JOY A. CAVAGNARO, PhD, DABT, RAC, Fellow ATS, RAPS Fellow

P.O. Box 240
Boyce, Virginia 22620
(540) 837-9002 (W) * (540) 837-9003 (F) * (703) 727-5241 (M) • jcavagnaro@accessbio.com •

Education

1979	Ph.D. (Biochemistry) University of North Carolina Chapel Hill, NC
1975	B.S. (Biology) University of Miami Coral Gables, Florida

Academic Positions and Research Experience

1976 – 1978	Teaching Assistant University of North Carolina / School of Medicine Chapel Hill, NC
1979 – 1980	National Toxicology Fellow Duke University / School of Medicine Durham, NC
1981 – 1982	Research Associate, Division of Pediatric Hematology-Oncology Boston University / School of Medicine Boston, MA
1982 – 1983	Research Assistant Professor, Division of Pediatric Hematology-Oncology Boston University / School of Medicine Boston, MA

Credentials/ Certifications

1997	Appointed to Department of Health and Human Services Senior Biomedical Research Service
1986	Diplomate American Board of Toxicology (current recertification)
1999	Regulatory Affairs Certificate (current recertification)
2003	NIH Human Participants Protection Education for Research Team
2006	CITI Course in the Protection of Human Research Subjects
2009	Fellow of the Academy of Toxicological Sciences
2009	Regulatory Affairs Professional Society Fellow

Patent

U.S. Patent 696,546
'Process for Producing Human Antibodies'

Current Role

1999 – Present Access BIO, L.C.
Boyce, VA
President and Founder

Consultancy specializing in science-based regulatory strategies and development services to facilitate translation of biomedical research, emerging technologies and product development. Product classes include vaccines, cellular [including stem cells] and gene therapies, animal-based and plant-based bio-therapeutics, biotechnology-derived and tissue engineered products as well as novel small molecule chemical entities. Specific areas of focus include due diligence assessments of preclinical data and preclinical development strategies to support First in Human studies.

Prior Experience

1997 – 1999 Human Genome Sciences, Inc.
Rockville, MD
Vice President,
Regulatory Affairs and Integrated Compliance

Established the Regulatory Affairs Department, which included regulatory affairs and clinical data management data programming functions and assisted in identifying and developing new pre-clinical opportunities. Served as company spokesperson with the FDA and foreign agencies in all aspects of the regulatory process. Provided regulatory oversight for the pilot manufacturing facility start-up and commissioning, validation and expansion initiatives. Additional responsibilities included management of an Integrated Compliance Program, a unit formed in 1998, comprised of Quality Assurance (QA), Environmental Health & Safety (EH&S) function and the cross-functional Quality Systems Team (QST.) Provided oversight for development of the HGS EH&S Master Health and Safety Plan which was designed to enhance the management of corporate compliance activities.

1989 - 1997 Food & Drug Administration
Center for Biologics Evaluation and Research (CBER)
Bethesda, MD
1996 – 1997 ***Senior Pharmacologist & Director of Quality Assurance***
Office of the Center Director

Responsible for inter-center and international policy guidance for the preclinical development and safety assessment of biological products. Spokesperson for CBER at local, and national and international meetings related to pharm/tox aspects of biologic product review. From 1990-1997 served as FDA safety topic lead for the International Conference on Harmonization of Technical requirements for Pharmaceuticals (ICH) initiative and as rapporteur for the ICH S6 guidance on preclinical safety evaluation of biotechnology-derived pharmaceuticals. Appointed to Senior Biomedical Research Service (SBRS).

Monitored quality and consistency of CBER review activities and provided oversight for CBER technical committees created to support review activities. Ensured the accuracy of review and tracking of application data collected and reported by CBER. Chaired and Clinical Hold and Refuse to File Oversight Committees and served as Product Jurisdiction Liaison and center Ombudsman for resolution of review activity disputes unresolved at the division or office level between individuals or entities inside and outside of CBER. Additional responsibilities included supervising the regulatory information management system (RIMS) staff and the project manager of electronic submissions. Served as a member of the Intercenter Prescription Drug User Fee Application (PDUFA) Reauthorization Team. In 1997 chaired the FDA Science Symposium. Served as CBER representative to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and chaired the Immunotoxicity Working Group.

1995 – 1996 ***Senior Pharmacologist and Assistant to the Deputy Director***
Office of the Center Director

Served as ex officio center representative to the National Center for Toxicological Research Scientific Advisory Board. (1993-1997) Assisted in planning and developing policy and programs that set standards for traditional biologicals and biotechnology products. Served as a member on the Review Management Coordinating Committee. Chaired working group to develop guidance for comparability programs for biological products (April, 1996 Guidance Document on Comparability), Chaired the Clinical Hold and Refuse to File Oversight Committees.

