



DARE TO DREAM

P R O J E C T

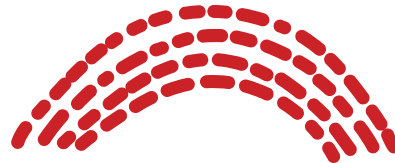
Transforming treatment and care
for kids with blood cancer.

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AGENDA



- **LLS Mission, Resources, and Support**
- **Dare to Dream Project**
- **The PedAL Trial**
- **Discussion, Q&A**



OUR MISSION

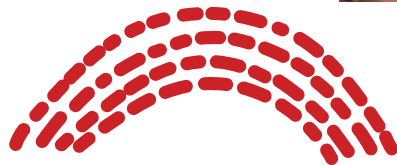



The mission of The Leukemia & Lymphoma Society (LLS) is: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families.

We fund **RESEARCH** to advance lifesaving treatments

We drive **ADVOCACY** for policies that protect patient access to lifesaving treatment

We provide patients and families with hope, guidance, education and **SUPPORT**





FREE RESOURCES FOR BLOOD CANCER SURVIVORS & THEIR FAMILIES

(800) 955-4572



Education

- Education programs (In-person and virtual)
- LLS Health Manager App
- Podcasts & Videos
- Booklets
- Nutrition Consultation

Financial Assistance

Support

- Family Support Groups
- Online Chats
- LLS Community
- Clinical Trial Support Center
- First Connection Program

INFORMATION RESOURCE CENTER



Contact:

- (800) 955-4572
- infocenter@lls.org
- Monday – Friday, 6am to 6pm PT
- www.LLS.org

Information Specialists assist patients and their families with financial and social challenges, and give accurate, up-to-date disease, treatment and support information at every stage of the cancer trajectory.

DARE TO DREAM RESOURCES AND SUPPORT

(800) 955-4572

LEUKEMIA & LYMPHOMA SOCIETY
PROVIDING THE LATEST INFORMATION FOR PARENTS & CAREGIVERS

Acute Lymphoblastic Leukemia (ALL) in Children and Teens

LEUKEMIA & LYMPHOMA SOCIETY
PROVIDING THE LATEST INFORMATION FOR PARENTS & CAREGIVERS

Learning & Living with Cancer

Advocating for your child's educational needs

Revised 2020

LEUKEMIA & LYMPHOMA SOCIETY
Side-Effect Management:
Effects of Childhood Cancer Treatment on Learning

Some treatments for childhood cancer can increase the risk of changes in cognitive (thinking) function. These changes may affect concentration and memory. For some childhood cancer survivors, cognitive effects can lead to learning problems at school.

Childhood leukemia and lymphoma patients may receive therapy that affects the central nervous system (CNS). The CNS includes the brain and spinal cord. Therapy that affects the CNS increases the risk for cognitive (thinking) effects, including educational issues. Examples of these therapies include:

- Methotrexate in combinations of drugs in high doses intravenously (IV) or injected into the spinal fluid intrathecally (IT)
- Hair body irradiation (HBI) given to a stem cell transplantation

Significant cognitive effects are more often associated with treatment plans that exclude radiation to the brain or brain surgery which are not routinely used to treat childhood leukemia or lymphoma.

For some childhood cancer survivors, cognitive effects can lead to learning problems that can affect performance in school.

TYPES OF LEARNING PROBLEMS

Attention and memory problems may begin during or soon after treatment ends or even after that. These can be short term or long-term problems.

Types of learning problems include:

- Difficulty concentrating
- Difficulty staying focused
- Difficulty processing information or learning as quickly as peers
- Difficulty completing multi-step tasks

Other factors can also contribute to cognitive issues and can be treated separately. These problems include poor nutrition, very fatigue, anxiety, depression, fatigue and insomnia. Treating these separately may help improve cognitive (thinking) function.

MANAGING LEARNING PROBLEMS AT SCHOOL

Going to school is a big part of learning normal for children and adolescents, but going back to school after cancer treatment can also bring new challenges for your family. It is important to identify the areas of learning where your child may struggle. Then you can work together with the healthcare team, teachers and school staff to provide support and resources to help your child be successful in school.

Neuropsychological Testing


Children who are at risk for cognitive effects, or who are having difficulty in school should have neuropsychological testing done by a licensed pediatric neuropsychologist to learn if there are any learning issues (to check for possible learning challenges). Discuss the need for neuropsychological testing with your child's healthcare team, who can refer you to a pediatric neuropsychologist.

