

Corners

CAATfeed

Postdoctoral Fellow David Pamies Wins Teratology Society Award

CAAT postdoctoral fellow David Pamies won a Student Travel Award from the Teratology Society for his paper: "A 3D *in vitro* mini-brain model to study Parkinson's disease." Each year the Teratology Society awards money to students and postdoctoral fellows to assist them with their travel expenses to the Teratology Society Annual Meeting.

Recent Workshops and Symposia

CAAT Activities at 2015 Society of Toxicology Annual Meeting

Updates on Activities Related to 21st Century Toxicology and Evidence-based Toxicology: Invited Presentations and Open Microphone

CAAT, the Human Toxome Project Consortium, and the Human Toxicology Project Consortium (HTPC) hosted their annual satellite meeting on 21st century toxicology activities and related efforts at the Society of Toxicology Annual Meeting in San Diego. The meeting featured a limited number of invited presentations and an open microphone segment in which participants gave brief presentations on germane topics. Invited speakers included:

- Richard Paules (US National Toxicology Program) Tox21 Update
- Russell Thomas (US Environmental Protection Agency) – ToxCast Update
- David Dix (US Environmental Protection Agency) EDSP21 Update
- Melvin Andersen (Hamner Institutes)
 Hamner TT21C Update

- Mark Cronin (Liverpool John Moores University) – SEURAT Update
- Thomas Hartung (Johns Hopkins) –
 CAAT's Read-across Initiative and Human Toxome-related Activity Update
- Catherine Willett (HTPC) Human Toxicology Project Consortium Update
- Martin Stephens (Johns Hopkins) –
 Evidence-based Toxicology Update

Thomas Hartung and Agilent: Exhibitor Hosted Session at SOT

CAAT Director Thomas Hartung sponsored a workshop entitled "Sharpen the Focus of your Toxicology Research Program Using Agilent's Integrated Biology Omics Solutions" which discussed Agilent Inc.'s GeneSpring Multi-omics Suite for analyzing the underlying mechanisms of toxicity through analysis and visualization of multi-omic data and mapping of affected pathways.

PhD Student Georgina Harris and Postdoctoral Fellow David Pamies Win Society of Toxicology Awards

CAAT PhD student Georgina Harris won the SOT Graduate Student Travel Award for her paper, "Molecular mechanisms of rotenone and MPP+ damage to dopaminergic neurons in a human neuronal 3D model." Postdoctoral fellow David Pamies took third place in the Neurotoxicology SS Toshio Narahashi Postdoctoral Fellow/Associate poster award, as well as receiving the Hispanic Organization of Toxicologists (HOT) travel award for his paper, "Predicting neurotoxicity in human-derived iPSC 3D mini-brains."

Revolution in Toxicology 101 Class

CAAT sponsored a unique, two-day class in Baltimore on February 24-25 aimed at presenting a comprehensive understanding of the rapidly changing field of safety sciences by leaders in the field who are implementing those changes. "Revolution in Toxicology 101" featured expert speakers including Mel Andersen (The Hamner Institute), David Dix (EPA), Thomas Hartung (Johns Hopkins), and Martin Stephens (Johns Hopkins). Slides from the talks are available; if interested, please email jderita1@jhu.edu.

The class will be repeated in the fall of 2015.

CAAT-Europe Workshop Held at European Parliament

On January 27, CAAT-Europe organized a workshop (Science Communication in Safety Testing & 3Rs on EU Policy Making: Challenges & Opportunities for the Scientific Community) to address issues in the field of consumer protection and the 3Rs in Brussels. In the first part, the functioning of EU institutions and agencies was presented (CAAT-Europe and INRA) as well as stakeholder strategy (Eurogroup for Animals) on communication to different EU bodies to gain support and/or acceptance. In the second part, representatives of national 3Rs centers (Francopa (FR), Swetox (SE) and FICAM (FI)) shared their experience and described their strategies for establishing their center and creating a favorable environment for sustainable activity.

The apogee of the day was a network reception between the MEPs and their



national scientific counterparts to discuss alternative non-animal test methods and new technologies to ensure better consumer protection. The event was hosted by Mrs Sirpa Pietikainen (Vice-president of the intergroup on animal welfare at the European Parliament). Seven different nationalities from EU Member States were represented at the reception.

