

Design and Analysis of a Multi-Frequency PRO Collection Strategy in a Clinical Trial

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Agenda

01

Background & Problem Statement

Why multi-frequency PRO collection?

02

Overview of workflow

Cross-Function workflow for implementing multi-frequency PRO collection

03

Key Takeaways

Practical guidance and conclusions

04

Future Opportunities

AI/Automation and Human collaboration



Patient-Reported Outcomes (PROs) in Clinical Trials

What are PROs?



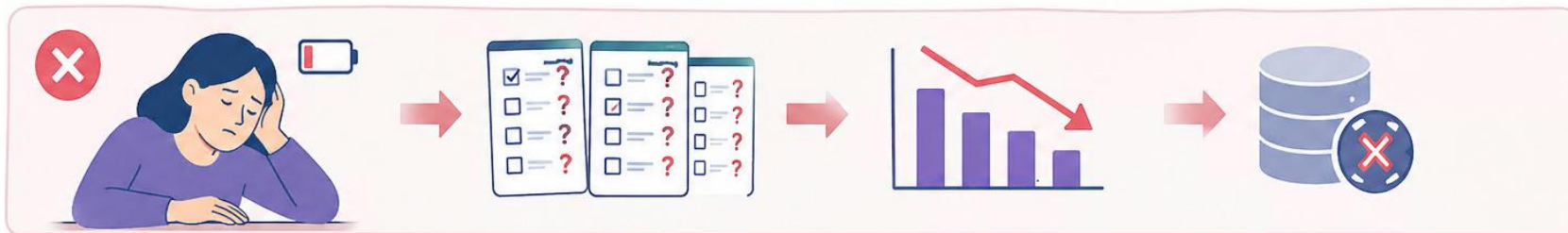
- Recognized by FDA as key components of benefit-risk assessment, and drug approval as primary or secondary endpoints

Patient-Reported Outcomes (PROs) in Clinical Trials

The Challenge of collecting PROs at fixed interval



- Different domains may change at different rates in response to intervention



- Collection frequency should balance sensitivity and patient burden as compliance and data quality suffer from over-burdening patients

