PATIENTS TODAY

Inspired by the families who are fearless in battling against one of the world’s most challenging diseases, ALS TDF was founded as a nonprofit biotechnology company that aggressively researches treatments for patients living with ALS today. Our approach combines the power of a nonprofit mission with the best practices of a leading-edge biotechnology company using rigorous, open-minded research and proven drug development techniques.
ALS TDF Today

Over the last four years we have completed testing most of the proposed ALS therapies in almost ten thousand mice, more than all other ALS labs combined. We have made significant discoveries and advances including overcoming the barrier of administering drugs directly into the spinal cord. We refined our method of testing, improved quality and confirmed that the mouse model still accurately predicts the results of clinical trials. These results set a desperately needed standard for preclinical validation for the entire ALS research field.

Our efforts are now focused on important new therapeutic target areas including protein conformation, inflammation, the proteasome and cell cycle. ALS TDF is building programs to identify new therapies in each of these areas. These targets offer real hope to slow ALS but we also need new discoveries to find treatments that will stop it.

To succeed, we must expand our scope beyond drugs and therapies. The skills we developed to tackle therapeutics can and must be applied to biomarkers. Comprehensive disease profiling is ready for the information technology and rigor ALS TDF can bring to bear. Integrating biomarker, therapeutics and comprehensive disease profiling, we can unlock new ideas and make them rapidly relevant to patients. This is the program that is required to find an effective treatment for ALS.

ALS TDF is ready for this challenge and today’s ALS patients deserve nothing less.

Thank you for making possible my faith that we can stop ALS.

James Allen Heywood
d’Arbeloff Founding Director
Intrathecal Mouse Catheter

While human ALS may spread along the length of the spinal cord and motor cortex, the mouse disease is more pronounced in the lumbar spinal cord. To treat the disease in mice, drugs will need to reach the primary site of degeneration in the lumbar spinal cord. In early 2004, ALS TDF measured drug levels in the spinal cord from conventional drug delivery methods and discovered that many drugs did not reach the spinal cord effectively. In medical literature there is little data addressing spinal cord penetration in mice, an animal model used for much medical research. In order to solve this critical problem, ALS TDF researchers developed an intrathecal infusion system which is a novel technique where a catheter and pump are used to continually deliver drugs directly into the mouse spinal cord.

ALS TDF made great strides in the development of the catheter system in the second half of 2004. The original system allowed for a one-time drug injection into the spinal cord. With the adaptation of a mini osmotic pump to the catheter, drugs are now pumped around the clock into the spinal cord. The device doses directly and continuously to the mouse spinal cord allowing researchers at ALS TDF to achieve drug levels that are much greater than pumping via the brain. Results suggest that the levels of drug reaching the spinal cord are fifty times higher than those achieved using brain delivery.

“ALS TDF’s ability to pump drugs directly into the spinal cord of a mouse is an impressive and unprecedented development that should speed drug discovery for ALS.”

FRED VINICK
Senior Vice President, Drug Discovery
Genzyme Corporation

Initially, pump implant surgeries required a two-hour procedure. Within a few months, ALS TDF streamlined the process to accommodate over forty animals in half a day, sufficient to implement full efficacy studies. Studies have been performed to monitor the impact of surgery on lifespan and neurological function. Results suggest that the procedure is not detrimental to the animal or the disease.

For patients this means that for the first time researchers can test drugs thoroughly and better utilize the most advanced therapies including siRNA, gene therapy, and protein therapeutics. In addition, the catheter is a hopeful advancement since many therapies tested in the past by ALS researchers likely did not achieve therapeutic levels because they simply did not reach the intended target. The creation of this innovative drug delivery system vastly increases the opportunity for success in the evaluation and eventual development of treatments for ALS.

Accelerating A Cure Inspired by Passion:
Mary Lou Krauseneck was diagnosed with ALS in June of 2000. Since that time she has fought the disease with uncommon courage and faith. Shortly after diagnosis, her family, friends and community formed A Passion for Life, an annual event that raises awareness of ALS and supports ALS TDF research. In 2004, A Passion for Life worked to help fund the development of the Intrathecal Mouse Catheter, a development that is promoting accurate research and ensuring every tested therapy reaches its intended target.

Mary Lou Krauseneck with niece Amy Whipple.
Our Team: Senior Research and Development Staff
Quantitative Gene Expression Core Program

ALS TDF is pursuing an aggressive program dedicated to finding biomarkers of disease progression critical for studying drug effect in the ALS mouse model. In 2004, ALS TDF purchased a real-time quantitative polymerase chain reaction (RT-qPCR) machine and hired the staff to design and manage our new Quantitative Gene Expression Core Program.

