

Single Day Event

Leveraging Data Visualization for Strategic
Decision-Making in Liver Safety Monitoring

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Disclaimer

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Agenda

- **Why Visualization Matters**
- **Key Liver Biomarkers**
- **Understanding eDISH Plots**
- **Case Study Application**
- **Interpreting Quadrants**
- **Insights from eDISH**
- **Impact on Safety Protocols**
- **Decision-Making Challenges**
- **Future Visualization Practices**



Why Data Visualization Matters?



Spots Safety Issues Early



Makes Complex Data Clear



Tracks Trends Over Time



**Supports Faster Decisions
Submissions**



Improves Team Understanding



Strengthens Regulatory



Focuses on Key Signals



Enhances Data Review Meetings



Customizable to Trial Needs



Key Liver Biomarkers and Their Role in Clinical Monitoring



Bilirubin (BILI) :

- Waste Product from the breakdown of red blood cells
- Processed by the liver and excreted in bile
- Elevated BILI may signal **liver dysfunction or bile duct blockage**



Alanine Aminotransferase (ALT):

- Enzyme mainly found in liver cells
- Released into the blood when liver cells are damaged
- **Indicator of liver injury**



Key Markers for Liver Monitoring: BILI and ALT are crucial for tracking liver function.



Regular Monitoring: Frequent checks help catch liver issues early.



Treatment Decisions: Changes in markers can lead to adjusting or stopping treatment.



The eDISH Plot: Overview & Concept

What is eDISH?

eDISH (*electronic Drug-Induced Serious Hepatotoxicity*) is a **visual tool** used in clinical trials to monitor **liver safety**.

Understanding the Quadrants:

-  **Possible Hy's Law (Upper Right)** - High ALT & High Bilirubin
May indicate serious liver injury; needs investigation
-  **Hyperbilirubinemia (Upper Left)** - High Bilirubin, Normal ALT
May reflect non-liver causes
-  **Temple's Range (Lower Right)** - High ALT, Normal Bilirubin
Liver cell injury without serious liver dysfunction.
-  **Normal Range (Lower Left)** - ALT & Bilirubin within normal limits
No liver safety concerns



Case Study

Title: Early Identification of Liver Toxicity in a Phase III Anti-Inflammation Drug Trial



Overview

Drug: Investigational anti-inflammation drug

Phase: III

Duration: 12 months

Participants: 300+ patients

Tool Used: eDISH Plot (Evaluation of Drug-Induced Serious Hepatotoxicity)



Objectives

Primary Objective: Evaluate liver safety of the drug using biomarkers (ALT, bilirubin)

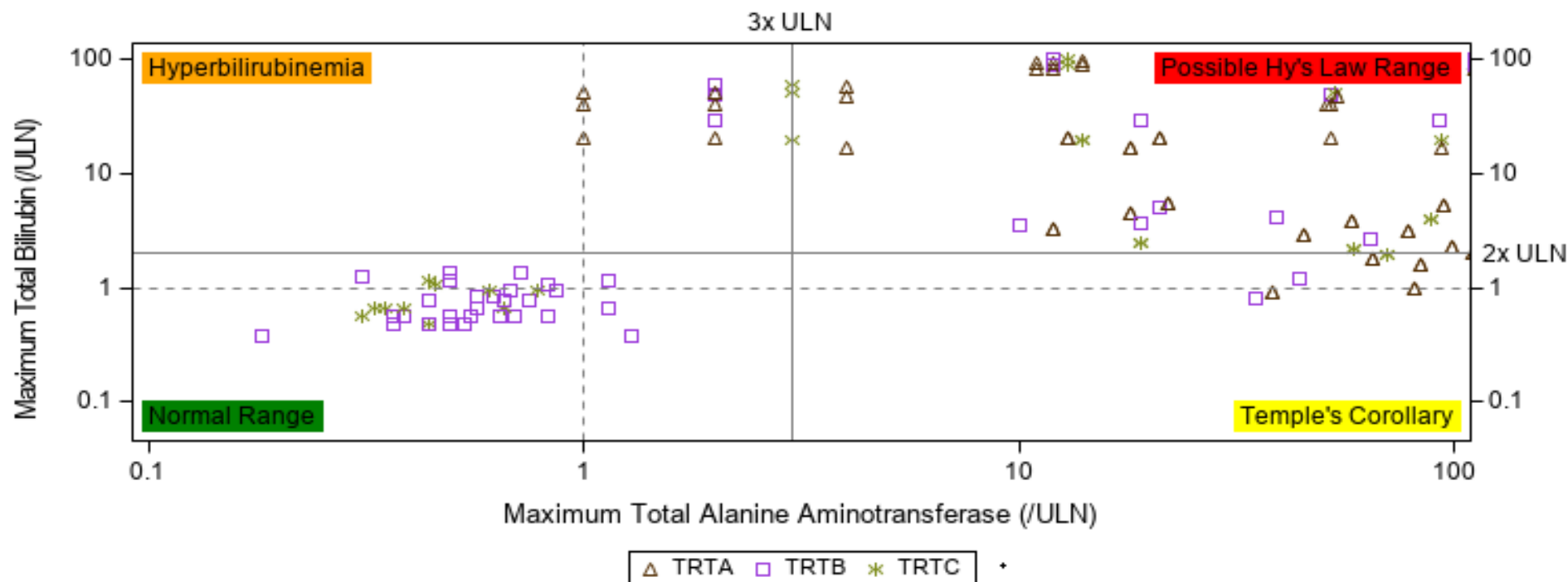
Secondary Objective: Identify early signs of potential drug-induced liver injury (DILI) to adjust treatment as needed



