

A Multidisciplinary Framework for the Management of Serious Adverse Events from Modern Anticancer Therapies

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Introduction

The rapid expansion of immune checkpoint inhibitors, immune effector-cell and T-cell-engaging therapies, Antibody-Drug Conjugates (ADCs), and molecularly targeted agents has transformed both clinical research and standard oncology care. These advances have improved survival across many malignancies, yet they have also introduced a heterogeneous spectrum of adverse events that may be inflammatory, on-target, off-tumor, payload-related, or pharmacologic. Toxicities vary in onset and urgency, may emerge after therapy has stopped, and can affect virtually any organ system [1]. Safe treatment therefore increasingly depends on coordinated expertise that extends beyond the traditional scope of medical oncology.

Clinical practice guidelines have evolved in parallel. Recommendations from the American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN), Society for Immunotherapy of Cancer (SITC), and European Society for Medical Oncology (ESMO) define toxicity grading, diagnostic evaluation, treatment holds, immunosuppression, and specialist consultation for many syndromes [2–6]. Cellular-therapy guidance similarly standardizes Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) grading and management [7–9]. These documents establish what clinicians should do; they generally do not define who receives the first call, how quickly a specialist responds, who

owns follow-up across care settings, or how an institution measures whether the recommended care was delivered. That operational gap is the focus of the framework described here.

The initiative covers the treatment strategies and representative agents shown in **Table 1**. The list is intentionally selective rather than exhaustive: the operational requirement is to map every newly adopted therapy to its sentinel toxicities, baseline and interval monitoring, red-flag symptoms, first-contact owner, and specialty escalation route before routine deployment.

Serious treatment toxicity often begins with nonspecific findings such as fatigue, rash, diarrhea, dyspnea, visual disturbance, weakness, hypotension, or an isolated laboratory abnormality. The same presentation may reflect infection, cancer progression, thrombosis, metabolic derangement, a concomitant medication, or treatment toxicity; empiric immunosuppression may be lifesaving in some syndromes but harmful when infection has not been considered. Combination regimens further complicate attribution: for example, checkpoint inhibitor plus VEGF-pathway inhibition can produce overlapping gastrointestinal, hepatic, endocrine, renal, cardiovascular, dermatologic, and fatigue syndromes. The system must therefore support simultaneous danger recognition, exclusion of mimics, agent-specific management, and early organ-specialist involvement rather than sequential ad hoc consultation.

Table 1. Treatment strategies, representative agents, and multidisciplinary toxicity priorities.

Treatment strategy	Representative agents	Sentinel serious toxicities / organs	Priority triage and co-management
Immune checkpoint inhibitors	PD-1/PD-L1: pembrolizumab, nivolumab, atezolizumab, durvalumab; CTLA-4: ipilimumab; LAG-3: relatlimab.	Inflammatory toxicity can involve skin, colon, liver, lung, endocrine glands, kidney, joints/muscle, heart, nervous system, blood, and eye. Grade 3+ events in I-CHECKIT most often involved liver, GI tract, skin, and lung [2–6,10].	Early danger screen; distinguish infection/progression; organ-specific workup; coordinated immunosuppression; delayed-event and rechallenge follow-up.
Immune effector-cell and T-cell-engaging therapy	CD19/BCMA CART cells (axi-cel, liso-cel, tisa-cel, ide-cel, cilta-cel); bispecific antibodies (teclistamab, epcoritamab).	CRS, ICANS, cytopenias, infection, coagulopathy, hypogammaglobulinemia, and immune effector cell-associated hemophagocytic syndrome-like toxicity [5,7–9].	Protocolized fever/hypotension/hypoxia and neurologic assessment; immediate hematology/cellular-therapy contact; critical care, neurology, infectious disease, and pharmacy readiness.
Antibody-drug conjugates	Trastuzumab deruxtecan, enfortumab vedotin, sacituzumab govitecan, tisotumab vedotin, mirvetuximab soravtansine.	Agent/payload-specific ILD/pneumonitis, ocular-surface or corneal toxicity, severe rash, neuropathy, cytopenia, diarrhea, nausea, bleeding, and hyperglycemia [11,12].	Drug-specific surveillance; urgent pulmonary evaluation for new cough/dyspnea; planned ophthalmic access for symptomatic or protocol-mandated examinations.
VEGF-pathway inhibition	Bevacizumab; axitinib, cabozantinib, lenvatinib, pazopanib, sunitinib, tivozanib.	Hypertension, proteinuria, thrombotic microangiopathy, and acute kidney injury [13]. Other agent-specific risks include thrombosis/bleeding, heart failure, wound-healing complications, diarrhea, and hand-foot toxicity.	Home BP and urine-protein monitoring; urgent evaluation of hypertensive emergency/PRES, nephrotic-range proteinuria, suspected TMA, thrombosis, bleeding, or cardiac dysfunction; onco-nephrology/cardio-oncology input.
MAPK-pathway inhibition	BRAF/MEK combinations such as dabrafenib/trametinib, encorafenib/binimetinib, vemurafenib/cobimetinib.	Pyrexia/dehydration, hepatotoxicity, cardiomyopathy, QT effects, and severe skin reactions; ocular effects include uveitis, retinal vein occlusion, and MEK-inhibitor-associated retinopathy [14].	Same-day assessment for persistent fever or visual symptoms; ophthalmology for vision change; dermatology and cardio-oncology for severe cutaneous or cardiac findings.
Other molecularly targeted agents	EGFR inhibitors (osimertinib, cetuximab); HIF-2alpha inhibitor (belzutifan); PARP and CDK4/6 inhibitors.	Examples include EGFR-related rash/diarrhea/ILD/cardiotoxicity; belzutifan-related anemia and hypoxia [15]; and class-specific cytopenic, hepatic, thrombotic, or pulmonary toxicity.	Pair agent-specific monitoring with rapid access to dermatology, pulmonology, cardiology, hematology, or transfusion support; avoid attributing dyspnea or cytopenia to cancer without evaluating treatment toxicity and competing causes.