School Psychological Assessment

Neuropsychological testing is often not covered by insurance and can be expensive. A school assessment may also be an option for you. A school assessment may also be an option for you. A school assessment may also be an option for you. A school assessment may also be an option for you.

LEUKEMIA & LYMPHOMA SOCIETY

A Caregiver's Guide to Navigating CHILDHOOD AND ADOLESCENT Blood Cancers



LEUKEMIA & LYMPHOMA SOCIETY
The LLS PedAL Master Trial:
A Clinical Trial for Acute Myeloid Leukemia Pediatric Patients

This study is designed to speed up the approval of acute myeloid leukemia (AML) drugs and bring safe and effective treatments to pediatric patients.

What is AML?

Acute myeloid leukemia (AML) is a type of cancer that begins in the bone marrow, the spongy tissue inside bones where blood cells are made. It is caused by damage to the DNA (genetic material) of a developing cell in the bone marrow. Once the marrow cell becomes a leukemia cell, it multiplies uncontrollably into billions of leukemia cells.

These cells, called "leukemic blasts":

- Do not function normally
- Are able to grow and survive better than normal cells
- Block the production of normal blood cells, resulting in a lower number of healthy blood cells (red blood cells, white blood cells and platelets)

What are clinical trials?

Every new drug or treatment regimen goes through a series of studies called "clinical trials" before it becomes part of standard therapy. The following information will help you better understand clinical trials, how they are conducted and how they can work for you.

- Clinical trials are carefully designed and thoroughly reviewed by expert doctors and researchers to make them as safe and scientifically correct as possible.
- Patients in clinical trials are watched closely by their doctors, as well as by other members of their medical team, to ensure their safety.
- The trial can be either changed or stopped at any time if there is a problem. Patients who take part in a clinical trial also have the option to leave the trial at any time.
- Participation in a carefully conducted clinical trial may offer other therapy options.
- Patient participation in past clinical trials has resulted in the treatments we have today.
- The Leukemia & Lymphoma Society (LLS) is leading the PedAL Master Trial to improve cancer treatment in children. The trial will be ongoing for many years and can be found at many centers. It involves:

• Academic research institutions
• Drug companies
• Biomarker and genetic analysis
• Regulators
• Cooperative Study Groups

A clinical research organization to help LLS coordinate the study.

The goal of LLS, through the PedAL trial, is to test more than one new treatment for AML in the same trial. The aim is to help speed up the time to get new approved treatments to more patients diagnosed with AML.

Your child has joined this study, now what?

1. You may have already provided consent for your child to receive cytogenetic screening and genomic testing (see genome study).
2. Your child will get a bone marrow biopsy.
3. The bone marrow sample will be quickly sent for genomic testing.
4. The cytogenetic screening may take about three weeks. The genomic testing will take longer.
5. While you and your child are waiting for the results, your child may have to stay in the hospital.
6. Once your child's unique leukemia biology results are received, the doctors will discuss with you and your child (if old enough) the treatment sub-studies that may be appropriate.
7. If your child's results do not match any of the treatment sub-studies, the doctor will discuss other treatment options.
8. Each sub-study of the trial will focus on a different group of the AML patient population.
9. However, no matter what the treatment, there will be many tests, assessments and appointments.

FACT SHEET

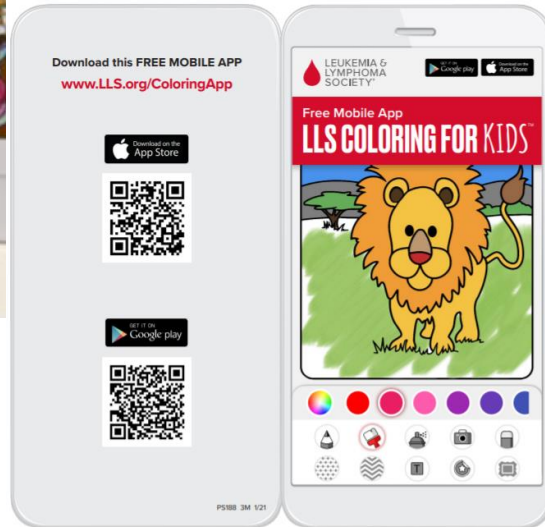
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NAVIGATING LIFE DURING AND AFTER
A BLOOD CANCER DIAGNOSIS

