SOCIETY FOR CLINICAL TRIALS

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CALENDAR OF EVENTS

Event	Date	For More Information
2020 SCT Virtual Program	Through April 30, 2021	REGISTER NOW
SCT 2021 Session Proposals	Due November 8, 2020	To submit your proposal, please click here
SCT 2021 Contributed Abstracts	Due November 30, 2020	To submit your proposal, please click here
SCT 2021 Educational Workshop Proposals	Due November 30, 2020	To submit your proposal, please click here
Thomas Chalmers Student Scholarship Applications	Due November 30, 2020	To submit your proposal, please click here
Sylvan Green Physician/Dentist Investigator Award Applications	Due November 30, 2020	To submit your proposal, please click here
SCT 2021 Fellow Nominations	November 2, 2020 through January 15, 2021	To submit your proposal, please click here
SCT 2021 Trial of the Year Nominations	November 2, 2020 through January 15, 2021	To submit your proposal, please click here
13th Annual U Penn Conference on Statistical Issues in Clinical Trials	April 21, 2021	https://www.cceb.med.upenn.edu/events/13th-university-pennsylvania-conference-statistical-issues-clinical-trials
Society for Clinical Trials 42nd Annual Meeting	May 16-19, 2021	http://www.sctweb.org/meeting/

Proposals/Abstracts for the SCT 42nd ANNUAL MEETING "Advancing Rigorous and Ethical Trials in the Pandemic Era" MAY 16-19, 2021 Chicago, IL

All submissions must be made via the SCT website

Session Proposals *(previously called "Invited Sessions")* due November 8, 2020

Proposals for a session which bring together a set of speakers and discussants to present the latest findings on an important and emerging issue in an area of clinical trials research, or which provide an up to date overview of an key aspect of clinical trials design, conduct, analysis or reporting, are very welcome.

Key Information

- Session formats can vary; however, the duration should be 90 minutes in length and there should be a session chair.
- A session typically includes 3-5 participants including the chair.

Two of the most successful formats used in the past are having 2-3 speakers with a discussant, or a structured and planned panel discussion with 3-4 panelists from different perspectives.

Your proposal should contain the following information

- Title
- Speakers with affiliation and e-mail addresses for each
- Session organizer (please add this individual's details in the additional contributors' section)
- Session chair (please add this individual's details in the additional contributors' section)
- Proposed session type (Invited talks, Panel, other)
- Written description of session to include focus, content, timeliness, appeal, and relevance to the theme, as well as specific titles for each speaker's talk (if applicable)

To submit your proposal, please click **here**

Contributed presentations for an Oral or Poster due November 30, 2020

An abstract for a short presentation of topic relevant to the clinical trials is requested.

Key Information

- Submitter will be requested to specify if they wish to be considered for both an oral and a poster presentation or only a poster presentation.
- Those selected for an oral presentation will be grouped with other oral presentations with a similar theme in the program.

Proposals/Abstracts for the SCT 42nd ANNUAL MEETING (continued)

- Papers are usually allotted 15 to 20 minutes (including time for questions).
- Submitted abstracts should be as accurate and specific as possible as they will be included in the conference program.

Preference will be given to abstracts that report completed investigation, analyses, designs, or methodological work over those that promise to report a work in progress if accepted. Similarly, preference will be given to new work and novel topics over reviews without any clear development or progression from previous research and understanding. Training or learning focused submissions should be submitted as educational submissions.

Your proposal should contain the following information

- Title in all capital letters with no abbreviations
- Full names of authors without degrees or titles
- Institutional affiliation, city, state or country of first author (additional contributors or authors can be added in space provided)
- Text of the abstract (500 word limit)

To submit your proposal, please click **here**

Educational Workshop Proposals

due November 30, 2020

Some of the themes we are interested in for workshops/tutorials include

- Clinical trial conduct: recruitment and retention, ethics, study start up/close-out in multi-center trials, international trials, trial evolution over time
- Patient reported outcomes and patient perspectives in clinical/trials decision making
- Trial design and/or analysis: innovations in trial methods and outcomes
- Artificial intelligence and 'data deluge'
- Data sharing: Preparing, submitting and accessing trial data from data sharing platforms

Pre-Conference Educational Workshops are courses on topical methods or issues related to clinical trials typically lasting around 4-hours, though 2-hour sessions will also be considered. The focus will be on education and training and will include hands-on work and plenty of time for questions and discussion. Please include a bullet point description of how the workshop will be structured (e.g. 10-min presentation followed by 30-mins of small group work with hands-on use of software etc).

In-Conference Tutorials are interactive sessions on a method or topic related to clinical trials. Tutorial sessions may include small-group work, hands-on use of tools and software, troubleshooting and 'ask-the-expert' time. In-conference tutorial sessions typically last 90 minutes.

Your proposal should contain the following information

- Primary contact (with affiliation and email address)
- Whether the proposal is tied to the overall theme (including a brief description)
- Category
- Target Audience
- Description of how the tutorial will be structured (e.g. 10-min presentation followed by 30-mins of small group work with hands-on use of software etc)

To submit your proposal, please click **here**

Society for Clinical Trials
Equity, Diversity and Inclusion (EDI) Task Force Recommendations

About the SCT Commitment to EDI:

Historically, the SCT was founded on diversity of disciplines all brought together by one purpose: using clinical trials to advance the health and welfare of society. However, SCT recognizes that discipline diversity is not sufficient, and the ongoing injustice of implicit and structural racism, particularly against Black, Indigenous People, and People of Color, must be proactively addressed. We are committed to taking actions to dismantle racism in all forms. The SCT is committed to building and maintaining an organization which is diverse and inclusive of, and provides professional opportunities and recognition for, all people regardless of their race, gender, nationality, language, sexual orientation, disability, religion, or region. Our members are encouraged to speak openly, honestly, and without retribution about their experience with racism and necessary improvements.

