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Vincent Amoruccio is the Director, and Functional Area Head of Clinical & Statistical Programming for Alexion Pharmaceuticals. He has earned a Master's Degree in Biostatistics and is expecting another in 2016 in Health Informatics. He is knowledgeable in CDASH, SDTM, ADaM, and Define XML. In addition, Vincent has 13 solid years of SAS experience including SAS/BASE, SAS/ACCESS, SAS/MACRO, SAS/STAT, SAS/SQL and SAS/GRAPH, and is experienced in JAVA, SQL, Python, R, and VBA.

Vincent is highly proficient in using statistical procedures to produce tables, listings, figures, statistical analyses and modeling including simultaneous
modeling of discrete and continuous variables. He has experience in all aspects and phases (I-IV) of Clinical Trials, epidemiology studies and authoring parts of SAPs and SOPs. Vincent's therapeutic experience includes autism, cardiovascular, diabetes, gastrointestinal, infectious diseases, rare fatal diseases, obstetrics and gynecology, oncology and sexual health.

Instructor: Jozef Aerts
Company: XML4Pharma
Courses Taught: Dataset-XML, Define-XML, ODM
Training Languages: English, German, Dutch
Conversant Language: French

Jozef Aerts is professor in Medical Informatics at the University of Applied Science FH Joanneum in Graz, Austria. He is also an active CDISC volunteer since 2002, and one of the main developers of the ODM and SDM-XML standards, with also contributions to other standards and CDISC documents such as define.xml and the Metadata Submission Guide.

Jozef is also owner and CEO of XML4Pharma, a software development and consultancy company specializing in implementation of CDISC standards (CDISC Registered Solutions Provider) and well known for its ODM and define.xml editing, viewing and checking tools, and for its ODM to SDTM mapping software.

In his sparse free time, Jozef likes to climb mountains in the Alps - he is also a mountaineering instructor for the German Alpine Club (DAV).

Instructor: Landen Bain
Company: CDISC
Courses Taught: Healthcare Link
Training Language: English

Landen Bain works with CDISC, a global medical research standards development organization, as liaison to the healthcare information community to develop and implement data exchange standards between healthcare and medical research. Mr. Bain focuses his efforts on realizing improved interoperability today, with the immediate demonstration and implementation of existing standards. An example is a cooperative effort Bain leads between CDISC and Integrating the Healthcare Enterprise (IHE) to enable data capture for clinical research from within Electronic Health Record (EHR) systems using an IHE...
research from within Electronic Health Record (EHR) systems, using an IHE integration profile called Retrieve Form for Data-capture (RFD). This work brings together for the first time biopharmaceutical, EHR and research technology companies to develop interoperable solutions. The work has been demonstrated at six HIMSS Interoperability Showcases, and continues today with the creation of a number of real world studies in live research sites.

Mr. Bain served as co-chair of the HITSP Clinical Research Tiger Team and the CCHIT Strategic Lead for Clinical Research Workgroup. Both of these efforts move the use of EHRs for clinical research into the mainstream of the healthcare and clinical research industries. Mr. Bain is currently working on integration profiles for automating business processes between research and healthcare (Retrieve Process for Execution) and on methods for capturing and respecting the privacy preferences of subjects (Redaction Services).

Mr. Bain served for over 20 years as Chief Information Officer of two large academic medical centers: Duke University Health System in Durham, North Carolina and Ohio State University Hospitals in Columbus, Ohio. Mr. Bain was recognized by the HL7 Board as an ‘HL7 Pioneer’ in 1991 for his work as an early adopter of HL7 while at Ohio State University. He is a charter member of the College of Healthcare Information Executives.

Instructor: Niels Both
Company: S-Cubed
Courses Taught: ADaM, SDTM
Training Languages: Danish, English
Conversant Language: Swedish

Having worked for more than 15 years within the different areas of clinical data flow ranging from collection to statistical analysis and submission, Niels Both provides training in CDISC standards, coupled with a unique understanding of the everyday problems encountered when submitting data in SDTM, define.xml or ADaM to FDA.

For the last 4 years, Niels has been working as Principal consultant for S-cubed, assisting companies across Europe implementing CDISC standards e2e ranging from CDASH over SDTM to ADaM.

