COVID-19 RESPONSE PLANNING AND RISK ASSESSMENT

COVID-19 has caused a dramatic shift in the way biotech and pharmaceutical companies do business. Many of our clients have expressed concerns about how they can best assess the varied impacts of COVID-19 on their operations. While we have prepared specific guidance for some of our clients to help them formulate their response action plans and risk assessments, it seemed that information might be useful more broadly. Here we summarize some of those approaches at a high level.

TIMING

The biggest question we hear asked is, how long should companies plan to be impacted by COVID-19? The answer to this question impacts every aspect of response planning. It is our view that significant impacts from COVID-19 will be felt for at least 18 months (the fastest possible time to vaccine availability). We suggest putting in place flexible action plans that can be implemented in a modular fashion as the situation evolves. We also suggest making plans for immediate (next 30 days), medium (2-5 months), and long-term (6-18 months) response.

TEAM

Involving the right people in planning a response to COVID-19 is critical. While leadership is likely already involved in decision making related to COVID-19, we suggest also involving front line personnel in response planning and risk identification. Each function should be encouraged to meet and discuss the impacts and risks related to their work and what their response action and risk management plans would be. Ideally a Project Manager should integrate this information and roll it up to senior leadership to use in planning strategy.

RESPONSE PLAN

We envision three critical aspects to any successful COVID-19 response plan:

We suggest a modular action plan, which allows flexibility to implement different modules of the plan as the COVID-19 situation evolves. Management will decide which scenarios to plan for based on intelligence gathered. A modular action plan should be created for each scenario. Functional teams should map their responses to each scenario, clearly noting actions to take and person(s) responsible. A Project Manager will roll-up functional team plans into the modular action plan.

The Implementation Strategy drives which Modular Action Plan should be executed. Adopting "if, then" logic to define which modules to implement in each situation would be a simple way to construct such a strategy.

The response plan should also include the Risk Assessment and Management Plan with clearly defined risks, planned responses (accept, avoid, reduce/mitigate, set contingency, or transfer), likelihood, timing, owner, and probability. The risk assessment and management plan should be used to track when risks become issues and to document the response taken, decisions impacting downstream activities, and/or any plan changes.

Please note the approach outlined here is one of the many possibilities. Companies should consider what would work best given their organizational structure and culture.

QUESTIONS TO CONSIDER

Below are key questions functional teams may want to consider as they start planning. The considerations listed are not all-encompassing but provide a starting point for teams planning a response to this crisis and assessing the risks underlying that plan.

CATEGORY	*CONSIDERATIONS*

RAW MATERIALS 	• How could COVID-19 impact your raw materials supplies?
	• Which raw materials would you consider at risk?
	• What alternate sources have you identified for any "at risk" raw materials?
	• Are there any raw materials for which alternate sources cannot be identified?
	• How are countries you receive supplies from impacted by travel or import restrictions?
	  o How might courier flights or shipments be impacted?
	  o How could overall flight reductions impact shipping timelines?
	• How long will inventories of raw materials last?
	• With the possibility of long-term impacts due to COVID-19, which raw material stocks do you need to increase as soon as possible in case supply is further disrupted?

SUPPLY CHAIN 	• How might COVID-19 impact your supply chains more broadly?
	• Consider impacts to the following partners, if applicable:
	  o Storage (Cells/Seeds, Bulk DS, Finished DP)
	  o CMO
	  o Fill/finish
	  o Label and packaging
	  o 3rd Party Logistics (3PL/TPL)
	  o Distributors/Specialty Distributors
	  o Specialty Pharmacies
	• Do you have material in Storage that could become short dated or expire due to decreased demand and how do you plan to deal with this material?

MANUFACTURING/ LABORATORY EQUIPMENT 	• How could manufacturing or laboratory equipment be impacted by COVID-19?
	• Are there any older pieces of equipment that might need parts or repairs in the next 18 months?
	• Do you have adequate supplies of replacement parts in inventory?
	• Do you anticipate any issues in being able to receive maintenance or technical support from equipment vendors during this time (consider travel restrictions and remote support)?
	• Are you taking delivery of or installing any new equipment in the next 6-12 months that could be impacted by COVID-19?
	• Could the timelines for installation of new equipment be sped up or slowed down in reaction to COVID-19?
	  o How would that impact other timelines?
	  o What are the advantages and disadvantages of either approach?

PPE/CLEANING 	• Are adequate PPE (Personal Protective Equipment) supplies available to continue production and/or release testing? • How can adequate supply of PPE and cleaning/sterilization supplies be ensured moving forward given the potential for an ongoing outbreak lasting 18 months or more? • If there are essential staff on-site during the outbreak, do they require masks or gloves to be in the facility around other staff? • What additional cleaning procedures/services may be needed during this time to ensure staff and product safety?
MANUFACTURING 	• Is your manufacturing site considered 'essential' by local definitions and how would you be impacted by site closures mandated by local governments? • How could manufacturing staff and schedules be impacted by government restrictions on working and gathering and do you have a mitigation plan in place? • If you will continue manufacturing, how do you plan to monitor staff for illness and protect others?

