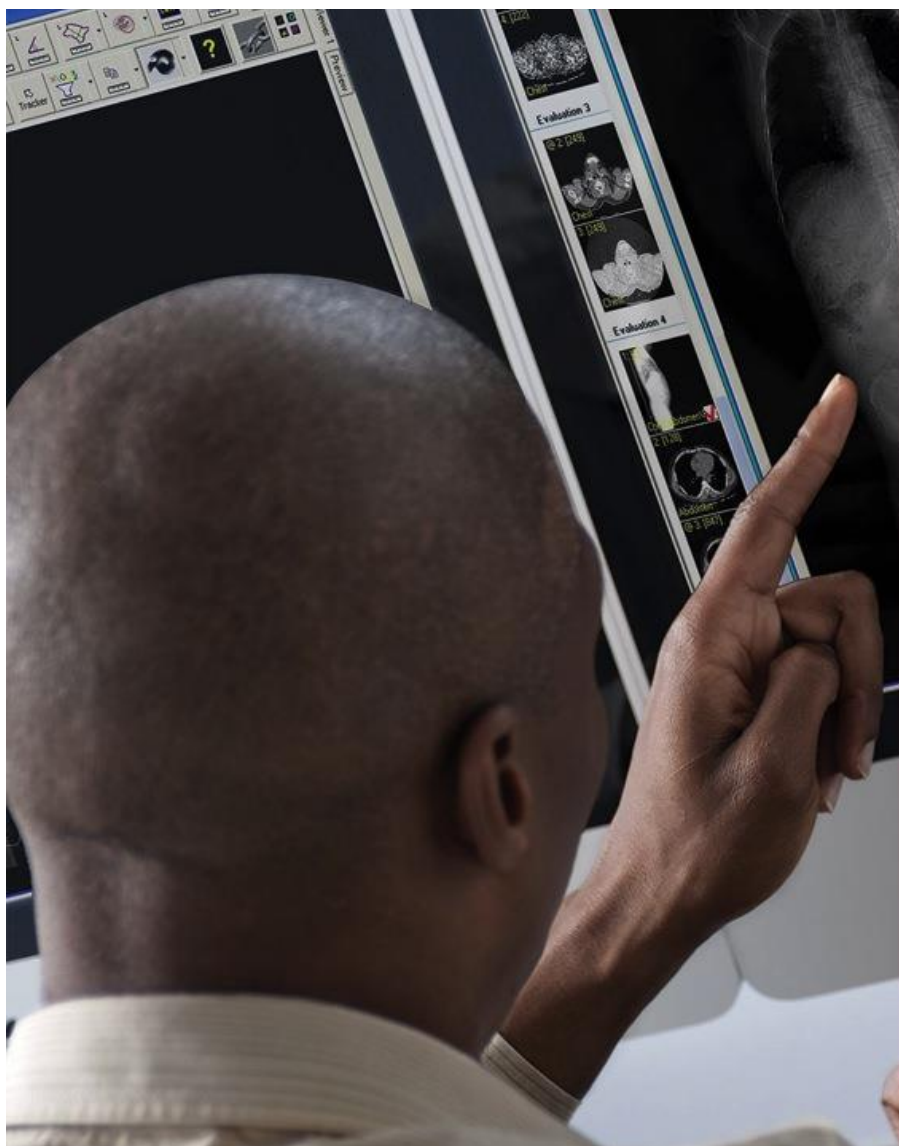




A Symbol of Excellence

PhUSE 2014 DH07

Study Data Handling:
A CRO Experience

Challenges for DM Programing



Supporting evolving data analysis requirements

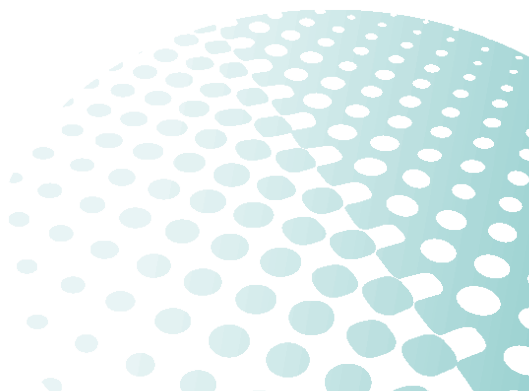
- Driven by approaches such as RBM, QbD and Adaptive Clinical Trials
- Data analysis earlier in trial
- Greater frequency of analysis
- Broader audience of data consumers

Availability of better tools

- More timely data collection and distribution
- Wider range of data presentation tools in use

