

Risk Due Diligence Programmes

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What is Risk and Due Diligence



- Risk is the possibility of something bad happening; potential for uncontrolled loss of something of value.
- Due Diligence is the investigation or exercise of care that a reasonable business or person is expected to take before entering into an agreement or contract with another party.
- Risk Due Diligence is the start not the end of Third Party Risk Management

Why is this important?



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Roche faces EU fine over drug-safety reporting

Europe's top drugs agency is investigating the Swiss pharmaceutical group Roche over its alleged failure to report fully thousands of possible cases of adverse drug reactions.



The EMA will decide whether Roche properly monitored the safety of 19 drugs it sells in the EU, including blockbuster cancer treatments like Herceptin and its popular flu drug Tamiflu. Photo: ALAMY

AstraZeneca fined £4m for backhanders to doctors ... It set up bogus conferences, supplied fake travel invoices and handed gifts to hospitals

By SABAH MEDDINGS FOR THE DAILY MAIL

PUBLISHED: 21:52, 31 August 2016 | UPDATED: 22:11, 31 August 2016



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AstraZeneca has been forced to fork out £4.2m to settle a bribery probe over allegations staff used gifts and cash to persuade doctors to buy its drugs.

The Anglo-Swedish drugs giant is accused of setting up bogus conferences, organising false travel documents and creating fake tax receipts to 'reward or influence' healthcare providers.

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GlaxoSmithKline fined \$490m by China for bribery

19 September 2014

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China has fined UK pharmaceuticals firm GlaxoSmithKline \$490m (£297m) after a court found it guilty of bribery.

The record penalty follows allegations the drug giant paid out bribes to doctors and hospitals in order to have their products promoted.

The challenge to our industry...



- The Goldilocks conundrum of risk management...
- Not too much, not too little, just right
- There are risks associated with being too slow or not being agile enough
- The balance can change over time



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- By taking steps to *manage* third party risk, we can:
 - **Protect** our brand and reputation
 - Be known as a **responsible** business
 - Be **assured** we and our third parties conduct our business ethically and in line with our values and principles
 - **Avoid** the penalties and consequences of getting it wrong

How can we define risk?

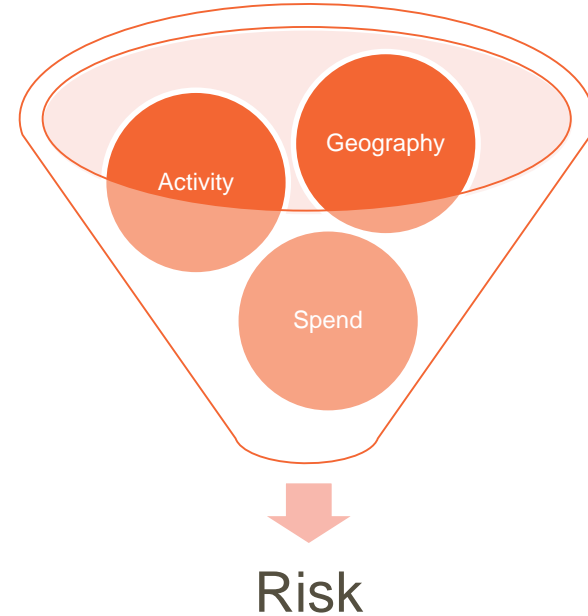


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- What elements contribute to the presence of and magnitude of risk?
 - We can distil down to three key elements

