



**Summary of Invited Presentations on Preparing
AllerGen Research for IP Protection and
Commercialization**

1st Annual Network Research Workshop,
Winnipeg, MB,
September 20, 2005

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AllerGen NCE Inc.
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1st Annual Network Research Workshop, September 21, 2005

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1.0 Executive summary

AllerGen NCE Inc.'s (AllerGen) 1st Annual Research Workshop was held September 20 – 21, 2005 at the Winnipeg Convention Centre in Winnipeg, MB. In total, 22 Primary Investigators (81% of all PIs), 8 Co-Investigators (7% of all Co-Investigators) and 22 trainees (25% of all trainees) attended what was the first face-to-face Network meeting for these groups. Eleven members of AllerGen's Research Management Committee (61% of the RMC membership) were also in attendance, as were 3 of 5 Theme Leaders (60%) and 4 of 5 Alternate Theme Leaders (80%).

On the evening of September 20, 2005, a dinner meeting was held, featuring invited speakers Drs. David Shindler and Patricia Lorenz, members of the Network's Research Management Committee. Dr. Lorenz's session was entitled 'Preparing for IP Protection of AllerGen Research Activities: *Best practices and lessons learned in the field*. Dr. Shindler's session was entitled 'What VCs Need and Want: *What are the value propositions VCs seek and how do researchers prepare their findings for early stage/seed financing?*'

Key points made in each presentation include:

- Understanding patent issues, the process of protecting IP, and preparing in advance for the potential impacts of discovery will protect network IP and prevent lengthy delays in publication of results/translation of knowledge.
- AllerGen researchers need to get to know their technology and business associates and make them colleagues. They particularly need to become familiar with the tech transfer contact at AllerGen, Dr. Diana Royce, and the tech transfer officers at their institution.
- Researchers should ensure they understand their responsibilities regarding confidentiality and other legal agreements, as well as proper lab procedures and lab documentation.

The summaries of Dr. Lorenz's and Dr. Shindler's presentations will be presented to AllerGen's Research Management Committee meeting on December 18, 2005 and will be included in the Network's strategic planning process.

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2.0 Introduction

AllerGen NCE Inc.'s (AllerGen) 1st Annual Research Workshop was held September 20 – 21, 2005 at the Winnipeg Convention Centre in Winnipeg, MB. The event brought together Network investigators and students for the first time to discuss:

- AllerGen's strategic objectives;
- the Network Research Program and Theme-based research goals;
- IP and knowledge translation issues;
- individual projects, including the relationship of project outcomes to Network goals;
- research strengths and gaps; and
- the student training program strategy and proposed operational plan.

The workshop agenda is attached in Appendix A.

In total, 22 Primary Investigators (81% of total PIs), 8 Co-Investigators (7% of all Co-Investigators) and 22 trainees (25% of all trainees) attended what was the first face-to-face Network meeting for these groups. Eleven members of AllerGen's Research Management Committee (61%) and were also in attendance, as were 3 of 5 Theme Leaders (60%) and 4 of 5 Alternate Theme Leaders (80%).

Because AllerGen's research program emphasizes the commercialization of new knowledge as a milestone of success, it is critical that Network researchers understand the importance of preparing for Intellectual Property (IP) protection of their research activities and preparation of findings for financing. To provide background and perspective on these issues, AllerGen invited Drs. David Shindler and Patricia Lorenz, members of the Network's Research Management Committee, to make presentations during the Workshop dinner on September 20, 2005.

Dr. Lorenz is the Director of the Business Development Office at the University of Guelph. Her session was entitled 'Preparing for IP Protection of AllerGen Research Activities: *Best practices and lessons learned in the field.*'

Dr. Shindler is President and CEO of Milestone Medica, created in 1998 by RBC Technology Ventures and Research Corporation Technologies to invest in product development opportunities derived from Canadian research and create commercial value and new products through planning, management and investment. His session was entitled 'What VCs Need and Want: *What are the value propositions VCs seek and how do researchers prepare their findings for early stage/seed financing?*'

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3.0 Presentation 1: *Preparing for IP Protection of AllerGen Research Activities: Best practices and lessons learned in the field.*

Presented by Dr. Patricia Lorenz, Director of the Business Development Office at the University of Guelph.

