MedImmune

A member of the AstraZeneca Group

3rd Party Vendor Management

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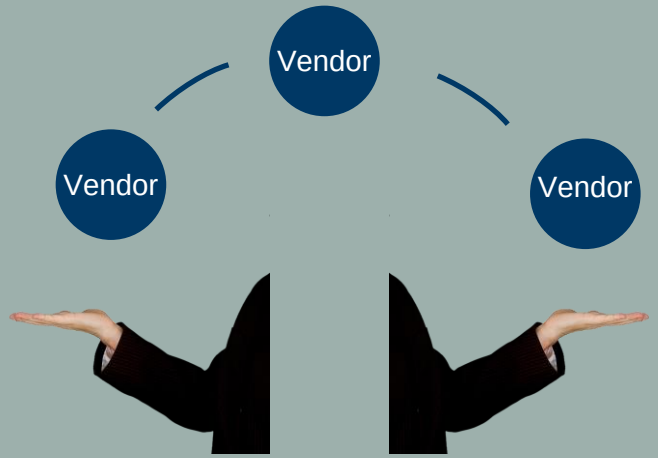
A Sponsor may outsource any or all of the Sponsor's trial-related **responsibilities** to a CRO,

but the ultimate **accountability** for the quality and integrity of the trial data always resides with the Sponsor.

Vendor Management

Vendor Management



Vendor Management

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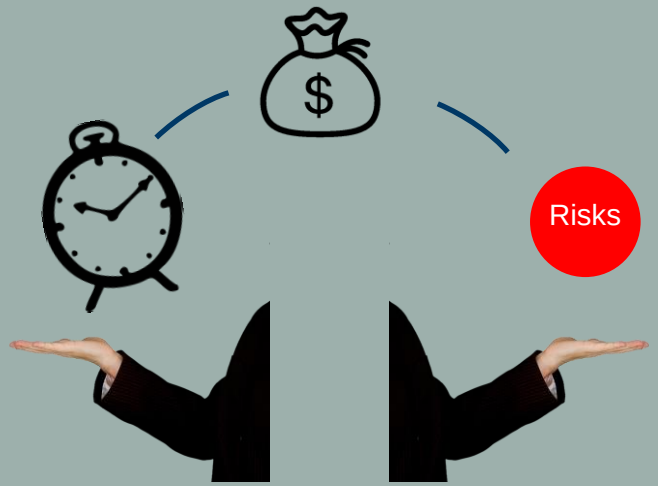

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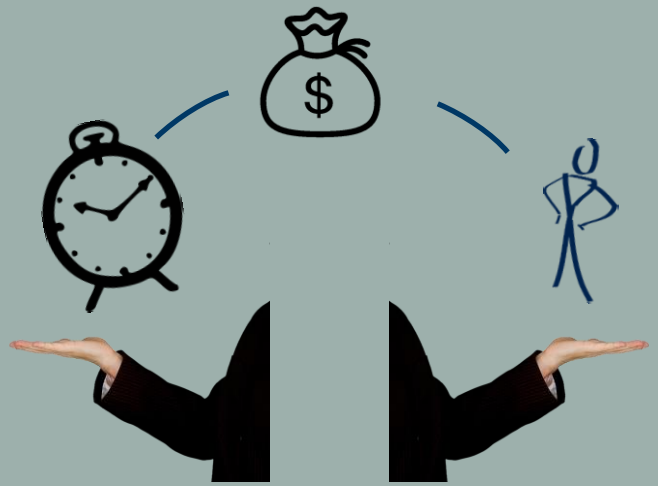


