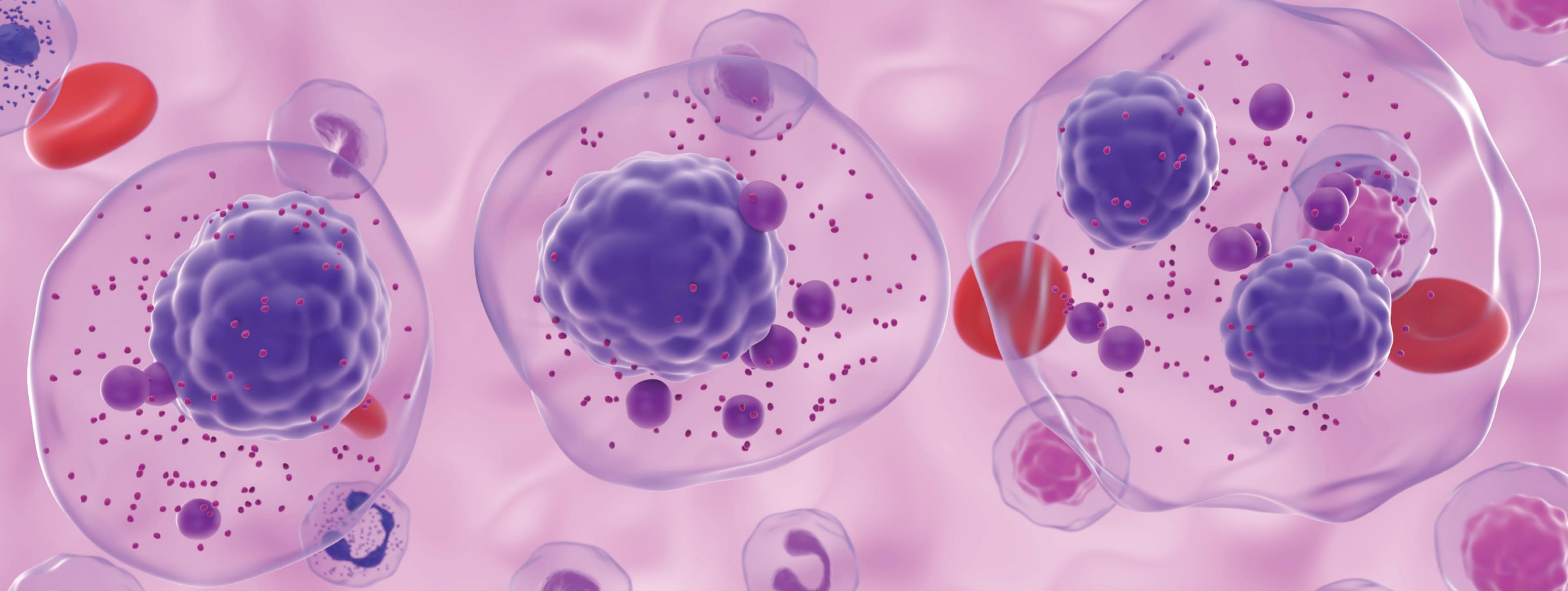




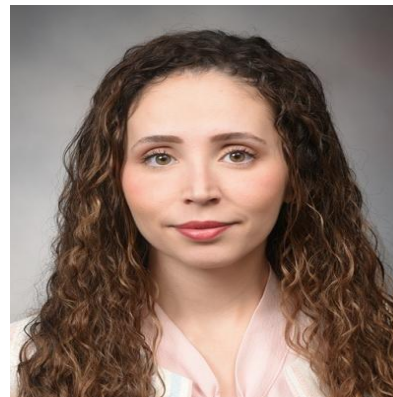
SUSTAIN

Systematic Uptake and Standardization of Treatment
Advances Through an Integrated Network for
BISPECIFIC ANTIBODY THERAPY

Planning Committee



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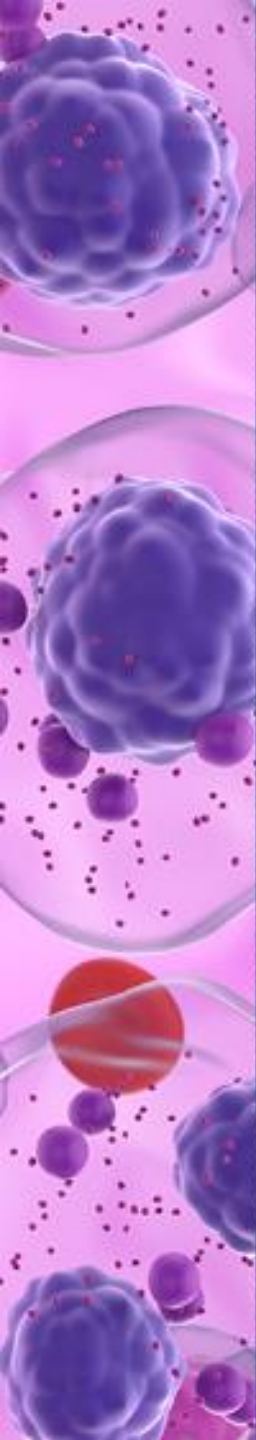
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Disclosures

All planners, faculty, and others in control of educational content are required to disclose all their financial relationships with ineligible companies within the prior 24 months. An ineligible company is defined as one whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.

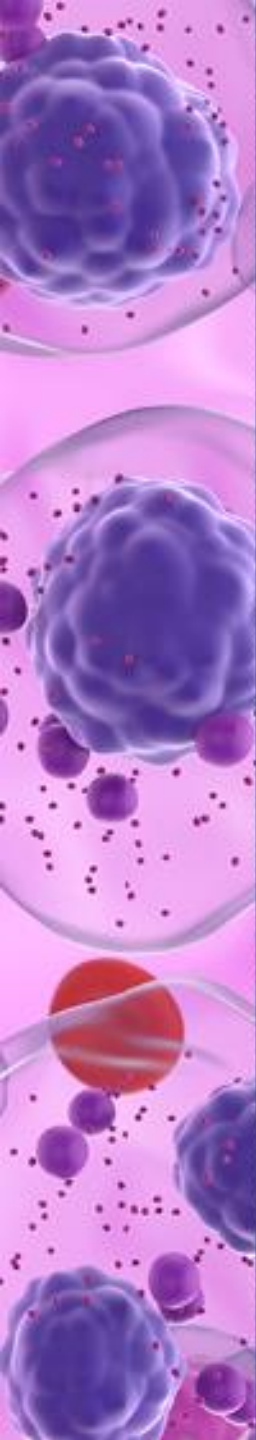
- Ayman Qasrawi, MD has served as a consultant for Sanofi Pharmaceuticals. The financial relationship ended in June 2025.

All of the relevant financial relationships listed for these individuals have been mitigated.

