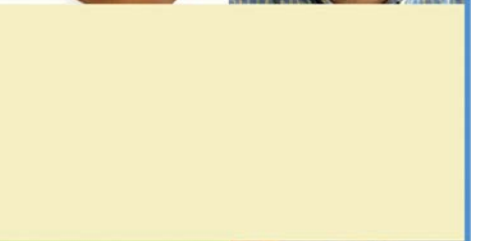
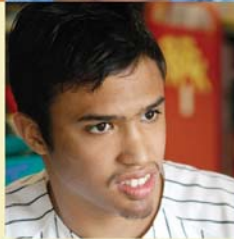


Autism Speaks Strategic Plan for Science



Overview and Executive Summary



AUTISM SPEAKS™
It's time to listen.



Autism Speaks Strategic 3-Year Plan for Science

Vision

A world in which suffering because of autism no longer exists

Values

Sense of urgency
Scientific excellence
Families as partners
Persons with ASD are at the heart of what we do

Mission

“To improve the future of those struggling with ASD by funding research and developing resources that will accelerate discovery, development, and dissemination of methods for prevention, treatment, and cure”

Key Goals

<i>Discover</i>	genetic and environmental risk factors and their interaction
<i>Translate</i>	biological findings into clinically useful tools for early detection, personalized medical approaches, and novel treatment discovery
<i>Develop</i>	behavioral/psychosocial and biomedical treatments that will be of immediate benefit to individuals with ASD
<i>Disseminate</i>	empirically-validated methods for screening, diagnosis and treatment to the community

Areas of Focus

Etiology

Biological mechanisms

Diagnosis/Screening

Beneficiaries

Persons with ASD
Family members
Health care providers
Teachers
Employers
Community at large

Treatment/Prevention

Dissemination

Autism Speaks Science Program

Interdisciplinary

Collaborative

Innovative

Consumer-focused

Cost-effective

Autism Speaks Strategic 3-Year Plan for Science

Strategic Directions

Identification of biomarkers that index meaningful subtypes, which point to specific etiologies and predict response to treatment

VISION

A world where suffering because of autism no longer exists

MISSION

“To improve the future of those struggling with ASD by funding research and developing resources that will accelerate discovery, development, and dissemination of methods for prevention, treatment, and cure”

Identification of environmental risk factors that contribute to autism and their interaction with genetic susceptibilities

Translation of genetic and other biological findings into clinically useful tools for risk assessment and treatment discovery

Development of treatments that ameliorate core symptoms of autism and associated medical conditions

Dissemination of empirically-validated treatments and practice standards into community settings, providing wide accessibility

Problem: Until we understand the causes of autism, it will be difficult to identify at-risk populations and develop effective strategies for prevention, treatment, or cure.

Our goal: Identify genetic and environmental risk factors for autism and their interaction

Strategies:

- Create and integrate large scale genetic and environmental exposure data bases
- Develop analytic tools for examining gene-environment interactions
- Leverage existing projects and international partnerships to enhance genetic and environmental data collection
- Promote data-sharing and large scale data base integration
- Enhance collaboration among geneticists, environment scientists, and clinicians

ETIOLOGY

Objectives:

- 1) To enhance resources for discovery of autism susceptibility genes
- 2) To promote identification, collection, and evaluation of environmental exposure data
- 3) To facilitate novel directions in the exploration of environmental factors and gene-environment interactions

Initiatives:

- Autism Genetic Resource Exchange (AGRE)
- Autism Genome Project (AGP)
- Collaborative Risk and Outcome Scientific Study (CROSS)
- National Children's Study (NCS) Collaboration
- Environmental Factors Initiative
- International Autism Epidemiology Initiative
- High-Risk/High-Impact Initiative
- Weatherstone Fellowships
- Trailblazer Awards

Outcomes:

2009

- SARAH upgraded to ensure ongoing integrity of AGRE data base
- AGRE and AGP multiplex, simplex, and twin data bases increased to improve genetic analysis
- Results from AGP initiative published
- NCS Advisory Panel created and autism outcome measures recommended to NCS board
- Novel Trailblazer, fellowship, pilot, basic, & epi studies on gene and environmental factors funded
- Workshops sponsored on (a) Translation of genetic and environmental discoveries into clinical practice, (b) Common phenotyping measures to enhance data base integration, (c) Mitochondrial disorders and autism, (d) toxicology and autism, and (e) International Autism Epidemiology Network
- Launch of HR-HI project to rapidly expand collection of autism biomaterials
- Two studies funded designed to validate briefer, more cost-effective autism diagnostic tools
- Meeting held with international colleagues to plan collaborative projects

2010

- AGRE software platform upgraded, allowing easier access and integration capabilities
- Results from AGP published; Proposal for AGP Phase Three written and reviewed
- Data collected in CROSS, HR-HI, and phenotype validation studies
- Autism outcome measures incorporated and piloted within NCS
- Novel Trailblazer, fellowship, pilot, basic, & epi studies on gene and environmental factors funded
- Peer-reviewed paper on use of genetic testing for risk assessment in clinical practice published
- Peer-reviewed paper on standards for common phenotyping published
- Plans drafted for new international projects.

2011

- Potential integration between AGRE and Simon Foundation data bases evaluated
- Results from AGP published and AGP Phase 3 focused on translating genetic results into clinical practice funded
- Enhanced practices for genetic diagnostic testing incorporated within Autism Treatment Network
- Data collected in CROSS and HR-HI studies
- NCS that includes autism outcomes launched
- Results of briefer diagnostic tools validation studies published
- Beginning results of Year 1 funded pilot studies published

Problem: Until we understand the underlying biological mechanisms of autism, it will be difficult to develop effective strategies for prevention, treatment, or cure.

