AIEOP
ASSOCIAZIONE ITALIANA EMATOLOGIA ONCOLOGIA PEDIATRICA

Presidente
A. Mastronuzzi

Segreteria Scientifica
A. Colombini, T. Perillo, A. Zibaldo

Giornate AIEOP

RIMINI
Hotel Savoia

13-14 aprile 2026

LINFOMI NON HODGKIN

Marta Pillon

Azienda Ospedaliera Università di Padova

Disclosures of Name Surname

Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other
TAKEDA					x		
JAZZ						x	
PIERRE FABRE					x		

Resoconto attività 2025-26

- Gruppo europeo EICNHL (6th SIOPE), Budapest, 12-13 Maggio 2025

- The 8th International Symphosium on Childhood, Adolescent and Young Adult Non-Hodgkin's Lymphoma, New York, 26-28 Settembre 2025

- XL Congresso Nazionale AIEOP, Roma, 22-23 Settembre 2025

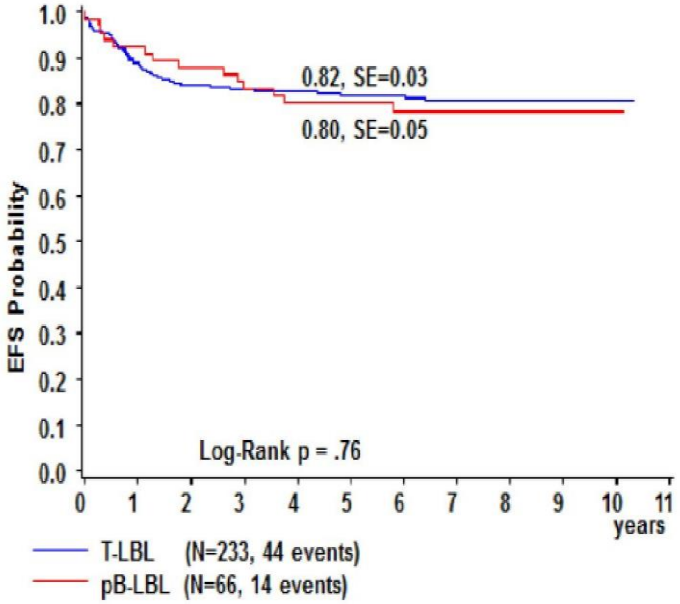
- EICNHL meeting, Padova, 24-25 Novembre 2025

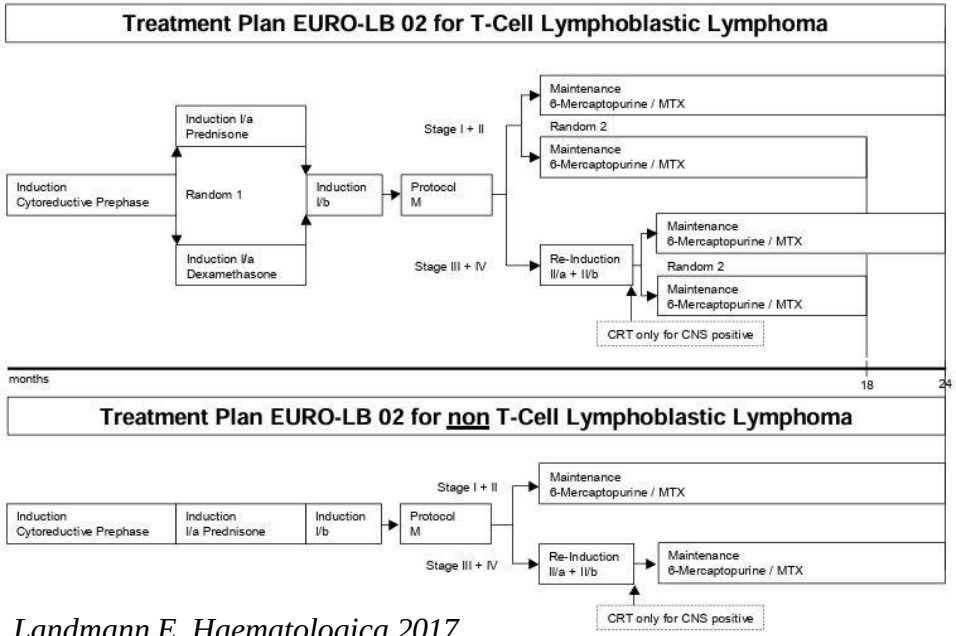
- GdL LNH 19.03.2026 – Virtual

- Riunioni del gruppo EICNHL ristretto- Virtual

Linfoma Linfoblastico

Protocollo EURO-LB02 (no random)





Landmann E, Haematologica 2017
(Stop random 2008)

LBL 2018

International cooperative treatment protocol for children and adolescents with lymphoblastic lymphoma

EudraCT- Nr.: 2017-001691-39
(EU-CT Nr.: 2023-508101-24-00)

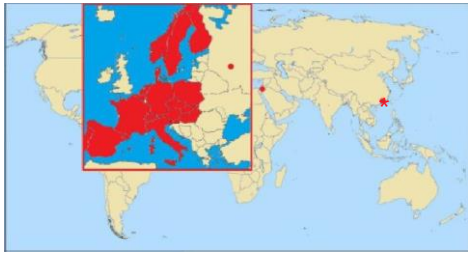
Sponsor:
Universitätsklinikum Münster
Albert-Schweitzer-Campus 1
48149 Münster

core study cohort

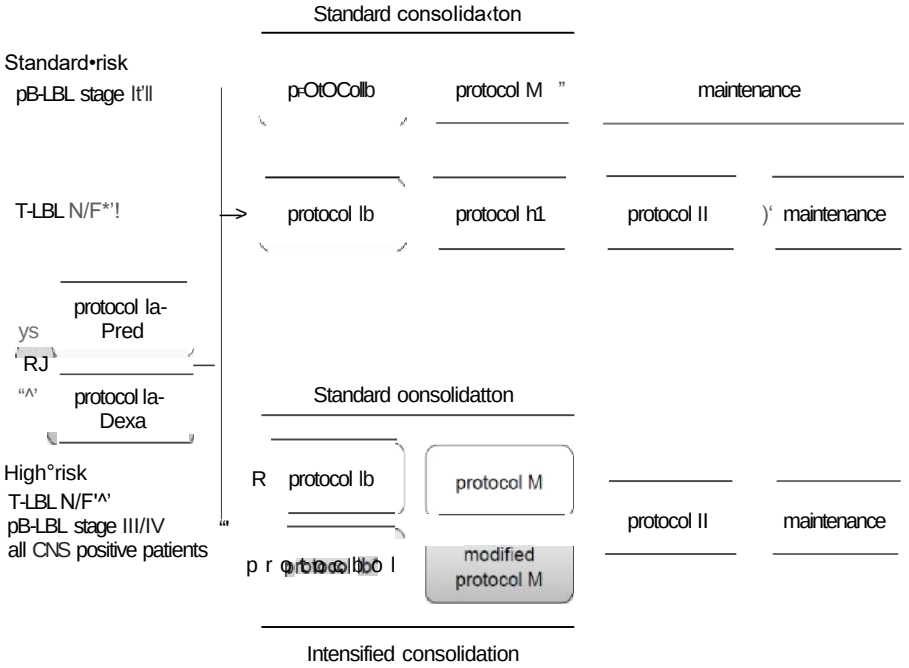
AIEOP	leafy
BFM	Aristria. Czech Republic. Gellleacy S 1tz=rlaiJd
BSPHO	Belg!um
CoALL	Germany
DCOG	The NetlnerlaiJ ds
NOPHO	Denmark. Finland fJo!'.a\ S'.eden
PPLSG	Polancl
SEHOP	Spain
SFCE	France
HKPHOSG	Hong Kong

extended study cohort

HPOG	HuiJgary
ISPHO	Israel
NSPHO	Mosco'.'
SHOP	Portugal
SPS	SlovaL RepulJlic

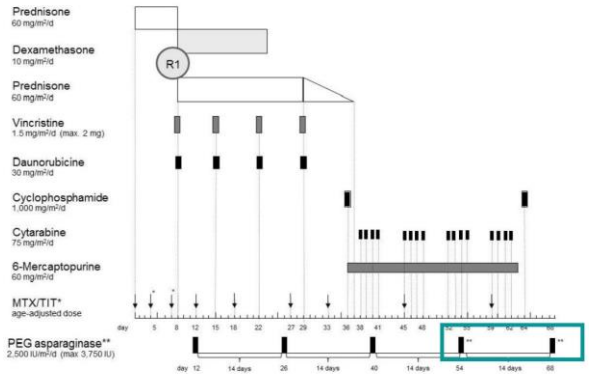


LBL 2018 - Treatment plan



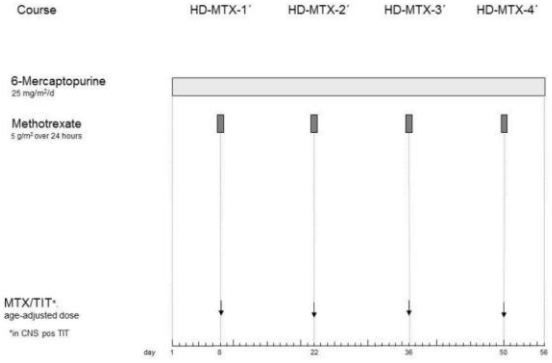
16.4 Schema of induction protocol I

R2 intensified arm



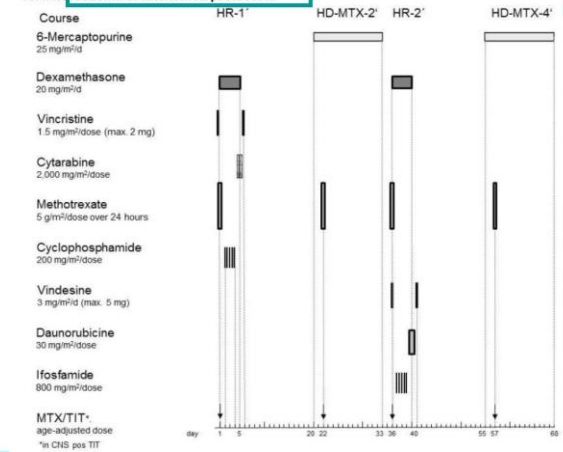
*in CNS pos pts twice weekly until clearance of blasts, 1st dose MTX IT, then TIT; **please strictly adhere to 14-day interval