Vendor Management

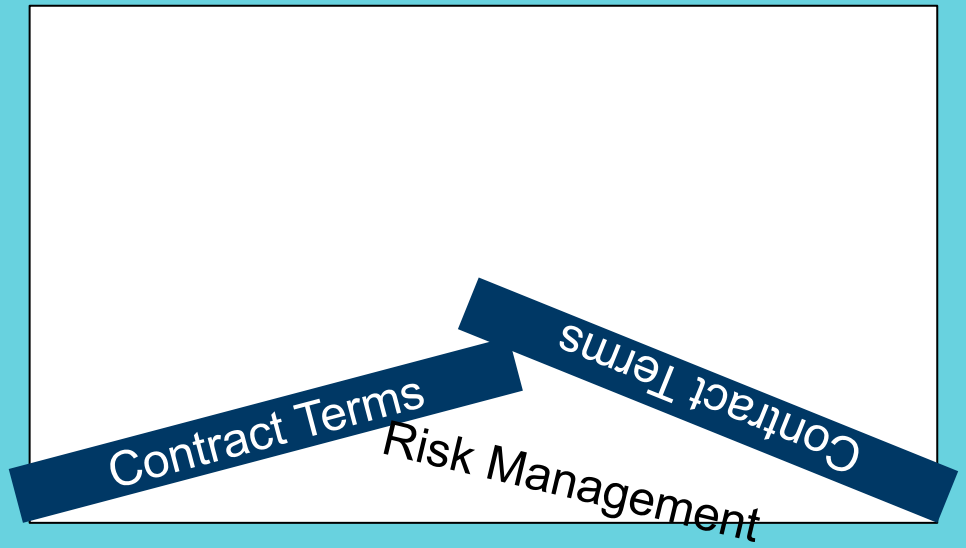
Risk Management

Risk Management

Contract Terms

Risk Management

Contract Terms


Contract Terms
Risk Management
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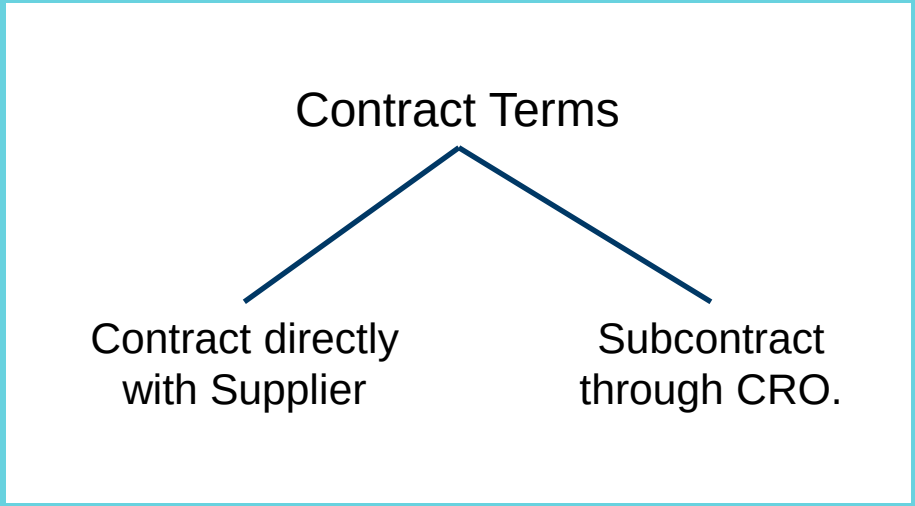
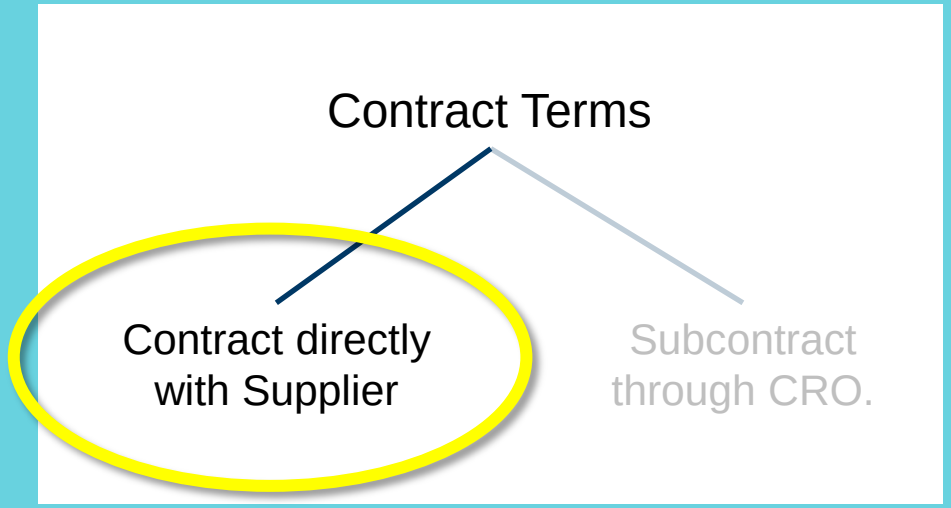

Contract Terms
Contract directly with Supplier
Subcontract through CRO.

Contract Terms
Risk Management
Contract Terms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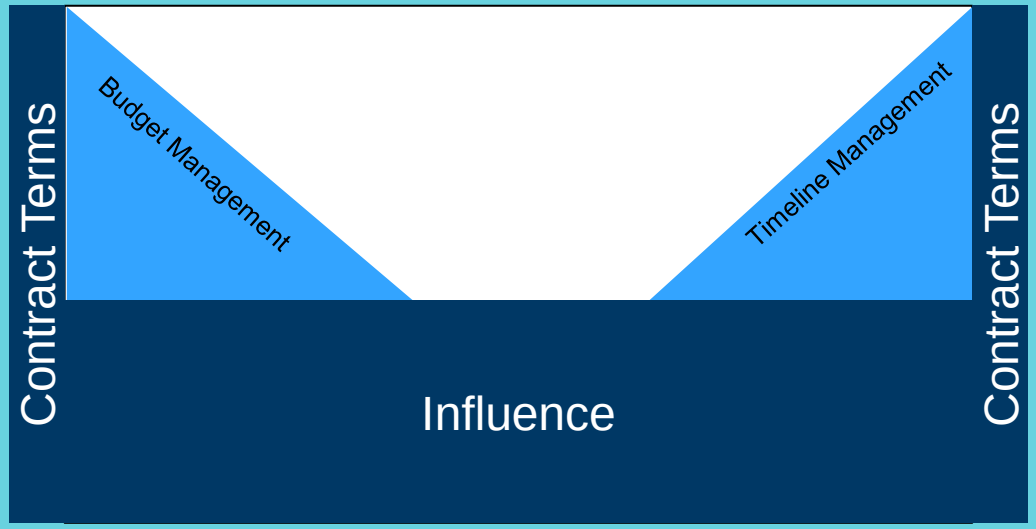
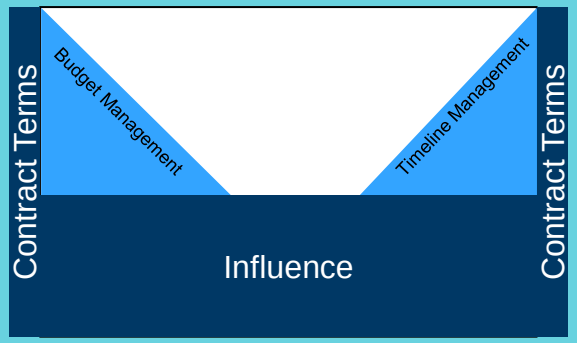
Contract Terms
Risk Management
Influence
Contract Terms


