



The Value of Strategic Early Engagement to Maximise Sponsor/CRO Partnerships

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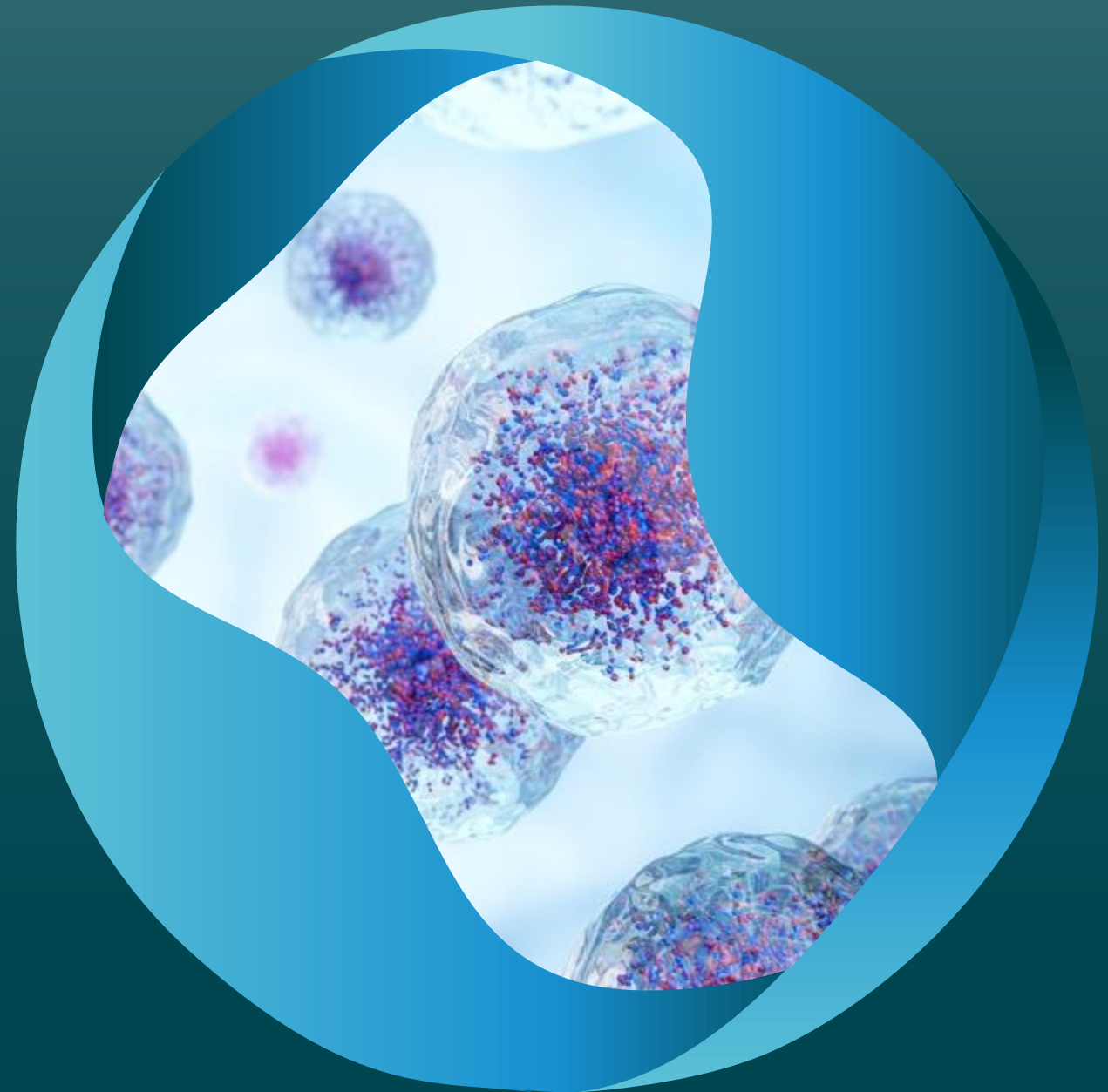
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Approach to Sponsor/CRO Relationship

Partnership / Consultative mindset:

- “No” is not in the vocabulary
- Value instead of services
- Evidence based solutions
- Listen and Communicate
- Flexible, Agile, Creative
- Focus on results



Transactional mindset:

- Sponsor directs, CRO follows
- CRO is on a “need to know basis”
- Requires a higher level of oversight from sponsor
- Focus on deliverables



