4 STUDY FORMS AND INSTRUCTIONS

This section provides information about two types of forms: data collection forms and administrative forms. Data collection forms are used to collect data from or about the participant. These forms are entered into the AsthmaNet database and submitted to the DCC. Administrative forms facilitate the processing of the participant and the visit flow by the performance sites and the DCC. Administrative forms are not entered into the AsthmaNet database and they are not submitted to the DCC in most cases.

These instructions are divided into two parts—instructions for data collection forms followed by instructions for administrative forms. The instructions for both parts are in alphabetical order based on the full form name found in the header of the form. Forms with a 'P1' prefix are specific to the VIDA protocol.

For each form, the following information is provided: the purpose of the form, who completes the form, when the form should be completed, and form instructions. Most forms have a comments section (Q6000) at the bottom of the form. The coordinator can record additional comments or information related to the form in this section. This information is entered into the AsthmaNet database management system. If you are unable to find the specific information needed to complete a form, please contact the VIDA Primary or Secondary Data Manager at (717) 531-3663.

4.1 List of Forms Contained in the Visit Packets:

Form Name	Form Code	Refer to AsthmaNet General MOP (Section 10) for Instructions
Visit 0 Packet: P1_VISITA		
BioLINCC Consent Tracking Form	BIOLINCC	*
VIDA Eligibility Checklist 1	P1_ELIG1	
Visit 1 Packet: P1_VISITB		
Asthma Control Test	ACT	*
Asthma Symptom Utility Index	ASUI	*
Asthma Bother Profile	ABP	*
Adult Asthma and Allergy History	ASTHMA_HX_ADULT	*
Prior Conditions for All Participants	PRIOR_COND_ALL	*
Prior Conditions for Adult Participants	PRIOR_COND_ADULT	*
Prior Asthma/Allergy Treatment	PRIOR_TRT	*
VIDA Eligibility Checklist 2	P1_ELIG2	
Adult Body Measurements	BODYMEAS_ADULT	*
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †
Maximum Reversibility Testing	MAXREV	*
VIDA Eligibility Checklist 3	P1_ELIG3	
Household Socio-Economic Information	HOUSEHOLD_SEI	*
Home Environment Questionnaire	HEQ	*
VIDA Laboratory Results	P1_LAB	
Visit 2 Packet: P1_VISITC		
Perceived Stress Scale	PSS_10	*
Asthma-Specific Work Productivity and Activity Impairment Questionnaire	WPAI_ASTHMA	*
VIDA Eligibility Checklist 4	P1_ELIG4	
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †

† Additional protocol specific information concerning the standard form is included in this section of the MOP. More generalized information on the standard form can be found in Section 10 of the General AsthmaNet MOP.

Form Name	Form Code	Refer to AsthmaNet General MOP (Section 10) for Instructions
Adult Methacholine Challenge Testing Checklist	METHACHK_ADULT	* †
Methacholine Challenge Testing	METHA	*
Allergy Skin Test Results	SKIN_TEST	* †
Spirotel® Quality Control	SPIROTELQC	*
VIDA Baseline PEF and Rescue Use Values	P1_BASELINE	
MEMS®6 Monitor Quality Control	MEMSQC	*
Visit 3 Packet: P1_VISITD		
Asthma Control Test	ACT	*
Asthma Symptom Utility Index	ASUI	*
Asthma Bother Profile	ABP	*
Sinonasal Questionnaire	SNQ	*
VIDA Compliance Checklist	P1_COMPLY	
VIDA Eligibility Checklist 5	P1_ELIG5	
VIDA Laboratory Results	P1_LAB	
VIDA Treatment Failure Checklist	P1_TXFAIL_CHK	
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †
Adult Methacholine Challenge Testing Checklist	METHACHK_ADULT	* †
Methacholine Challenge Testing	METHA	*
Sputum Induction Checklist	SPUTUMCHK	*
Sputum Induction	SPUTUM	*
MEMS®6 Monitor Quality Control	MEMSQC	*
VIDA Baseline PEF and Rescue Use Values	P1_BASELINE	
Spirotel® Quality Control	SPIROTELQC	*
Sun Exposure Questionnaire	P1_SEQ_3	
VIDA Vitamin D Intake Questionnaire	P1_VITD_INTAKE	
VIDA Melanin Recording Form	P1_MELANIN	

† Additional protocol specific information concerning the standard form is included in this section of the MOP. More generalized information on the standard form can be found in Section 10 of the General AsthmaNet MOP.

Form Name	Form Code	Refer to AsthmaNet General MOP (Section 10) for Instructions
Genetic Analysis Blood Draw	GABLOOD	*
VIDA Mechanistic Study Participation (Green)	P1_MECH_GREEN	
Visit 4 Packet: P1_VISITE		
Cold History	COLD_HX	*
VIDA Compliance Checklist	P1_COMPLY	
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †
VIDA Treatment Failure Checklist	P1_TXFAIL_CHK	
MEMS®6 Monitor Quality Control	MEMSQC	*
VIDA Scheduled Capsules	P1_MED	
Spirotel® Quality Control	SPIROTELQC	*
Visits 5, 7, 9 Packet: P1_VISITF		
Asthma Control Test	ACT	*
Asthma Symptom Utility Index	ASUI	*
VIDA Compliance Checklist	P1_COMPLY	
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †
VIDA Treatment Failure Checklist	P1_TXFAIL_CHK	
MEMS®6 Monitor Quality Control	MEMSQC	*
VIDA Scheduled Capsules	P1_MED	
Spirotel® Quality Control	SPIROTELQC	*
VIDA Laboratory Results	P1_LAB §	

§ The P1_LAB form is only at Visit 5 for the P1_VISITF checklist.

† Additional protocol specific information concerning the standard form is included in this section of the MOP. More generalized information on the standard form can be found in Section 10 of the General AsthmaNet MOP.

Form Name	Form Code	Refer to AsthmaNet General MOP (Section 10) for Instructions
Visit 6 Packet: P1_VISITG		
Asthma Control Test	ACT	*
Asthma Symptom Utility Index	ASUI	*
Sinonasal Questionnaire	SNQ	*
VIDA Compliance Checklist	P1_COMPLY	
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †
VIDA Treatment Failure Checklist	P1_TXFAIL_CHK	
VIDA Laboratory Results	P1_LAB	
Adult Methacholine Challenge Testing Checklist	METHACHK_ADULT	* †
Methacholine Challenge Testing	METHA	*
Sputum Induction Checklist	SPUTUMCHK	*
Sputum Induction	SPUTUM	*
MEMS®6 Monitor Quality Control	MEMSQC	*
VIDA ICS Taper Stability Assessment	P1_ICS_TAPER	
VIDA Scheduled Capsules	P1_MED	
Spirotel® Quality Control	SPIROTELQC	*
VIDA Mechanistic Study Participation (Green)	P1_MECH_GREEN	

† Additional protocol specific information concerning the standard form is included in this section of the MOP. More generalized information on the standard form can be found in Section 10 of the General AsthmaNet MOP.

Form Name	Form Code	Refer to AsthmaNet General MOP (Section 10) for Instructions
Visit 8 Packet: P1_VISITH		
Asthma Control Test	ACT	*
Asthma Symptom Utility Index	ASUI	*
VIDA Compliance Checklist	P1_COMPLY	
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †
VIDA Treatment Failure Checklist	P1_TXFAIL_CHK	
MEMS®6 Monitor Quality Control	MEMSQC	*
VIDA ICS Taper Stability Assessment	P1_ICS_TAPER	
VIDA Scheduled Capsules	P1_MED	
Spirotel® Quality Control	SPIROTELQC	*
Visit 10 Packet: P1_VISITI		
Asthma Control Test	ACT	*
Asthma Symptom Utility Index	ASUI	*
Asthma Bother Profile	ABP	*
Perceived Stress Scale	PSS_10	*
Asthma-Specific Work Productivity and Activity Impairment Questionnaire	WPAI_ASTHMA	*
VIDA Compliance Checklist	P1_COMPLY	
Adult Body Measurements	BODYMEAS_ADULT	*
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †
VIDA Treatment Failure Checklist	P1_TXFAIL_CHK	
MEMS®6 Monitor Quality Control	MEMSQC	*
Spirotel® Quality Control	SPIROTELQC	*
Sun Exposure Questionnaire	P1_SEQ_10	
VIDA Vitamin D Intake Questionnaire	P1_VITD_INTAKE	

† Additional protocol specific information concerning the standard form is included in this section of the MOP. More generalized information on the standard form can be found in Section 10 of the General AsthmaNet MOP.

Form Name	Form Code	Refer to AsthmaNet General MOP (Section 10) for Instructions
VIDA Melanin Recording Form	P1_MELANIN	
VIDA Laboratory Results	P1_LAB	
VIDA Termination of Study Participation	P1_TERM	
VIDA Participant Study Treatment Questionnaire	P1_PARTTXQX	
VIDA Coordinator Study Treatment Questionnaire	P1_CTXQX	
Visits 90-92 Packet: P1_VISITJ		
Asthma Control Test	ACT	*
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †
VIDA Treatment Failure Checklist	P1_TXFAIL_CHK	
VIDA Treatment Failure Information	P1_TXFAIL	
Visit 88 Packet: P1_VISITK		
Asthma Control Test	ACT	*
VIDA Compliance Checklist	P1_COMPLY	
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	
Spirometry Testing	SPIRO	* †
VIDA Treatment Failure Checklist	P1_TXFAIL_CHK	
MEMS®6 Monitor Quality Control	MEMSQC	*
Spirotel® Quality Control	SPIROTELQC	*
VIDA Termination of Study Participation	P1_TERM	
VIDA Participant Study Treatment Questionnaire	P1_PARTTXQX	
VIDA Coordinator Study Treatment Questionnaire	P1_CTXQX	

† Additional protocol specific information concerning the standard form is included in this section of the MOP. More generalized information on the standard form can be found in Section 10 of the General AsthmaNet MOP.

4.2 Data Collection Forms

Packet data forms are found in visit-specific packets, and they are submitted to the DCC as packets. Individual data forms (single forms) are submitted on an as-needed basis. Concurrent forms (AECLIN, CMED) are completed at each study visit and can be updated periodically throughout the VIDA study. All concurrent forms should be submitted when the participant concludes his or her participation in the VIDA study. Some forms (i.e., MEMS®6 Monitor Quality Control (MEMSQC)) can be submitted as part of a visit packet or as a single form, depending on the specific circumstances. The following is a list of data forms alphabetized by form code and indicating the form type.

Form Name	Form Code	Packet	Single	Concurrent
Asthma Bother Profile	ABP	*		
Asthma Control Test	ACT	*		
Clinical Adverse Events	AECLIN			*†
Adult Asthma and Allergy History	ASTHMA_HX_ADULT	*		
Asthma Symptom Utility Index	ASUI	*		
BioLINCC Consent Tracking Form	BIOLINCC	*		
Adult Body Measurements	BODYMEAS_ADULT	*		
Concomitant Medications for Asthma/Allergy and Adverse Events	CMED			*
Cold History	COLD_HX	*		
Genetic Analysis Blood Draw	GABLOOD	*	*	
Home Environment Questionnaire	HEQ	*		
Household Socio-Economic Information	HOUSEHOLD_SEI	*		
Maximum Reversibility Testing	MAXREV	*		
MEMS®6 Monitor Quality Control	MEMSQC	*	*	

Form Name	Form Code	Packet	Single	Concurrent
Additional Treatment Post Methacholine Challenge Testing	METHA_ADD_TRT		*	
Methacholine Challenge Testing	METHA	*		
Adult Methacholine Challenge Testing Checklist	METHACHK_ADULT	*		
VIDA Baseline PEF and Rescue Use Values	P1_BASELINE	*		
VIDA Change in Study Medications	P1_CHANGE_MEDS		*	
VIDA Compliance Checklist	P1_COMPLY	*	*	
VIDA Coordinator Study Treatment Questionnaire	P1_CTXQX	*	*	
VIDA Eligibility Checklist 1	P1_ELIG1	*		
VIDA Eligibility Checklist 2	P1_ELIG2	*		
VIDA Eligibility Checklist 3	P1_ELIG3	*		
VIDA Eligibility Checklist 4	P1_ELIG4	*		
VIDA Eligibility Checklist 5	P1_ELIG5	*		
VIDA ICS Taper Stability Assessment	P1_ICS_TAPER	*		
VIDA Laboratory Results	P1_LAB	*	*	
VIDA Mechanistic Study Participation (Green)	P1_MECH_GREEN	*		
VIDA Scheduled Capsules	P1_MED	*	*	
VIDA Melanin Recording Form	P1_MELANIN	*		
VIDA Participant Study Treatment Questionnaire	P1_PARTTXQX	*	*	
VIDA Pulmonary Procedure Checklist	P1_PULMONARYCHK	*	*	
Sun Exposure Questionnaire	P1_SEQ_3	*		
Sun Exposure Questionnaire	P1_SEQ_10	*		
VIDA Significant Asthma Exacerbation	P1_SIGEX		*	
VIDA Termination of Study	P1_TERM	*	*	

Form Name	Form Code	Packet	Single	Concurrent
Participation				
VIDA Treatment Failure Checklist	P1_TXFAIL_CHK	*	*	
VIDA Treatment Failure Information	P1_TXFAIL	*	*	
VIDA Vitamin D Intake Questionnaire	P1_VITD_INTAKE	*		
Post-Albuterol (4 puffs) Spirometry Testing	PALB4_SPIRO		*	
Urine Pregnancy Test	PREG_TEST		*	
Prior Conditions for Adult Participants	PRIOR_CONDITIONS_ADULT	*		
Prior Conditions for All Participants	PRIOR_CONDITIONS_ALL	*		
Prior Asthma/Allergy Treatment	PRIOR_TRT	*		
Perceived Stress Scale	PSS_10	*		
Serious Adverse Event Reporting Form	SERIOUS		*	
Allergy Skin Test Results	SKIN_TEST	*	*	
Sinonasal Questionnaire	SNQ	*		
Spirometry Testing	SPIRO	*	*	
Spirotel® Quality Control	SPIROTELQC	*	*	
Sputum Induction Lab Values	SPUTLAB		*	
Additional Treatment Post Sputum Induction	SPUTUM_ADD_TRT		*	
Sputum Induction	SPUTUM	*		
Sputum Induction Checklist	SPUTUMCHK	*		
Asthma-Specific Work Productivity and Activity Impairment Questionnaire	WPAI_ASTHMA	*		
Wisconsin Upper Respiratory Symptom Survey-21	WURSS_21		*	

4.2.1 Clinical Adverse Events (AECLIN)

Purpose: To record the details and events that occur each time a participant experiences a clinical adverse event.

Who: An AsthmaNet coordinator completes the form.

When: Visits 0-10, 88, 90-92

Note: This form should also be completed if the participant contacts study personnel to report a clinical adverse event outside of scheduled visits. This form should also be updated if the participant reports having an asthma/allergy or adverse event between visits. Questions on other forms may also prompt a coordinator to complete this form.

For participants re-enrolling at Visit 1/Visit 2 under the modified protocol: Review V0, V1, and V2 (if applicable) AECLIN forms for updates. If an event was marked as 'Ongoing at final visit' when this participant terminated and the event is still ongoing, cross out the mark in this box (with coordinator initials and date next to edit) and leave the 'Ongoing at current visit' box checked. If an event was marked as 'Ongoing at final visit' when this participant terminated and the event has since stopped, cross out the marks in both the 'Ongoing at current visit' and 'Ongoing at final visit' boxes and provide a stop date in Q1030. If updates need to be made to a V0 AECLIN form, or to a V1 AECLIN form for a V2 re-enrollee, please submit data corrections. If updates need to be made to a V1 or V2 AECLIN form for re-enrollees at these respective visits, you will be able to update the concurrent forms through participant data.

4.2.2 Concomitant Medications for Asthma/Allergy and Adverse Events (CMED)

Purpose: To record any asthma/allergy and adverse event related concomitant medications that the participant uses during the study.

Who: An AsthmaNet coordinator completes the form.

When: Visits 0-10, 88, 90-92

Note: This form should be completed if the participant contacts study personnel to report a concomitant medication used outside of scheduled visits. This form should also be updated if the participant reports taking an asthma/allergy or adverse event related concomitant medication between visits. Questions on other forms may also prompt a coordinator to complete this form.

Form Instructions:

During the screening phase of the study, participants will be on an asthma controller medication and this medication use should be recorded on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

If the participant is taking an ICS/long-acting beta-agonist combination drug, each component will be recorded as a separate entry on the form. For example, Advair would be recorded as one record for fluticasone and another record for salmeterol on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

At Visit 1, multiple entries will be required on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form to document the use of an asthma controller medication. The first set of record(s) will capture the start date after Visit 0 and the end date prior to Visit 1. The second set of record(s) will capture the start date after Visit 1 and remain ongoing until prior to Visit 2.

At Visit 2, the last set of record(s) will be updated with an end date prior to (for participant's completing spirometry) or at Visit 2.

If the participant is taking allergy shots or has received any vaccines, these should be noted on the CMED_NON form and not recorded on the CMED form.

For more information on recording Concomitant Medciations for Asthma/Allergy and Adverse Events (CMED), see Section 10 of the AsthmaNet General MOP.

For participants re-enrolling at Visit 1/Visit 2 under the modified protocol: Review V0, V1, and V2 (if applicable) CMED forms for updates. If a medication was marked as 'Ongoing at Final Visit' when this participant terminated and he/she is still taking the medication, cross out the mark in this box (with coordinator initials and date next to edit) and leave the 'Ongoing at Current Visit' box checked. If a medication was marked as 'Ongoing at Final Visit' when this participant terminated and he/she has since ceased taking the medication since the original consent date, cross out the marks in both the 'Ongoing at Current Visit' and 'Ongoing at Final Visit' boxes and provide a stop date in Q1070. If updates need to be made to a V0 CMED form, or to a V1 CMED form for a V2 re-enrollee, please submit data corrections. If updates need to be made to a V1 or V2 CMED form for re-enrollees at these respective visits, you will be able to update the concurrent forms through participant data.