Contract Terms
Budget Management
Timeline Management
Contract Terms
Influence

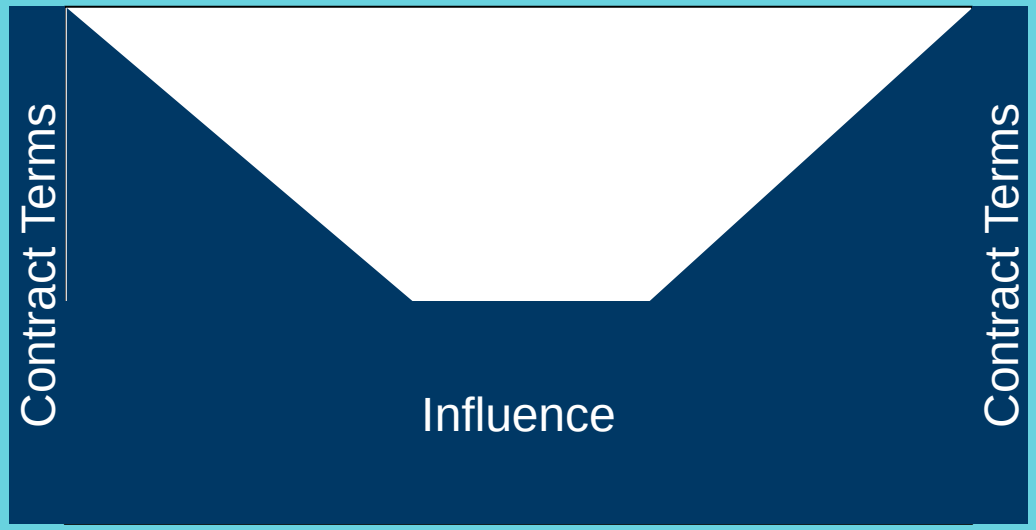


Government requirements

Leveraging and proactivity

Getting ahead of problems

Reducing burden


Contract Terms
Influence
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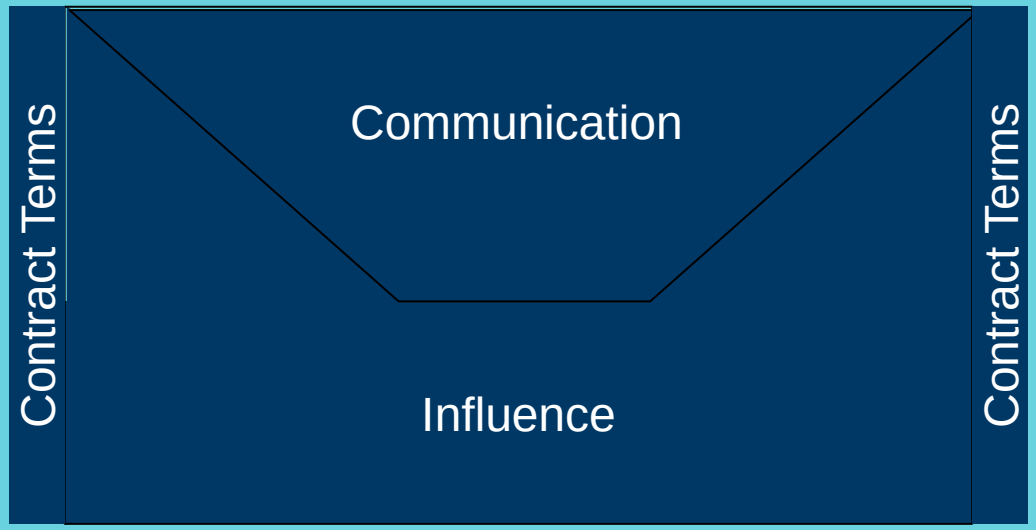
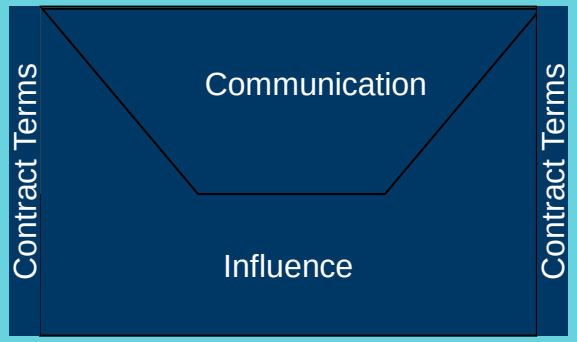

