A CRO’s perspective

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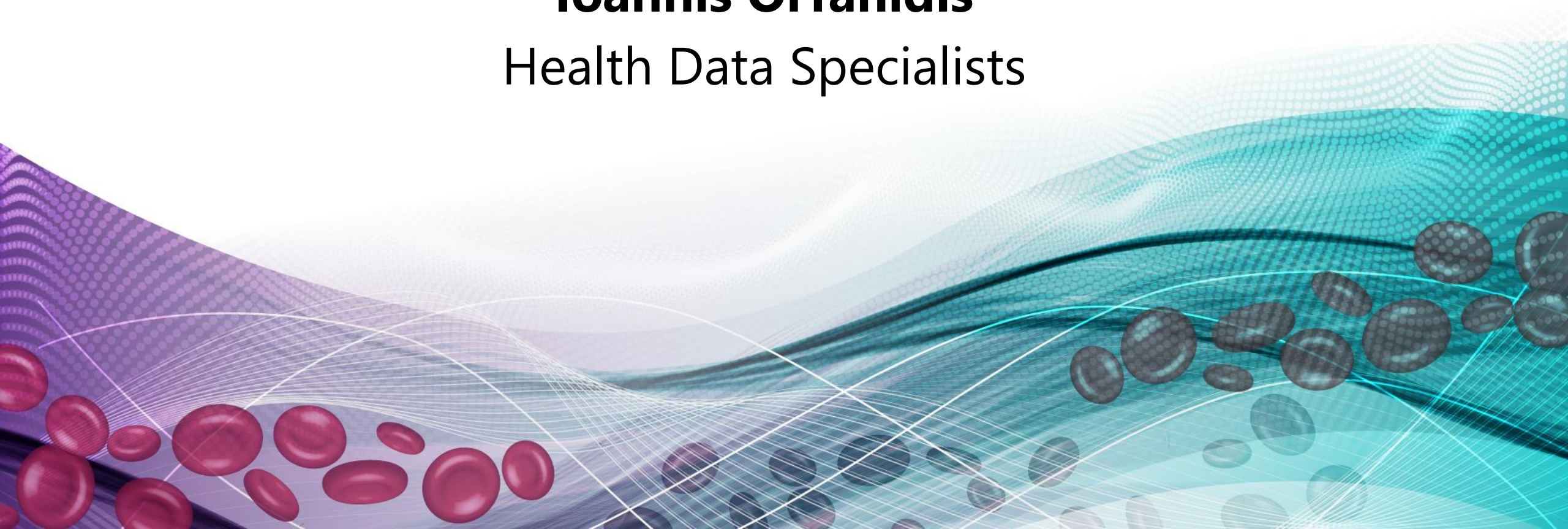


Objectives

- Outline the key practical aspects of collaborative research within the clinical study life cycle
- Clarify the role and importance of CROs
- High Level Proposal for Collaboration

The story so far

Academia

- Deep knowledge and clinical expertise
- Likes flexibility in processes and decision making
- Academically oriented goals

Industry

- Extremely stable and robust processes in place
- Relies on strict adherence to timelines
- Corporate oriented goals

Distinct paths by definition

Both absolutely required in Clinical Research

Is acknowledging these distinct expectations enough?

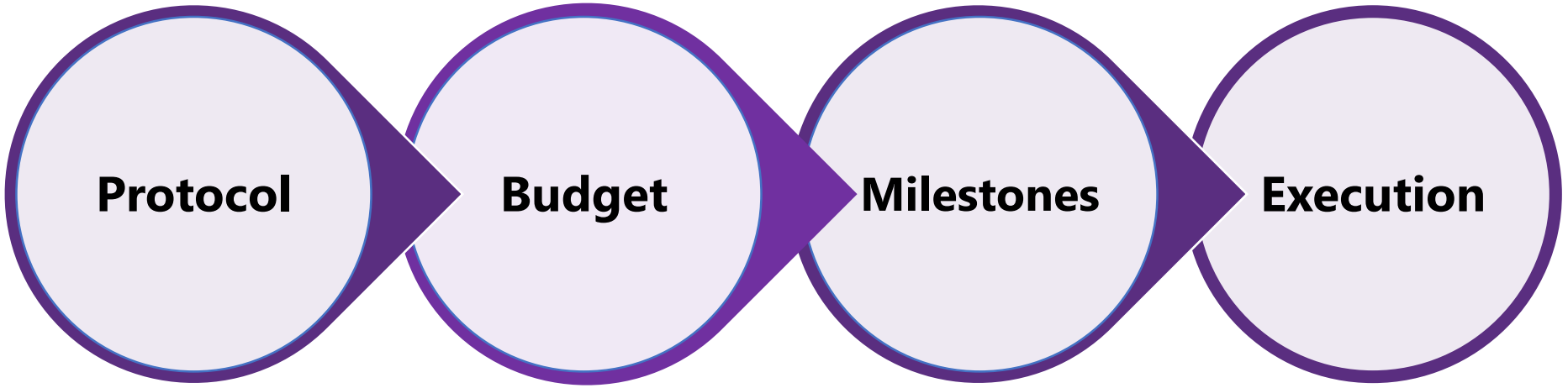
Is there a recipe for Success then?

