12 FUNDAMENTALS OF A CLINICAL DEVELOPMENT PLAN

Clinical Landscape Assessment

It is a crucial first step in designing a clinical development program to understand the clinical landscape, including current standard of care and competitor products. Many of the following points are affected by the outcome of the clinical landscape assessment.

Indication Definition

The indication selection has many downstream effects, including trial design and endpoint selection, eligibility for various regulatory pathways and programs, and eventual marketing potential.

Preclinical Testing

Depending on the stage of clinical development, it may be crucial to leverage findings from preclinical testing to develop a clinical dosing strategy as well as mitigate any potential safety concerns arising from such testing.

Biomarker Identification

Many clinical programs can benefit from use of an appropriate biomarker during development. Whether to refine the patient population or as a pharmacodynamic measure after treatment, identification and qualification of a relevant biomarker can dramatically improve a program's chances for success.

Clinical Trial Designs

There are many factors that need to be considered in a clinical trial design, such as choice of control (active or placebo), high-level patient population, and endpoints. A holistic view of the development program allows for optimal designs at each clinical phase.

Statistical Considerations (Power Analysis and Analysis Strategy)

it is important for product sponsors to understand the number of subjects that would need to be included in each trial to give it a reasonable probability of success. Based on the proposed analysis strategy (e.g., superiority or non-inferiority), a power analysis is critical to understanding the time and money required to carry a clinical program to completion.

Feasibility

In combination with trial designs and power calculations, a feasibility analysis can provide valuable information on potential trial sites based on factors such as location, local standard of care, and expected recruitment rate. This information is crucial for understanding how a clinical development program progresses on a timeline.

Regulatory Interactions

Throughout the development lifecycle, there will be opportunities for sponsors to have formal interactions with regional Health Authorities to gain valuable insights and institutional knowledge to efficiently proceed to the next stage of product development. The CDP will consider the timelines and objectives for these planned interactions and anticipate how possible meeting outcomes may influence decision making.

Early Interaction Meetings

Of particular importance for small and emerging biotech companies are the additional meeting pathways available for novel and innovative technologies (e.g., INTERACT meetings in the US) – the CDP can ensure sponsors take advantage of all available meeting opportunities with health authorities.

Safety Monitoring

Health Authorities will accept a safety package at the time of marketing application that is dependent on the product type and indication. A holistic view of a clinical program can identify opportunities to collect data or allow for modeling that can lessen the overall clinical package to demonstrate a product's safety profile.

Pediatric Study Requirements

There are a variety of regulations and requirements regarding conduct of pediatric studies during development. Early identification of these requirements may allow for their efficient inclusion in the clinical program as well as avoiding protocol amendments or the need to conduct additional studies unnecessarily.

Risk Assessment

A key aspect of any CDP is understanding the feasibility of technical, strategic, and commercial goals. A key goal is to identify critical decision points and determinants, which can impact the probability of success, as well as the practicality of mitigating or managing risks associated with such critical decision points.

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