Data Management in clinical research

Today's contents

Introduction
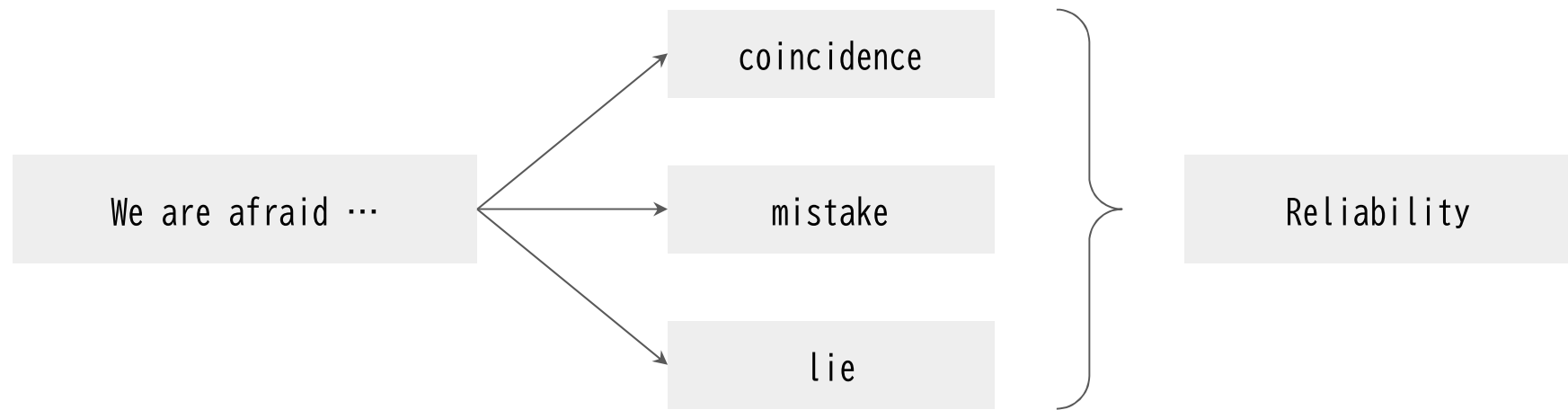
Statistics in Clinical Research

Data Management in Clinical Research
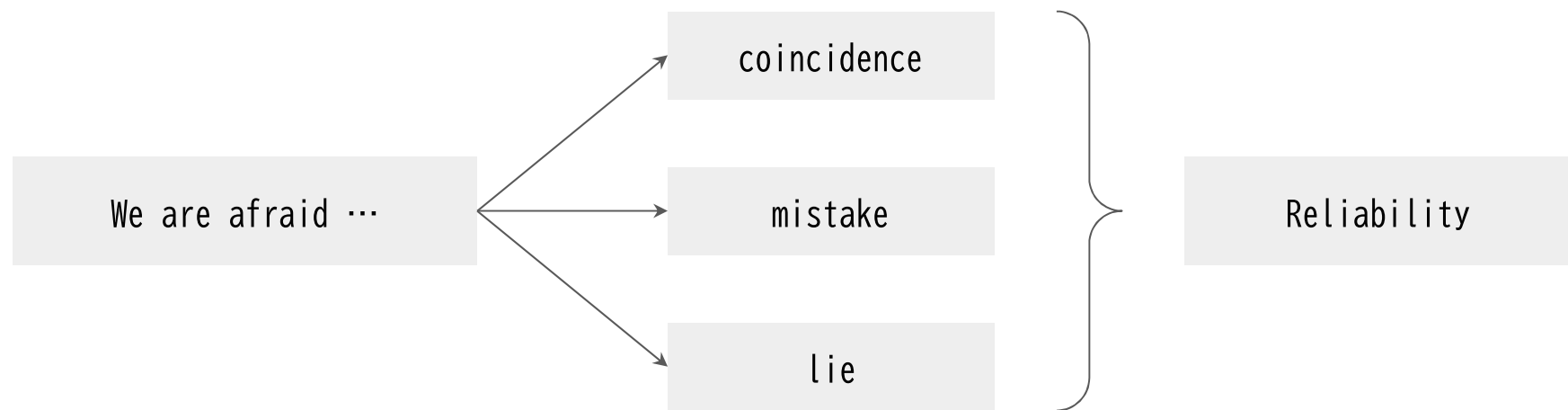
Wrap up meeting

Why can <u>not</u> we believe it?

coincidence

We are afraid …

mistake

lie

Reliability

Our mission is to keep the Reliability of Clinical Research.
We call it "Quality of Clinical Research".