Diversity, equity, and inclusion are important considerations in all aspects of the operations of the SCT, including in membership, leadership, meeting planning, advocacy, and in matters related to the SCT journal (currently Clinical Trials). We strongly believe it is the responsibility of all SCT members to ensure that we are collectively anti-racist in our operations and actions, and that we lead the way in increasing representation among the members of our Society, among those conducting clinical trials, and among those participating in clinical trials and research. This also provides a good opportunity for the SCT to encourage and facilitate continuing dialogue on EDI matters.

The SCT Task Force proposes that the Society for Clinical Trials establish a Standing Committee on Equity, Diversity & Inclusion (EDI). We propose the following charges for the committee:

- Draft the terms of reference for the EDI Committee to be approved by the BOD
- Set short- and long-term goals for the SCT with respect to increasing diversity, equity, and inclusion;
- Assign measurable outcomes to the goals, in order to hold the Society accountable for reaching goals;
- Serve as liaisons to other SCT committees, in order to ensure best practices in diversity and inclusion are upheld throughout the Society's practices;
- Collect and maintain information to help characterize the diversity among SCT membership in collaboration with the Membership Committee; and
- Promote open and honest dialogue among SCT members.

Further, the Task Force recommends the following for consideration:

- Members of the SCT EDI Committee be required to have training (TBD) in EDI;
- The SCT EDI Committee will also examine how to best educate the SCT about EDI issues relevant to the SCT
- The SCT EDI Committee examine how best to work with membership to promote equity, diversity, and inclusion among clinical trials participants.
- Consider opportunities to partner with external organizations to promote equity, diversity, and inclusion more broadly.

Membership:

- The SCT EDI Committee will be comprised of active SCT members in good standing. The composition of the committee membership will incorporate members with diverse background (demographic, geographic and specialty)
- The committee will be governed by a Chair to be appointed by the president, who will also serve as a liaison to the Board. The Chair will serve a 3-year term: 1 year as co-Chair, 1 year as Chair, and 1 years as Past Chair. In addition to the Chair, co-Chair and Past Chair, the committee will include XX members, each of whom will serve as the liaison to a different SCT committee. SCT EDI Committee members will serve XX year terms.
- The Task Force suggests implementing a grace period before the above suggested leadership transition kicks in, so that there is some continuity of leadership while the committee is getting the goals/plans up and running. The transition process may start after 2 or 3 years.

Reporting Structure:

The SCT EDI Committee reports to the SCT President.

Task-Force Members

Co-Chairs	Leslie McClure & Lehana Thabane
Members	Kaleab Z. Abebe, Susan Halabi, Dixie Ecklund, Robert Lindblad, Scott Rushing, Domenic Reda

Leslie McClure
Janet L. Norwood Award Recipient
Outstanding Achievement by a Woman in the Statistical Sciences

Please join us in congratulating Leslie A. McClure for receiving the Janet L. Norwood Award for outstanding achievement by a woman in the statistical sciences. Dr. McClure received the award on October 20, 2020 at the University of Alabama Birmingham.

Dr. McClure is Chair, Department of Epidemiology and Biostatistics, Dornsrife School of Public Health, Drexel University. Among her many professional accomplishments, she is a Fellow of the American Statistical Association and was instrumental in writing ASA's Policy on Sexual Misconduct. Leslie is also a Fellow of the Society for Clinical Trials and has served in many leadership roles for SCT, including Program Chair, Communications Committee Chair, and an elected member of the Board of Directors. Most recently, Dr. McClure co-chaired the SCT task force on Equity, Diversity and Inclusion.

2020 SCT Virtual Program
Through April 30, 2021
Upcoming Webinars

Created in 1978, the Society for Clinical Trials (SCT) is a multidisciplinary society with membership spanning myriad disciplines that are all critical to the field of clinical trials: biostatistics, clinical areas, IT and systems, data management, ethics, regulatory bodies, behavioral science, research coordination, patient partners, health outcomes researchers, and many others.

Please visit our **Membership page** for more information on the great benefits SCT offers its Members.

How to access the Virtual Program

- Registration is required for members, non-members and students in order to attend this event.
- All current SCT members can attend for free! Registration is required.
- All verified Students can purchase this Educational Content for the low price of just $50!
- Non-Members can purchase this Educational Content for the low price of $170!

REGISTER NOW

- Access to the recorded sessions will be provided via the Program Guide that will include links to each recorded session that you can access through April, 2021.
- The Program Guide will be posted on the SCT website and can also be accessed **here.**
- You are encouraged to check the website for the latest version of the Program Guide.
- You may download it to your desktop to keep as reference for the recorded sessions, but be sure to check back periodically for any updated versions.

How to access the Webinars

- Once you have registered for the Virtual Program, SCT will register you for each webinar that is scheduled through April 2021.
- You will receive an email confirmation on a monthly basis from SCT **(via Go To Webinar**) that will contain your dial-in information as well as a personalized link to access that month's webinar.

2020 SCT Virtual Program (continued)

- We will also send out notifications every month a webinar is scheduled that will contain all the information for that session, including the scheduled presenters.

