IMS Health & Quintiles are now

IQVIA™

Defining and Creating Efficient Statistical Outputs

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Introduction

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Define efficiency:

- Accomplishment of or ability to accomplish a job with a minimum expenditure of time and effort (From http://www.dictionary.com)

How are we becoming more efficient?

- Striving for full automation – producing more with less effort, through more efficient practices.
    - Are we possibly producing too many outputs.

Is less more and visa-versa?

Regulatory Requirements and Considerations

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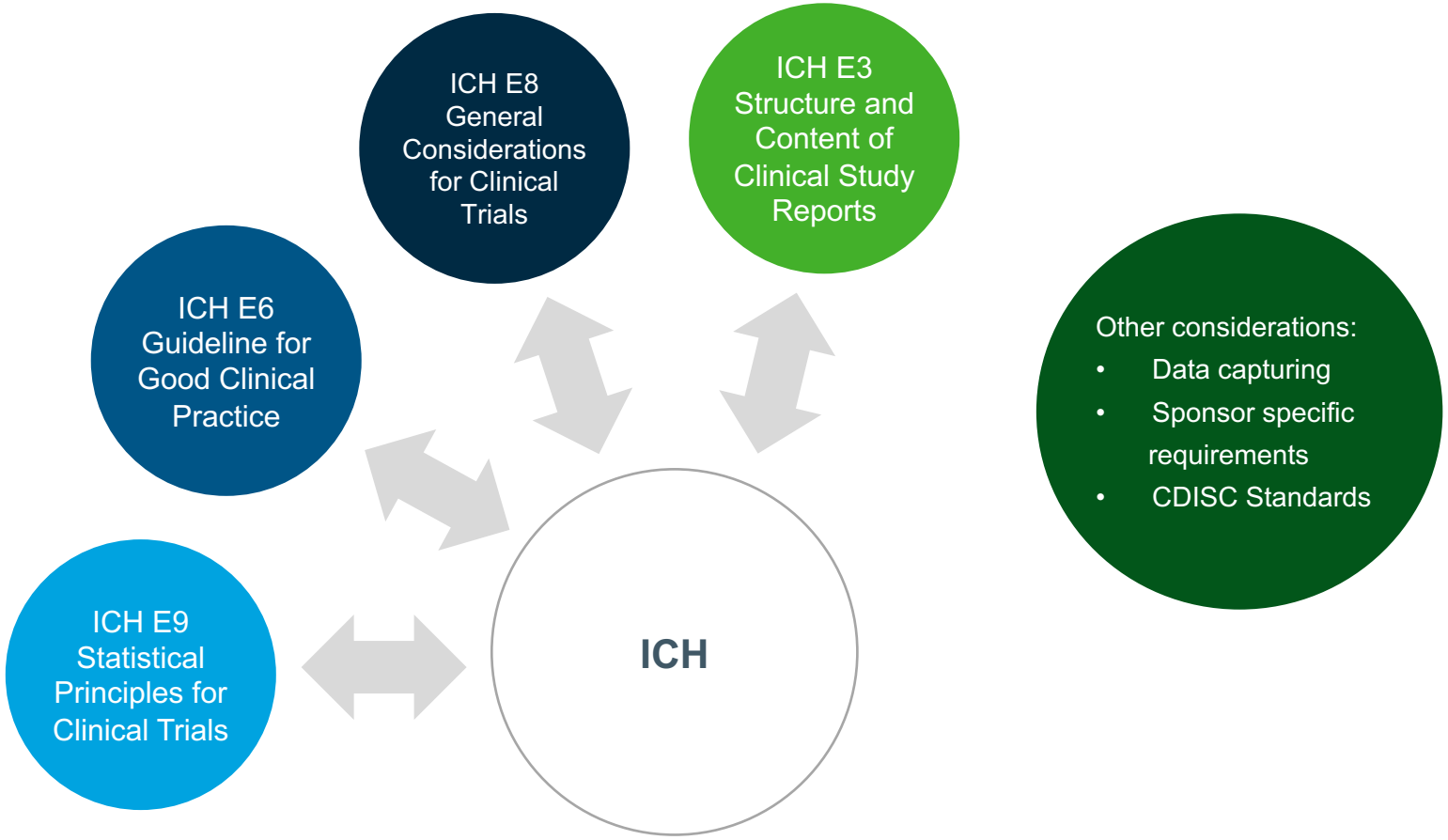
The International Conference on Harmonisation



Efficiency: Tools

Efficiency Tools: Review

TLFs

Pinnacle 21

Upstream with your statistician and a data visualization paddle (Cowans, 2016).

Defines

Patient Profiles and Narratives

Optimized data check tools:

- Visualizing CDISC SDTM for Monitoring and Review (Bartle, 2017).

J Review

Spot fire

Review data rather than creating an output:

- Making Graphs Easier to Validate (Holland, 2017).