MANAGE EXPECTATIONS

The Contract Research Organization “CRO”

- Critical in managing the expectations between Academia and Industry
  - The “glue” between Pharmaceutical Industry and Academia
- Should not be utilized/viewed as an outsource service due to cost or resource limitations
- Should be considered as a third “partner” in the collaborative framework
  - Increased transparency and overall project control
  - Increased expectations and responsibilities

A closer look into Clinical Studies



Clinical Study Protocol

- One of the most important steps in the Clinical Study life cycle
- Depending on type of study (IIS, Collaborative agreement) could be entire responsibility of the Investigator/Academic Group
- Regulatory Implications, e.g:
  - Study Drug Characterization
  - Concomitant Medication/Procedures Reimbursement
- Study Feasibility Implications, e.g.:
  - Biological sample handling
  - Feasibility of local assessments
- Need to ensure that regulatory environment as well as study operations are taken into account early in the design of the Protocol

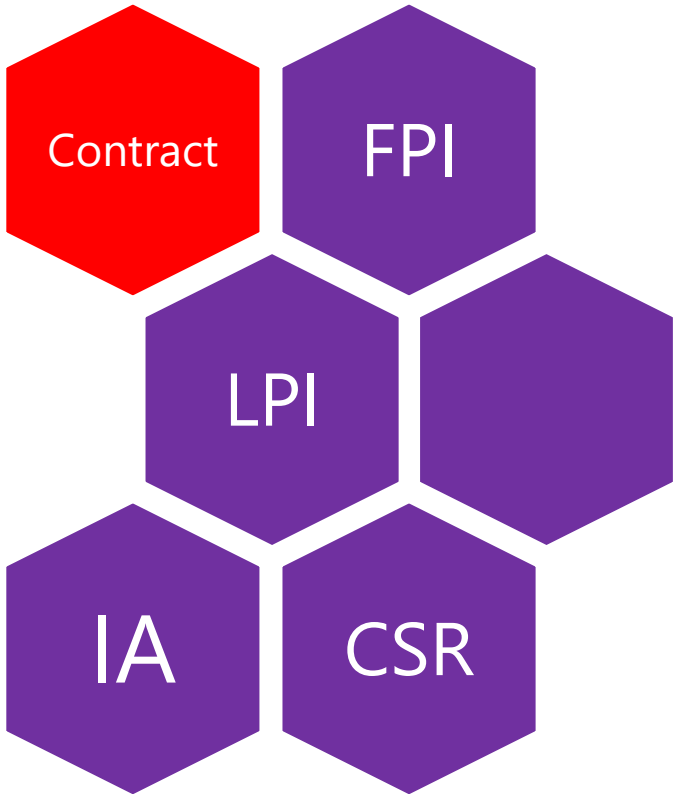
Clinical Study Budget

- Perhaps the most sensitive component in the clinical study cycle
- Frequently clinical studies are being under-budgeted
  - Significant budget increases
  - Delay in timelines and key milestones
- Must understand the Fair Market Value Assessment concept
- Must be able to translate the Protocol requirements and the regulatory variability into a comprehensive Budget
- **Industry: Provide clear specifications from the beginning**

