

# Fruitful Sponsor – CRO collaboration: How to succeed?



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- Preamble
- Why outsourcing?
- Challenges of outsourcing
- How to be successful?
- Conclusion

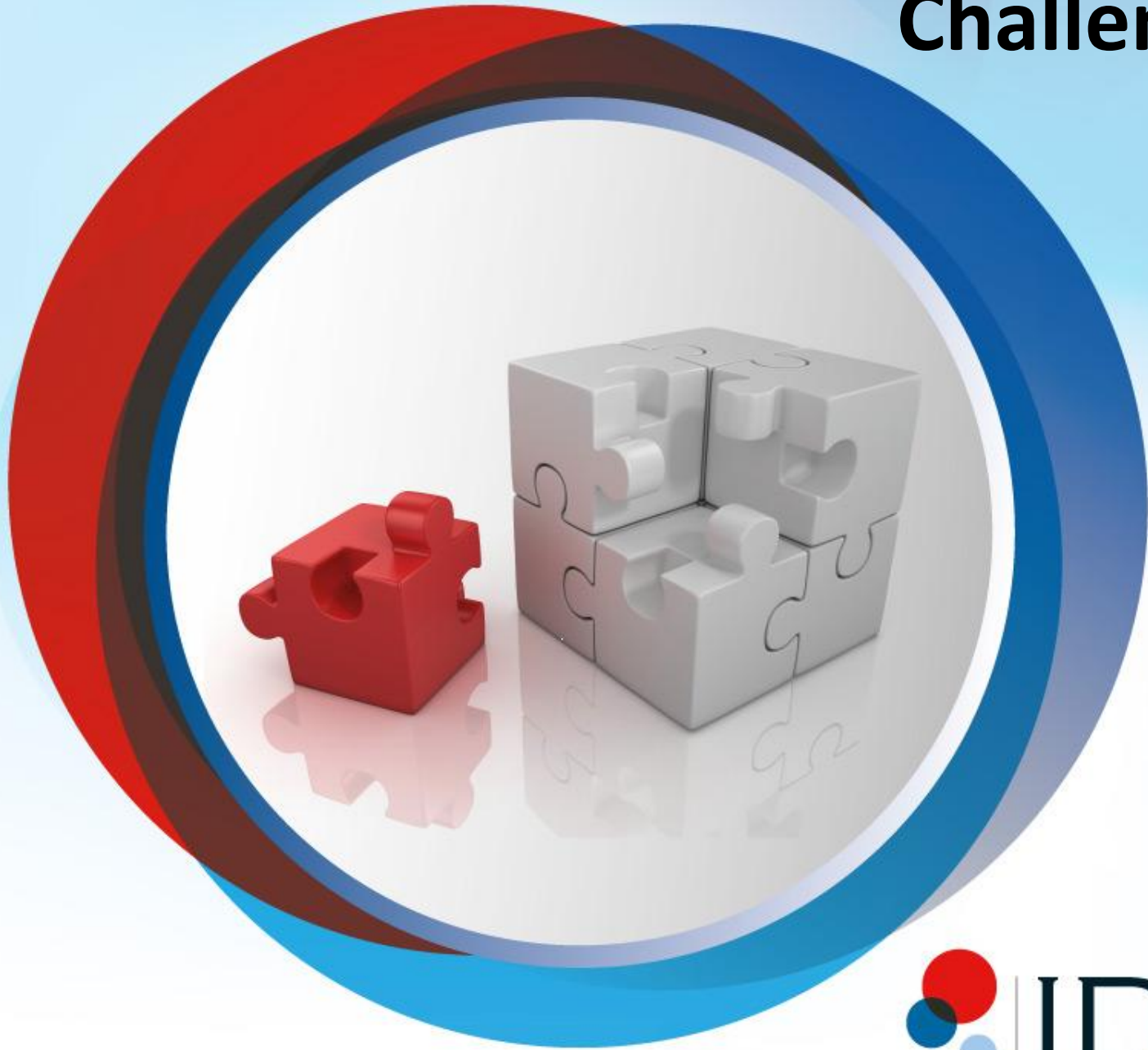
- Functional CRO (eClinical & Biostatistical services)
- Various models:
  - In-house
  - In-sourcing
  - Offshoring
  - Functional outsourcing
  - Full outsourcing
- Procedures to be used (CRO's vs sponsor's)
- Who is the sponsor & why does this matter?

