

# Core Outcomes Sets Development in COVID-19 Clinical Trials

Irena Parvanova and Joseph Finkelstein

Icahn School of Medicine at Mount Sinai, New York, NY, USA

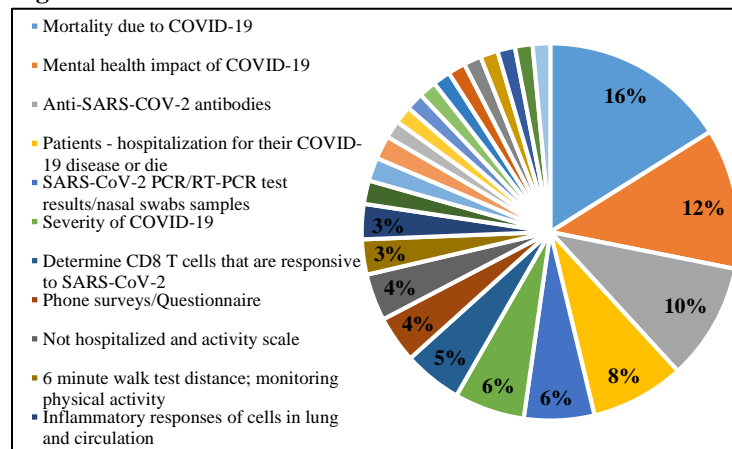
## 1. Introduction

A novel coronavirus disease (COVID-19) has caused a worldwide pandemic outbreak [1]. As of January 2021, the virus affected the population of 222 countries, with 83,910,356 confirmed cases at the time. Outcome reporting and standardization in COVID-19 clinical research depends on the use of a core outcome set (COS), collected and compared across all COVID-19 trials [2]. The growing research data are currently being integrated in data repositories, including publicly available repositories, such as ClinicalTrials.gov.

## 2. Methods

Primary and secondary outcomes from COVID-19 trials in ClinicalTrials.gov were analyzed using analytical query, combining “COVID-19” in the “Other terms” field with “United States” in “Country” and “NIH” in “Funder Type” fields, generating 120 studies at the time of our inquiry. We performed detailed analysis where we examined common data elements based on the studies outcomes.

**Figure 1:** List of COVID-19 Common Data Elements Databases.



## 3. Results

We examined the outcomes for the 120 clinical trials and ranked each outcome for the COVID-19 clinical trials by calculating the percentage of the appearance of each outcome in all 120 trials. For quantification purposes, we considered outcomes that were present in more than 1% of the studies. The most common COVID-19 clinical outcomes are: Mortality due to COVID-19 (16%), Mental health impact due to COVID-19 (12%), Anti-SARS-CoV2 Antibodies (10%), Proportion of patients that required hospitalization due to COVID-19 or die (8%), SARS-CoV-2

PCR/RT-PCR test results/nasal swabs samples and Severity of COVID-19 (6%), Determination of CD8 T cells that are responsive to SARS-CoV-2 (5%), and others (Figure 1).

## 4. Discussion

ClinicalTrials.gov contains enormous quantity registered clinical trials information, including COVID-19-related clinical trials. Our findings provide standardized approaches for representation of COVID-19 research to allow for cross-trial comparison of the results and building a comprehensive core outcome sets in COVID-19 clinical trials. Synchronization of common data elements and data exchange standards is necessary to facilitate data harmonization approaches in COVID-19 research.

## 5. Conclusion and future work

Future plans include implementing ontology-driven automated metadata extraction pipeline from ClinicalTrials.gov, combined with crowdsourcing for engaging multidisciplinary researchers in ranking COS candidates [3].

## References

- [1] Wang C, Horby PW, Hayden FG, Gao GF. A novel coronavirus outbreak of global health concern. *Lancet*. 2020;395(10223):470-473.
- [2] Tong A, et al. Core Outcome Measures for Trials in People with Coronavirus Disease 2019: Respiratory Failure, Multiorgan Failure, Shortness of Breath, and Recovery. *Crit Care Med*. 2021;49(3):503-516.
- [3] Finkelstein J, Parvanova I, Zhang, F. Informatics Approaches for Harmonized Intelligent Integration of Stem Cell Research. *Stem Cells and Cloning: Advances and Applications*. 2020 Jan 28;13:1-20.