PharmaSUG Single Day Event
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Effective Data Visualization for Decision-Making

Leveraging of Data Visualization in Eli Lilly

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Agenda

- Introduction
- Examples
  - Time course plot
  - Volcano Plot
  - Motion Graphics
- Conclusion

Introduction

Data Review

Data Readout

Submission

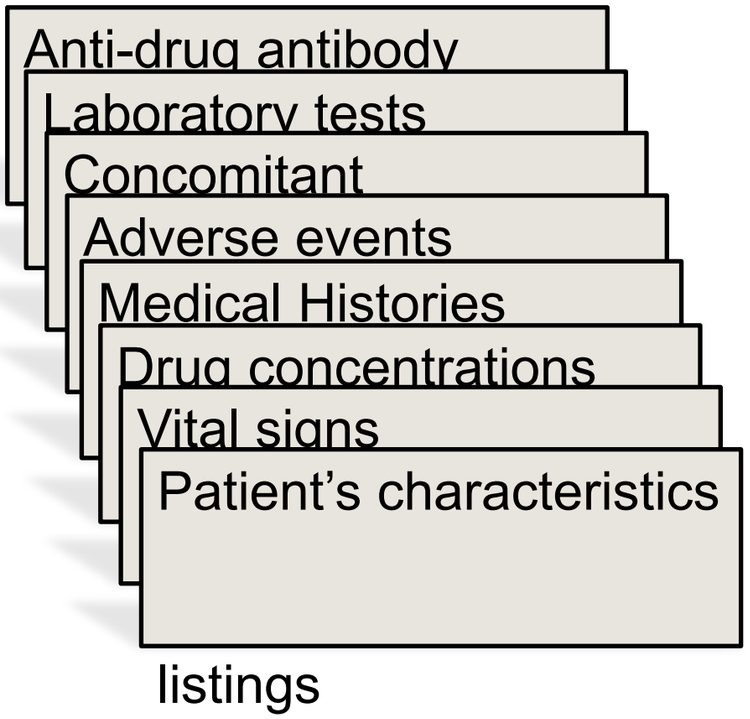
