



ANNUAL REPORT

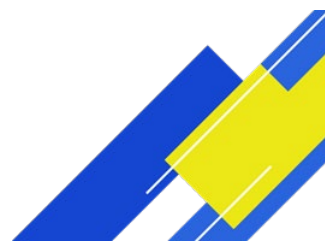
2024



Table of contents

<i>Letter to the EUpALS community</i>	2
<i>What is ALS?</i>	3
Symptoms of ALS	3
Occurrence and heredity of ALS	3
<i>About EUpALS</i>	4
Mission	4
Vision	4
Objectives	4
<i>EUpALS Board of Directors</i>	5
<i>EUpALS Patients and Carers Expert Board (PCEB)</i>	6
<i>EUpALS Scientific Expert Board (SEB)</i>	7
<i>EUpALS Member Associations 2024</i>	8-9
<i>EUpALS Industry Partners 2024</i>	9-10
<i>Academic partners</i>	10
<i>EUpALS activities 2024</i>	10
<i>EUpALS Round Table 2024</i>	12
<i>EUpALS Annual Meeting 2024</i>	12
<i>EUpALS Guideline on Management of ALS</i>	14
<i>EUpALS Position Paper 2024</i>	16-14
<i>EUpALS Governance News</i>	17
<i>EUpALS awareness campaigns 2024</i>	18
<i>EUpALS and EU policy impact 2024</i>	18
<i>EUpALS International Alliance of ALS/MND Association Meeting 2024</i>	19-17
<i>ALS clinical trials in 2024</i>	21
<i>EUpALS Consortium Meeting of EU Horizon project Real4Reg 2024</i>	14
<i>EUpALS entered partnership in EU project HEREDITARY</i>	Fout! Bladwijzer niet gedefinieerd.
<i>ALS Research News</i>	22
<i>EUpALS Authorship in Scientific Journals</i>	21
<i>EUpALS 2024 in numbers</i>	24
<i>Contact</i>	25





Letter to the EupALS community

Dear EupALS community,

2024 was a very exciting year.

Indeed, we mark February 23 2024 as a milestone in our common fight to find a cure for ALS. Indeed, that day the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending marketing authorization under exceptional circumstances for Tofersen for the treatment of adults with amyotrophic lateral sclerosis (ALS), associated with a mutation in the superoxide dismutase (SOD1) gene.

After decades of setbacks in clinical trials, this is a clear medical victory that provides hope for a specific subpopulation of people living with ALS.

This ASO therapy Tofersen was clinically developed by BIOGEN and will become commercially available as brand name QALSODY.

At the time of writing, QALSODY undergoes Health Technology Assessment (HTA) procedures in individual European Member States. HTA considers effectiveness, safety, economic impact and ethical implications of a new therapy. This should ultimately lead to negotiations on pricing and reimbursement.

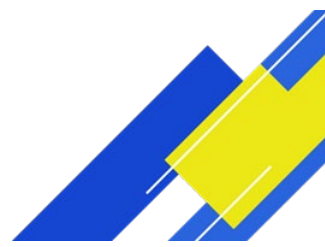
EupALS is hopeful that QALSODY will soon become available for as many as possible SOD1 pALS in Europe.

Despite this clear medical breakthrough showing that ALS is a treatable disease after all, QALSODY will only benefit about 10% of familial ALS, being about only 2% of the general pALS population.

Therefore, let us continue to stand united in our mission to improve the lives of all those affected by this challenging condition.

Evij Reijers
Chairwoman EupALS





What is ALS?

ALS stands for Amyotrophic Lateral Sclerosis, an incurable and lethal neuromuscular disease characterized by progressive paralysis.

In Europe, ALS is also known as

SLA, for Sclérose Latérale Amyotrophique (France and French-speaking Belgium) and for Sclerosi Laterale Amiotrofica (Italy)

MND, for Motor Neuron Disease (UK, Ireland, Iceland)

ELA, for Esclerosis Lateral Amiotrófica (Spain and Portugal)

Maladie de Charcot (France and French-speaking Belgium): less used than SLA

In the US the illness is often called Lou Gehrig disease, named after a legendary baseball player who passed away from this disease in 1941.

Symptoms of ALS

In brief, the following symptoms can be observed in patients with ALS. Not all symptoms occur in an individual ALS-patient.

