



BUILDING RELATIONSHIPS WHILE MAINTAINING COMPLIANCE

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Disclaimer

The content of this presentation is my exclusive responsibility and it doesn't reflect neither compromise the position of my working Company.

What type of relationships do we have to build?

Internally

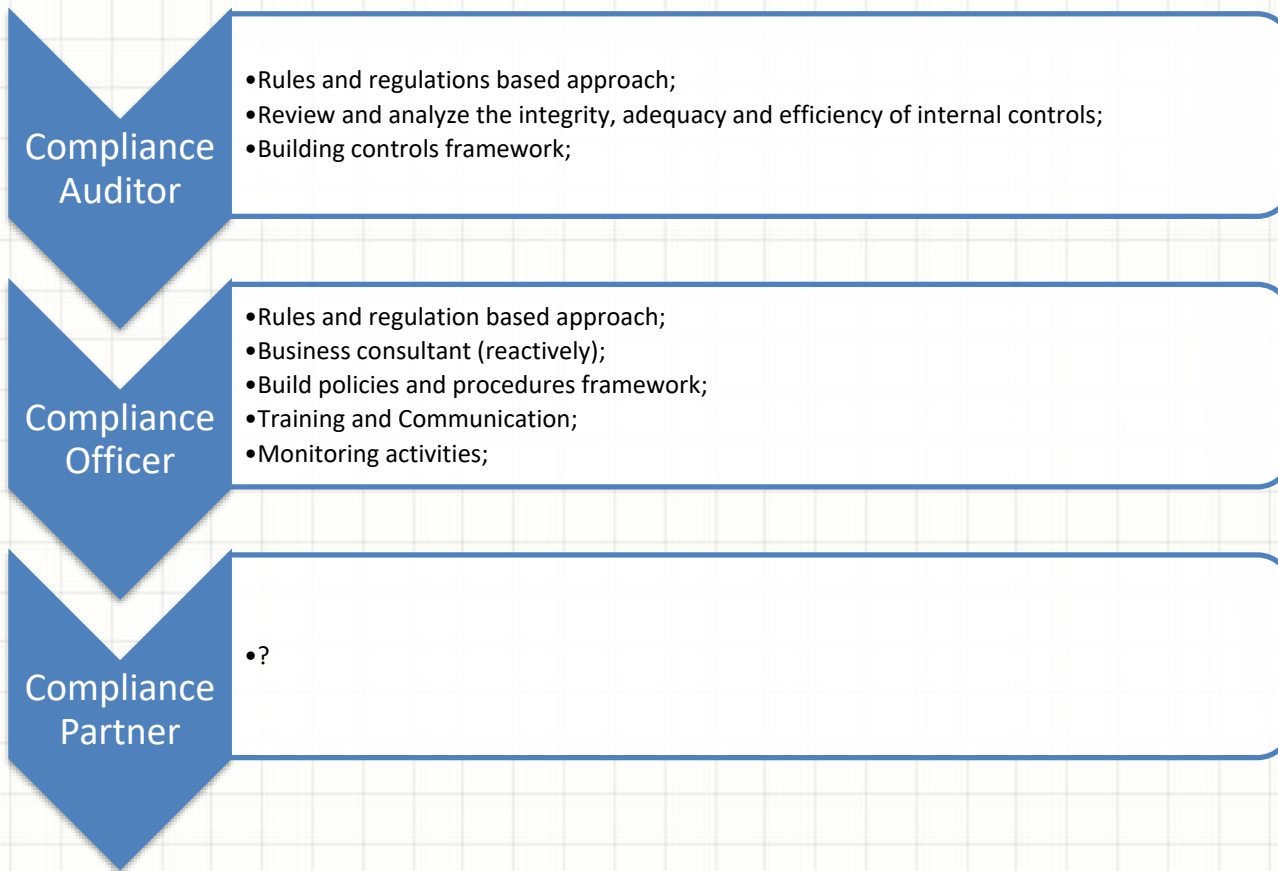
- ✓ Be positioned as Business enabler within Commercial /Marketing teams
- ✓ While looking for Compliance business partners such as Medical, Regulatory, Public Affairs, etc.

