



OpenClinica
Better data, faster.

Good Form

Designing Your eCRFs for Better Data, Faster



Today's Presenter



Bryan Farrow, eClinical Catalyst at
OpenClinica, LLC

Likes: Intelligible data, clear communication,
logic and set theory, stellar user
experiences

Dislikes: Paper forms, poor design,
ambiguity, web experiences reminiscent of
1998

A Tale of Two Forms

Table 1: Illustrating a well-designed and poorly designed data fields imparting the significance of visual cues to help the site personnel to understand the format

Poorly designed	Well designed
Date of visit: _____	Date of visit: □□/□□/□□□□ (DD/MM/YYYY)
Blood pressure: ____ / ____	Blood pressure: □□□/□□□ (mmHg)
Pulse: _____	Pulse: □□□ (beats/min)
Temperature: _____	Temperature: □□.□ (°C)
Respiration: _____	Respiration: □□ (/min)

« November 2018 »

Su	Mo	Tu	We	Th	Fr	Sa
28	29	30	31	1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	1
2	3	4	5	6	7	8

2018-11-22

Systolic blood pressure <i>(mmHg)</i> 100	Diastolic blood pressure <i>(mmHg)</i> 120 Diastolic pressure must be lower than systolic pressure.	Pulse <i>(beats/min)</i> 80	Respiration <i>(breaths/min)</i> 08 Respiration must be between 10 and 60 breaths per minute.
Was temperature measured? <input checked="" type="radio"/> Yes, in Fahrenheit (°F) <input type="radio"/> Yes, in Celcius (°C) <input type="radio"/> No	Temperature: 96.5	96.5 °F is equivalent to 35.8 °C. Analysis will use the Celcius value.	

Source (left image): Bellary S, Krishnankutty B, Latha M S. Basics of case report form designing in clinical research. *Perspect Clin Res* [serial online] 2014 [cited 2018 Nov 26];5:159-66. Available from: <http://www.picronline.org/text.asp?2014/5/4/159/140555>

A Tale of Two Forms


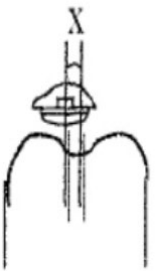
LATERAL DISPLACEMENT (check one)

(1) No

(2) Yes

Distance (in mm)

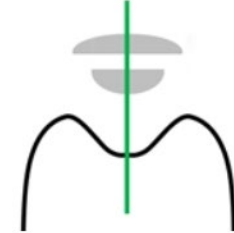
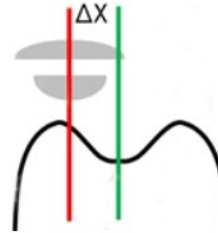
Elsewhere throughout this study:
1 = Yes
2 = No



* Lateral displacement? 

Yes

No



A Tale of Two Forms

Parameter	Assessment
Historical Data	
Fat: A	<input type="radio"/> 0: None <input type="radio"/> 1: 0-5% <input type="radio"/> 2: 6-33% <input type="radio"/> 3: 34-66% <input type="radio"/> 4: >66% ^{Pb}
Lobular Inflammation:	<input type="radio"/> 0: None <input type="radio"/> 1: Mild or few <input type="radio"/> 2: Moderate <input type="radio"/> 3: Marked or many ^{Pb}
Portal Inflammation:	<input type="radio"/> 0: None <input type="radio"/> 1: Mild or few <input type="radio"/> 2: Moderate <input type="radio"/> 3: Marked or many ^{Pb}
Ballooning:	<input type="radio"/> 0: None <input type="radio"/> 1: Mild or few <input type="radio"/> 2: Moderate <input type="radio"/> 3: Marked or many ^{Pb}
Mallory Bodies:	<input type="radio"/> 0: None <input type="radio"/> 1: Mild or few <input type="radio"/> 2: Moderate <input type="radio"/> 3: Marked or many ^{Pb}
Pericellular Fibrosis:	<input type="radio"/> 0: None <input type="radio"/> 1: Mild or few <input type="radio"/> 2: Moderate <input type="radio"/> 3: Marked or many ^{Pb}
Portal Fibrosis:	<input type="radio"/> 0: None <input type="radio"/> 1: Mild or few <input type="radio"/> 2: Moderate <input type="radio"/> 3: Marked or many ^{Pb}
Bridging Fibrosis:	<input type="radio"/> 0: Absent <input type="radio"/> 1: Few <input type="radio"/> 2: Many ^{Pb}
Cirrhosis:	<input type="radio"/> 0: Absent <input type="radio"/> 1: Incomplete <input type="radio"/> 2: Established ^{Pb}
Ishak Stage:	<input type="radio"/> 0: None ^{Pb} <input type="radio"/> 1: Portal (some) <input type="radio"/> 2: Portal (most) <input type="radio"/> 3: Occasional bridging <input type="radio"/> 4: Marked bridging <input type="radio"/> 5: Incomplete cirrhosis <input type="radio"/> 6: Established cirrhosis
NAS	
Fat: B	<input type="radio"/> 0: <5% <input type="radio"/> 1: 6-33% <input type="radio"/> 2: 34-66% <input type="radio"/> 3: >66% ^{Pb}
Ballooning:	<input type="radio"/> 0: None <input type="radio"/> 1: Few <input type="radio"/> 2: Many ^{Pb}
Lobular Inflammation:	<input type="radio"/> 0: None <input type="radio"/> 1: <2 per 20X field <input type="radio"/> 2: 2-4 per 20X field <input type="radio"/> 3: >4 per 20X field ^{Pb}
Stage:	<input type="radio"/> 0: None <input type="radio"/> 1: Perisinusoidal <input type="radio"/> 2: Perisinusoidal and portal/periportal <input type="radio"/> 3: Bridging <input type="radio"/> 4: Cirrhosis ^{Pb}
SAFIFLIP	
Fat: C	<input type="radio"/> 0: <5% <input type="radio"/> 1: 6-33% <input type="radio"/> 2: 34-66% <input type="radio"/> 3: >66% ^{Pb}

NAFLD Assessment

Histology

Fat <input type="radio"/> <5% <input type="radio"/> 5-33% <input type="radio"/> 34-66% <input type="radio"/> >66%	Bridging Fibrosis <input type="radio"/> Absent <input type="radio"/> Few <input type="radio"/> Many																				
Cirrhosis <input type="radio"/> Absent <input type="radio"/> Incomplete <input type="radio"/> Established	Ishak Stage <input type="text" value="none selected"/>																				
	<table border="1"> <thead> <tr> <th></th> <th>None</th> <th>Mild or few</th> <th>Moderate</th> <th>Marked or many</th> </tr> </thead> <tbody> <tr> <td>Lobular Inflammation</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Portal Inflammation</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>Ballooning</td> <td><input type="radio"/></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		None	Mild or few	Moderate	Marked or many	Lobular Inflammation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Portal Inflammation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Ballooning	<input type="radio"/>			
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Portal Inflammation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>																	
Ballooning	<input type="radio"/>																				

NAS

Fat

<5%
 5-33%
 34-66%
 >66%

Source (left image): Flaskdata.io website (blog). "2 mistakes you do not want to make in your medical device clinical trial". 29 January 2016. Available from: <https://www.flaskdata.io/2-mistakes-you-do-not-want-to-make-in-your-medical-device-clinical-trial/>

How does the story end?