The material presented in this course represents information obtained from the scientific literature as well as the clinical experiences of the speakers. In some cases, the presentations might include discussion of investigational agents and/or off-label indications for various agents used in clinical practice. Speakers will inform the audience when they are discussing investigational and/or off-label uses.

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This knowledge-based activity will award 1.00 contact hour(s) (0.100 CEUs) of continuing pharmacy education credit in states that recognize ACPE providers. Course JA-UAN Number: JA0000312-9999-26-031-L01-P

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This Live activity is designated for a maximum of 1.00 *AMA PRA Category 1 Credit™*. Physicians should claim only credit commensurate with the extent of their participation in the activity.

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The maximum number of hours awarded for this Continuing Nursing Education activity is 1.00 nursing contact hour(s).

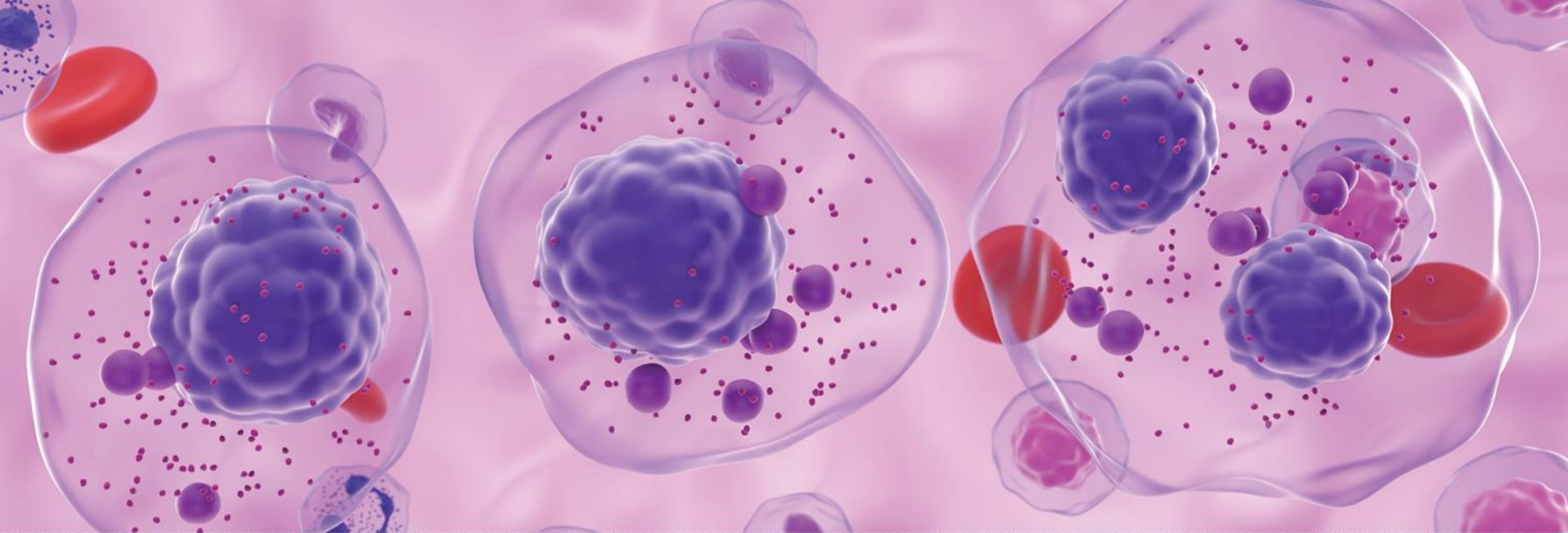
- **1.00 IPCE**

In support of improving patient care, UK HealthCare CECentral is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), the American Nurses Credentialing Center (ANCC), and the Association of Social Work Boards (ASWB) to provide continuing education for the healthcare team.

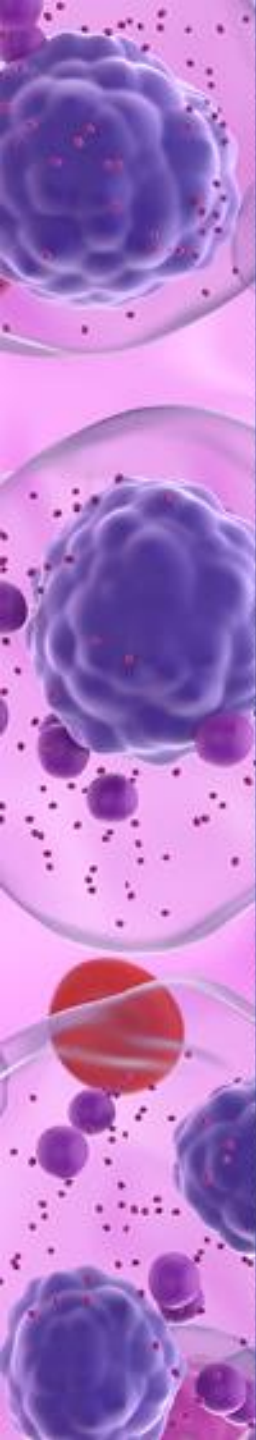
This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

For full course
information, visit:





Session 6: Developing Institutional Protocols



Curriculum Learning Objectives

- Develop and implement site-specific protocols for safe BsAb administration, including patient selection criteria, pre-medication regimens, dose escalation procedures, and post-infusion monitoring
- Establish emergency response protocols, multidisciplinary rapid response teams, and clear communication pathways with UKHC for complex cases
- Implement standardized data collection tools and quality metrics to monitor patient outcomes, adverse events, and protocol adherence

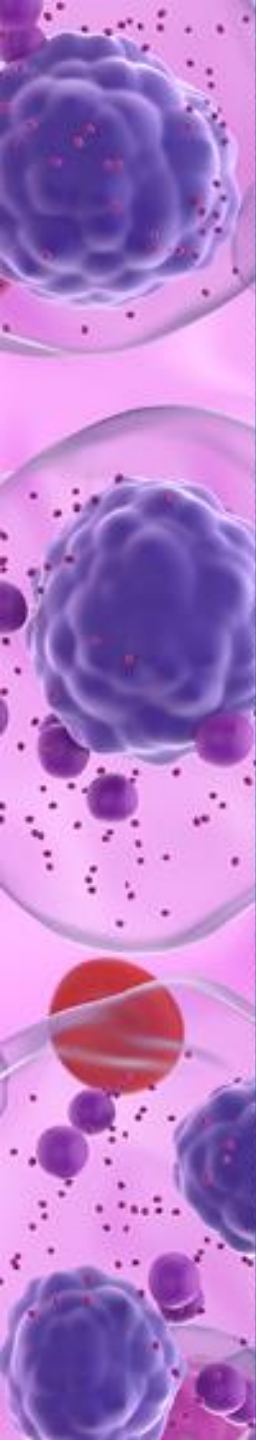
Session Objectives

1. Develop risk-based criteria for transitioning patients from inpatient step-up dosing to outpatient or community-based BsAb administration
2. Design standardized outpatient monitoring and toxicity assessment workflows aligned with the timing of CRS and ICANS onset
3. Establish structured communication and handoff protocols between academic centers and community oncology sites



Knowledge Check!

