Persons using assistive technology may not be able to fully access information in this file. For assistance, e-mail biolincc@imsweb.com. Include the Web site and filename in your message.

FORM A – Screening Part 1

CARRS Translation Trial

- All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)**
- Place cross [X] in the appropriate boxes. Write in fields clearly.
- See *Form Completion Notes* for definitions and explanations
- Store copies of available source documents (SD), where indicated, in patient's trial folder

Complete by STUDY PHYSICIAN

Form – A – Data is saved in "patient.csv" and is in wide format

1. Consent & Contact Information *mandatory fields

1.01 [ ] Y [ ] N Signed **informed consent** for study participation obtained

1.02	Name [firstname] [varchar(50)] [lasttname] [varchar(50)]	First:* Middle: Last:*
1.03	Mailing Address [line1] [varchar(250)] [line2] [varchar(250)] [city] [varchar(100)] [pincode] [varchar(20)] [state] [varchar(100)]	Address 1:* Address 2: City:* Pin code:* __ __ __ __ __ __ State:*
1.04	Mobile* [mobile] [varchar(10)]	91 - __ __ __ __ __ __ __ __ __ __
1.05	Phone 2 [phone] [varchar(20)]	_____ - _____
1.07	Email ID [email] [varchar(100)]	
1.08	Contact person	Relation: *Name: *Mobile: 91 - __ __ __ __ __ __ __ __ __ __ Telephone 2: _____ - _____

2. General Inclusion Criteria

	2.01	__ __ / __ __ __ / __ __ __ __ Date of Birth (dd/MMM/yyyy) [date_of_birth] [date] __ __ Age → **If <35 years, patient is ineligible. Stop here & go to 4.01 in this form.** [age] [int(11)]	
	2.02	[ ] male [ ] female [sex] [varchar(10)] *[Male M, Female F]*	
	2.03	[ ] Y [ ] N Diagnosis of **Type 2 Diabetes** (2006 WHO)	
SD	2.04	[ ] Y [ ] N **$HbA_1c \geq 8.0\%$** irrespective of medications	If available, last HbA1c: __ . __ % Date: __ __ / __ __ __ / __ __ __ __
SD	2.05	[ ] Y [ ] N [ ] unknown ***At least 1 of the following:***	
SD		[ ] **LDL ≥ 130 mg/dL**	If available, last LDL: __ __ __ mg/dL

Commented [CR1]: No values are stored in this variable

			irrespective of medications	Date: __ __ / __ __ __ / __ __ __ __
SD			[ ] **Systolic BP ≥ 140 mmHg** irrespective of medications	If available, last BP: __ __ __ / __ __ Date: __ __ / __ __ __ / __ __ __ __ BP today: __ __ __ / __ __
	2.06	[ ] Y [ ] N	Receiving diabetes care in the same clinic for at least 3 months OR even earlier if in the investigator's assessment the patient is likely to follow-up regularly as required by the protocol.	

2.07 **Review 2.03-2.06 above. If any boxes have been <u>marked 'N'</u> → Patient is ineligible. Stop here & <u>go to 4.01</u> in this form. Otherwise, continue to next section.**

3. General Exclusion Criteria

	Cross if present	
3.01	[ ]	Known Type 1 Diabetes
3.02	[ ]	Diabetes secondary to chronic pancreatitis
3.03	[ ]	Pregnant OR trying to become pregnant OR of child-bearing potential and not actively practicing birth control (including natural methods)
3.04	[ ]	Documented cardiovascular event <u>within the past 12 months</u> [ ] Coronary Revascularization [ ] Myocardial Infarction [ ] Unstable angina [ ] Stroke
3.05	[ ]	Current symptomatic CHF, NYHA Class 3 or 4 CHF effort intolerance
3.06	[ ]	Non-diabetic kidney disease
3.07	[ ]	Pre-existing end-stage renal disease (dialysis or transplant)
3.08	[ ]	Active liver disease
3.09	[ ]	Malignancy or life-threatening disease with death probable in less than 4 years
3.10	[ ]	Current medication with known adverse interactions with glycemic treatments (e.g. long-term steroids, protease inhibitors)
3.11	[ ]	Plans to shift to out of the city in the next 4 years
3.12	[ ]	On an investigational drug for clinical trial in the last 3 months
3.13	[ ]	Currently participating in a clinical trial
3.14	[ ]	A member of the participant's household is currently enrolled in CARRS Trial
3.15	[ ]	No fixed address or contact details
3.16	[ ]	Any other condition or circumstance that, by the study physician's judgment, would interfere with participant's diabetic status OR adherence, such as: [ ] Other endocrinopathy (adrenal, pituitary), [ ] History of organ transplant, [ ] On tuberculosis treatment, [ ] Significant psychiatric illness/ cognitive impairment, [ ] Alcohol or substance abuse [ ] Other: _____

3.17 **Review 3.01-3.16 above. If any boxes are crossed, patient is ineligible. Continue to next section.**

4. Eligibility

4.01 [ ] Y [ ] N **Patient ELIGIBLE** for the trial so far
If YES, continue to 4.02. If NO, go to Section 5.

4.02 __ __ / __ __ __ / __ __ __ __ Date of laboratory visit **(within 2 weeks from today)**

(1)serum creatinine (2)sodium & potassium (3)ALT (4)venous FBG (5)HbA1c
(6)lipid profile (Total Chol, HDL, LDL-indir, Trig) (7)urine albumin:creatinine ratio

Provide appointment slip for laboratory investigations to patient. Instruct patient to arrive FASTING overnight/minimum 8 hours.

4.03 __ __ / __ __ __ / __ __ __ __ Date of next study visit (same as lab visit above, OR within 4 weeks of today)

5. Signature of Study Physician

5.01 Name: _____ Signature: _____

5.02 Date Signed: __ __ / __ __ __ / __ __ __ __

5.03 Complete **Participant Log** for this patient

FORM B – Screening Part 2
CARRS Translation Trial

Complete by STUDY PHYSICIAN

- All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)**
- Place cross [X] in the appropriate boxes. Write in fields clearly.
- See *Form Completion Notes*, for definitions and explanations
- Store copies of available source documents (SD), where indicated, in patient's trial folder

Screening ID: S __ __ __ __ __

Participant Initials: _____

Date of Visit (dd/MMM/yyyy): __ __ / __ __ __ / __ __ __ __

[date_of_visit] [date]

Data entry by:
[dataentry_by] [varchar(50)]
Initials _____
DATE entered:
___ /_____ /_____
[dateenter] [date]

1. Intake (SD for 1.02-1.04)

1.01 [ ] Y [ ] N SAE since last visit (*MOP for definition*) → **If YES, complete Form X**
[adverse_event] **[varchar(6)]**

SAEs:
-Death
-Transient Ischemic Attack
-Stroke (intracerebral/ischemic)
-Stable Angina
-ACS: Unstable Angina OR MI
-Arrhythmia
-Gastrointestinal bleeding
-Eye diseases-Diabetic Retinopathy
-Major infection
-Renal failure
-Revascularization /other surgical procedures
-Other major health condition requiring hospitalization

1.02 Heart rate __ __ __ (beats/min)
[heart_rate] [int(3)]

1.03 Blood pressure 2nd reading __ __ __ / __ __ (mmHg)
[blood_pressure_h_1] [int(3)] / [blood_pressure_l_1] [int(3)]

1.04 Blood pressure 3rd reading __ __ __ / __ __ (mmHg)
[blood_pressure_h_2] [int(3)] / [blood_pressure_l_2] [int(3)]

1.05 BP AVERAGE (calculate) __ __ __ **/** __ __ **(mmHg) (review - below)**
[blood_pressure_h_avg] [double] [blood_pressure_l_avg] [double]

1.06 Waist circumference __ __ __ (cm)
[waist_circumference] [double]

1.07 Weight __ __ __ (kg)
[weight] [double]

1.08 Height __ __ __ (cm)
[height] [double]

1.09 BMI (calculate) __ __ **.** __ **(kg/m^2) (review - below)**
[bmi] [double]

2. Investigations (SD for 2.01-2.11) DATE: __ __ / __ __ __ / __ __ __ __ (dd/MMM/yyyy)

[investigation_date] [date]

2.01 Creatinine __ __ . __ __ (mg/dL)
[creatinine_mg] [double]

2.02 Sodium __ __ __ (mEq/L)
[sodium] [double]

2.03 Potassium __ . __ __ (mEq/L)
[potassium] [double]

2.04 HbA1c __ __ **.** __ **% (review - below)**
[hemoglobin_a1c] [double]

2.05 ALT __ __ __ **(units/L) (review - below)**
[alt] [double]

2.06 Total Cholesterol __ __ __ (mg/dL)
[total_cholesterol] [double]

2.07 HDL Cholesterol __ __ __ (mg/dL)
[hdl_cholesterol] [double]

2.08 LDL Cholesterol (indirect) __ __ __ **(mg/dL) (review - below)**
[ldl_cholesterol] [double]

2.09 Triglycerides __ __ __ (mg/dL)
[triglycerides] [double]

2.10 Fasting blood glucose (venous) __ __ __ (mg/dL)
[fasting_blood_glucose_mgdl] [double]

2.11 Urine Albumin:Creatinine Ratio __ __ __ (mg/g)
[s_albumin_mg] [double]

2.12 GFR (calculate www.nephron.com/cgi-bin/CGSI.cgi) ____ **ml/min/1.73m^2 (review - below)**
[gfr] [double]

3. Study Continuation / Selection Criteria [study_continuation] [No Data for this variable]

Participant is (check 1 or 2):

1[ ]	**INELIGIBLE for the study due to the FOLLOWING (Review values above with following criteria):** [ ] Serious Adverse Event *that falls under exclusion criteria* [ ] BMI ≥ 45 kg/m^2 *(obtain from calculation)* [ ] BOTH LDL ≤ 130 mg/dl AND systolic BP < 140 mmHg [ ] HbA1c < 8.0% [ ] ALT >3 times upper limit of normal [ ] GFR < 15 ml/min/1.73 m^2 *(obtain from calculation)* [ ] Participant is eligible but does not wish to continue [ ] Other, specify: _____ **Do not enroll patient. Stop here- complete Section 4 (Signature). Inform patient of ineligibility.**
2[ ]	**ELIGIBLE for the study and wishes to continue. Complete Section 4 & Continue to Form C.**

4. Signature of Study Physician

4.01 Name: _____ Signature: _____

4.02 Date Signed: __ __ / __ __ __ / __ __ __ __

4.03 Complete **Participant Log** for this patient

Participant ID: __ __ __ __ __
[participant_id] [varchar(20)]

FORM D – 3 monthly Visit_Intervention

Participant Initials: _____

CARRS Translation Trial

Date of Visit (dd/MMM/yyy): __ __ / __ __ __ / __ __ __ __

Care Coordinator

[dateofvisit] [date]

All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)**

- Place cross [X] in the appropriate boxes. Write number in spaces (f none, write 0)
- See *Form Completion Notes*, for definitions and explanations
- Store copies of available source documents (SD), where indicated, in patient's trial folder

Data entry by:
[data_entry_by] [varchar(100)]
Initials _____
DATE entered:
___ /_____ /_____
[date_entered] [date]

1. Intake FORM D – Data saved in **"patient_form_d.csv"** and is in long format

1.01	Reason for Visit: 1[ ] medication check 2[ ] Other, specify: [reason_of_visit] [Int(11)] *[medication check 1, other 2]* [reason_of_visit_other] [varchar(200)]	
1.02	Complaints/Update: [complaints] [varchar(500)]	
1.03	Number of severe hypoglycemic episodes since last visit (If present, **complete Form X** with investigator) [severe_hg_count] [Int(11)]	_____
1.04	Number of mild hypoglycemic episodes since last visit [mild_hg_count] [Int(11)]	_____
1.05	Other SAE since last visit (If present, **complete Form X** with investigator)	[ ]Y [ ]N

Commented [CR1]: If the response is [other 2] specify reason

2. Measures (SD for 2.02-2.04)

2.01	Weight [weight] [double]	_____ (kg)
2.02	Heart rate [heart_rate] [Int(11)]	_____ (beats/min)
2.03	Blood pressure 2nd reading [blood_pressure_h_1] [Int(11)] [blood_pressure_l_1] [Int(11)] [blood_pressure_h_avg] [double]	__ __ __ /__ __ (mmHg)
2.04	Blood pressure 3rd reading [blood_pressure_h_2] [Int(11)] [blood_pressure_l_2] [Int(11)] [blood_pressure_l_avg] [double]	__ __ __ /__ __ (mmHg)

3. Investigations (SD for all)

Write in other investigations/exams below. Retain records of results as source documents.

3.01	HbA1c [hemoglobin_a1c] [double] [hemoglobin_a1c_date] [date] [hba_not_applicable] [Int(11)] *[-1]*	__ __ . __ %	Date: __ __ / __ __ __ / __ __ __ __	[ ] N/A
3.02	Fasting blood glucose (venous) [fasting_blood_glucose] [double]	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __	[ ] N/A

Commented [CR2]: For Q.No. 3.01 to 3.03
If the response is [N/A] data is saved as '-1'

	[fasting_blood_glucose_date] [date] [fbg_not_applicable] [Int(11)] *[-1]*			
3.03	Post-prandial blood glucose (venous) [post_prandial_blood_glu] [double] [post_prandial_blood_glu_date] [date] [ppbg_not_applicable] [Int(11)] *[-1]*	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __	[ ] N/A
3.04	LDL [ldl] [double] [ldl_date] [date] [ldl_not_applicable] [Int(11)] *[-1]*	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __	[ ] N/A

Update Form G-Eye Exam results if not done at previous visit.
Indicate in Form C (Baseline_Randomization) or Form E (Follow-up 12 monthly_All).

4. Self-Care

The questions below ask you about your diabetes self-care activities **during the past 7 days**.

If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET		
4.01	On average, over the past month, how many DAYS PER WEEK have you followed your diet plan? [selfcare_id=1] [Int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
EXERCISE		
4.02	On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking) [selfcare_id=2] [Int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
BLOOD SUGAR TESTING		
4.03	Are you testing your blood sugar as recommended by your health care provider? [selfcare_id=3] [Int(11)] *[No 0, Yes 1, N/A -1]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A
FOOT CARE		
4.04	On how many of the last SEVEN DAYS did you check your feet? [selfcare_id=4] [Int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
MEDICATIONS		
4.05	On how many of the last SEVEN DAYS, did you take your recommended diabetes medication? (pills and/or insulin) [selfcare_id=5] [Int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
TOBACCO		
4.06	Smoke regularly? (most days of the week) [selfcare_id=6] [Int(11)] *[Never 0, Quit 1, Yes 2]* [if Quit 1]→ [quit_smoking_year] [varchar(20)]	0 [ ] Never 1 [ ] Quit: __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # smoked per day: ___

Formatted Table

	[if Yes 2]→ [smoke_per_day] [Int(11)]	
4.07	Chew tobacco regularly? (most days of the week) [selfcare_id=7] [Int(11)] *[Never 0, Quit 1, Yes 2]* [if Quit 1]→ [quit_tobacco_year] [varchar(20)] [if Yes 2]→ [packet_per_day] [Int(11)]	0 [ ] No 1 [ ] Quit __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # packets per day: ____
ALCOHOL		
4.08	Drink alcohol regularly? (at least once a week for most weeks in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [selfcare_id=8] [Int(11)] *[No 0, Yes 1]* [if Yes 1]→ [drink_per_day] [Int(11)]	0 [ ] No 1 [ ] Yes, # drinks per day: ____
STRESS		
4.09	How often do you feel stress (from work, responsibilities, etc)? [ ] daily [ ] few times a week [ ] few times a month [ ] never [selfcare_id=9] [Int(11)] *[daily 1, few times a week 2, few times a month 3, never 4]*	

Commented [CR3]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day

Commented [CR4]: If the response is [quit 1] specify the year & response is [yes 2] specify no. packet per day

Commented [CR5]: If the response is [yes 1] specify no. drink per day

5. Data Entry & Care Coordinator Signature

5.01 Name: _____ Signature: _____

5.02 Date Signed: __ __ / __ __ __ / __ __ __ __

5.03 **DSS Instructions:**

(1) Enter all visit information above into Form D eCRF. Print Form Z (Intervention Management Plan).
(2) Review patient medications. Update medication changes in writing on Form Z in medication section.
(3) Provide paper Form Z (with medication update) to study physician during consultation with participant.
(4) Attach completed Form Z to this Form D; Update patient with information.
(5) After patient leaves, update Form Z information in eCRF.
(6) Keep relevant source documents in participant's trial folder. Include copy of any visit note if available.

Form G - EYE EXAM FORM v1.2-17JUL2010 ***Participant ID:*** __ __ __ __ __
CARRS Translation Trial ***Participant Name:*** _____
Site: _____ ***Site No:*** ___
To be completed by qualified ophthalmologist only ***Investigator:*** _____

Referral to: _____ ***Appointment DATE:*** __ __ / __ __ __/ __ __ __ __

	EYE EXAM Date: __ __ / __ __ __ / __ __ __ __ [s_eye_exam_date] [date]

	Right Eye, Visual acuity	Snellen Fraction: 6/ ___ ___ [s_eye_exam_right_eye] [int(11)]	[ ] new or worsened [ ] unchanged or improved [eye_rgt_exam_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*
	Left Eye, Visual acuity	Snellen Fraction: 6/ ___ ___ [s_eye_exam_left_eye] [int(11)]	[ ] new or worsened [ ] unchanged or improved [eye_lft_exam_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*

Fundoscopy			
	Macular Edema [s_fundoscopy_macular_edema] [int(11)] *[absent 1, present 2, mild 3, moderate 4, severe 5]*	1[ ] absent 2[ ] mild 3[ ] moderate 4[ ] severe	[ ] new or worsened [ ] unchanged or improved [muculared_new_unch] [int(11)] *[new or worsened 1, unchanged or improved 0]*
	Diabetic Retinopathy [s_fundoscopy_diabetic] [int(11)] *[no apparent 1, mild non-proliferative 2, moderate non-proliferative 3, severe non-proliferative 4, proliferative 5]*	1[ ] no apparent 2[ ] mild non-proliferative 3[ ] moderate non-proliferative 4[ ] severe non-proliferative 5[ ] proliferative	[ ] new or worsened [ ] unchanged or improved [diabetic_reti_new_unch] [int(11)] *[new or worsened 1, unchanged or improved 0]*
	Previous Laser Therapy evident	1[ ] Y 2[ ] N	[ ] new or worsened [ ] unchanged or improved

Commented [CR1]: In Backend, data stored in 5 categories

Other details:

Please attach a copy of the exam note/results.

Ophthalmologist Name: _____ Signature: _____

Date Signed (dd/MMM/yyyy): __ __ / __ __ __ / __ __ __ __

To study staff- This Form G - Eye Exam must accompany all of the following:

Form C (Baseline_Randomization), Form E (12-monthly), and Form F (Close-out)

Participant ID: __ __ __ __ __
[participant_id] [varchar(20)]

FORM I.i – Intermediate Visit_Intervention

Participant Initials: _____

CARRS Translation Trial

Date of Visit (dd/MMM/yyy): __ __ / __ __ __ / __ __ __ __

Care Coordinator

[dateofvisit] [date]

All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)**

- Place cross [X] in the appropriate boxes. Write number in spaces (f none, write 0)
- Store copies of available source documents (SD), where indicated, in patient's trial folder

Data entry by:
[data_entry_by] [varchar(100)]
Initials _____
DATE entered:
___ /_____ /_____
[date_entered] [date]

1. Intake FORM D – Data saved in **"patient_form_d.csv"** and is in long format

1.01	Reason for Visit: 1[ ] medication check 2[ ] Other, specify: [reason_of_visit] [Int(11)] *[medication check 1, other 2]* [reason_of_visit_other] [varchar(200)]	
1.02	Complaints/Update: [complaints] [varchar(500)]	
1.03	Number of severe hypoglycemic episodes since last visit (If present, **complete Form X** with investigator) [severe_hg_count] [Int(11)]	_____
1.04	Number of mild hypoglycemic episodes since last visit [mild_hg_count] [Int(11)]	_____
1.05	Other SAE since last visit (If present, **complete Form X** with investigator)	[ ]Y [ ]N

Commented [r1]: If the response is [other 2] specify reason

2. Measures (SD for 2.02-2.04)

2.01	Weight [weight] [double]	_____ (kg)
2.02	Heart rate [heart_rate] [Int(11)]	_____ (beats/min)
2.03	Blood pressure 2nd reading [blood_pressure_h_1] [Int(11)] [blood_pressure_l_1] [Int(11)] [blood_pressure_h_avg] [double]	__ __ __ /__ __ (mmHg)
2.04	Blood pressure 3rd reading [blood_pressure_h_2] [Int(11)] [blood_pressure_l_2] [Int(11)] [blood_pressure_l_avg] [double]	__ __ __ /__ __ (mmHg)

3. Investigations (SD for all)

Write in other investigations/exams below. Retain records of results as source documents.

3.01	HbA1c [hemoglobin_a1c] [double] [hemoglobin_a1c_date] [date] [hba_not_applicable] [Int(11)] *[-1]*	__ __ . __ %	Date: __ __ / __ __ __ / __ __ __ __	[ ] N/A
3.02	Fasting blood glucose (venous) [fasting_blood_glucose] [double] [fasting_blood_glucose_date] [date]	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __	[ ] N/A

Commented [r2]: For Q.No. 3.01 to 3.03
If the response is [N/A] data is saved as '-1'

	[fbg_not_applicable] [Int(11)] *[-1]*			
3.03	Post-prandial blood glucose (venous) [post_prandial_blood_glu] [double] [post_prandial_blood_glu_date] [date] [ppbg_not_applicable] [Int(11)] *[-1]*	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __	[ ] N/A
3.04	LDL [ldl] [double] [ldl_date] [date] [ldl_not_applicable] [Int(11)] *[-1]*	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __	[ ] N/A

Update Form G-Eye Exam results if not done at previous visit.
Indicate in Form C (Baseline_Randomization) or Form E (Follow-up 12 monthly_All).

4. Self-Care

The questions below ask you about your diabetes self-care activities **during the past 7 days**.

If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET		
4.01	On average, over the past month, how many DAYS PER WEEK have you followed your diet plan? [selfcare_id=1] [Int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
EXERCISE		
4.02	On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking) [selfcare_id=2] [Int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
OOD SUGAR TESTING		
4.03	Are you testing your blood sugar as recommended by your health care provider? [selfcare_id=3] [Int(11)] *[No 0, Yes 1, N/A -1]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A
FOOT CARE		
4.04	On how many of the last SEVEN DAYS did you check your feet? [selfcare_id=4] [Int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
MEDICATIONS		
4.05	On how many of the last SEVEN DAYS, did you take your recommended diabetes medication? (pills and/or insulin) [selfcare_id=5] [Int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
TOBACCO		
4.06	Smoke regularly? (most days of the week) [selfcare_id=6] [Int(11)] *[Never 0, Quit 1, Yes 2]* [if Quit 1]→ [quit_smoking_year] [varchar(20)] [if Yes 2]→ [smoke_per_day] [Int(11)]	0 [ ] Never 1 [ ] Quit: __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # smoked per day: ___

Commented [r3]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day

4.07	Chew tobacco regularly? (most days of the week) [selfcare_id=7] [Int(11)] *[Never 0, Quit 1, Yes 2]* [if Quit 1]→ [quit_tobacco_year] [varchar(20)] [if Yes 2]→ [packet_per_day] [Int(11)]	0 [ ] No 1 [ ] Quit __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # packets per day: ____
ALCOHOL		
4.08	Drink alcohol regularly? (at least once a week for most weeks in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [selfcare_id=8] [Int(11)] *[No 0, Yes 1]* [if Yes 1]→ [drink_per_day] [Int(11)]	0 [ ] No 1 [ ] Yes, # drinks per day: ____
STRESS		
4.09	How often do you feel stress (from work, responsibilities, etc)? [ ] daily [ ] few times a week [ ] few times a month [ ] never [selfcare_id=9] [Int(11)] *[daily 1, few times a week 2, few times a month 3, never 4]*	

Commented [r4]: If the response is [quit 1] specify the year & response is [yes 2] specify no. packet per day

Commented [r5]: If the response is [yes 1] specify no. drink per day

5. Data Entry & Care Coordinator Signature

5.01 Name: _____ Signature: _____

5.02 Date Signed: __ __ / __ __ __ / __ __ __ __

5.03 **DSS Instructions:**

(1) Enter all visit information above into Form D eCRF. Print Form Z (Intervention Management Plan).
(2) Review patient medications. Update medication changes in writing on Form Z in medication section.
(3) Provide paper Form Z (with medication update) to study physician during consultation with participant.
(4) Attach completed Form Z to this Form D; Update patient with information.
(5) After patient leaves, update Form Z information in eCRF.
(6) Keep relevant source documents in participant's trial folder. Include copy of any visit note if available.

Form Z- Intervention Management Plan v1.2-17JUL2010 **CARRS Translation Trial Visit Date: [dd/MMM/yyyy]**

Form Z - Data saved in dataset as "patient_formz.csv" and is in long format

[First Name, Last Name] [Age] [M/F] DOB[dd/MMM/yyyy] Allergies: [none, listing]	[Conditions – from Form C, updates Form E]

	Wt	BMI
01/05/10		
02/02/10		
01/12/09		

Since last visit:	
Severe hypos	(#)
Mild hypos	(#)

Self-Care	Status
Adherence Medication	
Adherence SMBG	
Following Exercise	
Following Diet	
Smoking	
Chew Tobacco	
Alcohol	
Stress	

Commented [CR1]: Wt, BMI, Waist, HbA1c, FBG, PPBG, BP, TC, LDL, HDL, TG all fields come from in any of the Forms D/I, E

Date	HbA1c	FBG	PPBG

Prompt	Accept	If NO, reason
(from algorithm according to HbA1c and fasting blood glucose values – open space to accommodate length of prompt) [STATUS] [RECOMMENDATION] [diabetes_mplan] [varchar(500)]	[ ] Y [ ]N [diabetes_mplan_selected] [varchar(5)] *[Yes 1, No 2]*	[diabetes_no_mplan] [varchar(500)]

Date	BP
	130/80

Prompt	Accept	If NO, reason
(from algorithm according to blood pressure values – open space to accommodate length of prompt) [STATUS] [RECOMMENDATION] [bp_mplan] [varchar(500)]	[ ] Y [ ]N [bp_mplan_selected] [varchar(5)] *[Yes 1, No 2]*	[bp_no_mplan] [varchar(500)]

Date	TC	LDL	HDL	TG

Prompt	Accept	If NO, reason
(from algorithm according to LDL values – open space to accommodate length of prompt) [STATUS] [RECOMMENDATION] [ldl_mplan] [varchar(500)]	[ ] Y [ ]N [ldl_mplan_selected] [varchar(5)] *[Yes 1, No 2]*	[ldl_no_mplan] [varchar(500)]

PHYSICIAN NAME: _____ SIGNATURE: _____ [dd/MMM/yyyy]

Form Z- Intervention Management Plan v1.2-17JUL2010			**CARRS Translation Trial Visit Date: [dd/MMM/yyyy]**	
	RESULT		**LAST test**	**NEXT test**
ECG			(date)	(date)
EYE			(date)	(date)
FOOT			(date)	(date)
KIDNEY	**Creatinine**	**A:C Ratio**		(date)
			(date)	
			(date)	

[First Name, Last Name] [Age] [M/F] DOB[dd/MMM/yyyy] Allergies: [none, listing]	[Conditions – from Form C, updates Form E]

Current medications listed below. Make changes in right column. *Add NEW medications to bottom of list.*

___ (Y/N) TV = Telephonic contact with clinic/doctor to change meds since last visit (update below)
[doctor_change_med] [int(11)] *[Yes 1, No 2]*

___ (Y/N) Other outside changes to meds (update below)
[other_change_med] [int(11)] *[Yes 1, No 2]*

Brand Name (if available)	**Generic Name (constituents)**	**Single Dose (constituents)**	**Frequency**	**Total daily dose**	**√ to keep same OR write changes in dose**

PHYSICIAN NAME: _____ SIGNATURE: _____ [dd/MMM/yyyy]

Form Z- Intervention Management Plan v1.2-17JUL2010 **CARRS Translation Trial Visit Date: [dd/MMM/yyyy]**

[ ] Anti-platelet included **[ ] ACE-inhibitor or ARB included**

[anti_platelet] [int(11)] *[1]* [arb_included] [int(11)] *[1]*

	REFERRAL	Today	Other DATE
[ ]	Dietician/Educator [dietician_educator] [int(11)] *[1]*		__ __/ __ __ __ / __ __ [dietician_educator_date] [date]
[ ]	ECG [ecg] [int(11)] *[1]*		__ __/ __ __ __ / __ __ [ecg_date] [date]
[ ]	Ophthalmology [ophthalmogy] [int(11)] *[1]*		__ __/ __ __ __ / __ __ [ophthalmogy_date] [date]
[ ]	Podiatry [podiatry] [int(11)] *[1]*		__ __/ __ __ __ / __ __ [podiatry_date] [date]
[ ]			__ __/ __ __ __ / __ __
[ ]			__ __/ __ __ __ / __ __
[ ]	LAB today, tests: [lab_today] [int(11)] *[1]* [lab_test] [text]		

	NEXT VISIT in	____ mo __ __ /__ __ __/__ __ [next_visit] [date]
	Tests prior to next visit:	
[ ]	HbA1c [hba1c] [int(11)] *[1]*	
[ ]	Fasting blood glucose (venous) [fasting_glu] [int(11)] *[1]*	
[ ]	Post-prandial blood glucose [ppbg] [int(11)] *[1]*	
[ ]	Potassium & Sodium (serum) [potassium_sodium] [int(11)] *[1]*	
[ ]	Creatinine (serum) [creatinine] [int(11)] *[1]*	
[ ]	Urine microalbuminuria [urine_microal] [int(11)] *[1]*	
[ ]	Lipid Panel [lipid_panel] [int(11)] *[1]*	
[ ]	ALT [alt] [int(11)] *[1]*	
[ ]	Other: [other] [int(11)] *[1]*	

Commented [CR2]: If response is "other" there should be other specify variable not found in database

[ ] Care coordinator: Attach copy of prescription to this form.

