

THE FUTURE OF
CLINICAL DEVELOPMENT



PRAHEALTHSCIENCES



Automated SDTM creation – a human perspective

May 2016

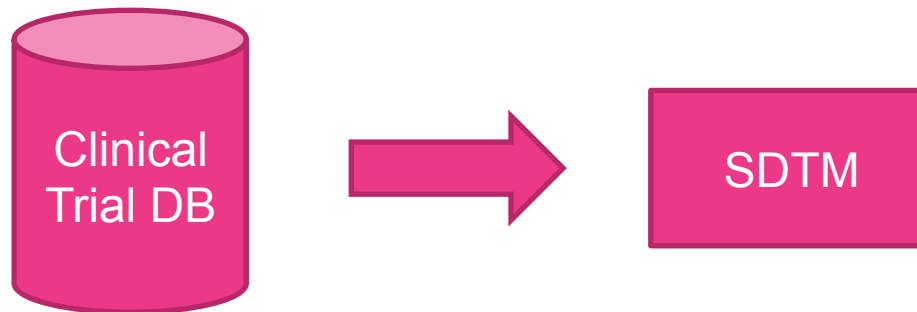
Edward Jones



Simpler SDTM creation – the dream



[<http://deepdreamgenerator.com/dream>]





Standards → Automation → ↑ Efficiency and Quality



The Bottom Line

- Make SDTM creation cheaper whilst improving quality



- Industry wants consistency (FDA, CDISC, Sponsors)



Code Structure

- SAS programs are broken into two steps: Pre-processing in which complex derivations are handled, and mappings which simple single data step actions can be completed. Enforcing this code structure on all programmers increases the **readability** and consistency of the resulting code increasing the potential for **reuse**
- Where a simple mapping has been used, because of the enforced code structure it is **easy** for a programmer who's unfamiliar with the trial to find and amend that mapping.

Library Usage

- Trials with standards compliant designs can **re-use** derivations, mapping elements and metadata from a library (pseudo) trial. Library derivations are written so that flexibility is built into macros called within those derivations. Thus, alterations are made within the macro meaning a programmer is less likely to unnecessarily alter the derivation code.
- Metadata is baked into the libraries resulting in reduced effort for **Define.xml** production.
- Library specification available. Contains additional column to indicating where in EXACT changes to a mapping can/ should be made



EXACT 6.0 Benefits

Inbuilt Conformance Checks

- **Pinnacle 21** validation tool built into EXACT. Custom conformance checks configurable within the system. System design helps prevent entry of non-conformant data structures

Traceability

- Improved data traceability via system based audit trails for data and programs



EXACT - SDTM Mapping Interface

CDISC Standards - SDTM

Mapping

Raw/Derived Da... SDTM Domain

Raw/Derived Da...	SDTM Domain
AE_DER	AE
DM_DER	SUPPDM
DM_DER	DM
DS_DER	CODS
DS_DER	DS
EX_DER	EX
IE_DER	IE
LB_DER	COLB02
LB_DER	COLB01
LB_DER	LB02
LB_DER	LB01
TA	TA
TE	TE
TI	TI
TS	TS
TV	TV
VS_DER	VS
XF_DER	XF

Legend: Unmapped (Black), Mapped (Green), Derived [N - Num, C - Char] [K - Key Variables] [Auto Map, Manual Map]

Derived : DM_DER
Demographics intermediate dataset

1. USUBJID (C)
2. CECITY (C)
3. CEINWFIR (C)
4. CEINNVNAM (C)
5. CENTRE (C)
6. CETYPE (N)
7. COUNTRY (N)
8. PROTID (C)
9. SUBJID (N)
10. BIRTHDA (N)
11. DESUBRC (N)
12. HISLATYN (N)
13. RACECM (C)
14. SEX (N)
15. DOSTRDA (N)
16. DOSTRDT (N)
17. SUBENDDT (N)
18. GESTAG (N)
19. enrollid (N)
20. dcrim (N)
21. bx_num (C)
22. slotstat (C)
23. segnum (N)
24. strata_1 (C)

