Supplemental online content for:

**Experience, Perceptions, and Recommendations Concerning COVID-19–Related Clinical Research Adjustments**

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### eTable 1. Perceptions of COVID-19–Related Clinical Trial Adjustments Among Respondents With Personal Experience With Specific Adjustments

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<th>Adjustment</th>
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Table 2. Perceptions of COVID-19–Related Clinical Trial Adjustments Among Respondents With No Personal Experience With Specific Adjustments

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eAppendix 1. Content From Webinar on COVID-19–Related Clinical Trial Adjustments

**FDA Guidance (updated 4.16.2020)**

Purpose: protect trial participants and manage study conduct
Recognized challenges: quarantines, site closures, travel limitations, interruptions to supply chain of investigational product, or possibility of staff/patients becoming infected with COVID-19
Thus difficulties meeting protocol-specified procedures (administering treatment; adhering to protocol-mandated visits, laboratory tests, imaging studies
Consider: telephone or video visits; local (ie, near patient’s home) laboratory and imaging studies; delaying some assessments; alternative sites for treatment administration; remote monitoring
*Remains in effect only during the COVID-19–related public health emergency*

**NIH Central Institutional Review Board (CIRB) Guidance**
- Clinical evaluations, blood tests, radiology studies, administration of noninvestigational study treatments may be administered by nonstudy local healthcare providers
- Can obtain informed consent remotely
- Can use electronic signatures

**NCI Cancer Therapy Evaluation Program (CTEP) Guidance**
- “Virtual” or “telemedicine” visits may be used
- Protocol-required laboratory/imaging tests and treatment may be delayed
- Local healthcare providers may perform study follow-up
- May ship oral study therapy directly to patients’ homes
eAppendix 2. COVID-19 Effects on Clinical Research Survey

Introduction
The purpose of this survey to help us understand experience with and perceptions of COVID-19 effects on clinical trials. There are NO right or wrong answers.

We are seeking feedback from all CRO staff, whether you have direct patient contact or not.

This survey study is anonymous and all answers will be aggregated for analysis. If you complete the survey, your answers cannot be linked to you as an individual. Participation is voluntary and you may decline to answer any of the questions or stop participation at any time.

If you have questions about the survey, please contact Dr. David Gerber (david.gerber@utsouthwestern.edu).

Background Information
What is your principal work site?

☐ UTSW (including Ft. Worth & Richardson)    ☐ Parkland    ☐ Children’s Medical Center

What category is your position?

☐ Administrative manager (eg, regulatory, QA, finance, administration)

☐ Clinical manager (eg, DOT manager)

☐ Research coordinator

☐ Research nurse

☐ Data specialist

☐ Regulatory coordinator

☐ QA/Education

☐ Finance

☐ Other – please specify: _______________________

What degrees or professional credentials, if any, do you have? (choose all that apply)

☐ AA    ☐ RN

☐ BA/BS    ☐ MSN

☐ LVN    ☐ MBA

☐ BSN    ☐ MPH

☐ Other – please specify: _______________________

Years of professional clinical trials experience:

☐ ≤1 y

☐ 2–5 y

☐ 6–10 y

☐ ≥11 y

Time in current position:

☐ ≤1 y

☐ 2–5 y

☐ 6–10 y

☐ ≥11 y

continued
eAppendix 2. COVID-19 Effects on Clinical Research Survey (cont.)

What is your disease site affiliation (if any)? (choose all that apply)

☐ Nonspecific (general CRO support)  ☐ Phase 1 (multidisease)
☐ Breast cancer  ☐ Gastrointestinal cancers
☐ Genitourinary cancers  ☐ Gynecologic malignancies
☐ Head and neck cancers  ☐ Hematologic malignancies/stem cell transplantation
☐ Lung cancer  ☐ Melanoma/Sarcoma
☐ Neurologic cancers  ☐ Pediatric cancers
☐ Other – please specify: ____________________________

Experience With COVID-19–Related Changes to Clinical Trials

Mark one box—use this format for all answers (except last one) in this section

How many patients have you been following on clinical trials during COVID-19 who were enrolled to the trial prior to COVID-19 (March 16, 2020)?

