The Right Tool for the Job: A Physician's Perspective

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Outline

- History of physician resistance to technology
- Social psychology and human behavior
- The right tool for the job
- Tips to increase physician acceptance of technology

Physician Resistance to Technology

- Computerized Physician Order Entry (CPOE)
  - Shifted traditional, paper-based coordination of care activities to an automated order entry process
  - Sought to eliminate illegible hand writing or confusing orders and minimize transcription errors
  - Moved the physician closer to the center of coordination of care activities
  - Integrated clinical decision support tools such as drug interaction alerts and clinical practice guidelines
  - Uptake by health systems was very slow despite the potential clinical advantages
  - Physician acceptance and adoption was a primary rate limiter

Physician Resistance to Technology

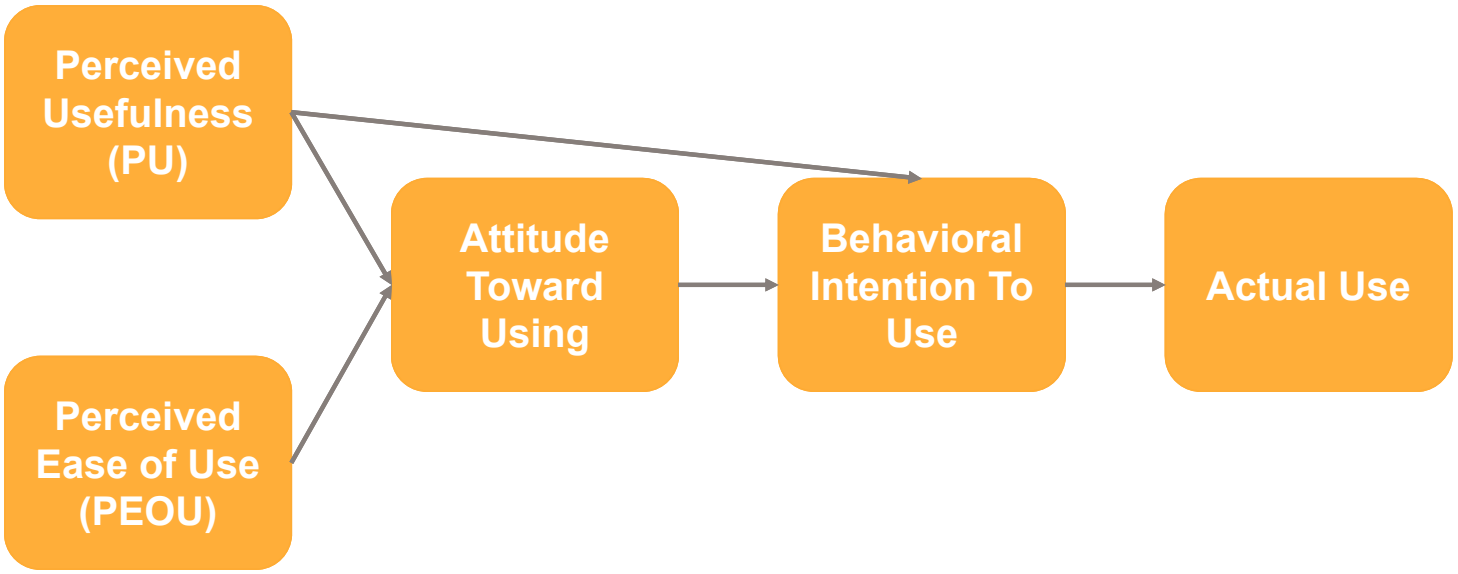
- Electronic Medical Record (EMR)
  - Considered essential for the efficient delivery of patient care and for the reduction in medical errors
  - Health Information Technology for Economic and Clinical Health Act (HITECH) outlines incentives, penalties, and eventual mandatory implementation
  - Medicare reimbursements reductions: 1% in 2015, 2% in 2016, 3% in 2017, 4% in 2018, and up to 95% depending on future adjustments
  - Published literature reveals initial low adoption/high failure rate for EMR implementation
  - Physician resistance again identified as one of the primary rate limiters in successful implementation

Social Psychology & Human Behavior

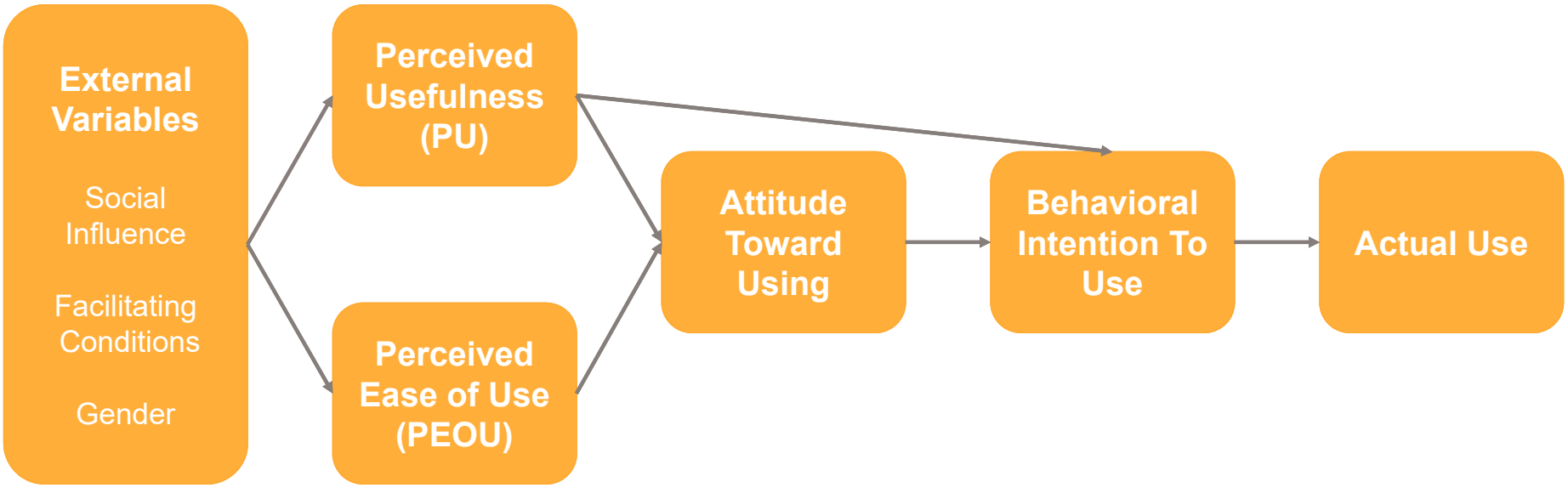
- Theory of Reasoned Action (TRA), Fishbein & Ajzen 1967
  - Intention to perform a certain behavior precedes the actual behavior
  - Intention is determined by *attitudes* and *subjective norms*
  - Once a person has formed an intention to act, he/she will be free to act without limitation

- Technology Acceptance Model (TAM), Davis 1989
  - An extension of the Theory of Reasoned Action
  - Intention is determined by Perceived Usefulness (PU) and Perceived Ease of Use (PEOU)
    - Perceived Usefulness (PU) is the degree to which a person believes that a using a particular system would enhance his/her job performance
    - Perceived Ease of Use (PEOU) is the degree to which a person believes that using a particular system would be free from effort

