

Technology: The Good and The Bad

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The Good

- No delay between subject visit and data entry.
- Provides Sponsor or CRO real time data and evaluation.
- Faster communication and collaborative feedback.
- Live edit checks minimize data errors in rating scales and reduce time in data management query/resolution.

The Bad

Duration of subject visits are inevitably increased whenever electronic devices are deployed.

An Example: C-SSRS

Ubiquitous, standardized, and highly familiar to clinicians.

“Study A” Paper: C-SSRS 8 visits per patient, 10 patients, 5 minutes administration + data entry time = **6.7 hours**

“Study B” Electronic: C-SSRS 8 visits per patient, 10 patients, 10 minutes administration/upload/download time = **13.3 hours**

A Little Data

In 2018, FLCR administered over 1000 C-SSRS scales

*If all were **paper**, that would have been **83** hours
(about two weeks) for that single assessment.*

*Had all been **electronic**, it would have come to
166 hours (or a month) for the same
assessment.*

Added Costs of Study Technology

- Technology failures require *immediate* help desk contact and interruption of the study visit.
- Devices are labeled with the help desk number and preferred contact.
- In 2018, FLCR trials using electronic devices required a median of 45 minutes of help desk time per visit (*range 0-minutes to 4-hours*) to address device failures, missing or corrupted data, failed upload communications, etc.

“Study A” **Paper**: 8 visits, 10 participants, no help desk time = **0 hours**

“Study B” **“Device”**: 8 visits, 10 participants, help desk time = **60 hours**

In 2018, FLCR completed more than 1000 subject visits. If all included electronic devices, help desk time would have totaled 750 hours

Summary

Task Relevant to Rating Scales	No Electronic Scales	Electronic Scales
Training Time for 3 staff members	45 hours	60 hours
Admin/Upload Time (5 scales, 8 visits)	13 hours per patient	27 hours per patient
Help Desk Time	0 hours per patient	6 hours per patient
Data Entry Time	2 hours per patient	0 hours per patient
Query Resolution Time (including data mgmt. and vendor queries)	1 hour per patient	2.5 hours per patient
Total Time Per Study for Rating Scales	160 hours	355 hours

When electronic devices are employed in a study, staff time, including the PI's, is doubled for any procedures that are completed on the device.

OUR "NEW" FILE ROOM



Thinking Positively

- Close collaboration is essential as we move forward in the 21st Century.
- Prior to a participant moving forward in a trial, a collegial discussion with documentation will allow all team members to concur that the participant is appropriate.
- Respectful, professional peer review allows all members of the research team to obtain the highest quality/integrity of data.

Moving Medicine Forward is the primary goal of clinical research