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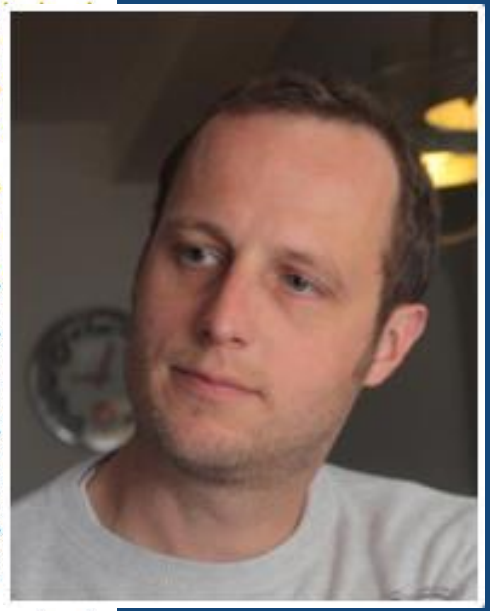
Coming together – a journey in the harmonization of clinical analysis standards

Warwick Benger, Director – Programming, Biostatistics, GSK



Meet the Speaker

Warwick Benger

Title: Director, Programming

Organization: Biostatistics, GSK

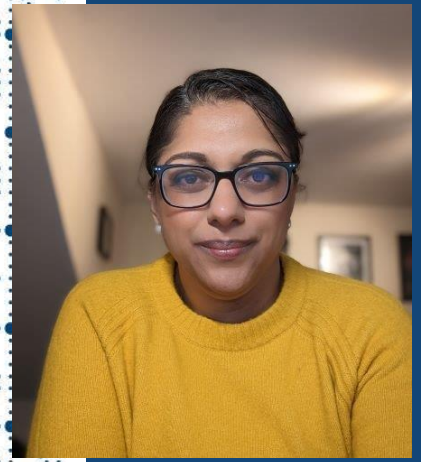
- Works in ‘Technical Excellence and Innovation’.
- Based in the UK.
- Over 20 years experience in clinical data delivery and analysis.
- Work passion is helping others to find their best self and putting people at the centre of technology.
- Co-lead of GSK’s “end to end standards” transformation programme.

Meet the co-authors

Edwin van Stein

Title: Analysis Standards Product Owner (Programming Leader)

Organization: Biostatistics, GSK



Saqwindar Singh

Title: Analysis Standards Analyst

Organization: Biostatistics, GSK

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC, or GSK.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. Coming Together
2. An example – AE reporting
3. An example – Collection and reporting of Race & Ethnicity
4. Analysis Results
5. Wrap up

Coming together

Coming together

come together phrasal verb

came together; come together; coming together; comes together

1 : to join or meet

> the place where two rivers *come together*

2 : to form a group

> People from many different areas have *come together* to try to find a solution.

3 : to begin to work or proceed in the desired way

> The project started slowly, but everything is finally starting to *come together* now.

Imagine Clinical Development with e2e standards

PROTOCOL DESIGN AND APPROVAL

- Reusable protocols
- Data-driven protocol design
- Efficient and better designs for other Therapeutic areas and indications

STUDY SETUP

- High standardization (CRF, DB)
- Faster setup, UQ
- Lesser time and effort
- Consistency in form design

STUDY CONDUCT

- Standardized data collection
- Improved trial experience through better quality of study design
- Lesser data quality issues

DATA CLEANUP AND REVIEW

- Significant time and effort reduction
- Automated Quality checks
- Significant increase in data quality
- Increased scope for digitization

MEDICAL WRITING & SUBMISSION

- Efficient study reporting
- Improved quality & compliance
- Improved employee experience

DATA ANALYSIS AND REPORTING

- Automation enabled
- Near real-time insight generation
- Higher standardization of analysis programs
- Highly streamlined data points
- Improved trustability of data

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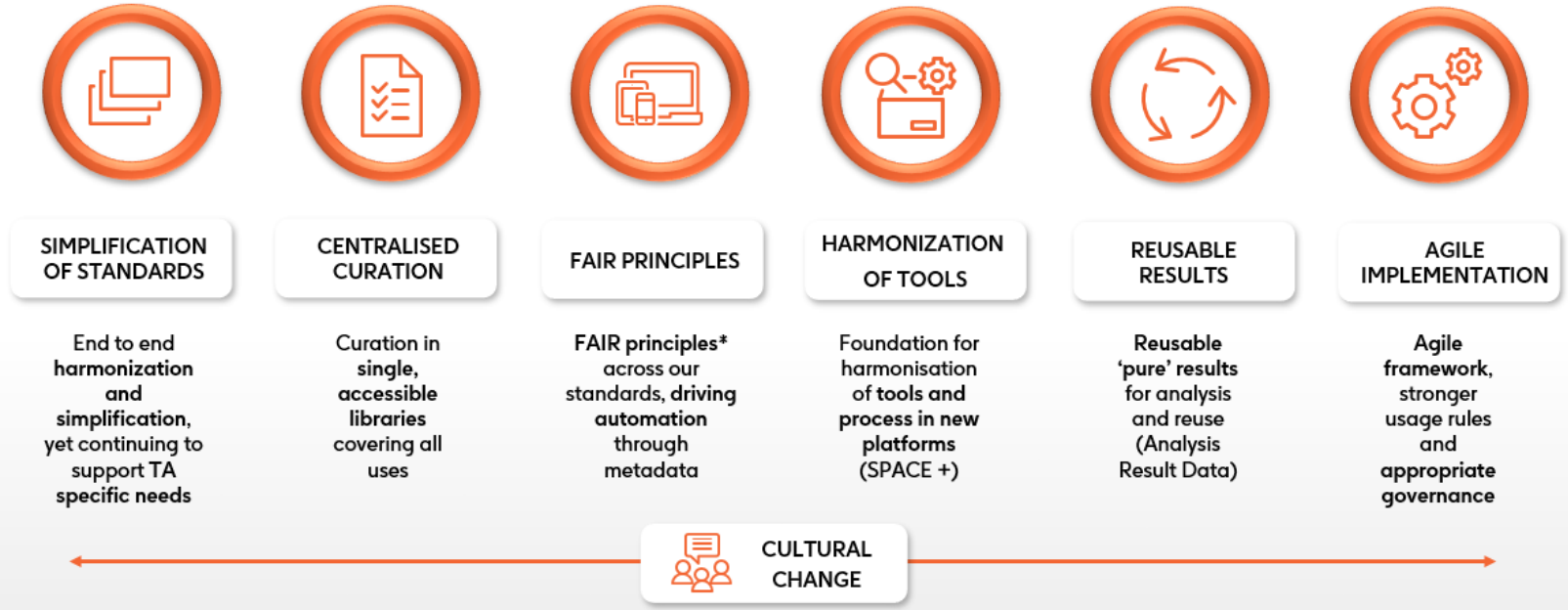
Coming together