Publication

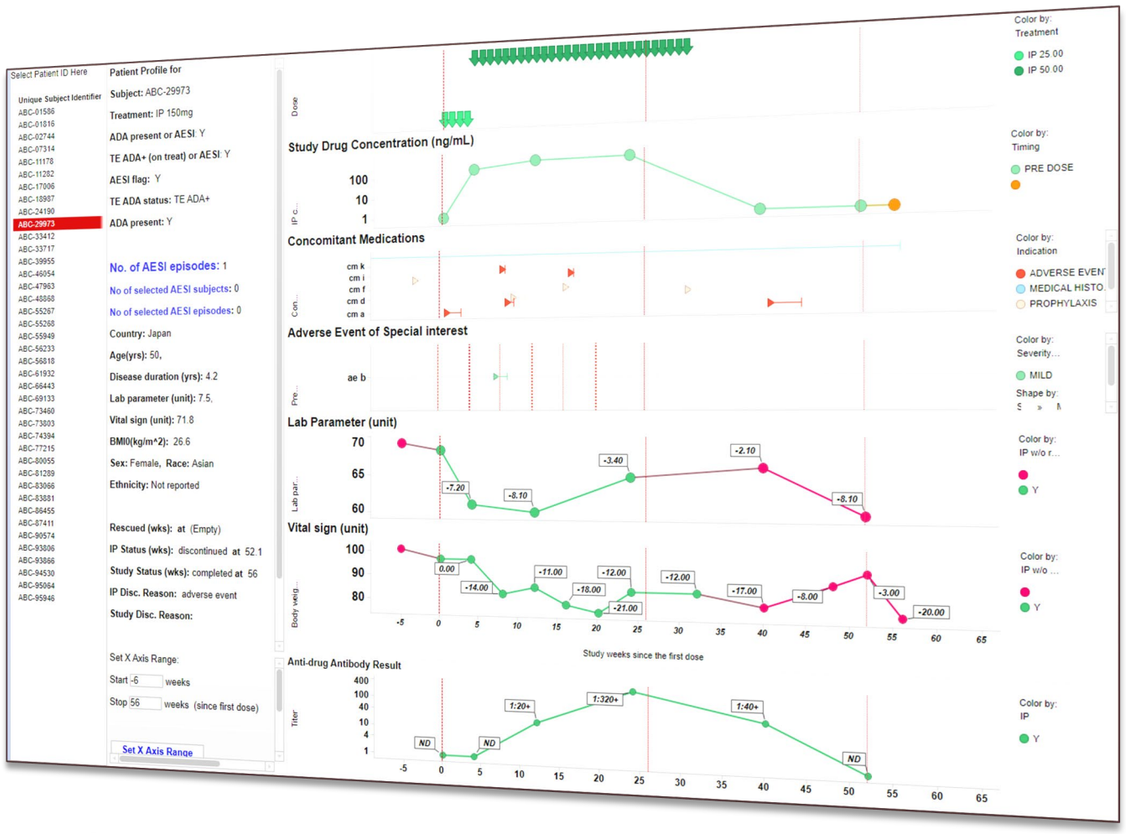
Data Visualization

Goal

- identify insight at the speed of thought
- Make data memorable

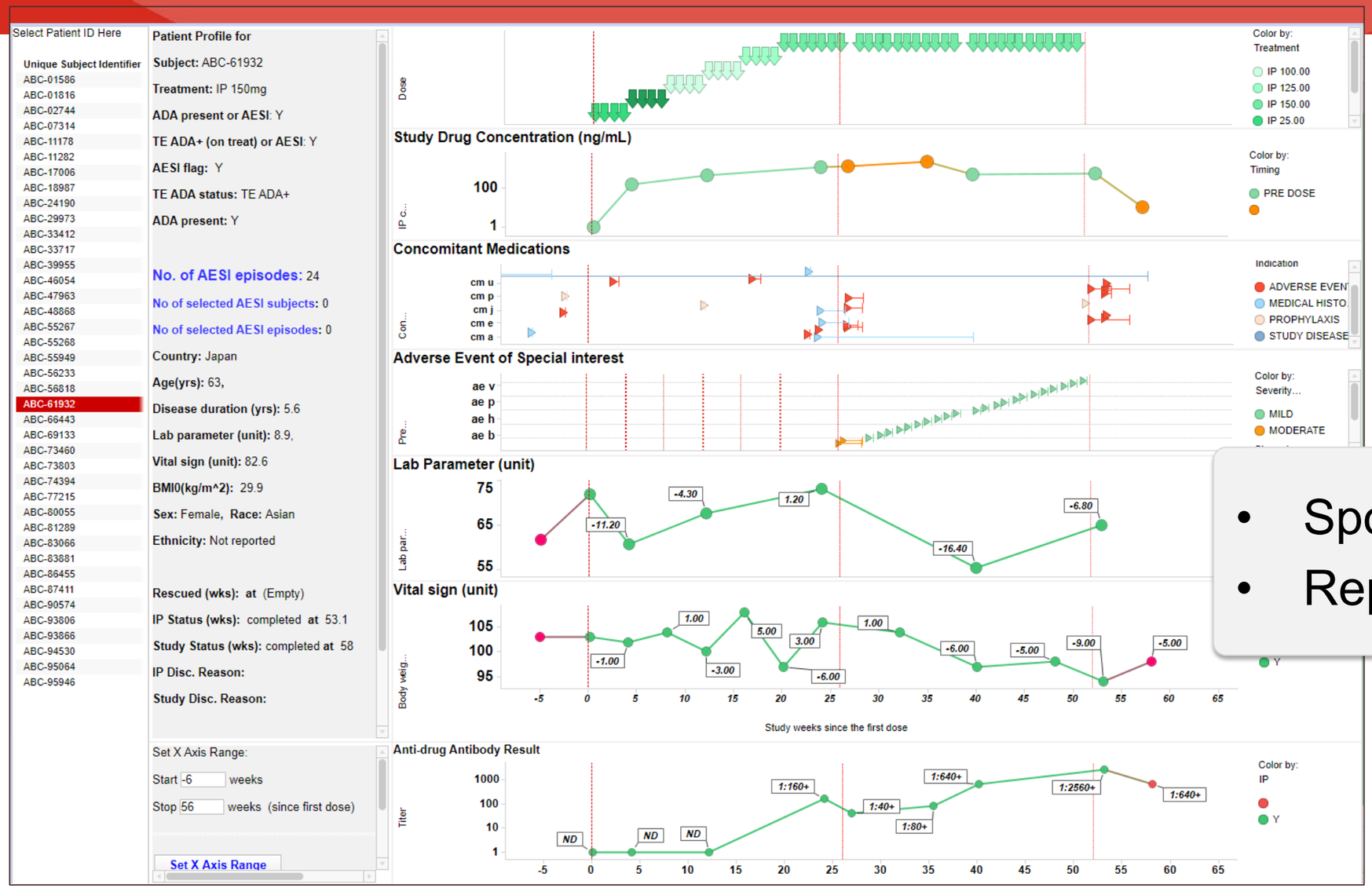
Example 1 - Time course plot





- Endpoints assess with relevant data domains
- A simple listing is difficult to access multiple data domains at the same time

Time course plot – Patient Profile



