# 20 YEARS OF IMPROVING PATIENT LIVES THROUGH RESEARCH & DATA ANALYSIS





### Improving Patient Lives Through Research and Data Analysis

Arbor Research Collaborative for Health is committed to improving patient care through research that shapes medical policies and practice. In particular, Arbor Research conducts health outcomes research on chronic disease and end-stage organ failure, with expertise in biostatistical analysis, clinical practice, health economics, public policy, database management and integration, and project coordination. Through research projects that are national and global in scope, Arbor Research's scientific collaborations provide valuable and timely information to the worldwide health care community.







When Arbor Research was formed in 1997, it had a different name, a single funded project, and finished its first year with six employees. Now in our 20th year, Arbor Research has grown to a staff of over 140, supporting more than 20 active projects funded by government and private sector sponsors. President Robert Merion, MD, FACS reflected on the growth of the organization and the vision for the future.

# The mission of Arbor Research is "improving patient care through research that shapes medical policies and practice." What does that mean to you?

To me it's all about individuals. When I think about our mission I don't think about groups of patients. I think about a 50-year-old woman with liver failure; I think about a 10-month-old baby with undiagnosed liver disease; and I think about an elderly man who has severe, lifestyle-limiting urinary symptoms.

Each of us, at some point in our lives, will be considered a patient. It could be for something minor, or it could be something major and life-threatening. At Arbor Research, we focus on issues where we can apply our methodologies, the brilliant minds of our staff, and our organized thinking about data, with the goal of reaching individual human beings.

#### How would you characterize the culture of Arbor Research?

The attributes that drew me to join this organization were the spirit, the energy, and the passion of the people who work here. I think a lot about how we can maintain that special spark, that all-important focus on research that will help people.

One of the most important aspects of our culture is that anybody can ask a question, anybody can question a statement, and there's no such thing as a dumb question. We describe ourselves as a learning organization and as a teaching organization. Each member of our staff demonstrates a commitment to revealing and understanding the right answer. The fact that this is an intellectually open and curious environment is our most positive feature.

#### What's your vision for the future of Arbor Research?

My vision for the future of Arbor Research is of an organization continuing to grow in size and scope. We can see the impact that our research has on the delivery of health care, and our growth as an organization is focused on improving care for a wider range of people.

As the contractor for the Scientific Registry of Transplant Recipients, we built simulation models to predict the effects of changes to the national rules for organ allocation.

Now, Victor Andreev and his team are looking at using simulation in situations where we may have exponentially more data to work with. With the dramatic increase in the amount of data available and with new kinds of data, simulation modeling and data visualization are two big areas for us to focus on in the future.

In recent years we've made a concerted effort to identify chronic diseases where we can make a difference. An example is the Childhood Liver Disease Research

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Network (ChiLDReN), which studies children with liver problems. The methodologies and approaches to research that we've developed over the past 20 years translate very nicely to improving the diagnosis and treatment of this new group of patients.

Another development, coming out of our health policy group, is a project to develop population health quality measures. Historically, quality measures have been assessed on an individual patient level and are increasingly used to pay health care providers for how well they take care of patients – not simply for how much health care they deliver. There have been many efforts to disincentivize inappropriate or unsuccessful care and incentivize the right kind of care with the right outcomes. Population health quality measures will go a big step further and evaluate whole groups of patients on the achievement of metrics that society deems important, transforming a public health focus into a health care delivery focus. We are excited to be at the forefront of these efforts.

As we mark 20 years of research, we're also looking ahead and planning for what the next 20 years will bring. Looking for new opportunities to reduce the burden of chronic diseases and improve the delivery of health care is the vision that carries us forward.

The Dialysis Outcomes and Practice Patterns Study (DOPPS) was the first research project run by Arbor Research. Investigators noted that survival on dialysis was substantially lower in the US than in Europe and Japan, and they initiated the DOPPS to understand the reasons for these international differences.

Bruce Robinson, MD, MS, FACP, the principal investigator of the DOPPS program, reflected on the accomplishments of the DOPPS after 20 years.

