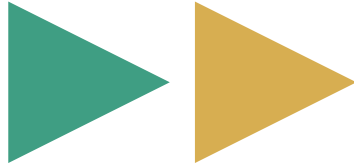


FMD K&L



Hit Refresh of Data Monitoring - Interaction and Automation

Chao Wang
2018-05-18

Today's Agenda



1 **Emerging Trends & Technology**
Hit Refresh

2 **Data Monitoring**
Guideline and process

3 **Dynamic Visualization**
Interactive review and auto update

4 **Sample Demonstration**
By different applications

5 **Discussion**
Proposal and Perspective

Emerging Trends & Technology

Hit Refresh – Internet of Things

Cloud Computing

- On-demand delivery of compute power, database storage, applications, and other IT resources through a cloud services platform
- Amazon AWS, Microsoft Azure, 阿里云
- SAS Grid

Reengineering Technology

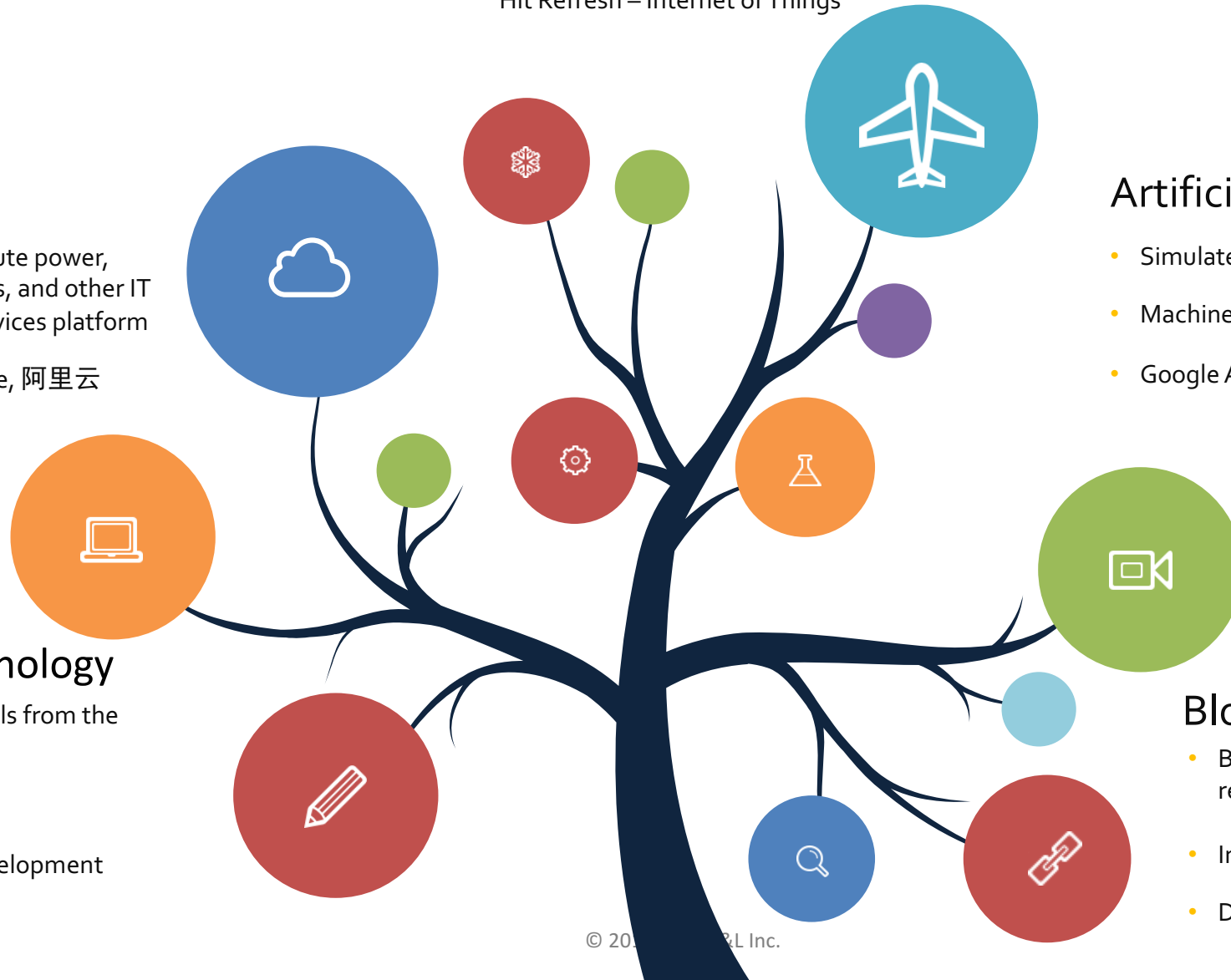
- Building new IT delivery models from the top down and bottom up
- Design Thinking
- User Focused Application Development

Artificial Intelligence

- Simulated intelligence in machines.
- Machine learning, Deep learning
- Google AlphaGo, Baidu Apollo

Blockchain

- Broad adoption and integration enter the realm of the possible
- Improve security and accuracy in transport
- Digital Signature, Bitcoin



Data Standards

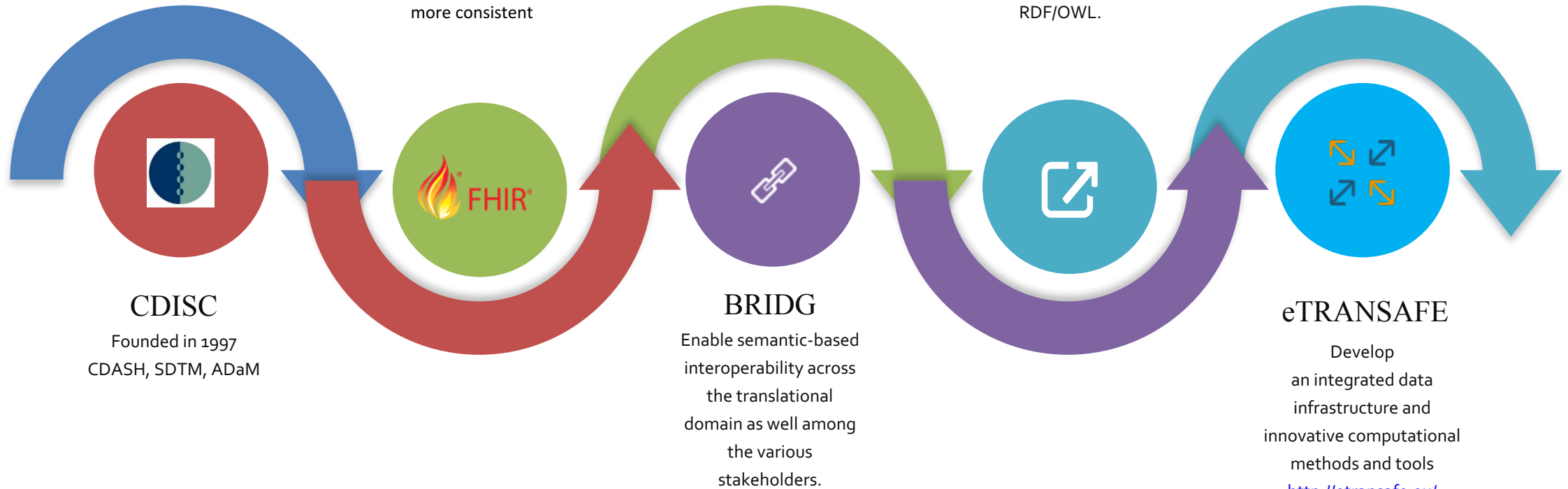
standing on the shoulder of giants

SEMANTIC

CDISC SHARE
BRIDG UML
CDISC CT
RDF/OWL.

