



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

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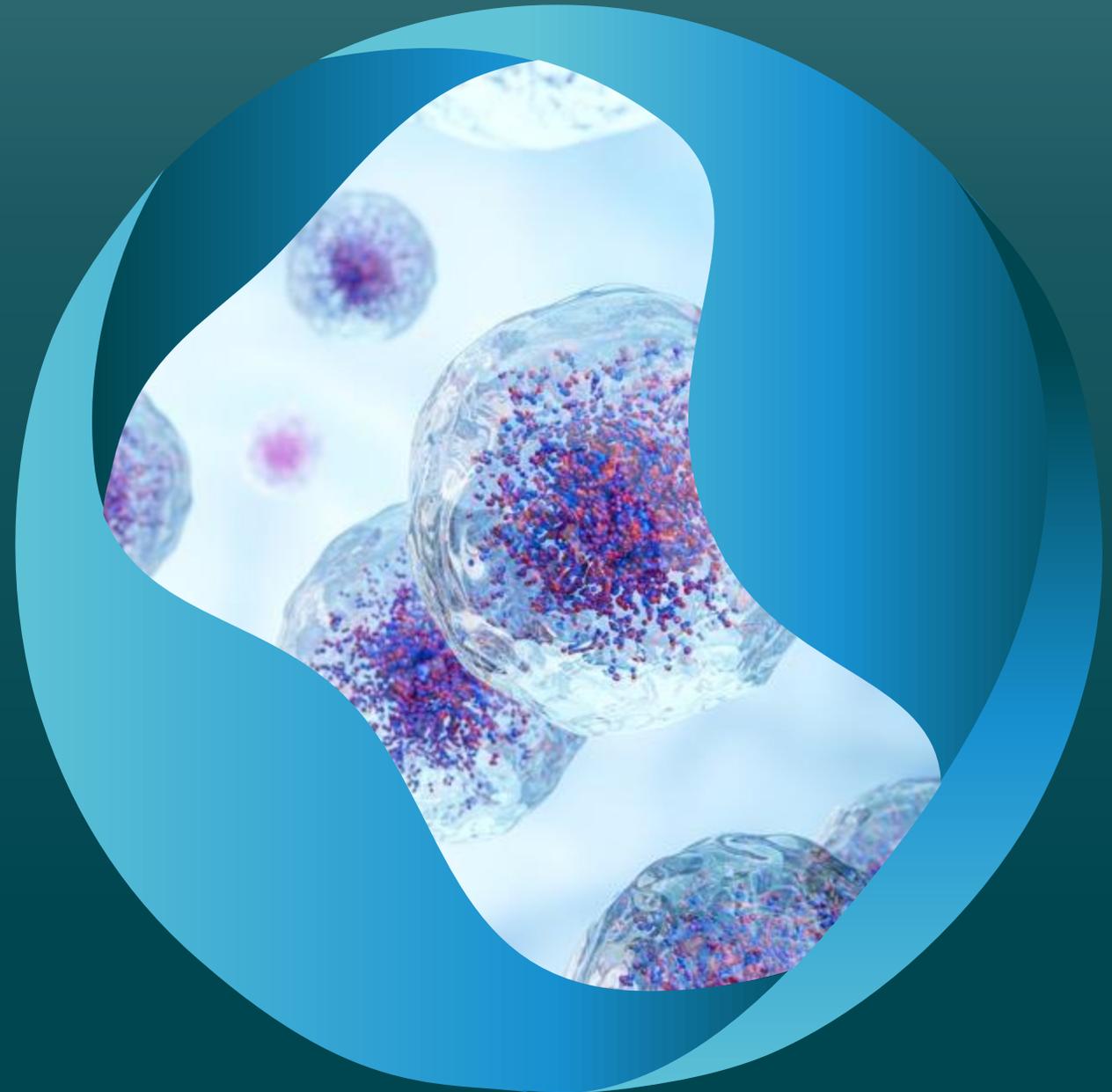
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# Approach to Sponsor/CRO Relationship