# The DOPPS Program



### How has the DOPPS influenced care and policy?

We focus on understanding variation in practice, and identifying discretionary practices that are associated with the best outcomes. Early in the study, DOPPS investigators found the use of surgical

vascular access for dialysis patients was much lower in the US than in other countries. Even in the US or any one country, we see differences in vascular access use and practices across dialysis facilities that almost certainly affect patient outcomes. We believe that our research is an important driver of policy change, as demonstrated by the implementation of the Fistula First Breakthrough initiative in the US, which was launched over 10 years ago by CMS and has led to a dramatic increase in the use of surgical arteriovenous access, for the clear benefit of patients.

We've done work looking at dialysis session length, demonstrating that patients who receive longer sessions have lower mortality rates. Indeed, this finding was in part the basis for policy changes in Germany and Japan, where dialysis reimbursement policies now incentivize longer treatment time. Each country now has among the longest average dialysis session length in the international DOPPS.

#### What has the DOPPS taught us about the state of dialysis?

Dialysis has been a life-sustaining therapy for many millions of patients over the years, and in this sense it is a real achievement. At the same time, it exerts a massive toll on patients. Dialysis doesn't replace anywhere near normal kidney function, so patients are left at a real deficit. We still see this in terms of dramatically reduced survival and high mortality rates. In part because of findings from the DOPPS, mortality on dialysis in the United States has dropped quite substantially. It's a wonderful achievement, but at the same time mortality remains much higher than it should.

The DOPPS has always been at the forefront of capturing and studying the experiences of dialysis patients. We've published papers showing the importance of quality of life as a predictor of mortality amongst dialysis patients. Patients with very low quality of life – mental or physical – tend to have higher mortality rates.

Dialysis is a life-altering intrusion into patients' lives, so the patient experience is really an important end-point in itself. Recent research on the time it takes to recover from each dialysis session shows a great deal of variation among patients – some recover in an hour or two but many others take all day to recover. For those patients, three days of every week are completely wiped out, in terms of any meaningful and enjoyable quality of life. This is a big issue for patients, and we plan to do more work to address this problem.

#### How has the study grown into related areas of research?

The DOPPS has published nearly 200 papers and we also have a strong record of getting information out into the community – influencing practice, and influencing policy as well. The DOPPS Practice Monitor publically reports trends in hemodialysis practice, with data from the United States,

As patients with advanced CKD approach end-stage kidney disease, we want to identify best practices to slow progression if possible, widen access to all options for end-stage kidney disease care, and ultimately lessen the hardships of this tumultuous period for patients and their families.

Canada, and Germany. Through these efforts, it became apparent that we could improve care for more patients by extending our research model into new areas.

The Peritoneal Dialysis Outcomes and Practice Patterns Study (PDOPPS) was launched in 2012, motivated by the dearth of meaningful information on variation in PD practice. The same year we also launched a study called the Chronic Kidney Disease Outcomes and Practice Patterns Study (CKDopps). The CKDopps arose from our understanding that it is very difficult to study patients as they transition

from advanced chronic kidney disease (CKD) to kidney failure. There are a lot of CKD cohort studies, but most enroll patients at academic centers and focus on biological determinants of progression and biomarker discovery. The motivation for our study is that much of the variation in patient outcomes is attributable to practice differences in 'real-world' settings. This area has not been studied well, and could have a large impact on patient outcomes in the near future.

#### What is your vision for the future of the DOPPS?

Our goal remains to improve outcomes for our patients. And there's still a long way to go to prevent unwarranted practice variation. We're focused on understanding what matters most to patients. As patients with advanced CKD approach end-stage kidney disease, we want to identify best practices to slow progression if possible, widen access to all options for end-stage kidney disease care, and ultimately lessen the hardships of this tumultuous period for patients and their families.

Another major goal for the DOPPS Program is to share our research and data with the broader community of stakeholders, including researchers, caretakers, and of course patients. We encourage researchers to submit requests to partner with us on our analyses or for separate use of our data. These are important ways for us to articulate and address questions that are the most important to the community, and ultimately have the most important impact on care.



# NEW EXPERTISE

# **EXPANDS METHODOLOGICAL**

# RESEARCH

Interview with Victor Andreev, PhD, DSc



Arbor Research has developed valuable experience in managing data coordinating centers.

These centers support research consortia made up of clinicians, biostatisticians, project managers, analysts, clinical monitors, project support personnel, and medical editors. Together, they investigate causes and optimal treatment for a wide range of diseases.

Dr. Victor Andreev joined Arbor Research in 2014, and has been working with the data coordinating centers to advance their research. Dr. Andreev spoke about his recent work on these projects.

