Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY)

Data Release Documentation

June 2014 Full Scale Data Release

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1 INTRODUCTION

1.1 General Information

TODAY was a multi-center trial designed to evaluate the safety and efficacy of three treatment regimens for T2DM in children and youth based on glycemic control. The three treatment regimens were: (1) metformin alone, (2) metformin plus rosiglitazone, and (3) metformin plus an intensive lifestyle intervention called the TODAY Lifestyle Program (TLP). Materials developed and used for the TODAY standard diabetes education program and the intensive lifestyle intervention program are available to the public at https://today.bsc.gwu.edu/. The study recruited and followed patients for a minimum of two years. Patients were randomized within two years of the diagnosis of T2DM. The primary outcome is time to treatment failure as defined in one of two ways:

1. **HbA1c ≥ 8% over a 6-month period.** All regularly scheduled HbA1c values must be ≥ 8% over a 6-month period. If any one value is < 8%, after which HbA1c re-elevates to ≥ 8%, the clock will restart at the time of the re-elevation. At least two consecutive measurements must be ≥ 8% over 6 months.
2. **Inability to wean from temporary insulin therapy due to metabolic decompensation.** Participants who experience metabolic decompensation requiring temporary use of insulin, who cannot safely be weaned from insulin within three months, will be classified as treatment failures.

This document describes the complete public release of the TODAY dataset and is based on participant data collected during the study. A brief description of the study is given below.

1.2 Data Collection Schedule

The table lists the schedule of data collection, measurements, and assessments included in the TODAY data and specimen repository.

Data Collection			
Measurement/ Assessment	**Baseline**	**Year 1** X = every 2 months	**Post Year 1 Follow-up** Q=quarterly; A=annual; 24=24 months P=primary outcome; E=end of study
Historical data (a)	X		
HbA1c	X (j)	X	Q, A, 24, P, E
Blood for storage	X	6,12	A, 24, P, E
Urine for storage	X	12	A, 24, P, E
Insulin sensitivity and secretion (b)	X	6, 12	A, 24, P, E
2-hour OGTT	X	6	A, 24, P, E
Pancreatic autoimmunity			P, E
Serum creatinine (c)		12	A, 24, P, E
LFTs		X	Q, A, 24, P, E
Hemoglobin, hematocrit		2, 6, 12	A, 24, P, E
BMI	X (j)	X	Q, A, 24, P, E
Other anthropometrics (d)	X	6	24, P, E
DXA	X	6	24, P, E
Blood pressure	X (j)	X	Q, A, 24, P, E
Lipids	X	6,12	A, 24, P, E
Physical exam (e)	X	X	Q, A, 24, P, E
Diabetes management	X	X	Q, A, 24, P, E
Diabetes complications	X	X	Q, A, 24, P, E
Interim history		X	Q, A, 24, P, E
Fitness, nutrition, activity (f)	X	6	24, P, E
Psychosocial and QoL (g)	X	6	24, P, E
Cardiovascular risk factors (h)	X	6,12	A, 24, P, E

Data Collection			
Measurement/ Assessment	**Baseline**	**Year 1** X = every 2 months	**Post Year 1 Follow-up** Q=quarterly; A=annual; 24=24 months P=primary outcome; E=end of study
Peripheral neuropathy (MNSI)	X	12	A, 24, P, E
Microalbuminuria	X	12	A, 24, P, E
Treatment group assignment	X		
Biological parent (i)	X		
Retinopathy screening			Final year of study
Echocardiogram			Final year of study

(a) Historical data include family and medical history, feeding, and demographics (including socioeconomic status).
(b) Insulin sensitivity and secretion measures include fasting glucose, insulin, C-peptide, and proinsulin.
(c) Serum creatinine is used to calculate creatinine clearance.
(d) Other anthropometric measurements are waist circumference and abdominal height.
(e) A comprehensive physical exam including Tanner stage and evaluation of acanthosis nigricans is performed at screening, baseline, all annual visits, and outcome. Otherwise a targeted physical exam is performed (every 2 months in year 1 follow-up and then quarterly).
(f) The FFQ is used for nutrition, 3-day PDPAR and 7-day recorded accelerometer for physical activity, and PWC 170 for fitness.
(g) The psychosocial and quality of life battery includes CDI, BDI, EDEQ, PEDS QL, and HUI-2.
(h) Cardiovascular risk factors include measurement of fibrinogen, c-reactive protein, homocysteine (vitamin B-12 will be obtained to assess homocysteine), plasminogen activator inhibitor-1, interleukin-6. Pro-inflammatory and hemostasis markers are assayed at baseline, 6 months, 12 months, and end of study; blood from other draws is stored.
(i) Data collected from the biological parent at baseline are self reported height, weight.
(j) Also collected during the pre-randomization run-in period.

Both the primary outcome and end of study visits have been recoded in the release datasets to match an otherwise scheduled assessment visit. Meaning there will be an imbalance of data collected as some visits (e.g. some participants may have quality of life data at a quarterly visit while the majority will not since this visit was also deemed a primary outcome or end of study visit for those participants).

1.3 Randomization

Randomization was stratified by clinical center to ensure balance among the treatment groups with respect to anticipated differences in the participant populations. Randomization began in July 2004 and ended in February 2009.

For each clinical center, the coordinating center generated a 1:1:1 randomization scheme using a permuted block design. Sample sizes across the three treatment arms remain relatively equivalent as the trial progresses, but the next treatment assignment cannot be anticipated.

The clinical center coordinator used a computer-based system to input eligibility data and receive a random treatment assignment.

2 DATA RELEASE INFORMATION

2.1 General Information

- No personal identifying information is included.
- RELEASEID uniquely identifies each participant. It consists of a 2-digit study identifier (65), followed by a random 5-digit, identifier which uniquely identifies the participant.
- No dates or specific time points are included. The variable DAYS represents the number of days since the individual participant's date of randomization.
- Data for all participants who were part of the TODAY cohort are included.
- In accordance with HIPAA regulations and to protect the identification of TODAY participants, the data has been modified to ensure that no participant is identifiable. For example, data was sorted into small clearly-identifiable groups (sex*race) and collapsed if the sample size was small.
- Only research data is included in the released data set, including data from all assessment visits, data for dietary consumption, data related to physical activity and sedentary behavior, fitness data, quality of life data and laboratory data. Non-research data, including tracking forms, are not included. Adverse event and serious adverse event data were collected but are not included in the data release.
- All available data from each form and central unit database is included. Missing data was due to a variety of reasons: variable was accidently not collected or measured; the variable was completed incorrectly; participant did not complete the form, etc.

2.2 Data Location

Data are released from the TODAY Coordinating Center at the George Washington University Biostatistics Center to the Data Repository at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health.

2.2.1 Structure of the SAS Data Files

- Multiple datasets are available as transport files in the TODAY Release library. One transport file exists for each TODAY form or dataset.
- The files are included as SAS datasets within transport files with the same name as the embedded form or dataset name and the extension XPT. The SAS code to import each dataset is given below:

```
libname today 'directory for the destination of SAS datasets on your
host';
filename tranfile 'name of the transport files on your host';
proc cimport data=today.data infile=tranfile; run;
```

  For example to import file today.baseline:

```
libname today 'c:\mysasfiles';
filename tranfile 'c:\myxptfiles\baseline.xpt';
proc cimport data=today.baseline infile=tranfile; run;
```

- The contents of variables in these datasets are provided via two means:
  - Form data have a companion form to the dataset which details the variable names and coding.

- For non-form data, a listing of variable names, descriptions, and coding is included in this document.

2.3 De-identified Data

The TODAY datasets were de-identified in the following manner. All personal identifiers were removed, including participant ID and other personal identifiers (date of birth, etc.), clinic ID, and all dates. In addition, variables that might identify a particular individual were collapsed into wider groupings. For example, race/ethnicity were coded as White, Black, Hispanic (anyone indicating 'Yes' to Hispanic origin), and Other. Age at baseline has been collapsed to truncate the upper and lower ages of the cohort at enrollment. Other demographic information was also altered. For example, history of diabetes in siblings was recoded to 'has a full sibling with history of diabetes' if any full sibling was reported with diabetes and similarly for half siblings and grandparents history of diabetes.

Anthropometric measures were also adjusted to protect the participant's identity. These measures were BMI, BMI percentile, BMI z-score, waist circumference, and abdominal height. Where possible actual values were reported but those below or above a certain cut point had their actual data collapsed into a group that contained all individuals that also met that criterion. The upper and lower cut points for BMI, BMI percentile, BMI z-score, waist circumference, and abdominal height are given below. Note: BMI percentile and BMI z-score are not applicable once the participant reaches 21 years of age.

Measure	Baseline		Post-Baseline	
	Lower Cut Point	Upper Cut Point	Lower Cut Point	Upper Cut Point
BMI	32	38	28	46
BMI Percentile	98.5	98.5	98.5	99.5
BMI Z-score	2.20	2.35	1.80	2.70
Waist Circumference	100	110	95	130
Abdominal Height	22	25	21	30

2.4 Structure of the Datasets

At most one record exists in each file for each participant for each visit, if the data is collected at multiple occasions. Variable RELEASEID is used to identify a particular participant and variable MVISIT is used to identify the visit occasion.

Each dataset includes data collected at all visits. Section 4 describes the data included in detail.

The number of participants participating in each follow-up visit for the cohort decreased over time. This is due to two reasons: loss to follow up and the extended recruitment period during which participants were randomized and all study participants were followed until the common February 28, 2011 termination date of the study. The table below shows the number of participants at each regularly-scheduled follow-up visit in the dataset.

Number of participants who completed in-clinic visits by treatment arm			
Visit	**Metformin Only**	**Metformin + Rosiglitazone**	**Metformin + Lifesyle**
Baseline	232	233	234
M02	227	223	228
M04	222	218	223

M06	227	221	224
M08	216	214	210
M10	212	208	209
M12	214	219	217
M15	206	212	203
M18	208	195	205
M21	197	197	196
M24	204	193	209
M27	176	177	187
M30	164	161	166
M33	160	151	150
M36	148	141	150
M39	132	118	133
M42	123	111	135
M45	120	101	111
M48	106	92	109
M51	91	76	94
M54	83	72	81
M57	73	56	77
M60	50	47	73
M63	44	40	54
M66	44	32	45
M69	24	22	26
M72	16	13	22
M75	4	7	14
M78	2	1	1

3 STATISTICAL CONSIDERATIONS

3.1 Definition of Treatment Failure

The primary endpoint for TODAY was time to treatment failure as defined in one of two ways:

1. **HbA1c ≥ 8% over a 6-month period.** All regularly scheduled HbA1c values must be ≥ 8% over a 6-month period. If any one value is < 8%, after which HbA1c re-elevates to ≥ 8%, the clock will restart at the time of the re-elevation. At least two consecutive measurements must be ≥ 8% over 6 months.
2. **Inability to wean from temporary insulin therapy due to metabolic decompensation.** Participants who experience metabolic decompensation requiring temporary use of insulin, who cannot safely be weaned from insulin within three months, will be classified as treatment failures.

HbA1c was collected at all scheduled assessment visits (every 2 months during the first year of enrollment in TODAY and quarterly thereafter) allowing for frequent checks of the HbA1c value for each participant. When the participant reaches treatment failure, treatment with insulin is instituted as add-on therapy, in combination with the subject's assigned oral agent(s).

3.2 Time to Treatment Failure

The declaration of treatment failure is the time interval during which the loss of glycemic control or metabolic decompensation was known to have occurred rather than as the exact date of failure.

For participants who did not have treatment failure, the total amount of time in the study when the participant could be evaluated was entered; this was the time to the last visit in most cases, unless the participant withdrew, did not return for follow-up, underwent bariatric surgery, or chose to take insulin.

All participants who either started on insulin or had one elevated HbA1c value were placed on an approaching endpoint list which included the earliest date the participant would reach the primary outcome endpoint (90 days for insulin use or 165 days for elevated HbA1c). If the participants missed their regularly scheduled clinic visit(s) and then came into the clinic after this watch date and were still on insulin or had an elevated HbA1c they were counted as having reached the primary endpoint and that date was used as the end of the interval.

3.3 Primary Analysis

The three treatment arms of TODAY were compared using time-to-event interval-censored survival methods. All randomized participants were included in the time-to-event analysis. PROC LIFETEST in SAS 9.2 was utilized and a log-logistic distribution was specified for time to failure. The survival curves for the three treatment groups were compared using the generalized log-rank test [Zhao & Sun, 2004] and pairwise comparisons were performed.

3.4 Intent-to-treat

TODAY was analyzed as an intent-to-treat trial; that is, the treatment groups were compared without regard to compliance to medication or lifestyle during the trial.

3.5 Repeated Measures

Much of the data in TODAY were collected at several time points over the years of follow-up. To account for the repeated and variable measurements over time, the average mean change from baseline, as well as comparisons of changes from baseline among the three treatment groups were computed using SAS PROC MIXED for continuous outcomes and using SAS PROC GENMOD for categorical and dichotomous outcomes, adjusted for the baseline value of the outcome where appropriate. The compound symmetry covariance structure was assumed.

4 FILE DESCRIPTIONS

4.1 Data Forms

4.1.1 General

Multiple data collection forms were completed for each participant at each data collection period. This release includes research data for each participant data form completed at each collection period.

Each form is available as a PDF for use in approved data-release analyses only – **no form is to be used for primary data collection without the specific permission of the TODAY study group.** Instructions for completing each form are often included on each form. The TODAY form identifier can be found at the top left corner of the page along with the form name. The forms provided have been modified to match what is provided in the datasets.

Data entry included responses in both check boxes and on data lines on the data collection forms. In general, 'other' responses requested specify information, but in order to protect against the identification of the participant, these responses have been removed from the database and from the form.

Over the course of TODAY some forms remained fixed while others were modified. The forms included with this release represent the final forms and when variables were or were not collected is indicated on the form. Not all variables were applicable at all time points with what was collected when indicated on the form prior to each question or set of questions.

4.1.2 Variable Names on Data Forms

- Variable names for each released data set are embedded in blue on the data form.
- All datasets are HIPAA compliant. Information that might identify a specific participant has been excluded from the release datasets and questions that captured this information have been removed from the forms.
- Coding and formats for all variables are found on the original data form except where described below.
- The numerical value for check-box style categorical variables is noted to the lower right of the check-boxes on the form.
- Text information that was written on all forms is not included in the release datasets.

4.2 Datasets for Non-Form Data

Data not collected on forms but for which datasets are included in this release are as follows:

- Laboratory data: One record for each participant per data collection schedule.
- Nutrition: One record of analyzed nutrition data from a self-administered food frequency questionnaire for each participant per data collection schedule.
- Activity: One record per participant per data collection schedule for both 3DPAR and accelerometery.
- Eye Exam: One record of results from Fundus and OCT analysis is provided per participant.
- Echocardiogram: One record of results from echocardiography analysis is provided per participant.
- Dual Energy X-Ray Absorptiometry: One record of results from DEXA analysis is provided per participant.

- Assignment and outcome: One record per participant that indicates treatment assignment and provides information about treatment outcome.