Our goal: Identify the underlying biological mechanisms of autism

BIOLOGICAL MECHANISMS

Strategies:

- Develop appropriate animal models
- Use animal models to study biological pathways, drug responses, and recovery
- Develop pre-clinical assays to study effects of risk genes and environmental factors on biological pathways and fast track screening of novel treatments
- Create state-of-the art tissue program, including brain, stem cell, and other tissues
- Collaborate with Allen Institute for Brain Sciences to study gene expression and brain development
- Develop novel brain imaging technologies to study early brain development

Objectives:

- 1) To stimulate innovative studies using animal models to understand biological mechanisms and explore novel treatments
- 2) To develop in vitro and in vivo methods for pre-clinical testing of drugs
- 3) To create state-of-the-art tissue bank
- 4) To facilitate development and application of novel brain imaging techniques

Initiatives:

- AS-MRC collaboration on Rett syndrome recovery
- AS-Allen Brain Institute Collaboration on brain development
- Autism Tissue Program Initiative
- AS-Simon Foundation-NIH initiative to create state-of-the-art Autism Tissue Bank
- High-Risk/High-Impact projects on Mitochondrial Disorder and Novel approaches to brain imaging
- Animal models workshop

Outcomes:

2009

- Workshop on animal models and translational research held
- Novel animal model and pre-clinical assay studies funded through Trailblazer, fellowship, pilot and basic/clinical studies mechanisms
- Data collected in Rett syndrome project
- Data collected and initial results disseminated from AS-Allen Brain Institute collaboration
- Additional tissue collected through ATP
- First project to create stem cells from brain tissue supported through ATP
- Collaborative tissue bank co-funded by AS, Simons and NIH
- HR-HI projects on mitochondrial disorder and brain imaging launched
- Trailblazer awards launched

2010

- Paper on standards for behavioral assays stemming from animal model workshop published
- Data collected in animal model and pre-clinical assay studies funded through Trailblazer, fellowship, pilot and basic/clinical studies mechanisms
- Data continue to be collected in Rett syndrome project
- Results from AS-Allen Brain Institute published
- Collaborative AS-Simons-NIH Autism Tissue Program launched
- Data collected in HR-HI projects

2011

- Results of studies funded in 2009 made available
- Preliminary results from Rett syndrome project made available and clinical trials are launched
- Demonstrated enhancements in quantity and quality of available tissue
- Data from HR-HI projects are analyzed and preliminary results made available

Problem: Reliable, efficient, and scalable diagnostic and risk assessment methods are not available, making it difficult to detect autism in infants, predict prognosis and response to treatment, and acquire large data bases for discovery of the causes and best treatments of autism.

Our goal: Develop improved and more efficient diagnosis and risk assessment methods

DIAGNOSIS AND PHENOTYPING

Strategies:

- Explore the validity and reliability of briefer, scalable methods of diagnosis that would allow acquisition of larger data bases
- Develop consensus standards for diagnosis and phenotyping in research studies to facilitate data base integration across studies
- Develop methods for screening and diagnosis for infants and toddlers, including biomarkers
- Examine the utility and feasibility of genetic, medical, and metabolic assessments as part of a diagnostic work-up and as predictors of response to specific treatments
- Encourage and prioritize research on adults and aging

Objectives:

- 1) To promote development of briefer, scalable methods of diagnosis that are useful in multiple research and clinical environments
- 2) To reach a consensus in the field on a standard set of diagnostic and phenotype measures
- 3) To promote identification of reliable and valid risk bio- markers for autism
- 4) To assess the utility and feasibility of genetic/medical testing as part of a diagnostic workup
- 5) Increase knowledge on adult outcomes and aging in ASD

Initiatives:

- AGRE/NIH study exploring the use of parent questionnaires for screening and diagnosis
- HR-HI/IAN Studies exploring the validity of parent questionnaires for screening and diagnosis and assessment of nonverbal persons
- Workgroup on Phenotyping Standards
- AGRE and AGP studies on gene discovery
- Baby Siblings Research Consortium
- Conference on Translating Genetic Discoveries into Clinical tools
- Autism Treatment Network
- Prioritize research on adults and aging through pilot and basic/clinical grants

Outcomes:

2009

- Data collected through AGRE/NIMH study to assess the reliability and validity of web-based parent questionnaires for diagnosing autism
- Data collected through IAN/High-Risk/High-Impact study on “light phenotyping”
- Data collected through HR-HI study on assessment of nonverbal persons
- Workgroup on Phenotyping Standards convened
- Conference on Translating Genetic Discoveries into Clinical Tools convened
- Common diagnostic protocol incorporating screening of medical conditions implemented through ATN
- BSRC meeting convened to share data on infant risk assessment
- Tools for assessment/screening of GI, Sleep, and Neurological problems drafted through ATN
- Studies on infant risk assessment and adults and aging encouraged and prioritized through Trailblazer, fellowship, pilot and basic/clinical studies mechanisms

2010

- Analysis of data from AGRE/NIMH study begun
- On-going data collected in two HR-HI projects
- Paper drafted by workgroup on phenotyping standards
- BSRC meeting to share data on infant risk assessment/submit paper on head growth as a risk marker
- Information on medical reimbursement gathered through ATN
- Guidelines for assessment of GI and Sleep problems drafted through ATN
- Data collected on infant risk assessment and adults and aging

2011

- Paper on light phenotyping approaches from AGRE and IAN project submitted
- Paper on phenotyping standards submitted
- BSRC meeting convened to share data on infant risk assessment / paper published on HC as a risk marker
- Guidelines for assessment of GI and Sleep programs refined by ATN
- Sleep toolkit tested in ATN
- Paper on sleep problems and algorithm presented
- Results available on infant risk assessment and adults and aging

Problem: Although early behavioral intervention is effective for improving outcomes, many persons with ASD continue to struggle despite early intervention. We don't yet have effective treatments for all individuals with ASD and we have almost no knowledge regarding how to prevent autism.

