Blinatumomab

Like Rock and Roll It's Here to Stay

JANUARY 25 2022

Presented by: Sue Zupanec MN NP

Disclosure

- Sue Zupanec has no industry relationships to disclose
- Off label use of Blinatumomab will be discussed
- Trial results will be presented - but will focus on highlights only to allow us to get to the administration, nursing care, and discussion (feel free to ask me later if you want more scientific details)

Author	Year	Ref. [1]	Patients	Title
Mikhailova	2020	[43]	90 patients	Immunophenotypic changes of leukemic blasts in children with R/R- ALL who have been treated with blinatumomb
Contreras	2020	[33]	27 children/young adults treated with blinatumomab and/or inotuzumab	Clinical utilization of blinatumomab and inotuzumab immunotherapy in children with relapsed or refractory B-ALL
Clesham	2020	[32]	11 infants	Blinatumomab for infant ALL
Horibe	2020	[35]	9 children	A phase 1 study of blinatumomab in Japanese children
Ampatzidou	2020	[34]	9 children	Insights from the Greek experience of the use of Blinatumomab in pediatric R/R ALL
Queudeville	2021	[36]	38 R/R-ALL patients	Blinatumomab in pediatric patients with relapsed/refractory B-cell precursor acute lymphoblastic leukemia
Sutton	2021	[37]	24 R/R-ALL patients outside of clinical trials	Outcomes for Australian children with relapsed/refractory acute lymphoblastic leukaemia treated with blinatumomab
Brethon	2021	[44]	case report	Targeting 2 antigens as a promising strategy in mixed phenotype acute leukemia: combination with blinatumomab with gemtuzumab ozogamicin in an infant with KMT2A-rearraged leukemia
Brown	2021	[38]	208 pts, 1 to 30 years	Effect of Postreinduction Therapy Consolidation with Blinatumomab vs. Chemotherapy on Disease-Free Survival in Children, Adolescents, and Young Adults with First relapse of B-Cell Acute Lymphoblastic Leukemia NCT02101853
Locatelli	2021	[39]	108 pts, 28 days to 18 years	Effect of Blinatumomab vs. Chemotherapy on Event-Free Survival Among Children with High-risk First-Relapse B-Cell Acute Lymphoblastic Leukemia: A Randomized Clinical Trial NCT02393859

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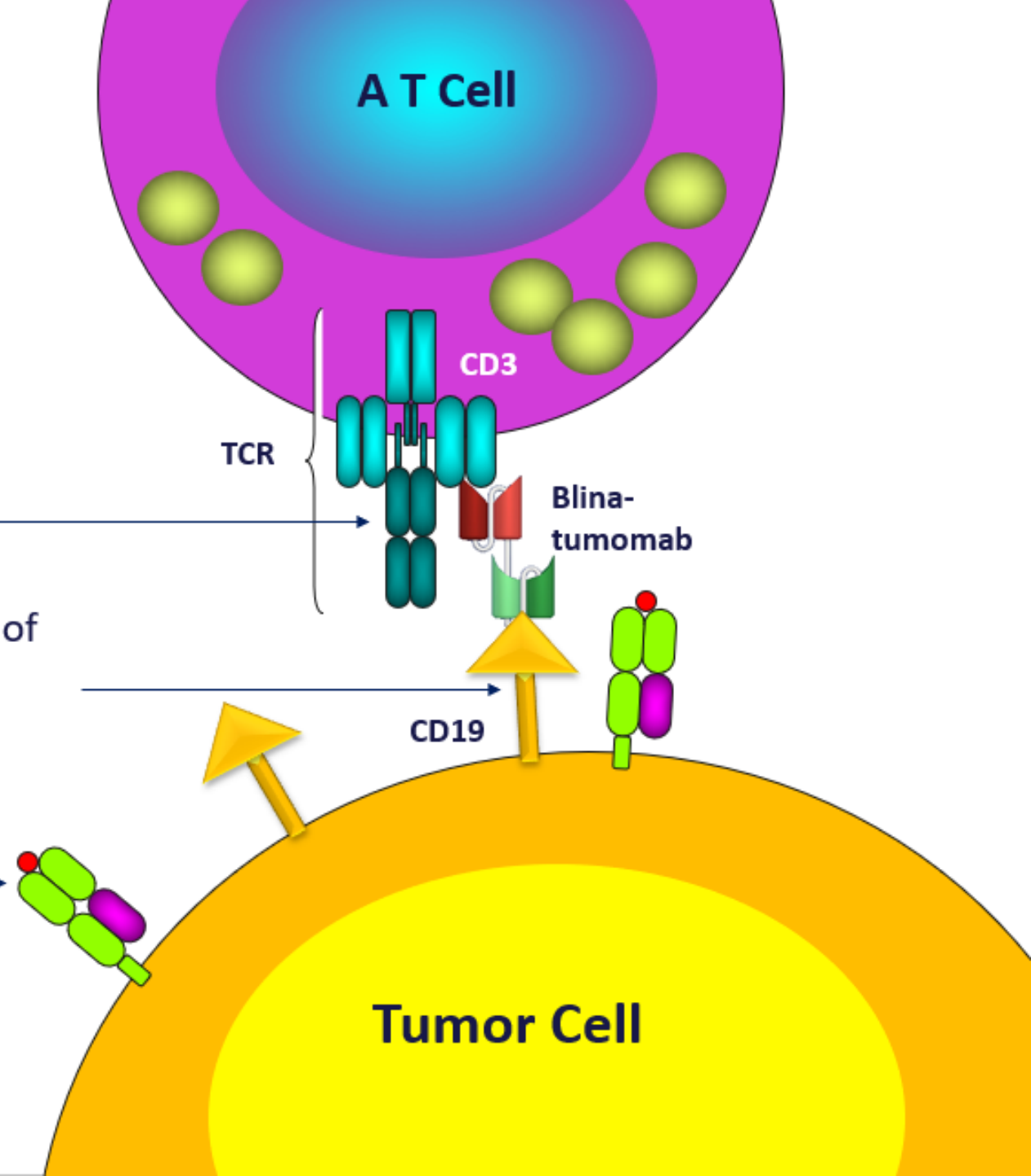
Queudeville, 2021

Objectives

- Discuss Blinatumomab
  - Briefly review mechanism of action
- Worries when administering Blinatumomab
  - Cytokine Release Syndrome
  - Neurotoxicity
  - Administration/dosing errors
- Updates on use of Blinatumomab for Clinical Problems in B-ALL
  - Indications, proven (now SOC) and possible/emerging (based on early data)
- Nursing Care for patients receiving blinatumomab
  - Administration – recommendations
  - Ponder some burning questions
  - Preparing Kids and Families
- New/ongoing projects Blinatumomab

Blinatumomab Mechamism of Action

(BiTE® = Bi-specific T-Cell Engager)



acts independently of specificity of T Cell Receptor (TCR)

Allows T cells recognition of tumor-associated surface antigen (TAA)

does not require MHC Class I and/or peptide antigen

Courtesy of Dr. Lia Gore

Cytokine Release Syndrome (CRS)

- **Most common toxicity associated with Blinatumomab**
- Constellation of inflammatory symptoms
  - Results from cytokine elevations
  - Associated with T cell proliferation
- CRS ranges from mild to severe to life threatening
  - Mild: flu-like symptoms, fever, myalgia
  - Severe: vascular leak, hypotension, pulmonary edema, coagulopathy
  - Life threatening: can lead to multi-system organ failure
- Cytokine elevations can be measured
  - Degree of elevation does not always correlate to clinical severity

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Barrett, D. et al. (2014) Current Opinions in Pediatrics

CRS Grading System

Toxicity Grade	Clinical Picture	Management
Grade 1	Mild: flu-like symptoms, fever, myalgia	• Supportive care • Anti-pyretics
Grade 2	Moderate: some signs or organ dysfunction (e.g. grade 2 creatinine. grade 3 LFTs)	• Hospitalization • IV therapies
Grade 3	Severe: increasing sign of organ dysfunction (e.g. grade 3 creatinine. grade 4 LFTs, hypotension, coagulopathy, hypoxia	• IV fluids or low-dose pressors • FFP or cryoprecipitate for coagulopathy • Supplemental O2 • Consider anti IL6 - Tocilizumab
Grade 4	Life threatening: Significant hypotension, significant hypoxia	• Multiple pressors • Mechanical ventilation • Anti IL6 – Tocilizumab

Porter, D. ASH meeting December 14, 2014

Management of CRS

- Reported with first cycle of Blinatumomab, typically within first 12-72 hours
- You can STOP the Blinatumomab (and possibly resume)
- Most Significantly elevated Cytokines:
  - IL10, IL6, IFNy
- Anti IL6 (tocilizumab) – resolution of CRS
  - Reversal and clinical improvement seen within 24 hours
  - FDA approved for JIA in children as young as 2 years
- Other agents for management of CRS include: Siltuximab, Anakinra, Ruxolitinib

Maude, Journal of Cancer, 2014; Barrett, Current Opinions in Pediatrics, 2014

Unique Neurotoxicity

Temporary disturbances in CNS function you may see:

- Trembling
- Disturbance or loss of movement of parts of the body
- Speech or coordination disorders
- Apraxia
- Dizziness
- Confusion, disorientation
- **Reversible seizures**
- Encephalopathy
- Somnolence, agitation

Management of Neurotoxicity

- You can STOP the Blinatumomab
- Seizures – treat
- Investigate other potential causes of symptoms (imaging)
- Possibly resume post seizure at a lower dose (check the protocol dosing recommendations for dose modifications)
- Some populations might require seizure prophylaxis (COG protocols recommend seizure prophylaxis for patients with Down Syndrome who are greater than 10 years old)

How often do these toxicities happen?

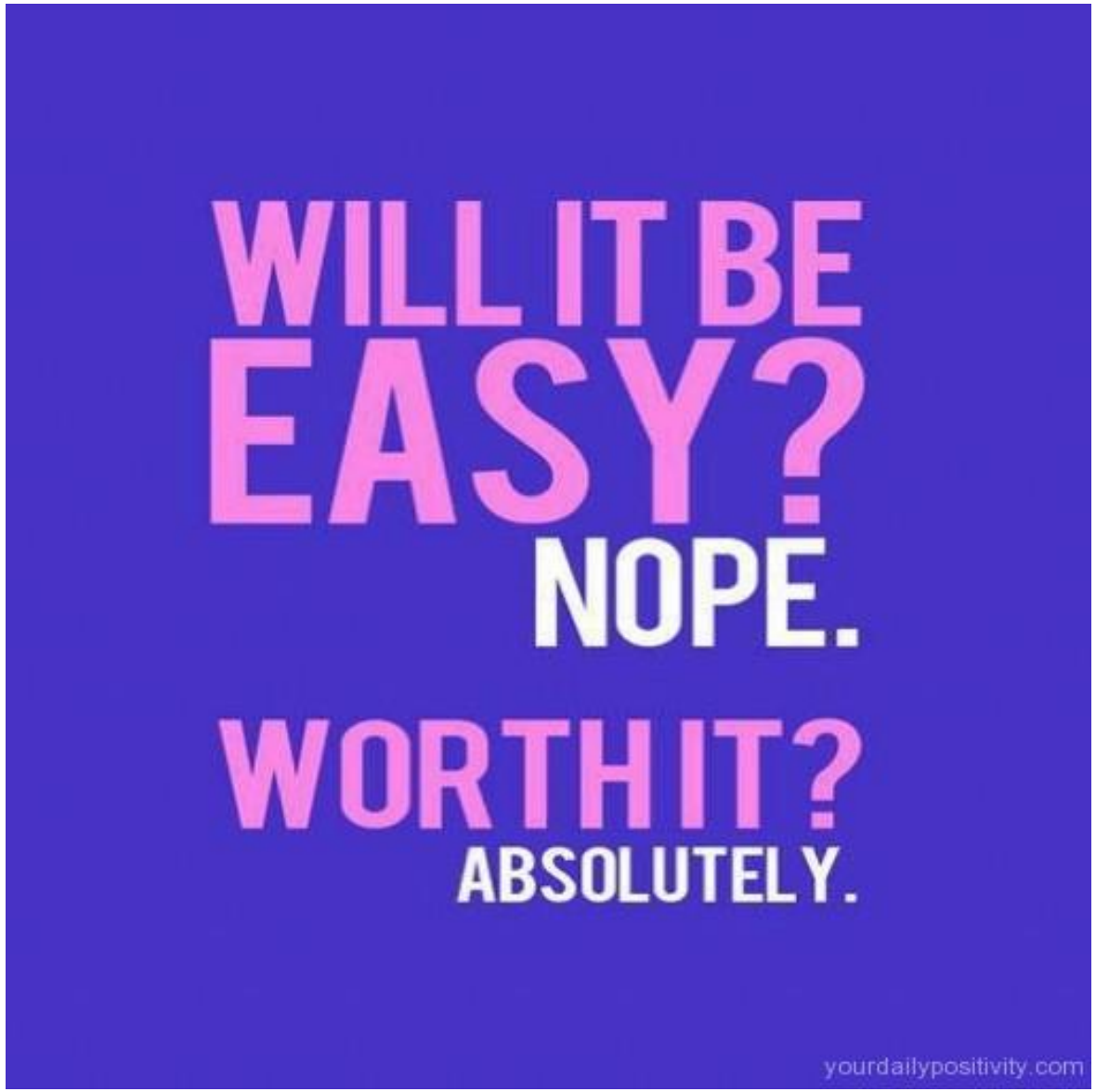
- Will try to embed this into the review of clinical trials throughout presentation
  - Captured as a significant adverse event of interest in clinical trials