Look for a brain symbol in the top right corner of the screen to find the answers to the “What Do You Know?” questions



What Do You Know?



A health system is shifting BsAb maintenance dosing from an academic center to community sites after step-up dosing. **Which protocol element is *most likely* to reduce serious toxicity-related morbidity?**

- A. Post-infusion symptom checklist at each visit
- B. Limiting community dosing to patients without prior grade ≥ 2 CRS or neurologic events
- C. 24-hour post-dose nursing follow-up calls with escalation guidance for reported symptoms
- D. Standardized toxicity grading with predefined escalation thresholds and direct admission pathways

Key Principles of Implementing BsAbs for MM



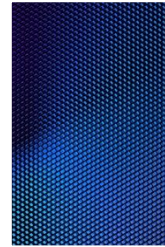
Patient safety and quality first



Evidence-based and standardized approach



Multidisciplinary collaboration

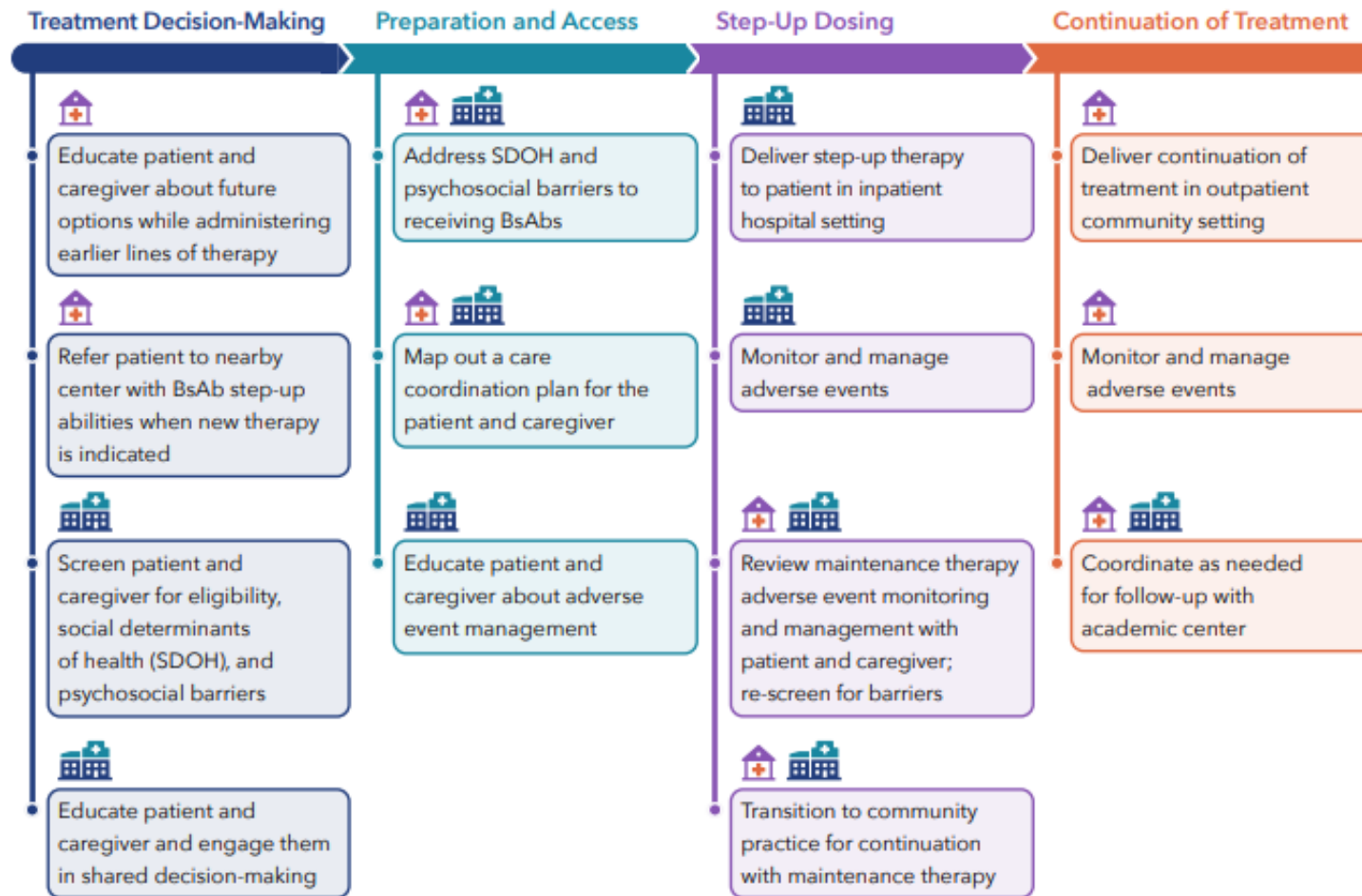


Transparency and reproducibility