Our goal: Identify effective treatment and prevention strategies for individuals with ASD

Strategies:

****NOTE:** Strategies and objectives outlined in the Etiology and Biology sections are also relevant to developing and testing treatments

- Develop and test the efficacy of interventions for infants and toddlers
- Develop best practice guidelines for medical and behavioral interventions
- Develop and test the efficacy of medical and behavioral/psychosocial treatments for school age, adult, and nonverbal individuals
- Improve outcome measures for treatment studies

Objectives:

- 1) To have effective, scalable interventions for infants and toddlers
- 2) To provide treatments that address the medical conditions associated with ASD
- 3) To publish practice guidelines for medical care
- 4) To have effective treatments for school age, adult, and nonverbal individuals
- 5) To develop sensitive and reliable outcomes measures for use in treatment studies

Initiatives:

- Toddler Treatment Network
- Autism Treatment Network
- Treatment Initiative/Grants Program
- Clinical Trials Network
- Innovative Technology for Autism Initiative
- High-Risk/High-Impact Initiative
- Interactive Autism Network
- RFA on Treatment of GI problems

Outcomes:

2009

- TTN meeting held to share methods and develop common outcome measures
- TTN has collected data on efficacy of infant interventions
- ATN has finalized design and measures and obtained IRB for studies in nutrition and sleep
- ATN has developed a mechanism for communicating effective treatments of associated medical conditions among ATN physicians
- ATN guidelines for assessment and treatment of GI and sleep problems are under development
- Treatment studies funded that address priorities of Treatment RFA mechanism
- RFA on treatment of GI problems posted, projects reviewed, reissued to capture broader applicant pool
- HR-HI project on treatment of nonverbal individuals is launched

2010

- TTN has analyzed individual site data and combined common measure data to compare outcomes across sites
- ATN has launched nutrition and sleep studies
- ATN physicians have improved clinical care through communication among practicing ATN physicians
- ATN guidelines for assessment and treatment of GI and sleep problems are developed
- Data collected in studies funded through Treatment RFA
- Data collected in HR-HI project on treatment of nonverbal individuals
- Study of treatment of GI conditions funded and launched

2011

- TTN papers on efficacy of infant intervention and common outcome paper submitted for publication
- Data from ATN nutrition and sleep studies analyzed
- ATN physicians have begun training and mentoring junior physicians in comprehensive care model
- ATN guidelines for assessment and treatment of GI and sleep problems submitted for publication
- Data are collected in studies funded through Treatment RFA mechanism
- Data continue to be collected in HR-HI study on treatment of nonverbal individuals
- Data collection is underway in study of treatment of GI conditions

Problem: Although effective methods for screening, diagnosis, and treatment of ASD exist, the majority of individuals with ASD do not have access to these clinical practices.

Our goal: Widespread dissemination of empirically-validated methods for screening, diagnosis, and treatment to the broader community worldwide.

Strategies:

- Convene “thought leaders” on effective dissemination and service delivery systems to discuss and develop a strategic plan for addressing the lack of dissemination of best practices in the community
- Establish functional linkages to promote communication and partnership among the government and professional groups invested in dissemination of health care to prevent duplication of effort, reduce cost and effort, and increase collaboration
- Work closely with Awareness, Government Relations, and Family Services components of Autism Speaks to coordinate with their efforts at policy change and dissemination
- Survey existing models for dissemination of autism best practices or similar models for other diseases
- Pilot dissemination model through Global Autism Public Health Initiative nationally and internationally

DISSEMINATION

Objectives:

- 1) To improve communication among the government, private, and professional groups invested in dissemination of clinical practices
- 2) To develop a coordinated vision for dissemination of empirically-based best practices into the community both nationally and internationally
- 3) To pilot GAPH model of dissemination of empirically-based practices

Initiatives:

- Global Autism Public Health Initiative
- Autism Treatment Network
- Interactive Autism Network

Outcomes:

2009

- Meeting held which includes ATN leadership, thought leaders and key stakeholders from private, government, and professional groups invested in dissemination science and models
- U.S. leadership team in dissemination science, models, and policy identified
- Autism Speaks funding priorities decided and strategies for promoting dissemination of best clinical practices in the U.S. formulated
- RFA developed / posted for testing the efficacy of web- or community-based training models
- Feedback obtained from thought leaders and key stakeholders on current GAPH model for international dissemination of best practices
- Proposal developed for three or more national and/or international partners for implementation of the GAPH model

2010

- White paper drafted describing a vision, strategy, and implementation plan for dissemination of best practices in the U.S.
- Implementation plan involving leadership team and other key stakeholders commenced for dissemination of best practices in the U.S.
- Web-based or community-based training models tested
- Funding secured for GAPH model, and implementation begun in partnership with national and/or international partners

2011

- Implementation of strategies for dissemination begun, which capitalize on ATN platform, as identified in vision and strategic plan of the U.S. leadership team
- Web-based or community-based training models tested
- GAPH model with national/international partners is being implemented



Strategic Plan for Science: Executive Summary

2009-2011

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Autism Speaks 2009-11 Strategic Plan for Science

Executive Summary

Autism is one of today's most urgent public health challenges. The estimated prevalence of autism spectrum disorder is 1 in 150, greater than Type 1 Diabetes (1 in 400), childhood cancer (1 in 2000) and cystic fibrosis (1 in 3500), combined. Moreover, based on the World Health Organization's measure of burden of disease (Disability Adjusted Life Year), autism is a larger burden to society than Type 1 diabetes, childhood leukemia, and cystic fibrosis. The annual cost of autism to society is estimated to be \$35 billion, most of which is due to lifelong adult care. Empirically-based practices such as early intensive behavioral intervention have been shown to significantly reduce these costs, but unfortunately, many barriers exist to accessing to such services. Individuals with autism and their families are struggling with unmet needs and a lack of effective treatments. There has never been a greater need for focused, cost-effective, and innovative research into the causes, treatment, prevention, and cure of autism. Moreover, research on the most effective means of implementing empirically-based practices is urgently needed.

