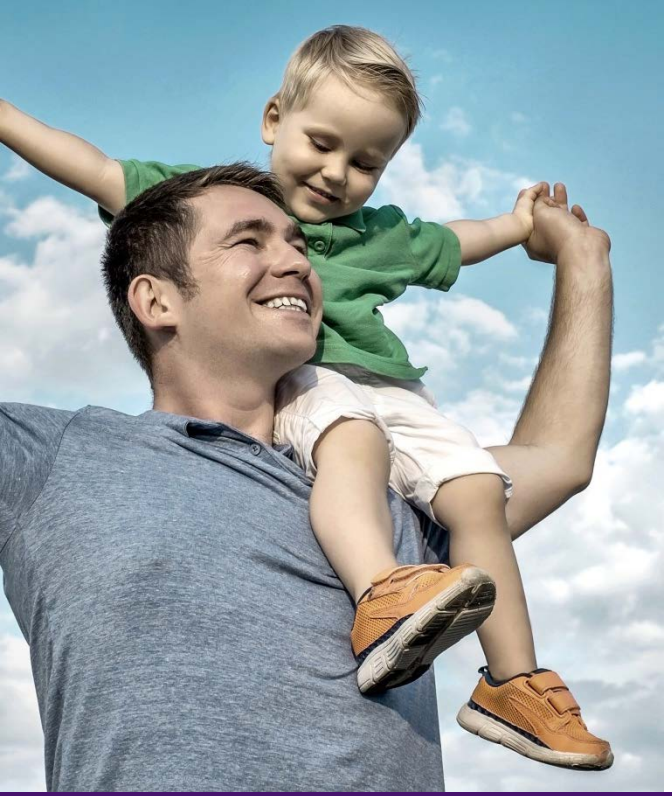


Data Visualization:

Analysing Data Using Dashboards and *Graphs*

Pooja Sharma

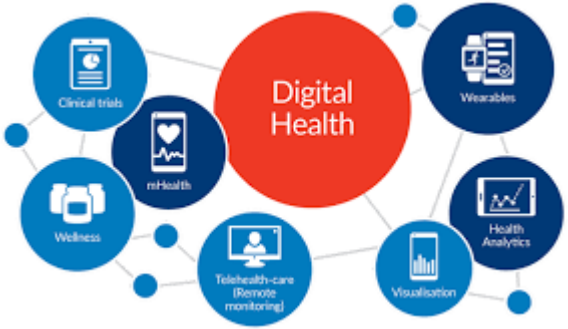
Necessity is mother of all inventions!!

- Increasing number of Data sources
  - Trial data in EDC
  - Third party (vendor data) data transfer
  - Operation data in CTMS
- Challenges
  - Data quality issues
  - Need of timely integration of all data
  - Operational challenges of orchestrating a cross-functional team and third party CRO.

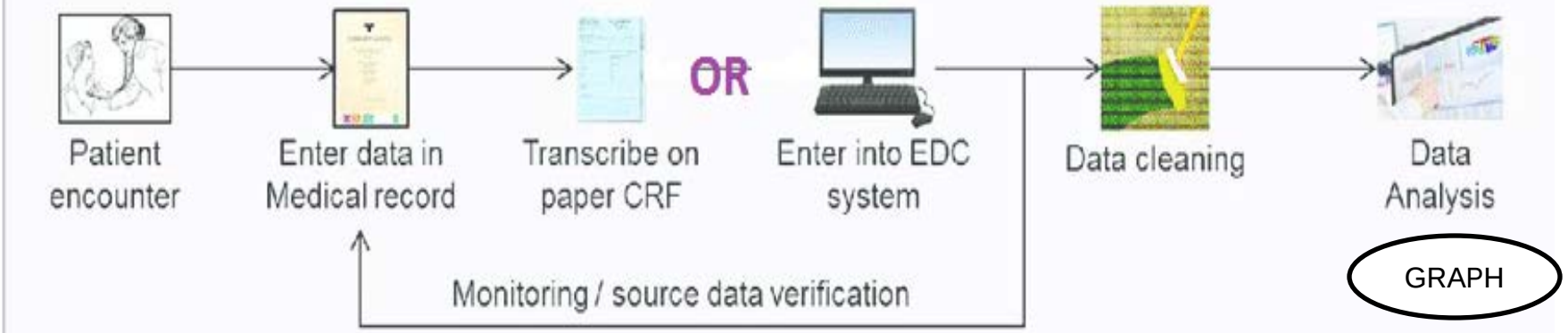
Data Visualization

- Identify data and process issues earlier
- Reduce the time to lock the database
- Improve resources Planning
- Facilitate better communication among projects team
- You need to get your audience 's attention.

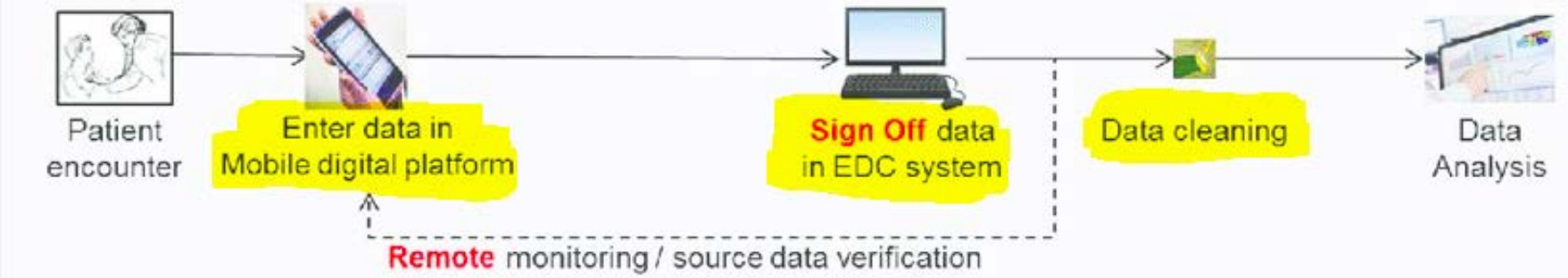
Data Visualization Tools



The typical approach to data collection in clinical trials



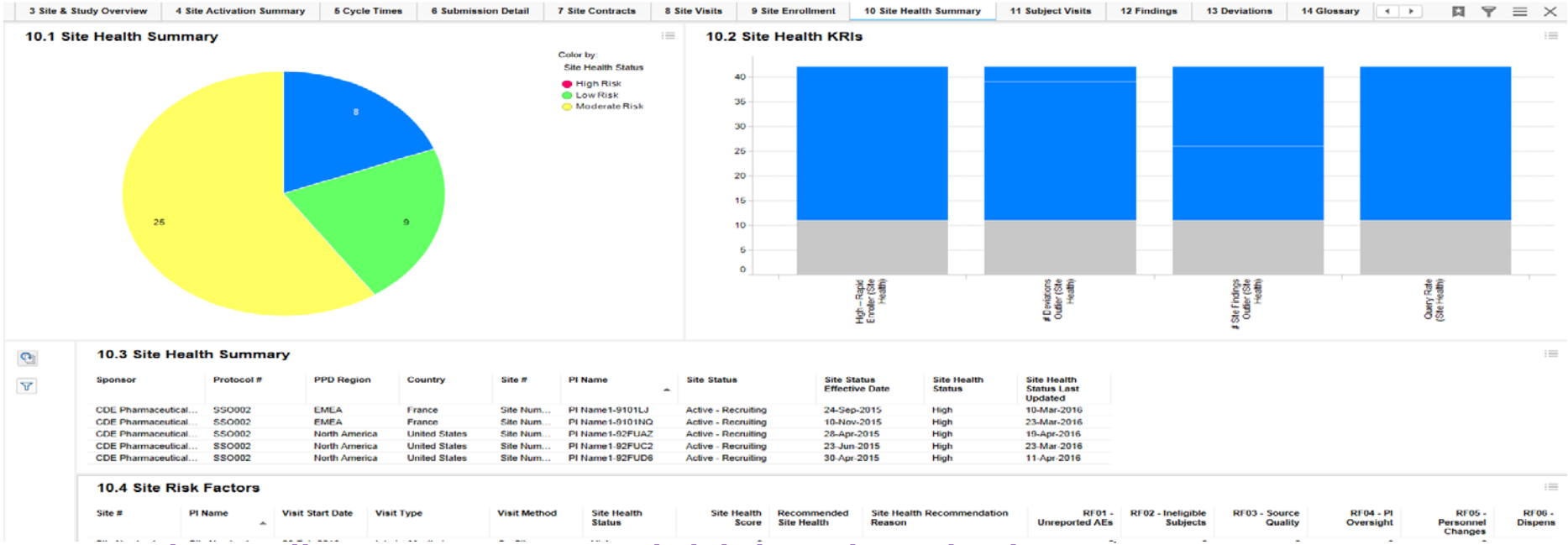
Mobile digital platform for clinical trial data collection



