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# Improving the odds of a successful contract research project – results from a sponsor-vendor collaboration

Working Group from the Institutional Council and the Faculty Advisory Council

## The Panel

- **William D. Marder**, PhD, IBM Watson Health, Winchester, MA, USA – Chair ISPOR Institutional Council
- **Ami R. Buikema**, MPH, Principal Consultant, VP, HEOR Optum, Eden Prairie MN USA, Incoming Chair ISPOR Institutional Council
- **David L. Van Brunt**, PhD, Senior Research Fellow and Head, HEOR Evidence and Analytics, Abbvie, North Chicago, IL USA; Past Chair ISPOR Institutional Council
- **Khalid M. Kamal**, MPharm, PhD, Professor, West Virginia University School of Pharmacy, Morgantown WV USA, Chair ISPOR Faculty Advisory Council

# Working Group Members

## Special thanks to:

Ingrid Cox, MD, MSc, Menzies Institute for Medical Research, Tasmania, Australia

Monica Frazer, PhD, Optum, Eden Prairie, MN USA

## Institutional Council Members:

Ami R. Buikema, MPH, Optum, Eden Prairie MN USA

Paulo Carita, DrPH, Sanofi, Chilly-Mazarin, France

Mark Lamotte, MD, IQVIA, Zaventem, Belgium

William D. Marder, PhD, IBM Watson Health, Winchester, MA, USA

James F. Murray, PhD, Eli Lilly and Company, Carmel, IN, USA

Julian Shepelev, MSc, Baxter HealthCare, London, UK

David L. Van Brunt, PhD, Abbvie, North Chicago, IL USA

Peter Wirth, RPh, RTI Health Solutions, Research Triangle Park, NC, USA

Patricia Wolfangel, Xcenda, Palm Harbor, FL, USA

## Faculty Advisory Council Chair

Khalid M. Kamal, MPharm, PhD, West Virginia University School of Pharmacy, Morgantown, WV USA

## ISPOR Staff

Richard J. Willke, PhD, Chief Science Officer

John Guerino, MHS, Manager, Scientific & Health Policy Initiatives

## The issue

- Each year industry funds thousands of research projects. Most run smoothly but problems do arise. This panel will identify a set of common problems and strategies to either prevent them or minimize their impact.
- In 2020, the ISPOR Institutional Council (IC) undertook a study to help improve sponsor-vendor interactions.
  - Literature Review
  - A qualitative survey of IC members was analyzed and used to design a quantitative survey questionnaire
  - The questionnaire was completed by 158 ISPOR members who were either sponsors or vendors involved in contract research
  - Five areas of concern were identified
- A working group and then the full IC identified project management strategies that could minimize the potential impact of each of these issues.
- White Paper will be posted on the Institutional Council on the ISPOR website.

SECTION

1

# Literature Review

## Literature Review

- The goal of the literature review was to identify the main challenges that are experienced in sponsor-vendor relationships.
- The results were utilized to inform the development of a qualitative survey for both sponsors and vendors.

## Literature Search Strategy

Databases: Medline, Embase, Scopus



Selected Key Search Terms: Vendor, Contractor, Sponsor, Outsourcing, contract research organization