- Weak and thin muscles, resulting in paralysis
- Joint and muscle pains; muscle contractions
- Fatigue, tiredness
- Reduced appetite resulting in weight loss
- Difficulty chewing, swallowing and speaking; drooling
- Problems with bowel movement
- Reduced lung vital capacity, resulting in difficult breathing
- Compulsive crying, laughing or yawning

Occurrence and heredity of ALS

ALS is not as rare as often thought, as it affects 6 to 7 people out of every 100.000. It occurs all over the world. Most people are affected by ALS between the age of 50 and 75 but there are also teenagers with ALS.

The diagnosis can only be determined after all other neurologic conditions have been excluded. The course of the disease is progressive but the evolution varies from one person to another.

In Europe, ALS affects about 50.000 individuals of middle age, killing about 10.000 people on a European level each year. Worldwide 450.000 people suffer from ALS. Each year 120.000 people are diagnosed with ALS. This means that every day there are 328 new known cases, which equals 2 new diagnoses of ALS per 100.000. Every year 120.000 patients die from ALS worldwide.



In about 10% of the ALS cases there is a familial pattern. When it concerns the familial type, ALS is usually genetically dominant, which means that a child has a 50% chance of becoming ill. The symptoms of familial ALS are the same as those of the sporadic form. The only difference is that people with familial ALS are usually younger when the first symptoms arise.

About EupALS

Mission

EupALS is the European association that takes the interests of European people with ALS (pALS) to heart. We want to obtain equal rights for all European pALS and provide them better access to clinical research and information about it.

Vision

Our organization aims to fight against ALS in Europe and make everybody aware of this terrible disease. This is why we unite all the European ALS/MND associations: to fight harder together on a European scale.

Objectives

- Stand up for the rights of all European people with ALS
- Create awareness about ALS on a European scale
- Improve access to and information about ALS research and clinical trials
- Obtain the same rules for ALS research and clinical trials across Europe



EupALS Board of Directors

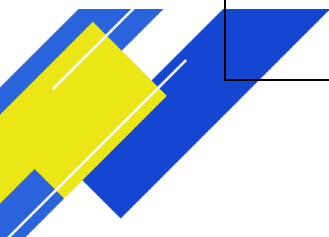
 Evy Reviers <i>Chairwoman</i> CEO ALS Liga Belgium	 Sabine Turgeman <i>Director</i> CEO ARSLA France	 Prof. Christian Lunetta <i>Director</i> Post Fata Resurgo Italy
 Joaquin de la Herrán <i>Director</i> Executive Committee member Fundación Luzón Spain	 Dr. Aylin Yaman <i>Director</i> Antalya Branch of ALS/MND Association Turkey	 Guðjón Sigurðsson <i>Secretary</i> Chairman MND Iceland
 Limore Noach <i>Treasurer</i> CEO Stichting ALS The Netherlands	EupALS Board of Directors meetings in 2024 • March 27 (web meeting) • June 17 (Stockholm; satellite to ENCALS 2024 or web meeting) • November 6 (web meeting)	





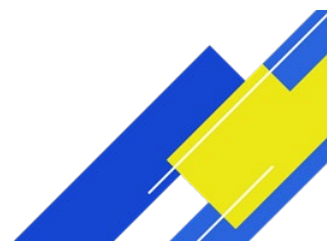
EupALS Patients and Carers Expert Board (PCEB)

 Alper Kaya <i>ALS/MND Association Turkey</i>	 Mia Möllberg <i>ALS Sweden</i>	 Jan Bastiaens <i>ALS Liga Belgium</i>
 Angélique van der Lit – van Veldhuizen <i>ALS patiëntenvereniging</i>	 Josefina Garcia Pastor <i>Fundació Miquel Valls Spain</i>	 Ywan Dierick <i>ALS Liga Belgium</i>
 Wim Van Minkelen <i>ALS Patiëntenvereniging</i>	 Giampaolo Merlini <i>conSLancio Italy</i>	
Major activities 2024 of the EupALS PCEB	- February 7 : meeting with EupALS Industry Partner - February 21-23 : Testimonies at TRICALS Masterclass - May 23 : meeting with EupALS Industry Partner - June 5 : meeting with EupALS Industry Partner - June 16 : Testimonies at EupALS Roundtable Stockholm - June 17 : Annual General Meeting Stockholm	October 14 : Real4Reg Workshop



