Maximizing the consultative partnership between CRO and pharma/biotech partners

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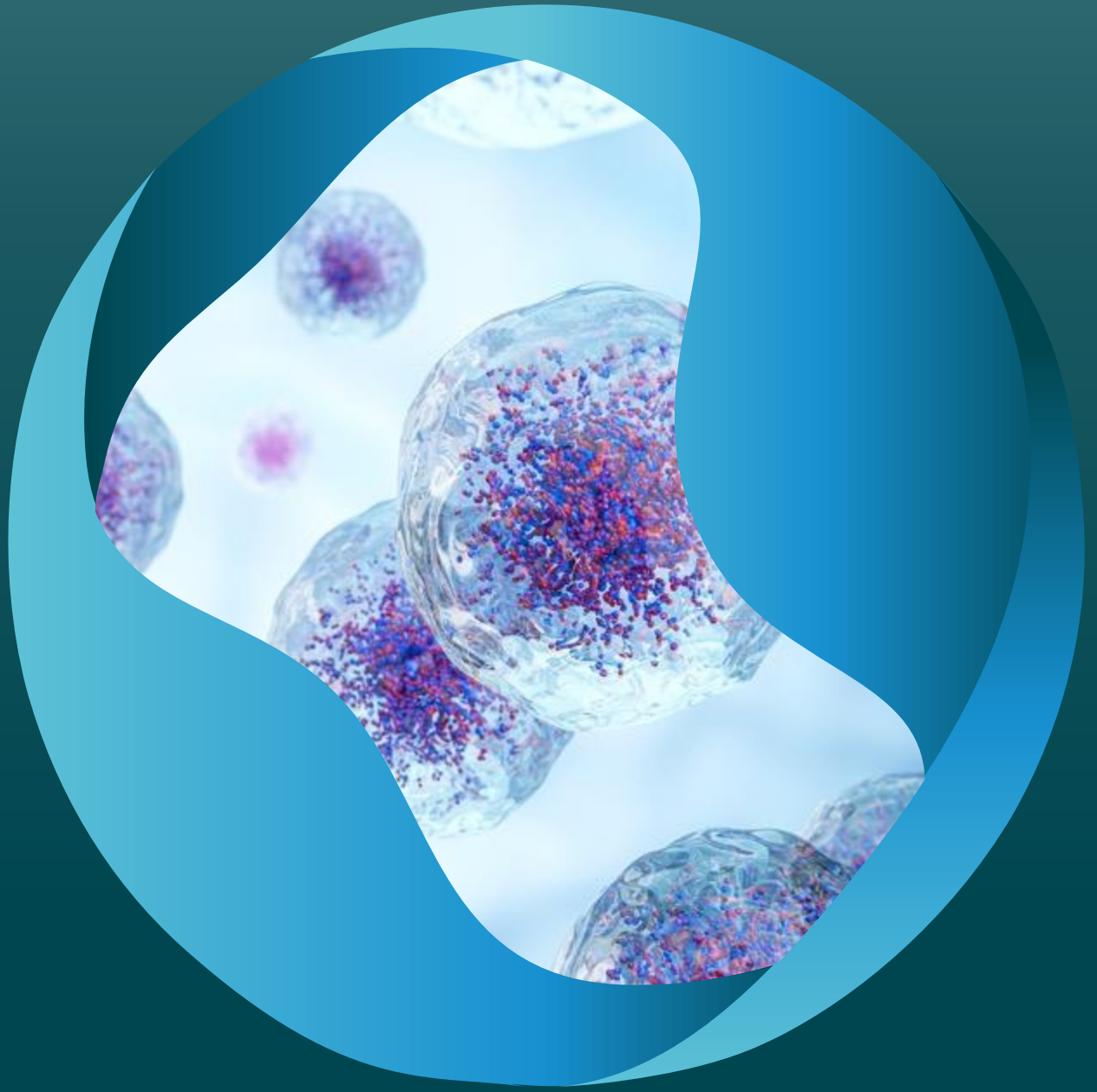

Maximizing the consultative partnership between CRO and pharma / biotech partners

How early engagement can improve outcomes

- Choose your own adventure
- Key ingredients for a tailored proposal
- Leveraging expertise to improve predictability / outcomes

How do we ensure we are speaking the same language, no one size fits all approach