Measurement of Risk



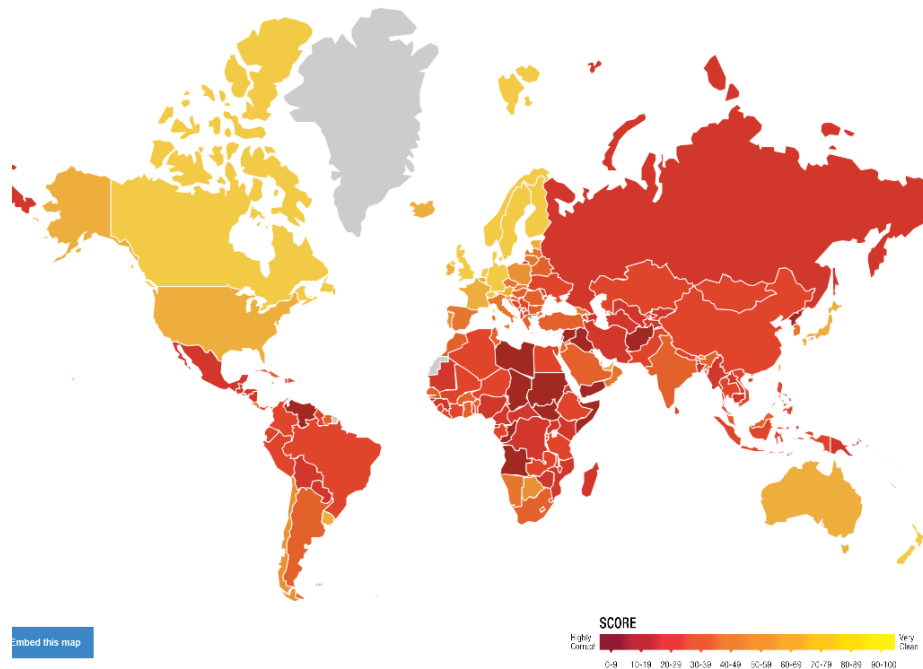
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- Key driver of risk profile
 - Eg risk of buying catalogue goods from a supplier is very different to the risk of running a clinical trial & interacting with patients
 - At GSK, activity is defined consistently across business via the use of commodity codes
 - Risks which may be associated with each commodity code are determined by risk Subject Matter Experts (SMEs)
 - Risk is then confirmed as present during the risk assessment of the engagement

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- The presence and magnitude of some risks can be affected by geographical location
 - Different countries have varying
 - legislation and track record regarding labour rights, health & safety, waste disposal, environment
 - Corruption Perceptions Index scores (ABAC)
 - Not a case of consistently 'high' or 'low' risk across all these elements
 - Within geographical regions there can be significantly different risk levels

Corruption Perceptions Index example



Spend/Value of engagement



- Can be an indicator of risk if used with care
- Important to consider the relative value of money throughout the world
- Even a relatively low spend engagement can be critical if acquiring novel or single sourced goods/services
- Consider any transfer of value

How we manage third party risk at GSK



Risks associated with working with Third Parties



Risk areas assessed by Third Party Oversight (TPO) programme

- ABAC
- Access & Benefit Sharing
- Animal Welfare
- Conflict Minerals
- Competition Law
- Contingent Workers
- Data Integrity
- Environment & Community Health & Safety
- Labour Rights
- Environment, Health & Safety R&D
- GxP – GCP, GCLP, GMP, GLP
- Human Biological Samples
- Human Safety Information
- Inappropriate Promotion
- Information Risk & Operational Technology
- Privacy
- Crisis & Continuity Management
- Suppliers Who Are Also Customers
- Sanctions

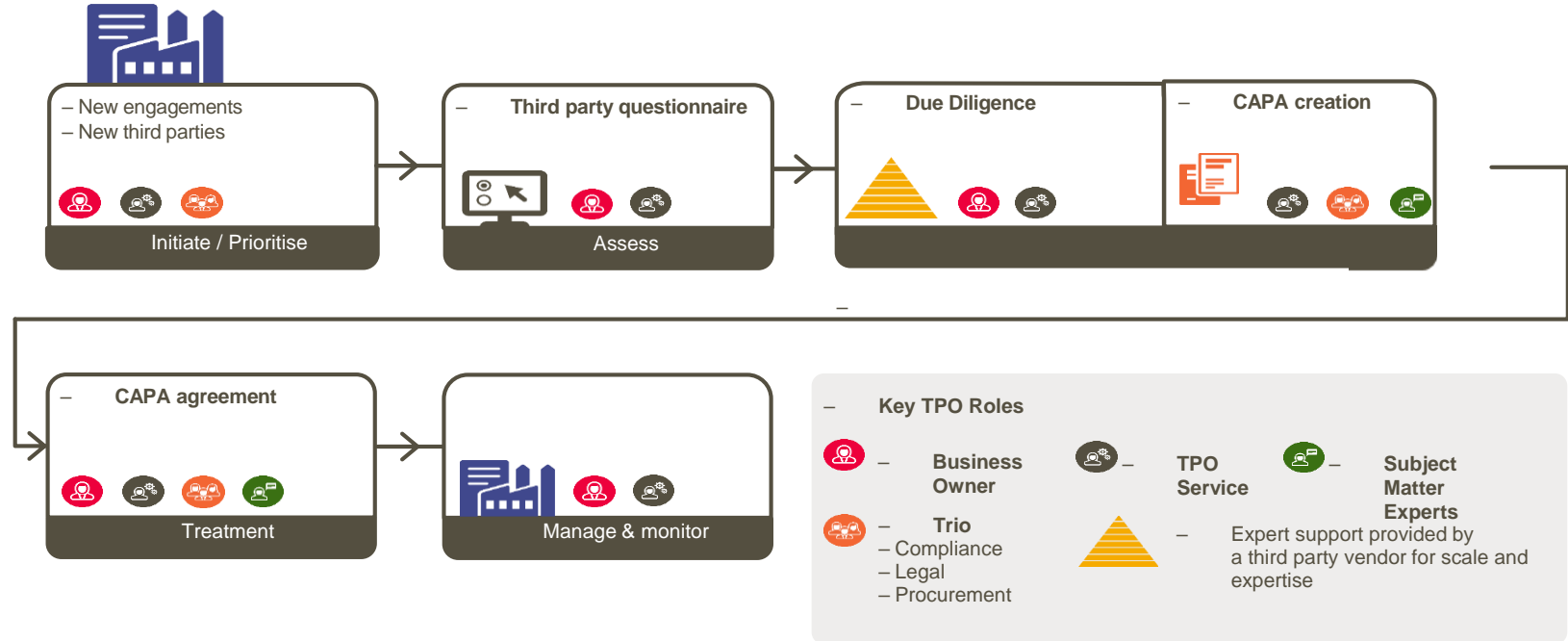
Identification of Risk with a given engagement/vendor