CHILDREN & ADOLESCENTS

DARE TO DREAM RESOURCES AND SUPPORT



(800) 955-4572

DARE TO DREAM RESOURCES AND SUPPORT

LEUKEMIA & LYMPHOMA SOCIETY Pediatric Education & Support Resources RESOURCES

The Leukemia & Lymphoma Society offers FREE disease-specific, treatment and support resources in multiple languages. The following are resources we hope are helpful. To access the full list of LLS publications, visit: www.LLS.org/Booklets For additional pediatric specific information please visit www.LLS.org/ChildhoodCancer or call (800) 955-4572 and speak to an Information Specialist.



www.LLS.org/SurvivorshipWorkbook

Introducing *The Dare to Dream Project*



LLS is investing \$175 million over the next five years to support global, collaborative research and treatments for children's blood cancers, the LLS PediA, Master Clinical Trial, as well as widening our range of free education, 1:1 support services, financial assistance, and advocacy on behalf of all children and their families.

www.LLS.org/DareToDream

LLS has produced child-friendly videos CAR T-cell therapy to help answer many questions that a child may have such as:

- What is CAR T-cell therapy?
- How does CAR T-cell therapy work?
- How might someone feel after receiving CAR T-cell therapy?



www.LLS.org/EducationVideos

LLS COLORING FOR KIDS™



www.LLS.org/ColoringApp



www.LLS.org/Booklets

For personalized disease, treatment or support information, please contact an LLS Information Specialist at 800.955.4572 or www.LLS.org/ContactUs



Pediatric Education & Support Resources

CAREGIVING



The Leukemia & Lymphoma Society (LLS) has created a comprehensive set of materials for caregivers of pediatric patients. Caregivers are encouraged to call with questions or to request additional pediatric resources. For information about these materials and other resources, call an Information Resource Specialist at 800.955.4572 or visit:

www.LLS.org/ContactUs

Resources for You and Your Child

The Pediatric Caregiver Workbook *

LLS created this resource full of tools, tips and encouragement for caregivers. Only Caregivers can request a copy of this workbook.



CAREGIVERS* may order a copy of the full workbook, the calendar and the Medi-Teddy and the Wiskurs Flip Book and Trilogy by calling (800) 955-4572

Most of these materials are available in both English and Spanish

*Only caregivers can request a workbook.

Visit www.LLS.org/FamilyWorkbook to download a PDF version of each chapter of *Caring for Kids and Adolescents with Blood Cancer*.

Additional Pediatric Resources Include:



Medi Teddy™ teddy bear that fits over IV and feeding tube bags to conceal the contents)



Dry erase/magnetic calendar



Wiskurs emotions flipbook



Stars Will Twinkle, *The Sun Will Shine*, a three book series about Olivia's leukemia diagnosis

For personalized disease, treatment or support information, please contact an LLS Information Specialist at 800.955.4572 or www.LLS.org/ContactUs

(800) 955-4572



LEUKEMIA & LYMPHOMA SOCIETY®

THE BLOODLINE WITH LLS

A PODCAST FOR PATIENTS AND CAREGIVERS

Cancer & Caregiving: Navigating My Child's Cancer – Survivorship

NOVEMBER 18, 2021 [LEAVE A COMMENT](#)

Cancer & Caregiving: Navigating My Child's Cancer – Schooling

NOVEMBER 16, 2021 [LEAVE A COMMENT](#)

Join us for our special series where we focus on parent caregivers of children with cancer. In this series we...

Training for the Unknown: Jason's Story

NOVEMBER 20, 2019 [LEAVE A COMMENT](#)

Listen in as Alicia speaks with Jason Khalipa. Jason is a devoted father, world champion, and global businessman. Jason is a force of nature in the fitness world whose life was turned upside down when his daughter, Ava, was diagnosed with leukemia in 2016 at the age of 4. Jason and his wife, Ashley, dedicated themselves to the fight armed with a positive mindset and an emphasis on physical and mental strength. Join Jason and Alicia as he shares more about how Ava was diagnosed, what their cancer journey taught him not only as a person, but as a father, and how his passion for fitness helped him remain strong and disciplined throughout this new journey.



Jason Khalipa

Cancer & Caregiving: Navigating My Child's Cancer – Diagnosis

NOVEMBER 2, 2021 [LEAVE A COMMENT](#)

Join us for our special series where we focus on parent caregivers of children with cancer. In this series we will be listening in on a conversation between a social worker and parent caregiver as they navigate the various stages of a child's cancer journey – diagnosis, treatment, post-treatment survivorship, and the child going back to school.



