

Using Metrics in a Pharma-CRO Partnership: Creating a Win-Win Scenario

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Curriculum Vitae - David S. Zuckerman

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Dave Zuckerman president of Customized Improvement Strategies LLC - a management consulting firm which focuses on Process Improvement, Teambuilding, Leadership Development and Change Management. Dave specializes in Process Improvement, Performance Measurement and Change Management, and has provided consulting, training and coaching for companies in a variety of industries, including pharmaceutical, health care, chemical, service, computer software, electronics, defense, aerospace and education. Some of his clients include:

- Searle
- Washington University School of Medicine
- University of Minnesota School of Medicine
- Northwestern University School of Medicine
- Teva Pharmaceuticals
- PDL BioPharma
- Bristol-Myers Squibb
- Johnson & Johnson
- Eli Lilly & Co
- AstraZeneca Pharmaceuticals
- Novartis Pharmaceuticals
- SCIREX
- Abbott Pharmaceuticals
- NeoPharm
- Astellas
- McNeil Pharmaceuticals
- Synarc
- Sepracor

Dave has helped a number of pharmaceutical clients develop and implement Balanced Scorecards to manage and improve their businesses, and has published articles in Scrip Magazine about how to create useful metric systems. He speaks regularly on the topic and chairs the annual IIR Performance Metrics conference.

Based on 20 years working with organizations in all phases of continuous improvement, Dave has developed his own, highly advanced approach to identifying and eliminating problems, and improving team performance. He has used his expertise to help these same organizations improve overall performance in areas such as:

- clinical trials
- contract negotiation
- outsourcing
- lab coordination & streamlining
- proposal development
- billing and accounts payable

Recently, he has developed a totally new technique for **simulating protocols**. This novel approach to improving protocol efficacy helps clinical trial teams **eliminate amendments**, reduce queries and cut cycle times in clinical trials.

Creative thinking is a key component of Dave's training and coaching. He has developed new techniques for stimulating creative thinking, including **Assumption Trees**. Dave teaches these techniques to his clients and supports their use in actual problem-solving situations. His **Creative Problem Solving** course has proven to be a crucial tool for helping clients to make rapid, substantive improvements.

Dave earned a Bachelor's degree in Mechanical Engineering from Princeton University and a Masters in Mechanical Engineering from Washington University. He is trained in systems analysis, activity based costing, quality assurance and quality improvement, marketing, and strategic planning. He has lectured nationally on Focused Improvement, Jumpstarting Improvement and Creative Problem Solving, has been a guest lecturer at Washington University's Olin School of Business, and has published numerous papers on technical and management subjects. He is a member of the American Society for Quality and the Drug Information Association, and was a three-term examiner for the Missouri Quality Award.

Dave is the author of "Measurement Systems in Pharmaceutical R&D" from Gower Press.

CIS Services for Pharma

Clinical Development

Development risk forecasting & mitigation
Decision making enhancement

Clinical Operations

Quantum Leap performance enhancement
Process streamlining & redesign
Cross-functional team development
Virtual team development
Balanced Scorecards
Enrollment forecasting, modeling & optimization

Protocol Development

Protocol optimization
Amendment & query reduction
Protocol Simulation workshops
Enrollment forecasting

Outsourcing for R&D & Mfg

Outsourcing strategy development
Performance measurement & balanced scorecards
Novel contracting approaches
CRO/CMO management best practices
Pharma-CRO team performance optimization

Site Selection & Improvement

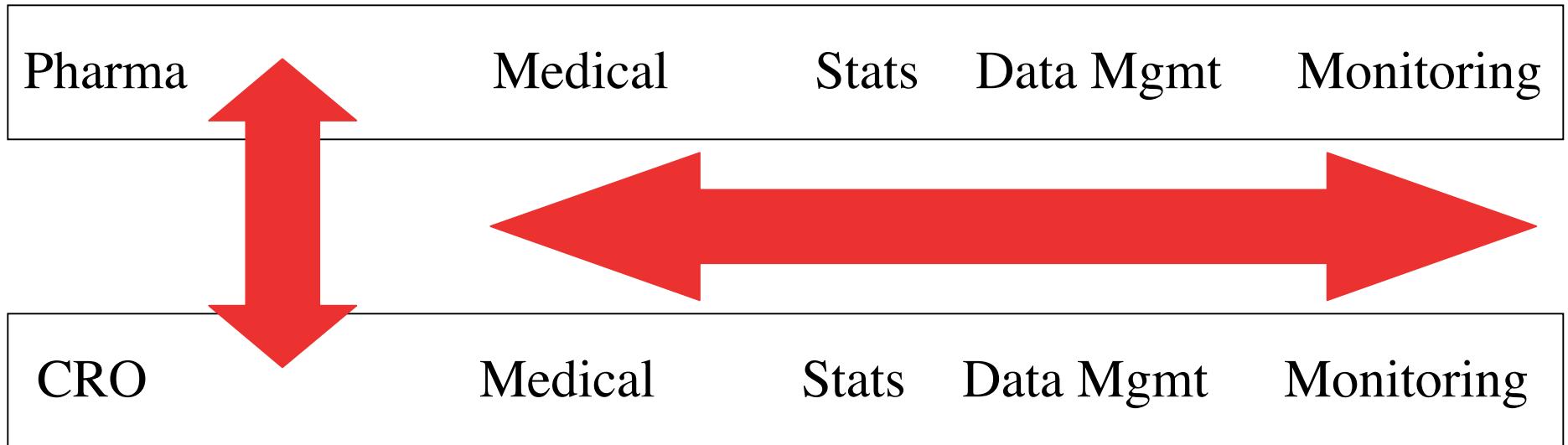
Site selection & initiation streamlining
Site performance measurement
Site Relationship Management training
Recruitment / Retention Planning

Why Measure?

