

Dear DF/HCC Investigator,

If you are considered a "sponsor-investigator" for any trials that have been (or will be) registered to clinicaltrials.gov (this can include PI-initiated, in house trials and NIH grant holders) it is your responsibility to post the basic results requested within the timeframe indicated below.

The **Clinical Trials Education Office** (CTEO) will be holding a training session on the new requirements in the beginning of March, details to follow.

To enter in results, access your account on <https://register.clinicaltrials.gov> and select "Modify" under Protocol Records. Select the appropriate protocol and the link to enter results is located under the protocol ID section of the registration record. **If you have any questions, or need access to your login information please contact the Clinical Trials Education Office (CTEO) at cteo@dfci.harvard.edu or 617-582-8310.**

In September of 2007 the FDA expanded the scope of the clinical trials registry known as clinicaltrials.gov via the Food and Drug Administration Amendments Act (FDAAA).

As of **September 27, 2008**, FDAAA requires "responsible parties" to **report results** for "applicable clinical trials". The law defines "responsible party" as the sponsor and also allows the role of responsible party to be assigned to the principal investigator if the principal investigator is conducting the trial and has sufficient data rights in accord with the law. The law defines "applicable clinical trials" as controlled, clinical investigations, other than Phase I investigations or small feasibility studies, of a product subject to FDA regulation and pediatric postmarket surveillance under section 522 of the Federal Food, Drug and Cosmetic Act.

Basic results are **required** to be reported on clinicaltrials.gov **within 12 months of the expected or actual completion (of primary outcome).**

Failure to comply with FDAAA can result in civil penalties, including the withdrawal of NIH funding.

NIH has developed detailed information and assistance materials to facilitate compliance with results reporting which can be found at <http://prsinfo.clinicaltrials.gov/fdaaa.html>.