Note: if SCT has registered you for the webinar, you do not need to re-register.

What the Virtual Program contains

The program will contain content submitted for the SCT Annual Meeting that was cancelled, including:

- Recorded Presentations from Contributed Sessions
- Webinars from Education Workshops and Tutorials
- Webinars from Invited Sessions
- Recorded content including the Annual Business Meeting, Trial of the Year Presentation, Sylvan Green, Chalmers Awards Presentations, and presentation of the 2020 Fellows of SCT

Virtual Educational Workshops Sessions		
From Ideas to Efficacy: Designing & Optimizing Behavioral Treatments for Chronic Diseases	Susan Czajkowski, Ken Freedland, Lynda Powell	October 29, 2020 2:00 pm – 3:30 pm ET
How to design and run an adaptive clinical trial: new resources and easy-to-use software	Munya Dimairo, Michael Grayling, and Graham Wheeler	November 11, 2020 10:00 am - 11:30 am ET
Improving Quality and Controlling Costs in Clinical Trials Using Responsive Survey Design	James Wagner and Brady West	April 6, 2021 11:00 am ET – 12:30 pm ET
Virtual Invited Sessions		
The win ratio approach to composite endpoints	Jing Jeong, KyungMann Kim, Lu Mao, David Oakes, Song Yang	November 6, 2020 12:00 pm – 1:00 pm ET
Methodological advances in the conduct of behavioral clinical trials: an international behavioural trials network (IBTN) update	Simon Bacon, Susan Czajkowski, Kenneth Freedland, Kim Lavoie	December 14, 2020 10:00 am -11:30 am ET
The design and implementation of master protocols using examples from oncology clinical trials	Timothy Chen, Shauna Hillman, Sumithra Mandrekar, Amy Stark, Pamela Tenaerts	January 12, 2021 12:00 pm - 1:00 pm ET
Strategies to collaboratively manage protocol deviations in multi-site clinical trials	Dikla Blumberg, Ashley Case, Phoebe Gauthier, Mitra Lewis, Carmen Rosa, Dagmar Salazar	January 27, 2021 12:00 pm - 1:30 pm ET

Call For 2021 Fellow Nominations!

Nominations due by January 15, 2021

By Elizabeth Thom

Chair, Fellows Committee

The Society's Distinguished Fellows

The Society for Clinical Trials established the title of "Fellow of the Society for Clinical Trials" in 2005 to honor Society members who have made significant contributions to the advancement of clinical trials and to the Society. The title may be granted to a small number of Society members each year at the Annual Meeting. It is a signal honor that denotes their importance in the field. Nominations for the Class of 2021 are being accepted from Nov 2, 2020 to January 15, 2021. Any member of the Society may nominate a candidate. We encourage you to put forward someone you consider to be a leader in our field.

Who May be Nominated

Candidates must have been an SCT member for at least five of the last 10 years or for a total of at least 10 years. Each nominee will be evaluated by the SCT Fellows Committee on the basis of contributions to the advancement of clinical trials in one or more of the following areas:

- Methodologic development
- Trials coordination, conduct, or leadership of individual clinical trials
- Education
- Ethics
- Information technology, data management, or data quality
- Promotion of a better understanding by the general public of the importance of randomized clinical trials
- Service to the Society

How to Submit a Nomination

If you know someone who meets these qualifications and is deserving of this particular Society honor, please follow this three-part process:

1. Check with the SCT office at info@sctweb.org to confirm the eligibility of your intended nominee

2. Prepare a Nomination Packet, which should include:

- ♦ Candidate's current full curriculum vitae (CV)
- ♦ Three or more letters of support from individuals qualified to describe the candidate's contributions. At least two of the letters should be from individuals at an institution, agency, or organization other than that of the candidate. The letters may include a letter of support from the nominator.
- ♦ Cover letter from the nominator to document that packet is complete and that the candidate meets criteria. (If the nominator writes a letter of support, documentation of meeting criteria may be incorporated into the letter of support instead.)

3. Submit the nomination on the SCT website at: http://www.sctweb.org/meeting/fellowNom/intro.cfm

Complete nomination packets are due by January 15, 2021

What Happens Next

Nomination packets will be reviewed in January by the SCT Fellows Committee. All committee members are Fellows themselves, and come from varied backgrounds and expertise. The Fellows Committee will submit the list of newly proposed to the Board of Directors for approval and those selected will be notified in February 2021. The Class of 2021 Fellows will be announced and honored at the SCT 42nd Annual Meeting.

2021 Award and Scholarship Programs

Apply online by November 30, 2020

The Society offers two scholarships to the SCT Annual Meeting (May 16-19, 2021 Chicago, IL)

SCT Thomas C. Chalmers Student Scholarship

Who is Eligible:
Full-time students enrolled in a graduate degree program (Masters and PhD) of an accredited college or university, or post-doctoral fellows. Previous finalists are not eligible.

Appropriate topics for Submission:
All clinical trial-related issues including (but not restricted to) study design and data analysis methods; meta-analysis; medical, ethical or legal issues in clinical trials; data entry, management, monitoring, sharing, informatics, software development, and computing as it relates to clinical trials; review of the results or methods of a class of trials; or scholarship in the history of clinical trials. Important papers illustrating applications of novel methodology in clinical trials are particularly encouraged.

