



CURRICULUM VITAE
Dr. Michela Casanova

ISTRUZIONE:

1988-1994 Laurea in Medicina a Chirurgia, Università degli Studi di Milano
1995-1998 Specializzazione in Oncologia, Università degli Studi di Milano

RUOLO ATTUALE:

Dal 1997 dirigente di ruolo presso la divisione di Pediatria della Fondazione IRCCS Istituto Nazionale dei Tumori di Milano. Dal 2014 incarico dirigenziale di alta professionalità "Nuovi farmaci: trials nazionali ed internazionali nei pazienti pediatrici".

Membro del Consiglio Direttivo dell'AIEOP (Associazione Italiana Ematologia Oncologia Pediatrica) per il triennio 2024-2027 e dal febbraio 2025 del Consiglio di Amministrazione della Fondazione Italiana Ematologia Oncologia Pediatrica (FIEOP).

Dal 2018 responsabile del Gruppo di Lavoro AIEOP Nuovi Farmaci e consulente del gruppo di lavoro Sarcomi delle parti molli.

Membro dell'Italian sarcoma Group.

A livello internazionale:

Membro del Comitato Esecutivo e segretario del consorzio europeo ITCC (Innovative Therapies for Children and adolescents with Cancer), co-chair del Solid Tumor Committee.

Membro fondatore dell'EpSSG (European pediatric Soft tissue sarcoma Study Group); membro del Phase I-II Trial Committee e del Non-Rhabdomyosarcoma Soft Tissue Sarcoma Scientific Committee.

Membro del Comitato Scientifico del Congresso Annuale della SIOPE (Società europea di oncologia pediatrica) e del gruppo SIOPEL (International Childhood Liver Tumours Strategy Group).

PRECEDENTI ESPERIENZE PROFESSIONALI:

Dal 2010 al 2020 membro del Clinical Trial Committee del consorzio europeo ITCC (Innovative Therapies for Children and adolescents with Cancer).

Dal 2010 al 2017 Membro del gruppo di lavoro Farmacologia clinica e farmacovigilanza e dal 2016 al 2018 Membro del gruppo di lavoro Tumori rari.



FONDAZIONE IRCCS
"ISTITUTO NAZIONALE
PER LO STUDIO
E LA CURA DEI TUMORI"

Dal 2016 al 2021 chair dell'EpSSG (European pediatric Soft tissue sarcoma Study Group) Phase I-II Trial Committee. ed è stata membro del Board dal 2018 al 2024.

Dal 2016 al 2019 Membro del SIOP Scientific Programme Advisory Committee (SPAC)

Pubblicazioni

Autore e co-autore di oltre 300 lavori pubblicati su riviste internazionali, di cui si elencano i più significativi.

Casanova M, et al. Efficacy, safety, and pharmacokinetics of eribulin as monotherapy or in combination with irinotecan for patients with pediatric rhabdomyosarcoma, non-rhabdomyosarcoma soft tissue sarcoma, or Ewing sarcoma. *ESMO Open*. 2025 Feb 4;10(2):104129.

Geoerger B, Bautista F, André N, Berlanga P, Gatz SA, Marshall LV, Rubino J, Archambaud B, Marchais A, Rubio-San-Simón A, Ducassou S, Zwaan CM, Casanova M, et al. Precision cancer medicine platform trials: Concepts and design of AcSé-ESMART. *Eur J Cancer* 2024 Jul 14; 208:114201.

Bautista F, Verdú-Amorós J, Geoerger B, Rubio-San-Simón A, Paoletti X, Zwaan CM, Casanova M, et al. Innovative Therapies For Children With Cancer Consortium. Evolution of the Innovative Therapies for Children With Cancer Consortium Trial Portfolio for Drug Development for Children With Cancer. *J Clin Oncol* 2024 Jul; 42(21):2516-2526

Ferrari A, Orbach D, Bergamaschi L, Schoot RA, van Noesel MM, Di Carlo D, Bisogno G, Alaggio R, Milano GM, Chiaravalli S, Fuccillo F, Laurence V, Corradini N, Gasparini P, Vennarini S, Pasquali S, Casanova M. Treatment at relapse for synovial sarcoma of children and adolescents: A multi-institutional European retrospective analysis. *Pediatr Blood Cancer* 2024;71(7): e31038

