

Premier Research

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Paper Case Report Form (CRF) Design Tools

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**PREMIER
RESEARCH**

Objectives

This presentation will...

- Review CRF Design Tools that may be used with OC's GLIB
- Discuss today's leading applications in this industry
- Illuminate **Features** and detail **Usability** of each tool
- Touch upon **Print Layout Quality** and **Cost** of each tool
- Create your own paper 'CRF Library'



Agenda

- 1. Form Design Software Assessment**
- 2. Design Tool Key Features**
- 3. Develop & Maintain Your 'CRF Library'**
- 4. Summary and Questions**



1. Form Design Software Assessment

1a.) What is form design software?

1b.) What are the CRF format Pros & Cons?

1c.) Which are the top technologies?

1a.) What is form design software?

- It is a software product used to develop CRFs for the collection of subject trial data.
- Form design software are platforms especially manufactured with explicit page layout capabilities. (i.e. blank spaces for data insertion)
- CRFs are functionally designed for:
 1. recording data on the form
 2. data entry into the computer
 3. data retrieval for analysis

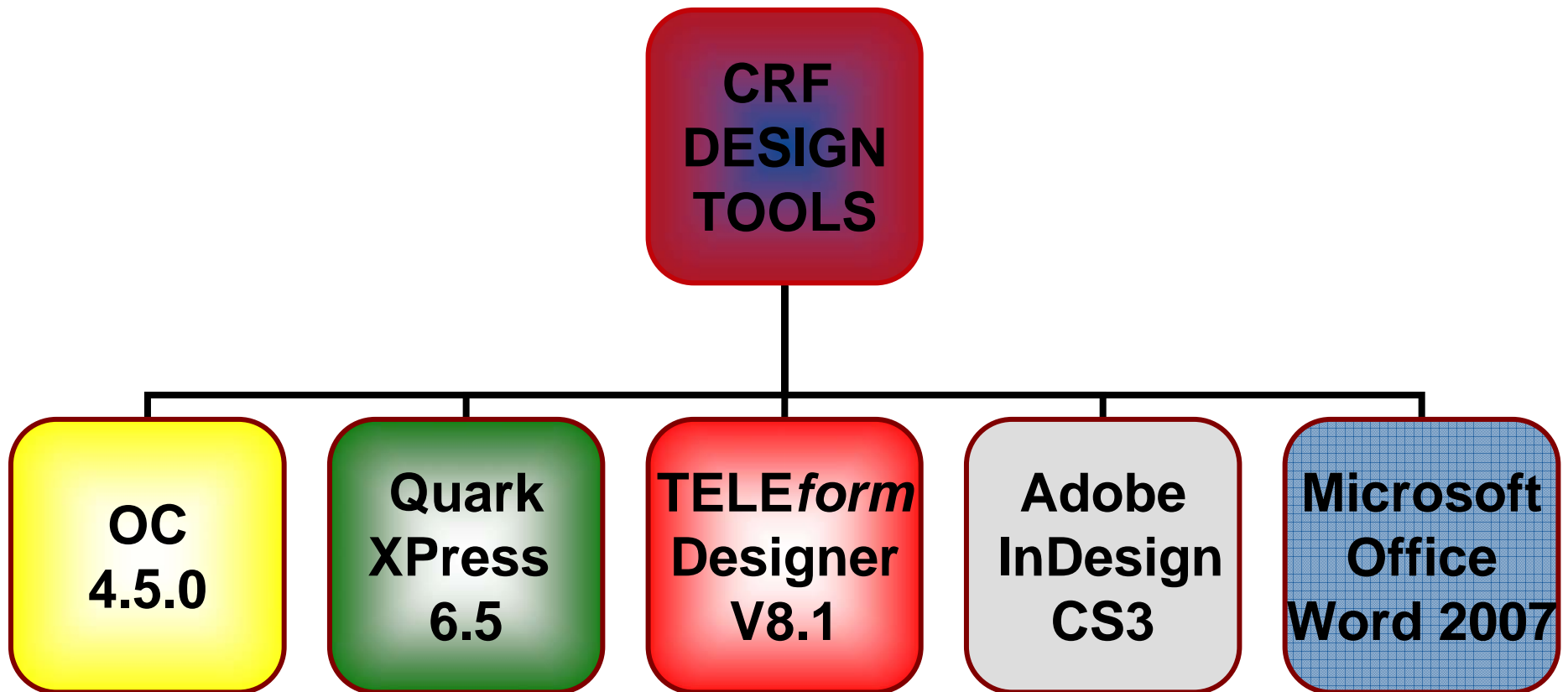


1b.) What are the CRF format Pros & Cons?