1993 – 1995 ***Assistant Director for Pharmacology/ Toxicology***
Office of Therapeutics Research and Review

Developed pharmacology/toxicology policy and implemented guiding principles for CBER product application review and surveillance. Ensured interdivisional and interoffice consistency regarding design and analysis of pre-clinical studies. Co-chaired the Intercenter committee on the Use of Transgenic Animals to Produce Therapeutics for Human Use. From 1993-1996, served as CBER representative to the FDA Regulatory Scientist Peer Review Committee and the FDA Chemical Selection Working Group.

1989 - 1992 ***Special Assistant to the Director***
Office of Biologics Research

Managed OBRR interface with intramural and extramural pharmacology/toxicology programs and issues. Provided leadership in addressing pharmacology/toxicology issues to the five research division staffs of OBR as well as other offices within CBER. Served as toxicology reviewer on hundreds of INDs and six product license application (PLA) committees. FDA representative to Office Technology Assessment Report on Identifying and Controlling Immunotoxic Substances and member of the Naval Research Advisory Committee Panel on Delivery of Artificial Blood to the Military.

1983 – 1989 Covance (formerly Hazleton Laboratories America, Inc.) Vienna, VA

1985 - 1989 ***Senior Staff Scientist***
Department of Toxicology

Principal study director for pharmaceutical products derived from biotechnology. Planned, executed, and carried out the program for the safety evaluation of biotechnology-derived products in cooperation with appropriate scientific specialists at the various Hazleton laboratories worldwide. Served as the primary contact for developing pre-clinical development testing strategies including protocol design, standards of technical performance, methods for data interpretation, and recommendations for future directions of the corporation. Managed costs for assigned studies. Also served as the primary contact for inquiries related to immunotoxicology for Hazleton Corporation worldwide. Authored more that 100 confidential study reports.

1984 - 1985 ***Manager***
Genetic and Immunotoxicology Laboratories

As principal investigator for all genetic toxicology studies, directed programs to evaluate chemicals, particulate, drugs and biologics in a series of assays designed to determine potential, mutagenic or carcinogenic risks. Managed all costs and revenues for the laboratories under supervision. Interfaced with the FDA, EPA and other regulatory agencies to assist clients in meeting regulatory requirements. Chaired, Hazleton R&D committee.

1983 – 1984 ***Staff Scientist***
Hybridoma Technology Services, Immunobiology Division

Established an in vitro immunization capability as part of a comprehensive monoclonal antibody production contract service. Initiated research and development efforts for an Immunotoxicology Program. Member of Hazleton Laboratories Corporation Research and Development Committee.

Selected Presentations

Program Chair "Designing Preclinical Safety Evaluation Programs for Novel Therapies: What is the Question?" Preclinical Drug Development Improving Efficiency and Prediction to Proof of Concept, Barnett International, November 28-29, 2001, Philadelphia, PA.

"Regulatory oversight of gene transfer and GLP compliance: good science, good sense and the three R's of preclinical testing," Preclinical development of gene therapy vectors: from petri dish to Patient. –Comprehensive Reviewer Course on Clinical Gene Transfer ASGT's 5th Annual Meeting, June 4, 2002, Boston, MA.

"The way toxicity evaluation of bio-pharmaceutical products should be conducted: ICH S6 guideline", The role of toxicology in accelerating drug development and improving safety evaluation. - 29th Annual Meeting of the Japanese Society of Toxicology, June 20, 2002, Nagoya, Japan.

Program Co-chair: DIA Worldwide Preclinical Development of Biotechnology-Derived Products: The Science and the Regulation, Oct 21-22, 2002, Bethesda, MD.

"Nonclincial Safety Assessment of Biotechnology-derived Medicinal Products," What you Need to Know about Optimal Transition from Animal to Man, DIA, Dec 4-5, 2002, Helsingor, Denmark.

Program Co-chair: "Discussion Forum: Development and Regulation of Cell-Based Therapies", RAPS, March 20-21, 2003, London, UK.

"Putting in all Together- Writing the Label," Nonclinical Toxicology in Support of Licensure of Gene Therapies, ASGT, March 13-14, 2003, Arlington, VA.

Invited Speaker Korean FDA: "Preclinical Safety Assessment of Cell Therapy and Related Products," International Symposium on the Current Status of Gene and Cell Therapy, September 2-3, 2003, Seoul, Korea

"Developing Immunotoxicology Guidelines for (Bio) Pharmaceuticals: What is the Question?" Immunotoxicology, Pharmaceutical Educations Associates, September 17, 2003, Rockville, MD

"The State of Vector Biodistribution: How we got here and what we have learned," 7th Annual ASGT Meting, June 2, 2004, Minneapolis, MN.

