Today’s overview

Disclaimer

- ✓ The opinions expressed in this presentation are the personal opinions of the speaker and not those of the organizers or the organizations to which they belong.

- ✓ This presentation reflects the views of the speaker and should not be construed as representing the official views or policies of any regulatory authority.

Today’ s contents

Introduction

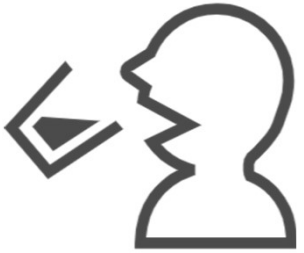
Statistics in Clinical Research

Data Management in Clinical Research

Wrap up meeting

Why do we need Clinical Research?

My illness was cured after taking the medicine.



Is the medicine effective?

Please raise your hand.

- Yes
- No

Is the medicine effective?

Investigator must answer both questions!

Today, we will unify researchers by calling them “investigator”.

Are there any patients who have been cured without taking the medicine?

Are there any patients who didn’t get better after taking the medicine?

However …

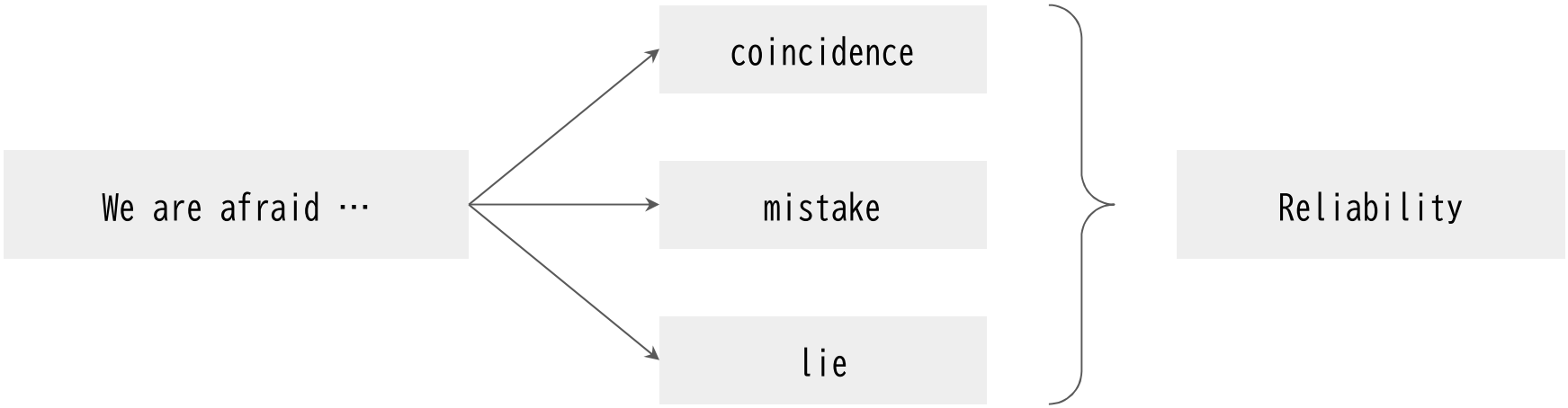
Can we believe the results of clinical research?

We got the result from the clinical research that the medicine is effective.

That study has enough data to answer both questions…

But, our confidence sometimes wavers …

Why can not we believe it?



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

How can we keep the quality of clinical research?

Standard regulation : ICH-E6 (GCP)

