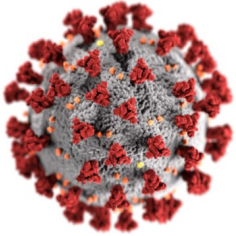


2020 COVID-19 Pandemic Regulatory Impact Pulse Survey



Final Study Report
December 6th, 2020



Welcome and “Thank You” for those who Participated

We hope you find the results, insights, and debrief valuable!

- The current COVID-19 health crisis marks 2020 as a significant year where the global pandemic is shifting how many businesses operate
- This research is part of a series to track responses over the next year to gain insight into what processes and priorities are being accelerated to adapt to the shifting environment and how those changes materialize post pandemic.
- We processed 183 responses from 52 unique global companies

2020 Pulse Survey Research Team



Katherine Yang-Iott
Study Lead



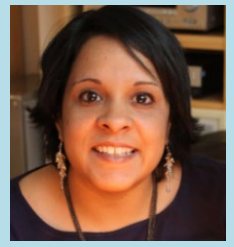
Steve Gens
Founder / Advisor



Greg Brolund



Kelly Hnat



Preeya Beczek

Learning Priority Interview Sessions

(4 Industry companies)
(4 Provider companies)
(2 Consulting Partners)

Study Contributors

Gens and Associates Advisory Board
Jesper Kihl

Formal Design Sessions

(5 Industry companies)
(3 Provider companies)
(Core Research Team)

This is our 36th study to support the improvement of the regulatory eco-system

Industry, service / software providers, standard forums, and health authorities

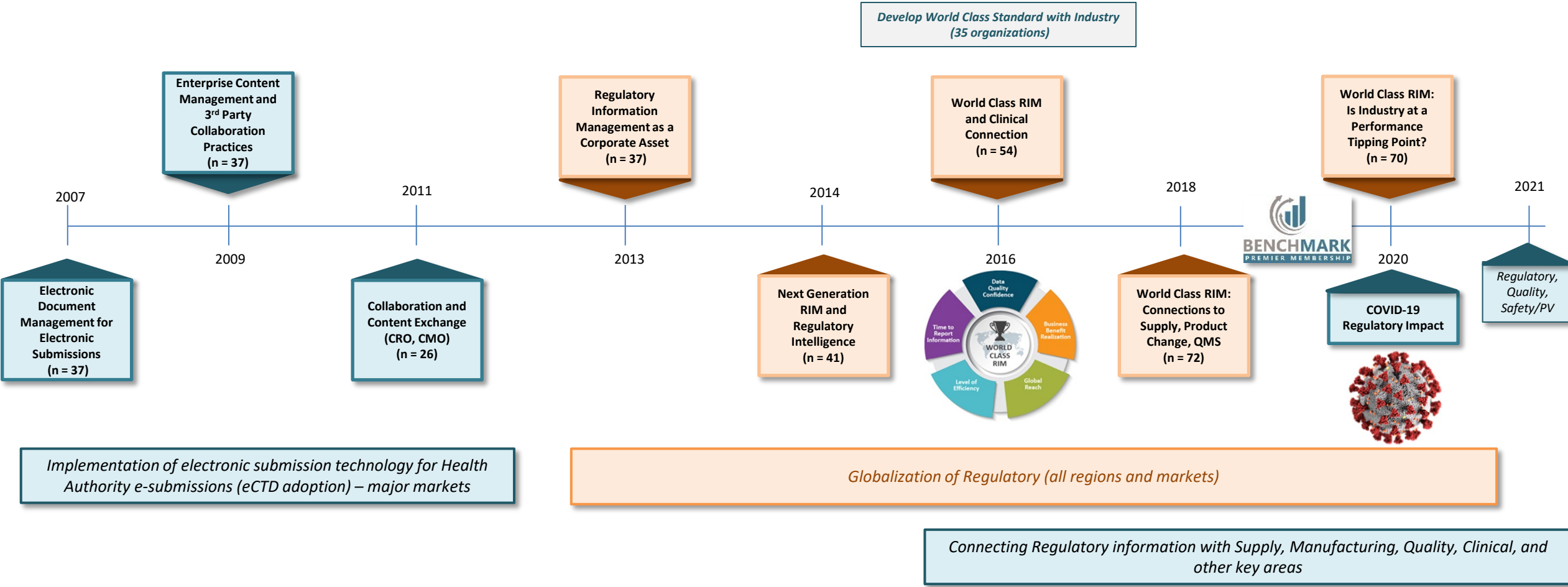


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These materials are provided for your internal organization employees.

Permission is granted to publicly utilize this benchmark information with proper citation and credit

Report Guidelines



- The report is structured into an Executive Summary (ES) and question-by-question results; the ES contains key insights, implications and interpretation of the data
- *It is important to note that any italicized statements indicates a qualitative view or opinion by the authors based on the data and personal experience*
- You will notice one of three images (shown below) in the top right-hand corner of the question-by-question section indicating the question type; some data graphs will total greater than 100% (e.g. check all that apply)



= *check all that apply*



= *check only one*



= *check one per row*

COVID19 Pulse Survey: Purpose and Design Process



Learn how regulatory organizations are responding to the impact of the COVID-19 Pandemic in 3 key areas:

- **Impact on Business Operations**
- **Impact on Ways of Working**
- **Impact on Regulatory Activities**

Study Purpose:

- Examine how the pandemic is impacting regulatory organizations today from an **individual personal perspective**
- Explore where current **processes and priorities are being accelerated** to support performance improvement
- **Measure the impact** on regulatory operations and organizational initiatives/priorities due to shifts in work environment
- Share performance improvement practices and **learning opportunities discovered from the survey**

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Key Survey Themes and Insights

What does the benchmark data tell us?



Breaking free of
“time to change
beliefs and
mindsets” –
increasing speed

Growing
organizational
dilemmas -
workforce flexibility
and digitization
skills

Accelerating
organizational
agility –
innovations from
within

Maximizing global
and virtual
investments

We see a 3-step process: Crisis Mode (adjust), Recovery (learn), Renewal (evolve)

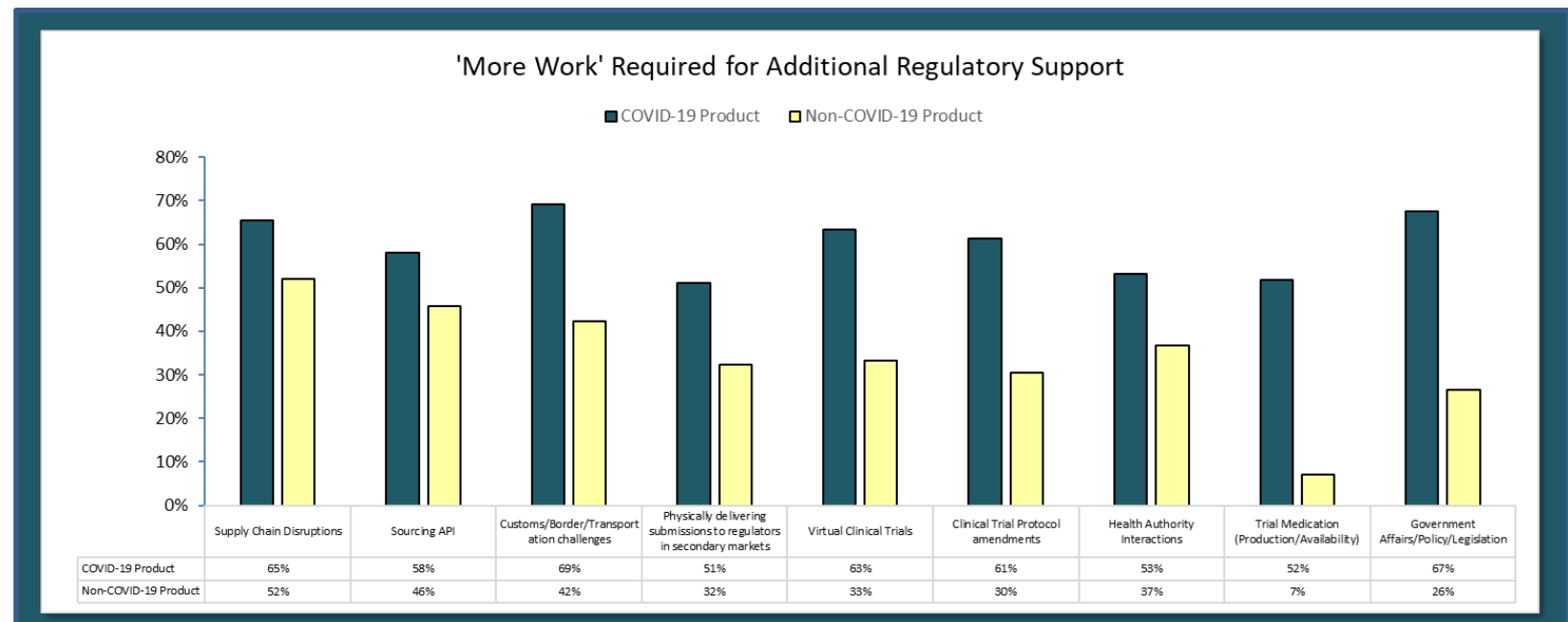
Breaking free of “time to change beliefs and mindsets”



- Our study found several great examples of “breaking mindsets”
 - **Large scale organizational changes don’t have to be complicated:** Immediate and successful shift to remote work
 - **Speed at which things can be completed:** A planned corporate conversion to Microsoft Teams pre-pandemic was estimated at 6 months; completed in 3 weeks – “we are now challenging our thinking *on what it actually takes to complete projects*”

- For companies actively working on COVID-19 products, there was a significant increase of work in the 9 areas we tested!

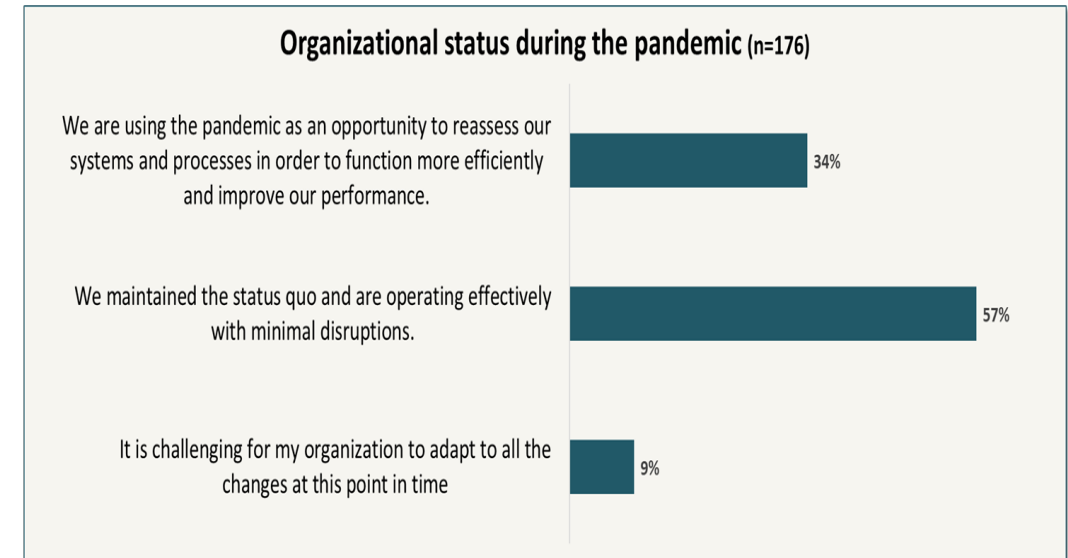
- *In crisis mode, organizations can find quicker paths without sacrificing quality, often challenging the status quo*



Accelerating Organizational Agility – Innovations from Within



- Clear theme of organizational resiliency and agility emerged from the research:
 - **Shift in Speed:** More important to focus on what is necessary (e.g. organizations setting up internal pandemic taskforces to prioritize tasks and accelerate decisions)
 - **Sense of community and shared organizational mission:** Virtual environments have made things more transparent and participants shared having a better understanding of what other teams are responsible for and how their work is all connected
 - Many responses of ‘now we see what is possible’ and recognition of others’ work experiences, such as ‘daily life at a small local affiliate’

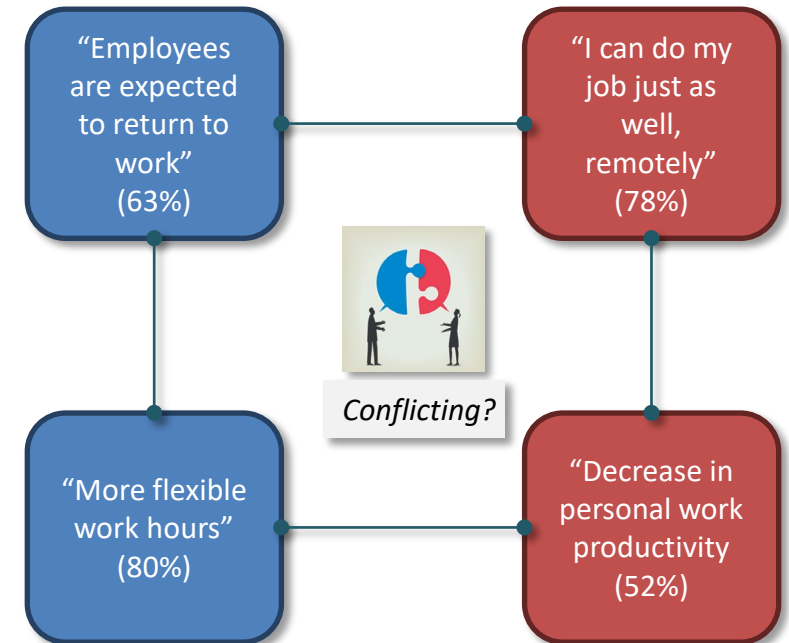


- The behavioral impact of the pandemic is significant, and organizations are realizing and experiencing firsthand what they are capable of in a crisis
 - Teams taking on temporary roles - regulatory submission associates helping out in the warehouse to package products
 - Making decisions quicker, and much faster rollouts and adoptions of new processes and systems by everyone
 - The challenge will be to see how to sustain the innovations and efficiencies post pandemic

Growing Organizational Dilemmas - Workforce Flexibility and Productivity



- While 80% stated an increased ability to work flexible hours, 52% stated a decrease in personal work productivity (e.g. childcare, remote learning, constant meetings, insufficient bandwidth etc.)
- 76% state a decreased ability to disconnect from work and 41% observed an increase in their colleague's availability
 - *We see this as a leadership and boundary management dynamic*
- 69% are investing in virtual collaboration initiatives requiring new technology and skills
 - Remote work and virtual environments have led to more direct communications
 - Access to information for more people
- Work flexibility is preferred, however *has effectiveness decreased temporarily?*
 - *There seems to be a flattening of hierarchies in the pandemic work environment, which supports developing and practicing organizational agility*
 - Several participants mentioned they had opportunities to have a ‘voice and seat at the table’ during the pandemic, which was not the case during normal times



“Compassion for everyone's life outside of work and appreciation of everyone's challenges with home, childcare, workspace boundaries and the stress of a global pandemic.”