Dashboard: Dynamic Analytics

- Real time data: The Power of Now.
- Integration of Data from multiple sources: EDC, CTMS, Central Labs, IVRS, 3rd party vendors.
- Better transparency
- Dig Deeper: Discover more.
- Cross –functional visibility
- Focused searches to monitor patient safety, recruitment and site activity.

Risk-based Monitoring Visibility

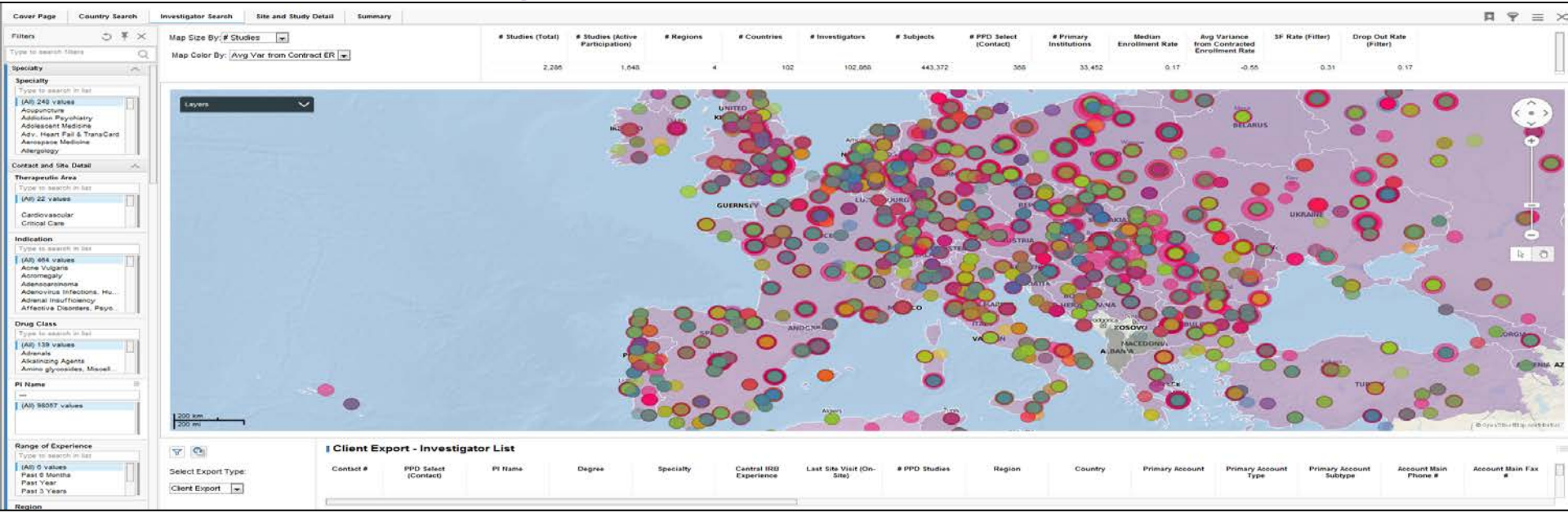


Purpose: Site quality management and risk-based monitoring

Users: RBM teams

+ **Health status / key risk indicators at study and site levels**
+ **Focuses CRA attention on site processes**

Proven Investigators: Global Site Selection



Purpose: Simplify end-user generation of potential sites

+ **Pivots greater than 60,000 investigators; Identifies strategic countries and sites**
+ **Objectively ranks investigators into tiers based upon past performance**

Users: Global site identification, clinical leadership, project management

Study Startup Visibility

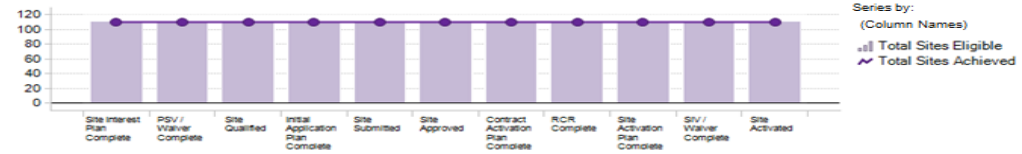
Country Status Summary

Country Status	Actual	TtD
Potential	0	2
Submitted	0	1
Revisions Requested	0	0
Approved	0	1
Active	1	1
Closed	0	0
Withdrawn	1	1

Key Activation Cycles

Cycle Times	Median Days
Final Protocol - Active	94.00
Potential - Active	95.50
Potential - Qualified	56.00
Qualified - Active	36.00
Submitted - Approved	1.00
Contract Plan Sent - Complete	39.00

Site Activation Critical Path Summary



Site Status Summary

Site Status	Actual	TtD
Potential	0	189
Eligible For Participation	0	127
Qualified	0	116
Submitted	0	114
Approved		
Eligible for Activation		
Active - Not Yet Recruiting		
Active - Recruiting		
Active - No Longer Recruiting		
Close-Out Ready		
Closed		
Disqualified		
Withdrawn		

Country Summary

Status	Country	Status Effective Date	Submission (Predicted)	Submission (Actual)	Approval (Predicted)	Approval (Actual)	First Site Active (Target)	First Site Active (Actual)	Last Site Active (Target)	Last Site Active (Actual)	Activation % to Weekly Target	Activation % to Total Target
Active	United States	20-Oct-2014	22-Aug-2014	22-Aug-2014	05-Sep-2014	03-Sep-2014	24-Oct-2014	20-Oct-2014	30-Jan-2015	27-Mar-2015	110/110 (100.00%)	110/110 (100.00%)
Withdrawn	Canada	07-Aug-2014										

