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SGS Pharma, Clinical Research

# PD09: Data Can't Do It Alone: The Untold Power of Soft Skills in IDMCs

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A handshaking image with financial charts and data overlays. The background is a blurred office setting with a computer monitor displaying various financial charts, including a line graph and a candlestick chart. Overlaid on the image is a network of white dots connected by thin lines, and a white line graph with several peaks and valleys. The overall color scheme is blue and white, with a warm glow at the bottom.

## Disclaimer and disclosures

The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the opinions of PHUSE members, respective companies or organizations

# Agenda



- 01 IDMCs and Hidden Challenges
- 02 The Myth: Data Speaks for Itself
- 03 The Reality: IDMCs Are Human Systems
- 04 Case Studies
- 05 Practical Strategies You Can Use
- 06 Conclusion

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# IDMCs

- **Independent Data Monitoring Committees (IDMCs)**
  - Safeguard **patient safety** and **trial integrity**
  - Evaluate **efficacy**, when applicable
- IDMCs are built on the assumption that



- Friction points that slow meetings, derail discussions, or create confusion come from **the way people interact under pressure**



# Hidden Challenges in IDMCs

- The IDMC challenges:
  - Unspoken expectations
  - Efficacy vs Safety
  - Different priorities
  - Communication gaps
  - Decision-making under uncertainty
  - Power dynamics
  - Time pressure and availability
- **Soft skills become the glue** that holds the scientific process together
  - Committee may still *meet*, but it won't *function*



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# Data is the input — not the decision

- Data provides
  - Evidence, Signals, Patterns and Probabilities
- IDMCs rarely get perfect information, they get
  - Incomplete data
  - Early signals
  - Statistical power
  - Conflicting trends
  - Time pressure
- Data never tells you **what to do**
  - Ambiguity, competing risks, or balance patient safety with trial viability



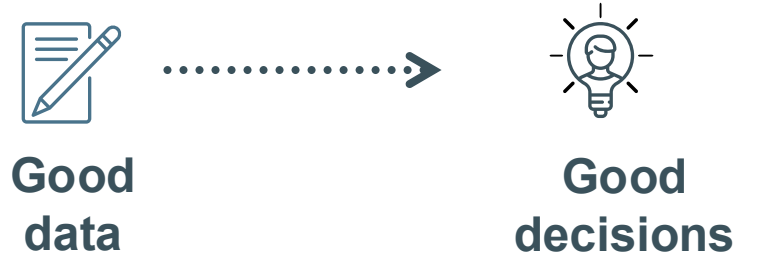
# The Myth: Data Speaks for Itself

- IDMC decisions depend on many stakeholders
- Committees using imperfect, evolving, incomplete data
- Data packages often contain an overflow of non-essential information
- **Human Reality**
  - Safety decisions require interpretation, communication, and judgment, not just numbers
  - Without clarity and prioritization, even strong data can lead to uncertainty or misalignment



# The Myth: Data Speaks for Itself

- Ideal world:



- The reality is more complex:



➤ IDMCs operate in a space where **data is necessary but not sufficient**

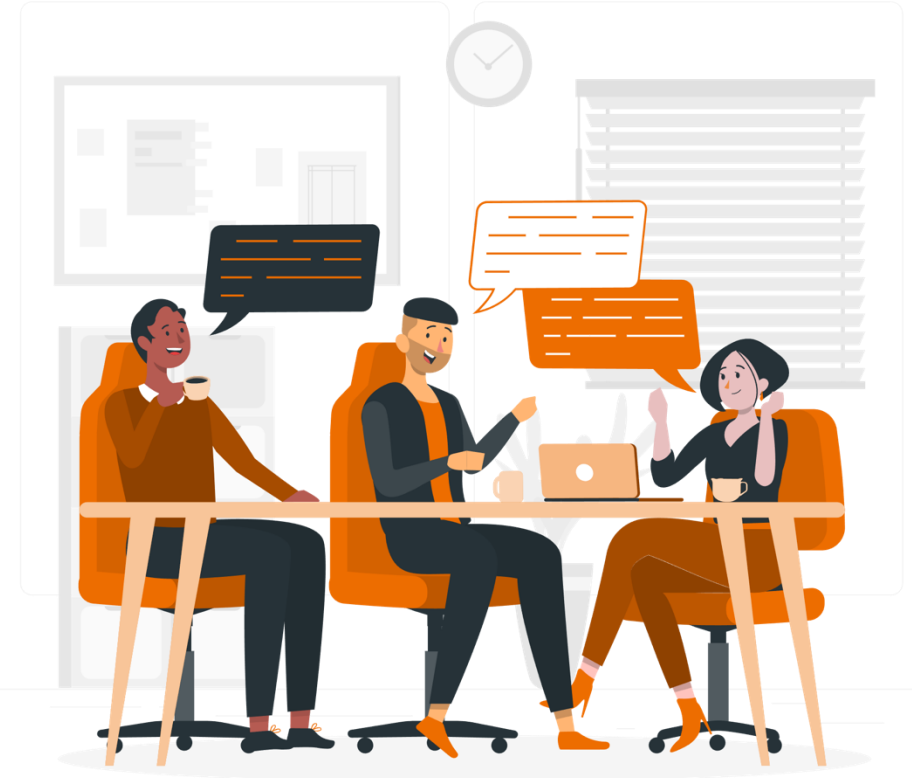
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# IDMC decisions based on Soft Skills