Niels has been active in the CDISC community for almost 10 years, presenting CDISC at road-shows, conferences and other events.
Instructor: Tineke Callant  
Company: SGS Life Science Services  
Courses Taught: ADaM  
Training Languages: English, Dutch  
Conversant Language: French

Tineke Callant is a Senior Biostatistical Analyst at the CRO SGS Life Science Services. She started working in the pharmaceutical industry in 2004 after obtaining a masters degree in biomedical sciences at the University of Antwerp. Her daily work includes project coordination, programming analysis datasets, TLFs, and narratives together with coordinating the implementation and development of the CDISC ADaM model within the company; the latter leading to presentations at the European CDISC Interchange and FSUG events. Tineke is a CDISC ADaM team member currently involved in ADaM PK sub team activities.

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Instructor: Sally Cassells  
Company: Next Step Clinical Systems LLC  
Courses Taught: Dataset-XML, Define-XML, ODM  
Training Language: English

Sally Cassells is the owner of Next Step Clinical Systems LLC a consulting company focused on facilitating the process of implementing CDISC standards. Sally was a founding member of the CDISC XML Technologies team and still volunteers as a team co-lead. She participates as a DefineXML team representative in the ADaM Metadata Team in the CAB Validation Project and on the Customer Advisory Board Validation Project. She is an ODM certified instructor. Prior to founding Next Step, Sally spent 8 years at Lincoln Technologies, Phase Forward and Oracle where she was the business and development lead for WebSDM and Empirica Study. Sally has over 25 years experience developing and implementing commercial clinical research software applications.

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Instructor: Ed Chappell  
Company: Formedix Ltd  
Courses Taught: ODM, Define-XML, Dataset-XML  
Training Languages: English
Switching from the electronics industry to the software industry in 2001, Ed first worked in electronic publication and machine readable documentation for USPTO Patent filings with Thomson Scientific. Seven years later he transitioned into the pharmaceutical industry with Formedix.

Initially working both on the Clinical Trial build (ODM-XML) and FDA submission (SDTM/Define-XML) areas, over the last few years he focused more on FDA submission standards (SDTM, SEND, ADaM), the Extract, Transform and Load (ETL) process and validation technologies.

As a Senior Consultant at Formedix, Ed provides training on CDISC Standards and XML technologies to customers.

Instructor: Gitte Frausing
Company: Data Standards Decisions
Courses Taught: SEND
Training Languages: English, Danish
Conversant Languages: French, Swedish

Gitte Frausing is Principal Consultant in Data Standards Decisions where she is working with companies implementing CDISC standards across the world. With her background in toxicology, she specializes in nonclinical and laboratory data with unique insight in the end-to-end data flow processes and brings this rare perspective and expertise to every client.

Gitte is a long-standing member of the CDISC SEND team. She has lead several efforts as a sub-team leader within the SEND team and has contributed to a substantial part of version 3.0 of the SEND Implementation guide as well as the next release (version 3.1).

Instructor: Nate Freimark
Company: Theorom Clinical Research
Courses Taught: ADaM
Training Language: English
Conversant Language: Hebrew

Nate Freimark is Senior Director of the Biometrics Operations Standards Group at Theorom Clinical Research. Nate is the current CDISC ADaM team lead, one of the ADaM instructors and a member of the SDS Oncology subteam. He has been a member of the ADaM team since 2005, a member of the ADaM Leadership Team
since its creation, and has been “doing CDISC” since 2004. Nate is also a lead programmer who has worked on numerous projects involving the creation of SDTM and ADaM datasets and the tables, listings, and graphs created based upon them dating back to 2004. Nate has been involved in ADaM Education since its inception from the development of the training material to giving public, private, and FDA ADaM training courses.

Instructor: Dave Gemzik
Company: Medidata Solutions
Courses Taught: Protocol Representation Model
Training Language: English

David brings more than 17 years of experience in enterprise software development and services in his role as Vice President, Implementation Services at Medidata Solutions. He has specialized in innovative applications in Clinical R&D and Operations. David has focused his most recent efforts on the development, and implementation of the first commercially-available, eClinical study design solution, Medidata Designer®.

