imarc
WE'LL EARN YOUR APPROVAL.

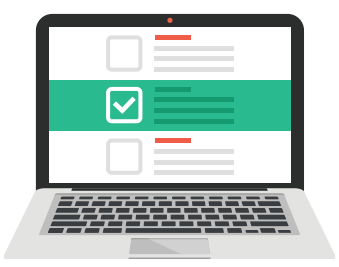
THE VALUE OF AN Electronic Trial Master File Audit

You already know the value of having an independent audit to review your Trial Master File before the FDA does. Historically, these audits have been done in person, but an electronic Trial Master File audit can save study sponsors significant time and money.

This infographic shows just how much you stand to save.

On-Site
TRIAL MASTER FILE AUDIT

- 1-2 auditors
- Up to a week spent on site = 40-80 hours



Electronic
TRIAL MASTER FILE AUDIT

- 1 auditor
- Documents reviewed over several days or weeks

PROS

On-Site

- Can be a good learning opportunity for new project managers
- Can share findings and make recommendations in person or remotely
- Little to no travel expense
- More convenient and flexible
- No need to ship paper files or sit with auditor when they have secure, read-only access to the eTMF

Electronic

- Can host opening meeting over the phone
- Good fit for experienced project managers
- Less time required from sponsor team – just attendance at the opening and closing meetings and availability for occasional questions
- Forces documentation to "stand on its own" to tell the study's story

CONS

On-Site

- Travel expenses: Up to $5,000
- Requires significant time from your team to host and attend to the auditor(s), especially if remote team members travel to join the audit

TOTAL ESTIMATED COSTS CAN EXCEED
$10,000-$15,000+

Electronic

- Q&A: No opportunity for real time Q&A or informal discussions with auditors on accuracy and quality.

REDUCES TOTAL COSTS BY
as much as half!

How much could *you* save with an electronic Trial Master File audit?

Tell us a little about your study to get a free quote from IMARC's auditing team.

GET A QUOTE