What is Data Management? Why do we need Data Management?

```
                          coincidence

We are afraid ···         mistake          }      Reliability

                          lie
```
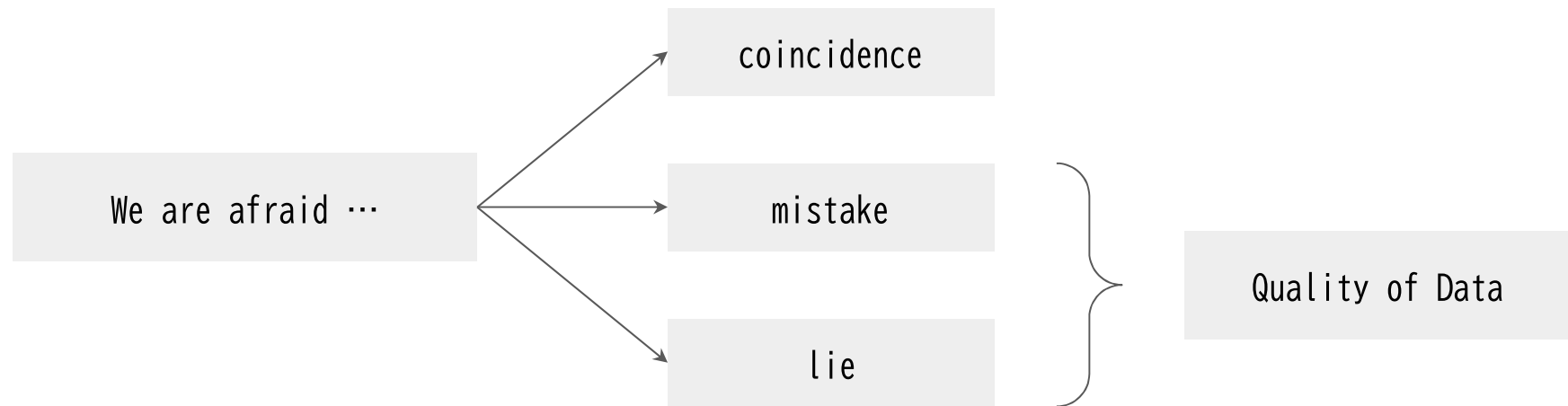
Our mission is to keep the Reliability of Clinical Research.
We call it "Quality of Clinical Research".

What is Data Management? Why do we need Data Management?

We are afraid …

coincidence

mistake

lie

Quality of Data

The mission of Data Management is to keep the Quality of Data

What is Data Management? Why do we need Data Management?

We are afraid …

coincidence

mistake

lie

Quality of Data
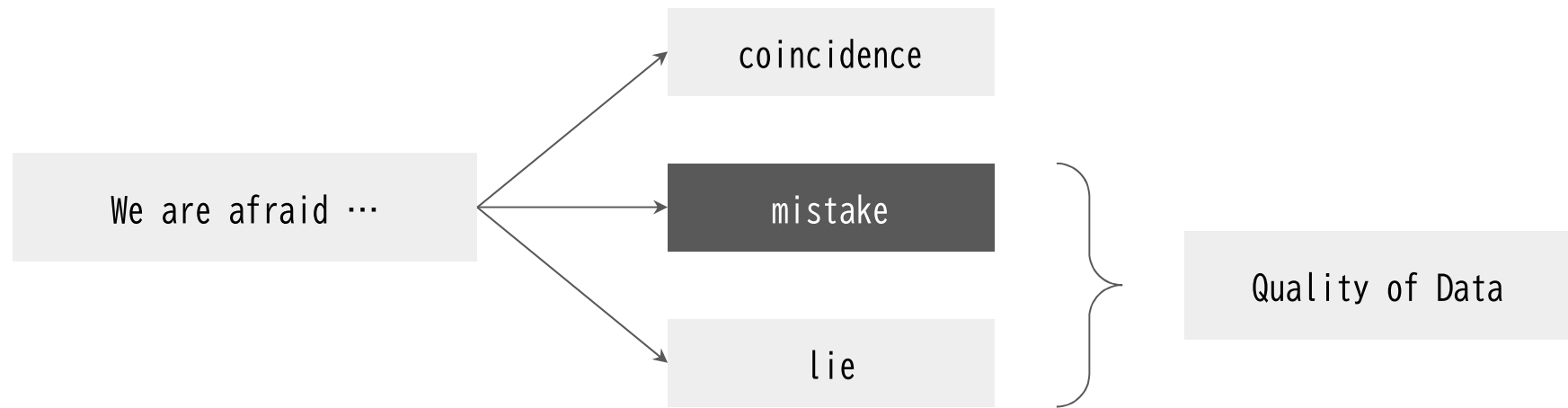
Why do mistakes occur?
Can we prevent it?