The purpose of the strategic plan is to help guide Autism Speaks' science goals and funding priorities and to communicate the philosophy, values, and intentions of the Autism Speaks science department. Such values and intentions reflect the input of many individuals, including the scientific, clinical, and stakeholder communities. The plan seeks to inspire synergy among each of the components of the science department, so that the department can have a unified strategy that leverages resources and expertise.

The mission of Autism Speaks is “*to improve the future for all who struggle with autism spectrum disorders. We are dedicated to funding global biomedical research into the causes, prevention, treatments, and cure for autism; to raising public awareness about autism and its effects on individuals, families, and society; and to bringing hope to all who deal with the hardships of this disorder.*” As such, the goals of the strategic plan for science must not only serve to accelerate science, attract new scientists to the field, and increase the knowledge base about autism- our strategic vision must strive to ***change the future for all who struggle with autism spectrum disorders.*** Thus, we must not be satisfied with the creation of a new screening tool for autism or the discovery of an autism susceptibility gene. The time is ripe to develop goals that seek to get the screening tools into the hands of practitioners who see individuals with ASD, and translate genetic findings into treatments and diagnostic tools.

The core values reflected in Autism Speaks' mission statement are (1) recognition that individuals with autism spectrum disorders (ASD) and their families are struggling, which inspires a sense of ***urgency***; (2) commitment to discovery through ***scientific excellence***, and the belief and commitment that ***parents are our partners*** in this effort. Each of these values relates to fundamental commitment at Autism Speaks to ***individuals with autism and their families.*** These families should be intimately involved in setting the direction and priorities for the science department. As we align our compass, people with autism and their families are the true north toward which we are oriented. To achieve these goals, we will utilize a core set of tactics, namely, promoting interdisciplinary collaboration, funding strategies that are highly leveraged, data-sharing, a balance between short- and long-term goals, and innovative science.





To address the need for clearly articulated goals and objectives, a framework utilized by the Gates Foundation¹ was adapted. Utilizing this framework, the Autism Speaks' science department carried out the following steps, the results of which are described in this document:

1. Two detailed analyses of the funding priorities and outcomes of past funding at Autism Speaks² were conducted, one by Autism Speaks' science staff and the other by the Washington Advisory Group, an independent consulting firm.
2. An assessment of the current status of initiatives and funding at Autism Speaks was conducted, including an assessment of the current data base resources that exist.
3. Two outside consultants were utilized in creating the plan: Fay Twersky, Director, Impact and Planning, Gates Foundation, and John Peabody, MD, PhD, FACP, Professor and Deputy Director, Institute for Global Health, University of California, San Francisco.
4. Autism Speaks solicited input from outside "thought leaders" and stakeholders on the strategic plan priorities and strategies. Six small strategic planning workgroups were convened pertaining to the following topic domains: (1) Etiology, (2) Biology, (3) Diagnosis, Phenotyping, and Epidemiology, (4) Treatment, (5) Dissemination, and (6) Bioinformatics. Each workgroup was comprised of Autism Speaks' science staff members, experts in the field, and at least one parent of a child with ASD. Each Strategic Planning Workgroup generated a document describing the highest priority goals, strategies, and metrics for measuring success for their domain. These documents were integrated into the first draft of the strategic plan and presented to the Scientific Advisory Committee for feedback.
5. Autism Speaks' science department met with the Scientific Advisory Committee (SAC) in New York City in September 2008 for a two day retreat to solicit their input on the priorities, strategies and metrics of the strategic plan. The SAC's input and feedback was integrated into the plan.
6. Additional feedback from the initial Strategic Plan workgroups was solicited.
7. The Strategic Plan was presented to the Autism Speaks Board of Directors in December of 2008 to be approved at the March 2009 meeting.

Strategic plan framework

The strategic plan framework we adopted requires defining end goals that directly involve health impact, i.e., translation of scientific results into real world outcomes and services. The process of achieving this end goal moves from *scientific discovery* to *development* and refinement of those discoveries to *dissemination*³ of results within a real world setting. Such strategic thinking depends on a "theory of change", i.e., a well-articulated plan for how change can be accomplished.

For the past several decades, the field of autism research has been primarily focused on discovery. For example, in 2007, whereas approximately \$160 million was spent on discovery research, less than \$20 million was spent on each of development and dissemination research. This is understandable given that, even a decade ago, we understood very little about autism, only a small number of committed scientists were devoted to autism, and the level of federal and private funding was extremely small. Thus, efforts have been largely focused on basic work aimed at defining and understanding the nature and causes of autism. Among the exceptions are studies in the areas of early recognition and intensive behavioral intervention. Now, in large part due to the historic efforts of Cure Autism Now, the National Alliance for

¹ Adapted from Fay Twersky, Director, Impact and Planning, Gates Foundation.

² Note that "Autism Speaks" in this document refer collectively to the activities of Cure Autism Now, National Alliance for Autism Research, and Autism Speaks, which now have merged into one entity.

³ Note that the path from discovery to dissemination is not unidirectional. In fact, we often have new discoveries about etiology and treatment that come from dissemination and clinical practice.





