

# Multi-site Clinical Trials: Improving Compliance and Quality Through Education

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# Learning Objectives

Identify key area's  
of assessment in  
ongoing trials

Understand the key  
elements of a good  
quality improvement  
program for clinical  
studies

# History of Quality Improvement

Hawthorne Experiments in the 1920s

Walter Shewhart developed Statistical Process Control and the Shewhart Cycle (PDCA)

Total Quality Management (TQM) emerged in the 1950s

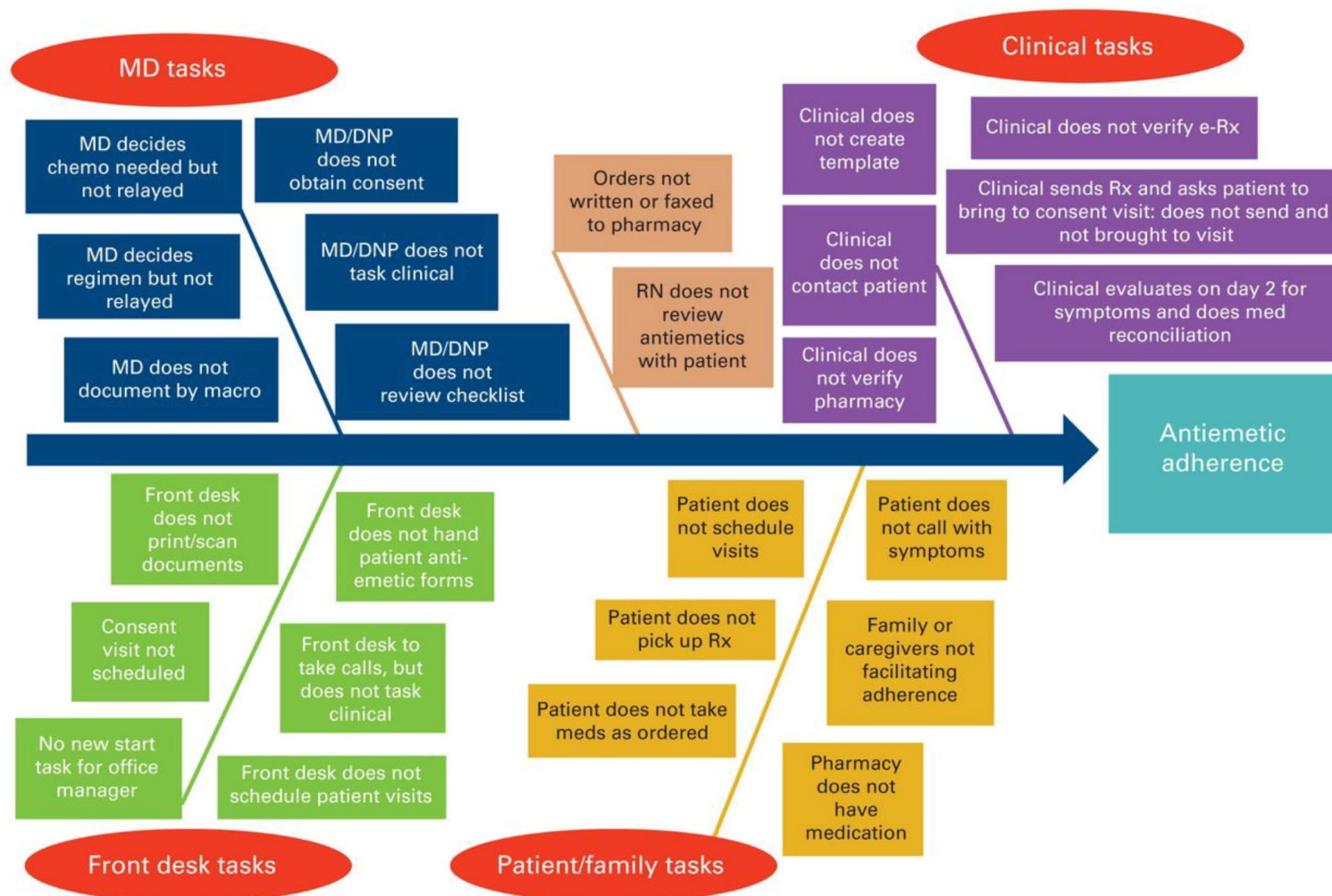
Ishikawa develops the Fishbone Diagram and TQM philosophy as continuous improvement in the 1960s

Application to healthcare began in the 2000s



# Plan, Do, Study, Act in Clinical Setting

- ▶ Identify the problem, intervention and determine what data need to be collected and by whom (Plan)
- ▶ Carry out the change or activity and collect the data (Do)
- ▶ Study the data collected (Study)
- ▶ Identify next steps or further PDSA cycles (Act).