Maximizing Global and Virtual Investments



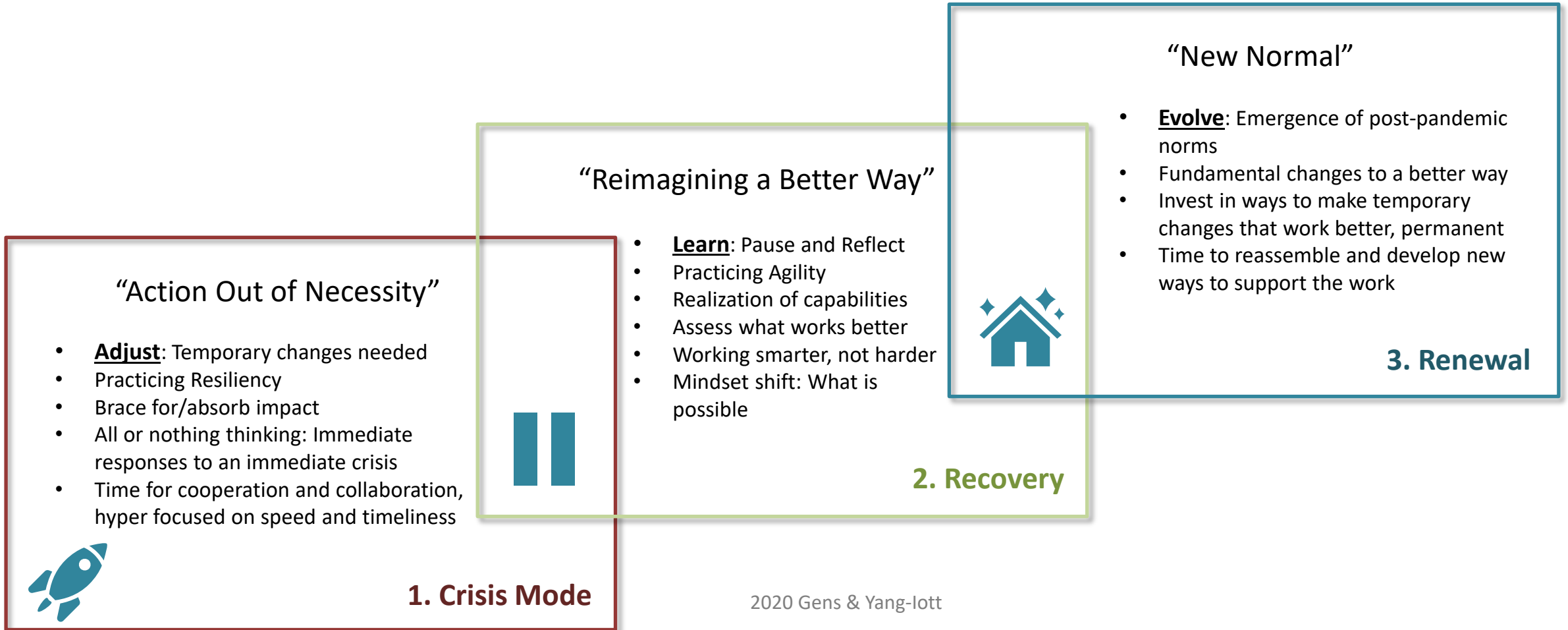
- Since 2014, Industry has been investing to improve “global processes and systems”, with 2020 priorities being:
 - 1) Global Dossier Strategy and Dossier Management Operations
 - 2) End to end Label Management
 - 3) End to end Variation Management
 - 4) Registration and Health Authority Commitment Management
- Our 2020 World Class RIM Top Performers have achieved global improvement of the following characteristics of key processes and systems
 - √ Capability efficiency (process maturity – standard “way of working”)
 - √ Real-time information access
 - √ 90% have successfully achieved a global RIM capability
 - √ Data quality confidence and sustainability

We believe the significant investment in regulatory organizations focused on end-to-end processes, global systems, and data quality since 2014 has resulted in the ability to rapidly shift and adapt to a virtual and remote environment

Points based on our 2020 World Class Regulatory Information Management (RIM)SM Survey of 70 companies



Viewpoint: Organizational Evolution during the COVID-19 Crisis

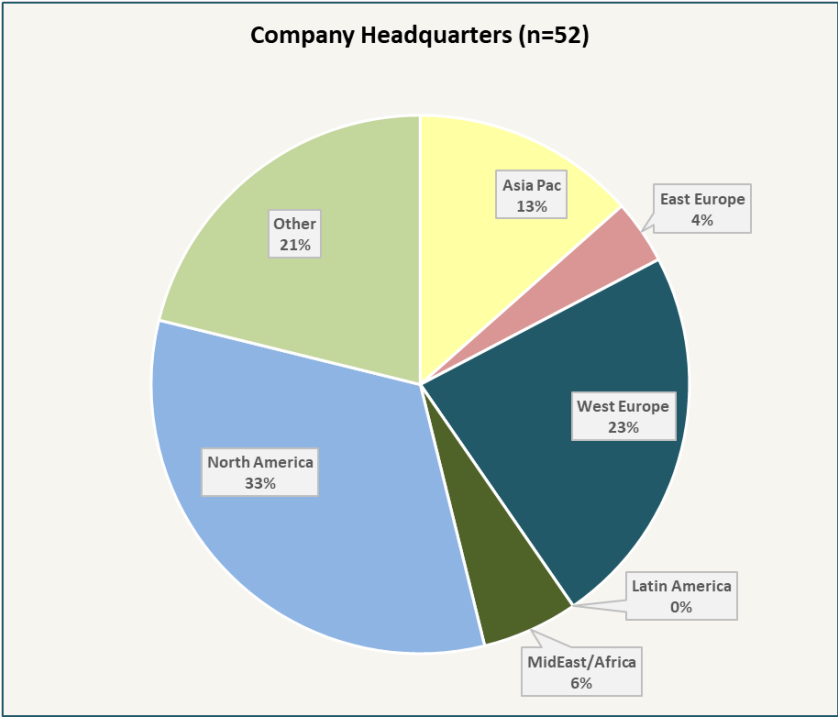


2020 Gens & Yang-lott

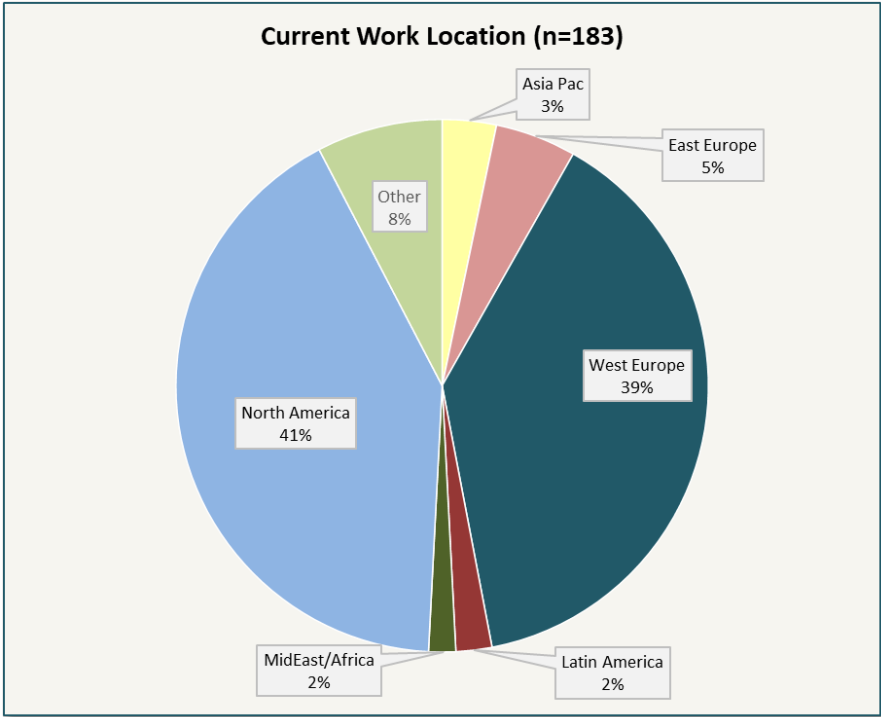
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Participant Demographics



52 companies participated in the research, representing a true **global perspective** of the COVID-19 Pandemic



Western Europe (39%) and North America (41%) make up the majority of where individuals are **currently working from**

*other: central Europe and central Asia

Q2 What is your primary function in your company?

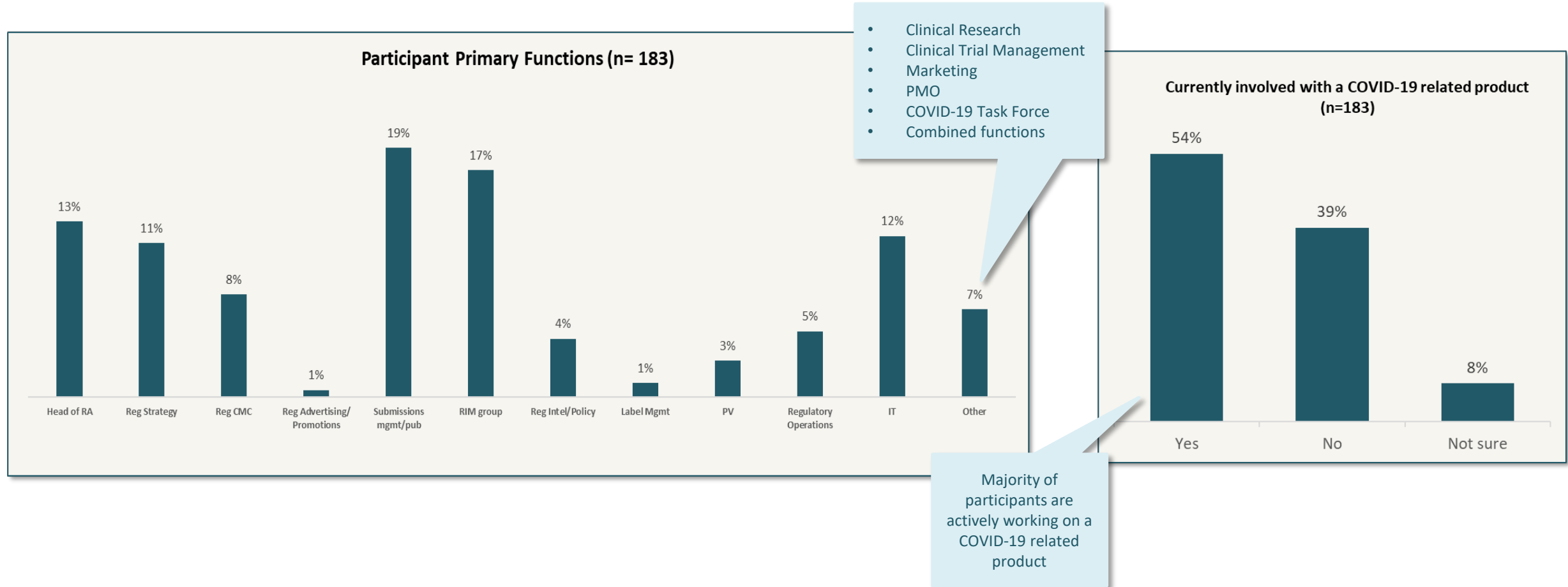


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Q5 In general, how has the COVID-19 Pandemic impacted priorities in your Regulatory organization for the following?

