

# Agenda



- ADaM datasets: Why, Who, How many
- Process improvement
  - Define
  - Measure
  - Analyse
  - Improve
  - Control
- Key messages









# Why ADaM datasets?

**iACE** (**I**CON's **A**DaM **C**entre of **E**xcellence) is ICON's umbrella strategy that focuses on ADaM delivery

## **CDISC End to end lifecycle**

- However despite the regulatory requirement currently approx. 35% of studies are not using ADaM standards. The reasons why some studies do not require ADaM datasets are as follows:
  - Client standards
  - Legacy study
  - Partial tasks such as DMC

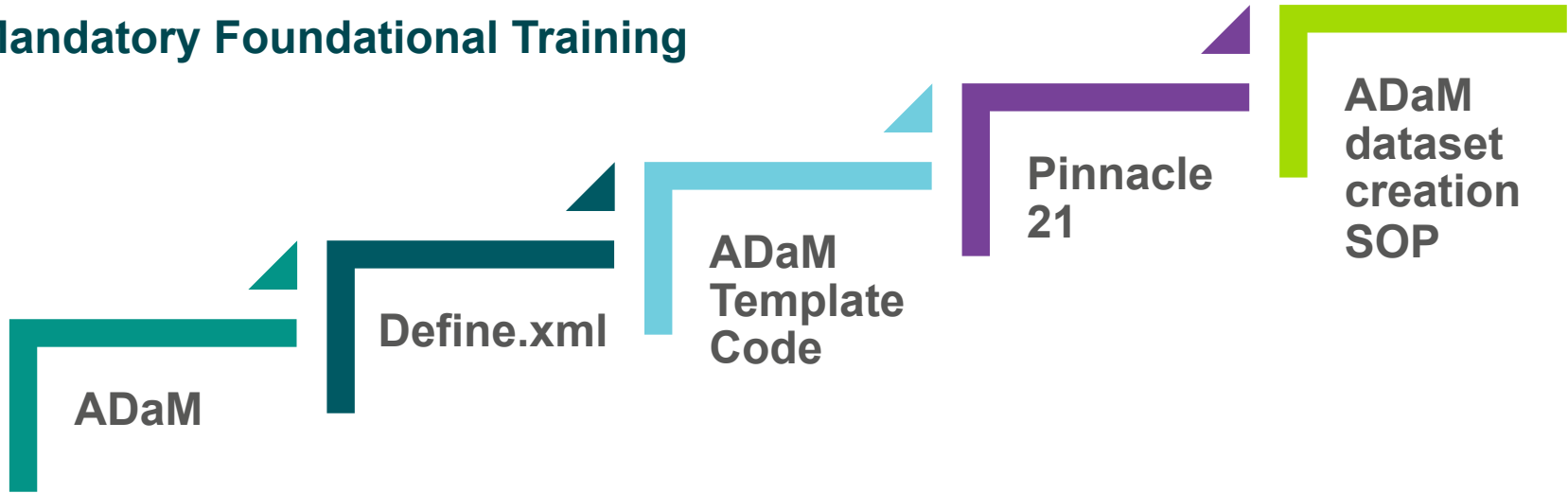
# Who: Roles and Responsibilities ADaM Datasets

	Specification	Development	Validation	Review
Project Statistician				
Lead Programmer				
Programming Team				

# Who generates ADaM datasets?

85% of programmers have developed or validated ADaM datasets

## Mandatory Foundational Training



# How many ADaM datasets?

Up to 900 datasets are built each quarter



## Simple Safety

Does not fit into the complex category



## Complex Safety

Datasets with either complex structure requiring significant manipulation of input data and/or with large volumes of derivations

