

**CURRICULUM VITAE**  
**Roberto Luksch, M.D.**

**Birth date and place:** 17 September 1962, Milan, Italy

**Citizenship:** Italy

**Work address:** S.C. Pediatria Oncologica, Fondazione IRCCS Istituto Nazionale dei Tumori,  
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**Position:** Permanent staff member

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**Education**

1977-1982:

Graduation from Liceo Classico, Milan, Italy

1982-1987:

M.D. medical graduate, *cum laude*, Università Statale di Milano, School of Medicine, Milan, Italy

1987-1991:

Specialty Board on Hematology, *cum laude*, Università Statale di Milano, School of Medicine, Italy

1995-1999:

Specialty Board on Oncology, *cum laude*, Università Statale di Milano, School of Medicine, Italy

**Professional Experience**

1985-1989:

Internship and then fellow in Hematology, Ospedale Maggiore Policlinico, Milan.

1989 to 1991:

Fellow at the Pediatric Oncology Dept. of Fondazione IRCCS Istituto Nazionale dei Tumori in Milan.

From 1992:

Permanent staff member at the Pediatric Oncology Dept. of Fondazione IRCCS Istituto Nazionale dei Tumori in Milan

From 2010:

High Specialty position for the management of the Institutional Pediatric Hemopoietic Transplant Program.

**Affiliations**

Associazione Italiana di Ematologia e Oncologia Pediatrica (AIEOP)

Italian Sarcoma Group (ISG)

Gruppo Italiano per il Trapianto di Midollo Osseo, cellule staminali emopoietiche e terapia cellulare (GITMO)

International Society of Pediatric Oncology (SIOP)

SIOP-Europe Neuroblastoma

Euro-EWING Consortium

European Bone Marrow Transplantation Study Group (EBMT)

**Main Research interests, scientific committees**

Involved in different clinical trials in accordance with ICH/GCP; main interests: clinical research in neuroblastoma and bone tumors, autologous hemopoietic stem cell transplantation in children.

From 2002 to date: National Coordinator of the SIOP-Europe Neuroblastoma Protocol for high-risk Neuroblastoma (Study 1 - NBL-HR-01-SIOPEN).

From May 2004 to date: Member of the Executive Committee of the Italian Sarcoma Group (ISG).

From May 2005 to April 2008: Member of the Executive Committee of the SIOP-Europe Neuroblastoma Group.

From 2007 to 2015 Chairman of the Scientific Committee on Bone tumors of the Associazione Italiana di Ematologia e Oncologia Pediatrica (AIEOP).

From October 2012 to October 2015: Member of the Executive Committee of AIEOP.

From May 2016 to date: Italian delegate for ISG and AIEOP in Euro-EWING Consortium

From March 2020: Member of the Executive Committee of Euro-EWING Consortium.

Principal Investigator or Co-investigator in national and international clinical trials according to GCP.

**Participation in clinical trials**

PI or National Coordinator in phase I/II/III clinical trials:

-National Coordinator for the "First European Protocol for High-Risk Neuroblastoma-SIOP-Europe Neuroblastoma (NBL-HR-01 trial). EudraCT 2006-001489-17; Study code INT 40/01

-PI for INT Milan of the study "A randomized phase IIb trial of bevacizumab added to temozolomide +/- irinotecan for children with refractory/relapsed neuroblastoma". EudraCT 2012-000072-42; Study code INT 71/15

-PI for INT Milan of the study "A phase I/II dose schedule finding study of ch14.18/cho continuous infusion combined with subcutaneous aldesleukin (IL-2) in patients with primary refractory or relapsed neuroblastoma - a SIOPEN study". EudraCT 2009-018077-31; Study code INT 16/13

-PI for INT Milan of the study "rEECur - International Randomised Controlled Trial of Chemotherapy for the Treatment of Recurrent and Primary Refractory Ewing Sarcoma". EudraCT 2014-000259-99 - Study code INT 91/15

- National Coordinator for the phase II trial of Italian Sarcoma Group/AIEOP "Protocollo terapeutico con chemioterapia ad alte dosi, radioterapia, terapia di mantenimento con ciclofosfamide a basse dosi e anti COX2 per sarcoma di Ewing metastatico". EudraCT 2009-011197-15; Study code INT 25/09

