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Japan sets COVID-19 drug trials up for success

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Clinical studies on drug candidates for COVID-19 may generate more robust results by ensuring randomization, early patient recruitment and treatment initiation, a new model shows

As scientists continue to search high and low for effective COVID-19 treatments, a new modeling study by Japanese researchers suggests that randomization, early patient enrollment and treatment initiation in clinical trials could be the keys to identifying effective antiviral drugs.

The researchers—led by Shingo Iwami, associate investigator at the Kyoto University Institute for the Advanced Study of Human Biology (ASHBi) and Keisuke Ejima, assistant research scientist at Indiana University Bloomington—reported their findings in PLOS Medicine.

Given the inconsistent results of past trials, Iwanami and colleagues used a mathematical model to first analyze longitudinal patient data from clinical studies.

By simulating the amount of virus in the upper respiratory specimens, the team found that virus-producing cells died at different rates, classifying patients into those with rapid, medium or slow virus decay.

In observational studies, physicians assess whether and when patients should receive antiviral treatment based on their symptoms, as opposed to randomization where patients are randomly assigned to treatment and control groups.

Since slow decay may be associated with more severe disease, observational studies may have been limited to certain patients, failing to capture the spectrum of viral dynamics and confounding the results.

“We found that for successful clinical trials, randomization is important because differences in virus decay rates can affect the effects of antivirals,” explained Iwanami.