CRF Format	Pros	Cons
Paper	<ul style="list-style-type: none"> • Usability ~ Less Difficult • Print Layout Quality ~ High • CRF Design Aesthetics ~ High • IT issues ~ Less 	<ul style="list-style-type: none"> • Cost ~ Higher • Industry ~ Not Preferred • Build DB / CRF ~ Separately • 'CRF Library' ~ Develop • CRF objects ~ Develop
Electronic	<ul style="list-style-type: none"> • Cost ~ Lower • Industry ~ Preferred • Build DB / CRF ~ Simultaneously • OC Global Library ~ Available • GLIB objects ~ Approved / Reuse 	<ul style="list-style-type: none"> • Usability ~ More Difficult • Print Layout Quality ~ Low • CRF Design Aesthetics ~ Low • IT issues ~ Greater

1c.) Which are the top technologies?

- These are the 5 leading tools available today.
- Choose a tool specializing in form production.



OC User Interface

OC
4.5.0

ADVE_V1_1_RDC SUBSET 1 LAYOUT 1 ADVERSE EVENT (ADVE01) - FOR RDC ONLY

File Edit Resize View Format Arrange Order Block Help

Zoom: 100% Not Laid Out

Arial 9 B I

ADVERSE EVENT (AE) REPORT Record all adverse events regardless of suspected study treatment causality.

NO ADVERSE EVENT

AE Site (Check (X) ONE only) OTHER LEFT EYE RIGHT EYE BOTH EYES

Adverse Event (If possible specify diagnosis, not individual symptoms) ADVE_TERM

Date of Onset (dd-MMM-yyyy): START_DATE (24 hour clock): Time of Onset START TIM

SEVERITY (Check (X) ONE only) MILD MODERATE SEVERE

ACTION (Check (X) all relevant actions)

Study treatment dose: (Check (X) ONE only and enter details in study treatment section)

NO ACTION TAKEN INCREASED REDUCED

STOPPED TEMPORARILY PERMANENTLY DISCONTINUED

Background study treatment dose: (Check (X) ONE only and enter details in study treatment section)

NO ACTION TAKEN INCREASED REDUCED

STOPPED TEMPORARILY PERMANENTLY DISCONTINUED

Subject: (Check (X) all relevant options and enter details in concomitant treatment section if applicable)

Withdrawn from study

Treatment given (specify details in concomitant treatment section)

Other (specify)

CAUSALITY: Is there a reasonable possibility the adverse event is related study treatment? YES UNKNOWN NO

If No, what was the most likely cause of the AE? (Check (X) ONE only)

DISEASE UNDER STUDY

BACKGROUND STUDY DRUG

OTHER ILLNESS (specify)

CONCOMITANT TREATMENT

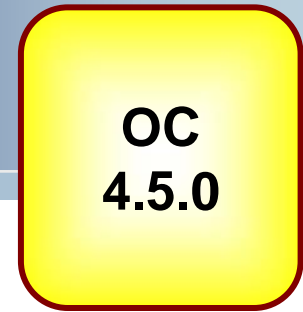
Block 1 : x: 27.1, y: 1.8

Record: 1/1 <OSC> 8

This is a screen shot of OC's toolbar layout in the Graphical Layout Editor (GLE).

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RESEARCH

OC example CRF – draft



ADVERSE EVENT (AE) REPORT Record all adverse events regardless of suspected study treatment causality.

