

## IDEA-FAST

**Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases.**

**Grant Agreement No. 853981**

### WP5 – Data Management

## D5.4: Public Version of IDEA-FAST Clinical and Sensor Data Standards

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## 1 Abstract

This document describes the data standards designed for the clinical studies of the IDEA-FAST project with respect to sleep/fatigue/activities of daily living (ADL) and the ontology for sensor measurements. It provides examples and guidelines for standardising clinical data and device data collected by the IDEA-FAST project. The data standards defined in this document are based on the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium (CDISC). This document (deliverable D5.4) was intended to be a public version of deliverable D5.3, with any confidential information removed. However, on review, it was decided that the full content of D5.3 can be made publicly available. Thus D5.4 is essentially the same document as D5.3.

## 2 Introduction

### 2.1 Data Standards

The main goal of the IDEA-FAST project is to identify digital endpoints that provide reliable, objective and sensitive evaluation of activities of daily living (ADL), disability and health-related quality of life (HRQoL) relevant for the neurodegenerative disorders of Parkinson's Disease (PD) and Huntington's Disease (HD), and the immune mediated inflammatory diseases (IMID) Rheumatoid Arthritis (RA), Systemic Lupus Erythematosus (SLE), Primary Sjögren's Syndrome (PSS), and Inflammatory Bowel Disease (IBD). To this end, a large amount of data, including clinical data (e.g., demographic data of the recruited patients) and device data (e.g., data collected by sensors and wearable devices for monitoring fatigue, sleep and selected activities of daily living), is needed for analysis.

Given the scale of the data collected in the project, adopting research/industry wide standards becomes crucial for the following reasons:

- Data standards create efficiency by introducing consistent identification codes for participants, events, etc., in the IDEA-FAST dataset. Therefore, a standardized dataset enables better data exchange among systems used by different WPs and allows easier reuse of the data to maximize the impact and exploitation.
- Standardizing the dataset underpins higher data quality. Errors and mistakes are more likely to be identified during the data acquisition and entry, which helps to reduce the time for cleaning/transforming the data before analysis.
- Adopting industry-recognized data standards makes industrial partners interested in developing solutions to the problems encountered in IDEA-FAST project.

### 2.2 CDISC Standards for IDEA-FAST

Data standards are normally developed by either government agencies or a group of people and organizations. In IDEA-FAST, we adopted CDISC standards, which are a set of well-defined standards popular in both industry and academia for standardizing clinical research data.

CDISC stands for Clinical Data Interchange Standards Consortium. CDISC is an open, multidisciplinary, non-profit standards organization formed in 1997. CDISC standards are supported by over 150 member companies including pharmaceutical companies, biotech companies, contract research organization's/service providers, and technology providers. Moreover, CDISC standards have been adopted by FDA as the mandatory standards for data submissions since 2016.

CDISC has developed different models and standards for different stages in a research process and WP5 has been mainly focusing on developing the standard for the stage of organizing the research data in IDEA-FAST.

The CDISC standard for data organization is called Study Data Tabulation Model (SDTM), which provides a standard for organizing and formatting data to streamline processes in collection, management, analysis and reporting [1]. As the team that is responsible for developing data management strategy, data standards and the Data Management Platform (DMP), WP5 is working on developing and maintaining SDTM-based standards for all the IDEA-FAST datasets stored on the DMP.

Other CDISC standards and models include Protocol Representation Model (PRM), that defines a standard for planning and designing a research protocol [2], Clinical Data Acquisition Standards Harmonization (CDASH), that is the standard which is used for the data collection stage [3], and Analysis Data Model (ADaM), that defines the dataset and metadata standards that support efficient generation, replication, and review of clinical trial statistical analyses, as well as traceability among analysis results, analysis data , and data represented in the SDTM [4].

Another important document included in CDISC standards is Define.xml, which describes the metadata for all submitted data structures (SDTM & ADaM).

### 3 Data Overview

The IDEA-FAST project collects and receives large and complex data sets from various sources. There are mainly three types of data involved in the project including:

- Pseudonymized participant demographic, clinical and patient-reported outcome data;
- Sensor data from participants during the periods of sensor use;
- Data generated from analyses of one or both of the above datasets.

#### 3.1 Clinical data

The clinical data collected in IDEA-FAST mainly includes demographics data and clinical assessments, such as disease-specific clinical assessments and self-reported fatigue/sleep assessment. The results of some assessments are acquired via questionnaires. The clinical data are entered onto a clinical database that is managed by UCAM during the clinical studies. The anonymized clinical data with identifiable personal data replaced with pseudo codes will be transferred to the IDEA-FAST data management platform, where the data standardization will be performed.

#### 3.2 Sensor data

A range of devices/sensors (e.g., bed sensor, wrist sensor) are used to collect the data that are related to sleep quality and fatigue in IDEA-FAST, including physical activity, general physiology and neurophysiology, cognition, social function and interaction. The device/sensor data are saved in different data formats as encrypted file containers together with a small number of metadata fields (study location, participant ID, device ID, start and end date/time for recording) that are logged in JSON or XML files. In order to standardize the sensor data, features of the data will be extracted.

#### 3.3 Data domains

According to SDTM implementation guide, the SDTM is built around the concept of observations collected about subjects participated in a clinical study [4]. The observations about study subjects are normally collected in a series of domains. A domain is defined as a collection of logically related

observations with a common topic [4]. In SDTM, each domain is distinguished by a unique, two-character code used consistently in the study. Most of the clinical data and the sensor data collected in IDEA-FAST belong to one of the following domains defined by SDTM.

- Demographics (DM)  
DM domain includes a set of essential standard variables that describe each participant in a clinical study. In IDEA-FAST, these variables include age, gender, etc.
- Medical History (MH)  
MH dataset includes the participant's history at the start of the study. In IDEA-FAST, disease (e.g., peptic ulcer, dementia, etc.) specific medical history are collected.
- Vital Sign (VS)  
VS domain includes vital signs measurements. In IDEA-FAST, vital signs such as height, weight, and blood pressure are collected.
- Laboratory Test Results (LB)  
LB domain contains laboratory test data. In IDEA-FAST, these data include clinical chemistry and urinalysis for subjects with pSS and RA.
- Concomitant Medications (CM)  
CM domain contains concomitant and prior medications used by the subject in IDEA-FAST.
- Questionnaires (QS)  
QS domain contains data for named, stand-alone instruments designed to provide an assessment of a concept. As mentioned in SDTM implementation guide, questionnaires often have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and usually document methods for administration and analysis [4]. Questionnaires often consist of defined questions with a defined set of potential answers, which are designed to collect data from the participants in an efficient and reliable way. Some widely used questionnaires are used in IDEA-FAST, including EQ-5D-5L, MFI, etc.
- Functional Test (FT)  
FT domain includes data for named, stand-alone, task-based evaluations designed to provide an assessment of mobility, dexterity, or cognitive ability.

## 4 Examples of Standardized Dataset

Following the implementation guide of SDTM, a list of standard variables that can be implemented in IDEA-FAST is given in this section.

### 4.1 Demographics

#### 4.1.1 List of Variables

The standard variables for demographics data in IDEA-FAST are given in Table 1.

*Table 1: List of variables for DM domain.*

Variable Name	Variable Label	Type	CDISC Notes [4]
STUDYID	Study Identifier	Char	Unique identifier for IDEA-FAST, e.g., “IDEAFAST-FS” for feasibility study
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product
SITEID	Study Site Identifier	Char	Unique identifier for a site within IDEA-FAST
AGE	Age	Num	Age expressed in AGEU
AGEU	Age Units	Char	Units associated with AGE
SEX	Sex	Char	Sex of the subject
RACE	Race	Char	Race of the subject

#### 4.1.2 Example

Table 2 shows the demographic data of subject AAA.

*Table 2: Demographic data of subject AAA.*

STUDYID	DOMAIN	USUBJID	SITEID	AGE	AGEU	SEX	RACE
IDEAFAST-FS	DM	AAA	1	75	YEARS	F	White
IDEAFAST-FS	DM	AAA	1	77	YEARS	F	Asian
IDEAFAST-FS	DM	AAA	1	80	YEARS	M	White

#### 4.2 Medical History

##### 4.2.1 List of Variables

The standard variables for medical history data in IDEA-FAST are given in Table 3.

*Table 3: List of variables for MH domain.*

Variable Name	Variable Label	Type	CDISC Notes [4]
STUDYID	Study Identifier	Char	Unique identifier for IDEA-FAST, e.g., “IDEAFAST-FS” for feasibility study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
MHSEQ	Sequence Number	Num	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.
MHTERM	Reported Term for the Medical History	Char	Verbatim or pre-printed CRF term for the medical condition or event.
MHDTC	Date/Time of History Collection	Char	Collection date and time of the medical history observation represented in ISO 8601 character format.
MHSTDTC	Start Date/Time of Medical History Event	Char	Start date/time of the medical history event represented in ISO 8601 character format.
MHENDTDC	End Date/Time of Medical History Event	Char	End date/time of the medical history event.

#### 4.2.2 Example

Table 4 shows the standardized medical history data of subject AAA.

*Table 4: Medical history data collected from subject.*

STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDTC	MHSTDTC	MHENDTDC
IDEAFAST-FS	MH	AAA	1	DEMENTIA	2020-09-01	2015-01-01	
IDEAFAST-FS	MH	AAA	2	PEPTIC ULCER	2020-09-01	2012-06-01	
IDEAFAST-FS	MH	AAA	3	CONGESTIVE HEART FAILURE	2020-09-01	2014-08-01	
IDEAFAST-FS	MH	AAA	4	HEMIPLEGIA	2020-09-01	2012-06-01	
IDEAFAST-FS	MH	AAA	5	DIABETES MELLITUS	2020-09-01	2015-01-01	

## 4.3 Vital Sign

### 4.3.1 List of Variables

The standard variables for medical history data in IDEA-FAST are given in Table 5.

*Table 5: List of variables for VS domain.*

Variable Name	Variable Label	Type	CDISC Notes [4]
STUDYID	Study Identifier	Char	Unique identifier for IDEA-FAST, e.g., IDEAFAST-FS for feasibility study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
VSSEQ	Sequence Number	Num	Sequence number given to ensure uniqueness of subject records within a domain.
VTESTCD	Vital Signs Test Short Name	Char	Short name of the measurement, test, or examination described in VTEST. The value in VTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). VTESTCD cannot contain characters other than letters, numbers, or underscores. Examples in IDEA-FAST: "SYSBP", "HEART".
VTEST	Vital Signs Test Name	Char	Verbatim name of the test or examination used to obtain the measurement or finding. The value in VTEST cannot be longer than 40 characters. Examples in IDEA-FAST: "Blood Pressure", "Heart Rate"
VSPOS	Vital Signs Position of Subject	Char	Position of the subject during a measurement or examination.
VSORRES	Result or Finding in Original Units	Char	Result of the vital signs measurement as originally received or collected.
VSORRESU	Original Units	Char	Original units in which the data were collected. The unit for VSORRES. Examples in IDEA-FAST: "beats/min", "mm".
VSSTRESPN	Numeric Result/ Finding in Standard Units	Num	Used for continuous or numeric results or findings in standard format; copied in numeric format from VSSTRESC. VSSTRESPN should store all numeric test results or findings.
VSSTRESU	Standard Units	Char	Standardized unit used for VSSTRESPN.
VISITNUM	Visit Number	Num	Clinical encounter number.
VSDTC	Date/Time of Measurements	Char	Date and time of the vital signs assessment represented in ISO 8601 character format.

### 4.3.2 Example

The Table 6 below shows the vital sign data of subject AAA.

Table 6: Vital signs collected from subject AAA.

STUDYID	DOMAIN	USUBJID	VSSEQ	VTESTCD	VTEST	VSPOS	VSORRES	VSOR-RESU	VSST-RESN	VSSTRESU	VISIT-NUM	VSDTC
IDEAFAST-FS	VS	AAA	1	HEIGHT	Height	Standing	170	cm	170	cm	2	2020-09-01
IDEAFAST-FS	VS	AAA	2	HEART	Heart Rate		66	beats/min	66	beats/min	2	2020-09-01
IDEAFAST-FS	VS	AAA	3	SYSBP	Systolic Blood Pressure	Lying	160	mmHg	160	mmHg	2	2020-09-01
IDEAFAST-FS	VS	AAA	4	DIABP	Diastolic Blood Pressure	Lying	80	mmHg	80	mmHg	2	2020-09-01
IDEAFAST-FS	VS	AAA	5	SYSBP	Systolic Blood Pressure	Sitting	180	mmHg	180	mmHg	2	2020-09-01
IDEAFAST-FS	VS	AAA	6	DIABP	Diastolic Blood Pressure	Sitting	80	mmHg	80	mmHg	2	2020-09-01
IDEAFAST-FS	VS	AAA	7	WEIGHT	Weight	Standing	65	kg	65	kg	2	2020-09-01

## 4.4 Laboratory Test Results

### 4.4.1 List of Variables

The standard variables for laboratory data in IDEA-FAST are given in Table 7.

*Table 7: List of variables for LB domain.*

Variable Name	Variable Label	Type	CDISC Notes [4]
STUDYID	Study Identifier	Char	Unique identifier for IDEA-FAST, e.g., IDEAFAST-FS for feasibility study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
LBSEQ	Sequence Number	Num	Sequence number given to ensure uniqueness of subject records within a domain.
LBTESTCD	Lab Test or Examination Short Name	Char	Short name of the measurement, test, or examination described in LBTEST. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). LBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "ALT"
LBTEST	Lab Test or Examination Name	Char	Verbatim name of the test or examination used to obtain the measurement or finding. Note any test normally performed by a clinical laboratory is considered a lab test. The value in LBTEST cannot be longer than 40 characters. Examples: "Alanine Aminotransferase"
LBCAT	Category for Lab Test	Char	Used to define a category of related records across subjects. Examples: "URINALYSIS".
LBORRES	Result or Finding in Original Units	Char	Result of the measurement or finding as originally received or collected.
LBORRESU	Original Units	Char	Original units in which the data were collected. The unit for LBORRES. Example: "g/L".
LBSTRESC	Character Result/Finding in Std Format	Char	Contains the result value for all findings, copied or derived from LBORRES in a standard format or standard units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in LBSTRESN.
LBSTRESN	Numeric Result/Finding in Standard Units	Num	Used for continuous or numeric results or findings in standard format; copied in numeric format from LBSTRESC. LBSTRESN should store all numeric test results or findings.
LBSPEC	Specimen Type	Char	Defines the type of specimen used for a measurement. Examples: "BLOOD", "URINE".
VISITNUM	Visit Number	Num	Clinical encounter number. Numeric version of VISIT, used for sorting.

### 4.4.2 Example

Table 8 shows the standardized laboratory test results data of subject AAA.

Table 8: Laboratory test results of subject AAA.

STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBOR-RESU	LBST-RESC	LBSTRESN	LBSPEC	VISIT-NUM
IDEAFAST-FS	LB	AAA	1	CRP	C Reactive Protein	CHEMISTRY	28	g/L	28	28	BLOOD	2
IDEAFAST-FS	LB	AAA	2	ESR	Erythrocyte Sedimentation Rate	HEMATOLOGY					BLOOD	2
IDEAFAST-FS	LB	AAA	3	UDR	Urine Dipstick Result	URINALYSIS	ABNORMAL		1	1	URINE	2
IDEAFAST-FS	LB	AAA	4	UPCR	Protein-creatinine Ratio	URINALYSIS	Missing		99999	99999	URINE	2
IDEAFAST-FS	LB	AAA	5	HGB	Hemoglobin	HEMATOLOGY	13.6	g/dL	13.6	13.6	BLOOD	2
IDEAFAST-FS	LB	AAA	6	WBC	Leukocytes	HEMATOLOGY	5.1	$\times 10^9/L$	5.1	5.1	BLOOD	2
IDEAFAST-FS	LB	AAA	7	NEUT	Neutrophils	HEMATOLOGY	4.2	$\times 10^9/L$	4.2	4.2	BLOOD	2
IDEAFAST-FS	LB	AAA	8	LYM	Lymphocytes	HEMATOLOGY	2	$\times 10^9/L$	2	2	BLOOD	2
IDEAFAST-FS	LB	AAA	9	PLAT	Platelets	HEMATOLOGY	366	$\times 10^9/L$	366	366	BLOOD	2
IDEAFAST-FS	LB	AAA	10	CREAT	Creatinine	CHEMISTRY	80	mm/L	80	80	BLOOD	2
IDEAFAST-FS	LB	AAA	11	EGFR	Epidermal Growth Factor Receptor	CHEMISTRY	88	mls/min	88	88	BLOOD	2
IDEAFAST-FS	LB	AAA	12	ALT	Alanine Aminotransferase	CHEMISTRY	16	IU/L	16	16	BLOOD	2
IDEAFAST-FS	LB	AAA	13	AST	Aspartate Aminotransferase	CHEMISTRY	Missing	IU/L	99999	99999	BLOOD	2
IDEAFAST-FS	LB	AAA	14	LDH	Lactate Dehydrogenase	CHEMISTRY	199	U/L	199	199	BLOOD	2
IDEAFAST-FS	LB	AAA	15	TSH	Thyrotropin	CHEMISTRY	1.23	ml/L	1.23	1.23	BLOOD	2
IDEAFAST-FS	LB	AAA	16	FERRITIN	Ferritin	CHEMISTRY	77	ug/L	77	77	BLOOD	2

## 4.5 Concomitant Medications

### 4.5.1 List of Variables

The standard variables for concomitant medications data in IDEA-FAST are given in Table 9.

*Table 9: List of variables for CM domain.*

Variable Name	Variable Label	Type	CDISC Notes [4]
STUDYID	Study Identifier	Char	Unique identifier for IDEA-FAST, e.g., IDEAFAST-FS for feasibility study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
CMSEQ	Sequence Number	Num	Sequence number given to ensure uniqueness of subject records within a domain.
CMTRT	Reported Name of Drug, Med, or Therapy	Char	Verbatim medication name that is either pre-printed or collected on a CRF.
CMCAT	Category for Medication	Char	Used to define a category of medications/treatment. Examples: "PRIOR", "CONCOMITANT".
CMDOSTXT	Dose Description	Char	Dosing amounts or a range of dosing information collected in text form. Units may be stored in CMDOSU. Examples: "200-400".
CMDOSU	Dose Units	Char	Units for CMDOSE, CMDOSTOT, or CMDOSTXT. Examples: "mg".

### 4.5.2 Example

Table 10 shows the standardized concomitant medications data of subject AAA.

*Table 10: Concomitant medications information of subject AAA.*

STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMCAT	CMDOSTXT	CMDOSU
IDEAFAST-FS	CM	AAA	1	Laxoberal			
IDEAFAST-FS	CM	AAA	2	Quetiapin			

## 4.6 Questionnaires

### 4.6.1 List of Variables

The standard variables for medical history data in IDEA-FAST are given in Table 11.