Geoerger B, Paoletti X, Bautista F, Gatz SA, Marshall LV, André N, Berlanga P, Ducassou S, Pasqualini C, Casanova M, et al. AcSé-ESMART, a European precision cancer medicine proof-of-concept platform trial. *Nat Med* 2023; 29(12): 2985-2987

Orbach D, Sparber-Sauer M, Corradini N, Ferrari A, Owens C, Casanova M. Infantile fibrosarcoma: Is spontaneous regression possible? *Pediatr Blood Cancer* 2023;70(11): e30623

Casanova M, et al. Regorafenib Plus Vincristine and Irinotecan in Pediatric Patients With Recurrent/Refractory Solid Tumors: An Innovative Therapies for Children With Cancer Study. *Clin Cancer Res* 2023;29(21):4341-4351

Kummar S, Shen L, Hong DS, McDermott R, Keedy VL, Casanova M, et al. Larotrectinib efficacy and safety in adult patients with tropomyosin receptor kinase fusion sarcomas. *Cancer* 2023;129(23):3772-3782

Ferrari A, Orbach D, Casanova M, et al. Metastatic adult-type non-rhabdomyosarcoma soft tissue sarcomas in children and adolescents: A cohort study from the European paediatric Soft tissue sarcoma Study Group. *Cancer* 2023; 129(16):2542-2552

Moreno L, DuBois SG, Glade Bender J, Mauguen A, Bird N, Buenger V, Casanova M, et al. Combination Early-Phase Trials of Anticancer Agents in Children and Adolescents. *J Clin Oncol* 2023; 41(18):3408-3422

Casanova M, et al. Relapse after non-metastatic rhabdomyosarcoma: the impact of routine surveillance imaging on early detection and post-relapse survival. *Pediatr Blood Cancer* 2023; 70(2):e30095

Ott M, Brack E, Kearns PR, Kozhaeva O, Ocokoljic M, Schoot RA, Vassal G, and the Essential Medicines Group (Achini F, Balduzzi A, Popovic MB, Beishuizen A, Bergamaschi L, Biondi A, Bourdeau F, Braicu E, Brok J, Brugières L, Burke A, Calaminus G, Casanova M, et al). Essential medicines for childhood cancer in Europe: a pan-European, systematic analysis by SIOPE. *Lancet Oncol* 2022; 23(12):1537-1546

Casanova M, et al. MiR-223 Exclusively Impairs In Vitro Tumor Growth through IGF1R Modulation in Rhabdomyosarcoma of Adolescents and Young Adults. *Int J Mol Sci* 2022; 23(22):13989



Pearson AD, Gaspar N, Janeway K, Campbell-Hewson Q, Lawlor ER, Copland C, Karres D, Norga K, Benzaghoul F, Weiner S, Weigel B, Weiss AR, Strauss SJ, Smith M, Setty BA, Seibel N, Scobie N, Pappo A, Okpara CE, Nysom K, McDonough J, Marshall LV, Ludwinski D, Ligas F, Lesa G, Knudsen S, Kauh J, Hsieh A, Heenen D, Hawkins DS, Graham A, Garmey E, DuBois SG, Fox E, Donoghue M, de Rojas T, Chung J, Casanova M, et al. Paediatric Strategy Forum for medicinal product development of multi-targeted kinase inhibitors in bone sarcomas: ACCELERATE in collaboration with the European Medicines Agency with participation of the Food and Drug Administration. *Eur J Cancer* 2022; 173:71-90

Ferrari A, Chisholm JC, Jenney M, Minard-Colin V, Orbach D, Casanova M, et al. Adolescents and young adults with rhabdomyosarcoma treated in the European paediatric Soft tissue sarcoma Study Group (EpSSG) protocols: a cohort study. *Lancet Child Adolesc Health* 2022; 6(8):545-554

Schoot RA, Chisholm JC, Casanova M, et al. Metastatic Rhabdomyosarcoma: Results of the European *Paediatric* Soft Tissue Sarcoma Study Group MTS 2008 Study and Pooled Analysis with the Concurrent BERNIE Study. *J Clin Oncol* 2022; 40(32):3730-3740

