Welcome & Introductions

Pediatric ALL - Update on Treatment

Susan R. Rheingold, M.D.
October 23, 2013
### Types of Childhood Cancer

- **CNS Tumors** (20%)
  - Retinoblastoma: 3%
  - Neuroblastoma: 8%
  - Wilms Tumor: 7%
  - Liver: 2%
- **Sarcomas** (7%)
- **Bone** (5%)
- **Lymphomas** (12%)
- **Other** (6%)
- **LEUKEMIA** (30% (25% ALL))

**Incidence and EFS**: 

- **LEUKEMIA**: 2,500 children/yr diagnosed with ALL and rising

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### ALL Incidence and EFS

**Smith MA et al. JCO May 2010**
Clinical Presentation of ALL

Diagnostic Procedures

- BM Aspirate & Biopsy
  - Morphology
  - Immunohistochemistry / Flow Cytometry
  - Cytogenetics
  - Microarray (SNP)
  - Biology studies

- Spinal Tap – CNS 1 (no leukemia)
  - CNS 2 (minimal leukemia)
  - CNS 3 (lots of leukemia)
Under the microscope

NCI/Rome Risk Classification for ALL

<table>
<thead>
<tr>
<th>Age</th>
<th>WBC &lt; 50,000/µl</th>
<th>WBC ≥ 50,000/µl</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 year</td>
<td>Infants (3%)</td>
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<tr>
<td>1-10 years</td>
<td>Standard risk (58%)</td>
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<tr>
<td>≥ 10 years</td>
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<td>High risk (39%)</td>
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</table>
Immunophenotyping / Flow

Table 2. Common Markers Used in Flow Cytometric Immunophenotyping

<table>
<thead>
<tr>
<th>Antigen</th>
<th>Myeloblasts</th>
<th>Promyelocytes</th>
<th>Myelocytes</th>
<th>Monocytes</th>
<th>Erythroblasts</th>
<th>B-cell</th>
<th>T-cell</th>
<th>Comments</th>
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<tbody>
<tr>
<td>CD2</td>
<td>+</td>
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<td>+</td>
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<td>CD3</td>
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<tr>
<td>CD117</td>
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<tr>
<td>CD13</td>
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<td>CD15</td>
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<td>CD18</td>
<td>+</td>
<td>Var</td>
<td>Var</td>
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<tr>
<td>CD23</td>
<td>+</td>
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<td>+</td>
<td>+</td>
<td>+</td>
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<td>CD45</td>
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<td>HLA-DR</td>
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<td>TdT</td>
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</tbody>
</table>

Pui, NEJM 2004

Childhood ALL Cytogenetics

Good Prognosis

- Hypodiploidy <45 chromosomes 19%
- Hyperdiploidy >50 chromosomes 25%
- B-Cell Lineage 88%
- T-Cell Lineage 12%

- TEL-AML1 t(12;21) 22%
- MLL-AF4 t(11;14) 59%
- E2A-PBX1 t(1;19) 5%
- MYC t(8;14), t(6;14) 2%
- 1p32 7%
- 19p13 1.5%
- 15q25 2.5%
- 1q21 1.5%
- MLL rearrangements e.g., t(4;11)(q21;q23), t(9;11) 9%
- MLL-ENL 0.3%
- HOX11 0.7%
- HOX11 0.7%
- MLL-ENL 0.3%

