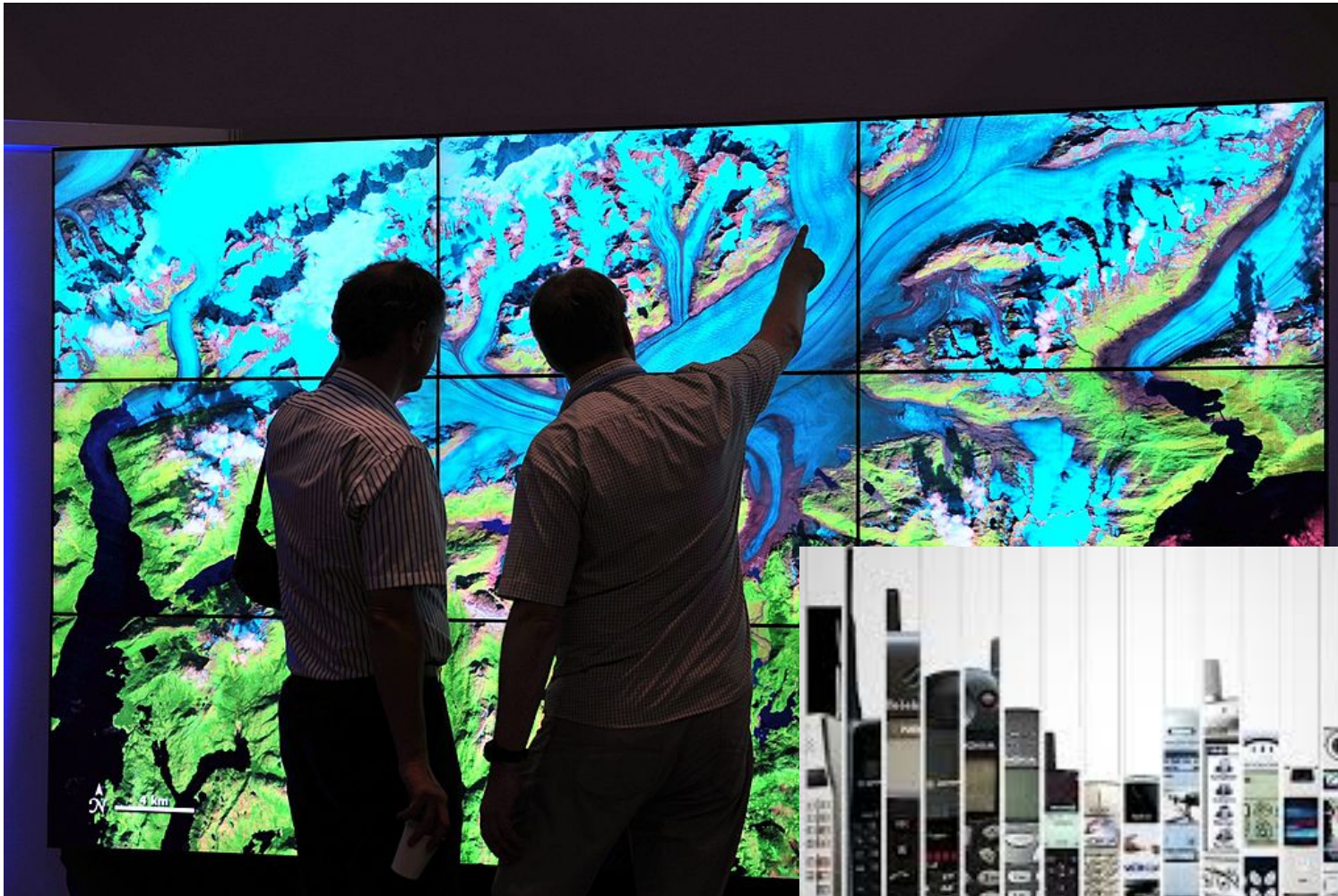


Dipping our Fingers into the World of Data Representation - A Visual Journey Using Encapsia Clinical Suite