PHYSICIAN NAME: _____ SIGNATURE: _____ [dd/MMM/yyyy]

- All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)**
- Place cross [X] in the appropriate boxes. Write in fields clearly.
- See *Form Completion Notes*, for definitions and explanations
- Store copies of available source documents (SD), where indicated, in patient's trial folder

Data entry by:
[data_entry_by] [varchar(100)]
Initials _____
DATE entered: ___ /_____ /_____
[date_entered] [date]

PART 1: complete by STUDY PHYSICIAN

FORM C – Baseline Randomization

CARRS Translation Trial

Screening ID: S __ __ __ __ __
Participant Initials: _____
[participant_id] [varchar(20)]

Date of Visit (dd/MMM/yyyy): __ __ / __ __ __ / __ __ __ __
[date_of_visit] [date]

1. History – Data saved in "patient_form_c.csv" and is in wide format

	Condition	Year of Diagnosis		
1.01	Type 2 Diabetes [h_type2_diabetes_year] [varchar(6)]	__ __ __ __	1[ ] Unknown [h_is_type2_diabetes] [int] *[Unknown 1]*	
1.02	Hypertension [h_hypertension_year] [varchar(6)]	__ __ __ __	1[ ] Unknown [h_is_hypertension] [int] *[Unknown 1, Not applicable -1]*	2[ ] Not applicable
1.03	Hyperlipidemia [h_hyperlipidemia_year] [varchar(6)]	__ __ __ __	1[ ] Unknown [h_is_hyperlipidemia] [int] *[Unknown 1, Not applicable -1]*	2[ ] Not applicable

1.04	How first diagnosed with diabetes: [h_first_diagnosed_with_diabetes] [int] *[Testing after symptoms emerged 1,* *At routine check-up, no symptoms 2,* *Active screening 3,* *Diagnosed during pregnancy 4,* *Other 5]*	1[ ] Testing after symptoms emerged (polydipsia, polyuria, polyphagia, weight loss, low energy, impotence, pruritis, vision problems, giddiness, aches/pains) 2[ ] At routine check-up, no symptoms (urine test, raised blood sugar, etc.) 3[ ] Active screening (testing by physician, at fair, etc) 4[ ] Diagnosed during pregnancy 5[ ] Other

		Diabetes?		Kidney failure?	
1.05	Number of children with [h_no_children_with_diabetes] [int(11)] [h_no_children_with_kidney_failure] [int(11)]	_ _ _ _ _ _	[ ] Unknown, N/A [is_child_with_diabetes_fail] [int] *[-1]*	__ _ __ _	[ ] Unknown, N/A [is_chid_with_kidney_fail] [int] *[-1]*
1.06	Number of brothers/sisters with [h_no_brother_sister_with_diabetes] [int(11)] [h_no_brother_sister_with_kidney_failure] [int(11)]	_ _ _	[ ] Unknown, N/A [is_brosis_with_diabetes] [int] *[-1]*	__ _	[ ] Unknown, N/A [is_brosis_with_kidney_fail [int] *[-1]*

Commented [CR1]: If the response is [Unknown] data is saved as '1'

Commented [CR2]: If the response is [Unknown] or [Not applicable] data is saved as '1' or '-1'

Commented [CR3]: If the response is [Unknown] or [Not applicable] data is saved as '1' or '-1'

Commented [CR5]: If the response is [Unknown, N/A] data is saved as '-1'

Commented [CR4]: If the response is [Unknown, N/A] data is saved as '-1'

Commented [CR7]: If the response is [Unknown, N/A] data is saved as '-1'

Commented [CR6]: If the response is [Unknown, N/A] data is saved as '-1'

1.07	Number of parents with [h_no_parents_with_diabetes] [int(11)] [h_no_parents_with_kidney_failure] [int(11)]	_ _ _	[ ] Unknown [is_parents_with_diabetes] [int] *[-1]*	__ _	[ ] Unknown [is_parents_with_kidney_fail] [int] *[-1]*
1.08	Number of grandparents with [h_no_grandparents_with_diabetes] [int(11)] [h_no_grandparents_with_kidney_failure] [int(11)]	_ _ _	[ ] Unknown [is_granparent_with_diabetes] [int] *[-1]*	__ _	[ ] Unknown [is_granparent_with_kidney_fail] [int] *[-1]*

Commented [CR8]: If the response is [Unknown] data is saved as '-1'

Commented [CR9]: If the response is [Unknown] data is saved as '-1'

Commented [CR10]: If the response is [Unknown] data is saved as '-1'

Commented [CR11]: If the response is [Unknown] data is saved as '-1'

1.09	Is there a history of HEART DISEASE or HEART ATTACK in a brother, sister, or parent? *If YES, was it at an early age? (*Early age = Before Age 55 for father/brother; 65 for mother/sister) [h_heart_attack_brother_sister_parents] [int(11)] *[Yes, at an EARLY AGE 1, Yes, age unknown 2, No 3, Unknown 4]*	1[ ] Yes, at an EARLY AGE 2[ ] Yes, age unknown 3[ ] No 4[ ] Unknown
1.10	Is there a history of STROKE in a brother, sister, or parent? *If YES, was it at an early age? (*Early age = Before Age 55 for father/brother; 65 for mother/sister) [h_stroke_brother_sister_parents] [int(11)] *[Yes, at an EARLY AGE 1, Yes, age unknown 2, No 3, Unknown 4]*	1[ ] Yes, at an EARLY AGE 2[ ] Yes, age unknown 3[ ] No 4[ ] Unknown

	Cardiovascular	no/ unsure	yes	
1.11	ACS: Myocardial Infarction or Unstable Angina [h_cardiovascular_acs] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, list year(s): [h_cardiovascular_acs_year] [varchar(20)]
1.12	Angioplasty (PCI) /Open-heart surgery (CABG) [h_cardiovascular_pci_cabg] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, list year(s): [h_cardiovascular_pci_cabg_year] [varchar(20)]
1.13	Chronic Stable Angina [h_cardiovascular_chronic_sa] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, since (year): _ _ _ _ [h_cardiovascular_chronic_sa_year] [varchar(20)]
1.14	Stroke (Ischemic or Hemorrhagic) or TIA [h_cardiovascular_stroke_tia] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, list year(s): [h_cardiovascular_stroke_tia_year] [varchar(20)]
1.15	Arrhythmia (requiring medical intervention) [h_cardiovascular_arrtythmia] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, since (year): _ _ _ _ [h_cardiovascular_arrtythmia_year] [varchar(20)]
1.16	Heart Failure	[ ]	[ ]	If yes, since (year): _ _ _ _

Commented [CR12]: If the response is [yes 1] for Q.no.1.11 to 1.16 - specify the year __

	[h_cardiovascular_heart_attack] [int(11)] *[Yes 1, no/unsure 2,]*			[h_cardiovascular_heart_attack_year] [varchar(20)]

	Peripheral Vascular/Neuropathy	no/ unsure	yes	
1.17	PVD (Intermittent claudication/ rest pain in legs) [h_peripheral_vascular_pvd] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, since (year): _ _ _ _ [h_peripheral_vascular_pvd_year] [varchar(20)]
1.18	Peripheral revascularization (angioplasty/ surgery) [h_peripheral_surgery] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, list year(s): [h_peripheral_surgery_year] [varchar(20)]
1.19	Chronic leg/foot ulcer (6 weeks or more) [h_peripheral_foot_ulcer] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, number of times: ___ [h_peripheral_foot_ulcer_year] [varchar(20)]
	Eyes			
1.20	Blindness in either eye thought to be due to diabetes [h_eyes_blindbess] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, [ ] R [ ] L [ ] both [h_eyes_is_blindbess] [varchar(20)] *[R right, L left, B both]*
1.21	Cataract [h_eyes_cataract] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, [ ] R [ ] L [ ] both [h_eyes_is_cataract] [varchar(20)] *[R right, L left, B both]*
1.22	Cataract Surgery [h_eyes_cataract_surgery] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, [ ] R [ ] L [ ] both [h_eyes_is_cataract_surgery] [varchar(20)] *[R right, L left, B both]*
1.23	Glaucoma [h_eyes_glaucoma] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.24	Macular Edema [h_eyes_macular_edema] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.25	Diabetic Retinopathy [h_eyes_diabetic_retinopathy] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.26	Laser photocoagulation therapy [h_eyes_laser_therapy] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, number of times: ___
1.27	Other therapy [h_eyes_other_therapy] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
	OTHER			
1.28	Neuropathy – hands/feet [h_other_neuropathy_hands_feet] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.29	Neuropathy – sexual (erectile dysfunction) [h_other_neuropathy_sexual] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.30	Nephropathy (protein in urine)	[ ]	[ ]	

Commented [CR13]: If the response is [yes 1] for Q.no.1.17, 1.18 - specify the year __ & for Q.no.1.19 response is [yes 1] – specify number of times __

Commented [CR14]: If the response is [yes 1] for Q.no.1.20 to 1.**22** - specify the direction [right, left or both

Commented [CR15]: We can ignore this because Variable not found in both front-end & back-end

	[h_other_neuropathy_urine] [int(11)] *[Yes 1, no/unsure 2,]*			
1.31	Chronic urinary tract infection (2+ in 6 months) [h_other_chronic_urinary] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.32	Past tuberculosis [h_other_past_tuberculosis] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.33	Asthma [h_other_asthma] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.34	COPD (Chronic Bronchitis, Emphysema) [h_other_copd] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.35	Liver disease [h_other_liver_disease] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.36	Gallbladder disorder (stones, disease) [h_other_gallbladder_disorder] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.37	Hip Fracture/Replacement [h_other_hip_facture] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.38	Depression [h_other_depression] [int(11)] *[yes 1, no/unsure 2,]*	[ ]	[ ]	
1.39	Major hypoglycemia episodes (hospitalization or emergency room visit) [h_other_major_hypoglycemia] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, number of times: ___ [h_other_is_major_hypoglycemia] [int(11)]
1.40	Other hospitalization for diabetes [h_other_hospitalization] [int(11)] *[Yes 1, no/unsure 2]*	[ ]	[ ]	If yes, number of times: ___ [h_other_is_hospitalization] [int(11)]
1.41	Other conditions (current or past) which have required medications or surgical intervention: [h_other_conditions] [varchar(200)]			

Commented [CR16]: If the response is [yes 1] for Q.no.1.39 & 1.40 – specify number of times

2. ECG & Eye Exam

May use results from past 1 month. Retain copies of ECG and eye exam results as source documents.

ECG: May use results from past 1 month. Otherwise, complete test today.

2.01	**ECG** Date: __ __ / __ __ __ / __ __ __ __ [s_ecg_date] [date]		
2.02	Q-waves diagnostic of previous MI [s_ecg_q_waves] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N
2.03	Left ventricular hypertrophy [s_ecg_left_ventricular] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N
2.04	Atrial Fibrillation [s_ecg_atrial] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N
2.05	Other arrhythmia [s_ecg_other_arrhythmia] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N

Commented [CR17]: ECG date should be within one month of Form B Date of visit

EYE EXAM: **May use results from past 1 month.**

[ ] Attach Form G-Eye Exam to end of this Form C – to be completed by qualified ophthalmologist only. If not completed prior to this visit, schedule ophthalmologist appointment and ensure completion within 2 weeks. Enter results in eCRF (EYE EXAM) as soon as available.

3. Foot Exam

		Right Foot		Left Foot	
3.01	Amputation [fe_amputation_right_foot] [int(11)] [fe_amputation_left_foot] [int(11)] *[N/A 1, toe 2, ray (metatarsal) 3, forefoot 4, foot 5, below knee 6, above knee 7]*	[ ] N/A [ ] toe [ ] ray (metatarsal) [ ] forefoot [ ] foot [ ] below knee [ ] above knee		[ ] N/A [ ] toe [ ] ray (metatarsal) [ ] forefoot [ ] foot [ ] below knee [ ] above knee	
3.02	Appearance [fe_appearance_right_foot_normal] [int(11)] *[normal 1, abnormal 2]* [fe_appearance_left_foot_normal] [int(11)] *[normal 1, abnormal 2]* [fe_appearance_right_foot_deformities] [int(11)] *[1]* [fe_appearance_right_foot_dystrophic] [int(11)] *[2]* [fe_appearance_right_foot_callus] [int(11)] *[3]* [fe_appearance_right_foot_unceration] [int(11)] *[4]* [fe_appearance_right_foot_infection] [int(11)] *[5]* [fe_appearance_right_foot_discoloration] [int(11)] *[6]* [fe_appearance_right_foot_other] [int(11)] *[7]* [fe_appearance_right_foot_other_details] [varchar(200)] *[other specify]*	1[ ] normal **2[ ] abnormal**, check all that apply: 1[ ] deformities 2[ ] dystrophic nails; dry skin/fissure 3[ ] callus 4[ ] ulceration 5[ ] infection 6[ ] discoloration 7[ ] other: _____		1[ ] normal **2[ ] abnormal**, check all that apply: 1[ ] deformities 2[ ] dystrophic nails; dry skin/fissure 3[ ] callus 4[ ] ulceration 5[ ] infection 6[ ] discoloration 7[]other: _____	
3.03	Posterior tibial pulse [fe_posterior_right_foot] [int(11)] *[Yes 1, No 2]* [fe_posterior_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.04	Doraslis pedis pulse [fe_doraslis_right_foot] [int(11)] *[Yes 1, No 2]* [fe_doraslis_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.05	Pre-tibial EDEMA today [fe_pre_tibial_edema_right_foot] [int(11)] [fe_pre_tibial_edema_left_foot] [int(11)] *[None 0, up to ankle 1,between ankle & mid-calf 2, between mid-calf & knee 3]*	[ ] none [ ] up to ankle [ ] between ankle & mid-calf [ ] between mid-calf & knee		[ ] none [ ] up to ankle [ ] between ankle & mid-calf [ ] between mid-calf & knee	
3.06	Ankle Reflex [fe_ankle_relax_right_foot] [int(11)] *[Yes 1, No 2]* [fe_ankle_relax_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.07	Knee Reflex [fe_knee_reflax_right_foot] [int(11)] *[Yes 1, No 2]* [fe_knee_reflax_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.08	Vibration, tuning fork (perception at great toe) [fe_vibration_right_foot] [int(11)] [fe_vibration_left_foot] [int(11)] *[present (≥10 sec) 1, reduced (<10 sec) 2, absent 3]*	[ ] present (≥10 sec) [ ] reduced (<10 sec) [ ] absent		[ ] present (≥10 sec) [ ] reduced (<10 sec) [ ] absent	

Commented [CR18]: If the response is [abnormal 2] specify below mentioned options 1 to 7 (check all that apply) for right foot & left foot

[fe_appearance_left_foot_deformities] [int(11)] *[1]*
[fe_appearance_left_foot_dystrophic] [int(11)] *[2]*
[fe_appearance_left_foot_callus] [int(11)] *[3]*
[fe_appearance_left_foot_unceration] [int(11)] *[4]*
[fe_appearance_left_foot_infection] [int(11)] *[5]*
[fe_appearance_left_foot_discoloration] [int(11)] *[6]*
[fe_appearance_left_foot_other] [int(11)] *[7]*
[fe_appearance_left_foot_other_details] [varchar(200)] *[other specify]*

3.09	10g Monofilament (number applications detected) [fe_monofilament_right_foot] [int(11)] [fe_monofilament_left_foot] [int(11)] *[present (≥8) 1, reduced (1-7) 2, absent 3]*	[ ] present (≥8) [ ] reduced (1-7) [ ] absent	[ ] present (≥8) [ ] reduced (1-7) [ ] absent
3.10	**Based on above the participant has:**		
	Deformities [fe_participant_has] [varchar(20)] *[Yes 1, No -1]*	1[ ] Yes	2[ ] No
	Foot ulceration/infection *[Yes 2, No -2]*	1[ ] Yes	2[ ] No
	PVD *[Yes 3, No -3]*	1[ ] Yes	2[ ] No
	Neuropathy *[Yes 4, No -4]*	1[ ] Yes	2[ ] No

Commented [CR19]: For Q.no.3.10 to 3.14 has multiple responses and data stored in this column as string so we are splitting & re naming the categories as [1,-1, 2,-2, 3,-3, 4,-4]

4. Heart Failure Exam

	Have you experienced any of the following since your last exam?		
4.01	swelling of your feet, ankles or legs [hf_swelling_feet] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_swelling_feet_new] *[new or worsened 1, unchanged or improved 0]*
4.02	shortness of breath while lying, sitting, or with minimal exertion [hf_shortness_of_breath] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_shortness_of_breath_new] *[new or worsened 1, unchanged or improved 0]*
4.03	need to pass urine two or more times per night [hf_pass_urine] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_pass_urine_new] *[new or worsened 1, unchanged or improved 0]*

Commented [CR20]: If the response is [yes 1] for Q.no.4.01 to 4.03 – specify '1' or '0'
[new or worsened 1, unchanged or improved 0]

If any 4.01-4.03 is YES, complete below.		
Chest Auscultation		
4.04	Lungs [hf_chest_ausculation_lungs] [int(11)] *[no rales 1, basilar rales only 2, more than basilar 3]*	1[ ] no rales more than basilar 2[ ] basilar rales only 3[ ]
4.05	Heart [hf_chest_ausculation_heart] [int(11)] *[normal 1, abnormal 3rd heart sound present 2]*	1[ ] normal 2[ ] abnormal, 3rd heart sound present

4.06	Heart Failure evident [hf_chest_ausculation_heart_failure] [int(11)] *[Yes 1, No 2]*	1[ ] Yes, grade: _____ [heart_failure_grade] [varchar(45)]	2[ ] No

Commented [CR21]: If the response is [yes 1] for Q.no.4.06 – specify grade

5. Neurological Exam

	Have you experienced any of the following since your last exam?		
5.01	Muscle weakness [ne_muscles_weakness] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [ne_is_muscles_weakness_new] [int(11)] *[new or worsened 1, unchanged or improved 0]*
5.02	Difficulty in speech [ne_difficulty_in_speech] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [ne_difficulty_in_speech_new] [int(11)] *[new or worsened 1, unchanged or improved 0]*
5.03	Loss of consciousness [ne_loss_consciousness] [int(11)] *[Yes 1, No 2, N/A 3]*	**1[ ] Yes** 2[ ] No	

Commented [CR22]: If the response is [yes 1] for Q.no.5.01 & 5.02 – specify '1' or '0'
[new or worsened 1, unchanged or improved 0]

If any 5.01-5.03 is YES, complete below.

	Muscles	Right	Left
5.04	ARMS-Tone [ne_arms_tone_right] [int(11)] [ne_arms_tone_left] [int(11)] *[normal 1, flaccid 2, rigid/spastic 3]*	[ ] normal [ ] flaccid [ ] rigid/spastic	[ ] normal [ ] flaccid [ ] rigid/spastic
5.05	ARMS-Strength [ne_arms_strengt_right] [int(11)] [ne_arms_strengt_left] [int(11)] *[normal 1, deficit 2]*	[ ] normal [ ] deficit	[ ] normal [ ] deficit
5.06	LEGS-Tone [ne_legs_tone_right] [int(11)] [ne_legs_tone_left] [int(11)] *[normal 1, flaccid 2, rigid/spastic 3]*	[ ] normal [ ] flaccid [ ] rigid/spastic	[ ] normal [ ] flaccid [ ] rigid/spastic
5.07	LEGS-Strength [ne_legs_strength_right] [int(11)] [ne_legs_strength_left] [int(11)] *[normal 1, deficit 2]*	[ ] normal [ ] deficit	[ ] normal [ ] deficit
	Reflexes	**Right**	**Left**
5.08	Biceps [ne_reflexes_biceps_right] [int(11)] [ne_reflexes_biceps_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.09	Triceps [ne_reflexes_triceps_right] [int(11)] [ne_reflexes_triceps_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.10	Knee [ne_reflexes_knee_right] [int(11)] [ne_reflexes_knee_right] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.11	Ankle [ne_reflexes_ankle_right] [int(11)] [ne_reflexes_ankle_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent

5.12	[ ] Old deficit evident [ne_old_deficit] [int(11)] *[Yes 1, No 2]*	1[ ] Yes	2[ ] No

6. MEDICATIONS and MANAGEMENT

6.01	**Drug Allergies** [othedrugallergy] [varchar(20)] *[Yes 1, No 2, unknown -1]* [drug_allergies] [varchar(200)]	[ ]No [ ]Unknown [ ]Yes, *specify:*

Commented [CR23]: If the response is [Yes 1] specify drug name

6.02 MEDICATIONS – Data is saved in "medication_mgt.csv" file and is in long format

Below, list all medications that the participant is presently taking *on a regular basis (prior to randomization).*

^For (1) Insulin, (2) OHAs, and (3) Blood pressure MIXED medications, describe all constituents separately under "Generic Name" and "Single Dose"

Type	Brand Name [name] [varchar(200)]	*^List ALL constituents for Insulin, OHAs, BP meds*		Frequency [frequency] [double]	Total daily dose **[total_daily_dose]** [double]
		Generic Name [generic_name] [varchar(200)]	Single Dose [single_dose] [double]		
Insulin					
OHAs					
BP					
Statin					

Type	Brand Name	*Generic Name*	Single Dose	Frequency	Total daily dose
Other					

6.03		**Management of diabetes in last 6 months** [dibetes_mgt] [varchar(50)]
	[ ]	Sulphonylurea (glibenclamide, gliclazide, glimipiride)
	[ ]	Biguanide (Metformin)
	[ ]	Thazolidineodione (Pioglitazone)
	[ ]	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)
	[ ]	Glinide (Nateglinide, Repaglinide, Mitiglinide)
	[ ]	Lispro, Aspart, Glulisine insulins (rapid-acting)
	[ ]	Regular Insulins (short-acting)
	[ ]	NPH or Lente Insulins (intermediate-acting)
	[ ]	Glargine or Determir Insulins (very long-acting)
	[ ]	Other diabetic treatment
	[ ]	Dietician or Educator referral
	[ ]	Weight control or exercise program
	[ ]	Home blood glucose monitoring
6.04		**Other medications** [other_dibetes_mgt] [varchar(100)]
	[ ]	Thaizide or thiazide-like diuretic
	[ ]	Other diuretic

[Sulphonylurea (glibenclamide, gliclazide, glimipiride) 1
Biguanide (Metformin) 2
Thazolidineodione (Pioglitazone) 3
Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)4
Glinide (Nateglinide, Repaglinide, Mitiglinide) 5
Lispro, Aspart, Glulisine insulins (rapid-acting) 6
Regular Insulins (short-acting) 7
NPH or Lente Insulins (intermediate-acting) 8
Glargine or Determir Insulins (very long-acting) 9
Other diabetic treatment 10
Dietician or Educator referral 11
Weight control or exercise program 12
Home blood glucose monitoring 13

	[ ]	ACE inhibitor
	[ ]	Angiotensin 2 receptor antagonist (ARB)
	[ ]	Beta-blocker
	[ ]	Calcium channel blocker (CCB)
	[ ]	Other antihypertensive agent
	[ ]	Statin
	[ ]	Other cholesterol lowering drug
	[ ]	Aspirin
	[ ]	Other anti-platelet agent
	[ ]	Oral anticoagulant
	[ ]	Nitrates (NOT sublingual)
	[ ]	Hormone replacement therapy
	[ ]	Thyroid Agents
	[ ]	Oral/inhaled steroids
	[ ]	Oral asthma drugs (exclude steroids)
	[ ]	Antidepressant
	[ ]	Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline)
	[ ]	Erectile Dysfunction drug
	[ ]	Herbal/alternative medicine
	[ ]	Vitamins/nutritional supplements
	[ ]	Other, not listed above

Thaizide or thiazide-like diuretic 1
Other diuretic 2
ACE inhibitor 3
Angiotensin 2 receptor antagonist (ARB) 4
Beta-blocker 5
Calcium channel blocker (CCB) 6
Other antihypertensive agent 7
Statin 8
Other cholesterol lowering drug 9
Aspirin 10
Other anti-platelet agent 11
Oral anticoagulant 12
Nitrates (NOT sublingual) 13
Hormone replacement therapy 14
Thyroid Agents 15
Oral/inhaled steroids 16
Oral asthma drugs (exclude steroids) 17
Antidepressant 18
Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline) 19
Erectile Dysfunction drug 20
Herbal/alternative medicine 21
Vitamins/nutritional supplements 22
Other, not listed above 23

7. Randomization

7.01	[ ] Y [ ] N	Completed all of Form C, Part 1 above. **If NO,** complete now.
7.02	[ ] Y [ ] N	Reviewed Forms and Eligibility with Investigator or Co-Investigator. **If NO,** review now.
7.03	[ ] Y [ ] N	Patient agrees to continue with the trial **If NO,** stop here and complete patient status in PARTICIPANT LOG.

If YES for ALL 7.01-7.03, continue to Randomization:

1. Information from **Participant Log** will be required to complete the Randomization.
2. Select Randomization option on website *www.coe-carrs.phfi.in* (CARRS Translation Trial > Randomization) and enter requested data
    a. Screening Officer Name
    b. Screening ID (do not include 'S' - only numbers)
    c. Confirm Screening ID (do not include 'S' - only numbers)
    d. Date of Birth (dd/MMM/yyyy)
    e. Confirm Date of Birth (dd/MMM/yyyy)
    f. Was the eligibility of the participants to both treatment arms confirmed by investigator?
    g. Has the participant met all eligibility criteria?

h. Has the participant met any of the exclusion criteria?

i. Did the participant sign informed consent?

OR IF INTERNET ACCESS NOT POSSIBLE:

3. Telephone +011 2685-0117/18 and ask for CARRS Translation Trial Randomization

7.04 Result of Randomization: - enter information below & attach print-out from randomization page:

PARTICIPANT ID: __ __ __ __ __	**USE THIS ID in future CRF and eCRF**

Allocation: [ ] Control Group [ ] Intervention Group

[treatment_group] [varchar (20)], *[INTERVENTION, CONTROL]*

8. Signature of Study Physician

8.01 Name: _____ Signature: _____

8.02 Date Signed: __ __ / __ __ __ / __ __ __ __

8.03 Complete **Participant Log** for this patient

8.04 Check one of the following:

[ ] **Control Group Participant** → send to **Research Officer** to complete Form C Part 2 (below)

[ ] **Intervention Group Participant** → send to **Care Coordinator** to complete Form C Part 2 (below)

PART 2: complete by CARE COORDINATOR or RESEARCH OFFICER

9. Demographics

9.01 Marital Status

[matrial_status] [int], *[Single 1, Married 2, Widow/Widower 3, Separated/Divorced 4]*

1[ ] Single
2[ ] Married
3[ ] Widow/Widower
4[ ] Separated/Divorced

9.02 Occupation

[occupation] [int]

[1 Professional, big business, landlord, university teacher, class 1 IAS/services officer, lawyer, 2 Trained, clerical, medium business owner, staff manager, mid-level farmer, teacher, 3 Skilled manual laborer, small business owner, small farmer, 4 Semi-skilled manual laborer, marginal landowner, rickshaw driver, army jawan, carpenter, fitter, 5 Unskilled manual laborer, landless laborer, 6 Homemaker, 8 Student, 9 Retired, 10 Unemployed, 11 Other]

1[ ] Professional, big business, landlord, university teacher, class 1 IAS/services officer, lawyer
2[ ] Trained, clerical, medium business owner, staff manager, mid-level farmer, teacher
3[ ] Skilled manual laborer, small business owner, small farmer
4[ ] Semi-skilled manual laborer, marginal landowner, rickshaw driver, army jawan, carpenter, fitter
5[ ] Unskilled manual laborer, landless laborer
6[ ] Homemaker
8[ ] Student
9[ ] Retired
10[ ] Unemployed
11[ ] Other

9.03 Days per week that you work: _____ [ ] N/A

[days_per_week_work] [int (1)] [days_per_week_work_na] [int] *[(N/A) 1]*

Commented [CR24]: If the response is [N/A] data is saved as '1'

Hours per day that you work: _____ [ ] N/A
[hours_per_day_work] [int(2)] [hours_per_day_work_na] [int] *[(N/A 1)]*

9.04 TOTAL number of household members: _____
[no_household] [int(2)]

9.05 Number of children in household: _____
[no_children] [int(2)]

9.06 Number of adults in household: _____
[no_adult] [int(2)]

9.07 Number of adults in household earning: _____
[no_adult_earning] [int(2)]

9.08 During last 12 months, HOUSEHOLD monthly income:
[household_income] [int] *[<3,000 1, 3,000-10,000 2, 10,000-20,000 3, 20,001-30,000 4, 30,001-40,000 5, 40,001-50,000 6, >50,000 7, Unknown/ Refuse 8]*

1[ ] <3,000
2[ ] 3,000-10,000
3[ ] 10,000-20,000
4[ ] 20,001-30,000
5[ ] 30,001-40,000
6[ ] 40,001-50,000
7[ ] >50,000
8[ ] Unknown/ Refuse

During last 12 months, INDIVIDUAL monthly income: _____Rupees
[individual_income] [int] *[<3,000 1, 3,000-10,000 2, 10,000-20,000 3, 20,001-30,000 4, 30,001-40,000 5, 40,001-50,000 6, >50,000 7, Unknown/ Refuse 8]*

1[ ] <3,000
2[ ] 3,000-10,000
3[ ] 10,000-20,000
4[ ] 20,001-30,000
5[ ] 30,001-40,000
6[ ] 40,001-50,000
7[ ] >50,000
8[ ] Unknown/ Refuse

9.09 Highest Level of Education of Participant:
[highest_education] [int] *[1 Professional degree/post graduate, 2 Graduate (BA, BSc, BCom, Diploma), 3 Secondary School, Standard, 4 Primary School (up to class 5), Standard 5 Literate, no formal education, 6 Illiterate, 7 Unknown]*

1[ ] Professional degree/post graduate
2[ ] Graduate (BA, BSc, BCom, Diploma)
3[ ] Secondary School, Standard: _____
4[ ] Primary School (up to class 5), Standard: _____
5[ ] Literate, no formal education
6[ ] Illiterate
7[ ] Unknown

9.10 Mother Tongue (Ethnic Origin):
[mother_tongue] [int (2)] *[1 Assamese, 2 Bengali, 3 Gujarati, 4 Hindi, 5 Kannada, 6 Kashmiri, 7 Maithili, 8 Malayalam, 9 Marathi, 10 Punjabi, 11 Sindhi, 12 Telugu, 13 Tamil, 14 Urdu, 15 other, specify, 16 Unknown]*

1[ ] Assamese
2[ ] Bengali
3[ ] Gujarati
4[ ] Hindi
5[ ] Kannada
6[ ] Kashmiri
7[ ] Maithili
8[ ] Malayalam
9[ ] Marathi
10[ ] Punjabi
11[ ] Sindhi
12[ ] Telugu
13[ ] Tamil
14[ ] Urdu
15[ ] Other, specify: _____
[mother_tongue_other] [varchar(50)]
16[ ] Unknown

9.11 Knows English language (check all that apply OR none):
[english_language] [int(10)] *[(understand 1, speak 2, read/write 3, None 4)]*
1[ ] understand

Commented [CR25]: If the response is [N/A] data is saved as '1'

2[ ] speak 4[ ] none
3[ ] read/write

9.12 Religion:
[religion] [int] *[1 Hindu, 2 Muslim, 3 Sikh, 4 Christian, 5 Jain, 6 Buddhism, 7 No religion, 8 other, specify, 9 unknown/refuse]*

1[ ] Hindu
2[ ] Muslim
3[ ] Sikh
4[ ] Christian
5[ ] Jain
6[ ] Buddhism
7[ ] No religion
8[ ] other, specify: _____
[religion_other] [varchar(50)]
9[ ] unknown/refuse

10. Lifestyle – Data is saved in "patient_life_style.csv" and is wide format

10.05	**Diet** (weekday/ routine day)	Meal 1	Meal 2	Meal 3	Meal 4	Meal 5	Meal 6
	Meal Time (approximate)	[meal1_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal2_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal3_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal4_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal5_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal6_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm
		[meal1_time] [varchar(5)]	[meal2_time] [varchar(5)]	[meal3_time] [varchar(5)]	[meal4_time] [varchar(5)]	[meal5_time] [varchar(5)]	[meal6_time] [varchar(5)]
	Type B=breakfast, L=lunch, D=dinner, S=snack	[meal1_type] [varchar(6)]	[meal2_type] [varchar(6)]	[meal3_type] [varchar(6)]	[meal4_type] [varchar(6)]	[meal5_type] [varchar(6)]	[meal6_type] [varchar(6)]

Commented [CR26]: Should specify [AM or PM]

Commented [CR27]: Should specify time of the meal

Commented [CR28]: Should specify type of meal i.e., B=breakfast, L=lunch, D=dinner, S=snack

10.02 Who decides the meal menu in the household? (check one)
[household_meal_menu] [varchar(10)] *[(Myself 1, other 2, shared (myself and other) 3)]*

[ ] Myself [ ] other (i.e. spouse, relative, hired cook) [ ] Shared (myself and other)

10.03 Who cooks the food in the household? (check one)
[household_cook_food] [varchar(10)] *[(Myself 1, other 2, shared (myself and other) 3)]*

[ ] Myself [ ] other (i.e. spouse, relative, hired cook) [ ] Shared (myself and other)

10.04	**Physical Activity (in leisure time) in average week**	*Days per week*	*Total time per day*	
			Hour(s)	*Minutes*
	Vigorous	[pa_vigorous_days_per_week] [int(11)]	[pa_vigorous_total_hr] [int(11)]	[pa_vigorous_total_min] [int(11)]
	Moderate	[pa_moderate_days_per_week] [int(11)]	[pa_moderate_total_hr] [int(11)]	[pa_moderate_total_min] [int(11)]
	Mild (Walking)	[pa_walking_days_per_week] [int(11)]	[pa_walking_total_hr] [int(11)]	[pa_walking_total_min] [int(11)]

10.05	Ever use tobacco [ever_use_tobacco] [int(11)] *[Yes=1; No=2]*	[ ] Y Continue below [ ] N Skip to 10.06

Commented [CR29]: If the response is[No 2] skip to Q.no.10.06

		Current regular use Y N	*Past regular use* Y N	*Number of years used*	*Current/past Average Quantity per day*
	Cigarette	[ ] [ ] [cigarette_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [cigarette_past_use] [int(11)] *[Yes=1; No=2]*	[cigarette_no_of_year] [int(11)]	[cigarette_qty_per_day] [int(11)]
	Beedi	[ ] [ ] [beedi_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [beedi_past_use] [int(11)] *[Yes=1; No=2]*	[beedi_no_of_year] [int(11)]	[beedi_qty_per_day] [int(11)]
	Cigar/Pipe	[ ] [ ] [cigar_pipe_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [cigar_pipe_past_use] [int(11)] *[Yes=1; No=2]*	[cigar_pipe_no_of_year] [int(11)]	[cigar_pipe_qty_per_day] [int(11)]
	chewing tobacco (in paan masala, paan, other mix)	[ ] [ ] [chewing_tobacco_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [chewing_tobacco_past_use] [int(11)] *[Yes=1; No=2]*	[chewing_tobacco_no_of_year] [int(11)]	[chewing_tobacco_qty_per_day] [int(11)]
	Other:	[ ] [ ] [other_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [other_past_use] [int(11)] *[Yes=1; No=2]*	[other_no_of_year] [int(11)]	[other_qty_per_day] [int(11)]

10.06	Ever drink alcohol [ever_drink_alcohol] [int(11)]	[ ] Y Continue below *[Yes=1; No=2]* [ ] N Skip to Section 11

Commented [CR30]: If the response is[No 2] skip to Q.no.11 (Selfcare)

	[ ]Y [ ]N	Currently drink alcohol once a week or more (for most weeks in past year) [currt_drink_alcohol] [int(11)] *[Yes=1; No=2]*
	[ ]Y [ ]N	Used to drink alcohol regularly in the past [drink_alcohol_regularly_past] [int(11)] *[Yes=1; No=2]*
	_____	Number of years of alcohol use [no_year_alcohol] [int(11)] [No data in this field]
	_____	Average days per week of alcohol use (current/past) [aveg_day_week_drink] [int(11)]
	_____	Average drinks per day (current/past) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [aveg_per_day_drink] [int(11)] [aveg_drink_wine_week] [int(11)] [aveg_drink_spirits_week] [aveg_drink_beer_week] {doubt in this 2 fields}
	_____	Most drinks in one day in past 3 months (0 if not currently drinking) [aveg_most_drink] [int(11)]

11. Self-Care - Data saved in "patient_self_care.csv" &"patient_selfcare_form_c.csv" and is in long format

The questions below ask you about your diabetes self-care activities **during the past 7 days**.