The Study with Well Designed Forms

- Because your forms are a joy to work with, **“time to entry” is shorter.**
- Because of proper item types and clarifying visuals, the **data is cleaner from the start.**
- Because of smart edit checks, **fewer queries are raised.**
- **Your database locks quicker and cleaner, with little missing data.**

The Study with Poorly Designed Forms

- Because the forms are confusing and unwieldy, CRCs postpone their data entry.
- Participants avoid your forms altogether!
- Unhelpful or absent edit checks let a lot of “dirt” in.
- **Database lock is delayed. Missing and invalid data undermine your results or submission.**

6 Principles of eCRF Design

1. **“Use the right tool for the job.”**
When to use number fields, checkboxes, radio buttons, etc.
2. **“Less is more.”**
Skip logic
3. **“Let the form do the work.”**
Calculations, scores and Boolean algebra
4. **“Check yourself.”**
How strict is too strict when it comes to edit checks?
5. **“Raise your standards.”**
CDISC and cross-study consistency
6. **“Know your audience.”**
Designing for CRCs and participants.

Principle #1

Use the right tool for the job.



Principle #1: Use the right tool for the job.

Decimal	Integer
<ul style="list-style-type: none">● Critical for many lab values (and a lot of clinical ones, too)● Allows for very precise data● Also opens the door to <i>false precision</i> (6.5 and 6.50 are not the same!)<ul style="list-style-type: none">○ Item instructions should specify desired level of precision (“nearest hundredth, i.e., 1.23”)○ Use regex to prompt a validation message if user inputs more or fewer decimal digits than desired <p>Recommended reading: Too many digits: the presentation of numerical data. Arch Dis Child. 2015;100(7):608-9.</p>	<ul style="list-style-type: none">● Vital sign units of measure (beats/min, mmHg), metric sub units (centimeters, milligrams)● Effective way to enforce whole number input, as the field typically won't recognize a “.”● But do not use integer fields when seeking an ordinal (e.g. rate pain from 1 to 10, 10 being most intense) <p>Recommended reading: https://www.mymarketresearchmethods.com/types-of-data-nominal-ordinal-interval-ratio/</p>

Principle #1: Use the right tool for the job.

Checkbox	Radio Button
<p data-bbox="343 361 388 380">Race</p> <ul data-bbox="343 399 823 674" style="list-style-type: none"><li data-bbox="343 399 739 426"><input type="checkbox"/> American Indian or Alaska Native<li data-bbox="343 440 450 467"><input checked="" type="checkbox"/> Asian<li data-bbox="343 480 662 507"><input checked="" type="checkbox"/> Black or African American<li data-bbox="343 520 823 548"><input type="checkbox"/> Native Hawaiian or Other Pacific Islander<li data-bbox="343 561 450 588"><input type="checkbox"/> White<li data-bbox="343 601 450 628"><input type="checkbox"/> Other<li data-bbox="343 642 755 669"><input type="checkbox"/> Undetermined/declined to answer <ul data-bbox="253 718 890 904" style="list-style-type: none"><li data-bbox="253 718 797 745">● For selecting one or more options<li data-bbox="253 758 890 904">● To ensure that item was not skipped:<ul data-bbox="343 798 890 904" style="list-style-type: none"><li data-bbox="343 798 739 825">○ Make the field required<li data-bbox="343 838 890 904">○ Include “none of the above” as an option	<p data-bbox="1049 369 1161 396">Ethnicity</p> <ul data-bbox="1049 423 1624 576" style="list-style-type: none"><li data-bbox="1049 423 1344 461"><input type="radio"/> Hispanic/Latino<li data-bbox="1049 475 1406 513"><input type="radio"/> Not Hispanic/Latino<li data-bbox="1049 526 1624 576"><input type="radio"/> Undetermined/declined to answer <ul data-bbox="1016 707 1696 887" style="list-style-type: none"><li data-bbox="1016 707 1537 734">● For selecting exactly one option<li data-bbox="1016 748 1696 887">● Ideal for nominal scales with 2 to 4 options<ul data-bbox="1107 784 1634 887" style="list-style-type: none"><li data-bbox="1107 784 1634 811">○ Indicating units of measurement<li data-bbox="1107 824 1421 851">○ Yes/no questions<li data-bbox="1107 864 1389 887">○ Nominal scales

Principle #1: Use the right tool for the job.

Pick list

1. Type of Cancer

none selected

Carcinoma

Sarcoma

Melanoma

Lymphoma

Leukemia

Germ Cell Tumors

- For selecting one or more options
 - But try to avoid “multi-select pick lists”, as they are rare and counter-intuitive; use checkboxes instead
- **Ideal for selecting exactly one of 5 or more options when:**
 - You want to save vertical space
 - Option labels are short and easily understood
- **Should never default to an option**

Recommended reading: <https://blog.prototypr.io/7-rules-of-using-radio-buttons-vs-drop-down-menus-fddf50d312d1>

Principle #1: Use the right tool for the job.

Date

The image illustrates the principle of using the right tool for the job in the context of date input in ECRFs. It shows three examples of date input fields:

- Left Example:** A form field labeled "Stop Date [YYYY-MM-DD]:" with a required field indicator (red asterisk) and a "This field is required" message. The input mask is "yyyy-mm-dd".
- Middle Example:** A calendar widget for November 2018, showing the date "2" selected. The input mask is "yyyy-mm-dd".
- Right Examples:** Two examples of date input fields with dropdown menus for format selection.
 - Top Right Example:** Labeled "Start Date of Usage" with a required field indicator. The input mask is "yyyy-mm-dd". The dropdown menu shows "YYYY-MM-DD" selected.
 - Bottom Right Example:** Labeled "Start Date [YYYY-MM]:" with a required field indicator. The input mask is "yyyy-mm". The dropdown menu shows "YYYY-MM-UNK" selected.

Principle #1: Use the right tool for the job.

Date

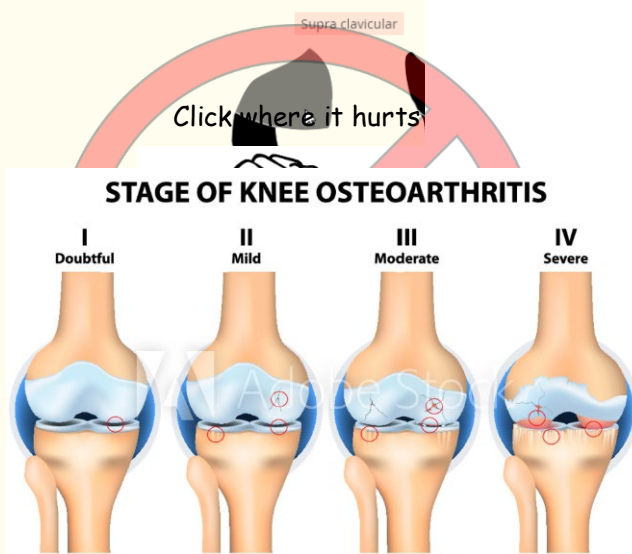
- CDISC / ISO8601 format is king! YYYY-MM-DD
- Do not assume the full date is available. Prompt the user to specify date precision.
- Use an input mechanism that:
 - Accommodates both point-and-click as well as typing
 - Allows for quick travel across months, years, and decades with point-and-click
 - Offers a calendar view



Principle #1: Use the right tool for the job.

Image maps and images as selection choices

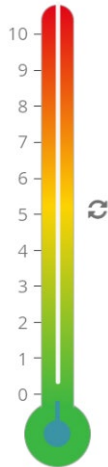
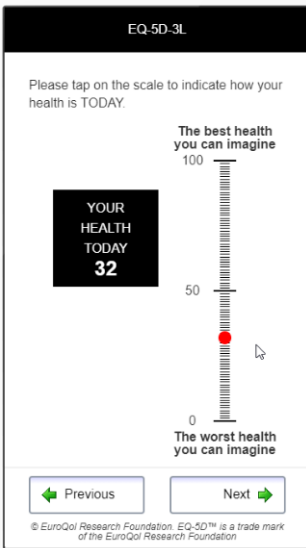
Select the area of injury



- Rare (and rarely among an EDC's feature set), but incredibly useful
- Selected regions of an image correspond to your code list options
- Overcome language barriers, medical vocabulary limitations
- Best implemented with professionally rendered web-based vector images (e.g. svg) that have been tested for reliability

Principle #1: Use the right tool for the job.