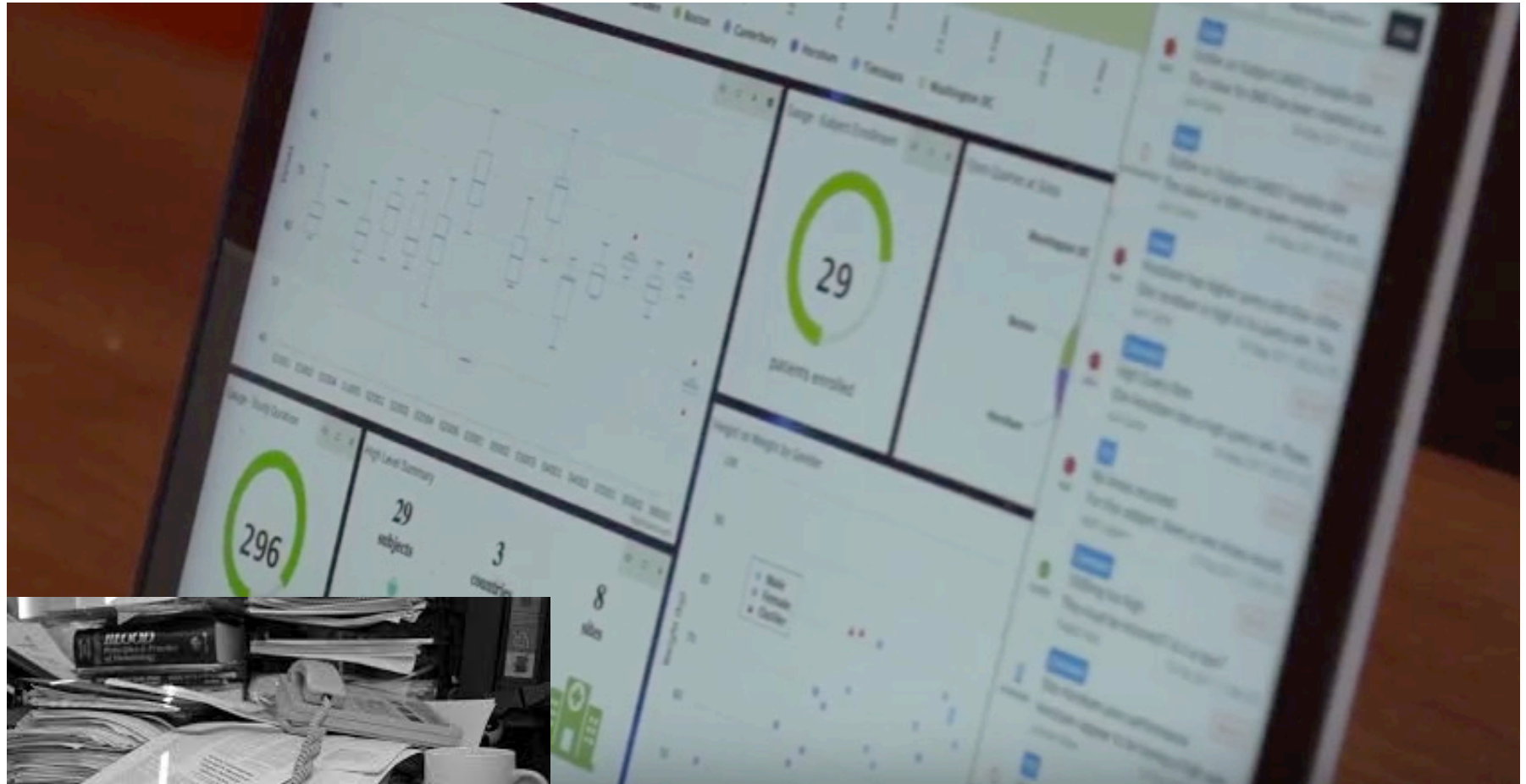
Phuse Annual Conference

11 Oct 2017

Technical advances in the last few decades have brought a significant change in the way the world looks at information.



