**Form 48: Family Understanding and Expectation Interview**

**Purpose:** To assess the potential support for or obstacles to a volunteer's participation on the part of family members or friends.

**Collection Schedule:** Eligibility screening only.

**Data Set Name:** F0481

**Structure:** One record per patient.

**Size:** 1298 observations of 29 variables.

**Known Anomalies:** This form was not obtained for patients who attended their screening visits alone.

(DH)

## DIABETES CONTROL AND COMPLICATIONS TRIAL

### Family Understanding and Expectation Interview

*This interview is to be given by the clinic coordinator to any family members or friends who may have accompanied the subject to the clinic. It should be given after the assessment of the behavioral tasks. The subject should not be present during this interview of his/her family or friends.*

*The interview is used (1) to assess the family's/friend's understanding of the treatments used in the trial, (2) to ascertain whether they have a strong preference for the subject being assigned to one treatment over the other, and (3) to determine whether they have any inaccurate or unrealistic expectations regarding the risks, inconveniences and benefits that may result from the subject's participation.*

*Most of the questions provide space for write-in responses as well as multiple-choice check-boxes. The Coordinating Center can tabulate only the check-box items, so be sure that these are completed, but try to avoid using them to suggest answers to the interviewee. Send a completed copy of this form to the Coordinating Center in the weekly forms mailing.*

## A. IDENTIFYING INFORMATION

**CLINIC** 1. Clinic Number ☐☐ *5-6*

**PATIENT** 2. Patient ID Number ☐☐☐☐☐ *7-11*

**INITIALS** 3. Patient's Initials ☐☐☐ *12-14*

**MMDATE** 4. Date of Interview ☐☐/☐☐/☐☐ *15-20* (Month / Day / Year)

## B. FAMILY ADAPTATION TO THE PROTOCOL

1. Can you tell me what you understand to be the purpose of the Diabetes Control and Complications Trial?

   *The family members should say something to the extent that the study will compare the effect of an experimental and a standard approach to the control of blood glucose on early vascular complications in persons with insulin-dependent diabetes mellitus.*

   *Rate their understanding:*

   **DHB1**
   Good ☐₁  *21*
   Fair ☐₂
   Poor ☐₃

2. Can you tell me how insulin will be used in the Standard Treatment Group?

   *They should state that the standard treatment consists of one or two daily injections of insulin.*

   *Rate their understanding:*

   **DHB2**
   Good ☐₁  *22*
   Fair ☐₂
   Poor ☐₃

3. Can you tell me how insulin will be used in the Experimental Treatment Group?

   *They should state that the Experimental Treatment consists of a choice of either multiple daily injections of insulin or use of an insulin infusion pump.*

   *Rate their understanding:*

   **DHB3**
   Good ☐₁  *23*
   Fair ☐₂
   Poor ☐₃

4. Can you tell me what is meant by randomization?

   *They should state that randomization is the process that will be used to assign the subject to treatment group; neither the subject nor his/her physician can choose the treatment group. Under randomization, there is a 50% chance that the subject will be assigned to either one of the two treatment groups.*

   *Rate their understanding:*

   **DHB4**
   Good ☐₁  *24*
   Fair ☐₂
   Poor ☐₃

Patient ID _____

5. Do you have a strong preference for _(name of subject)_ being assigned to one treatment group over the other? If so, which do you prefer and why?

No, has no strong preference　□ 1　25

Yes, has strong preference for Standard Treatment Group　□ 2

Yes, has strong preference for Experimental Treatment Group　□ 3　*10 DHB5*

There is disagreement among the family members and friends as to which treatment is to be preferred　□ 4

Reasons for preferences:

_____
_____
_____
_____

6. Would you be willing to support the decision of _(name of subject)_ to be randomized into either of the treatment groups?