Contract Terms
Communication
Influence
Contract Terms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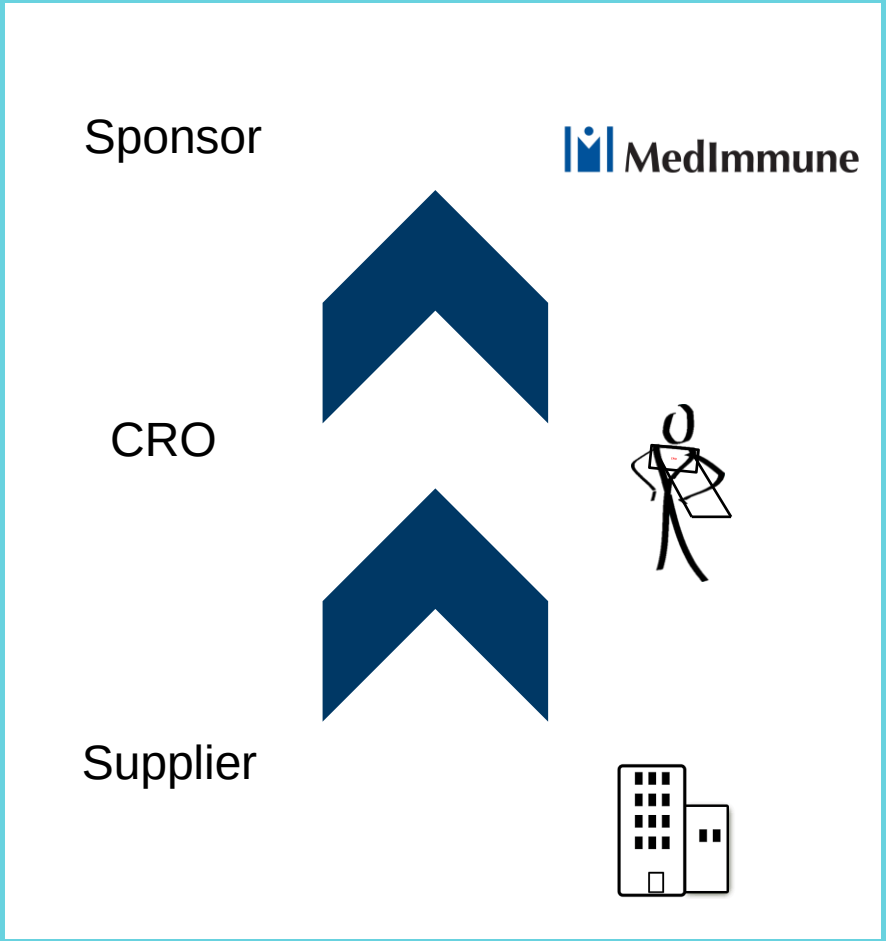

Sponsor
MedImmune
CRO
Supplier

Vendor Management

Contract Terms

Communication

Influence

Contract Terms

Vendor Management

Challenges

Vendor Management

Challenges

Vendors understanding the relationship

Vendor Management

Challenges

- Confusing to the third party
- Causing communication and responsiveness lag
- Sponsor required to intercede.

Vendors understanding the relationship

Vendor Management

Challenges

Proactively identifying issues / inflexible Vendors

Vendor Management

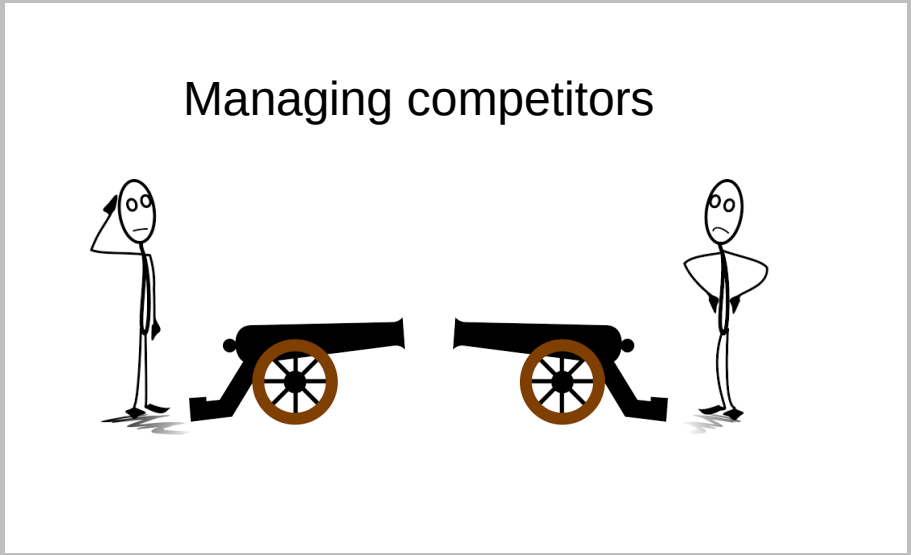
Challenges

- Inflexible
- Limited by 3rd Party SOPs
- Unwilling to adapt
- Difficult to be proactive