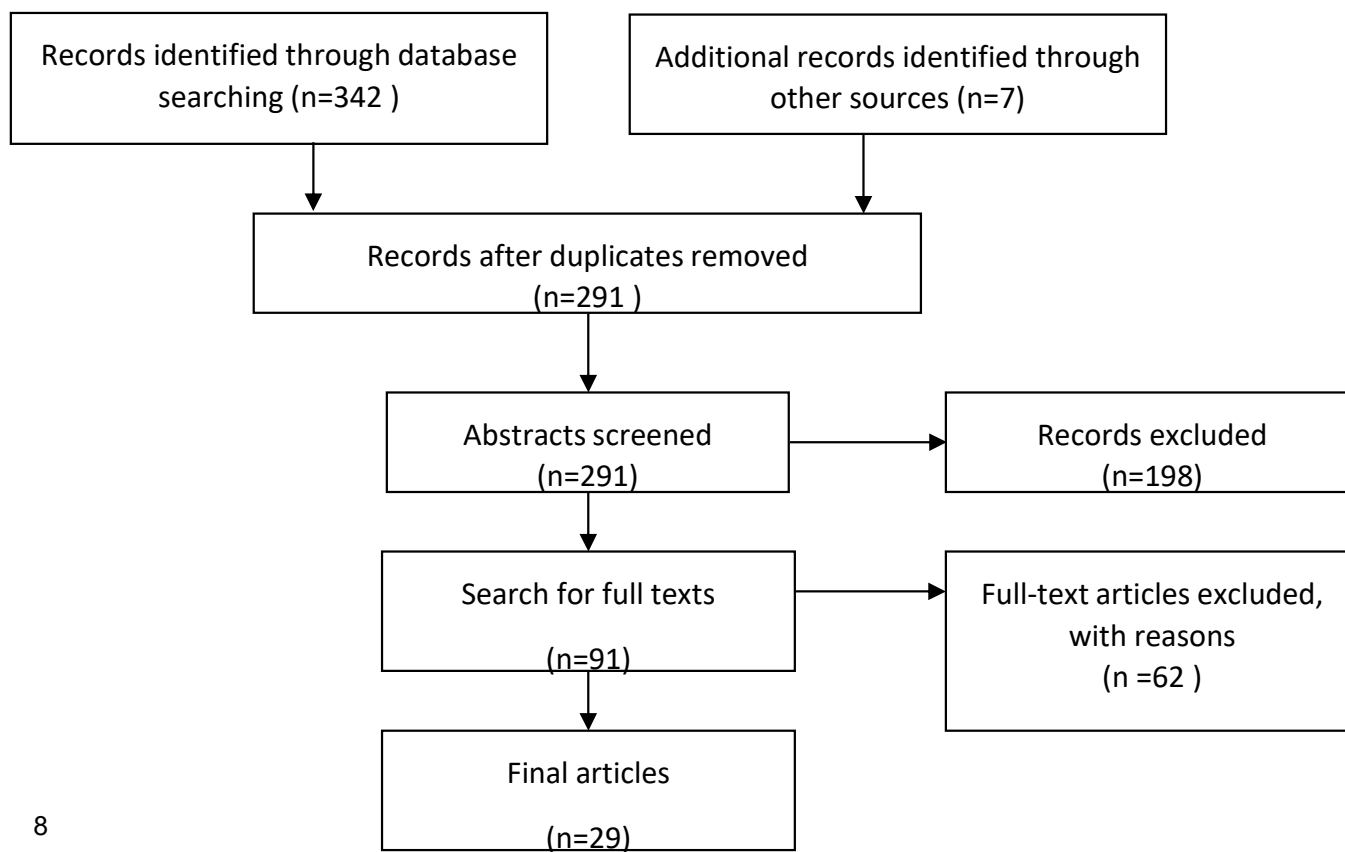


All articles up to July 15, 2020; English



Letters, editorials, news articles or expert opinions were excluded

# Literature Search Results

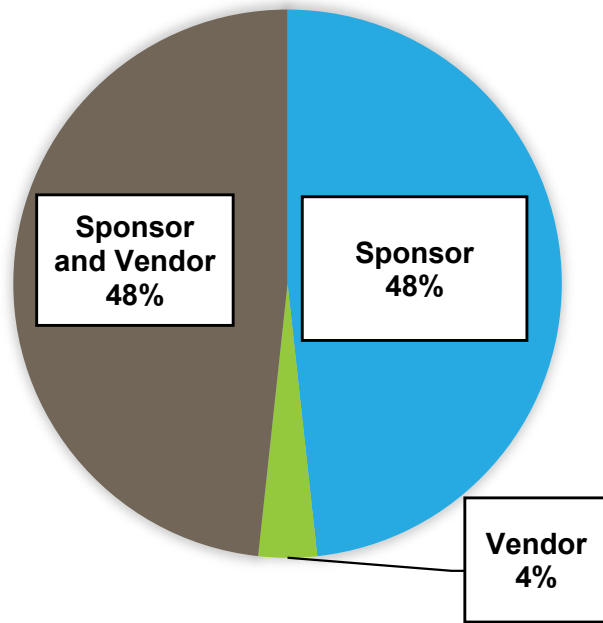


## Databases

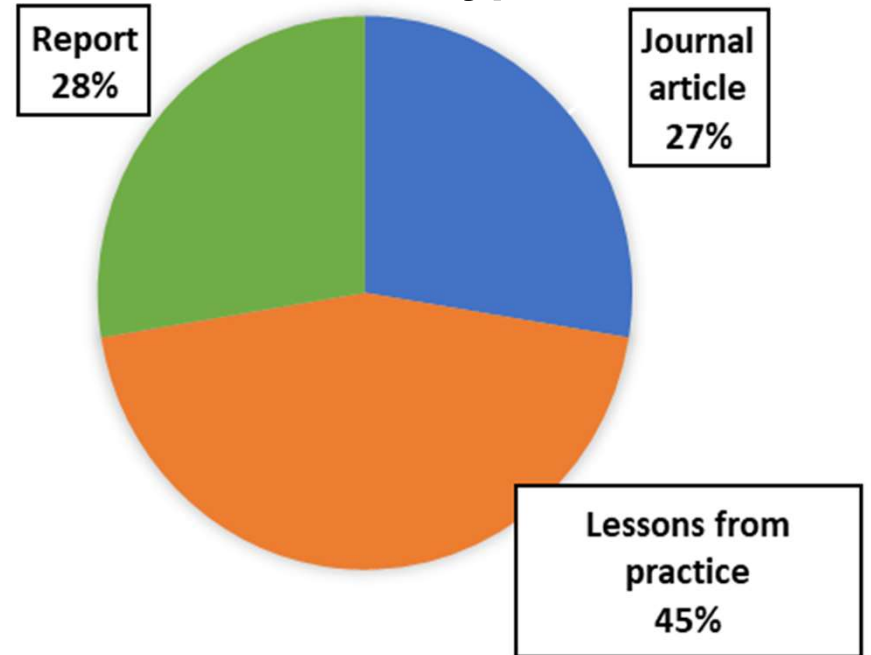
- Medline (58 articles)
- Embase (205 articles)
- Scopus (79 articles)