Data

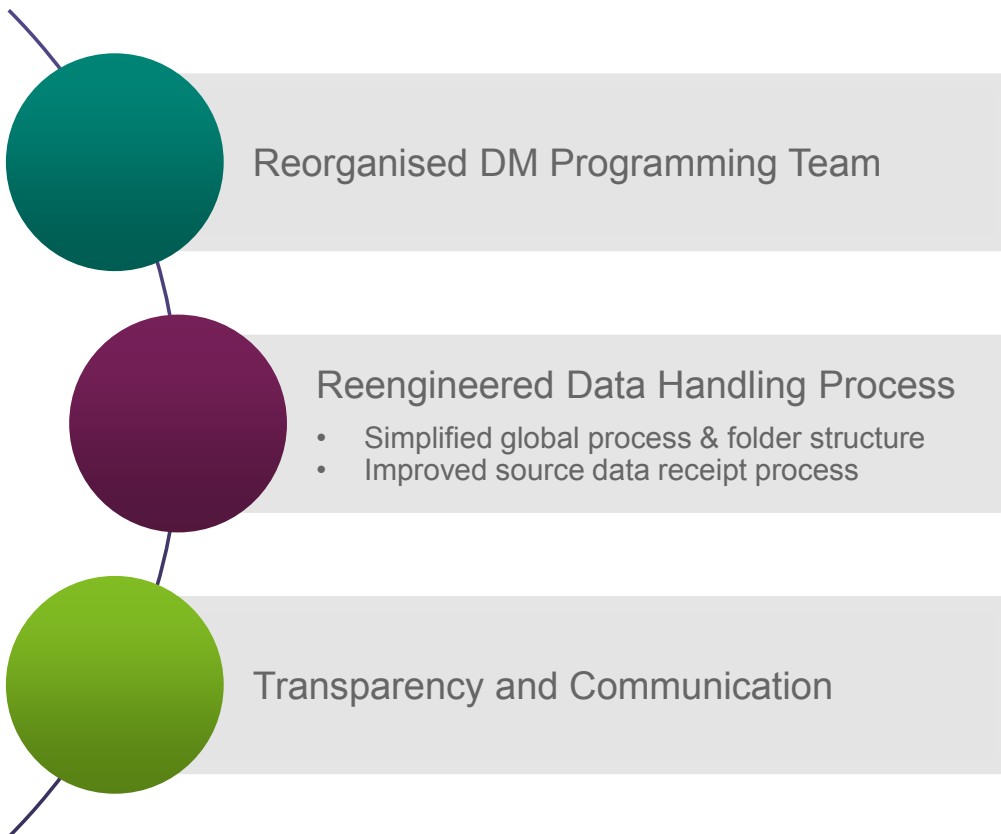
- Increase in complexity, volume and transfer rate