No (at least one would not be willing)　□ 1　26

Yes (all agree)　□ 2　*11 DHB6*

7. What do you think _(name of subject)_ will gain from the study?

_Let them generate responses but be sure that the following areas are addressed and correct any misconceptions._

_Rate their expectations:_

• _blood sugar_

Realistic　□ 1　27

Somewhat unrealistic　□ 2　*12 DHB7A*

Very unrealistic　□ 3

• _complications_

Realistic　□ 1　28

Somewhat unrealistic　□ 2　*13 DHB7B*

Very unrealistic　□ 3

7. (continued)

• _general well-being_

Realistic　□ 1　29

Somewhat unrealistic　□ 2　*14 DHB7C*

Very unrealistic　□ 3

Comments: _____
_____
_____
_____

8. If _(name of subject)_ is assigned to the Standard Treatment Group, how often will he/she need to come in to the clinic for routine follow-up appointments?

_They should answer that the appointments will be every three months._

_Rate their response:_　*15 DHB8*

Overestimate　□ 1　30

Accurate answer　□ 2

Underestimate　□ 3

9. If _(name of subject)_ is assigned to the Experimental Treatment Group, he/she will need to spend 3-10 days in the hospital and then he/she will need to come to the clinic weekly until he/she has become accustomed to the new therapy. Following this, how often will he/she need to come in to the clinic for routine follow-up appointments?

_They should state that the appointments will be once per month, and could be as often as once per week._

_Rate their response:_　*16 DHB9*

Overestimate　□ 1　31

Accurate answer　□ 2

Underestimate　□ 3

10. Do you realize that many times (name of subject) may have to give priority to this study, causing other family members and friends to change their plans? Do you understand that (name of subject) may have some expenses for transportation, telephoning the clinic, or hiring a babysitter? He/she may have to use vacation or sick days to keep clinic appointments. What kinds of problems will this cause?

*Rate their response:*  17 DHB10

They appear to understand the problems involved and agree that a considerable amount of inconvenience may result ☐ 32

They appear to understand the problems involved but do not believe that they will experience undue hardship ☐

They do not appear to understand the problems that may arise by giving priority to the study protocol ☐

11. How do you feel about (name of subject) using the insulin infusion pump? Would any of you have a problem (e.g., be annoyed) with him/her using the pump?

No one expects to have a problem with the subject's use of a pump  18 DHB11  ☐ 33

Someone expects to have a problem with the subject's use of a pump ☐

12. How do you feel about (name of subject) performing home blood glucose monitoring, which will have to be done several times each day if he/she is assigned to the Experimental Treatment Group? Would you have problems with him/her doing this?

No one expects to have a problem with the subject performing home blood glucose monitoring  19 DHB12  ☐ 34

Someone expects to have a problem with the subject performing home blood glucose monitoring ☐

13. How do you feel about (name of subject) performing urine tests several times per day, as he/she will have to do if he/she is assigned to the Standard Treatment Group? Would any of you have problems with him/her doing this?

20 DHB13

No one expects to have a problem with the subject performing urine testing ☐ 35

Someone expects to have a problem with the subject performing urine testing ☐

14. How would you feel about (name of subject) using the blood or urine testing equipment in public, as he/she may have to do when at work or school? Would any of you object to him/her doing this?

21 DHB14

No one would object to public use of testing equipment ☐ 36

Someone would object to public use of testing equipment ☐

15. Some aspects of this study, such as using diabetes supplies in public and having a less flexible lifestyle, may identify (name of subject) as having diabetes to people who otherwise might not have known. Would this be a problem for you?

No one would object to the subject following the treatment protocol simply because it may identify the subject as having diabetes  22 DHB15  ☐ 37

Someone would object to the subject following the treatment protocol because it may identify the subject as having diabetes ☐

16. If (name of subject) were to become ill or injured, do you feel you could help him/her to carry out the treatment program?