SDTM : DM
Demographics

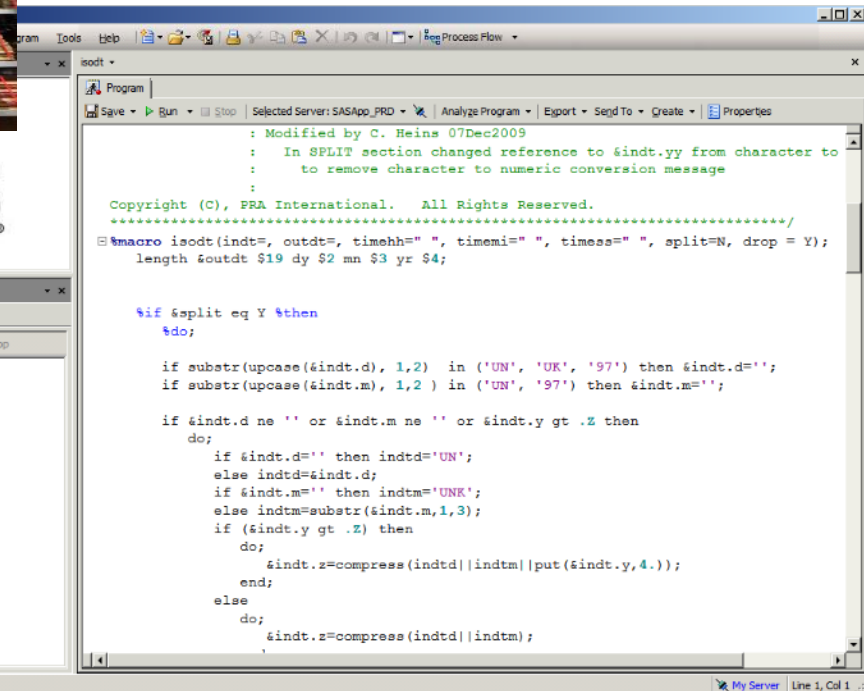
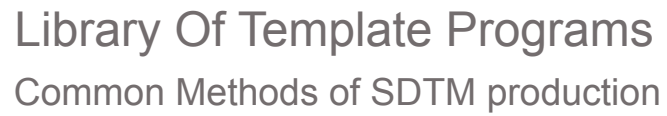
1. STUDYID (C) (Req) (K)
2. DOMAIN (C) (Req)
3. USUBJID (C) (Req) (K)
4. SUBJID (C) (Req)
5. RFSTDTC (C) (Exp)
6. RFENDTC (C) (Exp)
7. SITEID (C) (Req)
8. INVID (C) (Perm)
9. INVNAM (C) (Perm)
10. BRTHDTC (C) (Perm)
11. AGE (N) (Exp)
12. AGEU (C) (Exp)
13. SEX (C) (Req)
14. RACE (C) (Exp)
15. ETHNIC (C) (Perm)
16. ARMCD (C) (Req)
17. ARM (C) (Req)
18. COUNTRY (C) (Req)
19. DMDTC (C) (Perm)
20. DMDY (N) (Perm)

SDTM : SUPPDM
Supplemental Qualifiers for DM

1. STUDYID (C) (Req) (K)
2. RDOMAIN (C) (Exp) (K)
3. USUBJID (C) (Req) (K)
4. IDVAR (C) (Exp) (K)
5. IDVARVAL (C) (Exp) (K)
6. QNAM (C) (Req) (K)
7. QLABEL (C) (Req)
8. QVAL (C) (Req)
9. QORIG (C) (Req)
10. QEVAL (C) (Exp)

Check

For Help Press F1 | Logged in as : CDISC Analyst | Environment: Production



[illegible]

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Still Need Humans

PRA – Swansea CP team (Aug 2014)





I ♪ ❤️ EXACT ? ♪



Code Reuse

- Most SAS programmers will reuse their own code where possible
- Few SAS programmers will reuse the code of others due to:
 - Unfamiliarity
 - Prejudice
- The implementation of standards provide (some) opportunities to reuse code from one trial to the next



Programmers are creative



Programming is creative

Human perspective

- Despite being heavy on logic, programming is ultimately a creative art.
- There are many ways to program a data transformation and programmers like to experiment
- Programmers are often naturally curious
- Many enjoy the act of programming in SAS as much as the creation of the end product – SDTM
- Much of the reward in programming comes from fixing program problems. The more complicated the problem, the more rewarding it is when you finally solve it.

[Joel Lee: 2016; 6 Signs that You are Not Meant To Be A Programmer]



↑ automation = ↓ creativity?



Automation

Through automation the **business** seeks:

- Improved quality
- Reduced validation effort
- Reduced time spent writing new code
- Greater opportunity to use junior staff (decreased learning curve)





Automation

In automation the **programmers** dislike:

- Erosion of SAS skills
- Loss of SAS skill development path
- Loss of creativity, loss of individualism
- Devaluation of programming role





Automation = People Problems

Negative	into a Positive
Erosion of SAS skills	Simple manipulations/transformation now automated. More time can be spent on the tough stuff
Loss of SAS skill development path	Establish formal and rigorous SAS training
Demotivation of experienced staff	Success through deep expertise in standards and data. Opportunities to analyse data trends across many trials and help tune/guide the automation process to boost quality and efficiency



Can We Design Our Automation Tools To Make Them Better Suited For Our Users?



