



# ***Attempt for Quality Improvement by Standardization of Process***

***~Data Entry System Developed by ACRONET Corp.~***

***ACRONET Corp. Data Management & Biostatistics Dept.***

***Miyuki Takada\* Tadanori Hirano Tomoyoshi Sato***

***ACRONET***



# Contents



1

**Background**

2

**Motivation**

3

**In Development**

4

**Effect Achieved**

5

**Summary**

6

**Conclusion**

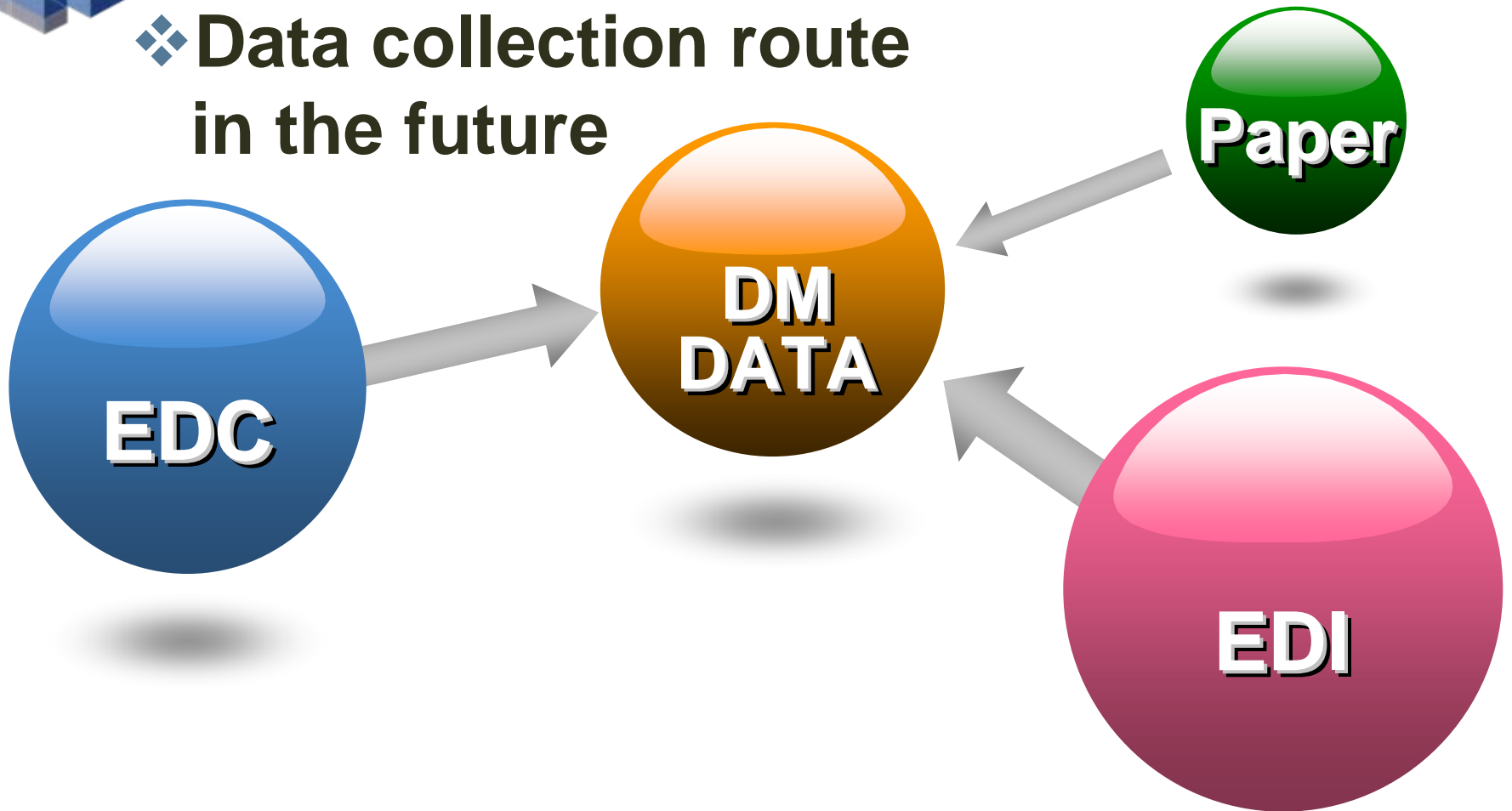


# *Background*

- ❖ **The data entry system developed by ACRONET Corp.**
  - Possible of customizing
  - Operational restriction free
  - Data entry system suitable for clinical trials developed by data manager