"Product Comparability: From a "Regulatory Viewpoint", 10th Annual Bio International Conference, June 7, 2004, San Francisco, CA.

Keynote Speaker: "From Bench to Bedside: How Scientist Move Novel Technologies for Test Tubes to Therapies", Junior Science and Humanities Symposium Greater Washington Metropolitan Area 2005, January 6, 2005, Georgetown University, DC.

Moderator Breakout Session –Pharmacology and Toxicology Studies, FDA/DIA Workshop on Follow-on Protein Products, February 14-16, 2005, Arlington, VA.

Scientific Advisory Board and Meeting Chairperson – "Do animal models of disease predict human risk better than normal volunteers" Integrative Preclinical Development for In Vivo and In Vitro Validation, Molecular Medicine Tri-Conference, April 10-12, 2005, San Francisco, CA.

Key Opinion Leaders Meeting for Adenovirus, GlaxoSmithKline, May 19-20, 2005, London, UK

"Optimizing Design and Analysis of Preclinical Development Programs," 8th Annual Meeting American Society of Gene Therapy, June 2, 2005, St. Louis, MO.

"Preclinical Perspectives Gene/Cellular Therapy and Tissue Engineered Products" 2005 RAPS Annual Conference, October 19, 2005, Baltimore, MD.

"Improving the Predictive Value of Preclinical Studies to Support Clinical Development" 19th Annual EuroDIA Meeting, March 28, 2007, Vienna Austria

"Key Considerations in Preclinical and Clinical Development of Stem Cell Therapies", 19th Annual EuroDIA Meeting, March 28, 2007, Vienna Austria

"Preclinical Safety Evaluation of Biopharmaceuticals Facilitating Clinical Development: The Principles of ICH S6"BioEco 2007, June 26, 2007, Tianjin, China

"Key Considerations regarding Preclinical Development of Cell-Based Therapies: Facilitating Clinical Trials" Advances in Therapeutics Discovery and Development: Preclinical Cell-Based Therapy Research, MPI and WiCell, August 17, 2007, Augusta, MI.

Invited Speaker "Rational Design of Less Immunogenic Biotherapeutics", BMWP/BWP Workshop on Immunogenicity Assessment of Therapeutic Proteins, EMEA, September 4, 2007, Canary Wharf, London

Preclinical Research and New Technologies in Medicine. The Impact on Conducting Clinical Research
Inova Loudoun Hospital CRC Lecture, September 6, 2007, Ashburn, VA

"Preclinical Safety Evaluation of Biopharmaceuticals" Principles vs. Practices" ACCP 36th Annual Meeting Drug Development and Biotechnology: Update 2007, September 11th, San Francisco, CA

"The Investigational New Drug Application/Non-Clinical Day Requirements for the IND and NDA" Medicademy Module 3: The Regulatory Affairs Environment in the USA, November 7, 2007, Snekkersten, Denmark

"The History of Biologics and the Regulatory Path"; Regulatory Aspects of Biologic Development"; "Toxicology of Stem Cell Products"PERI Biologics Drug Development: An Integrated Overview of Manufacturing, Nonclinical, Clinical, and Regulatory Requirements
December 10, 2007, San Francisco, CA

"Introduction: Issues in Developmental and Reproductive testing of Biopharmaceuticals and Communication of Human Risk, SOT Annual Meeting, March 19, 2008

"Importance of NHP Animal Models of Disease for Enabling Biopharm Clinical Development with Particular Emphasis on Stem Cell Therapies", 17th Covance Symposium Critical Contributions of Primate Models for Biopharmaceutical Drug Development, April 17, 2008, Munster, Germany

"Utility of Animal Models in HBOC Evaluation", HBOCs: Current Status and Future Directions- CBER/NIH/DHHS, April 30, 2008, Bethesda, MD

"Considerations in Design of Preclinical Safety Evaluation Programs for Vaccines" Vaccine Quality Control and Safety Issues NICPBP, June 6, 2008, Beijing China

Program Committee, Session Chair, and Speaker "Introduction: Regulatory Aspects of Preclinical Immunogenicity Testing; Where is Immunogenicity Covered, What is Expected, How is it Addressed", DIA/AAPS Immunogenicity of Therapeutic Proteins, September 10, 2008, Bethesda, MD

"Preclinical Development Strategies for Biopharmaceuticals Based Upon Product Attributes"
ISSX Symposium, October 14, 2008, San Diego, CA

"Preclinical Safety Evaluation of Stem Cell Therapies: Key Considerations for Facilitating Clinical Trials", American College of Toxicology 29th Annual Meeting, November 12, 2008, Tucson, AZ

