



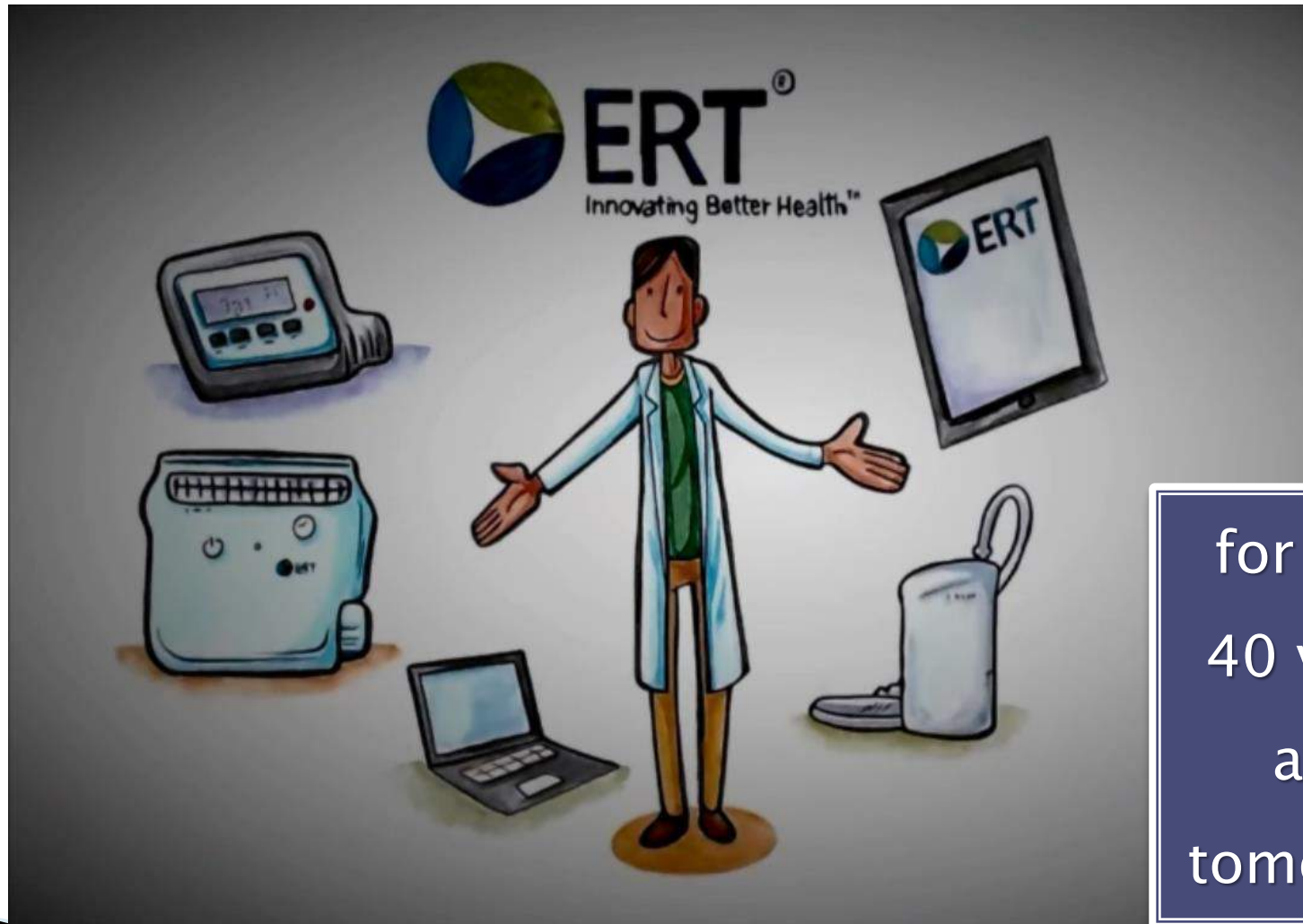
# Practical Experience in Implementing CDISC Standards

for Global Cardiovascular, Clinical Outcome  
Assessment and Respiratory Trials

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PharmaSUG China 2016  
Paper #8