- Spotfire with Python
- Replicate programming

Time course plot – Benefits

- Data assessment
  - Enables us to observe time-dependent change by each subject within one view
  - Enables a thorough assessment within an individual subject across multiple data domains
  - Accelerates data interpretation

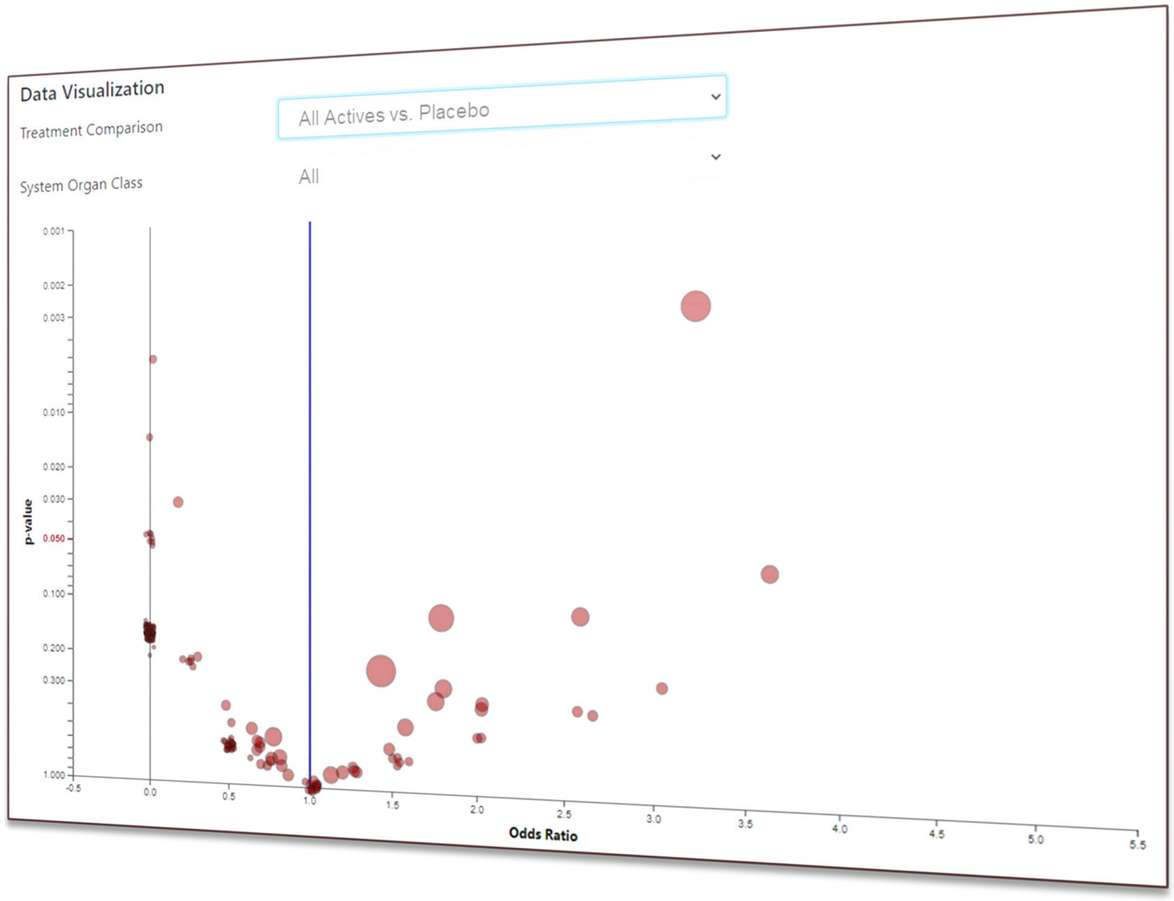
- Resource
  - Saves time to access information from multiple data domains