An active member in the development of Clinical Data Interchange Standards (CDISC) for over 7 years, David is the CDISC team lead for the Protocol Representation Group. David has also been a featured presenter at various Drug Information Association (DIA) meetings, AMWA, and CDISC International Interchange conferences. David received his B.S in industrial engineering from Lehigh University.

Instructor: Paul Graham
Company: Formedix
Courses Taught: Datset-XML, Define-XML, ODM
Training Languages: English

A Solutions Consultant at clinical trial automation software developers Formedix, Paul has three years’ experience working with CDISC standards on a daily basis. Paul has worked on projects including clinical trial build based on the ODM, developing best practices for - and aligning existing metadata to - the SDTM, and study submission in Define-XML.

An active CDISC volunteer and member of the XML Technologies team, he was also a contributor during the creation and specification of the Dataset-XML standard.

Paul comes from an IT background and has experience working in the e-Learning industry, creating and delivering interactive, web-based training materials for Vertex.
Smita Hastak is co-founder and CEO of Samvit Solutions, a health care consulting company focused on requirements analysis, systems modeling and data standards development. Smita has been a modeler and an analyst on the Biomedical Research Integrated Domain Group (BRIDG) Model since the early days of this CDISC Domain Analysis Model. She is a member of BRIDG Semantic Coordination Committee (SCC) which is responsible for harmonizing the domain semantics from all BRIDG stakeholder’s initiatives into BRIDG for a common shared representation of the clinical research. Smita has more than 17 years of systems analysis and design experience in the health care domain. This includes over 12 years working in the cancer clinical research community on various analysis and software development projects and 5 years in state Medicaid and bio-surveillance software initiatives. She has served in many lead and senior roles at Unisys, Oracle and ScenPro over the past years.

Wendy Ver Hoef is a senior systems analyst at Samvit Solutions, a health care consulting company focused on requirements analysis, systems modeling and data standards development. Wendy has been a modeler and an analyst on the Biomedical Research Integrated Domain Group (BRIDG) Model since 2007 and is a member of BRIDG Semantic Coordination Committee (SCC). She has participated in the harmonization of several CDISC standards into BRIDG and lead the harmonization efforts for numerous other BRIDG contributors. Wendy has more than 10 years of systems analysis and design experience in the health care domain, predominantly in the cancer clinical research community, but also in pharma initiatives. In her earlier career, she gained analysis, design and programming experience in other industries such as DoD and video-on-demand. Prior to joining Samvit, she worked in the consulting division at Oracle for 14 years and for the last 8 years was a Senior Analyst at ScenPro, Inc.
Kit Howard has been on the CDASH Leadership Team since CDASH’s early days, and has been a CDASH trainer since the course was developed. She also worked on the CDASH User Guide. She currently co-leads the Medical Devices Standards team, and was instrumental in producing the SDTM Supplement for Medical Devices. In addition, Kit is a CDISC Registered Solutions Provider.

Kit is the owner of Kestrel Consultants and is a recognized expert in clinical data management, quality and standards with almost 30 years of experience. She provides consulting and training services for biopharma, medical device, academic and regulatory organizations. She holds a graduate degree in Clinical Research Design and Statistical Analysis, is a certified clinical data manager and serves on the Society for Clinical Data Management’s Editorial Board.

Instructor: Sam Hume
Company: CDISC
Courses Taught: Define-XML, ODM
Training Language: English

Sam is Vice President of SHARE Technology and Services at CDISC. At CDISC he leads the SHARE project and co-leads the XML Technologies team. Sam has over 20 years of work experience in clinical research informatics. Previously, he worked as Director of IS Architecture at AstraZeneca, VP of Technical Operations at Phoenix Data Systems and Chief Technology Officer at CB Technologies. Sam has an MS in Information Science, MS in Telecommunications, and is completing his doctorate in Healthcare Informatics.

Instructor: Monika Kawohl
Company: Accovion GmbH
Courses Taught: ADaM
Training Languages: English, German

Monika Kawohl is a Principal Statistical Programmer at the CRO Accovion and has 20 years of experience in the industry. Her daily work includes the hands-on
application of CDISC standards towards submission as well as consulting clients regarding their implementation of SDTM, ADaM and define.xml. Monika joined the ADaM team in 2009 and currently contributes to the General Occurrence, Pilot 1 Update, and ADaM Metadata subteams. She is also a member of the executive committee of the German-speaking CDISC User Group.

