

Research Support: Doing Science in a Commercial Setting

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Research Issues: Clear Goal

- Do research for the right reasons
- Do research with the right criteria
- Do research the right way

Paths to the Goal: Opposing?

- **Government:** ideally, complete separation between scientific and commercial functions
- **Industry:** ideally, strategic integration for better efficiency/ productivity, higher likelihood of success

Expectation...

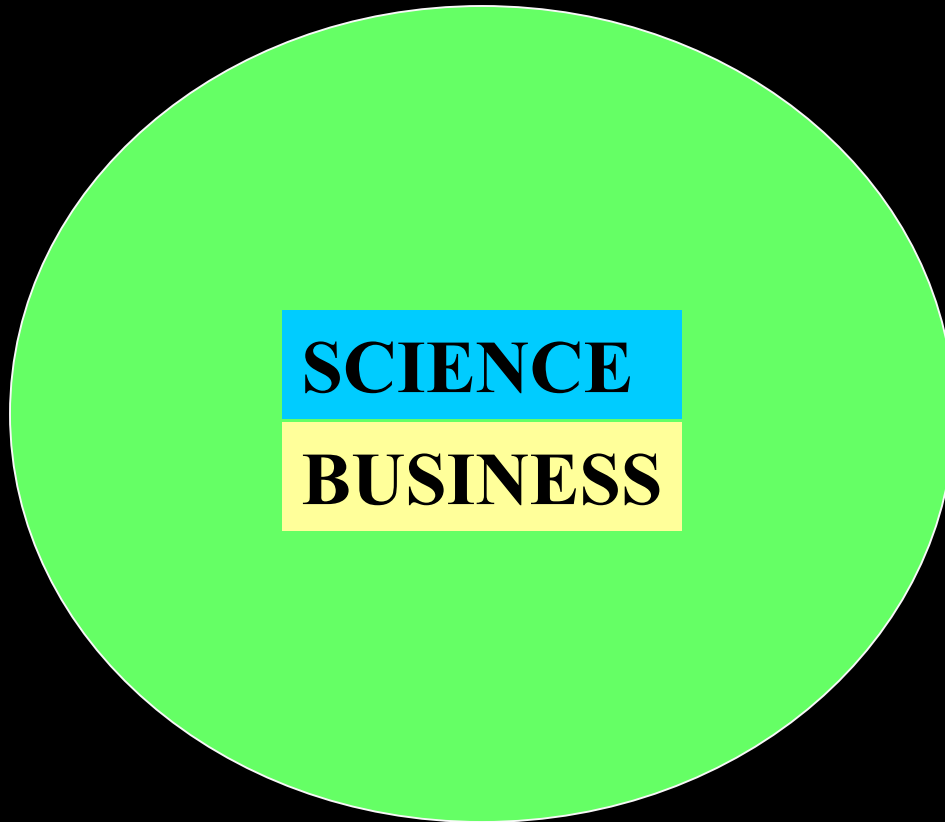


SCIENCE

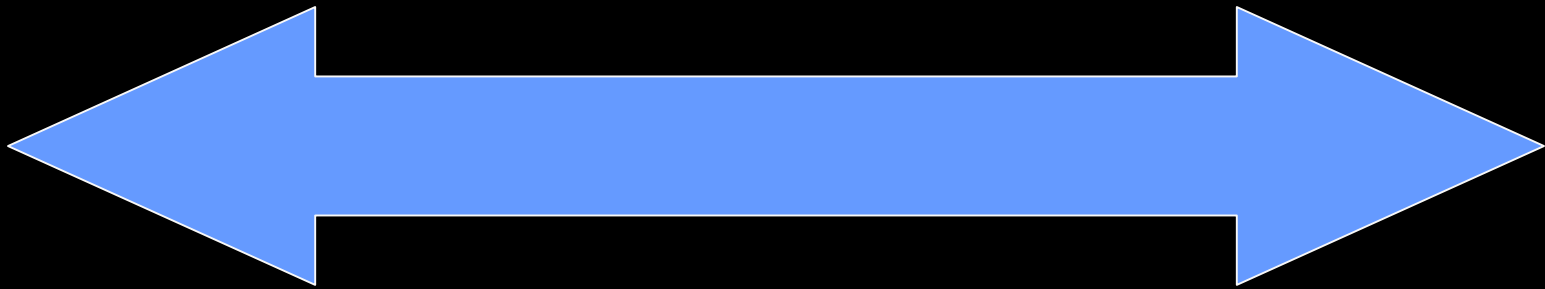


BUSINESS

...vs. Reality?



Risk Spectrum

