



# FACT Cellular Therapy Accreditation Workshop

**FEBRUARY 20, 2024 | 8:00 AM - 5:00 PM**

*Host*



**Joseph Schwartz, MD, MPH**

Director of Transfusion Services at H. Lee Moffitt Cancer Center & Research Institute Blood and Marrow Transplant Program

*Presenters*

*Agenda*



**Suzanne Birnley MS, MBA**

FACT Director of Operations



**Patrick Hanley, PhD**

Chief & Director of the Cellular Therapy Program at Children's National



**Kimberly Kasow, DO**

Director of Pediatric Bone Marrow Transplant at University of North Carolina



**Premal Lulla MD, MBBS**

Assistant Professor of Medicine at Baylor College of Medicine, Stem Cell Transplant Program, Texas Children's Hospital and Houston Methodist Hospital



**Nic Prokopishyn, PhD**

Cellular Therapy Lab Director for the Alberta Blood and Marrow Transplant Program



**Michele Sugrue, MS, MT(ASCP)SBB**

FACT Inspectorate



**Phyllis I. Warkentin, MD**

FACT Chief Medical Officer

## REGISTRATION

7:30 AM

## WELCOME

8:00 AM

**Joseph Schwartz, MD, MPH**

## OVERVIEW OF FACT ACCREDITATION

8:05 AM

**Joseph Schwartz, MD, MPH**

The accreditation process is described in detail from application to final accreditation, defining the common terminology for the accreditation process and explaining the function of the accreditation coordinator. This session summarizes the inspector's role in the process of accreditation. The audience has an opportunity to participate in interactive knowledge checks throughout the presentation.

## THE KEY TO COMPLIANCE SUCCESS

9:00 AM

**Michele Sugrue, MS, MT(ASCP)SBB**

In this session, the presenter reviews the entire compliance application process and identifies the documents required for submission.



## ACTIVITY: EVALUATING COMPLIANCE

9:30 AM

During this activity, the audience has the opportunity to identify what challenges the program faces after each case and is polled to determine what issues may not comply with the standards. With help from the facilitators, the audience assists in answering how the program can achieve compliance with FACT Standards and achieve FACT accreditation.

## ACCREDITATION SUCCESS STORY

10:00 AM

## BREAK

10:15 AM

## LEVERAGING FACT ACCREDITATION TO REDUCE AUDIT BURDENS

10:30 AM

**Phyllis I. Warkentin, MD**

This session discusses current activities aimed at leveraging FACT Accreditation to reduce commercial manufacturer audit burdens on programs.

## STANDARDS TEASER

11:00 AM

**Nic Prokopishyn, PhD**

This session provides an overview of the Standards development process and an update on the 9th Edition HCT Standards.

## ASK FACT ANYTHING

11:30 AM

Throughout the morning presentations, attendees have the opportunity to submit questions for FACT presenters to answer.

**LUNCH**

11:45 AM

**WHAT TO EXPECT DURING THE INSPECTION**

12:15 PM

**Kim Kasow, DO**

The presenter analyses clinical program requirements, offering insights for both preparation leading up to and during a FACT inspection. This presentation includes valuable tips and strategies to assist clinical programs in successfully navigating the inspection process.


**ACTIVITY: CLINICAL VIDEO TOUR**

1:00 PM

Participants are shown a tour video demonstrating an inspector conducting a clinical inspection. Participants are provided with a tour checklist and can mark compliant or not compliant next to the Standards applicable to the tour.

**WHAT TO EXPECT AFTER THE INSPECTION**

1:15 PM

**Suzanne Birnley MS, MBA**

Participants are provided an overview of the steps in the accreditation process that occur after the inspection, including receiving the report and responding to deficiencies.

**CORRECTION OF DEFICIENCIES**

1:30 PM

**Joseph Schwartz, MD, MPH**

This session reviews the most common challenges in clinical transplant and allows participants to construct a plan to correct the deficiencies.


**ACTIVITY: DISSECTING DEFICIENCIES**

1:45 PM

Participants practice evaluating deficiencies with the presenter and recommend corrective action.

Thank you to our partners for their generous support:

**ACCREDITATION SUCCESS STORY**

2:30 PM

**BREAK**

2:45 PM

**COMPONENTS OF CORRECTIVE ACTION PLANS AND AUDITS FOR OUTCOMES AND DATA MANAGEMENT**

3:00 PM

**Premal Lulla MD, MBBS**

This session reviews FACT requirements for corrective action plans to improve clinical outcomes and the expectations of applicants for data management.

**MAINTAINING FACT READINESS**

3:30 PM

**Patrick Hanley, PhD**

In this session, the presenter reviews plans to ensure continuous accreditation readiness and explains the self-assessment process. Participants will learn how to manage turnover to maintain accreditation readiness.


**ACTIVITY: STRATEGIES TO MAINTAIN READINESS**

4:00 PM

During this session, the presenter facilitates case studies and works with participants to determine how to maintain compliance readiness.

**ASK FACT ANYTHING**

4:30 PM

Throughout the afternoon presentations, attendees have the opportunity to submit questions for FACT presenters to answer.

**CLOSING**

4:45 PM

Access a complete directory of FACT resources and social channels by scanning this QR code or visiting <https://linktr.ee/factcelltherapy>