Pui, NEJM 2004
**Microarray/SNP**

**RESULTS**

<table>
<thead>
<tr>
<th>Chromosome/Arm Start</th>
<th>End</th>
<th>Abnormality/Notes</th>
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<tbody>
<tr>
<td>1p16.1</td>
<td>57,404,022</td>
<td>57,445,471</td>
</tr>
<tr>
<td>1q25</td>
<td>106,696,431</td>
<td>106,658,185</td>
</tr>
<tr>
<td>6q23.3</td>
<td>135,366,359</td>
<td>135,437,583</td>
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<tr>
<td>1p14.1</td>
<td>38,258,285</td>
<td>38,385,930</td>
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<tr>
<td>3p22.3</td>
<td>50,419,243</td>
<td>50,463,935</td>
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<tr>
<td>7q11.21</td>
<td>61,970,177</td>
<td>62,458,262</td>
</tr>
<tr>
<td>7q34</td>
<td>142,340,456</td>
<td>142,474,533</td>
</tr>
<tr>
<td>8q21.3</td>
<td>22,213,283</td>
<td>22,366,442</td>
</tr>
<tr>
<td>15p11.22</td>
<td>50,477,559</td>
<td>51,372,036</td>
</tr>
<tr>
<td>16p12.2</td>
<td>21,010,849</td>
<td>21,025,445</td>
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<tr>
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<td>17q22.33</td>
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<td>107,160,654</td>
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<td>18p11.12</td>
<td>16,001,089</td>
<td>21,561,392</td>
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<tr>
<td>18q13</td>
<td>57,221,865</td>
<td>57,330,434</td>
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<td>1p21.32</td>
<td>44,161,641</td>
<td>44,791,332</td>
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<tr>
<td>22q11.21</td>
<td>31,945,966</td>
<td>60,593,396</td>
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<tr>
<td>2q11.22</td>
<td>22,504,946</td>
<td>22,521,358</td>
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</table>

The probes used in this study have been developed and/or validated for FISH analysis by the laboratory. The probes have not yet been approved by the FDA for clinical diagnostic testing.

Whole genome SNP array results:

**Gene Expression**

**Copy Number**

**Methylation**

**Sequencing**

Why mapping the human genome was worth every penny: Genome-Wide Analyses to Discover Cancer Pathways
MRD: A stronger predictor of outcome in ALL

Day 29 MRD

More Predictive With Time

END CONSOLIDATION

St. Judes
Coustan-Smith, et al.
Blood 2000

POG 9900 series
Borowitz, M. J. et al.
Blood 2008;111:5477-5485
**MRD Trumps Cytogenetics**

**MRD in B vs T-ALL**

**COG ALL treatment allocation -2013**

**B-cell**

- **T-cell**
  - LOW
  - INTER
  - HIGH

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<td></td>
</tr>
<tr>
<td>1-9.99 yrs</td>
<td>Standard Risk (52%)</td>
<td></td>
</tr>
<tr>
<td>10-13 years</td>
<td>High Risk (25%)</td>
<td></td>
</tr>
<tr>
<td>&gt;13 years</td>
<td>Very High Risk (20%)</td>
<td></td>
</tr>
</tbody>
</table>

- Ph+ chemo/TKI
## B-ALL Post-Induction Risk Groups

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Low</th>
<th>Average</th>
<th>High</th>
<th>Very High</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-yr EFS</td>
<td>&gt;95%</td>
<td>90-95%</td>
<td>88-90%</td>
<td>&lt;80%</td>
</tr>
<tr>
<td>NCI Risk Group</td>
<td>SR</td>
<td>SR</td>
<td>SR</td>
<td>SR</td>
</tr>
<tr>
<td>Favorable genetics</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>MRD d8 (PB)</td>
<td>&lt;0.01</td>
<td>≥0.01</td>
<td>&lt;1</td>
<td>-</td>
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<tr>
<td>MRD d29 (BM)</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>≥0.01</td>
</tr>
</tbody>
</table>

## Therapy and Biology

CHILDREN’S ONCOLOGY GROUP

The world's childhood cancer experts

DANA-FARBER Cancer Institute
Boston Children's Hospital
St. Jude Children’s Research Hospital
TAACL: Therapeutic Advances in Childhood Leukemia & Lymphoma
**Why do Clinical Trials?**

(COG ALL trial outcome)

![Graph showing estimated survival percentage over years from study entry for different time periods.]

- **1996-2000**: (n=3421)
- **1989-1995**: (n=5121)
- **1983-1988**: (n=3711)
- **1978-1983**: (n=2984)
- **1975-1977**: (n=1313)
- **1972-1975**: (n=936)
- **1970-1972**: (n=499)
- **1968-1970**: (n=402)

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**How far have we come?**

COG 5yr EFS

- 1993-1996: 90%
- 1996-2000: 88%
- 2000-2006: 84%

*Hunger SP et al. JCO May 2012*
Why aren’t the 15-21 year olds doing better?

![Survival Rates Graph](image)

The graph shows the five-year survival rates for different age groups over time. The survival rates for the 15-19 year old group are consistently lower compared to the <15 year old group.

