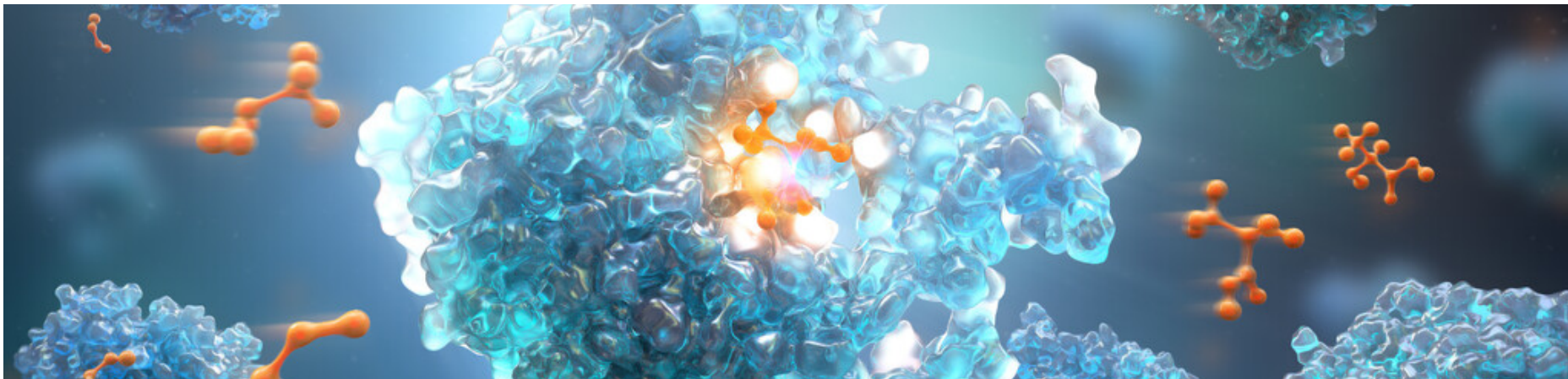


Using ODS LAYOUT to Create ABSOLUTE-ly Stunning Patient Profiles

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Agenda

- Introduction
- ODS LAYOUT
 - ODS LAYOUT GRIDDED
 - ODS LAYOUT ABSOLUTE
- Patient Profile – Version 1
- Patient Profile – Version 2
- Conclusion

Introduction

- Patient profiles are highly valued by physicians as an efficient method to get a high-level view of how the patients are progressing through a trial
- A wide variety of data – which is not always directly linked – is utilised
- Efficiently portraying information involves making the most out of the available space in an output



An interesting request

Arm <<>>, Cohort <<>>: <<Dose>>mg <<Schedule>>

<<ECODE>>: <<SITE>>, <<PI NAME>>

h<<ECODE: Male/Female, Age, Ethnicity/Race>> (Demography eCRF)

GBM History	Initial Diagnosis		Original Diagnosis Date (Screening)		GBM progression date	Recent progression date (Screening)
	Treatment for initial GBM	Chemotherapy: Cancer Therapy Agent Name; Start Date – End Date (Screening) This should include treatments <u>before</u> recent GBM progression date Radiotherapy: Total dose, Start Date – End Date (Screening)			Treatment for relapsed GBM	Cancer Therapy Agent Name; Start Date – End Date (Screening) This should include treatments <u>after</u> recent GBM progression date
GBM-seizure History/ Treatment	- GBM Seizure History: (Screening) all fields - Concomitant Medications (CM) Start – End dates					
Steroid Use	Concomitant Medications (CM) Start – End dates					
Cycle Dates	Cycle 0	C1W1	C2W1	DLT period complete	Follow Up #01	
	Visit Date (Cycle 0)	Visit Date (Cycle 1 Week 1 Visit A)	Visit Date (Cycle 2 Week 1 Visit A)	Visit Date (Cycle 2 Week 1 Visit A) + 7 days	Visit Date - Follow-up Visit 1	
Current Status						
AEs/SAEs	Please see next Slide					
Missed Doses?	Exposure log					
Seizure(s) on Study	Seizure Log					



An interesting request

- Titles are easily created directly from the data
- Line statement with style override to create output header
- Compute block to create coloured boxes within the first section
- Varying number of columns in each section
 - Split text across columns?