23 DHB16

Yes ☐ 38

No ☐

Please indicate who was interviewed: (Check all that apply)

Subject's father  24 DHDAD  ☐ 39
Subject's mother  25 DHMOM  ☐ 40
Subject's guardian  26 DHGUARD  ☐ 41
Subject's spouse  27 DHSPOUSE  ☐ 42
Subject's sibling  28 DHSIBLNG  ☐ 43
Subject's child  29 DHCHILD  ☐ 44
Subject's other relative  30 DHRELATV  ☐ 45
Subject's friend  31 DHFRIEND  ☐ 46

Type or print name of Clinic Coordinator:

Certification Numbers (if any)

☐☐-☐☐ 47-51

32 DHCERTNO
33 DHWEEKNO

CONTENTS PROCEDURE

Data Set Name: DCEXPORT.F0481
Member Type:   DATA
Engine:        V608
Created:       15:18 Friday, December 1, 1995
Last Modified: 15:18 Friday, December 1, 1995
Protection:
Data Set Type:
Label:

Observations:         1298
Variables:              29
Indexes:                 0
Observation Length:     66
Deleted Observations:    0
Compressed:             NO
Sorted:                YES

-----Engine/Host Dependent Information-----

Data Set Page Size:        4096
Number of Data Set Pages:    23
File Format:                607
First Data Page:              1
Max Obs per Page:            61
Obs in First Data Page:       2
Userid      :  ONITE1
File        :  F0481    DCEXPORT

-----Alphabetic List of Variables and Attributes-----

| #  | Variable | Type | Len | Pos | Format   | Label |
|----|----------|------|-----|-----|----------|-------|
| 3  | DHB1     | Num  | 2   | 6   |          | PURPOSE OF THE DCCT |
| 4  | DHB2     | Num  | 2   | 8   |          | HOW INSULIN USED IN STANDARD GROUP |
| 5  | DHB3     | Num  | 2   | 10  |          | HOW INSULIN USED IN EXPERIMENTAL GROUP |
| 6  | DHB4     | Num  | 2   | 12  |          | MEANING OF RANDOMIZATION |
| 7  | DHB5     | Num  | 2   | 14  |          | STRONG TREATMENT PREFERENCE |
| 8  | DHB6     | Num  | 2   | 16  |          | WILL SUPPORT PATIENTS DECISION |
| 12 | DHB8     | Num  | 2   | 24  |          | VISIT FREQUENCY IN STANDARD GROUP |
| 13 | DHB9     | Num  | 2   | 26  |          | VISIT FREQUENCY IN EXPERIMENTAL GROUP |
| 14 | DHB10    | Num  | 2   | 28  |          | PROBLEMS W/GIVING PRIORITY TO STUDY |
| 15 | DHB11    | Num  | 2   | 30  |          | ATTITUDE TOWARD INSULIN PUMP |
| 16 | DHB12    | Num  | 2   | 32  |          | ATTITUDE TOWARD BLOOD GLUCOSE MONITORING |
| 17 | DHB13    | Num  | 2   | 34  |          | ATTITUDE TOWARD URINE GLUCOSE MONITORING |
| 18 | DHB14    | Num  | 2   | 36  |          | ATTITUDE TOWARD MONITORING IN PUBLIC |
| 19 | DHB15    | Num  | 2   | 38  |          | ATTITUDE TOWARD IDENTIFYING DIABETIC |
| 20 | DHB16    | Num  | 2   | 40  |          | HELP IF SUBJECT BECOMES ILL |
| 9  | DHB7A    | Num  | 2   | 18  |          | BLOOD SUGAR EXPECTATIONS |
| 10 | DHB7B    | Num  | 2   | 20  |          | COMPLICATIONS EXPECTATIONS |
| 11 | DHB7C    | Num  | 2   | 22  |          | GENERAL WELL-BEING EXPECTATIONS |
| 26 | DHCHILD  | Num  | 2   | 52  |          | SUBJECT'S CHILD |
| 21 | DHDAD    | Num  | 2   | 42  |          | SUBJECT'S FATHER |
| 28 | DHFRIEND | Num  | 2   | 56  |          | SUBJECT'S FRIEND |
| 23 | DHGUARD  | Num  | 2   | 46  |          | SUBJECT'S GUARDIAN |
| 22 | DHMOM    | Num  | 2   | 44  |          | SUBJECT'S MOTHER |
| 27 | DHRELATV | Num  | 2   | 54  |          | SUBJECT'S OTHER RELATIVE |
| 25 | DHSIBLNG | Num  | 2   | 50  |          | SUBJECT'S SIBLING |
| 24 | DHSPOUSE | Num  | 2   | 48  |          | SUBJECT'S SPOUSE |
| 2  | FORM     | Num  | 3   | 3   |          | DCCT FORM NUMBER |
| 1  | FSASDATE | Num  | 3   | 0   | MMDDYY8. | FORMDATE AS SAS DATE VALUE |
| 29 | MASK_PAT | Num  | 8   | 58  |          | Patient ID number |