Waguespack SG, Drilon A, Lin JJ, Brose MS, McDermott R, Almubarak M, Bauman J, Casanova M, et al. Efficacy and safety of larotrectinib in patients with TRK fusion-positive thyroid carcinoma. *Eur J Endocrinol* 2022; 186(6):631-643

Berlenga P, Pierron G, Lacroix L, Chicard M, Adam de Beaumais T, Marchais A, Harttrampf AC, Iddir Y, Larive A, Soriano Fernandez A, Hezam I, Chevassus C, Bernard V, Cotteret S, Scoazec JY, Gauthier A, Abbou S, Corradini N, Andre N, Aerts I, Thebaud E, Casanova M, et al. The European MAPPYACTS trial: Precision Medicine Program in Pediatric and Adolescent Patients with Recurrent Malignancies. *Cancer Discov* 2022; 12(5):1266-1281

Fischer M, Moreno L, Ziegler DS, Marshall LV, Zwaan CM, Irwin MS, Casanova M, et al. Ceritinib in paediatric patients with anaplastic lymphoma kinase-positive malignancies: an open-label, multicentre, phase 1, dose-escalation and dose-expansion study. *Lancet Oncol* 2021; 22:1764-1776

Gaspar N, Campbell-Hewson Q, Gallego Melcon S, Locatelli F, Venkatramani R, Hecker-Nolting S, Gambart M, Bautista F, Thebaud E, Aerts I, Morland B, Rossig C, Canete Nieto A, Longhi A, Lervat C, Entz-Werle N, Strauss SJ, Marec-Berard P, Okpara CE, He C, Dutta L, Casanova M. Phase I/II study of single-agent lenvatinib in children and adolescents with refractory or relapsed solid malignancies and young adults with osteosarcoma (ITCC-050)*. *ESMO Open* 2021; 6:100250

Varlet P, Bouffet E, Casanova M, et al. Comprehensive analysis of the ErbB receptor family in pediatric nervous system tumors and rhabdomyosarcoma. *Pediatr Blood Cancer* 2021; 21:e29316

Pearson ADJ, Barry E, Mossé YP, Ligas F, Bird N, de Rojas T, Zimmerman ZF, Wilner K, Woessmann W, Weiner S, Weigel B, Venkatramani R, Valteau D, Trahair T, Smith M, Singh S, Selvaggi G, Scobie N, Schleiermacher G, Richardson N, Park J, Nysom K, Norga K, Merino M, McDonough J, Matloub Y, Marshall LV, Lowe E, Lesa G, Karres D, Gajjar A, Doz F, Fox E, DuBois SG, Donoghue M, Casanova M, et al. Second Paediatric Strategy Forum for anaplastic lymphoma kinase (ALK) inhibition in paediatric malignancies: ACCELERATE in collaboration with the European Medicines Agency with the participation of the Food and Drug Administration. *Eur J Cancer* 2021; 157:198-213

Gaspar N, Venkatramani R, Hecker-Nolting S, Melcon SG, Locatelli F, Bautista F, Longhi A, Lervat C, Entz-Werle N, Casanova M, et al. Lenvatinib with etoposide plus ifosfamide in patients with refractory or relapsed osteosarcoma (ITCC-050): a multicentre, open-label, multicohort, phase 1/2 study. *Lancet Oncol* 2021; 22 (9):1312-1321

Defachelles AS, Bogart E, Casanova M, et al. Randomized phase II trial of vincristine-irinotecan with or without Temozolomide, in children and adults with relapsed or refractory rhabdomyosarcoma: a European Paediatric Soft tissue Sarcoma Study Group and Innovative Therapies for Children with Cancer Trial. *J Clin Oncol* 2021; 39:2979-2990

Mahajan P, Casanova M, et al. Inflammatory myofibroblastic tumor: molecular landscape, targeted therapeutics, and remaining challenges. *Curr Probl Cancer* 2021; 45:100768

Cameron AL, Elze MC, Casanova M, et al. European Paediatric Soft Tissue Sarcoma Study Group (EpSSG) and the European Innovative Therapies for Children with Cancer (ITCC) Consortium. The impact of radiation therapy in children and adolescents with metastatic rhabdomyosarcoma. *Int J Radiat Oncol Biol Phys* 2021; 111 (4):968-978