16.4.4.4 Schema of protocol M

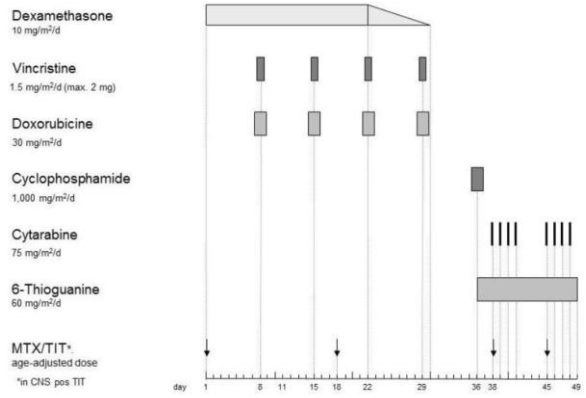


16.4.4.5 Schema of intensified protocol M

R2 intensified arm



16.4.5 Schema of reintensification phase - Protocol II

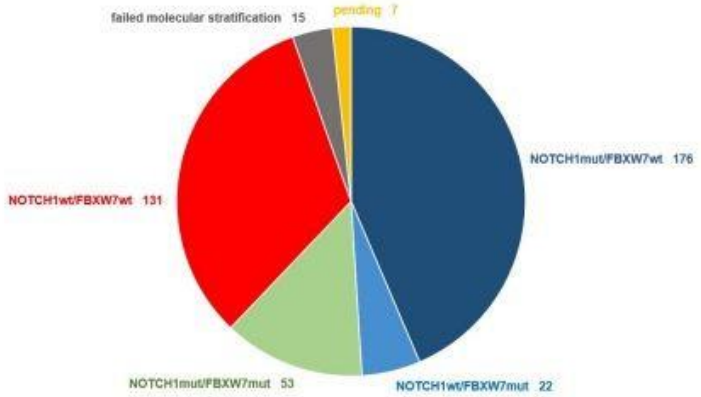


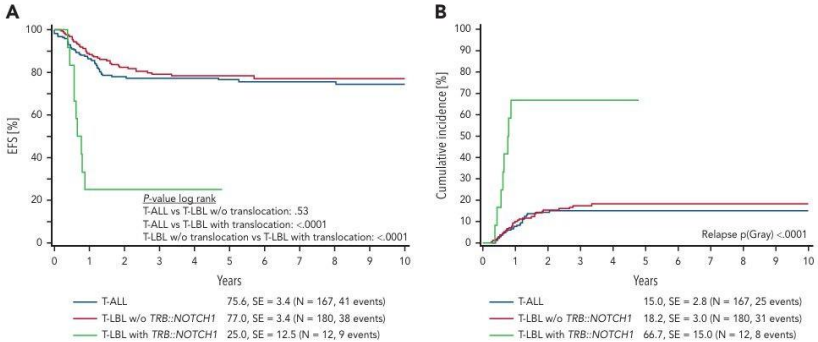
NOTCH1/FBXW7 (N/F) mutational status at diagnosis is employed for T-cell lymphoblastic lymphoma (T-LBL) patients stratification in the international protocol LBL 2018

Immunophenotype	N	%
T-LBL	407	79
pB-LBL	103	20
MPAL	7	1

Feasibility of molecular stratification in T-LBL

- recruited patients until August 31st, 2025: 517
- T-LBL: 407 **(79%)**
- successful molecular stratification: 382 (96 %)
- failed molecular stratification: 15 (4 %)





Te Vrugt et al, Blood 2024

Apertura ufficiale del primo centro AIEOP **giugno 2023**

Al 10/04/2026:

39 pazienti arruolati (4 esclusi per blasti > 25%, rev istologica)

26/28 centri aperti alla sperimentazione

STOP PREVISTO 11/11/24 → **NUOVA DEADLINE 01/04/2027**

OTTIMA COMPLIANCE ALL'INVIO DEL MATERIALE BIOLOGICO E ISTOLOGICO

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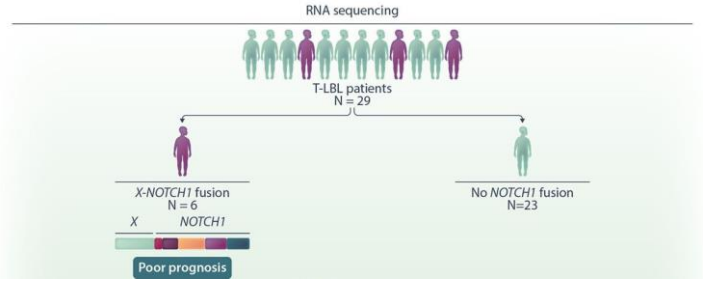
TARC levels as a non-invasive diagnostic biomarker

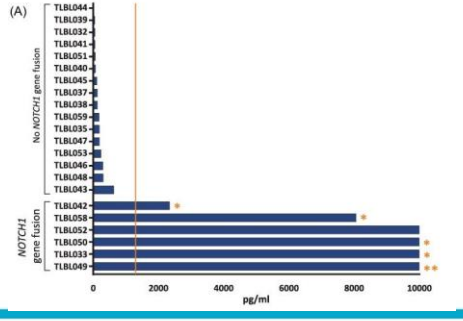
CCL17 measurements at diagnosis can be performed by ELISA assay using 100µl of serum or plasma.

- **Potential of TARC levels as a non-invasive diagnostic biomarker for identifying «very high-risk» T-LBL patients**

Upcoming Steps & Objective

Analyze a larger cohort of pediatric T-LBL patients to validate NOTCH1 gene fusions and TARC level results





Studi clinici di 2^ linea per r/r T-LNH

HEM-iSMART: International proof of concept therapeutic Stratification trial of Molecular Anomalies in Relapsed or Refractory HEMatological malignancies in children

- Pazienti < 18 years at first diagnosis with molecularly profiled R/R ALL/LBL
- Sponsor: Princess Máxima Center for Pediatric Oncology in collaboration with three pharmaceutical companies (Janssen, Novartis and ABBVIE).
- **Master Protocol and 4 Sub-Protocols**, each of which consists of a Phase I and a Phase II part. The sub-protocols will be running independently. The study will be open in around 36 sites in 15 countries.

- Sub protocol A: decitabina, venetoclax e navitoclax in r/r T-ALL/LBL in paz. apparentemente privi di alterazioni molecolari target.

- **Sub protocol B**: dasatinib, venetoclax, desametasone, ciclofosfamide e citarabina in paz. con alterazioni nella via Mitogen Activated Protein Kinase (MAPK)-SRC (**open**)

- **Sub protocol C**: ruxolitinib, venetoclax, desametasone, ciclofosfamide e citarabina in paz. con alterazioni della via IL7-R/JAKSTAT (Janus kinase (JAK)/signal transducer and activator of transcription) (**open**)

- **Sub protocol D**: trametinib, desametasone, ciclofosfamide e citarabina in paz. con alterazioni della via RAS-RAF-MAPK (**open**)

- **Sub protocol E**: capivasertinib, venetoclax, desametasone (**site feasibility**)

Non ancora aperto in Italia (Genova, Monza, Padova, Roma BG, Torino)

Recruiting

CD7-CAR-T Cells in Pediatric Relapsed/Refractory CD7+ T-ALULL (CD7-CAR01)

ClinicalTrials.gov ID @ NCT06064903

Sponsor @ Bambina Gesu Hospital and Research Instilule

Information provided by @ Bambino Gesu Hospital and Research Institute (Responsible Party)

Last Update Posted @ 2025-12-D2

LNH-B

PROTOCOLLI NAZIONALI ED INTERNAZIONALI IN USO:

- Protocollo **AIEOP LNH97+/- Rituximab**


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Rituximab for High-Risk, Mature B-Cell Non-Hodgkin's Lymphoma in Children

V. Minard-Colin, A. Aupérin, M. Pillon, G.A.A. Burke, D.A. Barkauskas, K. Wheatley, R.F. Delgado, S. Alexander, A. Uyttebroeck, C.M. Bollard, J. Zsiros, M. Csoka, B. Kazanowska, A.K. Chiang, R.R. Miles, A. Wotherspoon, P.C. Adamson, G. Vassal, C. Patte, and T.G. Gross, for the European Intergroup for Childhood Non-Hodgkin Lymphoma and the Children's Oncology Group*

- Protocollo **Inter B-NHL Ritux 2010**
  (2ys EFS: 93,9% Ritux vs 82,3% no Ritux)

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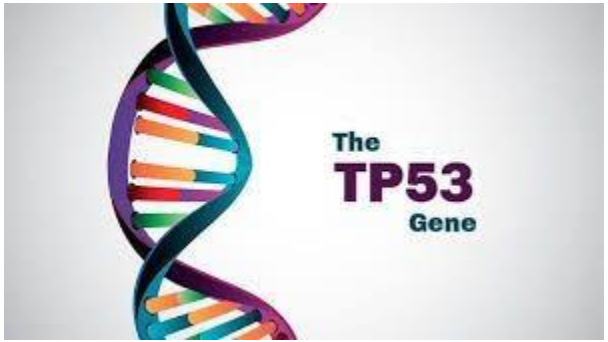
- Protocollo **NHL 2013** (BFM e NOPHO), in corso

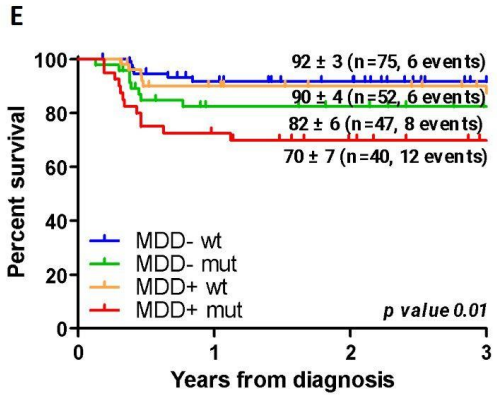
NHL BFM study centre

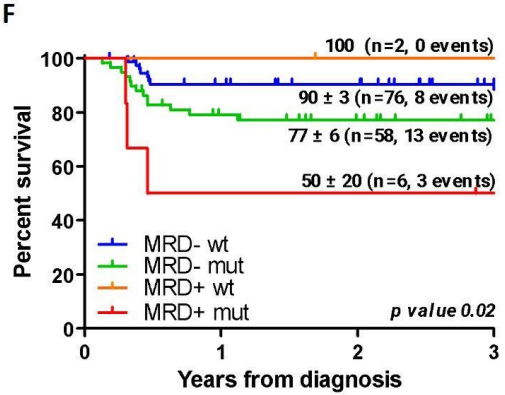
NOPHO



Nuovo marcatore molecolare per la stratificazione dei pazienti pediatrici affetti da linfoma di Burkitt e DLBCL

PATIENTS STRATIFICATION ACCORDING TO TP53 MUTATIONAL STATUS AND DISEASE DISSEMINATION





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Martire G et al, Haematologica 2024

UNIVARIATE AND MULTIVARIATE ANALYSIS BASED ON CLINICAL AND BIOLOGICAL CHARACTERISTICS

Patient characteristics		# Patients	# Events	3-y PFS % (SE%)	Univariate p-Value	Multivariate p-Value	Hazard Ratio (95% CI)
Gender	Male	180	24	86 (3)	0.088	n.s.	
	Female	34	8	76 (7)			
Median age (years)	<7,7	111	14	87 (3)	0.293	n.s.	
	≥7,7	103	18	85 (3)			
BM involvement*	No	188	27	80 (8)	0.518		
	Yes	26	5	77 (10)			
CNS involvement	No	200	30	84 (3)	0.968		
	Yes	14	2	85 (10)			
Risk group#	1-2-3 and B	45	1	98 (2)	0.01	n.s.	
	4 and C	166	30	81 (3)			
Stage°	1-2	38	1	97 (3)	0.0259	n.s.	
	3-4	176	31	82 (3)			
MDD	Neg	122	14	88 (3)	0.109	n.s.	
	Pos	92	18	80 (4)			
Rituximab	No	147	26	82 (3)	0.092	0.0318	0.4 (0.1-0.9)
	Yes	66	6	90 (4)			
TP53	WT	127	12	90 (3)	0.0055	0.0247	2.3 (1.1-4.9)
	Mut	87	20	77 (5)			