The objectives of the meeting included:

- Raising awareness of state-of-the-art alternative test methods and related tools such as *in vitro* and *in silico* test methods, organs-on-a-chip, or AOPs for newly elected MEPs
- Reducing reluctance towards innovative methods
- Inviting the scientific community to discover the EU policy-making process linked with the 3Rs
- Providing local feedback from the community of EU researchers

As some member states were not represented at the event, we plan to repeat this initiative. Any scientists interested in joining the next event should send an email to caat-eu-policy@uni-konstanz.de including CV and motivation letter. As a first follow-up, CAAT-Europe intends to launch a website collecting and summarizing information for policy makers as well as events linked with the EU Parliament and 3Rs activities for national, European and international legislation.

Workshop on Systematic Review: What is Systematic Review? An Introductory Course (Webinar)

March 9, 2015 College Park, Maryland

This workshop/webinar, organized by CAAT, EPA, FDA, NIEHS, and NIH, presented a framework for systematic review and evidence integration for reaching hazard identification conclusions. General steps used for the systematic review include: 1) formulate problem and develop protocol, 2) search for and select studies for inclusion, 3) extract data from selected studies, 4) assess the quality or risk of bias of individual studies, 5) rate the confidence in the body of evidence, 6) translate the confidence ratings into levels of evidence, and 7) integrate the informa-

tion from different evidence streams (human, animal, and "other relevant data" including mechanistic or *in vitro* studies) to develop hazard identification conclusions. Systematic review procedures are being adopted by other federal agencies, including EPA and NIEHS. Studies included in a systematic review are screened for quality, so that the findings of a large number of studies can be combined. Almost 100 people attended in person and more than 350 via the webinar.

CAAT Grants for 2016-17

CAAT solicited projects that focus on the implementation of the NAS Report: *Toxicity Testing in the 21st Century: A Vision and a Strategy* in the following areas:

- Proposals Relating to Toxicology: Maximum grant amount is \$25,000 per year. Projects should be developed to provide mechanistic understanding of computational systems biology approaches, focused on *in vitro* responses to toxicants in human cells. Consideration should be given to the translation of this new method to evaluate/predict health outcomes.
- Proposal Relating to Refinement:
 See Science-Based Animal Welfare
 Awards funded separately.

The deadline for submissions was March 27, 2015. For full details about the grants program, including past recipients, see: http://caat.jhsph.edu/programs/grants.

Upcoming Workshops and Symposia

Good Cell Culture Practice (GCCP) for Induced Pluripotent Stem Cells Workshop

June 1-3, 2015 Baltimore, MD

Planned participants include representatives from ECVAM, EPA, NIH, NCATS, EPA, stem cell banks, and other experts on iPSC. Details TBA.

Finding Opportunities in the Area of Alternative Methods to Animal Testing for Romania

June 5, 2015 Cluj-Napoca, Romania

This workshop, organized by the University of Agricultural Sciences and Veterinary Medicine Cluj-Napoca, represents a first attempt to initiate discussions, to map existing activities, and to identify opportunities in the area of alternative methods to animal testing in Romania. The objective is to bring together national and European stakeholders so that they can play a crucial role in the future developments in Romania. Participants with multiple backgrounds from academia, regulatory bodies, policy-makers, small and medium-sized enterprises (SMEs), and non-governmental organizations will attend the workshop.

Guest speakers from the European Commission (DG JRC – EURL EC-VAM) and 3Rs centers in Europe (CAAT-Europe) will be present at the event.

Registration and full details may found at: http://rocam.usamvcluj.ro

Joint Information Day on Biology Inspired Microphysiological Systems – Status and Future

June 11th, 2015 Berlin, Germany

Animals are traditionally used for hazard identification, safety testing, and disease modeling in pharmaceutical, (agro) chemical, food, and environmental industry laboratories. Though *in vivo* tests give an insight into systemic effects of chemicals, the physiological differences between animals and humans can undermine extrapolation of animal data to the human system. Human-relevant organoid *in vitro* systems that mimic human physiology are a novel solution to this problem and provide a new basis for *in vitro-in vivo* extrapolation (IVIVE).

Static human 3D cell culture models mimic human biology at a more physiological level than traditional 2D cell cultures. They add value to predictive toxicology but still do not fully emulate systemic human biology *in vitro*. Recent advanced microfabrication techniques enable the

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development of microfluidic "organ-on-a-chip" or even "human-on-a-chip" devices. These promise to emulate relevant aspects of single organ function and interaction among organs on a microphysiological scale, enabling a new level of physiologically relevant assays. This Information Day brings together renowned experts in the field to inform about the status quo, the promises, and current shortcomings of microphysiological systems.

