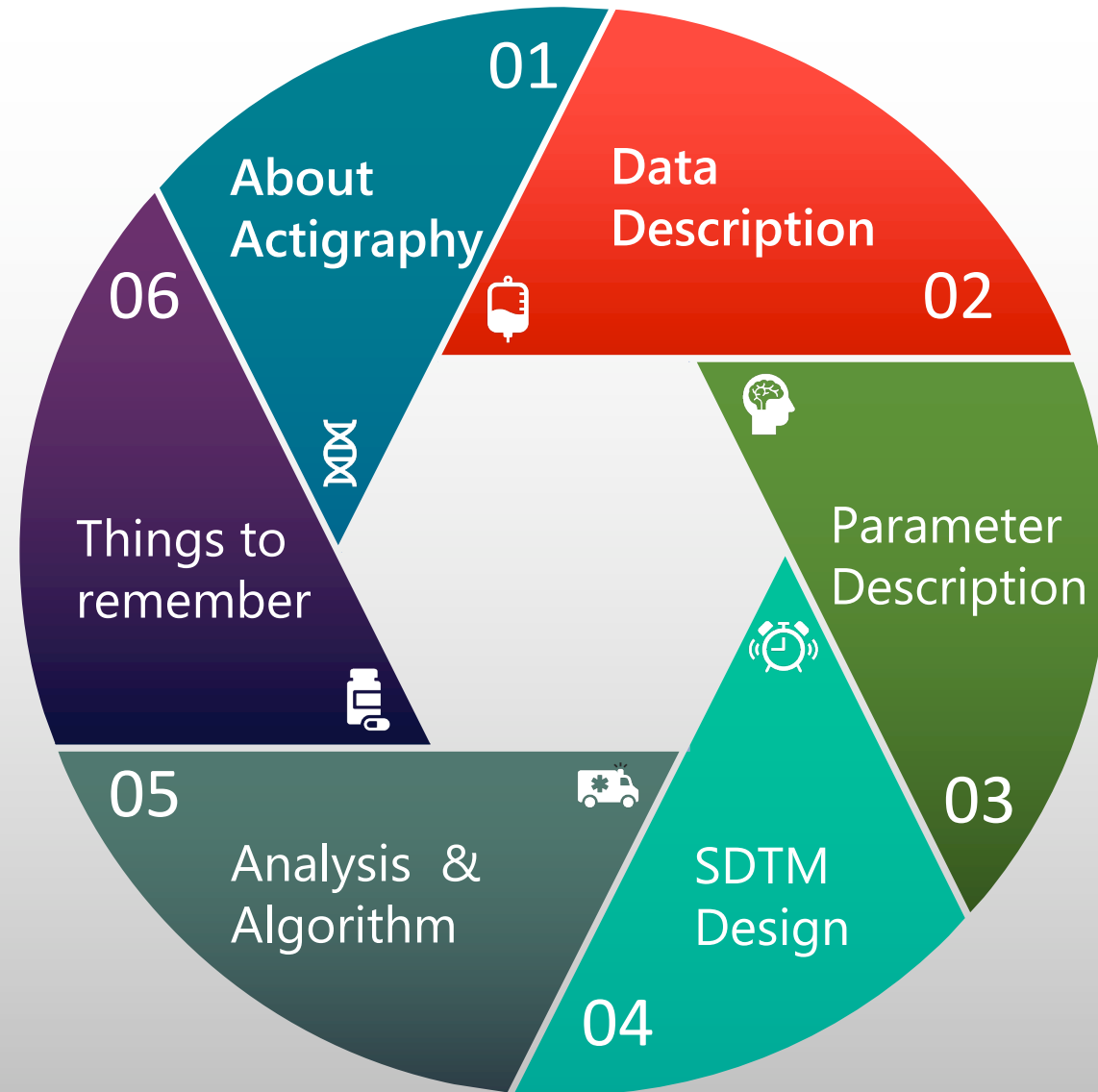


How to Act with the Actigraphy Data

Paper No RW06

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Agenda



About Actigraphy

What is Actigraphy?