Technology Acceptance Model

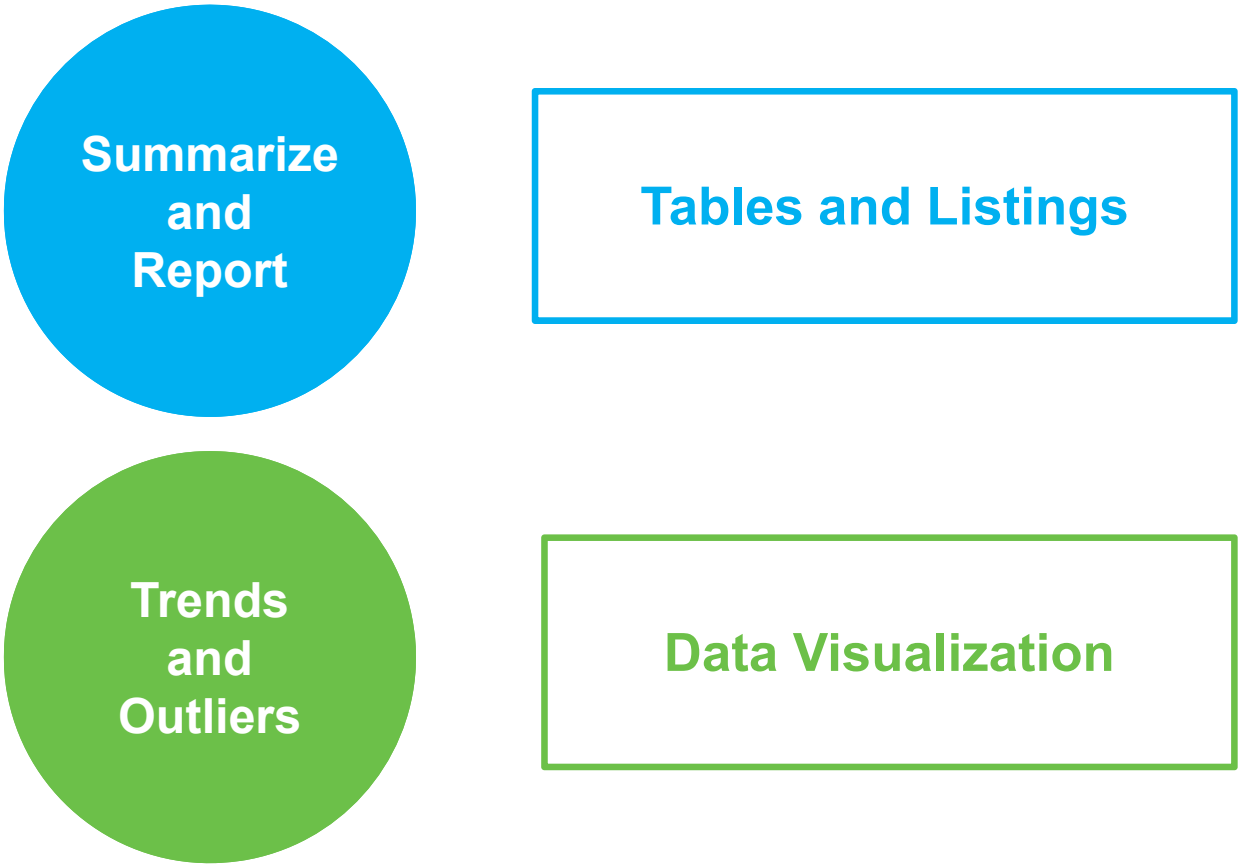


Technology Acceptance Model



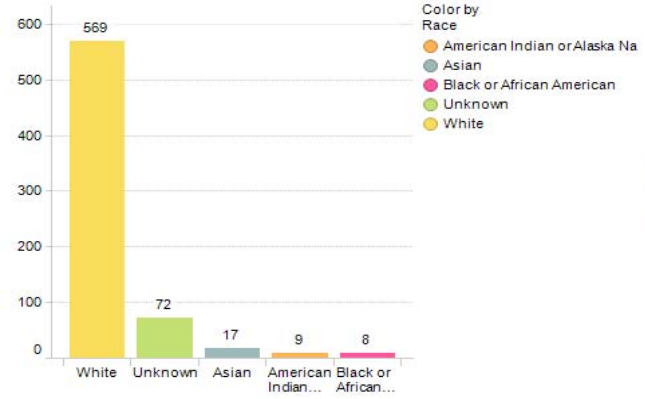
Perceived Usefulness (PU)