- However – it happens a lot less than we thought!

Administration Errors

- On clinical trials reported to be 3-4%
- Source of errors included:
  - increased flow rate of the infusion pump (through malfunction leading to an accidental increase, including setting of incorrect infusion rate)
  - Overdoses also resulted from preparation errors by pharmacists in calculating the incorrect concentration of blinatumomab solution to be administered to patients

FDA Briefing Document. Oncologic Drugs Advisory Committee MeetingBLA 125557 S-013. Blincy to (blinatumomab). Available from: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM599298.pdf


WILL IT BE
EASY?
NOPE.
WORTH IT?
ABSOLUTELY.
yourdailypositivity.com

Clinical Problems in ALL

- Infant ALL
- Relapse
- Resistance – MRD positive disease
  - MRD negative remission most important predictor of survival
- Toxicity
  - prevents standard chemotherapy
  - can prevent meeting transplant criteria to proceed

Challenges: Infant B-ALL

- Rare Disease with a dismal outcome
- Historical data: 1 year EFS 54.8% and 3 year EFS 39.6% (patients less than 1 with KMT2A rearrangement)
- Most relapses occur on therapy and during the first year (Relapse survival 20%)

What about Blinatumomab?

- Phase 2 trial adding once cycle of blinatumomab to Interfant backbone post Induction (non-randomized)
- Tolerated and found to be safe in infants (no neurotoxicity observed, fever common and infections common)
- MRD negative response post blina 89% (25/28) and 1-year EFS 96.2% (short follow-up – but very promising)
- Blinatumomab will now be tested in the next up front Infant ALL trials

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American Society of Hematology
Helping hematologists conquer blood diseases worldwide

Inge M. Van Der Sluis, Paola De Lorenzo, Rishi Sury Kotecha, Andishe Attarbaschi, Gabriele Escherich, Karsten Nysom, Jan Stary, Alina Ferster,Benoit Brethon, Phillip Ancliff, Andrea Biondi, Maria Grazia Valsecchi, Rob Pieters, A Phase 2 Study to Test the Feasibility, Safety and Efficacy of the Addition of Blinatumomab to the Interfant06 Backbone in Infants with Newly Diagnosed KMT2A-Rearranged Acute Lymphoblastic Leukemia. a Collaborative Study of the Interfant Network, Blood, 2021

Challenges: Relapsed B-ALL

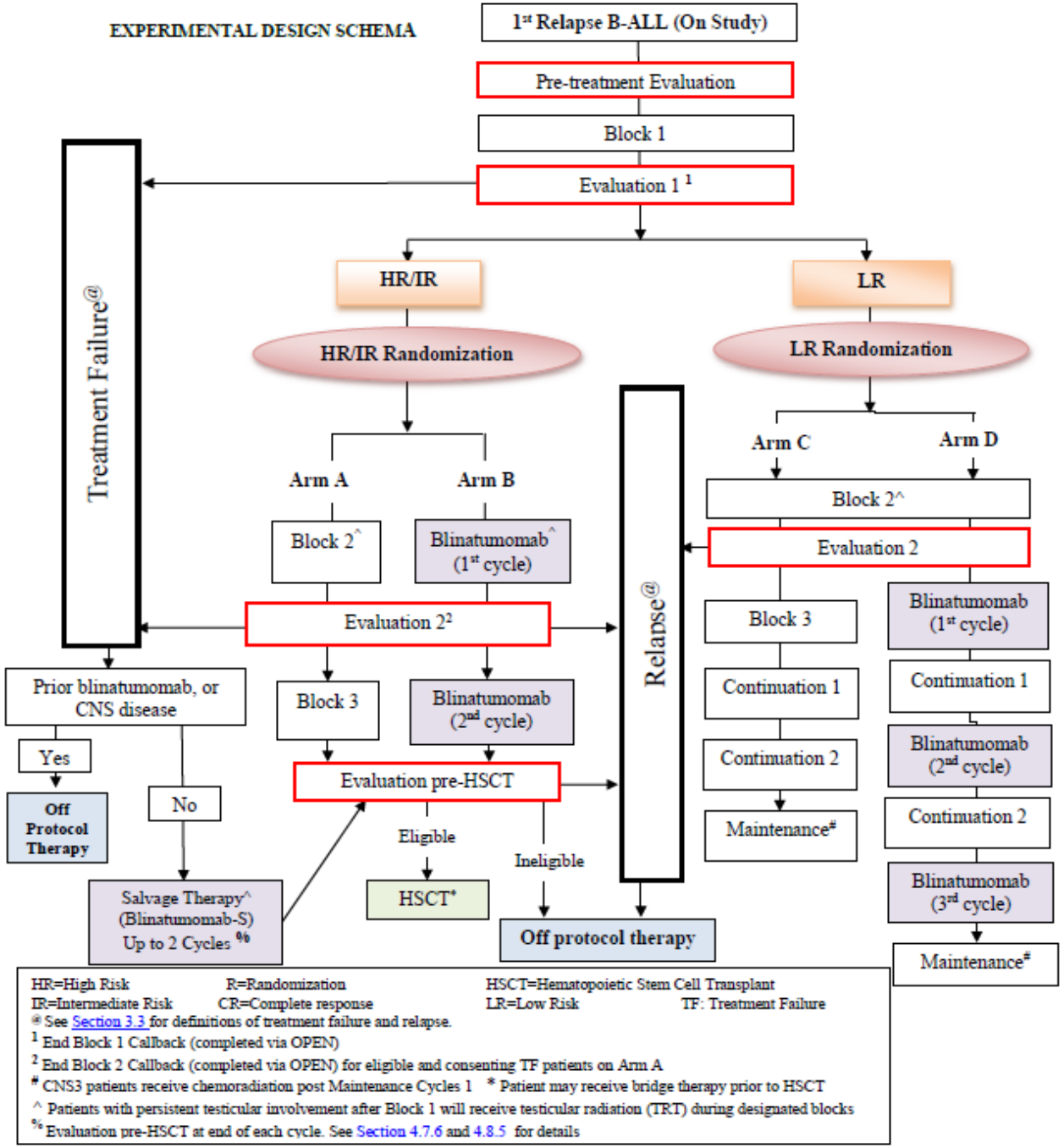
- Poor Outcomes (3-year DFS 39% and OS 58.4%)
- Traditional Chemotherapy for Relapsed B-ALL is very toxic (will show some data)
- Transplant – requires MRD negative response to be successful
  - Chemotherapy not very successful at inducing MRD negative remission (will show some data)

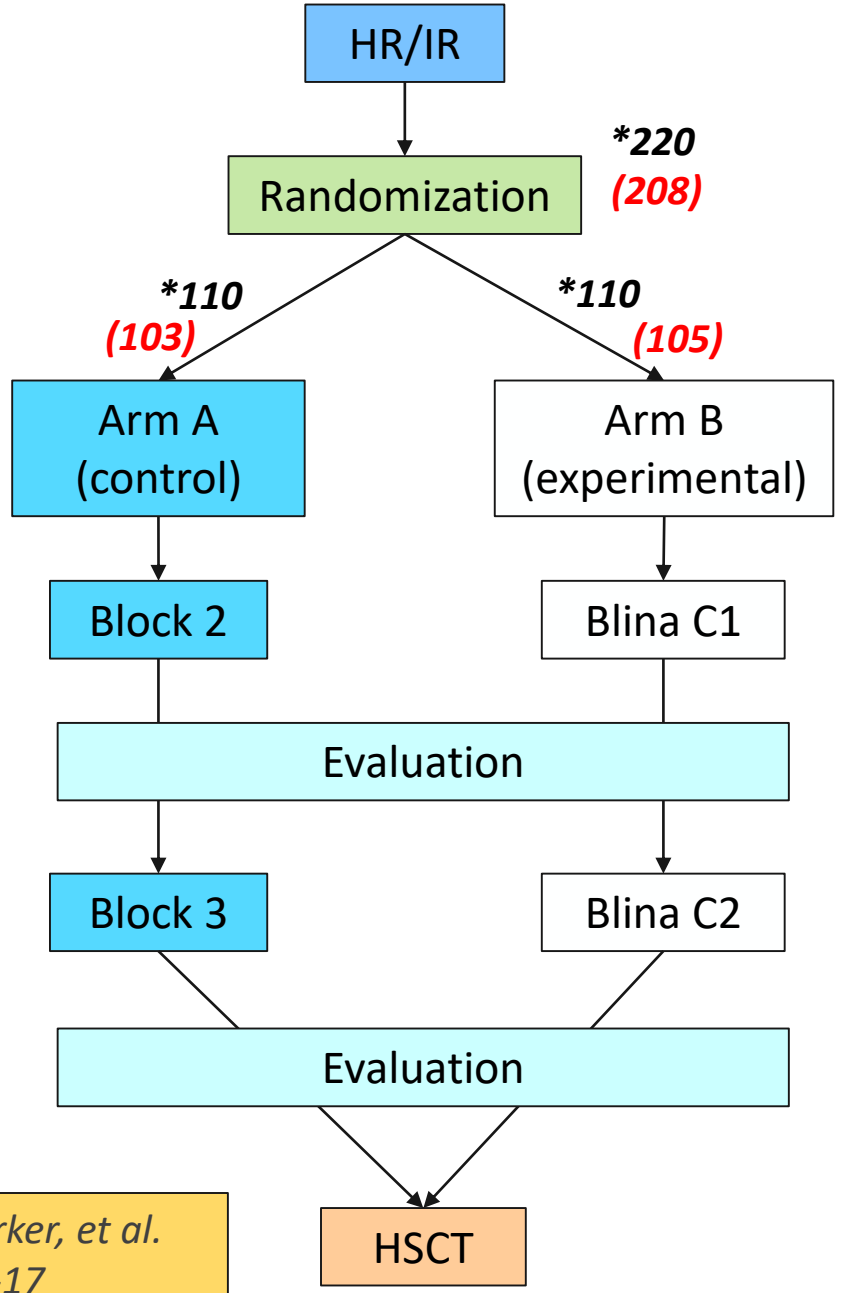
What about Blinatumomab?