Program Committee and Session Chair Manufacturing Site or Scale Changes Case Studies, DIA Workshop Comparability Challenges: Regulatory and Scientific Issues in the Assessment of Biopharmaceuticals, February 3, 2009, Arlington, VA

"Should Transgenic Animals or Animal Models of Disease Be Considered in Development Programs?" 48th SOT Meeting CE Basic Course, March 15, Baltimore, MD

Chair "Roundtable Session: Preclinical Evaluation of Cancer Hazard and Risk of Biopharmaceuticals" 48th Annual Society of Toxicology Meeting, March 18, 2009, Baltimore, MD

"The Value of Immunogenicity Assessment in Preclinical Development," 5th Annual PEGS Conference Immunogenicity of Therapeutic Biologics, April 8, 2009, Boston, MA

"Women in Food and Drug Law and Regulation Half Full- Upcoming Challenges and Opportunities in the Current Economy," 52nd FDLI/FDA Annual Conference, April 22, 2009, Washington, DC,

Invited Participant, "Discussion of Biodefense Regulatory Issues," Meeting #5 of the Biodefense Standing Committee for the US Department of Defense, April 27, 2009, Washington, DC

"Facilitating Clinical Trials of Biopharmaceuticals: Improving the Predictive Value of Preclinical Safety Evaluation Programs for Clinical Decision Making (or better predicting whether programs will be acceptable to regulators!), North Carolina Regulatory Affairs Forum, May 14, 2009, Durham, NC

Chair, Overcoming Key Challenges in Advancing a Clinical Trial through the Various Phases of FDA Approval, ASGT 11th Annual Meeting, May 27, 2009, San Diego, CA

Chair, "Making the Case for Case-by-Case", 2009 RAPS Annual Conference & Exhibition, September, 15, 2009, Philadelphia, PA

"Telling the Story", UCSD Writing Preclinical Study Reports Extension Course, October 23, 2009

"Current Regulatory Expectations for the Incorporation of Immunogenicity Assessments in Pre-Clinical Studies", CHI Immunogenicity Summit, October 27, 2009, Philadelphia, PA

"Translation of Safety Biomarkers for Early to Late Stage Clinical Development: Improving the Predictive Value of Preclinical Safety Evaluation for Clinical Decision Making", AAPS Annual Meeting and Expo, November 11, 2009, Los Angeles, CA

"Regulatory Requirements and Strategies", 4th Drug Discovery for Neurodegeneration Conference, February 1, 2010, Houston, TX

Co-chair Roundtable Session "The Ying and Yang of Immunomodulatory Biopharmaceuticals: What Have We Learned since Mabel and How Close are We to the Clinical Dose?" 49th Annual Society of Toxicology Meeting, March 9, 2010, Salt Lake City, UT.

"A Retrospective Look at Preclinical Study Considerations for Assessing Reproductive and Developmental Toxicity Potential of Biopharmaceuticals", 49th Annual Society of Toxicology Meeting, March 10, 2010, Salt Lake City, UT.

Co-chair DIA Clinical Development of Stem Cell Therapies: Scientific, Regulatory, and Ethical Considerations and presentation "Biodistribution, Ectopic Tissue and Tumorigenicity", April 12-13, 2010, North Bethesda, MD.

"Assessing Comparability" BioSafe General Membership Annual Meeting April 28-30, 2010, Boston, MA

"Due Diligence: Preclinical Safety and Regulatory Issues" 2010 BIO International Convention, May 3, 1010, Chicago, IL.

"Immunogenicity and Biosimilars", 6th Annual PEGS Summit, May 17, 2010, Boston, MA

Keynote Speaker "Revealing the "Magic" of Monoclonal Antibodies", 6th Annual PEGS Summit May 19, 2010, Boston, MA.

Co-Moderator and Speaker for Short Course Scientific and Regulatory Considerations in Assessing Comparability of Biopharmaceuticals Pre-and Post-approval and presentation "Comparability Assessment of Biopharmaceuticals: Characterizing Differences that Don't Make a Difference" 2010 AAPS National Biotechnology Conference, May 20, 2010, San Francisco, CA.

"Engineered T Cells in the Clinic: Emerging, Clinical and Regulatory Issues", 13th Annual American Society of Gene & Cell Therapy (ASGCT) Meeting, May 21, 2010, Washington, DC.

"Highlights of DIA Meeting "Clinical Development of Stem Cell Therapies: Scientific, Regulatory, and Ethical Considerations", 46th Annual DIA Meeting, June 14, 2010, Washington, DC.

"OSWG Exaggerated Pharmacology Subcommittee Report" 46th Annual DIA Meeting, June 16, 2010, Washington, DC.