For participants re-enrolling starting at Visit 1 or Visit 2, the following is an example of how to handle the information recorded on the CMED form. We want to capture all applicable medication and event information since the participant's initial termination to his/her re-enrollment visit. This example will be for a participant re-enrolling at Visit 1 who resumed taking Advair (Fluticasone and Salmeterol; records 1 and 2) on the previous termination date, and who also continued Flovent (nasal Fluticasone; record 3) use.

For the CMED form from the participant's initial Visit 1: Participant was consented on December 28th, and was taking both Advair and Flovent prior to that date, so the informed consent was used as start date. Due to the required holds for VIDA, a stop date of January 5th is recorded for Advair because Visit 1 occurred on January 6th. This participant was then found ineligible at Visit 1 due to an FEV_1 of 93% during spirometry. The Flovent record shows that this medication was ongoing at the current visit and ongoing at the final visit.

Updated CMED form from the participant's Visit 1 re-enrollment visit, which occurred on February 16$^{th:}$ Records 1 and 2 will remain as they are, as no changes are necessary because those records were appropriately completed and stopped prior to the initial Visit 1. Record 3, the nasal Fluticasone, will require update because Visit 1 is no longer the final visit for this participant who had an eligible FEV_1 at the re-enrollment visit. Therefore, the coordinator would cross out the mark in the 'Ongoing at Final Visit' checkbox (initial and date the edit) to indicate this should be null. In this case, the participant was still taking this medication, so the 'Ongoing at Current Visit' check will remain. If the participant had stopped taking the medication in between the termination and re-enrollment, the coordinator would also cross out the completion of the 'Ongoing at Current Visit' box and then complete the Stop Date field.

This participant had resumed taking Advair the day of termination from VIDA. Thus, two new records for Advair will be entered indicating a start date of January 6th, and the stop date should be February 15th, one day prior to the re-enrollment Visit 1 to meet VIDA holds.

4.2.3 Adult Methacholine Challenge Testing Checklist (METHACHK_ADULT)

Purpose: To determine if an adult participant is eligible to proceed with the diluent (solution #0) pulmonary function testing for methacholine challenge testing.

Who: A Pulmonary Function Technician completes the form.

When: Visits 2, 3, 6

Form Instructions:

Question 1050. Refer to the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form and the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG) for records regarding systemic corticosteroid use for the treatment of an asthma exacerbation in the last 4 weeks.

For more information on the Adult Methacholine Challenge Testing Checklist (METHACHK_ADULT), see Section 10 of the AsthmaNet General MOP.

4.2.4 Allergy Skin Test Results (SKIN_TEST)

Purpose: To record whether or not the participant has a positive reaction to various allergens.

Who: An AsthmaNet coordinator certified to perform skin testing completes the form.

When: Visit 2 or later visits, if necessary

Form Instructions:

Question 1000. Q1000 should be answered 'Yes' if (1) prior skin testing was performed by an AsthmaNet certified coordinator or technician, and (2) prior skin testing occurred within 3 years of the current date. If Q1000 is answered 'Yes,' provide the date of the previous skin test in Q1010, the ID of the coordinator who performed the skin test in Q1020, and attach a photocopy of pages 1, 2, 3 and 4 from the previous skin test form to page 1 of the current form. Update the participant ID and visit in the header of pages 2, 3 and 4 to reflect the current participant ID and visit. **At the time of data entry, enter Q1000-1020, and then enter the data recorded on the photocopy for pages 1, 2, 3 and 4.**

Complete the upper right-hand corner of the first page of the current Allergy Skin Test Results (SKIN_TEST) form with the visit date and visit number of the current visit and provide the ID of the coordinator who is performing the current visit.

Question 1040. For the VIDA protocol, this question should always be answered either 'Yes' or 'No'. 'N/A' is not an acceptable response, as an FEV1 measurement should have been obtained at the current visit. At visit 2, if spirometry is not performed (per protocol), the FEV1 value from Visit 1 should serve as the reference value.

Question 1060. If either of the shaded boxes is completed (Q1030 or Q1050), the participant is not eligible to proceed with allergy skin testing at this visit. If the participant is not able to be tested at Visit 2 because of medication use or a low FEV_1, reschedule the testing for an upcoming visit as soon as possible. Skin testing may be done at an another VIDA visit and submitted later in the study as a single form. The Visit 2 Allergy Skin Test (SKIN_TEST) form should be marked as missing in the packet.

If the participant is ineligible and cannot attempt skin testing at a later date, enter the partially completed Allergy Skin Test Results (SKIN_TEST) form at Visit 2 indicating the participant's ineligibility.

Question 1070. If the participant has had a severe systemic reaction to allergy skin testing in the past, repeat skin testing should **not** be performed. Complete page 1 of the Allergy Skin Test Results (SKIN_TEST) form indicating this information. Skin test data will be missing for this participant.

Questions 1080-1100. If the participant previously had an anaphylactic reaction to egg, peanut, and/or milk, the applicable allergen should not be administered when performing the skin test. Results for the applicable allergen (Q1430-1450, Q1490-1510, Q1550-1570) should be missing on the Allergy Skin Test Results (SKIN_TEST) form.

Question 1140 and 1170. If the skin test is not valid at the first attempt and the participant is willing to re-attempt the test at another visit, the first Allergy Skin Test Results (SKIN_TEST) form should be entered and the second SKIN_TEST form may be entered as a single form at the next attempt.

For more information on the Allergy Skin Test Results (SKIN_TEST) form, skin testing procedures, and definitions, see Section 10 of the AsthmaNet General MOP, the Allergy Skin Test Manual (Appendix 3) of the General MOP, and the Skin Testing discussion in Section 2 of the VIDA MOP.

4.2.5 Genetics Analysis Blood Draw (GABLOOD)

Purpose: To record information related to a participant's genetic analysis blood draw.

Who: An AsthmaNet coordinator completes the form.

When: Visit 3 or at a later visit, if necessary

Form Instructions:

If the genetics blood draw is not done at Visit 3, but is instead deferred to a later visit in the VIDA study, the Visit 3 packet Genetics Analysis Blood Draw (GABLOOD) form should be marked missing. The Genetics Analysis Blood Draw (GABLOOD) form should be completed and entered as a single form for the visit at which the blood draw takes place (e.g., Visit 6).

If the participant terminates early from the study and never completes a blood draw at a subsequent visit, submit a data correction to have the Visit 3 Genetics Analysis Blood Draw (GABLOOD) form set to present. Q1000 and Q1010 should be completed, indicating that a blood sample was not obtained. When the data correction is submitted through the AsthmaNet application, first-enter the form and send a copy of the Genetics Analysis Blood Draw (GABLOOD) form for Visit 3 to the DCC for second entry. A subsequent blood draw could also be missing because the participant is deemed ineligible or consent is withdrawn.

If the blood draw is attempted at Visit 3 but is unsuccessful, and the participant is unwilling to have another draw attempted at a future visit, then the Genetics Analysis Blood Draw (GABLOOD) form should be completed and data entered as part of the Visit 3 packet. In that case, Q1000 and Q1010 should be completed, indicating that a blood sample was not obtained, and the participant should provide source documentation.

See the Genetics Blood Draw discussion in Section 2 for more details on the genetics analysis blood draw and Appendix 4 of the AsthmaNet General MOP for more details on the Genetics Analysis Blood Draw (GABLOOD) form.

4.2.6 Serious Adverse Event Reporting Form (SERIOUS)

Purpose: To record the details of each serious adverse event.

Who: An AsthmaNet coordinator completes the form in collaboration with the Principal Investigator.

When: Visits 0-10, 88, 90-92

Form Instructions:

Question 1020. Any medications given out as part of the VIDA study should be considered "study drug" when answering this question. For instance, open-label Alvesco®, prednisone distributed for use during the OCS response period, and single-blinded capsules given out as part of the study are considered "study drug." However, Xopenex® and rescue prednisone should not be considered "study drug" when answering this question.

For more information on the Serious Adverse Event Reporting Form (SERIOUS), see Section 10 of the AsthmaNet General MOP.

4.2.7 Spirometry Testing (SPIRO)

Purpose: To record the outcome measurements from the participant's pre-bronchodilator spirometry procedure

Who: The Pulmonary Function Technician completes the form.

When: Visits 1-10, 88, 90-92

Form Instructions:

If the Spirometry Testing (SPIRO) form is completed between visits at an FEV_1 re-assessment visit, specify the number of the last visit completed and the current visit date in the upper right-hand corner. This form should be entered as a single form.

If maximum reversibility testing was completed at Visit 1, the Spirometry Testing Report (SPIRO_RPT) should be marked 'No' in the database. The Maximum Reversibility Testing Report (MAXREV_RPT) should be marked 'Yes' in the database. The spirometry session data is included on the Maximum Reversibility Testing Report (MAXREV_RPT) and a separate Spirometry Testing Report (SPIRO_RPT) does not need to be printed.

Similarly, if methacholine challenge testing is completed at Visits 2, 3, and 6, the Spirometry Testing Report (SPIRO_RPT) should also be marked 'No.' The Methacholine Challenge Testing Report (METHA_RPT) should be marked 'Yes' in this scenario. The spirometry session data is included on the Methacholine Challenge Testing Report (METHA_RPT) and a separate Spirometry Testing Report (SPIRO_RPT) does not need to be printed.

For more information on the Spirometry Testing (SPIRO) form, see Section 10 of the AsthmaNet General MOP.

4.2.8 Sun Exposure Questionnaire (Visit 3) (P1_SEQ_3)

Purpose: Information concerning UV exposure, such as average hours per week spent outdoors in summer and winter, and sunscreen and tanning salon habits, is collected on this form.

Who: The participant completes the form.

When: Visit 3

Form Instructions:

Questions 1000-1060. The participant should respond to each question using the last 3 years as his or her frame of reference.

4.2.9 Sun Exposure Questionnaire (Visit 10) (P1_SEQ_10)

Purpose: Information concerning UV exposure, such as average hours per week spent outdoors in summer and winter, and sunscreen and tanning salon habits, is collected on this form.

Who: The participant completes the form.

When: Visit 10

Form Instructions:

Questions 1000-1060. The participant should respond to each question using the last 7 months, the period of time since the participant was randomized in the VIDA study, as his or her frame of reference.

4.2.10 VIDA Baseline PEF and Rescue Use Values (P1_BASELINE)

Purpose: The participant's baseline peak flow (PEF) and baseline rescue use values are recorded on this form.

Who: An AsthmaNet coordinator completes the form.

When: Visits 2, 3

Form Instructions:

Question 1000. Record the participant's baseline peak flow (PEF) value in Q1000 according to the following rubric:

Visit	Scenario	Baseline Peak Flow (PEF) Value	Supporting Documents
2	Completed methacholine challenge	From prebronchodilator (baseline) spirometry at Visit 2, converted to L/M	
2	Did not complete methacholine challenge	From prebronchodilator (baseline) spirometry at Visit 1, converted to L/M	
3		Average of the AM PEFs collected the 14 days prior to Visit 3	Spirotel® VIDA Eligibility and Baseline Report (P1_ELIG_BASE_RPT)

Question 1010. Record the participant's baseline rescue use value in Q1010 according to the following rubric:

Visit	Baseline Peak Flow (PEF) Value	Supporting Documents
2	Self-reported average daily use of albuterol/levalbuterol during the 14 days prior to Visit 2	
3	Average daily use of levalbuterol/Xopenex® during the 14 days prior to Visit 3	Spirotel® VIDA Eligibility and Baseline Report (P1_ELIG_BASE_RPT)

4.2.11 VIDA Change in Study Medications (P1_CHANGE_MEDS)

Purpose: Changes in study medications after a participant experiences an adverse event or is eligible for a study-defined dose taper are recorded on this form.

Who: An AsthmaNet coordinator completes this form.

When: Visits 4-9, 90-92

Note: This form must be completed each time a change in study medications occurs. If the study medications are altered because of an adverse event, one copy of the form should be completed when the study medication regimen is initially altered; a second copy of the form should be completed if the study medication regimen is reverted back to its original or different state. If the change is the result of a study-defined taper, the form should be completed once each time a taper is instituted.

Form Instructions:

Question 1000. Indicate the reason for the change in study medications.

Question 1010. Record the adverse event number from the Clinical Adverse Events (AECLIN) form that corresponds to the event prompting a change in study medications. If the participant's study medication regimen was altered because of a study-defined taper, a related adverse event number should not be recorded in Q1010.

Question 1020. Alvesco® MDI is the study inhaled corticosteroid inhaler dispensed at VIDA visits as part of regular visit procedures. If a participant will continue to take the same dose from the study Alvesco® inhaler, Q1020 should be answered 'No.'

Questions 1030, 1040, and 1050. If a participant's study Alvesco® regimen is altered, record Q1030 ('Dose changed from') as the dose the participant was taking prior to the change in study medications. Record Q1040 ('Dose changed to') as the dose the participant was taking after the change in study medications. Record the start date as the first day the participant started the new regimen.

Question 1060. Study capsules refer to the regular dose capsule vial dispensed at Visits 4-9. If a participant will continue to take the study capsules, Q1060 should be answered 'No' and the rest of the form should not be completed.

Questions 1070, and 1080. If a participant's scheduled study capsules regimen is altered, record Q1070 ('Current status of participant's study capsules'). Record Q1080 ('Date change took effect') as the first day the participant started the new regimen.

At subsequent VIDA study visits, the study medication status should be reviewed. When another change to the study medication regimen is made, another copy of the form should be completed indicating to what dose the Alvesco® MDI was changed and when, as well as if the participant's study capsules regimen was resumed and when.

Each event indicating a change in study medications on the Clinical Adverse Events (AECLIN) form (Q1090 is answered '2') should have a corresponding VIDA Change in Study Medications (P1_CHANGE_MEDS) form completed.

The VIDA Change in Study Medications (P1_CHANGE_MEDS) form should be entered as a single form and submitted to the DCC with the current visit's packet, if applicable.

If a change to the study medication regimen occurs between visits, the VIDA Change in Study Medications (P1_CHANGE_MEDS) form should be entered as a single form with the visit number of the last visit completed.

For example, if it is determined that a participant experienced a treatment failure between visits, a VIDA Change in Study Medications (P1_CHANGE_MEDS) form would be submitted to indicate an increase/doubling in the dose of study inhaled corticosteroid (Alvesco®) according to the treatment failure rescue algorithm discussed in detail in the Treatment Failure section in Section 2 of the VIDA MOP. The doubling of the study inhaled corticosteroid would continue for 7 days.

A second VIDA Change in Study Medications (P1_CHANGE_MEDS) form would be submitted to indicate the decrease of study inhaled corticosteroids to the original dose after the 7 day period has ended. Both VIDA Change in Study Medications (P1_CHANGE_MEDS) forms should reference the same treatment failure adverse event recorded on the Clinical Adverse Events (AECLIN) form.

4.2.12 VIDA Compliance Checklist (P1_COMPLY)

Purpose: The participant's compliance with dosing from the Alvesco® MDI inhaler, scheduled daily capsules, prednisone tablets (Visit 4 only), and loading dose capsules (Visit 5 only), as well as the participant's diary and peak flow compliance are recorded on this form.

Who: An AsthmaNet coordinator completes this form.

When: Visits 3-10, 88

Form Instructions:

The information for Q1000-1050 is obtained from the participant's DOSER™ for the scheduled Alvesco® MDI at Visits 3-10.

Question 1000. The value for Q1000 is obtained from Question 1 on the VIDA Alvesco® Dosing Compliance Worksheet (P1_COMPLY_WKS).

Question 1010. The value for Q1010 is obtained from Question 2 on the VIDA Alvesco® Dosing Compliance Worksheet (P1_COMPLY_WKS).

Question 1030. The value for Q1030 is obtained from Question 4 on the VIDA Alvesco® Dosing Compliance Worksheet (P1_COMPLY_WKS).

Question 1040. The value for Q1040 is obtained from Question 5 on the VIDA Alvesco® Dosing Compliance Worksheet (P1_COMPLY_WKS).

The information for Q1060-1090 is obtained from the participant's MEMS®6 for the scheduled daily capsules at Visits 3-10.

Questions 1060-1090. Information for these questions is obtained from the MEMS®6 Monitor Report (MEMS_RPT).

The information for Q1100-1120 is obtained from the participant's Spirotel Participant Compliance Report (P1_COMPLY_RPT) at Visits 3-10.

Questions 1100-1120. The values will be transcribed directly from the report; the field annotations and text from the VIDA Compliance Checklist (P1_COMPLY) are used to display the results.

Question 1130. At Visit 4 only, count the number of tablets returned in the VIDA Tablet Vial – OCS Response Period Prednisone Vial' and record the value in Q1130.

Question 1140. At Visit 4 only, calculate the number of tablets taken by subtracting the number of tablets returned (Q1130) from the number of tablets dispensed (14) and record the value in Q1140.

Question 1150. At Visit 4 only, prescribed dose is 2 tablets per morning starting the morning after Visit 3 and including the morning of Visit 4.

Question 1160. At Visit 4 only, calculate the percent compliance by dividing the number of tablets taken (Q1140) by the number of prescribed tablets (Q1150) and multiplying by 100. Round to the nearest tenth of a percent and record the value in Q1160.

Question 1170. At Visit 5 only, count the number of capsules returned in the 'VIDA LOADING DOSE Capsule Vial' and record the value in Q1170.

Question 1180. At Visit 5 only, calculate the number of capsules taken by subtracting the number of capsules returned (Q1170) from the number of capsules dispensed (2) and record the value in Q1180.