# Fishbone Diagram

Improving Adherence With Oral Antiemetic Agents in Patients With Breast Cancer Receiving Chemotherapy

Carolyn B. Hendricks | Journal of Oncology Practice 2015 11:3, 216-218

# Why Clinical Trials?

- ▶ Answer specific questions about biomedical or behavioral interventions
- ▶ Generate data on safety and efficacy
- ▶ Receive Health Authority/Ethics oversight to make sure the research supports a risk/benefit that is “safe” and effective for conduct in human subjects

# Multi-Site Clinical Trials



- Research timelines
- Diverse range subject for enrollment
- Ethics committees
- Financial
- Develop new standard of care

# Multi-Site Clinical Trial Compliance

- ▶ Federal, State and local laws and regulations
- ▶ Protocol compliance
- ▶ Contract compliance
- ▶ Funding/Budget compliance
- ▶ Confidentiality compliance
- ▶ Billing compliance- corporate compliance -billing fraud-  
false claims act
- ▶ Conflicts of Interest



# Challenges



# Barriers that Affect Compliance

## Technology

- Internet Access
- Data Entry Timelines

## Language Barriers

- Translation of Documents
- Regulatory Authorities Rules

## Cultural Norms

- Assessments for Standard of Care
- Budget meet their cultural guidelines

## Time Zones

- How will you cover all Time Zones

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# Compliance



# Compliance- Off Target!



## Funding/Budget

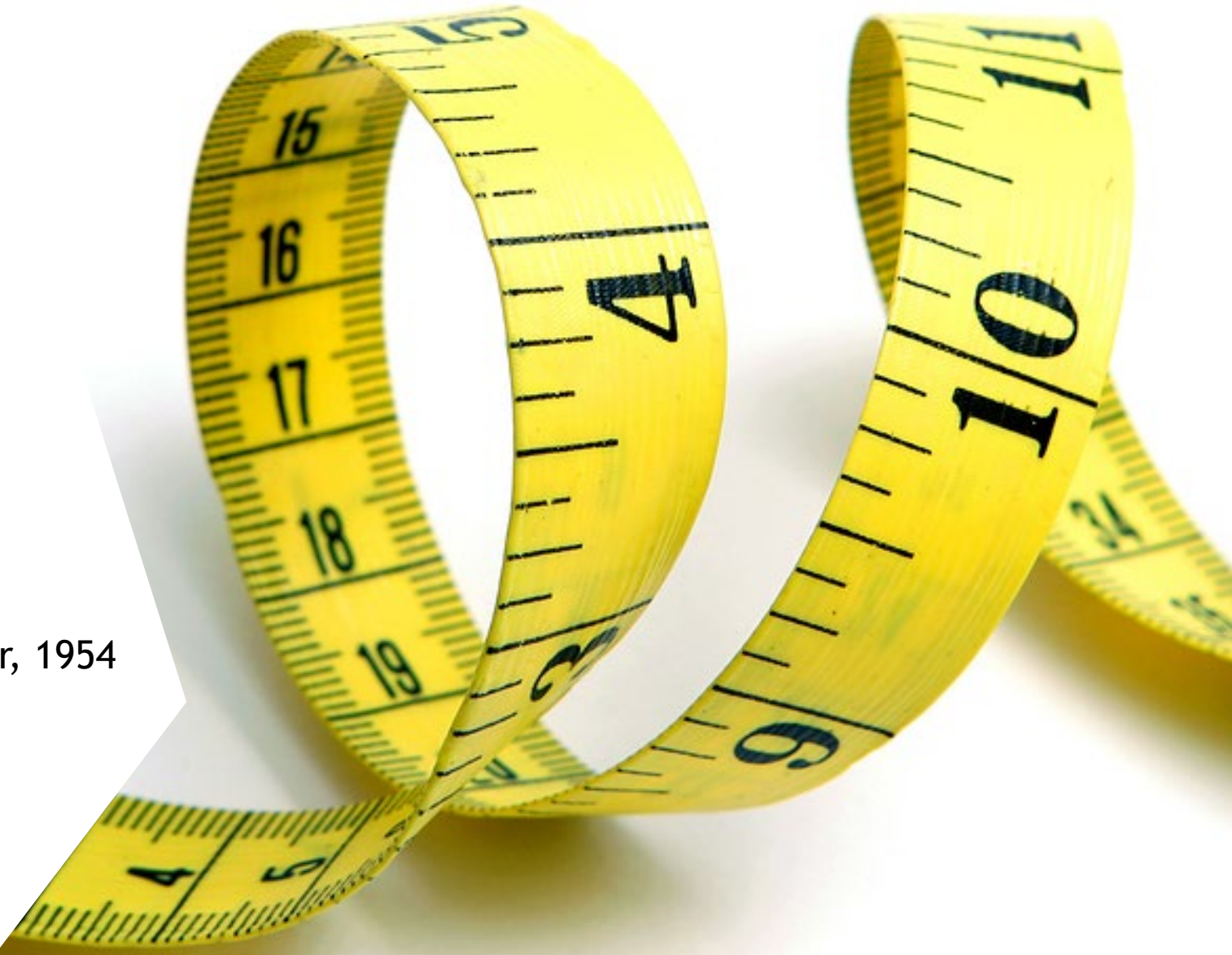
- ▶ 15 Countries
- ▶ Import/Export Laws

## Protocol Compliance

- ▶ Tissue Submission
- ▶ Patient Surveys'

# What Get Measured Gets Managed

By Peter Drucker, 1954





# Identify Key Areas to Assess

- ▶ What challenges put your study at risk for meeting your goals?
- ▶ What budget item may limit site participation?
- ▶ What import law could stop participation for a country?
- ▶ Is the patient journey in your country mix acceptable for meeting your inclusion criteria?
- ▶ What data do you need to reach your study objectives?



# Key Area's of Assessment

## Budget Considerations

1. Legal issues beyond import/export for payments of subjects.
2. Taxation
3. Shipping costs
4. 24 hours hotline access
5. Training and interpreter costs
6. Import/Export Costs

## Protocol Compliance

1. Track the submission of tissue
2. Track the submission of QOL at each timepoint for validation
3. Feedback to site on timelines
4. Client access to reports