To register, please contact caat-eu@ uni-konstanz.de

The information day is preceded by an invitation-only workshop on the same topic, which will be held on June 8-10.

Recent Publications

Busquet, F., Strecker, R., Rawlings, J. M. et al. (2014). OECD validation study to assess intra- and inter-laboratory reproducibility of the zebrafish embryo toxicity test for acute aquatic toxicity testing. *Regul Toxicol Pharmacol* 69,

496-511. http://dx.doi.org/10.1016/j. yrtph.2014.05.018

Maertens, A., Luechtefeld, T., Hartung, T. and Kleensang, A. (2015). Weighted gene correlation network analysis to assess MPTP's pathway of toxicity indicates central role of transcription factor SP1. Arch Tox, accepted for publication.
Zhao, L., and Hartung, T. (2015). Metabonomics and toxicology. In: Bjerrum, J. T. (ed.), Methods Mol Biol 1277, 209-231. http://dx.doi.org/10.1007/978-1-

4939-2377-9 15



News from the President of ECOPA on behalf of its Board

Last autumn-winter, ecopa became an accredited stakeholder for ECHA and was categorized under "platform." Costanza Rovida is ecopa's contact point with the EU Chemicals Agency.

News from the ECOPA members

The Danish 3R-Center

In 2015, the following projects will be supported:

- A Refined Approach to Producing Polyclonal Antibodies in Chickens – Completely Replacing All Invasive Elements by Combining Immunizations with Routine Aerosol-based Vaccinations
- An alternative to animal experiments:
 Development of an *in vitro* human skin model for evaluation of topical antimicrobial compounds
- An in vitro method to predict acute lung toxicity due to pulmonary surfactant inhibition

http://www.3rcenter.dk/Sider/The-Danish-3R-Center.aspx

FRANCOPA

- The French association for animal health industry (SIMV) joined the platform.
- The Working Group on teaching met in January and will be assessing French and European activities in order to identify areas that need specific improvements and promote pedagogic actions in France.
- The next joint meeting between the steering committee and its panel of experts will take place in Paris on June 9.
 Results from the WG on teaching will be the main focus of the meeting.
- The 2015 edition of the Alfred Kastler biology award is actively looking for applicants. Deadline: June 30, 2015.
 The Award is open to any researcher or teacher, biologist, doctor, pharmacist, veterinarian, agronomist whose country adopts French as an official language. For more details see: http://www.fondation-droit-animal.org/rubriques/connaitr_fond/connaitr_actions_kastler.htm#a1
- The French association OPAL (http://www.opal-association.org) and FRAN-COPA will co-organize a workshop on replacement in Paris on November 4, 2015.

- The updated FRANCOPA report is about to be finalized: it will be published in 2015 and will assess the "state of the art" of alternative methods in animal testing in France.

NORECOPA

- The Norwegian consensus-platform Norecopa has recently launched a new intelligent search engine for the 4 databases which it maintains. It can currently be accessed at http://search. norecopa.no. The search engine uses a range of parameters including a synonym list constructed by Norecopa, Boolean and fuzzy logic, and an autocomplete function based on an index of the contents of the databases. The search engine will be incorporated into a new website for Norecopa as soon as funds permit.
- Norecopa and the University of Bergen are arranging a workshop on May 27-28 entitled Systematic Reviews and Harm-Benefit Assessment of Animal Experiments, with lecturers from SYRCLE and the RSPCA. More information is available on http://norecopa.no/systematic-reviews.







News from NICEATM and ICCVAM

New Method Will Reduce Animal Use for Pertussis Vaccine Testing

Participants at the March 4-5 workshop, including regulators and vaccine manufacturers, evaluated data from a multilaboratory study that used a Chinese hamster ovary cell assay to measure pertussis toxin in reference preparations. Participants concluded that the relevance and reliability of the assay was sufficient, and recommended that vaccine manufacturers begin using the assay alongside current HIST testing to demonstrate its validity for their specific products. Participants discussed implementing an approach that would allow manufacturers to waive testing entirely under certain circumstances. The regulatory agency representatives attending the meeting agreed in principle to this suggestion.

The workshop, titled "In Search of Acceptable Alternatives to the Murine Histamine Sensitization Test (HIST): What Is Possible and Practical?" was organized by NICEATM and NC3Rs in collaboration with Health Canada, the U.S. Food and Drug Administration (FDA), the European Directorate for the Quality of Medicines, and EURL ECVAM, and was held at NC3Rs headquarters in London. Proceedings from the workshop will be submitted to Pharmeuropa Bio and Scientific Notes for publication later this year.