Question 1190. At Visit 5 only, calculate the percent compliance by dividing the number of capsules taken (Q1180) by the number of prescribed capsules (2) and multiplying by 100 and record the value in Q1190.

See the Dosing Compliance discussion in Section 2 for more details on the compliance calculations.

4.2.13 VIDA Coordinator Study Treatment Questionnaire (P1_CTXQX)

Purpose: This form helps to determine whether the blind on the scheduled capsules was effective from the coordinator's perspective.

Who: The AsthmaNet coordinator who was primarily responsible for the participant's VIDA visits completes the form.

When: Visits 5-10, 88, 90-92

Form Instructions:

The VIDA Coordinator Study Treatment Questionnaire (P1_CTXQX) form should be completed at Visit 10 or on the day of a randomized participant's last visit if he or she terminates prior to Visit 10.

If a randomized participant terminates:

- **during** a post-randomization visit, the VIDA Coordinator Study Treatment Questionnaire (P1_CTXQX) form should be completed at the visit and entered as a single form at Visits 5-9.

- between visits, the coordinator should complete the VIDA Coordinator Study Treatment Questionnaire (P1_CTXQX) form and enter it as a form in the Visit 88 packet.

The visit date recorded on the form should be the date the form was completed. If the coordinator who was primarily responsible for the participant's VIDA study visits is not present during a visit when this form is to be completed, it should be completed upon his or her return and dated appropriately.

Question 1000. Q1000 should be answered with the option that most closely represents the coordinator's feelings about which type of capsule the participant received during the treatment period. If unsure of which type of study capsule was received, Q1000 should be answered with option number 3, "I have no idea which type of capsules the participant received, but my best guess would be:," and choose either Placebo or Vitamin D for Q1010.

Question 1015D. Any comments with respect to any other observations the coordinator may have made that helped him or her make a choice in Q1 should be recorded in Q1015D and entered into the AsthmaNet database (up to 250 characters).

To verify that the information collected on this form is correct, the coordinator who completed the form should initial and date the form in the shaded source documentation box provided (Q1020-1030) at the bottom of the page.

4.2.14 VIDA Eligibility Checklist 1 (P1_ELIG1)

Purpose: This form is the first of five eligibility forms completed during Visits 0-3. It consists of basic interview questions that assist in determining if a participant is eligible to enroll in the VIDA study.

Who: An AsthmaNet coordinator completes the form.

When: Visit 0

Form Instructions:

For detailed information regarding eligibility criteria, see the Eligibility Criteria discussion in Section 2.

Question 1000. Do not ask the participant this question. Data can **only** be collected if the participant has signed an informed consent form for the VIDA study. See the Informed Consent discussion in Section 2 for further details.

Question 1010. The signature date should be the date the participant signed the consent document. If the consent was signed prior to the Visit 0, the consent should be reviewed by the participant on the day Visit 0 takes place. The date the consent form was signed should **not** be updated.

Question 1020. If a performance site is not participating in the Immune Substudy (i.e., Green mechanistic study) or recruitment has closed, Q1020 should be answered

Question 1140 and 1150. The participant must agree to either adhere to a specific dose of an intranasal steroid **OR** stop use of all intranasal steroids for the duration of the VIDA study, starting at or before Visit 2.

The intranasal steroid should be recorded on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form as an ongoing record.

For participants under original protocol:
Question 1170. The participant may not receive allergen immunotherapy 4 weeks prior to Visit 0 OR intend to receive therapy during the study.

For participants under modified protocol:

Question 1170. The participant may enroll in the study if an established maintenance regimen was implemented continuously for a minimum of 3 months prior to the Visit 0.

Question 1180. A respiratory tract infection is defined as a cough, runny nose with or without fever, or sore throat that is not related to allergen exposure.

Question 1210. If there is any possibility that the participant is physically able to bear children, Q1210 should be answered 'Yes' (even if the participant indicates she is not currently engaging in heterosexual intercourse). If the participant is surgically sterile or post-menopausal for at least one year, Q1210 should be answered 'No.' If the participant is male, Q1210 should be answered 'N/A.'

Questions 1220 and 1230. Answer Q1220 and Q1230 only if the participant is able to bear children.

Question 1220. If the participant is currently pregnant or lactating, she is ineligible to participate in the study at this time.

Question 1230. Show the participant the Birth Control Methods (BIRTH_CTRL) reference card found on the AsthmaNet secure website in the Standard Forms: Reference Cards folder and ask if she is using one of the listed birth control methods. A participant who is able to bear children **must** be using a birth control method listed on the reference card to be eligible for the study. If the participant is not engaging in heterosexual intercourse, abstinence applies as a legitimate birth control method.

Question 1240. If the participant indicates historical evidence of a disease or medical condition, but has no current evidence, Q1240 should be answered 'No.' The participant must have current evidence of one of the medical conditions for Q1240 to be answered 'Yes.'

If a participant screened at Visit 0 has one of these exclusionary medical conditions and is being allowed to progress through the study, then Q1240 should be answered 'Yes' and Q1280 should also be answered 'Yes.' Resulting errors should be marked unresolvable, and the participant's condition and physician approval to proceed should be documented in the comment provided. Such cases will be treated as protocol exceptions.

Question 1280. If any of the shaded boxes is completed, the participant is ineligible. The visit should be stopped and the visit packet should **not** be entered into the AsthmaNet database or sent to the DCC. File the visit packet in the participant's study folder at the clinic.

If the participant is eligible, continue with the rest of the Visit 0 visit procedures.

For more details pertaining to whether a coordinator should permit the participant to continue in the study, see the Eligibility Criteria discussion in Section 2.

General Instructions:

If an eligibility protocol exception was granted by the DCC, complete the question(s) that the exception was granted for accurately (i.e., complete the shaded box). Q1280 should be answered 'Yes' to indicate the participant is eligible to proceed and any entry errors that result from the exception should be marked unresolvable. In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

To verify that the information collected on this form is correct, have the participant initial and date the form in the shaded source documentation box provided (Q1290-1300) on the last page of the form.

4.2.15 VIDA Eligibility Checklist 2 (P1_ELIG2)

Purpose: This form is the second of five eligibility forms completed during Visits 0-3. It consists of questions that assist in determining if a participant is eligible to continue in the VIDA study.

Who: An AsthmaNet coordinator completes the form.

When: Visit 1

Form Instructions:

For detailed information regarding eligibility criteria, see the Eligibility Criteria discussion in Section 2.

Question 1010. The asthma controller medication should be recorded on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form. Multiple entries will be required on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form to document the use of the asthma controller medication. The first set of record(s) will capture the start date after Visit 0 and the end date prior to Visit 1. The second set of record(s) will capture the start date after Visit 1 and remain ongoing.

If the participant is taking an ICS combination drug, each component will be recorded as separate entries on the form. For example, Advair would be recorded as one record for fluticasone and another record for salmeterol on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

If the participant has taken an asthma controller medication for the two weeks prior to Visit 1, and that asthma controller medication is recorded on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form with a start date equal to the date the informed consent was signed, provide a comment in Q6000 on the VIDA Eligibility Checklist 2 (P1_ELIG2) form indicating the actual start date of the medication if before the informed consent date. If the exact start date is unknown, make a notation in Q6000 indicating a partial date or verify the participant has been taking the asthma controller medication for at least 14 days prior to Visit 1.

Question 1030. If a participant is found to have evidence of an exclusionary medical condition at Visit 1 based on the physical exam and medical history and is being allowed to progress through the study due to an approved exception, then Q1030 should be answered ‘Yes’ and Q1070 should also be answered ‘Yes.’ Resulting

errors should be marked unresolvable, and the participant's condition and physician approval to proceed should be documented in the comment section provided. Such cases will be tracked as protocol exceptions.

Question 1050. If the participant has taken one of the drugs that are listed as exclusionary within the specified time periods, but is allowed to progress through the study at the discretion of the study physician, Q1050 should be answered 'Yes' and Q1070 should also be answered 'Yes.' Resulting errors should be marked unresolvable, and the participant's VIDA-exclusionary medication and physician approval to proceed should be documented in the comment provided. Such cases will be tracked as protocol exceptions.

Question 1060. If the participant is currently taking prescription or OTC medications other than those listed on the Allowed Medications for VIDA (P1_MEDALLOW) reference card, the coordinator should confirm through the DCC that the medication is allowed before continuing. If the medication is approved by the DCC, Q1060 should be answered 'No.' If the medication is not approved by the DCC, the participant is ineligible to continue in the study and Q1060 should be answered 'Yes.'

Question 1070. If any of the shaded boxes is completed, the participant is ineligible. The visit should be stopped. Enter and submit all collected data, along with the VIDA Termination of Study Participation (P1_TERM) form.

If the participant is eligible, continue with the rest of the Visit 1 visit procedures.

General Instructions:

If an eligibility protocol exception was granted by the DCC, complete the question(s) that the exception was granted for accurately (i.e., complete the shaded box). Q1070 should be answered 'Yes' to indicate the participant is eligible to proceed and any entry errors that result from the exception should be marked unresolvable. In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

To verify that the information collected on this form is correct, have the participant initial and date the form in the shaded source documentation box provided (Q1080-1090) on the second page of the form.

4.2.16 VIDA Eligibility Checklist 3 (P1_ELIG3)

Purpose: This form is the third of five eligibility forms completed during Visits 0-3. It consists of questions that assist in determining if a participant is eligible to continue in the VIDA study.

Who: An AsthmaNet coordinator completes the form.

When: Visit 1

Form Instructions:

For detailed information regarding eligibility criteria, see the Eligibility Criteria discussion in Section 2.

Questions 1000-1020 should be completed if IRB approval has not yet been obtained to implement the FEV_1 protocol change.

Question 1000. The participant's prebronchodilator (baseline) FEV_1 (% predicted) value should be obtained from Q1040 on the Spirometry Testing (SPIRO) form completed at the visit. If the participant's FEV_1 (% predicted) value is less than 50% of predicted or more than 90% of predicted, the participant is ineligible for the study. The visit should be stopped. Enter and submit all collected data, along with the VIDA Termination of Study Participation (P1_TERM) form.

Question 1010. The percent difference in FEV_1 value should be calculated by hand from Q1030 on the Maximum Reversibility (MAXREV) form and Q1030 on the Spirometry Testing (SPIRO) form completed at the visit. If the participant's FEV_1 value did not improve more than or equal to 12% (no rounding) in response to four puffs of levalbuterol, the participant will need to undergo a methacholine challenge at Visit 2 if he or she continues to meet baseline FEV_1 criteria in Q1020.

If the participant's FEV_1 value did improve more than or equal to 12% (no rounding) in response to four puffs of levalbuterol, the participant has met spirometry eligibility requirements and will not need to undergo a methacholine challenge at Visit 2. Q1020 should not be completed and Q1030-1050 should be completed when lab results are available.

Question 1020. The participant's prebronchodilator (baseline) FEV_1 (% predicted) value should be obtained from Q1040 on the Spirometry Testing (SPIRO) form completed at the visit. If the participant's FEV_1 (% predicted) value is greater than

85% of predicted, the participant is ineligible for the study. The visit should be stopped. Enter and submit all collected data, along with the VIDA Termination of Study Participation (P1_TERM) form.

If the participant's FEV_1 (% predicted) value is less than or equal to 85% of predicted, the participant must undergo a methacholine challenge at Visit 2 to meet PC_{20} eligibility requirements. Continue with the remainder of the visit procedures and complete Q1030-1050 when lab results are available.

Question 1025 should be completed if IRB approval has been obtained to implement the FEV_1 protocol change.

Question 1025. The participant's prebronchodilator (baseline) FEV_1 (% predicted) value should be obtained from Q1040 on the Spirometry Testing (SPIRO) form completed at the visit. If the participant's FEV_1 (% predicted) value is less than 50% of predicted, the participant is ineligible for the study. The visit should be stopped. Enter and submit all collected data, along with the VIDA Termination of Study Participation (P1_TERM) form.

Question 1030. Results of the eGFR test are recorded on the VIDA Laboratory Results (P1_LAB) form at Visit 1. Q1030 should be completed after local lab results are received. If the participant's eGFR is less than 30 ml/min, the participant is ineligible to continue in the study. The VIDA Laboratory Results (P1_LAB) form is completed at Visit 1 and submitted as part of the Visit 1 packet. The local lab report should be included in the packet. All identifying information on the lab report should be blackened-out prior to forwarding to the DCC.

Question 1040. Results of the serum calcium test are recorded on the VIDA Laboratory Results (P1_LAB) form at Visit 1. Q1040 should be completed after local lab results are received. If the participant's serum calcium value is greater than 10.2 mg/dL, the participant is ineligible to continue in the study. The VIDA Laboratory Results (P1_LAB) form is completed at Visit 1 and submitted as part of the Visit 1 packet. The local lab report should be included in the packet. All identifying information on the lab report should be blackened-out prior to forwarding to the DCC.

Question 1050. Results of the urine calcium/creatinine test are recorded on the VIDA Laboratory Results (P1_LAB) form at Visit 1. Q1050 should be completed after local lab results are received.

If the participant's urine calcium/creatinine ratio is greater than 0.37, the participant is ineligible to continue in the study. However, if the participant has an elevated ratio but

otherwise qualifies for the study, the local investigator may opt to allow the participant to proceed in the pre-randomization phases of the study at his or her discretion.

If this exception is made:

- **Q1050** on the VIDA Eligibility Checklist 3 (P1_ELIG3) should be answered 'Yes' and Q1060 should be answered 'Yes.'
- Entry errors that result from the exception should be marked unresolvable.
- In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception.
- Provide a brief comment in the comments field (Q6000) with additional information on the exception.

The local lab report should be included in the packet. All identifying information on the lab report should be blackened-out prior to forwarding to the DCC.

Question 1060. If any of the shaded boxes is completed, the participant is ineligible. The visit should be stopped and a VIDA Termination of Study Participation (P1_TERM) form completed.

If the participant is eligible, continue with the rest of the Visit 1 procedures.

General Instructions:

If an eligibility protocol exception was granted through the DCC, complete the question(s) that the exception was granted for accurately (i.e. complete the shaded box). Q1060 should be answered 'Yes' to indicate the participant is eligible to proceed and any entry errors that result from the exception should be marked unresolvable. In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

4.2.17 VIDA Eligibility Checklist 4 (P1_ELIG4)

Purpose: This form is the fourth of five eligibility forms completed during Visits 0-3. It consists of questions that assist in determining if a participant is eligible to continue in the VIDA study.

Who: An AsthmaNet coordinator completes the form.

When: Visit 2

Form Instructions:

For detailed information regarding eligibility criteria, see the Eligibility Criteria discussion in Section 2. For a visual representation of how the VIDA Eligibility Checklist 4 (P1_ELIG4) form flows, please see the chart at the end of this form instruction section.

Depending on the participant's eligibility criteria, this form can be completed four different ways.

1. If the participant meets reversibility criteria at Visit 1, spirometry and methacholine challenge are not required at Visit 2. Sections 1 and 4 are completed.

2. If the participant does not meet reversibility criteria at Visit 1 and has valid source documentation for a methacholine challenge within the past 6 months, spirometry and methacholine challenge are not required at Visit 2. Sections 1, 2, and 4 are completed.

3. If the participant does not meet reversibility criteria at Visit 1 and does not have valid source documentation for a methacholine challenge within the past 6 months and is eligible for spirometry and methacholine challenge at Visit 2, spirometry and methacholine challenge are required at Visit 2. Sections 1, 3, and 4 are completed.

4. If the participant does not meet reversibility criteria and does not have valid source documentation for a methacholine challenge within the past 6 months and is not eligible for spirometry and/or methacholine challenge at Visit 2, he or she is ineligible. Sections 1 and 3 are completed.

See below for more detailed instructions on how to complete the form in each of these cases.

Question 1030. If any of the shaded boxes in Section 1 is completed, the participant is ineligible. The visit should be stopped and a VIDA Termination of Study Participation (P1_TERM) form completed.

If the participant is eligible, complete Q1040 and continue with the rest of the Visit 1 visit procedures, accordingly.

Question 1040. If the participant met the FEV_1 reversibility criterion at Visit 1, questions regarding methacholine challenge source documentation and spirometry and methacholine challenge at Visit 2 (Sections 2 and 3) should not be completed and the coordinator should skip to Section 4.

If the participant did not meet FEV_1 reversibility criterion at Visit 1, the coordinator should continue with Section 2.

Question 1050. Valid source documentation is acceptable for a methacholine challenge performed within six months of the visit date, performed in the AsthmaNet systems, and completed by a certified technician or supervised by a certified supervisor. The coordinator may use source documentation of a methacholine challenge from any AsthmaNet protocol. The source documentation methacholine challenge should be a test overread by AsthmaNet, and therefore a part of the export data from the Medgraphics system.

If the participant has valid source documentation (Q1050 is answered 'Yes'), complete Section 2. If the participant does not have valid source documentation, skip to Section 3.

Question 1060. If the participant has source documentation of a PC_{20} in the past six months, the values should be transcribed onto the VIDA Eligibility Checklist 4 (P1_ELIG4) form only. Do **not** transcribe these values on the Methacholine Challenge Testing (METHA) form; no Spirometry Testing (SPIRO) form nor Methacholine Challenge Testing (METHA) form should be submitted with the Visit 2 packet when providing source documentation.

A copy of the source documentation methacholine challenge report should be stored in the participant's study folder, as well as forwarded to the DCC along with the Visit 2 packet.

If the participant has source documentation of a PC_{20} in the past six months, do **not** mark the Methacholine Challenge Testing Report (METHA_RPT) as present when entering the Visit 2 packet.

Question 1070. Provide the date of the methacholine challenge used for source documentation.

