Study Oversight Checklist

Sponsors have a regulatory responsibility to ensure trial quality, integrity, patient safety, and internal sponsor/partner adherence to standard operating procedures (SOPs) in outsourced clinical trials. Sponsors must also be able to demonstrate they maintained oversight throughout the course of the study to inspectors.

See the checklist below for what you should look for in a CTMS application for study oversight to help ensure compliance with ICH E6(R2) guidelines.

Full lifecycle issue management

- [ ] Capture, track, and resolve protocol deviations
- [ ] Maintain records of all actions and follow-up items

Monitoring oversight

- [ ] Track monitoring visit report (MVR) reviews and approvals
- [ ] Maintain workflow history

Ability to receive data from systems

- [ ] Easily integrate CRO and sponsor CTMS and other clinical systems to view data holistically
- [ ] Collaborate more effectively with CROs for a better view of trial performance

Built-in oversight reporting and metrics

- [ ] Track KPIs and KRIs (protocol deviations by site/study, MVR quality findings, SAEs by site, missing ICFs, etc.)
- [ ] View data at summary and detailed levels

Documentation repository

- [ ] Store site communication logs and documents for key items such as escalation procedures
- [ ] Show proof of sponsor and CRO acceptance and approvals

Veeva CTMS is a modern cloud application that enables effective study oversight in outsourced clinical trials.