# Distribution of Articles

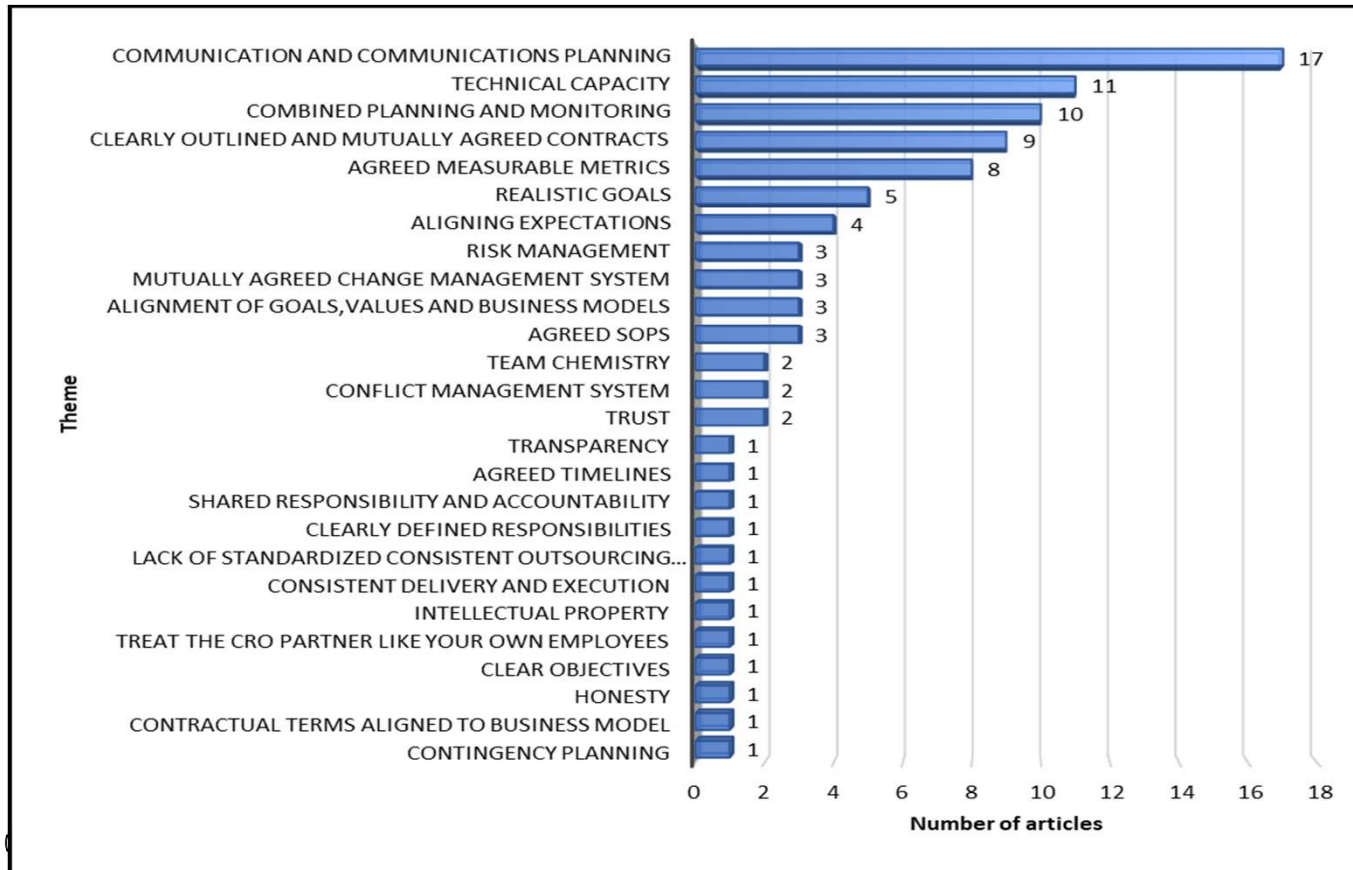
**Perspective**



**Article Type**



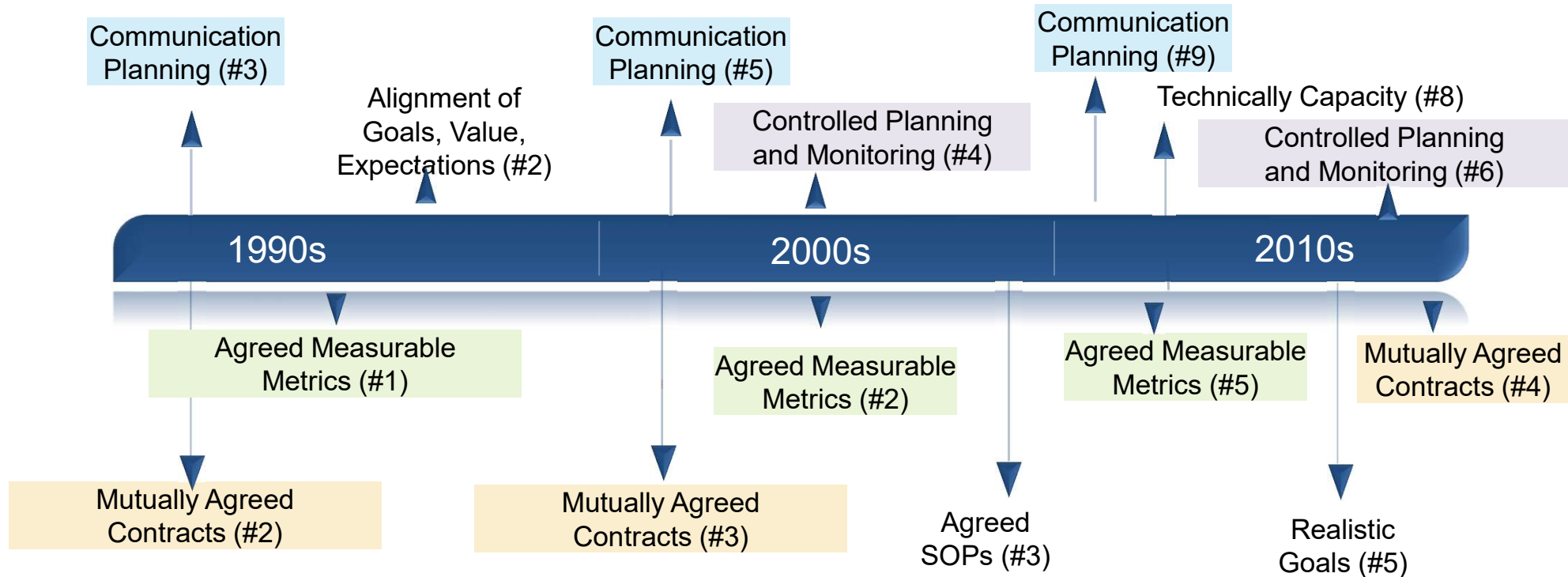
# Factors Influencing Vendor-Sponsor Relationship



## Major factors affecting Sponsor-Vendor Relationships

- Communication Planning (59%)
- Technical Capacity (38%)
- Combined Planning and Monitoring (34%)
- Clearly Outlined and Mutually Agreed Contracts (31%)

# Trends in Factors Since 1990s



## Literature Summary

- There has been a shift from tactical relationship such as “fee-for-service” to more strategic partnership.
- Most of these perspectives were from the sponsor’s point of view.
- Communication and technical capacity were highlighted as important components in the relationship between sponsor and vendor.
- Although the influential factors have varied by level of importance over the past decades, communication planning and measurable metrics remained relevant throughout.
- The evolving nature of contracts models over the years have provided the opportunity for vendors to have an opinion in improving relationships between the two entities.

SECTION

# 2

## Survey Methods and Results



## Qualitative Survey

Sequential exploratory design (Andrew & Halcomb, 2009, p. 40) used to inform creation of a quantitative survey instrument.

Asked all Institutional Council Members – well balanced between sponsors and vendors – a series of open-ended questions:

1. What are the key elements in establishing a relationship with a sponsor/vendor?
2. What factors are important to help a project collaboration succeed?
3. What factors can make a project collaboration fail?
4. What should the sponsor/vendor do that they often don't do during a project collaboration?
5. What insights can you offer that you feel are important to maintaining a long-term relationship with a sponsor/vendor?

## Qualitative Survey Response

- 34 questionnaire invitations sent
- 18 responses (53%); vendor = 8, sponsor = 7, both = 3
- Results were organized into 3 broad categories
  - Communication
  - Expectations
  - Organizational Culture
- Coded comments were assigned to subcategories (nodes) within each broad category
- 188 total comments were coded, some to >1 node

Coding is not just labeling, it is *linking*: “it leads you from the data to the idea, and from the idea to all the data pertaining to that idea (Richards & Morse, 2007, p. 137).

