



SPA MDR CDR SCE

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Harnessing the Power of R Shiny in a GxP compliant and validated manner for clinical trials use

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- 14+ years in Study Start-Up, Study Conduct, and Close-out of Clinical Trials
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Agenda

1. The Versatility of R
2. Shiny & Data Visualization in Clinical Trials
3. Data Visualization in a GxP-Compliant Environment
4. Conclusion
5. Case Study

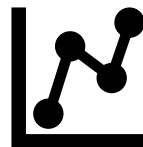


The Versatility of R



Statistical Computing

R provides a wide range of statistical tests, models and algorithms for data analysis and scientific research.



Data Visualization

R's extensive visualization libraries, such as ggplot2, allow users to create high quality, customizable plots and graphs for effective presentation.



Data Analysis

R offers powerful data manipulation and transformation tools, making it easy to clean, explore, and gain insights from complex datasets.

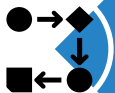


Academia and Industry

R is widely adopted in both academic and industrial settings, making it a valuable tool for researchers, data scientists, and business analysts.



Shiny & Data Visualization in Clinical Trials



Real-Time Data Monitoring



Enhanced Decision-Making Through Predictive Analytics



Centralized Data Access and Visualization



Customizable Visualizations for Diverse Stakeholders



Facilitating Cross-Functional Collaboration



Shiny & Data Visualization in Clinical Trials



Improved Risk Management



Scalability for Large, Multicenter Trials



Post-Trial Analysis and Efficient Results Dissemination



Cost Efficiency



**Data
Visualization
in a
GxP-Compliant
Environment**



Validation of Software and Packages



Support for the Entire Programming Lifecycle



Data Integrity and Security



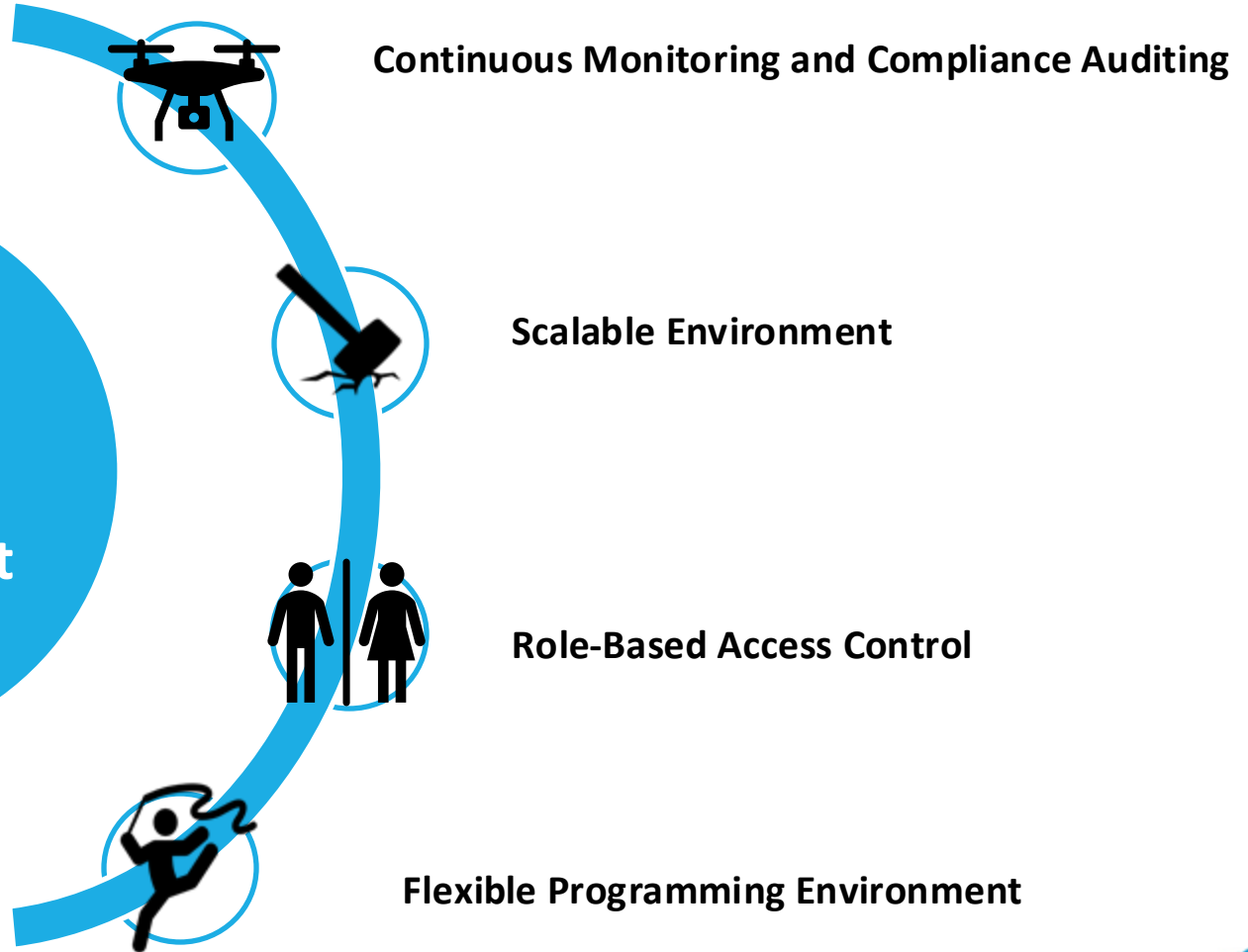
Audit Trails and Compliance with 21 CFR Part 11