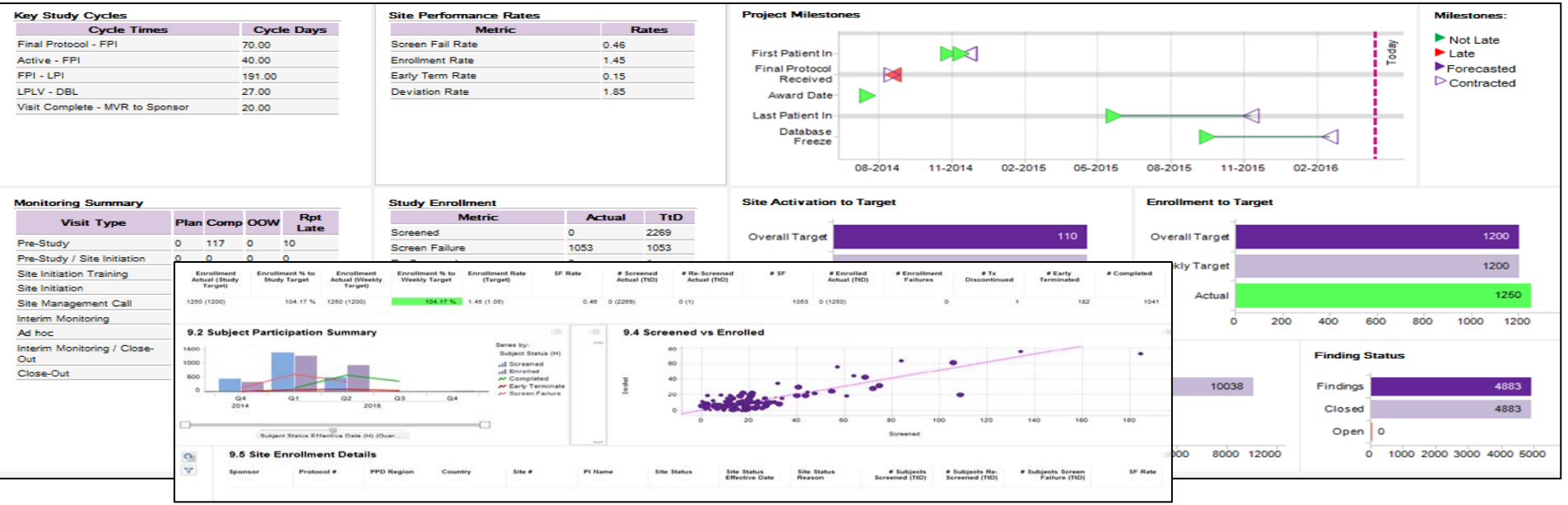
Country	Country Status	PI Name	Site #	Account	Site Status	Site Status Effective Date	PSV Status (Visit and MVR)	PSV Date	Submitted Date (H)	Approved Date (H)	Contract Activation Plan Complete Date	SIV Status (Visit and MVR)	SIV Date	Activation Plan % Docs Complete	Active - Not Yet Recruiting Date (H)	Ethics Type	Predicted Initial Submission Date	Predicted Approval Date	Predicted Activation Date
United States	Active	Adler...	097	Clinics...	Closed	27-Jan-2016	Complete	31-Oct-2014	14-Nov-2014	14-Nov-2014	02-Dec-2014	Complete	02-Dec-2014	100.00 %	08-Dec-2014	Central	31-Oct-2014	05-Nov-2014	10-Dec-2014
United States	Active	Bhand...	015	Delta...	Closed	15-Dec-2015	Complete	10-Sep-2014	10-Oct-2014	13-Oct-2014	14-Oct-2014	Complete	20-Nov-2014	100.00 %	21-Nov-2014	Central	10-Oct-2014	17-Oct-2014	10-Nov-2014
United States	Active	Clark...	059	Blue Ri...	Closed	14-Oct-2015	Complete	30-Sep-2014	02-Dec-2014	02-Dec-2014	11-Dec-2014	Complete	13-Jan-2015	100.00 %	13-Jan-2015	Central	03-Dec-2014	08-Dec-2014	16-Jan-2015
United States	Active	Clift...	010	Arkans...	Closed	07-Dec-2015	Complete	03-Sep-2014	11-Sep-2014	12-Sep-2014	22-Sep-2014	Complete	06-Nov-2014	100.00 %	06-Nov-2014	Central	12-Sep-2014	19-Sep-2014	06-Nov-2014
United States	Active	DeSa...	051	East V...	Closed	01-Feb-2016	Complete	23-Sep-2014	11-Sep-2014	15-Sep-2014	05-Nov-2014	Waived	17-Dec-2014	100.00 %	18-Nov-2014	Central	12-Sep-2014	19-Sep-2014	05-Dec-2014
United States	Active	Dulitz,...	037	Clinical...	Closed	08-Dec-2015	Complete	17-Sep-2014	12-Sep-2014	15-Sep-2014	23-Oct-2014	Complete	19-Nov-2014	100.00 %	19-Nov-2014	Central	12-Sep-2014	19-Sep-2014	17-Nov-2014
United States	Active	Fideh...	017	Highto...	Closed	13-Jan-2016	Complete	04-Sep-2014	07-Nov-2014	11-Nov-2014	03-Nov-2014	Waived	17-Dec-2014	100.00 %	18-Nov-2014	Central	07-Nov-2014	14-Nov-2014	15-Dec-2014
United States	Active	Fogel,...	060	Clinical...	Closed	29-Jan-2016	Complete	01-Oct-2014	24-Sep-2014	24-Sep-2014	07-Oct-2014	Complete	12-Nov-2014	100.00 %	12-Nov-2014	Central	26-Sep-2014	03-Oct-2014	19-Nov-2014
United States	Active	Fowler...	034	Carolin...	Closed	25-Nov-2015	Complete	17-Sep-2014	15-Sep-2014	22-Sep-2014	28-Oct-2014	Complete	25-Oct-2014	100.00 %	31-Oct-2014	Central	23-Sep-2014	30-Sep-2014	05-Nov-2014
United States	Active	Friede...	026	Great L...	Closed	14-Jan-2016	Complete	09-Sep-2014	17-Sep-2014	18-Sep-2014	07-Oct-2014	Complete	04-Nov-2014	100.00 %	06-Nov-2014	Central	17-Sep-2014	24-Sep-2014	23-Oct-2014
United States	Active	Gasic,...	032	Diagno...	Closed	21-Dec-2015	Complete	16-Sep-2014	24-Sep-2014	25-Sep-2014	30-Jan-2015	Complete	11-Feb-2015	100.00 %	11-Feb-2015	Central	24-Sep-2014	25-Sep-2014	13-Feb-2015
United States	Active	Gaspa...	058	Carolin...	Closed	18-Jan-2016	Complete	24-Sep-2014	15-Sep-2014	18-Sep-2014	28-Oct-2014	Complete	29-Oct-2014	100.00 %	31-Oct-2014	Central	18-Sep-2014	25-Sep-2014	31-Oct-2014
United States	Active	Goets...	039	Clinical...	Closed	15-Dec-2015	Complete	19-Sep-2014	12-Sep-2014	18-Sep-2014	27-Oct-2014	Waived	30-Mar-2015	100.00 %	30-Oct-2014	Central	12-Sep-2014	19-Sep-2014	04-Nov-2014
United States	Active	Griffin...	007	Lynn H...	Closed	03-Feb-2016	Complete	07-Oct-2014	03-Nov-2014	05-Nov-2014	29-Dec-2014	Complete (Train...	19-Dec-2014	100.00 %	06-Jan-2015	Central	03-Nov-2014	10-Nov-2014	09-Jan-2015
United States	Active	Hellst...	031	Nature...	Closed	13-Jan-2016	Complete	15-Sep-2014	08-Oct-2014	08-Oct-2014	11-Nov-2014	Complete	11-Nov-2014	100.00 %	12-Nov-2014	Central	10-Oct-2014	15-Oct-2014	12-Dec-2014
United States	Active	Zakko,...	077	Conne...	Closed	22-Dec-2015	Complete	14-Oct-2014	17-Nov-2014	18-Nov-2014	26-Jan-2015	Complete (Train...	07-Jan-2015	100.00 %	05-Feb-2015	Central	07-Nov-2014	19-Nov-2014	29-Feb-2015
United States	Active	Holme...	046	PMG R...	Closed	15-Jan-2016	Complete	22-Sep-2014	11-Sep-2014	12-Sep-2014	21-Oct-2014	Complete (Train...	19-Nov-2014	100.00 %	11-Nov-2014	Central	11-Sep-2014	19-Sep-2014	10-Nov-2014
United States	Active	Kraus...	012	ClinSe...	Closed	28-Jan-2016	Complete	28-Aug-2014	01-Oct-2014	03-Oct-2014	21-Oct-2014	Complete	03-Nov-2014	100.00 %	04-Nov-2014	Central	26-Sep-2014	03-Oct-2014	05-Nov-2014
United States	Active	Kuette...	014	Anahei...	Closed	01-Feb-2016	Complete	05-Sep-2014	15-Oct-2014	20-Oct-2014	07-Oct-2014	Complete	06-Nov-2014	100.00 %	06-Nov-2014	Central	17-Oct-2014	24-Oct-2014	05-Nov-2014