Visual analog scales

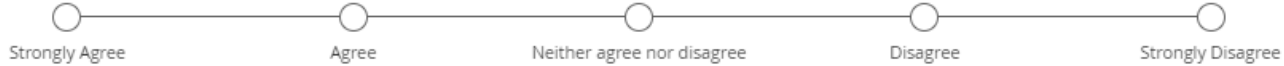


- Frequent component of PRO instruments
- Can be presented digitally, but licensed, validated instruments must meet equivalency standards
- Ideal use is in-clinic ePRO collected on a tablet, where the page rendering can be controlled

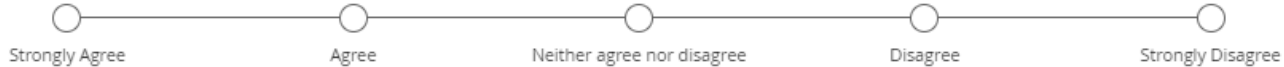
Principle #1: Use the right tool for the job.

Likert scales

I eat a balanced diet.



I get a lot of exercise.

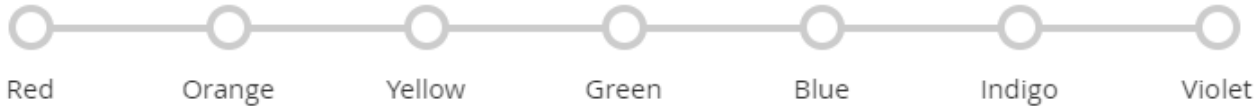


- Common and useful, but beware
- Should be used...
 - Almost exclusively as patient-facing scale
 - To measure intensity of agreement with a statement
- 5 or 7 points, with 1 neutral value
- Cannot assume this is an interval scale ("Strongly agree" may or may not represent twice as much agreement as "agree")

Principle #1: Use the right tool for the job.

Not likert scales!

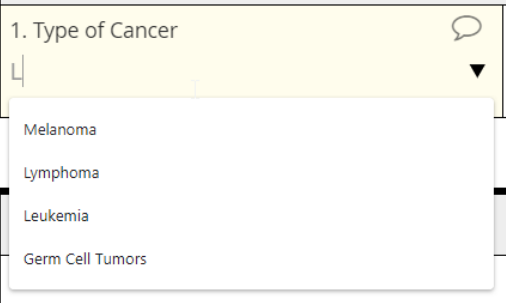

Which is your preferred color for a formal dress?



How often do you watch television?



Principle #1: Use the right tool for the job.

Autocomplete	Free text
 <ul style="list-style-type: none">● Ideal for select one of many options with similar spellings● Very intuitive and familiar (thanks Google!)● Can handle basic medical coding	

Principle #1: Use the right tool for the job.

Other “great-to-haves”

- “Any file” upload mechanism
- Draw field (including signature)
- Image annotation field
- Embedded video
 - Effective education tool for eConsent
 - Demonstrate procedures for CRCs (e.g. packaging lab samples)



Principle #1: Use the right tool for the job.

Design & layout considerations

- Item label above and left justified with selection choices (presented as a vertical list)
- Black text on a white background
- Color and bolding for key instructions only
- San serif fonts scale better
- Avoid item type variety for variety's sake
 - You don't hammer nails with a wrench.
 - Don't collect race with a Likert scale.



Principle #2

Less is more.



Principle #2: Less is more.

What do the following have in common?

- An item soliciting pregnancy status for a participant already identified as male
- An item soliciting participant age, when DOB was collected at screening
- A subtype checklist that includes 'Nodular lymphocyte-predominant Hodgkin lymphoma', when NHL was already identified as the participant's cancer type
- The phrase "if applicable"



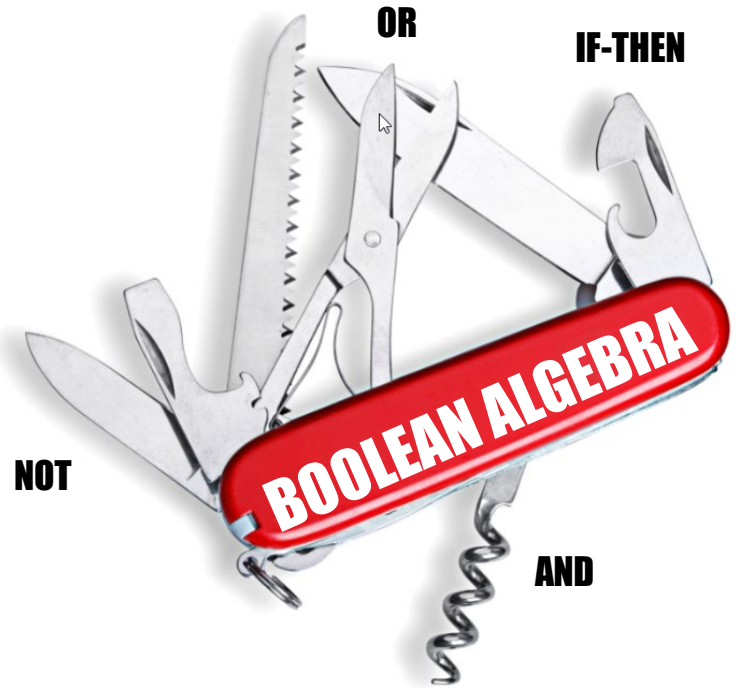
Principle #2: Less is more.



**THINGS THAT SHOULD
NEVER APPEAR ON
YOUR eCRF**

Principle #2: Less is more.

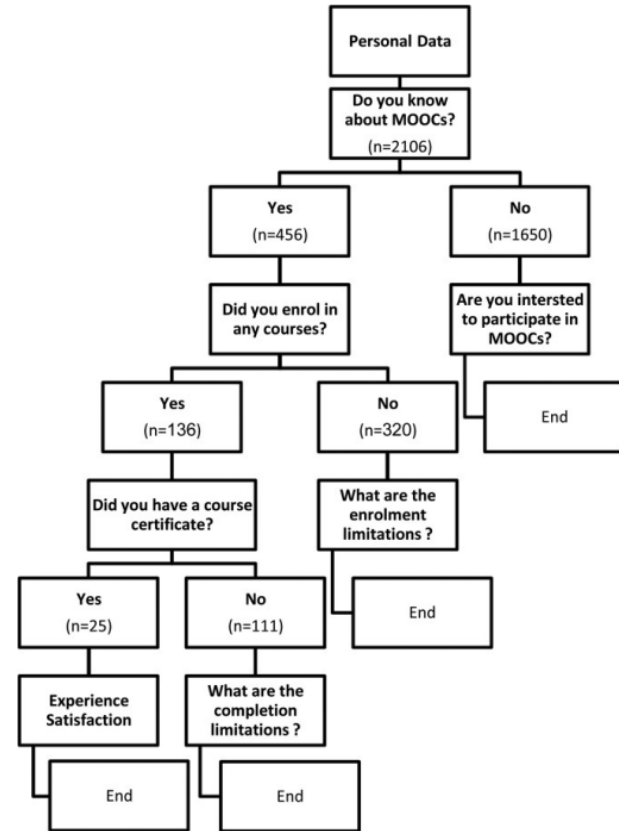
- Every EDC worthy of the name supports
 - Skip logic (a.k.a. branching logic)
 - Cross form edit checks
 - Complex validation rules
- The more capable ones support dynamic answer choices (one item whose list of options depends on prior input)
- **It's up to us to use these tools effectively**



Principle #2: Less is more.

