# Conducting Qualitative Interview Research in the Context of Clinical Trials: Opportunities and Challenges

Prepared by:
Carla Dias Barbosa, MSc,
Senior Research Leader, Exit/Embedded Interview Research Lead
Patient-Centered Research

May 8, 2023



Evidera | PPD

# Background and Purpose

- Over the last few years, there has been a growing interest in exit/embedded (in-trial) interview (EEI) studies, mainly driven by United States (US) regulators recommending EEI as a research methodology, to gather patient input and confirm patient relevance of treatment outcomes and identify meaningfulness of clinical benefit [1].
- These data are increasingly valued by regulatory bodies to enhance understanding of treatment outcomes and inform regulatory decision-making.
- Incorporating qualitative interviews within the clinical trial context poses unique operational and logistical challenges that require careful planning and preparation.
- This presentation will provide insights on benefits of EEI for regulatory decision-making and provide opportunities to learn about methodological approaches for collecting and analyzing qualitative data in clinical trials.

1. Food and Drug Administration. Patient-Focused Drug Development: Methods to Identify What Is Important to Patients Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders. 2022; https://www.fda.gov/media/131230/download; Accessed on April 24, 2023

# Agenda

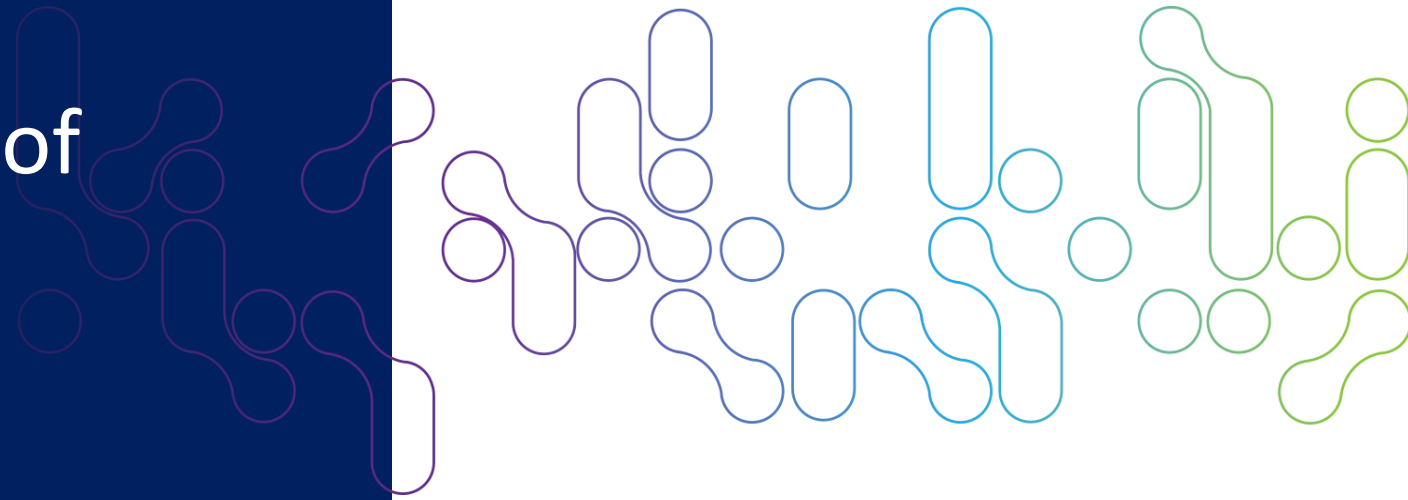
1. INTRODUCTION TO EEI RESEARCH AND VALUE OF THIS RESEARCH TO VARIOUS STAKEHOLDERS AND DECISION-MAKERS
2. KEY CHALLENGES AND POTENTIAL SOLUTIONS FOR CONDUCTING QUALITATIVE INTERVIEWS IN THE CONTEXT OF CLINICAL TRIALS
3. BEST PRACTICES FOR DESIGNING, IMPLEMENTING, ANALYZING QUALITATIVE INTERVIEW TRIAL DATA
4. KEY TAKEAWAY MESSAGES

# Key Learning Objectives

At the end of this session, participants will be able to:

- Understand what insights qualitative interviews within the context of clinical trials can provide to various stakeholders and decision makers and how this research can support product development strategies.
- Identify key challenges and solutions for embedding qualitative interviews into clinical trials.
- Understand best practice approaches for designing, implementing and analyzing qualitative interview trial data.

# Introduction to and Value of EEI Research to Various Stakeholders



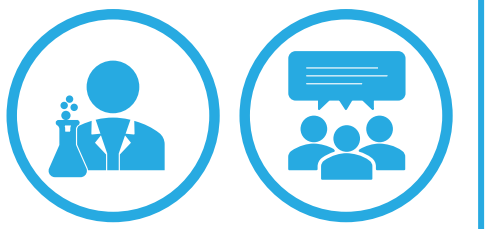
Evidera | PPD

# What are Embedded (In-trial) Interviews?

**Qualitative interviews with specific clinical trial participants** ≠ **Qualitative interviews outside of clinical trials with a sample not involved in a specific clinical trial**

## EMBEDDED INTERVIEWS

### Embedded Interviews

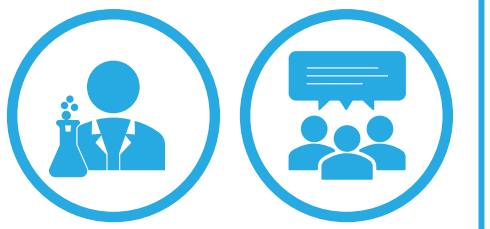



Interviews conducted **with clinical trial participants** <u>included</u> within your clinical trial protocol

**Trial participants can be patients, caregivers or clinical staff.**

## ASSOCIATED INTERVIEWS

### Associated Interviews




Interviews conducted **with clinical trial participants** <u>included</u> within your clinical trial protocol *(using a separate protocol- for example-recruiting same patients as they exit the trial or complete various stages)*

## STANDALONE INTERVIEW STUDY


### Associated Interviews


Interviews conducted <u>outside of the trial</u> **with a separate sample** *(using a separate protocol)*

# What are the Differences in Selecting Embedded versus Associated Interviews?

| | Embedded (In-trial) Interviews | Associated Interviews |
|---|---|---|
| **Design** | **Interviews embedded in clinical trials** are defined as a part of the study activities. They can aim at all trial participants or a subset, they can be voluntary or more mandatory, and can be conducted in some or all of countries in trial. | **Conducted "outside" of the trial**<br>Separate protocol, interviews optional and conducted with clinical trial participant sub-sample |
| **Ethics** | Can leverage existing study IRB/EC submissions and not have to duplicate that ***(must coordinate timing carefully)*** | Separate submission, large impact on timeline for completion. May have competing jurisdiction and restricted patient contact issues. ***Requires more time and resources.*** |
| **Site Contracting** | Study activities at sites are covered under same financial contract as main study, and do not have to be repeated | Separate financial contract(s) with sites<br>***Requires more time and additional costs*** |
| **AE Reporting** | AE reporting must dovetail with the clinical trial to not duplicate AE reporting (inflate AEs) and to keep focus on medical decision making. ***Can be complex step.*** | Coordination with sites and sponsor PV required. Must report directly to PV and must recognize possibility for differences in reporting between interviewers and clinicians, in-depth patient conversations and clinic visits. |
| **Report** | Can be included as an appendix in CTR or can be delivered as a separate report to use as needed. | Reported as a separate document |

Abbreviations: AE = adverse event; CTR = clinical trial report; IEC = international ethics committee; IRB = institutional review board; PV = pharmacovigilance