If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET		
11.01	**On average, over the past month, how many DAYS PER WEEK have you followed your diet plan?** [self_care_id=2] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.02	On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables? [self_care_id=3] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.03	On how many of the last SEVEN DAYS did you eat high fat foods such as fried items or full-fat dairy products? [self_care_id=4] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.04	On how many of the last SEVEN DAYS did you space eating meals evenly through the day? [self_care_id=5] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
EXERCISE		
11.05	**On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)** [self_care_id=6] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.06	On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work? [self_care_id=7] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
BLOOD SUGAR TESTING		
11.07	**Are you testing your blood sugar as recommended by your health care provider?** [self_care_id=9] [int(11)] *[Yes 1, No 0, N/A -1]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A (skip to 11.09)
11.08	On how many of the last SEVEN DAYS did you test your blood sugar? [self_care_id=8] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
MEDICATIONS		
11.09	**On how many of the last SEVEN DAYS, did you take your recommended diabetes medication? (pills and/or insulin)** [self_care_id=10] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
FOOT CARE		
11.10	On how many of the last SEVEN DAYS did you check your feet? [self_care_id=11] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
TOBACCO		
11.11	**Ever smoke regularly?** (most days of the week) [self_care_id=12] [int(11)] *[never 0, quit 1, Yes 2]* [if quit 1] → [quit_smoking_year] [varchar(20)] [if yes 2] → [smoke_per_day] [int(11)]	0 [ ] Never 1 [ ] Quit: __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # smoked per day: ___

Commented [CR31]: In Self-care section data is saved in 2 files 1. "patient_self_care.csv " & 2 ." patient_selfcare_form_c.csv and unique ID is "Self_care_id "

Commented [CR32]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day

11.12	**Ever chew tobacco regularly?** (most days of the week) [self_care_id=13] [int(11)] *[never 0, quit 1, Yes 2]* [if quit 1] → [quit_tobacco_year] [varchar(20)] [if yes 2] → [packet_per_day] [int(11)]	0 [ ] No 1 [ ] Quit __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # packets per day: ____
11.13	If you smoke or chew tobacco, at your last doctor's visit, did anyone counsel you about stopping or refer you to counseling? [self_care_id=14] [int(11)] *[N/A 0, yes 1, no 2]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A
ALCOHOL		
11.14	**Drink alcohol regularly?** (at least once a week for most weeks in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [self_care_id=15] [int(11)] *[never 0, yes 1]* [if yes 1] → [drink_per_day] [int(11)]	0 [ ] No 1 [ ] Yes, # drinks per day: ____
STRESS		
11.15	**How often do you feel stress (from work, responsibilities, etc)?** [ ] daily [ ] few times a week [ ] few times a month [ ] never [self_care_id=16] [int(11)] *[daily 1, few times a week 2, few times a month 3, never 4]*	
11.16	How are you coping with stress? [ ] very well [ ] moderate [ ] with difficulty [ ] not applicable (no stress) [self_care_id=17] [int(11)] *[very well 1, moderate 2, with difficulty 3, not applicable(no stress) 4]*	

Commented [CR33]: If the response is [quit 1] specify the year & response is [yes 2] specify no. packet per day

Commented [CR34]: If the response is [yes 1] specify no. drink per day

Commented [CR35]: Responses at backend for this variable are saved as [0 1 2 3 4]
but , there is no category for '0'

Commented [CR36]: Responses at backend for this variable are saved as [0 1 2 3 4]
but , there is no category for '0'

12. EQ-5D - Data saved in "eq_5d.csv" and is in wide format

Place a tick in one box in each group below for the statement that best describes your own health state today.

12.01 Mobility *[I have no problems in walking about 1, I have some problems in walking about 2,*
[mobility_id] [int (11)] *I am confined to bed 3]*

1 ☐ I have no problems in walking about
2 ☐ I have some problems in walking about
3 ☐ I am confined to bed

12.02 Self-Care *[I have no problems with self-care 1, I have some problems with self-care 2,*
[self_care_id] [int(11)] *I am unable to wash or dress myself 3]*

1 ☐ I have no problems with self-care
2 ☐ I have some problems with self-care
3 ☐ I am unable to wash or dress myself

12.03 Usual Activities (e.g. work, study, housework, family or leisure activities)
[usual_activities] [int(11)] *[I have no problems with performing my usual activities 1,*
I have some problems with performing my usual activities 2,
I am unable to perform my usual activities 3]

1 ☐ I have no problems with performing my usual activities
2 ☐ I have some problems with performing my usual activities
3 ☐ I am unable to perform my usual activities

12.04 Pain/Discomfort
[pain_discomfort] [int(11)] *[I have no pain or discomfort 1, I have moderate pain or discomfort 2,*
I have extreme pain or discomfort 3]

1 ☐ I have no pain or discomfort
2 ☐ I have moderate pain or discomfort
3 ☐ I have extreme pain or discomfort

12.05 Anxiety/Depression

[anxiety_depression] [int(11)] *[I am not worried or depressed 1, I am moderately anxious or depressed 2, I am extremely anxious or depressed 3]*

1 ☐ I am not worried or depressed

2 ☐ I am moderately anxious or depressed

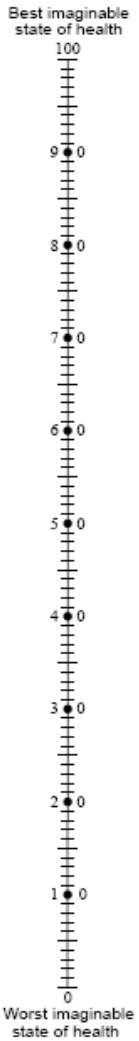
3 ☐ I am extremely anxious or depressed

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

I would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

12.06 Score: ___ ___ ___
[eq5d_score] [int(11)]

Your own health state today



13. Diabetes Treatment Satisfaction

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer each question by marking a number on every scale.

13.01 How satisfied are you with your current treatment?
[current_treatment] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.02 How often have you felt that your blood sugars have been unacceptability high recently?
[blood_sugar_high] [int] *[0, 1, 2, 3, 4, 5, 6]*

Most of the time — None of the time

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.03 How often have you felt that your blood sugars have been unacceptability low recently?
[blood_sugar_low] [int] *[0, 1, 2, 3, 4, 5, 6]*

Most of the time — None of the time

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.04 How convenient have been finding your treatment to be recently?
[convienent_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very convenient — Very inconvenient

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.05 How flexible have you been finding your treatment to be recently?
[flexible_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very flexible — Very inflexible

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.06 How satisfied are you with understanding of your diabetes?
[understand_dibetes] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.07 How satisfied would you be to continue with your present form of diabetes treatment?
[present_dib_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.08 Would you recommend this form of treatment to someone else?
[recommend_form] [int] *[0, 1, 2, 3, 4, 5, 6]*

Yes, I would definitely recommend this treatment — No, I would definitely NOT recommend this treatment

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

14. Health Utilities Index

This next questionnaire asks about aspects of your health. When answering these questions please think about your health and your ability to do things everyday in the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Focus your answers on your overall abilities, disabilities and how you felt during the past 4 weeks.

You may feel that some questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar, but please answer each question independently.

Please read each question and consider answers carefully. For each question, select one answer that best describes your level of ability or disability during the past 4 weeks. Select the answer by checking the box. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities/ feelings.

14.01. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint?

[ordinary_news_print] [int] *[1, 2, 3, 4]*

1☐ a. Able to see well enough without glasses or contact lenses
2☐ b. Able to see well enough with glasses or contact lenses
3☐ c. Unable to see well enough even with glasses or contact lenses
4☐ d. Unable to see at all

14.02. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street?

[recognize_friend] [int] *[1, 2, 3, 4]*

1☐ a. Able to see well enough without glasses or contact lenses
2☐ b. Able to see well enough with glasses or contact lenses
3☐ c. Unable to see well enough even with glasses or contact lenses
4☐ d. Unable to see at all

14.03. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people?

[group_conversation] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to hear what was said without a hearing aid
2☐ b. Able to hear what was said with a hearing aid
3☐ c. Unable to hear what was said even with a hearing aid.
4☐ d. Unable to hear what was said, but did not wear a hearing aid
5☐ e. Unable to hear at all

14.04. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a quiet room?

[other_person_conversation] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to hear what was said without a hearing aid
2☐ b. Able to hear what was said with a hearing aid
3☐ c. Unable to hear what was said even with a hearing aid
4☐ d. Unable to hear what was said, but did not wear a hearing aid
5☐ e. Unable to hear at all

14.05. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you?

[un_own_langauge] [int] *[1, 2, 3, 4]*

1☐ a. Able to be understood completely
2☐ b. Able to be understood partially
3☐ c. Unable to be understood
4☐ d. Unable to speak at all

14.06. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well?

[un_other_langauge] [int] *[1, 2, 3, 4]*

1☐ a. Able to be understood completely.
2☐ b. Able to be understood partially.
3☐ c. Unable to be understood.
4☐ d. Unable to speak at all.

14.07. Which one of the following best describes how you have been feeling during the past 4 weeks?

[feeling] [int] *[1, 2, 3, 4, 5]*

1☐ a. Happy and interested in life
2☐ b. somewhat happy
3☐ c. somewhat unhappy
4☐ d. Very unhappy
5☐ e. So unhappy that life was not worthwhile

14.08. Which one of the following best describes the pain and discomfort you have experienced during the past 4 weeks?

[discomfort_exp] [int] *[1, 2, 3, 4, 5]*

1☐ a. Free of pain and discomfort
2☐ b. Mild to moderate pain or discomfort that prevented no activities.
3☐ c. Moderate pain or discomfort that prevented a few activities
4☐ d. Moderate to severe pain or discomfort that prevented some activities
5☐ e. Severe pain or discomfort that prevented most activities

14.09. Which one of the following best describes your ability, during the past 4 weeks, to walk? (Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches, or a walker.)

[to_walk] [int] *[1, 2, 3, 4, 5, 6]*

1☐ a. Able to walk around the neighborhood without difficulty, and without walking equipment
2☐ b. Able to walk around the neighborhood with difficulty; but did not require walking equipment or the help of another person
3☐ c. Able to walk around the neighborhood with walking equipment, but without the help of another person
4☐ d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood
5☐ e. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood
6☐ f. Unable to walk at all

14.10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers? (Note: Special tools refer to hooks for buttoning clothes, gripping devices for opening jar or lifting small items, and other devices to compensate for limitations of hand or fingers.)

[hands_finger] [int] *[1, 2, 3, 4, 5, 6]*

1☐ a. Full use of hands and ten fingers
2☐ b. Limitations in the use of hand or fingers, but did not require special tools or the help of another person
3☐ c. Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person)
4☐ d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools)
5☐ e. Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools)
6☐ f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)

14.11. Which one of the following best describes your ability, during the past 4 weeks, to remember things?

[remember_things] [int] *[1, 2, 3, 4]*

1☐ a. Able to remember most things
2☐ b. Somewhat forgetful
3☐ c. Very forgetful
4☐ d. Unable to remember anything at all

14.12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems?

[think_solve] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to think clearly and solve day to day problems
2☐ b. Had a little difficulty when trying to think and solve day to day problems
3☐ c. Had some difficulty when trying to think and solve day to day problems
4☐ d. Had great difficulty when trying to think and solve day to day problems
5☐ e. Unable to think or solve day to day problems

14.13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities?

[basic_activity] [int] *[1, 2, 3, 4]*

1☐ a. Eat, bathe, dress and use the toilet normally
2☐ b. Eat, bathe, dress and use the toilet independently with difficulty
3☐ c. Required mechanical equipment to eat, bathe, dress or use the toilet independently
4☐ d. Required the help or another person to eat, bathe, dress or use the toilet

14.14. Which one of the following best describes how you have been feeling during the past 4 weeks?

[feeling_health_utility] [int] *[1, 2, 3, 4]*

1☐ a. Generally happy and free from worry
2☐ b. occasionally fretful, angry, irritable, anxious or depressed
3☐ c. often fretful, angry, irritable, anxious or depressed
4☐ d. extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help

14.15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks?

[discomfort_health_utility] [int] *[1, 2, 3, 4, 5]*

1☐ a. Free of pain and discomfort
2☐ b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities
3☐ c. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities
4☐ d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief
5☐ e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities

15. Processes of Care

In the past 12 months, how often did the following occur (EXCLUDE current visit):

		Indicate number	Month of last visit/test/exam (MMM/yyyy)	
15.01	Clinic Visits [fpc_clinic_visit_indicate_no] [int(11)] [fpc_clinic_visit_month_of_visit] [varchar(15)] [fpc_clinic_visit_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.02	HbA1c testing [fpc_hba_testing_indicate_no] [int(11)] [fpc_hba_testing_month_of_visit] [varchar(15)] [fpc_hba_testing_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.03	Cholesterol Testing [fpc_cholestrol_testing_indicate_no] [int(11)] [fpc_cholestrol_testing_month_of_visit] [varchar(15)] [fpc_cholestrol_testing_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.04	Foot Exam at clinic [fpc_foot_exam_indicate_no] [int(11)] [fpc_foot_exam_month_of_visit] [varchar(15)] [fpc_foot_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.05	Eye Exam [fpc_eye_exam_indicate_no] [int(11)] [fpc_eye_exam_month_of_visit] [varchar(15)] [fpc_eye_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown

Commented [CR37]: For Q.Nos. 15.01 – 15.09 , specify Indicate number, Month of last visit & unknown
If response is [unknown] data is saved as '-1'

15.06	Microalbuminuria check [fpc_microal_check_indicate_no] [int(11)] [fpc_microal_check_month_of_visit] [varchar(15)] [fpc_microal_check_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.07	ECG [fpc_ecg_indicate_no] [int(11)] [fpc_ecg_month_of_visit] [varchar(15)] [fpc_ecg_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.08	Dental Exam [fpc_dental_exam_indicate_no] [int(11)] [fpc_dental_exam_month_of_visit] [varchar(15)] [fpc_dental_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.09	Dietician/Diabetes Education [fpc_dietician_visit_indicate_no] [int(11)] [fpc_dietician_visit_month_of_visit] [varchar(15)] [fpc_dietician_visit_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown

15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care? ____
[other_doctors_count] [int(11)]

On average:

15.11 Total time spend commuting to clinic – ONE WAY _____ min
[time_commuting] [int(11)]

15.12 Total time spend for lab tests, include waiting (if done same day) _____ min
[lab_test] [int(11)]

15.13 Total time spend waitingfor consultation _____ min
[wait_consult] [int(11)]

15.14 Total time spend in-person with doctor _____ min
[in_person_doc] [int(11)]

15.15 Total time with dietician, nurse or clinic-staff receiving self-care education _____ min
[self_care_edu] [int(11)]

15.16 Other time for check-out, getting medications, etc (at end of visit) _____ min
[other_time] [int(11)]

15.17 What type of reminders do you receive from the clinic for your care? (check all that apply)
[type_of_reminder] [varchar (20)]

1 [ ] Verbal reminder for next visit, referral, or lab investigation (at current visit)
2 [ ] Written reminder for next visit, referral or lab investigation (at current visit)
3 [ ] Phone call for upcoming appointment (clinic or referral)
4 [ ] Phone call if missed appointment (clinic or referral)
5 [ ] Phone call to go for lab investigations
6 [ ] Mailing for upcoming appointment (clinic or referral)
7 [ ] Mailing for missed appointment (clinic or referral)
8 [ ] Mailing to go for lab investigations
9 [ ] other, specify: _____
[other_reminder] [varchar (20)]

16. Costs of Care

16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR:

Outpatient visits? Inpatient care?

_____% Out-of-pocket _____% Out-of-pocket

[out_of_pocket_opd] [double]
_____% Employer Insurance
[employer_insurance_opd] [double]
_____% Private Insurance
[private_insurance_opd] [double]
_____% Government insurance, non-job based
[govt_insurance_opd] [double]
_____% Other, please specify: _____
[other_opd] [double]
[other_details_opd] [varchar(200)]
= 100 % total

[out_of_pocket_ipd] [double]
_____% Employer Insurance
[employer_insurance_ipd] [double]
_____% Private Insurance
[private_insurance_ipd] [double]
_____% Government insurance, non-job based
[govt_insurance_ipd] [double]
_____% Other, please specify: _____
[other_ipd] [double]
[other_details_ipd] [varchar(200)]
=100 % total

OUTPATIENT CARE

Please respond to the following questions regarding outpatient care you received for diabetes in the previous 1 year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization.
EXCLUDE current visit.

16.02 How many outpatient visits did you make in the past 1 year (exclude current visit)? _____ times
[out_patient_visit] [int(11)]

16.03 How many days, including half days, did you miss from work for outpatient visits in the past 1 year? _____ days [ ] N/A
[days_miss_work] [int(11)]
[days_miss_work_na] [int(11)] *[1]*

16.04 List all persons who accompanied you to outpatient visits in the past 1 year:
This data is in file "patient_accompained _visit" & is in long format

Person Relation (e.g. father) [person_relation]	Occupation (number*) [occupation]	Monthly salary [monthly_salary]	Number visits accompanied [number_of_visit]

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

Please list the costs incurred in the past year in relation to outpatient visits:

	Item	Number of times	Average cost One-time (Rupees)
16.05	Consultation Fee [con_fee_frq] [int(11)] [avg_con_fee] [double]		
16.06	Lab Tests (HbA1c, blood glucose, urine check) [lab_test_frq] [int(11)] [avg_lab_test] [double]		
16.05	Eye Exam [eye_eam_frq] [int(11)] [avg_eye_exam] [double]		
16.06	ECG [ecg_frq] [int(11)] [avg_ecg_fee] [double]		
16.07	Medicines (tablets, insulin) [med_frq] [int(11)] [avg_med_fee] [double]		

Commented [CR38]: One more variable available for questions 16.05 to 16.12 "Total cost" and values also stored for this variable

16.08	Supplies (including glucose strips, gauze, sterile solution, etc.) [supply_frq] [int(11)] [avg_supply_fee] [double]		
16.09	Transportation [transport_frq] [int(11)] [avg_transport] [double]		
16.10	Food (personal) [food_personal_frq] [int(11)] [avg_food_personal] [double]		
16.11	Additional cost for escort(s) (e.g. food) [escorts_freq] [int(11)] [avg_escorts] [double]		
16.12	Other out-of-pocket expenses [outpocket_frq] [int(11)] [avg_outpocket_exp] [double]		

INPATIENT CARE

Please respond to the following questions regarding inpatient care you received FOR DIABETES-RELATED COMPLICATIONS* in the previous 1 year. Inpatient care is all instances of medical care that required you to stay in hospital or emergency room.

*chest pain, heart attack, stroke, infection, foot/leg problems, eye problems, kidney problems, blood sugar problem (too high/too low), etc. IF unsure that event is a diabetes-related complication, INCLUDE in listing.

16.13 How many Hospitalizations or Emergency Room visits for diabetes-related complications in the past 1 year? _____ times
[hospital_emergency] [int(11)]

16.14 For each of these Hospitalization or Emergency Room Visit, provide details below – (Make sure that visits listed below equals total number listed in 16.13)
When providing time, include half-days. This data is in file "patient_hospitalization_visit" & is in long format

	TYPE 1= Hospitalization, NO surgery 2= Surgery 3= Emergency Room [reason]	Days of stay [duration]	Hospital Cost including medicine/ supplies (total stay) **[hospital_cost]**	Transportation Cost, including ambulance fees (total stay) **[transport]**	Food Cost **[food_cost]**	Additional Escort(s) Cost **[escorts_cost]**	Person(s) accompanied (Escort) – list all			
							Relation **[person_accompained]**	Occupation (number*) **[occupation]**	Monthly Salary **[monthly_salary]**	Days accompanied **[days_person_accompained]**
1										
2										
3										
4										

5										
6										

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

17. Other Contacts

This data is confidential

Please list 2 contacts who do not live with you and would know where and how we can contact you.

***mandatory fields**

17.01	**Contact 1**
Name	First:*
	Middle:
	Last:*
Mailing Address	Address 1:*
	Address 2:
	City:*
	Pin code:* __ __ __ __ __ __
	State:*
Mobile*	91 - __ __ __ __ __ __ __ __ __ __
Phone 2	_____ - _____
Email ID	
Relation (e.g. father, friend) *	

17.02	**Contact 2**
Name	First:*
	Middle:
	Last:*
Mailing Address	Address 1:*
	Address 2:
	City:*
	Pin code:* __ __ __ __ __ __
	State:*
Mobile*	91 - __ __ __ __ __ __ __ __ __ __
Phone 2	_____ - _____
Email ID	
Relation (e.g. father, friend) *	

18. Care Coordinator/Research Officer Signature

18.01 Name: _____ Signature: _____

18.02 Date Signed: __ __ / __ __ __ / __ __ __ __

18.03 DSS Instructions:

(1) Enroll patient in DSS → Login. Select **Enroll patient** from left panel. Enter information and click on **Enroll** at bottom of page.

(2) Enter rest of Forms B and Form C in eCRFs found on patient main page.

FORM I.c – Intermediate Visit_Control
CARRS Translation Trial
Research Officer

Participant ID: __ __ __ __ __
[participant_id] [varchar(20)]
Participant Initials: _____
Date of Visit (dd/MMM/yyyy): __ __ / __ __ __ / __ __ __ __
[dateofvisit] [date]

Form I.c – Data is saved in the file **"patient_form_ic.csv"** and is in wide format

Data entry by:
[dataentry_by] [varchar(50)]
Initials _____
DATE entered:
___ /_____ /_____
[dateenter] [date]

- All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)**
- Place cross [X] in the appropriate boxes. Write number in spaces (f none, write 0)
- See *Form Completion Notes*, for definitions and explanations
- Store copies of available source documents (SD), where indicated, in patient's trial folder
- The Research Officer may only obtain information AFTER participant visit, from the visit records. Fill out all information that is **applicable/available. Indicate NAV if not available.**

1.01	Reason for Visit	1 [ ] Routine	2 [ ] Other	3 [ ] NAV
1.02	Mark [X] for all measures, investigations, or exams done at this visit. Include values if available.	1 [ ] heart rate [is_heart_rate] [varchar(10)] *[on]*	_____ (beats/min) [heart_rate] [int(11)]	
		2 [ ] blood pressure [is_blood_pressure] [varchar(10)] *[on]*	__ __ __ / __ __(mmHg) [blood_pressure_h_avg] / [blood_pressure_l_avg] [int(11)] [int(11)]	
		3 [ ] weight [is_weight] [varchar(10)] *[on]*	_____ (kg) [weight] [double]	
		4 [ ] HbA1c [is_hba1c] [varchar(10)] *[on]*	____ . __ % [hemoglobin_a1c] [double]	
		5 [ ] Fasting blood glucose (venous) [is_fbg] [varchar(10)] *[on]*	_____ [fasting_blood_glucose] [double]	
		6 [ ] Post-prandial blood glucose (venous) [is_ppbg] [varchar(10)] *[on]*	_____ (mg/dL) [post_prandial_blood_glu] [double]	
		7 [ ] Random blood glucose (capillary) [is_pbg] [varchar(10)] *[on]*	_____ (mg/dL) [random_blood_glucose] [double]	
		8 [ ] Sodium [is_sodium] [varchar(10)] *[on]*	_____ (mEq/L) [sodium] [double]	
		9 [ ] Potassium [is_potassium] [varchar(10)] *[on]*	_____ (mEq/L) [potassium] [double]	
		10 [ ] Total cholesterol [is_total_cholesterol] [varchar(10)] *[on]*	_____ (mg/dL) [total_cholesterol] [double]	
		11 [ ] HDL cholesterol [is_hdl_cholesterol] [varchar(10)] *[on]*	_____ (mg/dL) [hdl_cholesterol] [double]	
		12 [ ] LDL cholesterol [is_ldl_cholesterol] [varchar(10)] *[on]*	_____ (mg/dL) [ldl_cholesterol] [double]	
		13 [ ] Triglycerides [is_tryglycerides] [varchar(10)] *[on]*	_____ (mg/dL) [triglycerides] [double]	
		14 [ ] Creatinine (serum) [is_creatinine] [varchar(10)] *[on]*	_____ (mg/dL) [creatinine_mg] [double]	
		15 [ ] Urine microalbuminuria [is_albuminuria] [varchar(10)] *[on]*	_____ (mg/L) [albuminuria] [double]	
		16 [ ] Urine albumin:creatinine ratio [is_albumin_mg] [varchar(10)] *[on]*	_____(mg/g) [s_albumin_mg] [double]	
		17 [ ] Other blood test, specify: [is_other_blood_test] [varchar(10)] *[on]*	[other_blood_test] [varchar(100)]	
		18 [ ] ECG [is_ecg] [varchar(10)] *[on]*	[ecg] [varchar(20)]	
		19 [ ] Foot exam (monofilament) [is_foot_exam] [varchar(10)] *[on]*		
		20 [ ] Biothesiometry [is_biothesimetry] [varchar(10)] *[on]*		
		21 [ ] Ankle Brachial Index [is_ankle_brachaial] [varchar(10)] *[on]*		
		22 [ ] Eye Exam (fundoscopy/visual acuity) [is_eye_exam] [varchar(10)] *[on]*		
		23 [ ] Other Exam, specify:		

Commented [CR1]: No data is saved in this field

Commented [CR2]: If we select the response to the question 1.02 (1-23) it is saved as "on" otherwise "blank"

Commented [CR3]: No data is saved in this field

		[is_other_exam] [varchar(10)] *[on]*	[other_exam] [varchar(100)]
1.03	Mark [X] all details of management plan at this visit	1 [ ] Change in medications for diabetes, BP, lipid-lowering, or blood-thinner [change_med_yes] [varchar(10)] *[yes, no]* 2 [ ] Dietician/Educator Counseling [dietician_edu] [varchar(10)] *[yes, no]* 3 [ ] Eye Exam Referral [ophtmology] [varchar(10)] *[yes, no]* 4 [ ] Podiatry Referral [podiatry] [varchar(10)] *[yes, no]* 5 [ ] Further lab tests today [lab_test] *[yes, no]* 6 [ ] Lab tests for next visit specified [other_two] [varchar(10)] *[yes, no]* 7 [ ] Date of next visit specified. [other_visit] [varchar(10)] If yes, in _____ months [yes_lab_test] [varchar(10)] 8 [ ] Other referral/testing, [other_one] [varchar(10)] *[yes, no]* If yes, specify: _____ [yes_other_one] [varchar(10)]	
1.05	Other visit details		

2. Signature of Research Officer

2.01 Name: _____ Signature: _____

2.02 Date Signed: __ __ / __ __ __ / __ __ __ __

If necessary, update Form G-Eye Exam in Form C (Baseline_Randomization) or Form E (Follow-up 12 monthly_All). Enter this Form I.c into eCRF. Include visit note and any other investigation reports as source documents in participant trial folder.

*Definition of all the serious adverse events/ and adverse events are included in the Manual of Procedures.

List of Serious Adverse Events

[Please note - SAE has to be recorded using separate event sub-forms and should be submitted to the IRB and sponsors in expedited manner] *Detailed information on reporting timelines are provided in Manual of Procedures.

1. Severe hypoglycemia requiring medical attention/hospitalization (a hypoglycemic episode associated with transient central nervous system dysfunction without other apparent cause in which the individual was unable to treat him/herself and had help from another person to administer glucose or glucagon)
2. Acute hyperglycemia (e.g. Diabetic Keto Acidosis)
3. CVD events: Angina, non-fatal MI / Unstable Angina (ACS), revascularization procedure [angioplasty or CABG], TIA, Stroke (non-fatal), Arrhythmia
4. Gangrene or amputation due to diabetes-related peripheral neuropathy and peripheral vascular disease
5. Major bleeding (e.g. intracerebral or gastro-intestinal)
6. Renal: end-stage renal disease requiring renal replacement therapy (dialysis or transplantation)
7. Eyes: severe diabetes-related eye disease (defined as the requirement for retinal photocoagulation or similar treatment and development of diabetes-related blindness in either eye in a participant known not to have this condition at study entry)
8. Major infection: requiring hospitalization and/or parenteral antibiotics (UTI, skin infections, soft tissue infections, lower respiratory tract infections/physician-diagnosed pneumonia)
9. Inpatient hospitalization or prolongation of existing hospitalization
10. Death
11. Any other major health conditions/events (important medical event based upon appropriate medical judgment)

List of Adverse Events

[Please Note - Reporting of these events is covered in the regular CRF's / visits]:

1. Mild hypoglycemia not requiring medical attention
2. Side-effects of medications (e.g. *hepatic dysfunction or myopathy due to statins; dry cough due to ACE-I; negative effects of drugs on biochemical parameters such as hypo- or hyper- kalemia, hyperuricemia; and others per Investigator discretion)*
3. *PVD: intermittent claudication, rest pain*
4. *Allergic reactions/reactions on basis of drug interactions*
5. *Infection (UTI, skin infections, soft tissue infections, lower respiratory tract infections/physician-diagnosed pneumonia)*
6. *Weight gain*

Form X - Data saved in dataset as "form_x_patient.csv" and is in long format

Form X: Serious Adverse Event (pg 1 of 2)

Site/Clinic: _____ **Site No.** **Participant No.** **Participant ID:** | _ _ | _ _ _ | **Participant Initials:** __ __

[participant_id] [varchar (20)] [participant_initial]

1. Date of onset: _____
   [date_onset] [date]
2. Specify event: _____
   [specific_event] [varchar(20)] *[Death (Please complete subFORM 1) 1, Transient Ischemic Attack 2, Ischemic stroke 3, Intracerebral hemorrhage (ICH) 4, Stable Angina 5, ACS: Unstable Angina OR Myocardial Infarction 6, Arrhythmia 7, Gastrointestinal bleeding 8, Eye diseases – Diabetic Retinopathy 9, Infections 10, Renal failure 11, Revascularization / other surgical procedures 12, other major health condition requiring hospitalization 13]*

☐☐ Death (Please complete subFORM 1)
☐☐ Transient Ischemic Attack
☐☐ Ischemic stroke
☐☐ Intracerebral hemorrhage (ICH)
☐☐ Stable Angina
☐☐ ACS: Unstable Angina OR Myocardial Infarction (complete subFORM 2)
☐☐ Arrhythmia
☐☐ Gastrointestinal bleeding
☐☐ Eye diseases – Diabetic Retinopathy
☐☐ Infections
☐☐ Renal failure (complete subFORM 3)
☐☐ Revascularization / other surgical procedures (complete subFORM 4)
☐☐ Other major health condition requiring hospitalization (complete subFORM 5)

3. Prior (pre-enrollment) history of this event? ☐Yes ☐No
   [prior_history] [int(11)] *[Yes 1, No 2]*
4. Was event unexpected? ☐Yes ☐No
   [event_unexpected] [int(11)] *[Yes 1, No 2]*
5. Related to study intervention?
   [study_intervention] [int(11)] *[No 1, Unlikely 2, possibly 3, Probably 4, Definitely 5, Unknown 6]*
   ☐No
   ☐☐ Unlikely
   ☐☐ Possibly
   ☐☐ Probably
   ☐☐ Definitely
   ☐☐ Unknown

If SAE is unexpected (#4) and *possibly, probably, or definitely* related to study intervention (#5), then immediately call the RCC

Narrative for study intervention related to event:
[narrative_study] [text]

6. Severity:

[severity] [int(11)] *[Mild 1, Moderate 2, Severe 3, Life-threatening/fatal 4]*

☐☐ Mild
☐☐ Moderate
☐☐ Severe
☐☐ Lifethreatening/fatal

7. Was event serious (i.e. an SAE)? ☐Yes ☐No

[event_serious] [int(11)] *[Yes 1, No 2]*

If "Yes," Action Taken:

a. Medical therapy ☐Yes ☐No

[medical_therapy] [int(11)] *[Yes 1, No 2]*

b. Hospitalization (new/prolonged) ☐Yes ☐No

[hospitalization] [int(11)] *[Yes 1, No 2]*

If "Yes" Admission date: _____

[admission_date] [date]

Discharge date: _____

[dischagre_date] [date]

c. Surgery ☐Yes ☐No

[surgery] [int(11)] *[Yes 1, No 2]*

d. Transfusion ☐Yes ☐No

[transfustion] [int(11)] *[Yes 1, No 2]*

e. Interruption of study intervention ☐Yes ☐No

[interruption] [int(11)] *[Yes 1, No 2]*

If "Yes" ☐Temporary ☐Permanent

[interuption_type] [int(11)] *[Temporary 1, Permanent 2]*

8. Outcome of event:

[outcom_of_event] [int(11)] *[Ongoing 1, Resolved 2, Resolved with Sequelae 3, Death 4]*

☐☐Ongoing

☐☐Resolved, Resolution date: |__|__| / |__|__|__| / |__|__|__|__|

[If Resolved 2] → [resolution_date] [date]

☐☐Resolved with Sequelae, Resolution date: |__|__| / |__|__|__| / |__|__|__|__|

[resolution_sequel_date] Sequelae: _____

[If Resolved with Sequelae 3] → [sequalae] [varchar(50)]

☐☐Death, Date of death: |__|__| / |__|__|__| / |__|__|__|__|

[If Death 4] → [date_of_death] [date]

Proximate cause of death: _____

[If Death 4] → [cause_of_death] [varchar(50)]

Person Completing Report _____ Date Completed: _ _/_ _ _/_ _ _ _
Last name First name

Signature of Investigator: _____

Data entered by: | _ _ | initials Date entered: | _ _ | _ _ _ | _ _ _ _ |

Commented [CR1]: If the response is [Yes 1] specify admission date & discharge date

Commented [CR2]: If the response is [Yes 1] specify "Temporary 1" or "Permanent 2"

Commented [CR3]: If the response is [Resolved 2] specify resolution date

subForm 1: Death (pg 1 of 2)

Site No. Participant No.