Autism Research, and Autism Speaks, the field is turning a corner such that a greater investment in developing, translating, and disseminating results is justified. It will be important to consider how Autism Speaks can accelerate science along this pathway from discovery to delivery by utilizing targeted funding mechanisms.

LOOKING BACK: ANALYSIS OF PAST-FUNDING PRIORITIES

Internal review of our return on investments in scientist-initiated research

The staff at Autism Speaks conducted an internal assessment of the accomplishments and return on investments based on the past decade of grant funding⁴. Autism Speaks has granted research funds for the study of autism and related disorders since 1997. The number of proposals and funding levels were initially modest but grew over time. The total funds awarded for investigator-initiated grants through 2007 were approximately \$77M. These funds were distributed among 683 research projects and 649 scientists (including 181 pre- and post-doctoral fellows, across 205 institutions), in 35 U.S. states and 17 countries. Moreover, these funds led to \$143.8 million of multi-year federal funding, and one patent. Outside of the US, funds were primarily directed toward the UK and Canada, two countries that already had a strong research base.

Field-building research grants have always been a core feature of Autism Speaks science programs. This goal has primarily been reflected in the formation of Autism Speaks' fellowship programs, where the brightest up-and-coming researchers expressing an interest in autism are rewarded with support through their training years. Our fellowship program, which supports both pre- and post-doctoral researchers, has steadily grown over the years. To determine whether Autism Speaks funding has had an impact on their career choice, we recently tracked former fellows through 2005 (103 in all) and found that 69% had remained in autism or autism-related fields in the next phase of their career. Very interestingly, further analysis shows that the retention rate of our pre-doctoral fellows within autism is 82%, indicating that they are finding positions and scientific opportunities within autism, proof that we are indeed expanding the field. Such high retention also suggests that our selection process is rigorous and that our pre-doctoral fellows are among the best.

As the knowledge base increased and theories were tested through the benefit of our awards, the information was disseminated to the public through scientific publications in peer-reviewed journals. Our grant program has directly contributed 700 scientific publications on autism research, some published in the most prestigious peer-reviewed scientific journals and highly utilized by other researchers (over 10% of these articles have been cited in at least 50 subsequent publications). The research findings in these publications have had an enormous impact on how we think about the disorder, including its causes and treatments. In this way, the grant money has been far reaching, benefiting both the researchers who are the direct recipients and the entire autism research community. Indeed, there was a dramatic increase in the number of autism publications indexed in PubMed starting in the mid-1990s, which was the point at which Autism Speaks efforts began. This likely is the product of many factors, including efforts by Autism Speaks, NIH funding of the Collaborative Program of Excellence in Autism in 1996, new

⁴ Note that this analysis focuses primarily on investigator-initiated grant funding and does not include an exhaustive analysis of our return on investments based on funding of specific research resources, such as the Autism Genetic Resource Exchange, Autism Genome Project, Autism Tissue Program, Clinical Trials Network, and many others.





technological advances (such as the sequencing of the human genome), and the increased prevalence and awareness of autism, all occurring within the same timeframe.



External review



At the request of the Chairman of the Board of Directors, Autism Speaks also contracted with the Washington Advisory Group (WAG) to conduct an independent review of the results from the grants made by NAAR and CAN during fiscal years 2004-05. Dr. Purnell Choppin, a WAG Director and President Emeritus of the Howard Hughes Medical Institute, served as Lead Director on this project. In collaboration with Drs. Dawson and Colamarino, WAG developed a set of evaluation criteria and assembled a list of potential reviewers (outside the autism research community).



The WAG team concluded that they were “very impressed with the great breadth of the areas of research being addressed by investigators, both basic and clinical.” They added, “Though there is an enormous amount yet to be learned, very significant progress is being made on many fronts.” In response to Autism Speaks’ leadership question, “Did we get our money’s worth?”, the WAG team concluded, “the answer to that question is yes.” They did recommend that grants be made for periods longer than two years, as this was noted as a problem by many of the reviewers. Furthermore, they recommended that careful attention be paid to obtaining the necessary expertise on science review panels, and to the evaluation of interim and final reports so that more information for assessing progress is available in the future.

Analysis of past and present funding priorities

An analysis of 2007 funding showed that Autism Speaks devoted more funding to studies focused on basic science research in the areas of etiology and biology than to applied science research in the areas of diagnosis and treatment. Within the Biology Portfolio, more funds were devoted to animal than human research (human research is generally more expensive, however). Within the Etiology Portfolio, more funds were directed toward studying genetic than environmental factors and very few funds were devoted to studying gene-environment interactions. Within the Treatment Portfolio, most funding was directed toward school age children and relatively lower levels of funds were directed toward adult treatments.

2007 distributions made by Autism Speaks were also examined by type of research (discovery, development, dissemination). Discovery research was defined as basic science aimed at gaining knowledge or understanding about fundamental processes, whereas development research was defined as scientific studies in which knowledge obtained from basic research with genes, cells, or animals is translated into diagnostic or therapeutic applications. Dissemination science is a newer field of study. In fact, the first NIH conference on the science of dissemination was held in 2007. The goal of dissemination science is to promote implementation of evidence-based practices by the broader community, including health providers, insurers, policy makers, and the general public. It was found that the majority of funding was devoted to discovery research. Lower levels of funding were devoted to development research and very little funds targeted dissemination research.

Funding by other organizations was also examined. The total amount of funds spent in 2007 by the U.S. on autism research, not including funds spent by Autism Speaks, is \$150,989,910. Based on NIH, CDC, and the Simons Foundation, portfolio funding distributions are: Biology (28%), Treatment (13%), Diagnosis (20%), Risk Factors (24%), and Other (15%). One striking take-home message from these data is that treatment and dissemination research are highly underfunded.





