



1 December 2015

**Memorandum**

To: Trialists

Fr: Curtis Meinert

Re: The posting of results on [ClinicalTrials.gov](http://ClinicalTrials.gov)

Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) of 2007 included requirements for reporting results of drug trials on [ClinicalTrials.gov](http://ClinicalTrials.gov) within one year of completion. Failure to comply can result in sizeable fines.

The reporting requirement became effective for trials started or ongoing 27 September 2007. The requirement applies to:

Phase 2, 3, and 4 drug trials;

Studies involving drugs, biological products, and medical devices regulated by the FDA;  
and

Studies having at least one site in the United States or are conducted under an investigational new drug application or investigational device exemption.

So how is the trialist enterprise doing in complying with the requirement?

Not so good.

Slightly less than half of industry-funded phase 2, 3, and 4 drug trials and just 27% of NIH-funded drug trials completed in 2009 had results posted as of March 2015 dataset (Table 1).

The percentage of postings taking place within one year of completion is shown in Table 2. Less than half of the postings for industry-funded drug trials and just 20% of NIH-funded drug trials completed in 2009 had results posted within one year of completion.

**Table 1** Number of drug trials with results posted on [ClinicalTrials.gov](http://ClinicalTrials.gov)

	Industry-funded			NIH-funded		
	Number completed	No. with results posted	%	Number completed	No. with results posted	%
2008	2,720	1,304	47.9	474	129	27.2
2009	2,727	1,320	48.4	547	191	34.9
2010	2,616	1,213	46.4	554	232	41.9
2011	2,607	1,123	43.1	584	200	34.2
2012	2,734	1,128	41.3	591	245	41.5
2013	2,619	939	35.9	546	184	33.7
2014	2,415	470	19.5	491	126	25.7

**Table 2** Postings within one year of completion for drug trials

	Industry-funded				NIH-funded			
	No. completed	Total posted	Posted ≤ 1 yr	% posted ≤ 1 yr	No. completed	Total posted	Posted ≤ 1 yr	% posted ≤ 1 yr
2008	2,720	1,304	616	47.2	474	129	25	19.4
2009	2,727	1,320	631	47.8	547	191	36	18.8
2010	2,616	1,213	648	53.4	554	232	69	29.7
2011	2,607	1,123	629	56.0	584	200	91	45.5
2012	2,734	1,128	762	67.6	591	245	162	66.1
2013	2,619	939	796	84.8	546	184	156	84.8
2014	2,415	470	413	87.9	491	126	101	80.2