



Where do we go from here?

Regulatory Inspection Preparedness for ASPIRE Sites

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MTN Regional Meeting
Cape Town
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NIAID



National Institute of
Allergy and
Infectious Diseases

Maintain "State of Inspection Readiness"

Site Inspection Preparation Team established



Site Inspection Preparedness Checklist implemented



Site Regulatory Inspection SOP developed



Mock Inspections for targeted sites conducted



What can we do while we wait?

DAIDS/Protocol team

- 3Q2016-4Q2016
MTN Regional Meeting
 - Regulatory Inspection Preparedness Part III- F2F training
 - PPD special assignments
- 1Q2017
MTN Annual Meeting
 - More refresher training
 - Site suggestions?
- 3Q2017
Mock inspections at EMA selected sites only

Sites

- Develop transition plan for departing staff
- Resolve issues identified on Mock inspection
- Story boarding
- Role Play
- Take refresher GCP
- Review Site SOPS and in country regulations

ongoing

