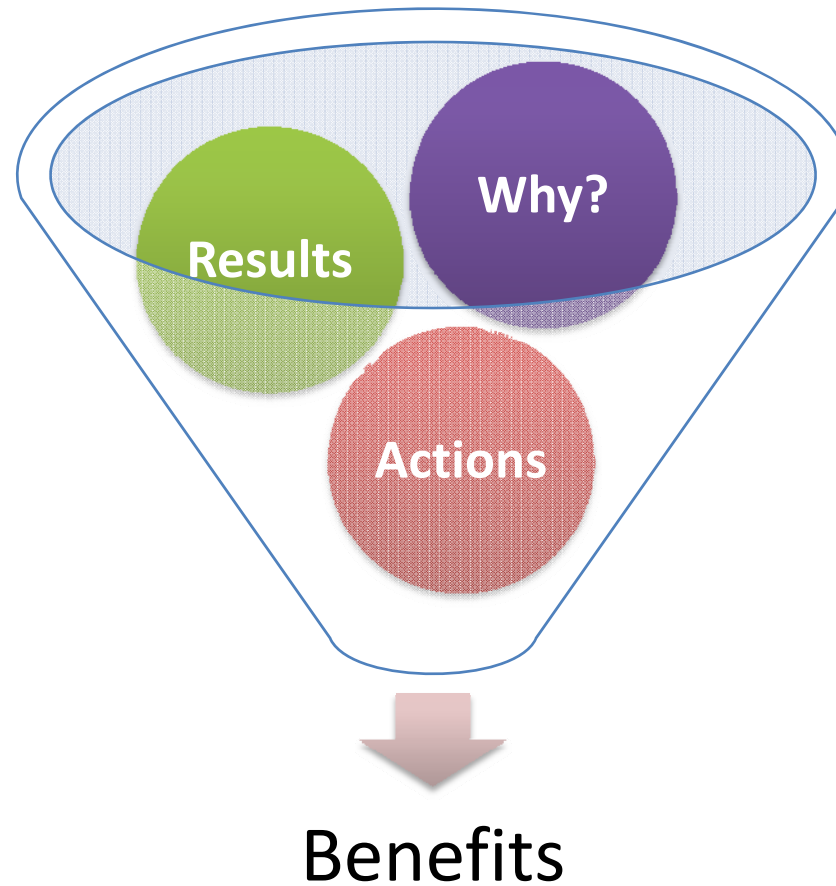




# Speeding Time to Market with the FDA's Quality by Design

John Avellanet