Physician Task or Deliverable

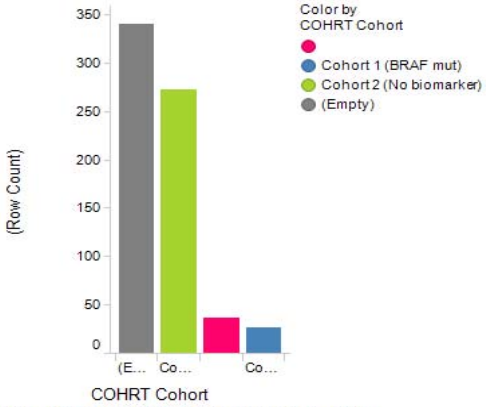


Demographics

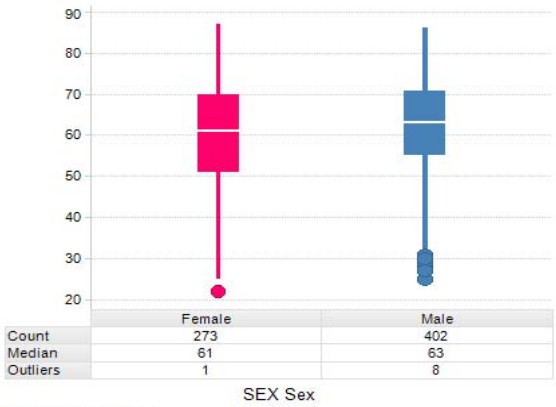
Number of Subjects by Race



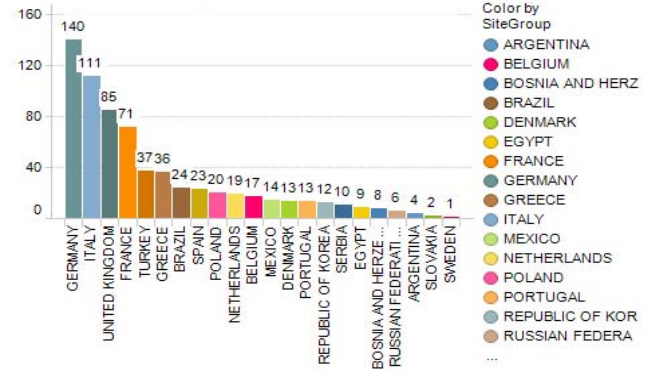
Number of Subjects by Cohort



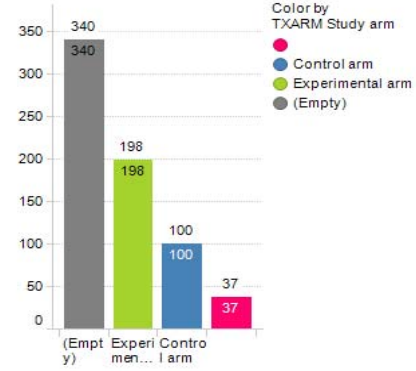
Age



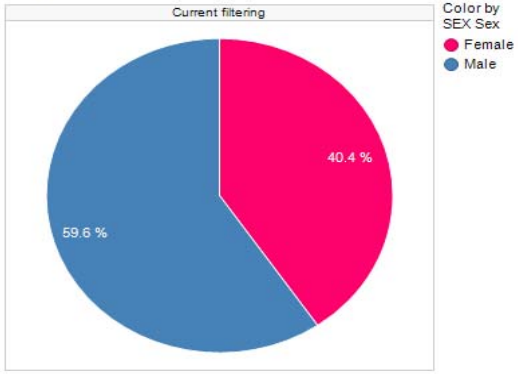
Number of Subjects by Country



Number of Subjects by Treatment Arm



Subjects by Sex



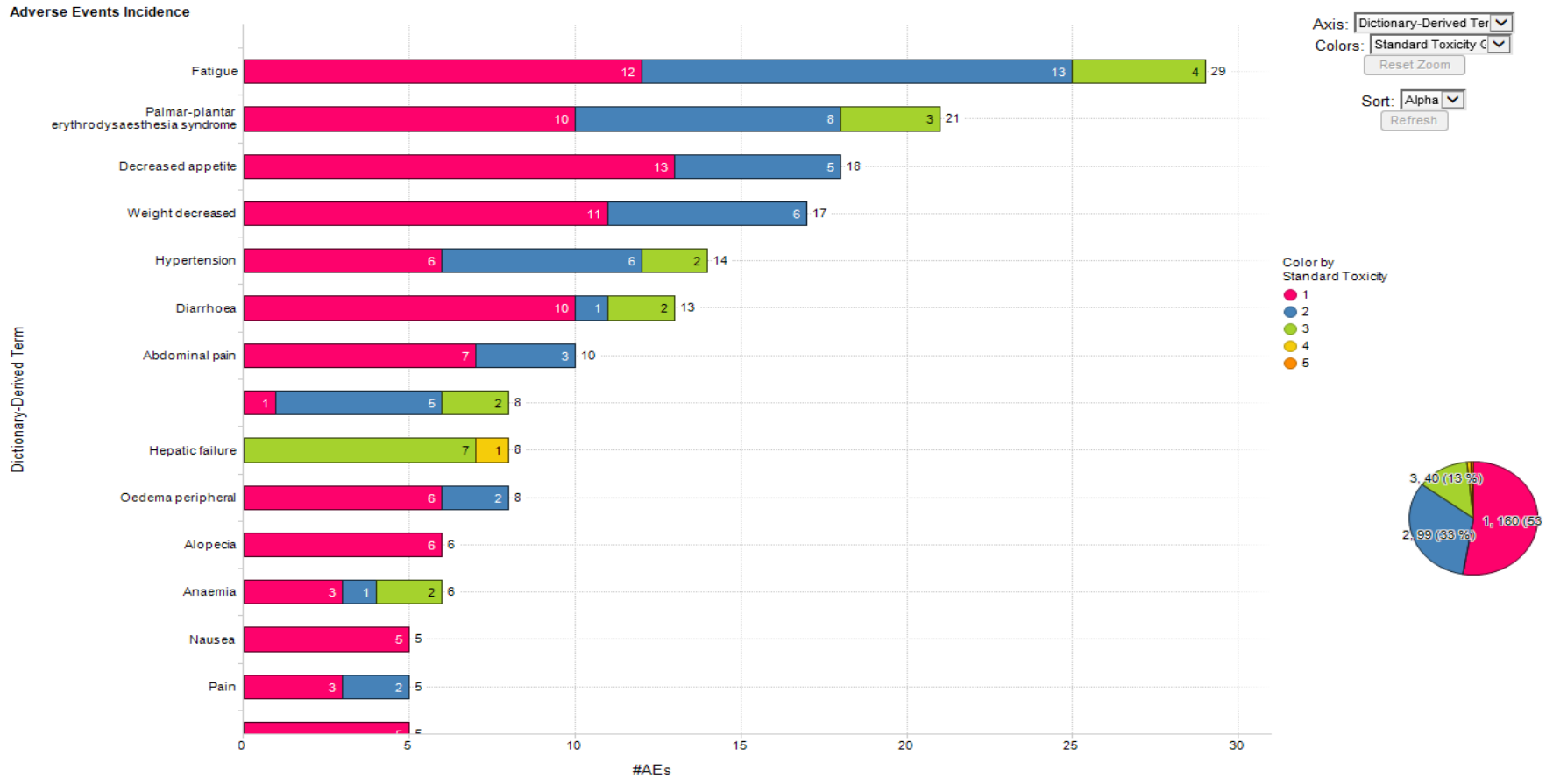
Summary of Patient Characteristics

Table 1. Baseline Characteristics of the 164 Participants.*

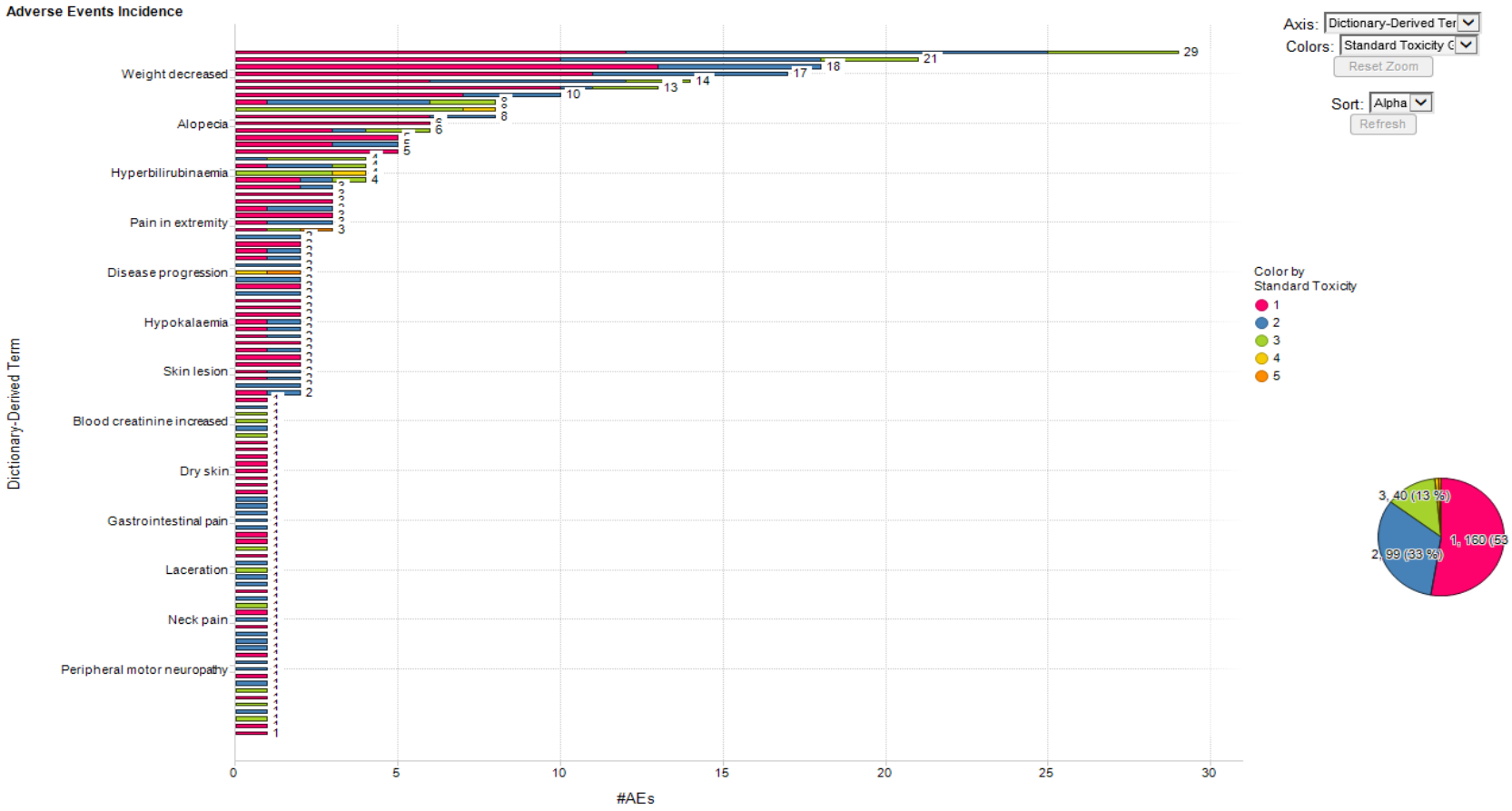
Characteristic	Control (N=81)	Hypertonic Saline (N=83)
Age (yr)	18.7±9.2	18.4±9.3
Female sex (%)	42	46
Body-mass index	20.1±3.6	19.9±3.9
FEV_1 (% of the predicted value)		
Mean	76±21	73±21
Range	40–127	40–132
FVC (% of the predicted value)		
Mean	88±18	85±18
Range	44–137	45–127
FEF_{25-75} (% of the predicted value)		
Mean	61±35	56±34
Range	10–151	11–155
Regular use of bronchodilator (%)	54	47
Regular use of rhDNase (%)	36	39
Regular use of antibiotic (%)	40	42
Regular use of inhaled tobramycin (%)	14	12
Regular use of inhaled colistin (%)	3	6
Regular use of oral antibiotic (%)	31	34
Regular use of azithromycin (%)	2	0
Regular use of physiotherapy (%)	70	71
Previous inhalation of a dose of hypertonic saline (%)	32	34
Sputum producers		
No. of patients	58	62
Pseudomonas aeruginosa in sputum (%)	78	79
Density (log CFU/g)	6.5±3.0	6.6±2.8
Staphylococcus aureus in sputum (%)	47	44
Density (log CFU/g)	2.1±2.8	1.8±2.5