4.3 Variables Common to All Datasets

Several variables are used to identify a specific participant and time on all datasets. These are:

- RELEASEID: This identification number consists of a two-digit study ID number (65) and a randomly generated five-digit identification number, separated by dashes. The final five-digit identification number will uniquely identify each participant even after the preceding numbers are removed. RELEASEID is used to link all records for an individual participant to all other records.
- MVISIT: This is a three character value that that identifies the time at which the measures were taken. This combined with RELEASEID is used to match a participant's information across multiple forms completed for that time period. This variable is not present in datasets which represent data collected only once. MVISIT is coded as:
    - RUN: Run-in visit (only applicable for HbA1c and form TODAY.RUN since all other run-in and screening data were compiled into other baseline forms)
    - M00: Baseline visit
    - M02, M04, M06, M08, M10, M12: Bi-monthly assessment visits conducted during each participant's first year
    - M15, M18, M21, …, M78: Quarterly visits conducted from beginning of second year in TODAY through the common ending date.
- DAYS: Number of days a particular visit occurred before (negative numbers) or after (positive values) randomization.

4.4 Participant Forms

This section pertains to forms either completed about the participant/their family or by the participant.

4.4.1 TODAY.BASELINE: Clinical Baseline Inventory

This form was used to collect and establish a set of baseline measurements for BMI, waist circumference, abdominal height, blood pressure, and medication usage. This form was only collected at baseline. There is no explicit MVISIT value on the form but if needed MVISIT can be assigned a value of M00.

Values for BMI, BMI percentile, BMI z-score, waist circumference and abdominal height are truncated to protect the identity of the participant.

4.4.2 TODAY.BDI: Beck Depression Inventory

This was used to collect information about depression during assessment visits for participants age 16 and older. It was self-administered by the participant interviewer following the instructions in the BDI-II manual. This form was collected at baseline, 6 months, 24 months and at any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The Beck Depression Inventory form is copyrighted and is not included in this data package.

4.4.3 TODAY.BPE: Brief Physical Exam

This form was used to collect acanthosis and insulin use information during a targeted physical exam. It was completed by trained research staff. This form was collected at all non-annual visits post-randomization, i.e. at visits where MVISIT is one of the following: M02, M04, M06, M08, M10, M15, M18, M21, M27, M30, M33, M39, M42, M45, M51, M54, M57, M63, M66, M69.

Questions related to safety were removed.

4.4.4 TODAY.CDI: Child Depression Inventory

This form was used to collect information about depression during assessment visits for participants under 16 years of age. It was self-administered by the child in the presence of a trained interviewer following the instructions in the Children's Depression Inventory Technical Manual. This form was collected at baseline, 6 months, 24 months and at any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The responses on this form were unchanged and are provided as recorded.

4.4.5 TODAY.EDEQ-C: Eating Disorders Examination Questionnaire, Participant Version

This form assessed participant's eating attitudes and behaviors. It is self-administered by the participant at baseline, 6 months, 24 months and any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The responses on this form were unchanged and are provided as recorded.

4.4.6 TODAY.HUI: Health Utilities Index

This form was used to evaluate the participant's health-related quality of life. It was interviewer administered following the script provided with the form. This form was administered at baseline, 6 months, 24 months, and any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The responses on this form were unchanged and are provided as recorded.

4.4.7 TODAY.NEURO: Neuropathy Screening

This form was used to record the presence of neuropathy symptoms. It is comprised of two parts: The Michigan Neuropathy Screening Instrument (MNSI) and the Semmes-Weinstein 5.70 10-gram monofilament test (SW-MF). The first part of the form is the MNSI. Part Ia is the MNSI survey (history) which was self-administered by the participant. Part Ib is the physical exam portion of the MNSI which was conducted by study staff. Together they are the full Michigan Neuropathy Screening Instrument (MNSI) which is based on a validated screening tool for detection of peripheral neuropathy [Feldman,

1994]. The second part is an additional exam, Semmes-Weinstein 5.70 10-gram monofilament, completed by study staff. Part Ia and PartIb/II were originally separate forms but to aid in the analysis of the data were combined for the data release. This form was administered at baseline, all annual visits and any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M12 for the 1 year assessment, M24 for the 2 year assessment, M36 for the 3 year assessment, M48 for the 4 year assessment, M60 for the 5 year assessment, and M72 for the 6 year assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The question asking about the occurrence of an amputation was removed due to the small sample size, and potentially identifiable information. All other questions were unchanged and are provided as recorded.

4.4.8 TODAY.PAT: Participant Survey and Medical History

This form was used to obtain participant and family demographic data and medical history. Non-responses and don't know responses were reported as missing values. Medical information was only collected only for biologically related relatives. It was interview administered with the participant and the parent or other knowledgeable adult. This form was only completed at baseline. There is no explicit MVISIT value on the form but if needed MVISIT can be assigned a value of M00.

Values for age, time since diagnosis, birth weight, household composition, household income, mother's age, mother's height, mother's weight, father's age, father's height, father's weight, sibling and grandparent history of diabetes, and race/ethnicity were collapsed to protect the identity of the participant. Questions related to the participant's previous medical history, insurance coverage beyond private insurance and Medicaid, health care usage beyond diabetes care, and mother and father's more detailed medical history were all dropped, again, to protect the identity of the participant.

4.4.9 TODAY.PE: Physical Exam

This form was used to obtain major physical examination information including: routine physical exam information, acanthosis, Tanner staging, and insulin use. It was completed by trained research staff. This form was completed at baseline, annual visits, and any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M12 for the 1 year assessment, M24 for the 2 year assessment, M36 for the 3 year assessment, M48 for the 4 year assessment, M60 for the 5 year assessment, and M72 for the 6 year assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

Questions related to safety were removed. Tanner stage was determined by physical examination of breasts and pubic hair for girls and testicles and pubic hair for boys, and converted to a dichotomous score (stages 1, 2, 3 versus stages 4, 5).

4.4.10 TODAY.PEDSQLGC: Pediatric Quality of Life Inventory Child Report

The child questionnaire (PedsQL-C) evaluates the participant's health-related quality of life. It was self-administered by the child after introductory instructions from the administrator. If the administrator determined that the child was unable to self-administer the PedsQL (e.g., due to illness, fatigue, reading difficulties), the PedsQL was read aloud to the child with intonation kept neutral to avoid suggesting an answer. The administration followed the guidelines provided on the PedsQL website (www.pedsql.org). This form was administered at baseline, 6 months, 24 months, and any visit originally classified as a

primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The responses on this form were unchanged and are provided as recorded.

4.4.11 TODAY.PEDSQLGT: Pediatric Quality of Life Inventory Teen Report

The adolescent questionnaire (PedsQL-A) evaluates the participant's health-related quality of life. It is self-administered by the adolescent after introductory instructions from the administrator. If the administrator determined that the teen was unable to self-administer the PedsQL-A (e.g., due to illness, fatigue, reading difficulties), the PedsQL-A was read aloud to the teen. The administration followed the guidelines provided on the PedsQL website (www.pedsql.org). This form was administered at baseline, 6 months, 24 months, and any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The responses on this form were unchanged and are provided as recorded.

4.4.12 TODAY.PEDSQLDC: Pediatric Quality of Life Inventory – Diabetes Module Child Report

The child questionnaire (PedsQL-DC) evaluates the participant's health-related quality of life pertaining to diabetes care. It is self-administered by the child. This is a standard questionnaire, and some of the items are more meaningful or relevant to type 1 diabetes or to youth who have had the primary outcome and are taking insulin. Some items refer to side effects (e.g., shaky, sweaty), wearing an ID bracelet, and tracking carbohydrates or exchanges. The participant was instructed to answer these items as accurately as possible. However, the participant was allowed to skip item #2 in section Treatment II referring to taking insulin shots if that is not applicable to the child. This form was administered at baseline, 6 months, 24 months, and any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The responses on this form were unchanged and are provided as recorded.

4.4.13 TODAY.PEDSQLDT: Pediatric Quality of Life Inventory – Diabetes Module Teen Report

The adolescent questionnaire (PedsQL-DT) evaluates the participant's health-related quality of life pertaining to diabetes care. It is self-administered by the adolescent. This is a standard questionnaire, and some of the items are more meaningful or relevant to type 1 diabetes or to youth who have had the primary outcome and are taking insulin. Some items refer to side effects (e.g., shaky, sweaty), wearing an ID bracelet, and tracking carbohydrates or exchanges. The participant was instructed to answer these items as accurately as possible. However, the participant was allowed to skip item #2 in section Treatment II referring to taking insulin shots if that is not applicable to the teen. This form was administered at baseline, 6 months, 24 months, and any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and

M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The responses on this form were unchanged and are provided as recorded.

4.4.14 TODAY.PWC: PWC 170

This form was used to record the participant's physical fitness evaluation. The PWC 170 was performed after the completion of the scheduled OGTT. Data from the Actigraph was downloaded and the 3 Day Physical Activity Recall (3DPAR) was performed on the same day that the PWC 170 was completed.

A PWC was not performed on a participant who weighed > 350 lbs. PWC was not be done fasting, must be done at least 48 hours after the OGTT.

The PWC170 consists of four 3-minute stages on the cycle ergometer. Participants were fitted with a heart rate monitor that fit just below the sternum allowing the technician to accurately and efficiently read heart rate during the test. Participants pedaled at 60 rpm on a Monark 818E (Quinton) cycle ergometer, while the ergometer provided resistance. All ergometers were calibrated twice a year. The initial workload was set using the subject's weight in kg as described below. Heart rate was measured the last five seconds of each minute of exercise. Heart rate response to each stage determined subsequent workloads, with increments of 0.25, 0.5, 1, or 2 kiloponds for the second and third stages. If the heart rate was less than 170 beats per minute at the end of the third stage, further resistance was added and an additional 3-minute stage completed. Upon completion of the test, the resistance on the bike was released and the participant pedaled slowly until heart rate returned to a normal level.

The protocol was designed to obtain heart rates in the range of 160+ beats/min during the third stage. Heart rates measured during the last minute of each stage are used to extrapolate a PWC at a heart rate of 170. The workload at that heart rate is then divided by the weight to get a power output per kilogram weight. The PWC 170 is computed in absolute terms, or watts (w), and relative to body weight in watts/kilogram (w/kg).

The procedures for the test were as follows:

1. Calibrate the cycle ergometer using a 4 kg weight according to the approved schedule of calibration (1 kilopond, Kp = 1 kg).
2. Set the workload to 0 Kp.
3. If the participant uses an inhaler before exercise, be sure this is consistent for all fitness tests for that participant across time.
4. Check that the heart rate is being transmitted correctly by getting a pulse and examining the heart rate monitor receiver output. Put the receiver on the handlebars so that the reading is facing the study staff person rather than the participant.
5. Adjust the seat height so that the leg is almost extended (165-170^{o} at the knee joint) when the participant is seated on the ergometer with the hands on the handlebars. Set the handlebars at approximately 20^{o} angle toward the rider.
6. With the aid of a metronome or music, the participant starts pedaling at 60 rpm for 20-30 seconds to establish the tempo. For simplicity, have the metronome set at 120; each sound being a down stroke by one leg.
7. If the participant cannot hold at least 25 rpm despite encouragement, the test is stopped, and the data is missing.

8. Stage 1: Once the participant is at 60 rpm, initiate the first workload of 0.5 Kp. The participant pedals at the prescribed workload for 3 minutes.
9. Monitor the participant to be sure he/she is attaining the proper pedal cadence.
10. Monitor and record the heart rate during the last 5 seconds of each minute.
11. Stage 2: At the end of the Stage 1, increase the workload by 0.5 Kp and pedal for 3 minutes.
12. Stage 3: Examine the heart rate at minute 2:30 of the stage 2.
    a. If the heart rate is 165-170, complete the stage and stop the test.
    b. If the heart rate is 130-165, increase the workload by 0.5 Kp for the next stage.
    c. If the heart rate is < 130, increase the workload by 1.0 Kp for the next stage.
13. Stage 4: If the heart rate is less than 150 during the third stage and the patient is capable of continuing, completing a fourth stage is desirable. Increase the workload by 0.5 Kp for the 4^{th} stage. This stage follows the same procedures as the previous three stages, with heart rates being recorded during the last ten seconds of each of the 3 minutes of the stage.
14. The ultimate goal is to obtain a heart rate of 165-170 beats per minute during the final stage of exercise. However, a heart rate of > 150 at the end of three completed stages is acceptable.
15. NOTE: There are multiple interpretable outcomes:
    a. Subject attains heart rate of at least 165 -170 and has completed at least 2 stages
    b. Subject attains heart rate greater than 150 and has completed at least 3 stages.
16. At the end of the test, have the participant continue to pedal at very little workload (~0.25 Kp; slow pedal rate) until heart rate is 120 or below; then end the test and have the participant remove the heart rate monitor.
17. If a participant quits early, obtain a reason and write it in the comments section of the form.
18. The heart rates for each successive stage should increase. If they do not, check the heart rate monitor—you may have obtained a spurious reading. Also take a 6 sec pulse rate (HR_6) using the radial pulse (HR_6 x 10 = HR/min). Record the pulse rate if the monitor appears not to be working.

This test was performed and form completed at baseline, 6 months, 24 months, and any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The weight measured immediately prior to the administration of the test has been removed but BMI is reported as a part of each of the visits and the information from TODAY Form VISIT can be used. All other responses on this form were unchanged and are provided as recorded.

4.4.15 TODAY.RUN: Run-In Visit Inventory

This form was used to document that a run-in visit was completed. A run-in visit includes all visits during the pre-randomization run-in period which lasted from 2 to 6 months. All visits during this period will have the visit code RUN and a negative number of days since randomization.

Values for height and weight were removed and replaced by BMI, BMI percentile and BMI z-score which all had their low and high values collapsed to protect the identity of the participant. Blood pressure was collected as a measurement taken 5 minutes after sitting, a second and third measurement after sitting for an additional minute each. The average of the second and third readings is reported. All other questions from the form have been dropped since they were primarily eligibility checks.

4.4.16 TODAY.TLP: Today Lifestyle Program (TLP) PAL Visit Form

This form was completed at every TODAY Lifestyle Program (TLP) scheduled contact and records the location of the contact as well as which phase of TLP the participant was in. No visit number is associated with this form since these contacts were different from assessment visits and will only be recorded for the participants randomized to the metformin + lifestyle arm of the study.

Phone was only recorded as the location of the contact if the session content was covered and not for rescheduling or reminder calls. This form also contained more detailed information about the material covered in each session for the different phases but due to the continual revising of the form the data are not consistent and are being dropped due to non-utility.

4.4.17 TODAY.TODQUEST: TODAY Questionnaire

This study developed survey collects information about the participant's school, smoking habits, drinking habits and their family. It is self-administered by the child after introductory instructions from the administrator. This form was administered at baseline, 6 months, 24 months, and any visit originally classified as a primary outcome or end of study visit. The value of MVISIT will be M00 for baseline, M06 for the 6 month assessment and M24 for the 24 month assessment. The value of MVISIT for any visit classified as a primary outcome or end of study visit will be any of the regularly scheduled assessment visit numbers.

The responses on this form were unchanged and are provided as recorded.

4.4.18 TODAY.VISIT: Clinical Visit Inventory

This form collects information at on anthropometrics, blood pressure, concomitant medications, interval medical history, and study medication adherence. Some measurements were only recorded at specified intervals, including anthropometrics (waist circumference, abdominal height), which were only recorded at the M06 and M24 visits. This form was administered at all scheduled assessment visits post-randomization, i.e. all visit codes except M00. That is, every two months in the first year (M02, M04, M06, M08, M10, M12) and every 3 months thereafter (M15, M18, M21, M24, M27, M30, M33, M36, M39, M42, M45, M48, M51, M54, M57, M60, M63, M66, M69, M72, 75, M78).

