



Managing the Money Trail in the Research Environment

Seth B. Whitelaw

Compliance Officer, Global R&D

GlaxoSmithKline

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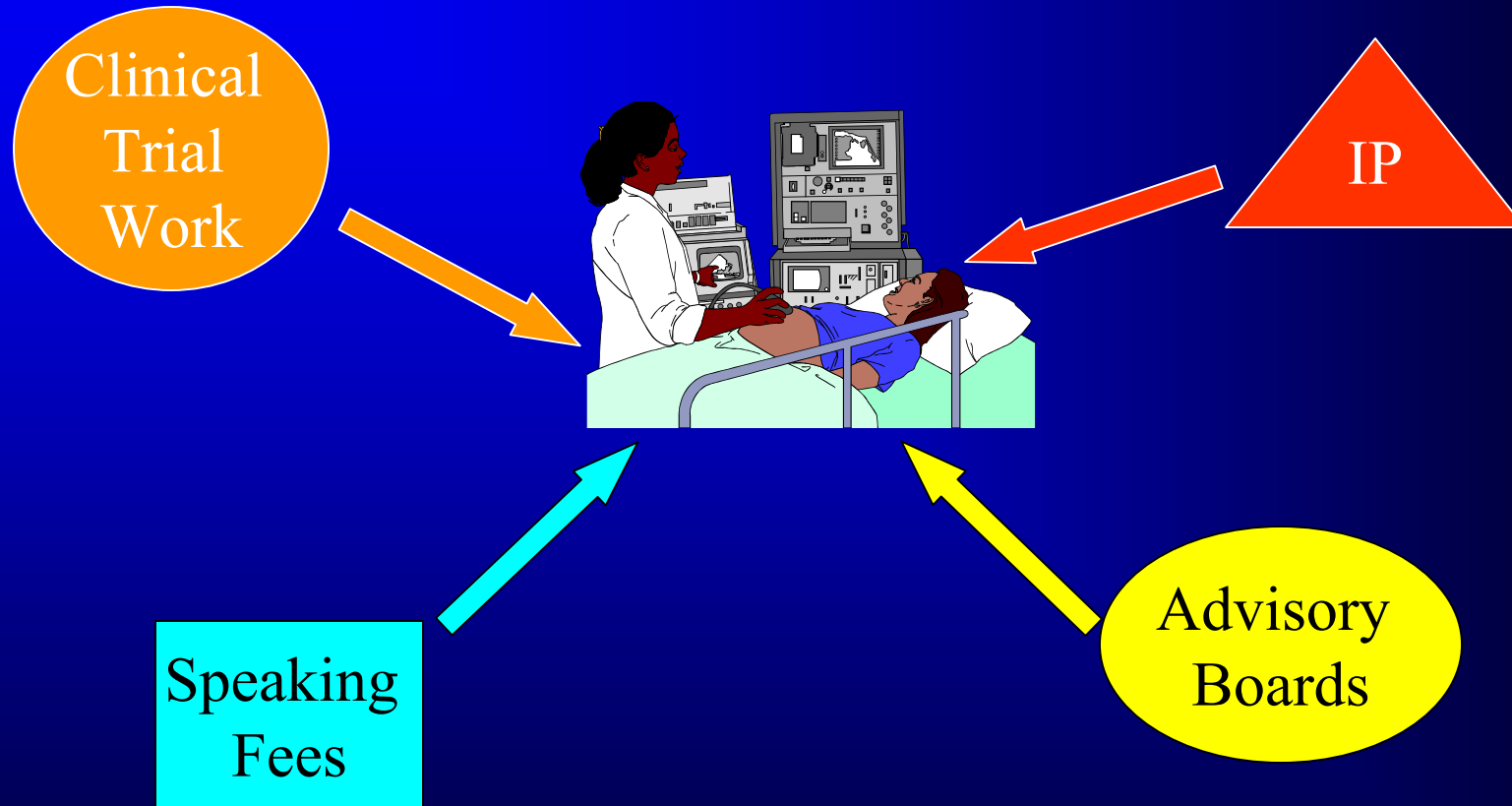
The Business Objective

Obtain the best
possible data, in the
shortest amount of
time

The Challenges

- Managing the process to avoid compromises in patient safety, data integrity or engaging in commercial bribery
- Demonstrating to the public, regulators, shareholders that the concern is understood and being addressed 24/7

Some Possible Income Sources for Clinicians



New Developments

- TAP Pharmaceuticals Case
- OIG Compliance Program Guidance
- PhRMA Principles (*Heather Stewart*)
- Post-marketing Studies (*Heather Stewart*)

TAP Pharmaceuticals

- Settlement of \$875M
- Criminal indictments
- Corporate Integrity Agreement (7 years)
 - Educational Grants
 - Research Grants
 - Consulting and advising arrangements

OIG Compliance Program Guidance: Risk Areas

- Consultants and advisors
- Grants for research and education
- Gifts and gratuities
- Vendors and other agents

OIG CPG: Risk Areas *(cont'd)*

- Consultants and advisors
 - Research, data collection, advisory boards, focus groups, speakers
 - Compensation only for “actual, reasonable and necessary services” not “token arrangements created to disguise otherwise improper payments.”
 - Manufacturers should “ensure appropriate documentation of the fair market value determination, as well as the performance of the services.”
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OIG CPG: Risk Areas (cont'd)

- Grants for research and education
 - Particular risk “where they involve parties in a position to prescribe or order the manufacturer’s product ...”
- Gifts and gratuities
 - Must not exceed nominal value and not exceed fair market value for services rendered
 - Does not take “into account, directly or indirectly, the volume or value of business generated”

OIG CPG: Risk Areas *(cont'd)*

- Vendors and other agents
 - CO should “ensur[e] that independent contractors and agents ... are aware of company’s compliance program ...”

OIG CPG: Compliance Activities

- Education and training
 - OIG considers this to be a “must” do
 - Specific training on risk areas (those in guidance and those identified by other means) for employees associated with relevant activities
 - New employee and refresher training is important; failure to attend should result in disciplinary action; should be part of employee evaluation

OIG CPG: Compliance Activities

(cont'd)

- Auditing and Monitoring
 - Flexibility on frequency and subject of audits; could be prospective or retrospective
 - Use of “internal or external evaluators who have relevant expertise”
 - Mechanisms for corrective action
 - Duty to investigate “reasonable indications of suspected noncompliance”
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What Does the Future Hold?



- Pressure to achieve the business objective will increase.
 - The challenges will remain and grow more acute.
 - The demand for accountability will increase and become global.
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The need for compliance programs tailored to the research environment will increase.