Why do mistakes occur? Can we prevent it?

tired and lost concentration	→ effort to make less
misunderstood	→ good explanation
difficult	→ easy
in a hurry	→ appropriate schedule management
nervous	→ relax
low motivation	→ high motivation

How can we prevent it?

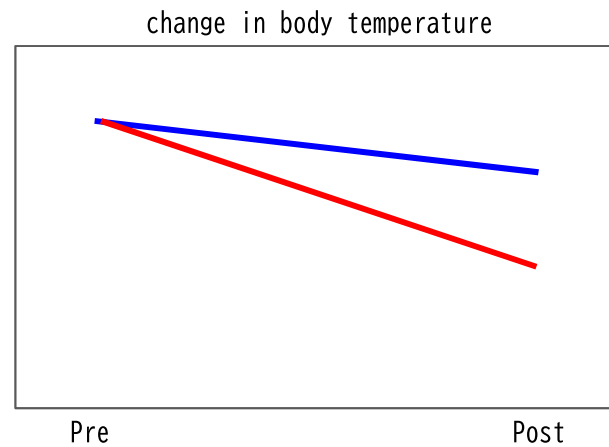|	
tired and lost concentration	→ effort to make less
misunderstood	→ good explanation
difficult	→ easy
in a hurry	→ appropriate schedule management
nervous	→ relax
low motivation	→ high motivation

effort to make less

Ex. We want to compare the effects of antipyretic A and antipyretic B.

change in body temperature

Pre   Post

What data should be collected in the clinical study?

let's discuss later!

How can we prevent it?

tired and lost concentration	→ effort to make less
misunderstood	→ good explanation
difficult	→ easy
in a hurry	→ appropriate schedule management
nervous	→ relax
low motivation	→ high motivation

easy

Key to success

Easy to use

Easy to understand

We should <u>design</u> our tools with these considerations in mind

CRF / EDC

How can we prevent it?