NO ADVERSE EVENT

AE Site (Check (X) ONE only) OTHER LEFT EYE RIGHT EYE BOTH EYES

Adverse Event
(If possible specify
diagnosis, not
individual symptoms)

Date of Onset (dd-MMM-yyyy):

Approximate date if actual not known) - -

(24 hour clock):

Time of Onset :

SEVERITY (Check (X) ONE only) MILD MODERATE SEVERE

ACTION (Check (X) all relevant actions)

Study treatment dose: (Check (X) ONE only and enter details in study treatment section)

NO ACTION TAKEN INCREASED REDUCED
 STOPPED TEMPORARILY PERMANENTLY DISCONTINUED

Background study treatment dose: (Check (X) ONE only and enter details in study treatment section)

NO ACTION TAKEN INCREASED REDUCED
 STOPPED TEMPORARILY PERMANENTLY DISCONTINUED

Subject: (Check (X) all relevant options and enter details in concomitant treatment section if applicable)

Withdrawn from study
 Treatment given (specify details in concomitant treatment section)
 Other (specify)

This is the same CRF Adverse Event (AE) page produced directly from OC's GLE with approved Global Library objects.

If No, what was the most likely cause of the AE? (Check (X) ONE only)

DISEASE UNDER STUDY
 BACKGROUND STUDY DRUG
 OTHER ILLNESS (specify)
 CONCOMITANT TREATMENT
DRUG OR NONDRUG (specify)
 OTHER (specify)

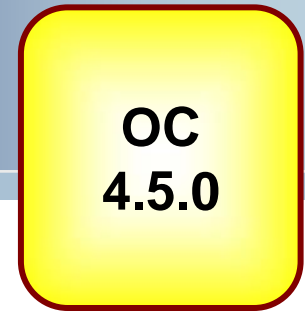
DEVICE VIGILANCE

Was the AE device related?

YES NO



OC example CRF – final



Protocol ID: CENTER SUBJECT ID
DATE OF VISIT
dd MM yyyy
Visit: Page:

ADVERSE EVENT (AE) REPORT Record all adverse events regardless of suspected study treatment causality.

NO ADVERSE EVENT

AE Site (Check (X) ONE only) OTHER LEFT EYE RIGHT EYE BOTH EYES

Adverse Event (If possible specify diagnosis, not individual symptoms)

Date of Onset (dd-MMM-yyyy): -- (24 hour clock): :

SEVERITY (Check (X) ONE only) MILD MODERATE SEVERE

ACTION (Check (X) all relevant actions)

Study treatment dose: (Check (X) ONE only and enter details in study treatment section)

NO ACTION TAKEN INCREASED REDUCED
 STOPPED TEMPORARILY PERMANENTLY DISCONTINUED

Background study treatment dose: (Check (X) ONE only and enter details in study treatment section)

NO ACTION TAKEN INCREASED REDUCED
 STOPPED TEMPORARILY PERMANENTLY DISCONTINUED

Subject: (Check (X) all relevant options and enter details in concomitant treatment section if applicable)

Withdrawn from study
 Treatment given (specify details in concomitant treatment section)
 Other (specify)

This is the same CRF AE page as OC's print-ready CRF in PDF format with header and footer.

If No, what was the most likely cause of the AE? (Check (X) ONE only)

DISEASE UNDER STUDY
 BACKGROUND STUDY DRUG
 OTHER ILLNESS (specify)
 CONCOMITANT TREATMENT DRUG OR NONDRUG (specify)
 OTHER (specify)