Questions 1080 and 1090. Provide the Technician ID and Supervisor ID, if applicable, of the methacholine challenge used for source documentation.

Question 1100. If the participant was using inhaled corticosteroids (ICS) at the time of the documented challenge, Q1100 should be answered 'Yes' and Q1110 should be completed. Skip to Q1130.

If the participant was not using ICS, Q1100 should be answered 'No' and Q1120 should be completed. Skip to Q1110. Continue with rest of form.

Question 1130. If either of the shaded boxes in Section 2 is completed, the participant must complete a methacholine challenge at the visit to be assessed for eligibility for the VIDA study. The coordinator should continue with Section 3.

If the participant is eligible, continue with the rest of the Visit 2 visit procedures and skip to Section 4.

Question 1140 should be completed if IRB approval has not yet been obtained to implement the FEV_1 protocol change.

Question 1140. The participant's prebronchodilator (baseline) FEV_1 (% predicted) value should be obtained from Q1040 on the Spirometry Testing (SPIRO) form completed at the visit. If the participant's FEV_1 (% predicted) value is less than 50% or more than 85%, the participant is ineligible for the study. The coordinator should skip to Q1190.

If the participant's FEV_1 (% predicted) value is greater than or equal to 50% and less than or equal to 85%, the participant's eligibility for completing a methacholine challenge at the visit should be indicated in Q1150.

Question 1145 should be completed if IRB approval has been obtained to implement the FEV_1 protocol change.

Question 1145. The participant's prebronchodilator (baseline) FEV_1 (% predicted) value should be obtained from Q1040 on the Spirometry Testing (SPIRO) form

completed at the visit. If the participant's FEV_1 (% predicted) value is less than 50%, the participant is ineligible for the study. The coordinator should skip to Q1190.

Question 1150. If the participant does not qualify for a methacholine challenge according to the Adult Methacholine Challenge Testing Checklist (METHACHK_ADULT), the participant is ineligible for the study. The coordinator should skip to Q1190.

If the participant does qualify for a methacholine challenge according to the Adult Methacholine Challenge Testing Checklist (METHACHK_ADULT), a methacholine challenge should be performed and Q1160 completed.

Question 1160. If the participant is using inhaled corticosteroids (ICS), Q1160 should be answered 'Yes' and Q1170 should be completed. Skip to Q1190.

If the participant is not using ICS, Q1160 should be answered 'No' and Q1180 should be completed. Skip to Q1170. Continue with rest of form.

Question 1190. If any of the shaded boxes in Section 3 is completed, the participant is ineligible. The visit should be stopped and a VIDA Termination of Study Participation (P1_TERM) form completed.

If the participant is eligible, continue with the rest of the Visit 2 procedures.

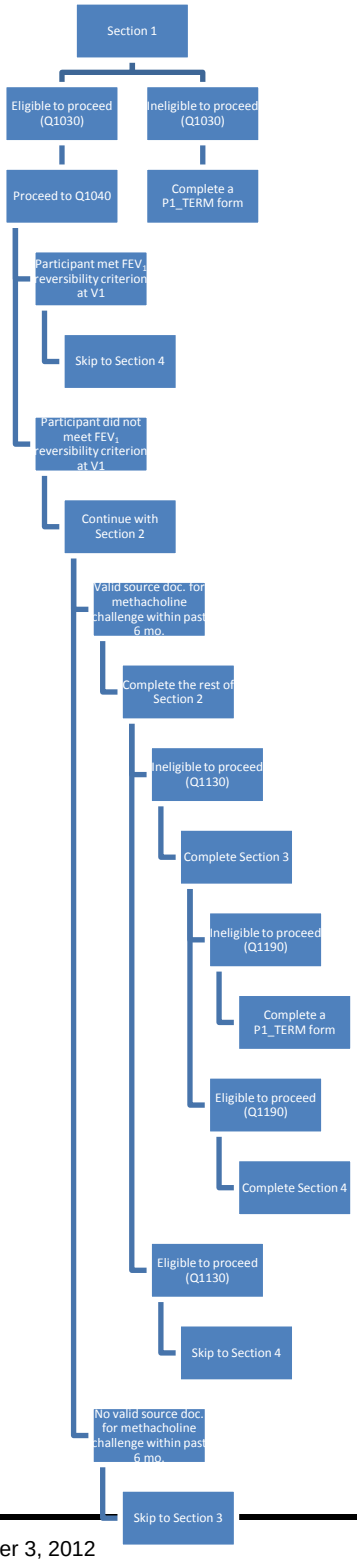
Question 1220. If any of the shaded boxes in Section 4 is completed, the participant is ineligible. The visit should be stopped and a VIDA Termination of Study Participation (P1_TERM) form completed.

If the participant is eligible, continue with the rest of the Visit 2 procedures.

General Instructions:

If an eligibility protocol exception was granted through the DCC, complete the question(s) that the exception was granted for accurately (i.e. complete the shaded box). The applicable eligibility question(s) (Q1030, Q1130, Q1190, and/or Q1220) should be answered 'Yes' to indicate the participant is eligible to proceed and any entry errors that result from the exception should be marked unresolvable. In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

P1_ELIG4 Flow Diagram



4.2.18 VIDA Eligibility Checklist 5 (P1_ELIG5)

Purpose: This form is the final eligibility form completed during Visits 0-3. It consists of questions that assist in determining if a participant is eligible to continue in the VIDA study.

Who: An AsthmaNet coordinator completes the form.

When: Visit 3

Form Instructions:

For detailed information regarding eligibility criteria, see the Eligibility Criteria discussion in Section 2.

Questions 1000-1010. These values are obtained from the Spirotel® VIDA Eligibility and Baseline Report (P1_ELIG_BASE_RPT). The format of the report will match the field annotations and question text of the VIDA Eligibility Checklist 5 (P1_ELG5) form.

Question 1020. If the participant has received treatment with any drug that is considered exclusionary, but is allowed to progress through the study at the discretion of the study physician and has been approved to do so through the DCC, Q1020 should be answered 'Yes' and Q1150 should also be answered 'Yes.' Resulting errors should be marked unresolvable, and the participant's VIDA-exclusionary medication and physician approval to proceed should be documented in the comment provided. Such cases will be treated as protocol exceptions. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

Question 1050. If treatment failure criteria appeared to be met for a participant during the run-in, but an investigator and coordinator do not feel a real treatment failure occurred, and an exception was granted by the DCC, Q1050 should be answered 'No' and Q1150 should also be answered 'Yes'.

Question 1060. This question is answered by reviewing the value in Question 1c on the VIDA Compliance Checklist (P1_COMPLY).

Question 1070. This question is answered by reviewing the value in Question 1f on the VIDA Compliance Checklist (P1_COMPLY).

Question 1080. This question is answered by reviewing the value in Question 2d on the VIDA Compliance Checklist (P1_COMPLY).

Questions 1090-1110 should be completed if IRB approval has not yet been obtained to implement the FEV_1 protocol change.

Question 1090. This question is answered by reviewing the value in Q1040 on the Spirometry Testing (SPIRO) form completed at the visit.

Question 1100. If the participant met the beta-agonist reversibility criterion at Visit 1, Q1100 should be answered 'Yes.' Skip to Q1120. If the participant did not meet the beta-agonist reversibility criterion at Visit 1, Q1100 should be answered 'No' and Q1110 should be completed.

Question 1110. If the participant did not meet the beta-agonist reversibility criterion at Visit 1, then the participant's prebronchodilator (baseline) FEV_1 must be ≤ 85% of predicted. Answer Q1110 accordingly based on the value obtained from Q1040 on the Spirometry Testing (SPIRO) form completed at the visit.

Question 1115 should be completed if IRB approval has been obtained to implement the FEV_1 protocol change.

Question 1115. This question is answered by reviewing the value in Q1040 on the Spirometry Testing (SPIRO) form completed at the visit.

Question 1140. Results of the urine calcium/creatinine test are recorded on the VIDA Laboratory Results (P1_LAB) form at Visit 3. Q1140 should be completed after local lab results are received. If the participant's urine calcium/creatinine ratio is greater than 0.37 at this visit, the participant is ineligible to continue in the study. The VIDA Laboratory Results (P1_LAB) form is completed at Visit 3 and submitted as part of the Visit 3 packet. The local lab report should be included in the packet. All identifying information on the lab report should be blackened-out prior to forwarding to the DCC.

Question 1150. If any of the shaded boxes is completed, the participant is ineligible for randomization. The visit should be stopped and a VIDA Termination of Study Participation (P1_TERM) form completed.

If the participant is eligible, continue with the rest of the Visit 3 procedures.

4.2.19 VIDA ICS Taper Stability Assessment (P1_ICS_TAPER)

Purpose: This form is completed once at the end of Phase I and again at the end of Phase IIa to determine if the participant meets criteria for tapering of his or her Alvesco® dose at that time.

Who: An AsthmaNet coordinator completes the form.

When: Visits 6, 8

Form Instructions:

For more information on completing the VIDA ICS Taper Stability Assessment (P1_ICS_TAPER) form, refer to the Inhaled Corticosteroid Dose Taper discussion in Section 2.

Question 1030. If any of the shaded boxes is completed in Q1000-1020, the participant is ineligible for an Alvesco® dose taper. The participant should continue using the same dose of Alvesco® as he or she used in the previous phase or the dose deemed appropriate to treat his or her current condition.

If the participant is eligible for an Alvesco® dose taper, the participant's current Alvesco® dose should be decreased by 50% for the subsequent phase. A VIDA Change in Study Medications (P1_CHANGE_MEDS) form must be completed for each dose taper.

4.2.20 VIDA Laboratory Results (P1_LAB)

Purpose: This form is completed after the local lab report with serum creatinine, urine calcium, urine creatinine, and/or serum calcium levels is received for various samples taken during the study.

Who: An AsthmaNet coordinator completes the form.

When: Visits 1, 3, 5, 6, 8, 10, as-needed for safety follow-up

Form Instructions:

For more information regarding conversions and calculations necessary for completing the VIDA Laboratory Results (P1_LAB) form, see the Serum Calcium and Creatinine/eGFR Laboratory Tests and Urine Calcium:Creatinine Ratio Laboratory Test discussions in Section 2.

Questions 1000-1010. Q1000 and Q1010 are completed at Visit 1 only. Values recorded for Q1000 must be recorded in mg/dL units. Any necessary conversions must be made prior to recording data on the form and entering the data into the AsthmaNet database.

To calculate the value for Q1010, the coordinator should access the on-line Cockcroft-Gault calculator via the following web address: www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation.

Before using the on-line calculator, the coordinator should complete the fields in the first 'Clinic Use Only' gray box on the VIDA Laboratory Results (P1_LAB) form. This box contains spaces to record the participant's gender, current age (in whole years), and weight (in pounds), as required for input into the on-line calculator. The weight measured at Visit 1 and recorded on the Adult Body Measurements (BODYMEAS_ADULT) form should be converted from kilograms to pounds by multiplying by 2.2. The converted weight should be recorded in the 'Clinic Use Only' gray box.

The completed 'Clinic Use Only' gray box will facilitate entry of data into the on-line calculator. Verify that the data was entered correctly and then click in the 'Creatinine Clearance' box. The participant's computed eGFR value will appear. Record this value to one decimal place in Q1010 on the VIDA Laboratory Results (P1_LAB) form.

Submit the original lab report with the participant's Visit 1 packet. The coordinator should record the participant's ID number in the upper right-hand corner of the report. All identifying information (name, medical record number, etc.) should be blackened-out prior to forwarding the report to the DCC with the packet. If the DCC receives a report for which the identifying information has not been blackened-out, a protocol violation may be assigned.

Questions 1020-1030. The gray 'Clinic Use Only' box directly below Q1020 and Q1030 can be used for converting mg/dL values to mg/L values, which are required in Q1020 and Q1030. In addition, the urine calcium/creatinine ratio should be calculated in this gray box. If the urine calcium or urine creatinine values recorded on the P1_LAB_RPT are censored, record the numeric value in the entry field and in Q6000 document how the value appears on the lab report. For example, if the urine calcium is reported as < 5.2 on the report, 5.2 will be entered in field Q1020 and the comment 'Q1020 appears on the lab report as < 5.2' is entered into Q6000 on the P1_LAB form.

Question 1040. The serum calcium measurement is entered in Q1040. If the measurement is greater than 10.2 mg/dL at Visit 1, the participant is ineligible to continue in the VIDA study. If the measurement is greater than 10.2 mg/dL after randomization, the participant must stop taking his or her scheduled study capsules. The coordinator must submit a VIDA Change in Study Medication (P1_CHANGE_MEDS) form for this change and follow safety procedures in the MOP. Report the adverse event on the Clinical Adverse Events (AECLIN) form using ICD-9 code 275.42 for hypercalcemia.

4.2.21 VIDA Mechanistic Study Participation (P1_MECH_GREEN)

Purpose: This form is completed **only** if a successful blood draw was done for the VIDA Immune Substudy sponsored by Drs. Green, Cernadas, and Umetsu, also known as the Green Mechanistic Study.

Who: An AsthmaNet coordinator completes the form.

When: Visits 3, 6

Form Instructions:

Question1000. Complete the number of red/grey top SST tubes collected.

Question 1010. Complete the number of green top tubes collected at the visit. If only two green top tubes are collected, these tubes should be labeled as GREEN_NA_HEP samples.

These samples should be entered into the AsthmaNet Biological Sample Tracking module upon collection.

This form should only be completed if at least two green top tubes were collected.

4.2.22 VIDA Melanin Recording Form (P1_MELANIN)

Purpose: Measurements, including calibration and skin pigmentation measurements, collected by the SmartProbe device are imported into this spreadsheet.

Who: An AsthmaNet coordinator completes the form.

When: Visits 3, 10

Form Instructions:

For more detailed information regarding the SmartProbe 400 device, see the SmartProbe 400 discussion in Section 2.

The VIDA Melanin Recording Form (P1_MELANIN) form is an Excel spreadsheet that collects data in conjunction with the SmartProbe device. The VIDA Melanin Recording Form (P1_MELANIN) Excel spreadsheet can be downloaded from the AsthmaNet secure website in the Forms: VIDA: Data Collection Forms folder.

Follow these steps for installing the SmartConnect software and connecting the SmartProbe device to the performance site's (non-spirometry) computer:

1. Install the SmartConnect Software on your computer. You will only need to do this the first time you use the device.
    a. You will need to be a member of your computer's local administrator group in order to install this software. Contact your IT support desk for assistance in obtaining this access if you do not already have it.
    b. Insert the disk labeled "SmartConnect Software Version 1.50" into the CD drive of your computer.
    c. Double click on the My Computer icon on your desktop.
    d. Double-click on SmartConnect CD-R.
    e. Double-click on SmartConnect Setup folder.
    f. Double-click on Setup.exe to launch Setup.
    g. At the SmartConnect Setup Screen, click OK, as shown in Figure 1.

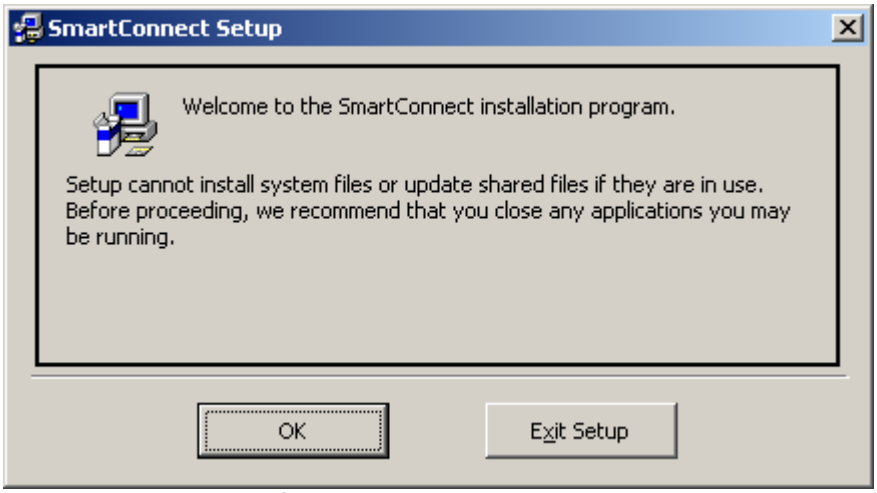


Figure 1: SmartConnect Setup

h. In the next SmartConnect Setup Screen, click on the computer icon button as shown in Figure 2 to begin the installation.