"Design Considerations for Preclinical Evaluation of Stem Cell Products", ISCT 2nd Annual Symposium on Stem Cell Translation: Strategies, Best Practices & Regulatory Considerations, September 27, 2010, San Francisco, CA.

"Challenges in Assessing and Communicating Carcinogenic Risk of Novel Therapies", SCCSOT Annual Meeting, October 8, 2010, Los Angeles, CA

"TCR: How We Got to Where We Are Today? SOT 50th Anniversary Annual Meeting, March 8, 2011, Washington, DC.

"Considerations in Comparability Assessments for Biopharmaceutical Product Development, Registration and Marketing: Progress Report on White Paper", BioSafe Membership Meeting, April 12, 2011, King of Prussia, PA

"Relevance of Nonclinical and Biological Testing", DIA The Future of Biosimilars in the US: Legal, Regulatory, Scientific, Clinical and Payer Issues, May 4, 2011, Bethesda, MD.

"Changing Guidance and Regulatory Expectations for Biologics: Preclinical Safety Assessment", PEGS: the essential protein engineering summit, May 12, 2011, Boston, MA.

"Practical Implementation of Immunogenicity Testing: "Rightsourcing" Strategies for Small and Large Companies", PEGS: the essential protein engineering summit, May 13, 2011, Boston, MA.

Program Committee and Speaker "Design of Preclinical Safety and Efficacy Studies: The Basics of Cell, Gene and Oligonucleotide-based Therapies, ASCGT Translational Science Course, May 17, Seattle, WA

"Facilitating Clinical Trials of Biopharmaceuticals: WWRD- "Telling the Story", MPI Innovations in Research an Educational Symposium, September 27, 2011, RTP, NC; September 28, 2011, Philadelphia, PA; September 19, 2012, San Francisco, CA.

"Can Carcinogenic Risk of Biopharmaceuticals be Communicated without a 2 year Bioassay? "and "Preclinical Considerations in Advancing Therapeutic Stem Cells into the Clinic", Modular Training Programme in Applied Toxicology: Biologics in Preclinical Research and Development, November, 16, 2011, University of Surrey, UK

"Demonstrating Biosimilarity Animal studies", DIA Webinar Biosimilar Draft Guidances: Explanation and Discussion, April 10, 2012
"Facilitating Clinical Trials for Novel Therapies: WWRD "Telling the Story", Planning Your Drug Development Success from Bench to Clinic, Innovations in Research MPI Educational Symposium, Seattle, WA, May 2, 2012

Organizing Committee and Panel member 'Manufacturing, Preclinical Studies and Assays, ASGCT Translational Science Training Course Best Practices and Lessons Learned, Philadelphia, PA, May 15, 2012

Session Chair Can Human Carcinogenic Risk be Communicated without a Rodent Bioassay? 48th Annual DIA Meeting, Philadelphia, PA, June 27, 2012

"Testing for Tumorigenicity and Ectopic Tissue Formation", Pluripotent Stem Cells in Translation: Preclinical Considerations, NIH/FDA workshop, Bethesda, MD, July 11, 2012

Session Co-chair and Speaker "Communicating Carcinogenic Risk without a 2-Year Bioassay", 33rd Annual Meeting American College of Toxicology, November 6, 2012, Orlando, FL.

Session Moderator-CIRM Alpha Stem Cell Workshop, November 14-15, 2012, Stanford University, CA

"Considerations and Consequences of NOAEL Determinations", BioSafe/FDA Meeting, January 9, 2012, Silver Spring, MD

"Designing Preclinical Studies to Optimize FIH Studies", CIRM Grantee Workshop, March 6, 2013, San Francisco, CA

"Use of Animal Models of Disease in Safety Assessments of Biotherapeutics: Is this the future?, 52nd Annual SOT Meeting, March 12, 2013, San Antonio, TX

"Preclinical Considerations for Stem Cell Therapy", NIH/NEI/NCRM 3rd Annual Stem Cell Meeting, June 24, 2013, Bethesda, MD

Session Moderator –Preclinical Animal Models, International Workshop on Cell Therapies: Regulatory Pathways, September 17, 2013, Bethesda, MD

"Overview and Regulatory Perspective on Emerging Technologies", Southern California Chapter –SOT, October 17, 2013, Irvine, CA

"Setting the Stage: Strategies for Tumorigenicity Testing of Cell-based Therapies", 37th Annual American College of Toxicology Meeting, November 4, 2013, San Antonio, TX

:Vector Platform Discussion on Biodistribution Introduction Developing Strategies for Leveraging Pre-Clinical Data, ASGCT Standardized Pathways Conference, February 20, 2014, Silver Spring, MD