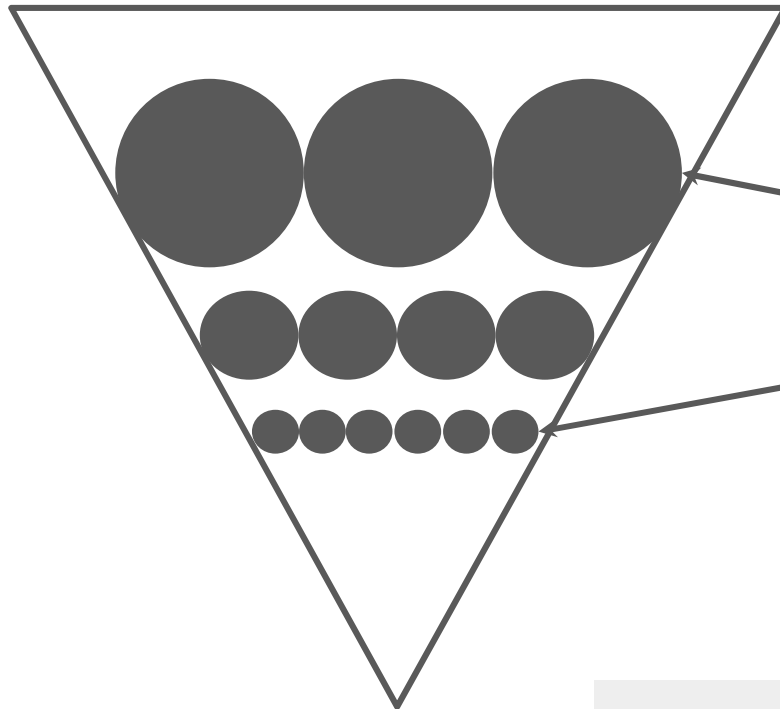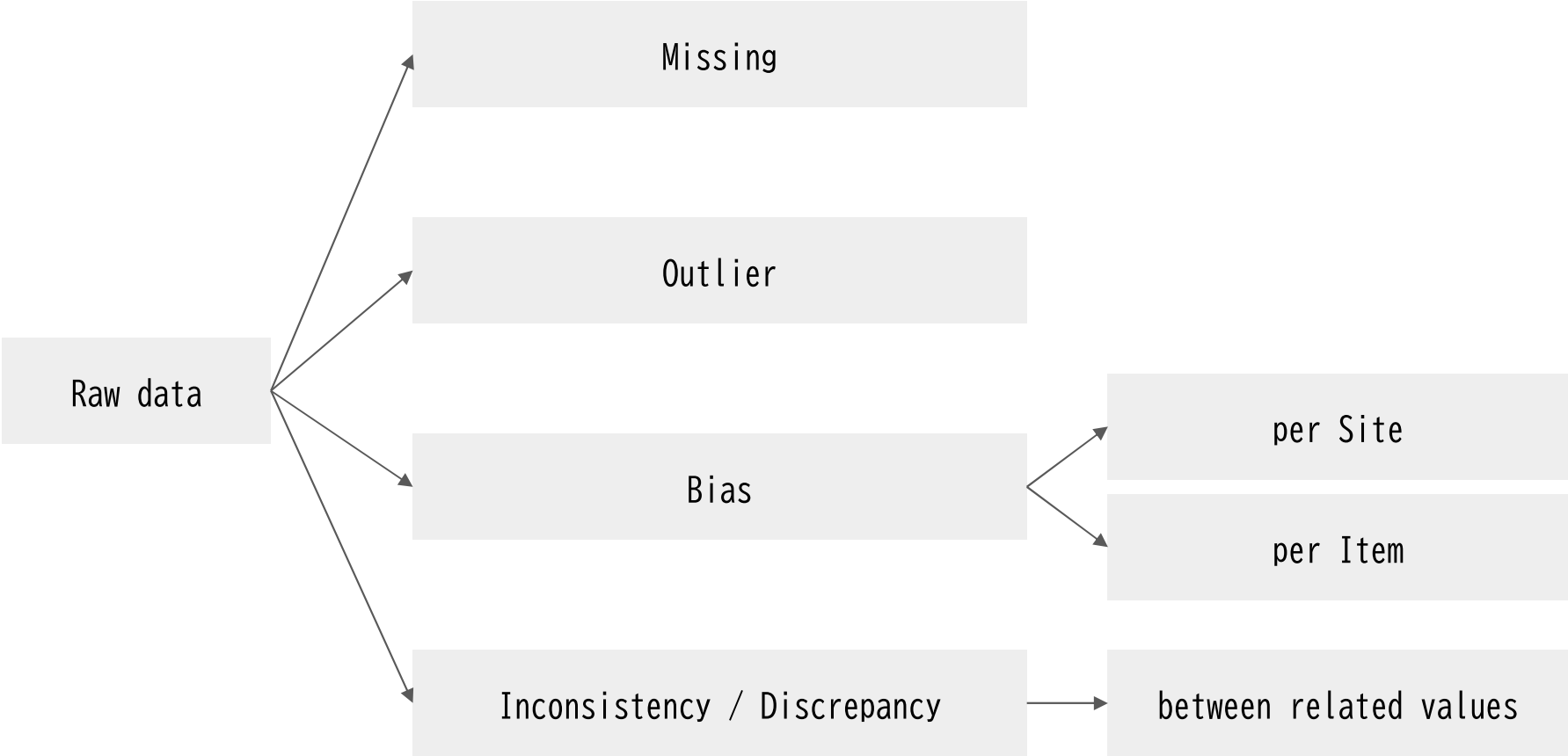|	
tired and lost concentration	→ effort to make less
misunderstood	→ good explanation
difficult	→ easy
in a hurry	→ appropriate schedule management
nervous	→ relax
low motivation	→ high motivation

relax

filter

if we tell investigators …

You are here

We are here

Investigators will relax a little

Data check & review is one of the important task

Points of Data check & Review

Raw data

Missing

Outlier

Bias → per Site
     → per Item

Inconsistency / Discrepancy → between related values

one point advise : "visualization" is important

Are all groups equal? (Anscombe's quartet)

|	A group	B group	C group	D group
mean of x	9.00	9.00	9.00	9.00