CONTENTS PROCEDURE

-----Sort Information-----

Sortedby:          MASK_PAT
Validated:         YES
Character Set: EBCDIC

# * * D I S T R I B U T I O N A L   S U M M A R Y * *

| Variable Attributes | Statistic | <--Int--> | <--Cnv--> | <-Total-> | <--Int--> | <--Cnv--> | <--Total-> | <--Int--> | <--Cnv--> | <Overall> |
|---|---|---|---|---|---|---|---|---|---|---|
| | | <-----Primary Retinopathy-----> | | | <-----Secondary Retinopathy-----> | | | <--Treatment Group--> | | |
| PURPOSE OF THE DCCT Variable Name: DHB1 | N | 310.00 | 347.00 | 657.00 | 322.00 | 314.00 | 636.00 | 632.00 | 661.00 | 1293.00 |
| | Nmiss | 1.00 | 2.00 | 3.00 | 1.00 | 1.00 | 2.00 | 2.00 | 3.00 | 5.00 |
| | Value (1) % | 62.26 | 68.59 | 65.60 | 69.25 | 71.34 | 70.28 | 65.82 | 69.89 | 67.90 |
| | Value (2) % | 30.32 | 22.48 | 26.18 | 25.16 | 22.61 | 23.90 | 27.69 | 22.54 | 25.06 |
| | Value (3) % | 7.42 | 8.93 | 8.22 | 5.59 | 6.05 | 5.82 | 6.49 | 7.56 | 7.04 |
| PROBLEMS W/GIVING PRIORITY TO STUDY Variable Name: DHB10 | N | 310.00 | 347.00 | 657.00 | 322.00 | 314.00 | 636.00 | 632.00 | 661.00 | 1293.00 |
| | Nmiss | 1.00 | 2.00 | 3.00 | 1.00 | 1.00 | 2.00 | 2.00 | 3.00 | 5.00 |
| | Value (1) % | 17.10 | 13.54 | 15.22 | 17.70 | 17.52 | 17.61 | 17.41 | 15.43 | 16.40 |
| | Value (2) % | 81.61 | 83.86 | 82.80 | 81.06 | 81.21 | 81.13 | 81.33 | 82.60 | 81.98 |
| | Value (3) % | 1.29 | 2.59 | 1.98 | 1.24 | 1.27 | 1.26 | 1.27 | 1.97 | 1.62 |
| ATTITUDE TOWARD INSULIN PUMP Variable Name: DHB11 | N | 307.00 | 342.00 | 649.00 | 317.00 | 304.00 | 621.00 | 624.00 | 646.00 | 1270.00 |
| | Nmiss | 4.00 | 7.00 | 11.00 | 6.00 | 11.00 | 17.00 | 10.00 | 18.00 | 28.00 |
| | Value (1) % | 82.41 | 82.75 | 82.59 | 81.07 | 85.20 | 83.09 | 81.73 | 83.90 | 82.83 |
| | Value (2) % | 17.59 | 17.25 | 17.41 | 18.93 | 14.80 | 16.91 | 18.27 | 16.10 | 17.17 |