EUpALS Scientific Expert Board (SEB)

 Prof. Philip Van Damme <i>UZ Leuven, Belgium</i>	 Prof. Leonard van den Berg <i>UMC Utrecht, The Netherlands</i>	 Prof. Philippe Corcia <i>CHRU Tours, France</i>
 Prof. Caroline Ingre <i>Karolinska Institutet Stockholm, Sweden</i>	 Prof. Adriano Chiò <i>University of Torino, Italy</i>	 Prof. Ammar Al-Chalabi <i>Kings College London, UK</i>
 Prof. Orla Hardiman <i>Trinity College Dublin, Ireland</i>	 Prof. Monica Povedano <i>IDIBELL Barcelona, Spain</i>	 Prof. Markus Weber <i>ALS Clinic, Kantonsspital St.Gallen, Switzerland. Professor of Neurology. Neuromuscular Diseases unit/</i>
Major activities 2024 of the EUpALS SEB	• EUpALS is represented in bi-weekly TRICALS Executive Board meeting • Co-drafting EUpALS Position Paper	



EupALS Member Associations 2024

Uniting 28 ALS/MND Associations from 22 European countries

 ASSOCIAZIONE ITALIANA SCLEROSI LATERALE AMIOTROFICA	 Schweiz Suisse Svizzera Svizra	
		
		
		
		
		



 MUSKELSVINDFONDEN plads til forskelle!	 POST FATA RESURGO	 FUNDACIÓN LUZÓN UNIDOS CONTRA LA ELA
 ULLA-CARIN LINDQUISTS STIFTELSE FÖR ALS-FORSKNING	 rmn Research Motor Neurone	 MDA EMMAΣ ΕΘΝΙΚΟ ΣΠΟΝΔΙΛΟ ΑΤΟΜΩΝ ΜΕ ΝΕΥΡΟΜΥΚΕΣ ΓΙΑΒΡΗΣΕΙΣ  MDA HELLAS MUSCULAR DYSTROPHY ASSOCIATION
 MUSCULAR DYSTROPHY ASSOCIATION OF SLOVENIA	 conSLancio	 eamda European Alliance of Neuromuscular Disorders Associations 
 LIVE NOW RUSSIA		

EupALS Industry Partners 2024

Gold

 AMYLYX	 argenx	 Biogen
 Corcept THERAPEUTICS	 ferrer for good	 Mitsubishi Tanabe Pharma
 NOVARTIS	 prilenia	 PTC THERAPEUTICS
 REGENERON	 sanofi	 VectorY THERAPEUTICS
 ucb Inspired by patients. Driven by science.	 ZBiotech Zambon Biotech	 uniQure

Silver

		
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Bronze



Academic partners

Close Collaboration

		
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EupALS activities 2024 - overview

January 7	Patients and Carers Expert Board meeting with Industry Partner
January 25	Kick-off meeting EU Horizon project HEREDITARY in Padua
February 21-23	TRICALS Masterclass in Amsterdam
March 27	Board of Directors meeting
April 10	EupALS Newsletter Spring edition
April 15-16	Cell and Gene Therapy Summit
May 23	Patients and Carers Expert Board meeting with Industry Partner
June 5	Patients and Carers Expert Board meeting with Industry Partner
June 16	EupALS Roundtable on Data Sharing in Stockholm
June 17	EupALS Annual General Meeting in Stockholm
June 17	Board of Directors meeting in Stockholm
June 26-27	Consortium Meeting EU Horizon Project Real4Reg in Helsinki
July 5	EupALS Newsletter Summer edition
September 30	EupALS Newsletter Autumn edition
October 14	EU Horizon Project Real4Reg workshop for patients: 'Demystifying Real World Data analysis with AI'
October 25	iMND Meeting in Leuven
November 6	Board of Directors meeting
December 4-5	International Alliance of ALS/MND Associations meeting and Allied Professionals Forum 2024
December 20	EupALS Newsletter Winter edition