Arm <<>>, Cohort <<>>: <<Dose>>mg <<Schedule>>				
<<ECODE>>: <<SITE>>. <<PI NAME>>				
h<<ECODE: Male/Female, Age, Ethnicity/Race>> (Demography eCRF)				
GBM History	Initial Diagnosis	Original Diagnosis Date (Screening)		GBM progression date
	Treatment for initial GBM	Chemotherapy: Cancer Therapy Agent Name; Start Date – End Date (Screening) This should include treatments before recent GBM progression date Radiotherapy: Total dose, Start Date – End Date (Screening)		Recent progression date (Screening) Cancer Therapy Agent Name; Start Date – End Date (Screening) This should include treatments after recent GBM progression date
GBM-seizure History/ Treatment	• GBM Seizure History: (Screening) all fields • Concomitant Medications (CM) Start – End dates			
Steroid Use	• Concomitant Medications (CM) Start – End dates			
Cycle Dates	Cycle 0	C1W1	C2W1	DLT period complete
	Visit Date (Cycle 0)	Visit Date (Cycle 1 Week 1 Visit A)	Visit Date (Cycle 2 Week 1 Visit A)	Visit Date (Cycle 2 Week 1 Visit A) + 7 days
Current Status				Follow Up #01
				Visit Date - Follow-up Visit 1
AEs/SAEs	Please see next Slide			
Missed Doses?	Exposure log			
Seizure(s) on Study	Seizure Log			



An interesting request

- Titles are easily created directly from the data
- Line statement with style override to create output header
- Compute block to create coloured boxes within the first section
- Varying number of columns in each section
 - ~~Split text across columns?~~
 - Equivalent of graphical layout lattice?

Arm <<>>, Cohort <<>>: <<Dose>>mg <<Schedule>>

<<ECODE>>: <<SITE>>, <<PI NAME>>

h<<ECODE: Male/Female, Age, Ethnicity/Race>> (Demography eCRF)					
GBM History	Initial Diagnosis		Original Diagnosis Date (Screening)		GBM progression date
	Treatment for initial GBM	Chemotherapy: Cancer Therapy Agent Name; Start Date – End Date (Screening) This should include treatments before recent GBM progression date Radiotherapy: Total dose, Start Date – End Date (Screening)		Treatment for relapsed GBM	Recent progression date (Screening) Cancer Therapy Agent Name; Start Date – End Date (Screening) This should include treatments after recent GBM progression date
GBM-seizure History/ Treatment	- GBM Seizure History; (Screening) all fields - Concomitant Medications (CM) Start – End dates				
Steroid Use	Concomitant Medications (CM) Start – End dates				
Cycle Dates	Cycle 0	C1W1	C2W1	DLT period complete	Follow Up #01
	Visit Date (Cycle 0)	Visit Date (Cycle 1 Week 1 Visit A)	Visit Date (Cycle 2 Week 1 Visit A)	Visit Date (Cycle 2 Week 1 Visit A) + 7 days	Visit Date - Follow-up Visit 1
Current Status					
AEs/SAEs	Please see next Slide				
Missed Doses?	Exposure log				
Seizure(s) on Study	Seizure Log				



ODS LAYOUT

- Allows you to arrange multiple SAS procedure outputs together into a single output
- The output area is divided into regions; each one contains the output of one procedure
- There are two variations of ODS LAYOUT:
 - GRIDDED
 - ABSOLUTE