- Efficacy in early phase trials (in patients with multiple relapses)
- Tested in phase 3 trial COG AALL1331

Aims:

- Will the addition of Blinatumomab to UKALLR3 backbone improve overall survival for pediatric patients in first relapse of B precursor ALL?
- Can Blinatumomab provide a salvage (bridge to transplant for resistant disease)?


EXPERIMENTAL DESIGN SCHEMA
1st Relapse B-ALL (On Study)
Pre-treatment Evaluation
Block 1
Evaluation 1 [1]
HR/IR
LR
HR/IR Randomization
LR Randomization
Treatment Failure@
Relapse@
Arm A
Arm B
Arm C
Arm D
Block 2^
Blinatumomab^ (1st cycle)
Evaluation 2[2]
Block 2^
Evaluation 2
Block 3
Blinatumomab (2nd cycle)
Evaluation pre-HSCT
Eligible
Ineligible
HSCT*
Prior blinatumomab, or CNS disease
Yes
No
Off Protocol Therapy
Salvage Therapy^ (Blinatumomab-S) Up to 2 Cycles %
Off protocol therapy
Block 3
Continuation 1
Continuation 2
Maintenance#
Blinatumomab (1st cycle)
Continuation 1
Blinatumomab (2nd cycle)
Continuation 2
Blinatumomab (3rd cycle)
Maintenance#
HR=High Risk
IR=Intermediate Risk
R=Randomization
CR=Complete response
HSCT=Hematopoietic Stem Cell Transplant
LR=Low Risk
TF: Treatment Failure
@ See Section 3.3 for definitions of treatment failure and relapse.
[1] End Block 1 Callback (completed via OPEN)
[2] End Block 2 Callback (completed via OPEN) for eligible and consenting TF patients on Arm A
CNS3 patients receive chemoradiation post Maintenance Cycles 1
* Patient may receive bridge therapy prior to HSCT
^ Patients with persistent testicular involvement after Block 1 will receive testicular radiation (TRT) during designated blocks
% Evaluation pre-HSCT at end of each cycle. See Section 4.7.6 and 4.8.5 for details



UKALLR3, Block 2*

- VCR, DEX week 1
- ID MTX, PEG week 2
- CPM/ETOP week 3
- IT MTX or ITT

UKALLR3, Block 3*

- VCR, DEX week 1
- HD ARAC, Erwinia Weeks 1-2
- ID MTX, Erwinia Week 4
- IT MTX or ITT

Blina C1 and Blina C2

- Blinatumomab 15 ug/m2/day x 28 days, then 7 days off
- Dex 5 mg/m2/dose x 1 premed

*UKALLR3 reference: *Parker, et al. Lancet. 2010; 376: 2009-17*

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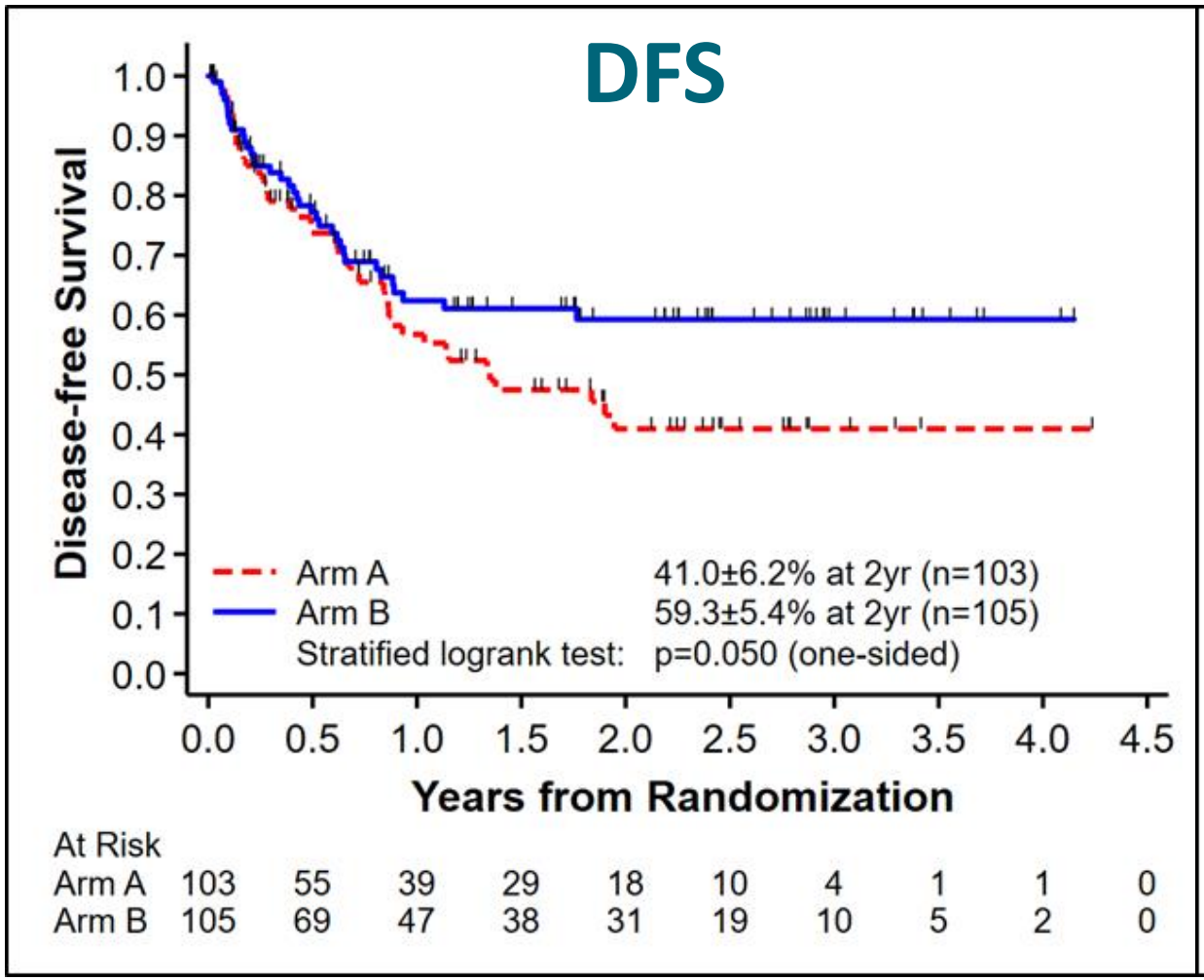
Permission, Dr. Pat Brown

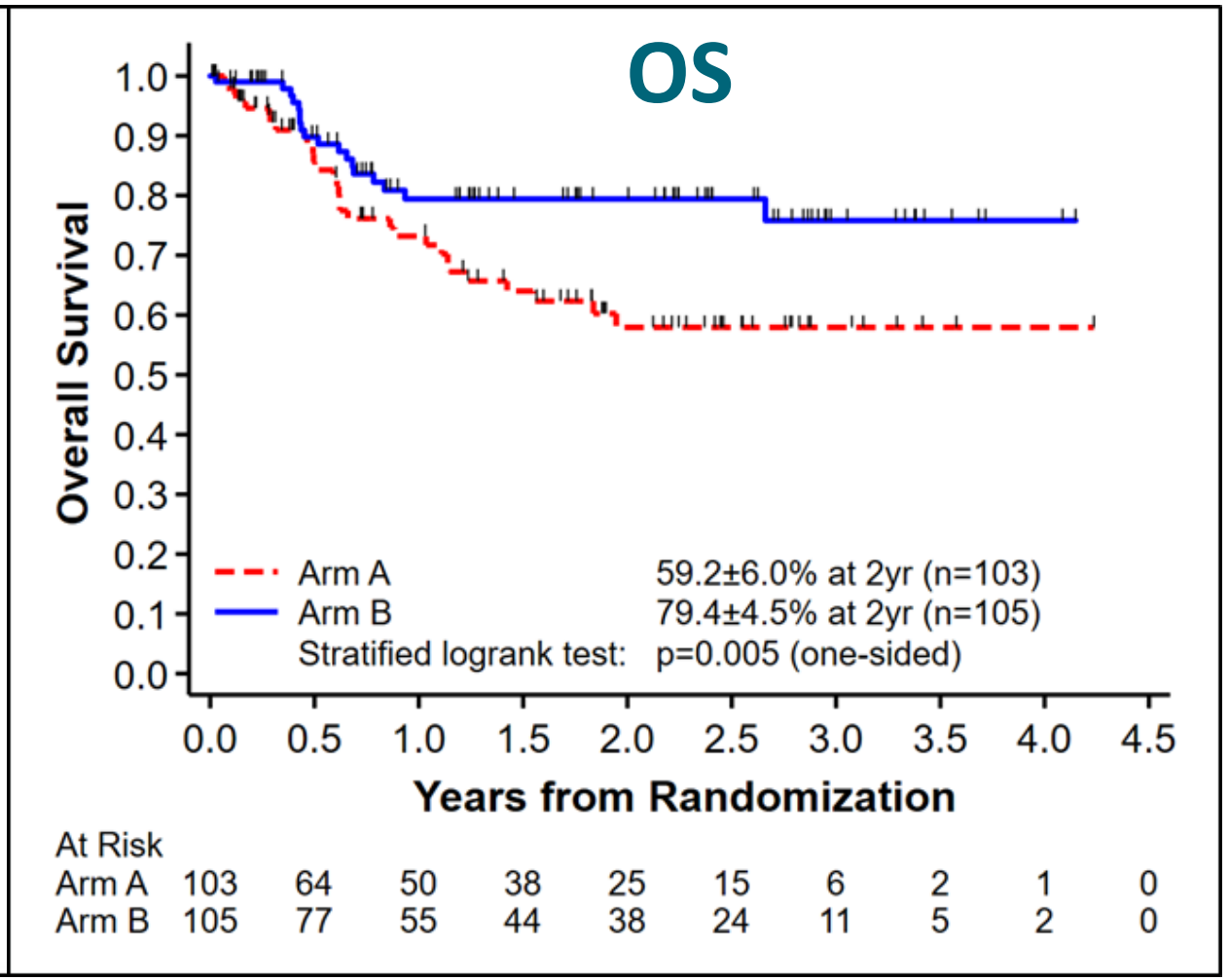
AALL1331 Early closure recommended by DSMC

- Scheduled review by DSMC (Sep 2019) using data cut-off 6/30/2019
  ***Recommendation*: Permanent closure of accrual to HR/IR randomization; Arm A should be offered crossover to Arm B**

- DSMC recommendation based on:
  - The **DFS and OS** results favoring Arm B that make it highly likely that DFS and OS on Arm B is as good as or better than Arm A
  - The profound difference in **toxicity** between Arms A and B
  - The highly significant difference in **MRD** levels favoring Arm B

Survival: Arm A (Chemo) vs. Arm B (Blina)