Please note that the following is a **summary** of key points made — it is not a verbatim report of Dr. Lorenz's presentation.

3.1 AllerGen's promised commercial deliverables

- AllerGen promises by theme:
 - I. Gene chips
 - II. Bio-analytic tests, hypoallergenic food products
 - III. Clinical diagnostic tests, new medications
- Clinical diagnostic tests and new medications within the first 7 years, patenting new novel biomarkers, three start-up companies, 10 licenses, 60 jobs.
- Tying these outcomes back to our research results and moving those research results forward into products can be a challenge.

3.2 Context and background

- At the research level, commercialization is often seen as another obstacle that has to be addressed in terms of writing grant applications.
- People on the front lines of clinical and research work have insight into issues and challenges of the first steps of the commercialization process better than anybody else and can contribute to meaningful solutions.
- The dialogue between people who are doing research and the people who are interfacing with the business community and potential investors is a critically important activity.
- In the context of the Network and academic institutions, whether a university or a teaching hospital, disclosure is usually what starts the formal commercialization process.
- Publications are traditionally a very important form of knowledge translation. Developing Highly Qualified People (HQP) is probably the most common type of knowledge transfer. Both of these methods typically involve knowledgeable audiences.

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- AllerGen's mandate is to translate results into commercial products that often are going to be used by people who are less knowledgeable and are always going to have a financial context.
- Researchers know a lot about the importance of money and finding funding, but as they move into the commercial realm, there are some other rules of thumb that apply which they must understand.

3.3 Why all the fuss about commercialization?

- It is important to remember that the Ministry of Health, CIHR, NSERC, SSHRC all fund health research and that the NCEs all fall under the portfolio of 'industry'.
- When they think of industry, governments focus on economic development: jobs, tax revenues and progress for Canada.
- In 1999, the Federal Government decided to look at the cluster development theory and how commercialization in Canada compared with the U.S. Their conclusion was that universities in Canada weren't maximizing the return on government investment.
- The Federal Government told research institutions to focus more on commercialization, but institutions complained that years of under-funding meant university infrastructure was crumbling. Universities argued that capital equipment and overhead on par with the U.S. was required to compete.
- The year 2000 brought reorganization to some funding bodies and the creation of new funding agencies such as Genome Canada and the CFI to address that issue.
- This is the era of more accountability and more focus. Government wants to both see and count the economic development.

3.4 Inventions and patents: Background

- An invention is an idea that has novelty (first in the world), is non-obvious (i.e. It demonstrates inventive ingenuity and would not be obvious to someone skilled in that area) and has utility (functional and operative).
- Products, processes, machines, manufactures or composition of matter or any new and useful improvement of them are patentable.

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- Reduction to Practice – there are two types: (a) actual – occurs when the invention is physically implemented, the article is manufactured, machine is built and tested, the method is performed and confirmed, or the composition of matter has been synthesized or produced and (b) constructive – filing of a patent application; to show one of average skill in the art how to make and use the invention.
- Patent applications are made public 18 months after their Canadian filing date, or an earlier foreign filing date, if applicable. Anyone else may raise questions about the patentability of an invention or one of its claims by filing what is known as "prior art" – information that might cause the patent examiner to object to one or more of your claims. The prior art can be patents, patent applications which have been open to public inspection, and published material that has a bearing on the case. An explanation of how the information is pertinent is also required.
- Most developed countries follow a policy of absolute novelty, i.e., no patent can be obtained if the invention has been publicly disclosed in any manner, anywhere in the world. This is critical when considering the effect of publication in a scientific or other journal on a foreign patent application.
- There is no international patent – countries grant their own patents according to their own criteria. Work is progressing on harmonizing the world's patent laws.

3.5 Network Agreement Promises

- Results with commercial potential and IP or prior art that could impact commercial potential should be promptly disclosed to the Network Managing Director of AllerGen and the PI's Institutional Technology Transfer Office.
- Publication should be withheld for 90 days pending evaluation.

