

Comparison of Mobile Data Entry Systems for Clinical Trials Data Collection



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Background

- In 2001, we began the Digital Mammographic Imaging Screening Trial (DMIST) funded through National Cancer Institute managed by American College of Radiology Imaging Network A Multi-Center Trial with over 35 sites enrolling a total of 49,500 patients.
- Over 25 forms for study data collection submitted using web-based data entry system.
- Total number of elements over 2500.

Background cont.

- At UNC, we enrolled an average of 6 patients a day into DMIST.
 - Minimum number of forms per case: 6.
 - Most forms over three pages with lots of skip patterns based on diagnostic scenario.
- At beginning of the trial the web-based interface was hard to use and time consuming especially for our clinical radiologists.

How we collected DMIST data at UNC

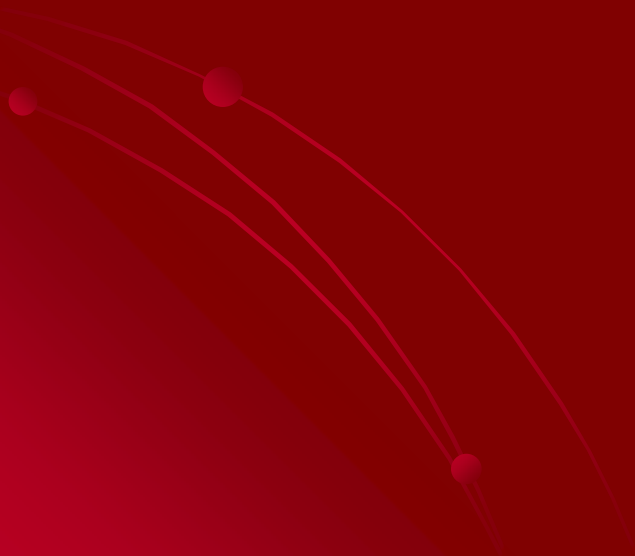
- Web access limited in clinic.
- Paper forms used requiring double data entry.
- Batch web entry of forms infrequently by numerous administrative assistants and RAs

Data Quality Verification


- Since the close of the trial to accrual, the study has been in data cleanup and analysis phase.
- At UNC, we decided to internally audit every one of our 2600 cases. In the process, we have to date identified over 1100 data entry errors (information entered electronically not matching what was written on paper forms) in 45% of our total cases.
- Each needing to be corrected by submitting a paper form for each error to ACRIN so that they can update the database.

Solution

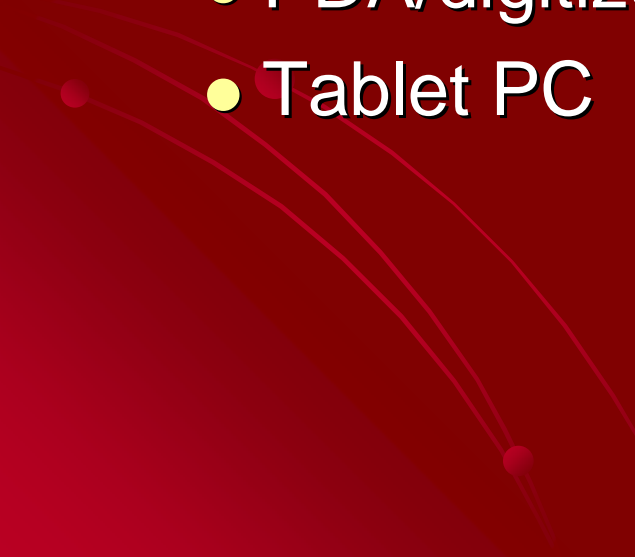
- Direct electronic data entry
...eliminate the need for secondary data
entry step



Direct Data Entry Needs

- Portability
 - Must not add significant time to forms completion over current paper and pen
 - Easy to Use
 - Built in business logic
- 

The Mi-Co Study

- Four mobile computing platforms running Mi-Forms software
 - Logitech io pen
 - PDA
 - PDA/digitizer hybrid
 - Tablet PC
- 

Tablet PC

- Pros

- Real time data validation
- Handwriting recognition verification
- Electronic handwritten source document

- Cons

- Hardware expense

The screenshot shows a web browser window titled "Mi-Forms" with a menu bar (File, Options, Tools, Help) and a toolbar. The main content area displays a form titled "WRK-IA/ID MAMMOGRAPHY INTERPRETATION WORKSHEET COVER PAGE".