- **Speed**
- **Quality**
- **Agility**
- **Capacity**
- **Improvement**
- **Best Practices**

A good measurement system helps you minimize cost and maximize performance (both CRO and pharma)

Pharma-CRO Teams: A Sophisticated Dance



Two Possible Metric Systems

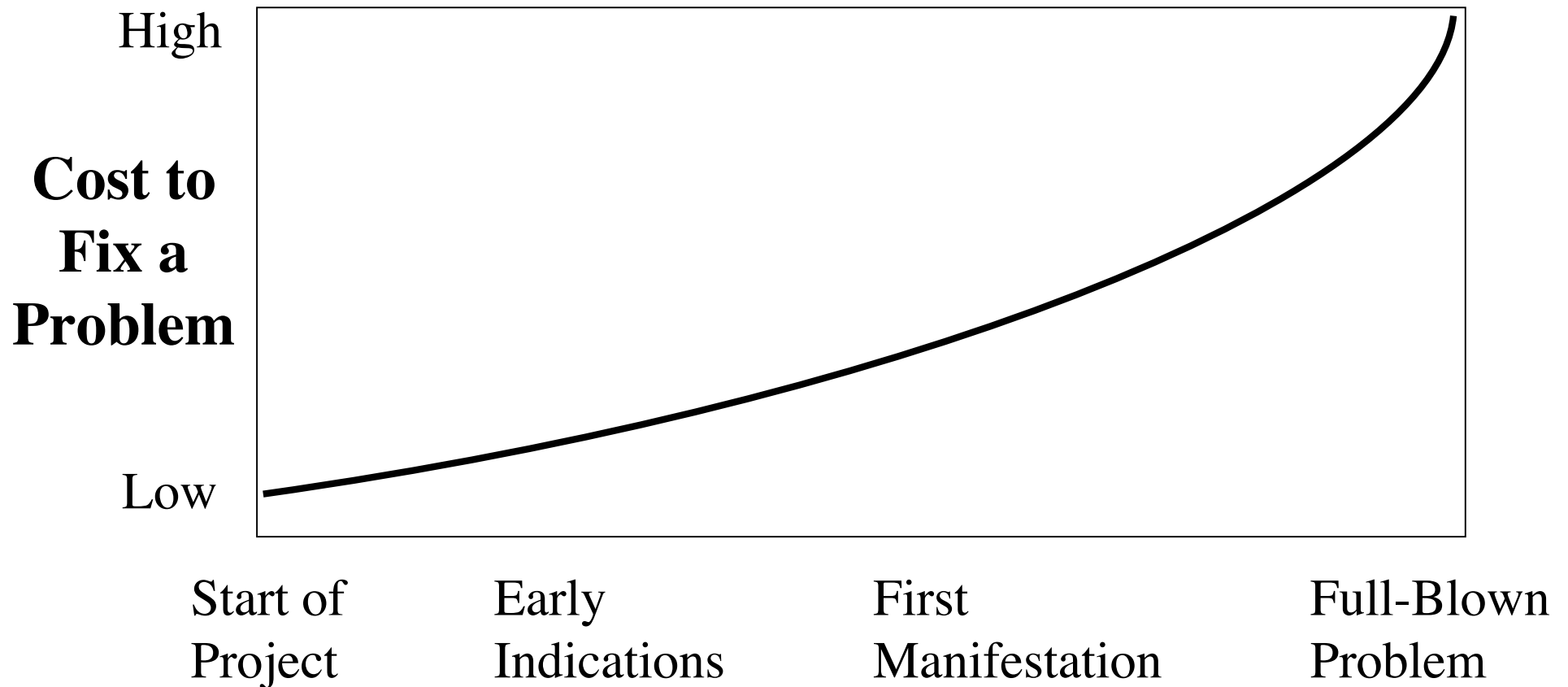
- **Project Performance Metrics**
- **Strategic Relationship Metrics**

Which system is appropriate for you?

