ThinkQuality, LLC

# *Navigating the Regulatory Landscape for Your Life Sciences Startup*

## *Practical Strategies and the Value Proposition*

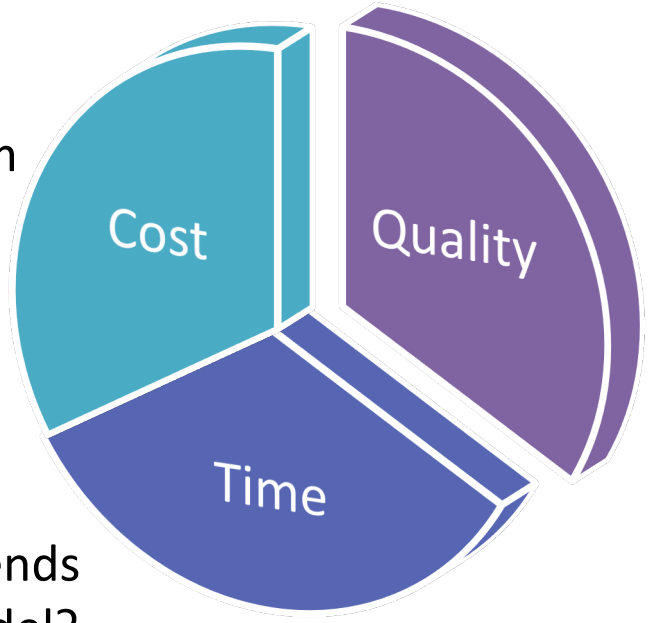
Kevin J. Slatkavitz, Ph.D.
*ThinkQuality, LLC* - President/Founder

*Boston Entrepreneurs' Network*
*21 April 2020*

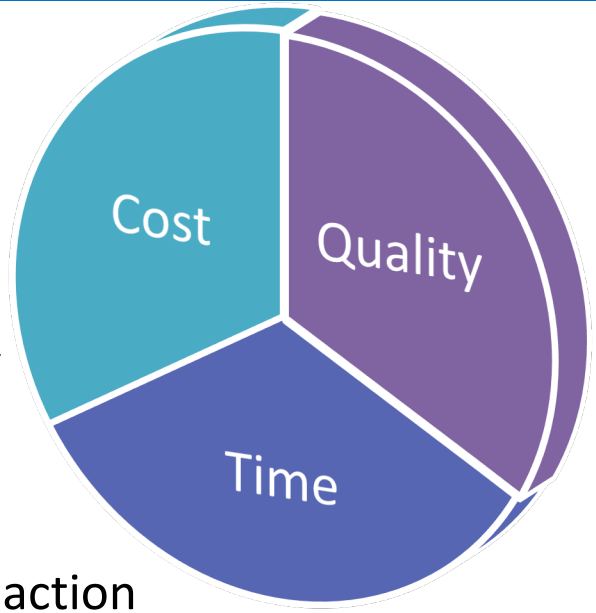
Rethinking Challenges, Opportunities and the Business Case for Quality

# Challenges and Opportunities for Life Science Startups

- Novel Science/Technology
  - Thinking outside the box
- First Time as Startup
  - Never done this before as team
  - Speed to FIH and beyond
- Outsourcing Model
  - Key studies done by others
  - "Fit-First-Time" vs. delays
- Limited Resources
  - Time and cost are not your friends
  - Is Quality in your Business Model?
- Real or Perceived Regulatory Constraints
  - Unexpected Regulatory Requests/Expectations
  - The Patient is Waiting



