

## INTRODUCTION

- SARS-CoV-2 (COVID-19) pandemic has put a significant burden on research coordinators to perform their tasks and establish rapport with the patients
- COVID-19 restrictions slowed/halted clinical trials due to lack of patient enrollment
- COVID-19 has also impacted how we pursue trials:
  - Remote screening and remote consenting

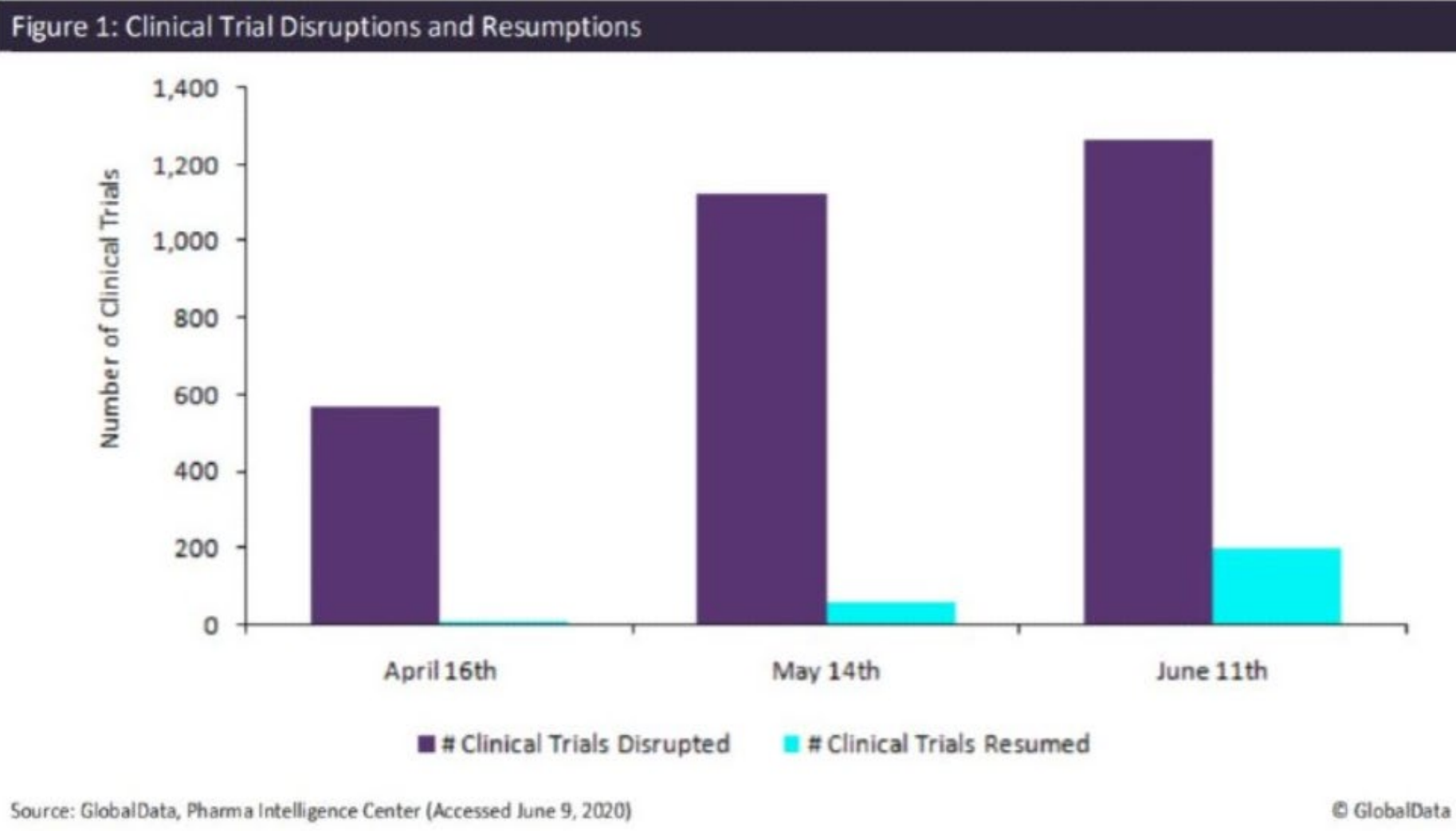


Table 1: Therapy Area Disruption Trends

|                    | April 16th | May 14th | June 11th | May to June change |
|--------------------|------------|----------|-----------|--------------------|
| Oncology           | 33.30%     | 31.20%   | 30.10%    | ↑                  |
| CNS                | 16.10%     | 17.50%   | 17.50%    | -                  |
| Infectious Disease | 9.30%      | 8.10%    | 7.70%     | ↓                  |