Table 11: List of variables for QS domain.

Variable Name	Variable Label	Type	CDISC Notes [4]
STUDYID	Study Identifier	Char	Unique identifier for IDEA-FAST, e.g., IDEAFAST-FS for feasibility study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
QSSEQ	Sequence Number	Num	Sequence number given to ensure uniqueness of subject records within a domain.
QTESTCD	Question Short Name	Char	<p>Topic variable for QS. Short name for the value in QTEST, which can be used as a column name when converting the dataset from a vertical format to a horizontal format. The value in QTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid).</p> <p>QTESTCD cannot contain characters other than letters, numbers, or underscores. Example: "EQ5D0201" for one of the EQ-5D questions.</p>
QTEST	Question Name	Char	Verbatim name of the question or group of questions used to obtain the measurement or finding. The value in QTEST cannot be longer than 40 characters.
QSCAT	Category of Question	Char	Used to specify the questionnaire in which the question identified by QTEST and QTESTCD was included. Example: "EQ-5D-5L".
QSORRES	Finding in Original Units	Char	Finding as originally received or collected (e.g., "RARELY", "SOMETIMES").
QSORRESU	Original Units	Char	Original units in which the data were collected. The unit for QSORRES. In this IDEA-FAST, this could be minutes and seconds.
QSSTRESC	Character Result/ Finding in Std Format	Char	Contains the finding for all questions or sub-scores, copied or derived from QSORRES in a standard format or standard units. QSSTRESC should store all findings in character format; if findings are numeric, they should also be stored in numeric format in QSSTRESN. If question scores are derived from the original finding, then the standard format is the score.
QSSTRESU	Standard Units	Char	Standardized unit used for QSSTRESC or QSSTRESN.
QSSTRESN	Numeric Finding in Std Units	Num	Used for continuous or numeric findings in standard format; copied in numeric format from QSSTRESC. QSSTRESN should store all numeric results or findings.
VISITNUM	Visit Number	Num	Clinical encounter number. Numeric version of VISIT, used for sorting.
QSDTC	Date/Time of Finding	Timing	Date of questionnaire.

## 4.6.2 Examples

- Brief Pain Inventory (BPI)

BPI is used for assessing the intensity of pain and its impact on the everyday functioning of life in IDEA-FAST. An example of the standardized BPI data for subject AAA is given in Table 12.

- Epworth Sleepiness Scale (ESSc)

ESSc is used in IDEA-FAST as a subjective assessment of daytime sleepiness. An example of the standardized ESSc data for subject AAA is given in Table 13.

- EQ-5D

EQ-5D is a self-reported questionnaire used in IDEA-FAST for evaluating a respondent's health-related quality of life. Table 14 shows the standardized EQ-5D data from subject AAA. An example of the codelist for EQ-5D is given in Table S1.

- The Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F)

FACIT-F is a 40-item questionnaire that measures self-reported fatigue and its impact on the everyday functioning of life. In IDEA-FAST, 13 out of 40 items are used for the measurement of fatigue and its impact. An example of the standardized FACIT-F dataset is given in Table 15.

- Fatigue Visual Analogue Scale (fVAS)

In IDEA-FAST, fVAS is used for assessing abnormal fatigue. Table 16 shows the standardized fVAS data.

- Generalised Anxiety Disorder Assessment (GAD-7)

GAD-7 is adopted in IDEA-FAST as a severity measure for generalised anxiety disorder. An example of the standardized GAD-7 data is given in Table 17.

- Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ)

GSLTPAQ is adopted in IDEA-FAST to measure a subject's leisure time exercise. Table 18 gives an example of the standardized GSS data.

- Health Assessment Questionnaire - Disability Index (HAQ-DI)

HAQ-DI is used as a self-reported measure of functionality in IDEA-FAST. A standardized HAQ-DI dataset collected from subject AAA is given in Table 19.

- Huntington's Disease - Pain-Related Beliefs and Attitudes about Sleep (HD-PBAS)

HD-PBAS is used in IDEA-FAST to assess pain-related dysfunctional beliefs and attitudes about sleep among subjects who have HD. Table 20 shows a standardized HD-PBAS dataset collected from subject AAA.

- Huntington's Disease - Quality of Life Questionnaire (HD-QOL)

HD-QOL is used in IDEA-FAST to assess the quality of life for subjects who have HD. An example of a standardized HD-QOL dataset is given in Table 21.

- Unified Huntington's Disease Rating Scale (UHDRS)

UHDRS is adopted in IDEA-FAST as a clinical rating scale to assess different domains of clinical performance and capacity in HD. Table 22 shows an example of standardized UHDRS data.

- Medical Outcomes Study Sleep Scale (MOSSS)

MOSSS is used in IDEA-FAST to capture the sleep problems of subjects. An example of a standardized MOSSS dataset is given in Table 23.

- Inflammatory Bowel Disease - Control (IBD-Control)  
IBD-Control is used in IDEA-FAST to measure overall disease control from a patient's perspective. Table 24 shows an example of a standardized IBD-Control dataset.
- Inflammatory Bowel Disease - History of Present Illness (IBD-HPI)  
IBD-HPI is used in IDEA-FAST to collect details of chief complaints from subjects who have IBD. Table 25 gives an example of a standardized IBD-HPI dataset.
- Inflammatory Bowel Disease - Simple Clinical Colitis Activity Index (IBD-SCCAI)  
IBD-SCCAI is used for quantifying disease activity among IBD patients in IDEA-FAST. An example of standardized IBD-SCCAI data is given in Table 26.
- Multidimensional Fatigue Inventory (MFI)  
MFI is a self-reported questionnaire used in IDEA-FAST for measuring fatigue. Table 27 shows the standardized MFI data.
- Montreal Cognitive Assessment (MoCA)  
MoCA is used in IDEA-FAST to determine whether a subject has mild cognitive impairment and Alzheimer's disease. An example of standardized MoCA data is presented in Table 28.
- PD\_FATIGUE\_UCB\_PRO  
A questionnaire developed by UCB is used in IDEA-FAST to measure fatigue and the impact that it can have. An example of standardized questionnaire data is shown in Table 29.
- Parkinson's Disease - Lille Apathy Rating Scale (LARS)  
LARS is used in IDEA-FAST to detect and quantify apathy among subjects with PD. Table 30 gives an example of standardised LARS data.
- Parkinson's Disease - Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS)  
MDS-UPDRS is used in IDEA-FAST to evaluate various aspects of subjects with PD. An example of standardized MDS-UPDRS data is given in Table 31.
- Parkinson's Disease Questionnaire (PDQ-8)  
PDQ-8 is adopted in IDEA-FAST to evaluate how often subjects with PD experience difficulties. Table 32 gives an example of standardized PDQ-8 data.
- Parkinson's Disease Sleep Scale (PDSS-2)  
PDSS-2 is used in IDEA-FAST to self-rate and quantify the level of sleep disruption of the subjects. Table 33 shows an example of standardized PDSS-2 data.
- Scales for Outcomes in Parkinson's Disease - Autonomic Dysfunction (SCOPA-AUT)  
SCOPA-AUT is used in IDEA-FAST to assess autonomic symptoms in subjects with PD. An example of standardized SCOPA-AUT data is given in Table 34.
- Patient Health Questionnaire-9 (PHQ-9)  
PHQ-9 is used in IDEA-FAST to screen, measure and diagnose the degree of depression in general medical and mental health settings. Table 35 gives an example of standardized PHQ-9 data.
- Pittsburgh Sleep Quality Index (PSQI)  
PSQI is used in IDEA-FAST to assess the sleep quality of subjects over a 1-month time interval. Table 36 shows an example of standardized PSQI data.

- Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29)  
PROMIS-29 is a questionnaire used in IDEA-FAST to measure health-related domains including medication management, depression, fatigue, sleep disturbance, etc. An example of standardized PROMIS-29 data is given in Table 37.
- EULAR Sjögren's syndrome disease activity index (ESSDAI)  
ESSDAI is a systemic disease activity index used in IDEA-FAST to evaluate disease activity among subjects with pSS. An example of standardized ESSDAI data is given in Table 38.
- EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI)  
ESSPRI is used in IDEA-FAST to evaluate three main pSS domains using three questions about dryness, fatigue and pain. An example of standardized ESSDAI data is given in Table 39.
- primary Sjögren's Syndrome - Fatigue (pSS-Fatigue)  
pSS-Fatigue used in IDEA-FAST is a questionnaire to evaluate the fatigue and its impact among subjects with pSS. Table 40 gives an example of standardized pSS-Fatigue data.
- Rheumatoid Arthritis - Routine Assessment of Patient Index Data 3 (RA-RAPID3)  
RA-RAPID3 is used in IDEA-FAST to monitor disease activity in RA. An example of standardized RA-RAPID3 data is given in Table 41.
- Social Functioning Questionnaire (SFQ)  
SFQ is used for assessing perceived social function in IDEA-FAST. Table 42 shows an example of standardized SFQ data.
- British Isles Lupus Assessment Group (BILAG 2004)  
BILAG 2004 is used in IDEA-FAST to assess disease activity in SLE. An example of standardized BILAG 2004 data is given in Table 43.
- Systemic Lupus Erythematosus - Fatigue (SLE-Fatigue)  
SLE -Fatigue used in IDEA-FAST is a questionnaire to evaluate the fatigue and its impact among subjects with SLE. Table 44 gives an example of standardized SLE-Fatigue data.
- Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI2k)  
SLEDAI2k is used in IDEA-FAST to evaluate severity of SLE. An example of standardized SLEDAI2k data is shown in Table 45.

Table 12: BPI questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSOR-RESU	QSST-RESC	QSST-RESU	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	BPI201	BPI2-Pain Other Than Everyday Kinds	BPI SHORT FORM	Yes		1		1	13
IDEAFAST-FS	QS	AAA	2	BPI202A	BPI2-Areas of Pain	BPI SHORT FORM						13
IDEAFAST-FS	QS	AAA	3	BPI202B	BPI2-Area Hurts Most	BPI SHORT FORM						13
IDEAFAST-FS	QS	AAA	4	BPI203	BPI2-Pain at its Worst in Last 24 Hours	BPI SHORT FORM	Pain as bad as you can imagine		10		10	13
IDEAFAST-FS	QS	AAA	5	BPI204	BPI2-Pain at its Least in Last 24 Hours	BPI SHORT FORM	No Pain		0		0	13
IDEAFAST-FS	QS	AAA	6	BPI205	BPI2-Pain on the Average	BPI SHORT FORM	4		4		4	13
IDEAFAST-FS	QS	AAA	7	BPI206	BPI2-Pain Right Now	BPI SHORT FORM	2		2		2	13
IDEAFAST-FS	QS	AAA	8	BPI207	BPI2-Treatments Receiving for Pain	BPI SHORT FORM	Paracetamol		Paracetamol			13
IDEAFAST-FS	QS	AAA	9	BPI208	BPI2-Relief Pain Treatments Provided	BPI SHORT FORM	60	%	6		6	13
IDEAFAST-FS	QS	AAA	10	BPI209A	BPI2-Pain Interfered General Activity	BPI SHORT FORM	Does not Interfere		0		0	13
IDEAFAST-FS	QS	AAA	11	BPI209B	BPI2-Pain Interfered with Mood	BPI SHORT FORM	Completely Interferes		10		10	13
IDEAFAST-FS	QS	AAA	12	BPI209C	BPI2-Pain Interfered Walking Ability	BPI SHORT FORM	3		3		3	13
IDEAFAST-FS	QS	AAA	13	BPI209D	BPI2-Pain Interfered with Normal Work	BPI SHORT FORM	4		4		4	13
IDEAFAST-FS	QS	AAA	14	BPI209E	BPI2-Pain Interfered with Relations	BPI SHORT FORM	2		2		2	13
IDEAFAST-FS	QS	AAA	15	BPI209F	BPI2-Pain Interfered with Sleep	BPI SHORT FORM	6		6		6	13
IDEAFAST-FS	QS	AAA	16	BPI209G	BPI2-Pain Interfered Enjoyment of Life	BPI SHORT FORM	9		9		9	13

Table 13: ESSc questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	ESSC0101	ESSC01-Sitting and Reading	ESSC	moderate chance of dozing	2	2	2
IDEAFAST-FS	QS	AAA	2	ESSC0102	ESSCC01-Watching TV	ESSC	slight chance of dozing	1	1	2
IDEAFAST-FS	QS	AAA	3	ESSC0103	ESSC01-Sitting Inactive in a Public Place	ESSC	would never doze	0	0	2
IDEAFAST-FS	QS	AAA	4	ESSC0104	ESSC01-Passenger for Hour Without Break	ESSC	high chance of dozing	3	3	2
IDEAFAST-FS	QS	AAA	5	ESSC0105	ESSC01-Lying Down to Rest In Afternoon	ESSC	slight chance of dozing	1	1	2
IDEAFAST-FS	QS	AAA	6	ESSC0106	ESSC01-Sitting and Talking to Someone	ESSC	slight chance of dozing	1	1	2
IDEAFAST-FS	QS	AAA	7	ESSC0107	ESSC01-Sitting Quietly After Lunch	ESSC	slight chance of dozing	1	1	2
IDEAFAST-FS	QS	AAA	8	ESSC0108	ESSC01-In Car Stopped Few Minutes Traffic	ESSC	slight chance of dozing	1	1	2

Table 14: EQ-5D questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	EQ5D0201	EQ5D02-Mobility	EQ-5D-5L	I have no problems in walking about	0	0	2
IDEAFAST-FS	QS	AAA	2	EQ5D0202	EQ5D02-SelfCare	EQ-5D-5L	I have no problems washing or dressing myself	0	0	2
IDEAFAST-FS	QS	AAA	3	EQ5D0203	EQ5D02-UsualActivities	EQ-5D-5L	I have no problems doing my usual activities	0	0	2
IDEAFAST-FS	QS	AAA	4	EQ5D0204	EQ5D02-PainDiscomfort	EQ-5D-5L	I have no pain or discomfort	0	0	2
IDEAFAST-FS	QS	AAA	5	EQ5D0205	EQ5D02-AnxietyDepression	EQ-5D-5L	I am not anxious or depressed	0	0	2
IDEAFAST-FS	QS	AAA	6	EQ5D0206	EQ5D02-HealthToday	EQ-5D-5L	80	80	80	2

Table 15: FACIT-F questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESP	QSSTRESPN	VISITNUM
IDEAFAST-FS	QS	AAA	1	FAC07128	FAC071-I Feel Fatigued	FACIT-F V4	Not at all	0	0	3
IDEAFAST-FS	QS	AAA	2	FAC07129	FAC071-I Feel Weak All Over	FACIT-F V4	A little bit	1	1	3
IDEAFAST-FS	QS	AAA	3	FAC07130	FAC071-I Feel Listless	FACIT-F V4	Somewhat	2	2	3
IDEAFAST-FS	QS	AAA	4	FAC07131	FAC071-I Feel Tired	FACIT-F V4	Quite a bit	3	3	3
IDEAFAST-FS	QS	AAA	5	FAC07132	FAC071-Trouble Starting Things	FACIT-F V4	Very much	4	4	3
IDEAFAST-FS	QS	AAA	6	FAC07133	FAC071-Trouble Finishing Things	FACIT-F V4	Not at all	0	0	3
IDEAFAST-FS	QS	AAA	7	FAC07134	FAC071-I Have Energy	FACIT-F V4	A little bit	1	1	3
IDEAFAST-FS	QS	AAA	8	FAC07135	FAC071-Able to Do My Usual Activities	FACIT-F V4	Somewhat	2	2	3
IDEAFAST-FS	QS	AAA	9	FAC07136	FAC071-I Need to Sleep During the Day	FACIT-F V4	Quite a bit	3	3	3
IDEAFAST-FS	QS	AAA	10	FAC07137	FAC071-I Am Too Tired to Eat	FACIT-F V4	Very much	4	4	3
IDEAFAST-FS	QS	AAA	11	FAC07138	FAC071-Need Help Doing Usual Activities	FACIT-F V4	Not at all	0	0	3
IDEAFAST-FS	QS	AAA	12	FAC07139	FAC071-Frustrated by Being Too Tired	FACIT-F V4	A little bit	1	1	3
IDEAFAST-FS	QS	AAA	13	FAC07140	FAC071-Limit Social Activity, I am Tired	FACIT-F V4	Somewhat	2	2	3

Table 16: fVAS questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QTESTCD	QTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	FAC07128	FVA01-Level of abnormal fatigue today	FVAS	60	60	60	2

Table 17: GAD-7 questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QTESTCD	QTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	GAD0101	GAD01-Feeling Nervous Anxious or On Edge	GAD-7	Not at all	0	0	2
IDEAFAST-FS	QS	AAA	1	GAD0102	GAD01-Feeling Nervous Anxious or On Edge	GAD-7	Several days	1	1	2
IDEAFAST-FS	QS	AAA	1	GAD0103	GAD01-Not Able to Stop/Control Worrying	GAD-7	More than half the days	2	2	2
IDEAFAST-FS	QS	AAA	1	GAD0104	GAD01-Worrying Too Much About Things	GAD-7	Nearly every day	3	3	2
IDEAFAST-FS	QS	AAA	1	GAD0105	GAD01-Trouble Relaxing	GAD-7	Not at all	0	0	2
IDEAFAST-FS	QS	AAA	1	GAD0106	GAD01-Being Restless Hard to Sit Still	GAD-7	Several days	1	1	2
IDEAFAST-FS	QS	AAA	1	GAD0107	GAD01-Becoming Easily Annoyed/Irritable	GAD-7	More than half the days	2	2	2
IDEAFAST-FS	QS	AAA	1	GAD0108	GAD01-Feel Afraid/Something Awful Happen	GAD-7	Nearly every day	3	3	2

Table 18: GODIN questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	GOD0101	GOD01-STRENUOUS EXERCISE	GODIN	0	0	0	2
IDEAFAST-FS	QS	AAA	2	GOD0102	GOD01-MODERATE EXERCISE	GODIN	3	3	3	2
IDEAFAST-FS	QS	AAA	3	GOD0103	GOD01-MILD/LIGHT EXERCISE	GODIN	3	3	3	2
IDEAFAST-FS	QS	AAA	4	GOD0104	GOD01-Weekly Leisure-Time Activity Score	GODIN	6	6	6	2
IDEAFAST-FS	QS	AAA	5	GOD0105	GOD01-STRENUOUS EXERCISE Total	GODIN	0	0	0	2
IDEAFAST-FS	QS	AAA	6	GOD0106	GOD01-MODERATE EXERCISE Total	GODIN	15	15	15	2
IDEAFAST-FS	QS	AAA	7	GOD0107	GOD01-MILD/LIGHT EXERCISE Total	GODIN	18	18	18	2
IDEAFAST-FS	QS	AAA	8	GOD0108	GOD01-Weekly Leisure-Time Activity Score Total	GODIN	33	33	33	2