A

Actigraphy is a non-invasive method to assess cycles of activity, rest and sleep

What is an Actigraph?

A

An actigraph is a wristwatch-sized device which uses accelerometer to record motion data

Usage of Actigraphy

A

An ePRO device output data, which is analyzed for quality of life/sleep in CNS trials

Use in Parkinson's Disease Dementia?

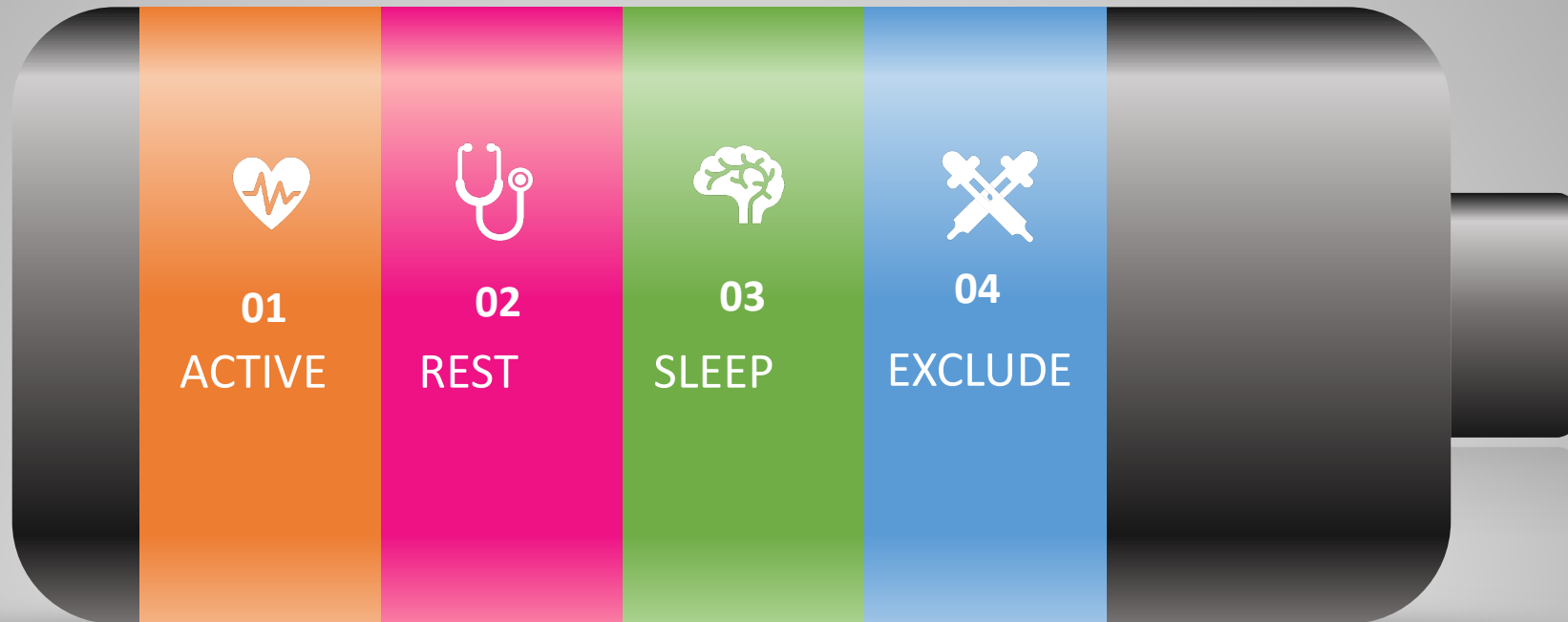
A

- Actigraphy is an alternative method to measure sleep quality for PDD patients
- It is used to study motor activity of a subject with PD

Actigraphy Data Description

Intervals in Actigraphy Data and general vendor data structure

- The sensor in the actigraphy device tracks the movement of the limbs and accordingly segments the data into the following intervals: Sleep, Active, Rest and Exclude**
- A Day can consist of multiple number of intervals. So essentially the structure of the Actigraphy data is one record per Interval #, per start date, per visit, per subject