Source: GlobalData, Pharma Intelligence Center (Accessed June 9, 2020) © GlobalData

Note: Data from GlobalData Pharma Intelligence Center, Released in June 2020. Trials numbers are across trials that were surveyed globally including those in the US, UK, France, Sweden, and Canada.

## OBJECTIVES

Establish alternative strategies for screening and enrolling patients to accommodate COVID-19 restrictions

## METHODS

### Timeline:

#### March – May 2020:

- Therapeutic trials were suspended and we did not enroll any patients.
  - 10-15 potential patients could not be enrolled (across 4 interventional, non-treatment, surgical-window clinical trials)

#### Mid-May 2020:

- Non-treatment/interventional clinical trials re-opened but with restrictions for the research coordinators including
  - limited clinic access
  - digitalized patient interaction
  - indefinite telecommuting / on campus on an as-needed basis

This prevented traditional patient contact on clinic visit days.

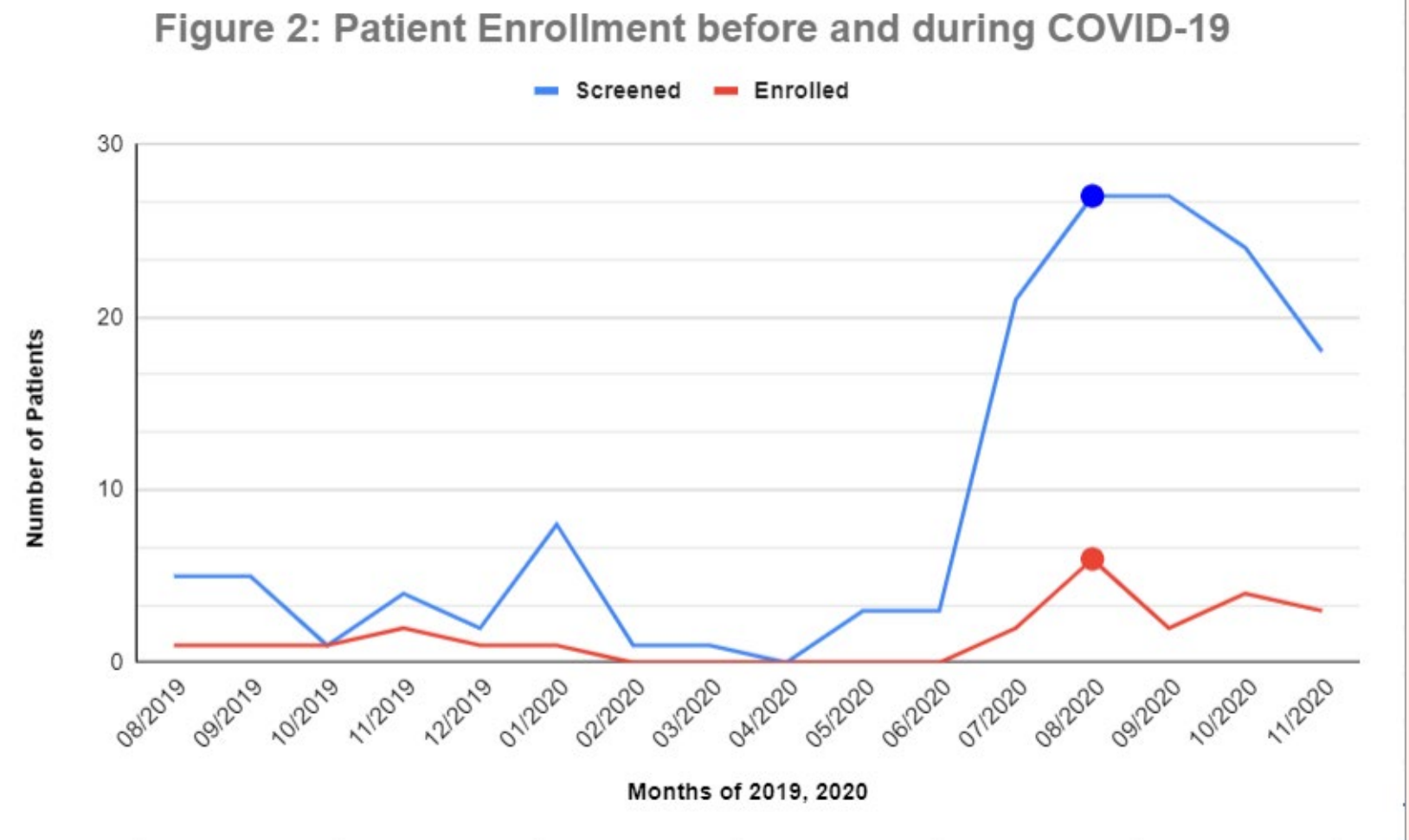
### Countermeasures were developed:

- Broad approval for coordinators to have limited face-to-face contact without prior approval (needed approval 48-72 hours prior to seeing a patient in-person – lost lots of potential patients)
- More frequent phone calls to potential trial candidates
- Tele-consenting
- Coordination of same-day Standard of Care and trial appointment visits to reduce travel burden
- Screened for patients who lived within 2-3 hours from the research site (due to travel restrictions and county curfews)
- Include overnight stay for patients in budget

## RESULTS

Table 2: Patient Enrollment before and during COVID-19

|                       | Month   | Screened | Enrolled |
|-----------------------|---------|----------|----------|
| Pre-COVID-19          | 08/2019 | 5        | 1        |
|                       | 09/2019 | 5        | 1        |
|                       | 10/2019 | 1        | 1        |
|                       | 11/2019 | 4        | 2        |
|                       | 12/2019 | 2        | 1        |
|                       | 01/2020 | 8        | 1        |
| Start of COVID-19     | 02/2020 | 1        | 0        |
|                       | 03/2020 | 1        | 0        |
|                       | 04/2020 | 0        | 0        |
|                       | 05/2020 | 3        | 0        |
|                       | 06/2020 | 3        | 0        |
|                       | 07/2020 | 21       | 2        |
| New COVID-19 workflow | 08/2020 | 27       | 6        |
|                       | 09/2020 | 27       | 2        |
|                       | 10/2020 | 24       | 4        |
|                       | 11/2020 | 18       | 3        |