Elkins MR. A controlled trial of long-term inhaled hypertonic saline in patients with cystic fibrosis. N Engl J Med 2006; 354:229-40

Adverse Events



Adverse Events



Adverse Events by SOC & PT

Table 14.3.1.2.1 Adverse Events by System Organ Class and Preferred Term
(All patients enrolled in Stage I for Colorectal Cancer Cohort)

System Organ class Preferred Term	Colorectal Cancer (N=7) n	(%)	Events
Number of Patients with at least one AE	6	(85.7)	66
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	6	(85.7)	14
RASH	3	(42.9)	5
HYPERKERATOSIS	3	(42.9)	3
PRURITUS	2	(28.6)	2
DRY SKIN	1	(14.3)	1
ERYTHEMA	1	(14.3)	1
MILIA	1	(14.3)	1
RASH MACULO-PAPULAR	1	(14.3)	1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	6	(85.7)	12
ASTHENIA	5	(71.4)	8
MUCOSAL INFLAMMATION	2	(28.6)	2
PYREXIA	1	(14.3)	2
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	5	(71.4)	10
ARTHRALGIA	5	(71.4)	9
MYALGIA	1	(14.3)	1
PENDING	3	(42.9)	8
PENDING	3	(42.9)	8

Produced: 31 July 2012, 15:49 - Results are based on data cut-off: 30 July 2012 Page 1 of 3
Source: 16.2.7.1.1
Notes: [1] All treatment emergent adverse events including Serious Adverse Events are included in summary statistics.
[2] If a patient has multiple occurrences of an AE, the patient is presented only once in the respective patient count.
[3] Table presents number and percentage of patients (n(%)) and number of events (Events).
[4] Percentages are based on the number of enrolled patients.

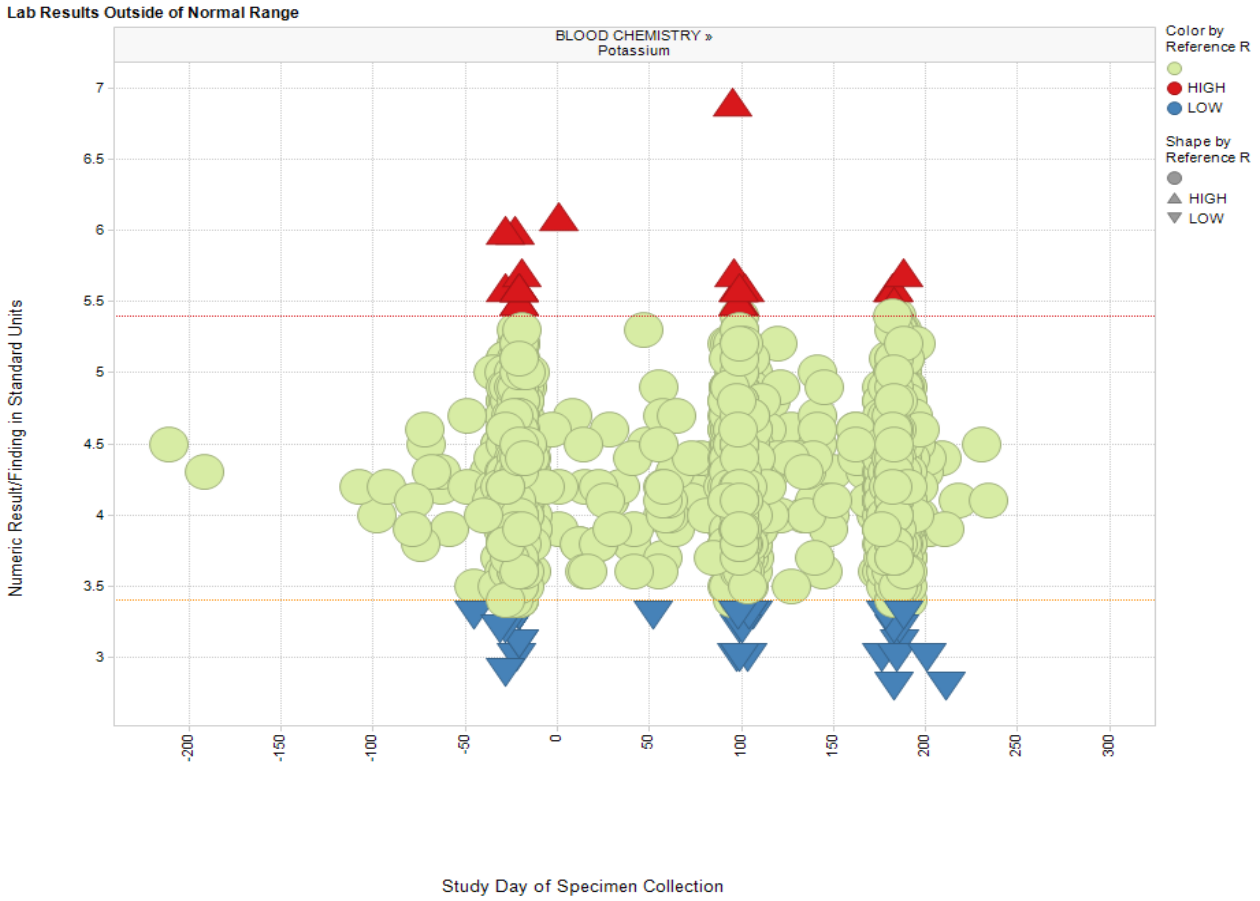
Outliers & Trends

Listing 16.2.7.3.2 Laboratory Results - Biochemistry
(All patients enrolled for Solid Tumors - Cohort 7)