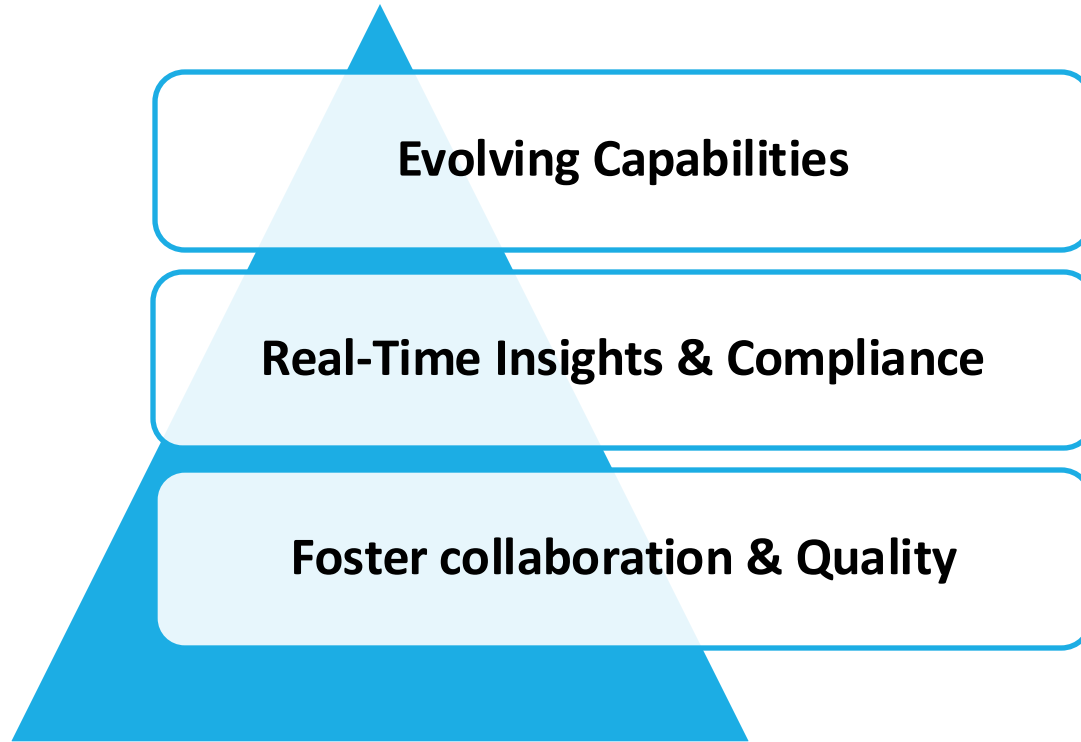
Support for Submission Preparation



**Data
Visualization
in a
GxP-Compliant
Environment**



Conclusion



Case Study

A mid-sized pharmaceutical company conducting a Phase III clinical trial for a new cardiovascular drug needs to analyze and present complex clinical trial data, including demographics, medical history, summary of concomitant medications (conmed) being used for the medical history, for 1,500 subjects. Traditional methods of data analysis are time-consuming and fail to provide clear insights.

