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Harnessing The Power of Phase IV Observational Studies

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Abstracts

Phase IV studies: Pioneering approaches are re-engineering processes, timelines and costs

Phase IV is in a state of flux. New digital methods are on trial, there’s an explosion of data sources, and more questions about the level of evidence needed are being asked. At the same time, drug companies are trying to control costs. What’s the best way forward?

If you want to design and carry out more effective Phase IV trials studies, you need to find out what lessons have already been learned about lean protocol design, opportunities for savings and considering the patient voice, from companies like Genentech and Sanofi (see the full list). You'll also get fresh insights into how key studies have performed, and clear pointers to what could be improved.

Top Takeaways

Separate standard operating procedures are needed for Phase IV studies

Planning should start earlier for Phase IV studies to improve their effectiveness and business value

Research objectives need to be clear and focussed to avoid waste of resources

New protocols and platforms are beginning to impact on study design, data collection and methodologies

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Potential for significant savings exists but these won't be realised until confidence in the methodologies improves

Including the patient's voice is easier – but there are still careful considerations required

Key real-world drug-use learnings can result from new approaches

Key Issues Explored

When should you start considering Phase IV studies in your testing processes?

How patient insights and various customer needs can result in benefits for all stakeholders

Insight into ground-breaking trials and lessons learned so far in 2 key case studies including the Salford Lung Study

The new integrated evidence pathways gaining ground and what their true long-term value is likely to be

The growth and use of databases by researchers

How new partnerships forged by drug companies to progress studies are working in practice

Concerns around quality and reliability of evidence gathered

Who needs this report?

Anyone involved in designing, recruiting, executing or analysing Phase IV studies – to see how they can be improved

Regulatory teams – to gain insights into current and new practices

Executives who want to understand evolution of best practice and explore potential cost savings

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Data managers at pharma companies, CROs and associated organisations

Manufacturers and programmers of wearable medical and health devices (such as FitBit) – to understand potential future applications

Patient engagement teams – to understand new ways of involving patients

Who needs this report

Professionals charged with hiring, training, managing or evaluating MSLs and intent on fully leveraging their potential.

Executives who wish to optimise the utility of the MSL function in their organisations.

Managers looking for insights on the future of the MSL role in pharma.

MSLs who want to continue to excel in the field in the years to come.

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