How to Apply:
- Visit the online submission form by **clicking here,** then click **Contributed Sessions**.
- Submit an abstract (400 word limit), a short manuscript (maximum of 3500 words, not including title, author names, tables, figures or bibliography; maximum four figures and tables) and a letter from the student's advisor or mentor confirming status as a full-time student or post-doctoral fellow at the time of submission.
- Applicant must be first author on manuscript
- Indicate Thomas Chalmers Student Scholarship for abstract type.
- You may specify that if your submission is not chosen for this award, you would like it to be considered by the Program Committee for an oral or poster presentation.

Submission deadline: November 30, 2020

NOTE: Each candidate can only submit one entry. However, candidates can be co-authors (not first author) on other entries.

What the Three Finalists and One Winner Receive:
Three students will be designated Thomas C. Chalmers Student Scholarship Finalists and will receive travel and hotel expense support to present their papers at the 2021 SCT meeting in Chicago, IL. The three finalists will present their papers at the meeting. The winner will then be selected by the SCT scholarship committee and be presented the Thomas C. Chalmers Student Scholarship Award in addition to a $500 cash prize.

For more information please visit: http://www.sctweb.org/chalmers.cfm

SCT Sylvan Green Award

Who is Eligible:
Physicians and dentists engaged in clinical trials or epidemiology projects.

Appropriate topics for Submission:
All clinical trial-related issues such as study design and data analysis methods; meta-analysis; medical, ethical or legal issues in clinical trials; data entry, management, monitoring, sharing, informatics, and computing as it relates to clinical trials; review of the results or methods of a class of trials; or scholarship in the history of clinical trials. Important papers illustrating applications are particularly encouraged.

How to Apply:
- Visit the online submission form by **clicking here,** then click **Contributed Sessions**.
- Submit a short paper (1000-word limit, excluding author names, title, table, figure or bibliography; limit 1 table or figure) on the online abstract submission form.
- Applicant must be first author on manuscript
- Indicate your physician or dental degree for eligibility

2021 Award and Scholarship Programs (continued)

Submission deadline: November 30, 2020

NOTE: Each candidate can only submit one entry. However, candidates can be co-authors (not first author) on other entries.

What the Winner Receives:

The winner will receive an Award covering travel and hotel expenses to present at the 2021 SCT meeting in Chicago, IL. If your submission is not chosen for this award, it will still be considered by the Program Committee for an oral or poster presentation.

Call For The David Sackett Trial Of The Year Nominations open November 2, 2020

The Society for Clinical Trials presents an annual award to the randomized clinical trial published (either electronically or in print) in the previous year (2020 in this case) that best fulfills the following standards:

- It improves the lot of humankind.
- It provides the basis for a substantial, beneficial change in health care.
- It reflects expertise in subject matter, excellence in methodology, and concern for study participants.
- It overcame obstacles in implementation.
- The presentation of its design, execution, and results is a model of clarity and intellectual soundness.

The deadline for nominations is January 15, 2021.

The award will be presented at the 42nd SCT Annual Meeting held May 16-19, 2021, in Chicago, IL.

Nominations can be submitted online at **http://www.sctweb.org/meeting/#abstract** between November 2, 2020 and January 15, 2021.

For questions, please contact Marc Buyse (**marc.buyse@iddi.com**), Chair of the David Sackett Trial of The Year Committee.

CLINICAL TRIALS
Journal of the Society for Clinical Trials

October, 2020 Issue Highlights

Follow us on twitter @clintrialsj to keep up to date with the latest from the journal.

By Colin Begg, Editor

A major focus of the October issue of *Clinical Trials* is the design and analysis of clinical trials during the COVID-19 pandemic. Three invited articles from leading experts on clinical trials are featured, accompanied by an editorial from the Editors. **Lori Dodd** and an international team of colleagues address the issue of how to select the appropriate endpoint for COVID-19 trials, concluding that this depends on the severity of the disease in the population under study. **Steve Piantadosi** argues that novel designs are needed to address the unique features of COVID-19: urgency; availability of many agents; and large numbers of patients. **Susan Ellenberg** provides an overview of the state of play, highlighting the rapid response of clinical trials investigators. Other COVID-related contributions are an article **Brett Houston** and colleagues describing the design of an international adaptive COVID-19 trial of multiple drugs, and an article by **Kay See Tan** providing caution about using standard actuarial methods to analyze studies in the critical care setting such as those involving hospitalized COVID-19 patients. The issue also features an article by **Nicolas Bamat** and colleagues showing that non-inferiority trials are more likely to result in hypothesis confirmation than superiority trials, with an accompanying commentary by **Everardo Saad** and **Marc Buyse**.

DEPARTMENT of BIOSTATISTICS EPIDEMIOLOGY & INFORMATICS | Perelman School of Medicine

13th Annual Clinical Trials Conference
VIRTUAL

SAVE THE DATE!