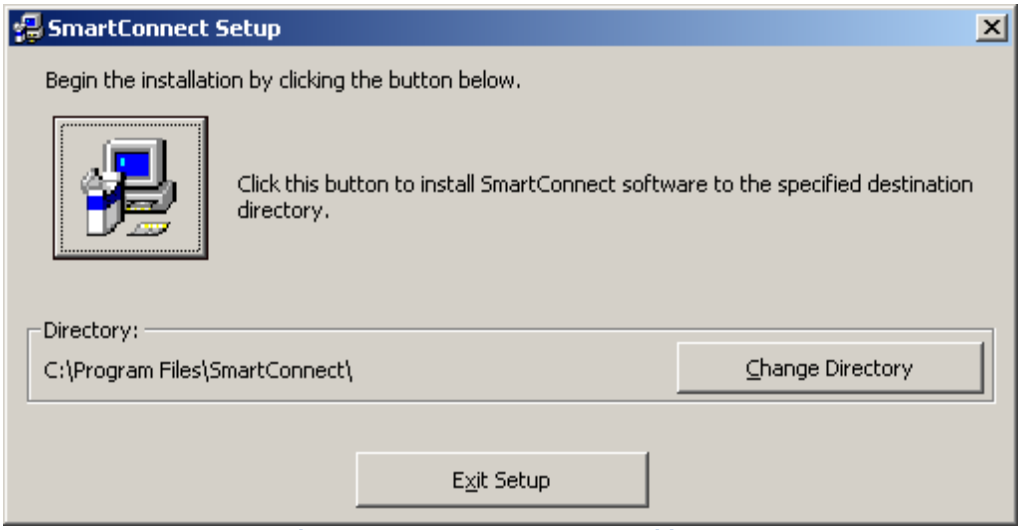


Figure 2: SmartConnect Setup with Icon

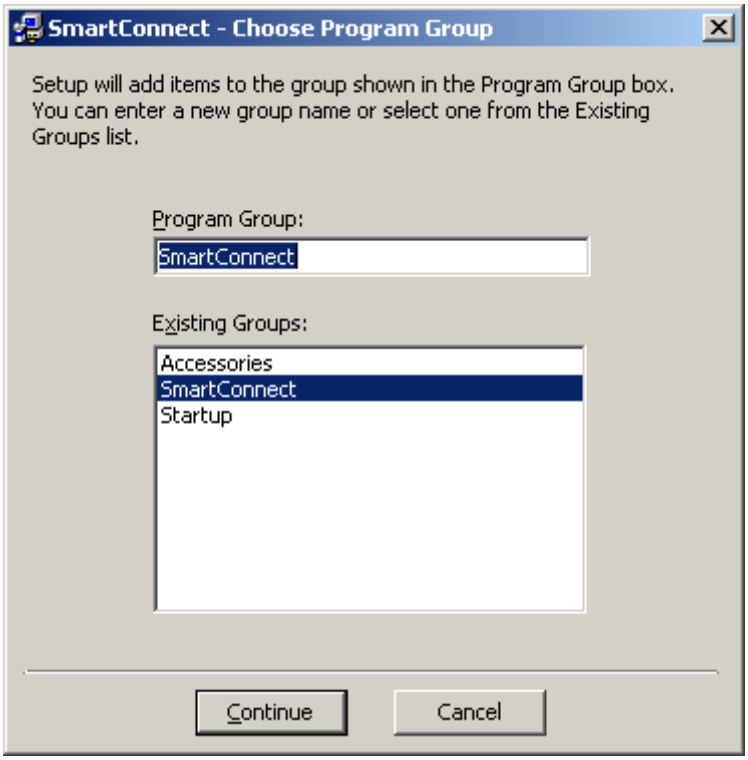


Figure 3: Choose Program Group

i. In the Choose Program Group page, leave the default settings and click Continue, as shown in Figure 3.

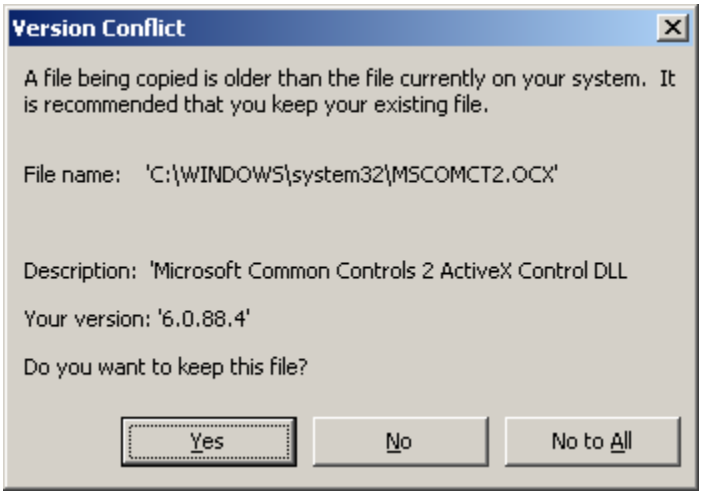


Figure 4: Version Conflict

j. If prompted with the Version Conflict screen, click Yes to keep all old files, as shown in Figure 4. You will have to click this four times.

k. **For Windows 7 Users Only**: After the fourth Version Conflict screen, you will receive the error: "Error - C:\Program Files\Common Files\Microsoft Shared\DAO\DAO350.DLL"
    i. Click IGNORE and you will receive a screen that says "Setup completed successfully."
l. **For Windows XP Users Only**: You will receive the below screen after you click Yes to the Version Conflict screen the fourth time.

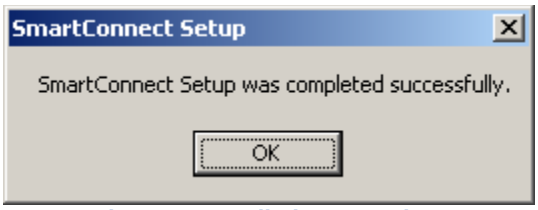


Figure 5: Installation Complete

m. Once you receive the screen shown in Figure 5, your installation is complete.

2. Make the SmartConnect program available to all users who log onto your computer.

For Windows XP Users Only:

a. Double-click on your My Computer icon.
b. Navigate to C:\Documents and Settings\[youruseraccount]\Start Menu\Programs where [youruseraccount] represents the user name you use to log on to the computer. Note that SmartConnect appears as a folder in this window. Keep this window open.
c. Double-click on My Computer.
d. Navigate to C:\Documents and Settings\All Users\Start Menu\Programs
e. Copy the SmartConnect folder from step K (above) into the folder you opened in step M. This will copy the link to the SmartConnect executable into the Start -> Programs Menu for all users who access this computer.

For Windows 7 Users Only:

a. Double-click on your Computer icon on your desktop, or click Start -> Computer.
b. Navigate to C:\ProgramData\Microsoft\Windows\Start Menu\Programs.
c. Leave that window open.
d. Click on the Start Menu.
e. Click All Programs.
f. Locate the SmartConnect Folder.
g. Drag the SmartConnect folder into the Programs folder you opened in step G above.

3. Install the Tripp-Lite Keyspan USB Serial Adapter. You will only need to do this the first time you use the device.

a. Insert the disk labeled “Tripp-Lite Keyspan USB Serial Adapter” into your computer’s CD drive.
b. Double-click on the My Computer icon on your desktop.
c. Double-click on the CD-Rom drive.
d. Double-click on the folder labeled “Windows Drivers.”
e. Double-click on the USA-19HS Installation file appropriate for your operating system. For Windows 7 users, select the Vista driver version.
f. At the Setup Screen, click Next to begin Setup.
g. Accept the License Agreement.
h. Click Next to install the device to the default installation folder.
i. Setup will complete.
j. At the Keyspan Registration screen, click Cancel and then Exit Registration. Registration is not needed.
k. Click Finish to complete the installation wizard.

4. Connect the USB-to-serial cable to the USB serial adapter.

USB-to-Serial Cable →

← USB Serial Adapter

5. Connect the USB serial adapter to the RJ45-to-serial port cable.

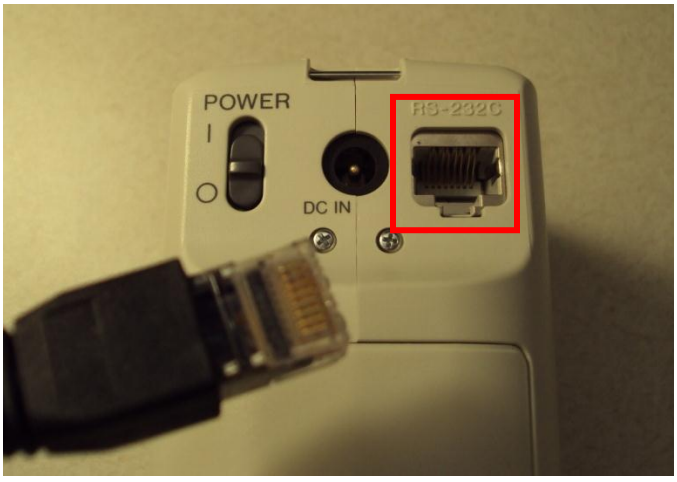
RJ45-to-Serial Port Cable

RJ-45 end →

← Serial end

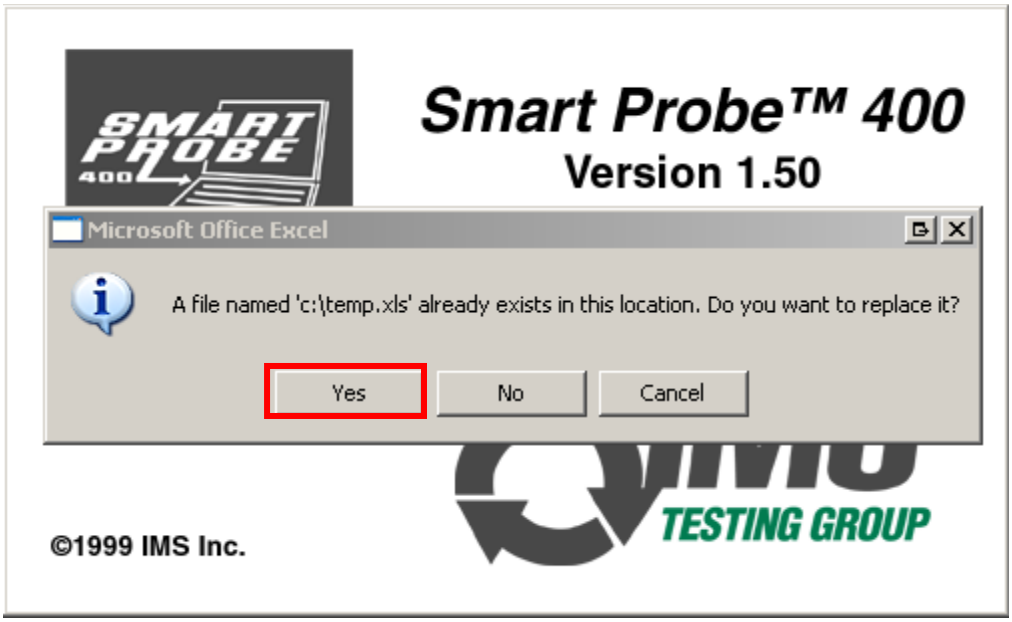
Close-up of RJ45 end	Close-up of Serial end
	

6. Insert the USB end of the USB-to-serial cable into a USB port on the computer tower (or monitor).
7. Insert the RJ45 end of the RJ45-to-serial port cable into the RS-232C port of the SmartProbe device.



8. Open the SmartConnect software on the computer.
9. Answer 'Yes' when a dialog box appears asking the user the following question:

a. “A file named ‘c:\temp.xls’ already exists in this location. Do you want to replace it?”



10. The first time you use the SmartProbe device, you will need to tell your computer which port to use for reading the device input. We have had success using Port 4, but depending on your hardware setup, you may need to experiment with the different ports until you find the one that places data from the device into your spreadsheet.
    a. To change the port number, select the Port Options drop-down menu and select the port number you wish to use. This is shown the top left of Figure 6. Note that “Please pick a Communications Port” will flash in the lower part of the screen until a port is chosen.

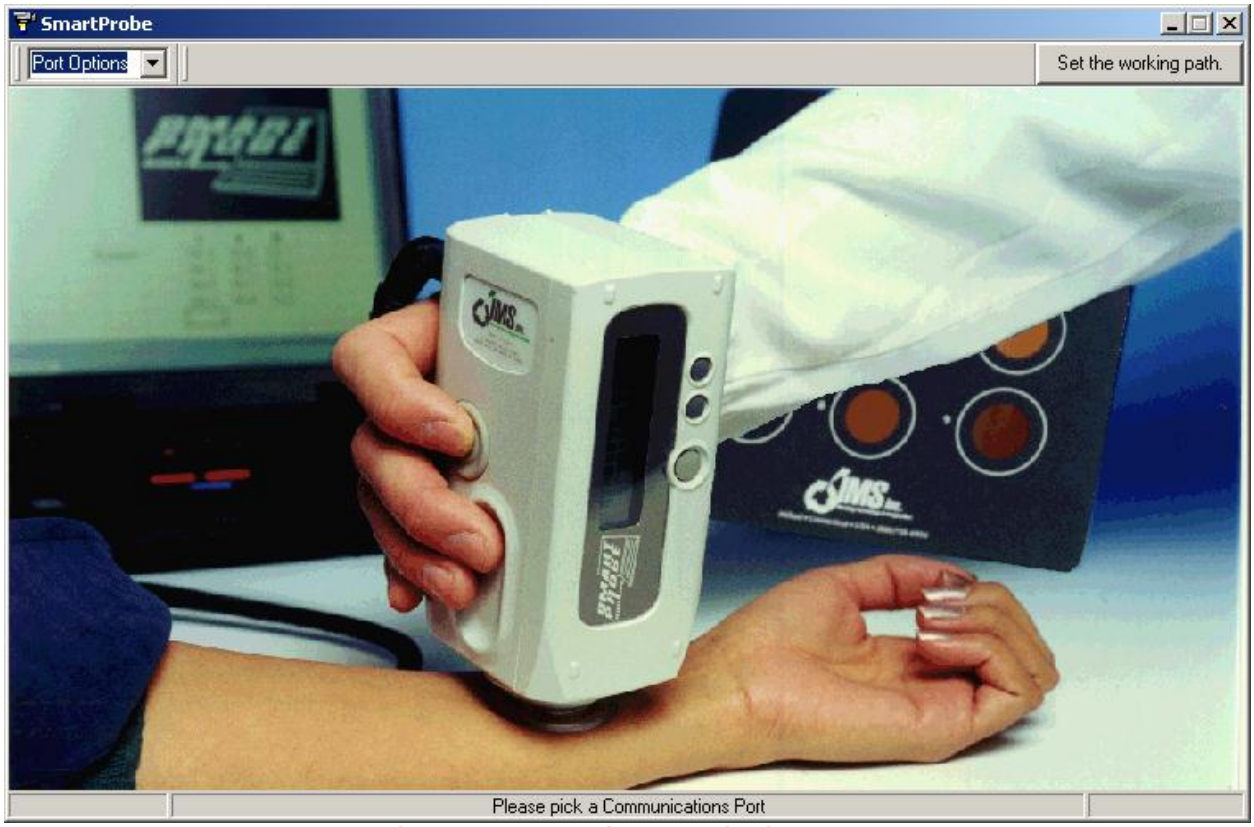
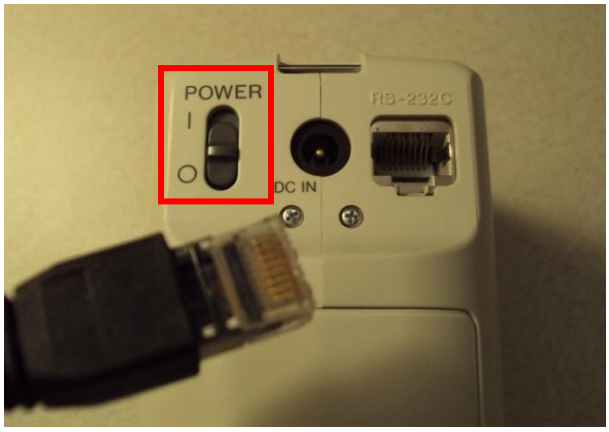


Figure 6: Smart Probe Port Selection

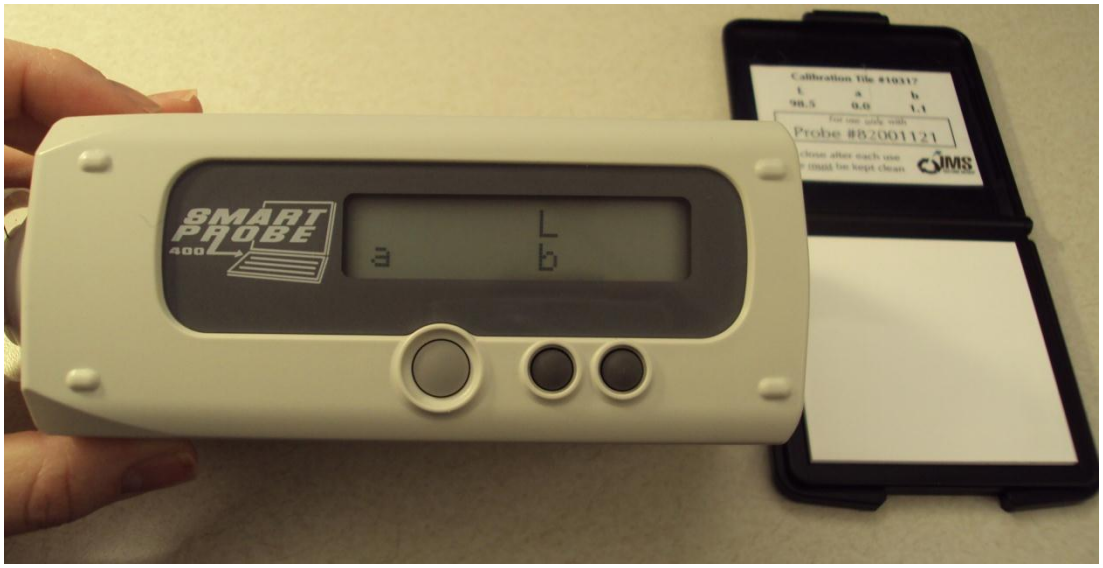
11. Minimize the Excel spreadsheet that is opened after selecting 'Yes.'
12. Open the VIDA Melanin Recording Form (P1_MELANIN) Excel spreadsheet previously saved to the computer or download it from the AsthmaNet secure website.
13. Turn on the SmartProbe device. The power switch is located on the opposite side of the device from the screen.



14. The device is ready for use.

The participant ID, initials, visit number, visit date, and coordinator ID are entered into the header portion of the spreadsheet by the coordinator.

Calibration with the white tile is required each time the device is powered on for use. When the SmartProbe device is turned on and the user is prompted to calibrate the device by the “Set Cal. Plate” screen (above), place the device on the white calibration tile provided and press the primary button (on top side of device) once. A blank calibration measurement screen will appear (below).