INSTRUCTIONS: This worksheet is related forms IA and form ID. It is to be completed by the radiologist to record the information from the initial study entry mammogram interpretation. Complete one worksheet for the digital interpretation and one for the film screen interpretation. When it, and all other appropriate worksheets related to form IA or form ID have been completed for this case, then the data on this worksheet should be entered into ACRIN's web-based data form IA or ID. Do not send or fax this worksheet to the Data Management Center; keep it in the patient's study record at your institution. Be sure to sign and date it when you complete it.

Form Fields:

- CASE ID:** A row of 10 input boxes, with the last four containing the digits 1, 3, 5, and 4.
- INCIDENT DATE:** A row of 6 input boxes, with the first three containing 1, 2, and 2, and the last three containing 1, 0, and 3, representing the date 12/21/03.
- DATA ENTRY METHOD:** A row of 10 input boxes, with the last one containing the digit 4.
- READERS INITIALS:** A row of 2 input boxes, with the first containing 'E' and the second containing 'P'.

Image Display:

- Hard
- Soft

Density of Breast Parenchyma:

- Almost entirely fat
- Scattered fibroglandular densities
- Heterogeneously dense
- Extremely dense

Mammography Findings?

- No (If there are NO findings, skip rest of form and complete form IA-O1)
- Yes (If yes, indicate which breast)
 - Right Breast
 - Left Breast
 - Both Breasts

Continue button at the bottom left.

Logitech io pen

M-Forms

File Options Tools Help

Low Confidence Fields:

- Business Rule Errors
- Incident Date Required
- Reader Initials Required
- Coversheet Signature Required
- Coversheet Date Required
- Number of WRK-M Filled
- Largest Dimension WRK-M-1 Required
- Confidence Scale WRK-M-1 Required
- WRK-M-1 Signature Required
- Date WRK-M-1 Required
- Summary Page Confidence Scale Required
- Summary Page Signature Required
- Summary Page Date Required

Case Number
Incident Date
Reader Initials
Data Entry Method
Image Display
Density of Breast Parenchyma
Mammography Findings?
WRK-M
Page_2
2
Masses:
NumberOfMasses:
Asymmetric Denoties:
NumberOfDenoties:
Architectural Distortion:
NumberOfDistortions:
Clusters of Calcifications:
NumberOfCalcifications:
Received By
Incident Date
Page_27
Page_3
Page_15
Page_21
Page_9
3
Case Number
DEPTH: (select one)
NUMBER OF CLINICALLY RELEVANT MASSES:
Mass #
Location/WRK-M
O'CLOCK Position
SHAPE:
MARGINS:
ASSOCIATED FEATURES:
DENSITY:
Page_4

WRK-M MAMMOGRAPHY INTERPRETATION WORKSHEET OF INDIVIDUAL MASS 1

INSTRUCTIONS: This worksheet is related to Question 8 of forms IA and form ID. It is to be completed by the radiologist to record the overall mammographic impression for this case. Complete only one WRK-OI worksheet for each digital case and one for each film screen case. When this worksheet has been completed, along with all other appropriate worksheets related to form IA or form ID for this case, then the data on this worksheet should be entered into ACRIN's web-based data form IA or ID. Do not send or fax this worksheet to the Data Management Center; keep it in the patient's study record at your institution. Be sure to sign and date this worksheet when you complete it.

CASE ID: 1354

NUMBER OF CLINICALLY RELEVANT MASSES:
Right Breast
Left Breast
Mass # 1 of 1

LOCATION: Mark the o'clock location or choose from list for other. Select all that apply.

O'CLOCK Position:
 12-1 Axillary Tail
 1-2 Subareolar Hipple
 2-3 MLO: Superior
 3-4 MLO: Inferior
 4-5 MLO: Subareolar
 5-6 CC: Medial
 6-7 CC: Lateral
 7-8 CC: Subareolar
 8-9
 9-10
 10-11

DEPTH: (select one)
 Anterior
 Central
 Posterior
 Anterior and central
 Central and posterior
 Anterior, central and posterior

SHAPE:
 Round
 Oval
 Lobular
 Irregular

MARGINS:
 Circumscribed
 Microlobulated
 Obscured
 Indistinct
 Spiculated

ASSOCIATED FEATURES:
 Asymmetry

Case Number: 1354

Previous Next New Low Confidence Finish

- Pros
 - Pen on paper
 - Portable
 - Cheap to implement
- Cons
 - No real time data verification
 - Not capable of automatic database upload