Values for height and weight were removed and replaced by BMI, BMI percentile and BMI z-score which all had their low and high values collapsed to protect the identity of the participant. Values for waist circumference and abdominal height also had the low and high values collapsed to protect the participant. Blood pressure was collected as a measurement taken 5 minutes after sitting, a second and third measurement after sitting for an additional minute each. The average of the second and third readings is reported. All information about pregnancy was removed since a relatively small number of participants became pregnant during TODAY. The results for the eye chart test were also dropped since this collection wasn't begun until the middle of the study time making the results useless. Information about specific medication usage was collapsed into broad categories of medications as well as information related to the dispensing of study medications. All other questions from the form have been dropped since they were administrative in nature and/or related to safety.

4.4.19 TODAY.YLS: Youth Life Stressors

This form was completed once for each participant during the end of study phase. It was handed to the participant to record, in a standard manner, sources of stress experienced over the past year. Since this form was completed at a visit originally classified as an end of study visit the value of MVISIT will be any of the regularly scheduled assessment numbers closet in time to the end of study visit.

The responses on this form were unchanged and are provided as recorded.

4.5 Central Unit and Non Form Datasets

4.5.1 TODAY.CBL: Laboratory Data

TODAY.CBL includes the laboratory results from the pre-randomization run-in phase, baseline, and regularly scheduled visits. During the pre-randomization, run-in phase only the values for hemoglobin A1c (HbA1c) are reported since this laboratory test was done consistently across time for all participants. At baseline (M00), 6 months (M06), all annual visits (M12, M24, M36, M48, M60, M72), and all visits originally coded as a primary outcome or end of study visit (then recoded to a regular visit number) had a fasting blood draw with the full battery of laboratory tests including a 2-hour OGTT. All other regularly scheduled assessment visits had a non-fasting blood draw with only HbA1c, alanine aminotransferase (ALT), and aspartate aminotransferase (AST) analyzed. The laboratory results are outlined in the table below and are reported as provided from the laboratory.

Variable Name	Description	Units / Coding
RELEASEID	Participant ID for NIDDK Database Repository	
MVISIT	Release visit number	R=Pre-randomization M00 = Baseline M02-M78=Month 2 – Month78
DAYS	Days from randomization to CBL completion	Days
HBA1C	Hemoglobin A1c	
LDL	Low density lipoprotein cholesterol - without the contribution of IDL and Lp(a)	mg/dL
CHOL	Total cholesterol	mg/dL
HSCRP	High-sensitivity C-reactive protein (cardiovascular risk assessment)	mg/dL
ALT	Alanine aminotransferase	U/L
AST	Aspartate aminotransferase	U/L
FFA	Free fatty acid	mEq/L
FIB	Fibrinogen	mg/dL
GLUCOSE	Fasting glucose	mg/dL
HOM	Homocysteine	μmol/L
LDLB	Apo B-100 in LDL fractions	mg/dL
LDLC	LDL cholesterol measures in LD particles only without the contribution of IDL and Lp(a)	mg/dL
PIN	Proinsulin	pM
RF	LDL Relative floatation rate - indicates the mean density of LDL particles	
TRIG	Triglyceride	mg/dL
CPEP0MIN	C-peptide measurement right before consuming glucose solution	ng/mL
GLU0MIN	Glucose measurement right before consuming glucose solution	mg/dL
INS0MIN	Insulin measurement right before consuming glucose solution	μU/mL

CPEP30MIN	C-peptide measurement 30 minutes after consuming glucose solution	ng/mL
GLU30MIN	Glucose measurement 30 minutes after consuming glucose solution	mg/dL
INS30MIN	Insulin measurement 30 minutes after consuming glucose solution	μU/mL
CPEP60MIN	C-peptide measurement 1 hour after consuming glucose solution	ng/mL
GLU60MIN	Glucose measurement 1 hour after consuming glucose solution	mg/dL
INS60MIN	Insulin measurement 1 hour after consuming glucose solution	μU/mL
CPEP90MIN	C-peptide measurement 90 minutes after consuming glucose solution	ng/mL
GLU90MIN	Glucose measurement 90 minutes after consuming glucose solution	mg/dL
INS90MIN	Insulin measurement 90 minutes after consuming glucose solution	μU/mL
CPEP2HR	C-peptide measurement 2 hours after consuming glucose solution	ng/mL
GLU2HR	Glucose measurement 2 hours after consuming glucose solution	mg/dL
INS2HR	Insulin measurement 2 hours after consuming glucose solution	μU/mL
APOB	Total plasma apo B-100	mg/dL
CPEP	C-peptide	ng/mL
ESTCREATCLEAR	Estimated creatinine Clearance	mL/min
HDL	High density lipoprotein cholesterol	mg/dL
INS	Fasting Insulin	μU/mL
LDLCB	LDLC/ApoB ratio	
SERUMCREAT	Serum creatinine	mg/dL
UALB	Urine albumin	mg/dL
UALBCREAT	Urine albumin creatinine ratio	
UCREAT	Urine creatinine	mg/dL
VB12	Vitamin B12	pg/mL
VLDL	Very low density lipoprotein	mg/dL
GADINDEX	Glutamic acid decarboxylase	
IA2INDEX	Insulinoma antigen 2	
IL6	Interleukin 6	pg/mL
PAI1	Human plasminogen activator inhibitor-1	ng/mL

4.5.2 TODAY.FFQ: Food Frequency Nutrient Data

TODAY data nutrient analysis to a modified food frequency questionnaire administered at baseline (M00), 6 months (M06), 24 months (M24), and at all visits originally coded as a primary outcome or end of study visit (then recoded to a regular visit number) are provided. This questionnaire provides a measurement of participant dietary intake. It was interviewer-administered by a certified interviewer and data were entered directly onto a dedicated study laptop and transmitted to the University of South

Carolina Diet Assessment Center. Based on the participant's responses, nutrient analysis was conducted by the Diet Assessment Center in Columbia, SC. Free text responses were removed. The actual questionnaire is not available for release. The data included in the release are outlined in the table below and includes the summary information provided by the Diet Assessment Center.

Variable Name	Description	Units / Coding
RELEASEID	Participant ID for NIDDK Database Repository	
MVISIT	Release visit number	
DAYS	Days from randomization to FFQ completion	Days
TYPICAL	Was what you ate last week fairly typical for you, for what you were doing last week?	1=Yes 0=No
NO_TYPICAL1	If No to TYPICAL question, would you say you ate:	1=A lot more 2=A little more 3=A little less 4=A lot less
NO_TYPICAL2	If NO to TYPICAL question, what made last week different from most other weeks?	1=Sick 2=Trying a new diet 3=Other
FG1	Bread, cereal, rice & pasta (high fiber)	Servings per day
FG2	Bread, cereal, rice & pasta (low fiber)	Servings per day
FG4	Vegetable (tomato)	Servings per day
FG5	Vegetable (dark green, deep yellow)	Servings per day
FG6	Vegetable (cruciferous)	Servings per day
FG7	Vegetable (other: green salad, green beans, beans, corn, okra, peas, potatoes)	Servings per day
FG8	Fruit & Fruit juice (citrus)	Servings per day
FG9	Fruit & Fruit juice (other)	Servings per day
FG10	Dairy (high fat)	Servings per day
FG11	Dairy (low fat)	Servings per day
FG12	Fish (high fat)	Servings per day
FG15	Dried beans	Servings per day
FG16	Eggs	Servings per day
FG17	Meat (high fat)	Servings per day
FG19	Poultry (high fat)	Servings per day
FG20	Poultry (low fat)	Servings per day
FG21	Sweets & desserts	Servings per day
FG22	Fats & oils	Servings per day
FG24	Nuts & seeds	Servings per day
FG25	Coffee & tea	Servings per day
FG26	Meal replacement	Servings per day
FG27	Soda, Fruit flavor drink	Servings per day
FG28	Chips, high fat crackers, popcorn	Servings per day
FG29	Lower fat cracker, pretzels	Servings per day
FG30	Sports bars	Servings per day
PFG1	Bread, cereal, rice & pasta	Servings per day
PFG2	Vegetable	Servings per day
PFG3	Fruit	Servings per day
PFG4	Milk, yogurt & cheese	Servings per day
PFG5	Meat, poultry, fish, dry beans, eggs & nuts	Servings per day

PFG6	Fats, oils & sweets	Servings per day
FANDV	Fruit and Veg servings	Servings per day
ALAN	Daily intake of Alanine from diet	G
APRO	Daily intake of Animal Protein from diet	G
ARGI	Daily intake of Arginine from diet	G
ASPT	Daily intake of Aspartame from diet	?
ATC	Daily intake of Vitamin E (Total Alpha-Tocopherol) from diet	?
BCAR	Daily intake of Beta-Carotene (provitamin A carotenoid) from diet	MCG
BCEQ	Daily intake of Beta-Carotene Equivalents (derived from provitamin A carotenoids)from diet	MCG
BCRY	Daily intake of Beta-Cryptoxanthin (provitamin A carotenoid) from diet	MCG
BTC	Daily intake of Beta-Tocopherol from diet	MG?
CA	Daily intake of Calcium from diet	MG
CHOL	Daily intake of Cholesterol from diet	MG
CU	Daily intake of Copper from diet	MG
CYST	Daily intake of Cystine from diet	G
DAID	Daily intake of Daidzein from diet	MG?
DFE	Daily intake of Dietary Folate Equivalents	MCG
DFIB	Total Dietary Fiber from daily diet	G
DTC	Daily intake of Delta-Tocopherol from diet	MG?
FAT	Total Fat from daily diet	G
FE	Daily intake of Iron from diet	MG
FOL	Daily intake of Total Folate from diet	MCG
FRUC	Daily intake of Fructose from diet	G
GALA	Daily intake of Galactose from diet	G
GLUC	Daily intake of Glucose from diet	G
GLUT	Daily intake of Glutamic Acid from diet	G
GLYC	Daily intake of Glycine from diet	G
GTC	Daily intake of Gamma-Tocopherol from diet	MG?
HIST	Daily intake of Histidine from diet	G
IFIB	Daily intake of Insoluble Dietary Fiber	G
ISOL	Daily intake of Isoleucine from diet	G
K	Daily intake of Potassium from diet	MG
KCAL	Energy	KCAL
KJ	Energy (kilojoules)	KJ
LACT	Daily intake of Lactose from diet	G
LEUC	Daily intake of Leucine from diet	G
LYCO	Daily intake of Lycopene from diet	MCG
LYSI	Daily intake of Lysine from diet	G
LZ	Daily intake of Lutein + Zeaxanthin from diet	MCG
M14_1X	Daily intake of MUFA 14:1 (myristoleic acid) from diet	G
M16_1X	Daily intake of MUFA 16:1 (palmitoleic acid) from diet	G
M18_1X	Daily intake of MUFA 18:1 (oleic acid) from diet	G
M20_1X	Daily intake of MUFA 20:1 (gadoleic acid) from diet	G
M22_1X	Daily intake of MUFA 22:1 (erucic acid) from diet	G

MALT	Daily intake of Maltose from diet	G
METH	Daily intake of Methionine from diet	G
MFA	Total Monounsaturated Fatty Acids (MUFA) from diet	G
MG	Daily intake of Magnesium from diet	MG
NA	Daily intake of Sodium from diet	MG
NFOL	Daily intake of Natural Folate from diet	MCG
NIA	Daily intake of Niacin (vitamin B3) from diet	MG
NIAEQ	Daily intake of Niacin Equivalents from diet	MG
OMEGA3X	Daily intake of Omega-3 Fatty Acids from diet	G
P	Daily intake of Phosphorus from diet	MG
P18_2X	Daily intake of PUFA 18:2 (linoleic acid) from diet	G
P18_3X	Daily intake of PUFA 18:3 (linoleic acid) from diet	G
P18_4X	Daily intake of PUFA 18:4 (parinaric acid) from diet	G
P20_4X	Daily intake of PUFA 20:4 (arachidonic acid) from diet	G
P20_5X	Daily intake of PUFA 20:5 (eicosapentaenoic acid [EPA]) from diet	G
P22_5X	Daily intake of PUFA 22:5 (docosapentaenoic acid [DPA]) from diet	G
P22_6X	Daily intake of PUFA 22:6 (docosahexaenoic acid [DHA]) from diet	G
PANT	Daily intake of Pantothenic acid from diet	MG
PECT	Daily intake of Pectins from diet	G
PFA	Total Polyunsaturated Fatty Acids (PUFA) from diet	G
PHEN	Daily intake of Phenylalanine from diet	G
PRO	Total Protein from diet	G
PROL	Daily intake of Proline from diet	G
RIB	Daily intake of Riboflavin (vitamin B2) from diet	MG
RL	Daily intake of Retinol from diet	MCG
S04_0X	Daily intake of SFA 4:0 (butyric acid) from diet	G
S06_0X	Daily intake of SFA 6:0 (caproic acid) from diet	G
S08_0X	Daily intake of SFA 8:0 (caprylic acid) from diet	G
S10_0X	Daily intake of SFA 10:0 (capric acid) from diet	G
S12_0X	Daily intake of SFA 12:0 (lauric acid) from diet	G
S14_0X	Daily intake of SFA 14:0 (myristic acid) from diet	G
S16_0X	Daily intake of SFA 16:0 (palmitic acid) from diet	G
S17_0X	Daily intake of SFA 17:0 (margaric acid) from diet	G
S20_0X	Daily intake of SFA 20:0 (arachidic acid) from diet	G
S22_0X	Daily intake of SFA 22:0 (behenic acid) from diet	G
SE	Daily intake of Selenium from diet	MCG
SERI	Daily intake of Serine from diet	G
SFA	Total Saturated Fatty Acids (SFA) from diet	G
SFOL	Daily intake of Synthetic Folate from diet	MCG
STAR	Daily intake of Starch from diet	G
SUCR	Daily intake of Sucrose from diet	G
TCHO	Total Carbohydrate from diet	G
THI	Daily intake of Thiamin (vitamin B1) from diet	MG
THRE	Daily intake of Threonine from diet	G
TRYP	Daily intake of Tryptophan from diet	G

TSUGAR	Total Sugars from diet	G
TYRO	Daily intake of Tyrosine from diet	G
VA	Total Vitamin A Activity from diet	IU?
VALI	Daily intake of Valine from diet	G
VARAE	Total Vitamin A Activity (Retinol Activity Equivalents) from diet	MCG?
VARE	Total Vitamin A Activity (Retinol Equivalents) from diet	MCG?
VB6X	Daily intake of Vitamin B-6 (pyridoxine, pyridoxyl, & pyridoxamine) from diet	MG
VB12X	Daily intake of Vitamin B-12 (cobalamin) from diet	MCG
VC	Daily intake of Vitamin C (ascorbic acid) from diet	MG
VD	Daily intake of Vitamin D (calciferol) from diet	MCG
VITE	Daily intake of Vitamin E from diet	IU?
VK	Daily intake of Vitamin K (phylloquinone) from diet	MCG
VPRO	Daily intake of Vegetable Protein from diet	G
WSDF	Daily intake of Soluble Dietary Fiber	G
ZN	Daily intake of Zinc from diet	MG
PERCFAT	Percent of Calories from Fat	N/A
PERCCARB	Percent of Calories from Carbohydrate	N/A
PERCPRO	Percent of Calories from Protein	N/A
PERCSFA	Percent of Calories from Saturated Fatty Acids	N/A
PERCMFA	Percent of Calories from Monounsaturated Fatty Acids	N/A
PERCPFA	Percent of Calories from Polyunsaturated Fatty Acids	N/A

4.5.3 TODAY.ACCEL: Accelerometery

Accelerometers were used in TODAY to document activity changes. The monitor used in the TODAY cohort is the MTI Actigraph (MTI Health Services, Fort Walton Beach, FL), which has been tested for field-based assessments of physical activity levels. The uniaxial, hip worn Actigraph accelerometer measures physical activity in a single plane (vertical accelerations ranging from 0.05 – 2.0 G's). These parameters permit the detection of normal body motion but filter out frequencies outside of the frequency range of human bodily acceleration such as vibrations. A 60 second epoch, or sampling interval, was used. At the end of each interval the activity count is stored in non-volatile RAM and the accumulator is reset to zero to begin the next sampling interval. The participants were instructed to wear the monitor during all waking hours of the day but to remove the monitor for sleeping, swimming and bathing activitiy and to be careful not to get the monitor wet in rainy conditions.