# Why Do EEI (In-Trial and Associated) Matter in Drug Development?

| Capture Patients' Experience Participating in Clinical Trial | Understand Disease | Test / Validate PRO Measurement Strategy | Understand Patients' Experience with Treatment | Support Interpretation of Trial Outcomes |
|---|---|---|---|---|
| ▪ Identify barriers to patient participation<br>▪ Describe experience of procedures/processes during the clinical trial<br>▪ Describe views on adequacy of information provided<br>▪ Provide information to optimize future clinical trial design | ▪ Identify concepts of importance to patients<br>▪ Develop a conceptual disease model | ▪ Support content validity of a PRO<br>▪ Conduct psychometric evaluation in the context of the trial<br>▪ Explore meaningful change and support establishing responder definitions<br>▪ Provide support for PRO endpoints in phase III trials | ▪ Determine an early safety profile and risk-benefit assessment from patient perspective<br>▪ Understand the unmet needs of patients<br>▪ Explore patient adherence and compliance<br>▪ Identify drivers of differentiation against competitors | ▪ Complement and support clinical trial endpoints<br>▪ Help interpret a clinically meaningful change<br>▪ Contextualize Global Impressions of Change/ Severity ratings |
| ▪ Aid in designing patient-centered clinical trials<br>▪ Optimize the design(s) of your future protocols<br>▪ Foster patient retention | ▪ Generate evidence to design, support, test or validate a patient-focused measurement strategy for your clinical programs<br>▪ Support endpoint model (good for rare disease, disease where course is not known) | | ▪ Generate evidence to support the value of your product | ▪ Generate evidence on clinical benefit from the patient perspective<br>▪ Foster product adoption |

Abbreviation: PRO = patient-reported outcome

# The EEI Interview Data is Relevant throughout Drug Development

## EARLY PHASES (PHASE IIA AND IIB)

### Understanding the Disease

- Understand patients' experience
- Develop conceptual model
- Identify concepts/ outcomes of importance to patients
- Inform endpoint strategy
- Better understand treatment side effects

- Particularly useful in rare disease

### Characterization of treatment benefit and safety profile

- Understand patient experience with new treatment
- Generate hypothesis on treatment benefit
- Identify what constitutes meaningful effect/change
- Confirm concepts/outcomes of importance
- Cognitively assess new PROs

- Maximize signal detection and support internal decision-making
- Build strong differentiation strategy
- Confirm phase III measurement strategy

## PHASE III

### Interpretation of trial outcomes

- Help interpret a clinically meaningful change in clinical outcome score
- Support value messages based on direct input from patients

- Could be part of 'patient experience' section in label and FDA reviews

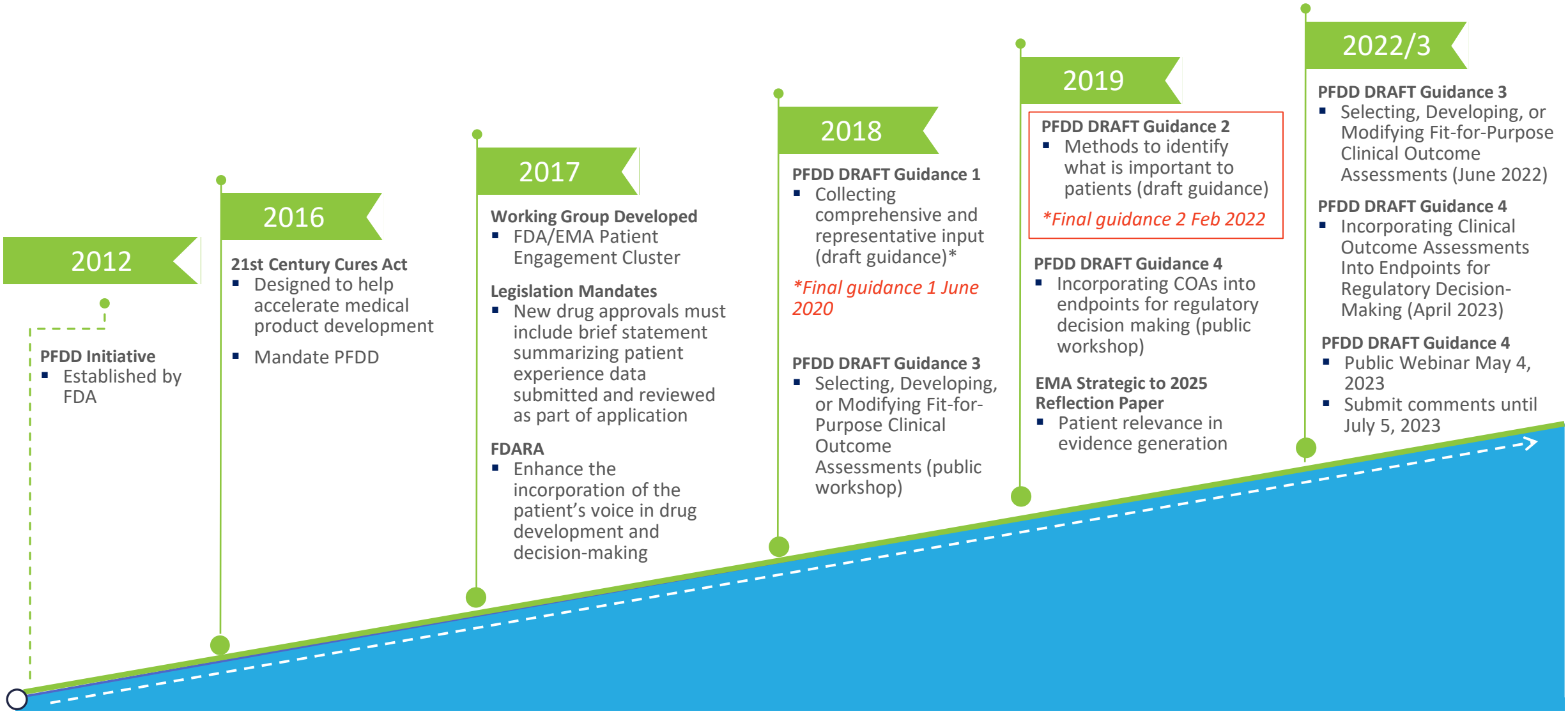
## PHASE IV, POST-MARKETING

### Product safety and market surveillance

- Optimize product implementation into clinical practice
- Detect long-term effects of treatment
- Explore long-term experience of living with new treatment
- Explore adherence and compliance to treatment

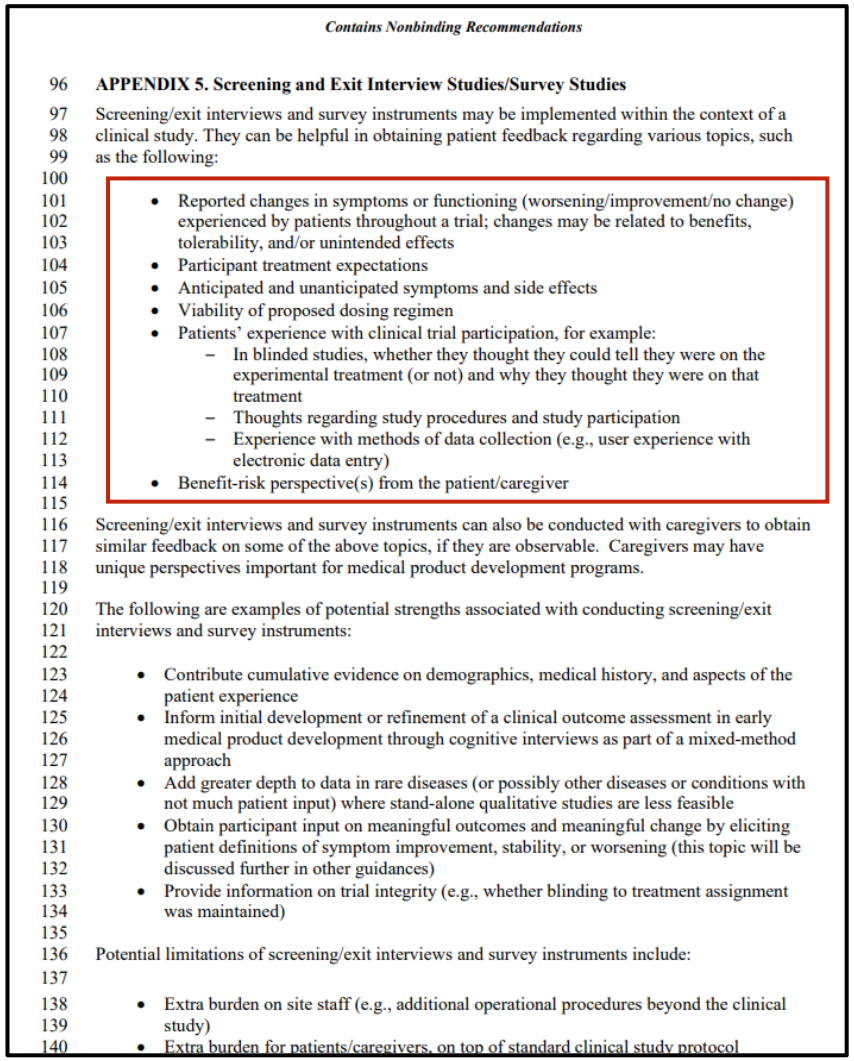
Abbreviation: FDA = Food and Drug Administration; PRO = patient-reported outcome