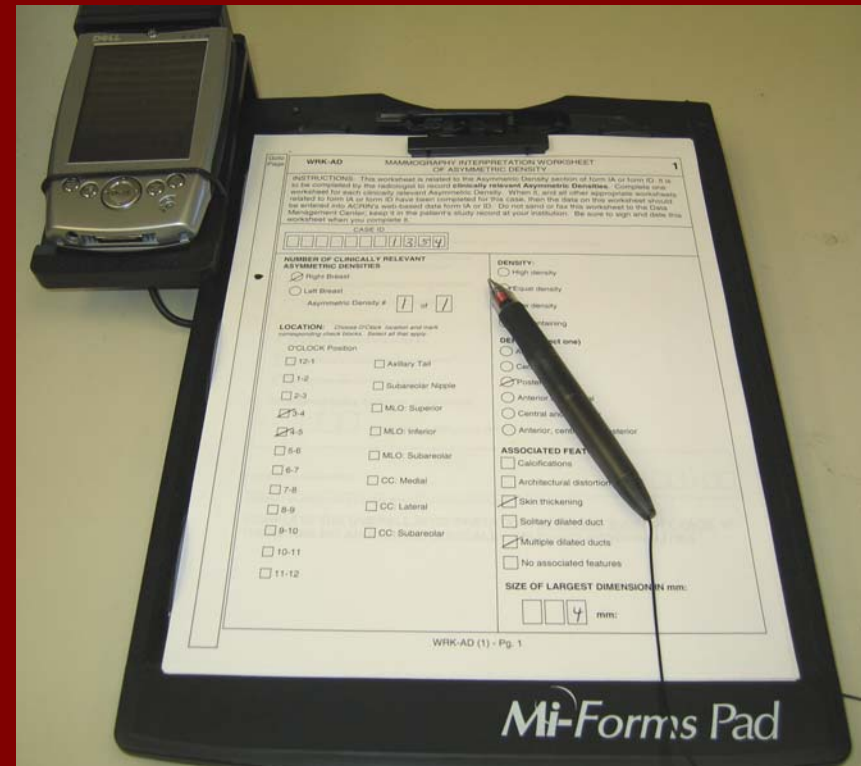
PDA/Digitizer Hybrid

- Pros

- Pen on paper
- Source document
- Real-time validation

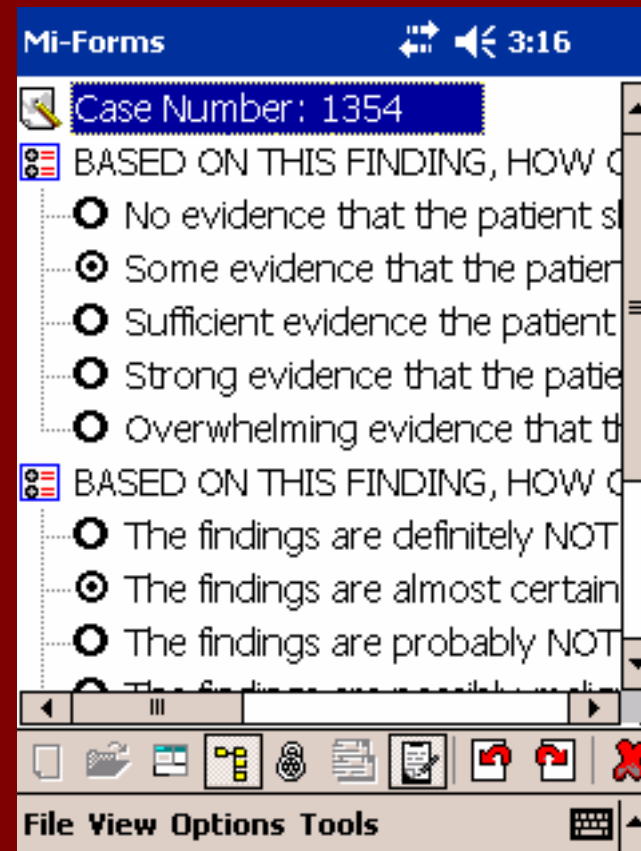
- Cons

- Navigation thru multi-page cumbersome
- Validation requires user to look at PDA screen



