

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

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Patient-Centered Outcomes

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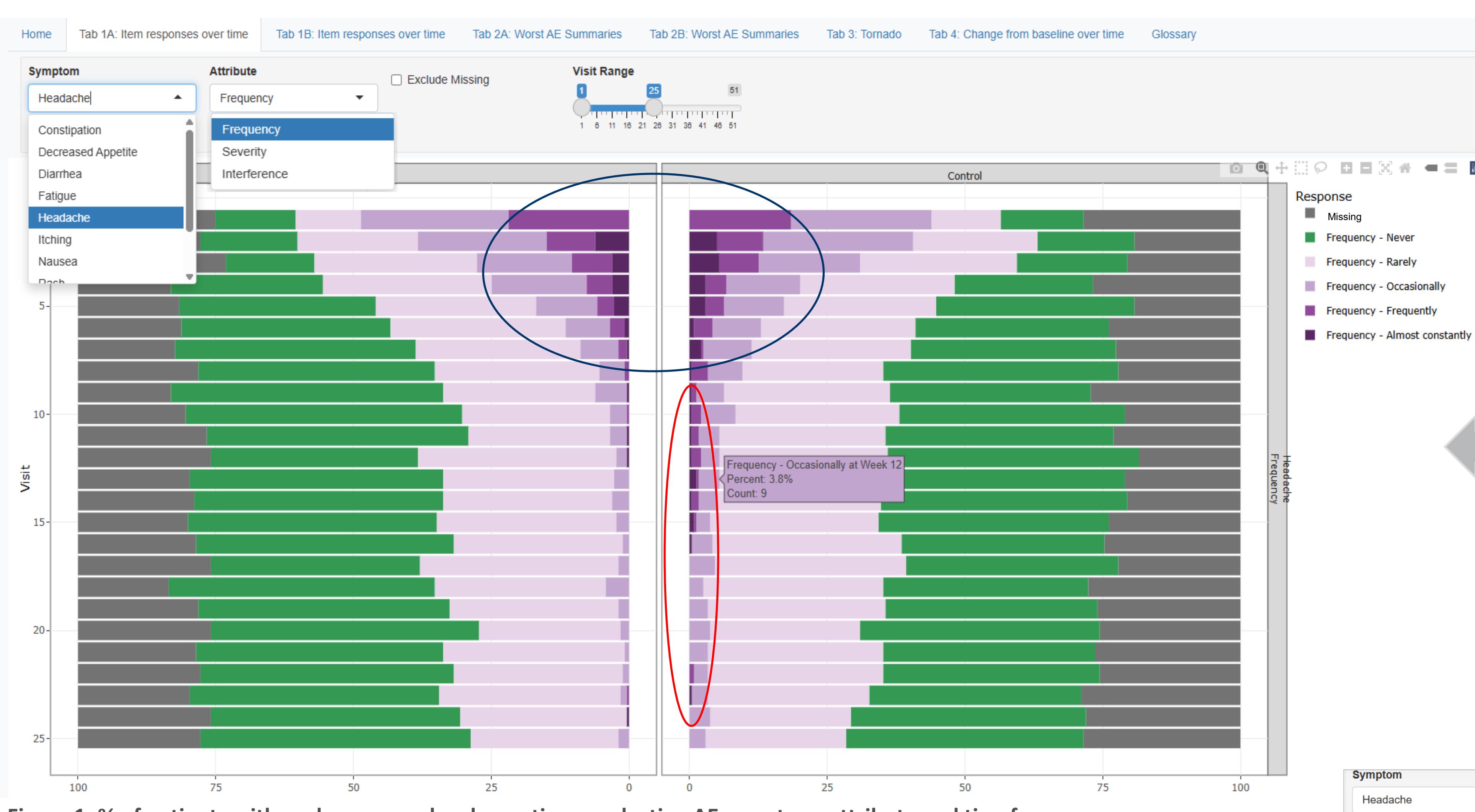
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## BACKGROUND