variance of x	11.00	11.00	11.00	11.00
mean of y	7.50	7.50	7.50	7.50
variance of y	4.13	4.13	4.12	4.12
regression line	y=3.00+0.500x	y=3.00+0.500x	y=3.00+0.500x	y=3.00+0.500x

Will you check raw data?

one point advise : "visualization" is important

A group		B group		C group		D group	
x	y	x	y	x	y	x	y
10.00	8.04	10.00	9.14	10.00	7.46	8.00	6.58
8.00	6.95	8.00	8.14	8.00	6.77	8.00	5.76
13.00	7.58	13.00	8.74	13.00	12.74	8.00	7.71
9.00	8.81	9.00	8.77	9.00	7.11	8.00	8.84
11.00	8.33	11.00	9.26	11.00	7.81	8.00	8.47
14.00	9.96	14.00	8.10	14.00	8.84	8.00	7.04
6.00	7.24	6.00	6.13	6.00	6.08	8.00	5.25
4.00	4.26	4.00	3.10	4.00	5.39	19.00	12.50
12.00	10.84	12.00	9.13	12.00	8.15	8.00	5.56
7.00	4.82	7.00	7.26	7.00	6.42	8.00	7.91
5.00	5.68	5.00	4.74	5.00	5.73	8.00	6.89

