



# SCT

SOCIETY FOR CLINICAL TRIALS



# It Takes a Village: Multi-Disciplinary Approach to Designing Stellar Data Collection Forms

Moderator: Gustavo Jimenez-Maggiora

Presenters: Emily Dressler, Letitia Perdue, Laura Lovato, Mark King, and Lindsay Tysinger

# Today's Faculty



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# Today's Faculty



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# On Today's Webinar

- Our presenters will cover:
  - An overview of Form Development from Various Perspectives: Investigator, Project Manager, Biostatistician, Programmer, Clinical Staff
  - Advanced Topics and Questions and Answers

# Before We Begin Our Presentations...

- We will hold a Q&A session after today's presentations.
- We encourage all webinar attendees to submit questions via the Question Box.
- If we don't get to your questions today, we will follow up with you after the webinar via email.
- Today's webinar is being recorded and will be available to SCT members in the Members-Only Area of the SCT website.

# It Takes a Village: Multi-Disciplinary Approach to Designing Stellar Data Collection Forms

Emily Dressler, Principal Investigator

Tisha Perdue, Project Manager

Lindsay Tysinger, Clinical Site Coordinator

Mark King, Programmer

Laura Lovato, Biostatistician

# Disclosures

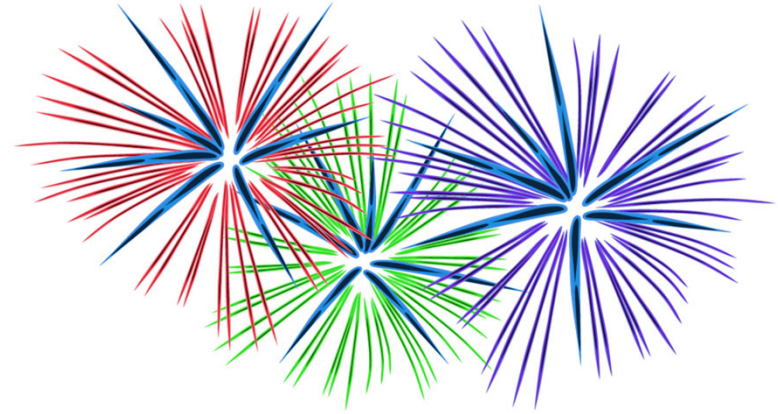
- Emily Dressler – No Disclosures
- Letitia Perdue – No Disclosures
- Lindsay Tysinger – No Disclosures
- Mark King – No Disclosures
- Laura Lovato – No Disclosures



A person wearing glasses and a large earring is seated at a desk, looking at a computer monitor. The monitor displays a medical CT scan of a human torso, showing internal organs. The person's hand is visible near a keyboard. The background is slightly blurred, showing other medical equipment and a person in the distance.

# Introduction

# Overview



- Brief lectures discussing stellar data collection form considerations and development from various research perspectives
  - Principal Investigator
  - Project Manager
  - Clinical Site Coordinator
  - Programmer
  - Biostatistician
- Review and discussion







# **Perspective: Principal Investigator**

# I GOT MY STUDY FUNDED!!!



# Principal Investigator: What are my questions?

- Forms must capture my trial questions



- All of my questions!!!
  - That includes my primary.
  - And secondary..
  - And exploratory...



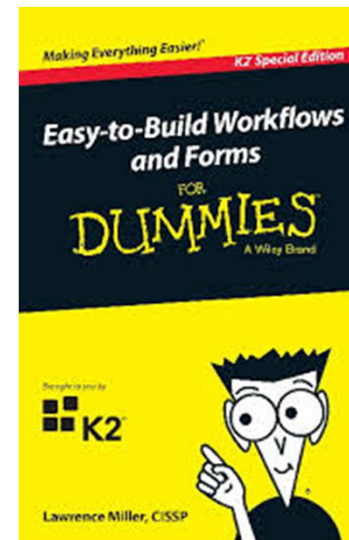
And all supporting evidence..... ☺

# Principal Investigator: Design of Forms

- Forms should be clear to understand
- Easy to fill out
- Fast for patients and staff!
- Limited data entry errors
- Direct patient entry or wearable technology is fine with me



- It can't really be that hard right?!?!