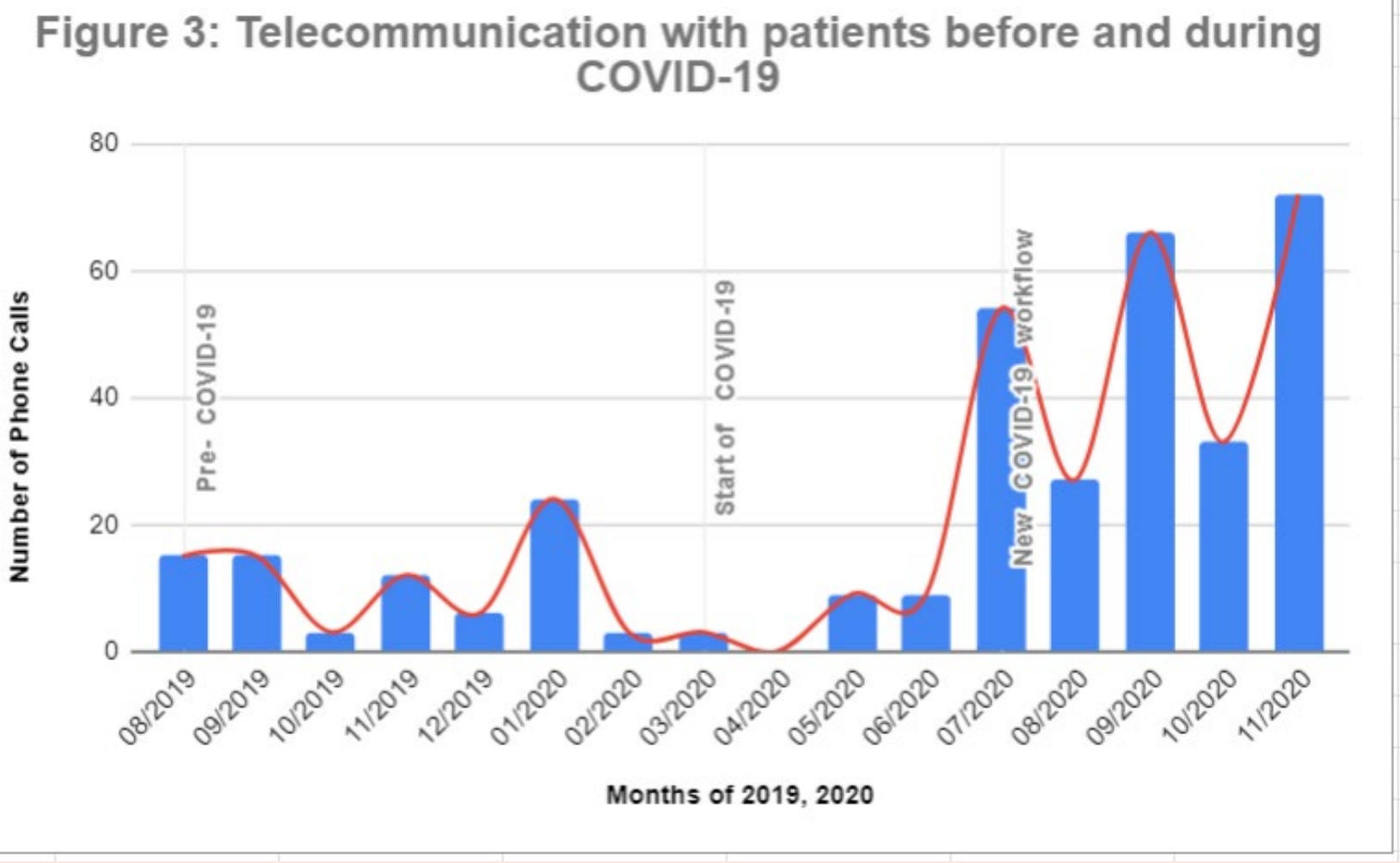


### Increased Screening and Accrual Numbers during COVID-19

- screened 24 patients per month, 100% increase from the numbers screened from pre- and start-of-COVID-19 times
- enrolled an average of 3 patients per month, 300% increase from pre- and start-of-COVID-19 accrual counts
- Should see that to get 1 patient enrolled, needed to screen 8 more patients post-start-of-COVID-19 compared to pre-COVID-19 when we enrolled 1 patient per an average of 3 patients screened