Patient Number/ Stage 1/2	Gender/ Race/ Age	Date of First/ Last Study Medication[1]	Treatment Duration (Days)[2]	Parameter	Cycle/ Visit	Date/ Day of Collection	Result[3]	Unit	Normal Range
2442100004 No/No	Female/ White/ 77	23JUL2012/ 10SEP2012	50	Magnesium	Week 8 (Day 44-71)	12SEP2012/52		mg/dL	1.8 - 2.9
					Week 8 (Day 44-71)	26SEP2012/66	2.2	mg/dL	1.8 - 2.9
				Potassium	Baseline (Day -28 to 1)	19JUL2012/-4	4.6	mEq/L	3.5 - 5
					Week 2 (Day 2-22)	06AUG2012/15	4.6	mEq/L	3.5 - 5
					Week 4 (Day 23-43)	21AUG2012/30	3.5	mEq/L	3.5 - 5
					Week 4 (Day 23-43)	24AUG2012/33	3.5	mEq/L	3.5 - 5
					Week 4 (Day 23-43)	27AUG2012/36	4.1	mEq/L	3.5 - 5
					Week 4 (Day 23-43)	31AUG2012/40	4	mEq/L	3.5 - 5
					Week 4 (Day 23-43)	01SEP2012/41	3.5	mEq/L	3.5 - 5
					Week 4 (Day 23-43)	02SEP2012/42	3.3 (L*)	mEq/L	3.5 - 5
					Week 4 (Day 23-43)	03SEP2012/43	3.7	mEq/L	3.5 - 5
					Week 8 (Day 44-71)	10SEP2012/50	3.4 (L*)	mEq/L	3.5 - 5
					Week 8 (Day 44-71)	12SEP2012/52	3.8	mEq/L	3.5 - 5
					Week 8 (Day 44-71)	26SEP2012/66	4.9	mEq/L	3.5 - 5
				Sodium	Baseline (Day -28 to 1)	19JUL2012/-4	140	mEq/L	135 - 147
					Week 2 (Day 2-22)	06AUG2012/15	139	mEq/L	135 - 147
					Week 4 (Day 23-43)	21AUG2012/30	134 (L)	mEq/L	135 - 147
					Week 4 (Day 23-43)	24AUG2012/33	137	mEq/L	135 - 147
					Week 4 (Day 23-43)	27AUG2012/36	137	mEq/L	135 - 147
					Week 4 (Day 23-43)	31AUG2012/40	137	mEq/L	135 - 147
					Week 4 (Day 23-43)	01SEP2012/41	140	mEq/L	135 - 147
					Week 4 (Day 23-43)	02SEP2012/42	139	mEq/L	135 - 147
					Week 4 (Day 23-43)	03SEP2012/43	135	mEq/L	135 - 147
					Week 8 (Day 44-71)	10SEP2012/50	136	mEq/L	135 - 147
					Week 8 (Day 44-71)	12SEP2012/52	138	mEq/L	135 - 147
					Week 8 (Day 44-71)	26SEP2012/66	140	mEq/L	135 - 147
				Total bilirubin (dir./ind.)	Baseline (Day -28 to 1)	19JUL2012/-4	0.5	mg/dL	0 - 1

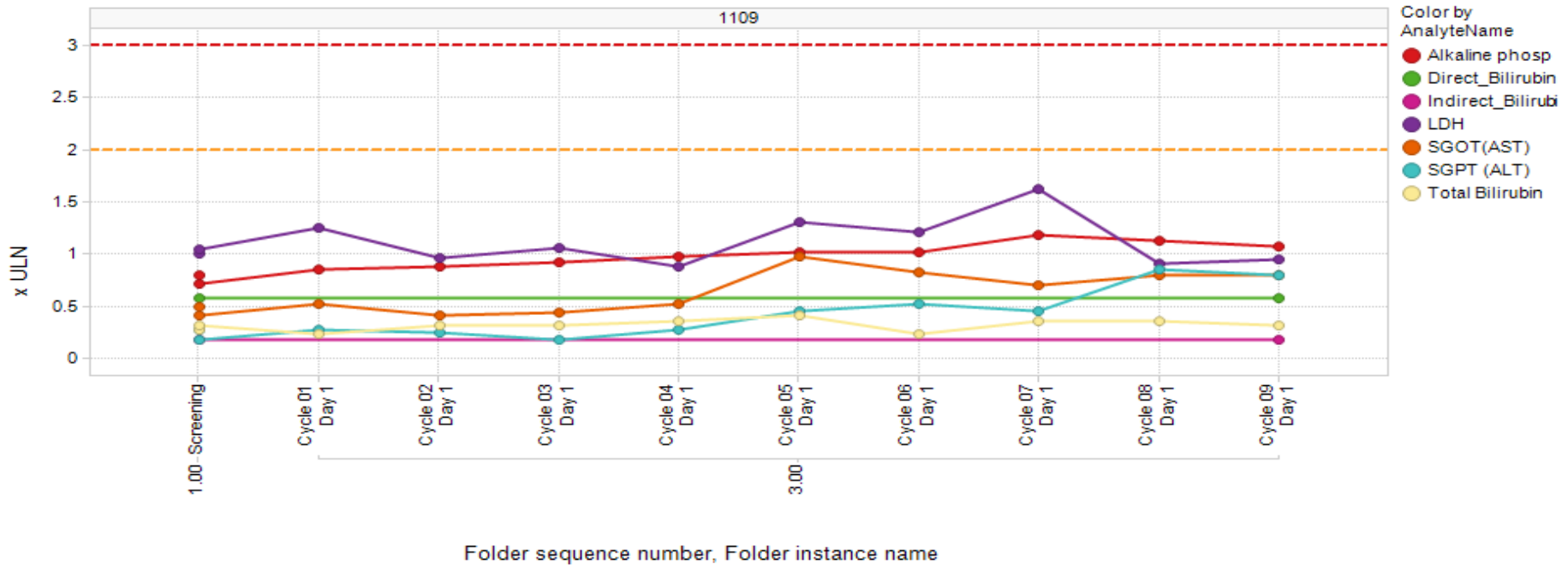
Produced: 4 July 2016, 15:49 - Results are based on data cut-off: 17 June 2016 Page 7 of 364
Source Data: LAB.sas7bdat - 04JUL2016 12:06, DDPATINF.sas7bdat - 04JUL2016 14:23
Notes: [1] Date of Last study medication refers to date registered in 'End of treatment' module; if date missing, substituted by cut-off date and marked with *.
[2] Treatment duration refers to days from date of first to date of last administration of study treatment or date of data cut-off, whatever comes first.
[3] H, L indicate results above and below Reference Range respectively; * indicates a Clinically Significant result.

Population Outliers



Patient Trend

Labs x ULN



Change from Baseline

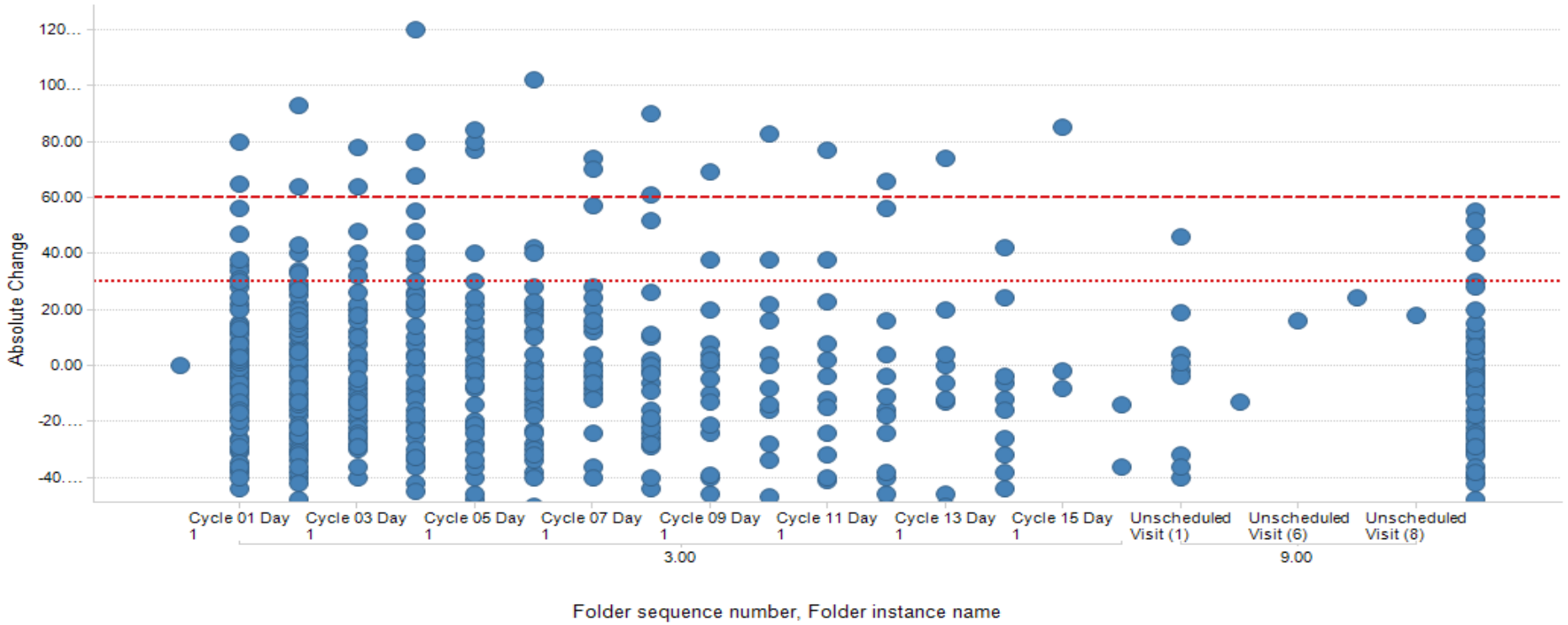
Listing 16.2.7.5 ECG Results
(All patients enrolled for Solid Tumors - Cohort 7)

