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Common sources of design flaws in clinical trial protocols

Failures related to market-based realities

These include lack of forethought to endpoint needs. For instance, careful consideration must be given—up front—to whether or not there is an adequate market for the drug, and whether the prevailing standard of care may prevent strong market uptake for the new therapy. Inclusion of endpoints that can help to differentiate the product (in terms of safety, efficacy, side effects profile, how the product may fit in with prevailing health plans and more) can yield valuable insights that can then be leveraged later by the global market-access team. These specific details should be established up front in the trial protocol.

Inadequate attention to patient-centricity

This includes issues related to inclusion/exclusion criteria, failure to consider patient-specific issues, and challenges to reduce the burden, cost and discomfort, inappropriate instruments, recruitment issues, adherence challenges, patient retention and more.

Excessive or burdensome site requirements

These include failure to appropriately streamline site requirements to reduce the burden on investigators and their clinical staff, excessive safety burdens and more.

Design-efficiency failures

Looking at the trial design through a sustainability and carbon-footprint lens can help to identify opportunities to improve productivity. For instance, such considerations may help protocol designers to improve timelines and reduce unnecessary site visits, reduce sampling overlaps and more. Efforts to streamline such activities provide opportunities to reduce waste for both trial investigators and patients (that is, waste related to redundant or inefficient tasks, time, logistics, travel and wasted materials). This is discussed in greater detail below.

Incorrect assumptions for the primary endpoint

This would result in under-powered studies that don't recruit enough subjects. This common pitfall can be resolved by a robust review of the literature, prior clinical trial results and other drugs in the class or by additional interventions approved by regulatory agencies.

Recommendations to guide protocol design

All stakeholders—patients, sites and sponsors—benefit from a more streamlined trial protocol and it leads to a more efficient overall trial. Here are some recommendations. When carried out at scale—at multiple sites across the globe—these efforts will translate into considerable savings in terms of labor, budget and timeline.

- **Early patient engagement**
- **Lean into concepts of human-centered design**
- **Early site engagement**
- **Balance the needs of trial and participants**
- **Streamline excessive inclusion/exclusion criteria**
- **Avoid denying access through inconsiderate protocol design**
- **Incorporate digital health techniques where possible**
- **Develop educational materials that fit the population need**

Learn how refining protocol design can significantly boost clinical trial outcomes while minimizing inefficiencies and delays. Check out this insightful **productivity article**.

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