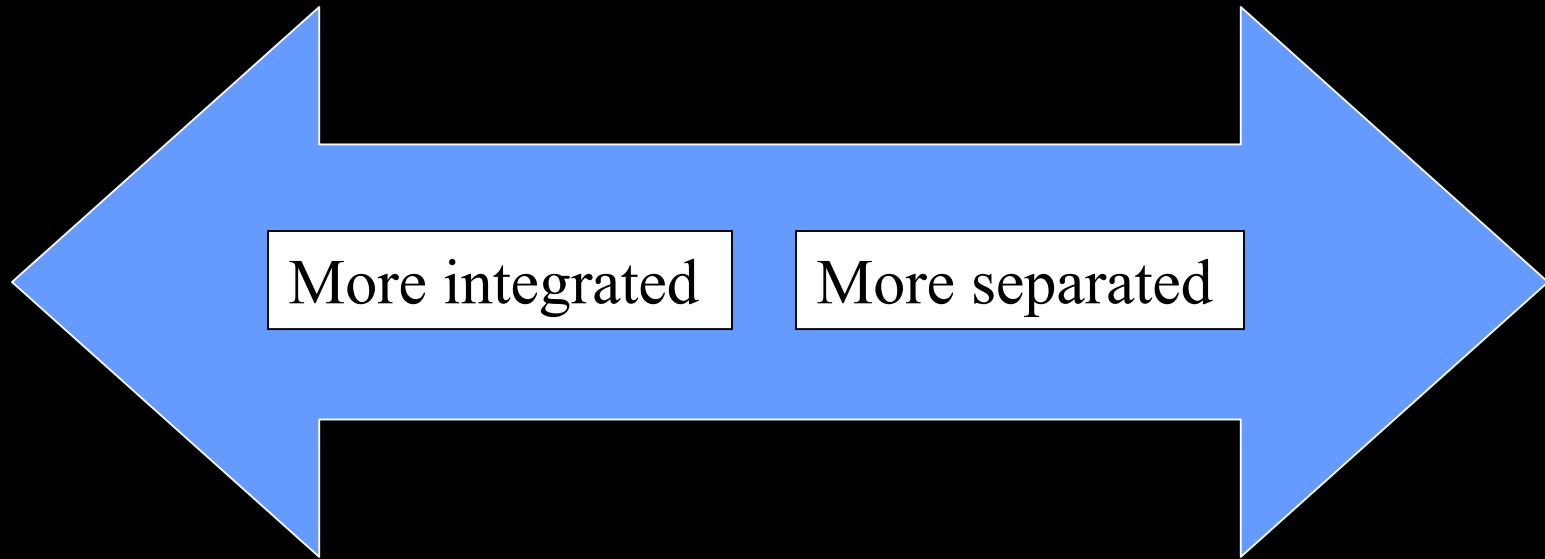


Enterprise
mission

Directional
strategy

Tactical
activities

Separation and Control Spectrum



Enterprise
mission

Directional
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Tactical
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Communication Reinforcing Control

- Avoid disconnects along spectrum from general/ strategic to specific/ tactical
- Clearly identify who controls:
 - Decision-making
 - Execution
- Watch the “one-purpose” test

Research Issues: Linking Controls

- Good Clinical Practice
- Good Laboratory Practice
- Informed consent
- Privacy

- Medicare fraud and abuse issues