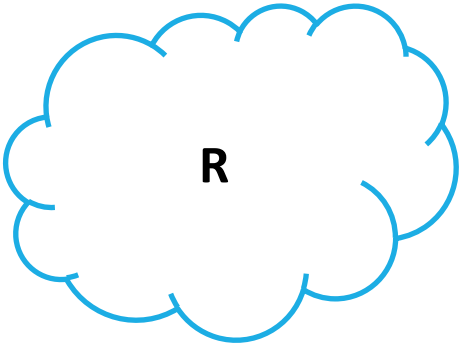


Problems with the Traditional Approach

- 1. Data Complexity:** The dataset includes a variety of variables, such as age, gender, ethnicity, medical conditions, and concomitant medications (conmed), all of which need to be analyzed and presented in a digestible format.
- 2. Time Constraints:** The research team is under tight deadlines to analyze the data and prepare reports for regulatory submissions and internal decision-making. Traditional methods often lead to delays in generating meaningful insights.
- 3. Communication Gaps:** Static tables and lengthy reports make it difficult to effectively communicate key findings to different stakeholders, including clinical researchers, regulators, and executive teams. Important insights often get lost in the details of large datasets.



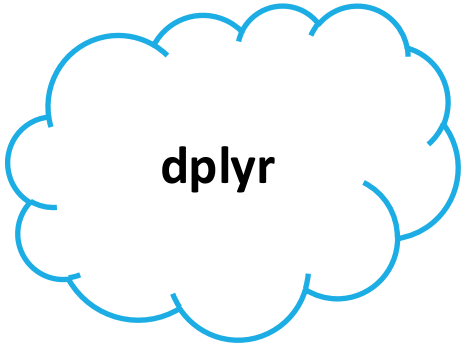
The Solution: Interactive and Static Visualizations



R



Shiny



dplyr



Highcharter



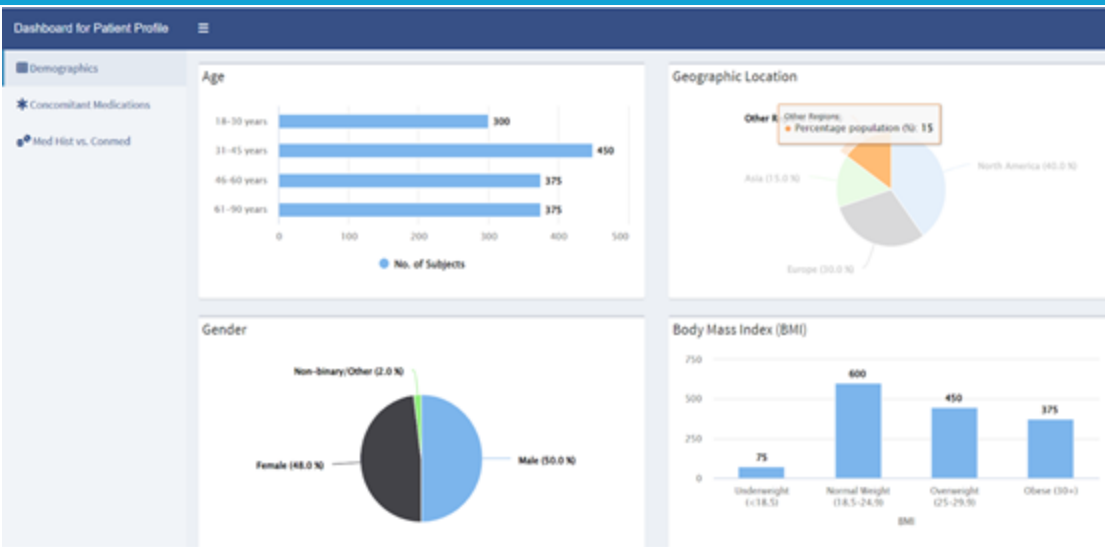
Outcome: Overview of Demographic Data



Main Audience for Clinical Trial Demographics Data Visualizations: Regulatory Agencies, Sponsors, Clinical Research Investigators, Clinicians, Patient and Advocacy Groups, Investors & Stakeholders



Key demographic variables often visualized include age, gender, race, ethnicity, geographic location, BMI and other relevant factors.



By presenting demographic data visually, stakeholders can quickly grasp key insights, identify trends, and make informed decisions about the trial's design, execution, and applicability.