Best Therapy for Adolescents (15-21 years)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Pediatric</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>FRALLE-93/LALA-9428</td>
<td>5-y EFS: 67%</td>
<td>5-y EFS: 41%</td>
</tr>
<tr>
<td>CALGB/CCG34</td>
<td>7-y EFS: 63%</td>
<td>7-y EFS: 34%</td>
</tr>
<tr>
<td>MRC ALL97/99/UKALLXI-E299329</td>
<td>5-y EFS: 65%</td>
<td>5-y EFS: 49%</td>
</tr>
<tr>
<td>GIMEMA/AIEOP20</td>
<td>2-y OS: 80%</td>
<td>2-y OS: 71%</td>
</tr>
<tr>
<td>HOVON/DCOG21</td>
<td>5-y EFS: 71%</td>
<td>5-y EFS: 38%</td>
</tr>
<tr>
<td>Adult ALL Grp/NOPHO-9222</td>
<td>5-y OS: 74%</td>
<td>5-y OS: 39%</td>
</tr>
<tr>
<td>Finnish Leukemia/NOPHO23</td>
<td>5-y OS: 67%</td>
<td>5-y OS: 60%</td>
</tr>
</tbody>
</table>

Last COG Trial
> 16 years – 79% 5yr EFS

Wood, W. Blood 2011
What do Clinical Trials for ALL Ask?

1) Reduction in Therapy Questions:
   - Decrease toxicity and late effects
2) “Re-arranging the Deck Chairs”:
   - Varying the drug, dose, order
3) Introducing New Agents:
   - Higher cure rates?
   - Toxicity / Tolerability

Reduction in Therapy
Changing Drug or Dose

What is the best way to give Methotrexate?

AALL0232

Dex x 14 days for ≤ 10 years
Pred x 28 days for > 10 years

AALL0232
Adding New Agents

- Newer chemotherapy agents
  - Clofarabine
  - Nelaarabine - T cell targeted drug
- Targeted agents
  - Imatinib/Dasatinib
  - Lestaurtinib for MLL
- Immunotherapy
  - Monoclonal Antibodies
  - Engineered T-cells

VHR ALL - Schema

**Induction**

- **Control Arm**
  - Consolidation (Day 1-28)
- **Exp Arm 1**
  - Consolidation (Day 29-57) MBFM
  - Evaluation (MRD Flow)
  - Interim Maintenance I
    - HD MTX x 4
  - Delayed Intensification (Day 1-28)
    - MBFM
- **Exp Arm 2**
  - Consolidation (Day 29-57) CLOF/CPM/ETOP
  - Evaluation (MRD Flow)
  - Interim Maintenance I
    - HD MTX x 4
  - Delayed Intensification (Day 1-28)
    - CLOF/CPM/ETO

**Maintenance**

**Hypodiploidy, Induction failure**

Patients will have the option of receiving SCT.
New Drug for T-cell ALL

AALL0434 Induction

Day 15 BM Response, DAY 29 Minimal Residual Disease

- <10 yr, WBC <50K
  - RER, no CNS dz
  - MRD < 0.1% day 29

- NCI SR or HR
  - RER or SER
  - MRD <1% day 29

- Day 29 M2
  - or MRD ≥ 1% day 29

AALL0434-LOW

IV MTX

HD MTX

AALL0434-INTER/HIGH

IV MTX

+/- HD MTX

Nelarabine

Targeted Leukemia Therapy

Lineage Specific Antigens

Drug Transporters

Cytokine Receptors

Signal Transduction Pathways

Transcription/Translation

Immunotherapy

Arceci & Cripe, Ped Clin NA (49) Dec. 2002
The first molecularly targeted drug

Faderl S et al. Oncology (Huntingt).
Targeted Therapy: the way of the future

Adding a single drug, Imatinib, to chemotherapy increased survival from 30% to 70%

Adding New Agents into Therapy: AALL07P1

T. Horton Study Chair
### ADVL1114: Temsirolimus

<table>
<thead>
<tr>
<th>Day</th>
<th>Tem</th>
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<th>Tem</th>
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<tbody>
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<td>36</td>
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**BM**

