What Clinicians Want to Know About Toxicity Considerations Associated with BTK Inhibitors

A CME/MOC-Accredited Virtual Event

Wednesday, August 30, 2023
5:00 PM – 6:00 PM ET

Faculty

Nicole Lamanna, MD
William G Wierda, MD, PhD

Moderator

Neil Love, MD

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Faculty

Nicole Lamanna, MD
Professor of Medicine, Leukemia Service
Director of the Chronic Lymphocytic Leukemia Program
Hematologic Malignancies Section
Herbert Irving Comprehensive Cancer Center
NewYork-Presbyterian/Columbia University Medical Center
New York, New York

William G Wierda, MD, PhD
Jane and John Justin Distinguished Chair in Leukemia
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Section Chief, Chronic Lymphocytic Leukemia
Center Medical Director
Department of Leukemia
Division of Cancer Medicine
Executive Medical Director
Inpatient Medical Services
The University of Texas MD Anderson Cancer Center
Houston, Texas

Moderator
Neil Love, MD
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Commercial Support

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Dr Love — Disclosures

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Dr Lamanna — Disclosures

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Dr Wierda — Disclosures

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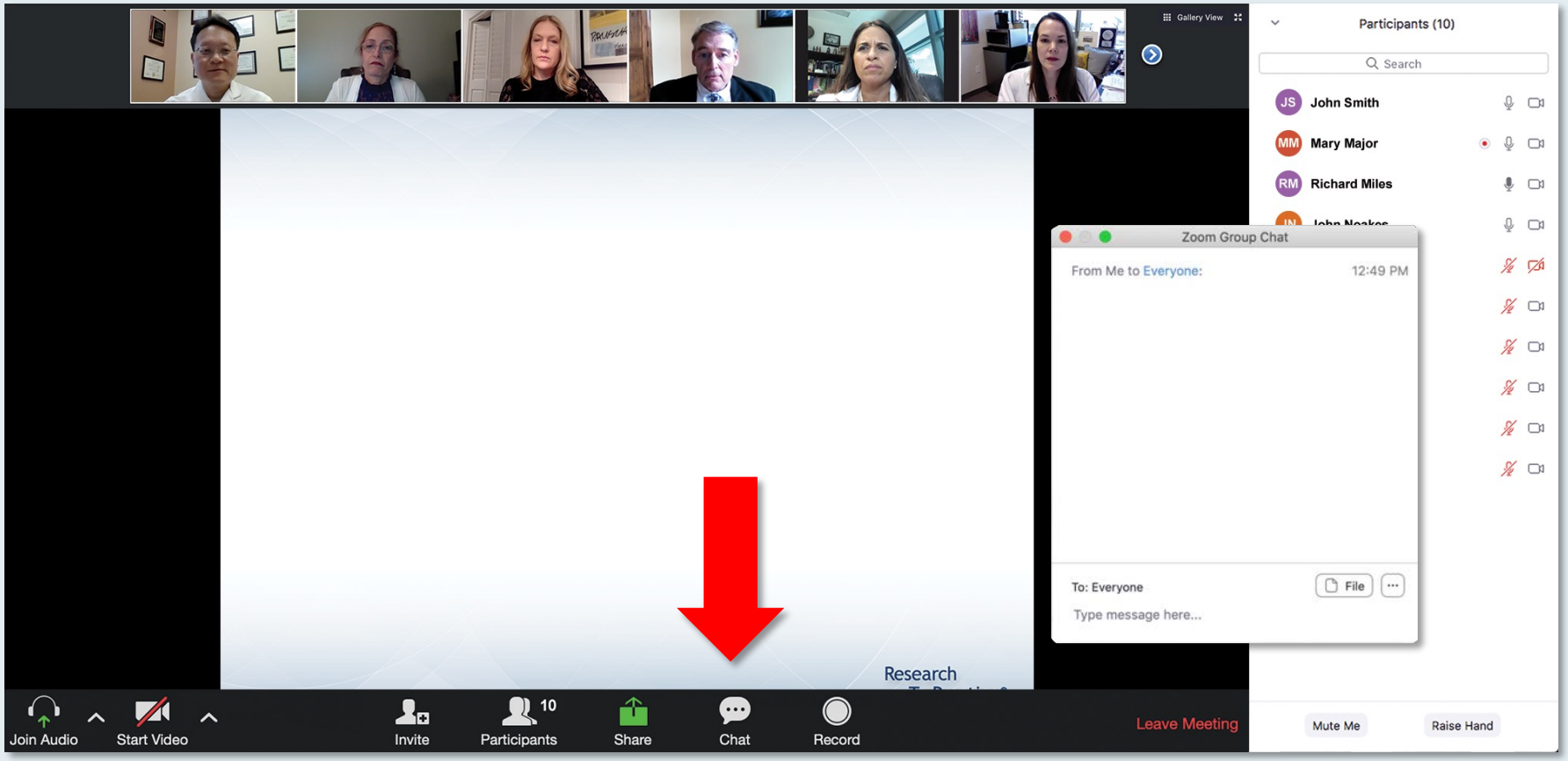
Nonrelevant Financial Relationship	National Comprehensive Cancer Network (Chair, CLL)

We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

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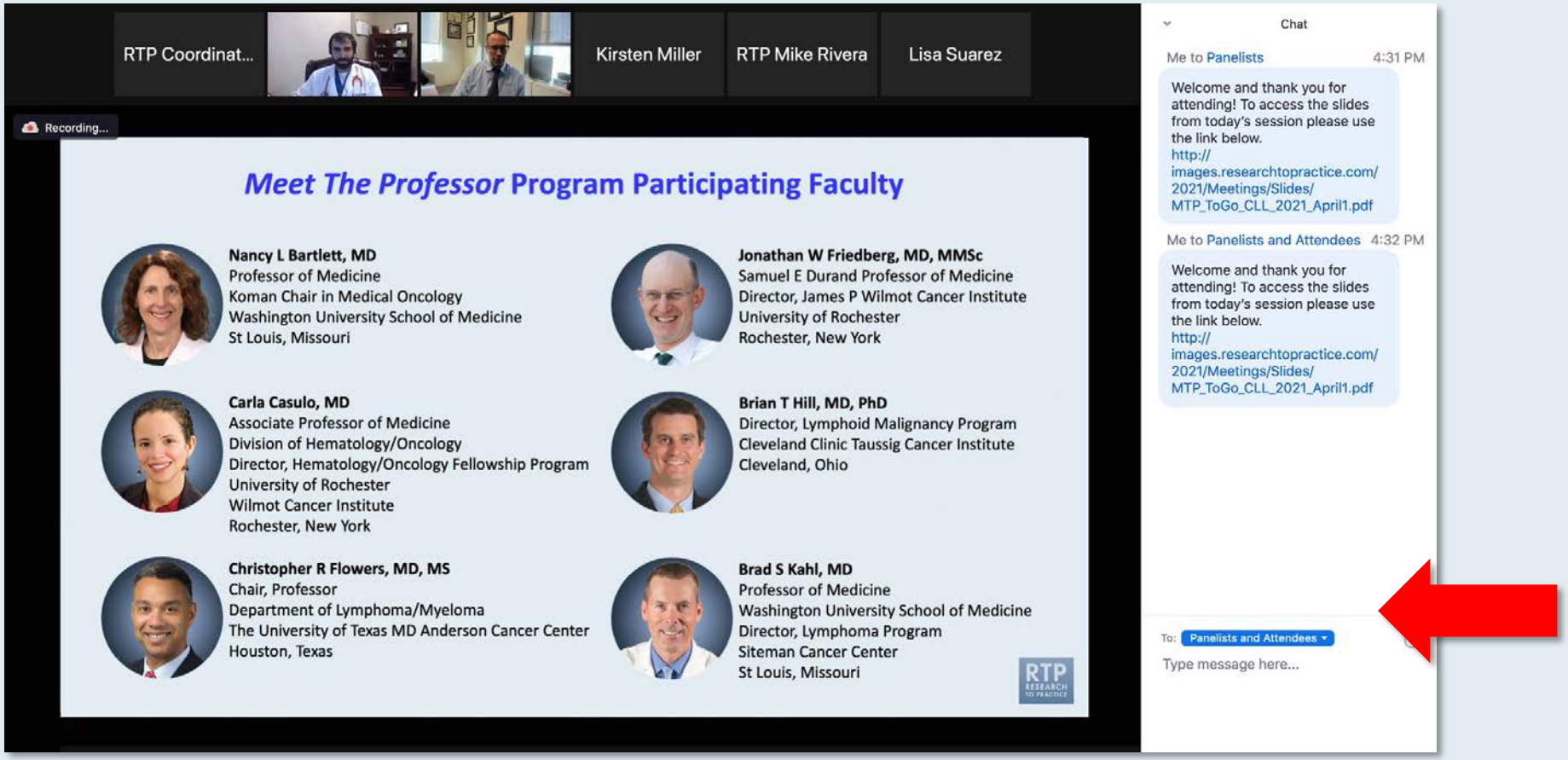
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