Patient Number/ Stage 1/2	Gender/ Race/ Age	Date of First/ Last Study Medication[1]	Treatment Duration (Days)[2]	Cycle/ Visit	Date:Time/ Day of Assessment	Heart Rate (bpm)	PR Interval (msec)	QRS Interval (msec)	QT Interval (msec)	QTc Interval (msec) [3]	QTcF Interval (msec) [4]	QTc Correction Method	Findings[5] If CS: Specify
2442130001/ Yes/Yes	Female/ White/ 67	20NOV2012/ 17JUN2016*	1306	Week 8 (Day 44-71)	15JAN2013:8:48 /57	63	160	92	422	431	429	QTcB	Abnormal, NCS
				Week 12 (Day 72-99)	12FEB2013:9:44 /85	67	168	90	414	437	430	QTcB	Abnormal, NCS
				Week 16 (Day 100-127)	11MAR2013:08:41 /112	66	168	90	396	415	409	QTcB	Abnormal, NCS
				Week 28 (Day 184-211)	04JUN2013:11:04 /197	59	166	90	442	437	440	QTcB	Abnormal, NCS
				Week 32 (Day 212-239)	02JUL2013:08:01 /225	62	188	92	418	424	423	QTcB	Abnormal, NCS
				Week 40 (Day 268-295)	28AUG2013:09:19 /282	63	174	92	434	444	441	QTcB	Abnormal, NCS
				Week 44 (Day 296-323)	25SEP2013:08:46 /310	62	178	92	434	440	439	QTcB	Abnormal, NCS
				Week 48 (Day 324-351)	23OCT2013:10:02 /338	58	176	90	448	439	443	QTcB	Abnormal, NCS
				Week 68 (Day 464-491)	13MAR2014:08:13 /479	65	174	94	414	430	425	QTcB	Abnormal, NCS
				Week 88 (Day 604-631)	30JUL2014:08:25 /618	59	186	90	428	423	426	QTcB	Abnormal, NCS
				Week 96 (Day 660-687)	24SEP2014:07:55 /674	67	182	94	404	426	419	QTcB	Abnormal, NCS
				Week 100 (Day 688-715)	22OCT2014:08:08 /702	63	164	92	420	429	427	QTcB	Abnormal, NCS

Produced: 4 July 2016, 15:49 - Results are based on data cut-off: 17 June 2016 Page 2 of 33
Source Data: ECG.sas7bdat - 04JUL2016 12:03, DDPATINF.sas7bdat - 04JUL2016 14:23
Notes: [1] Date of Last study medication refers to date registered in 'End of treatment' module; if date missing, substituted by cut-off date and marked with *.
[2] Treatment duration refers to days from date of first to date of last administration of study treatment or date of data cut-off, whatever comes first.
[3] QTc interval as of database, derived according to method as of column "QTc Correction Method"
[4] QTcF = corrected QC interval, derived from QT and RR values, using Fridericia's formula
[5] Finding: Abnormal, CS=Abnormal and clinically significant; Abnormal, NCS=Abnormal but not clinically significant.

Change from Baseline

QT Box Plot - Change from Baseline



Perceived Ease of Use (PEOU)

