

Round Table Discussion: Shared Views and Perspectives on Outsourcing

IQ Drug Metabolism Leadership Group

Pharmaceutical Industry Benchmarking

CPSA Shanghai, April 17th, 2018



INTERNATIONAL CONSORTIUM *for*
INNOVATION & QUALITY
in PHARMACEUTICAL DEVELOPMENT
www.iqconsortium.org

IQ: Collaboration to Bring Better Drugs to Patients Faster

“As I survey the issues facing the world of biomedical innovation, it is clear that no single organization... can muster all of the knowledge, talent, creativity, and resources required to decipher our continuously expanding knowledge... I cannot agree more ... about the need for creating a common precompetitive space in biomedical research that should facilitate intelligent, effective, and safe innovation for all.” - Elias Zerhouni

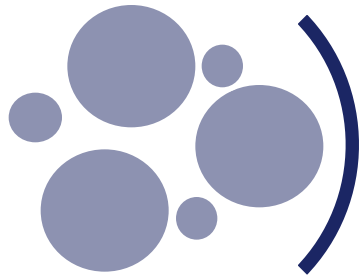
Source: Peer-to-peer sharing spurs scientific innovation. Sci Transl. Med. 1. 9ed (2009)



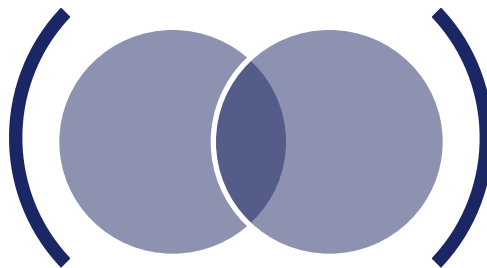
IQ: A Sustainable Platform for Collaboration

IQ provides a sustained platform for information exchange, benchmarking, data sharing, and other joint initiatives.

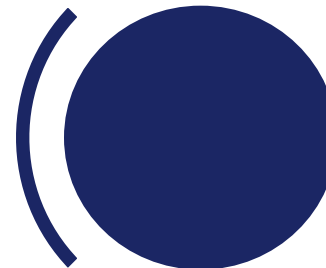
The Consortium proactively communicates with other stakeholders through publications, scientific conferences and workshops, and regulatory interactions.



**Increase resources available
to member companies**



**Facilitate pre-competitive
collaborations among
member companies**



**Proactively build consensus
with regulators and other
stakeholders**



Member Companies: Critical Mass for Collaboration

AbbVie • Agios • Alkermes • Allergan • Amgen • Astellas
• AstraZeneca • Baxter • Bayer • Biogen •
Blueprint Medicines • Boehringer Ingelheim •
Bristol-Myers Squibb • Celgene • Daiichi Sankyo • Eisai •
Eli Lilly • EMD Serono • Endo Pharmaceuticals •
Genentech • Gilead • GlaxoSmithKline • Incyte •
Ironwood • Johnson & Johnson • Merck • Novartis •
Otsuka • Pfizer • Pierre Fabre • Roche • sanofi • Seattle
Genetics • Shire • Sunovion • Takeda •
Teva • Theravance Biopharma • UCB • Vertex



Benchmarking Proposal

- Value proposition:
To enhance the impact of DMPK as a discipline by gaining a better understanding of the challenges and opportunities we all face.
- Topics:
 - Organizational structure
 - Internal vs external resources
 - Scientific gaps and opportunities
- Approach:
 - Short Survey to gather relevant, anonymous information

Contributors

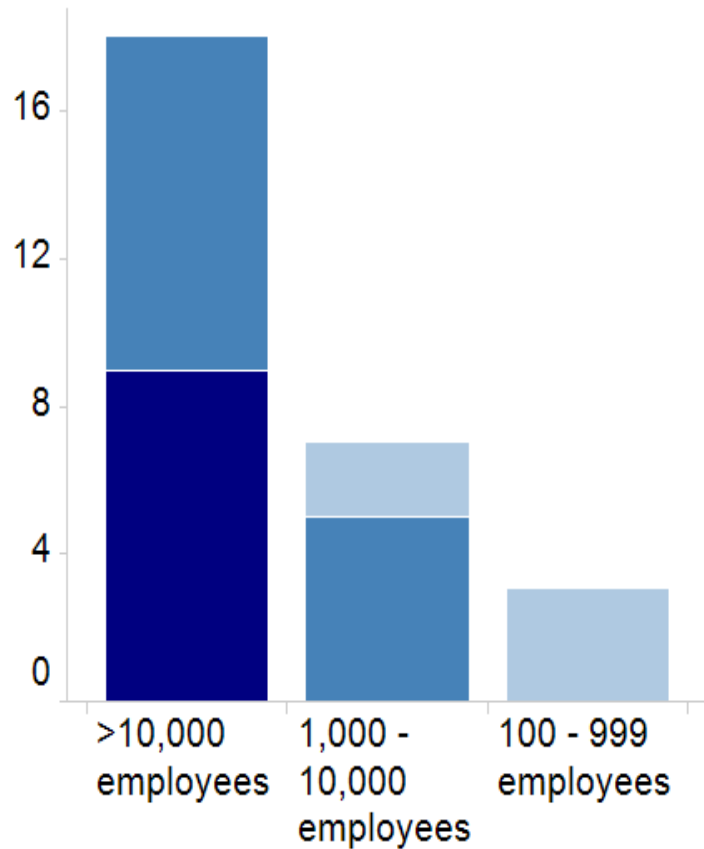
- Mira Hinman & Volker Fischer - **Abbvie**
- Francoise Berlioz - **Vertex**
- Bill Brian - **Sanofi**
- Radford Decker - **Sunovion**
- Marcel Hop - **Genentech**
- Lana Lyapustina - **DBR**
- Nancy Agrawal - **Merck**
- All DMLG members