HL7 FHIR

Standards for Health
Make healthcare data
more consistent



Introduction & Clarification

standing on the shoulder of giants

Data Monitoring Committee

- Responsible for the stewardship of a clinical trial
- Used in pharmaceutical industry clinical trials since at least 1988

Early Monitoring Methods

- Source data verification
- Thresholds driven
- Centralized Data Monitoring: Cluster Analysis, Digit Preference, Multivariate Inliers and Outliers

Risk Based Monitoring

- Initiated by TransCelerate in 2015
- Centralized Statistical Monitoring
- Enhance patient safety and ensure the quality of clinical data

Subject Level Data Review

- Improve patient safety
- See issues earlier
- Ensure medical congruency

Industry Guideline

Mandatory?

Guidance for Clinical Trial Sponsors

Establishment and Operation of Clinical Trial Data Monitoring Committees

For questions on the content of this guidance, contact the Office of Communication, Training, and Manufacturers Assistance (CBER) at 800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Center for Drug Evaluation and Research (CDER)
Center for Devices and Radiological Health (CDRH)
March 2006

OMB Control No. 0910-0581
Expiration Date: 12/31/2018
See additional PRA statement in Section 8 of this guidance

NIH National Institutes of Health
Research, Training, and Statistics Administration
Office of Research Safety
Safety Monitoring of Clinical Trials

NIH Policy and Guidance

- NIH Policy for Data and Safety Monitoring (<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>)
- Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multi-Center Clinical Trials (<http://grants1.nih.gov/grants/guide/notice-files/not99-307.html>)
- Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials (<http://grants.nih.gov/grants/guide/notice-files/NOT-00-00-038.html>)

Institute/Center Policy and Guidance

NCI

- Data and Safety Monitoring Guidelines (<http://deainfo.nci.nih.gov/grants/policies/datasafety.pdf>)
- Data and Safety Monitoring Information (http://rmp.cancer.gov/clinicalTrials/data_safety_monitoring_plan.htm)

NEI

- NEI Guidelines for Data and Safety Monitoring of Clinical Trials (<https://nei.nih.gov/funding/policy/policy6>)

NHLBI

- Data and Safety Monitoring Policy (<http://www.nhlbi.nih.gov/funding/policies/dsmpolicy.htm>)

NIA

- Implementation of Policies for Human Intervention Studies (<http://www.nia.nih.gov/research/dea/implementation-policies-human-intervention-studies>)

NIAAA

- NIAAA Guidelines for Data and Safety Monitoring Plans (<http://www.niaaa.nih.gov/ResearchInformation/ExtramuralResearch/ResourcesAppGrantees/guidelines.html>)

NIAID

- Research Using Human Subjects (<https://www.niaid.nih.gov/grants-contracts/human-subjects>)
- Trans-NIAID Clinical Toolkit (<https://www.niaid.nih.gov/research/trans-niaid-clinical-research-toolkit>)
- Research Rules & Policies by Division (<https://www.niaid.nih.gov/research/rules#d1>)

NIAMS

- Data and Safety Monitoring Guidelines (http://www.niams.nih.gov/Funding/Clinical_Research/data_safety_monitoring_guidelines.pdf)

NICHD

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

ICH HARMONISED GUIDELINE

INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2)

Current Step 4 version
dated 9 November 2016

Guidance for Industry

Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Good Clinical Practice (OGCP)
Office of Regulatory Affairs (ORA)
August 2013
Procedural

OMB Control No. 0910-0733
Expiration Date: 06/30/2019 (Note: Expiration date updated 07/15/2016)
See additional PRA statement in section VII of this guidance.

Discusses the roles, responsibilities and operating procedures of Data Monitoring Committees

Literature oriented toward NIH-sponsored trials would include the NIH guideline

A combination of on-site and centralized monitoring activities may be appropriate.

Enhance human subject protection and the quality of clinical trial data by focusing sponsor oversight on the most important aspects of study conduct and reporting.

Benefit of Data Monitoring

Safety and Quality

Protection

Tendency to underplay the importance of adverse events

Data Quality

Improve data quality
Separate signal from noise
Data make sense within/across subjects

Stewardship

Add to the objectivity and credibility of trials
Avoid bias



Cost

Reduce cost by technology
Review by method

Time

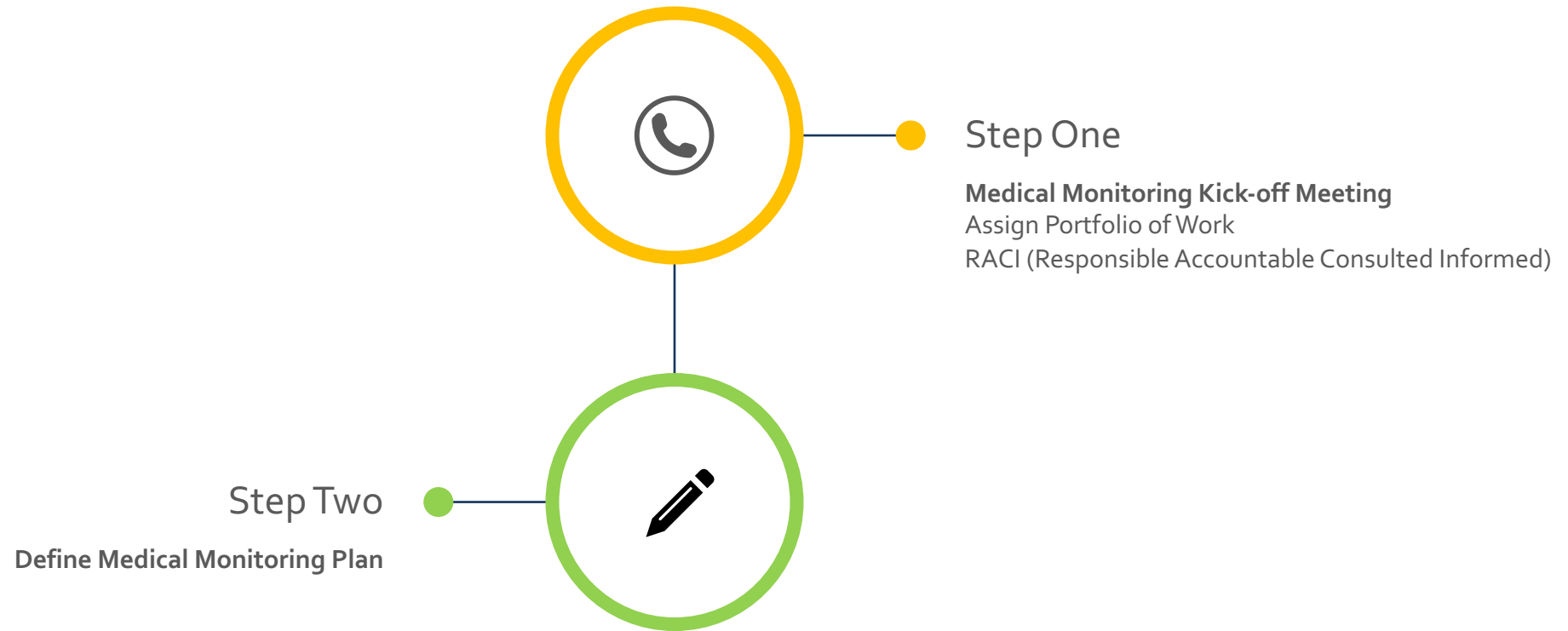
Achieve the target milestone on time
Eliminate surprises

