

Smart



Using the Digital Pen in Clinical Research

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KNOW NOW

Environment

- Several remote sites submitting data
- Data collected over multiple visits
- Case Report Forms = 50 – 200 patterns used per book
- Tightly Regulated environment

Challenges

- Installation and Support of Software at remote sites
 - Multiple pieces to install
- User Training & Support
 - Can't select the users
 - Make movies?

Challenges

- Aggressive Study Startup Timelines
- Regulated Environment: difficult to apply patches/upgrades in timely manner

Lessons Learned

- Use big boxes
- Design forms to be completed in one sitting
- Warning messages:

<input type="checkbox"/> No ADEX_011	<input type="checkbox"/> No ADEX_012	<input type="checkbox"/> No ADEX_013	<input type="checkbox"/> Intense erythema with edema and vascular lesions or erosions ADEX_014
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This is an extra ADEX form. Be sure to dock the pen after filling out each form.

Advantages

- Paperless – significant shipping/storage savings
- Low Impact Technology – sites can use a pen
- Images in database – FDA will soon require submission of images of forms