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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Ontology of **hypoxia**

Hypoxia

Also known as low oxygen levels, low oxygen saturation

Definition
A state in which oxygen is not available in sufficient amounts at the tissue level to maintain adequate homeostasis

Measure
As a surrogate* for hypoxia in CRS, a functional oxygen saturation (sO_2) below the threshold functional oxygen saturation

Key
Primary measures | Secondary measures | Metadata

Concepts	Properties	Values *(or nested properties)*
Summary statistics	Drop in oxygen levels	Blood oxygen saturation (% SpO_2) over time (hours, minutes, seconds), time frame (hours, minutes, seconds)
Blood oxygen saturation*		% SpO_2
	Baseline	
	Current	
	Threshold	
Respiratory rate		Number of breaths
Measurement interval	Interval between oxygen level* measurements	Days, hours, minutes, seconds
	Time post-treatment	
	Start/end	Initiation timestamp/termination, minimum and maximum duration of monitoring
	Minimum number of oxygen level* recordings	Number of recordings
Metadata	Individual-specific variables	Age, BMI, baseline health status (disease history, disease burden, etc.)
	Environmental variables	Location, indoor or outdoor, transition of indoor to outdoor (or vice versa), weather, etc.
	Context-of-use dependent	Pre-treatment, immunotherapy type, condition or therapeutic area (if relevant), therapeutic interventions
	Measurement modality	Technology type and model, evaluation method/algorithm, sensor placement

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 SpO_2 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

Ontology of hypoxia

Visit the project page

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