Externally

- ✓ Support the business to meet the expectations of our main health related stakeholders:
 - ✓ HCPs
 - ✓ Patients/Patient Groups
 - ✓ Payors
 - ✓ Pharmacies

Building relationships

Journey of Compliance Function:

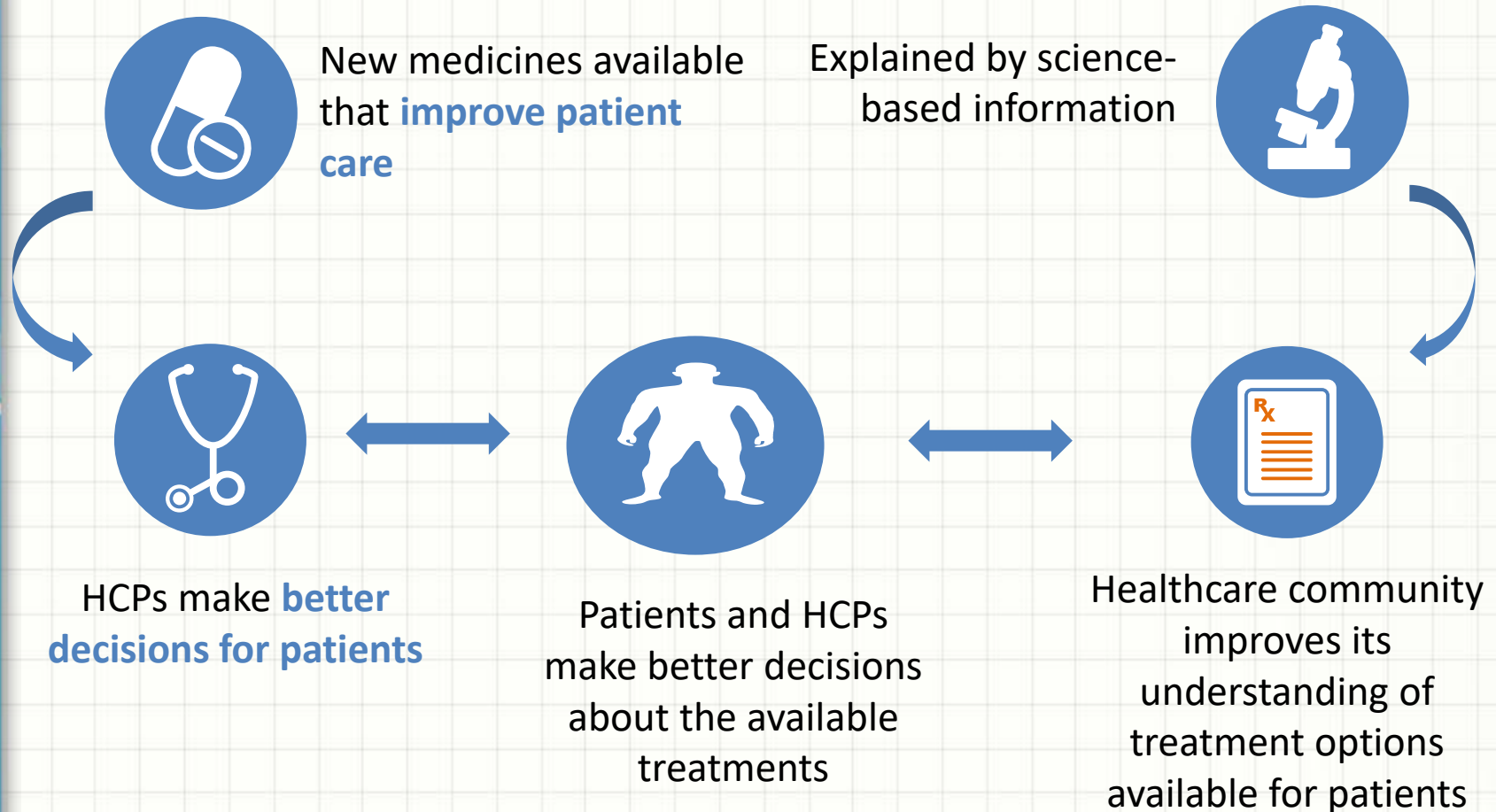


Building relationships

Compliance is dead... or almost:

- Compliance programs, traditionally focused on following what was legal, have failed;
- Big scandals (WV, Valeant, FIFA gate, Odebrech) are just a testament to this;
- Ultimately, Compliance programs are just tools, where its *output* is dependent on its *input* which is our human behavior;
- Law enforcement is simply inadequate to deal with the very complex human behavior;

Why do we have to build such external relationships?



Building relationships with HCPs

Funding attendance to Events



Fund only provided to “active” participants



Events focused only on Medical education (e.g. Preceptorships)



Don't organize or fund events at venues that are, or that can be perceived, as touristic



Have adequate supporting documentation (detailed list of participants, itemized billing of meals consumption & hotel, etc.)



Communicate our rules of the funding to HCPs prior to the event



Don't fund touristic/entertainment/leisure activities

Building relationships with HCPs

Engagements



Fees based on Fair Market Value developed on an objective criteria and based on market analysis



Selection process leaded by non-commercial functions



Have a process to identify Public Officials



Ask for Conflict of Interest disclosure



Define a reasonable cap of engagements



Don't consider the engagement as a method of building loyalty, or maintaining or strengthening a relationship with an HCP.

Building relationships with HCPs

Gifts and Samples



Provide items which have a **real and direct patient benefit**



Provide items which do not offset routine business practices



Don't provide cash or cash equivalents



Don't provide items for HCPs personal benefit



Provide a **reasonable amount** of samples per HCP



Have a proper tracking of samples from the company until HCPs

Building relationships with Patients

Provide materials containing information enabling patients to improve their compliance with the treatment and/or their disease understanding



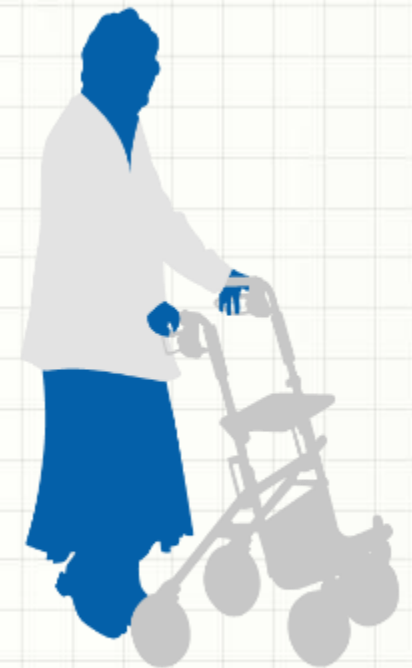
Support Patient Groups in activities for disease state awareness/ Education, psycho-social support during diagnosis and/or treatment



Careful should be taken with these activities to not be and not be perceived as promotional. Also Data privacy requirements are applicable.



Only provide items which support patients in the administration of their treatment or management of their medical condition



Building relationships with Pharmacies

Lease of exhibition spaces in pharmacies based in Fair Market Value



Execute activities centered on patient benefit, educational content or promotional activities relating to our products



Don't execute activities which provide value to pharmacies in terms of helping them run their business



Funding attendance to Site Visits with an active role, without involvement in the selection process



Building relationships with Payors



Funding to trainings which focus on a topic relevant for the pharma industry as a whole and therefore other companies will benefit as well



Don't choose the persons who would attend. The attending person is nominated by his/her superior



Analyze potential conflicts of interest and address them



Can be engaged as Speakers or members of Advisory Boards.



Based on a contract with a FMV. Expertise and background should be documented.

