



Exploratory Review

**People Powered Pathways to
success within a Critical Risk
based approach.**

Simon Jackson,
Principal Clinical Data Scientist Lead
Data Operations, ICON Biotech Solutions

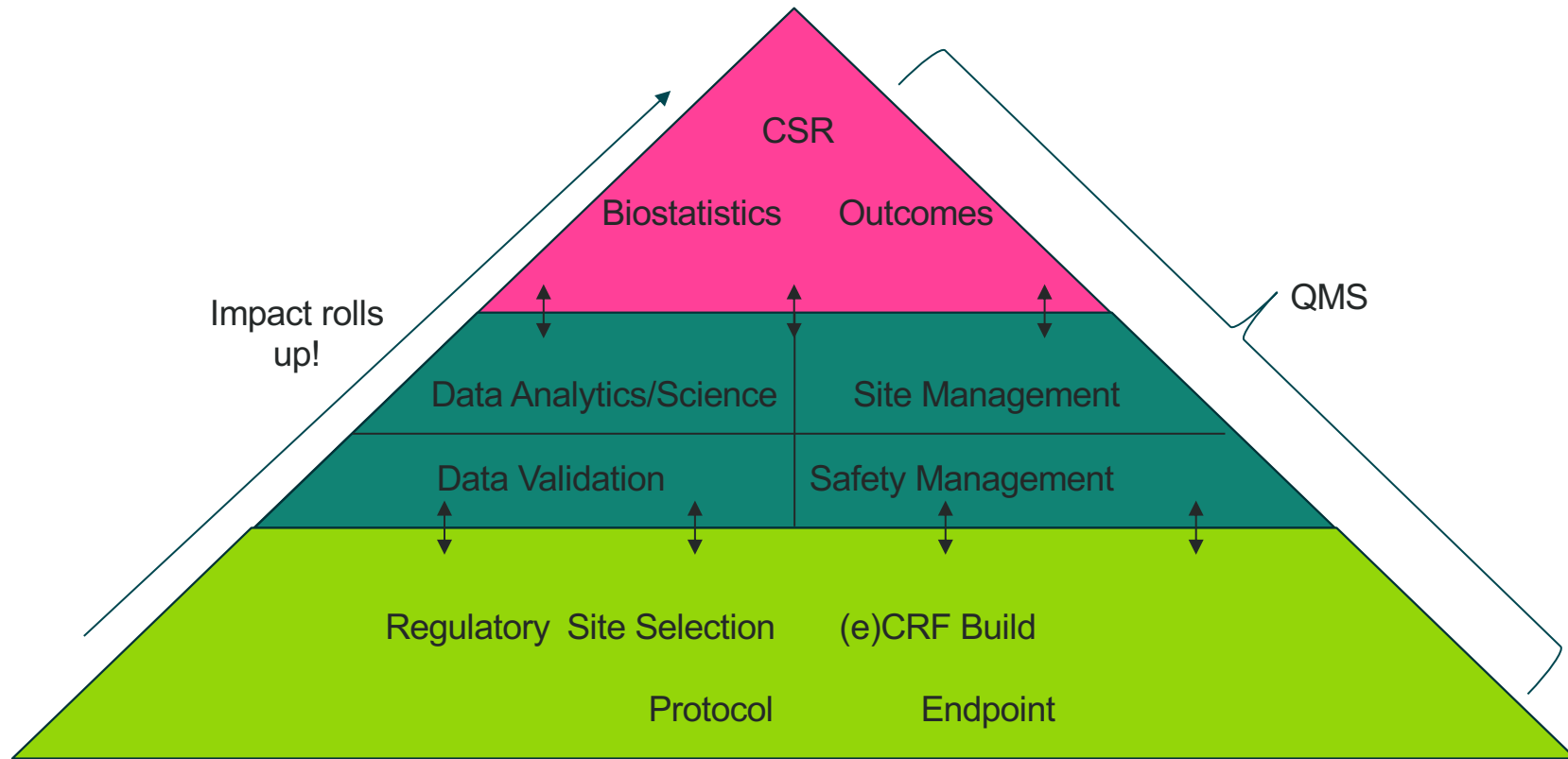
Simon.Jackson@iconplc.com



Agenda

- Context
- Definitions + Risks
- Optimum Scenarios
- Factors for success
- Outcomes of exploratory review
- Sample Outputs