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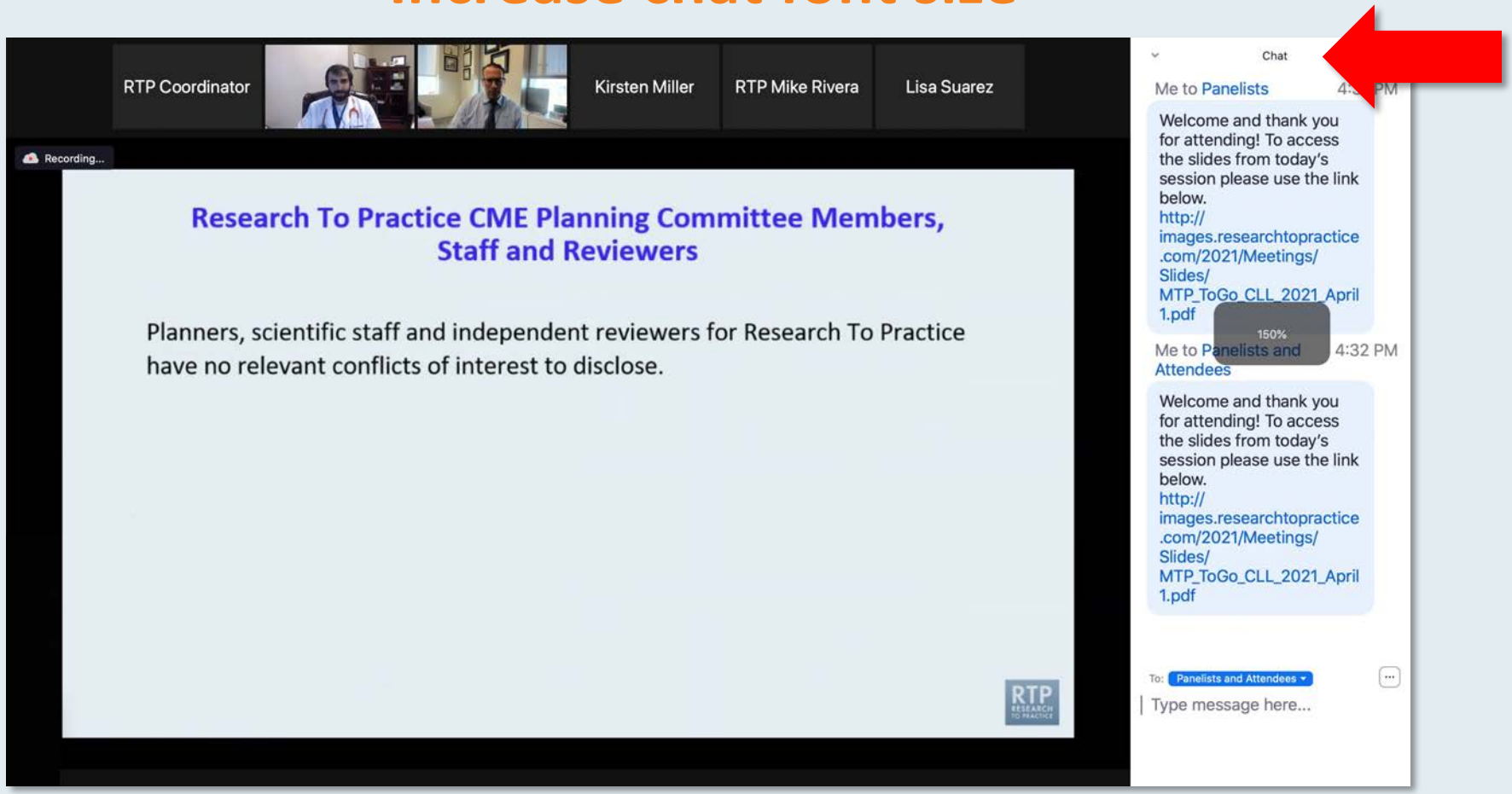
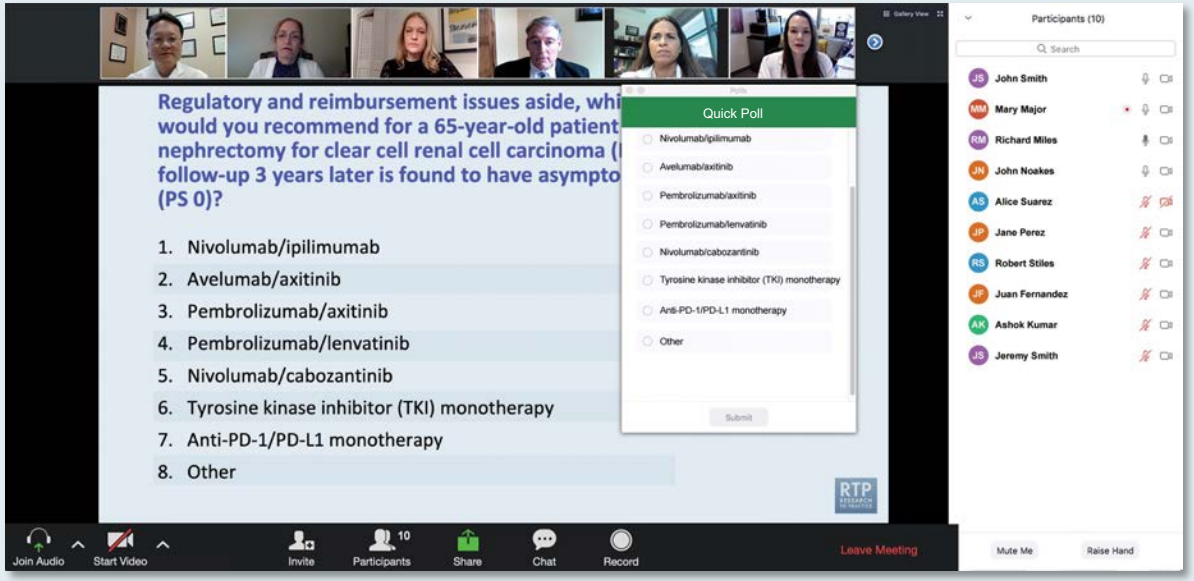


Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

Clinicians in the Audience, Please Complete the Pre- and Postmeeting Surveys



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WITH DR NEIL LOVE

Role of BTK Inhibitors in Therapy for Mantle Cell Lymphoma

DR MICHAEL WANG

THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

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Consensus or Controversy? Documenting and Discussing Clinical Investigators' Practice Patterns in Myelofibrosis

A CME Satellite Symposium During the Society of Hematologic Oncology 2023 Annual Meeting

Thursday, September 7, 2023
6:34 PM – 7:34 PM CT (7:34 PM – 8:34 PM ET)

Faculty

Prithviraj Bose, MD
Andrew T Kuykendall, MD

Moderator

John Mascarenhas, MD

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Cases from the Community: Investigators Discuss the Application of Available Research in the Care of Patients with Diffuse Large B-Cell Lymphoma

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Friday, September 8, 2023
11:37 AM – 12:37 PM CT (12:37 PM – 1:37 PM ET)

Faculty

Matthew Lunning, DO
Laurie H Sehn, MD, MPH

Moderator

Christopher R Flowers, MD, MS

RTP RESEARCH TO PRACTICE

Inside the Issue: Optimizing the Management of Metastatic BRCA-Negative, Triple-Negative Breast Cancer

A CME/MOC-Accredited Live Webinar

Monday, September 11, 2023
5:00 PM – 6:00 PM ET

Faculty

Hope S Rugo, MD
Tiffany A Traina, MD, FASCO

Moderator

Neil Love, MD

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Meet The Professor

Optimizing the Management of Ovarian Cancer

Thursday, September 14, 2023
5:00 PM – 6:00 PM ET

Faculty

Kathleen N Moore, MD, MS

Moderator

Neil Love, MD

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Inside the Issue: Integrating Targeted and Immunotherapy into the Management of Localized Non-Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Thursday, September 21, 2023
5:00 PM – 6:00 PM ET

Faculty

Jamie E Chaft, MD
John V Heymach, MD, PhD

Moderator

Neil Love, MD

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What Clinicians Want to Know About the Management of Relapsed/Refractory Mantle Cell Lymphoma

