National Institute of Allergy and Infectious Diseases

P1090 and P1093

Regulatory Inspection Preparedness

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NIAID

National Institute of Allergy and Infectious Diseases

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Upcoming P1090 and P1093 FDA & EMA Submissions 4Q2019

P1090	P1093 Cohort
Cohort I	Cohort III
Cohort II	Cohort IV
	Cohort V
	All weight bands
	All data through 4/29/19

Upcoming P1090 and P1093 Regulatory Submissions – General Timeline

2Q19	3Q19	4Q19	1Q20	2Q20	3Q20	4Q20	1Q21	2Q21

P1090 → Regulatory Inspection

P1093 → Regulatory Inspection

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Regulatory Submissions lead to Regulatory Inspections

- We expect that some sites will be inspected by the EMA or FDA as a result of the regulatory submissions

Why?

✓To verify the quality and integrity of the data

✓To determine if participants safety and rights were protected

✓To verify compliance with protocol, SOPs, ICH/GCP, and local regulations were upheld

What should sites do now?

Perform a Comprehensive QA of Regulatory Binder

DELEGATION OF DUTIES LOG

- Task must be delegated prior to being performed
- Training must be performed prior to task being delegated
- Focus on staff turnover

TRAINING LOG

- All protocol specific training must be present
- HSP/GCP training documented
- Site SOP training document
- Training must be performed prior to task being delegated

CURRICULUM VITAE

- CV must be signed/dated and reviewed by investigator prior to task being delegated
- Qualification of individual based on education/experience

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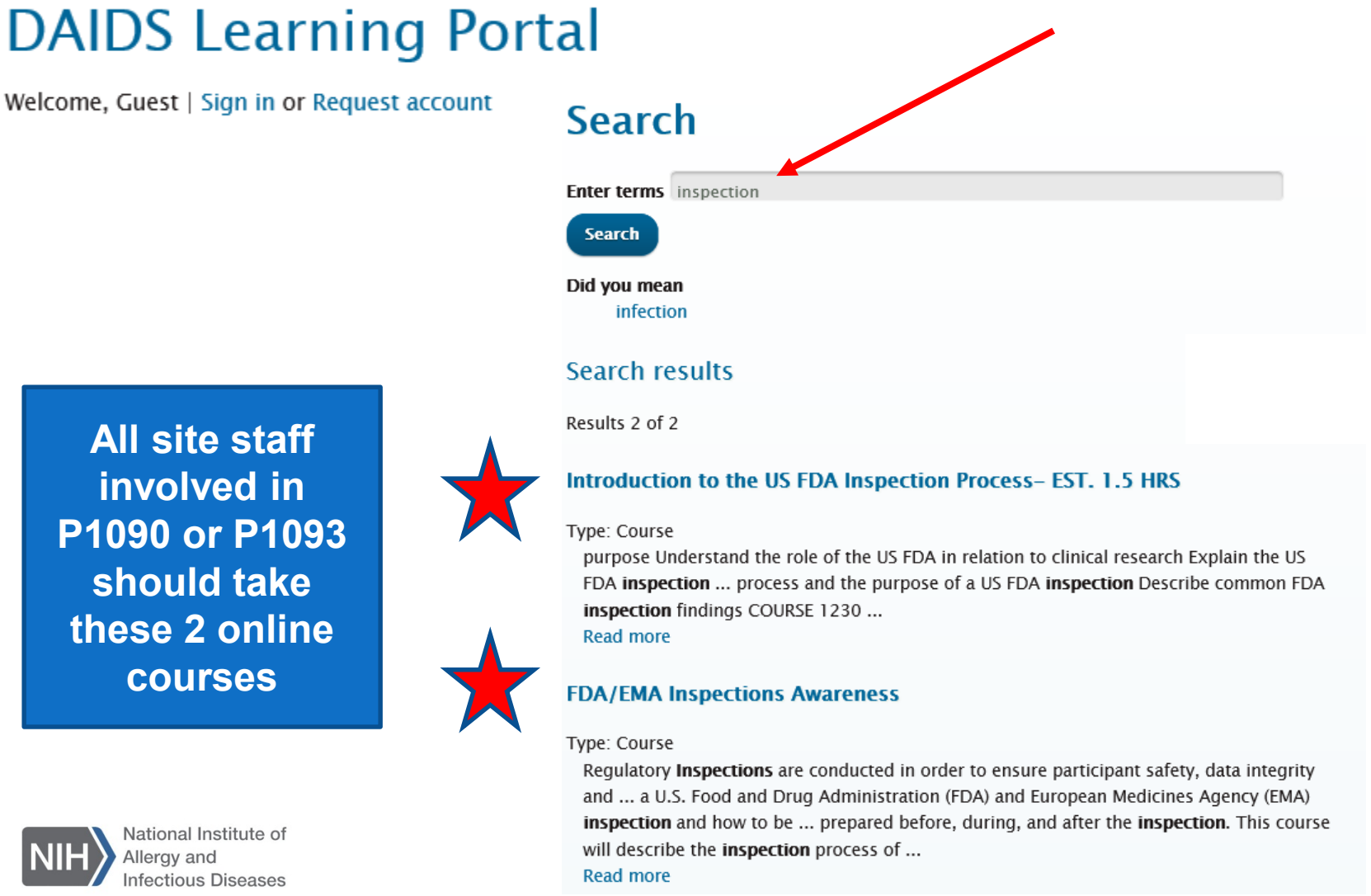
Online Trainings To Help Sites Prepare