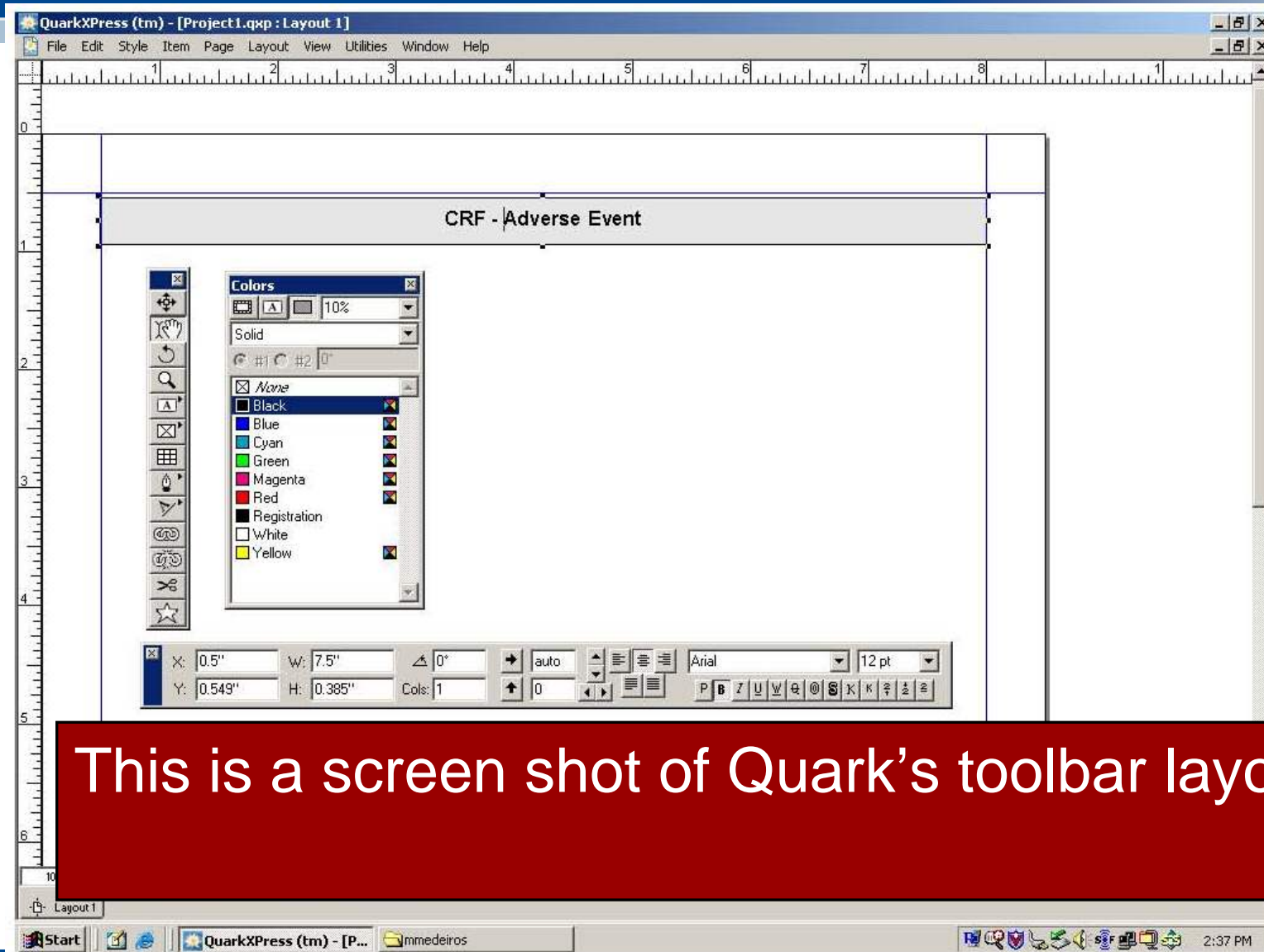
DEVICE VIGILANCE Was the AE device related? YES NO

FOR USE ONLY -Case ID #



Quark User Interface

Quark
XPress
6.5



This is a screen shot of Quark's toolbar layout.

Quark example CRF

Quark
XPress
6.5

	Site #	Subject #	Subject Initials
	□ □ □	□ □ □	□ □ □

Adverse Events Log

Has the patient experienced any Adverse Events (new signs, symptoms or diagnoses) since Baseline, or an exacerbation in a preexisting condition recorded in the Medical History? No Yes

Adverse Event Description	Duration	Tx Required <small>(Con Med reported)</small>	Serious <small>(S AE report attached)</small>	Toxicity Level/Severity	Relationship to Study Drug	Action Taken w/ Study Drug	Outcome
	Start Date □□-□□-□□□□ <small>day month year</small> Stop Date □□-□□-□□□□ <small>day month year</small>	<input type="checkbox"/> No <input type="checkbox"/> Yes*	<input type="checkbox"/> No <input type="checkbox"/> Yes**	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Life Threatening	<input type="checkbox"/> Not related <input type="checkbox"/> Unlikely Related <input type="checkbox"/> Probably Related <input type="checkbox"/> Definitely Related	<input type="checkbox"/> None <input type="checkbox"/> Temporarily Discontinued <input type="checkbox"/> Permanently Discontinued	<input type="checkbox"/> Resolved; no residual effects <input type="checkbox"/> Resolved; residual effects <input type="checkbox"/> Continuing <input type="checkbox"/> None <input type="checkbox"/> Death
	Start Date □□-□□-□□□□ <small>day month year</small>	<input type="checkbox"/> No <input type="checkbox"/> Yes*	<input type="checkbox"/> No <input type="checkbox"/> Yes**	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Not related <input type="checkbox"/> Unlikely Related <input type="checkbox"/> Possibly Related	<input type="checkbox"/> None <input type="checkbox"/> Temporarily Discontinued <input type="checkbox"/> Permanently Discontinued	<input type="checkbox"/> Resolved; no residual effects <input type="checkbox"/> Resolved; residual effects

