

1. Name

First name: Erika	Last name: Schirinzi
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2. Contact

3. Present Position with Work Address

Position: Research Fellow	Street address or postal address: Via Roma 67
Name of institution or organization: Neurological Clinic, University of Pisa, S. Chiara Hospital	City & postal/zip code: 56126
Start date (at least year): 2019	Country: Pisa, Italy
Position: Honorary Fellow in Neurology	Street address or postal address: Via Roma 67
Name of institution or organization: Neurological Clinic, University of Pisa, S. Chiara Hospital	City & postal/zip code: 56126
Start date (at least year): 2024	Country: Pisa, Italy
Position: PhD Student in Clinical and Translational Medicine, Neuroscience	Street address or postal address: Via Roma 67
Name of institution or organization: University of Pisa	City & postal/zip code: 56126
Start date (at least year): 2024	Country: Pisa, Italy

4. Main University Degree(s)

Name of university/institute: University of Pisa	Degree awarded: Medicine and Surgery Degree
City & country: Pisa	Year of graduation: 2012 (16 th October)
Name of university/institute: University of Florence	Degree awarded: II level Master in Rare Diseases
City & country: Florence	Year of graduation: 2023 (14th March)

5. Professional Training

Name of university/institute: Neurological Clinic-University of Pisa	City & country: Pisa, Italy
Qualification: Scholarship in Neurology	Dates of attendance: To December 2018

6. Registration/Medical License number

Number: Physicians register of Pisa, Inscr. N. 05961- 28 Feb 2013
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7. Previous Appointments

Position: Clinical Trial Manager - Freelance employment contract	Street address or postal address: Via Mura Cappuccine 14
Name of institution or organization: Neurological Clinic – EO Ospedali Galliera	City & postal/zip code: 16128
Date: May 2016-May 2022	Country: Genoa, Italy
Position: Freelance employment contract for research activity	Dates: January 2019-June 2019
Scholarship	December 2015-December 2018
Institution/organization: Neurological Clinic-University of Pisa	City & country: Pisa Italy

Document ID: 123456789	Date: 2023-09-15
Institution/organization: Neurological Clinic-Ospedale San'Andrea	City & country: La Spezia, Italy

Languages	Speech	Comprehension	Writing
Italian (first language)			
English	B2	B2	C1

June 2013-June 2015: Fellowship at the Neurological Clinic –S.Andrea Hospital in La Spezia, Italy
(Title project: 18-FDG-PET as a predictor of response to cognitive rehabilitation for MILD cognitive impairment), with more general collaboration in clinical activity of the Neurological Unit, in particular at ambulatory for peripheral inflammatory neuropathies (Referent Dr. Luana Benedetti)

December 2015-December 2018: Fellowship at the Neurological Clinic –S.Chiera Hospital in Pisa, Italy
(Title project: Evaluation study of immunological biomarkers in neuromuscular disorders-Studio di valutazione di parametri immunologici nelle malattie neuromuscolari)

January 2018- June 2019: Freelance employment contract for research activity at Neuromuscular Disease Centre, Neurological Clinic, Department of Clinical and Experimental Medicine, University of Pisa

June 2019- to date: Research Fellow at Neuromuscular Disease Centre, Neurological Clinic, Department of Clinical and Experimental Medicine, University of Pisa (Title projects: " Development of effectiveness measures of clinical trials in facio-scapulo-humeral muscular dystrophy (FSHD); Clinical data sharing network for therapeutic trials in rare neuromuscular diseases").

She is interested in Neuromuscular Disorders, dealing mainly with acquired (especially dysimmune) and genetic neuropathies especially by focusing on search and development of clinical outcome measures and trial readiness useful in clinical follow-up and response to therapy, in particular with focus on immunomodulatory treatments.

She collaborates for conceptualization and writing of research projects to be applied in national and international calls.

She collaborates in the context of the management activities regarding neuromuscular diseases at Neurological Clinic of University of Pisa, which is Tuscany Referral Center for Neuromuscular Disorders and European Health Care Provider within the European Rare Network for Neuromuscular Disorders (ERN-EURO-NMD).

She is Project Manager for INSTANT (INtegrated System in Tuscany for Approaching Neuromuscular Treatments), working group in Tuscany for the coordination of diagnostic activities and treatment approaches in neuromuscular disorders.

She manages since October 2012 with Prof. Gabriele Siciliano, Head of Neurological Clinic of Azienda Ospedaliero Universitaria Pisana –AOU clinical activities on outpatients for peripheral neuropathies, principally focusing on diagnosis, follow-up and treatment especially in patients with inflammatory neuropathies.