Median follow up 1.4 years

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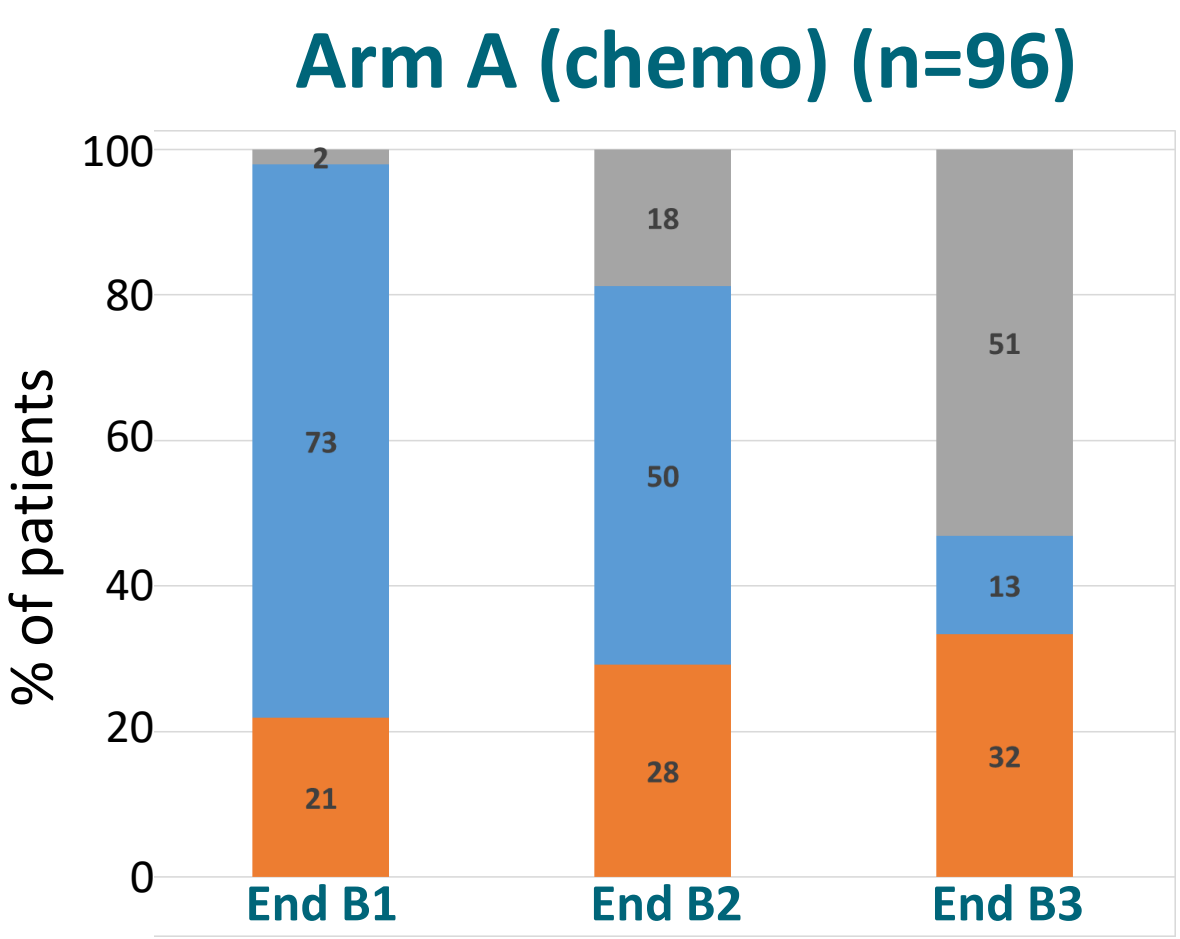
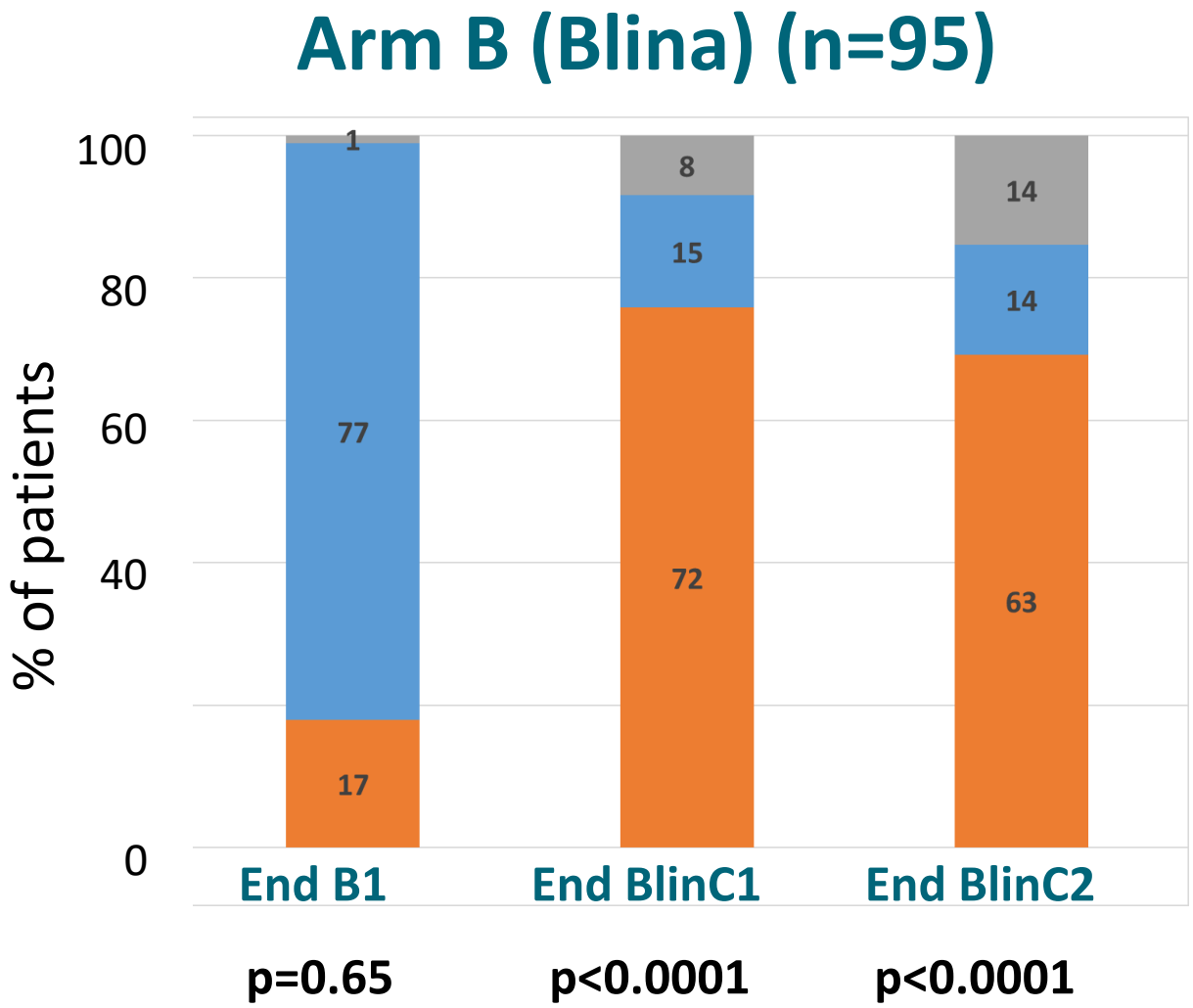
MRD Clearance (for iBM and BM+EM)