Proactively identifying issues / inflexible Vendors

Vendor Management

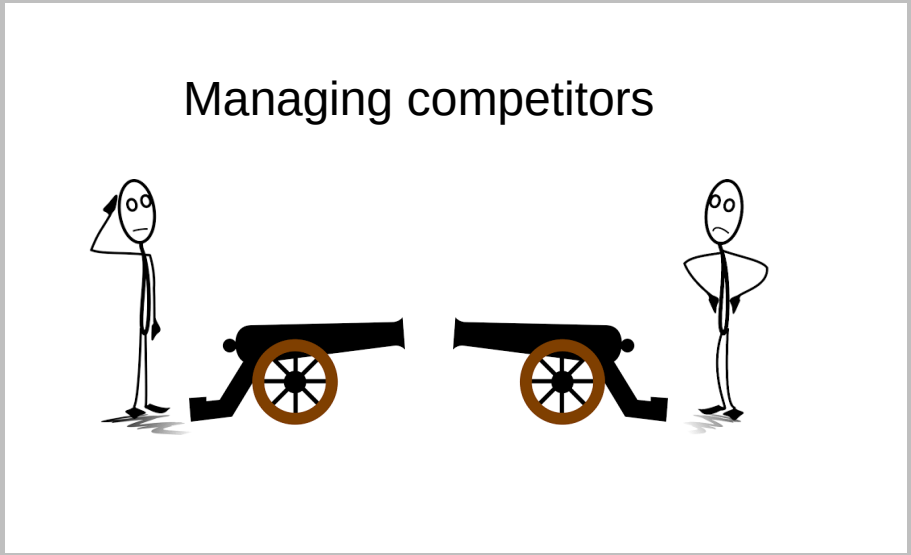
Challenges



Vendor Management

Challenges

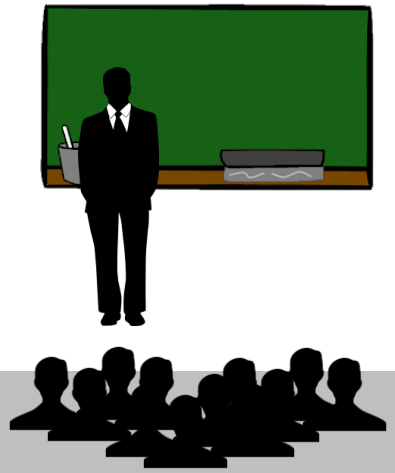
- Strategic suppliers diff. categories
- Reluctant to share information
- Proprietary concerns
- Reluctant to accept feedback



Vendor Management

Challenges

Sharing lessons learned across portfolio

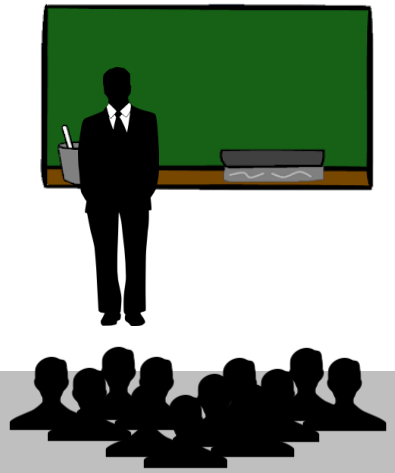


Vendor Management

Challenges

- Complicated web of feedback
- Changing of personnel
- Changing of vendors per study

Sharing lessons learned across portfolio



Vendor Management

Successes!

Vendor Management

Successes!

Regular Meetings

Vendor Management

Successes!

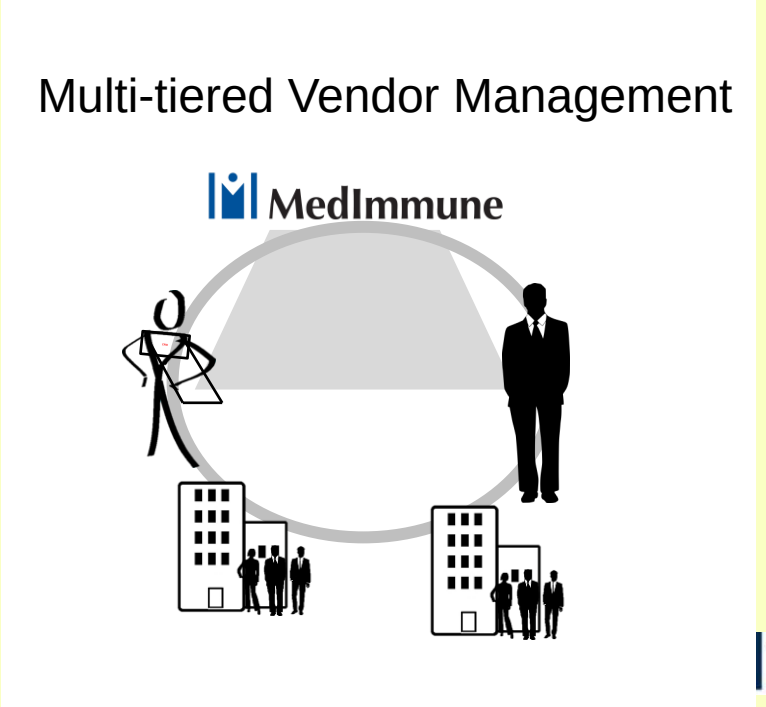
- Greater visibility
- Insight to CRO on expectations

Reduce meetings as relationship matures

Regular Meetings

Vendor Management

Successes!