# Innovating better health

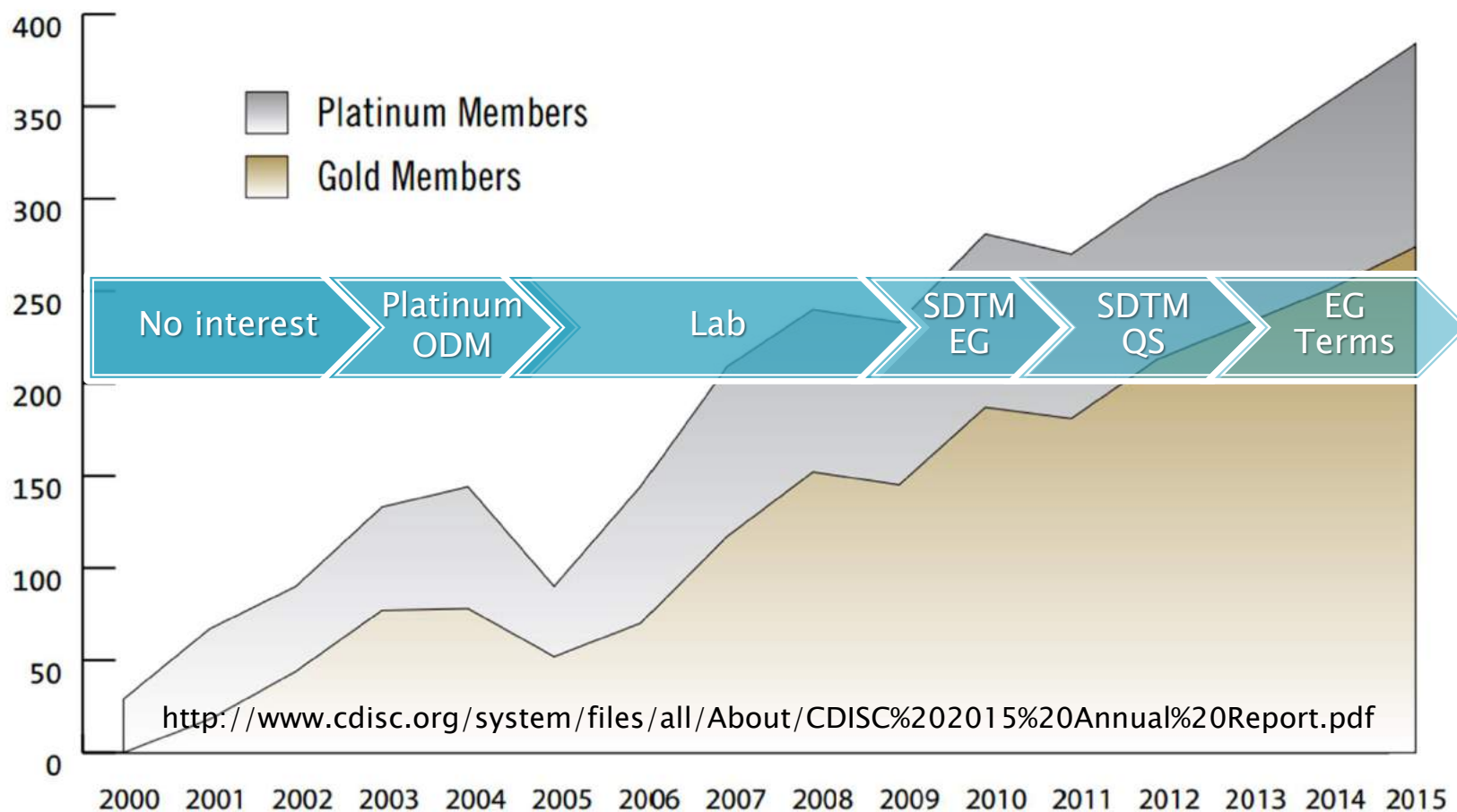


for over  
40 years  
and  
tomorrow

# Section 1 : EXPERIENCES

# EXPERIENCES WITH CDISC

## 2000-2014 Membership Trend



# EXPERIENCES WITH CDISC

- ▶ Built EXPERT, an ODM Compliant System, in 2002
- ▶ Provided a file per Lab Model in 2004
  - Searched CDISC website
  - Used a template and Built a program
  - Mapped findings to LOINC code
- ▶ Provided a file per SDTM EG since 2009
  - More sponsors used SDTM variable names
  - FDA wanted to receive the data in SDTM
- ▶ Provided a file per SDTM QS since 2010