Clinical Trials Quality Pyramid



Purpose & Definitions

Purpose

- **Surface undiscovered risks**
- **Gain insights and confirm a narrative about study conduct**

Definition:

- **A set of analyses/analytics used to investigate data wherein an issue has not yet been clearly defined**

Definition Refined

Yes

- Open Format
- Risk Driven
- Creation and interpretation of *unvalidated* outputs

No

- An excuse to use unvalidated outputs for ongoing risk mitigation

Unvalidated Outputs & Risk Mitigation

Exploratory outputs are:

Flexible, risk driven outputs produced in realtime

- Can't make a decision about trial conduct
- We can validate “general purpose” analytics ie % compliance of all assessments at site
- We can validate a listing / data dump
- We can train and get experienced personnel
- We can utilise the potential insights to *investigate* & **confirm** by other means
 - Follow up via queries to get clarifications
 - Follow up via remote Site contact/onsite visit

Optimum scenarios for best results



- + Essential for Reduced SDV scenarios
- + Well suited to large trials with multiple subjects at site (expected avg of >5 sbjs per site) across multiple territories
 - + Larger Phase 2/3/4
 - + RWS?
- Trends may be more difficult to see on smaller phase I



Factors For Success

Prerequisites For Success



Study Team

Forum to
discuss
Experience
Knowledge



Risk Assessment



Critical Thinking



Data

Source

Volume



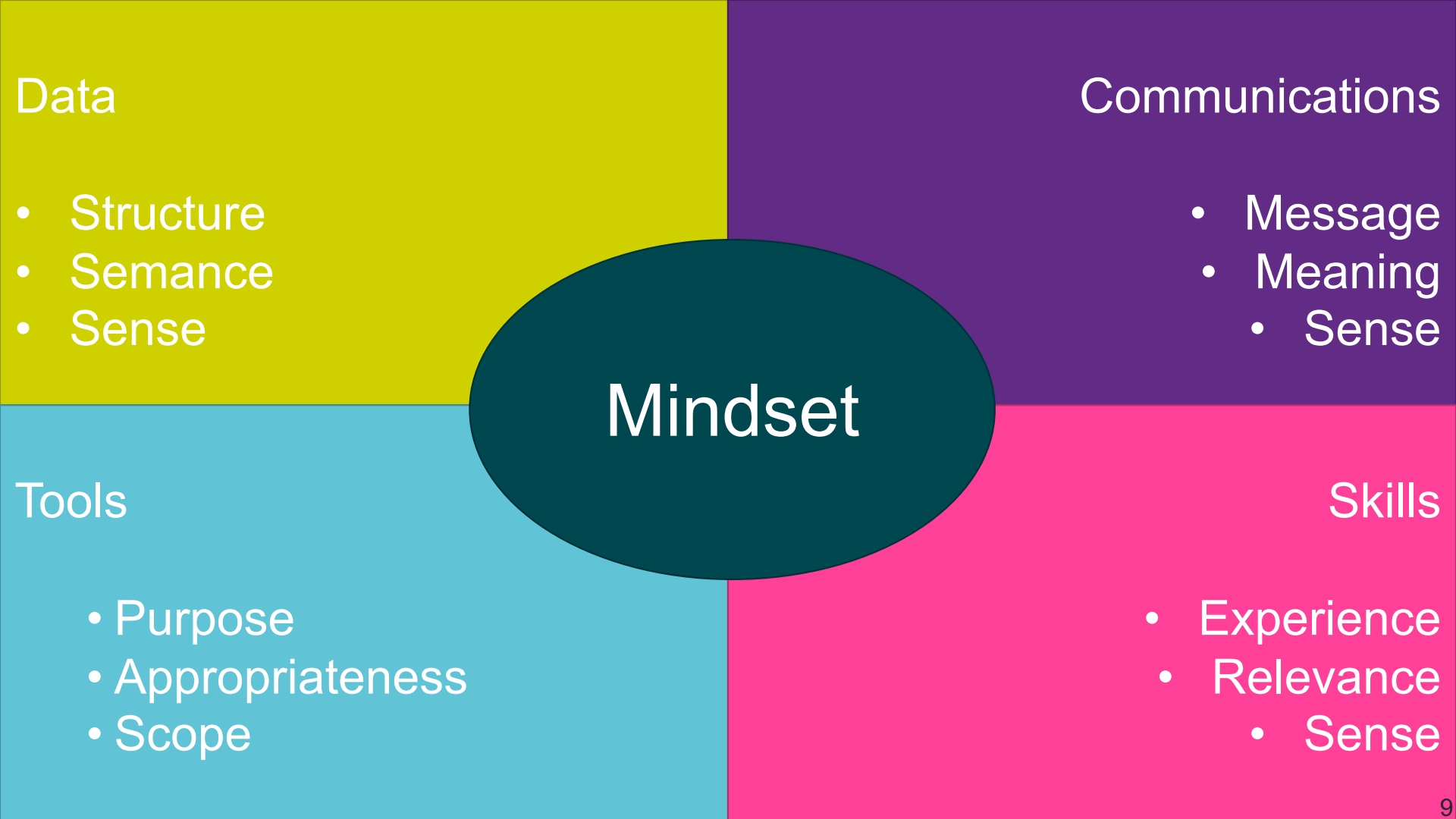
Documented
framework

Review
processes
Tools



Analytics
Tool

Training +
Experience



Critical Thinking

Critical Approach

Think like an Auditor:

- What
- Where
- When
- How
- Why
 - **Why**
 - **Why**
 - **Why**
 - **Why**

Critical Approach...Critical Data

- Understand your critical data
 - Subject Safety
 - Primary /Secondary Endpoint
 - What is the sought *outcome*
- Assess + Document Critical factors for trial success
- Be mindful of potential “rabbit holes” when assessing non-critical data

Outcomes



Platform For Discussion

Discussion
Action logging
Minutes



Follow up in a system of record

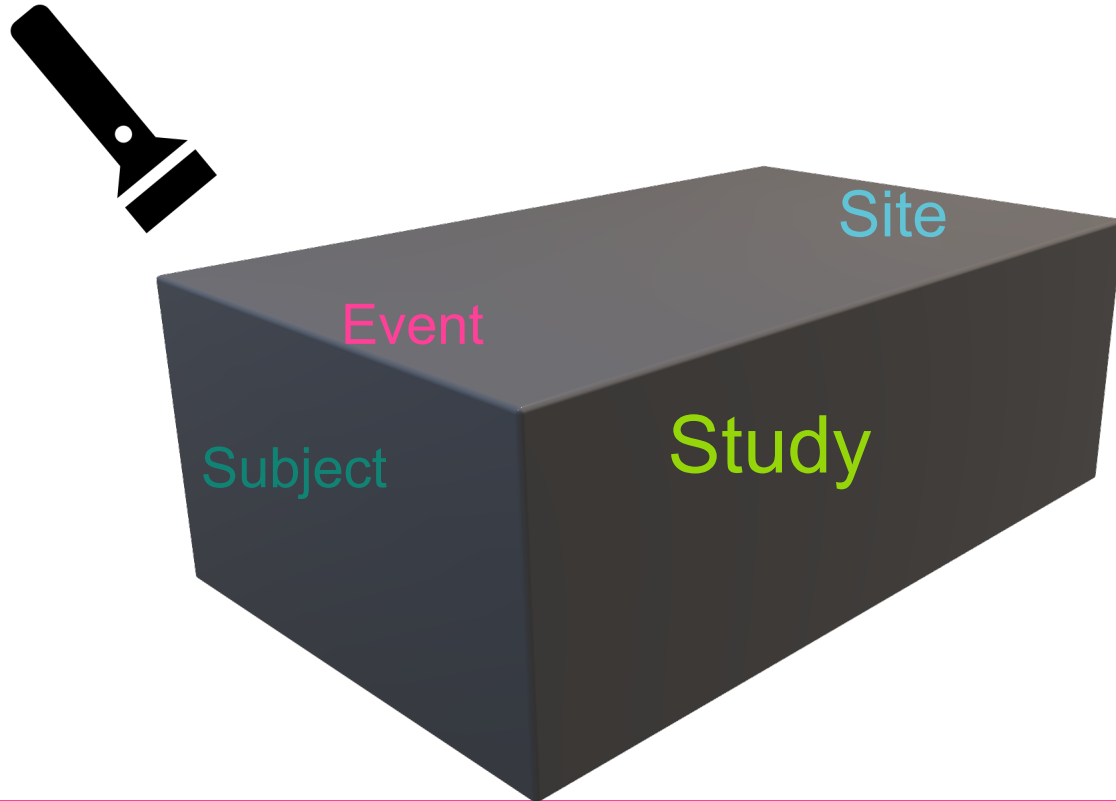
Demonstrate FU as result of
centralised review
Document resolution