Abbreviations: ADC: Antibody-Drug Conjugate; CART: Chimeric Antigen Receptor T cell; CTCAE: Common Terminology Criteria for Adverse Events; GI: Gastrointestinal; ICANS: Immune effector Cell-Associated Neurotoxicity Syndrome; ILD: Interstitial Lung Disease; PRES: Posterior Reversible Encephalopathy Syndrome; TMA: Thrombotic Microangiopathy. This selective table supports triage and does not replace current prescribing information or organ-specific guidance.

An Operational Framework at the University of Kansas

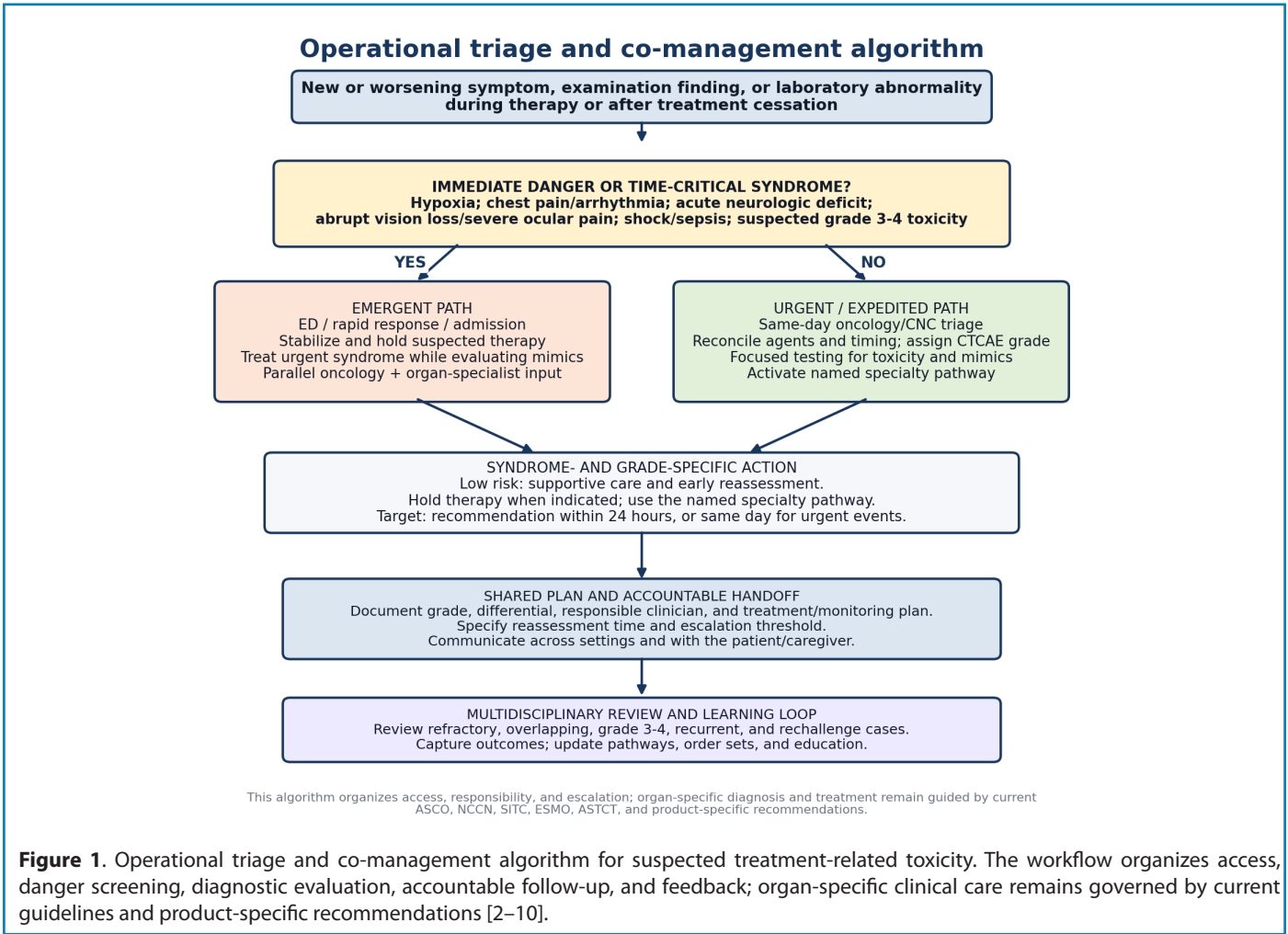
At the University of Kansas Medical Center and the University of Kansas Cancer Center, these challenges prompted development of a multidisciplinary serious-adverse-event initiative. The initial clinical network integrates oncology with endocrinology, dermatology, and ophthalmology and is expanding through named pathways in neurology, pulmonology, gastroenterology, cardiology, rheumatology, nephrology, infectious diseases, and critical care. The program is not intended to replace the treating oncologist or organ-specific guidelines. It supplies an accountable operating layer: a common entry point, urgency rules, designated specialty champions, explicit handoffs, shared documentation, and a learning system that connects clinical care, education, and research.