- Established Feedback loops – case studies from CRO experience, leverage to improve outcomes

Simplifying the complex, in the midst of plentiful outsourcing options and models

- Your teams are an extension of your organization – create an environment of retention
- Ownership is on the CRO / service to drive value
- Minimalist approach

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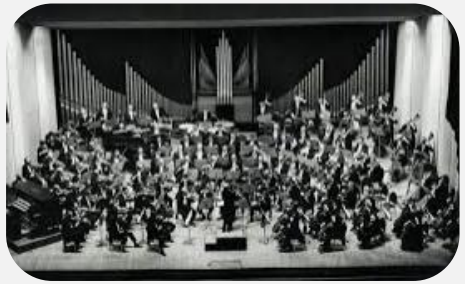
Choose your own adventure…

The Best “Choose Your Own Adventure” books for Sponsors

Partnership/consultative mindset:

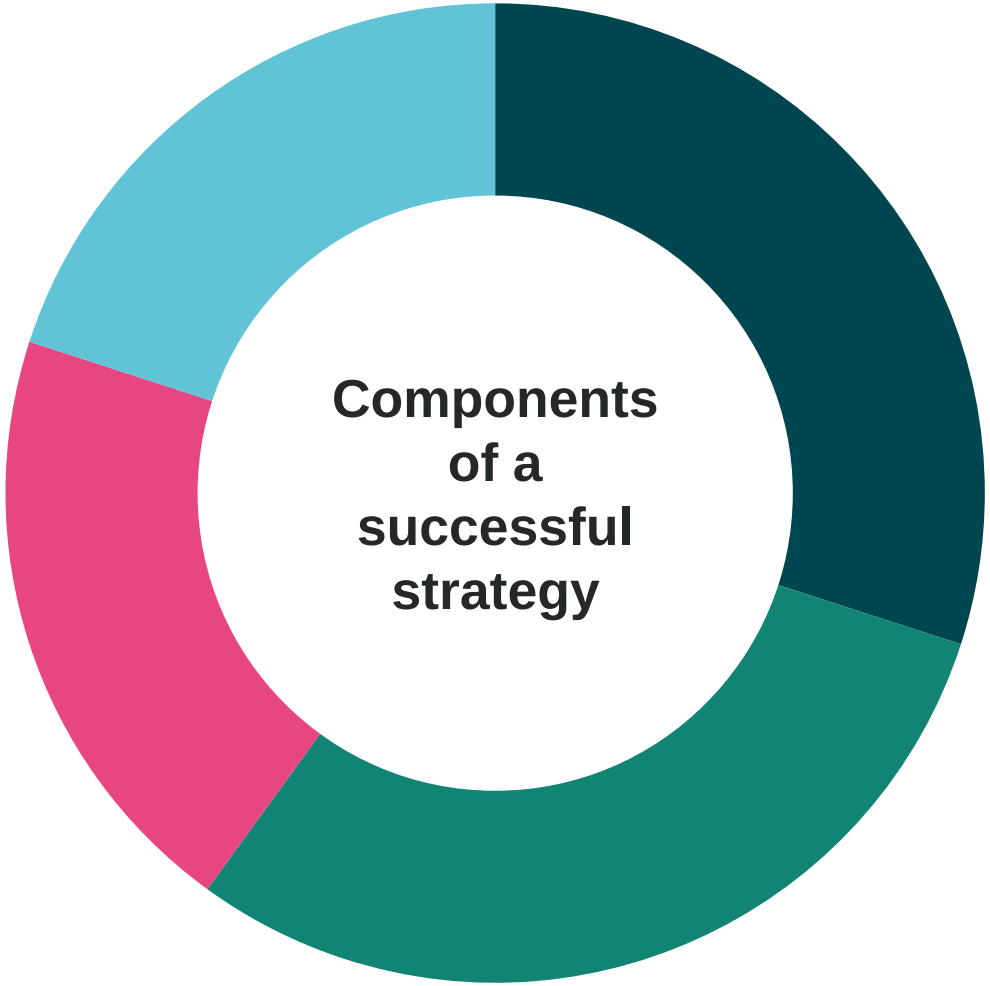
– “No” is not in the vocabulary
– Value instead of services
– Evidence based solutions
– LISTEN and Communicate
– Flexible, Agile, Creative



Transactional mindset:

– You direct, I follow
– Need to know basis
– Record and reproduce

What drives a successful end-to-end strategy?



