Appendix A: Interview Questions for Pharmaceutical Companies

Future Value of AI in Regulatory Intelligence

1. What do you believe are the biggest challenges and hurdles in regulatory intelligence for your company?

2. **A.** What areas or activities of regulatory intelligence do you think pose the most significant opportunity for AI?
   B. Can you think of a time in your work that you did not have the best information to make decisions? What were the consequences?
   C. Imagine a situation where the best information was always at hand when making decisions. How would this impact your work?
   D. What suggestions do you have for how to best capture the potential value offered by artificial intelligence in regulatory intelligence?

Regulatory Intelligence, AI and the Organization

3. Have you or your company tried using AI in regulatory activities? If so, for what? If not, why?

4. **A.** Do you or your company have plans within the next two years to try AI or introduce more AI into regulatory intelligence?
   B. If so, for what? What do you expect to learn? How do you anticipate it will help you?

5. What type of information from the public domain would you see as the most valuable to analyze using AI? How could it be combined with other external information? Other internal information?

6. What are the internal risks and barriers to using AI in regulatory intelligence? What are the external ones?

7. Do you foresee any difficulty in justifying a decision taken based on such a tool to regulators / regulatory agencies? Internal colleagues?

8. Do you think you would ever be able to base a decision on such a tool? If so, what reassurance would you need before doing so?

Collaborating to Use AI

9. What role, if any, could a precompetitive consortium play in advancing AI's use for regulatory intelligence?

10. If a precompetitive consortium were initiated, what other stakeholders (besides biotechnology companies) should be included?

11. **A.** Hypothetically, would you consider joining a precompetitive consortium focused on artificial intelligence for regulatory intelligence? Why or why not?
    B. What type of information would be needed to help inform your decision to join?

12. Do you have any other thoughts on how a precompetitive consortium could be successful?

Glossary of Key Terms

Artificial intelligence: the ability of computer systems to perform tasks that typically require human intelligence, including but not limited to speech recognition, translation, and decision-making.

Regulatory intelligence: the act of processing targeted information and data from multiple sources, analyzing them in relevant context and generating a meaningful output to the regulatory strategy. The process is driven by business needs and linked to decisions and actions.

Precompetitive consortium: a collaboration among different pharmaceutical companies and entities to work on the early stage of research and development, the results of which will benefit all members. For example, Innovative Medicines Initiative in the European Union which focusing on solving bottlenecks in drug discovery and development. Another example is TransCelerate in the US.

Appendix B: Interview Questions for Technology Companies

Artificial Intelligence

1. Can you describe your perspective on current AI technologies and their capabilities? Where is the technology headed in the next 5 to 10 years?

2. What hinders the progress of AI development and what are the most common issues encountered?

3. What types of activities or information are problematic for the application of AI? What approaches do developers take to tackle these problems and others such as data quality, data volume, incomplete data?

AI for Regulatory Intelligence

4. Currently, are there any heavily regulated sectors that have started developing and/or using AI technology that could be applied to the regulatory field?

5. From your knowledge, have there been any advances in AI technologies for the regulatory intelligence domain? If so, can you describe their status (currently under consideration, development started, etc.)?

6. What type of AI capability would offer the most promise or value for monitoring, analyzing, communicating multitude sources of information (internal and/or external)?

7. How long is the development timeline for an AI technology capable of facilitating regulatory intelligence activities (processing, analyzing, communicating large amounts of varied information)?

8. What challenges or barriers could you foresee in applying AI to the regulatory field?

9. How much do you estimate it would cost to develop this technology for the regulatory field (or, more generally, a new field)? In personnel (FTE)? In financial investment?

10. Which are the most common clients using your service?

Collaborating to Use AI

11. Would your company consider participating in a precompetitive consortium focused on developing AI technology for regulatory intelligence? Why or why not?

