SOCIETY FOR CLINICAL TRIALS

VOLUME 31, #2 FEBRUARY 2020

INSIDE THIS ISSUE:

Registration is open for the 41st Annual Meeting of the Society for Clinical Trials!

Please join us! This year's theme will be:

"Enhancing and Enabling the Clinical Trials Ecosystem through Interdisciplinary Collaborations"

Our Annual Meeting brings together the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups and centers and clinical research entities.

Click here to learn more about SCT's 41st Annual Meeting

REGISTER NOW

May 17 - May 20, 2020

at the

Baltimore Marriott Waterfront Hotel

700 Aliceanna Street

Baltimore, MD 21202

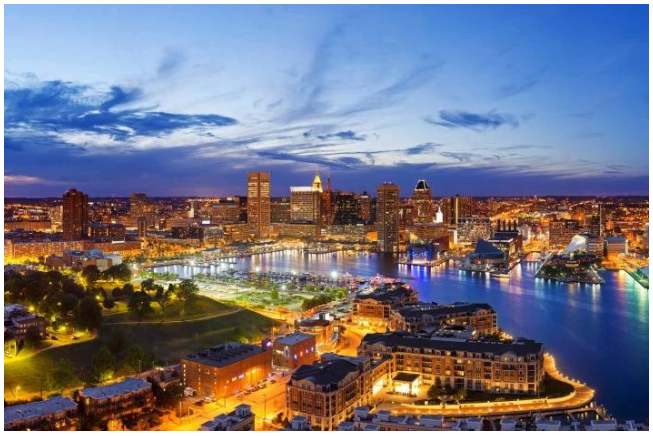
SCT 41st Annual Meeting Overview

About the Annual Meeting

The Annual Meeting of the Society for Clinical Trials is a multidisciplinary program with broad participation. The Meeting brings together the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups and centers and clinical research entities.

Educational Highlights include:

- Plenary sessions, simultaneous workshops and contributed presentations in presentations and posters
- Pre-meeting workshop courses by leaders in the field
- Annual Student Scholarship Competition
- Exhibits from vendors showcasing publications, technology and other resources for clinical trials
- Discussions of timely issues and research experiences among colleagues in the field of clinical trials
- National/International travel opportunities
- Presentation of the 2019 Trial of the Year Award
- Presentation of the SCT Class of 2020 Fellows



This year's meeting will be held at the Baltimore Marriott Waterfront in Baltimore, Maryland, USA. Located in Harbor East, the Marriott provides unparalleled access to Fells Point, the National Aquarium and the restaurants and shops of the Inner Harbor. We look forward to welcoming you to the Baltimore Marriott Waterfront, providing the perfect forum to host over 500 clinical trials colleagues, located in the heart of the city near fabulous restaurants and shopping.

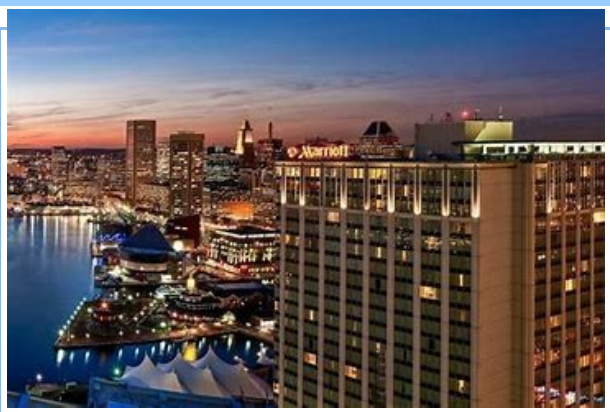
The program is being developed by the SCT Program and & Education Committees, and promises to make the best of this unique opportunity for international collaboration.

We look forward to welcoming you to Baltimore!