On the computer, place the cursor within the 'L' cell (Q500) of the Calibration Tile Measurement #1 section of the VIDA Melanin Recording Form (P1_MELANIN) spreadsheet and press the primary button a second time. The calibration measurements will populate within the spreadsheet. Place the cursor within the 'L' cell (Q530) of the Calibration Tile Measurement #2 section of the VIDA Melanin Recording Form (P1_MELANIN) spreadsheet and press the primary button a third time. The calibration measurements will populate within the spreadsheet. Given the device is correctly calibrated according to the SmartProbe "Calibration with White Tile" discussion in Section 2, it can now be used to take readings of the participant's skin pigmentation.

Place the cursor within the 'L' cell (Q1000) of the Upper Inner Arm Measurement #1 section of the VIDA Melanin Recording Form (P1_MELANIN) spreadsheet. Position the device in the correct location on the participant's upper inner arm according to the directions on the form and press the primary button on the device. The measurements will populate within the spreadsheet. Repeat the process to collect the second measurement on the upper inner arm (Q1030).

Repeat the process of placing the cursor in the 'L' cell of the desired measurement in the VIDA Melanin Recording Form (P1_MELANIN) spreadsheet before taking each measurement so that all values populate within the spreadsheet correctly.

Detailed instructions on calibration specifications and where and how to perform measurements on a participant are included in Section 2.

When all measurements are complete, save the spreadsheet as p1_melanin_[*insert participant ID here*]_[*insert visit ID here*], for example, **p1_melanin_1121001_3** for participant 1-121-001's measurements at Visit 3. Print a copy of the spreadsheet and place it in the visit packet for data entry.

When the participant completes the study, two VIDA Melanin Recording Form (P1_MELANIN) spreadsheets will be saved for that participant, one for Visit 3 and one for Visit 10.

4.2.23 VIDA Participant Study Treatment Questionnaire (P1_PARTTXQX)

Purpose: Any observations the participant may have made during the VIDA study that may have compromised the study blind on the scheduled capsules are recorded on this form.

Who: The participant completes the form.

When: Visits 5-10, 88, 90-92

Form Instructions:

The VIDA Participant Study Treatment Questionnaire (P1_PARTTXQX) should be completed at Visit 10 or on the day of a randomized participant's last visit if he or she terminates prior to Visit 10. If the participant completes the study and terminates at Visit 10, the form should be entered as part of the Visit 10 packet.

If the randomized participant terminates:

- **during** a post-randomization visit, VIDA Participant Study Treatment Questionnaire (P1_PARTTXQX) should be completed at the visit and entered as a single form at Visits 5-9.

- between visits and can come to the clinic for an early termination visit (Visit 88), have the participant complete the VIDA Participant Study Treatment Questionnaire (P1_PARTTXQX) and enter the form as part of the Visit 88 packet.

- between visits and cannot come to the clinic for an early termination visit (Visit 88), the coordinator may administer the VIDA Participant Study Treatment Questionnaire (P1_PARTTXQX) over the phone. The shaded source documentation box provided (Q1060-1070) on the second page should be left blank. The form should be entered as part of the Visit 88 packet.

Question 1000. The participant should check the box that most closely represents his or her feelings about which type of scheduled capsules was used since randomization at Visit 4. If unsure of which type of study capsules was received, Q1000 should be answered with option number 3, "I have no idea which type of capsules I received, but

my best guess would be:," and he or she should choose either Placebo or Vitamin D for Q1010.

Questions 1020-1040. The participant should check the boxes that most closely represent his or her feelings about the taste of (Q1020), smell of (Q1030), and physical sensations (Q1040) produced by the capsules he or she received during the VIDA study. If the participant chooses options 1 or 3 for any of the questions, he or she can comment on the taste of, smell of, or physical sensations produced by the capsules.

Question 1050. If the participant answers Q1050 with option 2, he or she can comment further on observations made regarding the scheduled capsules.

Question 1050D. Any comments with respect to any other observations the participant may have made regarding his or her scheduled capsules should be recorded in Q1050D and entered into the AsthmaNet database (up to 250 characters).

To verify that the information collected on this form was provided by the participant, have the participant initial and date the form in the shaded source documentation box provided (Q1060-1070) on the second page.

4.2.24 VIDA Pulmonary Procedure Checklist (P1_PULMONARYCHK)

Purpose: This form assists the coordinator in determining if the participant is eligible to proceed with pulmonary function testing.

Who: The Pulmonary Function Technician or an AsthmaNet coordinator interviews the participant and completes the form. The coordinator **must** possess VIDA protocol certification.

When: Visits 1-10, 88, 90-92

Form Instructions:

If the VIDA Pulmonary Procedure Checklist (P1_PULMONARYCHK) form is completed at an FEV_1 re-assessment visit, specify the number of the last visit completed and the current visit date in the upper right-hand corner. This form should be entered as a single form.

If any medications other than the study Alvesco® or rescue Xopenex® medication were used, record the medications on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

Question 1150. The participant is ineligible to perform pulmonary function testing if any of the shaded boxes are completed. However, two exceptions for an ineligible participant to continue with spirometry are as follows:

1. An ineligible participant may proceed with spirometry if this is an FEV_1 reassessment visit for evaluation of a treatment failure.

2. An ineligible participant may proceed with spirometry if he or she is already known to be a treatment failure at this visit.

If the participant is not eligible to proceed with spirometry and is willing to reschedule the visit, file the collected data in his or her study folder; do not enter the data or forward it to the DCC.

If a spirometry eligibility protocol exception was granted through the DCC, complete the question(s) for which the exception was granted accurately (i.e. complete the shaded box). Q1150 should be answered 'Yes' to indicate the participant is eligible to proceed and any entry errors that result from the exception should be marked unresolvable. In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

Question 1160. Only record an updated height (without shoes) for participants who have not yet had their 21st birthday at Visits 2-9, 88, and 90-92. At Visits 1 and 10, refer to the height recorded on the Adult Body Measurements (BODYMEAS_ADULT) form and do not record the height on the VIDA Pulmonary Procedure Checklist (P1_PULMONARYCHK) form.

.

4.2.25 VIDA Scheduled Capsules (P1_MED)

Purpose: The dispensation of post-randomization scheduled capsules is recorded on this form.

Who: An AsthmaNet coordinator completes the form.

When: Visits 4-9

Note: This form must be completed every time scheduled capsules are dispensed at regular visits (Visits 4-9) and in the event of backup dispensation for lost scheduled capsules.

Form Instructions:

The VIDA Scheduled Capsules (P1_MED) form must be completed **every** time scheduled capsules are dispensed.

Following the loss of capsules, complete a new VIDA Scheduled Capsules (P1_MED) form with the current date and the visit number corresponding to the last visit completed in the upper right-hand corner. Indicate backup capsule dispensation in Q1000.

Within 24 hours of distributing backup capsules, immediately fax the VIDA Scheduled Capsules (P1_MED) form to the project coordinator at the DCC. In the comment field provided, describe the circumstances regarding the dispensation of backup capsules. This comment field is not entered into the AsthmaNet database. For more information on backup drug procedures, see Section 5 of this MOP and the Study Medications discussion in Section 2.

If backup capsules are dispensed, complete the VIDA Scheduled Capsules (P1_MED) form and enter it as a single form. For example, when scheduled capsules are dispensed at Visit 5, complete the packet Visit 5 VIDA Scheduled Capsules (P1_MED) form. If the participant loses the vial dispensed at regular Visit 5, generate a backup vial number and complete the VIDA Scheduled Capsules (P1_MED) form for the backup capsule dispensation. Enter this form as a Visit 5 single form at the time of backup capsule dispensation.

Question 1010 and Label. At Visits 4-9, remove the label from the dispensed regular dose vial and affix it to the VIDA Scheduled Capsules (P1_MED) form in the box

under Q1010. Copy the vial number into field Q1010. Do not enter the 'R' in the AsthmaNet database.

Question 1020 and Label. At Visit 4 only, remove the label from the dispensed loading dose vial and affix it to the VIDA Scheduled Capsules (P1_MED) form in the box under Q1020. Copy the vial number into field Q1020. Do not enter the 'L' in the AsthmaNet database.

After affixing the labels, the coordinator should sign and date the source documentation box provided (Q1030-1040).

4.2.26 VIDA Significant Asthma Exacerbation (P1_SIGEX)

Purpose: This form outlines the significant asthma exacerbation criteria to determine if a participant experienced an event during the VIDA study.

Who: An AsthmaNet coordinator completes the form.

When: Visits 2-10, 88, 90-92

Form Instructions:

The VIDA Significant Asthma Exacerbation (P1_SIGEX) form is completed **only** if the participant experiences a significant asthma exacerbation as defined in the Significant Asthma Exacerbation discussion in Section 2.

The VIDA Significant Asthma Exacerbation (P1_SIGEX) form is a single form that should be entered and forwarded to the DCC within one week of form completion. If this form is completed between Visits 2 and 3 or Visits 3 and 4, specify the number of the last visit completed (Visit 2 or 3) and the current date in the upper right-hand corner. If the participant experiences a significant asthma exacerbation after randomization, this form should be entered as a single form at the appropriate visit (a regular or treatment failure visit 90-92).

Question 1010. Refer to the Q17 column 'Number of RESCUE Xopenex® puffs taken during the past 24 hours' on the participant's Spirotel® Participant Visit Report (P1_SPIROTEL_RPT) to answer Q1010.

Question 1020. Refer to Q1030 on the participant's spirometry data collected on the Spirometry Testing (SPIRO) form(s) at two consecutive visits (either two regular study visits or a regular study visit and a FEV_1 re-assessment visit). The baseline value is Q1030 on the Spirometry Testing (SPIRO) form at Visit 3. If two consecutive FEV_1 values are below 50% of the baseline prebronchodilator value the criterion is met.

If the participant's FEV_1 is less than 50% of the baseline prebronchodilator value at the regular visit and a second spirometry session (FEV_1 re-assessment visit) is not completed, Q1020 should be answered 'Not evaluated.'

Question 1030. Refer to Q1040 on the participant's spirometry data collected on the Spirometry Testing (SPIRO) form at two consecutive visits (either two regular study

visits or a regular study visit and a FEV_1 re-assessment visit). If two consecutive FEV_1 values are below 40% of predicted according to Q1040, the criterion is met.

If the participant's FEV_1 is less than 40% of predicted at the regular visit and a second spirometry session (FEV_1 re-assessment visit) is not completed, Q1030 should be answered 'Not evaluated.'

Question 1035. If the study or treating physician prescribed the participant oral/parenteral corticosteroids for the treatment of his or her asthma, record the details on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

Question 1050. If any of the shaded boxes is completed in Q1000-1040, the participant experienced a significant asthma exacerbation. Complete Q1060 and record the event on the Clinical Adverse Events (AECLIN) form using ICD-9 code 493.92. If non-study medication was taken for treatment of the significant asthma exacerbation, record the medication on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form and link the medication to the significant asthma exacerbation event. Do this by recording the event record ID in Q1020 on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

If the completed form indicates the participant did not experience a significant asthma exacerbation, do not complete Q1060 and do **not** submit the form to the DCC.

Question 1060. Record the date when the exacerbation criteria is met. If multiple criteria were met to indicate a significant asthma exacerbation, record the earliest date criterion was confirmed.

If a criterion requires confirmation (i.e., a second spirometry session) and upon the second spirometry session, the participant experiences a significant exacerbation event, record the date conditions were met using the date of the second measurement.

4.2.27 VIDA Termination of Study Participation (P1_TERM)

Purpose: The date and the primary reason for a participant's termination of study participation are recorded on this form.

Who: An AsthmaNet coordinator completes the form.

When: Visits 0-10, 88, 90-92

Note: This form is completed at Visit 10 for those participants who complete the entire VIDA study. It may be completed at regular study visits (Visits 0-9) and treatment failure visits (90-92) when the participant withdraws consent, becomes pregnant, or is terminated by performance site staff. This form may also be completed at Visit 88 as part of the early termination visit for randomized participants only.

Form Instructions:

If a participant withdraws consent or is terminated from the VIDA study during a visit, specify the number of the current visit and the current visit date in the upper right-hand corner. For example, if the participant terminates during Visit 5, then the visit number on the form should be '5.' This form is entered into the AsthmaNet database as a single form.

If a randomized participant withdraws consent by contacting performance site personnel between visits, he or she should be asked to return to the clinic for a brief termination visit, designated by visit number 88. Participants should be asked to complete all Visit 88 procedures, if at all possible. If this is not possible, any partial data should be submitted as part of the Visit 88 packet and remaining forms should be marked missing. At minimum, the VIDA Termination of Study Participation (P1_TERM) form should be entered with this visit packet.

If a non-randomized participant withdraws between visits, submit the VIDA Termination of Study Participant (P1_TERM) form with the number of the last visit completed in the upper right-hand corner. For instance, a participant could be terminated from the VIDA study following Visit 0 because of an ineligible vitamin D level. In this case, the VIDA Termination of Study Participant (P1_TERM) form should be entered as a single form with the last visit number completed in the upper right-hand corner of the form, or Visit 0.

Question 1000. This question should only be completed if the VIDA Termination of Study Participation (P1_TERM) form is being completed as part of the early termination visit, designated by visit number 88.

Question 1030. If the participant is being terminated from the VIDA study because of an ineligible Visit 0 vitamin D level, the coordinator should give or send to the participant the standard AsthmaNet notification letter. This letter should be printed on local performance site letterhead from the AsthmaNet secure website, accessed via the following path: Forms: VIDA: Handouts: Visit 0.

Question 1040. If Q1040 is answered 'Participant,' complete Q1050 and Q1060D, if applicable, and skip to the signatures section of the form. Otherwise, skip to Q1070 and complete the rest of the form.

Question 1060D. An explanation should be provided for Q1060D if Q1050 was answered 1, 2, 6, 7, 8, or 10. If an explanation is provided, enter the full explanation (up to 100 characters) into the AsthmaNet database; otherwise, leave the field blank during data entry.

Question 1070. If the participant is male, Q1070 should be answered 'N/A.' If the participant is female and surgically sterile or postmenopausal, Q1070 should be answered 'No.' Q1070 should be answered 'Yes' if the participant becomes pregnant during the course of the VIDA study.

Question 1220D. An explanation should be provided for Q1220D if Q1080, Q1110, Q1120, Q1130, Q1140, Q1150, Q1160, Q1170, Q1180, Q1190, Q1200, and/or Q1210 was answered 'Yes.' If an explanation was provided, enter the full explanation (up to 100 characters) into the AsthmaNet database. Otherwise, leave the field blank during data entry.

Question 1230. At least one of the questions in Q1070-1210 must be answered 'Yes' if clinical staff terminated the participant. Of the questions Q1070-1210 marked 'Yes', indicate the letter associated with the **primary** reason for termination in Q1230.

This form requires the signatures of the coordinator and AsthmaNet investigator to verify that all data collected for this participant are correct to the best of their knowledge.

Question 1235. If the coordinator is planning to bring the terminated participant back for rescreening, this question should be answered 'No' and a comment added in Q1235D that the letter will be sent to the participant after the subsequent enrollment terminates.

Questions 1240 and 1260. If a signature is not present, this field should be left missing during data entry.

Any AsthmaNet investigator (site director, Principal Investigator, or other) may sign field Q1260 to verify that all data collected for this participant are correct to the best of their knowledge.

4.2.28 VIDA Treatment Failure Checklist (P1_TXFAIL_CHK)

Purpose: This form ensures that the participant is assessed thoroughly for treatment failure criteria at all applicable visits.

Who: An AsthmaNet coordinator completes the form.

When: Visits 2-10, 88, 90-92

Note: If this form is completed at Visit 2 or 3 because the participant experienced a treatment failure during the run-in portion of the VIDA study and is seen prior to Visit 3 or 4, complete this form as a single form using visit number '2' or '3,' respectively.

Form Instructions:

Question 1000. If this form was completed at Visits 90, 91, and/or 92 only, complete the number of the last regular visit completed.

Question 1010. Reference the PEF column on the participant's Spirotel® Participant Visit Report (P1_SPIROTEL_RPT) and Q1000 on the VIDA Baseline PEF and Rescue Use Values (P1_BASELINE) form to determine if the participant experienced a fall in prebronchodilator PEF to less than or equal to 65% of baseline on two of three consecutive, scheduled AM or PM measurements.

Question 1020. Reference the Q17 column on the participant's Spirotel® Participant Visit Report (P1_SPIROTEL_RPT) and Q1010 on the VIDA Baseline PEF and Rescue Use Values (P1_BASELINE) form to determine if the participant experienced an increase in rescue levalbuterol use of 8 or more puffs per 24 hours over baseline use for a period of 48 hours.

If treatment failure criteria appeared to be met for a participant during the run-in, but an investigator and coordinator do not feel a real treatment failure occurred, and an exception was granted by the DCC, on the P1_TXFAIL_CHK form, the criteria met should be answered 'Yes' (either Q1010 and Q1020) and Q1090 should be answered 'No' to indicate no treatment failure occurred. Resulting errors should be marked unresolvable, and the symptom review and exception granted shold be documented in the comment provided for the error. Also, complete the comment field (Q6000) provided with additional information on the exception. In these cases, a P1_TXFAIL

form does not need to be completed nor should a treatment failure event be recorded on the AECLIN form.

For post-randomization cases where treatment failure criteria appear to be met but a PI decided that the symptoms are an extension of a previously documented event, on the P1_TXFAIL_CHK form, the criteria met should be answered 'Yes' (either Q1010 and Q1020) and Q1090 should also be answered 'No' to indicate no additional treatment failure occurred. A comment should be provided in Q6000 on the P1_TXFAIL_CHK form to document that the coordinator and the PI considered and resolved the issue. Resulting errors should be marked unresolvable, and the symptom review and exception granted shold be documented in the comment provided for the error.