Nancy Cincotta, LCSW, MPhil, CPA Dave Garcia

In the first episode of this series, Nancy Cincotta, LCSW, MPhil, CPA will talk with parent caregiver, Dave Garcia about the experience of caregiving for his young son, Andy, through the diagnosis stage of acute myeloid leukemia (AML).

How Will My Child's Cancer Diagnosis Impact Their Emotions?

MARCH 5, 2020 [LEAVE A COMMENT](#)

When you think about a pediatric patient, they are not a child living in a vacuum. They are part of...

(800) 955-4572



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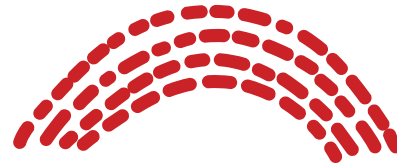
PATTI ROBINSON KAUFMANN FIRST CONNECTION PEER SUPPORT PROGRAM



(800) 955-4572

The *Patti Robinson Kaufmann
First Connection*

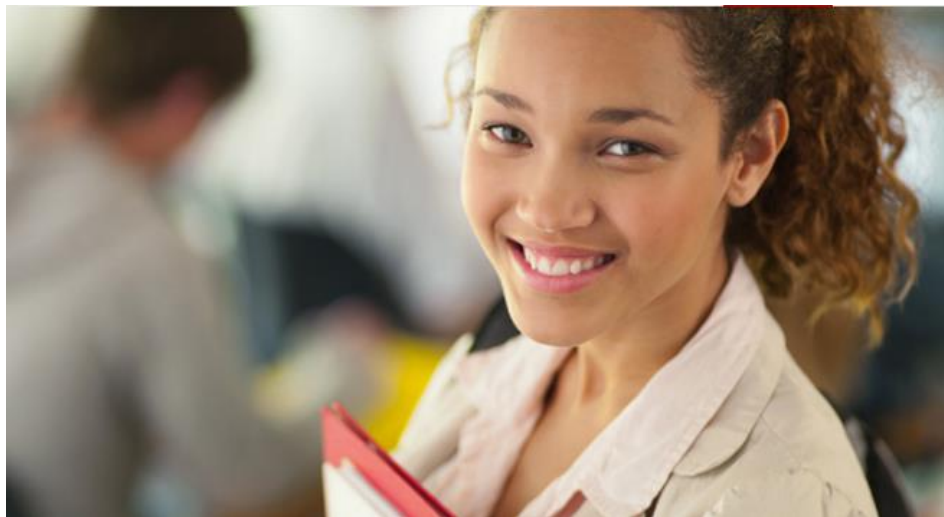
Program introduces caregivers
and adult patients to a trained
peer volunteer who has gone
through a similar experience.



LLS SCHOLARSHIP FOR BLOOD CANCER SURVIVORS

Accepting applications for the 2024-2025 academic year

Deadline: October 31, 2023



(800) 955-4572

QUARTERLY VIRTUAL PEDIATRIC CANCER PROGRAMS

***The Power of Play & Creative Therapies for Families
Coping with Childhood Cancer***

Thursday, December 7, 2023, 1:00-2:30pm (EST)

***Love, Strength, Support - Sibling Care in the Pediatric
Blood Cancer Journey***

End of Feb/early March 2024 (TBD)

Summer Fun for the Family

May 2024 (TBD)

(800) 955-4572





THE DARE TO DREAM

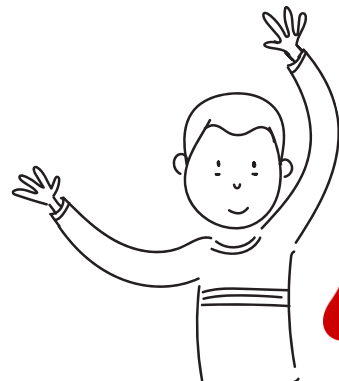
Transforming treatment and
PROJECT.
care for kids with blood



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THE WHY...

- In 2014, my daughter Anna was diagnosed with Acute Myeloid Leukemia (AML) at age 11
- She spent nearly five months hospitalized continuously
- Four rounds of intense chemotherapy, lasting about a month at a time
- Over 40 blood product transfusions
- Six different infections, including one that put her into septic shock and acute respiratory failure



Anna, Diagnosis



Anna and Brett, 4th Round



Anna, PICU

IN DECEMBER 2022, SHE CELEBRATED 8 YEARS OF SURVIVORSHIP!