Pathway for validation

Encourage validation of critical
analyses

Exploration Hierarchy



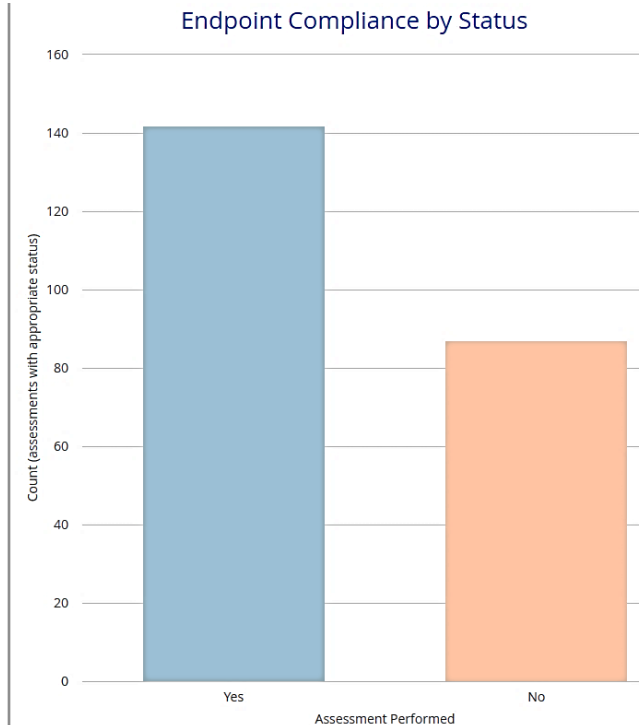
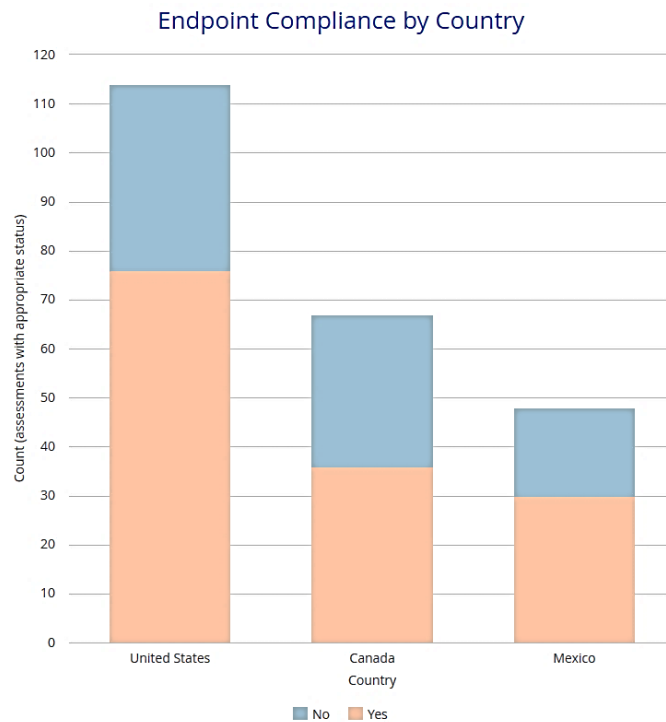


Example Visualisations

Bar Charts

Great for Compliance analysis!