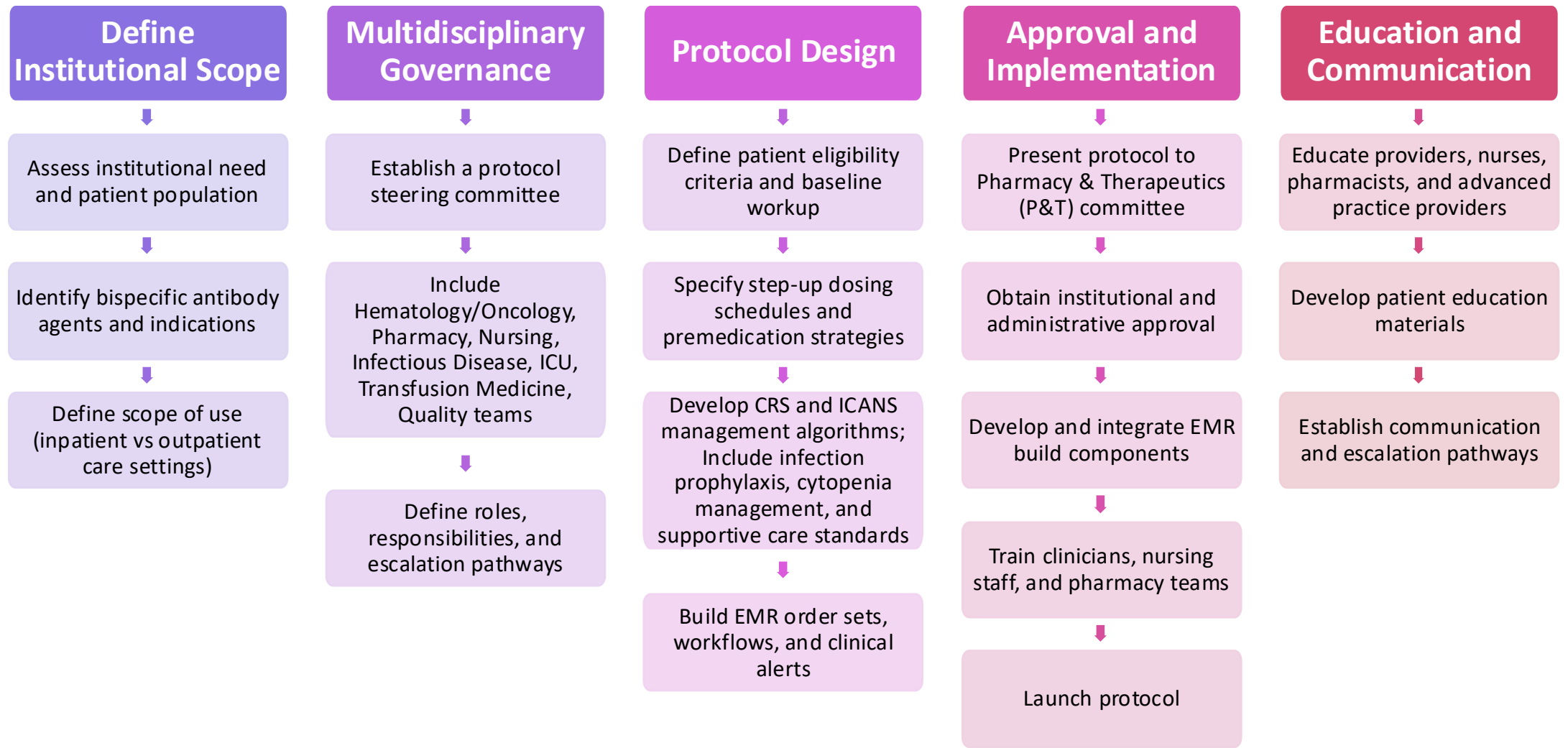


Continuous data-driven improvement

Model for Care Coordination Between Academic and Community Cancer Centers for BsAb Maintenance



Institutional Protocol Map



CRS = cytokine release syndrome; EMR = electronic medical record; ICANS = immune effector cell-associated neurotoxicity syndrome
American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/6ff749df8c110fd1e994d9a405cde79817f68d6b.pdf>; Garfall AL, et al. *Front Oncol*. 2025;15:1630146; American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/adea20091117bc5591d4f48a163667bd543d88ce.pdf>; Rajee N, et al. *Blood Cancer J*. 2023;13(1):116.

Defining Institutional Scope

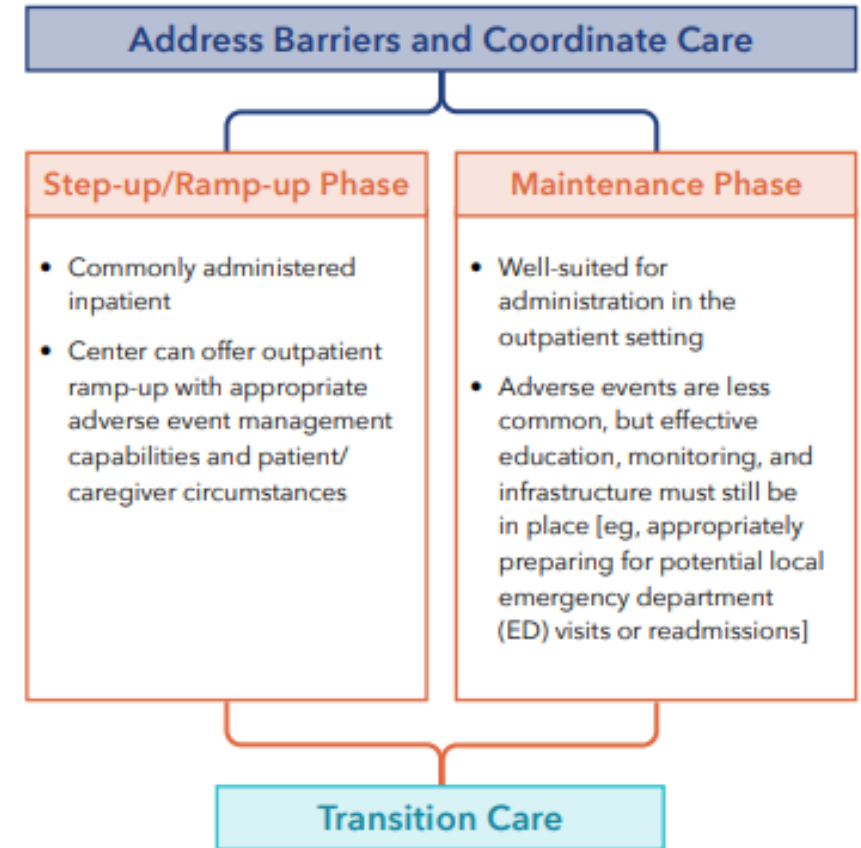
Review institutional relapsed/refractory MM population volume and referral trends

Evaluate real-world evidence and safety signals

Identify eligible bispecific antibody therapies

Define scope of use (inpatient vs outpatient care settings)

