

R&D Hidden Risks Behind Clinical Trial Recruitment, including FMV, invoicing

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Key Takeaways

- A focus on R&D compliance risks – in addition to more traditional sales, marketing and medical affairs compliance – is required
- Examples of risk areas for the R&D compliance program to address include:
 - **Fair Market Value re: Payments and Transfers of Value**
 - Global FMV framework and process
 - Incentives to drive recruitment
 - Invoice reconciliation risks
 - FCPA / anti-bribery controls
 - **Interactions with Patients / Subjects**
 - Avoiding promotional claims
 - Use of social media
 - Coverage of costs
 - Privacy considerations
- Approaches to help drive efficiency and effectiveness for the R&D compliance program:
 - **Leverage data for better insights**
 - **Coordinate and partner with GCP Quality colleagues**