# Why would I outsource?

- Cost control
- Specific expertise
- Allow to grow the trial portfolio
- Flexibility
- Free up resources
- Knowledge of the increasing regulatory requirements
- Out of the box thinking about processes

**=> Outsourcing: increase operational efficiency**

# Challenges?



- Remote collaboration
- Different time zone
- Language barrier
- Cultural differences
- Sponsor staff reluctance
- CRO staff availability
- Staff turnover (on both sides!)
- Sponsor changes (bought by another company)
- Several 3<sup>rd</sup> parties involved

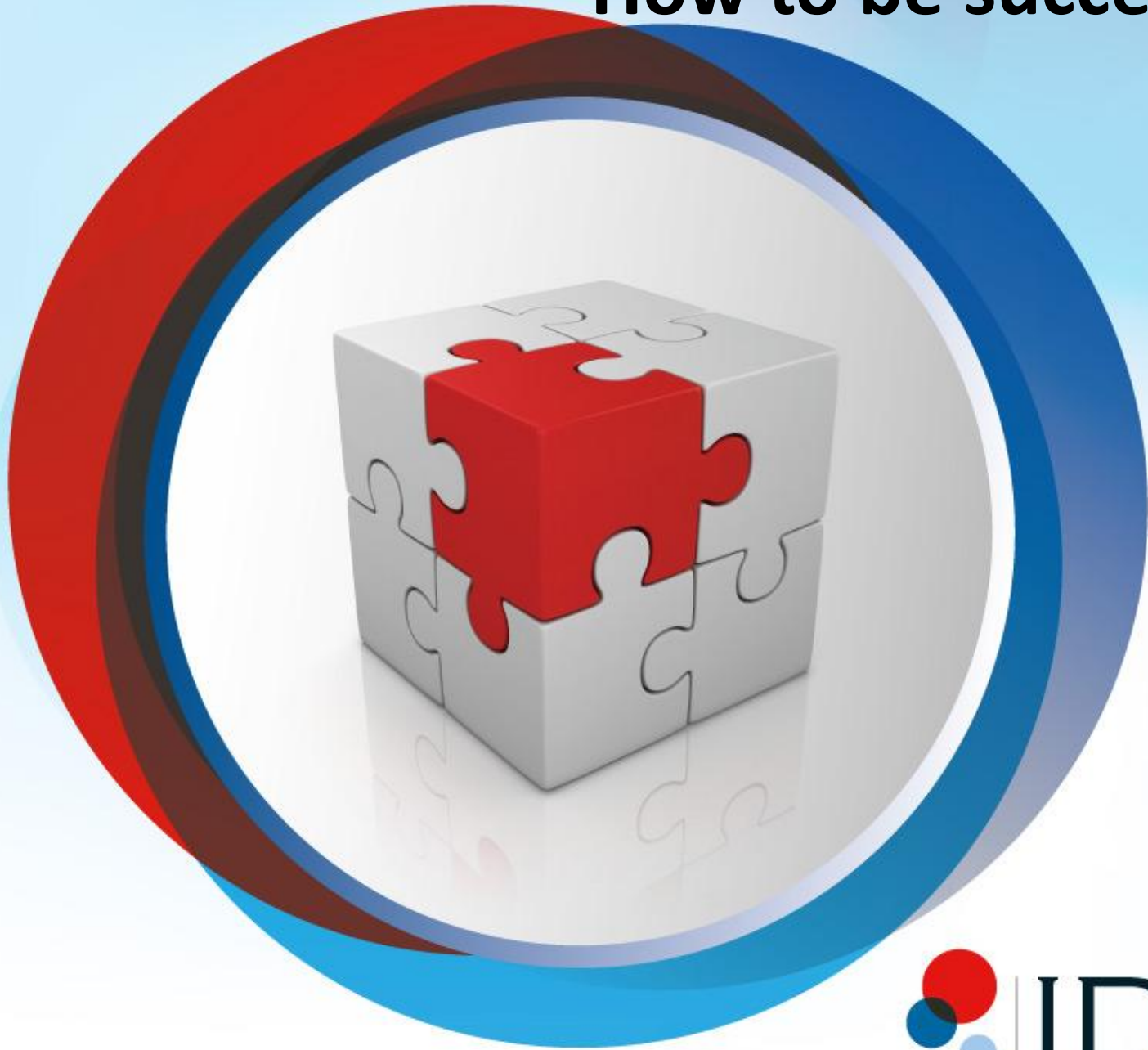
- Communication
  - **Vital for success**
- Work, resources, cost definition
- CRO selection and offer comparison
- Mistake/failure will not disappear
- Oversight of CRO