Project Performance Systems

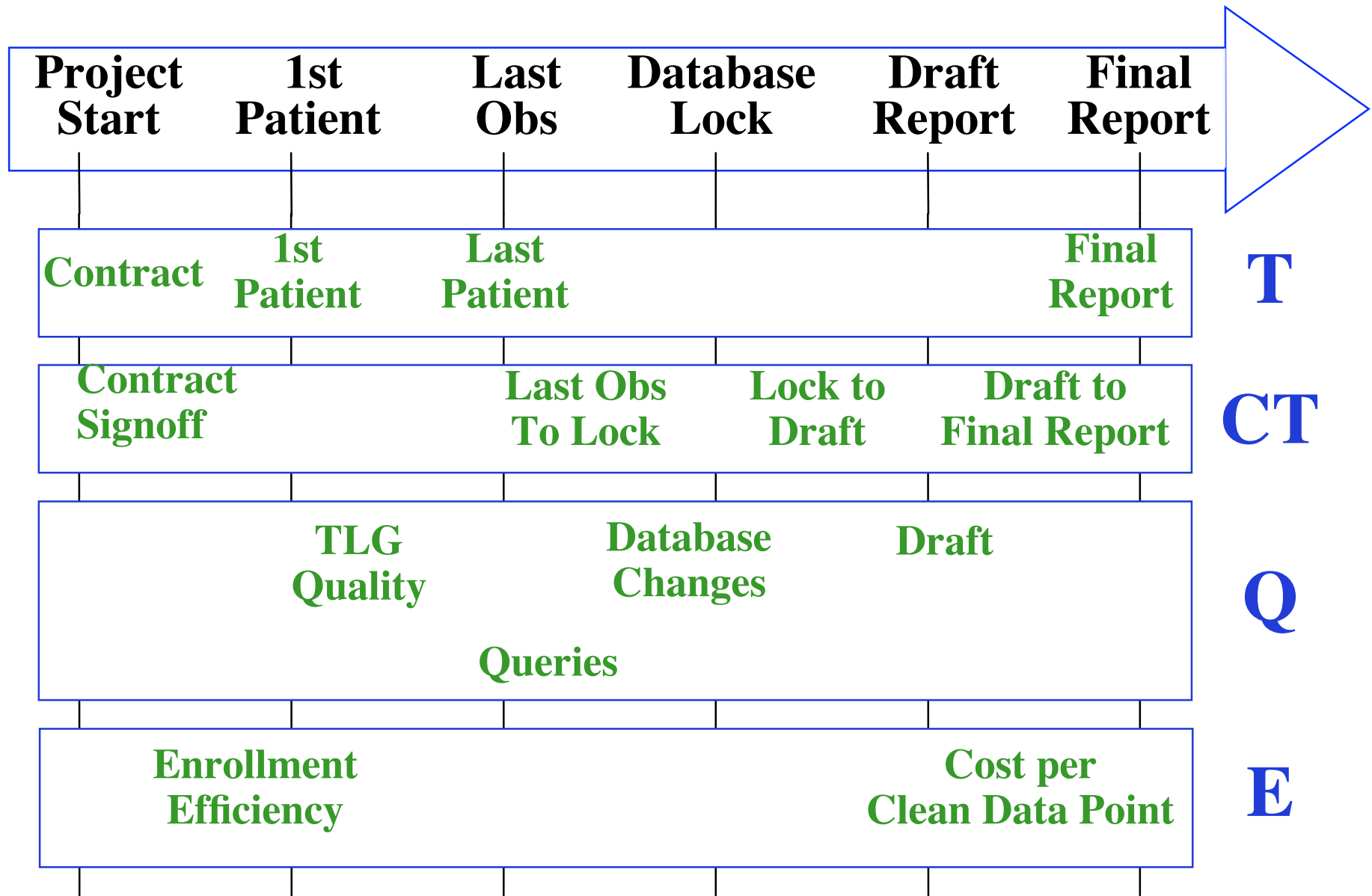
- **Tracking performance on one or more projects**
- **Heading off problems**
- **Gleaning best practices and lessons learned for next time**
- **No promise/agreement to a future relationship**
- **Metrics are balanced across performance:**
 - Q, E, T, CT