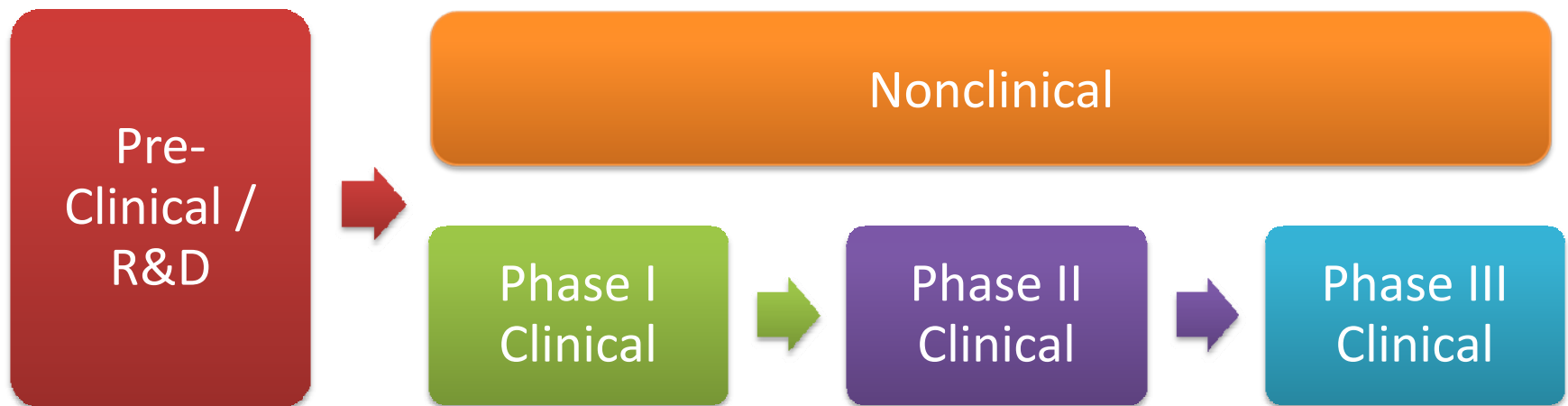
# Quality by Design



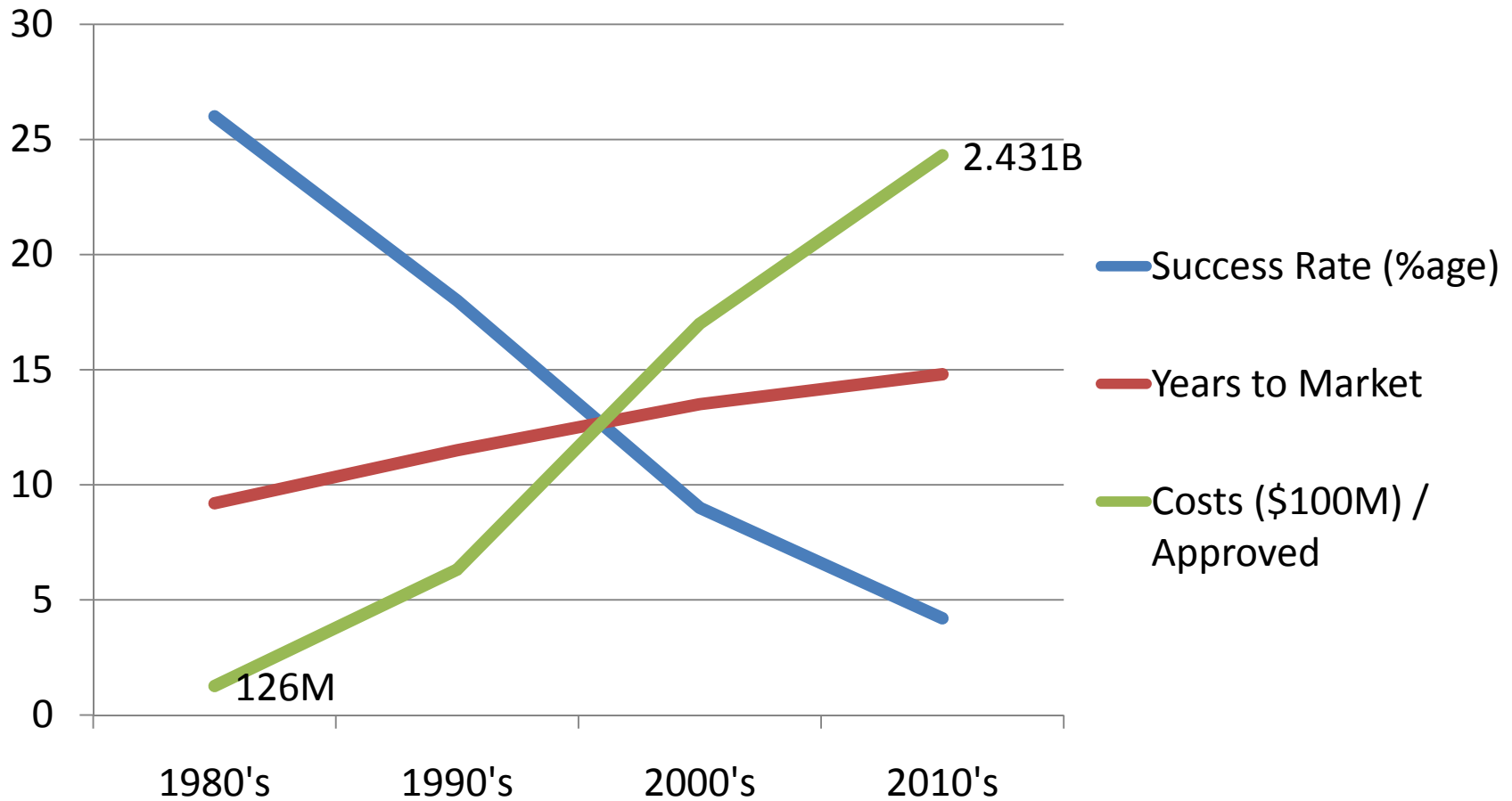
## Why Quality by Design?



