

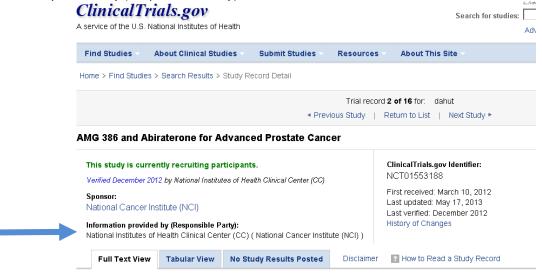
Monday Morning Practice Pearls #11

What should I do if I find incorrect or missing information on *ClinicalTrials.gov*?

You have looked on Clinicaltrials.gov and noticed that there is incorrect or missing information about your protocol. To get the information corrected, you first need to know who the responsible party (RP) is. The RP complies with NIH Policy and FDAAA regulations for registration and reporting.

The intramural research program (IRP) studies are registered by the Office of Research Support and Compliance (ORSC) Protocol services Section (PSS) **EXCEPT** when the IRP is not the responsible party (e.g., we are a participating site on a multi-site trial or the pharmaceutical company is the RP).

If the IRP is the RP, you will see "National Institutes of Health Clinical Center (CC)" followed by the IC in the "Information provided by (Responsible Party)" field.



PSS uses the information provided in the IRB study application in PROTECT, the CC PROTRAK Query System (PQS) and the protocol to provide clinicaltrials.gov with the registration information. PSS staff enters this data into the CC PQS which feeds nightly to clinicaltrials.gov.

How to I get the information corrected or added?

E-mail Stacie (stacie.jeter@nih.gov) and CCR PSO Central (NCICCRPSOCentral@nih.gov) to request any updates.