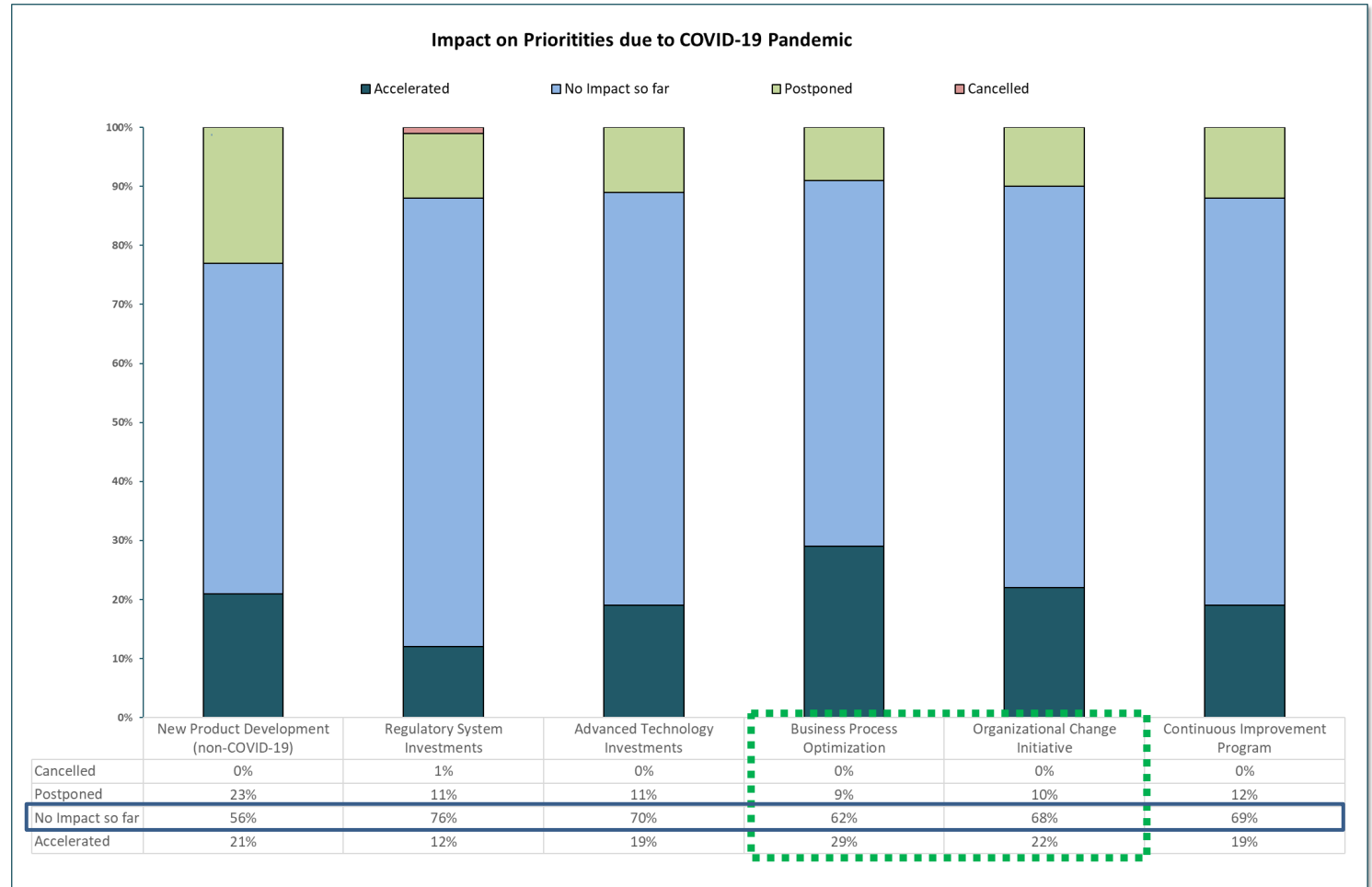


While most respondents saw no impact so far, there are several areas of accelerated priorities including:

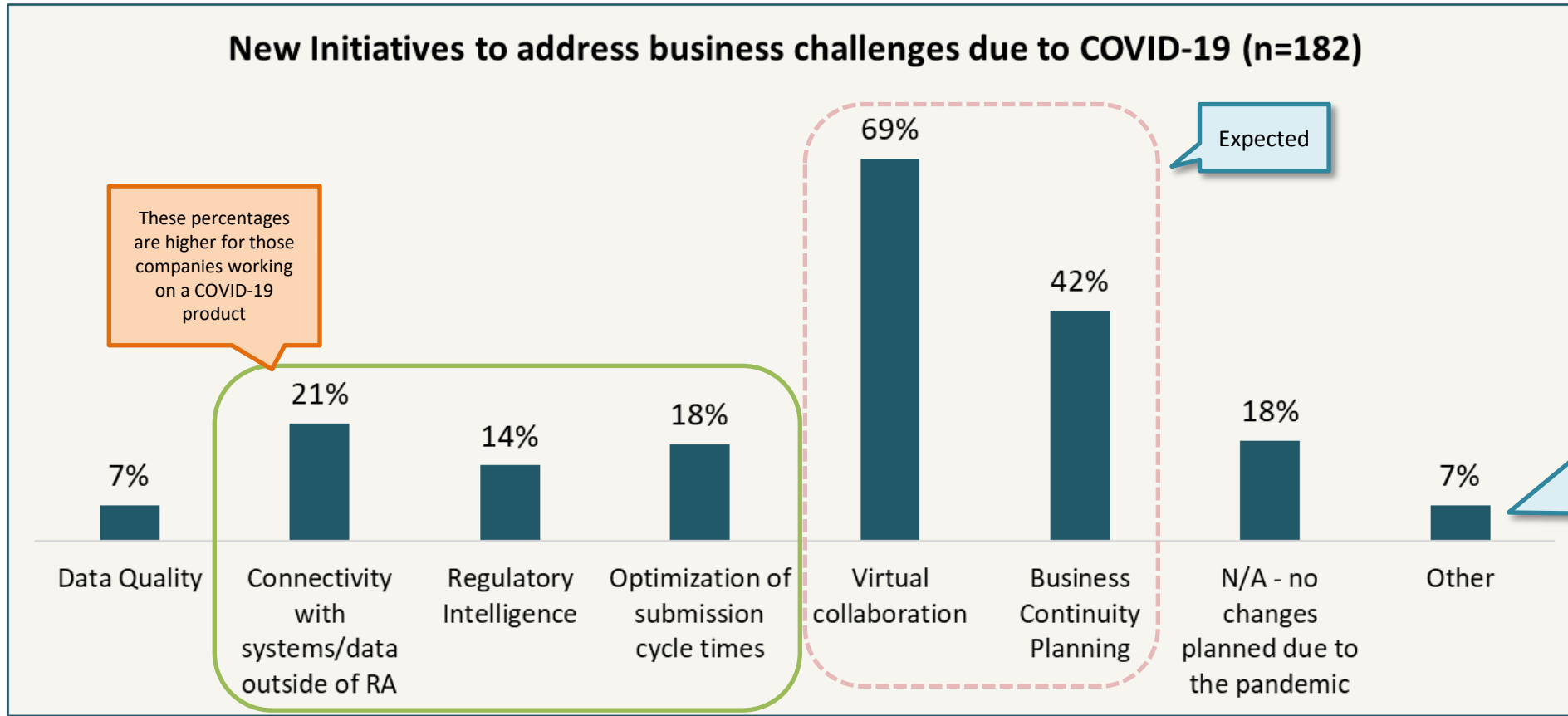
a) Business Process Optimization (29%)

- Our 2020 World Class Regulatory Information Management Study (n = 70) found 60% are working on end-to-end Label Management, Variation Management, and Global Dossier Strategy

b) Regulatory System and Advanced Technology investments are geared towards a global RIM capability and operational efficiency according to our other 2020 research



Q6 Has the COVID-19 Pandemic served as a catalyst for your organization to launch (or plan) a new initiative to address any of the following business challenges?



- Digitalization acceleration
 - Electronic signatures
 - Paperless operations
- Fast tracking other areas of support and operations
- Enterprise Content Management
- Professional and leadership development
- Prioritization Framework
- Greater access to information/more direct communications

Q7 Generally, how has the inability to meet in person impacted your relationships with outsource service providers and software partners?



- Greater than 75% of responses noted **no current impact** on current provider relationships
- *As expected, social distancing and remote business practices have negatively impacted the ability to build **new provider relationships**. This is one instance where the value of having face-to-face interactions is hard to replicate in a virtual environment (even webcams!)*