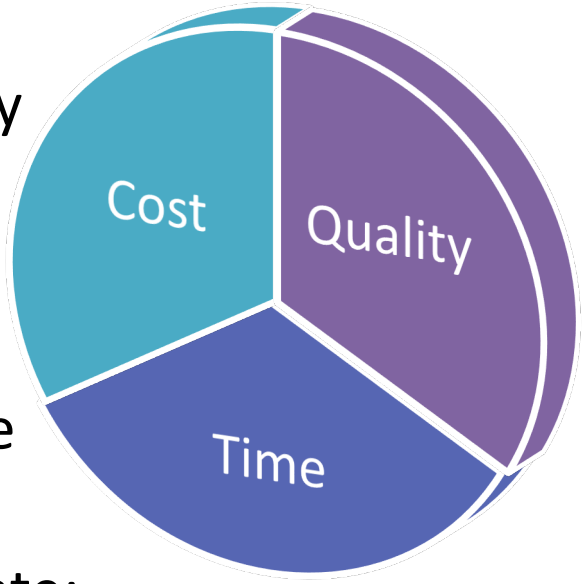
# What If . . .




- Your Regulatory Strategy:
  - Embraces all three early on
  - Fully aligned with the Business Strategy
  - And your innovation/science/technology
  - Relational and transactional
  - Understands the patient is waiting
  - Thinking outside the box with discipline, action
- How well do you know:
  - Your innovation and associated risks – what don't you know well enough, what could go wrong and how to reduce those risks?
  - Your key stakeholders and their needs and understandings/concerns?
  - Your regulatory pathway options and what fits your strategy best?

# Building Your Regulatory Strategy

Data-driven/relational-driven or myth-driven? It's your choice




- Myth #1 - Investors don't care about Quality
- Myth #2 – It's too early to have a strategy
- Myth #3 – Regulators don't care to innovate
- Myth #4 – Just use a one-size-fits-all template;
  Anyone with experience can do it
- Myth #5 – No need for transparency with key stakeholders

# Navigating Real or Perceived Regulatory Constraints

- Not a One-Size-Fits-All Challenge or Opportunity
  - Know your space, what fits best for your innovation and your strategy
- Consistencies and inconsistencies both within and across both Regulatory Agencies (e.g., US FDA, EMA, TGA, NMPA, Health Canada, etc.) and therapeutic areas. For US FDA:
  - Center for Biologics Evaluation and Research
  - Center for Drug Evaluation and Research
  - Center for Devices and Radiological Health
- For FDA, 21st Century Cures Act has been a game changer
  - Early engagement, fast track, breakthrough therapy, enhanced guidances, communications and commitment to innovations
- Mutual Recognition across the world is progressing but more is needed – know your regulatory pathway options

# Plus the Impact of the Pandemic (as of 4/20/20 with no crystal ball)

- No doubt - Added regulatory and supply chain uncertainty
- All Regulators engaged with diagnostics/therapies in response
  - For US FDA - Coronavirus Treatment Acceleration Program (CTAP)
- Timing is everything:
  - Some Sponsors placing clinical studies on hold or stopping new enrollment or delaying the start of new studies – how long?
  - EU-Medical Device Regulation (MDR) postponed by one year
  - Non-essential US FDA meetings cancelled or postponed in April (TBD going forward) but CDER SBIA offering webinars for small businesses
  - Recent new drug approvals mostly by CDER's Oncology Center of Excellence – one under Project Orbis (the collaborative review with Australia (TGA), Health Canada, Singapore (HAS) and Swissmedic – but will approvals ultimately be slowed with most inspections on hold?
  - Sponsor companies must pivot their CRO/CMO oversight – Go Virtual

