

Pandemic of Professional Subjects: Impact of Recession on Clinical Trials

Shiovitz TM^{1,2}, Steinmetz CB¹, Steinmiller BL¹

¹CTSdatabase LLC, Sherman Oaks, CA; ²California Neuroscience Research, Sherman Oaks, CA;

Abstract

Introduction: Following the Great Recession of 2008-2009, unemployment rose from 5% in 2007 to nearly 10%. It took until at least 2014 for unemployment to return to 2007 levels¹. Duplicate and professional subjects are a significant consideration in the conduct of clinical trials, as they may adversely affect data integrity as well as safety and efficacy signals. In particular, studies with subjective endpoints (e.g. CNS or pain), are particularly vulnerable to professional subjects who may change their presentation in order to qualify for studies². CTSdatabase is a subject registry that was founded in 2010 following an uptick in professional subjects noted by the lead author in the years following the Great Recession. When we explored the demographics of these duplicate subjects in 2013, we found that they consisted of all ages and genders, but men in their 40's were the most prevalent.. This was not surprising, as the Great Recession was also known as the "Mancession" because mid-level males were the most affected³. We wondered whether the COVID-19 pandemic-induced recession of 2020 would show an increase in the percentage of professional subjects, as the unemployment rate has increased dramatically.

Methods: 48,358 subjects presented to U.S. investigative sites between January 1st, 2016 and June 30th, 2020 and were entered into the registry. Entries were segregated by the quarter in which they enrolled to determine match rate) at unique sites (i.e. subjects coming back to the same site were not counted) within 30, 90 days and 180 days of the first screen. These matches could be "backward" i.e. they had already screened somewhere else within 30/90/180 days at the time of showing up at the index site, or they could be "forward", i.e. they showed up at another site 30/90/180 days later. Only those subjects considered "virtually certain" matches, i.e. <1/10M likelihood of matching partial identifiers by chance, were included in the dataset. The algorithm for determining such matches is validated with regression testing at least annually (last validated 10-Oct-2019). These match rates were examined alongside quarterly unemployment rates for the same time period (Q1 2016 – Q2 2020)⁴.

Results: An uptick in subjects presenting to multiple sites within a within a 180-day period were noted in the first 2 quarters of 2020. There was a significant increase in unemployment, especially in the 2nd quarter of 2020.

Conclusion: There appears to be an early signal of a correlation between levels of unemployment and the frequency with which subjects show up at multiple sites within a three to six month period. In addition, the economic hardships due to the COVID-19 pandemic are only beginning and more research is necessary to determine if unemployment rates and numbers of professional subjects are directly correlated. In any case, sponsors of clinical trials should maintain an even higher level of vigilance for the presence of duplicate and professional subjects now and during the period of pandemic-related high unemployment levels that may last for several years to come.

Background

Following the Great Recession of 2008-2009, unemployment rose from 5% in 2007 to nearly 10%. It took until at least 2014 for unemployment to return to 2007 levels¹. Duplicate and professional subjects are a significant consideration in the conduct of clinical trials, as they may adversely affect data integrity as well as safety and efficacy signals. In particular, studies with subjective endpoints (e.g. CNS or pain), are particularly vulnerable to professional subjects who may change their presentation in order to qualify for studies². CTSdatabase is a subject registry that was founded in 2010 following an uptick in professional subjects noted by the lead author in the years following the Great Recession. When we explored the demographics of these duplicate subjects in 2013, we found that they consisted of all ages and genders, but men in their 40's were the most prevalent.. This was not surprising, as the Great Recession was also known as the "Mancession" because mid-level males were the most affected³. We wondered whether the COVID-19 pandemic-induced recession of 2020 would show an increase in the percentage of professional subjects, as the unemployment rate has increased dramatically.