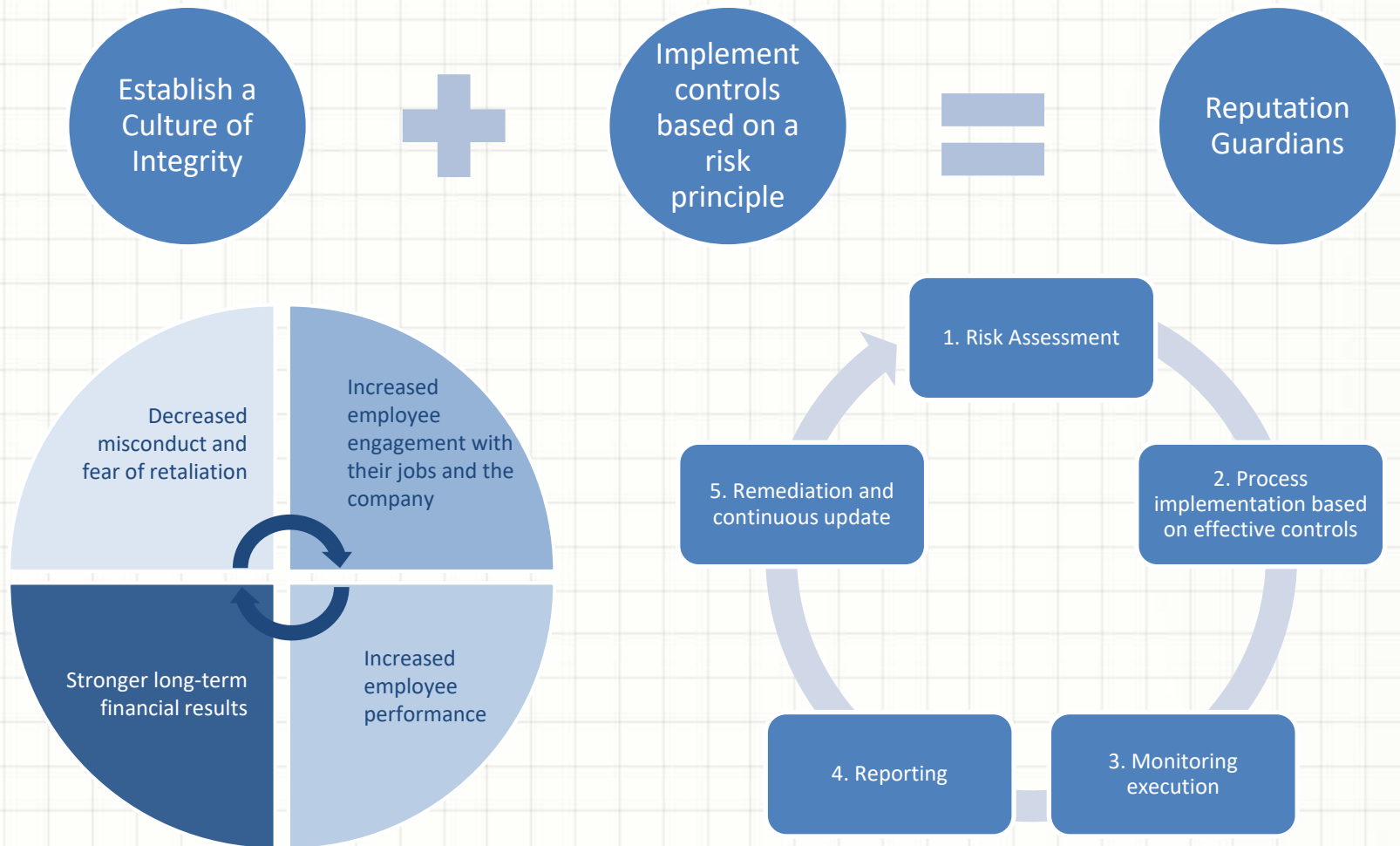


Seek a written confirmation by the institution that he/she is eligible to receive honoraria or be paid the travel/accommodation expenses.