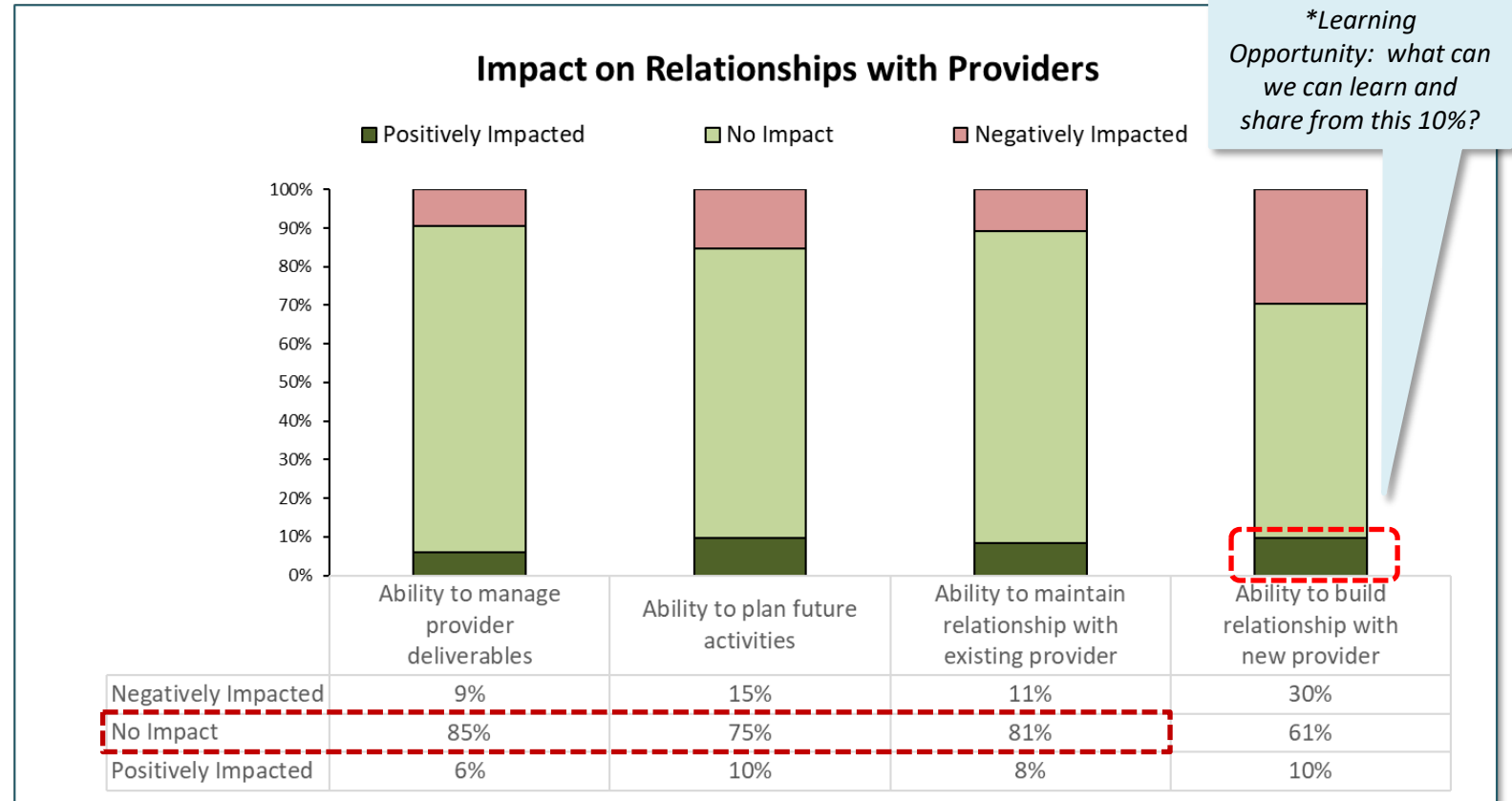


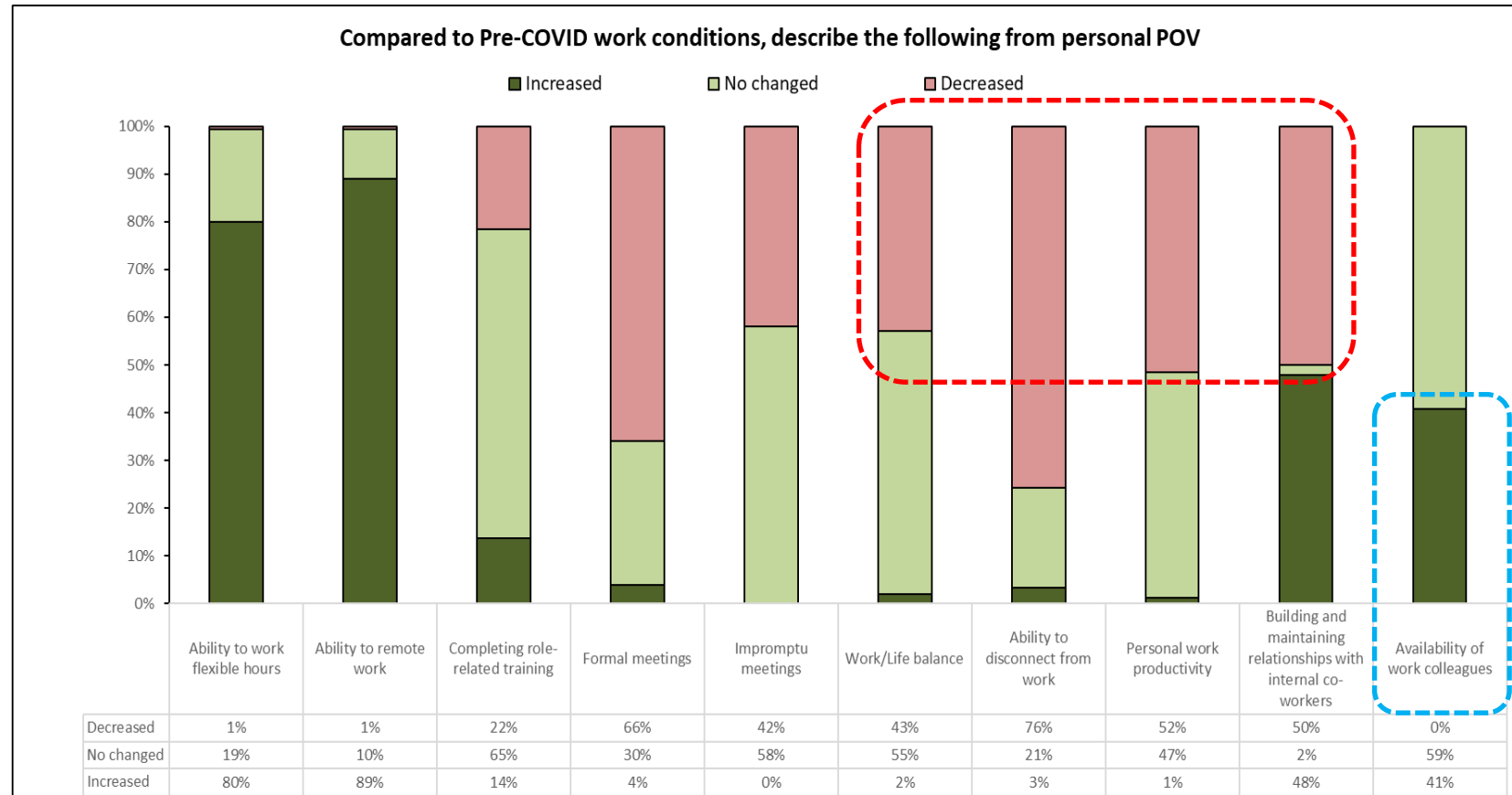
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Q8 Compared to pre-COVID-19 work conditions, how would you describe the following from your point of view, as it applies to you within your organization?



- COVID-19 control and mitigation efforts required most organizations to shift to remote work, leading to a substantial decrease in formal and impromptu meetings
- How people communicate, collaborate, and network have significantly changed (i.e., stopping by office, having lunch, breaks, throwing out ideas in person)
- Work hour flexibility has led to more availability of colleagues (41% increase)
- 76% stated a decrease in ability to disconnect from work:
 - During interview sessions, we learned that visual cues (e.g. people leaving the office around 5-6pm) were missing to prompt the end of a workday, resulting in people staying logged in much longer and anytime



*n = varied for each column: not all participants provided a response for each category. Data shows only those that provided a response

Q9

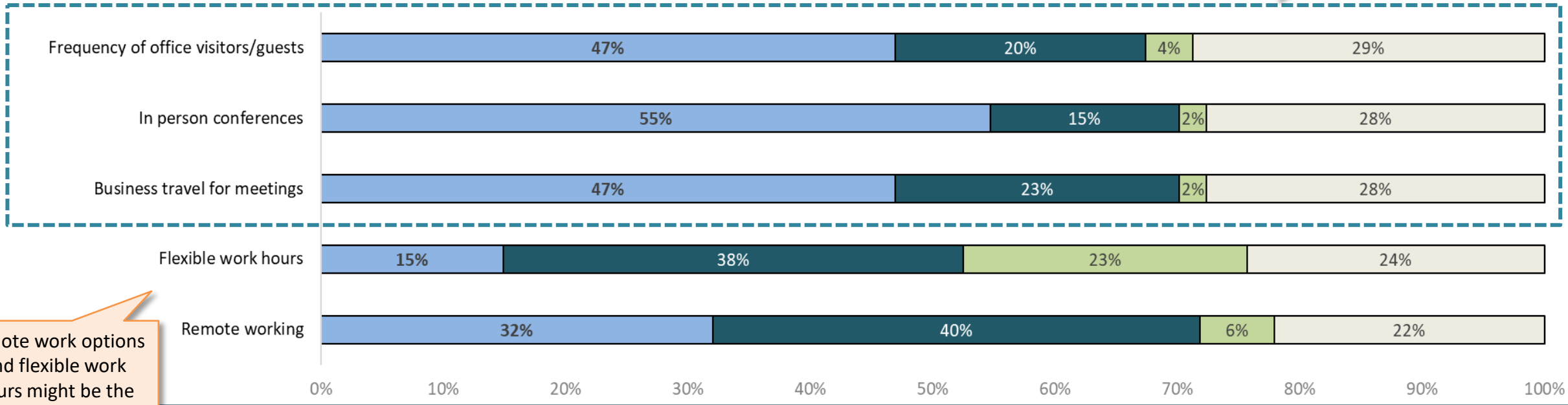
Many organizations are adopting new policies for communicating and collaborating, we are interested to see if these new methods become the new normal when the pandemic is over



Most people think that these policies and methods are only temporary, due to social distancing and quarantining requirements, and will shift back to 'pre-COVID' ways

What will new policies and methods look like after the pandemic is over? (n=181)

■ Temporary change ■ Permanent change ■ No COVID-19 related change ■ Not sure



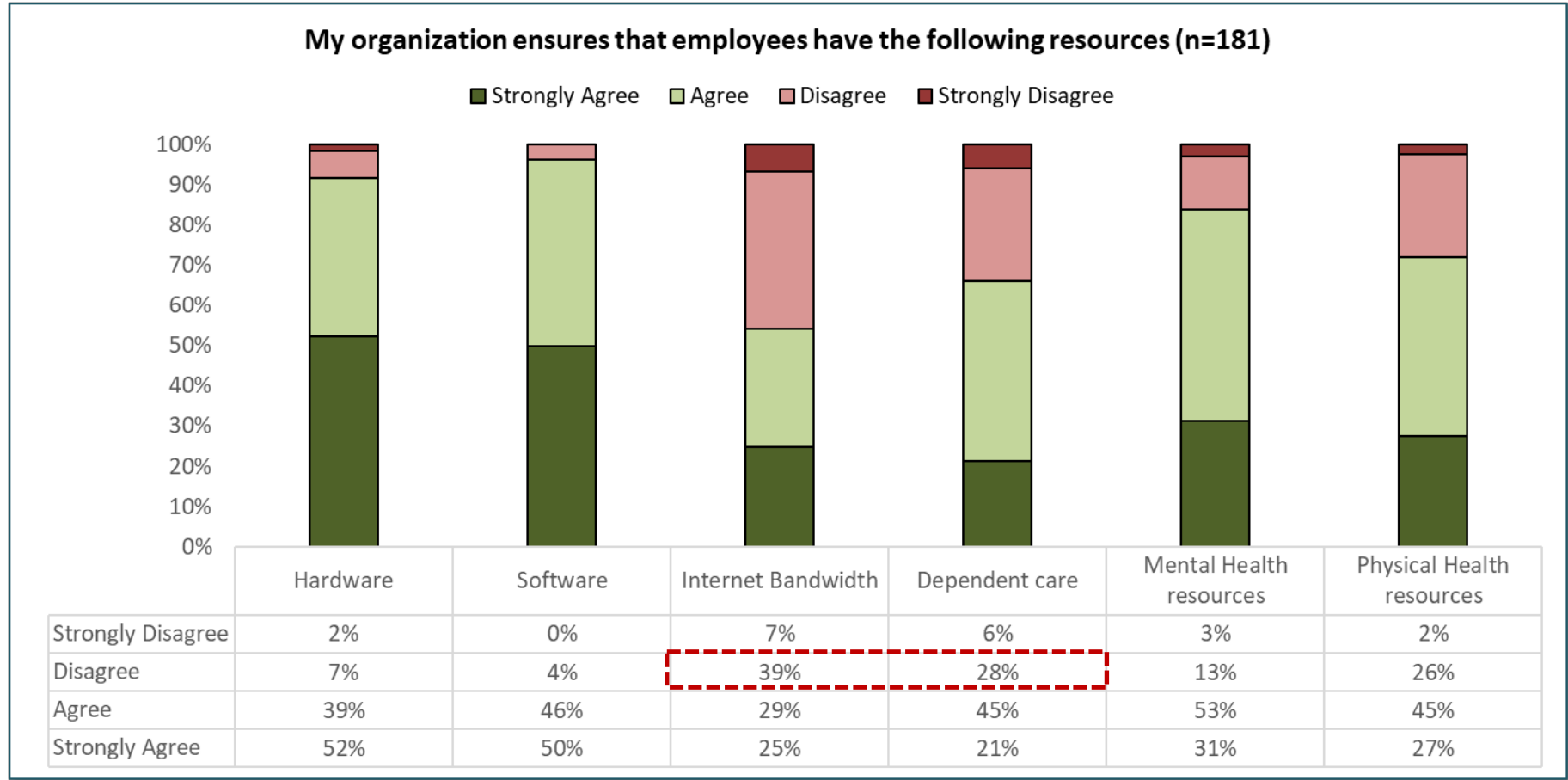
Remote work options and flexible work hours might be the future of work

Q10

My organization is invested to ensure employees have the following resources in order to effectively work remotely:



- We expected the responses for having hardware and software as most Life Science organizations are global and mobile...
- ...however, 46% shared that internet bandwidth is not part of the package, which may have an impact on productivity
- *Dependent care, mental health and physical health resources are more company-specific “policy” related; it will be interesting to see how corporate policies change in 2021*

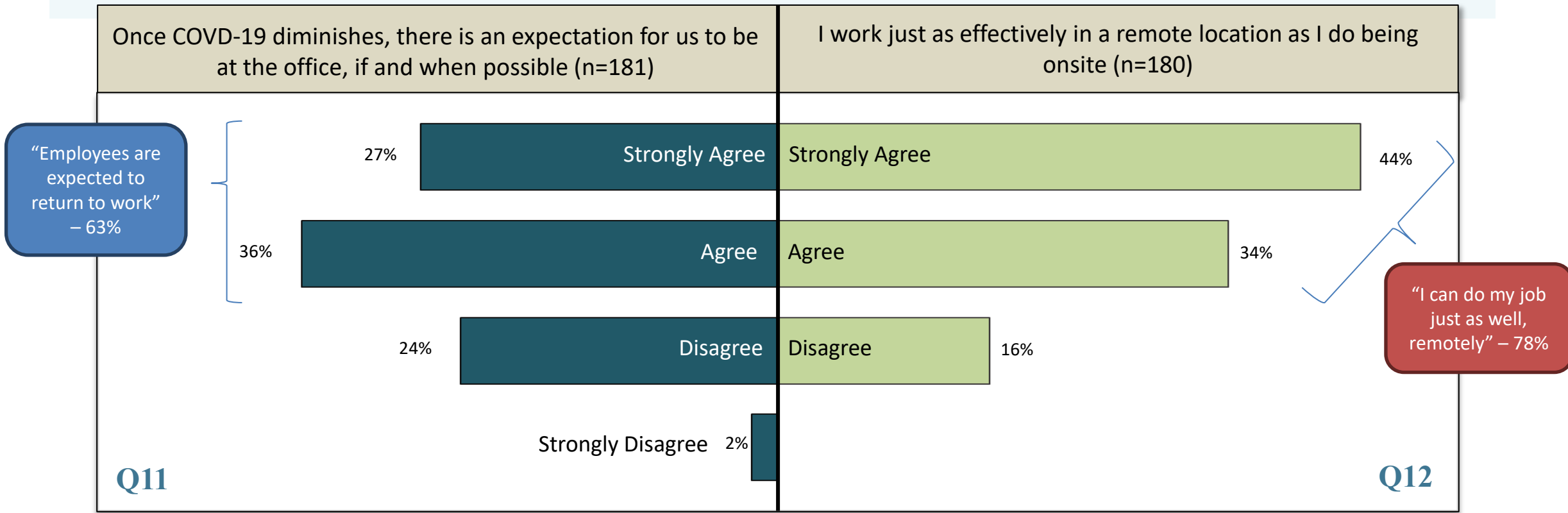




Q11/12 Post-pandemic Remote Work conditions:

An interesting organizational dilemma

- 63% of respondents think there is an expectation for them to return to the office once the pandemic is over, even though 78% feel they work just as effectively in a remote setting
- The 'in-person' culture is deeply imbedded at many companies. How will other long-standing cultures shift post pandemic?



Q13 I believe our organization...