A person with glasses and a large earring is seen from the side, working at a desk with multiple computer monitors. The central monitor displays a medical scan of a human torso. The background is slightly blurred, showing other equipment and a clinical environment.

# Perspective: Project Manager



# Project Manager

- My focus:
  - Adapting the research question and protocol and putting it into action in a logical way for data collection
  - Ensuring high standards of data quality and consistent data collection across sites and throughout the trial
  - Balancing requests from all key players



# Project Manager: Deciding What Questions to Ask

- Balancing investigators requests vs participant burden and logistical concerns
  - Both initially and throughout the trial with form changes
  - Regulatory approvals, translations, etc.
- Balancing burden vs necessary information
  - What are the key questions?
  - What are the most important forms/questions to be asked



# Project Manager: Deciding Who to Ask

- What needs to be asked to participants?
- Are there questions that can be gathered from EMR?
  - Questions that have to be verified through EMR?
- Addressing the questions to the right party
  - Physicians?
  - Parents/caregivers?
  - Participants?

At the time you were (*your child was*) diagnosed with diabetes, diabetes, would you consider your (*their*) body size as thin, medium or heavy?

Thin	<input type="checkbox"/>	1
Medium	<input type="checkbox"/>	2
Heavy	<input type="checkbox"/>	3
*Don't know	<input type="checkbox"/>	9

- Staff-interview or participant completed
  - Participants must understand the questions being asked!

# Project Manager: Answer Choices



- Asking questions participants know
  - What age were you diagnosed? Have another way to answer the question (year)
  - Hospitalizations – when they aren't sure of the exact date
- Having a “don't know” “refused to answer”
- Using cue cards for list items
- Question by Question instructions to deal with nuisances

PLEASE READ THE ENTIRE LIST BELOW AND REPORT TO THE INTERVIEWER ANY AND ALL DISEASES THAT YOU (OR YOUR CHILD) HAVE HAD DIAGNOSED.

Multiple sclerosis  
Celiac disease  
Thyroid disease  
Myasthenia gravis  
Pernicious anemia  
Lupus or SLE  
Rheumatoid arthritis

# Project Manager: Flow of the visit and the form

- Pre-screening to decrease burden on staff/participants
- Critical forms/questions first
- Clearly label when form should be stopped

Are you currently on dialysis?

Yes - Participant is ineligible. STOP HERE.

No

No Answer

- Eligibility checks that make it easy to identify

ELIGIBILITY ISSUES - click row to jump to question.

Ineligible - Average waist circumference < 102

# Project Manager: Ensuring Quality



- Make forms easy to read!
  - Paper forms should have enough room to write on the form (including notes as needed)
- Logical skip patterns (e.g., smoking) - automatic when possible
- Question phrasing
  - Don't use "Did the participant" when staff/participant are reading the questions
  - Instead use "Did you"
- Automatic checks to ensure all questions are answered
  - Timing and process of data entry
  - Timing of queries

# Project Manager: Updating What Questions to Ask



- Form changes -- ensuring consistent quality and recognizing when updates are needed
- Create a schedule for form changes to ensure consistent data collection

Rollout	From Investigators	To Translators	To IRB	In the Clinics
Rollout 1	January 1	February 1	March 1	April 1
Rollout 2	May 1	June 1	July 1	August 1
Rollout 3	September 1	October 1	November 1	December 1





# **Perspective: Clinical Site Coordinator**



# Clinical Site Coordinator

My focus:

- How to operationalizing protocol
- Participant experience



# Clinical Site Coordinator

- What are we collecting?
- When?
- Who is administering forms?
  - Masking
- How are we collecting the data?
  - Phone call v. in-person v. direct data entry
  - Do forms need to be printed in clinic?
  - What do we do with information we ascertain that is not on the forms?