# EXPERIENCES WITH CDISC

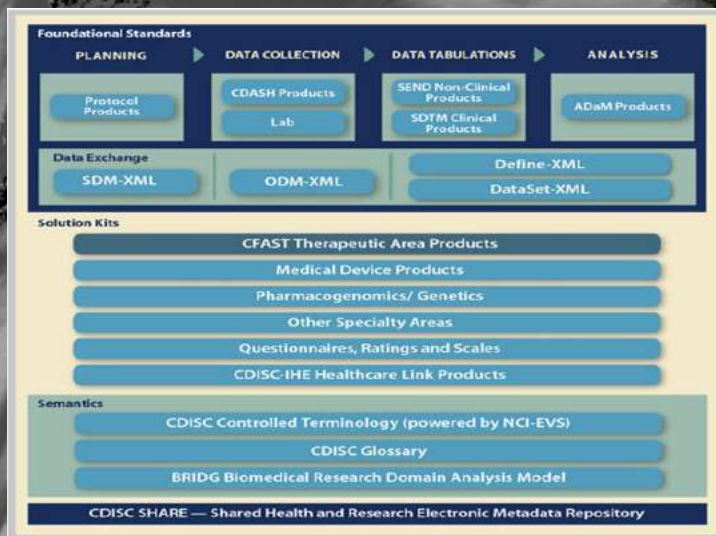
- ▶ Joined EG Terminology committee in 2012
  - Standard Terminology for ECG and Holter
- ▶ Supported sponsors in implementing data specifications for SDTM EG
- ERT Insights Cloud has been built in ODM



# Section 2: DIFFERENT APPROACHES PER CUSTOMERS' EXPERIENCES



# 群盲撫象





# APPROACHES PER CUSTOMER

- ▶ CUSTOMERS FOLLOWING CDISC WITH CDISC SYSTEMS / PROCEDURES
  - EG for Cardiac data, QS for eCOA and custom domain for Respiratory
- ▶ CUSTOMERS WITH LITTLE KNOWLEDGE WHO WANT TO RECEIVE DATA IN CDISC
  - ERT provides data specifications
  - Customers review and finalize the specifications

# APPROACHES PER CUSTOMER

- ▶ CUSTOMERS FOLLOWING SOME OF CDISC
  - 5 to 10 variables follow SDTM
- ▶ WHEN SPONSORS WANT TO RECEIVE DATA IN CDISC ON A REAL-TIME BASIS
  - ERT PROVIDES DATA IN ODM XML
  - CTMS, EDC
  - ERT INSIGHTS CLOUD

# Section 3: CHALLENGES / RECOMMENDATIONS

# SOFT SKILLS

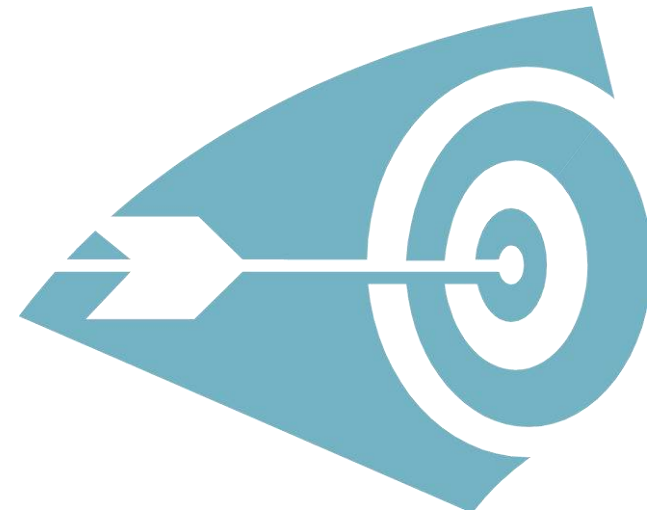
- ▶ Different levels of understanding
  - Sales
  - Project Manager
  - Medical doctor / specialist
  - Data Acquisition / Data Manager / Data Programmer
  - Developer / Vendor
  