The “Fix It When We See It” Trap



Metrics which anticipate future problems are invaluable

Searle's Balanced Performance Metrics Set



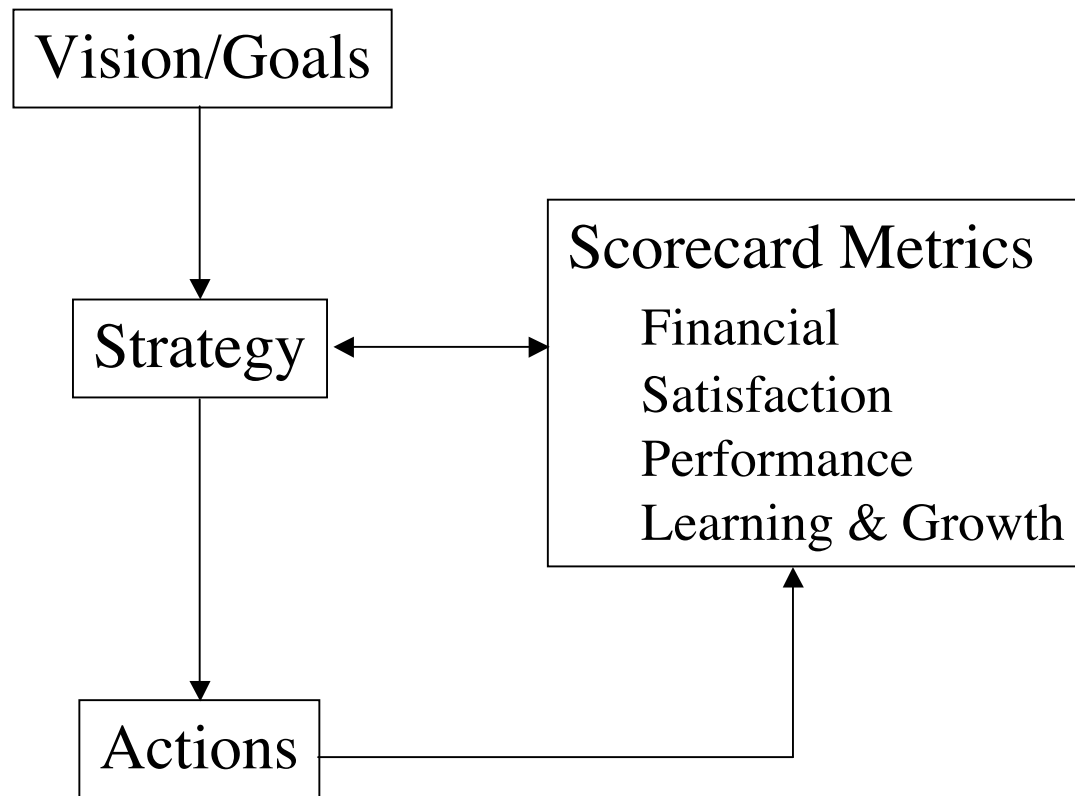
Mapping Searle to Our System

	T	CT	Q	E
BO/Fin	<ul style="list-style-type: none"> • On-time Contract 	<ul style="list-style-type: none"> • Contract Signoff 		<ul style="list-style-type: none"> • Cost per Clean Data Point
Clin Ops/PM	<ul style="list-style-type: none"> • First Subject In • Last Subject In 			<ul style="list-style-type: none"> • Enrollment Efficiency
DM/stats		<ul style="list-style-type: none"> • Last Obs to Lock 	<ul style="list-style-type: none"> • TLG Quality • Queries • DB Changes 	
Drug Supply/IVRS				
MW/QA	<ul style="list-style-type: none"> • Final Report Signed Off 	<ul style="list-style-type: none"> • Lock to Draft • Draft to Final Report 	<ul style="list-style-type: none"> • Draft Report Quality 	

Strategic Relationship Metrics

- **Based on longer-term relationship**
- **Metric system goal is to support joint improvement in quality and efficiency**
- **Metrics are balanced across relationship:**
 - Performance
 - Satisfaction
 - Growth

Making Your Scorecard Work



What are the key attributes of a strategic relationship?

Pharma Perspective

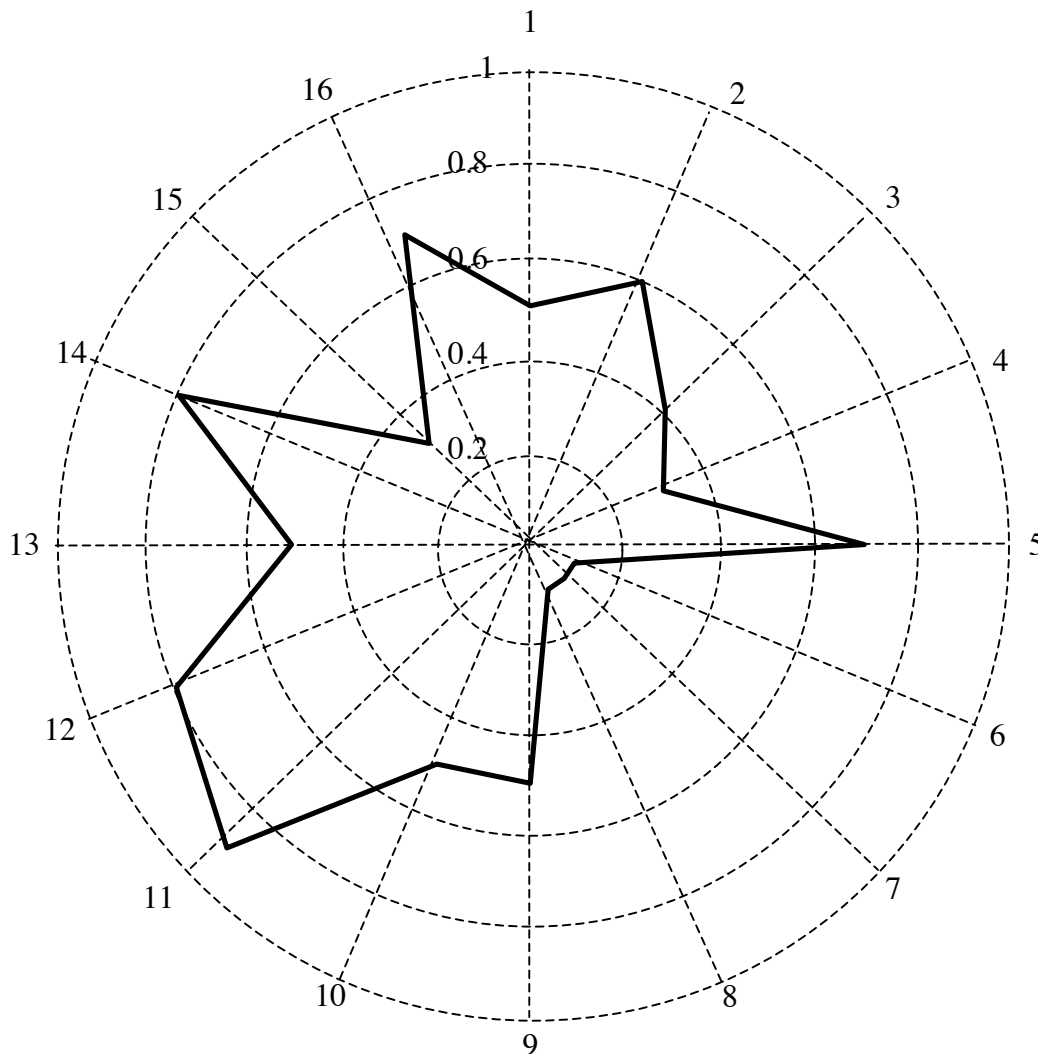
- Contracts on-time**
- Consistent, high-quality deliverables**
- High customer satisfaction**
- Experienced people**
- Continuity**
- Financial transparency**
- Divulging weaknesses**
- Continuous improvement**
- Exclusivity**

