# From Complex Data to Clearer Insight

## SDAC Approaches to Strengthen Independent Data Monitoring

IDDI | 30+ Years of Independent Data Monitoring Expertise

# The SDAC: Turning Data Into Insight

## An effective SDAC is more than an independent source of statistical outputs

Working collaboratively with IDMC experts and other stakeholders, the statistical data analysis center (SDAC) helps identify emerging signals and trends, investigate questions, bring together relevant evidence, and present complex findings in ways that support meaningful interpretation.

**Evolving Data**

**Emerging Questions**

**Potential Signals**

# From Safety Signal to Deeper Understanding

Identifying a potential safety signal is only the beginning.
Understanding its clinical relevance requires deeper investigation and context.

## CASE STUDY

In a program of four related studies, the SDAC worked collaboratively with IDMC experts to identify and investigate potential safety signals through three complementary approaches:

### Statistical Signal Detection

Highlight potential meaningful imbalances for discussion and further investigation

### In-Depth Clinical Exploration

Explore suspicious patterns using case narratives, subgroup analyses, patient-level listings, and visualizations

### External Contextual Evidence

Consider the investigator's brochure, historical and real-world data, and blinded trial and safety updates

Reference: From Signals to Insight: Integrated Approaches for Improved IDMC Safety Evaluation
N. Dubois, C. Mauquoi | Presented at: PSI Annual Conference 2026

# From Safety Signal to Deeper Understanding

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**Together, these approaches helped the IDMC build a more complete picture of an emerging safety concern.**

**IDMCs can also help identify efficacy signals earlier by reviewing pre-specified interim analyses and recommending whether a study should continue, be modified, or stop early for overwhelming efficacy.**

Reference: From Signals to Insight: Integrated Approaches for Improved IDMC Safety Evaluation
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# Collaboration Brings Greater Context

When the analysis identified a safety pattern specific to one study, the IDMC recommended that selected information be shared with the IDMC monitoring the related sister study.

With the sponsor's support and appropriate legal documentation, the SDAC facilitated information sharing between the two IDMCs, enabling the second committee to introduce additional analyses to monitor the signal.

**Collaboration across IDMCs provided broader context for interpreting and monitoring the emerging safety concern**

Reference: From Signals to Insight: Integrated Approaches for Improved IDMC Safety Evaluation
N. Dubois, C. Mauquoi | Presented at: PSI Annual Conference 2026

# Beyond Tables: Make Complex Data Easier to Explore

IDMCs need to assess complex interim data quickly, but relying on multiple tables and listings can slow interpretation and obscure important signals.

Interactive visualization can bring safety, efficacy, and patient-level data together, allowing committee members to explore emerging findings without repeatedly cross-checking separate outputs.

### Traditional Review

- ✗ Multiple tables and listings
- ✗ Fragmented safety and efficacy view
- ✗ Time-consuming cross-checks

### Interactive Visualization

- ✓ Integrated patient-level insights
- ✓ Instant signal exploration
- ✓ Faster, more confident discussions

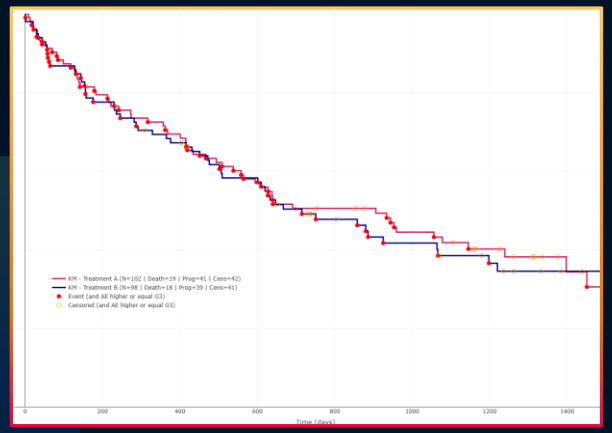
**Visualizations reduce cognitive burden and enable faster, more reliable decision-making**

Reference: Beyond Tables: Visualization as a Decision-Support Tool for IDMCs
S. Cambier, L. Timsina, S. Srikanth | Presented at: PSI Annual Conference 2026

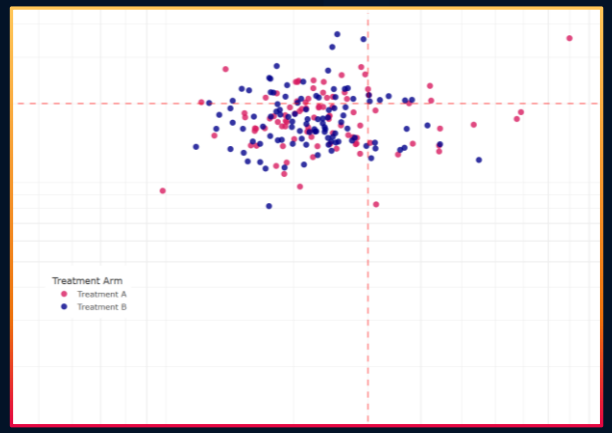
# From Visualization to Insight

Traditional Review:

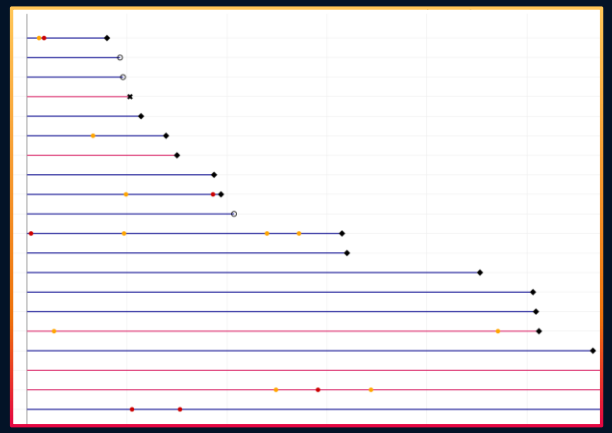
**Kaplan–Meier**



**eDISH**




**Swim-Lane**



**Patient-level information is not available**

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# From Visualization to Insight

Interactive Visualization:

### Dynamic Kaplan–Meier

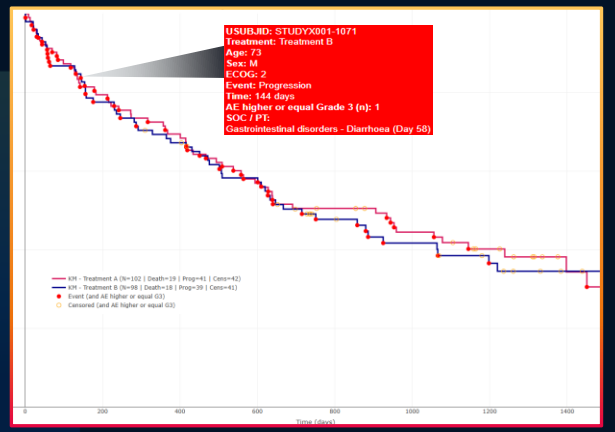
Integrates efficacy, safety, and patient-level data within a single interactive visualization

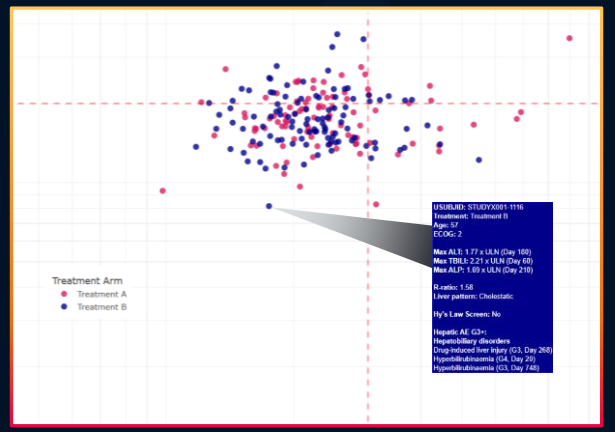
### Dynamic eDISH

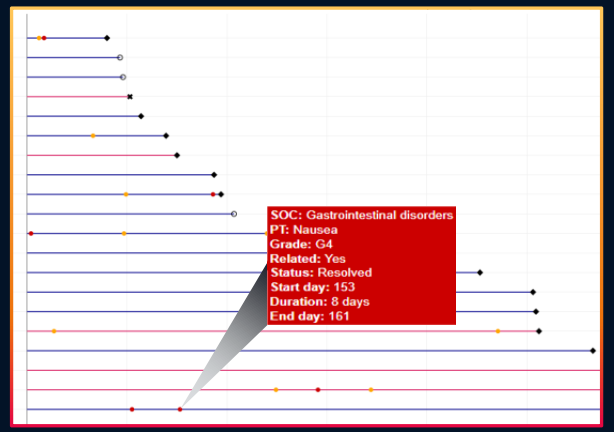
Supports detection of potential hepatic safety signals and rapid exploration of outliers and clinically relevant cases

### Dynamic Swim-Lane

Displays patient-level timelines and clinical outcomes




**Interactive hover enables immediate exploration of points of interest**

Reference: Beyond Tables: Visualization as a Decision-Support Tool for IDMCs
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DATA WITH PURPOSE

# What Should You Expect From Your SDAC?

## Deep statistical expertise
Beyond programming and standard outputs

## Proactive analysis
The ability to anticipate questions and surface findings that warrant attention

## Clear, adaptable reporting
Reports designed around the IDMC's needs and able to evolve with them

## Advanced visualization
Approaches that make complex patterns and relationships easier to interpret

## First-hand IDMC understanding
Experience of what committees need, not simply what an analysis plan requires

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DATA WITH PURPOSE

# De-risk Your Trial With the Right IDMC Strategy

**350+ IDMCs | 1,000+ meetings | 1,400+ reports**

*More than 30 years on both sides of the IDMC table*

IDDI brings deep statistical and regulatory expertise, advanced methodologies, data visualization, and first-hand committee experience to every stage of the IDMC process.

**Partner with IDDI to bring clarity, context, and perspective to complex interim data, reducing uncertainty, safeguarding trial integrity, and protecting patients.**