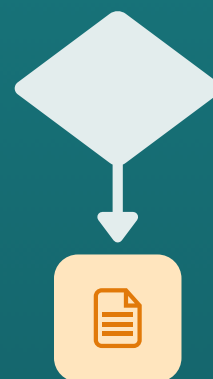


CRS Adjudication Flowchart



A systematic approach to assessing potential CRS events in patients receiving CAR-T or T-cell engager therapies

September 2026

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PRODUCED BY PROJECT

DECODE
CRS

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KEY

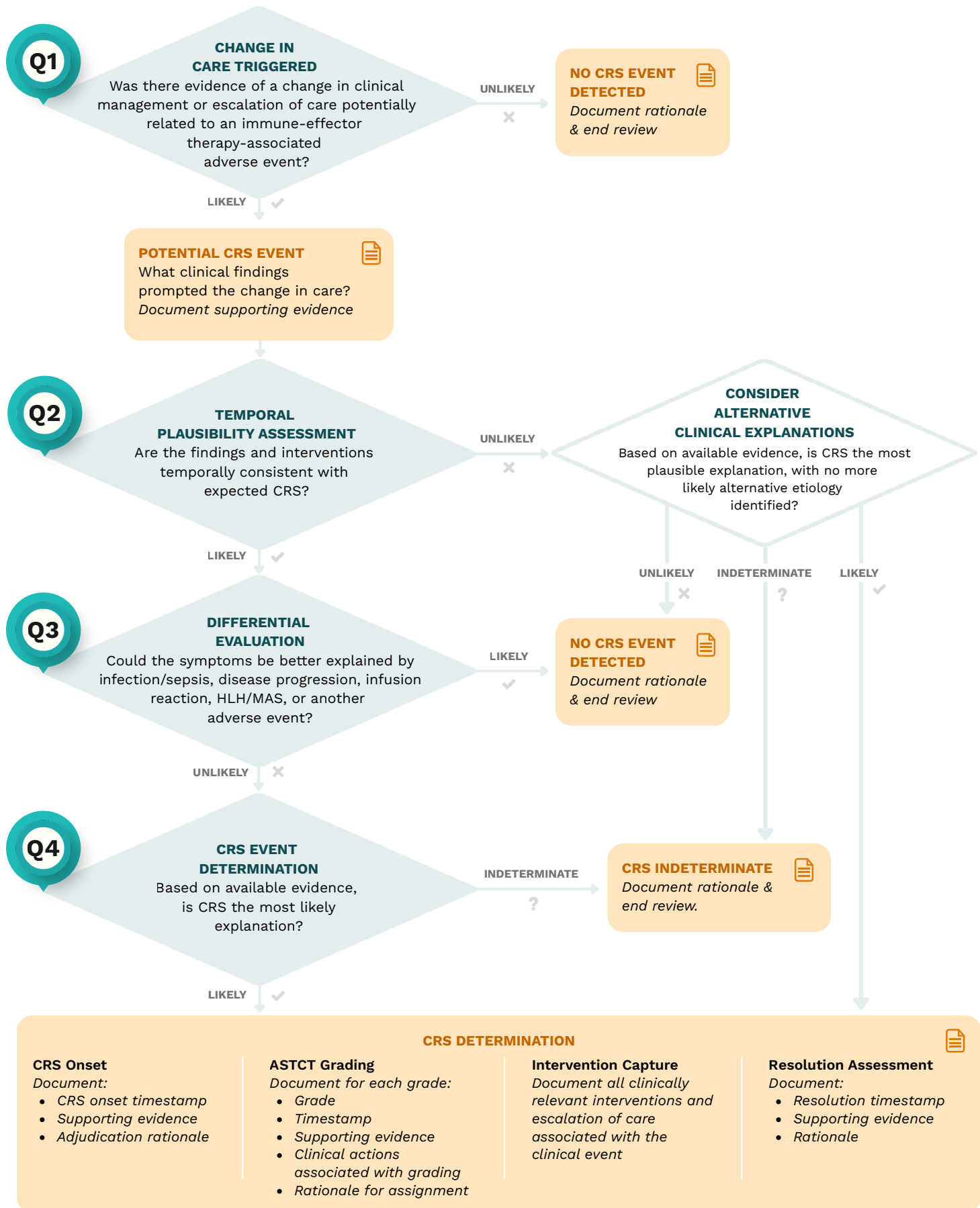


Decision nodes (diamonds) represent key clinical assessment questions used to guide adjudication



Documentation nodes (boxes) represent required data capture elements to support event characterization

CRS Adjudication Flowchart



A closer look at key decisions

Q1

CHANGE IN CARE TRIGGERED

Was there evidence of a change in clinical management or escalation of care potentially related to an immune-effector therapy-associated adverse event?

Why start with this question?

