

1. Demographics and Background Information

Your company and individual information are held in strict confidence and is never released to any organization. Companies will not know and cannot find out how individuals within their company responded to the survey. All participants and participant companies are blinded in the study results. Thank you for your participation!

The purpose of the survey is to explore the resiliency and agility of regulatory organizations in industry as a result of the COVID-19 pandemic.

* 1. Please enter your contact information for follow up and results.

First Name:

Last Name:

Company:

Title or Role:

Email for questions /
notification of results

* 2. What is your primary function in your company?

- Head of Regulatory Affairs
- Regulatory Strategy
- Regulatory CMC
- Regulatory Advertising and Promotions
- Submissions Management/Publishing
- Regulatory Information Management Group
- Regulatory Intelligence and/or Policy
- Label Management
- Pharmacovigilance
- Commercial or Manufacturing
- Government Affairs and/or Policy
- Information Technology
- Other (please specify)

* 3. What geographical location are you currently working from?

- Asia Pacific
- Eastern Europe
- Western Europe
- Latin America
- Middle East / Africa
- North America
- Other (please specify)

* 4. Is your organization directly involved with a COVID-19 related product at this time?

- Yes
- No
- Not Sure

2. Impact on Business

* 5. In general, how has the COVID-19 Pandemic impacted priorities in your Regulatory organization for the following? (Check all rows with one check per row)

	Accelerated	No Impact so far	Postponed	Cancelled	Not Applicable	I do not have the information to respond to this row
New Product Development (non-COVID-19 therapies or vaccines)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Regulatory System Investments	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Advanced Technology Investments (AI, Robotics, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Business Process Optimization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Organizational Change Initiative	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Continuous Improvement Program	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 6. 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? (Please select no more than 3 responses)

- Data Quality
- Connectivity with systems/data outside of RA
- Regulatory Intelligence
- Optimization of submission cycle times
- Virtual collaboration
- Business Continuity Planning
- N/A - no changes planned due to the pandemic
- Other (please specify)

* 7. Generally, how has the inability to meet in person impacted your relationships with outsource service providers and software partners? (Check all rows with one check per row)

	Positively impacted	No impact	Negatively impacted	Not applicable to my situation
Ability to manage provider deliverables	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability to plan future activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability to maintain relationship with existing provider	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability to build relationship with new provider	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. Impact on Ways of Working

* 8. 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? (Check all rows with one check per row)

	Increased	No Change	Decreased	Not Applicable
Ability to work flexible hours	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability to remote work (outside the office)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Completing role-related training and/or education	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Formal meetings	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Impromptu meetings	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability to balance work life and personal life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability to disconnect from work	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Personal work productivity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Building and maintaining relationships with internal co-workers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Availability of work colleagues	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 9. 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. (Check all rows with one check per row)

	This is only temporary	This will be a permanent change	No COVID-19 related impact or change	Not sure
Remote working	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Flexible work hours	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Business travel for meetings	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In person conferences	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frequency of office visitors/guests	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other systems or processes? (please specify)

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

	Strongly Agree	Agree	Disagree	Strongly Disagree	Not Applicable to my situation
Hardware (e.g. laptop, extra screens, printers)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Internet Bandwidth	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dependent care	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mental Health resources	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Physical Health resources	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other resources provided (please specify)

* 11. Once the COVID-19 public health crisis diminishes, there is an expectation for us to be at the office, if and when possible.

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Other (please specify)

* 12. I work just as effectively in a remote location as I do being onsite.

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Other (please specify)

* 13. I believe our organization... (Check all rows with one check per row)

	Strongly Agree	Agree	Disagree	Strongly Disagree
Is able to adjust effectively to the pandemic conditions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Is becoming more innovative as a result of the pandemic conditions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Is flexible and can quickly adapt to unpredictability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Has been able to 'do more with less' due to the pandemic environment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Has become more effective in global communications due to the pandemic conditions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. Impact on Regulatory Activities

* 14. In general, how has COVID-19 impacted the following Regulatory tasks and activities for your organization?(Check all rows with one check per row)

	Increased	No Impact (same)	Decreased	I do not have the information to respond to this row	Not Applicable
Number of investigational applications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Number of marketing applications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Number of Health Authority approvals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Number of Health Authority correspondence	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Number of Health Authority Interaction Cancellations and/or Delays	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Number of Health Authority planning meetings	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability to analyze and react to new Regulatory guidance documents	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changes to regulatory strategy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 15. How would you rate your organization's RIM capability effectiveness (processes and tools) in supporting remote work? (Check all rows with one check per row)

Dossier Management is related to creation and management of the dossier plan. The dossier plan is the specific assembly structure and associated content (planned and actual) needed to complete the production of a submission to be filed with a regulatory authority

	Very Effective	Effective	Ineffective	Very Ineffective	Not Applicable to my situation
Document Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Publishing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Registration Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Label Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Regulatory Intelligence	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dossier Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

	More Work	No Change	Less Work	My position does not have the visibility to respond to this question
Supply Chain Disruptions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sourcing API	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Customs/Border/Transportation challenges	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Physically delivering submissions to regulators in secondary markets	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Virtual Clinical Trials	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Clinical Trial Protocol amendments	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Health Authority Interactions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trial Medication (Production and Availability)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Government Affairs/Policy/Legislation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

- It is challenging for my organization to adapt to all the changes at this point in time
- We maintained the status quo and are operating effectively with minimal disruptions.
- We are using the pandemic as an opportunity to reassess our systems and processes in order to function more efficiently and improve our performance.

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

* 19. 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)

- Yes
- Maybe
- No, Thank You