The accelerometer was worn for a period of 7 days before the assessment visits occurring at baseline (M00), 6 months (M06), 24 months (M24), and at all visits originally coded as a primary outcome or end of study visit (then recoded to a regular visit number).

At the end of the 7 day period, the participant returned the accelerometer and diary at their clinic visit. Data from the accelerometer were downloaded, processed, screened for wear time using a modified version of previously reported methods (http://riskfactor.cancer.gov/tools/nhanes), and summarized into per day per participant measures. Average total activity counts per day were calculated using summed daily counts detected over wear periods. Time in minutes spent in different activity intensities was calculated using age-specific formulas for count cut-points (METs = 2.757 + (0.0015 x counts/min) – (0.0896 x age[yrs]) – (0.000038 x counts/min x age) corresponding to light, (1-3.99 METs), moderate (4-6.99 METs) and vigorous intensity (≥ 7 METs). A MET is an estimate of relative intensity such that one

MET represents the energy expenditure for an individual at rest whereas a 10 MET activity requires 10 times that amount. These intensity levels were derived from a published age specific, energy expenditure prediction equation [Freedson et al, 2005, Trost SG et al, 1998]. Time spent in sedentary behavior was defined as the amount of time accumulated in counts that were < 100 counts per minute. Non-wear time was defined as intervals of at least 60 consecutive minutes of zero counts with allowance for up to two minutes of observations of 1-100 counts per minute. Wear time was determined by subtracting non-wear time from the total observation time for that day.

The data included in the release are outlined in the table below.

Variable Name	Description	Units / Coding
releaseid	Participant ID for NIDDK Database Repository	
mvisit	Release visit number	
days	Days from randomization to ACCEL completion	Days
day_2	Sequence/day of monitoring	Days
ctd	Average count	Count/min/day
totctd	Total count	Count/day
ctmax	Maximum count value	Count/day
totalwrtime	Estimated wear time	Min/day
totalnwrtime	Estimated non wear time	Min/day
sedentot	Accumulated sedentary minutes (0-99 count)	Min/day
totalact	Total activity minutes (light + MVPA)	Min/day
lightAct	Light activity minutes	Min/day
moderateAct	Moderate activity minutes	Min/day
vigorousAct	Vigorous activity minutes	Min/day
mvpa	Moderate to vigorous activity (MVPA)	Min/day

4.5.4 TODAY.3DPAR: 3-Day Physical Activity Recall

This form measured the participant's physical activity over the prior 3 days prior to the assessment visit. It is self-administered by the participant while guided by a trained interviewer during the assessment visit. The time-period covered by the questionnaire should coincide with the final three days that the accelerometer was used. The participant was asked to record the number corresponding to any activities in which they engaged for at least 30 minutes during the three day period for each 30 minute time period in which they engaged in that activity. In addition, they were asked to indicate how intensely they engaged in that particular activity. Light activity required little or no movement with slow breathing. Moderate activities require some movement with normal breathing. Hard activities require a moderate amount of movement and increased breathing. Finally, very hard activities require quick movements and hard breathing. If multiple activities were performed during a 30 minute block, the participant was to record the number they spent the majority of the 30 minute block doing. If equal amounts of time were spent doing activities during a 30 minute block then the participant was to record the number for the activity which was the hardest. Upon the completion of the survey, while the participant was still present, the interviewer or other study staff member reviewed the form to make sure the code numbers made sense. They also checked for any sport or physically demanding activity listed for more than 2 hours and questioned the participant about this if any such activity was identified.

The 3-day physical activity recall was completed at baseline (M00), 6 months (M06), 24 months (M24), and at all visits originally coded as a primary outcome or end of study visit (then recoded to a regular visit number). The 3DPAR dataset variables, descriptions and coding results are outlined in the table below

and are reported as recorded. The 3DPAR activities are provided in a table following the variable descriptions. The actual questionnaire is not available for release.

Variable Name	Description	Units / Coding
RELEASEID	Participant ID for Release	
MVISIT	Release visit number	
DAYS	Days from randomization to 3DPAR completion	Days
UD1ACT	Did participant record any activity?	1=Yes; 0=No
UD1DT	Day 1 – Days from randomization	Days from randomization
UD1DOW	Day 1- Day of the week	1=Sunday; 2=Monday; 3=Tuesday 4=Wednesday; 5=Thursday; 6=Friday 7=Saturday
UAN16A	Activity number - Early morning - 6-6:30AM	See table below
UXR16A	Activity Scale - Early Morning - 6-6:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN163A	Activity number - Early morning - 6:30-7AM	See table below
UXR163A	Activity Scale - Early Morning - 6:30-7AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN17A	Activity number - Early morning - 7-7:30AM	See table below
UXR17A	Activity Scale - Early Morning - 7-7:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN173A	Activity number - Early morning - 7:30-8AM	See table below
UXR173A	Activity Scale - Early Morning - 7:30-8AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN18A	Activity number - Early morning - 8-8:30AM	See table below
UXR18A	Activity Scale - Early Morning - 8-8:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN183A	Activity number - Early morning - 8:30-9AM	See table below
UXR183A	Activity Scale - Early Morning - 8:30-9AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN19A	Activity number - Morning - 9-9:30AM	See table below
UXR19A	Activity Scale - Morning - 9-9:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN193A	Activity number - Morning - 9:30-10AM	See table below
UXR193A	Activity Scale - Morning - 9:30-10AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN110A	Activity number - Morning - 10-10:30AM	See table below
UXR110A	Activity Scale - Morning - 10-10:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN1103A	Activity number - Morning - 10:30-11AM	See table below
UXR1103A	Activity Scale - Morning - 10:30-11AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN111A	Activity number - Morning - 11-11:30AM	See table below
UXR111A	Activity Scale - Morning - 11-11:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN1113A	Activity number - Morning - 11:30-12PM	See table below
UXR1113A	Activity Scale - Morning - 11:30-12PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard

UAN112P	Activity number - Afternoon Day 1 - 12-12:30	See table below
UXR112P	Activity Scale - Afternoon Day 1 - 12-12:30	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN1123P	Activity number - Afternoon Day 1 - 12:30-1	See table below
UXR1123P	Activity Scale - Afternoon Day 1 - 12:30-1	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN11P	Activity number - Afternoon - 1-1:30PM	See table below
UXR11P	Activity Scale - Afternoon - 1-1:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN113P	Activity number - Afternoon - 1:30-2PM	See table below
UXR113P	Activity Scale - Afternoon - 1:30-2PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN12P	Activity number - Afternoon - 2-2:30PM	See table below
UXR12P	Activity Scale - Afternoon - 2-2:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN123P	Activity number - Afternoon - 2:30-3PM	See table below
UXR123P	Activity Scale - Afternoon - 2:30-3PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN13P	Activity number - Afternoon - 3-3:30PM	See table below
UXR13P	Activity Scale - Afternoon - 3-3:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN133P	Activity number - Afternoon - 3:30-4PM	See table below
UXR133P	Activity Scale - Afternoon - 3:30-4PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN14P	Activity number- Afternoon - 4-4:30PM	See table below
UXR14P	Activity Scale - Afternoon - 4-4:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN143P	Activity number - Afternoon - 4:30-5PM	See table below
UXR143P	Activity Scale - Afternoon - 4:30-5PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN15P	Activity number- Afternoon - 5-5:30PM	See table below
UXR15P	Activity Scale - Afternoon - 5-5:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN153P	Activity number- Evening - 5:30-6PM	See table below
UXR153P	Activity Scale - Evening - 5:30-6PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN16P	Activity number- Evening - 6-6:30PM	See table below
UXR16P	Activity Scale - Evening - 6-6:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN163P	Activity number- Evening - 6:30-7PM	See table below
UXR163P	Activity Scale - Evening - 6:30-7PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN17P	Activity number- Evening - 7-7:30PM	See table below
UXR17P	Activity Scale - Evening - 7-7:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN173P	Activity number- Evening - 7:30-8PM	See table below
UXR173P	Activity Scale - Evening - 7:30-8PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN18P	Activity number- Evening - 8-8:30PM	See table below

UXR18P	Activity Scale - Evening - 8-8:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN183P	Activity number- Evening -8:30-9PM	See table below
UXR183P	Activity Scale - Evening - 8:30-9PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN19P	Activity number- Evening - 9-9:30PM	See table below
UXR19P	Activity Scale - Evening - 9-9:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN193P	Activity number- Evening - 9:30-10PM	See table below
UXR193P	Activity Scale - Evening - 9:30-10PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN110P	Activity number- Evening - 10-10:30PM	See table below
UXR110P	Activity Scale - Evening - 10-10:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN1103P	Activity number- Evening - 10:30-11PM	See table below
UXR1103P	Activity Scale - Evening - 10:30-11PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN111P	Activity number- Evening - 11-11:30PM	See table below
UXR111P	Activity Scale - Evening - 11-11:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN1113P	Activity number- Evening - 11:30-12AM	See table below
UXR1113P	Activity Scale - Evening - 11:30-12AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UD2ACT	Did participant record any activity?	1=Yes; 0=No
UD2DT	Day 2 – Days from randomization	Days from randomization
UD2DOW	Day 2- Day of the week	1=Sunday; 2=Monday; 3=Tuesday 4=Wednesday; 5=Thursday; 6=Friday 7=Saturday
UAN26A	Activity number - Early morning Day 2 - 6-6:30AM	See table below
UXR26A	Activity Scale - Early Morning Day 2 - 6-6:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN263A	Activity number - Early morning Day 2 - 6:30-7AM	See table below
UXR263A	Activity Scale - Early Morning Day 2 - 6:30-7AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN27A	Activity number - Early morning Day 2 - 7-7:30AM	See table below
UXR27A	Activity Scale - Early Morning Day 2- 7-7:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN273A	Activity number - Early morning Day 2 - 7:30-8AM	See table below
UXR273A	Activity Scale - Early Morning Day 2- 7:30-8AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN28A	Activity number - Early morning Day 2 - 8-8:30AM	See table below
UXR28A	Activity Scale - Early Morning Day 2 - 8-8:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN283A	Activity number - Early morning Day 2 -	See table below

	8:30-9AM	
UXR283A	Activity Scale - Early Morning Day 2 - 8:30-9AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN29A	Activity number - Morning Day 2- 9-9:30AM	See table below
UXR29A	Activity Scale - Morning Day 2- 9-9:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN293A	Activity number - Morning Day 2- 9:30-10AM	See table below
UXR293A	Activity Scale - Morning Day 2- 9:30-10AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN210A	Activity number - Morning Day 2- 10-10:30AM	See table below
UXR210A	Activity Scale - Morning Day 2- 10-10:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN21103A	Activity number - Morning Day 2- 10:30-11AM	See table below
UXR21103A	Activity Scale - Morning Day 2- 10:30-11AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN211A	Activity number - Morning Day 2- 11-11:30AM	See table below
UXR211A	Activity Scale - Morning Day 2- 11-11:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN2113A	Activity number - Morning Day 2- 11:30-12PM	See table below
UXR2113A	Activity Scale - Morning Day 2- 11:30-12PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN212P	Activity number - Afternoon Day 2- 12-12:30PM	See table below
UXR212P	Activity Scale - Afternoon Day 2- 12-12:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN2123P	Activity number - Afternoon Day 2- 12:30-1PM	See table below
UXR2123P	Activity Scale - Afternoon Day 2- 12:30-1PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN21P	Activity number - Afternoon Day 2- 1-1:30PM	See table below
UXR21P	Activity Scale - Afternoon Day 2- 1-1:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN213P	Activity number - Afternoon Day 2- 1:30-2PM	See table below
UXR213P	Activity Scale - Afternoon Day 2- 1:30-2PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN22P	Activity number - Afternoon Day 2- 2-2:30PM	See table below
UXR22P	Activity Scale - Afternoon Day 2- 2-2:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN223P	Activity number - Afternoon Day 2- 2:30-3PM	See table below
UXR223P	Activity Scale - Afternoon Day 2- 2:30-3PM	1=Light; 2=Moderate; 3=Hard

		4=Very Hard
UAN23P	Activity number - Afternoon Day 2- 3-3:30PM	See table below
UXR23P	Activity Scale - Afternoon Day 2- 3-3:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN233P	Activity number - Afternoon Day 2- 3:30-4PM	See table below
UXR233P	Activity Scale - Afternoon Day 2- 3:30-4PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN24P	Activity number- Afternoon Day 2- 4-4:30PM	See table below
UXR24P	Activity Scale - Afternoon Day 2- 4-4:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN243P	Activity number - Afternoon Day 2- 4:30-5PM	See table below
UXR243P	Activity Scale - Afternoon Day 2- 4:30-5PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN25P	Activity number- Afternoon Day 2- 5-5:30PM	See table below
UXR25P	Activity Scale - Afternoon Day 2- 5-5:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN253P	Activity number- Evening Day 2- 5:30-6PM	See table below
UXR253P	Activity Scale - Evening Day 2- 5:30-6PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN26P	Activity number- Evening Day 2- 6-6:30PM	See table below
UXR26P	Activity Scale - Evening Day 2- 6-6:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN263P	Activity number- Evening Day 2- 6:30-7PM	See table below
UXR263P	Activity Scale - Evening Day 2- 6:30-7PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN27P	Activity number- Evening Day 2- 7-7:30PM	See table below
UXR27P	Activity Scale - Evening Day 2- 7-7:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN273P	Activity number- Evening Day 2- 7:30-8PM	See table below
UXR273P	Activity Scale - Evening Day 2- 7:30-8PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN28P	Activity number- Evening Day 2- 8-8:30PM	See table below
UXR28P	Activity Scale - Evening Day 2- 8-8:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN283P	Activity number- Evening Day 2- 8:30-9PM	See table below
UXR283P	Activity Scale - Evening Day 2- 8:30-9PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN29P	Activity number- Evening Day 2- 9-9:30PM	See table below
UXR29P	Activity Scale - Evening Day 2- 9-9:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN293P	Activity number- Evening Day 2- 9:30-10PM	See table below
UXR293P	Activity Scale - Evening Day 2- 9:30-10PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN210P	Activity number- Evening Day 2- 10-10:30PM	See table below
UXR210P	Activity Scale - Evening Day 2- 10-10:30PM	1=Light; 2=Moderate; 3=Hard