A CME/MOC-Accredited Virtual Event

Tuesday, September 26, 2023
5:00 PM – 6:00 PM ET

Faculty

Toby A Eyre, MBChB, DipMedEd, MRCP, MD
Brad S Kahl, MD

Moderator

Neil Love, MD

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Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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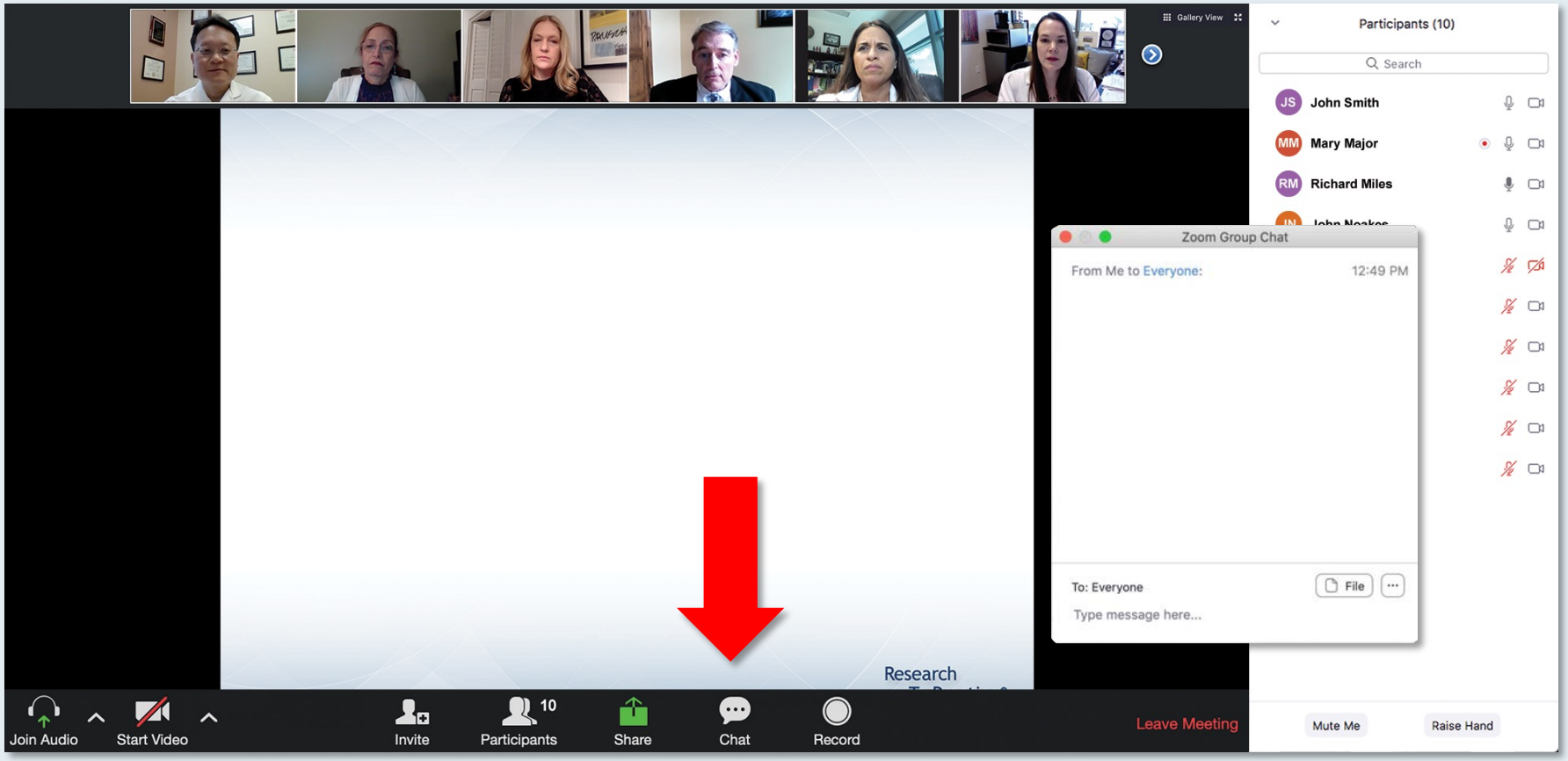

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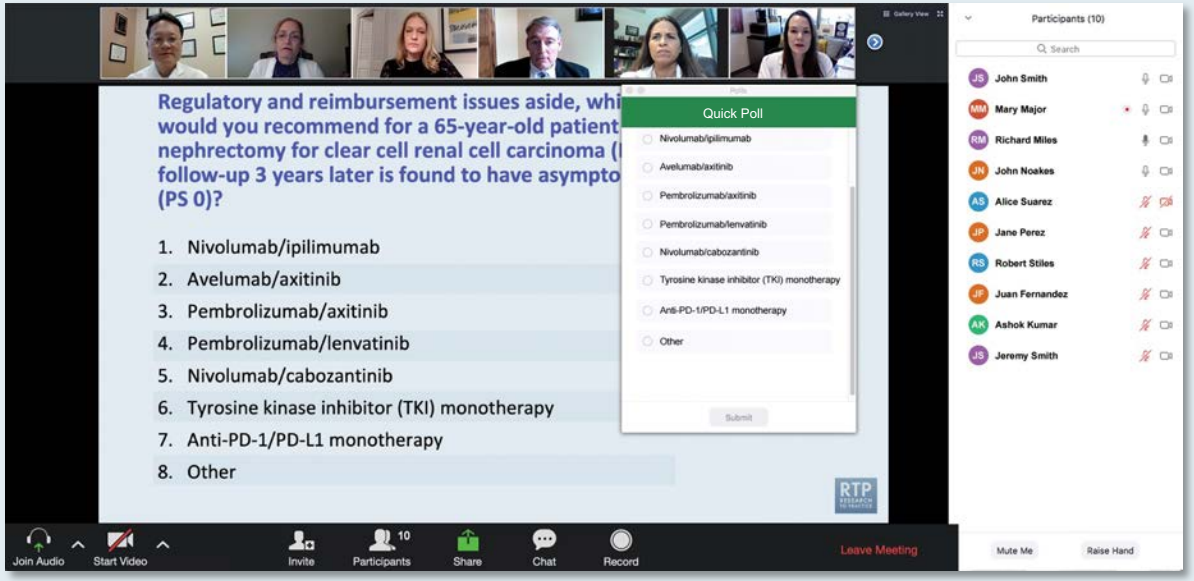

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Spencer Henick Bachow, MD
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Boca Raton, Florida

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Trinity, Florida

Warren S Brenner, MD
Lynn Cancer Institute
Boca Raton, Florida

Eric H Lee, MD, PhD
Compassionate Cancer Care
Medical Group
Fountain Valley, California

Gigi Chen, MD
John Muir Health
Pleasant Hill, California

Henna Malik, MD
Texas Oncology
Houston, Texas

Mamta Choksi, MD
Florida Cancer Specialists
New Port Richey, Florida

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Agenda

INTRODUCTION: Mentoring Fellows

CASE PRESENTATIONS:

- Dr Bachow – 56-year-old woman with cardiovascular comorbidities and relapsed CLL
- Dr Brenner – 77-year-old man with relapsed del(11q) CLL develops atrial fibrillation on ibrutinib
- Dr Chen – 72-year-old man with CLL develops rash and bruising on ibrutinib
- Dr Kumar – 88-year-old man with CLL experiences thrombocytopenia on acalabrutinib
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- Dr Malik – 79-year-old man with CLL and on esomeprazole receives acalabrutinib

MEDICAL ONCOLOGIST SURVEY: Questions from the Community

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MEDICAL ONCOLOGIST SURVEY: Questions from the Community

Dr Spencer Bachow (Boca Raton, Florida)

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Survey of US-based general medical oncologists
August 17, 2023 – August 28, 2023
N = 55*

* To qualify, participants must have seen at least 2 patients each with CLL, MCL and MM in the past year