Monday, April 12, 2021 (8:30 A.M. to 4:30 PM)

13th Annual University of Pennsylvania Conference on Statistical Issues in Clinical Trials:

Cluster Randomized Clinical Trials: Challenges and Opportunities

Registration opens January 2021

SPEAKERS AND TOPICS	
DAVID MURRAY NIH	*Overview: Innovations in the Design and Analysis of Group - or Cluster-Randomized Trials*
VICTOR DeGRUTTOLA Harvard	*Using Network-level (and Individual-level) Information in Design and Analysis*
LUKE J. KEELE University of Pennsylvania	*Complexities Caused by Noncompliance in Cluster Randomized Trials*
JAMES P. HUGHES University of Washington	*Current Issues in the Design and Analysis of Stepped Wedge Trials*
LAWRENCE H. MOULTON Johns Hopkins University	*Randomization: Beyond the Closurization Principle*
NATALIE E. DEAN University of Florida	*The Ring Trial Design for the Estimation of Vaccine Efficacy and Effectiveness During Infectious Disease Outbreaks*
DEBORAH J. DONNELL University of Washington	*Challenges in Implementing CRTs: from Hawthorne Effect to Measurement Bias*
WEILI HE AbbVie	*Practical Considerations in Utilizing Cluster Randomization Trials in Medical Research*
PANELISTS	
Andrew Copas	**University College London**
Karla Hemming	**University of Birmingham**
David Murray	**NIH**
Mike Proschan	**NIH**
Jeffrey Roberts	**FDA CBER**
Alisa J. Stephens-Shields	**University of Pennsylvania**

Up to date information at:
https://www.cceb.med.upenn.edu/events/13th-university-pennsylvania-conference-statistical-issues-clinical-trials

ICTMC 2021

6th International Clinical Trials Methodology Conference. Harrogate, UK 11 - 14 October

International Clinical Trials Methodology Conference 2021 will take place from Monday 11th to Thursday 14th October 2021 at Harrogate Convention Centre, Harrogate, Yorkshire, UK.

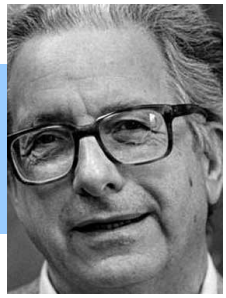
ICTMC 2021 promises to be a unique opportunity for those working in clinical trials to meet and discuss the current issues within trials and trials methodology.

ICTMC is the leading international platform for researchers and practitioners to present the very latest in trials methodology research. The meeting also offers valuable networking and training opportunities, with over 750 delegates from 22 countries attending in 2019.

Register Your Interest

www.ictmc.org

SCT Spotlight – Paul Meier's Role in the Discovery and Evaluation of The Cutter Incident—part 1



Paul Meier

By Chris Barker

Background

In 2020, during the covid19 pandemic, several pharmaceutical companies are conducting Phase III randomized blinded clinical trials for a vaccine to give immunity to the virus, SARS-COV-2 that causes the disease covid19. Phase III Clinical trial protocols are available online for download for Moderna, AstraZeneca/Oxford and Pfizer /BioNtech. Johnson & Johnson has started enrolling a phase III clinical trial. Vaccines manufactured in China and Russia possibly skipped a Phase III step and administered a vaccine directly to health care workers- The details about Russian And Chinese vaccines are sketchy and difficult to confirm- these vaccines are not available in the US.

Astra Zeneca/Oxford recently suspended a clinical trial for safety . Dr. Fauci at NIAID has stated (paraphrasing) that this is evidence the "process works safety evaluation of vaccine". Several of my friends and colleagues recalled "problems with the polio vaccine". I recall, as I'm sure many of the readers, decades ago, visiting elementary school with my parents to get a sugar cube with a polio vaccine. And since that time, I have the vaguest memories of the fear of possibly getting polio and then being treated in an "iron lung".

I dug into the history in depth. During the Polio field trials, an event, forever known as "The Cutter Incident" was uncovered, somewhat dramatically, by Paul Meier during attendance at a seminar by Cutter scientists. This led to changes in evaluation of the safety of vaccines. I defer to others for the history of changes in vaccine review and legislation arising from the Cutter Incident.

Brief Polio Vaccine Overview

The safety concerns described in this note and the role of Paul Meier arose from the inactivated (Salk) vaccine IPV. Prior to the Salk and Sabin vaccines, two other vaccines, named after their developers, Kolmer and Brodle were withdrawn from use. Brodie was a "killed" virus and Kolmer was an attenuated virus (Halpern,2006) .

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1472109/

There were two polio vaccines, one by Jonas Salk and the other by Albert Bruce Sabin. Salk announced his vaccine in 1953. Salk used "inactivated Polio virus" (IPV) and Sabin used "attenuated virus" also known as "oral polio vaccine" (OPV). Salk deactivated virus using Formalin (formaldehyde) . Salk also collaborated with Pfizer for the large-scale manufacturing of the vaccine. An interesting historical note is that the Sabin vaccine was tested and proven safe in tests 1957 in about 10.000,000 people in Russia (the former Soviet Union).

https://www.virology.ws/2015/09/10/why-do-we-still-use-sabin-poliovirus-vaccine/

I'll mention what seems to be a possible second name for the Polio vaccine clinical trials. One author (Monto) refers to the trials as the Francis Field trials, named after Dr. Thomas Francis Jr. M.D. the overall director of the trials. Dr. Salk worked in Dr. Francis' department of Epidemiology at Johns Hopkins. Dr. Monto also makes a remarkable comment about "slavish reverence to significance testing" and the absence of p-values in the final report of vaccine results, excerpted at length here:

The essential results are shown in table 2, with little modification from the way they were originally presented except for certain combination of groups. An unusual feature in the table, to the modern reader, is the lack of any reference to statistical significance. This did not indicate, as will be discussed, that statistical issues, especially p values, were not recorded as a necessary consideration, but, rather, it reflected the era and the lack of our current slavish reverence for significance testing often over other relevant concerns. It also may have indicated the realization that differences in this trial could have been statistically significant even in the absence of effects that would have been important from a public health standpoint, given its large size.