- National Coordinator for the phase III trial of Italian Sarcoma Group/AIEOP "Studio di fase 3 sull'efficacia dell'intensificazione della dose in pazienti con sarcoma di Ewing non metastatico". EudraCT 2008-008361-35; Study code INT 22/09

- PI for INT Milan of the study "Phase 1/2 Combined Dose Ranging and Randomised, Open-label, Comparative Study of the Efficacy and Safety of Plerixafor in Addition to Standard Regimens for Mobilisation of Haematopoietic Stem Cells into Peripheral Blood, and Subsequent Collection by Apheresis, Versus Standard Mobilisation Regimens Alone in Paediatric Patients, Aged 2 to <18 Years, with Solid Tumours Eligible for Autologous Transplants" Genzyme Study MOZ15609. EudraCT 2010-019340-40 – Study code INT 53/10

-PI for INT Milan of the Study "Phase I/II, Open-Label, Multicenter Study to evaluate the safety, tolerability and preliminary efficacy of Durvalumab monotherapy or Durvalumab in combination with tremelimumab in pediatric Patients with advanced solid tumors and haematological malignancies. Study D419EC00001-Study code INT200/18

-PI for INT Milan of the Study "A Phase 1 Study of Aurora Kinase A Inhibitor LY3295668 erbumine as a Single Agent and in Combination in Patients with Relapsed/Refractory Neuroblastoma". Study J1O-MC-JZHD LY3295668. Study code INT213/19

-National Coordinator for the phase II Study "An international multicenter phase II randomised trial evaluating and comparing two intensification treatment strategies for metastatic neuroblastoma patients with a poor response to induction chemotherapy - A SIOPEN Study" EudraCT N°: 2015-003130-27.

## **Publications**

Author or Co-author of 172 manuscripts published in peer-reviewed international scientific journals and 14 chapters of scientific books.

Peer-reviewer for National and International scientific journals.

### **Selected publications 2015-2021:**

Apolone G, Ardizzone A, Biondi A, Bortolami A, Cardone C, Ciniselli CM, Conte P, Crippa C, de Braud F, Duca M, Gori S, Gritti G, Inno A, Luksch R, Lussana F, Maio M, Pasello G, Perrone F, Rambaldi A, Rossi G, Signorelli D, Soverini G, Valente M, Verderio P, Buzzetti G.  
Skip pattern approach toward the early access of innovative anticancer drugs. *ESMO Open*. 2021 Aug;6(4):100227. doi: 10.1016/j.esmoop.2021.100227. Epub 2021 Aug 2. PMID: 34352703; PMCID: PMC8350180.

Asaftei SD, Puma N, Paioli A, Petraz M, Morosi C, Podda M, Tamburini A, Palmerini E, Coccoli L, Grignani G, Manzitti C, Bertulli R, De Leonardis F, Rabusin M, Campello A, Tirtei E, Picci P, Prete A, Longhi A, Fagioli F, Luksch R.

Front-Line Window Therapy with Temozolomide and Irinotecan in Patients with Primary Disseminated Multifocal Ewing Sarcoma: Results of the ISG/AIEOP EW-2 Study. *Cancers (Basel)*. 2021 Jun 18;13(12):3046. doi: 10.3390/cancers13123046. PMID: 34207428; PMCID: PMC8234176.

Abate ME, Cammelli S, Ronchi L, Diletto B, Gandola L, Paioli A, Longhi A, Palmerini E, Puma N, Tamburini A, Mascarin M, Coassin E, Prete A, Asaftei SD, Manzitti C, Bisogno G, Pierobon M, Coccoli L, Capasso M, Grignani G, Milano GM, Kiren V, Fagioli F, Ferrari S, Picci P, Carretta E, Luksch R.

Whole Lung Irradiation after High-Dose Busulfan/Melphalan in Ewing Sarcoma with Lung Metastases: An Italian Sarcoma Group and Associazione Italiana Ematologia Oncologia Pediatrica Joint Study. *Cancers (Basel)*. 2021 Jun 3;13(11):2789. doi: 10.3390/cancers13112789. PMID: 34205124; PMCID: PMC8199967.