Goal: To transform our expansive, siloed, and manually operated data standards to a set of **harmonized, simplified, and connected e2e data standards**



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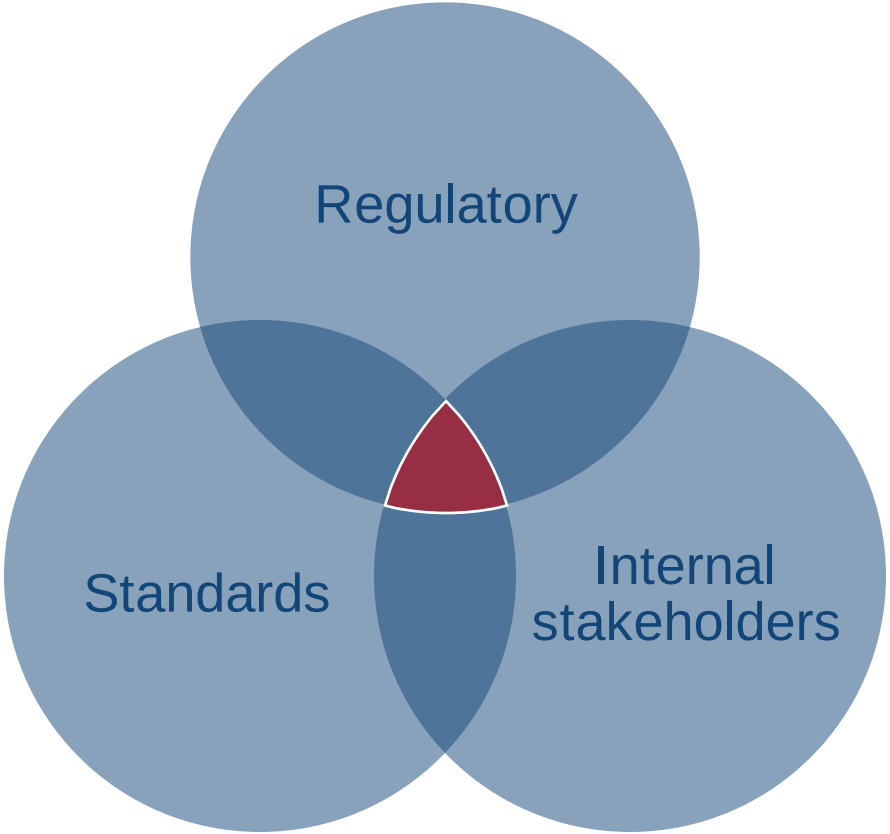
Coming together

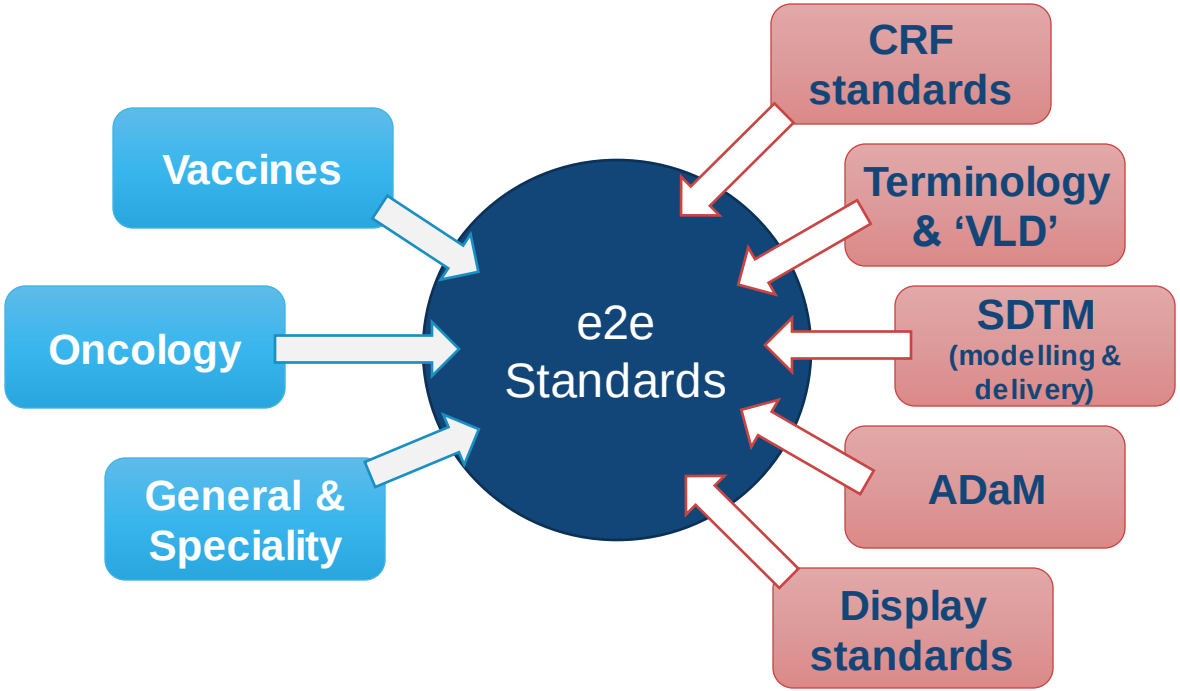
Generally, the implementation of standards involve addressing the requirements of 3 broad groups of stakeholders