Cross-function workflow for implementing multi-frequency PRO collection

1. Scheduling Design

- define frequency per domain
- select questionnaires and item lists

Sponsor

2. ePRO Data Collection

- administer full and subset questionnaires at planned timepoints

eCOA Provider

3. Data Quality Control

- verify schedule adherence
- identify duplicates and/or missing responses

Analytics Team

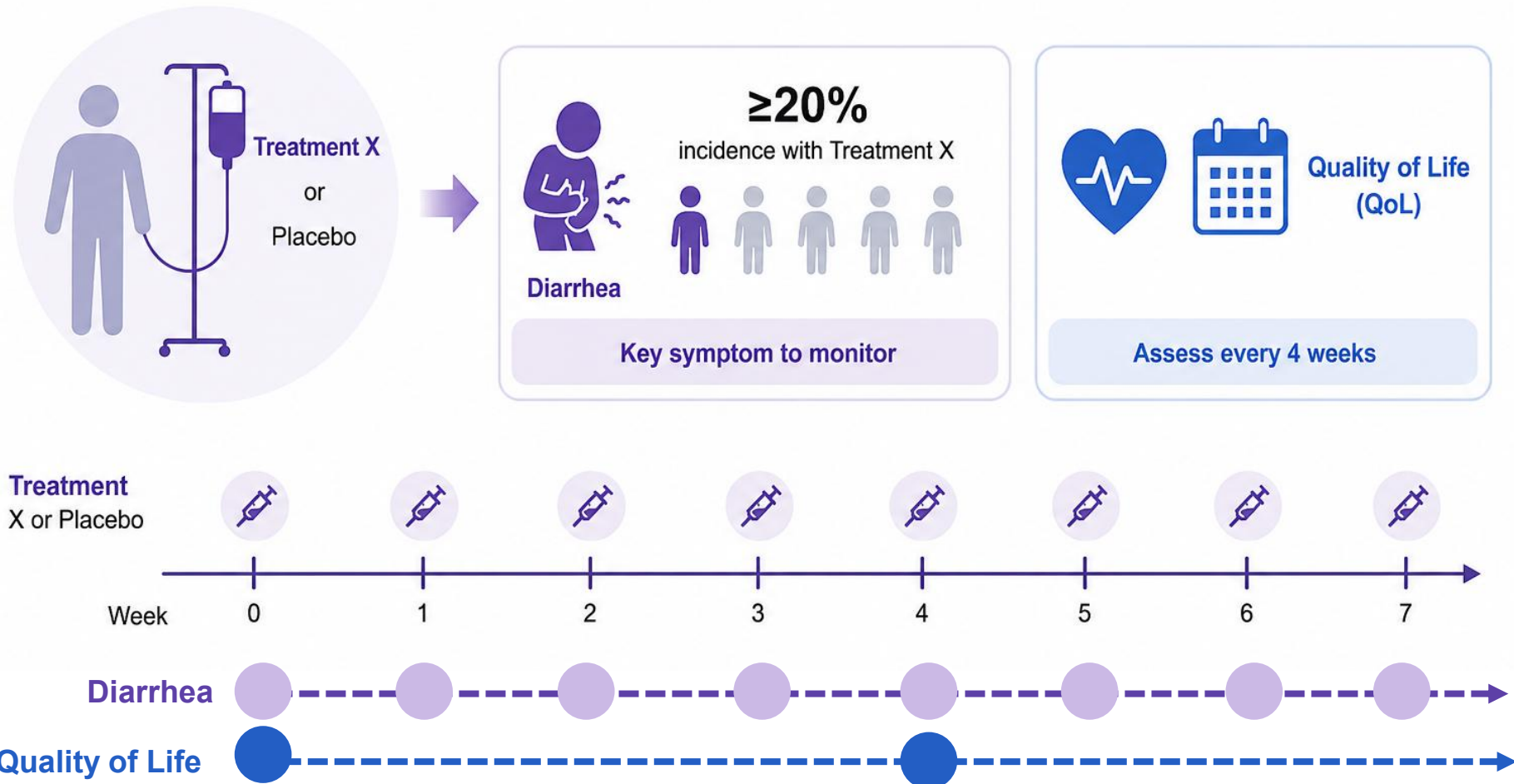
4. Data Standardization and Analysis

- create CDISC compliant SDTM and ADaM datasets to derive study endpoints

eCOA: Electronic clinical outcome assessment.

1. Scheduling design

CASE STUDY



1. Scheduling design

EORTC QLQ-C30



During the past week:

17. Have you had diarrhea?

**Not at
All**

**A
Little**

**Quite
a Bit**

**Very
Much**

1

2

3

4



For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1

2

3

4

5

6

7

Very poor

Excellent

30. How would you rate your overall quality of life during the past week?

1

2

3

4

5

6

7

Very poor

Excellent

1. Scheduling design

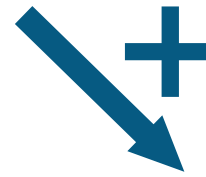
CASE STUDY



EORTC QLQ-C30 (v3.0)



Measure Quality of Life (QoL)
every 4 weeks



IL163 (subset of EORTC
QLQ-C30 (v3.0))

Measure Diarrhea every week



1. Scheduling design

Schedule of Assessments

Instrument	C1D1 (Baseline)	C2D1 (Week 1)	C3D1 (Week 2)	C4D1 (Week 3)	C5D1 (Week 4)	C6D1+ (Ongoing)
IL163 (Weekly Subset)	—	✓	✓	✓	—	Weekly
EORTC QLQ-C30 (Full)	✓	—	—	—	✓	Every 4 weeks (Q4W)

Cycle length = 7 days; Visit window = ± 3 days from C6D1 onwards

- PRO assessments completed PRIOR to each treatment infusion
- The two questionnaires are NEVER administered at the same timepoint

2. ePRO Data Collection

eCOA provider

- **Use digital device to administer PRO**
- **Ensure language version is available for the region**
- **Review PRO completion status and record partial or complete missing case**