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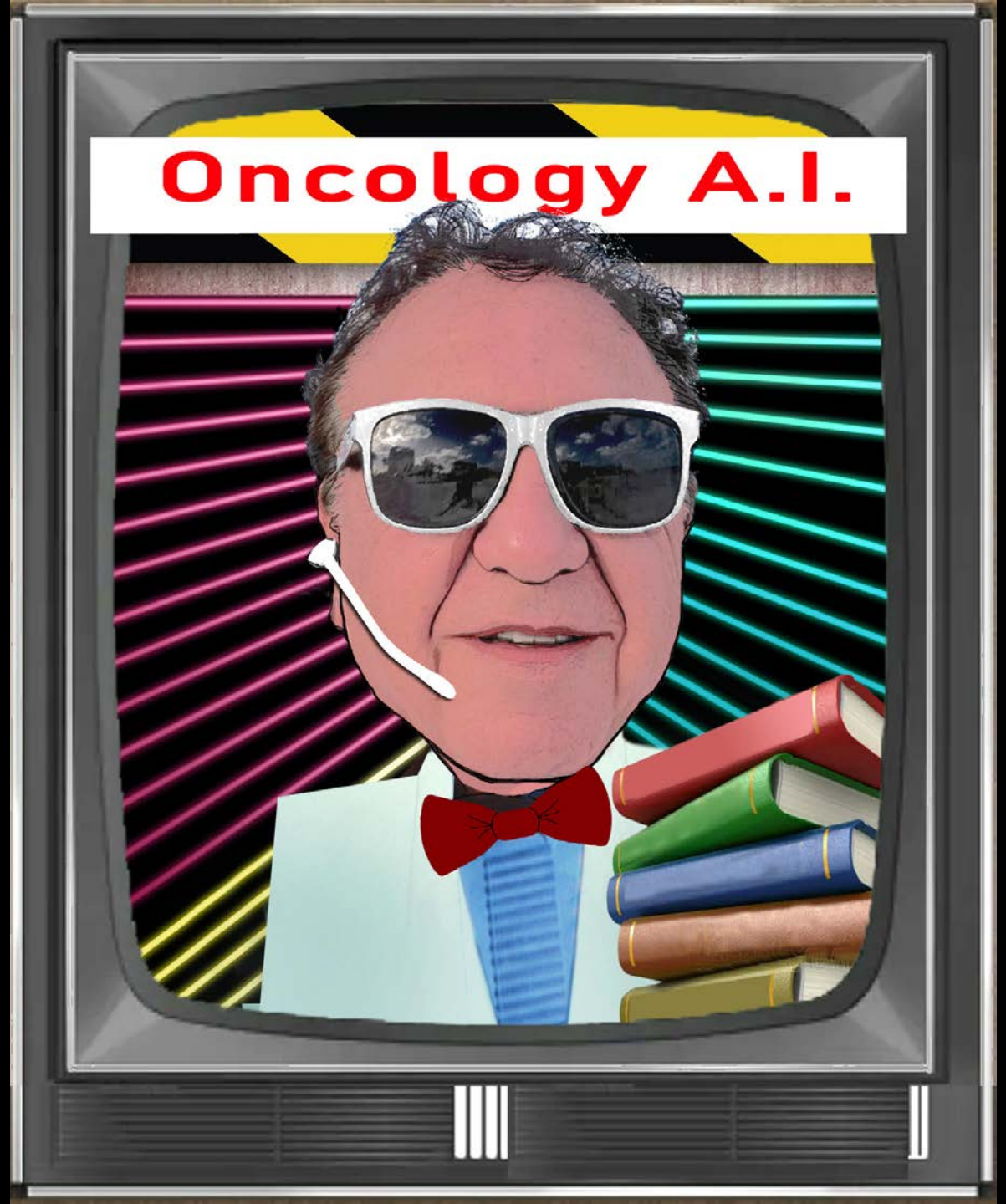
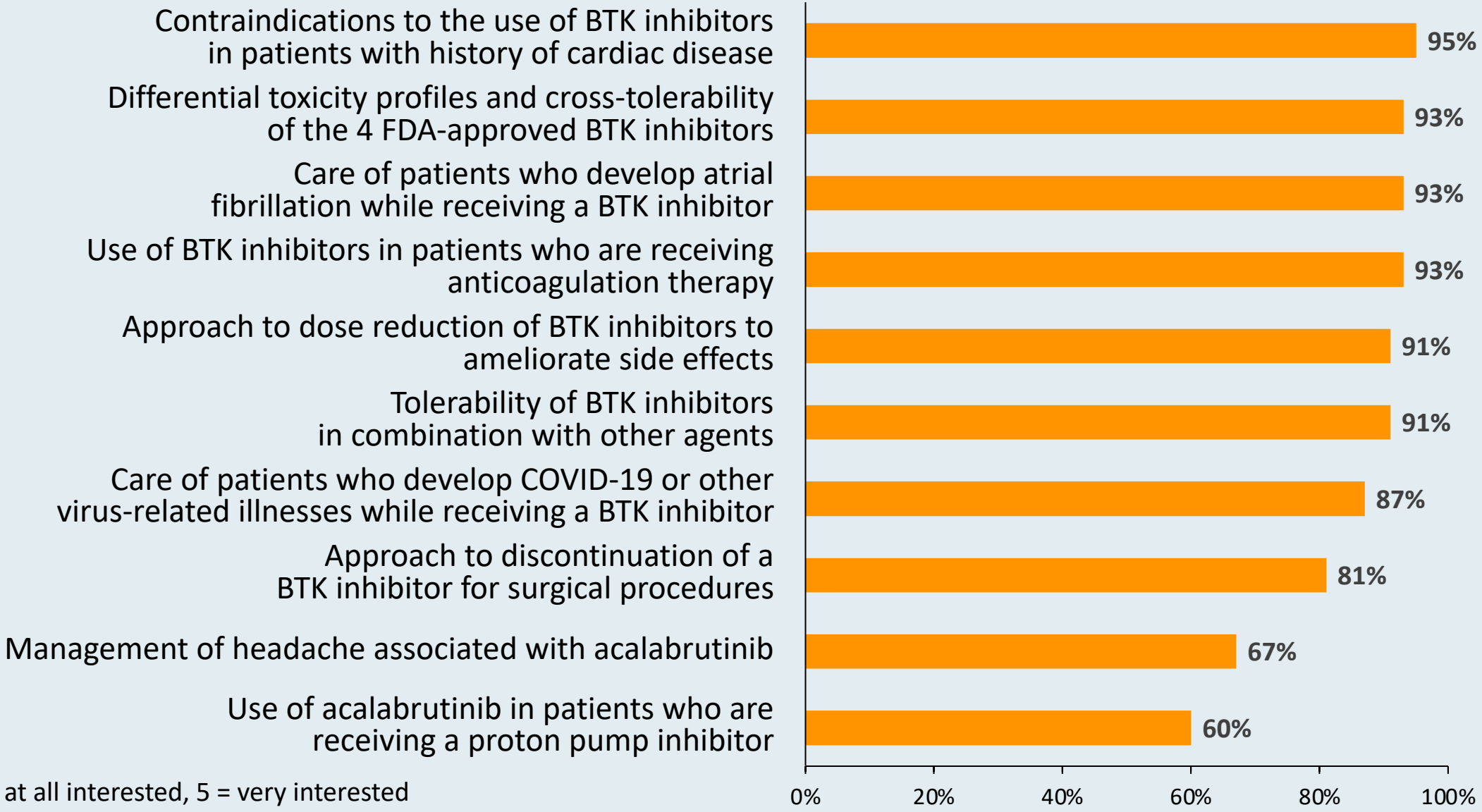
MAX HEADROOM


Oncology A.I.

Level of interest in listening to clinical investigators discuss the following topics: % of participants who responded 4 or 5*



*1 = not at all interested, 5 = very interested

Survey of US-based general medical oncologists, August 2023. N = 55

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Meet Ask the Professor

OVERVIEW	CARDIAC	BLEEDING	PERIOP HOLDS	INFECTIONS/ CYTOPENIAS	SIDE EFFECTS/ COMPLICATIONS	CLL DECISIONS	MCL DECISIONS
$200	$200	$200	$200	$200	$200	$200	$200
$400	$400	$400	$400	$400	$400	$400	$400
$600	$600	$600	$600	$600	$600	$600	$600
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MEDICAL ONCOLOGIST SURVEY: Questions from the Community

Case Presentation: 56-year-old woman with multiple cardiovascular comorbidities and R/R CLL s/p BR induction followed by venetoclax/rituximab consolidation on clinical trial

Dr Spencer Bachow (Boca Raton, Florida)

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Case Presentation: 77-year-old man with relapsed del(11q) CLL develops atrial fibrillation on ibrutinib

Dr Warren Brenner (Boca Raton, Florida)

Case Presentation: 72-year-old man with CLL develops rash and bruising while on ibrutinib

Dr Gigi Chen (Pleasant Hill, California)

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Case Presentation: 88-year-old man with CLL receives acalabrutinib as initial therapy and experiences thrombocytopenia

Dr KS Kumar (Trinity, Florida)

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Case Presentation: 85-year-old woman with relapsed CLL (TP53 mutation) discontinues ibrutinib due to bruising

Dr Warren Brenner (Boca Raton, Florida)

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Dr Spencer Bachow
(Boca Raton, Florida)

Case Presentation: 83-year-old man with R/R MCL discontinues ibrutinib due to bleeding risks after a traumatic head injury

Dr Mamta Choksi
(New Port Richey, Florida)

Questions and Comments: Concomitant administration of anticoagulation medication with BTK inhibitors; choice of BTK inhibitor

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Is MCL the new CLL which was the new CML?

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Case Presentation: 59-year-old man with CLL and response to acalabrutinib develops worsening myalgias a year later

Dr Eric Lee (Fountain Valley, California)

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Case Presentation: 82-year-old woman with relapsed del(17p) CLL develops Stevens-Johnson syndrome while receiving ibrutinib

Dr Spencer Bachow (Boca Raton, Florida)

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Case Presentation: 79-year-old man with newly diagnosed CLL and on esomeprazole receives acalabrutinib

Dr Henna Malik (Houston, Texas)

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Questions from General Medical Oncologists
Toxicity: Overview

- **One of my patients has been on ibrutinib for a long time for CLL. He is tolerating treatment, and his disease is well controlled. He asked whether he should switch to acalabrutinib or zanubrutinib**
- **I have a patient (petite elderly woman) who was not tolerating acalabrutinib and required a dose decrease. I went to once a day dosing, but is this the correct thing to do?**
- **85 yr old with a history of HTN controlled on four anti-hypertensive drugs, needs treatment of CLL with 17p deletion for B symptoms and is interested in oral therapy only. Based on indirect comparison, acalabrutinib has less incidence of HTN compared to ibrutinib and zanubrutinib — what do investigators think about the choice of BTK inhibitors?**

Survey of US-based general medical oncologists, August 2023. N = 55

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Questions from General Medical Oncologists
Toxicity: Overview

- **BTKi use in patients who have had CVA**
- **I have a patient who developed grade 3/4 rash while on ibrutinib which resolved after drug withdrawal. I do not intend to rechallenge her with ibrutinib but do wonder whether it is safe to try another drug in this class?**
- **Are BTKi associated with visual impairment? I have had to stop ibrutinib on two patients with visual impairment while on therapy**

Survey of US-based general medical oncologists, August 2023. N = 55

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Questions from General Medical Oncologists
Toxicity: Cardiac

- **75 y/o male with stable disease on ibrutinib. Develops afib with RVR and requires anticoagulation and rate control therapy. Now is stable again. When do you rechallange with BTKi? Would you use the same BTKi?**

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Questions from General Medical Oncologists
Toxicity: Bleeding

- **72 y/o female on acalabrutinib for two years. Develops melanotic stools and hospitalized with 2 units pRBCs given due to low hgb. EGD shows a bleeding gastric ulcer that has APC done. Now not bleeding. When do you rechallenge BTKi vs switching to another therapy?**

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Questions from General Medical Oncologists
Toxicity: Pre- and Post-op

