IQVIA's Evidence-Driven Study Design

Connecting data sources and applying analytics early to optimize study design

Fit-for-purpose analytics answer key questions throughout the early design development process

Data used in study design may be fragmented, making it hard to know what evidence is available and what might be needed, leading to gaps in information. IQVIA's Evidence-Driven Study Design connects multiple complementary data sources, like insights from patient communities, real-world data, AI-based simulations and regulatory expertise to enable data-informed design decisions.

This solution follows a design thinking process where questions like "What are the most relevant endpoints for my study? How can I optimize my choice of eligibility criteria? Should I use a broader net to capture more patients?" are explored by applying data and using consultative analytics to iterate upon decisions for designing a study. This process yields evidence-based insights that streamline study designs and may result in reduced data points, fewer deviations, decreased cost and a higher probability of technical success.

Evidence-Driven Study Design connects multiple tools and data sources that operate synergistically to support informed study design decisions

Applied analytics empower study teams to make better design decisions

Waiting until a protocol is near final to validate design decisions is risky. Making changes late in protocol development can cause rework or delays in authoring, review, and approvals. Applying design analytics and modeling "what-if" scenarios early in study design development allows study teams to iterate on ideas throughout the design development process, reducing uncertainty and minimizing risks downstream.

IQVIA's Evidence-Driven Study Design focuses on eight key areas to support study teams during protocol design. Using analytics focused on these areas helps sponsors make early, in-flight design decisions prior to protocol authoring.

Insights in 8 key decision areas decrease uncertainty and minimize risk:

ELIGIBILITY CRITERIA

Optimize choice of eligibility criteria and its impact on potential patient prevalence

ENDPOINTS

Assess competitive intelligence and use claims data to aid in endpoint selection

STUDY DESIGN ELEMENTS

Review competitive intelligence, beyond endpoints, on design and strategies for similar trials

DESIGN CONSISTENCY

Audit for misalignment or gaps in defined evidence trail

REAL-WORLD TREATMENT PATTERNS

Analyze real-world diagnosis and patient treatment journeys to align study design with clinical care

COMPETITIVE LANDSCAPE

Understand trial competition and implications to recruitment risk

PATIENT PERSPECTIVE

Identify patient needs and expectations for a more patient-friendly study

REGULATORY CONSIDERATIONS

Use regulatory insights to prepare for clinical trial application submission

In addition, data and AI modeling can be used to generate simulations for further exploration of endpoints and their probability of technical success, eligibility criteria, and efficacy and safety.*

Gain insights from a collaborative eco-system of resources

Combining technology, data, analytics, and expertise helps study teams evaluate multiple scenarios to determine the best path forward for their study design. Evidence-Driven Study Design can be applied to any indication, even rare diseases where data is more limited. A tailored solution — which includes a combination of analytics that considers where you are in the design process coupled with our subject matter expertise — is developed to meet your specific needs.

Our team is ready to help you with optimizing your trial design. We can support you with a single protocol, your complete program or on a subscription basis. Let's discuss how we can best support you with optimizing your study design.

*Provided by QuantHealth, an IQVIA partner

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Design analytics experts to extend your team's capabilities

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