Maximizing the Consultative Partnership

How early engagement can improve outcomes

- Establish trust by building a relationship based upon frequent & open communication
- Create collaborative environment to drive CRO ownership & accountability
- Align on goals and expectations & discuss pain points
- Gain a full awareness of CRO capabilities & service offerings
- Demo available tools and technology to create tailored solutions
- Leveraging expertise of SMEs to ensure predictable outcomes & anticipate obstacles
- Review case studies and lessons learned from CRO experience
- Make data driven decisions to improve outcomes
- Allows for multiple meetings to build rapport
- Invest in a mutually beneficial partnership

Long Term Value Creation on the Path to Approval and Launch

- Early focus on both regulatory and reimbursement development pathway for successful launch
- Milestones met mean risk reduction and valuation uplift.
- How can we approach this?

Value Inflection Points Planning for successful launch and value creation

Preliminary efficacy shown

Optimal dose for pivotal studies selected

Approvable safety & efficacy in large human trials

Successful Launch

Average Launch

Missed Opportunity

Not Approved

Phase

Discovery

Preclinical

Phase 1

Phase 1b/2a

Phase 2b

Phase 3

Regulatory & Price Review

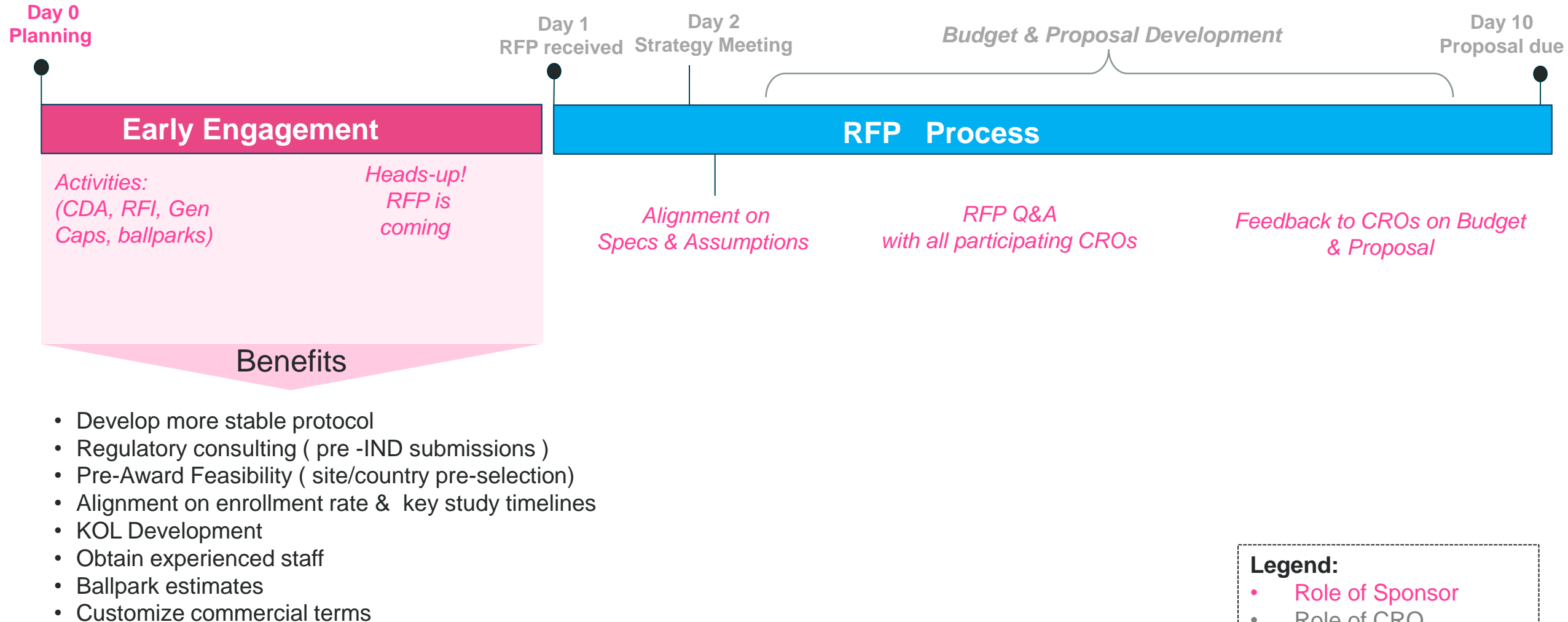
Marketed Drug

Insert Slido question #1 here

What is the best time to engage your CRO vendors for your Ph 1/b – 4 Study:

- a) After study concept is established
- b) After synopsis is drafted
- c) 1 year in advance of RFP
- d) At the time of RFP

Strategic Early Engagement Begins on “Day Zero”



ICON / Sponsor Engagement Timeline

Continuous Collaboration Across ICON Divisions Leads to Successful Partnership

Sponsor 



Negotiations



Changing the Wheels On The Plane As We Fly It

The ICON/Sponsor Team:

- Operational strategy changed **4** times
- Prepared multiple budgets/ballparks generated across 3 pivotal studies
- Attended multiple Clinical Maestro training meetings
- Alignment milestone payment schedule
- **30+** meetings held b/w April 2022 and February 2023 prior to award
- CEO Engagement
- Alignment on enrollment rate

“Gladys Ingle saves pilot from crashing by changing wheel in Mid-Air (1926)”



Case Study – Sponsor Feedback



What Value Did CRO Bring to the Table?

- Team willingness to engage early
- Team demonstrated an adaptive learning process
- Team cranked through iterations of strategy



What Was Different about CRO?

- The team gave us confidence that we won't get "lost" in a large organization
- The team showed us their ability to listen, take action and deliver on the end result



What Problem did CRO Solve?

- Financial flexibility around commercial terms
- Sponsor has ability to balance other assets
- Can pivot to other compounds if asset doesn't yield + results



Key Factors that Lead to choosing CRO?

- We asked a lot of the team and they delivered – built confidence
- BDM performance better than competitors
- CRO's ability to work through challenges

Insert Slido question #2 here

How long does each protocol amendment extend the site activation period?

- a) 2 weeks
- b) 1 month
- c) 3 months
- d) 6 months and above

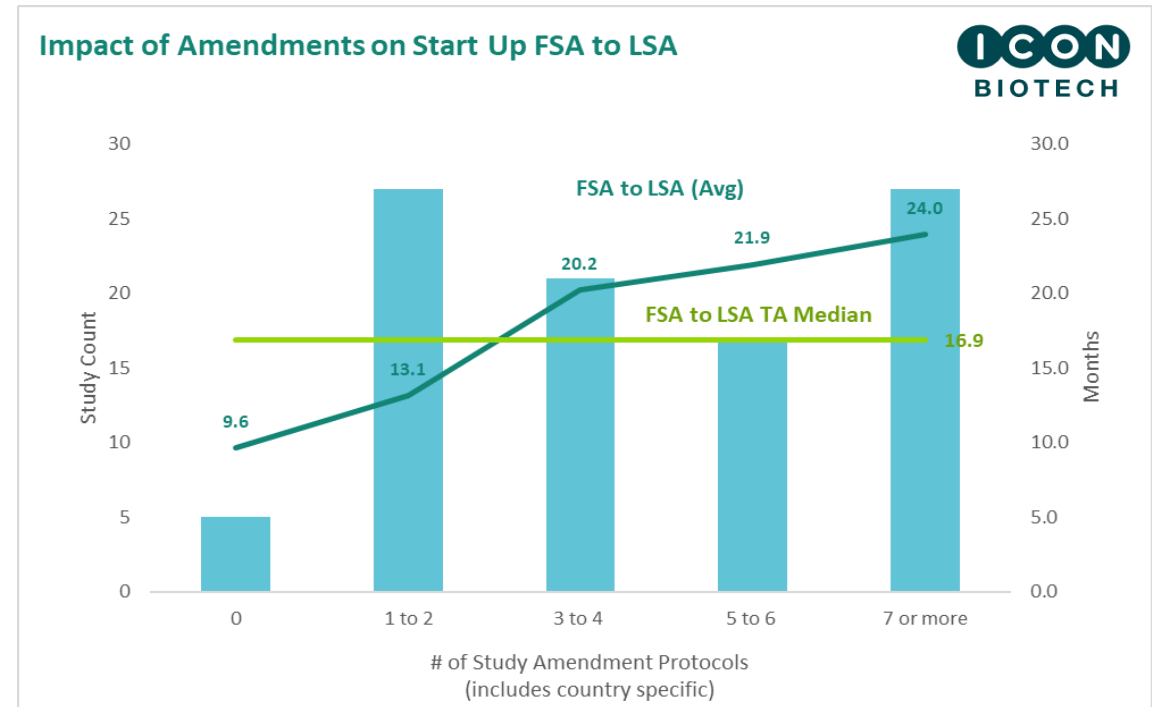
Mitigating Impact to Study Timeline for Protocol Amendments