ICH E6 mentioned about quality multiple times

for examples…

ICH-E6	Introduction

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

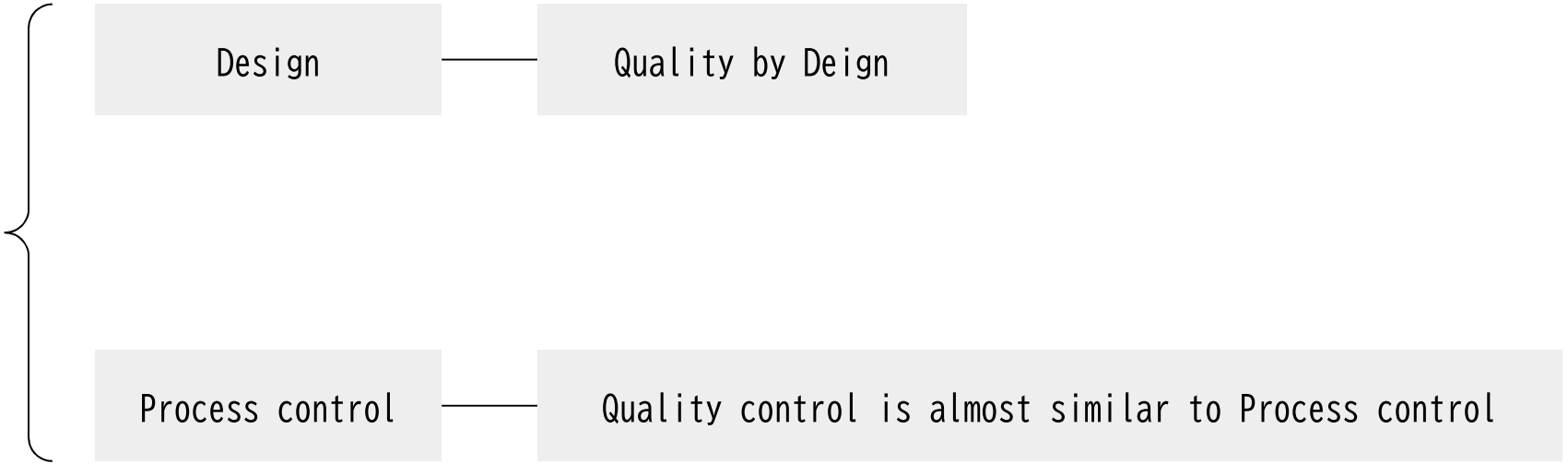
ICH-E6	5.0 Quality Management

Quality management includes the design of efficient clinical trial protocols and tools and procedures for data collection and processing, as well as the collection of information that is essential to decision making.

ICH-E6	5.1.3 Quality Assurance and Quality Control

Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

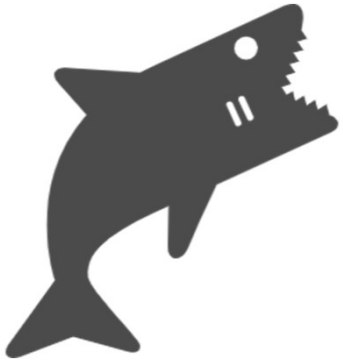
We will keep the quality of clinical research by …



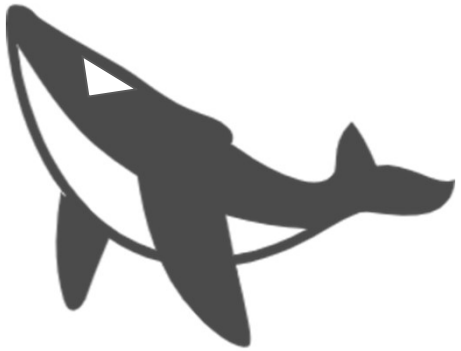
We will keep the quality of clinical research by …

Why and What is “Design” ?

Which one is stronger?



What is the definition of ”stronger”?



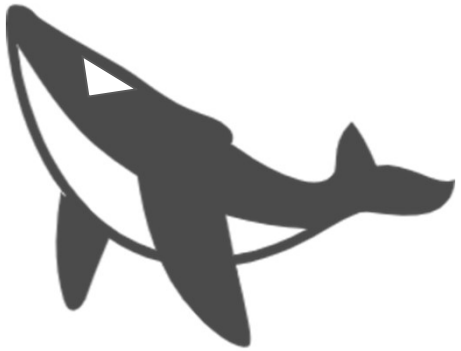
What is the condition of ”win”?

Is it fair?

Why and What is “Design” ?

Which one is stronger?

What is the definition of ”stronger”?



What is the condition of ”win”?

Is it fair?

Why and What is “Design”?

Which one is stronger?