Ferrari A, van Noesel MM, Brennan B, Zanetti I, Corradini N, Casanova M, et al. Paediatric non-rhabdomyosarcoma soft tissue sarcomas: the prospective NRSTS 2005 study by the European Pediatric Soft Tissue Sarcoma Study Group (EpSSG). *Lancet Child Adolesc Health* 2021; 5:546-558



Ben-Ami T, Kontny U, Surun A, Brecht IB, Almaraz RL, Dragomir M, Pourtsidis A, Casanova M, et al. Nasopharyngeal carcinoma in children and adolescents: The EXPeRT/PARTNER diagnostic and therapeutic recommendations. *Pediatr Blood Cancer* 2021; 12:e29018

Sparber-Sauer M, Orbach D, Navid F, Hettmer S, Skapek S, Corradini N, Casanova M, et al. Rationale for the use of tyrosine kinase inhibitors in the treatment of paediatric desmoid-type fibromatosis. *Br J Cancer* 2021; 124:1637-1646

Orbach D, Sparber-Sauer M, Laetsch TW, Minard-Colin V, Bielack SS, Casanova M, et al. Spotlight on the treatment of infantile fibrosarcoma in the era of neurotrophic tropomyosin receptor kinase inhibitors: International consensus and remaining controversies. *Eur J Cancer* 2020; 137:183-192

Amoroso L, Castel V, Bisogno G, Casanova M, et al. Phase II results from a phase I/II study to assess the safety and efficacy of weekly nab-paclitaxel in paediatric patients with recurrent or refractory solid tumours: A collaboration with the European Innovative Therapies for Children with Cancer Network. *Eur J Cancer* 2020; 135:89-97

Casanova M, et al. How young patients with cancer perceive the Covid-19 (coronavirus) epidemic in Milan, Italy: is there room for other fears? *Pediatr Blood Cancer* 2020; e28318

Casanova M, et al. Inflammatory myofibroblastic tumor: The experience of the European pediatric Soft Tissue Sarcoma Study Group (EpSSG). *Eur J Cancer* 2020; 127:123-129

Ferrari A, Merks JHM, Chisholm JC, Orbach D, Brennan B, Gallego S, van Noesel MM, McHugh K, van Rijn RR, Gaze MN, Martelli H, Bergeron C, Corradini N, Minard-Colin V, Bisogno G, Georger B, Caron HN, De Salvo GL, Casanova M. Outcomes of metastatic non-rhabdomyosarcoma soft tissue sarcomas (NRSTS) treated within the BERNIE study: a randomised, phase II study evaluating the addition of bevacizumab to chemotherapy. *Eur J Cancer* 2020; 130:72-80

Georger B, Zwaan CM, Marshall LV, Michon J, Bourdeaut F, Casanova M, et al. Atezolizumab for children and young adults with previously treated solid tumours, non-Hodgkin lymphoma, and Hodgkin lymphoma (iMATRIX): a multicentre phase 1-2 study. *Lancet Oncol* 2020; 21:134-144

Bisogno G, De Salvo GL, Bergeron C, Gallego Melcón S, Merks JH, Kelsey A, Martelli H, Minard-Colin V, Orbach D, Glosli H, Chisholm J, Casanova M, et al; European paediatric Soft tissue sarcoma Study Group. Vinorelbine and continuous low-dose cyclophosphamide as maintenance chemotherapy in patients with high-risk rhabdomyosarcoma (RMS 2005): a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol* 2019; 20:1566-1575

Albert CM, Davis JL, Federman N, Casanova M, Laetsch TW. TRK Fusion Cancers in Children: A Clinical Review and Recommendations for Screening. *J Clin Oncol* 2019; 37:513-524

Ferrari A, Orbach D, Affinita MC, Chiaravalli S, Corradini N, Meazza C, Bisogno G, Casanova M. Evidence of hydroxyurea activity in children with pretreated desmoid-type fibromatosis: A new option in the armamentarium of systemic therapies. *Pediatr Blood Cancer* 2018; e27472