Consider...

- For non-required measurements, asking if they were taken before presenting the relevant input fields
- Allowing the user to specify the units of measure, and using 'if-then' to perform conversions and activate the relevant constraint messages
- Using cross-form logic to determine whether items are necessary in the first place



Principle #2: Less is more.

Describe the AE:
Intermittent vertigo

Start Date 2018-10-29	Ongoing? <input type="radio"/> Yes <input checked="" type="radio"/> No	Stop Date yyyy-mm-dd	Toxicity Grade none selected
Relationship to Study Drug Possible	Expected <input type="radio"/> Yes <input checked="" type="radio"/> No	December 2018 Su Mo Tu We Th Fr Sa 25 26 27 28 29 30 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Outcome none selected
AE Serious? <input type="radio"/> Yes			

Describe the AE:
Intermittent vertigo

Start Date 2018-10-29	Ongoing? <input checked="" type="radio"/> Yes <input type="radio"/> No	Please follow this AE until resolution and enter the stop date when applicable.	Toxicity Grade none selected
Relationship to Study Drug Possible	Expected <input type="radio"/> Yes <input checked="" type="radio"/> No	Action Taken Dose reduced	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life Threatening <input type="radio"/> Fatal
AE Serious? <input type="radio"/> Yes			

Principle #3

Let the form do the work.



Principle #3: Let the form do the work.

What do the following have in common?

- Performing a unit conversion
- Looking up a study's ULN for creatinine for a 54-year-old male
- Figuring out how many days have elapsed since the last recorded dose



Principle #3: Let the form do the work.

**THINGS A CRC USING
YOUR FORM SHOULD
NEVER HAVE TO DO**



Principle #3: Let the form do the work.

Participant ID: **ABC-001**

Study Event Definition: *

Start Date/Time: : (DD-MMM-YYYY HH:MM) *

End Date/Time:

Leave blank if n/a.

Participant ID: **ABC-001**

Study Event Definition: *

Start Date/Time:

End Date/Time:

Leave blank if n/a.


ABC-001: Dosing Visit 2 Formulation Worksheet

Enter the participant's current weight, rounded to the nearest kilogram. 

Principle #3: Let the form do the work.

Participant ID: **ABC-200**

Study Event Definition: **Dosing Visit 1 (Non-repeating)** *


Start Date/Time: **10-Oct-2018**  **11** : **0** (DD-MMM-YYYY HH:MM) *

End Date/Time:

Leave blank if n/a

Participant ID: **ABC-200**

Study Event Definition: **Dosing Visit 2 (Non-repeating)** *

Start Date/Time: **16-Oct-2018** 

End Date/Time:

Leave blank if n/a

ABC-200: Dosing Visit 2 Formulation Worksheet

You indicated a start date of **Wed Oct 10 2018 at 11:00 (24-hour-time)** for Dosing Visit 1 and a start date of **Tue Oct 16 2018 at 16:15 (24-hour-time)** for Dosing Visit 2.

Fewer than 7 days have elapsed between these events.

If you have already dosed the participant, please discontinue drug and submit a protocol deviation report. If not, note that Dosing Visit 2 must start no earlier than **Wed Oct 17 2018 at 11:00 (24-hour-time)** and no later than **Sat Oct 20 2018 at 11:00 (24-hour-time)**.

Principle #3: Let the form do the work.

At Visit 1/Screening

1. Have T2DM in accordance with ADA guidelines [] and be ≥ 18 years of age on the day of signing the ICF.
2. Meet one of the following criteria:
 - On metformin monotherapy ≥ 1500 mg/day for ≥ 8 weeks with Visit 1/Screening AIC $\geq 7.0\%$ and $< 9.0\%$ (≥ 53 mmol/mol and ≤ 75 mmol/mol)
 - OR
 - On metformin monotherapy ≥ 1500 mg/day for < 8 weeks with Visit 1/Screening AIC $\geq 7.0\%$ and $< 9.0\%$ (≥ 53 mmol/mol and ≤ 75 mmol/mol)
 - OR
 - On metformin monotherapy < 1500 mg/day with a Visit 1/Screening AIC $\geq 7.5\%$ and $\leq 9.5\%$ (≥ 58 mmol/mol and ≤ 80 mmol/mol)

- Screening Visit, Eligibility eCRF
- Break the criteria up into the smallest logic units
 - Simple YN radio buttons
 - Numeric fields
- Prompt the CRC to enter values for these simple items
- Let the form evaluate candidate qualification, based on your Boolean expression
 - If ((A or B) and (C or D)) or ((E and F) and not-H), then eligible, otherwise, not eligible
- By collecting the values for these discrete items and letting the form perform the logic, you ensure accuracy, save the coordinator time, and find out exactly why candidates are screen failing!

Principle #3: Let the form do the work.

