EFS Site Best Practices Meeting

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EFS Site Best Practices Meeting
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Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies

Guidance for Industry and Food and Drug Administration Staff

Document issued on: October 1, 2013

The draft of this document was issued on November 10, 2011.

For questions regarding this document, contact CDRH's Andrew Farb, 301-796-6343, Andrew.Farb@fda.hhs.gov or Dorothy Abel, 301-796-6366, Dorothy.Abel@fda.hhs.gov, or CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

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Federal Guidance Document

- Document addressed regulatory issues
- Local site issues were never the focus
- Outmigration of clinical studies OUS continued to fall to <50%
- New Zealand dominated the landscape for not only rugby but EFS

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Federal Guidance Document
What didn't it do

- Identification of the problem – site and implement issues
- Components of the problem – root cause analysis
- Approaches to the problem
- Consequences of problem
- Action items

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Federal Guidance Document
Components to be considered

- Patients
- Investigators
- Sponsors
- FDA
- IRB's
- Clinical study sites
- Payers
- Public and private funders

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Fundamental next steps

- Address an ecosystem with multiple parts

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What's in it for me

- Goals: Improve patient care, solve unmet clinical needs
- Streamline and codify best practices at each institution
- Optimize resource utilization
- Maintain and enhance funding sources for research and development
- Enhance and maintain professional satisfaction
- Encourage IP development
- Enhance institutional profile

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Potential Approaches to Address IRB Issues

Submission of well-organized complete documents
Agreed upon goals of completion of review by IRB, sponsor, and investigator
Parallel processes of contract and legal review
Establish FDA liaison relationships to IRBs
Acceptance of central IRB and uniform consent forms

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Optimal EFS Site Qualities

A culture of clinical study quality, and a commitment to and enthusiasm for EFS
A well-developed infrastructure to support clinical studies
A history of efficient and successful conduct of prior studies
A track record of human subject monitoring, and protection and excellence in maintaining study data integrity
Technically qualified site investigators
Commitment from the site IRB to expeditiously review EFS submissions or a willingness to defer to a central IRB
Parallel and timely contracting and IRB processes
Access to sufficient patient populations with the disease being treated (the intended treatment population); sites with electronic health records may have readily available information in this regard
A commitment to constrain both direct and indirect costs

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Optimal Industry Partner Qualities

Knowledge of and interest in participating in EFS
Resources for protocol design and implementation
Commitment to patient-centric device development
Acceptance of the issues of site selection, protocol design, and legal contractual site issues
A close collaborative working relationship between the physician champions involved in the protocol design, and the FDA regulatory and design personnel
Ability to adapt to issues related to treating patients with new approaches
Resources for statistical design and methodology
Track record of working with AROs or CROs on data acquisition
Ability to provide expeditious device design and clinical protocol iteration in response to early protocol screening and case experiences

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Necessary Concessions By Ecosystem Participants

	Participants in the Clinical Study Ecosystem							
	Patients	Investigators	Sponsors	FDA	IRB	Sites	Payers	Funders
Accepting a greater degree of risk	√	√	√	√	√	√	√	√
Submitting to additional oversight and reporting		√	√			√		
Expending additional time and resources	√	√	√	√	√	√		

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