Five linked components define the initiative. First, standardized triage scripts identify red-flag presentations and route patients to emergency, same-day, or expedited

outpatient assessment. Second, named inpatient and outpatient owners preserve continuity through admission, steroid taper, specialty follow-up, and treatment-rechallenge decisions. Third, institution-specific pathways translate national and product-specific recommendations into order sets, referral instructions, and response-time expectations. Fourth, difficult, overlapping, refractory, recurrent, and rechallenge cases are reviewed in a multidisciplinary forum. Fifth, a structured registry captures treatments, organ systems, diagnostic certainty, management, and outcomes so that pathway performance can be audited and refined.

A Practical Front Door for Suspected Toxicity

Figure 1 provides a therapy-agnostic front door for suspected toxicity. It is not a substitute for organ-specific management. Its purpose is to prevent delay while the diagnosis remains uncertain: danger is assessed first, the anticancer exposure and timing are reconciled, CTCAE grade and a working syndrome are assigned, mimics are evaluated in parallel, and a named clinician owns the next reassessment.



This initiative is supported by an institutional environment that integrates clinical care, translational research, and early-phase drug development. The University of Kansas Cancer Center is an NCI-designated comprehensive cancer center operating as a matrix organization across multiple campuses and partner institutions [16]. Rapid adoption of novel therapies creates both the need and the opportunity to develop reusable toxicity pathways, connect community sites to subspecialty expertise, and study uncommon events across the cancer center network.

Prospective toxicity investigation is a central pillar. SWOG S2013 (I-CHECKIT; NCT04871542), available at our institution, is a multicenter observational study of patients receiving standard-of-care immune checkpoint inhibitor therapy [10,17]. In the completed checkpoint-inhibitor cohort reported in 2026, 2,020 eligible patients were evaluated: 13.3% experienced a grade 3 or higher nonhematologic immune-related Adverse Event (irAE) within one year, with a higher incidence after combination checkpoint blockade than single-agent therapy (27.4% vs 10.5%). Among grade 3 or higher events, hepatitis (21.2%), gastrointestinal disorders (19.3%), skin toxicity (11.9%), and respiratory toxicity (10.0%) were most frequent [10]. These prospective data underscore both the multisystem scope and the need to anticipate higher-risk regimens.