Each of these have any number of subgroups which each have their own considerations and requirements

The key challenge is meeting the 'lowest (/highest?) common denominator'



Coming together



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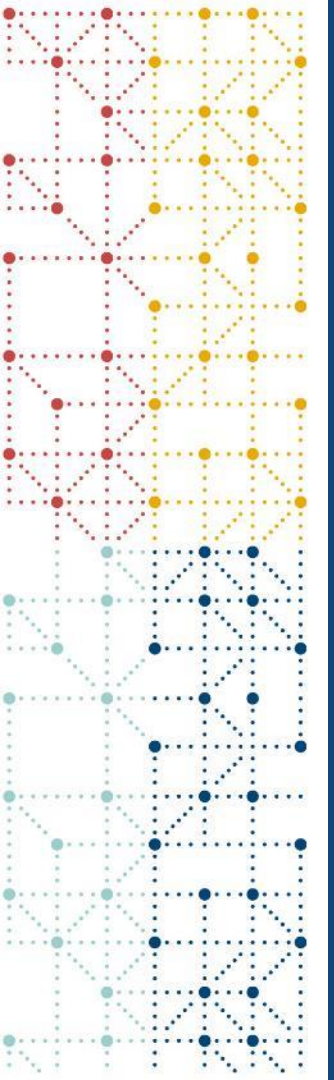
Coming together



Coming together

An example – AE reporting

An example – AE reporting

Goal: Define an analysis solution to meet all reporting requirements for Adverse Events

- Basic AE reporting is quite straightforward…
- … though we found that, for cross-over studies, we need more than the predefined occurrence flags

A typical basic reporting of AE frequencies

Protocol: ABC123456 — Page 1 of 1

Analysis Set: FAS/Safety/Unsolicited Safety/Other study specific — (Data as of: 30MAY2011)

Table X: Summary of [COVID-19] [Unsolicited] Adverse Events by System Organ Class and Preferred Term

[By group: By group value]

System Organ Class Preferred Term	Placebo (N=78)	Treatment B (N=78)	Treatment C (N=75)	Total (N=78)
ANY [COVID-19] [UNSOLICITED] EVENT	58 (74%)	64 (82%)	64 (85%)	64 (85%)
Gastrointestinal disorders				
Any event	28 (36%)	34 (44%)	22 (29%)	34 (44%)
Dyspepsia	9 (12%)	11 (14%)	5 (7%)	15 (19%)
Nausea	6 (8%)	8 (10%)	4 (5%)	11 (14%)
Vomiting Nos	3 (4%)	10 (13%)	3 (4%)	10 (13%)
Constipation	6 (8%)	6 (8%)	3 (4%)	7 (9%)
Diarrhoea Nos	2 (3%)	4 (5%)	2 (3%)	6 (8%)

ADaM OCCDS

Variable Name	Variable Label	CDISC Notes
AOCCFL	1st Occurrence within Subject Flag	Character indicator for the first occurrence of any event/intervention/finding within the subject Example derivation: Sort the data in the required order and flag the first treatment emergent record for each subject.
AOCCSFL	1st Occurrence of SOC Flag	Character indicator for the first occurrence of the system organ class within the subject Example derivation: Sort the data in the required order and flag the first treatment-emergent record for each body system for each subject.
AOCCPFL	1st Occurrence of Preferred Term Flag	Character indicator for the first occurrence of the preferred term within the subject Example derivation: Sort the data in the required order and flag the first treatment emergent record for each --DECOD for each subject.

An example – AE reporting

Things become increasingly complicated as we looked at Vaccines studies

- Different permutations can be required for vaccines studies (e.g., overall, with onset within 4 days, 7 days, and 31 days).

More complex reporting of AE frequencies

Protocol: ABC123456 — Page 1 of 1

Analysis Set: FAS/Unsolicited Safety/Safety/Other study specific — (Data as of: 30MAY2011)

Table X: Overview of Adverse Events <With Onset Within X Days of Any Dose>

	Treatment A (N=118)	Treatment B (N=112)
Any [unsolicited] AE	50 (50%)	50 (50%)
[Unsolicited] AEs related to study treatment	20 (10%)	20 (10%)
AEs leading to permanent discontinuation of study treatment	5 (5%)	5 (5%)
AE leading to dose reduction	10 (10%)	10 (10%)
AE leading to dose interruption/delay	10 (10%)	10 (10%)
Medically attended unsolicited AEs	10 (10%)	10 (10%)
Any [unsolicited] SAE	10 (10%)	10 (10%)
[Unsolicited] SAEs related to study treatment	5 (5%)	5 (5%)
Fatal [unsolicited] SAEs	2 (2%)	2 (2%)
Fatal [unsolicited] SAEs related to study treatment	1 (1%)	1 (1%)

An example – AE reporting

How does the ARM look?

ARMID	DOMAIN	ANALYSIS SET	BY VARS	GROUP VARS	WHERE	ANALYSIS METHOD	Rx	Vx1	Vx2
ARM-AE-001	ADAE	SAFFL	AESOC AEDECOD	TRTA		COUNT DISTINCT SUBJECT	Y	Y	Y
ARM-AE-002	ADAE	SAFFL	AESOC AEDECOD	TRTA	AEACN="DRUG WITHDRAWN"	COUNT DISTINCT SUBJECT		Y	Y
ARM-AE-003	ADAE	SAFFL	AESOC AEDECOD	TRTA	AEACN="DOSE REDUCED"	COUNT DISTINCT SUBJECT		Y	Y
ARM-AE-004	ADAE	SAFFL	AESOC AEDECOD	TRTA	AEACN="DRUG INTERRUPTED"	COUNT DISTINCT SUBJECT		Y	Y
ARM-AE-005	ADAE	SAFFL	AESOC AEDECOD	TRTA	AEACN="DRUG WITHDRAWN" & ARELTM <= 7	COUNT DISTINCT SUBJECT			Y
ARM-AE-006	ADAE	SAFFL	AESOC AEDECOD	TRTA	AEACN="DOSE REDUCED" & ARELTM <= 7	COUNT DISTINCT SUBJECT			Y
ARM-AE-007	ADAE	SAFFL	AESOC AEDECOD	TRTA	AEACN="DRUG INTERRUPTED" & ARELTM <= 7	COUNT DISTINCT SUBJECT			Y

An example – AE reporting

Key challenge: How to handle in ADaM:

(NOTE: Some or all of these are <u>not</u> the right solution!!)