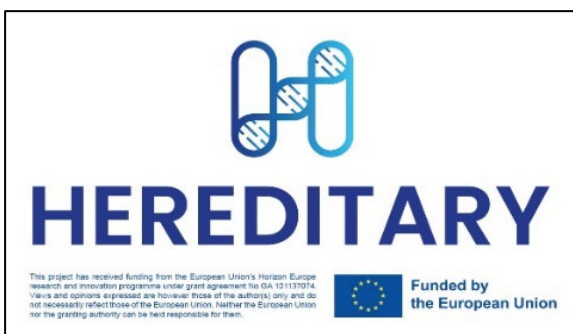


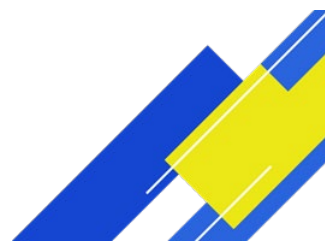
EupALS activities 2024 - highlights

Kick-off meeting EU project HEREDITARY

On January 25 2024, EupALS participated in the kick-off meeting of EU Horizon project HEREDITARY.

In HEREDITARY artificial intelligence is explored to integrate diverse semantic data sources related to the gut-brain interaction.





EUpALS TRICALS Masterclass 2024

February 23 2024: EUpALS moderated the session 'The Impact of patient advocacy on drug development' at the **TRICALS Masterclass 2024 in Amsterdam**. Thank you members of the EUpALS Patients and Carers Expert Board for your testimonies.



Cell and Gene Therapy Summit

April 15-16 2024: EUpALS attended the **Cell and Gene Therapy Summit 2024 in Brussels**. This forum united pharmaceutical companies, patient associations, investors and policy makers to advance the field of innovative cell and gene therapy.





EUPALS Roundtable 2024

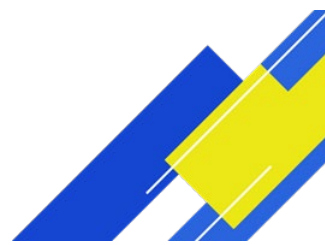
On June 16 2024, EUPALS organized its **Roundtable on Data Sharing in Stockholm** satellite to ENCALS. Thank you all our Member Associations, Industry Partners and other stakeholders who attended in person or virtually. Your active participation and valuable input is greatly appreciated.



EUPALS Annual General Meeting 2024

On June 17 2024, EUPALS organized its **Annual General Meeting 2024 in Stockholm** satellite to ENCALS. Thank you all our Member Associations, Industry Partners and other stakeholders who attended in person or virtually.





Consortium meeting of EU Horizon project Real4Reg 2024

On June 26-27 2024, EUpALS attended the Consortium meeting of EU Horizon project Real4Reg in Helsinki to catch up with all partners. We were discussing the progress and future activities of this exciting project on the use of Real World Data for regulatory decision making.



iMND Meeting 2024

October 25 2024: EUpALS attended the iMND Meeting 2024 in Leuven organized by Prof. Ludo Van Den Bosch (KU Leuven/VIB). It was great to see the technically challenging field of iPSC Modelling in Neuromuscular Disorders making great progress. Organoids become ready as innovative tools for high-throughput screening of potential new ALS therapies.



EupALS Guideline on Management of ALS

June 19 2024: EupALS collaborated with the European Academy of Neurology (EAN) to publish the new **Guideline on Management of ALS**. At ENCALS 2024 this document was presented by Prof. Phillip Van Damme as chair of EAN ALS Guideline working group.



EUpALS Position Paper 2024

Following the EUpALS Round Table 2024, an EUpALS Working Group on Market Access was set up. In close collaboration with the EUpALS Scientific Expert Board, the EUpALS Position Paper 'Need of EU harmonization of pricing and reimbursement processes And Managed Access Programs' was drafted by the Working Group.

On March 23 2024, the Position Paper was communicated to Members of the European Parliament.



Position Paper

Bringing novel therapies as soon as possible to people with ALS: Need of EU harmonization of pricing and reimbursement processes And Managed Access Programs

People living with ALS draw hope from final stages of clinical trials

As of today, the progressive neurodegenerative condition Amyotrophic Lateral Sclerosis (ALS) is still a fatal disease with an average life expectancy of 33 months after diagnosis.

However, having no time to wait and after decades of early discontinued clinical trials, people with ALS (pALS) nowadays draw hope from the final stages of clinical studies with multiple potential new therapies showing that ALS is a treatable disease after all.