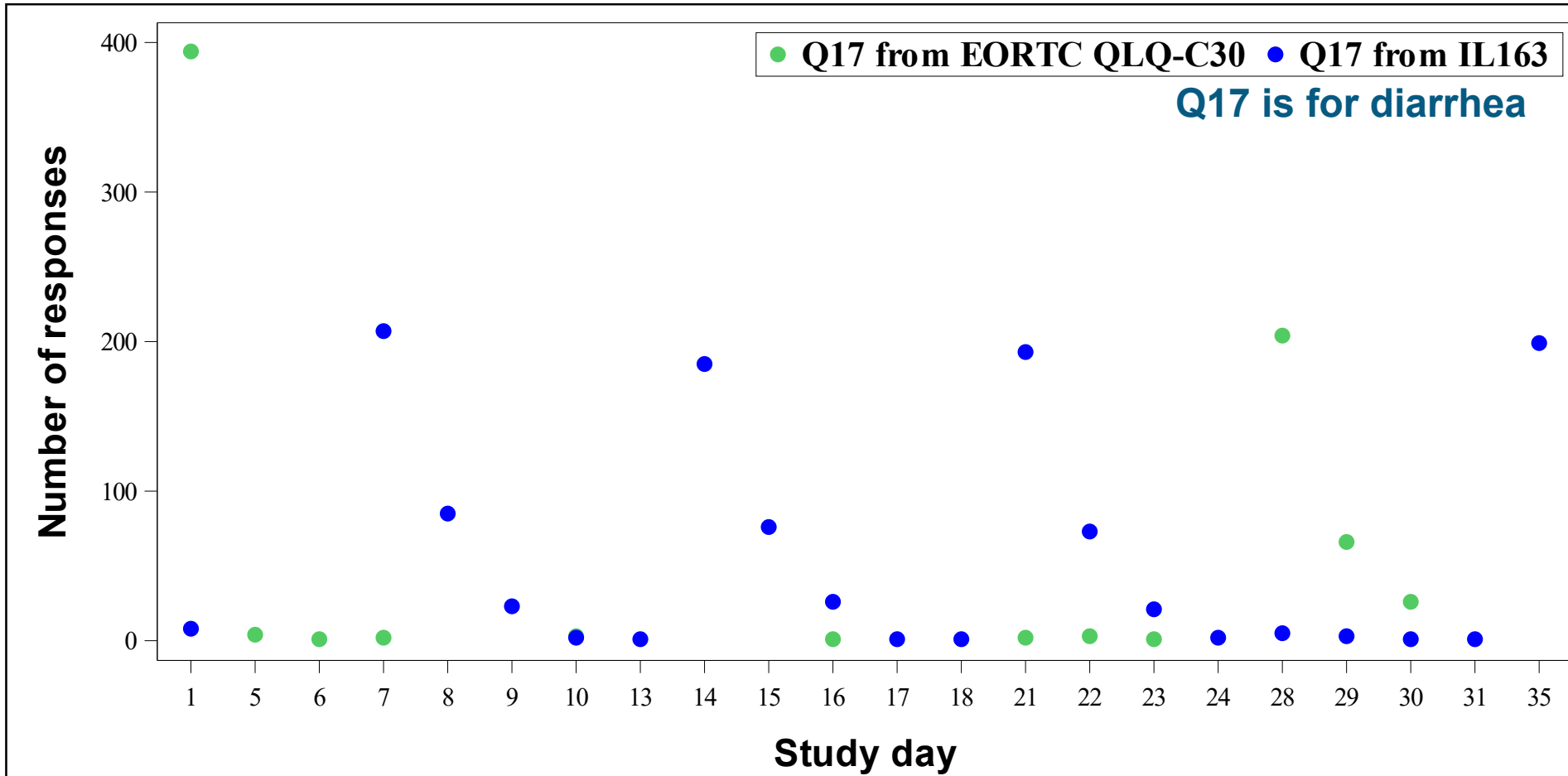
3. Data Quality Control

Key QC Checks by eCOA provider & Analytics team

- Each instrument collected at scheduled visits only
- Full questionnaire & subset NOT administered same day
- One response per item per timepoint per subject
- Missing responses captured and flagged in raw data
- Unscheduled / duplicate responses reviewed before analysis

3. Data Quality Control

Visual check by Analytics team



- Weekly peaks (IL163) + 4-week peaks (QLQ-C30) confirm scheduling adherence

4. Data Standardization and Analysis

CDISC-compliant datasets

- **SDTM**
 - ❖ **QS**
- **ADaM**
 - ❖ **ADQS (Analysis Questionnaire Data)**
 - ❖ **ADQSTTE (Analysis Questionnaire Time-to-Event Data)**
- **Highlighting:**
 - ❖ **Representation of missing assessments**
 - ❖ **End-to-end traceability from collection to analysis**
 - ❖ **Standardized derivation of clinically meaningful change**
 - ❖ **Support for longitudinal and time-to-event endpoint analyses**