Vendor Management

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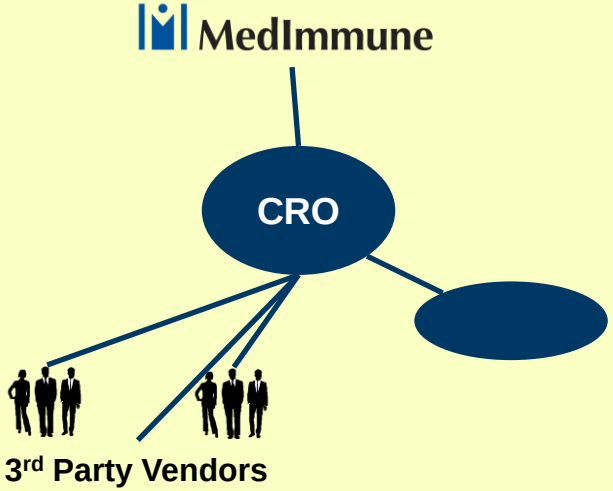
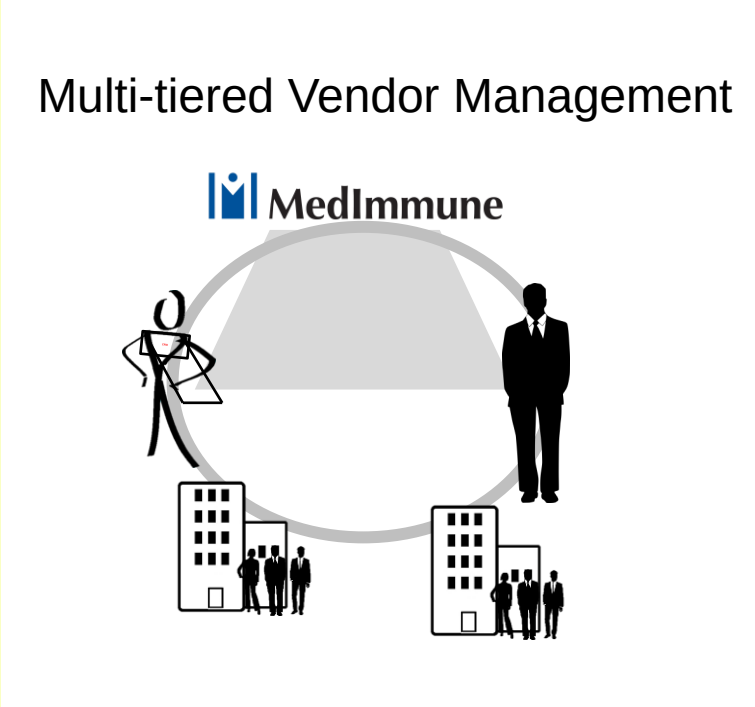
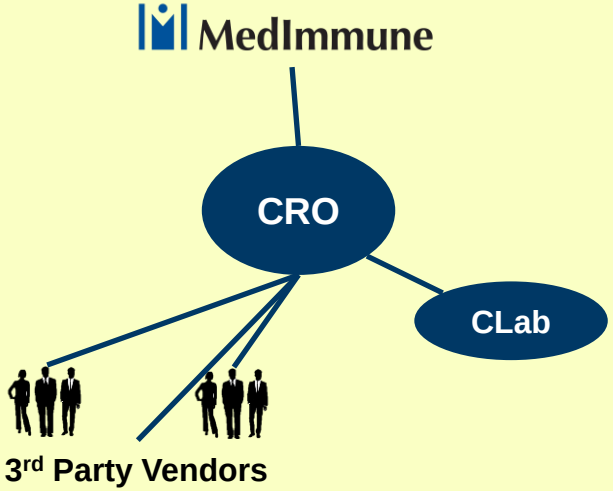
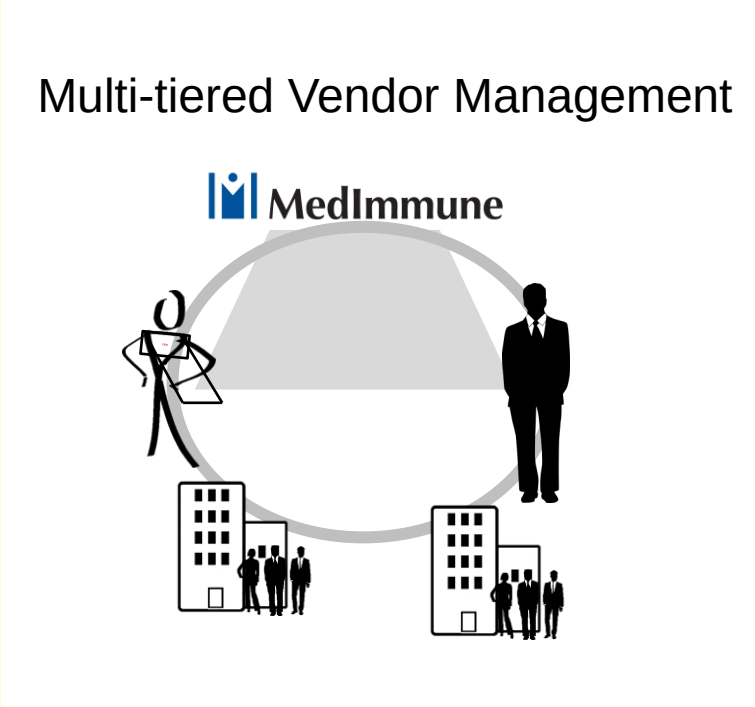




Vendor Management

Successes!