Early Bird registration deadline is March 30, 2020

REGISTER NOW

SCT 41st Annual Meeting Venue



Baltimore Marriott Waterfront

700 Aliceanna Street
Baltimore, MD 21202

Experience Charm City like never before at Baltimore Marriott Waterfront. Located in Harbor East, our hotel provides unparalleled access to Fells Point, the National Aquarium and the restaurants and shops of the Inner Harbor. Redesigned accommodations offer views of the waterfront or the Baltimore skyline, and include modern technology, premium amenities and deep soaking tubs. Elsewhere at the hotel, we invite you to enjoy sustainable local fare at Apropoe's, our stylish waterfront restaurant. We also offer a heated indoor pool and a fully equipped on-site fitness center. Host your next event with us in Baltimore, and impress your guests with our light-filled, flexible venues, several of which overlook the harbor. In addition to being near many of the city's most iconic attractions, we're just a short distance from Baltimore Convention Center, making it easy to attend events there. Whether you're joining us for work or on vacation, we know you're going to love your stay at Baltimore Marriott Waterfront.

SCT Group Rate: $219 single / double (+17.5% tax)
For best availability, make your reservation online at:
Internet: https://book.passkey.com/go/SCTAnnualMeeting2020
Phone: 1-888-511-7809 and mention the Society for Clinical Trials Meeting
The deadline for hotel reservations is Friday, April 24, 2020.
Hotel reservations/rate availability are not guaranteed after the room block is full or after April 24, 2020. Please register early – only a limited number of rooms are available.
Government rates are also available for qualifying attendees by clicking here https://book.passkey.com/go/SCTAnnualMeetingGov. Please note you will be required to verify you qualify for the government rate upon check-in with a valid ID. Please contact info@sctweb.org for additional information.

Check In / Check Out Times

- Check-in: 4:00 pm **- Check-out: 12:00 pm**

Parking

- On-site parking: $8.50 / hour; $26 / day **- Valet: $45 / day**

WARNING: Beware of Unauthorized Hotel Solicitations

SCT does not contract with any provider for hotel reservations associated with our meeting. While other hotel resellers may contact you offering accommodations for your trip, they are not endorsed by or affiliated with the meeting. Beware that entering into financial agreements with non-endorsed companies can have costly consequences. Should you be contacted by any agency other than SCT, please email SCT at info@sctweb.org with the details.

SCT 2020 Board Election is Now Open!

Voting closes March 13, 2020 at 11:59pm CT

Please submit one vote for President Elect and two for the Board of Director seats.

Online voting can be found in the **members only section** of the SCT website.

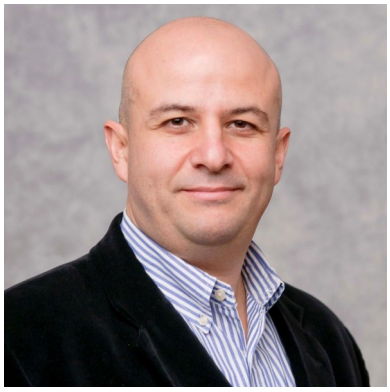
Please note that you must log in to the member area to cast your vote.

Once logged in, you will be able to cast your votes

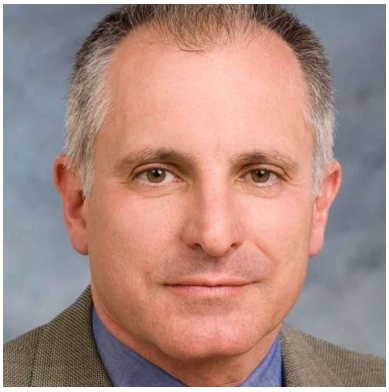
Questions? Issues logging in? Please contact us at info@sctweb.org

President Elect Candidates (Select One)

Mithat Gönen
Memorial Sloan Kettering Cancer Center
View BioSketch



Roger Lewis
Harbor-UCLA Medical Center
View BioSketch



Board of Director Candidates (Select Two)

Kaleab Abebe
University of Pittsburgh School of Medicine
View BioSketch

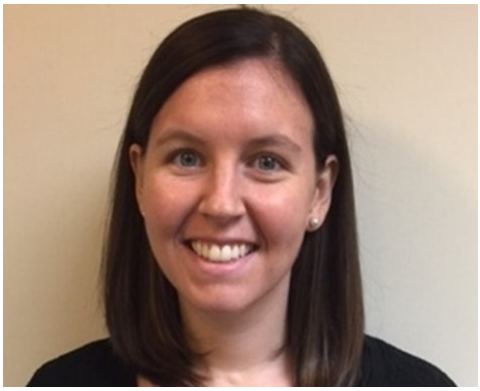
Sin-Ho Jung
Duke University
View BioSketch

Toshi Hamasaki
George Washington University Biostatistics Center and the Department of Biostatistics and Bioinformatics
View BioSketch

Elizabeth Garrett-Mayer
American Society of Clinical Oncology
View BioSketch

Letitia Perdue
Wake Forest School of Medicine
View BioSketch

SCT Member Spotlight – Julia Collins



Julia Collins, M.S.