Instructor: Bron Kisler  
Company: CDISC  
Courses Taught: Controlled Terminology  
Training Language: English

Bron Kisler is a Co-Founder of CDISC and currently serves as Vice President, Strategic Initiatives. Within this role, he is responsible for identifying new growth opportunities for CDISC, steering the organization into new clinical and geographic markets, and managing key strategic alliances. Bron has 25-years of technical and business experience from both the public and private sectors, and has worked in the pharmaceutical industry for 15-years, developing innovative clinical research solutions. He spearheaded the CDISC Terminology Program in 2005, and has been successful in launching CDISC Therapeutic Area projects. Bron is currently Chair of the Joint Initiative Council for global standards harmonization and serves on the BRIDG Board of Directors. He is a graduate of the University of Central Florida and holds 3 Bachelor of Science degrees in Mathematics, Computer Science and Statistics.

Instructor: Rebecca Kush  
Company: CDISC  
Courses Taught: Global Approach to Accelerating Medical Research  
Training Language: English  
Conversant Language: Japanese

Rebecca Daniels Kush, Ph.D. is a Founder and the current President and CEO of CDISC. Dr. Kush has over 25 years of experience in the area of clinical research. She has worked for the U.S. National Institutes of Health, academia, a global contract research organization and pharmaceutical companies in the U.S. and Japan. Among numerous publications, Dr. Kush is lead author of the book, eClinical Trials: Planning and Implementation. Dr. Kush has given invited presentations (including keynotes) and tutorials at industry conferences, FDA and other venues in the U.S., Europe, and Japan for over 20 years. She earned a Ph.D. in Physiology and Pharmacology from the University of California (UCSD) School of Medicine in La Jolla, CA and has a B.S. in Chemistry and Biology from the University of New Mexico.
Instructor: Shannon Labout
Company: CDISC
Courses Taught: CDASH, Global Approach to Accelerating Medical Research, Legacy Data Conversion, SDTM
Training Language: English

Shannon Labout is a Certified Clinical Data Manager (CCDM) with 20+ years experience in healthcare technologies, project management and clinical research. She has managed clinical data management teams in both the U.S. and Europe, and has participated in CRF standardization, and contributed to data standards development, harmonization and implementation at multiple global pharmaceutical organizations and CROs for more than a decade. She has been an active member and team lead on the CDASH team since 2006 and on the SDS team since 2007. Shannon has been training on CDISC standards in North America, Europe and Asia since 2007. She is currently Vice President, Education at CDISC.

Instructor: Erin Muhlbradt, PhD
Company: Medical Science and Computing, Inc.
Courses Taught: Controlled Terminology
Training Language: English

Dr. Erin Muhlbradt is a contractor for the National Cancer Institute’s Enterprise Vocabulary Services (NCI EVS) and is the NCI EVS project lead for the Clinical Data Interchange Standards Consortium (CDISC) terminologies. Erin has over 5 years’ experience in the bioinformatics and pharmaceutical industries, including data standardization, database and metadata repository development, and terminology development. She manages a team at EVS that is responsible for the development and maintenance of CDISC controlled vocabularies in use by the pharmaceutical industry and the US Food and Drug Administration (FDA). Her duties include project management, biomedical and clinical trial subject matter expertise, terminology development, quarterly terminology publications, managing the CDISC terminology change request mechanism, and developing the content around the CDISC metadata repository. Previously, Erin was a doctoral candidate at Georgetown University in the Tumor Biology department and she performed her thesis work in laboratories at Georgetown University and Columbia University.

Erin holds a Bachelor of Science Degree (Honors) in Molecular and Cellular Biology from the University of Glasgow (Glasgow, Scotland) and a Doctoral Degree in Tumor Biology from Georgetown University (Washington DC).