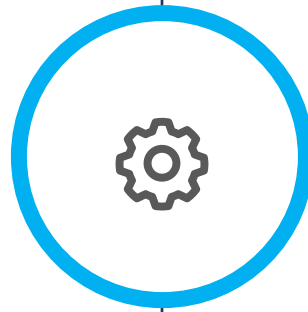
Resource

Reduce resource
Beyond key risk indicators

Medical Monitoring Process

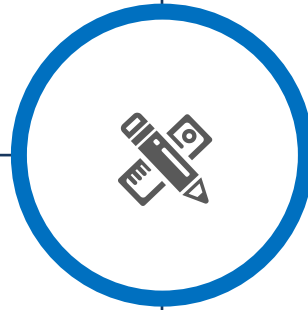
End to End





Step Three

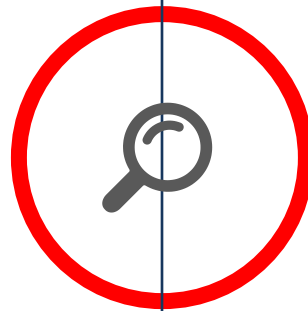
- Data Collection
- Data Clean
- Data Extraction



Step Four

Draft Programming Specification

- Standard Reports
- TA Standard Reports
- Non-standard Reports

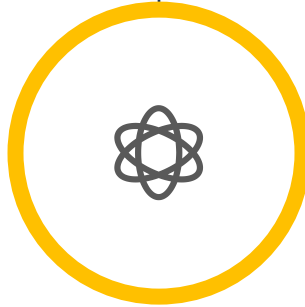
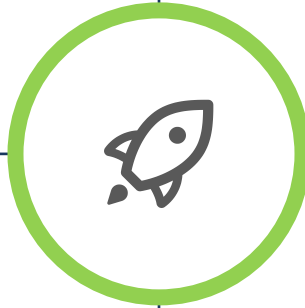


Step Five

Internal Review

- Test , Validation and Update

- Step Six
- Delivery**
- Publish Reports
 - Monthly Meeting Review, Discussion and Update



Step Seven

Lifecycle Management

- Study Close and Standard Library Maintenance

Output Samples

the same way they were 20 years ago



J-Review

Developed over the past 24 years based on suggestions from many of the installed pharmaceutical and regulatory government customers

Excel/RTF

Some sponsors use Excel or SAS to output the monitoring reports, some sponsors use part of CSR listing/Tables.