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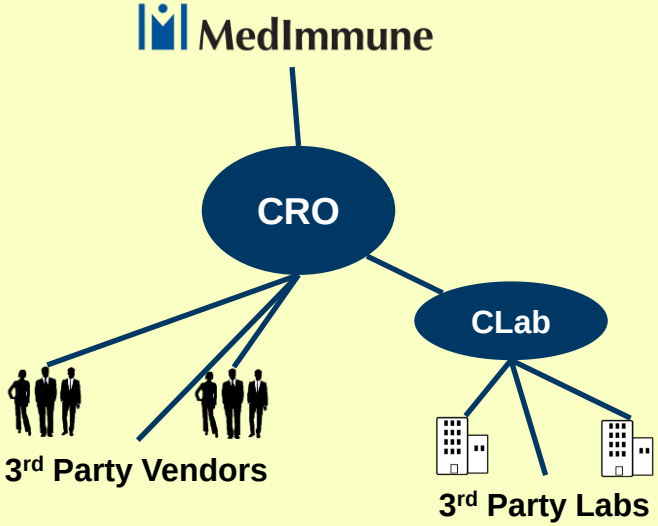
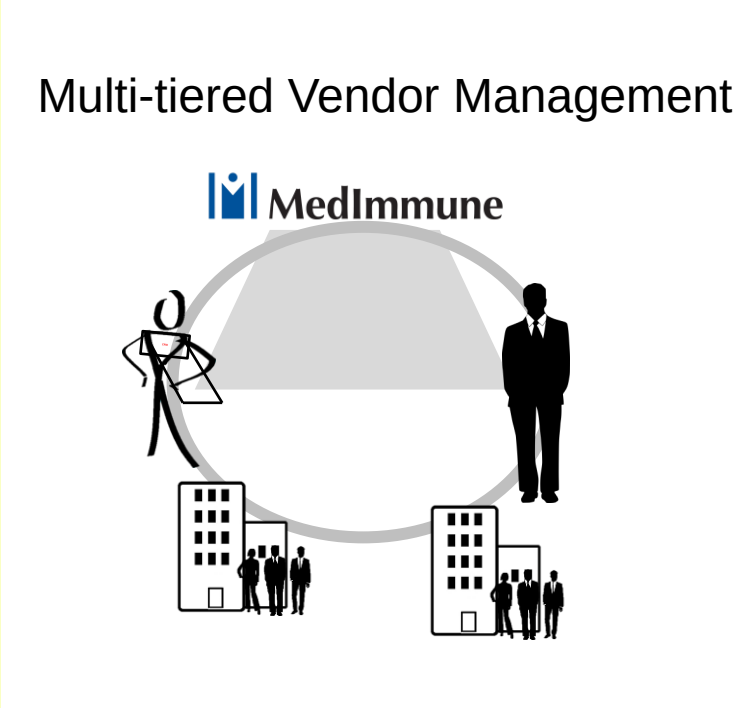
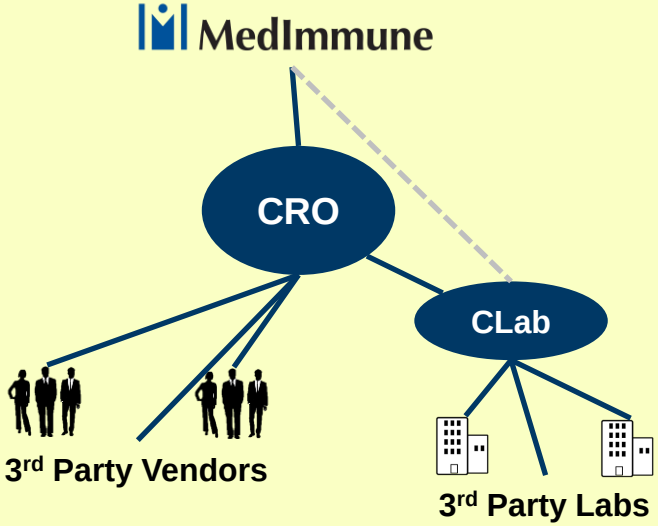
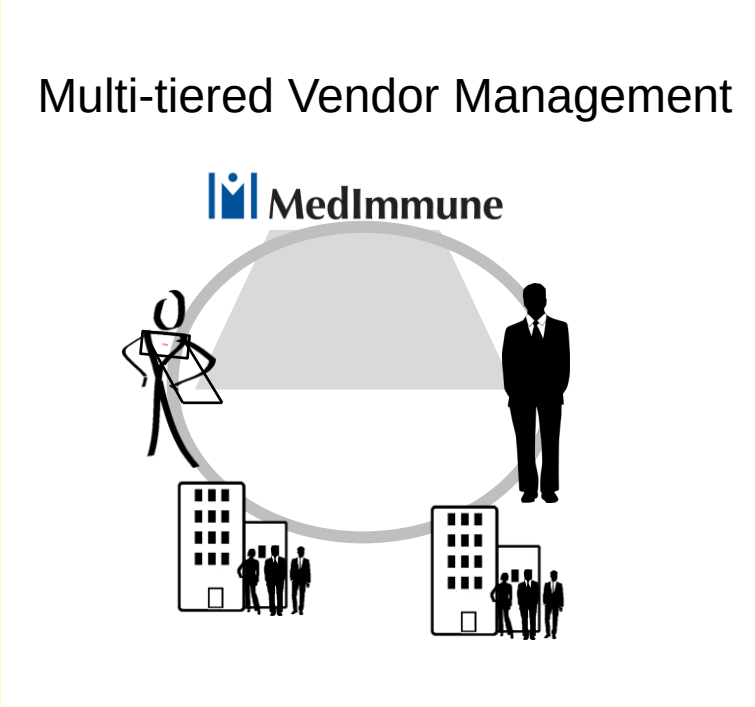




Vendor Management

Successes!