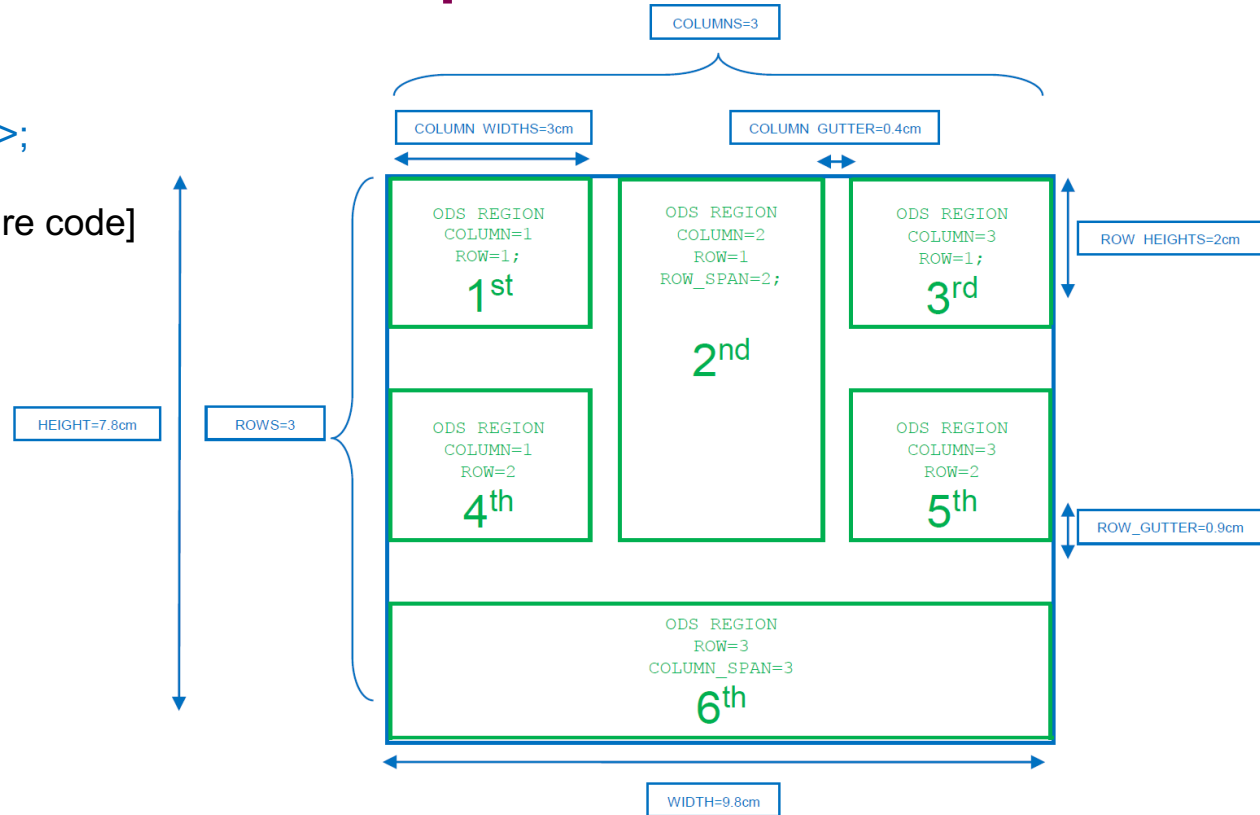
ODS LAYOUT - GRIDDED

- The output area is divided into a two dimensional grid, where cells contain outputs from individual SAS procedures
- The structure of the overall grid is controlled by options on the ODS LAYOUT GRIDDED statement
- Alignment and sizing of regions within the grid can be done automatically
- Valid in printer destinations (e.g. PDF) and PowerPoint destination



ODS LAYOUT – GRIDDED: Example

```
ODS LAYOUT GRIDDED <options>;  
  ODS REGION <options>;  
    [Output generating procedure code]  
ODS LAYOUT END;
```