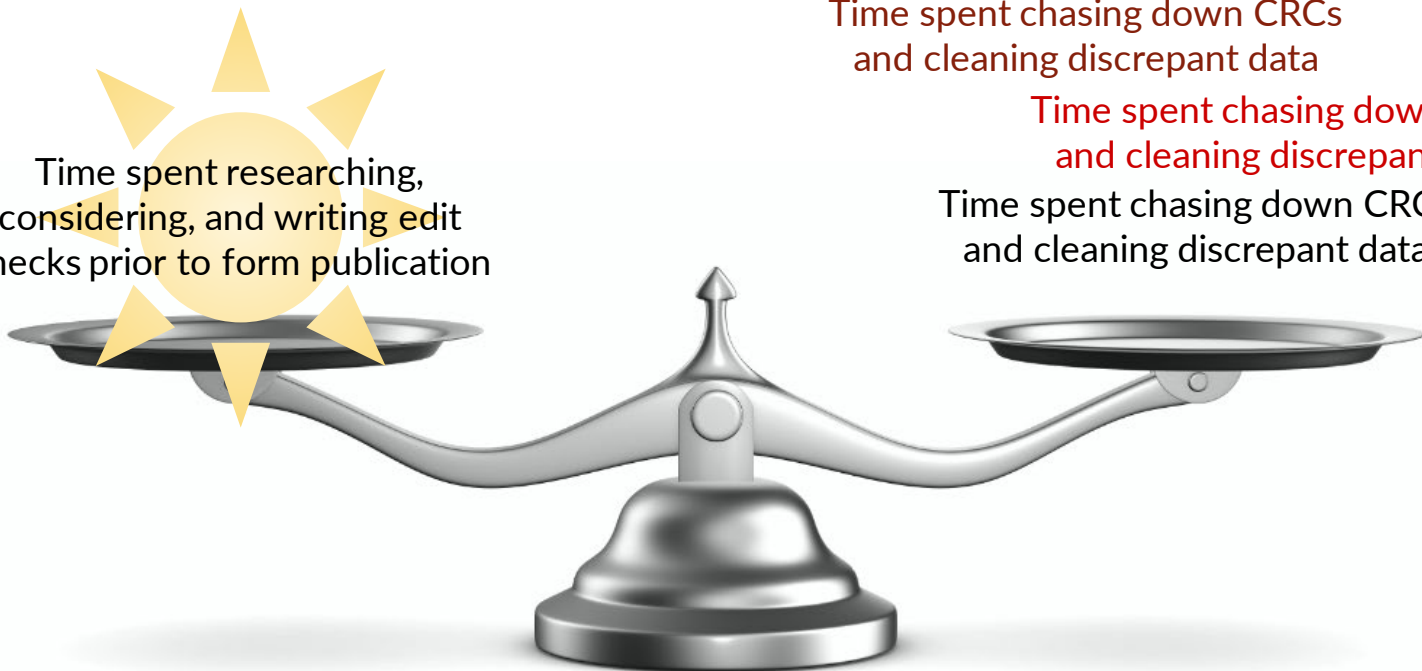
<p>Date of Cycle 1 dose (Day 0)</p> <p>2018-12-03</p>	<p>Select a date for Cycle 2 dose</p> <p><input type="radio"/> Sat Dec 22 2018 (Day 19)</p> <p><input type="radio"/> Sun Dec 23 2018 (Day 20)</p> <p><input type="radio"/> Mon Dec 24 2018 (Day 21)</p> <p><input checked="" type="radio"/> Tue Dec 25 2018 (Day 22)</p> <p><input type="radio"/> Wed Dec 26 2018 (Day 23)</p>	<p>Select a date for Cycle 3 dose</p> <p><input type="radio"/> Sat Jan 12 2019 (Day 40)</p> <p><input type="radio"/> Sun Jan 13 2019 (Day 41)</p> <p><input type="radio"/> Mon Jan 14 2019 (Day 42)</p> <p><input type="radio"/> Tue Jan 15 2019 (Day 43)</p> <p><input checked="" type="radio"/> Wed Jan 16 2019 (Day 44)</p>
<p>Select a date for Cycle 4 dose</p> <p><input type="radio"/> Sat Feb 2 2019 (Day 61)</p> <p><input type="radio"/> Sun Feb 3 2019 (Day 62)</p> <p><input checked="" type="radio"/> Mon Feb 4 2019 (Day 63)</p> <p><input type="radio"/> Tue Feb 5 2019 (Day 64)</p> <p><input type="radio"/> Wed Feb 6 2019 (Day 65)</p>	<p>Select a date for Cycle 5 dose</p> <p><input type="radio"/> Sat Feb 23 2019 (Day 82)</p> <p><input type="radio"/> Sun Feb 24 2019 (Day 83)</p> <p><input type="radio"/> Mon Feb 25 2019 (Day 84)</p> <p><input checked="" type="radio"/> Tue Feb 26 2019 (Day 85)</p> <p><input type="radio"/> Wed Feb 27 2019 (Day 86)</p>	<p>Select a date for Cycle 6 dose</p> <p><input type="radio"/> Sat Mar 16 2019 (Day 103)</p> <p><input type="radio"/> Sun Mar 17 2019 (Day 104)</p> <p><input type="radio"/> Mon Mar 18 2019 (Day 105)</p> <p><input type="radio"/> Tue Mar 19 2019 (Day 106)</p> <p><input checked="" type="radio"/> Wed Mar 20 2019 (Day 107)</p>
<p>Select a date for Cycle 7 dose</p> <p><input type="radio"/> Sat Apr 6 2019 (Day 124)</p> <p><input type="radio"/> Sun Apr 7 2019 (Day 125)</p> <p><input checked="" type="radio"/> Mon Apr 8 2019 (Day 126)</p> <p><input type="radio"/> Tue Apr 9 2019 (Day 127)</p> <p><input type="radio"/> Wed Apr 10 2019 (Day 128)</p>	<p>Select a date for Cycle 8 dose</p> <p><input type="radio"/> Sat Apr 27 2019 (Day 145)</p> <p><input type="radio"/> Sun Apr 28 2019 (Day 146)</p> <p><input type="radio"/> Mon Apr 29 2019 (Day 147)</p> <p><input checked="" type="radio"/> Tue Apr 30 2019 (Day 148)</p> <p><input type="radio"/> Wed May 1 2019 (Day 149)</p>	<p>Select a date for Cycle 9 dose</p> <p><input type="radio"/> Sat May 18 2019 (Day 166)</p> <p><input type="radio"/> Sun May 19 2019 (Day 167)</p> <p><input type="radio"/> Mon May 20 2019 (Day 168)</p> <p><input type="radio"/> Tue May 21 2019 (Day 169)</p> <p><input checked="" type="radio"/> Wed May 22 2019 (Day 170)</p>

Principle #4

Check yourself.



Principle #4: Check yourself.



Time spent researching, considering, and writing edit checks prior to form publication

Time spent chasing down CRCs and cleaning discrepant data

Time spent chasing down CRCs and cleaning discrepant data

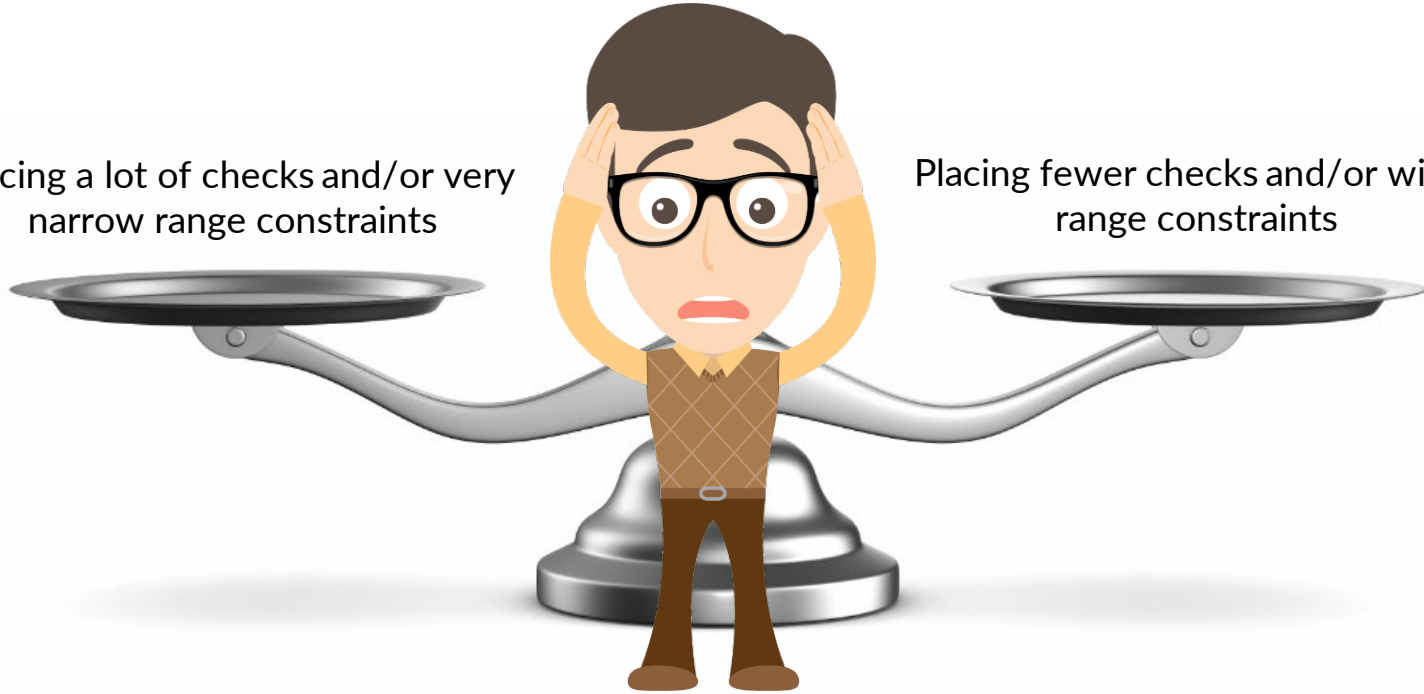
Time spent chasing down CRCs and cleaning discrepant data

Time spent chasing down CRCs and cleaning discrepant data

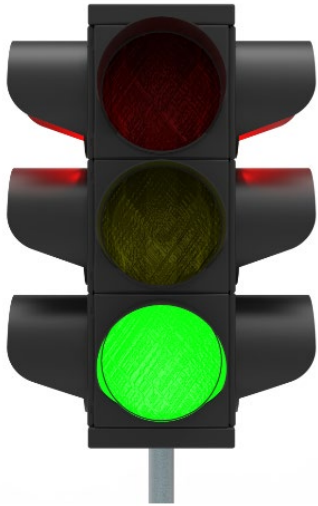
Principle #4: Check yourself.