**An interval is usually flagged exclude if the actigraphy device is removed without stopping it.

A snippet of Actigraphy Vendor Data for a particular Subject at Baseline Visit

Parameters of Actigraphy data

Visit	Interval Type	Interval#	Start Date	Start Time	End Date	End Time	Duration (minutes)	Off-Wrist (minutes)	%Off-Wrist (%)	Total AC (counts)
V1 BL	REST	1	05-11-2013	9:37:45 PM	06-11-2013	5:18:45 AM	461	0	0	3139
V1 BL	REST	2	06-11-2013	10:15:00 PM	07-11-2013	5:39:30 AM	444.5	0	0	2875
V1 BL	REST	3	07-11-2013	6:34:45 AM	07-11-2013	7:15:15 AM	40.5	0	0	194
V1 BL	REST	4	07-11-2013	6:56:30 PM	07-11-2013	8:01:15 PM	64.75	0	0	1765
V1 BL	REST	5	07-11-2013	10:35:00 PM	08-11-2013	6:19:15 AM	464.25	0	0	4439
V1 BL	REST	6	08-11-2013	10:34:30 PM	09-11-2013	6:27:30 AM	473	0	0	5405
V1 BL	REST	7	09-11-2013	10:37:30 AM	09-11-2013	11:28:00 AM	50.5	0	0	1087
V1 BL	REST	8	09-11-2013	9:44:30 PM	10-11-2013	5:14:00 AM	449.5	0	0	3791
V1 BL	REST	9	10-11-2013	10:17:30 PM	11-11-2013	7:50:00 AM	572.5	0	0	3929
V1 BL	REST	10	11-11-2013	9:34:00 AM	11-11-2013	10:28:15 AM	54.25	0	0	951
V1 BL	ACTIVE	1	05-11-2013	3:51:00 PM	05-11-2013	9:37:45 PM	346.75	0	0	36937
V1 BL	ACTIVE	2	06-11-2013	5:18:45 AM	06-11-2013	10:15:00 PM	1016.25	31.75	3.12	89743
V1 BL	ACTIVE	3	07-11-2013	5:39:30 AM	07-11-2013	6:34:45 AM	55.25	0	0	10590
V1 BL	ACTIVE	4	07-11-2013	7:15:15 AM	07-11-2013	6:56:30 PM	701.25	0	0	50695
V1 BL	ACTIVE	5	07-11-2013	8:01:15 PM	07-11-2013	10:35:00 PM	153.75	0	0	22660
V1 BL	ACTIVE	6	08-11-2013	6:19:15 AM	08-11-2013	10:34:30 PM	975.25	0	0	137416
V1 BL	ACTIVE	7	09-11-2013	6:27:30 AM	09-11-2013	10:37:30 AM	250	0	0	24257
V1 BL	ACTIVE	8	09-11-2013	11:28:00 AM	09-11-2013	9:44:30 PM	616.5	0	0	78796

Actigraphy Parameters

SOL (min)

Sleep Onset Latency is defined as the duration between rest start and sleep start

WASO (min)

Wake After Sleep Onset is defined as the duration of wake within the sleep interval

TST (min)

Total Sleep Time is defined as the total duration of sleep within a given interval

FI (%)