one point advise : "visualization" is important
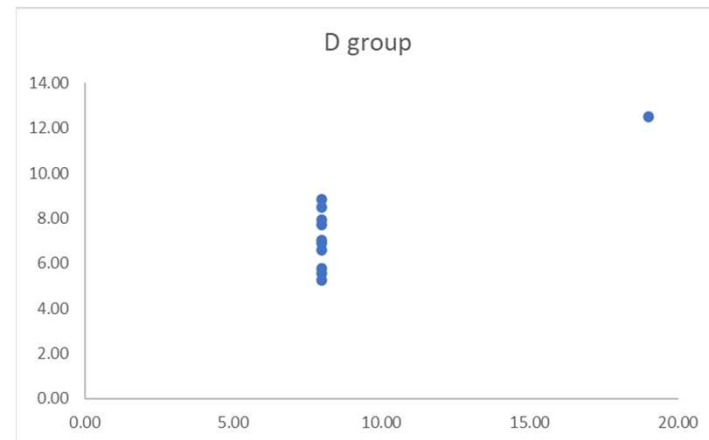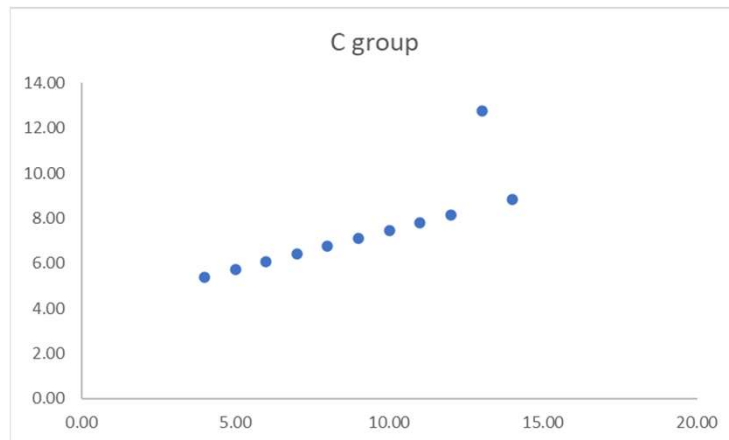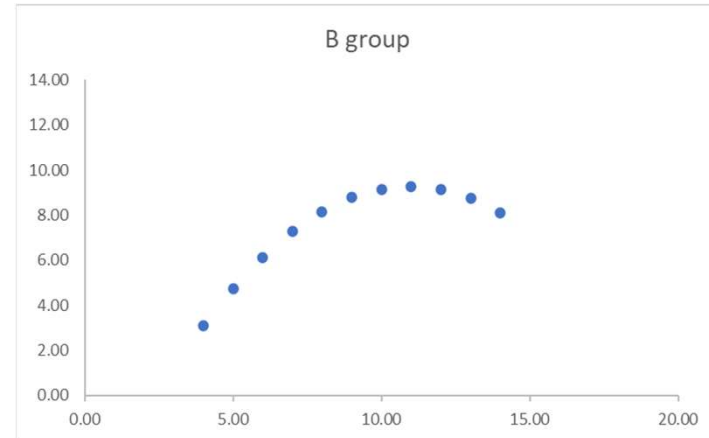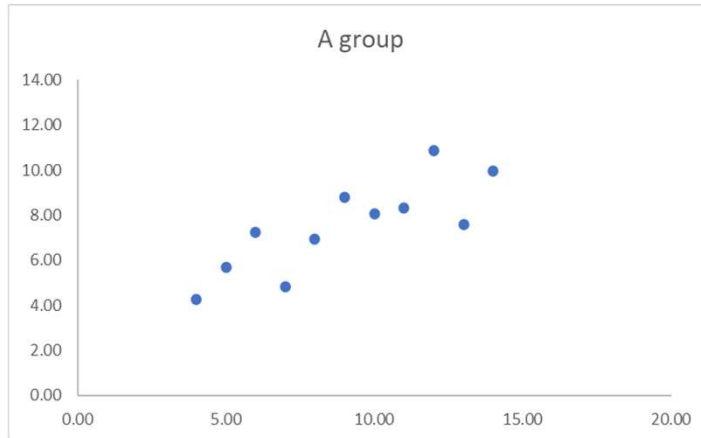
What is Data Management? Why do we need Data Management?
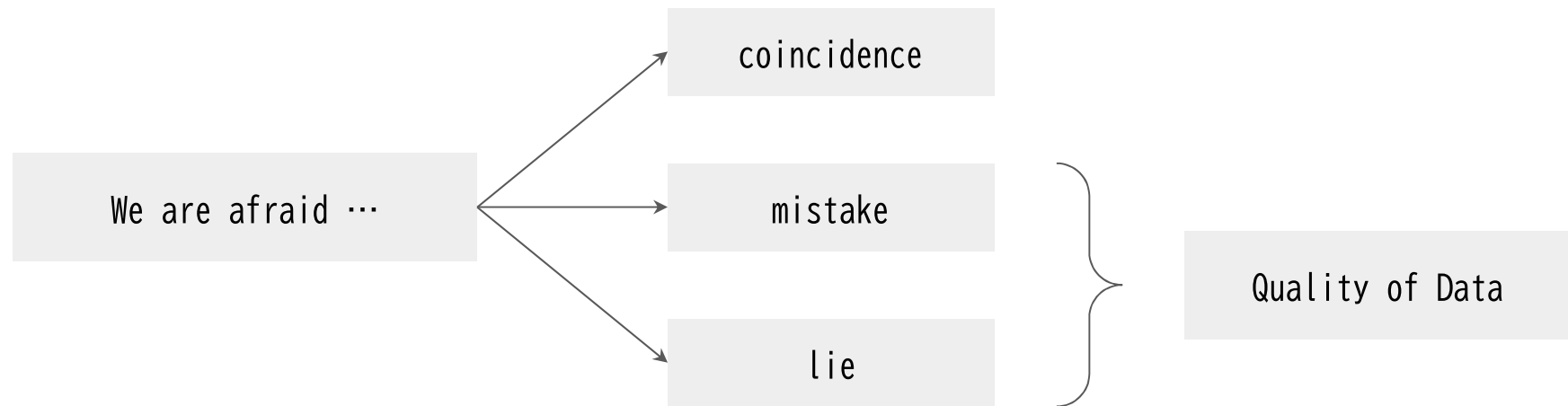
We are afraid … → coincidence