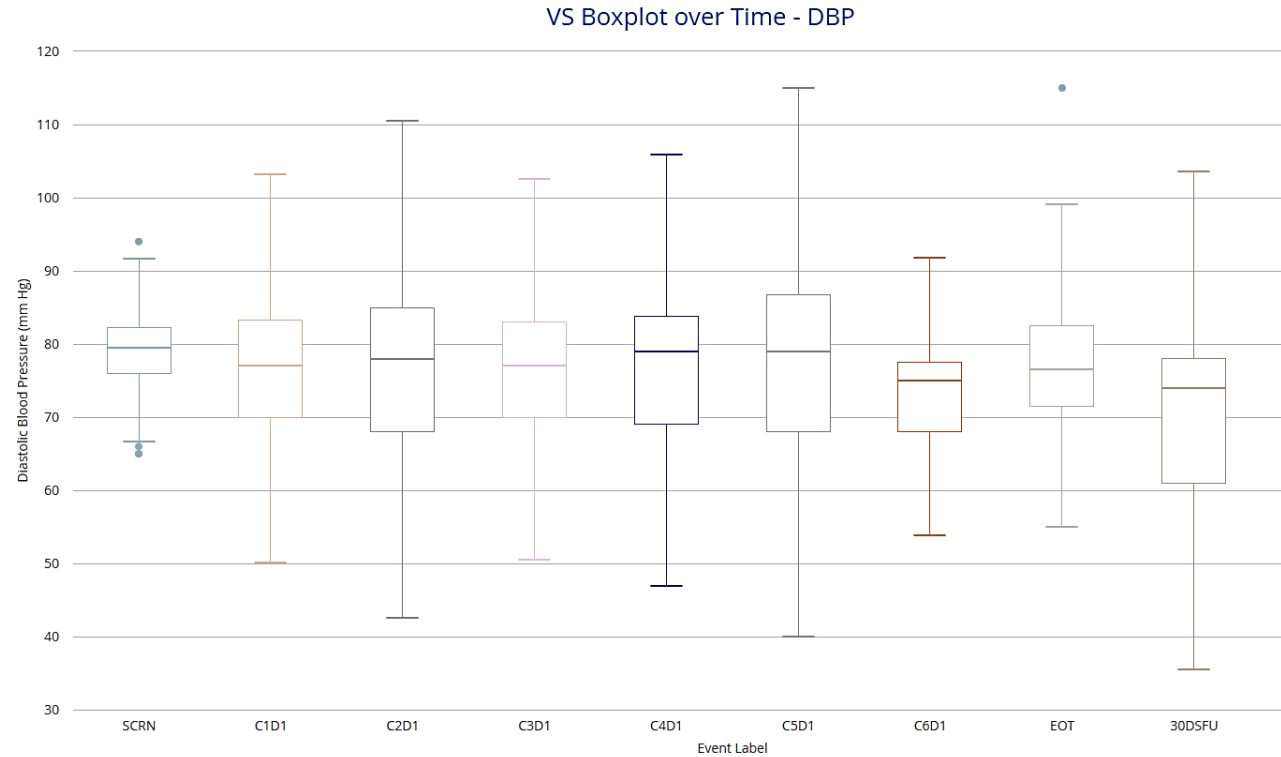
- Simple way to show proportional data values across a number of parameters