Example 2 - Volcano Plot

System organ class Preferred term	PBO (N=245) n (%)	Active M (N=256) n (%)	Active H (N=267) n (%)	Any Active (N=523) n (%)	Total (N=768) n (%)
Patients with >=1 TEAE	138 (46.9%)	162 (55.7%)	163 (57.6%)	325 (56.6%)	463 (53.3%)
Infections and infestations	46 (15.6%)	77 (26.5%)	66 (23.3%)	143 (24.9%)	189 (21.8%)
Nasopharyngitis	15 (5.1%)	24 (8.2%)	17 (6.0%)	41 (7.1%)	56 (6.5%)
Upper respiratory tract infection	9 (3.1%)	19 (6.5%)	12 (4.2%)	31 (5.4%)	40 (4.6%)
Pharyngitis	4 (1.4%)	6 (2.1%)	6 (2.1%)	12 (2.1%)	16 (1.8%)
Bronchitis	3 (1.0%)	4 (1.4%)	3 (1.1%)	7 (1.2%)	10 (1.2%)
Diarrhoea infectious	0	1 (0.3%)	5 (1.8%)	6 (1.0%)	6 (0.7%)
Oral herpes	4 (1.4%)	4 (1.4%)	2 (0.7%)	6 (1.0%)	10 (1.2%)
Urinary tract infection	0	2 (0.7%)	3 (1.1%)	5 (0.9%)	5 (0.6%)
Sinusitis	2 (0.7%)	3 (1.0%)	2 (0.7%)	5 (0.9%)	7 (0.8%)
Gastroenteritis	0	3 (1.0%)	2 (0.7%)	5 (0.9%)	5 (0.6%)
Respiratory tract infection	0	3 (1.0%)	2 (0.7%)	5 (0.9%)	5 (0.6%)
Tonsillitis	2 (0.7%)	2 (0.7%)	2 (0.7%)	4 (0.7%)	6 (0.7%)
Rhinitis	0	2 (0.7%)	2 (0.7%)	4 (0.7%)	4 (0.5%)
Vulvovaginal candidiasis	1 (1.1%)	1 (1.2%)	0	1 (0.6%)	2 (0.7%)
Bacterial vaginosis	0	1 (1.2%)	0	1 (0.6%)	1 (0.4%)
Bartholinitis	0	1 (1.2%)	0	1 (0.6%)	1 (0.4%)
Conjunctivitis	3 (1.0%)	1 (0.3%)	2 (0.7%)	3 (0.5%)	6 (0.7%)
Influenza	1 (0.3%)	1 (0.3%)	2 (0.7%)	3 (0.5%)	4 (0.5%)
Gastroenteritis viral	0	2 (0.7%)	1 (0.4%)	3 (0.5%)	3 (0.3%)
Fungal skin infection	0	3 (1.0%)	0	3 (0.5%)	3 (0.3%)
Gastroenteritis bacterial	1 (0.3%)	1 (0.3%)	1 (0.4%)	2 (0.3%)	3 (0.3%)
Furuncle	0	1 (0.3%)	1 (0.4%)	2 (0.3%)	2 (0.2%)