DMLG Benchmarking Results 2017

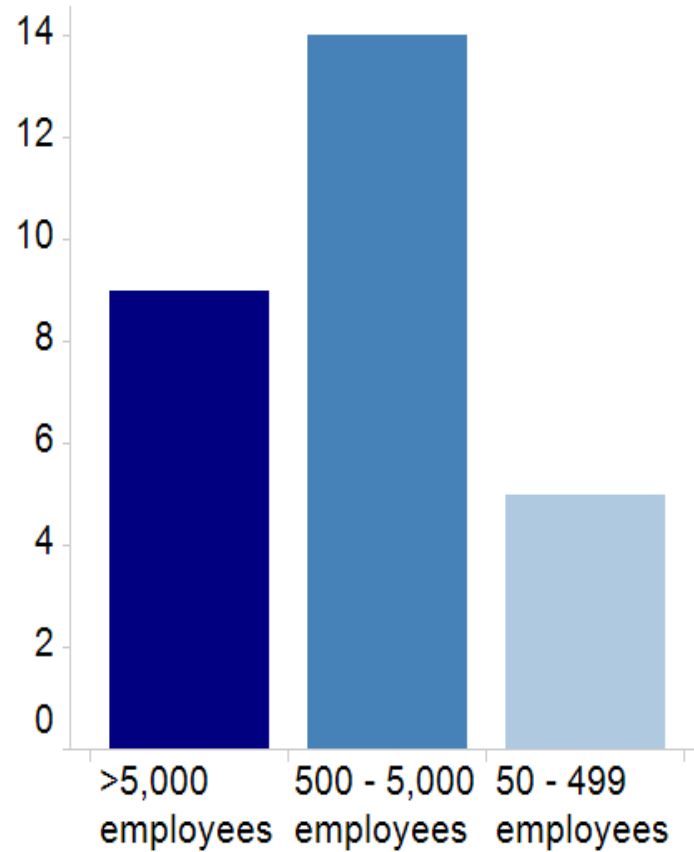
Total responses: 28

Basic Company Demographics

What Size is your Company?
Colored by R&D size



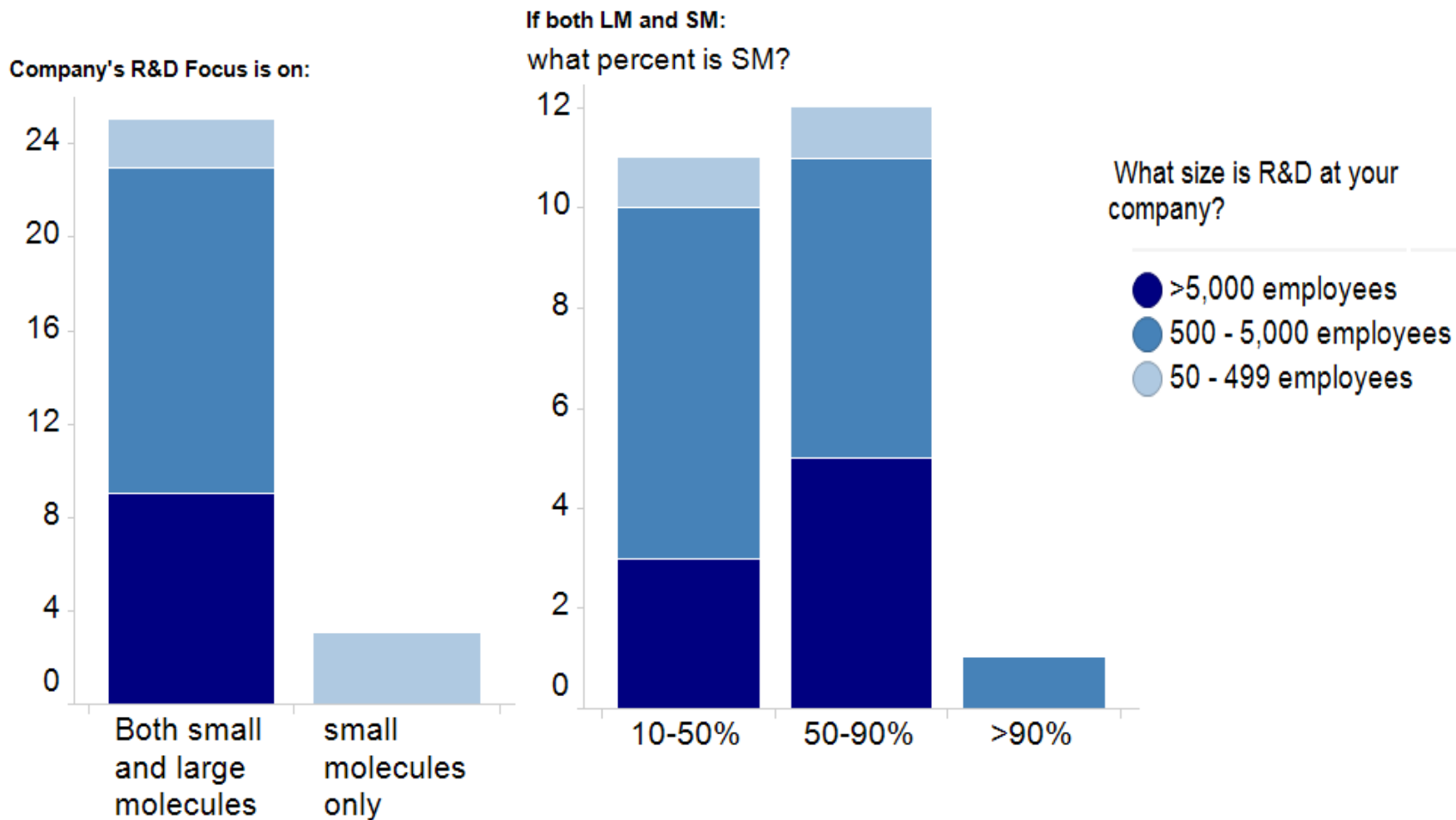
What Size is R&D?



What size is R&D at your company?

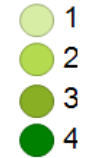
- >5,000 employees
- 500 - 5,000 employees
- 50 - 499 employees

Basic Company Demographics

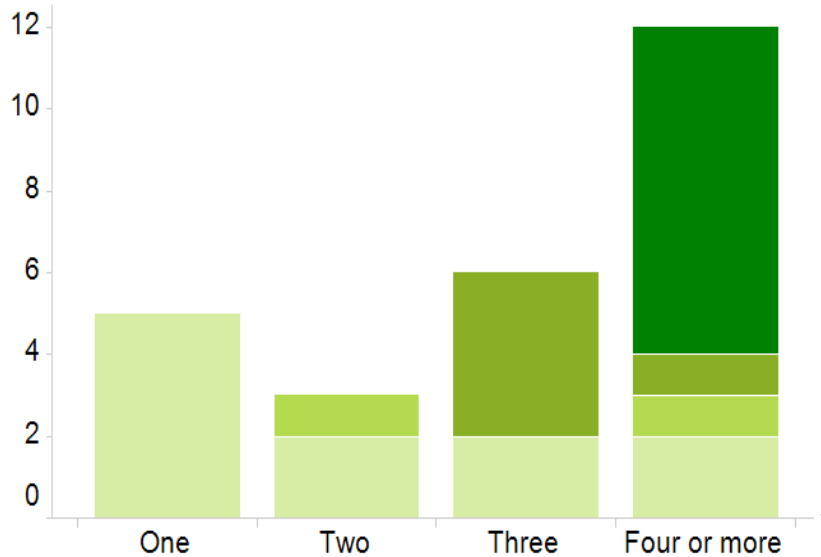


Basic Company Demographics

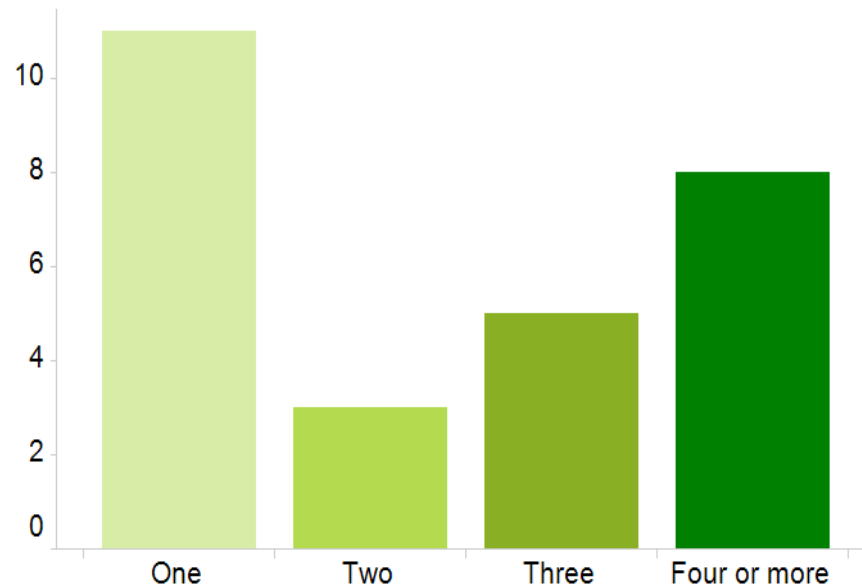
How Many R&D Locations With DMPK-BA?