		4=Very Hard
UAN2103P	Activity number- Evening Day 2- 10:30-11PM	See table below
UXR2103P	Activity Scale - Evening Day 2- 10:30-11PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN211P	Activity number- Evening Day 2- 11-11:30PM	See table below
UXR211P	Activity Scale - Evening Day 2- 11-11:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN2113P	Activity number- Evening Day 2- 11:30-12AM	See table below
UXR2113P	Activity Scale - Evening Day 2- 11:30-12AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UD3ACT	Did participant record any activity?	1=Yes; 0=No
UD3DT	Day 3 – Days from randomization	Days from randomization
UD3DOW	Day 3- Day of the week	1=Sunday; 2=Monday; 3=Tuesday 4=Wednesday; 5=Thursday; 6=Friday 7=Saturday
UAN36A	Activity number - Early morning Day 3 - 6-6:30AM	See table below
UXR36A	Activity Scale - Early Morning Day 3 - 6-6:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN363A	Activity number - Early morning Day 3 - 6:30-7AM	See table below
UXR363A	Activity Scale - Early Morning Day 3 - 6:30-7AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN37A	Activity number - Early morning Day 3 - 7-7:30AM	See table below
UXR37A	Activity Scale - Early Morning Day 3- 7-7:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN373A	Activity number - Early morning Day 3 - 7:30-8AM	See table below
UXR373A	Activity Scale - Early Morning Day 3- 7:30-8AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN38A	Activity number - Early morning Day 3 - 8-8:30AM	See table below
UXR38A	Activity Scale - Early Morning Day 3 - 8-8:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN383A	Activity number - Early morning Day 3 - 8:30-9AM	See table below
UXR383A	Activity Scale - Early Morning Day 3 - 8:30-9AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN39A	Activity number - Morning Day 3- 9-9:30AM	See table below
UXR39A	Activity Scale - Morning Day 3- 9-9:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN393A	Activity number - Morning Day 3- 9:30-10AM	See table below
UXR393A	Activity Scale - Morning Day 3- 9:30-10AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard

UAN310A	Activity number - Morning Day 3- 10-10:30AM	See table below
UXR310A	Activity Scale - Morning Day 3- 10-10:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN3103A	Activity number - Morning Day 3- 10:30-11AM	See table below
UXR3103A	Activity Scale - Morning Day 3- 10:30-11AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN311A	Activity number - Morning Day 3- 11-11:30AM	See table below
UXR311A	Activity Scale - Morning Day 3- 11-11:30AM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN3113A	Activity number - Morning Day 3- 11:30-12PM	See table below
UXR3113A	Activity Scale - Morning Day 3- 11:30-12PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN312P	Activity number - Afternoon Day 3- 12-12:30PM	See table below
UXR312P	Activity Scale - Afternoon Day 3- 12-12:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN3123A	Activity number - Afternoon Day 3- 12:30-1PM	See table below
UXR3123A	Activity Scale - Afternoon Day 3- 12:30-1PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN31P	Activity number - Afternoon Day 3- 1-1:30PM	See table below
UXR31P	Activity Scale - Afternoon Day 3- 1-1:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN313P	Activity number - Afternoon Day 3- 1:30-2PM	See table below
UXR313P	Activity Scale - Afternoon Day 3- 1:30-2PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN32P	Activity number - Afternoon Day 3- 2-2:30PM	See table below
UXR32P	Activity Scale - Afternoon Day 3- 2-2:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN323P	Activity number - Afternoon Day 3- 2:30-3PM	See table below
UXR323P	Activity Scale - Afternoon Day 3- 2:30-3PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN33P	Activity number - Afternoon Day 3- 3-3:30PM	See table below
UXR33P	Activity Scale - Afternoon Day 3- 3-3:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN333P	Activity number - Afternoon Day 3- 3:30-4PM	See table below
UXR333P	Activity Scale - Afternoon Day 3- 3:30-4PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN34P	Activity number- Afternoon Day 3- 4-4:30PM	See table below

UXR34P	Activity Scale - Afternoon Day 3- 4-4:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN343P	Activity number - Afternoon Day 3- 4:30-5PM	See table below
UXR343P	Activity Scale - Afternoon Day 3- 4:30-5PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN35P	Activity number- Afternoon Day 3- 5-5:30PM	See table below
UXR35P	Activity Scale - Afternoon Day 3- 5-5:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN353P	Activity number- Evening Day 3- 5:30-6PM	See table below
UXR353P	Activity Scale - Evening Day 3- 5:30-6PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN36P	Activity number- Evening Day 3- 6-6:30PM	See table below
UXR36P	Activity Scale - Evening Day 3- 6-6:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN363P	Activity number- Evening Day 3- 6:30-7PM	See table below
UXR363P	Activity Scale - Evening Day 3- 6:30-7PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN37P	Activity number- Evening Day 3- 7-7:30PM	See table below
UXR37P	Activity Scale - Evening Day 3- 7-7:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN373P	Activity number- Evening Day 3- 7:30-8PM	See table below
UXR373P	Activity Scale - Evening Day 3- 7:30-8PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN38P	Activity number- Evening Day 3- 8-8:30PM	See table below
UXR38P	Activity Scale - Evening Day 3- 8-8:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN383P	Activity number- Evening Day 3- 8:30-9PM	See table below
UXR383P	Activity Scale - Evening Day 2- 8:30-9PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN39P	Activity number- Evening Day 3- 9-9:30PM	See table below
UXR39P	Activity Scale - Evening Day 3- 9-9:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN393P	Activity number- Evening Day 3- 9:30-10PM	See table below
UXR393P	Activity Scale - Evening Day 3- 9:30-10PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN310P	Activity number- Evening Day 3- 10-10:30PM	See table below
UXR310P	Activity Scale - Evening Day 3- 10-10:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN3103P	Activity number- Evening Day 3- 10:30-11PM	See table below
UXR3103P	Activity Scale - Evening Day 3- 10:30-11PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN311P	Activity number- Evening Day 3- 11-1:30PM	See table below
UXR311P	Activity Scale - Evening Day 3- 11-11:30PM	1=Light; 2=Moderate; 3=Hard 4=Very Hard
UAN3113P	Activity number- Evening Day 3- 11:30-2AM	See table below
UXR3113P	Activity Scale - Evening Day 3- 11:30-12AM	1=Light; 2=Moderate; 3=Hard

		4=Very Hard

Activity Numbers	
1 = Sleeping	40 = Football
2 = Getting dressed	41 = Fishing
3 = Getting ready (hair, make-up, shaving, etc.)	42 = Frisbee
4 = Showering/bathing	43 = Golf/Mini-golf
5 = Eating a meal	44 = Gymnastics/Tumbling
6 = Snacking	45 = Hiking
7 = Sitting in class	46 = Hockey (field, ice, street, or floor)
8 = Free time/study hall	47 = Horseback riding
9 = Club, student activity	48 = Hunting
10 = P.E. class	49 = Jumping rope
11 = Church	50 = Kick-boxing
12 = Hanging around	51 = Lacrosse
13 = Homework	52 = Martial arts (karate, judo, boxing, tai kwan do, tai chi)
14 = Listening to music	53 = Playground games (dodge ball, kick ball, four square, tether ball)
15 = Marching band/flag corps/drill team	54 = Playing catch
16 = Music lesson/playing instrument	55 = Playing with younger children
17 = Playing video games/surfing internet	56 = Riding scooters
18 = Reading	57 = Rock climbing
19 = Shopping	58 = Rugby
20 = Talking on the telephone	59 = Running/Jogging/Cross country
21 = Watching TV or movie	60 = Skateboarding
22 = Riding in a car/bus	61 = Skating (roller, ice, or roller blading)
23 = Travel by walking	62 = Skiing (downhill, cross country, or water)
24 = Travel by bicycling	63 = Sledding, tobogganning, bobsledding
25 = Working (part-time job, child care)	64 = Snowboarding
26 = Doing house chores (vacuuming, washing dishes, etc.)	65 = Snowshoeing
27 = Yard Work (mowing, raking leaves, washing car, walking dog etc.)	66 = Soccer
28 = Aerobics, jazzercise, water aerobics, taebo	67 = Surfing (board or body) /Skimboarding
29 = Archery	68 = Swimming (laps)
30 = Baseball/Softball	69 = Swimming (play, pool games, water volleyball, snorkeling)
31 = Basketball	70 = Tennis, racquetball, badminton, paddleball
32 = Bicycling, mountain biking	71 = Trampolining
33 = Boating (canoe, kayak, rafting, sailboat)	72 = Track & Field
34 = Bowling	73 = Volleyball
35 = Broomball	74 = Walking for exercise
36 = Calisthenics/Exercises (push-ups, sit-ups, jamping jacks, etc.)	75 = Weightlifting
37 = Cheerleading/drill team	76 = Wrestling

38 = Dance (at home, in schoool, at a class, party, or place of worship)	77 = Yoga, stretching
39 = Exercise machine (treadmill, cycle, stair master, rowing machine)	78 = Other

4.5.5 TODAY.DEXA: Dual Energy X-Ray Absorptiometry

Dual X-ray absorptiometry (DXA) scans were performed using the existing densitometry system at each clinical center (models QDR4500A, Discovery A, Discovery W/Wi, Delphi W, and Delphi A from Hologic Inc., Bedford, MA; models Prodigy and iDXA from GE Lunar Corp, Madison, WI; model DPX-IQ from Lunar Corp, Madison, WI). All scans were performed according to study-specific guidelines for subject positioning standardized across the different DXA systems. DXA quality assurance procedures included phantom crosscalibration and longitudinal monitoring. Although there are well-known systematic differences in the absolute values of these systems, the change in the Hologic and GE-Lunar body composition values (i.e., relative results to baseline) is comparable because of the demonstrated linear relationship across a wide range of ages for both sexes. All scans were analyzed centrally at the TODAY DXA Central Reading Center (University of California at San Francisco) by study-trained personnel using software according to manufacturer guidelines. The software versions for analyzing the scans were Hologic Discovery 12.3 for the Hologic scans, Prodigy 11.4 for the Prodigy and iDXA scans, and GE-Lunar 4.7e for the DPX-L scans.

About one-quarter of the DXA scans collected were invalidated due to either weight and size limitations set by the equipment manufacturers or because a body part (e.g., arm or leg) was completely or partially off the scanner, there was hand-hip overlap, or there was movement during the scan. Invalidity codes were applied by DXA study-trained personnel from the Central Reading Center to indicate reasons regions of the body could not be analyzed accurately. The invalidity codes are provided in the data file.

TODAY DXA scans are completed at baseline (M00), 6 months (M06), 24 months (M24), and at all visits originally coded as a primary outcome or end of study visit (then recoded to a regular visit number). The DXA scans provide bone and soft tissue measurements for the total body, for both arms and both legs, the trunk (including thoracic and lumbar spine, left and right ribs, and pelvis), and head. The DXA dataset variables, descriptions and coding results are outlined in the table below and are reported as recorded. Longitudinal calibration corrections and cross-calibration between similar systems were applied for the whole body scans. Measurements using the proportional correction factor are specified in the table below and denoted by a "_P" at the end of the variable name.

Variable Name	Description	Units / Coding
RELEASEID	Participant ID for NIDDK Database Repository	
MVISIT	Release visit number	
DAYS	Days from randomization to DXA completion	Days
MACHINE	DXA machine type	'HO'=Hologic Delphi/A and W 'IQ'= GE Lunar DPX-IQ 'LU'=GE Lunar Prodigy
HEADB_QA	Head bone invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner

		6=Positioning problem 7= Other (motion, etc.)
ARMB_L_QA	Left arm bone invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)
ARMT_L_QA	Left arm tissue invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)
ARMB_R_QA	Right arm bone invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)
ARMT_R_QA	Right arm tissue invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)
LEGB_L_QA	Left leg bone invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)
LEGT_L_QA	Left leg tissue invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)

LEGB_R_QA	Right leg bone invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)
LEGT_R_QA	Right leg tissue invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)
TRUNKB_QA	Trunk bone invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)
TRUNKT_QA	Trunk tissue invalidity code	0=Normal for region 1=Removable object 2=Non-removable object 3=Obesity 4=Hand/hip overlap 5=Body part off the scanner 6=Positioning problem 7= Other (motion, etc.)
WB_HEAD_AREA	Whole body head area	CM^2
WB_HEAD_BMC	Whole body head bone mineral content	G
WB_HEAD_BMD	Whole body head bone mineral density	G/CM^2
WB_HEAD_FAT	Whole body head fat	G
WB_HEAD_Lean	Whole body head lean	G
WB_HEAD_MASS	Whole body head mass	G
WB_HEAD_PFAT	Whole body head percent fat	%
WB_LARM_AREA	Whole body left arm area	CM^2
WB_LARM_BMC	Whole body left arm bone mineral content	G
WB_LARM_BMD	Whole body left arm bone mineral density	G/CM^2
WB_LARM_FAT	Whole body left arm fat	G
WB_LARM_Lean	Whole body left arm lean	G
WB_LARM_MASS	Whole body left arm mass	G
WB_LARM_PFAT	Whole body left arm percent fat	%
WB_RARM_AREA	Whole body right arm area	CM^2
WB_RARM_BMC	Whole body right arm bone mineral content	G
WB_RARM_BMD	Whole body right arm bone mineral density	G/CM^2

WB_RARM_FAT	Whole body right arm fat	G
WB_RARM_Lean	Whole body right arm lean	G
WB_RARM_MASS	Whole body right arm mass	G
WB_RARM_PFAT	Whole body right arm percent fat	%
WB_LLEG_AREA	Whole body left leg area	CM^2
WB_LLEG_BMC	Whole body left leg bone mineral content	G
WB_LLEG_BMD	Whole body left leg bone mineral density	G/CM^2
WB_LLEG_FAT	Whole body left leg fat	G
WB_LLEG_Lean	Whole body left leg lean	G
WB_LLEG_MASS	Whole body left leg mass	G
WB_LLEG_PFAT	Whole body left leg percent fat	%
WB_RLEG_AREA	Whole body right leg area	CM^2
WB_RLEG_BMC	Whole body right leg bone mineral content	G
WB_RLEG_BMD	Whole body right leg bone mineral density	G/CM^2
WB_RLEG_FAT	Whole body right leg fat	G
WB_RLEG_Lean	Whole body right leg lean	G
WB_RLEG_MASS	Whole body right leg mass	G
WB_RLEG_PFAT	Whole body right leg percent fat	%
WB_TS_AREA	Whole body thoracic spine area	CM^2
WB_TS_BMC	Whole body thoracic spine bone mineral content	G
WB_TS_BMD	Whole body thoracic spine bone mineral density	G/CM^2
WB_TRUNK_FAT	Whole body trunk fat	G
WB_TRUNK_Lean	Whole body trunk lean	G
WB_TRUNK_MASS	Whole body trunk mass	G
WB_TRUNK_PFAT	Whole body trunk percent fat	%
WB_SUBTOT_AREA	Whole body sub total area	CM^2
WB_SUBTOT_BMC	Whole body sub total bone mineral content	G
WB_SUBTOT_BMD	Whole body sub total bone mineral density	G/CM^2
WB_SUBTOT_FAT	Whole body sub total fat	G
WB_SUBTOT_Lean	Whole body sub total lean	G
WB_SUBTOT_MASS	Whole body sub total mass	G
WB_SUBTOT_PFAT	Whole body sub total percent fat	%
WB_TOT_AREA	Whole body total area	CM^2
WB_TOT_BMC	Whole body total bone mineral content	G
WB_TOT_BMD	Whole body total bone mineral density	G/CM^2
WB_TOT_FAT	Whole body total fat	G
WB_TOT_Lean	Whole body total lean	G
WB_TOT_MASS	Whole body total mass	G
WB_TOT_PFAT	Whole body total percent fat	%
WB_LRIB_AREA	Whole body left rib area	CM^2
WB_LRIB_BMC	Whole body left rib bone mineral content	G
WB_LRIB_BMD	Whole body left rib bone mineral density	G/CM^2
WB_RRIB_AREA	Whole body right rib area	CM^2
WB_RRIB_BMC	Whole body right rib bone mineral content	G
WB_RRIB_BMD	Whole body right rib bone mineral density	G/CM^2
WB_LS_AREA	Whole body right lumbar spine area	CM^2
WB_LS_BMC	Whole body right lumbar spine bone mineral content	G

WB_LS_BMD	Whole body right lumbar spine bone mineral density	G/CM^2
WB_PELV_AREA	Whole body pelvic area	CM^2
WB_PELV_BMC	Whole body pelvic bone mineral content	G
WB_PELV_BMD	Whole body pelvic bone mineral density	G/CM^2
WB_TOT_BMC_P	Corrected whole body total bone mineral content (Proportional)	CM^2
WB_TOT_BMD_P	Corrected whole body total bone mineral density (Proportional)	G/CM^2
WB_TOT_FAT_P	Corrected whole body total fat (Proportional)	G
WB_TOT_LEAN_P	Corrected whole body total lean (Proportional)	G
WB_TOT_MASS_P	Corrected whole body total mass(Proportional)	G
WB_TOT_PFAT_P	Corrected whole body total percent fat (Proportional)	%
WB_TOT_PLEAN_P	Corrected whole body total percent lean (Proportional)	%

4.5.6 TODAY.ECHO: Echocardiography

Echocardiography was preformed only once during the last year of TODAY. The patient was placed in the left lateral decubitus position. Twenty-six regular views and 6 speckle tracking views were obtained. All images required adequate ECG tracing and NSR 3 cardiac cycles. They were captured at a high frame rate (40-60/min or 60-70% of heart size), were able to see all segments without dropouts, and sectors were adjusted so all the segments are visible through the cardiac cycle. All information captured was transferred to the Nemours Cardiac Center for reading.