## 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

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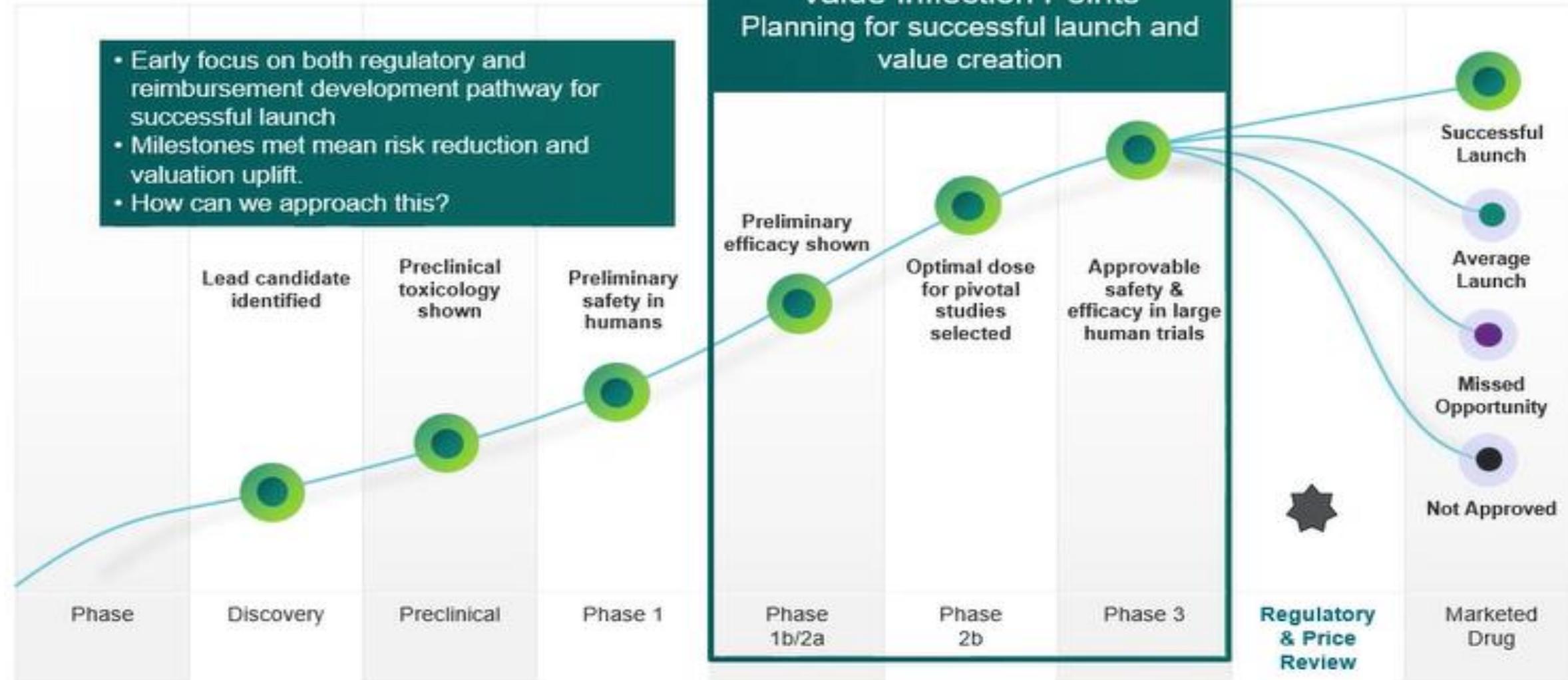
## How early engagement can improve outcomes