- Occurrence flags
  - With related events, severe events, related severe events, serious events, related serious events, etc. this could lead to over a hundred flags
- Create multiple ADAE records per AE record
  - Requires us to also use categorisation variables (ACAT??!)
- Deal with it in the “display programs”
- Implement solutions borrowed from BDS? MCRIT?
- Combinations of the above?

- Handle it in the ARM?

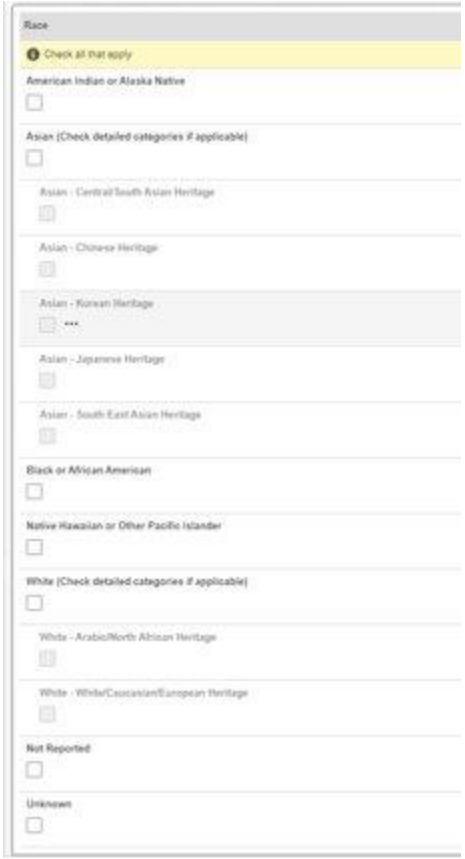
Coming together

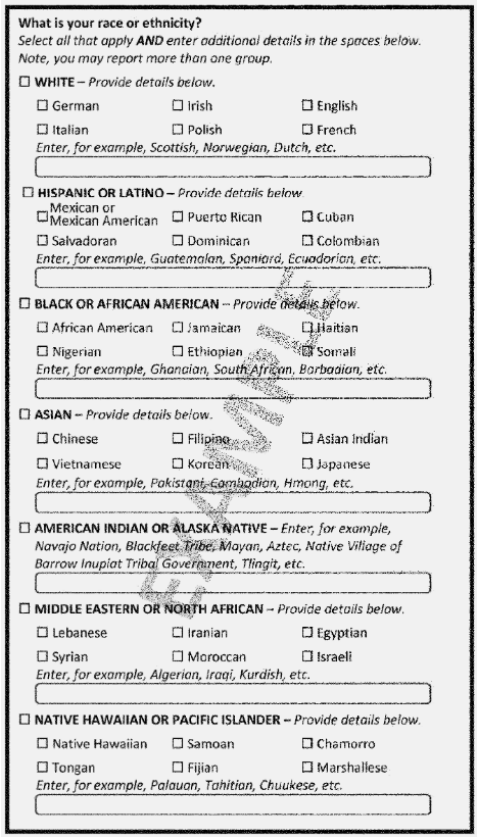
An example – Collection and reporting of Race & Ethnicity

An example challenge – Collection and reporting of Race & Ethnicity

Goals:

- Optimise collection and reporting of Race and Ethnicity information
- Support scientific and regulatory needs including ethnopharmacology, disclosure, etc
- Explore requirements of OMB refinement of SPD-15
- Comply with EMA expectations for collection of Race





An example challenge – Collection and reporting of Race & Ethnicity

Table X: Summary of Demographic and Baseline Characteristics

	No Treatment (N=xx)	[Treatment A/ Treatment Sequence] (N=xx)	[Treatment B/ Treatment Sequence] (N=xx)	Total (N=xx)
Ethnicity				
n	xxx	xxx	xxx	xxx
HISPANIC OR LATINO	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
NOT HISPANIC OR LATINO	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
NOT REPORTED	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
High Level Race				
n	xxx	xxx	xxx	xxx
AMERICAN INDIAN OR ALASKA NATIVE	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
ASIAN	xx (xx%)			
BLACK OR AFRICAN AMERICAN	xx (xx%)			
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	xx (xx%)			
WHITE	xx (xx%)			
MULTIPLE RACE CATEGORIES	xx (xx%)			
NOT REPORTED	xx (xx%)			
UNKNOWN	xx (xx%)			

Table X: Summary of Demographic and Baseline Characteristics

	No Treatment (N=xx)	[Treatment A/ Treatment Sequence] (N=xx)	[Treatment B/ Treatment Sequence] (N=xx)	Total (N=xx)
High Level Race				
n	xxx	xxx	xxx	xxx
AMERICAN INDIAN OR ALASKA NATIVE	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
ASIAN	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
BLACK OR AFRICAN AMERICAN	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
HISPANIC OR LATINO	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
WHITE	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
MULTIPLE RACE CATEGORIES	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
NOT REPORTED	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
UNKNOWN	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Coming together