Placing a lot of checks and/or very narrow range constraints

Placing fewer checks and/or wider range constraints



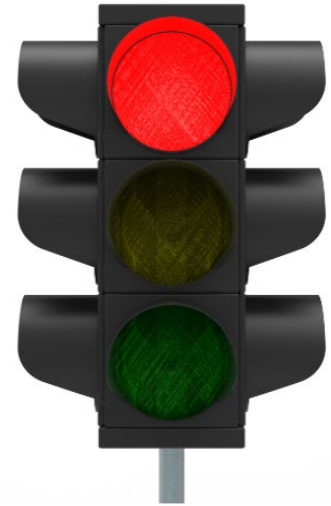
Principle #4: Check yourself.



- Show warning and/or prompt for confirmation
- Otherwise, allow status of complete w/o autoquery



- State violation(s) clearly
- Present range of expected values
- Allow completion but auto-query if violation still present



- Do not allow user to mark as complete until violation is resolved

Principle #4: Check yourself.

When to err on the strict side

- Any value that may signal an AE or is part of an AE form
- Endpoint data
- Plain 'ol incoherence (i.e. medical history start date that is in the future)
 - In this case, a hard edit check is called for



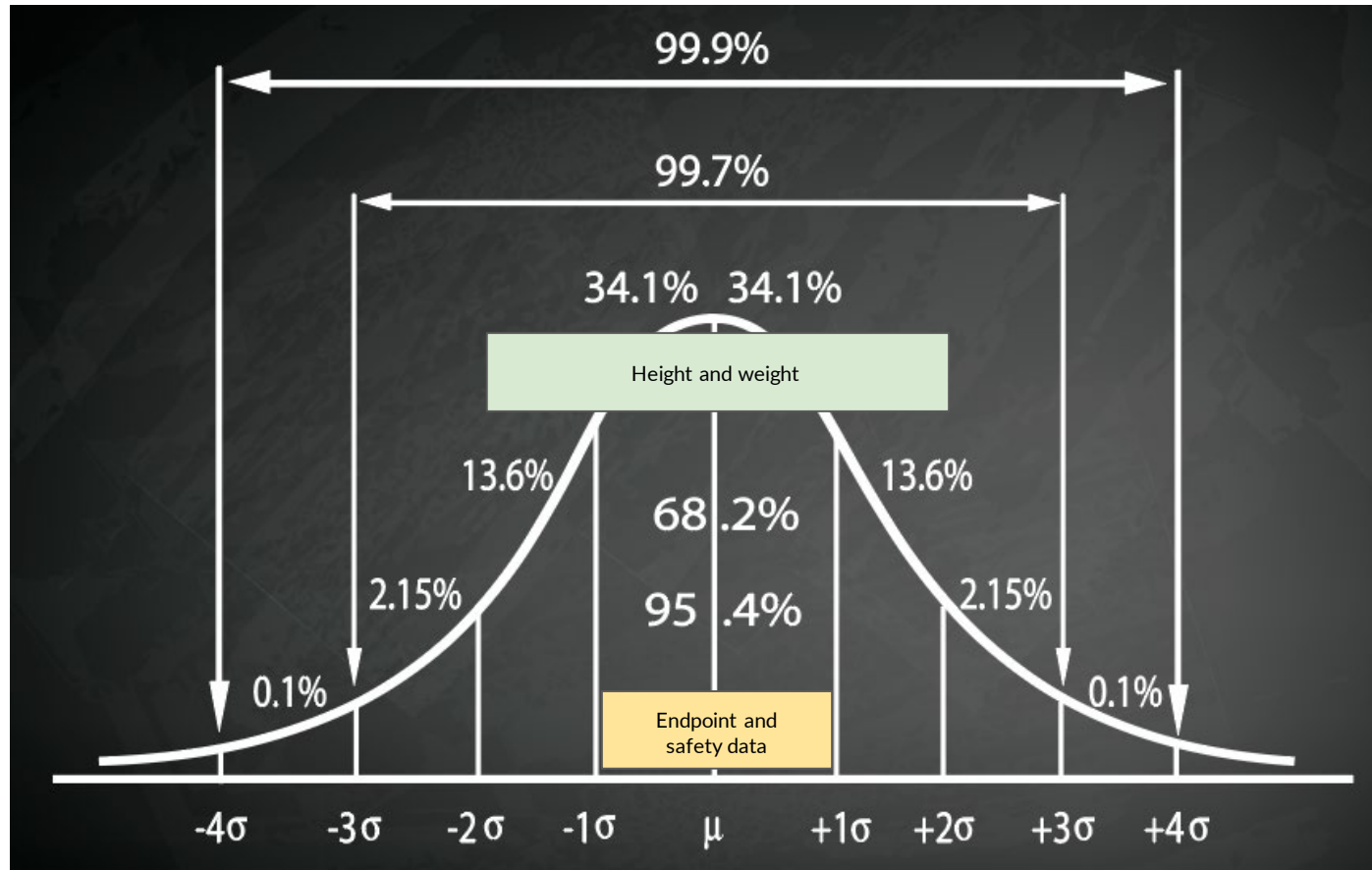
Principle #4: Check yourself.

When to open the gate wider (initially)

- Long forms
 - Don't slow the coordinator down, batch check later
- Missing data unlikely to bear on participant's eligibility or dosing



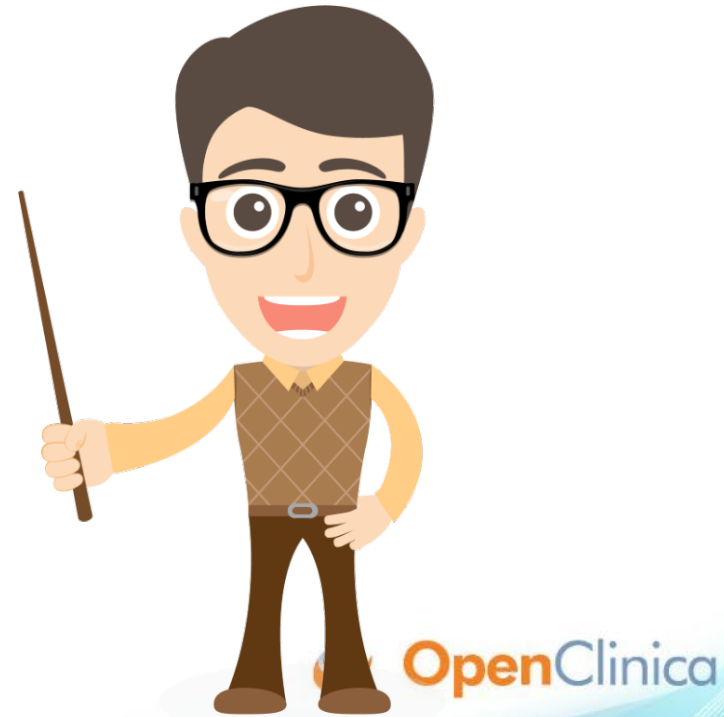
Principle #4: Check yourself.