Question 1030. Refer to Q1030 of the participant's spirometry data collected on the Spirometry Testing (SPIRO) form at two consecutive visits (either two regular study visits or a regular study visit and a FEV_1 re-assessment visit). The baseline reference value is Q1030 on the Spirometry Testing (SPIRO) form at Visit 3. If two consecutive FEV_1 values are (below) less than or equal to 80% of the baseline prebronchodilator value the criterion is met.

If the participant's prebronchodilator FEV_1 is less than or equal to 80% of baseline for the first time and the participant meets at least one other treatment failure criterion at the visit (according to the VIDA Treatment Failure Checklist (P1_TXFAIL_CHK)), select 'Not evaluated'.

If the participant's prebronchodilator FEV_1 is less than or equal to 80% of baseline for the first time and the participant does not meet any other treatment failure criteria according to the VIDA Treatment Failure Checklist (P1_TXFAIL_CHK), schedule the participant to return to the clinic for repeat spirometry within 1-4 days (i.e., FEV_1 reassessment visit). If the participant does not return for the re-assessment visit, or if he/she does not perform spirometry at the FEV_1 re-assessment visit, select 'Not evaluated'. The VIDA Asthma Monitoring Log (P1_ASTHMA_LOG) should be returned to the participant for use prior to the scheduled FEV_1 re-assessment visit.

The following forms should have already been partially or fully completed at the regularly scheduled visit and will need to be updated at the FEV_1 re-assessment visit: the VIDA Treatment Failure Checklist (P1_TXFAIL_CHK) and the VIDA Compliance Checklist (P1_COMPLY). Because the FEV_1 re-assessment visit occurs after the VIDA Treatment Failure Checklist (P1_TXFAIL_CHK) form was started at the regularly scheduled visit, the visit date on the form should be updated to reflect the date of the FEV_1 re-assessment visit. The visit date on the VIDA Compliance Checklist (P1_COMPLY) should also be updated.

At the FEV_1 re-assessment visit, the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG) is collected and reviewed, and the Spirotel® Participant Visit Report (P1_SPIROTEL_RPT) and Spirotel® Participant Compliance Report (P1_COMPLY_RPT) are printed. These reports should replace the reports by the same name previously printed at the first part of the visit.

Because spirometry is repeated at the FEV_1 re-assessment visit, a new VIDA Pulmonary Procedure Checklist (P1_PULMONARYCHK) and a Spirometry Testing (SPIRO) form should be completed. These forms should be entered as single forms with the visit date of the FEV_1 re-assessment visit and the visit number corresponding to the visit packet.

Question 1040. If the study or treating physician prescribed the participant non-study inhaled corticosteroids or oral/parenteral corticosteroids for the treatment of his or her asthma, record the details on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form. Any changes to the study Alvesco® MDI will be recorded on the VIDA Change in Study Medications (P1_CHANGE_MEDS) form. If the participant used oral/parenteral corticosteroids, a VIDA Significant Asthma Exacerbation (P1_SIGEX) form should be completed.

Question 1050. If the participant was hospitalized, submit a Serious Adverse Event Reporting Form (SERIOUS). Also, record the details of systemic corticosteroid treatment, if applicable, on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

Question 1080. If the participant experienced a significant asthma exacerbation, complete a VIDA Significant Asthma Exacerbation (P1_SIGEX) form.

Question 1090. If any of the shaded boxes is completed, the participant experienced a treatment failure. The rest of this form should be completed and the treatment failure event should be recorded on the Clinical Adverse Events (AECLIN) form using ICD-9 code 000.00 (the study specific treatment failure event code). In addition, a VIDA Treatment Failure Information (P1_TXFAIL) form should be completed.

If non-study medication was taken for treatment of a treatment failure and the participant did not experience a significant asthma exacerbation, record the medication on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form and link the medication to the treatment failure event. Do this by recording the treatment failure event record ID in Q1020 of the medication record on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

If the participant's study medications are changed as a result of the treatment failure, link the change in study medications to the treatment failure event by recording the event record ID in Q1010 on the VIDA Change in Study Medications (P1_CHANGE_MEDS) form.

A significant asthma exacerbation should be recorded on the Clinical Adverse Events (AECLIN) form as both a treatment failure and a significant asthma exacerbation. Therefore, if a participant experienced a significant asthma exacerbation since the last visit, both the significant asthma exacerbation and treatment failure event ICD-9 codes should be recorded on the appropriate Clinical Adverse Events (AECLIN) form. The ICD-9 codes for a significant asthma exacerbation and a treatment failure are 493.92 and 000.00, respectively.

If non-study medication, like prednisone, was taken for treatment of a significant asthma exacerbation (which also qualifies as a treatment failure, by definition), record the medication on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form and link the medication record to the significant asthma exacerbation event. Do this by recording the significant asthma exacerbation event record ID in Q1020 of the medication record on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form. Any treatment required should also be indicated in the significant asthma event record on the Clinical Adverse Events (AECLIN) form, not the treatment failure event record. In other words, Q1110 should be answered '2,' or 'medication,' for the significant asthma exacerbation event and '1,' or 'none,' for the treatment failure event.

If the participant's study medications are changed as a direct result of the significant asthma exacerbation, link the change in study medications to the significant asthma exacerbation event, not the treatment failure event, by recording the significant asthma exacerbation event record ID in Q1010 on the VIDA Change in Study Medications (P1_CHANGE_MEDS) form. Any change in study drug(s) should also be indicated in the significant asthma event record on the Clinical Adverse Events (AECLIN) form, not the treatment failure event record. In other words, Q1090 should be answered '2,' or 'altered,' for the significant asthma exacerbation event and '1,' or 'unchanged,' for the treatment failure event.

If it was determined the participant did not experience a treatment failure, continue with the remaining visit procedures. Do **not** complete a VIDA Treatment Failure Information (P1_TXFAIL) form.

A Visit 90-92 packet should be completed for a randomized participant who has experienced a treatment failure and for whom the safety follow-up visit is scheduled

outside of the regular protocol visit window. Any single forms completed at the extra study visit will use the visit numbers 90-92 for data entry.

The first extra study visit entered in the database will use visit 90 and subsequent extra study visits will continue with 91 and 92 (if the treatment failure event is confirmed). Do not enter a Visit 90-92 packet into the database if a treatment failure did not occur according to the VIDA Treatment Failure Checklist (P1_TXFAIL_CHK) form. The VIDA Treatment Failure Information (P1_TXFAIL) form is included as a required packet form at the treatment failure visit.

For additional information on FEV_1 re-assessment and treatment failure visits, see the Extra Study Visits discussion in Section 2.

4.2.29 VIDA Treatment Failure Information (P1_TXFAIL)

Purpose: The details of each treatment failure event, including type of care, treatment, and physician assessment, are recorded on this form.

Who: An AsthmaNet coordinator completes the form.

When: This form should be completed only when the VIDA Treatment Failure Checklist (P1_TXFAIL_CHK) form indicates that the participant met treatment failure criteria.

Form Instructions:

Question 1100-1150. If the participant required treatment with non-study inhaled corticosteroids, oral corticosteroids, IM or IV steroids, antibiotics, or other medications, record the details on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form. Link the medication to the significant asthma exacerbation event on the Clinical Adverse Events (AECLIN) form if the treatment failure qualifies as a significant asthma exacerbation; otherwise, link the medication to the treatment failure event on the Clinical Adverse Events (AECLIN) form.

If oral corticosteroids and/or IM or IV steroids were taken, a VIDA Significant Asthma Exacerbation (P1_SIGEX) form should be completed.

The VIDA Treatment Failure Information (P1_TXFAIL) form should be completed at an FEV_1 re-assessment visit only if the participant is found to have met treatment failure criteria at that visit. This form should be entered as a single form with the visit date of the FEV_1 re-assessment visit and the visit number corresponding to the visit packet.

The VIDA Treatment Failure Information (P1_TXFAIL) form is entered as a single form except at Visits 90-92. This form is included as a required packet form at treatment failure/extra study visits.

4.2.30 VIDA Vitamin D Intake Questionnaire (P1_VITD_INTAKE)

Purpose: The amount of vitamin D the participant ingests through supplementation and some of the most common dietary sources of vitamin D are recorded on this form.

Who: An AsthmaNet coordinator interviews the participant and completes the form.

When: Visits 3, 10

Form Instructions:

Questions 1010D, 1050D, and 1090D. While referencing the supplement bottle(s), record the supplement names on the comment lines provided. If a supplement name was provided, enter the full name (up to 100 characters) into the AsthmaNet database for each comment field.

Questions 1020, 1060, and 1100. While referencing the supplement bottle(s), determine which vitamin D type is included in the supplement. If the type is not evident, select 'Vitamin D (unspecified).'

Questions 1030, 1070, and 1110. While referencing the supplement bottle(s), determine the vitamin D per capsule/tablet and record the value in IU.

If the participant uses only one or two supplements, leave the remaining supplement section(s) blank.

4.2.31 Wisconsin Upper Respiratory Symptom Survey—21 Daily Symptom Report (WURSS_21)

Purpose: To record a participant's daily upper respiratory symptoms when he or she is experiencing a cold.

Who: The participant completes the form.

When: Visits 4-10, 88, 90-92

Form Instructions:

Participants in the VIDA study will be given 21 copies of the Wisconsin Upper Respiratory Symptom Survey—21 Daily Symptom Report (WURSS_21) form at Visit 4.

At subsequent visits, if the participant's supply is running low, print additional Wisconsin Upper Respiratory Symptom Survey—21 Daily Symptom Report (WURSS_21) forms from the AsthmaNet secure website. A group of Wisconsin Upper Respiratory Symptom Survey—21 Daily Symptom Report (WURSS_21) forms is posted in the following folder: Forms: VIDA: Visit Packets.

Select the link for the Wisconsin Upper Respiratory Symptom Survey—21 Daily Symptom Report (WURSS_21) form and a prefilled version of this form will open and contain 21 copies of the form. Enter the participant ID and initials in the prefilled fields and this header information will populate on all 21 pages. Next, select print and specify the number of pages required to replenish the participant's supply in the Print dialog box.

When a set of Wisconsin Upper Respiratory Symptom Survey—21 Daily Symptom Report (WURSS_21) forms is returned to the clinic, the coordinator will complete the visit, return visit date, and coordinator ID fields on each form. The set of forms will be entered as a group, or "cold packet," under the single form entry type in the database.

For more information on the Wisconsin Upper Respiratory Symptom Survey—21 Daily Symptom Report (WURSS_21) form, see Section 10 of the AsthmaNet General MOP or the Wisconsin Upper Respiratory Symptom Survey—21 discussion in Section 2.

4.3 Administrative Forms

Administrative forms facilitate processing of the participant and visit flow by the performance sites and the DCC. They are not entered into the AsthmaNet database and they are not submitted to the DCC in most cases. The following is a list of all VIDA study administrative forms and related instructions:

Administrative Form Name	Form Code
VIDA Alvesco® Dates-of-Use Worksheet	P1_DRG_ALV_DOU
VIDA Alvesco® Dosing Compliance Worksheet	P1_COMPLY_WKS
VIDA Asthma Monitoring Log	P1_ASTHMA_LOG
VIDA Drug Dispensing Log: Alvesco® ICS Inhaler	P1_DRG_ALV
VIDA Drug Dispensing Log: OCS Response Period Prednisone	P1_DRG_OCS_RESP_PRED
VIDA Drug Dispensing Log: OCS Response Period Scheduled Capsules	P1_DRG_OCS_RESP_CAPS
VIDA Drug Dispensing Log: Post-Randomization Study Medications	P1_DRG_SCH
VIDA Drug Dispensing Log: Rescue Prednisone Tablets	P1_DRG_RESC_PRED
VIDA Drug Dispensing Log: Run-In Scheduled Capsules	P1_DRG_RUNIN_CAPS
VIDA Drug Dispensing Log: Xopenex® (RESCUE) Inhaler	P1_DRG_XOP
VIDA Participant Assignment Log	P1_LOG
VIDA Phone Contact Form	P1_PHONE_CONTACT
VIDA SmartProbe Skin Tone Calibration Spreadsheet	P1_SMARTPROBECAL
VIDA Visit Procedure Checklists	P1_VISITA, P1_VISITB, P1_VISITC, P1_VISITD, P1_VISITE, P1_VISITF, P1_VISITG, P1_VISITH, P1_VISITI, P1_VISITJ, P1_VISITK
VIDA Vitamin D Serum Sample Log	P1_VITD_SAMP_LOG

4.3.1 VIDA Alvesco® Dates-of-Use Worksheet (P1_DRG_ALV_DOU)

Purpose: This form assists the coordinator in completing the 'use from/to' blanks on the label of each Alvesco® inhaler.

Who: An AsthmaNet coordinator completes the worksheet.

When: This worksheet is completed at each visit before dispensing multiple Alvesco® inhalers to the participant.

Form Instructions:

When multiple Alvesco® inhalers are dispensed, complete the visit ID, today's visit date, the next scheduled visit date, the scheduled duration (in days) between visits, the current daily dose of Alvesco®, and the maximum duration (in days).

For each inhaler, complete the dates of use column based on the participant's current daily dose. If the scheduled duration exceeds the maximum duration for one Alvesco® inhaler, then additional Alvesco® inhalers will need to be dispensed.

This worksheet should be stored in the participant's folder.

This worksheet will be reviewed during AsthmaNet site visits.

4.3.2 VIDA Alvesco® Dosing Compliance Worksheet (P1_COMPLY_WKS)

Purpose: This form aids the coordinator in assessing participant compliance with using the study Alvesco® inhaler. The information on this form is used to answer questions on the VIDA Compliance Checklist (P1_COMPLY) form.

Who: An AsthmaNet coordinator completes the form.

When: Visits 3-10, 88

Form Instructions:

Complete the '# Scheduled Puffs' row. If the participant's dose fluctuated during the past 30 days, these changes should be indicated. Refer to the VIDA Change in Study Medications (P1_CHANGE_MEDS) form for dates and changes in inhaled corticosteroid dose.

When recalling the history in the DOSER™ for each complete day between visits, record the number of puffs taken each day in the grid provided. The number of actuations made the day of the study visit will be displayed on the DOSER™ prior to going into History mode under the 'Today' section on the face of the device. Do not record this information; start with DOSER™ Day 1, which represents the number of puffs the participant took the day before the current visit. DOSER™ information for today's visit and the day of the last visit should not be included in compliance calculations (because they are not full/complete days).

The 'Compliant?' row should be completed next. If the 'number of scheduled puffs' is equal to the 'number of puffs in DOSER™ history', the participant is considered to have been compliant for the given day. If compliant for a given day, place a check in the appropriate column.

If the participant took the scheduled puffs around or after midnight, they will register in the total for the following day. Count these as compliant days if the Spirotel® Participant Visit Report (P1_SPIROTEL_RPT) indicates the puffs were taken around or after midnight and the totals add up across consecutive days. Make a notation on the VIDA Alvesco® Dosing Compliance Worksheet (P1_COMPLY_WKS).

If the number of puffs in the DOSER™ history is more than the number of scheduled puffs, and the reason is not due to puffs being taken around midnight, ask the participant if he or she took the number of puffs indicated in the DOSER™ history. If

the participant indicates the number of puffs in the DOSER™ history is a result of misfires, note this on the VIDA Alvesco® Dosing Compliance Worksheet (P1_COMPLY_WKS), and count the day as compliant.

The information calculated for Questions 1-6 will be used to complete Q1000-1050 on the VIDA Compliance Checklist (P1_COMPLY) form.

Question 1. Add total scheduled puffs total from the first table (Total 1) plus the total scheduled puffs from second table (Total 2) and record the value in Q1.

Question 2. Add the total number of puffs in the DOSER™ from the first table (Total 1) plus the total number of puffs in the DOSER™ from the second table (Total 2) and record the value in Q2.

Question 3. Calculate the overall compliance percent and record the value in Q3.

Question 4. This value corresponds to the number of full days between visits. If more than 30 full days are present between visits, only the last 30 full days should be counted because the DOSER™ holds only 30 days' worth of information. Do not include the previous visit date or the current visit date.

Question 5. Add the total number of compliant days from the first table (Total 1) plus the total number of compliant days from the second table (Total 2) and record the value in Q5.

Question 6. Calculate the daily compliance percent and record the value in Q6.

This form is not entered during data entry.

This form will be reviewed during AsthmaNet site visits.

For use only at the performance site – DO NOT forward to the DCC.

4.3.3 VIDA Asthma Monitoring Log (P1_ASTHMA_LOG)

Purpose: The participant's scheduled AM and PM peak flows (PEF) and daily RESCUE Xopenex® inhaler puffs are recorded on this form as a reference.

Who: The participant completes the form.

When: Return Visits 3-10

Form Instructions:

The following information is recorded daily on the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG) at each session performed on the spirotel device. This log will be used by the participant and coordinator as a reference because the spirotel® device will not allow the participant to go back and review data from previous days:

1. Scheduled AM and PM peak flows (PEF)

2. Daily RESCUE Xopenex® inhaler puffs

The last page of the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG) is designed to record the following information that occurred since the last study visit:

1. Any non-study medications the participant took since the last study visit

2. Details of any medical problems the participant experienced since the last study visit (adverse events)

The first field of the Date column in the .pdf version of the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG) is fillable. This form is available on the AsthmaNet secure website via the following path: Forms: VIDA: Admin Forms.

Before printing out this form to give to the participant, the coordinator can prefill all date fields on the form by entering the current date in the first field of the Date column and then clicking elsewhere in the form. The rest of the fields will prefill with subsequent dates up to 8 weeks from the current date.

The coordinator should complete the peak flow (PEF) and RESCUE Xopenex® puff treatment failure reference values in the "IMPORTANT" paragraph before giving the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG) to the participant.

