RAPID Pathways Annual (Virtual) Think Tank

Wednesday, January 27, 2021
12:30-17:45 PM (Eastern Time)

Meeting Objectives:

- To review the current status of PTX safety concerns and evidence updates
- To review the status of 2020 Pathways PTX Working Group deliverables
- To introduce the 2021 Use Case Focus: Pandemic Impact on Clinical Research in Vascular Intervention
- To identify Pathways working groups, priorities and directions going forward for 2021

12:30-12:35 **Welcoming remarks**

Mitchell Krucoff, Duke University Medical Center/Duke Clinical Research Institute

12:35-13:45 **Session #1 Paclitaxel (PTX) Data Efforts & Updates 2021**

Moderator: Mitchell Krucoff, Duke Clinical Research Institute

12:35-12:45 (10min) **The Pan-Industry Data Development Program Update**
Christopher Tieche, Medtronic; William Gray, Lankenau Medical Center

12:45-12:55 (10 min) **The ANSWER Task Force Analysis Update**
Aaron Lottes, Purdue University

12:55-13:05 (10 min) **PAD Registry Infrastructure 2021**
Jens Jorgensen, Society for Vascular Surgery

13:05-13:25 (20min as 5 min each Panelist) **Special Roundtable: Reaching the tipping point for weight of evidence on PTX safety in 2021: What are we looking for?**
Panelists: Michael Jaff, Boston Scientific; William Gray, Lankenau Medical Center; Andrew Farb, U.S. Food and Drug Administration; Kenneth Rosenfield, Multi-specialty Coalition on Paclitaxel (PTX)

13:25 - 13:45 Open Q&A/Discussion

13:45-14:45 **Session #2: Working group reports: 2020 Deliverables Updates**
Moderator: Melanie Raska, Boston Scientific

13:45-13:55 LEAN CRF (10 min) *James Black, Vascular and Endovascular Surgery Society*

13:55-14:05 SMART Common Data Model (CDM) (10 min*) James Tcheng, Duke Clinical Research Institute*

14:05-14:15 Patient Science (10 min) *Daniel Bertges, Society for Vascular Surgery, Vascular Quality Initiative*

14:15-14:25 Paclitaxel (PTX) Collaborative (10 min) *Sara Royce, U.S. Food and Drug Administration*

14:25-14:35 Safety Signal Discernment & Biostats (SANEST) (10 min) *Danica Marinac-Dabic, U.S. Food and Drug Administration*

14:35-14:45 Open Q&A/Discussion

14:45-15:00 **Break**

15:00-16:45: **Session #3 Break-out Sessions: Priorities Looking Forward in 2021**

15:00-15:05 (5 Minutes) Break-out Session Introduction & Instructions: Misti Malone, U.S. Food and Drug Administration

1. *Wrap up work from 2020*
2. *Priority new directions for 2021*

- LEAN and SMART in 2021
  James Black, Vascular and Endovascular Surgery Society; Donna Buckley, U.S. Food and Drug Administration; James Tcheng, Duke Clinical Research Institute; Ted Heise, MED Institute)

  - **Review of updated RAPID LEAN common data elements** (CDE's) (30 min)
    James Black, Vascular and Endovascular Surgery Society

  - **Review of RAPID Common Data Model** (CDM) (25 min)
    Marti Velezis, *U.S. Food and Drug Administration Contractor*

- **Review of Informatics Landscape** (30 min)
  - IEEE ISO 11073/medical device communications standards (5 min)
    Konstantino Makrodimitris, U.S. Food and Drug Administration

  - OMOP, ODHSI Common Data Models (5 min)
    Asiyah Lin, National Institutes of Health

  - HL7 processes, FHIR Implementation Guides (5 min)
    Marti Velezis, U.S. Food and Drug Administration Contractor

  - MedMorph, VULCAN (5 min)
    James Tcheng, Duke Clinical Research Institute

  - PCOR Trust Fund, Applications (5 min)
    Danica Marinac-Dabic, U.S. Food and Drug Administration

- **LEAN + SMART Work Group's Plans for 2021** (20 min)
  Donna Buckley, U.S. Food and Drug Administration; Ted Heise, MED Institute

- **Patient Science in 2021**
  Daniel Bertges, Society for Vascular Surgery, Vascular Quality Initiative; Michelle Tarver, U.S. Food and Drug Administration; Shelby Reed, Duke Clinical Research Institute; Dan Stephens, Boston Scientific

  - **Recruit Patient Advisor Panel**

  - **PAD PRO Manuscripts**
    - Description of the VQI MyPAD pilot study
    - Methods manuscript for PRO instrument launch in VQI Registry

  - **PAD Patient Preference Study Overview**
    - Quantifying Patients' Benefit-Risk Tradeoffs Associated with Percutaneous Revascularization Options for PAD

  - **Making PRO data elements LEAN and SMART**

  - **Applying Patient Engagement Science**
    - Addressing data structure for ethnicity/race data collection in PAD registries and trials

- Promoting balanced diversity in PAD research

- **Statistical Methodology and Inference in 2021**
  Mary Beth Ritchey, MedTechEpi; Roseann White, Natera; Eleni Whatley, U.S. Food and Drug Administration; Christopher Mullin NAMSA

  - **PTX Use Case**:
    - **ANSWER & Pan-Industry PTX follow-up analyses**: Will we have the answer?
    - **PTX themes addressed through SANEST submissions to ISPOR** (signal discernment) **ISPE, & Educational webinars** related to signal identification, management, and discernment (Epidemiology vs Biostatistics perspectives)
  - **Pandemic impact on PAD research data and statistical inference**:
    - **Optimal statistical methods for interrupted data sets, social behavioral change** (late presentations, medical non-compliance)
    - **Bridging real world and prospective trial data: Can we bridge bio statistical and epidemiological methods?**

- **2021 Use Case: Pandemic Impact on Vascular Device Research**
  Ajay Kirtane, Columbia University Medical Center; *Jennifer Rymer, Duke Clinical Research Institute; Misti Malone, U.S. Food and Drug Administration*

  - **Interruptions in research operations at various stages** (start-up, middle, end of study)
  - **Impact on analyses of various types of research studies** (RCT, Single arm, RWD/RWE)
  - **Diversity, equity, inclusivity of study participants**: Recognizing the issue, changing the landscape

16:45-17:00 **Break**

17:00-17:40 **Session #4**: **Breakout Group Reports**

Moderator: Misti Malone, U.S. Food and Drug Administration; Mitchell Krucoff, Duke Clinical Research Institute

17:00-17:10: **LEAN and SMART in 2021** *(10 min)*
Asiyah Lin, National Institutes of Health

17:10-17:20: **Patient Science in 2021** *(10 min)*
Daniel Bertges, Society for Vascular Surgery, Vascular Quality Initiative

17:20-17:30: **Statistical Methodology and Inference in 2021** *(10 min)*
Mary Beth Ritchey, MedTechEpi

17:30-17:40: **2021 Use Case: Pandemic Impact on Vascular Device Research** *(10 min)*
Ajay Kirtane, Columbia University

17:40-17:45 **Adjourn**