# Traditional Model



# Results



# Bottom Line Losses

\$112,500,000,000.00



## Does Quality by Design Show Different Results?



# Quality by Design Defined


***Everything* you do to directly promote and prove the safety, efficacy and quality of your product, from proof of concept to the point at which customers are buying it on a *regular basis*.**

# Quality by Design Difference

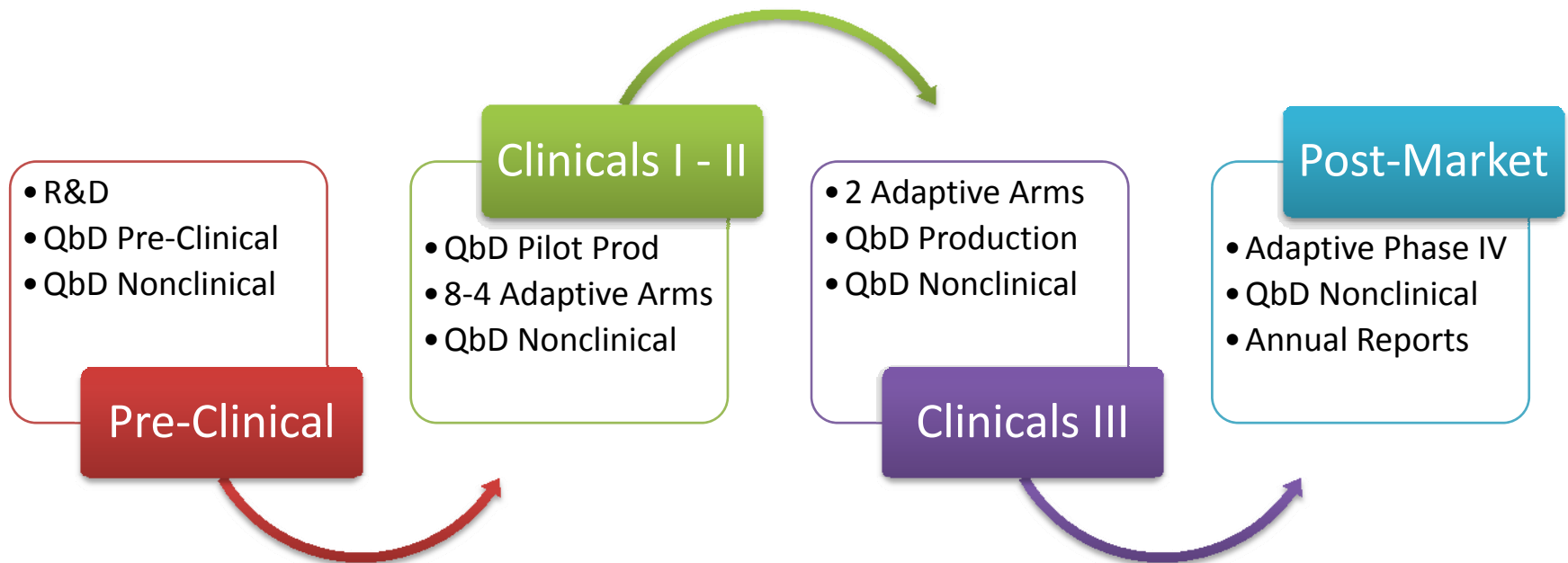
	<u>Traditional</u>		<u>QbD Client #1</u>
<i>Concept - CLINICAL:</i>	<b>6 years</b>		<b>5 years</b>
<i>Costs:</i>	<b>+11%</b>		<b>- 3%</b>
<i>Success Rate:</i>	<b>9%</b>		<b>32%</b>

