

eSource – What EDC Should Be



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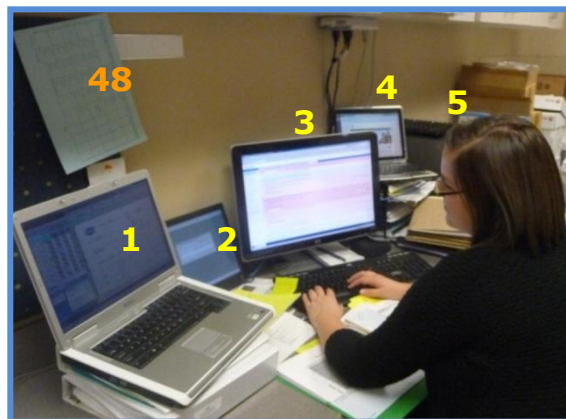
DIGITAL SOURCE DOCUMENTS



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99% Paper Source



# Days	Task	Category
0	Record patient data on <u>paper</u> forms	SOURCE
5 – 10+	<u>Manually</u> input data into database	EDC
21 – 45+	<u>On-site</u> comparison of Source to EDC	MONITOR

100% eSource



Chart Room (Faupharma Miffliken) Subject: ASP (462798) Visit 2

Site #: 001 Protocol #: HJH-57 Created: 12/23/2008 1:30 PM
 Screening #: 462798 Visit: Visit 2

Vital Signs

Blood pressure readings must be completed by an Omron device prior to 10:00 AM. The subject must have been seated for at least 5 minutes. There must be at least 2 minutes between each blood pressure measurement. Blood pressure and pulse rate will be determined and recorded in triplicate. The mean of these values will constitute the BP and pulse rate for the visit.

Arm Used: Left Right
 Cuff Size Used: Regular Large

Blood Pressure #1: 10 : 00 160 / 98 mm/Hg
 Blood Pressure #2: 10 : 05 120 / 75 mm/Hg
 Blood Pressure #3: 10 : 10 120 / 75 mm/Hg
 Mean Blood Pressure: 133 / 63 mm/Hg

Sitting Pulse Rate: 72 beats/min
 Respiration Rate: 20 breaths/min
 Temperature: 99.0 °C° F°

Height: 75.0 in 190.5 cm
 Weight: 190.0 lbs 86.4 kg
 Body Mass Index: 23.8 kg/m2
 Vitals Obtained By: Doug Pierce

** Subject ran in farm car - was out of breath.*

Clinical *WAVE* Currently logged onto Pierce's LE1700 as Doug Pierce (dpierce) 2:11:29 PM

# Days	Task	Benefit
0	Record patient data on <u>digital</u> forms	No Paper
0	<u>Automatically</u> record to database	No Errors
0	<u>Remotely</u> review source docs	No Travel



Technologies:

ePRO, Tablets, Fax/OCR,
Digital Pen/Paper, EMRs

Applications:

Study Visit Information,
Conmeds, Med History,
Drug Accountability, AEs,
Patient Consents, etc.

Source Document	CRF
Original Record	Temporary Copy
Comprehensive Content	Limited Dataset
Clinical Focus (GCP)	Data Focus
Investigator Control	Sponsor Control
REVIEWED for context, safety, trends, compliance	VERIFIED for accuracy, validity, errors
NECESSARY	UNNECESSARY

CRF vs Source

VITAL SIGNS Patient: ---/

Vital Signs	
1.	Enter assessment date if different from visit date [] / [] / []
2.*	Position for Blood Pressure and Pulse Rate <input checked="" type="radio"/> sitting <input type="radio"/> semi-recumbent <input type="radio"/> standing <input type="radio"/> supine <input type="radio"/> prone
3.*	Blood Pressure (Systolic/Diastolic) 141 / 84 mmHg
4.*	Weight 90.6 <input type="radio"/> lb <input checked="" type="radio"/> kg
5.*	Height 165.8 <input type="radio"/> in <input checked="" type="radio"/> cm
6.	Body Mass Index 33.0 kg/m ²

CRF vs Source

VITAL SIGNS: (After 5 min seated & 1-2 min apart)

Use Digital Bp Tru cuff

Use Non-dominant arm (preferred)

**Use Hide Mode, leave the room to allow Digital machine to acquire all 6 BP's*

Average BP's 3, 4, & 5; then insure that each BP does not differ > 5mmHg of the average BP.