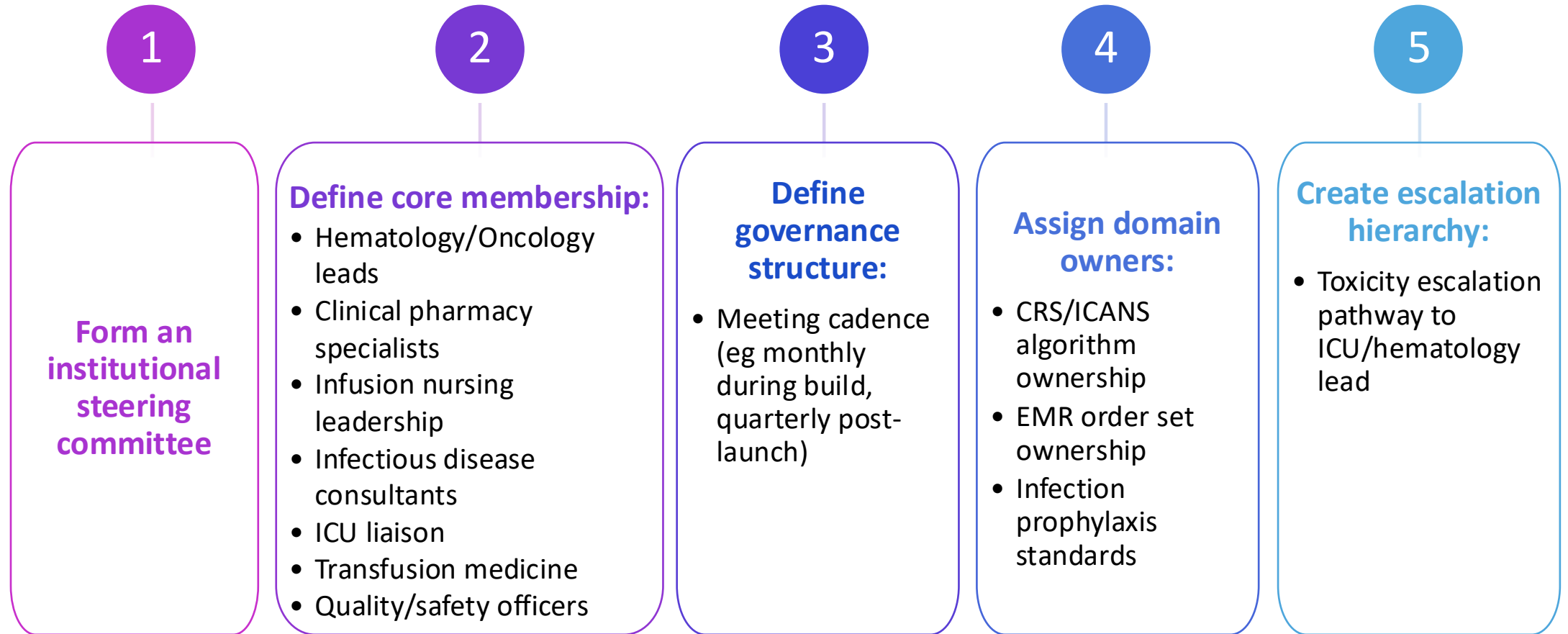
Benchmark practices with peer institutions



MM = multiple myeloma

American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/6ff749df8c110fd1e994d9a405cde79817f68d6b.pdf>; Garfall AL, et al. *Front Oncol*. 2025;15:1630146; American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/adea20091117bc5591d4f48a163667bd543d88ce.pdf>

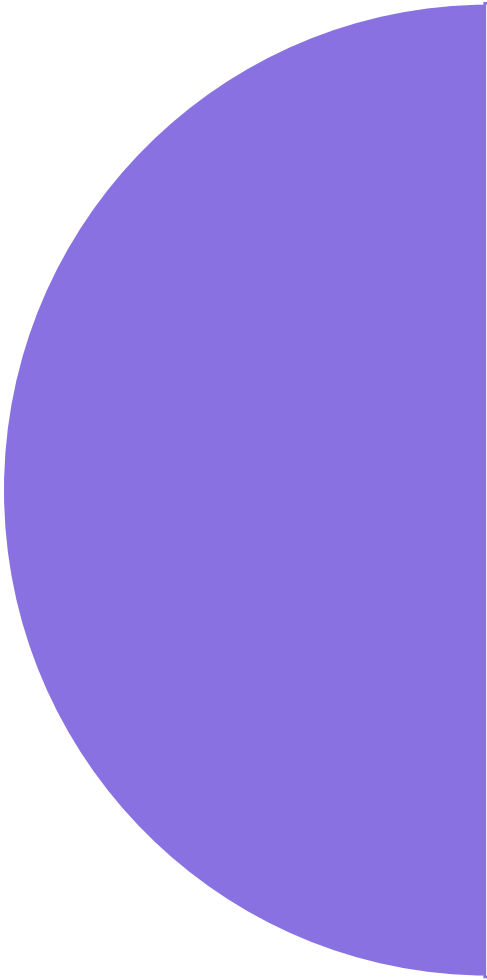
Multidisciplinary Governance for Implementing BsAbs



ICU = intensive care unit

American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/6ff749df8c110fd1e994d9a405cde79817f68d6b.pdf>; Garfall AL, et al. *Front Oncol*. 2025;15:1630146; American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/adea20091117bc5591d4f48a163667bd543d88ce.pdf>

Operationalizing Drug Administration



Physicians and
pharmacies
will need to
sign up as a
part of REMS
program

- The goal of the REMS is to mitigate the risks of CRS and neurologic toxicity including ICANS by ensuring prescribers are aware of the importance of monitoring for signs and symptoms of CRS and neurologic toxicity, including ICANS, in patients exposed to BsAbs
- Prescribers, pharmacies, and healthcare settings must be certified in the REMS program for specific therapies

REMS Overview

Physician training requirements:

- Review training requirements
- Take knowledge assessment
- Enroll as a prescriber



Pharmacies and healthcare settings:

- Designate authorized representative who is responsible for completing the REMS certification process and overseeing implementation and compliance
- Cannot be a physician
- Obtain REMS Dispense Authorization (RDA) prior to dispensing drug to ensure physician is certified to prescribe



Pharmacy and nurses training regarding requirements of the drug and toxicities



Consider in-services to train all involved across several shifts

REMS = risk evaluation mitigation strategies

Role of Multidisciplinary Care in Patients With MM Receiving Bispecific Antibodies. Cancer Network. Updated May 3, 2023. Accessed September 20, 2024.

<https://www.cancernetwork.com/view/role-of-multidisciplinary-care-in-with-mm-receiving-bispecific-antibodies>; Risk evaluation and mitigation strategies [REMS] program considerations for bispecific therapy. *American Journal of Managed Care*. Updated January 11, 2024. Accessed September 20, 2024.

<https://www.ajmc.com/view/risk-evaluation-and-mitigation-strategies-rems-program-considerations-for-bispecific-therapy>

Protocol Design: Defining Patient Eligibility

- Disease status (RR MM definition)
- Prior therapies required (IMiD, PI, anti-CD38 exposure)
- Performance status thresholds (ECOG)
- Stable organ function

Define inclusion criteria:



- Active infection
- Uncontrolled comorbidities
- Severe baseline cytopenias
- Poor health
- Inability to meet monitoring requirements

Define exclusion criteria:



Requirement	Details
Hospitalization	24-48 hours after each step-up dose
Premedication	1–3 hours before each step-up dose
Caregiver	24-hour caretaker required until 48h after last step-up
Distance	Must stay within 30 minutes of emergency care

American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/6ff749df8c110fd1e994d9a405cde79817f68d6b.pdf>; Garfall AL, et al. *Front Oncol*. 2025;15:1630146; American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/adea20091117bc5591d4f48a163667bd543d88ce.pdf>; Teclistamab-cqyv (Tecvayli) [prescribing information]. Janssen Biotech, Inc; March 2026; Elranatamab-bcmm (Elrexio) [prescribing information]. Pfizer Inc; July 2025; Talquetamab-tgvs (Talvey) [prescribing information]. Janssen Biotech, Inc; August 2023. Linvoseltamab-gcpt (Lynozytic) [prescribing information]. Regeneron Pharmaceuticals, Inc; July 2025