Since the studies were all performed in the last year of TODAY they are not associated with a study visit. The data included in the release are listed in the table below. The data indicate functional and anatomic changes in the heart, including left ventricular and septal hypertrophy, decreased ejection fraction, and decreased distensibility.

Variable Name	**Description**	**Units / Coding**
RELEASEID	Participant ID for NIDDK Database Repository	
DAYS	Days from randomization to echocardiogram	Days
ASCEND2D	2-D – aorta ascending	cm
DIASTO2D	2-D – aortic root end diastolic dimension	cm
SYSTOL2D	2-D – aortic root end systole systolic	cm
LAAREA2D	2-D – four chamber LA area	cm^2
DIAVOL2D	2-D – four chamber LV end diastolic volume	cm
LVE	Doppler diastology E/Em ratio – LV mitral valve peak E	cm/second
LVEM	Doppler diastology E/Em ratio – LV Em	cm/second
LVRATIO	Doppler diastology E/Em ratio – LV E/Em	
PEAKVELO	Doppler reg flow – tricuspid valve peak velocity	cm/second
RVSYSTOL	Doppler reg flow – tricuspid valve RV systolic pressure	mmHg
AORTROOT	MMODE aorta and LA – aortic root	cm
LADIMEN	MMODE aorta and LA – LA internal dimensions	cm

MMODEHR	MMODE LV and RV – heart rate	beats/minute
IVSDIAS	MMODE LV and RV – inter-ventricular septum diastole	cm
IVSSYST	MMODE LV and RV – inter-ventricular septum systole	cm
LVINDEX	MMODE LV and RV – LV cardiac index	liters/minute/m^2
LVOUTPUT	MMODE LV and RV – LV cardiac output	liters/minute
LVEJECT	MMODE LV and RV – LV ejection fraction	%
DIAVOLMM	MMODE LV and RV – LV end diastolic volume	mm
SYSVOLMM	MMODE LV and RV – LV end systolic volume	mm
PCTSHORT	MMODE LV and RV – LV % fractional shortening	%
LVDIAST	MMODE LV and RV – LV internal dimension diastole	cm
LVSYSTOL	MMODE LV and RV – LV internal dimension systole	cm
LVMASS	MMODE LV and RV – LV mass	g
WALLDIAS	MMODE LV and RV – LV posterior wall diastole	cm
WALLSYST	MMODE LV and RV – LV posterior wall systole	cm
LVSTROKE	MMODE LV and RV – LV stroke volume	ml
TAPSE	MMODE – tricuspid annular plane systolic excursion systolic dimension	cm
MMODEQC	MMODE – quality score	0=poor/not available, 1=fair, 2=good, 3=excellent
WALTHICK	Relative wall thickness = (walldias x 2) / lvdiast	
LADIAMHT	LA diameter/height in m	
LVDIASHT	LV internal dimension diastole/height in m	
LVBSA	LV mass/body surface area where bsa=$[(\text{height\_cm} \times \text{weight\_kg}) / 3600]^{1/2}$	
LVMASSHT	LV mass/ht2.7 where height in m	

4.5.7 TODAY.FUNDUS: Fundus Photography

Fundus photography was completed in the last year of TODAY and was collected using the University of Wisconsin Fundus Photography Reading Center (FPRC) Modified 7 Standard Digital Color Fundus Photography procedure (7M-D) using FPRC-certified photographers. All images were captured using a digital system that was FPRC certified for color and capture capability (typically a minimum 3 megapixel resolution or higher with a preferred 5 or 6 megapixel resolution color image capture system). The modified 7-standard stereoscopic fields for color photography specified by the 7M-D procedure differs from the ETDRS 7-standard field protocol in the position of two fields: Field 1M and Field 3M are both modified to include the center of the macula, in Field 1M near the edge of the field and in Field 3M midway between the edge and center of the field. A tutorial on how to capture the images is located on the FPRC website (Fundus Photograph Reading Center). Information about the systems used to capture the image in addition results from FPRC analysis are included in the data release. Information about the individual variables, their descriptions and any associated coding are provided in the table below.

Variable	Description	Coding
RELEASEID	Participant ID for the NIDDK Database Repository	
DAYS	Number of days from randomization to Fundus photography completion	Days
EYE	Eye photographed	L=Left; R=Right
CAMERATYPE	Camera type used for fundus photograph	0=Zeiss FF 2-4 (no notch) [Zeiss classic 30^{o} grid] 1=Topcon 35^{o} (square notch) [Zeiss classic 30^{o} grid] 2=Kowa 30^{o} (triangle at 12:00) or other [Zeiss classic 30^{o} grid] 3=Zeiss FF 450 (triangle at 4:30) [Zeiss FF 450 30^{o} grid] 4=Cannon 40^{o} (round notch) [Cannon 40^{o} grid] 5=Topcon 50^{o} (square notch) [Wide angle] 6=Cannon 60^{o} (round notch) [Wide angle] 7=Other; 8=Cannot grade
FUNDUSREFLEX	Fundus reflex	0=No or mild opacity 1=Lens opacity: mild central or moderate peripheral 2=Lens opacity: moderate central or severe peripheral 3=Lens opacity: precludes photos 4=Vitreous opacity: precludes photos 5=Pseudophakia: no or mild secondary opacity 6=Pseudophakia: moderate to severe secondary opacity 7=Other notable abnormality 8=FR photo absent or ungradable
PC_FOR_ME	Focal/grid photocoagulation for macular edema	0=None; 1=Questionable; 2=Definite; 8=Cannot grade 9=Not applicable
PC_PANRETINAL	Scatter (panretinal) photocoagulation	0=None; 1=Questionable; 2=Partial scatter or local PC for NV 3=Complete scatter (± local); 8=Cannot grade

Variable	Description	Coding
		9=Not applicable
DRSEVERITY	Diabetic retinopathy (DR) severity level of study eye	10=MA and other characteristics absent 12=DR absent but other non-diabetic lesions present 14A=HE definite; MA absent; 14B=SE definite; MA absent 14C=IRMA definite; MA absent 14Z=Venous loops ≥ D/1; MA absent 15=Hemorrhages(s) definite; MA absent 20=MA definite; other characteristics absent 35A=Venous loops ≥ D/1; 35B=SE, IRMA or VB=Q 35C=Retinal hemorrhages present 35D=HE ≥ D/1; 35E=HE ≥ M/1; 35F=SE ≥ D/1 43A=H/Ma=M/4-5 or S/1; 43B=IRMA=D/1-3 47A=Both 43A and 43B; 47B=IRMA=D/4-5 47C=H/Ma=S/2-3; 47D=VB=D/1 53A=Two or more of 47A, 47B and 47C 53B=H/Ma ≥ s/4-5; 53C=IRMA ≥ M/1 53D=VB ≥ D/2-3 53E=Two or more of 53B, 53C, and 53D 60=Panretinal photocoagulation or local Rx of NV 61A=FPD or FPE present with NVD and NVe absent 61B=NVE=D/1-5 65A=NVE ≥ N/1; and VHJ and PRH=A or Q 65B=NVD=D; and Vh and PRH=A or Q 65C=VH or PRH=D and NVE<M/1 and NVD absent 71A=VH or PRH ≥ M/1 71B=NVE ≥ M/1 and VH or PRH ≥ D/1 71C=NVD=2 and Vh or PRH ≥ D/1; 71D=NVD ≥ M

Variable	Description	Coding
		75=NVD ≥ M and VH or PRH ≥ D/1 81=NVD=CG, or NVD<D and NVE=CG in ≥ 1 field and absent in all others; and RDCM<D 85A=VH=VS in Field 1 or 2; 85B=RDCM=D 90=Cannot grade
MACOUNT	Number of microaneurysms – required only if DRSeverity ≤ 20	0=None; Q=Questionable; 1=10 (discrete count) 11=11 or more; 88=Cannot grade; 99=Not applicable
PS_1	Papillary swelling, field 1	0=No evidence; 1=Questionable; 2=Examples A, B, C, D 3=Examples D, F; 8=Cannot grade
HMAINGRID	Hemorrhages/microaneurysms, within grid, field 2	0=No evidence; 1=Questionable; 2=<standard photo#1 3=<standard photo#2A; 4=<standard photo#2B 5= ≥ standard photo#2B; 8=Cannot grade; 9=Not applicable
RTPRESENCE	Presence of retinal thickening	0=None; 1=Questionable; 2=Definite, outside grid 3=Definite, within grid; 8=Cannot grade; 9=Not applicable
RTPROXIMITY	Proximity of retinal thickening/adjacent hard exudates to the center in microns	0, 100, 101, 200, 300, 301, 400, 500, 600-3000 (by increments of 100) – proximity in μm 8888=Cannot grade; 9999=Not applicable
RTATCENTER	Retinal thickening at center of macula	0=None; 1=Questionable; 2=Definite, <1X reference 3=Definite, <2X reference; 4=Definite, ≥ 2X reference 8=Cannot grade; 9=Not applicable
CSME	Clinically significant macular edema (ETDRS)	0=None; 1=Questionable 2=Zone or RT ≥ 1 DA, part ≤ 1 DD from center 3=RT or adjacent HE ≤ 500 μm from center 8=Cannot grade; 9=Not applicable
RTCIOMETHOD	Method used to collect RT Center Inner Outer	0=Not present; 1=Estimation; 2=Grid calculation 8=Cannot grade; 9=Not applicable

Variable	Description	Coding
RT_CENTERINNERESTIMATE	Total estimated DA of RT in center and inner subfields	00.00-4.00 total DA; 88.88=Cannot grade 99.99=Not applicable
RT_CENTERINNERGRIDCALC	Total calculated DA of RT in center and inner subfields	0.0000-3.9996 total DA; 8.8888=Cannot grade 9.9999=Not applicable
RT_CENTERINNEROUTERESTIMATE	Total estimated DA of RT in center, inner, and outer subfields	00.00-16.00 total DA; 88.88=Cannot grade 99.99=Not applicable
RT_CENTERINNEROUTERGRIDCALC	Total calculated DT of RT in center, inner and outer subfields	0.0000-16.0000 total DA; 8.8888=Cannot grade 9.9999=Not applicable
HEINGRID	Hard exudates within grid, field 2	0=None; 1=Questionable; 2=Definite; 8=Cannot grade 9=Not applicable
OCULARABNORMALITIES	Confounding ocular abnormality likely to confound the assessment of drug treatment effect or visual acuity measurement	0=None; 1=Questionable; 2=Present, unconfirmed 3=Urgent condition confirmed by FPRC ophthalmologist 4=Possible adverse event confirmed by FPRC ophthalmologist 8=Cannot grade; 9=Not applicable
ABNORMALITY1	Name of ocular abnormality 1	00=Large drusen area (>circle in I2 in area) within the grid 01=AMD RPE depigmentation02 – AMD RPE hyperpigmentation 03=AMD subretinal hemorrhage; 04=AMD subretinal fibrous scar 05=AMD SSR/RPE detachment; 06=AMD geographic atrophy 07=Angioid streaks; 08=Asteroid hyalosis 09=Central or branch artery occlusion 10=Central or branch vein occlusion 11=Chorioretinal scar: POHS, toxoplasmosis, other 12=Confounding anterior opacity (other than lens) 13=Drusen on the optic nervehead; 14=Hollenhorst plaque 15=Large cup/disk ratio; 16=Confounding lens opacity

Variable	Description	Coding
		17=Macular hole or pseudohole; 18=Nevus 19=Papillary swelling 20=Peripapillary atrophy, myopic crescent 21=Surface wrinkling/epiretinal membrane 22=Tension lines, dragged macular 23=Vitreous opacity or glial remnant 24=Other; 99=Not applicable
ABNORMALITY2	Name of ocular abnormality 2	Blank=No second abnormality 00=Large drusen area (>circle in I2 in area) within the grid 01=AMD RPE depigmentation02 – AMD RPE hyperpigmentation 03=AMD subretinal hemorrhage; 04=AMD subretinal fibrous scar 05=AMD SSR/RPE detachment 06=AMD geographic atrophy; 07=Angioid streaks 08=Asteroid hyalosis; 09=Central or branch artery occlusion 10=Central or branch vein occlusion 11=Chorioretinal scar: POHS, toxoplasmosis, other 12=Confounding anterior opacity (other than lens) 13=Drusen on the optic nervehead; 14=Hollenhorst plaque 15=Large cup/disk ratio; 16=Confounding lens opacity 17=Macular hole or pseudohole; 18=Nevus 19=Papillary swelling; 20=Peripapillary atrophy, myopic crescent 21=Surface wrinkling/epiretinal membrane 22=Tension lines, dragged macular 23=Vitreous opacity or glial remnant 24=Other; 99=Not applicable
MACULARABNORMALITIES	Presence of macular abnormalities	0=No evidence; 1=Questionable or definite; 8=Cannot grade 9=Not applicable