TP53 DNA binding domain mutational status and rituximab-based treatment are independent prognostic factors for pediatric Burkitt lymphoma patients stratification. *Martire G et al, Haematologica 2024*

B-NHL 2025 - Treatment protocol for mature B-cell lymphoma and leukemia in children and adolescents

- 5 anni di arruolamento + 2 follow-up
- 185 pazienti/anno, totale 925 pazienti
- Paesi coinvolti/numero pazienti attesi/anno: AIEOP; NHL-BFM; NOPHO; PPLLSG; SEHOP.
- Pazienti eleggibili: pazienti <18 aa con diagnosi di LNH-B/LLA-B (no PMLBL)

- Braccio W&W per linfomi rari
- Ridefinizione dei gruppi di rischio

→ possibile inizio Settembre 2026

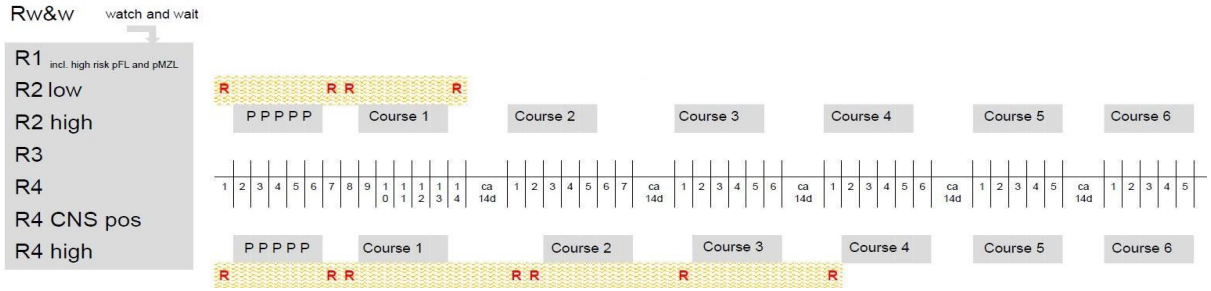
Stratification

risk group (RG)	stage and initial serum LDH level
RGw&w	pMZL and pFL
RG1	stage I + II, complete resection
RG2 low	stage I + II, incomplete resection
RG2 high	stage III and LDH < 2 x ULN (upper normal limit of local reference value for adults)
RG3	all stages, CNS-, LDH ≥ 2 x ULN but < 4 x ULN and all DLBCL stage III/IV with LDH < 4 x ULN
RG4	all stages, LDH ≥ 4 x ULN
RG5	RG3 and RG4 with *TP53*$^{mut\ (w/o\ R248Q)}$, MRD^{pos}

B-NHL 2025

Obiettivi:

- Ottimizzazione dell'**utilizzo di rituximab** (randomizzazione 4 rituximab vs 7 rituximab per tutti)
- **Riduzione della chemioterapia** classica (randomizzazione 2 e 3 secondo nuovi GR)
- Introdurre **intensificazione terapeutica** con nuovi farmaci per pazienti ad altissimo rischio



Endpoint primari:

- EFS
- QoL
- Tasso di non aderenza alla strategia W&W

Endpoint secondari:

- OS
- Frequenza tossicità e mortalità protocol related
- CIR
- Ricostituzione immunologica
- Biomarkers per predisposizione, risposta, rischio di ricaduta o tossicità

B-NHL 2025

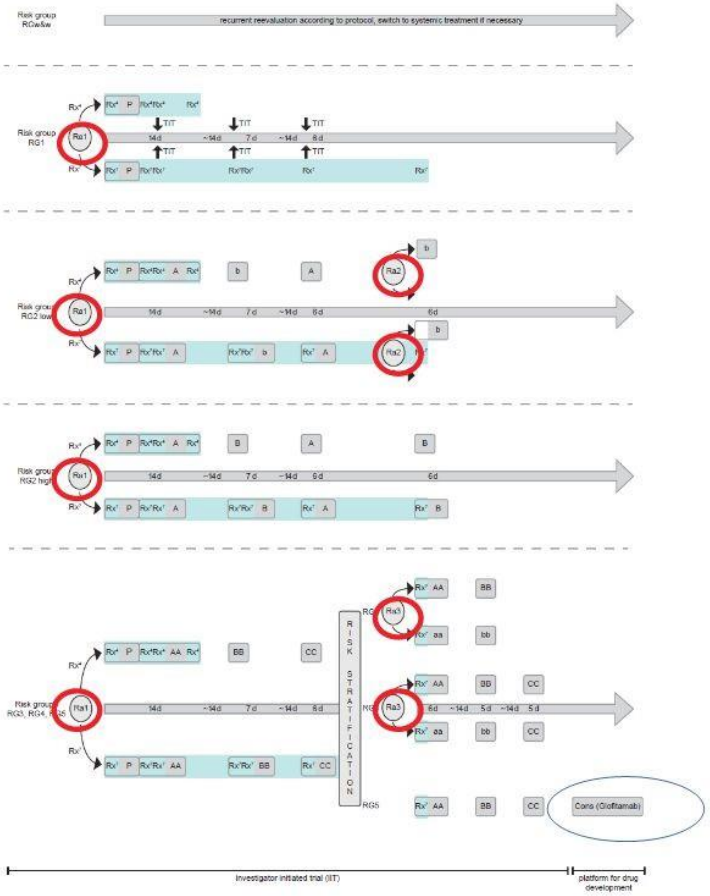
Protocollo prevede 3 randomizzazioni:

- numero rituximab
- riduzione antracicline
- intensificazione con anticorpo monoclonale bispecifico per very high risk

Stato di avanzamento:

- in lettura ai centri coordinatori partecipanti
- contatto con le aziende farmaceutiche per nuovi farmaci
- definizione di progetti ancillari

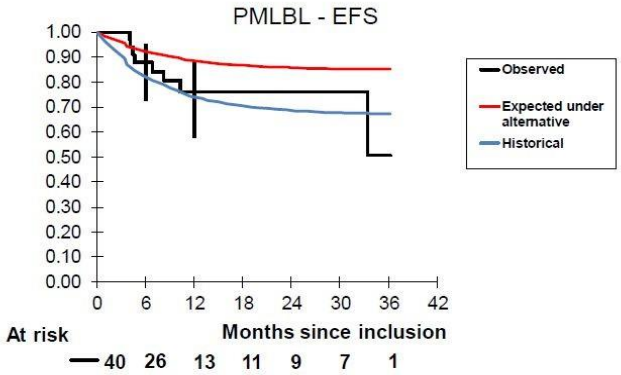
Avviate le procedure di start-up

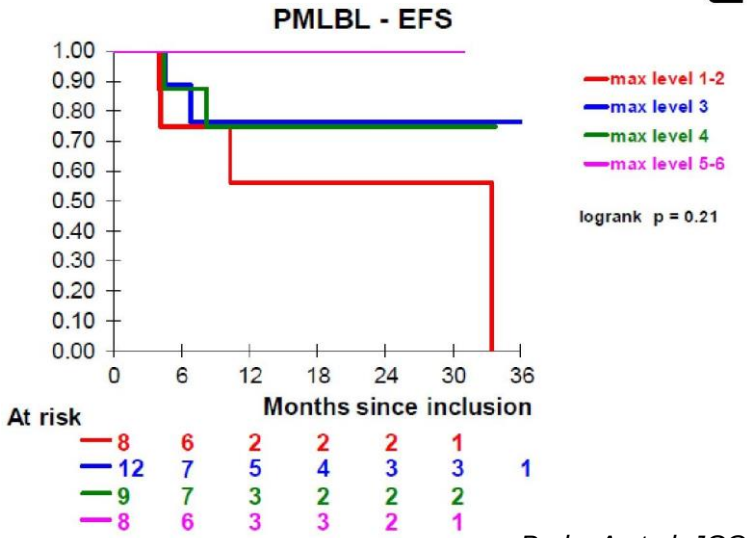


PMLBL: R-DA-EPOCH + rachicentesi

EFS rates:

	Observed rate (95%CI)	Expected rate under alternative $[0.67 + 0.33\{\exp(-1.5t)\}]^{0.406}$	Historical rate $0.67 + 0.33\{\exp(-1.5t)\}$
At 6 months	87.8% (72.6%-95.2%)	92.5%	82.6%
At 12 months	76.2% (57.9%-88.1%)	88.7%	74.4%





Burke A et al, JCO 2021

6 courses of EPOCH with rituximab, with dose adaptation (DA) at each course based on previous course ANC nadir

R-EPOCH | R-EPOCH | R-EPOCH | R-EPOCH | R-EPOCH | R-EPOCH

Doxorubicin, VCR, VP16 infused over 96h, no IT, no HDMTX

Woessmann W, NEJM 2013

DA-EPOCH-R Standard of care in (young) adults, current BFM treatment recommendation

or

LMB-based chemotherapy + Ritux (Inter-B-NHL ritux 2010 protocol)

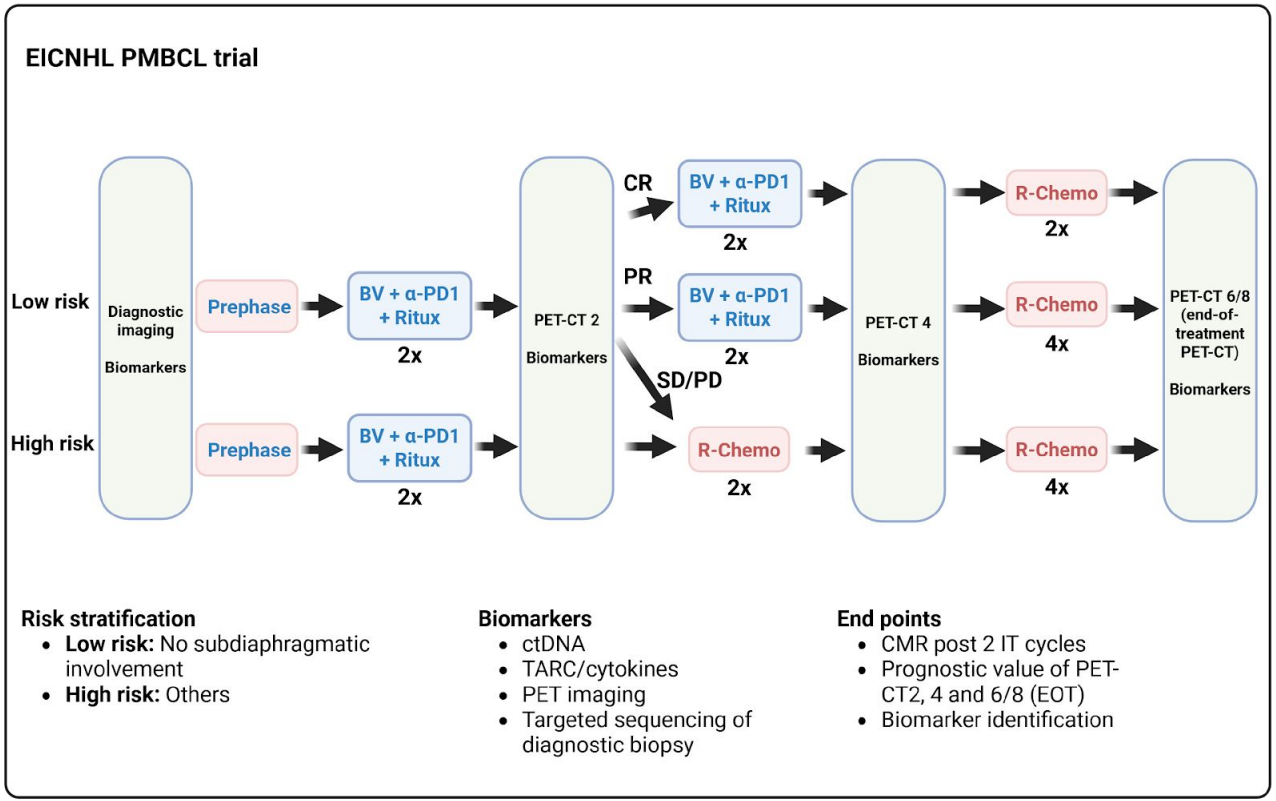
DA-EPOCH-R in adults, single center, uncontrolled phase II NCI study of 51 pts.: 5y EFS 93%/OS 97%