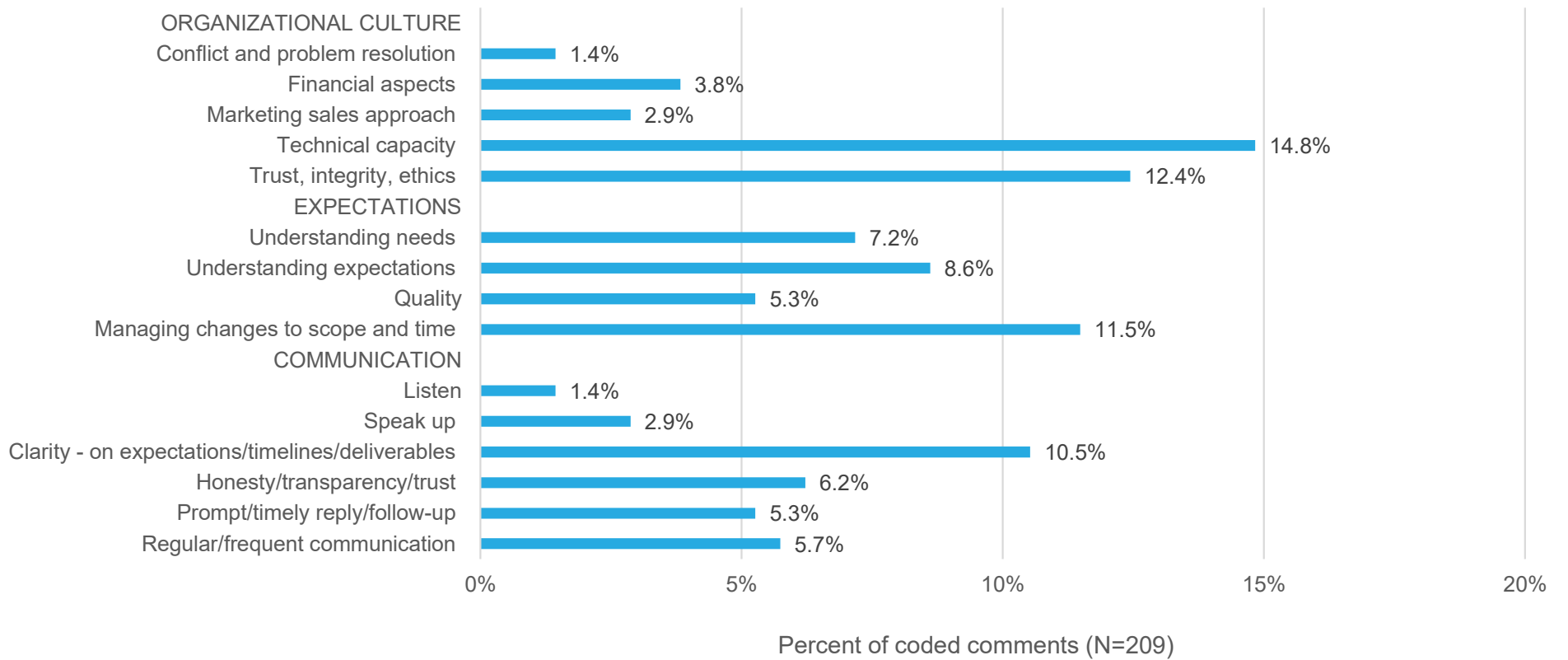
## What is a 'Node'

- “A word or short phrase that symbolically assigns a summative, salient, essence-capturing, and/or evocative attribute for the portion of language-based or visual data...” (Saldaña, 2013, p.3)
- “A researcher-generated construct that symbolizes and thus attributes interpreted meaning to each individual datum for later purposes of pattern detection, categorization, theory building, and other analytic processes.” (Saldaña, 2013, p. 4)
- “Assigning groups of words or ‘quotes’ into buckets that group similar ideas.” (Monica Frazer)

## Qualitative Survey Analysis

- Coding was conducted using an open coding process (Strauss & Corbin, 1990) by two researchers.
  - Initial coding on 20% of the text
  - Discussion and reconciliation of node definitions
  - Final coding on 100% of text
  - Discussion and reconciliation of discrepancies
  - 100% agreement between researchers
- NVivo software versions 11 and 12 were used.

# Comments Coded by Node



## Communication Comments

### Regular/frequent communication & prompt/timely follow-up (23 responses)

“Strong two-way communication.”

“Regular communication.”

“Proactively conveying timelines and progress.”

“Prompt response to emails and phone calls, even just to acknowledge the communication and that vendor will follow-up and providing time frame for that next communication.”

“The sponsor is respectful of the vendor's time - doesn't go silent for weeks on end when vendor is looking for answers to keep the project moving forward.”

## **Communication Comments**

### **Honesty/transparency/trust (13 responses)**

“Trust, commitment, good understanding of the sponsor unmet needs.”

“It takes quite a while to establish a trusted relationship to the point where a sponsor will share with me the most important factors to their decision-making so I can incorporate that into the solutions I propose.”

“Be upfront about the limitations and the available steps for mitigation.”

“Lack of transparency on both sides, overpromising on the part of the vendor.”

## Expectation Comments

### Managing changes to scope and time & financial aspects (32 responses)

“During a project there are always scope issues. Sometimes they have a very big impact on the time needed and as such on the budget. It takes willingness from the vendor to accept some scope changes within the agreed budget. But it also takes willingness of the sponsor to discuss budget changes.”