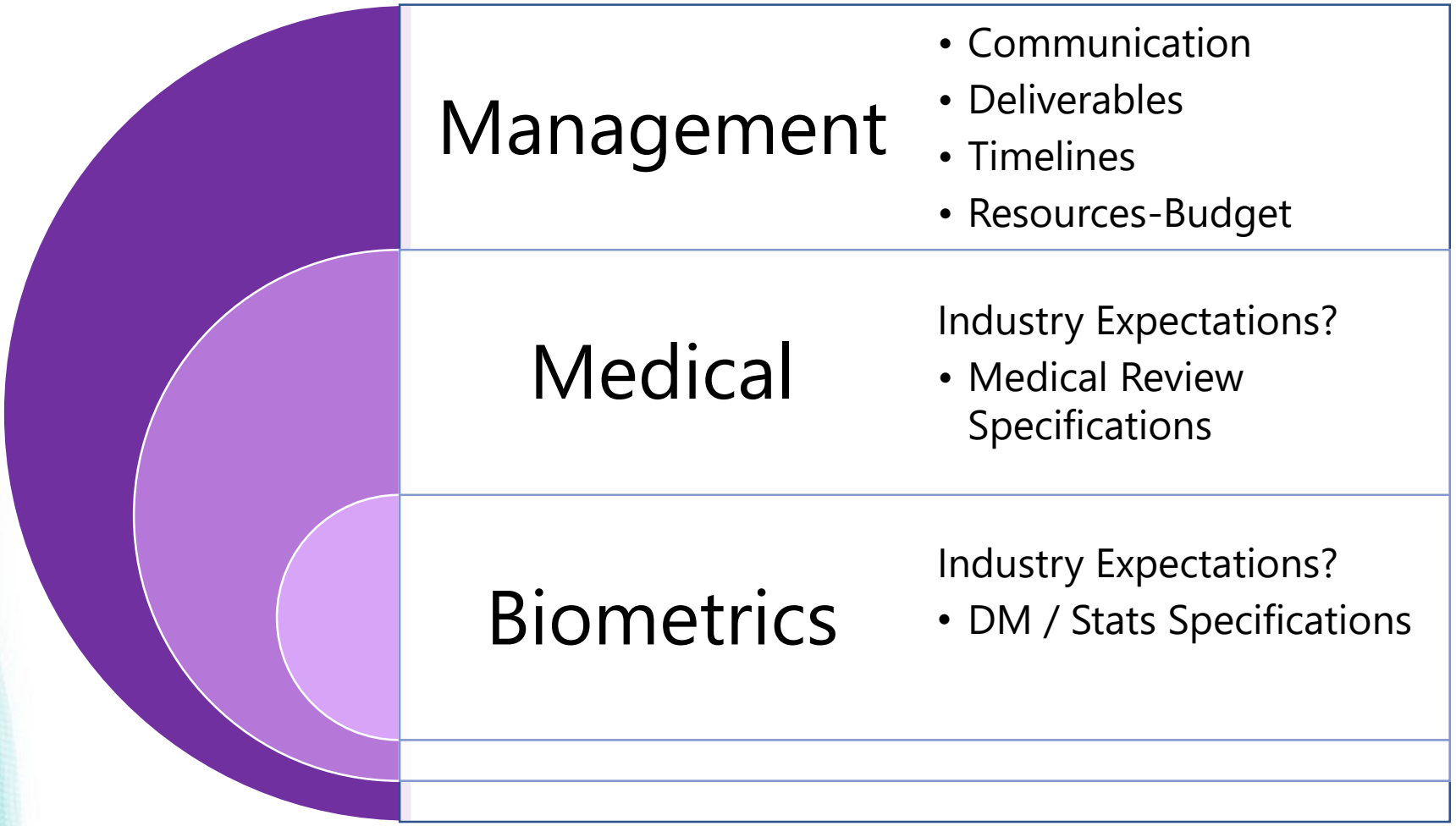
Contract and Milestones

Clear Responsibilities and Realistic Milestones Upfront

1. Has a clear task list been agreed?
2. Has the regulatory framework been carefully considered?
3. Have we set realistic recruitment targets?
4. Are the resources aligned with the expectations?



