

**From:** Fauci, Anthony (NIH/NIAID) [E]  
**Sent:** Sat, 20 Jun 2020 08:24:51 -0500  
**To:** Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]  
**Subject:** RE: HEADS UP: NHLBI ORCHID clinical trial will be stopped

Thanks, Not unexpected, but good o have solid science behind our recommendations. We now need results of the trials for prophylaxis.

---

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Saturday, June 20, 2020 8:08 AM  
**To:** Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Cc:** Fauci, Anthony (NIH/NIAID) [E] (b) (6)  
**Subject:** RE: HEADS UP: NHLBI ORCHID clinical trial will be stopped

(b) (5) Well, that fits with the outcome of the RECOVERY trial. I hope NHLBI will quickly publish the results.

Looping in Tony.

Francis

---

**From:** Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Sent:** Friday, June 19, 2020 8:27 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Subject:** HEADS UP: NHLBI ORCHID clinical trial will be stopped

Francis,

Based on the recommendations from the DSMB that met late today, NHLBI is stopping the ORCHID clinical trial – this is the randomized controlled trial comparing hydroxychloroquine vs. placebo/Standard of care in hospitalized patients with confirmed SARS-CoV2 infection. This was a scheduled interim analysis – actually the 4<sup>th</sup> in a series – looking at both safety and outcomes data. **Bottom line:** There was no harm signal. However, based on the conditional power analysis there is less than a 1% probability that HCQ would prove more effective than standard of care even if we enrolled twice the number of patients. Therefore, we are concurring with the DSMB's recommendation and stopping the trial in accordance with standard trial monitoring and oversight practices. The trial was almost completed (475 patients enrolled out of 510 target); however, based on these results there is no need to continue the study.

Notifications are underway to the investigative team, and the NHLBI communications office is already coordinating with OCPL, since we anticipate that there will be much public interest in this finding.

I will let Danielle know. Anyone else that I should ping?

Larry