Well defined critical success factors

- Primary end point protection
- Operationalization
  - Patient Pathway- site and patient profile
  - Project Team staffing - design
  - Training Development- CRO, Site, external vendors
  - Speed
  - Listening to what the client is saying/not saying they need
  - Reg submission strategy

Value-driven solutions to challenges

- Client's perspective
- Operational perspective
- Site & Patient perspective
- Marketing / Commercialization

Differentiated service offerings

- Unique, Creative, innovative

End-to-end- optimize CRO offerings

- Ease of contracting- streamlining agreements
- Ease of management, communication
- More comprehensive for better overall operational success

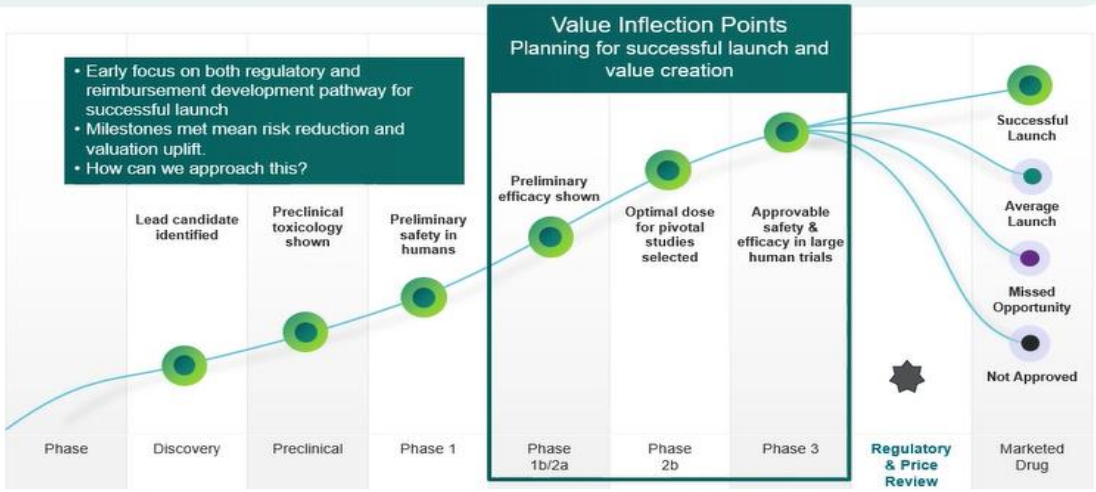
→ Improves outcomes for Sponsor / CRO

Leveraging expertise to improve predictability

If a sponsor's greatest asset is their data, then our respective organizations can multiply its effectiveness by initiating discussion and action:

- Define inflection points on the path to approval/ launch
- Align on “SWOT” analyses
- Benefit from combined experience and perspectives
- Maximize a smaller pipeline by continually “writing the story” to support fundraising, value creation, and scientific interest