Clinical Study Implementation



CRO

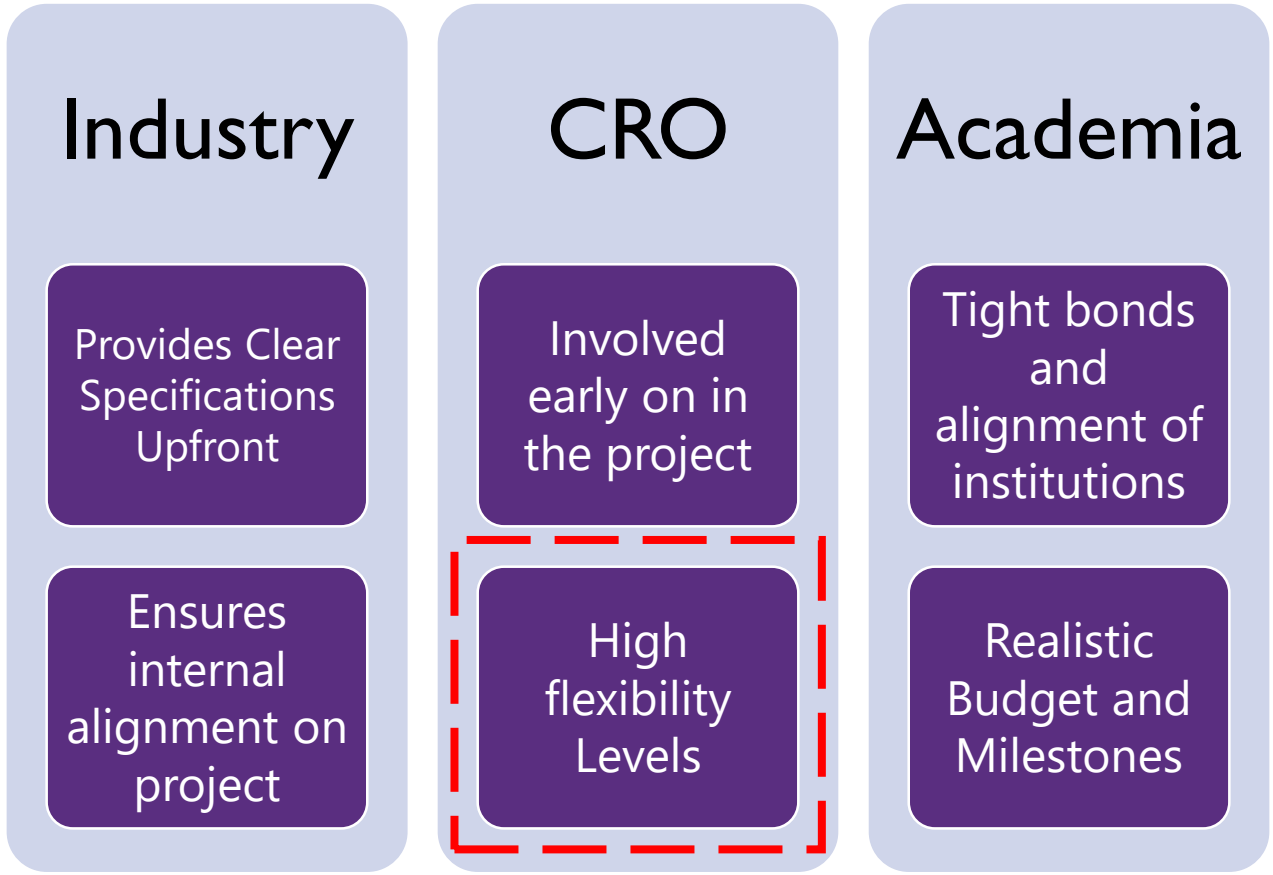
In a nutshell

- A Clinical Study is a complex and multifactorial project
  - A collaborative framework must take into account the distinct nature of the 2 stakeholders (Industry and Academia)
- All steps must be carefully studied and agreed early in the start up phase
  - Effective Protocol Development
  - Realistic Budget and Milestones
  - Clear task list (Industry-Academia-CRO)
- Management of Industry and Academia expectations is key to the success of a Clinical Study