# *Background*

❖ **Data collection route  
in the future**





# *Motivation*

- ❖ **Early stage when development started without standardizing process**
  - Development time depended on the developer
  - Quality depended on the developer
  - Difference of operability occurred by difference of development procedure
  - Expanding risk by repeated entry system file copy



# *Motivation*

**Development  
time depended  
on the developer**

**Quality  
depended on  
the developer**

**Difference of  
operability**

**Expanding risk  
by repeated  
entry system  
file copy**

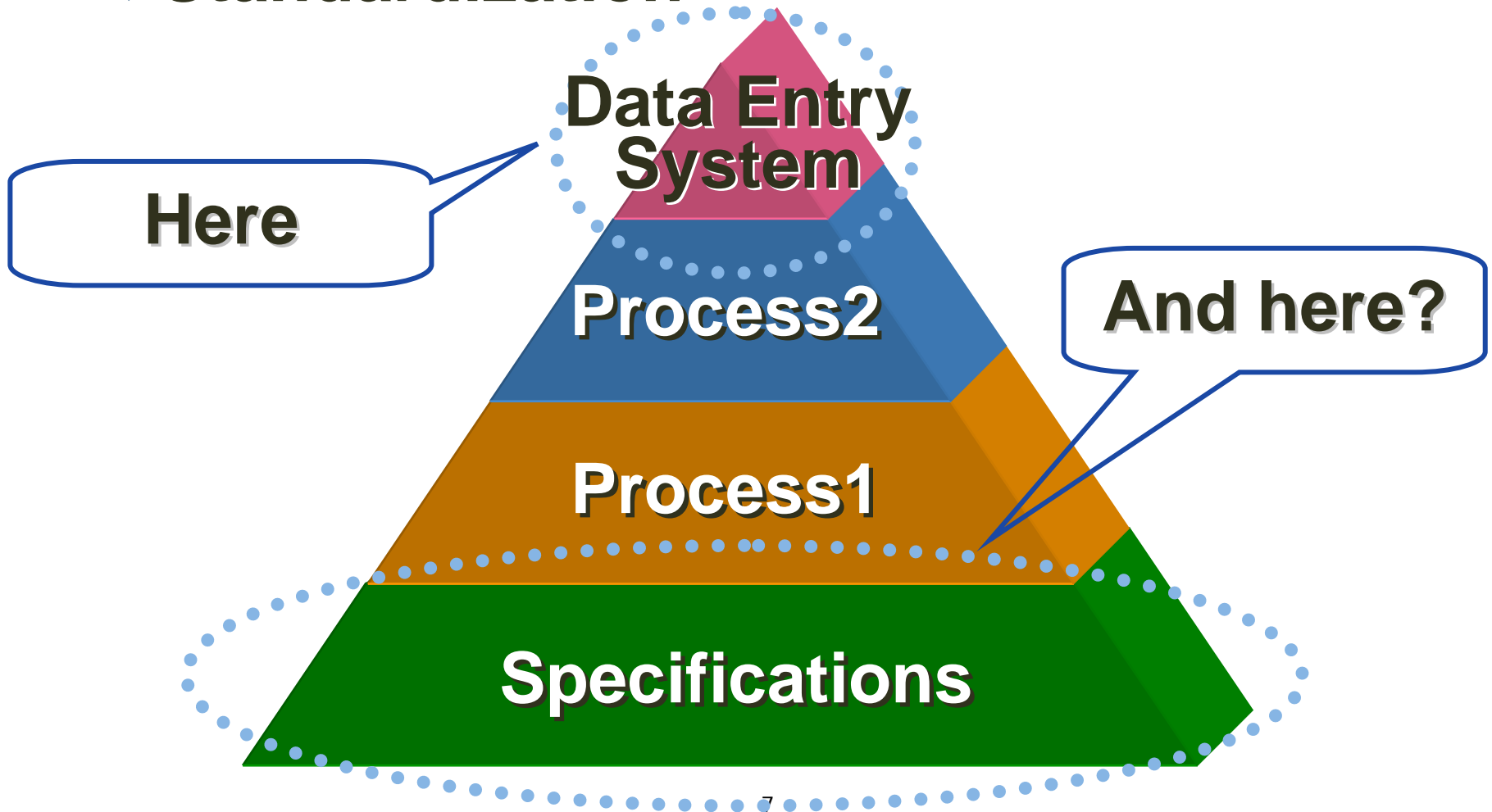
**Solution method**

**Standardization**



# *In Development*

## ❖ Standardization





# *In Development*

## ❖ Standardization



**Data Entry  
System**

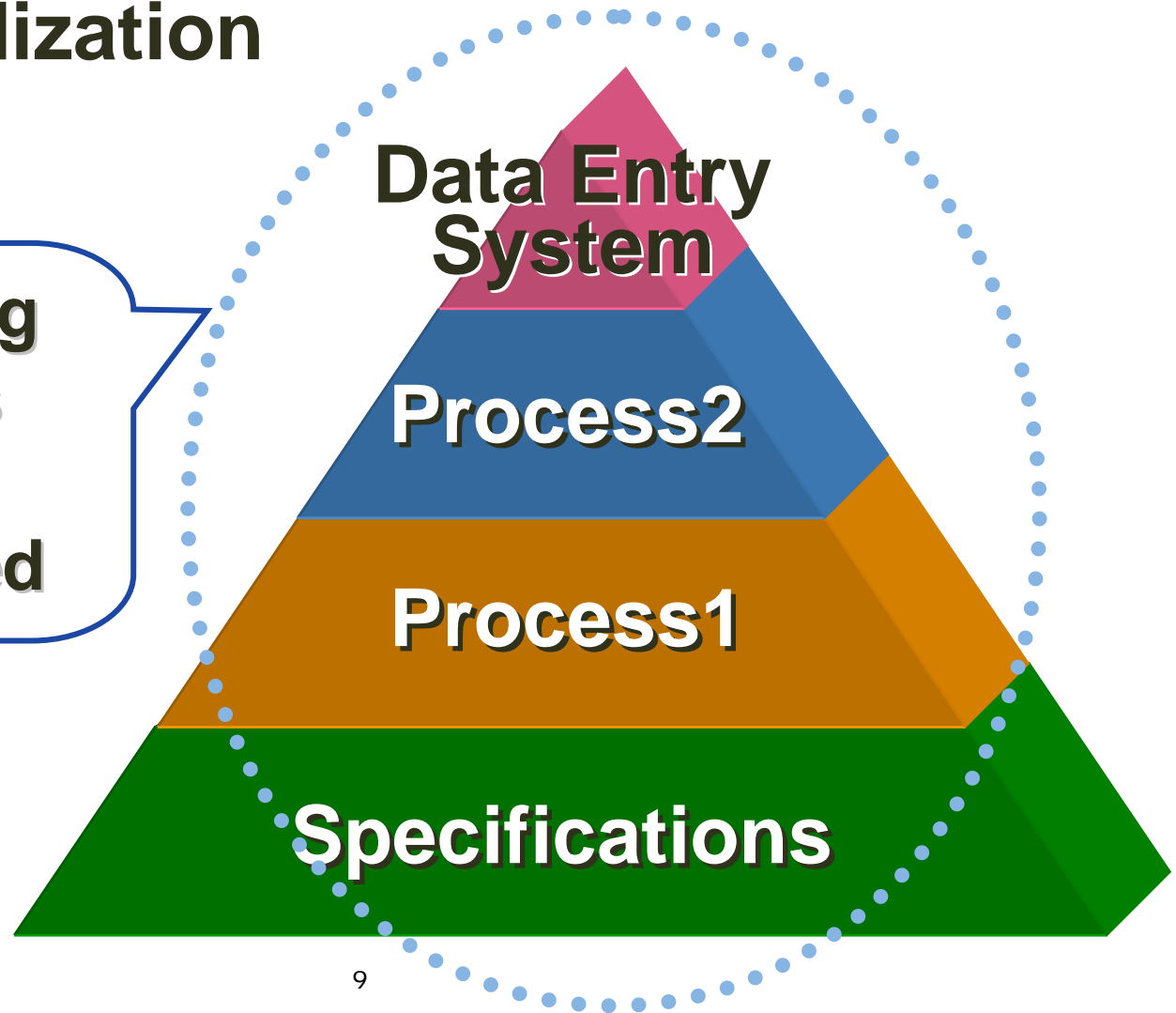


**Specifications**

# *In Development*

## ❖ Standardization

All including  
processes  
should be  
standardized





# *In Development*



## ❖ **Standardization**

- Data entry system template
- Manual of data entry system development
- Checklist