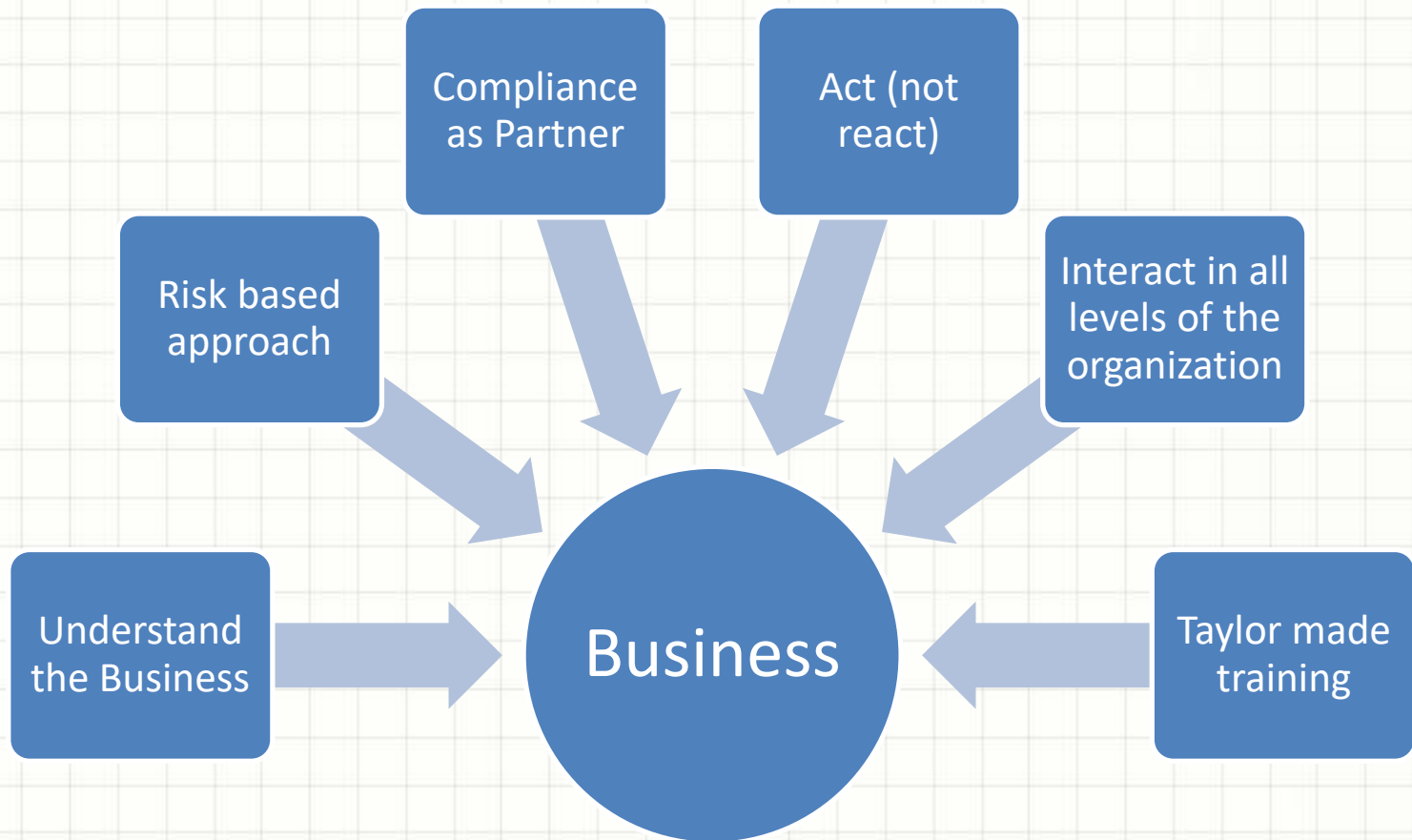
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Why do we have to build such internal relationships?