How many R&D Locations for your company?
(Colored by the number of locations with DMPK)



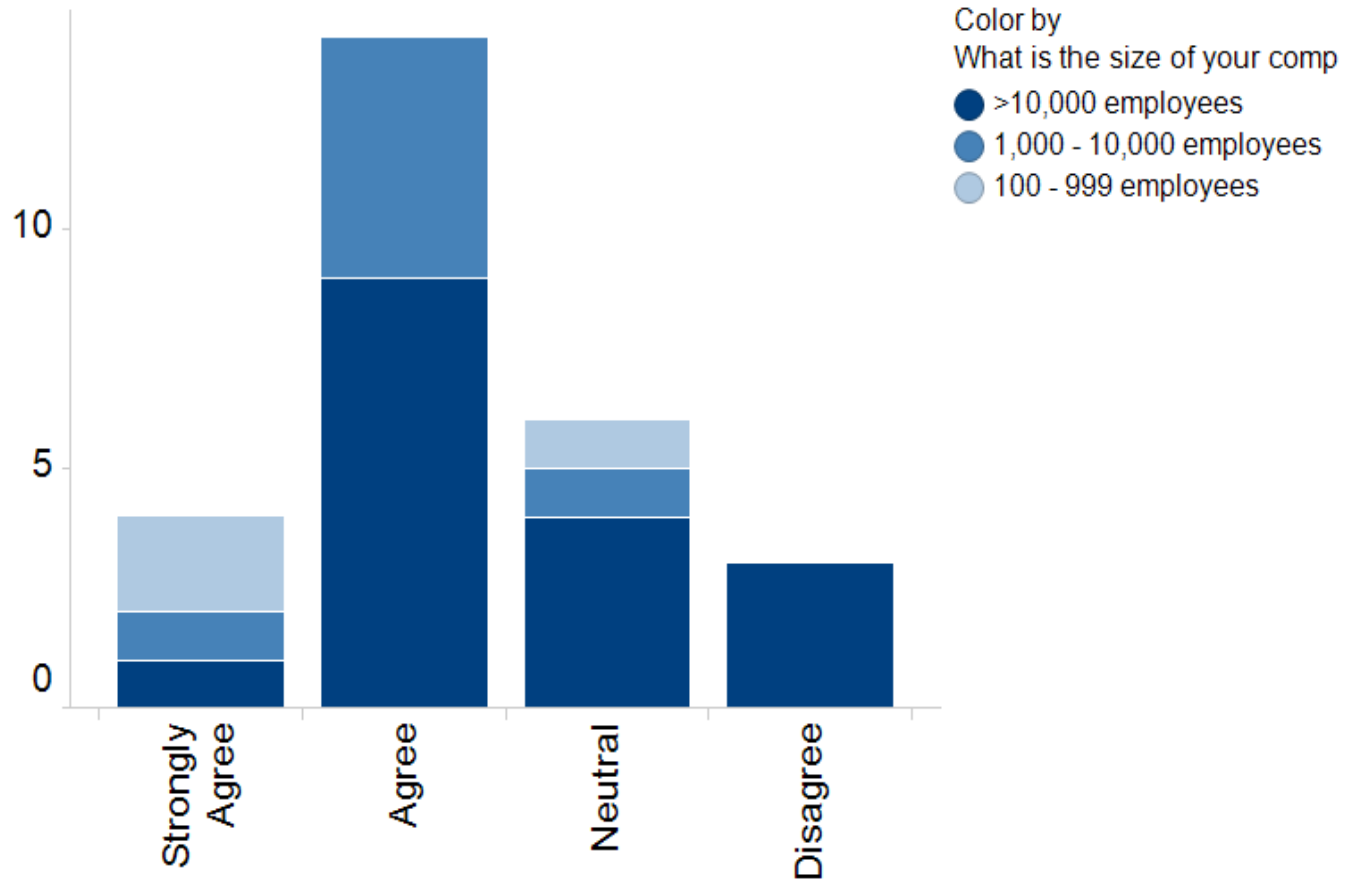
How many Locations with a DMPK presence?



Most Agree that Organizational Structure at their Company Facilitates Efficient Operation

Organization of DMPK-BA in my company facilitates efficient interaction

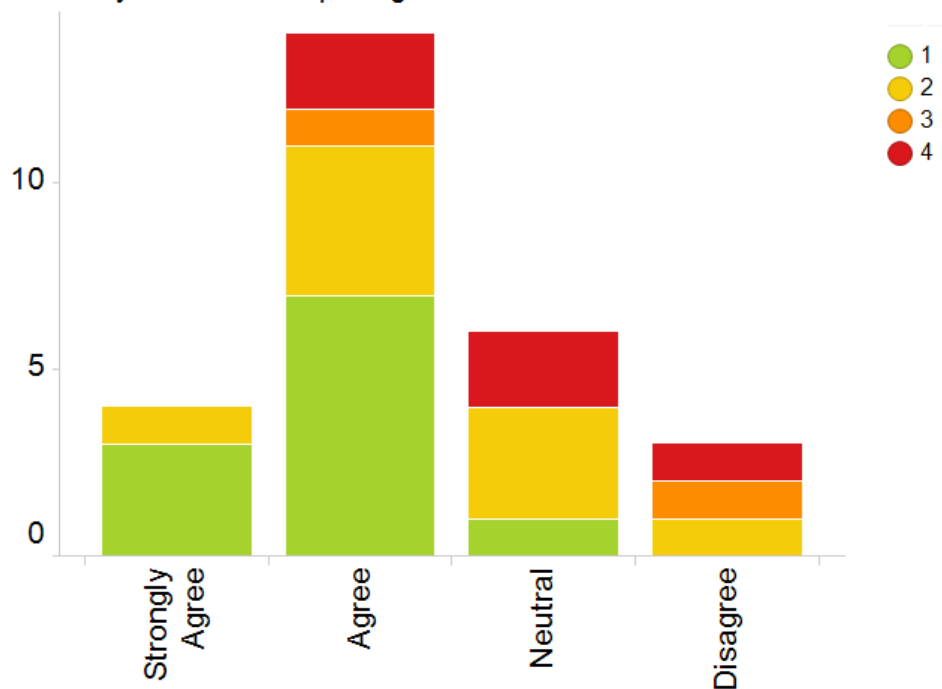
Colored by Size of Organization



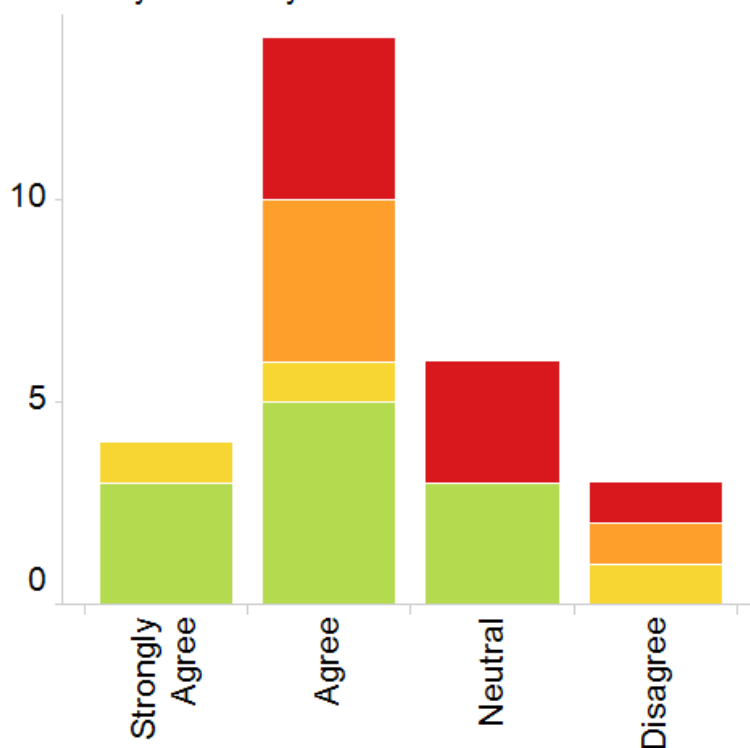
Fewer Reporting Lines, R&D Sites Correlated with Positive Interaction Assessment