Table 19: HAQ-DI questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	HAQ0101	HAQ01-Dress Yourself	HAQ-DI	Without ANY Difficulty	0	0	2
IDEAFAST-FS	QS	AAA	2	HAQ0102	HAQ01-Shampoo Your Hair	HAQ-DI	Without SOME Difficulty	1	1	2
IDEAFAST-FS	QS	AAA	3	HAQ0103	HAQ01-Stand Up From a Straight Chair	HAQ-DI	Without MUCH Difficulty	2	2	2
IDEAFAST-FS	QS	AAA	4	HAQ0104	HAQ01-Get In and Out of Bed	HAQ-DI	UNABLE To Do	3	3	2
IDEAFAST-FS	QS	AAA	5	HAQ0105	HAQ01-Cut Your Meat	HAQ-DI	Without ANY Difficulty	0	0	2
IDEAFAST-FS	QS	AAA	6	HAQ0106	HAQ01-Lift a Full Cup or Glass to Mouth	HAQ-DI	Without SOME Difficulty	1	1	2
IDEAFAST-FS	QS	AAA	7	HAQ0107	HAQ01-Open a New Milk Carton	HAQ-DI	Without MUCH Difficulty	2	2	2
IDEAFAST-FS	QS	AAA	8	HAQ0108	HAQ01-Walk Outdoors on Flat Ground	HAQ-DI	UNABLE To Do	3	3	2
IDEAFAST-FS	QS	AAA	9	HAQ0109	HAQ01-Climb Up Five Steps	HAQ-DI	Without ANY Difficulty	0	0	2
IDEAFAST-FS	QS	AAA	10	HAQ0110	HAQ01-Aid: Cane	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	11	HAQ0111	HAQ01-Aid: Walker	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	12	HAQ0112	HAQ01-Aid: Crutches	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	13	HAQ0113	HAQ01-Aid: Wheelchair	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	14	HAQ0114	HAQ01-Aid: Devices Used for Dressing	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	15	HAQ0115	HAQ01-Aid: Built Up or Special Utensils	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	16	HAQ0116	HAQ01-Aid: Special or Built Up Chair	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	17	HAQ0117	HAQ01-Othr Aid (Dress/Arising/Eat/Walk)	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	18	HAQ0118	HAQ01-Spec Aid (Dress/Arising/Eat/Walk)	HAQ-DI	bath seat	bath seat		2
IDEAFAST-FS	QS	AAA	19	HAQ0119	HAQ01-Help: Dressing and Grooming	HAQ-DI	TRUE	1	1	2

IDEAFAST-FS	QS	AAA	20	HAQ0120	HAQ01-Help: Arising	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	21	HAQ0121	HAQ01-Help: Eating	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	22	HAQ0122	HAQ01-Help: Walking	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	23	HAQ0123	HAQ01-Wash and Dry Your Body	HAQ-DI	Without ANY Difficulty	0	0	2
IDEAFAST-FS	QS	AAA	24	HAQ0124	HAQ01-Take a Tub Bath	HAQ-DI	Without SOME Difficulty	1	1	2
IDEAFAST-FS	QS	AAA	25	HAQ0125	HAQ01-Get On and Off The Toilet	HAQ-DI	Without MUCH Difficulty	2	2	2
IDEAFAST-FS	QS	AAA	26	HAQ0126	HAQ01-Reach-Get Down 5 Lb Obj Above Head	HAQ-DI	UNABLE To Do	3	3	2
IDEAFAST-FS	QS	AAA	27	HAQ0127	HAQ01-Bend Down Pick Up Clothing - Floor	HAQ-DI	Without ANY Difficulty	0	0	2
IDEAFAST-FS	QS	AAA	28	HAQ0128	HAQ01-Open Car Doors	HAQ-DI	Without SOME Difficulty	1	1	2
IDEAFAST-FS	QS	AAA	29	HAQ0129	HAQ01-Open Jars Previously Opened	HAQ-DI	Without MUCH Difficulty	2	2	2
IDEAFAST-FS	QS	AAA	30	HAQ0130	HAQ01-Turn Faucets On And Off	HAQ-DI	UNABLE To Do	3	3	2
IDEAFAST-FS	QS	AAA	31	HAQ0131	HAQ01-Run Errands and Shop	HAQ-DI	Without ANY Difficulty	0	0	2
IDEAFAST-FS	QS	AAA	32	HAQ0132	HAQ01-Get In and Out of a Car	HAQ-DI	Without SOME Difficulty	1	1	2
IDEAFAST-FS	QS	AAA	33	HAQ0133	HAQ01-Able to Do Chores	HAQ-DI	Without MUCH Difficulty	2	2	2
IDEAFAST-FS	QS	AAA	34	HAQ0134	HAQ01-Aid: Raised Toilet Seat	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	35	HAQ0135	HAQ01-Aid: Bathtub Seat	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	36	HAQ0136	HAQ01-Aid: Jar Opener (Previously Open)	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	37	HAQ0137	HAQ01-Aid: Bathtub Bar	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	38	HAQ0138	HAQ01-Aid: Long-Handled Appl Reach	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	39	HAQ0139	HAQ01-Aid: Long-Handled Appl Bathroom	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	40	HAQ0140	HAQ01-Othr Aid (Hygiene/Reach/Grip/Act)	HAQ-DI	FALSE	0	0	2

IDEAFAST-FS	QS	AAA	41	HAQ0141	HAQ01-Spec Aid (Hygiene/Reach/Grip/Act)	HAQ-DI	shoehorn	shoehorn		2
IDEAFAST-FS	QS	AAA	42	HAQ0142	HAQ01-Help: Hygiene	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	43	HAQ0143	HAQ01-Help: Reach	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	44	HAQ0144	HAQ01-Help: Gripping and Opening Things	HAQ-DI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	45	HAQ0145	HAQ01-Help: Errands and Chores	HAQ-DI	TRUE	1	1	2
IDEAFAST-FS	QS	AAA	46	HAQ0146	HAQ01-Severity of Pain	HAQ-DI	60	60	60	2

Table 20: HD-PBAS questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	HD0201	HD02-Domain Scores (Depression)	HD-PBAS	4	4	4	2
IDEAFAST-FS	QS	AAA	2	HD0202	HD02-Domain Scores (Irritability/aggression)	HD-PBAS	9	9	9	2
IDEAFAST-FS	QS	AAA	3	HD0203	HD02-Domain Scores (Psychosis)	HD-PBAS	5	5	5	2
IDEAFAST-FS	QS	AAA	4	HD0204	HD02-Domain Scores (Apathy)	HD-PBAS	0	0	0	2
IDEAFAST-FS	QS	AAA	5	HD0205	HD02-Domain Scores (Executive function)	HD-PBAS	10	10	0	2
IDEAFAST-FS	QS	AAA	6	HD0206	HD02-Depressed Mood (Severity)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	7	HD0207	HD02-Depressed Mood (Frequency)	HD-PBAS	seldom (less than once/week)	1	1	2
IDEAFAST-FS	QS	AAA	8	HD0208	HD02-seldom (less than once/week)	HD-PBAS	slight, questionable	1	1	2
IDEAFAST-FS	QS	AAA	9	HD0209	HD02-Suicidal ideation (Severity)	HD-PBAS	mild (present, not a problem)	2	2	2
IDEAFAST-FS	QS	AAA	10	HD0210	HD02-Suicidal ideation (Frequency)	HD-PBAS	sometimes (up to four times a week)	2	2	2

IDEAFAST-FS	QS	AAA	11	HD0211	HD02-Suicidal ideation (Worst)	HD-PBAS	moderate (symptom causing problem)	3	3	2
IDEAFAST-FS	QS	AAA	12	HD0212	HD02-Anxiety (Severity)	HD-PBAS	severe (almost intolerable for carer)	4	4	2
IDEAFAST-FS	QS	AAA	13	HD0213	HD02-Anxiety (Frequency)	HD-PBAS	frequently (most days/5, 6 or 7 times a week)	3	3	2
IDEAFAST-FS	QS	AAA	14	HD0214	HD02-Anxiety (Worst)	HD-PBAS	moderate (symptom causing problem)	3	3	2
IDEAFAST-FS	QS	AAA	15	HD0215	HD02-Irritability (Severity)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	16	HD0216	HD02-Irritability (Frequency)	HD-PBAS	never/almost never	0	0	2
IDEAFAST-FS	QS	AAA	17	HD0217	HD02-Irritability (Worst)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	18	HD0218	HD02-Angry or aggressive behaviour (Severity)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	19	HD0219	HD02-Angry or aggressive behaviour (Frequency)	HD-PBAS	never/almost never	0	0	2
IDEAFAST-FS	QS	AAA	20	HD0220	HD02-Angry or aggressive behaviour (Worst)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	21	HD0221	HD02-Lack of initiative (apathy) (Severity)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	22	HD0222	HD02-Lack of initiative (apathy) (Frequency)	HD-PBAS	never/almost never	0	0	2
IDEAFAST-FS	QS	AAA	23	HD0223	HD02-Lack of initiative (apathy) (Worst)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	24	HD0224	HD02-Perseverative thinking or behaviour (Severity)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	25	HD0225	HD02-Perseverative thinking or behaviour (Frequency)	HD-PBAS	never/almost never	0	0	2

IDEAFAST-FS	QS	AAA	26	HD0226	HD02-Perseverative thinking or behaviour (Worst)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	27	HD0227	HD02-Obsessive-Compulsive Behaviours (Severity)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	28	HD0228	HD02-Obsessive-Compulsive Behaviours (Frequency)	HD-PBAS	never/almost never	0	0	2
IDEAFAST-FS	QS	AAA	29	HD0229	HD02-Obsessive-Compulsive Behaviours (Worst)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	30	HD0230	HD02-Delusions/paranoid thinking (Severity)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	31	HD0231	HD02-Delusions/paranoid thinking (Frequency)	HD-PBAS	never/almost never	0	0	2
IDEAFAST-FS	QS	AAA	32	HD0232	HD02-Delusions/paranoid thinking (Worst)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	33	HD0233	HD02-Hallucinations (Severity)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	34	HD0234	HD02-Hallucinations (Frequency)	HD-PBAS	never/almost never	0	0	2
IDEAFAST-FS	QS	AAA	35	HD0235	HD02-Hallucinations (Worst)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	36	HD0236	HD02-Disoriented (Severity)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	37	HD0237	HD02-Disoriented (Frequency)	HD-PBAS	never/almost never	0	0	2
IDEAFAST-FS	QS	AAA	38	HD0238	HD02-Disoriented (Worst)	HD-PBAS	absent	0	0	2
IDEAFAST-FS	QS	AAA	39	HD0239	HD02-Is informant a relative?	HD-PBAS	spouse or partner	0	0	2
IDEAFAST-FS	QS	AAA	40	HD0240	HD02-Is informant a household member?	HD-PBAS	household member (i.e. relative or friend who lives with participant)	0	0	2

*Table 21: HD-QOL questionnaire.*

USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSOR-RESU	QSSTRESC	QSST-RESU	QSST-RESN	VISIT-NUM	QSDTC
AAA	1	HD0301	HD03-Assessment Done?	HD-QOL	TRUE		TRUE		0	2	13/11/2020
AAA	2	HD0302	HD03-Date	HD-QOL	10/11/2020		10/11/2020		0	2	13/11/2020
AAA	3	HD0303	HD03-Reasons for Declining	HD-QOL					2		13/11/2020
AAA	4	HD0304	HD03-Decline Reason Other	HD-QOL					2		13/11/2020
AAA	5	HD0305	HD03-Had difficulty carrying things without dropping them?	HD-QOL	never		0		0	2	13/11/2020
AAA	6	HD0306	HD03-Lacked confidence with your balance?	HD-QOL	very rarely		1		1	2	13/11/2020
AAA	7	HD0307	HD03-Had difficulty walking independently?	HD-QOL	infrequently		2		2	2	13/11/2020
AAA	8	HD0308	HD03-Had difficulty doing jobs around the house?	HD-QOL	sometimes		3		3	2	13/11/2020
AAA	9	HD0309	HD03-Had difficulty maintaining your weight?	HD-QOL	often		4		4	2	13/11/2020
AAA	10	HD0310	HD03-Had difficulty doing your hobby?	HD-QOL	most of the time		5		5	2	13/11/2020
AAA	11	HD0311	HD03-Had difficulty dressing yourself?	HD-QOL	all of the time		6		6	2	13/11/2020
AAA	12	HD0312	HD03-Felt cautious about swallowing food or drink?	HD-QOL	never		0		0	2	13/11/2020
AAA	13	HD0313	HD03-Found it hard to manage eating on your own?	HD-QOL	very rarely		1		1	2	13/11/2020
AAA	14	HD0314	HD03-Could not operate a television?	HD-QOL	infrequently		2		2	2	13/11/2020
AAA	15	HD0315	HD03-Got tired easily?	HD-QOL	sometimes		3		3	2	13/11/2020
AAA	16	HD0316	HD03-Felt dissatisfied with your sleep?	HD-QOL	often		4		4	2	13/11/2020

AAA	17	HD0317	HD03-Lacked confidence in doing more than one thing at a time?	HD-QOL	most of the time		5		5	2	13/11/2020
AAA	18	HD0318	HD03-Took too long to do things?	HD-QOL	all of the time		6		6	2	13/11/2020
AAA	19	HD0319	HD03-Lacked confidence with expressing your thoughts with words?	HD-QOL	never		0		0	2	13/11/2020
AAA	20	HD0320	HD03-Could not concentrate on the task at hand properly?	HD-QOL	very rarely		1		1	2	13/11/2020
AAA	21	HD0321	HD03-Found it hard to make a decision?	HD-QOL	infrequently		2		2	2	13/11/2020
AAA	22	HD0322	HD03-Had difficulty remembering day to day things?	HD-QOL	sometimes		3		3	2	13/11/2020
AAA	23	HD0323	HD03-Found it hard to organize your day?	HD-QOL	often		4		4	2	13/11/2020
AAA	24	HD0324	HD03-Could not follow a conversation properly?	HD-QOL	most of the time		5		5	2	13/11/2020
AAA	25	HD0325	HD03-Could not remember what day and month it is?	HD-QOL	all of the time		6		6	2	13/11/2020
AAA	26	HD0326	HD03-Worried about the impact of Huntington's on your family?	HD-QOL	never		0		0	2	13/11/2020
AAA	27	HD0327	HD03-Worried about showing symptoms of Huntington's disease progression?	HD-QOL	very rarely		1		1	2	13/11/2020
AAA	28	HD0328	HD03-Found it hard to feel hopeful about the future?	HD-QOL	infrequently		2		2	2	13/11/2020
AAA	29	HD0329	HD03-Could not easily get motivated to do things?	HD-QOL	sometimes		3		3	2	13/11/2020
AAA	30	HD0330	HD03-Found it hard to get on with your life?	HD-QOL	often		4		4	2	13/11/2020
AAA	31	HD0331	HD03-Had problems with being independent?	HD-QOL	most of the time		5		5	2	13/11/2020
AAA	32	HD0332	HD03-Did not feel confident in yourself?	HD-QOL	all of the time		6		6	2	13/11/2020
AAA	33	HD0333	HD03-Felt down or depressed?	HD-QOL	never		0		0	2	13/11/2020

AAA	34	HD0334	HD03-Lacked confidence in fulfilling your personal wishes in life?	HD-QOL	very rarely		1		1	2	13/11/2020
AAA	35	HD0335	HD03-Had problems with maintaining a meaningful role in your immediate family?	HD-QOL	infrequently		2		2	2	13/11/2020
AAA	36	HD0336	HD03-Had financial concerns for the future?	HD-QOL	sometimes		3		3	2	13/11/2020
AAA	37	HD0337	HD03-Felt irritated easily?	HD-QOL	often		4		4	2	13/11/2020
AAA	38	HD0338	HD03-Lost your temper easily?	HD-QOL	most of the time		5		5	2	13/11/2020
AAA	39	HD0339	HD03-Did not feel keen on going out to socialize?	HD-QOL	all of the time		6		6	2	13/11/2020
AAA	40	HD0340	HD03-Felt conscious of peoples attitude to your condition (i.e. Huntingtons)?	HD-QOL	never		0		0	2	13/11/2020
AAA	41	HD0341	HD03-Had problems with getting support from your family or friends?	HD-QOL	very rarely		1		1	2	13/11/2020
AAA	42	HD0342	HD03-Felt dissatisfied with local services/advice in relation to Huntingtons?	HD-QOL	infrequently		2		2	2	13/11/2020
AAA	43	HD0343	HD03-Felt dissatisfied with medical management of Huntingtons?	HD-QOL	sometimes		3		3	2	13/11/2020
AAA	44	HD0344	HD03-Had problems with accessing information about Huntingtons?	HD-QOL	often		4		4	2	13/11/2020
AAA	45	HD0345	HD03-Overall, how do you rate your quality of life?	HD-QOL	fair		1		1	2	13/11/2020
AAA	46	HD0346	HD03-What is your date of birth?	HD-QOL	16/01/1980		16/01/1980			2	13/11/2020
AAA	47	HD0347	HD03-What is your sex?	HD-QOL	male		0		0	2	13/11/2020
AAA	48	HD0348	HD03-What is your country of residence?	HD-QOL	Britain		Britain			2	13/11/2020

AAA	49	HD0349	HD03-How many years of full-time equivalent education have you had till now?	HD-QOL	10		10		10	2	13/11/2020
AAA	50	HD0350	HD03-What is the highest-level job that you ever held?	HD-QOL	manager		manager			2	13/11/2020
AAA	51	HD0351	HD03-Are you currently using Huntingtons related medications?	HD-QOL	Yes		1		1	2	13/11/2020
AAA	52	HD0352	HD03-What is your marital status?	HD-QOL	single		2		2	2	13/11/2020
AAA	53	HD0353	HD03-Which describes your current work status?	HD-QOL	I have a full-time paid job		0		0	2	13/11/2020
AAA	54	HD0354	HD03-Did you take the Huntingtons genetic test?	HD-QOL	1		1		1	2	13/11/2020
AAA	55	HD0355	HD03-In which year?	HD-QOL	2016		2016		2016	2	13/11/2020
AAA	56	HD0356	HD03-Did you receive a clinical/symptomatic diagnosis of Huntington's?	HD-QOL	manager		manager			2	13/11/2020
AAA	55	HD0357	HD03-In which year?	HD-QOL	2016		2016		2016	2	13/11/2020
AAA	56	HD0358	HD03-Which of the following describes your carer arrangement?	HD-QOL	I do not have a carer		0		0	2	13/11/2020
AAA	57	HD0359	HD03-Which of the following describes you the best as a person living with Huntington's disease?	HD-QOL	I am a gene carrier with no symptoms		1		1	2	13/11/2020
AAA	58	HD0360	HD03-How long did it take you to complete the questionnaire?	HD-QOL	15	min	15	min	15	2	13/11/2020

Table 22: UHDR questionnaire.