- Most individuals have a positive perception of their organization's resiliency and agility levels

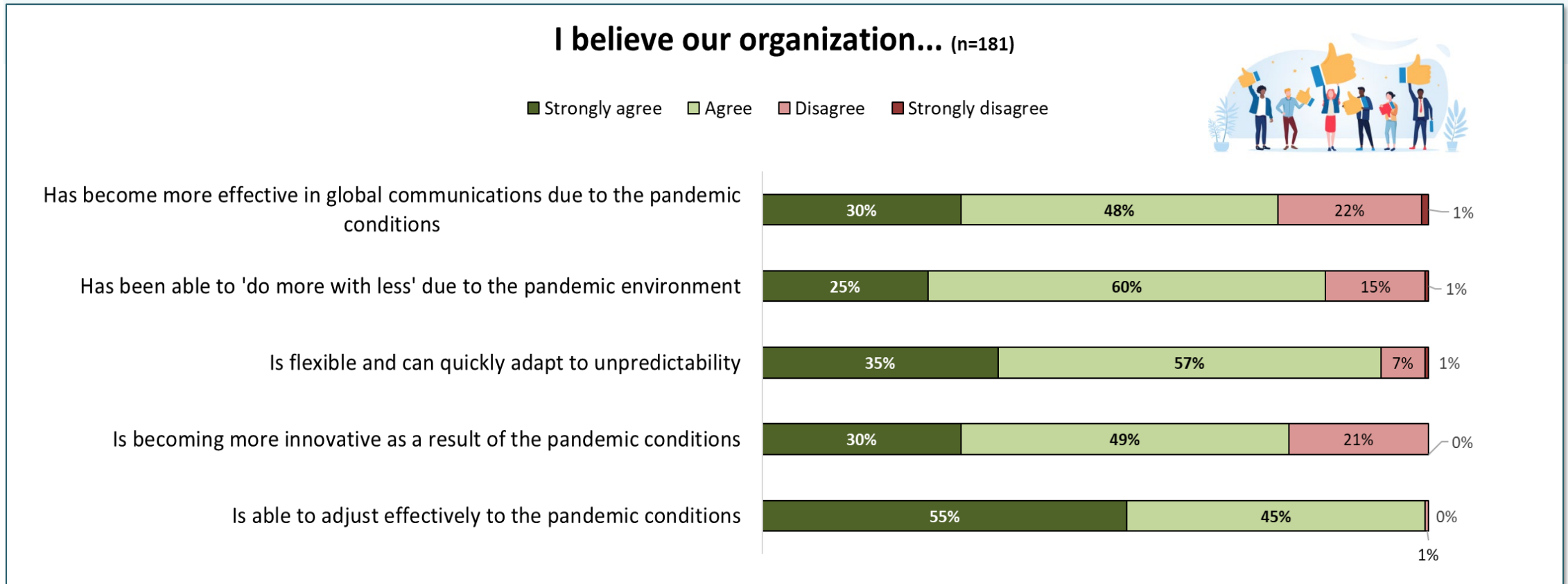


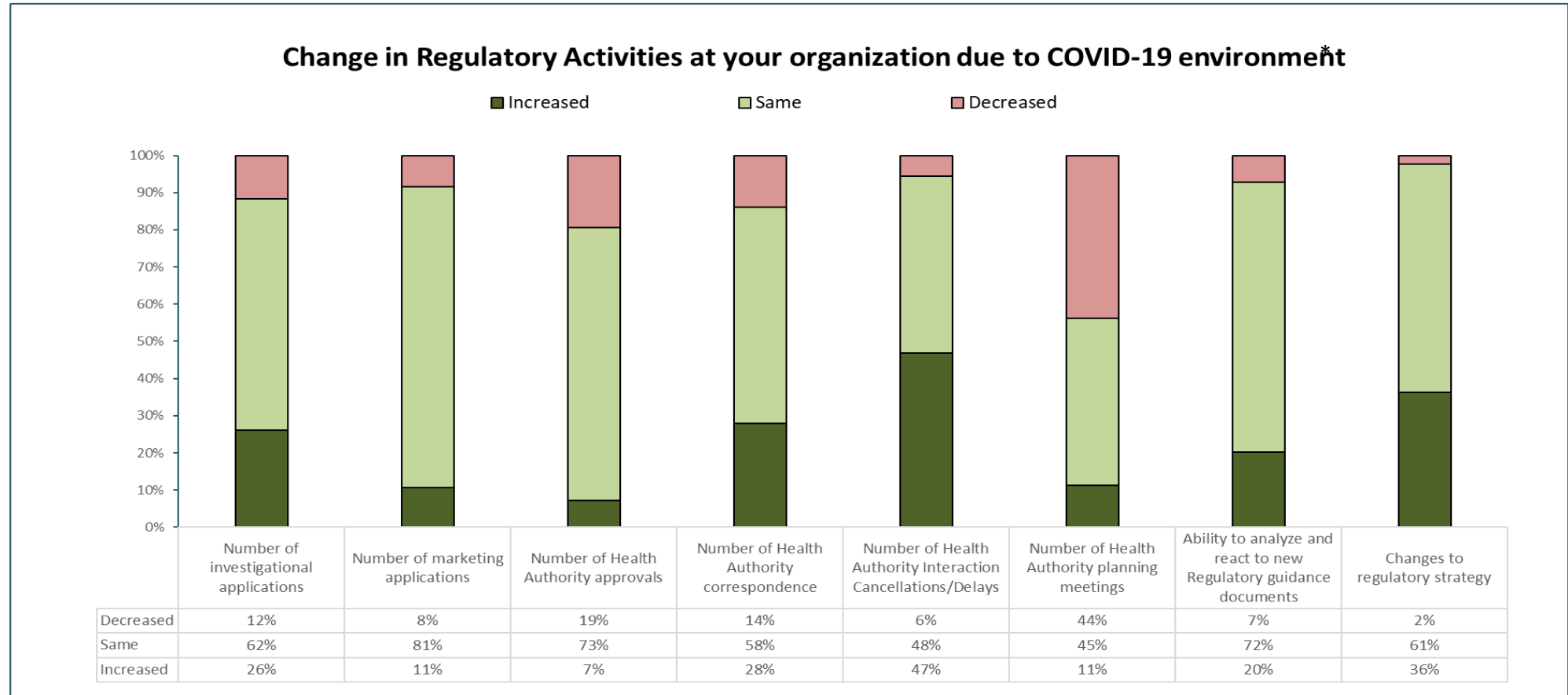
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Q14 In general, how has COVID-19 impacted the following Regulatory tasks and activities for your organization?



- Companies working on a COVID-19 product had higher increases in number of health authority correspondence and changes to regulatory strategy
- *Is the 44% decrease in health authority planning meetings being attributed by priority (COVID-19) product review at the expense of other products? – what are the longer-term implications if this is true?*

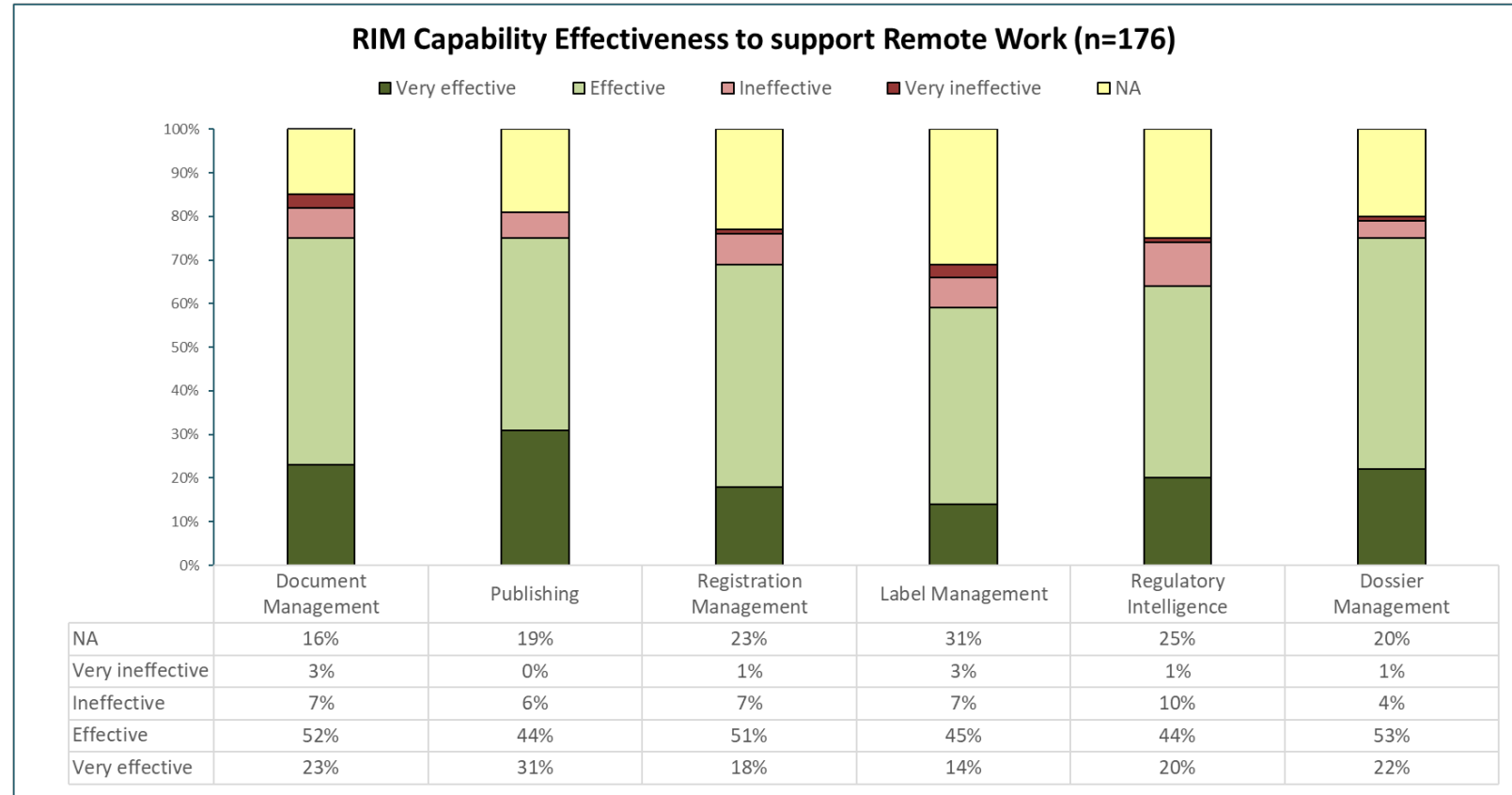


* n = variable: not all participants provided a response for each category. Calculations are made with the number of responses for individual categories

Q15 How would you rate your organization's RIM capability effectiveness (processes and tools) in supporting remote work?



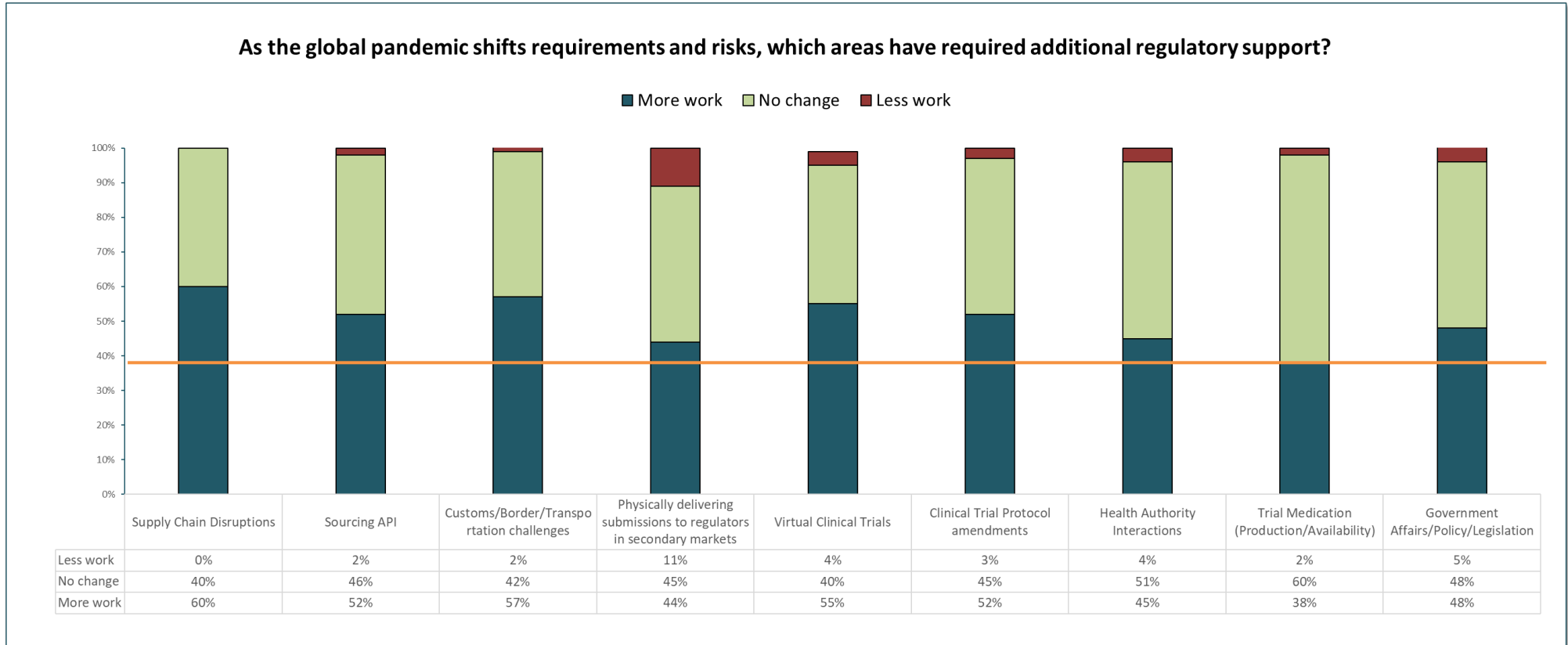
- 80%-90% of survey participants state that their organizations' RIM capabilities are effective (effective + very effective)
- Companies working on a COVID-19 related product scored higher for 'Very Effective' compared to companies that are not working on a COVID-19 related product, for all RIM capabilities listed
- Publishing, Submission Document Management, and Ad/Promo Management had the highest capability efficiency rating in our 2020 World Class RIM



Q16 As the global pandemic shifts requirements and risks, which areas have required additional regulatory support?