Therapeutic Area: Autoimmune / Inflammatory Disorders

eDISH Plot on Treatment Output

Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH) Scatter Plot on Treatment Safety Population





Hyperbilirubinemia: Bilirubin > 2x ULN vs. ALT < 3x ULN

 **BILI > 2x ULN:** Indicates significant bile flow problems or liver dysfunction.

 **ALT < 3x ULN:** Suggest Mild liver injury or inflammation.

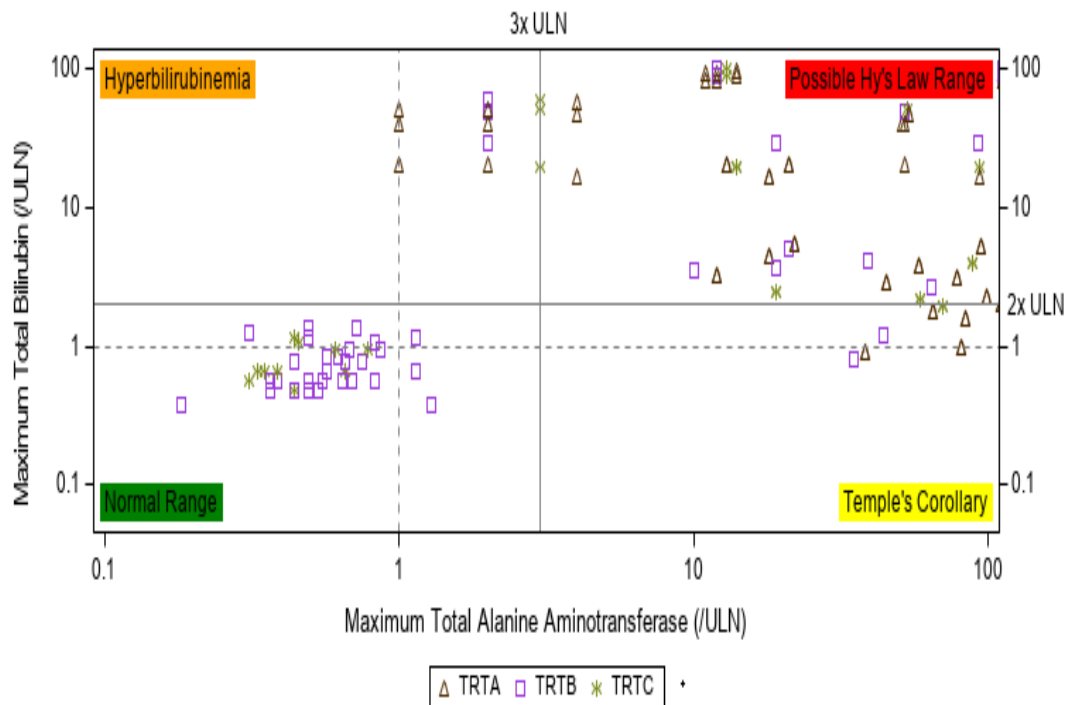
 **Combined Levels:** A bile flow problem or liver function problem with mild liver damage.