☐ None/Not applicable
☐ 1–5
☐ 6–10
☐ 11–15
☐ 16–20
☐ ≥21

How many patients have you enrolled to clinical trials during COVID-19 (March 16, 2020, or later)?

☐ None/Not applicable
☐ 1–5
☐ 6–10
☐ 11–15
☐ 16–20
☐ ≥21

For your patients, approximately how many COVID-19–related protocol deviations have occurred per patient?

☐ None/Not applicable
☐ 1–5
☐ 6–10
☐ 11–15
☐ 16–20
☐ ≥21

For your patients, approximately how many total COVID-19–related protocol deviations have occurred?

☐ None/Not applicable
☐ 1–5
☐ 6–10
☐ 11–15
☐ 16–20
☐ ≥21

continued
eAppendix 2. COVID-19 Effects on Clinical Research Survey (cont.)

For your patients, approximately how many COVID-19–related protocol deviations have been requested but not approved (eg, by sponsor, Institutional Review Board)?

- None/Not applicable
- 1–5
- 6–10
- 11–15
- 16–20
- ≥21

Which types of COVID-19–related adjustments have occurred for your patients on clinical trials? (choose all that apply)

- None/Not applicable
- Remote initial consent
- Remote re-consent
- Performance of study-related procedures at nonstudy site
- Telehealth study-related visits
- Shipment of oral study therapy to patient
- Administration of treatment at nonstudy site
- Delayed or skipped visits
- Delayed or skipped laboratory tests
- Delayed or skipped radiology studies
- Delayed or skipped treatment
- Remote monitoring
- Other — please describe: _______________________

Comments on your experience with COVID-19-related changes to clinical trials (open-ended):

Overall Perceptions of COVID-19–Related Clinical Trial Adjustments

How do you feel the following adjustments compare with standard practice?
(Answer scale for each adjustment: Much worse, Worse, Somewhat worse, Same, Somewhat better, Better, Much better, No experience/opinion)

Remote consent _______________________
Telehealth visits _______________________
Shipment of study therapy to patients _______________________
Performance of diagnostic procedures (laboratory test, radiology) at nonstudy sites _______________________
Administration of treatment at nonstudy sites _______________________
Remote monitoring _______________________
eAppendix 2. COVID-19 Effects on Clinical Research Survey (cont.)

Patients' Perceptions of COVID-19–Related Clinical Trial Adjustments

How do patients feel about the following adjustments compared with usual practice?
(Answer scale for each adjustment: Much worse, Worse, Somewhat worse, Same, Somewhat better, Better, Much better, No experience/opinion)

- Remote consent
- Telehealth visits
- Shipment of study therapy to patients
- Performance of diagnostic procedures (laboratory tests, radiology) at nonstudy sites
- Administration of treatment at nonstudy sites
- Remote monitoring

Clinician/Investigator Perceptions of COVID-19–Related Clinical Trial Adjustments

How do you think clinicians/investigators feel about the following adjustments compared with usual practice?
(Answer scale for each adjustment: Much worse, Worse, Somewhat worse, Same, Somewhat better, Better, Much better, No experience/opinion)

- Remote consent
- Telehealth visits
- Shipment of study therapy to patients
- Performance of diagnostic procedures (laboratory tests, radiology) at nonstudy sites
- Administration of treatment at nonstudy sites
- Remote monitoring

Comments on your, patients', and/or clinician/investigator perceptions of COVID-19–related changes to clinical trials (open-ended):

Impact of COVID-19–Related Clinical Trial Adjustments

For each question you will be asked to rate the impact on a scale of 1–5:
1 – No change
2 – A little
3 – Some
4 – A fair amount
5 – A lot

Have adjustments impacted patient safety positively or negatively?
☐ Positive ☐ Negative ☐ Unsure
On a scale of 1–5, how much do these adjustments impact patient safety?

Have adjustments impacted treatment efficacy positively or negatively?
☐ Positive ☐ Negative ☐ Unsure
On a scale of 1–5, how much do these adjustments impact treatment efficacy?

Have adjustments impacted data quality positively or negatively?
☐ Positive ☐ Negative ☐ Unsure
On a scale of 1–5, how much do these adjustments impact data quality?