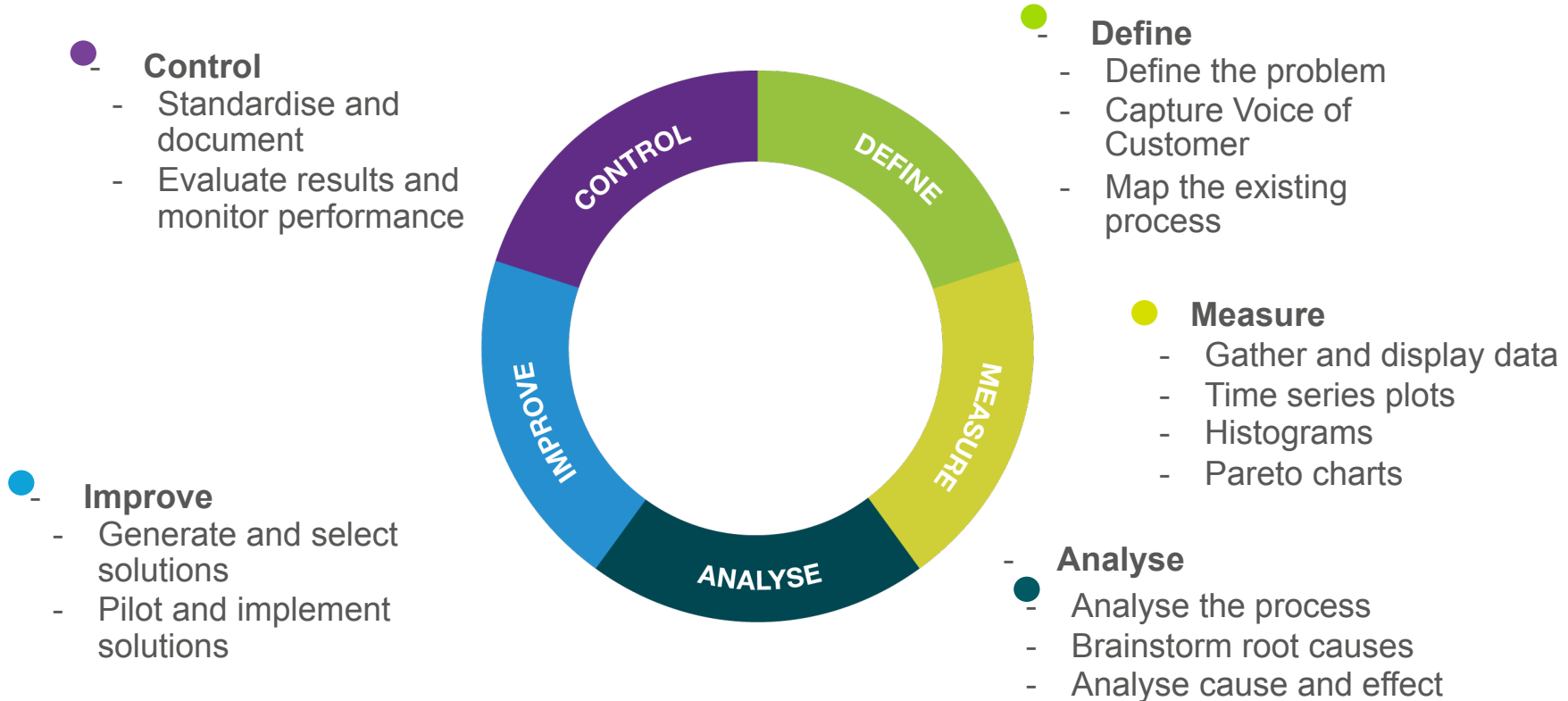


## Efficacy

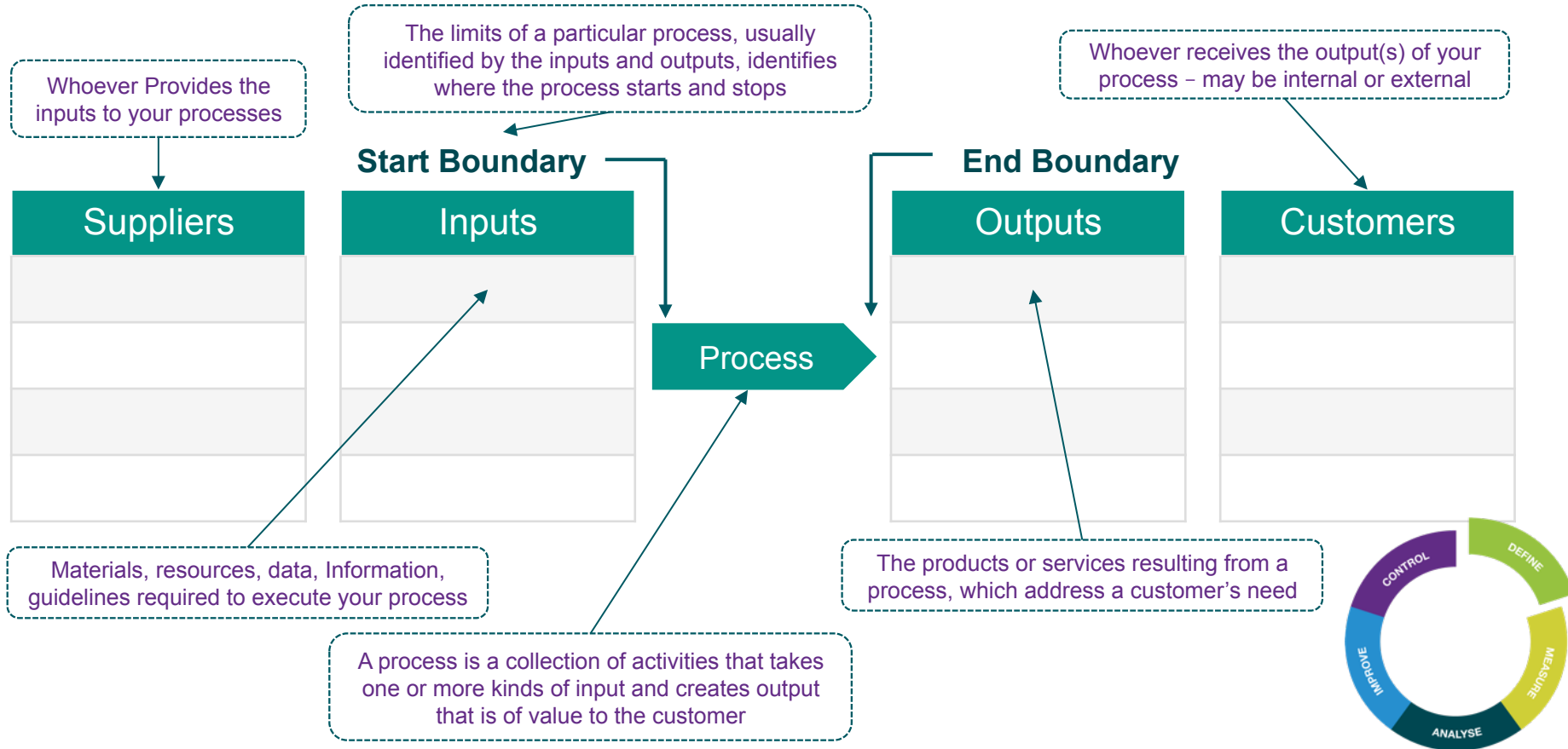
Datasets with efficacy parameters

# ADaM Process Improvement

# Continuous improvement - DMAIC



# Define: Map the process





# Define: Map the ADaM datasets process

Suppliers	Inputs	Process	Outputs	Customers
<ul style="list-style-type: none"><li>- DM</li><li>- Clients</li><li>- Biostatistics</li><li>- Clinical</li><li>- Patients</li></ul>	<ul style="list-style-type: none"><li>- Protocol</li><li>- Data</li><li>- SAP</li><li>- ADaM dataset specifications</li><li>- ADaM template code</li><li>- Metadata</li><li>- Programming rules</li><li>- Training materials</li></ul>	<ul style="list-style-type: none"><li>- ADaM specifications</li><li>- ADaM Program Development</li><li>- ADaM Program validation</li><li>- Various reviews</li></ul>	<ul style="list-style-type: none"><li>- Datasets</li><li>- Programs</li><li>- Logs</li><li>- Documentation</li><li>- Metadata</li><li>- Systems</li><li>- Specification changes</li></ul>	<ul style="list-style-type: none"><li>- Programmers</li><li>- Biostatistics</li><li>- Medical Writing</li><li>- Clients</li><li>- Regulatory authorities</li><li>- Patients</li></ul>



# Measure: Gather and display data

## Output Type

## Failure Reason

- |          |   |
|----------|---|
| Datasets | <ul style="list-style-type: none"> <li>- Data Displayed Incorrectly</li> <li>- Derivation Incorrect</li> <li>- Updated/Corrected Data Received</li> </ul> |
| Others   | <ul style="list-style-type: none"> <li>- .....</li> </ul>   |

## Process Output

## Measure

## Defect

### Datasets

# of ADaM with errors divided by # of ADaM datasets delivered

Error is defined as....

