

 **WHITE PAPER**

The Use of Data Analytics During the COVID-19 Pandemic

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The COVID-19 pandemic poses a number of challenges to the success of clinical trials. Patient safety and data validity are the two critical aspects that need to be prioritized.¹ From the perspective of data analytics, the impact of COVID-19 pandemic can be broken into 2 broad categories.

1 OPERATIONAL DISRUPTION OF CLINICAL TRIAL CONDUCT

COVID-19 is causing widespread problems in the conduct of clinical trials. Research sites may be closed or severely understaffed, certified personnel including the PI may be quarantined, patients may not be able to travel to the sites, and assessments may need to be conducted over phone or over a video link. Disruptions are expected in supply chains, medicine availability as well as on-site monitoring.

2 DIRECT IMPACT OF COVID-19 PANDEMIC ON PATIENTS

The second category, equally important but with less clear impact on the data, is the direct effect of the pandemic and the disease on the patients themselves. Forced social distancing, inability to leave home, fears for loved ones, economic insecurity, increased levels of domestic violence and sexual abuse, increased alcohol and drug consumption and many others will impact how symptoms manifest, as well as their severity and variability, both between and within patients.

Patients who contracted the virus may experience changes in severity of existing symptoms and/or develop new symptoms, some already documented such as anosmia² and others possibly still unknown.

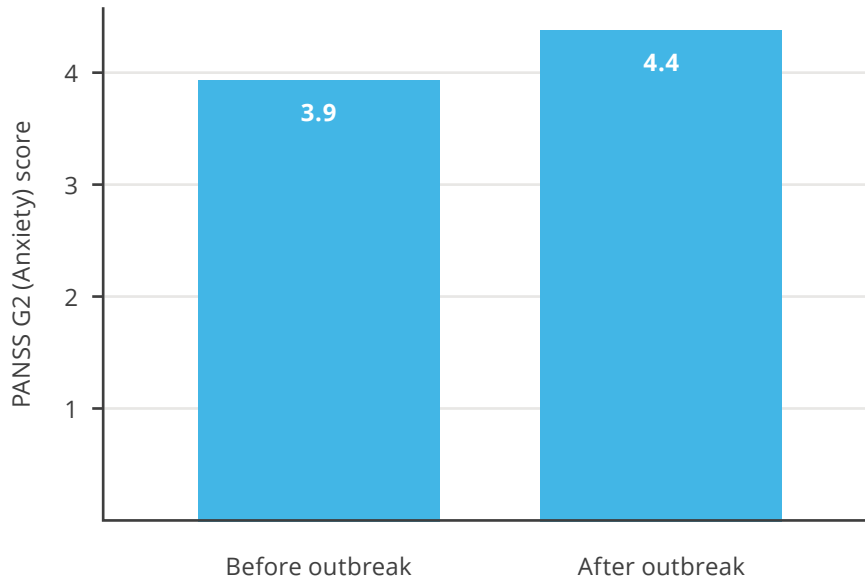
Last, but not least, given the operational disruptions mentioned above, emerging safety concerns may go undetected and endanger patient safety. Of special concern is the possible increase in suicidality previously reported in Hong-Kong during and after the 2003 SARS epidemic^{3,4} and likely expected to be seen during the COVID-19 pandemic as well.

All these factors result in a number of data quality concerns:

- 1 Partially or completely missing data
- 2 Increased noise in the data due to operational challenges such as frequent rater changes or changes in assessment modality
- 3 Data tampering or data fabrication
- 4 Increased noise in the data due to symptom changes caused by direct or indirect impact of COVID-19 - for example in acute schizophrenics we see significantly increased levels of anxiety and tension in the data collected after the COVID outbreak (figure 1)

FIGURE 1. INCREASE IN ANXIETY OBSERVED AFTER COVID-19 OUTBREAK IN ACUTE SCHIZOPHRENIC PATIENTS

Anxiety in acute schizophrenic patients before and after COVID-19 outbreak
N=399, p<0.001

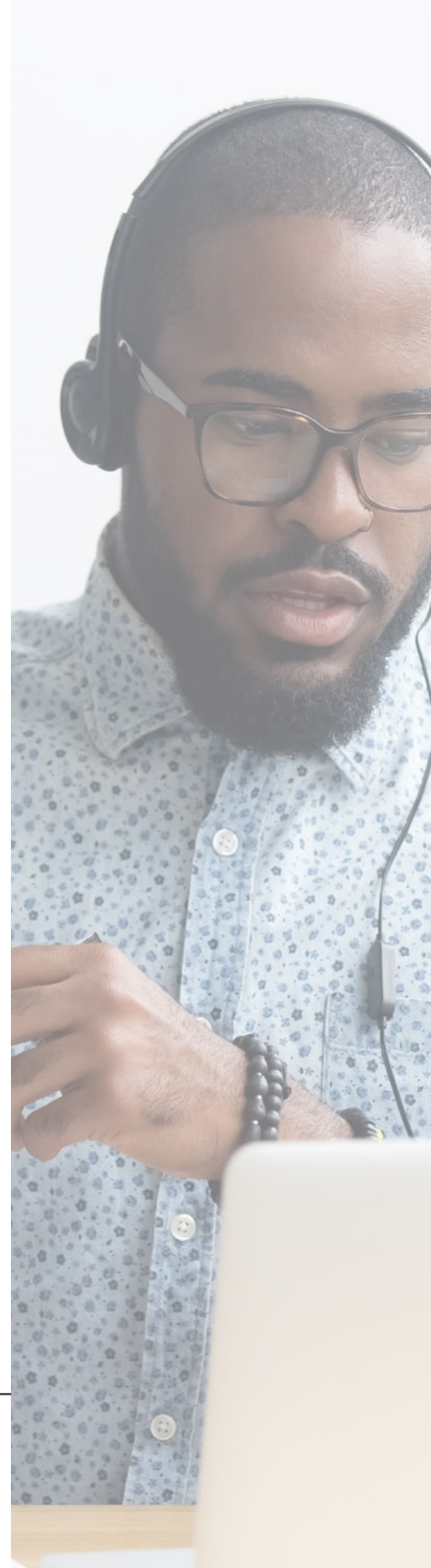


Signant Health Blinded Data Analytics are well positioned to identify any and all of these data quality concerns.

Since 2010, we have been developing a robust system that allows early detection and ongoing monitoring of data anomalies at all study levels (patient, rater, site, region, country, study), coupled with rigorous, targeted and timely clinical intervention.

Specifically for the COVID-19 situation, we are enhancing the system with additional features allowing us to directly monitor the impact of COVID-19 on the data, such as missing data, changes in symptom severity and variability, and data tampering.

Additionally, given the likely safety concerns and possible increase in suicidality, we are at the same time introducing tools that will allow focus on patient safety with increased rigor and reporting back to sponsors any emerging signals. Data from available clinician and patient completed scales and instruments will be pooled together and queried for any possible patient safety concerns.



CONCLUSIONS

The COVID-19 pandemic is expected to increase levels of noise in the data through operational disruptions of clinical trial conduct and direct impact on trial patients. While likely not totally avoidable, the increase in noise levels can be minimized. Pro-active rater training and calibration in remote scale administration should occur if change from in-person to remote assessment modality is expected. To prevent additional noise introduced by unavoidable rater changes, sites should increase intra-site calibrations. Continuous oversight of incoming data through blinded data analytics should be used to identify sources of data noise and trigger targeted and timely clinical intervention.

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