STUDYID	DOMAIN	USUBJ-ID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	UHDR100A	UHDR1-Functional Score	UHDR	100	100	100	2
IDEAFAST-FS	QS	AAA	2	UHDR100B	UHDR1-Occupation	UHDR	marginal work only	1	1	2
IDEAFAST-FS	QS	AAA	3	UHDR100C	UHDR1-Finances	UHDR	unable	0	0	2
IDEAFAST-FS	QS	AAA	4	UHDR100D	UHDR1-Domestic Chores	UHDR	impair	1	1	2
IDEAFAST-FS	QS	AAA	5	UHDR100E	UHDR1-ADL	UHDR	minimal impairment	2	2	2
IDEAFAST-FS	QS	AAA	6	UHDR100F	UHDR1-Care Level	UHDR	home or chronic care	1	1	2
IDEAFAST-FS	QS	AAA	7	UHDR100G	UHDR1-Information Source (Where was the information obtained from)	UHDR	participant only	1	1	2
IDEAFAST-FS	QS	AAA	8	UHDR101A	UHDR1-Ocular Pursuit: Horizontal	UHDR	complete (normal)	0	0	2
IDEAFAST-FS	QS	AAA	9	UHDR101B	UHDR1-Ocular Pursuit: Vertical	UHDR	jerky movement	1	1	2
IDEAFAST-FS	QS	AAA	10	UHDR102A	UHDR1-Saccade Initiation: Horizontal	UHDR	normal	0	0	2
IDEAFAST-FS	QS	AAA	11	UHDR102B	UHDR1-Saccade Initiation: Vertical	UHDR	increased latency only	1	1	2
IDEAFAST-FS	QS	AAA	12	UHDR103A	UHDR1-Saccade Velocity: Horizontal	UHDR	mild slowing	1	1	2
IDEAFAST-FS	QS	AAA	13	UHDR103B	UHDR1-Saccade Velocity: Vertical	UHDR	moderate slowing	2	2	2
IDEAFAST-FS	QS	AAA	14	UHDR104	UHDR1-Dysarthria	UHDR	unclear, no need to repeat	1	1	2
IDEAFAST-FS	QS	AAA	15	UHDR105	UHDR1-Tongue Protrusion	UHDR	can hold tongue fully protruded for 10 sec	0	0	2
IDEAFAST-FS	QS	AAA	16	UHDR106A	UHDR1-Finger Taps: Right	UHDR	mild slowing, reduction in amplitude (11-14/5 sec.)	1	1	2
IDEAFAST-FS	QS	AAA	17	UHDR106B	UHDR1-Finger Taps: Left	UHDR	moderately impaired (7-10/5 sec.)	2	2	2
IDEAFAST-FS	QS	AAA	18	UHDR107A	UHDR1-Pronate/Supinate: Hands: Right	UHDR	moderate slowing and irregular	2	2	2

IDEAFAST-FS	QS	AAA	19	UHDR107B	UHDR1-Pronate/Supinate: Hands: Left	UHDR	cannot perform	4	4	2
IDEAFAST-FS	QS	AAA	20	UHDR108	UHDR1-Luria	UHDR	<4 in 10 sec with cues	3	3	2
IDEAFAST-FS	QS	AAA	21	UHDR109A	UHDR1-Rigidity: Arms: Right	UHDR	severe with limited range	4	4	2
IDEAFAST-FS	QS	AAA	22	UHDR109B	UHDR1-Rigidity: Arms: Left	UHDR	severe, full range	3	3	2
IDEAFAST-FS	QS	AAA	23	UHDR110	UHDR1-Bradykinesia: Body	UHDR	mildly but clearly slow	2	2	2
IDEAFAST-FS	QS	AAA	24	UHDR111A	UHDR1-Maximal Dystonia: Trunk	UHDR	marked/prolonged	4	4	2
IDEAFAST-FS	QS	AAA	25	UHDR111B	UHDR1-Maximal Dystonia: RUE	UHDR	moderate/common	3	3	2
IDEAFAST-FS	QS	AAA	26	UHDR111C	UHDR1-Maximal Dystonia: LUE	UHDR	mild/common or moderate/intermittent	2	2	2
IDEAFAST-FS	QS	AAA	27	UHDR111D	UHDR1-Maximal Dystonia: RLE	UHDR	slight/intermittent	1	1	2
IDEAFAST-FS	QS	AAA	28	UHDR111E	UHDR1-Maximal Dystonia: LLE	UHDR	absent	0	0	2
IDEAFAST-FS	QS	AAA	29	UHDR112A	UHDR1-Maximal Chorea: Face	UHDR	slight/intermittent	1	1	2
IDEAFAST-FS	QS	AAA	30	UHDR112B	UHDR1-Maximal Chorea: BOL	UHDR	mild/common or moderate/intermittent	2	2	2
IDEAFAST-FS	QS	AAA	31	UHDR112C	UHDR1-Maximal Chorea: Trunk	UHDR	moderate/common	3	3	2
IDEAFAST-FS	QS	AAA	32	UHDR112D	UHDR1-Maximal Chorea: RUE	UHDR	marked/prolonged	4	4	2
IDEAFAST-FS	QS	AAA	33	UHDR112E	UHDR1-Maximal Chorea: LUE	UHDR	moderate/common	3	3	2
IDEAFAST-FS	QS	AAA	34	UHDR112F	UHDR1-Maximal Chorea: RLE	UHDR	mild/common or moderate/intermittent	2	2	2
IDEAFAST-FS	QS	AAA	35	UHDR112G	UHDR1-Maximal Chorea: LLE	UHDR	slight/intermittent	1	1	2
IDEAFAST-FS	QS	AAA	36	UHDR113	UHDR1-Gait	UHDR	normal gait, narrow base	0	0	2
IDEAFAST-FS	QS	AAA	37	UHDR114	UHDR1-Tandem Walking	UHDR	normal for 10 steps	0	0	2
IDEAFAST-FS	QS	AAA	38	UHDR115	UHDR1-Retropulsion Pull Test	UHDR	recovers spontaneously	1	1	2
IDEAFAST-FS	QS	AAA	39	UHDR117	UHDR1-Diagnosis Confidence Level	UHDR	motor abnormalities that may be signs of HD (50 - 89 % confidence)	2	2	2

Table 23: MOSS questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSOR-RESU	QSST-RESC	QSST-RESU	QSST-RESN	VISIT-NUM	QSDTC
IDEAFAST-FS	QS	AAA	1	HOM0101	HOM01-Fall Asleep	Sleep Survey	0-15	min	0		0	2	13/11/2020
IDEAFAST-FS	QS	AAA	2	HOM0102	HOM01-Length Of Sleep	Sleep Survey	7	min	7	hour	7	2	13/11/2020
IDEAFAST-FS	QS	AAA	3	HOM0103	HOM01-Sleep Not Quiet	Sleep Survey	All of the time		0		0	2	13/11/2020
IDEAFAST-FS	QS	AAA	4	HOM0104	HOM01-Feel Rested	Sleep Survey	Most of the time		1		1	2	13/11/2020
IDEAFAST-FS	QS	AAA	5	HOM0105	HOM01-Short Breath Headache	Sleep Survey	A good bit of the time		2		2	2	13/11/2020
IDEAFAST-FS	QS	AAA	6	HOM0106	HOM01-Drowsy	Sleep Survey	Some of the time		3		3	2	13/11/2020
IDEAFAST-FS	QS	AAA	7	HOM0107	HOM01-Trouble Falling Asleep	Sleep Survey	A little of the time		4		4	2	13/11/2020
IDEAFAST-FS	QS	AAA	8	HOM0108	HOM01-Wake During Sleep	Sleep Survey	None of the time		5		5	2	13/11/2020
IDEAFAST-FS	QS	AAA	9	HOM0109	HOM01-Trouble Staying Awake	Sleep Survey	All of the time		0		0	2	13/11/2020
IDEAFAST-FS	QS	AAA	10	HOM0110	HOM01-Wake During Sleep	Sleep Survey	Most of the time		1		1	2	13/11/2020
IDEAFAST-FS	QS	AAA	11	HOM0111	HOM01-Trouble Staying Awake	Sleep Survey	A good bit of the time		2		2	2	13/11/2020
IDEAFAST-FS	QS	AAA	12	HOM0112	HOM01-Snoring	Sleep Survey	Some of the time		3		3	2	13/11/2020
IDEAFAST-FS	QS	AAA	13	HOM0113	HOM01-Naps During Day	Sleep Survey	A little of the time		4		4	2	14/11/2020
IDEAFAST-FS	QS	AAA	14	HOM0114	HOM01-Sleep Amount Needed	Sleep Survey	None of the time		5		5	2	15/11/2020

Table 24: IBD-CONTROL questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	IBD0101	IBD01-Do you believe that your IBD has been well controlled over the past two weeks?	IBD-CONTROL	No	0	0	2
IDEAFAST-FS	QS	AAA	2	IBD0102	IBD01-Do you believe that your current treatment is useful in controlling your IBD?	IBD-CONTROL	Not sure	1	1	2
IDEAFAST-FS	QS	AAA	3	IBD0103	IBD01-If you are not taking any treatment please tick this box	IBD-CONTROL	No	0	0	2
IDEAFAST-FS	QS	AAA	4	IBD0104	IBD01-Over the past two weeks, have your bowel symptoms been getting worse, getting better or not changed?	IBD-CONTROL	Worse	0	0	2
IDEAFAST-FS	QS	AAA	5	IBD0105	IBD01-In the past two weeks, did you miss any planned activities because of IBD? (e.g. attending college/school, going to work or a social event)	IBD-CONTROL	Yes	0	0	2
IDEAFAST-FS	QS	AAA	6	IBD0106	IBD01-In the past two weeks, did you: wake up at night because of symptoms of IBD?	IBD-CONTROL	Not sure	1	1	2
IDEAFAST-FS	QS	AAA	7	IBD0107	IBD01-In the past two weeks, did you: suffer from significant pain or discomfort?	IBD-CONTROL	No	2	2	2
IDEAFAST-FS	QS	AAA	8	IBD0108	IBD01-In the past two weeks, did you: often feel lacking in energy (fatigued)?	IBD-CONTROL	Yes	0	0	2
IDEAFAST-FS	QS	AAA	9	IBD0109	IBD01-In the past two weeks, did you: feel anxious or depressed because of your IBD?	IBD-CONTROL	Not sure	1	1	2
IDEAFAST-FS	QS	AAA	10	IBD0110	IBD01-In the past two weeks, did you: feel you needed a change to your treatment?	IBD-CONTROL	No	2	2	2

IDEAFAST-FS	QS	AAA	11	IBD0111	IBD01-At your next clinic visit, would you like to discuss: alternative types of drug for controlling IBD	IBD-CONTROL	Yes	0	0	2
IDEAFAST-FS	QS	AAA	12	IBD0112	IBD01-At your next clinic visit, would you like to discuss: ways to adjust your own treatment	IBD-CONTROL	Not sure	1	1	2
IDEAFAST-FS	QS	AAA	13	IBD0113	IBD01-At your next clinic visit, would you like to discuss: side effects or difficulties with using your medicine	IBD-CONTROL	No	2	2	2
IDEAFAST-FS	QS	AAA	14	IBD0114	IBD01-At your next clinic visit, would you like to discuss: new symptoms that have developed since your last visit	IBD-CONTROL	Yes	0	0	2
IDEAFAST-FS	QS	AAA	15	IBD0115	IBD01-How would you rate the OVERALL control of your IBD over the past two weeks?	IBD-CONTROL	100	100	100	2

Table 25: IBD-HPI questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	IBD0201	IBD02-General well-being (the previous day)	IBD-HPI	very well	0	0	2
IDEAFAST-FS	QS	AAA	2	IBD0202	IBD02-Abdominal pain (the previous day)	IBD-HPI	none	0	0	2
IDEAFAST-FS	QS	AAA	3	IBD0203	IBD02-Number of liquid/soft stools (the previous day)	IBD-HPI	3	3	3	2
IDEAFAST-FS	QS	AAA	4	IBD0204	IBD02-Abdominal mass	IBD-HPI	dubious	1	1	2
IDEAFAST-FS	QS	AAA	5	IBD0205	IBD02-Complications - none	IBD-HPI	FALSE	0	0	2
IDEAFAST-FS	QS	AAA	6	IBD0206	IBD02-Complications - arthralgia	IBD-HPI	Yes	1	1	2
IDEAFAST-FS	QS	AAA	7	IBD0207	IBD02-Complications - uveitis	IBD-HPI	No	0	0	2
IDEAFAST-FS	QS	AAA	8	IBD0208	IBD02-Complications - erythema nodosum	IBD-HPI	Yes	1	1	2
IDEAFAST-FS	QS	AAA	9	IBD0209	IBD02-Complications - aphthous ulcer	IBD-HPI	No	0	0	2
IDEAFAST-FS	QS	AAA	10	IBD0210	IBD02-Complications - pyoderma gangrenosum	IBD-HPI	Yes	1	1	2
IDEAFAST-FS	QS	AAA	11	IBD0211	IBD02-Complications - anal fissures	IBD-HPI	Yes	1	1	2
IDEAFAST-FS	QS	AAA	12	IBD0212	IBD02-Complications - appearance of a new fistula	IBD-HPI	No	0	0	2
IDEAFAST-FS	QS	AAA	13	IBD0213	IBD02-Complications - abcess	IBD-HPI	Yes	1	1	2
IDEAFAST-FS	QS	AAA	14	IBD0214	IBD02-Complication Total Score	IBD-HPI	5	5	5	2
IDEAFAST-FS	QS	AAA	15	IBD0215	IBD02-Total score: sum from Q1-Q5	IBD-HPI	9	9	9	2
IDEAFAST-FS	QS	AAA	16	IBD0216	IBD02-Total Score	IBD-HPI	8-16	2	2	3

Table 26: IBD-SCCAI questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	IBDS0101	IBDS01-Daytime Bowel Motions	IBD-SCCAI	1-3 times	0	0	2
IDEAFAST-FS	QS	AAA	2	IBDS0102	IBDS01-Nightime Bowel Motions	IBD-SCCAI	4-6 times	1	1	2
IDEAFAST-FS	QS	AAA	3	IBDS0103	IBDS01-Urgency Of Defecation	IBD-SCCAI	I have no urgency at all (i.e. just as normal)	0	0	2
IDEAFAST-FS	QS	AAA	4	IBDS0104	IBDS01-Quantity Blood In Stool	IBD-SCCAI	Moderate	2	2	2
IDEAFAST-FS	QS	AAA	5	IBDS0105	IBDS01-Wellbeing	IBD-SCCAI	Slightly below par	1	1	2
IDEAFAST-FS	QS	AAA	6	IBDS0106	IBDS01-Joint Problems	IBD-SCCAI	No	0	0	2
IDEAFAST-FS	QS	AAA	7	IBDS0107	IBDS01-Eye Problems	IBD-SCCAI	Yes	1	1	2
IDEAFAST-FS	QS	AAA	8	IBDS0108	IBDS01-Mouth Problems	IBD-SCCAI	No	0	0	2
IDEAFAST-FS	QS	AAA	9	IBDS0109	IBDS01-Skin Problems Ulcers	IBD-SCCAI	Yes	1	1	2
IDEAFAST-FS	QS	AAA	10	IBDS0110	IBDS01-Skin Problems Bumps	IBD-SCCAI	No	0	0	2
IDEAFAST-FS	QS	AAA	11	IBDS0111	IBDS01-Perianal Problems	IBD-SCCAI	Yes	1	1	2
IDEAFAST-FS	QS	AAA	12	IBDS0112	IBDS01-Total Score	IBD-SCCAI	1-3 times	7	7	2

Table 27: MFI questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	MFI0101	MFI01-I feel fit	MFI	1 (Yes, that is true)	0	0	2
IDEAFAST-FS	QS	AAA	2	MFI0102	MFI01-Physically, I feel only able to do a little	MFI	2	1	1	2
IDEAFAST-FS	QS	AAA	3	MFI0103	MFI01-I feel very active	MFI	3	2	2	2
IDEAFAST-FS	QS	AAA	4	MFI0104	MFI01-I feel like doing all sorts of nice things	MFI	4	3	3	2
IDEAFAST-FS	QS	AAA	5	MFI0105	MFI01-I feel tired	MFI	5 (No, that is not true)	4	4	2
IDEAFAST-FS	QS	AAA	6	MFI0106	MFI01-I think I do a lot in a day	MFI	1 (Yes, that is true)	0	0	2
IDEAFAST-FS	QS	AAA	7	MFI0107	MFI01-When I am doing something, I can keep my thoughts on it	MFI	2	1	1	2
IDEAFAST-FS	QS	AAA	8	MFI0108	MFI01-Physically I can take on a lot	MFI	3	2	2	2
IDEAFAST-FS	QS	AAA	9	MFI0109	MFI01-I dread having to do things	MFI	4	3	3	2
IDEAFAST-FS	QS	AAA	10	MFI0110	MFI01-I think I do very little in a day	MFI	5 (No, that is not true)	4	4	2
IDEAFAST-FS	QS	AAA	11	MFI0111	MFI01-I can concentrate well	MFI	1 (Yes, that is true)	0	0	2
IDEAFAST-FS	QS	AAA	12	MFI0112	MFI01-I am rested	MFI	2	1	1	2
IDEAFAST-FS	QS	AAA	13	MFI0113	MFI01-It takes a lot of effort to concentrate on things	MFI	3	2	2	2
IDEAFAST-FS	QS	AAA	14	MFI0114	MFI01-Physically I feel I am in a bad condition	MFI	4	3	3	2
IDEAFAST-FS	QS	AAA	15	MFI0115	MFI01-I have a lot of plans	MFI	5 (No, that is not true)	4	4	2
IDEAFAST-FS	QS	AAA	16	MFI0116	MFI01-I tired easily	MFI	1 (Yes, that is true)	0	0	2
IDEAFAST-FS	QS	AAA	17	MFI0117	MFI01-I got little done	MFI	2	1	1	2

IDEAFAST-FS	QS	AAA	18	MFI0118	MFI01-I don't feel like doing anything	MFI	3	2	2	2
IDEAFAST-FS	QS	AAA	19	MFI0119	MFI01-My thoughts easily wander	MFI	4	3	3	2
IDEAFAST-FS	QS	AAA	20	MFI0120	MFI01-Physically I feel I am in an excellent condition	MFI	5 (No, that is not true)	4	4	2