# Why is oversight needed?

- ICH E6 – GCP says: *“A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor.”*
- Regulatory authorities focusing their inspections on partnerships and oversight

# How to be successful?



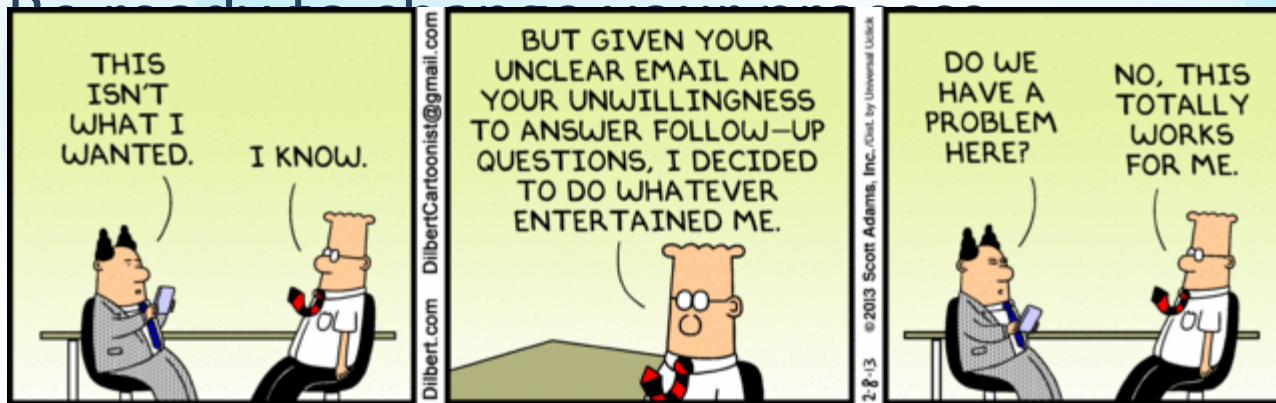
# How to be successful?

- True partnership
  - Fundamentals
  - Vendor role
  - Sponsor role
- Partner driven approach based on
  - Expertise
  - Experience
  - Enthusiasm
- Partner selection
- Metrics
- Satisfaction survey

- Discuss client goals/expectations
- Define roles and responsibilities for partnership
- Understand each-other's "culture"
- Discuss "pain points" and other areas in need of assistance
- Build a strong communication pathway:
  - Establish communication plan
  - Set clear guidelines for issue escalation
  - Regular meetings (F2F, Video, TC)
  - Encourage phone conversation
- Kick off meeting

- Initiate the relationship
- Assign strong team of qualified individuals
- Ensure vendor team meets goals and deliverables
- Foster communication
- Provide regular updates
- Transparency about issues
- Check general sponsor satisfaction on a regular basis

- Establish foundations internally
- Provide clear goals and objectives
- Provide needed information to meet those goals
- Be available for assistance