Site/Clinic: _____ **Participant ID:** | _ _ | _ _ _ | **Participant Initials:** __ __

Date of death: _ _/_ _ _/_ _ _ _ (dd/MMM/yyyy) [death_date] [date]

1. Chronology of death:

[chronology_death] [int(11)] *[Not a sudden or unobserved death 1, Sudden unexpected death within 60 minutes of onset of symptoms or unobserved death within 60 minutes of being seen alive without 2, Sudden unexpected death between 1 and 24 hours of onset of symptoms 3, Unobserved death between one and 24 hours of being seen alive without symptoms 4, Unobserved death more than 24 hours of being seen alive without symptoms 5, Unknown 6]*

☐☐ Not a sudden or unobserved death
☐☐ Sudden unexpected death within 60 minutes of onset of symptoms or unobserved death within 60 minutes of being seen alive without
☐☐ Sudden unexpected death between 1 and 24 hours of onset of symptoms
☐☐ Unobserved death between one and 24 hours of being seen alive without symptoms
☐☐ Unobserved death more than 24 hours of being seen alive without symptoms
☐☐ Unknown

2. Immediate cause of death:

[immediate_cause_death] [int(11)] *[MI 1, Stroke 2, ICH 3, Worsening CHF 4, Arrythmia 5, Cardiac rupture 6, Cardiac tamponade 7, Sudden unexplained cardiovascular 8, Aortic aneurysm 9, Cardiac surgery 10, Other cardiovascular 11, Accidental 12, Pulmonary embolism 13, Non-embolic respiratory disease 14, Renal failure 15, Hepatic failure 16, Malignancy 17, Infection 18, Non-ICH hemorrhage 19, Other non-cardiovascular 20, Unknown 21]*

☐☐ MI
☐☐ Stroke
☐☐ ICH
☐☐ Worsening CHF
☐☐ Arrythmia
☐☐ Cardiac rupture
☐☐ Cardiac tamponade
☐☐ Sudden unexplained cardiovascular
☐☐ Aortic aneurysm
☐☐ Cardiac surgery
☐☐ Other cardiovascular
☐☐ Accidental
☐☐ Pulmonary embolism
☐☐ Non-embolic respiratory disease
☐☐ Renal failure
☐☐ Hepatic failure
☐☐ Malignancy
☐☐ Infection
☐☐ Non-ICH hemorrhage
☐☐ Other non-cardiovascular
☐☐ Unknown

subForm 1: Death (pg 2 of 2)

2. Primary underlying cause of death:
   [pri_cause_death] [int(11)] *[MI 1, Stroke 2, ICH 3, Worsening CHF 4, Arrythmia 5, Cardiac rupture 6, Cardiac tamponade 7, Sudden unexplained cardiovascular 8, Aortic aneurysm 9, Cardiac surgery 10, Other cardiovascular 11, Accidental 12, Pulmonary embolism 13, Non-embolic respiratory disease 14, Renal failure 15, Hepatic failure 16, Malignancy 17, Infection 18, Non-ICH hemorrhage 19, Other non-cardiovascular 20, Unknown 21]*
   - ☐☐ MI
   - ☐☐ Stroke
   - ☐☐ ICH
   - ☐☐ Worsening CHF
   - ☐☐ Arrythmia
   - ☐☐ Cardiac rupture
   - ☐☐ Cardiac tamponade
   - ☐☐ Sudden unexplained cardiovascular
   - ☐☐ Aortic aneurysm
   - ☐☐ Cardiac surgery
   - ☐☐ Other cardiovascular
   - ☐☐ Accidental
   - ☐☐ Pulmonary embolism
   - ☐☐ Non-embolic respiratory disease
   - ☐☐ Renal failure
   - ☐☐ Hepatic failure
   - ☐☐ Malignancy
   - ☐☐ Infection
   - ☐☐ Non-ICH hemorrhage
   - ☐☐ Other non-cardiovascular
   - ☐☐ Unknown

3. At onset of fatal event, patient was in:
   [fatal_event] [int(11)] *[Hospital for CHF 1, Hospital for other reason 2, Nursing home 3, Home 4, Rehabilitation center 5, Other 6, Unknown 7]*

   - ☐☐ Hospital for CHF
   - ☐☐ Hospital for other reason
   - ☐☐ Nursing home
   - ☐☐ Home
   - ☐☐ Rehabilitation center
   - ☐☐ Other
   - ☐☐ Unknown

Person Completing Report _____ Date Completed: _ _/_ _ _/_ _ _ _
Last name First name

Signature of Investigator: _____

Data entered by: | _ _ | initials Date entered: | _ _ | _ _ _ | _ _ _ _ |

subFORM 2: Acute Coronary Syndrome Event (MI/Unstable Angina) (pg 1 of 2)

Site/Clinic: _____ **Site No.** **Participant No.** **Participant ID:** | _ _ | _ _ _ | **Participant Initials:** __ __

Date: _ _/_ _ _ /_ _ _ _ (dd/MMM/yyyy)

Narrative Summary: [narrative_summary] [text]

FROM ECG Reading:

1. Heart rate: _____bpm
   [heart_rate] [double]

2. Rhythm:
   a. Sinus: ☐Yes ☐No
      [sinus] [int(11)] *[Yes 1, No 2]*
   b. Atrial fibrillation: ☐Yes ☐No
      [atrial] [int(11)] *[Yes 1, No 2]*
   c. Atrial flutter: ☐Yes ☐No
      [atrial_flutter] [int(11)] *[Yes 1, No 2]*
   d. Paced: ☐Yes ☐No
      [paced] [int(11)] *[Yes 1, No 2]*

3. PVC: ☐Yes ☐No
   [pvc] [int(11)] *[Yes 1, No 2]*
4. LVH: ☐Yes ☐No
   [lvh] [int(11)] *[Yes 1, No 2]*

5. QRS <110 msec: ☐Yes ☐No
   a. RBBB: ☐Yes ☐No
      [rbbb] [int(11)] *[Yes 1, No 2]*
   b. LBBB: ☐Yes ☐No
      [lbbb] [int(11)] *[Yes 1, No 2]*
   c. IVCD: ☐Yes ☐No
      [ivcd] [int(11)] *[Yes 1, No 2]*

6. Q Waves: ☐Yes ☐No

   a. I, aVL: ☐Yes ☐No
      [qwave_a] [int(11)] *[Yes 1, No 2]*
   b. II, III, aVF: ☐Yes ☐No
      [qwave_b] [int(11)] *[Yes 1, No 2]*
   c. V^1 - V^4 : ☐Yes ☐No
      [qwave_c] [int(11)] *[Yes 1, No 2]*
   d. V^5 - V^6 : ☐Yes ☐No
      [qwave_d] [int(11)] *[Yes 1, No 2]*

subFORM 2: Acute Coronary Syndrome Event (MI/Unstable Angina) (pg 2 of 2)

7. Were enzymes drawn? ☐Yes ☐No
[enzymes] [int(11)] *[Yes 1, No 2]*

If "Yes":

CK Total Value: _____
[ck_toal_value] [double]
Lab upper normal: _____ Date drawn: _ _/_ _ _/_ _ _ _
[ck_lab_upper] [double] [ck_lba_date] [date]

CK MB Value: ☐☐ % ☐☐Units
[ck_mb_value] [int(11)]
Lab upper normal: _____ Date drawn: _ _/_ _ _/_ _ _ _
[ck_mb_lab_upper] [double] [ck_lba_date] [date]

Troponin T Units Used (check following):
[troponin_t] [int(11)] *[Positive 1, Negative 2, Numeric 3]*
☐Positive
☐Negative
☐Numeric, Value: _____
[troponin_t_value] [double]
Lab upper normal: _____ Date drawn: _ _/_ _ _/_ _ _ _
[troponin_t_upper] [double] [troponin_t_upper_date] [date]

Troponin I Units Used (check following):
[troponin_i] [int(11)] *[Positive 1, Negative 2, Numeric 3]*
☐Positive
☐Negative
☐Numeric, Value: _____
[troponin_i_value] [double]
Lab upper normal: _____ Date drawn: _ _/_ _ _/_ _ _ _
[troponin_i_upper] [double] [troponin_i_upper_date] [date]

Comments:
[comment] [text]

Person Completing Report _____ Date Completed: _ _/_ _ _/_ _ _ _
Last name First name

Signature of Investigator: _____

Data entered by: | _ _ | initials Date entered: | _ _ | _ _ _ | _ _ _ _ |

subFORM 3: Renal Failure Event (pg 1 of 1)

Site/Clinic: _____ **Site No.** **Participant No.** **Participant ID:** | _ _ | _ _ _ | **Participant Initials:** __ __

Date and Time of Onset of Symptoms: _ _/_ _ _/_ _ _ _; _ _:_ _ (24 hours clock)
[onset_sym_date]

Complete this form if the participant has renal failure requiring dialysis.

1. Was the patient hospitalized? ☐Yes ☐No
[patient_hospitalize] [int(11)] *[Yes 1, No 2]*
[if Yes 1] →
☐☐ → ☐☐Physician's Office ☐☐Emergency Room ☐☐Other: _____
[hospitalization_type] [int(11)] *[Physician's Office 1, Emergency Room 2, Other 3]*
_ _/_ _ _ /_ _ _ _ (Date of Hospitalization)
[hospitalization_date] [date]
_ _/_ _ _ / _ _ _ _ (Date of Discharge)
[hospitalization_dis_date] [date]

2. Did the participant require any of the following:

	No	Yes
Hemo dialysis [hemo_dialysis] [int(11)] *[Yes 1, No 2]*	☐	☐
Peritoneal dialysis [peritoneal_dialysis] [int(11)] *[Yes 1, No 2]*	☐	☐
Continuous hemofiltration/ Dialysis [conti_dialysis] [int(11)] *[Yes 1, No 2]*	☐	☐
Renal transplant [retal_transplant] [int(11)] *[Yes 1, No 2]*	☐	☐

3. Serum Creatinine (highest level before any dialysis) ☐mg/ dL
[serum_creatinine_mg] double]

4. Date of first dialysis (if applicable): _ _/_ _ _/_ _ _ _ (dd/MMM/yyyy)
[first_dialysis] [date]

Person Completing Report _____ Date Completed: _ _/_ _ _/_ _ _ _
Last name First name

Signature of Investigator: _____

Data entered by: | _ _ | initials Date entered: | _ _ | _ _ _ | _ _ _ _ |

subFORM 4: Surgical Procedures (pg 1 of 1)

Site/Clinic: _____ **Site No.** **Participant No.** **Participant ID:** | _ _ | _ _ _ | **Participant Initials:** __ __

Person Completing Report _____ Date Completed: _ _/_ _ _ /_ _ _ _

Surgical Intervention Procedures

1. **Procedure** _____
   [p_procedure] [varchar(50)]

2. **Date of procedure** |__|__| / |__|__|__| / |__|__|__|__|
   d d M M M y y y y
   [p_procedure_date] [date]
   Last name First name

Signature of Investigator: _____

Data entered by: | _ _ | initials Date entered: | _ _ | _ _ _ | _ _ _ _ |

subFORM 5: Hospitalization (pg 1 of 1)

Site/Clinic: _____ **Site No.** **Participant No.** **Participant ID:** | _ _ | _ _ _ | **Participant Initials:** __ __

1. **Admission date** |__|__| / |__|__|__| / |__|__|__|__|
   d d M M M y y y y
   [hospital_addm_date] [date]
2. **Reason for Hospitalization:**
   [hospitaliza_reason] [int(11)] *[Severe hypoglycemia 1, ☐Acute hyperglycemia (e.g. Diabetic Keto Acidosis) 2, ☐Angina 3, ☐Peripheral Vascular disease 4, ☐Revascularization procedure [angioplasty or CABG] 5, ☐TIA 6, ☐Stroke 7, ☐Arrhythmia 8, ☐Gangrene or amputation 9, ☐Major bleeding (e.g. intracerebral or gastro-intestinal) 10, ☐Renal failure 11, ☐severe diabetes-related eye 12, ☐Major infections 13, ☐Inpatient hospitalization or prolongation of existing hospitalization 14, ☐Death 15, ☐Any other major health conditions/events 16]*
   ☐☐Severe hypoglycemia
   ☐☐Acute hyperglycemia (e.g. Diabetic Keto Acidosis)
   ☐☐Angina
   ☐☐Peripheral Vascular disease
   ☐☐Revascularization procedure [angioplasty or CABG],
   ☐☐TIA
   ☐☐Stroke
   ☐☐Arrhythmia
   ☐☐Gangrene or amputation
   ☐☐Major bleeding (e.g. intracerebral or gastro-intestinal)
   ☐☐Renal failure
   ☐☐severe diabetes-related eye
   ☐☐Major infections
   ☐☐Inpatient hospitalization or prolongation of existing hospitalization
   ☐☐Death
   ☐☐Any other major health conditions/events

3. Still in hospital at study completion

[still_in_hospital] [int(11)] *[Yes 1, No 2]*

☐ **Yes** ☐ **No**

Discharge date

[hospital_discharge_date] [date]

|__|__| / |__|__|__| / |__|__|__|__|

d d M M M y y y y

Person Completing Report _____

Last name First name

[last_name] [varchar(20)] [frist_name] [varchar(20)]

Date Completed: _ _/_ _ _/_ _ _ _

[date_completed] [date]

Signature of Investigator: _____

Data entered: | _ _ | initials

[data_entry_by] [varchar(20)]

Date entered: | _ _ | _ _ _ | _ _ _ _ |

[data_entered] [date]

- All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)**
- Place cross [X] in the appropriate boxes. Write in fields clearly.
- See *Form Completion Notes*, for definitions and explanations
- Store copies of available source documents (SD), where indicated, in patient's trial folder

Data entry by:
[data_entry_by] [varchar(100)]
Initials _____
DATE entered: ___ /_____ /_____
[date_entered] [date]

PART 1: complete by STUDY PHYSICIAN

FORM C – Baseline Randomization

CARRS Translation Trial

Screening ID: S __ __ __ __ __
Participant Initials: _____
[participant_id] [varchar(20)]

Date of Visit (dd/MMM/yyyy): __ __ / __ __ __ / __ __ __ __
[date_of_visit] [date]

1. History – Data saved in "patient_form_c.csv" and is in wide format

	Condition	Year of Diagnosis		
1.01	Type 2 Diabetes [h_type2_diabetes_year] [varchar(6)]	__ __ __ __	1[ ] Unknown [h_is_type2_diabetes] [int] *[Unknown 1]*	
1.02	Hypertension [h_hypertension_year] [varchar(6)]	__ __ __ __	1[ ] Unknown [h_is_hypertension] [int] *[Unknown 1, Not applicable -1]*	2[ ] Not applicable
1.03	Hyperlipidemia [h_hyperlipidemia_year] [varchar(6)]	__ __ __ __	1[ ] Unknown [h_is_hyperlipidemia] [int] *[Unknown 1, Not applicable -1]*	2[ ] Not applicable

1.04	How first diagnosed with diabetes: [h_first_diagnosed_with_diabetes] [int] *[Testing after symptoms emerged 1,* *At routine check-up, no symptoms 2,* *Active screening 3,* *Diagnosed during pregnancy 4,* *Other 5]*	1[ ] Testing after symptoms emerged (polydipsia, polyuria, polyphagia, weight loss, low energy, impotence, pruritis, vision problems, giddiness, aches/pains) 2[ ] At routine check-up, no symptoms (urine test, raised blood sugar, etc.) 3[ ] Active screening (testing by physician, at fair, etc) 4[ ] Diagnosed during pregnancy 5[ ] Other

		Diabetes?		Kidney failure?	
1.05	Number of children with [h_no_children_with_diabetes] [int(11)] [h_no_children_with_kidney_failure] [int(11)]	_ _ _ _ _ _	[ ] Unknown, N/A [is_child_with_diabetes_fail] [int] *[-1]*	__ _ __ _	[ ] Unknown, N/A [is_chid_with_kidney_fail] [int] *[-1]*
1.06	Number of brothers/sisters with [h_no_brother_sister_with_diabetes] [int(11)] [h_no_brother_sister_with_kidney_failure] [int(11)]	_ _ _	[ ] Unknown, N/A [is_brosis_with_diabetes] [int] *[-1]*	__ _	[ ] Unknown, N/A [is_brosis_with_kidney_fail [int] *[-1]*

Commented [CR1]: If the response is [Unknown] data is saved as '1'

Commented [CR2]: If the response is [Unknown] or [Not applicable] data is saved as '1' or '-1'

Commented [CR3]: If the response is [Unknown] or [Not applicable] data is saved as '1' or '-1'

Commented [CR5]: If the response is [Unknown, N/A] data is saved as '-1'

Commented [CR4]: If the response is [Unknown, N/A] data is saved as '-1'

Commented [CR7]: If the response is [Unknown, N/A] data is saved as '-1'

Commented [CR6]: If the response is [Unknown, N/A] data is saved as '-1'

1.07	Number of parents with [h_no_parents_with_diabetes] [int(11)] [h_no_parents_with_kidney_failure] [int(11)]	_ _ _	[ ] Unknown [is_parents_with_diabetes] [int] *[-1]*	__ _	[ ] Unknown [is_parents_with_kidney_fail] [int] *[-1]*
1.08	Number of grandparents with [h_no_grandparents_with_diabetes] [int(11)] [h_no_grandparents_with_kidney_failure] [int(11)]	_ _ _	[ ] Unknown [is_granparent_with_diabetes] [int] *[-1]*	__ _	[ ] Unknown [is_granparent_with_kidney_fail] [int] *[-1]*

Commented [CR8]: If the response is [Unknown] data is saved as '-1'

Commented [CR9]: If the response is [Unknown] data is saved as '-1'

Commented [CR10]: If the response is [Unknown] data is saved as '-1'

Commented [CR11]: If the response is [Unknown] data is saved as '-1'

1.09	Is there a history of HEART DISEASE or HEART ATTACK in a brother, sister, or parent? *If YES, was it at an early age? (*Early age = Before Age 55 for father/brother; 65 for mother/sister) [h_heart_attack_brother_sister_parents] [int(11)] *[Yes, at an EARLY AGE 1, Yes, age unknown 2, No 3, Unknown 4]*	1[ ] Yes, at an EARLY AGE 2[ ] Yes, age unknown 3[ ] No 4[ ] Unknown
1.10	Is there a history of STROKE in a brother, sister, or parent? *If YES, was it at an early age? (*Early age = Before Age 55 for father/brother; 65 for mother/sister) [h_stroke_brother_sister_parents] [int(11)] *[Yes, at an EARLY AGE 1, Yes, age unknown 2, No 3, Unknown 4]*	1[ ] Yes, at an EARLY AGE 2[ ] Yes, age unknown 3[ ] No 4[ ] Unknown

	Cardiovascular	no/ unsure	yes	
1.11	ACS: Myocardial Infarction or Unstable Angina [h_cardiovascular_acs] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, list year(s): [h_cardiovascular_acs_year] [varchar(20)]
1.12	Angioplasty (PCI) /Open-heart surgery (CABG) [h_cardiovascular_pci_cabg] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, list year(s): [h_cardiovascular_pci_cabg_year] [varchar(20)]
1.13	Chronic Stable Angina [h_cardiovascular_chronic_sa] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, since (year): _ _ _ _ [h_cardiovascular_chronic_sa_year] [varchar(20)]
1.14	Stroke (Ischemic or Hemorrhagic) or TIA [h_cardiovascular_stroke_tia] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, list year(s): [h_cardiovascular_stroke_tia_year] [varchar(20)]
1.15	Arrhythmia (requiring medical intervention) [h_cardiovascular_arrtythmia] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, since (year): _ _ _ _ [h_cardiovascular_arrtythmia_year] [varchar(20)]
1.16	Heart Failure	[ ]	[ ]	If yes, since (year): _ _ _ _

Commented [CR12]: If the response is [yes 1] for Q.no.1.11 to 1.16 - specify the year __

	[h_cardiovascular_heart_attack] [int(11)] *[Yes 1, no/unsure 2,]*			[h_cardiovascular_heart_attack_year] [varchar(20)]

	Peripheral Vascular/Neuropathy	no/ unsure	yes	
1.17	PVD (Intermittent claudication/ rest pain in legs) [h_peripheral_vascular_pvd] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, since (year): _ _ _ _ [h_peripheral_vascular_pvd_year] [varchar(20)]
1.18	Peripheral revascularization (angioplasty/ surgery) [h_peripheral_surgery] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, list year(s): [h_peripheral_surgery_year] [varchar(20)]
1.19	Chronic leg/foot ulcer (6 weeks or more) [h_peripheral_foot_ulcer] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, number of times: ___ [h_peripheral_foot_ulcer_year] [varchar(20)]
	Eyes			
1.20	Blindness in either eye thought to be due to diabetes [h_eyes_blindbess] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, [ ] R [ ] L [ ] both [h_eyes_is_blindbess] [varchar(20)] *[R right, L left, B both]*
1.21	Cataract [h_eyes_cataract] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, [ ] R [ ] L [ ] both [h_eyes_is_cataract] [varchar(20)] *[R right, L left, B both]*
1.22	Cataract Surgery [h_eyes_cataract_surgery] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, [ ] R [ ] L [ ] both [h_eyes_is_cataract_surgery] [varchar(20)] *[R right, L left, B both]*
1.23	Glaucoma [h_eyes_glaucoma] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.24	Macular Edema [h_eyes_macular_edema] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.25	Diabetic Retinopathy [h_eyes_diabetic_retinopathy] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.26	Laser photocoagulation therapy [h_eyes_laser_therapy] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, number of times: ___
1.27	Other therapy [h_eyes_other_therapy] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
	OTHER			
1.28	Neuropathy – hands/feet [h_other_neuropathy_hands_feet] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.29	Neuropathy – sexual (erectile dysfunction) [h_other_neuropathy_sexual] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.30	Nephropathy (protein in urine)	[ ]	[ ]	

Commented [CR13]: If the response is [yes 1] for Q.no.1.17, 1.18 - specify the year __ & for Q.no.1.19 response is [yes 1] – specify number of times __

Commented [CR14]: If the response is [yes 1] for Q.no.1.20 to 1.**22** - specify the direction [right, left or both

Commented [CR15]: We can ignore this because Variable not found in both front-end & back-end

	[h_other_neuropathy_urine] [int(11)] *[Yes 1, no/unsure 2,]*			
1.31	Chronic urinary tract infection (2+ in 6 months) [h_other_chronic_urinary] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.32	Past tuberculosis [h_other_past_tuberculosis] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.33	Asthma [h_other_asthma] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.34	COPD (Chronic Bronchitis, Emphysema) [h_other_copd] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.35	Liver disease [h_other_liver_disease] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.36	Gallbladder disorder (stones, disease) [h_other_gallbladder_disorder] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.37	Hip Fracture/Replacement [h_other_hip_facture] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	
1.38	Depression [h_other_depression] [int(11)] *[yes 1, no/unsure 2,]*	[ ]	[ ]	
1.39	Major hypoglycemia episodes (hospitalization or emergency room visit) [h_other_major_hypoglycemia] [int(11)] *[Yes 1, no/unsure 2,]*	[ ]	[ ]	If yes, number of times: ___ [h_other_is_major_hypoglycemia] [int(11)]
1.40	Other hospitalization for diabetes [h_other_hospitalization] [int(11)] *[Yes 1, no/unsure 2]*	[ ]	[ ]	If yes, number of times: ___ [h_other_is_hospitalization] [int(11)]
1.41	Other conditions (current or past) which have required medications or surgical intervention: [h_other_conditions] [varchar(200)]			

Commented [CR16]: If the response is [yes 1] for Q.no.1.39 & 1.40 – specify number of times

2. ECG & Eye Exam

May use results from past 1 month. Retain copies of ECG and eye exam results as source documents.

ECG: May use results from past 1 month. Otherwise, complete test today.

2.01	**ECG** Date: __ __ / __ __ __ / __ __ __ __ [s_ecg_date] [date]		
2.02	Q-waves diagnostic of previous MI [s_ecg_q_waves] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N
2.03	Left ventricular hypertrophy [s_ecg_left_ventricular] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N
2.04	Atrial Fibrillation [s_ecg_atrial] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N
2.05	Other arrhythmia [s_ecg_other_arrhythmia] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N

Commented [CR17]: ECG date should be within one month of Form B Date of visit

EYE EXAM: **May use results from past 1 month.**

[ ] Attach Form G-Eye Exam to end of this Form C – to be completed by qualified ophthalmologist only. If not completed prior to this visit, schedule ophthalmologist appointment and ensure completion within 2 weeks. Enter results in eCRF (EYE EXAM) as soon as available.

3. Foot Exam

		Right Foot		Left Foot	
3.01	Amputation [fe_amputation_right_foot] [int(11)] [fe_amputation_left_foot] [int(11)] *[N/A 1, toe 2, ray (metatarsal) 3, forefoot 4, foot 5, below knee 6, above knee 7]*	[ ] N/A [ ] toe [ ] ray (metatarsal) [ ] forefoot [ ] foot [ ] below knee [ ] above knee		[ ] N/A [ ] toe [ ] ray (metatarsal) [ ] forefoot [ ] foot [ ] below knee [ ] above knee	
3.02	Appearance [fe_appearance_right_foot_normal] [int(11)] *[normal 1, abnormal 2]* [fe_appearance_left_foot_normal] [int(11)] *[normal 1, abnormal 2]* [fe_appearance_right_foot_deformities] [int(11)] *[1]* [fe_appearance_right_foot_dystrophic] [int(11)] *[2]* [fe_appearance_right_foot_callus] [int(11)] *[3]* [fe_appearance_right_foot_unceration] [int(11)] *[4]* [fe_appearance_right_foot_infection] [int(11)] *[5]* [fe_appearance_right_foot_discoloration] [int(11)] *[6]* [fe_appearance_right_foot_other] [int(11)] *[7]* [fe_appearance_right_foot_other_details] [varchar(200)] *[other specify]*	1[ ] normal **2[ ] abnormal**, check all that apply: 1[ ] deformities 2[ ] dystrophic nails; dry skin/fissure 3[ ] callus 4[ ] ulceration 5[ ] infection 6[ ] discoloration 7[ ] other: _____		1[ ] normal **2[ ] abnormal**, check all that apply: 1[ ] deformities 2[ ] dystrophic nails; dry skin/fissure 3[ ] callus 4[ ] ulceration 5[ ] infection 6[ ] discoloration 7[]other: _____	
3.03	Posterior tibial pulse [fe_posterior_right_foot] [int(11)] *[Yes 1, No 2]* [fe_posterior_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.04	Doraslis pedis pulse [fe_doraslis_right_foot] [int(11)] *[Yes 1, No 2]* [fe_doraslis_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.05	Pre-tibial EDEMA today [fe_pre_tibial_edema_right_foot] [int(11)] [fe_pre_tibial_edema_left_foot] [int(11)] *[None 0, up to ankle 1,between ankle & mid-calf 2, between mid-calf & knee 3]*	[ ] none [ ] up to ankle [ ] between ankle & mid-calf [ ] between mid-calf & knee		[ ] none [ ] up to ankle [ ] between ankle & mid-calf [ ] between mid-calf & knee	
3.06	Ankle Reflex [fe_ankle_relax_right_foot] [int(11)] *[Yes 1, No 2]* [fe_ankle_relax_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.07	Knee Reflex [fe_knee_reflax_right_foot] [int(11)] *[Yes 1, No 2]* [fe_knee_reflax_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.08	Vibration, tuning fork (perception at great toe) [fe_vibration_right_foot] [int(11)] [fe_vibration_left_foot] [int(11)] *[present (≥10 sec) 1, reduced (<10 sec) 2, absent 3]*	[ ] present (≥10 sec) [ ] reduced (<10 sec) [ ] absent		[ ] present (≥10 sec) [ ] reduced (<10 sec) [ ] absent	

Commented [CR18]: If the response is [abnormal 2] specify below mentioned options 1 to 7 (check all that apply) for right foot & left foot

[fe_appearance_left_foot_deformities] [int(11)] *[1]*
[fe_appearance_left_foot_dystrophic] [int(11)] *[2]*
[fe_appearance_left_foot_callus] [int(11)] *[3]*
[fe_appearance_left_foot_unceration] [int(11)] *[4]*
[fe_appearance_left_foot_infection] [int(11)] *[5]*
[fe_appearance_left_foot_discoloration] [int(11)] *[6]*
[fe_appearance_left_foot_other] [int(11)] *[7]*
[fe_appearance_left_foot_other_details] [varchar(200)] *[other specify]*

3.09	10g Monofilament (number applications detected) [fe_monofilament_right_foot] [int(11)] [fe_monofilament_left_foot] [int(11)] *[present (≥8) 1, reduced (1-7) 2, absent 3]*	[ ] present (≥8) [ ] reduced (1-7) [ ] absent	[ ] present (≥8) [ ] reduced (1-7) [ ] absent
3.10	**Based on above the participant has:**		
	Deformities [fe_participant_has] [varchar(20)] *[Yes 1, No -1]*	1[ ] Yes	2[ ] No
	Foot ulceration/infection *[Yes 2, No -2]*	1[ ] Yes	2[ ] No
	PVD *[Yes 3, No -3]*	1[ ] Yes	2[ ] No
	Neuropathy *[Yes 4, No -4]*	1[ ] Yes	2[ ] No

Commented [CR19]: For Q.no.3.10 to 3.14 has multiple responses and data stored in this column as string so we are splitting & re naming the categories as [1,-1, 2,-2, 3,-3, 4,-4]

4. Heart Failure Exam

	Have you experienced any of the following since your last exam?		
4.01	swelling of your feet, ankles or legs [hf_swelling_feet] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_swelling_feet_new] *[new or worsened 1, unchanged or improved 0]*
4.02	shortness of breath while lying, sitting, or with minimal exertion [hf_shortness_of_breath] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_shortness_of_breath_new] *[new or worsened 1, unchanged or improved 0]*
4.03	need to pass urine two or more times per night [hf_pass_urine] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_pass_urine_new] *[new or worsened 1, unchanged or improved 0]*

Commented [CR20]: If the response is [yes 1] for Q.no.4.01 to 4.03 – specify '1' or '0'
[new or worsened 1, unchanged or improved 0]

If any 4.01-4.03 is YES, complete below.		
Chest Auscultation		
4.04	Lungs [hf_chest_ausculation_lungs] [int(11)] *[no rales 1, basilar rales only 2, more than basilar 3]*	1[ ] no rales more than basilar 2[ ] basilar rales only 3[ ]
4.05	Heart [hf_chest_ausculation_heart] [int(11)] *[normal 1, abnormal 3rd heart sound present 2]*	1[ ] normal 2[ ] abnormal, 3rd heart sound present

4.06	Heart Failure evident [hf_chest_ausculation_heart_failure] [int(11)] *[Yes 1, No 2]*	1[ ] Yes, grade: _____ [heart_failure_grade] [varchar(45)]	2[ ] No

Commented [CR21]: If the response is [yes 1] for Q.no.4.06 – specify grade

5. Neurological Exam

	Have you experienced any of the following since your last exam?		
5.01	Muscle weakness [ne_muscles_weakness] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [ne_is_muscles_weakness_new] [int(11)] *[new or worsened 1, unchanged or improved 0]*
5.02	Difficulty in speech [ne_difficulty_in_speech] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [ne_difficulty_in_speech_new] [int(11)] *[new or worsened 1, unchanged or improved 0]*
5.03	Loss of consciousness [ne_loss_consciousness] [int(11)] *[Yes 1, No 2, N/A 3]*	**1[ ] Yes** 2[ ] No	

Commented [CR22]: If the response is [yes 1] for Q.no.5.01 & 5.02 – specify '1' or '0'
[new or worsened 1, unchanged or improved 0]

If any 5.01-5.03 is YES, complete below.

	Muscles	Right	Left
5.04	ARMS-Tone [ne_arms_tone_right] [int(11)] [ne_arms_tone_left] [int(11)] *[normal 1, flaccid 2, rigid/spastic 3]*	[ ] normal [ ] flaccid [ ] rigid/spastic	[ ] normal [ ] flaccid [ ] rigid/spastic
5.05	ARMS-Strength [ne_arms_strengt_right] [int(11)] [ne_arms_strengt_left] [int(11)] *[normal 1, deficit 2]*	[ ] normal [ ] deficit	[ ] normal [ ] deficit
5.06	LEGS-Tone [ne_legs_tone_right] [int(11)] [ne_legs_tone_left] [int(11)] *[normal 1, flaccid 2, rigid/spastic 3]*	[ ] normal [ ] flaccid [ ] rigid/spastic	[ ] normal [ ] flaccid [ ] rigid/spastic
5.07	LEGS-Strength [ne_legs_strength_right] [int(11)] [ne_legs_strength_left] [int(11)] *[normal 1, deficit 2]*	[ ] normal [ ] deficit	[ ] normal [ ] deficit
	Reflexes	**Right**	**Left**
5.08	Biceps [ne_reflexes_biceps_right] [int(11)] [ne_reflexes_biceps_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.09	Triceps [ne_reflexes_triceps_right] [int(11)] [ne_reflexes_triceps_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.10	Knee [ne_reflexes_knee_right] [int(11)] [ne_reflexes_knee_right] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.11	Ankle [ne_reflexes_ankle_right] [int(11)] [ne_reflexes_ankle_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent

5.12	[ ] Old deficit evident [ne_old_deficit] [int(11)] *[Yes 1, No 2]*	1[ ] Yes	2[ ] No

6. MEDICATIONS and MANAGEMENT

6.01	**Drug Allergies** [othedrugallergy] [varchar(20)] *[Yes 1, No 2, unknown -1]* [drug_allergies] [varchar(200)]	[ ]No [ ]Unknown [ ]Yes, *specify:*

Commented [CR23]: If the response is [Yes 1] specify drug name

6.02 MEDICATIONS – Data is saved in "medication_mgt.csv" file and is in long format

Below, list all medications that the participant is presently taking *on a regular basis (prior to randomization).*

^For (1) Insulin, (2) OHAs, and (3) Blood pressure MIXED medications, describe all constituents separately under "Generic Name" and "Single Dose"

Type	Brand Name [name] [varchar(200)]	*^List ALL constituents for Insulin, OHAs, BP meds*		Frequency [frequency] [double]	Total daily dose **[total_daily_dose]** [double]
		Generic Name [generic_name] [varchar(200)]	Single Dose [single_dose] [double]		
Insulin					
OHAs					
BP					
Statin					

Type	Brand Name	*Generic Name*	Single Dose	Frequency	Total daily dose
Other					

6.03		**Management of diabetes in last 6 months** [dibetes_mgt] [varchar(50)]
	[ ]	Sulphonylurea (glibenclamide, gliclazide, glimipiride)
	[ ]	Biguanide (Metformin)
	[ ]	Thazolidineodione (Pioglitazone)
	[ ]	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)
	[ ]	Glinide (Nateglinide, Repaglinide, Mitiglinide)
	[ ]	Lispro, Aspart, Glulisine insulins (rapid-acting)
	[ ]	Regular Insulins (short-acting)
	[ ]	NPH or Lente Insulins (intermediate-acting)
	[ ]	Glargine or Determir Insulins (very long-acting)
	[ ]	Other diabetic treatment
	[ ]	Dietician or Educator referral
	[ ]	Weight control or exercise program
	[ ]	Home blood glucose monitoring
6.04		**Other medications** [other_dibetes_mgt] [varchar(100)]
	[ ]	Thaizide or thiazide-like diuretic
	[ ]	Other diuretic

[Sulphonylurea (glibenclamide, gliclazide, glimipiride) 1
Biguanide (Metformin) 2
Thazolidineodione (Pioglitazone) 3
Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)4
Glinide (Nateglinide, Repaglinide, Mitiglinide) 5
Lispro, Aspart, Glulisine insulins (rapid-acting) 6
Regular Insulins (short-acting) 7
NPH or Lente Insulins (intermediate-acting) 8
Glargine or Determir Insulins (very long-acting) 9
Other diabetic treatment 10
Dietician or Educator referral 11
Weight control or exercise program 12
Home blood glucose monitoring 13

	[ ]	ACE inhibitor
	[ ]	Angiotensin 2 receptor antagonist (ARB)
	[ ]	Beta-blocker
	[ ]	Calcium channel blocker (CCB)
	[ ]	Other antihypertensive agent
	[ ]	Statin
	[ ]	Other cholesterol lowering drug
	[ ]	Aspirin
	[ ]	Other anti-platelet agent
	[ ]	Oral anticoagulant
	[ ]	Nitrates (NOT sublingual)
	[ ]	Hormone replacement therapy
	[ ]	Thyroid Agents
	[ ]	Oral/inhaled steroids
	[ ]	Oral asthma drugs (exclude steroids)
	[ ]	Antidepressant
	[ ]	Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline)
	[ ]	Erectile Dysfunction drug
	[ ]	Herbal/alternative medicine
	[ ]	Vitamins/nutritional supplements
	[ ]	Other, not listed above

Thaizide or thiazide-like diuretic 1
Other diuretic 2
ACE inhibitor 3
Angiotensin 2 receptor antagonist (ARB) 4
Beta-blocker 5
Calcium channel blocker (CCB) 6
Other antihypertensive agent 7
Statin 8
Other cholesterol lowering drug 9
Aspirin 10
Other anti-platelet agent 11
Oral anticoagulant 12
Nitrates (NOT sublingual) 13
Hormone replacement therapy 14
Thyroid Agents 15
Oral/inhaled steroids 16
Oral asthma drugs (exclude steroids) 17
Antidepressant 18
Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline) 19
Erectile Dysfunction drug 20
Herbal/alternative medicine 21
Vitamins/nutritional supplements 22
Other, not listed above 23

7. Randomization

7.01	[ ] Y [ ] N	Completed all of Form C, Part 1 above. **If NO,** complete now.
7.02	[ ] Y [ ] N	Reviewed Forms and Eligibility with Investigator or Co-Investigator. **If NO,** review now.
7.03	[ ] Y [ ] N	Patient agrees to continue with the trial **If NO,** stop here and complete patient status in PARTICIPANT LOG.