CRO Perspective

- Clear expectations**
- Financial growth**
- Respect**
- Trust**
- Protocol stability**
- Timely information sharing**
- Fast response times**
- Time dedicated to relationship-building**
- Senior-level commitment**

Key to a good measurement system is making sure
both sides share the pain AND the gain

Example 1 Partnership Metrics



Project Performance

1. Project setup cycle time
2. Project completion cycle time
3. Enrollment efficiency
4. Project cost

Teams

5. Team performance index
6. Pharma team turnover
7. CRO team turnover
8. Team meeting quality

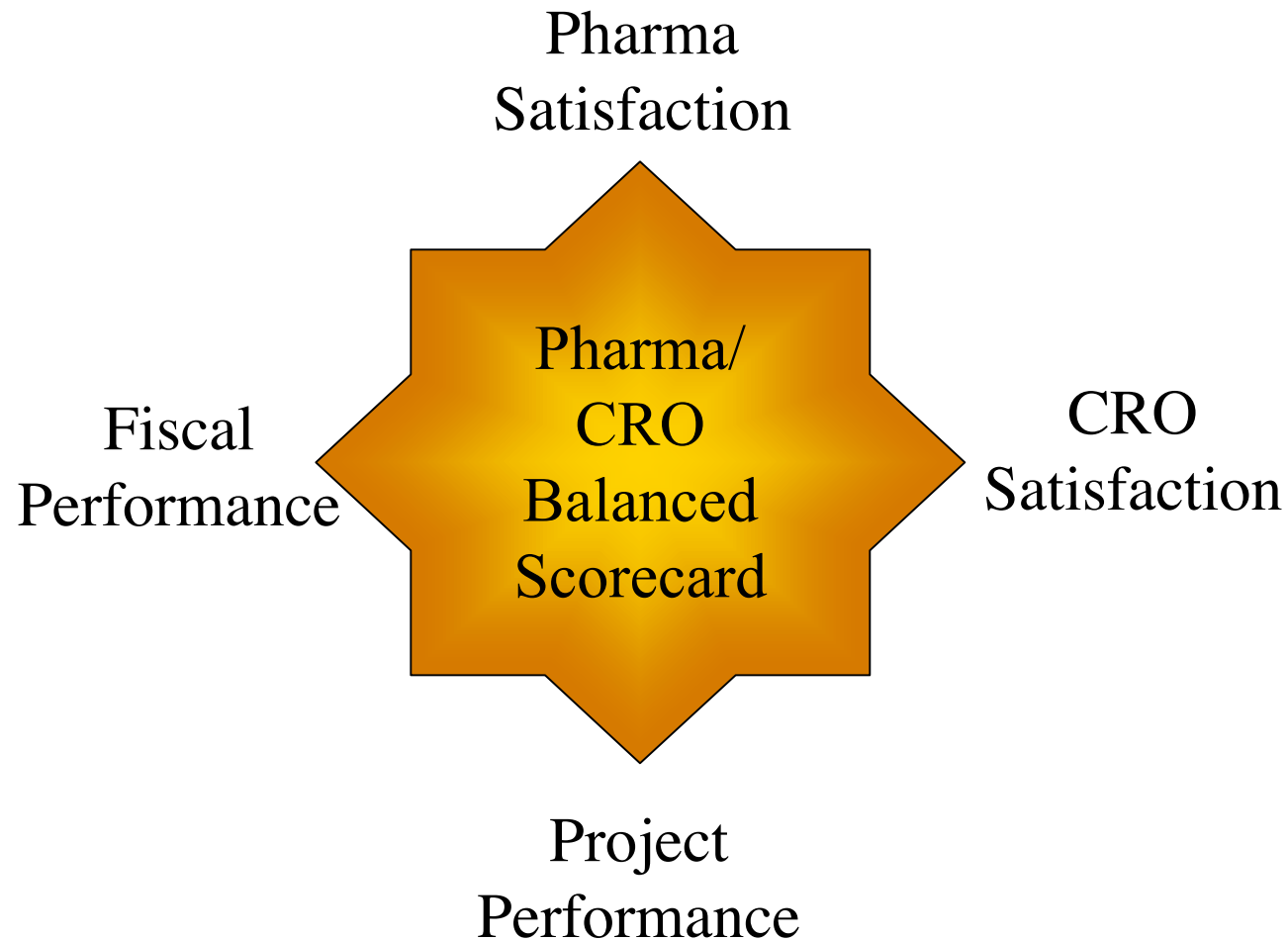
Pharma-CRO Relationship

9. % of projects with preferred CROs
10. % of repeat business
11. Pharma team experience level
12. CRO team experience level

