

Ontology of **hypoxia**

As related to Cytokine Release Syndrome (CRS)

Hypoxia is a common manifestation of CRS and a critical factor in determining its severity.

DE-RISKING CYTOKINE RELEASE SYNDROME

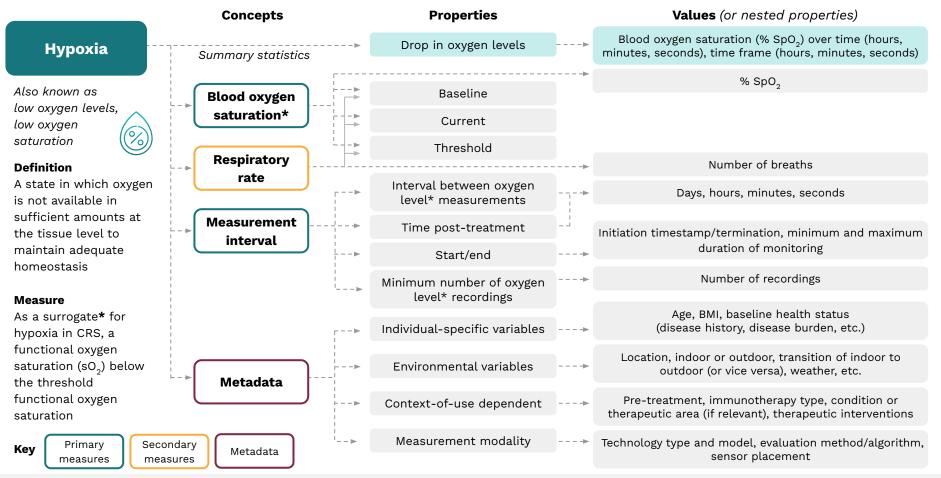


Digital Measures Development

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Examples

Blood oxygen saturation

Baseline

Baseline: Blood oxygen levels at pre-infusion time; blood oxygen levels over last two days.

Definition: Blood oxygen levels over a specified timeframe for use as a comparator to future blood oxygen level recordings.

Defining the parameters of baseline blood oxygen levels will lead to more personalized evaluation of the development of hypoxia.

Blood oxygen saturation

Threshold

Threshold: <90% SpO2; below 2 standard deviations from baseline.

Definition: The point at which the measurement signals reach a critical transition.

Defining the parameters of threshold SpO_2 will lead to earlier identification of CRS progression and consistency in CRS grading.

Measurement interval

Interval between measures: Every four hours (standard of care) with continuous monitoring.

Duration: 14 days (recommended observation period for CRS).

Measure considerations and assumptions:

- Sensor detection for blood oxygen saturation should be clinically validated for use in diverse patient populations and should reflect the use population. This includes ensuring the sensors accurately capture SpO₂ levels across different skin tones.
- Context is key; respiration rates can be influenced by factors such as circadian rhythm, emotional states, physical activity, and medical conditions. Movement can disrupt photoplethysmography (PPG) signals from pulse oximeters, leading to inaccurate oxygen saturation measurements.
- Sensor placement (e.g., wear location) can influence the measurement, conversion, and prediction algorithms for blood oxygen saturation and hypoxia, respectively.
- Blood oxygen saturation levels may be influenced by confounding disease states (e.g., COPD, sleep apnea). Baseline blood oxygen saturation is essential for creating safe thresholds while limiting false positives.

More more CRS resources are available to support you.

Full ontology of early warning signs of CRS



Ontology of fever generation



Ontology of tachycardia



Ontology of hypotension



<u>Ontology of hypoxia</u>

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