Erin is active on all CDISC controlled terminology teams, a member of the management team for the CDISC SHARE project and active on therapeutic area standards development teams.
Instructor: Sandra Minjoe  
Company: Accenture Life Sciences  
Courses Taught: ADaM  
Training Language: English  

Sandra is a Senior ADaM Consultant in the Data Consulting Group at Accenture, helping clients implement ADaM. She has been an active part of the ADaM team since 2001, suggesting the creation of what have become ADSL and ADAE. Currently Sandra leads the ADaM sub-team for the General Occurrence structure, is helping develop ADaM Integration structures, and reviews all ADaM drafts for traceability and transparency. In addition to her ADaM work, she is a co-lead of the Computational Sciences Symposium work group on Transparency and Data Flow, helps coordinate the Bay Area (San Francisco) CDISC Implementation Network meetings, and is an Executive Committee member for PharmaSUG. Sandra has worked in the industry since 1993, at both sponsor and vendor organizations, in a variety of roles, including programmer, statistician, data manager, and filing team lead.

Instructor: Peter van Reusel  
Company: Business & Decision  
Courses Taught: CDASH, Global Approach to Accelerating Medical Research, SDTM  
Training Language: English  
Conversant Languages: French, Dutch, German  

Peter started his career with Janssen Pharmaceutica, a Johnson & Johnson company. He started working as a database analyst and over the years became responsible for the Janssen Pharmaceutica global data standard. Peter Van Reusel is currently the Business Unit Director of the CRO Services at Business & Decision Life Sciences. His team is specialized in CDISC data standards and statistical programming. Peter is currently also one of the CDISC SDTM and CDASH instructors, delivering courses across Europe. Peter is the chair of the CDISC E3C committee and a member of the CDISC Advisory Committee.

Instructor: Jon Roth  
Company: Independent Consultant  
Courses Taught: ADaM
With over 25 years in this industry, Jon is a highly experienced consultant in pharmaceutical drug development life-cycle projects. He has been a member of the ADaM team since 2006, and since that time, most of his consultant work has focused on CDISC ADaM implementations in support of statistical programming, study integration and regulatory filing activities. Of note, he was the first authorized CDISC ADaM trainer within Europe and was responsible for the analysis data and reporting of the industry’s first ADaM compliant regulatory submission to the FDA. In later years, he has been instrumental in numerous regulatory data filings with the FDA and European authorities on projects involving Lundbeck, Takeda, Forest Labs, Novo Nordisk, Merck, Abbott, Solvay, Wyeth, Novartis, and Sandoz.

Instructor: Jerry Salyers
Company: Accenture Life Sciences
Courses Taught: CDASH, SDTM
Training Language: English

Jerry joined Octagon Research Solutions (now part of Accenture Life Sciences) Data Standards Consulting group in January 2009 after 15 years in clinical data management at Procter and Gamble Pharmaceuticals. During his time with P&G, Jerry was involved in getting several new drugs and indications through the clinical-trial process and ultimate submission. He presented at numerous investigator meetings across the US and throughout Europe. With P&G, he was also active within the industry, representing P&G at the e-Clinical Forum (in both the US and Europe), where he presented a number of papers on electronic data capture and data warehousing.

With Accenture, Jerry provides an internal consulting resource to the Data Standards and Integration department as well as the in-house data management group. He also works one-on-one directly with several sponsors in review of mapping specifications (via CRFs and datasets) from source to SDTM-based datasets.

Instructor: Lauren Shinaberry
Courses Taught: CDASH, SDTM
Training Language: English

Lauren is a Certified Clinical Data Manager with over 15 years experience in data management, programming and project management. She has managed clinical and statistical programming teams in both North America and Europe and developed CRF standards for an international CRO as well as several client...
organizations. Lauren is the 2012 Chair of the CDISC Advisory Board and is part of the CDASH Leadership Team.

Instructor: Jack Shostak  
Company: Duke Clinical Research Institute  
Courses Taught: ADaM  
Training Language: English

Jack Shostak manages a group of statistical programmers and is an Associate Director of Statistics at the Duke Clinical Research Institute. He is the author of SAS Programming in the Pharmaceutical Industry and coauthor of Common Statistical Methods for Clinical Research with SAS Examples, Third Edition. Jack is also coauthoring the book Implementing CDISC Using SAS: An End-to-End Guide which should be published by the end of 2012. Jack has been active in CDISC since 2002 primarily as a contributor to ADaM model development and more recently to the Statistics Domain Analysis Model. Jack serves as a member of the ADaM alternate leadership team and has been a CDISC ADaM instructor for industry and the FDA for the past four years.