Box Plot

Great to show spread of numerical data
Able to see outliers clearly

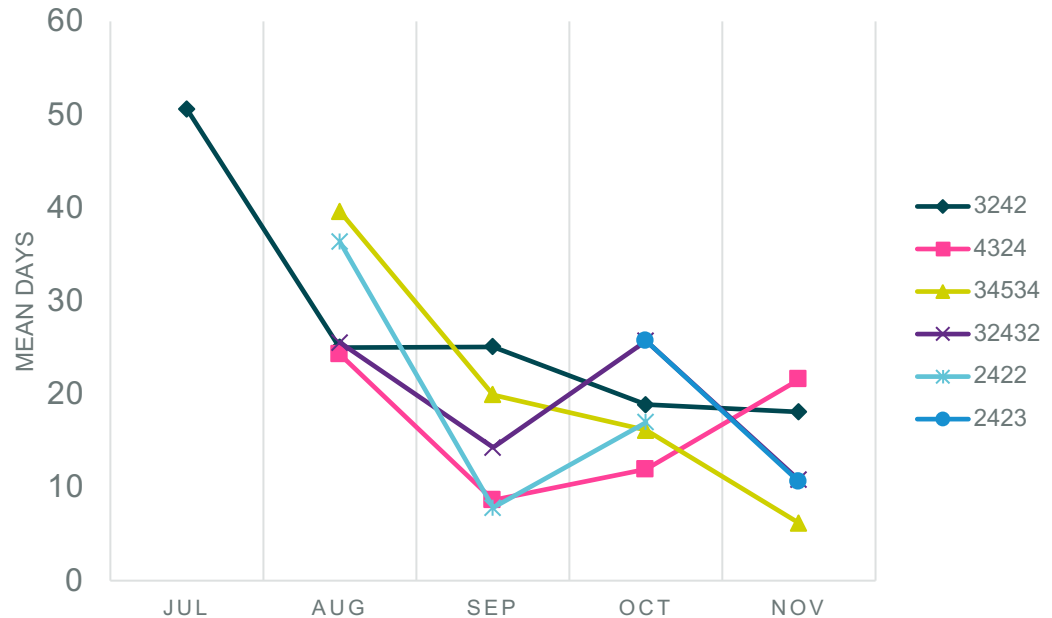


Line Charts

Excellent for (aggregate) Numerical data over time

- Absolute or relative time

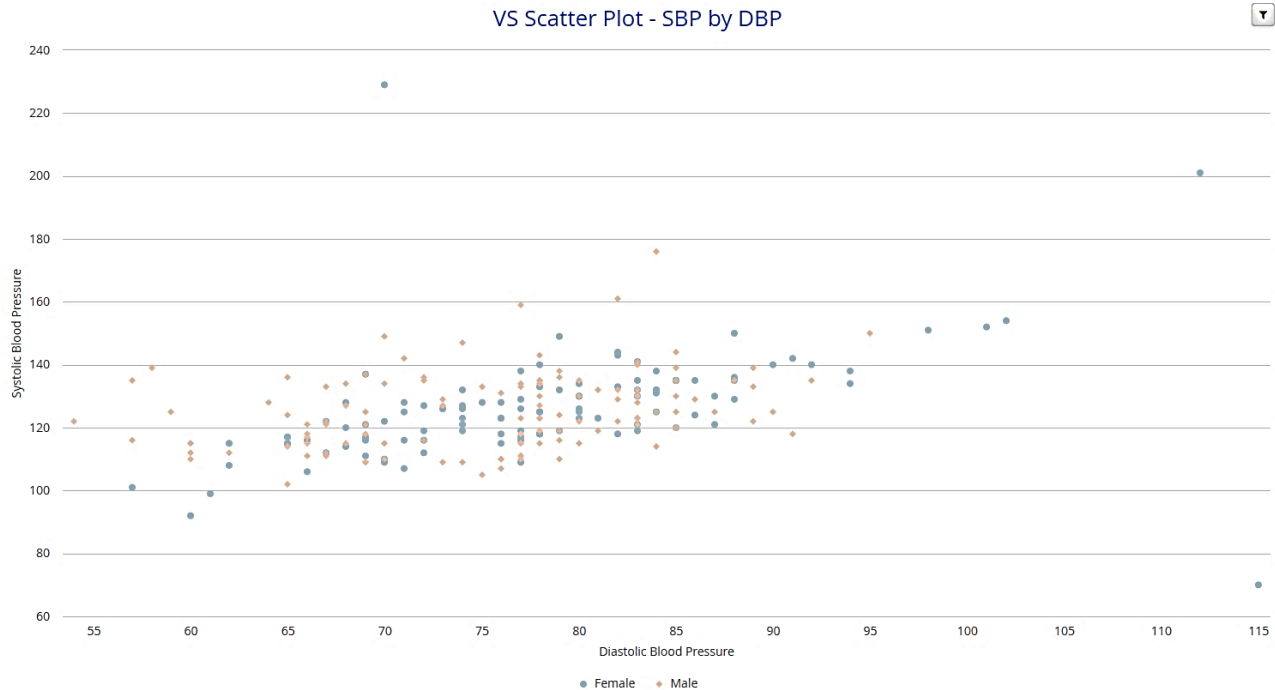
MEAN TIME TO DATA ENTRY BY SITE PER MONTH



