

AALL 1732

Satellite Educational Training Module

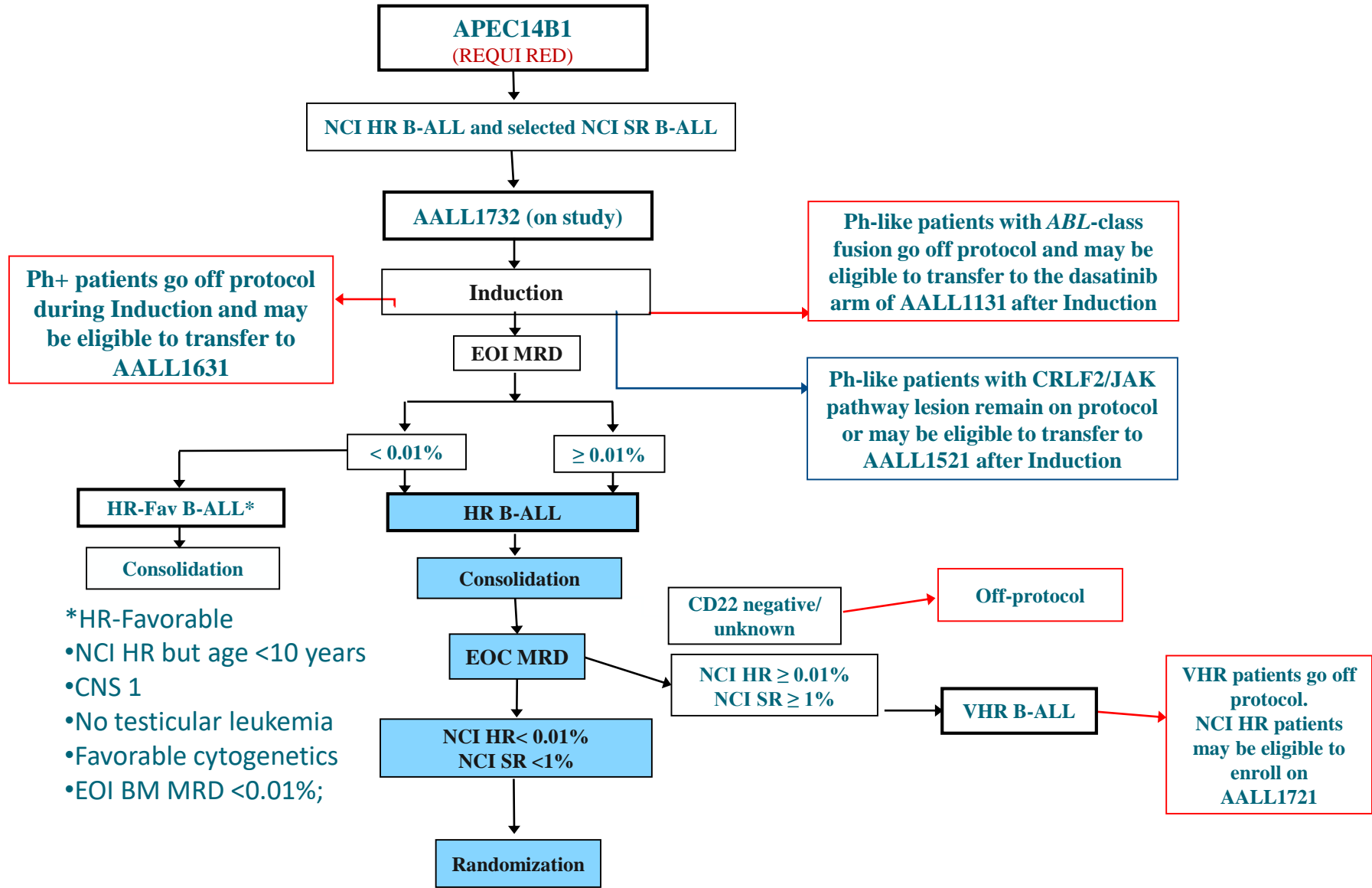
MARCH 2020

Presented to: Satellite Clinic Healthcare Providers
Presented by: Dr. Paul Gibson and Christina McCauley

AALL 1732

- A Phase 3 Randomized Trial of Inotuzumab Ozogamicin (IND# 133494, NSC# 722518) for Newly Diagnosed High Risk B-ALL; Risk Adapted Post-Induction Therapy for High Risk B-ALL, Mixed Phenotype Acute Leukemia, and Disseminated B-LLy