Analysis Results

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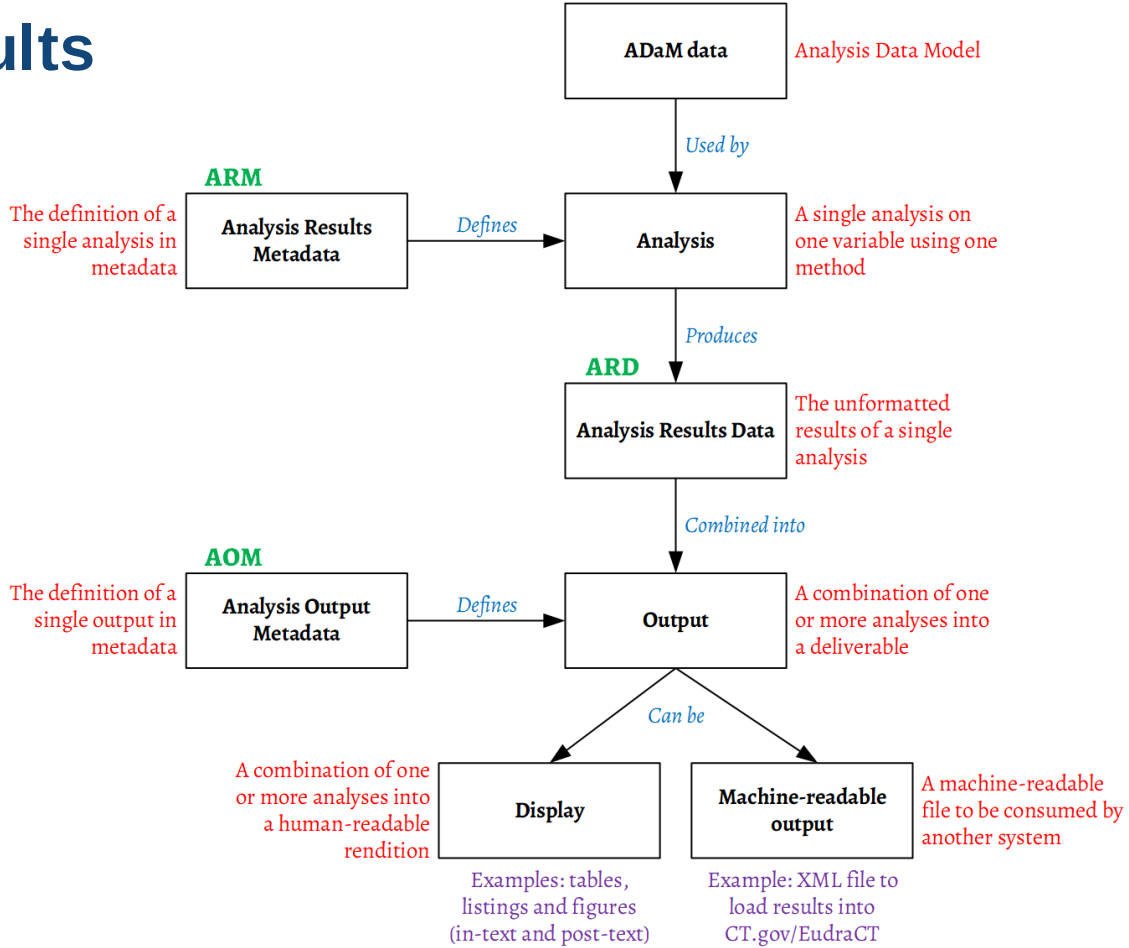
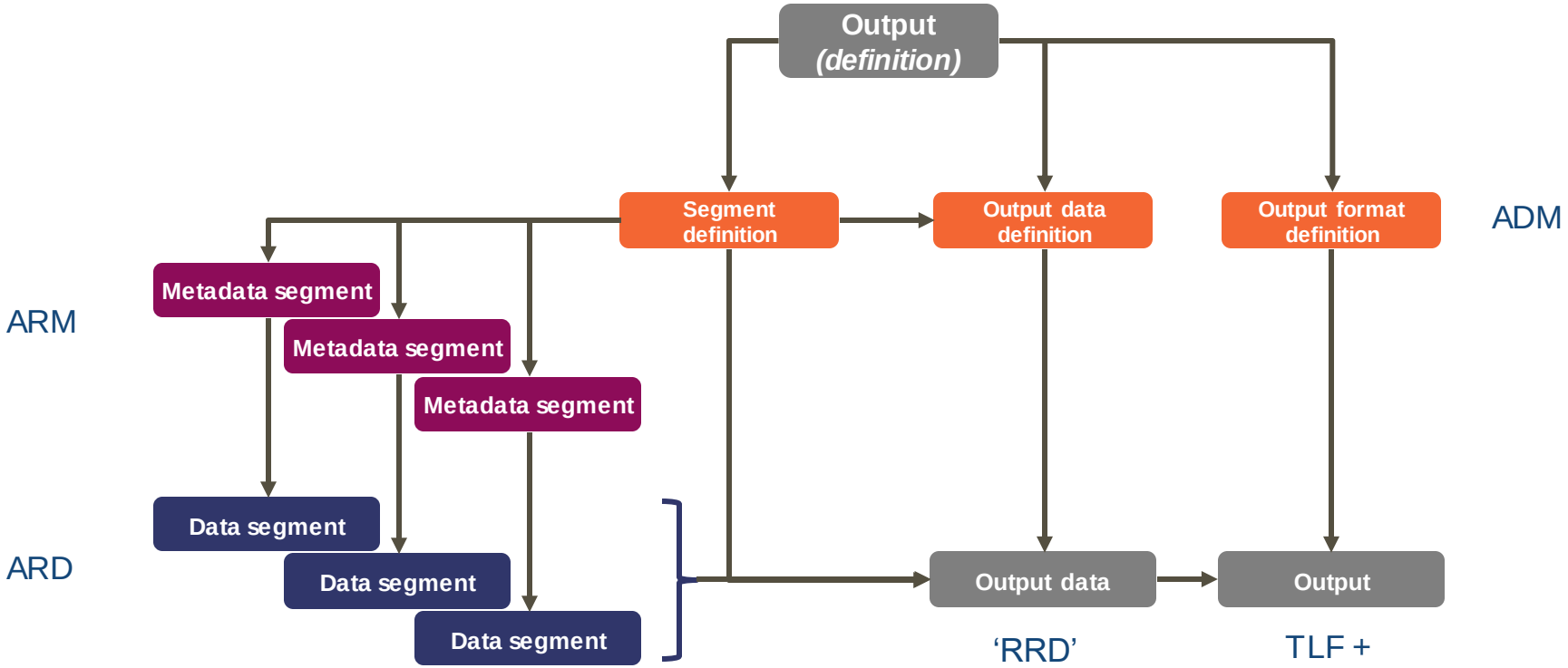


Analysis results

Why analysis results?