# Quality by Design Difference

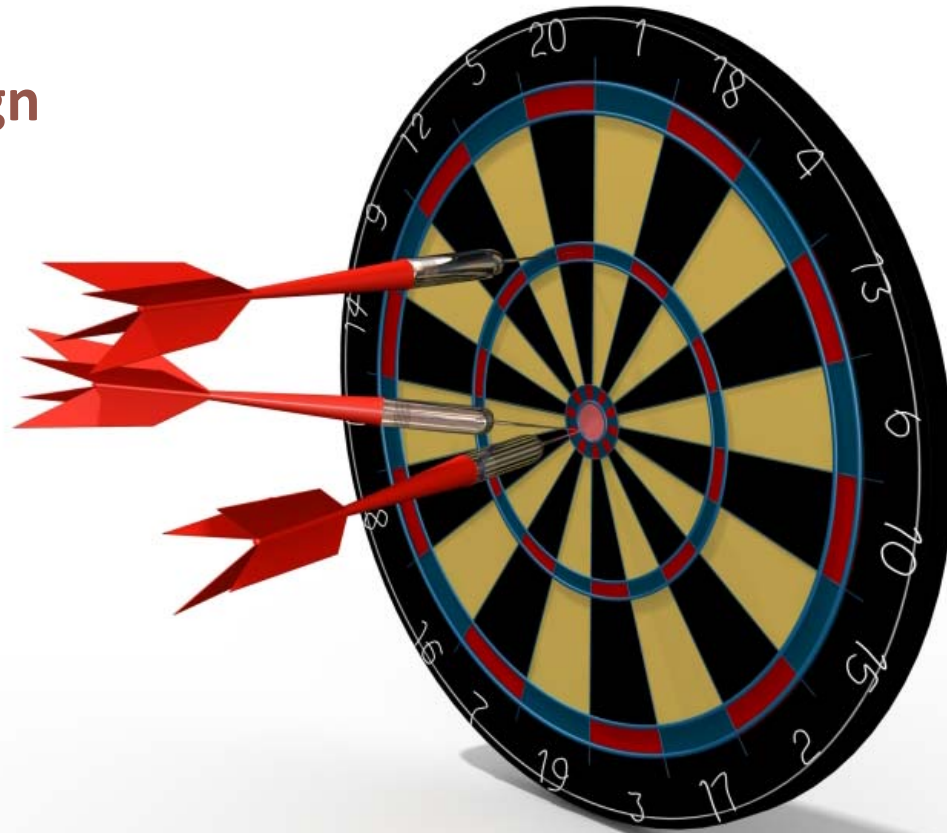
	<u>Traditional</u>	<u>QbD Client #2</u>
<i>Concept - MARKET:</i>	<b>13.5 years</b>	<b>9 years</b>
<i>Costs:</i>	<b>+14%</b>	<b>- 8%</b>
<i>Success Rate:</i>	<b>20%</b>	<b>85%</b>
<i>Chance of Positive ROI:</i>	<b>30%</b>	<b>71%</b>



# Quality by Design Model



## Five Specific Quality by Design Actions



# Voice of Customer

- Marketing / Business Dev
- Finance
- IT



# Transfer Learning

Comprehensive knowledge report:

- Decisions, logic and results
- Lessons learned
- Incorporate into on-boarding



# Universities

- Literature surveys
- Stumbling block resolution
- Database reviews
- Statisticians for adaptive trials