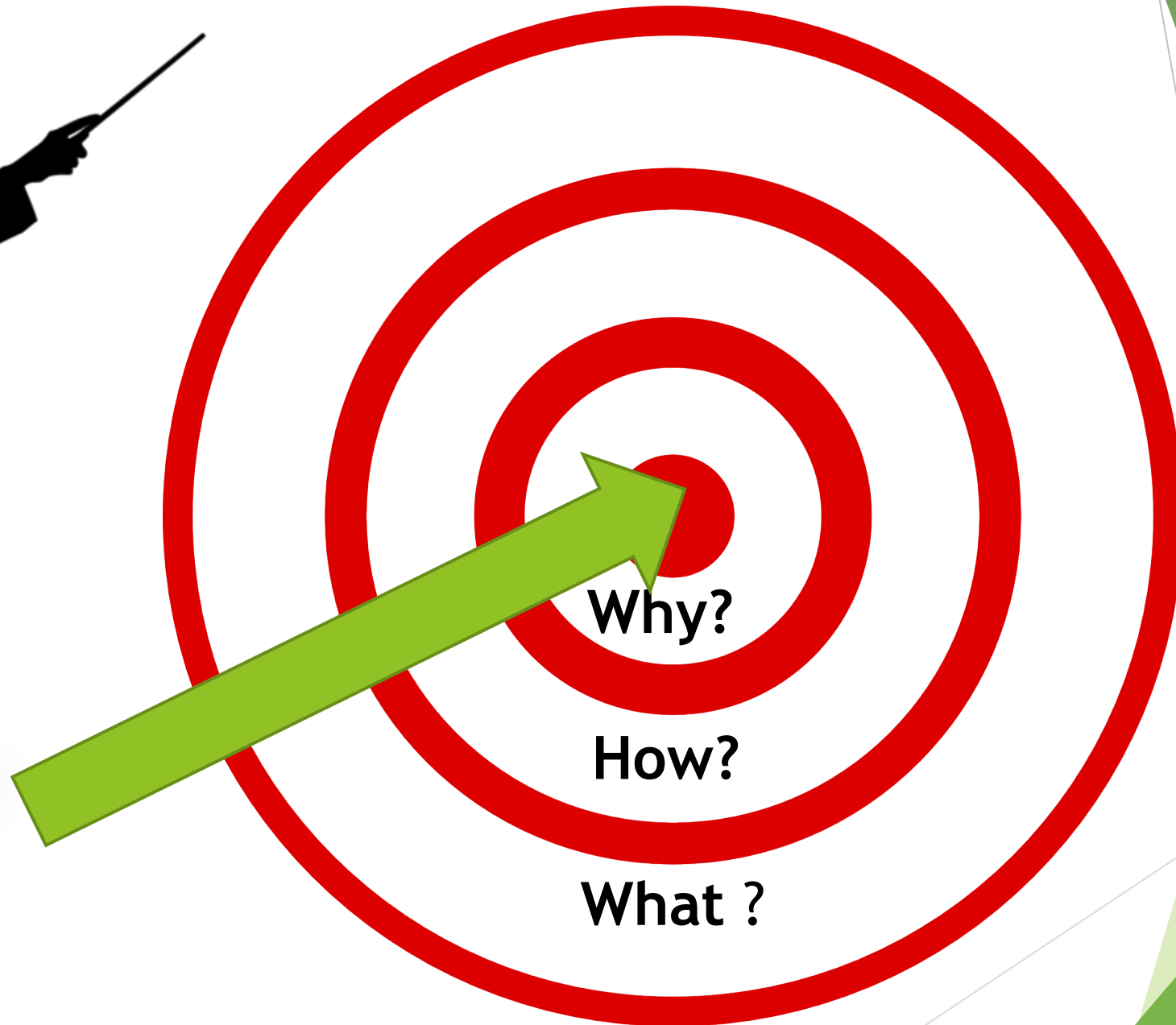


People don't buy what you do;  
they buy why you do it.

And what you do simply  
proves what you believe”

— Simon Sinek, Start with Why: How Great  
Leaders Inspire Everyone to Take Action