- **What is your current position?**

I am a clinical study manager at The Emmes Company, LLC, a full-service Contract Research Organization with headquarters in Rockville, Maryland. As part of the Clinical Coordinating Center (CCC) for the NIDA National Drug Abuse Treatment Clinical Trials Network, I am involved in managing substance-use-focused clinical protocols and study implementation at multiple clinical sites across the U.S. I also assist with the development and management of clinical study documents (e.g., clinical trial protocols, operations manuals, informed consent forms, etc.) and am responsible for investigational product procurement and management.

- **What are your past positions?**

Prior to coming to Emmes, I worked as a Clinical Research Coordinator in various fields including sleep medicine, cardiology, and cardiac surgery. In these roles, I coordinated several studies conducted under an IND or IDE. I also previously served as a Clinical Research Unit Manager.

- **What is your training?**

I hold a bachelor's degree in Behavioral Neuroscience from Northeastern University and a master's degree in Regulatory Science from the University of Maryland, Baltimore.

- **What are your specific research interests?**

I am especially fascinated with research related to mental health and neurological disorders.

♦ **What are your hobbies (outside of work)?**

I enjoy hiking, running, traveling, reading, and spending time with family. I also stay busy taking care of my 2-year-old son and preparing for my life with twins, who will be born in the Spring.

- **What role(s) did/do you play in SCT?**

At past SCT Annual Meetings, I have had the opportunity to present an in-conference tutorial, two oral presentations, and one poster, as well as collaborate on many abstracts presented by my colleagues at Emmes. I also currently serve on the SCT Membership Committee.

- **What is your favorite part about being involved in clinical trials?**

After months (and sometimes years) of arduous preparation, I love the deep exhale of relief that comes with the successful activation of study sites and the relatively smooth implementation of the trial (this is also a fun way to see how your fore-thought and planning has paid off!).

  - **Your least favorite?**

  The agony of trying to meet recruitment targets for a difficult population.

- **What do you enjoy most about attending the SCT Annual Meeting?**

In addition to attending sessions and getting insight from external collaborators on topics that could improve my own work flow, it's always a fun opportunity to connect with colleagues outside of the normal work setting and in an interesting town.

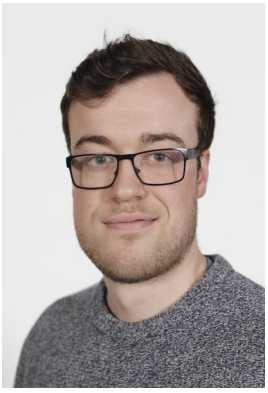
- **Where and when was your favorite SCT meeting (so far)?**

Portland, Oregon – not only was it a great meeting, but I also had the opportunity to visit many friends of mine who live in Portland!

- **What advice would you have for junior researchers just starting out in the field of clinical trials?**

Build your relationships and professional network – this is key! Also, the field of clinical trials is vast with many opportunities for engagement – take your time to find out where your passions and strengths come together and then focus on this area.

SCT Needs Your Help—Webinar Proposals Wanted



Michael Grayling

By Michael Grayling, SCT 2020 Education Committee Co-Chair

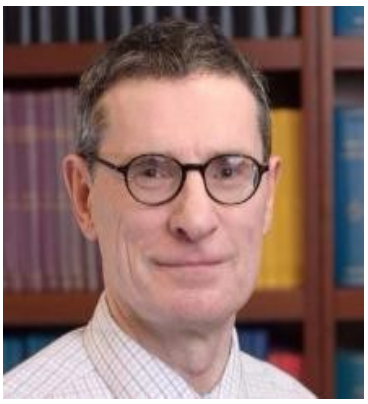
Since 2014, the Education Committee of the Society for Clinical Trials has organized a selection of webinars on cutting-edge topics. Typically one hour in length (with approximately 45 mins reserved for presentation and 15 mins for questions), these webinars are free for SCT members and form a major component of the wonderful educational opportunities that the Society provides each year.