Due to the highly regulated environment pharma is only now discovering that a picture can be worth a thousand ... Listings

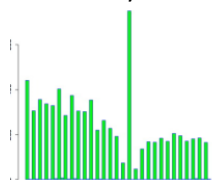


My initial contact with what we now know as Encapsia™ was an inter-department effort to identify checks that could enhance overall quality of data

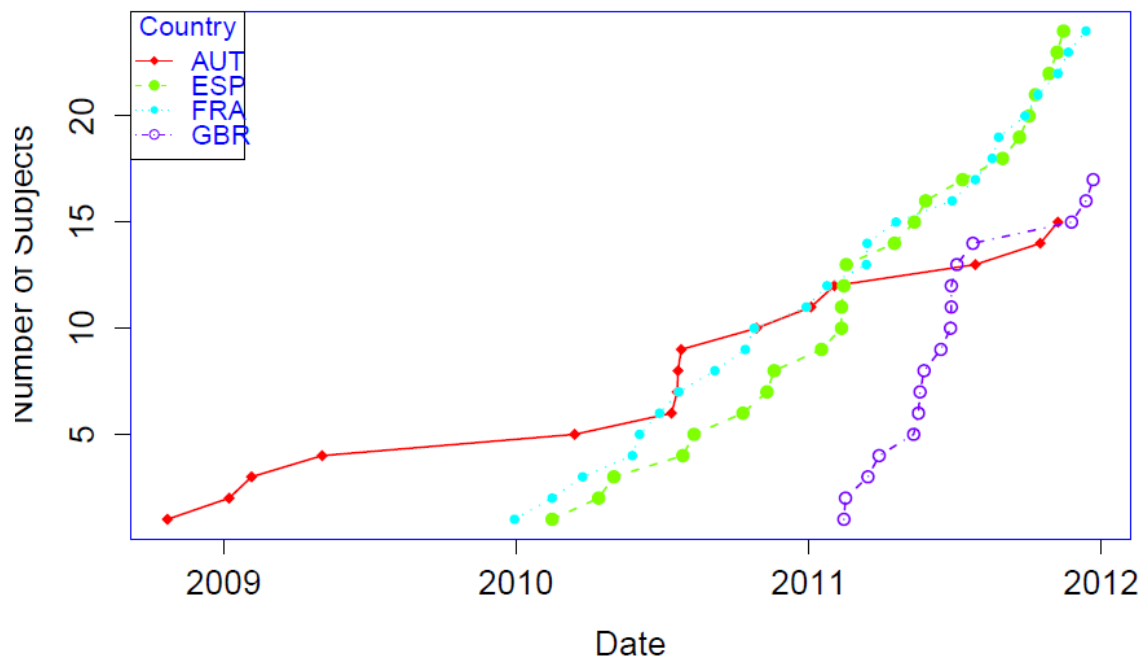
Description	Potential Uses	Description	Potent
# SAEs/AEs per site and compared eg incidence rates	Fraud - similar patients - identify patterns	Confidence plots and means/medians by site - for key variables eg efficacy/safety	To asse
Drug Admin date/time - varies across patients within a site	Fraud - similar patients - identify patterns	Drill down options on graphs eg outliers, point and click to patient number	drill do
Sat/Sunday checks for visits	Fraud - similar patients - identify patterns	view other software eg spotfire/jmp	
Mean and compared to the range +/- 2.5 sds	Labs - ranges/units for outliers	Box plots	Far Out
pre and post dose results eg increase/decrease	pk, Biomarker, immunogenicity		