Source: Monto

I (re-)discovered an event, forever after called the "Cutter Incident". I (re-) discovered that Paul Meier was part of a team in 1955 that discovered that Cutter Laboratories had not correctly attenuated the live polio virus. Worse, it appears that Cutter had been hiding details of the "virus attenuation". Children receiving the vaccine developed a polio like illness later described as the "largest biological disaster in the history of the US". Laws and safety review of vaccines changed because of the Cutter Incident.

SCT Spotlight – Paul Meier's Role in the Discovery and Evaluation of The Cutter Incident (continued)

Below I cite some of the legal outcomes and defer to others for the complete history of the litigation following cutter.

Polio Vaccine Manufacturing Data Suppression

The nearly unfathomable discovery of Cutter was the discovery data suppression. Excerpting at length from Paul's paper,

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3477951/

Excerpting from Betts 2012.

"But the biggest issue, for Meier, emerged during a seminar attended by many of the researchers working on the project, where it became apparent that members of the team were suppressing the data related to some of the test vaccine lots. As soon became clear, the polio virus used in the trial vaccines was not always properly inactivated. Jonas Salk, the vaccine's inventor, "cut out data in order not to show what happened to some lots," Meier charged. He said that the National Foundation for Infantile Paralysis, which sponsored the study, dropped from its advisory committee scientists who did not agree with how the results were being presented.

The field trial's findings were reported to show the vaccine's effectiveness, over the objections of some of the committee members, Meier said. Soon after, the US Public Health Service reported cases of paralytic polio in children inoculated with the vaccine. The original cases were traced back to lots produced by Cutter Laboratories, of Berkeley, CA, one of six manufacturers licensed to produce the vaccine. However, Meier said that the problem was more widespread. He said:

"I got some data from a physician who was working on this, and we found that not only was Cutter wrong, but there were various other companies that had the same polio virus in their samples, although not as much as the samples from Cutter Laboratories. But because there were so many improperly diagnosed cases out there, and because the other manufacturers went around to various newspapers and threatened to cut their advertising, it was dumped on Cutter. Cutter was responsible because they did things in producing and testing the vaccine they were told not to do".

Biological Disaster? How Serious was the vaccine manufacturing problem?

Children developed a polio like illness Vaccine-associated paralytic poliomyelitis (VAPP)

https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html

Excerpting from the CDC

...In April 1955 more than 200 000 children in five Western and mid-Western USA states received a polio vaccine in which the process of inactivating the live virus proved to be defective. Within days there were reports of paralysis and within a month the first mass vaccination programme against polio had to be abandoned. Subsequent investigations revealed that the vaccine, manufactured by the California-based family firm of Cutter Laboratories, had caused 40 000 cases of polio, leaving 200 children with varying degrees of paralysis and killing 10.... and excerpting about the law, from Fitzpatrick review of the book by Offitt.

Near Elimination of Vaccine development by lawsuits

Vaccine safety evaluation, manufacturing and the law changed because of the Cutter Incident. Excerpting from Offit. ...The Cutter Incident had an ambivalent legacy. On the one hand, it led to the effective federal regulation of vaccines, which today enjoy a record of safety `unmatched by any other medical product'. On the other hand, the court ruling that Cutter was liable to pay compensation to those damaged by its polio vaccine—even though it was not found to be negligent in its production—opened the floodgates to a wave of litigation. As a result, `vaccines were among the first medical products almost eliminated by lawsuits'. Indeed, the National Vaccine Injury Compensation Program was introduced in 1986 to protect vaccine manufacturers from litigation on a scale that threatened the continuing production of vaccines. Still, many companies have opted out of this low-profit, high-risk field, leaving only a handful of firms to meet a growing demand (resulting in recent shortages of flu and other vaccines)....

CDC lists safety concerns for other approved vaccines

https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html

(to be continued in the next SCT newsletter)

National Institutes of Health
Office of Extramural Research

Extramural Nexus

From the Aug, Sept and Oct Editions

Open Mike

More Thoughts on Cyber Safety and NIH-Funded Research By **Mike Lauer**

In this post, we would like to remind you of some of the important cybersecurity policies that apply to your NIH-supported research. These policies are designed to protect not only the NIH, but also you, your coworkers, your study participants, your institution, and your research. As healthcare and research institutions continue to face mounting threats from cyberattacks, it's important that we all not only know how to protect sensitive information, but also make a personal commitment to keeping data safe. Continue reading →

Institute and Center Award Rates and Funding Disparities By **Mike Lauer**

In 2011, Ginther et al. first demonstrated that African American and Black applicants to the National Institutes of Health received grant awards at a lower rate than their white counterparts. Since then, multiple studies have reproduced and extended this finding (Ginther 2011; Ginther 2016; Hoppe 2019; Erosheva 2020). Recently we reported that African American and Black (AAB) PIs are more likely to propose research on topics that are less likely to be funded (Hoppe 2019). We found that topic choice has little or no effect on whether an application is chosen for discussion, but after considering a number of confounders, it accounts for over 20% of the gap in funding success for applications that are discussed. Why are applications linked to certain topics less likely to be funded? Continue reading →

Case Study in Review Integrity: Abuse of Power By **Mike Lauer**

What would you do if, as the Dean of Research at a major university, a group of students, postdocs, and junior faculty reported that they had been pressured into writing reviewer critiques for a senior faculty member? We were so impressed by the careful handling of just such a situation by an institutional official recently that we wanted to share this story with you (we've changed details and fictionalized names). Continue reading →