PDA

- Pros
 - Portable
- Cons
 - Small screen
 - scrolling required
 - No jumps



System Features and Costs

System Features	Handheld ("PDA") System	"Tablet PC" System	Hybrid Handheld/ Pen-on-Paper System "Hybrid"	Electronic Pen System "Digital Pen"
Pen-on-paper interface			X	X
Immediate validations	X	X	X	
Offline validations	X	X	X	X
Real-time Handwriting Recognition	X	X	X	
Deferred Handwriting Recognition	X	X	X	X
Deferred Correction of Recognition Errors	X	X	X	X
Picklists	X	X	X	
Real-time capture to database	X	X	X	
Store-and-forward capture to database	X	X	X	X
Hardware Cost (Approximate)	\$500	\$2000	\$900	\$200

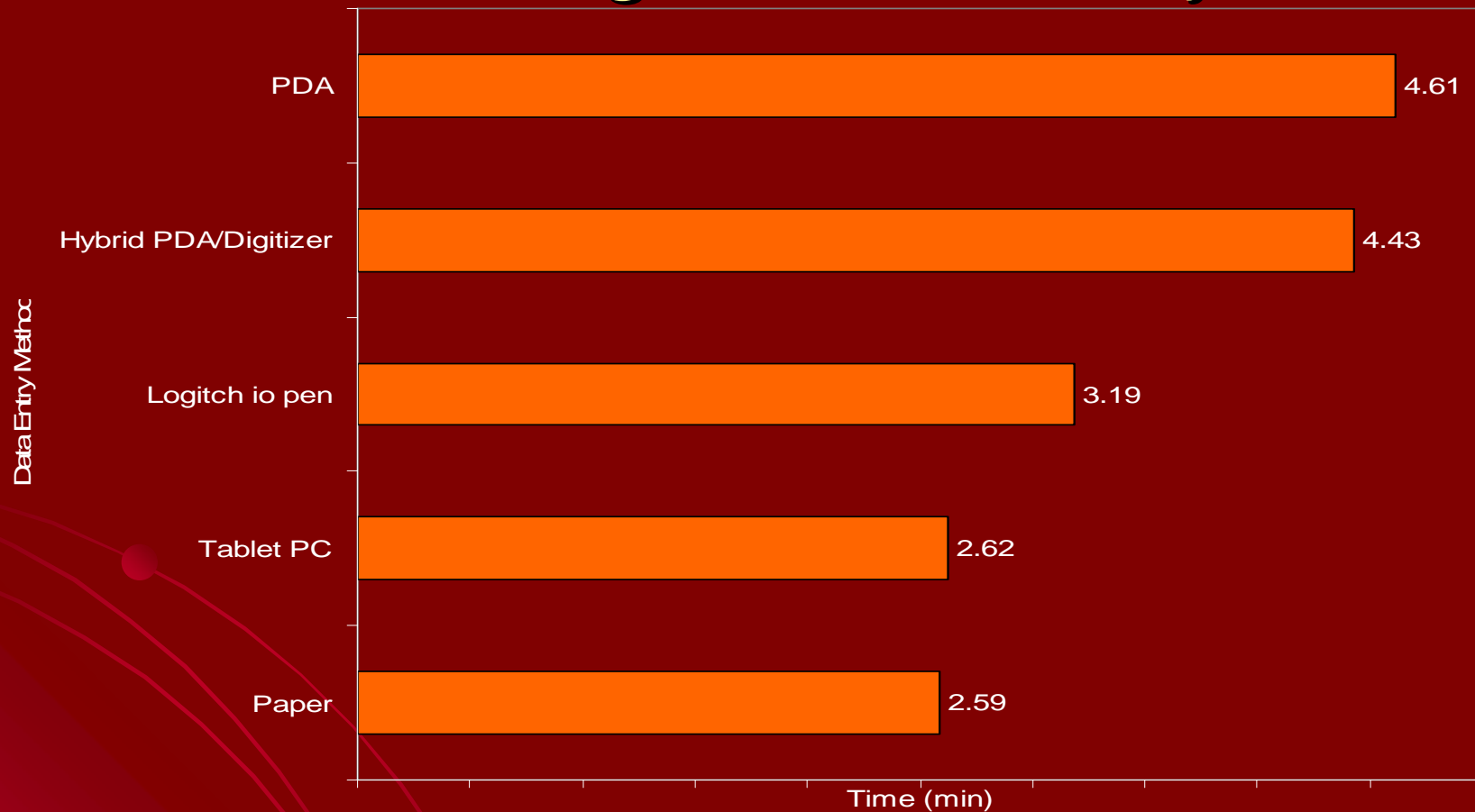
Methods and Materials

- Each of the four platforms used Mi-Co's Mi-Forms software.
- Standard paper data entry was used as control.
- The forms content was taken from UNC mammography interpretation worksheets.
- Five radiologists participated in the study. Each radiologist reader was assigned to enter their interpretations for 20 screen-film mammograms using three out of the five data entry methods.
- There was a total of 300 separate interpretations.

Data Collected

- Speed
 - Research assistants recorded both start and stop data entry times of the radiologists.
- Ease-of-Use
 - The number of help requests was also recorded.
- Accuracy
 - The data was checked for handwriting recognition accuracy following human review and correction for the Logitech io pen platform and Tablet PC.
 - Mi-Forms/Logitech io pen data entry was compared to manual data entry in terms of entry time and accuracy.
- User Satisfaction
 - Survey administered.

Average Time Radiologist Data Entry



There was no significant difference in time spent using Logitech Pen, Pen and Paper and Tablet PC (pairwise p-values are in turn 1.00, 0.86 and 0.98).