#### What are the research questions that interest you most?

Most of my life I was doing mathematical modeling and signal processing. A field I am particularly interested in now is called unsupervised learning, which includes methods to classify people or events based on multi-dimensional information. And we're doing some interesting methodological and practical research in this field here at Arbor Research.

# Tell me about some of the work that you're doing currently and the projects that you're working on.

I'm working with the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN). Lower urinary tract symptoms (LUTS) are interesting because they are very prevalent and affect quality of life. But it's also a wonderful example of a common complex disease. It's not just one gene determining one disease. It's a lot of genes and multiple environmental factors and a lot of things happening in your brain. We integrate all of these data: biomarkers, neuroimaging, organ-based, system-based. A theme coming through the project is determination of subtypes of disease based on unsupervised learning.

On the methodological side, we're currently developing the first ever simulator that determines sample size for unsupervised learning. We will have an online tool available soon that will determine which clustering methods to use for the expected type of data, how many patients are needed

Unsupervised learning includes methods to classify people or events based on multi-dimensional information. These methods can be applied to many different research questions.

in the sample, depending on the expected effect size and number of clusters. This will have applications that extend well beyond the LURN study.

Another thing coming from LURN that I am very excited about is comparison of connectivity matrices. Researchers with the study use fMRI, a non-invasive brain imaging technique, to look at different areas in your brain and examine how oscillations of the blood flow to different regions of the brain are correlated with each other in the resting state. That gives us information about the connections in the brain that exist, which can differ in health and disease.



There's some preliminary data showing that in LUTS there are some changes in connectivity matrices. Up until now nobody has done this kind of systematic analysis of brain connectivity matrices for anything that is happening outside of the brain. They've done this for Alzheimer's, but the situation is different when you're dealing with LUTS. First, the effect is not that great. Second, it's not just deteriorating connectivity; it's also some additional connections that could be formed. There are no established methods for statistical comparison of connectivity matrices, and that's the problem we are working to solve.

The work that we're doing can be applied to many different research questions. For instance, we're starting a study with the DOPPS Program on discrete event simulation of cardiovascular complications in dialysis. We are looking at rather detailed information like blood pressure profile in dialysis sessions and using our expertise in clustering profiles. And that's where signal processing methods are coming into play.

# What brought you to Arbor Research? Why was Arbor Research the right fit for your interests?

When I first heard about Arbor Research I looked at the website and I looked at the publications, and I was very impressed. I was especially impressed when I came here and saw the culture, saw the friendliness, the openness of the organization. A great part of working at Arbor Research is freedom: freedom to express your ideas, freedom to be heard.

And the most important thing is that you have a lot of data – a lot of high-quality data. And for a person who is doing mathematical modeling, data analysis, and signal processing that's very important to have a lot of high-quality data. At Arbor Research, there are a lot of people who understand the subject matter and how to work with data.

# Rigorous Standards, Comprehensive Data

Interview with David Dickinson, MA

Good research starts with sound evidence. In order to rely on sound evidence, researchers need accurate and valid sources of data. Arbor Research Vice President for Information and Operations David Dickinson discussed the data management approach that underlies the work at Arbor Research.



How do data management capabilities advance the mission of Arbor Research to improve patient care through research that shapes medical policies and practice?

Our data management team understands the context and purpose of the data we use; whether they were originally intended for payment purposes or abstracted from records for care purposes, we are skilled at translating those data to support our research.

Historically, the core skills of our research group start with leveraging data that are collected for purposes other than research, and transforming them to make something that's really valuable for research. For instance, using Medicare claims or other payment claims to learn all we can about the dialysis experience. One of the core skills that our data management team has is to figure out what questions we can answer with existing accessible data, and to ensure we take into account the original context purpose when interpreting the data.

Even when we collect data specifically for research purposes, we need to be aware of what sources are easily at hand for our collaborators at study sites. By making it easier for them to share good data, we improve the quality of the research. It's "garbage in, garbage out." If we are to produce quality research, we need to base that research on really high-quality underlying evidence.

### How do teams at Arbor Research work together? How do programmers work with other members of the organization?

From the very beginning of the DOPPS, all of our study design discussions had clinicians, biostatisticians, programmers, and many others together in the same conversations. That was one of my formative experiences at Arbor Research: the chance to be engaged in study design with other experts to integrate their clinical and biostatistical knowledge with whatever I could contribute. That multidisciplinary dynamic is why, almost 20 years later, I'm still at Arbor Research.