Principle #4: Check yourself.

In every case

- Test, re-test, and test again
- Regularly review auto-queries and adjust as needed
- Except for protocol specific checks, try to keep your checks on a given field consistent across forms, events, and studies



Principle #5

Raise your standards.

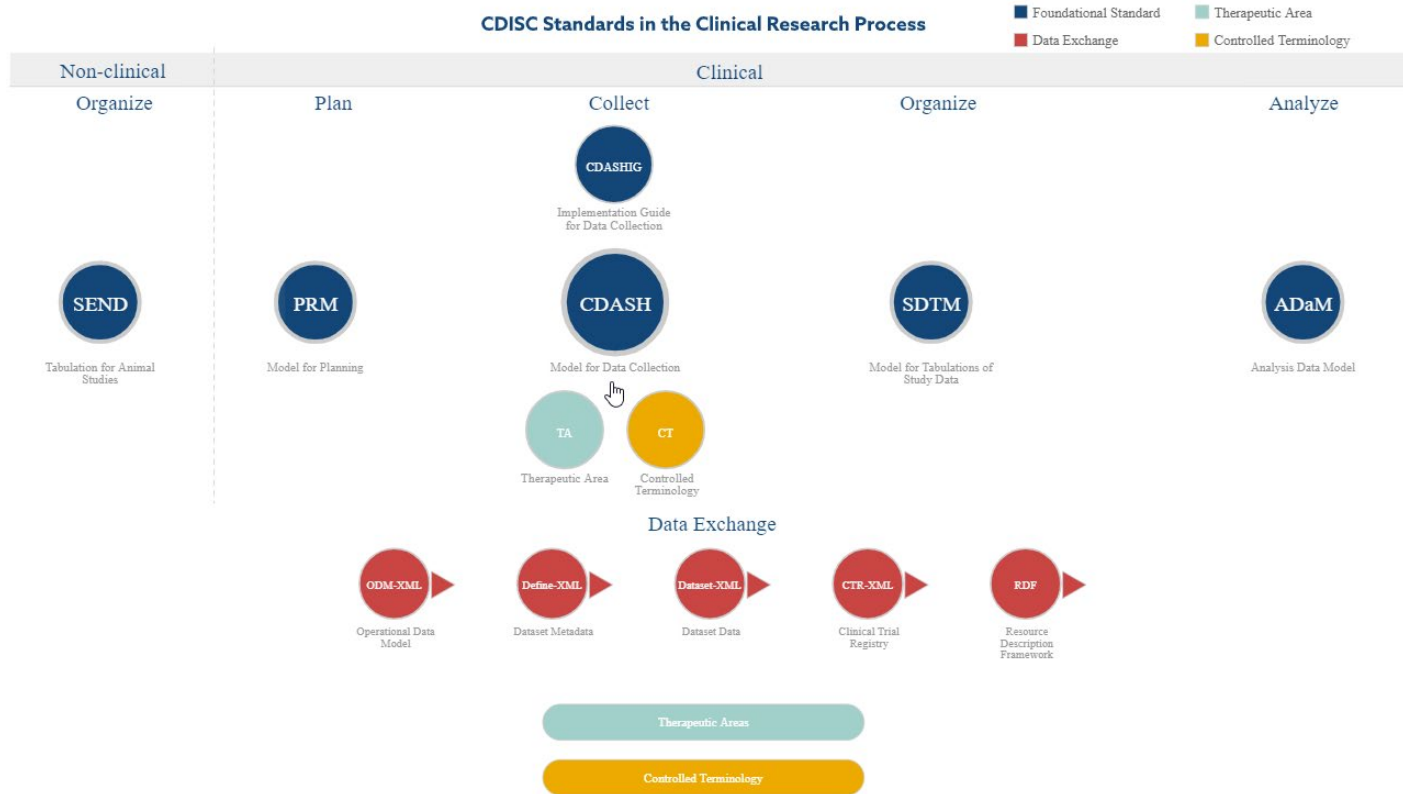


Principle #5: Raise your standards.



Clinical Data Interchange Standards Consortium

Principle #5: Raise your standards.



Principle #5: Raise your standards.

“Where do I start?”

ODM (Operational Data Model)	CDASH (Clinical Data Acquisition Standards Harmonization)
<ul style="list-style-type: none">● a vendor-neutral, platform-independent format for exchanging and archiving<ul style="list-style-type: none">○ clinical and translational research data○ associated metadata○ administrative data, reference data, and audit information● language of choice for representing case report form content in many electronic data capture (EDC) tools● ODM-XML v1.3.2 is the most current version of the standard	<ul style="list-style-type: none">● a standard way to collect data in a similar way across studies and sponsors so that data collection formats and structures provide clear traceability of submission data into the Study Data Tabulation Model (SDTM)● delivers more transparency to regulators and others who conduct data review.

Principle #5: Raise your standards.

“Where do I start?”

<p style="text-align: center;">ODM (Operational Data Model)</p>	<p style="text-align: center;">CDASH (Clinical Data Acquisition Standards Harmonization)</p>																																							
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Principle #5: Raise your standards.

Internal standards are just as important!

- Consistent code lists on consistent forms
- Reuse across events and studies
- Keep an internal library



Principle #6

Know your audience.



Principle #6: Know your audience.

The Site User	The Participant
<ul style="list-style-type: none">● Excellent multitaskers● Experienced with massive data collection● Has “signed on” to the study’s SOPs, including language of communication● Genuinely wants to advance research	<ul style="list-style-type: none">● Involved in just your study (most of the time)● Vested interest in compliance● Often grateful for the chance to participate● Genuinely wants to advance research

Principle #6: Know your audience.

The Site User	The Participant
<ul style="list-style-type: none">● Your study competes with other studies and (often) clinical work.● Your EDC may be their most preferred, or their least.● Reports to the PI, not to the data manager.● DM's rules for "days to entry" and "query response" are suggestions, at best.	<ul style="list-style-type: none">● Your form competes with far more exciting digital content, not to mention real life.● Doesn't report to anyone. (They don't <i>have</i> to do anything.)● Remembering to complete your form is a courtesy, not an obligation.● May abandon form at first hint of an obstacle.● Is under no obligation to know the language of your forms.

Principle #6: Know your audience.

The Site User	The Participant
<ul style="list-style-type: none">● Your form must make data entry efficient.● At the very least, your form must render legibly and function as intended on all common browsers for laptop and tablet screens.● Your edit checks and layout/pagination must drive speed and accuracy.● Poll your CRCs: “Could my eCRF, rendered on a tablet, replace paper source and transcription?”	<ul style="list-style-type: none">● Your form must make data entry a pleasure.● Ideally, your form should render legibly and function as intended on any device.● Your form must make it impossible to submit invalid data. (Queries aren’t an option here.)● For int’l trials, your form should accommodate participant language preferences.

Principle #6: Know your audience.

999-001: Eating Habits Assessment

Date of assessment 🗨️*

yyyy-mm-dd 🔄

« November 2018 »

Su	Mo	Tu	We	Th	Fr	Sa
28	29	30	31	1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	1
2	3	4	5	6	7	8

All changes saved.