In addition, with many members typically registering to view the webinars live, the webinar series offers a fantastic opportunity for presenters to widely disseminate their work to the trials community. And now, the Education Committee is seeking proposals from presenters for webinars in 2020, from any area of interest to the Society and its membership.

For an idea of the typical format of a webinar, please refer to the recordings of previous presentations available online in the members only section. Otherwise, to submit a proposal for a webinar (or to receive additional information) please contact Michael Grayling at michael.grayling@ncl.ac.uk, including an indicative title and an outline description of what would be discussed. The Education Committee looks forward to hearing from you!

CLINICAL TRIALS
Journal of the Society for Clinical Trials

Highlights from the February, 2020 Issue



By Colin Begg, Editor

The February 2020 issue of *Clinical Trials* includes articles on the usual wide variety of topics of interest to Society members.

Nicole Engen and colleagues examined the question of whether on-site monitoring is worth all the cost and effort, concluding that the answer is no.

John Lachin and Ionut Bebu present a new strategy for conducting multiple testing in the context of a multi-arm clinical trial.

In a systematic review of published randomized trials O'Mareen Spence and colleagues show that the publicly available statistical analysis plans do not generally represent the pre-study protocols of randomized trials. In a study of a related topic Adelaide Doussau and colleagues show that protocols for studies about predictive biomarkers and patient outcomes are typically either not accessible or unavailable. When protocols are used, pre-specified methods are often discordant with those reported in publications.

As always, the Editors welcome articles on novel methods or articles addressing topics of contemporary interest to clinical trialists.

Follow us on twitter

@clintrialsj to keep up to date with the latest from the journal.

DEPARTMENT of BIOSTATISTICS EPIDEMIOLOGY & INFORMATICS

13th Annual Conference on Statistical Issues in Clinical Trials

Rubenstein Auditorium

UPenn School of Medicine Philadelphia, PA 19104

April 29, 2020

Cluster Randomized Clinical Trials (CRTs): Opportunities and Challenges

Registration is now Open

www.cceb.med.upenn.edu/events/13th-annual-conference-statistical-issues

METHODS
David Murray, PhD (NIH) Overview: ***Innovations in the Design and Analysis of Group- or Cluster- Randomized Trials***
Victor DeGruttola, ScD (Harvard) ***Using Network- and Individual-Level Information in Design and Analysis of Clustered Trials***
Luke J. Keele, PhD (University of Pennsylvania) ***Complexities Cause by Noncompliance in Cluster Randomized Trials***
James P. Hughes, PhD (University of Washington) ***Current Issues in the Design & Analysis of Stepped Wedge Trials***
APPLICATIONS
Lawrence H. Moulton, PhD (Johns Hopkins University) **Randomization: Beyond the Closurization Principle**
Ira Longini, PhD (University of Florida) ***The Ring Vaccine Trial Design for the Estimation of Vaccine Efficacy and Effectiveness During Infectious Disease Outbreaks***
Deborah J. Donnell, PhD (University of Washington) ***Challenges in Implementing CRTs: From Hawthorne Effect to Measurement Bias***
Weili He, PhD (AbbVie) ***Practical Considerations in Utilizing Cluster Randomized Trials in Medical Research***
PANEL DISCUSSIONS
Karla Hemming, PhD (University of Birmingham) **David Murray, PhD (National Institutes of Health)** **Michael Proschan, PhD (National Institutes of Health)** **Jeffrey Roberts, MD (US Food and Drug Administration)** **Alisa Shields-Stephens, PhD (University of Pennsylvania)** **Monica Taljaard, PhD (Ottawa Hospital Research Institute)**

National Institutes of Health
Office of Extramural Research

Extramural Nexus

From the February 2020 Update

Open Mike

Broadening the Pool of NIH Reviewers

Guest post by **Noni Byrnes**

The scientific peer review process benefits greatly when the study section reviewers bring not only strong scientific qualifications and expertise, but also a broad range of backgrounds and varying scientific perspectives. Read on to learn more about the Center for Scientific Review's efforts to facilitate broader participation in review. Continue reading →