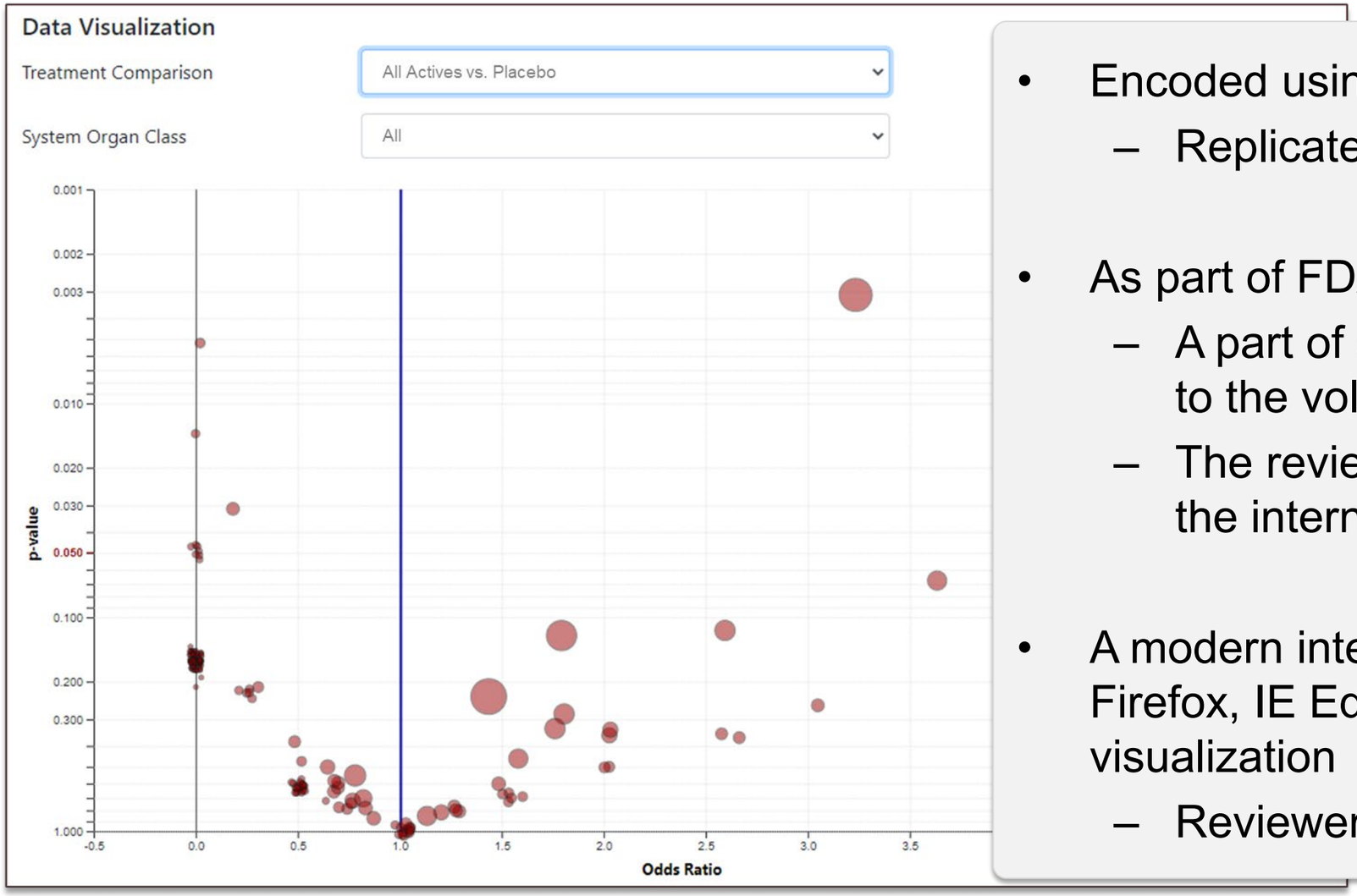
Abbreviations: PBO = Placebo; N = number of patients in the analysis population; n = number of patients with at least one treatment-emergent adverse event (TEAE) in the specified category; TEAE = treatment-emergent adverse event.

Note: Percentage is calculated by n/N*100%.



