

## **EMBLEM Site-Specific Challenges (Summary Lessons from the past year)**

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### **Questionnaire interpretation**

- Question interpretation/ while interviewing
- Inadequate time allocated for questionnaire administration

### **HOSPITAL STAFF**

- Staff mentoring to conform to high impact high quality GCP requirements.

### **Proficiency testing**

- Not all test done are covered by EQA testing.

### **SUPPLY CHAIN**

- Procurement delays which have resulted in delayed procedure or missed sample collection.
- Stock card usage
- Re-order levels
- Expiry of study reagents
- Hospital reagent shortages

### **EQUIPMENT**

- Equipment 'adaptation' to the study sites.
  - Microscopes, QBC, Freezers
- The unstable power in some sites
- Lack of local technical support
- No service contracts
- Variation in types of hospital equipment
- Lack of regional reference ranges

### FIELD ENGAGEMENT

- Field activities that overwhelmed daily work flows.
- Key roles were neglected while the teams left for the field

### Impact of Clinical BL Vs Histological BL on case Enrolment

- Mis-interpretation of the protocol regarding enrolment of cases.

### Documentation

- There has been a slow uptake of the documentation culture across the sites.
- E.g -No SOPs
  - - Low rate of documented CA forms
  - - Undocumented trainings
  - - Competency checks

### Consent

- Roles of:
  - Witness
  - Assent

### Investigators File

- Incomplete Investigators files
- Regulatory Binders
- Missing signature logs
- Copies of IRB Approvals missing on binders
- Communications missing

### Analysis of Enrolment strategies

- There is need to have an idea which strategy works best