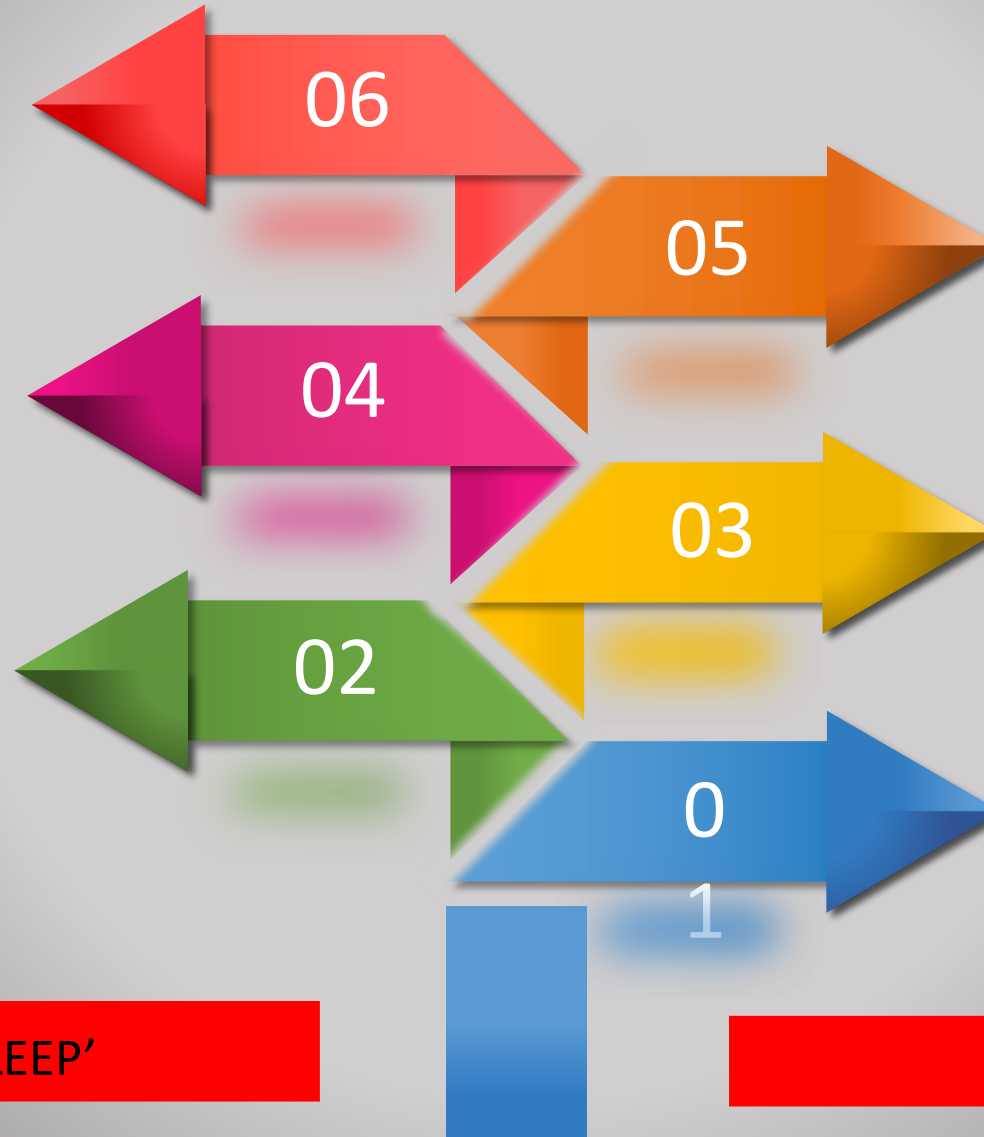
Fragmentation Index is Sum of %Mobile (proportion of mobile epochs within the given interval) and %1min Imm B (proportion of immobile bouts of ≤ 1 minute duration)

MAS (counts/min)

Mean Activity Score is Total AC divided by duration of the given interval

TAS (counts)

Total Activity Score is the total count of activities within a given interval



SDTM

Custom
Finding Domain
XU created

Key: USUBJID,
XUCAT, XUSCAT,
XUTEST, VISITNUM,
XUDTC

Data
Arrangement

XUSCAT → Interval Type
XUTEST → parameters
XUDTC → Vendor date

SUPPXU
elements

- Interval Number
- End Date of each assessment

Analysis of Actigraphy Parameters

MMRM analysis of Change from Baseline to EOT by treatment and visit is performed for each Actigraphy parameters

- Correlation analysis of WASO/SOL/TST with ISI total score, ESS total score and RBDSQ total score.
- Correlation analysis of TAS/MAS with MDS-UPDRS part II (M-EDL) total score, UPDRS part III (Motor Examination) total score.**



