

## Background

Cytokine Release Syndrome (CRS) is a common and severe adverse event (AE) for oncology patients and those with other immunological conditions receiving potentially life-saving immunotherapy treatments [1]. Due to the serious nature of CRS, immunotherapy patients are often hospitalized for considerable durations following infusions.

Timely response to CRS can mitigate worsening severity and costs and improve patient outcomes [2]. Cost effective patient management following infusions remains a challenge in immunotherapy treatment [3]. We are advancing a novel risk-monitoring solution that leverages the Ametris Connect platform to gather first-in-kind continuous data in these patient populations. This enables a deeper understanding of immunotherapy-related challenges in oncology and immunology clinical trials and develop early-warning algorithms to address these challenges.

### **Treatment Pathway**

When patients are set to receive an immunotherapy, they are enrolled onto an eligible care platform and physiological baselines are established leading up to the infusion. Patients are then monitored for AEs that

may onset immediately following treatment. Algorithms aid healthcare professionals (HCPs) in deciding to discharge patients to an outpatient setting. In the outpatient setting, HCPs still have a continuous view of the patient and Al-powered algorithms to alert them if an AE requiring inpatient treatment is onsetting so patients can be instructed to return to the hospital for timely treatment.



### **Features and Benefits**



#### **Immunotherapy Cost**

Immunotherapies can have prohibitively high costs because of the need for hospitalization following infusion. If treatments could be given on an outpatient basis, trials could be conducted at lower costs. This would increase the number of patients able to afford life-saving treatment.

#### **Patient Safety and Comfort**

CRS is a dangerous AE that requires timely intervention, and remote monitoring allows for rapid response to AE onset. Lengthy hospital stays are burdensome on already sick patients. Treatment on an outpatient basis would be less burdensome and encourage clinical trial participation.

#### **Clinical Trial Access**

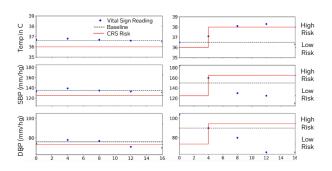
The need for hospitalization following treatment also restricts the geography of patients who can participate. If more trials could be done remotely, more patients could access these trials, which would allow for more rapid development.

#### **Novel Clinical Insights**

The current standard of care for CRS consists of episodic monitoring of patient vitals and treatment based on a physician's discretion, which can introduce subjectivity. The collection of continuous, objective physiological data provides a more wholistic view of the immune response and when it may become dangerous, advancing our understanding of how to safely develop effective immunotherapy treatments.

# **AI-Powered CRS Monitoring**

With existing standard-of-care immunotherapy data, we have developed multivariate AI algorithms to distinguish between CRS of certain grades. Two case studies from real-world data are shown: i. a patient who did not develop CRS with temperature and blood pressure values at pre-infusion levels in the 16 hrs after treatment; ii. another patient who developed CRS Grade ≥2 post-infusion with signs of fever and hypotension.



#### References

- [1]: Shimabukuro-Vornhagen et al., 2018.
- [2]: Abramson et al., 2021.
- [3]: Immunotherapy: Precision medicine in action. Johns Hopkins. 2017.



Learn more about how Ametris' Al-powered solutions can advance immuno-oncology trials