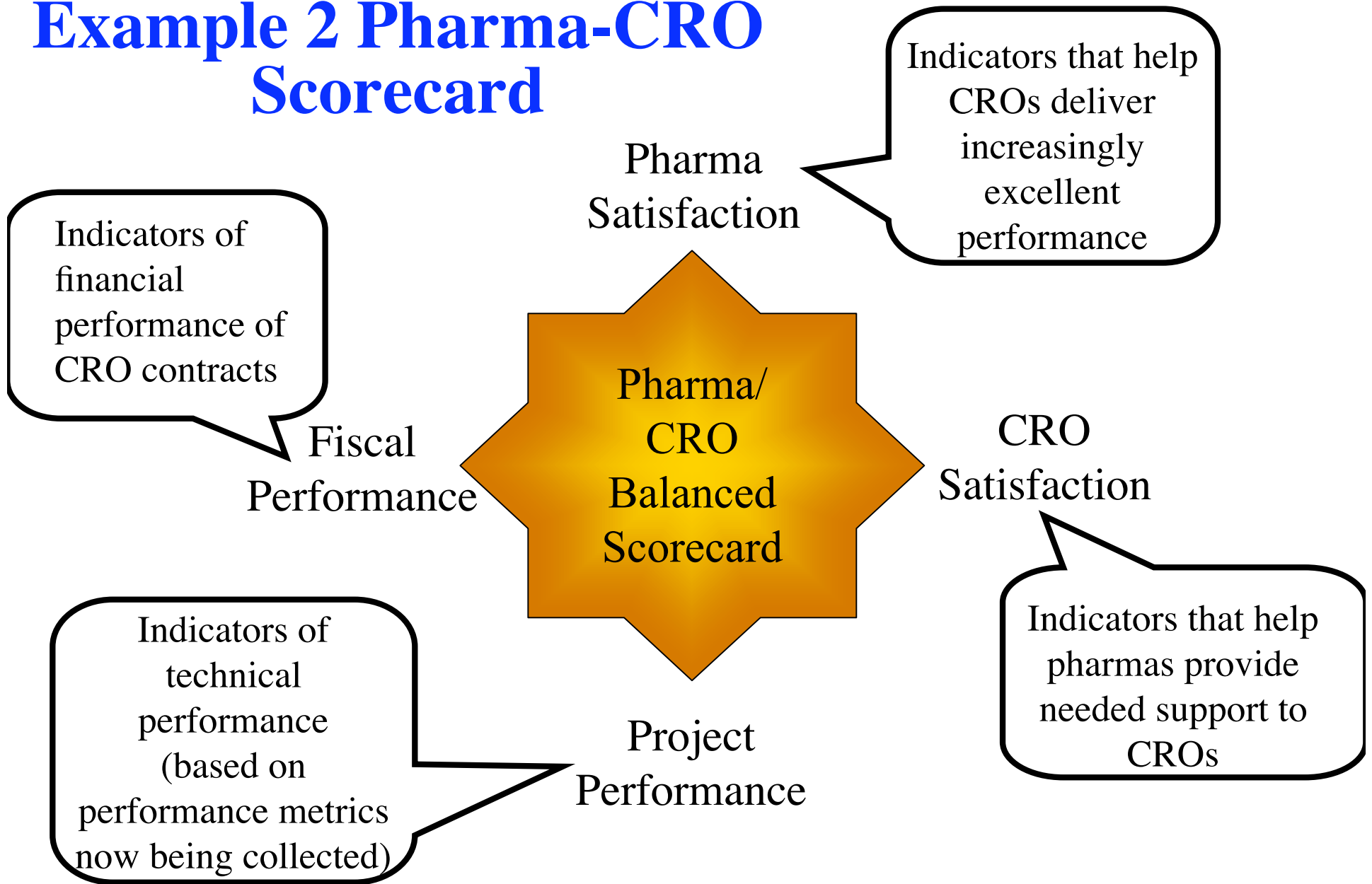
Site Performance

13. EDC usage
14. Cutting edge systems usage
15. Average site effectiveness
16. % of sites achieving 90% of enroll target