- All categories saw at least a 38% increase in work with supply chain disruptions and customs / borders / transportation challenges being the highest



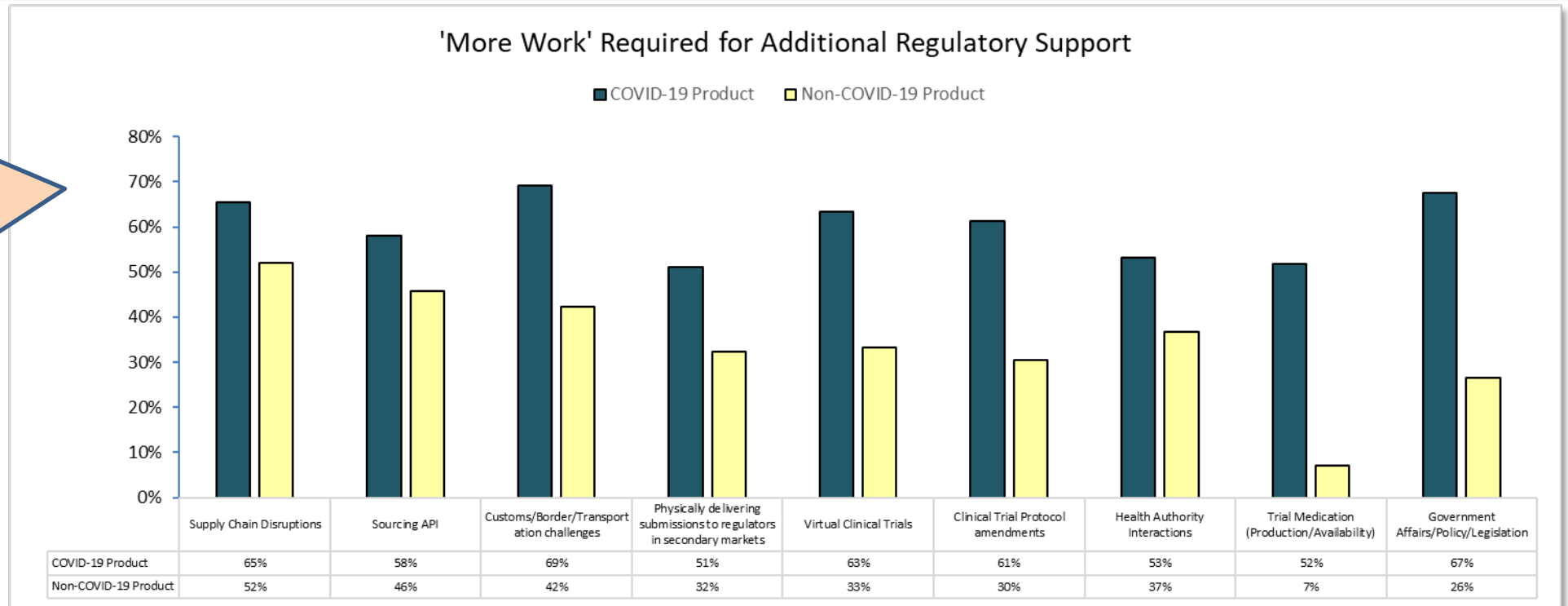
* n = variable: not all participants provided a response for each category. Calculations are made with the number of responses for individual categories

Q16 As the global pandemic shifts requirements and risks, which areas have required additional regulatory support?



- There is a higher increase of additional regulatory support needed for those actively working on a COVID-19 related product compared to companies that are not. In particular, and as expected due to the race for a vaccination, Trial Medication, Virtual Clinical Trials, and Government Affairs support are >2x as high for COVID-19 product development

The combination of compressed time frames and more actions and support needed for these Regulatory activities contribute to the measure of 'More work' requirements

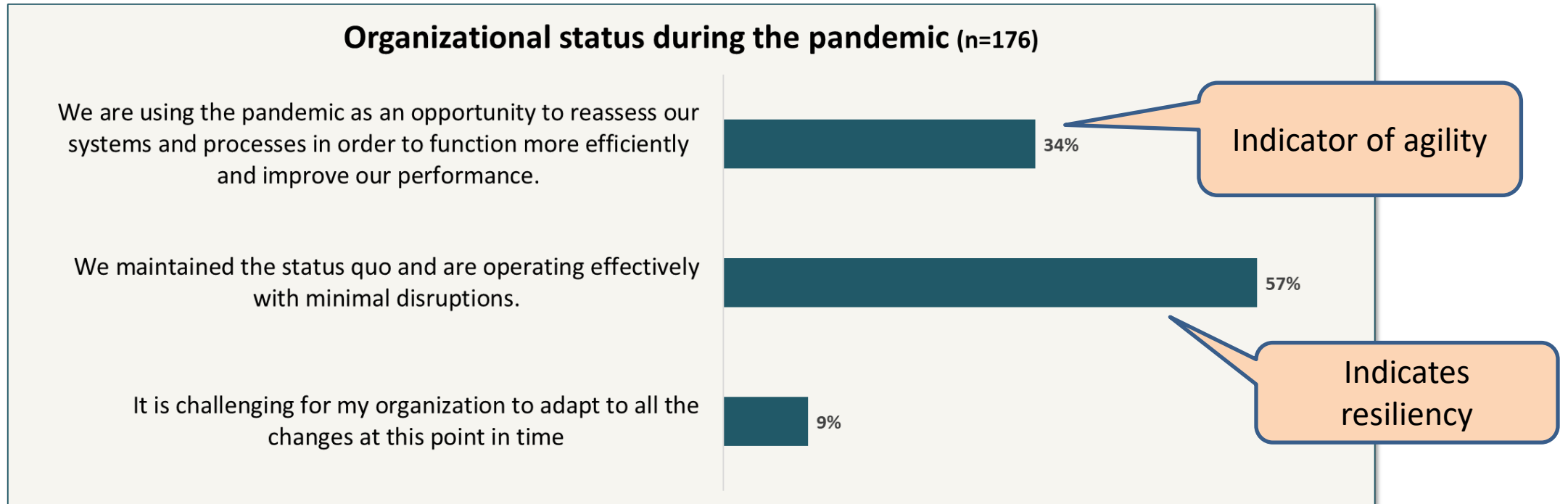


* n = variable: not all participants provided a response for each category. Calculations are made with the number of responses for individual categories

Q17 Overall, how would you characterize your organization's response to changes due to the current pandemic?

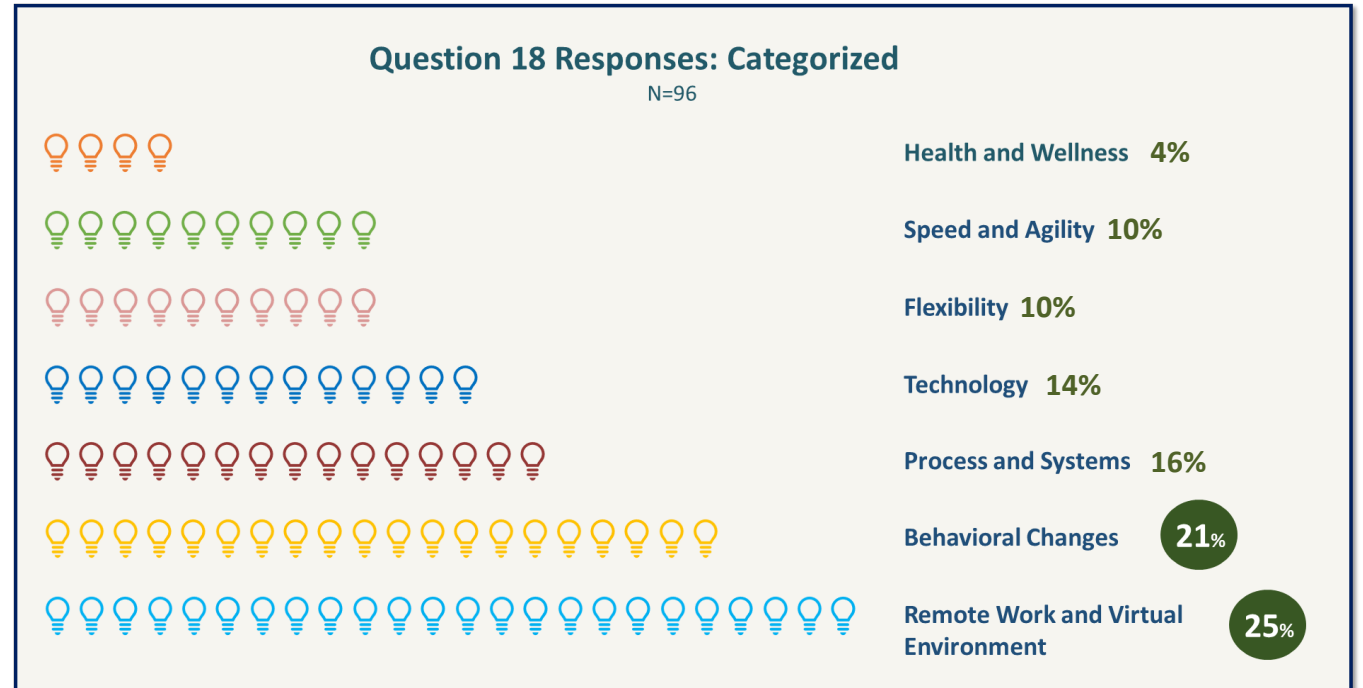


- Most individuals (57%) have yet to see their companies be dramatically impacted by the pandemic. So far, they continue to operate effectively with minimal disruptions. Responses were collected in early fall (Sept/Oct 2020)
- Only 9% of survey responses recognize this time as challenging for their organization
- 34% of participants are 'leaning in' to the challenges as a learning opportunity to improve and become more efficient



Q18 What have you learned from the pandemic that is helping or will help to improve your organization's overall performance?

- Almost half the comments were geared towards “cultural” and “mindset” aspects, along with building competency in a global virtual environment
- Many people shared that remote work provided flexibility, which they hope will be permanent
- There was a focus on speeding up technology solutions and integrations leading to:
 - More access / collaboration
 - Direct communication (less hierarchy)
 - Better system processes
- People stated how they were able and willing to adapt quickly, allowing organizations to transition effectively, even for large-scale changes



Q18 What have you learned from the pandemic that is helping or will help to improve your organization's overall performance?

Selection of Responses:

“**Flexibility in work practices** is a positive development, both for business and personal well-being”

“Definitely difficult and challenging times, but also exciting to see the **industry mobilize in ways we've never thought possible**”

“Regulatory Authorities are discussing how to **preserve COVID era efficiencies**, post the pandemic”

“There needs to be **more focus and investment in large changes** to optimize processes, tools and standards to increase efficiency”

“**New mind set** - everything is possible, and we make it possible”

“One challenge is some Health Authorities do not support standard conferencing technology (Zoom, Teams, Go To Meeting) for confidential meetings”

“Remote working = **broader/deeper talent pool**”

“More novel ways of interacting with regulatory agencies to allow for faster **incremental submissions** – a more agile way of submitting”

“We learned that people are able to handle and **adapt to change** well which should serve us as plan and implement change in the future”

Q19 As we continue to track the progress of COVID-19 Regulatory impact, would you be interested in participating in our follow-up survey? (6 months from now)



- Even though the race for an effective COVID-19 vaccine is in full force, predictions on post-pandemic foundational changes to Regulatory organizations continue to vary
- The next 6-12 months will provide more evidence to make the case for changes to become permanent or allow them to shift back to a 'new normal', likely resembling a 'pre-COVID' time.