- > 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

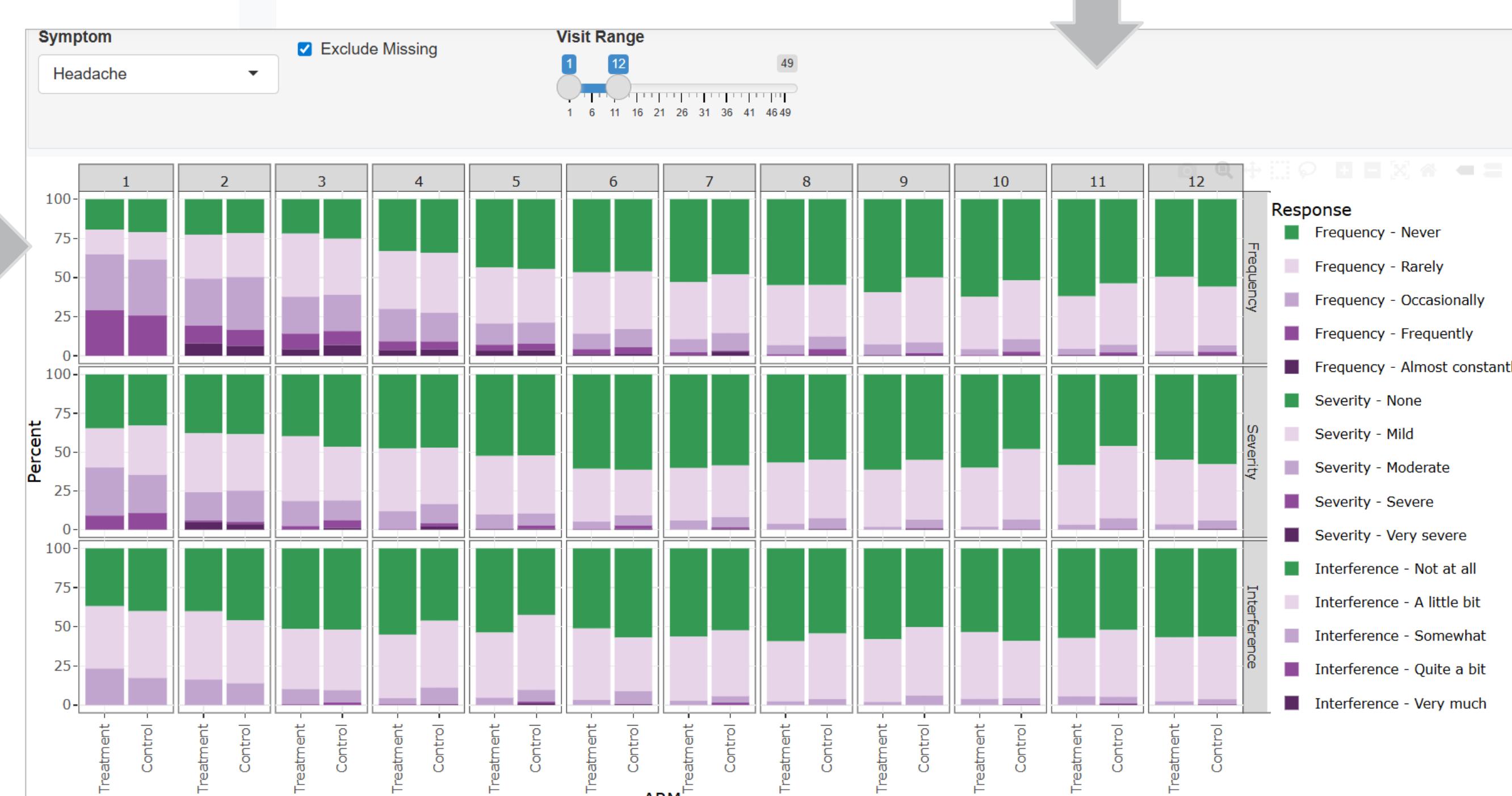
- > Our primary aim was to identify what are the **key research questions** that may follow from the collection of PRO-CTCAE data
- > Our next aim was to demonstrate how these research questions could be addressed through **effective visualisation methods**. We designed an interactive R Shiny dashboard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