Garaventa A, Poetschger U, Valteau-Couanet D, Luksch R, Castel V, Elliott M, Ash S, Chan GCF, Laureys G, Beck-Popovic M, Vettenranta K, Balwierz W, Schroeder H, Owens C, Cesen M, Papadakis V, Trahair T, Schleiermacher G, Ambros P, Sorrentino S, Pearson ADJ, Ladenstein RL.

Randomized Trial of Two Induction Therapy Regimens for High-Risk Neuroblastoma: HR-NBL1.5 International Society of Pediatric Oncology European Neuroblastoma Group Study. *J Clin Oncol*. 2021 Aug 10;39(23):2552-2563. doi: 10.1200/JCO.20.03144. Epub 2021 Jun 21. PMID: 34152804.

Bellini A, Pötschger U, Bernard V, Lapouble E, Baulande S, Ambros PF, Auger N, Beiske K, Bernkopf M, Betts DR, Bhalshankar J, Bown N, de Preter K, Clément N, Combaret V, Font de Mora J, George SL, Jiménez I, Jeison M, Marques B, Martinsson T, Mazzocco K, Morini M, Mühlenthaler-Mottet A, Noguera R, Pierron G, Rossing M, Taschner-Mandl S, Van Roy N, Vicha A, Chesler L, Balwierz W, Castel V, Elliott M, Kogner P, Laureys G, Luksch R, Malis J, Popovic-Beck M, Ash S, Delattre O, Valteau-Couanet D, Tweddle DA, Ladenstein R, Schleiermacher G. Frequency and Prognostic Impact of <i>ALK</i> Amplifications and Mutations in the European Neuroblastoma Study Group (SIOPEN) High-Risk Neuroblastoma Trial (HR-NBL1). *J Clin Oncol*. 2021 Oct 20;39(30):3377-3390. doi: 10.1200/JCO.21.00086. Epub 2021 Jun 11. PMID: 34115544.

Meazza C, Luksch R, Luzzati A.

Managing axial bone sarcomas in childhood. *Expert Rev Anticancer Ther*. 2021 Jul;21(7):747-764. doi: 10.1080/14737140.2021.1891886. Epub 2021 Mar 1. PMID: 33593222.

Biassoni V, Schiavello E, Gandola L, Pecori E, Poggi G, Spreafico F, Terenziani M, Meazza C, Podda M, Ferrari A, Luksch R, Casanova M, Puma N, Chiaravalli S, Bergamaschi L, Cefalo G, Simonetti F, Gattuso G, Seregni EC, Pallotti F, Gianno F, Diletto B, Barretta F, Massimino M. Secreting Germ Cell Tumors of the Central Nervous System: A Long-Term Follow-up Experience. *Cancers (Basel)*. 2020 Sep 21;12(9):2688. doi: 10.3390/cancers12092688. PMID: 32967085; PMCID: PMC7565315.

Berlanga P, Pasqualini C, Pötschger U, Sangüesa C, Castellani MR, Cañete A, Luksch R, Elliot M, Schreier G, Kropf M, Morgenstern D, Papadakis V, Ash S, Ruud E, Brock P, Wieczorek A, Kogner P, Trahair T, Ambros P, Boterberg T, Castel V, Valteau-Couanet D, Ladenstein R. Central nervous system relapse in high-risk stage 4 neuroblastoma: The HR-NBL1/SIOPEN trial experience. *Eur J Cancer*. 2021 Feb;144:1-8. doi: 10.1016/j.ejca.2020.10.020. Epub 2020 Dec 11. PMID: 33316634.

Holmes K, Pötschger U, Pearson ADJ, Sarnacki S, Cecchetto G, Gomez-Chacon J, Squire R, Freud E, Bysiek A, Matthysseens LE, Metzelder M, Monclair T, Stenman J, Rygl M, Rasmussen L, Joseph JM, Irtan S, Avanzini S, Godzinski J, Björnland K, Elliott M, Luksch R, Castel V, Ash S, Balwierz W, Laureys G, Ruud E, Papadakis V, Malis J, Owens C, Schroeder H, Beck-Popovic M, Trahair T, Forjaz de Lacerda A, Ambros PF, Gaze MN, McHugh K, Valteau-Couanet D, Ladenstein RL; International Society of Paediatric Oncology Europe Neuroblastoma Group (SIOPEN).