Moreno L, Casanova M, et al. Phase I results of a phase I/II study of weekly nab-paclitaxel in paediatric patients with recurrent/refractory solid tumours: A collaboration with Innovative Therapies for Children with Cancer. *Eur J Cancer* 2018; 100:27-34

Carceller F, Bautista F, Jiménez I, Hladun-Álvaro R, Giraud C, Bergamaschi L, Dandapani M, Aerts I, Doz F, Frappaz D, Casanova M, et al. Outcome of children and adolescents with central nervous system tumors in phase I trials. *J Neurooncol* 2018; 137:83-92

Bertolini G, Bergamaschi L, Ferrari A, Renne SL, Collini P, Gardelli C, Barisella M, Centonze G, Chiaravalli S, Paolino C, Milione M, Massimino M, Casanova M, et al. PD-L1 assessment in pediatric rhabdomyosarcoma: a pilot study. *BMC Cancer* 2018; 18:652

Chisholm JC, Suvada J, Dunkel IJ, Casanova M, et al. BRIM-P: A phase I, open-label, multicenter, dose-escalation study of vemurafenib in pediatric patients with surgically incurable, BRAF mutation-positive melanoma. *Pediatr Blood Cancer* 2018; 65:e26947

Laetsch TW, Nagasubramanian R, Casanova M. Targeting NTRK fusions for the treatment of congenital mesoblastic nephroma. *Pediatr Blood Cancer* 2018; 65(1)

Pearson ADJ, Pfister SM, Baruchel A, Bourquin JP, Casanova M, et al; Executive and biology committees of the Innovative Therapies for Children with Cancer European Consortium. From class waivers to precision medicine in paediatric oncology. *Lancet Oncol* 2017; 18:e394-e404. Review



FONDAZIONE IRCCS
"ISTITUTO NAZIONALE
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Kieran MW, Chisholm J, Casanova M, et al. Phase I study of oral sonidegib (LDE225) in pediatric brain and solid tumors and a phase II study in children and adults with relapsed medulloblastoma. *Neuro Oncol* 2017; 19:1542-1552

Casanova M, et al. Response to pazopanib in two pediatric patients with pretreated relapsing synovial sarcoma. *Tumori* 2017; 21; 103:e1-e3

Gasparini P, Casanova M, et al. Anaplastic lymphoma kinase aberrations correlate with metastatic features in pediatric rhabdomyosarcoma. *Oncotarget* 2016; 7:58903-58914

Carceller F, Bautista FJ, Jiménez I, Hladun-Álvaro R, Giraud C, Bergamaschi L, Dandapani M, Aerts I, Doz F, Frappaz D, Casanova M, et al. Prognostic factors of overall survival in children and adolescents enrolled in dose-finding trials in Europe: An Innovative Therapies for Children with Cancer study. *Eur J Cancer* 2016; 67:130-140

Casanova M, et al. International randomized phase 2 study on the addition of docetaxel to the combination of cisplatin and 5-fluorouracil in the induction treatment for nasopharyngeal carcinoma in children and adolescents. *Cancer Chemother Pharmacol* 2016; 77:289-298

Casanova M, et al. Vinorelbine and low-dose cyclophosphamide in pediatric sarcomas: pilot study for the future European Rhabdomyosarcoma Protocol. *Cancer* 2004; 101:1664-1671

Casanova M, et al. Vinorelbine in previously treated advanced childhood sarcomas: evidence of activity in rhabdomyosarcoma. *Cancer* 2002; 94:3263-3268

ESPERIENZA IN SPERIMENTAZIONE CLINICA:

Principal Investigator e sub-investigatore in numerosi protocolli clinici accademici e sponsorizzati in collaborazione con varie case farmaceutiche.