Instructor: Gary Walker  
Company: Quintiles  
Courses Taught: CDASH, SDTM  
Training Language: English

Gary Walker has worked in the pharmaceutical industry since 1992 and tells people his career path took the proverbial "scenic route." He started in IT and moved to Research and Development IT, supporting CANDA (Computer Assisted New Drug Applications) submissions. He subsequently moved to Regulatory Affairs and Publishing where Gary helped to create numerous marketing applications and supplements in electronic format from 1997 through 2005. In 2001, while working in regulatory, Gary became a member of the CDISC SDS team. In 2005 Gary moved from regulatory to Data Standards within Quintiles' Global Data Management department. In this role, Gary supported CDISC standards for data preparation within Data Management and Biostatistics, both for submission using SDTM and in the data collection and cleaning processes of Data Management, through the adoption of SDTM-friendly variables and the use of SDTM naming fragments for non-standard variables. Gary joined the CDASH initiative in 2006 and led the Demographics domain team for version 1.0. Gary continues to actively participate on the work on many of the CDISC standards including SDTM, CDASH and CDISC SHARE. Gary currently work for Quintiles in Innovation, a group focused on new and innovative products, where he is a part of a team focused on EHR data use for clinical research.
Instructor: Mario Widel  
Company: Eli Lilly  
Courses Taught: ADaM  
Training Languages: English, Spanish  

Mario Widel is a Research Scientist at Eli Lilly and Company. He has been doing statistical programming since 1992. He has been involved in CDISC related activities since 2007 on a previous company having a key role in the transition to CDISC standards CDASH, SDTM and ADaM. In his current role Mario oversees and participates in the metadata definition for SDTM and ADaM datasets, the design, creation and validation of TFL’s. He received his M.S. degree on Computer Science from the University of Illinois at Chicago. He is a regular presenter at conferences like JSM, PharmaSUG, SAS Global Forum, PhUSE and CDISC and a member of ASA and the CDISC ADaM team.

Instructor: Fred Wood  
Company: Accenture Life Sciences  
Courses Taught: SEND  
Training Language: English  

Fred is Senior Manager and Lead of the Data Standards Consulting Group within Accelerated R&D Services, a group he has led since 2007. He has been active in leading the development of CDISC standards since 1999. He is one of the principal contributors to the CDISC Study Data Tabulation Model (SDTM). Fred is a founding member of the SDS Team (1999), the SEND Team (2002), and the Devices Team (2007), and has led or co-led these for many years; he currently serves on the Leadership Teams of all three. Fred is currently a member of the CDISC Standards Review Council (SRC), the CDISC SDTM Governance Committee (SGC), and the CDISC Technical Leadership Committee (TLC). He has been a member of many other CDISC SDTM-related teams since 1999, and is providing SDTM expertise to therapeutic-area projects conducted as part of the CFAST initiative.

Fred joined Accenture via the Octagon acquisition in 2012. He joined Octagon in 2006, coming from Procter & Gamble Pharmaceuticals, where he was the Global Data Standards Manager in the Clinical Data Management Department. This position was preceded by many years as a Senior Toxicologist at P&G, supporting Rx and OTC products. Fred has a Ph.D. and an M.S. in Biochemistry.
Bernice Yost currently serves as Manager, Standards Development in CDISC. She coordinates the global development and harmonization of controlled terminology standards for medical research, supporting the CDISC standards, including SDTM (Study Data Tabulation Model), ADaM (Analysis Data Model), and SEND (Standards for the Exchange of Non-clinical Data) all for regulatory submissions, and CDASH (Clinical Data Acquisition Standards Harmonization) for data collection. These controlled terminology standards have been widely adopted and implemented throughout the world.

She is currently involved in developing standard terminology for multiple global therapeutic area standards projects and is active with the CDISC SHARE project.

Bernice has worked in the pharmaceutical industry for more than 20 years. Her past experience as Therapeutic Area Data Standards Specialist gives her the pharmaceutical industry prospective in the development of global standards across multiple disease areas. This work included successfully bringing together diverse global views to satisfy the needs for submission to many different regulatory bodies while developing global standards that all departments and users could implement including regulatory, clinical (for data collection), statisticians and data managers.

Bernice holds a Bachelor’s degree in Biology from the University of Pennsylvania (Philadelphia, PA) and a Master’s degree in Computer Science from Villanova University (Villanova, PA).