IQVIA Data-Informed Protocol Assessment

Make evidence-based decisions, identify protocol risks and minimize avoidable amendments

Pressure test your protocols with data analytics

Clinical studies are becoming larger, longer and more complex. Industry analysis reveals significant inefficiencies that can lead to unnecessary data collection and costly protocol amendments. Nearly 77% of clinical protocols require at least one substantial amendment.[1] Study durations for protocols with these amendments can take an average of three months longer and end up costing hundreds of thousands of dollars more.

IQVIA's Data-Informed Protocol Assessment helps you improve protocols by evaluating key areas of potential impact, such as patient burden and design inconsistencies. DIPA analytics validate your design decisions and identify potential study risks prior to protocol approval. Extend your team by partnering with trusted experts who understand the complexity of protocol design and can provide data-driven solutions to give you insights quickly.

Based on an independent study, IQVIA ranked #1 for protocol analyzing and optimization capabilities, which explains why 200+ customers have leveraged our Data-Informed Protocol Assessments[2]

Industry analysis shows significant costs and inefficiencies within protocol design

Protocol amendments

~77% of protocols have ≥ 1 substantial amendment

~70% of these include changes to study assessments and design

~$140K – $535K and **3 months** delay per amendment[3]

Unnecessary data

26% of Phase II procedures collect non-core data

46% increase in non-core procedures[4]

~25% of study costs are for non-core procedures

Protocol complexity

37% increase in number of endpoints

42% increase in procedures performed

30% increase in study initiation timelines[5]

Improve clinical trial outcomes with applied analytics

IQVIA medical, operational, and analytical experts apply multiple analytics to pressure test protocol design decisions to ensure sound results.

Data-Informed Protocol Assessments are best applied from synopsis through near final protocol to proactively identify potential study risks prior to protocol finalization.

IQVIA Analysis of more than 1200 draft protocols[6]

of protocols were unclear or inconsistent

included elements that increased patient burden

varied in design choices from competitor protocols

Evaluate 5 key areas to assess protocol design decisions

Design consistency

Internal consistency is checked to ensure each objective has a matching endpoint. Without a clear line of evidence, the probability of success of your study may be compromised and you may experience increased risk due to missing data — or spend resources collecting incorrect or unnecessary data.

Patient and site burden

For every protocol assessment, we uncover qualitative insights to complement our design analytics by mining patient and advocacy feedback while leveraging IQVIA's patient burden survey data. These analytics identify barriers to patient recruitment and retention, helping you understand differences by race and ethnicity.

Study procedures

Costly and non-core procedures are identified across the study duration and are then compared to standard of care. With this information, extraneous procedures can be eliminated to decrease the patient burden and save time and money.

Eligibility criteria

Inclusion/exclusion criteria is reviewed to determine the impact on potential patient volume and screen failure. Real-world data provides insights on how key inclusion/exclusion might impact the patient population. Understanding the impact of criteria on your patient pool can help you improve your study design and make better-informed decisions prior to execution.

Competitor trials

Competitive intelligence on design and strategies for similar trials with the same indication and phase is also assessed. Looking across multiple studies, IQVIA field experts check to confirm common design elements. Clinical outcome assessments used in approved labeling for the indication of interest are reviewed against those in the assessed protocol to help you understand how your protocol measures up against competition.

IQVIA's real-world data, analytics and expertise have positively impacted 90% of Design Analytics reviewed protocols awarded.

At IQVIA, we understand that protocol design is a complex, ever-evolving part of clinical development. Having the ability to quickly assess your design decisions and support your conversations with data is a gamechanger. Investing in pressure testing your protocol upfront by applying design analytics can reduce risk and ultimately increase the probability of success of your study. Our Data-Informed Protocol Assessment has a proven track record of reducing patient burden, improving patient safety assessments and preparing sponsors for regulatory submission, as well as helping to minimize avoidable amendments.

Our team is ready to help address your current trial design challenges. We can support you with a single protocol, complete program or on a subscription basis. Let's connect so we can hear more about your needs and learn how we can best help you as you work to optimize your protocols.

Partnering with IQVIA brings you:

Insights from IQVIA's unparalleled real-world data

Design analytics experts to extend your team's capabilities

[1] Tufts CSDD Impact Report 2023
[2] Research Conducted by Life Science Strategy Group 2023
[3] Median direct cost $140k for Phase 2 studies, $535k for Phase 3 studies, according to the 2016 Tufts Impact Report. Tufts CSDD Impact Report 2016;18
[4] Phase 2 studies, 2016-2021 versus 2011-2015; Source: Tufts CSDD Impact Report 2023;25
[5] Phase 3 studies, 2017-2020 versus 2013-2016
[6] Based on IQVIA review of 1281 protocol synopses, Q4 2016 – Sep 2023

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