WE NEED SAFER, LESS TOXIC, MORE EFFECTIVE

40%

Of Pediatric Cancers
Are Blood Cancers

Approximately

80%

Of Childhood Cancer
Survivors Develop Chronic
Health Issues From Treatment

Only

5%

Of Oncology Drugs Have
Been Approved For First
Time Use In Children

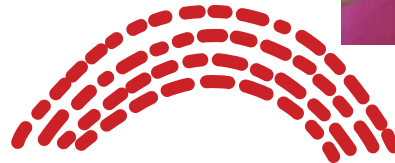


BECAUSE KIDS ARE DIFFERENT



LLS is raising \$175 million over the next five years to fund *The Dare to Dream Project*, a next-level global, groundbreaking approach to:

- Expedite pediatric blood cancer research.
- Bring new, safer treatments to more kids through the PedAL Master Clinical Trial.
- Grow our education and support services as well as drive advocacy for young patients with blood cancer and their families.



ATTACKING PEDIATRIC BLOOD CANCER FROM

LLS PedAL MASTER CLINICAL TRIAL

Test new, safer therapies on kids with acute leukemia who are matched to treatments based on their unique tumor biology in this, the first integrated, global, pediatric AML master clinical trial.

RESEARCH

Focus on global collaboration, uniting doctors, pharmaceuticals, and scientists to expedite pediatric blood cancer cures and care.



POLICY & ADVOCACY

Drive policy to advance research for childhood cancers, break down barriers to care.

PATIENT EDUCATION & SUPPORT

Expand free education, 1:1 support, and financial services for children and their families.

TODD MICHAEL COOPER, DO

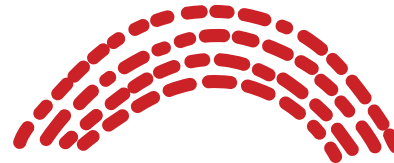


SEATTLE CHILDREN'S

Professor of Pediatrics | University of Washington
Evans Family Endowed Chair in Pediatric Cancer
Chair, COG Myeloid Diseases Committee
Co-Chair, LLS Pediatric Acute Leukemia Initiative
Section Head - Pediatric Oncology | Seattle Children's Cancer
and Blood Disorders Center
Director – Leukemia/Lymphoma Program



Seattle Children's[®]
HOSPITAL · RESEARCH · FOUNDATION



PEDIATRIC DRUG DEVELOPMENT PARADIGM IS

Current State

Precision medicine progress in adults not seen for children; children are not mini-adults

- Unfavorable business case for pharma industry – cost and operational challenges
- Regulations are onerous and not globally uniform
- Data is siloed and not every child has access to sequencing

The LLS Dare to Dream Initiative and LLS PedAL

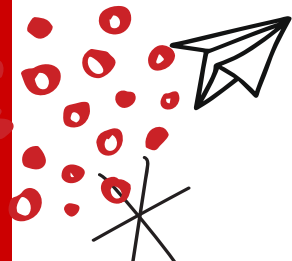


LLS PedAL will ensure dedicated research testing therapies specially targeting the biological drivers of pediatric cancer

Master Trials like Beat AML and LLS PedAL allow testing of multiple agents and bring cost-saving efficiencies