Have adjustments impacted patient experience positively or negatively?
☐ Positive ☐ Negative ☐ Unsure
On a scale of 1–5, how much do these adjustments impact patient experience?

continued
eAppendix 2. COVID-19 Effects on Clinical Research Survey (cont.)

Have adjustments impacted communication with patients positively or negatively?
- ☐ Positive
- ☐ Negative
- ☐ Unsure

On a scale of 1–5, how much do these adjustments impact communication with patients?

Have adjustments impacted communication with clinicians/investigators positively or negatively?
- ☐ Positive
- ☐ Negative
- ☐ Unsure

On a scale of 1–5, how much do these adjustments impact communication with clinicians/investigators?

Have adjustments impacted communication with sponsors/monitors positively or negatively?
- ☐ Positive
- ☐ Negative
- ☐ Unsure

On a scale of 1–5, how much do these adjustments impact communications with sponsors/monitors?

Have adjustments impacted your experience positively or negatively?
- ☐ Positive
- ☐ Negative
- ☐ Unsure

On a scale of 1–5, how much do these adjustments impact your experience?

For any adjustments you feel have had positive impacts, how important is it explore ways to sustain these changes after COVID crisis?
- ☐ Not important
- ☐ Somewhat important
- ☐ Important
- ☐ Pretty Important
- ☐ Very important

How would you rate our ability as an organization to respond to crisis?
- ☐ Very Weak
- ☐ Weak
- ☐ Average
- ☐ Strong
- ☐ Very Strong

How would you rate our ability as an organization to apply learning from crisis to improve overall operations?
- ☐ Very Weak
- ☐ Weak
- ☐ Average
- ☐ Strong
- ☐ Very Strong

Comments on the impact of COVID-19–related changes to clinical trials (open-ended):

continued
eAppendix 2. COVID-19 Effects on Clinical Research Survey (cont.)

Potential Impact of COVID-19 on Future Clinical Trial Practice

Which of the following COVID-19-related adjustments should be continued after the COVID-19 situation ends? (can select multiple)

☐ Remote consent
☐ Telehealth visits
☐ Shipment of study therapy to patients
☐ Performance of diagnostic procedures (laboratory tests, radiology) at nonstudy sites
☐ Administration of treatment at nonstudy sites
☐ Remote monitoring

Comments on the impact of COVID-19–related changes to future clinical trial practice (open-ended):

Final Comments

Please provide any other feedback, examples, recommendations, etc related to COVID-19–associated adjustments to clinical trials (open-ended):

Thank you for your participation.
eAppendix 3. Selected Open-Ended Responses

Several respondents observed that, in effect, a crisis was required to push the institution to adopt technologic processes that had been available but not previously implemented.

…moving ahead with electronic technology that normally would have taken years at this institution.

Overall response and quick adaption of new technology are impressive and greatly appreciated. Tracking of some information (eg, patients in screening, study status) speaks to the need for better systems to centrally track information.

Remote monitoring can already occur relating to data….if study binders are permitted to be kept electronically with documents that can be completed and signed electronically via DocuSign and/or PDF. Keeping physical study binders should not be necessary in this tech-savvy time, especially with cloud services and shared drives we have available and access to.

Respondents also noted that sustaining positive change would require not just trial-associated staff but also physicians to adjust:

All of this new technology has only given us more options that will allow us to be more efficient and safer going forward. It has been somewhat harder to communicate with and obtain source documentation from physicians who have not embraced the technology changes.

MDs should be able to give ample heads up about a patient who needs consent. Coordinators can call the patient with information about the study and discuss details of the study (schedule and risks), and then the MD could consent the patient if coordinator isn’t on site.

I have not heard from any monitors as to whether they feel this way is better overall. I do know they like being able to speak with the PI instead of being told “Sorry but I’m busy.”

… Some physicians are [not] paying attention to any of this. They still need guidance from the coordinator. They are not setting up drug shipment or scheduling procedures/laboratories at other places. I really think they just want stuff done and they will sign off on what the coordinators need. [However, overall], I think [physicians] are having good experiences with telehealth.