Indication specific inspection tools

Dashboard

Efficiency Tools: Planning

Standardized Templates

TLF Shell setup tools

Dynamic Indication Specific Templates

Efficiency Tools: Execution

Automation tools:
TLFs
Programming headers
Compares
Log cleaning
Back ups

Hybrid outputs

Output and data visualization:

- Concepts and Strategies for Developing Effective Data Visualizations (Bates, 2016).

Indication specific automation tools

Dynamic and Interactive TLFs:

- Only Interactive Graphics Will Do (Kinnersley, 2005).

Efficiency Tools: Delivery

- Number of outputs
  - › Is more less?
  - › Endpoints
- Type of delivery
  - › Interim and Final Deliveries.
    - » Are listings necessary?
    - » Potential of dynamic figures
    - » Blinded/Unblinded data

Possible Considerations

Possible Considerations

- Type of deliverables
  - PDFs
  - Listings
  - Basic output delivery combined with SAS outputs.

A Cost-Effective Data Visualization System using BASE SAS (Kane, 2016).

- Efficiency in “re-using”
- Appropriate tool use
- Predefined sponsor team standards
- Medical writing
  - What can we do to make their lives easier?
    - In-text tables
    - Summary tables layout
    - Collaboration

Previous PhUSE Research and Application

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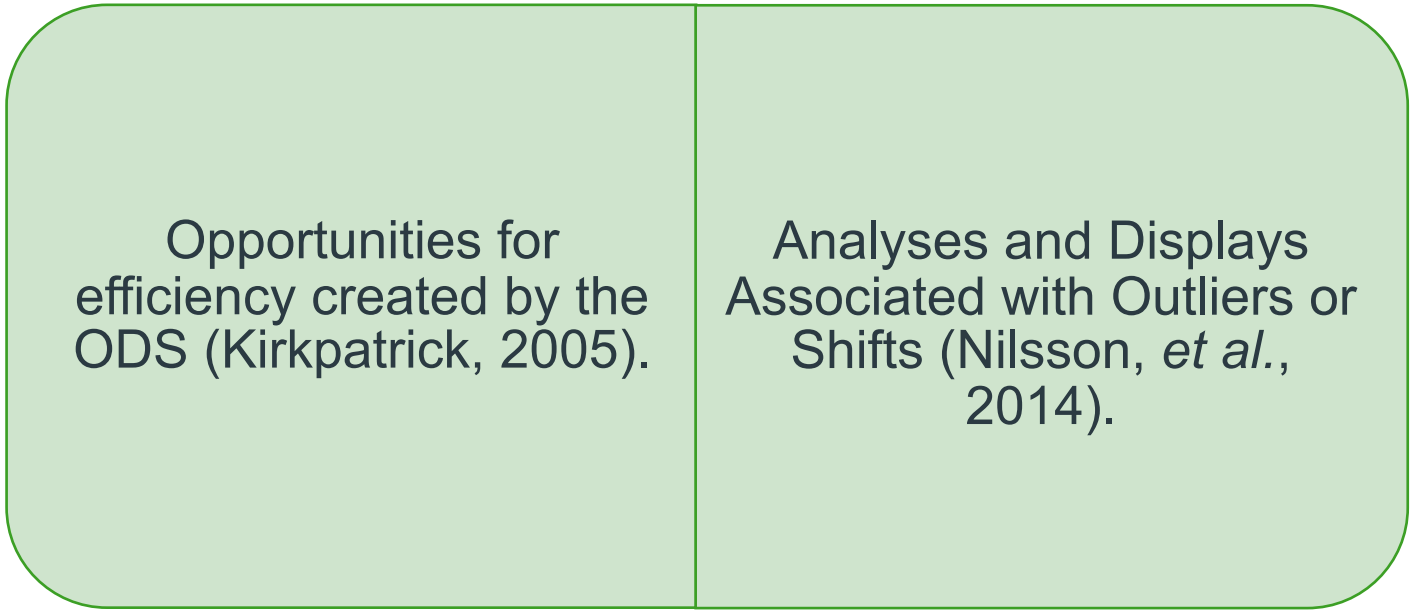
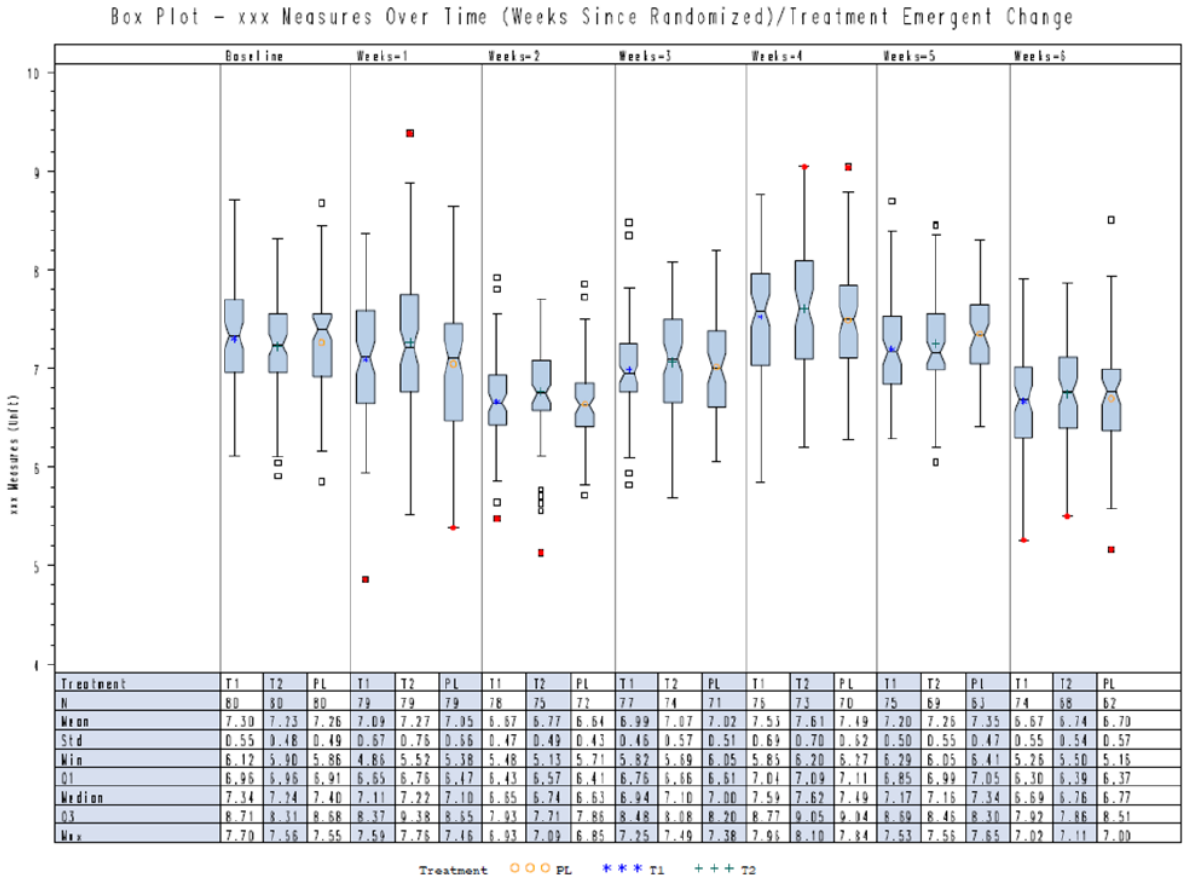