The job of the data managers and programmers goes far beyond software development. They integrate across all of our research projects, and across all phases from design to data gathering to research and dissemination. The people in programming roles cannot do them successfully without day-to-day interaction with the people who are going to be using the data. Not only does this level of integration make it a better product, it makes Arbor Research a fun place to work.

# What innovations are you most proud of? How have these solved problems that arise in research projects?

It always makes me proud that we contribute a multidisci-

We contribute a multidisciplinary approach that addresses the needs of our customers. Understanding the full context of the research allows us to develop tools to communicate health practice and health information.

plinary approach that addresses the needs of our customers. Understanding the full context of the research allows us to develop tools to communicate health practice and health information. Our work with the Centers for Disease Control and Prevention (CDC) to develop a website for communicating data about chronic kidney disease and our work with Medicare to translate payment data into measures of performance are two examples of projects that have succeeded because of this approach.

ArborLink data collection software is another major accomplishment for us. When we faced the need to collect



data for the DOPPS Program in more than 20 different countries and languages, around the world using the same protocol, we looked for off-the-shelf software, but none fit those specific needs without great expense. It always makes me proud that this organization said "we can do that." It's always a little harder than we think it will be, but at the end of the day we've been successful at creating solutions that are different from clinical trial software – they are specifically designed for our type of observational research.

### What opportunities are you most excited about pursuing in the future?

The next step in our development will be to do a better job of communicating information back to our audience and collaborators. In the context of some projects, this means improving our data dissemination tools and making them more interactive. People learn better when they are engaged and encouraged to interact with the information. Our goal is to give users enough flexibility to find the information they want, but also give them enough guidance to find information that they may not have known they wanted.

That's the kind of thing that excites me about the next several years – being able to think of better ways to recognize the range of audiences who are interested in health information, recognize they all learn differently, and hopefully provide them with the kinds of interactive tools that will help them learn.

# Informed Policy Decisions

### Interview with Marc Turenne, PhD

Arbor Research supports health care policy development through several contracts and grants with CMS and the National Institutes of Health (NIH). Marc Turenne, PhD spoke about the history of these projects and his vision for expanding upon this work in the future.

# Tell me about the role that Arbor Research plays as a contractor on federally-funded projects. What types of expertise do you contribute?

We provide expert analysis and data-driven support to the government in designing, implementing, and evaluating health policies and programs. The work we do can take different forms, depending on what the project is. At a high level, we're either helping the government to make informed policy decisions, or we're helping to roll out new policies and programs, or we're helping them to make conclusions about whether certain initiatives are effective.

# What health policy projects has Arbor Research contributed to in the past?

There has been a strong focus on work to develop new quality initiatives and new payment systems. For example, we have developed measures of quality of care that are used in CMS programs, including both value-based purchasing and public-reporting programs.

We've also been involved in payment system development. Recently, we helped to develop a new Medicare payment system for Federally Qualified Health Centers. These are examples of recent work we have done on the development and design side of things.

Over time, we've concentrated quite a bit of our effort in the area of end-stage renal disease (ESRD), but we've also recently expanded our scope to include aspects of primary care and population health. We've found that we're able to leverage the experience we've gained in chronic disease research and apply that to other areas.

### What makes Arbor Research a successful partner in health policy projects?

I would say that starts with our vision as an organization, which is to reduce the burden of chronic disease and improve the delivery of care. Our health policy work has the potential to help the government to stimulate improvements on a wide scale. Our team shares a commitment to doing work that will accomplish that.

The form that work will take can vary. For example, it might involve analyzing data, convening public meetings with a panel of invited experts, preparing research reports, or responding to questions from providers about their performance in CMS programs. Regardless of the form the work takes, we are motivated and organized as a team to be successful on these projects. As a contractor, we set goals to provide objective, valid, and timely information. We aim to be nimble and responsive in the way we do our work – and at the same time to be up front about any barriers or limitations we may face.

But most of all, what has struck me in my time here at Arbor Research is how there is such a shared focus on being extremely proficient in what we do, and on recognizing and respecting how others are applying their skill and experience to their work. When we each do that, it's almost as though there is this chemical reaction when we come





Health policy work at Arbor Research focuses on improving access to care, the quality of care, and the efficiency with which care is delivered.

together as a team. It's inspiring to see what we can do together – that's what really stands out.