- **70-year-old man requiring dental extractions. Has a TP53-mutant CLL with very aggressive presentation. What is the risk of stopping the BTK inhibitor to which he has responded in terms of being able to control the disease again after the procedure?**
- **Should I hold BTKi therapy for my patient undergoing knee replacement? He will be on enoxaparin for 4 weeks after and has high bleeding risk — should I hold his acala for 4 weeks?**
- **CLL patient on acalabrutinib requiring emergent major surgery. Recommendations? Which BTKI is safest in terms of bleeding?**

Survey of US-based general medical oncologists, August 2023. N = 55

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Questions from General Medical Oncologists
Toxicity: Infections, cytopenias

- **I have a patient who developed Covid-19 with moderate symptoms. Should the BTKi be held during the infection?**
- **A patient with CLL that has thrombocytopenia — which BTKi would be least thrombocytopenic?**
- **A 72 y/o gentleman started on zanubrutinib has developed neutropenia? What would you recommend for the management of neutropenia?**
- **64 yo patient with CLL has been on ibrutinib for 3 years and CLL is in remission, has developed fungal pneumonia. Patient is getting treated for fungal pneumonia, while I'm holding ibrutinib. When would you resume ibrutinib — would you reduce the dose or consider switching to another BTKi?**

Survey of US-based general medical oncologists, August 2023. N = 55

RTP RESEARCH TO PRACTICE

Questions from General Medical Oncologists
Toxicity: Infections, cytopenias

- **I have seen some clinicians use growth factors with BTK inhibitors for neutropenia. I was of the opinion that dose reduction is the way to approach these patients instead of using growth factors. I want to know the faculty's opinion on the management of patients with moderate to severe neutropenia on BTK inhibitors**

Survey of US-based general medical oncologists, August 2023. N = 55

Questions from General Medical Oncologists
Toxicity: Side effects, complications

- **I have a CLL pt on ibrutinib. She developed headache. MRI of brain is negative. Should I stop ibrutinib and switch to another BTKi?**
- **What is the recommended strategy dealing with headache related to acalabrutinib use? One of my patients told me that he found eating a snack or small meal helps with headaches — not sure if others have similar experiences?**
- **The most common side effect for my patients on acala is headache. How to mitigate this?**

Survey of US-based general medical oncologists, August 2023. N = 55

RTP RESEARCH TO PRACTICE

Questions from General Medical Oncologists
Toxicity: Side effects, complications

- **I have a patient on a BTKi who developed a spontaneous intramuscular hematoma. Is this an absolute contradiction to further use of a BTKi?**
- **Patient on ibrutinib with severe arthralgias. Break vs dose reduction? Any supportive tricks?**

Survey of US-based general medical oncologists, August 2023. N = 55

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Questions from General Medical Oncologists
Clinical decisions – CLL

- **An 80 yo male patient with CLL that is symptomatic and needs treatment. Which BTK inhibitor would be most tolerable in such frail elderly patient population?**
- **65 yr old lady CLL on ibrutinib for 5 yrs, in remission, asking if she can stop therapy, what do you advise?**
- **Patient with CLL and recent MI <4 weeks ago. 17p deletion. Requiring treatment. What would you do? Which BTK inhibitor?**

Survey of US-based general medical oncologists, August 2023. N = 55

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Questions from General Medical Oncologists
Clinical decisions – MCL

- **I have a 90 year old female with MCL and a malignant pericardial effusion. Her main comorbidity is CKD. What are reasonable regimens for her?**
- **What is the recommended regimen for TP53 mutated, frail patient with stage IV mantle cell lymphoma?**
- **What 1st line treatment would you recommend for a healthy 69 yo with mantle cell and TP53 mutation and del17p by FISH? Needs treatment due to symptomatic splenomegaly**

Survey of US-based general medical oncologists, August 2023. N = 55

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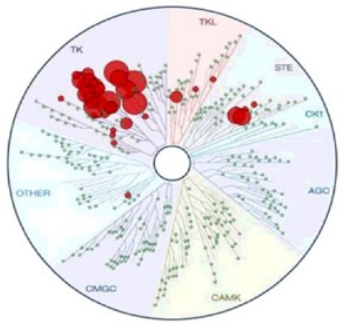
APPENDIX

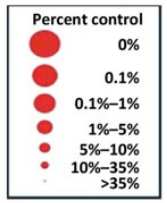
Irreversible and Reversible Bruton Tyrosine Kinase Inhibitors in CLL

BTKi	Binding	T1/2 (hours)	IC50 [nM]	Dosing
Ibrutinib	Covalent irreversible C481	4-8	0.5	420 mg
Acalabrutinib	Covalent irreversible C481	0.9	5.1	100 mg BID
Zanubrutinib	Covalent irreversible C481	2-4	0.5	160 or 320 mg BID
Pirtobrutinib	Noncovalent reversible	Not available	0.85	200 mg

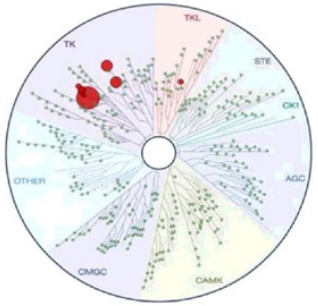
Irreversible

Ibrutinib

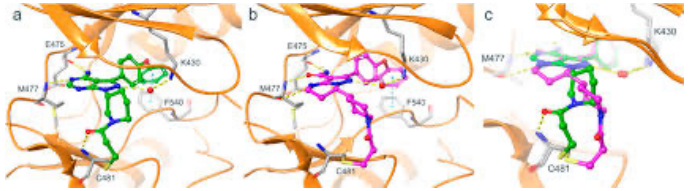




Acalabrutinib

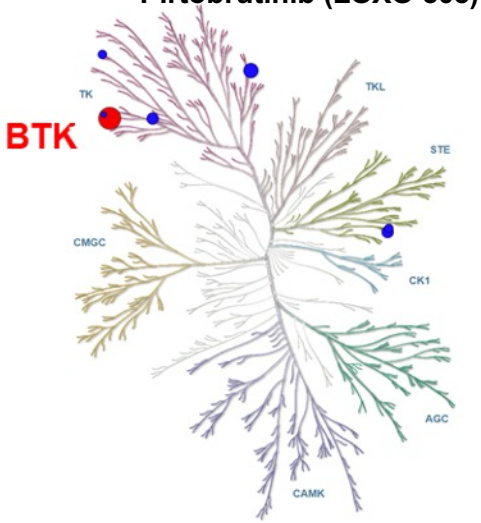


Zanubrutinib



Reversible

Pirtobrutinib (LOXO-305)



Robak T et al. *Cancers* 2022 February 2;14(3):771.

Key Differences Between Available Covalent and Reversible BTK Inhibitors

	Ibrutinib	Acalabrutinib	Zanubrutinib	Pirtobrutinib
BTK binding	Covalent C481	Covalent C481	Covalent C481	Reversible ATP pocket Distant from C481
Half-life	6 hours	1 hour	4 hours	20 hours >90% BTK inhibition
BTK Y223 autophosphorylation	Inhibited	Inhibited	Inhibited	Inhibited
BTK Y551 phosphorylation	No effect	No effect	No effect	Inhibited (maintenance of closed conformation)
BTK C481S mutation	Common	Reported	Reported	Not described Effective against C481S
Kinase-dead mutations	Uncommon and restricted to C481* (active against HCK)	Not reported to date	Reported: L528W > C481Y	Reported: L528W > V416L, A428D, C481R, M477I, and M437R
T474I/T474L gatekeeper mutation	Uncommon*; active against T474I and T474L	Reported	Not reported to date	Reported
Off-target hits†	BLK BMX BRK EGFR HER2 HER4 ITK JAK3 RLK TEC	HER4	BLK BMX BRK EGFR HER4 RLK	HER4 BRK

Thompson PA, Tam CS. *Blood* 2023;141(26):3137-42.