Table 28: MOCA questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	MOCA0101	MOCA01-Visuospatial/Executive Score	MOCA	0	0	0	2
IDEAFAST-FS	QS	AAA	2	MOCA0102	MOCA01-Naming Score	MOCA	1	1	1	2
IDEAFAST-FS	QS	AAA	3	MOCA0103	MOCA01-Attention Sub-score 1	MOCA	1	1	1	2
IDEAFAST-FS	QS	AAA	4	MOCA0104	MOCA01-Attention Sub-score 2	MOCA	1	1	1	2
IDEAFAST-FS	QS	AAA	5	MOCA0105	MOCA01-Attention Sub-score 3	MOCA	1	1	1	2
IDEAFAST-FS	QS	AAA	6	MOCA0106	MOCA01-Language Sub-score 1	MOCA	1	1	1	2
IDEAFAST-FS	QS	AAA	7	MOCA0107	MOCA01-Language Sub-score 2	MOCA	1	1	1	2
IDEAFAST-FS	QS	AAA	8	MOCA0108	MOCA01-Abstraction Score	MOCA	1	1	1	2
IDEAFAST-FS	QS	AAA	9	MOCA0109	MOCA01-Delayed Recall Score	MOCA	1	1	1	2
IDEAFAST-FS	QS	AAA	10	MOCA0110	MOCA01-Orientation	MOCA	1	1	1	2
IDEAFAST-FS	QS	AAA	11	MOCA0111	MOCA01-Total MoCA Score	MOCA	9	9	9	2
IDEAFAST-FS	QS	AAA	12	MOCA0112	MOCA01-Passed screening (MoCA >= 16)	MOCA	Yes	1	1	2
IDEAFAST-FS	QS	AAA	13	MOCA0113	MOCA01-Years of Education <= 12 years?	MOCA	Yes	1	1	2

Table 29: PD\_Fatigue\_UCB\_Pro questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
IDEAFAST-FS	QS	AAA	1	FUCB0100	FUCB01-FatigueUCB available	FATIGUE-UCB	TRUE	TRUE		2
IDEAFAST-FS	QS	AAA	2	FUCB0101	FUCB01-Physically Tired	FATIGUE-UCB	None of the time	1	1	2
IDEAFAST-FS	QS	AAA	3	FUCB0102	FUCB01-Lack Energy	FATIGUE-UCB	A little of the time	2	2	2
IDEAFAST-FS	QS	AAA	4	FUCB0103	FUCB01-Getting Up Hard	FATIGUE-UCB	Some of the time	3	3	2
IDEAFAST-FS	QS	AAA	5	FUCB0104	FUCB01-Weak Legs	FATIGUE-UCB	Most of the time	4	4	2
IDEAFAST-FS	QS	AAA	6	FUCB0105	FUCB01-Weak Body	FATIGUE-UCB	All of the time	5	5	2
IDEAFAST-FS	QS	AAA	7	FUCB0106	FUCB01-Heavy Legs	FATIGUE-UCB	None of the time	1	1	2
IDEAFAST-FS	QS	AAA	8	FUCB0107	FUCB01-Weak Arms	FATIGUE-UCB	A little of the time	2	2	2
IDEAFAST-FS	QS	AAA	9	FUCB0108	FUCB01-Heavy Body	FATIGUE-UCB	Some of the time	3	3	2
IDEAFAST-FS	QS	AAA	10	FUCB0109	FUCB01-Heavy Arms	FATIGUE-UCB	Most of the time	4	4	2
IDEAFAST-FS	QS	AAA	11	FUCB0110	FUCB01-Mentally Tired	FATIGUE-UCB	All of the time	5	5	2
IDEAFAST-FS	QS	AAA	12	FUCB0111	FUCB01-Concentration	FATIGUE-UCB	None of the time	1	1	2
IDEAFAST-FS	QS	AAA	13	FUCB0112	FUCB01-Motivation	FATIGUE-UCB	A little of the time	2	2	2
IDEAFAST-FS	QS	AAA	14	FUCB0113	FUCB01-Forgetful	FATIGUE-UCB	Some of the time	3	3	2
IDEAFAST-FS	QS	AAA	15	FUCB0114	FUCB01-Mentally Overwhelmed	FATIGUE-UCB	Most of the time	4	4	2
IDEAFAST-FS	QS	AAA	16	FUCB0115	FUCB01-Focus	FATIGUE-UCB	All of the time	5	5	2

IDEAFAST-FS	QS	AAA	17	FUCB0116	FUCB01-No Mental Energy	FATIGUE-UCB	None of the time	1	1	2
IDEAFAST-FS	QS	AAA	18	FUCB0117	FUCB01-Lost Track Thoughts	FATIGUE-UCB	A little of the time	2	2	2
IDEAFAST-FS	QS	AAA	19	FUCB0118	FUCB01-Brain Fog	FATIGUE-UCB	Some of the time	3	3	2
IDEAFAST-FS	QS	AAA	20	FUCB0119	FUCB01-Hard Coping	FATIGUE-UCB	Most of the time	4	4	2
IDEAFAST-FS	QS	AAA	21	FUCB0120	FUCB01-Not Absorb Message	FATIGUE-UCB	All of the time	5	5	2
IDEAFAST-FS	QS	AAA	22	FUCB0121	FUCB01-Amount Sleep	FATIGUE-UCB	None of the time	1	1	2
IDEAFAST-FS	QS	AAA	23	FUCB0122	FUCB01-Tired Morning	FATIGUE-UCB	A little of the time	2	2	2
IDEAFAST-FS	QS	AAA	24	FUCB0123	FUCB01-Physical Effort	FATIGUE-UCB	Some of the time	3	3	2
IDEAFAST-FS	QS	AAA	25	FUCB0124	FUCB01-Breaks Needed	FATIGUE-UCB	Most of the time	4	4	2
IDEAFAST-FS	QS	AAA	26	FUCB0125	FUCB01-Sleep Needed	FATIGUE-UCB	All of the time	5	5	2
IDEAFAST-FS	QS	AAA	27	FUCB0126	FUCB01-Lie Down Needed	FATIGUE-UCB	None of the time	1	1	2
IDEAFAST-FS	QS	AAA	28	FUCB0127	FUCB01-Morning Out Of Bed	FATIGUE-UCB	A little of the time	2	2	2
IDEAFAST-FS	QS	AAA	29	FUCB0128	FUCB01-Suddenly Tired	FATIGUE-UCB	Some of the time	3	3	2
IDEAFAST-FS	QS	AAA	30	FUCB0129	FUCB01-Mental Effort	FATIGUE-UCB	Most of the time	4	4	2
IDEAFAST-FS	QS	AAA	31	FUCB0130	FUCB01-Sleep All Day	FATIGUE-UCB	All of the time	5	5	2
IDEAFAST-FS	QS	AAA	32	FUCB0131	FUCB01-Tired Eyes Closing	FATIGUE-UCB	All of the time	5	5	2

Table 30: LARS questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	LARS0101	LARS0101-EP1a	LARS	No reply	2	2	2
IDEAFAST-FS	QS	AAA	2	LARS0102	LARS0101-Ep1b	LARS	One activity but prompting needed to obtain another	1	1	2
IDEAFAST-FS	QS	AAA	3	LARS0103	LARS0101-INT1a	LARS	Reply after prompting	1	1	2
IDEAFAST-FS	QS	AAA	4	LARS0104	LARS0101-INT1b	LARS	Regrets having to choose between so many activities	-1	-1	2
IDEAFAST-FS	QS	AAA	5	LARS0105	LARS0101-INI1	LARS	I decide to do things myself	-1	-1	2
IDEAFAST-FS	QS	AAA	6	LARS0106	LARS0101-INI4	LARS	I take part spontaneously	-1	-1	2
IDEAFAST-FS	QS	AAA	7	LARS0107	LARS0101-NS2	LARS	No, that doesn't interest me	1	1	2
IDEAFAST-FS	QS	AAA	8	LARS0108	LARS0101-NS3	LARS	N.A. Non-classifiable reply	0	0	2
IDEAFAST-FS	QS	AAA	9	LARS0109	LARS0101-M3	LARS	I tend to give up (I am easily discouraged)	1	1	2
IDEAFAST-FS	QS	AAA	10	LARS0110	LARS0101-ER1	LARS	No, I don't experience any particular emotion	1	1	2
IDEAFAST-FS	QS	AAA	11	LARS0111	LARS0101-ER2	LARS	No, I don't experience any particular emotion	1	1	2
IDEAFAST-FS	QS	AAA	12	LARS0112	LARS0101-SL3	LARS	I start talking with no prompting	-1	-1	2
IDEAFAST-FS	QS	AAA	13	LARS0113	LARS0101-Total Score	LARS	4	4	4	2
IDEAFAST-FS	QS	AAA	14	LARS0114	LARS0101-Subscale_EP	LARS	-4	0	0	2
IDEAFAST-FS	QS	AAA	15	LARS0115	LARS0101-Subscale_INT	LARS	-3	0	0	2

IDEAFAST-FS	QS	AAA	16	LARS0116	LARS0101-SubScale_INI	LARS	-2	0	0	2
IDEAFAST-FS	QS	AAA	17	LARS0117	LARS0101-SubScale_NS	LARS	-1	1	1	2
IDEAFAST-FS	QS	AAA	18	LARS0118	LARS0101-SubScale_M	LARS	0	1	1	2
IDEAFAST-FS	QS	AAA	19	LARS0119	LARS0101-SubScale_ER	LARS	-2	0	0	2
IDEAFAST-FS	QS	AAA	20	LARS0120	LARS0101-SubScale_SL	LARS	-1	0	0	2

Table 31: MDS-UPDRS questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSORRES_U	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	UPD2100A	UPD2-Primary source of information for 1.1-1.6	MDS-UPDRS	Patient		0	0	2
IDEAFAST-FS	QS	AAA	2	UPD2100B	UPD2-Primary source of information for questionnaire	MDS-UPDRS	Caregiver		1	1	2
IDEAFAST-FS	QS	AAA	3	UPD2101	UPD2-Cognitive Impairment	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	4	UPD2102	UPD2-Hallucinations and Psychosis	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	5	UPD2103	UPD2-Depressed Mood	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	6	UPD2104	UPD2-Anxious Mood	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	7	UPD2105	UPD2-Apathy	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	8	UPD2106	UPD2-Ftrs Dopa Dysregulation Synd	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	9	UPD2107	UPD2-Sleep Problems	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	10	UPD2108	UPD2-Daytime Sleepiness	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	11	UPD2109	UPD2-Pain and other Sensations	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	12	UPD2110	UPD2-Urinary Problems	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	13	UPD2111	UPD2-Constipation Problems	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	14	UPD2112	UPD2-Lightheadedness on Standing	MDS-UPDRS	Slight		1	1	2

IDEAFAST-FS	QS	AAA	15	UPD2113	UPD2-Fatigue	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	16	UPD2201	UPD2-Speech	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	17	UPD2202	UPD2-Saliva and Drooling	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	18	UPD2203	UPD2-Chewing and Swallowing	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	19	UPD2204	UPD2-Eating Tasks	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	20	UPD2205	UPD2-Dressing	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	21	UPD2206	UPD2-Hygiene	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	22	UPD2207	UPD2-Handwriting	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	23	UPD2208	UPD2-Doing Hobbies/Other Activities	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	24	UPD2209	UPD2-Turning in Bed	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	25	UPD2210	UPD2-Tremor	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	26	UPD2211	UPD2-Get Out of Bed/Car/Deep Chair	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	27	UPD2212	UPD2-Walking and Balance	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	28	UPD2213	UPD2-Freezing	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	29	UPD23A	UPD2-Medication for PD	MDS-UPDRS	Yes		1	1	2
IDEAFAST-FS	QS	AAA	30	UPD23B	UPD2-Clinical State on Meds	MDS-UPDRS	On		0	0	2

IDEAFAST-FS	QS	AAA	31	UPD23C	UPD2-Taking Levodopa	MDS-UPDRS	No		0	0	2
IDEAFAST-FS	QS	AAA	32	UPD23C1	UPD2-Minutes Since Levodopa Dose	MDS-UPDRS	60	minutes	60	60	2
IDEAFAST-FS	QS	AAA	33	UPD2301	UPD2-Speech Problems	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	34	UPD2302	UPD2-Facial Expression	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	35	UPD2303A	UPD2-Rigidity Neck	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	36	UPD2303B	UPD2-Rigidity RT Upper Extremity	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	37	UPD2303C	UPD2-Rigidity Left Upper Extremity	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	38	UPD2303D	UPD2-Rigidity RT Lower Extremity	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	39	UPD2303E	UPD2-Rigidity Left Lower Extremity	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	40	UPD2304A	UPD2-Right Finger Tapping	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	41	UPD2304B	UPD2-Left Finger Tapping	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	42	UPD2305A	UPD2-Right Hand Movements	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	43	UPD2305B	UPD2-Left Hand Movements	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	44	UPD2306A	UPD2-Pron/Sup Movement of RT Hand	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	45	UPD2306B	UPD2-Pron/Sup Movement of Left Hand	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	46	UPD2307A	UPD2-Right Toe Tapping	MDS-UPDRS	Moderate		3	3	2

IDEAFAST-FS	QS	AAA	47	UPD2307B	UPD2-Left Toe Tapping	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	48	UPD2308A	UPD2-Right Leg Agility	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	49	UPD2308B	UPD2-Left Leg Agility	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	50	UPD2309	UPD2-Arising from Chair	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	51	UPD2310	UPD2-Gait	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	52	UPD2311	UPD2-Freezing of Gait	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	53	UPD2312	UPD2-Postural Stability	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	54	UPD2313	UPD2-Posture	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	55	UPD2314	UPD2-Body Bradykinesia	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	56	UPD2315A	UPD2-Postural Tremor of Right Hand	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	57	UPD2315B	UPD2-Postural Tremor of Left Hand	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	58	UPD2316A	UPD2-Kinetic Tremor of Right Hand	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	59	UPD2316B	UPD2-Kinetic Tremor of Left Hand	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	60	UPD2317A	UPD2-Rest Tremor Amplitude RUE	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	61	UPD2317B	UPD2-Rest Tremor Amplitude LUE	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	62	UPD2317C	UPD2-Rest Tremor Amplitude RLE	MDS-UPDRS	Severe		4	4	2

IDEAFAST-FS	QS	AAA	63	UPD2317D	UPD2-Rest Tremor Amplitude LLE	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	64	UPD2317E	UPD2-Rest Tremor Amplitude Lip/Jaw	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	65	UPD2318	UPD2-Consistency of Rest Tremor	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	66	UPD2DA	UPD2-Dyskinesias During Exam	MDS-UPDRS	Yes		1	1	2
IDEAFAST-FS	QS	AAA	67	UPD2DB	UPD2-Movements Interfere Ratings	MDS-UPDRS	Yes		1	1	2
IDEAFAST-FS	QS	AAA	68	UPD2HY	UPD2-Hoehn and Yahr Stage	MDS-UPDRS	Unilateral Involvement Only		1	1	2
IDEAFAST-FS	QS	AAA	69	UPD2401	UPD2-Time Spent with Dyskinesias	MDS-UPDRS	Normal		0	0	2
IDEAFAST-FS	QS	AAA	70	UPD2402	UPD2-Functional Impact Dyskinesias	MDS-UPDRS	Slight		1	1	2
IDEAFAST-FS	QS	AAA	71	UPD2403	UPD2-Time Spent in the Off State	MDS-UPDRS	Mild		2	2	2
IDEAFAST-FS	QS	AAA	72	UPD2404	UPD2-Functional Impact Fluctuations	MDS-UPDRS	Moderate		3	3	2
IDEAFAST-FS	QS	AAA	73	UPD2405	UPD2-Complexity Motor Fluctuations	MDS-UPDRS	Severe		4	4	2
IDEAFAST-FS	QS	AAA	74	UPD2406	UPD2-Painful Off-state Dystonia	MDS-UPDRS	Normal		0	0	2

Table 32: PDQ-8 questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	PDQ39125	PDQ391-Difficulty Getting in Public	PDQ-8	never	0	0	2
IDEAFAST-FS	QS	AAA	2	PDQ39112	PDQ391-Had Difficulty Dressing Yourself	PDQ-8	occasionally	1	1	2
IDEAFAST-FS	QS	AAA	3	PDQ39117	PDQ391-Felt Depressed	PDQ-8	sometimes	2	2	2
IDEAFAST-FS	QS	AAA	4	PDQ39127	PDQ391-Problems with Close Relations	PDQ-8	often	3	3	2
IDEAFAST-FS	QS	AAA	5	PDQ39129	PDQ391-Problems with Your Concentration	PDQ-8	always	4	4	2
IDEAFAST-FS	QS	AAA	6	PDQ39135	PDQ391-Unable to Communicate Properly	PDQ-8	never	0	0	2
IDEAFAST-FS	QS	AAA	7	PDQ39137	PDQ391-Painful Muscle Cramps or Spasms	PDQ-8	occasionally	1	1	2
IDEAFAST-FS	QS	AAA	8	PDQ39125	PDQ391-Felt Embarrassed Due to PD	PDQ-8	sometimes	2	2	2

Table 33: PDSS-2 questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	PDSS0201	PDSS02-Sleep Well	PDSS-2	never	0	0	2
IDEAFAST-FS	QS	AAA	2	PDSS0202	PDSS02-Falling Asleep	PDSS-2	occasionally	1	1	2
IDEAFAST-FS	QS	AAA	3	PDSS0203	PDSS02-Staying Asleep	PDSS-2	sometimes	2	2	2
IDEAFAST-FS	QS	AAA	4	PDSS0204	PDSS02-Restless Legs	PDSS-2	often	3	3	2
IDEAFAST-FS	QS	AAA	5	PDSS0205	PDSS02-Sleep Move Arms Legs	PDSS-2	very often	4	4	2
IDEAFAST-FS	QS	AAA	6	PDSS0206	PDSS02-Distressing Dreems	PDSS-2	never	0	0	2
IDEAFAST-FS	QS	AAA	7	PDSS0207	PDSS02-Hallucinations Night	PDSS-2	occasionally	1	1	2
IDEAFAST-FS	QS	AAA	8	PDSS0208	PDSS02-Night Urine	PDSS-2	sometimes	2	2	2
IDEAFAST-FS	QS	AAA	9	PDSS0209	PDSS02-Night Immobility	PDSS-2	often	3	3	2
IDEAFAST-FS	QS	AAA	10	PDSS0210	PDSS02-Pain Sleep	PDSS-2	very often	4	4	2
IDEAFAST-FS	QS	AAA	11	PDSS0211	PDSS02-Cramps Sleep	PDSS-2	never	0	0	2
IDEAFAST-FS	QS	AAA	12	PDSS0212	PDSS02-Painful Posture Arms Legs Morning	PDSS-2	occasionally	1	1	2
IDEAFAST-FS	QS	AAA	13	PDSS0213	PDSS02-Tremor Morning	PDSS-2	sometimes	2	2	2
IDEAFAST-FS	QS	AAA	14	PDSS0214	PDSS02-Tired	PDSS-2	often	3	3	2
IDEAFAST-FS	QS	AAA	15	PDSS0215	PDSS02-Waking Up Breathing Snoring	PDSS-2	very often	4	4	2