This initial screening question identifies patients who warrant structured review for a possible CRS event. The trigger may be a change in clinical status, a change in management, or both. It is intended to ensure that potentially relevant immune-effector therapy-associated toxicities undergo consistent evaluation.

Consider

Initiating review does not establish a diagnosis of CRS. The subsequent steps in the framework evaluate temporal plausibility, alternative etiologies, and available clinical evidence before determining whether CRS is the most likely explanation.

Examples of review triggers

Clinical findings:

- Fever
- Hypotension
- Hypoxia
- New or worsening constitutional symptoms

Clinical management:

- Increased monitoring
- Tocilizumab administration
- Corticosteroid administration
- Antipyretic administration
- Intravenous fluids
- Supplemental oxygen
- ICU transfer
- Vasopressor support

Q2

TEMPORAL PLAUSIBILITY ASSESSMENT

Are the findings and interventions temporally consistent with expected CRS?

Purpose

Determine whether the timing of clinical findings is compatible with CRS following administration of CAR-T or TCE therapy.

Consider

- Time from therapy administration
- Expected CRS onset window for the specific product
- Delayed CRS
- Recurrent symptoms
- Timing of interventions relative to symptom onset
- Premedication (e.g., antipyretics, steroids) that may mask or delay findings
- Documentation may lag the actual clinical timeline. Corroborate reported times against the vital sign and medication records where possible.
- Symptoms appearing after treatment for an unrelated condition do not rule out CRS; assess timing against therapy administration independently.
- Distinguish from infusion-related reactions (which typically occur earlier (during or shortly after infusion) and infections

Review

- Administration time of therapy
- Medication administration
- Vital sign timeline
- Clinical notes

A closer look at key decisions

Q3

DIFFERENTIAL EVALUATION

Could the symptoms be better explained by infection/sepsis, disease progression, infusion reaction, HLH/MAS, or another adverse event?

Purpose

Evaluate competing clinical explanations before concluding that CRS is the most likely diagnosis.

Consider

- Infection or sepsis
- Disease progression
- Infusion-related reaction
- Hemophagocytic lymphohistiocytosis / macrophage activation syndrome (HLH/MAS)
- Immune effector Cell-Associated Neurotoxicity Syndrome (ICANS)
- Tumor lysis syndrome
- Cardiac events
- Pulmonary complications
- Other adverse events
- Relevant confounding medical history

Review

- Vital signs
- Laboratory results
- Medication administration records
- Clinical notes

Document

- Alternative diagnoses considered
- Supporting evidence
- Final determination

Q4

CRS EVENT DETERMINATION

Based on available evidence, is CRS the most likely explanation?

Purpose

Integrate all available clinical information to determine whether the presentation is most consistent with CRS.

Consider

- Overall clinical presentation and course
- Temporal relationship to administered therapy
- Alternative diagnoses
- Clinical response to interventions
- Clinical judgment

Review

- All available sources

Document

- CRS likely, unlikely or indeterminate

A closer look at the documentation of CRS determination

CRS ONSET



Purpose

Document the earliest evidence supporting CRS onset.

Consider

- Overall clinical presentation and course
- Temporal relationship to administered therapy
- Clinical response to interventions
- Clinical judgment

Review

- Vital signs
- Clinical interventions
- Clinical notes

Document

- CRS onset date / time
- Supporting evidence
- Adjudication and timing rationale

ASTCT GRADING



Purpose

Apply established ASTCT grading criteria consistently throughout the clinical course of the event.

Consider

- Grade may change over time
- Grade reflects the patient's clinical status at each time point
- Management decisions may influence subsequent grading
- Fever is not required for Grade 2–4 if CRS has previously been documented and the patient has received antipyretic or anticytokine therapy

Review

- Vital signs (temperature, blood pressure, oxygen saturation)
- Clinical interventions

Document for each grade

- Grade
- Date / time
- Supporting evidence
- Clinical actions associated with grading
- Clinical rationale for assignment

A closer look at the documentation of CRS determination

INTERVENTION CAPTURE



Purpose

Document interventions associated with the CRS event and the clinical findings that led to each intervention.

Consider

- Why was the intervention initiated?
- Was escalation protocol-driven or clinician-driven?
- Did the intervention alter the clinical course?

Review

- Medication administration record
- Hospitalization records
- Clinical notes

Document for each intervention

- Date / time
- Intervention type
- Clinical response
- Clinical rationale

RESOLUTION ASSESSMENT



Purpose

Determine when the CRS event has resolved and document the evidence supporting resolution.

Consider

- Have fever, hypoxia, and hypotension resolved, absent an alternative explanation for those findings?
- Resolution after intervention
- Ongoing supportive care
- Persistent abnormalities attributable to another diagnosis

Review

- Clinical notes
- Vital signs (temperature, blood pressure, oxygen saturation)
- Laboratory values (e.g., CRP, WBC)
- Hospitalization records

Document

- Resolution status
- Resolution date / time
- Supporting evidence
- Clinical rationale