The program aims to measure changes in gene expression (the quantity of RNA produced for a given gene) as a result of the disease process. Thus far we have detected genes whose expression is altered by 20-fold or more. This highly quantifiable system will allow us to validate alterations that were previously seen in microarray data generated for this purpose.

With this new, leading-edge technology, we can accurately and precisely measure gene expression changes. Tracking can be done in all tissue types from blood to spinal cord to brain. This program is a significant and vital boost to our ability to rapidly generate biomarkers and validate drug effect.

Through a concerted fundraising effort mounted by ALS TDF supporters, The Research Center at ALS TDF has been equipped with the necessary materials and resources needed to launch this much needed research. Ultimately our RT-qPCR approach will lead to identification of targets for disease intervention and establishment of biomarkers that can be used for the prognosis and tracking of ALS. Once an effective biomarker for ALS is discovered patients will be one step closer to a cure.

Funding the Research:

Several groups came together to raise the funds necessary to launch our Quantitative Gene Expression Core Program. When ALS TDF’s need was outlined, each of these donors generated contributions to support our planned initiative. Many thanks to the Ken Melanson’s Quest for a Cure, Ride for Life’s Research Fund, The William & Elizabeth Rieth Charitable Trust, Ms. Marilyn Adams, and an anonymous donor. Together, we will open a new door for ALS research in 2005.

Our Team:

The Development Office staff cultivates relationships with individuals and foundations supporting ALS TDF’s research program, as well as interaction with both state and federal government.
Families Make a Difference

MATT DOWD AND FAMILY

Soon after Matt Dowd’s diagnosis in 2002, he attended one of the ALS 101 Seminars. Matt was driven to understand the disease, the science and research and found kindred spirits in ALS TDF’s community and staff. Since then Matt has become a prolific voice in the ALS community, regularly posting to his website and participating in online forums. Matt is a close friend and constant supporter of the foundation, continuing to inspire and challenge ALS TDF staff.

“Over the last few years I’ve been a witness to the way others look at TDF; what once was a fringe radical research group has evolved into an innovative and trusted source of testing within the ALS research community,” says Matt, “I have trust in the results and opinions that TDF generates because it is based on repeatable data-driven research.”

Matt has both intellectually encouraged ALS TDF research and funded it. Since 2003, Matt and his friends, David MacTavish and Scott Govoni, have planned an annual golf tournament at Glen Ellen Country Club in Holliston, Massachusetts to fund ALS TDF research. In addition, he and fellow patient Brent Paulhus sparked the “Reverse the Curse, Cure ALS” program in 2004 that not only brought much needed funds to ALS TDF but also helped to spur on Matt’s beloved Red Sox to victory.

THE ADRAKTAS FAMILY

Devastated by their brother Dean’s diagnosis of ALS, Stephanie Adraktas and her sisters became determined to help find a cure for their brother. While searching the internet for possible ALS therapies, Stephanie discovered the story of the Heywoods. She was immediately inspired, and knew that her family should join in the mission of ALS TDF. Initially, Stephanie and her husband, John Krull, began fundraising for ALS TDF by donating earnings from items they sold on eBay. A few months later, Dean and Katherine’s neighbor, Keith Lipp, wanted to make a donation on Dean’s behalf, so the family contacted ALS TDF about setting up a special fund and the Dean Adraktas Fund was born.

“By supporting ALS TDF, we are supporting the organization we believe will find a cure any day now,” said Dean’s wife, Katherine Adraktas. “ALS TDF’s determination, aggressive research, and overall understanding of the disease gives us confidence that soon we will receive a call from Jamie Heywood telling us the good news. We are waiting for that day.”

Dean’s family appreciates that money raised for ALS TDF goes primarily toward research. Since their initial involvement, family and friends of the Adraktas’ have held a multitude of events year-round to raise funds and awareness for ALS TDF. Dean Adraktas’ family has unquestionably made a considerable impact in ALS TDF’s mission to find a cure.

Our Team:

The staff of Program Services works to help people who are actively advocating a cure for ALS through events and awareness programs.
Inspiration

**DR. RICHARD K. OLNEY**

Dr. Olney first developed an interest in ALS when the daughter of his favorite teacher in junior high school died of the disease. His interest in central nervous system disorders led him to consider ALS one of the most intellectually compelling and alarming in its manifestation. Consequently, Olney devoted much of his twenty-five years as a neurologist to the care of ALS patients and founded the ALS Patient Care and Research Center at the University of California at San Francisco.