- WORM (Write Once Read Many)
  - Tables
  - Figures
  - In-text (CSR)
  - Publication
  - Disclosure
- Improved traceability / transparency
- Industry / regulatory alignment
- Increased flexibility
- Standardisation of results
  - Easier to validate / QC
  - Easier to reuse
  - Easier to build multilingual / multipurpose tools
- Increased automation

Analysis results



Analysis results

Protocol: ABC123456 — Page 1 of 1
Analysis Set: Safety — (Data as of: 30MAY2011)

Table X: Summary of Demographic and Baseline Characteristics

	GSK987654 50 mg (N=xx)	GSK987654 100 mg (N=xx)	Total (N=xx)
Sex			
n	xxx	xxx	xxx
F	xx (xx%)	xx (xx%)	xx (xx%)
M	xx (xx%)	xx (xx%)	xx (xx%)
Age (YEARS) at Informed Consent [1]			
n	xxx	xxx	xxx
Mean	xx	xx	xx
SD	xx	xx	xx
Height (cm)			
Max.	xx	xx	xx

[1] Age is imputed when full date of birth is not provided.
/Directory/program.sas 01JAN2002 12:01

ARMID	DenomID	Domain	AnalysisSet	PoolingGroupID	AnalysisVariable	ByVariables	GroupVariable	WhereClause	Method
as_saf		adsl	saffl	saf_trta_total			trtan[trta]		CountDistinctSubject
dm_sex		adsl	saffl	saf_trta_total	sexn[sex]		trtan[trta]		CountDistinctSubject
dm_aage1		adsl	saffl	saf_trta_total	aage1		trtan[trta]		SummaryStat
dm_agegr1n		adsl	saffl	saf_trta_total	agegr1n[agegr1]		trtan[trta]		CountDistinctSubject
dm_heightbl		adsl	saffl	saf_trta_total	heightbl		trtan[trta]		SummaryStat

PoolingGroupID	PoolingVariable	InputValue	PooledValue	PoolingLabelVariable	PooledLabel
saf_trta_total	trtan	1	9	trta	Total
saf_trta_total	trtan	2	9	trta	Total

Analysis results

ARMID	DenomID	Domain	AnalysisSet	PoolingGroupID	AnalysisVariable	ByVariables	GroupVariable	WhereClause	Method
as_saf		adsl	saffl	saf_trta_total			trtan[trta]		CountDistinctSubject
dm_sex		adsl	saffl	saf_trta_total	sexn[sex]		trtan[trta]		CountDistinctSubject
dm_aage1		adsl	saffl	saf_trta_total	aage1		trtan[trta]		SummaryStat
dm_agegr1n		adsl	saffl	saf_trta_total	agegr1n[agegr1]		trtan[trta]		CountDistinctSubject
dm_heightbl		adsl	saffl	saf_trta_total	heightbl		trtan[trta]		SummaryStat

PoolingGroupID	PoolingVariable	InputValue	PooledValue	PoolingLabelVariable	PooledLabel
saf_trta_total	trtan	1	9	trta	Total
saf_trta_total	trtan	2	9	trta	Total

ARMID	QualifierID	Order	Variable	Value	Role
as_saf	1	1	trtan	1	GroupVariable
as_saf	1	2	trta	GSK987 50 mg	GroupVariableLabel
as_saf	1	3		N	Statistic
as_saf	1	4		xxx	Value
as_saf	2	1	trtan	2	GroupVariable
as_saf	2	2	trta	GSK987 100 mg	GroupVariableLabel
as_saf	2	3		N	Statistic
as_saf	2	4		xxx	Value
as_saf	9	1	trtan	9	GroupVariable
as_saf	9	2	trta	Total	GroupVariableLabel
as_saf	9	3		N	Statistic
as_saf	9	4		xxx	Value

ARMID	DenomID	Domain	AnalysisSet	PoolingGroupID	AnalysisVariable	ByVariables	GroupVariable	WhereClause	Method
as_saf		adsl	saffl	saf_trta_total			trtan[trta]		CountDistinctSubject
dm_sex		adsl	saffl	saf_trta_total	sexn[sex]		trtan[trta]		CountDistinctSubject
dm_aage1		adsl	saffl	saf_trta_total	aage1		trtan[trta]		SummaryStat
dm_agegr1n		adsl	saffl	saf_trta_total	agegr1n[agegr1]		trtan[trta]		CountDistinctSubject
dm_heightbl		adsl	saffl	saf_trta_total	heightbl		trtan[trta]		SummaryStat

ARMID	QualifierID	Order	Variable	Value	Role
dm_sex	1	1	trtan	1	GroupVariable
dm_sex	1	2	trta	GSK987 50 mg	GroupVariableLabel
dm_sex	1	3	sexn		AnalysisVariable
dm_sex	1	4	sex		GroupVariableLabel
dm_sex	1	5		NonMiss	Statistic
dm_sex	1	6		xxx	Value
dm_sex	2.1	1	trtan	1	GroupVariable
dm_sex	2.1	2	trta	GSK987 50 mg	GroupVariableLabel
dm_sex	2.1	3	sexn	1	AnalysisVariable
dm_sex	2.1	4	sex	M	AnalysisVariableLabel
dm_sex	2.1	5		N	Statistic
dm_sex	2.1	6		xxx	Value
dm_sex	2.2	1	trtan	1	GroupVariable
dm_sex	2.2	2	trta	GSK987 50 mg	GroupVariableLabel
dm_sex	2.2	3	sexn	1	AnalysisVariable
dm_sex	2.2	4	sex	M	AnalysisVariableLabel
dm_sex	2.2	5		Percent	Statistic
dm_sex	2.2	6		xx.xxxxxxxxx	Value
dm_sex	3.1	1	trtan	1	GroupVariable
dm_sex	3.1	2	trta	GSK987 50 mg	GroupVariableLabel
dm_sex	3.1	3	sexn	2	AnalysisVariable
dm_sex	3.1	4	sex	F	AnalysisVariableLabel
dm_sex	3.1	5		N	Statistic
dm_sex	3.1	6		xxx	Value
dm_sex	3.2	1	trtan	2	GroupVariable
dm_sex	3.2	2	trta	GSK987 50 mg	GroupVariableLabel
dm_sex	3.2	3	sexn	2	AnalysisVariable
dm_sex	3.2	4	sex	F	AnalysisVariableLabel
dm_sex	3.2	5		Percent	Statistic
dm_sex	3.2	6		xx.xxxxxxxxx	Value