Grant and program analyses: moving forward

The utility of program evaluation is twofold: first, it measures our accomplishments against our goals, and second, it is a tool for strategic planning. Data from the evaluation of our grant program aids in our subsequent funding decisions, in expanding programs that yield returns or extending our reach into new growth territories, or even in retreating from approaches that have not produced. To move forward requires our collective scientific experience as well as concrete knowledge about our past performance. Evaluation will afford us the ability to correct ourselves and/or align our priorities, if necessary, to save valuable time and resources. To assist us in these efforts going forward, Autism Speaks' science department will be establishing an Advisory Committee on Impact and Analysis.

It is important that evaluation mechanisms be built into our grant process to provide reference for comparing our past, present and future funding decisions. Our grant program has pre- and post-grants components: “pre-grants” consisting of the submission, review, prioritization and awarding of grants, and “post-grants” consisting of the gathering of return-on-investment (ROI) data and grants analysis. Between these components lie “current grants,” where interim productivity on long-term grants and the overall distribution of our grant portfolio can also be evaluated. At present our grants database software manages pre-grants and current grants adequately but has very little capacity for post-grants analysis. Upgrading our grants analysis system so that it can automatically collect and track ROI data will greatly facilitate evaluation and be a high priority for 2009-11. Examples of ROI data to be collected include publications (articles, book chapters, etc.), additional leveraged funding, inventions (patents, reagents, research tools, etc), career development, and information dissemination (news articles, posters presentations, lectures, etc.), which can be obtained from the grantees themselves, from online databases, or other sources (e.g., in-house staff, other experts, etc.). The ROI on a grant usually materializes after the funding period, so follow up data collection should take place 3-5 years beyond grant completion. Computational analysis is possible if grants data are entered into the database in machine-accessible format, i.e., they are coded. Rapid real-time evaluation can then be performed with pre-programmed queries, and the results used for strategic planning that will allow us to respond to changing funding environments and shifting scientific priorities.

What should we measure? Flexibility should be built into the system so we can evolve our evaluation criteria and data collection. As autism research matures and moves closer to treatment dissemination, new and different program goals will be set, novel evaluation questions will be asked, and, most likely, more innovative metrics will be devised. Based on a survey we recently conducted and information derived from the Health Research Alliance, it appears that we are well-aligned with other foundations in the evaluation metrics we currently collect.

In the future we will also want to collect data that will allow us to answer questions that are more directly aligned with our mission, such as: *Have we improved clinical practice and patient quality of life? Have we lowered the prevalence of autism? Do our programs provide economic benefit to families?* Therefore, our program analyses, and the system we put in place for such analyses, must be able to accommodate more mission-based goals, which are not so reliant on publications but instead measure progress in terms of real impact for families.



LOOKING FORWARD: 2009-11 STRATEGIC PLAN FOR SCIENCE



Strategic directions

Five strategic directions were identified by multiple workgroups and the Scientific Advisory Committee. Their near universal endorsement is noteworthy as they may provide insight into particularly effective common strategies that can potentially influence success in several domains. *First*, the need for *an individualized approach to diagnosis and treatment* was identified as an important common goal by four of the five strategic plan workgroups and the SAC. Specifically, the need to identify *biomarkers or clinical features that index meaningful subtypes of ASD*, point to specific etiologies, and predict response to treatment was endorsed by all of these groups. It is recognized that autism is comprised of many different diseases with different etiologies, symptom profiles, courses and prognoses, and treatment responses. Given the multiple etiologies related to autism, incorporation of more comprehensive genetic and environmental exposure testing, assessment of underlying and associated medical conditions, and eventually the identification of new biomarkers will enable clinicians to provide more individualized and more targeted and effective treatments. Progress in this area will require a multi-pronged approach, including but not limited to studies focused on identification of useful biomarkers, (e.g., electrophysiological, immunological, metabolic), examination of genetic and other biomarkers as predictors of vulnerability to environmental triggers and moderators of response to treatment, and closer collaboration between researchers and clinicians, among others.

Second, the need for *better tools and more attention focused on understanding environmental risk factors and gene-environment interactions* was highlighted throughout. Prevention and treatment of autism through alteration of potential environmental factors is now considered a fundamental goal of research. Closer collaboration between geneticists and environmental scientists will be necessary, as well as new methods for measuring exposures and analyzing their interaction with genetic factors. A wide range of environmental factors needs to be vigorously explored including but not limited to exposure to toxins, vaccines, chemicals, immune challenges, and the role of early behavioral intervention in altering the course of brain and behavioral development. Methods for identifying children who are medically vulnerable to adverse effects of environmental events need to be developed. Closely tied to this theme is the need to develop methods of early assessment of risk. The identification of infants at risk for autism will allow implementation of prevention strategies during the early postnatal and toddler period when significant changes in brain development are occurring.

A third strategic goal endorsed across the workgroups and SAC was the urgent *need to translate genetic and other biological findings into clinically useful tools* that can facilitate risk assessment and drug discovery. Again, multiple strategies will be required, including the development of appropriate animal models, development of preclinical assays to fast-track screening of novel treatments, practice guidelines for the communication, and use of new and sometimes poorly-understood genetic findings or exposure data within a clinical setting. It was agreed that the development of model systems that uniformly characterize the most relevant biological and behavioral abnormalities found in autism is paramount in moving the field forward. More generally, there is a need for the development of clinical standards and practice parameters for clinicians serving individuals with autism and their families. A better understanding of the factors that promote or impede acceptance of empirically-supported practices will be an important step in the dissemination of findings to the clinical community.