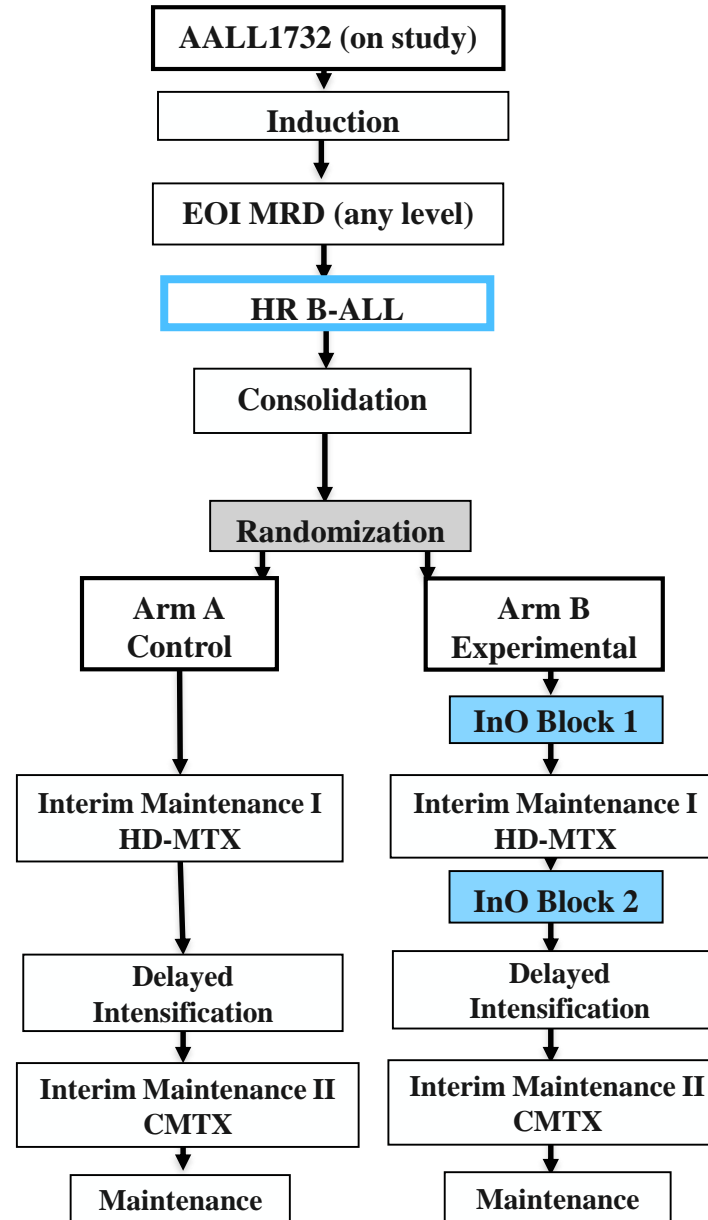
AALL 1732 Schema



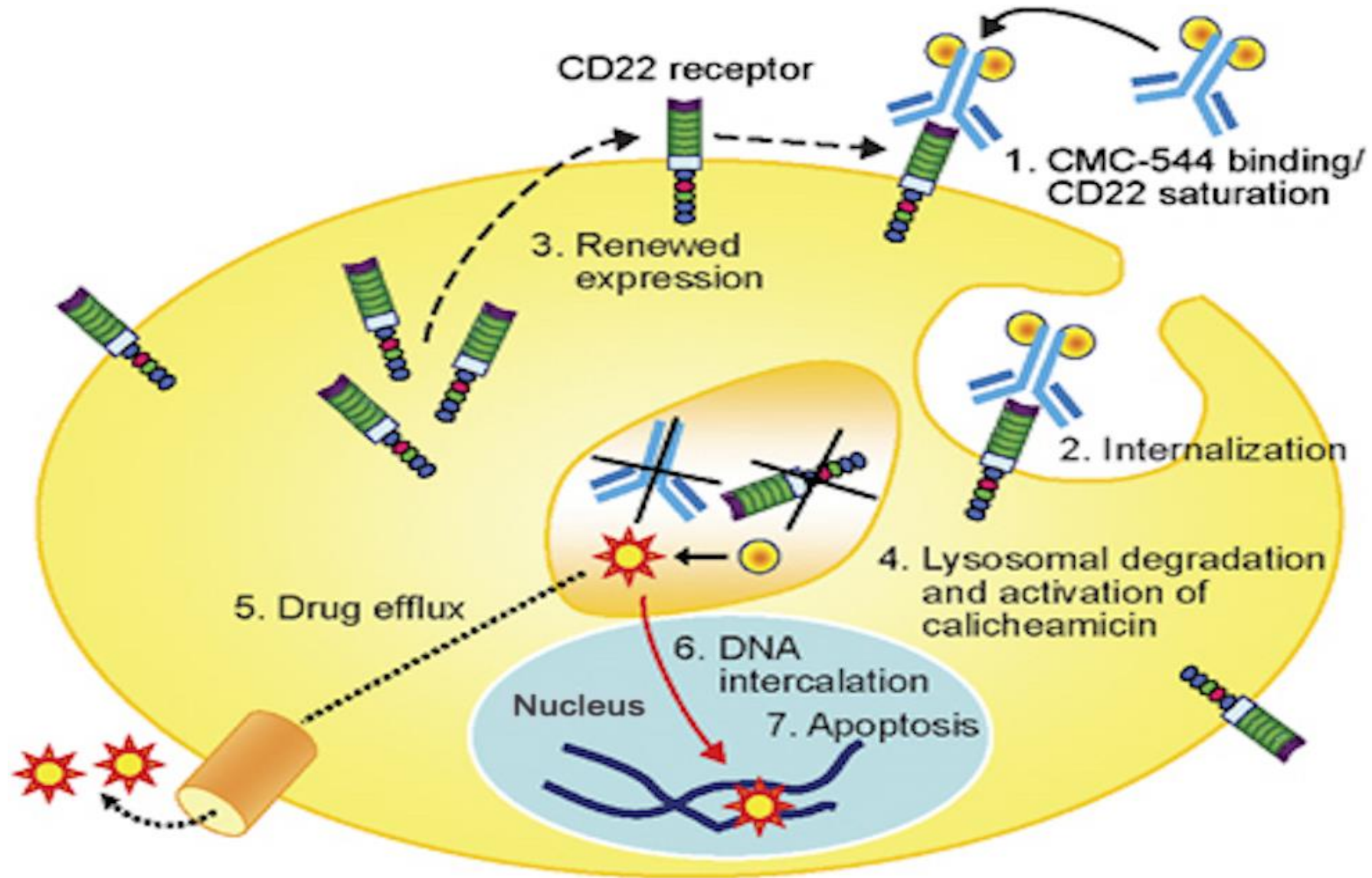
- *HR-Favorable
- NCI HR but age < 10 years
- CNS 1
- No testicular leukemia
- Favorable cytogenetics
- EOI BM MRD < 0.01%;

HR B-ALL

- NCI SR - End of Consolidation (EOC) <1%
- NCI HR - EOC MRD <0.01%
- These patients will be eligible for Inotuzumab randomization



Inotuzumab



Inotuzumab

- Administered as short infusion at outpatient in **Tertiary Centre**
- Kids who are getting Inotuzumab (INO) are at high risk of veno-occlusive disease (a.k.a. sinusoidal obstruction syndrome)
 - **Weight gain from fluid retention**
 - **Abdominal pain**
 - **Rise in bilirubin**
 - **Platelet refractoriness**
- Main risk is in children who get INO and then get transplant
 - But 6-TG can also cause VOD (Second half of Delayed Intensification)
- Treatment:
 - Transfer!
 - Tight Fluid Management/Supportive Care
 - Defibrotide

Duration of Maintenance in Boys

- The Children's Cancer Group (CCG) previously noted that boys with ALL did slightly worse than girls, so they extended their maintenance duration to 2.5 years

Trial Group	Length of therapy	Gender-based difference?
BFM-ALL 2000	24 months from diagnosis	No
St Jude Total XV	120 – 146 weeks*	Yes*
DFCI 00-01	104 weeks post CR	No
UK ALL 2003	2-3 years from beginning of Interim Maintenance	Yes
DCOG ALL-9	109 weeks	No
NOPHO ALL-2000	2-2.5 years post diagnosis	No

- On 1732, duration of maintenance therapy will be 2 years regardless of sex

What do I need to know at the satellite?

- All Inotuzumab related administration and impacts will happen at the primary treatment centre, not satellites
- Inotuzumab cycles are in ADDITION to standard therapy, so all 'regular' chemo visits should continue
- Similar to AALL 1731, maintenance therapy duration is the same for both boys and girls
- As with all studies, clinical documentation and communication with satellite about any potential toxicities remains crucial

Training Complete

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1. Download your certificate.
2. Enter your name, POGO Satellite Clinic, and the date.
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4. Email a copy to Mandy Sala, Program Assistant, Clinical Programs and Analytics, POGO (msala@pogo.ca).

Upon receiving your Certificate of Completion, POGO notifies your affiliated tertiary hospital(s) that your training for AALL 1732 is complete.



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