Organization of DMPK-BA in my company facilitates efficient interaction

Colored by Number of Reporting Lines in DMPK-BA



Colored by how Many R&D Sites

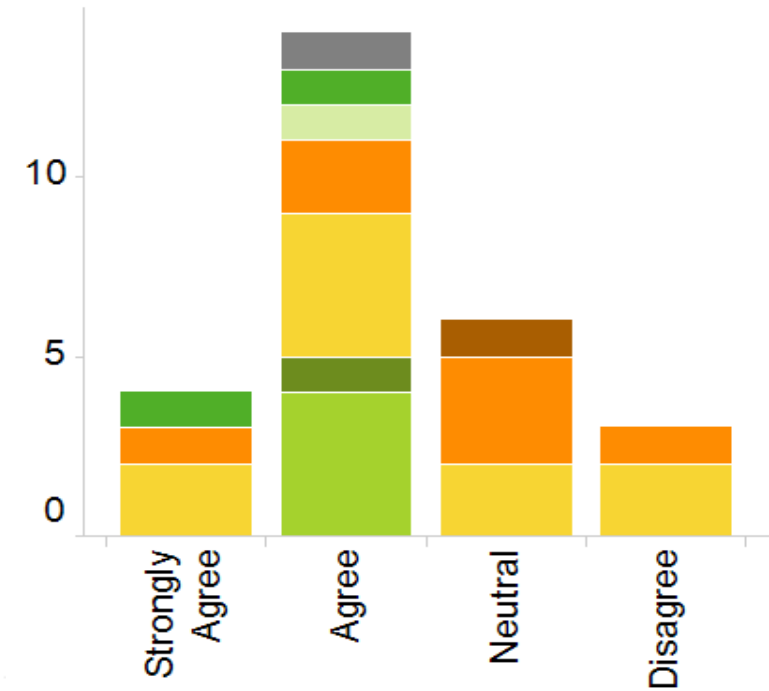


- DMPK Leaders at organizations with fewer reporting lines in DMPK-BA and fewer R&D sites agreed more strongly that their organizational structure facilitates efficient interaction.

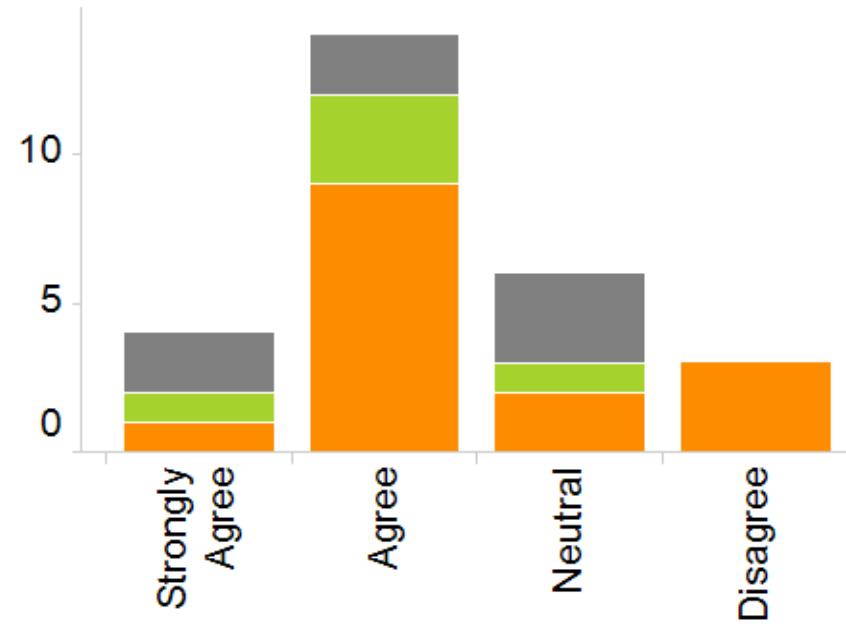
Reporting Structure and Centralization Do Not Correlate with Interaction Assessment

Organization of DMPK-BA in my company facilitates efficient interaction

Colored by Reporting Relationship of DMPK-BA



Centralization of DMPK-BA Activities.



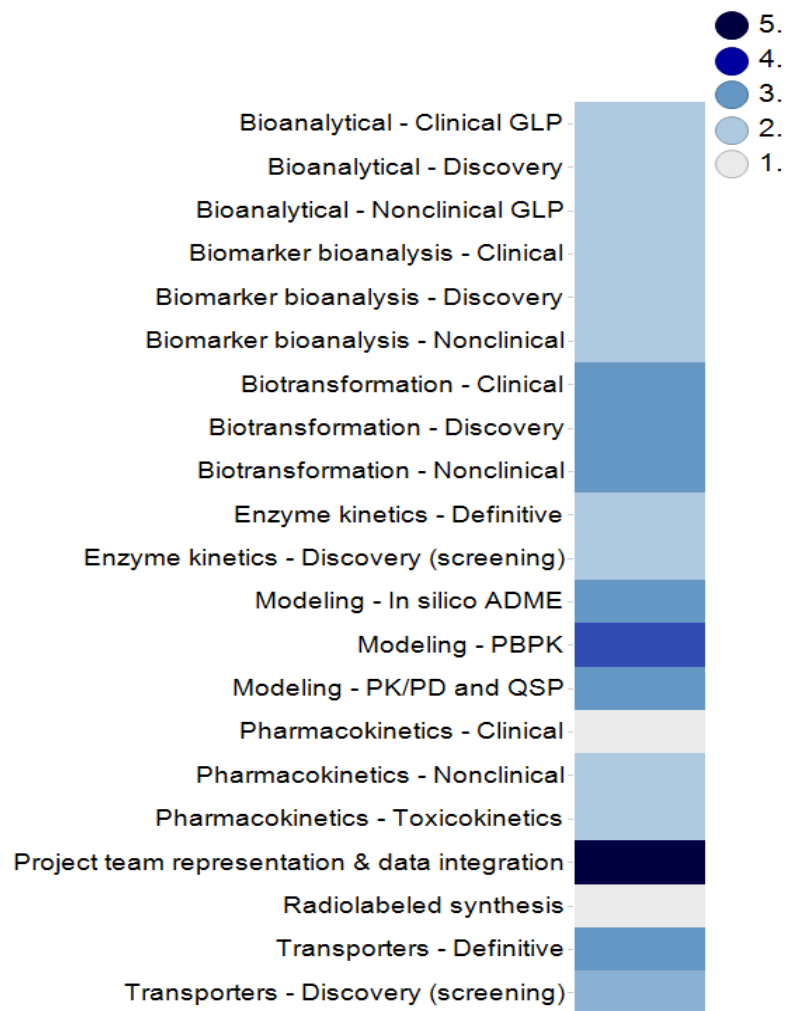
- Report into Development
- Report into Development and into Therapeutic Areas
- Report into Research
- Report into Research and into Development
- Report into Research and into Development and into Therapeutic Areas
- Report into Research and into Therapeutic Areas
- Report into Site Head
- (Empty)