Purpose: Cross-functional management of study, country and site startup

+ **End-to-end visibility of startup process**
+ **Tracking / communication in a single system**
+ **Presents progress in context of contract**

Users: Study Start Up Team, Contracts and PM

Operations Visibility

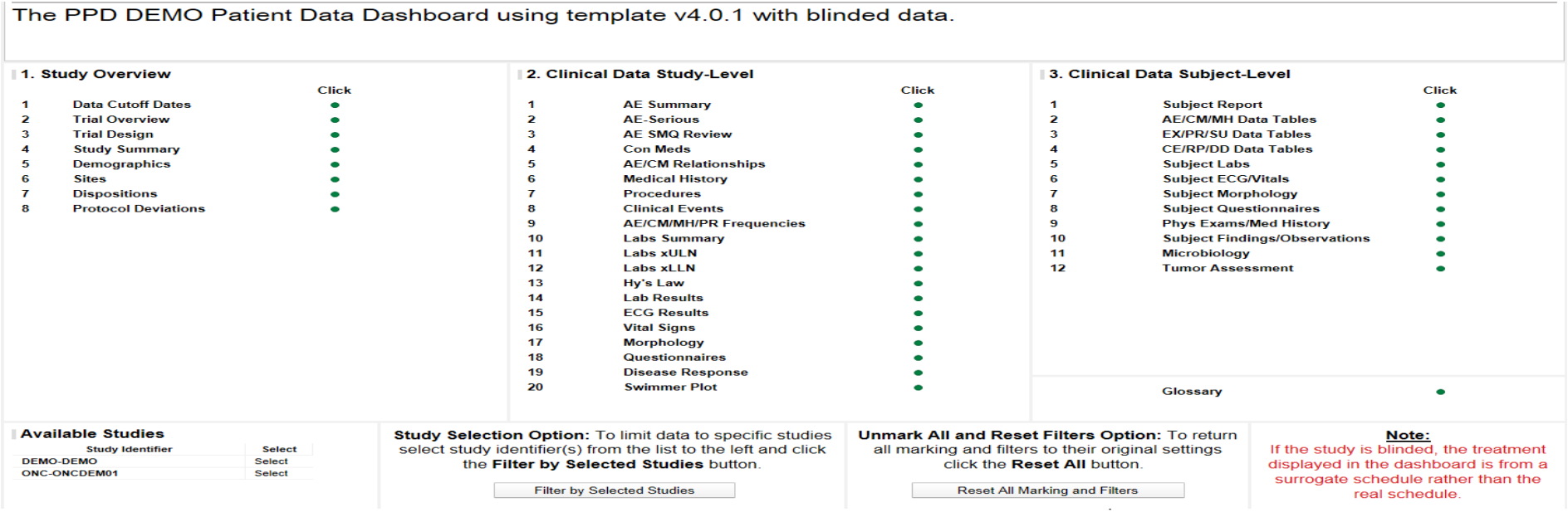


Purpose: Patient recruitment / monitoring

+ **Surfaces risk factors through key indicators / site assessments**
+ **Presents progress in context of contract; Highlights risk at all levels**

Users: All levels of clinical management

Accelerated Safety Data Access: Patient Data Dashboard


The PPD DEMO Patient Data Dashboard using template v4.0.1 with blinded data.

1. Study Overview

		Click
1	Data Cutoff Dates	
2	Trial Overview	
3	Trial Design	
4	Study Summary	
5	Demographics	
6	Sites	
7	Dispositions	
8	Protocol Deviations	

2. Clinical Data Study-Level

		Click
1	AE Summary	
2	AE-Serious	
3	AE SMQ Review	
4	Con Meds	
5	AE/CM Relationships	
6	Medical History	
7	Procedures	
8	Clinical Events	
9	AE/CM/MH/PR Frequencies	
10	Labs Summary	
11	Labs xULN	
12	Labs xLLN	
13	Hy's Law	
14	Lab Results	
15	ECG Results	
16	Vital Signs	
17	Morphology	
18	Questionnaires	
19	Disease Response	
20	Swimmer Plot	

3. Clinical Data Subject-Level

		Click
1	Subject Report	
2	AE/CM/MH Data Tables	
3	EX/PR/SU Data Tables	
4	CE/RP/DD Data Tables	
5	Subject Labs	
6	Subject ECG/Vitals	
7	Subject Morphology	
8	Subject Questionnaires	
9	Phys Exams/Med History	
10	Subject Findings/Observations	
11	Microbiology	
12	Tumor Assessment	

Glossary

Available Studies

Study Identifier	Select
DEMO-DEMO	Select
ONC-ONCDEM01	Select

Study Selection Option: To limit data to specific studies select study identifier(s) from the list to the left and click the **Filter by Selected Studies** button.

Filter by Selected Studies

Unmark All and Reset Filters Option: To return all marking and filters to their original settings click the **Reset All** button.

Reset All Marking and Filters

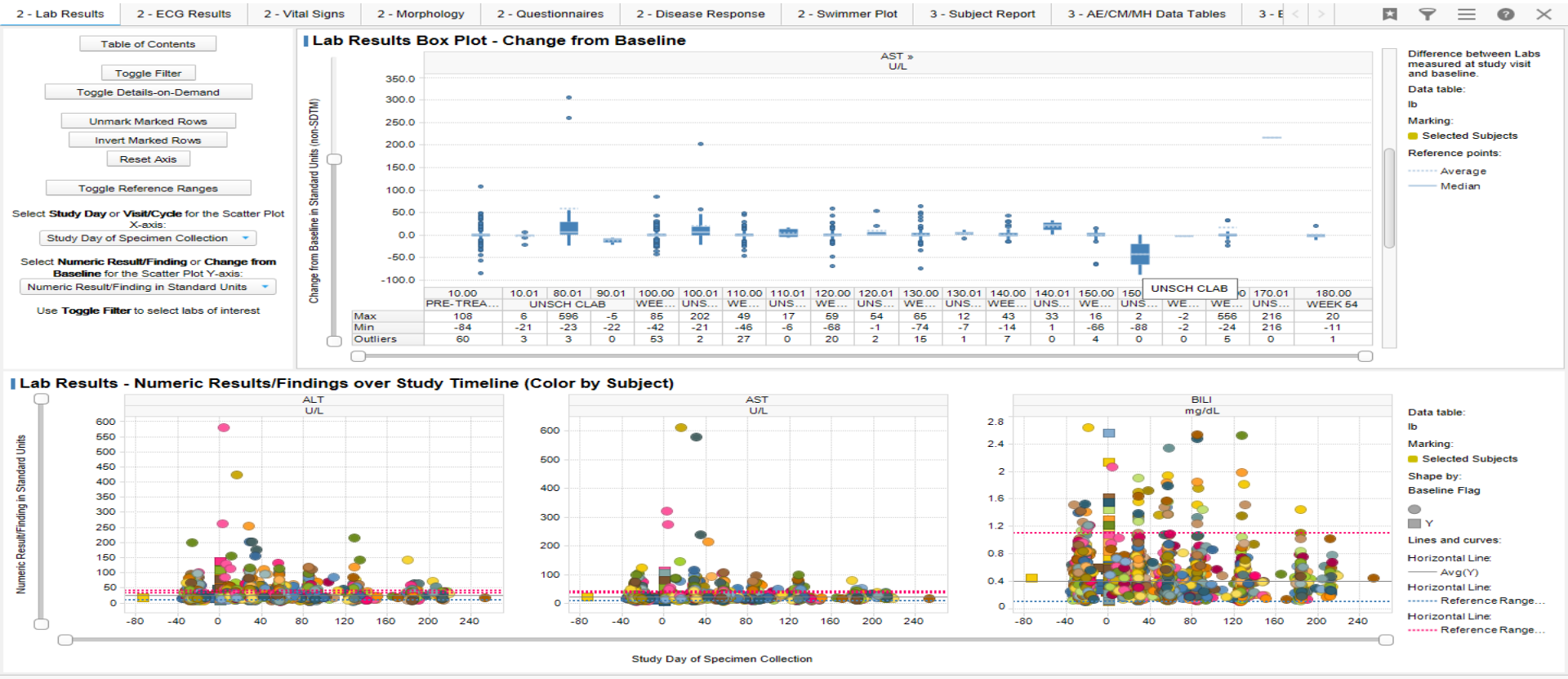
Note:
If the study is blinded, the treatment displayed in the dashboard is from a surrogate schedule rather than the real schedule.