Blood pressure: (after sitting 5 min. & 1-2 min apart)

Arm: R or L Cuff Size: Reg. or Large

1) Time: <u>10:28</u>	BP: <u>132/82</u> mmHg	Pulse: <u>78</u> bpm
2) Time: <u>10:30</u>	BP: <u>149/81</u> mmHg	Pulse: <u>81</u> bpm
3) Time: <u>10:32</u>	BP: <u>131/84</u> mmHg	Pulse: <u>79</u> bpm
4) Time: <u>10:34</u>	BP: <u>144/85</u> mmHg	Pulse: <u>84</u> bpm
5) Time: <u>10:36</u>	BP: <u>123/78</u> mmHg	Pulse: <u>79</u> bpm
6) Time: <u>10:38</u>	BP: <u>128/85</u> mmHg	Pulse: <u>85</u> bpm

Avg. BP: 133/82 repeat OK

*Weight: 90.6 kg = 199.6 lbs (2 consecutive measurements must not differ > 0.25kg)

*Weight: 90.4 kg = 199.6 lbs

(*Study Specific TANITA scale: w/o coat & shoes after voiding)

Height: 165.7cm Height: 165.8cm BMI: 33.3

(*should not differ > 2.5cm)

2nd BP

10:43	1) 129/83	78
10:45	2) 136/85	82
10:47	3) 127/86	80
10:49	4) 130/86	80
10:51	5) 139/86	79
10:53	6) 132/87	81

CRF vs Source

VISIT 4 : PHYSICAL EXAM - Form Version: 17-Nov-2008 18:25		
Site: Patient: Patient No: 8245-005		
Physical Exam		
1.	Enter assessment date if different from visit date	<input type="text"/> / <input type="text"/> / <input type="text"/>
2.	Result	<input type="radio"/> Normal <input type="radio"/> Abnormal (enter clinically significant findings on MH or AE form)

CRF vs Source

Physical Exam				
	V1	V4 (Day -1)	V7 (Wk 6) / ET	
BODY SYSTEM	Normal	Abnormal	CHANGE FROM V2 <input type="checkbox"/> NA @ V2	specify the abnormalities
GENERAL APPEARANCE			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
SKIN			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
HEENT			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
HEART			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
LUNGS			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
ABDOMEN			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
REFLEXES			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
LYMPH NODES			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
NERVOUS SYSTEM			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
EXTREMITIES			<input type="checkbox"/> CS <input type="checkbox"/> NCS	
OTHER			<input type="checkbox"/> CS <input type="checkbox"/> NCS	

Investigator's Signature _____ Date ____/____/____

Investigator's Signature _____ Date ____/____/____

Co-sign if Necessary

- Enter data ONCE!
 - More time with patients (or recruiting)
- Validated data at time of capture
 - Fewer queries, data omissions and errors
- Familiar document-based solution
 - Ease of use and limited training
- Supports effective patient interaction
 - Maintain eye contact, freedom of motion

- Eliminate Source Data Verification
 - Most monotonous activity; fewer queries
 - Fewer on-site visits but more frequent interactions
- Focus on Source Document Review
 - Evaluate source for higher value context
- Prepared prior to a site visit
 - More productive on-site time; recruitment/compliance
- Audit trail of source document
 - Who filled out data, when, what changed, why?

- **Explicit Cost Reduction; Definitive ROI**
 - Reduced monitoring visits (time & length)
 - Eliminate 60-70% data queries
- **Immediate availability of validated data**
 - 100% source data verification; NO data errors
 - Reduces “dead” time and “crunch” time
- **Site analytics/reporting**
 - Automated capture of metrics

- EMRs are “*ultimate*” eSource goal
 - Limited data (demographics and labs)
 - Inflexible environment; different purpose
 - Inability to define what you need
 - Discrepancy between CODING and DISEASE
 - UK experience?
 - Not technically practical/possible

Solve the problem at the SOURCE

eSource addresses biggest cost/resource constraints

- EDC has run its course – no impact on study cost

ROI can be calculated definitively

- Query cost * # queries reduced
- Monitor visit cost * # visits eliminated

Sites growing intolerant of ineffective systems

eSource actually satisfies ALCOA criteria better than paper

Attributable – username/password

Legible – handwriting recognition

Contemporaneous/**O**riginal – date/time record at time of patient visit

Accurate – Instant edit checks, guided data entry

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DIGITAL SOURCE DOCUMENTS



Keep the pen. Not the paper.™