Visit	1	Baseline	2	3	4
Visit Name / Month	Baseline* Appoint 1 Fasting	Baseline Appoint 2 Not fasting	Month 6	Month 12	Month 18
Visit Window (# Weeks)			+/- 3	+/- 3	+/- 3
Informed Consent for Enrollment, HIPAA	X				
Review Inclusion & Exclusion Criteria	X				
Demographics Review	X				
Medical History Review	X				
Unmasked Intake Interview			X	X	X
Medication Review	X		X	X	X
Brief Physical Exam	X				
Vital Signs	X			X	
Height	X				
Weight	X			X	
Waist Circumference	X			X	
Brief Neurological Exam	X				
Fasting Clinical Blood Labs	X			X	
12-Lead Resting ECG	X				
Blood Collection for APOE Genotyping & DNA Banking	X				
Fasting Blood Collection for Banking	X			X	
AE Monitoring at Clinic			X	X	X

# Clinical Site Coordinator

- Prioritizing collection of data especially inclusion/exclusion criteria questions
  - Does ordering of questions make sense?
  - Does data pull from different forms so not collecting twice?
  - Can staff adequately make decisions based on information from forms?
  - Where are the hard stops?

PARTICIPANT NAME:		PID:	
PARTICIPANT PHYSICAL ADDRESS:			
PARTICIPANT MAILING ADDRESS (IF DIFFERENT FROM PHYSICAL):			
Ask the following questions to determine initial eligibility to continue screening:		Eligible for screening?	
1. What is your age? _____		YES (age 60-79)	NO
2. Do you exercise regularly? If yes, brief description. _____		YES (not a regular exerciser)	NO
3. Do you have any health problems or physical disabilities that prevent you from exercising now? If yes, please describe: _____		YES (no major health problems)	NO

# Clinical Site Coordinator

- Do forms make sense?
  - If single site or multi-national trial, are forms appropriate for our culture?
  - Appropriate space on forms to collect data
- Units collected match study needs
  - Ex: collect height in centimeters but weight in pounds
  - Ex: making sure you collect what's needed for other testing measures
- Are we collecting data to assess our hypothesis?

1. Fasting Glucose	<input type="text"/> <input type="text"/> <input type="text"/> mg/dL
2. HbA1c	<input type="text"/> <input type="text"/> . <input type="text"/> %
3. Total Cholesterol	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mg/dL
4. Triglycerides	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mg/dL
5. HDL-C	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mg/dL
6. LDL-C	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mg/dL

# Clinical Site Coordinator

- How tracked when form is completed?
- Length of visit
  - Participant burden
  - Staff time and clinic resources
  - Time to complete data entry



# Clinical Site Coordinator

- Feedback
- Plan and adapt





# Perspective: Programmer



# Programmer

My focus:

- Implementation
- Building the data entry screens to collect the desired information
- Complete data
- Clean data
- Easy to use interface





# Programmer

How will data be collected?

- Direct data entry by participant
- Direct data entry by clinic staff
- Collected on paper and data entered at a later time

# Programmer

## Direct data entry

- Display form question by question
- Display full form
- Data validation checks are different for direct data entry

# Programmer

Collected on paper forms and data entered later

- Data entry screens need to match layout of paper forms
- Data validation checks
- Ability to correct immediately
- Option to correct or verify data at a later time through a Data Query System

# Programmer

## Form Design

### Consistency on how questions are asked

- Yes = 1 and No = 0
- The way questions are asked – phrased positively or negatively – be consistent

Please rate how well you agree with the following statements		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1.	I love eating bananas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	I love eating apples	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	I hate eating oranges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	I love eating mango	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

# Programmer

## Forms vs Data Entry Screens

- Length of forms
- May need to be broken down into smaller data entry screens
- Form Packets - multiple data entry screens