If YES for ALL 7.01-7.03, continue to Randomization:

1. Information from **Participant Log** will be required to complete the Randomization.
2. Select Randomization option on website *www.coe-carrs.phfi.in* (CARRS Translation Trial > Randomization) and enter requested data
    a. Screening Officer Name
    b. Screening ID (do not include 'S' - only numbers)
    c. Confirm Screening ID (do not include 'S' - only numbers)
    d. Date of Birth (dd/MMM/yyyy)
    e. Confirm Date of Birth (dd/MMM/yyyy)
    f. Was the eligibility of the participants to both treatment arms confirmed by investigator?
    g. Has the participant met all eligibility criteria?

h. Has the participant met any of the exclusion criteria?

i. Did the participant sign informed consent?

OR IF INTERNET ACCESS NOT POSSIBLE:

3. Telephone +011 2685-0117/18 and ask for CARRS Translation Trial Randomization

7.04 Result of Randomization: - enter information below & attach print-out from randomization page:

PARTICIPANT ID: __ __ __ __ __	**USE THIS ID in future CRF and eCRF**

Allocation: [ ] Control Group [ ] Intervention Group

[treatment_group] [varchar (20)], *[INTERVENTION, CONTROL]*

8. Signature of Study Physician

8.01 Name: _____ Signature: _____

8.02 Date Signed: __ __ / __ __ __ / __ __ __ __

8.03 Complete **Participant Log** for this patient

8.04 Check one of the following:

[ ] **Control Group Participant** → send to **Research Officer** to complete Form C Part 2 (below)

[ ] **Intervention Group Participant** → send to **Care Coordinator** to complete Form C Part 2 (below)

PART 2: complete by CARE COORDINATOR or RESEARCH OFFICER

9. Demographics

9.01 Marital Status

[matrial_status] [int], *[Single 1, Married 2, Widow/Widower 3, Separated/Divorced 4]*

1[ ] Single
2[ ] Married
3[ ] Widow/Widower
4[ ] Separated/Divorced

9.02 Occupation

[occupation] [int]

[1 Professional, big business, landlord, university teacher, class 1 IAS/services officer, lawyer, 2 Trained, clerical, medium business owner, staff manager, mid-level farmer, teacher, 3 Skilled manual laborer, small business owner, small farmer, 4 Semi-skilled manual laborer, marginal landowner, rickshaw driver, army jawan, carpenter, fitter, 5 Unskilled manual laborer, landless laborer, 6 Homemaker, 8 Student, 9 Retired, 10 Unemployed, 11 Other]

1[ ] Professional, big business, landlord, university teacher, class 1 IAS/services officer, lawyer
2[ ] Trained, clerical, medium business owner, staff manager, mid-level farmer, teacher
3[ ] Skilled manual laborer, small business owner, small farmer
4[ ] Semi-skilled manual laborer, marginal landowner, rickshaw driver, army jawan, carpenter, fitter
5[ ] Unskilled manual laborer, landless laborer
6[ ] Homemaker
8[ ] Student
9[ ] Retired
10[ ] Unemployed
11[ ] Other

9.03 Days per week that you work: _____ [ ] N/A

[days_per_week_work] [int (1)] [days_per_week_work_na] [int] *[(N/A) 1]*

Commented [CR24]: If the response is [N/A] data is saved as '1'

Hours per day that you work: _____ [ ] N/A
[hours_per_day_work] [int(2)] [hours_per_day_work_na] [int] *[(N/A 1)]*

9.04 TOTAL number of household members: _____
[no_household] [int(2)]

9.05 Number of children in household: _____
[no_children] [int(2)]

9.06 Number of adults in household: _____
[no_adult] [int(2)]

9.07 Number of adults in household earning: _____
[no_adult_earning] [int(2)]

9.08 During last 12 months, HOUSEHOLD monthly income:
[household_income] [int] *[<3,000 1, 3,000-10,000 2, 10,000-20,000 3, 20,001-30,000 4, 30,001-40,000 5, 40,001-50,000 6, >50,000 7, Unknown/ Refuse 8]*

1[ ] <3,000
2[ ] 3,000-10,000
3[ ] 10,000-20,000
4[ ] 20,001-30,000
5[ ] 30,001-40,000
6[ ] 40,001-50,000
7[ ] >50,000
8[ ] Unknown/ Refuse

During last 12 months, INDIVIDUAL monthly income: _____Rupees
[individual_income] [int] *[<3,000 1, 3,000-10,000 2, 10,000-20,000 3, 20,001-30,000 4, 30,001-40,000 5, 40,001-50,000 6, >50,000 7, Unknown/ Refuse 8]*

1[ ] <3,000
2[ ] 3,000-10,000
3[ ] 10,000-20,000
4[ ] 20,001-30,000
5[ ] 30,001-40,000
6[ ] 40,001-50,000
7[ ] >50,000
8[ ] Unknown/ Refuse

9.09 Highest Level of Education of Participant:
[highest_education] [int] *[1 Professional degree/post graduate, 2 Graduate (BA, BSc, BCom, Diploma), 3 Secondary School, Standard, 4 Primary School (up to class 5), Standard 5 Literate, no formal education, 6 Illiterate, 7 Unknown]*

1[ ] Professional degree/post graduate
2[ ] Graduate (BA, BSc, BCom, Diploma)
3[ ] Secondary School, Standard: _____
4[ ] Primary School (up to class 5), Standard: _____
5[ ] Literate, no formal education
6[ ] Illiterate
7[ ] Unknown

9.10 Mother Tongue (Ethnic Origin):
[mother_tongue] [int (2)] *[1 Assamese, 2 Bengali, 3 Gujarati, 4 Hindi, 5 Kannada, 6 Kashmiri, 7 Maithili, 8 Malayalam, 9 Marathi, 10 Punjabi, 11 Sindhi, 12 Telugu, 13 Tamil, 14 Urdu, 15 other, specify, 16 Unknown]*

1[ ] Assamese
2[ ] Bengali
3[ ] Gujarati
4[ ] Hindi
5[ ] Kannada
6[ ] Kashmiri
7[ ] Maithili
8[ ] Malayalam
9[ ] Marathi
10[ ] Punjabi
11[ ] Sindhi
12[ ] Telugu
13[ ] Tamil
14[ ] Urdu
15[ ] Other, specify: _____
[mother_tongue_other] [varchar(50)]
16[ ] Unknown

9.11 Knows English language (check all that apply OR none):
[english_language] [int(10)] *[(understand 1, speak 2, read/write 3, None 4)]*
1[ ] understand

Commented [CR25]: If the response is [N/A] data is saved as '1'

2[ ] speak 4[ ] none
3[ ] read/write

9.12 Religion:
[religion] [int] *[1 Hindu, 2 Muslim, 3 Sikh, 4 Christian, 5 Jain, 6 Buddhism, 7 No religion, 8 other, specify, 9 unknown/refuse]*

1[ ] Hindu
2[ ] Muslim
3[ ] Sikh
4[ ] Christian
5[ ] Jain
6[ ] Buddhism
7[ ] No religion
8[ ] other, specify: _____
[religion_other] [varchar(50)]
9[ ] unknown/refuse

10. Lifestyle – Data is saved in "patient_life_style.csv" and is wide format

10.05	**Diet** (weekday/ routine day)	Meal 1	Meal 2	Meal 3	Meal 4	Meal 5	Meal 6
	Meal Time (approximate)	[meal1_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal2_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal3_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal4_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal5_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm	[meal6_ampm] [varchar(6)] *[AM or PM]* _:_ _ amPm
		[meal1_time] [varchar(5)]	[meal2_time] [varchar(5)]	[meal3_time] [varchar(5)]	[meal4_time] [varchar(5)]	[meal5_time] [varchar(5)]	[meal6_time] [varchar(5)]
	Type B=breakfast, L=lunch, D=dinner, S=snack	[meal1_type] [varchar(6)]	[meal2_type] [varchar(6)]	[meal3_type] [varchar(6)]	[meal4_type] [varchar(6)]	[meal5_type] [varchar(6)]	[meal6_type] [varchar(6)]

Commented [CR26]: Should specify [AM or PM]

Commented [CR27]: Should specify time of the meal

Commented [CR28]: Should specify type of meal i.e., B=breakfast, L=lunch, D=dinner, S=snack

10.02 Who decides the meal menu in the household? (check one)
[household_meal_menu] [varchar(10)] *[(Myself 1, other 2, shared (myself and other) 3)]*

[ ] Myself [ ] other (i.e. spouse, relative, hired cook) [ ] Shared (myself and other)

10.03 Who cooks the food in the household? (check one)
[household_cook_food] [varchar(10)] *[(Myself 1, other 2, shared (myself and other) 3)]*

[ ] Myself [ ] other (i.e. spouse, relative, hired cook) [ ] Shared (myself and other)

10.04	**Physical Activity (in leisure time) in average week**	*Days per week*	*Total time per day*	
			Hour(s)	*Minutes*
	Vigorous	[pa_vigorous_days_per_week] [int(11)]	[pa_vigorous_total_hr] [int(11)]	[pa_vigorous_total_min] [int(11)]
	Moderate	[pa_moderate_days_per_week] [int(11)]	[pa_moderate_total_hr] [int(11)]	[pa_moderate_total_min] [int(11)]
	Mild (Walking)	[pa_walking_days_per_week] [int(11)]	[pa_walking_total_hr] [int(11)]	[pa_walking_total_min] [int(11)]

10.05	Ever use tobacco [ever_use_tobacco] [int(11)] *[Yes=1; No=2]*	[ ] Y Continue below [ ] N Skip to 10.06

Commented [CR29]: If the response is[No 2] skip to Q.no.10.06

		Current regular use Y N	*Past regular use* Y N	*Number of years used*	*Current/past Average Quantity per day*
	Cigarette	[ ] [ ] [cigarette_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [cigarette_past_use] [int(11)] *[Yes=1; No=2]*	[cigarette_no_of_year] [int(11)]	[cigarette_qty_per_day] [int(11)]
	Beedi	[ ] [ ] [beedi_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [beedi_past_use] [int(11)] *[Yes=1; No=2]*	[beedi_no_of_year] [int(11)]	[beedi_qty_per_day] [int(11)]
	Cigar/Pipe	[ ] [ ] [cigar_pipe_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [cigar_pipe_past_use] [int(11)] *[Yes=1; No=2]*	[cigar_pipe_no_of_year] [int(11)]	[cigar_pipe_qty_per_day] [int(11)]
	chewing tobacco (in paan masala, paan, other mix)	[ ] [ ] [chewing_tobacco_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [chewing_tobacco_past_use] [int(11)] *[Yes=1; No=2]*	[chewing_tobacco_no_of_year] [int(11)]	[chewing_tobacco_qty_per_day] [int(11)]
	Other:	[ ] [ ] [other_regular_use] [int(11)] *[Yes=1; No=2]*	[ ] [ ] [other_past_use] [int(11)] *[Yes=1; No=2]*	[other_no_of_year] [int(11)]	[other_qty_per_day] [int(11)]

10.06	Ever drink alcohol [ever_drink_alcohol] [int(11)]	[ ] Y Continue below *[Yes=1; No=2]* [ ] N Skip to Section 11

Commented [CR30]: If the response is[No 2] skip to Q.no.11 (Selfcare)

	[ ]Y [ ]N	Currently drink alcohol once a week or more (for most weeks in past year) [currt_drink_alcohol] [int(11)] *[Yes=1; No=2]*
	[ ]Y [ ]N	Used to drink alcohol regularly in the past [drink_alcohol_regularly_past] [int(11)] *[Yes=1; No=2]*
	_____	Number of years of alcohol use [no_year_alcohol] [int(11)] [No data in this field]
	_____	Average days per week of alcohol use (current/past) [aveg_day_week_drink] [int(11)]
	_____	Average drinks per day (current/past) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [aveg_per_day_drink] [int(11)] [aveg_drink_wine_week] [int(11)] [aveg_drink_spirits_week] [aveg_drink_beer_week] {doubt in this 2 fields}
	_____	Most drinks in one day in past 3 months (0 if not currently drinking) [aveg_most_drink] [int(11)]

11. Self-Care - Data saved in "patient_self_care.csv" &"patient_selfcare_form_c.csv" and is in long format

The questions below ask you about your diabetes self-care activities **during the past 7 days**.

If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET		
11.01	**On average, over the past month, how many DAYS PER WEEK have you followed your diet plan?** [self_care_id=2] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.02	On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables? [self_care_id=3] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.03	On how many of the last SEVEN DAYS did you eat high fat foods such as fried items or full-fat dairy products? [self_care_id=4] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.04	On how many of the last SEVEN DAYS did you space eating meals evenly through the day? [self_care_id=5] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
EXERCISE		
11.05	**On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)** [self_care_id=6] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.06	On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work? [self_care_id=7] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
BLOOD SUGAR TESTING		
11.07	**Are you testing your blood sugar as recommended by your health care provider?** [self_care_id=9] [int(11)] *[Yes 1, No 0, N/A -1]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A (skip to 11.09)
11.08	On how many of the last SEVEN DAYS did you test your blood sugar? [self_care_id=8] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
MEDICATIONS		
11.09	**On how many of the last SEVEN DAYS, did you take your recommended diabetes medication? (pills and/or insulin)** [self_care_id=10] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
FOOT CARE		
11.10	On how many of the last SEVEN DAYS did you check your feet? [self_care_id=11] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
TOBACCO		
11.11	**Ever smoke regularly?** (most days of the week) [self_care_id=12] [int(11)] *[never 0, quit 1, Yes 2]* [if quit 1] → [quit_smoking_year] [varchar(20)] [if yes 2] → [smoke_per_day] [int(11)]	0 [ ] Never 1 [ ] Quit: __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # smoked per day: ___

Commented [CR31]: In Self-care section data is saved in 2 files 1. "patient_self_care.csv " & 2 ." patient_selfcare_form_c.csv and unique ID is "Self_care_id "

Commented [CR32]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day

11.12	**Ever chew tobacco regularly?** (most days of the week) [self_care_id=13] [int(11)] *[never 0, quit 1, Yes 2]* [if quit 1] → [quit_tobacco_year] [varchar(20)] [if yes 2] → [packet_per_day] [int(11)]	0 [ ] No 1 [ ] Quit __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # packets per day: ____
11.13	If you smoke or chew tobacco, at your last doctor's visit, did anyone counsel you about stopping or refer you to counseling? [self_care_id=14] [int(11)] *[N/A 0, yes 1, no 2]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A
ALCOHOL		
11.14	**Drink alcohol regularly?** (at least once a week for most weeks in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [self_care_id=15] [int(11)] *[never 0, yes 1]* [if yes 1] → [drink_per_day] [int(11)]	0 [ ] No 1 [ ] Yes, # drinks per day: ____
STRESS		
11.15	**How often do you feel stress (from work, responsibilities, etc)?** [ ] daily [ ] few times a week [ ] few times a month [ ] never [self_care_id=16] [int(11)] *[daily 1, few times a week 2, few times a month 3, never 4]*	
11.16	How are you coping with stress? [ ] very well [ ] moderate [ ] with difficulty [ ] not applicable (no stress) [self_care_id=17] [int(11)] *[very well 1, moderate 2, with difficulty 3, not applicable(no stress) 4]*	

Commented [CR33]: If the response is [quit 1] specify the year & response is [yes 2] specify no. packet per day

Commented [CR34]: If the response is [yes 1] specify no. drink per day

Commented [CR35]: Responses at backend for this variable are saved as [0 1 2 3 4]
but , there is no category for '0'

Commented [CR36]: Responses at backend for this variable are saved as [0 1 2 3 4]
but , there is no category for '0'

12. EQ-5D - Data saved in "eq_5d.csv" and is in wide format

Place a tick in one box in each group below for the statement that best describes your own health state today.

12.01 Mobility *[I have no problems in walking about 1, I have some problems in walking about 2,*
[mobility_id] [int (11)] *I am confined to bed 3]*

1 ☐ I have no problems in walking about
2 ☐ I have some problems in walking about
3 ☐ I am confined to bed

12.02 Self-Care *[I have no problems with self-care 1, I have some problems with self-care 2,*
[self_care_id] [int(11)] *I am unable to wash or dress myself 3]*

1 ☐ I have no problems with self-care
2 ☐ I have some problems with self-care
3 ☐ I am unable to wash or dress myself

12.03 Usual Activities (e.g. work, study, housework, family or leisure activities)
[usual_activities] [int(11)] *[I have no problems with performing my usual activities 1,*
I have some problems with performing my usual activities 2,
I am unable to perform my usual activities 3]

1 ☐ I have no problems with performing my usual activities
2 ☐ I have some problems with performing my usual activities
3 ☐ I am unable to perform my usual activities

12.04 Pain/Discomfort
[pain_discomfort] [int(11)] *[I have no pain or discomfort 1, I have moderate pain or discomfort 2,*
I have extreme pain or discomfort 3]

1 ☐ I have no pain or discomfort
2 ☐ I have moderate pain or discomfort
3 ☐ I have extreme pain or discomfort

12.05 Anxiety/Depression

[anxiety_depression] [int(11)] *[I am not worried or depressed 1, I am moderately anxious or depressed 2, I am extremely anxious or depressed 3]*

1 ☐ I am not worried or depressed

2 ☐ I am moderately anxious or depressed

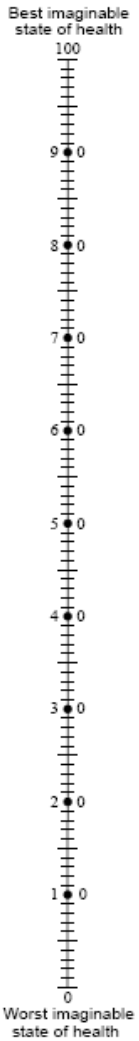
3 ☐ I am extremely anxious or depressed

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

I would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

12.06 Score: ___ ___ ___
[eq5d_score] [int(11)]

Your own health state today



13. Diabetes Treatment Satisfaction

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer each question by marking a number on every scale.

13.01 How satisfied are you with your current treatment?
[current_treatment] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.02 How often have you felt that your blood sugars have been unacceptability high recently?
[blood_sugar_high] [int] *[0, 1, 2, 3, 4, 5, 6]*

Most of the time — None of the time

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.03 How often have you felt that your blood sugars have been unacceptability low recently?
[blood_sugar_low] [int] *[0, 1, 2, 3, 4, 5, 6]*

Most of the time — None of the time

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.04 How convenient have been finding your treatment to be recently?
[convienent_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very convenient — Very inconvenient

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.05 How flexible have you been finding your treatment to be recently?
[flexible_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very flexible — Very inflexible

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.06 How satisfied are you with understanding of your diabetes?
[understand_dibetes] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.07 How satisfied would you be to continue with your present form of diabetes treatment?
[present_dib_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.08 Would you recommend this form of treatment to someone else?
[recommend_form] [int] *[0, 1, 2, 3, 4, 5, 6]*

Yes, I would definitely recommend this treatment — No, I would definitely NOT recommend this treatment

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

14. Health Utilities Index

This next questionnaire asks about aspects of your health. When answering these questions please think about your health and your ability to do things everyday in the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Focus your answers on your overall abilities, disabilities and how you felt during the past 4 weeks.

You may feel that some questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar, but please answer each question independently.

Please read each question and consider answers carefully. For each question, select one answer that best describes your level of ability or disability during the past 4 weeks. Select the answer by checking the box. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities/ feelings.

14.01. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint?

[ordinary_news_print] [int] *[1, 2, 3, 4]*

1☐ a. Able to see well enough without glasses or contact lenses
2☐ b. Able to see well enough with glasses or contact lenses
3☐ c. Unable to see well enough even with glasses or contact lenses
4☐ d. Unable to see at all

14.02. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street?

[recognize_friend] [int] *[1, 2, 3, 4]*

1☐ a. Able to see well enough without glasses or contact lenses
2☐ b. Able to see well enough with glasses or contact lenses
3☐ c. Unable to see well enough even with glasses or contact lenses
4☐ d. Unable to see at all

14.03. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people?

[group_conversation] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to hear what was said without a hearing aid
2☐ b. Able to hear what was said with a hearing aid
3☐ c. Unable to hear what was said even with a hearing aid.
4☐ d. Unable to hear what was said, but did not wear a hearing aid
5☐ e. Unable to hear at all

14.04. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a quiet room?

[other_person_conversation] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to hear what was said without a hearing aid
2☐ b. Able to hear what was said with a hearing aid
3☐ c. Unable to hear what was said even with a hearing aid
4☐ d. Unable to hear what was said, but did not wear a hearing aid
5☐ e. Unable to hear at all

14.05. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you?

[un_own_langauge] [int] *[1, 2, 3, 4]*

1☐ a. Able to be understood completely
2☐ b. Able to be understood partially
3☐ c. Unable to be understood
4☐ d. Unable to speak at all

14.06. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well?

[un_other_langauge] [int] *[1, 2, 3, 4]*

1☐ a. Able to be understood completely.
2☐ b. Able to be understood partially.
3☐ c. Unable to be understood.
4☐ d. Unable to speak at all.

14.07. Which one of the following best describes how you have been feeling during the past 4 weeks?

[feeling] [int] *[1, 2, 3, 4, 5]*

1☐ a. Happy and interested in life
2☐ b. somewhat happy
3☐ c. somewhat unhappy
4☐ d. Very unhappy
5☐ e. So unhappy that life was not worthwhile

14.08. Which one of the following best describes the pain and discomfort you have experienced during the past 4 weeks?

[discomfort_exp] [int] *[1, 2, 3, 4, 5]*

1☐ a. Free of pain and discomfort
2☐ b. Mild to moderate pain or discomfort that prevented no activities.
3☐ c. Moderate pain or discomfort that prevented a few activities
4☐ d. Moderate to severe pain or discomfort that prevented some activities
5☐ e. Severe pain or discomfort that prevented most activities

14.09. Which one of the following best describes your ability, during the past 4 weeks, to walk? (Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches, or a walker.)

[to_walk] [int] *[1, 2, 3, 4, 5, 6]*

1☐ a. Able to walk around the neighborhood without difficulty, and without walking equipment
2☐ b. Able to walk around the neighborhood with difficulty; but did not require walking equipment or the help of another person
3☐ c. Able to walk around the neighborhood with walking equipment, but without the help of another person
4☐ d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood
5☐ e. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood
6☐ f. Unable to walk at all

14.10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers? (Note: Special tools refer to hooks for buttoning clothes, gripping devices for opening jar or lifting small items, and other devices to compensate for limitations of hand or fingers.)

[hands_finger] [int] *[1, 2, 3, 4, 5, 6]*

1☐ a. Full use of hands and ten fingers
2☐ b. Limitations in the use of hand or fingers, but did not require special tools or the help of another person
3☐ c. Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person)
4☐ d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools)
5☐ e. Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools)
6☐ f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)

14.11. Which one of the following best describes your ability, during the past 4 weeks, to remember things?

[remember_things] [int] *[1, 2, 3, 4]*

1☐ a. Able to remember most things
2☐ b. Somewhat forgetful
3☐ c. Very forgetful
4☐ d. Unable to remember anything at all

14.12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems?

[think_solve] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to think clearly and solve day to day problems
2☐ b. Had a little difficulty when trying to think and solve day to day problems
3☐ c. Had some difficulty when trying to think and solve day to day problems
4☐ d. Had great difficulty when trying to think and solve day to day problems
5☐ e. Unable to think or solve day to day problems

14.13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities?

[basic_activity] [int] *[1, 2, 3, 4]*

1☐ a. Eat, bathe, dress and use the toilet normally
2☐ b. Eat, bathe, dress and use the toilet independently with difficulty
3☐ c. Required mechanical equipment to eat, bathe, dress or use the toilet independently
4☐ d. Required the help or another person to eat, bathe, dress or use the toilet

14.14. Which one of the following best describes how you have been feeling during the past 4 weeks?

[feeling_health_utility] [int] *[1, 2, 3, 4]*

1☐ a. Generally happy and free from worry
2☐ b. occasionally fretful, angry, irritable, anxious or depressed
3☐ c. often fretful, angry, irritable, anxious or depressed
4☐ d. extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help

14.15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks?

[discomfort_health_utility] [int] *[1, 2, 3, 4, 5]*

1☐ a. Free of pain and discomfort
2☐ b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities
3☐ c. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities
4☐ d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief
5☐ e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities

15. Processes of Care

In the past 12 months, how often did the following occur (EXCLUDE current visit):

		Indicate number	Month of last visit/test/exam (MMM/yyyy)	
15.01	Clinic Visits [fpc_clinic_visit_indicate_no] [int(11)] [fpc_clinic_visit_month_of_visit] [varchar(15)] [fpc_clinic_visit_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.02	HbA1c testing [fpc_hba_testing_indicate_no] [int(11)] [fpc_hba_testing_month_of_visit] [varchar(15)] [fpc_hba_testing_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.03	Cholesterol Testing [fpc_cholestrol_testing_indicate_no] [int(11)] [fpc_cholestrol_testing_month_of_visit] [varchar(15)] [fpc_cholestrol_testing_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.04	Foot Exam at clinic [fpc_foot_exam_indicate_no] [int(11)] [fpc_foot_exam_month_of_visit] [varchar(15)] [fpc_foot_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.05	Eye Exam [fpc_eye_exam_indicate_no] [int(11)] [fpc_eye_exam_month_of_visit] [varchar(15)] [fpc_eye_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown

Commented [r37]: The dates for the below listed variables are generated by the system in YY-MMM format:
[fpc_clinic_visit_month_of_visit]
[fpc_hba_testing_month_of_visit]
[fpc_cholestrol_testing_month_of_visit]
[fpc_foot_exam_unknown]
[fpc_eye_exam_month_of_visit]
[fpc_microal_check_month_of_visit]
[fpc_ecg_month_of_visit]
[fpc_dental_exam_month_of_visit]
[fpc_dietician_visit_month_of_visit]

Commented [CR38]: For Q.Nos. 15.01 – 15.09 , specify Indicate number, Month of last visit & unknown
If response is [unknown] data is saved as '-1'

15.06	Microalbuminuria check [fpc_microal_check_indicate_no] [int(11)] [fpc_microal_check_month_of_visit] [varchar(15)] [fpc_microal_check_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.07	ECG [fpc_ecg_indicate_no] [int(11)] [fpc_ecg_month_of_visit] [varchar(15)] [fpc_ecg_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.08	Dental Exam [fpc_dental_exam_indicate_no] [int(11)] [fpc_dental_exam_month_of_visit] [varchar(15)] [fpc_dental_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.09	Dietician/Diabetes Education [fpc_dietician_visit_indicate_no] [int(11)] [fpc_dietician_visit_month_of_visit] [varchar(15)] [fpc_dietician_visit_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown

15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care? ____
[other_doctors_count] [int(11)]

On average:

15.11 Total time spend commuting to clinic – ONE WAY _____ min
[time_commuting] [int(11)]

15.12 Total time spend for lab tests, include waiting (if done same day) _____ min
[lab_test] [int(11)]

15.13 Total time spend waitingfor consultation _____ min
[wait_consult] [int(11)]

15.14 Total time spend in-person with doctor _____ min
[in_person_doc] [int(11)]

15.15 Total time with dietician, nurse or clinic-staff receiving self-care education _____ min
[self_care_edu] [int(11)]

15.16 Other time for check-out, getting medications, etc (at end of visit) _____ min
[other_time] [int(11)]

15.17 What type of reminders do you receive from the clinic for your care? (check all that apply)
[type_of_reminder] [varchar (20)]

1 [ ] Verbal reminder for next visit, referral, or lab investigation (at current visit)
2 [ ] Written reminder for next visit, referral or lab investigation (at current visit)
3 [ ] Phone call for upcoming appointment (clinic or referral)
4 [ ] Phone call if missed appointment (clinic or referral)
5 [ ] Phone call to go for lab investigations
6 [ ] Mailing for upcoming appointment (clinic or referral)
7 [ ] Mailing for missed appointment (clinic or referral)
8 [ ] Mailing to go for lab investigations
9 [ ] other, specify: _____
[other_reminder] [varchar (20)]

16. Costs of Care

16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR:

Outpatient visits? Inpatient care?

_____% Out-of-pocket _____% Out-of-pocket

[out_of_pocket_opd] [double]
_____% Employer Insurance
[employer_insurance_opd] [double]
_____% Private Insurance
[private_insurance_opd] [double]
_____% Government insurance, non-job based
[govt_insurance_opd] [double]
_____% Other, please specify: _____
[other_opd] [double]
[other_details_opd] [varchar(200)]
= 100 % total

[out_of_pocket_ipd] [double]
_____% Employer Insurance
[employer_insurance_ipd] [double]
_____% Private Insurance
[private_insurance_ipd] [double]
_____% Government insurance, non-job based
[govt_insurance_ipd] [double]
_____% Other, please specify: _____
[other_ipd] [double]
[other_details_ipd] [varchar(200)]
=100 % total

OUTPATIENT CARE

Please respond to the following questions regarding outpatient care you received for diabetes in the previous 1 year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization.
EXCLUDE current visit.

16.02 How many outpatient visits did you make in the past 1 year (exclude current visit)? _____ times
[out_patient_visit] [int(11)]

16.03 How many days, including half days, did you miss from work for outpatient visits in the past 1 year? _____ days [ ] N/A
[days_miss_work] [int(11)]
[days_miss_work_na] [int(11)] *[1]*

16.04 List all persons who accompanied you to outpatient visits in the past 1 year:
This data is in file "patient_accompained _visit" & is in long format

Person Relation (e.g. father) [person_relation]	Occupation (number*) [occupation]	Monthly salary [monthly_salary]	Number visits accompanied [number_of_visit]

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

Please list the costs incurred in the past year in relation to outpatient visits:

	Item	Number of times	Average cost One-time (Rupees)
16.05	Consultation Fee [con_fee_frq] [int(11)] [avg_con_fee] [double]		
16.06	Lab Tests (HbA1c, blood glucose, urine check) [lab_test_frq] [int(11)] [avg_lab_test] [double]		
16.05	Eye Exam [eye_eam_frq] [int(11)] [avg_eye_exam] [double]		
16.06	ECG [ecg_frq] [int(11)] [avg_ecg_fee] [double]		
16.07	Medicines (tablets, insulin) [med_frq] [int(11)] [avg_med_fee] [double]		

Commented [CR39]: One more variable available for questions 16.05 to 16.12 "Total cost" and values also stored for this variable

16.08	Supplies (including glucose strips, gauze, sterile solution, etc.) [supply_frq] [int(11)] [avg_supply_fee] [double]		
16.09	Transportation [transport_frq] [int(11)] [avg_transport] [double]		
16.10	Food (personal) [food_personal_frq] [int(11)] [avg_food_personal] [double]		
16.11	Additional cost for escort(s) (e.g. food) [escorts_freq] [int(11)] [avg_escorts] [double]		
16.12	Other out-of-pocket expenses [outpocket_frq] [int(11)] [avg_outpocket_exp] [double]		

INPATIENT CARE

Please respond to the following questions regarding inpatient care you received FOR DIABETES-RELATED COMPLICATIONS* in the previous 1 year. Inpatient care is all instances of medical care that required you to stay in hospital or emergency room.

*chest pain, heart attack, stroke, infection, foot/leg problems, eye problems, kidney problems, blood sugar problem (too high/too low), etc. IF unsure that event is a diabetes-related complication, INCLUDE in listing.

16.13 How many Hospitalizations or Emergency Room visits for diabetes-related complications in the past 1 year? _____ times
[hospital_emergency] [int(11)]

16.14 For each of these Hospitalization or Emergency Room Visit, provide details below – (Make sure that visits listed below equals total number listed in 16.13)
When providing time, include half-days. This data is in file "patient_hospitalization_visit" & is in long format

	TYPE 1= Hospitalization, NO surgery 2= Surgery 3= Emergency Room [reason]	Days of stay [duration]	Hospital Cost including medicine/ supplies (total stay) **[hospital_cost]**	Transportation Cost, including ambulance fees (total stay) **[transport]**	Food Cost **[food_cost]**	Additional Escort(s) Cost **[escorts_cost]**	Person(s) accompanied (Escort) – list all			
							Relation **[person_accompained]**	Occupation (number*) **[occupation]**	Monthly Salary **[monthly_salary]**	Days accompanied **[days_person_accompained]**
1										
2										
3										
4										

5										
6										

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

17. Other Contacts

This data is confidential

Please list 2 contacts who do not live with you and would know where and how we can contact you.