Table 2. Summary of Studies in Pediatric Patients With PMBCL

Reference	Regimen	Type of Study	n	Median Age	EFS (95% CI)	OS (95% CI)
Dourthe et al[25]	LMB2001	Prospective, multicenter	42	15 y	88% (75%–94.8%)	95.2% (84%–98.7%)
Knörr et al[24]	DA-EPCOH-R NHL-BFM-04 N95	Prospective, multicenter, retrospective comparison	116	16.2 y	DA-EPOCH-R: 84% (72%–91%) BFM-04: 59% (39%–74%) N95: 39% (19%–60%)	DA-EPOCH-R: 90% (79%–95%) BFM-04: 72% (51%–85%) N95: 70% (45%–85%)
Burke et al[11]	DA-EPCOH-R	Prospective, multicenter	46	15.4 y	69.6% (55.2%–80.9%)	84.8% (71.8%–92.4%)
Giulino-Roth et al[12]	DA-EPCOH-R	Retrospective, multicenter	38	16 y	81.0%	90.7%
Gerrard et al[23]	FAB/LMB96	Prospective, multicenter	42	15.7 y	66.0% (49%–78%)	73% (56%–84%)
Seidemann et al[22]	NHL-BFM 86/90/95	Pooled analysis	30	14.3 y	70%	

Forlenza CJ, Chadburn A, Giulino-Roth L.J Natl Compr Canc Netw. 2023 Mar;21(3):323-330.

PMLBL: proposal for a new treatment study



eicnhl

Studi clinici di 2^ linea per r/r B-LNH

RECRUITING

A Study to Evaluate **Glofitamab** Monotherapy and **Glofitamab** + Chemoimmunotherapy in Pediatric and Young Adult Participants With Relapsed/Refractory Mature B-Cell Non-Hodgkin Lymphoma (iMATRIX GLO)

ClinicalTrials.gov ID NCT05533775

Roma BG, Torino

RECRUITING

A Study to Evaluate the Safety, Tolerabili[illegible], [illegible]g Leve[illegible]s, and Preliminary Efficacy of Relatlimab Plus Nivolumab in Pediatric and Young Adult[illegible] With [illegible]odgk[illegible] and Non-Hodgkin Lymphoma (RELATIVITY-069)

ClinicalTrials.gov ID NCT05255601

Roma BG, Torino, Bologna, Firenze, Milano INT, Monza, Padova

RECRUITING

A Single Arm, Open-Label, Phase 1b Trial of Epcoritamab (bispecifi[illegible]ntib[illegible]dy ant[illegible]D3-CD20) in Pediatric Patients With Relapsed/Refractory Aggressive Mature B-cell Neoplasms

Roma BG, Firenze

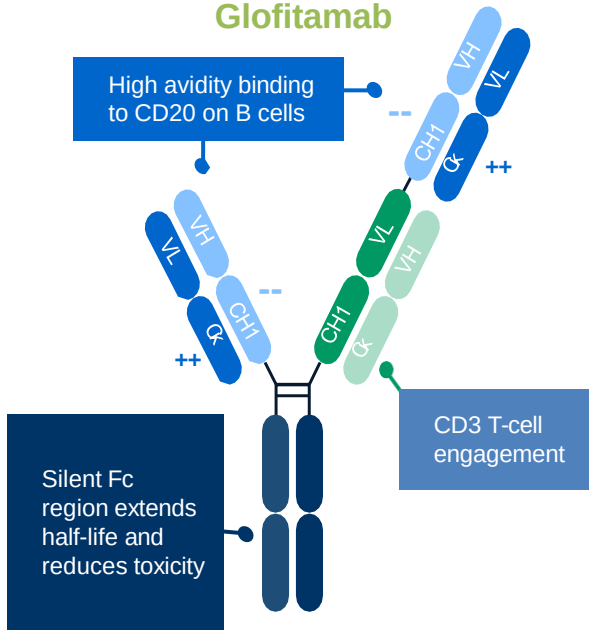
A phase I/II, open-label, single-arm, two-part trial to evaluate safety, Tolerability, pharmacokinetics, and anti-tumor activity of **Glofitamab** in Monotherapy and in combination with chemoimmunotherapy in pediatric and young adult participants with relapsed/refractory mature
B-cell non-hodgkin lymphoma

Glofitamab

- T cell-bispecific antibody targeting CD20 expressed on B cells and CD3ε chain present on T cells

Inclusion Criteria:

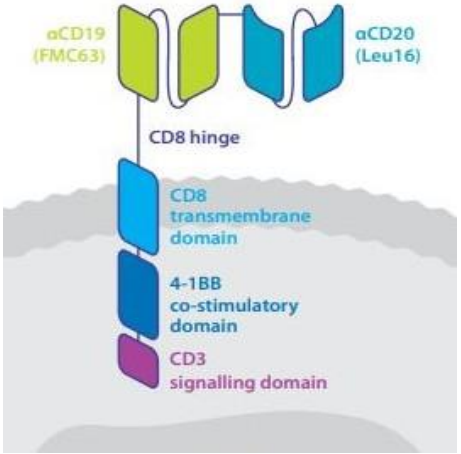
- Histologically re-confirmed diagnosis of mature B-cell non-Hodgkin lymphoma that expresses CD20 (reconfirmed by IHC) at the time of first R/R disease for Cohort A and second or greater R/R disease for Cohort B



A single-arm, multi-center, open-label Phase II study to determine the safety and efficacy of **MB-CART2019.1** in pediatric subjects with relapsed/refractory (r/r) mature B–cell neoplasms who have relapsed after one or more prior therapies, including subjects with primary refractory disease

MB-CART2019.1 (*zamtocabtagene autoleucel*)

- An autologous CD4-/CD8-enriched CAR T-cell therapy genetically engineered to target CD19 and CD20 on B cells



Inclusion Criteria:

Histologically confirmed mature CD19+ and/or CD20+ B-cell neoplasm (WHO 2022 classification) such as:

- Burkitt lymphoma/Burkitt leukemia
- Diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS)
- Primary mediastinal (thymic) large B-cell lymphoma
- Burkitt-like lymphoma with 11q aberration
- Other rare aggressive B-cell non-Hodgkin lymphoma (NHL)

FT04 PROTOCOL: ALLOGENEIC CARCIK-CD19 IN NHL

Sponsor: Fondazione Tettamanti - EU CT 2023-505511-20-00
CIK cells, non viral, transposon system, allogeneic setting

Patients

- Adult and paediatric (age ≥1 years)
- R/R CD19+ B-cell **NHL or CLL**
- ≥2 prior therapies
- Ineligible to commercially available CART due to age or comorbidities (including HIV)
- CIK cells, non viral, transposon system
- allogeneic setting, at least haplo donor

Primary objectives

- Safety and RP2D (Phase I)
- Efficacy (ORR) (Phase II)

Dose escalation (Phase I) and expansion (Phase II)

Donor: at least haploidentical (i.e. 4/8 HLA matched by allele typing)

Phase I
(3+3 design)
9-12 patients

DL1 7.5×10^6/Kg → **DL2** 15×10^6/Kg

Phase II (Simon Design)
Up to 17 patients

9 patients → 8 patients

≥3 CR/PR

Status: 16 adult patients enrolled, 10 infused (up to March 2026)
Pediatric enrollment expected since May 2026

Studi clinici di 2^ linea per r/r B-LNH

Glo-BNHL- prioritisation

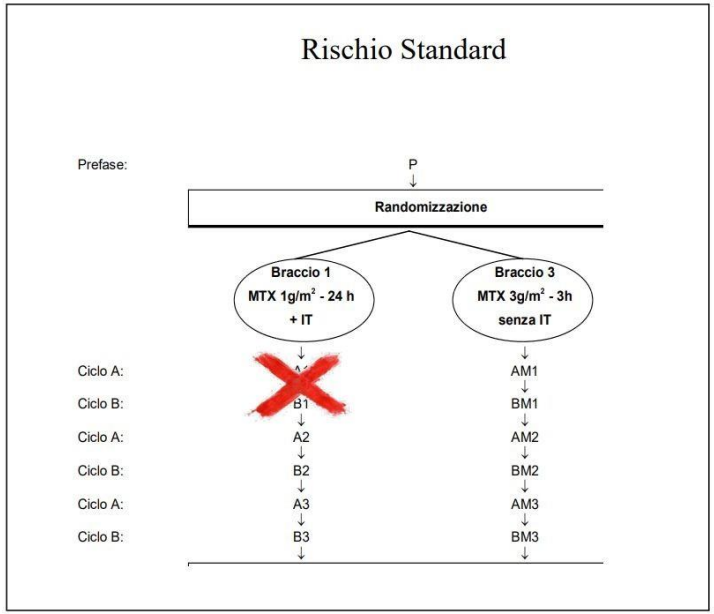
- Cohort 1: bispecific T-cell engager (BiTE)
- Cohort 2: antibody-drug conjugate (ADC) with standard chemotherapy
- Cohort 3: chimeric antigen receptor (CAR) T-cells (or haematopoietic stem cell transplant (HSCT))