# *In Development*

## ❖ **Data entry system template**

- Including only the template program and versatile parts commonly used in any studies
- Data entry panel can be customized according to study
- Fewer program settings



# *In Development*

- ❖ **Manual of data entry system development**
  - Data entry system specifications
  - Procedures for data entry system development using the template
  - Naming rule for each program etc in the system
  - Validation method

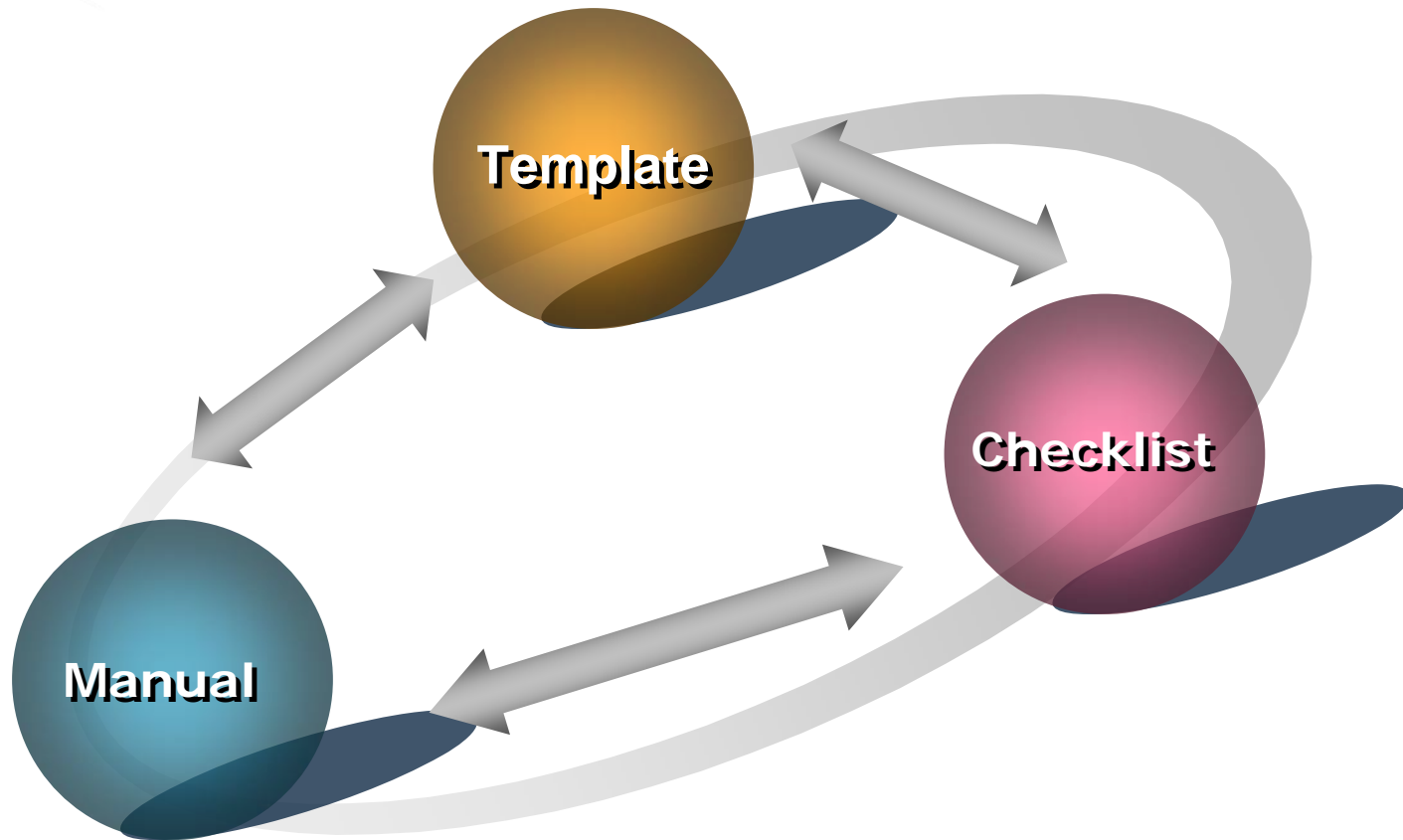


# *In Development*

## ❖ Checklist

- Prepared based on items that the developer tend to miss or make mistakes in
- Self checking is possible as needed during the development

