

# PATIENT-REPORTED OUTCOMES VERSION OF THE COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (PRO-CTCAE™) ITEM LIBRARY (Version 1.0)

| Oral   |    |
|--|----|
| Dry mouth  | S  |
| Difficulty swallowing                                      | S  |
| Mouth/throat sores   | SI |
| Cracking at the corners of the mouth (cheilosis/cheilitis) | S  |
| Voice quality changes                                      | P  |
| Hoarseness   | S  |

| Gastrointestinal   |     |
|--------------------|-----|
| Taste changes      | S   |
| Decreased appetite | SI  |
| Nausea             | FS  |
| Vomiting           | FS  |
| Heartburn          | FS  |
| Gas                | P   |
| Bloating           | FS  |
| Hiccups            | FS  |
| Constipation       | S   |
| Diarrhea           | F   |
| Abdominal pain     | FSI |
| Fecal incontinence | FI  |

| Respiratory         |    |
|---------------------|----|
| Shortness of breath | SI |
| Cough               | SI |
| Wheezing            | S  |

| Cardio/Circulatory |     |
|--------------------|-----|
| Swelling           | FSI |
| Heart palpitations | FS  |

| Cutaneous    |   |
|--------------|---|
| Rash         | P |
| Skin dryness | S |
| Acne         | S |
| Hair loss    | A |
| Itching      | S |
| Hives        | P |

|                         |   |
|-------------------------|---|
| Hand-foot syndrome      | S |
| Nail loss               | P |
| Nail ridging            | P |
| Nail discoloration      | P |
| Sensitivity to sunlight | P |
| Bed/pressure sores      | P |
| Radiation skin reaction | S |
| Skin darkening          | P |
| Stretch marks           | P |

| Neurological        |    |
|---------------------|----|
| Numbness & tingling | SI |
| Dizziness           | SI |

| Visual/Perceptual |    |
|-------------------|----|
| Blurred vision    | SI |
| Flashing lights   | P  |
| Visual floaters   | P  |
| Watery eyes       | SI |
| ringing in ears   | S  |

| Attention/Memory |    |
|------------------|----|
| Concentration    | SI |
| Memory           | SI |

| Pain         |     |
|--------------|-----|
| General pain | FSI |
| Headache     | FSI |
| Muscle pain  | FSI |
| Joint pain   | FSI |

| Sleep/Wake |    |
|------------|----|
| Insomnia   | SI |
| Fatigue    | SI |

| Mood        |     |
|-------------|-----|
| Anxious     | FSI |
| Discouraged | FSI |
| Sad         | FSI |

| Gynecologic/Urinary                |    |
|------------------------------------|----|
| Irregular periods/vaginal bleeding | P  |
| Missed expected menstrual period   | P  |
| Vaginal discharge                  | A  |
| Vaginal dryness                    | S  |
| Painful urination                  | S  |
| Urinary urgency                    | FI |
| Urinary frequency                  | FI |
| Change in usual urine color        | P  |
| Urinary incontinence               | FI |

| Sexual                        |   |
|-------------------------------|---|
| Achieve and maintain erection | S |
| Ejaculation                   | F |
| Decreased libido              | S |
| Delayed orgasm                | P |
| Unable to have orgasm         | P |
| Pain w/sexual intercourse     | S |

| Miscellaneous                       |    |
|-------------------------------------|----|
| Breast swelling and tenderness      | S  |
| Bruising                            | P  |
| Chills                              | FS |
| Increased sweating                  | FS |
| Decreased sweating                  | P  |
| Hot flashes                         | FS |
| Nosebleed                           | FS |
| Pain and swelling at injection site | P  |
| Body odor                           | S  |



| Attributes   |                     |
|--------------|---------------------|
| F: Frequency | I: Interference     |
| S: Severity  | P: Presence/Absence |
| A: Amount    |                     |