# Supplemental Information

## Survey

**Clinical considerations and health system workflow approaches for monoclonal antibody (mAb) treatments**

* Given the growing experience implementing mAbs workflows, what changes were made compared to when the program was stood up? What necessitated workflow changes?
* How did approaches to administration route and mAbs treatment product consider patient and provider preferences?
* What were the trigger points or entry routes used by patients to onboard into the health system? How were vulnerable patients served by the health system able to access mAbs?
* How did the health system organize the mAb supply chain and distribution?
	+ What strategy was used to monitor treatment uptake? Provider prescribing practices and patterns?
	+ Was there any variation observed across zip codes and counties with respect to prescribing patterns? Did the variation observed in prescribing patterns have an impact on health outcomes?
	+ How did the health system prepare for and address demand for mAbs treatments against the onset of new COVID-19 variants?

**Patient risk stratification strategies**

* What was the approach used to confirm COVID-19 cases?
* What key variables were important to include beyond the EUA criteria for purposes of efficiently and equitably distributing mAbs treatments to patient populations?
* Did any part of the risk model not perform the way expected?
* How does the model deal with symptom onset of COVID and specifically mAbs administration outside of the 10-day window?
* Were patient identification guidelines modified in response to new evidence and regulatory developments? What effect did shifting supply and demand have on patient prioritization?

**Infrastructure and platforms, i.e., data infrastructure and physical infrastructure for delivering mAb infusions**

* Broadly, two types of infrastructure include data infrastructure for purposes of collecting clinical data and supporting administrative processes, as well as physical infrastructure for delivering mAbs treatments.
* What infrastructure components were most important to the health systems’ mAb workflow?
	+ Of these key infrastructure components, what was previously available to the mAbs program and what needed to be sourced externally?
	+ For external sourcing of infrastructure requirements were any partnerships developed?
	+ What capital investments were made to establish the necessary data or physical infrastructure needed to implement mAbs data collection and clinical workflows?
* Data infrastructure questions.
	+ What were the key challenges with data collection efforts?
	+ How were key variables from the risk stratification strategy collected (e.g., symptom onset date or COVID symptoms)? What approaches were used to pull unstructured data (e.g., natural language processing vs manual data extraction)?
	+ How was program effectiveness and continuous improvement monitoring implemented? What process or outcome metrics were used (e.g., leading or lagging indicators) or other types of feedback mechanisms?

**Governance and policy considerations.**

* What were the most critical success factors for developing mAbs delivery programs?
* How could your experience be replicated to encourage less sophisticated healthcare systems to participate in future RWE research on therapeutics?
* What governance structures were developed to stand up mAbs programs?
* What was the decision-making chain of command?
* How involved was health system leadership in the development of the mAbs program?
* Which stakeholders and partnerships were essential to implementing the mAbs program? To what extent was there engagement with the broader healthcare industry in the development and implementation of the mAb program?
* Which stakeholders and partnerships were most important for improving access to and equity for mAbs treatments?
* After receiving the completed, written survey from the health system, a follow-up interview was scheduled to further explore key issues and insights.

## Interview Guide and Script

A formal interview guide was created to provide consistency across video interviews. The guide was heavily based on the initial survey questions with sub-questions added in along with a final questions section.

**Interview Script**

**Note***: This script and set of instructions are intended as a guide for the interviewer. Interviewer discretion in phrasing, using prompts and additional questions or explanation may be necessary because this is a qualitative interview. Qualitative interviews necessarily have a conversational aspect, and will almost always diverge at some points from a script. The interviewer may therefore adjust wording, for instance, to acknowledge and take into account that an interviewee has already offered some information in response to a prior question, to clarify a response, or to solicit more information.*

**INTRODUCTION**

Hello. This is [NAME], calling from [ORGANIZATION].

We previously scheduled this time/day for an interview. Is this still a good time for us to talk? We will need about 45 minutes.

*If not good or not enough time:* Could we set up another time for the interview? I’d be happy to call back at a time that is better for you.

*If time is still good:* Wonderful! Did you get a chance to review the study information sheet?

*If yes:* Ok great, we’ll go ahead and get started.

*If no:* No problem, I’ll go over some of the background information with you.

*[go over information]*

Do you have any questions about the study or the study information sheet?

*[answer questions as needed]*

I would like to, first, ask for your permission to record our conversation. The purpose of the recording is so that we have an accurate record of the interview and for our internal analysis of your responses. Do I have your permission to record our interview today?

I also want to remind you that you can skip any questions you’d rather not answer, and you can end the interview at any time.

Do you have any other questions for me before we start?

*[answer questions as needed]*

To begin, might you share with us your professional role within your health system?

*[If willing to share: Ask him/her/them to elaborate. Engage with the use of follow up questions, if needed.]*

*[If not willing to share: Skip to the next question.]*

***Clinical Considerations and Health System Workflow Approaches for mAb Treatments***

**Question 1:** Given the growing experience implementing mAbs workflows, what changes were made compared to when the program was stood up? What necessitated workflow changes?

*How would you describe these changes? Were additional investments necessary to support these changes?*

**Question 2:** How did approaches to administration route and mAbs treatment product consider patient and provider preferences?

*How might have these preferences changed over time given three mAb treatments authorized—along with one mAb treatment authorized for subcutaneous injection?*

**Question 3:** What were the trigger points or entry routes used by patients to onboard into the health system? How were vulnerable patients served by the health system able to access mAbs?