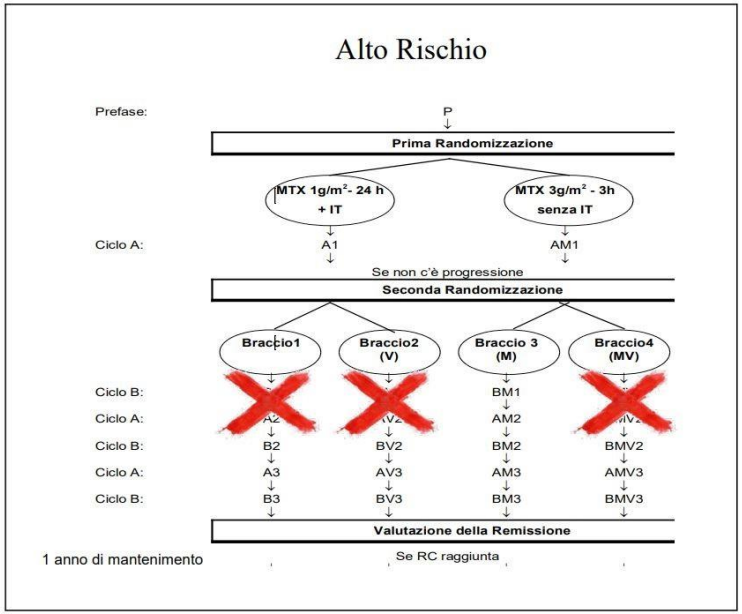
In Italia è in corso negoziazione del contratto con lo Sponsor

(UK recruiting)

Linfoma anaplastico

"INTERNATIONAL TRIAL ALCL 99"
PER IL TRATTAMENTO DEGLI ALCL – SENZA RANDOM





Frontline: VBL (Basso rischio)

Linfoma anaplastico

cancers
MDPI

Article

Prognostic Factors in Childhood Anaplastic Large Cell Lymphoma: Long Term Results of the International ALCL99 Trial

Lara Mussolin [1,2,*,†], Marié-Cecilé Le Deley [3,†], Elisa Carraro [1], Christine Damm-Welk [4], Andishe Attarbaschi [5], Denise Williams [6], Amos Burke [6], Keizo Horibe [7], Atsuko Nakazawa [8], Grazyna Wrobel [9], Georg Mann [5], Monika Csóka [10], Anne Uyttebroeck [11], Rafael Fernández-Delgado Cerdá [12], Auke Beishuizen [13], Karin Mellgren [14], Birgit Burkhardt [15], Wolfram Klapper [16], Suzanne D. Turner [17,18], Emanuele S.G. d'Amore [19], Laurence Lamant [20], Alfred Reiter [21], Wilhelm Woessmann [4], Laurence Brugières [22,‡], Marta Pillon [23,‡] and on behalf of the European Inter-Group for Childhood Non-Hodgkin lymphoma (EICNHL) [§]

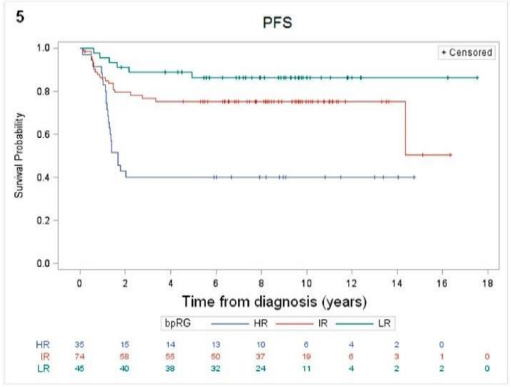
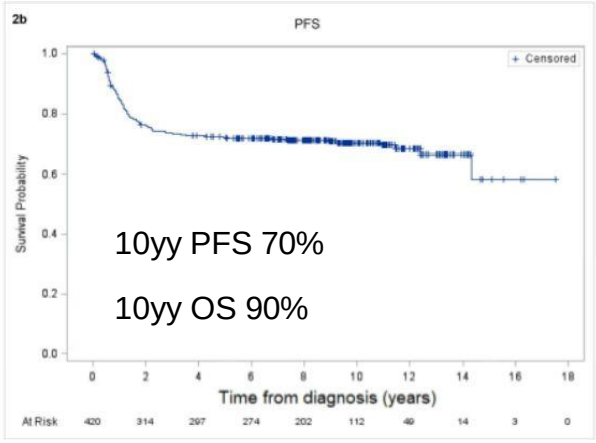


Figure 5. The 10-year PFS was 40% (SE ± 8%), 75% (SE ± 5%) and 86% (SE ± 5%) for bpHR (n = 35), bpIR (n = 74) and bpLR (n = 45), respectively (p < 0.0001).



10yy PFS 70%

10yy OS 90%

Histological subtype SC/LH (8 mv)	No	95	19	81 (4)	0.0006	0.009	2.4 (1.23–4.66)
	Yes	59	27	53 (7)			
MDD	Neg	75	12	83 (4)	0.001	0.038	2.15 (1.04–4.64)
	Pos	87	34	62 (5)			

Mussolin L et al, Cancers 2020

eicnhl

Contatto con le aziende farmaceutiche per nuovi farmaci

eicnhl
European Inter-Group for Childhood Non-Hodgkin Lymphoma

CHILDREN'S ONCOLOGY GROUP

Crizotinib in Combination With Chemotherapy for Pediatric Patients With ALK+ Anaplastic Large-Cell Lymphoma: The Results of Children's Oncology Group Trial ANHL12P1

Eric J. Lowe, MD[1]; Anne F. Reilly, MD, MPH[2]; Megan S. Lim, MD, PhD[3]; Thomas G. Gross, MD, PhD[4]; Lauren Saguilig, MS[5]; Donald A. Barkauskas, PhD[6]; Rui Wu, MD, PhD[3]; Sarah Alexander, MD[7]; and Catherine M. Bollard, MD[8]

TABLE 1. Chemotherapy Schedule

Course	Drug	Dose per Day	Schedule
Prophase (days 1-5)	Cyclophosphamide	200 mg/m^2 once a day	Days 1, 2
	Dexamethasone	5 mg/m^2 once a day 10 mg/m^2 divided twice per day	Days 1, 2 Days 3-5
	Triple intrathecal	Age-based	Day 1
Cycles 1, 3, 5	CZ	165 mg/m^2/dose twice a day	Day 1-21
	Methotrexate	3 g/m^2 over 3 hours	Day 1
	Dexamethasone	10 mg/m^2 divided twice per day	Days 1-5
	Ifosfamide	800 mg/m^2 once a day	Days 1-5
	Etoposide	100 mg/m^2 once a day	Days 4, 5
	Cytarabine	150 mg/m^2 twice per day	Days 4, 5
Cycles 2, 4, 6	CZ	165 mg/m^2/dose twice a day	Day 1-21
	Methotrexate	3 g/m^2 over 3 hours	Day 1
	Dexamethasone	10 mg/m^2 divided twice per day	Days 1-5
	Cyclophosphamide	200 mg/m^2 once per day	Day 1-5
	Doxorubicin	25 mg/m^2 once per day	Days 4, 5

Brentuximab vedotin in combination with chemotherapy for pediatric patients with ALK$^+$ ALCL: results of COG trial ANHL12P1

Eric J. Lowe,[1] Anne F. Reilly,[2] Megan S. Lim,[3] Thomas G. Gross,[4] Lauren Saguilig,[5] Donald A. Barkauskas,[6] Rui Wu,[3] Sarah Alexander,[7] and Catherine M. Bollard[8]

Table 2. Chemotherapy schedule

Course	Drug	Daily dose	Schedule
Prophase (days 1-5)	Cyclophosphamide Dexamethasone Triple intrathecal	200 mg/m^2 5 mg/m^2 10 mg/m^2 Age based	Days 1 and 2 Days 1 and 2 Days 3-5 Day 1
Cycles 1, 3, and 5	Brentuximab vedotin* Methotrexate Dexamethasone Ifosfamide Etoposide Cytarabine	1.8 mg/kg 3 g/m^2 over 3 h 10 mg/m^2 800 mg/m^2 100 mg/m^2 150 mg/m^2 × 2	Day 1 Day 1 Days 1-5 Days 1-5 Days 4 and 5 Days 4 and 5
Cycles 2, 4, and 6	Brentuximab vedotin* Methotrexate Dexamethasone Cyclophosphamide Doxorubicin	1.8 mg/kg 3 g/m^2 over 3 h 10 mg/m^2 200 mg/m^2 25 mg/m^2	Day 1 Day 1 Days 1-5 Day 1-5 Days 4 and 5

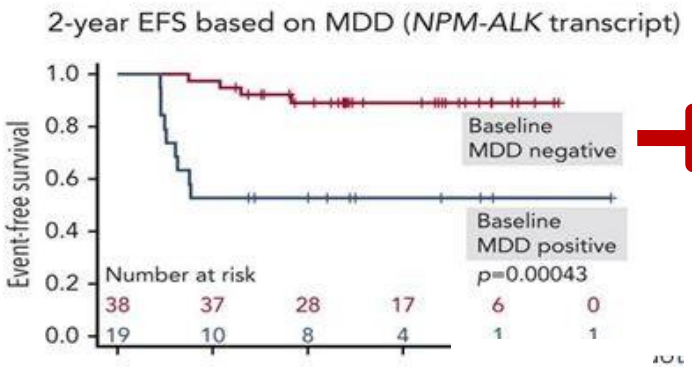
*Brentuximab vedotin was given prior to any other chemotherapy on day 1.

ANHL12P1 trial: studio randomizzato di fase 2.
Obiettivo primario: determinare efficacia e tossicità di **BV (EFS 79,1%-OS 97%)** e **Crizotinib (EFS 76,8% - OS 95,2%)** in pazienti ALCL CD30+
Conclusioni:
-Previene ricadute durante il trattamento
-Risultati di EFS/OS sovrapponibili allo storico - >> eventi tromboembolici per Crizotinib

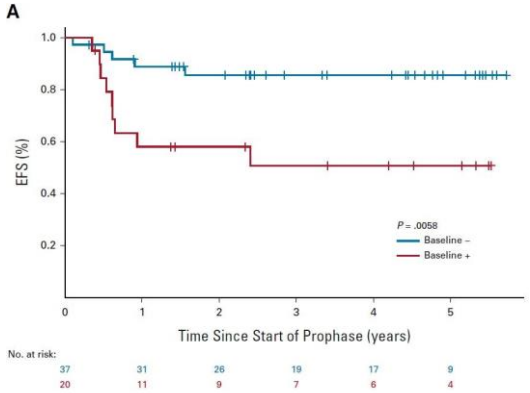
Lowe E, Blood 2021
Lowe E, JCO 2022

ALCL and MDD

BV



CRIZO



CHILDREN'S ONCOLOGY GROUP

Lowe E et al, Blood 2021; Lowe E et al, JCO 2022

CLINICAL TRIALS AND OBSERVATIONS

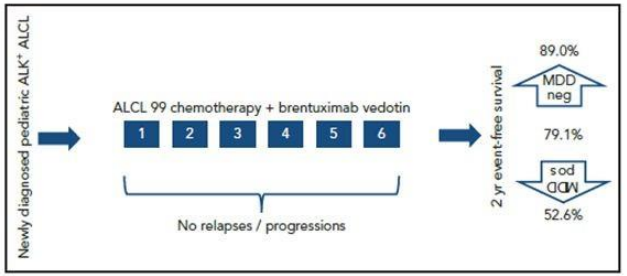
Comment on Lowe et al, page 3595

Brentuximab vedotin: frontline help in ALCL

G. A. Amos Burke | Cambridge University Hospitals NHS Foundation Trust

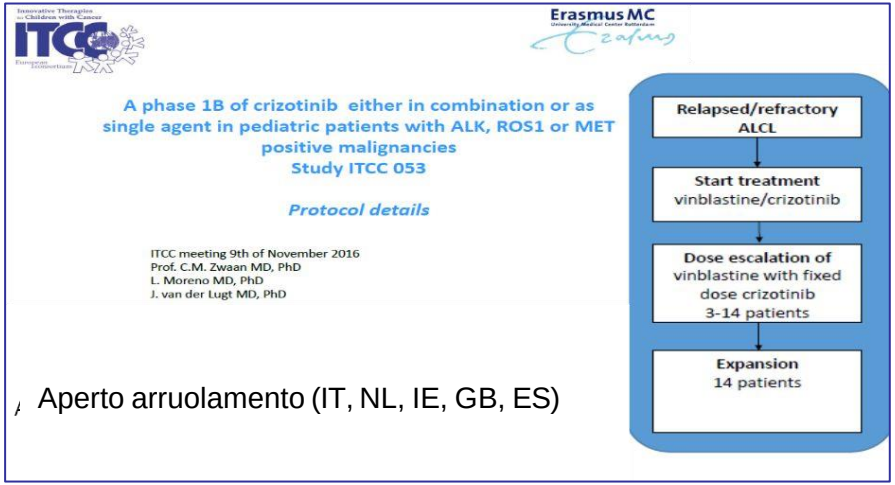
In this issue of *Blood*, Lowe et al present results of a phase 2 study combining brentuximab vedotin (BV) with standard chemotherapy in the treatment of newly diagnosed pediatric anaplastic lymphoma kinase–positive (ALK$^+$) anaplastic large-cell lymphoma (ALCL) and observe that it eliminated almost all relapses while receiving therapy, a significant breakthrough in the management of this disease.[1]