12. What information or features would ensure that your company participates in a precompetitive consortium?

13. What other stakeholders do you think should be included in such a venture?

Company-specific questions, if applicable

14. What other regulatory intelligence activities can be handled by artificial intelligence?

15. Can you describe the validation process for artificial intelligence technologies?

16. How do you get end-users to trust the technology?

17. What is the competitive landscape for AI technologies applied to regulatory intelligence?

18. How often does your technology give the wrong answer? How are these mistakes investigated?

19. What is the computing capacity necessary to facilitate optimize speed in regulatory intelligence activities?

Glossary of Key Terms

Artificial intelligence: the ability of computer systems to perform tasks that typically require human intelligence, including but not limited to speech recognition, translation, and decision-making.

Regulatory intelligence: the act of processing targeted information and data from multiple sources, analyzing them in relevant context and generating a meaningful output to the regulatory strategy. The process is driven by business needs and linked to decisions and actions.

Precompetitive consortium: a collaboration among different pharmaceutical companies and entities to work on the early stage of research and development, the results of which will benefit all members. For example, Innovative Medicines Initiative in the European Union which focusing on solving bottlenecks in drug discovery and development. Another example is TransCelerate in the US.

Appendix C: Follow-Up Survey for Pharmaceutical Companies

Thank you for your willingness to participate in our research.

STUDY LEADERSHIP. We are graduate students at Keck Graduate Institute (KGI) in Claremont, CA. We are asking you to participate in a research project for our Team Master's Project. This project is sponsored by Eli Lilly and Company. Professor Rajesh Parti, a KGI faculty member, is supervising this project.

PURPOSE. The purpose of this study is to research and explore the potential utilization of artificial intelligence and machine learning in the regulatory field. We will interview regulatory professionals of different pharmaceutical companies to identify the best path for the development of this technology. The output of this research will be anonymized and presented in an executive summary which will help articulate the potential of this technology in the regulatory space and promote the creation of a precompetitive consortium which may enable it.

ELIGIBILITY. To take part in this study, you must be over the age of 18.

PARTICIPATION. During the study, you will take a survey asking about your opinions regarding artificial intelligence and machine learning, and their applications in the regulatory intelligence field. This may include questions about your experiences at your company and within the regulatory or technology spaces. Completing this survey will take about 15 minutes.

RISKS OF PARTICIPATION. The risks you run by taking part in this study are minimal, and not higher than those faced in everyday life. The risk includes the possibility that you may be offended by some of the questions in the survey. You are free to skip any question that makes you uncomfortable, or stop and exit the survey at any time.

BENEFITS OF PARTICIPATION. Subsequent to your participation in this study, you will receive a comprehensive summary of the anonymized study results. Notably, excerpts of the study results may be shared in future industry settings, but will not be communicated in their entirety in these settings. This study will benefit our team by informing our research and contributing to our education, professional development, and Team Master's Project, which is a requirement for the completion of our degrees.

COMPENSATION. There is no compensation for your participation in this survey.

VOLUNTARY PARTICIPATION. Your participation in this study is completely voluntary. You may stop or withdraw from the study at any time, or refuse to answer any particular question for any reason without it being held against you. Your

decision whether or not to participate will have no effect on your current or future connection with anyone at KGI.

CONFIDENTIALITY. Any reports or publications will not identify individual participants by name or initials. A list of participating companies may be included in the output of this research but all responses will be deidentified. Any identifying information about participating individuals (or their companies) will be generalized and presented in aggregate form. Eli Lilly, the company sponsor of this project, will not have access to identifiable information about participants or their individual responses. If you have any questions regarding the research, or would like further information about your rights as a participant please contact Rajesh Parti of KGI at (909) 607-0209 or Rajesh_Parti@kgi.edu.

Clicking the "Yes" entry below means that you understand the information on this form, that any questions you may have about this study have been answered, and that you are eligible and voluntarily agree to participate.

- ○ Yes
- ○ No

Please enter the alphanumeric code provided to your company. This will be used to prevent duplicate surveys responses from your company. This will not be used to link your survey responses to your company.

Company

Tell us about your company

Information about participating companies will only be presented in aggregate form and will not be connected to individual responses.