- ❖ Know yourself and your customers
  - ❖ Communicate with customers in terms of their function and usage of CDISC
  - ❖ Internal customers are usually middle people





# SOFT SKILLS

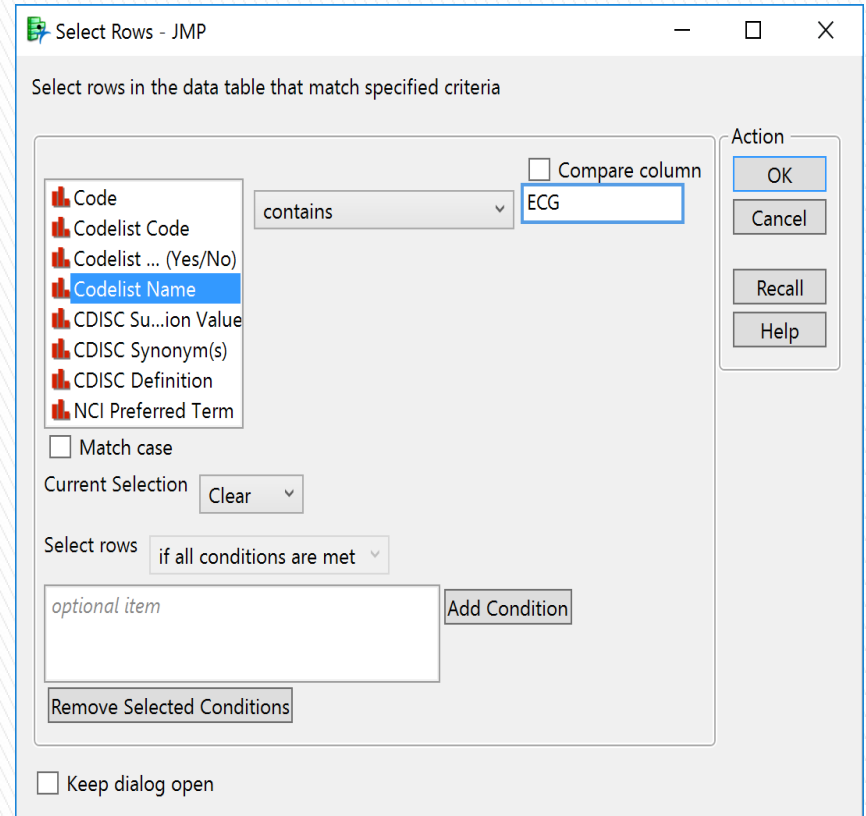
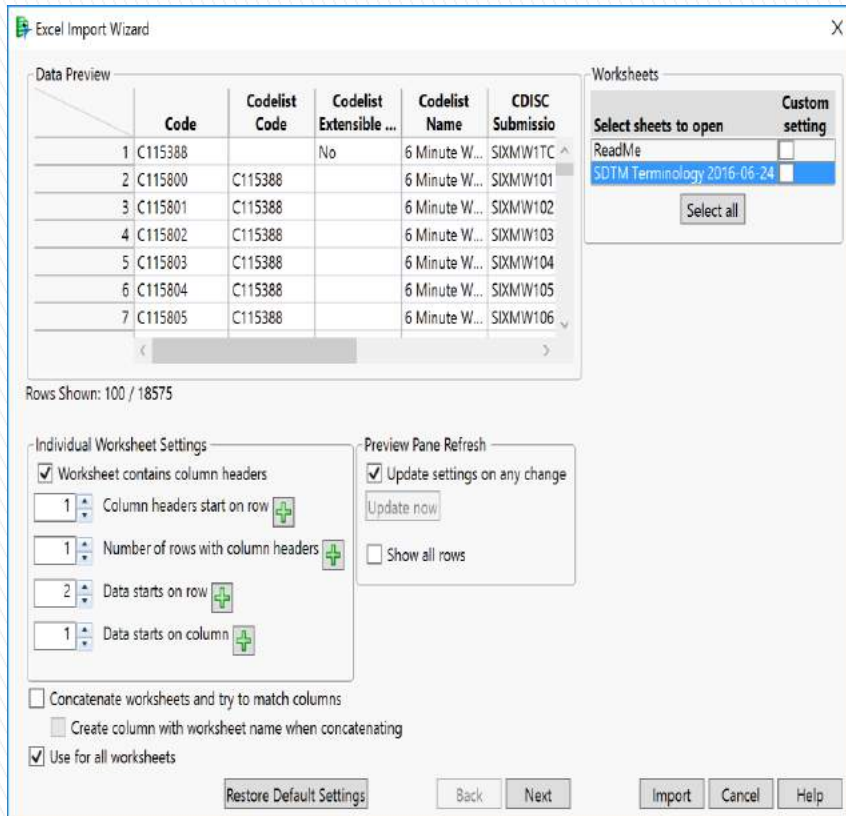
- ▶ A Moving target
  - Updates in Domains, New Domains
  - Terminology updates
  - Therapeutic Area Standards
- ❖ Focus on SDTM/SEND & ADAM, and look at other standards