**Question 4:** How did the health system organize the mAb supply chain and distribution?

*Was the mAb supply the chain and distribution organized centrally or did local sites have their own autonomy to organize and implement distribution?*

**Question 4a:** What strategy was used to monitor treatment uptake? Provider prescribing practices and patterns?

**Question 4b:** Was there any variation observed across zip codes and counties with respect to prescribing patterns? Did the variation observed in prescribing patterns have an impact on health outcomes?

**Question 4c:** How did the health system prepare for and address demand for mAbs treatments against the onset of new COVID-19 variants?

***Patient Risk Stratification Strategies***

**Question 5:** What was the approach used to confirm COVID-19 cases?

*What were the advantages and limitations of this approach?*

**Question 6:** What key variables were important to include beyond the EUA criteria for purposes of efficiently and equitably distributing mAbs treatments to patient populations?

**Question 7:** Did any part of the risk model not perform the way expected?

*How were you expecting those parts of the risk model to perform? Was it immediately obvious or did it take time to understand the model’s behavior?*

 **Question 8:** How does the model deal with symptom onset of COVID and specifically mAbs administration outside of the 10-day window?

**Question 9:** Were patient identification guidelines modified in response to new evidence and regulatory developments? What effect did shifting supply and demand have on patient prioritization?

***Infrastructure and Data Platforms***

**Question 10:** Broadly, two types of infrastructure include data infrastructure for purposes of collecting clinical data and supporting administrative processes, as well as physical infrastructure for delivering mAbs treatments. What physical and data infrastructure components were most important to the health systems’ mAb workflow?

**Question 11:** Of these key infrastructure components, what was previously available to the mAbs program and what needed to be sourced externally?

**Question 11a:** For external sourcing of infrastructure requirements were any partnerships developed?

**Question 11b:** What capital investments were made to establish the necessary data or physical infrastructure needed to implement mAbs data collection and clinical workflows?

**Question 12:** Data collection questions.

**Question 12a:** What were the key challenges with data collection efforts?

**Question 12b:** How were key variables from the risk stratification strategy collected (e.g., symptom onset date or COVID symptoms)? What approaches were used to pull unstructured data (e.g., natural language processing vs manual data extraction)?

**Question 12c:** How was program effectiveness and continuous improvement monitoring implemented? What process or outcome metrics were used (e.g., leading or lagging indicators) or other types of feedback mechanisms?

***Policy/Governance***

**Question 13:** What were the most critical success factors for developing mAbs delivery programs?

*Why do you believe these were the most critical factors?*

*Is there any precursor work or investment needed to realize these critical factors?*

**Question 14:** How could your experience be replicated to encourage less sophisticated healthcare systems to participate in future RWE research on therapeutics?

*What are the biggest barriers to conducting RWE research?*

*Are there specific tools or workflows you think would be important for health systems that would remove these barriers?*

**Question 14a:** What implementation experiences could inform continued healthcare system learning around mAbs and new COVID-19 treatments coming to market?

**Question 15:** What governance structures were developed to stand up mAbs programs?

**Question 15a:** What was the decision-making chain of command?

**Question 16:** How involved was health system leadership in the development of the mAbs program?

*If the health system’s leadership was involved and actively supported the development of the mAbs program, what factors or considerations were important to getting this level of buy-in?*

**Question 17:** Which stakeholders and partnerships were essential to implementing the mAbs program? To what extent was there engagement with the broader healthcare industry in the development and implementation of the mAb program?

**Question 18:** Which stakeholders and partnerships were most important for improving access to and equity for mAbs treatments?

*Were any partnerships developed with organizations outside of the health system?*

***Final Questions***

**Question 19:** Thank you, are there lessons learned that could be applied to other treatment modalities, such as antiviral medications or other treatment modalities?

*If yes:* *What was your experience? Can you elaborate?*

*[If no: Ask to elaborate why there may not be any lessons learned. For example, were there any logistical or operational barriers that hindered the development of lessons learned?]*

**Question 20:** Considering what we’ve discussed today, I have a few more questions that may require more elaborative responses:

**Question 21:** How could you envision that your health system could contribute mAb patient outcomes information for rapid cycle RWE outcomes research at the regional or national level?

**Question 22:** How could your experience be replicated to encourage less sophisticated healthcare systems to participate in future RWE research on therapeutics?

*What capital investments were made in your health system that you feel might be needed to encourage ongoing RWE research in other health systems who are beginning to build data infrastructure for real-time, continuous learning activities?*

***\*\* A number of the interview questions may yield yes/no types of responses among the participants. We anticipate that most interviewees, especially once the interview is underway, will elaborate without prompting. If the interviewee answers only “yes” or “no” use one of more of the prompts below to encourage them to elaborate as appropriate. \*\****

**OPTIONAL PROMPTS TO USE THROUGHOUT THE INTERVIEW AS NEEDED**

Could you tell me more about what happened?

Do you remember anything else about that?

Do you recall anything else about that?

Could you tell me more about that?

Could you say more about that?

Could you elaborate?

Could you tell me more about how the situation unfolded?

Could you tell me more about what happened?

How could that have been handled better?

What would have prevented that from happening?

How would having/doing X improve the situation?

Great! We have reached the end of the interview.

Do you have any comments or questions for me?

*[If yes: Address participant questions.]*

*[If no: Proceed to conclude the interview.]*

Thank you again for taking the time to interview with me. We truly appreciate and value the time spent. Good bye.

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