Summary of Absolute and Change from Baseline values is performed for each parameter

**Note: For Sleep Related Actigraphy Parameters correlation is measured with respect to other Sleep Related Scores. For Activity related parameters correlation is measured with respect to MDS-UPDRS which is 'gold standard' for measuring severity of activity related PD symptoms

Analysis Algorithm

Read From SDTM

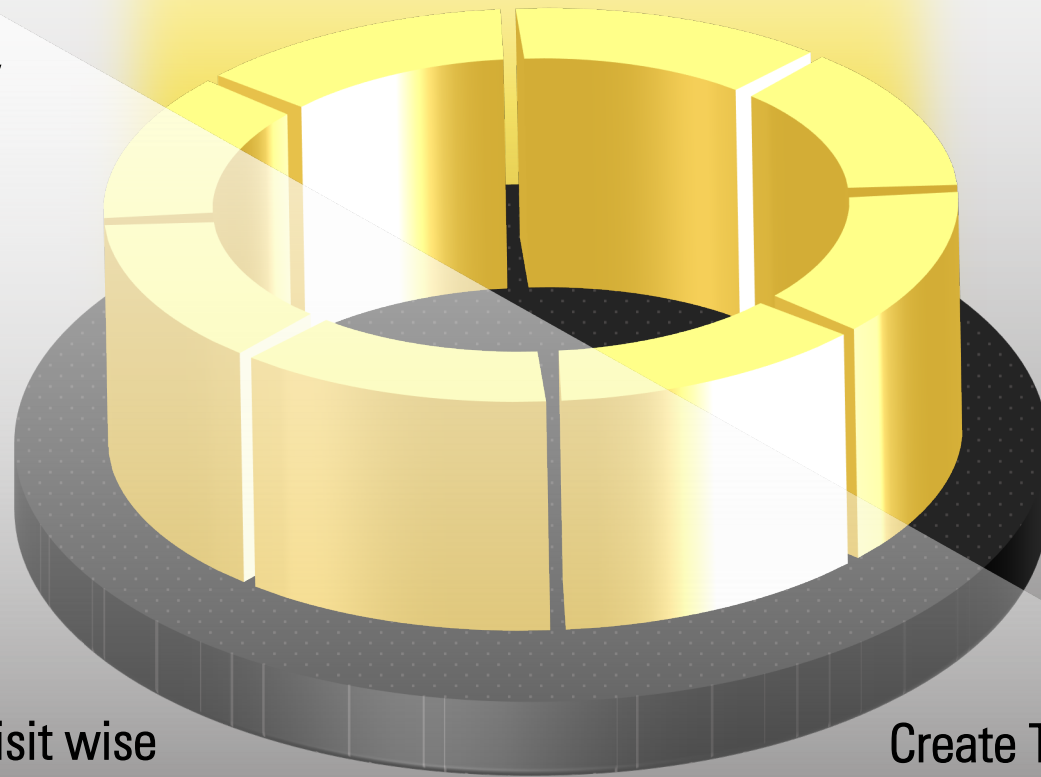
Read the records where XUSCAT in 'ACTIVE' or 'SLEEP'

Analysis Flag Creation

If XUTEST in 'SOL', 'TST' or 'WASO' and XCSCAT='SLEEP' then ANL01FL='Y'. Else if XUTEST in 'TAS', 'MAS', 'FI' and XCSCAT='ACTIVE' then ANL01FL='Y'

Summarizing Assessment to Visit wise

Take average of interval wise data by Visit to get one record per visit per parameter per subject when ANL01FL='Y'



Info. Related to ADQS parameters

Merge with ADQS to populate RBDSQ, ISI and MDS-UPDRS values as separate variables for each subject and Visit