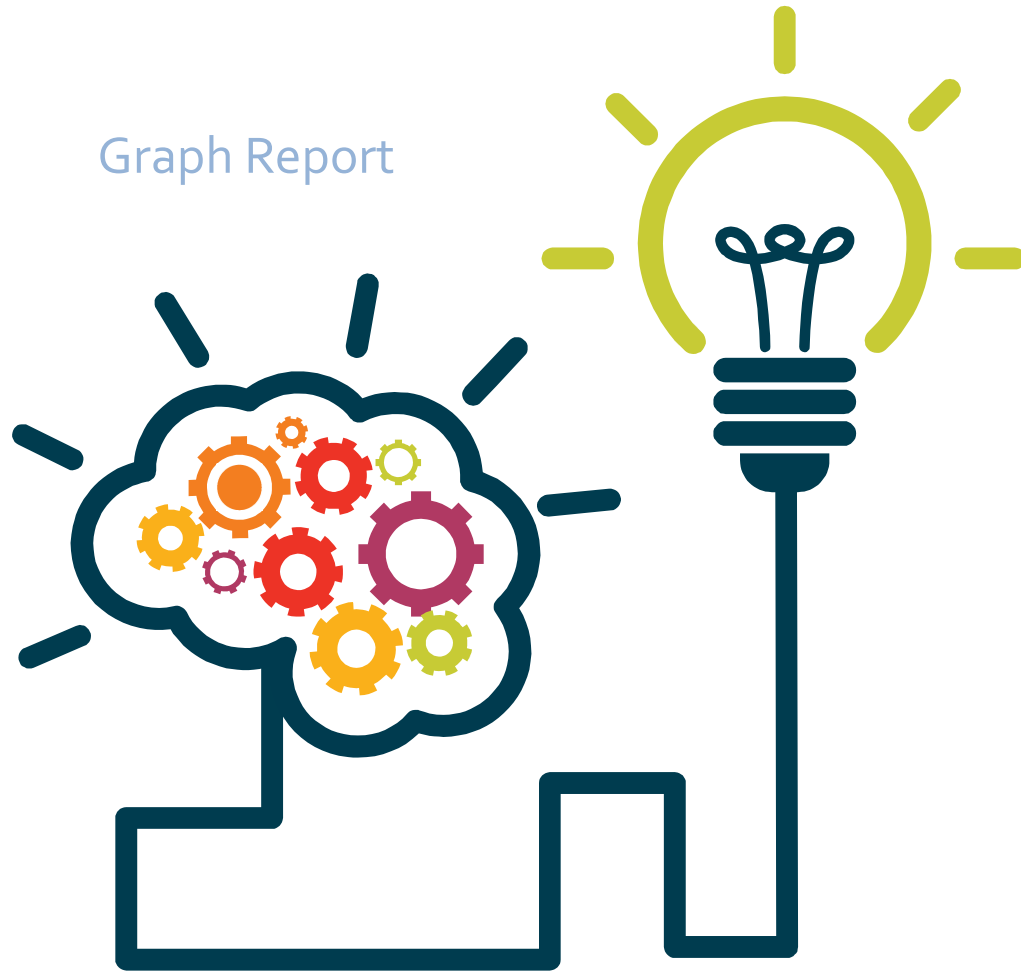
Subject	Date of Initial Onset (dd-MMM-yyyy)	Date of Onset (dd-MMM-yyyy)	Date of Initial Onset (dd-MMM-yyyy)	Date of Onset (dd-MMM-yyyy)	Year from Onset to Initial Diagnosis
1	10-OCT-2010	10-OCT-2010	10-OCT-2010	10-OCT-2010	1.74
2	10-JAN-2010	10-JAN-2010	10-JAN-2010	10-JAN-2010	1.10
3	10-FEB-2010	10-FEB-2010	10-FEB-2010	10-FEB-2010	1.10
4	10-MAR-2010	10-MAR-2010	10-MAR-2010	10-MAR-2010	1.10
5	10-APR-2010	10-APR-2010	10-APR-2010	10-APR-2010	1.10
6	10-MAY-2010	10-MAY-2010	10-MAY-2010	10-MAY-2010	1.10
7	10-JUN-2010	10-JUN-2010	10-JUN-2010	10-JUN-2010	1.10
8	10-JUL-2010	10-JUL-2010	10-JUL-2010	10-JUL-2010	1.10
9	10-AUG-2010	10-AUG-2010	10-AUG-2010	10-AUG-2010	1.10
10	10-SEP-2010	10-SEP-2010	10-SEP-2010	10-SEP-2010	1.10
11	10-OCT-2010	10-OCT-2010	10-OCT-2010	10-OCT-2010	1.10
12	10-NOV-2010	10-NOV-2010	10-NOV-2010	10-NOV-2010	1.10
13	10-DEC-2010	10-DEC-2010	10-DEC-2010	10-DEC-2010	1.10
14	10-JAN-2011	10-JAN-2011	10-JAN-2011	10-JAN-2011	1.10
15	10-FEB-2011	10-FEB-2011	10-FEB-2011	10-FEB-2011	1.10
16	10-MAR-2011	10-MAR-2011	10-MAR-2011	10-MAR-2011	1.10
17	10-APR-2011	10-APR-2011	10-APR-2011	10-APR-2011	1.10
18	10-MAY-2011	10-MAY-2011	10-MAY-2011	10-MAY-2011	1.10
19	10-JUN-2011	10-JUN-2011	10-JUN-2011	10-JUN-2011	1.10
20	10-JUL-2011	10-JUL-2011	10-JUL-2011	10-JUL-2011	1.10
21	10-AUG-2011	10-AUG-2011	10-AUG-2011	10-AUG-2011	1.10
22	10-SEP-2011	10-SEP-2011	10-SEP-2011	10-SEP-2011	1.10
23	10-OCT-2011	10-OCT-2011	10-OCT-2011	10-OCT-2011	1.10
24	10-NOV-2011	10-NOV-2011	10-NOV-2011	10-NOV-2011	1.10
25	10-DEC-2011	10-DEC-2011	10-DEC-2011	10-DEC-2011	1.10
26	10-JAN-2012	10-JAN-2012	10-JAN-2012	10-JAN-2012	1.10
27	10-FEB-2012	10-FEB-2012	10-FEB-2012	10-FEB-2012	1.10
28	10-MAR-2012	10-MAR-2012	10-MAR-2012	10-MAR-2012	1.10
29	10-APR-2012	10-APR-2012	10-APR-2012	10-APR-2012	1.10
30	10-MAY-2012	10-MAY-2012	10-MAY-2012	10-MAY-2012	1.10
31	10-JUN-2012	10-JUN-2012	10-JUN-2012	10-JUN-2012	1.10
32	10-JUL-2012	10-JUL-2012	10-JUL-2012	10-JUL-2012	1.10
33	10-AUG-2012	10-AUG-2012	10-AUG-2012	10-AUG-2012	1.10
34	10-SEP-2012	10-SEP-2012	10-SEP-2012	10-SEP-2012	1.10
35	10-OCT-2012	10-OCT-2012	10-OCT-2012	10-OCT-2012	1.10
36	10-NOV-2012	10-NOV-2012	10-NOV-2012	10-NOV-2012	1.10
37	10-DEC-2012	10-DEC-2012	10-DEC-2012	10-DEC-2012	1.10
38	10-JAN-2013	10-JAN-2013	10-JAN-2013	10-JAN-2013	1.10
39	10-FEB-2013	10-FEB-2013	10-FEB-2013	10-FEB-2013	1.10
40	10-MAR-2013	10-MAR-2013	10-MAR-2013	10-MAR-2013	1.10
41	10-APR-2013	10-APR-2013	10-APR-2013	10-APR-2013	1.10
42	10-MAY-2013	10-MAY-2013	10-MAY-2013	10-MAY-2013	1.10
43	10-JUN-2013	10-JUN-2013	10-JUN-2013	10-JUN-2013	1.10
44	10-JUL-2013	10-JUL-2013	10-JUL-2013	10-JUL-2013	1.10
45	10-AUG-2013	10-AUG-2013	10-AUG-2013	10-AUG-2013	1.10
46	10-SEP-2013	10-SEP-2013	10-SEP-2013	10-SEP-2013	1.10
47	10-OCT-2013	10-OCT-2013	10-OCT-2013	10-OCT-2013	1.10
48	10-NOV-2013	10-NOV-2013	10-NOV-2013	10-NOV-2013	1.10
49	10-DEC-2013	10-DEC-2013	10-DEC-2013	10-DEC-2013	1.10
50	10-JAN-2014	10-JAN-2014	10-JAN-2014	10-JAN-2014	1.10
51	10-FEB-2014	10-FEB-2014	10-FEB-2014	10-FEB-2014	1.10
52	10-MAR-2014	10-MAR-2014	10-MAR-2014	10-MAR-2014	1.10
53	10-APR-2014	10-APR-2014	10-APR-2014	10-APR-2014	1.10
54	10-MAY-2014	10-MAY-2014	10-MAY-2014	10-MAY-2014	1.10
55	10-JUN-2014	10-JUN-2014	10-JUN-2014	10-JUN-2014	1.10
56	10-JUL-2014	10-JUL-2014	10-JUL-2014	10-JUL-2014	1.10
57	10-AUG-2014	10-AUG-2014	10-AUG-2014	10-AUG-2014	1.10
58	10-SEP-2014	10-SEP-2014	10-SEP-2014	10-SEP-2014	1.10
59	10-OCT-2014	10-OCT-2014	10-OCT-2014	10-OCT-2014	1.10
60	10-NOV-2014	10-NOV-2014	10-NOV-2014	10-NOV-2014	1.10
61	10-DEC-2014	10-DEC-2014	10-DEC-2014	10-DEC-2014	1.10
62	10-JAN-2015	10-JAN-2015	10-JAN-2015	10-JAN-2015	1.10
63	10-FEB-2015	10-FEB-2015	10-FEB-2015	10-FEB-2015	1.10
64	10-MAR-2015	10-MAR-2015	10-MAR-2015	10-MAR-2015	1.10
65	10-APR-2015	10-APR-2015	10-APR-2015	10-APR-2015	1.10
66	10-MAY-2015	10-MAY-2015	10-MAY-2015	10-MAY-2015	1.10
67	10-JUN-2015	10-JUN-2015	10-JUN-2015	10-JUN-2015	1.10
68	10-JUL-2015	10-JUL-2015	10-JUL-2015	10-JUL-2015	1.10
69	10-AUG-2015	10-AUG-2015	10-AUG-2015	10-AUG-2015	1.10
70	10-SEP-2015	10-SEP-2015	10-SEP-2015	10-SEP-2015	1.10
71	10-OCT-2015	10-OCT-2015	10-OCT-2015	10-OCT-2015	1.10
72	10-NOV-2015	10-NOV-2015	10-NOV-2015	10-NOV-2015	1.10
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74	10-JAN-2016	10-JAN-2016	10-JAN-2016	10-JAN-2016	1.10
75	10-FEB-2016	10-FEB-2016	10-FEB-2016	10-FEB-2016	1.10
76	10-MAR-2016	10-MAR-2016	10-MAR-2016	10-MAR-2016	1.10
77	10-APR-2016	10-APR-2016	10-APR-2016	10-APR-2016	1.10
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79	10-JUN-2016	10-JUN-2016	10-JUN-2016	10-JUN-2016	1.10
80	10-JUL-2016	10-JUL-2016	10-JUL-2016	10-JUL-2016	1.10
81	10-AUG-2016	10-AUG-2016	10-AUG-2016	10-AUG-2016	1.10
82	10-SEP-2016	10-SEP-2016	10-SEP-2016	10-SEP-2016	1.10
83	10-OCT-2016	10-OCT-2016	10-OCT-2016	10-OCT-2016	1.10
84	10-NOV-2016	10-NOV-2016	10-NOV-2016	10-NOV-2016	1.10
85	10-DEC-2016	10-DEC-2016	10-DEC-2016	10-DEC-2016	1.10
86	10-JAN-2017	10-JAN-2017	10-JAN-2017	10-JAN-2017	1.10
87	10-FEB-2017	10-FEB-2017	10-FEB-2017	10-FEB-2017	1.10
88	10-MAR-2017	10-MAR-2017	10-MAR-2017	10-MAR-2017	1.10
89	10-APR-2017	10-APR-2017	10-APR-2017	10-APR-2017	1.10
90	10-MAY-2017	10-MAY-2017	10-MAY-2017	10-MAY-2017	1.10
91	10-JUN-2017	10-JUN-2017	10-JUN-2017	10-JUN-2017	1.10
92	10-JUL-2017	10-JUL-2017	10-JUL-2017	10-JUL-2017	1.10
93	10-AUG-2017	10-AUG-2017	10-AUG-2017	10-AUG-2017	1.10
94	10-SEP-2017	10-SEP-2017	10-SEP-2017	10-SEP-2017	1.10
95	10-OCT-2017	10-OCT-2017	10-OCT-2017	10-OCT-2017	1.10
96	10-NOV-2017	10-NOV-2017	10-NOV-2017	10-NOV-2017	1.10
97	10-DEC-2017	10-DEC-2017	10-DEC-2017	10-DEC-2017	1.10
98	10-JAN-2018	10-JAN-2018	10-JAN-2018	10-JAN-2018	1.10
99	10-FEB-2018	10-FEB-2018	10-FEB-2018	10-FEB-2018	1.10
100	10-MAR-2018	10-MAR-2018	10-MAR-2018	10-MAR-2018	1.10