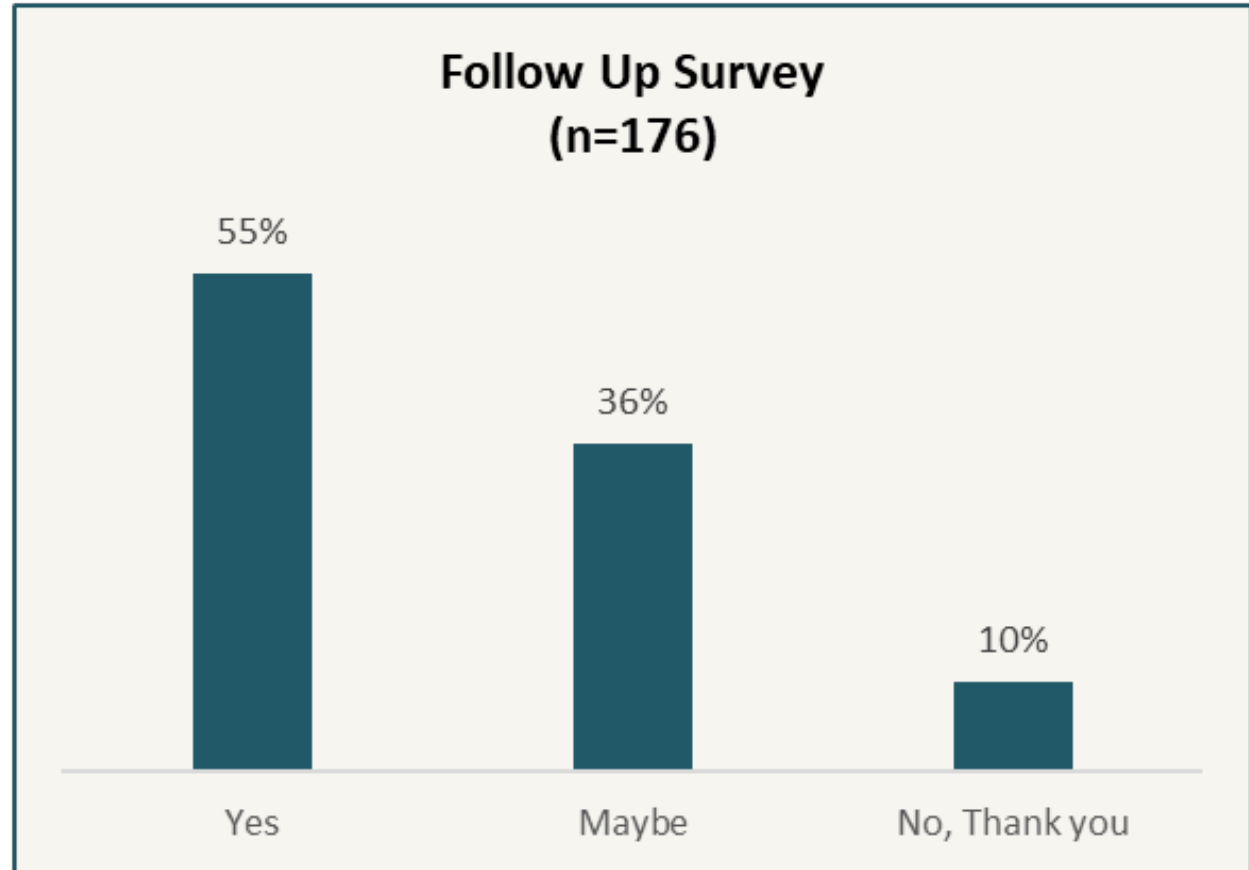


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Contact Information: Research Team Leads

Survey Authors	Business Phone	E-Mail	Practice Specialty
Katherine Yang-Iott	+1-914-420-1465	kyang-iott@gens-associates.com	Benchmarking, Organizational Performance, Continuous Improvement, Leadership Development
Steve Gens	+1-267-614-0935	sgens@gens-associates.com	Strategy and Roadmap Development, RIM Program Performance, Benchmarking, Organizational Performance

Research Team Leads

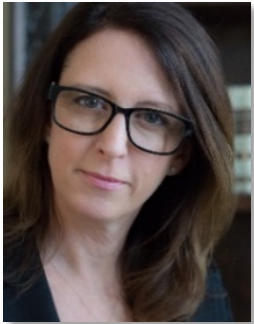


Katherine Yang-Iott (MSOD) is a core member of the Gens and Associates team with over 15 years of experience in the healthcare and pharmaceutical industry leading and managing complex interdisciplinary projects. She worked as a research scientist at Regeneron Pharmaceuticals and The Children's Hospital of Philadelphia before transitioning to consulting work, where she focused on strategy development and continuous improvement projects to support research operations. Katherine has a Masters of Science in Organizational Dynamics from the University of Pennsylvania and a Bachelors of Science in Biochemistry.



Steve Gens (MSOD) is the survey co-founder with the first industry survey conducted in 2007. The COVID-19 Regulatory Impact survey will be the 36th survey conducted under Steve's leadership. He has over 30 years of business experience with the majority in the biopharmaceutical and healthcare industries. His early career was spent at Johnson and Johnson and then moved into consulting where he managed several healthcare consulting practices for Booz Allen Hamilton and First Consulting Group. Steve has deep experience in strategy formulation and implementation, organization development and performance, industry benchmarking, information management strategy, and facilitating strategic change. He consults with many different sized life science organizations. He has a Master of Science in Organization Development from American University with distinction for his field work and an undergraduate degree in Business Computer Science. Steve is a frequent speaker and was named as one of the 2017 PharmaVoice 100 and recently to the 2020 R&D Pharmaceutical Innovators for his contributions to industry.

Supporting Research Team



Kelly Hnat of K2 Consulting has over 20 years' experience in the pharmaceutical industry leading both IT and RIM/Reg Ops organizations in several companies, including Wyeth, Pfizer, Shire and Teva. She is a key industry leader in the EU implementation of IDMP as a member of the SPOR Task Force and its PMS sub team and is a member of ISO TC/215. Kelly is Vice President of IRISS (www.iriss-forum.org) and is on the leadership team for IRISS' IDMP Topic Group. Her company, K2 Consulting (www.k2rim.com), is a specialty firm focused on Regulatory Affairs and a partner of Gens and Associates.



Preeya Beczek has over 23 years' experience across the life sciences industry. She has led regulatory projects across the entire product lifecycle in various therapeutic areas and platforms. Preeya has held roles at PAREXEL, GSK, Pfizer, JNJ, Ipsen, DOW Chemicals and worked with many other organizations as part of her client base and professional network. She has extensive industry experience and insights to lead and support teams across regulatory and compliance functions. Preeya has undertaken many large strategic and operational projects to help organizations reach operational effectiveness and increase regulatory compliance. Preeya holds a Bachelor's of Science degree in Chemistry and Management Studies and a Master of Science in Environmental Strategy from the University of Surrey, UK. She is also a qualified Lean Six Sigma Green Belt.

Supporting Research Team



Greg Brolund of Chicopee Falls Consulting (supporting survey process since 2009) is a management and technology consultant with experience with global Pharmaceutical companies in product labeling, submission publishing, Health Authority interactions, pharmaceutical safety and pharmacovigilance programs and ICH eCTD, E2B and HL7 ICSR electronic submissions.

He has over 25 years of experience in all aspects of information technology including the Food and Drug Administration's drug review process and supporting systems and as Chief Technology Officer for the US Department of Health and Human Services. He holds a Masters of Chemistry degree from the American University in Washington DC.

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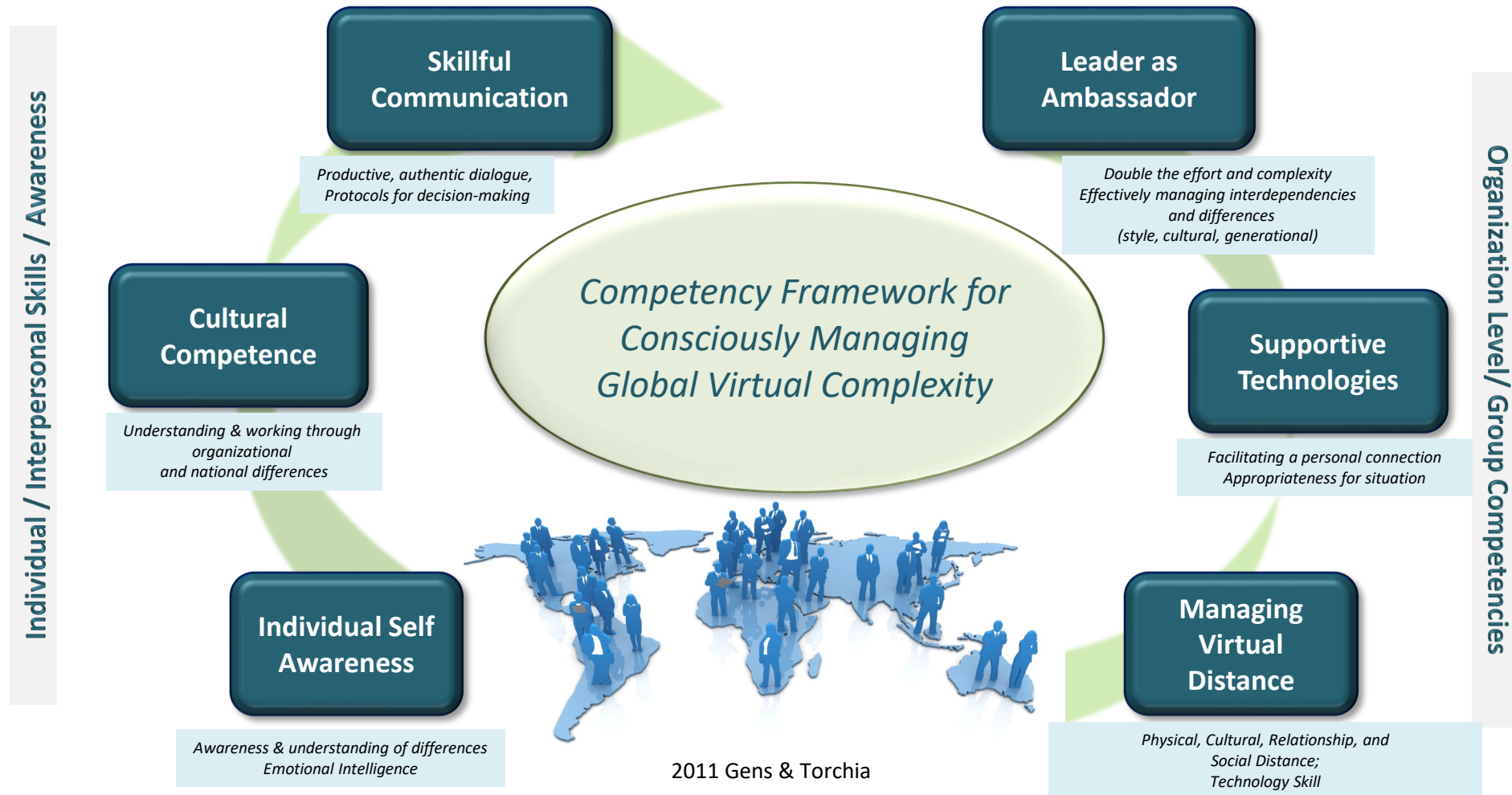
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Reference Materials

The following Model (2011 Gens & Torchia) was published over a decade ago on the skills and competency required to be successful in a global virtual environment

Improving Global-Virtual Effectiveness Model (Gens & Torchia)

Reducing Execution Risk and Increasing Innovation



Versatile Leadership

Flexibility and adaptability to manage diverse groups

Leader as
Ambassador

2011 Gens & Torchia

Leading global virtual teams takes 2 x's more effort than leading co-located teams. - Dyer & Dyer

Versatile leadership spans geographic, cultural and organizational boundaries to foster trusting relationships while balancing concern for both tasks and people

Competencies required:

- **Communication clarity and contextual awareness** – communicates clearly; ensures that understanding each other's contexts is a priority; is authentic and encourages other viewpoints
- **Bridge-building and advocacy** – facilitates the co-existence of differences; helps members to build relationships and form a collective identity that is recognized, celebrated and rewarded by others
- **Shared and situational leadership** – willingly shares sensitive information and builds relationships by providing guidance around intentions and larger goals; trusts team members to make decisions; adjusts management style to the situation at hand
- **Cross-cultural resourcefulness & agility** - appreciates cultural diversity understanding how different approaches work in different places; operates effectively under ambiguous or uncertain conditions; respects different value sets; leverages diversity to enhance innovation

Key Skills for Building Trust

Critical for forging productive, respectful relationships

**Skillful
Communication**

2011 Gens & Torchia

Communication Style Differences

- Recognizing someone's inherent style preferences based on culture, etc.. (High context vs. low context, direct and indirect)

Productive Dialogue

- Listening with the intent to understand rather than to respond; balancing advocacy with inquiry knowing that more creative and insightful realizations occur when people combine multiple perspectives

Building Shared Meaning

- Taking care to make evident the meaning – or lack of meaning –to ensure we are talking about the same thing; providing context for deeper understanding

Protocols for Decision-making

- Tools and skills to both broaden and focus the scale and scope of conversation with the intention of coming to closure on some topic or issue

Supportive Communication (for difficult conversations)

- Communication skills that seek to preserve or enhance a positive relationship while still addressing a problem, giving constructive feedback, or tackling a difficult issue

Understanding Cultural Differences

The most important global divide is no longer between political ideologies but between cultures