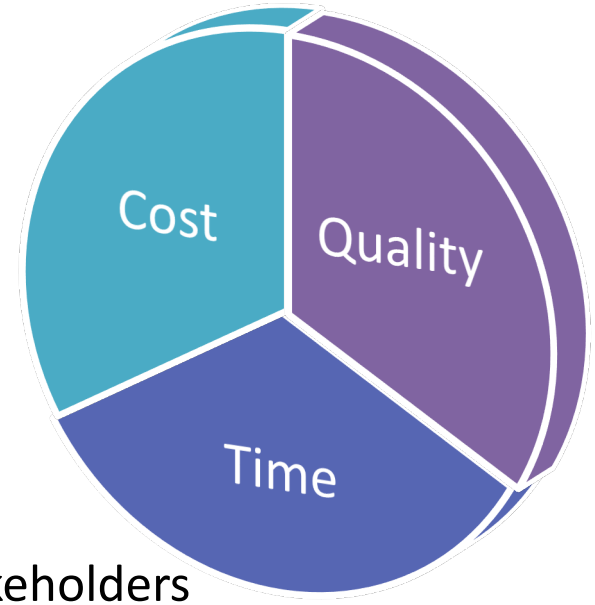
ThinkQuality, LLC

# Quality Beyond Compliance - Think with the End in Mind

- Anticipate – Identify – Resolve ("AIR") potential issues before they become significant pain points for your startup
- Unexpected issues will always arise
  - Minimize potential damage to value and reputation quickly/effectively
- What can go wrong? Pitfalls and pain points can be very real - Do you learn from others or say "that's not my problem"?
  - Clinical (e.g., are studies aligned with regulatory expectations to demonstrate efficacy?)
  - Non-clinical (e.g., were early studies conducted with data integrity)
  - CMC (e.g., stability, cross contamination, interrupted supply chain)
  - Fast-track/breakthrough designation is great but are you prepared to meet development timelines at warp speed without delays?
  - Does the market want/need, is it ready for your innovation?

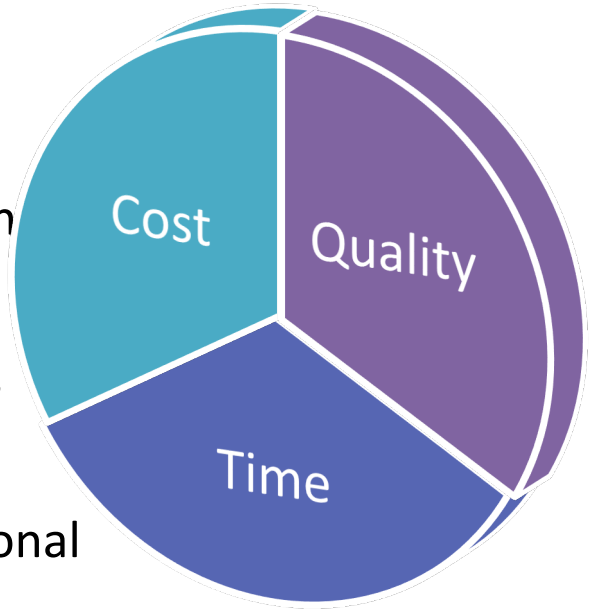
# What If Revisited . . . The Value Proposition

- You know what you know/don't know about your innovation
  - And what keeps you up at night
- You know your key stakeholders
  - And what's important to them, their concerns
- You know your regulatory pathway options
  - And when to approach Regulators
- You know your inherent risks
  - And can prioritize what and when to mitigate
  - And how to align with your business plan & stakeholders
- You know that if this was easy anyone could do it
  - That's why you've built mutual trust and respect into your strategy
  - And appreciate the patient is waiting



# Navigating the Regulatory Landscape
# Final Thoughts . . .

- Be data and relational-driven, not myth-driven – Know your space
- Be proactive and forward thinking – "Fit-First-Time"
  - Later is a lot sooner than you think
- Don't stop being the entrepreneur
  - Think outside the box with discipline then action
- It takes a village – not one expert
  - Be aligned with the business & key stakeholders
- Secret Sauce #1 – Building trust and respect
  - Transparency is key; it's transactional and relational
- Secret Sauce #2 – Timing is everything
  - When to engage with investors, when to meet with the Regulators . . .
- Decision making amid added uncertainty
  - Never a more critical time than now (pandemic)



ThinkQuality, LLC

**Kevin J. Slatkavitz, Ph.D.**
**President/Founder**

*Vested in Working Across The Life Science Ecosystem to Integrate Quality Proactively, Strategically, Relationally and as Value into Business/Regulatory Plans for delivering Predictability, Patient Needs and Success*

kevinslatkavitz@thinkqualityllc.com

www.linkedin.com/in/kevinslatkavitz

www.massbio.org/members/thinkquality-llc/

Tel (617) 460.7034

Rethinking Challenges, Opportunities and the Business Case for Quality