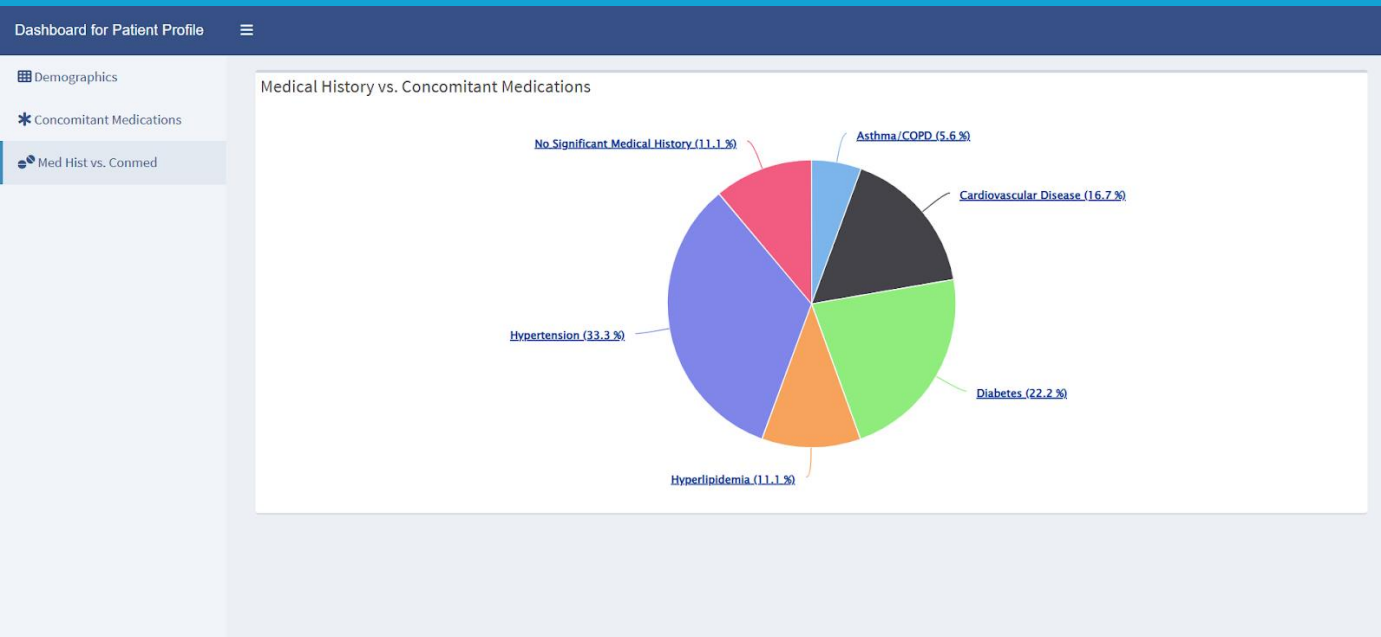


Outcome: Concomitant Meds used for Medical History



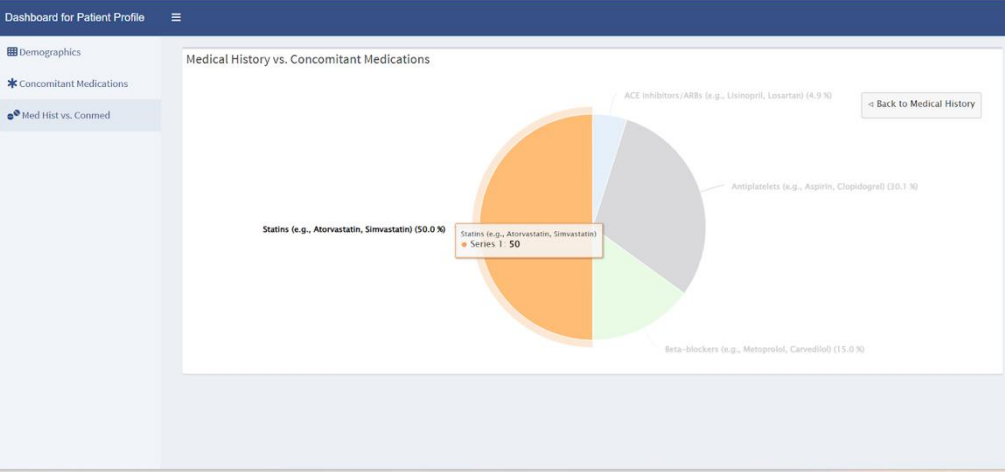
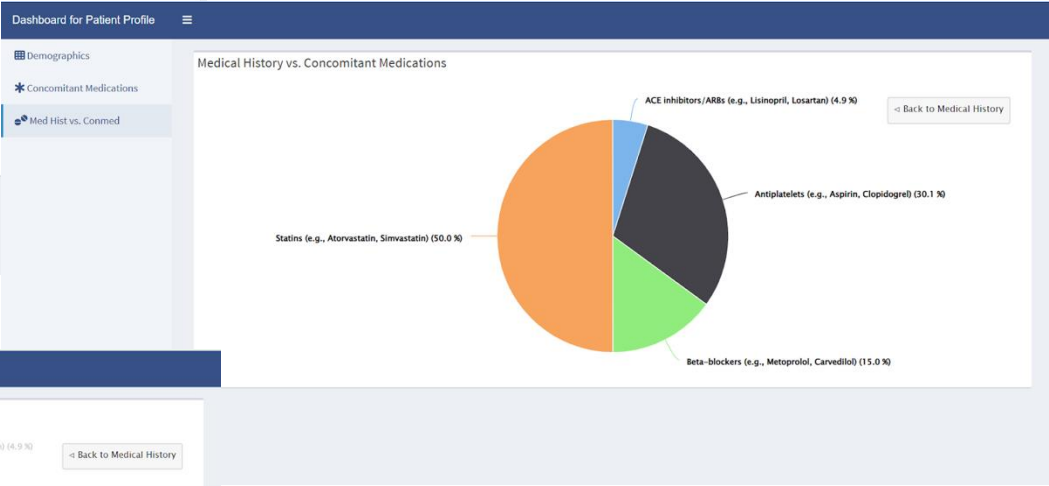
Main Audience for Concomitant Medications vs. Pre-existing Condition Data Visualizations: Regulatory Agencies, Data Safety Monitoring Board