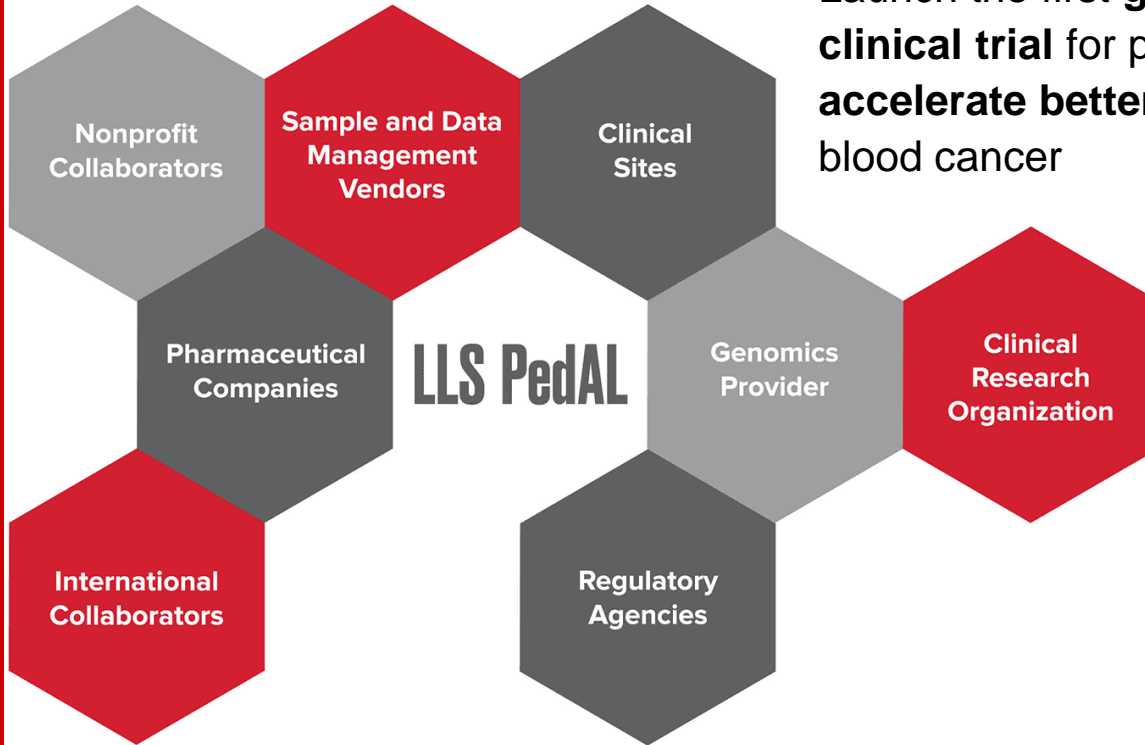
LLS PedAL will create a platform for International cooperation helping pharma companies meet regulatory requirements

Open source Data Commons created through LLS PedAL will consolidate pediatric acute leukemia data from multiple institutions into a single data set, establish a common language and make that data available to researchers worldwide



DARE TO DREAM

THE PEDAL TRIAL



Launch the first **global precision medicine clinical trial** for pediatric acute leukemia to **accelerate better treatments** for children with blood cancer

LLS PedAL will align scientific, medical, corporate and regulatory partners to test multiple targeted therapies simultaneously at up to

200 CLINICAL SITES IN THE UNITED STATES AND AROUND THE WORLD.

PEDAL/EUPAL MISSION & GOALS

- **SCREEN** – *Via APAL2020SC and EuPAL registry*
 - Screen all children with relapsed AML, B-ALL (subset), and T-ALL for therapeutic sub-trial eligibility based on clinical, flow cytometry immunophenotyping, genomic sequencing.
- **DISCOVERY** –
 - Sample acquisition for correlative biology, target discovery, and biobanking
- **ACCESS** –
 - Partner with pharma, NCI and FDA/EMA, and European study groups (via the EuPAL Foundation) to support drug development platform that achieves regulatory objectives to ensure that children have early access to effective therapies
 - Partner with LLS Navigators to navigate compassionate use access of potentially beneficial agents for those that do not have other trial/therapeutic options
- **CHANGE** –
 - Improve post-relapse data collection to inform changes in primary outcome measures and toxicity definitions that better reflect the realities of routine care for children with relapsed leukemia