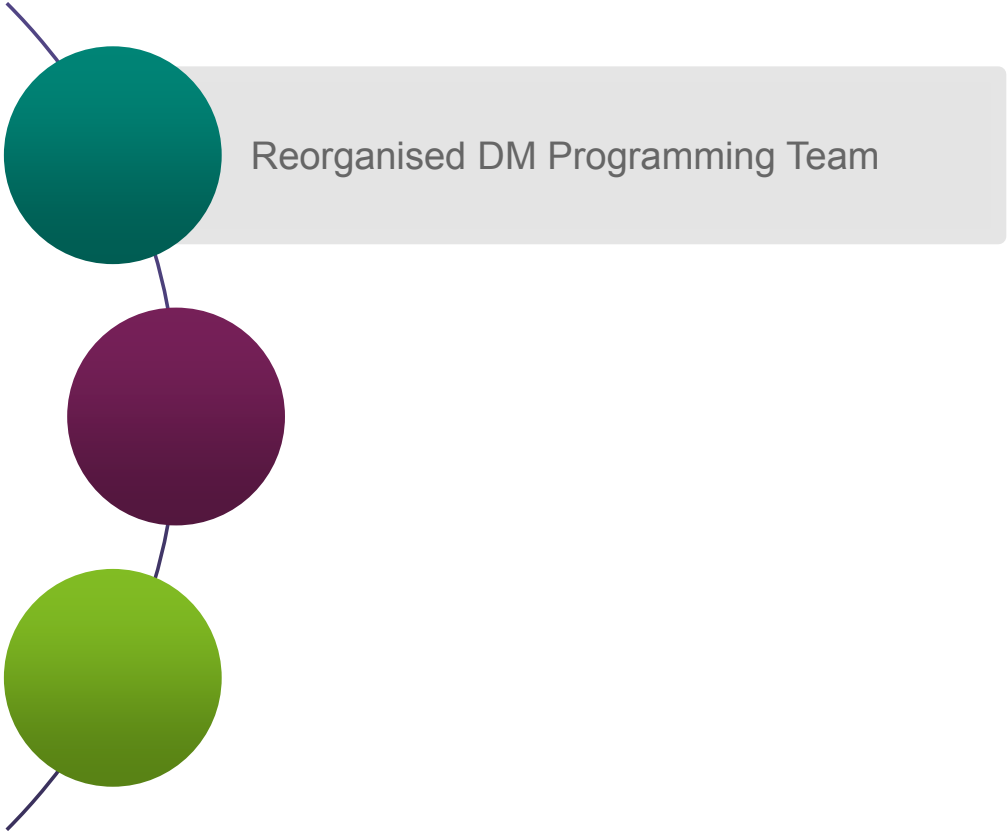
Adapting to New Requirements



New technology is only a part of the solution



Study Data Handling: A CRO Experience



Reorganised DM Programming Team



Team of generalist DBAs no longer appropriate

- Wider range of collection systems to support
- More complex and specialist outputs required
- More specialist technical knowledge required

Programming team reorganised into specialist teams

Clinical Data Management Systems

CDMS

- Database builds and validation
- Sub-teams for each EDC platform

Clinical Data Services

CDS

- Production of clinical data outputs
- Sub-teams by output type
 - SDTM & data standards
 - Listing & report outputs
 - Warehousing & visualisation

Study Data Handling: A CRO Experience



Reengineered Data Handling Process

- Simplified global process & folder structure
- Improved source data receipt process

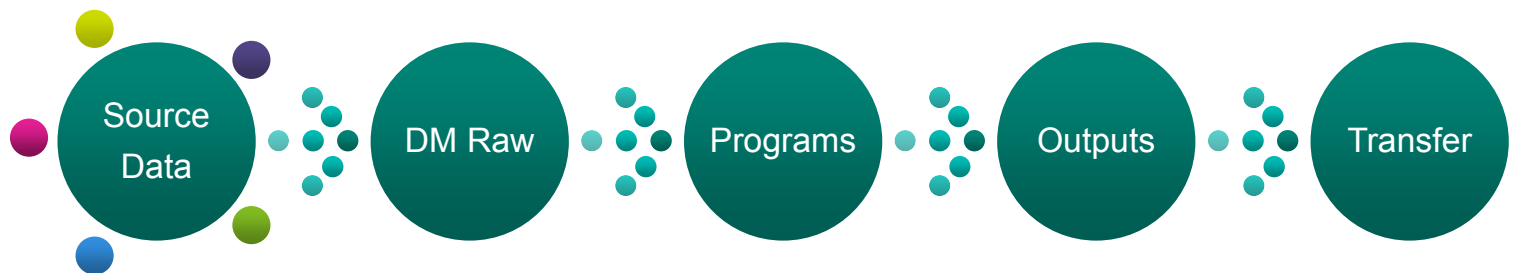
Global Data Handling Process



Existing situation – little consistency across studies

- Data, outputs, program and documentation spread across drives
- Reduced opportunity for reuse

New global process rolled out in 2014



- Simplified, predictable process
- Applies to all DM clinical data outputs
- Required on all new studies
- Reinforced by standard folder structure

Standard Folder Structure

Three guiding concepts:

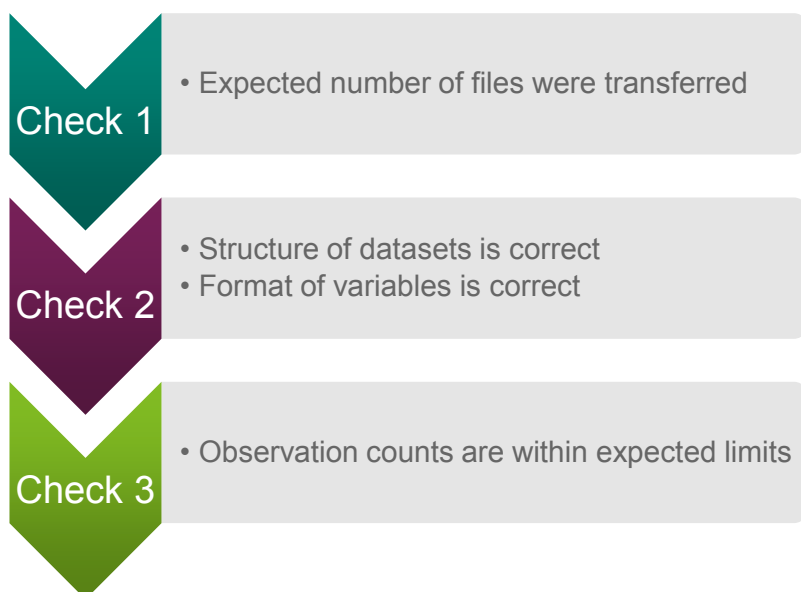
- “One stop shopping”: All DM clinical data outputs and associated documentation, programs and logs in one place
- “Self service”: Non-DM study team to collect outputs rather than receive internal transfers
- “Clear and consistent”