Scatter Plot

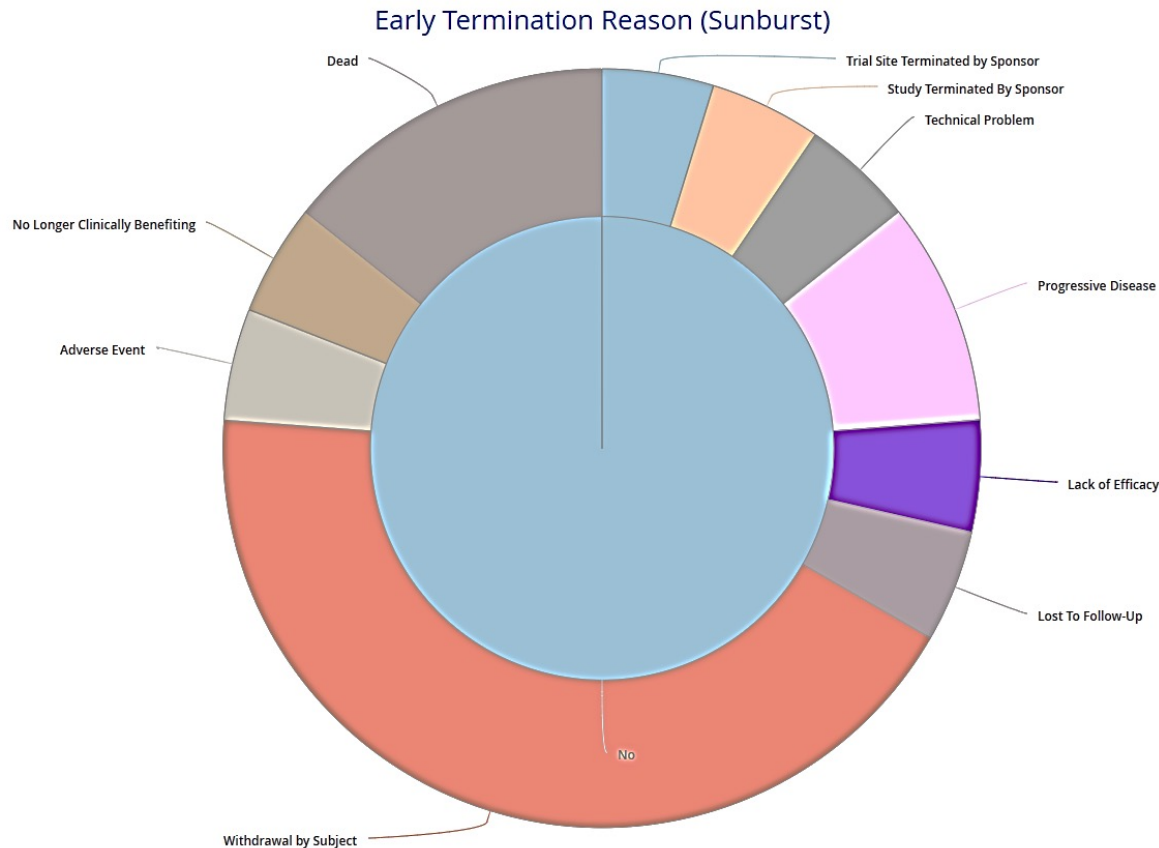
Really useful for (numerical values):

- Seeing trends in linked data
- Assessing spread of results
- Potentially able to quickly spot duplicate data
- Potentially able to see outliers



Sunburst/Pie chart

- Great for multi tiered data with a small number of divisions
- Great way to summarise dispositional data





Thanks for Listening

Q & A



ICONplc.com

© 2022 ICON. All rights reserved.