No data (off protocol) | MRD positive | MRD negative

Permission, Dr. Pat Brown

Chemotherapy (UKALLR3 Blocks) or Blinatumomab

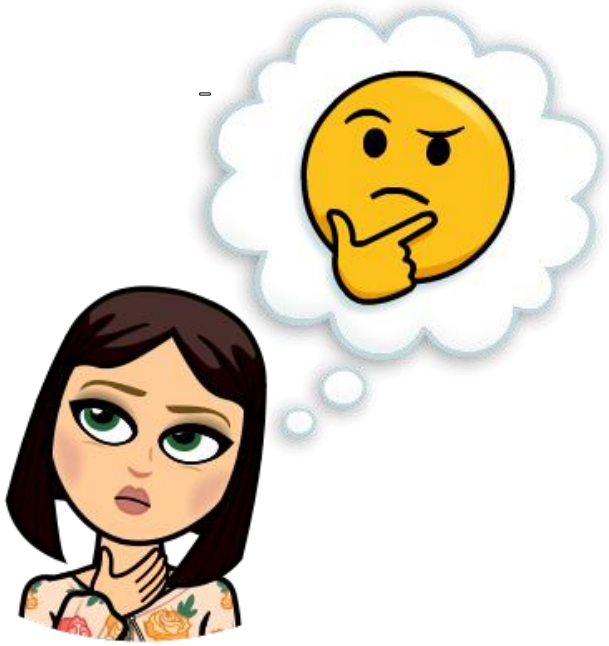
UKALLR3-Chemo

Block 2

DEX
VCR
MTX
IT chemo
PEG ASP
CPM
VP16

Block 3

DEX
VCR
ARAC
Erwinia
ASP
MTX



Blinatumomab

Blinatumomab
Cycle 1
Cycle 2

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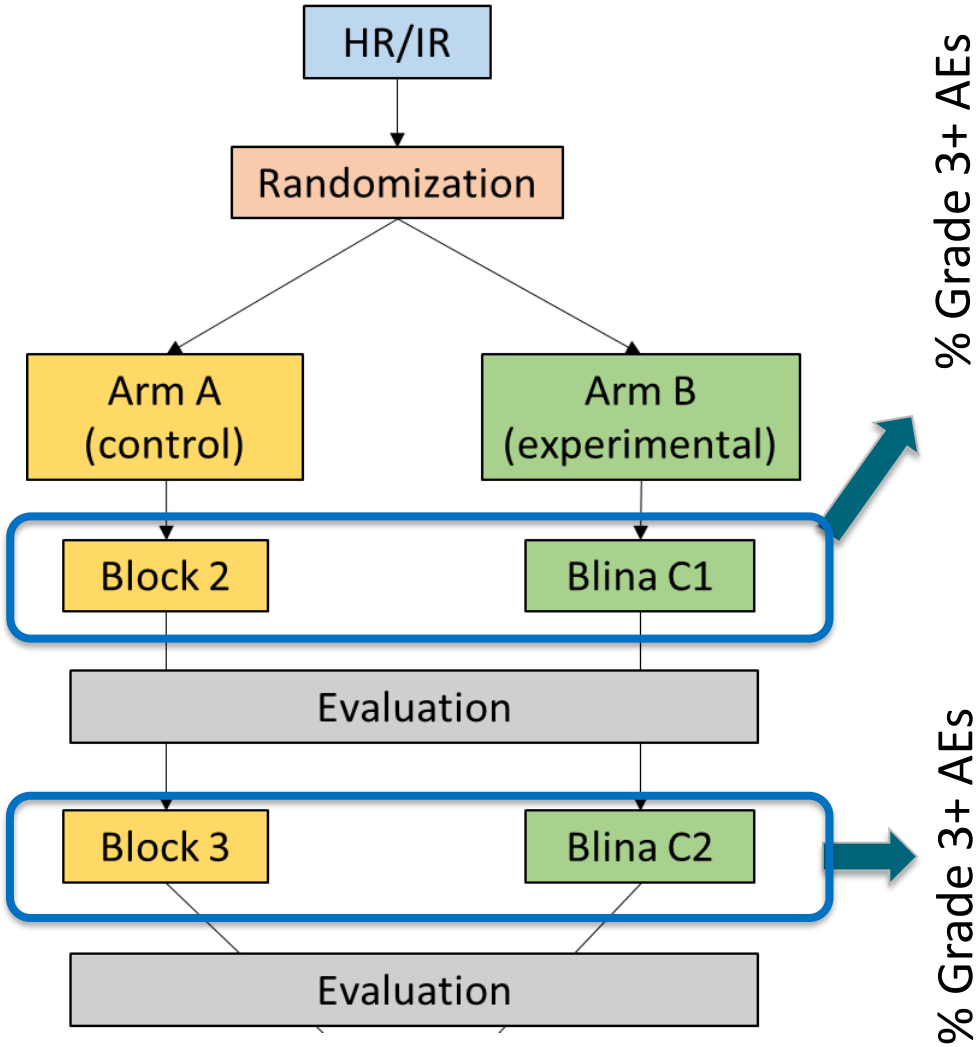
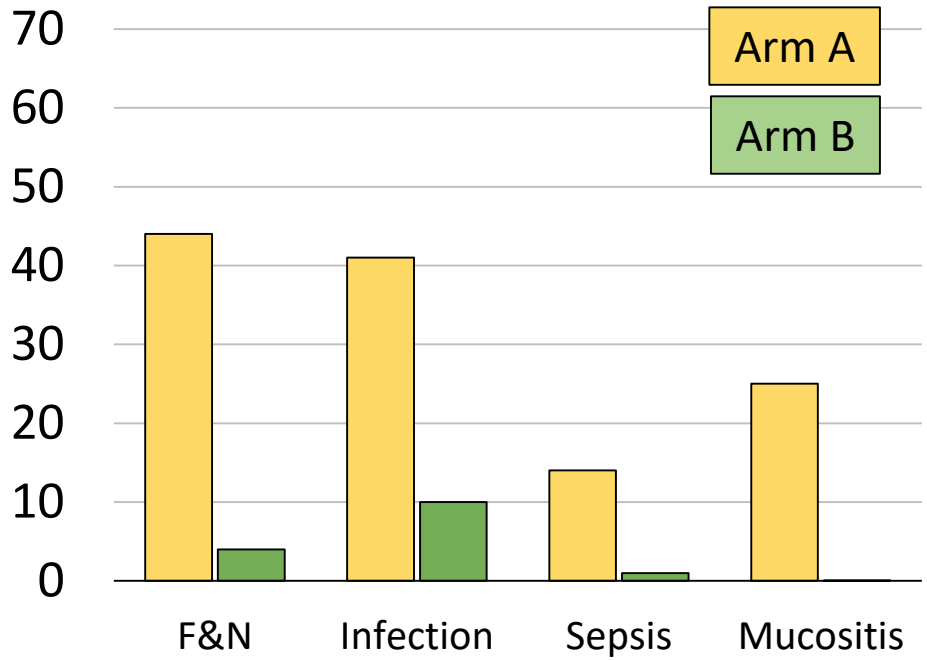
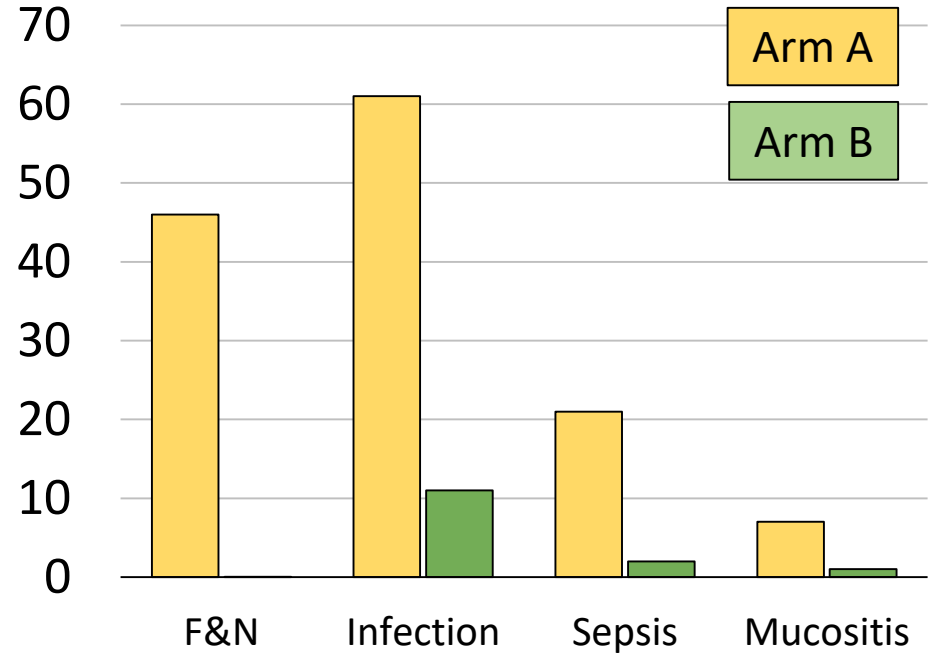
Adverse Events



% Grade 3+ AEs



% Grade 3+ AEs



Blina-related AEs on HR/IR Arm B AALL1331 (n=99)

Blinatumomab-related AEs	Any grade (%)	Grade 3-4 (%)
Cytokine Release Syndrome	22%	1%
Neurotoxicity	18%	11%
Seizure	4%	0%
Other (Encephalopathic)	14%	11%

Low Risk Arm – AALL1331

Quick Reminder

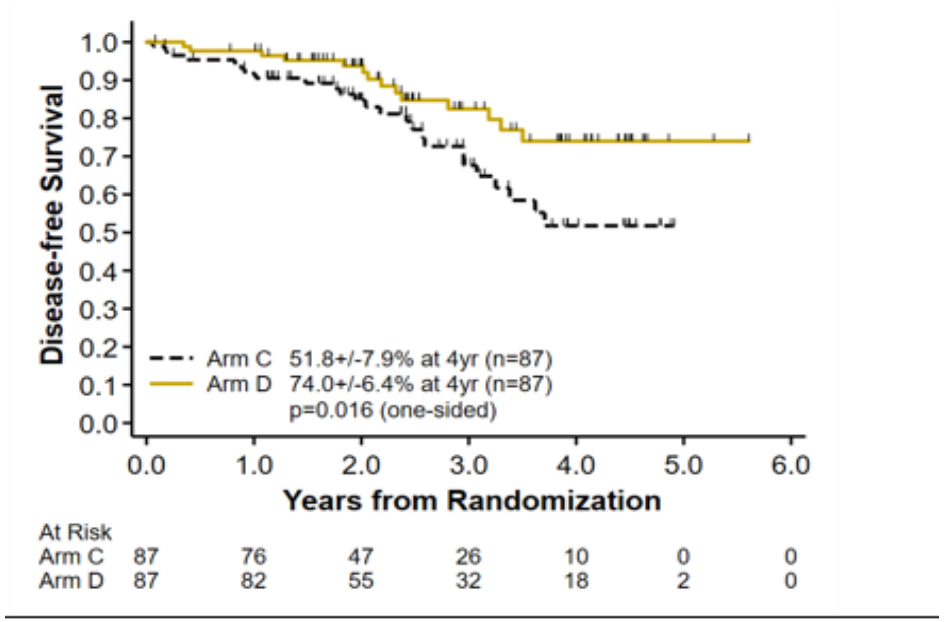
- No transplant indication for LR group
- Relapsed Chemotherapy (plus radiation for EM – CNS radiation for CNS disease)

Sneak Peek:

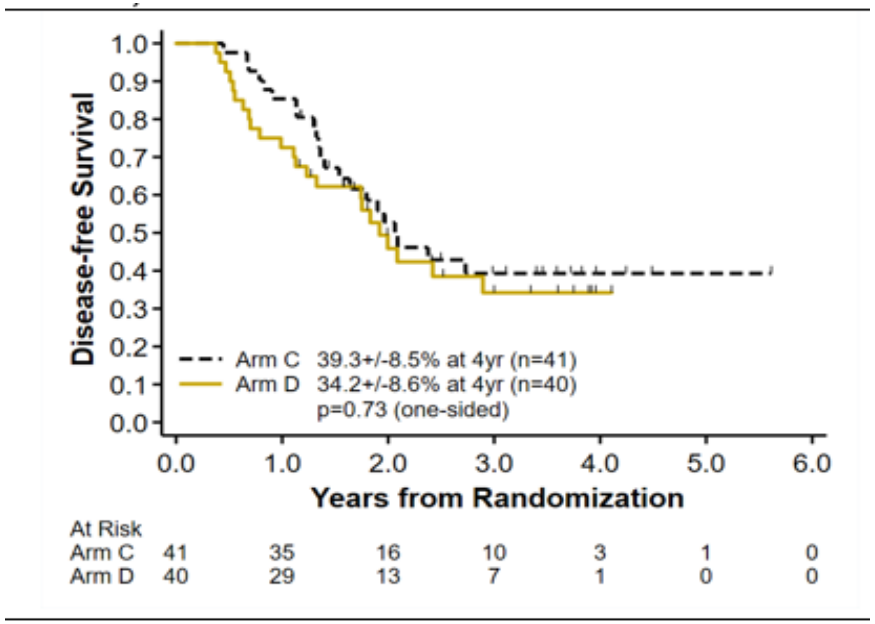
- Final results and publication pending
- ASH abstract presented December 2021

AALL1331 Low Risk Results

Late marrow patients with MRD <0.1% had improved DFS and OS on blina arm (C)



Late IEM patients with MRD <0.1% had similar DFS on both arms, markedly decreased from prior



Brown, 2021

Early Highlights LR ARM AALL1331

- For patients with BM±EM disease DFS 74.0 % for Arm C (Blina) compared to DFS 51.8% Arm D (Chemo)
- For patients with BM±EM OS 96.6% for Arm C (Blina) compared to 84.4% for Arm D (Chemo)
- **For patients with IEM 4-year DFS rates were dismal for both arms 34.2% and 39.3%**
- Toxicity compared between Block 3 of UKALLR3 and Blinatumomab
  - Significantly less F/N and infection with blinatumomab compared to chemotherapy
- **CRS rates were low for patients receiving Blinatumomab (12% grade 1, 7% grade 2, and 7% grade 3. No grade 4/5)**
- **Neurotoxicity was observed but all reversible (seizures 7%, other neurotoxicity 33% but mostly grade 1 – 19%)**

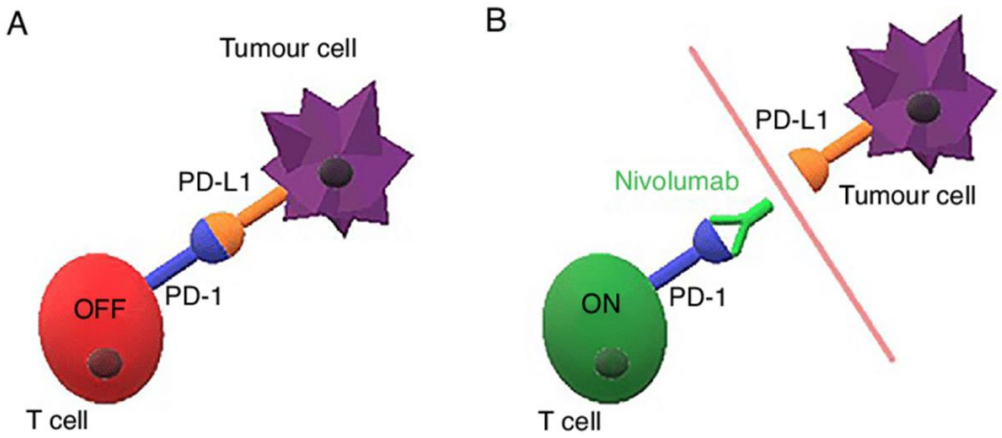
AALL1331 – Some conclusions

- For children and AYA patients with HR/IR or LR BM±EM disease in first relapse of B-ALL, blinatumomab is superior to standard chemotherapy
  - Improved disease-free and overall survival
  - Fewer and less severe toxicities
  - Higher rates of MRD response
  - Greater likelihood of proceeding to HSCT for HR/IR group

