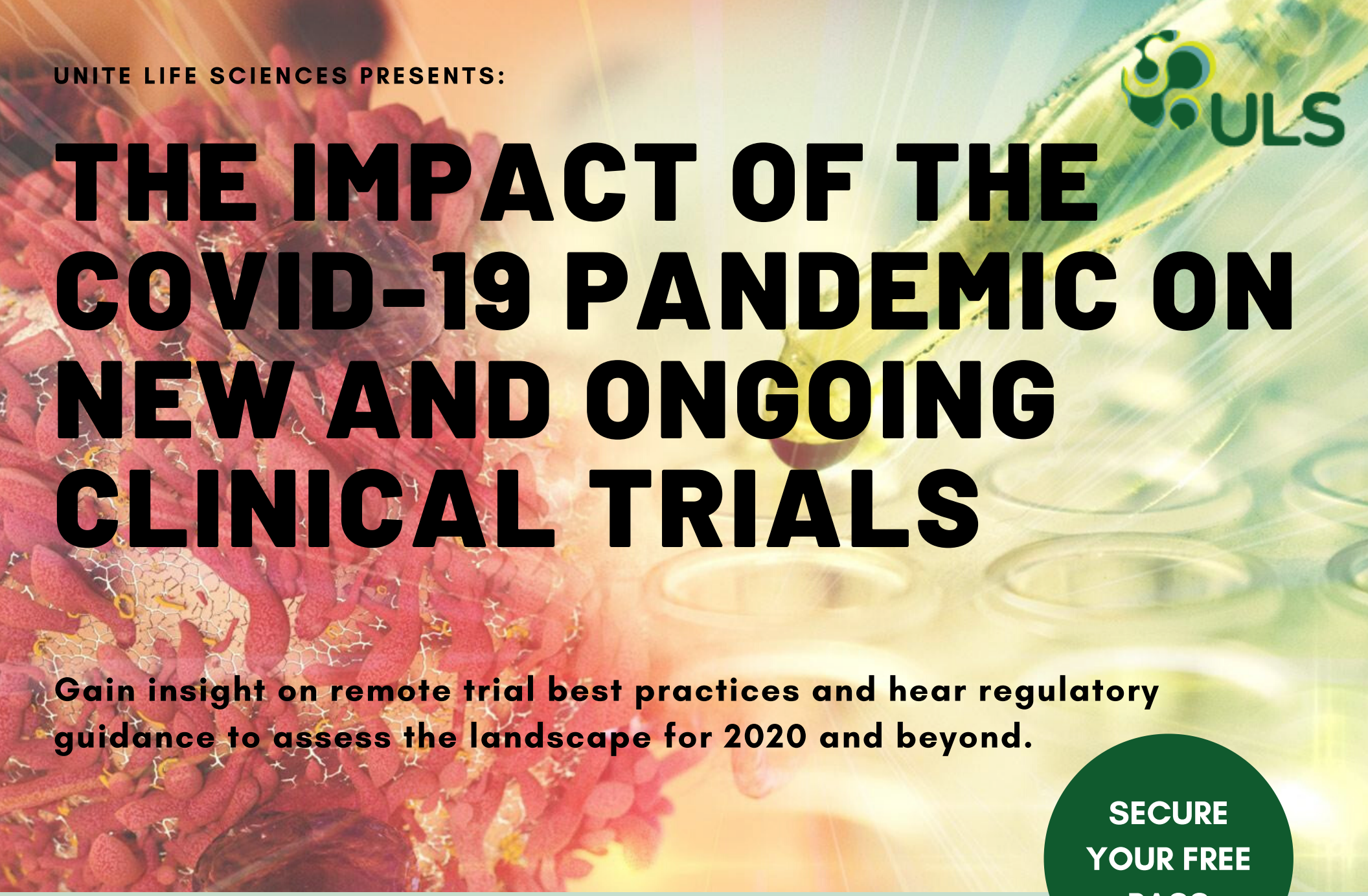

UNITE LIFE SCIENCES PRESENTS:

ULS

THE IMPACT OF THE COVID-19 PANDEMIC ON NEW AND ONGOING CLINICAL TRIALS

Gain insight on remote trial best practices and hear regulatory guidance to assess the landscape for 2020 and beyond.

