

*Navigating the Regulatory Landscape
for Your Life Sciences Startup*

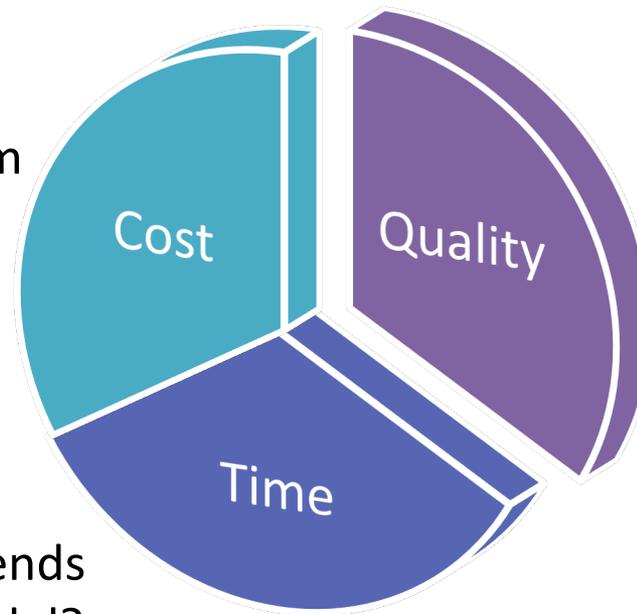
Practical Strategies and the Value Proposition

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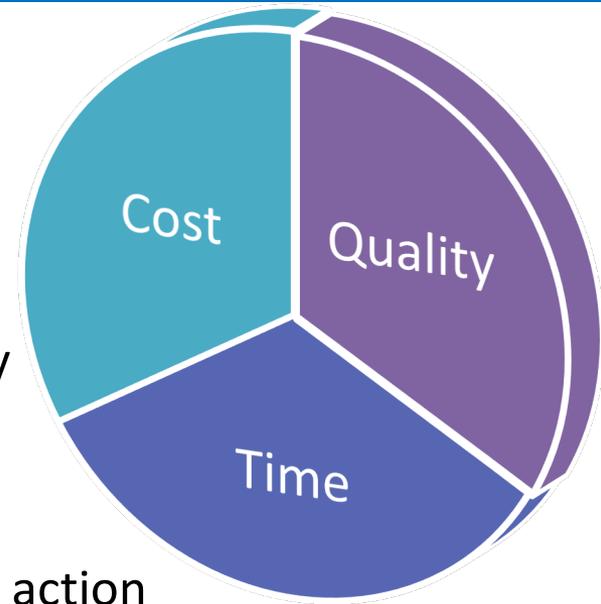
Challenges and Opportunities for Life Science Startups

- 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



➤ 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



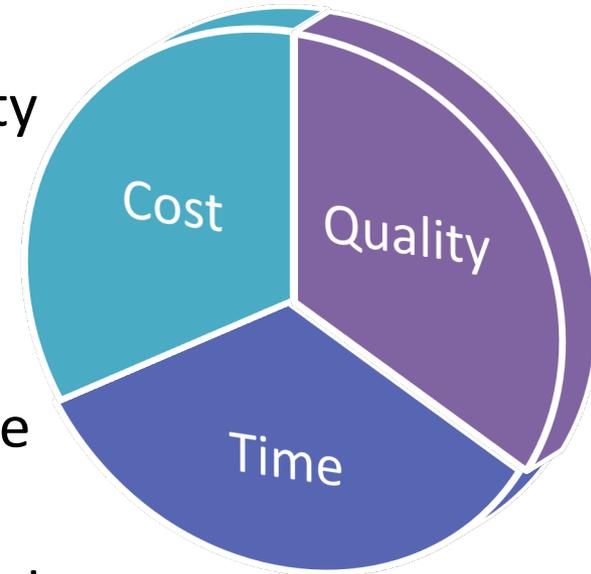
➤ How well do you know:

- 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

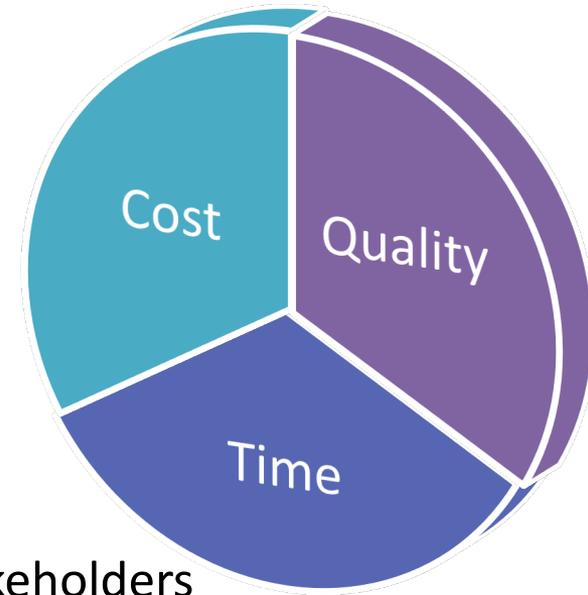


- Not a One-Size-Fits-All Challenge or Opportunity
 - Know your space, what fits best for your innovation and your strategy
- Consistencies and inconsistencies both within and across both Regulatory Agencies (e.g., US FDA, EMA, TGA, NMPA, Health Canada, etc.) and therapeutic areas. For US FDA:
 - Center 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

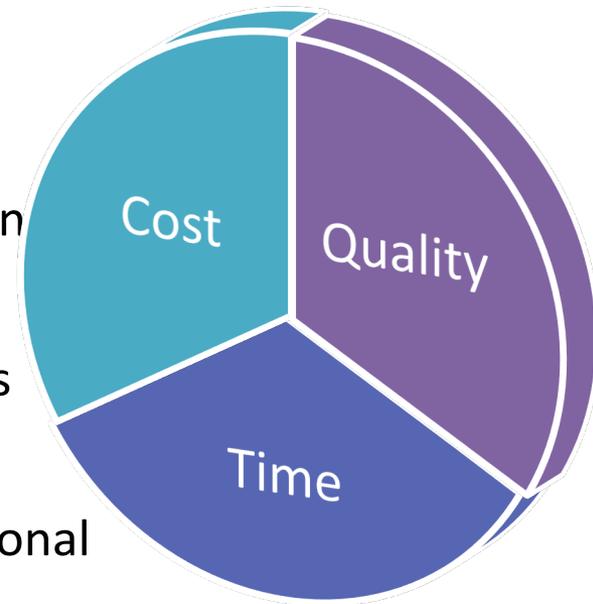
- No doubt - Added regulatory and supply chain uncertainty
- All Regulators engaged with diagnostics/therapies in response
 - For US FDA - Coronavirus Treatment Acceleration Program (CTAP)
- Timing is everything:
 - Some Sponsors placing clinical studies on hold or stopping new enrollment or delaying 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

- 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?

- 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



- 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)





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

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