- 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



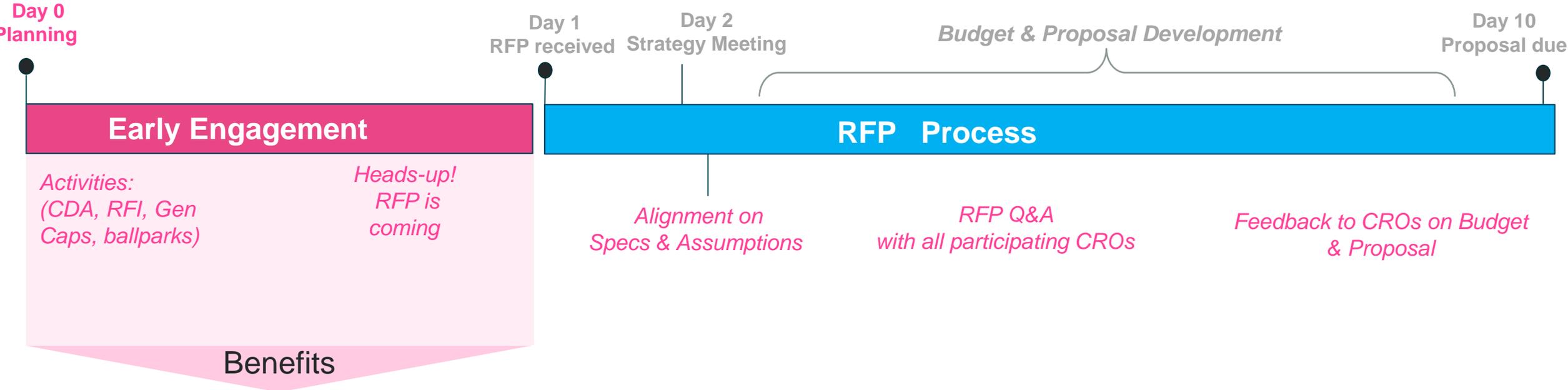
## Insert Slido question #1 here

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**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”



- Develop more stable protocol
- Regulatory consulting ( pre -IND submissions )
- Pre-Award Feasibility ( site/country pre-selection)
- Alignment on enrollment rate & key study timelines
- KOL Development
- Obtain experienced staff
- Ballpark estimates
- Customize commercial terms

**Legend:**

- Role of Sponsor
- Role of CRO

# ICON / Sponsor Engagement Timeline

## Continuous Collaboration Across ICON Divisions Leads to Successful Partnership

Sponsor 

**April 2022** – Sponsor 1<sup>st</sup> meeting to discuss the Program Overview, Ph 2 PoC study with a possible 2nd study, another CRO running Ph 1

**July 2022** – Discussed a roadmap for Sponsor's Program program, coaches/provides insight

**September 6, 2022** – Sponsor meeting to discuss pipeline evolution, now 3 Pivotal PH III's and an OLE, requested first ballpark

**September 20, 2022** – Ballparks delivered along with Commercial terms

**October 19, 2022** – Started the MSA process

**November 22, 2022** – Sponsor regroup, new synopses and new strategy

**December 7, 2022** – Sponsor meeting to demo Clinical Maestro

**December 14, 2022** – Sponsor meeting to discuss AEBC vendor experience

*Proposal Development*

*Proposal Development*

**June 2022** – Sponsor requested specific members of ICON's oversight team

**August 2022** – General Capabilities and alignment on enrollment rate

**September 7, 2022** – Sponsor request for CEO presentation: "Why use only one CRO across program & "Why ICON"?"

**October 6, 2022** – Sponsor meeting, inform of new synopses 2nd request, now want full proposal with several scenario's per study

**October 21, 2022** – Delivered full proposal

**November 28, 2022** – Received full RFP request, notified we had to use Clinical Maestro to submit the proposal

**December 8, 2022** – Proposal team formed a 4 person ICON team solely dedicated to submitting into CM

**December 16, 2022** – Invited to Bid Defense meeting January 9th

### Negotiations

**January 9, 2023** – Bid Defense meeting

**January 11, 2023** – New Synopses received, request for updated proposals, couple day turnaround

**January 18, 2023** – Sponsor strategy/ER discussion

**January 26, 2023** – Sponsor/ICON Diversity discussion

**January 30, 2023** – Sponsor study start up strategy meeting

**February 1, 2023** – CEO of Sponsor and ICON CEO meeting

**February 3, 2023** – Sponsor meeting with our Medical Writing team to discuss finalizing synopses

**January 6, 2023** – Sponsor meeting to discuss our proposal

**January 10, 2023** – Feedback meeting with Sponsor and Exec Leadership

**January 17, 2023** – Meeting Clin Ops team to discuss different scenario's

**January 23, 2023** – New synopses received, new request for revised proposals

**January 27, 2023** – Delivered revised proposal

**January 31, 2023** – Yearly spend reports and Cash flow analysis provided to Sponsor

**February 2, 2023** – Leadership meeting to finalize commercial terms

**February 3, 2023** – Official email award received!!!!

# 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

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**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

