CTMS
Data Surveillance Log (DSL)

Pam Monds
Clinical Operations

Mindy Mattison
DCRI IT Training
Purpose of Demo

- What is the DSL?
- Provide History of DSL
- Demonstrate DSL Functionality
- DSL Considerations
- Determine Next Steps
What is the DSL?

- **Data Surveillance Log (DSL)** allows you to track issues at the **protocol** level
  - **Issue Log** captures issues at site level
  - **Follow-Up** tab captures issues at site visit level
- Option to “push” a record to one or more of the protocol’s sites
- Record(s) will then appear on each of the selected site’s **Issue Log** tab, as well as on the protocol’s **Data Surveillance** tab
Initiated small trials pilot within the SOC (Solutions Optimization Center)

Risk based monitoring approach with a significant focus on data surveillance activities as part of our overall monitoring & oversight of study quality

Mechanism to document & track these activities

Demonstrate compliance with our plans as well as to inform us of areas of potential risk

Focus our efforts to optimize effort/resources
DSL Development Background

- Met with several IT representatives to determine best solution
- Decided to use CTMS platform
- Worked closely with CTMS developers to customize
- Implemented in early 2013 for piloting
- Want to demonstrate and discuss now to determine next steps
  - Useful tool?
  - Concerns?
  - Suggestions for improvement?
Demonstration of Functionality

- Recording a Data Surveillance Record
- Pushing a Data Surveillance Issue to Sites
- Updating an Existing DSL Site Record
- Adding Sites to an Existing DSL Record
DSL Considerations

- DSL rights currently given at user-role level, NOT per protocol
- Records on the DSL cannot be copied (including records listed on the Sites applet)
- Protocol deviations cannot be added to the DSL (should be added on the site’s Protocol Deviations tab)
- As a business rule, you should wait until all sites have resolved the issue before marking a DSL record as Done
- No site field feeds back to the DSL record. Site-level fields feed back to the site record on the DSL’s Sites applet
Next Steps

- Gather opinions/suggestions
- Provide feedback to decision makers
- Determine plan moving forward
QUESTIONS?