Influence of Surgical Excision on the Survival of Patients With Stage 4 High-Risk Neuroblastoma: A Report From the HR-NBL1/SIOPEN Study. *J Clin Oncol*. 2020 Sep 1;38(25):2902-2915. doi: 10.1200/JCO.19.03117. Epub 2020 Jul 8. PMID: 32639845.

Ferrari A, Zecca M, Rizzari C, Porta F, Provenzi M, Marinoni M, Schumacher RF, Luksch R, Terenziani M, Casanova M, Spreafico F, Chiaravalli S, Compagno F, Bruni F, Piccolo C, Bettini L, D'Angio M, Ferrari GM, Biondi A, Massimino M, Balduzzi A.

Children with cancer in the time of COVID-19: An 8-week report from the six pediatric onco-hematology centers in Lombardia, Italy. *Pediatr Blood Cancer*. 2020 Aug;67(8):e28410. doi: 10.1002/pbc.28410. Epub 2020 May 26. PMID: 32452123; PMCID: PMC7267084.

Morland B, Kepak T, Dallorso S, Sevilla J, Murphy D, Luksch R, Yaniv I, Bader P, Rößler J, Bisogno G, Maecker-Kolhoff B, Lang P, Zwaan CM, Sumerauer D, Kriván G, Bernard J, Liu Q, Doyle E, Locatelli F.

Plerixafor combined with standard regimens for hematopoietic stem cell mobilization in pediatric patients with solid tumors eligible for autologous transplants: two-arm phase I/II study (MOZAIC). *Bone Marrow Transplant*. 2020 Sep;55(9):1744-1753. doi: 10.1038/s41409-020-0836-2. Epub 2020 Mar 3. PMID: 32127657; PMCID: PMC7452813.

Ladenstein R, Pötschger U, Valteau-Couanet D, Luksch R, Castel V, Ash S, Laureys G, Brock P, Michon JM, Owens C, Trahair T, Chi Fung Chan G, Ruud E, Schroeder H, Beck-Popovic M, Schreier G, Loibner H, Ambros P, Holmes K, Castellani MR, Gaze MN, Garaventa A, Pearson ADJ, Lode HN.

Investigation of the Role of Dinutuximab Beta-Based Immunotherapy in the SIOPEN High-Risk Neuroblastoma 1 Trial (HR-NBL1). *Cancers (Basel)*. 2020 Jan 28;12(2):309. doi: 10.3390/cancers12020309. PMID: 32013055; PMCID: PMC7072500.

Morini M, Cangeli D, Segalerba D, Marimpietri D, Raggi F, Castellano A, Fruci D, de Mora JF, Cañete A, Yáñez Y, Viprey V, Corrias MV, Carlini B, Pezzolo A, Schleiermacher G, Mazzocco K, Ladenstein R, Sementa AR, Conte M, Garaventa A, Burchill S, Luksch R, Bosco MC, Eva A, Varesio L.

Exosomal microRNAs from Longitudinal Liquid Biopsies for the Prediction of Response to Induction Chemotherapy in High-Risk Neuroblastoma Patients: A Proof of Concept SIOPEN Study. *Cancers (Basel)*. 2019 Sep 30;11(10):1476. doi: 10.3390/cancers11101476. PMID: 31575060; PMCID: PMC6826693.

Ladenstein R, Pötschger U, Valteau-Couanet D, Luksch R, Castel V, Yaniv I, Laureys G, Brock P, Michon JM, Owens C, Trahair T, Chan GCF, Ruud E, Schroeder H, Beck Popovic M, Schreier G, Loibner H, Ambros P, Holmes K, Castellani MR, Gaze MN, Garaventa A, Pearson ADJ, Lode HN.