“Sponsor continually changes the research questions during the conduct of the study... requests additional looks at the data or posing additional questions to study subjects that do not support the original study's research and business objectives.”

“Unexpected expenses and/or charges outside of agreed budget.”

“Nickel-and-diming”

## **Expectation Comments**

### **Quality (11 responses)**

“Delivering high quality deliverables that are accurate and on time.”

“Quality checking deliverables and aligning with client needs/expectations.”

“Issues with the quality of work and deliverables. Lack of vendors QC processes.”

“Insufficient subject matter expertise... Very small team - one person doing all the work or limited quality checks.”

## Organizational Culture Comments

### Trust, integrity, ethics (26 responses)

“Trust, confidence in the vendor's ability to deliver on promises. Vendor demonstrates they are truly working on behalf of the sponsor. Vendor is open about possible conflicts of interest.”

"Honest communication about issues on the sponsor side, willingness to admit mistakes."

"Inexperience, lack of clarity about their own organizational priorities, inability to advocate for their project to internal stakeholders, lack of research ethics, stressful/unsupportive organizational culture on the sponsor side."

"Lack of transparency on both sides, overpromising on the part of the vendor, poor or inconsistent communication, inability of the sponsor to make definitive decisions or clearly present expectations."

"Don't treat the vendor like a servant or graduate assistant. Treat them with respect as you would a colleague/partner."

# Organizational Culture Comments

## Technical capacity (31 responses)

“Experienced research [leadership] on the sponsor side is critical. The sponsor lead needs to be able to have a good understanding of their own organizations processes, goals and objectives, how the research project will meet those objectives, and how to manage all of the internal stakeholders -- when to shift the project to meet changing priorities, and when to push back and stay on track.”

“Creative/strategic thinking on the part of the vendor, thorough and high-quality work on the part of the vendor, and appreciation of the complexity of the analysis and the time required on the part of the sponsor.”

“Keeping the same or mainly the same study team for all the studies related to the same therapeutic area or, if possible, the same sponsor. You are learning about our processes and procedures; we don't want to lose that institutional knowledge and train someone new if it can be avoided.”

## Quantitative Survey

- Developed leveraging the results of the literature review and qualitative analysis (sequential exploratory design)
- Sent to all ISPOR members whose sector of employment was industry, CRO, or academic (not students) in the autumn of 2020
  - 4,496 ISPOR members were invited to participate
  - 158 responded (3.5%; ~5% is typical for ISPOR)
- 15 dimensions were probed within 3 broad categories:
  - communication (4 items)
  - expectations (4 items)
  - organizational culture (7 items)
- Respondents were asked to
  - Rate the importance of each dimension
  - Identify the frequency of problems in each dimension
- Results were tabulated separately for respondents who self-identified as sponsors and as vendors; among vendors, results were stratified by vendor type

## Demographics by Role

	Sponsor (N=71)	Vendor (N=87)	Total (N=158)
<b>Sex/Gender (%)</b>			
Male	44%	51%	47%
Female	49%	41%	45%
Unknown	7%	8%	8%
<b>Region (%)</b>			
Africa	8%	2%	5%
Asia	25%	23%	24%
Europe	49%	54%	52%
Middle East	11%	6%	8%
North America	55%	62%	59%
Oceania	8%	2%	5%
<b>Years of HEOR experience</b>			
Mean	13.3	18.7	16.3
Median	10	20	15
<b>Number of HEOR projects per year</b>			
Average	9.8	18.8	14.8
Median	5.5	10	10