Data Analysis / Impact:

- Average three (3) protocol amendments between FSA → LSA across all Therapeutic Areas
- Oncology activation period extends >10 months on average when 3-4 amendments occur
- **A first protocol Amendment (resulting in 1 or 2 country updates) increases activation period (FSA → LSA) by 3.5 months (avg)**
- Additional amendments compound delays to overall activation period (FSA → LSA) between 2-3.5 months extension

Best Practices from Lessons Learned:

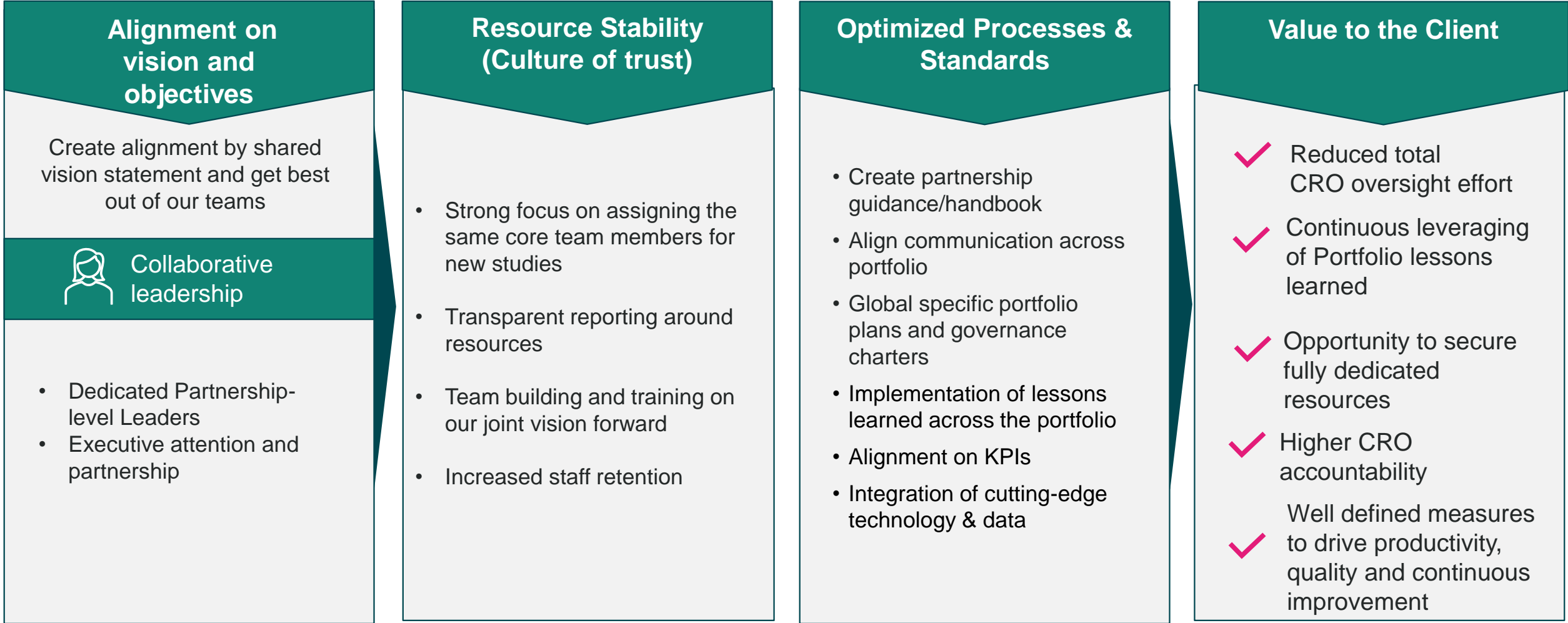
- Seize the opportunity to either offer early engagement in protocol consultancy, or offer risk analysis and plan of action, e.g.
 - Partner with Medical, Regulatory, SSU, etc. to give stronger consultancy on protocol quality impacts, at pre and/or post services launch
 - Set expectations early re: timeline/scope impacts from AMDs, using this data
 - Hold proactive discussions regarding how to manage amendments timing, i.e. during early engagements and through cross-functional forums
 - Keep ‘chatter’ with sites about future amendments to a minimum unless crucial



