Hello fellow SCTians,

It is my distinct pleasure and honor to write this newsletter article as we prepare for our 40th Annual Meeting from May 19th-22nd in the beautiful city of New Orleans. The theme of our meeting is Clinical Trials: A Catalyst for Societal Advancement through Innovation. Amidst all the different activities the meeting will offer, we will take some time to celebrate our society and the many ways it has touched all of us at a dance reception on Monday, May 20th. Please come and celebrate with everyone. We also have a special Founders session on Monday evening where a few of our past presidents will provide insights on the Founders of our Society and their motivations behind the foundation of the Society, to take stock of what the Society has accomplished since its foundation in 1978, and to envision the future of the Society beyond its first 40 years.

As we are gearing up for our 40th Annual Meeting, I want to pause and extend my thanks to our education and program committee co-chairs and members for their phenomenal efforts in putting together this exceptional meeting for all of us. A few highlights of our meeting coming up include:

- The Scleroderma: Cyclophosphamide or Transplantation (SCOT) trial is the recipient of the prestigious David Sackett Trial of the Year Award, presented annually by the Society for Clinical Trials (SCT). Dr. Lynette Keyes-Elstein, Principal Statistical Scientist at Rho will accept the award on behalf of the SCOT trial team. She will present the SCOT trial on May 20, 2019 at the Society's 40th Annual Meeting in New Orleans, Louisiana. Please read more details about this in this newsletter.
- Dr. Thomas Fleming will deliver the Curtis Meinert Keynote lecture on Monday, May 20th, 2019 focusing on the topic of striving to achieve and protect the integrity of clinical trials, in alignment with the theme for the 40th year meeting.
- Dr. Monica Bertagnolli will deliver the Founder's lecture on Tuesday, May 21st, 2019, focusing on building a learning health care system, and learning from every patient. This talk fits well with the theme of societal advancement and will largely be futuristic in its perspective.

New in 2019, we have organized a few round-table sessions to give our new members an opportunity to learn about our society, and our current members a glimpse into the many opportunities for leadership and involvement with the society. The education workshops are offered on Sunday, May 19th and have a diverse set of topics to choose from. Please consider registering for these sessions.

As I write this letter, the number of registrations for the annual meeting is well over 500! This is exciting! Thank you to each of you who participate in the society's activities and present in our annual meeting - this is a great educational opportunity for all of us engaged in clinical trials conduct and research.

I am excited as I am sure all of you are for the meeting in New Orleans. See you all in a few weeks as we celebrate the society's 40th year!
Sincerely,
Sumithra Mandrekar, PhD
SCT President, 2018-2019
mandrekar.sumithra@mayo.edu

SCT's 40th Annual Meeting

"Clinical Trials: A Catalyst for Societal Advancement through Innovation"

REGISTER NOW  View Schedule of Events

Schedule subject to change

Learn more about SCT's 40th Annual Meeting
## Calendar of Upcoming Events

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<td><strong>ICTMC 2019</strong>&lt;br&gt;5th International Clinical Trials Methodology Conference&lt;br&gt;6 – 9 October, Brighton, UK&lt;br&gt;Abstract Submission Deadline</td>
<td>May 5, 2019</td>
<td><a href="#">Click Here for Abstract Submission</a></td>
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<td><strong>SCT 40th Annual Meeting</strong>&lt;br&gt;Society for Clinical Trials</td>
<td>May 19-22&lt;br&gt;New Orleans, LA</td>
<td><a href="#">Click Here for Online PROGRAM</a> &lt;br&gt;<a href="#">REGISTER NOW</a></td>
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<td><strong>International Clinical Trials Day!</strong></td>
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<td><strong>Webinar</strong>&lt;br&gt;New Standard for Outcome Reporting in Clinical Trials: Instrument for Reporting Planned Endpoints in Clinical Trials InsPECT 2019&lt;br&gt;Martin Offringa and Nancy Butcher</td>
<td>July 2019&lt;br&gt;Date TBA</td>
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<td><strong>Webinar</strong>&lt;br&gt;Innovative Statistical Approaches for Utilization of External Evidence in Clinical Trials: Challenges and Opportunities&lt;br&gt;Yunling Xu, CDRH/FDA</td>
<td>October 2019&lt;br&gt;Date TBA</td>
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| **Webinar** | **Understanding the Estimand Framework**  
*Vlad Dragalin, Janssen* | **December 2019**  
*Date TBA* | **TBA** |
|---|---|---|---|
| **41st Annual Meeting** | **41st Annual Meeting** | **May 17-20, 2020**  
*Baltimore, MD* | **Save the Date!** |
| **42nd Annual Meeting** | **42nd Annual Meeting** | **May 16-19, 2021**  
*Chicago, IL* | **Save the Date!** |
2018 David Sackett Trial of the Year Award
By Scott Evans, Trial of the Year Committee Chair

The Scleroderma: Cyclophosphamide or Transplantation (SCOT) trial is the recipient of the prestigious David Sackett Trial of the Year Award, presented annually by the Society for Clinical Trials (SCT). Dr. Lynette Keyes-Elstein, Principal Statistical Scientist at Rho will accept the award on behalf of the SCOT trial team. She will present the SCOT trial on May 20, 2019 at the Society’s 40th Annual Meeting in New Orleans, Louisiana.

Scleroderma is a devastating progressive heterogeneous autoimmune disease that is associated with considerable mortality and morbidity. No FDA-approved therapy is available for patients with scleroderma, and mortality rates have remained constant over the past forty years. In the SCOT trial, adults with severe scleroderma were randomly assigned to undergo myeloablative autologous hematopoietic stem-cell transplantation (AHCT) or to receive cyclophosphamide. AHCT resulted in improvement in the primary end point a global rank composite score incorporating survival, event-free survival (survival without respiratory, renal, or cardiac failure), forced vital capacity, the score on the Disability Index of the Health Assessment Questionnaire, and the modified Rodnan skin score. The American Society for Blood and Marrow Transplantation Task Force now recommends AHCT as the standard of care for patients with severe disease. The SCOT trial was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health.

Each year since 2008, the SCT has awarded the David Sackett Trial of the Year Award to a randomized, controlled trial published (either electronically or in print) in the previous calendar year that best fulfills the following standards:

- Improves the lot of humankind;
- Provides the basis for a substantial, beneficial change in health care;
- Reflects expertise in subject matter, excellence in methodology, and concern for study participants;
- Overcomes obstacles in implementation; and
- Based on the presentation of its design, execution, and results is a model of clarity and intellectual soundness.

Nominations are submitted by Society members, investigators, and interested scholars from around the world. The 2018 Trial of the Year selection committee included Marc Buyse, Henry Bob Dworkin, Susan Ellenberg, Scott Evans (Chair), Dean Follmann, Toshimitsu Hamasaki, Frank Rockhold, Dan Rubin, and Yves Rosenberg.

The 2019 Trial of the Year Selection Committee will issue a call for nominations in fall, 2019. Visit www.sct.org for updates.

About the Society for Clinical Trials: The Society for Clinical Trials, created in 1978, is an international professional organization dedicated to the development and dissemination of knowledge about the design, conduct, analyses, and reporting of government and industry-sponsored clinical trials and related health care research methodologies. Visit www.sctweb.org. About the Trial of the Year: find a list of past Trials of the Year on www.sctweb.org/public/about/toty.cfm.
Featured Sessions at the 40th Annual Meeting

By Letitia Perdue, Program Committee Chair

Before you head home, the last day of the conference is full of some great sessions! In this newsletter, we feature some invited sessions scheduled for the final day of the meeting.

THE UNITED STATES’ RIGHT-TO-TRY LEGISLATION: IMPLICATIONS FOR CLINICAL TRIALS

Background: Since the 1960s, federal law has required drug manufacturers to demonstrate to the United States Food and Drug Administration (FDA) that their products are safe and effective before they can be marketed. Although this requirement increased the time it took to make new treatments available—since manufacturers had to conduct clinical trials to demonstrate adequate safety and effectiveness—this was justified by the belief that the social cost (i.e., restricted or delayed patient access to new therapies) was generally outweighed by public health and consumer protection benefits (i.e., evidence that approved products offered a favorable risk/benefit balance).

However, in some cases, this social justification does not seem adequate. For example, some patients (or patient populations) with life-threatening conditions are willing to accept the increased risks of harm from unproven interventions in order to have quicker access to new potentially-therapeutic options. And while the first choice, benefitting both individual patients and society as a whole, is to have individuals try investigational medical products in a clinical trial, not all patients are able to participate in clinical trials, for a variety of reasons.

In recognition of this problem—and responding to requests from HIV patients—in the late 1980s, the FDA formalized an “Expanded Access” (EA) pathway allowing certain patients to receive unapproved drugs outside of a clinical trial, if the entity developing the drug was willing to grant access and the FDA authorized the access. Since that time, thousands of patients have received access to unapproved, experimental interventions through expanded access programs.

Yet, in just the past few years, nearly all of the US states have passed so-called “right-to-try” laws, which purport to allow pre-approval access to experimental drugs outside of clinical trials without FDA or Institutional Review Board (IRB) authorization. On May 30, 2017, the U.S. President signed a federal “right-to-try” bill into law, creating a federal “right to try” pathway like the ones provided for in the state laws. But as many commentators have observed, the actual effect of these laws for patient access is unclear, in part because manufacturers are not required to honor requests made via “right to try” laws any more than they are requests made via EA. There is also a concern that if patients can access experimental interventions outside of clinical trials, they may be less inclined to enroll in trials (which
already face recruitment challenges), and this could further delay the research, development, and approval process. Both the FDA’s EA regulations and the federal “right to try” law include provisions intended to mitigate this concern. In the case of EA, the doctor, the drug company, and the FDA all work to ensure that providing the experimental product will not interfere with completion of clinical investigations. Under the federal “right to try” pathway, concerns about interfering with clinical trial enrollment are heightened, both because the FDA, which often has the best information about clinical trial progress, is not required to authorize access and it is not yet clear how the requirement that “right to try” patients be unable to participate in clinical trials will be implemented.

In this panel session, our speakers will offer their perspectives on what these right-to-try laws mean for patient safety, clinical trials, and the integrity of the clinical research and regulatory enterprises. We will begin the session with short presentations from each speaker. This will be followed by discussion of a few prepared questions, before opening the floor to panel Q&A with the audience for the remainder of the session.

CHALLENGES AND BEST PRACTICES FOR DATA MONITORING COMMITTEES (DMCs) OVERSEEING ADAPTIVE CLINICAL TRIALS

1. Introduction to the Challenges Facing Committees Overseeing Adaptive Clinical Trials – Roger J. Lewis, MD, PhD

In this introduction, Dr. Lewis will briefly summarize the roles, responsibilities, and purpose of DMCs for a non-adaptive trial, for an adaptive trial, and how they are similar or different. An emphasis will be placed on the importance of following the prespecified design to ensure the designed operating characteristics are realized and trial integrity is maintained.

2. Operational Challenges of Interim Analyses – Robert Silbergleit, MD

The conduct of prespecified interim analyses for adaptive trials requires that comparative outcomes data be rapidly compiled and cleaned so that they may be used to implement the adaptative algorithm. Dr. Silbergleit will discuss these operational challenges and trade-offs that exist between data availability and data quality.

3. The Data Monitoring Committee and the “Adaptation Committee” – Michelle A. Detry, PhD

The September 2018 draft FDA guidance on adaptive designs for clinical trials describes potential models for maintaining trial integrity during adaptive trial implementation where the DMC may serve as the executing body for adaptations, or for the creation of a separate independent “adaptation committee.” Dr. Detry will discuss the advantages and disadvantages of these two possible structures as well as FDA recommendations on associated data access plan documentation. She will present models for information flow between the committees and the sponsor as well as best practices for guarding against potential operational bias.
4. When, if Ever, Should the DMC Deviate from the Prespecified Adaptive Algorithm – Janet Wittes, PhD

The DMC has access to a broad array of information not incorporated into the adaptive algorithm. This additional information may lead to a situation in which the DMC considers deviating from the prespecified algorithm, either, for example, stopping the trial early before the first prespecified futility analysis or continuing the trial when the prespecified algorithm dictates stopping the trial for early success or for futility. This raises a number of questions. Should anyone who has seen unblinded data be allowed, in essence, to redesign the trial? If the DMC issues a recommendation that deviates from the prespecified algorithm, is there an obligation to inform the trial sponsor or steering committee? How could this be done in a manner that is minimally unblinding and maintains trial integrity?

FROM GRANT TO GANNT, THE CHALLENGES OF SETTING UP A TRIAL IN 2018 – LESSONS LEARNT FOR THE INTERNATIONAL STAGE

Managing large national and international multi-centre randomised controlled trials in the current research climate is demanding. Even within the (assumed) security of a multidisciplinary, accredited trials unit, setting up a new trial represents a unique and diverse set of challenges each time. From an ever changing ethical and regulatory environment, to managing difficult situations and people many challenges affect the speed and quality of trial set up, ultimately setting the stage for the continuing performance – and arguably, success – of the trial.

These challenges can manifest themselves at various stages during the set up phase and include identification and approval of clinical centres; gaining the necessary financial and regulatory approvals in a timely manner and engaging and training local staff in trial procedures; and the potential delays). Many of these challenges are largely influenced by the different levels of engagement demonstrated from all members of the trial team from the Chief Investigator to the staff at the local clinical centres. Careful selection of clinical centers (from previous research experience and/ or early engagement of all parties involved) and tailoring of communication and training methods appropriate to these individual centres is essential for trial success. This session includes a series of talks focusing on the experiences of trial managers/researcher who have both national and international, and drug and non-drug (surgical) trial experience. The first talk will discuss common themes in robust trial conception and start up and lessons learnt from past trial successes and failures. The second talk will focus on the potential benefit of pursuing ‘follow on trials’ using the same research staff/clinical centres. The third talk will focus on what our collaborators found useful during the set-up process, including training needs and methods of communication. The fourth talk will discuss differences between the trial start up process in the UK versus the US and consider what the international trial management community as a whole could learn from this analysis.

This invited session will be informative to an international audience involved in the management of randomized controlled trials, particularly during the start-up phase of the trial.
THE GLOBAL REGULATORY LANDSCAPE AND A SAFETY MINDSET: MEDICAL JUDGMENT AND DECISION-MAKING WITHIN A QUANTITATIVE FRAMEWORK

The purpose of clinical trial safety monitoring is to identify, understand and manage risks in order to increase the opportunity to deliver effective medicines with favorable benefit-risk profiles to the right patients. A multi-disciplinary team, regularly reviewing aggregate safety data throughout the development program, is vital for early signal detection, but also for generating a better understanding of the accumulating data and context needed for decreasing false alarms. By identifying, as early as possible, distinct patient populations where the benefits outweigh the risks, perhaps with a suitable risk mitigation strategy, medicines can be better positioned in the marketplace, allowing an appropriate subset to realize important health benefits of an effective treatment.

We will define a systematic, coordinated approach to identify, assess and characterize safety topics of interest that enables investigators to develop clinical as well as quantitative understanding of the safety profile. We will also explore the application of appropriate statistical techniques with a safety mindset, as opposed to strict statistical inference, with the emphasis shifted from testing and confirming to exploration, learning, and medical decision-making within a quantitative framework.

Raffael Kurek, MD (Global Patient Safety, Eli Lilly and Company, Windlesham, UK): Recent guidance on safety monitoring during medicine development, issued by regulatory authorities in the United States and European Union, indicate a shift in focus towards aggregate safety monitoring and scientific evaluation of integrated safety data throughout the development program. Despite some differences in approach between the agencies, particularly in regards to expedited reporting of safety data from clinical trials, both agencies require sponsors to regularly conduct program-level reviews, considering data from completed and ongoing clinical trials. This shift in emphasis provides an opportunity for stakeholders to engage in the advancement of cross-disciplinary procedures for aggregate safety analysis to further improve identification and characterization of risks for a medicine on a program level, especially at the stage of clinical trial safety monitoring.

Barbara Hendrickson, MD (Pharmacovigilance and Patient Safety, AbbVie, North Chicago, IL, USA): Aggregate product safety assessment requires multidisciplinary collaboration among clinicians, statisticians, epidemiologists, and other subject matter experts. Proactive planning is critical to understand the epidemiology of the patient population and identify the key product safety questions to be answered during the clinical development program. Determination of the safety topics of interest, the safety estimands, and approaches to data collection and analysis spans from pre-marketing into post-marketing. Early characterization of important product risks enables the development of risk management strategies. Systematic preparation for a structured benefit risk assessment ensures that essential data is collected to inform patient, healthcare provider and regulatory authority decision making. These efforts necessitate attention equal to that of the efficacy and effectiveness evaluations. In addition, the changing regulatory expectations for safety assessment require new skills and methodologies, which present both challenges and opportunities.
Greg Ball, PhD (Clinical Safety Statistics, Merck Research Laboratories, Rahway, NJ, USA): Safety monitoring during clinical development requires a partnership between clinical and statistical scientists. A special challenge in ongoing aggregate evaluation of safety data is applying appropriate statistical techniques with a safety mindset. To meet the spirit of the FDA IND safety reporting final rule, sponsors conducting clinical trials under the authority of the FDA have responded by developing processes and tools to evaluate, assess and act on accumulating safety information during development on an ongoing basis to ensure earlier identification of safety concerns and to take appropriate steps to mitigate risks. For AEs “anticipated” or “expected” to occur in a trial, determining “reasonable possibility” of causal association would require an assessment of increased frequency based on aggregate data. Auspiciously, some multi-disciplinary teams (advocated for in CIOMS VI) have been implementing procedures for review of aggregate blinded clinical trial data to support safety signal detection and risk-management activities, minimizing the need to unblind data in ongoing studies. The important thing is to have a thoughtful process; a system in place to look for these imbalances, applying the best clinical and quantitative judgment, while maintaining trial integrity.

Jacqueline Corrigan-Curay, JD, MD (Office of Medical Policy, CDER, FDA, Silver Spring, MD, USA): The call for aggregate reviews of accumulating safety data, including from ongoing studies, provides an opportunity to leverage the scientific expertise and medical judgment of safety management teams with 1) a multi-disciplinary approach, 2) quantitative frameworks to measure level of evidence, and 3) assessments that are product-specific and driven by medical judgment. The goal is development of a thorough understanding of product risks in order to inform healthcare providers and patients as well as to develop risk mitigation strategies or target-specific patient populations that maximize the benefit-risk of products. We will discuss how systematic aggregate reviews of data enable a robust understanding of the evolving product safety profile and the identification of effective risk-management strategies.
The April issue of Clinical Trials features articles addressing important issues in study design, ethics, recruitment and policy. Ron Brookmeyer examines sample size requirements for studies to prevent or slow the symptoms of Alzheimer's Disease, showing that much larger sample sizes are needed than in trials conducted to date. In a commentary Dave Schoenfeld argues in favor of the benefits of such large trials.

Emily Largent and colleagues study in depth the use of financial "completion bonuses" to discourage attrition in clinical trials, laying out the pros and cons. Emily Largent and colleagues review the literature and summarize the evidence on the benefits of using electronic medical records and alerts to facilitate recruitment to clinical trials.

Finally, Amelie Duhamel and colleagues examine labelling of investigational drugs based on a survey of protocols, finding wide variability in the labeling with key information missing from labels affixed to internal containers.

Please add @clintrialsj to the accounts you follow on Twitter to keep up to date with the latest from the journal.
FDA Announcements

The following announcements are via the Food & Drug Administration (FDA):

Statement from FDA Commissioner Scott Gottlieb, M.D. on steps toward a new, tailored review framework for artificial intelligence-based medical

Artificial intelligence and machine learning have the potential to fundamentally transform the delivery of health care. As technology and science advance, we can expect to see earlier disease detection, more accurate diagnosis, more targeted therapies and significant improvements in personalized medicine.

The ability of artificial intelligence and machine learning software to learn from real-world feedback and improve its performance is spurring innovation and leading to the development of novel medical devices.

Today, we’re announcing steps to consider a new regulatory framework specifically tailored to ...

Statement by FDA Commissioner Scott Gottlieb, M.D., Director of FDA’s Center for Drug Evaluation and Research Janet Woodcock, M.D. and Director of FDA’s Center for Biologics Evaluation and Research Peter Marks, M.D. on Expanded Access - Looking Forward

For more than 30 years, the FDA has supported patients’ access to investigational medical products for treatment, outside of participation in a clinical trial, when appropriate. The FDA remains deeply committed to this effort. Helping to facilitate access to promising medicines for patients with serious or immediately life-threatening diseases or conditions when no comparable or satisfactory alternative therapy options are available is a high priority for the agency.

We cannot know in advance whether a drug obtained through expanded access (EA) will provide a benefit for these patients who have no other FDA-approved treatment options and cannot enroll in a ...

FDA In Brief: FDA takes new steps to advance natural history studies for accelerating novel treatments for rare diseases

The U.S. Food and Drug Administration today issued the draft guidance, Rare Diseases: Natural History Studies for Drug Development. This draft guidance is intended to help inform the design and implementation of natural history studies that can be used to support the development of safe and effective drugs and biological products for rare diseases.

Specifically, this guidance describes the broad potential uses of a natural history study in all phases of drug development for rare diseases. It covers the strengths and weaknesses of various types of natural history study designs, common data elements and research plans, and a practical framework for the conduct of ...

Read more
Open Mike

NIH Annual Snapshot – FY 2018 By the Numbers
By Mike Lauer
We recently released our annual web reports and success rate data with updated numbers for fiscal year 2018. These web products represent annual snapshots of NIH research investments, which are highlighted in this post. Continue reading →

New Resources
Get the Latest on an NIH Institute or Center’s Funding Strategies
Interested in the latest funding policies from your favorite NIH Institute or Center (IC)? Find funding strategies for each NIH IC, in addition to NIH fiscal policies and budget overview, on our NIH Funding Strategies page. Use this information as you prepare your application to better understand NIH’s approach to grant funding and stay updated on key budget policies. Continue reading →

The Protocol Template for Behavioral and Social Sciences Research Involving Humans Is Here
A new Behavioral and Social Sciences Research Template is now available to guide investigators through the systematic development of a comprehensive clinical protocol. The new template, based on the previously released Phase 2 & 3 Clinical Trial Template, is fully integrated into the NIH’s Clinical e-Protocol Writing Tool, and can be used by behavioral and social science researchers to prepare research protocols for human studies measuring a behavioral or social outcome, or testing a behavioral or social science based intervention. This template may be especially helpful to investigators who are less familiar with the information and the level of detail that is required in a clinical protocol. Continue reading →

You Ask, We Answer
Looking for Help Developing Your Biosketch?
The biosketch provides an opportunity for each senior/key person listed in an NIH grant application to describe why they are well-suited for their role(s) in the project. If you have never written a biosketch for an NIH grant application or need to brush up and look at a sample or the instructions, continue reading →
Where Should I Address the Inclusion Across the Lifespan Policy in My Application?
Applicants should include a rationale for the age range of study participants and justification for age-based exclusion in the Inclusion of Women, Minorities, and Children section of the PHS Human Subjects and Clinical Trials Information Form (Section 2.4). This section will continue to have the heading “Inclusion of Women, Minorities, and Children” until the next forms update. See the instructions under Inclusion of Children in the application guide for additional information. Continue reading →
New Recommendations on Engaging Patients and Sites in Mobile Trials

CTTI released new recommendations designed to help sponsors, CROs, and other stakeholders gain the full benefits of using mobile technologies in clinical trials. A recording of the recommendations launch webinar is also available.

Recording Available for CTTI, FDA Workshop on Incorporating Patient Perspectives in Clinical Trials

A video recording, presentations, and other materials from CTTI and the FDA's "Enhancing the Incorporation of Patient Perspectives in Clinical Trials" workshop are now available.

Panel discussions explored enhancing awareness and access to clinical trials, designing and conducting patient-centric trials, and post-trial communication and engagement.

Patients and IRBs are Amenable to Early Enrollment Strategy

An article co-authored by CTTI and recently published in Clinical Trials outlines lessons learned from the planning phase of the IMPACT-AFib trial, the first large pragmatic clinical trial that used the Sentinel infrastructure. This work is part of CTTI's larger effort to advance trials that use real world data sources.

Upcoming CTTI Events

- OHRP Community Research Forum
- 2019 Accelerating Anticancer Agent Development and Validation (AAADV) Workshop
- The 2019 Digital Medicine Symposium
- Global Innovations in Patient-Centered Kidney Care International Summit
- DIA China
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