QUALITY ASSURANCE 	• How could QA processes and batch release be affected, and do you have a mitigation plan in place? • Are any outside testing labs used for release testing that could be impacted by ability to ship samples or otherwise? • If any outside testing labs utilized are at Academic Centers how are these impacted by COVID-19 and university closures? • Is your local regulatory agency involved in batch release and how might that process be impacted?
CLINICAL 	• Have you read the "FDA Guidance on Conduct of Clinical Trials of Medical Product during COVID-19 Pandemic"? Safety of trial patients is vital, and your study may need to be modified. *Clinical Trials-In study startup phase* • Will you need to update your protocol and ICF to include COVID-19 testing based on sites' IRB/EC requests or due to other policy changes? • Will sites still engage in study start-up activities during this time or is the study site staff available? • Will site qualification or site initiation visits be on hold or is it possible to have these virtually? • What study start-up activities can be conducted while sites may have put the trial enrollment on hold (site feasibility, phone qualification visits, study plans, study document creation)? • Have you reviewed your budget and discussed options for vendor/site fees should your start-up activities be placed on hold? *Clinical Trials-In progress* • Is your study patient population impacted specifically due to COVID-19 (emergency room enrollment, indication is a COVID-19 risk factor, etc.)? • Is the study staff available at the investigational site? Have they implemented COVID-19 control measures? • Will you need to amend the protocol and ICF due to sponsor, site or IRB/EC policy and procedure changes? • Will patients still be able to obtain and continue use of the investigational product? • Are in-person patient visits necessary to maintain the safety of trial participants? • Have you determined options to conduct safety assessments (virtual, alternative locations)? • Is on-site monitoring possible? • Have you addressed the fact that missed visits and missing data (and study discontinuation due to COVID-19) will need to be explained in the case report form?
REGULATORY 	• Do you anticipate any delays from your local regulatory authority on approvals or inspections due to COVID-19? • How do you plan to mitigate those delays?
MEDICAL AFFAIRS/ SAFETY 	• How will Medical Information inquiries be handled if staff must work remotely to ensure that there is continuity of processes and all requests are captured and responded to? • How will AE reporting be impacted and what steps need to be taken to ensure continuity of AE reporting processes? • How will Medical Affairs Field Team be impacted and how will open communication with this group be maintained? • What opportunities exist for utilizing Medical Affairs Field Team while they cannot call on their accounts?
COMMERCIAL 	• How will Commercial Field Team be impacted and how will open communication with this group be maintained? • How will the decision to allow the Commercial Field Team to return to work be handled? • What opportunities exist for utilizing Commercial Field Team while they cannot call on their accounts?
HUMAN RESOURCES 	• How are management staff impacted by COVID-19? • What steps have you taken to ensure the safety of your employees as relates to COVID-19? • What mechanisms are in place for employees to report illness and for confidentially tracking staff that may have been impacted by COVID-19? • How should travel policies be adjusted to reflect the current reality and to be prepared for future travel issues related to COVID-19? • How should sick time/leave policies be adjusted for COVID-19?

BUSINESS CONTINUITY 	• Which key functions are currently in need of back-up personnel being trained to do work should someone fall ill? • If back-up personnel are not available could the activity be automated? • Are all key documents stored in shared areas where they can be accessed by the person with primary responsibility for the document and their back-up?
FACILITIES 	• What is your facility closing plan? • Have you looked into whether your activities would be deemed "essential" and how this could impact decisions and planning around facility closure? • What are your plans for reopening facilities?
DOCUMENTATION/ COMMUNICATION 	• How are you documenting the decisions made surrounding COVID-19? • In what ways are you communicating response plans to the key players and all staff? Are different levels of communication needed for different internal audiences? • How should staff communicate concerns, risks, or issues they identify to ensure these are reviewed and evaluated appropriately?
INTELLIGENCE 	• Which individuals/groups are responsible for gathering intelligence, environmental monitoring, conducting situational analysis, and synthesizing that data to produce planning scenarios? • Is there a way to centralize the intelligence gathering process to ensure a more coordinated response? • How should individuals or functions escalate intelligence to those responsible for analyzing and collating this information? • What decision making groups will review intelligence gathered and make the final decisions on which situations the modules of the response action plan should address?
OTHER RISKS 	• What other critical path risks to your business related to COVID-19 have you identified? • Given the above, how do the identified risks impact timelines for key corporate goals?

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