# Perspective: Biostatistician

# Biostatistician

- My focus:
  - Are all elements of the protocol collected?
  - Monitoring during the trial
  - End product: final paper



Numbers 1-10

NUMBER	CHINESE Pinyin	CHINESE CHARACTER
1	yi	一
2	er	二
3	san	三
4	si	四
5	wu	五
6	liu	六
7	qi	七
8	ba	八
9	jiu	九
10	shi	十
11	shi yi	十一
12	shi er	十二

*When statisticians are not included in trial design:*



**"Oh look, a data trail to follow."**



# Biostatistician

- Eye on the Prize:
  - Eligibility
  - Adherence/Intervention
  - Retention/Outcomes
- **NO** ambiguous questions
- Data types
  - Numeric, Character, Dates, Free Text
- Precision (rounding can make a difference!)



# Biostatistician

ADHERENCE: are participants sticking with the intervention



RETENTION: are we getting outcomes data on participants

HDG103-MP



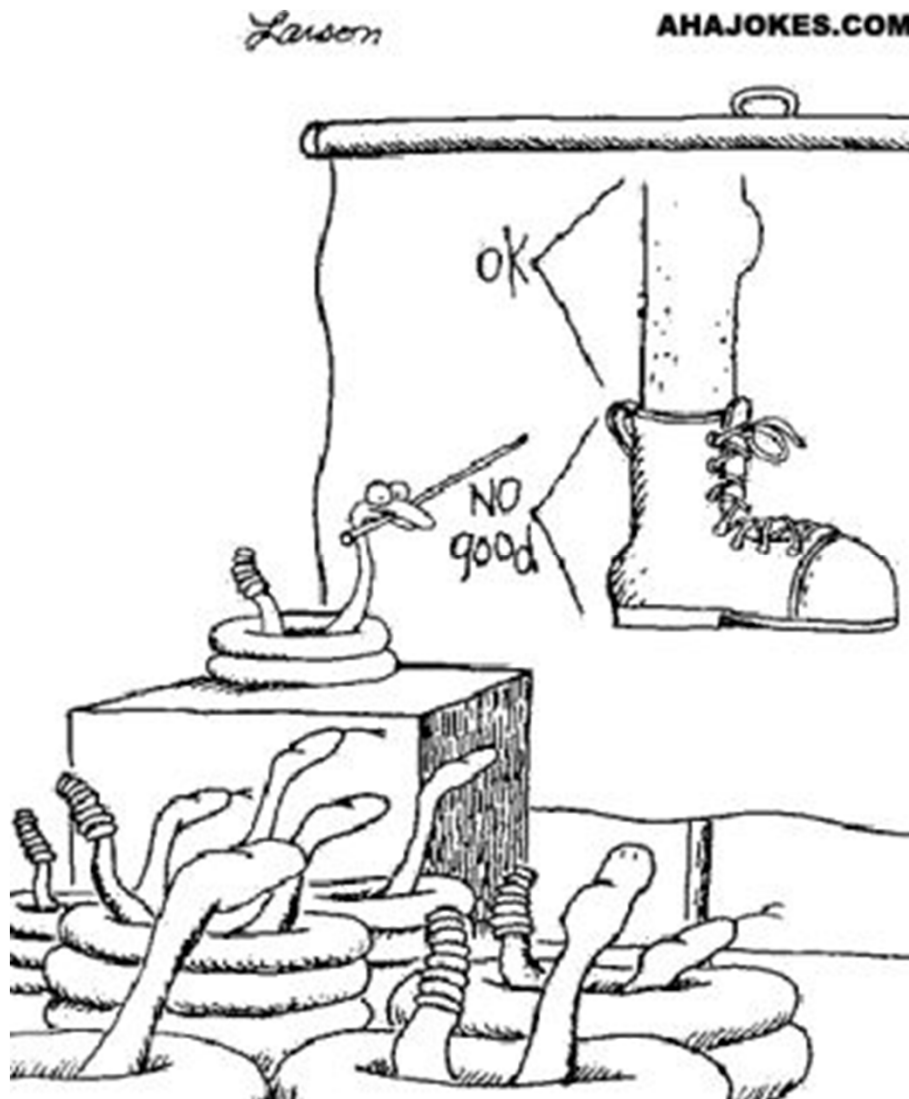
"Don't even tell me it's a wart."