Report Type	Title (Unique Across all reports)	Description	Version	Priority	Category (only one value)	Tags (multiple values allowed)	Scope (multiple values allowed)	Comparison Options (multiple values allowed for each scope)	Data Types (multiple values allowed)
LLQ checks/ULQ checks							Trial	Site, Country, Subject	
% frequency sites/patient							Country	Site, Subject, Country against Trial	
odd distributions							Subject, Site against Country, Site against Trial		
Scores for questionnaire							Site		Any continuous data points
Outliers	Outliers	Some description...	1.0	Y	Data Quality	RBM/DR			
Inliers	Inliers		1.0	Y	Data Quality	RBM/DR		All, Country, site	Any continuous data points
Enrollment	Enrollment		1.0	Y	Study Conduct	RBM	Trial	Overall, Country, Site	
							Country	Overall, Site	
							Site	Overall	* Cumulative per day * Cumulative per month * Monthly rate
Dropouts	Dropouts Rate		1.0	Y	Study Conduct	RBM		predicted at study start, country, site	screen failures, withdrawals
Dropouts	Dropouts Reasons		1.0	Y	Study Conduct	RBM		country, site	withdrawals
eCRF completion	CRF completion		1.0	Y	Study Conduct	RBM/DR		Time from visit to eCRF completion	

A few months later a small team was working on the first demo version of what would later become the Insights module

Randomiza-tion by week day (last 3 month)	Histogram	x-axis: week days (Monday, Tuesday, .. Sunday); y-axis: number of patient randomized on each week day Select data from the last 3 months (i.e. if the report is run 15JUN2015, the report should include all the data from 01MAR2015) 	Should be around the same for each day (Monday to Friday) and none on Saturday/ Sunday
Randomiza-tion by week day (last 3 month)	Histogram	Lattice plot of Scope = Trial, ComparisonOption = Overall and Value = Randomization by week day (last 3 months) - Panel: country - x-axis: week days (Monday, Tuesday, .. Sunday); - y-axis: number of patient randomized on each week day	Should be around the same for each day (Monday to Friday) and none on Saturday/ Sunday
Randomiza-tion by week day (last 3 month)	Histogram	NOTE: TO BE PRODUCED ONLY IF < 15 SITES Lattice plot of Scope = Trial, ComparisonOption = Overall and Value = Randomization by week day (last 3 months) - Panel: site - x-axis: week days (Monday, Tuesday, .. Sunday); - y-axis: number of patient randomized on each week day	Should be around the same for each day (Monday to Friday) and none on Saturday/ Sunday

Cumulative Randomization over Time by Country



After 2 more years I was very excited to see our ideas come to light in live studies leading to the birth of a new department and essentially a new profession in CMed

Results for Systolic Blood Pressure

Show All		Hide All		Comparison to FAR		Visit	
FAR and Post-FAR		Change from FAR		Mean change from FAR			
FAR value		Post-FAR mean		Mean change from FAR			
Search:							
Centre Subject	FAR value	FAR and Post-FAR values	Post-FAR mean	Change from FAR	Mean change from FAR	Comparison to FAR	Visit
Cmed UAT2 0201EC14141	545.0		2221.00		1676.00		
Cmed UAT2 0201EC13131	120.0		169.08		49.08		
Cmed UAT2 0201EC12121	74.0		115.00		41.00		
Cmed UAT2 0201EC15151	55.0		74.10		19.10		
Cmed UAT2 0201IT50005	343.0		333.00		-10.00		