### Question 1. When do symptoms occur?

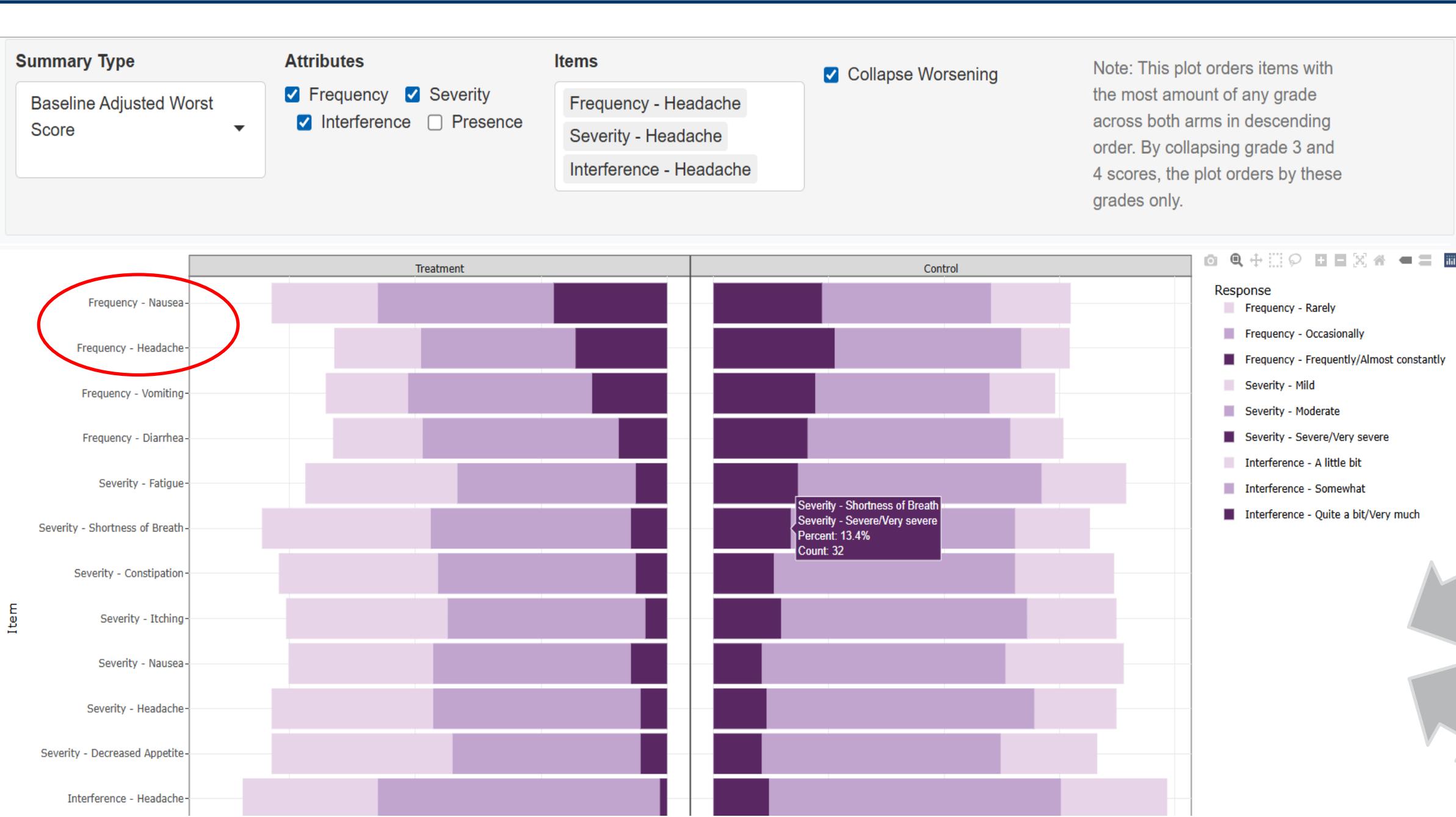
#### Figure 1:

- 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.



### 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)