# Regulatory Interest in Hearing the Patient Voice Has Increased Over Time




Abbreviations: COA=clinical outcome assessment; EMA=European Medicines Agency; FDA=Food and Drug Administration; FDARA=FDA Reauthorization Act; PFDD=patient-focused drug development

# PFDD Guidance 2: Methods to Identify What Is Important to Patients



*Contains Nonbinding Recommendations*

**APPENDIX 5. Screening and Exit Interview Studies/Survey Studies**

Screening/exit interviews and survey instruments may be implemented within the context of a clinical study. They can be helpful in obtaining patient feedback regarding various topics, such as the following:

- Reported changes in symptoms or functioning (worsening/improvement/no change) experienced by patients throughout a trial; changes may be related to benefits, tolerability, and/or unintended effects
- Participant treatment expectations
- Anticipated and unanticipated symptoms and side effects
- Viability of proposed dosing regimen
- Patients' experience with clinical trial participation, for example:
  - In blinded studies, whether they thought they could tell they were on the experimental treatment (or not) and why they thought they were on that treatment
  - Thoughts regarding study procedures and study participation
  - Experience with methods of data collection (e.g., user experience with electronic data entry)
- Benefit-risk perspective(s) from the patient/caregiver

Screening/exit interviews and survey instruments can also be conducted with caregivers to obtain similar feedback on some of the above topics, if they are observable. Caregivers may have unique perspectives important for medical product development programs.

The following are examples of potential strengths associated with conducting screening/exit interviews and survey instruments:

- Contribute cumulative evidence on demographics, medical history, and aspects of the patient experience
- Inform initial development or refinement of a clinical outcome assessment in early medical product development through cognitive interviews as part of a mixed-method approach
- Add greater depth to data in rare diseases (or possibly other diseases or conditions with not much patient input) where stand-alone qualitative studies are less feasible
- Obtain participant input on meaningful outcomes and meaningful change by eliciting patient definitions of symptom improvement, stability, or worsening (this topic will be discussed further in other guidances)
- Provide information on trial integrity (e.g., whether blinding to treatment assignment was maintained)

Potential limitations of screening/exit interviews and survey instruments include:

- Extra burden on site staff (e.g., additional operational procedures beyond the clinical study)
- Extra burden for patients/caregivers, on top of standard clinical study protocol

## Key Highlights

- Screening and exit interviews and/ or survey studies can be incorporated into clinical trials to obtain patient/caregiver perspectives:
  - Reported changes in symptoms or functioning
  - Safety reports
  - Experience in the trial
- Results can be helpful to understand benefit-risk perspective(s) from the patient/ caregiver

# EEI Interviews are Relevant to Various Stakeholders

## DRUG MANUFACTURERS

- Inform design of patient-focused measurement strategy
- Refine or establish PRO content validity
- Address regulators' requests/needs
- Optimize trial design(s) and protocols and increase patient retention

## REGULATORS

- Supplement, support and help interpret trial data
- Provide insights on risks vs. benefits of drug to inform regulatory decision-making

## PAYERS


- Develop better value messages on treatment benefit, treatment satisfaction, and patient/caregiver burden
- Provide insights on risks vs. benefits of drug to inform reimbursement decision-making

## PATIENTS

- Design clinical trials more patient-centric
- Develop plain language summaries to increase awareness about clinical programs/ innovation
- Generate data that helps future products meet the needs of patients
- Foster drug adoption

# Example of FDA's Use of EEI Interview Data


**HIGHLIGHTS OF PRESCRIBING INFORMATION**
**These highlights do not include all the information needed to use XERMELO safely and effectively. See full prescribing information for XERMELO.**

**XERMELO (telotristat ethyl) tablets, for oral use**
**Initial U.S. Approval: 2017**

**----------INDICATIONS AND USAGE----------**
Xermelo is a tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy. (1)

**----------DOSAGE AND ADMINISTRATION----------**
- The recommended dosage of Xermelo in adult patients is 250 mg three times daily for patients whose diarrhea is inadequately controlled by a SSA therapy. (2)
- Take Xermelo with food. (2)
- When short-acting octreotide is used in combination with Xermelo, administer short-acting octreotide at least 30 minutes after administering Xermelo. (2, 7.1)
- Discontinue Xermelo if severe constipation develops. (2, 5.1)

**----------DOSAGE FORMS AND STRENGTHS----------**
Tablets: 250 mg telotristat ethyl (3)

***Extract from publicly available Multi-Discipline Review***

"

**FDA's comments to the applicant:**

- Reduction of two BMs or 30% from baseline per day is considered meaningful by the patients interviewed in the patient-reported outcome sub-study (patient exit interviews conducted in study LX1606.301). However, this responder definition was not proposed as a study endpoint.

**Exit Interview design**

- A total of 35 patients were recruited across 16 clinical sites and 5 countries and completed the exit interview sub-study

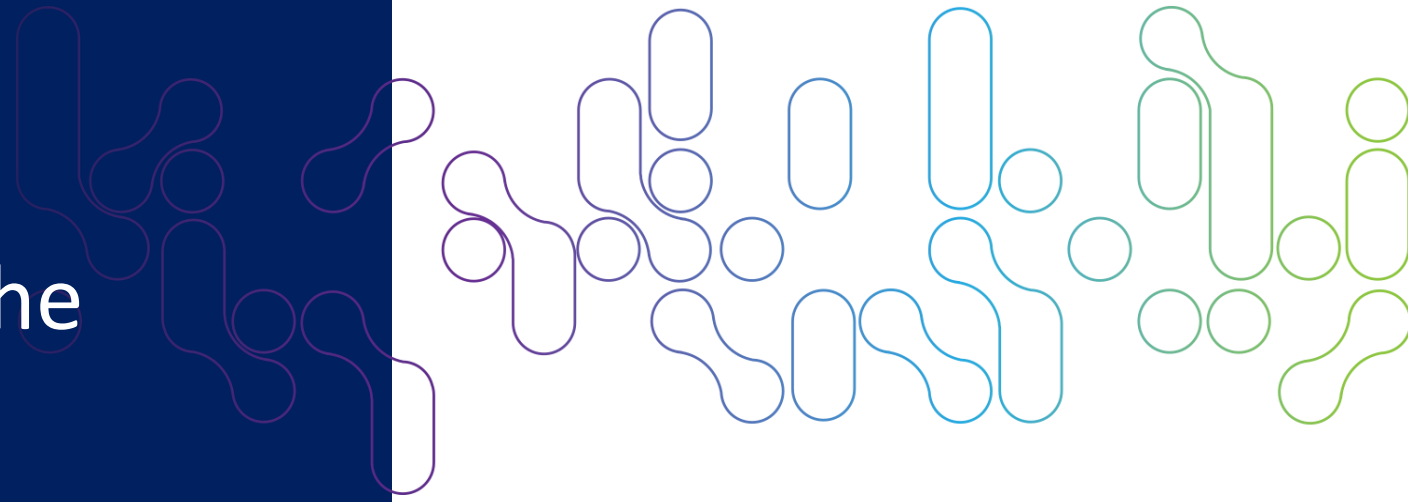
***Results of exit interviews presented and used for interpretation of the scores (section 6)***

"

*– 2017 Review*

FDA = Food and Drug Administration

# Key Challenges and Solutions for Conducting Qualitative Interviews in the Context of Clinical Trials



Evidera | PPD

# Challenges and Solutions for Successful Implementation: ***Trial Conduct***

| CHALLENGES | SOLUTIONS |
|---|---|
| **EXTRA BURDEN ON SITE STAFF**<br>▪ Worry that adding qualitative interviews may put excessive burden on local clinical site staff<br>(This is a new experience for many sites) | ▪ Interviews should be presented as part of the study activities from the start<br>▪ **Not optional to sites**<br>▪ Investigators and staff should receive training to understand importance and process |
| **EXTRA BURDEN ON PATIENTS/CAREGIVERS**<br>▪ Patients worry about feeling too unwell to participate and that they will be locked into a fixed time commitment | ▪ Patients should be presented with importance of interviews at consenting<br>▪ Patients and staff to understand patients can leave interview any time<br>▪ Pilot testing of interview guide |
| **ETHICS AND CONFIDENTIALITY**<br>▪ Potential issues with IRBs and ECs around personal contact information and confidentiality | ▪ **Specific process definition** should be tailored to each study to describe how the team will **maintain patient confidentiality** |

