Data Set I
Concept elicitation focus groups (n=10) with:
- 15 subjects with severe depression
- 8 subjects with moderate depression
- 7 subjects with mild depression
- 8 subjects in remission

Pre-Coding
Initial code book developed
- Root concept codes (i.e., symptoms or impacts)
- Dimension codes (e.g., severity and frequency)
Sensitizing concepts to the code book added and based on:
- Word review in transcripts
- Coding of the first transcript

Coding
Iterative harmonization of the code book to produce reliable coding scheme
Transcripts coded and coding reviewed
Code book refined as new concepts emerge, or merging of codes as needed based on linguistically or conceptual equivalence

Analyses
All coded quotations reviewed to compare and contrast concepts and their dimensions across participants and groups
Frequency of the occurrence of each concept
Synthesis of findings to distinguish between simple concepts and multidimensional concepts given participants’ meaning and importance attributed to concepts
Sample size confirmed as sufficient to obtain a comprehensive list of symptoms related to MDD (concept saturation and domain comprehensiveness)
Coding scheme and conceptual framework reviewed by clinician for clinical relevance of concepts

Conceptual Framework

Item Generation
New items generated to reflect the conceptual framework by PRO development and clinical experts

2nd Data Set
Iterative cognitive interviews with 20 patients
- 2 subjects with severe depression
- 7 subjects with moderate depression
- 7 subjects with mild depression
- 4 subjects in remission
Brief concept elicitation and debriefing of 35 items

Coding and Analysis
Interviews coded for comprehensiveness of concepts
Items coded for
- Interpretability of items and instructions
- Appropriate recall period
- Fit between item stem and response options
- Clarity of words

Finalization of Major Depressive Disorder Patient Reported Outcome Measure
15 Daily Items (24-hour recall period)
20 Weekly items (7-day recall period)