



CTMS HEALTH CHECK:

# 10-Point Diagnostic Worksheet

This 10-point CTMS Health Check helps sponsors and CROs spot the real causes of slowdowns, such as process issues and owner gaps, before they become inspection findings.

The framework is vendor-agnostic and focuses on elements you can verify today, including:



Named governance and RACI assignments



Executable monitoring and CAPA follow-ups



Fit-for-purpose study and site status transitions



Payment triggers tied to verified events



Feasibility intake that doesn't require re-keying



Basic controls such as least-privilege access



SSU readiness with controlled document versions



Time-zone-aware timestamps



Contemporaneous CTMS-to-eTMF filing with required metadata



Documented audit-trail reviews

Use this worksheet to confirm that what's recorded in CTMS reflects how work actually moves, and to establish clear accountability where it doesn't.

For each item, mark Meets (1) or Needs Work (0) and note the accountable owner. Sum your score (0-10). 0-3 Lagging; 4-7 Progressing; 8-10 Optimized

## 1. Ownership & Governance

**What good looks like:** There is a named CTMS process owner; RACI is current for study setup, site management, monitoring, payments, metrics, and integrations. Decisions route through a documented change process.

**Quick diagnostic:** Can you point to one document that names the CTMS process owner and delegates for study activation, monitoring, and finance? If not, you have an owner gap.

**Accountable owner:** Clinical Operations Lead (with QA and IT as stakeholders)

## 2. Study & Site Lifecycle Statuses

**What good looks like:** Status lists and transitions match your SOPs (e.g., Planned -> Active -> On Hold -> Closed), with entry/exit criteria defined and enforced. No "miscellaneous" status.

**Quick diagnostic:** Pick three sites across two studies. Do their status changes align with the documented transition rules and timestamps? If not, statuses aren't driving work, they are labels.

**Accountable owner:** Study Startup Manager

## 3. Milestones & Planning Accuracy

**What good looks like:** Core milestones (FPI/LPI, SIVs, submissions, approvals, closeout) are templated, date-stamped, and used for forecasting. Slips generate tasks, not emails.

**Quick diagnostic:** Compare planned vs. actual for last quarter's SIVs. If  $\pm 20\%$  variance is common and no follow-up tasks exist, then planning is ornamental.

**Accountable owner:** Program/Project Manager

## 4. Feasibility Intake to CTMS



**What good looks like:** Feasibility outputs flow into CTMS without re-keying: ranked site list, notes, attachments, and status seeds.

**Quick diagnostic:** Trace one site from feasibility to “Selected.” If cut-and-paste is required for ranking, you’re losing time and context.

**Accountable owner:** Feasibility Lead (with CTMS Admin)

## 5. SSU Readiness & eISF Linkage



**What good looks like:** SSU tasks in CTMS reference controlled document versions, site packs collected early are traceable and point to the eISF record you’ll use later.

**Quick diagnostic:** Open any site’s CTMS SSU checklist. Do documents cited there match the versions in the eISF? If “near-match” is common, you need to expect rework.

**Accountable owner:** Site Activation Lead

## 6. CTMS to eTMF Handoffs



**What good looks like:** CTMS actions that create artifacts (e.g., SIV confirmation, monitoring follow-ups) are filed contemporaneously with required metadata in the TMF.

**Quick diagnostic:** Pick two recently completed activities in CTMS. Are the corresponding TMF artifacts present with correct metadata within five business days? If not, filing is after-the-fact.

**Accountable owner:** TMF Lead (with CRA Manager)

## 7. Monitoring, Issues, and Follow-Ups



**What good looks like:** Visit planning, report finalization, findings, and CAPA tasks are tracked with due dates and closure evidence. Aging views are used in weekly ops.

**Quick diagnostic:** Open your aging findings view. If items older than 30 days lack an owner and next action, it means the process is tracking, not managing, the risk.

**Accountable owner:** CRA Manager

## 8. Deviations & Action Management

**What good looks like:** Protocol deviations, issues, and actions are logged once, linked to the site/subject, and flow through a standard disposition path.

**Quick diagnostic:** Pull three deviations from last month. Are disposition, impact, and corrective action present with timestamps and responsible party? If not, expect repeat issues.

**Accountable owner:** Clinical Quality (with Medical Monitor)

## 9. Finance & Payments Triggers

**What good looks like:** Visit-based and pass-through payments are triggered from verified events (e.g., visit finalized), with queries used to hold, not to guess.

**Quick diagnostic:** Check last payment run. How many line items were adjusted manually because events weren't aligned? More than 10% suggests trigger design or discipline gaps.

**Accountable owner:** Clinical Finance (with CTMS Admin)

## 10. Data Quality, Access, and Audit Trail Reviews

**What good looks like:** Role-based access is least-privilege and reviewed quarterly, time-zone-aware timestamps are standard, and monthly audit-trail spot checks are documented.

**Quick diagnostic:** Produce last month's access review and audit-trail spot check. If you can't, you cannot demonstrate control under inspection.

**Accountable owner:** CTMS Admin (with QA and IT Security)

**For each item,** mark Meets **(1)** or Needs Work **(0)** and note the accountable owner.

**Sum your score (0-10).** 0-3 Lagging; 4-7 Progressing; 8-10 Optimized

## Scoring & Action:

Mark each item Meets **(1)** or Needs Work **(0)** and total your score.

### 0-3 Lagging:

Governance and handoffs are unclear. Start by naming the CTMS process owner and fixing status transitions (Items 1-2), then repair CTMS to eTMF filing (Item 6).

### 4-7 Progressing:

Lock in feasibility/SSU intake (Items 4-5) and make monitoring/follow-ups executable (Item 7).

### 8-10 Optimized:

Maintain your edge: quarterly access and audit-trail checks (Item 10) and variance tracking for milestones (Item 3).

**Total:**

# Bring this worksheet to life in a connected platform.

See how Trial Interactive turns governance, statuses, handoffs, and filings into one inspection-ready flow.