### What is your vision for pursuing health policy work in the future?

One priority that I see for us is to continue to do work that involves a spectrum of different types of health policy projects. More specifically, I would like that to include work in the areas of design, implementation, and evaluation. There are some real synergies in doing work in those various areas that give you a perspective on how you can do the other better.

We can think about this as it relates to our current End-Stage Renal Disease (ESRD) Disparities project, which is a great example of a project that presents opportunities to consider the intended and unintended effects of establishing a new payment policy. There is certainly a need to do this in the policy design stage, thinking about both policy goals and the risks of unintended consequences. But this is also the case when doing an evaluation. When a new policy like the new Medicare payment system for dialysis is imple-

mented, you really need to have follow-through to measure its effects, both intended and unintended. There is also insight you gain when doing an evaluation that can benefit policy design and implementation efforts. For example, it gives you a perspective on what information may be most important to try to collect as a new policy is being implemented so that it will be available for a future evaluation.

Finally, we consider the extent to which the work that we're considering is going to improve access to care, the quality of care, or the efficiency with which care is delivered. We look for the most promising opportunities to make improvements in those areas. There is an established history here at Arbor Research of doing work that is aligned with those goals. We have a strong track record of doing research that focusses on the care of chronically ill, vulnerable populations. Important strides have been made in the care of these populations, but we know there is a lot of room for improvement. Let's find especially promising opportunities to contribute to future improvements. That should always be at the forefront of our minds as we make decisions about the kind of work we will do.

# Our vision for patient-centered research

Interview with Francesca Tentori, MD, MS

Arbor Research embraces patients as partners in research. Dr. Francesca Tentori leads a new research group to advance patient-centered research. She outlined her vision for this work in the following interview.

### How did you first become interested in patient-centered research?

I trained as a nephrologist in Italy. I came to the US to work with the Zuni Indians – that was my first experience with population-based research and observational studies. Dr. Friedrich Port asked me to join the DOPPS, which I had been working on as a fellow in Italy – and it was almost like a circle came to close. It's been a privilege to be part of the Arbor Research team for the past nine years.

Research that embraces patients has always been interesting to me. My grandfather was a family doctor at a time when doctors did everything from delivering babies to pulling teeth. It was clear that the single most important thing – especially when you have few tools at your disposal – is

to listen to the people you're taking care of. You can treat a patient, but if you don't establish that empathic relationship, then providing the best care is impossible.

When I switched from clinical practice to research it was a little bit dry at the beginning. But then I realized that same outlook – that same interest in the person – can be applied to research in much larger numbers. Since the very beginning – for 20 years now – the DOPPS has been collecting data on the patient experience through the patient questionnaire, which patients fill out once a year. Recently there has been more and more interest in patient engagement and soliciting more of the patient experience.

### In what ways has your work embraced patients as stakeholders?

Three years ago I was very fortunate to get one of the first awards from the Patient-Centered Outcomes Research Institute (PCORI) to study the factors that are important to patients. This work is culminating now with the development

of a patient decision aid that we hope will be helpful to patients who are choosing between hemodialysis and peritoneal dialysis. Perhaps most importantly, we resonate with patients and their families because we work very closely with an advisory panel that includes patients, family members, and researchers to really reflect their experiences. So my hope is that this is truly a patient-centered decision aid.

# How has this recent work shaped your thinking about research that speaks directly to patients?

When I put together the proposal for the Empowering Patients on Choices for Renal Replacement Therapy (EPOCH-RRT) study for PCORI, it was a requirement to have a stakeholder advisory panel. And the experience of working with patients as collaborators has really been eye opening for me. I have always listened to patients and wanted to learn from them, but I had never had the opportunity to do so in a research setting. The EPOCH-RRT patient advisory panel has really opened my mind – in the sense that they have very determined opinions and they're not shy about expressing them. Most of the time their experience has really resonated with my sense, gut feelings, and my experience. But sometimes it was completely new and it really opened my eyes to a completely different experience.

# You can treat a patient, but if you don't establish that empathic relationship, then providing the best care is impossible.

I was very mindful, especially in the beginning, of how frequent these meetings would be. At this point all of the patients on the panel are on in-center hemodialysis, so we know that three days of their week are busy, so we didn't want to be too demanding with their time. But actually we got the opposite feedback: "Please keep us more informed, more involved. Let's meet more rather than less." So that also tells me, I think, that the experience has been positive on their side.