Abbreviations: EC = Ethics Committee; IRB = Institutional Review Board

# Challenges and Solutions for Successful Implementation: ***Interview Conduct***

## CHALLENGES

### SOURCE DOCUMENTS VS AUDIO RECORDINGS

- Interview recordings may contain identifiable information (PII) and cannot stand as study source documents

### TIMING OF THE INTERVIEW

- Need to select the interview windows for coverage of the period of most expected change from treatment without altering patient responses to study measures

### ADVERSE EVENTS (AE) REPORTING

- Worry that embedded interviews will increase AE reporting, and cause problems with compliance

## SOLUTIONS

- A process of **transcript certification** can be used to provide transcripts as source documents
- **Documented destruction** of audio files should happen after study analysis

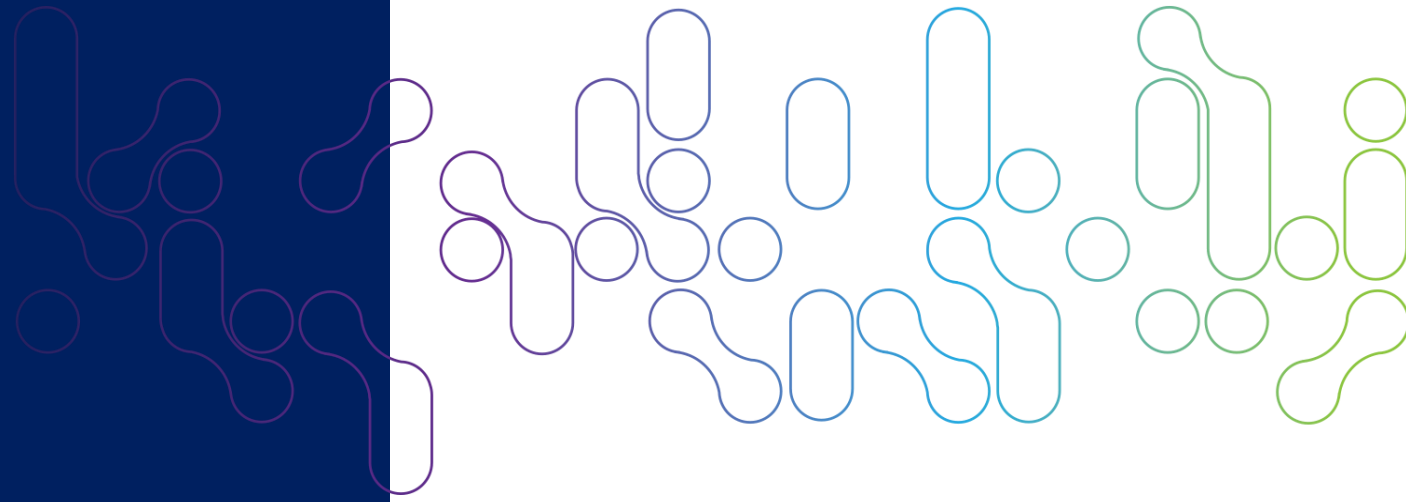
- Conduct interviews after the treatment event and administration of study measures, not before
- **Tailor interview windows to study design**

- Methods will be developed to supplement the AE reporting process established in the clinical trial, **not duplicate, not run counter**, and dovetail with the standard processes for reconciliation and monitoring

# Challenges and Solutions for Successful Implementation: ***Quality Control and Trainings***

| CHALLENGES | SOLUTIONS |
| --- | --- |
| **CROSS CULTURAL DIVERSITY**<br>▪ Global studies require site training and interviews to be conducted in native languages | ▪ Use well trained **bilingual interviewers** with **appropriate qualitative interview background and experience**<br>▪ Monitor interviews to assure consistency across countries |
| **TRAINING OF INTERVIEWERS**<br>▪ Interviewers from different countries with various background and cultures | ▪ **Conduct standard assessment** of interviewer performance and qualitative technique skills |
| **TRAINING OF CODERS**<br>▪ High volume of data to analyze; involvement of several coders | ▪ **Train and monitor** each coder for consistency and accuracy<br>▪ **Conduct quality control** and **provide regular feedback** on individual basis<br>▪ Assess **inter-rater agreement** |

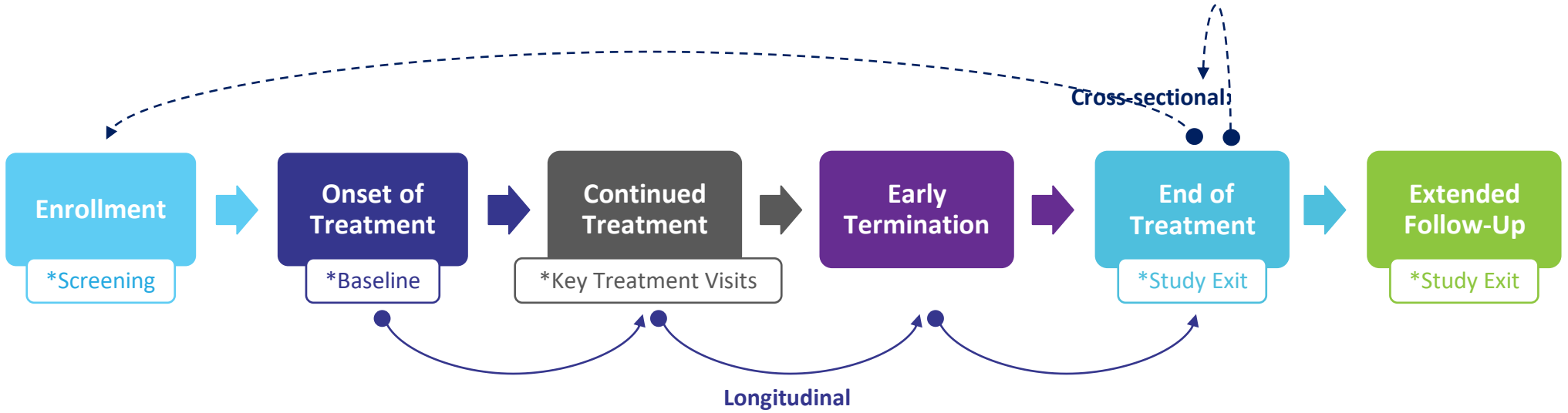
# Best Practices for Design, Implementing, and Analyzing EEI Qualitative Interview Data



Type & Timing

# When should the Interviews be Conducted? What are the Different Types of Interviews?

- **Timing:** Embedded/associated interviews can be conducted at any stage during the clinical trial




- **Type:** Embedded/associated can be conducted as:
  - One-time interviews (cross-sectional) that ask patients about their recent experience and it can include retrospective experience (e.g., before the study, earlier events in the study)
  - Repeated series of interviews (longitudinal) that ask for their recent experience and changes since their last interview

Type & Timing

# When should the Interviews be Conducted?

**The timing of the interviews should work within your existing clinical trial study design and should be timed to reflect a period of patient experience that can accomplish your objectives for including the interviews.**

## Possible Objectives of Embedded (in-trial) and Associated Interview Study

| Capture Patients' Trial Participation Experience | Understand Patients' Disease Experience | Test / Validate PRO Measurement Strategy | Understand Patients' Treatment Experience | Support Interpretation of Trial Outcomes |
|---|---|---|---|---|
| ▪ Interviews at screening or baseline<br>▪ Interviews at exit (with a retrospective section) | ▪ Interviews at screening or baseline<br>▪ Interviews at exit (retrospective section) | ▪ Interviews during treatment phase of study<br>▪ Interviews at end of treatment or follow up visits | ▪ End of treatment or early termination interviews<br>▪ End of follow-up interviews<br>▪ Interviews done early in the study as well as later with retrospective sections or comparisons sections in the interview guide can address treatment experience prior to study. | |