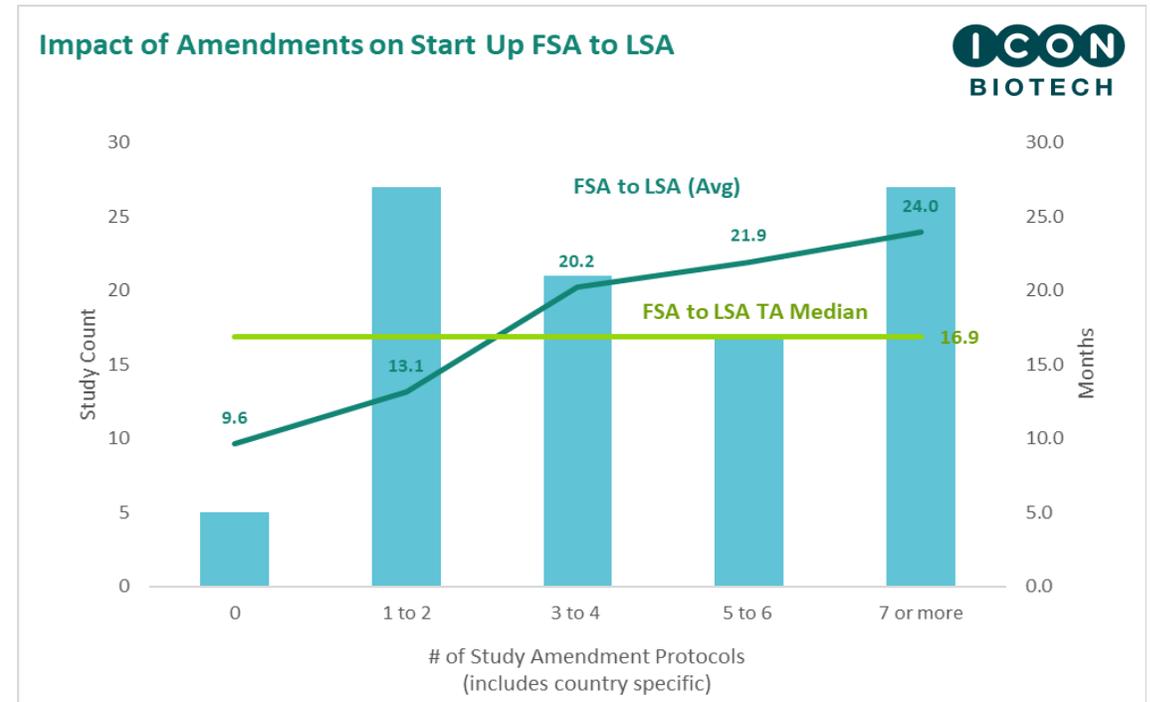
# Mitigating Impact to Study Timeline for Protocol Amendments

## 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

## Alignment on vision and objectives

Create alignment by shared vision statement and get best out of our teams



### Collaborative leadership

- Dedicated Partnership-level Leaders
- Executive attention and partnership

## Resource Stability (Culture of trust)

- Strong focus on assigning the same core team members for new studies
- Transparent reporting around resources
- Team building and training on our joint vision forward
- Increased staff retention