Purpose: Consolidates / standardizes patient data from multiple sources

+ **Study-team access to safety data**
+ **Evaluation of safety profiles across a project, highlighting data trends; Data sourced from SDTM**

Users: data management, medical monitoring, biostatistics

PDD Dashboard (Lab Result)



	10.00 PRE-TREA...	10.01 UNSCH CLAB	80.01	90.01	100.00 WEE...	100.01 UNS...	110.00 WE...	110.01 UNS...	120.00 WE...	120.01 UNS...	130.00 WE...	130.01 UNS...	140.00 WEE...	140.01 UNS...	150.00 WE...	150.01 UNS...	WE...	WE...	170.01 UNS...	180.00 WEEK 54
Max	108	6	596	-5	85	202	49	17	59	54	65	12	43	33	16	2	-2	556	216	20
Min	-84	-21	-23	-22	-42	-21	-46	-6	-68	-1	-74	-7	-14	1	-66	-88	-2	-24	216	-11
Outliers	60	3	3	0	53	2	27	0	20	2	15	1	7	0	4	0	0	5	0	1

HELPING DELIVER LIFE-CHANGING THERAPIES

PPD®

PDD Dashboard (Lab Result)

3 - Subject Labs | 3 - Subject ECG/Vitals | 3 - Subject Morphology | 3 - Subject Questionnaires | 3 - Phys Exams/Med History | 3 - Subject Findings/Observations | 3 - Microbiology | 3 - Tumor As

Table of Contents

Toggle Filter

Toggle Details-on-Demand

Unmark Marked Rows

Invert Marked Rows

Reset Axis

Toggle Reference Ranges

Overlay selected **Subjects** or **Tests** or plot across multiple axes:

Overlay Subjects

Select **Study Day** or **Visit/Cycle** for the X-axis:

Visit/Cycle Number and Name

Select **Numeric Result/Finding** or **Change from Baseline** for the Y-axis:

Change from Baseline with Base Value

Use slider to set **Marker** size:

Use **Toggle Filter** to select labs of interest.

Note

To drill down into the data of particular subjects in section 3, first add those patients to the **Selected Subjects** marking to populate the **Subject List** table; then mark the row from this table corresponding to the subject of interest.

Subject List

Unique Subject Identifier	Age	Sex	Race	Country	Subject Reference Start
DEMO-001-0002	47...	M	BL...	USA	19/07/2012
DEMO-001-0004	57...	F	W...	USA	17/07/2012
DEMO-001-0006	45...	F	W...	USA	18/07/2012
DEMO-001-0030	44...	F	BL...	USA	27/08/2012
DEMO-003-0010	40...	F	W...	USA	18/12/2012
DEMO-005-0006	53...	F	W...	USA	22/08/2012
DEMO-011-0004	36...	F	W...	USA	30/07/2012

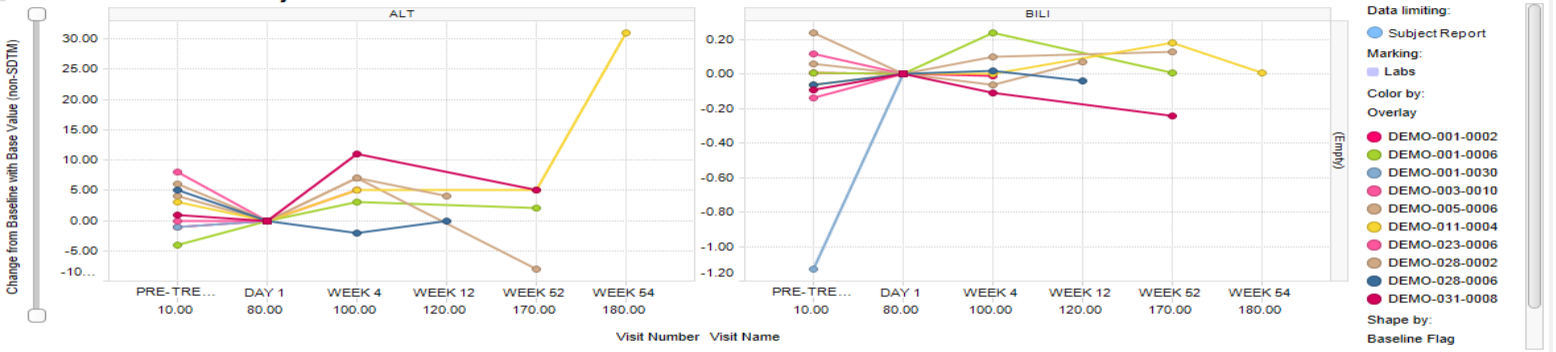
Data limiting: Selected Subjects
Data table: dm
Marking: Subject Report

Max xULN Lab Values - Selected Subjects

Unique Subject...	ALT(U/L)...	BILI(mg/dL)...	DILI Category for Hy's Law
DEMO-001-0002	0.43	0.24	Below CLC
DEMO-001-0006	0.79	0.69	Below CLC
DEMO-001-0030	1.06	2.33	Elevated BILI
DEMO-003-0010	0.48	0.33	Below CLC
DEMO-005-0006	1.12	0.36	Below CLC
DEMO-011-0004	1.24	0.31	Below CLC
DEMO-023-0006	0.24	0.51	Below CLC
DEMO-028-0002	1.27	0.28	Below CLC

Data limiting: Subject Report

Lab Results - Selected Subjects



Data limiting: Subject Report
Marking: Labs
Color by: Overlay
- DEMO-001-0002
- DEMO-001-0006
- DEMO-001-0030
- DEMO-003-0010
- DEMO-005-0006
- DEMO-011-0004
- DEMO-023-0006
- DEMO-028-0002
- DEMO-028-0006
- DEMO-031-0008

Shape by: Baseline Flag

Lab Results Details - Selected Subjects

Unique Subject Identifier	Date/Time of Specimen...	Lab Test or Examination Name	Lab Test or Examination Short Name	Numeric Result/Finding in Standard	Reference Range Lower Limit-Std Units	Reference Range Upper Limit-Std Units	Reference Range Indicator	Baseline Flag	Study Day of Specimen Collection
DEMO-003-0010	2012-11-16	Alanine Aminotransferase	ALT	16.00	10.00	33.00	NORMAL		-32.00
DEMO-003-0010	2012-11-16	Bilirubin	BILI	0.36	0.10	1.10	NORMAL		-32.00
DEMO-005-0006	2012-07-24	Alanine Aminotransferase	ALT	34.00	10.00	33.00	HIGH NORMAL		-29.00
DEMO-028-0002	2012-07-18	Alanine Aminotransferase	ALT	41.00	10.00	33.00	HIGH NORMAL		-29.00
DEMO-005-0006	2012-07-24	Bilirubin	BILI	0.40	0.10	1.10	NORMAL		-29.00
DEMO-028-0002	2012-07-18	Bilirubin	BILI	0.30	0.10	1.10	NORMAL		-29.00
DEMO-028-0006	2012-10-01	Alanine Aminotransferase	ALT	19.00	10.00	33.00	NORMAL		-28.00
DEMO-031-0008	2012-07-30	Alanine Aminotransferase	ALT	15.00	10.00	33.00	NORMAL		-28.00
DEMO-028-0006	2012-10-01	Bilirubin	BILI	0.33	0.10	1.10	NORMAL		-28.00
DEMO-031-0008	2012-07-30	Bilirubin	BILI	0.33	0.10	1.10	NORMAL		-28.00