Folder	Guidelines
0_docs\	Documentation related to programs, program sources, outputs and transfers
1_source_data\	Study source data, data verification programs and coding programs
2_dmraw\	Verified source data folder for study programs
3_progs\	Study programs, macros and logs
4_outputs\	Study outputs
5_transfer\	Outputs released for use to non-DM study teams and external organizations

Source Data Receipt: Existing Situation

Two existing processes

- Manual process – prone to error
- Clinical Data Warehouse process controlled by Oracle® Life Sciences Data Hub – strict control, inefficient change management



Neither fit for purpose due to increase in data volume, refresh rate and structural changes

Source Data Receipt: New Process



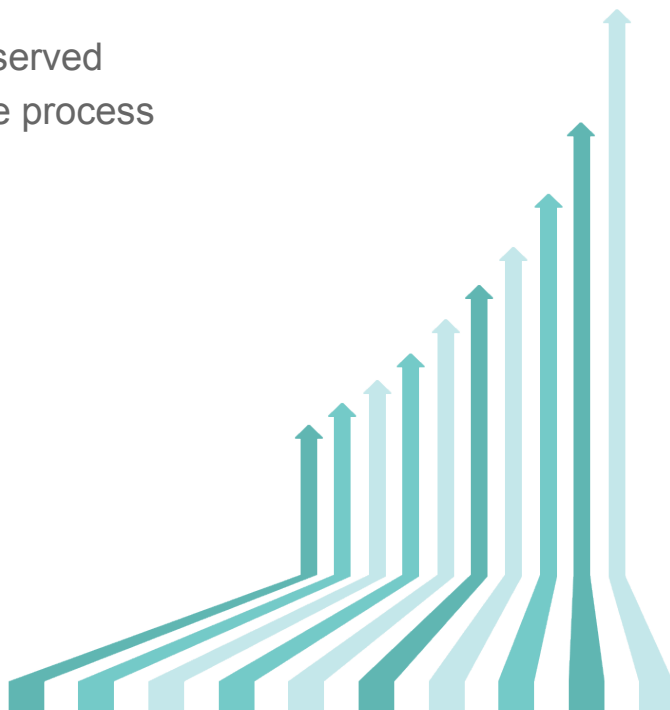
Combines rigour of Data Warehouse process and speed of manual process

Metadata controlled

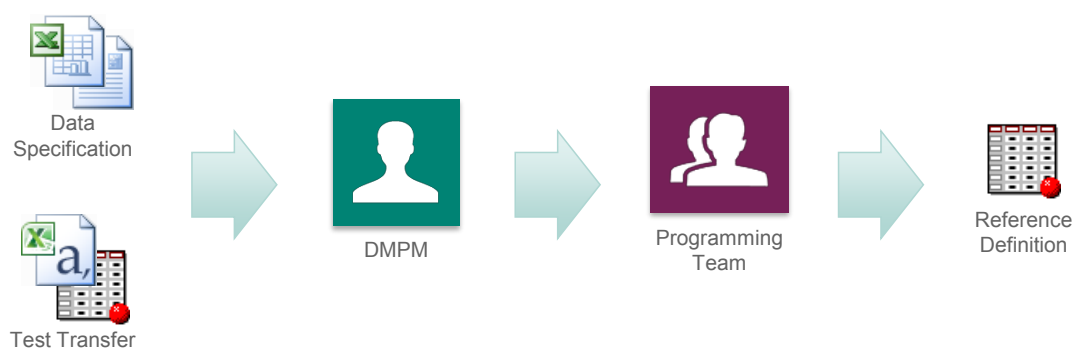
- “Reference Definition” – a metadata description of transfer specifications - maintained for each study source
- Version history of structural changes preserved
- `Metadata trail created at all stages of the process

Driven by standard programs

- Simple, repeatable, predictable



Source Data Receipt: Creation of Reference Definition



Data Provider (internal or external)

- Provides DM with a Data Specification and test transfer

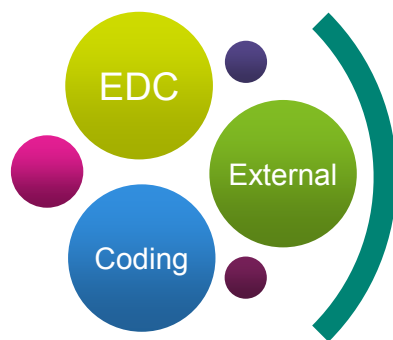
DMPM

- Verifies validity of test transfer and supplies transfer to programming team

Programming team

- Converts transfer to SAS® data sets (if necessary)
- Creates Reference Definition metadata using standard program
 - Reference definition is an enhanced PROC CONTENTS output