Case Study in Review Integrity: Asking for Favorable Treatment

By **Mike Lauer**

What happens when a former colleague contacts you, a reviewer, out of the blue to ask if the application on which he is a principal investigator could be treated favorably at the review meeting? Do you brush off the investigator and figure you will not let the contact influence your review of that application? Or do you instead immediately notify NIH? Intrigued? We have a case for you. Continue reading →

Top Stories

FY 2020 Salary Limitation for Grants and Cooperative Agreements

The Office of Personnel Management has recently released new salary levels for the Executive Pay Scale. Effective January 5, 2020, the salary limitation for Executive Level II is $197,300. Continue reading →

Reminder of NIH Requirement to Adhere to the Revised Common Rule and Use a Single IRB for Multi-Site Studies

As of January 20, 2020, studies subject to the Revised Common Rule Cooperative Research Provision must use a single IRB as required by the terms and conditions of award. This includes studies that are not subject to the NIH sIRB policy – such as domestic, multisite career development (K) and fellowship (F) awards. Continue reading →

Spring Brings Computing Clouds and eRA Downtime

With the coming of spring, eRA modules and data will be migrated to the Amazon Web Services cloud. From 8 a.m. ET on Friday, April 17 to 8 p.m. ET on Monday, April 20, all eRA modules will be unavailable. Any affected due dates will be extended and the 2-day viewing window for successfully submitted applications will be adjusted to provide the full two days. Continue reading →

Legislative Mandates for FY 2020

NIH issued a notice detailing statutory provisions that limit or condition the use of funds on NIH grant, cooperative agreement, and contract awards for FY 2020. Continue reading →

FY 2020 Fiscal Policies for Grant Awards: Funding Levels, Salary Limits, and Stipend Levels

NIH issued guidance for NIH Fiscal Operations for FY 2020, announcing increases in NRSA stipends, 2020 award funding levels, and more. Continue reading →

New Resources

Searching for Funding Just Got a Little Easier

What's new with the NIH Guide for Grants and Contracts? In addition to faster, more precise search results, a few key filtering features have been introduced, including filtering for NOSIs. Continue reading →

NIH National Institutes of Health
Office of Extramural Research

Extramural Nexus

From the January 2020 Update (continued)

Tips Before You Submit

Clarifying Due Dates vs. Expiration Dates on Funding Opportunity Announcements

An application due date is *not* the same as a funding opportunity expiration date. If you submit on the expiration date – you're late, the opportunity has expired. When standard due dates are used, applicants can submit applications to any of the appropriate due dates up until the funding opportunity announcement (FOA) expires. Continue reading →

You Ask, We Answer

How Do I Include Videos as Post-Submission Materials?

Effective immediately, post-submission videos do not need to be embedded in .pdf files. Acceptable formats for videos are .mp4, .mov, .avi, and .wmv. All other aspects of our video policy remain unchanged. Continue reading →

Calendar

NIH & HHS Experts Ready to Meet & Share with You in Baltimore, MD this Spring!

If you're looking for an opportunity to talk with NIH & HHS program, review, grants management and/or policy experts then keep reading! From April 20-22, 2020, over 100 NIH & HHS experts will be on hand at the NIH Regional Seminar on Program Funding & Grants Administration in Baltimore, Maryland, ready to provide you with the latest policy and process information. Continue reading →

NIH National Institutes of Health
Office of Disease Prevention

Request for Information-Stakeholder Input on Opportunities for Increased Collaboration to Advance Prevention Research

The **NIH Office of Disease Prevention (ODP)** has as its mission to improve the public health by increasing the scope, quality, dissemination, and impact of prevention research supported by the NIH. One of our strategic priorities is to promote the use of the best available methods and support the development of better methods. ODP offers methods-based webinars, an online course in cluster randomized trials, a website with research methods resources related to cluster-randomized trials and individually randomized group treatment trials, as examples of its work under that strategic priority. The ODP also provides consultation to the Institutes and Centers on design and analytic issues for new prevention research initiatives, and those often involve clinical trials. For all these reasons, we are interested in hearing from the Society of Clinical Trials.