"Considerations in Dose Extrapolation of Stem Cell-based Therapies: Optimizing First in Human Trial Design," 53rd Annual Meeting Society of Toxicology, March 25, 2014, Phoenix, AZ

"Considerations in Preclinical Safety Evaluation of Stem-Cell Based Therapies", GTC Stem Cell Summit 2014, April 24, 2014, Cambridge MA

Facilitating Clinical Development: Preclinical Case Studies Fulfilling FDA Guidance
Clinical Trials Training Course: Lab to Licensure, ASGCT 17th Annual Meeting, May 20, 2104, Washington, DC

Selected Publications

LE Black, JG Farrelly, JA **Cavagnaro,** C-H Ahn, JJ DeGeorge and AS Taylor (1994). Regulatory considerations for oligonucleotide drugs: Updated recommendations for pharmacology and toxicology studies. *Antisense Res. Devel.* 4: 299-301.

JA Cavagnaro (1995). Perspectives on the immunotoxicological evaluation of therapeutic products: assessment of safety. In *Methods in Immunotoxicology*, vol. 1, G.R. Burleson, H.H. Dean and A.E. Munson, Wiley-Liss, NY, pp37-49.

JA Cavagnaro (1996). Safety Testing of Biotechnology Products. In *Comprehensive Toxicology, vol. 2, Toxicity Testing & Evaluation*, P.D. Williams and G.H. Hottendorf, Elsevier Science, pp. 291-298.

KL Goldenthal, **JA** Cavagnaro**,** CR Alving, FR Vogel (1993). Safety Evaluation of Vaccine Adjuvants. National Cooperative Vaccine Development Working Group. AIDS Research & Human Retroviruses 9, S45-S49.

J Cavagnaro (1998). Influence of regulatory systems: A viewpoint of the US FDA process. In *Safety Evaluation of Biotechnology-derived Pharmaceuticals: Facilitating a Scientific approach*, S.A. Griffiths & C.E. Lumley, Kluwer Academic Publishers, UK, pp 31-38.

JA Cavagnaro (2002). Preclinical safety evaluation of biotechnology-derived pharmaceuticals. Nature Rev Drug Discov 1: 469-75.

W Frings and **JA Cavagnaro (**2005). "Predicting Clinical Immunogenicity: Intended or Unintended" in New Developments and Challenges in *Primate Toxicology* eds GF Weinbauer, E Buse, W Muller and F Vogel. Waxmann Munster, pp 9-21.

J Clarke, C Hurst, P Martin, J Vahle, R Ponce, B Mounho, S Heidel, L Andrews, T Reynolds and **J Cavagnaro** (2008). Duration of chronic toxicity studies for biotechnology-derived pharmaceuticals: is 6 months still appropriate? Regul Toxicolo Pharmacol 50:2-22.

JA Cavagnaro (2008). The Principles of ICH S6 and the Case-by-Case Approach in *Preclinical Safety Evaluation of Biopharmaceuticals: A Science-based Approach to Facilitating Clinical Trials*, ed. JA Cavagnaro, John Wiley & Sons, NJ. pp 45-65.

JA Cavagnaro (2008). Assessment of Carcinogenic Risk of Biopharmaceuticals in *Preclinical Safety Evaluation of Biopharmaceuticals: A Science-based Approach to Facilitating Clinical Trials*, ed. JA Cavagnaro, John Wiley & Sons, NJ. pp 399-477

JA Cavagnaro (2008). Considerations in Design of Preclinical Safety Evaluation Programs to Support Human Cell-Based Therapies in *Preclinical Safety Evaluation of Biopharmaceuticals: A Science-based Approach to Facilitating Clinical Trials*, ed. JA Cavagnaro, John Wiley & Sons, NJ. pp 749-781.

P Martin, W Breslin, M Rocca, D Wright and J **Cavagnaro** (2009). Considerations in Assessing the Reproductive and Developmental Toxicity Potential of Biopharmaceuticals. Birth Defects Res (Part B), 33:176-203.

J Cavagnaro (2010). Considerations in the Preclinical Development of Biopharmaceuticals in *Comprehensive Toxicology, 2nd Ed, Vol. 3 Toxicity Testing & Evaluation*, Editor-in-Chief Charlene A. McQueen, Elsevier, pp 29-52

J Tibbitts, **JA Cavagnaro,** CA Haller, B Marafino, PA Andrews, and JT Sullivan (2010). Practical Approaches to Dose Selection for First-in-Human Clinical Trials with Novel Biopharmaceuticals. Reg Tox and Pharm 58: 243-251

M.W. Leach, W.G. Halpern, C. Johnson, JL Rojko, TK .MacLachlan, CM Chan, EJ Galbreath, AM Nidfor, DL Blanset, E Polack and JA **Cavagnaro** (2010) Use of Tissue Cross-Reactivity Studies in the Development of Antibody-based Biopharmaceuticals: History, Experience, Methodology, and Future Directions. Tox Path 38:1138-1166.