Data limiting: Subject R...
Data table: lb
Marking: Labs

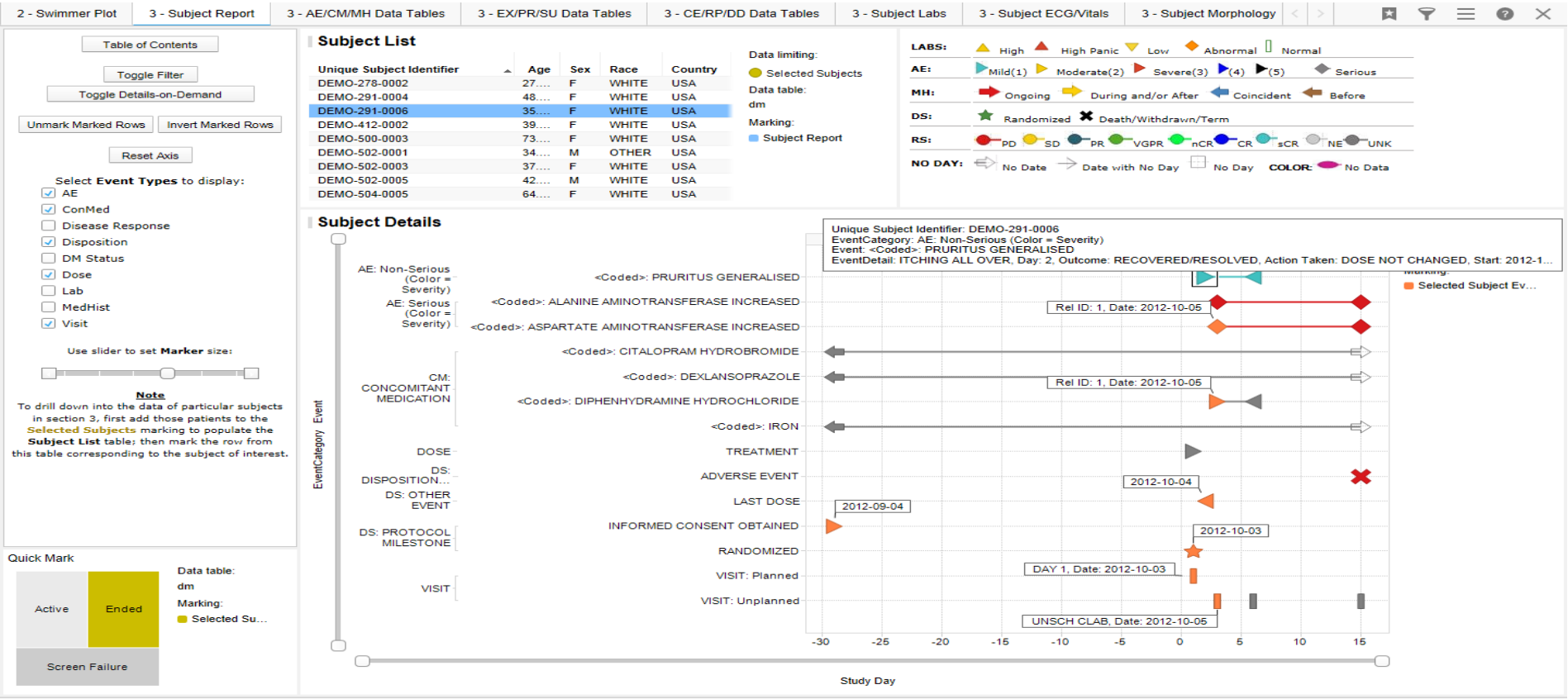
Ready | 1,447 of 1,588 rows | 10 marked | 45 columns | dm

100%

HELPING DELIVER LIFE-CHANGING THERAPIES

PPD

PDD Dashboard (Subject details)



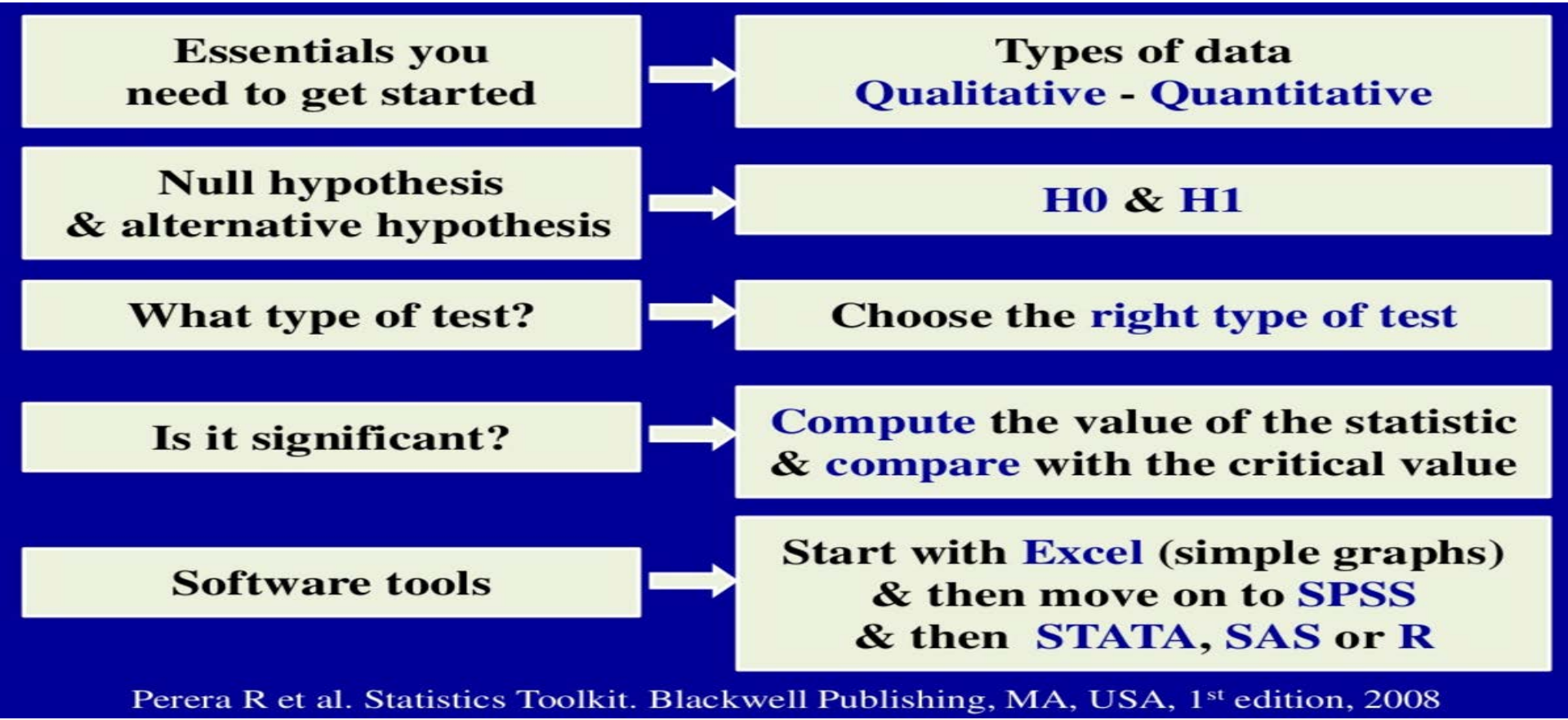
Dashboard: Benefits

- Rapid enrollment and site activation
- Early insight into trends / risks
- Detailed views of protocol deviations
- Risk-based monitoring plans
- On-going access to medical and safety trends
- Real-time visualization of data flow to drive project data currency

Statistical analysis coupled with effective data visualization key to efficient data review ….