Methods

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Results

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Match Rates vs. Unemployment Rates

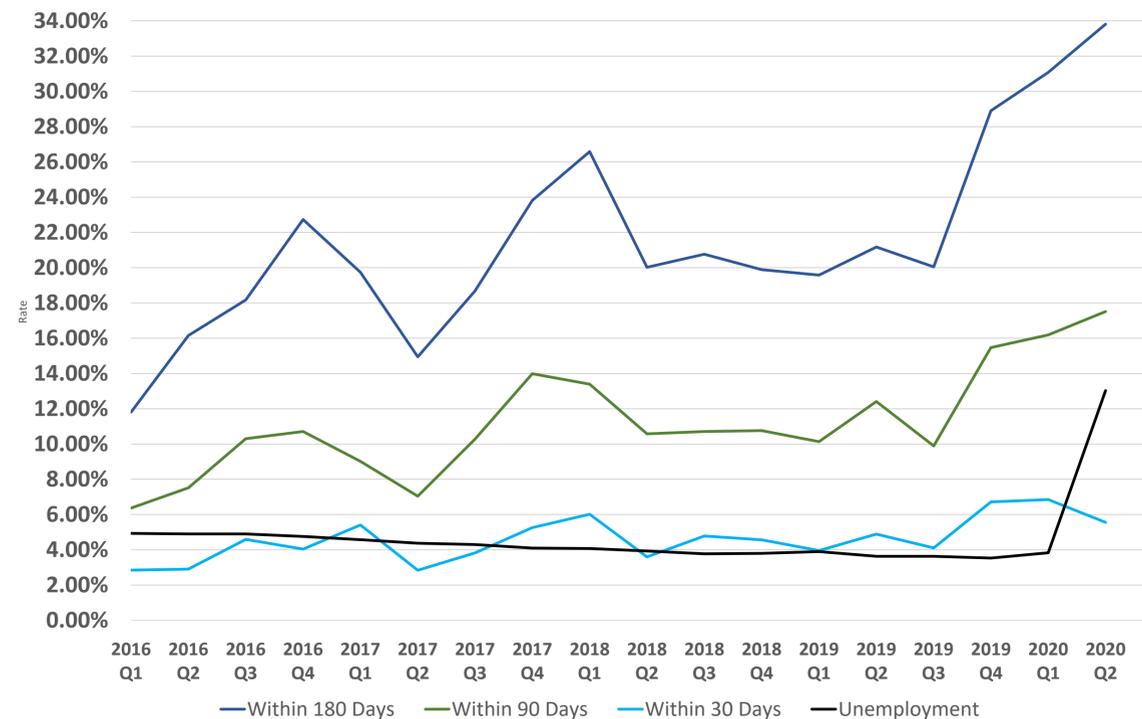


Figure 1. Unemployment rates have increased dramatically in early 2020. There appears to be an increase in subjects presenting at multiple sites during the same time period.

Discussion and Conclusion

- There is an early signal of a correlation between levels of unemployment and the frequency with which subjects show up at multiple sites within a three to six month period.
- The economic hardships due to the COVID-19 pandemic are only beginning; More research is necessary to determine if unemployment rates and numbers of professional subjects are directly correlated.
- Sponsors of clinical trials should maintain an even higher level of vigilance for the presence of duplicate and professional subjects during the period of pandemic-related high unemployment levels.
- Use of an available clinical trial registry (or a combination of available registries) is one way to detect these professional patients

References

1. Amadeo, Kimberly, and Somer G. Anderson. "Compare Today's Unemployment with the Past." *The Balance*, 3 Apr. 2020, www.thebalance.com/unemployment-rate-by-year-3305506.
2. Shiovitz TM, Bain EE, McCann DJ, et al. Mitigating the Effects of Nonadherence in Clinical Trials. *J Clin Pharmacol*. 2016, 56(9): 1151-1164.
3. Shiovitz TM, Manlosa NB, Gevorgyan L, et al. Characteristics of Duplicate Subjects in Clinical Trial Subject Registry. NCDEU Annual meeting; 23 May 2013; Hollywood FL
4. Civilian unemployment rate. (2020, July 02). Retrieved July 09, 2020, from <https://www.bls.gov/charts/employment-situation/civilian-unemployment-rate.htm>.

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