Click on the icon to download the corresponding data

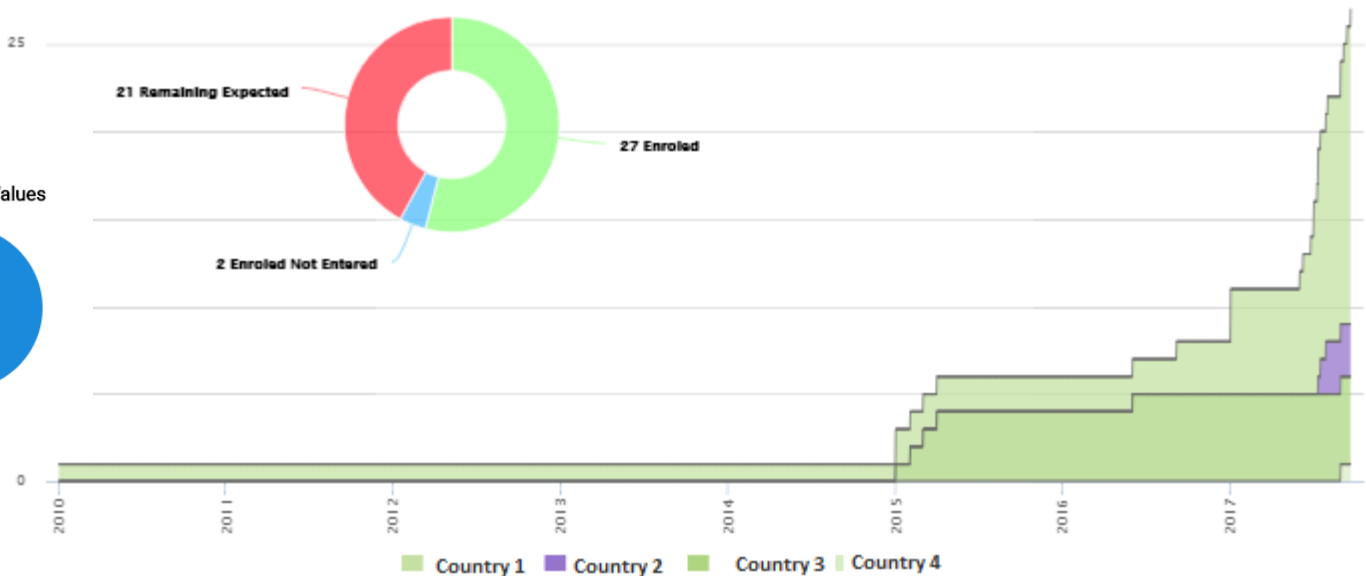
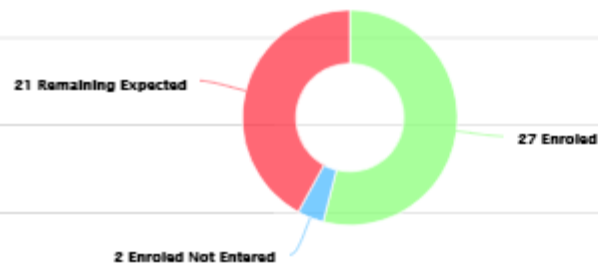
552

Records without Ranges



303

Out of Range Values



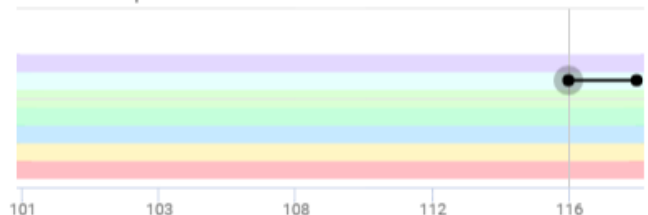
Designing visualizations requires a better understanding of clinical trial data and conduct as a whole than generally required by other functions

Disease Evaluation vs Overall Response

Cmed UAT2 - 0201MI00002

[Show Colour](#)

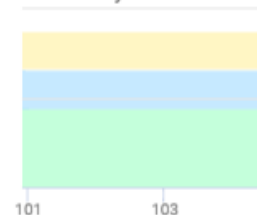
Overall Response Visit 116 - Complete response (CR)



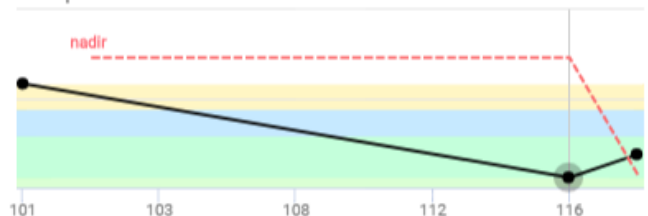
Count of Lesions Visit 117 - 2 lesion(s)