Variable	Description	Coding
SWRERMINGRID	Surface wrinkling retinopathy/epiretinal membrane within grid	0=None; 1=Questionable; 2=Cellophane reflex 3=Subtle membrane; 4=Obvious membrane; 8=Cannot grade 9=Not applicable
CYST	Cyst	0=No evidence (none); 1=Questionable; 2=Definite 8=Cannot grade; 9=Not applicable
TRACTIONINGRID	Retinal traction within grid	0=None; 1=Questionable; 2=Tension lines only 3=Vessel distorted; 4=Dragged macula; 8=Cannot grade 9=Not applicable
RELINGRID	Retinal elevation within grid	0=None; 1=Questionable; 2=Definite, not center 3=Involving center; 8=Cannot grade; 9=Not applicable
HEPLAQUESCAR	HE organized plaque/fibrous scar at center	0=None; 1=Questionable; 2=Organized plaque 3=Fibrous scar; 8=Cannot grade; 9=Not applicable
OTHMACABNORM	Other macular abnormality	0=None; 1=Questionable; 2=Definite 8=Cannot grade; 9=Not applicable
RT_CENTER	Retinal thickening area within grid (center circle subfield)	0-100%=Retinal involvement; Q=Questionable C=Cannot grade
RT_INNERSUPERIOR	Retinal thickening area within grid (inner superior subfield)	0-100%=Retinal involvement; Q=Questionable C=Cannot grade
RT_INNERNASAL	Retinal thickening area within grid (inner nasal subfield)	0-100%=Retinal involvement; Q=Questionable C=Cannot grade
RT_INNERINFERIOR	Retinal thickening area within grid (inner inferior subfield)	0-100%=Retinal involvement; Q=Questionable C=Cannot grade
RT_INNERTEMPORAL	Retinal thickening area within grid (inner temporal subfield)	0-100%=Retinal involvement; Q=Questionable C=Cannot grade

Variable	Description	Coding
RT_OUTERSUPERIOR	Retinal thickening area within grid (outer superior subfield)	0-100%=Retinal involvement; Q=Questionable C=Cannot grade
RT_OUTERNASAL	Retinal thickening area within grid (outer nasal subfield)	0-100%=Retinal involvement; Q=Questionable C=Cannot grade
RT_OUTERINFERIOR	Retinal thickening area within grid (outer inferior subfield)	0-100%=Retinal involvement; Q=Questionable C=Cannot grade
RT_OUTERTEMPORAL	Retinal thickening area within grid (outer temporal subfield)	0-100%=Retinal involvement; Q=Questionable C=Cannot grade
HE_CENTERPOINT	Hard exudates at center point (Pt) of grid	0=None; 1=Questionable; 2=Definite; 8=Cannot grade 9=Not applicable
HE_CENTER	Hard exudates within grid (center circle subfield)	0=None; 1=Questionable; 2= < circle C_0; 3= < circle C_1 4= < circle C_2; 5= < circle I_2; 6= < circle O_2; 7= ≥ circle O_2 8=Cannot grade; 9=Not applicable
HE_INNERSUPERIOR	Hard exudates within grid (inner superior subfield)	0=None; 1=Questionable; 2= < circle C_0; 3= < circle C_1 4= < circle C_2; 5= < circle I_2; 6= < circle O_2, 7= ≥ circle O_2 8=Cannot grade; 9=Not applicable
HE_INNERNASAL	Hard exudates within grid (inner nasal subfield)	0=None; 1=Questionable; 2= < circle C_0; 3= < circle C_1 4= < circle C_2; 5= < circle I_2; 6= < circle O_2; 7= ≥ circle O_2 8=Cannot grade; 9=Not applicable
HE_INNERINFERIOR	Hard exudates within grid (inner inferior subfield)	0=None; 1=Questionable; 2= < circle C_0; 3= < circle C_1 4= < circle C_2; 5= < circle I_2; 6= < circle O_2; 7= ≥ circle O_2 8=Cannot grade; 9=Not applicable
HE_INNERTEMPORAL	Hard exudates within grid (inner temporal subfield)	0=None; 1=Questionable; 2= < circle C_0; 3= < circle C_1 4= < circle C_2; 5= < circle I_2; 6= < circle O_2; 7= ≥ circle O_2 8=Cannot grade; 9=Not applicable

Variable	Description	Coding
HE_OUTERSUPERIOR	Hard exudates within grid (outer superior subfield)	0=None; 1=Questionable; 2= < circle C_0; 3= < circle C_1 4= < circle C_2; 5= < circle I_2; 6= < circle O_2; 7= ≥ circle O_2 8=Cannot grade; 9=Not applicable
HE_OUTERNASAL	Hard exudates within grid (outer nasal subfield)	0=None; 1=Questionable; 2= < circle C_0; 3= < circle C_1 4= < circle C_2; 5= < circle I_2; 6= < circle O_2; 7= ≥ circle O_2 8=Cannot grade; 9=Not applicable
HE_OUTERINFERIOR	Hard exudates within grid (outer inferior subfield)	0=None; 1=Questionable; 2= < circle C_0; 3= < circle C_1 4= < circle C_2; 5= < circle I_2; 6= < circle O_2; 7= ≥ circle O_2 8=Cannot grade; 9=Not applicable
HE_OUTERTEMPORAL	Hard exudates within grid (outer temporal subfield)	0=None; 1=Questionable; 2= < circle C_0; 3= < circle C_1 4= < circle C_2; 5= < circle I_2; 6= < circle O_2; 7= ≥ circle O_2 8=Cannot grade; 9=Not applicable
RT_CENTERINNER	Total DA of RT in center and inner subfields	0.0000-3.9996 total DA; 88.88=Cannot grade 99.99=Not applicable
RT_CENTERINNER_CANTGRADE	Total DA of RT in ungradable center and inner subfields	0.00-4.00 total DA; 8.88=Cannot grade 9.99=Not applicable
RT_CENTERINNEROUTER	Total DA of RT in center, inner and outer subfields	0.0000-16.0000 total DA; 88.88=Cannot grade 99.99=Not applicable
RT_CENTERINNEROUTER_CANTGRADE	Total DA of RT in ungradable center, inner and outer subfields	0.00-16.00 total DA; 88.88=Cannot grade 99.99=Not applicable
HE_CENTERINNER	Total DA of HE in center and inner subfields	0.0000-0.9625 total DA; 88.8888=Cannot grade 99.9999=Not applicable
HE_CENTERINNER_CANTGRADE	Number of HE ungradable center and inner subfields	0-5 Subfields
HE_CENTERINNEROUTER	Total DA of HE in center, inner and outer	0.0000-1.7325 total DA; 88.8888=Cannot grade

Variable	Description	Coding
	subfields	99.9999=Not applicable
HE_CENTERINNEROUTER_CANTGRADE	Number of HE in ungradeable center, inner and outer subfields	0-9 subfields
DRSEVERITYSUBJECT	Diabetic retinopathy severity level of both eyes for the specified subject	10<10 = One eye DRSERVITY=10; other eye DRSERVITY <10 10=10 = Both eyes DRSERVITY=10 10=90 = One eye DRSERVITY=10; other eye DRSERVITY=90 12<12 = One eye DRSERVITY=12; other eye DRSERVITY<12 12=12 = Both eyes DRSERVITY=12 12=90 = One eye DRSERVITY=12; other eye DRSERVITY=90 14<14 = One eye DRSERVITY=14A, 14B, 14C or 14Z; other eye DRSERVITY<14A 14=14 = Both eyes DRSERVITY=14A, 14B, 14C, or 14Z 14=90 = One eye DRSERVITY=14A, 14B, 14C, or 14Z; other eye DRSERVITY=90 15<14 = One eye DRSERVITY=15; other eye DRSERVITY<14A, 14B, 14C or 14Z 15=14 = One eye DRSERVITY=15; other eye DRSERVITY=14A, 14B, 14C, or 14Z 15=15 = Both eyes DRSERVITY=15 15=90 = One eye DRSERVITY=15; other eye DRSERVITY=90 20<14 = One eye DRSERVITY=20; other eye DRSERVITY<14A, 14B, 14C or 14Z 20=14 = One eye DRSERVITY=20; other eye DRSERVITY=14A, 14B, 14C or 14Z 20=15 = One eye DRSERVITY=20; other eye DRSERVITY=15 20=20 = Both eyes DRSERVITY=20 20=90 = One eye DRSERVITY=20; other eye DRSERVITY=90 35<35 = One eye DRSERVITY=35A, 35B, 35C, 35D, or 35F;

Variable	Description	Coding
		other eye DRSERVITY<35A 35=35 = Both eyes DRSERVITY=35A, 35B, 35C, 35D, or 35F 35=90 = One eye DRSERVITY=35A, 35B, 35C, 35D, or 35F; other eye DRSERVITY=90 43<43 = One eye DRSERVITY=43A or 43B; other eye DRSERVITY<43A 43=43 = Both eyes DRSERVITY=43A or 43B 43=90 = One eye DRSERVITY=43A or 43B; other eye DRSERVITY=90 47<47 = One eye DRSERVITY=47A, 47B, 47C or 47D; other eye DRSERVITY<47A 47=47 = Both eyes DRSERVITY=47A, 47B, 47C or 47D 47=90 = One eye DRSERVITY=47A, 47B, 47C, or 47D; other eye DRSERVITY=90 53<53 = One eye DRSERVITY=53A, 53B, 53C, 53D or 53E; other eye DRSERVITY<53A 53=53 = Both eyes DRSERVITY=53A, 53B, 53C, 53D, or 53E 53=90 = One eye DRSERVITY=53A, 53B, 53C, 53D, or 53E; other eye DRSERVITY=90 60<60 = Both eyes DRSERVITY<60 60=60 = Both eyes DRSERVITY=60 60=90 = One eye DRSERVITY=60; other eye DRSERVITY=90 61<60 = One eye DRSERVITY=61A or 61B; other eye DRSERVITY<60 61=60 = One eye DRSERVITY=61A or 61B; other eye DRSERVITY=60 61=61 = Both eyes DRSERVITY=61A or 61B 61=90 = One eye DRSERVITY=61A or 61B; other eye DRSERVITY=90

Variable	Description	Coding
		65<65 = One eye DRSERVITY=65A, 65B, or 65C; other eye <65A 65=65 = Both eyes DRSERVITY=65A, 65B or 65C 65=90 = One eye DRSERVITY=65A, 65B, or 65C; other eye DRSERVITY=90 71<71 = One eye DRSERVITY=71A, 71B, 71C, or 71D; other eye DRSERVITY<71A 71=71 = Both eyes DRSERVITY=71A, 71B, 71C or 71D 71=90 = One eye DRSERVITY=71A, 71B, 71C, or 71D; other eye DRSERVITY=90 75<75 = One eye DRSERVITY=75; other eye DRSERVITY<75 75=75 = Both eyes DRSERVITY=75 75=90 = One eye DRSERVITY=75; other eye DRSERVITY=90 81<81 = One eye DRSERVITY=81; other eye DRSERVITY<81 81=81 = Both eyes DRSERVITY=81 81=90 = One eye DRSERVITY=81; other eye DRSERVITY=90 85<85 = One eye DRSERVITY=85A or 85B; other eye DRSERVITY<85A 85=85 = Both eyes DRSERVITY=85 85=90 = One eye DRSERVITY=85; other eye DRSERVITY=90 90=90 = Both eyes DRSERVITY=90
DRSEVERITYRECODE	Integer recode of DR Severity for study eye	1=DRSeverity levels 10, 12 2=DRSeverity levels 14A, 14B, 14C, 14Z, 15, 20 3=DRSeverity levels 35A, 35B, 35C, 35D, 35E, 35F 4= DRSeverity levels 43A, 43B 5= DRSeverity levels 47A, 47B, 47C, 47D 6= DRSeverity levels 53A, 53B, 53C, 53D, 53E 7= DRSeverity levels 60, 61A, 61B

Variable	Description	Coding
		8= DRSeverity levels 65A, 65B, 65C 9= DRSeverity levels 71A, 71B, 71C, 71D 10= DRSeverity level 75; 11= DRSeverity level 81 12= DRSeverity levels 85A, 85B; 90= DRSeverity level 90
DRSEVERITYRECODESUBJECT	Integer recode of DR Severity level for specified subject	1=DRSeveritySubject levels 10=10, 10=19, 12<12, 12=12, 12=90 2=DRSeveritySubject levels 14<14, 15<14, 20<14 3=DRSeveritySubject levels 14=14, 14=90, 15=14, 15=15, 15=90, 20=14, 20=15, 20=20, 20=90 4=DRSeveritySubject level 35<35 5=DRSeveritySubject levels 35=35, 35=90 6=DRSeveritySubject level 43<43 7=DRSeveritySubject levels 43=43, 43=90 8=DRSeveritySubject level 47<47 9=DRSeveritySubject levels 47=47, 47=90 10=DRSeveritySubject level 53<53 11=DRSeveritySubject levels 53=53, 53=90 12=DRSeveritySubject levels 61<60, 60<60 13=DRSeveritySubject levels 61=61, 61=60, 60=60, 60=90, 61=90 14=DRSeveritySubject level 65<65 15=DRSeveritySubject levels 65=65, 65=90 16=DRSeveritySubject level 71<71 17=DRSeveritySubject levels71=71, 71=90 18=DRSeveritySubject level 75<75 19=DRSeveritySubject levels 75=75, 75=90 20=DRSeveritySubject level 81<81 21=DRSeveritySubject levels 81=81, 81=90

Variable	Description	Coding
		22=DRSeveritySubject level 85<85 23=DRSeveritySubject levels 85=85, 85=90 90=DRSeveritySubject level 90=90
CS_CONFIDENCESCORE	Image quality score	0=CS1 – High confidence; 1=CS2 – Adequate confidence 2=CS3 – Inadequate confidence

4.5.8 TODAY.OCT: OCT Photography

Status Optical Coherence Tomography (OCT 3) and Spectral Domain Optical Coherence Tomography (SD OCT) scans were completed in the last year of TODAY and was collected using standard clinic procedures to obtain optimal quality scans. Only University of Wisconsin Fundus Photography Reading Center (FPRC) certified OCT operators were allowed to take scans and each center was only allowed to use FPRC approved machines. OCT scans were selected that identified the retina's inner limiting membrane (ILM) and the retinal pigment epithelium (RPE). Fast Macular Thickness scans were repeated in cases where only one of the analysis scans displayed an inaccurately identified ILM or RPE boundary and the operator believed a second attempt might produce a more suitable scan for analysis. Information about the systems used to capture the image and the results from the FPRC analysis are included in the data release. Information about the individual variables, their descriptions and any associated coding are provided in the table below.