Previous PhUSE Research and Application: Example



Treatment	T1	T2	PL	T1	T2	PL	T1	T2	PL	T1	T2	PL	T1	T2	PL	T1	T2	PL	T1	T2	PL
N	80	80	80	79	79	79	78	75	72	77	74	71	75	73	70	75	69	63	74	68	62
Mean	7.30	7.23	7.26	7.09	7.27	7.05	6.67	6.77	6.64	6.99	7.07	7.02	7.53	7.61	7.49	7.20	7.26	7.35	6.67	6.74	6.70
Std	0.55	0.48	0.49	0.67	0.76	0.66	0.47	0.49	0.43	0.46	0.57	0.51	0.69	0.70	0.62	0.50	0.55	0.47	0.55	0.54	0.57
Min	6.12	5.90	5.86	4.86	5.52	5.38	5.48	5.13	5.71	5.82	5.69	6.05	5.85	6.20	6.27	6.29	6.05	6.41	5.26	5.50	5.15
Q1	6.96	6.96	6.91	6.55	6.75	6.47	6.43	6.57	6.41	6.75	6.66	6.61	7.04	7.09	7.11	6.85	6.99	7.05	6.30	6.39	6.37
Median	7.34	7.24	7.40	7.11	7.22	7.10	6.65	6.74	6.63	6.94	7.10	7.00	7.59	7.62	7.49	7.17	7.16	7.34	6.69	6.76	6.77
Q3	8.71	8.31	8.68	8.37	9.38	8.65	7.93	7.71	7.86	8.48	8.08	8.20	8.77	9.05	9.04	8.69	8.46	8.30	7.92	7.86	8.51
Max	7.70	7.56	7.55	7.59	7.76	7.46	6.93	7.09	6.85	7.25	7.49	7.38	7.96	8.10	7.84	7.53	7.56	7.65	7.02	7.11	7.00

Box plot type=schematic, the box shows median,interquatile range (IQR, edge of the bar), min and max within 1.5 IQR below 25% and above 75% (ends of the whisker).
Values outside the 1.5 IQR below 25% and above 75% are shown as outliers. Means plotted as different symbols by treatments. Red dots indicate out of normal reference range measures.

