

Appendix B  
Pretest/Main Study Screeners

## Pretest/Main Study Screeners: Diagnosed Consumers

### IMPORTANT GLOBAL PROGRAMMING NOTES:

- This annotated questionnaire is color coded:
  - **BLUE = The main text of programming notes and logical operators**
  - **RED= Value names and labels, which are not meant to appear on screen. These correspond to parameters set in the data shell**
  - **GREY= Variable names (i.e., question numbers). These correspond to variable names in the data shell**
  - **BLACK= Question stems, response options and instructions that are meant to appear on screen**
- Insert a no back prompt for every screen throughout the survey
- Include a variable named “CASEID” in the dataset to record a unique identification number for each subject.
- Include a variable named “COGTEST” in the dataset to record whether the participant is accessing the survey for the cognitive interview phase. This variable can take one of two values: COGTEST= 1 ‘Yes, cognitive interview phase’ or COGTEST = 0 ‘No, not cognitive interview phase’.
  - If COGTEST = 1, skip screener and consent, start at Section A.
- Include a variable named “EFLAG” in the dataset to record eligibility, where 1 ‘Eligible’ and 0 ‘Ineligible’. Set initial value for all cases to EFLAG = 1 ‘Eligible’.
- Include a variable named “COHORT” in the dataset to record which version of the DCE participants will complete. This variable can take one of two values: COHORT = 1 ‘Psoriasis’ or COHORT = 2 ‘Diabetes’. See programming note at start of Section A.
  - Dynata will invite respondents to participate in *either* the psoriasis version of the study or the type 2 diabetes version. The screener will confirm whether each respondent meets the eligibility criteria for his/her respective group.
  - If a respondent is eligible for both versions of the study, they should be assigned to COHORT = 1 ‘Psoriasis’ unless that target sample size for that study has been met.
- Include a variable named “BLOCK” in the dataset to assign/record which set of DCE tasks participants will complete. This variable can take integer values from 1 to 200. See programming note at top of Section A.
  - After the consent screen and before Section C, Dynata will randomly assign participants a value from 1 – 200 for “BLOCK”.

- Include a variable named “TIME\_TOTAL” in the dataset to record the total amount of time in milliseconds that each respondent takes to complete the survey.
- Include soft prompts for all questions. If a question is skipped, display the following prompt (or if Dynata survey platform has default soft prompt language, use that): “You have not answered one or more questions on this screen. Please make a selection before continuing.” Prompt once, and then allow respondent to continue.

**[IMPORTANT:** Do not change question numbers/names after version submitted for programming. Changing question numbers will cause delays and potentially errors in the program.]

**[PROGRAMMER:** Include a placeholder for the OMB control number and expiration date, which will need to appear at the bottom of every screen. It should be as unobtrusive as possible: OMB control #: XXXX-XXXX; Exp: MM/DD/YYYY]

**[PROGRAMMER:** Some questions have conditional piping in item stems or response options that will depend on the study cohort, as captured in the **COHORT** variable (defined above). The conditional text appears in curly brackets “{ }” with the following rules:

Conditional text	COHORT	Display
{plaque psoriasis \ type 2 diabetes}	1 'Psoriasis'	plaque psoriasis
	2 'Diabetes'	type 2 diabetes
{\ <u>other than insulin</u> }	1 'Psoriasis'	
	2 'Diabetes'	<u>other than insulin</u>
{for plaque psoriasis \ <u>other than insulin</u> for type 2 diabetes}	1 'Psoriasis'	for plaque psoriasis
	2 'Diabetes'	<u>other than insulin</u> for type 2 diabetes
{four \ five}	1 'Psoriasis'	four
	2 'Diabetes'	five
{\$5.00 \ \$4.00}	1 'Psoriasis'	\$5.00
	2 'Diabetes'	\$4.00

Example: For the bracketed text {plaque psoriasis \ type 2 diabetes}, IF COHORT= 1 'Psoriasis', then display “plaque psoriasis” in place of the bracketed text.

**[PROGRAMMER:** For question sections that would require more complicated piping, we instead created two distinct sets of questions designated by the suffix `_P` or `_D`. The skip logic for those questions is given in separate programming notes.]

**[QUOTA REQUIREMENTS:**

- 20% of completes must have low health literacy, defined as `S11 >= 3`]

OMB Control No. 0910-NEW  
Expiration date: xx/xx/xxxx

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-NEW and the expiration date is xx/xx/xxxx. The time required to complete this information collection is estimated to average 5 minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**[SCREENER]**

**[Age]**  
**[NUMERICAL FIELD; INTEGER RANGE 0 - 100]**

S1. What is your current age?