By visualizing medical history versus concomitant medication data, stakeholders can gain a deeper understanding of the trial population, identify potential risks or confounding factors, and make informed decisions about the trial's design, execution, and applicability.





Thank you!



Appendix

Demographics		
Age Range (years)	Percentage population (%)	No. of Subjects
18–30 years	20	300
31–45 years	30	450
46–60 years	25	375
61–90 years	25	375
Gender	Percentage population (%)	No. of Subjects
Male	50	750
Female	48	720
Non-binary/Other	2	30
Geographic Location	Percentage population (%)	No. of Subjects
North America	40	600
Europe	30	450
Asia	15	225
Other Regions	15	225
Body Mass Index (BMI)	Percentage population (%)	No. of Subjects
Underweight (<18.5)	5	75
Normal Weight (18.5–24.9)	40	600
Overweight (25–29.9)	30	450
Obese (30+)	25	375



Appendix

Medical History		
Medical History	Percentage population (%)	No. of Subjects
Hypertension	30	450
Diabetes	20	300
Cardiovascular Disease	15	225
Hyperlipidemia	10	150
Asthma/COPD	5	75
No Significant Medical History	20	300



Appendix

Summary of Concomitant Medication Used for Medical History

Medical History	Concomitant Medication	Estimated % of Subjects	Estimated Number of Subjects
Hypertension	ACE inhibitors (e.g., Lisinopril, Enalapril)	40	180
Hypertension	Calcium channel blockers (e.g., Amlodipine, Diltiazem)	30	135
Hypertension	Beta-blockers (e.g., Metoprolol, Atenolol)	20	90
Hypertension	Diuretics (e.g., Hydrochlorothiazide, Furosemide)	10	45
Diabetes	Metformin	50	150
Diabetes	Sulfonylureas (e.g., Glipizide, Glyburide)	20	60
Diabetes	DPP-4 inhibitors (e.g., Sitagliptin, Saxagliptin)	15	45
Diabetes	Insulin	15	45
Cardiovascular Disease	Statins (e.g., Atorvastatin, Simvastatin)	50	113
Cardiovascular Disease	Antiplatelets (e.g., Aspirin, Clopidogrel)	30	68
Cardiovascular Disease	Beta-blockers (e.g., Metoprolol, Carvedilol)	15	34
Cardiovascular Disease	ACE inhibitors/ARBs (e.g., Lisinopril, Losartan)	5	11
Hyperlipidemia	Statins (e.g., Atorvastatin, Rosuvastatin)	70	105
Hyperlipidemia	Ezetimibe	20	30
Hyperlipidemia	PCSK9 inhibitors (e.g., Alirocumab)	10	15
Asthma/COPD	Inhaled corticosteroids (e.g., Fluticasone, Budesonide)	40	30
Asthma/COPD	Bronchodilators (e.g., Albuterol, Salmeterol)	40	30
Asthma/COPD	Leukotriene modifiers (e.g., Montelukast)	10	8
Asthma/COPD	Theophylline	10	8
No Significant Medical History	OTC Pain Relievers (e.g., Acetaminophen, Ibuprofen)	20	60
No Significant Medical History	Vitamins/Supplements (e.g., Multivitamins, Vitamin D)	15	45
No Significant Medical History	Antihistamines (e.g., Loratadine, Cetirizine)	10	30
No Significant Medical History	Proton Pump Inhibitors (e.g., Omeprazole)	5	15