***mandatory fields**

17.01	**Contact 1**
Name	First:*
	Middle:
	Last:*
Mailing Address	Address 1:*
	Address 2:
	City:*
	Pin code:* __ __ __ __ __ __
	State:*
Mobile*	91 - __ __ __ __ __ __ __ __ __ __
Phone 2	_____ - _____
Email ID	
Relation (e.g. father, friend) *	

17.02	**Contact 2**
Name	First:*
	Middle:
	Last:*
Mailing Address	Address 1:*
	Address 2:
	City:*
	Pin code:* __ __ __ __ __ __
	State:*
Mobile*	91 - __ __ __ __ __ __ __ __ __ __
Phone 2	_____ - _____
Email ID	
Relation (e.g. father, friend) *	

18. Care Coordinator/Research Officer Signature

18.01 Name: _____ Signature: _____

18.02 Date Signed: __ __ / __ __ __ / __ __ __ __

18.03 DSS Instructions:

(1) Enroll patient in DSS → Login. Select **Enroll patient** from left panel. Enter information and click on **Enroll** at bottom of page.

(2) Enter rest of Forms B and Form C in eCRFs found on patient main page.

- **FORM E – Follow-up 12 monthly_All**
  - All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)**
  - Place cross [X] in the appropriate boxes. Write number in spaces (f none, write 0)
  - See *Form Completion Notes*, for definitions and explanations
  - Store copies of available source documents (SD), where indicated, in patient's trial folder

PART 1: To be completed by CARE COORDINATOR or RESEARCH OFFICER

Data entry by:
[data_entry_by] [varchar (100)]
Initials _____
DATE entered: ___ /_____ /_____

Screening ID: S __ __ __ __ __

Participant ID: _____
[participant_id] [varchar (20)]

Date of Visit (dd/MMM/yyyy): __ __ / __ __ __ / __ __ __ __
[date_of_visit] [date]

FORM E – Data saved in "patient_forme.csv" and is in long format

1. Intake

A1.01	Complaints/Update: [complaints] [varchar(500)]	
1.02-1.04 For intervention group/care coordinator only:		
A1.02	Number of severe hypoglycemic episodes since last visit (If present, **complete Form X**) [severe_hg_count] [int(11)]	
A1.03	Number of mild hypoglycemic episodes since last visit [mild_hg_count] [int(11)]	
A1.04	Other SAE since last visit (If present, **complete Form X** with investigator) [other_sae] *Yes=1, No=2*	[ ]Y [ ]N

2. Measures

B1.02	Heart rate [heart_rate] [int(11)]	__ __ __ (beats/min)
B1.03	Blood pressure 2nd reading [blood_pressure_h_1] [int(11)] / [blood_pressure_l_1] [int(11)]	__ __ __ /__ __ (mmHg)
B1.04	Blood pressure 3rd reading [blood_pressure_h_2] [int(11)] / [blood_pressure_l_2] [int(11)]	__ __ __ /__ __ (mmHg)
B1.06	Waist circumference [waist_circumference] [double]	__ __ __ (cm)
B1.07	Weight [weight] [double]	__ __ (kg)

3. Investigations

B2.04	Hemoglobin A1c [hemoglobin_a1c] [double]	__ __ . __ %	Date: __ __ / __ __ __ / __ __ __ __ [hemoglobin_a1c_date] [date]
B2.10	Fasting blood glucose (venous) [fasting_blood_glucose_mgdl] [double]	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [fasting_blood_glucose_date] [date]
B2.13	Post-prandial blood glucose (venous) **– optional**	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [post_prandial_blood_glu_date] [date]

	[post_prandial_blood_glu] [double]		
B2.05	ALT **– optional** [alt] [double]	__ __ __ (units/L)	Date: __ __ / __ __ __ / __ __ __ __ [alt_date] [date]
A2.06	Total Cholesterol [total_cholesterol] [double]	__ __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [total_cholesterol_date] [date]
B2.07	HDL Cholesterol [hdl_cholesterol] [double]	__ __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [hdl_cholesterol_date] [date]
B2.08	LDL Cholesterol (indirect) [ldl_cholesterol] [double]	__ __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [ldl_cholesterol_date] [date]
B2.09	Triglycerides [triglycerides] [double]	__ __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [triglycerides_date] [date]
B2.02	Sodium **– optional** [sodium] [double]	__ __ __ (mEq/L)	Date: __ __ / __ __ __ / __ __ __ __ [sodium_date] [date]
B2.03	Potassium **– optional** [potassium] [double]	__ __ __ (mEq/L)	Date: __ __ / __ __ __ / __ __ __ __ [potassium_date] [date]
B2.01	Creatinine [creatinine_mg] [double]	__ __ . __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [creatinine_date] [date]
B2.12	Albumin:creatinine ratio [s_albumin_mg] [double]	__ __ __ . __ (mg/g)	Date: __ __ / __ __ __ / __ __ __ __ [s_albumin_date] [date]

11. Self-Care - Data saved in "patient_selfcare_e.csv" &"patient_selfcare_form_e.csv" files & they are in wide format and long formats

Commented [CR1]: In Self-care section data is saved in 2 files
1. "patient_self_care_e.csv " &
2 ." patient_selfcare_form_e.csv and unique ID is "self_care_id "

The questions below ask you about your diabetes self-care activities **during the past 7 days**.
If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET		
11.01	**On average, over the past month, how many DAYS PER WEEK have you followed your diet plan?** [self_care_id=2] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.02	On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables? [self_care_id=3] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.03	On how many of the last SEVEN DAYS did you eat high fat foods such as fried items or full-fat dairy products? [self_care_id=4] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.04	On how many of the last SEVEN DAYS did you space eating meals evenly through the day? [self_care_id=5] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
EXERCISE		
11.05	**On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)** [self_care_id=6] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.06	On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work? [self_care_id=7] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7

BLOOD SUGAR TESTING		
11.07	**Are you testing your blood sugar as recommended by your health care provider?** [self_care_id=9] [int(11)] *[Yes 1, No 0, N/A -1]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A (skip to 11.09)
11.08	On how many of the last SEVEN DAYS did you test your blood sugar? [self_care_id=8] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
MEDICATIONS		
11.09	**On how many of the last SEVEN DAYS, did you take your recommended diabetes medication? (pills and/or insulin)** [self_care_id=10] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
FOOT CARE		
11.10	On how many of the last SEVEN DAYS did you check your feet? [self_care_id=11] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
TOBACCO		
11.11	**Ever smoke regularly?** (most days of the week) [self_care_id=12] [int(11)] *[never 0, quit 1, Yes 2]* [if quit 1] → [quit_smoking_year] [varchar(20)] [if yes 2] → [smoke_per_day] [int(11)]	0 [ ] Never 1 [ ] Quit: __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # smoked per day: ___
11.12	**Ever chew tobacco regularly?** (most days of the week) [self_care_id=13] [int(11)] *[never 0, quit 1, Yes 2]* [if quit 1] → [quit_tobacco_year] [varchar(20)] [if yes 2] → [packet_per_day] [int(11)]	0 [ ] No 1 [ ] Quit __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # packets per day:
11.13	If you smoke or chew tobacco, at your last doctor's visit, did anyone counsel you about stopping or refer you to counseling? [self_care_id=14] [int(11)] *[N/A 0, Yes 1, no 2]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A
ALCOHOL		
11.14	**Drink alcohol regularly?** (at least once a week for most weeks in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [self_care_id=15] [int(11)] *[never 0, Yes 1]* [if yes 1] → [drink_per_day] [int(11)]	0 [ ] No 1 [ ] Yes, # drinks per day: ____
STRESS		
11.15	**How often do you feel stress (from work, responsibilities, etc)?** [ ] daily [ ] few times a week [ ] few times a month [ ] never [self_care_id=16] [int(11)] *[daily 1, few times a week 2, few times a month 3, never 4]*	
11.16	How are you coping with stress? [ ] very well [ ] moderate [ ] with difficulty [ ] not applicable (no stress) [self_care_id=17] [int(11)] *[very well 1, moderate 2, with difficulty 3, not applicable(no stress) 4]*	

Commented [CR2]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day

Commented [CR3]: If the response is [quit 1] specify the year & response is [yes 2] specify no. packet per day

Commented [CR4]: If the response is [yes 1] specify no. drink per day

Commented [CR5]: Responses at backend for this variable are saved as [0 1 2 3 4]
but , there is no category for '0'

Commented [CR6]: Responses at backend for this variable are saved as [0 1 2 3 4]
but , there is no category for '0'

10. **Lifestyle** – Data is saved in "patient_life_style.csv" and is wide format

10.05	**Diet** (weekday/ routine day)	Meal 1	Meal 2	Meal 3	Meal 4	Meal 5	Meal 6
	Meal Time (approximate)	[meal1_ampm] [varchar(6)] *[AM or PM]* :__ amPm [meal1_time] [varchar(5)]	[meal2_ampm] [varchar(6)] *[AM or PM]* :__ amPm [meal2_time] [varchar(5)]	[meal3_ampm] [varchar(6)] *[AM or PM]* :__ amPm [meal3_time] [varchar(5)]	[meal4_ampm] [varchar(6)] *[AM or PM]* :__ amPm [meal4_time] [varchar(5)]	[meal5_ampm] [varchar(6)] *[AM or PM]* :__ amPm [meal5_time] [varchar(5)]	[meal6_ampm] [varchar(6)] *[AM or PM]* :__ amPm [meal6_time] [varchar(5)]
	Type B=breakfast, L=lunch, D=dinner, S=snack	[meal1_type] [varchar(6)]	[meal2_type] [varchar(6)]	[meal3_type] [varchar(6)]	[meal4_type] [varchar(6)]	[meal5_type] [varchar(6)]	[meal6_type] [varchar(6)]

Commented [CR7]: Should specify [AM or PM]

Commented [CR8]: Should specify time of the meal

Commented [CR9]: Should specify type of meal i.e., B=breakfast, L=lunch, D=dinner, S=snack

10.04	**Physical Activity (in leisure time) in average week**	*Days per week*	*Total time per day*	
			Hour(s)	*Minutes*
	Vigorous	[pa_vigorous_days_per_week] [int(11)]	[pa_vigorous_total_hr] [int(11)]	[pa_vigorous_total_min] [int(11)]
	Moderate	[pa_moderate_days_per_week] [int(11)]	[pa_moderate_total_hr] [int(11)]	[pa_moderate_total_min] [int(11)]
	Mild (Walking)	[pa_walking_days_per_week] [int(11)]	[pa_walking_total_hr] [int(11)]	[pa_walking_total_min] [int(11)]

12. **EQ-5D -** Data saved in **"eq_5d.csv"** and is in wide format

Place a tick in one box in each group below for the statement that best describes your own health state today.

12.01 Mobility *[I have no problems in walking about 1, I have some problems in walking about 2,*
[mobility_id] [int (11)] *I am confined to bed 3]*

1 ☐ I have no problems in walking about
2 ☐ I have some problems in walking about
3 ☐ I am confined to bed

12.02 Self-Care *[I have no problems with self-care 1, I have some problems with self-care 2,*
[self_care_id] [int(11)] *I am unable to wash or dress myself 3]*

1 ☐ I have no problems with self-care
2 ☐ I have some problems with self-care
3 ☐ I am unable to wash or dress myself

12.03 Usual Activities (e.g. work, study, housework, family or leisure activities)
[usual_activities] [int(11)] *[I have no problems with performing my usual activities 1,*
I have some problems with performing my usual activities 2,
I am unable to perform my usual activities 3]

1 ☐ I have no problems with performing my usual activities
2 ☐ I have some problems with performing my usual activities
3 ☐ I am unable to perform my usual activities

12.04 Pain/Discomfort

[pain_discomfort] [int(11)] *[I have no pain or discomfort 1, I have moderate pain or discomfort 2, I have extreme pain or discomfort 3]*

1 ☐ I have no pain or discomfort
2 ☐ I have moderate pain or discomfort
3 ☐ I have extreme pain or discomfort

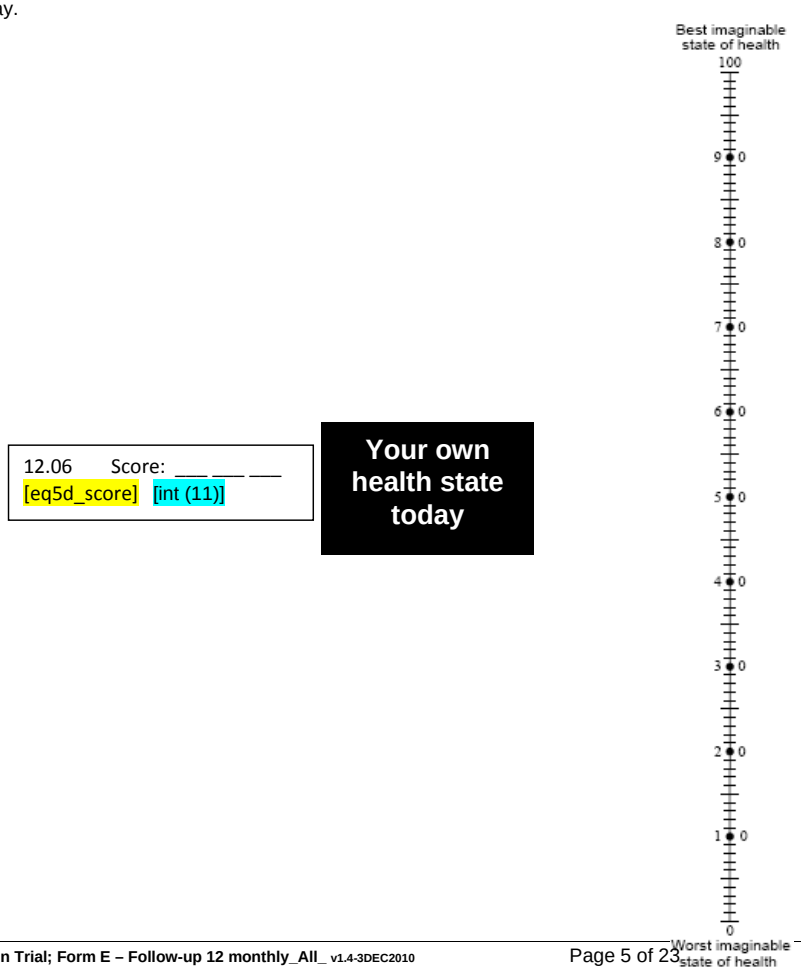
12.05 Anxiety/Depression

[anxiety_depression] [int(11)] *[I am not worried or depressed 1; I am moderately anxious or depressed 2, I am extremely anxious or depressed 3]*

1 ☐ I am not worried or depressed
2 ☐ I am moderately anxious or depressed
3 ☐ I am extremely anxious or depressed

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

I would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.



13. Diabetes Treatment Satisfaction

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer each question by marking a number on every scale.

13.01 How satisfied are you with your current treatment?
[current_treatment] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.02 How often have you felt that your blood sugars have been unacceptability high recently?
[blood_sugar_high] [int] *[0, 1, 2, 3, 4, 5, 6]*

Most of the time — None of the time

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.03 How often have you felt that your blood sugars have been unacceptability low recently?
[blood_sugar_low] [int] *[0, 1, 2, 3, 4, 5, 6]*

Most of the time — None of the time

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.04 How convenient have been finding your treatment to be recently?
[convienent_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very convenient — Very inconvenient

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.05 How flexible have you been finding your treatment to be recently?
[flexible_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very flexible — Very inflexible

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.06 How satisfied are you with understanding of your diabetes?
[understand_dibetes] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.07 How satisfied would you be to continue with your present form of diabetes treatment?
[present_dib_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.08 Would you recommend this form of treatment to someone else?
[recommend_form] [int] *[0, 1, 2, 3, 4, 5, 6]*

Yes, I would definitely recommend this treatment — No, I would definitely NOT recommend this treatment

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

14. Health Utilities Index

This next questionnaire asks about aspects of your health. When answering these questions please think about your health and your ability to do things everyday in the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Focus your answers on your overall abilities, disabilities and how you felt during the past 4 weeks.

You may feel that some questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar, but please answer each question independently.

Please read each question and consider answers carefully. For each question, select one answer that best describes your level of ability or disability during the past 4 weeks. Select the answer by checking the box. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities/ feelings.

14.01. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint?

[ordinary_news_print] [int] *[1, 2, 3, 4]*

1☐ a. Able to see well enough without glasses or contact lenses
2☐ b. Able to see well enough with glasses or contact lenses
3☐ c. Unable to see well enough even with glasses or contact lenses
4☐ d. Unable to see at all

14.02. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street?

[recognize_friend] [int] *[1, 2, 3, 4]*

1☐ a. Able to see well enough without glasses or contact lenses
2☐ b. Able to see well enough with glasses or contact lenses
3☐ c. Unable to see well enough even with glasses or contact lenses
4☐ d. Unable to see at all

14.03. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people?

[group_conversation] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to hear what was said without a hearing aid
2☐ b. Able to hear what was said with a hearing aid
3☐ c. Unable to hear what was said even with a hearing aid.
4☐ d. Unable to hear what was said, but did not wear a hearing aid
5☐ e. Unable to hear at all

14.04. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a quiet room?

[other_person_conversation] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to hear what was said without a hearing aid
2☐ b. Able to hear what was said with a hearing aid
3☐ c. Unable to hear what was said even with a hearing aid
4☐ d. Unable to hear what was said, but did not wear a hearing aid
5☐ e. Unable to hear at all

14.05. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you?

[un_own_langauge] [int] *[1, 2, 3, 4]*

1☐ a. Able to be understood completely
2☐ b. Able to be understood partially
3☐ c. Unable to be understood
4☐ d. Unable to speak at all

14.06. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well?

[un_other_langauge] [int] *[1, 2, 3, 4]*

1☐ a. Able to be understood completely.
2☐ b. Able to be understood partially.
3☐ c. Unable to be understood.
4☐ d. Unable to speak at all.

14.07. Which one of the following best describes how you have been feeling during the past 4 weeks?

[feeling] [int] *[1, 2, 3, 4, 5]*

1☐ a. Happy and interested in life
2☐ b. somewhat happy
3☐ c. somewhat unhappy
4☐ d. Very unhappy
5☐ e. So unhappy that life was not worthwhile

14.08. Which one of the following best describes the pain and discomfort you have experienced during

the past 4 weeks?

[discomfort_exp] [int] *[1, 2, 3, 4, 5]*

1☐ a. Free of pain and discomfort
2☐ b. Mild to moderate pain or discomfort that prevented no activities.
3☐ c. Moderate pain or discomfort that prevented a few activities
4☐ d. Moderate to severe pain or discomfort that prevented some activities
5☐ e. severe pain or discomfort that prevented most activities

14.09. Which one of the following best describes your ability, during the past 4 weeks, to walk? (Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches, or a walker.)

[to_walk] [int] *[1, 2, 3, 4, 5, 6]*

1☐ a. Able to walk around the neighborhood without difficulty, and without walking equipment
2☐ b. Able to walk around the neighborhood with difficulty; but did not require walking equipment or the help of another person
3☐ c. Able to walk around the neighborhood with walking equipment, but without the help of another person
4☐ d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood
5☐ e. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood
6☐ f. Unable to walk at all

14.10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers? (Note: Special tools refer to hooks for buttoning clothes, gripping devices for opening jar or lifting small items, and other devices to compensate for limitations of hand or fingers.)

[hands_finger] [int] *[1, 2, 3, 4, 5, 6]*

1☐ a. Full use of hands and ten fingers
2☐ b. Limitations in the use of hand or fingers, but did not require special tools or the help of another person
3☐ c. Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person)
4☐ d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools)
5☐ e. Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools)
6☐ f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)

14.11. Which one of the following best describes your ability, during the past 4 weeks, to remember things?

[remember_things] [int] *[1, 2, 3, 4]*

1☐ a. Able to remember most things
2☐ b. Somewhat forgetful
3☐ c. Very forgetful
4☐ d. Unable to remember anything at all

14.12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems?

[think_solve] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to think clearly and solve day to day problems
2☐ b. Had a little difficulty when trying to think and solve day to day problems
3☐ c. Had some difficulty when trying to think and solve day to day problems
4☐ d. Had great difficulty when trying to think and solve day to day problems
5☐ e. Unable to think or solve day to day problems

14.13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities?

[basic_activity] [int] *[1, 2, 3, 4]*

1☐ a. Eat, bathe, dress and use the toilet normally
2☐ b. Eat, bathe, dress and use the toilet independently with difficulty
3☐ c. Required mechanical equipment to eat, bathe, dress or use the toilet independently
4☐ d. Required the help or another person to eat, bathe, dress or use the toilet

14.14. Which one of the following best describes how you have been feeling during the past 4 weeks?
[feeling_health_utility] [int] *[1, 2, 3, 4]*
1☐ a. Generally happy and free from worry
2☐ b. occasionally fretful, angry, irritable, anxious or depressed
3☐ c. often fretful, angry, irritable, anxious or depressed
4☐ d. extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help

14.15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks?
[discomfort_health_utility] [int] *[1, 2, 3, 4, 5]*
1☐ a. Free of pain and discomfort
2☐ b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities
3☐ c. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities
4☐ d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief
5☐ e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities

15&16. Frequency & Costs of Care

Please respond to the following questions regarding **outpatient** care you received in the previous **12 months.** Outpatient care is all instances of clinic visits that did not necessitate hospitalization. **(Exclude current visit)**

		Indicate number	Month of last visit/test/exam (MMM/yyyy)	
15.01	Clinic Visits [fpc_clinic_visit_indicate_no] [int(11)] [fpc_clinic_visit_month_of_visit] [varchar(15)] [fpc_clinic_visit_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.02	HbA1c testing [fpc_hba_testing_indicate_no] [int(11)] [fpc_hba_testing_month_of_visit] [varchar(15)] [fpc_hba_testing_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.03	Cholesterol Testing [fpc_cholestrol_testing_indicate_no] [int(11)] [fpc_cholestrol_testing_month_of_visit] [varchar(15)] [fpc_cholestrol_testing_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.04	Foot Exam at clinic [fpc_foot_exam_indicate_no] [int(11)] [fpc_foot_exam_month_of_visit] [varchar(15)] [fpc_foot_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.05	Eye Exam [fpc_eye_exam_indicate_no] [int(11)] [fpc_eye_exam_month_of_visit] [varchar(15)] [fpc_eye_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.06	Microalbuminuria check		__ __ __ / __ __ __ __	[ ]unknown

Commented [r10]: The day (DD) for the below listed variables are correct and are auto generated by the system and therefore the date is in DD-MMM-YY format:
[fpc_clinic_visit_month_of_visit]
[fpc_hba_testing_month_of_visit]
[fpc_cholestrol_testing_month_of_visit]
[fpc_foot_exam_unknown]
[fpc_eye_exam_month_of_visit]
[fpc_microal_check_month_of_visit]
[fpc_ecg_month_of_visit]
[fpc_dental_exam_month_of_visit]
[fpc_dietician_visit_month_of_visit]

Commented [CR11]: For Q.Nos. 15.01 – 15.09 , specify Indicate number, Month of last visit & unknown
If response is [unknown] data is saved as '-1'

	[fpc_microal_check_indicate_no] [int(11)] [fpc_microal_check_month_of_visit] [varchar(15)] [fpc_microal_check_unknown] [int(11)] *[-1]*			
15.07	ECG [fpc_ecg_indicate_no] [int(11)] [fpc_ecg_month_of_visit] [varchar(15)] [fpc_ecg_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.08	Dental Exam [fpc_dental_exam_indicate_no] [int(11)] [fpc_dental_exam_month_of_visit] [varchar(15)] [fpc_dental_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.09	Dietician/Diabetes Education [fpc_dietician_visit_indicate_no] [int(11)] [fpc_dietician_visit_month_of_visit] [varchar(15)] [fpc_dietician_visit_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown

16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR:

Outpatient visits?

_____% Out-of-pocket
[out_of_pocket_opd] [double]
_____% Employer Insurance
[employer_insurance_opd] [double]
_____% Private Insurance
[private_insurance_opd] [double]
_____% Government insurance, non-job based
[govt_insurance_opd] [double]
_____% Other, please specify: _____
[other_opd] [double]
[other_details_opd] [varchar(200)]
= 100 % total

Inpatient care?

_____% Out-of-pocket
[out_of_pocket_ipd] [double]
_____% Employer Insurance
[employer_insurance_ipd] [double]
_____% Private Insurance
[private_insurance_ipd] [double]
_____% Government insurance, non-job based
[govt_insurance_ipd] [double]
_____% Other, please specify: _____
[other_ipd] [double]
[other_details_ipd] [varchar(200)]
=100 % total

OUTPATIENT CARE

Please respond to the following questions regarding outpatient care you received for diabetes in the previous **1 year**. Outpatient care is all instances of clinic visits that did not necessitate hospitalization.
EXCLUDE current visit.

Please respond to the following questions regarding outpatient care you received for diabetes in the previous 1 year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization.
EXCLUDE current visit.

16.02 How many outpatient visits did you make in the past 1 year (exclude current visit)? _____ times
[out_patient_visit] [int(11)]

16.03 How many days, including half days, did you miss from work for outpatient visits in the past 1 year? _____ days [ ] N/A
[days_miss_work] [int(11)]
[days_miss_work_na] [int(11)] *[1]*

16.04 List all persons who accompanied you to outpatient visits in the past 1 year:

Person Relation (e.g. father)	Occupation (number*)	Monthly salary	Number visits accompanied

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

Please list the costs incurred in the past year in relation to outpatient visits:

	Item	Number of times	Average cost One-time (Rupees)
16.05	Consultation Fee [con_fee_frq] [int(11)] [avg_con_fee] [double]		
16.06	Lab Tests (HbA1c, blood glucose, urine check) [lab_test_frq] [int(11)] [avg_lab_test] [double]		
16.05	Eye Exam [eye_eam_frq] [int(11)] [avg_eye_exam] [double]		
16.06	ECG [ecg_frq] [int(11)] [avg_ecg_fee] [double]		
16.07	Medicines (tablets, insulin) [med_frq] [int(11)] [avg_med_fee] [double]		
16.08	Supplies (including glucose strips, gauze, sterile solution, etc.) [supply_frq] [int(11)] [avg_supply_fee] [double]		
16.09	Transportation [transport_frq] [int(11)] [avg_transport] [double]		
16.10	Food (personal) [food_personal_frq] [int(11)] [avg_food_personal] [double]		
16.11	Additional cost for escort(s) (e.g. food) [escorts_freq] [int(11)] [avg_escorts] [double]		
16.12	Other out-of-pocket expenses [outpocket_frq] [int(11)] [avg_outpocket_exp] [double]		

Commented [CR12]: For Q.no 16.05 to 16.12 [frq] indicates "Number of times" & [avg] indicates "Average cost"

INPATIENT CARE

Please respond to the following questions regarding inpatient care you received FOR DIABETES-RELATED COMPLICATIONS* in the previous 1 year. Inpatient care is all instances of medical care that required you to stay in hospital or emergency room.

*chest pain, heart attack, stroke, infection, foot/leg problems, eye problems, kidney problems, blood sugar problem (too high/too low), etc. IF unsure that event is a diabetes-related complication, INCLUDE in listing.

16.13 How many Hospitalizations or Emergency Room visits for diabetes-related complications in the past 1 year? _____ times
[hospital_emergency] [int(11)]

16.14 For each of these Hospitalization or Emergency Room Visit, provide details below – (Make sure that visits listed below equals total number listed in 16.13)
When providing time, include half-days.

	TYPE 1= Hospitalization, NO surgery 2= Surgery 3= Emergency Room	Days of stay	Hospital Cost including medicine/ supplies (total stay)	Transportation Cost, including ambulance fees (total stay)	Food Cost	Additional Escort(s) Cost	Person(s) accompanied (Escort) – list all			
							Relation	Occupation (number*)	Monthly Salary	Days accompanied
1										
2										
3										
4										
5										
6										

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

18. Signature of Care Coordinator/Research Officer

18.01Name: _____ Signature: _____

18.02Date Signed: __ __ / __ __ __ / __ __ __ __

Instructions for Continuation (after completion of Form E Part 1)

[ ] **Attach Reports of ECG and Form G-Eye Exam.**

[ ] **Control Group**: Take participant to STUDY PHYSICIAN to complete PART 2 of Form E. After completion, enter Form E Parts 1 & 2 into eCRF. Include all source documents in patient's trial folder.

[ ] **Intervention Group:**

(1) Enter Form E Sections 1-4 into EHR-DSS (including update of contact information)
(2) Review patient medications. Update medication changes in writing on Form Z.
(3) Provide paper Form Z (with medication update) and rest of Form E Part 2 to STUDY PHYSICIAN during consultation with participant.
(4) Attach completed Form Z to this Form E. Update patient with information.
(5) After patient leaves, enter Form Z and rest of Form E in eCRF.
(6) Include all source documents in patient's trial folder.

PART 2: complete by STUDY PHYSICIAN

2. ECG and Eye Exam

May use results within past 1 month for ECG and Form G-Eye Exam (attach to end of this form). Otherwise, attempt to complete TODAY, or ensure that testing is done within 2 weeks of today's date. Update in paper and eCRF as soon as available. Retain copies of ECG and eye exam results as source documents.

ECG:

2.01	**ECG** Date: __ __ / __ __ __ / __ __ __ __ [s_ecg_date] [date]		
	☐ not available form within past month. Scheduled today. update below once results available.		
2.02	Q-waves diagnostic of previous MI [s_ecg_q_waves] [int(11)] *[Yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N
2.03	Left ventricular hypertrophy [s_ecg_left_ventricular] [int(11)] *[Yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N
2.04	Atrial Fibrillation [s_ecg_atrial] [int(11)] *[Yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N
2.05	Other arrhythmia [s_ecg_other_arrhythmia] [int(11)] *[Yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improve	2[ ] N

Commented [CR13]: This option is added in CRF

Commented [CR14]: Options (new or worsened & unchanged or improved) are not present at both front-end and back-end for Q.Nos 2.02 to 2.05

EYE EXAM:

May use results from past 1 month.

[ ] Attach Form G-Eye Exam to end of this Form E – to be completed by qualified ophthalmologist only. If not completed prior to this visit, schedule ophthalmologist appointment and ensure completion within 2 weeks. Enter results in eCRF (EYE EXAM) as soon as available.

12. Complications Update

In the past year, since the last baseline/annual visit, has the patient had any of the following:

		no/unsure	Yes, number	
	New/Worsening Blindness in either eye thought to be due to diabetes [h_eyes_blindbess] [int(11)] *[no/unsure 0,Right 1, Left 2, Both 3]*	[ ]	[ ] R [ ] L	Form X
	New/Worsening Glaucoma [h_eyes_glaucoma] [int(11)] *[no/unsure 0,Right 1, Left 2, Both 3]*	[ ]	[ ] R [ ] L	
	New/Worsening Cataract [h_eyes_cataract] [int(11)] *[no/unsure 0,Right 1, Left 2, Both 3]*	[ ]	[ ] R [ ] L	
	Cataract Surgery [h_eyes_cataract_surgery] [int(11)] *[no/unsure 0,Right 1, Left 2, Both 3]*	[ ]	[ ] R [ ] L	Form X
	Laser photocoagulation therapy [h_eyes_laser_therapy] *[no/unsure -1, Yes 1]*	[ ]	[eye_laser_therepy_lft] *[Right 1, Left 2]* [ ] R, ___	Form X

			[eye_laser_therepy_rgt_no] [ ] L, ___ [eye_laser_therepy_lft] [eye_laser_therepy_lft_no]	
	Other eye therapy [h_eyes_other_therapy] *[1 Yes,-1 No]*	[ ]	[ ], specify: [h_eyes_other_therapy_spcify]	Form X

In the past year, since the last baseline/annual visit, has the patient had any of the following:

		no/ unsure	Yes, number	
1.11	ACS: Myocardial Infarction or Unstable Angina [h_cardiovascular_acs] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [acs_num] [int(11)]	[ ]	[ ]____	Form X
1.12	Angioplasty (PCI) /Open-heart surgery (CABG) [h_cardiovascular_pci_cabg] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [pci_num] [int(11)]	[ ]	[ ]____	Form X
1.13	New/Worsened Stable Angina [stable_angina] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	Form X
1.14	Stroke (Ischemic or Hemorrhagic) or TIA [h_cardiovascular_stroke_tia] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [stroke_num] [int(11)]	[ ]	[ ]____	Form X
1.15	New/Worsened Arrhythmia (requiring med intervention) [h_cardiovascular_arrtythmia] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	Form X
1.16	New/Worsened Heart Failure [h_cardiovascular_heart_attack] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.28	New/Worsened Neuropathy – hands/feet [h_other_neuropathy_hands_feet] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	
1.29	New/Worsened Neuropathy – sexual:erectile dysfunction [h_other_neuropathy_sexual] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	
	New Amputation [foot_ampu_yesno] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [foot_ampu_num] [int(11)]	[ ]	[ ]____	Form X
1.18	Peripheral revascularization (angioplasty/ surgery) [h_peripheral_surgery] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [h_peripheral_surgery_year] [varchar(11)]	[ ]	[ ]____	Form X
1.19	Chronic leg/foot ulcer (6 weeks or more) – include current [h_peripheral_foot_ulcer] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [h_peripheral_foot_ulcer_year] [varchar(11)]	[ ]	[ ]____	[ ] if hosp/ER – Form X
1.43	Other Major Infection (hospitalization) [oth_maj_infec_yesno] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]____	Form X

Commented [CR15]: If the response for "h_cardiovascular_acs" is [Yes 1] specify Number

Commented [CR16]: If the response for "h_cardiovascular_pci_cabg" is [Yes 1] specify Number

Commented [CR17]: If the response for "h_cardiovascular_stroke_tia" is [Yes 1] specify Number

Commented [CR18]: If the response for "foot_ampu_yesno" is [Yes 1] specify Number

Commented [CR19]: If the response for "h_peripheral_surgery" is [Yes 1] specify Number

Commented [CR20]: If the response for "h_peripheral_foot_ulcer" is [Yes 1] specify Number

	[if Yes 1] → [oth_maj_infec_num] [int(11)]			
1.44	Minor Infection (NO hospitalization) [maj_inf_yesno] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [maj_inf_num] [int(11)]	[ ]	[ ]____	
1.33	New/Worsened Asthma [h_other_asthma] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.34	New/Worsened COPD (Chronic Bronchitis, Emphysema) [h_other_copd] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.35	New/Worsened Liver disease [h_other_liver_disease] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.36	New/Worsened Gallbladder disorder (stones, disease) [h_other_gallbladder_disorder] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.37	New/Worsened Hip Fracture/Replacement [h_other_hip_facture] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	Form X
1.38	New/Worsened Depression [h_other_depression] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.39	Severe HYPOglycemia (hospitalization/ER) [sever_hypoglycemia] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [sever_hypoglycemia_num] [int(11)]	[ ]	[ ] _____	Form X
	Mild HYPOglycemia [mild_hypoglycemia] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [mild_hypoglycemia_num] [int(11)]	[ ]	[ ] _____	
1.40	Other hospitalization for Diabetes	[ ]	[ ] _____	Form X
1.41	Other major health condition(s), hospitalizations, emergency room visits not listed above, specify: [oth_maj_health_cond] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ] _____	Form X
1.42	Total Number of Hospitalizations/emergency room visits from past year [no_of_time_hospitaiz] [int(11)]			

Commented [CR21]: If the response for "oth_maj_infec_yesno" is [Yes 1] specify Number

Commented [CR22]: If the response for "maj_inf_yesno" is [Yes 1] specify Number

Commented [CR23]: If the response for "sever_hypoglycemia" is [Yes 1] specify Number

Commented [CR24]: Need to check, This variable "mild_hypoglycemia" is not seen in front-end
But present in back-end
If the response for "mild_hypoglycemia" is [Yes 1] specify Number

Commented [CR25]: If the response is [If Yes 1] no. of times not found

Complete a Form X for all SAE events listed above. For each hospitalization/emergency room visit, document in source notes, when, where and why it was made. If available, include discharge summary as source document.