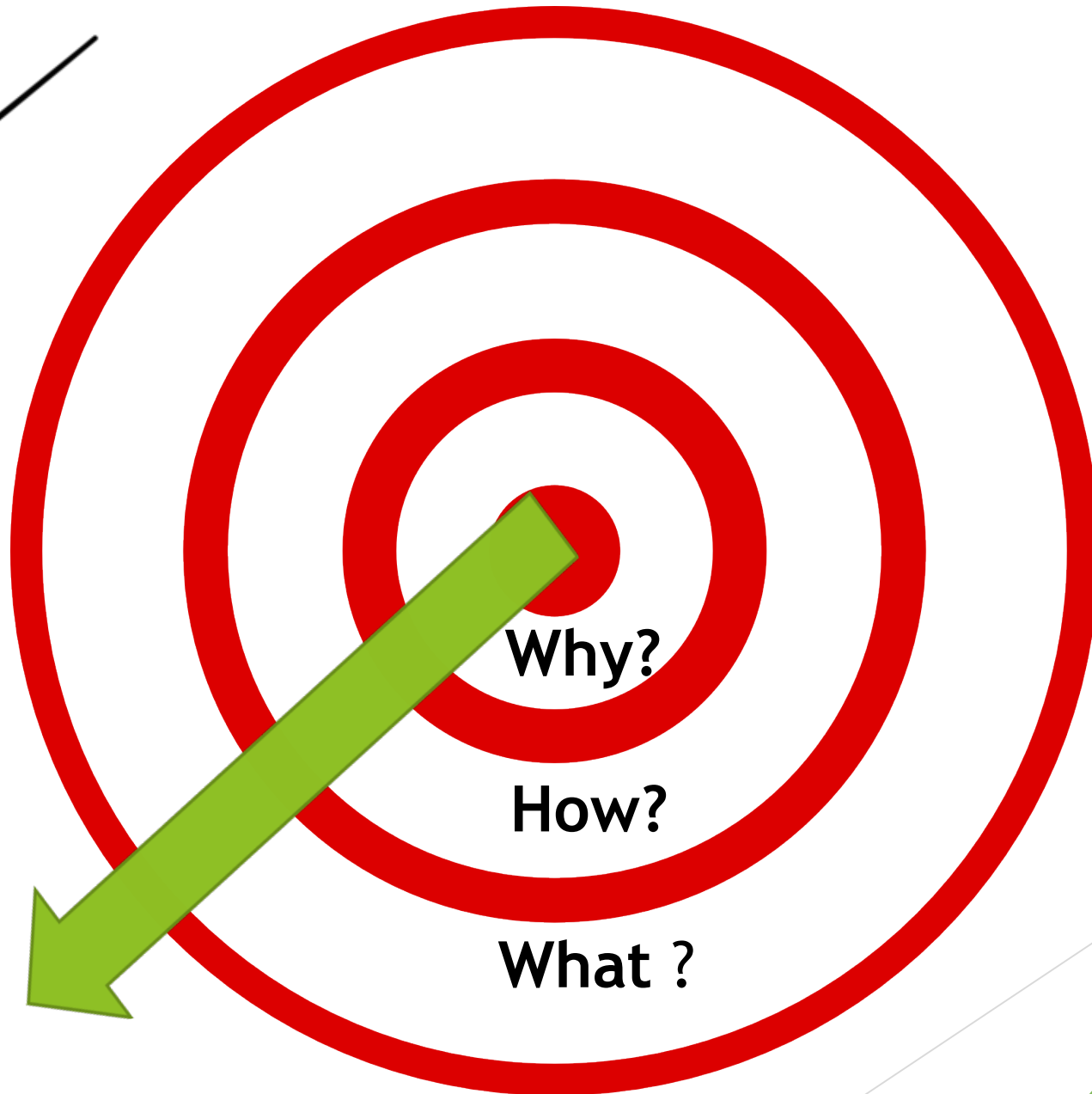




**Why?**

**How?**

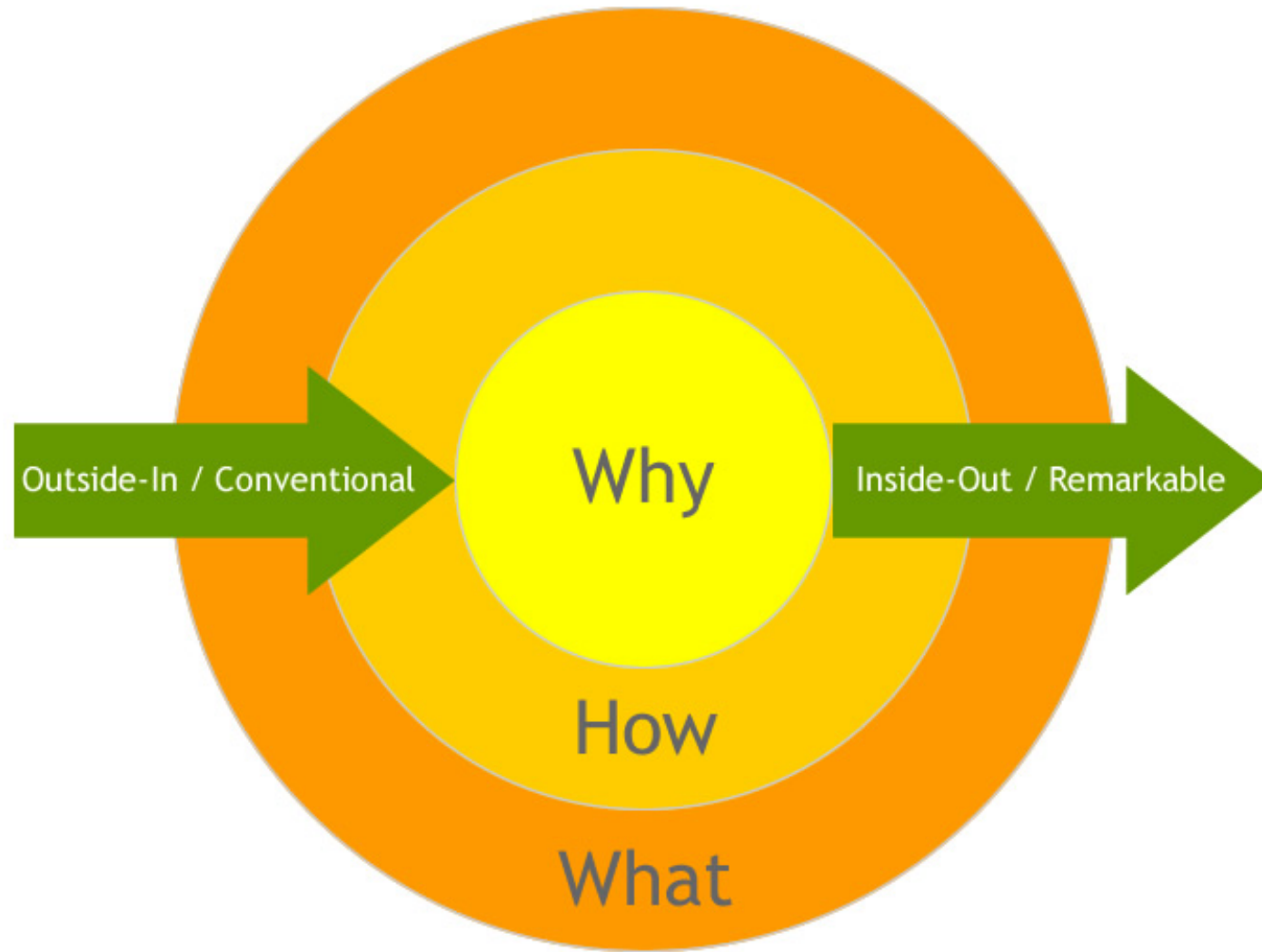
**What ?**



**Why?**

**How?**

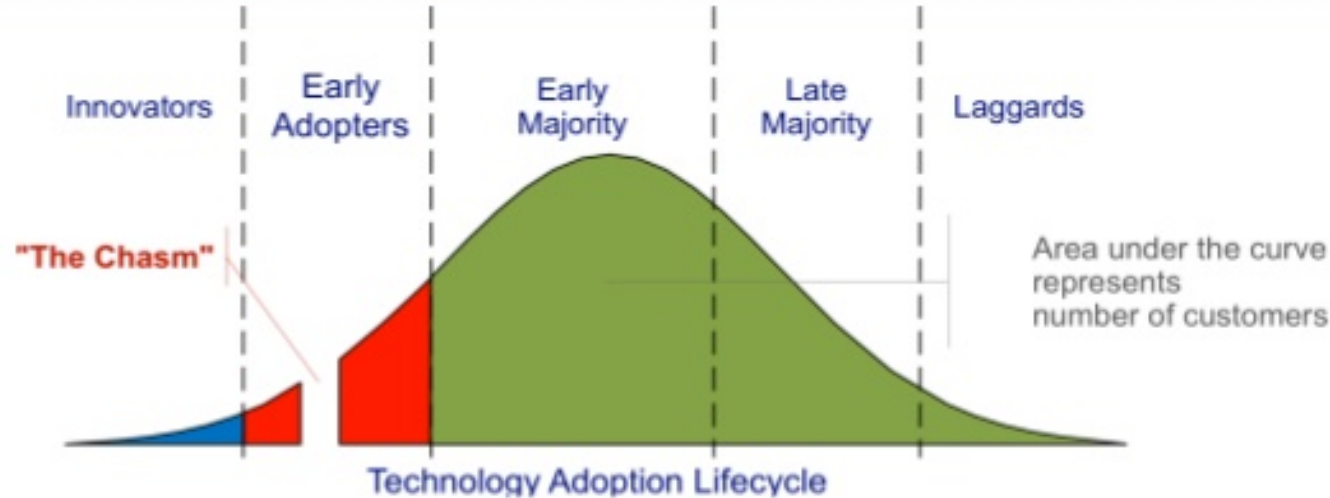
**What ?**



# Teaching Compliance to Get Quality

- ▶ Diffusion of innovations is a theory that seeks to explain how, why, and at what rate new ideas and technology spread

# Diffusion of Innovation & Adopter Categories



- **Innovators** : First 2.5% of individuals to adopt an innovation.
  - Adventurous, comfortable with a high degree of complexity and uncertainty
  - have access to substantial financial resources
- **Early Adopters** : 13.5%
  - Adopt the innovation
  - are excellent "missionaries" for new products or processes.
- **Early Majority** : 34%.
  - Adopt innovations slightly before the average member of a social system.
- **Late Majority** : 34%
  - Adopt innovation with a skeptical air
  - They may have scarce resources.
- **Laggards**: 16%

## Law of Diffusion of Innovation

By Everett Rogers, 2003  
Diffusion of Innovations



# Those who lead-Inspire

“Great leaders must have two things: a vision of the world that does not yet exist and the ability to communicate that vision clearly.”