Type & Timing

# When should the Interviews be Conducted?

**The "type" of interview usually indicates what type of information you are looking to obtain and your objective for doing the interview (for example, "concept elicitation, exploratory, content validity, etc.).**

## Possible Objectives of Embedded/ Associated Interview Study

| Capture Patients' Trial Participation Experience | Understand Patients' Disease Experience | Test / Validate PRO Measurement Strategy | Understand Patients' Treatment Experience | Support Interpretation of Trial Outcomes |
|---|---|---|---|---|
| ▪ **Exploratory (descriptive) interviews**<br>▪ **Feasibility** *(to test a plan or assumption)* | ▪ **Exploratory (descriptive) interviews**<br>▪ **Concept Elicitation interviews** | ▪ **Content Validity Interviews** *(concept elicitation, cognitive assessment)*<br>▪ **Exploratory (descriptive) interviews** | ▪ **"Exit" interviews** *(retrospective to study experience)*<br>▪ **Exploratory Interviews** *(meaningful change, satisfaction, retrospective description of symptom experience and changes)*<br>▪ **Cognitive Interviews on trial PROs** | |

Abbreviation: PRO = patient-reported outcome

How Many & Who

# How many Participants need to be Interviewed?

**The sample size is the primary consideration when considering conducting qualitative interviews in the context of clinical trials.**

**The number of participants needed to interview must relate to study objectives.**

**Possible Objectives of Embedded (in-trial) and Associated Interview Study**

| Capture Patients' Trial Participation Experience | Understand Patients' Disease Experience | Test / Validate PRO Measurement Strategy | Understand Patients' Treatment Experience | Support Interpretation of Trial Outcomes |
|---|---|---|---|---|
| **Small Sample**<br>▪ 20 to 30 participants (of a fairly homogenous group)<br>▪ Should be enough to meet "saturation of concept"<br>▪ May be necessary in rare diseases | **Diverse Sample**<br>▪ Gender/age group<br>▪ Race/ethnicity<br>▪ Geography/country<br>▪ Disease severity<br>▪ Care experience | **Diverse Sample (targeted)**<br>▪ Gender/age group<br>▪ Race/Ethnicity<br>▪ Geography/country<br>▪ By treatment subgroups (if known) | **Most of Study Sample**<br>▪ Attempt to capture most of the patients treated in study | |

How Many & Who

# How many Participants need to be Interviewed?

**There will always be participants who decline to participate in interviews, so aiming at total sample is not feasible or practical. Clinical trials rarely bring on all countries at the same time, so subsets need to establish proportional quotas based on sites and expected enrollment across global trial countries**

| | |
|---|---|
| Small Sample | Example: first (30?) accepting interview among English speaking countries enrolled |
| Diverse Sample | Need to set a minimum per country to minimize cultural bias, and need enough patients in subsample to cover range of key characteristics in the clinical trial |
| Targeted Sample | Set known group quotas for each site based on known characteristics. (Example: 50% having had surgery and 50% having had chemotherapy) |
| Most of Sample | Invite everyone consenting to clinical trial, and track and document reasons for those who decline or cannot be interviewed. |

How to

# Conduct of the Interviews

## Interview Guide

- **Objective:** to guide the conversation with the participant in a manner that addresses study objectives *(but this is not an interview script)*.

- A clear open-ended interview guide is essential to avoid undue influence of the researcher, interviewer, or interview guide bias.
  - Allows for patients to speak spontaneously before probes are used
  - Allows for the discussion to flow naturally, some topics may be covered out of order
  - Spontaneous probes and un-scripted follow up questions may be necessary for clarification, based on the information provided by the participants
- Also includes closed-ended questions e.g., severity ratings, ranking questions.
- Use of terms that participants can understand (not technical terms).

## Pilot Testing of the Interview Guide is Necessary

- Examples of pilot testing approaches:

**Mock Interview**

**Involvement of a patient advocate**

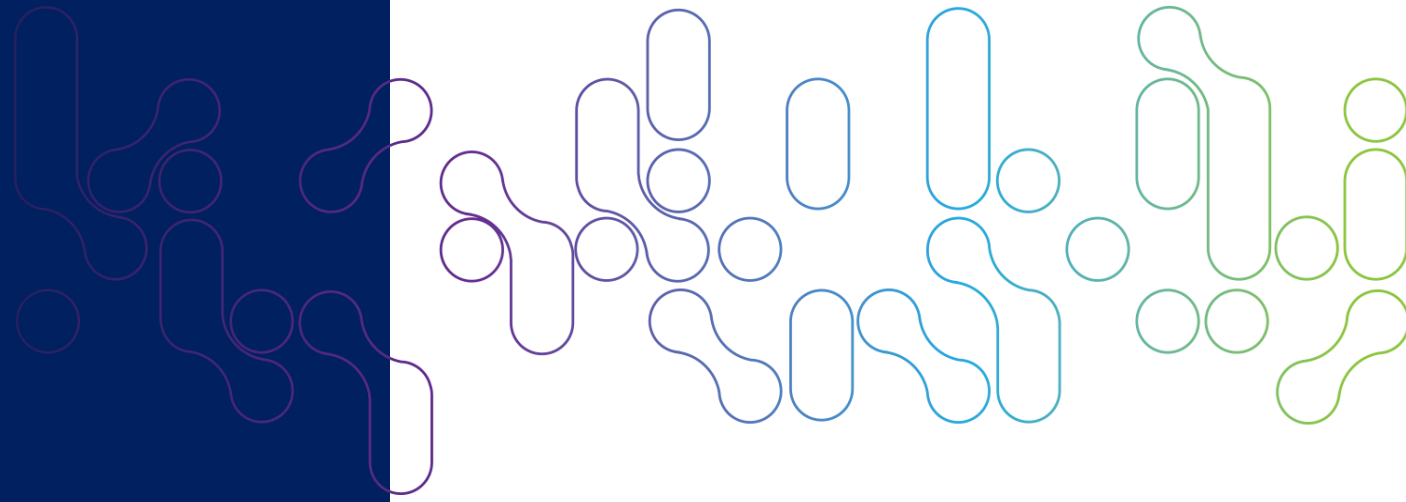
**Pilot testing with a small number of participants**

## Trained Qualitative Interviewers

- Skilled in qualitative research and trained on the study
- Native in the local language and fluent in English

| Study Design | | | Study Logistics | | Analysis Plans | | | |
|---|---|---|---|---|---|---|---|---|
| Type & Timing | How Many & Who | How to Conduct | Process Documents | Footprint Decisions | Cross vs. Longitudinal | Interim vs. Final Analysis | Blinded vs. Unblinded | Mixed Method Analysis |

# Best Practices for Design, Implementing, and Analyzing EEI Qualitative Interview Data



Evidera | PPD

# Process Documents – Good Practices

**PROCESS DOCUMENTS** are a good way to document how various logistical challenges will be handled. These documents are useful for the following reasons:

Logistical details for the qualitative interview are not usually spelled out in the clinical trial protocol. Process documents can be added to the clinical trial files to have a record of how these study activities were carried out, and how confidentiality and compliance was achieved.

There are several logistics where multiple stakeholders have high concern about how it will happen and how it will relate to the trial procedures and sponsor's *SOPs (for example, communications about AEs, handling of identifying information for patients),* and the process needs to be explained.

Process documents provide information, clarity on expectations and agreements, and directives for training of project team and site staff, particularly where non-usual logistics are being implemented.

Some process documents identify compliance with "footprint decisions" a company may have already made regarding a specific logistical issue in the qualitative interview process –or- may already have.