Users fear complexity



UX design approach

User Experience (UX)

- Huge numbers of users will leave within five minutes of trying a website, blog or application
- Make your tool simple, concise
- Make your tool highly focused

But



Tim Bow, <https://www.flickr.com/photos/timboss81>



- **Problem:** If users aren't willing to experiment with your new tool and improve their outcomes over time, then your investment in the technology is wasted.
- **Solution:** Gamify
- Heavily utilised in videogames
- Tap into basic human needs:
 - Autonomy (control your own pace)
 - Mastery (get better over time)
 - Sense of purpose (provide a well-defined goal)
 - Social factors (pit skills against one another and compare how you are doing versus your colleague)



BEST SCORE		
RANK	SCORE	NAME
1	126020	OLL
2	20000	ABC
3	10000	DEF
4	8000	GHI
5	7000	JKL
6	6000	MNO
7	5000	PQR
8	4000	STU
9	3000	VWX
10	2000	YZ
YOUR RANKING 1 OLL TIMER 9		



Gamification Drives User Behaviour



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Q

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Ferm PRA1011 Router Table

by [Ferm](#)

★★★★★ ▾ [2 customer reviews](#)

Price: **£39.99** FREE UK delivery.

In stock.

Estimated delivery 28 - 30 Apr. when you choose Express Delivery at checkout. [Details](#)

Dispatched from and sold by [iShop247](#).

- Mains voltage 230 V
- Frequency 50 Hz
- Table size 455 x 330 mm
- Robust and stable aluminium construction, provided with rubber anti-skid feet
- Synchronic dust free switch

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Top Customer Reviews

★☆☆☆☆ worst pice of junk i ever bought

By [mr v woodcock](#) on 29 April 2014

this P.O.S. took over an hour to put together then after the first run started to loosen and fall apart, the power switch is dangerous and will snap at the least bit of pressure mine is now in the bin along side of the ferm router witch also failed after a week DONT WAST YOUR MONEY.



mr v woodcock

Reviewer ranking: #209,093

85% helpful

votes received on reviews
(29 of 34)

ACTIVITIES



Reviewed
The Friendly Swede Silicone 7 LED
Bike Light Set, White and Red

★★★★★ **Five Stars**

2015-08-03

Very good quality



Reviewed
Ferm PRA1011 Router Table

22 of 22 people found this review helpful



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		Sorted by rank (high to low)		
Rank	Customer Reviewer	Total Reviews	Helpful Votes	Percent Helpful
# 1	 Mr Baz See all 3,943 reviews	3,943	21,674	96%
# 2	 JackJack See all 351 reviews	351	10,384	96%
# 3	 Chris M See all 1,256 reviews	1,256	11,205	95%



Gamification - downsides

Problem:

- Badges or points can be seen to trivialise work
- Big brother is always watching!

Solution:

- Prototype gamification on a small scale to catch problems early and address them prior to mass rollout.



How Can We Smooth the Transition to Automation Tools?



“It follows that an acceleration in the rate of change will result in an increasing need for reorganization. Reorganization is usually feared, because it means disturbance of the status quo, a threat to people’s vested interests in their jobs, and an upset to established ways of doing things. For these reasons, needed reorganization is often deferred, with a resulting loss in effectiveness and an increase in costs.”

Marvin Bower and C. Lee Walton, Jr., “Gearing a Business to the Future,” in *Challenge to Leadership* (The Conference Board, 1973).



Change Management

- Even changes that appear to be “positive” or “rational” involve loss and uncertainty.
- Four most common forms of resistance
 - Desire not to lose something of value (act in own best interests)
 - Misunderstanding and lack of trust
 - Belief that the change does not make sense for the organisation (different assessments)
 - Low tolerance for change

JOHN P. KOTTER and LEONARD A. SCHLESINGER
“Choosing Strategies for Change”: HBR; July–August 2008



Dealing with Resistance

Education and Communication

- Educate the team on the change prior to its implementation

Participation and Involvement

- Involve potential resisters in the change design and/or implementation

Facilitation and Support

- Provide training in new skills
- Provide time off after a demanding period
- Listen and provide emotional support



Negotiation and Agreement

- Offer incentives to resisters

Manipulations and Co-optation

- Selective use of information and conscious structuring of events
- Co-opt resister into key role. Different from participation as only endorsement is sought.

Explicit and Implicit Coercion

- Threaten, fire, transfer



- Use multiple methods to deal with resistance
- Select the appropriate pace of change:



Fast	Slow
Clearly planned	Not clearly planned at the beginning
Little involvement of others	Lots of involvement of others
Overcome resistance	Minimise resistance

JOHN P. KOTTER and LEONARD A. SCHLESINGER
“Choosing Strategies for Change”: HBR; July–August 2008



Happy Team





Conclusions



Conclusions

Programmers aren't always receptive to automation

When designing automation tools consider UX aspects carefully

Make use of gamification techniques – they can help

Establish a change management strategy

NO MATTER WHERE YOUR
CLINICAL DEVELOPMENT TAKES YOU,
WE'RE ALREADY THERE.



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