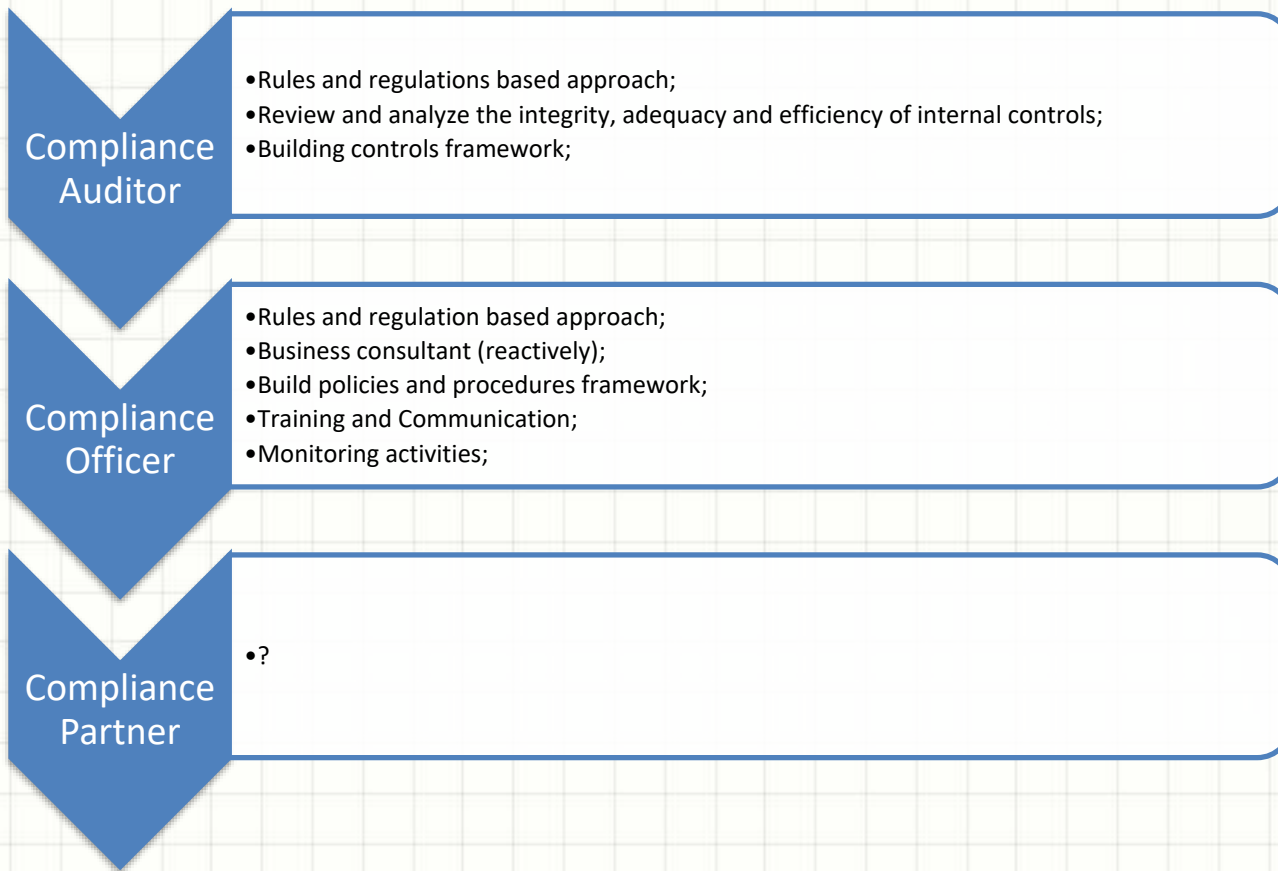
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Building relationships with Commercial/Business