- 158 respondents
  - 71 sponsors
  - 87 vendors
  
- 16.3 years HEOR experience (mean)
  - 13.3 sponsors
  - 18.7 vendors
  
- 14.8 projects/year (mean)
  - 9.8 sponsors
  - 18.8 vendors

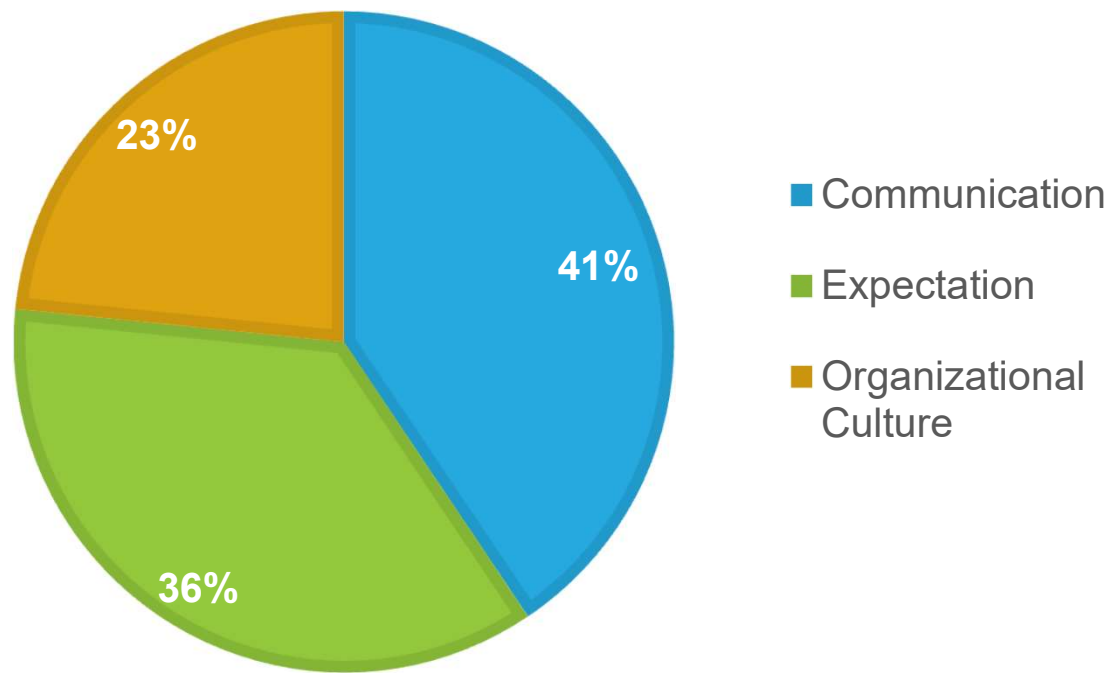
## Demographics by Vendor Type

	Academia (N=21)	CRO (N=42)	Independent Contractor (N=19)
<b>Sex/Gender (%)</b>			
Male	71%	43%	58%
Female	29%	55%	37%
Unknown		2%	5%
<b>Years of HEOR experience</b>			
Mean	22.7	17.4	17.6
Median	25	17	18
<b>Number of HEOR projects per year</b>			
Average	6.7	23.5	12.5
Median	5	15	7

\* 5 vendor respondents with unknown vendor type not included

- 87 vendor respondents
  - 21 academics
  - 42 CRO
  - 19 independent contractors
  - 5 unknown vendor type\*
- 18.7 years HEOR experience (mean)
  - 22.7 academia
  - 17.4 CRO
  - 17.6 independent contractors
- 18.8 projects/year (mean)
  - 6.7 academia
  - 23.5 CRO
  - 12.5 independent contractors

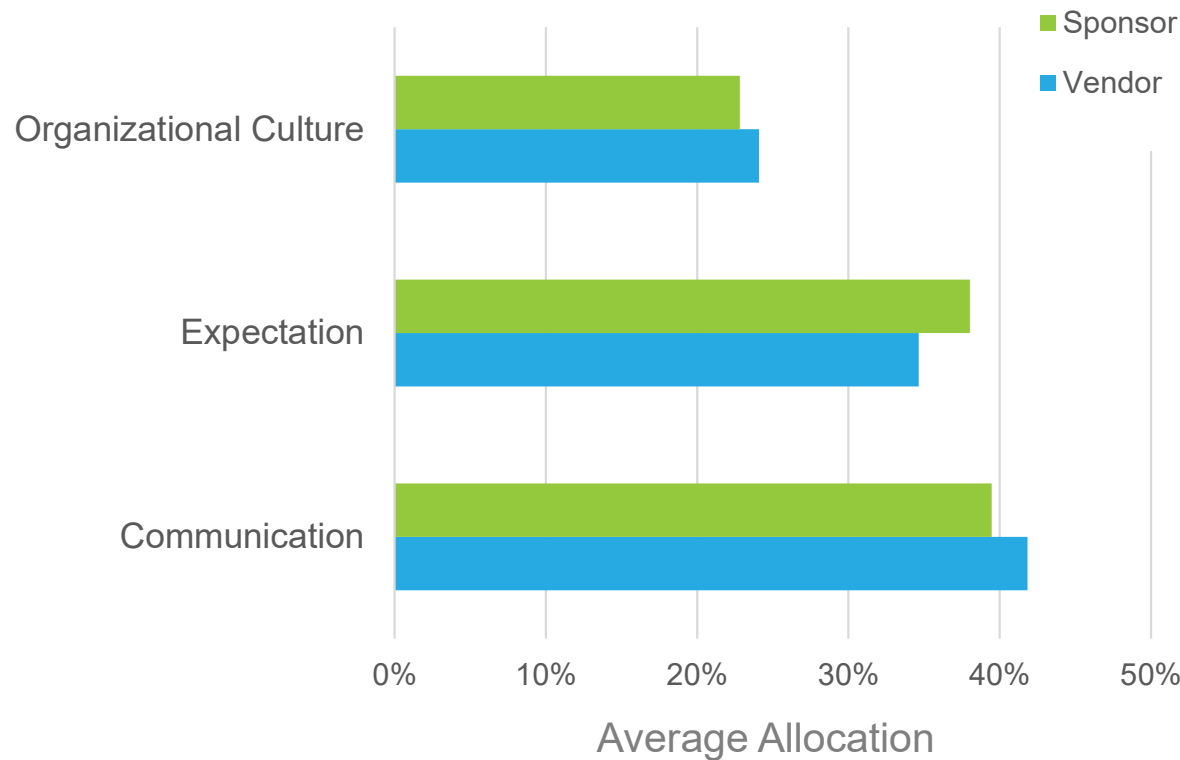
## Relative Importance of Broad Response Categories



Respondents were asked to allocate 100% between three broad categories in terms of the importance for completion of a successful project

- Communication was rated as most important by both sponsors and vendors, followed closely by expectations.
- Organizational culture was less important.