CrossTab - All Patients							
	Active	Male	Female	Placebo	Male	Female	Subjects
AE Coded	Total			Total			
SKIN:burning sensation skin	9 (9.28%)	8 (8.25%)	1 (1.03%)	9 (9.09%)	8 (8.08%)	1 (1.01%)	18 (9.18%)
NER :Headache	4 (4.12%)	4 (4.12%)	0 (0.00%)	4 (4.04%)	3 (3.03%)	1 (1.01%)	8 (4.08%)
BOOY:Surgery	3 (3.09%)	3 (3.09%)	0 (0.00%)	5 (5.05%)	5 (5.05%)	0 (0.00%)	8 (4.08%)
RES :Upper respiratory infection	3 (3.09%)	3 (3.09%)	0 (0.00%)	1 (1.01%)	0 (0.00%)	1 (1.01%)	4 (2.04%)
BOOY:Back pain	2 (2.06%)	1 (1.03%)	1 (1.03%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	3 (1.53%)
RES :Cough increased	1 (1.03%)	1 (1.03%)	0 (0.00%)	2 (2.02%)	2 (2.02%)	0 (0.00%)	3 (1.53%)
RES :Sinusitis	2 (2.06%)	2 (2.06%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	3 (1.53%)
UG :Urinary tract infection	3 (3.09%)	1 (1.03%)	2 (2.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.53%)
SKIN:Pruritus	2 (2.06%)	0 (0.00%)	2 (2.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.02%)
DIG :Tooth disorder	1 (1.03%)	1 (1.03%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	2 (1.02%)
NER :Dizziness	1 (1.03%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
DIG :Rectal pain	1 (1.03%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
HAL :Echymosis	1 (1.03%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
RES :Respiratory disorder	1 (1.03%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
MS :Arthritis	1 (1.03%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
NER :Somnolence	1 (1.03%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
BOOY:Allergic reaction	1 (1.03%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
SS :Taste perversion	1 (1.03%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
BOOY:Pain	1 (1.03%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
DIG :Duodenal ulcer	1 (1.03%)	0 (0.00%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
UG :Vaginitis	1 (1.03%)	0 (0.00%)	1 (1.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
SKIN:Skin disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
DIG :Periodontal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
BOOY:body odor	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
DIG :Diarrhea	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
MAN :Peripheral edema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
SS :Glaucoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
MS :Myalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
DIG :Sore throat	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
BOOY:Unfavorable reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
DIG :Vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.01%)	1 (1.01%)	0 (0.00%)	1 (0.51%)
(missing)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subjects	97 (100.00%)	78 (80.41%)	19 (19.59%)	99 (100.00%)	83 (83.84%)	16 (16.16%)	196 (100.00%)
1stCol:Subjects	97 (100.00%)	97 (100.00%)	97 (100.00%)	99 (100.00%)	99 (100.00%)	99 (100.00%)	(Denom=1stColTot)

User Friendly

beautiful summary

Graph Report



1: What are the target organs?

Can we rank order them based on frequency of findings?

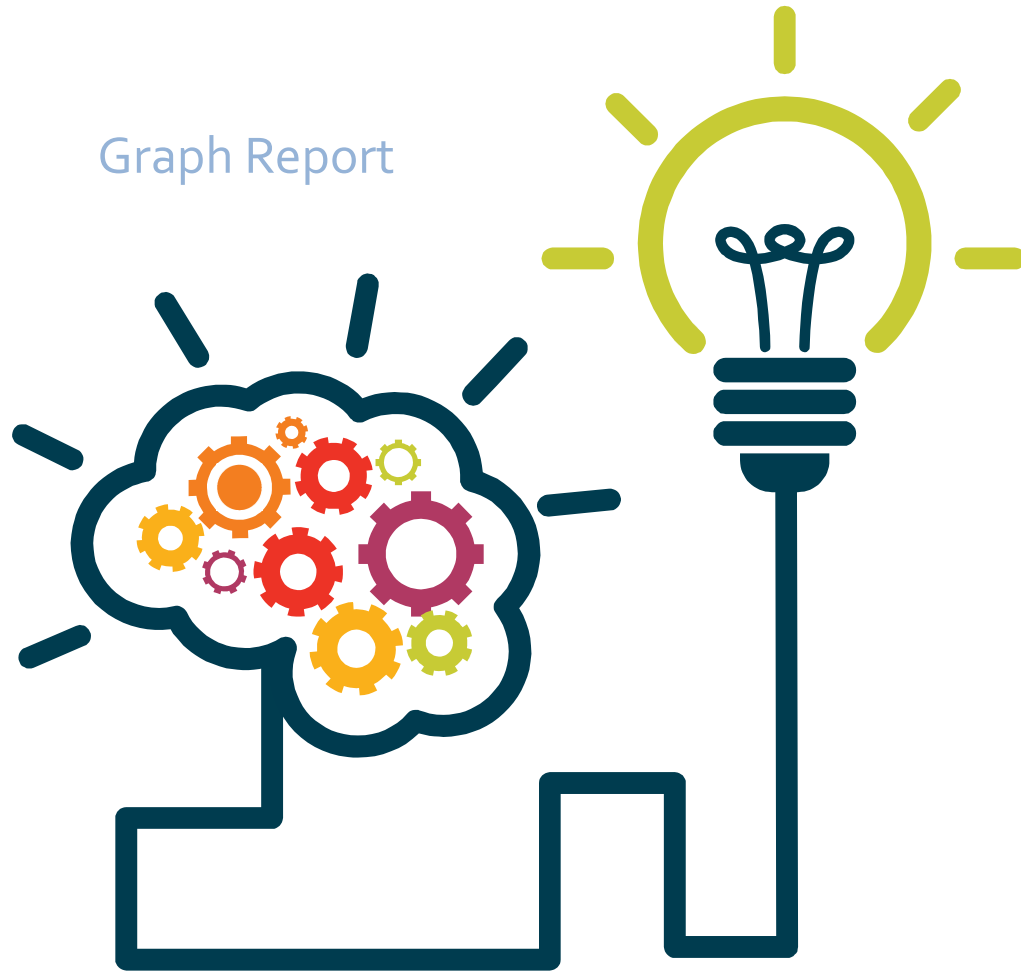
Ileum	1%
Set of skeletal muscles	1%
Submandibular gland	1%
Stomach	1%
Parotid gland	0.8%
Rectum	0.8%
Small intestine	0.8%
Heart	0.7%
Thyroid gland	0.5%
Mammary gland	0.5%
Tongue	0.5%
Prostate gland	0.5%
Ovary	0.4%
Gastrointestinal system mesentery	0.4%
Esophagus	0.4%
Mediastinal tissue	0.4%
Lacrimal gland	0.4%
Parathyroid gland	0.3%
Skin	0.3%
Spinal cord	0.3%
Eye	0.3%
Brain	0.3%
Pancreas	0.1%