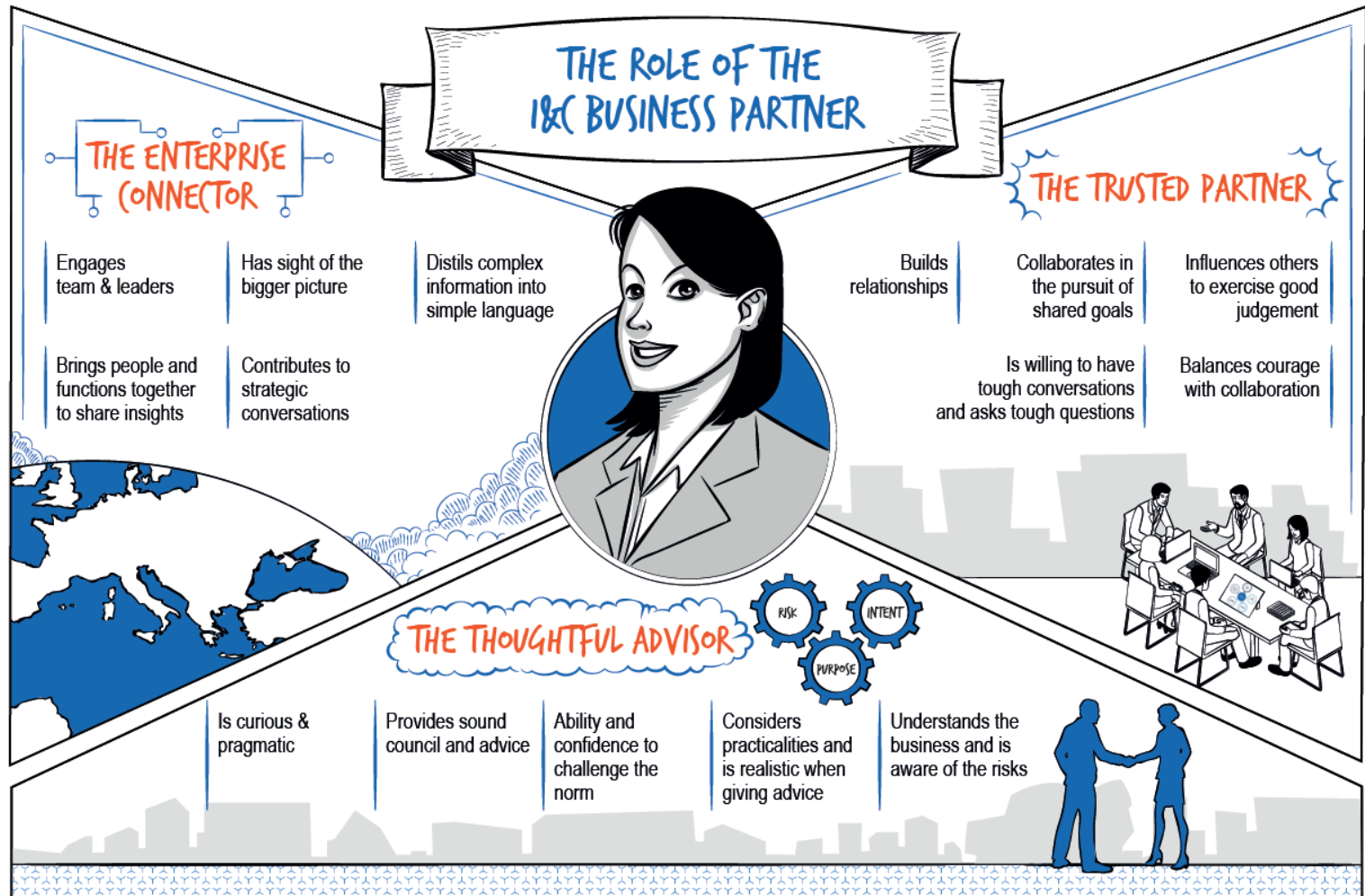
Building relationships

Journey of Compliance Function:



Building relationships

Compliance Partner:



Key take-aways messages


- Be balanced between internal work and external relationships;
- Know your people;
- Leave the desk. Go to the field!
- Understand your market, your business and your local/internal associated risks.
- Have clear and realistic policies/controls;
- Train your people based on real examples, explaining the WHY behind your rules and use innovative tools;
- Work on the message about compliance as a competitive advantage at all levels, internal and externally;

Think beyond

- Are we thinking seriously on the real patient benefit when we define our internal rules?
- Which can be the new stakeholders that we would have to build new relationships?
- How are we controlling activities performed by our Third parties? Can this trigger small and local companies to “play” with the same rules?
- In our region, how can we deal with “personal contacts” that are a big part of our culture?



Questions?



Muito obrigado!
Thanks!
Gracias!

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