# Biostatistician

- Eye on the Prize:
  - Eligibility
  - Adherence/Intervention
  - Retention/Outcomes
- **NO** ambiguous questions
- Data types
  - Numeric, Character, Dates, Free Text
- Precision (rounding can make a difference!)



# Ambiguity



# Biostatistician

Example: form assessing SEDENTARY status of potential participants

5. I do some VIGOROUS physical activities.		
<input type="checkbox"/> Yes, every week <input type="checkbox"/> Yes, but not every week <input type="checkbox"/> Rarely or never		
If you answered "Yes" to Question 5 above, please list the VIGOROUS physical activities that you do, and indicate how often you do the activity and for how long each time.		
VIGOROUS PHYSICAL ACTIVITY	HOW MANY TIMES PER MONTH?	HOW MANY MINUTES EACH TIME?

# Biostatistician

- Eye on the Prize:
  - Eligibility
  - Adherence/Intervention
  - Retention/Outcomes
- **NO** ambiguous questions
- Data types
  - Numeric, Character, Dates, Free Text
- Precision (rounding can make a difference!)



# Biostatistician

*0 2 % # )3 )/ .*

E.g., pounds to 2.2046 kilograms  
(esp. with elderly women, children)

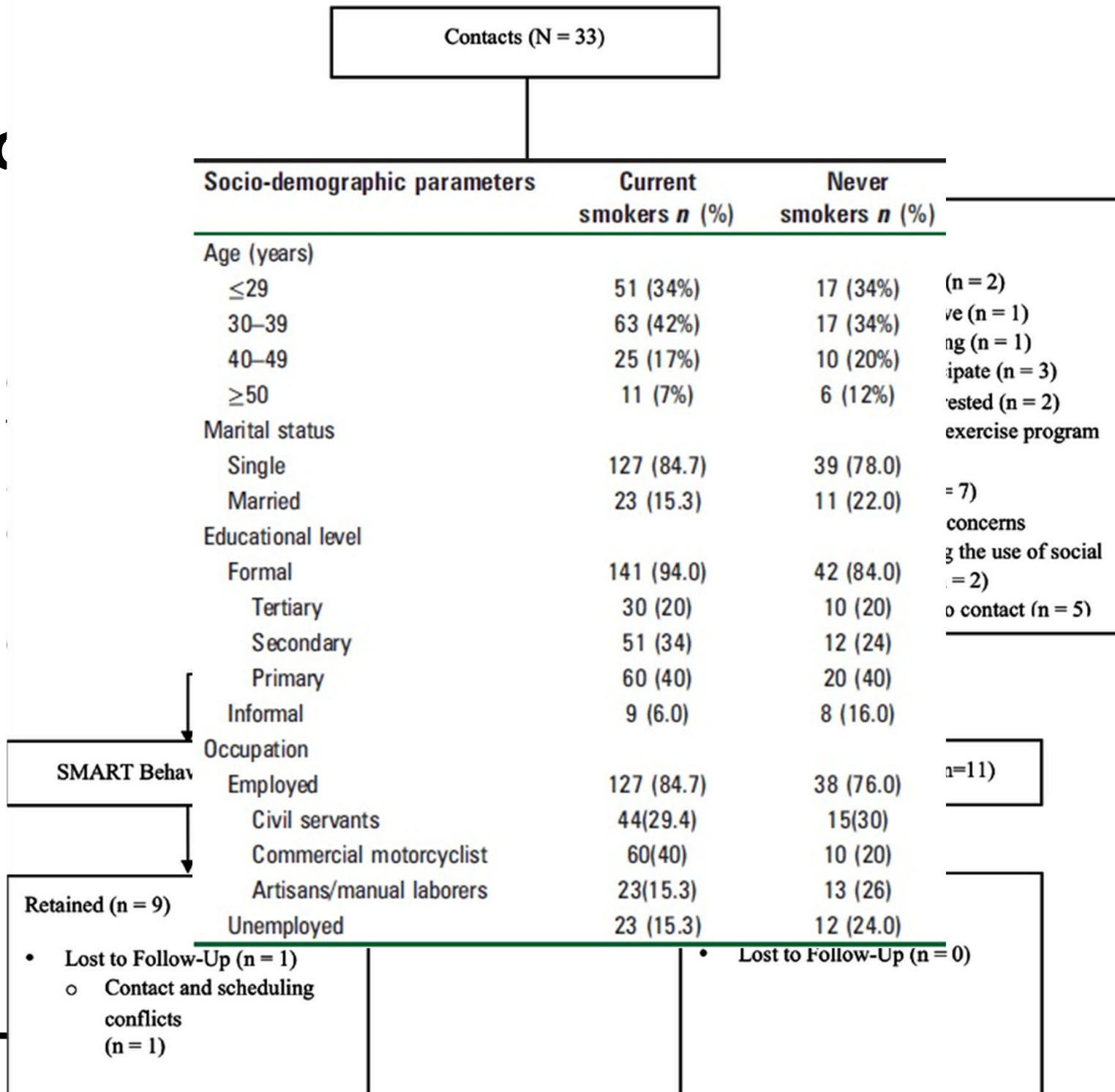
E.g., lab values  
(hba1c, serum creatinine VS. SBP, total cholesterol)