- Blinatumomab constitutes a new standard of care in this setting

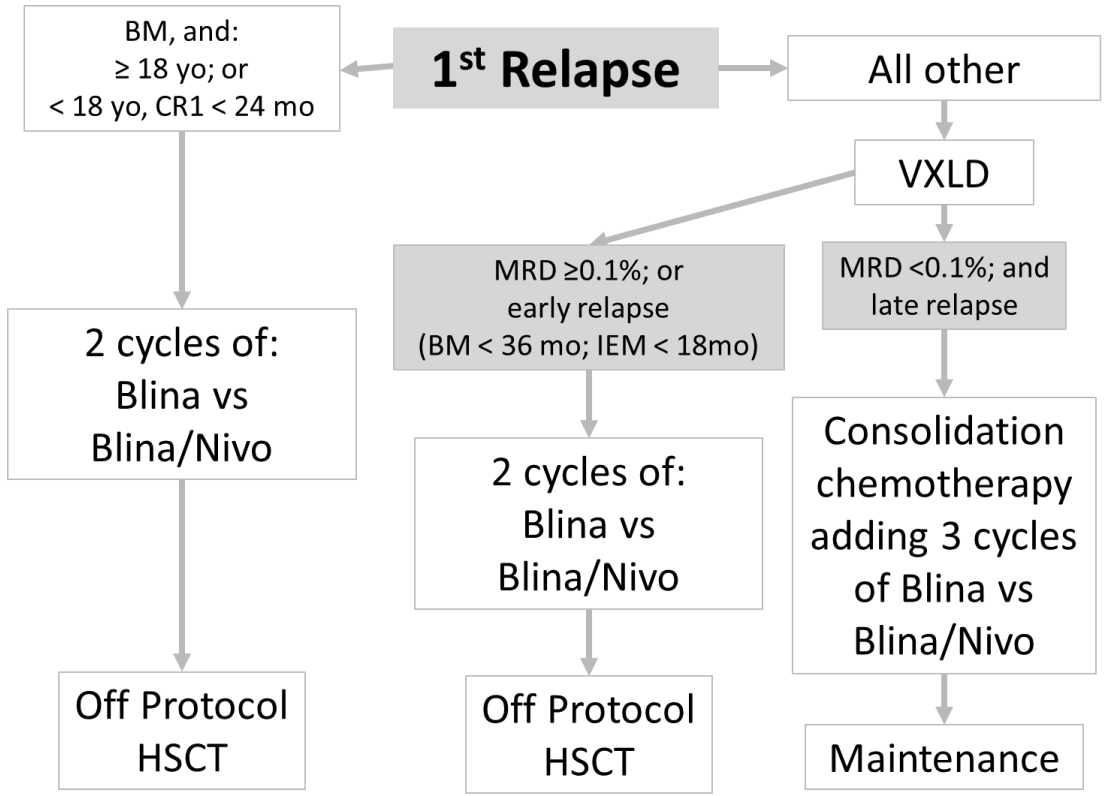
What's next for Relapsed B-ALL?

- Reinduction Chemotherapy – Too Toxic!
  - Remember all patients on AALL1331 received Block 1 chemotherapy
- A major mechanism of resistance increasingly recognized as endogenous T-cell exhaustion
- Emerging evidence that checkpoint inhibitors can overcome this blinatumomab resistance
  - Nivolumab, FDA approved PD-1 inhibitor



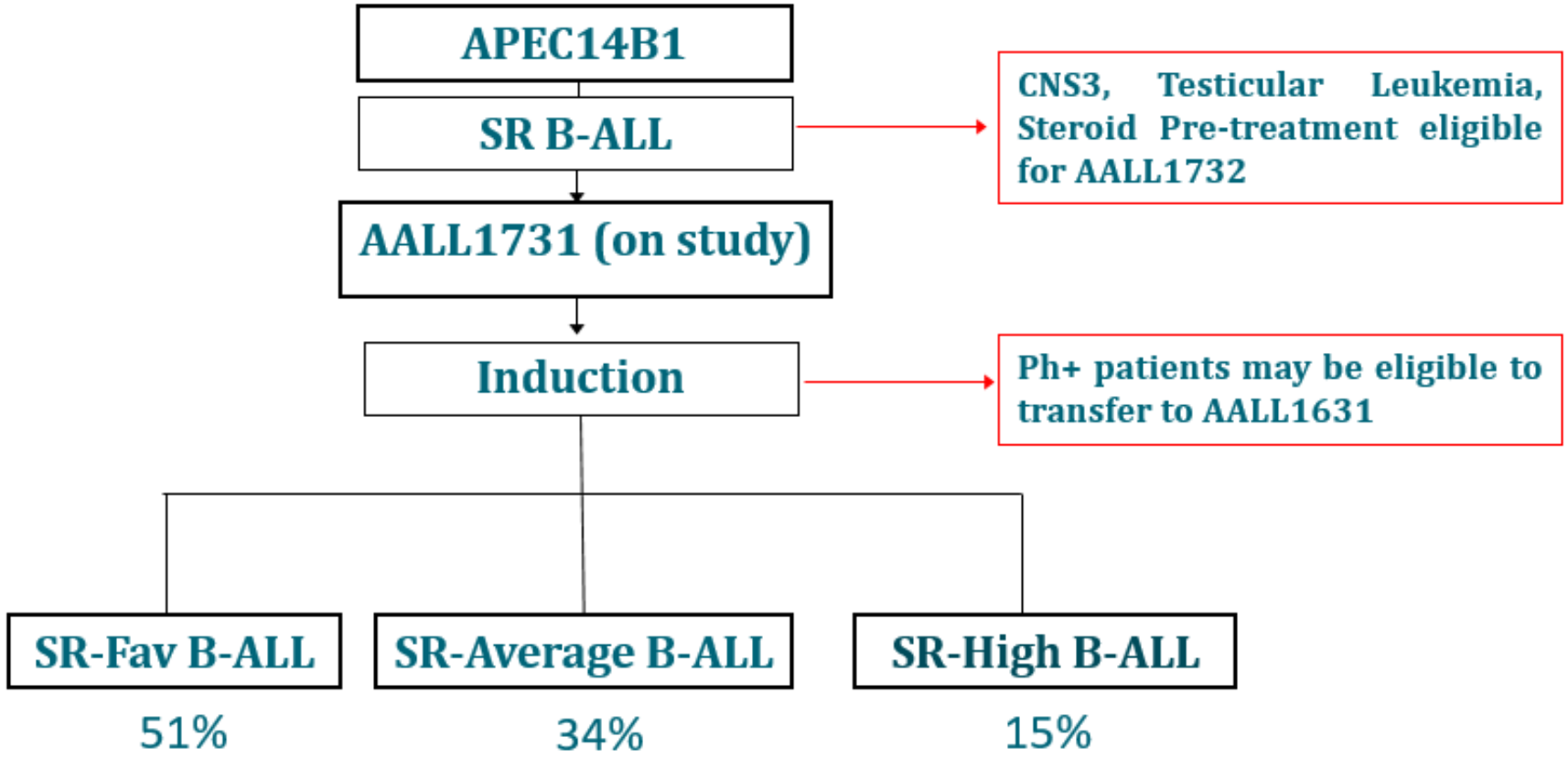
AALL1821 – current open trial

- VXLD – “chemo-lite”
- No Reinduction chemotherapy for VHR subset
- Waiting on an amendment for Isolated Extramedullary Relapse
  - Currently not eligible for AALL1821



If it works in the relapse setting can it prevent relapse?

Risk Groups AALL1731



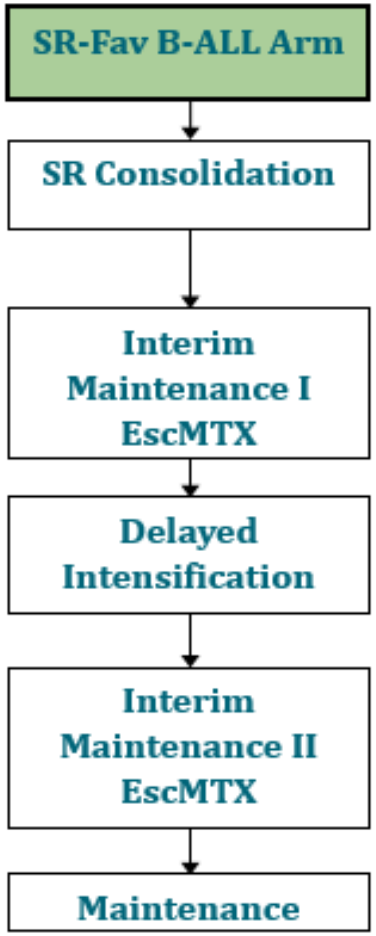
With Permission from Dr. S. Gupta

ALL1731

- All NCI SR patients will enroll on and stay on AALL1731
- Investigational agent – Blinatumomab
  - SR – Avg B ALL: Randomization Blinatumomab
  - SR – High BALL: Randomization Blinatumomab
- SR – Fav B ALL Arm will NOT be randomized

SR-Favorable

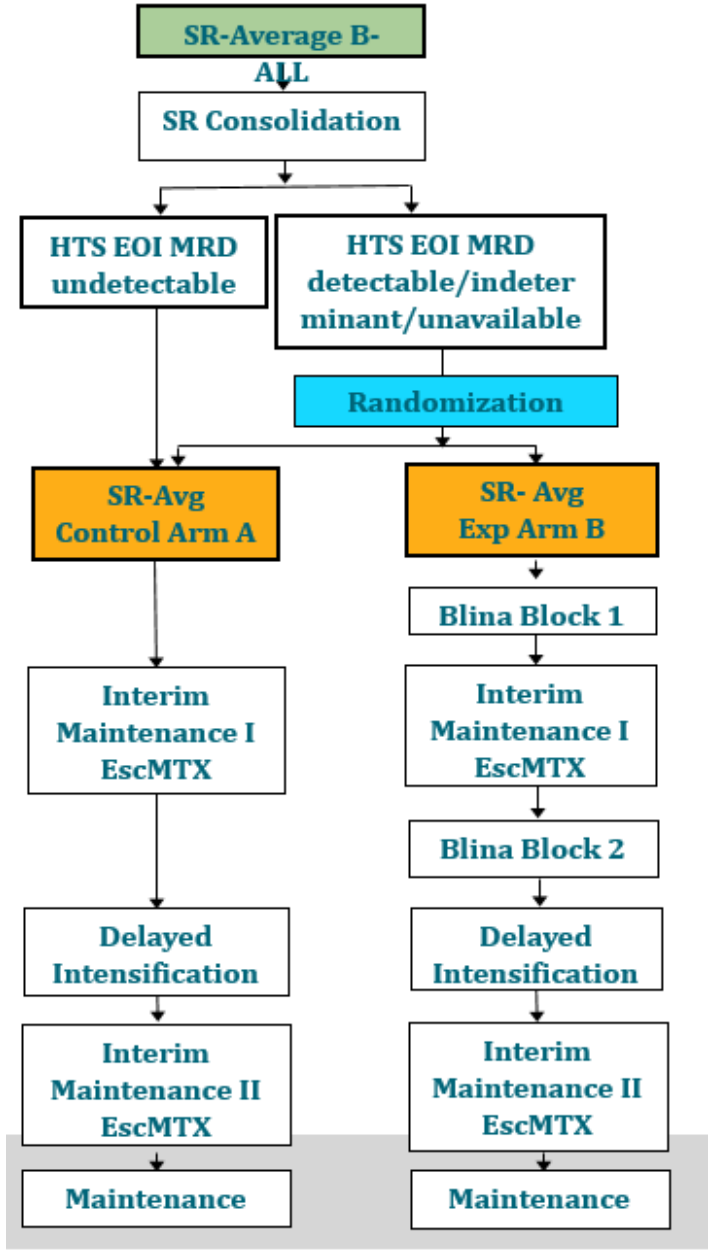
- NCI SR (**non-DS and DS**)
- CNS 1/2
- Favorable Cytogenetics (ETV6/RUNX1 or DT)
- D8 PB MRD <1%
- EOI BM MRD <0.01%