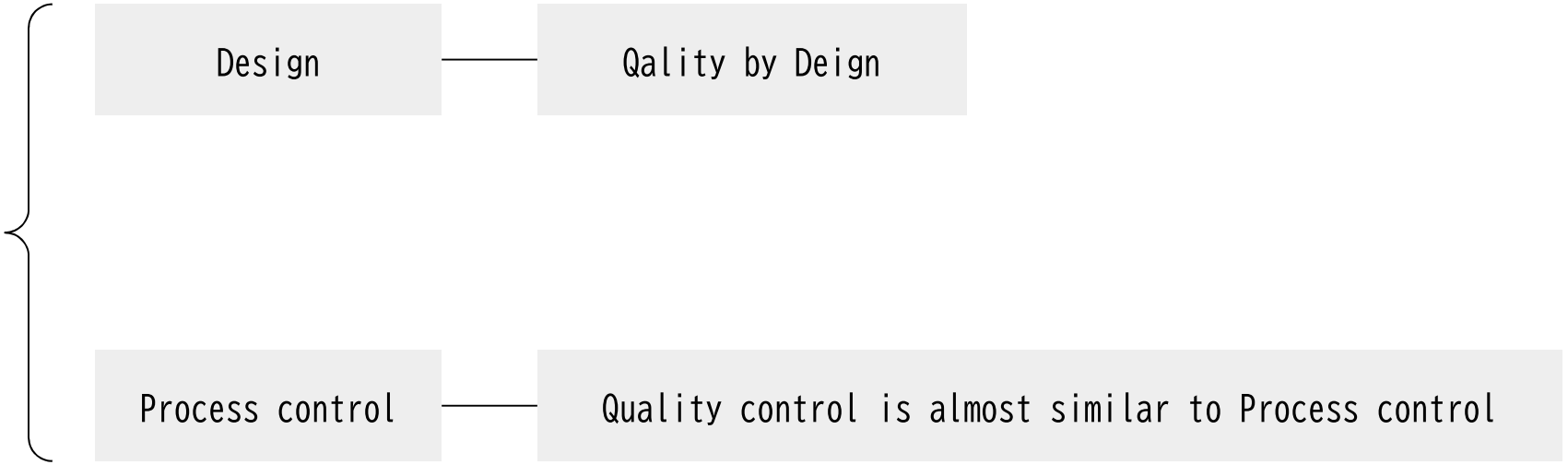
Purpose must be clear

Control group must be similar

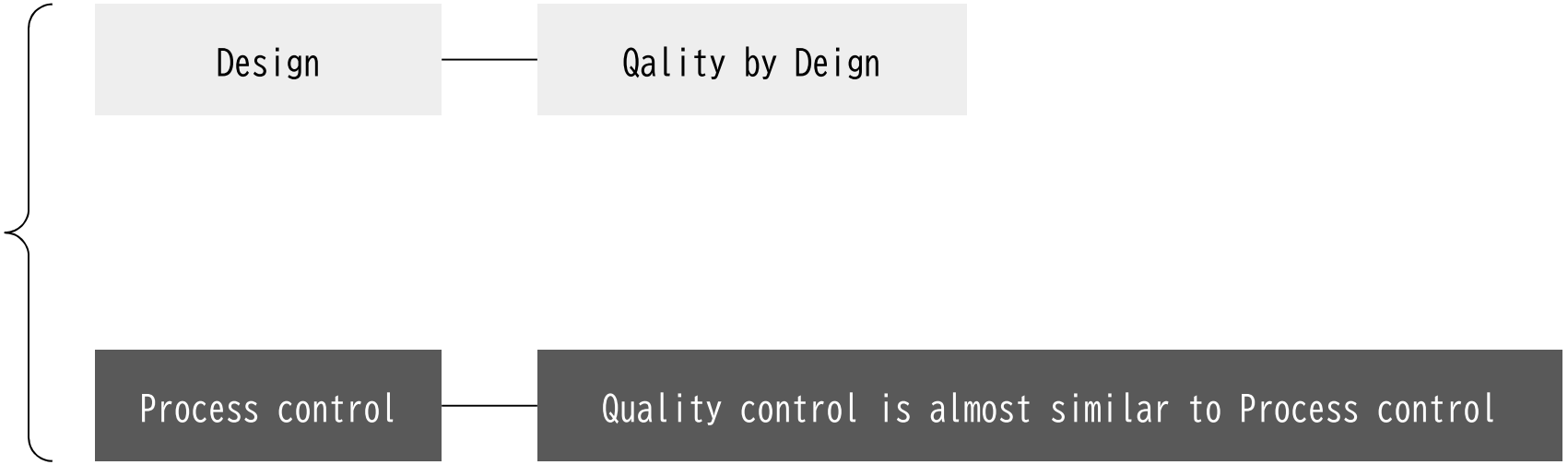
Conditions must be same

Evaluation metrics must be clear

We will keep the quality of clinical research by …



We will keep the quality of clinical research by …



Why and What is “Process control” ?