ODP has released a Request for Information to identify opportunities to foster and engage in partnerships and dialogue with our stakeholders. We hope this effort will help us determine areas where the ODP can collaborate to advance prevention research priorities, develop training opportunities, and better meet the needs of the disease prevention community. Your input would be greatly appreciated.

We encourage you to share this opportunity to comment with your colleagues, stakeholders, and anyone else interested in how the ODP can enhance opportunities for dialogue, partnerships, collaboration, and engagement. A Word version of this announcement and suggested promotional messages are attached to help you spread the word.

Responses must be submitted electronically via our website by **March 29, 2020 at 5:00 p.m. ET** to ensure consideration.

CLINICAL TRIALS NEWS & ANNOUNCEMENTS

Recording Available: CTTI's Framework for Evaluating the NIH Single IRB Policy

A recording of CTTI's Jan. 16 webinar on single IRB (sIRB) is now available.The webinar provides a recap of resources available to help implement a sIRB model, as well as an overview of a recently developed framework for evaluating the NIH's sIRB policy.

CTTI Holds First Expert Meeting on Master Protocols

Expertise in the use of master protocol studies is critically limited, and few resources exist to guide planning and implementation. CTTI recently held its first Master Protocol Studies expert meeting in an effort to fill this void. Learn more about the meeting and next steps on our work to advance master protocol adoption.

CTTI | | ctti@mc.duke.edu | https://www.ctti-clinicaltrials.org/

CTTI, 200 Morris St., Durham, NC 27701

IN CASE YOU MISSED IT

FDA Patient Engagement Webinar Recording Now Available

Watch the CTTI-hosted webinar, "Patient Engagement in Action: Insights from Patients & the FDA," highlighting the FDA's large portfolio

of activities to integrate patient engagement throughout the agency

CTTI IN THE NEWS

Solutions for Improving GCP Training

A new preprint paper outlines feedback on Good Clinical Practice (GCP) training gleaned from interviews CTTI conducted with clinical investigators and research sponsors.

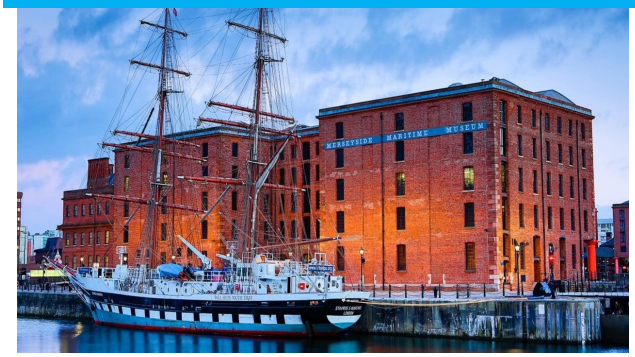
Investigator Qualification Recs Featured in New Paper

This peer-reviewed article highlights CTTI recommendations on improving investigator qualification.

Core Outcome Measures in Effectiveness Trials (COMET)

COMET VIII

Registration is now open



The COMET Initiative will hold its eighth meeting in Liverpool on 8th to 9th October 2020. Planning is now underway and we are preparing an exciting programme. This will bring together individuals interested in the development and application of "core outcome sets" in many different areas of health care. There is no registration fee for the meeting. Delegates will be responsible for the costs of their own travel and accommodation. Visit the website now to find out more information about registering and submitting an abstract.

Visit the COMET website

Recently Posted Notices

FDA launches mobile-friendly database with information on life-saving HIV drugs as part of ongoing mission to empower the public through increased access to information and data

The following is attributed to Dr. Stephen M. Hahn, M.D. Commissioner of the U.S. Food and Drug Administration:

Today, the U.S. Food and Drug Administration announced the launch of an interactive database that will offer a wealth of critical information about antiretrovirals (ARVs) eligible for purchase under the President's Emergency Plan for AIDS Relief (PEPFAR) program. This launch is an important step in our ongoing commitment to address the global HIV epidemic and is consistent with our efforts to modernize and improve access to information and unleash the power of data.

In my years as a practicing physician, I spent time on-the-ground involved in a program for those impacted by HIV in Botswana, Africa. I saw first-hand how essential it is to have access to low-cost, life-saving treatments for those impacted by HIV, regardless of where ...

