



Maximizing Network Efficiency and Site Start-Up Performance 9/26/2016

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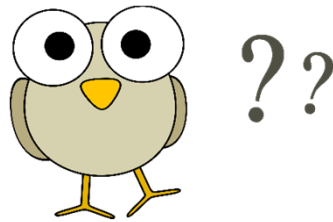
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IT'S ABOUT SEEING THE BIG PICTURE...



WE DON'T KNOW WHAT WE DON'T KNOW!!!



So how can *you* maximize our performance & efficiency?

Provide Accurate Information for CIRB Review

- CIRB can not review for state or locally specific requirements unless it is provided
 - Need to work collaboratively with local IRB to ensure study compliance when using CIRB *and* accuracy of returned Local Context Form, CIRB Submission Form and ICF

Solution - CIRB Local Site & IRB / HSP Review Form for Trials to...

- Verify all state, local elements are present
- Local ancillary reviews are scheduled or performed (e.g. radiation safety committee review)
- ***Will require sign-off by local IRB representative.***

Considerations When Processing Site Documents

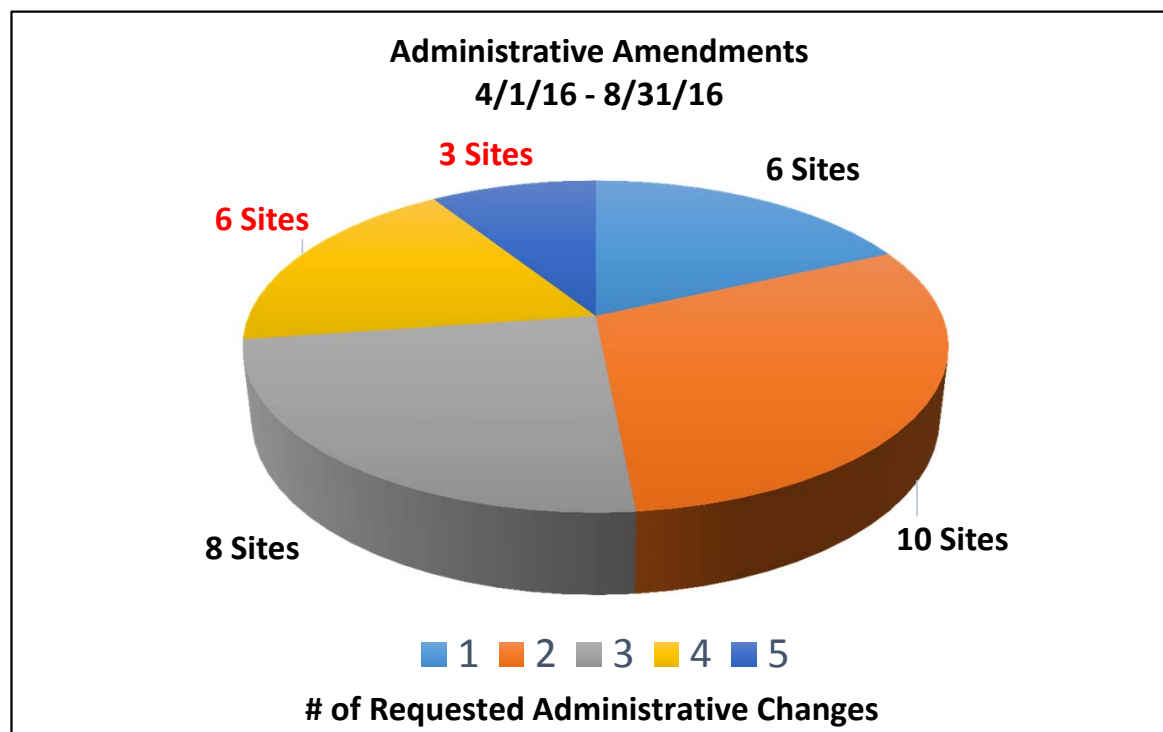
- Ensure documents filled out completely (e.g., name, address, institutional name if requested, signature, date)
- CV's need to be initialed and dated and show current institutional affiliation
- Posting of right document for the right person in the right document category

Administrative Amendments (e.g., personnel changes, ICF revisions)

**Are we on the
same page?**

What is reasonable versus poor planning???

What is the impact to the Network???



RCC's Management Role ...

- Monitor performance issues
- Mistakes and other problems occur (e.g., use of unapproved consent, failure to obtain consent prior to a study related procedure)
- Per the Management SOPs, each RCC needs to assist its performance sites in developing appropriate Corrective and Preventive Action (CAPA) plans

HIPAA Language and Foreign Language ICF's

- Translation for foreign language ICF documents is managed by the NCC Policy for Translations
- HIPAA language that is incorporated into the ICF will be translated as part of that document
- Translation for stand alone HIPAA and other site specific documents not incorporated in the ICF will be the financial responsibility of the site



Questions???

Comments...

Concerns!!!