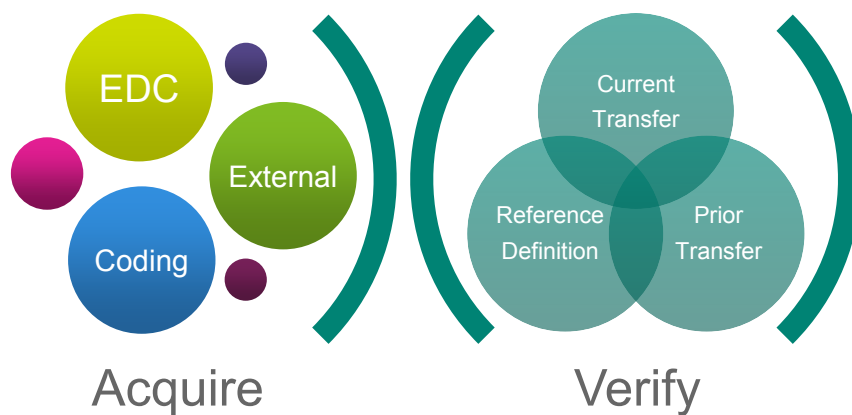
Source Data Receipt : Operational Process



Acquire

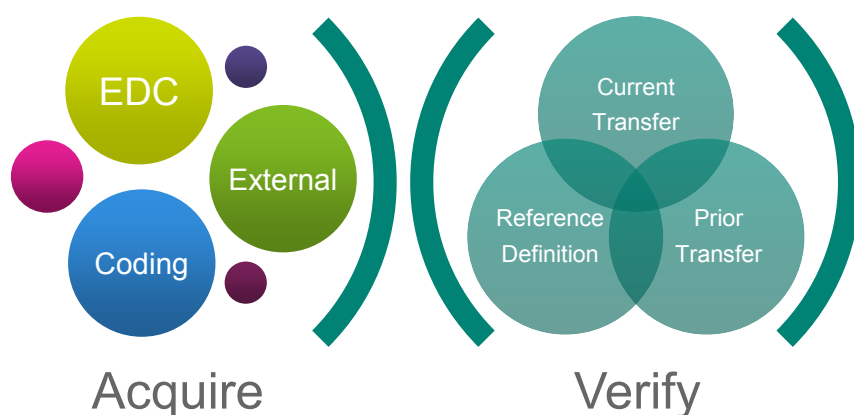
1. **Acquire:** Data is quarantined in source data area

Source Data Receipt : Operational Process



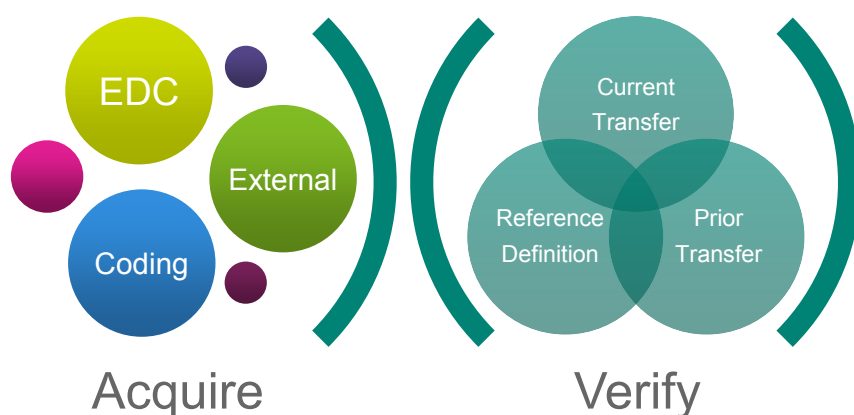
1. **Acquire:** Data is quarantined in source data area
2. **Verify:** Data is verified against Reference Definition and previous transfer
 - If the transfer does not comply with Reference Definition, or no definition is found, the process stops with a status of **FAIL**

Source Data Receipt : Operational Process



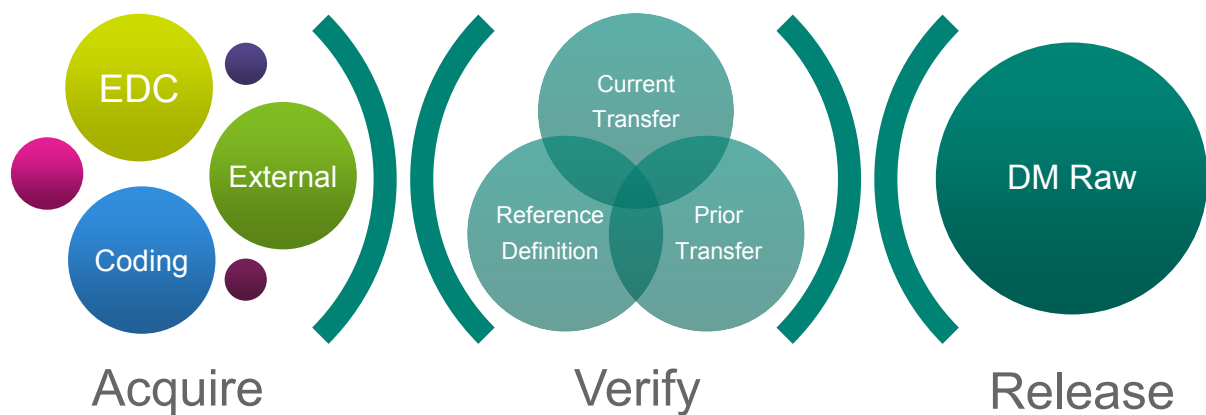
1. **Acquire:** Data is quarantined in source data area
2. **Verify:** Data is verified against Reference Definition and previous transfer
 - If the transfer does not comply with Reference Definition, or no definition is found, the process stops with a status of **FAIL**
 - If the data complies with definition and there is a drop in observations compared to previous, the data is pre-released with a status of **WARNING**