Read More

FDA In Brief: FDA Updates Prioritization Policy for Original Abbreviated New Drug Applications, Amendments and Supplements to Maximize Impact on Public Health

The following quote is attributed to Sally Choe, Ph.D., director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research

Today, the U.S. Food and Drug Administration is making critical updates to our policy for prioritizing the review of abbreviated new drug applications (ANDAs) to advance the public health, efficiently allocate limited agency resources and ensure fairness to applicants, which reflects the FDA's longstanding practice to prioritize the review of ANDAs that would have the greatest potential impact on public health, if approved….

Read More

FDA Expertise Advancing the Understanding of Intentional Genomic Alterations in Animals

The following statement is attributed to FDA Commissioner Stephen M. Hahn, M.D.

"Genome editing is a groundbreaking technology used to introduce intentional genomic alterations in animals and has the potential to improve human and animal health, animal well-being and to enhance food production and quality. It is paramount, however, that as we move forward, we maintain standards of safety and effectiveness.

This is a tremendously exciting field. Because we're committed to fostering advances in this space, we take a risk-based approach to oversight. We want to ensure that the intentional genomic alterations in animals are safe for the animal, safe for people eating food products from the animal and that the alteration does what it's intended to do. That's why we encourage sponsors to participate in our Veterinary Innovation Program, which …

Read More

Recently Posted Guidance Documents

2/21/2020 - Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry

2/6/2020 - Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed Guidance for Industry: Draft Guidance for Industry

2/3/2020 - Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers Guidance for Industry

1/30/2020 - Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

1/28/2020 - Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs): Guidance for Industry

1/28/2020 - Human Gene Therapy for Hemophilia: Guidance for Industry

1/28/2020 - Human Gene Therapy for Rare Diseases: Guidance for Industry

1/28/2020 - Human Gene Therapy for Retinal Disorders: Guidance for Industry

1/28/2020 - Long Term Follow-up After Administration of Human Gene Therapy Products: Guidance for Industry

1/28/2020 - Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up: Guidance for Industry

1/27/2020 - Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations: Draft Guidance for Industry

6th International Clinical Trials Methodology Conference

Save the Date

Harrogate Convention Centre, Harrogate, UK

Monday 11th – Thursday 14th October 2021

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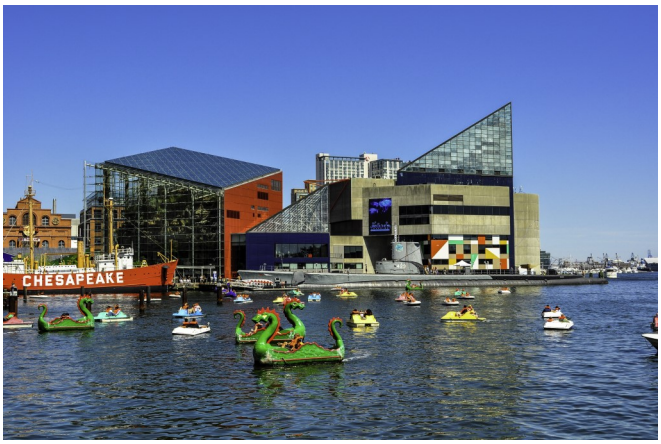
Save the Dates—Upcoming SCT Annual Meetings



41st Annual Meeting May 17-20, 2020

Baltimore, Maryland USA

42nd Annual Meeting May 16-19, 2021

Chicago, Illinois USA

Information About SCT

SOCIETY FOR CLINICAL TRIALS

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Executive Committee

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Susan Halabi (President-Elect)
Sumithra Mandrekar (Past-President)
Domenic Reda (Secretary)
Li Chen (Treasurer)

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Program: Jonathan Cook (Co-Chair)
Education: Yves Rosenberg
Education: Michael Grayling (Co-Chair)
Communications: Liz Garrett-Meyer
Development: Ivan Chan
Fellows: Mithat Gönen
Membership: Jody Ciolino and Dixie Ecklund
Nominating: Lehana Thabane
Student Scholarship: Sharon Yeatts and Lee McDaniel

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Dean Fergusson (Planning)
Leslie Ain McClure (Code of Conduct)

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Webmaster—John Hepler