The institutional registry is designed to complement trial data by capturing real-world events across therapeutic classes, disease settings, and care locations. A minimum dataset includes anticancer agents and exposure dates; suspected organ system and CTCAE grade; alternative diagnoses considered; diagnostic tests and specialty input; treatment interruption, corticosteroid exposure, second-line immunosuppression, and supportive care; emergency department use, hospitalization, intensive care, readmission, time to improvement, persistent organ dysfunction, and treatment rechallenge. Standardized terminology and adjudication rules are needed because administrative codes alone may misclassify both toxicity and competing diagnoses [6].

Institutional experience with cellular therapy provides a mature model for this approach. Standardized CRS and ICANS grading, scheduled neurologic assessment, 24-hour escalation capability, pharmacy access to tocilizumab and other syndrome-directed therapy, infectious evaluation, and coordinated inpatient/outpatient follow-up define roles before a patient deteriorates [7–9]. The same design principles—predefined triggers, named responders, shared order sets, and prospective surveillance—can be adapted to checkpoint inhibitors, T-cell-engaging bispecific antibodies, ADCs, and targeted therapies without assuming that their mechanisms or treatments are interchangeable.

Evidence Supporting Multidisciplinary Models

Although comparative evidence remains limited, published institutional programs demonstrate feasibility and signal potential benefit. A Johns Hopkins virtual multidisciplinary irAE team received 117 referrals involving 102 patients over 8 months; recommendations were delivered within 24 hours for all referrals, all surveyed referring clinicians used the recommendations, and 74% reported changing management [18]. An irAE tumor board model has similarly been used to streamline complex cases and identify recurrent service and educational needs [19].

At Massachusetts General Hospital, implementation of the multidisciplinary Severe Immunotherapy Complications Service was associated in a before-after analysis with lower irAE readmission (14.8% after vs 25.9% before; adjusted odds ratio 0.46, 95% CI 0.22–0.95) and a one-day reduction in median readmission length of stay; mortality, immunosuppressive use, and treatment discontinuation did not significantly differ [20]. These observational findings support evaluation but do not establish causality because secular changes and case-mix differences may remain.

MD Anderson's IOTOX initiative integrates standardized clinical practice, education, and clinical/translational research [21]. In a 126-patient pre/post study of hospitalized immune-mediated diarrhea and colitis, implementation of an inpatient algorithm and focused GI service increased GI consultation, shortened median time to clinical remission from 10 to 4 days, and was associated with fewer readmissions and recurrences [22]. Together, these programs provide benchmarks for response time, clinician adoption, readmission, length of stay, and organ-specific disease control.

Education, Symposium, and Shared Learning

Structured education is being consolidated into a recurring multidisciplinary symposium on serious adverse events from modern anticancer therapy. The program will combine new-agent and guideline updates with case-based sessions, organ-specific breakout discussions, nursing and Clinical Nurse Coordinator (CNC) triage training, simulation of time-critical syndromes, patient/caregiver perspectives, and review of institutional performance data. Shorter case conferences and faculty updates between symposia will translate lessons into revised scripts and pathways. This model parallels the educational and operational integration of the MD Anderson IOTOX initiative while remaining tailored to local resources and referral geography [21].

The ophthalmology pathway illustrates how a general framework becomes an actionable local process. KU Ophthalmology designated two triage technicians to receive acute oncology messages through a single telephone route

(913-588-6600, option 3). Oncology teams leave a structured message identifying the anticancer agent, timing, symptoms, visual acuity when available, and callback contact; messages received during business hours are reviewed before 4 PM. Abrupt vision loss, severe ocular pain, photophobia with marked vision change, field loss, or suspected retinal, optic-nerve, or orbital emergency bypasses the routine queue for emergency assessment. This pathway is relevant to checkpoint-inhibitor uveitis and neuro-ophthalmic events, ADC-associated ocular-surface and corneal toxicity, and MEK-inhibitor retinopathy, for which prompt ophthalmic characterization may prevent unnecessary treatment discontinuation or irreversible injury [12,14].

Prospective Evaluation and Measurable Outcomes

The KU initiative is in an implementation and prospective-evaluation phase. We do not yet have a mature, analytically validated institutional cohort that can support a claim of improved outcomes; anecdotal feedback is therefore not presented as evidence of effectiveness. Evaluation will distinguish implementation outcomes from clinical outcomes and use prespecified definitions (Table 2) [23].