- Every IDMC decision involves:
  - Interpretation
  - Prioritization
  - Perspective
  - Communication
  - Alignment
- Rely on clarity, trust, emotional intelligence, and facilitation
  - Not just statistical output
- **Judgment** becomes the decisive factor
  - Improved when guided by an **efficient IDMC coordination**



# Coordinator as engine of IDMC Efficiency

- **IDMC Coordinator** shapes entire meeting experience
- Efficient management reduces noise and **increases clarity**
- Strong coordination protects the committee's **focus on science**
  - **Clear timelines** and expectation-setting
  - **Structured communication** across all stakeholders
  - **Proactive issue-spotting** before meetings
  - **Smooth logistics** enabling uninterrupted discussion
  - Convergence toward **decisions**



# Impact of an efficient IDMC

- Impact on the **stakeholder experience**
  - IDMC members feel prepared and respected
  - Sponsors receive clearer recommendations
  - Cross-functional trust
  - Tension decreases as expectations are aligned



# Impact of an efficient IDMC

- Impact on **trial oversight**

- Cleaner discussions
- Better risk detection
- More consistent decision-making
- Higher confidence
- Stronger documentation



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# Case Study 1: Conflicting Statistical Results



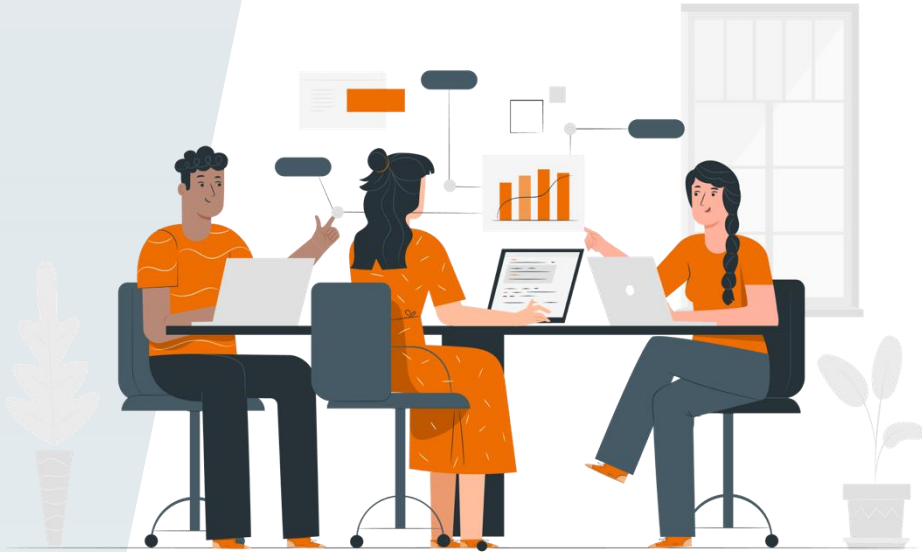
## ■ Scenario

- Two independent statistical approaches producing opposing conclusions about the IMP's efficacy
- Clinical interpretation the results through different lenses
- IDMC members arrive with diverging expectations

## ■ Risk

- High likelihood of a fragmented, unfocused discussion
- Potential for misalignment between clinical and statistical perspectives

# Case Study 1: Conflicting Statistical Results



## ▪ What Efficient Coordination Looked Like

- Pre-meeting clarification with the statistical team
- Guided discussion
- Framing questions

## ▪ Outcome

- Rapid alignment on the root cause
- Shared understanding based on the study specific scenario on which analysis was most decision-appropriate
- Unified, well-justified recommendation
- Increased trust in the process

# Case Study 2: Managing Complex Timelines Under Pressure



## ■ Scenario

- IDMC member calendars were nearly impossible to align, with several experts traveling or double-booked
- Data packages were large and evolving, making it difficult to prioritize the data review

## ■ Risk

- Delayed or low-quality meeting was high, threatening trial timelines and stakeholder confidence

# Case Study 2: Managing Complex Timelines Under Pressure



## ▪ What Efficient Coordination Looked Like

- Creative calendar alignment
- Meeting structure built for speed and clarity
- Focused review of the data

## ▪ Outcome

- IDMC meeting happened on time
- Members arrived prepared
- Discussion stayed sharp and efficient
- Clear, confident recommendation
- Stakeholder trust increased