**[Numerical Entry]** ← [Must be 18 or more to be Eligible]

**[IF S1 < 18, set EFLAG = 0 'Ineligible']**

**[Language]**  
**[RADIO; SINGLE PUNCH]**

S2\_C. Do you read and speak English fluently?

**1** Yes ← [Must select 1 'Yes' to be Eligible]

**2** No

**[IF (S2\_C = 2 'No' OR S2\_C = NULL), set EFLAG = 0 'Ineligible']**

**[Occupation\_Health]**  
**[RADIO; SINGLE PUNCH]**

S3\_C. Do you currently work in any of the following occupations?

**1** Medical doctor

**2** Any other type of health care provider (example: nurse, physician assistant)

**3** None of the above ← [Must select 3 'None...' to be Eligible]

**[IF (S3\_C = 1 'Medical doctor' OR S3\_C = 2 'Any other...' OR S3\_C = NULL), set EFLAG = 0 'Ineligible']**

**[Occupation\_Orgs]**  
**[CHECKBOX; MULTI-PUNCH]**

S4\_C. Do you currently work for any of the following organizations? *(Select all that apply)*

- S4\_C\_1. US Department of Health and Human Services
- S4\_C\_2. Pharmaceutical company
- S4\_C\_3. Market research firm
- S4\_C\_4. RTI International
- S4\_C\_5. None of the above ← [Must select S4\_C\_5 to be Eligible]

**[Programmer:**

- **IF S4\_C\_5 'None of the above' is selected, disable other response options**
- **IF S4\_C\_5 'None of the above' NOT selected, set EFLAG = 0 'Ineligible']**

**[Diagnosis]**  
**[CHECKBOX; MULTI-PUNCH]**

S5\_C. Has a doctor, nurse, or other health professional ever told you that you had any of the following health conditions? *(Select all that apply)*

- S5\_C\_1. Allergies
- S5\_C\_2. Asthma
- S5\_C\_3. Chronic pain
- S5\_C\_4. High blood pressure
- S5\_C\_5. High cholesterol
- S5\_C\_6. Plaque psoriasis ← [S5\_C\_6 'Plaque psoriasis' - Eligible]
- S5\_C\_7. Type 2 diabetes ← [S5\_C\_7 'T2 diabetes' - Eligible]
- S5\_C\_8. None of the above

**[Programmer:**

- **IF S5\_C\_8 'None of the above' is selected, disable other response options**
- **IF S5\_C\_6 'Plaque psoriasis' is NOT selected AND S5\_C\_7 'Type 2 diabetes' is NOT selected, set EFLAG = 0 'Ineligible']**

**[Gender]**  
**[RADIO; SINGLE PUNCH]**

S6\_C. What is your gender?

- 1 Male
- 2 Female
- 998 Prefer not to answer

**[SCREEN FOR A MIX WHERE S6\_C = 1 'MALE' OR S6\_C = 2 'FEMALE']**

**[Ethnicity]**  
**[RADIO; SINGLE PUNCH]**

S7\_C. What is your ethnicity?

- 1 Hispanic or Latino
- 2 Not Hispanic or Latino

**[SCREEN FOR A MIX ON S7\_C]**

**[Race]**  
**[CHECKBOX; MULTI-PUNCH]**

S8\_C. What is your race? *(Select all that apply)*

- S8\_C\_1. American Indian or Alaska Native
- S8\_C\_2. Asian
- S8\_C\_3. Black or African American
- S8\_C\_4. Native Hawaiian or Other Pacific Islander
- S8\_C\_5. White

**[SCREEN FOR A MIX ON S8\_C]**

**[Educational Attainment]**  
**[RADIO; SINGLE PUNCH]**

S9\_C. What is the highest degree or level of school you have completed?

- 1 Less than high school
- 2 High school graduate or GED
- 3 Some college but no degree
- 4 Associate degree (for example: AA, AS)
- 5 Bachelor's degree (for example: BA, BS)
- 6 Postgraduate or advanced professional degree (for example: MA, MS, PhD,

MD, DDS, JD)

**[SCREEN FOR A MIX ON S9\_C]**

**[State]**  
**[DROPDOWN: SINGLE PUNCH]**

S10\_C. In what state do you currently live?

[Drop-down menu U.S. states + District of Columbia + U.S. Territories]

**[Health-Literacy]**  
**[RADIO; SINGLE PUNCH]**

S11\_C. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often
- 5 Always

**[LOW HEALTH LITERACY QUOTA: 20% OF COMPLETES WITH S11 >= 3]**

[-----New screen-----]  
**[DISPLAY 'Thank and Terminate' IF EFLAG=0 'INELIGIBLE']**

**[Thank and Terminate]**

We're sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible for this study. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.