Principal Investigator nei seguenti studi:

1. Open-label, multi-centre, randomized phase II study evaluating the addition of bevacizumab to chemotherapy for childhood and adolescent patients presenting with metastatic rhabdomyosarcoma and non-rhabdomyosarcoma soft tissue sarcoma (the BERNIE study). EudraCT 2005-000217-35
2. Phase 2 single-arm studies of gemcitabine in combination with oxaliplatin in refractory and relapsed pediatric solid tumors. EudraCT 2006-001065-41
3. International randomized study to evaluate the addition of docetaxel to the combination of cisplatin-5-fluorouracil (TCF) vs. cisplatin-5-fluorouracil (CF) in the induction treatment of nasopharyngeal carcinoma (NPC) in children and adolescents. EudraCT 2007-001211-33
4. Phase 2 single-arm studies of temozolomide in combination with topotecan in refractory or relapsing neuroblastoma and other paediatric solid tumor. EudraCT 2008-001436-12
5. A phase 1 study of LDE225 in pediatric patients with recurrent or refractory medulloblastoma or other tumors potentially dependent on the Hedgehog-signaling pathway. EudraCT 2010-019348-37
6. International randomized phase II trial of the combination of vincristine and irinotecan with or without temozolomide (VI or VIT) in children and adults with refractory or relapsed rhabdomyosarcoma. EudraCT 2010-023135-42
7. A Phase I, open-label, dose escalation study of LDK378 in pediatric patients with malignancies that have a genetic alteration in anaplastic lymphoma kinase (ALK). EudraCT 2012-002074-31
8. A phase II, multi-center, open-label, single-arm study of the efficacy and safety of oral LDE225 in patients with Hh-pathway activated relapsed medulloblastoma. EudraCT 2012-003066-40
9. A phase 1/2, multicenter, open-label, dose finding study to assess the safety, tolerability, and preliminary efficacy of weekly nab®-paclitaxel in pediatric patients with recurrent or refractory solid tumors. EudraCT 2013-000144-26
10. Phase 1/2 Study of Lenvatinib in Children and Adolescents with Refractory or Relapsed Solid Malignancies. EudraCT 2013-005534-38
11. A multi-center, open-label, non-randomized, phase I dose escalation study of regorafenib (BAY 73-4506) in pediatric subjects with solid malignant tumors that are recurrent or refractory to standard therapy. EudraCT 2013-003579-36



12. An early-phase, multicenter, open-label study of the safety and pharmacokinetics of anti-PDL1 antibody (MPDL3280A) in pediatric and young adult patients with previously treated solid tumors. EudraCT 2014-004697-41
13. Phase I open label, dose escalation trial to determine the MTD, safety, PK and efficacy of afatinib monotherapy in children aged 2 years to <18 years with recurrent/refractory neuroectodermal tumours, rhabdomyosarcoma and/or other solid tumours with known ErbB pathway deregulation regardless of tumour histology. EudraCT 2014-002123-10
14. A Phase I/II, multicenter, open-label, dose-escalation study of the safety and pharmacokinetics of cobimetinib in pediatric and young adult patients with previously treated solid tumors. EudraCT 2014-004685-25
15. A Phase 1 study of the EZH2 inhibitor tazemetostat in pediatric subjects with relapsed or refractory INI1-Negative tumors or Synovial Sarcoma. EudraCT 2015-002468-18
16. Molecular Profiling for Pediatric and Young Adult Cancer Treatment Stratification – MAPPYACTS. Registration number: 2015-A00464-45
17. A phase 1B of crizotinib either in combination or as single agent in pediatric patients with ALK, ROS1 or MET positive malignancies (Study ITCC 053). EudraCT 2015-005437-53
18. A Phase 1/2 Study of the Oral TRK Inhibitor LOXO-101 in Pediatric Patients with Advanced Solid or Primary Central Nervous System Tumors. EudraCT 2016-003498-16
19. A Phase 1/2 single-arm study evaluating the safety and efficacy of eribulin mesilate in combination with irinotecan in children with refractory or recurrent solid tumors. EudraCT 2016-003352-67
20. European Proof-of-Concept Therapeutic Stratification Trial of Molecular Anomalies in Relapsed or Refractory Tumors - ESMART. EudraCT 2016-000133-40
21. A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers. EudraCT 2017-004246-20
22. A Phase 1/2 Study of Oral RET Inhibitor LOXO-292 in Pediatric Patients with Advanced RET-Altered Solid or Primary Central Nervous System Tumors. EudraCT 2019-000212-28
23. A Phase 1/2, open-label, dose-escalation and expansion study of entrectinib (RXDX-101) in pediatrics and young adults with no curative first-line treatment option or recurrent/refractory solid tumors and primary CNS tumors. EudraCT 2019-001155-39
24. An Open-Label, Multicenter Phase 2 Basket Study to Evaluate the Antitumor Activity and Safety of lenvatinib in Children, Adolescents, and Young Adults with Relapse or Refractory Solid Malignancies. EudraCT 2019-004441-33
25. Tumor-agnostic precision immuno-oncology and somatic targeting rational for you (Tapistry) phase II platform trial. EudraCT 2020-001847-16
26. A phase 1/2, open-label, multicenter study evaluating the safety, PK and efficacy of alectinib in pediatric patients with ALK fusion-positive solid or CNS tumors from whom prior treatment has proved to be ineffective or from whom there is no curative standard treatment available. EudraCT 2020-004239-25
27. A Phase 1/2, Single-arm Study to Evaluate the Safety, Pharmacokinetics, and Antitumor Activity of Avapritinib in Pediatric Patients with Solid Tumors Dependent on KIT or PDGFRA Signaling. EudraCT 2020-005234-15
28. A Phase 1/2, Open-label, Safety, Tolerability, Pharmacokinetics, and Anti-tumor Activity Study of Repotrectinib in Pediatric and Young Adult Subjects with Advanced or Metastatic Malignancies Harboring ALK, ROS1, or NTRK1-3 Alterations (CARE). EudraCT 2019-003055-11