# Case Study 3: Navigating ambiguous signals



## ■ Scenario

- Emerging laboratory abnormalities appeared sporadically across sites
- Findings were **not severe, not consistent, and not clearly linked** to the IMP
- IDMC team was split
  - Some saw random variation, others feared early toxicity

## ■ Risk

- Misalignment between IDMC perspectives
- High likelihood of an unfocused, unproductive meeting without clear direction

# Case Study 3: Navigating ambiguous signals



## ▪ What Efficient Coordination Looked Like

- Clarified the facts before/during the meeting
- Identified key questions to guide the discussion
- Redirected conversations to structured evaluation
- Summarized emerging points of alignment

## ▪ Outcome

- Committee agreed abnormalities did not **yet** constitute a safety signal
- Recommended continuing the trial with:
  - Enhanced laboratory monitoring
  - Clearer site guidance
  - A focused re-evaluation at the next meeting
- Decision was balanced and transparent

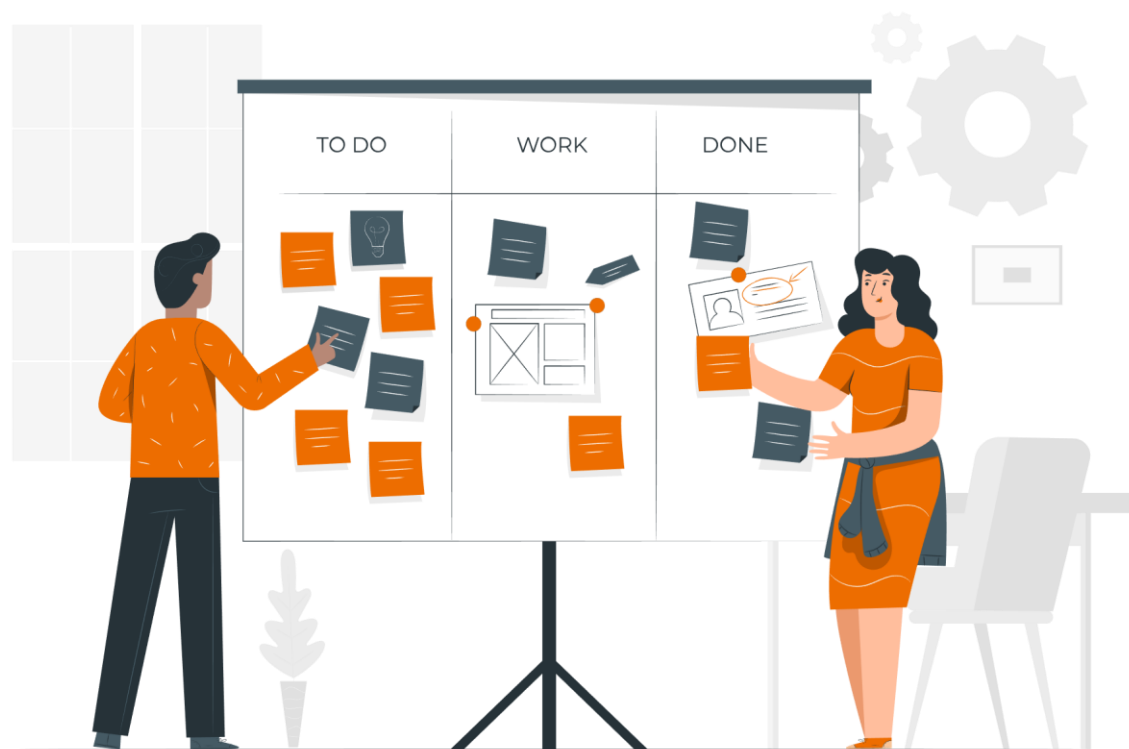
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# Practical Strategies for IDMC Coordination

- Before the IDMC Meeting — Setting the conditions for success
  - **Alignment upfront** with IDMC members and sponsor
  - Clear, structured **pre-read material**
  - **Anticipation** of possible friction points
  - **Logistics** that reduce cognitive load





# Practical Strategies for IDMC Coordination

- After the Meeting — Ensuring continuity and effective follow-up
  - Document **decisions with precision**
  - **Communicate outcomes** consistently
  - **Maintain context** across meetings
  - Follow-through that **builds trust**



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# Conclusion

- **Why IDMC Coordination is a soft skill powerhouse**
  - **Facilitation** under pressure
  - **Communication** that bridges disciplines
  - **Emotional intelligence** in tense moments
  - **Strategic thinking** that anticipates obstacles
  
- **Data can't do it alone**
  - **Efficient coordination** amplifies the committee's expertise
  - Soft skills ensure timely **decisions**
  - Coordination is not administrative — it's **leadership**
  - IDMCs excel when the human system is **well-managed**





# Questions?

# Contact us

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