Protocol Design: Treatment Initiation

Pre-treatment assessment:

- Review laboratory results
- Complete provider assessment
- Confirm treatment parameters are met

Premedication:

- Administer corticosteroid, antihistamine, and antipyretic per the prescription insert protocol

Drug administration:

- Verify treatment order, dose level, and completion of required premedication
- Do not shake the product prior to administration
- Administer the BsAb as a subcutaneous injection

Documentation:

- Date and time of administration
- Dose and dose level (step-up dose 1, step-up dose 2, full dose)
- Injection site
- Premedications administered
- Immediate adverse events

Post-Dose Monitoring:

- Monitor for CRS, ICANS, and injection-related reactions
- Assess vital signs and neurologic status per institutional policy

American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/6ff749df8c110fd1e994d9a405cde79817f68d6b.pdf>; Garfall AL, et al. *Front Oncol*. 2025;15:1630146; American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/adea20091117bc5591d4f48a163667bd543d88ce.pdf>; Teclistamab-cqyv (Tecvayli) [prescribing information]. Janssen Biotech, Inc; March 2026; Elranatamab-bcmm (Elrexio) [prescribing information]. Pfizer Inc; July 2025; Talquetamab-tgvs (Talvey) [prescribing information]. Janssen Biotech, Inc; August 2023. Linvoseltamab-gcpt (Lynozytic) [prescribing information]. Regeneron Pharmaceuticals, Inc; July 2025

Protocol Design: Step-Up Dosing

Please review the prescription inserts for each agent to find specific recommendations for step-up dosing procedures, including actions to take in case of delays or adverse events.

Dosage reductions for any of these agents are not recommended.

Teclistamab-cqyv (Tecvayli) [prescribing information]. Janssen Biotech, Inc; March 2026; Elranatamab-bcmm (Elrexio) [prescribing information]. Pfizer Inc; July 2025; Talquetamab-tgvs (Talvey) [prescribing information]. Janssen Biotech, Inc; August 2023. Linvoseltamab-gcpt (Lynozytic) [prescribing information]. Regeneron Pharmaceuticals, Inc; July 2025

Agent	Step-Up Dosing Schedule
Teclistamab + Daratumumab	- Day 1 (Step-up dose 1) [≥ 20 hours after daratumumab/hyaluronidase] - Day 3 (Step-up dose 2) - Day 7 (First treatment dose)
Teclistamab monotherapy	- Day 1 (Step-up dose 1) - Day 4 (Step-up dose 2) - Day 7 (First treatment dose)
Elranatamab	- Day 1 (Step-up dose 1) - Day 4 (Step-up dose 2) - Day 8 (First treatment dose)
Talquetamab	- Day 1 (Step-up dose 1) - Day 4 (Step-up dose 2) - Day 7 (Step-up dose 3, biweekly administration)/Day 7 (First treatment dose, weekly administration) - Day 10 (First treatment dose, biweekly administration)
Linvoseltamab	- Day 1 (Step-up dose 1) - Day 8 (Step-up dose 2) - Day 15 (First treatment dose)

Protocol Design: Maintenance Dosing

Please review the prescription inserts for each agent to find specific recommendations for step-up dosing procedures, including actions to take in case of delays or adverse events.

Dosage reductions for any of these agents are not recommended.

Teclistamab-cqyv (Tecvayli) [prescribing information]. Janssen Biotech, Inc; March 2026; Elranatamab-bcmm (Elrexio) [prescribing information]. Pfizer Inc; July 2025; Talquetamab-tgvs (Talvey) [prescribing information]. Janssen Biotech, Inc; August 2023. Linvoseltamab-gcpt (Lynozzyfic) [prescribing information]. Regeneron Pharmaceuticals, Inc; July 2025

Agent	Dosing Schedule
Teclistamab + Daratumumab	• Weekly (Weeks 2-8) • Biweekly (Weeks 9-24) • Every 4 weeks (Weeks 25-onwards)
Teclistamab monotherapy	• Weekly • Biweekly in patients who have achieved and maintained a complete response or better ≥ 6 months
Elranatamab	• Weekly (Weeks 2-24) • Biweekly* (Weeks 25-48) • Every 4 weeks[†]
Talquetamab	• Weekly or biweekly
Linvoseltamab	• Weekly (Weeks 3-13) • Biweekly (Weeks 14-24) • Every 4 weeks[‡]

*Responders only

[†]In patients who have maintained a response following 24 weeks of treatment at the biweekly dosing schedule

[‡]Patients who have achieved and maintained VGPR or better at or after Week 24 and received at least 17 doses of 200 mg

Protocol Design: Planning of Coordination of Care

- Identification of where patient will be admitted for step-up dosing as well as if unplanned toxicity occurs
- Schedule of administration
 - **Example:** Dr. Chahine sees patients in clinic on Tuesdays, clears for BsAb administration, and then admits into the hospital for step-up dosing with first dose to be given same day or next day
- Counseling and consenting of patient with distribution of wallet card by physician
 - Required through REMS

Step-up doses



Teclistamab-cqyv (Tecvayli) [prescribing information]. Janssen Biotech, Inc; March 2026; Elranatamab-bcmm (Elrexio) [prescribing information]. Pfizer Inc; July 2025; Talquetamab-tgvs (Talvey) [prescribing information]. Janssen Biotech, Inc; August 2023. Linvoseltamab-gcpt (Lynozyfic) [prescribing information]. Regeneron Pharmaceuticals, Inc; July 2025; Risk evaluation and mitigation strategies [REMS] program considerations for bispecific therapy. *American Journal of Managed Care*. Updated January 11, 2024. Accessed September 20, 2024. <https://www.ajmc.com/view/risk-evaluation-and-mitigation-strategies-rems-program-considerations-for-bispecific-therapy>