Bringing novel ALS therapies as soon as possible to PLWALS: the view of PLWALS and their advocates

Bringing novel ALS therapies to pALS involves many stakeholders, such as: clinical researchers, pharmaceutical and biotech companies, pALS and their advocates, the European Medicines Agency (EMA), national competent authorities and payers.

Optimal cooperation between all parties is favored to proceed smoothly and swiftly through outlined procedures. However, there might be differences in stakeholders' specific interests and understanding of ALS complexity, desired timelines and willingness to seek solutions to overcome hurdles.

This position paper represents the view of pALS and their advocates on this matter, as put forward by EUpALS – The European Organization for Professionals and People with ALS.

The ideal path: Simultaneous availability for all European pALS under same conditions, upon aligned HTA procedures at national level

EUpALS supports the centralized authorization procedure to market a new medicinal product in Europe, in which the European Medicinal Agency (EMA) is responsible for the evaluation of the application.

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We especially welcomed conditional marketing legislation for fast-track approval of therapies that fulfill an unmet medical need. However, despite conditional approval requiring that the medicine fulfils an unmet medical need, the EMA has not yet authorized a novel ALS therapy under these conditions. EUpALS, therefore, calls for more flexibility when evaluating novel ALS therapies under EMA procedures.

Following EU-wide marketing authorization, pricing and reimbursement processes are performed by the authorities of the individual EU member states to make decisions on e.g. means of administration and reimbursement with minimal out of pocket contribution in their respective country. EUpALS welcomed the Regulation (EU) 2021/2282 that outlines a new framework for health technology assessment that e.g. covers joint clinical assessments, joint scientific consultations, and should reduce duplication of efforts for both the national authorities and industry.

EUpALS recognizes the importance of these practical improvements in health technology assessment procedures that will take effect for some medicines in 2025. However, we note that essential national provisions will still apply, e.g. national pricing and reimbursement processes, including defining criteria for eligibility of administration to specified patient groups, and the associated timelines. As this can be a breeding ground of frustration in the European pALS community, EUpALS calls for further EU harmonization of the national pricing and reimbursement processes.

Bridging the time to availability with Managed Access Programs

Obtaining centralized authorization to market a new medicinal product in Europe, followed by the completion of pricing and reimbursement processes with different timelines at the national level, is usually a long process.

As pALS have no time to wait, there is an urgent need to bridge the time to availability to new ALS treatments via fast-track Managed Access Programs. Ideally, a single EU Early Access Program at the initiative of the pharmaceutical company with limited administrative burden, should apply.

Alternatively, already existing Early Access Programs at the initiative of national authorities – as best practice examples already exist in France (AAP) and Italy (Law 648) – should be implemented in all EU member states and aligned for eligibility conditions, timelines, and reimbursement. To avoid inequalities in the treatment of people suffering from a progressive fatal disease, it is preferable to implement such a program.

During implementation of such Managed Access Programs, EUpALS strongly supports the formal collection of Real World Data and Patient Reported Outcomes to further evaluate effectiveness of the new ALS therapy.

Call to action to Members of the European Parliament and national policy makers

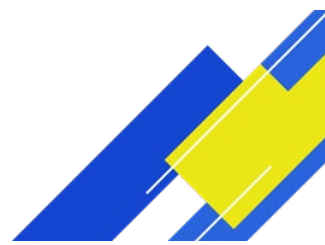
- More flexibility needs to be applied by EMA when evaluating centralized marketing authorization applications for novel ALS therapies, in particular for conditional approval.
- Further EU harmonization of pricing and reimbursement processes needs to be applied, including the criteria for eligibility of administration to specified patient groups, and timelines.
- Fulfill the urgent need to bridge the time to availability to new ALS treatments via fast-track Managed Access Programs, ideally an EU Early Access Program at the initiative of the pharmaceutical company, or by the implementation of Early Access Programs at the initiative of national authorities in all EU member states (such as the AAP in France and Law 648 in Italy).

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EUpALS Governance News

On July 29 2024: upon the initiative of the Board of Directors and following the endorsement by the Annual Meeting held in Stockholm June 17, EUpALS whole name was changed to 'European Organisation for Professionals and People with ALS' via publication in the Belgian Official Gazette. In this way, EUpALS connects better with the international consensus today on how to address those who are affected by ALS.