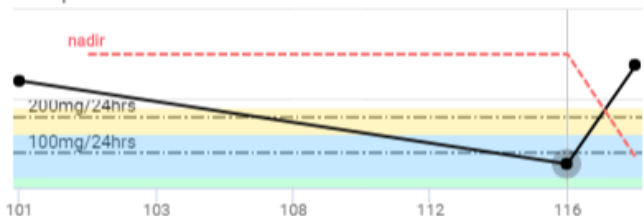
Plasmacytomas



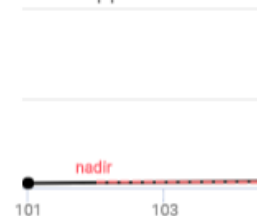
Paraprotein in Serum Visit 116 - 23 g/dL



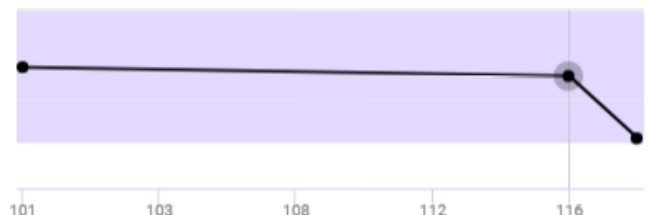
Paraprotein in Urine Visit 116 - 67 mg/24 hours



FLC Kappa - Lambda



FLC Ratio Visit 116 - 0.63



Calcium (corr)