Burke GA, Blood 2021



- Importante ridurre le r/r in terapia vista la peggior prognosi
- BV può essere utilizzato in prima linea in associazione alle terapie standard o come singolo agente con l'obiettivo di ridurre la tossicità e aumentare l'efficacia
- Limite attuale: il BV non previene le ricadute SNC

Studi clinici di 2^ linea per r/r ALCL



Aperto arruolamento (IT, NL, IE, GB, ES)

Efficacy analysis of crizotinib at 165 mg/m2 BID in paediatric patients CRISP (ITCC-053) is scheduled to be provided to the EMA by 31 August 2027

Altre terapie di seconda linea:

- BV (*Locatelli F et al, Haematologica 2018*)
- BV + Bendamustina (*Vinti L et al, abs*)
- VBL (*Knorr F et al, JCO 2020*)
- allo TCSE (*Knorr F et al, JCO 2020*)

Dal 25/03/2025

Nuove Indicazioni Terapeutiche rimborsate: Xalkori (crizotinib) è indicato per il

- *Il trattamento di pazienti pediatrici (da ≥6 a < 18 anni) con tumore miofibroblastico infiammatorio (Inflammatory Myofibroblastic Tumour, IMT) non resecabile, recidivante o refrattario, positivo per ALK (chinasi del linfoma anaplastico);*
- *Il trattamento di pazienti pediatrici (da ≥6 a < 18 anni) con linfoma anaplastico a grandi cellule (Anaplastic Large Cell Lymphoma, ALCL) di tipo sistemico recidivante o refrattario, positivo per ALK (chinasi del linfoma anaplastico.*

ALCL: 1. relapse

confidential

- **progressive disease** (ALCL99 or VBL)
- **very early rel. (<3 m*)** after ALCL99

(CNS prophylaxis needed)

~~**1) BrigaPED (2y)**~~
2) ALKi 2nd 3rd gen.
3) Crizo + CNS proph.

- **Relapse 3–7 m*** after ALCL99
- **any relapse after VBL**

1) CRISP
~~**2) BrigaPED (2y)**~~
3) ALCL99 for post VBL rel. (?)

late relapse after ALCL99 (>7 m*)

1) VBL 24 m
2) CRISP
~~**3) BrigaPED**~~

Option for consolidation:

~~**NivoALCL**~~ ~~(cohort 2)~~

~~**NivoALCL**~~ ~~(cohort 2) after ALK-I~~

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European Inter-Group for Childhood Non-Hodgkin Lymphoma

*after end of frontline therapy

ALCL: 2. or later relapse

Progression / relapse after

ALK-I allo-SCT**

~~**1) NivoALCL** (cohort 1)~~
~~2) BrigaPED*~~
3) ALKi 2nd 3rd*
4) Conventional CT (+/- BV)
* adapt acc. to previous ALK-I

Nivo alloSCT

~~**1) BrigaPED**~~
2) ALKi 2nd 3rd
3) Conventional CT + BV

VBL

~~**1) BrigaPED**~~
2) ALKi 2nd 3rd
3) CRISP (Crizo)
4) Conventional CT+ BV

Consolidation (if not done):

~~**NivoALCL** (cohort 2)~~

~~**NivoALCL** (cohort 2)~~

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**if late + no GvHD

AIEOP
ASSOCIAZIONE ITALIANA EMATOLOGIA ONCOLOGIA PEDIATRICA

AIEOP LNH-2024

Studio Multicentrico Nazionale sul Linfoma non Hodgkin del bambino, adolescente e giovane adulto

Studio osservazionale retrospettivo e prospettico

Titolo	AIEOP LNH-2024: Studio Multicentrico Nazionale sul Linfoma non Hodgkin (LNH) del bambino, adolescente e giovane adulto (AYA). Studio osservazionale retrospettivo e prospettico
Pazienti	Pazienti di età < 18 anni con diagnosi istologica di LNH. Il limite di età può essere elevato fino ai 25 anni, per pazienti trattati all'interno di specifiche unità per AYA con diagnosi di LNH.
Obiettivo primario dello studio	Descrizione delle caratteristiche cliniche, ematochimiche, biologiche e istopatologiche all'esordio, delle terapie applicate e dell'outcome
Obiettivi secondari dello studio	- Valutare la Sopravvivenza libera da eventi (EFS) - Valutare la Sopravvivenza globale (OS) - Valutare la Sopravvivenza libera da progressione (PFS) - Valutare la Sopravvivenza Libera da Malattia (DFS) - Studiare i fattori prognostici e le caratteristiche epidemiologiche della malattia, considerando le diverse fasce di età, le sedi di insorgenza, il sottotipo istologico della variante classica, l'estensione di malattia all'esordio. - Descrivere i trattamenti somministrati, le deviazioni dai protocolli standard e le eventuali tossicità - Correlare i dati clinici con i dati biologici/ematochimici/istopatologici e con l'outcome
Disegno dello Studio	Studio osservazionale multicentrico, retrospettivo e prospettico
Popolazione in Studio	Si stimano circa 100 pazienti all'anno a livello nazionale.
Centri Partecipanti allo Studio	Centri di cura della Associazione Italiana di Ematologia-Oncologia Pediatrica (AIEOP)
Durata dello studio	10 anni. Inizio arruolamento previsto per il 01.06.2025

- Sottomesso al CE di Padova il 13/01/2026

- In corso definizione agreement

General Data Protection Regulation

Regolamento Europeo 536/2014
AIFA Agenzia Italiana del Farmaco
EUROPEAN MEDICINES AGENCY

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

DataRiver
big data for smart industry

Prospective Observational International Registry and biobank of Children, Adolescents and Young Adults (CAYA) with Newly Diagnosed Rare non-Hodgkin Lymphoma (NHL) sec. WHO 2022

PI: A. Attarbaschi

In female/male participants younger than 26 years of age with newly diagnosed rare forms of NHL as specified below:

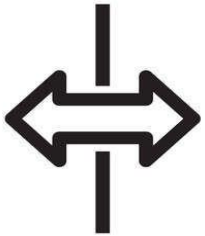
Objectives and Endpoints:
Primary
• To establish a prospective collection of data and biospecimens to allow validated information on CAYA rare NHL
• To prospectively characterize the pathology, biology, clinical features, treatment patterns, response and outcomes for rare NHL in CAYA
Secondary
• To investigate the molecular-genetic landscape of rare NHL in CAYA on an international scale
• To determine associations between clinicopathological features, disease biology, and treatment outcomes for specific lymphoma histologies
• To bank biology samples from pathology tissues in a federated manner, and make them available for biology studies aimed at identifying new molecular therapeutic targets

incluso in AIEOP LNH-2024

eicnhl

Advancing Pediatric Non-Hodgkin Lymphoma Research Exploring …

Liquid Biopsy
as a source of biomarkers
and
to understand the mechanism of aggressiveness



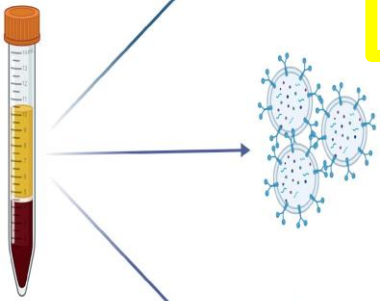
Overcoming Treatment resistance

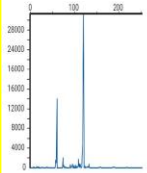
WES and CRISPR/Cas9 Technology for genomic screening and validation

Artificial Intelligence for data analysis and prediction

AIEOP ASSOCIAZIONE ITALIANA EMATOLOGIA ONCOLOGIA PEDIATRICA
MUR PRIN
MARIE CURIE ACTIONS
Fondazione Cassa di Risparmio di Padova e Rovigo

Lymphoma Diagnostics evolution: from MRD to comprehensive Liquid Biopsy

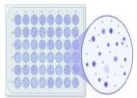




- Cell free DNA- cell tumor DNA

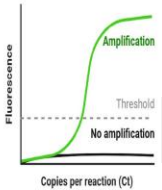
Genes Represented in the 56G Oncology Panel v2 and Number of Amplicons

ABL1	5	CSF1R	2	FBXW7	6	GNAS	2	KIT	14	NPM1	1	STK11	5
AKT1	2	CTNNB1	1	FGFR1	2	HNF1A	4	KRAS	3	NRAS	3	SMAD4	10
ALK	2	DDR2	1	FGFR2	4	HRAS	2	MAP2K1	5	PDGFRA	4	SMARCB1	4
APC	9	DNMT3A	1	FGFR3	6	IDH1	1	MET	6	PIK3CA	11	SMO	5
ATM	19	EGFR	9	FLT3	4	IDH2	2	MLH1	1	PTEN	14	SRC	1
BRAF	2	ERBB2	4	FOXL2	1	JAK2	2	MPL	1	PTPN11	2	TP53	21
CDH1	3	ERBB4	8	GNA11	2	JAK3	3	MSH6	4	RB1	12	TSC1	1
CDKN2A	2	EZH2	1	GNAQ	2	KDR	9	NOTCH1	3	RET	6	VHL	3



- Extracellular vesicles

Salzmann et al , Int J Mol Sci 2025
Garbin A et al, Biochem Pharmacol 2023
Damanti el al, Cancer Comm 2023