**IT MTX**

**IT MTX/ITT**

**CNS 3 only**

*LLS funded research*

### Monoclonal Antibodies: Targeting specific cancer proteins

<table>
<thead>
<tr>
<th>Agent</th>
<th>Mechanism of Action</th>
<th>Target</th>
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<tbody>
<tr>
<td>Rituximab</td>
<td>antibody to CD-20</td>
<td>B-ALL</td>
</tr>
<tr>
<td>Epratuzamab</td>
<td>antibody to CD-22</td>
<td>B-ALL</td>
</tr>
<tr>
<td>Alemtuzumab</td>
<td>antibody to CD-52</td>
<td>B &amp; T-ALL</td>
</tr>
<tr>
<td>Combotox</td>
<td>antibody to CD-19 &amp; 22</td>
<td>B-ALL</td>
</tr>
<tr>
<td>Blinatumomab</td>
<td>Attach patient CD3 T-cells to CD19</td>
<td>B-ALL</td>
</tr>
<tr>
<td>Moxetumomab</td>
<td>antibody to CD-22</td>
<td>B-ALL</td>
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<tr>
<td>Inotuzumab</td>
<td>antibody to CD-22</td>
<td>B-ALL</td>
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</table>
Blinatumomab (MT103) is a Bispecific T-cell Engager (BiTE®) antibody designed to direct cytotoxic T-cells to CD19 expressing cancer cells.

**Adult phase 1 Blinatumomab Trial: Best Response During First 2 Cycles**

<table>
<thead>
<tr>
<th></th>
<th>Cohort 1 15 µg/m²/d (n = 7)</th>
<th>Cohort 2a 5-15 µg/m²/d (n = 5)</th>
<th>Overall (N = 12)</th>
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<tbody>
<tr>
<td>CR/CRh*, n (%)</td>
<td>5 (71)</td>
<td>4 (80)</td>
<td>9 (75)</td>
</tr>
<tr>
<td>CR</td>
<td>2 (29)</td>
<td>4 (80)</td>
<td>6 (50)</td>
</tr>
<tr>
<td>CRh*</td>
<td>3 (43)</td>
<td>0</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Non-responder</td>
<td>1 (14)</td>
<td>1 (20)</td>
<td>2 (17)</td>
</tr>
<tr>
<td>Not available</td>
<td>1 (14)</td>
<td>0</td>
<td>1 (8)</td>
</tr>
<tr>
<td>MRD response (&lt;10^-4), n (%)</td>
<td>5 (71)</td>
<td>4 (80)</td>
<td>9 (75)</td>
</tr>
<tr>
<td>No response or progression</td>
<td>1 (14)</td>
<td>1 (20)</td>
<td>2 (17)</td>
</tr>
<tr>
<td>Not available</td>
<td>1 (14)</td>
<td>0</td>
<td>1 (8)</td>
</tr>
</tbody>
</table>

CRh*: CR with only partial hematologic recovery: ≤5% blasts in the bone marrow, no evidence of circulating blasts or extramedullary disease, partial recovery of peripheral blood counts.
What is CART-19 (CTL019) Immunotherapy?

Immunotherapy reprograms a patient’s own immune system to better fight cancer.

T cells are workhorses of the immune system. They recognize cells that don’t belong and attack them. However, T cells are blind to cancer cells, which fly under the radar.

Custom-designed T cells engineered to seek out the CD19 + B-ALL cells in the body. These specialized T cells can target the B cell leukemia, attach to its CD19 protein and then kill off the leukemia cell.

LLS funded research

Clinical Update of Pediatric and Adult ALL Patients treated with CART19

5 Children
- Refractory or 3rd+ Relapse
- 3 to 8+ prior therapies
- 4 with prior all BMT
  - 4 CR, 3 A&W up to 1 year out
  - 1 relapsed with CD 19 (-) leukemia
    - Now Infusing 2-3/month (over 16 total)

- Adult
  - 1 CR

Barrett, D et al. AACR 2013
Take Home Message

1) We are curing more and more children with ALL
2) Conventional chemotherapy is not going to make much more of a difference
3) Targeted therapy is much more specific and often less toxic
4) Today's experimental therapy (Phase 1) is tomorrow's cure
5) Adolescents and Young adults should be treated like Children (when it comes to ALL)

Side Effects of Therapy

Cara L. Simon, Ph.D.
Side Effects of Treatment

- Can occur after chemotherapy, radiation therapy, or supportive care therapy
- Type of cancer, its location and age of the child will affect the severity of the side effects
- Side effects can encompass all body symptoms