- Activities are centralized
- Each site contains all or most activities
- (Empty)

Outsourcing

Project Representation is the most Difficult to Outsource

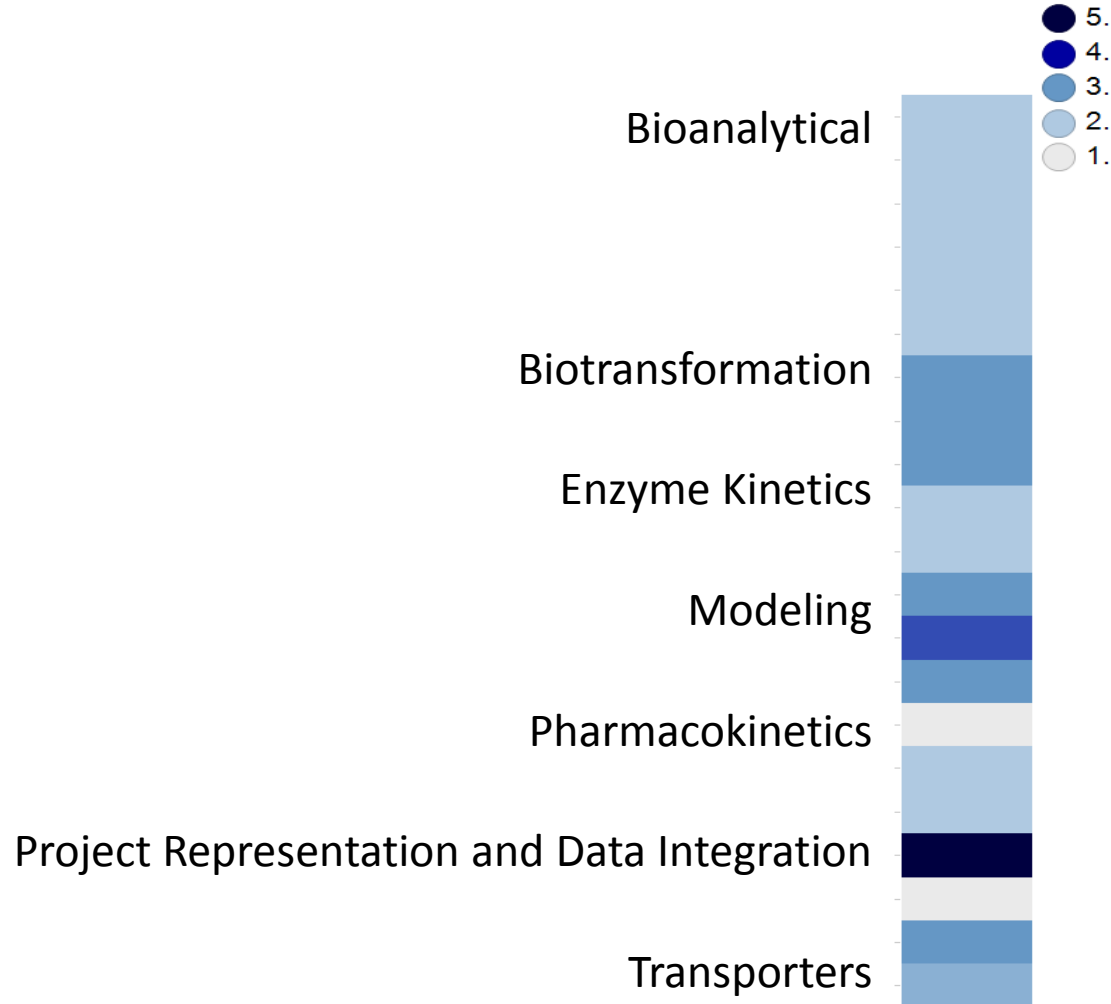
Rate the Difficulty** of Outsourcing on a scale of 1 to 5 (1 being easy and 5 being very difficult)