Sub- Investigator nei seguenti studi:

1. Phase 1/2 Study of lenvatinib in children and adolescents with refractory or relapsed solid malignancies and young adults with osteosarcoma. EudraCT 2013-005534-38
2. International randomised controlled trial of chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma. EudraCT 2014-000259-99
3. Phase II open-label global study to evaluate the effect of dabrafenib in combination with trametinib in children and adolescent patients with BRAF V600 mutation positive Low Grade Glioma (LGG) or relapsed or refractory High Grade Glioma (HGG). EudraCT 2015-004015-20
4. A phase 2 clinical study of pomalidomide (CC-4047) monotherapy for children and young adults with recurrent or progressive primary brain tumors. EudraCT 2016-002903-25
5. A randomized, open-label, safety and efficacy study of ibrutinib in pediatric and young adult patients with relapsed or refractory mature B-cell non-Hodgkin lymphoma. EudraCT 2016-000259-28



6. A pivotal phase 2 trial of antibody naxitamab (hu3F8) and Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) in high-risk neuroblastoma patients with primary refractory disease or incomplete response to salvage treatment in bone and/or bone marrow. EudraCT 2017-001829-40
7. 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 hematological malignancies. EudraCT 2018-003118-42
8. A multicenter, open-label phase 1b study of the combination of binimetinib and encorafenib in adolescent patients with unresectable or metastatic *BRAF* V600-mutant melanoma (Clinical study ARRAY-162-115). EudraCT 2018-001946-32
9. An open-label, single-arm, phase 1/2 study evaluating the safety and efficacy of ponatinib for the treatment of recurrent or refractory leukemias or solid tumors in pediatric participants. EudraCT 2018-004878-99
10. A randomized, open-label phase 1/2 study evaluating ramucirumab in pediatric patients and young adults with relapsed, recurrent, or refractory desmoplastic small round cell tumor. EudraCT 2018-004242-42
11. A randomized, open-label phase 1/2 study evaluating ramucirumab in pediatric patients and young adults with relapsed, recurrent, or refractory synovial sarcoma. EudraCT 2018-004243-23
12. A phase 1 study of aurora kinase a inhibitor LY3295668 erbumine as a single agent and in combination in patients with relapsed/refractory neuroblastoma. EudraCT 2019-001042-18
13. Phase 1/2 study of bempegaldesleukin in combination with nivolumab in children, adolescents, and young adults with recurrent or refractory malignancies (PIVOT IO 020). EudraCT 2020-000854-85
14. Phase I/II multicenter study to assess efficacy and safety of ribociclib (LEE011) in combination with topotecan and temozolomide (TOTEM) in pediatric patients with relapsed or refractory neuroblastoma and other solid tumors. EudraCT 2021-005617-14