ICCVAM Presents Webinar on Reverse Toxicokinetic Models

ICCVAM presented a January 27 webinar on "Reverse Toxicokinetics: Using In Vitro Data to Estimate Exposures that Could Be Associated with Adverse Effects In Vivo." The webinar focused on the development and application of reverse toxicokinetic models for extrapolation of high-throughput screening data to in vivo dosimetry. John Wambaugh, PhD, Physical Scientist at the EPA's National Center for Computational Toxicology (NCCT), provided an overview of the development of reverse toxicokinetic models. Barbara Wetmore, PhD, Senior Research Investigator at the Hamner Institutes for Health Sciences, discussed the consideration of population variability and sensitive subpopulations in the use of these models. NICEATM and NCCT hosted the webinar on behalf of ICCVAM. Slide presentations and a video recording of the webinar are available at http://ntp.niehs.nih. gov/go/ivive-webinar.

NICEATM Supports Meeting on Inhaled Nanomaterials Testing

NICEATM co-organized a February 24-25 expert meeting on inhalation toxicity of nanomaterials with the PETA International Science Consortium (PISC). The meeting, held at the U.S. Environmental Protection Agency (EPA) in Washington, DC, focused on the technical details for preliminary validation of an *in vitro* test to assess inhalation toxicity hazards of

aerosolized multi-walled carbon nanotubes. Experts from a variety of sectors and disciplines considered and made recommendations on cell types, exposure systems, endpoints, and dosimetry parameters required to develop the *in* vitro model.

The recommendations from the workshop formed the basis for a request for proposals issued by PISC March 16 to identify facilities that have the technical expertise to conduct validation studies. The deadline for proposals is May 29. More information and an application form are available at http://www.piscltd.org.uk/wp-content/uploads/2015/03/PISC-RFP-FINAL_FORM-2.pdf. A workshop report will be submitted for publication later this year.

NICEATM Scientists Provide Advice on International Validation Studies

NICEATM scientists joined international collaborators at recent validation study management team meetings in Kyoto, Japan.

Nicole Kleinstreuer, PhD, a NICEATM support contractor, participated in meetings in January reviewing evaluations of methods that use the Vitrigel collagen membrane platform to identify potential eye irritants and skin sensitizers. The validation study management team determined that the experimental work on the Vitrigel-EIT method for eye irritation is complete and will submit the method to OECD

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- in 2015; experimental work on the Vitrigel-SST method for skin sensitization will be completed later this spring.
- NICEATM Director Warren Casey, PhD, participated in two February meetings to review results from ongoing validation studies of two new test methods. The SIRC-CVS test method uses a rabbit corneal line to identify eye irritants, while the Hand1-luc test method uses mouse embryonic stem cells to identify potential developmental toxicants.

Handbook on Systematic Review Available

The National Toxicology Program Office of Heath Assessment and Translation (OHAT) has released a handbook describing standard operating procedures for implementing systematic review for OHAT evaluations. The handbook also includes OHAT's tool for assessing study quality, or "risk of bias," that applies a parallel approach to evaluation of risk of bias for human and non-human animal studies. OHAT, like NICEATM, is an office within the Division of the National Toxicology Program at the U.S. National Institute of Environmental Health Sciences.

The OHAT handbook is available at http://ntp.niehs.nih.gov/go/38673. Additional information about OHAT and its activities is available at http://ntp.niehs.nih.gov/go/ohat.

FDA Issues Guidance on Photosafety Testing

The FDA has issued guidance document "S10 Photosafety Evaluation of Pharmaceuticals." This guidance outlines details on when photosafety testing is warranted and on possible assessment strategies, including *in vitro* test methods that might be useful. The purpose of the guidance is to recommend international standards for photosafety assessment and to harmonize such assessments that support human clinical trials and marketing authorization for pharmaceuticals.

An announcement of availability of guidance was published in the January 27 Federal Register and is available at http://www.gpo.gov/fdsys/pkg/FR-2015-01-27/pdf/2015-01406.pdf.