ARMID	QualifierID	Order	Variable	Value	Role
dm_sex	4	1	trtan	2	GroupVariable
dm_sex	4	2	trta	GSK987 100 mg	GroupVariableLabel
dm_sex	4	3	sexn		AnalysisVariable
dm_sex	4	4	sex		GroupVariableLabel
dm_sex	4	5		NonMiss	Statistic
dm_sex	4	6		xxx	Value
dm_sex	5.1	1	trtan	2	GroupVariable
dm_sex	5.1	2	trta	GSK987 100 mg	GroupVariableLabel
dm_sex	5.1	3	sexn	1	AnalysisVariable
dm_sex	5.1	4	sex	M	AnalysisVariableLabel
dm_sex	5.1	5		N	Statistic
dm_sex	5.1	6		xxx	Value
dm_sex	5.2	1	trtan	2	GroupVariable
dm_sex	5.2	2	trta	GSK987 100 mg	GroupVariableLabel
dm_sex	5.2	3	sexn	1	AnalysisVariable
dm_sex	5.2	4	sex	M	AnalysisVariableLabel
dm_sex	5.2	5		Percent	Statistic
dm_sex	5.2	6		xx.xxxxxxxxx	Value
dm_sex	6.1	1	trtan	2	GroupVariable
dm_sex	6.1	2	trta	GSK987 100 mg	GroupVariableLabel
dm_sex	6.1	3	sexn	2	AnalysisVariable
dm_sex	6.1	4	sex	F	AnalysisVariableLabel
dm_sex	6.1	5		N	Statistic
dm_sex	6.1	6		xxx	Value
dm_sex	6.2	1	trtan	2	GroupVariable
dm_sex	6.2	2	trta	GSK987 100 mg	GroupVariableLabel
dm_sex	6.2	3	sexn	2	AnalysisVariable
dm_sex	6.2	4	sex	F	AnalysisVariableLabel
dm_sex	6.2	5		Percent	Statistic
dm_sex	6.2	6		xx.xxxxxxxxx	Value

ARMID	DenomID	Domain	AnalysisSet	PoolingGroupID	AnalysisVariable	ByVariables	GroupVariable	WhereClause	Method
as_saf		adsl	saffl	saf_trta_total			trtan[trta]		CountDistinctSubject
dm_sex		adsl	saffl	saf_trta_total	sexn[sex]		trtan[trta]		CountDistinctSubject
dr							trtan[trta]		SummaryStat
dr							trtan[trta]		CountDistinctSubject
dr							trtan[trta]		SummaryStat

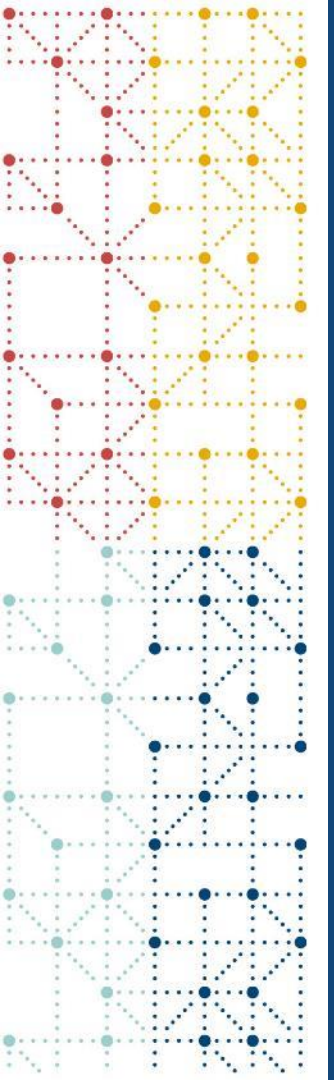
PoolingGroupID	PoolingVariable	InputValue	PooledValue	PoolingLabelVariable	PooledLabel
saf_trta_total	trtan	1	9	trta	Total
saf_trta_total	trtan	2	9	trta	Total

ARMID	QualifierID	Order	Variable	Value	Role
dm_sex	7	1	trtan	9	GroupVariable
dm_sex	7	2	trta	Total	GroupVariableLabel
dm_sex	7	3	sexn		AnalysisVariable
dm_sex	7	4	sex		GroupVariableLabel
dm_sex	7	5		NonMiss	Statistic
dm_sex	7	6		xxx	Value
dm_sex	8.1	1	trtan	9	GroupVariable
dm_sex	8.1	2	trta	Total	GroupVariableLabel
dm_sex	8.1	3	sexn	1	AnalysisVariable
dm_sex	8.1	4	sex	M	AnalysisVariableLabel
dm_sex	8.1	5		N	Statistic
dm_sex	8.1	6		xxx	Value
dm_sex	8.2	1	trtan	9	GroupVariable
dm_sex	8.2	2	trta	Total	GroupVariableLabel
dm_sex	8.2	3	sexn	1	AnalysisVariable
dm_sex	8.2	4	sex	M	AnalysisVariableLabel
dm_sex	8.2	5		Percent	Statistic
dm_sex	8.2	6		xx.xxxxxxxxx	Value
dm_sex	9.1	1	trtan	9	GroupVariable
dm_sex	9.1	2	trta	Total	GroupVariableLabel
dm_sex	9.1	3	sexn	2	AnalysisVariable
dm_sex	9.1	4	sex	F	AnalysisVariableLabel
dm_sex	9.1	5		N	Statistic
dm_sex	9.1	6		xxx	Value
dm_sex	9.2	1	trtan	9	GroupVariable
dm_sex	9.2	2	trta	Total	GroupVariableLabel
dm_sex	9.2	3	sexn	2	AnalysisVariable
dm_sex	9.2	4	sex	F	AnalysisVariableLabel
dm_sex	9.2	5		Percent	Statistic
dm_sex	9.2	6		xx.xxxxxxxxx	Value

