Breaking Barriers with Digital Health Technologies: Advancing CRS Risk Prediction

DATAcc
Digital Health Measurement Collaborative Community
by DiMe

DE-RISKING CYTOKINE RELEASE SYNDROME
Digital Measures Development

WEBINAR

Thursday, February 13

11 am - 12 pm ET

RECORDINGS POSTED HERE

Agenda

- **Welcome and background of project**
- Overview of research conducted, common measures & resources
- Fireside chat: A decade of resilience
- Panel discussion - Current Best Practices, Innovative Approaches, and Unmet Needs in CRS Management: Charting a Future with Technology
- Panel Discussion - Technical requirements and considerations for clinical evidence generation for developing CRS de-risking products
- Panel discussion - Developing CRS de-risking products: Balancing clinical strategy with regulatory requirements
- Closing remarks

But first, housekeeping

- **Today's session is being recorded.**
  - Slides and recording will be available on DiMe's webinar page after the session
- **Type your question** into the chat box for discussion.
- **Participants are not permitted to transcribe this webinar**. Violators will be removed from the session

DiMe convenes stakeholders to take action to fix the problems in our complex field

DATACC by DME

OUR MISSION:

To advance the safe, effective, and equitable use of digital approaches to **redefine healthcare** and **improve lives**

OUR VISION:

Better health powered by digital innovation

DE-RISKING CYTOKINE RELEASE SYNDROME

Digital Measures Development

Leveraging digital innovations to support the development of a risk prediction tool for CRS

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Project Partners

ACCC
ActiGraph
Analog Devices
Atrium Health Levine Cancer Institute
Best Buy Health
Biofourmis
blue spark
Bristol Myers Squibb
canopy
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FDA
FNIH Foundation for the National Institutes of Health
Friends of Cancer Research
Genentech A Member of the Roche Group
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Johnson & Johnson Innovative Medicine
Leukemia & Lymphoma Society
Mika
Orion Pharma
Pfizer
Takeda
verily a precision health company

Partners also include the National Cancer Institute

Source: CRS

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Leveraging digital innovations to support the development of CRS de-risking products

+ LEARN MORE HERE

Today, Cytokine Release Syndrome (CRS) requires regular clinical oversight through extended hospitalizations, creating barriers to care and limiting patient access to vital immunotherapies. Digital health technologies (DHTs) have matured to a point where we can—and should—rely on them to detect the onset of CRS, enabling monitoring and risk prediction **beyond the clinic**.

To support, DATAcc by DiMe has developed resources to **support the development of trustworthy CRS de-risking products** that can enable earlier detection and management, empowering oncologists to improve patient outcomes globally.

Bring your CRS de-risking product to market

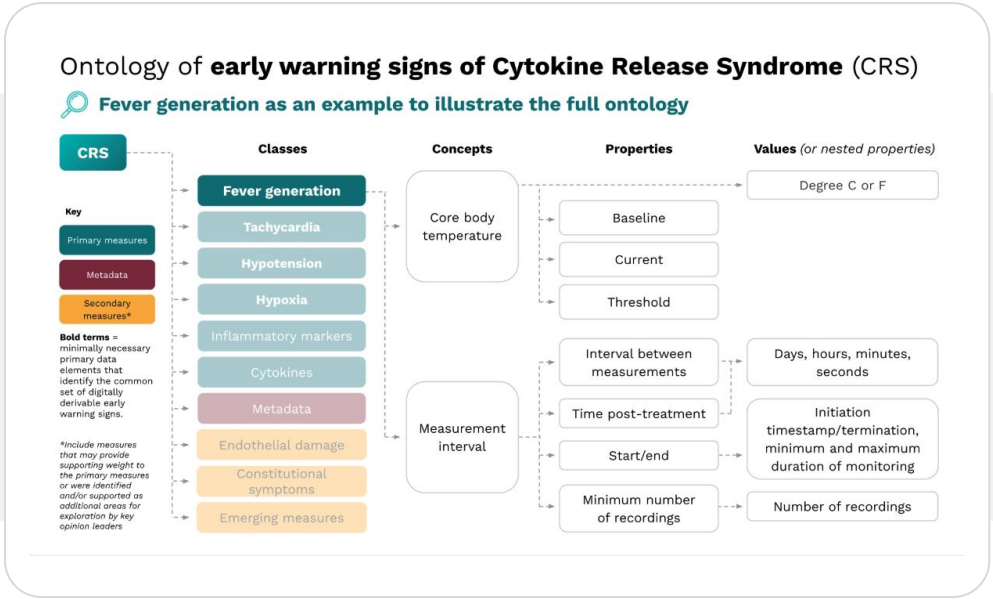
A practical, interactive guide

- ✓ Value proposition
- ✓ Current opportunities of DHTs, including harmonization of data collection
- ✓ Insights for navigating key developmental milestone