No Randomization – Predicted EFS 97%

SR-Average

- **NCI SR (non-DS and DS)**
  - CNS1/2, Fav cyto, D8 PB MRD>1%, EOI MRD <0.01%
  - CNS1, Neutral cyto, EOI MRD <0.01%
  - CNS1/2, **DT**, Any Day 8, ***EOI MRD 0.01-<0.1%***
- **EOI HTS MRD Stratification**
  - EOI HTS undetectable
    - Non-random, standard treatment
  - EOI HTS detectable/indeterminate/unavailable
    - Randomized to chemo +/- Blinatumomab



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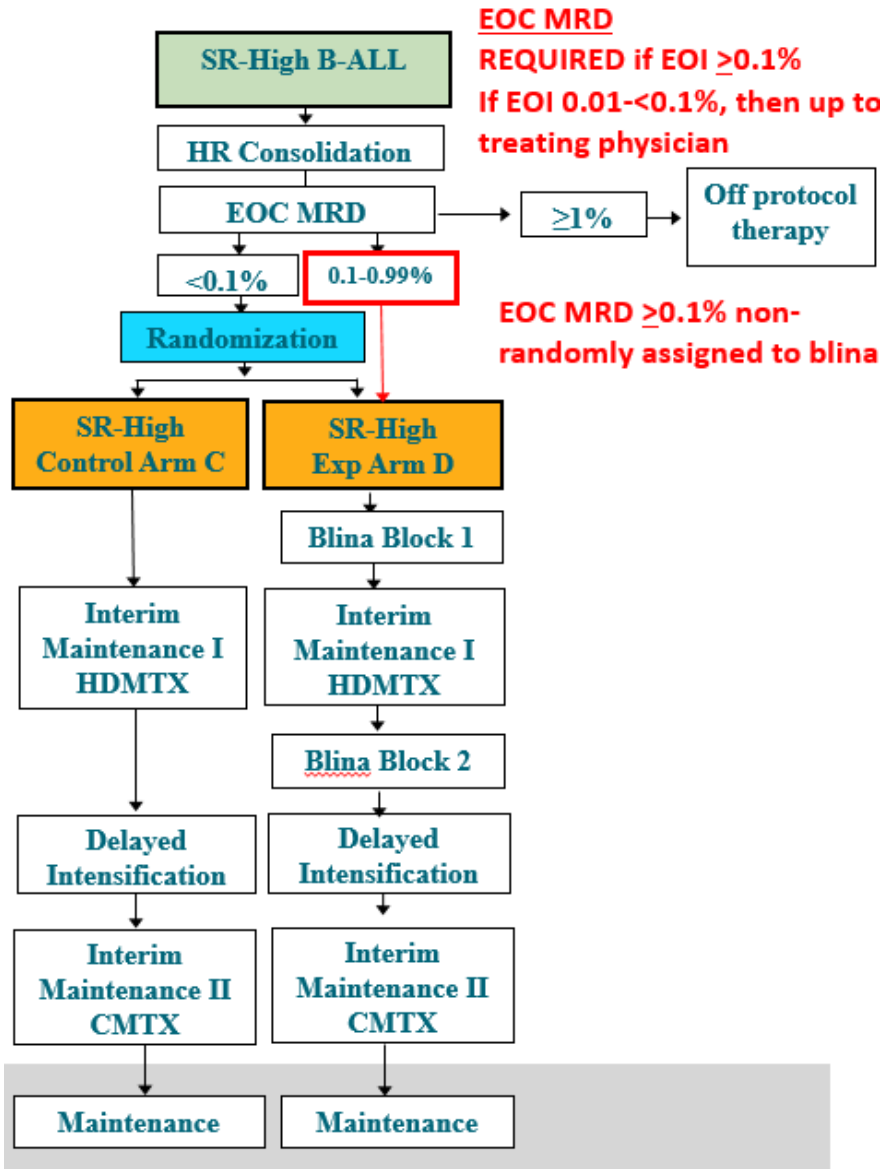
SR-High

- **<u>NCI SR (non-DS ONLY)</u>**
  - EOI MRD ≥0.01% (***<u>≥0.1% for DT patients</u>***)
  - Unfavorable Cytogenetics
  - CNS2 and Neutral Cytogenetics
- **<u>EOI MRD+ SR-High patients: EOC MRD</u>**
- <0.1% - Randomized
- 0.1-0.99% - NON-RANDOM assignment to Experimental Arm D (blinatumomab)
- ≥1% = Consolidation Failures, off protocol therapy



Down Syndrome DS and B-ALL AALL1731

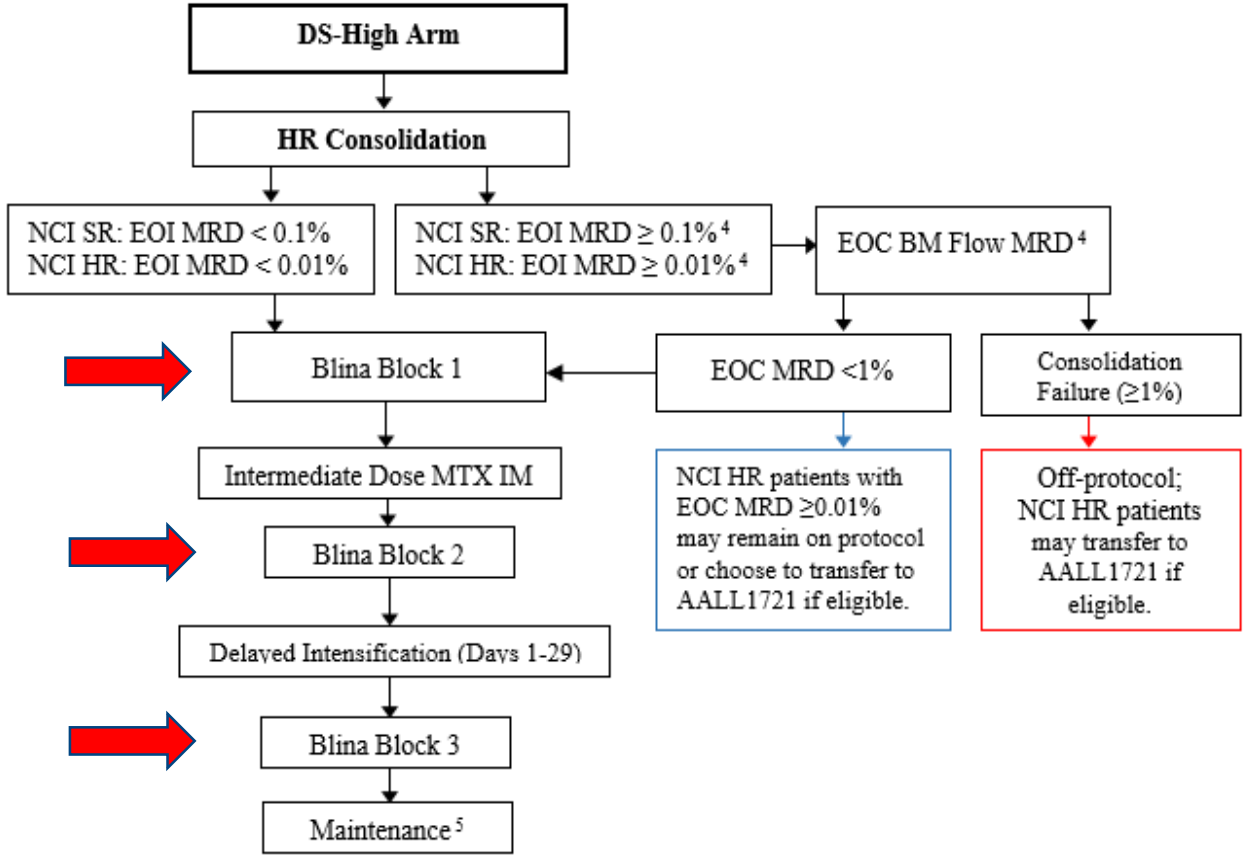
- All patients with B-ALL and DS will remain on AALL1731
  - BOTH NCI SR and HR

- Three risk groups:
  - Standard Risk-Favorable (SR-Fav) DS B-ALL (non-randomized)
  - Standard Risk-Average (SR-Avg) DS B-ALL (eligible for randomization)
  - DS-High B-ALL – unique study arm – 3 cycles of Blinatumomab

- Patients with Down Syndrome over age 10 will receive Seizure prophylaxis on COG trials

DS High B-ALL AALL1731

- DS B-ALL patients with **ANY** high risk features will be:
  - Non-randomly assigned to single arm of SR-high ALL therapy with 3 cycles of Blinatumomab



Blinatumomab as a bridge

- Toxicity
  - No evidence but commonly used clinically for patients who experience toxicity and proceeding with chemotherapy is considered dangerous
  - Case Studies published
  - Examples – Pancreatitis, significant infection
- Persistent MRD
  - Evidence from AALL1331
  - Evidence from patients in second relapse
  - Case studies

Wadwa, 2018
Elitzur, 2019
Bader, 2009

Are you convinced?

- Blinatumomab is here to stay – already the standard of care from many patients
- More and more pediatric patients will receive blinatumomab

Complex Administration Blinatumomab

- Provider Resources
  - Nursing and Pharmacy
- Family Resources
  - Burden of care - falls to the family for most of the cycle
  - When and Who to call
  - Managing possible complications – possible scenarios

JOURNAL OF ONCOLOGY PHARMACY PRACTICE

Practice Issues

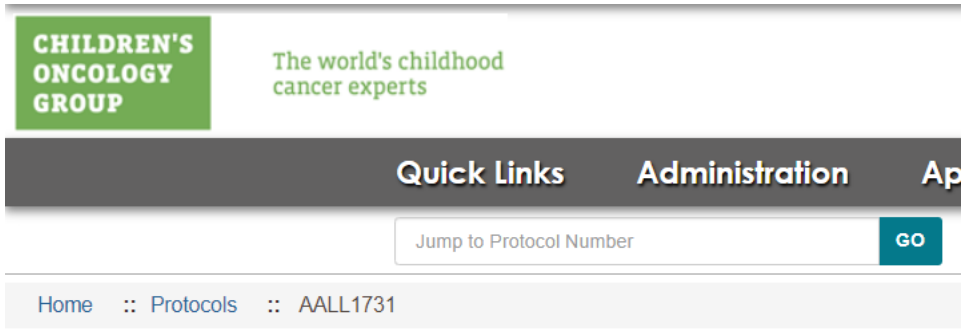
Blinatumomab use in pediatric ALL: Taking a BiTE out of preparation, administration and toxicity challenges

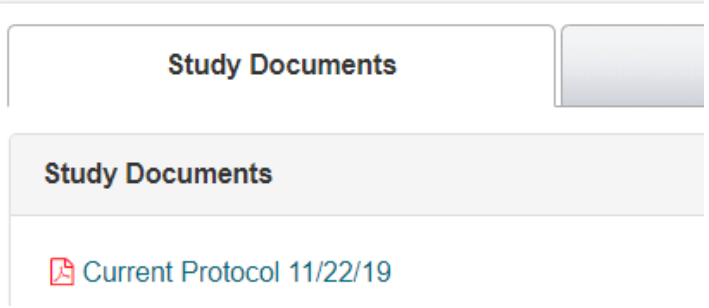
Melanie B Bernhardt[1,2], Olga Militano[3], Lisa Honeyford[4] and Sue Zupanec[4]

J Oncol Pharm Practice
0(0) 1–13

DOI: 10.1177/1078155220979047
journals.sagepub.com/home/opp
SAGE

Blinatumomab - FAQs





- Blinatumomab Administration and Preparation Training
- Blinatumomab Home Health Care Manual
- Blinatumomab FAQ
- Blinatumomab Drug Information Sheet for Patients

Blinatumomab - FAQ

- What kind of line
- How to minimize interruptions
- Flushing Considerations
- How often to change the bag and tubing
- Recommended Pumps – options for access
- Managing blood back up in the line
- What to do if infusion end early
- Managing line breaks
- Extravasation
- Advice for securing the lines

CHILDREN'S ONCOLOGY GROUP

Frequently Asked Questions Regarding Blinatumomab Administration in AALL1731

1. **What kind of central line can be used for infusing blinatumomab?**
   - Any type of central line can be used for infusion of blinatumomab. Port-a-Cath lines are the most common in this specific patient group. Port-a-Cath administration of blinatumomab will result in some unavoidable infusion interruptions.
   - There is no consensus regarding peripheral IV (PIV) administration of blinatumomab at this time.