This is Quark's print-ready CRF with customized QuarkXTensions modules with a header and footer.

	Stop Date □□-□□-□□□□ <small>day month year</small>			<input type="checkbox"/> Life Threatening <input type="checkbox"/> Probably Related <input type="checkbox"/> Definitely Related	<input type="checkbox"/> Discontinued <input type="checkbox"/> Continuing <input type="checkbox"/> None <input type="checkbox"/> Death
--	--	--	--	---	---

* If treatment is required for an Adverse Event, please record the corresponding Con Med on the Concomitant Medications page.

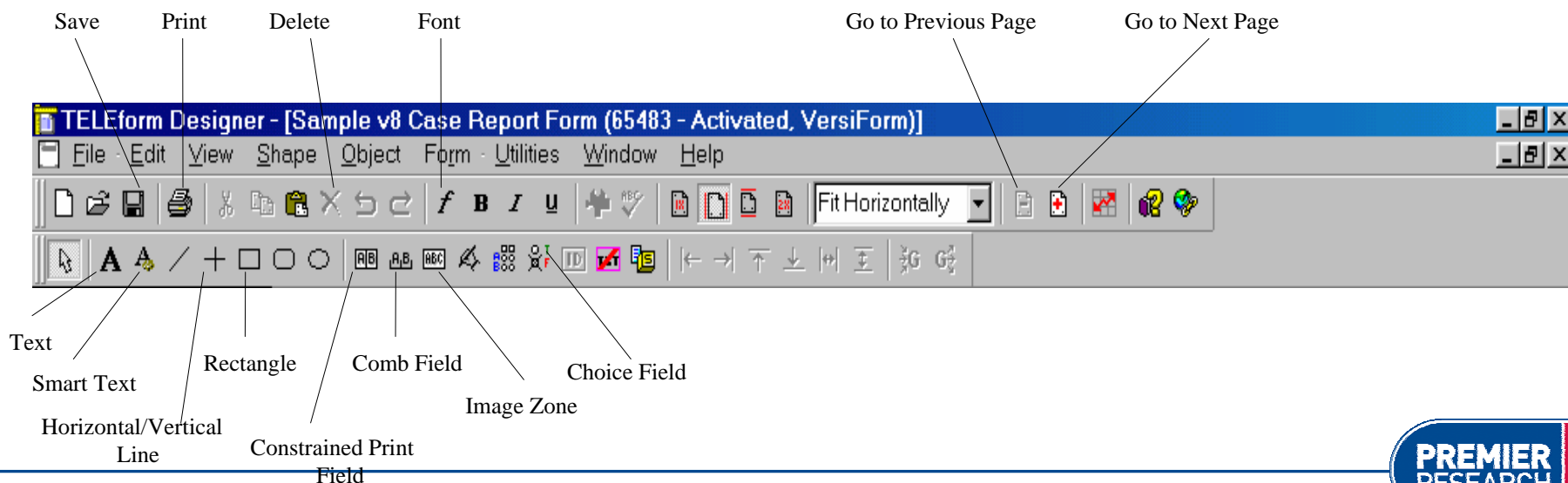
** If an Adverse Event is serious, please complete and attach a corresponding Serious Adverse Event report and notify the Sponsor within 24 hours.

TELEform User Interface

TELEform
Designer
V8.1

- Do you recognize the menu structure?
- Some of TELEform's toolbar buttons or icons are identical to those you see in other Windows-based programs.