DARE TO DREAM

BUILDING STANDARDIZED RESOURCES

Data Commons



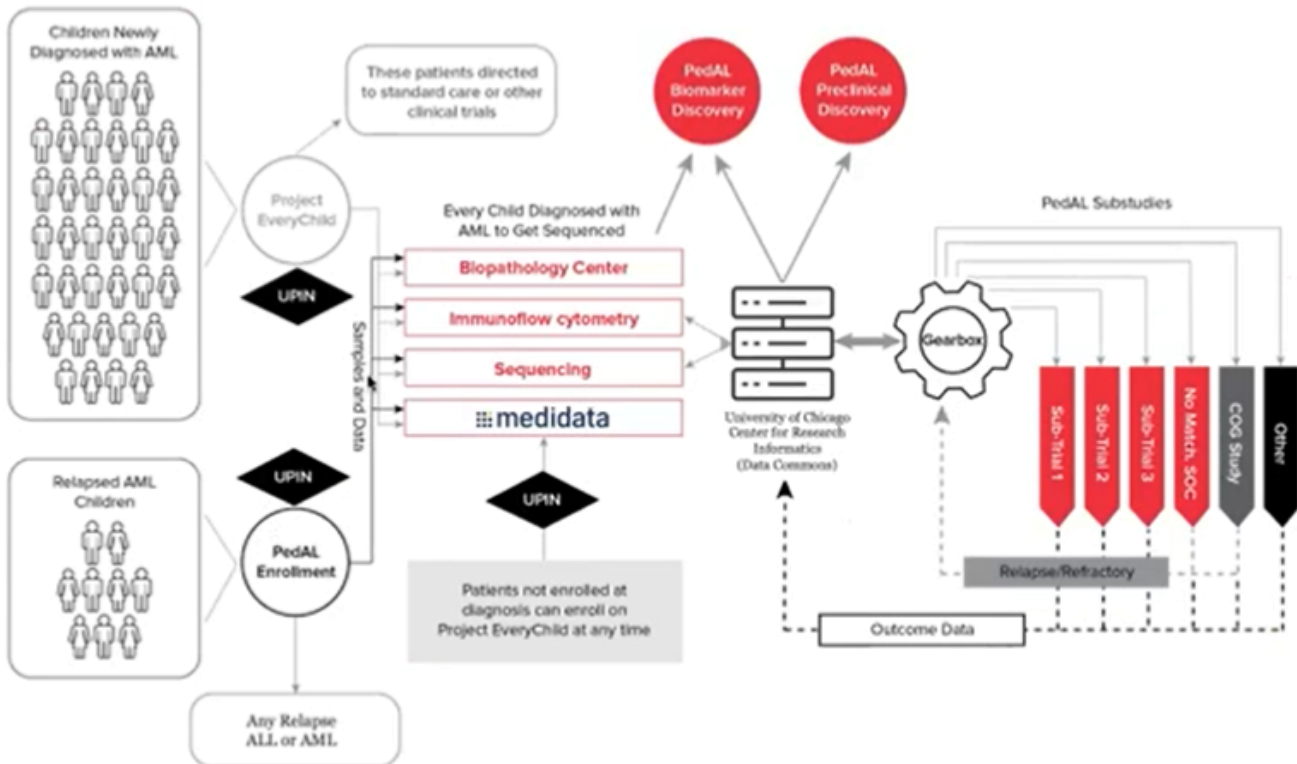
- Provides a shared platform to aggregate data
- Ensures consistency in data reporting for doctors, nurses, and researchers to facilitate research progress
- Enables researchers to detect meaningful patterns and drive innovation using a large, uniform data set

GEARBOX (Genomic Eligibility Algorithm at Relapse for Better Outcomes)

- Decision support tool for clinicians and nurse navigators
- Web-based tool that uses patient data to identify appropriate trials rapidly and accurately