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4.0 Presentation 2: What VCs Need and Want: What are the value propositions VCs seek and how do researchers prepare their findings for early stage/seed financing?

Presented by Dr. David Shindler, President and CEO of Milestone Medica

4.1 Background on Innovation and Commercialization in Canada

- Canada lagged behind other industrialized nations, especially the U.S., in developing a biotech sector. Canadian efforts to develop a biotech sector started in the 1960s.
- By 1995, Canada had a handful of companies that were true biotech companies, working with the kinds of technology that we work with today. They were not very robust and were poorly funded.
- By 2000, Canada was second in the world in terms of the number of biotech companies. In 2005 we have ~500 companies, 100 of which (if they had adequate financing) could emerge into world-class companies.
- The Canadian economy does not have the capital available to fund our own innovative capacity, so we depend on U.S. capital or in some cases European capital. This has implications to what happens to our innovations.
- Canada still falls behind in terms of drug exports. We invent, but those inventions go somewhere else and other people make money from them.
- Improvement: Today, we have a third generation of biotech leaders in Canada. These are scientists, entrepreneurs and managers who have developed their careers in this country, and many of them are staunchly Canadian. They have the potential of keeping the companies in Canada even though we're attracting investment from elsewhere.
- Risk: If we don't concentrate on our own country and our own communities Canada won't be economically successful in the very competitive world we live in. AllerGen researchers play an important role in this process.

4.2 Knowledge translation and the application of research

- Much work needs to be done to develop the right kinds of relationships that support tech transfer, and the NCEs afford a very unique opportunity of developing

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relationships among colleagues and business leaders that would normally not be possible.

- Researchers need to know who the technology transfer officer is at their institution, and how to get in touch with them and when.
- All researchers should know what a non-disclosure agreement is and what they are used for.
- Bottom line: AllerGen researchers need to get to know their technology and business associates and make them colleagues.
- The current environment in Canada means commercialization opportunities for AllerGen:
 - i. Aging population
 - ii. Growth in chronic disease prevalence
 - iii. Pharmaceutical company growth requirements
 - iv. Increasing cost of health care
 - v. Need to improve clinical practice and contain costs
 - vi. Need to improve diagnostics and prevention, accelerate drug discovery
- The universal starting point for achievement in commercialization is excellent science.
- 2 kinds of impact from research: non-commercial and commercial
 - *Non-commercial* means increasing knowledge; it could mean inventing something that had no commercial value but helps people e.g. new clinical practice
 - *Commercial* e.g. a drug or a patented device that makes money
- Science and business can have opposing needs and mandates:
Academe: Publish or perish; be the first to discover a phenomenon; teach to convey knowledge; for the public good
Industry: Patent or perish; gain market edge through products; learn for competitive advantage; for profit
- Innovation depends on both public and private sectors – if that combination is effective you have innovation. AllerGen is an example of a strong bridge between the public/ private and the scientific worlds.
- What constitutes an opportunity for commercialization:
 - i. Good data with the potential to solve an important problem

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- ii. Robust intellectual property which means claims that exclude others from doing what you're doing in an adequate way
 - iii. Market size to justify investment.
- Commercialization involves technology investment management, clinical expertise, corporate expertise and market expertise, with each category taking charge of the process at different times. There are going to be a lot of different people involved and researchers may only be a small part of the commercialization process.

4.3 Partnering with Business/Industry

- Researchers need to understand that their business colleagues have a completely different kind of expertise.
- Researcher's role in business is to maintain the knowledge of what is happening in your field and provide an interpretation for the state of the art application.
- The business culture is open and frank. Researchers should be very straightforward and adopt a direct style with partners regarding risks, ambiguities or uncertainties.
- Researchers should respect the essential components of business – be responsive and timely, respect deadlines and dress appropriately.
- Researchers should ensure that they understand their responsibilities regarding confidentiality, legal agreements, proper lab procedures and lab documentation.