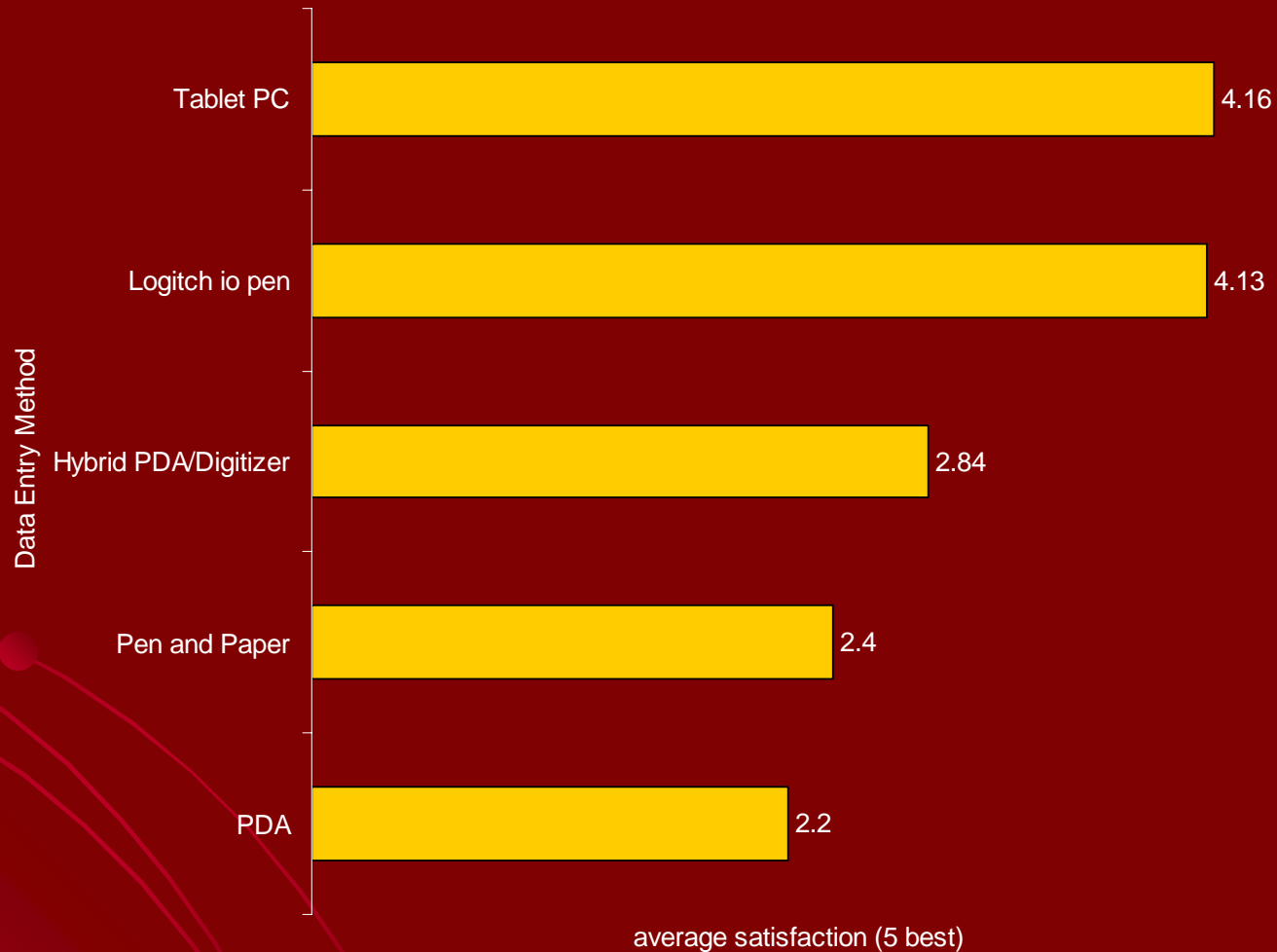
Ease of Use

- Based on the percentage of cases reviewed requiring the user to seek assistance in getting the data into the electronic device.
 - The PDA was the least easy-to-use with 70% (14/20)
 - 42%(42/100) for Hybrid Digitizer/PDA
 - 14%(14/100) for the Tablet PC
 - 8.3%(4.98/60) for Logitech pen
- There is no significant difference in number of help attempts observed between Logitech Pen and Tablet PC (p-value=0.26).

Handwriting Recognition/Review

- Mi-Forms handwriting recognition results review and correction was compared to manual, “secondary” data entry of paper forms.
- Visual verification of captured electronic data for Logitech io pen was significantly less than secondary electronic data entry of paper forms (p-value <0.001).
- The number of errors in handwriting recognition for Logitech io pen was less than secondary electronic data entry of the paper forms data.
 - 27.5% of cases had at least one data entry error for secondary entry of paper forms, 10% of cases had at least two errors, and 6.25% had at least three errors.
 - With the Logitech io pen, 13.33% of the cases had at least one handwriting recognition error, 3.33% of the cases had at least two errors, none of the cases had more than two errors.