~Simon Sinek



# Teach Why!

- ▶ What are the key area for your trial that are at risk for compliance
- ▶ What elements of the study are challenging for sites to complete or agree to
- ▶ Understand your clients needs
- ▶ Change your message
- ▶ Measure your areas of risk

# Teaching Compliance to Get Quality

## Why

We want to know how this study treatments affects your patients lives

## How

Ask your subject to complete QOL questionnaires during their time on study

## What

4 Questionnaires that ask your patients questions about their quality of life

# Teaching Compliance to Get Quality

## Why

Knowing the drug levels in the subjects one hour after infusion will help us understand the right drug dosage

## How

Please keep the patient in clinic for an extra hour for an additional blood draw

## What

One blood draw one hour after infusion needs to be sent to central lab

# Elements of quality improvement program

- ▶ Teach Compliance to Drive Quality
- ▶ Measure metrics
- ▶ Verify Data
- ▶ Verify Process
- ▶ Assess Frequently
- ▶ Be Creative!

# Measure Metrics

- ▶ Use metrics that are measurable
- ▶ Perform monitoring & Processes Improvement
- ▶ Reporting
- ▶ Predictive Analytics & Forecasting



# Technology

- ▶ Use Tablets to collected data electronically
- ▶ App's on cell phones can collect data from subjects
- ▶ Web Based Portals