Accessibility

Platform

- Portal
- Web based
- Desktop

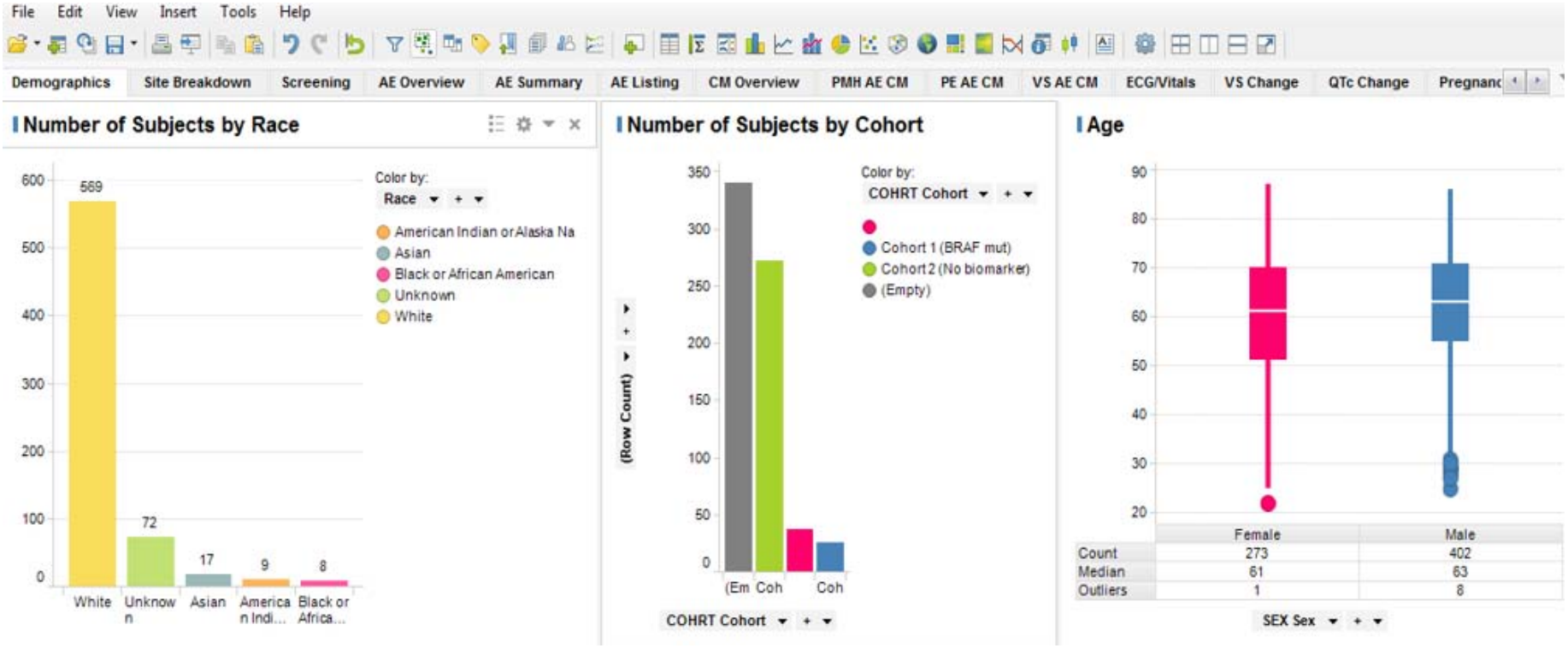
Training

- Formalized
  - Video
  - Hands-on
- Self-guided

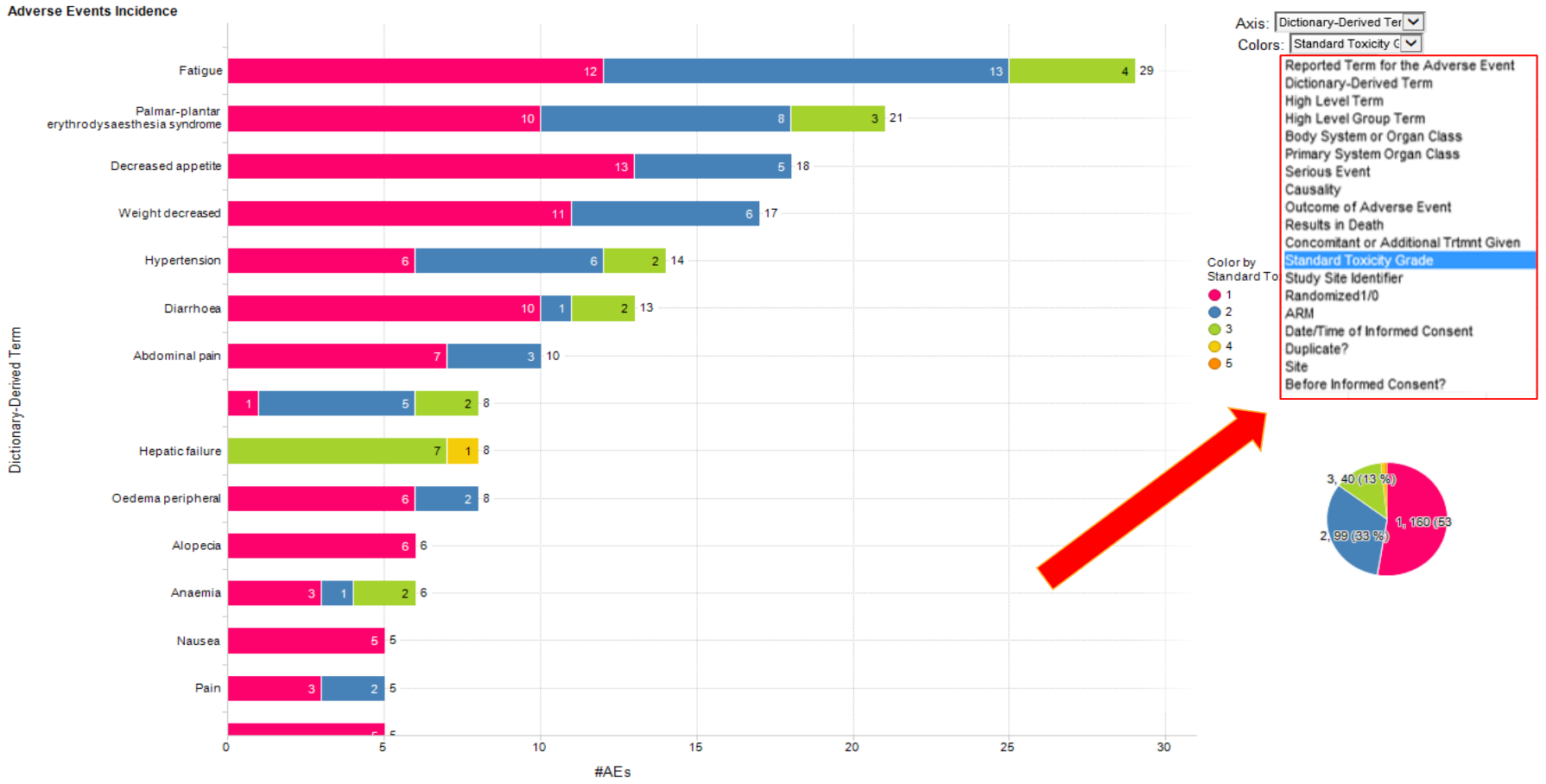
Support

- Password reset
- “How to” support
  - Functionality
  - Application

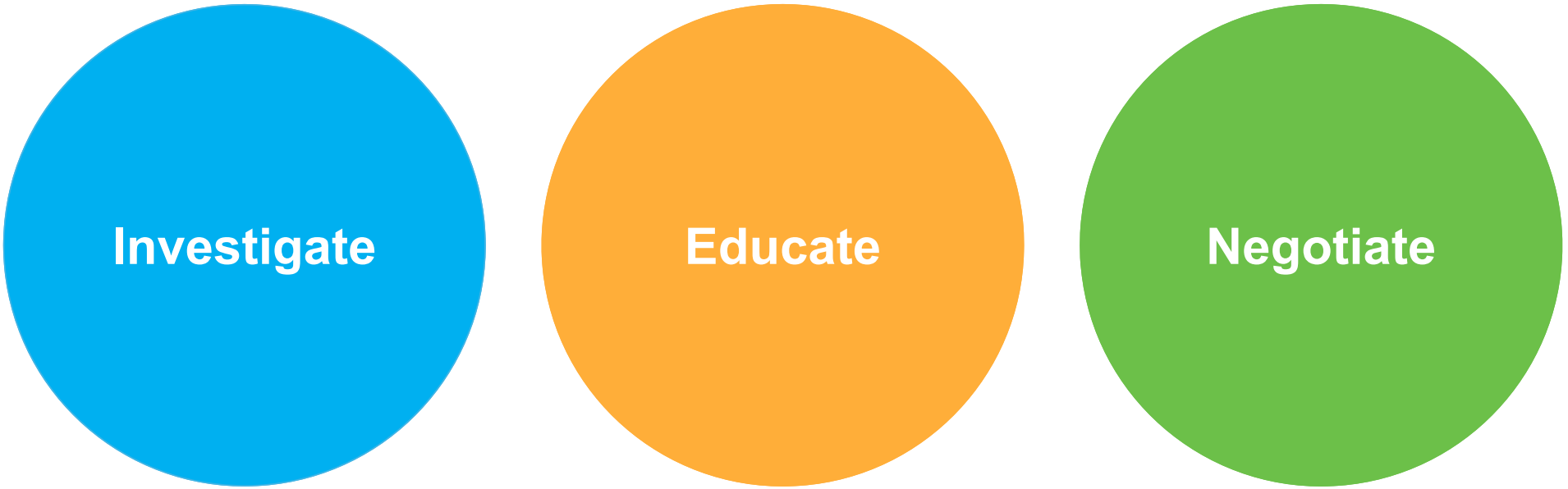
Organization & Data Flow