- Summary table of AE by SOC/PT
- Many pages AE table into one place

Volcano Plot



- Encoded using HTML, CSS and JavaScript
  - Replicate programming using R markdown
- As part of FDA pilot project
  - A part of submission document (Reference to the volcano plot with a hyperlink)
  - The reviewer did not need to connect to the internet
- A modern internet browser (e.g., Chrome, Firefox, IE Edge) was used for the interactive visualization
  - Reviewers used his/her default browser

Volcano Plot - Benefits

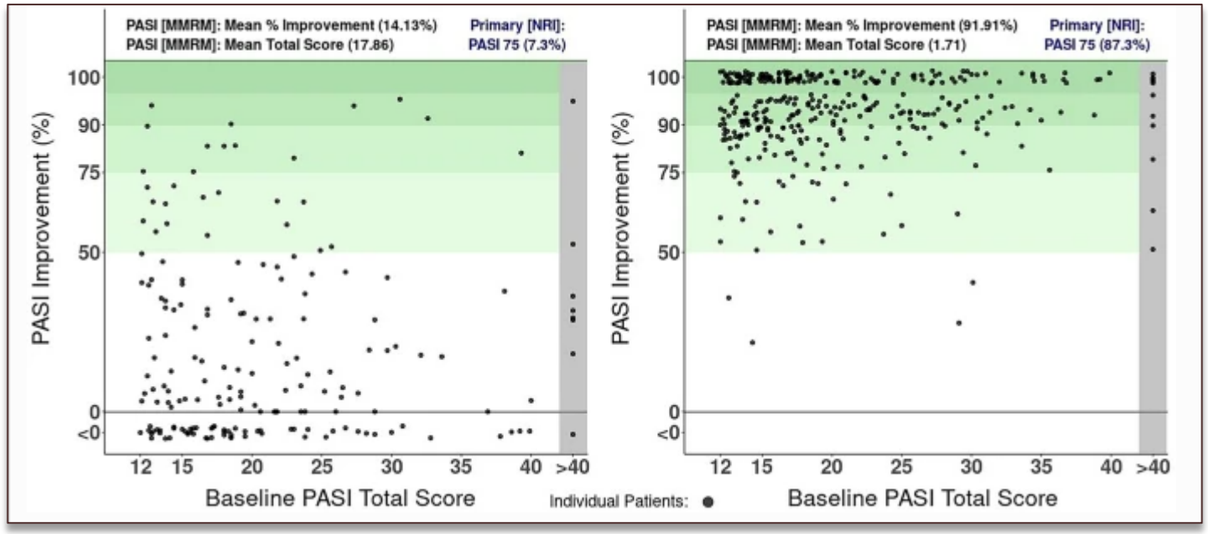
- Data assessment
  - Allows the reader to visually see AEs in one page
  - Allows for additional review flexibility
    (via drop down menus with different viewing options)
  - Combines an assessment of strength of evidence
    - Imbalance between the treatment group and placebo
      (via p-values)
    - Magnitude of the estimated effect (via odds ratios)

Example 3 - Motion Graphics

- Complex summaries of statistical analysis
- An individual data with statistical analysis summary

Individual subject data

Complex data from statistical analysis summary



Hawkes, J.E., See, K., Burge, R. et al. Dermatol Ther, 2021; 11, 1107–1118 https://doi.org/10.1007/s13555-021-00548-2

- Embedded graphics in web-based publication
- R software (including R shiny) for the motion graphics
- Validated graphics data to draw animations

Motion Graphics - Demo (1)

Dynamic Visual Representation of Clinical Efficacy of Ixekizumab in Psoriasis

A Video

Hawkes, J.E., See, K., Burge, R. et al. Dermatol Ther, 2021; 11, 1107–1118 https://doi.org/10.1007/s13555-021-00548-2

Motion Graphics - Demo (2)

Dynamic Visual Representation of Clinical Efficacy of Ixekizumab in Psoriasis

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Motion Graphics - Benefits

- Data interpretation
  - Simplifies complex data from clinical trial
  - Highlights both aggregate and individual response rates from study treatment
  - Shows the indirect comparison of relative treatment effects
  - Can be used to identify meaningful aspects of clinical trial data

Hawkes, J.E., See, K., Burge, R. et al. Dermatol Ther, 2021; 11, 1107–1118 https://doi.org/10.1007/s13555-021-00548-2

Conclusion

- Data visualization
  - Opens a new dimension of data review compared to a simple listing
  - Makes data memorable
  - Helps communicate about message of data
  - Accelerates the next action after decision-making based on data
- Point to note
  - Do not exaggerate/misuse