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Managing Investigator Initiated Research

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Abstracts

Investigator-initiated research (IIR) is a vital aspect of the full life-cycle management of many drugs and devices, providing needed scientific and clinical information, as well as supporting the discovery of innovative uses for existing medical treatments.

However, the IIR community continues to have inconsistent industry policies and procedures and often a general lack of knowledge in setting up an IIR programme. There are also legal ambiguities surrounding safety reporting, fair market value (FMV) and the financial reporting of grants under the sunshine provisions of the Patient Protection and Affordable Care Act (PPACA).

It is therefore becoming increasingly critical for pharma, biotech and device companies to get their IIR programmes into alignment with regulatory and legal requirements.

IIR programmes can also benefit from improved processes, more meaningful measurement, and a fresh perspective on stakeholders' roles and responsibilities.

Report Overview

Managing Investigator-Initiated Research

This comprehensive report brings together industry data, exclusive expert opinions, and a wealth of practical know-how, in one highly accessible resource.

After a thorough overview of IIR's recent changes and challenges, the report provides actionable recommendations on every aspect of IIR, from transparent, consistent processes for registration and review of submissions; to compliant, productive sponsor-grantor communications; to clear and regular reporting of what has been achieved.

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The report includes considerable input from the board members of the Investigator Initiated Sponsored Research Association (IISRA), as well as exclusive opinions from pharma and investigators.

Anyone involved with investigator-initiated research will find this report invaluable in their goal to make their IIR programmes transparent, consistent, and effective.

Key Report Features

Up-to-the-minute overview of the changing face of IIR

Guidance on making IIR programmes compliant with the sunshine provisions of the Patient Protection and Affordable Care Act (PPACA)

Practical guidelines for submissions, contracts (including START clauses), and fair market valuation/compensation

Details on potential pitfalls when facilitating IIR (and how to avoid them)

Recommended metrics to measure the performance of an IIR programme

Definitions of key IIR terminology

Information about web-based tools for end-to-end IIR programme management

Who Would Benefit From This Report?

Managers and Executives with responsibilities in:

Investigator-initiated research (IIR) programmes

Branding and Marketing

Medical Affairs

Medical Science Liaisons (MSLs)

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Key Questions Answered

Is IIR still a viable approach, with the increasing demands for transparency?

What does a good IIR programme look like?

What is Fair Market Value? How can I negotiate a fair rate of pay?

What metrics should be embedded in the programme?

What can MSLs do and not do when liaising with investigators?

How and when can I respond to requests to help (or proactively intervene)?

How can I minimise exposure to regulatory problems?

What are the roles and responsibilities of each party?

Key Benefits

Manage your IIR programmes effectively and compliantly

Gain a clear understanding of the risks of not ensuring transparent processes in your IIR programmes

Understand how perceptions of responsibilities affect relationships (e.g., is the investigator a collaborator, customer, or independent researcher?)

Learn why and when standard operating procedures for MSLs are necessary Be fully prepared for the challenging new requirements of the PPACA

Key quotes

“There are so many restrictions on reps now that the IIR programme is the main way to start a relationship … it’s a good relationship developer because it’s clean. We really are engaging in science. It’s a wonderful dialogue.”
– Ornah Levine-Dolberg, director, Medical Affairs, Mood & Anxiety Disorders, Lundbeck

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Concern over being perceived as unduly influencing study design is strong enough that some companies are now ‘sterilising’ the grant review communications to applicants [such that] they are often reduced to a formal written communication of a yes or no grant decision. That’s a big shift from what we were seeing in this space ten to 15 years ago,”
– Anton Ehrhardt, Sanofi

“There are many legal and operational questions [small-to-midsize companies] don't know how to address, so they just make their best assumptions … It exposes both them as a pharmaceutical company and the sponsor-investigator to unnecessary risks.”
– Ran Frenkel, vice-president, International Business Development, Clinipace Worldwide

Expert Views

Anton Ehrhardt, president, IISRA, and senior director, US Oncology & Transplant Field Medical Affairs, Sanofi

Ornah Levine-Dolberg, director, Medical Affairs, Mood & Anxiety Disorders, Lundbeck

Matthew Sidovar, director, Medical Affairs, Acorda Therapeutics

Patricia Westergren, secretary, IISRA, and product manager, MedNet Solutions

Harvey M Arbit, adjunct professor, University of Minnestota College of Pharmacy

Ran Frenkel, vice-president, International Business Development, Clinipace Worldwide

Cameron Tew, managing director, Best Practices LLC

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