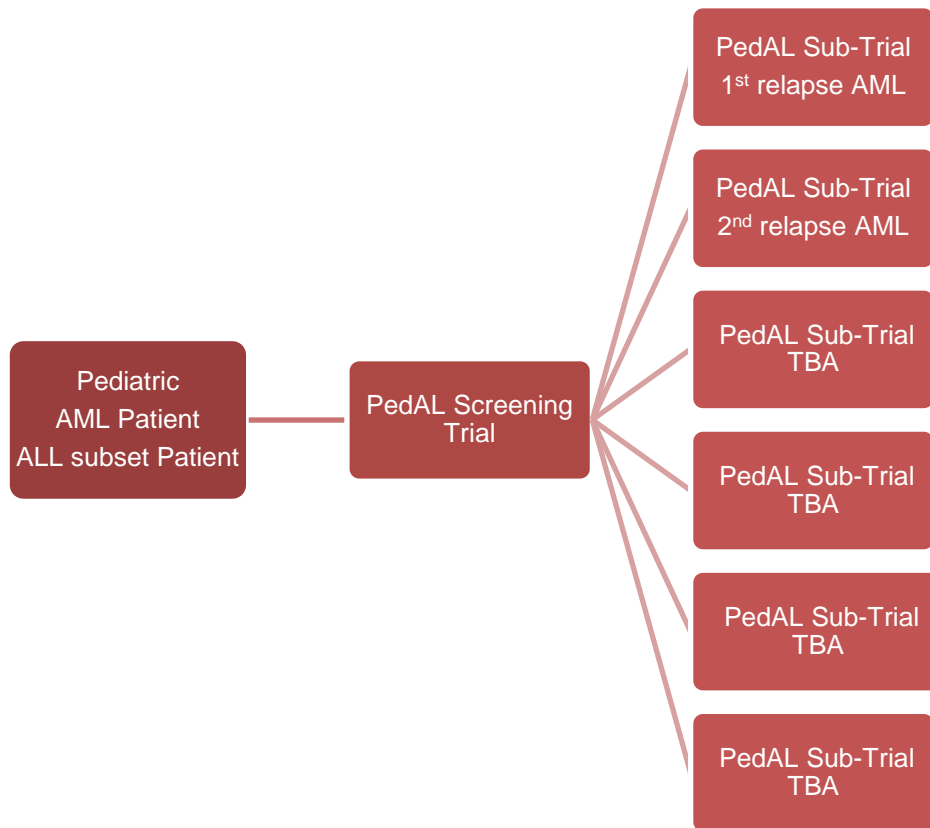
DARE TO DREAM THE PEDAL TRIAL

How the LLS PedAL Master Clinical Trial Works




DARE TO DREAM

THE PEDAL TRIALS IN THE PNW



- Seattle Children's Hospital
- Mary Bridge Children's Hospital and Health Center
- Madigan Army Medical Center
- Providence Sacred Heart Medical Center and Children's Hospital
- Providence Alaska Medical Center
- OHSU Doernbecher Children's Hospital
- Randall Children's Hospital at Legacy Emanuel



**APAL2020SC
PEDIATRIC ACUTE LEUKEMIA (PEDAL)
SCREENING TRIAL –
DEVELOPING NEW THERAPIES FOR
RELAPSED LEUKEMIAS**

**Michele Redell – Study Chair
Maureen O'Brien – Study Vice-Chair**

APAL2020SC: PROGRESS

170+ approved sites (Thanks! High Impact Initiative)

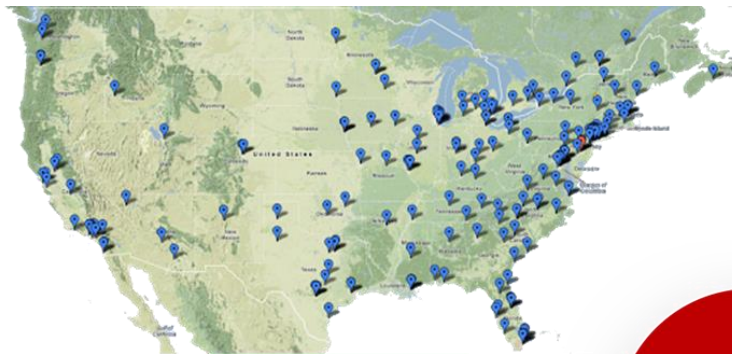
74 sites have enrolled at least 1 patient

6 in Canada; 1 in Australia

181 patients enrolled, 133 confirmed (73%)

Myeloid Diagnoses (73%)		Lymphoid Diagnoses (27%)	
AML relapsed/refractory	86	B-ALL 1 st relapse with KMT2Ar	5
Myeloid Leukemia of DS r/r	2	B-ALL 2 nd relapse no KMT2Ar	19
Treatment-related AML	9	T-ALL relapsed/refractory	7
		MPAL relapsed/refractory	5

PEDAL/EUPAL – EUROPEAN AND NORTH AMERICAN COLLABORATION



**CHILDREN'S
ONCOLOGY
GROUP**



**EuPAL
Consortium**

UNIFYING EFFORTS ACROSS SECTORS, SCIENTIFIC

LLS PEDAL: OUR STRATEGIC APPROACH



WHAT ARE THE DIRECT IMPACTS OF THE DARE TO DREAM/PEDAL TRIAL FOR OUR CHILDREN?

- **Access** to the most innovative targeted therapies
 - LLS navigators
 - Clinical trials leading to future approvals and unlimited access
- **Knowledge**
 - Provides critical biologic information for targeted therapies
- **Discovery**
 - Provides a source for rare and vital samples at relapse to identify new targets and therapies

PedAL GLOBAL MASTER CLINICAL TRIAL

It is **bold**.

It is **game changing**.

It is **global**.

It is **happening**.

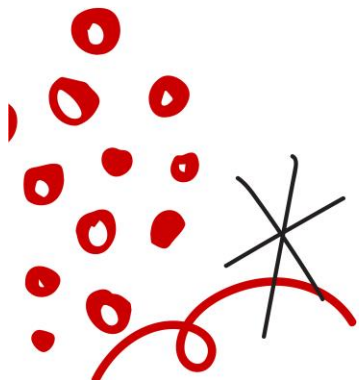
DISCUSSION & QUESTIONS



LEUKEMIA &
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DARE TO DREAM
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*Contact our Information Specialists at
(800) 955-4572 for additional resources!*



**Join LLS In Supporting
The Accelerating
Kids' Access to Care Act!**
Learn more here:



SOCIETY