4. Data Standardization and Analysis – SDTM QS

QSCAT

Identifies the instrument

QSSCAT

Identifies the subset

Row	USUBJID	VISIT	QSCAT	QSSCAT	QSTESTCD	QSTEST	QSOFT	QSDY
1	A001	CYCLE 1 DAY 1	EORTC QLQ-C30		EOR0117	EOR01-Have You Had Diarrhea	A Little	
2	A001	CYCLE 2 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	A Little	
3	A001	CYCLE 3 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	Quite	4
4	A001	CYCLE 4 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	Quite	1
5	A001	CYCLE 5 DAY 1	EORTC QLQ-C30		EOR0117	EOR01-Have You Had Diarrhea	A Little	28
6	A001	CYCLE 6 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	A Little	2 2025-10-12 35
7	A001	CYCLE 7 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	Not at All	1 2025-10-19 42
8	A001	CYCLE 8 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea		NOT DONE SUBJECT FORGOT 2025-10-26 49
9	A001	CYCLE 9 DAY 1	EORTC QLQ-C30		EOR0117	EOR01-Have You Had Diarrhea	Not at All	1 2025-11-02 56
10	A001	CYCLE 1 DAY 1	EORTC QLQ-C30		EOR0129	EOR01-Rate Your Overall Health	4	4 Y 2025-09-08 1
11	A001	CYCLE 1 DAY 1	EORTC QLQ-C30		EOR0130	EOR01-Rate Your Overall Quality of Life	5	5 Y 2025-09-08 1
12	A001	CYCLE 5 DAY 1	EORTC QLQ-C30		EOR0129	EOR01-Rate Your Overall Health	5	5 2025-10-05 28
13	A001	CYCLE 5 DAY 1	EORTC QLQ-C30		EOR0130	EOR01-Rate Your Overall Quality of Life	5	5 2025-10-05 28
14	A001	CYCLE 9 DAY 1	EORTC QLQ-C30		EOR0129	EOR01-Rate Your Overall Health	6	6 2025-11-02 56
15	A001	CYCLE 9 DAY 1	EORTC QLQ-C30		EOR0130	EOR01-Rate Your Overall Quality of Life	5	5 2025-11-02 56

QSCAT + QSSCAT combination uniquely identifies source instrument - enabling full data traceability

4. Data Standardization and Analysis – SDTM QS

QSREASND Reason Not Performed

QSSTAT Completion status

Missing data should be recorded and presented in the dataset

Row	USUBJID	VISIT	QSCAT	QSSCAT	QSTESTCD	QSTEST	QSORRES	QSSTRESN	QSSTAT	QSREASND	QSBFLF	QSDTC	QSDY
1	A001	CYCLE 1 DAY 1	EORTC QLQ-C30		EOR0117	EOR01-Have You Had Diarrhea	A Little	2			Y	2025-09-08	1
2	A001	CYCLE 2 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	A Little	2				2025-09-14	7
3	A001	CYCLE 3 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	Quite a Bit	3				2025-09-21	14
4	A001	CYCLE 4 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	Quite a Bit	3				2025-09-28	21
5	A001	CYCLE 5 DAY 1	EORTC QLQ-C30		EOR0117	EOR01-Have You Had Diarrhea	A Little	2				2025-10-05	28
6	A001	CYCLE 6 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	A Little	2				2025-10-12	35
7	A001	CYCLE 7 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	Not at All	1				2025-10-19	42
8	A001	CYCLE 8 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea			NOT DONE	SUBJECT FORGOT		2025-10-26	49
9	A001	CYCLE 9 DAY 1	EORTC QLQ-C30		EOR0117	EOR01-Have You Had Diarrhea	Not at All	1				2025-11-02	56
10	A001	CYCLE 1 DAY 1	EORTC QLQ-C30		EOR0129	EOR01-Rate Your Overall Health	4	4			Y	2025-09-08	1
11	A001	CYCLE 1 DAY 1	EORTC QLQ-C30		EOR0130	EOR01-Rate Your Overall Quality of Life	5	5			Y	2025-09-08	1
12	A001	CYCLE 5 DAY 1	EORTC QLQ-C30		EOR0129	EOR01-Rate Your Overall Health	5	5				2025-10-05	28
13	A001	CYCLE 5 DAY 1	EORTC QLQ-C30		EOR0130	EOR01-Rate Your Overall Quality of Life	5	5				2025-10-05	28
14	A001	CYCLE 9 DAY 1	EORTC QLQ-C30		EOR0129	EOR01-Rate Your Overall Health	6	6				2025-11-02	56
15	A001	CYCLE 9 DAY 1	EORTC QLQ-C30		EOR0130	EOR01-Rate Your Overall Quality of Life	5	5				2025-11-02	56

4. Data Standardization and Analysis - ADQS

PARCAT1

Analysis purpose

PARCAT2

Data source

Maintain traceability

Row	USUBJID	VISIT	AVISIT	PARCAT1	PARCAT2	PARAMCD	PARAM	AVAL	PARAMTYP	QSSTAT	BASE	CHG	CHGCAT1	ADT	ADY
1	A001	CYCLE 1 DAY 1	BASELINE	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED					2025-09-08	1
2	A001	CYCLE 2 DAY 1	C2D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-09-14	7
3	A001	CYCLE 3 DAY 1	C3D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-21	14
4	A001	CYCLE 4 DAY 1	C4D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-28	21
5	A001	CYCLE 5 DAY 1	C5D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28
6	A001	CYCLE 6 DAY 1	C6D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-12	35
7	A001	CYCLE 7 DAY 1	C7D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-10-19	42
8	A001	CYCLE 8 DAY 1	C8D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)		DERIVED	NOT DONE	33.33		MISSING	2025-10-26	49
9	A001	CYCLE 9 DAY 1	C9D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
10	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED					2025-09-08	1
11	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28
12	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
13	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	58.33	DERIVED		58.33	0	NO CHANGE	2025-09-08	1
14	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	66.67	DERIVED		58.33	8.34	NO CHANGE	2025-10-05	28
15	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	75	DERIVED		58.33	16.67	IMPROVEMENT	2025-11-02	56