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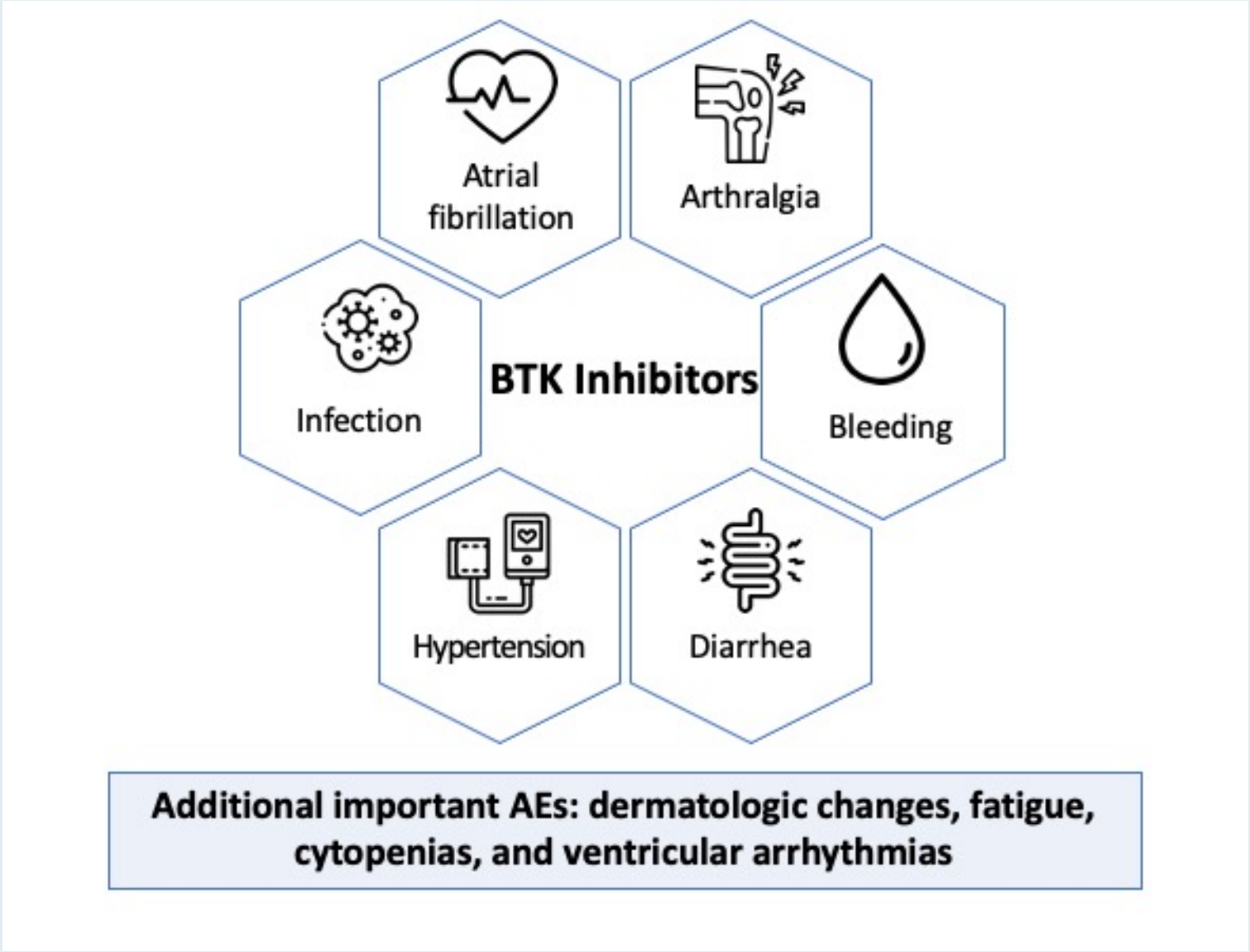
Summary of Adverse Events with BTK Inhibitors



Courtesy of Matthew S Davids, MD, MMSc

Overview of Cardiotoxicities of FDA-Approved BTK Inhibitors (BTKi)

BTKi	Mechanism	Approved Indications (United States)	Key Trials	Cardiac Adverse Events		
First Generation						
Ibrutinib	Irreversible, covalent binding to Cysteine-481	CLL/SLL Waldenstrom's Macroglobulinemia Chronic Graft versus Host Disease (GVHD)	RESONATE RESONATE-2 ILLUMINATE	*Arrhythmia*	*AF:* *VA:*	13-16 % 1.9 %
				Hypertension:		9-23 %
				Major Bleeding:		3.9-10 %
Second Generation						
Acalabrutinib	Irreversible, covalent binding to Cysteine-481	CLL/SLL Mantle Cell Lymphoma*	ELEVATE T-N ELEVATE R-R	*Arrhythmia*	*AF:* *VA:*	9.4% 0.4 %
				Hypertension:		9.4 %
				Major Bleeding:		4.5 %
Zanubrutinib	Irreversible, covalent binding to Cysteine-481	CLL/SLL Mantle cell lymphoma* Relapsed/refractory Marginal zone lymphoma** Waldenstrom's Macroglobulinemia	SEQUOIA ASPEN ALPINE	*Arrhythmia*	*AF:* *VA:*	2-5 % 0.2-0.8 %
				Hypertension:		10-23.5 %
				Major Bleeding:		2.9-5.9 %
Third Generation						
Pirtobrutinib	Reversible, non-covalent binding to ATP pocket	Relapsed or Refractory CLL/SLL Mantle Cell Lymphoma***	BRUIN	*Arrhythmia*	*AF:* *VA:*	3.9 % NR
				Hypertension:		2.3 %
				Major Bleeding		2.4 %

Ng J et al. American College of Cardiology August 16, 2023. https://www.acc.org/Latest-in-Cardiology/Articles/2023/08/15/16/45/CV-Adverse-Effects-of-Novel-Bruton-Tyrosine-Kinase-Inhibitors

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Hematology Am Soc Hematol Educ Program 2020;2020(1):336-45

Managing toxicities of Bruton tyrosine kinase inhibitors

Andrew Lipsky and Nicole Lamanna
Columbia University Medical Center, New York, NY

Management of Select Cardiovascular Adverse Events

Adverse event	Management recommendations
Atrial fibrillation	• Obtain a baseline clinical risk assessment of cardiovascular risk factors before initiating therapy. • New AF: Interdisciplinary risk–benefit assessment. CHA2DS2-VASc 0-1, most clinicians favor continuing BTKi therapy; ≥2, consider temporary drug hold until AF control or discontinuation. • Consider beta-blockade, often preferred as the first choice over CYP3A4 inhibitors (eg, verapamil and diltiazem) or P-glycoprotein substrates (amiodarone), which interact with BTKis. • Anticoagulation strategies include either low-dose apixaban (2.5 mg twice daily given CYP3A4 interaction) or enoxaparin (at regular doses in patients with a platelet count >50,000/μL). Where possible, avoid combination with vitamin K antagonists.
Ventricular arrhythmia	• Obtain a detailed cardiac history and baseline electrocardiogram for all patients; reserve echocardiogram for patients with significant cardiac history or risk factors. • Instruct patients to remain vigilant for potential early warning signs of ventricular arrhythmia and immediately investigate incident lightheadedness, palpitations, or syncope.
Bleeding risk	• Commonly encountered bruising seen with BTKis does not confer an increased risk of major hemorrhage and does not necessitate cessation of therapy. • When possible, send patients for necessary procedures before starting therapy. • Hold BTKis for either 3 days (minor procedure) or 7 days (major procedure) both before and after invasive procedures because of increased periprocedural bleeding risk. • For minor bleeding, holding BTKi results in the resolution of bleeding tendency in 2-3 days. For severe bleeds, transfuse platelets as appropriate to overcome clinical bleeding, regardless of platelet count. • Encourage patients with bleeding to abstain from over-the-counter supplements that may exacerbate bleeding risk, such as vitamin E or fish oil. • Consider treatment options other than BTKi when dual antiplatelet therapy is indicated.
Hypertension	• Optimize pharmacotherapy for control of baseline hypertension before treatment initiation. • Routinely monitor and begin appropriate medical therapy for incident hypertension in conjunction with the patient's primary care provider.

Lipsky A, Lamanna N. *Hematology Am Soc Hematol Educ Program* 2020;2020(1):336-45.

RTP RESEARCH TO PRACTICE

REVIEW ARTICLE

blood advances

International consensus statement on the management of cardiovascular risk of Bruton's tyrosine kinase inhibitors in CLL

Farrukh T. Awan,[1] Daniel Addison,[2] Feras Alfraih,[3] Sergio J. Baratta,[4] Rodrigo Noronha Campos,[5] María Silvana Cugliari,[6] Yeow Tee Goh,[7] Valery Alexandrovich Ionin,[8] Stefanie Mundnich,[9] Aaron L. Sverdlov,[10] Constantine Tam,[11] and Loïc Ysebaert[12]

[1]Harold C. Simmons Comprehensive Cancer Center, University of Texas Southwestern Medical Center, Dallas, TX; [2]Cardio–Oncology Program, Division of Cardiology, The Ohio State University Medical Center, Columbus, OH; [3]Oncology Center, King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia; [4]Hospital Universitario Austral, Buenos Aires, Argentina; [5]Benefieciencia Portuguesa Hospital, São Paulo, Brazil; [6]Hematology Department, Angel Roffo Institute of Oncology University of Buenos Aires, Buenos Aires, Argentina; [7]Singapore General Hospital, Duke–National University of Singapore Graduate Medical School, Singapore, Singapore; [8]Almazov National Medical Research Centre and Pavlov University, St. Petersburg, Russia; [9]Clínica Red Salud Vitacura y Providencia, Santiago, Chile; [10]Cardiovascular Department, John Hunter Hospital, Hunter New England Local Health District and University of Newcastle, Callaghan, NSW, Australia; [11]Alfred Health and Monash University, Melbourne, Australia; and [12]Institut Universitaire du Cancer de Toulouse Oncopole, Toulouse, France

2022;6(18):5516-25

Recommendations for Patients with CLL and Atrial Fibrillation Risk

Atrial fibrillation

- Determine whether the patient is high or low risk
- Low-risk cases may be safely treated with BTKis
  - Favor more second-generation BTKis (acalabrutinib or zanubrutinib) or alternative treatments
- BTKi treatment may be continued in consultation with MDT for patients with:
  - Permanent/persistent AF
  - HTN
  - History of myocardial infarction
- BTKis **NOT** recommended for patients with:
  - History of ventricular arrhythmia
    - Family history of sudden cardiac death
  - Severe, uncontrolled HTN
  - Severe or uncontrolled congestive heart failure (LVEF <30%)

CLL = chronic lymphocytic leukemia; MDT = multidisciplinary team; HTN = hypertension

Awan FT et al. *Blood Adv* 2022;6(18):5516-25.