** based on availability of CROs, their expertise, supervision required

Project Representation is the most Difficult to Outsource

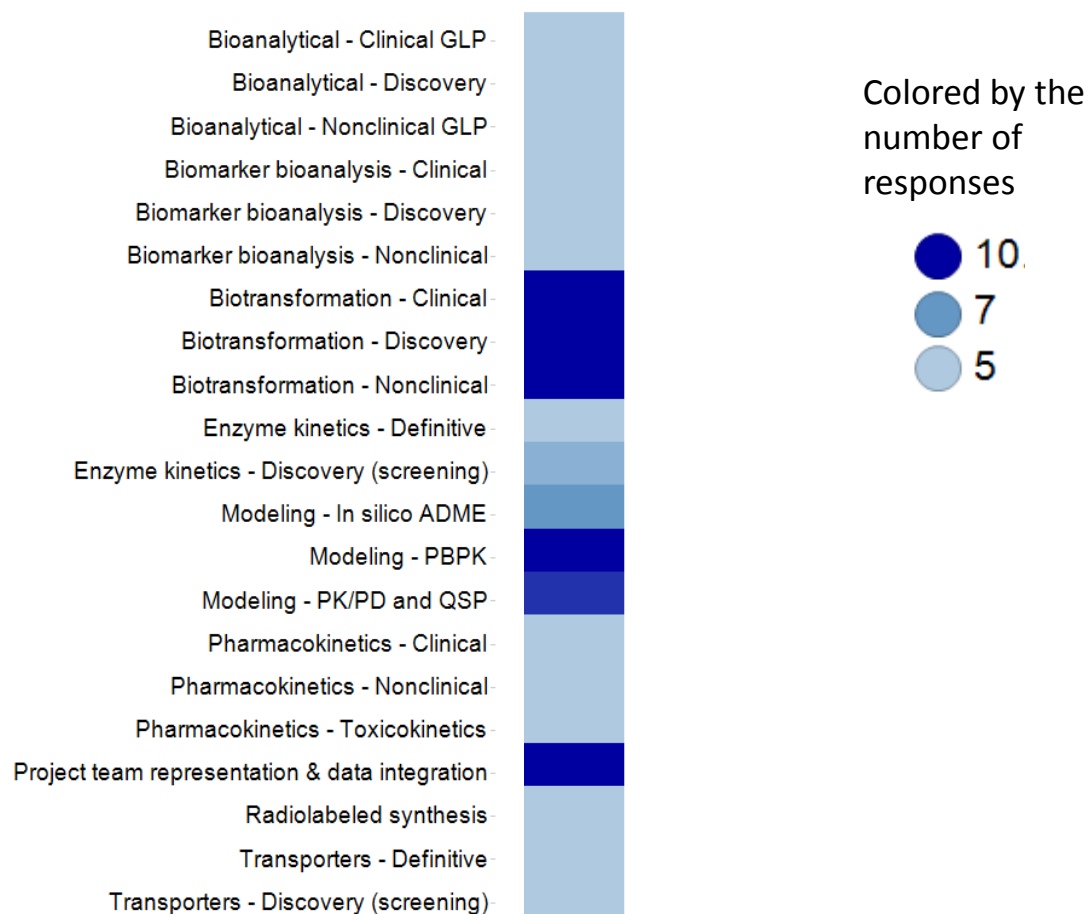
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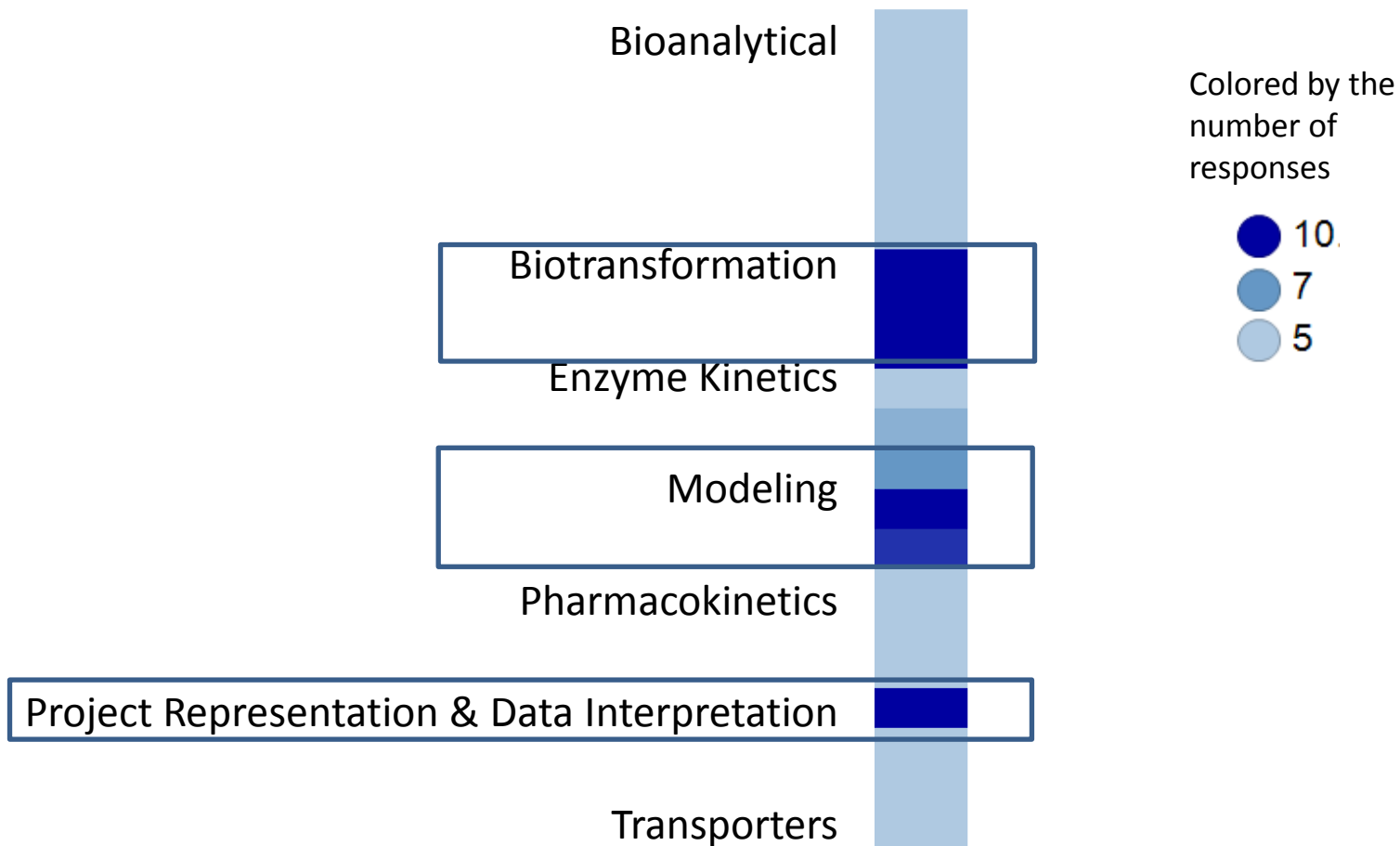
Most Agree On Activities That Should Not Be Outsourced

What Should
Never be
Outsourced?



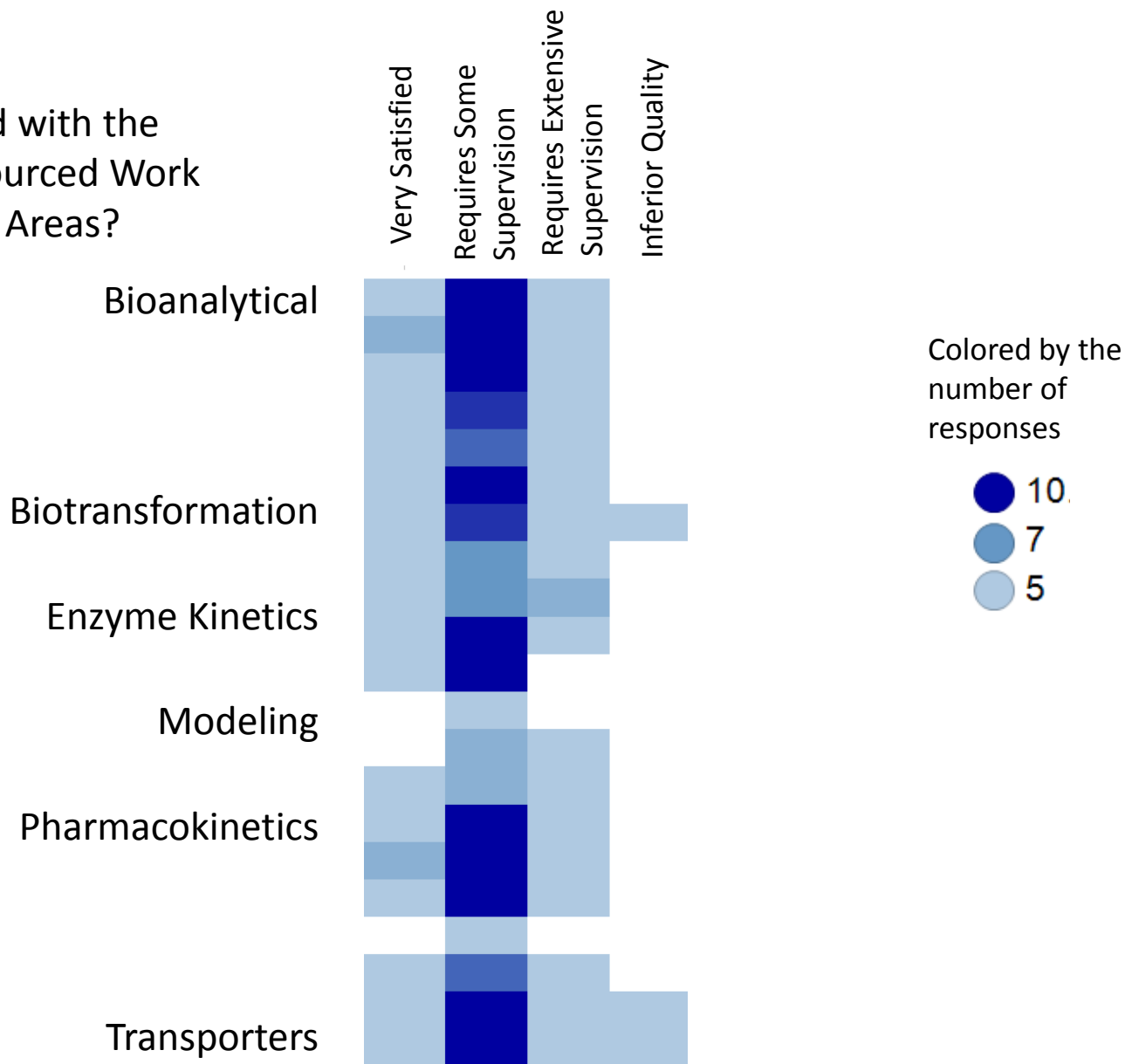
Most Agree On Activities That Should Not Be Outsourced