LLS has top notch resources

Curesearch.org is also a great pediatric reference for parents and families newly diagnosed, in treatment, at the end of treatment and after treatment
Most common side effects of ALL treatment

- Hair loss
- Bone marrow suppression
- Impairment of the immune system
- Central nervous system complications
- Musculoskeletal complications
- Gastrointestinal complications
- Growth and development
- Pain

Hair Loss

- Also called alopecia
- Some chemotherapy causes loss or thinning of hair
- Typically starts 14 days after treatment is started
- Hair grows back when treatment is finished or treatment becomes less intensive
Side Effects of Treatment

- Bone marrow suppression
  - Most common dose-limiting component of cancer therapy
  - Bone marrow provides environment for formation of red blood cells, white blood cells and platelets

Bone marrow suppression

Anemia
- Also means low red blood cell count
- Red blood cells carry oxygen throughout the body
- May cause shortness of breath, headache, feeling tired, fast heart rate, pale skin
Bone marrow suppression

Thrombocytopenia
- Also means low platelet count
- Platelets stop bleeding by forming clots
- Risk of bleeding when platelet count is low
- Signs of low platelets: bruising or petechiae, bleeding, black stools

Bone Marrow Suppression

Neutropenia
- Reduction in circulating neutrophils
- Absolute Neutrophil Count (ANC)
- Severity can be mild, moderate or severe
- Can be asymptomatic, fevers can occur
- Increases risk for serious infection, risk increases with prolonged neutropenia
### Side Effects of Treatment

- **Impairment of the immune system**
  - Increased risk for infection
  - PCP prophylaxis- *bactrim, pentamidine, atovaquone*
  - Routine immunizations are held during treatment and for a time after therapy has ended
  - Yearly Flu vaccine recommended

### Central Nervous System

- **Central nervous system complications**
  - Cognitive deficits
  - Behavioral changes
  - Neuropathic pain, Flat Footed Gait
- **Rare**
  - Seizure
  - Stroke
  - Change in Mental Status
Musculoskeletal Concerns

- Steroid Myopathy
- Weakness
- Osteonecrosis
- Osteopenia
- Increased risk of Bone Fractures
- Pain at bone marrow sites

Gastrointestinal

- Mucositis
- Nausea/vomiting
- Diarrhea/constipation
- Perirectal cellulitis
- Chemical or reactive hepatitis
- Pancreatitis
- Veno-occlusive disease
Side Effects of Treatment

- Growth and development
  - Monitor throughout treatment
  - Intervene early
- Pain
  - Can be acute and/or chronic
  - May be from disease and/or treatment
  - Treat underlying cause of pain
  - Pharmacologic and non-pharmacologic treatment of pain

Psychosocial Effects

- Fear
  - Fear of unknown
  - Treatment and procedures
- Guilt
  - Parents often feel guilty for not knowing that their child was sick
  - Siblings may feel guilty that they are healthy
  - Something they did caused this

LLS Care for the Caregivers
Psychosocial Effects

- **Anger**
  - Feeling angry is a normal reaction
  - Steroid behavior

- **Depression**
  - Feeling sad or blue is a normal reaction to diagnosis and treatment
  - The changes in family routine may bring feelings of social isolation and loss

  No Stigma for seeking therapy/support

Quality of life (QOL)

- Numerous studies on treatment of ALL and QOL
  - QOL impaired during treatment
  - QOL can be affected both on therapy and after therapy
  - Children/adolescents with ALL have decreased QOL when compared to norms
Survivorship

- Patients should be followed annually, even when years off therapy
- Late effects need to be screened
  - Cardiovascular
  - Growth/Development
  - School Performance
  - Liver and renal function
  - Radiation field second cancer screen

 Pediatric ALL
 Update on Treatment and Follow-Up Care

Question and Answer Session
The speakers' slides are available for download at www.LLS.org/programs
Pediatric ALL
Update on Treatment and Follow-Up Care

For more information about pediatric ALL and other programs from The Leukemia & Lymphoma Society (LLS), please contact an LLS Information Specialist.

• TOLL-FREE PHONE: (800) 955-4572
• EMAIL: infocenter@LLS.org
• LIVE ONLINE CHAT: www.LLS.org/informationspecialists