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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: A disconnect

Trial review board raises concerns about AstraZeneca vaccine data

CNN headline: 23 March 2021

The independent board that reviews data from multiple Covid-19 vaccine candidates has expressed concern over AstraZeneca's announcements on its latest findings, according to a statement posted early Tuesday (23 March 2021) by the National Institute of Allergy and Infectious Diseases.

Late Monday, the Data and Safety Monitoring Board (DSMB) notified NIAID, BARDA, and AstraZeneca that it was concerned by information released by AstraZeneca on initial data from its COVID-19 vaccine clinical trial. The DSMB expressed concern that AstraZeneca may have included outdated information from that trial, which may have provided an incomplete view of the efficacy data.

Early Monday, AstraZeneca issued a press release saying its Covid-19 vaccine showed 79% efficacy against symptomatic disease and 100% efficacy against severe disease and hospitalization, citing long-awaited US trial data.

DSMBs sometimes disagree with investigators over the interpretation of trial results, Stephen Evans, a professor of pharmacoepidemiology at the London School of Hygiene & Tropical Medicine, said in a statement to the Science Media Centre in the UK. But that's usually done in private, he said, "so this is unprecedented in my opinion."

The article goes on to state that *The DSMB is an independent expert group that sees trial data before the pharmaceutical companies, the doctors running the trials, or even the US Food and Drug Administration.*

OK, but sponsors have responsibility to clear communications intended for the public with DSMBs. The disconnect is unfortunate because it erodes public trust in the results of the trial and in COVID trials in general.