Plan a safe AI evaluation

Write unknown when evidence is missing. Use public or deidentified information only. This worksheet does not validate a clinical tool or replace local review.

1. Scope and ownership

Intended task, excluded uses, tool version, clinical owner, technical owner and affected teams. Avoid patient identifiers.

2. Information and access

Required data, permission, retention, vendor training use, access controls and deletion process. Identify your privacy reviewer.

3. Human review and escalation

Who checks outputs, handles uncertainty and corrects errors? Define the route to a qualified clinician and the fallback when the tool is unavailable.

4. Baseline and outcomes

Comparator, sample, duration, patient outcomes, workflow burden, safety incidents and subgroup measures. Define how each will be collected.

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5. Scenario testing

Use approved synthetic cases. Include missing data, ambiguous input, language differences and cases outside the intended use. Record expected safe behavior.

6. Pause and rollback criteria

Specify the measurable trigger, who can stop use, how staff are notified and how normal care resumes. Include harmful output and data failures.

7. Monitoring and changes

Review frequency, incident reporting, model updates, revalidation triggers and the person responsible for each action.

8. Review decision

Clinical, patient representative, privacy and technical reviewers; actual review dates; unresolved issues; decision and next review. Blank fields do not imply approval.