Source: <http://www.phusewiki.org/docs/2018%20US%20CSS/posters/PP18.pdf>

User Friendly

dynamic

Graph Report



NEXT AMERICA

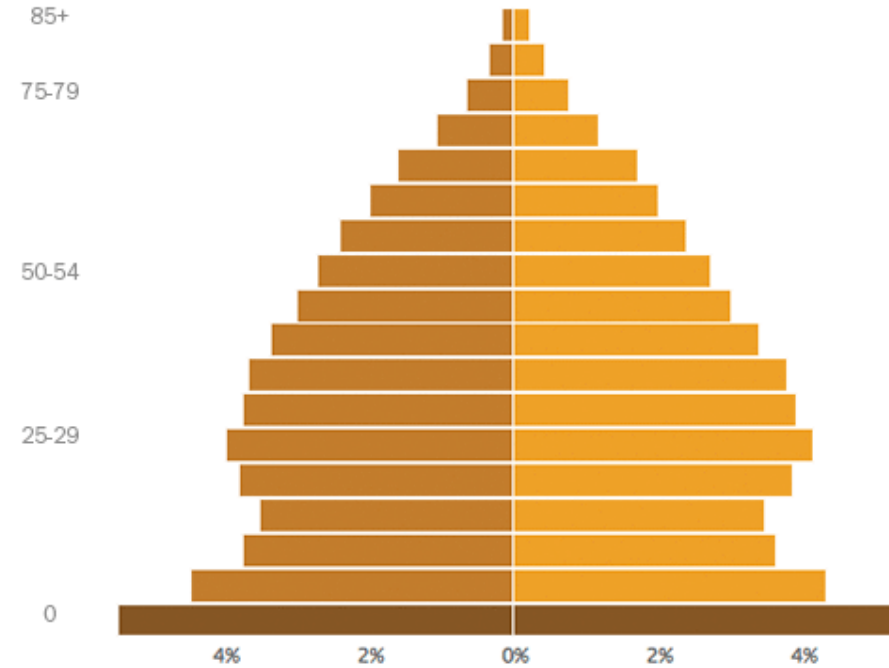
Percent of U.S. Population by Age Group, 1950-2060