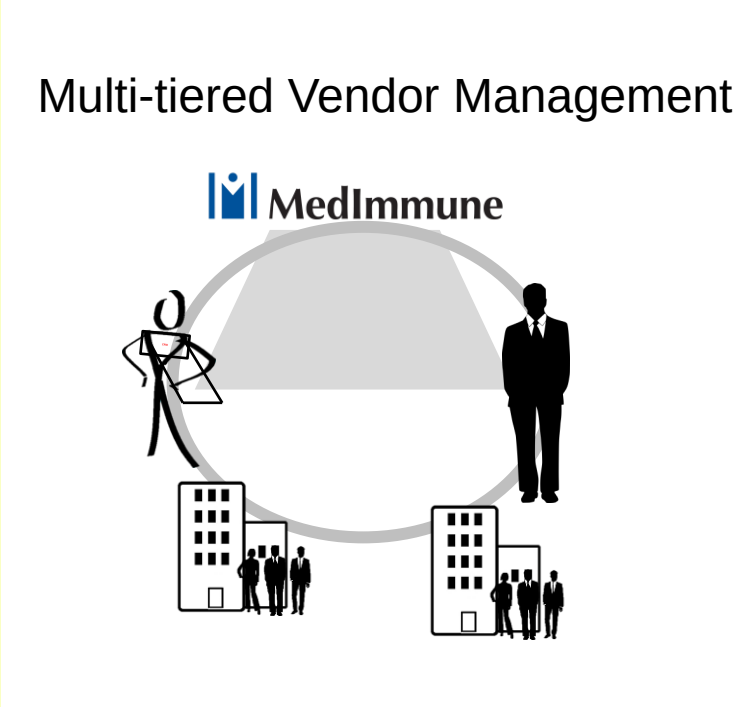




Vendor Management

Successes!

- Reduce complexity for CRO
- Lab's manage labs (expertise)



Vendor Management

Challenges

- Vendors understanding the relationship
- Proactively identifying issues / inflexible vendors
- Managing competitors
- Sharing lessons learned across portfolio

Successes!

- Regular Meetings
- Multi-tiered Vendor Management

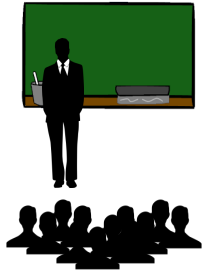
3 Case Studies

CRO managing:

Laboratory Testing Services Vendors

Case Study #1

Share Lessons Learned Across the Portfolio



Challenges

Issue: Reagent shortages *led to* halting collection kit production.
Occurrence: numerous times.

Standing Remedy: no adequate backup plan

Solution

VM Solution: Increase vendor oversight.
Actions:
- CAPA issued
- Dedicated CRO VM across portfolio

Future Remedy: Repeat issues escalated to vendor PM and Medi PM immediately after second occurrence.

Case Study #2

Inflexible vendors

Challenges

Issue: Test result missing.
Reason: 2 tubes provided to lab with identical label. Per lab SOP, 1 tube discarded without further inquiry.

Standing Remedy: none

Solution

VM Solution: Increase vendor oversight.
Actions:

- Installed 2nd tier of VM
- Dedicated CLab BioSpecimen PM

Future Remedy: all discrepancies in will be reconciled by the CLab BioSpecimen PM.

Case Study #3

Vendors understanding the relationship

Challenges

Issue: Prescreening delayed

Reasons:

- Lab Manuals not dispersed in time *(b/c)*
- Labs did not provide info to CRO *(b/c)*
- Labs reluctant to be managed by CRO

Other actions: Labs (several) requested meetings with Medi to "correct" relationship structure.

Solution

VM Solution: Increase vendor oversight.

Actions: Installed 2nd tier of VM

Future Remedy: Regular meetings with vendor PM and CLab BioSpecimen PM (weekly tracker). And regular meetings between CRO VM and CLab BioSpecimen PM.

Vendor Management

Contract Terms

Communication

Influence

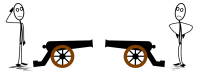
Contract Terms

Challenges

Vendors understanding the relationship

Proactively identifying issues / inflexible vendors

Managing competitors

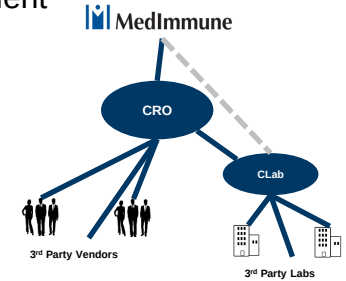


Sharing lessons learned across portfolio

Successes!

Regular Meetings

Multi-tiered Vendor Management



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