Table 34: SCOPA-AUT questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	SCO0101	SCO01-Swallowing	SCOPA AUT	never	0	0	2
IDEAFAST-FS	QS	AAA	2	SCO0102	SCO01-Dribbling	SCOPA AUT	sometimes	1	1	2
IDEAFAST-FS	QS	AAA	3	SCO0103	SCO01-Food Stuck	SCOPA AUT	regularly	2	2	2
IDEAFAST-FS	QS	AAA	4	SCO0104	SCO01-Meal Full Quickly	SCOPA AUT	often	3	3	2
IDEAFAST-FS	QS	AAA	5	SCO0105	SCO01-Constipation	SCOPA AUT	never	0	0	2
IDEAFAST-FS	QS	AAA	6	SCO0106	SCO01-Stool Difficult	SCOPA AUT	sometimes	1	1	2
IDEAFAST-FS	QS	AAA	7	SCO0107	SCO01-Involuntary Stool	SCOPA AUT	regularly	2	2	2
IDEAFAST-FS	QS	AAA	8	SCO0108	SCO01-Difficulty Retaining Urine	SCOPA AUT	often	3	3	2
IDEAFAST-FS	QS	AAA	9	SCO0109	SCO01-Involuntary Urine	SCOPA AUT	never	0	0	2
IDEAFAST-FS	QS	AAA	10	SCO0110	SCO01-Bladder Not Empty	SCOPA AUT	sometimes	1	1	2
IDEAFAST-FS	QS	AAA	11	SCO0111	SCO01-Weak Urine Stream	SCOPA AUT	regularly	2	2	2
IDEAFAST-FS	QS	AAA	12	SCO0112	SCO01-Urine Within Two Hours	SCOPA AUT	often	3	3	2
IDEAFAST-FS	QS	AAA	13	SCO0113	SCO01-Urine At Night	SCOPA AUT	never	0	0	2
IDEAFAST-FS	QS	AAA	14	SCO0114	SCO01-Dizzy Standing Up	SCOPA AUT	sometimes	1	1	2
IDEAFAST-FS	QS	AAA	15	SCO0115	SCO01-Dizzy After Standing	SCOPA AUT	regularly	2	2	2
IDEAFAST-FS	QS	AAA	16	SCO0116	SCO01-Fainted	SCOPA AUT	often	3	3	2
IDEAFAST-FS	QS	AAA	17	SCO0117	SCO01-Excessive Perspiration	SCOPA AUT	never	0	0	2
IDEAFAST-FS	QS	AAA	18	SCO0118	SCO01-Excessive Perspiration Night	SCOPA AUT	sometimes	1	1	2
IDEAFAST-FS	QS	AAA	19	SCO0119	SCO01-Oversensitive Light	SCOPA AUT	regularly	2	2	2
IDEAFAST-FS	QS	AAA	20	SCO0120	SCO01-Trouble Cold	SCOPA AUT	often	3	3	2
IDEAFAST-FS	QS	AAA	21	SCO0121	SCO01-Trouble Heat	SCOPA AUT	never	0	0	2

IDEAFAST-FS	QS	AAA	22	SCO0122	SCO01-Impotent Male Only	SCOPA AUT	sometimes	1	1	2
IDEAFAST-FS	QS	AAA	23	SCO0123	SCO01-Unable Ejaculate Male Only	SCOPA AUT	never	0	0	2
IDEAFAST-FS	QS	AAA	24	SCO0124	SCO01-Medication Erection Disorder Male Only	SCOPA AUT	No	0	0	2
IDEAFAST-FS	QS	AAA	25	SCO0125	SCO01-Medication Erection Disorder Male Only Name	SCOPA AUT	missing	99999	99999	2
IDEAFAST-FS	QS	AAA	26	SCO0126	SCO01-Vagina Dry Female Only	SCOPA AUT				2
IDEAFAST-FS	QS	AAA	27	SCO0127	SCO01-Orgasm Female Only	SCOPA AUT				2
IDEAFAST-FS	QS	AAA	28	SCO0128	SCO01-Medication Constipation	SCOPA AUT	Yes	1	1	2
IDEAFAST-FS	QS	AAA	29	SCO0129	SCO01-Medication Constipation Name	SCOPA AUT	Laxoberal	Laxoberal		2
IDEAFAST-FS	QS	AAA	30	SCO0130	SCO01-Medication Urinary Problems	SCOPA AUT	No	0	0	2
IDEAFAST-FS	QS	AAA	31	SCO0131	SCO01-Medication Urinary Problems Name	SCOPA AUT				2
IDEAFAST-FS	QS	AAA	32	SCO0132	SCO01-Medication BP	SCOPA AUT	No	0	0	2
IDEAFAST-FS	QS	AAA	33	SCO0133	SCO01-Medication BP Name	SCOPA AUT				2
IDEAFAST-FS	QS	AAA	34	SCO0134	SCO01-Medication Non PD	SCOPA AUT	No	0	0	2
IDEAFAST-FS	QS	AAA	35	SCO0135	SCO01-Medication Non PD Name	SCOPA AUT				2

Table 35: PHQ-9 questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	PHQ0101	PHQ01-Little Interest/Pleasure in Things	PHQ-9	Not at all	0	0	2
IDEAFAST-FS	QS	AAA	2	PHQ0102	PHQ01-Feeling Down Depressed or Hopeless	PHQ-9	Several days	1	1	2
IDEAFAST-FS	QS	AAA	3	PHQ0103	PHQ01-Trouble Falling or Staying Asleep	PHQ-9	More than half the days	2	2	2
IDEAFAST-FS	QS	AAA	4	PHQ0104	PHQ01-Feeling Tired or Little Energy	PHQ-9	Nearly every day	3	3	2
IDEAFAST-FS	QS	AAA	5	PHQ0105	PHQ01-Poor Appetite or Overeating	PHQ-9	Not at all	0	0	2
IDEAFAST-FS	QS	AAA	6	PHQ0106	PHQ01-Feeling Bad About Yourself	PHQ-9	Several days	1	1	2
IDEAFAST-FS	QS	AAA	7	PHQ0107	PHQ01-Trouble Concentrating on Things	PHQ-9	More than half the days	2	2	2
IDEAFAST-FS	QS	AAA	8	PHQ0108	PHQ01-Moving Slowly or Fidgety/Restless	PHQ-9	Nearly every day	3	3	2
IDEAFAST-FS	QS	AAA	9	PHQ0109	PHQ01-Thoughts You Be Better Off Dead	PHQ-9	Not at all	0	0	2
IDEAFAST-FS	QS	AAA	10	PHQ0110	PHQ01-Difficult to Work/Take Care Things	PHQ-9	Not difficult at all	0	0	2

Table 36: PSQI questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QTESTCD	QTEST	QSCAT	QSORRES	QSORRESU	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	PIT0101	PIT01-During the past month, what time have you usually gone to bed at night?	PITTSBURG	22:00		22:00		2
IDEAFAST-FS	QS	AAA	2	PIT0102	PIT01-During the past month, how long (in minutes) has it usually taken you to fall asleep each night?	PITTSBURG	10	minute	10	10	2
IDEAFAST-FS	QS	AAA	3	PIT0103	PIT01-During the past month, what time have you usually gotten up in the morning?	PITTSBURG	07:00		07:00		2
IDEAFAST-FS	QS	AAA	4	PIT0104	PIT01-During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)	PITTSBURG	9	hour	9	9	2
IDEAFAST-FS	QS	AAA	5	PIT0105	PIT01-Cannot get to sleep within 30 minutes	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	6	PIT0106	PIT01-Wake up in the middle of the night or early morning	PITTSBURG	Less than once a week		1	1	2
IDEAFAST-FS	QS	AAA	7	PIT0107	PIT01-Have to get up to use the bathroom	PITTSBURG	Once or twice a week		2	2	2
IDEAFAST-FS	QS	AAA	8	PIT0108	PIT01-Cannot breathe comfortably	PITTSBURG	Three or more times a week		3	3	2

IDEAFAST-FS	QS	AAA	9	PIT0109	PIT01-Cough or snore loudly	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	10	PIT0110	PIT01-Feel too cold	PITTSBURG	Less than once a week		1	1	2
IDEAFAST-FS	QS	AAA	11	PIT0111	PIT01-Feel too hot	PITTSBURG	Once or twice a week		2	2	2
IDEAFAST-FS	QS	AAA	12	PIT0112	PIT01-Have bad dreams	PITTSBURG	Three or more times a week		3	3	2
IDEAFAST-FS	QS	AAA	13	PIT0113	PIT01-Have pain	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	14	PIT0114	PIT01-Other reason(s), please describe:	PITTSBURG					2
IDEAFAST-FS	QS	AAA	15	PIT0115	PIT01-Other reason(s), describe	PITTSBURG					2
IDEAFAST-FS	QS	AAA	16	PIT0116	PIT01-During the past month, how often have you taken medicine to help you sleep (prescribed or ?over the counter?)?	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	17	PIT0117	PIT01-During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	18	PIT0118	PIT01-During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?	PITTSBURG	No problem at all		0	0	2

IDEAFAST-FS	QS	AAA	19	PIT0119	PIT01-During the past month, how would you rate your sleep quality overall?	PITTSBURG	Very good		0	0	2
IDEAFAST-FS	QS	AAA	20	PIT0120	PIT01-Do you have a bed partner or room mate?	PITTSBURG	No bed partner or room mate		0	0	2
IDEAFAST-FS	QS	AAA	21	PIT0121	PIT01-Loud snoring	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	22	PIT0122	PIT01-Long pauses between breaths while asleep	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	23	PIT0123	PIT01-Legs twitching or jerking while you sleep	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	24	PIT0124	PIT01-Episodes of disorientation or confusion during sleep	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	25	PIT0125	PIT01-Other restlessness while you sleep, please describe:	PITTSBURG	Not during the past month		0	0	2
IDEAFAST-FS	QS	AAA	26	PIT0126	PIT01-Other restlessness, describe	PITTSBURG					3

*Table 37: PROMIS-29 questionnaire.*

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	PRO0101	PRO01-Able to Do Chores	PROMIS-29	UNABLE To Do	1	1	2
IDEAFAST-FS	QS	AAA	2	PRO0102	PRO01-Able to Go Up and Down Stairs	PROMIS-29	With MUCH Difficulty	2	2	2
IDEAFAST-FS	QS	AAA	3	PRO0103	PRO01-Able to Go for a 15 Minutes Walk	PROMIS-29	With SOME Difficulty	3	3	2
IDEAFAST-FS	QS	AAA	4	PRO0104	PRO01-PRO01-Run Errands and Shop	PROMIS-29	With A LITTLE difficulty	4	4	2
IDEAFAST-FS	QS	AAA	5	PRO0105	PRO01-Felt Fearful	PROMIS-29	Never	1	1	2
IDEAFAST-FS	QS	AAA	6	PRO0106	PRO01-Focus on my Anxiety	PROMIS-29	Not at all	1	1	2
IDEAFAST-FS	QS	AAA	7	PRO0107	PRO01-My Worries Overwhelmed Me	PROMIS-29	A little bit	2	2	2
IDEAFAST-FS	QS	AAA	8	PRO0108	PRO01-Felt Uneasy	PROMIS-29	Somewhat	3	3	2
IDEAFAST-FS	QS	AAA	9	PRO0109	PRO01-Felt Worthless	PROMIS-29	Quite a bit	4	4	2
IDEAFAST-FS	QS	AAA	10	PRO0110	PRO01-Felt Helpless	PROMIS-29	Very much	5	5	2
IDEAFAST-FS	QS	AAA	11	PRO0111	PRO01-Felt Depressed	PROMIS-29	Not at all	1	1	2
IDEAFAST-FS	QS	AAA	12	PRO0112	PRO01-I felt hopeless	PROMIS-29	A little bit	2	2	2
IDEAFAST-FS	QS	AAA	13	PRO0113	PRO01-Feel Fatigued	PROMIS-29	Somewhat	3	3	2
IDEAFAST-FS	QS	AAA	14	PRO0114	PRO01-Trouble Starting Things	PROMIS-29	Quite a bit	4	4	2
IDEAFAST-FS	QS	AAA	15	PRO0115	PRO01-Run-Down Feel on Average	PROMIS-29	Very much	5	5	2
IDEAFAST-FS	QS	AAA	16	PRO0116	PRO01-Fatigued on Average	PROMIS-29	Not at all	1	1	2
IDEAFAST-FS	QS	AAA	17	PRO0117	PRO01-Sleep Quality	PROMIS-29	A little bit	2	2	2
IDEAFAST-FS	QS	AAA	18	PRO0118	PRO01-Sleep Refreshing	PROMIS-29	Somewhat	3	3	2

IDEAFAST-FS	QS	AAA	19	PRO0119	PRO01-Problem with Sleep	PROMIS-29	Quite a bit	4	4	2
IDEAFAST-FS	QS	AAA	20	PRO0120	PRO01-Difficulty Falling Asleep	PROMIS-29	Very much	5	5	2
IDEAFAST-FS	QS	AAA	21	PRO0121	PRO01-Trouble Regular Leisure Activities	PROMIS-29	Not at all	1	1	2
IDEAFAST-FS	QS	AAA	22	PRO0122	PRO01-Trouble Family Activities	PROMIS-29	A little bit	2	2	2
IDEAFAST-FS	QS	AAA	23	PRO0123	PRO01-Trouble Usual Work	PROMIS-29	Somewhat	3	3	2
IDEAFAST-FS	QS	AAA	24	PRO0124	PRO01-Trouble Activities with Friends	PROMIS-29	Quite a bit	4	4	2
IDEAFAST-FS	QS	AAA	25	PRO0125	PRO01-Pain with Day to Day Activities	PROMIS-29	Very much	5	5	2
IDEAFAST-FS	QS	AAA	26	PRO0126	PRO01-Pain with Work Around Home	PROMIS-29	Not at all	1	1	2
IDEAFAST-FS	QS	AAA	27	PRO0127	PRO01-Pain with Social Activities	PROMIS-29	A little bit	2	2	2
IDEAFAST-FS	QS	AAA	28	PRO0128	PRO01-Pain with Household Chores	PROMIS-29	Somewhat	3	3	2
IDEAFAST-FS	QS	AAA	29	PRO0129	PRO01-Pain on the Average	PROMIS-29	Worst imaginable pain	10	10	2

Table 38: ESSDAI questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	ESSDAI01	ESSDAI-Continital	ESSDAI	No Activity (Absence of the following symptoms)	0	0	2
IDEAFAST-FS	QS	AAA	2	ESSDAI02	ESSDAI-Lymphadenopathy	ESSDAI	Low Activity (Lymphadenopathy = 1cm in any nodal region or = 2cm in inguinal region)	1	1	2
IDEAFAST-FS	QS	AAA	3	ESSDAI03	ESSDAI-Glandular	ESSDAI	Moderate Activity (Major glandular swelling with enlarged parotid (>3cm) or important submandibular or lachrymal swelling)	2	2	2
IDEAFAST-FS	QS	AAA	4	ESSDAI04	ESSDAI-Articular	ESSDAI	Moderate Activity (1 to 5 synovitis among a 28 count)	2	2	2
IDEAFAST-FS	QS	AAA	5	ESSDAI05	ESSDAI-Cutaneous	ESSDAI	Low Activity (Erythema multiforme)	1	1	2
IDEAFAST-FS	QS	AAA	6	ESSDAI06	ESSDAI-Muscular	ESSDAI	Moderate Activity (Moderately active myositis proven by abnormal EMG or biopsy with weakness (maximal deficit of 4/5), or elevated creatine kinase (2N < CK = 4N))	2	2	2
IDEAFAST-FS	QS	AAA	7	ESSDAI07	ESSDAI-Respiratory	ESSDAI	Low Activity (Persistent cough or bronchial involvement with no radiographic abnormalities on X-ray Or radiological or HRCT evidence of interstitial lung disease with no breathlessness and normal lung function test)	1	1	2
IDEAFAST-FS	QS	AAA	8	ESSDAI08	ESSDAI-Peripheral Nervous System	ESSDAI	No Activity (Absence of currently active PNS involvement)	0	0	2
IDEAFAST-FS	QS	AAA	9	ESSDAI09	ESSDAI-Central Nervous System	ESSDAI	No Activity (Absence of currently active CNS involvement)	0	0	2
IDEAFAST-FS	QS	AAA	10	ESSDAI10	ESSDAI-Hematological	ESSDAI	No Activity (Absence of auto-immune cytopenia)	0	0	2
IDEAFAST-FS	QS	AAA	11	ESSDAI11	ESSDAI-Biological	ESSDAI	No Activity (Absence of any of the following biological features)	0	0	2
IDEAFAST-FS	QS	AAA	12	ESSDAI12	ESSDAI-Renal	ESSDAI	No Activity (Absence of currently active renal involvement, Proteinuria< 0.5g/d, no hematuria, no leucocyturia, no acidosis. Long lasting stable proteinuria due to damage)	0	0	2

*Table 39: ESSPRI questionnaire.*

<b>STUDYID</b>	<b>DOMAIN</b>	<b>USUBJID</b>	<b>QSSEQ</b>	<b>QTESTCD</b>	<b>QTEST</b>	<b>QSCAT</b>	<b>QSORRES</b>	<b>QSST-RESC</b>	<b>QSST-RESN</b>	<b>VISIT-NUM</b>
IDEAFAST-FS	QS	AAA	1	ESSPRI01	ESSPRI-Self Eval Dry	PSS-ESSPRI	No dryness	0	0	2
IDEAFAST-FS	QS	AAA	2	ESSPRI02	ESSPRI-Self Eval Fatigue	PSS-ESSPRI	Maximal imaginable fatigue	0	0	2
IDEAFAST-FS	QS	AAA	3	ESSPRI03	ESSPRI-Self Eval Pain	PSS-ESSPRI	5	5	5	2
IDEAFAST-FS	QS	AAA	4	ESSPRI04	ESSPRI-Self Eval Mental Fatigue	PSS-ESSPRI	4	4	4	2
IDEAFAST-FS	QS	AAA	5	ESSPRI05	ESSPRI-Self Eval Eye Dryness	PSS-ESSPRI	3	3	3	2
IDEAFAST-FS	QS	AAA	6	ESSPRI06	ESSPRI-Self Eval Oral Dryness	PSS-ESSPRI	2	2	2	2

