Evaluate Vantage

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Woodcock’s next target: trials with no summary results

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If the US FDA’s acting commissioner, Janet Woodcock, wants to be seen to be getting tough with biopharma then she appears to have pinpointed her next target: companies that do not post on clinicaltrials.gov summary results of completed studies. Yesterday the agency called out one such company, Acceleron, which it has sent a notice of noncompliance for this misdemeanour, having earlier issued it a pre-notice of noncompliance. However, the numbers show the FDA to be nowhere close to scratching the surface of this problem. Out of over 67,000 industry-funded studies completed over a year ago, the maximum time usually allowed before results must be submitted, 63% have no results posted on clinicaltrials.gov. Yet amazingly the FDA has sent only 40 pre-notices of noncompliance. And the Acceleron trial in question, the Dart study of dalantercept, is hardly high-level, the project having been discontinued in 2017. The FDA’s other show of toughness, a three-day adcom scrutinising “dangling” approvals of oncology drugs with failed confirmatory trials, has so far had the effect of strongly endorsing the first four indications. The adcom concludes after today's discussion of Keytruda in gastric and Keytruda and Opdivo in liver cancer.

Completed studies with no summary results posted on clinicaltrials.gov

	Completed	With results posted	Pct without results
All trials	201,816	40,921	80%
All with Apr 2020 primary completion	178,641	40,642	77%
Funded by industry	74,968	24,785	67%
Industry-funded, with Apr 2020 primary completion	67,175	24,656	63%

Source: clinicaltrials.gov.