This is a screen shot of TELEform's toolbar layout.



TELEform example CRF

TELEform
Designer
V8.1

Visit: AE 1

Center: [REDACTED] Subject ID: [REDACTED]

Date of Visit: dd - MMM - yyyy

Subject Initials: [REDACTED] Page 12001

Please print all details, and INITIAL and DATE all corrections. Indicate where applicable.

Form 19 - Adverse Event

(1) ADVERSE EVENT (Record only one per page)
Condition/Diagnosis or if No AEs, write in 'NONE' (all caps)

(2) Was this event treatment emergent?
Definition:
-Any event not seen during Screening or Baseline and not recorded as continuing on Medical History,
OR
-Any event that has worsened relative to Screening, Baseline, or Medical History.
 1 No, or the event occurred before active treatment
 2 Yes

(3) SERIOUS ADVERSE EVENT
 1 No
 2 Yes, includes at least one of the following:
-Death
-Life-threatening adverse event
-Inpatient hospitalization required
-Hospitalization prolonged
-Persistent or significant disability/incapacity
-Congenital anomaly/birth defect

(4) CLINICAL OUTCOME

(5) NATURE OF EVENT
 1 Single episode
 2 Multiple episode

(6) INTENSITY
 1 Mild
 2 Moderate
 3 Severe

(7) RELATIONSHIP TO STUDY DRUG - PHYSICIAN'S ASSESSMENT
 1 Definitely not
 2 Unlikely
 3 Possibly
 4 Probably
 5 Definitely
 7 Unknown (According to regulations, "Unknown" will be interpreted as "Possibly" Related.)

(8) ACTION TAKEN REGARDING STUDY DRUG DOSAGE (for this Adverse Event only)
 1 None
 2 Dose reduced
 3 Dose interrupted
 4 Discontinued (Complete appropriate Patient Status form)

(9) CLINICAL OUTCOME

Time Entered: (24-Hour Clock) [REDACTED] or 1 Continuing 2 Yes, (specify below)

(11) Comments (Please print):
[REDACTED] (select the comment tool on the tool bar)

Procedure: _____
Date Began: (Day/Month/Year) [REDACTED]
Serious AE # [REDACTED]

INVESTIGATOR'S SIGNATURE: (Investigator must sign and date this form) [REDACTED] DATE: _____

Yellow - Investigator's Copy

This is TELEform's CRF in PDF format with Shape Library modules with a header and footer.

2. Design Tool Key Features

2a.) Which key features are for you?

2b.) How do your features compare?

2c.) What are the overall Pros & Cons?

2a.) Which key features are for you?

> Study Type



> Usability



> Print Layout Quality



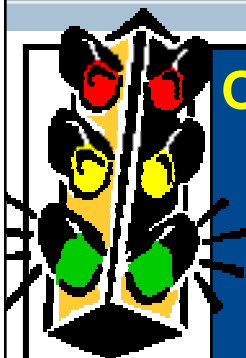
> Cost



2b.) How do your features compare?

KEY Features	OC OC 4.5	QUARK Quark XPress 6.5	TELEform TELEform Designer v8.1
Study Type	<ul style="list-style-type: none"> • Paper • Electronic 	<ul style="list-style-type: none"> • Paper • Electronic 	<ul style="list-style-type: none"> • Paper • Electronic
Usability	<ul style="list-style-type: none"> • Training • Global Library • OC interface • RDC & GLE • Build DB / CRF 	<ul style="list-style-type: none"> • Training • XTensions modules • Windows interface • Form Controls • Traditional order 	<ul style="list-style-type: none"> • Training • Shape Library • Windows interface • Form Toolbar • Traditional order
Print Layout Quality	<ul style="list-style-type: none"> • Many steps • PDF quality • Add software 	<ul style="list-style-type: none"> • Print-ready • Excellent quality • Inclusive software 	<ul style="list-style-type: none"> • Print to PDF • PDF quality • Add software
Cost	<ul style="list-style-type: none"> • Negligible • Use OC 4.5 	<ul style="list-style-type: none"> • Moderate price • Use design features 	<ul style="list-style-type: none"> • Expensive • Use form features

2c.) What are the overall Pros & Cons?



