

# Utilizing patient interviews to inform and optimize the design of a Phase IV clinical trial

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**What is the Methodological Question Being Addressed?** How can we ensure that life engagement and a proposed subscale to measure it in a Canadian Phase IV study are relevant to patients with MDD?

**Introduction** It is increasingly recognized that patients' experiences, perspectives, needs, and priorities should be captured and meaningfully incorporated into drug development and evaluation. Integrating the patient's perspective can help identify and measure outcomes and burdens that matter most to patients, and serve to design better clinical studies overall. During protocol development for a Canadian Phase IV study exploring life engagement in patients with major depressive disorder (MDD), a series of patient interviews were conducted to inform several elements of the study design, including the primary outcome measure.

**Methods** During protocol development of a Canadian Phase IV study protocol exploring life engagement in patients with MDD, semi-structured, 60-minute video interviews were conducted with adult patients in the United States. Patients were first asked to provide words that described good, average, and bad days. This exercise was conducted in order to transfer patients' own words into take-home diaries for the creation of an exploratory patient experience 'word cloud'. Next, patients were asked to discuss their feelings, thoughts and behaviours when they felt engaged with life, and were asked to review, discuss, and rate the relevance of ten items from the Inventory of Depressive Symptoms - Self Report (IDS-SR10) scale with the concept of life engagement in patients with MDD. The IDS-SR10 was initially proposed by a group of physicians to characterize life engagement, and was the proposed co-primary endpoint of the Canadian Phase IV study.

**Results** Twenty patients were interviewed, with mean age 43 years (range: 20-70 years) and mean duration of diagnosis 14.8 years (range: 2-50 years). Patient's own words to describe good, average and bad days frequently included "happy," "energetic" and "productive" for good days, and "sad," "down" and "irritable" for bad days. The concept of life engagement resonated with all patients, and was deemed clinically important by all. Nineteen of the 20 patients (95%) indicated that all ten IDS-SR10 Life Engagement items were relevant to patient engagement, which confirmed from the patients' perspective the relevance of this subscale as a co-primary endpoint.

**Conclusion** By conducting patient interviews as part of the Canadian Phase IV study protocol development, MDD patients confirmed the clinical relevance of the life engagement concept, the

selection and composition of the subscale used as a co-primary endpoint, and the appropriate components of an exploratory assessment.

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