Value creation on the path to approval and launch



Therapeutic Area SWOT Analysis – *SAMPLE*

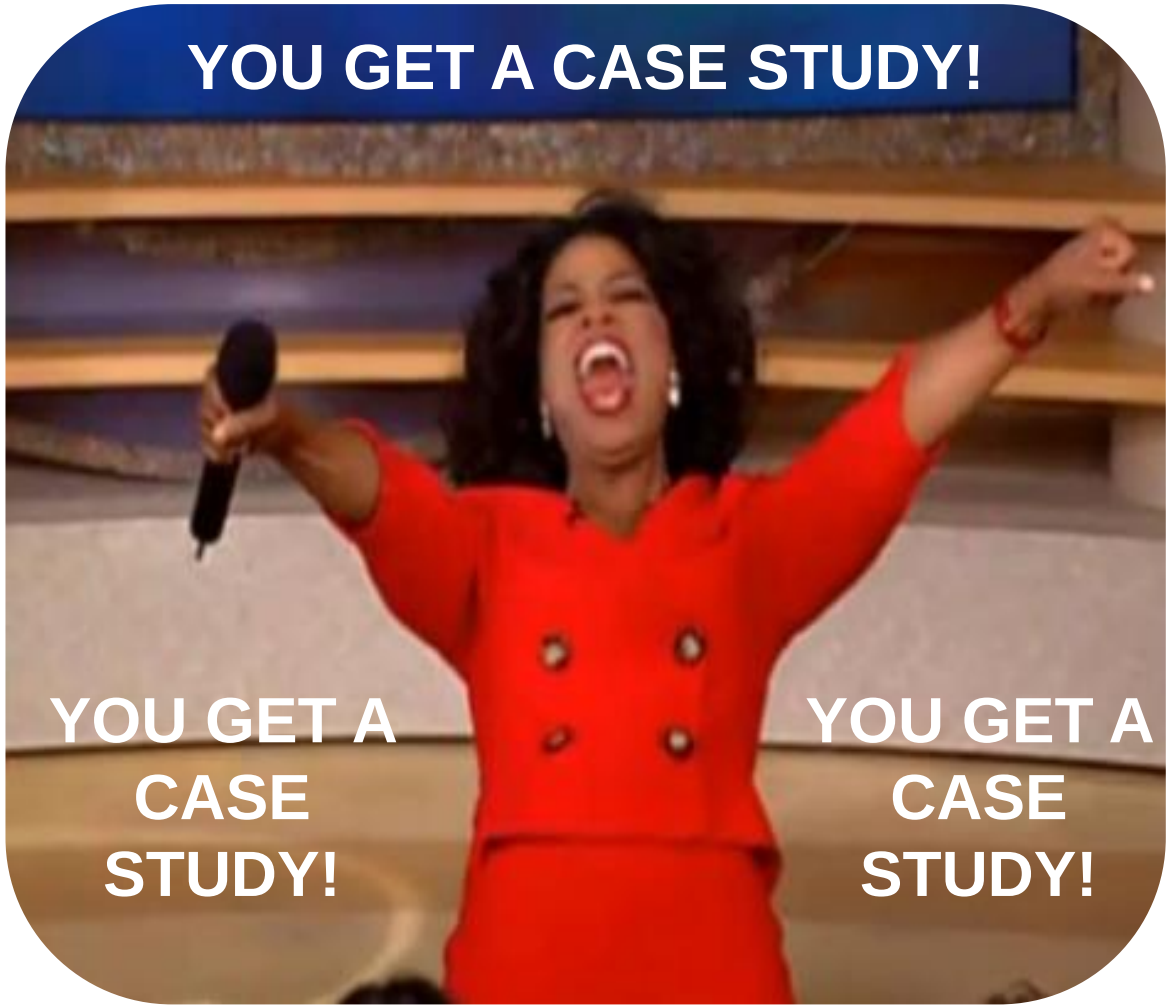
Strengths
- Industry leader in select indications
- CTLs with doctorate level client extensions, rapid PI insight, leveraging relationships
- Diverse TA experience to source staff
- Diverse TA experience, collaborates w/ many TA / horizontal experience streams (Rare, peds, device)
- Experience working w/ CV AROs
- Relationships with key site networks

Weaknesses
- Experience ramp up in growth areas
- Requires a reproducible model to “specialize” a team
- CV: Research Expenditures have been relatively low relative to burden

Opportunities
- Deep opportunities to tailor experience tables to specific opportunities (repeat business, spanning all endpoints, % market capture/asset ownership, etc)
- Strategic site network partnerships
- Commercial strategy in target indications
- Maximize DCT / Hybrid capabilities (Technology to drive down costs, relative to burden)
- Organic growth of staff w/ experience in co-morbidities through training investment
- No shortage of patients in Obesity / burden of cardiovascular disease is the leading cause of death in men/women
- APAC Biotechs in CV space (Most of the early growth is in APAC (Phase I-II)
- Potential CV, Hepatic, Endocrine outcomes benefits to Obesity

Threats
- CRO differentiation
- Providing the “A-Team” in key indications
- Patient retention: Impact of new drug approvals, Obesity-perceived lack of treatment affect
- Key Talent retention / experience base / loss of investment
- Biotech funding levels (CV expenditures)