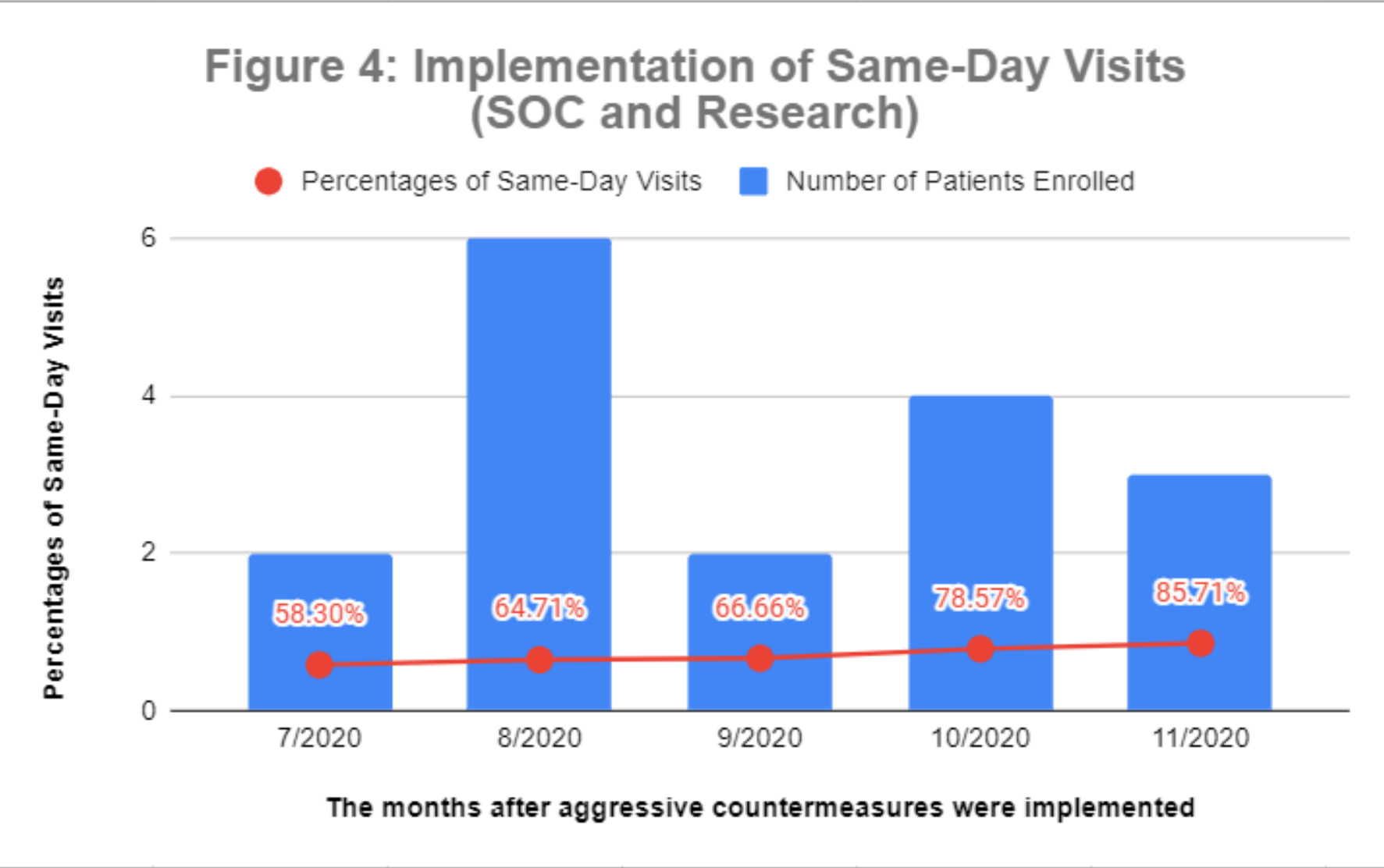
Table 3: Telecommunication with patients before and during COVID-19

|                       | Month   | Number of Phone calls |
|-----------------------|---------|-----------------------|
| Pre-COVID-19          | 08/2019 | 15                    |
|                       | 09/2019 | 15                    |
|                       | 10/2019 | 3                     |
|                       | 11/2019 | 12                    |
|                       | 12/2019 | 6                     |
|                       | 01/2020 | 24                    |
| Start of COVID-19     | 02/2020 | 3                     |
|                       | 03/2020 | 3                     |
|                       | 04/2020 | 0                     |
|                       | 05/2020 | 9                     |
|                       | 06/2020 | 9                     |
|                       | 07/2020 | 54                    |
| New COVID-19 workflow | 08/2020 | 27                    |
|                       | 09/2020 | 66                    |
|                       | 10/2020 | 33                    |
|                       | 11/2020 | 72                    |



### Increased telecommunication during COVID-19

- 238% increase after COVID related restrictions were put in place
- Pre- /start of- COVID-19: 15-24 calls per month
- New COVID-19 workflow: 54-81 phone calls per month



### Increased Same-Day Visits led to Increased rate of Enrollment

At the start of utilizing these countermeasures:

- July 2020: coordinated 58% same-day appointments at the start of COVID-19 regulations had started
- November 2020: coordinated 86% same-day appointments
- Same day visits improved enrollment because patients would be more willing to participate in the trial if they had to take fewer trips or the same number of trips as their standard of care visits to Stanford.

## CONCLUSIONS

- COVID-19 countermeasures included: frequent phone calls, re-implementation of face-to-face contact, option of overnight stay, and coordination of appointments
- Implementation of new COVID-19 countermeasure increased telecommunication by 238%, increased patient screening by 100% and increased patient enrollment by 300%

## REFERENCES

<https://www.clinicaltrialsarena.com/comment/clinical-trial-disruption-slowing/>

## ACKNOWLEDGEMENTS & CONTACT

Thank you to Dr. Rosenthal and the Rosenthal Lab

Presenter: Grace Yi, BS

Email: [gracesyi@stanford.edu](mailto:gracesyi@stanford.edu), Phone: 650-723-0387