2. ERT personnel adjudicate an ECG to be an exact duplicate of one previously received. An exact duplicate is by definition when both ECGs have identical date, time (HH.MM.SS) and trace.
3. An ECG is a TEST ECG. A test ECG MUST have 'dummy' identifiers, such as # 9999999.
4. A site recorded a replacement ECG due to artifact or incorrect placement of leads

If an ECG is deactivated after it has been reported, an Inactivation notification will be posted to My Study Portal.

### 18.2 Query Process

#### Querying the Investigator

When data discrepancies arise, sites will be emailed My Study Portal Query Notifications. The site must log into My Study Portal and provide a response to the query. When responses are provided through My Study Portal, a confirmation email is issued to the site.

If a My Study Portal Query Notification cannot be issued (i.e. site query recipient does not have access to My Study Portal) a Data Clarification Form will be issued to the site containing a data query message. The site must answer the query, sign and date the form and fax the resolution back to ERT. The updates will be made to the data and the query resolved. Please refer to the Query Resolution section for the frequency of query attempts.

If applicable, paper documentation is retained by ERT. The electronic audit trail will indicate 'Site Response' as the reason for the change. All changes from the source data (original report) or since the last report (subsequent reports) will be documented in the Remarks Section of the ECG Analysis Report.

ERT will attempt to resolve all missing visits that occur within the received visit schedule for that individual patient (i.e., if a visit is determined to be missing because the following visit was received). ERT will attempt to resolve these visits by querying the site. ERT will not query for missing future visits. Parexel is expected to retrieve any missing ECGs in this situation. ERT is unable to query for missing ECGs if no ECGs have been received for a subject. Parexel is expected to retrieve any missing ECGs in this situation.

After the query attempts are exhausted, Parexel is expected to provide resolution to any outstanding queries.

### 18.3 Query Resolution

Use Portal E-Mail Notifications: Yes

Query Attempt	Query Recipient	Delivery Type	Time to Action (After previous query attempt)
1	Site DCF Receiver	E-mail	-
2	Monitor Site DCF Receiver	E-mail E-mail	72 Hours
3	Monitor Sponsor DCF Receiver	E-mail E-mail	6 Days

## 18.4 Data Delivery

### 18.4.1 Data Encoding/Transfer Plan

## 18. Data Management

### 18.4 Data Delivery

#### 18.4.1 Data Encoding/Transfer Plan

##### Data Transfer Frequency and Method

Transmission Frequency: Cumulative Monthly, Delivery Method: Encrypted E-mail, Data Format: SAS

##### Data Transfer Process

Parexel should supply file specifications including visit coding conventions, file structure (vertical), how to handle multiple lead ECGs (combine to one record or leave as is) and data transfer type (cumulative) to ERT before FPFV. These file specifications are utilized by ERT's Programming staff when determining accurate data collection and in writing protocol specific SAS programs and edit checks. In the event that Parexel does not have specifications for data transfer ERT will provide data in SAS datasets or SAS Transport data files following standard ERT conventions.

A sample data transfer will be sent after sufficient (30) records have been processed to provide a robust test. Data provided in the test transfer may not be QC'd and should be utilized for format and file structure testing only. ERT will send a Data Transfer Agreement along with the sample data file transfer. If the file format meets Parexel's requirements, the form will be signed and returned. ERT will then coordinate scheduled production transfers to Parexel.

ERT will provide two data transfers during database lock for no additional fee; termed Complete Data Send and Final Data Send. A Database Lock Approval Form will be sent after the Final data send. Parexel is required to sign and return the DBLA to ERT indicating the Data lock has occurred.

##### Data Inclusions/Exclusions

There are no Data Exclusions for this study.

##### Data Transfer Instructions

Data will be sent by password protected email to the Data Management team and the password will remain consistent throughout the study. The password will be sent directly after Sample data is sent.

#### 18.4.2 Reconciliation with CRF data

##### Date/Time Discrepancies

Dates and times on digitally transmitted ECGs are generated by the ECG machine's internal clock and are considered source data. ERT recommend that a site contact our Customer Care group to update the machine's internal clock if the time displayed significantly varies from the clinic clock.

If CRF reconciliation identifies a time discrepancy, the digitally transmitted date and time will be considered source data.

In instances where the site is requesting date or time changes, ERT will require documentation as to why this change is needed from Parexel authorizing ERT to apply those changes.

##### Demography and Visit Discrepancies

Where differences in demography data and visit type are identified by Parexel, ERT will update the data as directed by Parexel.

Documentation is required for all Parexel directed changes. Acceptable documentation includes Data Correction Requests, Database Edit Request Form, Data Clarification Form, emails and spreadsheets. It is important that requests for database updates include all applicable subject identifiers. In the event that Parexel does not have documentation to use for reconciliation purposes, ERT will provide a properly formatted document for such purposes.

ERT will make updates based on electronic documentation if they are received from one of the contacts listed in the Contacts section. If changes are requested from other personnel, a signature will be required. Electronic documentation is retained by ERT (i.e. emails, spreadsheets). The electronic audit trail will indicate 'Sponsor Response' as the reason for the change.

**18. Data Management****18.4 Data Delivery****18.4.2 Reconciliation with CRF data**

All changes from the source data (original report) or since the last report (subsequent reports) will be documented in the Remarks Section of the ECG Analysis Report.

**18.4.3 Special Instructions****Timelines**

Reconciliation Timelines are based on the Data Transfer Schedule. When studies receive monthly data transfers, Parexel should load and reconcile the data and supply feedback to ERT within 1-2 weeks after receiving the transfer. ERT will then make database updates and issue queries as directed so that all issues are resolved prior to the subsequent transfer. In the event that the transfer timelines are compressed, the timings of the reconciliation feedback will also be compressed. Failure to provide reconciliation on a regular or timely basis may result in database lock timelines being extended.

