



Where do we go from here?

Regulatory Inspection Preparedness for ASPIRE Sites

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NIAID



National Institute of
Allergy and
Infectious Diseases

Establish “State of Inspection Readiness”

- Establish Site Inspection preparation team
 - Clinical, Lab, Pharmacy, Regulatory, QA/QC
 - Appoint 1 person as Point of Contact

- Complete Site Inspection Preparedness Checklist
 - Focus on “un-monitored” PIDs for chart review
 - Delegate individual(s) to oversee completion of each section
 - Schedule regular meetings to discuss progress

- Update Regulatory Inspection SOP with specific personnel involved in inspection

Coming Soon...

Mock Inspections at Your Site!

- Targeting 1-2 day “mock inspections”
- Conducted by PPD
- Timeline: Conducted 4Q 2015 through 1Q 2016
- Targeting sites that are “most likely to be inspected”
 - eThekwini CRS
 - Isipingo CRS
 - WITS RHI CRS
 - Emavundleni CRS
 - Tongaat CRS
 - Botha’s Hill CRS

Additional Resources

- See you at the 2016 MTN Annual Meeting in North Bethesda in March
- Attend Part II – Preparation for “After” the Inspection
 - Focus on how to address inspection findings