EupALS awareness campaigns 2024

- June 21 2024: EupALS awareness campaign **10 years Icebucket Challenge**. EupALS remembers the 10 anniversary of the Icebucket Challenge and honors its 3 founders, late PLWALS Anthony Senerechia, Pete Frates and Pat Quinn.



- June 21 2024: On the occasion of the awareness campaign of 10 years Icebucket Challenge, EupALS launched a video campaign with a compilation of Icebucket challenges and information about the founders.

EupALS and EU policy impact 2024

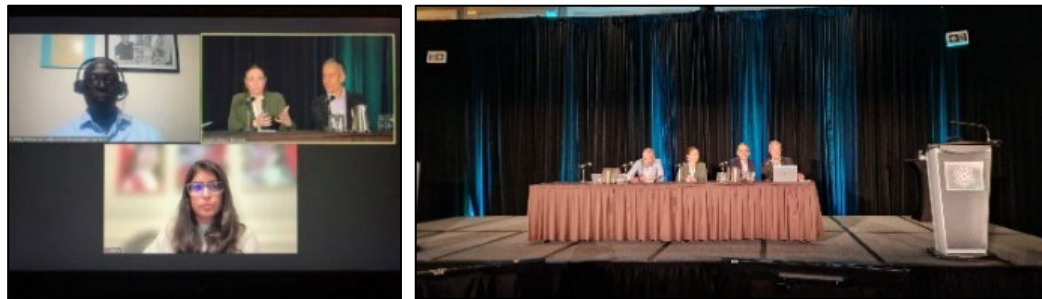
- March 20 2024: EupALS visited the European Parliament for **policy session on genetic screening**. Newborn screening for SMA is leading the way for EU harmonized broad screening programs with according diagnostics and available therapies, to which also PLWALS will benefit.
- September 24 2024: EupALS participated in the **Freedom Drive march** organized by the European Independent Living Movement (ENIL). People with disabilities from all over Europe and their representing associations came together in Brussels to make their voices heard to European policy makers. All want adequate living with good quality of life. EupALS once again brought to the political attention the recommendations that should lead to better diagnosis, care and treatment of all European pALS.





EupALS International Alliance of ALS/MND Association Meeting 2024

- 4-5 December 2024: EupALS attended the International Alliance of ALS/MND Association meeting 2024 in Montreal, Canada.
- EupALS Chairwoman Evy Reviérs brought the European voice and perspective to a panel debate, 'Beyond Borders, Beyond Barriers: advocating collaboratively for a world without ALS/ MND'.



- EupALS Chairwoman Evy Reviërs presented 'The EU ALS Coalition call for Action: Roadmap of the Policy Changes Needed to Improve the Lives of pALS and cALS'. Other continents were introduced to the EU ALS Coalition and its policy recommendations aimed at policymakers to enhance ALS/MND diagnosis, care and treatment.



- A special highlight for EupALS attending The International Alliance of ALS/MND Associations Meeting 2024 in Montreal, Evy Reviërs received the Humanitarian Award (The International Alliance of ALS/MND Association).



ALS clinical trials in 2024

In 2024, the following ALS clinical trials were conducted by EupALS Industry Partners (alphabetical):

- PHOENIX Phase 3 study with AMX-0035, conducted by Amylyx
- APL2-ALS-206 Phase 2 study with APL2 (pegcetacoplan), conducted by Apellis
- reALiSe study with ARGX-119, conducted by Argenx
- VALOR study with SOD1 (gene mutation), conducted by Biogen
- DAZALS Phase 2 study with dazucorilant, conducted by Corcept Therapeutics
- COURAGE-ALS Phase 3 study with reldesemtiv, conducted by Cytokinetics
- ADORE Phase 3 study with FNP122 (oral edaravone), conducted by Ferrer
- CARDINALS trial phase II study with PTC-857 conducted by PTC Therapeutics Inc
- MAGNET Phase 3 platform trial with lithium carbonate by TRICALS
- FOCUS-C9 Phase 1b/2a study with WVE-004 (C9orf72 ASO), conducted by Wave