Power vs. Complexity

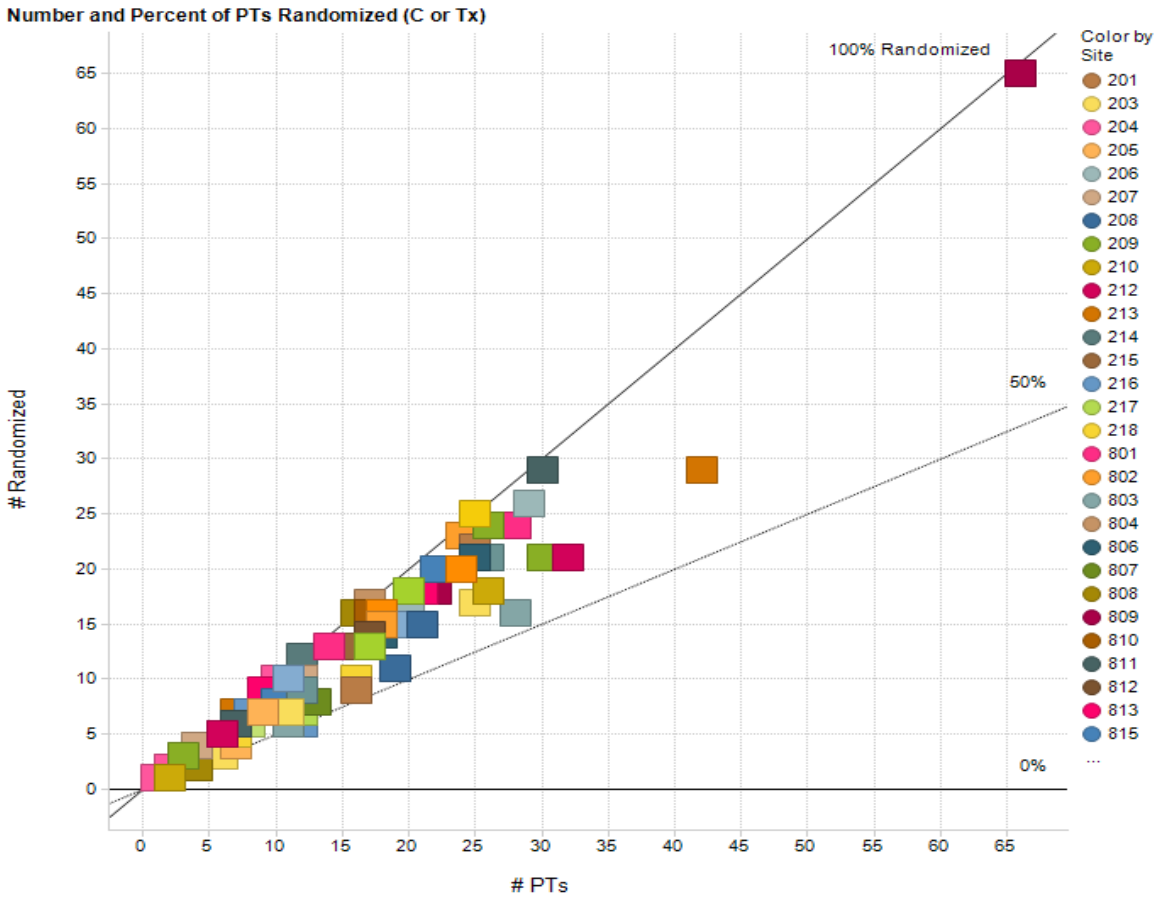


Improving Physician Acceptance

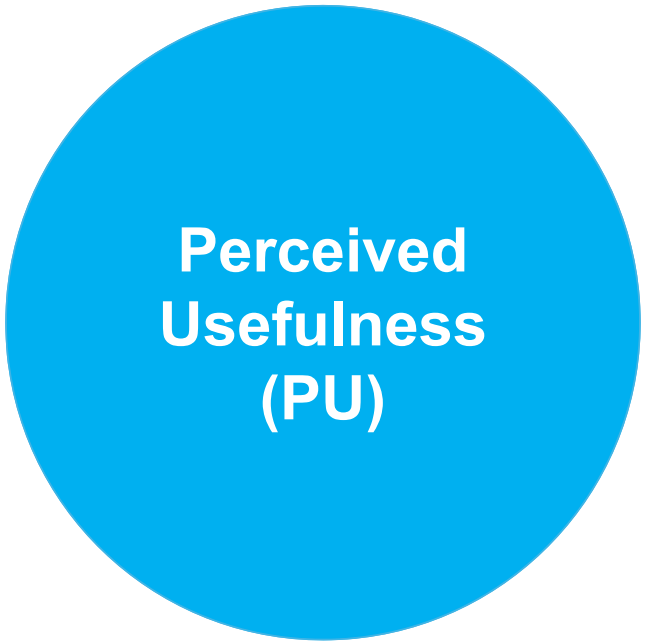


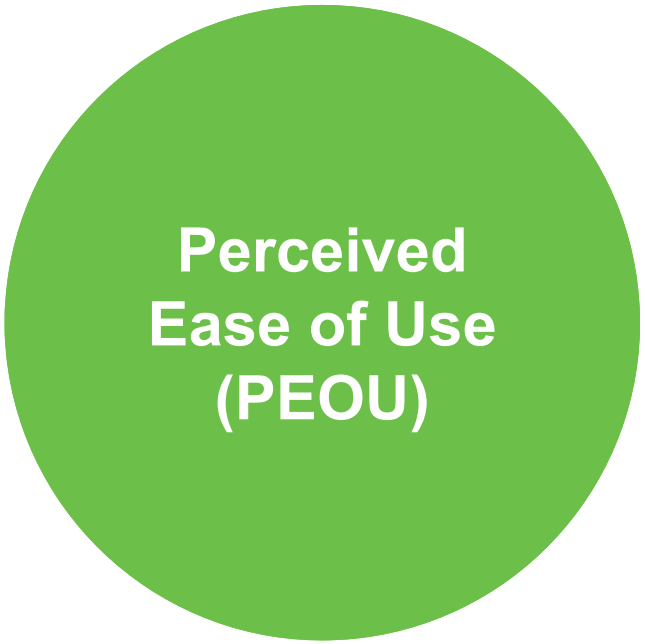
Improving Physician Acceptance

Valuable Insight

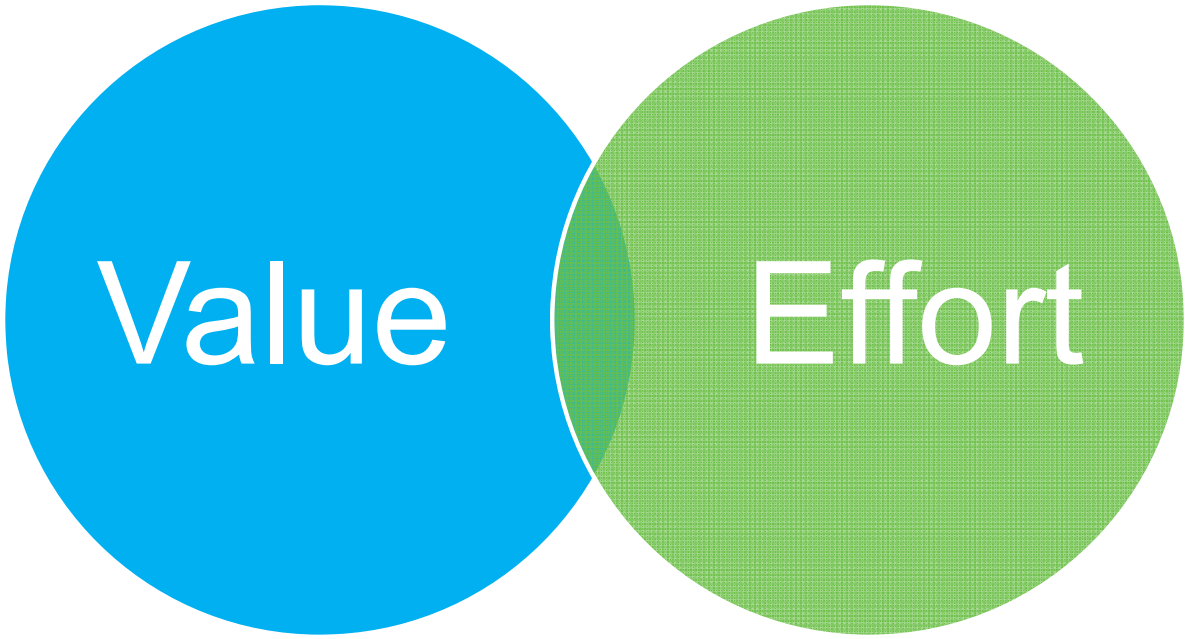


Technology Acceptance





Technology Acceptance



Questions?