NICEATM and ICCVAM Activities at SOT

The Annual Meeting of the Society of Toxicology was held March 22-26 at the San Diego Convention Center in San Diego, California. NICEATM and ICCVAM activities at SOT included:

- Dr Casey co-chaired sessions titled "Applications of ToxCast/Tox21 Data: Confidence and Predictivity" and "Incorporating In Vitro Pharmacokinetic Data and Tools into Toxicity Testing and Risk Assessment" and gave two platform presentations.
- Anna Lowit, PhD, (EPA; ICCVAM Co-chair) co-chaired a session on "Assessing Potential Age-Related Sensitivity to Neurotoxicity of Pyrethroids."
- Suzanne Fitzpatrick, PhD, (FDA; ICCVAM member) co-chaired sessions titled "In Vitro Microphysiological Systems: Developing Confidence in Predictive Ability" and "Risk Communication and Management in the Era of Social Media and the Internet."
- NICEATM staff members were coauthors on 11 posters presented at the meeting, and ICCVAM members were co-authors on six posters describing alternative testing methods and strategies.

A complete list of NICEATM and ICC-VAM activities at SOT 2015 is available at http://ntp.niehs.nih.gov/go/742110.

Upcoming Meetings and Workshops

 ICCVAM will hold a public forum on Wednesday, May 27, at the National Institutes of Health Natcher Conference Center in Bethesda, Maryland. The forum will give stakeholders and members of the public an opportunity to provide ideas and suggestions to

- representatives of the federal agencies that comprise ICCVAM. Attendees will have the opportunity to make short public statements and ask questions regarding the topics discussed. Participants planning to submit comments are encouraged to attend in person to facilitate interaction. A link to registration forms and information for participants are available at http://ntp.niehs.nih.gov/go/iccvamforum-2015; please register to attend by May 15.
- The Society of Toxicology will hold its third FutureTox conference on November 19-20, 2015, at the Hilton Crystal City in Arlington, Virginia. The conference, titled "Bridges for Translation - Transforming 21st Century Science into Risk Assessment and Regulatory Decision-Making," will include plenary and poster presentations as well as topical breakout groups. The objectives of the meeting include advancing the cornerstones for high-throughput risk assessment; taking in vitro data and in silico models forward while reducing reliance on animal testing; and exploring progress and identifying challenges in implementing the emerging "big data" toolbox for regulatory decision-making. A link to the conference website is available at https://www.toxicology. org/ai/meet/cct_futureToxIII/cct_ futureToxIII.asp.

NICEATM Publications and Presentations

- NICEATM scientists attended the OpenTox USA Conference in February, where Dr Kleinstreuer presented a summary of NICEATM activities supporting development of an integrated testing strategy for skin sensitization. A summary of her presentation is available at http://opentox.net/ opentoxusa15/session4/develop-skinsensitization-its.
- NICEATM collaborated with researchers at the University of North Carolina-Chapel Hill on the development of quantitative structure-activity relationship models for skin perme-



- ability and skin sensitization and applied them to predicting chemically induced skin reactions.
- Alves et al. Predicting chemically-induced skin reactions. Part I: QSAR models of skin sensitization and their application to identify potentially hazardous compounds. Toxicology and Applied Pharmacology http://dx.doi.org/10.1016/j.taap.2014.12.014.
- Alves et al. Predicting chemicallyinduced skin reactions. Part II: QSAR models of skin permeability and the relationships between skin permeability and skin sensitization. Toxicology and Applied Pharmacology http://dx.doi. org/10.1016/j.taap.2014.12.013.
- NICEATM scientists used metabolic clearance and plasma protein binding data with population-based phar-
- macokinetic models to quantitatively compare *in vitro* and *in vivo* dosimetry for 230 environmental chemicals that potentially interact with the estrogen receptor pathway.
- Chang et al. Application of reverse dosimetry to compare in vitro and in vivo estrogen receptor activity. Applied In Vitro Toxicology 1, 33-44.



IIVS News & Views

New Management Roles at IIVS

IIVS is pleased to announce a new management structure in 2015. Rodger Curren has assumed the role of Chief Executive Officer and will remain Chairman of the Board of Directors. As the senior corporate officer, Rodger will concentrate on key programs and strategies for the organization's growth. Erin Hill has been promoted to President and will be responsible for planning, directing and supervising IIVS activities and programs. Hans Raabe will continue in his capacity as Vice President and will also assume the responsibilities of Chief Operating Officer where he will implement strategies and policies to maximize efficiencies across all IIVS programs. Through these new positions, all three officers will continue to ensure that IIVS maintains a leadership role in the promotion of in vitro test methods.