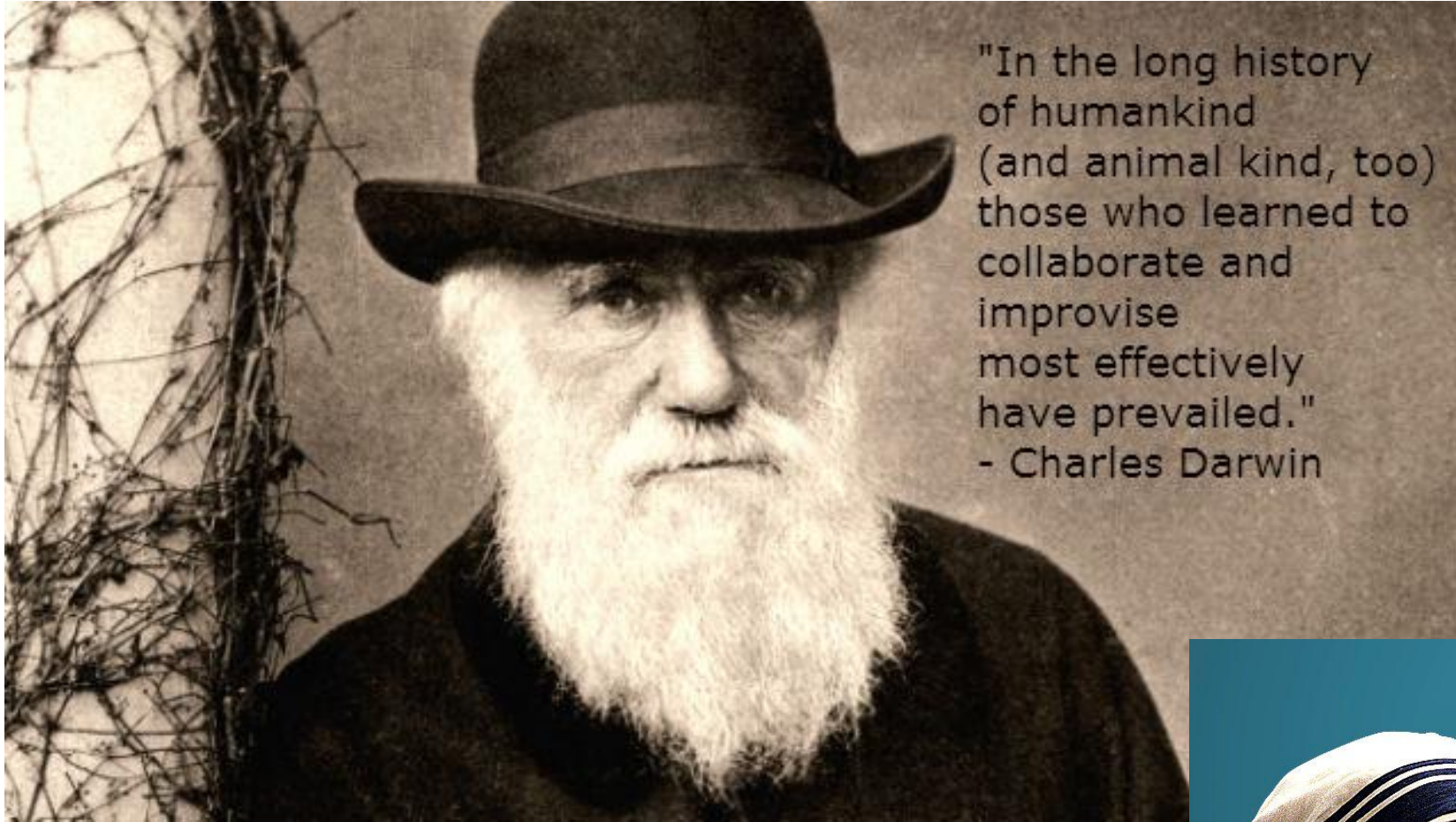
Note: This shows volume of amendments / impacts during SSU Period only, between FSA and LSA

Protocol Amendments may be a given, but current-state mindset should be challenged.
The way we plan for amendments must evolve.

Value of a Purposeful Partnership



Reinforced with joint governance, c-suite oversight, and commercial terms aligned with the desired outcomes



"In the long history of humankind (and animal kind, too) those who learned to collaborate and improvise most effectively have prevailed."
- Charles Darwin

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"I can do things you cannot, you can do things I cannot; together we can do great things."

- Mother Teresa