Finalize ADaM

Calculate Baseline and Change from Baseline to finalize the ADaM

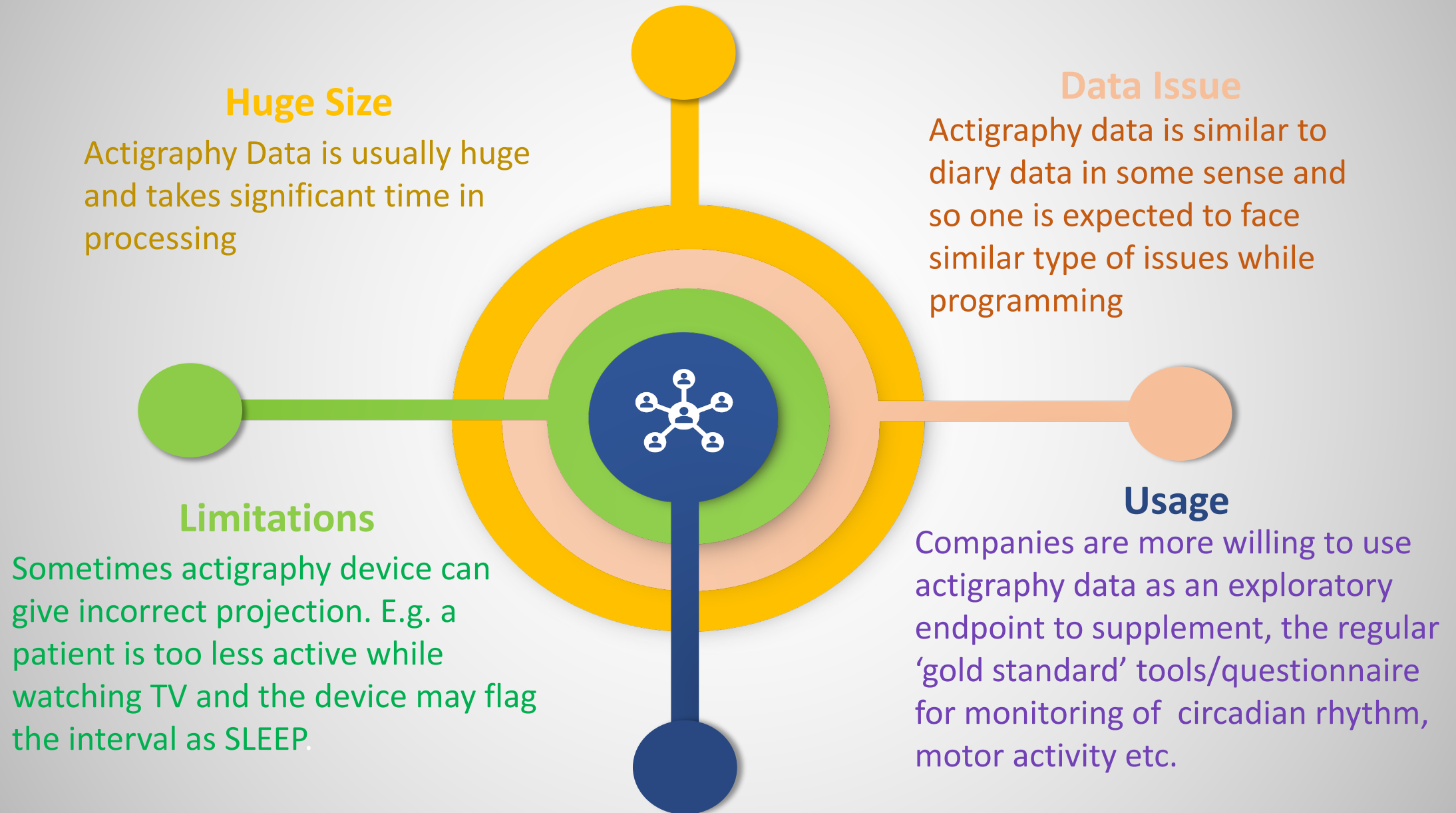
Create TFL

Use different PROC's in TFL code to generate required output

SDFM to ADaM: An illustration for 2 parameters

XUTESTCD	XUTEST	XUCAT	XUSCAT	XUSTRESN	XUSTRESU	VISIT	EPOCH	XUDTC	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	ACTIVE	103.76	cpm	VISIT 0	SCREENING	2019-01-11T09:57:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	ACTIVE	136.02	cpm	VISIT 0	SCREENING	2019-01-12T06:48:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	ACTIVE	107.89	cpm	VISIT 0	SCREENING	2019-01-13T08:31:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	ACTIVE	123.02	cpm	VISIT 0	SCREENING	2019-01-14T06:31:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	ACTIVE	134.24	cpm	VISIT 0	SCREENING	2019-01-15T06:02:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	ACTIVE	112.38	cpm	VISIT 0	SCREENING	2019-01-16T07:25:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	ACTIVE	98.69	cpm	VISIT 0	SCREENING	2019-01-17T07:08:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	ACTIVE	107.63	cpm	VISIT 0	SCREENING	2019-01-18T08:59:00	
AVGACMIN	Avg activity counts per minute	USUBJID	PARAMCD	AVAL	ESS	MDS3SCR	AVISIT		
AVGACMIN	Avg activity counts per minute								
AVGACMIN	Avg activity counts per minute	ANAVEX2-73-PDD-001-101001	AVGACMIN	124.512			11.1	Baseline	
AVGACMIN	Avg activity counts per minute								
SLEEPTM	Duration of sleep within interval	ANAVEX2-73-PDD-001-101001	SLEEPTM	405.6	9.7			Baseline	
SLEEPTM	Duration of sleep within interval								
SLEEPTM	Duration of sleep within interval	ANAVEX2-73-PDD-001-101001	SLEEPTM	405.6	9.7			Baseline	
SLEEPTM	Duration of sleep within interval								