OC

**OC
4.5**

QUARK

**Quark
XPress
6.5**

TELEform

**TELEform
Designer
v8.1**

Pros

- **Cost**
- GLIB approved
- Build DB / CRF

- **Print Layout Quality**
- **Usability**
- Inclusive software

- Form toolbar
- Shape Library
- Use form features

Cons

- **Usability**
- Add software
- IT issues

- **Cost**
- Library development
- Creative design tool

- **Cost**
- Add software
- Only form design

3. Develop & Maintain Your ‘CRF Library’”

3a.) How do you establish and standardize a paper ‘CRF Library’?

3b.) How can paper CRFs consider DB design and reuse of OC’s GLIB objects?

3c.) Should paper CRFs match OC screenshots of the same CRF?

3a.) How do you establish and standardize a paper 'CRF Library'?

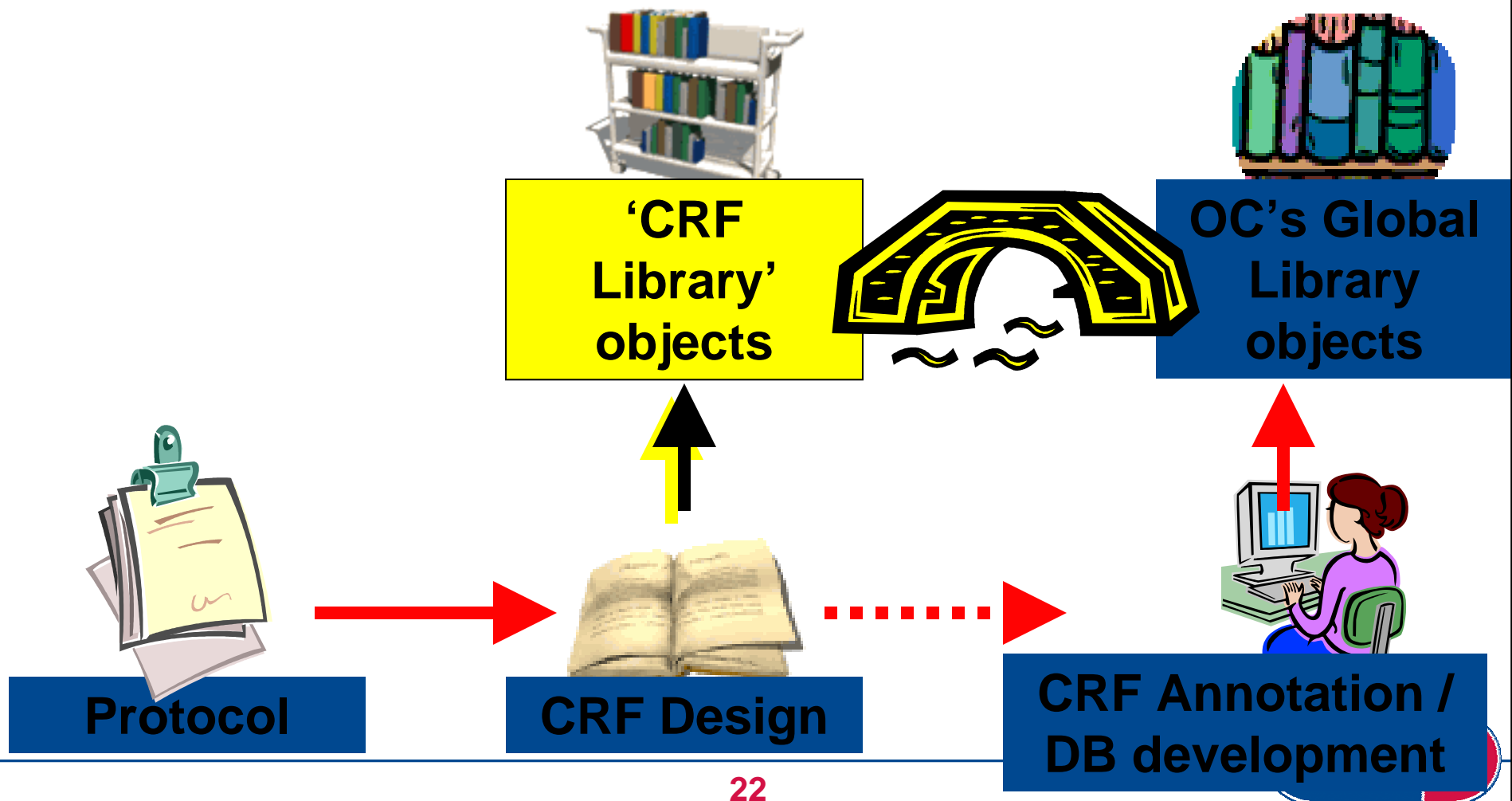
- Remember: Your CRF is designed to collect complete clinical trial study data and to ensure data standardization and consistency across all participating investigational sites.
- OC's GLIB is separated by domain with standard objects in each domain. Your paper 'CRF Library' should be separated into these same domains (therapeutic area, compound, sponsor, etc.).
- A formal approval and / or Quality Control (QC) process should be in place for all new objects needed on a CRF.
- Adopt a naming convention - i.e. the CDISC (Clinical Data Interchange Standards Consortium)