RM Lewis and J Cavagnaro (2010). The Application of ICH S6 to the Preclinical Safety Evaluation of Plasma Derivative Therapeutic Products. Biologicals 38:494-500.

Schubert D, Levin, A, Kornbrust D, Berman CL, Cavagnaro J, Henry S, Sequin R, Ferrari N and Shrewsbury SB, (2012) Oligonucleotide Safety Working Group (OSWG) Nucleic Acid Therapeutics 22:211-212.

Kornbrust D, Cavagnaro J, Levin A, Foy J, Pavco P, Gambo-Vitalo C and Guimond A (2013). Consensus Position of the Oligonculeotide Safety Working Group Exaggerated Pharmacology Subcommittee, Nucleic Acid Therapeutics 23:21-28.

Cavagnaro J and Sims J (2013). ICHS6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals in Global Approach in Safety Testing: ICH Guidelines Explained, eds JW van der Laan and JJ DeGeroge, Springer, NY. pp 215-242.

Nasis R, Cunningham J, Brandon E and Cavagnaro J (2013) Considerations in the Development of Pluripotent Stem Cell-Based Therapies in Current Approaches to the Nonclinical Development of Novel Biologics, Biosimilars and Specialty Biologics eds L Plitnick and D. Herzyk, Elsevier, NY, pp 373-408..

MacLachlan TK, McIntyre M, Mitrophanous K, Miskin J, Jolly DJ and Cavagnaro JA (2013)Not reinventing the wheel – applying 3Rs concepts to viral vector gene therapy biodistribution studies. Human Gene Therapy Clinical Development24:1-4.

Cavagnaro J, Berman C, Kornbrust D, White T, Campion S and Henry S Considerations for Assessment of Reproductive and Developmental Toxicity of Oligonucleotide Therapeutics (manuscript in preparation).

Cavagnaro J, Putnam W, Zhou H, Hurst S, Kendrick B, Sidor L, Warner G and Lewis R Comparability Assessment s for Biopharmaceutical Products in Development, Registration and Life Cycle Management (manuscript in preparation)

Professional Affiliations

Chesapeake Research Review (CRRI) IRB - independent central IRB- ***(Member since 2000- Chair 2004 to present; Member Executive Committee; Conflict of Interest Committee; SAE Subcommittee***)
Society of Toxicology (SOT); National Capital Area Chapter society of Toxicology (NCAC-SOT)
Bio Organization (BIO)
American Society of Gene and Cell Therapy (ASGCT)
Drug Information Association (DIA)
Regulatory Affairs Professional Society (RAPS)
FDA Alumni Association (FDAAA) –***Charter Member*; Member, Membership Services Committee**

Professional Appointments/Committees

2010- Present	Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)-**Member**
2000 – Present	Bio Organization Preclinical Safety Expert Working Group (BioSafe-***Founder and Committee Chair 2003-2005***); Leadership **Committee (2003-2012; Ex Officio LC member-present);** Past Member Regulatory Affairs Committee (RAC); RAC Lead Work Group; Member, BIO Science and Regulatory Biosimilars Working Group; current SBEWG Cell Therapy Subcommittee Chair
2009-Present	California Institute Regenerative Medicine (CIRM) Disease Team Grant Review Working Group – ad hoc reviewer; Early Translational Research Awards; Disease Team Therapy Development Awards; Strategic Partnership Awards; Clinical Development Advisor –*Preclinical Regulatory Reviewer*
2008-Present	Oligonucleotide Safety Working Group (OSWG); Member Exaggerated Pharmacology, Immunomodulatory, Inhalation Subcommittees; **Chair,** Reproductive Toxicology/Carcinogenicity Subcommittee
2013- Present	Member AIBS NYSTEM Oversight Panel review of Regenerative Research Foundation Consortium
2007, 2011	Member of Independent Review Committee- National Research Council of the National Academies Report on Recognition and Alleviation of Distress in Laboratory Animals: Reviewer Animal Models for Assessing Countermeasures to Bioterrorism Agents
2010-2012	Member of The Association Française contre les Myopathies (AFM) Strategic and Therapeutic Development Committees (COSET) whose mission is to accelerate clinical development for patients with rare diseases
2003	NIH Scientific Review Program – ***Chairperson Review Committee*** -In Vitro and Animal Models for Emerging Diseases and Biodefense
2009, 2011	NIH-NIAID-DMID Special Emphasis Panel Animal Models of Infectious Disease II-***Contract Reviewer*;** NIAID Clinical Training Planning Grant ***-Contract Reviewer*;**
2004	***US Proposal Reviewer*** for International Science and Technology Center (ISTC) and Science and Technology Center in Ukraine (STCU) Project-CRDF Proposal Evaluation Form for Science - Harmonization of the Conditions Perform Pre-Clinical Trails According to the Russian and US Standards
2002- 2006	National Gene Vector Laboratory ***Steering Committee Member***
2002- Present	American Society of Gene and Cell Therapy ***Industry Liaison Committee*** **(2002-2005)** ***Clinical and Regulatory Affairs Committee (2005-2009))-Chair (2008-2009); Translational Science & Product Development Committee (2010-present)***
1986 – Present	Society of Toxicology ***Chair Regulatory and Legislative Assistance Committee (1994-1997, Chair) Education Committee (2001-2004); Chair Subcommittee for Minority Initiatives (2002-2003), Chair Committee on Public Communications (1997-1999); Member Biotechnology Specialty Section, Councilor (2011-2013); Member Committee on Public Communications; Women in Toxicology, Immunotoxicology Specialty Sections***
1995 – Present	National Capital Area Chapter of the Society of Toxicology ***President (1999-2000), Vice President (1998-1999), Treasurer (1995-1997)***
1987-1995	American College of Toxicology **(Education Committee (1990-1991); Animals in Research Committee (1993-1995)**
2005- Present	Drug Information Association (DIA) – (***North America Chairperson*** – **Biotechnology SIAC (chair 2005-2009) and Innovative Preclinical Sciences SIAC (2009-2010)**; **Biotechnology**