	Treatment Emergent High			
Treatment Group	N	n	%	P value
T1	xxx	xxx	xx.x	.xxx
T2	xxx	xxx	xx.x	.xxx
PL	xxx	xxx	xx.x	

Outside the box

Outside the box

- Dynamic summary report
- Standard structure deliveries
- Standard indication specific outputs

Breaking the Mold - Clinical Trials Data as Resource Description Framework (RDF) (Williams & Oliva, 2017).

From Data to Knowledge - Semantics and Implementations (Goud, 2015).

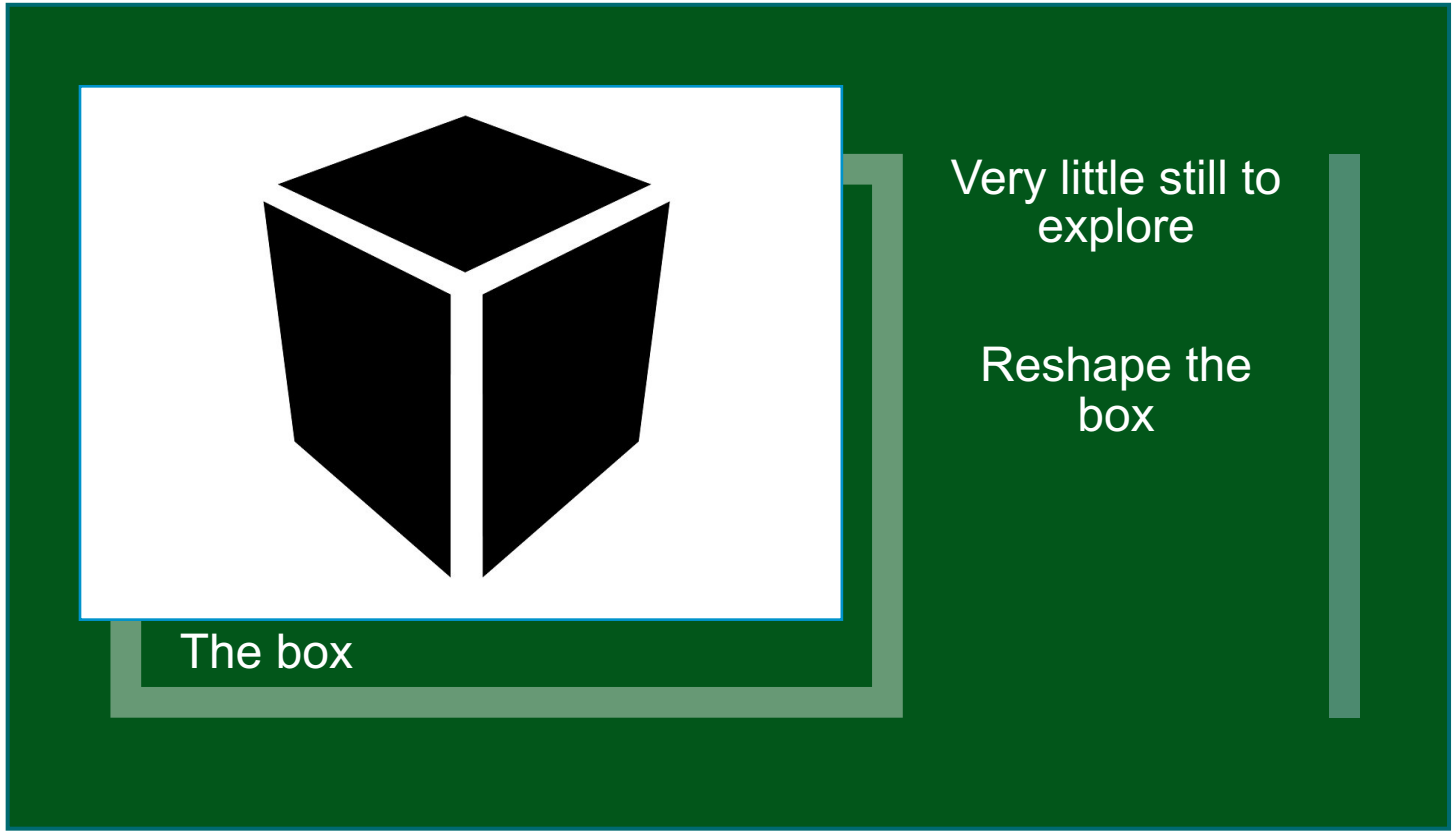
Outside the box

- New age pharmaceutical data scientist
- Going digital

Future Drug Applications with No Tables, Listings and Graphs (Langendorf, 2015).

Conclusion

Conclusion



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