



Multiple Modes of Administration and Data Capture: Practical Considerations

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Mixing or Migrating Modes?

- Migrating Modes
 - Demonstrate equivalence for prospective use
 - Most common today is from paper to electronic
- Mixing Modes
 - Demonstrate equivalence for concurrent use
 - Paper-electronic, or electronic-electronic mix

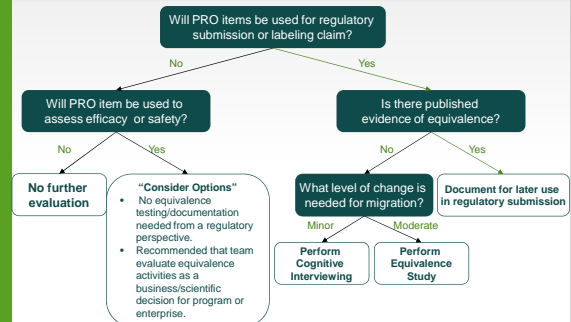
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Migrating Modes



Instrument Implementation: Paper to Electronic Equivalence Decision Tree



Note: The appropriate license must be procured, regardless of equivalence activities

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Regulatory Considerations

- Is data from PRO endpoint going to be used to support product labeling (claims)?
- If going to support labeling, the PRO Guidance is applicable
- If not supporting labeling, then a business/scientific decision
 - E.g., Studies for publication only
- This can potentially alleviate significant effort

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Scientific Considerations

- Has the equivalence between paper and this electronic format been previously demonstrated?
- It is important that the current and published format are similar
- What type of equivalence work as published?
 - Is it adequate to defend to regulators?
- If no published work, then need to evaluate level of equivalence work needed

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Operational Considerations

- Design of screens to ensure 'faithful' migration
 - Retain look of question as much as possible
 - Retain exact wording where possible
 - Keep question and response together
 - Evaluate need for instructions on same screen or different screens
 - PRO and ePRO Collaboration is key
- Migrating to 'new' hardware
 - Consider equivalence data as applied to new hardware



Legal Considerations

- Many PRO instruments are copyrighted
 - Licenses are for paper implementation
 - Licenses may vary by hardware
- Any change requires appropriate license
 - Electronic implementation is a change
- Independent of issue of equivalence



Mixing Modes



Mixing Modes

- ⦿ Has migration occurred?
- ⦿ Has equivalence been previously demonstrated?
- ⦿ What are risks of mixing specific modes of interest?



Mixing Paper and Electronic

- ⦿ Avoid as much as possible
- ⦿ Mixing site-based instruments
 - ⦿ Less risk, if equivalence previously demonstrated
- ⦿ Mixing diary paper and electronic instruments
 - ⦿ Significant potential equivalence issues
 - ⦿ Mixing format and procedural issues



Mixing Electronic Modes

- ⦿ Mixing visual only methods
 - ⦿ Potentially easier to demonstrate equivalence and implement
- ⦿ Mixing visual and auditory modes
 - ⦿ Potentially more challenging to demonstrate equivalence
 - ⦿ Implementation challenges



Summary

- ⊙ Migrate before mixing
- ⊙ Establishing equivalence has varying challenges depending upon mode, and whether site or diary based
- ⊙ Avoid mixing paper and electronic