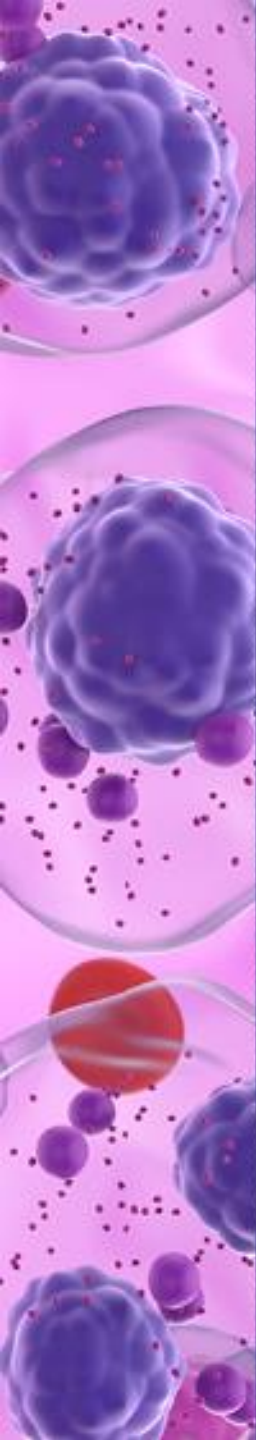


Approval and Implementation: Preparing Materials

- Prepare P&T committee submission package:
 - Clinical rationale
 - Safety data summary
 - Operational workflow map
- Obtain institutional approvals:
 - Pharmacy & Therapeutics Committee
 - Medical executive committee (if required)
- Build EMR system components:
 - Order sets validated by pharmacy + IT
 - Documentation templates
 - Alert triggers (CRS/ICANS monitoring)
- To reduce serious toxicity-related morbidity, standardize toxicity grading with predefined escalation thresholds and direct admission pathways

You learned about how to monitor for and manage adverse events, including CRS, ICANS, and infections, in ECHO Sessions 3, 4, and 5!

American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/6ff749df8c110fd1e994d9a405cde79817f68d6b.pdf>; Garfall AL, et al. *Front Oncol*. 2025;15:1630146; American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/adea20091117bc5591d4f48a163667bd543d88ce.pdf>; Teclistamab-cqyv (Tecvayli) [prescribing information]. Janssen Biotech, Inc; March 2026; Elranatamab-bcmm (Elrexio) [prescribing information]. Pfizer Inc; July 2025; Talquetamab-tgvs (Talvey) [prescribing information]. Janssen Biotech, Inc; August 2023. Linvoseltamab-gcpt (Lynozytic) [prescribing information]. Regeneron Pharmaceuticals, Inc; July 2025



Approval and Implementation: Providing Staff Training

Conduct staff training:

- Physicians: dosing + toxicity recognition
- Nursing: infusion monitoring + CRS recognition
- Pharmacy: preparation + verification workflow

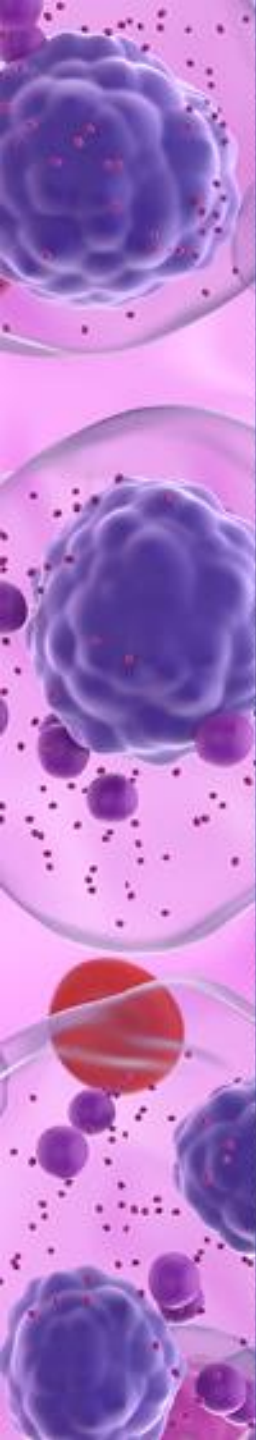
Validate infusion center readiness:

- Emergency medication availability (tocilizumab, steroids)
- Rapid response protocols

Launch protocol (go-live):

- Pilot phase (optional)
- Full deployment

American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/6ff749df8c110fd1e994d9a405cde79817f68d6b.pdf>; Garfall AL, et al. *Front Oncol.* 2025;15:1630146; American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/adea20091117bc5591d4f48a163667bd543d88ce.pdf>; Teclistamab-cqyv (Tecvayli) [prescribing information]. Janssen Biotech, Inc; March 2026; Elranatamab-bcmm (Elrexio) [prescribing information]. Pfizer Inc; July 2025; Talquetamab-tgvs (Talvey) [prescribing information]. Janssen Biotech, Inc; August 2023. Linvoseltamab-gcpt (Lynozytic) [prescribing information]. Regeneron Pharmaceuticals, Inc; July 2025

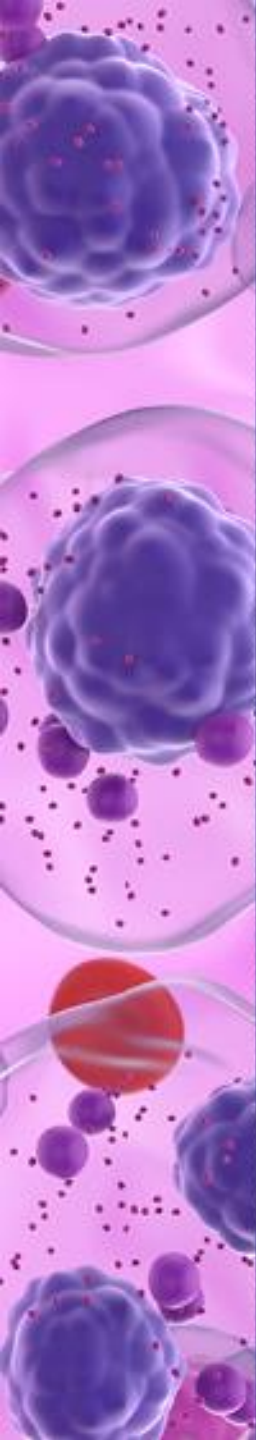


Approval and Implementation: Role of the Pharmacy

- Identification of authorized representative
- How drug is obtained for delivery
- Maintaining training records of education regarding use of the drug for pharmacy and nurses
- Order set development with informatics for both drug administration as well as toxicity management
- Per REMS, generation of RDA code may be required prior to dispensing to confirm the prescriber is REMS-certified