In the past year, since the last baseline/annual visit, has the patient had any of the following:

1.43	Out of ordinary severe muscle aches/pains [outof_ordinary_musclespain] [int(11)] *[Yes 1, No 2]*	[ ] N	[ ] Y, Obtain CPK
1.44	Medication side effects (i.e. cough from Ace-I, allergic reaction) [medic_side_effect] [int(11)] *[Yes 1, No 2]*	[ ] N	[ ] Y

3. Foot Exam

		Right Foot	Left Foot
3.01	Amputation [fe_amputation_right_foot] [int(11)] [fe_amputation_left_foot] [int(11)] *[N/A 1, toe 2, ray (metatarsal) 3, forefoot 4, foot 5, below knee 6, above knee 7]*	[ ] N/A [ ] toe [ ] ray (metatarsal) [ ] forefoot [ ] foot [ ] below the knee [ ] above the knee	[ ] N/A [ ] toe [ ] ray (metatarsal) [ ] forefoot [ ] foot [ ] below the knee [ ] above the knee
3.02	Appearance [fe_appearance_right_foot_normal]	1[ ] normal **2[ ] abnormal**, check	1[ ] normal **2[ ] abnormal**, check

Commented [CR26]: If the response is [abnormal 2] specify below mentioned options 1 to 7 (check all that apply) for right foot & left foot

	[int(11)] *[normal 1, abnormal 2]* [fe_appearance_left_foot_normal] [int(11)] *[normal 1, abnormal 2]* [fe_appearance_right_foot_deformities] [int(11)] *[1]* [fe_appearance_right_foot_dystrophic] [int(11)] *[2]* [fe_appearance_right_foot_callus] [int(11)] *[3]* [fe_appearance_right_foot_unceration] [int(11)] *[4]* [fe_appearance_right_foot_infection] [int(11)] *[5]* [fe_appearance_right_foot_dys] [int(11)] *[6]* [fe_appearance_right_foot_other] [int(11)] *[7]* [fe_appearance_right_foot_otherd] [varchar(200)] *[other specify]*	all that apply: 1[ ] deformities 2[ ] dystrophic nails; dry skin/fissure 3[ ] callus 4[ ] ulceration 5[ ] infection 6[ ] discoloration 7[ ] other: _____		all that apply: 1[ ] deformities 2[ ] dystrophic nails; dry skin/fissure 3[ ] callus 4[ ] ulceration 5[ ] infection 6[ ] discoloration 7[ ] other: _____	
3.03	Posterior tibial pulse [fe_posterior_right_foot] [int(11)] *[Yes 1, No 2]* [fe_posterior_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.04	Doraslis pedis pulse [fe_doraslis_right_foot] [int(11)] *[Yes 1, No 2]* [fe_doraslis_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.05	Pre-tibial EDEMA today [fe_pre_tibial_edema_right_foot] [int(11)] [fe_pre_tibial_edema_left_foot] [int(11)] *[None 0, up to ankle 1,between ankle & mid-calf 2, between mid-calf & knee 3]*	[ ] none [ ] up to ankle [ ] between ankle & mid-calf [ ] between mid-calf & knee		[ ] none [ ] up to ankle [ ] between ankle & mid-calf [ ] between mid-calf & knee	
3.06	Ankle Reflex [fe_ankle_relax_right_foot] [int(11)] *[Yes 1, No 2]* [fe_ankle_relax_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.07	Knee Reflex [fe_knee_reflax_right_foot] [int(11)] *[Yes 1, No 2]* [fe_knee_reflax_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.08	Vibration, tuning fork (perception at great toe) [fe_vibration_right_foot] [int(11)] [fe_vibration_left_foot] [int(11)] *[present (≥10 sec) 1, reduced (<10 sec) 2, absent 3]*	[ ] present (≥10 sec) [ ] reduced (<10 sec) [ ] absent		[ ] present (≥10 sec) [ ] reduced (<10 sec) [ ] absent	
3.09	10g Monofilament (number applications detected) [fe_monofilament_right_foot] [int(11)] [fe_monofilament_left_foot] [int(11)] *[present (≥8) 1, reduced (1-7) 2, absent 3]*	[ ] present (≥8) [ ] reduced (1-7) [ ] absent		[ ] present (≥8) [ ] reduced (1-7) [ ] absent	
	Assessment				
3.10	Deformities [fe_participant_has] [varchar(20)] *[Yes 1, No -1]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [assm_amputation_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*		2[ ] N	
3.11	Foot ulceration/infection *[Yes 2, No -2]* [assm_foot_ulcer_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved		2[ ] N	

[fe_appearance_left_foot_deformities] [int(11)] *[1]*
[fe_appearance_left_foot_dystrophic] [int(11)] *[2]*
[fe_appearance_left_foot_callus] [int(11)] *[3]*
[fe_appearance_left_foot_unceration] [int(11)] *[4]*
[fe_appearance_left_foot_infection] [int(11)] *[5]*
[fe_appearance_left_foot_dys] [int(11)] *[6]*
[fe_appearance_left_foot_other] [int(11)] *[7]*
[fe_appearance_left_foot_other_d]
[varchar(200)] *[other specify]*

Commented [CR27]: Q.no.3.10 has multiple responses, and data stored in this column as string so we are splitting & re naming the categories as
[1,-1, 2,-2, 3,-3, 4,-4]

Commented [CR28]: Doubt about the naming convention of this variable but based on values,
taken as [assm_amputation_newunch]

3.13	PVD *[Yes 3, No -3]* [assm_pvd_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N
3.14	Neuropathy *[Yes 4, No -4]* [assm_neuropathy_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N

14. Heart Failure Exam

	Have you experienced any of the following since your last exam?		
4.01	swelling of your feet, ankles or legs [hf_swelling_feet] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes →** 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_swelling_feet_new] *[new or worsened 1, unchanged or improved 0]*
4.02	shortness of breath while lying, sitting, or with minimal exertion [hf_shortness_of_breath] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes →** 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_shortness_of_breath_new] *[new or worsened 1, unchanged or improved 0]*
4.03	need to pass urine two or more times per night [hf_pass_urine] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes →** 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_pass_urine_new] *[new or worsened 1, unchanged or improved 0]*

If any 4.01-4.03 is YES, complete below.		
Chest Auscultation		
4.04	Lungs [hf_chest_ausculation_lungs] [int(11)] *[no rales 1, basilar rales only 2, more than basilar 3]*	1[ ] no rales 2[ ] basilar rales only 3[ ] more than basilar
4.05	Heart [hf_chest_ausculation_heart] [int(11)] *[normal 1, abnormal 3rd heart sound present 2]*	1[ ] normal 2[ ] abnormal, 3rd heart sound present

4.06	Heart Failure evident [hf_chest_ausculation_heart_failure] [int(11)] *[Yes 1, No 2]* [ ]	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N

5. Neurological Exam

	Have you experienced any of the following since your last exam?		
5.01	Muscle weakness [ne_muscles_weakness] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [ne_is_muscles_weakness_new] [int(11)] *[new or worsened 1, unchanged or improved 0]*	2[ ] N
5.02	Difficulty in speech [ne_difficulty_in_speech] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [ne_difficulty_in_speech_new] [int(11)] *[new or worsened 1, unchanged or improved 0]*	2[ ] N
5.03	Loss of consciousness [ne_loss_consciousness] [int(11)] *[Yes 1, No 2, N/A 3]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [ne_is_loss_consciousness] [int(11)]	2[ ] N

Commented [CR29]: If the response is [yes 1] for Q.no.4.01 to 4.03 – specify '1' or '0'
[new or worsened 1, unchanged or improved 0]

Commented [CR30]: Variable not found

Commented [CR31]: If the response is [yes 1] for Q.no.5.01 to 5.03 – specify '1' or '0'
[new or worsened 1, unchanged or improved 0]

If any 5.01-5.03 is YES, complete below.			
	Muscles	**Right**	**Left**
5.04	ARMS-Tone [ne_arms_tone_right] [int(11)] [ne_arms_tone_left] [int(11)] *[normal 1, flaccid 2, rigid/spastic 3]*	[ ] normal [ ] flaccid [ ] rigid/spastic	[ ] normal [ ] flaccid [ ] rigid/spastic
5.05	ARMS-Strength [ne_arms_strengt_right] [int(11)] [ne_arms_strengt_left] [int(11)] *[normal 1, deficit 2]*	[ ] normal [ ] deficit	[ ] normal [ ] deficit
5.06	LEGS-Tone [ne_legs_tone_right] [int(11)] [ne_legs_tone_left] [int(11)] *[normal 1, flaccid 2, rigid/spastic 3]*	[ ] normal [ ] flaccid [ ] rigid/spastic	[ ] normal [ ] flaccid [ ] rigid/spastic
5.07	LEGS-Strength [ne_legs_strength_right] [int(11)] [ne_legs_strength_left] [int(11)] *[normal 1, deficit 2]*	[ ] normal [ ] deficit	[ ] normal [ ] deficit
	Reflexes	**Right**	**Left**
5.08	Biceps [ne_reflexes_biceps_right] [int(11)] [ne_reflexes_biceps_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.09	Triceps [ne_reflexes_triceps_right] [int(11)] [ne_reflexes_triceps_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.10	Knee [ne_reflexes_knee_right] [int(11)] [ne_reflexes_knee_right] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.11	Ankle [ne_reflexes_ankle_right] [int(11)] [ne_reflexes_ankle_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent

5.12	[ ] Deficit evident [ne_old_deficit] [int(11)] *[Yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [ne_old_deficit_newunch] [int(11)]	2[ ] N

6. MEDICATIONS and MANAGEMENT

6.01	Drug Allergies [other_drug_allergies] [int(11)] *[Yes 1, No 2, unknown -1]*	[ ]no/unknown [ ] yes, specify any changes since baseline: [if Yes 1] → [drug_allergies] [varchar(20)]

Commented [CR32]: If the response is [Yes 1] specify the changes since baseline

6.02 MEDICATIONS – CONTROL GROUP ONLY [ ] N/A, INTERVENTION GROUP

Below, list all medications that the participant is presently taking *on a regular basis currently*
^For (1) Insulin, (2) OHAs, and (3) Blood pressure/lipid-lowering/blood-thinner MIXED medications, describe all constituents separately under "Generic Name" and "Single Dose"

Type	Brand Name [name] [varchar(200)]	^*List ALL constituents for Insulin, OHAs, BP meds*		Frequency [frequency] [double	Total daily dose **[total_daily_ dose]** [double]
		Generic Name [generic_name] [varchar(200)]	Single Dose [single_dose] [double]		
Insulin					
OHAs					
BP					
Lipid-lowering					

Blood-thinner					
Type	**Brand Name**	***Generic Name***	**Single Dose**	**Frequency**	**Total daily dose**
Other					

CONTROL GROUP: Review Form E with Principal Investigator/Co-Investigator. Have PI/Co-I make any changes to medications above. Strike out old medications and write in changed/new medications. Make sure final medication list is obvious and legible. Attach prescription with updated medications as source document.

→ COMPLETE BELOW FOR CONTROL AND INTERVENTION PARTICIPANTS.

6.03		**Management of diabetes in last 6 months** [dibetes_mgt] [varchar(50)]
	[ ]	Sulphonylurea (glibenclamide, gliclazide, glimipiride)
	[ ]	Biguanide (Metformin)
	[ ]	Thazolidineodione (Pioglitazone)
	[ ]	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)
	[ ]	Glinide (Nateglinide, Repaglinide, Mitiglinide)
	[ ]	Lispro, Aspart, Glulisine insulins (rapid-acting)
	[ ]	Regular Insulins (short-acting)
	[ ]	NPH or Lente Insulins (intermediate-acting)
	[ ]	Glargine or Determir Insulins (very long-acting)

[Sulphonylurea (glibenclamide, gliclazide, glimipiride) 1
Biguanide (Metformin) 2
Thazolidineodione (Pioglitazone) 3
Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)4
Glinide (Nateglinide, Repaglinide, Mitiglinide) 5
Lispro, Aspart, Glulisine insulins (rapid-acting) 6
Regular Insulins (short-acting) 7
NPH or Lente Insulins (intermediate-acting) 8
Glargine or Determir Insulins (very long-acting) 9
Other diabetic treatment 10
Dietician or Educator referral 11
Weight control or exercise program 12
Home blood glucose monitoring 13

	[ ]	Other diabetic treatment
	[ ]	Dietician or Educator referral
	[ ]	Weight control or exercise program
	[ ]	Home blood glucose monitoring
6.04		**Other medications** [other_dibetes_mgt] [varchar(100)]
	[ ]	Thaizide or thiazide-like diuretic
	[ ]	Other diuretic
	[ ]	ACE inhibitor
	[ ]	Angiotensin 2 receptor antagonist (ARB)
	[ ]	Beta-blocker
	[ ]	Calcium channel blocker (CCB)
	[ ]	Other antihypertensive agent
	[ ]	Statin
	[ ]	Other cholesterol lowering drug
	[ ]	Aspirin
	[ ]	Other anti-platelet agent
	[ ]	Oral anticoagulant
	[ ]	Nitrates (NOT sublingual)
	[ ]	Hormone replacement therapy
	[ ]	Thyroid Agents
	[ ]	Oral/inhaled steroids
	[ ]	Oral asthma drugs (exclude steroids)
	[ ]	Antidepressant
	[ ]	Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline)
	[ ]	Erectile Dysfunction drug
	[ ]	Herbal/alternative medicine
	[ ]	Vitamins/nutritional supplements
	[ ]	Other, not listed above

Thaizide or thiazide-like diuretic 1
Other diuretic 2
ACE inhibitor 3
Angiotensin 2 receptor antagonist (ARB) 4
Beta-blocker 5
Calcium channel blocker (CCB) 6
Other antihypertensive agent 7
Statin 8
Other cholesterol lowering drug 9
Aspirin 10
Other anti-platelet agent 11
Oral anticoagulant 12
Nitrates (NOT sublingual) 13
Hormone replacement therapy 14
Thyroid Agents 15
Oral/inhaled steroids 16
Oral asthma drugs (exclude steroids) 17
Antidepressant 18
Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline) 19
Erectile Dysfunction drug 20
Herbal/alternative medicine 21
Vitamins/nutritional supplements 22
Other, not listed above 23

8. Signature of Physician

8.01 Name: _____ Signature: _____

8.02 Date Signed: __ __ / __ __ __ / __ __ __ __

8.05

Control Group: Date of Next Participant Visit: __ __ / __ __ __ / __ __ __ __

Intervention Group: Study physician reviews and completes Form Z (Management Plan). Date to be listed in Form Z management plan by physician.

FORM F – Close-out_All

CARRS Translation Trial

- All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)**
- Place cross [X] in the appropriate boxes. Write number in spaces (f none, write 0)
- See *Form Completion Notes*, for definitions and explanations
- Store copies of available source documents (SD), where indicated, in patient's trial folder

PART 1: To be completed by CARE COORDINATOR or RESEARCH OFFICER

Data entry by:
[data_entry_by] [varchar (100)]
Initials _____
DATE entered: ___ /_____ /_____

Screening ID: S __ __ __ __ __

Participant ID: _____
[participant_id] [varchar (20)]

Date of Visit (dd/MMM/yyyy): __ __ / __ __ __ / __ __ __ __
[date_of_visit] [date]

FORM E – Data saved in "patient_forme.csv" and is in wide format

1. Intake

A1.01	Complaints/Update: [complaints] [varchar(500)]	
1.02-1.04 For intervention group/care coordinator only:		
A1.02	Number of severe hypoglycemic episodes since last visit (If present, **complete Form X**) [severe_hg_count] [int(11)]	
A1.03	Number of mild hypoglycemic episodes since last visit [mild_hg_count] [int(11)]	
A1.04	Other SAE since last visit (If present, **complete Form X** with investigator) [other_sae] *Yes=1, No=0*	[ ]Y [ ]N

2. Measures

B1.02	Heart rate [heart_rate] [int(11)]	__ __ __ (beats/min)
B1.03	Blood pressure 2nd reading [blood_pressure_h_1] [int(11)] / [blood_pressure_l_1] [int(11)]	__ __ __ /__ __ (mmHg)
B1.04	Blood pressure 3rd reading [blood_pressure_h_2] [int(11)] / [blood_pressure_l_2] [int(11)]	__ __ __ /__ __ (mmHg)
B1.06	Waist circumference [waist_circumference] [double]	__ __ __ (cm)
B1.07	Weight [weight] [double]	__ __ (kg)

3. Investigations

B2.04	Hemoglobin A1c [hemoglobin_a1c] [double]	__ __ . __ %	Date: __ __ / __ __ __ / __ __ __ __ [hemoglobin_a1c_date] [date]
B2.10	Fasting blood glucose (venous) [fasting_blood_glucose_mgdl] [double]	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [fasting_blood_glucose_date] [date]
B2.13	Post-prandial blood glucose (venous) **– optional** [post_prandial_blood_glu] [double]	_____ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [post_prandial_blood_glu_date] [date]
B2.05	ALT **– optional** [alt] [double]	__ __ __ (units/L)	Date: __ __ / __ __ __ / __ __ __ __ [alt_date] [date]

A2.06	Total Cholesterol [total_cholesterol] [double]	__ __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [total_cholesterol_date] [date]
B2.07	HDL Cholesterol [hdl_cholesterol] [double]	__ __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [hdl_cholesterol_date] [date]
B2.08	LDL Cholesterol (indirect) [ldl_cholesterol] [double]	__ __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [ldl_cholesterol_date] [date]
B2.09	Triglycerides [triglycerides] [double]	__ __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [triglycerides_date] [date]
B2.02	Sodium **– optional** [sodium] [double]	__ __ __ (mEq/L)	Date: __ __ / __ __ __ / __ __ __ __ [sodium_date] [date]
B2.03	Potassium **– optional** [potassium] [double]	__ __ __ (mEq/L)	Date: __ __ / __ __ __ / __ __ __ __ [potassium_date] [date]
B2.01	Creatinine [creatinine_mg] [double]	__ __ . __ __ (mg/dL)	Date: __ __ / __ __ __ / __ __ __ __ [creatinine_date] [date]
B2.12	Albumin:creatinine ratio [s_albumin_mg] [double]	__ __ __ . __ (mg/g)	Date: __ __ / __ __ __ / __ __ __ __ [s_albumin_date] [date]

11. Self-Care - Data saved in "patient_selfcare_e.csv" &"patient_selfcare_form_e.csv" and is in long format

The questions below ask you about your diabetes self-care activities **during the past 7 days**.
If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET		
11.01	**On average, over the past month, how many DAYS PER WEEK have you followed your diet plan?** [self_care_id=2] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.02	On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables? [self_care_id=3] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.03	On how many of the last SEVEN DAYS did you eat high fat foods such as fried items or full-fat dairy products? [self_care_id=4] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.04	On how many of the last SEVEN DAYS did you space eating meals evenly through the day? [self_care_id=5] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
EXERCISE		
11.05	**On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)** [self_care_id=6] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
11.06	On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work? [self_care_id=7] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
BLOOD SUGAR TESTING		
11.07	**Are you testing your blood sugar as recommended by your health care provider?** [self_care_id=9] [int(11)] *[Yes 1, No 0, N/A -1]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A (skip to 11.09)

Commented [CR1]: In Self-care section, data is saved in 2 files 1. "patient_self_care_e.csv "& 2." patient_selfcare_form_e.csv and unique ID is "self_care_id "

11.08	On how many of the last SEVEN DAYS did you test your blood sugar? [self_care_id=8] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
MEDICATIONS		
11.09	**On how many of the last SEVEN DAYS, did you take your recommended diabetes medication? (pills and/or insulin)** [self_care_id=10] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
FOOT CARE		
11.10	On how many of the last SEVEN DAYS did you check your feet? [self_care_id=11] [int(11)] *[0 1 2 3 4 5 6 7]*	0 1 2 3 4 5 6 7
TOBACCO		
11.11	**Ever smoke regularly?** (most days of the week) [self_care_id=12] [int(11)] *[never 0, quit 1, Yes 2]* [if quit 1] → [quit_smoking_year] [varchar(20)] [if yes 2] → [smoke_per_day] [int(11)]	0 [ ] Never 1 [ ] Quit: __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # smoked per day: ___
11.12	**Ever chew tobacco regularly?** (most days of the week) [self_care_id=13] [int(11)] *[never 0, quit 1, Yes 2]* [if quit 1] → [quit_tobacco_year] [varchar(20)] [if yes 2] → [packet_per_day] [int(11)]	0 [ ] No 1 [ ] Quit __ __ __ / __ __ __ __ (MMM/yyyy) 2 [ ] Yes, # packets per day: ____
11.13	If you smoke or chew tobacco, at your last doctor's visit, did anyone counsel you about stopping or refer you to counseling? [self_care_id=14] [int(11)] *[N/A 0, Yes 1, no 2]*	0 [ ] No 1 [ ] Yes 2 [ ] N/A
ALCOHOL		
11.14	**Drink alcohol regularly?** (at least once a week for most weeks in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [self_care_id=15] [int(11)] *[never 0, Yes 1]* [if yes 1] → [drink_per_day] [int(11)]	0 [ ] No 1 [ ] Yes, # drinks per day: ____
STRESS		
11.15	**How often do you feel stress (from work, responsibilities, etc)?** [ ] daily [ ] few times a week [ ] few times a month [ ] never [self_care_id=16] [int(11)] *[daily 1, few times a week 2, few times a month 3, never 4]*	
11.16	How are you coping with stress? [ ] very well [ ] moderate [ ] with difficulty [ ] not applicable (no stress) [self_care_id=17] [int(11)] *[very well 1, moderate 2, with difficulty 3, not applicable(no stress) 4]*	

Commented [CR2]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day

Commented [CR3]: If the response is [quit 1] specify the year & response is [yes 2] specify no. packet per day

Commented [CR4]: If the response is [yes 1] specify no. drink per day

Commented [CR5]: Responses at backend for this variable are saved as [0 1 2 3 4]
but , there is no category for '0'

Commented [CR6]: Responses at backend for this variable are saved as [0 1 2 3 4]
but , there is no category for '0'

10. Lifestyle – Data is saved in "patient_life_style.csv" and is wide format

10.05	**Diet** (weekday/ routine day)	Meal 1	Meal 2	Meal 3	Meal 4	Meal 5	Meal 6
	Meal Time (approximate)	[meal1_ampm] [varchar(6)] *[AM or PM]* : amPm [meal1_time] [varchar(5)]	[meal2_ampm] [varchar(6)] *[AM or PM]* : amPm [meal2_time] [varchar(5)]	[meal3_ampm] [varchar(6)] *[AM or PM]* : amPm [meal3_time] [varchar(5)]	[meal4_ampm] [varchar(6)] *[AM or PM]* : amPm [meal4_time] [varchar(5)]	[meal5_ampm] [varchar(6)] *[AM or PM]* : amPm [meal5_time] [varchar(5)]	[meal6_ampm] [varchar(6)] *[AM or PM]* : amPm [meal6_time] [varchar(5)]
	Type B=breakfast, L=lunch, D=dinner, S=snack	[meal1_type] [varchar(6)]	[meal2_type] [varchar(6)]	[meal3_type] [varchar(6)]	[meal4_type] [varchar(6)]	[meal5_type] [varchar(6)]	[meal6_type] [varchar(6)]

Commented [CR7]: Should specify [AM or PM]

Commented [CR8]: Should specify time of the meal

Commented [CR9]: Should specify type of meal i.e., B=breakfast, L=lunch, D=dinner, S=snack

10.04	**Physical Activity (in leisure time) in average week**	*Days per week*	*Total time per day*	
			Hour(s)	*Minutes*
	Vigorous	[pa_vigorous_days_per_week] [int(11)]	[pa_vigorous_total_hr] [int(11)]	[pa_vigorous_total_min] [int(11)]
	Moderate	[pa_moderate_days_per_week] [int(11)]	[pa_moderate_total_hr] [int(11)]	[pa_moderate_total_min] [int(11)]
	Mild (Walking)	[pa_walking_days_per_week] [int(11)]	[pa_walking_total_hr] [int(11)]	[pa_walking_total_min] [int(11)]

12. EQ-5D - Data saved in **"eq_5d.csv"** and is in wide format

Place a tick in one box in each group below for the statement that best describes your own health state today.

12.01 Mobility *[I have no problems in walking about 1, I have some problems in walking about 2,*

[mobility_id] [int (11)] *I am confined to bed 3]*

1 ☐ I have no problems in walking about

2 ☐ I have some problems in walking about

3 ☐ I am confined to bed

12.02 Self-Care *[I have no problems with self-care 1, I have some problems with self-care 2,*

[self_care_id] [int(11)] *I am unable to wash or dress myself 3]*

1 ☐ I have no problems with self-care

2 ☐ I have some problems with self-care

3 ☐ I am unable to wash or dress myself

12.03 Usual Activities (e.g. work, study, housework, family or leisure activities)

[usual_activities] [int(11)] *[I have no problems with performing my usual activities 1,*
I have some problems with performing my usual activities 2,
I am unable to perform my usual activities 3]

1 ☐ I have no problems with performing my usual activities

2 ☐ I have some problems with performing my usual activities

3 ☐ I am unable to perform my usual activities

12.04 Pain/Discomfort

[pain_discomfort] [int(11)] *[I have no pain or discomfort 1, I have moderate pain or discomfort 2, I have extreme pain or discomfort 3]*

1 ☐ I have no pain or discomfort
2 ☐ I have moderate pain or discomfort
3 ☐ I have extreme pain or discomfort

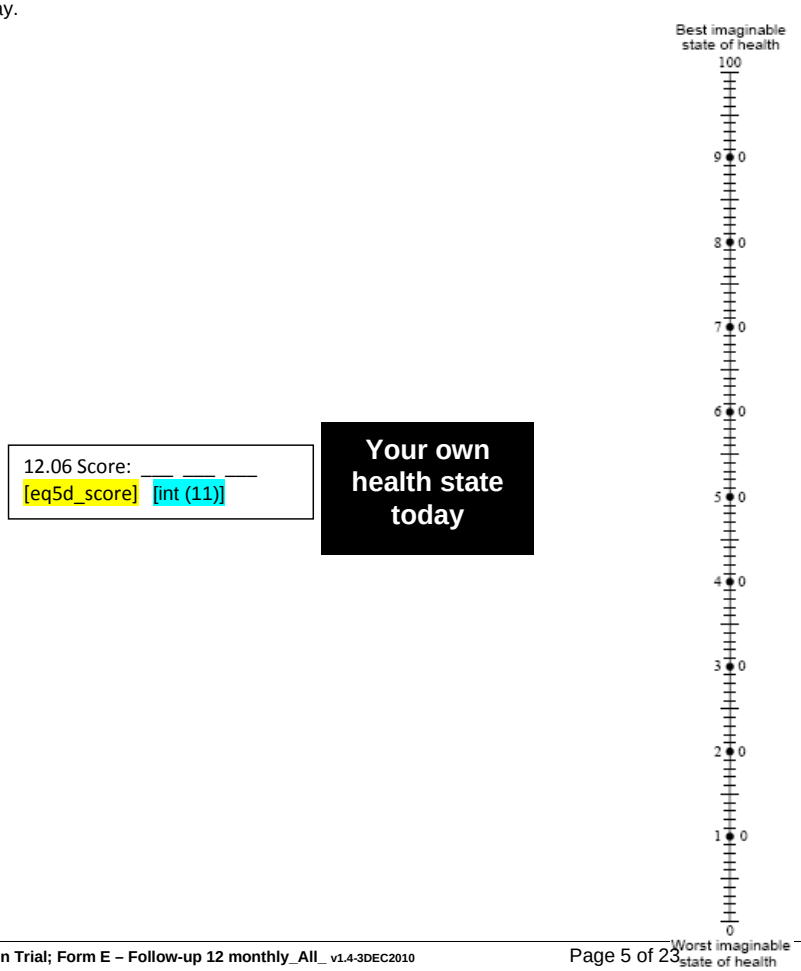
12.05 Anxiety/Depression

[anxiety_depression] [int(11)] *[I am not worried or depressed 1; I am moderately anxious or depressed 2, I am extremely anxious or depressed 3]*

1 ☐ I am not worried or depressed
2 ☐ I am moderately anxious or depressed
3 ☐ I am extremely anxious or depressed

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

I would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.



13. Diabetes Treatment Satisfaction

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer each question by marking a number on every scale.

13.01 How satisfied are you with your current treatment?
[current_treatment] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.02 How often have you felt that your blood sugars have been unacceptability high recently?
[blood_sugar_high] [int] *[0, 1, 2, 3, 4, 5, 6]*

Most of the time — None of the time

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.03 How often have you felt that your blood sugars have been unacceptability low recently?
[blood_sugar_low] [int] *[0, 1, 2, 3, 4, 5, 6]*

Most of the time — None of the time

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.04 How convenient have been finding your treatment to be recently?
[convienent_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very convenient — Very inconvenient

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.05 How flexible have you been finding your treatment to be recently?
[flexible_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very flexible — Very inflexible

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.06 How satisfied are you with understanding of your diabetes?
[understand_dibetes] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.07 How satisfied would you be to continue with your present form of diabetes treatment?
[present_dib_treat] [int] *[0, 1, 2, 3, 4, 5, 6]*

Very satisfied — Very dissatisfied

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

13.08 Would you recommend this form of treatment to someone else?
[recommend_form] [int] *[0, 1, 2, 3, 4, 5, 6]*

Yes, I would definitely recommend this treatment — No, I would definitely NOT recommend this treatment

6[ ] 5[ ] 4[ ] 3[ ] 2[ ] 1[ ] 0[ ]

14. Health Utilities Index

This next questionnaire asks about aspects of your health. When answering these questions please think about your health and your ability to do things everyday in the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Focus your answers on your overall abilities, disabilities and how you felt during the past 4 weeks.

You may feel that some questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar, but please answer each question independently.

Please read each question and consider answers carefully. For each question, select one answer that best describes your level of ability or disability during the past 4 weeks. Select the answer by checking the box. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities/ feelings.

14.01. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint?

[ordinary_news_print] [int] *[1, 2, 3, 4]*

1☐ a. Able to see well enough without glasses or contact lenses
2☐ b. Able to see well enough with glasses or contact lenses
3☐ c. Unable to see well enough even with glasses or contact lenses
4☐ d. Unable to see at all

14.02. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street?

[recognize_friend] [int] *[1, 2, 3, 4]*

1☐ a. Able to see well enough without glasses or contact lenses
2☐ b. Able to see well enough with glasses or contact lenses
3☐ c. Unable to see well enough even with glasses or contact lenses
4☐ d. Unable to see at all

14.03. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people?

[group_conversation] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to hear what was said without a hearing aid
2☐ b. Able to hear what was said with a hearing aid
3☐ c. Unable to hear what was said even with a hearing aid.
4☐ d. Unable to hear what was said, but did not wear a hearing aid
5☐ e. Unable to hear at all

14.04. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a quiet room?

[other_person_conversation] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to hear what was said without a hearing aid
2☐ b. Able to hear what was said with a hearing aid
3☐ c. Unable to hear what was said even with a hearing aid
4☐ d. Unable to hear what was said, but did not wear a hearing aid
5☐ e. Unable to hear at all

14.05. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you?

[un_own_langauge] [int] *[1, 2, 3, 4]*

1☐ a. Able to be understood completely
2☐ b. Able to be understood partially
3☐ c. Unable to be understood
4☐ d. Unable to speak at all

14.06. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well?

[un_other_langauge] [int] *[1, 2, 3, 4]*

1☐ a. Able to be understood completely.
2☐ b. Able to be understood partially.
3☐ c. Unable to be understood.
4☐ d. Unable to speak at all.

14.07. Which one of the following best describes how you have been feeling during the past 4 weeks?

[feeling] [int] *[1, 2, 3, 4, 5]*

1☐ a. Happy and interested in life
2☐ b. somewhat happy
3☐ c. somewhat unhappy
4☐ d. Very unhappy
5☐ e. So unhappy that life was not worthwhile

14.08. Which one of the following best describes the pain and discomfort you have experienced during

the past 4 weeks?

