



Medical Information FAWG: How COVID-19 EUA Impacted the Provision of **Medical Information**

Disclaimer

The views expressed in this Webinar are those of the presenters, and are not an official position statement by MAPS, nor do they necessarily represent the views of the MAPS organization or its members.

This presentation is for informational purposes only and is not intended as legal or regulatory advice.

Moderators



Sara Doshi Director, Global Medical Affairs Intelligence Eli Lilly and Company



Leena Jindia Senior Director, Content Strategy & Innovation Janssen Pharmaceuticals

Presenters



Prachee Satpute, **PharmD**

Associate Director Medical Information

Gilead Sciences



Ana Barrias, **PharmD**

Director, Global COVID-19 Vaccine Readiness Lead & Regional Vaccines - I&I Lead

Pfizer



Laura Miesle, PharmD, RPh

Consultant Global Medical Information – Biomedicines

Eli Lilly and Company

Housekeeping

Questions for Presenters:

Please submit questions throughout the presentation using the Q&A button in your control panel.

Evaluations:

The control panel includes a webinar evaluation. Please complete that evaluation so that we can work to ensure the highest quality presentations.

On-demand Availability of Webinar:

As with all previous webinars, the webinar recording, and this PowerPoint deck, will be av ailable on-demand next week for download by MAPS members via in the MAPS website Content Hub.

Educational Objectives

This session will provide a learning opportunity for our audience by:

- Providing a brief introduction to EUA
- Informing as to what measures were taken to prepare medical information to respond to customer requests for an EUA product from a resourcing and content perspective
- Seeing unique opportunities to leverage new methods of delivery and channels for medical information in an EUA scenario



Emergency Use Authorization (EUA)

EUA Background

- During public health emergency, may be urgent need for products to help protect against chemical, biological, radiological, and nuclear threats
- Provide more timely access to drugs, diagnostic tests, etc.
- Can't wait for all evidence so FDA reviews what is available, evaluates risk/benefits
- EUA guidance finalized January 2017
- On Feb 4, 2020: notice of declaration under PREP Act for medical countermeasures against COVID-19



Medical Information Preparedness

Considerations for resourcing, content creation, handling media and consumers, contact centers and channels, and external partnerships

MI at the Forefront

- MI serves as primary point of contact for drug and companysponsored program information
- Anticipated influx in calls and overall inquiries
- Leverage call center personnel to handle influx
 - Consider need for expanding hours of operation
 - Modify phone tree
 - New channels (callback service, digital)
- Flex in-house staff for coverage

Resourcing

- Expected exponential growth in inquiries volume, difficult to predict realistic resources needs
- No large-scale experience with simultaneous launch worldwide to global population



- Expanding hours of operation and need of qualified staff
- Direct relationship with MI strategy Traditional vs Digital (self-service penetration)
- Explore New Ways of Working Digital/tech, Flex in-house staff, Flex X-Teams, Vendors
- Select or up-scale qualified Vendors
- Agile/timely recruitment & training of large new teams (in-house/vendor)
- Build capacity to manage expanded teams, KPIs delivery
- Ability to motivate and retain talent (pressure environment)
- Quick responsiveness in readjusting resource needs



Content

Content Creation & Frequency of Update

Challenges **Opportunities** Innovation



- Create Large Content Collections in lightspeed, Anticipate frequently asked topics
- Manage Initial Limited Data (Label, Recommendations, Publications)
- Develop optimized Methodology to timely Access New Data (internal & external)
- Need to Include Specific Disclaimers (reflecting EUA nature)
- Create Different Content Formats (MI Channels and HCPs & Patients/non-HCPs)
- Internal Collaborations (Clinical, Medical, Regulatory, Manufacturing, Drug Safety, Comms)
- Need of SME MI Involved (expertise & resilience, country & global understanding)
- Manage Frequent Data Updates, Agile Internal Review/Approval Process (MI & non-MI)



Managing Media Impact

Managing Media Impact

- Massive & Daily Media Exposition, Any Arising Topic Promptly Escalated & Deeply Scrutinized
- Target Audience is General Public with Iower Health Literacy
- Lack of Proactive Visibility of what will be made Public
- Need to Promptly Generate Content able to Respond
- Create Adjusted Content (Clear and Objective Messages)
- Need of Internal Collaborations for prompt access to data and X-alignment
- Ensure Content Transparency, Support Company Proactive Data Disclose (Vaccine & Vaccination Trust)





Consumer Focus

How to Handle Patients/Consumers

Agility in Implementing/ /Delivering Specific MI Service



- Unique situation, disproportionate Patients/Consumers inquiry volumes vs HCPs
- Need to train MI teams to efficiently manage:
 - Patients Anxiety & Urgent Demand
 - Media Influence
 - Limited Health Literacy
 - Show Empathy
- Create specific MI content (plain language, adjusted to health literacy, respect label)
- Manage customer frustration on limited advice
- Quick responsiveness for key topics (access, supply, safety/AE, efficacy)
- Opportunity to develop specific Digital/Tech Channels for Patients



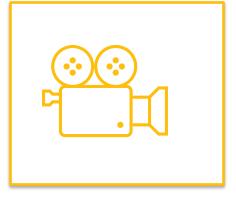
Medical Information Channels

Alternate Content Modalities for a Multichannel Approach

- Due to the sense of urgency around content creation to support the EUA products, the repurposing of deliverables from other workstreams for RUR was necessary to round out the RUR portfolio
- Content needed to be accessible through multiple RUR channels