**[IF EFLAG=0 'INELIGIBLE, END HERE]**

## Pretest/Main Study Screeners: Physicians

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  - IF COGTEST = 1, skip screener and consent, start at Section A.
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- Include a variable named “COHORT” in the dataset to record which version of the DCE participants will complete. This variable can take one of two values: COHORT = 1 ‘Psoriasis’ or COHORT = 2 ‘Diabetes’. See programming note at start of Section A.
  - Dynata will invite respondents to participate in *either* the psoriasis version of the study or the type 2 diabetes version. The screener will confirm whether each respondent meets the eligibility criteria for his/her respective group.
  - If a respondent is eligible for both versions of the study, they should be assigned to COHORT = 1 ‘Psoriasis’ unless that target sample size for that study has been met.
- Include a variable named “BLOCK” in the dataset to assign/record which set of DCE tasks participants will complete. This variable can take integer values from 1 to 200. See programming note at top of Section A.
  - After the consent screen and before Section C, Dynata will randomly assign participants a value from 1 - 200 for “BLOCK”.
- Include a variable named “TIME\_TOTAL” in the dataset to record the total amount of time in milliseconds that each respondent takes to complete the survey.

- Include soft prompts for all questions. If a question is skipped, display the following prompt (or if Dynata survey platform has default soft prompt language, use that): “You have not answered one or more questions on this screen. Please make a selection before continuing.” Prompt once, and then allow respondent to continue.

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Conditional text	COHORT	Display
{plaque psoriasis \ type 2 diabetes}	1 'Psoriasis'	plaque psoriasis
	2 'Diabetes'	type 2 diabetes
{four \ five}	1 'Psoriasis'	four
	2 'Diabetes'	five

Example: For the bracketed text {plaque psoriasis \ type 2 diabetes}, IF COHORT= 1 'Psoriasis', then display “plaque psoriasis” in place of the bracketed text.

**[PROGRAMMER:** For question sections that would require more complicated piping, we instead created two distinct sets of questions designated by the suffix \_P or \_D. The skip logic for those questions is given in separate programming notes.]

**[SCREENER]**

**[Age]**  
**[NUMERICAL FIELD; INTEGER RANGE 0 - 100]**

S1. What is your current age?

[Numerical Entry] ← [Must be 18 or more to be Eligible]

**[IF S1 < 18, set EFLAG = 0 'Ineligible']**

**[ProviderType]  
[RADIO; SINGLE PUNCH]**

S2\_M. Are you a...?

- 1 Physician ← [Must select 1 'Physician' to be Eligible]
- 2 Any Other Type of Health Care Provider (example: nurse, physician assistant)
- 3 None of the above

**[IF (S2\_M = 2 'Any other...' OR S2\_M = 3 'None of the above' OR S2\_M = NULL), set EFLAG = 0 'Ineligible' AND SKIP TO S11\_M]**

**[Specialty]  
[RADIO; SINGLE PUNCH]**

S3\_M. What is your primary area of specialization?

- 1 Cardiology
- 2 Dermatology
- 3 Endocrinology
- 4 Gastroenterology
- 5 Infectious Disease/Antiviral
- 6 Internal and Family Medicine/General Practitioner
- 7 Mental and Behavioral Health
- 8 Nephrology
- 9 Neurology
- 10 Oncology
- 11 Pulmonology/Allergy
- 12 Rheumatology/Auto-Immune
- 13 Other (please specify)

S3\_M\_13\_Open. [TEXT FIELD]

**[IF S3\_M = 13 'Other' is selected, DISPLAY Text Field S3\_M\_13\_Open]**

**[Practicing]**  
**[RADIO; SINGLE PUNCH]**

S4\_M. Are you currently practicing medicine?

- 1 Yes ← [Must select 1 'Yes' to be Eligible]
- 2 No

**[IF (S4\_M = 2 'No' OR S4\_M = NULL), set EFLAG = 0 'Ineligible'**  
**AND SKIP TO S11\_M]**

**[Percent Care]**  
**[NUMERICAL FIELD; INTEGER RANGE 0 - 100]**

S5\_M. What percentage of your time do you spend providing direct patient care? Your best estimate is fine.