[discomfort_exp] [int] *[1, 2, 3, 4, 5]*

1☐ a. Free of pain and discomfort
2☐ b. Mild to moderate pain or discomfort that prevented no activities.
3☐ c. Moderate pain or discomfort that prevented a few activities
4☐ d. Moderate to severe pain or discomfort that prevented some activities
5☐ e. severe pain or discomfort that prevented most activities

14.09. Which one of the following best describes your ability, during the past 4 weeks, to walk? (Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches, or a walker.)

[to_walk] [int] *[1, 2, 3, 4, 5, 6]*

1☐ a. Able to walk around the neighborhood without difficulty, and without walking equipment
2☐ b. Able to walk around the neighborhood with difficulty; but did not require walking equipment or the help of another person
3☐ c. Able to walk around the neighborhood with walking equipment, but without the help of another person
4☐ d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood
5☐ e. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood
6☐ f. Unable to walk at all

14.10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers? (Note: Special tools refer to hooks for buttoning clothes, gripping devices for opening jar or lifting small items, and other devices to compensate for limitations of hand or fingers.)

[hands_finger] [int] *[1, 2, 3, 4, 5, 6]*

1☐ a. Full use of hands and ten fingers
2☐ b. Limitations in the use of hand or fingers, but did not require special tools or the help of another person
3☐ c. Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person)
4☐ d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools)
5☐ e. Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools)
6☐ f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)

14.11. Which one of the following best describes your ability, during the past 4 weeks, to remember things?

[remember_things] [int] *[1, 2, 3, 4]*

1☐ a. Able to remember most things
2☐ b. Somewhat forgetful
3☐ c. Very forgetful
4☐ d. Unable to remember anything at all

14.12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems?

[think_solve] [int] *[1, 2, 3, 4, 5]*

1☐ a. Able to think clearly and solve day to day problems
2☐ b. Had a little difficulty when trying to think and solve day to day problems
3☐ c. Had some difficulty when trying to think and solve day to day problems
4☐ d. Had great difficulty when trying to think and solve day to day problems
5☐ e. Unable to think or solve day to day problems

14.13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities?

[basic_activity] [int] *[1, 2, 3, 4]*

1☐ a. Eat, bathe, dress and use the toilet normally
2☐ b. Eat, bathe, dress and use the toilet independently with difficulty

3☐ c. Required mechanical equipment to eat, bathe, dress or use the toilet independently
4☐ d. Required the help or another person to eat, bathe, dress or use the toilet

14.14. Which one of the following best describes how you have been feeling during the past 4 weeks?

[feeling_health_utility] [int] *[1, 2, 3, 4]*

1☐ a. Generally happy and free from worry
2☐ b. occasionally fretful, angry, irritable, anxious or depressed
3☐ c. often fretful, angry, irritable, anxious or depressed
4☐ d. extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help

14.15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks?

[discomfort_health_utility] [int] *[1, 2, 3, 4, 5]*

1☐ a. Free of pain and discomfort
2☐ b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities
3☐ c. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities
4☐ d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief
5☐ e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities

15&16. Frequency & Costs of Care

Please respond to the following questions regarding **outpatient** care you received in the previous **12 months.** Outpatient care is all instances of clinic visits that did not necessitate hospitalization. **(Exclude current visit)**

		Indicate number	Month of last visit/test/exam (MMM/yyyy)	
15.01	Clinic Visits [fpc_clinic_visit_indicate_no] [int(11)] [fpc_clinic_visit_month_of_visit] [varchar(15)] [fpc_clinic_visit_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.02	HbA1c testing [fpc_hba_testing_indicate_no] [int(11)] [fpc_hba_testing_month_of_visit] [varchar(15)] [fpc_hba_testing_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.03	Cholesterol Testing [fpc_cholestrol_testing_indicate_no] [int(11)] [fpc_cholestrol_testing_month_of_visit] [varchar(15)] [fpc_cholestrol_testing_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.04	Foot Exam at clinic [fpc_foot_exam_indicate_no] [int(11)] [fpc_foot_exam_month_of_visit] [varchar(15)] [fpc_foot_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.05	Eye Exam [fpc_eye_exam_indicate_no] [int(11)] [fpc_eye_exam_month_of_visit] [varchar(15)] [fpc_eye_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.06	Microalbuminuria check [fpc_microal_check_indicate_no] [int(11)] [fpc_microal_check_month_of_visit] [varchar(15)] [fpc_microal_check_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown

Commented [r10]: The day (DD) for the below listed variables are correct and are auto generated by the system and therefore the date is in DD-MMM-YY format:
[fpc_clinic_visit_month_of_visit]
[fpc_hba_testing_month_of_visit]
[fpc_cholestrol_testing_month_of_visit]
[fpc_foot_exam_unknown]
[fpc_eye_exam_month_of_visit]
[fpc_microal_check_month_of_visit]
[fpc_ecg_month_of_visit]
[fpc_dental_exam_month_of_visit]
[fpc_dietician_visit_month_of_visit]

Commented [CR11]: For Q.Nos. 15.01 – 15.09 , specify Indicate number, Month of last visit & unknown
If response is [unknown] data is saved as '-1'

15.07	ECG [fpc_ecg_indicate_no] [int(11)] [fpc_ecg_month_of_visit] [varchar(15)] [fpc_ecg_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.08	Dental Exam [fpc_dental_exam_indicate_no] [int(11)] [fpc_dental_exam_month_of_visit] [varchar(15)] [fpc_dental_exam_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown
15.09	Dietician/Diabetes Education [fpc_dietician_visit_indicate_no] [int(11)] [fpc_dietician_visit_month_of_visit] [varchar(15)] [fpc_dietician_visit_unknown] [int(11)] *[-1]*		__ __ __ / __ __ __ __	[ ]unknown

16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR:

Outpatient visits?

_____% Out-of-pocket
[out_of_pocket_opd] [double]
_____% Employer Insurance
[employer_insurance_opd] [double]
_____% Private Insurance
[private_insurance_opd] [double]
_____% Government insurance, non-job based
[govt_insurance_opd] [double]
_____% Other, please specify: _____
[other_opd] [double]
[other_details_opd] [varchar(200)]
= 100 % total

Inpatient care?

_____% Out-of-pocket
[out_of_pocket_ipd] [double]
_____% Employer Insurance
[employer_insurance_ipd] [double]
_____% Private Insurance
[private_insurance_ipd] [double]
_____% Government insurance, non-job based
[govt_insurance_ipd] [double]
_____% Other, please specify: _____
[other_ipd] [double]
[other_details_ipd] [varchar(200)]
=100 % total

OUTPATIENT CARE

Please respond to the following questions regarding outpatient care you received for diabetes in the previous **1 year**. Outpatient care is all instances of clinic visits that did not necessitate hospitalization.
EXCLUDE current visit.

Please respond to the following questions regarding outpatient care you received for diabetes in the previous 1 year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization.
EXCLUDE current visit.

16.02 How many outpatient visits did you make in the past 1 year (exclude current visit)? _____ times
[out_patient_visit] [int(11)]

16.03 How many days, including half days, did you miss from work for outpatient visits in the past 1 year? _____ days [ ] N/A
[days_miss_work] [int(11)]
[days_miss_work_na] [int(11)] *[1]*

16.04 List all persons who accompanied you to outpatient visits in the past 1 year:

Person Relation (e.g. father) [person_relation]	Occupation (number*) [occupation]	Monthly salary [monthly_salary]	Number visits accompanied [number_of_visit]

Commented [r12]: Not in main file

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

Please list the costs incurred in the past year in relation to outpatient visits:

	Item	Number of times	Average cost One-time (Rupees)
16.05	Consultation Fee [con_fee_frq] [int(11)] [avg_con_fee] [double]		
16.06	Lab Tests (HbA1c, blood glucose, urine check) [lab_test_frq] [int(11)] [avg_lab_test] [double]		
16.05	Eye Exam [eye_eam_frq] [int(11)] [avg_eye_exam] [double]		
16.06	ECG [ecg_frq] [int(11)] [avg_ecg_fee] [double]		
16.07	Medicines (tablets, insulin) [med_frq] [int(11)] [avg_med_fee] [double]		
16.08	Supplies (including glucose strips, gauze, sterile solution, etc.) [supply_frq] [int(11)] [avg_supply_fee] [double]		
16.09	Transportation [transport_frq] [int(11)] [avg_transport] [double]		
16.10	Food (personal) [food_personal_frq] [int(11)] [avg_food_personal] [double]		
16.11	Additional cost for escort(s) (e.g. food) [escorts_freq] [int(11)] [avg_escorts] [double]		
16.12	Other out-of-pocket expenses [outpocket_frq] [int(11)] [avg_outpocket_exp] [double]		

Commented [CR13]: For Q.no 16.05 to 16.12
[frq] indicates "Number of times" &
[avg] indicates "Average cost"

INPATIENT CARE

Please respond to the following questions regarding inpatient care you received FOR DIABETES-RELATED COMPLICATIONS* in the previous 1 year. Inpatient care is all instances of medical care that required you to stay in hospital or emergency room.

*chest pain, heart attack, stroke, infection, foot/leg problems, eye problems, kidney problems, blood sugar problem (too high/too low), etc. IF unsure that event is a diabetes-related complication, INCLUDE in listing.

16.13 How many Hospitalizations or Emergency Room visits for diabetes-related complications in the past 1 year? _____ times
[hospital_emergency] [int (11)]

16.14 For each of these Hospitalization or Emergency Room Visit, provide details below – (Make sure that visits listed below equals total number listed in 16.13)
When providing time, include half-days.

	TYPE 1= Hospitalization, NO surgery 2= Surgery 3= Emergency Room [reason]	Days of stay [duration]	Hospital Cost including medicine/ supplies (total stay) **[hospital_cost]**	Transportation Cost, including ambulance fees (total stay) **[transport]**	Food Cost **[food_cost]**	Additional Escort(s) Cost **[escorts_cost]**	Person(s) accompanied (Escort) – list all			
							Relation **[person_accompained]**	Occupation (number*) **[occupation]**	Monthly Salary **[monthly_salary]**	Days accompanied **[days_person_accompained]**
1										
2										
3										
4										
5										
6										

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

Commented [r14]: Not in main sheet

18. Signature of Care Coordinator/Research Officer

18.01Name: _____ Signature: _____

18.02Date Signed: __ __ / __ __ __ / __ __ __ __

Instructions for Continuation (after completion of Form E Part 1)

[ ] **Attach Reports of ECG and Form G-Eye Exam.**

[ ] **Control Group**: Take participant to STUDY PHYSICIAN to complete PART 2 of Form E. After completion, enter Form E Parts 1 & 2 into eCRF. Include all source documents in patient's trial folder.

[ ] **Intervention Group:**

(1) Enter Form E Sections 1-4 into EHR-DSS (including update of contact information)
(2) Review patient medications. Update medication changes in writing on Form Z.
(3) Provide paper Form Z (with medication update) and rest of Form E Part 2 to STUDY PHYSICIAN during consultation with participant.
(4) Attach completed Form Z to this Form E. Update patient with information.
(5) After patient leaves, enter Form Z and rest of Form E in eCRF.
(6) Include all source documents in patient's trial folder.

PART 2: complete by STUDY PHYSICIAN

2. ECG and Eye Exam

May use results within past 1 month for ECG and Form G-Eye Exam (attach to end of this form). Otherwise, attempt to complete TODAY, or ensure that testing is done within 2 weeks of today's date. Update in paper and eCRF as soon as available. Retain copies of ECG and eye exam results as source documents.

ECG:

2.01	**ECG** Date: __ __ / __ __ __ / __ __ __ __ [s_ecg_date] [date]		
	☐ not available form within past month. Scheduled today. update below once results available.		
2.02	Q-waves diagnostic of previous MI [s_ecg_q_waves] [int(11)] *[yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N
2.03	Left ventricular hypertrophy [s_ecg_left_ventricular] [int(11)] *[yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N
2.04	Atrial Fibrillation [s_ecg_atrial] [int(11)] *[yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N
2.05	Other arrhythmia [s_ecg_other_arrhythmia] [int(11)] *[yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improve	2[ ] N

Commented [CR15]: This option is added in CRF

Commented [CR16]: Options (new or worsened & unchanged or improved) are not present at both front-end and back-end for Q.Nos 2.02 to 2.05

EYE EXAM:

May use results from past 1 month.

[ ] Attach Form G-Eye Exam to end of this Form E – to be completed by qualified ophthalmologist only. If not completed prior to this visit, schedule ophthalmologist appointment and ensure completion within 2 weeks. Enter results in eCRF (EYE EXAM) as soon as available.

12. Complications Update

In the past year, since the last baseline/annual visit, has the patient had any of the following:

		no/unsure	Yes, number	
	New/Worsening Blindness in either eye thought to be due to diabetes [h_eyes_blindbess] *[no/unsure 0, R 1, L 2, Both 3]*	[ ]	[ ] R [ ] L	Form X
	New/Worsening Glaucoma [h_eyes_glaucoma] *[no/unsure 0, R 1, L 2, Both 3]*	[ ]	[ ] R [ ] L	
	New/Worsening Cataract [h_eyes_cataract] *[no/unsure 0, R 1, L 2, Both 3]*	[ ]	[ ] R [ ] L	
	Cataract Surgery [h_eyes_cataract_surgery] *[no/unsure 0, R 1, L 2, Both 3]*	[ ]	[ ] R [ ] L	Form X
	Laser photocoagulation therapy [h_eyes_laser_therapy] *[no/unsure -1, Yes 1]*	[ ]	[eye_laser_therepy_lft] *[Right 1, Left 2]* [ ] R, ___ [eye_laser_therepy_rgt_no] [ ] L, ___ [eye_laser_therepy_lft_no]	Form X
	Other eye therapy [h_eyes_other_therapy] *[1 Yes,-1 No]*	[ ]	[ ], specify: [h_eyes_other_therapy_spcify]	Form X

In the past year, since the last baseline/annual visit, has the patient had any of the following:

		no/ unsure	Yes, number	
1.11	ACS: Myocardial Infarction or Unstable Angina [h_cardiovascular_acs] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [acs_num] [int(11)]	[ ]	[ ]____	Form X
1.12	Angioplasty (PCI) /Open-heart surgery (CABG) [h_cardiovascular_pci_cabg] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [pci_num] [int(11)]	[ ]	[ ]____	Form X
1.13	New/Worsened Stable Angina [stable_angina] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	Form X
1.14	Stroke (Ischemic or Hemorrhagic) or TIA [h_cardiovascular_stroke_tia] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [stroke_num] [int(11)]	[ ]	[ ]____	Form X
1.15	New/Worsened Arrhythmia (requiring med intervention) [h_cardiovascular_arrtythmia] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	Form X
1.16	New/Worsened Heart Failure [h_cardiovascular_heart_attack] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.28	New/Worsened Neuropathy – hands/feet [h_other_neuropathy_hands_feet] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	
1.29	New/Worsened Neuropathy – sexual:erectile dysfunction [h_other_neuropathy_sexual] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	
	New Amputation [foot_ampu_yesno] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [foot_ampu_num] [int(11)]	[ ]	[ ]____	Form X
1.18	Peripheral revascularization (angioplasty/ surgery) [h_peripheral_surgery] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [h_peripheral_surgery_year] [varchar(11)]	[ ]	[ ]____	Form X
1.19	Chronic leg/foot ulcer (6 weeks or more) – include current [h_peripheral_foot_ulcer] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [h_peripheral_foot_ulcer_year] [varchar(11)]	[ ]	[ ]____	[ ] if hosp/ER – Form X
1.43	Other Major Infection (hospitalization) [oth_maj_infec_yesno] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [oth_maj_infec_num] [int(11)]	[ ]	[ ]____	Form X
1.44	Minor Infection (NO hospitalization) [maj_inf_yesno] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [maj_inf_num] [int(11)]	[ ]	[ ]____	
1.33	New/Worsened Asthma [h_other_asthma] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.34	New/Worsened COPD (Chronic Bronchitis, Emphysema) [h_other_copd] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.35	New/Worsened Liver disease [h_other_liver_disease] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.36	New/Worsened Gallbladder disorder (stones, disease) [h_other_gallbladder_disorder] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.37	New/Worsened Hip Fracture/Replacement [h_other_hip_facture] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	Form X

Commented [CR17]: If the response for "h_cardiovascular_acs" is [Yes 1] specify Number

Commented [CR18]: If the response for "h_cardiovascular_pci_cabg" is [Yes 1] specify Number

Commented [CR19]: If the response for "h_cardiovascular_stroke_tia" is [Yes 1] specify Number

Commented [CR20]: If the response for "foot_ampu_yesno" is [Yes 1] specify Number

Commented [CR21]: If the response for "h_peripheral_surgery" is [Yes 1] specify Number

Commented [CR22]: If the response for "h_peripheral_foot_ulcer" is [Yes 1] specify Number

Commented [CR23]: If the response for "oth_maj_infec_yesno" is [Yes 1] specify Number

Commented [CR24]: If the response for "maj_inf_yesno" is [Yes 1] specify Number

1.38	New/Worsened Depression [h_other_depression] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ]	[ ] if hosp/ER – Form X
1.39	Severe HYPOglycemia (hospitalization/ER) [sever_hypoglycemia] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [sever_hypoglycemia_num] [int(11)]	[ ]	[ ] _____	Form X
	Mild HYPOglycemia [mild_hypoglycemia] [int(11)] *[no/unsure -1, Yes 1]* [if Yes 1] → [mild_hypoglycemia_num] [int(11)]	[ ]	[ ] _____	
1.41	Other major health condition(s), hospitalizations, emergency room visits not listed above, specify: [oth_maj_health_cond] [int(11)] *[no/unsure -1, Yes 1]*	[ ]	[ ] _____	Form X
1.42	Total Number of Hospitalizations/emergency room visits from past year [no_of_time_hospitaiz] [int(11)]			

Commented [CR25]: If the response for "sever_hypoglycemia" is [Yes 1] specify Number

Commented [CR26]: Need to check, This variable "mild_hypoglycemia" is not seen in front-end
But present in back-end
If the response for "mild_hypoglycemia" is [Yes 1] specify Number

Commented [CR27]: If the response "oth_maj_health_cond" is [If Yes 1] no. of times not found

Complete a Form X for all SAE events listed above. For each hospitalization/emergency room visit, document in source notes, when, where and why it was made. If available, include discharge summary as source document.

In the past year, since the last baseline/annual visit, has the patient had any of the following:

1.43	Out of ordinary severe muscle aches/pains [outof_ordinary_musclespain] [int(11)] *[Yes 1, No 2]*	[ ] N	[ ] Y, Obtain CPK
1.44	Medication side effects (i.e. cough from Ace-I, allergic reaction) [medic_side_effect] [int(11)] *[Yes 1, No 2]*	[ ] N	[ ] Y

3. Foot Exam

		Right Foot	Left Foot
3.01	Amputation [fe_amputation_right_foot] [int(11)] [fe_amputation_left_foot] [int(11)] *[N/A 1, toe 2, ray (metatarsal) 3, forefoot 4, foot 5, below knee 6, above knee 7]*	[ ] N/A [ ] toe [ ] ray (metatarsal) [ ] forefoot [ ] foot [ ] below the knee [ ] above the knee	[ ] N/A [ ] toe [ ] ray (metatarsal) [ ] forefoot [ ] foot [ ] below the knee [ ] above the knee
3.02	Appearance [fe_appearance_right_foot_normal] [int(11)] *[normal 1, abnormal 2]* [fe_appearance_left_foot_normal] [int(11)] *[normal 1, abnormal 2]* [fe_appearance_right_foot_deformities] [int(11)] *[1]* [fe_appearance_right_foot_dystrophic] [int(11)] *[2]* [fe_appearance_right_foot_callus] [int(11)] *[3]* [fe_appearance_right_foot_unceration] [int(11)] *[4]* [fe_appearance_right_foot_infection] [int(11)] *[5]* [fe_appearance_right_foot_dys] [int(11)] *[6]* [fe_appearance_right_foot_other] [int(11)] *[7]* [fe_appearance_right_foot_otherd] [varchar(200)] *[other specify]*	1[ ] normal **2[ ] abnormal**, check all that apply: 1[ ] deformities 2[ ] dystrophic nails; dry skin/fissure 3[ ] callus 4[ ] ulceration 5[ ] infection 6[ ] discoloration 7[ ] other: _____	1[ ] normal **2[ ] abnormal**, check all that apply: 1[ ] deformities 2[ ] dystrophic nails; dry skin/fissure 3[ ] callus 4[ ] ulceration 5[ ] infection 6[ ] discoloration 7[ ] other: _____
3.03	Posterior tibial pulse [fe_posterior_right_foot] [int(11)] *[Yes 1, No 2]* [fe_posterior_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y 2[ ] N	1[ ] Y 2[ ] N

Commented [CR28]: If the response is [abnormal 2] specify below mentioned options 1 to 7 (check all that apply) for right foot & left foot

[fe_appearance_left_foot_deformities] [int(11)] *[1]*
[fe_appearance_left_foot_dystrophic] [int(11)] *[2]*
[fe_appearance_left_foot_callus] [int(11)] *[3]*
[fe_appearance_left_foot_unceration] [int(11)] *[4]*
[fe_appearance_left_foot_infection] [int(11)] *[5]*
[fe_appearance_left_foot_dys] [int(11)] *[6]*
[fe_appearance_left_foot_other] [int(11)] *[7]*
[fe_appearance_left_foot_other_d]
[varchar(200)] *[other specify]*

3.04	Doraslis pedis pulse [fe_doraslis_right_foot] [int(11)] *[Yes 1, No 2]* [fe_doraslis_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.05	Pre-tibial EDEMA today [fe_pre_tibial_edema_right_foot] [int(11)] [fe_pre_tibial_edema_left_foot] [int(11)] *[None 0, up to ankle 1,between ankle & mid-calf 2, between mid-calf & knee 3]*	[ ] none [ ] up to ankle [ ] between ankle & mid-calf [ ] between mid-calf & knee		[ ] none [ ] up to ankle [ ] between ankle & mid-calf [ ] between mid-calf & knee	
3.06	Ankle Reflex [fe_ankle_relax_right_foot] [int(11)] *[Yes 1, No 2]* [fe_ankle_relax_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.07	Knee Reflex [fe_knee_reflax_right_foot] [int(11)] *[Yes 1, No 2]* [fe_knee_reflax_left_foot] [int(11)] *[Yes 1, No 2]*	1[ ] Y	2[ ] N	1[ ] Y	2[ ] N
3.08	Vibration, tuning fork (perception at great toe) [fe_vibration_right_foot] [int(11)] [fe_vibration_left_foot] [int(11)] *[present (≥10 sec) 1, reduced (<10 sec) 2, absent 3]*	[ ] present (≥10 sec) [ ] reduced (<10 sec) [ ] absent		[ ] present (≥10 sec) [ ] reduced (<10 sec) [ ] absent	
3.09	10g Monofilament (number applications detected) [fe_monofilament_right_foot] [int(11)] [fe_monofilament_left_foot] [int(11)] *[present (≥8) 1, reduced (1-7) 2, absent 3]*	[ ] present (≥8) [ ] reduced (1-7) [ ] absent		[ ] present (≥8) [ ] reduced (1-7) [ ] absent	
	Assessment				
3.10	Deformities [fe_participant_has] [varchar(20)] *[Yes 1, No -1]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [assm_amputation_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*		2[ ] N	
3.11	Foot ulceration/infection *[Yes 2, No -2]* [assm_foot_ulcer_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved		2[ ] N	
3.13	PVD *[Yes 3, No -3]* [assm_pvd_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved		2[ ] N	
3.14	Neuropathy *[Yes 4, No -4]* [assm_neuropathy_newunch] [int(11)] *[new or worsened 1, unchanged or improved 0]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved		2[ ] N	

14. Heart Failure Exam

	Have you experienced any of the following since your last exam?		
4.01	swelling of your feet, ankles or legs [hf_swelling_feet] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes** → 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_swelling_feet_new] *[new or worsened 1, unchanged or improved 0]*

Commented [CR29]: Q.no.3.10-3.14 has multiple responses and data stored in this column as string so we are splitting & re naming the categories as [1,-1, 2,-2, 3,-3, 4,-4]

Commented [CR30]: Doubt about the naming convention of this variable but based on values, taken as [assm_amputation_newunch]

Commented [CR31]: If the response is [yes 1] for Q.no.4.01 to 4.03 – specify '1' or '0' [new or worsened 1, unchanged or improved 0]

4.02	shortness of breath while lying, sitting, or with minimal exertion [hf_shortness_of_breath] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes →** 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_shortness_of_breath_new] *[new or worsened 1, unchanged or improved 0]*
4.03	need to pass urine two or more times per night [hf_pass_urine] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	**1[ ] Yes →** 2[ ] No	1[ ] new or worsened 2[ ] unchanged or improved [hf_is_pass_urine_new] *[new or worsened 1, unchanged or improved 0]*

If any 4.01-4.03 is YES, complete below.		
Chest Auscultation		
4.04	Lungs [hf_chest_ausculation_lungs] [int(11)] *[no rales 1, basilar rales only 2, more than basilar 3]*	1[ ] no rales 2[ ] basilar rales only 3[ ] more than basilar
4.05	Heart [hf_chest_ausculation_heart] [int(11)] *[normal 1, abnormal 3rd heart sound present 2]*	1[ ] normal 2[ ] abnormal, 3rd heart sound present

4.06	Heart Failure evident [hf_chest_ausculation_heart_failure] [int(11)] *[Yes 1, No 2]* [ ]	1[ ] Y → [ ] new or worsened [ ] unchanged or improved	2[ ] N

Commented [CR32]: Variable not found

5. Neurological Exam

	Have you experienced any of the following since your last exam?		
5.01	Muscle weakness [ne_muscles_weakness] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [ne_is_muscles_weakness_new] [int(11)] *[new or worsened 1, unchanged or improved 0]*	2[ ] N
5.02	Difficulty in speech [ne_difficulty_in_speech] [int(11)] *[Yes 1, No 2, N/A 3]* [if Yes 1] →	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [ne_difficulty_in_speech_new] [int(11)] *[new or worsened 1, unchanged or improved 0]*	2[ ] N
5.03	Loss of consciousness [ne_loss_consciousness] [int(11)] *[Yes 1, No 2, N/A 3]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [ne_is_loss_consciousness] [int(11)] *[new or worsened 1, unchanged or improved 0]*	2[ ] N

Commented [CR33]: If the response is [yes 1] for Q.no.5.01 & 5.02 – specify '1' or '0'
[new or worsened 1, unchanged or improved 0]

If any 5.01-5.03 is YES, complete below.			
	Muscles	**Right**	**Left**
5.04	ARMS-Tone [ne_arms_tone_right] [int(11)] [ne_arms_tone_left] [int(11)] *[normal 1, flaccid 2, rigid/spastic 3]*	[ ] normal [ ] flaccid [ ] rigid/spastic	[ ] normal [ ] flaccid [ ] rigid/spastic
5.05	ARMS-Strength [ne_arms_strengt_right] [int(11)] [ne_arms_strengt_left] [int(11)]	[ ] normal [ ] deficit	[ ] normal [ ] deficit

	[normal 1, deficit 2]		
5.06	LEGS-Tone [ne_legs_tone_right] [int(11)] [ne_legs_tone_left] [int(11)] *[normal 1, flaccid 2, rigid/spastic 3]*	[ ] normal [ ] flaccid [ ] rigid/spastic	[ ] normal [ ] flaccid [ ] rigid/spastic
5.07	LEGS-Strength [ne_legs_strength_right] [int(11)] [ne_legs_strength_left] [int(11)] *[normal 1, deficit 2]*	[ ] normal [ ] deficit	[ ] normal [ ] deficit
	Reflexes	**Right**	**Left**
5.08	Biceps [ne_reflexes_biceps_right] [int(11)] [ne_reflexes_biceps_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.09	Triceps [ne_reflexes_triceps_right] [int(11)] [ne_reflexes_triceps_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.10	Knee [ne_reflexes_knee_right] [int(11)] [ne_reflexes_knee_right] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent
5.11	Ankle [ne_reflexes_ankle_right] [int(11)] [ne_reflexes_ankle_left] [int(11)] *[present 1, absent 2]*	[ ]present [ ]absent	[ ]present [ ]absent

5.12	[ ] Deficit evident [ne_old_deficit] [int(11)] *[Yes 1, No 2]*	1[ ] Y → [ ] new or worsened [ ] unchanged or improved [ne_old_deficit_newunch] [int(11)] *[new or worsened 1, unchanged or improved 2]*	2[ ] N

6. MEDICATIONS and MANAGEMENT

6.01	Drug Allergies [other_drug_allergies] [int(11)] *[Yes 1, No 2, unknown -1]*	[ ]no/unknown [ ] yes, specify any changes since baseline: [if Yes 1] → [drug_allergies] [varchar(20)]

Commented [CR34]: If the response is [Yes 1] specify the changes

6.02 MEDICATIONS – CONTROL GROUP ONLY [ ] N/A, INTERVENTION GROUP

Below, list all medications that the participant is presently taking *on a regular basis currently*
^For (1) Insulin, (2) OHAs, and (3) Blood pressure/lipid-lowering/blood-thinner MIXED medications, describe all constituents separately under "Generic Name" and "Single Dose"

Type	Brand Name [name] [varchar(200)]	*^List ALL constituents for Insulin, OHAs, BP meds*		Frequency [frequency] [double	Total daily dose [total_daily_dose] [double]
		Generic Name [generic_name] [varchar(200)]	Single Dose [single_dose] [double]		
Insulin					
OHAs					
BP					
Lipid-lowering					

Blood-thinner					
Type	**Brand Name**	***Generic Name***	**Single Dose**	**Frequency**	**Total daily dose**
Other					

CONTROL GROUP: Review Form E with Principal Investigator/Co-Investigator. Have PI/Co-I make any changes to medications above. Strike out old medications and write in changed/new medications. Make sure final medication list is obvious and legible. Attach prescription with updated medications as source document.

→ COMPLETE BELOW FOR CONTROL AND INTERVENTION PARTICIPANTS.

6.03		**Management of diabetes in last 6 months** [dibetes_mgt] [varchar(50)]
	[ ]	Sulphonylurea (glibenclamide, gliclazide, glimipiride)
	[ ]	Biguanide (Metformin)
	[ ]	Thazolidineodione (Pioglitazone)
	[ ]	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)
	[ ]	Glinide (Nateglinide, Repaglinide, Mitiglinide)
	[ ]	Lispro, Aspart, Glulisine insulins (rapid-acting)
	[ ]	Regular Insulins (short-acting)
	[ ]	NPH or Lente Insulins (intermediate-acting)
	[ ]	Glargine or Determir Insulins (very long-acting)

[Sulphonylurea (glibenclamide, gliclazide, glimipiride) 1
Biguanide (Metformin) 2
Thazolidineodione (Pioglitazone) 3
Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)4
Glinide (Nateglinide, Repaglinide, Mitiglinide) 5
Lispro, Aspart, Glulisine insulins (rapid-acting) 6
Regular Insulins (short-acting) 7
NPH or Lente Insulins (intermediate-acting) 8
Glargine or Determir Insulins (very long-acting) 9
Other diabetic treatment 10
Dietician or Educator referral 11
Weight control or exercise program 12
Home blood glucose monitoring 13

	[ ]	Other diabetic treatment
	[ ]	Dietician or Educator referral
	[ ]	Weight control or exercise program
	[ ]	Home blood glucose monitoring
6.04		**Other medications** [other_dibetes_mgt] [varchar(100)]
	[ ]	Thaizide or thiazide-like diuretic
	[ ]	Other diuretic
	[ ]	ACE inhibitor
	[ ]	Angiotensin 2 receptor antagonist (ARB)
	[ ]	Beta-blocker
	[ ]	Calcium channel blocker (CCB)
	[ ]	Other antihypertensive agent
	[ ]	Statin
	[ ]	Other cholesterol lowering drug
	[ ]	Aspirin
	[ ]	Other anti-platelet agent
	[ ]	Oral anticoagulant
	[ ]	Nitrates (NOT sublingual)
	[ ]	Hormone replacement therapy
	[ ]	Thyroid Agents
	[ ]	Oral/inhaled steroids
	[ ]	Oral asthma drugs (exclude steroids)
	[ ]	Antidepressant
	[ ]	Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline)
	[ ]	Erectile Dysfunction drug
	[ ]	Herbal/alternative medicine
	[ ]	Vitamins/nutritional supplements
	[ ]	Other, not listed above

Thaizide or thiazide-like diuretic 1
Other diuretic 2
ACE inhibitor 3
Angiotensin 2 receptor antagonist (ARB) 4
Beta-blocker 5
Calcium channel blocker (CCB) 6
Other antihypertensive agent 7
Statin 8
Other cholesterol lowering drug 9
Aspirin 10
Other anti-platelet agent 11
Oral anticoagulant 12
Nitrates (NOT sublingual) 13
Hormone replacement therapy 14
Thyroid Agents 15
Oral/inhaled steroids 16
Oral asthma drugs (exclude steroids) 17
Antidepressant 18
Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline) 19
Erectile Dysfunction drug 20
Herbal/alternative medicine 21
Vitamins/nutritional supplements 22
Other, not listed above 23

7.	**DATA OBTAINED** [fe_data_obtained_option]	[fe_data_obtained_option_value]	
		1[ ] Y → Assessment type: [ ] Phone call with patient [4] [ ] Clinic / In person [5] [ ] Phone call or contact with relative [6] [ ] Phone call or contact with other health care provider [7] [ ] Other, Specify [8] [fe_data_obtained_option_yes_other]	**2[ ] N →Reason not obtained:** [ ] Not Done [0] [ ] Refuses further participation [1] [ ] Unable to contact participant [2] [ ] Patient died [3]

Commented [r35]: Response as Yes (1) or No (2)

8. Signature of Physician

8.01 Name: _____ Signature: _____

8.02 Date Signed: __ __ / __ __ __ / __ __ __ __