Interleukin 2 with anti-GD2 antibody ch14.18/CHO (dinutuximab beta) in patients with high-risk neuroblastoma (HR- NBL1/SIOPEN): a multicentre, randomised, phase 3 trial. *Lancet Oncol*. 2018 Dec;19(12):1617-1629. doi: 10.1016/S1470-2045(18)30578-3. Epub 2018 Nov 12. PMID: 30442501.

Camisaschi C, Renne SL, Beretta V, Rini F, Spagnuolo RD, Tuccitto A, Podda MG, Parmiani G, Rivoltini L, Collini P, Castelli C, Luksch R.

Immune landscape and in vivo immunogenicity of NY-ESO-1 tumor antigen in advanced neuroblastoma patients. *BMC Cancer*. 2018 Oct 16;18(1):983. doi: 10.1186/s12885-018-4910-8. PMID: 30326856; PMCID: PMC6192300.

Faraci M, Bertaina A, Luksch R, Calore E, Lanino E, Saglio F, Prete A, Menconi M, De Simone G, Tintori V, Cesaro S, Santarone S, Orofino MG, Locatelli F, Zecca M.

Sinusoidal Obstruction Syndrome/Veno-Occlusive Disease after Autologous or Allogeneic Hematopoietic Stem Cell Transplantation in Children: a retrospective study of the Italian Hematology-Oncology Association-Hematopoietic Stem Cell Transplantation Group. *Biol Blood Marrow Transplant*. 2019 Feb;25(2):313-320. doi: 10.1016/j.bbmt.2018.09.027. Epub 2018 Sep 26. PMID: 30266674.

Morgenstern DA, Pötschger U, Moreno L, Papadakis V, Owens C, Ash S, Pasqualini C, Luksch R, Garaventa A, Canete A, Elliot M, Wieczorek A, Laureys G, Kogner P, Malis J, Ruud E, Beck-Popovic M, Schleiermacher G, Valteau-Couanet D, Ladenstein R. Risk stratification of high-risk metastatic neuroblastoma: A report from the HR-NBL-1/SIOPEN study. *Pediatr Blood Cancer*. 2018 Nov;65(11):e27363. doi: 10.1002/pbc.27363. Epub 2018 Jul 17. PMID: 30015396.

Corrias MV, Parodi S, Tchirkov A, Lammens T, Vicha A, Pasqualini C, Träger C, Yáñez Y, Dallorso S, Varesio L, Luksch R, Laureys G, Valteau-Couanet D, Canete A, Pötschger U, Ladenstein R, Burchill SA. Event-free survival of infants and toddlers enrolled in the HR-NBL-1/SIOPEN trial is associated with the level of neuroblastoma mRNAs at diagnosis. *Pediatr Blood Cancer*. 2018 Jul;65(7):e27052. doi: 10.1002/pbc.27052. Epub 2018 Mar 30. PMID: 29603574.

Palmerini E, Jones RL, Setola E, Picci P, Marchesi E, Luksch R, Grignani G, Cesari M, Longhi A, Abate ME, Paioli A, Szucs Z, D'ambrosio L, Scotlandi K, Fagioli F, Asaftei S, Ferrari S. Irinotecan and temozolamide in recurrent Ewing sarcoma: an analysis in 51 adult and pediatric patients. *Acta Oncol*. 2018 Jul;57(7):958-964. doi: 10.1080/0284186X.2018.1449250. Epub 2018 Mar 13. PMID: 29533113.

Meazza C, Cefalo G, Massimino M, Daolio P, Pastorino U, Scanagatta P, Morosi C, Podda M, Ferrari A, Terenziani M, Spreafico F, Casanova M, Paraforiti A, Collini P, Gandola L, Bastoni S, Biassoni V, Schiavello E, Chiaravalli S, Puma N, Bergamaschi L, Luksch R. Primary metastatic osteosarcoma: results of a prospective study in children given chemotherapy and interleukin-2. *Med Oncol*. 2017 Nov 1;34(12):191. doi: 10.1007/s12032-017-1052-9. PMID: 29094224.