Show me the data…



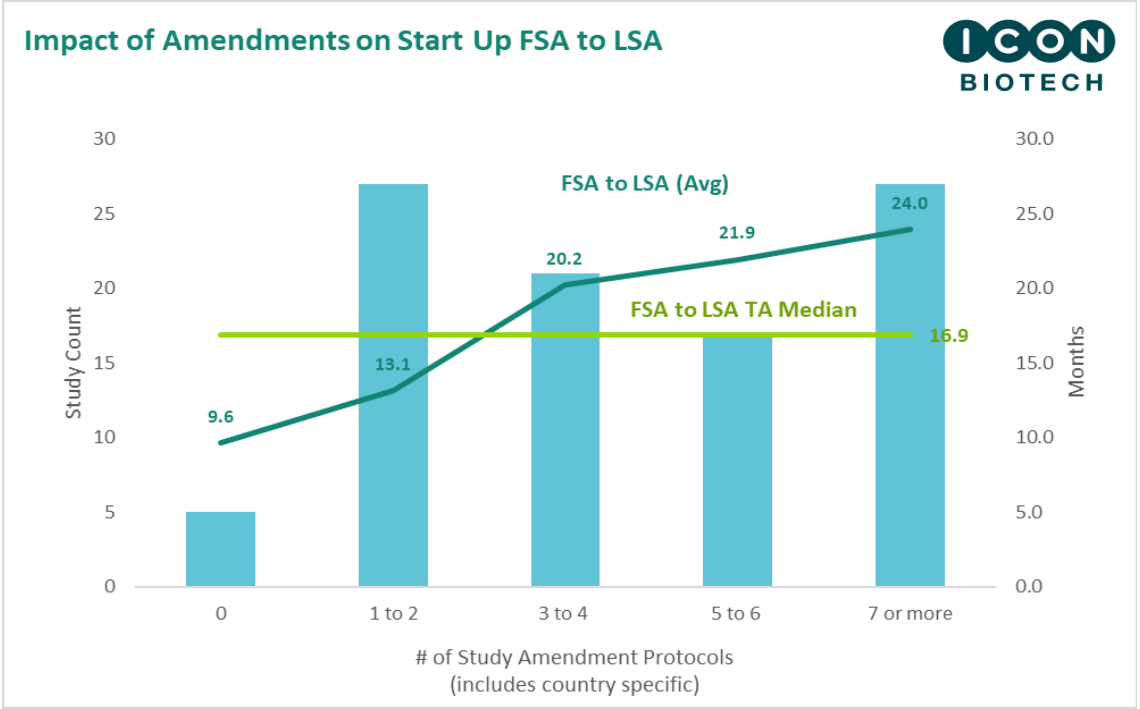
With careful planning, Protocol Amendment impacts could be lessened

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:

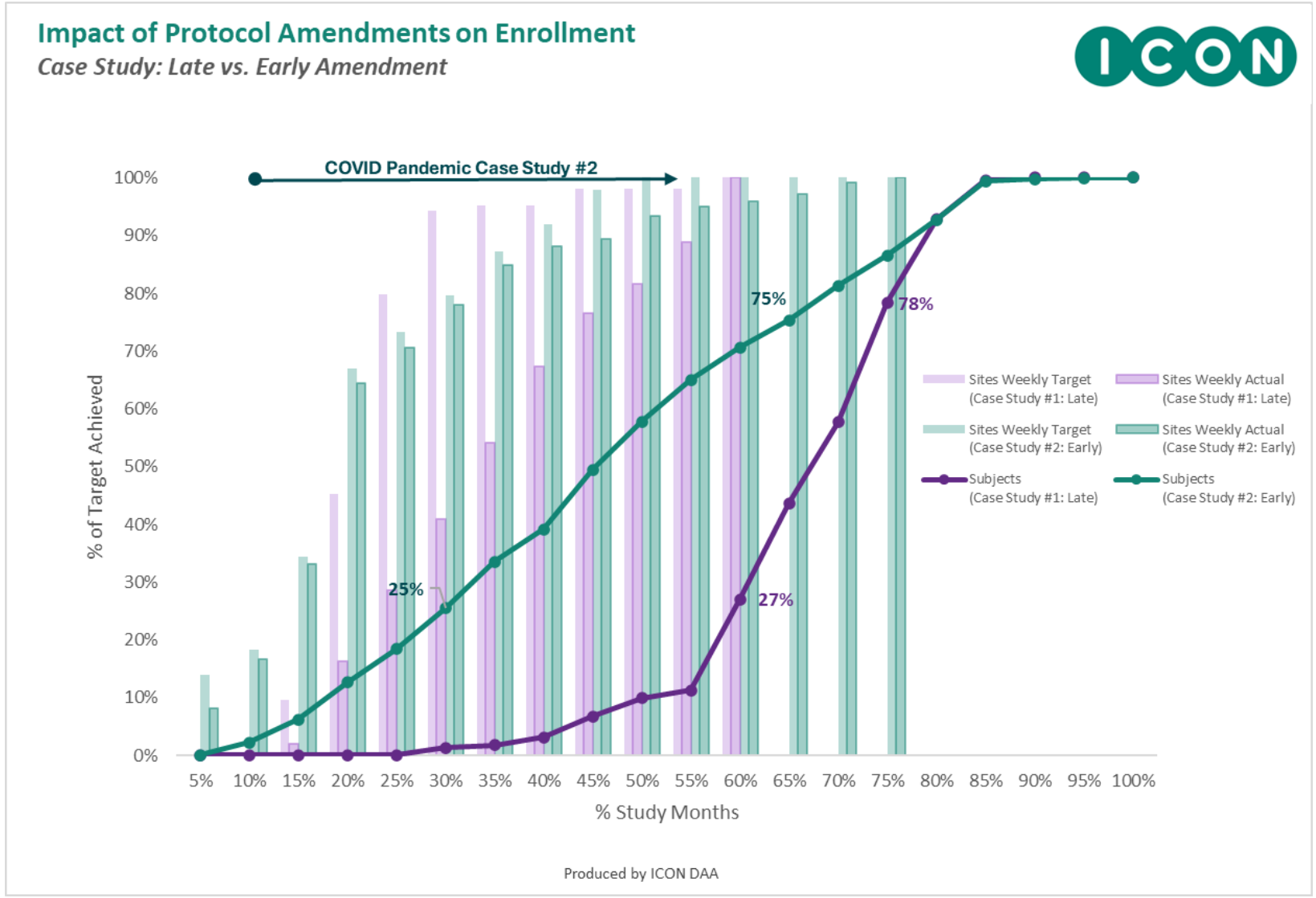
- Seize the opportunity to either offer early engagement in protocol consultancy, or offer risk analysis and plan of action, e.g.
  - Partner with Medical, Regulatory, SSU, etc. to give stronger consultancy on protocol quality impacts, at pre and/or post services launch
  - Set expectations early re: 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.

Protocol amendments on enrollment case study



Data analysis/impact:

- **Client #2** required nearly 67% of the total study months to achieve 25% of enrollment target
- **Client #1** achieved 75% of the enrollment target in 67% of the study months.

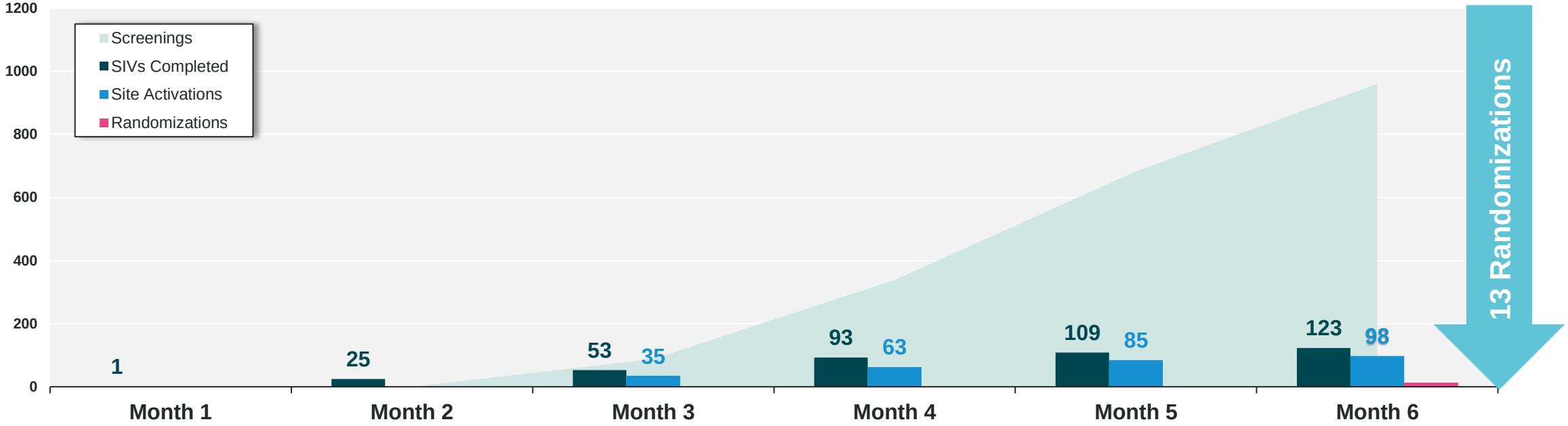
Best practices from lessons learned:

- Implementing AMD feedback loop early during site ID vs. only after enrollment improves:
  - Rate of enrollment
  - Opportunity for reaction to safety signals
  - Site burden and efficient resource usage

Phase III case study

Proven path to first patient in

Data Analysis | ICON supported global site start-up activities for a Phase 3 study, leveraging a **hybrid feasibility** approach and a **seamless transition** from *feasibility* to *global start-up.* **First patient randomized within 4 months of first site activation** *(*12-week screening period)**.**



Best Practices from Lessons Learned

- Investigator feedback incorporated early- no need for protocol amendments during initial start-up phase
- Leveraging Early Engagement teams for efficient country feasibility and site selection
- Timely vendor set-up and contract execution
- Comprehensive and robust training by the CRAs and Medical Team at the SIVs
- Early scientific engagement with sites supporting screenings
- Leveraging customized dashboards to manage screening windows

Optimal onboarding and program staffing

Resource Optimization

- Rollover Relationships – prior relevant programs
- Study Specific Welcome Packet
- Understanding Sensitivity of Competitive Environment
- Plan for growth mindset and succession within the team
- Creating an environment of retention in partnership with Sponsor

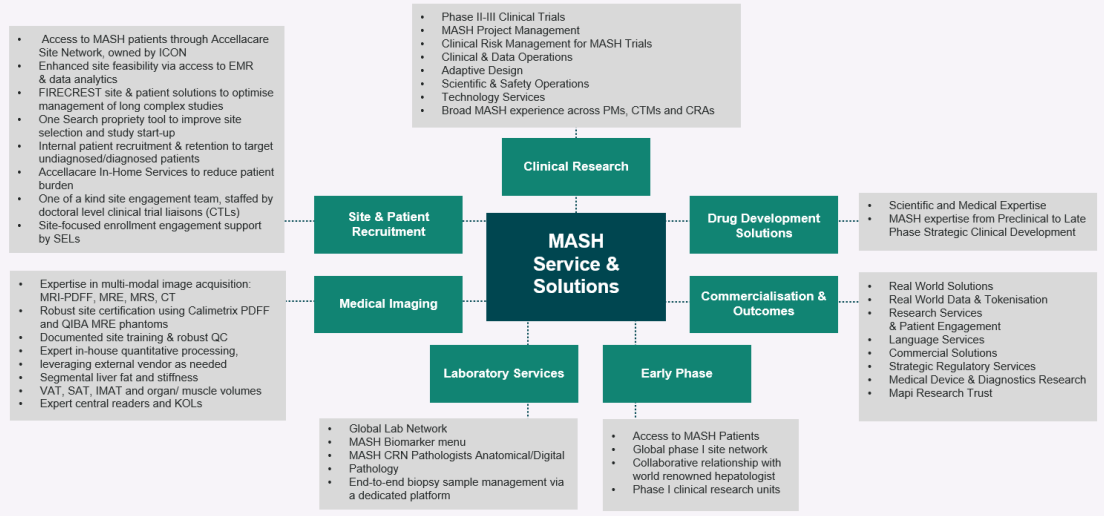
Therapeutic Area/ Endpoint Training

- Therapeutic
- Protocol
- Current Landscape
- Approved therapy(ies)
- Standard of Care
- Competitive environment
- Who’s Who
- Capturing missed endpoints / outcomes trial strategy (if applicable)