Source Data Receipt : Operational Process



1. **Acquire:** Data is quarantined in source data area
2. **Verify:** Data is verified against Reference Definition and previous transfer
 - If the transfer does not comply with Reference Definition, or no definition is found, the process stops with a status of **FAIL**
 - If the data complies with definition and there is a drop in observations compared to previous, the data is pre-released with a status of **WARNING**
 - If the data complies with definition and there is no drop in observations, the data is pre-released with a status of **PASS**

Source Data Receipt : Operational Process



1. **Acquire:** Data is quarantined in source data area
2. **Verify:** Data is verified against Reference Definition and previous transfer
 - If the transfer does not comply with Reference Definition, or no definition is found, the process stops with a status of **FAIL**
 - If the data complies with definition and there is a drop in observations compared to previous, the data is pre-released with a status of **WARNING**
 - If the data complies with definition and there is no drop in observations, the data is pre-released with a status of **PASS**
3. **Release:** Automated process moves pre-released data to the DM Raw area for use by study and programming teams

Post Production Changes



Post production changes are inevitable

EDC systems support change process with varying degrees of success

Occurring with increasing frequency and complexity

- CDMS team: 40% setup / 60% change

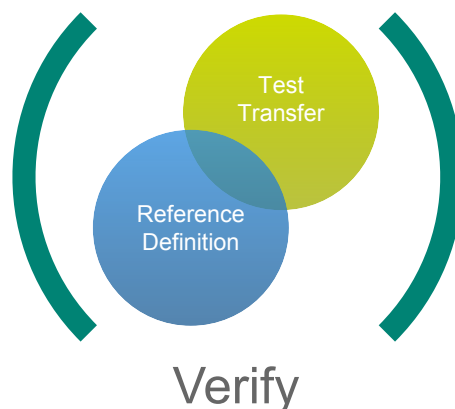


Post Production Changes: Impact Analysis



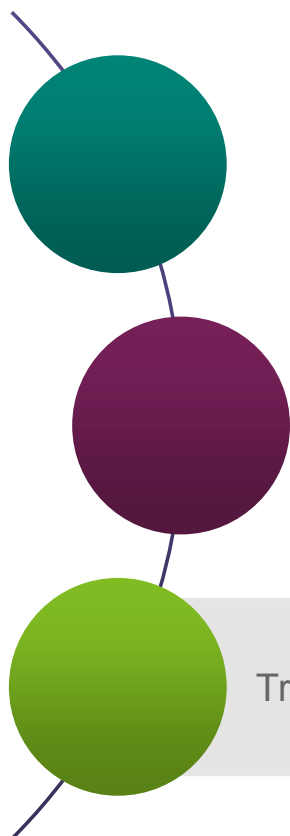
Impact Analysis Process

- Extension of source data receipt
- Verify program compares the post-change test data to Reference Definition



- Definition Comparison report is distributed to downstream data consumers
- Post-change Reference Definition used to confirm actual change matches planned