Ferrari A, Gaggiotti P, Silva M, Veneroni L, Magni C, Signoroni S, Casanova M, Luksch R, Terenziani M, Spreafico F, Meazza C, Clerici CA, Massimino M. Searching for Happiness. *J Clin Oncol*. 2017 Jul 1;35(19):2209-2212. doi: 10.1200/JCO.2017.72.8733. Epub 2017 Apr 27. PMID: 28448240.

Luksch R, Grignani G, D'Angelo P, Prete A, Puma N, Podda M, Casanova M, Ferrari A, Morosi C, Fagioli F, Aglietta M, Ferrari S, Picci P, Massimino M. Front-line window therapy with cisplatin in patients with primary disseminated Ewing sarcoma: A study by the Associazione Italiana di Ematologia ed Oncologia Pediatrica and Italian Sarcoma Group. *Pediatr Blood Cancer*. 2017 Dec;64(12). doi: 10.1002/pbc.26650. Epub 2017 Jun 14. PMID: 28612488.

Amoroso L, Erminio G, Makin G, Pearson ADJ, Brock P, Valteau-Couanet D, Castel V, Pasquet M, Laureys G, Thomas C, Luksch R, Ladenstein R, Haupt R, Garaventa A; SIOPEN Group. Topotecan-Vincristine-Doxorubicin in Stage 4 High-Risk Neuroblastoma Patients Failing to Achieve a Complete Metastatic Response to Rapid COJEC: A SIOPEN Study. *Cancer Res Treat*. 2018 Jan;50(1):148-155. doi: 10.4143/crt.2016.511. Epub 2017 Mar 21. PMID: 28324923; PMCID: PMC5784636.

Ladenstein R, Pötschger U, Pearson ADJ, Brock P, Luksch R, Castel V, Yaniv I, Papadakis V, Laureys G, Malis J, Balwierz W, Ruud E, Kogner P, Schroeder H, de Lacerda AF, Beck-Popovic M, Bician P, Garami M, Trahair T, Canete A, Ambros PF, Holmes K, Gaze M, Schreier G, Garaventa A, Vassal G, Michon J, Valteau-Couanet D; SIOP Europe Neuroblastoma Group (SIOPEN).

Busulfan and melphalan versus carboplatin, etoposide, and melphalan as high-dose chemotherapy for high-risk neuroblastoma (HR-NBL1/SIOPEN): an international, randomised, multi-arm, open-label, phase 3 trial. *Lancet Oncol*. 2017 Apr;18(4):500-514. doi: 10.1016/S1470-2045(17)30070-0. Epub 2017 Mar 2. PMID: 28259608.

Luksch R, Castellani MR, Collini P, De Bernardi B, Conte M, Gambini C, Gandola L, Garaventa A, Biasoni D, Podda M, Sementa AR, Gatta G, Tonini GP. Neuroblastoma (Peripheral neuroblastic tumours). *Crit Rev Oncol Hematol*. 2016 Nov;107:163-181. doi: 10.1016/j.critrevonc.2016.10.001. Epub 2016 Oct 6. PMID: 27823645.

Parafioriti A, Bason C, Armiraglio E, Calciano L, Daolio PA, Berardocco M, Di Bernardo A, Colosimo A, Luksch R, Berardi AC. Ewing's Sarcoma: An Analysis of miRNA Expression Profiles and Target Genes in Paraffin-Embedded Primary Tumor Tissue. *Int J Mol Sci*. 2016 Apr 30;17(5):656. doi: 10.3390/ijms17050656. PMID: 27144561; PMCID: PMC4881482.

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Meazza C, Scanagatta P, Luksch R, Massimino M. How far can we go with surgery in metastatic osteosarcoma patients? *Med Oncol*. 2015 Sep;32(9):223. doi: 10.1007/s12032-015-0668-x. Epub 2015 Jul 25. PMID: 26208650.

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#### Training on ICH/GCP

-Certification of ICH GCP vers. 1.0, Training by TransCelerate Biopharma Inc. on 19 April 2016  
-Course "Sperimentazioni Cliniche di Fase I", 12 July 2018, INT Milan  
-ICH Good Clinical Practice E6 (R2) 24/02/2020

*I authorize the use of personal data, according to Italian Privacy Law, D. Lgs. 196/0.*

Milan, 12 December 2021

Dr. Roberto Luksch