Close

Next →



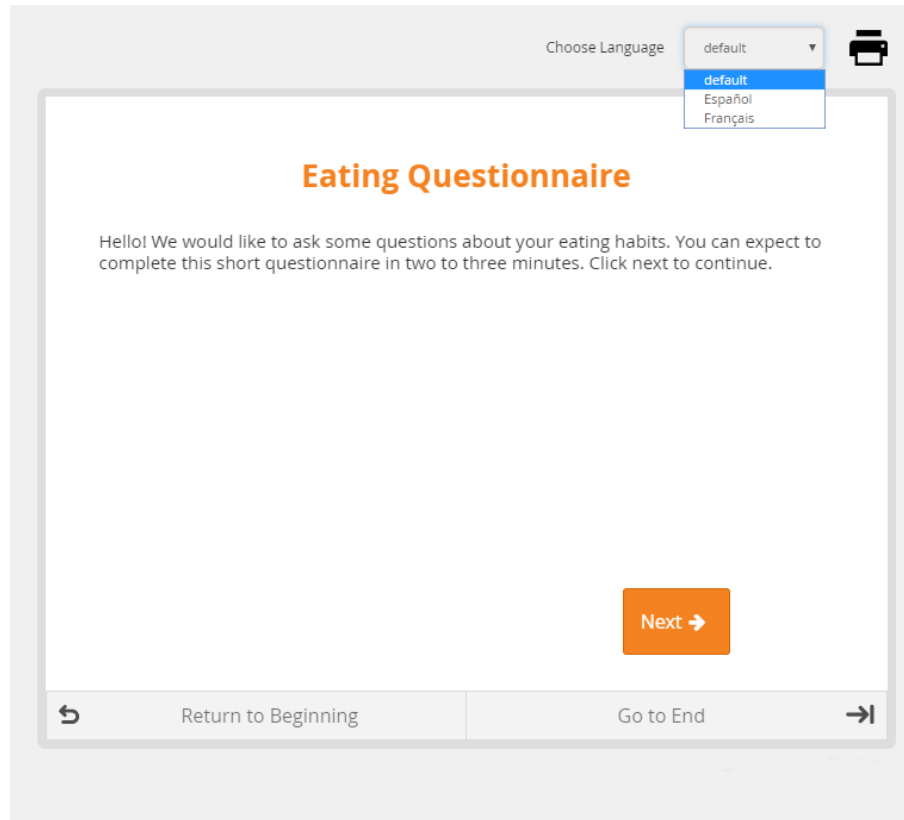
Return to Beginning

Go to End




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Principle #6: Know your audience.



The screenshot shows a web-based questionnaire interface. At the top right, there is a 'Choose Language' dropdown menu with options for 'default', 'Español', and 'Français'. A printer icon is located to the right of the language menu. The main content area features the title 'Eating Questionnaire' in orange, followed by a welcome message: 'Hello! We would like to ask some questions about your eating habits. You can expect to complete this short questionnaire in two to three minutes. Click next to continue.' Below the text is an orange 'Next →' button. At the bottom, there are two navigation buttons: 'Return to Beginning' with a left arrow icon and 'Go to End' with a right arrow icon.

Principle #6: Know your audience.

<p>Frçais</p> <h2>Eating Questionnaire</h2> <p>Je prends délibérément de petites portions comme moyen de contrôler mon poids. <i>Choisissez la réponse la plus proche de la vérité de votre affirmation.</i></p> <ul style="list-style-type: none"><input type="radio"/> Définitivement vrai<input checked="" type="radio"/> Surtout vrai<input type="radio"/> Surtout faux<input type="radio"/> Définitivement faux<input type="radio"/> Je préfère ne pas accepter. <p>← Back</p> <p>Powered by OpenClinica</p> <p>↶ Return to Beginning</p>	<p>Frçais</p> <h2>Eating Questionnaire</h2> <p>Lorsque je sens un steak grésillant et de la viande juteux, il est très difficile de résister même si je viens de terminer un repas. <i>Choisissez la réponse la plus proche de la vérité de votre affirmation.</i></p> <ul style="list-style-type: none"><input type="radio"/> Définitivement vrai<input type="radio"/> Surtout vrai<input type="radio"/> Surtout faux<input checked="" type="radio"/> Définitivement faux<input type="radio"/> Je préfère ne pas accepter. <p>← Back</p> <p>Powered by OpenClinica</p> <p>↶ Return to Beginning</p>	<p>Frçais</p> <h2>Eating Questionnaire</h2> <p>Quand je me sens anxieux, je mange plus. <i>Choisissez la réponse la plus proche de la vérité de votre affirmation.</i></p> <ul style="list-style-type: none"><input type="radio"/> Définitivement vrai<input type="radio"/> Surtout vrai<input type="radio"/> Surtout faux<input checked="" type="radio"/> Définitivement faux<input type="radio"/> Je préfère ne pas accepter. <p>← Back</p> <p>Powered by OpenClinica</p> <p>↶ Return to Beginning</p>	<p>default</p> <h2>Eating Questionnaire</h2> <p>Click the picture of the food that is more appetizing to you right now.</p> <div data-bbox="1257 419 1624 532"></div> <p>Niether of these foods are appetizing to me.</p> <p>← Back Next →</p> <p>Powered by OpenClinica</p> <p>↶ Return to Beginning Go to End →</p>
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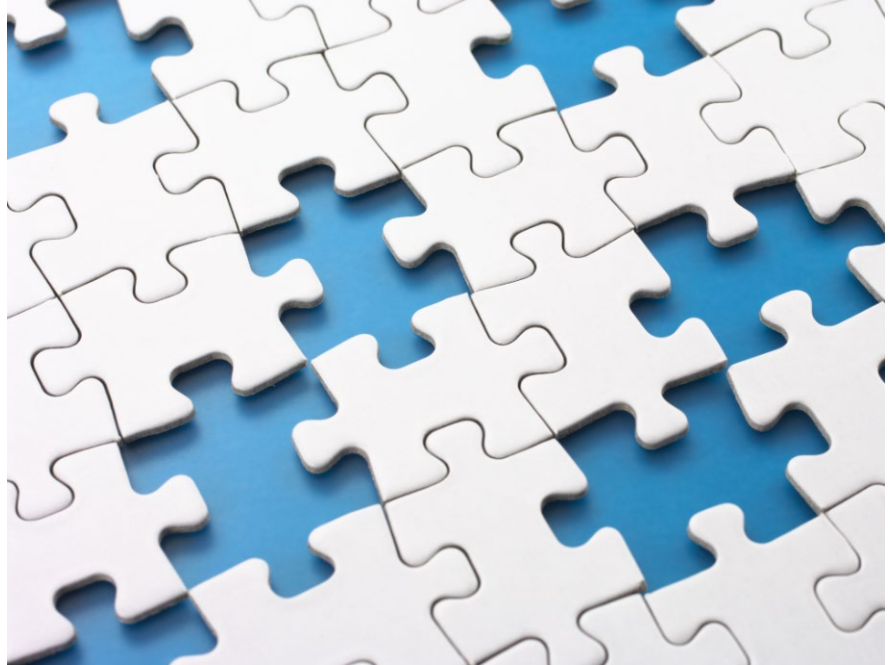
Principle #6: Know your audience.

The Site User	The Participant
<ul style="list-style-type: none">● Follow (or direct) the clinical workflow when ordering items● Don't assume units of measure● Use tables and grids for input fields to save on page advancing● Lose the paper mindset, esp. where responsive fields and a cleaner layout will boost efficiency● Mimic paper forms where the forms are very familiar	<ul style="list-style-type: none">● Consider the culture● Just-in-time reminder texts to prompt entry● Discourage "skips" by offering a "I prefer not to answer" choice● Published, validated instruments must be licensed (\$) and must not be modified without equivalence testing

Important and related topics we didn't cover today

- Identifying the data you need to collect in the first place!
- Form versioning
- Exporting, transforming, and analyzing your dataset
- Reporting (operational metrics and clinical data)
- Training your team and site partners

Check out the [OpenClinica blog](#) and [LinkedIn page](#). And get in touch to request more sessions like this one!



Thank you!



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