*Table 40: pSS-Fatigue questionnaire.*

<b>STUDYID</b>	<b>DOMAIN</b>	<b>USUBJID</b>	<b>QSSEQ</b>	<b>QTESTCD</b>	<b>QTEST</b>	<b>QSCAT</b>	<b>QSORRES</b>	<b>QSST-RESC</b>	<b>QSST-RESN</b>	<b>VISIT-NUM</b>
IDEAFAST-FS	QS	AAA	1	PSSF0101	PSSF01-Rest	PSS-FATIGUE	no need to rest at all	0	0	2
IDEAFAST-FS	QS	AAA	2	PSSF0102	PSSF01-Get Going	PSS-FATIGUE	as bad as imaginable	7	7	3
IDEAFAST-FS	QS	AAA	3	PSSF0103	PSSF01-Keep Going	PSS-FATIGUE	not hard to keep going at all	0	0	4
IDEAFAST-FS	QS	AAA	4	PSSF0104	PSSF01-Strength	PSS-FATIGUE	no lack of strength at all	0	0	5
IDEAFAST-FS	QS	AAA	5	PSSF0105	PSSF01-Concentrate	PSS-FATIGUE	no such problem at all	0	0	6
IDEAFAST-FS	QS	AAA	6	PSSF0106	PSSF01-Mistakes	PSS-FATIGUE	no such problem at all	0	0	7

Table 41: RA-RAPID3 questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	RARA01	RARA01-Dressing	RA-RAPID3	without any difficulty	0	0	2
IDEAFAST-FS	QS	AAA	2	RARA02	RARA01-Get In Out Bed	RA-RAPID3	with some difficulty	1	1	2
IDEAFAST-FS	QS	AAA	3	RARA03	RARA01-Lift Cup	RA-RAPID3	with much difficulty	2	2	2
IDEAFAST-FS	QS	AAA	4	RARA04	RARA01-Walk Outdoors	RA-RAPID3	unable to do	3	3	2
IDEAFAST-FS	QS	AAA	5	RARA05	RARA01-Wash Self	RA-RAPID3	without any difficulty	0	0	2
IDEAFAST-FS	QS	AAA	6	RARA06	RARA01-Bend Down	RA-RAPID3	with some difficulty	1	1	2
IDEAFAST-FS	QS	AAA	7	RARA07	RARA01-Turn Taps	RA-RAPID3	with much difficulty	2	2	2
IDEAFAST-FS	QS	AAA	8	RARA08	RARA01-Access Transport	RA-RAPID3	unable to do	3	3	2
IDEAFAST-FS	QS	AAA	9	RARA09	RARA01-Walk 2 Miles	RA-RAPID3	without any difficulty	0	0	2
IDEAFAST-FS	QS	AAA	10	RARA10	RARA01-Sports	RA-RAPID3	with some difficulty	1	1	2
IDEAFAST-FS	QS	AAA	11	RARA11	RARA01-Sleep	RA-RAPID3	with much difficulty	2	2	2
IDEAFAST-FS	QS	AAA	12	RARA12	RARA01-Anxiety	RA-RAPID3	unable to do	3	3	2
IDEAFAST-FS	QS	AAA	13	RARA13	RARA01-Depression	RA-RAPID3	unable to do	3	3	2
IDEAFAST-FS	QS	AAA	14	RARA14	RARA01-Global Pain	RA-RAPID3	No Pain	0	0	2
IDEAFAST-FS	QS	AAA	15	RARA15	RARA01-Global Health	RA-RAPID3	0.5	0.5	0.5	2
IDEAFAST-FS	QS	AAA	16	RARA16	RARA01-FN Score	RA-RAPID3	4	4	4	2
IDEAFAST-FS	QS	AAA	17	RARA17	RARA01-PN Score	RA-RAPID3	3	3	3	2
IDEAFAST-FS	QS	AAA	18	RARA18	RARA01-PTGE Score	RA-RAPID3	2	2	2	2
IDEAFAST-FS	QS	AAA	19	RARA19	RARA01-Total Score	RA-RAPID3	9	9	9	2

*Table 42: SFQ questionnaire.*

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	SFQ0101	SFQ01-I complete my tasks at work and home satisfactorily.	SFQ	Most of the time	0	0	2
IDEAFAST-FS	QS	AAA	2	SFQ0102	SFQ01-I find my tasks at work and at home very stressful.	SFQ	Most of the time	3	3	2
IDEAFAST-FS	QS	AAA	3	SFQ0103	SFQ01-I have no money problems.	SFQ	No problems at all	0	0	2
IDEAFAST-FS	QS	AAA	4	SFQ0104	SFQ01-I have difficulties in getting and keeping close relationships.	SFQ	Severe difficulties	3	3	2
IDEAFAST-FS	QS	AAA	5	SFQ0105	SFQ01-I have problems in my sex life.	SFQ	Severe problems	3	3	2
IDEAFAST-FS	QS	AAA	6	SFQ0106	SFQ01-I get on well with my family and other relatives.	SFQ	Yes, definitely	0	0	2
IDEAFAST-FS	QS	AAA	7	SFQ0107	SFQ01-I feel lonely and isolated from other people.	SFQ	Almost all the time	3	3	2
IDEAFAST-FS	QS	AAA	8	SFQ0108	SFQ01-I enjoy my spare time	SFQ	Very much	0	0	2

Table 43: BILAG 2004 questionnaire.

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QTEST	QSCAT	QSORRES	QSORRESU	QSST-RESC	QSST-RESN	VISIT-NUM
IDEAFAST-FS	QS	AAA	1	BILA0101	BILA01-Pyrexia	BILAG2004	Not present		0	0	2
IDEAFAST-FS	QS	AAA	2	BILA0102	BILA01-Weight Loss	BILAG2004	Improving		1	1	2
IDEAFAST-FS	QS	AAA	3	BILA0103	BILA01-Lymphadenopathy	BILAG2004	Same		2	2	2
IDEAFAST-FS	QS	AAA	4	BILA0104	BILA01-Anorexia	BILAG2004	Worse		3	3	2
IDEAFAST-FS	QS	AAA	5	BILA0105	BILA01-Skin Severe	BILAG2004	New		4	4	2
IDEAFAST-FS	QS	AAA	6	BILA0106	BILA01-Skin Mild	BILAG2004	Not done		5	5	2
IDEAFAST-FS	QS	AAA	7	BILA0107	BILA01-Angio Severe	BILAG2004	Not present		0	0	2
IDEAFAST-FS	QS	AAA	8	BILA0108	BILA01-Angio Mild	BILAG2004	Improving		1	1	2
IDEAFAST-FS	QS	AAA	9	BILA0109	BILA01-Mucosal Ulceration Severe	BILAG2004	Same		2	2	2
IDEAFAST-FS	QS	AAA	10	BILA0110	BILA01-Mucosal Ulceration Mild	BILAG2004	Worse		3	3	2
IDEAFAST-FS	QS	AAA	11	BILA0111	BILA01-Panniculitis Severe	BILAG2004	New		4	4	2
IDEAFAST-FS	QS	AAA	12	BILA0112	BILA01-Panniculitis Mild	BILAG2004	Not done		5	5	2
IDEAFAST-FS	QS	AAA	13	BILA0113	BILA01-Major Vasculitis	BILAG2004	Not present		0	0	2
IDEAFAST-FS	QS	AAA	14	BILA0114	BILA01-Digital Infarc	BILAG2004	Improving		1	1	2
IDEAFAST-FS	QS	AAA	15	BILA0115	BILA01-Alopecia Severe	BILAG2004	Same		2	2	2
IDEAFAST-FS	QS	AAA	16	BILA0116	BILA01-Alopecia Mild	BILAG2004	Worse		3	3	2
IDEAFAST-FS	QS	AAA	17	BILA0117	BILA01-Chilblains	BILAG2004	New		4	4	2
IDEAFAST-FS	QS	AAA	18	BILA0118	BILA01-Splint Haem	BILAG2004	Not done		5	5	2
IDEAFAST-FS	QS	AAA	19	BILA0119	BILA01-Aseptic Mening	BILAG2004	Not present		0	0	2
IDEAFAST-FS	QS	AAA	20	BILA0120	BILA01-Cereb Vasc	BILAG2004	Improving		1	1	2
IDEAFAST-FS	QS	AAA	21	BILA0121	BILA01-Demy1	BILAG2004	Same		2	2	2
IDEAFAST-FS	QS	AAA	22	BILA0122	BILA01-Myelopathy	BILAG2004	Worse		3	3	2

IDEAFAST-FS	QS	AAA	23	BILA0123	BILA01-Confusion	BILAG2004	New			4	4	2
IDEAFAST-FS	QS	AAA	24	BILA0124	BILA01-Psychosis	BILAG2004	Not done			5	5	2
IDEAFAST-FS	QS	AAA	25	BILA0125	BILA01-AIDP	BILAG2004	Not present			0	0	2
IDEAFAST-FS	QS	AAA	26	BILA0126	BILA01-Mononeuro	BILAG2004	Improving			1	1	2
IDEAFAST-FS	QS	AAA	27	BILA0127	BILA01-Cranial Neuro	BILAG2004	Same			2	2	2
IDEAFAST-FS	QS	AAA	28	BILA0128	BILA01-Plexopathy	BILAG2004	Worse			3	3	2
IDEAFAST-FS	QS	AAA	29	BILA0129	BILA01-Polyneuro	BILAG2004	New			4	4	2
IDEAFAST-FS	QS	AAA	30	BILA0130	BILA01-Seizure	BILAG2004	Not done			5	5	2
IDEAFAST-FS	QS	AAA	31	BILA0131	BILA01-Epi	BILAG2004	Not present			0	0	2
IDEAFAST-FS	QS	AAA	32	BILA0132	BILA01-Cerebro Vasc	BILAG2004	Improving			1	1	2
IDEAFAST-FS	QS	AAA	33	BILA0133	BILA01-Cognitive	BILAG2004	Same			2	2	2
IDEAFAST-FS	QS	AAA	34	BILA0134	BILA01-Movement	BILAG2004	Worse			3	3	2
IDEAFAST-FS	QS	AAA	35	BILA0135	BILA01-Autonomic	BILAG2004	New			4	4	2
IDEAFAST-FS	QS	AAA	36	BILA0136	BILA01-Cereb Atax	BILAG2004	Not done			5	5	2
IDEAFAST-FS	QS	AAA	37	BILA0137	BILA01-Lupus Headache	BILAG2004	Not present			0	0	2
IDEAFAST-FS	QS	AAA	38	BILA0138	BILA01-Hypertensive Headache	BILAG2004	Improving			1	1	2
IDEAFAST-FS	QS	AAA	39	BILA0139	BILA01-Myo Severe	BILAG2004	Same			2	2	2
IDEAFAST-FS	QS	AAA	40	BILA0140	BILA01-Myo Mild	BILAG2004	Worse			3	3	2
IDEAFAST-FS	QS	AAA	41	BILA0141	BILA01-Arth Severe	BILAG2004	New			4	4	2
IDEAFAST-FS	QS	AAA	42	BILA0142	BILA01-Arth Moderate	BILAG2004	Not done			5	5	2
IDEAFAST-FS	QS	AAA	43	BILA0143	BILA01-Arth Mild	BILAG2004	Not present			0	0	2
IDEAFAST-FS	QS	AAA	44	BILA0144	BILA01-Myocard Mild	BILAG2004	Improving			1	1	2
IDEAFAST-FS	QS	AAA	45	BILA0145	BILA01-Myo Endo Cardiac	BILAG2004	Same			2	2	2
IDEAFAST-FS	QS	AAA	46	BILA0146	BILA01-Arrythmia	BILAG2004	Worse			3	3	2
IDEAFAST-FS	QS	AAA	47	BILA0147	BILA01-Valv Dysf	BILAG2004	New			4	4	2
IDEAFAST-FS	QS	AAA	48	BILA0148	BILA01-Pleurisy	BILAG2004	Not done			5	5	2
IDEAFAST-FS	QS	AAA	49	BILA0149	BILA01-Card Tamp	BILAG2004	Not present			0	0	2
IDEAFAST-FS	QS	AAA	50	BILA0150	BILA01-Pleur Eff	BILAG2004	Improving			1	1	2

IDEAFAST-FS	QS	AAA	51	BILA0151	BILA01-Pulm Haem Vasc	BILAG2004	Same		2	2	2
IDEAFAST-FS	QS	AAA	52	BILA0152	BILA01-Inter Aleo	BILAG2004	Worse		3	3	2
IDEAFAST-FS	QS	AAA	53	BILA0153	BILA01-Shrinking Lung	BILAG2004	New		4	4	2
IDEAFAST-FS	QS	AAA	54	BILA0154	BILA01-Aortitis	BILAG2004	Not done		5	5	2
IDEAFAST-FS	QS	AAA	55	BILA0155	BILA01-Cor Vasc	BILAG2004	Not present		0	0	2
IDEAFAST-FS	QS	AAA	56	BILA0156	BILA01-Peritonitis	BILAG2004	Improving		1	1	2
IDEAFAST-FS	QS	AAA	57	BILA0157	BILA01-Serositis	BILAG2004	Same		2	2	2
IDEAFAST-FS	QS	AAA	58	BILA0158	BILA01-Enteritis	BILAG2004	Worse		3	3	2
IDEAFAST-FS	QS	AAA	59	BILA0159	BILA01-Malabsorption	BILAG2004	New		4	4	2
IDEAFAST-FS	QS	AAA	60	BILA0160	BILA01-Protein Losing	BILAG2004	Not done		5	5	2
IDEAFAST-FS	QS	AAA	61	BILA0161	BILA01-Pseudo Obstruction	BILAG2004	Not present		0	0	2
IDEAFAST-FS	QS	AAA	62	BILA0162	BILA01-Hepatitis	BILAG2004	Improving		1	1	2
IDEAFAST-FS	QS	AAA	63	BILA0163	BILA01-Cholecystitis	BILAG2004	Same		2	2	2
IDEAFAST-FS	QS	AAA	64	BILA0164	BILA01-Pancreatitis	BILAG2004	Worse		3	3	2
IDEAFAST-FS	QS	AAA	65	BILA0165	BILA01-Orbital Infl	BILAG2004	New		4	4	2
IDEAFAST-FS	QS	AAA	66	BILA0166	BILA01-Kerat Severe	BILAG2004	Not done		5	5	2
IDEAFAST-FS	QS	AAA	67	BILA0167	BILA01-Kerat Mild	BILAG2004	Not present		0	0	2
IDEAFAST-FS	QS	AAA	68	BILA0168	BILA01-Ant Uveitis	BILAG2004	Improving		1	1	2
IDEAFAST-FS	QS	AAA	69	BILA0169	BILA01-Post Uveitis Severe	BILAG2004	Same		2	2	2
IDEAFAST-FS	QS	AAA	70	BILA0170	BILA01-Post Uveitis Mild	BILAG2004	Worse		3	3	2
IDEAFAST-FS	QS	AAA	71	BILA0171	BILA01-Episcleritis	BILAG2004	New		4	4	2
IDEAFAST-FS	QS	AAA	72	BILA0172	BILA01-Scleritis Severe	BILAG2004	Not done		5	5	2
IDEAFAST-FS	QS	AAA	73	BILA0173	BILA01-Scleritis Mild	BILAG2004	Not present		0	0	2
IDEAFAST-FS	QS	AAA	74	BILA0174	BILA01-Vaso Occ	BILAG2004	Improving		1	1	2
IDEAFAST-FS	QS	AAA	75	BILA0175	BILA01-Cotton Wool Spots	BILAG2004	Same		2	2	2

IDEAFAST-FS	QS	AAA	76	BILA0176	BILA01-Optic Neuritis	BILAG2004	Worse		3	3	2
IDEAFAST-FS	QS	AAA	77	BILA0177	BILA01-AntION	BILAG2004	New		4	4	2
IDEAFAST-FS	QS	AAA	78	BILA0178	BILA01-BPSys	BILAG2004	100		100	100	2
IDEAFAST-FS	QS	AAA	79	BILA0179	BILA01-BPSysSLE	BILAG2004	Yes		1	1	2
IDEAFAST-FS	QS	AAA	80	BILA0180	BILA01-BPDia	BILAG2004					2
IDEAFAST-FS	QS	AAA	81	BILA0181	BILA01-BPDiaSLE	BILAG2004	Yes		1	1	2
IDEAFAST-FS	QS	AAA	82	BILA0182	BILA01-Hypertension	BILAG2004	Yes		1	1	2
IDEAFAST-FS	QS	AAA	83	BILA0183	BILA01-Urine Protein	BILAG2004	"+"		1	1	2
IDEAFAST-FS	QS	AAA	84	BILA0184	BILA01-Urine Protein SLE	BILAG2004	No		0	0	2
IDEAFAST-FS	QS	AAA	85	BILA0185	BILA01-Urine Albumin Ratio	BILAG2004	100.5		100.5	100.5	2
IDEAFAST-FS	QS	AAA	86	BILA0186	BILA01-Urine Albumin SLE	BILAG2004	No		0	0	2
IDEAFAST-FS	QS	AAA	87	BILA0187	BILA01-Urine Protein Ratio	BILAG2004	100.5		100.5	100.5	2
IDEAFAST-FS	QS	AAA	88	BILA0188	BILA01-Urine Protein Ratio SLE	BILAG2004	No		0	0	2
IDEAFAST-FS	QS	AAA	89	BILA0189	BILA01-Urine 24h Protein	BILAG2004	100.5		100.5	100.5	2
IDEAFAST-FS	QS	AAA	90	BILA0190	BILA01-Urine 24h Protein SLE	BILAG2004	Yes		1	1	2
IDEAFAST-FS	QS	AAA	91	BILA0191	BILA01-Nephrotic	BILAG2004	No		0	0	2
IDEAFAST-FS	QS	AAA	92	BILA0192	BILA01-Creatinine	BILAG2004	1000.5		1000.5	1000.5	2
IDEAFAST-FS	QS	AAA	93	BILA0193	BILA01-Creatinine SLE	BILAG2004	No		0	0	2
IDEAFAST-FS	QS	AAA	94	BILA0194	BILA01-GFR	BILAG2004	100		100	100	2
IDEAFAST-FS	QS	AAA	95	BILA0195	BILA01-GFRSLE	BILAG2004	Yes		1	1	2
IDEAFAST-FS	QS	AAA	96	BILA0196	BILA01-Sediment	BILAG2004	No		0	0	2
IDEAFAST-FS	QS	AAA	97	BILA0197	BILA01-Nephritis	BILAG2004	Not done		2	2	2
IDEAFAST-FS	QS	AAA	98	BILA0198	BILA01-Haemoglobin	BILAG2004	10.5		10.5	10.5	2
IDEAFAST-FS	QS	AAA	99	BILA0199	BILA01-Haemoglobin SLE	BILAG2004	No		0	0	2

IDEAFAST-FS	QS	AAA	100	BILA0200	BILA01-White Count	BILAG2004	10.5			10.5		2
IDEAFAST-FS	QS	AAA	101	BILA0201	BILA01-White Count SLE	BILAG2004	No			0	0	2
IDEAFAST-FS	QS	AAA	102	BILA0202	BILA01-Neutrophils	BILAG2004	10.5			10.5	10.5	2
IDEAFAST-FS	QS	AAA	103	BILA0203	BILA01- Neutrophils SLE	BILAG2004	No			0	0	2
IDEAFAST-FS	QS	AAA	104	BILA0204	BILA01- Lymphocytes	BILAG2004	10.5			10.5	10.5	2
IDEAFAST-FS	QS	AAA	105	BILA0205	BILA01- Lymphocytes SLE	BILAG2004	No			0	0	2
IDEAFAST-FS	QS	AAA	106	BILA0206	BILA01-Platelets	BILAG2004	100.5			100.5	100.5	2
IDEAFAST-FS	QS	AAA	107	BILA0207	BILA01-Platelets SLE	BILAG2004	No			0	0	2
IDEAFAST-FS	QS	AAA	108	BILA0208	BILA01-TTP	BILAG2004	Not present			0	0	2
IDEAFAST-FS	QS	AAA	109	BILA0209	BILA01-Haemolysis	BILAG2004	No			0	0	2
IDEAFAST-FS	QS	AAA	110	BILA0210	BILA01-Coombs	BILAG2004	No			0	0	2
IDEAFAST-FS	QS	AAA	111	BILA0211	BILA01-Weight	BILAG2004	60	kg				2
IDEAFAST-FS	QS	AAA	112	BILA0212	BILA01-African	BILAG2004	No			0	0	2
IDEAFAST-FS	QS	AAA	113	BILA0213	BILA01-Urea	BILAG2004	10.5			10.5	10.5	2
IDEAFAST-FS	QS	AAA	114	BILA0214	BILA01-Albumin	BILAG2004	10	g/L	10	10	10	2

Table 44: SLE-Fatigue questionnaire.

DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSST-RESC	QSST-RESN	VISIT-NUM
QS	AAA	1	SLEF0101	SLEF01-Physically Tired	SLE-FATIGUE	None of the time	0	0	2
QS	AAA	2	SLEF0102	SLEF01-Lack Energy	SLE-FATIGUE	A little of the time	1	1	2
QS	AAA	3	SLEF0103	SLEF01-Get Up	SLE-FATIGUE	Some of the time	2	2	2
QS	AAA	4	SLEF0104	SLEF01-Weak Legs	SLE-FATIGUE	Most of the time	3	3	2
QS	AAA	5	SLEF0105	SLEF01-Weak Body	SLE-FATIGUE	All of the time	4	4	2
QS	AAA	6	SLEF0106	SLEF01-Heavy Legs	SLE-FATIGUE	None of the time	0	0	2
QS	AAA	7	SLEF0107	SLEF01-Weak Arms	SLE-FATIGUE	A little of the time	1	1	2
QS	AAA	8	SLEF0108	SLEF01-Heavy Body	SLE-FATIGUE	Some of the time	2	2	2
QS	AAA	9	SLEF0109	SLEF01-Heavy Arms	SLE-FATIGUE	Most of the time	3	3	2
QS	AAA	10	SLEF0110	SLEF01-Mentally Tired	SLE-FATIGUE	All of the time	4	4	2
QS	AAA	11	SLEF0111	SLEF01-Concentration	SLE-FATIGUE	None of the time	0	0	2
QS	AAA	12	SLEF0112	SLEF01-Motivation	SLE-FATIGUE	A little of the time	1	1	2
QS	AAA	13	SLEF0113	SLEF01-Memory	SLE-FATIGUE	Some of the time	2	2	2
QS	AAA	14	SLEF0114	SLEF01-Overwhelmed	SLE-FATIGUE	Most of the time	3	3	2
QS	AAA	15	SLEF0115	SLEF01-Difficulty Focussing	SLE-FATIGUE	All of the time	4	4	2
QS	AAA	16	SLEF0116	SLEF01-Lack Mental Energy	SLE-FATIGUE	None of the time	0	0	2
QS	AAA	17	SLEF0117	SLEF01-Lose Track Thoughts	SLE-FATIGUE	A little of the time	1	1	2
QS	AAA	18	SLEF0118	SLEF01-Brain Fog	SLE-FATIGUE	Some of the time	2	2	2
QS	AAA	19	SLEF0119	SLEF01-Hard To Cope	SLE-FATIGUE	Most of the time	3	3	2
QS	AAA	20	SLEF0120	SLEF01-Not Absorb	SLE-FATIGUE	All of the time	4	4	2
QS	AAA	21	SLEF0121	SLEF01-Not Sleep	SLE-FATIGUE	None of the time	0	0	2
QS	AAA	22	SLEF0122	SLEF01-Wake Up Tired	SLE-FATIGUE	A little of the time	1	1	2
QS	AAA	23	SLEF0123	SLEF01-Maintain Activity Physical	SLE-FATIGUE	Some of the time	2	2	2

QS	AAA	24	SLEF0124	SLEF01-Breaks	SLE-FATIGUE	Most of the time	3	3	2
QS	AAA	25	SLEF0125	SLEF01-Sleep During Day	SLE-FATIGUE	All of the time	4	4	2
QS	AAA	26	SLEF0126	SLEF01-Lie Down	SLE-FATIGUE	None of the time	0	0	2
QS	AAA	27	SLEF0127	SLEF01-Stay In Bed	SLE-FATIGUE	A little of the time	1	1	2
QS	AAA	28	SLEF0128	SLEF01-Sudden Tiredness	SLE-FATIGUE	Some of the time	2	2	2
QS	AAA	29	SLEF0129	SLEF01-Maintain Activity Mental	SLE-FATIGUE	Most of the time	3	3	2
QS	AAA	30	SLEF0130	SLEF01-Sleep All Day	SLE-FATIGUE	All of the time	4	4	2
QS	AAA	31	SLEF0131	SLEF01-Keep Eyes Open	SLE-FATIGUE	All of the time	4	4	2

Table 45: SLEDAI2k questionnaire.

DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM
QS	AAA	1	SLED0101	SLED01-Seizures	SLEDAI2k	No	0	0	2
QS	AAA	2	SLED0102	SLED01-Psychosis	SLEDAI2k	Yes	1	1	2
QS	AAA	3	SLED0103	SLED01-Organic Brain	SLEDAI2k	No	0	0	2
QS	AAA	4	SLED0104	SLED01-Visual Disturbance	SLEDAI2k	Yes	1	1	2
QS	AAA	5	SLED0105	SLED01-Cranial Nerve	SLEDAI2k	No	0	0	2
QS	AAA	6	SLED0106	SLED01-Lupus Headache	SLEDAI2k	Yes	1	1	2
QS	AAA	7	SLED0107	SLED01-CVA	SLEDAI2k	No	0	0	2
QS	AAA	8	SLED0108	SLED01-Vasculitis	SLEDAI2k	Yes	1	1	2
QS	AAA	9	SLED0109	SLED01-Arthritis	SLEDAI2k	No	0	0	2
QS	AAA	10	SLED0110	SLED01-Myotosis	SLEDAI2k	Yes	1	1	2
QS	AAA	11	SLED0111	SLED01-Urinary Casts	SLEDAI2k	No	0	0	2
QS	AAA	12	SLED0112	SLED01-Hematuria	SLEDAI2k	Yes	1	1	2
QS	AAA	13	SLED0113	SLED01-Proteinuria	SLEDAI2k	No	0	0	2
QS	AAA	14	SLED0114	SLED01-Pyuria	SLEDAI2k	Yes	1	1	2
QS	AAA	15	SLED0115	SLED01-Rash	SLEDAI2k	No	0	0	2
QS	AAA	16	SLED0116	SLED01-Alopecia	SLEDAI2k	Yes	1	1	2
QS	AAA	17	SLED0117	SLED01-Mucosal Ulcers	SLEDAI2k	No	0	0	2
QS	AAA	18	SLED0118	SLED01-Pleurisy	SLEDAI2k	Yes	1	1	2
QS	AAA	19	SLED0119	SLED01-Pericarditis	SLEDAI2k	No	0	0	2
QS	AAA	20	SLED0120	SLED01-Low Complement	SLEDAI2k	Yes	1	1	2
QS	AAA	21	SLED0121	SLED01-DNA Binding	SLEDAI2k	No	0	0	2
QS	AAA	22	SLED0122	SLED01-Fever	SLEDAI2k	Yes	1	1	2
QS	AAA	23	SLED0123	SLED01-Thrombocytopenia	SLEDAI2k	No	0	0	2
QS	AAA	24	SLED0124	SLED01-Leukopenia	SLEDAI2k	Yes	1	1	2
QS	AAA	25	SLED0125	SLED01-Total Score	SLEDAI2k	12	12	12	2

## 4.7 Functional Test

### 4.7.1 List of Variables

The standard variables for functional test data in IDEA-FAST are given in Table 46.

*Table 46: List of variables for FT domain.*

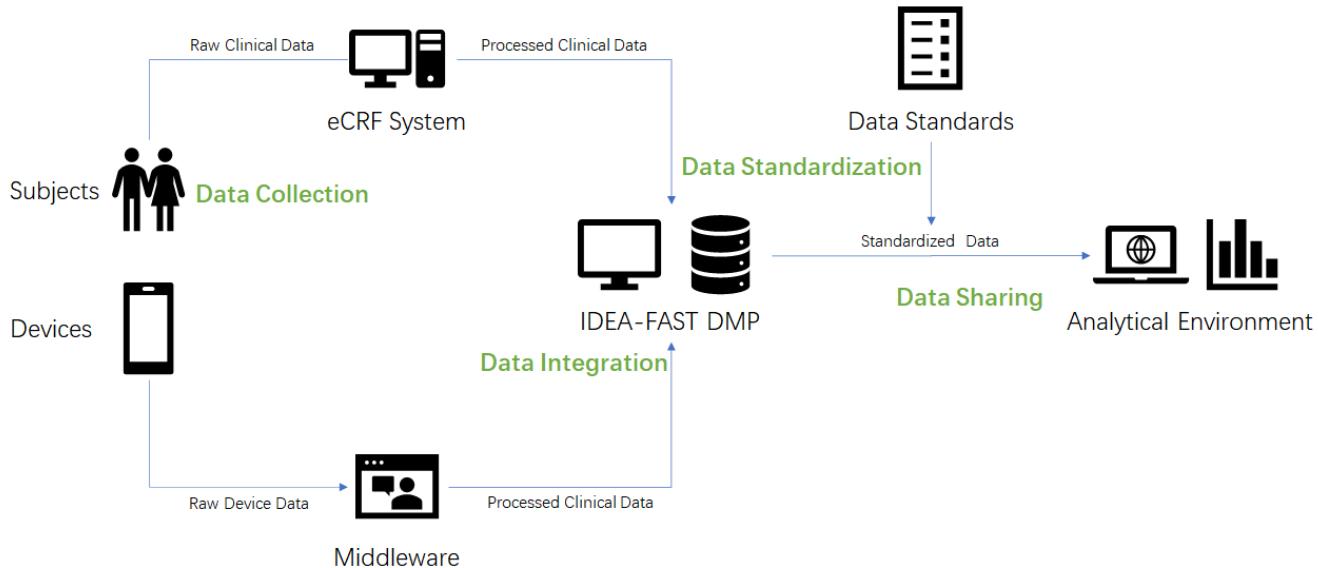
Variable Name	Variable Label	Type	CDISC Notes [4]
STUDYID	Study Identifier	Char	Unique identifier for IDEA-FAST, e.g., IDEAFAST-FS for feasibility study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
FTSEQ	Sequence Number	Num	Sequence number to ensure uniqueness of records within a dataset for a subject.
FTTESTCD	Short Name of Test	Char	Short character value for FTTEST, which can be used as a column name when converting a dataset from a vertical format to a horizontal format. The value cannot be longer than 8 characters, nor can it start with a number. FTTESTCD cannot contain characters other than letters, numbers, or underscores.
FTTEST	Name of Test	Char	Verbatim name of the question used to obtain the finding. The value in FTTEST cannot be longer than 40 characters.
FTCAT	Category	Char	Used to specify the functional test in which the functional test question identified by FTTEST and FTTESTCD was included.
FTORRES	Result or Finding in Original Units	Char	Result of the measurement or finding as originally received or collected.
FTORRESU	Original Units	Char	Original units in which the data were collected. Unit for FTORRES.
FTDTC	Date/Time of Test	Char	Collection date and time of functional test.
VISITNUM	Visit Number	Char	Clinical encounter number. Numeric version of VISIT, used for sorting.

## 4.7.2 Example

*Table 47: Actigraphy data of subject AAA.*

STUDYID	SUBJID	DOMAIN	FTSEQ	FTCAT	FTORRES	FTORRESU	FTDTC	FTTESTCD	FTTEST	VISITNUM
IDEAFAST-FS	AAA	FT	1	Actigraphy	21.95	%	11/03/2020 14:28	ACTI0220	ACTI02-Percent of Sleep	2
IDEAFAST-FS	AAA	FT	2	Actigraphy	267.97	cpm	11/03/2020 14:28	ACTI0203	ACTI02-Total AC/min	2
IDEAFAST-FS	AAA	FT	3	Actigraphy	78.44	%	11/03/2020 14:28	ACTI0228	ACTI02-Percent of Mobile	2
IDEAFAST-FS	AAA	FT	4	Actigraphy	15		11/03/2020 14:28	ACTI0231	ACTI02-Number of 1min Imm B	2
IDEAFAST-FS	AAA	FT	5	Actigraphy	93.01	%	11/03/2020 14:28	ACTI0240	ACTI02-Fragmentation	2
IDEAFAST-FS	AAA	FT	6	Actigraphy	103		11/03/2020 14:28	ACTI0232	ACTI02-Number of Imm Bouts	2
IDEAFAST-FS	AAA	FT	7	Actigraphy	120.5	min	11/03/2020 14:28	ACTI0230	ACTI02-Immobile Time	2

## 5 Implementation on the DMP



*Figure 1: Data flow of the IDEA-FAST project. Both raw clinical and device data are pre-processed to be allowed to upload to the DMP via APIs. The data is integrated in the database of the DMP in a customized format. The data standards are defined and managed by the data managers. When there is a request for standardized data, the DMP will formalize the data to the standardized format automatically based on the data standards.*

### 5.1 Raw data saved on the DMP

The DMP defines several simplified data standards (raw standards) that must be satisfied when data is uploaded to the DMP. For example, the name of the files of sensor data must contain necessary information in a strict order; the data type (e.g., integer, string) of clinical variables must be determined before uploading related clinical data. The DMP provides several APIs for data uploaders to upload data to the DMP. Such data is stored in the DMP as the raw format (not standardized).

### 5.2 Data Standardization on the DMP

As the data standards are developed by WP5, WP5 will implement and maintain these standards on the DMP. The DMP will design a mechanism to help convert the raw data to standardized data. When data standardization is required, the DMP will automatically convert the existing data to the standardized format and outputs to the data users.

### 5.3 Application Programming Interfaces (APIs)

Although the users of the DMP can access and view data via <https://data.ideafast.eu/>, we recommend users to use the APIs, particularly for computing tasks. We maintain several simplified data standards that must be satisfied as follows:

### 5.3.1 Uploading data to the DMP

The DMP provides an API (uploadFile) to upload a file to an existing dataset, and two APIs (createField, uploadDataInArray) to upload data defined by variables.

- UploadFile  
Need to specify the descriptions of the file for sensor data: the ID of the site, the ID of the participant, the ID of the device, the start date and the end date.
- CreateField  
Need to specify the ID of the field, the name of the field, the data type (select one from several options) of the field, the unit of the field (not compulsory) and the possible values of the field if the field is categorical.
- UploadDataInArray  
Need to specify the ID of the participant, the ID of the visit number, the ID of the field and the value of the data.

### 5.3.2 Accessing data from the DMP

The DMP provides two approaches to access the data: the getDataRecords API will return the data immediately but without saving the results; while the query APIs (createQuery, createQueryCurationJob and getQueries) will execute and save the request, whose results can be accessed later directly without requesting again. The data will be standardized based on the data standards mentioned above if needed.

Users can customize their requests in both approaches by adding filters and limiting returned fields, similar to that in MySQL and other databases.

## 6 Conclusions

This document gives guidelines and examples for standardising clinical and device data collected in IDEA-FAST. The data standards described in this document are based on CDISC SDTM.

## 7 References

- [1] <https://www.cdisc.org/standards/foundational/sdtm>, accessed 30 April, 2021
- [2] <https://www.cdisc.org/standards/foundational/protocol>, accessed 30 April, 2021
- [3] <https://www.cdisc.org/standards/foundational/cdash>, accessed 30 April, 2021
- [4] <https://www.cdisc.org/standards/foundational/adam>, accessed 30 April, 2021

## 8 Appendix A

*Table A1: Codelist for EQ-5D.*

QSTEST	Code	Description
EQ5D02-Mobility	0	I have no problems in walking about
EQ5D02-Mobility	1	I have slight problems in walking about
EQ5D02-Mobility	2	I have moderate problems in walking about
EQ5D02-Mobility	3	I have severe problems in walking about
EQ5D02-Mobility	4	I am unable to walk about
EQ5D02-SelfCare	0	I have no problems washing or dressing myself
EQ5D02-SelfCare	1	I have slight problems washing or dressing myself
EQ5D02-SelfCare	2	I have moderate problems washing or dressing myself
EQ5D02-SelfCare	3	I have severe problems washing or dressing myself
EQ5D02-SelfCare	4	I am unable to wash or dress myself
EQ5D02-UsualActivities	0	I have no problems doing my usual activities
EQ5D02-UsualActivities	1	I have slight problems doing my usual activities
EQ5D02-UsualActivities	2	I have moderate problems doing my usual activities
EQ5D02-UsualActivities	3	I have severe problems doing my usual activities
EQ5D02-UsualActivities	4	I am unable to do my usual activities
EQ5D02-PainDiscomfort	0	I have no pain or discomfort
EQ5D02-PainDiscomfort	1	I have slight pain or discomfort
EQ5D02-PainDiscomfort	2	I have moderate pain or discomfort
EQ5D02-PainDiscomfort	3	I have severe pain or discomfort
EQ5D02-PainDiscomfort	4	I have extreme pain or discomfort
EQ5D02-AnxietyDepression	0	I am not anxious or depressed
EQ5D02-AnxietyDepression	1	I am slightly anxious or depressed
EQ5D02-AnxietyDepression	2	I am moderately anxious or depressed
EQ5D02-AnxietyDepression	3	I am severely anxious or depressed
EQ5D02-AnxietyDepression	4	I am extremely anxious or depressed