4. Data Standardization and Analysis - ADQS

AVAL

Analysis value

PARAM

Parameter for different analysis purpose

Raw responses → standardized 0 -100 scores (EORTC manual)

Row	USUBJID	VISIT	AVISIT	PARCAT1	PARCAT2	PARAMCD	PARAM	AVAL	PARAMTYP	QSSTAT	BASE	CHG	CHGCAT1	ADT	ADY
1	A001	CYCLE 1 DAY 1	BASELINE	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED					2025-09-08	1
2	A001	CYCLE 2 DAY 1	C2D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-09-14	7
3	A001	CYCLE 3 DAY 1	C3D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-21	14
4	A001	CYCLE 4 DAY 1	C4D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-28	21
5	A001	CYCLE 5 DAY 1	C5D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28
6	A001	CYCLE 6 DAY 1	C6D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-12	35
7	A001	CYCLE 7 DAY 1	C7D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-10-19	42
8	A001	CYCLE 8 DAY 1	C8D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)		DERIVED	NOT DONE	33.33		MISSING	2025-10-26	49
9	A001	CYCLE 9 DAY 1	C9D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
10	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED					2025-09-08	1
11	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28
12	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
13	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	58.33	DERIVED		58.33	0	NO CHANGE	2025-09-08	1
14	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	66.67	DERIVED		58.33	8.34	NO CHANGE	2025-10-05	28
15	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	75	DERIVED		58.33	16.67	IMPROVEMENT	2025-11-02	56

4. Data Standardization and Analysis - ADQS

Scoring

SDTM QS

Row	USUBJID	VISIT	QSCAT	QSSCAT	QSTESTCD	QSTEST	QSORRES	QSSTRESN	QSSTAT	QSREASND	QSBLFL	QSDTC	QSDY
4	A001	CYCLE 4 DAY 1	EORTC QLQ-C30	IL163	EOR0117	EOR01-Have You Had Diarrhea	Quite a Bit	3				2025-09-28	21
5	A001	CYCLE 5 DAY 1	EORTC QLQ-C30		EOR0117	EOR01-Have You Had Diarrhea	A Little	2				2025-10-05	28

ADQS

Row	USUBJID	VISIT	AVISIT	PARCAT1	PARCAT2	PARAMCD	PARAM	AVAL	PARAMTYP	QSSTAT	BASE	CHG	CHGCAT1	ADT	ADY
4	A001	CYCLE 4 DAY 1	C4D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-28	21
5	A001	CYCLE 5 DAY 1	C5D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28

$$AVAL = \frac{3-1}{3} \times 100 = 66.67$$

$$AVAL = \frac{2-1}{3} \times 100 = 33.33$$

Scoring manual

For all scales, the *RawScore*, *RS*, is the mean of the component items:

$$RawScore = RS = (I_1 + I_2 + \dots + I_n) / n$$

and for **Symptom scales / items** and **Global health status / QoL**:

$$Score = \{(RS - 1) / range\} \times 100$$

A high score for a symptom: a high level of symptomatology/problems

A high score for function/QoL: a high/healthy level of functioning/QoL

4. Data Standardization and Analysis - ADQS

CHG Change from Baseline

CHGCAT1 Change from baseline category

CHG Change from Baseline

Row	USUBJID	VISIT	AVISIT	PARCAT1	PARCAT2	PARAMCD	PARAM	AVAL	PARAMTYP	QSSTAT	BASE	CHG	CHGCAT1	ADT	ADY
1	A001	CYCLE 1 DAY 1	BASELINE	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED					2025-09-08	1
2	A001	CYCLE 2 DAY 1	C2D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-09-14	7
3	A001	CYCLE 3 DAY 1	C3D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-21	14
4	A001	CYCLE 4 DAY 1	C4D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-28	21
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6	A001	CYCLE 6 DAY 1	C6D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-12	35
7	A001	CYCLE 7 DAY 1	C7D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-10-19	42
8	A001	CYCLE 8 DAY 1	C8D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)		DERIVED	NOT DONE	33.33		MISSING	2025-10-26	49
9	A001	CYCLE 9 DAY 1	C9D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
10	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED					2025-09-08	1
11	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28
12	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
13	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	58.33	DERIVED		58.33	0	NO CHANGE	2025-09-08	1
14	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	66.67	DERIVED		58.33	8.34	NO CHANGE	2025-10-05	28
15	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	75	DERIVED		58.33	16.67	IMPROVEMENT	2025-11-02	56