Abbreviations: AE = adverse event; SOP = standard operating procedure

Footprint Decisions

# Process Documents

**FOOTPRINT DECISIONS** are decisions made about the conduct of qualitative embedded interview logistics that affect larger functions within the company (*like quality assurance, safety, pharmacovigilance, etc*.). These need to be examined from a company wide function level to assure compliance.
Typical **"footprint decisions"** include the following examples:

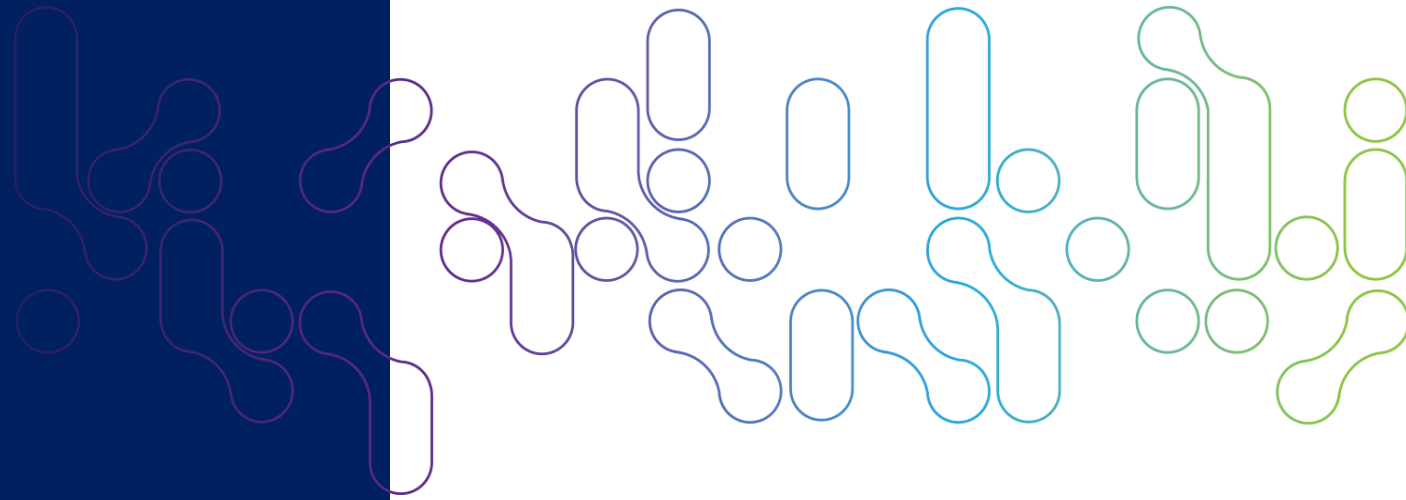
How will AEs and/or SAEs be communicated from interview process into clinical trial process to avoid duplication, artificial inflation of AEs, or bypass of the medical decision making established in the clinical trial process.

Acceptance of "Certified" anonymized transcripts as source documents for the TMF so the audio files, which might contain PII, can be destroyed.

These decisions can be then used in repetition as "footprint" decisions for future studies with embedded qualitative interviews.

Abbreviations: AE = adverse event; PII = participant identifying information; SAE = serious adverse event; TMF = trial master file


# Best Practices for Design, Implementing, and Analyzing EEI Qualitative Interview Data



Evidera | PPD

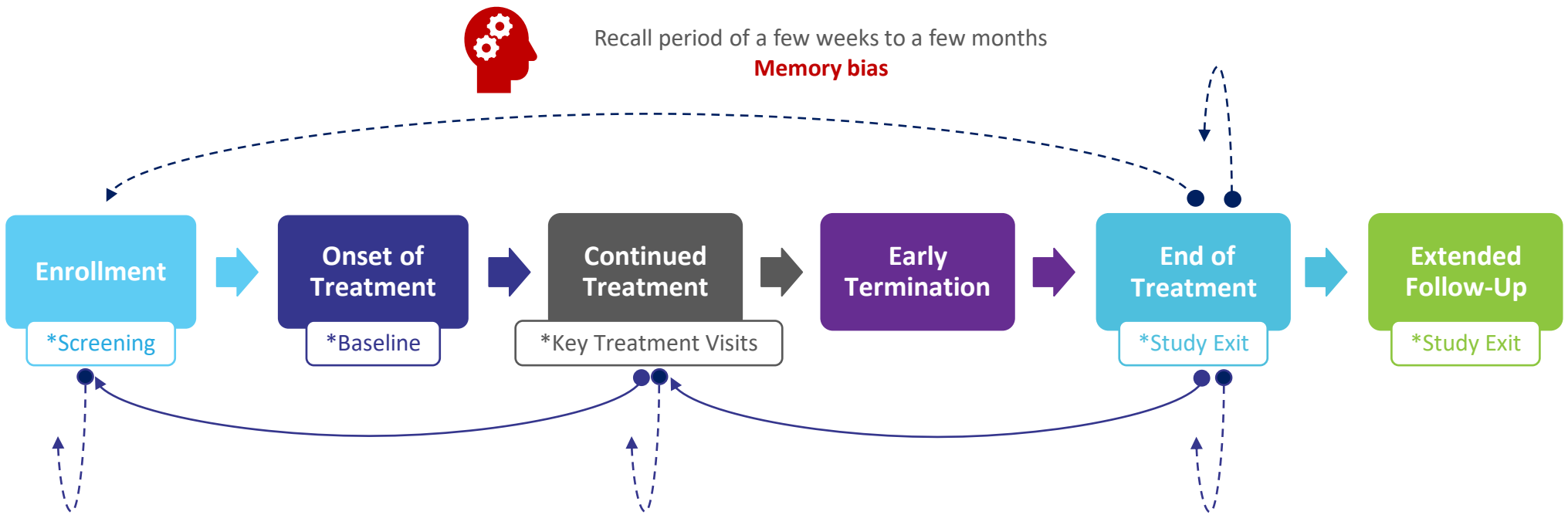
Cross vs. Longitudinal

# One-time vs. Longitudinal Interviews

| | One-time Interviews | Longitudinal Interviews |
|---|---|---|
| **Design** | Interviews with patients at **one timepoint** (study entry, exit or early discontinuation) | Interviews with patients at **multiple timepoints** (study entry, exit and/or early discontinuation, during follow-up) |
| **Focus** | Understand patients' experiences **in a specific time and context** | Understand patients' experiences **over time**; characterize meaningful change<br>Allows **qualitative comparisons** of the same population **over a period of time** |
| **Process** | Retrospective reports of previous experiences based on participant recall; **Can be influenced by recall bias** | Implies returning to patients to explore changes as they occur in real time; **less recall bias** |
| **Analysis** | **Cross-sectional analysis** (snapshot of the population at a certain time); simple qualitative analysis or mixed-method analysis | **Longitudinal qualitative analysis** (i.e., qualitative comparisons of the interviewed population over a period of time) and mixed-method analysis across multiple timepoints |

# Cross sectional vs. longitudinal Qualitative analysis

- **Cross sectional:** reports on actual and retrospective experience, **can be influenced by recall bias**