ODS LAYOUT - ABSOLUTE

- The output area is a single page where regions are specified by exact coordinate points and dimensions
- Regions can be placed anywhere on the page and even overlap with each other
- Valid only in printer destinations (e.g. PDF)



Patient Profile – Draft 1

GBM History	E0000001: Male, 50, (White) Most Recent Visit (FOLLOW-UP 12SEP2019)				
	Initial Diagnosis		01JAN2000		
	GBM progression date		02FEB2002		
GBM-Seizure History / Treatment	Treatment for initial GBM		Cancer Therapy: Rituximab 02JAN2000-03MAR2001 Pembrolizumab 10APR2001-05MAY2001		
	Treatment for relapsed GBM		Radiotherapy: 52Gy 06MAR2002-18MAR2002		
Steroid Use	GHM Seizure History: Freq [<1 /MONTH] Features [Focal, Generalised] (Pre-Study) Levetiracetam 100mg QD 01JUN2005-28JUL2006				
	(Pre-Study) Hydrocortisone 10mg QD 01APR2005-08AUG2006 Prednisone 40mg BID 02OCT2018-16OCT2018 Dexamethasone 10mg BID 12NOV2018-22DEC2018 Dexamethasone 12mg BID 23DEV2018-12FEB2019 Dexamethasone 10mg QD 13FEB2019-Present				
Cycle Dates	Cycle 0	Cycle 1	Cycle 2	DLT Period Complete	Follow-up #1
Missed Doses	17SEP2018	24SEP2018	12OCT2018	01NOV2018	15JAN2019
	AZD1234: Dose Interrupted on 15OCT2018 (Cycle 2) due to Adverse Event (Nausea) Radiotherapy: No missed doses				
Seizures on Study	2 Episodes of [Focal] seizure on 04DEC2018 1 Episode of [Generalized] seizure on 18DEC2018				



Patient Profile – Draft 1

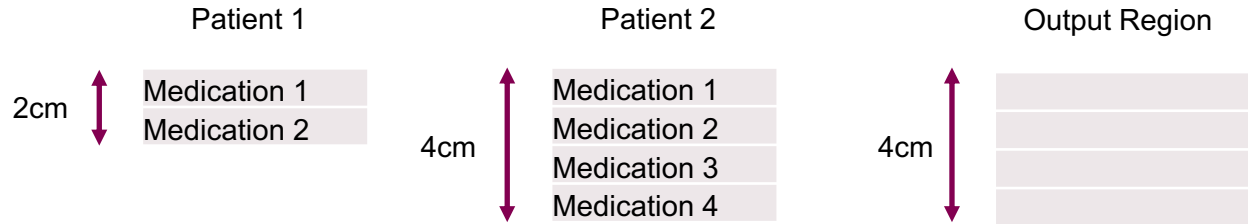
- Aesthetically faithful to original template
- Consistent alignment of all regions in the output
- However...
 - Large amounts of unused space

GBM History	E0000001: Male, 50, (White) Most Recent Visit (FOLLOW-UP 12SEP2019)				
	Initial Diagnosis: 01JAN2000		GBM progression date: 02FEB2002		
	Treatment for initial GBM	Cancer Therapy: Rintuximab 02JAN2000-03MAR2001 Pembrolizumab 10APR2001-05MAY2001		Treatment for relapsed GBM	Radiotherapy: 52Gy 06MAR2002-18MAR2002
GBM-Seizure History / Treatment	GHM Seizure History: Freq [-1MONTH] Features [Focal, Generalised] (Pre-Study) Levetiracetam 100mg QD 01JUN2005-28JUL2006				
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Cycle Dates	Cycle 0 17SEP2018	Cycle 1 24SEP2018	Cycle 2 12OCT2018	DLT Period Complete 01NOV2018	Follow-up #1 15JAN2019
Missed Doses	AZD1234: Dose Interrupted on 15OCT2018 (Cycle 2) due to Adverse Event (Nausea) Radiotherapy: No missed doses				
Seizures on Study	2 Episodes of [Focal] seizure on 04DEC2018 1 Episode of [Generalized] seizure on 18DEC2018				