Third Party Oversight Programme

- At GSK we have a structured approach to Third Party Risk Assessment utilising a logic based electronic questionnaire
- Commodity codes – define activity & inherent risks present based on activity performed
- Considers geography involved, spend & level of business impact
- Follows a series of questions based on above factors and responses provided throughout the questionnaire
- Risk profile output with Due Diligence next steps

Third Party Oversight Process



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- Commodity codes trigger GCP questions
 - GCP confirmed as in scope by engagement Business Owner
 - GCLP questionnaire to send to Third Party
 - All other GCP activities reviewed by SME eg protocol review/contract review and any necessary actions taken with CAPAs raised if necessary

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- The risk profile output from the Risk Due Diligence exercise determines the risk area for which oversight is required
 - Guidance provided to Business Owners on what form that oversight should take
 - Any CAPAs identified can be included in the Oversight Plan
 - TPO combines both Corporate and R&D risk oversight

Advantages of a Structured Risk Due Diligence programme



- Structured Process, delivers consistency globally
- Expertise
 - TPO delivers appropriate, proportionate and defensible risk management in line with legal, regulatory and industry standards
 - GSK risk subject matter experts bring detailed knowledge not always available at locally
- Diligent, defensible and documented
- Local control
 - The Business remains accountable for the Third Party risks and agrees to any resulting CAPAs
- Independent Risk Due Diligence Managers (impartial & experienced)

Assessment Process Management & Metrics



- All data from the risk assessment is uploaded into cloud based software through which the assessment process is managed
- Fully searchable, can generate reports
- Allows interrogation of risk profile of engagements to instruct future changes
- Can be used to mine data for other purposes
 - Brexit impact planning (using location)
 - GDPR (using location & privacy risk rating)

Structured Risk Due Diligence & Analytics



Evolution



Assurance that an individual engagement has completed appropriate Risk Due Diligence

By collating all individual assessments greater visibility of all engagements at a Third Party – efficiency savings can be identified throughout process eg DD, Quality audit etc

Can proactively use data to instruct future changes and adjustments in risk Management. Improve proportionality

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- Proportionality!
 - Application required across a range of interactions, geography and third party types
 - Leveraging external best practice & feedback
 - Working with third parties to provide some elements of the programme
 - Listening to and addressing feedback about ease of use/proportionality
 - Evolution
 - Review of the data has allowed us to identify low risk engagement types which can now progress to contract without a Third Party Risk Assessment, where contractual controls and oversight are sufficient to manage the risk
 - Regular review of data to inform risk profiles/threshold settings etc

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- Risk Due Diligence has a key role to play in Third Party risk management
 - Risks present themselves from a variety of sources within a single engagement
 - Many benefits to having a structured approach to Risk Due Diligence
 - Proportionality is key to having an effective Risk Due Diligence Programme



Thank you

Questions?

Questions to the audience



- Is it a centralised process run by specialist DD managers or incorporated into Procurement/CM function
- Do you have a structured framework
- Do you use external providers for any aspects of DD eg CSR/back ground checks
- What feedback do you get from your suppliers on your Risk Due Diligence process?
- Do you think that your Risk Due Diligence process is proportionate?