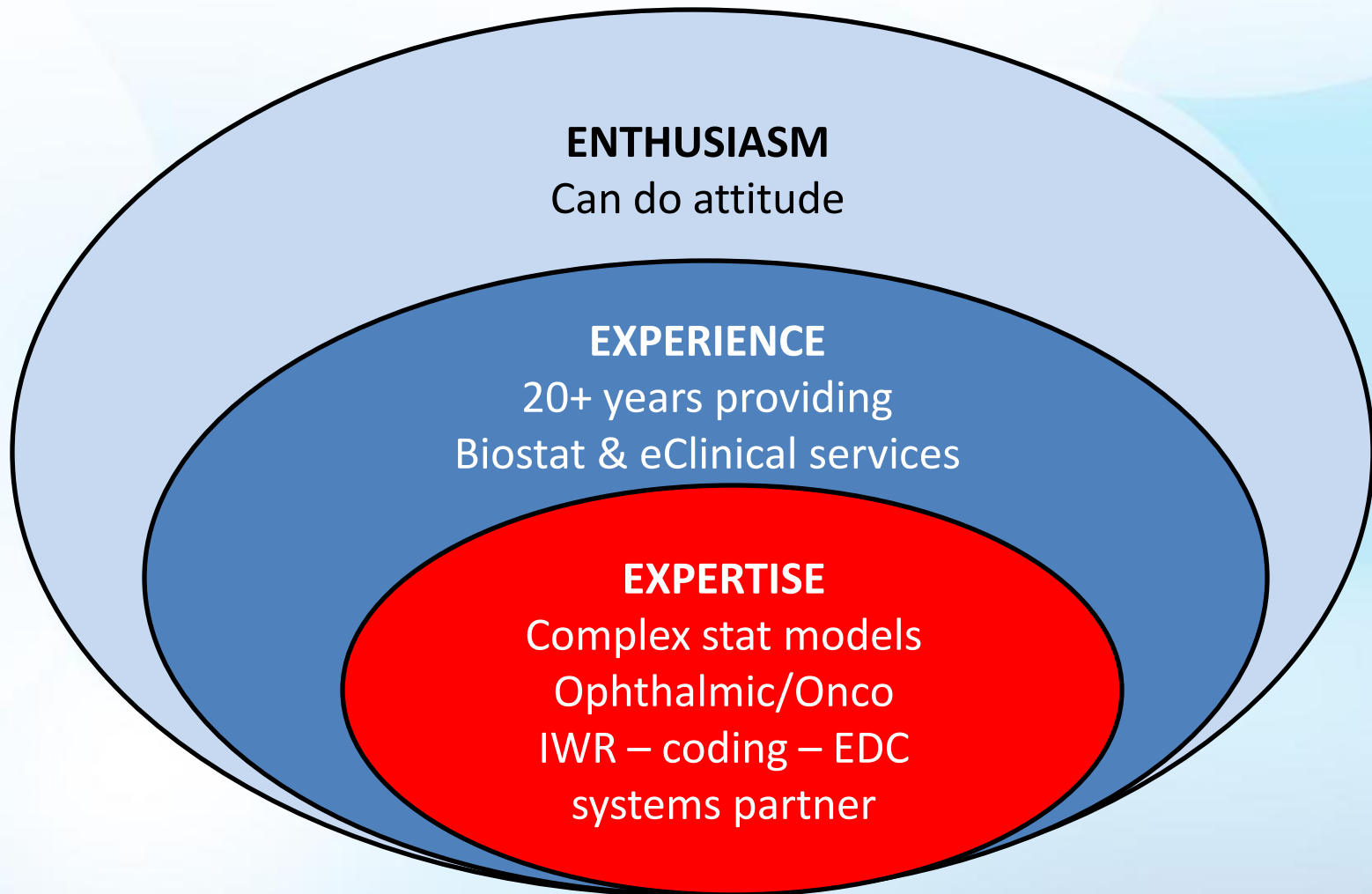


- Institute true partnership

# Working partnership?

- |  |  |
|--|--|
| <ul style="list-style-type: none"><li>• When it works</li></ul>  | <ul style="list-style-type: none"><li>• When it is not working</li></ul>   |
| <ul style="list-style-type: none"><li>• Strong communication</li><li>• Mutual respect &amp; trust</li><li>• Better anticipation of needs</li><li>• Two-way sharing of knowledge and expertise</li><li>• Handle bumps in the road</li><li>• Job satisfaction</li><li>• It is “Us” as a team</li></ul> | <ul style="list-style-type: none"><li>• Lack of communication</li><li>• Contractor mentality</li><li>• Unable to anticipate needs</li><li>• No sharing</li><li>• Difficulties in solving issues</li><li>• Low job satisfaction</li><li>• No sense of “team”: it is “You” and “Me” not “Us”</li></ul> |