4.4 Venture Capital in Canada

- There is a partnership gap in Canada – pharmaceutical companies are not investing in early stage research. This approach does not feed the pipeline of new drugs.
- AllerGen should be urging pharmaceutical companies to resume their research - based approach.
- For researchers, the secret of commercialization is to understand the field they are in and the context of discovery in that field, and to be able to translate discovery into a series of actions that produce results.

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5.0 Conclusion

Drs. Lorenz and Shindler provided background on the underlying concepts of intellectual property and the need for AllerGen and its researchers to develop an understanding of these issues well before making any disclosures.

Dr. Shindler noted that the universal starting point for achievement in commercialization is excellent science, and that commercial development and exploitation is a complex, challenging and costly process in which AllerGen and the NCE program can play a pivotal role.

Other key points that were stressed by both Drs. Shindler and Lorenz included:

- Understanding patent issues and processes, and preparing in advance for the potential impacts of discovery will protect network IP and prevent lengthy delays in publication of results/translation of knowledge.
- AllerGen researchers need to get to know their technology and business associates and make them colleagues. They particularly need to become familiar with the tech transfer contact at AllerGen, Dr. Diana Royce, and the tech transfer officer at their institution.
- Researchers should ensure that they understand their responsibilities regarding confidentiality and other legal agreements, as well as proper lab procedures and lab documentation.
- AllerGen needs to develop a clear standard operating procedure (SOP) for IP protection.
- AllerGen needs to communicate to pharmaceutical companies and other large sources of venture capital that funding research in the early stages is important, and has been the basis of their success to date, despite their current preference for buying drugs to take directly to market.

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Appendix A: Network-Wide Research Workshop Agenda

AllerGen NCE Inc.
RESEARCH WORKSHOP, WINNIPEG, MANITOBA
SEPTEMBER 20 – 21, 2005

Item #	Time	TUESDAY SEPTEMBER 20, 2005 - Campaign A Rm, Second Floor, Delta Hotel
1.	5:00 p.m. – 6:30 p.m.	Welcome Reception
2.	6:30 p.m. – 10:00 p.m.	Dinner: Welcoming Remarks, <i>Dr. Judah Denburg</i>
3.	8:00 p.m. – 10:00 p.m.	Preparing AllerGen Research for Intellectual Property Protection and Commercialization <ol style="list-style-type: none"> 1. Preparing for IP protection of AllerGen research activities – Best practices and lessons learned in the field. - Pat Lorenz <i>AllerGen Research Management Committee, Director, Business Development, University of Guelph</i> 2. What VC's need and want: What are the value propositions VC's seek and how do researchers prepare their findings for early stage / seed financing? David Shindler, <i>AllerGen Research Management Committee, President and CEO, Milestone Medical Corporation</i> 3. General discussion – What AllerGen researchers can do to best prepare their research and their teams to exploit Network-supported intellectual property.
4.	10:00 p.m.	Overview of Research Workshop Agenda – Dr. Diana Royce, Managing Director, AllerGen NCE Inc.
5.	10:05 p.m.	Adjournment – Dr. Judah Denburg
Item #	Time	WEDNESDAY SEPTEMBER 21, 2005, MILLENIUM SUITE, SECOND FLOOR, WINNIPEG CONVENTION CENTRE

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Item #	Time	TUESDAY SEPTEMBER 20, 2005 - Campaign A Rm, Second Floor, Delta Hotel
1.	7:30 a.m.	Buffet Breakfast
2.	8:00 a.m. - 8:15 a.m.	Welcome and Introductions – Dr. Judah Denburg, Scientific Director & CEO 2.1 Overview and discussion of AllerGen’s strategic objectives
3.	8:15 a.m. – 8:30 a.m.	Overview and discussion of the Network Research Program and Themes Theme-based research goals, cross-cutting initiatives, and platforms 3.1 Dr. Thomas Hudson – Theme I – Genes & Early Life Determinants
	8:30 a.m. – 8:45 a.m.	3.2 Dr. Frances Silverman – Theme II – Environments, Population & Society
	8:45 a.m. – 9:00 a.m.	3.3 Dr. Dean Befus – Theme III – Mechanisms & Biomarkers
	9:00 a.m. – 9:15 a.m.	3.4 Dr. Judah Denburg for Dr. Paul O’Byrne– Theme IV – Therapeutics & Drug
	9:15 a.m. – 9:30 a.m.	Discovery 3.5 Dr. Allan Becker – Theme V – Prevention, Control & Public Policy