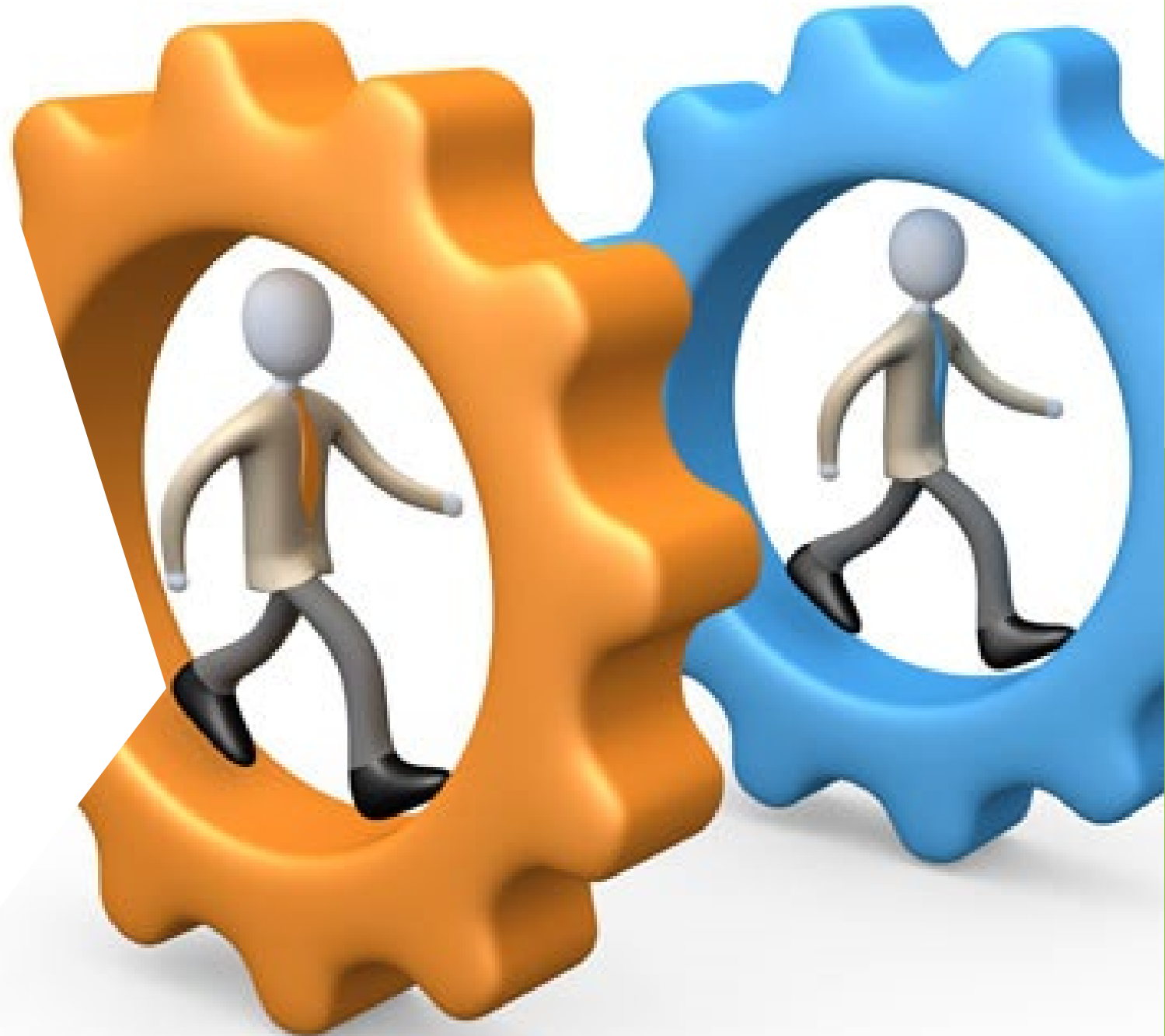


Verify Data



# Verify Process

- ▶ Standard Operating Procedures
- ▶ Good Clinical Practice
- ▶ ICH Guidelines
- ▶ Import/Export Laws
- ▶ Billing Compliance



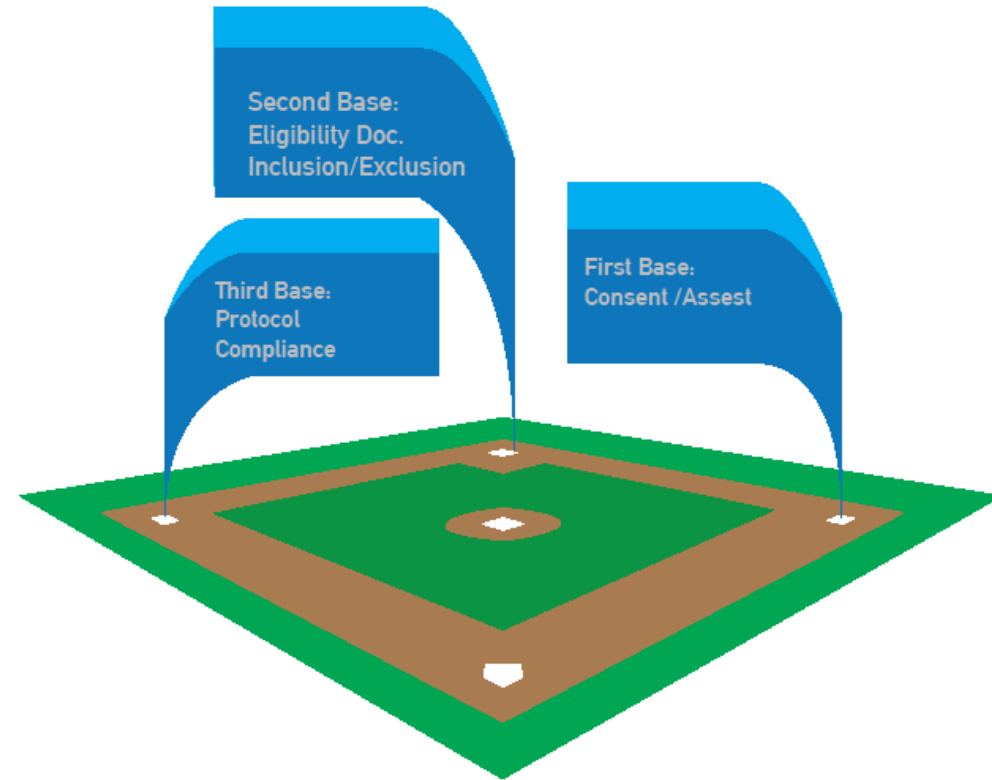




# Spring Training

Be Creative!

► Home Run Score Card



	# Bat	1 <sup>st</sup> Base	2 <sup>nd</sup> Base	3 <sup>rd</sup> Base	Home Runs
Pre Training 2015 Audit	136	8	11	115	2
Post Training March-Oct	1909	9	2	30	1868

# Elements of quality improvement program

- ▶ Teach Compliance to Drive Quality
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- ▶ Assess Frequently
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# Why Challenges



The background of the slide is a solid light green. On the right side, there is a complex geometric design consisting of several overlapping triangles and polygons in various shades of green, ranging from a very light, almost white green to a dark forest green. These shapes create a sense of depth and movement. A thin, dark green line also runs diagonally across the right side, intersecting the geometric shapes.

► Be Creative

“The role of a leader is not to come up with all the great ideas. The role of a leader is to create an environment in which great ideas can happen.”

— Simon Sinek, [Start with Why: How Great Leaders Inspire Everyone to Take Action](#)

# Questions

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