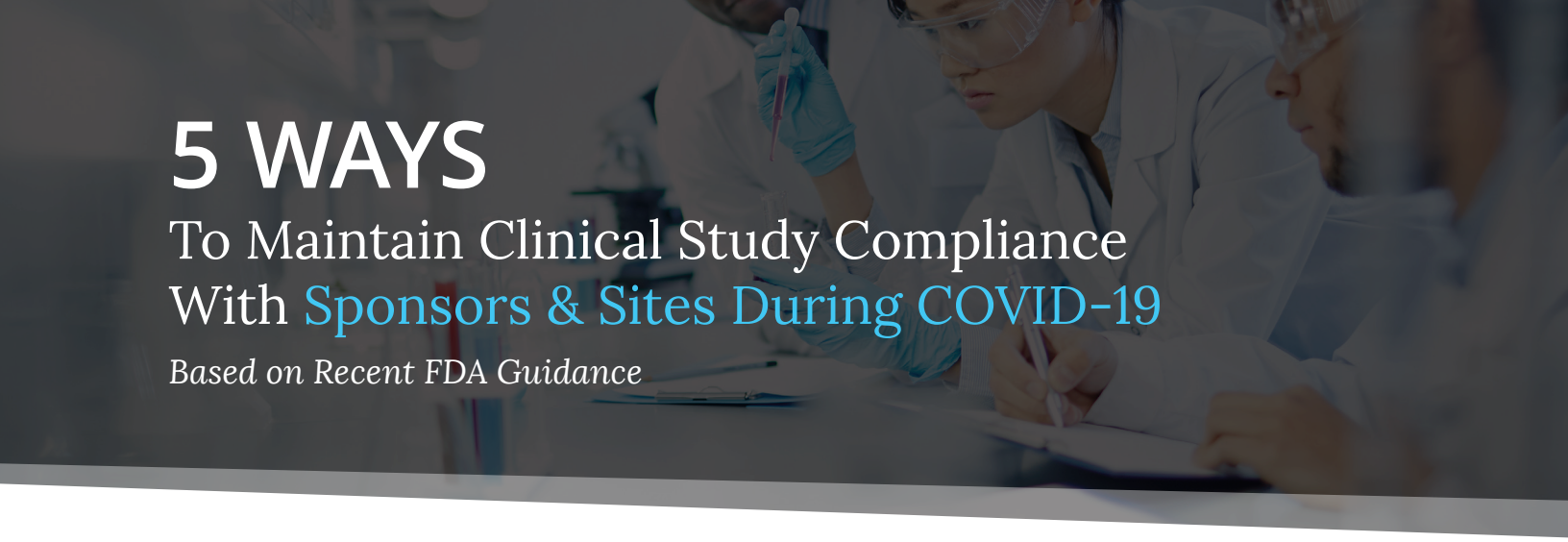

5 WAYS

To Maintain Clinical Study Compliance With Sponsors & Sites During COVID-19

Based on Recent FDA Guidance

1

COMMUNICATE

- Clinical study status and alternative plans (i.e. protocol modification regarding subject follow-up)
- Subject recruitment, enrollment and safety
- Remote monitoring plans and source/document sharing, including access to secure electronic medical records
- PI oversight (i.e. adverse event assessment)
- IRB correspondence (i.e. protocol amendment)

2

PRIORITIZE

- Training (i.e. GCP training)
- Safety of trial participants, by minimizing or eliminating potential hazards like on-site follow-up visits
- Safety-related endpoints
- Enrollment or study discontinuation by placing a hold on recruitment

3

EVALUATE

- Protocol, procedures, and policies modifications or amendments
- Notes-to-file/Memos explaining why those modifications were made
- Alternative locations and measures (i.e. product storage)

4

CONTINUE

- Remote monitoring (i.e. study data and medical records)
- Internal audits
- Trial Master File reviews
- Site management (i.e. resolving queries)

5

DOCUMENT

- "Unavoidable protocol deviations," as noted in the FDA guidance
- Policy and procedure revisions
- Study limitations and restrictions

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WE'LL EARN YOUR APPROVAL.

SOURCE: FDA Guidance On Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic (March 18, 2020)