Study Data Handling: A CRO Experience



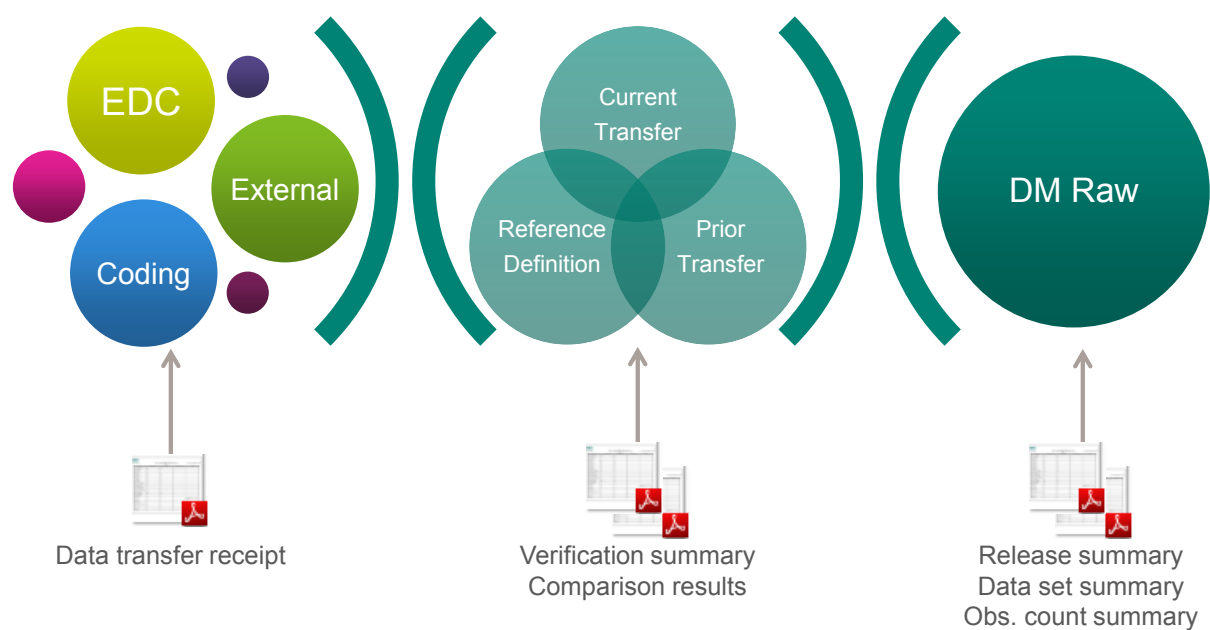
Transparency and Communication



Source Data Receipt: Traceability

Metadata and documentation trail created at each step

- Available to all team members
- Every document retained for duration of study



Data Handling Dashboard: Screenshots



Study & Data Type

Growth

Total Obs.

Last Status

»

0810

edc

584387

WARN

»

0113

lab

49675

PASS

»

0246

diary

3688

PASS

edc_coded

235476

PASS

»

0262

ivrs

278

PASS

edc_coded

290338

PASS

»

0338

edc_coded

164167

PASS

Sponsor

Data Type

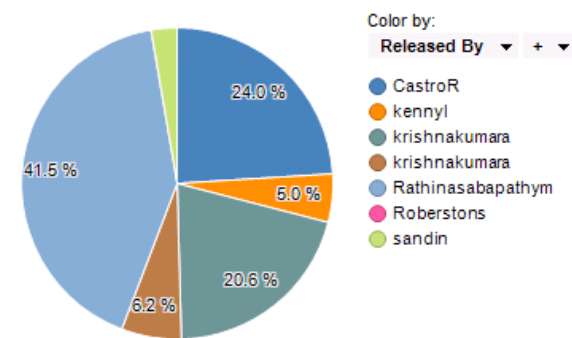
Study Code

Observations & Release Status				
Type	Dataset	7/21/2014	7/29/2014	8/11/2014
		30 (PASS)	30 (PASS)	30 (PASS)
		30 (PASS)	30 (PASS)	30 (PASS)
		0 (PASS)	0 (PASS)	0 (PASS)
		564 (PASS)	600 (PASS)	795 (PASS)
		694 (PASS)	708 (PASS)	876 (PASS)
		573 (PASS)	596 (PASS)	725 (PASS)
		906 (PASS)	960 (PASS)	1168 (PASS)
		757 (PASS)	802 (PASS)	1050 (PASS)
	edc	346 (PASS)	352 (PASS)	415 (PASS)
	edc	143 (PASS)	147 (PASS)	176 (PASS)
	edc	347 (PASS)	354 (PASS)	438 (PASS)
	edc	0 (PASS)	0 (PASS)	0 (PASS)
	edc	901 (PASS)	946 (PASS)	1208 (PASS)
	edc	0 (PASS)	0 (PASS)	1 (PASS)
	edc	0 (PASS)	0 (PASS)	0 (PASS)

