

COVID-19 Challenges and “Solutions”

The Impact of the COVID-19 Pandemic on Research Participant Experience

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- Follow usual safety practices
- Closely monitor news

Evolution of research response to the pandemic



- Data integrity
- Safety of staff and participants

COVID-19 SURVEY OF THE COMMUNITY

Learn more at rarediseases.org/covid-19

772

Individuals with a rare disease, caregivers, and family members responded to the survey

98%

are worried about COVID-19



74%

Have had a medical appointment **CANCELED** due to COVID-19

59%

Have been offered a telephone or video call as an alternative to an in-office appointment



95%

of individuals and families have been impacted due to COVID-19



69%

Concerned about medication and medical supply shortages

29%

Have lost jobs temporarily or permanently due to COVID-19



11%

of job losses have resulted in loss of health insurance

- COVID concerns, but also...
- Abrupt shift to telehealth
- Financial, insurance, school impact
- Loss of social support, isolation



Patients as partners

- The pandemic created tremendous challenges to research centers
- **Do not lose sight of the ramifications for study participants!**
- Shared concerns & suggestions
 - PPE availability
 - Elevator crowding
 - Ancillary testing
 - Waiting rooms

Varying levels of concern about the pandemic

“ I don’t agree with all this COVID screening, they’re just trying to get the numbers higher”

“ I don’t want my child going into a possibly crowded lab with potentially COVID positive people to get her screening done.”

“ I’m not coming anywhere near the hospital! That place is COVID central!”



Questions for
our
participant



How did you first learn
about what was later
named COVID-19?

How did this affect your
personal life and your
interaction with your
healthcare team?

Experience
varied with
stages of
participation

Enrolled Patients

Those about to enroll

Those who were new to
research altogether

Enrolled Study Participants' Experience

Disruption of study visits

Difficult obtaining IP

Safety monitoring possible disruptions

New COVID-19 screening requirements
once visits resumed

Would additional time requirements
alter study stipends.

Enrolling Study Participants' Experience

Requirements changed re:
screening during pre-study
consent process

Study start up delayed by COVID-
19

Some sponsors closed enrollment
early

New Study Participants' Experience

Can clinical visits be combined
with research

Contingency planning given
frequency of protocol changes

Comparison of research and
clinical protocols (testing, safety,
availability)



Questions for
our
participant

Share how and
when you first
participated in a
research study?

How did you
decide to enroll
during the
pandemic?



Opportunities to
improve:
“Ease my way”

- Drive Up parking lot COVID screening
- Outsourcing a local COVID screening location for non-local participants
- Limiting number of study participants in the clinic at one time
- Outsourcing safety labs
- Home health visits
- Telehealth visits (recruiting)
- Courier service for IP delivery