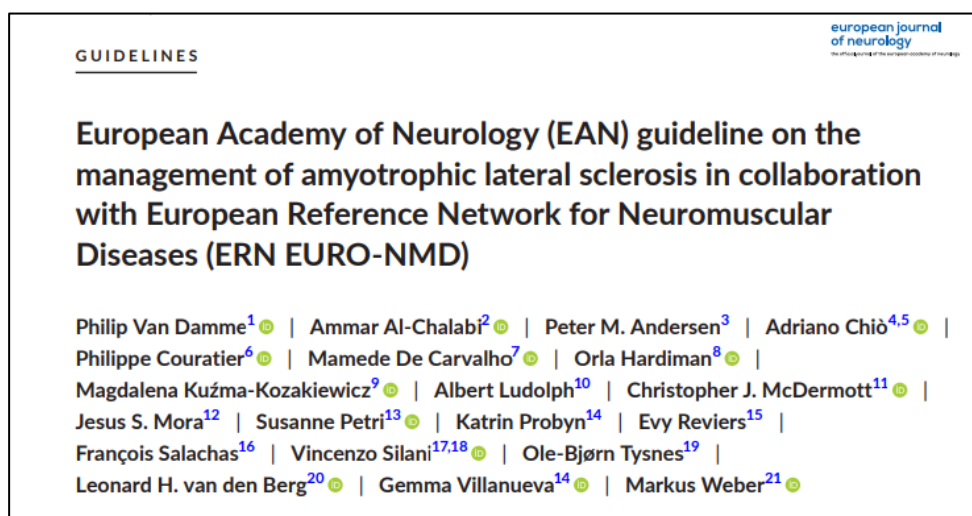
ALS Research News

- January 10, 2024 - Ferrer Phase 3 ADORE trial with FAB122 (oral Edaravone) does not meet primary and secondary endpoints
- January 23, 2024 - Prilenia Announces Clinical Data in Support of its Plans to Initiate Global Phase 3 Study in ALS
- January 26, 2024 - EMA written submission needed
- January 29, 2024 - European Union funds groundbreaking research into psychedelic therapy
- February 21, 2024 - Sanofi Himalaya update for EUpALS
- February 26, 2024 - Biogen Community Statement on Tofersen CHMP Opinion
- March 11, 2024 - Amylyx announces topline results from global Phase 3 PHOENIX trial of AMX0035 in ALS
- March 25, 2024 - Ferrer and Verge Genomics Announce Agreement to Co-Develop Clinical-Stage ALS Therapy VRG50635
- March 27, 2024 - Top line results TUDCA
- April 08, 2024 - Amylyx announces formal intention to Remove RELYVRIO®- ALBRIOZA™ from the market, provides update on access to therapy, and on pipeline
- May 17, 2024 - Biogen and Ionis Announce Topline Phase 1-2 Study Results of Investigational Drug in ALS
- May 31, 2024 - Biogen Receives European Commission Approval for QALSODY® (tofersen), the First Therapy to Treat a Rare, Genetic Form of ALS
- September 5, 2024 - Decoding regulatory agency decisions - The case of Amylyx's Relyvrío-Albrioza in the US and EU
- October 15, 2024 - uniQure announces dosing first patient in Phase I-II clinical trial of AMT-162 for SOD1-ALS
- November 12, 2024 - Biogen published results of Phase I study with BIIB078 C9orf72 ASO
- November 28, 2024 - Topline results PTC Therapeutics cardinALS trial
- December 12, 2024 - Corcept Announces Results From Phase 2 DAZALS Study of Dazucorilant in ALS