	Track Co-Chair Annual Meeting 2007 thru 2010; **ACNA Executive Committee Research and Development SIAC Liaison (2009-present); Innovative Preclinical Sciences Community (chair 2012-present)**
2006- 2006	US Bio representative to APBI/BIA Early Stage Clinical Trials Taskforce
1996 – Present	Regulatory Affairs Professional Society (RAPS) ***Chair of the Board (2001-2002), President (2000-2001), Fellows Selection Committee (2010-2011)***
1999 – 2002	***(Bio Industry Organization Rep)*** to the Nonclinical Sciences Subcommittee of the FDA CDER/ Research Advisory Committee for Pharmaceutical Science

Selected Awards and Honors

Letter of Commendation (1996) From the Secretary of Health and Human Services for special tasks related to emergency preparedness planning for the 1996 Centennial Olympic Games
FDA Group Award (1996) for outstanding contributions regarding tissue engineered medical products for developing a strategy to evaluate associated safety and efficacy issues.
FDA Award of Merit (1994) for outstanding effort in the rapid approval of DNAse for the treatment of cystic fibrosis.
FDA Award of Merit (1993) for outstanding leadership, which led to the FDA's ability to harmonize with the international community its pre-clinical reproductive and developmental toxicity guidelines.
FDA Commendable Service Award (1992) for outstanding leadership in design and review of pre-clinical studies of cytokine and growth factor products.
Special Olympics Virginia Area Volunteer Award 2008 "Helping You Is what We Do Best"
Emcee CBER FDA Awards Ceremony (2009, 2010, 2011, 2012, 2013)
Career Achievement Award (2011) Society of Toxicology –Biotechnology Specialty Section

Additional Training

"Biotechnology: Strategies for Value Creation" - Kellogg Graduate School of Management Executive Program, March 13-16, 2002, Chicago, IL.
"Advances in Tissue Engineering" – Rice University, August 14-17, 2002, Houston, TX.
"The State of Bioethics: From Seminal Works to Contemporary Explorations", Georgetown University's Kennedy Institute of Ethics, April 5-7, 2002, Washington, D.C.
"Bio-Pharmaceuticals for the 21st Century: Responsibility, Sustainability & Public Trust"- Fordham University Center for Ethics Education, January 10-11, 2005, NYC, NY.
2005 and 2006 Annual PRIM&R Conference
CITI Good Clinical Practices and ICH Course (June 2008)
"First International Symposium on Regeneration, Repair and Restoration of Function after Spinal Cord Injury", November 16-17, 2012, Stanford University, CA.

Personal Data

Place of Birth- Boston, MA. Married, 3 children.

Community Service: Former Coach Odyssey of the Mind, Former Coach Loudoun Youth Soccer Association, Former Team Manager- Washington Area Girls Soccer Association, Former Judge- Virginia State Science and Engineering Fair,

Special Olympics Volunteer 2001-present. Coach -Virginia Area 14 Special Olympics (Volleyball and Swimming); Certification of Completion Principles of Coach for Special Olympics Course (2010); Mentor Global Messenger Class of 2013; 2014 USA Games Coach Team Virginia (Aquatics).