Top Stories

Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module

Effective November 12, 2020, NIH funded recipients will be required to submit their publicly assessible Financial Conflict of Interest (FCOI) policy to NIH via the eRA Commons Institution Profile (IPF) Module. A PDF of the FCOI policy must be submitted by the institutional signing official via the IPF Module under a new tab labeled, "Policy Documents". Continue reading →

Guidance on Charging Personal Protective Equipment for Grants that Support Clinical Trials and Clinical Research

NIH has received many inquiries from recipients regarding their ability to direct charge personal protective equipment (PPE) costs to their clinical trials and clinical research awards. In this recent Guide Notice, NIH provides criteria for applicants/recipients on when it is appropriate to direct charge PPE costs. Continue reading →

NIH Natural Disaster Policy Reminder – Hurricane Laura and Wildfires

If your institution closes due to severe weather or other natural disasters, NIH has policies in place to help your research to continue. We recently published NIH Guide Notices that remind those impacted by Hurricane Laura and the US wildfires about the flexibilities for application and report submission provided by these policies. Continue reading →

NIH Will Continue to Accept Preliminary Data as Post-Submission Material Through May 2021 Council

The ability to submit preliminary data as post-submission materials for applications submitted for the January 2021 council (NOT-OD-20-123) has been extended to apply to the May 2021 council (NOT-OD-20-163). This is a temporary flexibility due to the effects of the COVID-19 pandemic. Continue reading →

New Resources

New "All About Grants" Podcast – Research Misconduct

That's a bit…odd. That gel image looks photoshopped. The data looks too good to be true. And, wait a second, that figure appeared in another paper! These are examples of research misconduct. What do you do if you suspect research misconduct? Join

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us for this next installment of NIH's All About Grants podcast with Dr. Christine Ring on addressing research misconduct. Continue reading →

Tips Before You Submit

Reminder: NIH Policy on Use of Hypertext in NIH Grant Applications

The use of hypertext (e.g. hyperlinks and URLS) in NIH applications is restricted due to concerns including reviewer confidentiality, "overstuffing" applications, review consistency, and malware. There is no change in the NIH policy on the use of hyperlinks. Continue reading →

You Ask, We Answer

How Do I Submit Post-Submission Materials for My Application?

Post-submission materials are those submitted after submission of the grant application but prior to initial peer review. They are not intended to correct oversights or errors discovered after submission of the application, but rather allow applicants the opportunity to respond to unforeseen events. Our policy on post-submission materials outlines allowable materials and how to submit them. The steps to submit these materials are summarized here. Continue reading →

What Are the Reporting Requirements for the Inclusion Across the Lifespan Policy?

The Inclusion Across the Lifespan policy requires submission of de-identified individual-level participant data, including participant age at enrollment, in progress reports. Wondering how to provide individual-level inclusion data? Use the template file provided on the Inclusion Enrollment Report in the Human Subjects System. Continue reading →

Applications To NIH Loan Repayment Programs Accepted Sept. 1 Through Nov. 20

We are pleased to announce that the Fiscal year 2021 NIH Loan Repayment Program (LRP) application cycle opened on September 1, 2020 (closing on November 15th). LRP award funds repay a recipient's qualified educational debt in return for a commitment to engage in NIH mission-relevant research at a domestic, nonprofit, or government entity. Continue reading →

Invitation to Join Expert Working Group for Code System Development

The COVID-19 Knowledge Accelerator (COKA) initiative is starting an open project to develop controlled vocabularies (called "Code Systems") for standard computable expression of concepts in evaluation and reporting of scientific evidence. The Code Systems will enable researchers and other information specialists to create, search, interpret, report, display and disseminate concepts more efficiently across and between systems. ***To sign up*** for any of the 4 Expert Working Groups, please complete the brief (3-5 minutes) Code System Development Intake Form.

We are looking for your expertise in creating 4 Code Systems:

1. Study Design Code System to describe methodology characteristics of scientific observations such as randomization, crossover allocation, and qualitative analysis.
2. Statistic Type Code System to describe statistical measures such as mean, proportion, relative risk, p value, confidence interval, and I-squared measure of heterogeneity.
3. Statistic Model Code System to describe the model characteristics such as linear regression, random-effects analysis, and tau estimation method.
4. Risk of Bias Code System to describe trustworthiness in methods or reporting of evidence such as selection bias, gaps in blinding, and selective outcome reporting.

Specifically, for each of the 4 Code Systems, we will follow a Code System Development Protocol to:

1. Identify tools or systems commonly used today to express these concepts.
2. Map out a single list of non-redundant concepts for common needs.

Expert Working Group for Code System Development (continued)

3. Determine the optimal phrasing for terms and definitions in the code system.
4. Achieve (near-)universal agreement in the code system.

We are not developing protocols, guidelines or policies for how to conduct research, statistical analysis or critical appraisal of evidence. We are not duplicating the work of others.

Expertise needed: If you express these concepts (or you are developing a system to support people who express these concepts) then you are an expert. The expertise most needed is the insight and input to assure the code system works for the functional efforts we already do.

Expectations and Time Commitment: Expert Working Group members may provide feedback by email and are welcome to attend open, 50-minute, weekly meetings of the specific Code System Development Steering Group. There is no minimum requirement of effort for engagement.

Benefits for Participation: You help create a code system to make communicating scientific evidence more efficient. You also get acknowledged for contributions. To be acknowledged as an author for the first version of the Code System, the minimal requirement is to vote on agreement (or suggest changes) for each of the code system entries (starting with step 7 of the protocol). The voting can be done online without requiring presence at a defined meeting time.

To sign up for any of the 4 Expert Working Groups, please complete the brief (3-5 minutes) Code System Development Intake Form.

If you have any questions, email Brian S. Alper at balper@computablepublishing.com

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Report Available from ICH E6 Public Conference

This past summer the FDA, in collaboration with CTTI, held a conference on "Stakeholder Engagement on ICH E6 Guidance for Good Clinical Practice," which was attended by more than 1300 people. A report is now available that provides an overview of the presentations from a diverse group of participants, including academic researchers, human subject protection and ethics experts, as well as patients. Click here for more of CTTI's work on ICH E6 Renovation.

Public Launch of Resources from Master Protocols Project

On Tuesday, October 13 at 11 a.m. ET, CTTI held a public webinar to announce a new roadmap for designing and running master protocols. Speakers included:

- Abby Bronson, Edgewise Therapeutics
- Marianne Chase, Massachusetts General Hospital
- Daniel Millar, Janssen
- Nick Richardson, FDA

Thank you to Abby, Marianne, Daniel and Nick for presenting the results of the Master Protocol Studies project.

New CTTI Publications

A new manuscript in Therapeutic Innovation & Regulatory Science details CTTI's prioritization tool, from the Patient Group Engagement project, to help sponsors and patient groups pinpoint mutually beneficial engagement activities. The web-based tool provides 24 unique engagement activities that span the medical product development lifecycle. For more information, please contact senior project manager Zach Hallinan.

CTTI has also published a new manuscript in *Contemporary Clinical Trials Communications* that features the evidence-based set of recommendations for incorporating patient and site perspectives in digital health trials from the Engaging Patients and Sites project. For more information, please contact project manager Lindsay Kehoe

Recently Posted Notices & Guidance

FDA Approves First Treatment for Ebola Virus

Today, the U.S. Food and Drug Administration approved Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn), a mixture of three monoclonal antibodies, as the first FDA-approved treatment for Zaire ebolavirus (Ebola virus) infection in adult and pediatric patients.

Read More

The FDA launches Digital Health Center of Excellence

Today, the U.S. Food and Drug Administration (FDA) launched the Digital Health Center of Excellence. This new Center of Excellence seeks to empower digital health stakeholders to advance health care by fostering responsible and high-quality digital health innovation.

The Digital Health Center of Excellence aims to connect and build partnerships among stakeholders to:

- Accelerate digital health advancements
- Share knowledge to increase awareness and understanding, drive synergy, and advance best practices
- Innovate regulatory approaches to provide efficient and least burdensome oversight while meeting FDA standards.

The Digital Health Center of Excellence will align and coordinate digital health work across the FDA and is part of the planned evolution of the Digital Health program in the FDA's Center for Devices and Radiological Health. A key benefit of the Digital Health Center of Excellence is that it will support and encourage developers—including those who are new to the health care space—to translate digital advances into tools that benefit patients and consumers.

This announcement marks the beginning of a comprehensive approach to digital health technology, setting the stage to advancing and realizing the potential of digital health. The Digital Health Center of Excellence will build new capacity and leverage the strength of the FDA to ensure access to high-quality health technologies. In addition to current efforts, such as the Pre-Cert Pilot Program, the new FDA Digital Health Center of Excellence introduces new initiatives such as the Digital Health Network of Experts and Digital Health Partnerships to advance the field of digital health.

FDA Draft Guidance on Patient-Reported Outcome Instruments for Medical Devices

The FDA issued a draft guidance, Principles for Selecting, Developing, Modifying and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation. This draft provides the FDA's current thinking about the best practices for incorporating patient-reported outcome (PRO) instruments throughout the lifecycle of a medical device.

9/21/2020 - FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency: Guidance for Industry, Investigators, and Institutional Review Boards

9/14/2020 - Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment

8/25/2020 - Evaluating Cancer Drugs in Patients with Central Nervous System Metastases: Draft Guidance for Industry

8/14/2020 - Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to FDA, and FDA Staff

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Frontier Science Foundation is a not-for-profit research organization dedicated to the improvement of data management and statistical quality in clinical trials and medical research.

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We provide unrivaled biostatistics and operations research knowledge to our customers. Our knowledge is available in the form of both software and services. This knowledge, supported by our trial implementation capabilities, is what makes us different. We are leaders in the design and implementation of adaptive clinical trials.

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JAEB CENTER FOR HEALTH RESEARCH

The Jaeb Center for Health Research was established in 1993 as a freestanding, nonprofit coordinating center for multi-center clinical trials and epidemiologic research. The Jaeb Center's focus is eye disorders or type 1 diabetes.

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Emmes collaborates with clients to produce valued, trusted scientific research. We are passionate about making a difference in the quality of human health, and have supported more than a thousand studies across a diverse range of diseases since our formation in 1977.

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JOURNAL OF CLINICAL MEDICINE

JCM (IF = 5.583) is an international scientific open access journal, providing a platform for advances in clinical practices, the study of direct observation of patients and general medical research. The journal is indexed by SCIE and PubMed.

Save the Dates - Upcoming SCT Annual Meetings

42nd Annual Meeting May 16-19, 2021

Chicago, Illinois USA

43rd Annual Meeting May 15-18, 2022

San Diego, California USA

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