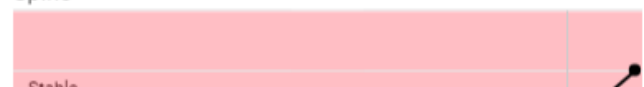
Plasma Cells in Bone M



Plasma Cells in Bone Marrow - Biopsy Visit 116 - 25

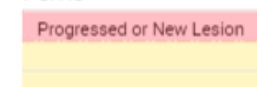


Spine

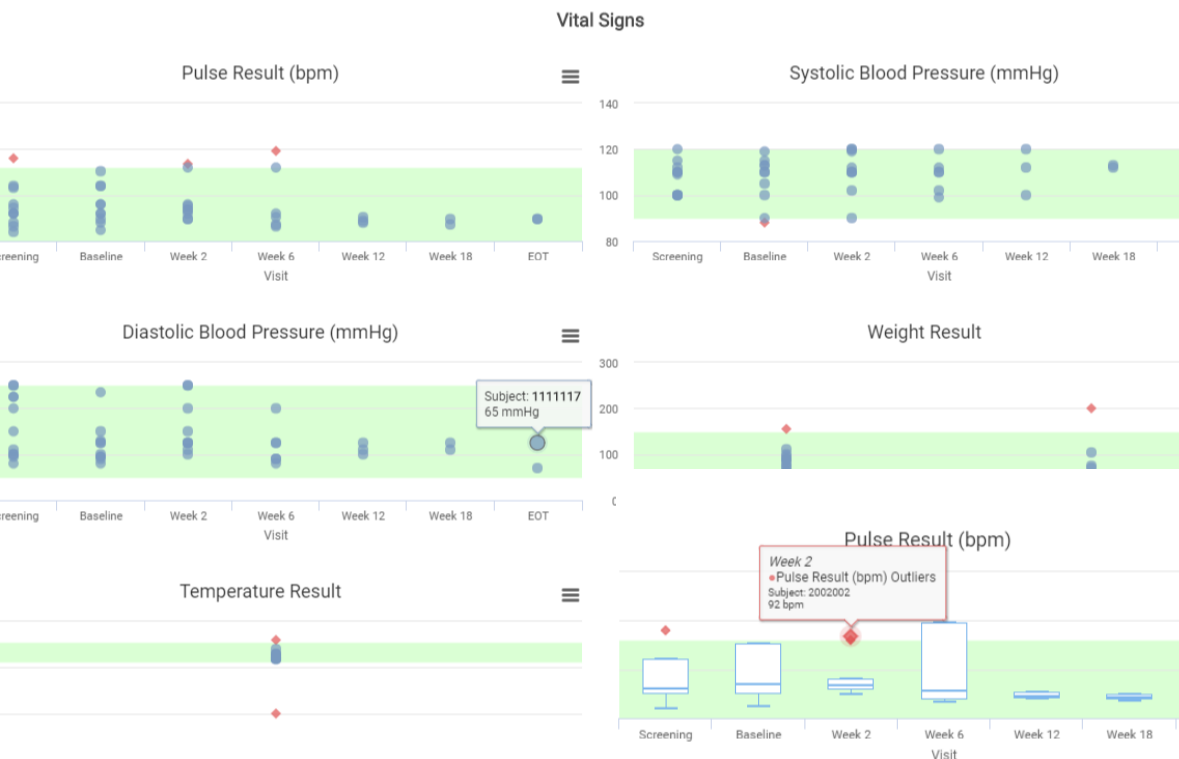


Visit 116 - Stable

Pelvis



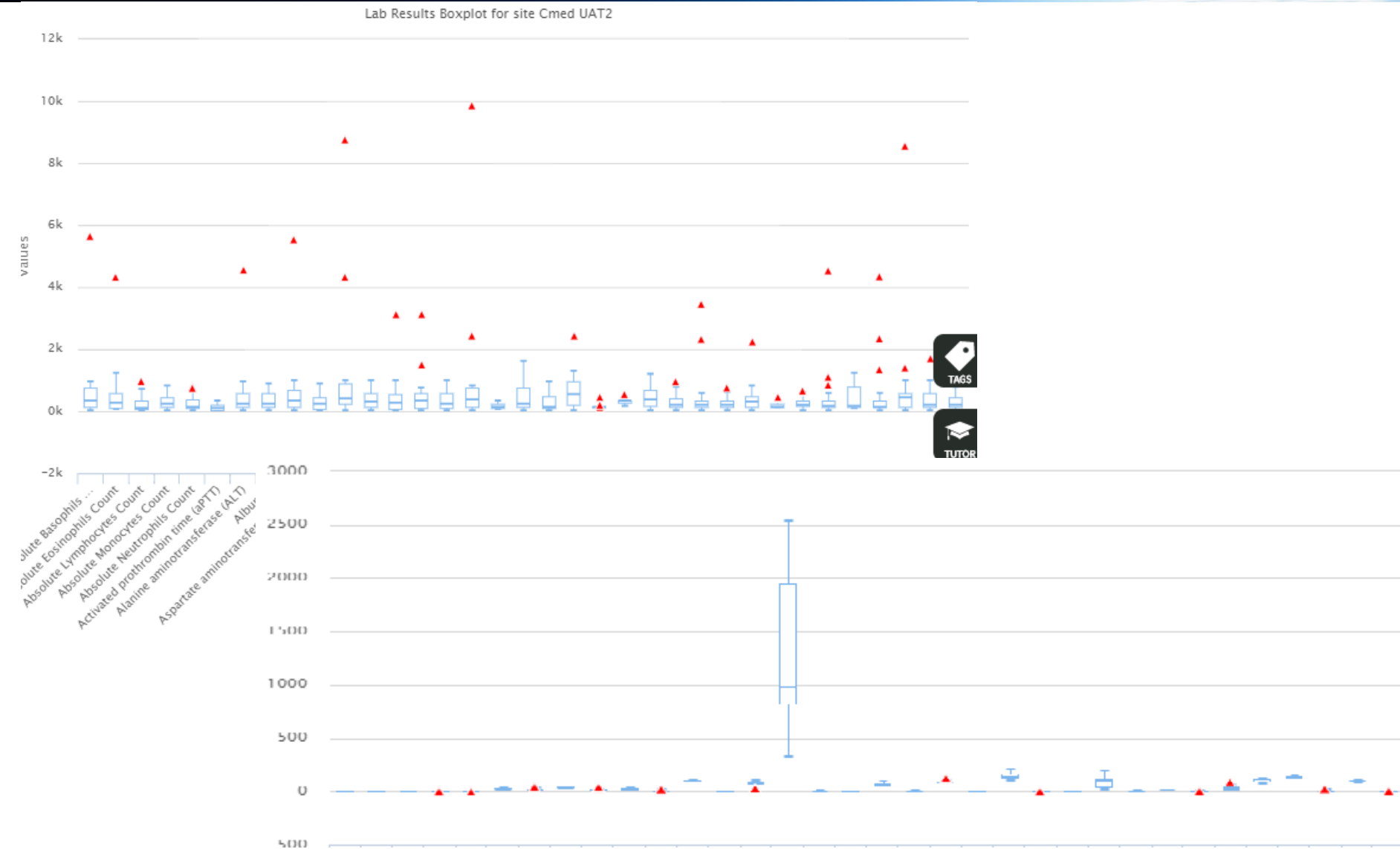
Understanding the specific needs and scope of each review is a major challenge in designing visualizations.