# HARD SKILLS

- ▶ How to merge data for many studies
  - Receive data in ODM xml
    - Use a tool to convert ODM to CDASH/SDTM
  - Receive data in SDTM
    - Combine them
  
- ▶ Map Findings
  - Review Terminology spreadsheet regularly
  - Compare old and new version
  - Use a tool, e.g. JMP, SAS (PROC COMPARE), and etc.

# Compare terminology using JMP



Read SDTM  
Terminology.xls

Select Rows

# Compare terminology using JMP

**Subset - JMP**

Creates a new data table from the selected rows and columns of the source data table, or within each group generated with the 'by' columns.

☐ Subset by

Rows

☐ All rows

☒ Selected Rows

☐ Random - sampling rate : 0.5

☐ Random - sample size : 375

☐ Stratify

Columns

☒ All columns ☐ Selected columns

☐ Keep by columns

Output table name: Subset of Subset of SDTM Terminology 2016-06-24

☐ Link to original data table

☒ Copy formula

☒ Suppress formula evaluation

Save Default Options

☐ Keep dialog open

Action

OK

Cancel

Recall

Help

**Compare Data Tables - JMP**

**Compare Data Tables**

Compare Subset of SDTM Terminology 2016-06-24

With Subset of SDTM Terminology 2015-12-18

Limit 500 differences

Compare

☐ Fuzzy Compare

**Tables Info**

Subset of SDTM Terminology 2016-06-24	Subset of SDTM Terminology 2016-06-24.jmp (8 columns, 751 rows)
Subset of SDTM Terminology 2015-12-18	Subset of SDTM Terminology 2015-12-18.jmp (8 columns, 751 rows)

Create a Subset

Compare Data tables



# Other Technical tips

- ▶ Heart Rate in VS vs. EG:
  - HR (Heart Rate) – Vital Sign
  - EGHRMN (ECG Mean Heart Rate)
- ▶ Aggregate vs. Mean
- ▶ Not Done vs. Missing
- ▶ Holter vs. ECG
- ▶ Respiratory data

# Concluding Thoughts

- ▶ A team effort
  - Clinical / Medical team
  - Study Project / Data Management
  - Developer / Vendor
- ▶ Get involved
  - Be a member  
<http://cdisc.org/register>
  - Public reviews  
<http://cdisc.org/standards-and-implementations>
  - Participate in a working group  
<https://cdisc.wufoo.com/forms/r1b2e7kp1c8hoi9/>
  - The more you participate, the more you get out of CDISC



# Questions?



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U.S. FDA Publishes Binding Guidance Documents and  
Technical Conformance Guide in December 2014.  
.. After Dec. 17, 2016 .. must submit data in the data  
formats..