- Minimal Disseminated Disease – Minimal Residual Disease

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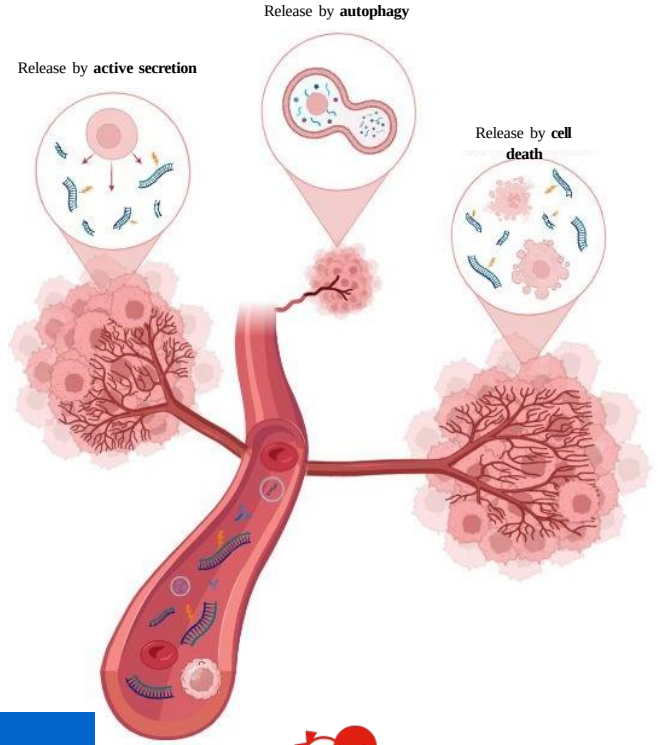
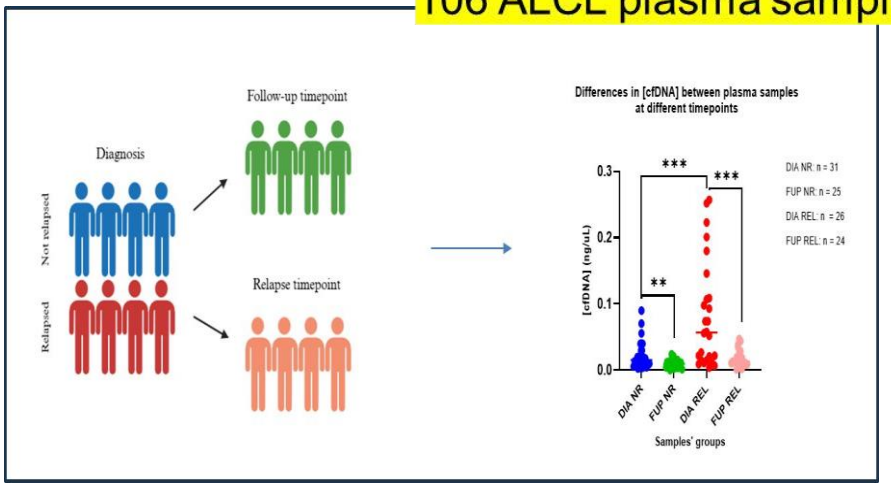
Dissecting cell-free DNA dynamics and mutational heterogeneity in pediatric ALK+ ALCL

Mechanisms of release of cfDNA into the bloodstream



Workflow

106 ALCL plasma samples



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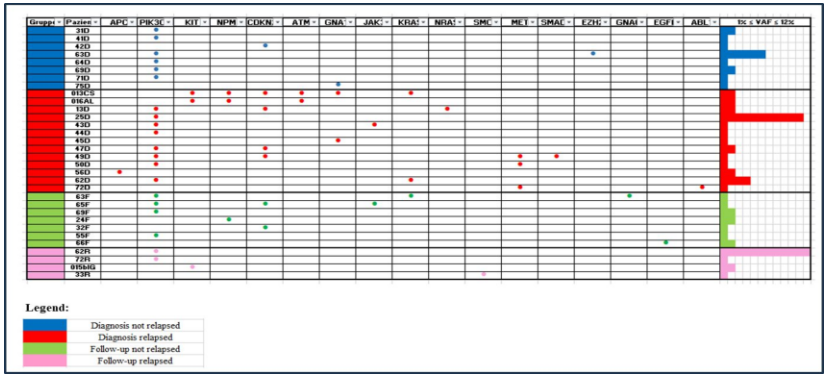

MUR PRIN

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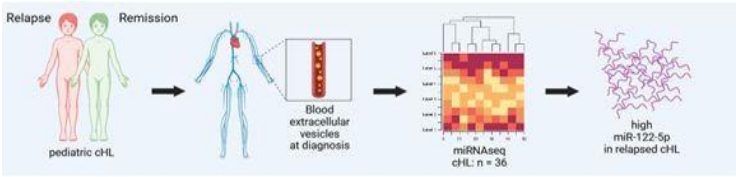
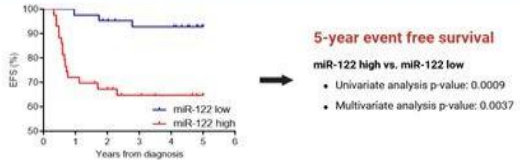
ASSOCIAZIONE ITALIANA EMATOLOGIA ONCOLOGIA PEDIATRICA

Received: 22 August 2022 | Revised: 13 March 2023 | Accepted: 20 March 2023
DOI: 10.1002/cac2.12415
CANCER COMMUNICATIONS

Plasma small-extracellular vesicles enriched in miR-122-5p promote disease aggressiveness in pediatric anaplastic large-cell lymphoma

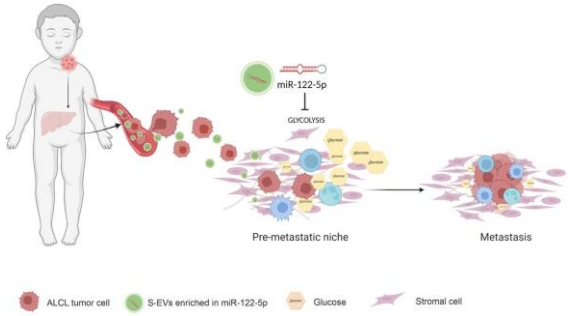




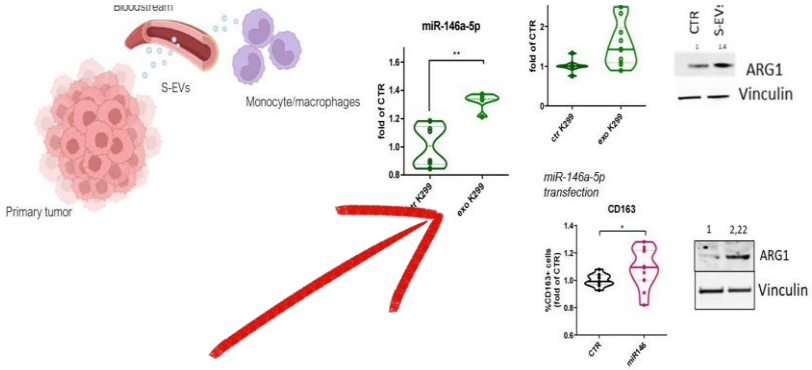
5-year event free survival

miR-122 high vs. miR-122 low

- Univariate analysis p-value: 0.0009
- Multivariate analysis p-value: 0.0037



ALCL cell lines derived s-EVs increase macrophage tumor infiltration and induce M2-like differentiation through miR-146a-5p action



Salzmann et al , Int J Mol Sci 2025
Garbin A et al, Biochem Pharmacol 2023
Damanti el al, Cancer Comm 2023

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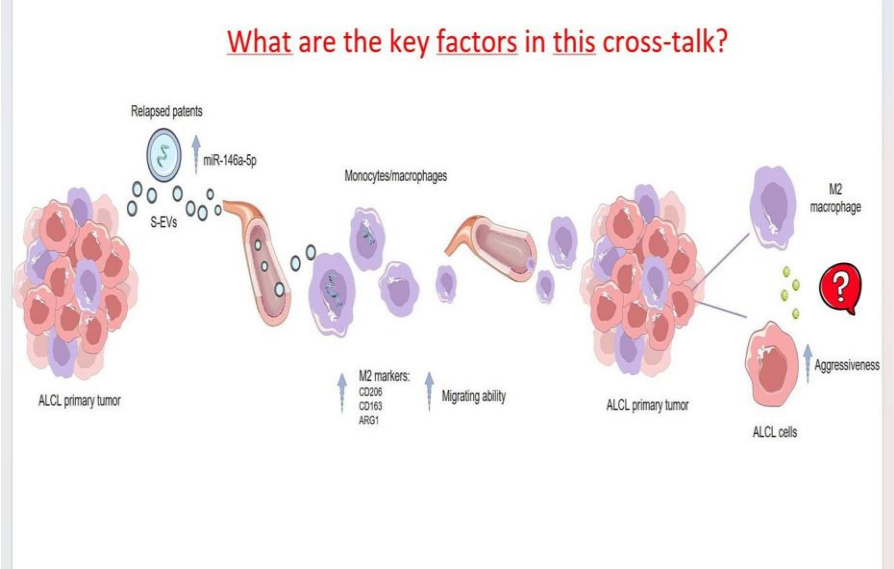
ASSOCIAZIONE ITALIANA EMATOLOGIA ONCOLOGIA PEDIATRICA

Mechanisms of relapse in the cross-talk between ALK+ALCL and macrophages



- Investigations with primary macrophages in lymphoma microenvironment
- Lipidomics
- Spatial trascriptomic

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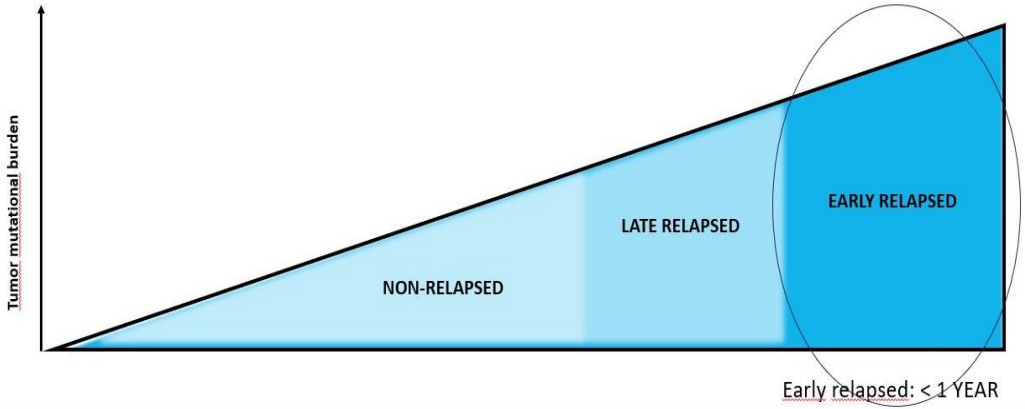
ASSOCIAZIONE ITALIANA EMATOLOGIA ONCOLOGIA PEDIATRICA

MARIE CURIE ACTIONS

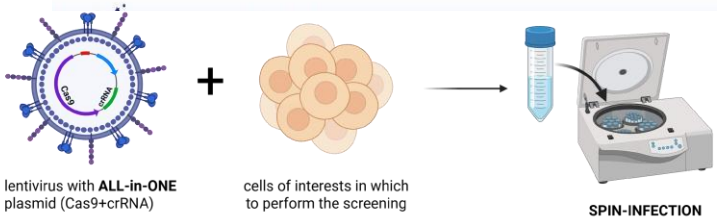
Overcoming treatment resistance mechanisms in ALK-driven cancers