 **Severity Monitor :** Helps determine how serious the liver problem is.

 **Treatment Adjustments:** Guides decisions on modifying treatment.

 **Track Health Over Time:** Regular monitoring ensures early Detection of any Liver issues.

Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH) Scatter Plot on Treatment Safety Population





Hy's Law: Bilirubin > 2x ULN vs. ALT > 3x ULN

 **BILI > 2x ULN:** Indicates significant bile or liver dysfunction.

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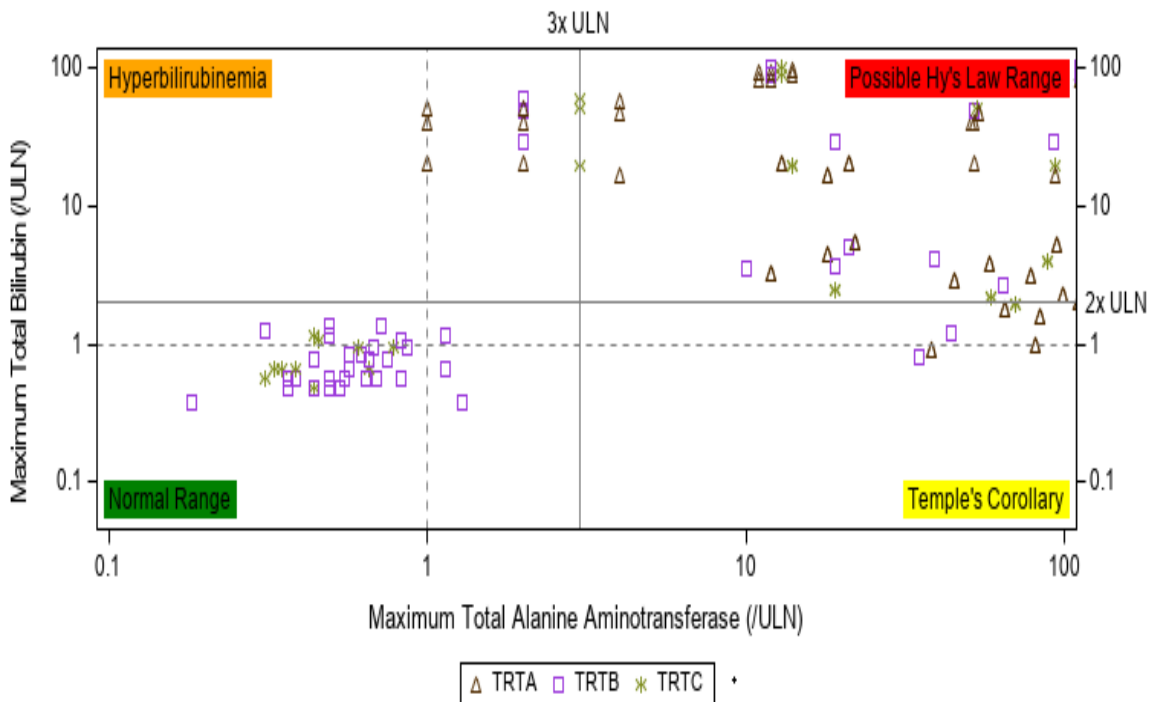
 **Combined Levels:** Liver injury with bile flow issues.