IIVS's Industry Council for the Advancement of Regulatory Acceptance of Alternatives (ICARAA): Training at NIFDC Beijing, China

Through the support of the member companies of its Industry Council for the Advancement of Regulatory Acceptance of Alternatives (ICAARA), IIVS presented training at the National Institute for Food and Drug Control (NIFDC) in Beijing over the course of four and a half days in the fourth quarter of 2014. The training focused on practical, hands-on laboratory techniques for in vitro toxicology assays such as the Bovine Corneal Opacity and Permeability (BCOP) assay, chorioallantoic membrane assay (CAMVA) and Skin Irritation Test (SIT). Three-dimensional skin constructs were obtained from the Chinese company TecSkin for use in the training. Twenty-eight scientists representing several institutions including Food and Drug, Medical Device Control, and General Logistics Institute for Drug Control (among others) attended the training.

Wang You-chun, Deputy Director at NIFDC, attended the post-training graduation ceremony and stressed the need to accelerate the further development of in vitro methods for use in cosmetic, food, and drug safety evaluation. He hopes that the participants of the course can easily apply the methods to their day-to-day work. IIVS presenters praised the course participants for their thoughtful questions and high level of interaction, specifically concerning the application of the methods to satisfy regulatory requirements. IIVS staff and scientists will continue to share their expertise with the participants of this program to answer any questions they may have about further implementation of the methods.



2015 Practical Methods for *In Vitro* Toxicology Training Course

The Practical Methods training is one of the key educational programs at the Institute. For over 18 years IIVS has instructed scientists from industry, government, and academic institutions on laboratory techniques for conducting in vitro assays through the hands-on laboratory activities practiced in this course. IIVS Study Directors assist participants in learning how to interpret the resulting data from these assays through case study presentations and round-table discussions. During the multi-day program, participants are exposed to a variety of in vitro methods through lectures and hands-on activities with highly trained biologists and Study Directors.

This year's course, held January 12-16, featured hands-on instruction on the Bovine Corneal Opacity and Permeability Assay (BCOP), 3T3 Phototoxicity assay, and use of 3D tissue constructs for Skin Irritation Testing (SIT). Participants observed demonstrations of a number of other assays during the 3 and a half day course including the Cytosensor Microphysiometer assay for eye irritation testing, and the Corrositex assay for determining DOT packing groups and hazard classification. Presentations on the Noci-Ocular (to determine eye sting), percutaneous penetration, global acceptance of in vitro methods, the use of Good Laboratory Practices, the US Tox 21 program, and new technologies for cell cultures rounded out the program. The number of participants in this year's program was at a record high. IIVS thanks guest speakers, Dr Martin Stephens of the Johns Hopkins Center for the Alternatives to Animal Testing (CAAT) and Dr Terry Riss of Promega for their valuable contributions to the course.

Slides Available from the PISC/Chemical Watch Webinar Series on the Use of Alternative Methods for REACH

Chemical Watch and the PETA International Science Consortium, Ltd. (PISC) co-sponsored a series of REACH focused webinars. The webinars presented alternative methods and testing strategies that can be used to meet REACH requirements. IIVS Study Directors Dr Emilia Costin and Dr Kimberly Norman served as presenters for two of the topics in the series. Slides and recordings of these complimentary webinars have been made available on the PISC website.

IIVS Hosted Workshop – Assessment of *In Vitro* COPD Models for Tobacco Regulatory Science

The Food and Drug Administration Center for Tobacco Products (CTP) has articulated research priorities that include the identification of *in vitro* models and assays for assessing tobacco constituent or compound hazards, and for comparing the respiratory toxicity of different tobacco products. With its experience in working collaboratively to optimize and validate *in vitro* methods, IIVS de-

signed a workshop to bring together a consortium of experts and participants to specifically address the CTP's relevant research goals. Speakers from the CTP, TCOR centers, animal welfare groups, academia, and tobacco companies joined IIVS scientists to discuss the need for non-animal models to explore potential inhalation toxicology and determine the current state of the science. Chronic Obstructive Pulmonary Disease (COPD) can be a very complex disorder with many pathways leading toward disease expression. The areas of inflammation and oxidative stress, ciliary dysfunction and ion transport, goblet cell hyperplasia and mucus production, and parenchymal/ bronchial tissue destruction and remodeling were the focus of this three day workshop. A poster session and breakout groups were held to engage all participants in determining a path forward on these topics.

The momentum gained during the December meeting continues through discussions among participants. IIVS presented a summary workshop report at the annual SOT meeting and a full manuscript on the conference proceedings is currently being drafted.

Funding for this conference was made possible, in part, by the Food and Drug Administration through grant 1 R13 FD 005299 - 01. Views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Humans Services; nor does any mention of the trade names, commercial practices or organization imply endorsement by the United States Government.