# Importance of Broad Response Categories by Role



Sponsors rated expectations as slightly more important than did vendors

Vendors rated communication as slightly more important than did sponsors

# Importance of Dimensions by Role



The most important dimensions for sponsors and vendors combined included “clarity on overall goals and execution”, honesty/transparency on both sides”, “achieving expected quality”, “integrity, ethics” and “trusting relationships”

Biggest differences were observed for “financial aspects”, “managing changes to scope and time”, and “conflict and problem resolution”

# Frequency of Problems by Role



The most frequent problem for both sponsors and vendors was “managing changes to time and scope”

The largest difference was in “achieving the quality expected for the project” (more frequent for sponsors, less frequent for vendors)

## Conclusions

- Several common and important themes around vendor / sponsor relationships emerged including setting expectations, effective communications and operational excellence.
- Qualitative research allowed for the capture of a variety of important aspects of vendor / sponsor relationships to inform the design of a subsequent quantitative survey.
- Because of the qualitative research, we have more confidence that we were able to capture the most important aspects of vendor / sponsor relationships in the quantitative survey to better inform best-practice recommendations.

SECTION

3

Recommendations

## Areas of focus that lead to better outcomes

- Establishing a **strong foundation** at the start
- Scope and timeline management
- Proactive communication
- Quality assurance
- Governance

## Establishing a strong foundation at the start

“Give me six hours to chop down a tree and I will spend the first four sharpening the axe.”

*-apocryphal, often attributed to Lincoln*



## Sample Kickoff Agenda

### Share prior to meeting with all attendees (who does it):

- The Statement of Work/Contract/ Research Agreement (Pharma) highlighting the assumptions regarding deliverables and budget
- The preliminary execution plan including a detailed timeline (Provider)
- Relevant policies and procedures that apply to this work (Both)
- Draft RACI or DAI for this project (Both)

### To be discussed and decided at this meeting:

- Modifications to the objectives, deliverables, budget or timetable and implications to scope
- Changes to the RACI (Responsible, Accountable, Consulted and Informed) or DAI (Decision-maker, Accountable, Informed) for both partners and how these stakeholders will be integrated to status meetings, project closure, etc.
- Finalize status, meeting cadence, format, length of time and agenda meeting below) format (see example in status Who prepares and schedules them?
- Finalize plans for output or disclosures.
- How often do the project strategy and goals need to be examined? (suggested monthly or as changes occur)
- What platform will be utilized for information Management (Shared files)
- What might we expect to be some of the key challenges to project success? How can the team prepare for them?
- Will a post-completion project review be scheduled to examine key learnings?
- Are there any post-completion read outs that should be considered? With whom? (eg senior leadership, brand teams etc.) If the supplier is to be a part of them, is this billable work? If so, are these fees included in current scope?

### Next Steps, Timing, Responsible Parties

## Proactive communication

- Declare primary points of contact for day-to-day communication
- There should be an involvement of a senior member of each team for key and quick decision-making
  - Build in timelines for sponsor and vendor internal review
- Keep written Minutes of all substantive discussions and action points
  - on shared platform, with time for review and follow up
  - Consider rolling minutes where all are in the same document (like a patient chart)
  - Key action and decision-making items must be communicated and documented in writing in a timely fashion, ideally 24-48 hrs post meeting.

## Quality assurance

- Both sides should be transparent about QC processes.
  - These may be triggered by a formal submission of a deliverable.
- When possible, vendor should share draft materials for a preliminary review so that informal discussion and remediation can move the project along more quickly.
- At the end of the project there should be an overall project review and assessment.
  - Both project leaders should describe what worked well and what could be improved. This too should be documented in a form that could be shared internally and with other key stakeholders.
  - If there are important lessons learned they should be communicated as appropriate through both organizations

## Governance

- **Organizations** make commitments to complete a scope of work- not just individuals.
- Turnover in project teams and leadership positions on either side can be a serious and unexpected challenge for both sponsors and vendors.
- Timely communication and candid discussion of potential risks can mitigate the impact of change.
  - Leaders from vendors and sponsors should communicate their organizational structure and who has responsibility should they have to change roles.

## A deliberate strong start, with plans and accountability, leads to a strong finish

- Establishing a **strong foundation**:
- Scope and timeline management
- Proactive communication
- Quality assurance
- Governance



SECTION

4

Discussion