Variable	Description	Coding
RELEASEID	Participant ID for the NIDDK Database Repository	
DAYS	Number of days from randomization to Fundus photography completion	Days
EYE	Eye photographed	L=Left; R=Right
OCT_TYPE	Type of OCT machine	2=SD (spectral domain) OCT; 3=TD (time domain) OCT; 4=Other
MODEL	OCT manufacturer – model	1=Zeiss-Stratus; 2=Zeiss-Cirrus; 3=Heidelberg-Spectralis 4=Topcon-3D OCT; 5=OptoVue-RTVue; 6=Opko-Spectral OCT/SLO 7=Optopol-Copernicus; 8=Bioptgen-Bioptgen; 9=Other
MODELSOFTWAREVERSION	Software version used	Positive number; NA=Not applicable
SOFTWAREVERSIONUSED	Software used for analysis	1=Manufacturer specific; 2=Non-manufacturer specific; 9=Not applicable
PROT_SPECS	Scanned per protocol specifications?	0=No; 2=Yes; 8=Expired query; 9=Not applicable
PROT_SPECS_LL	Line length is not per protocol	0=No; 2=Yes; 9=Not applicable
PROT_SPECS_SDEN	Scan density is not per protocol	0=No; 2=Yes; 9=Not applicable
PROT_SPECS_ORIEN	Scan orientation is not per protocol	0=No; 2=Yes; 9=Not applicable
PROT_SPECS_OTHER	Other aspect of scan is not per protocol	0=No; 2=Yes; 9=Not applicable
IMG_QUAL_METRIC	Image quality metric	Integer 0-100 (varies by manufacturer)
CPAVAILREP	Center point available from report	0=No; 2=Yes
CENTERPOINT	Original center point value from scan	0-2000 μm; 9999=Not applicable
CENTERPOINT_RELIABLE	Original center point value reliability	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
RT_CENTER	Original retinal thickness (grid center subfield)	0-2000 μm; 9999=Not applicable
RT_CENTER_RELIABLE	Original retinal thickness reliability (grid center subfield)	0=No (unreliable); 2=Yes (reliable); 9=Not applicable

Variable	Description	Coding
RT_INNERSUPERIOR	Original retinal thickness (grid inner superior subfield)	0-2000 μm; 9999=Not applicable
RT_INNERSUPERIOR_RELIABLE	Original retinal thickness reliability (grid inner superior subfield)	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
RT_INNERNASAL	Original retinal thickness (grid inner nasal subfield)	0-2000 μm; 9999=Not applicable
RT_INNERNASAL_RELIABLE	Original retinal thickness reliability (grid inner nasal subfield)	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
RT_INNERINFERIOR	Original retinal thickness (grid inner inferior subfield)	0-2000 μm; 9999=Not applicable
RT_INNERINFERIOR_RELIABLE	Original retinal thickness reliability (grid inner inferior subfield)	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
RT_INNERTEMPORAL	Original retinal thickness (grid inner temporal subfield)	0-2000 μm; 9999=Not applicable
RT_INNERTEMPORAL_RELIABLE	Original retinal thickness reliability (grid inner temporal subfield)	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
RT_OUTERSUPERIOR	Original retinal thickness (grid outer superior subfield)	0-2000 μm; 9999=Not applicable
RT_OUTERSUPERIOR_RELIABLE	Original retinal thickness reliability (grid outer superior subfield)	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
RT_OUTERNASAL	Original retinal thickness (grid outer nasal subfield)	0-2000 μm; 9999=Not applicable
RT_OUTERNASAL_RELIABLE	Original retinal thickness reliability (grid outer nasal subfield)	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
RT_OUTERINFERIOR	Original retinal thickness (grid outer inferior subfield)	0-2000 μm; 9999=Not applicable

Variable	Description	Coding
RT_OUTERINFERIOR_RELIABLE	Original retinal thickness reliability (grid outer inferior subfield)	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
RT_OUTERTEMPORAL	Original retinal thickness (grid outer temporal subfield)	0-2000 μm; 9999=Not applicable
RT_OUTERTEMPORAL_RELIABLE	Original retinal thickness reliability (grid outer temporal subfield)	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
CENTERSTDDEV	Original retinal thickness standard deviation	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
TOTALVOLUME	Total volume	0.00-60.00 mm^3; 88.88=Cannot grade; 99.99=Not applicable
TOTALVOLUME_RELIABLE	Total volume reliability	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
ALT_VAL_GRID	Do altered values from grid need to be entered	0=No; 2=Yes; 9=Not applicable
ALT_CENTERPOINT	Altered center point from report	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
ALT_CENTERPOINT_RELIABLE	Altered center point reliability	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
ALT_RT_CENTER	Altered retinal thickness (grid center subfield)	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
ALT_RT_INNERSUPERIOR	Altered retinal thickness (grid inner superior subfield)	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
ALT_RT_INNERNASAL	Altered retinal thickness (grid inner nasal subfield)	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
ALT_RT_INNERINFERIOR	Altered retinal thickness (grid inner inferior subfield)	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
ALT_RT_INNERTEMPORAL	Altered retinal thickness (grid inner temporal subfield)	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
ALT_RT_OUTERSUPERIOR	Altered retinal thickness (grid outer superior subfield)	0-2000 μm; 8888=Cannot grade; 9999=Not applicable

Variable	Description	Coding
ALT_RT_OUTERNASAL	Altered retinal thickness (grid outer nasal subfield)	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
ALT_RT_OUTERINFERIOR	Altered retinal thickness (grid outer inferior subfield)	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
ALT_RT_OUTERTEMPORAL	Altered retinal thickness (grid outer temporal subfield)	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
ALT_TOTALVOLUME	Altered total volume	0.00-60.00 mm^3; 88.88=Cannot grade; 99.99=Not applicable
ALT_TOTALVOLUME_RELIABLE	Altered total volume reliablility	0=No (unreliable); 2=Yes (reliable); 9=Not applicable
PER_MM_CP	Manual measurement of center point performed	0=No; 2=Yes
MM_CP_BSCAN	B-scan used to perform the manual measurement	1=6-12 scan; 2=7-1 scan; 3=8-2 scan; 4=9-3 scan; 5=10-4 scan; 6=11-5 scan
MM_CP_ASCAN	A-scan number used to perform the manual measurement OR distance (μm) from left edge to spot of manual measurement	Integer: 1-10000; 88888=Cannot grade; 99999=Not applicable
MM_CP_TOOL	Tool used for manual measurment	1=Calipers; 2=A-scan line indicator; 9=Not applicable
MM_CP_THICKNESS	Manual measurement center point thickness	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
CENTERPOINT_FINANALYSIS	Center point for analysis	0-2000 μm; 8888=Cannot grade
CENTER_FINANALYSIS	Center subfield for analysis	0-2000 μm; 8888=Cannot grade
TOTALVOLUME_FINANALYSIS	Total volume for analysis	0.00-60.00 mm^3; 88.88=Cannot grade; 99.99=No map report available
SSR_PRESENCE	SSR (Subretinal Fluid) - presence	0=Absent; 1=Questionable; 2=Definite, SSR only present outside central 1mm 3=Definite, SSR only present within central 1mm

Variable	Description	Coding
		4=Definite, SSR present within the central 1mm and outside the central 1mm 7=Definite, unable to determine location; 8=Cannot grade; 9=Not applicable
SSR_MM_CP_BSCAN	B-scan used for SSR (subretinal fluid) manual measurement at center point	1-1000 [for SD-OCT] If Zeiss-Stratus: 1=6-12 scan; 2=7-1 scan; 3=8-2 scan; 4=9-3 scan; 5=10-4 scan; 6=11-5 scan 8888=Cannot grade; 9999=Not applicable
SSR_MM_CP_ASCAN	A-scan number used to perform the manual measurement (μm) from left edge to spot of manual measurement	Integer: 1-10000; 88888=Cannot grade; 99999=Not applicable
SSR_MM_CP_THICKNESS	SSRD manually measured thickness at center point	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
SSR_MM_MAX_BSCAN	B-scan used for SSR (subretinal fluid) manual measurement of maximum thickness at center point	1-1000 [for SD-OCT] If Zeiss-Stratus: 1=6-12 scan; 2=7-1 scan; 3=8-2 scan; 4=9-3 scan; 5=10-4 scan; 6=11-5 scan 8888=Cannot grade; 9999=Not applicable
SSR_MM_MAX_ASCAN	A-scan number used to perform the manual measurement OR distance (μm) from left edge to spot of manual measurement of maximum thickness at center point	Integer: 1-10000; 88888=Cannot grade; 99999=Not applicable
SSR_MM_MAX_THICKNESS	SSRD manual measured thickness along any scan	0-2000 μm; 8888=Cannot grade; 9999=Not applicable
CYST_LOCLATEXTENT	Cystoid spaces – location and lateral extent	0=Absent; 1=Questionable 2=Definite, cystoid spaces present only outside central 1mm 3=Definite, cystoid spaces present only within central 1mm 4=Definite, cystoid spaces present within and outside central 1mm 7=Definite, unable to determine location; 8=Cannot grade

Variable	Description	Coding
CYST_AXIALDIAM_CP	Cystoid spaces – largest diameter measured axially in the central subfield cyst	1=Small, ≤ 200 μm; 2=Medium, ≤ 400 μm; 3=Large, > 400 μm 8=Cannot grade; 9=Not applicable
VITAB_PVD	Vitreoretinal interface abnormalities – posterior vitreous detachment (PVD)	0=Absent; 1=Questionable; 2=Definite, non-adherent 3=Definite, questionably adherent; 4=Definite, partially adherent 8=Cannot grade; 9=Not applicable
VITAB_ERM	Vitreoretinal interface abnormalities – epiretinal membrane (ERM)	0=Absent; 1=Questionable; 2=Definite, outside central 1mm 3=Definite, central 1mm involved - questionable 4=Definite, central 1mm involved - definite 8=Cannot grade; 9=Not applicable
VITAB_RTD	Vitreoretinal interface abnormalities – retinal traction and/or distortion (RTD)	0=Absent; 1=Questionable; 2=Definite, outside central 1mm 3=Definite, central 1mm involved - questionable 4=Definite, central 1mm involved - definite 8=Cannot grade; 9=Not applicable
VITAB_MH	Vitreoretinal interface abnormalities – macular hole (MH)	0=Absent; 1=Questionable; 2=Pseudohole or lamellar hole 3=Definite, stage 1; 4=Definite, stage 2, stage 3 or stage 4 8=Cannot grade; 9=Not applicable
RPE_RIPTEAR_PRESENCE	Retinal pigment epithelium (RPE) rip or tear presence	0=Absent; 1=Questionable; 2=Definite; 8=Cannot grade
RPELC_PRESENCE	RPE lesion complex (RPELC) presence	0=Absent; 1=Questionable; 2=Predominantly Type I CNV 3=Predominantly Type II CNV; 4=Definite, indeterminate CNV 5=Other; 8=Cannot grade
RPELC_LOCATION	RPE lesion complex location	2=Definite, RPELC present only outside central 1mm 3=Definite, RPELC present only within central 1mm 4=Definite, RPELC present within and outside central 1mm 7=Definite, unable to determine location; 8=Cannot grade; 9-Not applicable

Variable	Description	Coding
RPELC_MM_CP_BSCAN	B-scan used for manual measurement of RPELC at center point	1-1000 [for SD-OCT] If Zeiss-Stratus: 1=6-12 scan; 2=7-1 scan; 3=8-2 scan; 4=9-3 scan; 5=10-4 scan; 6=11-5 scan 8888=Cannot grade; 9999=Not applicable
RPELC_MM_CP_ASCAN	A-scan number used to perform the manual measurement OR distance (μm) from left edge to spot of manual measurement of RPELC at center point	Integer: 1-10000; 88888=Cannot grade; 99999=Not applicable
RPELC_MM_CP_THICKNESS	Manually measured thickness of RPELC at center point	1-2000 μm; 8888=Cannot grade; 9999=Not applicable
RPELC_MM_MAX_BSCAN	B-scan used for manual measurement of RPELC maximum thickness	1-1000 [for SD-OCT] If Zeiss-Stratus: 1=6-12 scan; 2=7-1 scan; 3=8-2 scan; 4=9-3 scan; 5=10-4 scan; 6=11-5 scan 8888=Cannot grade; 9999=Not applicable
RPELC_MM_MAX_ASCAN	A-scan number used to perform the manual measurement OR distance (μm) from left edge to spot of manual measurement of RPELC maximum thickness	Integer: 1-10000; 88888=Cannot grade; 99999=Not applicable
RPELC_MM_MAX_THICKNESS	Maximum manually measured RPELC thickness along any scan	1-2000 μm; 8888=Cannot grade; 9999=Not applicable
SERHEMPED_PRESENCE	Serous/hemorrhagic PED presence	0=Absent; 1=Questionable; 2=Definite, PED present only outside central 1mm 3=Definite, PED present only within central 1mm 4=Definite, PED present within and outside central 1mm 7=Definite, unable to determine location; 8=Cannot grade
SERHEMPED_MM_CP_BSCAN	B-scan used for manual measurement of	1-1000 [for SD-OCT]

Variable	Description	Coding
	serous/hemorrhagic PED at center point	If Zeiss-Stratus: 1=6-12 scan; 2=7-1 scan; 3=8-2 scan; 4=9-3 scan; 5=10-4 scan; 6=11-5 scan 8888=Cannot grade; 9999=Not applicable
SERHEMPED_MM_CP_ASCAN	A-scan number used to perform the manual measurement OR distance (μm) from left edge to spot of manual measurement of serous/hemorrhagic PED at center point	Integer: 1-10000; 88888=Cannot grade; 99999=Not applicable
SERHEMPED_MM_CP_THICKNESS	Maximum manually measured thickness of serous/hemorrhagic PED at center point	1-2000 μm; 8888=Cannot grade; 9999=Not applicable
SERHEMPED_MM_MAX_BSCAN	B-scan used for manual measurement of serous/hemorrhagic PED maximum thickness	1-1000 [for SD-OCT] If Zeiss-Stratus: 1=6-12 scan; 2=7-1 scan; 3=8-2 scan; 4=9-3 scan; 5=10-4 scan; 6=11-5 scan 8888=Cannot grade; 9999=Not applicable
SERHEMPED_MM_MAX_ASCAN	A-scan number used to perform the manual measurement OR distance (μm) from left edge to spot of manual measurement of serous/hemorrhagic PED maximum thickness	Integer: 1-10000; 88888=Cannot grade; 99999=Not applicable
SERHEMPED_MM_MAX_THICKNESS	Maximum manually measured serous/hemorrhagic PED thickness along any scan	1-2000 μm; 8888=Cannot grade; 9999=Not applicable
CONFIDENCESCORE	Image quality score	1=CS1 – High confidence; 2=CS2 – Adequate confidence 3=CS3 – Inadequate confidence
CS_DECNTRDREPOS	Grid was decentered and has been repositioned	0=No; 2=Yes; 9=Not applicable
CS_DECNTRDNOTREPOS	Grid was decentered and cannot be	0=No; 2=Yes; 9=Not applicable

Variable	Description	Coding
	repositioned	
CS_SDHIGH	Standard deviation is too great	0=No; 2=Yes; 9=Not applicable
CS_BOUNDLINES	Machine software drawn boundary lines are incorrect	0=No; 2=Yes; 9=Not applicable
CS_SCANMISSING	Scan(s) missing	0=No; 2=Yes; 9=Not applicable
CS_IMGQUALMETRIC	Image quality metric is too small	0=No; 2=Yes; 9=Not applicable
CS_ZOFFSET	Scan profile (Z-offset) error	0=No; 2=Yes; 9=Not applicable
CS_EYEMOVART	Eye movement artifacts	0=No; 2=Yes; 9=Not applicable
CS_OTHER	Other	0=No; 2=Yes; 9=Not applicable

4.6 Created Datasets

4.6.1 TODAY PRIMOUT: Randomization Assignments and Primary Outcome Status

TODAY data PRIMOUT includes one record for each participant indicating their randomization assignment and primary outcome (PO) information. This is data essential to the analysis of any treatment effects and/or any analysis involving if/when a participant had the TODAY primary outcome. Information about the individual variables, their descriptions and any associated coding are provided in the table below.

Variable Name	Description	Units / Coding
RELEASEID	Participant ID for NIDDK Database Repository	
TX	Randomization assignment	1=Metformin only 2=Metformin + rosiglitazone 3=Metformin + lifestyle
OUTCOME	PO status	0=Did not reach PO 1=Reached PO
REASON	Reason for PO attainment (loss of glycemic control)	1=HbA1c 2=Insulin 3=Metabolic decompensation
DAYSTOCENSOR	Days from randomization to censor date *(for no PO group only, missing otherwise)*	Days
DAYSTOPO_S	Days from randomization to primary outcome interval start date *(for PO group only, missing otherwise)*	Days
DAYSTOPO_E	Days from randomization to primary outcome interval end date *(for PO group only, missing otherwise)*	Days