https://daidslearningportal.niaid.nih.gov/



All site staff involved in P1090 or P1093 should take these 2 online courses

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Mock Inspections vs. Pre-Inspection Visits

Mock-Inspection

Monitors mimic a formal regulatory inspection

Not-facilitative – there is no training component

Pre-Inspection Visit

Monitors perform an extensive review of regulatory materials and provide training

Facilitative – assist sites to prepare

Sites to Receive a 'Mock-Inspection'

CRS #	CRS Name
31890	Harare Family Care CRS
5112	David Geffen School of Medicine at UCLA NICHD CRS
5115	Siriraj Hospital, Mahidol University NICHD CRS
5118	Kilimanjaro Christian Medical Centre (KCMC)
5073	SOM Federal University Minas Gerais Brazil NICHD CRS

Sites to Receive a 'Pre-Inspection Visit'

CRS #	CRS Name
5071	Instituto de Puericultura e Pediatria Martagao Gesteira – UFRJ NICHD CRS
12702	Molepolole CRS
5072	Hospital Federal dos Servidores do Estado NICHD CRS
5074	Univ. of Sao Paulo Brazil NICHD CRS
5097	Hosp. Geral De Nova Igaucu Brazil NICHD CRS
30300	Umlazi CRS
8950	FAM-CRU CRS
8051	Wits RHI Shandukani Research Centre CRS
4001	Lurie Children's Hospital of Chicago (LCH) CRS
4201	Pediatric Perinatal HIV Clinical Trials Unit CRS
5116	Chiangrai Prachanukroh Hospital NICHD CRS
31784	Chiang Mai University HIV Treatment CRS
5055	South Florida CDTC Ft Lauderdale NICHD CRS
12701	Gaborone CRS
5017	Seattle Children's Research Institute CRS
5114	Bronx-Lebanon Hospital Center NICHD CRS
5013	Jacobi Med. Ctr. Bronx NICHD CRS

Inspection Preparation Materials for Sites

- Handout 1: OCSO Job Aid to provide tips and tools
- Handout 2: OCSO Job Aid – site inspection preparedness checklist
- Handout 3: General Do's and Don'ts during an inspection interview
- Handout 4: EMA instructions to Investigators re: flow of inspections at sites
- Handout 5: EMA instructions to Investigators re: GCP review
- Handout 6: Potential inspections questions
- Handout 7: OCSO Job Aid for tracking documents provided to inspectors

What's Next?

- For NIAID sites:
  - OCSO POs will send the handouts electronically
- For NICHD sites:
  - Westat will be send the handouts electronically
- All sites will be contacted by the monitors to schedule the mock-inspections and pre-visit inspections, which are expected to occur in 4Q2019

Sites should be 'inspection ready' at all times !


Questions