 **Severity Monitor :** Helps assess how serious the liver problem is.

 **Treatment Adjustments:** Guides changes in treatment or further test.

 **Track Health Over Time:** Regular monitoring ensures early Detection of any liver issues.

Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH) Scatter Plot on Treatment Safety Population





Normal Range: Bilirubin $<2x$ ULN vs. ALT $<3x$ ULN

 **BILI $< 2x$ ULN:** Normal or Mild bilirubin

 **ALT $< 3x$ ULN:** Mild or no liver injury.

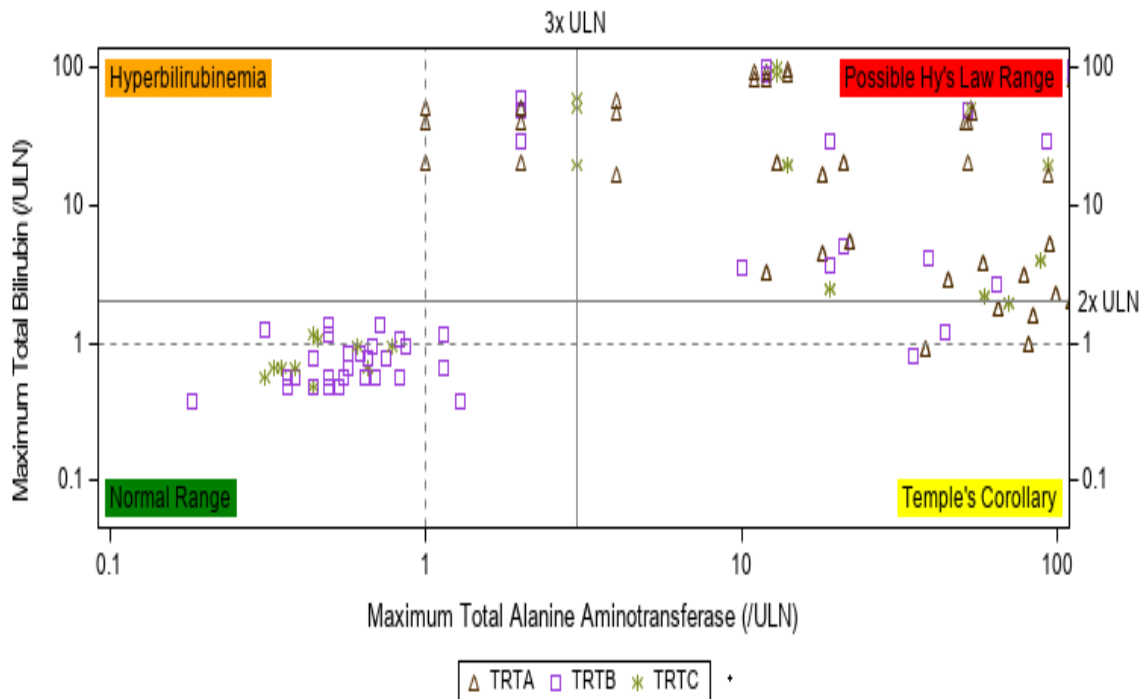
 **Combined Levels:** Minor or no liver damage.

 **Severity Monitor :** Levels are normal but should be checked regularly

 **Treatment Adjustments:** No changes needed if levels stay normal

 **Track Health Over Time:** Regular monitoring ensures early Detection of any liver issues.

Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH) Scatter Plot on Treatment Safety Population