| ATTITUDE TOWARD BLOOD GLUCOSE MONITORING Variable Name: DHB12 | N | 310.00 | 348.00 | 658.00 | 321.00 | 314.00 | 635.00 | 631.00 | 662.00 | 1293.00 |
| | Nmiss | 1.00 | 1.00 | 2.00 | 2.00 | 1.00 | 3.00 | 3.00 | 2.00 | 5.00 |
| | Value (1) % | 99.03 | 98.85 | 98.94 | 99.07 | 99.36 | 99.21 | 99.05 | 99.09 | 99.07 |
| | Value (2) % | 0.97 | 1.15 | 1.06 | 0.93 | 0.64 | 0.79 | 0.95 | 0.91 | 0.93 |
| ATTITUDE TOWARD URINE GLUCOSE MONITORING Variable Name: DHB13 | N | 308.00 | 348.00 | 656.00 | 321.00 | 314.00 | 635.00 | 629.00 | 662.00 | 1291.00 |
| | Nmiss | 3.00 | 1.00 | 4.00 | 2.00 | 1.00 | 3.00 | 5.00 | 2.00 | 7.00 |
| | Value (1) % | 97.08 | 96.55 | 96.80 | 98.75 | 98.41 | 98.58 | 97.93 | 97.43 | 97.68 |
| | Value (2) % | 2.92 | 3.45 | 3.20 | 1.25 | 1.59 | 1.42 | 2.07 | 2.57 | 2.32 |
| ATTITUDE TOWARD MONITORING IN PUBLIC Variable Name: DHB14 | N | 310.00 | 348.00 | 658.00 | 321.00 | 314.00 | 635.00 | 631.00 | 662.00 | 1293.00 |
| | Nmiss | 1.00 | 1.00 | 2.00 | 2.00 | 1.00 | 3.00 | 3.00 | 2.00 | 5.00 |
| | Value (1) % | 98.71 | 99.14 | 98.94 | 99.38 | 99.68 | 99.53 | 99.05 | 99.40 | 99.23 |
| | Value (2) % | 1.29 | 0.86 | 1.06 | 0.62 | 0.32 | 0.47 | 0.95 | 0.60 | 0.77 |
| ATTITUDE TOWARD IDENTIFYING DIABETIC Variable Name: DHB15 | N | 309.00 | 348.00 | 657.00 | 321.00 | 313.00 | 634.00 | 630.00 | 661.00 | 1291.00 |
| | Nmiss | 2.00 | 1.00 | 3.00 | 2.00 | 2.00 | 4.00 | 4.00 | 3.00 | 7.00 |
| | Value (1) % | 100.00 | 99.43 | 99.70 | 99.38 | 99.36 | 99.37 | 99.68 | 99.39 | 99.54 |
| | Value (2) % | 0.00 | 0.57 | 0.30 | 0.62 | 0.64 | 0.63 | 0.32 | 0.61 | 0.46 |
| HELP IF SUBJECT BECOMES ILL Variable Name: DHB16 | N | 310.00 | 348.00 | 658.00 | 319.00 | 313.00 | 632.00 | 629.00 | 661.00 | 1290.00 |
| | Nmiss | 1.00 | 1.00 | 2.00 | 4.00 | 2.00 | 6.00 | 5.00 | 3.00 | 8.00 |
| | Value (1) % | 97.10 | 98.56 | 97.87 | 98.43 | 97.44 | 97.94 | 97.77 | 98.03 | 97.91 |
| | Value (2) % | 2.90 | 1.44 | 2.13 | 1.57 | 2.56 | 2.06 | 2.23 | 1.97 | 2.09 |