Ontology of early warning signs of CRS

CRS Innovation Roadmap

Early digital clinical measures of CRS to advance CRS de-risking products



Common set of digital clinical measures

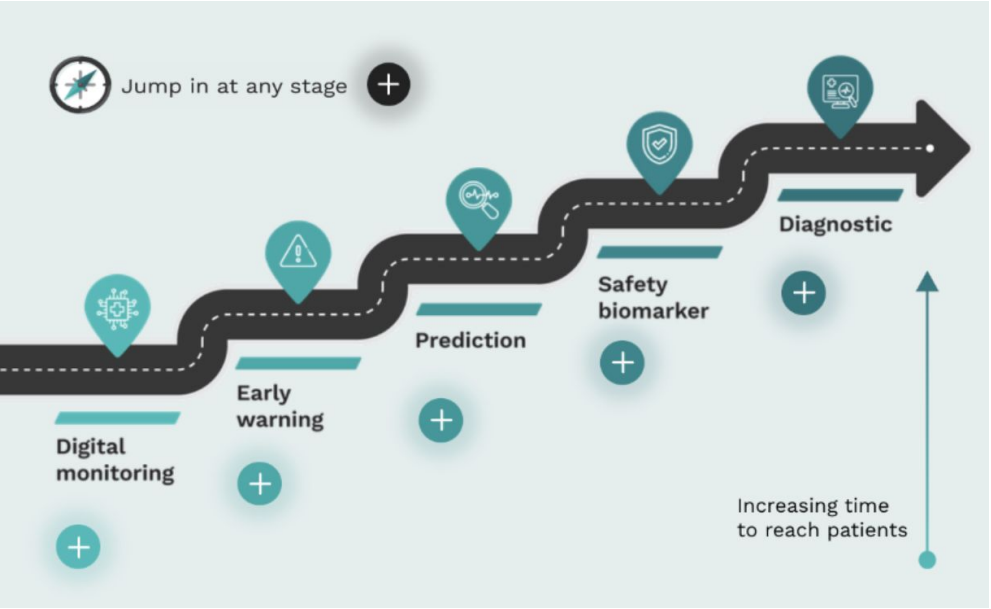

Ontology of fever generation


Ontology of tachycardia


Ontology of hypotension


Ontology of hypoxia

From vision to reality, a strategic approach for developing CRS de-risking products



Digital monitoring

- **Goal**: Deploy DHTs available today to monitor the same or similar vital signs and symptoms currently observed in the hospital environment. {add link to measures page resource}
- **Impact**: Shorten time-to-market by relying on existing DHTs and standard of care measures to immediately support healthcare providers and immunotherapies in the outpatient setting, reduce patient burden, and shorten hospitalization periods.
- **Barriers to adoption**: The technical challenges are largely resolved, however, work is needed to make clinical workflows compatible with a remote patient monitoring approach, including reimbursement and EHR integration challenges.
- **Examples**: TempTraq, Current Health RPM Platform, and the Apple Watch are used in clinical trials and care for remote monitoring of CRS and other immunotherapy-related events in outpatient settings.

BACK TO ROADMAP ↑

Breaking Barriers with Digital Health Technologies: Advancing CRS Risk Prediction

Fireside chat - A decade of resilience

Michael Hibberts
Lived experience patient

Samantha McClenahan
Program Lead,
Digital Medicine Society (DiMe)

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Panel discussion - Current Best Practices, Innovative Approaches, and Unmet Needs in CRS Management: Charting a Future with Technology

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Cindy Varga
Physician, Hematology and Oncology
Atrium Health

Matt Wilkes
Senior Medical Director
Best Buy Health

Nazila Shafagati
Medical Oncologist
Johns Hopkins Medicine

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Panel discussion - Technical requirements and considerations for clinical evidence generation for developing CRS de-risking products

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Erik Koenig
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Executive Vice President, Marketing and Innovation
Blue Spark Technologies

Michael Pettinati
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ActiGraph

Nunzio Camerlingo
Manager, AI/ML Quantitative & Digital Sciences
Pfizer

Breaking Barriers with Digital Health Technologies: Advancing CRS Risk Prediction

Panel discussion - Developing CRS de-risking products: Balancing clinical strategy with regulatory requirements

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Benjamin Vandendriessche
Chief Delivery Officer
Digital Medicine Society (DiMe), Moderator

Chris Medberry
Director, Global Regulatory Affairs Digital Health
The Janssen Pharmaceutical Companies of Johnson & Johnson

Seth Kuzdzal
Principal Consultant
Digital Health Regulatory Solutions

Breaking Barriers with Digital Health Technologies: Advancing CRS Risk Prediction

Closing remarks

Jennifer Goldsack
CEO
Digital Medicine Society (DiMe)

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Driving innovation and impact in pediatric care

WEBINAR

Thursday, February 25

11 am - 12 pm ET

DIGITAL MEDICINE SOCIETY

The Playbook

Pediatric Digital Medicine

DiME Boston Children's Hospital

Adriana Krasniansky
Principal, Head of Research
Rock Health

Amy Molten
Chair, Section on Advances in Therapeutics & Technology
American Academy of Pediatrics

David Bergman
Professor Emeritus, Pediatrics
Stanford University School of Medicine

Katerina Placek
Senior Manager, Digital Health Sciences
Takeda Pharmaceuticals

Katie Taylor
Founder and CEO
Child Life On Call

Mary Mulcare
Chief Medical Officer
Summus

Sallie Guezuraga
Director, International Services & Business Development
Children's Mercy Hospital

Sarah Scalia
Director, Innovation Business Development
Boston Children's Hospital

Optimizing Treatment *of* **Type 2 Diabetes** using Sensor Data

Unlocking digital health data to advance type 2 diabetes and comorbidities care

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