**Source Document Return**

After Database Lock, ERT will send all Source ECG Tracings (if applicable) and FDA XMLs to the primary Parexel study contact.

**Logistics Requirements**

Document Translation Requirements: Not required.

Initial Supply Shipment Requirements: 100 Electrodes

Maximum Resupply amount: 150 Electrodes

ECG Machine Date of Birth (DOB) Format: EU

**19. Revision History**

Version	Date	User	Revision comment
v0.01	19-DEC-2014 05:49:36	Sturm, Christian	Initial Setup
v0.02	13-JAN-2015 05:19:39	Sturm, Christian	Setup corrections
v0.03	04-FEB-2015 07:57:43	Sturm, Christian	<p>5.2 Changed at of birth, changed patient number  6.1 Changed visit label  6.2 Added IPD  8.1 Changed workflow, added inclusion step, added additional step if FeNO is skipped, changed Post PFT timing  8.2 Deleted reversibility test, added asthma exclusion criteria, changed timing rules  8.3 Added asthma exclusion criteria, changed timing rules, changed to hard rule for randomization  8.4, 8.5, 8.7, 8.8, 8.10 Added asthma withdrawal criteria, changed timing rules  8.6, 8.9 Added asthma withdrawal criteria, changed timing rules, change added additional message boxes for variation not met, workflow can be continued if variation too high  8.11 Added asthma withdrawal criteria, changed timing rules  8.15 Added IPD visit  9 Added, changed, deleted variables according to input during Kick-Off meeting  10 Added, changed, deleted rules according to input during Kick-Off meeting  11 Added, changed, deleted messages according to input during Kick-Off meeting  14.2 Changed Questionnaire, added questionnaire workflows</p>
v0.04	09-FEB-2015 05:03:49	Sturm, Christian	<p>9 Added V3_PrePFT_Precent_Predicted_Mean, deleted V3_Average_Precent_Predicted  12 Added Cardiac Safety section</p>
v0.05	09-FEB-2015 05:41:43	Sturm, Christian	<p>8.1 Modified Workflow  8.2 Added AM reprogram  8.4, 8.6, 8.10 Added visit success flag  8.11 Moved visit success flag</p>
v0.06	10-FEB-2015 08:34:39	Sturm, Christian	<p>5.2 Change patient number to 7 digits  6.3 Changed maximum reschedule to 2 for V1  8.1 Added Patient on ICS_LABA Reminder, added exclusion criteria for ACQ5 Score &gt;=3.0  8.15 Changed visit name, changed workflow  10, 11 Changed subject to patient  10.31 Added exclusion rule for V1 (ACQ5 &gt;= 3.0)  11.3 Added E to patient number  11.5 Corrected wording  11.6 Added Patients on ICS_LABA reminder  11.12 Changed wording</p>
v0.07	17-FEB-2015 02:43:04	Sturm, Christian	<p>8.3 Added V3_Asthma_Safety_exclusion, deleted Asthma_Safety_exclusion  9.30 Added V1_V3_Compliance  10.31 Changed rule name  10.32, 10.33 Added rules to implement AM compliance check at V3  11.3 Changed subject to patient</p>
v0.08	23-FEB-2015 03:48:06	Tiwana, Manjinder	Addition of ECG sections, draft version for client review.
v0.09	27-FEB-2015 04:41:08	Sturm, Christian	5.2 Deleted date of birth, changed patient number to 3 digits, use site number as part of patient number, changed comment for age entry field



**19. Revision History**

Version	Date	User	Revision comment
			8.2 changed order of rules 8.3 changed standard compliance (from scheduled to scheduled visit) to soft rule 8.5, 8.8 Added not schedule flag after AM reprogram 8.9 Changed variability rules to V9 8.11 Added not schedule flag after AM close 9.1 Variable only to be used at V1 9.5, 9.7, 9.23, 9.24 Added VET 9.9, 9.10 Added V3 9.20, 9.21 Changed description text 9.32, 9.33 Added compliance calculation for treatment period 2 and 3 10 Deleted rule V1_Rule_Exclusion (not needed anymore) 10.27 Changed from exclusion to withdrawal, deleted VUNR 15.2 Corrected MQ1 and MQ3, added ) to answer 2 of MQ1, changed puff range for EQ2 to 0-99 puff(s), added modules, updated questionnaire workflows
v0.10	02-MAR-2015 06:01:31	Tiwana, Manjinder	<ul style="list-style-type: none"> <li>- Update to estimated ECG procedures.</li> <li>- Collection of year of birth instead of full date of birth.</li> <li>- Addition of Relationship Manager</li> <li>- Removed reference to translations.</li> </ul>
v0.11	02-MAR-2015 09:19:10	Tiwana, Manjinder	Included abbreviations for subject demography, version for client review.
v0.12	05-MAR-2015 08:24:17	Tiwana, Manjinder	FPPV updated, estimated total number of ECGs updated and ECG machine type updated.
v0.13	05-MAR-2015 10:37:25	Sturm, Christian	Study version deployment
v0.14	05-MAR-2015 11:18:30	Sturm, Christian	9.26, 9.30 Changed variables
v1.00	06-Mar-2015 10:17:11	Sturm, Christian	9.11-21, 9.25, 9.29-30 Added display name 9.22 Added Follow-up 9.23 Changed best PEF to best morning PEF 9.31.32 Changed description 10.1 Changed 12% to 12.00% 10.6 Corrected description 11.11 Changed 20% to 20.00% All The finalization is for the MasterScope part only.