ARMID	QualifierID	GroupVariable	GroupVariable Value	GroupVariableLabel	AnalysisVariable	AnalysisVariable Value	AnalysisVariable Label	Statistic	Value
as_saf	1	trtan	1	GSK987 50 mg				N	xxx
as_saf	2	trtan	2	GSK987 100 mg				N	xxx
as_saf	3	trtan	9	Total				N	xxx
dm_sex	1	trtan	1	GSK987 50 mg	sexn			NonMiss	xxx
dm_sex	2.1	trtan	1	GSK987 50 mg	sexn	1	M	N	xxx
dm_sex	2.2	trtan	1	GSK987 50 mg	sexn	1	M	Percent	xx.xxxxxxxxx
dm_sex	3.1	trtan	1	GSK987 50 mg	sexn	2	F	N	xxx
dm_sex	3.2	trtan	1	GSK987 50 mg	sexn	2	F	Percent	xx.xxxxxxxxx
dm_sex	4	trtan	2	GSK987 100 mg	sexn			NonMiss	xxx
dm_sex	5.1	trtan	2	GSK987 100 mg	sexn	1	M	N	xxx
dm_sex	5.2	trtan	2	GSK987 100 mg	sexn	1	M	Percent	xx.xxxxxxxxx
dm_sex	6.1	trtan	2	GSK987 100 mg	sexn	2	F	N	xxx
dm_sex	6.2	trtan	2	GSK987 100 mg	sexn	2	F	Percent	xx.xxxxxxxxx
dm_sex	7	trtan	9	Total	sexn			NonMiss	xxx
dm_sex	8.1	trtan	9	Total	sexn	1	M	N	xxx
dm_sex	8.2	trtan	9	Total	sexn	1	M	Percent	xx.xxxxxxxxx
dm_sex	9.1	trtan	9	Total	sexn	2	F	N	xxx
dm_sex	9.2	trtan	9	Total	sexn	2	F	Percent	xx.xxxxxxxxx

DisplayID	DisplaySectionID	DisplaySection Order	ARMID	Transpose	ResultFormat	RowLabel	OrderVariable	IdentifierColumns
dm_t01	dm_t01_sex	1	dm_sex	GroupVariable * Statistic	<NonMiss> || <N> (<Percent +1>%)	Sex	AnalysisVariable Value	%TAB% AnalysisVariableLabel || %TAB% "n"
dm_t01	dm_t01_aage1	2	dm_aage1	GroupVariable	<N> && <Mean +1> && <SD +2> && <Median +1> && <Min.> && <Max.>	Age (YEARS) at Informed Consent [1]	Statistic	%TAB% Statistic
dm_t01	dm_t01_agegr1n	3	dm_agegr1n	GroupVariable * Statistic	<NonMiss> || <N> (<Percent +1>%)	Age Group (YEARS) at Informed Consent [1]	AnalysisVariable Value	%TAB% AnalysisVariableLabel || %TAB% "n"
dm_t01	dm_t01_heightbl	4	dm_heightbl	GroupVariable	<N> && <Mean +1> && <SD +2> && <Median +1> && <Min.> && <Max.>	Height (cm)	Statistic	%TAB% Statistic

DisplayID	DisplaySectionID	DisplaySectionOrder	Order	RowLabel	IdentifierColumn01	trtan1Result	trtan2Result	trtan9Result
dm_t01	dm_t01_sex	1		Sex	n	xxx	xxx	xxx
dm_t01	dm_t01_sex	1	1	Sex	M	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
dm_t01	dm_t01_sex	1	2	Sex	F	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
dm_t01	dm_t01_aage1	2	1	Age (YEARS) at Informed Consent [1]	N	xxx	xxx	xxx
dm_t01	dm_t01_aage1	2	2	Age (YEARS) at Informed Consent [1]	Mean	xx.x	xx.x	xx.x
dm_t01	dm_t01_aage1	2	3	Age (YEARS) at Informed Consent [1]	SD	xx.xx	xx.xx	xx.xx
dm_t01	dm_t01_aage1	2	4	Age (YEARS) at Informed Consent [1]	Median	xx.x	xx.x	xx.x
dm_t01	dm_t01_aage1	2	5	Age (YEARS) at Informed Consent [1]	Min.	xx	xx	xx
dm_t01	dm_t01_aage1	2	6	Age (YEARS) at Informed Consent [1]	Max.	xx	xx	xx
dm_t01	dm_t01_agegr1n	3		Age Group (YEARS) at Informed Consent [1]	n	xxx	xxx	xxx
dm_t01	dm_t01_agegr1n	3	1	Age Group (YEARS) at Informed Consent [1]	<=18	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
dm_t01	dm_t01_agegr1n	3	2	Age Group (YEARS) at Informed Consent [1]	19-64	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
dm_t01	dm_t01_agegr1n	3	3	Age Group (YEARS) at Informed Consent [1]	>=65	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
dm_t01	dm_t01_heightbl	4	1	Height (cm)	N	xxx	xxx	xxx
dm_t01	dm_t01_heightbl	4	2	Height (cm)	Mean	xx.x	xx.x	xx.x
dm_t01	dm_t01_heightbl	4	3	Height (cm)	SD	xx.xx	xx.xx	xx.xx
dm_t01	dm_t01_heightbl	4	4	Height (cm)	Median	xx.x	xx.x	xx.x
dm_t01	dm_t01_heightbl	4	5	Height (cm)	Min.	xx	xx	xx
dm_t01	dm_t01_heightbl	4	6	Height (cm)	Max.	xx	xx	xx



Coming together

Wrap up

Analysis results

What we've learnt (so far)

- ARM is a good method of accurately describing our results
- Allows us to provide clearer usage instructions
- Significant automation opportunity

Some of the challenges (so far!)

- Fairly significant up-front effort to implement
- Potentially big change / steep learning curve for end user
- Some practical challenges to overcome
  - What does the workflow look like?
  - How best to store the data
  - Trade-offs in how we structure the ARD
- Modelling AOM for ingestion
- How can we connect through from Protocol, to Analysis Plan, to CSR
- Achieve automation

Thank You!