4. Data Standardization and Analysis - ADQS

Clinically meaningful interpretation of PRO changes

Row	USUBJID	VISIT	AVISIT	PARCAT1	PARCAT2	PARAMCD	PARAM	AVAL	PARAMTYP	QSSTAT	BASE	CHG	CHGCAT1	ADT	ADY
4	A001	CYCLE 4 DAY 1	C4D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-28	21
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14	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	66.67	DERIVED		58.33	8.34	NO CHANGE	2025-10-05	28
15	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	75	DERIVED		58.33	16.67	IMPROVEMENT	2025-11-02	56

- Clinically meaningful change: >10 points from baseline
 - ❖ Symptom: increase = deterioration
 - ❖ Functioning/QoL: increase = improvement

4. Data Standardization and Analysis - ADQS

All records retained - including missing - for CDISC compliance

Row	USUBJID	VISIT	AVISIT	PARCAT1	PARCAT2	PARAMCD	PARAM	AVAL	PARAMTYP	QSSTAT	BASE	CHG	CHGCAT1	ADT	ADY
1	A001	CYCLE 1 DAY 1	BASELINE	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED					2025-09-08	1
2	A001	CYCLE 2 DAY 1	C2D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-09-14	7
3	A001	CYCLE 3 DAY 1	C3D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-21	14
4	A001	CYCLE 4 DAY 1	C4D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-28	21
5	A001	CYCLE 5 DAY 1	C5D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28
6	A001	CYCLE 6 DAY 1	C6D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-12	35
7	A001	CYCLE 7 DAY 1	C7D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-10-19	42
8	A001	CYCLE 8 DAY 1	C8D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)		DERIVED	NOT DONE	33.33		MISSING	2025-10-26	49
9	A001	CYCLE 9 DAY 1	C9D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
10	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED					2025-09-08	1
11	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28
12	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
13	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	58.33	DERIVED		58.33	0	NO CHANGE	2025-09-08	1
14	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	66.67	DERIVED		58.33	8.34	NO CHANGE	2025-10-05	28
15	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	75	DERIVED		58.33	16.67	IMPROVEMENT	2025-11-02	56

4. Data Standardization and Analysis - ADQSTTE

Definition of time to deterioration analysis

- Time from C1D1 to the first deterioration, confirmed at a subsequent visit
- Subjects without a confirmed event are censored at last evaluable assessment (CNSR = 1)

4. Data Standardization and Analysis - ADQSTTE

Row	USUBJID	VISIT	AVISIT	PARCAT1	PARCAT2	PARAMCD	PARAM	AVAL	PARAMTYP	QSSTAT	BASE	CHG	CHGCAT1	ADT	ADY
1	A001	CYCLE 1 DAY 1	BASELINE	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED					2025-09-08	1
2	A001	CYCLE 2 DAY 1	C2D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-09-14	7
3	A001	CYCLE 3 DAY 1	C3D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-21	14
4	A001	CYCLE 4 DAY 1	C4D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	66.67	DERIVED		33.33	33.34	DETERIORATION	2025-09-28	21
5	A001	CYCLE 5 DAY 1	C5D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28
6	A001	CYCLE 6 DAY 1	C6D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-12	35
7	A001	CYCLE 7 DAY 1	C7D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-10-19	42
8	A001	CYCLE 8 DAY 1	C8D1	Symptoms	IL163	ILDASC	Diarrhea Score (QW)		DERIVED	NOT DONE	33.33		MISSING	2025-10-26	49
9	A001	CYCLE 9 DAY 1	C9D1	Symptoms	EORTC QLQ-C30	ILDASC	Diarrhea Score (QW)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
10	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED					2025-09-08	1
11	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	33.33	DERIVED		33.33	0	NO CHANGE	2025-10-05	28
12	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EODASC	Diarrhea Score (Q4W)	0	DERIVED		33.33	-33.33	IMPROVEMENT	2025-11-02	56
13	A001	CYCLE 1 DAY 1	BASELINE	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	58.33	DERIVED		58.33	0	NO CHANGE	2025-09-08	1
14	A001	CYCLE 5 DAY 1	C5D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	66.67	DERIVED		58.33	8.34	NO CHANGE	2025-10-05	28
15	A001	CYCLE 9 DAY 1	C9D1	EORTC QLQ-C30	EORTC QLQ-C30	EOQLSC	QoL Score (Q4W)	75	DERIVED		58.33	16.67	IMPROVEMENT	2025-11-02	56

4. Data Standardization and Analysis - ADQSTTE

Time to deterioration analysis

Row	USUBJID	PARCAT1	PARCAT2	PARAMCD	PARAM	AVAL
1	A001	Symptoms	IL163	ILDATD	Diarrhea TTD (QW)	14
2	A001	EORTC QLQ-C30	EORTC QLQ-C30	EODATD	Diarrhea TTD (Q4W)*	56
3	A001	EORTC QLQ-C30	EORTC QLQ-C30	EOQLTD	QoL TTD (Q4W)	56

Row	ADT	CNSR	EVNTDESC
1	2025-09-21	0	Confirmed deterioration
2	2025-11-02	1	Last evaluable assessment
3	2025-11-02	1	Last evaluable assessment

*In actual studies, Diarrhea (Q4W) analysis is not included when a weekly version is available but is included here for illustration.