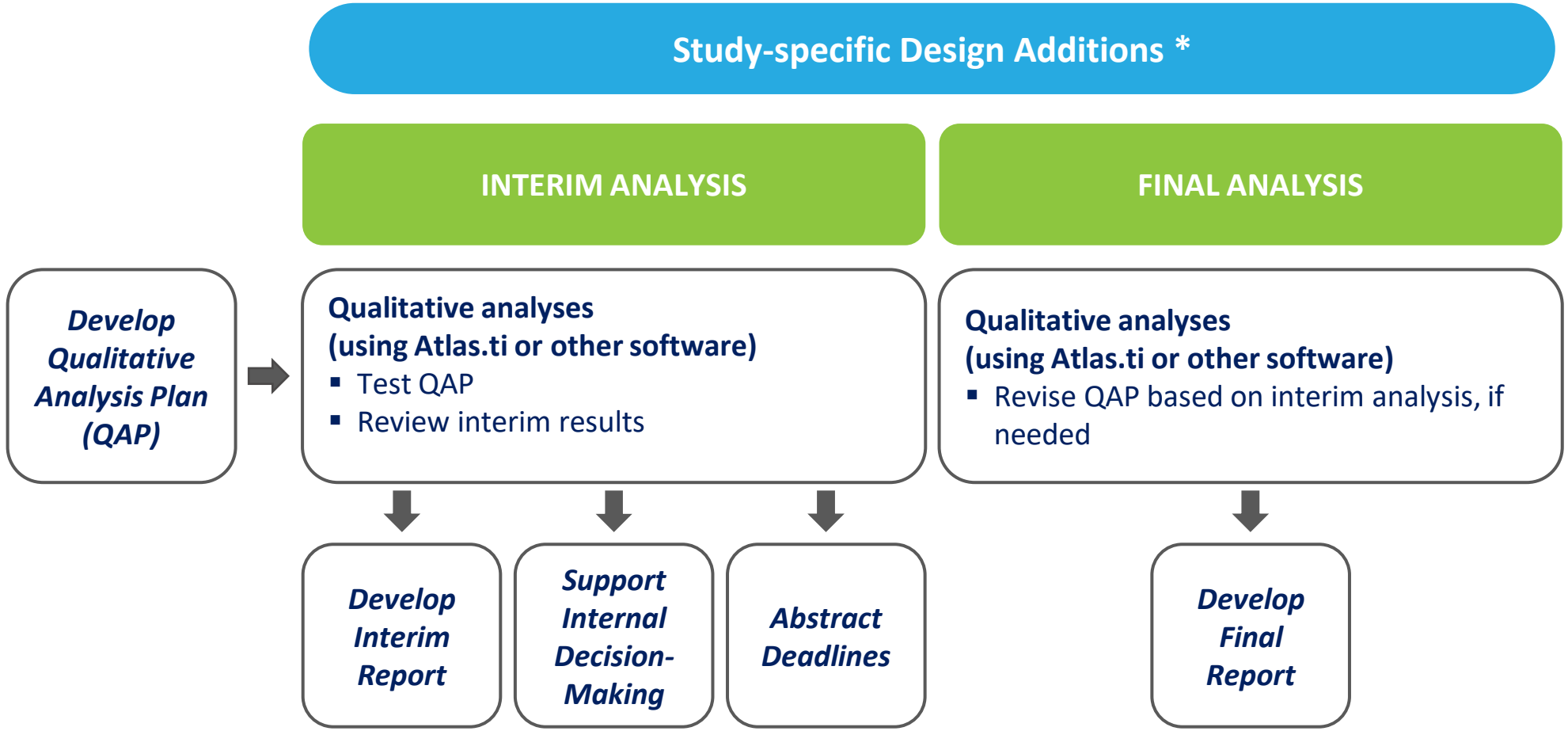



- **Longitudinal:** Implies returning to patients to explore changes as they occur and magnitude of change since last interview; **less recall bias**

# Consider the Analysis up Front to Guide Design

- **A Qualitative Analysis Plan (QAP)** is the document that links the scientific strategy and the operational processes for a study or project. This is a key deliverable and should be reviewed carefully by the project team to ensure that the study activities answer the study objectives.
- **The type of strategy** you envision for analysis of the interview data can impact study design, time, and resources. If the study is long and you can consider an interim analysis, that must be accounted for in time and budget.
- **Examples of analytic strategies** are shown on the next few slides to help your considerations.

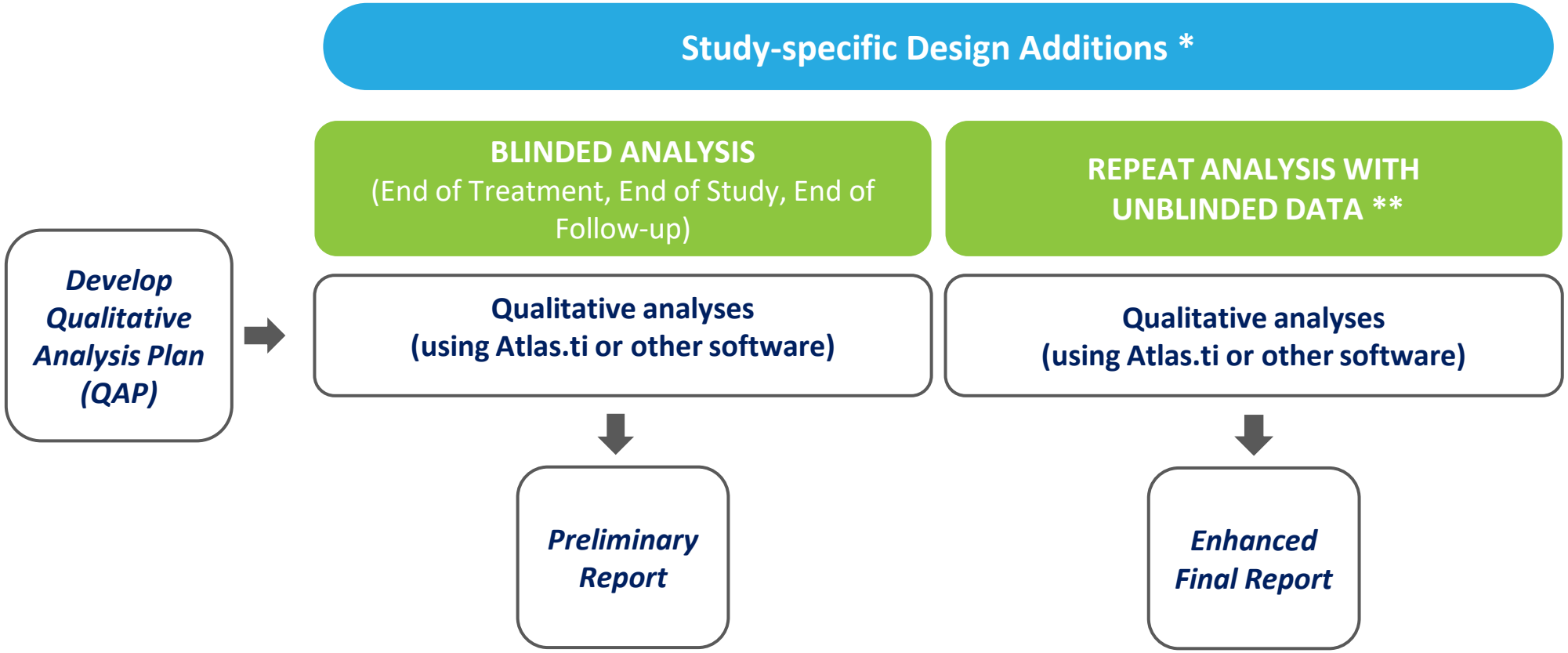
# Example: Preliminary and Final Data Analyses




* Demographic data on interview participants may be needed to characterize the interview population.

Blinded vs. Unblinded

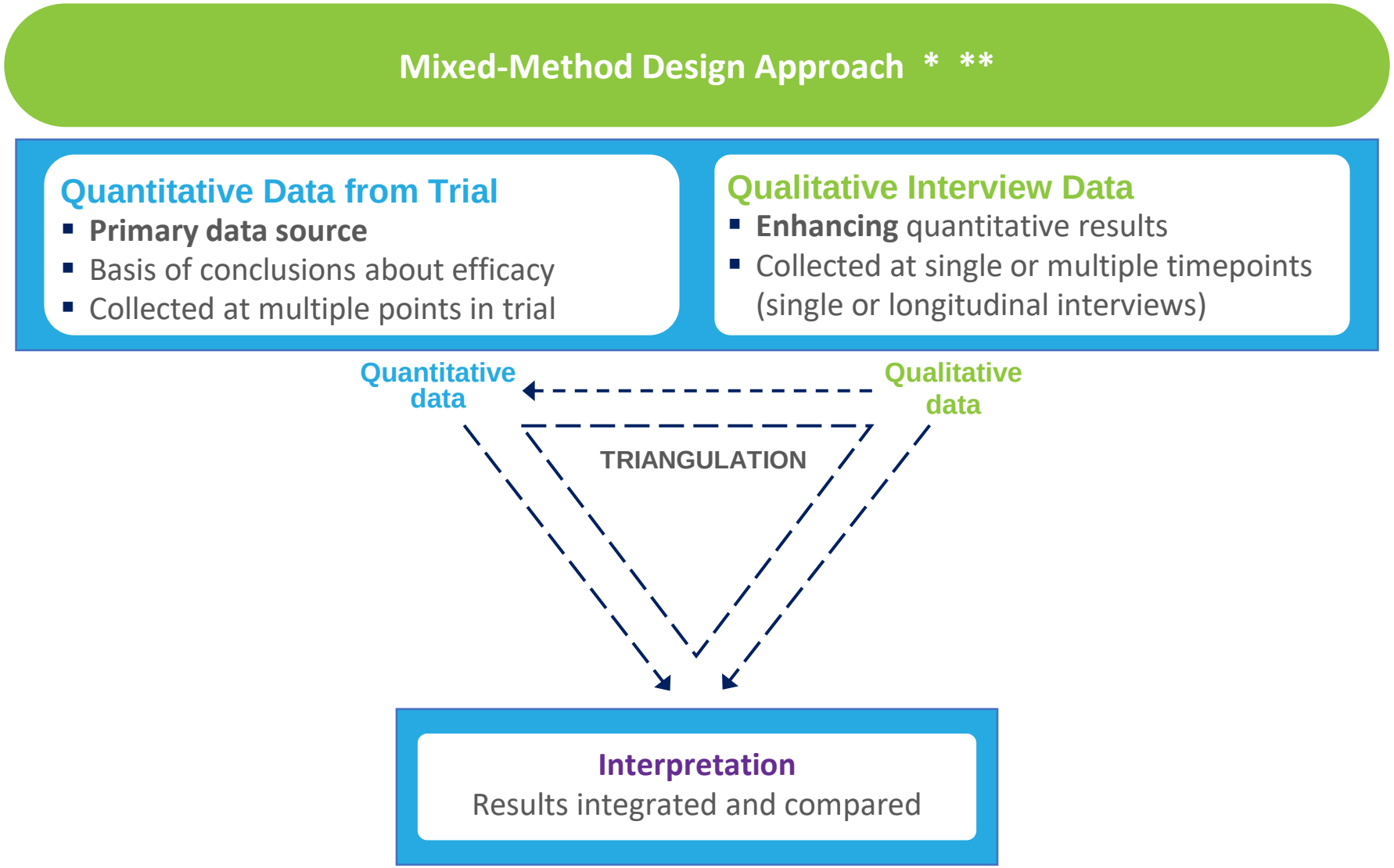
# Example: Analyses of Data Blinded and Unblinded to Treatment




* Demographic data on interview participants may be needed to characterize the interview population.
** Blinding codes will be needed for the repeat analysis with un-blinded data

Mixed Method Analysis

# Integration of Interview and Clinical Trial Data: Mixed-Methods Analysis




* Demographic data on interview participants may be needed to characterize the interview population.
**Key clinical trial variables will be needed for Mixed Methods Analysis

Mixed Method Analysis

# Integration of Interview and Clinical Trial Data: Mixed-Methods Analysis

**Mixed-Method Approach * ****

**Qualitative analyses of interview data**

**Integration of qualitative and quantitative data from clinical trial**

***Develop Qualitative Analysis Plan (QAP)***

**Qualitative analyses (using Atlas.ti or other qualitative software)**

- Code frequency tables (thematic analysis)
- Quotation tables describing the language used by the patients (thematic analysis)
- Saturation of concept table

**Quantitative analyses (using SAS)**

- Use clinical and patient-reported outcome variables collected in the trial to describe the interviewed sub-sample
- Comparative tables and/or figures by relevant subgroups with sample quotations
- Develop individual profiles using qualitative and quantitative data

***Develop Final report***

* Demographic data on interview participants may be needed to characterize the interview population.
**Key clinical trial variables will be needed for Mixed Methods Analysis

# Case Study: Embedded, Longitudinal Interview Design Using a Mixed-Method Approach

## BACKGROUND

- There is a high unmet need for effective treatments in relapsing/refractory multiple myeloma (RRMM)
- Client's treatment (GSK's Belantamab) showed positive efficacy, but many patients reported the expected significant side effect of impaired vision
- More information on the patient experience with this new treatment in real time was needed to better understand the product safety profile.

## APPROACH

- Qualitative interviews were embedded in Phase I and II clinical trials at two time points in the clinical trials
- The semi-structured qualitative interviews focused on the patient reports of disease and treatment-related symptoms and impacts, as well as satisfaction with treatment
- A mixed methods analysis approach was used to compare qualitative interview data (NRS ratings of severity and symptom bother) and with a variety of clinical variables collected in the clinical trial dataset

## RESULTS

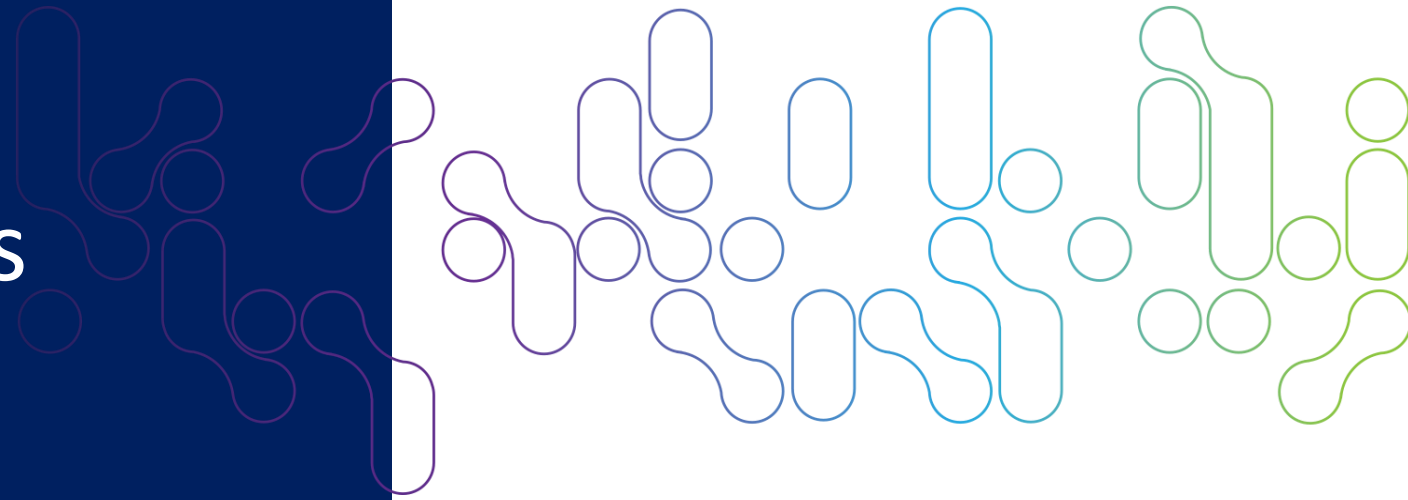
- Results from patient interviews showed:
  - Most patients experienced ocular symptoms; however, they were generally described as manageable and improved after the patient stopped treatment
  - At end-of treatment interviews, patients noted continued decrease in severity of ocular symptoms
  - Patients registered high levels of treatment satisfaction and noted less overall impact on their daily life compared to other treatments

## IMPACT

- Phase I and phase II interview results provided valuable insights into the symptom and impact experiences of patients in real time and how they changed during and following treatment.
- Results help to overcome regulatory concerns by showing how these side effects resolved after treatment, and the overall value the patients expressed for the efficacy of the treatment despite these side effects.

Abbreviations: EOT = end of treatment; GSK = GlaxoSmithKline; NRS = numerical rating scale; RRMM = relapsing refractory multiple myeloma

# Key Takeaway Messages



Evidera | PPD

# Key Takeaways

**GROWING ATTENTION BY DIFFERENT STAKEHOLDERS IS BEING PAID TO PATIENT EXPERIENCE DATA**

*Anticipation and planning are key. Think ahead and involve internal stakeholders early in the drug development process*

**GET STARTED AS EARLY AS POSSIBLE**

*In early phases (phase 1/2) if possible, particularly important in rare diseases*
*At the beginning of the protocol development, to avoid protocol amendment.*

**INTERVIEWS CONDUCTED IN CLINICAL TRIALS CAN SERVE DIFFERENT PURPOSES DURING DRUG DEVELOPMENT**

*Use of clinical trial interview data throughout drug development can improve the value story of your treatment or intervention and help to ensure successful implementation into clinical practice*

**THIS TYPE OF RESEARCH MAY PRESENT SOME CHALLENGES TO CLINICAL SITES AND CLINICAL OPERATIONS TEAMS**

*Planning ahead, training, and education are key. Implement appropriate approaches and processes to ensure success*

**BEST PRACTICES FOR DESIGNING, IMPLEMENTING, AND ANALYZING QUALITATIVE INTERVIEW TRIAL FOR SUCCESSFUL IMPLEMENTATION**

*Using best practices to design, implement and analyze qualitative interview research is key to ensure rigor and high-quality patient experience data that addresses your study objectives.*

# Contact Slide

**Carla Dias Barbosa, MSc**
Senior Research Leader, Exit/Embedded
Interview Research Lead
Patient-Centered Research

**E-MAIL**
Carla.Dias-Barbosa@evidera.com

**PHONE**
+44 7545 439187

**LOCATION**
London, UK

Evidera | PPD® Part of Thermo Fisher Scientific


THANK YOU!
To Continue the Conversation,
Visit Us at
BOOTH 931