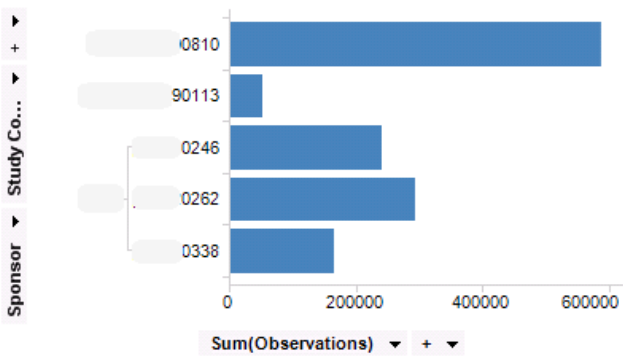
Data Handling Dashboard: Screenshots



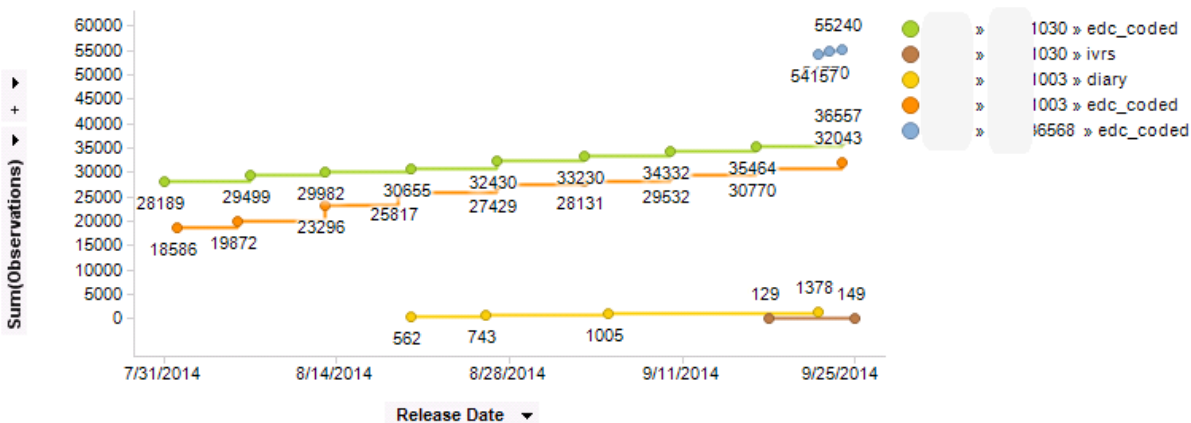
Release Users



Total Observations by Study



Total Observations by Data Type



Working Together to Find Solutions



Launch of “The CDS Crowd” innovation challenge to CDS programming team



Looking to the Future: Do you have a potential improvement that you'd like to share – an idea for simplifying a complex process, a way of improving our quality, a quicker way of doing things, or a suggestion for a new standard macro/utility?

[If so, add your idea here](#)



CDS Global Forum: The CDS Global Forum launched in July 2014 to share knowledge and to provide focused training. Use this space to provide feedback on topics covered so far, to suggest new topics or to find out how to present to the forum.

[Contribute to the forum](#)



Feedback: What do you think of this tool (Challenge Center)? Would a tool like this be useful in CDS for sharing ideas and information? What functionality could be added to the tool to make it better?

[Leave your feedback here](#)



69% of contributors
put in 80% of ideas



58% of contributors
put in 80% of comments



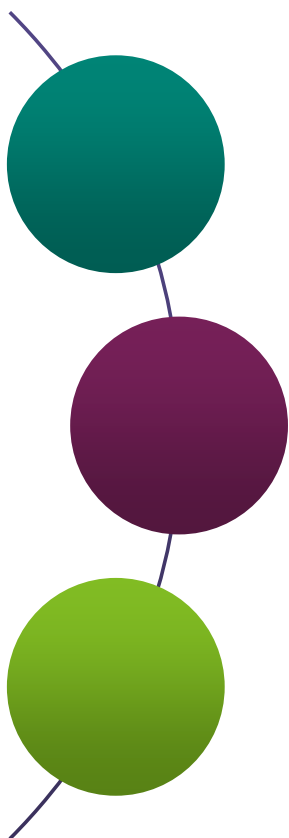
47% of contributors
put in 80% of votes

Current Buzz

Filter Events ▼

based check clinical conversion create data
database dataset developed domain flow help
implement individual inform mentor merge
opendisc oracle person process program
rave sdtn sheet standard study training
variable

Study Data Handling: A CRO Experience



ICON
A Symbol of Excellence

Lessons Learned



Process and technology is not enough

- Communication is critical to successful implementation
- “Hearts and minds” campaign – what, when and **WHY**

Avoiding analysis paralysis

- Start with a workable solution with the agreement it will change
- Actively seek feedback and adapt accordingly

Acknowledgements & Contact Details



- **Stephen Robertson** (Senior Clinical Data Delivery Lead)
 - Lead developer for source data receipt automation
- **Margaret Skrzypczak** (Clinical Data Delivery Lead)
 - Lead tester for source data receipt automation
- **Louise Kenny** (Senior Clinical Data Delivery Lead)
 - Design of impact analysis process
- **Niall AlRubeai** (Clinical Data Developer)
 - Designer of data processing dashboard

Paul Crean

CDS Development Manager

Clinical & Data Operations, ICON

Email: paul.crean@iconplc.com

Web: www.iconplc.com