# *In Development*



# *In Development*

## ❖ Standardization

**Template**

**Data Entry System**

**Manual  
&  
Checklist**

**Process2**

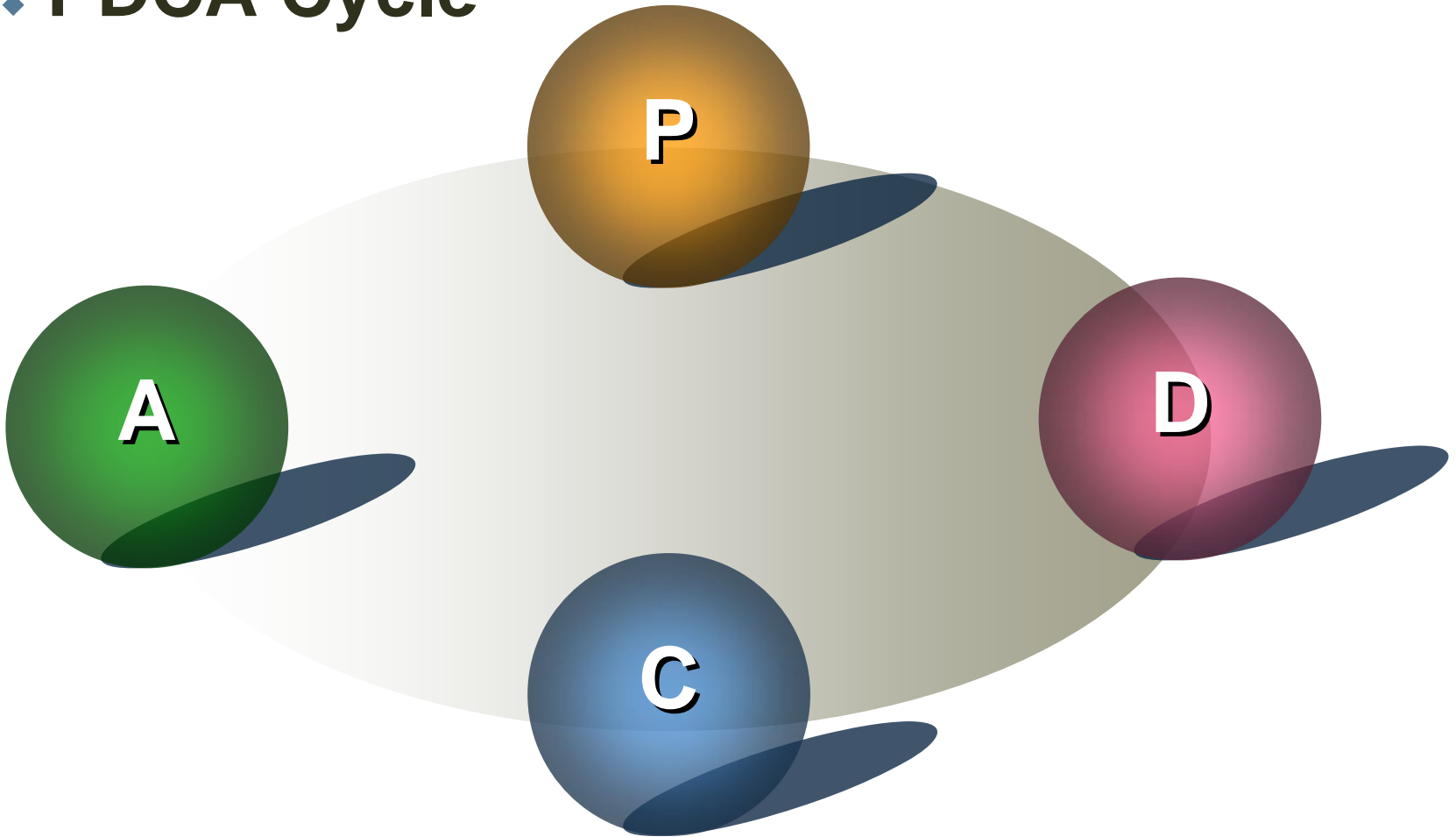
**Manual**

**Process1**

**Specifications**

# *In Development*

## ❖ PDCA Cycle





# *Effect Achieved*

❖ **Number of mistakes specified during validation process?**

Developer	Percentage (%)	
	Before standardization	After standardization
A	80	20
B	70	20
C	50	30
D	50	20