Recommendations for Patients with CLL and Other Cardiovascular Risks

Hypertension

- If HTN is well-controlled, BTKi therapy may be used
- Monitor blood pressure at least biweekly for the first 3-6 mo of BTKi therapy
- Maintain early threshold for treatment during BTKi therapy

CHF

- Examine with echocardiogram
- Restrict to <2 g daily sodium intake
- Monitor weight daily
- Monitor blood pressure twice weekly
- Manage care with MDT (preferred) or in collaboration with a cardio-oncologist

Ventricular arrhythmias

- Ibrutinib should be avoided
- The risk of second-generation BTKis (acalabrutinib or zanubrutinib) is not currently known

Awan FT et al. *Blood Adv* 2022;6(18):5516-25.

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Recommendations for the Management of Cardiovascular Toxicities During BTK Inhibitor Treatment for Patients with CLL

Emerging atrial fibrillation

- Manage care using an MDT
- If other risk factors are limited (eg, CHA2DS2-VASc score = 0 or 1), BTKi therapy can be continued
- Warfarin less preferred to alternative anticoagulant therapies
- If recurrent events on ibrutinib, trial with acalabrutinib

Emerging HTN

- Begin regular home blood pressure monitoring
- New treatments for HTN or adjustments to ongoing treatments should be decided in conjunction with MDT
- Follow management guidelines and avoid CYP3A4 inhibitors where possible
- Non-ACEi in the first instance
- Use combination therapy if needed to attain systolic blood pressure control

Emerging CHF

- Initiate ACEi/ARB/ARNI plus β-blockers as tolerated and according to guidelines
- Periodic echocardiogram or other EF assessment every 6-12 mo in the setting of active CHF

Awan FT et al. *Blood Adv* 2022;6(18):5516-25.

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Recommended Acalabrutinib Dose Modifications for Adverse Reactions

Event	Adverse reaction occurrence	Dose modifications (Starting dose 100 mg approximately every 12 h)
Grade ≥3 nonhematologic toxicities Grade 3 thrombocytopenia with bleeding Grade 4 thrombocytopenia or Grade 4 neutropenia lasting longer than 7 days	First and second	• Interrupt acalabrutinib • Once toxicity has resolved to Grade 1 or baseline level, acalabrutinib may be resumed at 100 mg approximately every 12 h
	Third	• Interrupt acalabrutinib • Once toxicity has resolved to Grade 1 or baseline level, acalabrutinib may be resumed at a reduced frequency of 100 mg once daily
	Fourth	• Discontinue acalabrutinib

Acalabrutinib package insert, revised 8/2022.

Recommended Zanubrutinib Dose Modifications for Adverse Hematologic Reactions

Event	Adverse reaction occurrence	Dose modifications (Starting dose 160 mg BID or 320 mg qd)
Grade ≥3 or Grade 4 febrile neutropenia Platelet count decreased to 25,000-50,000/mm^3 with significant bleeding Neutrophil count decreased to <500/mm^3 (lasting more than 10 consecutive days) Platelet count decreased to <25,000/mm^3 (lasting more than 10 consecutive days)	First	• Interrupt zanubrutinib • Once toxicity has resolved to Grade 1 or lower or baseline, resume at 160 mg twice daily or 320 mg once daily
	Second	• Interrupt zanubrutinib • Once toxicity has resolved to Grade 1 or lower or baseline, resume at 80 mg twice daily or 160 mg once daily
	Third	• Interrupt zanubrutinib • Once toxicity has resolved to Grade 1 or lower or baseline, resume at 80 mg once daily
	Fourth	• Discontinue zanubrutinib

Zanubrutinib package insert, revised 4/2023.

Recommended Zanubrutinib Dose Modifications for Adverse Nonhematologic Reactions

Event	Adverse reaction occurrence	Dose modifications (Starting dose 160 mg BID or 320 mg qd)
Severe or life-threatening nonhematologic toxicities	First	• Interrupt zanubrutinib • Once toxicity has resolved to Grade 1 or lower or baseline, resume at 160 mg twice daily or 320 mg once daily
	Second	• Interrupt zanubrutinib • Once toxicity has resolved to Grade 1 or lower or baseline, resume at 80 mg twice daily or 160 mg once daily
	Third	• Interrupt zanubrutinib • Once toxicity has resolved to Grade 1 or lower or baseline, resume at 80 mg once daily
	Fourth	• Discontinue zanubrutinib

Zanubrutinib package insert, revised 4/2023.

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Recommended Pirtobrutinib Dose Modifications for Adverse Reactions

Event	Adverse reaction occurrence	Dose modifications (Starting dose = 100 mg approximately every 12h)
Grade ≥3 nonhematologic toxicities Absolute neutrophil count <1 to 0.5 x 10^9/L with fever and/or infection Absolute neutrophil count <0.5 x 10^9/L lasting 7 or more days Platelet count <50 to 25 x 10^9/L with bleeding Platelet count <25 x 10^9/L	First	Interrupt pirtobrutinib until recovery to Grade 1 or baseline; restart at original dose (200 mg once daily)
	Second	Interrupt pirtobrutinib until recovery to Grade 1 or baseline; restart at 100 mg once daily
	Third	Interrupt pirtobrutinib until recovery to Grade 1 or baseline; restart at 50 mg once daily
	Fourth	Discontinue pirtobrutinib

Pirtobrutinib package insert, revised 1/2023.

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BRUIN Trial: Select Adverse Events with Pirtobrutinib in Patients with CLL/SLL

	Safety population (n = 317)			
	AE		TRAE	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Infections	71.0%	28.1%	12.0%	3.8%
Neutropenia	32.5%	26.8%	19.6%	14.8%
Diarrhea	26.5%	0.6%	8.8%	0.3%
Headache	17.4%	0.6%	5.4%	0.3%
Upper respiratory tract infection	16.4%	0.3%	3.5%	0
Anemia	15.1%	8.8%	4.7%	2.2%

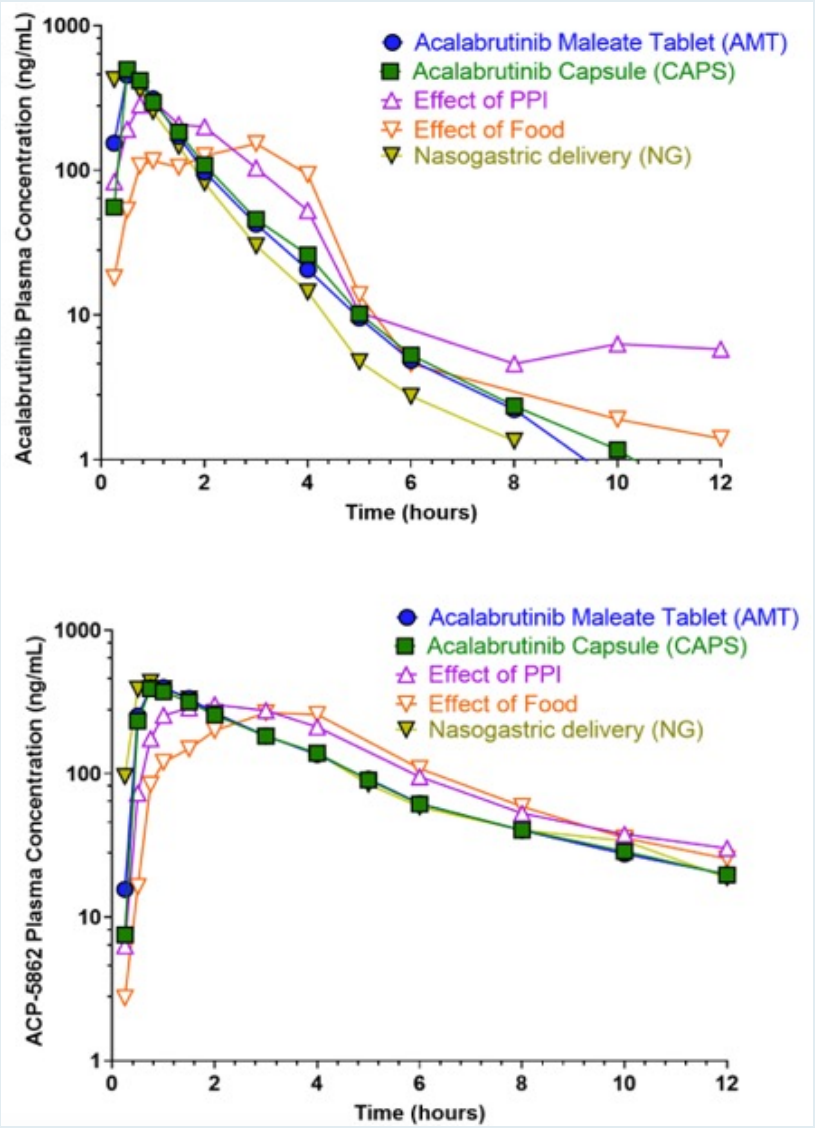
SLL = small lymphocytic lymphoma; AE = adverse event; TRAE = treatment-related AE

Mato AR et al. *N. Engl J Med* 2023;389(1):33-44.

ELEVATE-PLUS Trial: Acalabrutinib Maleate Tablet (AMT) Formulation Allowing Coadministration with PPI and Administration to Patients Unable to Swallow Capsules

- **Three Phase I, open-label, single-dose, crossover studies conducted in healthy subjects demonstrated**
  - **Similar systemic exposure between AMT and acalabrutinib capsules**
  - **No clinically relevant differences in acalabrutinib and ACP-5862 exposures observed after administration of AMT +/- PPI**
  - **No clinically relevant impact of food on exposures**
  - **Similar BTK target occupancy**
  - **No new safety concerns with AMT**

PK Profiles of Acalabrutinib/ACP-5862



PPI = proton pump inhibitor

ACP-5862 is a major pharmacologically active metabolite of acalabrutinib.