Notes:

** D I S T R I B U T I O N A L   S U M M A R Y **

| Variable Attributes | Statistic | <------Primary Retinopathy------> | | | <-----Secondary Retinopathy-----> | | | <--Treatment Group--> | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | <--Int--> | <--Cnv--> | <--Total-> | <--Int--> | <--Cnv--> | <--Total-> | <--Int--> | <--Cnv--> | <Overall> |
| HOW INSULIN USED IN STANDARD GROUP Variable Name: DHB2 | N | 310.00 | 347.00 | 657.00 | 322.00 | 314.00 | 636.00 | 632.00 | 661.00 | 1293.00 |
| | Nmiss | 1.00 | 2.00 | 3.00 | 1.00 | 1.00 | 2.00 | 2.00 | 3.00 | 5.00 |
| | Value (1) % | 73.87 | 78.67 | 76.41 | 79.19 | 74.20 | 76.73 | 76.58 | 76.55 | 76.57 |
| | Value (2) % | 18.06 | 14.70 | 16.29 | 15.22 | 19.11 | 17.14 | 16.61 | 16.79 | 16.71 |
| | Value (3) % | 8.06 | 6.63 | 7.31 | 5.59 | 6.69 | 6.13 | 6.80 | 6.66 | 6.73 |
| HOW INSULIN USED IN EXPERIMENTAL GROUP Variable Name: DHB3 | N | 310.00 | 348.00 | 658.00 | 321.00 | 314.00 | 635.00 | 631.00 | 662.00 | 1293.00 |
| | Nmiss | 1.00 | 1.00 | 2.00 | 2.00 | 1.00 | 3.00 | 3.00 | 2.00 | 5.00 |
| | Value (1) % | 71.61 | 76.15 | 74.01 | 80.69 | 72.93 | 76.85 | 76.23 | 74.62 | 75.41 |
| | Value (2) % | 20.00 | 17.53 | 18.69 | 14.95 | 21.34 | 18.11 | 17.43 | 19.34 | 18.41 |
| | Value (3) % | 8.39 | 6.32 | 7.29 | 4.36 | 5.73 | 5.04 | 6.34 | 6.04 | 6.19 |
| MEANING OF RANDOMIZATION Variable Name: DHB4 | N | 310.00 | 348.00 | 658.00 | 322.00 | 314.00 | 636.00 | 632.00 | 662.00 | 1294.00 |
| | Nmiss | 1.00 | 1.00 | 2.00 | 1.00 | 1.00 | 2.00 | 2.00 | 2.00 | 4.00 |
| | Value (1) % | 81.61 | 78.16 | 79.79 | 84.47 | 84.08 | 84.28 | 83.07 | 80.97 | 81.99 |
| | Value (2) % | 11.94 | 14.94 | 13.53 | 10.56 | 9.24 | 9.91 | 11.23 | 12.24 | 11.75 |
| | Value (3) % | 6.45 | 6.90 | 6.69 | 4.97 | 6.69 | 5.82 | 5.70 | 6.80 | 6.26 |
| STRONG TREATMENT PREFERENCE Variable Name: DHB5 | N | 310.00 | 348.00 | 658.00 | 322.00 | 314.00 | 636.00 | 632.00 | 662.00 | 1294.00 |
| | Nmiss | 1.00 | 1.00 | 2.00 | 1.00 | 1.00 | 2.00 | 2.00 | 2.00 | 4.00 |
| | Value (1) % | 85.48 | 88.51 | 87.08 | 81.99 | 85.03 | 83.49 | 83.70 | 86.86 | 85.32 |
| | Value (2) % | 6.45 | 6.03 | 6.23 | 7.14 | 7.32 | 7.23 | 6.80 | 6.65 | 6.72 |
| | Value (3) % | 7.10 | 5.46 | 6.23 | 9.63 | 6.69 | 8.18 | 8.39 | 6.04 | 7.19 |
| | Value (4) % | 0.97 | 0.00 | 0.46 | 1.24 | 0.96 | 1.10 | 1.11 | 0.45 | 0.77 |
| WILL SUPPORT PATIENTS DECISION Variable Name: DHB6 | N | 309.00 | 348.00 | 657.00 | 322.00 | 314.00 | 636.00 | 631.00 | 662.00 | 1293.00 |
| | Nmiss | 2.00 | 1.00 | 3.00 | 1.00 | 1.00 | 2.00 | 3.00 | 2.00 | 5.00 |
| | Value (1) % | 4.21 | 4.89 | 4.57 | 3.73 | 1.59 | 2.67 | 3.96 | 3.32 | 3.63 |
| | Value (2) % | 95.79 | 95.11 | 95.43 | 96.27 | 98.41 | 97.33 | 96.04 | 96.68 | 96.37 |
| BLOOD SUGAR EXPECTATIONS Variable Name: DHB7A | N | 309.00 | 348.00 | 657.00 | 322.00 | 313.00 | 635.00 | 631.00 | 661.00 | 1292.00 |
| | Nmiss | 2.00 | 1.00 | 3.00 | 1.00 | 2.00 | 3.00 | 3.00 | 3.00 | 6.00 |
| | Value (1) % | 92.88 | 94.54 | 93.76 | 93.48 | 93.93 | 93.70 | 93.19 | 94.25 | 93.73 |
| | Value (2) % | 6.47 | 4.89 | 5.63 | 6.52 | 6.07 | 6.30 | 6.50 | 5.45 | 5.96 |
| | Value (3) % | 0.65 | 0.57 | 0.61 | 0.00 | 0.00 | 0.00 | 0.32 | 0.30 | 0.31 |
| COMPLICATIONS EXPECTATIONS Variable Name: DHB7B | N | 309.00 | 348.00 | 657.00 | 321.00 | 313.00 | 634.00 | 630.00 | 661.00 | 1291.00 |
| | Nmiss | 2.00 | 1.00 | 3.00 | 2.00 | 2.00 | 4.00 | 4.00 | 3.00 | 7.00 |
| | Value (1) % | 90.94 | 91.95 | 91.48 | 94.39 | 92.33 | 93.38 | 92.70 | 92.13 | 92.41 |
| | Value (2) % | 8.41 | 7.18 | 7.76 | 5.30 | 7.67 | 6.47 | 6.83 | 7.41 | 7.13 |
| | Value (3) % | 0.65 | 0.86 | 0.76 | 0.31 | 0.00 | 0.16 | 0.48 | 0.45 | 0.46 |