We are afraid … → mistake

We are afraid … → lie

Quality of Data

The mission of Data Management is to keep the Quality of Data

What is Data Management? Why do we need Data Management?

coincidence

We are afraid …

mistake

lie

Quality of Data
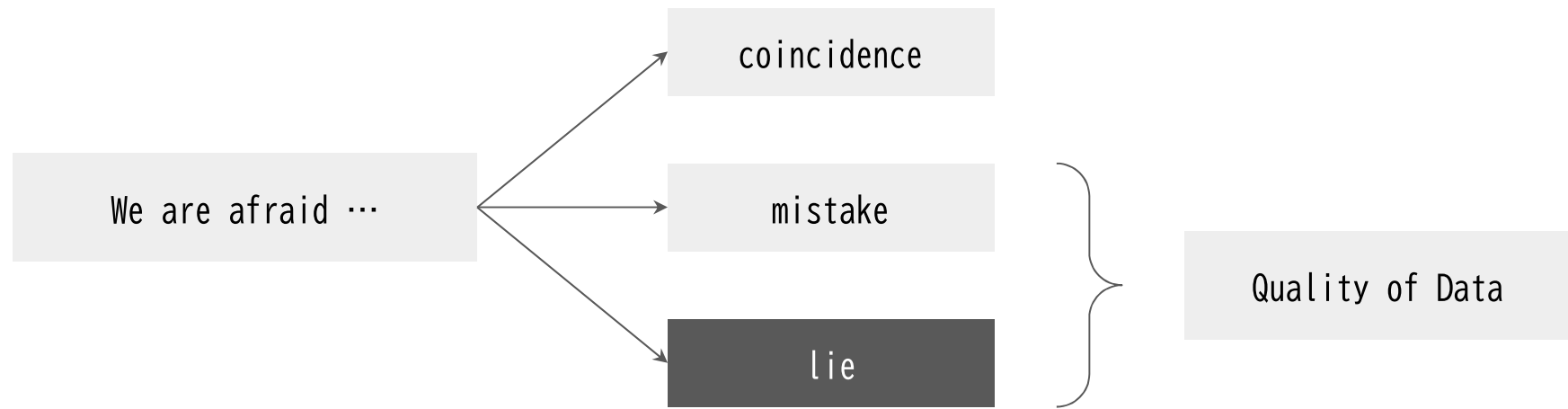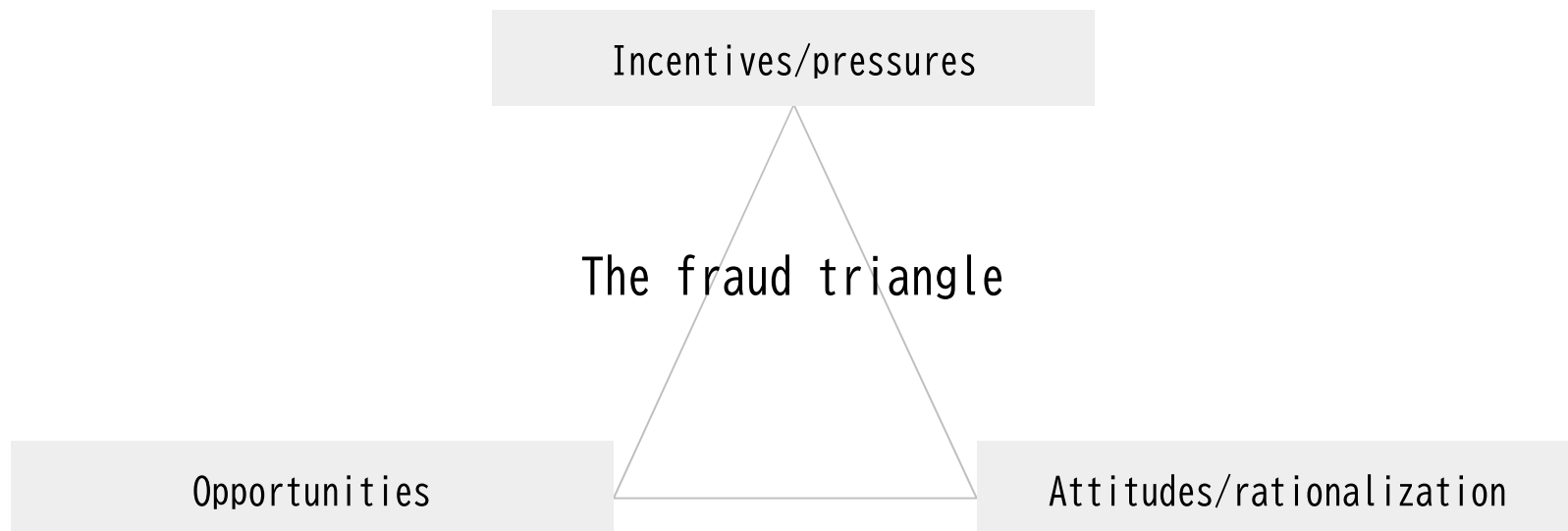
Why do people lie?
Can we avoid it?

Why do people lie? Can we avoid it?

People lie when three conditions are met   Donald Ray Cressey

Incentives/pressures

The fraud triangle

Opportunities   Attitudes/rationalization

if we can remove of these …

Why do people lie? Can we avoid it?