Boxplots vs scatterplots in identifying unusual data.



Lack of Clinical Data expertise can lead to programming of very efficient and organized but completely inefficient reports.



Switching between programming languages is very common in technology fields, however for a Clinical SAS programmer it is a rare opportunity

```
data hello;  
  text="Hello, World!";  
run;  
  
proc print data=hello;  
run;
```

```
#include <stdio.h>
```

```
int main() {  
  printf("Hello, World!");  
  return 0;}
```

```
myString <- "Hello, World!"  
print ( myString)
```

```
print("Hello, World!")
```

```
<html>  
<body>  
Hello  
world  
</body>  
</html>
```

```
public class HelloWorld {  
  
    public static void main(String[] args) {  
        System.out.println("Hello, World");  
    }  
}
```

While with TFL's our quality check steps focus on ensuring a particular delivery is correct, on Insights we need to ensure the output will be correct at any time it is ran

		Site displays chart by site: 1001name 1002name AUTOLUS Country displays per country: Spain UK
3	Confirm that the x axis show the dates while the y axis show the number of subjects	PASS X axis shows the visit 1 dates Y axis shows the number of subjects
4	Confirm that each category (country or site) has a different colour	PASS Countries/Sites have different colours 1001name 1002name AUTOLUS Spain UK
5	Confirm that hovering the mouse it will display the counts for each category (country or site)	FAIL Tooltip shows the count for selected category - however only one site is shown so where there is overlap Propose adding the following to the options dictionary (line 109) <pre>'tooltip': {'shared': True},</pre>
6	Confirm that if a new subject is enrolled, this is reflected in the stacked area/line.	PASS Stacked area / line charts updated with new patient
7	Confirm enrolling new subject without entering visit data increases	PASS Enrolled not entered count increased when new patient was added Remaining Expected count was decreased accordingly



My personal biggest challenge: Trial Installation Packages



One of the short term goals for the Data Programming team is to minimize the need of study specific work by creating a standard library of Insights.



inspiring **progress**

The Future: Recent advancements in AI and Big Data Analytics open the door to a whole new world where clinical trials analysis as we know it might become a thing of the past.



thank **you**

Experienced people and innovative
technology significantly enhancing the
delivery of clinical trials



inspiring **progress**

Cmed Group Ltd

Holmwood, Broadlands Business Campus
Langhurstwood Road
Horsham, RH12 4QP
United Kingdom

T: +44(0)1403 755 050

Cmed Inc

Maplewood Building
4620 Creekstone Drive, Suite 160
Durham, NC 27703
United States

T: +1 919 595 6900

Cmed Inc

485 Massachusetts Avenue
Cambridge
MA 02139-4018
United States

T: +1 857 998 4180

Cmed Inc

1001 Bayhill Dr.
Second Floor
San Bruno, CA 94066
United States

T: : +1 650 616 4291

Cmed SRL

Str. Coriolan Brediceanu, Nr. 10
City Business Centre Building A, Second Floor
Timișoara, 300011
România

T: +40 356 43 39 02

www.cmedresearch.com