## * * D I S T R I B U T I O N A L   S U M M A R Y * *

| Variable Attributes | Statistic | Primary Retinopathy | | | Secondary Retinopathy | | | Treatment Group | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | <--Int--> | <--Cnv--> | <-Total-> | <--Int--> | <--Cnv--> | <-Total-> | <--Int--> | <--Cnv--> | <Overall> |
| GENERAL WELL-BEING EXPECTATIONS Variable Name: DHB7C | N | 310.00 | 347.00 | 657.00 | 322.00 | 313.00 | 635.00 | 632.00 | 660.00 | 1292.00 |
| | Nmiss | 1.00 | 2.00 | 3.00 | 1.00 | 2.00 | 3.00 | 2.00 | 4.00 | 6.00 |
| | Value (1) % | 97.74 | 97.41 | 97.56 | 98.76 | 98.40 | 98.58 | 98.26 | 97.88 | 98.07 |
| | Value (2) % | 1.94 | 2.31 | 2.13 | 1.24 | 1.28 | 1.26 | 1.58 | 1.82 | 1.70 |
| | Value (3) % | 0.32 | 0.29 | 0.30 | 0.00 | 0.32 | 0.16 | 0.16 | 0.30 | 0.23 |
| VISIT FREQUENCY IN STANDARD GROUP Variable Name: DHB8 | N | 306.00 | 345.00 | 651.00 | 316.00 | 306.00 | 622.00 | 622.00 | 651.00 | 1273.00 |
| | Nmiss | 5.00 | 4.00 | 9.00 | 7.00 | 9.00 | 16.00 | 12.00 | 13.00 | 25.00 |
| | Value (1) % | 16.34 | 15.07 | 15.67 | 14.87 | 14.05 | 14.47 | 15.59 | 14.59 | 15.08 |
| | Value (2) % | 75.82 | 73.04 | 74.35 | 75.00 | 76.14 | 75.56 | 75.40 | 74.50 | 74.94 |
| | Value (3) % | 7.84 | 11.88 | 9.98 | 10.13 | 9.80 | 9.97 | 9.00 | 10.91 | 9.98 |
| VISIT FREQUENCY IN EXPERIMENTAL GROUP Variable Name: DHB9 | N | 308.00 | 348.00 | 656.00 | 314.00 | 308.00 | 622.00 | 622.00 | 656.00 | 1278.00 |
| | Nmiss | 3.00 | 1.00 | 4.00 | 9.00 | 7.00 | 16.00 | 12.00 | 8.00 | 20.00 |
| | Value (1) % | 5.19 | 4.60 | 4.88 | 4.14 | 5.52 | 4.82 | 4.66 | 5.03 | 4.85 |
| | Value (2) % | 83.12 | 80.75 | 81.86 | 82.48 | 81.17 | 81.83 | 82.80 | 80.95 | 81.85 |
| | Value (3) % | 11.69 | 14.66 | 13.26 | 13.38 | 13.31 | 13.34 | 12.54 | 14.02 | 13.30 |
| SUBJECT'S CHILD Variable Name: DHCHILD | N | 4.00 | 2.00 | 6.00 | 6.00 | 1.00 | 7.00 | 10.00 | 3.00 | 13.00 |
| | Nmiss | 307.00 | 347.00 | 654.00 | 317.00 | 314.00 | 631.00 | 624.00 | 661.00 | 1285.00 |
| | Value (1) % | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 |
| SUBJECT'S FATHER Variable Name: DHDAD | N | 32.00 | 32.00 | 64.00 | 25.00 | 39.00 | 64.00 | 57.00 | 71.00 | 128.00 |
| | Nmiss | 279.00 | 317.00 | 596.00 | 298.00 | 276.00 | 574.00 | 577.00 | 593.00 | 1170.00 |
| | Value (1) % | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 |
| SUBJECT'S FRIEND Variable Name: DHFRIEND | N | 37.00 | 35.00 | 72.00 | 36.00 | 49.00 | 85.00 | 73.00 | 84.00 | 157.00 |
| | Nmiss | 274.00 | 314.00 | 588.00 | 287.00 | 266.00 | 553.00 | 561.00 | 580.00 | 1141.00 |
| | Value (1) % | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 |
| SUBJECT'S GUARDIAN Variable Name: DHGUARD | N | 1.00 | 0.00 | 1.00 | 2.00 | 1.00 | 3.00 | 3.00 | 1.00 | 4.00 |
| | Nmiss | 310.00 | 349.00 | 659.00 | 321.00 | 314.00 | 635.00 | 631.00 | 663.00 | 1294.00 |
| | Value (1) % | 100.00 | 0.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 |
| SUBJECT'S MOTHER Variable Name: DHMOM | N | 98.00 | 102.00 | 200.00 | 79.00 | 79.00 | 158.00 | 177.00 | 181.00 | 358.00 |
| | Nmiss | 213.00 | 247.00 | 460.00 | 244.00 | 236.00 | 480.00 | 457.00 | 483.00 | 940.00 |
| | Value (1) % | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 |
| SUBJECT'S OTHER RELATIVE Variable Name: DHRELATV | N | 2.00 | 1.00 | 3.00 | 3.00 | 3.00 | 6.00 | 5.00 | 4.00 | 9.00 |
| | Nmiss | 309.00 | 348.00 | 657.00 | 320.00 | 312.00 | 632.00 | 629.00 | 660.00 | 1289.00 |
| | Value (1) % | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 |

