

June 28–30, 2018



Wound Healing: Science & Industry

16th Annual Conference
New York Marriott East Side | New York, NY

BLUE-SKY WORKSHOPS / ROUND TABLE DISCUSSION

Thursday, June 28, 2018 | 2:00pm – 5:15pm | Morgan Rooms A-C

INNOVATION IN CLINICAL TRIAL DESIGN

Paul Rudolf, MD, Arnold & Porter, LLC | Kurt Kruger, WR Hambrecht + Co. | Stephanie C. Wu, DPM, Rosalind Franklin University of Medicine and Science

Moderators: Paulita LaPlante | Tamar Tennenbaum, MD, PhD

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- Is there a disconnect between the regulatory requirements for clinical trials and the future of new technology being adopted to support them?
 - How can adoption of new or faster technology speed existing clinical trial design processes?
 - How could existing trial management processes promote medtech or pharma companies to compete in a new research model?
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This roundtable discussion will particularly focus on the realm of treatment modalities of patients suffering from wounds as a sequelae of Type 2 Diabetes Mellitus (T2DM). Currently, in contrast to any known disease, regulatory agencies require complete healing of wounds (complete wound closure) as the singular primary end-point for approval of efficacy in drug/biologics treatment modalities. Interestingly, the discrepancies in requirements of device versus pharma/biologics development in this field provides insight of changes required in clinical trial design and regulatory concepts.

- How can we narrow the gap in time and monetary investment needed to address FDA's current requirements and encourage change in future regulatory requirements?
- What are the obstacles facing current wound healing clinical study design in struggle to show success in wound healing studies?
- Risk-based approach to clinical trial design and execution vs. traditional model of phased studies and "waterfall" clinical trials?
- How can we promote transparency to EU and US regulatory bodies throughout clinical trial?
- Insurance companies want to see comparative cost and efficacy with available clinical options prior to the product reaching the market.
- What changes in clinical trial design can support and align with new technologies which could affect regulatory roadmaps and support business and research requirements?
- Incorporating real-time clinical data analysis using new technologies – How should we do it and is this particularly important to wound healing tech assessment?
- How can we close the gap between regulatory requirements for devices versus pharma/biologics in the chronic wound healing field?
- Consider the sector of the market which provides plaque removal/reducing devices for patients suffering from CLI. Their primary end-point for success or failure is more nuanced when compared to – for example – stem cell therapy. What is the rationale (clinical, regulatory, historical)?
- Can a company meet regulatory expectations and remain competitive in product development?
- Technology has changed so rapidly – how can we use hi-tech technology in the wound healing field - taking into account that a company needs to deal with analytics and reporting to meet the requirements of a broad range of stakeholders – from the traditional executive team all the way to tech-savvy data analysts?
- Do the tech giants have a role in clinical trial design?

Friday, June 29, 2018 | 2:00pm – 5:00pm | Morgan Rooms A-C

INNOVATION IN CHRONIC DISEASE PREEMPTION

Gene D. Morse, PharmD, FFCP, BCPS, UB New York State Center of Excellence in Bioinformatics and life Sciences |

Jeffrey Niezgoda, MD, WebCME | Jonathan Rosenblum, DPM, Shaarei Zedek Medical Center, Israel | Tamar Tennenbaum, MD, PhD, Director, PSDC Foundation, Israel

Moderators: Bijan Najafi, PhD | Patrick Sheehan

- Is there a disconnect between healthcare provider strategies for care delivery and the increasingly consumer-driven environment of chronic disease prevention and management?
 - How will the adoption of new technologies affect healthcare infrastructure and capacity building?
 - How can chronic disease management models promote collaboration for improved health outcomes?
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This roundtable discussion will particularly focus on the future of healthcare delivery for people suffering from diabetes and its related chronic conditions, notably wounds. Currently, medical service providers are increasingly employing home health and remote monitoring strategies to assure the progress of treatment and the prevention of costly adverse events. Interestingly, the evolution of the point-of-care from the hospital into the community and home settings provides insight of changes required in healthcare delivery and chronic disease management concepts.

- How can we improve access to preventive services, while simultaneously reducing wait times and opportunity cost, for people with diabetes?
 - How can we effectively gather and analyze evidence-based data for risk stratification and patient safety reporting? Is it unethical to communicate this critical medical information to the patient?
 - How will we leverage technology-enabled models to preempt adverse events for patients at-risk of costly complications, hospitalization, and non-compliance?
 - How can we accelerate the adoption of the next generation of technologies without further disrupting the clinical workflow of physicians?
 - “High-tech” telemedicine and other virtual models are struggling to achieve their promise. Are we overlooking the role and the “high-touch” value of nurses, assistants, and caregivers?
 - The future of health and wellness innovation is personalized and patient-centered. How do we leverage investments to better address the significant ethnic health disparities associated with diabetes and its complications?
 - The adoption of big data generating healthcare technologies means greater opportunities for sharing medical information. How will this affect decision-making and accountability between stakeholders?
 - What are traditionally non-medical sectors that are increasingly important partners in designing the future of patient care?
 - People with diabetes are very complex and costly patients requiring the attention of large care teams. How do we make diabetes care a “turn-key” solution and improve healthcare navigation?
 - Is it sustainable with the current healthcare capacity to approach lower-risk people with prediabetes or early diabetes with more intensive services and support?
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