Study Execution Training

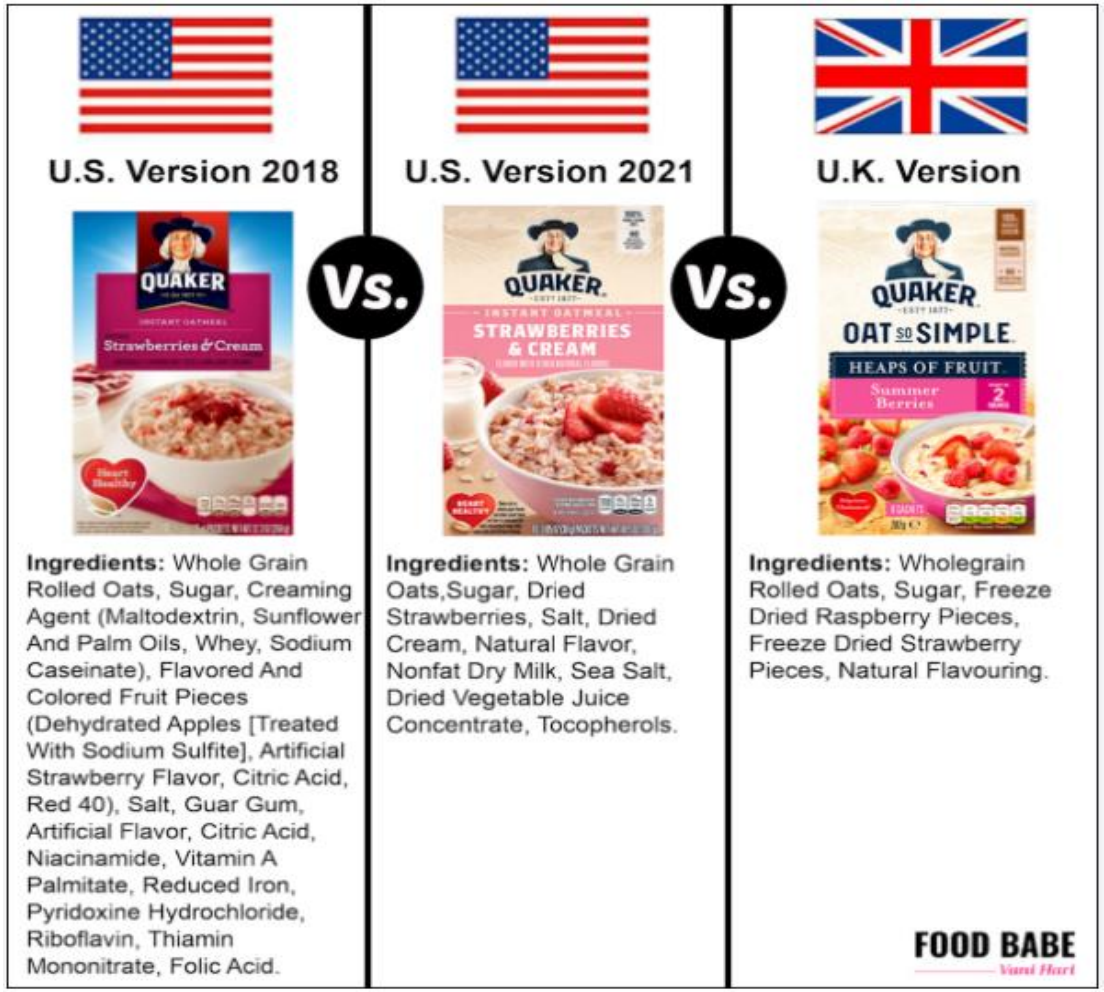
- Study Strategy / KPIs
- Biotech Consultative Mindset
- Best Practices from TA execution
- Project Specific Training
- Partnership / Program Guiding Principles
- Operational Relationship Guidance
- Portfolio Level Templates
- Lessons Learned Forums

A menu should be a la carte…



– Value add services that are tailored to the indication, client needs, phase, patient population, and industry climate

– Sponsors to leverage consultative relationships with CROs to advocate for fit for purpose solutions



Fit for Purpose Solutions

Beginning with the end in mind: Construct a development and execution plan with consideration to your commercial goals:

- Define your commercial opportunity: Markets, competition (now and in 5-10 years), pricing, Net Present Value of your asset, reimbursement paradigm
- Build a regulatory strategy around your commercial strategy. Country considerations, early assessment of necessary trials
- Write your protocol(s) to support your regulatory and commercial strategy
- Select an experienced partner whose experience can generate considerable momentum
- Deploy data driven agile solutions and services with a focus on simplistic quality
- Invest and demonstrate transparency with your service partners so they can be the best global extensions of you
- Establish proactive feedback loops to improve outcomes

The Jurassic Park problem: "*You were so concerned with whether or not you could, you never stopped to ask whether you should*."

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