## Analysis - 6 months

## Percentage

Number of ADS with errors

9%

Number of first time right ADS

91%

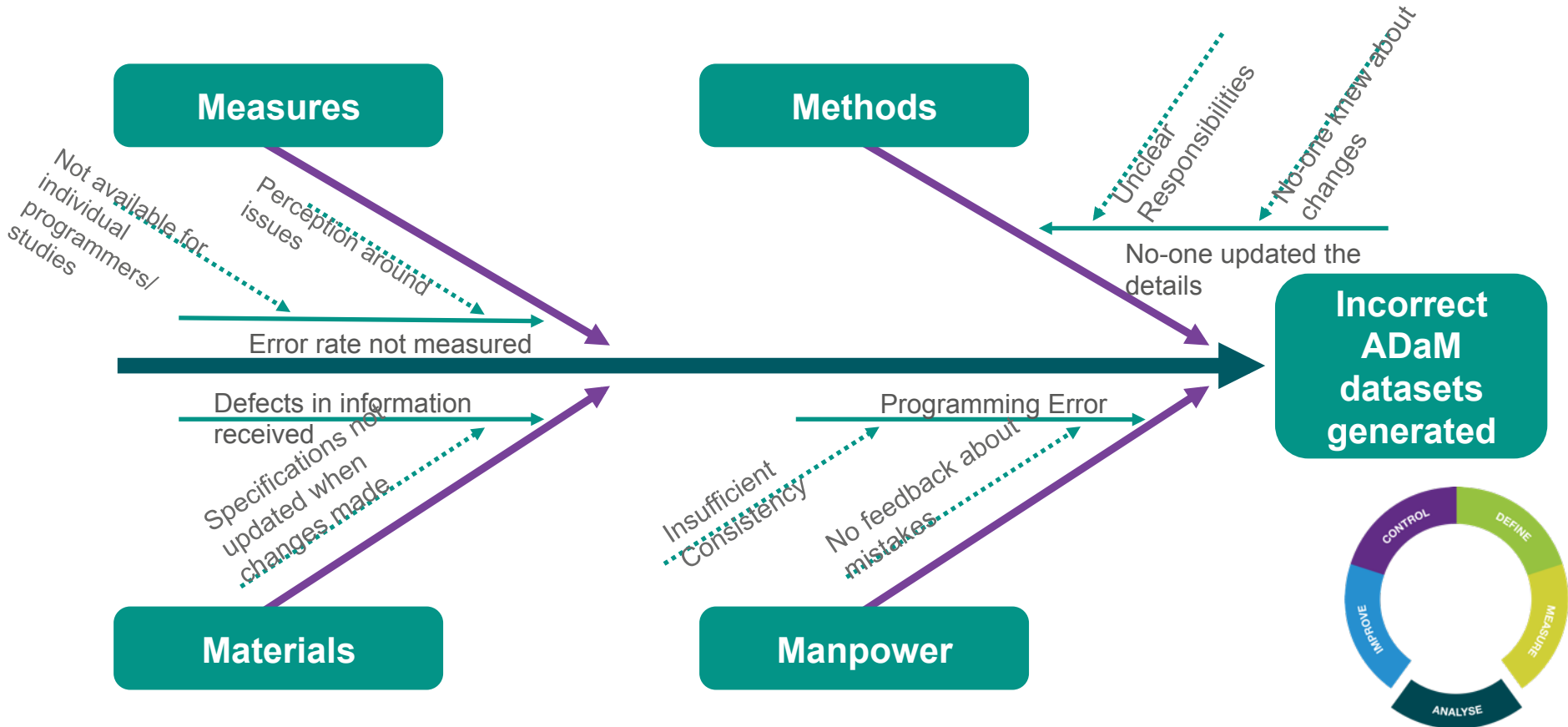


# Analyse: Common root cause categories

6 M's	Related Categories	Illustrative Questions
<b>Manpower</b>	People, Staffing, Organisation, Skills, Management	<ul style="list-style-type: none"> <li>- Are people trained with right skills?</li> <li>- <b>Is there person to person variation?</b></li> <li>- Are people over-worked?</li> </ul>
<b>Mother Nature</b>	Environment, Work Environment, Market Conditions, Regulatory Environment	<ul style="list-style-type: none"> <li>- Is the workplace safe and comfortable?</li> <li>- Are outside regulations impacting the business?</li> <li>- Does the company culture aid the process?</li> </ul>
<b>Materials</b>	Parts, Supplies, Forms, Information, Inputs	<ul style="list-style-type: none"> <li>- Are parts, forms or supplies obsolete?</li> <li>- <b>Are there defects in the inputs/specifications?</b></li> <li>- <b>Is information stable throughout process?</b></li> </ul>
<b>Methods</b>	Procedures, Policies, Documentation, Management Systems	<ul style="list-style-type: none"> <li>- <b>How is the work performed?</b></li> <li>- Are procedures correct?</li> <li>- Are procedures enforced?</li> </ul>
<b>Machines</b>	Tools, Software, Technology, Equipment, Facilities	<ul style="list-style-type: none"> <li>- Is equipment reliable? Properly maintained?</li> <li>- Is there sufficient capacity?</li> <li>- Are software platforms compatible?</li> </ul>
<b>Measures</b>	Judgment, Evaluation, Measurement Units/Methods/ Devices	<ul style="list-style-type: none"> <li>- <b>Is data good enough? Is data readily available?</b></li> <li>- <b>Is data open to interpretation or bias?</b></li> <li>- Do different people judge inputs and outputs the same way?</li> </ul>