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Item #	Time	TUESDAY SEPTEMBER 20, 2005 - Campaign A Rm, Second Floor, Delta Hotel
4.		<p>Research Presentations</p> <p><u>Genes & Early Life Determinants</u></p> <p>9:30 a.m. – Project # 1.1: Thomas Hudson, McGill University - 9:38 a.m. <i>Validation of Genetic Associations in Asthma and Allergy</i></p> <p>9:38 a.m. – Project # 1.2: Scott Tebbutt, University of British Columbia - 9:46 a.m. <i>AllerChip Genotyping for Allergy and Asthma</i></p> <p><i>Birth Cohort Studies</i></p> <p>9:46 a.m. – Project # 2.9: P.J. Subbarao for Malcolm Sears, McMaster University 10:04 a.m. - <i>Canadian Asthma and Allergy Birth Cohort Planning</i></p> <p>10:04 a.m. – Project # 2.11: Padmaja Subbarao, Hospital for Sick Children – 10:12 a.m. <i>Infant Inflammatory Markers and Lung Function</i></p> <p>10:12 a.m. : Project # 2.1: Allan Becker, University of Manitoba - <i>Gender-Related</i> – <i>Biologic and Sociologic Impact of Obesity</i> 10:20 a.m.</p> <p>Project # 2.5: Claire Infante-Rivard, McGill University – <i>Candidate Genes and Exposure models in Childhood Asthma</i></p> <p>No presentation</p> <p><i>Air Pollution and Allergic Disease</i></p> <p>10:20 a.m. Project # 2.8: Jeremy Scott, University of Toronto – <i>Air Pollution and Murine Allergic Asthma</i></p> <p>– 10:28 a.m. Project # 2.10: Frances Silverman, St. Michael's Hospital - <i>Allergic Asthma: Air Pollution and Allergen Interactions</i></p> <p>10:28 a.m. – 10:36 a.m.</p>
	10:36 a.m. – 10:45 a.m.	Break

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Item #	Time	TUESDAY SEPTEMBER 20, 2005 - Campaign A Rm, Second Floor, Delta Hotel
		Research Presentations (continued)
	No presentation	Project # 2.2: Michael Brauer, University of British Columbia - <i>Urban Air Pollution and Allergy in Infants</i>
		<i>Neuroimmune Interactions in Allergy</i>
	10:45 a.m. -	Project # 3.2: Dean Befus, University of Alberta – <i>The Mind-Body of Allergy</i>
	10:53 a.m. -	<u>Innate Immunity and Allergic Inflammation</u>
	10:53 a.m. -	Project # 3.5: Michael Cyr for Judah Denburg, McMaster University – <i>Progenitors in Atopy Development</i>
	11:01 a.m. -	Project # 3.6: Kent HayGlass, University of Manitoba – <i>TLR Function in Human Neonates</i>
	11:01 a.m. -	Project # 3.8: Dean Befus for Jean Marshall, Dalhousie University - <i>Functional Consequences of Innate Immune Receptor Polymorphisms</i>
	11:09 a.m. -	Project # 3.3: John Bienenstock, McMaster University – <i>Effects of Probiotics on Murine Models of Asthma</i>
	11:17 a.m. -	Project # 3.11: Bruce Mazer for Qutayba Hamid, Meakins Christie Laboratory - <i>TLR-4+T Cells in Children</i>
	11:25 a.m. -	<i>Exocytosis and Mediators</i>
	11:25 a.m. -	Project # 3.7: Paige Lacy, University of Alberta – <i>Modulation of Exocytosis in Allergic Inflammation</i>
	11:33 a.m. -	Project # 3.9: Redwan Moqbel, University of Alberta – <i>IDO, Glutamate Receptors and Allergic Inflammation</i>
	11:33 a.m. -	Project # 3.1: Darryl Adamko, University of Alberta - <i>Urine NMR in Asthma</i>
	11:41 a.m. -	<u>Food Allergy</u>
	11:41 a.m. -	Project # 3.10: Susan Wasserman, McMaster University - <i>Predicting Peanut Allergy</i>
	11:49 a.m. -	Project # 2.3: Ann Clarke, McGill University - <i>Is the Prevalence of Peanut Allergy Increasing? A Five Year Follow-up</i>