GMI









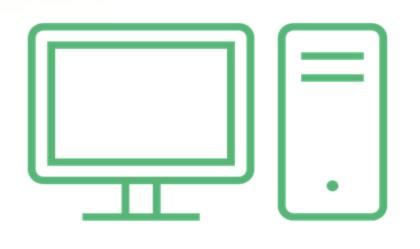
Marketing Medical Affairs

Corporate Communications

Health Education

Scientific Communications

Digital Maximization – COVID-19 Website Enhancements





Leveraged existing US **HCP** website for

- product specific MI
- disease state resources

Contributed to content reviews for

EUA specific HCP/consumer website



Developed novel global **HCP** website for

- product specific MI
- disease state resources

Digital Maximization – US COVID-19 Chatbot Development





What information would you like to learn about next?





OK. Here are some other topics we can review together:

FAQs and Resources Authorized Use Dosage and Administration Clinical Data Access

Report an Adverse Event or Product Complaint

Digital Maximization – US Drug Information Compendia

Due to the sense of urgency in reaching HCPs with accurate information where they are, we proactively submitted HCP Fact Sheets for COVID-19 EUA products to US drug information compendia

Field Medical Teams



Dedicated team of US MSLs for COVID-19 EUA products



Information Request

Medical Science Liaison Request

Launched digital access to request MSL on US HCP MI website



Launched direct escalation to MSL from Contact Center

Contact Centers



Dedicated team of COVID-19 contact center agents for EUA products



Dedicated COVID-19 Hotline Phone number Expanded coverage hours with weekend on-call coverage as well

Call Us

If you have immediate questions regarding COVID-19, or to report an Adverse Event or Product Complaint, please call us.

1-855-LillyC19 (1-855-545-5921)

Daily Live Support: 9am to 7pm ET. After Hours: Call Back Support Available Or you can

- E Chat with us
- Submit a Request Information Request

Click to chat with a live agent on US HCP MI website



External Partnerships and Collaborations

External Partnerships and Collaborations



- Health Authorities, HCP Professional Associations & NGOs
- Government Organizations
- Food and Drug Administration
- Healthcare Systems
- Medical Education Providers



Transition from EUA to Full Market Approval

Transition to Full Market Approval

- Update all content to align with approved label
- Train call center staff

Conduct necessary trainings for new commercial field teams and related activities

Prepare for increase in inquiries from commercial field team



Lessons Learned

Keeping Teams Engaged

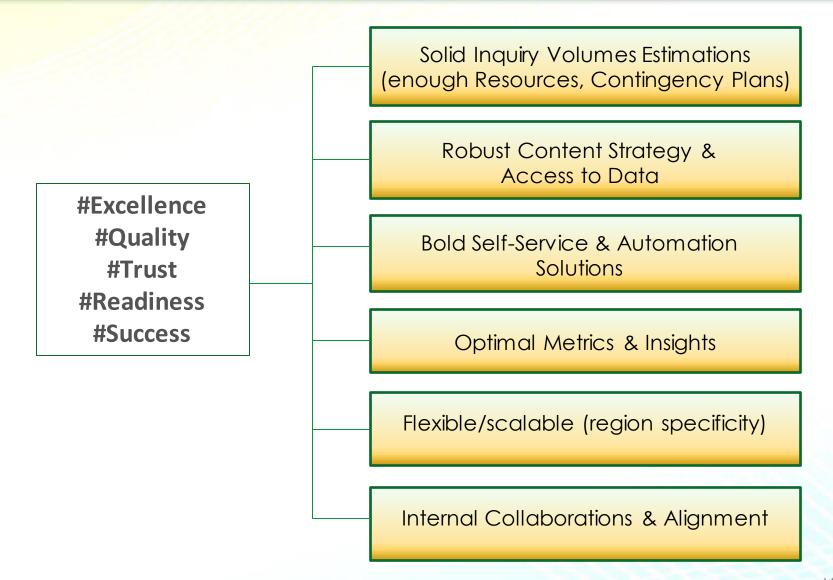
- Realize significance of rapidly evolving disease state and data
- Increase communication and transparency (reciprocal)
 - Information and knowledge sharing
 - Key metrics and SLAs
- Ensure needs of teams are met

 Engage call center teams by soliciting feedback on content and interactions with customers

Data Sources in the Pandemic

- Maximize internal library services and auto alerts for key websites and preprint servers if possible
 - Data surveillance was key driver of MI content updates
- Realize significance of data disclosure by press release
 - Information published in lay press became critical drivers of questions
 - Engaged library services to monitor lay press for critical communications
- Importance of close collaboration with internal corporate communications
 - Understand planned media communications to proactively create responses based on anticipated questions

Well Defined Strategy







Prachee Satpute, PharmD Associate Director Medical Information Gilead Sciences



Ana Barrias, PharmD Director, Global COVID-19 Vaccine Readiness Lead & Regional Vaccines - I&I Lead Pfizer



Laura Miesle, PharmD, RPh Consultant Global Medical Information – Biomedicines Eli Lilly and Company

Thank you! Questions?