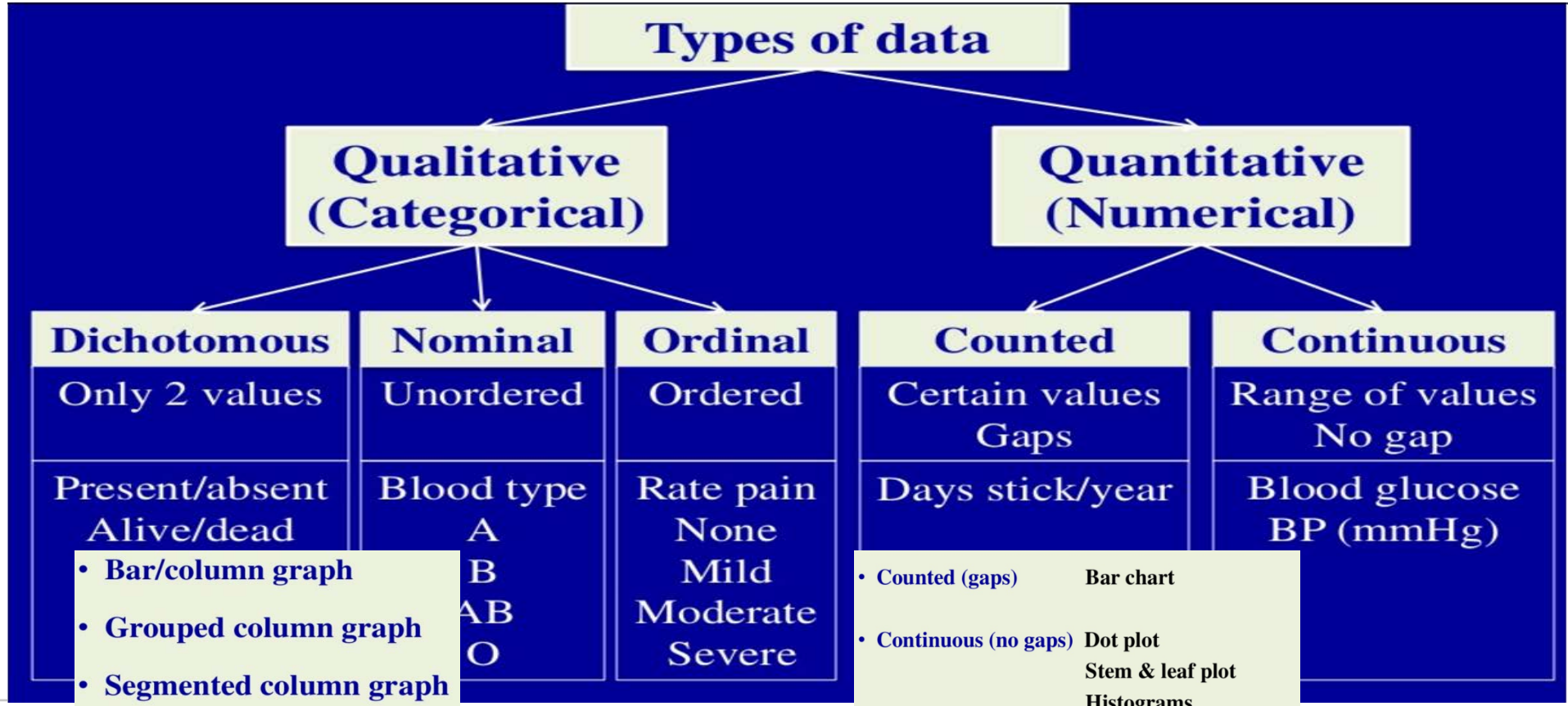
GRAPHS

Graph – How to start??



Perera R et al. Statistics Toolkit. Blackwell Publishing, MA, USA, 1st edition, 2008

Graph – Understand the Data



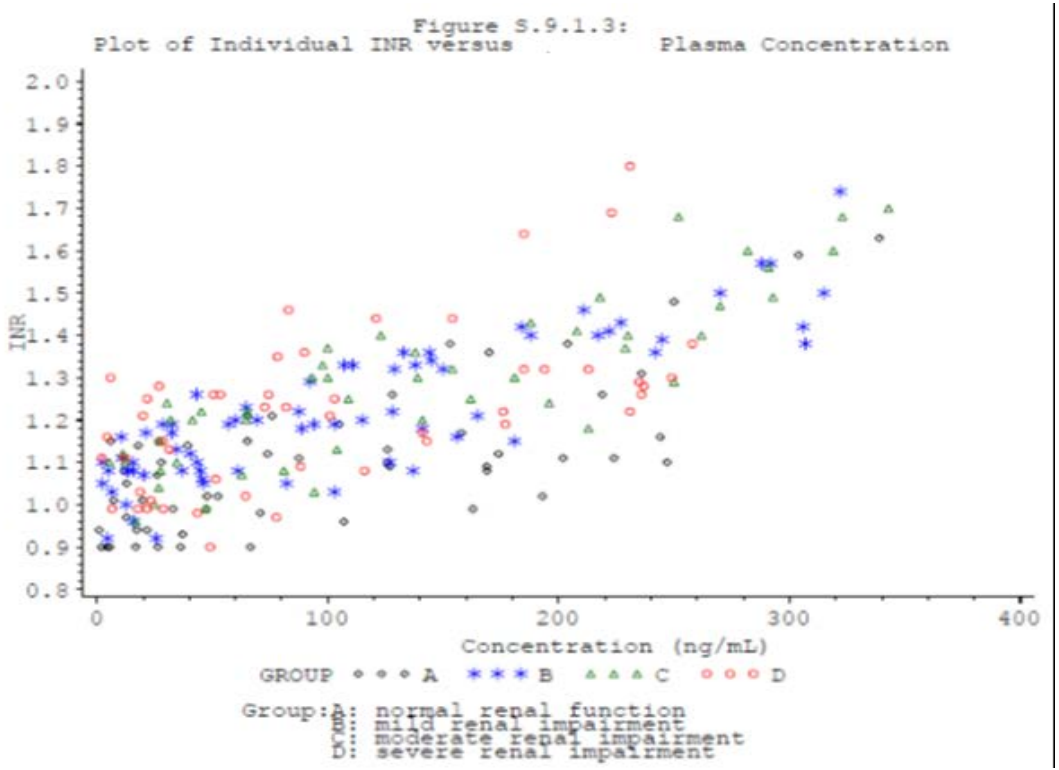
- Bar/column graph
- Grouped column graph
- Segmented column graph
- Pie graph

- Counted (gaps) Bar chart
- Continuous (no gaps) Dot plot
  Stem & leaf plot
  Histograms
  Box-whisker plot

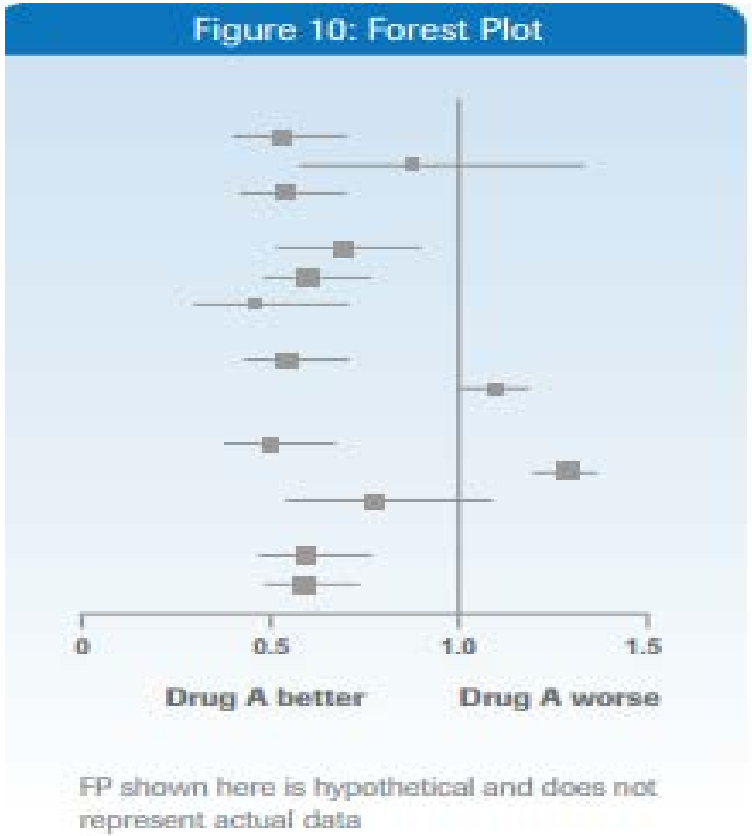
Some more simple/complex Graph: Scatter Plot

It provide a great way to visually look for relationships between two variables.