■ Baby Boomers

MALE

1950

FEMALE



PEW RESEARCH CENTER

Source: <http://www.pewresearch.org/files/2014/04/847889448.gif>

Visualization Brainstorm

a graph is worth a thousand words



Medical Monitoring Needs

be happy at work



Cloud Review

Access through Web with permission



Interaction

Check the tactility by click

Known risks vs. unknown risks



Automation

Results will be auto updated per the source data

Best analysis type for the data



Available Tools

Colorful World



All-in-One

selection criteria

Source Data Requirement

Raw, SDTM-like, SDTM

Graphical Profile

Link Data,

Integrate all the findings/events together by day



Tabular Summary

Dynamic reports

Standard layout or customized layouts

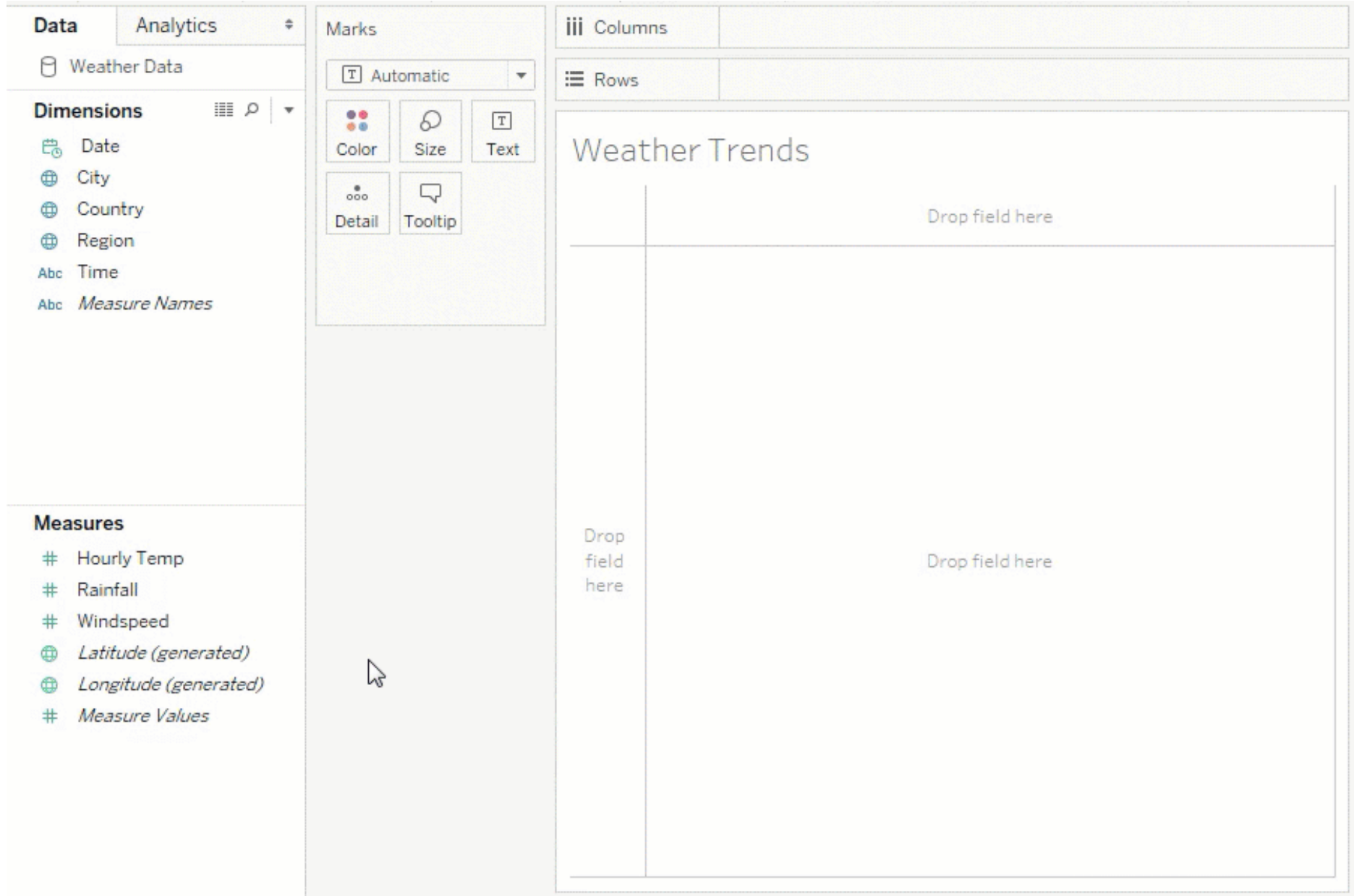
Narratives

Automatic generation of patient

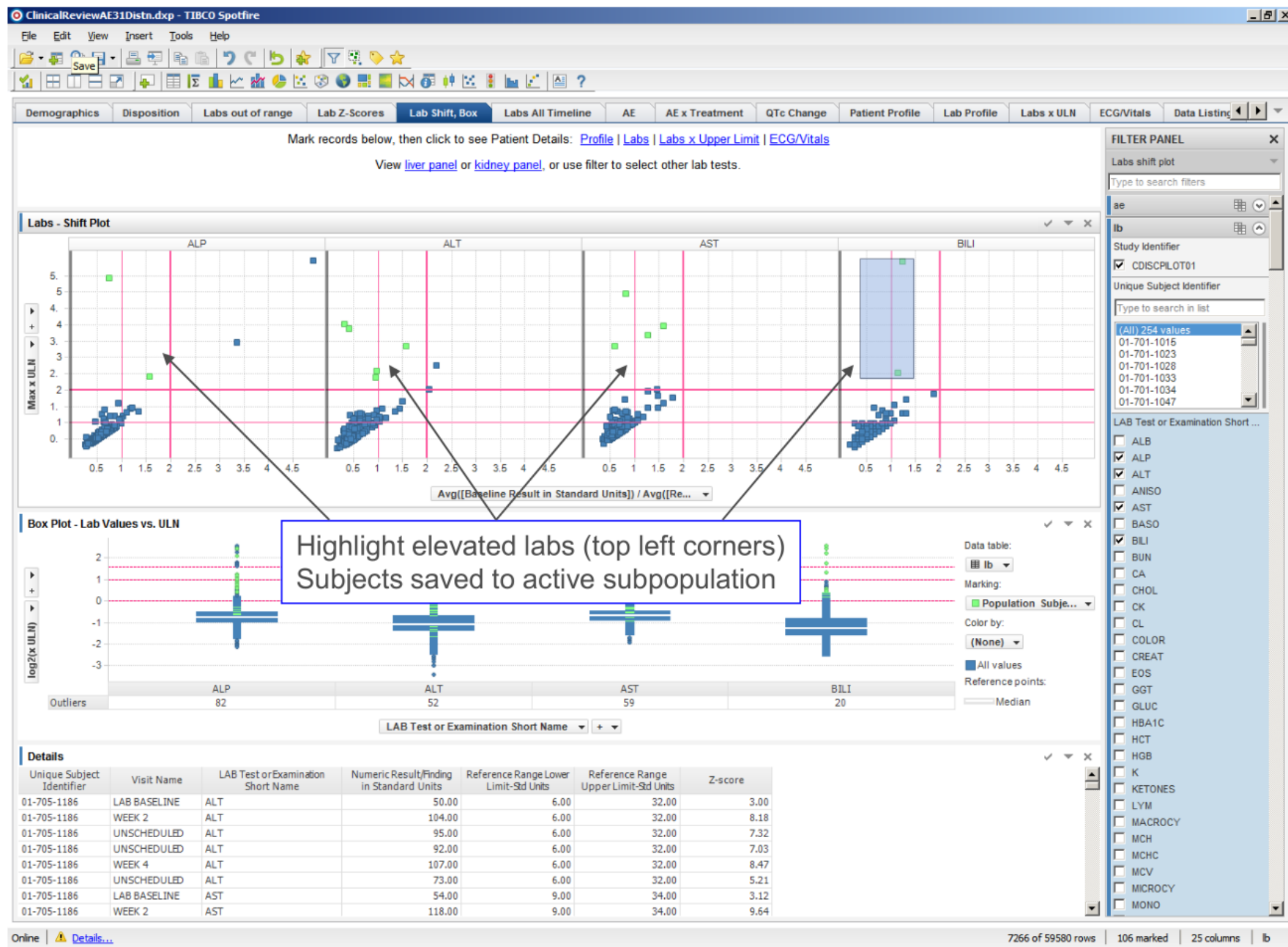
Narrative?

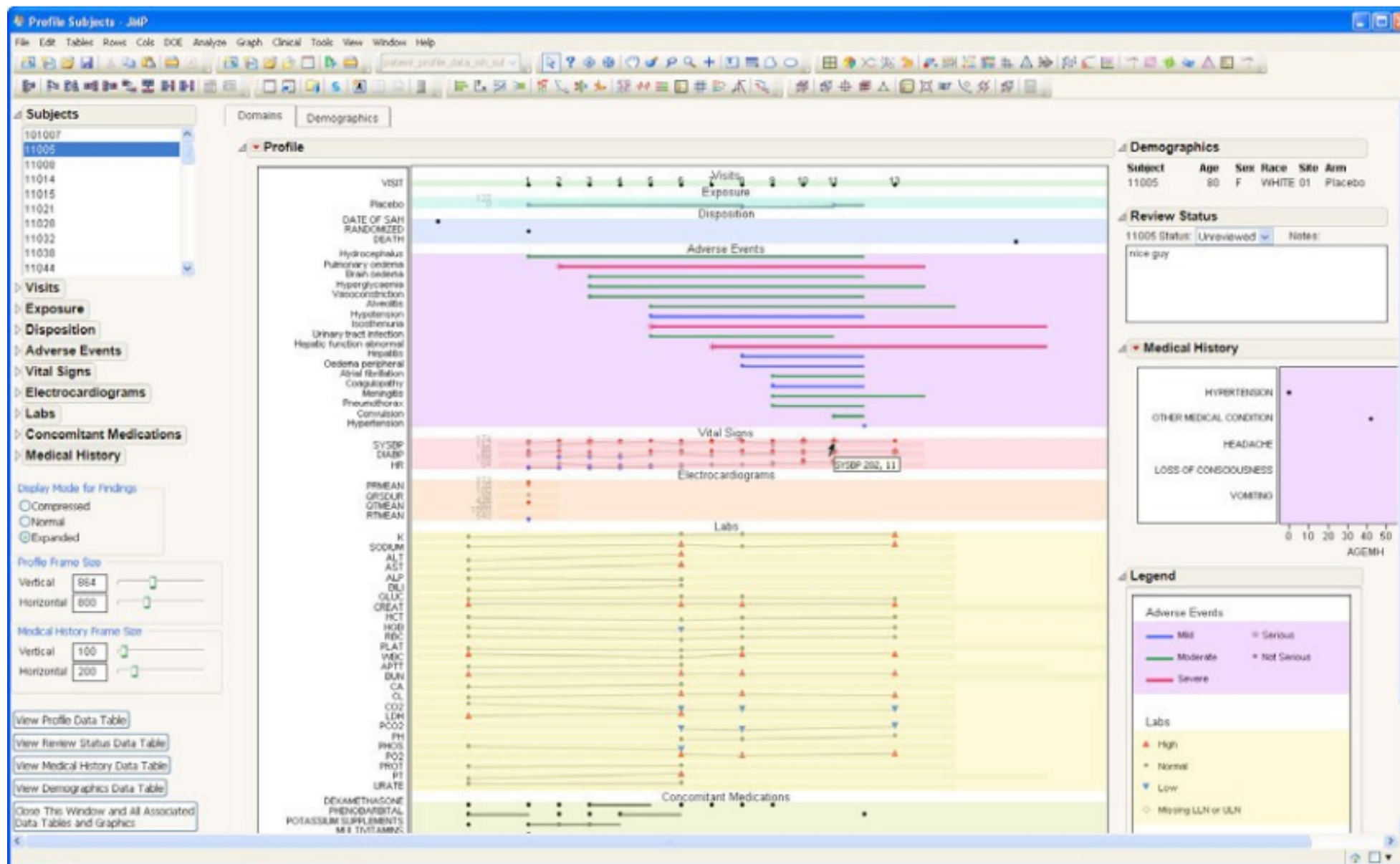
Source:

<http://www.phusewiki.org/docs/2018%20US%20CSS/posters/PP23.pdf>

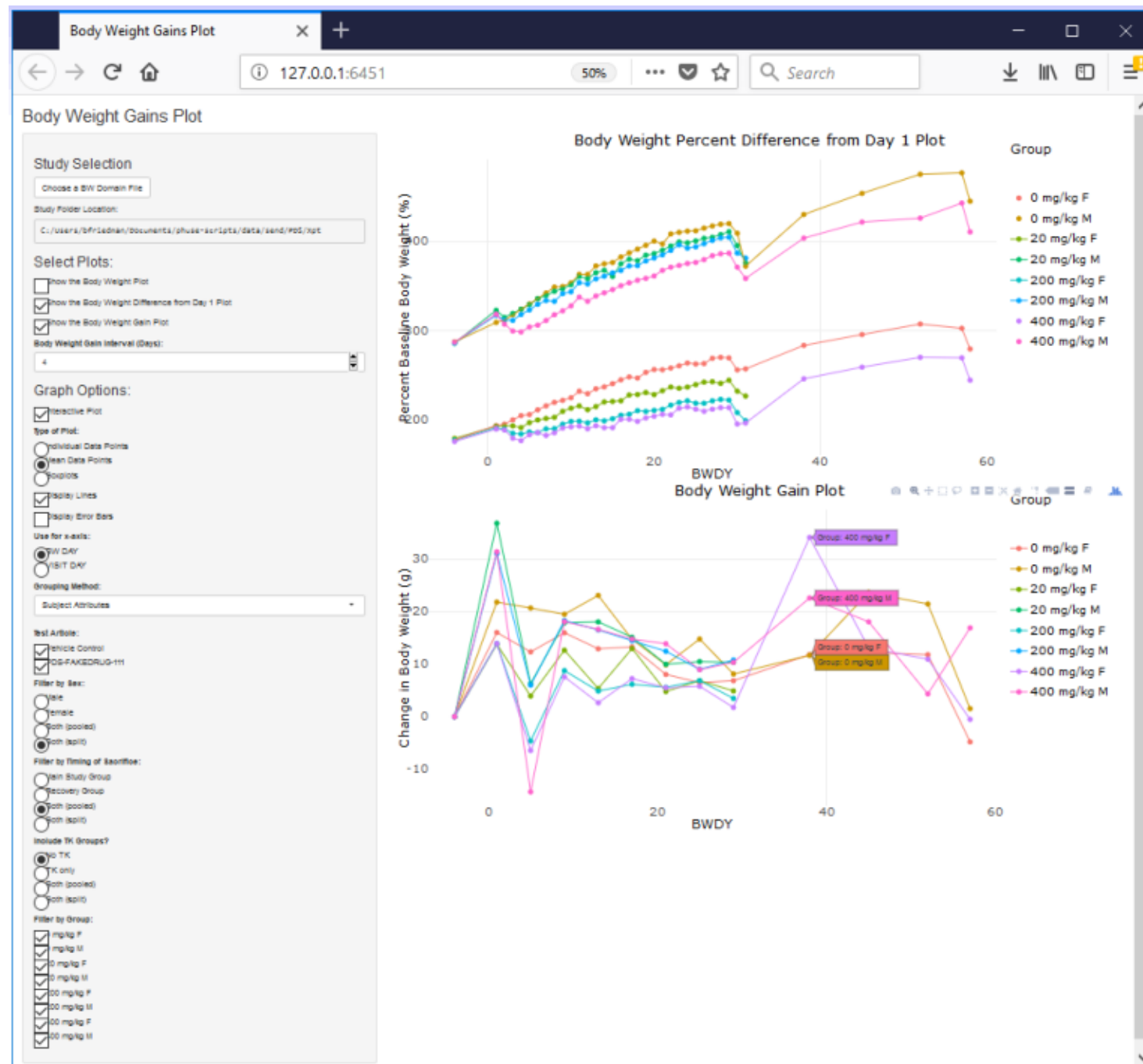


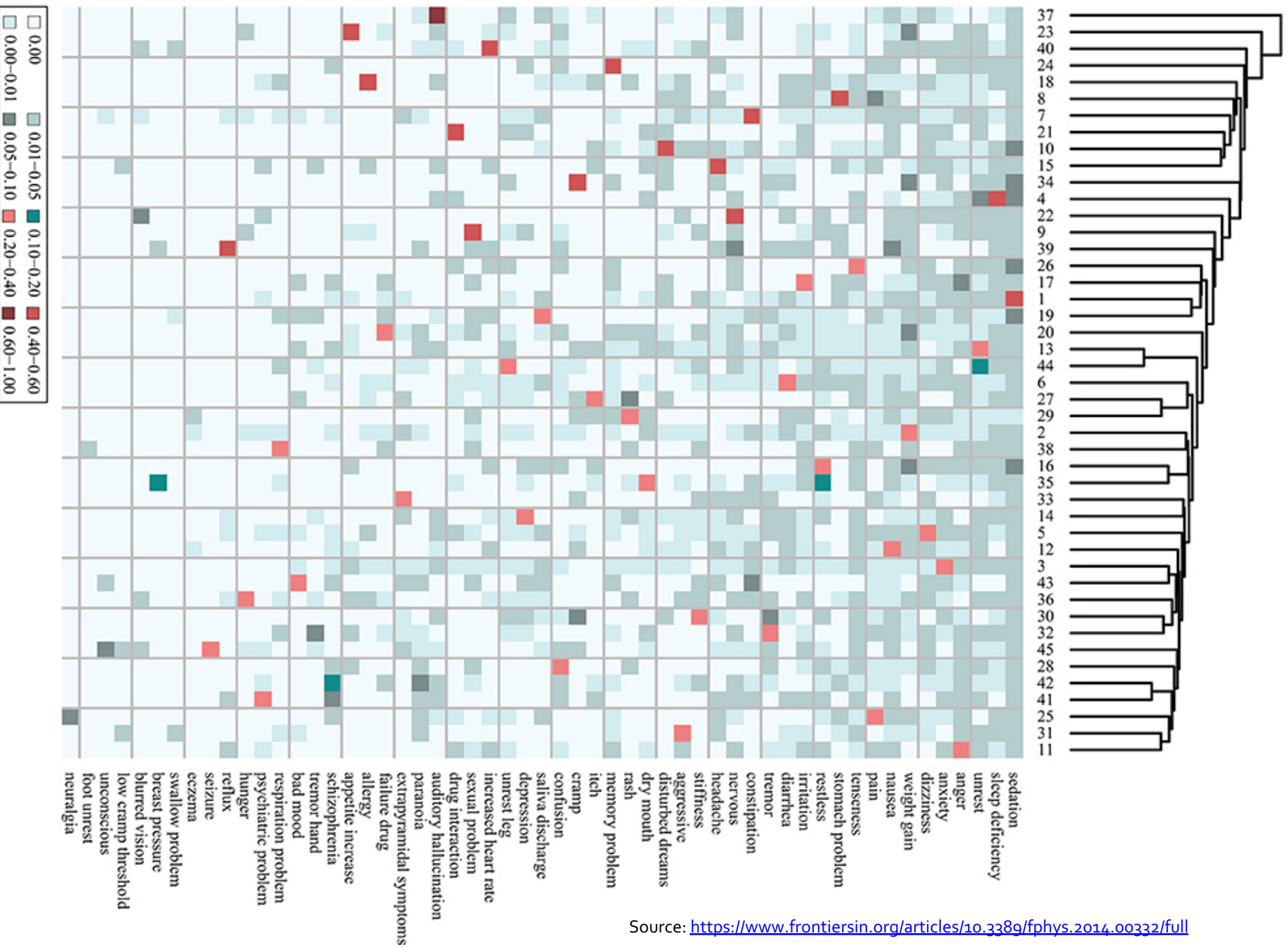
The screenshot displays the Tableau Analytics interface. On the left, the 'Data' pane shows the 'Weather Data' source. Below it, the 'Dimensions' pane lists fields: Date, City, Country, Region, Time, and Measure Names. The 'Measures' pane lists: Hourly Temp, Rainfall, Windspeed, Latitude (generated), Longitude (generated), and Measure Values. The 'Marks' pane shows 'Automatic' with options for Color, Size, Text, Detail, and Tooltip. The 'Columns' and 'Rows' shelves are empty. The main view area is titled 'Weather Trends' and contains three 'Drop field here' prompts.





Source: https://www.jmp.com/en_ch/customer-stories/aci.html





Adverse event (AE) composition of 45 clusters of patients, stratified based on the AE profiles of the patients.

Industry Engagement

Smart Technology Wave



Onward in China

Strength Through Collaboration



Strategy

Chase technology trends
Set up communities



Framework

Volunteers and Committee
Education and Training



Topics

Conference, Seminars, Online Sharing



Beyond SAS

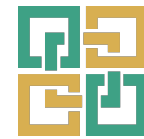
Next Generation Programming

Brave New World

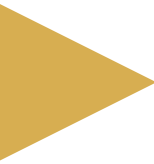
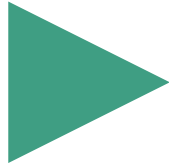
Instead of twisting data to fit into rigid, disconnected formats, we must learn to fit analytics directly to the data as captured. This is how analytics are applied throughout the modern world – why not research too?

Wayne Kubick, CTO HL7





FMD K&L



Thanks for your attention!