Association between high mutational profile and early disease relapse

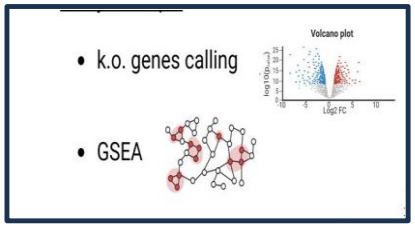
<u>Phase1</u>:
WES on patients DNA
(relapsed vs no-relapsed)



<u>Phase2</u>:
Genome-wide screening
through *CRISPR/Cas9*
technology

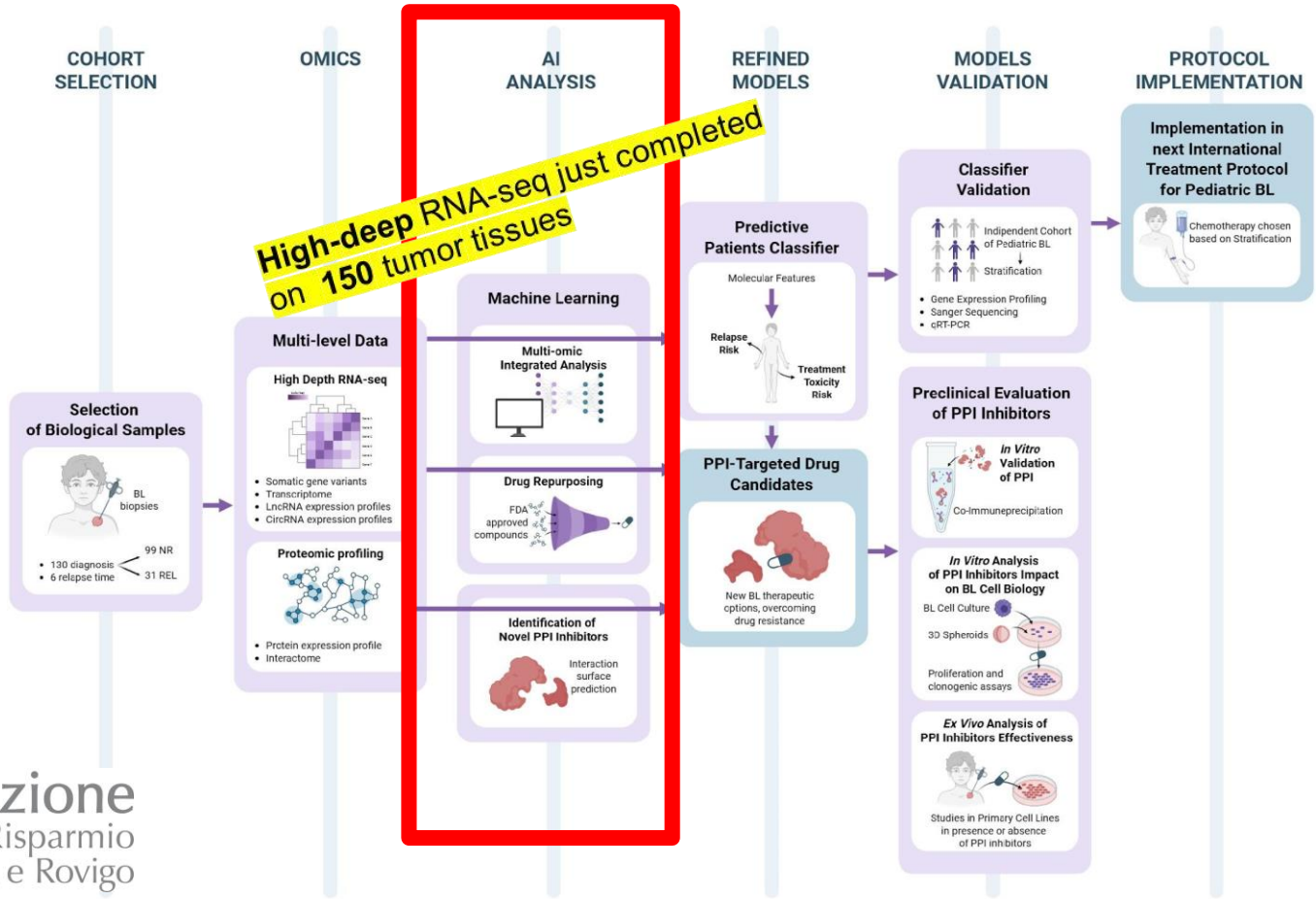


Finding genes responsible for ALK inhibitors resistence



Marzi M et al, 2026

Machine Learning-Based Model for the Prognosis and Treatment of aggressive Burkitt Lymphoma of Childhood



Fondazione Cassa di Risparmio di Padova e Rovigo

AIEOP
ASSOCIAZIONE ITALIANA EMATOLOGIA ONCOLOGIA PEDIATRICA

Proposte di nuovi studi

- Espressione di CD20 nei LNH-B recidivati
-Terapia di seconda linea dei PMLBL
- Casistica retrospettiva LNH
- TCSE e LNH
- Linfomi ossei
- Complicanze trombotiche nei LBL-T e LLA-T
- Linfomi cutanei
- Ruolo della RMN e sequenze DWIBS nelle rivalutazioni di malattia e nel follow up dei LNH
- Immunodeficit e linfomi
- …….

CAYANHL SYMPOSIUM 2025

Children & Young Adult Non Hodgkins Lymphoma

CD20-NEGATIVE RELAPSED/REFRACTORY MATURE B-CELL NON-HODGKIN LYMPHOMA (B-NHLs) AND MATURE B-CELL LEUKEMIA IN CHILDREN, ADOLESCENT AND YOUNG ADULTS: A RETROSPECTIVE REVIEW

Luciana Vinti[1], Jolanda Pianese[1], Daniela Onofrillo[2], Irene D'Alba[3], Raffaella De Santis[4], Veronica Barat[5], Elisabetta Schiavello[6], Paola Muggeo[7], Concetta Micalizzi[8], Katia Perruccio[9], Valentina Bertaina[1], Lara Mussolin[10], Elisa Carraro[10], Marta Pillon[10], Barbara Buldini[10], Rita De Vito[1], Franco Locatelli[1]

QUALITATIVE AND QUANTITATIVE MINIMAL DISEASE MEASUREMENT IN ALK-POSITIVE ANAPLASTIC LARGE CELL LYMPHOMA: EFFICACY OF INTERNATIONAL QUALITY CONTROL AND EVENT-FREE SURVIVAL ACCORDING TO DIFFERENT MINIMAL DISSEMINATED DISEASE CUT-OFFS

Christine Damm-Welk[1], Cathy Quelen[2], Laurence Lamant[2], Gaia Martire[3,4], Lukas Duscher[1], Reiji Fukano[5], Yuka Iijima-Yamashita[6], Itziar Sallevaria[7], Julia Salmeron-Villalobos[7], Liz Yuet-Ping Yuen[8], Yu-Kwan Tong[8], Suzanne D. Turner[9], Rogier ten Hoopen[9], Edwin Sonneveld[10], Eric Strengman[10], Maria Hansen[11], Guy Wayne Novotny[11], Megan S. Lim[12], Rui Wu[12], Ariel Long[13], Feng Xu[13], Marilyn M. Li[13], Grace Kee-See Lam[14], Jaime Verdu-Amoros[15], Charlotte Rigaud[16], Martin Zimmermann[17], Marta Pillon[2], Wilhelm Woessmann[1], Lara Mussolin[3,4]

DISSECTING CELL-FREE DNA DYNAMICS AND MUTATIONAL HETEROGENEITY IN PEDIATRIC ALK+ ALCL: A COMPARISON WITH MDD LEVELES

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EXTRACELLULAR VESICLES AS KEY ORCHESTRATORS OF BONE MARROW NICHE REMODELING IN PEDIATRIC MATURE-B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA

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MECHANISMS OF RELAPSE IN THE CROSS-TALK BETWEEN ALK+ALCL AND MACROPHAGES

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PERSISTENT FDG-PET UPTAKE AFTER FIRST-LINE THERAPY IN PAEDIATRIC LYMPHOMA AND RISK OF PROGRESSION: A MONOCENTRIC RETROSPECTIVE ANAYSIS

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...ION SITES INFLUENCE PROGNOSTIC SIGNIFICANCE OF *TP53* MUTATIONS IN PEDIATRIC B-CELL NON-HODGKIN LYMPHOMA

Marcel te Vrugt[1], Amelie Alfert[1], Lara Mussolin[2], Mara Andres[3], Alex Blain[4], Chris Bacon[4], Elisa Carraro[2], Christine Damm-Welk[5], Eric Hermann[6], Marc Hotfilder[1], Fabian Knörr[5], Luisa Kruppa[5], Claudia Lanvers-Kaminsky[1], Sara Mato[7], Gaia Martire[2], Stephanie Mueller[1], Alexander Newman[4], Katrin Reutter[1], Elina Richter[1], Gerrit Randau[1], Vikki Rand[8], Kenneth Scholten[1], Ida Tölle[1], Jaime Verdu-Amoros[7,9], Simon Bomken[4], Itziar Salaverria[7,10], Martin Zimmermann[11], Birgit Burkhardt[1]

PEDIATRIC ALK-NEGATIVE ANAPLASTIC LARGE CELL LYMPHOMA GENETICALLY DIFFERS FROM THE ADULT COUNTERPART

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WHOLE EXOME SEQUENCING IN PEDIATRIC ALCL: HIGH TUMOR MUTATIONAL BURDEN CHARACTERIZES EARLY RELAPSE PATIENTS

Matteo Marzi[1,2], Alessia Danieli[1,2], Daniele Ramazzotti[3], Federica Malighetti[3], Carlo Zanon[1,2], Carlotta Caterina Damanti[1,2], Gaia Martire[1,2], Elisa Carraro[1], Andrea Carraro[4], Marco Pizzi[4], Teresa Battaglia[5], Rosa Maria Mura[6], Annalisa Tondo[7], Elisabetta Schiavello[8], Marta Pillon[1], Luca Mologni[3], Lara Mussolin[1,2]

BEST abstract!

A PEDIATRIC CASE OF MEDIASTINAL B-CELL NON HODGKIN LYMPHOMA PRESENTING WITH A RARE/COMPLEX CYTOGENETIC PROFILE

Schiavello Elisabetta[1], Aiello Antonella[2], Lorenzini Daniele[2,3], Volpi Chiara[2], Toma Martina[2], Colombo Valeria[1], Gattuso Giovanna[1], Spreafico Filippo[1], Terenziani Monica[1], Massimino Maura[1], Monti Valentina[2]

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PSYCHOLOGICAL WELL-BEING AND COPING STRATEGIES IN PEDIATRIC PATIENTS WITH HODGKIN AND NON-HODGKIN LYMPHOMAS AND THEIR MOTHERS: A PILOT STUDY

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Pubblicazioni 2024-2026

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Prossimi appuntamenti

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GdL LNH allargato. PADOVA 23 Giugno 2026

EICNHL Meeting. Vienna, Novembre 2026

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M. Pizzi - An Pat PD

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