Example: Individual INR Vs Biomarker Parameter



Some more simple/complex Graph: Forest Plot

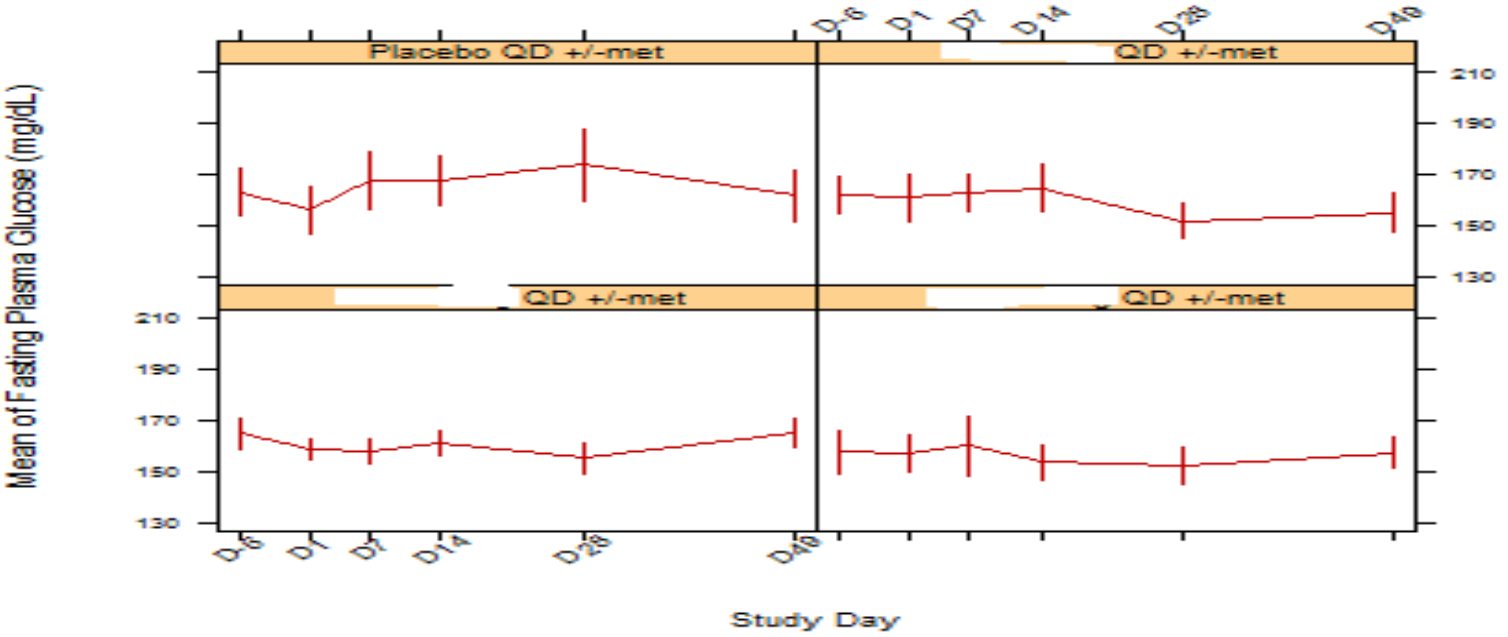


Forest Plot (FP) is a way to show and compare different groups of data.

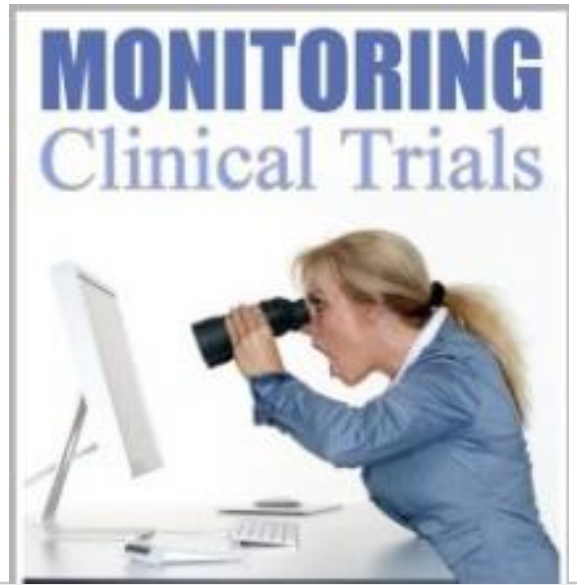
This example shows that Treatment A is more effective than treatment B in patient subgroups that fall to the left of the vertical line. However the subgroups that are on the right of the vertical line mean that in those patient subgroups treatment B is more effective than treatment A.

Some more simple/complex Graph: Mean Plot

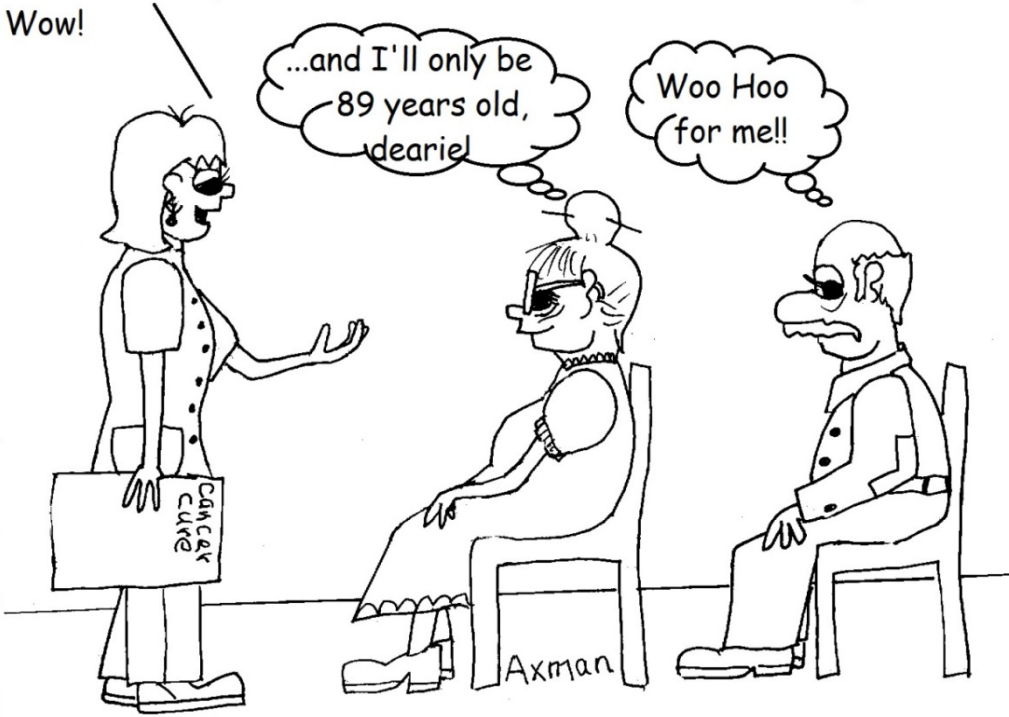
Parameters vs. Time by Treatment



PPD



Great news guys! This new drug has great potential to stop your cancer and help you lead a long and normal life! We're starting trials next year and (with luck) will be ready to submit it to the FDA in 7 to 9 years. Should be on the market in 10 to 12 years. Wow!



Time is not the same to different age groups--teens can't wait to get older and seniors want time to slow down...a lot!

EVERY **ENDING**
IS REALLY JUST A
NEW BEGINNING