A pragmatic evaluation can begin with a 12-month pre-implementation baseline followed by prospective surveillance and segmented interrupted-time-series or risk-adjusted pre/post analysis. Rare fatal syndromes should be reported descriptively and pooled across sites when possible. Pathway changes, data definitions, and contextual factors should be documented in accordance with SQUIRE 2.0 principles so that positive and negative findings are interpretable [24]. Electronic patient-reported symptom monitoring may supplement, but should not replace, clear human review and escalation [25].

Implementation and service outcomes should be reported separately from clinical outcomes. Syndrome-specific definitions and response-time targets should be version controlled as guidance evolves.

Implementation Challenges

Implementation barriers are predictable. Specialty capacity is finite; a new centralized service may create referrals without reducing work elsewhere. Diagnostic uncertainty can produce both delayed treatment and over-immunosuppression. Guidelines and product labels evolve faster than static order

Table 2. Prespecified evaluation domains for the multidisciplinary serious-adverse-event framework.

Measurement domain	Operational definition / examples	Purpose and analytic approach
Reach and case mix	Number/proportion of treated patients entering the pathway; therapy class, organ system, severity, site of care, and referral source.	Defines denominator, case mix, pathway reach, and equity of access; stratify by campus, rurality, race/ethnicity, language, and insurance when feasible.
Timeliness	Symptom report to first clinical contact; contact to CTCAE grading; contact to diagnostic testing, specialist recommendation, corticosteroid/syndrome-directed treatment, ED transfer, or admission.	Primary operational target: same-day triage and specialist recommendation within 24 hours for urgent nonemergent cases; shorter syndrome-specific targets for cardiac, neurologic, respiratory, and vision-threatening events.
Pathway fidelity	Proportion with documented agent/timing, grade, differential diagnosis, responsible clinician, follow-up interval, escalation threshold, and guideline-concordant hold/treatment decision.	Identifies where the system fails even when the final clinical outcome is favorable.
Clinical outcomes	Time to grade 1 or lower/resolution; ED, hospital, and ICU use; length of stay; 30/60-day readmission; additional immunosuppression; infection; permanent organ injury; toxicity-related mortality.	Risk-adjusted comparison with baseline or contemporaneous care by agent, combination, cancer, comorbidity, performance status, toxicity type, and grade.
Oncology continuity	Steroid exposure and taper duration; time to anticancer treatment resumption; permanent discontinuation; rechallenge rate and recurrent toxicity; trial protocol deviation.	Tests whether toxicity is controlled without unnecessary loss of effective anticancer treatment.
Experience, cost, and balancing measures	Patient/caregiver understanding and confidence; provider usefulness/acceptability; specialist workload; false-positive referrals; delayed diagnosis of infection/progression; total acute-care utilization and implementation cost.	Prevents a narrow focus on speed from obscuring diagnostic harm, inequitable access, workload, or unsustainable resource use.

sets. Inpatient and outpatient teams may disagree about ownership, and community clinicians may lack direct access to tertiary subspecialists. Finally, documentation burden and rare-event denominators make outcome measurement difficult.

Mitigation requires tiered urgency criteria, named alternates for specialty champions, concise EHR templates, pharmacy and nursing participation, scheduled pathway review, and protected administrative/data support. Infectious disease and critical-care input should be incorporated when immunosuppression or organ failure is likely. Governance should specify who may activate a pathway, who can recommend treatment interruption, how disagreement is resolved, and when a case returns to the treating oncologist.

Limitations

Important limitations remain. This article describes a single-center framework at an early stage, and the workflow has not yet been shown to improve KU patient outcomes. The external studies cited are largely observational and focused on checkpoint-inhibitor toxicity; their findings may not transfer to ADCs, cellular therapy, bispecific antibodies, or targeted agents. The representative drug/toxicity table cannot replace current prescribing information. Resource needs, reimbursement, and referral geography will vary, and faster specialist access could increase low-value consultation if triage criteria are not audited.

Conclusion

As anticancer therapy becomes more mechanistically diverse, safe delivery will depend not only on drug efficacy and published toxicity recommendations but also on reliable systems for recognition, escalation, co-management, and learning. The proposed KU framework converts guidance into an operational model with a common triage architecture, therapy-and organ-specific pathways, accountable handoffs, multidisciplinary education, and prospective measurement. Its effectiveness remains to be established locally; publishing prespecified implementation and clinical outcomes, including negative findings and balancing measures, will be essential. Transferability to other settings should not be inferred until the model has been evaluated prospectively and its resource requirements and contextual dependencies are described.

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