Independent / Organization

Incentives/pressures

The fraud triangle

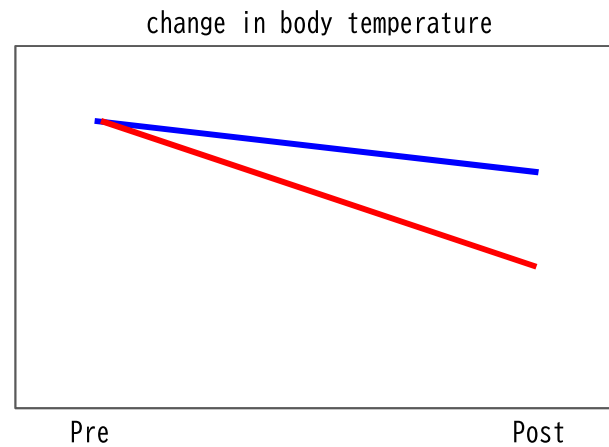Disclosed / Recorded

Opportunities

Education / Communication

Attitudes/rationalization
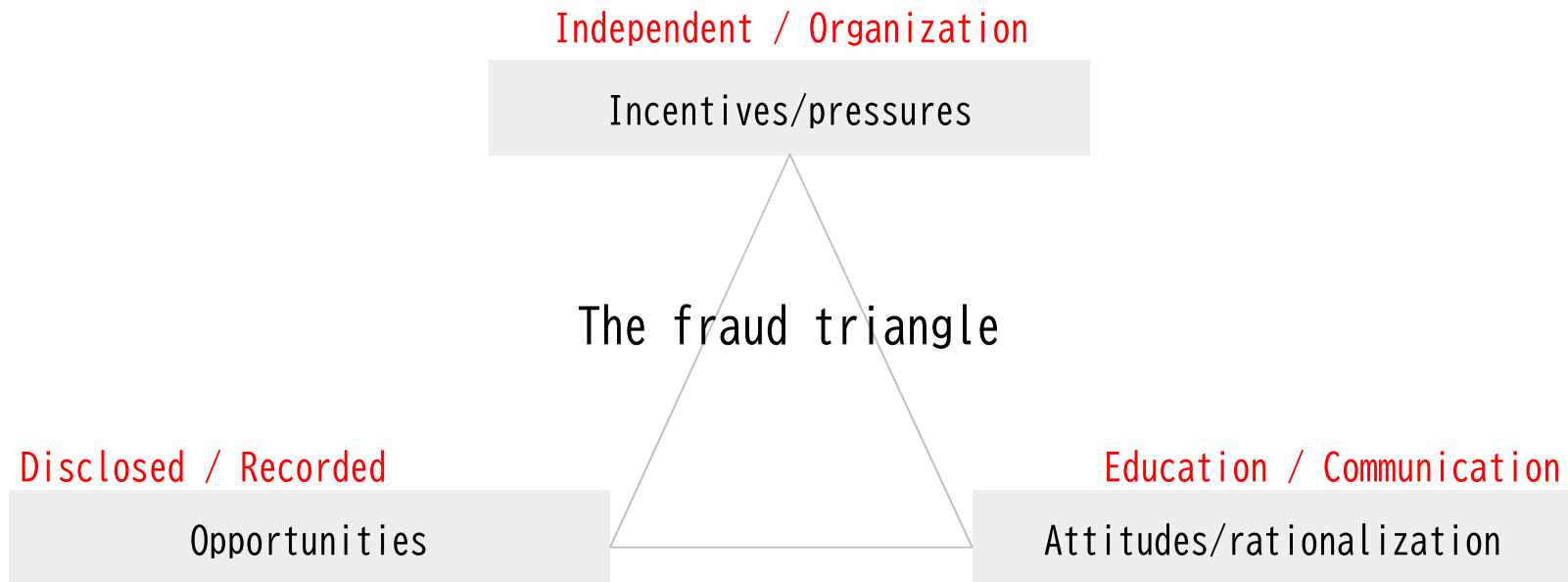
Data manager is an important role

Discussion

Ex. We want to compare the effects of antipyretic A and antipyretic B.

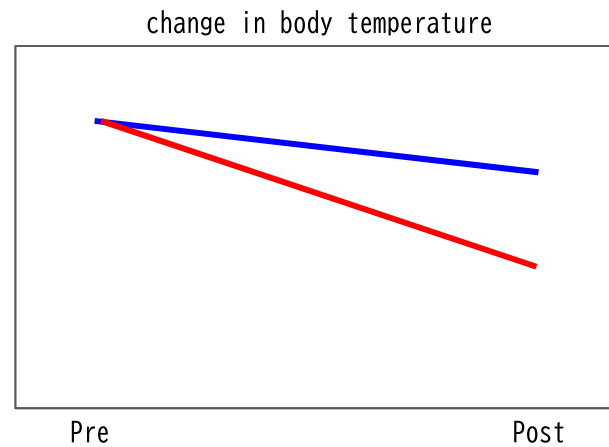change in body temperature

Pre   Post

What data should be collected in the clinical study?

Please consider a minimal observations

Discussion 2

Ex. We want to compare the effects of antipyretic A and antipyretic B.

change in body temperature
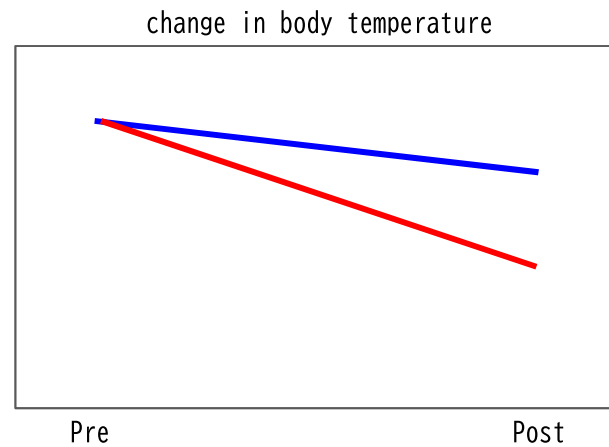
Pre   Post

What questions do you have if you see this result?(critical appraisal)

Please list all the questions that come to your mind

Discussion 3

Ex. We want to compare the effects of antipyretic A and antipyretic B.

change in body temperature

Pre   Post

How will you answer all the questions?

Please consider the observations we need to make to answer all questions logically

Today's contents

Introduction

Statistics in Clinical Research

Data Management in Clinical Research

Wrap up meeting

Today's contents

Introduction

Statistics in Clinical Research

Data Management in Clinical Research

Wrap up meeting