What to look out for:



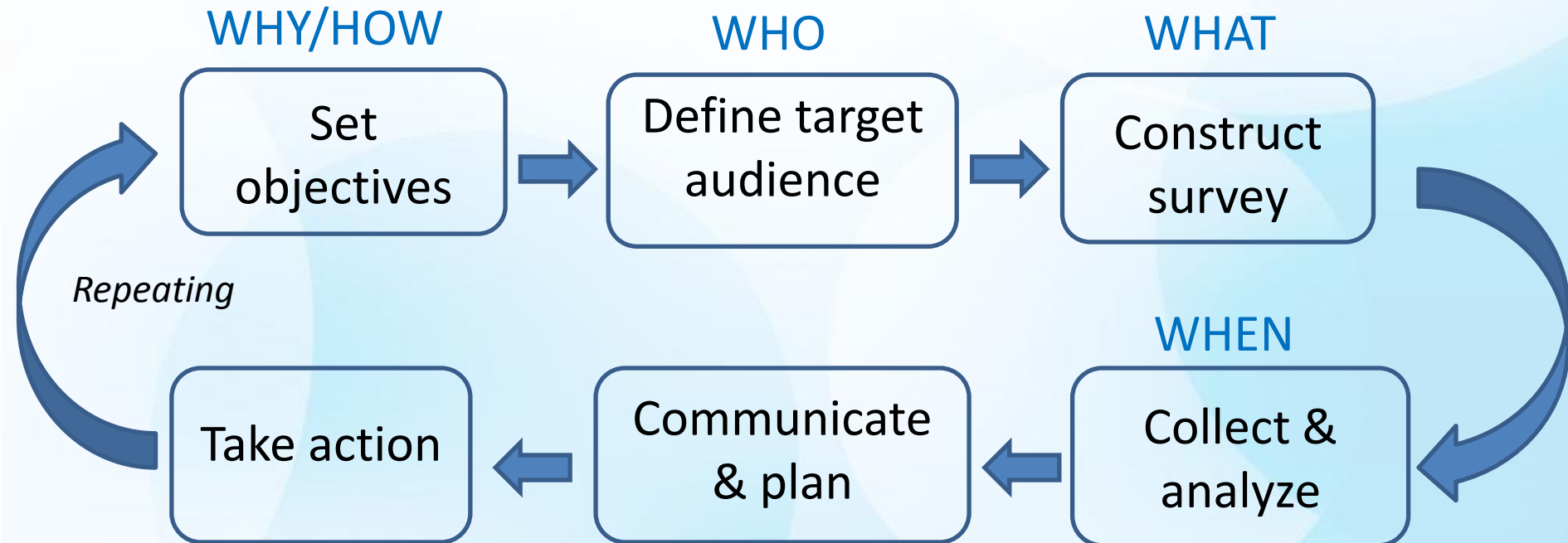


- Not only COSTS !
  - How long is the CRO in the business
  - Experience with similar/complex work
  - Scale-up capacities
  - Relationship with regulatory agencies
  - Well-trained teams
  - Project management
  - Financially stable
  - Retention/Turnover rate
  - Referrals
  - Prospective partner visit (F2F)
  - Realistic/honest CRO
  - Gut feeling counts