Patient Profile – Draft 1: Grey Space

- Region dimensions must be large enough to contain the assigned output
- Different patients had different amounts of information to be displayed in each section of the output
- Each region was sized according to the “maximum data” scenario



- Manually sized regions make the code far more laborious to maintain
 - Adjusting the height of one output affects the y position of all subsequent outputs **by the same amount**



Patient Profile – Automation

- Updating the region specifications for new data was simple but repetitive
- There were 2 components to update
 - Y coordinate position
 - Height
- Y coordinate was relatively straightforward
 - $(y \text{ coordinate from previous region}) + (\text{height of previous region}) + (\text{buffer amount})$
- Height was the key value to determine



Patient Profile – Automation: count_rep_rows macro

- Counts the number of rows required to display the final report
- Parameters:
 - Data= (The input dataset which will go into proc report)
 - Newline= (String delimiter which is used to create a new line within a single observation [e.g. ^{newline}])
- Returns 2 global macro variables:
 - sasObs – The number of observations in the input dataset
 - Newlines – The sum of the maximum number of additional line feed delimiters in each row
- Assumes no text wrapping will occur in output

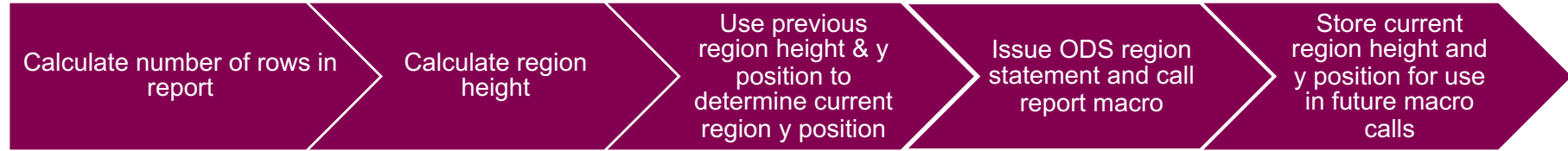


Patient Profile – Automation: build_region macro

- Creates a single region in an absolute layout, assigning height based on the data and y coordinate position based on all previous regions built by this macro
- Key parameters:
 - reportData= (Dataset being reported [used to estimate height based on number of rows required])
 - reportMacro= (Call to sub macro containing proc report code)
 - rowHeight= (Height required for each additional observation in dataset used in report)
 - newlineHeight= (Height required for newlines within the same observation)
 - rowGutter= (Additional space placed between current region and previous region)
 - unit= (Unit used for all coordinate & and height values)



Patient Profile – Automation: Logic Flow



Patient Profile – Draft 2

GBM History	E0000001: Male, 50, (White) Most Recent Visit (FOLLOW-UP 12SEP2019)				
	Initial Diagnosis 01JAN2000		GBM progression date 02FEB2002		
	Treatment for initial GBM	Cancer Therapy: Rituximab 02JAN2000-03MAR2001 Pembrolizumab 10APR2001-05MAY2001		Treatment for relapsed GBM	Radiotherapy: 52Gy 06MAR2002-18MAR2002
GBM-Seizure History / Treatment	GHM Seizure History: Freq [<1/MONTH] Features [Focal, Generalised] (Pre-Study) Levetiracetam 100mg QD 01JUN2005-28JUL2006				
Steroid Use	(Pre-Study) Hydrocortisone 10mg QD 01APR2005-08AUG2006 Prednisone 40mg BID 02OCT2018-16OCT2018 Dexamethasone 10mg BID 12NOV2018-22DEC2018 Dexamethasone 12mg BID 23DEV2018-12FEB2019 Dexamethasone 10mg QD 13FEB2019-Present				
Cycle Dates	Cycle 0	Cycle 1	Cycle 2	DLT Period Complete	Follow-up #1
	17SEP2018	24SEP2018	12OCT2018	01NOV2018	15JAN2019
Missed Doses?	AZD1234: Dose Interrupted on 15OCT2018 (Cycle 2) due to Adverse Event (Nausea) Radiotherapy: No missed doses				
Seizure(s) on study	2 Episodes of [Focal] seizure on 04DEC2018 1 Episode of [Generalized] seizure on 18DEC2018				