Moving Forward – The role of the CRO

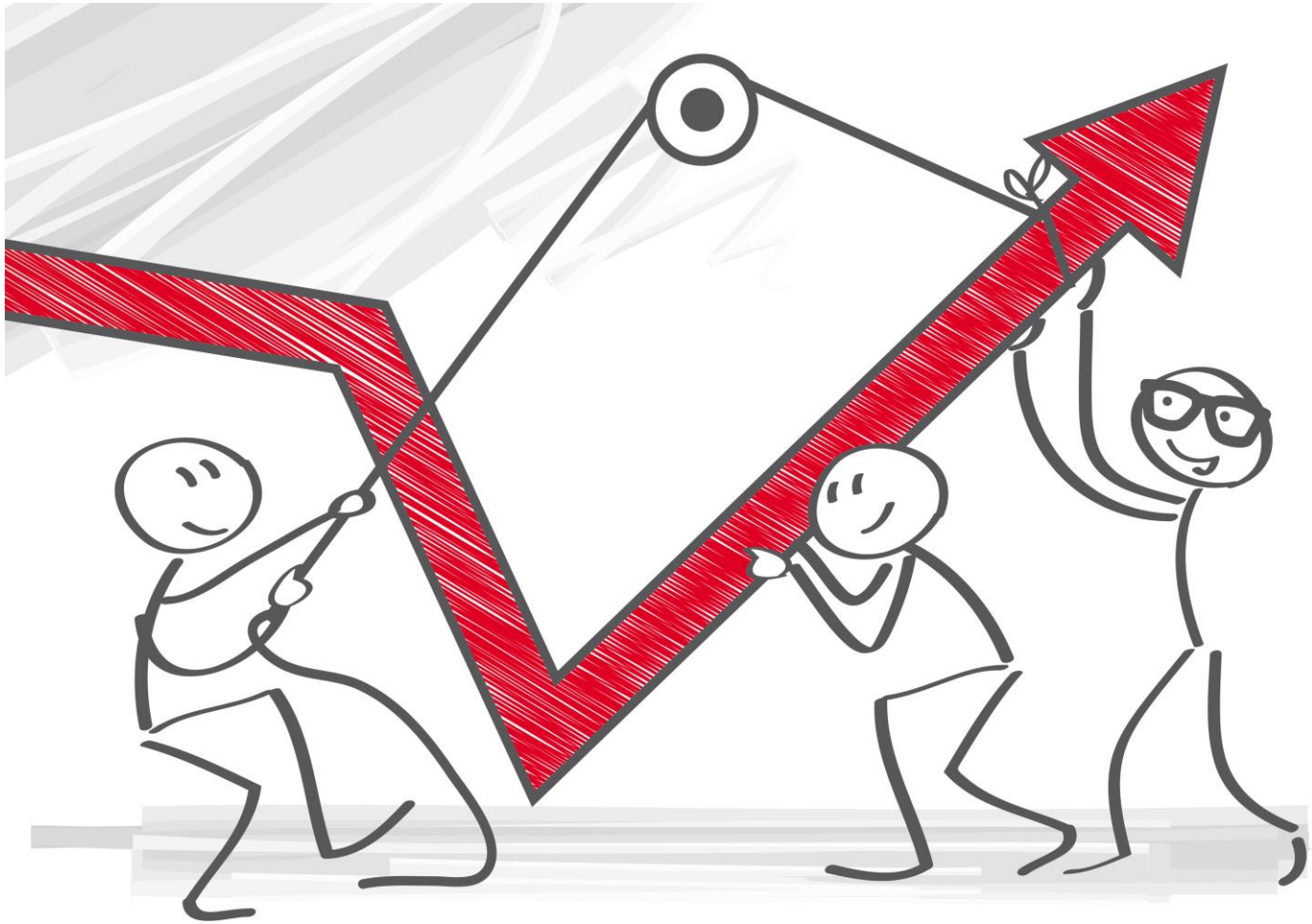
- The CRO should be involved deeper and earlier in the project life cycle
  - A CRO should be considered a true consultancy and not just an outsource service
  - CROs need to be consulted as early as possible in the project lifecycle
- Request specifications – Take Responsibility – Consult!
- A preferred CRO vendor list should be established at the academic level
  - Standard processes
  - Faster set up
  - Less risks

Proposed Collaborative Framework



Early alignment between Industry-CRO-Academia is ESSENTIAL

Collaboration: Team Work Above All



Thank You!