4. Data Standardization and Analysis - ADQSTTE



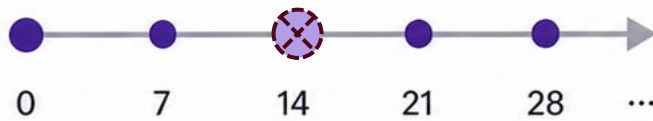
Diarrhea TTD (QW)



IL163 + QLQ-C30



Weekly



Deterioration



Early signal
at day 14



Diarrhea TTD (Q4W)



QLQ-C30



Every 4 Weeks



No
deterioration

Censored at
last evaluable
assessment



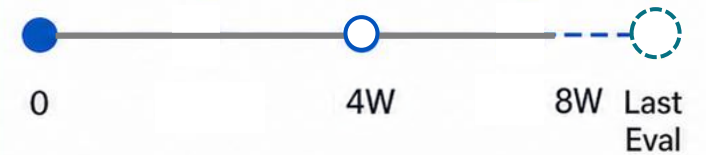
QoL TTD (Q4W)



QLQ-C30



Every 4 Weeks



Censored at
last evaluable
assessment

Key takeaways

1

Clinically Driven Assessment Design

2

Reduced Patient Burden with Maintained Sensitivity

3

CDISC-Compliant Data Standardization

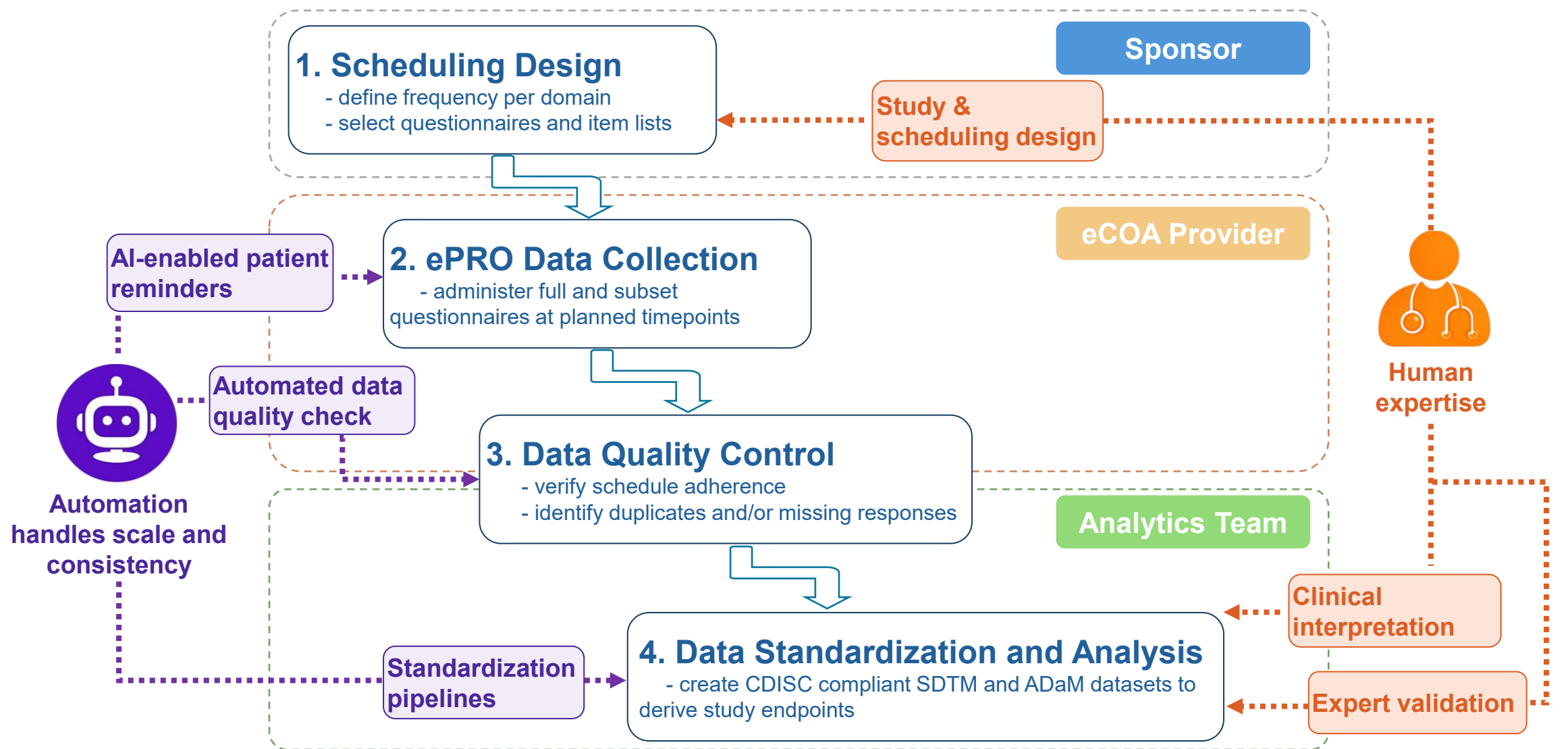
4

Cross-Functional Collaboration is Critical

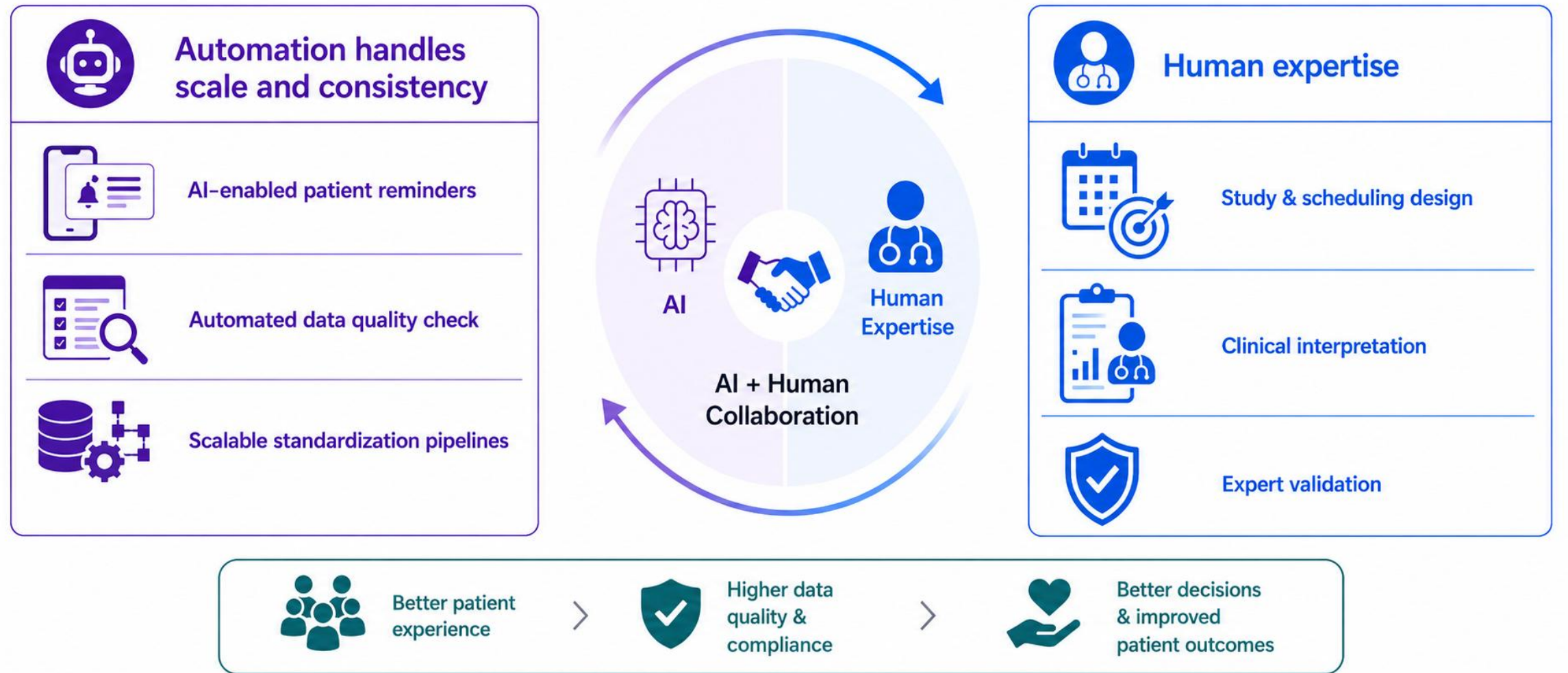
5

Scalable and Reusable Framework

AI/Automation and human collaboration in the workflow



Future Opportunities: AI/Automation and human collaboration



Thank You

Questions & Discussion

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