It's time to report the results of our trial on ClinicalTrials.gov, but the principal investigator is still analyzing the data and writing the manuscript and does not want to publicly disclose the results until accepted for publication. What should we do?

The data must be reported on ClinicalTrials.gov as soon as possible. The International Committee of Medical Journal Editors has indicated that they do not consider publishing to ClinicalTrials.gov as “pre-publication.” Here’s a link to their FAQs that may be useful. http://icmje.org/faq_clinical.html

One can ask for an extension/delay in disclosing results by contacting the ClinicalTrials.gov staff (register@clinicaltrials.gov), but the request would need to meet their definition of “good cause” and publication issues are generally excluded from that definition.

Communication with the journal regarding the legal obligatory requirements may also be useful. It’s unlikely that the journal would refuse a manuscript when the institution/investigator is mandated by law to disclose publicly. However, if the trial was not registered according to the ICMJE journal requirements (prior to enrollment of first participant), the journal may take issue with that and reject the manuscript on that basis.

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