# Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development in the United States —November 18-19, 2019

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# **Disclosures**

**Sue Cammarata** is a full-time employee at Melinta Therapeutics.

**Ryan Cirz** is a paid consultant for Cipla.

**Sara Cosgrove**: 1) Consulting--member of an external infection adjudication committee for Theravance (past); 2) Consulting--member of an external infection adjudication committee for Basilea (current).

**Aaron Dane** has consulted for Achaogen, Allecra, Amicrobe, Amplyx, Cidara, ContraFect, Davolterra, Destiny, F2G, Geom, GSK, Gyroscope, Kymab, Mironid, Nabriva, Pfizer, Phico, Pled, Roche, Scynexis, Spero, TenNor, Transcrip Partners, VenatoRx and Zavante.

**Erin Duffy:** CARB-X receives funding from the governments of the United States (BARDA, NIAID), United Kingdom (DHSC/GAMRIF), Germany (BMBF) and two charitable foundations, the Wellcome Trust and the Bill & Melinda Gates Foundation.

Scott Evans has grant funding from NIH. He has consultancies with AstraZeneca (Trial Executive Committee). He's received funding for editorial activities from DeGruyter and publishing royalties from Taylor & Francis. He's received travel expenses / honorariums for educational activities and meetings from the American Statistical Association, CIOMS, Huntington's Study Group, ACTTION, FDA, Osaka University, National Cerebral and Cardiovascular Center of Japan, NIH, Society for Clinical Trials, American Society for Microbiology, Clinical Trials Transformation Initiative, University of Colorado, UCLA, International Society for Biopharmaceutical Statistics, Deming Conference on Applied Statistics, Antimicrobial Resistance and Stewardship Conference, World Antimicrobial Congress, and the CRT Conference. Dr. Evans serves on DMC or advisory committees for Takeda / Millennium, Pfizer, Roche, Novartis, Achaogen, Genentech, Amgen, GSK, Teva, Zeiss, Dexcom, Claret Medical, Vir, Arrevus, Five Prime, Shire, Gilead, Spark, Nuvelution, Tracon, Chiesi, WAVE, Advantagene, Braeburn, Cardinal Health, Covance, Lipocine, Microbiotix, Stryker, Rakuten, BENEFIT, Almmune, and the Austrian Breast & Colorectal Cancer Study Group (ABCSG)/Breast International Group (BIG) and the Alliance Foundation Trials (AFT).

**Vance Fowler**: Consultant: Pfizer, Novartis, Galderma, Novadigm, Durata, Debiopharm, Genentech, Achaogen, Affinium, Medicines Co., Cerexa, Tetraphase, Trius, MedImmune, Bayer, Theravance, Cubist, Basilea, Affinergy, Janssen, xBiotech, Contrafect, Regeneron, Basilea, Destiny, Amphliphi Biosciences. Integrated Biotherapeutics.

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-Educational fees: Green Cross, Cubist, Cerexa, Durata, Theravance; Debiopharm

-Royalties: UpToDate

-Patent pending: Sepsis diagnostics

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Wes Kim leads efforts to spur the innovation of new antibiotics for Pew's antibiotic resistance project. His work focuses on research and policies that will help to advance antibiotic discovery and development. Before joining Pew, Wes was a management consultant in the pharmaceutical and life sciences industry, advising clients on R&D strategy and operations, with a focus on infectious diseases.

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**Cynthia Sears**: BMS: Grant/Research Support, Research Grant.

**Pamela Tenaerts**: The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative. Dr. Tenaerts is an Employee of Duke University. Salary support comes from pooled membership fees of the Clinical Trials Transformation Initiative and from an FDA grant.

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