In 2004, Dr. Olney was himself diagnosed with ALS. Since his diagnosis, he continues his efforts to battle the disease, working to raise awareness and funds to support the quest for a cure. Amid an outpouring of sympathy, his diagnosis has focused new public attention on efforts to find the cause of, and eventually a cure for this fatal disease. ALS TDF’s relationship with Olney began in 2000, when the world-renowned neurologist and ALS researcher engaged in ALS TDF’s efforts to investigate the intrathecal IGG treatment that patients were receiving in Puerto Rico. Since then, Dr. Olney has been a trusted collaborator and advisor to ALS TDF’s research team.

“Rick is a man who never forgets that each patient is a person,” commented Sean Scott, ALS TDF’s Vice President of Research and Development, whose mother was treated by Dr. Olney. “Rick was strong for patients when they no longer had strength. He was their voice when they could no longer speak.”

Although Olney handled patients directly, he also emphasized the need for more research and contributed in a number of national multi-center trials. In an amazingly selfless act, Olney was the first to sign up for an ALS TDF-sponsored clinical trial at UCSF for two drugs that have shown promise in extending the lifespan of laboratory SOD1 mice. Dr. Olney is the very embodiment of the passionate collaborators with whom ALS TDF endeavors to partner. Dr. Olney’s tireless efforts continue to guide our research program and serve to augment our efforts to leave no stone unturned in the quest to cure ALS.

**CHRISTY SLOAN**

ALS TDF wishes to celebrate and honor the life of Sarah Christine “Christy” Sloan for her passionate and extraordinary contribution to the fight against ALS. Following her diagnosis, Christy, an active outdoors-woman and banking executive with First Union Bank in Charlotte, North Carolina, founded the ALS Race for Research Foundation together with her parents, Jim and Joanna Sloan.

Since 2001, the ALS Race for Research Foundation has hosted a number of golf tournaments and events to raise funds for ALS research, always guided by Christy’s motto that, “doing nothing is not an option.” The ALS Race for Research Foundation and the Sloan Family became good friends of ALS TDF and have been generous supporters of our research program with contributions exceeding $100,000 over the last four years. Despite the recent loss of Christy in September of 2004, the Sloan family remains steadfastly committed to the cause and are determined to continue helping other families affected by the ravages of ALS.
Driving 4 Life

Driving 4 Life, the ALS research fundraising program founded by former PGA TOUR® pros Jeff Julian and Tom Watson, and caddy Bruce Edwards, has raised nearly $2 million for The Research Center at ALS TDF, significantly advancing its aggressive approach to curing ALS. In 2004, both Jeff and Bruce lost long, hard-fought battles to ALS. Bruce in April, Jeff in July. Bruce passed away the day after being awarded the distinguished Ben Hogan Award. Jeff won the honor in 2003.

In late December 2004, Kim Julian joined the ALS TDF staff full-time, moving her son, Tyler, from their home in Branson, Missouri to Cambridge, Massachusetts to act as Founding Director of Driving 4 Life. Continuing to carry out the mission of her late husband Jeff, and friend Bruce, she has laid the groundwork for a host of new relationships within the golfing and ALS communities. In the fall of 2005, Curt Schilling joins Kim as Honorary Co-Chair of the 2nd Annual Driving 4 Life Invitational, being held at Trump National, Bedminster, New Jersey.

“ALS will not be cured soon unless we increase our research efforts,” explains Tom Watson. “Funding of these efforts simply must be increased to make the percentages favor a cure being found sooner rather than later.”

Dozens of tournaments and other fundraisers are planned under the Driving 4 Life umbrella every year with thousands of golfers joining the fight against ALS and continuing Bruce and Jeff’s legacy. Driving 4 Life has quickly become the premiere charity golf program in the United States thanks to the efforts of supporters, event organizers, country clubs, retailers, and the PGA TOUR® family.

Doug McGuiness first learned about ALS TDF from an article in 2000 and found the story of Jamie and Stephen Heywood compelling. As a person with ALS he appreciates the protocol that speeds the process of searching for a cure or a treatment that could slow disease progression.

Doug was invited to participate in the golf tournament sponsored by HMS Host International in Tampa, Florida for the first time in 2003 by Jeff Yablun, the Vice President of Operations for HMS Host. At every subsequent event, Doug has been asked to speak on behalf of other ALS patients and drive home the need for action in the face of ALS.

“All I can say is thank you to Jeff Yablun for hosting these events. With a disease like ALS, time is something that we all fight,” says Doug, “and money is needed to carry on that fight.”

Since its inception, the HMS Host Golf Classic has become a model for the Driving 4 Life charity golf program at ALS TDF. Along with funding ALS research to find treatments, the event continues to raise significant awareness of ALS.