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	12:13 p.m. – 1:00 p.m.	Lunch - Millenium Suite
		Research Presentations (continued)
		<i>Therapeutics & Drug Discovery</i>
	1:00 p.m. – 1:08 p.m.	Project # 4.1A & 4.1B: Dr. Denburg for Paul O-Byrne, McMaster University – <i>Clinical Investigator Collaborative/Clinical Trial Effects of IVX-0142 on Allergen Induced Airway Responses</i>
	1:08 p.m. – 1:16 p.m.	Project # 3.4: Dr. Paul Keith for Louis-Philippe Boulet, Université Laval – <i>Rhinitis and Asthma</i>
	1:16 p.m. – 1:24 p.m.	<i>Psycho-social Factors in Allergy and Asthma</i>
	1:24 p.m. – 1:32 p.m.	Project # 5.4: Wendy Ungar, Hospital for Sick Children – <i>Effect of Financial Barriers on Outcomes in Kids With Asthma</i>
	1:32 p.m. – 1:40 p.m.	Project # 2.6: Anita Kozyrskyj, University of Manitoba – <i>Maternal Stress and Childhood Asthma</i>
	1:40 p.m. – 1:48 p.m.	Project # 2.7: Cameron Mustard, University of Toronto – <i>Antenatal Steroid and Childhood Asthma</i>
		<i>Occupational Allergy & Asthma</i>
	1:48 p.m. – 1:56 p.m.	Project # 5.1: Nicola Cherry, University of Alberta – <i>Surveillance of Occupational Asthma</i>
	1:56 p.m. – 2:04 p.m.	Project # 5.2: Dorothy Linn Holness, University of Toronto – <i>Workplace Sensitizers Skin and Lung Exposure, Responses and Prevention</i>
		Project # 5.3: Susan Kennedy for Mieke Koehoorn, University of British Columbia – <i>Asthma and BC Workers</i>

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Item #	Time	TUESDAY SEPTEMBER 20, 2005 - Campaign A Rm, Second Floor, Delta Hotel
5.	2:05 pm – 2:45 pm	<p>Break-out groups: Identifying Network Research Strengths and Gaps, and Opportunities for Collaboration and Partnership</p> <p><i>Each break-out group (see hand-out for your group and table) is asked to identify:</i></p> <p>A) <i>Three to five strengths of AllerGen’s current research program.</i></p> <p>B) <i>Three to five significant weaknesses and/or gaps in AllerGen’s current research program in relation to the objectives of the NCE program and why they should be addressed.</i></p> <p>C) <i>Opportunities for new collaborations across projects / Themes within the Network.</i></p> <p>D) <i>Opportunities for new partnerships with research users (e.g. industry, government, not-for-profit organizations, other organizations).</i></p>
6.	2:45 – 3:15 p.m.	Reporting back by break-out group facilitators and general discussion of recommendations
7.	3:15 – 3:30 p.m.	Prioritization of results
	3:30 pm – 3:45 pm	Break
8.	3:45 pm – 4:15 pm	<p>Presentation – Dr. Kent HayGlass – Advanced Educational Advisory Committee</p> <p>Presentation of AllerGen’s proposed operational plan to develop highly qualified personnel</p>
9.	4:15 pm – 5:00 pm	Summary of workshop outcomes, final comments, next steps – Dr. Judah Denburg, Scientific Director & CEO
10.	5:00 pm	Adjournment