Since 2012 she is involved in GCP Clinical Trial as sub-investigator and study coordinator principally on neuromuscular diseases studies, obtained GCP and IATA training certificates

Trials on neuromuscular topic in the last five years (as SI and SC):

- Long-Term Tolerability and Safety of HYQVIA/HyQvia in CIDP-161505, ongoing (Italian Coordinator)
- A Phase 2 Trial to Investigate the Efficacy, Safety, and Tolerability of Efgartigimod PH20 SC in Adult Patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)- ARGX-113-1802 (ADHERE), ongoing (Italian Coordinator)
- Open-label Extension of the ARGX-113-1802 Trial to Investigate the Long-term Safety, Tolerability, and Efficacy of Efgartigimod PH20 SC in Patients With Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) – ARGX-113-1902, ongoing (Italian Coordinator)
- A Phase 2, Randomized, Double-Blinded, Placebo- Controlled, Parallel-Group, Multicenter Trial to Evaluate the Safety and Tolerability, Efficacy, Pharmacokinetics, Pharmacodynamics, and Immunogenicity of 2 Dose Regimens of ARGX-117 in Adults With Multifocal Motor Neuropathy- ARGX-117-2002, completed
- A Long-term Extension of the ARGX-117-2002 Trial to Evaluate the Long-term Safety and Tolerability, Efficacy, Pharmacodynamics, Pharmacokinetics, and Immunogenicity of ARGX-117 in Adults With Multifocal Motor Neuropathy, ongoing
- A Phase 3b, Randomized, Open-label, Parallel-Group Study to Evaluate Different Dosing Regimens of Intravenous Efgartigimod to Maximize and Maintain Clinical Benefit in Patients With Generalized Myasthenia Gravis, ARGX-113-2003, ongoing
- Phase III Efficacy, Safety, and Tolerability Study of HYQVIA/HyQvia and GAMMAGARD LIQUID/KIOVIG in CIDP -161403, completed (Italian Coordinator)
- A Phase 2 Placebo-Controlled, Double-Blind, Enriched Enrollment Randomized Withdrawal Study to Evaluate the Efficacy and Safety of BIIB074 in Treating Pain Experienced by Subjects With Confirmed Small Fiber Neuropathy That is Idiopathic or Associated With Diabetes Mellitus - CONVEY/802NP206, completed
- Effects of oral Levosimendan (odm-109) on respiratory function in patients with ALS-3119002, completed (Italian Coordinator)
- “The effects of RNS60 on ALS biomarkers”, completed
- “Protein misfolding, amyotrophic lateral sclerosis and guanabenz: a phase II RCT with futility design”– PROMISE, completed
- A Multi-Center, Low Interventional Study with a Retrospective Component in Participants with Late Onset Pompe Disease - SPK-GAA-100, completed
- A Double-blind, Randomized, Multicenter, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Fingolimod 0.5 mg Administered Orally Once Daily Versus Placebo in Patients With Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)-FTY720, completed
- Study to assess the effectiveness of high doses of immunoglobulin in the treatment of polyneuropathy painful diabetic resistant to conventional therapies. –IGD002, completed
- A Non-interventional Study of Clinical Experience in Patients Prescribed Raxone® for the Treatment of Leber's Hereditary Optic Neuropathy (LHON), SNT-IV-003, completed
- AIGkit: un'applicazione per smartphone come nuovo strumento per favorire l'interazione medico-paziente nel follow-up della Malattia di Pompe, ongoing (coordinating center, ongoing)
- Early indicators for perspective clinical recovery in Guillaine-Barré syndrome patients treated with intravenous immunoglobulins - GBS-ER, ongoing (coordinating center)
- A Phase 2b, Multi-center, Randomized, Double-blind, Placebo-controlled Study of IMVT-1402 Treatment in Adult Participants with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), IMVT-1402-2401, ongoing
- A phase III, double blind placebo-controlled study to evaluate efficacy and safety of Riliprubart in patients affected by refractory chronic inflammatory polyneuropathy –EFC17236-MOBILIZE, ongoing

May 2016-May 2022: freelance contract at Neurological Clinic of EO Ospedali Galliera, Genoa, as scientific project and data manager and SI in sponsored and non-sponsored local and multi-centric trials, in particular focused on neurovascular and neurodegenerative disorders,. She has collaborated for conceptualization and writing of research projects to be applied in national and international calls

Other activities:

Invited speaker in:

- e-NMD Congress E-Health & Innovation to overcome barriers in Neuromuscular Diseases, Nice (FR) 22-23 March 2019
- SNO-SIN Tuscany Congress in Viareggio 5-7 April 2019
- "La polineuropatia HATTR: verso un protocollo diagnostico regionale- INSTANT FAP-network", webinar 28th October 2020
- SNO-SIN Tuscany Congress in Siena 16-18 September 2021
- SNO-SIN Tuscany Congress in Firenze 15-17 September 2022
- Convegno "Aurora e tramonto del cervello", Catania, Az. Osp. Garibaldi, 16 and 19 December 2022
- Convegno "Le disabilità", Catania, Az. Osp. Garibaldi, 8 May 2023
- Convegno "Cervello Aurora e Tramonto", Catania, Az. Osp. Garibaldi, 18-19 December 2023
- SIONG –Italian Society Oto-Neuro-Geriatry, Castellammare di Stabia, 14-16 May 2024

Other:

- Member Advisory Board for aTTR polineuropathy in Tuscany Region
- Scientific Referent for "Screen and Care Amiloidosi hATTR: riconoscerla per curarla" project in Tuscany, 2021
- Member of scientific board for Summer School "Muscle School: muscle exercise in health and disease" years 2017, 2018, 2019
- Teaching fellow at Summer School "Muscle School: muscle exercise in health and disease", III edition, 15-26 July 2019
- Membership of the local Organizing Committee of the Joint National Congress AINP and NC, Pisa-30th May- 1st June 2013,
- Member of the Scientific Organizing Committee of the Italian Association of Myology (AIM), Lecce-8th-11th June 2016
- Membership of the local Organizing Committee of the "E-NMD Congress E-Health & Innovation to overcome barriers in Neuromuscular Diseases", 30th-31st October 2020, virtual
- Member Advisory Board "La Polineuropatia Amiloide Familiare in Toscana", Firenze 24th October 2019
- Scientific Director of the project "Screen&care Amiloidosi h-ATTR: riconoscerla per curarla", 26th March and 1st October 2021
- Membership of the local Organizing Committee of the "E-NMD Congress E-Health & Innovation to overcome barriers in Neuromuscular Diseases", 29th-30th October 2021, hybrid event-Tirrenia (Pisa)
- Member of the Scientific Organizing Committee for the "Neuromuscular Diseases Day" in Pisa, March 2017-2018-2019-2021
- Membership of the Scientific Organizing Committee of the Congress "La SLA una malattia complessa: attualità e nuovi orizzonti", S.Giuliano Terme –Pisa, 24 May 2024

Supervision and management for Pisa site of disease registers in Neuromuscular Diseases (Italian CIDP Register, Italian MMN Register, CIDP-MMN VACCINO Covid19)

Price for best oral communication ("Neuropathic pain in inherited peripheral neuropathies: quality of life, exercise and markers of neuroinflammation") at SNO-SIN Tuscany Congress in Viareggio 5-7 April 2019

Affiliation and consulting in patients associations: CIDP ONLUS (Associazione per la Poliradicoloneuropatia Infiammatoria Demielinizzante Cronica), UILDM (Unione Italiana Lotta Distrofia Muscolare), A.L.I.C.E (Associazione per la Lotta all'Ictus Cerebrale)

Member of Board of Trustees of "Un Passo per Te", Research Foundation in Neuromuscular Diseases, since March 2023

Certified course:

- Training course - Multifocal Motor Neuropathy Master Class, Utrecht 26th-27th April 2013
- GIMBE training course "Clinical Trials: planning, management, analysis and reporting", Bologna 8th-11th May 2018

Membership in Scientific Society: AIM (Italian Association of Myology), ASNP (Association for Peripheral Nerve Study).

Membership of "SCIg and Chronic Dysimmune Neuropathies Italian Network" study group

Membership of "Italian CIDP Database study group"

Membership of "Italian Project on Stroke at Young Age (IPSYS) Investigators" group

Research activity and publications

She is involved in research projects, in particular she is responsible for protocols concept, design and writing, ensuring the right conduction, data collection and management.

She is author of 43 full papers in indexed peer-reviewed International Journals and more than 100 abstracts presented in International and National congresses as results of national and international scientific collaborative projects.

H.I. 12 (SCOPUS)

I authorize data personal treatment according to Regolamento UE n.679/2016 e del Dlgs 2003 n. 196 e successive modificazioni

Pisa, 3 December 2024

Dr.Erika Schirinzi