

How to Ensure Your Topline Results Are Correct?

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Disclaimer

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- Any views or opinions in this presentation are solely those of the author.

Agenda

- Introduction
- Areas where errors could be introduced
- Enhanced double-programming for double saving
- Thoughts and discussions

Introduction

- Topline results require top priority
 - ✓ So important as to be named at or near the top of a newspaper item... (*dictionary.com*)

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Health

WELL | HEALTH GUIDE



GETTY IMAGES

PHYS ED

Running May Be Socially Contagious

Our workouts may be shaped by what our (virtual) friends do.

3h ago · By GRETCHEN REYNOLDS



LAURA MORTON FOR THE NEW YORK TIMES

A California Court for Young Adults Calls on Science

San Francisco's Young Adult Court, created in 2015, is based on recent research suggesting that brain development extends beyond age 18, into the 20s.

1d ago · By TIM REQUARTH

PERSONAL HEALTH

The Cost of Not Taking Your Medicine

Nonadherence to prescriptions causes some 125,000 deaths a year in the United States alone.

2d ago · By JANE E. BRODY



THE CHECKUP

Too Clean for Our Children's Good?

We need to study the health consequences of the modern and more "hygienic" built environment, which is clean but by no means sterile.

2d ago · By PERRI KLASS, M.D.



Introduction

- Topline results require top priority
 - ✓ Timepressure



Areas where ... could be made 😞

- To explain a few...

Areas where ... could be made 😞

- Baseline derivations: whether to include unscheduled visits (certain labs), worst case or best case scenario



Areas where ... could be made☹

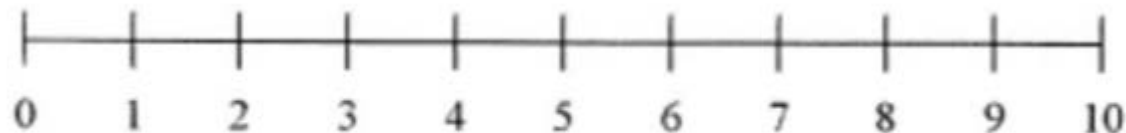
- Baseline derivations: whether to include unscheduled visits (certain labs), worst case or best case scenario

Last.USUBJID or
First.USUBJID?



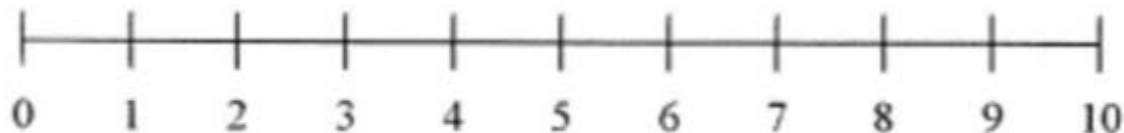
Areas where ... could be made 😞

- Numbers for NA etc. were used incorrectly, e.g. when 99 was entered in EDC for not done in the following pain score...



Areas where ... could be made 😞

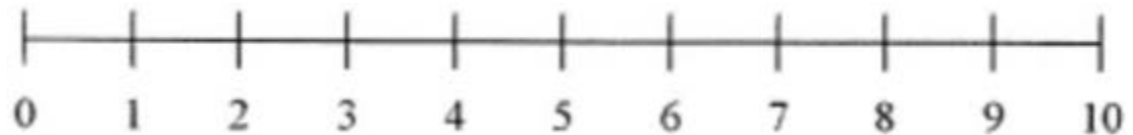
- Numbers for NA etc. were used incorrectly, e.g. when 99 was entered in EDC for not done in the following pain score...
 - ✓ Why am I getting mean score > 10 ?



Areas where ... could be made 😞

- Certain questionnaire answers need standardization

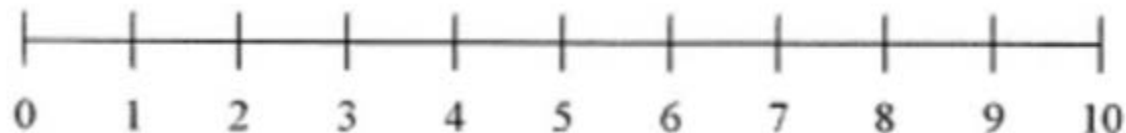
Q1: 10 is the best result



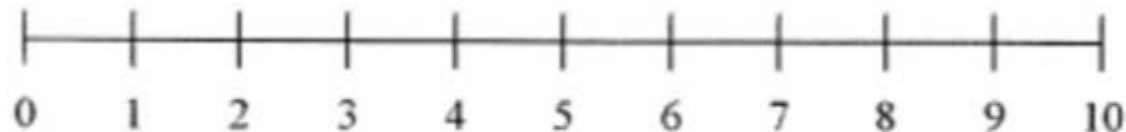
Areas where ... could be made 😞

- Certain questionnaire answers need standardization

Q1: 10 is the best result



Q2: 0 is the best result



Enhanced double-programming for
double saving 😊

- CDISC requirements HAVEN'T
created these error-prone areas!

Enhanced double-programming for
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- CDISC requirements HAVEN'T created these error-prone areas!
- CDISC requirements DO increase the complexity of validations!

Enhanced double-programming for double saving 😊

- To validate through the RAW-data approach
 - ✓ Independency
 - Not mingled with the CDISC routines
 - Directly deriving the primary endpoints from the raw data sets

Enhanced double-programming for double saving 😊

- To validate through the RAW-data approach

- ✓ Independency

- ✓ Saving time

No intermediate datasets to depend on

Avoiding QC of many variables unrelated to the topline results

Enhanced double-programming for double saving 😊

- Raw data approach is not reinventing the wheel
 - ✓ In parallel to CDISC programming
 - ✓ Avoiding many variables required in CDISC but unrelated to the topline results

Enhanced double-programming for double saving 😊

- Raw data approach is not reinventing the wheel
 - ✓ In parallel to CDISC programming
Avoiding many variables required in CDISC but unrelated to the topline results
 - ✓ Utilizing the data construct concept, etc.

Enhanced double-programming for
double saving 😊

- Reconciliations between the QC and
Production
 - ✓ Results match?

Enhanced double-programming for double saving 😊

- Reconciliations between the QC and Production
 - ✓ Results match? If not, then
 - ✓ Endpoint values match at each timepoint/visit?

Generally, validation data sets should adopt the BDS-like structure to facilitate comparisons

Enhanced double-programming for double saving 😊

- Reconciliations between the QC and Production

- ✓ Results match? If not, then

- ✓ Endpoint values match at each timepoint/visit?

Allowing flexibility for study specific construct for data sets in order to increase the clarity and effectiveness of comparisons

Discussions

- How soon to get started on CDISC?



Discussions

- How soon to get started on CDISC?
- What's the challenge for starting CDISC ASAP?

Discussions

- How soon to get started on validations for topline analysis?



Discussions

- How soon to get started on validations for topline analysis?
- What's the challenge to start validations ASAP?

Appreciation

T h a n k s C D I S C
o r g a n i z a t i o n a n d a l l
w h o v o l u n t e e r e d
t h e i r v a l u a b l e t i m e
a n d e f f o r t s o n t h e
o n g o i n g s t a n d a r d s
p r o j e c t s !



Q & A

Q & A

Further discussions:

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