User Satisfaction Survey



User satisfaction scores were from 1 to 5 (from strongly disagree to strongly agree)

User Satisfaction Cont.

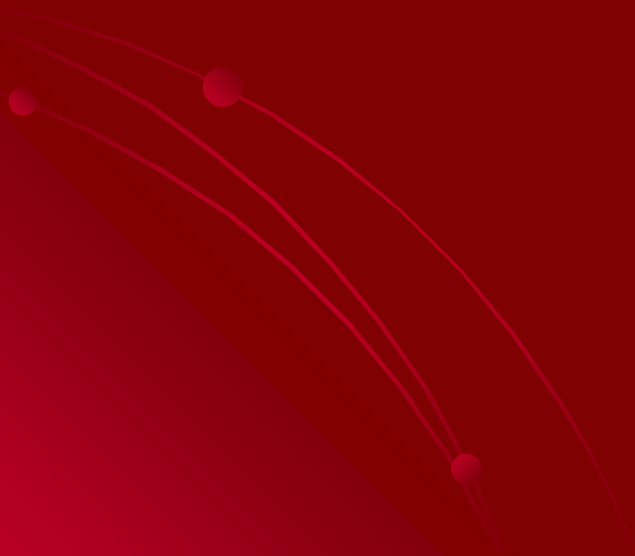
- No significant differences in user satisfaction among Hybrid, PDA and Pen and Paper.
- Hybrid and PDA have significantly smaller scores than either Tablet PC or Logitech Pen (p-value<0.003).
- No significant difference between Tablet PC or Logitech pen (p-value=0.96)

Conclusions

- The Tablet PC and Logitech io Digital Pen with Mi-Forms software are equally fast and equally easy-to-use data entry methods
- Both are faster and easier to use than the PDA and Hybrid alternatives.
- Users are equally satisfied with the Logitech io Digital Pen and Tablet PC and more satisfied with these platforms than with the PDA and Hybrid alternatives.
- Mi-Forms handwriting recognition results review and correction for the Logitech io Digital Pen is significantly faster and more accurate than secondary manual keyboard and mouse data entry.

What's Next

- Field testing of tablet pc and logitech io pen in an upcoming clinical trial at UNC.



Logitech io Pen



PDA



PDA/Digitizer Tablet Hybrid



Tablet PC