SLEEPTM	Duration of sleep within interval	ACTIGRAPHY ENDPOINT	ACTIVE	376	mins	VISIT 0	SCREENING	2019-01-16T07:25:00	
SLEEPTM	Duration of sleep within interval	ACTIGRAPHY ENDPOINT	ACTIVE	362	mins	VISIT 0	SCREENING	2019-01-17T07:08:00	
SLEEPTM	Duration of sleep within interval	ACTIGRAPHY ENDPOINT	ACTIVE	378	mins	VISIT 0	SCREENING	2019-01-18T08:59:00	
SLEEPTM	Duration of sleep within interval	ACTIGRAPHY ENDPOINT	ACTIVE	293	mins	VISIT 0	SCREENING	2019-01-19T08:33:00	
SLEEPTM	Duration of sleep within interval	ACTIGRAPHY ENDPOINT	ACTIVE	373	mins	VISIT 0	SCREENING	2019-01-20T08:48:00	
SLEEPTM	Duration of sleep within interval	ACTIGRAPHY ENDPOINT	ACTIVE	362	mins	VISIT 0	SCREENING	2019-01-21T08:28:00	
SLEEPTM	Duration of sleep within interval	ACTIGRAPHY ENDPOINT	ACTIVE	425	mins	VISIT 0	SCREENING	2019-01-22T07:18:00	
SLEEPTM	Duration of sleep within interval	ACTIGRAPHY ENDPOINT	ACTIVE	453	mins	VISIT 0	SCREENING	2019-01-23T07:56:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	REST	10.23	cpm	VISIT 0	SCREENING	2019-01-11T23:20:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	REST	19.02	cpm	VISIT 0	SCREENING	2019-01-12T23:28:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	REST	12.06	cpm	VISIT 0	SCREENING	2019-01-13T23:11:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	REST	12.18	cpm	VISIT 0	SCREENING	2019-01-14T23:17:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	REST	18.03	cpm	VISIT 0	SCREENING	2019-01-15T22:18:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	REST	14.36	cpm	VISIT 0	SCREENING	2019-01-16T23:21:00	
AVGACMIN	Avg activity counts per minute	ACTIGRAPHY ENDPOINT	REST	16.77	cpm	VISIT 0	SCREENING	2019-01-17T23:18:00	

Things to remember



Thank you - Any questions?



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Thank you!!!