# Threshold Question



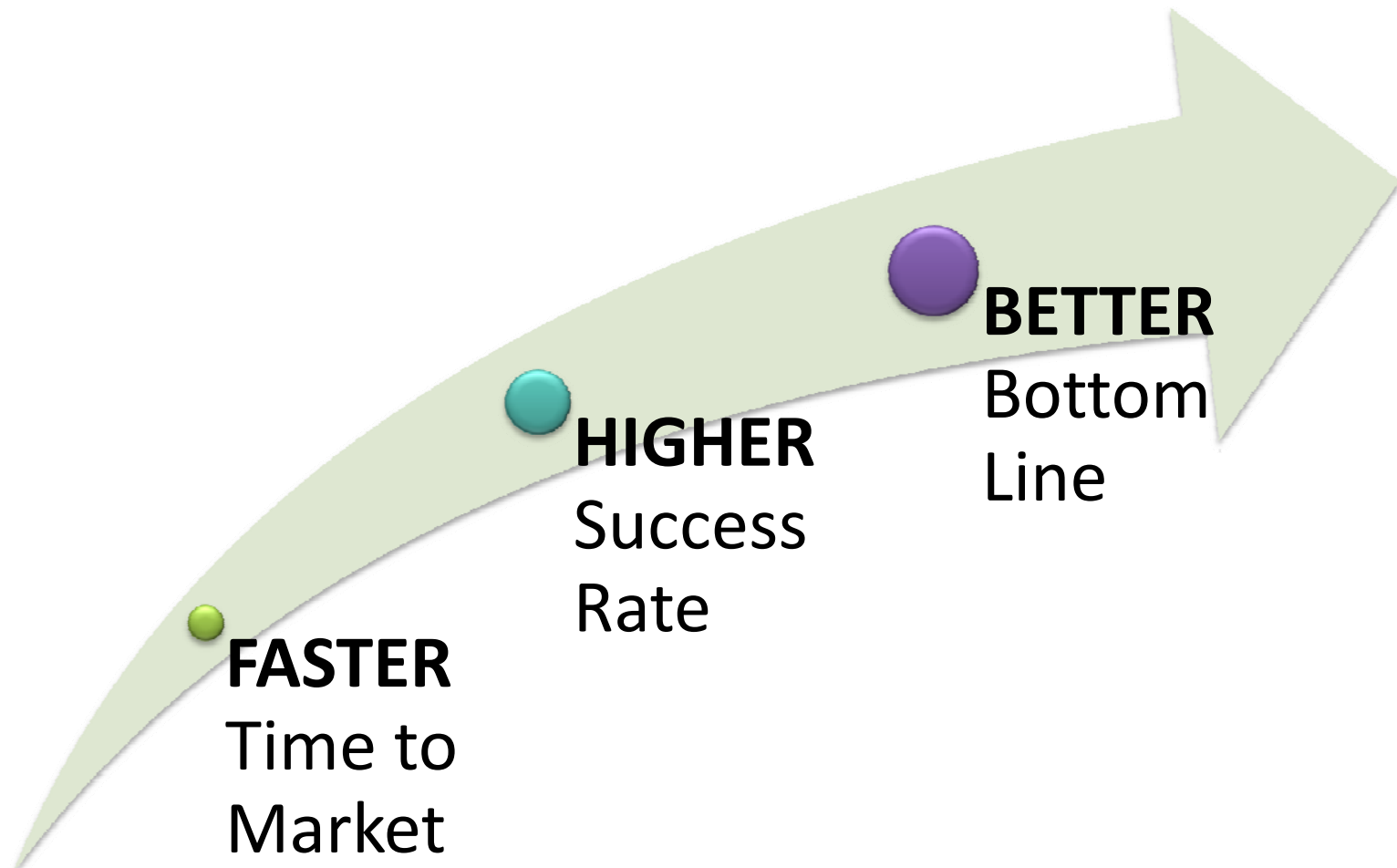
*HOW will this  
prove or improve  
safety or efficacy?*

# eData Integrity

- IT Departments
- Records Management Groups
- Legal counsel
- Vendors / suppliers



# Quality by Design Benefits



# Additional Resources

**Monthly Newsletter for Executives at:**

[www.CeruleanLLC.com](http://www.CeruleanLLC.com)

[www.CeruleanLLC.com/SmarterCompliance\\_Newsletter.htm](http://www.CeruleanLLC.com/SmarterCompliance_Newsletter.htm)

**Complimentary eReport:**

*Is Quality by Design Right for My Organization...?*

Download at: [www.ceruleanllc.com](http://www.ceruleanllc.com)

**Don't miss our next webinar:**

*FDA enforcement trends for 2008-2009*

Details and registration information at:

[www.expertbriefings.com](http://www.expertbriefings.com)

# About the Speaker

John Avellanet is a co-founder and Principal of Cerulean Associates LLC, and a coauthor of *Best Practices for Biotechnology Business Development*.

He is also the publisher of the monthly *SMARTERCOMPLIANCE*<sup>™</sup> newsletter delivered to executives around the world and a columnist for the international quarterly *Journal of Commercial Biotechnology*.

As a result of his work, Mr. Avellanet's clients have seen faster times to market and higher product development success rates.

For more than 15 years, he served as an executive accountable for regulatory compliance, information technology and records management, most recently as a C-level executive for a *Fortune 50* biotechnology and medical device subsidiary.