Patient Profile – Draft 2

- The height of each region is set very closely to the exact size of the report it contains
- More space available on the page for additional sections to be added in the future
- The code is much simpler to maintain, requiring no updates if the amount of information in each section changes

GBM History	E0000001: Male, 50, (White) Most Recent Visit (FOLLOW-UP 12SEP2019)									
	Initial Diagnosis		01JAN2000		GBM progression date	02FEB2002				
	Treatment for initial GBM		Cancer Therapy: Rintuximab 02JAN2000-03MAR2001 Pembrolizumab 10APR2001-05MAY2001			Treatment for relapsed GBM		Radiotherapy: 52Gy 06MAR2002-18MAR2002		
GBM-Seizure History / Treatment	GHM Seizure History: Freq [-1/MONTH] Features [Focal, Generalised] (Pre-Study) Levetiracetam 100mg QD 01JUN2005-28JUL2006									
Steroid Use	(Pre-Study) Hydrocortisone 10mg QD 01APR2005-08AUG2006									
	Prednisone 40mg BID 02OCT2018-16OCT2018									
	Dexamethasone 10mg BID 12NOV2018-22DEC2018									
	Dexamethasone 12mg BID 23DEV2018-12FEB2019									
	Dexamethasone 10mg QD 13FEB2019-Present									
Cycle Dates	Cycle 0		Cycle 1		Cycle 2		DLT Period Complete		Follow-up #1	
	17SEP2018		24SEP2018		12OCT2018		01NOV2018		15JAN2019	
Missed Doses?	AZD1234: Dose Interrupted on 15OCT2018 (Cycle 2) due to Adverse Event (Nausea) Radiotherapy: No missed doses									
Seizure(s) on study	2 Episodes of [Focal] seizure on 04DEC2018 1 Episode of [Generalized] seizure on 18DEC2018									



Conclusion

GRIDDED LAYOUT	ABSOLUTE LAYOUT
Region size and position determined automatically	Region size and position must be specified exactly
Regions may not overlap	Regions can be placed anywhere on the page
Layout may continue onto additional pages	Layout limited to a single page
Can output to printer and PowerPoint destinations	Can only output to printer destinations

- ODS LAYOUT can be a fantastic tool for creating information-dense outputs which make the most out of the available space
- Both GRIDDED and ABSOLUTE have their benefits depending on the requirements of the specific output



Thanks for listening!