3b.) How can paper CRFs consider DB design and reuse of GLIB objects?

- Train CRF Designers in OC to **BRIDGE** the gap between paper CRF Design and OC DB Build
- Design the CRF with OC's GLIB and with OC compatibility and restrictions in mind
- Matching the CRFs with OC's objects easily promotes a standard 'CRF Library' and reuse of objects
- OC's GLIB enforces standard questions and QG. Therefore, CRFs should enforce the same standards.

BRIDGE between paper CRF Design and OC DB Build

BRIDGE the gap between both library's objects:



3c.) Should paper CRFs match OC screenshots of the same CRF?

- Paper CRFs may or may not match the Data Entry (DE) screen.
- In many cases, DE guidelines and study-specific training are needed to avoid errors in DE.
- Benefits of the **BRIDGE** are:
 1. easier data entry with fewer errors.
 2. less study-specific training and guidelines are required.



Example - Paper CRF Library object

PRIOR PROCEDURES OR EVALUATIONS PERFORMED FOR PRIMARY DIAGNOSIS

Note: Procedures to be recorded include head CT and/or MRI, endoscopy, gastric emptying, ultrasound, etc.

PD
pdrgg
PD

Procedure:	PROC Char(30)
Assessment Date:	PROCDT DATE ____-____-____ (Day) (Month) (Year)
<input type="checkbox"/> Normal CLINSG *{ NORMAL_ABNORMAL} Char (30) <input type="checkbox"/> Abnormal, not clinically significant (please comment) <input type="checkbox"/> Abnormal, clinically significant (please comment)	Comments: PDCOM Char(200)

Procedure:	
Assessment Date:	____-____-____ (Day) (Month) (Year)
<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, not clinically significant (please comment) <input type="checkbox"/> Abnormal, clinically significant (please comment)	Comments:

Procedure:	
Assessment Date:	____-____-____ (Day) (Month) (Year)
<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, not clinically significant (please comment) <input type="checkbox"/> Abnormal, clinically significant (please comment)	Comments:

Paper 'CRF
Library'
object -
(PD)
Repeating
group

Example - OC GLIB object

PRIOR PROCEDURES OR EVALUATIONS PERFORMED FOR PRIMARY DIAGNOSIS

Prior Procedure	<input type="text" value="PROC"/>
Procedure Date	<input type="text" value="PROCDT"/>
Clin Sign	<input type="text" value="CLNSG"/>
Procedure Comments	<input type="text" value="PDCOM"/>

OC GLIB
object –
(PD)
Repeat
question
1 of 3

4. Summary and Questions

1. Form Design Software Assessment

- 1a.) What is form design software?
- 1b.) What are the CRF format Pros & Cons?
- 1c.) Which are the top technologies?



2. Design Tool Key Features

- 2a.) Which key features are for you?
- 2b.) How do your features compare?
- 2c.) What are the overall Pros & Cons?

3. Develop & Maintain Your 'CRF Library'

- 3a.) How do you establish and standardize a paper 'CRF Library'?
- 3a.) How can paper CRFs consider DB design and reuse of GLIB objects?
- 3c.) Should paper CRFs match OC screenshots of the same CRF?



Paper Case Report Form (CRF) Design Tools

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