Temple's Range: Bilirubin $<2x$ ULN vs. ALT $> 3x$ ULN

 **BILI $< 2x$ ULN:** Normal or Mild bilirubin level.

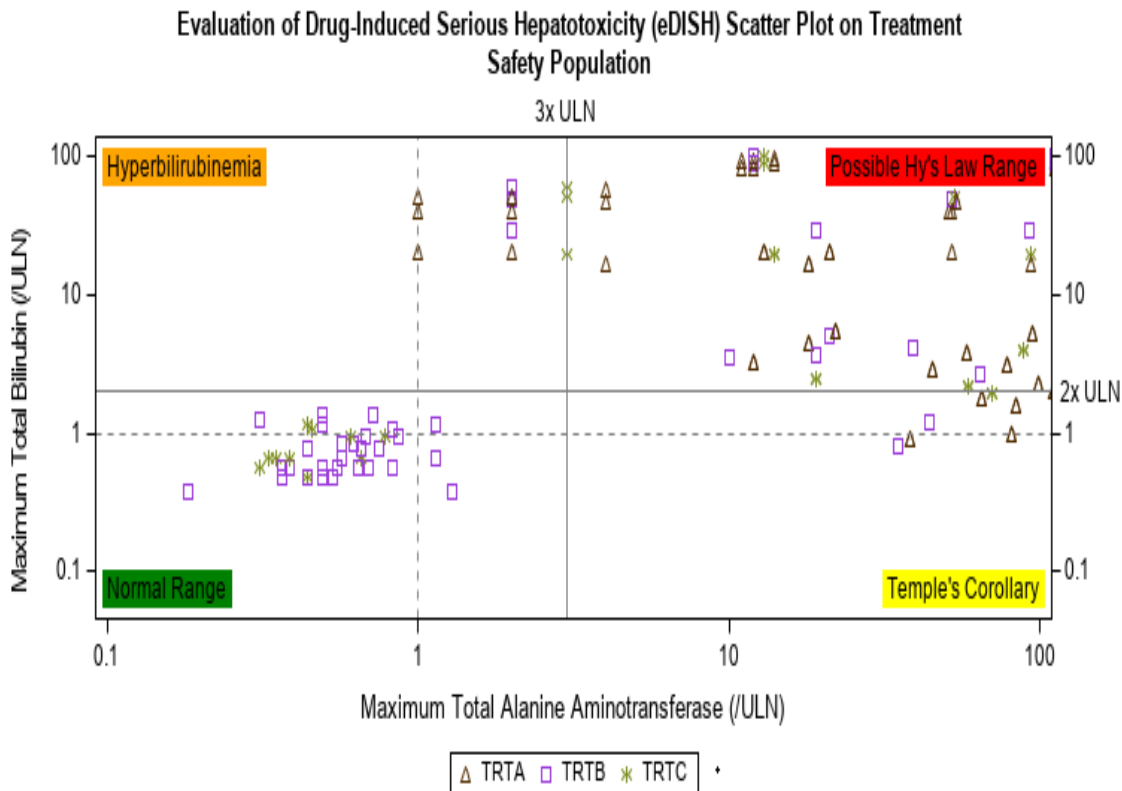
 **ALT $> 3x$ ULN:** Suggest liver cell injury or inflammation.

 **Combined Levels:** Liver injury without serious bile flow problems.

 **Severity Monitor:** Elevated ALT needs ongoing observation.

 **Treatment Adjustments:** May require dose adjustments or further evaluation.

 **Track Health Over Time:** Regular monitoring is key for early detection of issues.





Findings of eDISH Visualization Tool



Key Findings

Risk Detection: eDISH plot showed a **large cluster** of patients with **Hy's Law** cases

Early Warning:

Signs of liver toxicity **before clinical symptoms** appeared

Enabled **early intervention** for at-risk patients

Additional Observation: Small cluster with **BILI > 2× ULN but ALT < 3× ULN** also flagged for monitoring



Interpretation

eDISH enabled real-time assessment of liver signals and **stratification of patient risk**

Image suggestion:

Annotated eDISH plot showing Hy's Law quadrant and clusters

Visuals/icons for "risk detection" and "early warning"



Impact of eDISH on Clinical Protocols and Safety Monitoring



Protocol Adaptations

Regulatory Review:

The eDISH tool made liver safety easier to see and understand.
This helped health agencies plan better safety checks for future studies.

Treatment Adjustments:

Stop treatment in high-risk patients and **Dose reduction** in moderate-risk patients

Trial Outcome Changes: Introduced **more frequent liver tests**

Better safety signal tracking led to **reduced risk** and enhanced patient safety



Future Implications

eDISH tool is now embedded in early-phase safety workflows
Proactively used for **DILI risk management** in upcoming programs