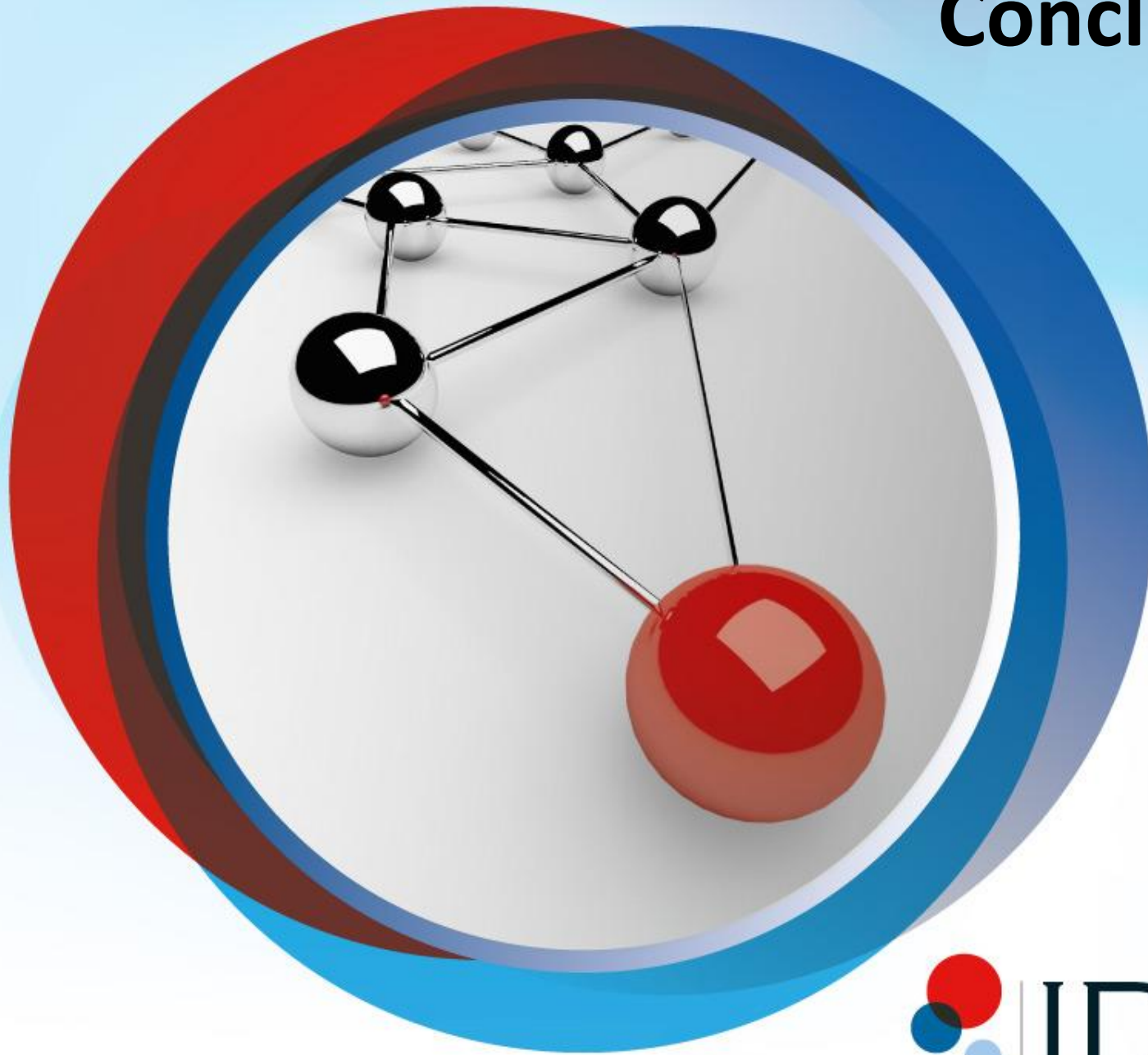
- KPI: Measuring CRO's performance
  - Query handling, query closing, listing generation, delay in drug distribution, ...
- Functional Summary Dashboard
  - Query metrics report, data processing status, edit checks frequency report, ...

- Review them!
  - Numbers
  - Formulas and assumptions
  - Are these relevant?
  - Worth the time spent?
- Power of metrics: both CRO & Sponsor
  - Striving for excellence
  - Show results

# Satisfaction Survey



# Conclusion



- High communication
- True partnership => shared objective
- Partner selection
- Metrics
- Satisfaction survey
- Do not underestimate the need of project management on both sides





**THANK YOU!**