RDA = REMS dispense authorization

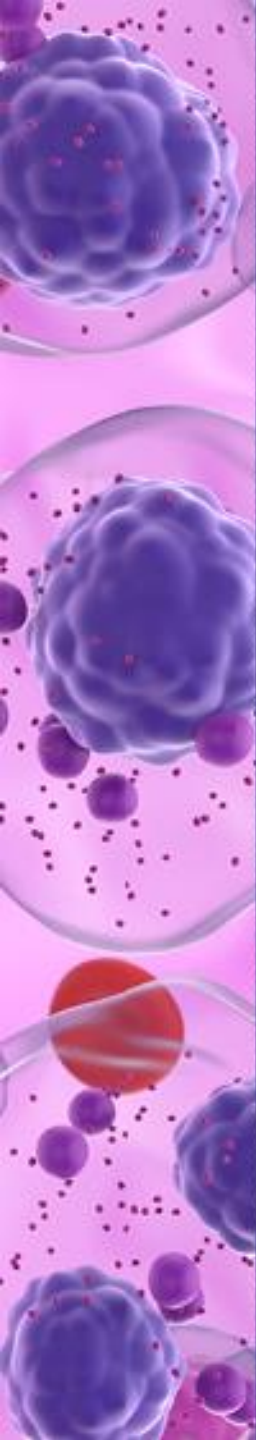
American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/6ff749df8c110fd1e994d9a405cde79817f68d6b.pdf>; Garfall AL, et al. *Front Oncol*. 2025;15:1630146; American Association of Cancer Care Centers. Accessed March 30, 2026. <https://cdn.sanity.io/files/0vv8moc6/accc-cancer/adea20091117bc5591d4f48a163667bd543d88ce.pdf>; Teclistamab-cqyv (Tecvayli) [prescribing information]. Janssen Biotech, Inc; March 2026; Elranatamab-bcmm (Elrexio) [prescribing information]. Pfizer Inc; July 2025; Talquetamab-tgvs (Talvey) [prescribing information]. Janssen Biotech, Inc; August 2023. Linvoseltamab-gcpt (Lynozyfic) [prescribing information]. Regeneron Pharmaceuticals, Inc; July 2025



Approval and Implementation: Establishing Communication

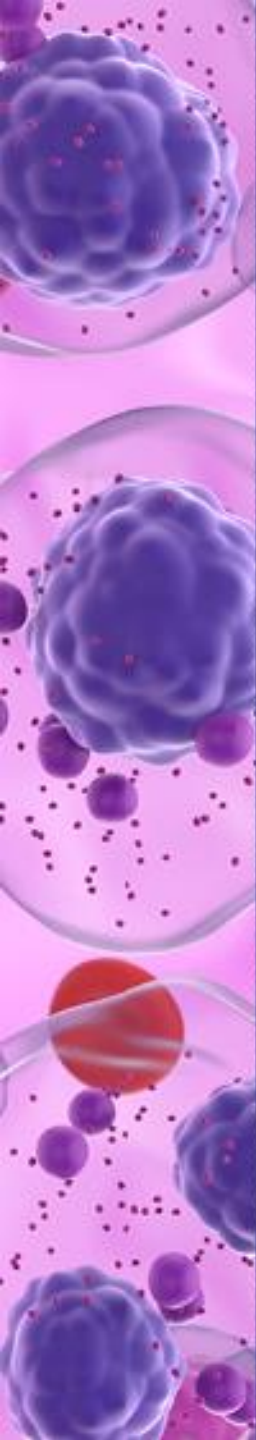
Effective communication among team members is crucial for coordinated care. This can be achieved through:

1. Regular multidisciplinary team meetings to discuss patient cases
2. Shared electronic health records for up-to-date information
3. Clear documentation of treatment plans and patient progress
4. Designated points of contact for inter-team communication
5. Patient care conferences including the patient and family when appropriate



Key Takeaways

- It is important to implement clear, risk-stratified criteria to identify patients appropriate for outpatient step-up and maintenance dosing
- Clear communication pathways between community sites and academic centers are essential for the timely management of severe immune-related toxicities
 - Develop structured handoff tools for transitions from inpatient step-up dosing to outpatient or community care
 - Design protocols that clearly delineate responsibilities across providers, nurses, and pharmacists at each step of care

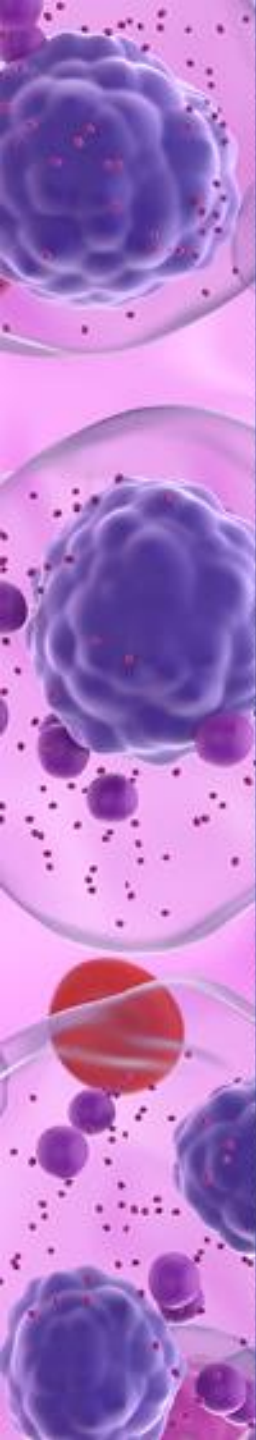


What Did You Learn?



A health system is shifting BsAb maintenance dosing from an academic center to community sites after step-up dosing. **Which protocol element is *most likely* to reduce serious toxicity-related morbidity?**

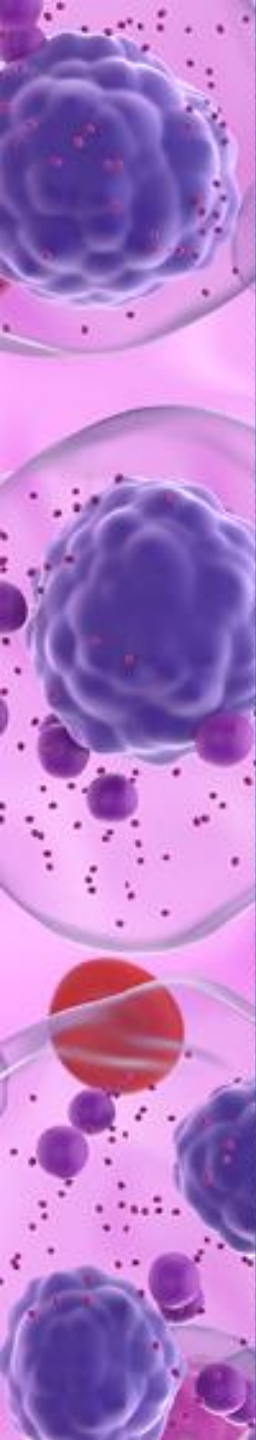
- A. Post-infusion symptom checklist at each visit
- B. Limiting community dosing to patients without prior grade ≥ 2 CRS or neurologic events
- C. 24-hour post-dose nursing follow-up calls with escalation guidance for reported symptoms
- D. Standardized toxicity grading with predefined escalation thresholds and direct admission pathways



Ask the Audience!

Please unmute or use the chat feature to discuss with your colleagues.

What questions do you have about
implementing new protocols for
BsAbs?



Case Studies

Please come off mute or use the chat feature to discuss with your colleagues and ask questions about your patient cases.

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1. Go to www.xxxxx and “Take Course” then “Start Course”
2. Enter Attendance Code **xxxxx** when prompted
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For questions, please contact support@cecentral.com