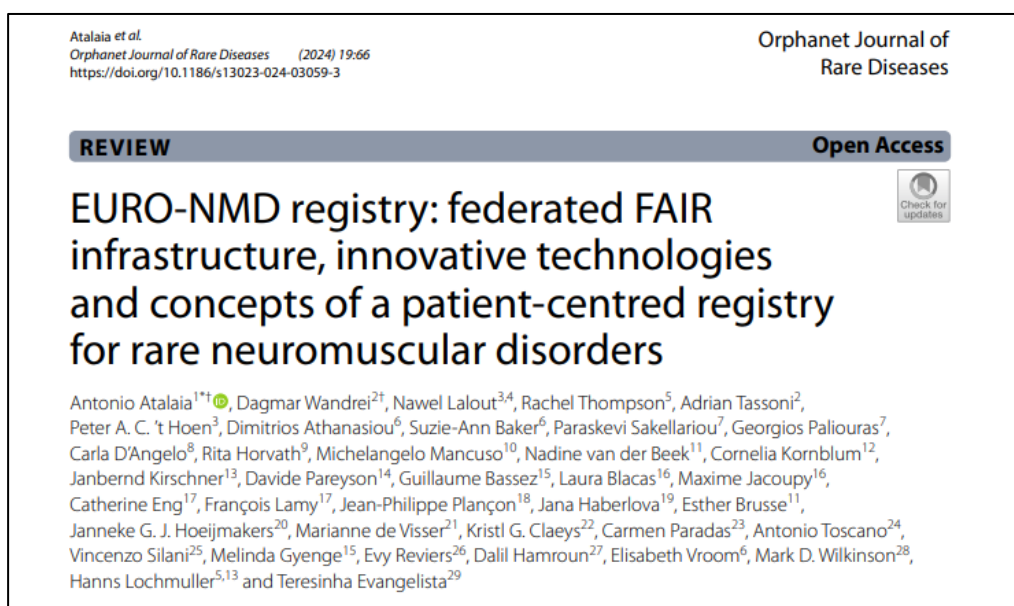


EupALS Authorship in Scientific Journals

- February 15, 2023, *European Academy of Neurology (EAN) guideline on the management of amyotrophic lateral sclerosis in collaboration with European Reference Network for Neuromuscular Diseases (ERN EURO-NMD)*



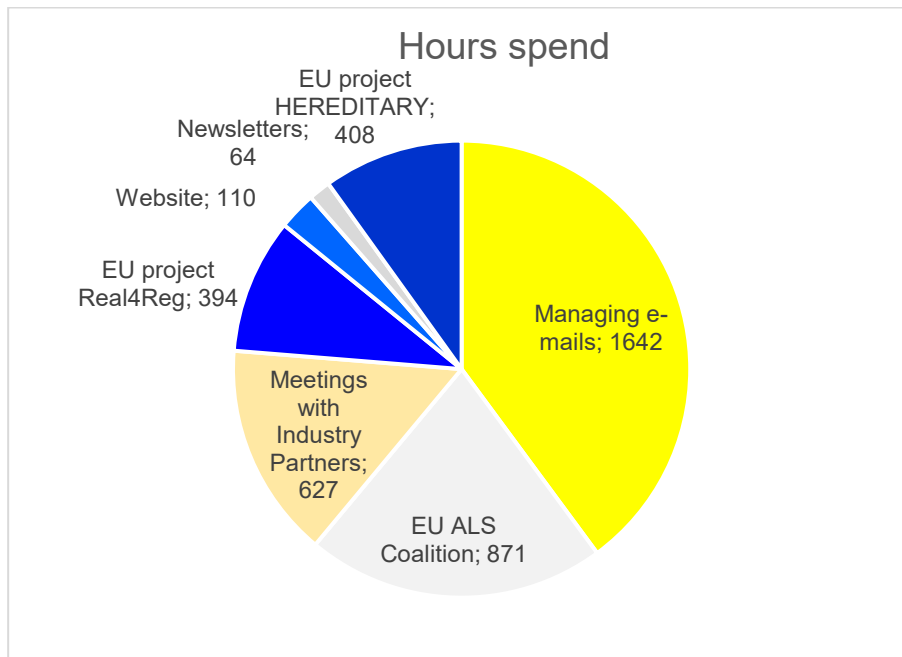
- February 14, 2024, *EURO-NMD registry: federated FAIR infrastructure, innovative technologies and concepts of a patient-centred registry for rare neuromuscular disorders*



EupALS 2024 in numbers

In 2024, EupALS invested resources and time in

- updating the EupALS website, representing 110 hours
- Production of 4 Newsletters, representing 64 hours
- Catch-up meetings with Industry Partners, representing 627 hours
- Managing 6823 e-mail contacts, representing 1642 hours
- Managing partnership in EU project Real4Reg, representing 394 hours
- Co-chairing the EU ALS Coalition, representing 871 hours
- Managing partnership in EU project HEREDITARY, representing 408 hours



Contact

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