2. **How do we minimize interruptions of blinatumomab?**
   - IV Infusions: Use a blinatumomab bag that allows for the longest infusion time possible as allowed by patient weight and hospital policy and guidelines (available options are 24, 48, 72, 96 hour, and 7-day infusion times). Note, however, that 7-day continuous infusion of blinatumomab may result in blood backing up in the line due to low infusion rates. While potential solutions are outlined in #6 below, centers may also choose to use 96-hour infusion bags instead.
   - Port-a-Cath needle changes: Start the blinatumomab infusion through a newly changed needle to eliminate the need to stop the infusion during the first 7 days of infusion when a reaction is most likely to occur. Interruption during a blinatumomab infusion for a Port-a-Cath needle change will be acceptable. However, try to limit the Port-a-Cath needle change to less than one hour.
   - Procedural sedation: It is acceptable to interrupt a blinatumomab infusion to administer sedation medications. If blinatumomab is interrupted, the infusion should be run until just prior to the procedure when the line is needed for sedation and restarted right after procedural sedation is completed. Alternatively, a PIV can be inserted for procedural sedation, IV fluid requirements, and other IV supportive care.
   - Fever (patient clinically stable): It is acceptable to interrupt a blinatumomab infusion in order to obtain blood cultures, CBC and/or administer IV antibiotic per institutional policy. Alternatively, a PIV can be inserted to facilitate IV antibiotic administration.

3. **What is the acceptable method of flushing the blinatumomab line?**
   - It is up to the institution to decide whether the line should be flushed or the blinatumomab withdrawn from the line prior to using the line for other medications or normal saline flushes. (Institutional guidelines for volume of line + Port-a-Cath dwell volume + any additional volume, if necessary, should be followed to determine volume of blood to withdraw.)
   - Flushing is discouraged during the first 72 hours of blinatumomab infusion.

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Interruptions of Blinatumomab

- New COG Protocol Language – **interruptions are unavoidable**
- Dose Clarification – due to unavoidable interruptions for patient care
  - Consideration of PORT care (For 96 hour bags - needle changes at minimum 7 times per cycle – approximately a minimal interruption of 7 hours)

…when the interruption time over 28 days is greater than 24 hours missed hours of Blinatumomab may be added to the infusion time…at the discretion of the treating physician…

Equipment for Blinatumomab

- IV bags can be made up to 8 days in advance
  - Next bag always ready to go – plus a back-up bag is available
- 24, 48, 72, 96 and 7 day bag options
- Blinatumomab stable 96 hours (BUD) at room temperature
  - IV bag change q 96 hours – rate of infusion 5ml/hr
- 7-day bag (preservative free) Blinatumomab option – available for patients weighing over 22kg
  - rate of infusion 0.6ml/hr
- CADD VIP and VIP solis, prizm or legacy
  - Spare pumps available (2 per patient)
- Infused through 0.2 micometer filter, DEHP free tubing
- Cassettes have DEHP!
- Extra 9 Volt batteries to families as back-up

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SK Resources – Nursing Tip Sheet for Administration

- "Blinatumomab Tip Sheet" created at SickKids for administering nurses
- Based on COG protocols and SK SOCs, real world experience, COG Blinatumomab FAQ, and expert consensus from Sue Zupanec & Sumit Gupta

Covers topics including:

- Principles for initiating the infusion
- Equipment needed and equipment sign-out process at SickKids
- CADD tubing
- Programming the CADD pump
- Patient Assessment
- Administration Considerations
  - Line considerations
  - Flushing & Bloodwork
  - Interruptions
- Patient Discharge
- Completion of Cycle
- Adverse Effects

SK Resources – Caregiver Education

- Blinatumomab Caregiver Education created at SickKids
  - Handout and 1:1 education session
- Based on COG protocols and SK SOCs, real world experience, conversations with previous families, and expert consensus from Sue Zupanec & Sumit Gupta

Education Covers topics including:

- About Blinatumomab and the Infusion
- Who to Call for Help
- About the CADD Pump
- What to do at Home
  - Make sure the pump is on and running
  - Keep the pump charged
  - Keep track of any interruptions
  - Keep the line secure
  - Call if you are concerned
- Managing Broken Tubing
- CADD Pump Functions
  - How to: Stop the pump, power off the pump, power on the pump, restart the pump
  - Managing Alarms: Downstream occlusion, reservoir volume low, low battery
  - Replacing the batteries

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The Questions…

- Monitoring – What is the recommended nurse-patient ratio? What is the recommended frequency of vital signs? What is the right location to start?
- Hospitalization – how long is necessary?
- Do patients need a second IV access during the cycle, or even during the first 72 hours?
- Do you start antibiotics for fever in the first 72 hours of a cycle?
- Can you pause to use the line, flush, use for sedation for LP and IT chemotherapy administration, flush and resume?
- Can blinatumomab bag changes be done at a satellite center or in the community?
- What about temperature protection? Does it affect rate of infusion?

Tips and Tricks Study: The COG Experience

- There is considerable variation in practice
- No current evidence to provide “Evidence-Based” recommendations (unclear what is best)

- When there is a lack of evidence – build expert consensus recommendations!
- Survey of COG Sites, and Qualitative Interviews
- Received 80% response rate, 20 Interviews completed
- Starting data analysis now
- Results to be presented - COG track at APHON 2022 (September)

Goals for the Tips and Tricks Study

- Describe variation in practice
- Used expert opinion to develop consensus recommendations to address where there is significant variation
- Predicted Topics for building future recommendations:
  - Fever Management
  - Nurse-Patient Ratios
  - Monitoring Guidelines (frequency of vital signs and neuro-checks)
  - Need (lack of) for second IV access during high-risk period of CRS and Neurotoxicity
  - Development of resources both for providers and patients and families
- Understand ongoing barriers at COG sites to administering Blinatumomab

What can we do to make Blinatumomab acceptable?

- Understand the patient and family experience (distress? Coping strategies?)
- Provide anticipatory guidance (survival skills, set expectations about what to expect)
- Provide equipment that is designed for children, that can improve QoL (mobility, self efficacy, self management, ability to do desired activities)
- Provide equipment that supports parents to care for their children receiving blinatumomab

Qualitative Study

- To understand the experiences of family caregivers caring for pediatric patients receiving outpatient blinatumomab
- Multi-site study, PI Dr. Lindsay Jibb
- Awaiting Ethics Approval

Objectives:

Primary: To describe the parents' experience of caring for their child who has pediatric B-ALL and is receiving blinatumomab on COG protocol AALL1731 at home

Secondary: To learn, from the perspectives of parents, what informational and educational resources should be developed, and in what format resources would be perceived useful, that would be provided to future parents of children with B-ALL receiving blinatumomab at home.

Carrying Bags – Are they kid/teen/family friendly?

- QI project (PI Sue Zupanec)
- Funded by Education Grant from AMGEN
- Family Interviews
- Design Team including Industrial Designer
- Develop Prototypes

- Completed!

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Frustrations/concerns with existing bag

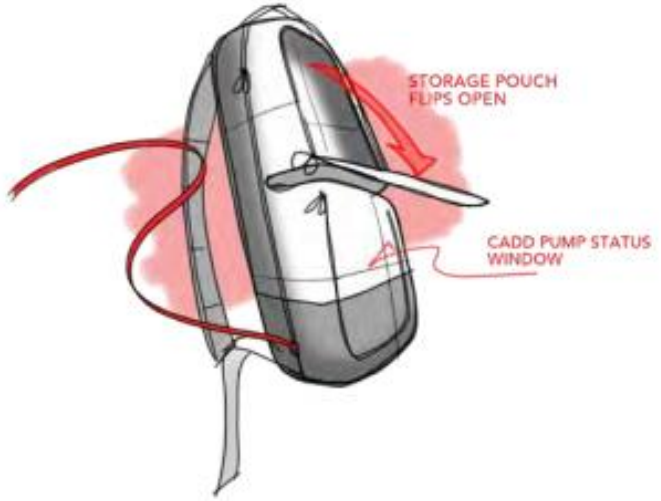
- Bag length too short – requires pinching of the Blinatumomab bag
- Poor fit and uncomfortable (heavy on day 1, single strap with no padding or support
- Single strap limited adjustment to length
  - For younger patients required another person to hold/carry
- Identified as a medical bag (sick stigma)
- Limited padding and protection
  - Families worried about damaging the expensive pump
  - Noise of operating pump

Project Success Criteria for New Bags

- Washable surface, easily laundered or wiped down
- Some level of waterproofing
- Small interior space for CVL kit, thermometer
- Flexibility to be worn more comfortably (keep mid-size)
- Handle on the top for easy lifting/moving
- Insulate and isolate the pump to reduce operating noise
- Secure and protect the mediation bag from damage
- Padded bottom to protect pump from damage
- Semi-rigid back surface to allow to stand more upright when placed on the ground
- Customization, improved appearance to be “less medical”

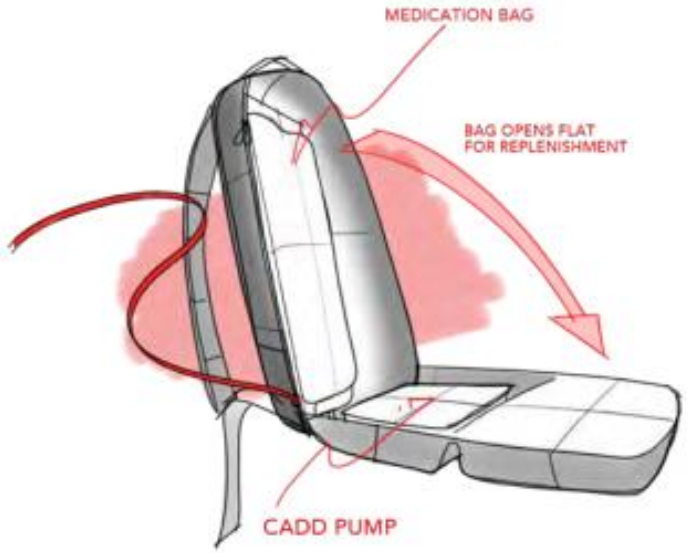
AS WORN

Storage pouch (above) and CADD access flap are accessible while bag is closed. The port tubing line also freely exits the bag while closed.



TO ACCESS STORAGE

A small zippered pouch located above the pump allows for easy storage and access to hospital-trip items (CVL kit, thermometer, etc).



TO SERVICE

The perimeter zipper allows the bag to open flat for easy replenishment on hospital visits.

Sneak Peek!

Next Steps for Backpacks

- Test the bags with the kids receiving blinatumomab
  - Use feedback to improve the prototype and produce final design
- Currently seeking funding

Future Opportunities:

- Make the new improved backpack available to all kids receiving blinatumomab!

QUESTIONS?