Fourth, in an effort to balance short and long term goals and improve the lives of persons with ASD now, the need to *develop treatments that can address the core symptoms and associated medical conditions* from





which people with ASD suffered was recognized. There is a need to identify new treatment approaches, both behavioral and medical, that are appropriate for individuals across the life span. In particular, there is a need to promote the development of a comprehensive care model that can address common medical conditions, such as GI and sleep problems, as well as depression and anxiety. Addressing such issues will require new approaches to clinical diagnosis and assessment, training of physicians and other health care providers in recognizing and treatment persons with ASD, and testing the efficacy and safety of medical and other treatments.

Fifth, the need to direct resources into *dissemination of empirically-validated treatment approaches*, such as early behavioral intervention, that could significantly alter the life trajectory and improve outcomes and quality of life for many individuals with ASD and their families today was strongly endorsed. In fact, this goal was identified as the number one priority by the Scientific Advisory Committee. This will require investing in (1) studies that demonstrate the effectiveness of feasible, exportable, and scalable early intervention programs, (2) the identification of factors that promote or impede the implementation of such programs in the community, (3) novel methods for provider training that can be accessed by the wider community (e.g. web-based technologies), (4) implementation of training programs that can build capacity of the community to provide interventions, and (5) changes in insurance benefits for early intervention and other empirically-validated treatments.

Given the rapidly expanding knowledge base pertaining to autism and related fields of inquiry and the complexity of the ASD, the *development of central information repositories* that are highly useful and flexible for scientific exploration will be vital for moving the field forward toward discovery of prevention and treatment methods. These information systems need accommodate international efforts and provide a platform for web-based training modules and wide-scale information dissemination.

Furthermore, *closer collaboration and improved communication* among scientists of different disciplines and between families and scientists, clinicians and researchers, public and private funders, and stakeholders and scientists world-wide will allow for the discovery of more effective treatments and prevention strategies and their dissemination and implementation in the broader community, so that all individuals with ASD and their families can benefit from the work we are striving to accomplish.

Other recommendations from the Scientific Advisory Committee

The SAC noted that Autism Speaks should place high priority on innovation rather than incremental research. They strongly endorsed developing a funding mechanism designed to respond quickly to opportunities and novel ideas. Autism Speaks has already implemented changes in its review criteria to reflect greater emphasis on innovation and relevance to Autism Speaks' mission. Furthermore, in 2009, following the SAC recommendation, Autism Speaks will establish the Trailblazer Awards which will be modeled after the Rapid Response Innovation Awards offered by the Michael J. Fox Foundation for Parkinson's Research. The Trailblazer Award mechanism will be a rolling application to support highly novel autism-related research that addresses significant roadblocks and can open new avenues for understanding the causes and treatments for autism spectrum disorders. No preliminary data are required, but the project needs to have the potential to substantially impact our understanding of the causes or effective treatments for autism. Awards will be made for one year at a level of \$100,000 or less.

The SAC recommended that Autism Speaks continue to explore opportunities to form strategic partnerships, including partnerships with other disease foundations that share similar goals (e.g., Epilepsy Foundation, United Mitochondrial Disorders Foundation), government and private funding agencies in





other countries (e.g., UK, Middle East), NIH, Gates Foundation, World Health Organization, pharmaceutical companies, and biotechnology companies.



Noting the high level of retention of scientists (particularly predoctoral fellows) funded through the fellowship program, the SAC strongly recommended that fellowships continue to be a core part of the funding portfolio at Autism Speaks. The possibility of providing career development awards should also be considered.



The SAC also strongly recommended that the science component of Autism Speaks' website be better designed, "meticulously curated," and better utilized to promote research and science information dissemination. Among the ideas discussed were more detailed and personal science stories that are more reader friendly for the general public, conference and other event postings, interviews with funded scientists, job postings, and others. Collaboration with the Interactive Autism Network and International Society for Autism Research on this effort was recommended.



Finally, the SAC remarked on the great usefulness of interdisciplinary workshops that focus on topics in which Autism Speaks wishes to stimulate investment. Such workshops serve to develop the needed communication among diverse types of scientists and clinicians that is needed to move in novel directions and provide translation from the bench to the bedside and vice versa.





Summary of goals and priorities for 2009-11

Table 1 provides a summary of the goals, strategies, objectives, and initiatives identified in the 2009-2011 strategic plan for science. Although many challenges exist, including the current downturn in the world economy which is certain to affect funding for autism research and services, there is reason to be optimistic about our ability to make significant discoveries, translate those discoveries into treatments and prevention strategies, and disseminate these into the wider community for the benefit of individuals with ASD and their families. The number of scientists devoted to studying autism and the amount of resources (albeit still far below what is needed) have never been higher. In large part due to Autism Speaks' efforts, the stakeholder community has developed a strong and unified voice, increasing our ability to influence policy and resources. President Obama recognizes the urgent need to investigate the causes and treatment of individuals with ASD, making federal support for autism research and policy changes that could influence access to treatment more possible now than ever before. New and exciting technological advances and bioinformatic resources are becoming available at an extremely rapid pace, making new discoveries and fast dissemination of information possible. All of these factors give us real hope that the lives of individuals with ASD and their families will be improved through our efforts. To this goal, we remain steadfastly committed.

Autism Speaks Science Leadership

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Sophia Colamarino, Ph.D., Vice President, Research

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Clara Lajonchere, Ph.D., Vice President, Clinical Programs

Anita Miller Sostek, Ph.D., Vice President, Scientific Review and Operations

Andy Shih, Ph.D., Vice President, Scientific Affairs



Table 1. Goals, Strategies, Objectives, and Initiatives

Goal	Strategies	Objectives	Initiatives
<p>1 - Identify genetic and environmental risk factors for autism and their interaction</p>	<ul style="list-style-type: none"> • Create and integrate large scale genetic and environmental exposure data bases • Develop analytic tools for examining gene-environment interactions • Leverage existing projects and international partnerships to enhance genetic and environmental data collection • Promote data-sharing and large scale data base integration • Enhance collaboration among geneticists, environment scientists, and clinicians 	<ol style="list-style-type: none"> 1. To enhance resources for discovery of autism susceptibility genes 2. To promote identification, collection, and evaluation environmental exposure data 3. To facilitate novel directions in the exploration of environmental factors and gene-environment interactions 	<ul style="list-style-type: none"> • Autism Genetic Resource Exchange • Autism Genome Project (AGP) • Collaborative Risk and Outcome Scientific Study (CROSS) • National Children’s Study (NCS) Collaboration • Environmental Factors Initiative • International Autism Epidemiology Initiative • High-risk/High impact Initiative • Weatherstone Fellowships • Trailblazer Awards
<p>2 - Identify the underlying biological mechanisms of autism</p>	<ul style="list-style-type: none"> • Develop appropriate of animal models • Use animal models to study biological pathways, drug responses, and recovery • Develop pre-clinical assays to study effects of risk genes and environmental factors on biological pathways and fast track screening of novel treatments • Create state-of-the-art tissue program, including brain, stem cell, and other tissues • Collaborate with Allen Institute for Brain Sciences to study gene expression and brain development • Develop novel brain imaging technologies to study early brain development 	<ol style="list-style-type: none"> 1. To stimulate innovative studies using animal models to understand biological mechanisms and test novel treatments 2. To develop in vitro and in vivo methods for pre-clinical testing of drugs 3. To create state-of-the-art tissue bank 4. To facilitate development and application of novel brain imaging techniques 	<ul style="list-style-type: none"> • AS-MRC collaboration on Rett syndrome recovery • AS-Allen Brain Institute Collaboration on brain development • Autism Tissue Program Initiative • AS-Simon Foundation-NIH initiative to create state-of-the-art Autism Tissue Bank • High-Risk High-Impact projects on Mitochondrial Disorder and Novel approaches to brain imaging



<p>- Develop improved and more efficient diagnosis and risk assessment methods</p>	<ul style="list-style-type: none"> • Explore the validity and reliability of briefer, scalable methods of diagnosis that would allow acquisition of larger data bases • Develop consensus standards for diagnosis and phenotyping in research studies to facilitate data base integration across studies • Develop methods for screening and diagnosis for infants and toddlers, including biomarkers • Examine the utility and feasibility of genetic, medical, and metabolic assessments as part of a diagnostic work-up and as predictors of response to specific treatments • Encourage and prioritize research on adults and aging 	<ol style="list-style-type: none"> 1. To promote the development of briefer, scalable methods of diagnosis that are useful in multiple research and clinical environments 2. To reach a consensus in the field on a standard set of diagnostic and phenotype measures 3. To promote identification of reliable and valid risk/bio markers for autism 4. To assess the utility and feasibility of genetic/medical testing as part of a diagnostic workup 5. Increase knowledge on adult outcomes and aging in ASD 	<ul style="list-style-type: none"> • AGRE/NIH study exploring the use of parent questionnaires for screening and diagnosis • HR-HI IAN Studies exploring the validity of parent questionnaires for screening and diagnosis and assessment of nonverbal persons • Workgroup on Phenotyping Standards • AGRE and AGP studies on gene discovery • Baby Siblings Research Consortium • Conference on Translating Genetic Discoveries into Clinical tools • Autism Treatment Network • Prioritize research on adults and aging through pilot and basic/clinical grants
<p>4 - Identify effective treatment and prevention strategies for individuals with ASD⁵</p>	<ul style="list-style-type: none"> • Develop and test the efficacy of interventions for infants • Develop best practice guidelines for medical and behavioral interventions • Develop and test the efficacy of medical and behavioral/psychosocial treatments for school age, adult, and nonverbal individuals • Improved outcome measures for treatment studies are needed 	<ol style="list-style-type: none"> 1. To have effective, scalable interventions for infants and toddlers 2. To provide treatments that address the medical conditions associated with ASD 3. To publish practice guidelines for medical care 4. To have effective treatments for school age, adult, and nonverbal individuals 5. To develop sensitive and reliable outcomes measures for use in treatment studies 	<ul style="list-style-type: none"> • Toddler Treatment Network • Autism Treatment Network • Treatment Initiative/Grants Program • Clinical Trials Network • Innovative Technology for Autism Initiative • High-Risk High Impact Initiative • Interactive Autism Network • RFA on Treatment of GI Problems

⁵ Strategies, objectives and initiatives for meeting Goal 1 and 2 also are important for the development of effective treatments (See Goals 1 and 2)



<p>5 - Widespread dissemination of empirically-validated methods for screening, diagnosis, and treatment to the broader community worldwide</p>	<ul style="list-style-type: none"> • Convene “thought leaders” on effective dissemination and service delivery systems to discuss and develop a strategic plan for addressing the lack of dissemination of best practices in the community • Establish functional linkages to promote communication and partnership among the government and professional groups invested in dissemination of health care to prevent duplication of effort, reduce cost and effort, and increase collaboration • Work closely with Awareness, Government Relations, and Family Services components of Autism Speaks to coordinate with their efforts at policy change and dissemination • Survey existing models for dissemination of autism best practices or similar models for other diseases • Pilot dissemination model through Global Autism Public Health Initiative nationally and internationally 	<ol style="list-style-type: none"> 1. To improve communication among the government, private, and professional groups invested in dissemination of clinical practices 2. To develop a coordinated vision for dissemination of empirically-based best practices into the community both nationally and internationally 3. To pilot GAPH model of dissemination of empirically-based practices 	<ul style="list-style-type: none"> • Global Autism Public Health Initiative • Autism Treatment Network • Interactive Autism Network
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