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Designing Clinical Trials to Show Value

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Abstracts

Once, they were the benchmark for product development. But these days, randomised controlled trials (RCTs) are simply a starting point—and a starting point under pressure to carry even more value.

As notions of ‘value’ broaden, and product development faces higher benchmarks to gain regulatory acceptance, professional support and financial viability, the pharmaceutical industry faces the task of rethinking how RCTs are designed in order to meet stakeholder requirements.

The new tools are already in the toolbox—from biomarkers and access to patient-reported outcomes to adaptive licensing, real-world data and health economic modelling that transcends established RCT parameters. But how will they be utilised?

FirstWord’s Designing Clinical Trials to Show Value report skilfully delves into the pressures of increased value expectations faced by the pharmaceutical industry’s product development programmes. Based on wide-ranging research and expert interviews, the report offers the industry critical and timely insight into how to address these new priorities in practical, strategic ways. For those working in R&D, marketing, market access, health outcomes and pharma management, it is quite simply a must-read.

Key Report Features of Designing Clinical Trials to Show Value include:

Up-to-date insight into how RCTs must evolve to meet cost-constrained stakeholder demands

A look at supportive trends and technologies, such as adaptive licensing, joint HTA-regulator consultations and access to real-world data

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Advice on how RCTs can be made more efficient in line with regional and global objectives

Discussion on how regulatory trends can help maintain pharma product value beyond licensing

Key Benefits

The pharmaceutical industry's view of RCTs is changing. In Designing Clinical Trials to Show Value, you will:

Understand how new concepts of value created by cost-conscious healthcare stakeholders are transforming clinical development programmes

Gain insight into predictions of emerging trends in big data, patient involvement in trial design and the relationship between drug regulators and health technology assessment bodies

Be able to plan for multi-faceted clinical development programmes that include new value parameters

Understand new trends in clinical trials that promise to deliver product value sought by regulators, health systems and patients

Designing Clinical Trials to Show Value answers key questions:

What does 'value' mean in the current, cost-consciousregulatory and healthcare environment?

How is 'value' understood by stakeholders who increasingly hold sway over market access and product uptake?

How can the industry adapt traditional RCT design to deliver more sophisticated value across a range of levels?

What can be gleaned about product development programmes from composite

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trials such as the Salford Lung Study?

How can pharma manage its various functions to deliver comprehensive value though clinical development programmes?

Key quotes

“It used to be feasible to build an evidence base around a product entirely by levering clinical trials. Now, outside select disease areas, you need both RCTs and strong evidence of actual value in the real world.” Dr Benjamin Hughes, Senior Principal, RWE (Real-World Evidence Solutions), IMS Health in the UK.

“The way in which the value of medicines will be assessed in the future is going to need to be much more holistic. It’s far more important to focus on real-world evidence and comparative effectiveness evidence. So this is looking at how a product is truly cost-effective for both the healthcare and the social care systems.” Dr Bina Rawal, Director of Medical, Innovation and Research for the Association of the British Pharmaceutical Industry (ABPI).

“Everyone is looking for value, basically in the sense of better or the same patient outcomes but at a lower cost. This forces the industry to rethink the way it is doing business. But it’s not led by the industry, sadly enough, and I think companies are slowly waking up to the fact that they will have to change significantly their model of doing business.” Charles De Wet, Medical Director, UK and Ireland, Boehringer Ingelheim

Content Highlights

As RCTs undergo rethinking by pharma, the industry must better understand the impetus for change. In this report, you will discover:

The importance of delivering value propositions that meet health outcomes, cost-effectiveness and patient outcomes

How multi-faceted clinical development programmes can incorporate new parameters in support of traditional RCTs

New trends in trial design, including adaptive licensing, real-world data-gathering

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