What Should
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Most Outsourced Activities Rated as Requiring “Some” Supervision

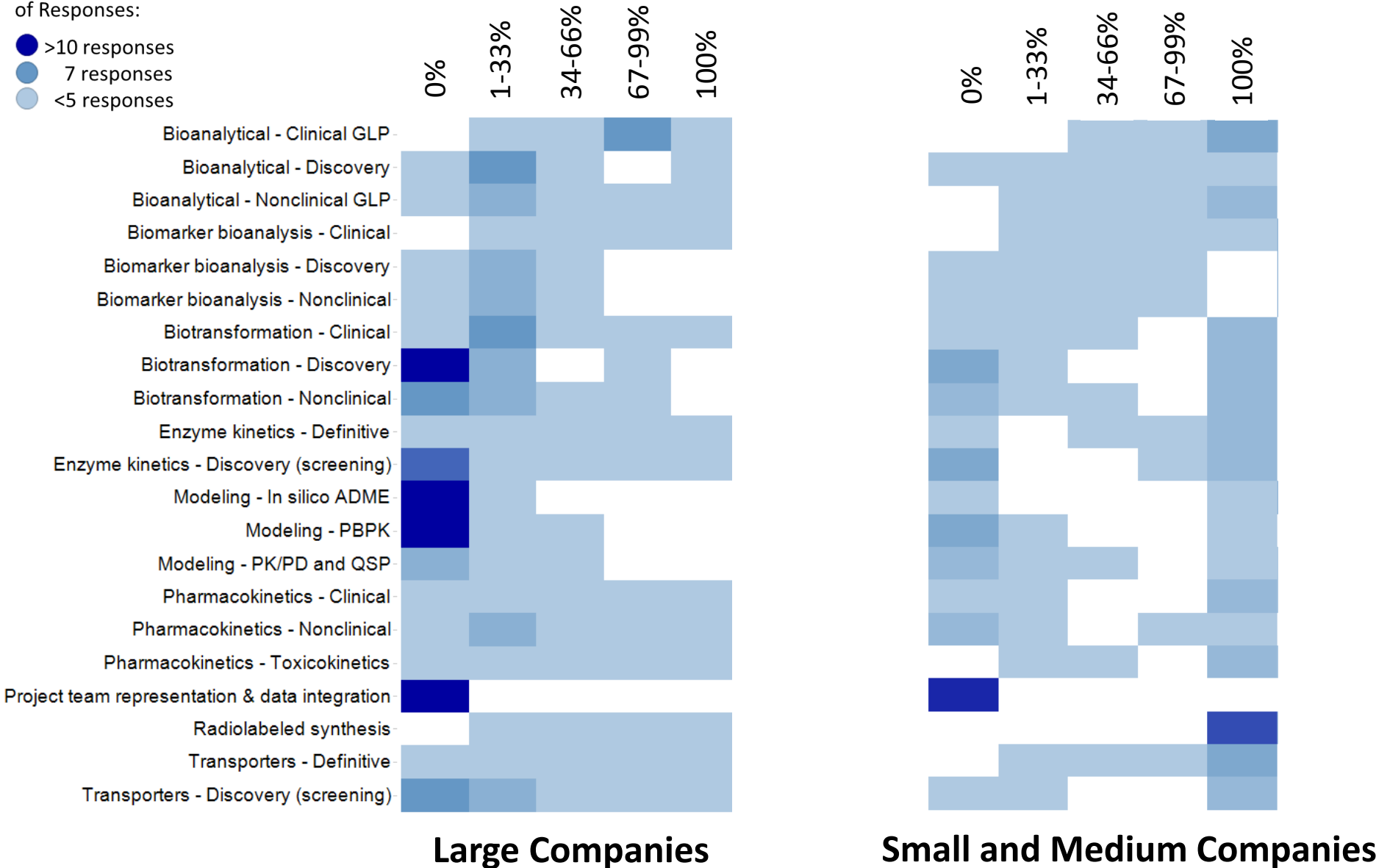
Are You Satisfied with the Quality of Outsourced Work in the Following Areas?



Small and Medium Companies Outsource More

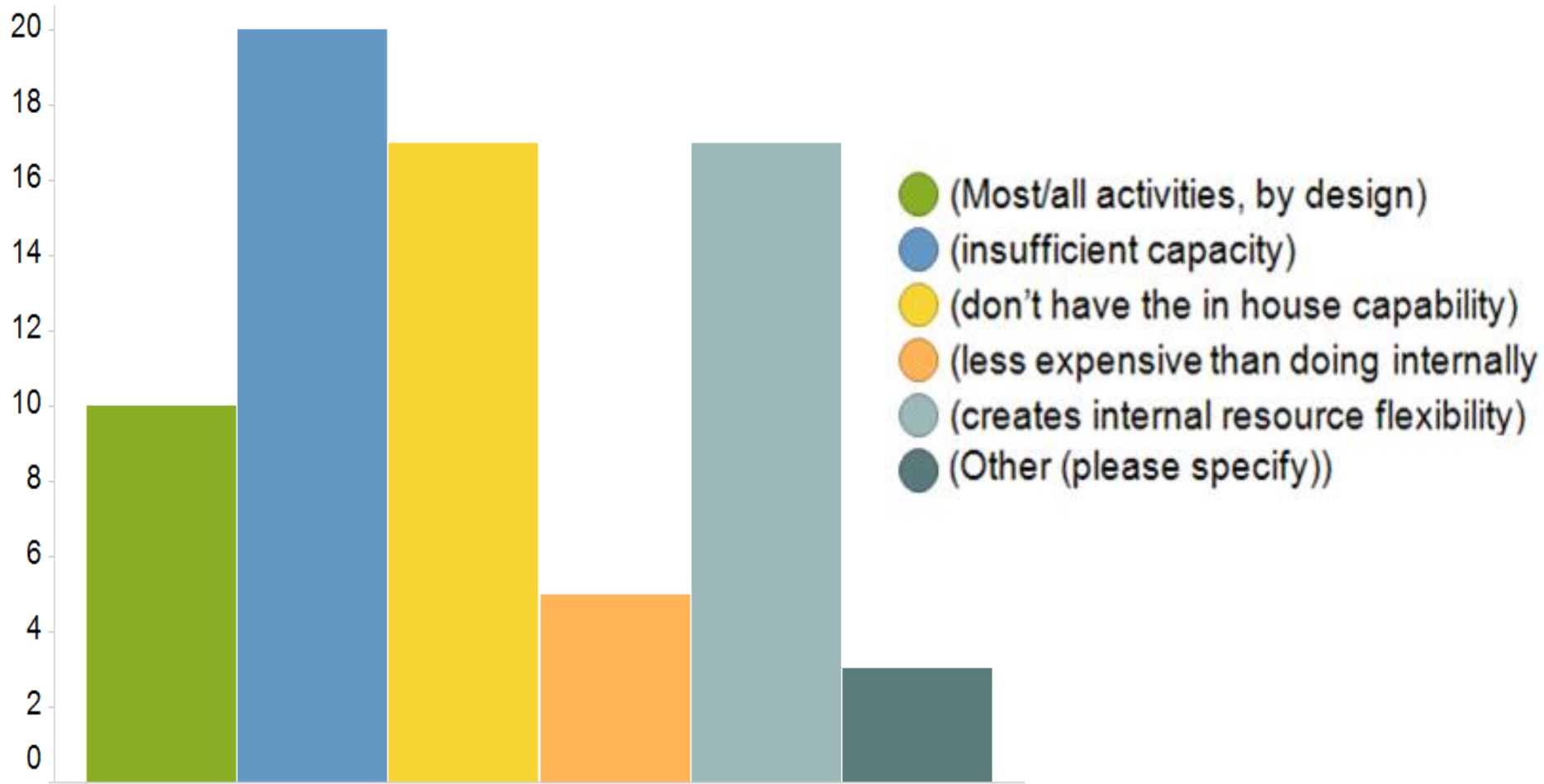
Colored by Number of Responses:

- >10 responses
- 7 responses
- <5 responses

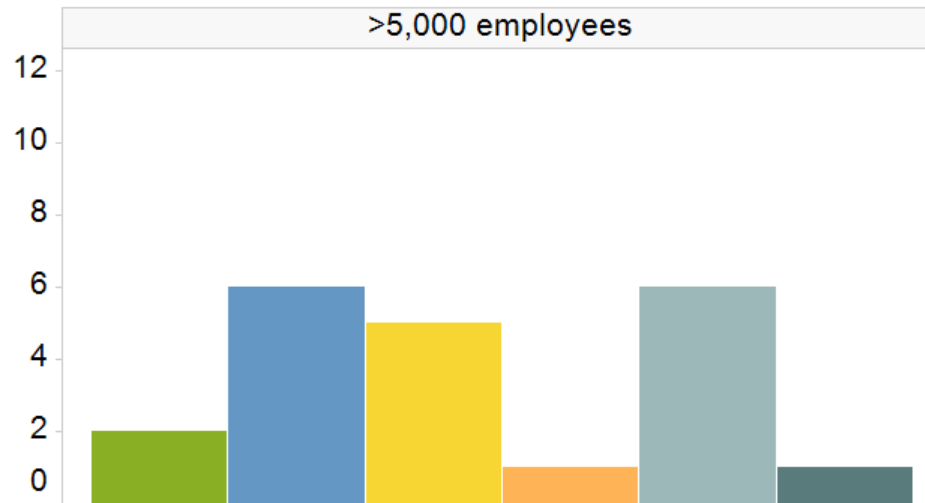


Many Reasons Motivate Choice to Outsource

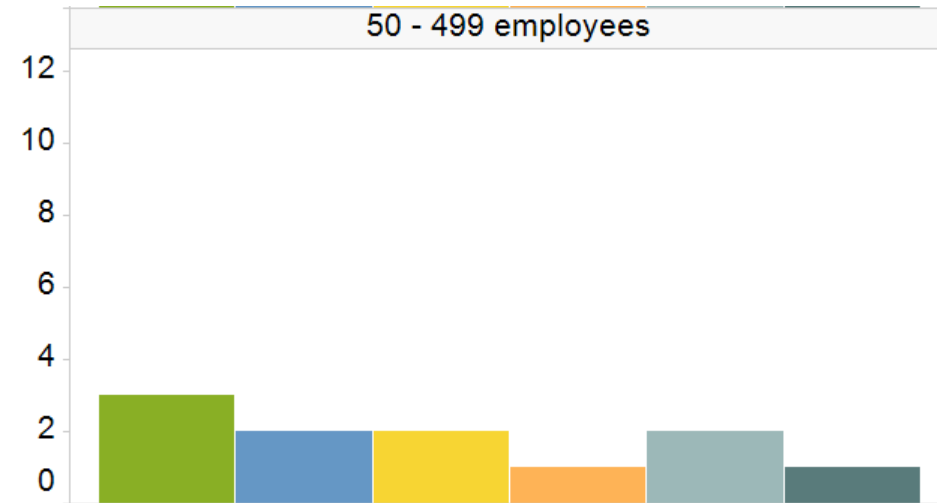
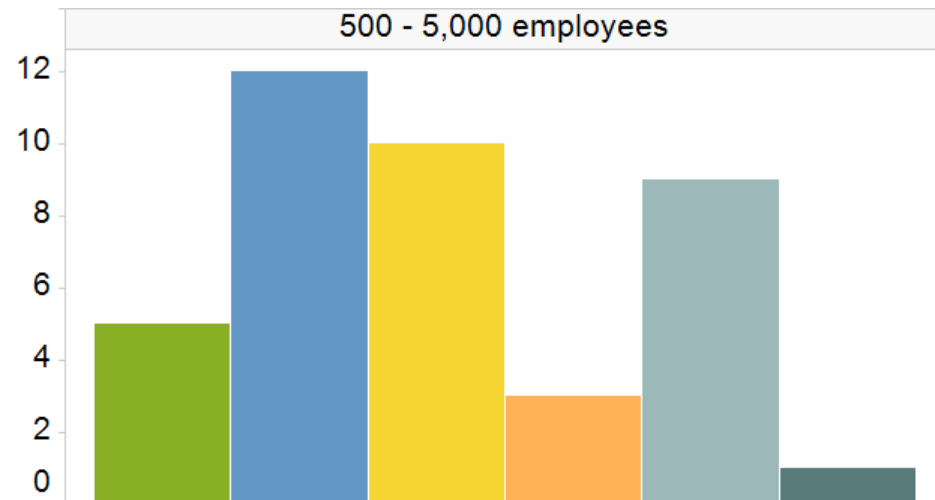
If you outsource, what motivates that choice?



Outsourcing Drivers Vary Slightly by Size of Company



- (Most/all activities, by design)
- (insufficient capacity)
- (don't have the in house capability)
- (less expensive than doing internally)
- (creates internal resource flexibility)
- (Other (please specify))



What are the Strengths and Weaknesses of DMPK-BA in Your organization?

- Strengths:
 - Integration with cross-functional discovery and development teams
 - Impacting decision making
 - Broad expertise and strong scientific/mechanistic thinking
- Weaknesses:
 - Limited in house capabilities; not enough FTE support
 - Fragmented DMPK-BA organizational structure
 - Not as fully integrated as desirable

What do You See as the Most Important Opportunities for DMPK-BA?

- More mechanistic, quantitative modeling and simulation
- Translation from preclinical to clinical (ADME, safety and efficacy)
- Incorporation of biomarkers and improved bioanalysis thereof
- Influencing compound design
- Patient selection
- Near-patient testing

Thank-You!

Round Table Discussion: Shared Views and Perspectives on Outsourcing

Mira Hinman, AbbVie

Ajai Chaudhary, Merck

Helen Yu, Novartis

Round Table Discussion: Shared Views and Perspectives on Outsourcing

Some Questions to start the conversation:

- What Industry do you represent (Pharma, CRO, other)?
- What are the drivers for your company to outsource to China?
- What hurdles to you experience in outsourcing to China?
- How do recent regulatory changes affect your strategy for outsourcing to China?
- How has the transition to a mixed large- and small-molecule portfolio affected your company's outsourcing strategy?
- What trends do you see coming that will affect outsourcing?