Site Information Forms

- Complete for every site that listed on MTA

- All questions must be answered (except literacy info)

- Partially completed forms = incomplete

- For sites not yet in WebDCU, submit in excel

- RCC overall completion status = the % of MTA sites with <u>fully</u> completed forms

Feasibility Surveys

- Complete **<u>only for sites</u>** listed on MTA and capable of participating
  Example = hospitals with rehab facilitates for rehab studies

- Do not complete for sites incapable of participating
  Example = pediatric hospitals for adult only studies

- Full credit is given to an RCC for at least one complete survey

- Any questions should be directed to the NDMC or NCC

Remote Monitor Access to EMR

- The average cost of a phase III clinical trial is $100,000,000

- On-site monitoring is ~30% of the costs

- FDA Guidance for Industry encourages consideration of other approaches
  - central
  - risk-based
  - remote

How to do it

- Need site champion to initiate the process

- Find the decision maker
  - usually IT
  - usually not medical records/dept. head

- Approach is critical
  - Say 'view'
  - Do not say 'audit'

How to do it

- Start early
  - takes time to find decision maker
  - may involve legal depts.

- Different requirements across sites
  - confidentiality agreement
  - BAA
  - training certification
  - background check

How to do it

- StrokeNet Sites that allow remote access to EMR
  - Detroit Receiving
  - Ohio State
  - Children's Hospital of Philadelphia
  - Emory
  - University of California San Diego*