# *Effect Achieved*

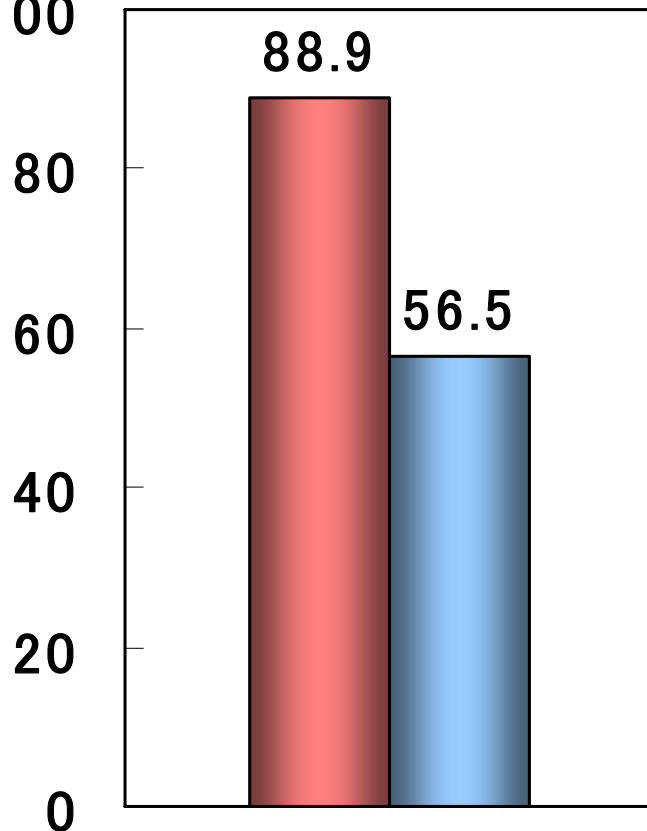
## ❖ Development time reduced

Developer	Percentage (%)
A	60
B	70
C	50
D	55

# *Effect Achieved*

## ❖ Mean development time spent

Time (hour)



- Post-Marketing Surveillance
- Same Developer

■ Before Standardization  
■ After Standardization



# Summary

## ❖ Summary

- What we have achieved
  - Early detection of errors
  - Development time independent of developer's skill
  - Quality independent of developer's skill



# *Summary*

## ❖ **Summary**

- **What we have achieved**
  - Standard operation process of data entry system
  - Standard development process of data entry system



# *Summary*

## ❖ Summary

- What we have achieved
  - Reduced development time
  - Avoiding risk by repeated entry system file copy
  - Easier to Customize



# *Conclusion*

## **Importance of process standardization**



**Homogenization of quality  
and operation procedure**



**More stable data entry system**



**Thank you for your attention.**

# In Development

## ❖ Data entry system template

```
'*****連番を振るプログラム（設定が必要です!!）*****'
```

```
*-----注意-----*  
' 連番をふりなおすプログラムとセットです！  
' 必ず、セットで埋め込んでください！！  
'*-----*
```

```
*-----書き方-----*  
' AA = 連番の変数  
' BB = AAのMAXの値を入れるための変数（任意設定）  
' CC = AAの変数が入っているデータセット  
' DD = 該当の親フォーム名  
' EE = 親フォームのKEY変数（PATNO、SUBJIDなど）  
'*-----*
```

```
Private Sub Form_BeforeInsert(Cancel As Integer)
```

```
Dim db As Database  
Dim rs As DAO.Recordset  
Dim wk_rep As Integer  
Dim strSQL As String
```

```
Set db = CurrentDb  
strSQL = "SELECT MAX(AA) as BB FROM [CC] WHERE PATNO = '" & Forms("DD").Controls("EE") & "' "  
Set rs = db.OpenRecordset(strSQL)
```

```
    If IsNull(rs![BB]) Then  
        rs.AddNew
```