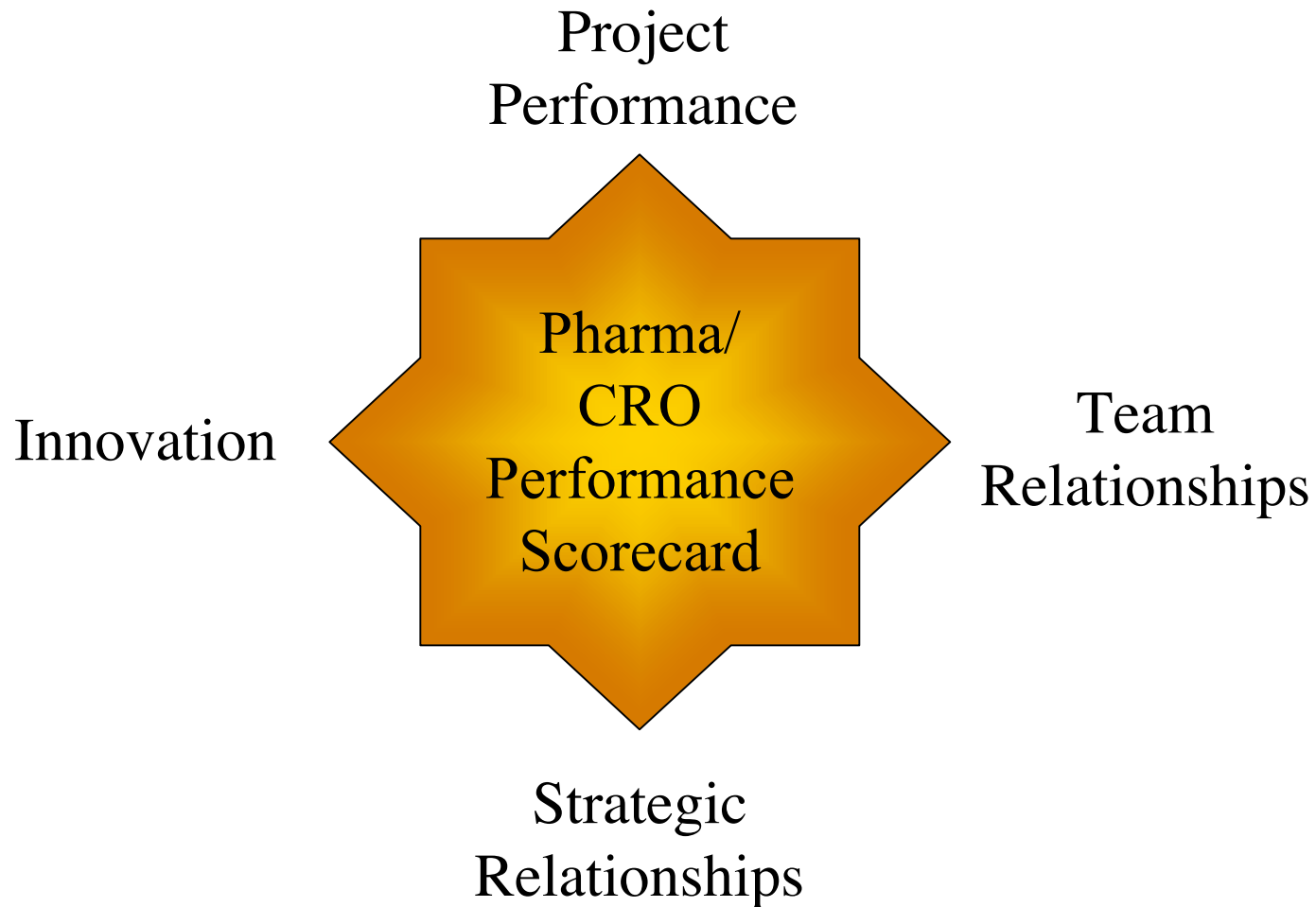
Example 2 Pharma-CRO Scorecard



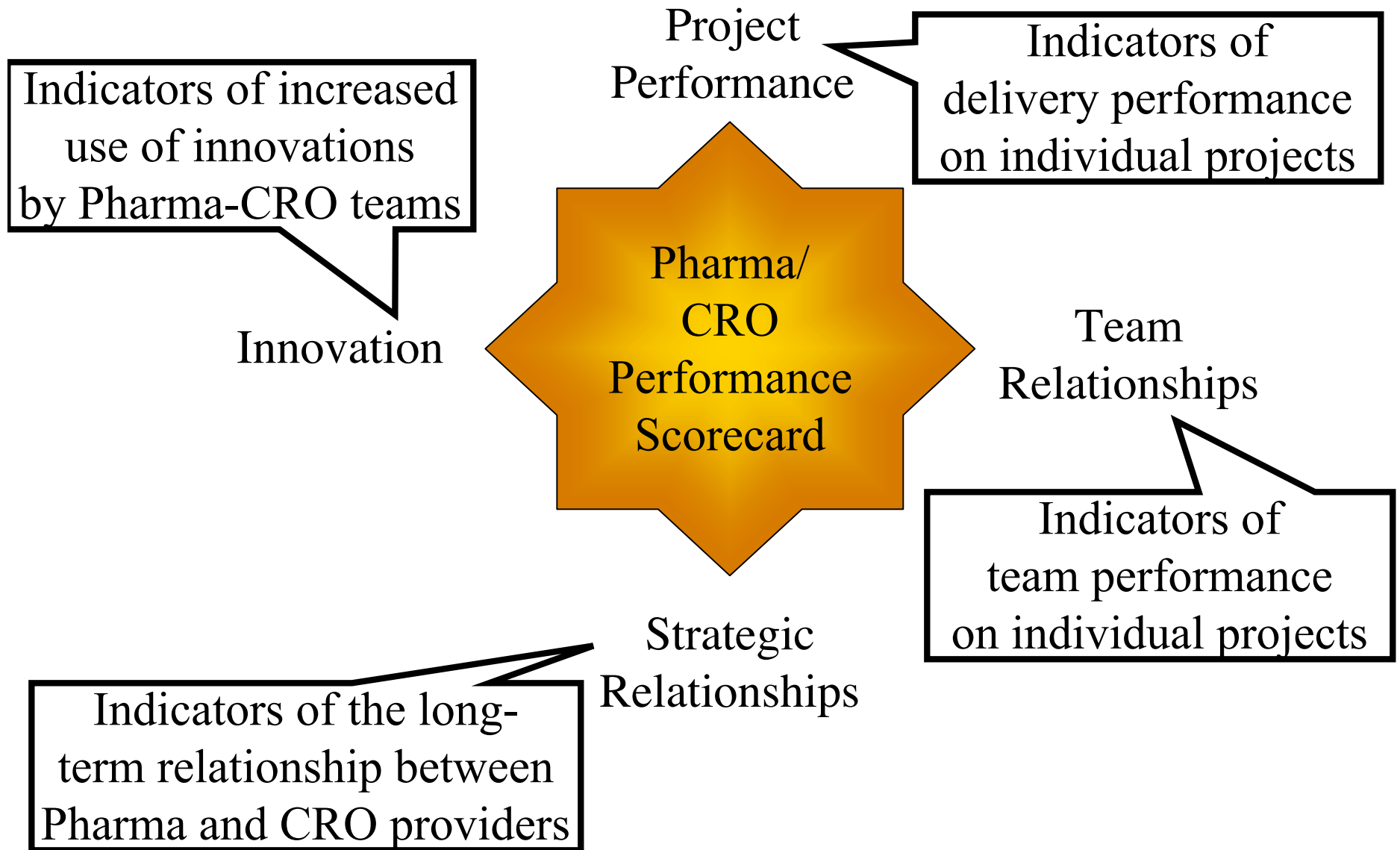
Example 2 Pharma-CRO Scorecard



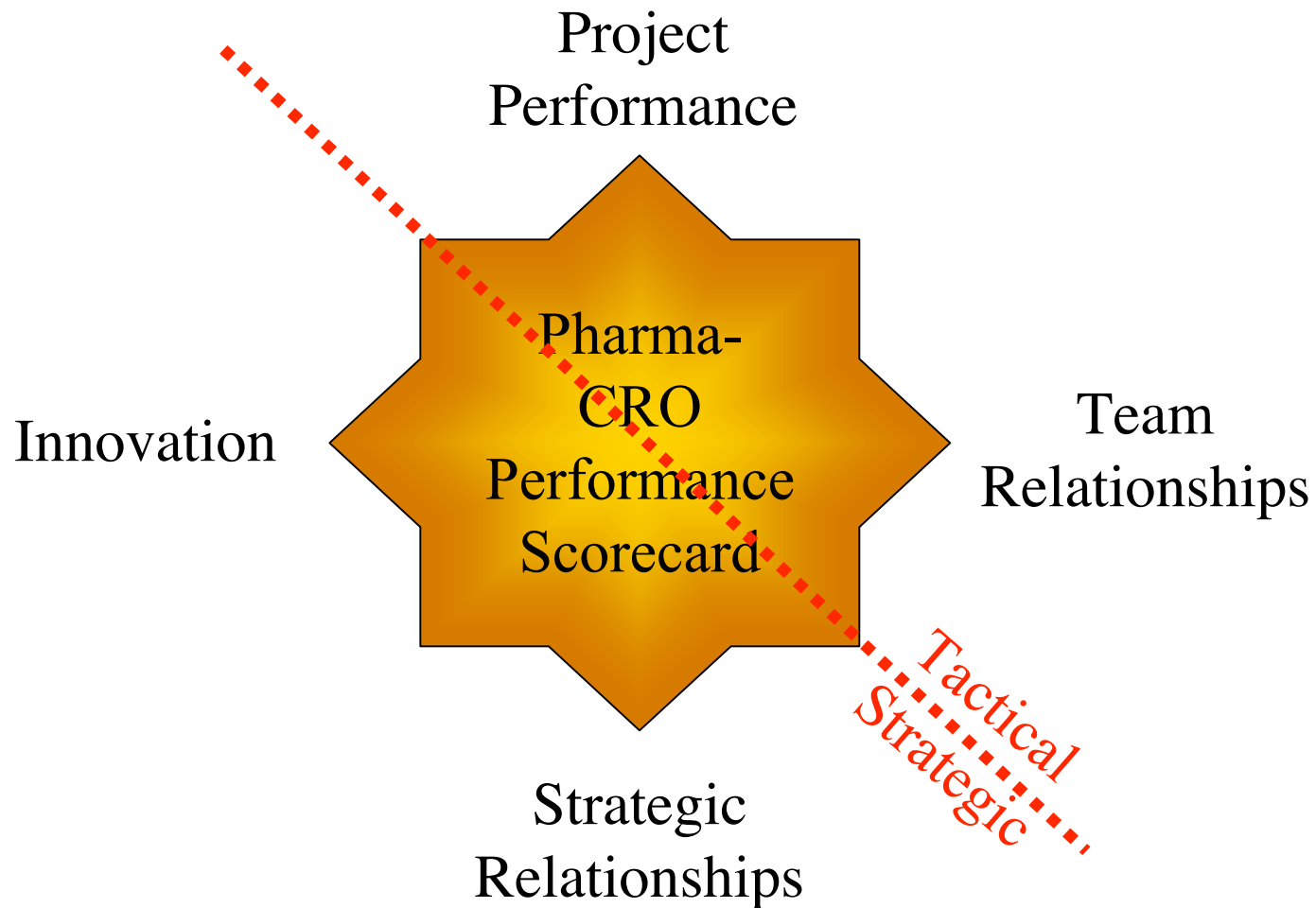
Example 3 Pharma-CRO Scorecard



Example 3 Pharma-CRO Scorecard



Example 3 Pharma-CRO Scorecard



Improving tactical measures achieves short-term gain.

Improving strategic measures achieves sustained, long-term growth.

A Key Pharma-CRO Metric: Risk

- **Forecasting risk**
- **Mitigating risk**
- **Tracking risk**

A Key Pharma-CRO Metric: Risk

- **Forecasting risk**
 - On a normalized scale, what is the risk value of this protocol/project?
 - Protocol execution risk
 - Data management risk
 - Financial risk
 - Medical writing risk
 - Drug supply risk
- **Mitigating risk**
- **Tracking risk**

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- **Forecasting risk**
 - On a normalized scale, what is the risk value of this protocol/project?
- **Mitigating risk**
 - What actions have we taken to reduce risk prior to protocol execution and what is the revised risk value?
- **Tracking risk**

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- **Mitigating risk**
 - What actions have we taken to reduce risk prior to protocol execution and what is the revised risk value?
- **Tracking risk**
 - How is risk increasing or decreasing over time during the project?