[Numerical Entry] % ← [Must be 50% or more to be Eligible]

**[IF S5\_M < 50, set EFLAG = 0 'Ineligible']**

**[Conditions]**  
**[CHECKBOX; MULTI-PUNCH]**

S6\_M. Which of the following conditions do you treat? *(Select all that apply)*

- S6\_M\_1. Allergies
- S6\_M\_2. Asthma
- S6\_M\_3. Chronic pain
- S6\_M\_4. High blood pressure
- S6\_M\_5. High cholesterol
- S6\_M\_6. Plaque psoriasis ← [Must select S6\_M\_6 'Plaque psoriasis' - Eligible]
- S6\_M\_7. Type 2 diabetes mellitus ← [Must select S6\_M\_7 'T2 diabetes' - Eligible]
- S6\_M\_8. None of the above

**[Programmer:**

- **IF S6\_M\_8 'None of the above' is selected, disable other response options**
- **IF S6\_M\_6 'Plaque psoriasis' NOT selected AND S6\_M\_7 'Type 2 diabetes' is NOT selected, set EFLAG = 0 'Ineligible'**
- **IF S6\_M\_6 'Plaque psoriasis' is selected AND S6\_M\_7 'Type 2 diabetes' is selected, GO TO S7\_M (ELSE SKIP TO S10)]**

**[Condition\_Freq]**  
**[RADIO; SINGLE PUNCH]**

S7\_M. You mentioned you treat both type 2 diabetes mellitus and plaque psoriasis. Between these two conditions, which would you say you treat more often?

- 1 Plaque psoriasis
- 2 Type 2 diabetes mellitus

**[PsoriasisRx]**  
**[NUMERICAL FIELD; INTEGER RANGE >= 0]**  
**[ASK IF S7\_M = 1 'Plaque psoriasis']**

S8\_M. In a typical week, how many prescriptions do you write for plaque psoriasis treatments? Your best estimate is fine.

[Numerical Entry]

**[DiabetesRx]**  
**[NUMERICAL FIELD; INTEGER RANGE >= 0]**  
**[ASK IF S7\_M = 2 'Type 2 diabetes']**

S9\_M. In a typical week, how many prescriptions do you write for type 2 diabetes mellitus treatments? Your best estimate is fine.

[Numerical Entry]

**[Occupation\_Orgs]**  
**[CHECKBOX; MULTI-PUNCH]**

S10\_M. Do you currently work for any of the following organizations? (*Select all that apply*)

- S10\_M\_1. US Department of Health and Human Services
- S10\_M\_2. Pharmaceutical company
- S10\_M\_3. Market research firm
- S10\_M\_4. RTI International
- S10\_M\_5. None of the above ← [Must select S10\_M\_5 to be Eligible]

**[Programmer:**

- **IF S10\_M\_5 'None of the above' is selected, disable other response options**
- **IF S10PM\_5 'None of the above' NOT selected, set EFLAG = 0 'Ineligible']**

**[Gender]**  
**[RADIO; SINGLE PUNCH]**

S11\_M.What is your gender?

- 1 Male
- 2 Female
- 998 Prefer not to answer

**[Screen for a mix where S11\_M = 1 'Male' or S11\_M = 2 'Female']**

**[Ethnicity]**  
**[RADIO; SINGLE PUNCH]**

S12\_M.What is your ethnicity?

- 1 Hispanic or Latino
- 2 Not Hispanic or Latino

**[SCREEN FOR A MIX ON S12\_M]**

**[Race]**  
**[CHECKBOX; MULTI-PUNCH]**

S13\_M. What is your race? *(Select all that apply)*

- S13\_M\_1. American Indian or Alaska Native
- S13\_M\_2. Asian
- S13\_M\_3. Black or African American
- S13\_M\_4. Native Hawaiian or Other Pacific Islander
- S13\_M\_5. White

**[SCREEN FOR A MIX ON S13\_M]**

**[IF (S2\_M = 2 'Any other...' OR S2\_M = 3 'None of the above' OR S2\_M = NULL) OR (S4\_M = 2 'No' OR S4\_M = NULL), SKIP TO 'Thank and Terminate']**

**[State]**  
**[DROPDOWN; SINGLE PUNCH]**

S14\_M.In what state is the majority of your practice located?

**[Drop-down menu U.S. states + District of Columbia + U.S. Territories]**

**[PracticeTime]**  
**[RADIO; SINGLE PUNCH]**

S15\_M.How long have you been practicing medicine?

- 1 Less than 5 years

- 2 6 - 10 years
- 3 11 - 20 years
- 4 21 - 30 years
- 5 31 or more years

**[SCREEN FOR A MIX ON S15\_M]**

**[-----New screen-----]  
[DISPLAY 'Thank and Terminate' IF EFLAG=0 'INELIGIBLE']**

**[Thank and Terminate]**

We're sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible for this study. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.

**[IF EFLAG=0 'INELIGIBLE, END HERE]**