Sharma S et al. ASH 2021;Abstract 4365.

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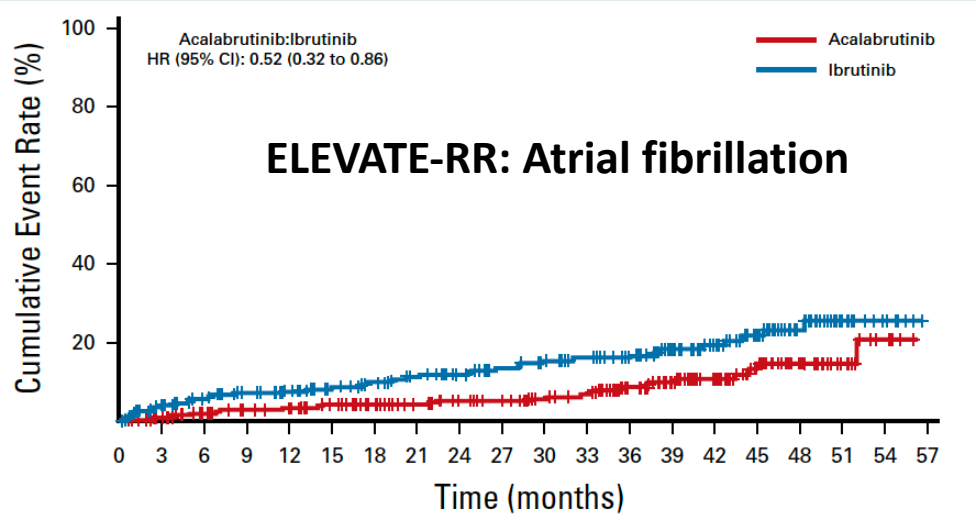
ELEVATE-RR and ALPINE: Cardiac, Hypertension and Bleeding Events

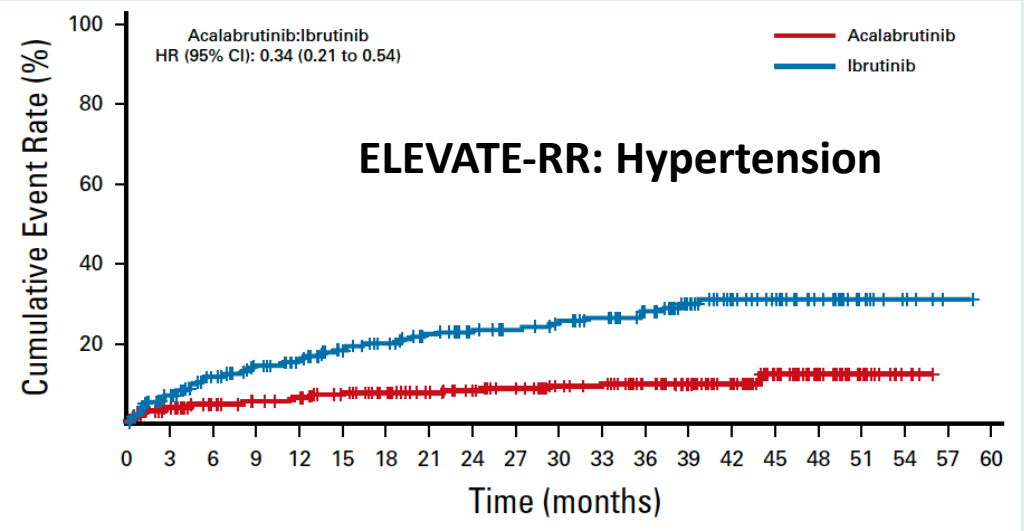
	ELEVATE-RR[1]				ALPINE[2]			
	Acalabrutinib (n = 266)		Ibrutinib (n = 263)		Zanubrutinib (n = 324)		Ibrutinib (n = 324)	
	Any grade	Grade ≥3	Any grade	Grade ≥3	Any grade	Grade ≥3	Any grade	Grade ≥3
Any cardiac event	24.1%	8.6%	30.0%	9.5%	21.3%	NR	29.6%	NR
Atrial fibrillation/flutter	9.4%	4.9%	16.4%	3.8%	5.2%	2.5%	13.3%	4.0$
Hypertension	8.6%	4.1%	23.2%	9.1%	23.5%	15.1%	22.8%	13.6%
Hemorrhage	38.0%	3.8%	51.3%	4.6%	42.3%	3.4%	41.4%	3.7%

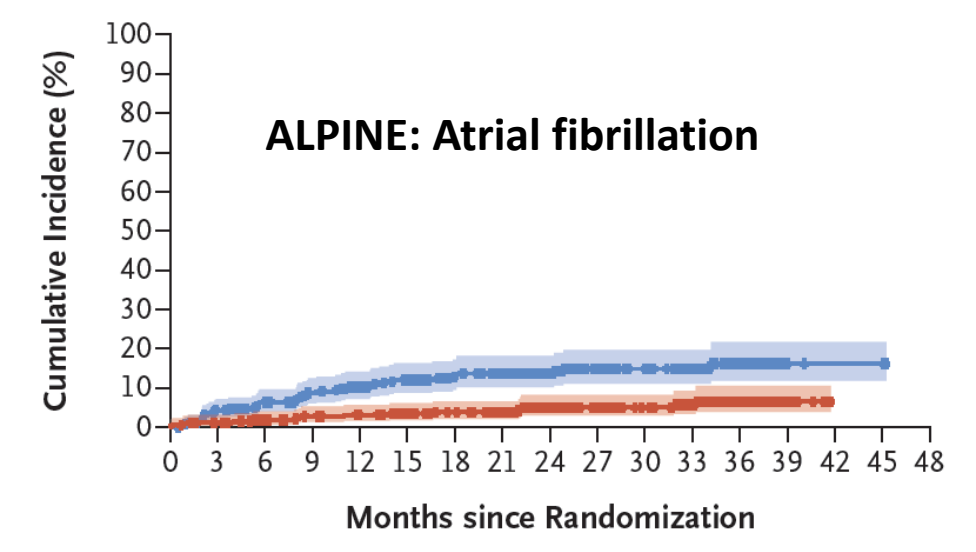
NR = not reported

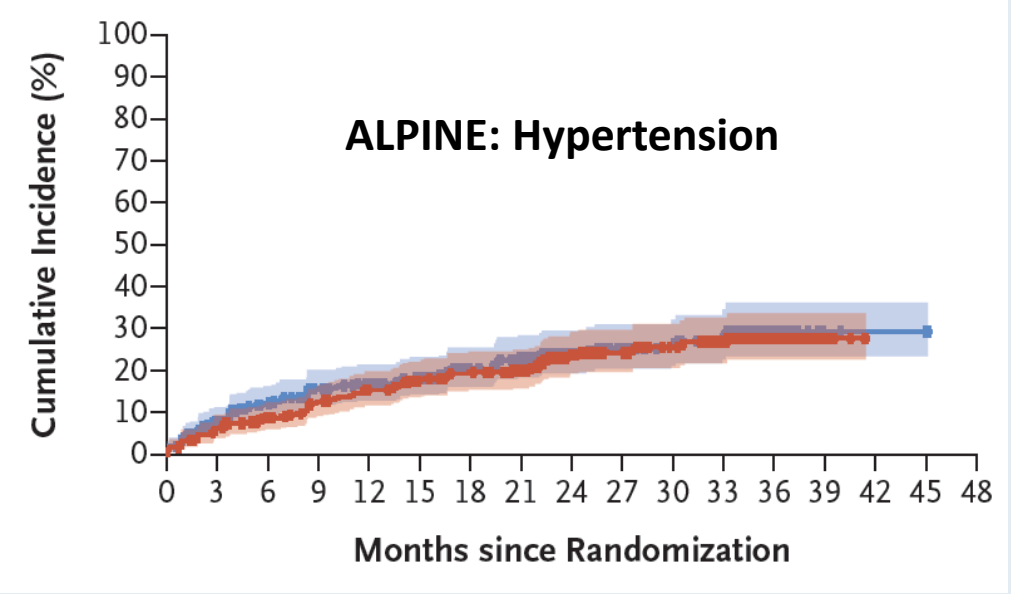
[1] Byrd JC et al. *J Clin Oncol* 2021;39:3441-52; [2] Brown JR et al. *N Engl J Med* 2022 December 13;[Online ahead of print].

ELEVATE-RR and ALPINE: Atrial Fibrillation and Hypertension









Byrd JC et al. *J Clin Oncol* 2021;39:3441-52; Brown JR et al. *N Engl J Med* 2022 December 13;[Online ahead of print].

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RTP
RESEARCH
TO PRACTICE

Consensus or Controversy? Documenting and Discussing Clinical Investigators' Practice Patterns in Myelofibrosis

A CME Satellite Symposium During the Society of Hematologic Oncology 2023 Annual Meeting

Thursday, September 7, 2023
6:34 PM – 7:34 PM CT (7:34 PM – 8:34 PM ET)

Faculty

Prithviraj Bose, MD
Andrew T Kuykendall, MD

Moderator

John Mascarenhas, MD

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Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open up to 5 minutes after the meeting ends.

CME and MOC credit information will be emailed to each participant within 5 business days.

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