Patients hope to hear …

Not only the result of the subject who attended to the clinical research …

“Will the treatment work for me or not?”

We don’t have to keep only the quality but the reproducibility

Reproducibility means …

We can expect the same results no matter when or who will use it

So …

We have to control not only Result but Process!

“True” Goal of Clinical Reserch

To answer the question from patients

“Will the treatment cure my disease?”

So …

We need not only Impression but Evidence!

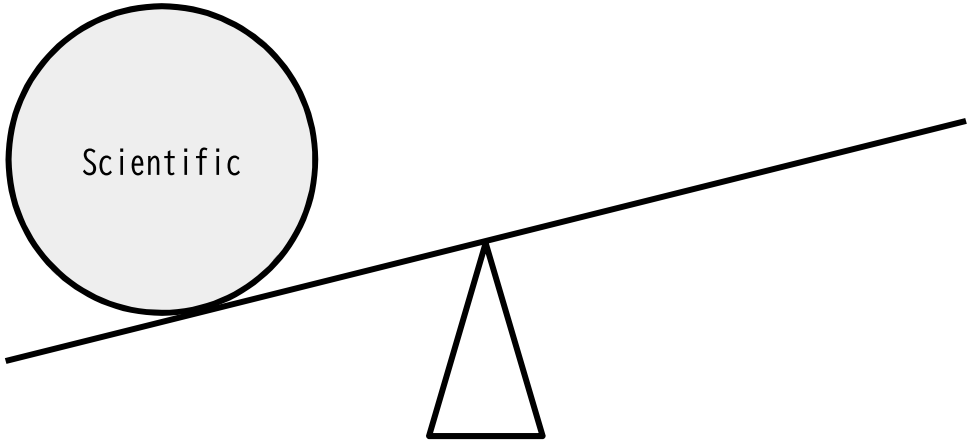
Today, we will focus on “Statistic” and “Data management”

We will discuss how to get reliable evidence in each session

One more thing

I’d like to say to you

We are talking about “Clinical research”



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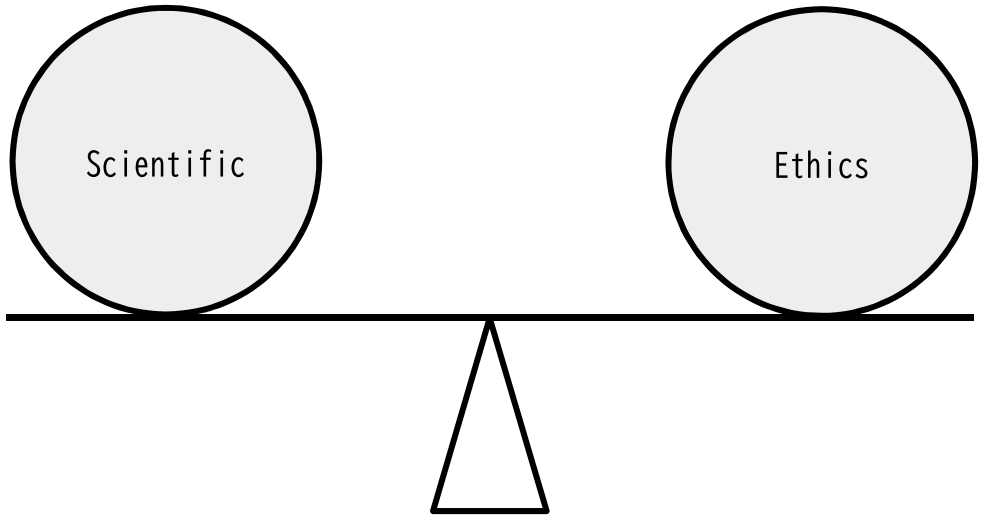

Discussion

Discussion

After completing the fifth subjects in one clinical research,

It became necessary to exclude women from the research for safety reasons.

But by that time, two women had already started.

What should we do?

What should we do?

What about the two subjects who have already started?

What about new registrations?

What should we pay attention to when analyzing after finish?

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