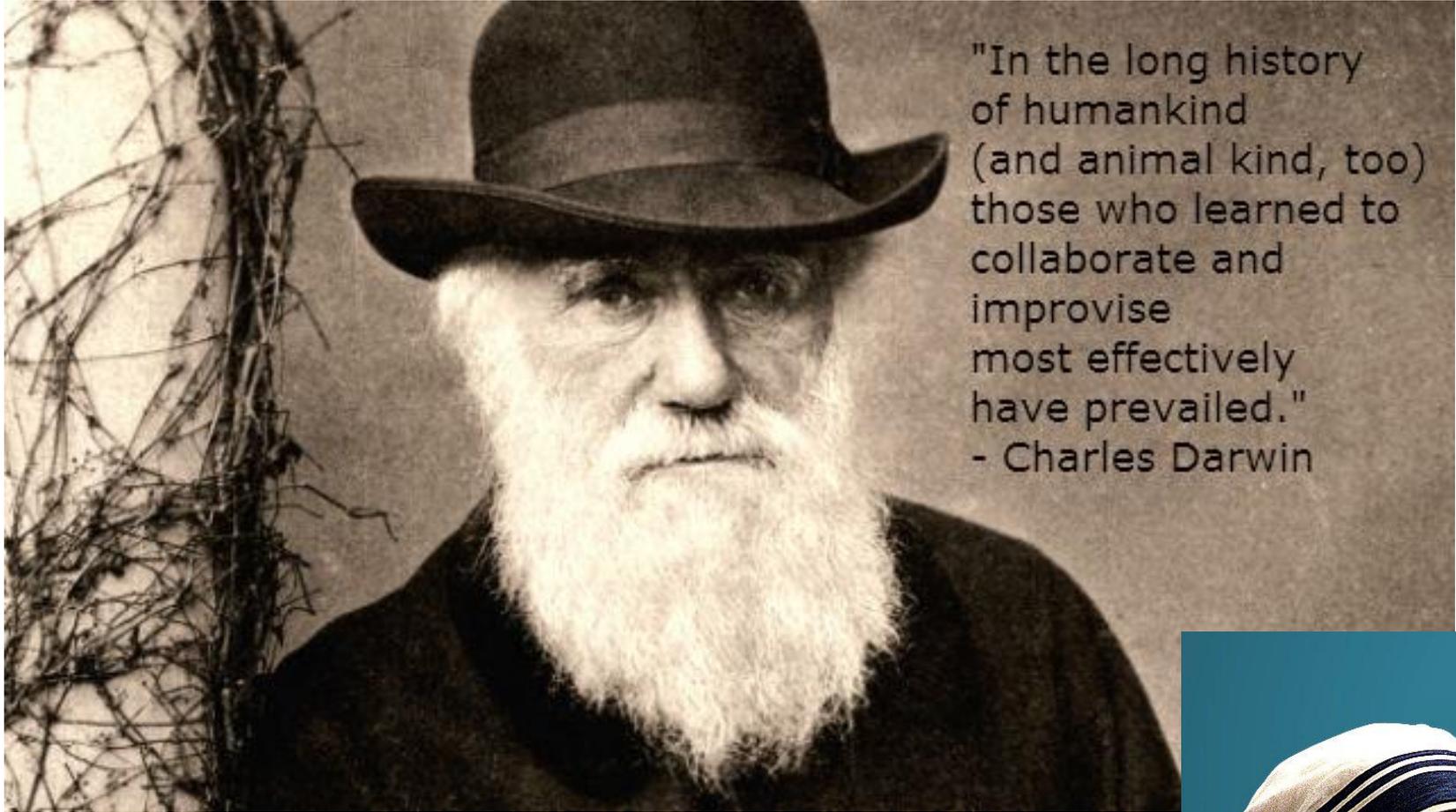
## Optimized Processes & Standards

- Create partnership guidance/handbook
- Align communication across portfolio
- Global specific portfolio plans and governance charters
- Implementation of lessons learned across the portfolio
- Alignment on KPIs
- Integration of cutting-edge technology & data

## Value to the Client

- ✓ Reduced total CRO oversight effort
- ✓ Continuous leveraging of Portfolio lessons learned
- ✓ Opportunity to secure fully dedicated resources
- ✓ Higher CRO accountability
- ✓ Well defined measures to drive productivity, quality and continuous improvement

**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

# ICON BIOTECH



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

*- Mother Teresa*