

# Interpreting PRO-CTCAE Data: Defining and answering the right questions

Joel Sims<sup>1</sup>, Alex Hind<sup>1</sup>, Katie Frampton<sup>1</sup>, Rachael Lawrance<sup>1</sup>

<sup>1</sup>Adelphi Values Patient-Centered Outcomes, Bollington, Cheshire, United Kingdom.

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## BACKGROUND

- > Interpreting Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) data is essential for understanding patients' experiences of symptomatic toxicity in oncology trials.
- > When appropriately used and interpreted, PRO-CTCAE offers valuable, direct insight into patient symptom burden, complementing clinician-reported adverse event data and supporting risk-benefit assessment in trials.
- > While a range of methods for operationalising and visualising PRO-CTCAE data are established<sup>1-4</sup>, less guidance exists on which research questions are most meaningful to address and how to interpret these data for clinical, regulatory, and patient audiences.

## AIMS

- > Our primary aim was to identify what are the **key research questions** that may follow from the collection of PRO-CTCAE data
- > Our next aim was to demonstrate how these research questions could be addressed through **effective visualisation methods**. We designed an interactive R Shiny dashboard to facilitate visualisation and interpretation for a comparative setting with two treatment arms (data based on a simulated scenario).

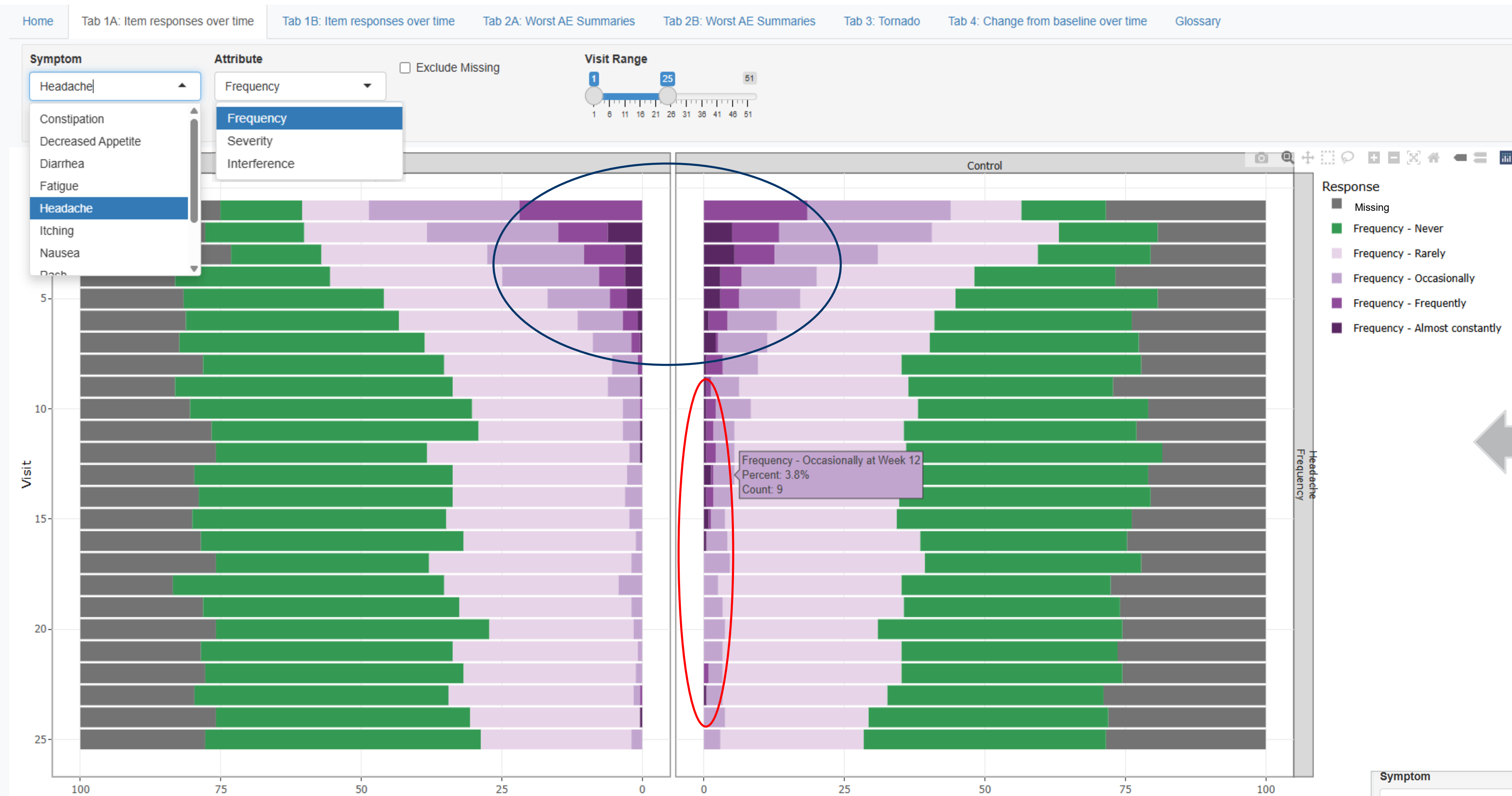


Figure 1. % of patients with each response level over time – selecting AE symptom, attribute and timeframe

### Question 1. When do symptoms occur?

#### Figure 1:

- Frequency of symptomatic headache is highest in the first 5 weeks (circled) and relatively similar between arms (with most patients in both arms experiencing headache during this period).
- After 5 weeks, frequency remains low (most patients rarely or never experience headache in both arms)
- However, in control arm, highest category of headache frequency (frequently/almost constantly) persists for longer through to week 15+ (circled), though proportion of patients is relatively small (<5%).

### Question 2. What is the relationship over time between symptom frequency, severity and interference?

- **Figure 2:** Frequency, severity and interference appear related over time. It can be seen that timepoints with higher frequency of headache also show higher severity / interference levels.
- Frequency attribute shows the most grade 3 and 4 reports, followed by severity then interference.



Figure 2. % of patients with each response level over time – showing all attributes per symptom.



Figure 3. Tornado plot of baseline-adjusted worst score – ordered in decreasing severity

### Question 3. What are the most common or most severe symptoms?

- **Figure 3** presents a tornado plot that summarises for each PRO-CTCAE item the worst scores reported by patients across the study period adjusting for baseline. This can be filtered to just frequency, severity or interference attributes to help answer which is the most common, most severe or most bothersome.

### Question 4. What symptoms display the most grade 3/4 reports?

- **Figure 3** allows grade 3/4 response to be combined into one category (as shown). This is a typically used approach aligned with clinician AE reporting summaries. Nausea and headache frequency appear to show the worst grade 3/4 reports (circled in red).

### Question 5. How does the proportion of patients with levels of improvement or deterioration in symptoms change over time?

Dashboard includes stacked bar charts with score changes ranging from -4 (highest category of improvement) to +4 (highest category of worsening)

## CONCLUSIONS

- > A barrier to interpretation of the rich and extensive symptom AE data collected from patients using PRO-CTCAE is developing and prioritising the research questions of interest.
- > We developed key research questions along with an interactive tool that enables efficient interpretation of patient experiences with symptomatic toxicity, as captured by PRO-CTCAE data.



SCAN TO VIEW  
DASHBOARD VIDEO  
DEMO (~2 MIN)