# Analyse: Root cause analysis



# ADaM strategies implemented

## Measure

- Systemic method of collecting data on ADaM datasets
- Analysis done on sources of programming errors

## Methods

- ADaM template code
- Patient walk through
- Additional checks

## Materials

- Review specifications
- Only work from stable specifications

## Manpower

- Measuring study/individual performance on a regular basis



# ADaM template code



## Consistent

- Consistent source of ADaM code
- Increase effectiveness
- Defensive programming
- Process around exceptions



## Adaptive

- Based on the latest ADaM guidance
- Includes many standard safety datasets
- User feedback encouraged and incorporated



## Robust

- Governance process and steering committee
- Commitment to continue to develop and improve
- Follows SDLC and documented processes



# Patient walk through



- Documented check of the traceability of raw/SDTM data to ADaM derived variables
- Done a defined # of patients / different types of patients
- Scope of review is pre-specified in QC Plan
- Checking implementation/programming of key derivations and algorithms
- Biostatistics activity



# Tools and Utilities



Compliance checks



Utility that converts the study ADaM specification to shell datasets, that are then checked by P21 and the ICON customised utilities.



Additional ADaM checks added



Sponsor specific checks

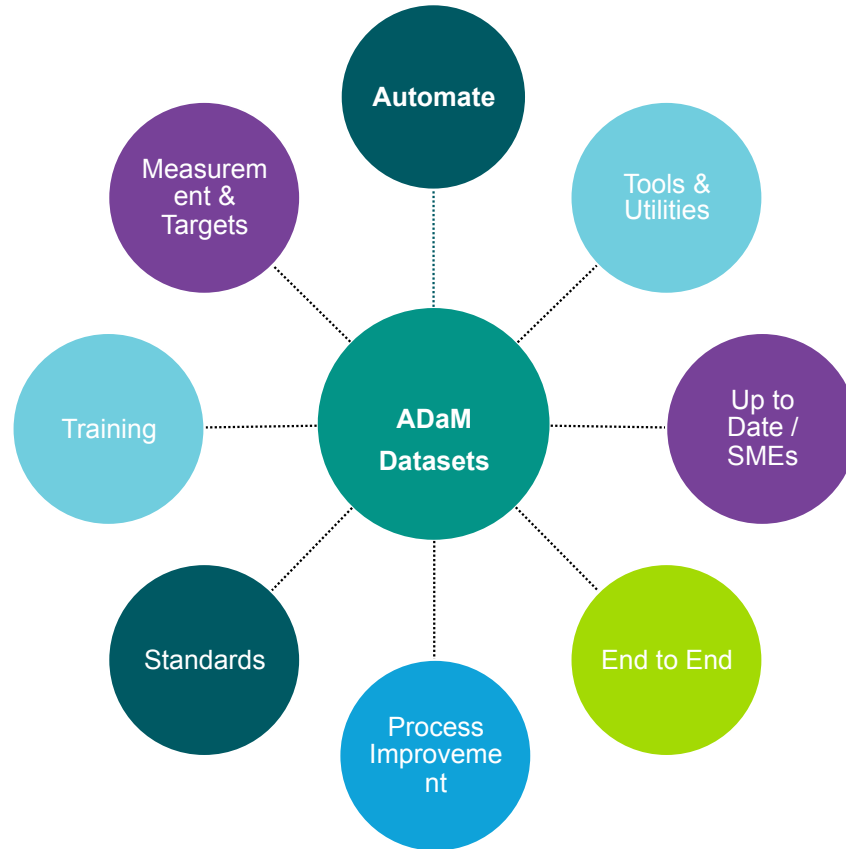


TA specific checks





# Control: Evaluate results and monitor performance



# ADaM Datasets – Key Messages



ADaM datasets key deliverables



Leveraging standards and processes



Continuous Process Improvement needed



Therapeutic area & client focus



Time, quality & cost

Thank you

[iconplc.com](http://iconplc.com)