Backup Slides

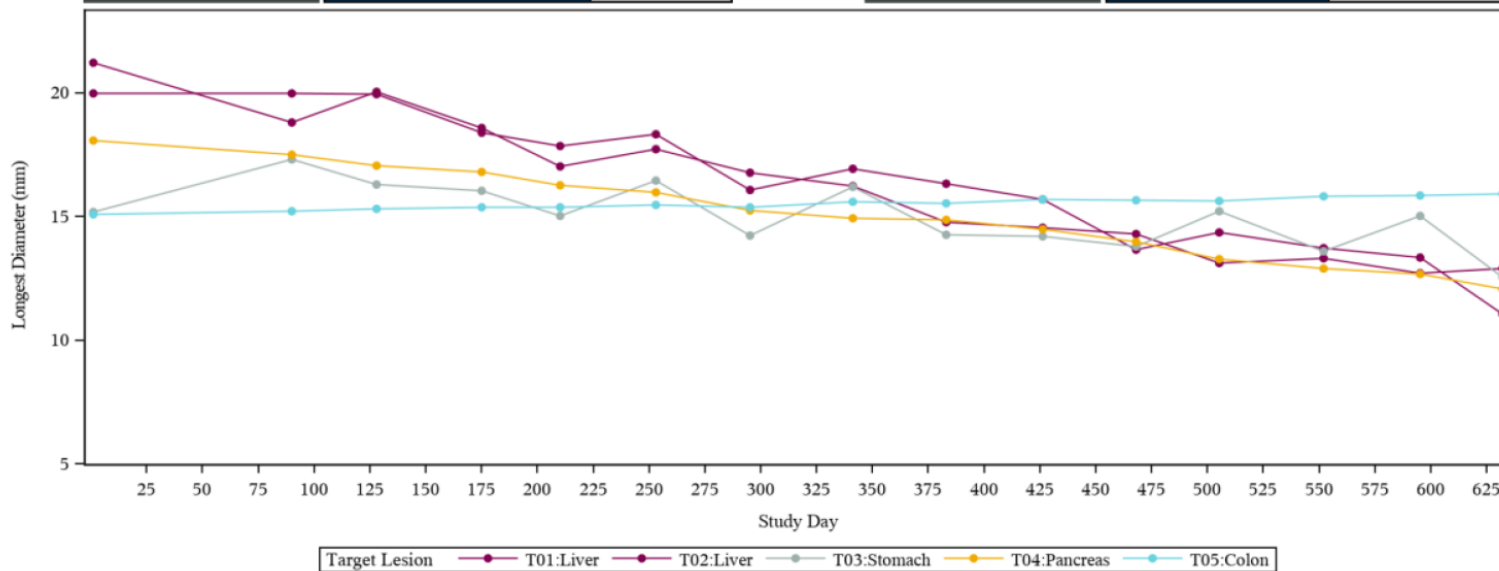


Another ODS LAYOUT Example – Oncology Dashboard

Patient 001: Oncology Profile

Demographic Information	Site	001
	Sex	M
	Age	50
	Country	UK
	Treatment Group	AZD1234
	Treatment Duration	632 Days

Genetic Information	Mutation 1	Positive
	Mutation 2	Negative
	Mutation 3	Negative
	Mutation 4	Positive
	Mutation 5	Negative
	Mutation 6	Positive



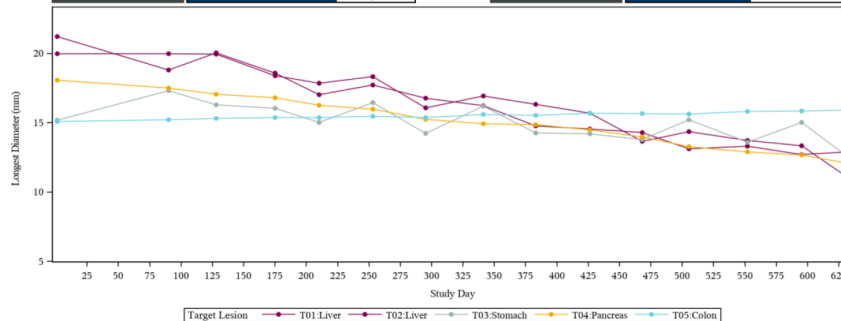
Another ODS LAYOUT Example – Oncology Dashboard

- Proc odstext used to label sections of the layout
- The graphic is drawn first, the reports and odstext actually “overlap” with the top of the graph
- The input data for this output is easy to validate

Patient 001: Oncology Profile

Demographic Information	Site	001
	Sex	M
	Age	50
	Country	UK
	Treatment Group	AZD1234
	Treatment Duration	632 Days

Genetic Information	Mutation 1	Positive
	Mutation 2	Negative
	Mutation 3	Negative
	Mutation 4	Positive
	Mutation 5	Negative
	Mutation 6	Positive



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