E.g., scales or dietary intake  
(need decimals for “partial credit”)

Bio

End

- 
- 
- 
- 







# Review and Conclusions

# Multi-Disciplinary Approach to Designing Stellar Data Collection Forms

- Duplication of points brought up today **is a good thing**
- Process needs to be a collaborative effort with each perspective being involved early on
- Final (When are forms ever final?!?) design will be the result of an iterative process involving input and feedback from all parties involved

# Q&A

A panoramic view of the Vancouver skyline at sunset, featuring the city's skyscrapers and the waterfront. The sky is a mix of orange, pink, and blue, reflecting on the water. The Vancouver Convention Centre is prominent in the foreground.

**46<sup>th</sup>**  
**ANNUAL**  
**MEETING**



**SAVE  
THE  
DATE**

May 18-21, 2025

**VANCOUVER**  
**CANADA**





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  - Continuing Education
  - Webinars
  - Subscription to the *Clinical Trials* Journal
  - Substantially discounted registration fees to SCT Annual Meetings
  - Professional development, leadership, and presentation opportunities
  - Social outreach and communication
- <https://sctweb.org/membership.cfm>

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- On the SCT website, click on the Member Sign-In button and login.
- On the Members-Only Area Home page, click on “Propose a SCT Webinar!” in the menu on the righthand side.
- Complete and return the Webinar Proposal Form to [contact@sctweb.org](mailto:contact@sctweb.org) for the SCT Education Committee’s review and consideration.

# Have you completed your SCT member profile?

- The SCT leadership is making a concerted effort to learn more about our membership community in an effort to develop more appropriate programs and services, increase engagement, and ensure members' voices are heard regarding barriers in clinical trials research and education. As such, we ask that you please update your member profile.
- To complete your SCT member profile, please follow the steps below:
  - Log onto the Members-Only Area of the SCT website.
  - Click on the "Your Membership Account" option in the right-hand side menu.
  - Complete the optional questions on the "Profile" tab.

# SCT's LinkedIn Page is Now Public!

- We're moving! Follow our new public page for clinical trial updates, events, and networking. The old private group will close in a few months – make the switch today!
- Follow the new SCT LinkedIn page here:  
<https://www.linkedin.com/company/society-for-clinical-trials/>



# Thank You!