What is your vision for the future of patient-centered research at Arbor Research? What questions would you like to answer/what populations would you like to reach?



My vision in one word is growth. Growth in terms of continuing to expand what we have been doing in the area of kidney disease. We will look for ways to get patients more engaged in their care. Within the ESRD realm this is important because we're moving towards having quality indicators that are based on the patient experience. Given our expertise at Arbor Research, we are in an excellent position to engage with patients who have chronic disease. But with any disease – diabetes, hypertension, psychiatric disorders – any condition that has such a huge impact on life, being more aware of the patient perspective will help us identify better ways to provide better care.



# Message from Karen Crow, Vice President, Finance and Board Treasurer

2015 was a landmark year for Arbor Research. Following our achievement of surpassing \$17.0 million in total revenues in 2014, we reached the \$24.8 million mark in total revenues in 2015. We continue to be well positioned to continue our growth in 2016. The 2015 Statement of Financial Position remains strong, with assets at \$19.5 million, including cash and investments of \$14.1 million.

Over the past fiscal year we have enhanced our service and products portfolio both organically and through targeted project growth. Our strategy for future growth is built on a solid foundation supported by our ability to execute and deliver on complex projects.

As we move forward, we believe the strength of our company and business model will enable us to continue our mission to improve care for a wider range of people.

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### **Statement of Financial Position**

ASSETS	2015	2014
Cash and investments	\$14,107,925	\$19,526,853
Grants and contract receivables	3,860,478	2,426,282
Prepaid expenses and other assets	360,342	397,988
Property & equipment, n	et 1,187,635	963,026
Total assets	\$19,516,380	\$23,314,149

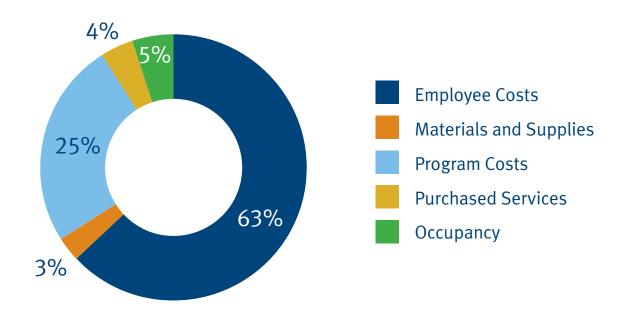
### **Liabilities and Net Assets**

LIABILITIES		
Accounts payable & accrued expenses	\$2,709,652	\$3,072,081
Deferred revenue	0	6,472,541
Total liabilities	2,709,652	9,544,622
NET ASSETS		
Total net assets	16,806,728	13,769,527
Total liabilities and net assets	\$19,516,380	\$23,314,149

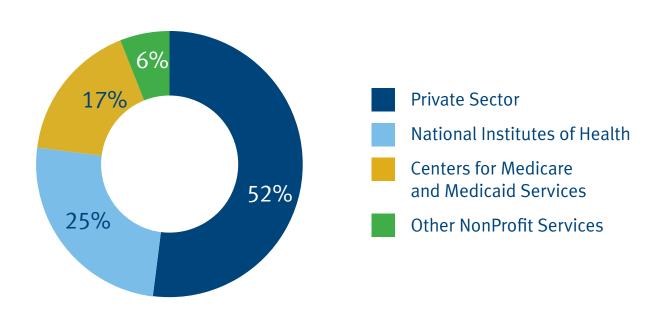
### **Statement of Activities**

REVENUE AND SUPPOR	T 2015	2014
Grants and contracts	\$25,057,579	\$16,510,654
Net investment		
earnings (loss)	(241,516)	713,951
Other income	5,536	12,110
Total revenue		
and support	24,821,599	17,236,715
EXPENSES		
Total program services-	20 112 052	4 / 000 / 04
research and analysis	20,112,853	14,033,401
Total facilities and administration	1,671,545	3,286,850
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Total expenses	21,784,398	17,320,251
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Change in net assets	3,037,201	(83,536)
Net assets,		
beginning of year	13,769,527	13,853,063
Net assets, end of year	\$16,806,728	\$13,769,527

### **EXPENSES**



### **FUNDING SOURCES**



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