Notes:

# * D I S T R I B U T I O N A L   S U M M A R Y * *

| Variable Attributes | Statistic | Primary Retinopathy | | | Secondary Retinopathy | | | Treatment Group | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | <--Int--> | <--Cnv--> | <--Total-> | <--Int--> | <--Cnv--> | <--Total-> | <--Int--> | <--Cnv--> | <Overall> |
| SUBJECT'S SIBLING Variable Name: DHSIBLNG | N Nmiss Value (1) % | 11.00 300.00 100.00 | 8.00 341.00 100.00 | 19.00 641.00 100.00 | 15.00 308.00 100.00 | 9.00 306.00 100.00 | 24.00 614.00 100.00 | 26.00 608.00 100.00 | 17.00 647.00 100.00 | 43.00 1255.00 100.00 |
| SUBJECT'S SPOUSE Variable Name: DHSPOUSE | N Nmiss Value (1) % | 146.00 165.00 100.00 | 176.00 173.00 100.00 | 322.00 338.00 100.00 | 171.00 152.00 100.00 | 152.00 163.00 100.00 | 323.00 315.00 100.00 | 317.00 317.00 100.00 | 328.00 336.00 100.00 | 645.00 653.00 100.00 |
| DCCT FORM NUMBER Variable Name: FORM | N Nmiss Value (481) % | 311.00 0.00 100.00 | 349.00 0.00 100.00 | 660.00 0.00 100.00 | 323.00 0.00 100.00 | 315.00 0.00 100.00 | 638.00 0.00 100.00 | 634.00 0.00 100.00 | 664.00 0.00 100.00 | 1298.00 0.00 100.00 |

Notes: