PPD™ EVIDERA™ PATIENT-CENTERED RESEARCH

PRO Endpoint Strategy & Analysis

Maximise the scientific value of clinical-trial PRO data—from early endpoint strategy and SAP input through treatment-effect estimation, clinical interpretation, and dissemination.

Turn patient-reported outcome (PRO) data into decision-ready patient-experience evidence.

Clinical trials can leave important questions about patients' experiences unanswered. The best opportunity to answer these questions comes before endpoint and statistical analysis plan (SAP) decisions are locked, while the treatment-benefit question, estimands, endpoint definitions, intercurrent-event strategy, missing-data approach, and planned analyses can still be aligned. PPD Evidera helps sponsors build an integrated evidence strategy, conducts validated analyses, and translates findings for regulatory and scientific audiences.

Four Questions That Turn PRO Data Into Patient-Experience Evidence

Can PRO data be interpreted with confidence?

Characterise analysis populations, baseline PRO profiles, available-data and completion rates, missing data patterns, patient follow-up, and posttreatment data availability.

What did patients experience over time?

Describe symptom trajectories, health-related quality of life, functioning, side effects, and overall symptom burden over time.

Did treatment improve patient experience?

Estimate treatment effects using endpoint-specific estimands, including change-from-baseline analyses, responder endpoints, sustained/confirmed response, time-to-event methods, sensitivity analyses, and subgroups.

What do the treatment effects mean clinically?

Interpret PRO data using meaningful within-patient change and contextualise PRO findings against clinical outcomes, including clinical response, treatment-related side effects, contemporaneous disease markers, treatment milestones, and other anchors relevant to the trial.

Types of Analyses

Data quality & interpretability
Baseline patient/PRO profile, available-data rate, completion rate, missing data patterns, expected PRO population, follow-up and disposition.

Time-to-event & novel endpoints
Time to first or confirmed improvement/deterioration, symptom resolution, symptom-burden reduction, composite or fit-for-purpose patient-centered endpoints.

Longitudinal patient experience
Observed scores, change from baseline, trajectories over time, improvement/stable/worsening distributions, posttreatment follow-up.

Meaningful change & responders
Meaningful within-patient change thresholds, responder definitions, cumulative distribution function/probability density function displays, improvement/worsening, confirmed or sustained response.

Clinical contextualisation
PROs by clinical response/status and treatment toxicities, change before/after clinical milestones, relationships with biomarkers/clinical endpoints, prespecified subgroup analyses.

Complementary analyses clearly positioned

We can identify additional patient-centered endpoints that address unmet evidence needs, while maintaining alignment with study design, endpoint hierarchy, and estimand principles.

Start the conversation. Email **Shien.Guo@thermofisher.com.**

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From Data to an Integrated Evidence Package

Flexible support for a focused endpoint question, a set of targeted analyses, or end-to-end PRO evidence generation.

From Scientific Question to Decision-ready Evidence

Align the scientific question
Review of trial protocol, SAP, case report forms, prior outputs, endpoint hierarchy, assessment schedule, evidence needs, and PRO instruments.

Define endpoints and estimands
Early scientific consultation, ideally before protocol/SAP lock on objectives, endpoint definitions, estimands, analysis populations, intercurrent events, missing data, subgroups, sensitivity analyses, and fit-for-purpose methods incorporated into a PRO SAP.

Confirm data and derive endpoints
Dataset receipt checks, key variable availability, timing, completeness, derivation feasibility, alignment with planned analyses.

Analyse and quality control
Programming, quality check (QC), derived endpoints, tables and figures, documented deviations and fit-for-purpose refinements.

Interpretate treatment effects
Top-line results deck, treatment-effect interpretation, integrated patient-experience narrative, recommendations.

Package and communicate the evidence
Full analysis report; optional regulatory materials, abstracts, posters, manuscripts, and publication-ready outputs

What Your Team Receives

Strategy & planning
Early endpoint/estimand strategy, protocol/SAP consultation before decisions are locked; SAP development or review, endpoint derivations, analysis recommendations and specifications.

Interpretation
Top-line results deck, integrated interpretation of treatment effects, clinical contextualisation, decision-ready patient-experience narrative.

Analysis outputs
Derived patient-centered endpoints, validated tables and figures, responder and meaningful-change analyses, subgroup and sensitivity outputs.

Reporting & dissemination
Full analysis report; regulatory-support materials; publication-ready tables/figures; optional abstract, poster, and manuscript support.

Why Evidera

15 dedicated clinical outcome assessment (COA) quantitative scientists	**20+** COA endpoint-analysis studies completed in 2025–2026	**30+** years of collective COA analysis and validation experience
>10 statisticians/ programmers supporting data management and analytics	**12** FDA or EMA labels supported by COA evidence	**40+** regulatory meetings supported in the past 5 years

Additional scale: 150+ dedicated Patient-Centered Research scientists and >100 publications annually. Figures reflect current 2026 capability materials.

Why This Approach Is Different

Integrated scientific expertise
COA strategy, estimands, psychometrics, biostatistics, regulatory science, and clinical interpretation are considered together, not as disconnected steps.

Rigorous analytical delivery
Analysis plans, derivations, statistical programmes, outputs, and interpretation undergo fit-for-purpose quality control, with independent programming/QC approaches available for study-critical analyses.

Patient-centered endpoint thinking
We anchor analyses in what the measure captures, what constitutes meaningful change for patients, and the specific treatment-benefit question the study is designed to answer. Analyses and interpretation are tailored to the trial context and clinical outcomes that may influence the patient experience

Evidence that can travel
Outputs are designed to support multiple downstream needs, including regulatory interaction and review, clinical study report interpretation, scientific publication, medical affairs, health technology assessment, and lifecycle evidence generation.

Flexible Ways to Engage

Strategy	Planning	Analysis	End-to-end
Endpoint/ estimand consultation	SAP and analysis specifications	Focused or comprehensive PRO analyses	Evidence package through interpretation and dissemination

Engage us early—while the protocol, endpoint strategy, and SAP are still being developed—or provide an existing PRO dataset that you want to maximise.
We can help shape the right patient-experience questions and analysis strategy before execution begins, then deliver the validated analyses, interpretation, and evidence package needed for downstream decisions.

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