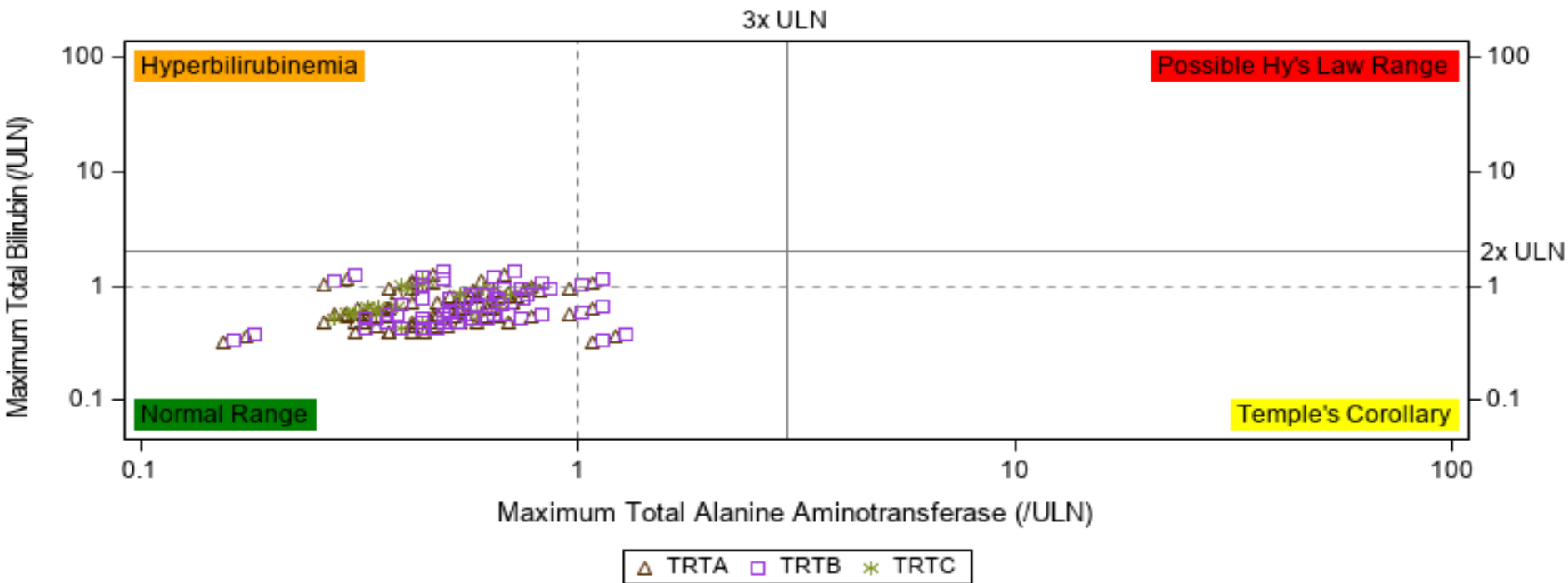
Image suggestion:

Flowchart showing protocol change (eDISH → Detection → Action)



eDISH Plot showcasing Improved Liver Safety Post Dose Reduction

Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH) Scatter Plot on Treatment Safety Population





Improved Liver Safety Profile After Dose Optimization



Background

Initial analysis via eDISH identified high-risk clusters ($ALT > 3 \times ULN$, $BILI > 2 \times ULN$)
Triggered **dose reduction** strategy for at-risk patients



Post-Intervention Findings

All patient data points now fall within **normal safety range**



Risk Mitigation Outcome

Improved liver safety profile with sustained drug efficacy
Supports **dose-dependent hepatotoxicity** hypothesis

Image suggestion:

Side-by-side comparison of **Before vs. After eDISH plots**
Highlight clusters moving from high-risk to safe zones



Challenges in Decision-Making with eDISH plot



Complex Data



Data Overload



Spotting Risks



Threshold Interpretation



Missed Signals



Inaccurate Decisions



Inconsistent Analysis



Lack of Visualization



Cognitive Load



Succeeding guidance in Data Visualization



Real-Time Monitoring



AI & Predictive Tools



Clinical Decision Support



Mobile & Remote Access



Standardized Reporting



Patient Education



Key Takeaways

-  Data Visualization Enhances Decisions
-  Biomarkers (ALT and BILI)
-  eDISH plot's Role
-  Effective Interpretation of Ranges
-  Early Detection Leads to Safer Treatment
-  Improvement in Clinical Protocols
-  Post-Dose Reduction Benefits
-  Future of Liver Safety Monitoring



Thank You



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