Our Team:
The Driving 4 Life team develops opportunities to fund ALS research through celebrity golf events and by guiding local events with the aid of campaign supporters nationwide.
FINANCIAL REPORT 2004

Assets
Cash 865,970.00
Accounts Receivable 20,000.00
Fixed Assets-Net 139,692.00
Other Assets-Net 16,908.00
Total Assets $1,042,570.00

Liabilities and Net Assets
Liabilities 348,558.00
Net Assets 694,012.00
Total Liabilities and Net Assets $1,042,570.00

Support & Revenue
Contributions 1,180,135.00
Grant Receipts 482,806.00
Fundraising Events 1,631,686.00
In-Kind Donations 156,235.00
Interest, Dividends & Gains/Losses (2,899.00)
Total Income $3,447,963.00

Expenses
Research & Development 2,802,277.00
Patient Services 231,106.00
Fundraising 461,427.00
Management & General 301,014.00
Total Expenses $3,795,824.00

Increase/(Decrease) in Net Assets (347,861.00)
Net Assets: Beginning of Year 1,041,873.00
Net Assets: End of Year $694,012.00

Where the Money Comes From:
- Individual Contributions 34%
- In-Kind Donations 5%
- Grants 14%
- Events 47%

Where the Money Goes:
- R&D 74%
- Patient Services 6%
- Fundraising 12%
- Management & General 8%
MEMORIALS

ALS TDF acknowledges the following individuals who received gifts made in their memory during 2004. Our staff extends our deepest sympathies to their families and friends who continue to fight ALS even after their loved ones’ death.

James Airey
Dorothy Airey-Shupper
Mark Allain
Sheilah Allison
Jerry Anthony
Jane Antonelli
Randy Armstrong
Betty Arthur
Jack Bailey
Patricia Bell Barnes
Roger Baula
James Bayster
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Raymond Bell
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Bob Blum
Laura Boardman
Joseph Bollini
Robert Brady
Nancy Brindisi
John Btattian
Mary Kay Byrne-Jones
Faith Lucille Campbell
Gordon Campbell
Carl Carlson
Gordon Canney
Thomas Catanzano
Sylvia Chadis
Mary Kay Chappell-Brock
James Chisholm
Ingrid Cibuls
Colleen Clary
Marjorie Conley
Sue Cookson
Carol Lee Cordes
Francis Cronin
Dolly Crowell
Dorothy Cunningham
Walter Cunningham
Carl Cura
Frank Dabartolo
Robert Dake
James Dalthorp
Alston Daniel
Jack Darcy
Richard Delong
Emilio Delgadillo
Laura Diamond
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Eileen Dunphy-Rear
Joyce Ebner
Bruce Edwards
Ann Egnor
June Eisenberg
Larry Ellis
Sue Elston
David Eitschlagler
Alice English
Glenda Evans
John C. Farie
Jim Fitzhenry
Erie Ford
Stephen Formica
DeeDee Forengo
Millie Fouse
Colman Fram
David Paul Freed
Carolyn Freeman
Peter Ganzel
Marie Garratt
Paul Gerbick
Jeff Gilbert
Hilda Glassman
Joan Gluck
Greg Goldberg
Herbert Goren
Jeanne Gosland
Frank Graham
David Green
Ken Green
Steven Greenfield
Rick Guttenberg
Doris Hable
Donald Hacker
Kyle Hahn
Thomas Hall
Oscar Hampton
Gail Haynie
Kenneth Heitkamp
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Beryl Sil
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Jimmy Starnes
Marty Stayer
Scott Stein
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+ Ronya Kozmetsky
+ Mary Lou Krauseneck Fund
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+ Stephen Heywood Fund
+ Stephen Milne Society

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Anthony Tucker Fund
Celgene Corporation
DeeDee Fornego Fund
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Jenny Huntington
InSource Services, Inc.
Ken Melanson’s Quest for a Cure
Larry Ellis Fund
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Jonathan Orloff
Pittsburgh Families Efforts
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Ride for Life
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John & Iola Sobeck
Stanfield Family ALS Fund
Ternet Friends Fighting ALS Fund
The James & Alice McGonagle Charitable Fund
The Jeff Julian ALS Foundation
Vanguard Charitable Endowment Program
William & Elizabeth Rieth Charitable Foundation

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$10,000 - plus annually
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Teaching to Fight ALS
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The Kirk & Megan Kellogg Foundation
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The O’Reilly Foundation
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Will Hubben ALS Research Fund

Benefactors’ Circle
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