The “Do you have a cold today” column in the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG) should be completed daily by the participant. If the participant answers ‘Yes’ for any day after Visit 4, he or she should complete a Wisconsin Upper Respiratory System Survey—21 Daily Symptom Report (WURSS_21) form.
Any comments or unscheduled peak flow (PEF) measurements should be recorded by the participant in the “Comments and Unscheduled PEFs” column.

4.3.4 VIDA Drug Dispensing Log: Alvesco® ICS Inhaler (P1_DRG_ALV)

Purpose: This is a log for recording all Alvesco® inhalers dispensed and returned during the VIDA study.

Who: An AsthmaNet coordinator completes the log.

When: This log is completed at Visits 2-9, or every time an Alvesco® inhaler is dispensed or returned.

Form Instructions:

Complete the Site number in the upper right hand corner of the log. When an Alvesco® inhaler is dispensed or returned, complete the appropriate part of the VIDA Drug Dispensing Log: Alvesco® ICS Inhaler (P1_DRG_ALV).

When an Alvesco® inhaler is dispensed, record the visit number, visit date, the participant's ID, the participant's initials, the lot number, the expiration date, the dispenser's initials, and the number of inhalers dispensed in the next available row on the log. The recorded balance in each row is the total number of remaining, unissued Alvesco® inhalers at the performance site. When the balance gets low (<50 inhalers left), contact the DCC for replenishments.

When an Alvesco® inhaler is returned, record the date returned, the number returned, and the collector's initials. If an Alvesco® inhaler is lost or not returned, note this in the Date Returned column. Indicate the reason the Alvesco® inhaler was not returned, if known.

See the Drug Logging and Dispensation discussions in Section 5 for more information.

This log will be reviewed during AsthmaNet site visits.

4.3.5 VIDA Drug Dispensing Log: OCS Response Period Prednisone (P1_DRG_OCS_RESP_PRED)

Purpose: This is a log for recording all OCS response period prednisone vials dispensed and returned during the VIDA study.

Who: An AsthmaNet coordinator completes the log.

When: Visit 3

Form Instructions:

Complete the Site number in the upper right hand corner of the log. When an OCS response period prednisone vial is dispensed or returned, complete the appropriate part of the VIDA Drug Dispensing Log: OCS Response Period Prednisone (P1_DRG_OCS_RESP_PRED).

When an OCS response period prednisone vial is dispensed, record the visit date, the participant's ID, the participant's initials, the lot number, the expiration date, the dispenser's initials, and the number dispensed in the next available row on the log. The recorded balance in each row is the total number of remaining, unissued OCS response period prednisone vials at the performance site. When the balance gets low, contact the DCC for replenishments.

When an OCS response period prednisone vial is returned, record the date returned, the number returned, and the collector's initials. If an OCS response period prednisone vial is lost or not returned, note this in the Date Returned column. Indicate the reason the OCS response period prednisone vial was not returned, if known.

See the Drug Logging and Dispensation discussions in Section 5 for more information.

This log will be reviewed during AsthmaNet site visits.

4.3.6 VIDA Drug Dispensing Log: OCS Response Period Scheduled Capsules (P1_DRG_OCS_RESP_CAPS)

Purpose: This is a log for recording all OCS response period scheduled capsule vials dispensed and returned during the VIDA study.

Who: An AsthmaNet coordinator completes the log.

When: Visit 3

Form Instructions:

Complete the Site number in the upper right hand corner of the log. When an OCS response period scheduled capsule vial is dispensed or returned, complete the appropriate part of the VIDA Drug Dispensing Log: OCS Response Period Scheduled Capsules (P1_DRG_OCS_RESP_CAPS).

When an OCS response period scheduled capsule vial is dispensed, record the visit date, the participant's ID, the participant's initials, the lot number, the expiration date, the dispenser's initials, and the number dispensed in the next available row on the log. The recorded balance in each row is the total number of remaining, unissued OCS response period scheduled capsule vials at the performance site. When the balance gets low, contact the DCC for replenishments.

When an OCS response period scheduled capsule vial is returned, record the date returned, the number returned, and the collector's initials. If an OCS response period scheduled capsule vial is lost or not returned, note this in the Date Returned column. Indicate the reason the OCS response period scheduled capsule vial was not returned, if known.

See the Drug Logging and Dispensation discussions in Section 5 for more information.

This log will be reviewed during AsthmaNet site visits.

4.3.7 VIDA Drug Dispensing Log: Post-Randomization Study Medications (P1_DRG_SCH)

Purpose: This is a log for recording all Alvesco® inhalers and scheduled capsule vials dispensed and returned during the VIDA study.

Who: An AsthmaNet coordinator completes the log.

When: Visits 4-9

Form Instructions:

When Alvesco® inhalers and scheduled capsule vials are dispensed, record the date dispensed, the dispenser's initials, the Alvesco® dose, the number of Alvesco® inhalers dispensed, and the loading and/or regular scheduled capsule vial numbers in the appropriate row on the log.

When medications are returned, record the date returned, the collector's initials, the number of Alvesco® inhalers returned, and the type of scheduled capsule vial returned. If no Alvesco® inhalers were returned at the visit, record a '0' in the Number of Alvesco® Inhalers Returned column. If no scheduled capsule vials were returned at the visit, do not check the box in the Scheduled Capsule Vial Returned column. Note loss on the log.

See the Drug Logging and Dispensation discussions in Section 5 for more information.

This log will be reviewed during AsthmaNet site visits.

4.3.8 VIDA Drug Dispensing Log: Rescue Prednisone Tablets (P1_DRG_RESC_PRED)

Purpose: This is a log for recording all rescue prednisone tablets dispensed and returned during the VIDA study.

Who: An AsthmaNet coordinator completes the log.

When: Visit 4

Form Instructions:

Complete the Site number in the upper right hand corner of the log. When rescue prednisone tablets are dispensed or returned, complete the appropriate part of the VIDA Drug Dispensing Log: Rescue Prednisone Tablets (P1_DRG_ RESC_PRED).

When rescue prednisone tablets are dispensed, record the date dispensed, the participant's ID, the participant's initials, the manufacturer/lot number, the expiration date, the dispenser's initials, and the number of tablets dispensed in the next available row on the log.

When rescue prednisone tablets are returned, record the date returned, the number returned, and the collector's initials. If rescue prednisone tablets are lost or not returned, note this in the If Not Returned column. Indicate the reason the rescue prednisone vial was not returned, if known.

See the Drug Logging and Dispensation discussions in Section 5 for more information.

This log will be reviewed during AsthmaNet site visits.

4.3.9 VIDA Drug Dispensing Log: Run-In Scheduled Capsules (P1_DRG_RUNIN_CAPS)

Purpose: This is a log for recording all run-in scheduled capsule vials dispensed and returned during the VIDA study.

Who: An AsthmaNet coordinator completes the log.

When: Visit 2

Form Instructions:

Complete the Site number in the upper right hand corner of the log. When a run-in scheduled capsule vial is dispensed or returned, complete the appropriate part of the VIDA Drug Dispensing Log: Run-In Scheduled Capsules (P1_DRG_RUNIN_CAPS).

When a run-in scheduled capsule vial is dispensed, record the visit date, the participant's ID, the participant's initials, the lot number, the expiration date,the dispenser's initials, and the number dispensed in the next available row on the log. The recorded balance in each row is the total number of remaining, unissued run-in scheduled capsule vials at the performance site. When the balance gets low, contact the DCC for replenishments.

When a run-in scheduled capsule vial is returned, record the date returned, the number returned, and the collector's initials. If a run-in scheduled capsule vial is lost or not returned, note this in the Date Returned column. Indicate the reason the run-in scheduled capsule vial was not returned, if known.

See the Drug Logging and Dispensation discussions in Section 5 for more information.

This log will be reviewed during AsthmaNet site visits.

4.3.10 VIDA Drug Dispensing Log: Xopenex® (RESCUE) Inhaler (P1_DRG_XOP)

Purpose: This is a log for recording all Xopenex® (RESCUE) inhalers dispensed and returned during the VIDA study.

Who: An AsthmaNet coordinator completes the log.

When: This log is completed at Visits 2-9, or every time a Xopenex® inhaler is dispensed or returned.

Form Instructions:

Complete the Site number in the upper right hand corner of the log. When a Xopenex® inhaler is dispensed or returned, complete the appropriate part of the VIDA Drug Dispensing Log: Xopenex® (RESCUE) Inhaler (P1_DRG_XOP).

When a Xopenex® inhaler is dispensed, record the visit number, visit date, the participant's ID, the participant's initials, the lot number, the expiration date, the dispenser's initials, and the number dispensed in the next available row on the log. The recorded balance in each row is the total number of remaining, unissued Xopenex® inhalers at the performance site. When the balance gets low, contact the DCC for replenishments.

When a Xopenex® inhaler is returned, record the date returned, the number returned, and the collector's initials. If a Xopenex® inhaler is lost or not returned, note this in the Date Returned column. Indicate the reason the Xopenex® inhaler was not returned, if known.

See the Drug Logging and Dispensation discussions in Section 5 for more information.

This log will be reviewed during AsthmaNet site visits.

4.3.11 VIDA Participant Assignment Log (P1_LOG)

Purpose: This form is a log of all participants enrolled in the VIDA study.

Who: An AsthmaNet coordinator completes the log.

When: Visits 0, 4-9

Form Instructions:

The VIDA Participant Assignment Log (P1_LOG) must be used each time a **new** participant ID number is assigned. A new participant ID number is assigned by completing the next available blank entry on the log at Visit 0. The protocol ID, site ID, and participant ID will be pre-filled on the assignment log printed from Forms: VIDA: Admin Forms section on the AsthmaNet secure website.

Participant initials must have three letters. The letter "X" should be used for an initial only if a participant does not have a middle initial. The participant's initials must be the same initials entered in the AsthmaNet Registry module.

The participant's name should be written last name first, followed by first name on the VIDA Participant Assignment Log (P1_LOG).

At Visit 4, when the participant is randomized, record the participant's loading and regular dose assigned vial numbers in the V4 column.

At Visits 5-9, continue to record the regular dose assigned vial numbers at each subsequent visit on the log.

This log will be reviewed during AsthmaNet site visits.

4.3.12 VIDA Phone Contact Form (P1_PHONE_CONTACT)

Purpose: This form guides the coordinator in completing a scheduled phone contact with the participant. The questions assist in checking the participant's asthma control, scheduled medication usage, and medical care.

Who: An AsthmaNet coordinator interviews the participant while completing this form.

When: Visits 4, 5

Form Instructions:

When completing this form, specify the number of the last visit completed in the upper right-hand corner.

Complete the gray box with coordinator ID, date, time, and if contact occurred for each attempt made to contact the participant. Record any comments regarding the contact attempt in the Contact Occurred column.

When contact is made with the participant, ask him or her to refer to the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG) as the coordinator will be asking the participant questions regarding RESCUE Xopenex® use, compliance, and treatment failure assessment.

Question 5. Before calling the participant, the coordinator should record the participants high rescue use from the Visit 3 Spirotel® VIDA Eligibility and Baseline Report (P1_ELIG_BASE_RPT) in the question text. If the participant indicates that he or she has used the same amount or more than his or her High Rescue Use value (recorded on the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG)) of RESCUE Xopenex® on any day since the last visit, complete Q5a for assessment of treatment failure.

Question 6. Before calling the participant, the coordinator should record the participant's 65% baseline PEF value from the Visit 3 Spirotel® VIDA Eligibility and Baseline Report (P1_ELIG_BASE_RPT) in the question text. If the participant indicates that his or her peak flow has been less than or equal to 65% of his or her baseline PEF value (recorded on the VIDA Asthma Monitoring Log (P1_ASTHMA_LOG)) on any scheduled measurement since the last visit, complete Q6a for assessment of treatment failure.

Question 9. If the participant indicates that he or she experienced a medical problem since the last visit, record the event on the Clinical Adverse Events (AECLIN) form at the next visit.

Question 11. If the participant indicates that he or she took any new medications other than those given as part of the study since the last visit, record the medication on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form at the next visit.

Question 12. If the participant indicates that he or she had any changes to non-study medications since the last visit, record the medication change on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form at the next visit. Depending on the type of medication that was changed, the Concomitant Medications for Non-Asthma Drugs (CMED_NON) form may instead need to be updated.

If, based on the results of the phone contact, the coordinator feels the participant has had a treatment failure, the participant should be scheduled for a clinic visit within 24 hours of the phone call.

This form will be reviewed during AsthmaNet site visits.

For use only at the performance site – DO NOT forward to the DCC.

4.3.13 VIDA SmartProbe Skin Tone Calibration Spreadsheet (P1_SMARTPROBECAL)

Purpose: This form collects data from the monthly calibration of the SmartProbe device using the IMS Human Skin Tone Chart.

Who: An AsthmaNet coordinator completes the form.

When: On a monthly basis.

Form Instructions:

Detailed instructions on monthly calibration specifications are included in the SmartProbe 400 discussion in Section 2.

Follow these steps to complete the monthly calibration process using the IMS Human Skin Tone Chart:

1. Connect the SmartProbe device to the computer using the USB serial adapter, USB-to-serial cable, and RJ45-to-serial port cable. See the VIDA Melanin Recording Form (P1_MELANIN) form section of this MOP for more details on how to hook up the SmartProbe device.
2. Open the SmartConnect software on the computer.
3. Answer 'Yes' when a dialog box appears asking the user the following question:
    a. "A file named 'c:\temp.xls' already exists in this location. Do you want to replace it?"
4. Minimize the Excel spreadsheet that is opened after selecting 'Yes.'
5. Open the VIDA SmartProbe Skin Tone Calibration Spreadsheet (P1_SMARTPROBECAL) previously saved to the computer or download it from the AsthmaNet secure website via the following path: VIDA: Admin Forms.
6. Turn on the SmartProbe device. The power switch is located on the opposite side of the device from the screen.

Calibration with the IMS Human Skin Tone Chart is required once a month. When the SmartProbe device is turned on and the user is prompted to calibrate the device by the "Set Cal. Plate" screen (above), place the device on the white calibration tile provided and press the primary button (on top side of device) once. A blank calibration measurement screen will appear (below).

On the computer, place the cursor within the 'L' cell of the Skin Tone Measurement #1 section of the VIDA SmartProbe Skin Tone Calibration Spreadsheet (P1_SMARTPROBECAL). Place the device on the first skin tone and press the

primary button. The calibration measurement will populate within the spreadsheet. Place the cursor within the 'L' cell of the Skin Tone Measurement #2 section of the spreadsheet. Place the device on the second skin tone and press the primary button. The calibration measurements will populate within the spreadsheet. Repeat the process of placing the cursor in the 'L' cell of the desired measurement in the VIDA SmartProbe Skin Tone Calibration Spreadsheet (P1_SMARTPROBECAL) before taking each measurement so that all values populate within the spreadsheet correctly.

When all measurements are complete, save the spreadsheet as p1_smartprobecal_[*insert current date here*], for example, **p1_smartprobecal_03142011** for calibration performed on March 14, 2011. Print a copy of the spreadsheet and store it in a calibration folder. Calibration results will be subject to audit during a VIDA data quality performance site visit.

For use only at the performance site – DO NOT forward to the DCC.

4.3.14 VIDA Visit Procedure Checklists (P1_VISITA, P1_VISITB, P1_VISITC, P1_VISITD, P1_VISITE, P1_VISITF, P1_VISITG, P1_VISITH, P1_VISITI, P1_VISITJ, P1_VISITK)

Purpose: To provide the coordinator with a checklist of all procedures and forms completed during a visit.

Who: An AsthmaNet coordinator completes the form.

When: At the specified visit

Form Instructions:

These checklists serves as guides for the coordinator and should be sent to the DCC, in front of the visit packet, with the other forms in the packet.

For all procedures and forms, indicate whether or not the procedure or form was completed. If it was not completed, indicate the reason in the comment field.

At Visits 5, 7, and 9: If a visit is missed, complete the checklist indicating the missed visit and document if any other actions were completed (i.e., dispensation of additional study medications, quality control testing of the spirotel® device, etc.). The completed checklist should be filed at the performance site and does not need to be sent to the DCC.

Procedures should be followed in the order they are presented on the visit checklist for applicable visits. If certain procedures, such as pulmonary function testing and questionnaire completion, are performed out of order, a protocol deviation will be assigned.

This form is not entered during data entry.

4.3.15 VIDA Vitamin D Serum Sample Log (P1_VITD_SAMP_LOG)

Purpose: This form must be completed each time blood is drawn and processed for vitamin D analysis.

Who: An AsthmaNet coordinator completes the form.

When: Visits 0, 6, 8, 10, 88, as-needed for safety follow-up between visits 6 and 10, and at early post-randomization termination visits (5-9)

Form Instructions:

After collecting one 5 ml red-top vacutainer with the participant's blood, complete an entry for the blood draw on the VIDA Vitamin D Serum Sample Log (P1_VITD_SAMP_LOG) by recording the participant's VIDA ID number, visit number, and collection date/time.

After the blood sample has been allowed to clot at room temperature between 1 and 2 hours, complete the time spinning is initiated on the VIDA Vitamin D Serum Sample Log (P1_VITD_SAMP_LOG).

After labeling the serum vial with a barcode label generated through the Biological Sample Tracking (BST) module of the AsthmaNet database managementsystem, complete the cryovial barcode number and sample volume on the VIDA Vitamin D Serum Sample Log (P1_VITD_SAMP_LOG).

After storing the serum sample at 4 degrees Celsius (refrigerated), record the date/time the sample is placed in the refrigerator and the current refrigerator temperature on the VIDA Vitamin D Serum Sample Log (P1_VITD_SAMP_LOG).

For use only at the performance site – DO NOT forward to the DCC.