- O'Hara - Devereaux

Organization Culture

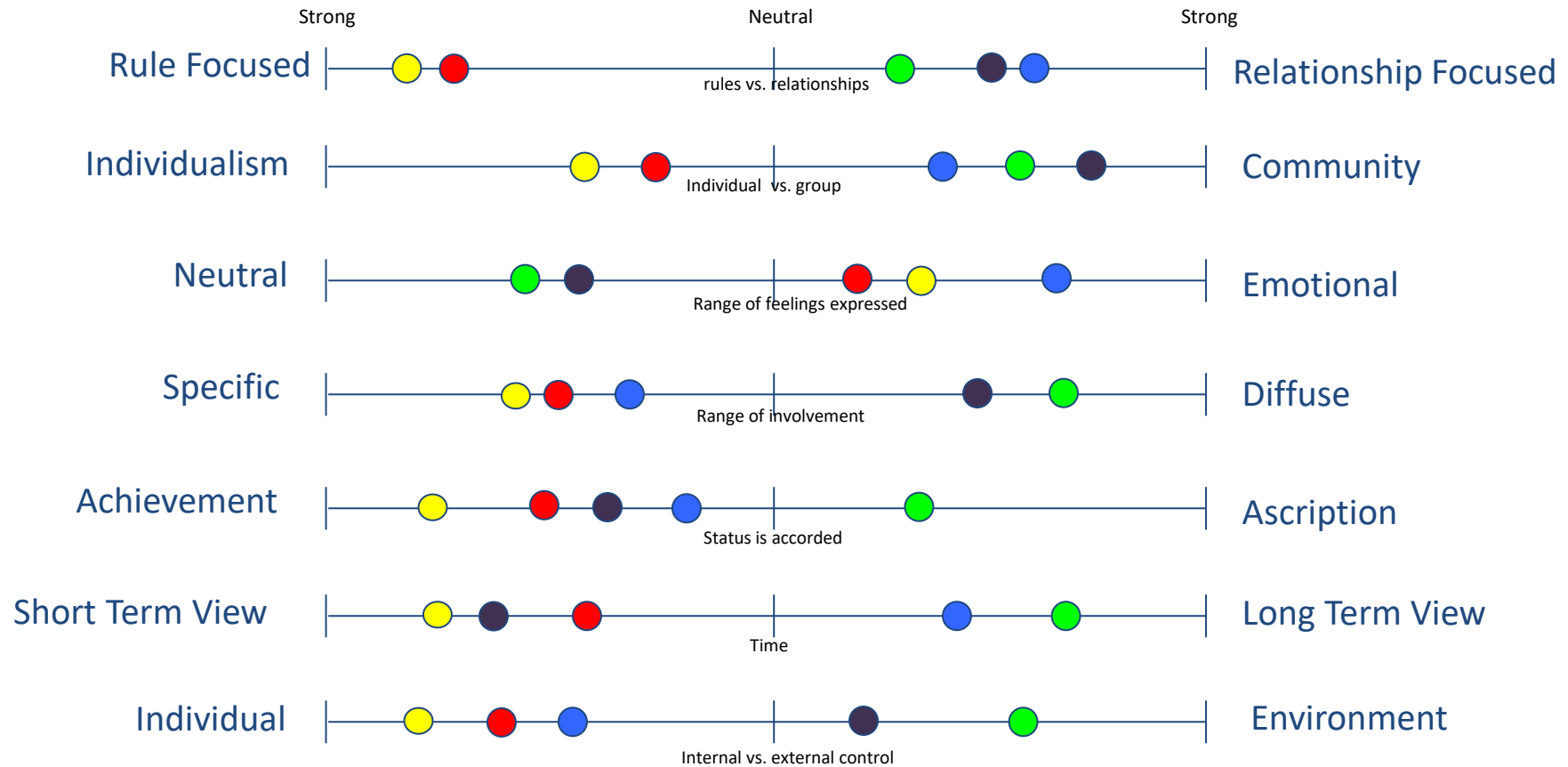
- How things get done; decision-making
- The “unsaid rules”; who has the power
- Priorities (focus on financials vs. all aspects of the business)
- Organization structure (by function vs. line of business)
- Communication norms (formal & closed vs. informal & open)

National Culture

- Language and orientation differences
- Rules vs. relationship
- Short-term vs. long-term
- Candid & outspoken vs. discreet & subtle
- Independent vs. duty to group
- Competitive vs. cooperative
- Obedience vs. consultation

Differences that may pose challenges in multi-national teams

- = France
- = United States
- = United Kingdom
- = China
- = India



How does one navigate these natural dynamics when you are not often face-to-face?

Cultural Company Resources

To “guide” and not “judge”

- Websites

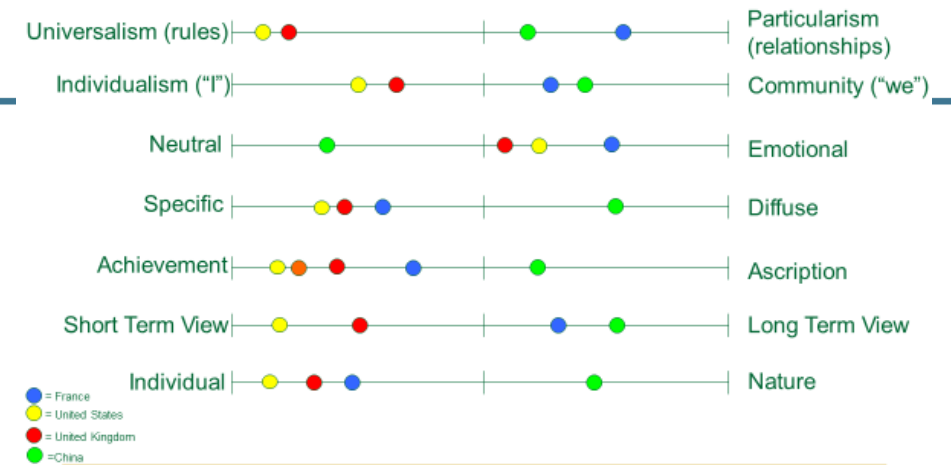
- <https://www.mindtools.com/pages/article/seven-dimensions.htm>
- <https://www.hofstede-insights.com/product/compare-countries/>

- Books

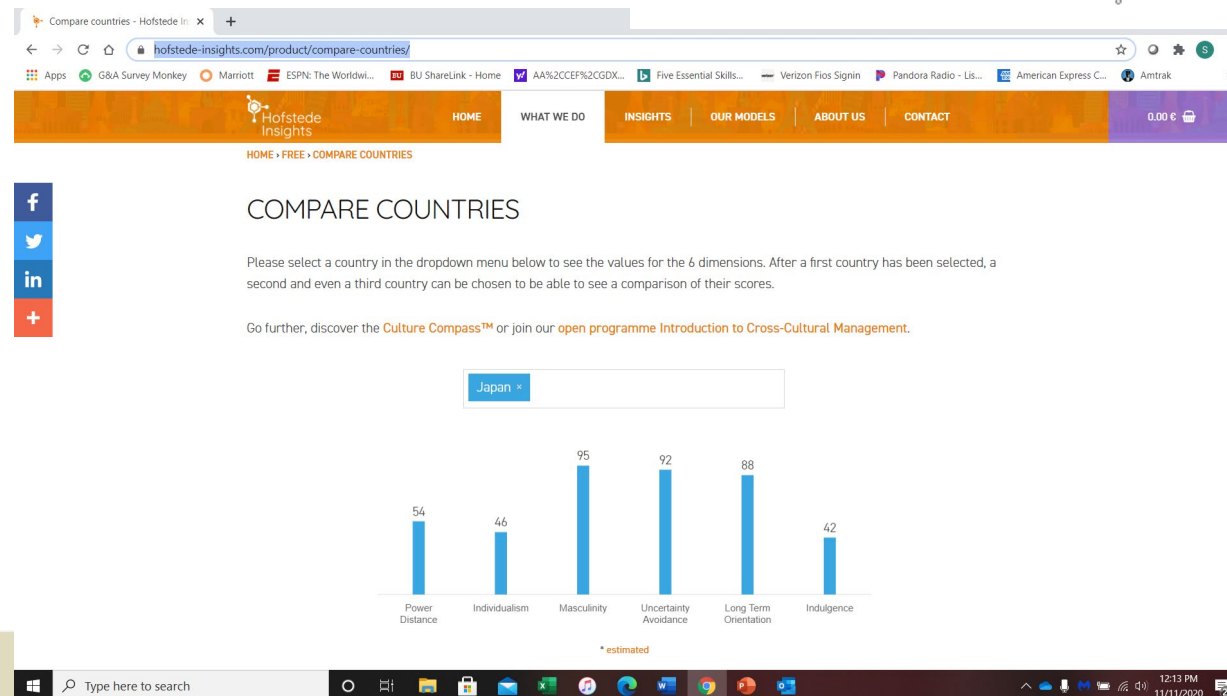
- Trompeers Hampen-Turnder – *Riding the Waves of Culture*
- Morrison, Conaway, and Boren – *Kiss, Bow, or Shake Hands* (classic)
- Hofstede – *Cultures and Organizations, Software of the mind*

Cultural Differences Scale Example

So...What's really going on with your team?



Source: Seven Fundamental Dimensions – Trompenaars Hampton Turner Grid: Gens and Associates Inc.

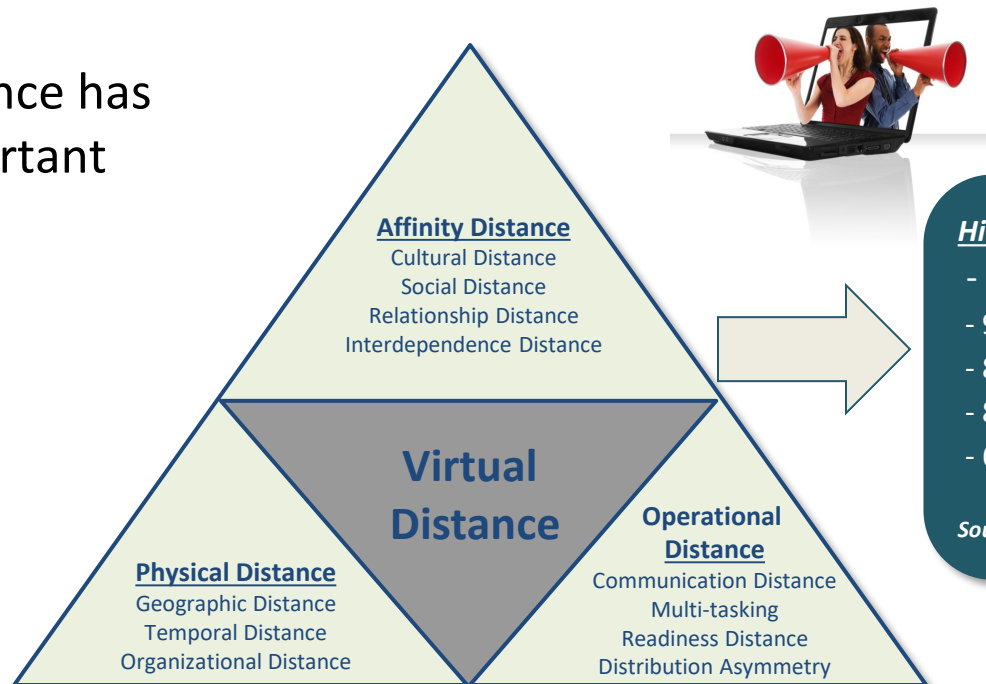


Virtual Distance™ and Performance

Applies to co-located, virtual, and global virtual teams

Virtual Distance exists whether people are separated by a table, miles or continents

- *Virtual Distance™* is the perceived distance between individuals and between groups when their primary method of communication and coordination is not face to face
- Virtual Distance has several important dimensions:



High Virtual Distance / Impact to Outcomes

- 50% decline in project success
- 90% drop in innovation effectiveness
- 80% plummet in work satisfaction
- 83% fall off in trust
- 65% decrease in role and goal clarity

Source: Logeski & Reilly (2008) survey of 400+ companies

Gens & Associates at a glance

Trusted source for regulatory benchmarking, thought leadership, and consulting excellence

A boutique **Life Science management and organizational consultancy** specializing in strategy, benchmarking, regulatory information management, and organizational transition

Benchmark Practice Goal: “Everybody Gets Better”

- ✓ **We have conducted 36 industry benchmarks to date;** Our data is considered the “industry standard” – widely quoted by industry analysts, providers and thought leaders.
- ✓ 160 unique companies have participated in our industry benchmarks with **90 companies currently active and benefiting from our latest research and insight**
- ✓ **30% participate in design** sessions that enhance the benchmark quality and credibility
- ✓ **35 + regulatory providers** (software, services, data) have benefited from this data so they are better aligned with where “industry is headed”



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Our 13-year Survey History

- Gens & Associates large biennial survey is conducted free for industry whose mission is **“everybody gets better”**
 - *The surveys are used extensively to determine individual company performance, peer comparison, understanding of key trends, and a detailed view of the provider landscape*
 - *Most participants use the benchmark to support their internal strategy, business cases, and organizational goals*
- Our first industry benchmark was in 2007 where 37 of the 50 largest biopharmaceuticals participated in our landmark research
 - *We have conducted a large empirical study every two years with small “pulse surveys” annually (deep dive in a specific topic)*
 - *We have a large cross-section of over **160 Life Science companies** (pharma, biotech, medical device, generic, consumer, agricultural etc.)*
- *In 2019, we began a **Premier Benchmark Membership** having additional benefits (strategic advisory retainer, private webinars, executive lounge of our private content) for a nominal annual fee in addition to our “pro-bona” benchmark relationship*
- We are first a consultancy with extensive knowledge and expertise of industry, health authorities, and the service/solution providers
 - *We design benchmarks that pull relevant data and trends*
 - ***We bring deep insight to the survey data and debrief sessions** unlike traditional market research firms who may only provide “surface” information*
 - *We conduct industry survey design sessions to maximize the value of our research*