SECURE YOUR FREE PASS

FREE VIRTUAL SUMMIT

JUNE 25 - 26, 2020

www.ulsclinicaltrialsdigital.com

*vendor participation is not free

ULS

The first half of 2020 has significantly impacted the clinical trial landscape. As the country continues to navigate the ongoing COVID-19 pandemic:

- Hear FDA guidance in in real-time for new and ongoing trials, and take part in an interactive Q&A to discuss due diligence, compliance and preparation for what comes next
- Learn from those who have already navigated telehealth, decentralized models and e-health solutions, what do they have to tell you?
- Understand the risk and what needs to be in place before diving into remote, digital trial models
- Take part in an interactive virtual experience and convene with key decision makers in clinical trial design, strategy and operations as they discuss challenges facing the industry and how to overcome them

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FEAUTRED SPEAKERS

Diane Maloney
Associate Director Policy, Center for Biologics Evaluation & Research (CBER)
Food and Drug Administration (FDA)

Leslie Jebson
Executive Director, Clinical Strategy
Texas A&M Health

Jennifer Healey
Global Head, Medical Operations
Sanofi

Prof. Steffen Thirstrup, MD, PhD
Director
NDA Regulatory Advisory Board

Jeff Douglas
Head of Clinical Operations
MyoKardia

Len Rosenberg PhD, RPh
Head, Clinical Operations
Beat AML/LLS

Craig Lipset
Fmr. Head of Clinical Innovation
Pfizer

Rose Gerber
Director of Patient Advocacy & Education
Community Oncology Alliance (COA)

DAY 1: THURSDAY JUNE 25

9:30 AM ET

Current Regulatory Guidance on Managing New and Ongoing Clinical Trials in the Ongoing COVID-19 Pandemic and 2020

Hear an update from the FDA on the latest regulatory guidance, how the agency is taking the current climate into consideration for clinical trials impacted by the ongoing pandemic, and what study teams can do to prepare for the rest of the year. 10 minute Q&A to follow presentation.

45 min

Diane Maloney, *Associate Director, Policy, Center for Biologic Evaluation and Research (CBER)*, **Food and Drug Administration (FDA)**

10:30AM ET

Global Regulatory Lessons From COVID19 to Shape The Future of Clinical Trials For Industry and Agencies

Discuss the contingency measures organizations have put into place during the pandemic and the impact on their way of working and procedures for long term. How are companies managing with the intelligence of and compliance with varying country-specific, unique COVID-19 requirements and what influence can the industry put on the Agencies to maintain the flexibility of executing clinical trials that has been allowed during the pandemic phase? Examine Measures being taken to adapt to the changing nature of inspections in a Remote-Audit World and what challenges and remediation measures are being faced such as data privacy concerns.

45 Min

Prof. Steffen Thirstrup, MD, PhD, *Director*, **NDA Regulatory Advisory Board**

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DAY 1: THURSDAY JUNE 25

11:30 AM ET

Patient Engagement in 2020 and Beyond

Learn how to take advantage of decentralized, patient-centric approaches and opportunities. How can organizations optimize patient identification and communication when in person communication is not feasible? Examine strategies for leveraging telehealth and remote monitoring solutions for clinical trial participants. Explore the pros and cons of clinical trial promotions during a pandemic.

45 min

Leslie Jebson, *Executive Director of Clinical Business Operations*, **Texas A&M Health Science Center**
Rose Gerber, *Director of Patient Advocacy and Education*, **Community Oncology Alliance (COA)**

12:30PM - 2:30 PM ET

Scheduled Virtual Networking Meetings

DAY 2: FRIDAY JUNE 26

10:00 AM ET

Moderated Chat: Navigating Outbreak-Related Challenges in Ongoing Clinical Trials

Discuss what it means to navigate the COVID-19 Pandemic, day to day operations, management, remote working and planning a return to "normalcy. Explore strategies for ongoing clinical trial management during and after outbreaks, site closures, and other obstacles in 2020 like preparing for a 2nd
wave of COVID19.

45 min

Jeff Douglas, *Head of Clinical Operations*, **MyoKardia**
Jennifer Healey, *Global Head of Medical Operations*, **Sanofi**

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DAY 2: FRIDAY JUNE 26

11:00 AM ET

Moderated Chat: Accelerating the Drive to Digital, Virtual and Hybrid Clinical Trials

The impact of the current pandemic and COVID19 on clinical trials has acted as an accelerant to the shift towards partial or fully virtual trial designs. What best practices can be gleaned by early pioneers of this model, and how can existing and future trials streamline the transition?

45 min

Craig Lipset, *Fmr. Head of Clinical Innovation*, **Pfizer**
Moderator: Len Rosenberg, *PhD, RPh, Head, Clinical Operations*, **Beat AML/LLS**

12:00PM - 1:00 PM ET

Break

1:00 PM ET

Moderated Chat: Diagnostics & Testing Integration in Future Patient Screening

How might future trial design change to accommodate new requirements? Explore digital options like eHealth diagnostic devices and other technology innovations.

30 Min

1:45 PM ET

The Implications for Risk Mitigation in Clinical Trials After COVID-19

Identify future aspects of liability exposure and risk management for clinical sites. What type of inclusion of protection and language around documents for clinical trial participation will need to be considered for future trials?

30 Min

12:30PM - 2:30 PM ET

Scheduled Virtual Networking Meetings

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