What is the annual revenue of your company?

- ○ More than $50B USD
- ○ $40 - 50B USD
- ○ $30 - 40B USD
- ○ $20 - 30B USD
- ○ $10 - 20B USD

- ○ Less than $10B USD

What is the size of your company in number of employees worldwide?

- ○ More than 125,000 employees
- ○ 100,000 - 125,000 employees
- ○ 75,000 - 100,000 employees
- ○ 50,000 - 75,000 employees
- ○ 25,000 - 50,000 employees
- ○ Less than 25,000 employees

What is the size of your company in number of employees worldwide?

- ○ More than 125,000 employees
- ○ 100,000 - 125,000 employees
- ○ 75,000 - 100,000 employees
- ○ 50,000 - 75,000 employees
- ○ 25,000 - 50,000 employees
- ○ Less than 25,000 employees

What is the geographical reach of your company? **Select all that apply.**

- ☐ North America
- ☐ Europe
- ☐ Asia
- ☐ Australia
- ☐ Africa

RI and AI

Regulatory Intelligence and the Potential of AI

Regulatory intelligence is the act of processing targeted information and data from multiple sources, analyzing them in its relevant context and generating a meaningful output to the regulatory strategy. The process is driven by business needs and linked to decisions and actions.

Artificial intelligence is the ability of computer systems to perform tasks that typically require human intelligence, including but not limited to speech recognition, translation, and decision making.

What level of impact do you think regulatory intelligence has on the decision making processes for your product regulatory strategies?

- ○ Major impact
- ○ Moderate impact
- ○ Some impact
- ○ Low impact
- ○ No impact

How much does your company currently use artificial intelligence in the regulatory intelligence space in the following activities:

	Never	Very Rarely	Rarely	Occassionally	Very Frequently	Always
Collecting information (e.g., monitoring regulatory websites)	○	○	○	○	○	○
Analyzing information	○	○	○	○	○	○
Communicating information (e.g., generating a meaningful output to the regulatory strategy)	○	○	○	○	○	○
Other:	○	○	○	○	○	○

How much value do you foresee AI adding in the following regulatory intelligence activities:

	No Value	Low Value	Moderate Value	High Value
Collecting information (e.g., monitoring regulatory websites)	○	○	○	○
Analyzing information	○	○	○	○
Communicating information (e.g., generating a meaningful output to the regulatory strategy)	○	○	○	○
Other:	○	○	○	○

For the activities you see high potential for AI to add value, what type of target information would benefit you the most?

- ○ Competitor regulatory information
- ○ Regulatory information (guidances, laws)
- ○ Other:

How much would you trust AI at this point in time to inform your regulatory decisions or activities?

- ○ A great deal
- ○ A lot
- ○ A moderate amount
- ○ A little
- ○ Not at all

How quickly do you foresee your company integrating AI regulatory intelligence technologies into daily activities after they become available?

- [ ] Select response...
- [ ] Already implemented some AI approach
- [ ] 1 year
- [ ] 2 years
- [ ] 3 years
- [ ] 4 years
- [ ] 5 years
- [ ] 6 years
- [ ] 7 years
- [ ] 8 years
- [ ] 9 years
- [ ] 10 years
- [ ] More than 10 years

How long do you think it will take from now for AI to be used in regulatory intelligence routinely across pharmaceutical companies to inform decisions?

- [ ] Select response...
- [ ] 1 year
- [ ] 2 years
- [ ] 3 years
- [ ] 4 years
- [ ] 5 years
- [ ] More than 5 years

Collaborating

Collaborating to Use AI

A precompetitive consortium is a collaboration among different pharmaceutical companies and entities to work on the early stage of research and development, the results of which will benefit all members. For example, Innovative Medicines Initiative in the European Union which focusing on solving bottlenecks in drug discovery and development.

Would you consider participating in a precompetitive consortium focused on developing AI technology to facilitate regulatory activities?

- ○ Yes
- ○ No
- ○ Maybe

What level of financial investment do you believe necessary across industry to develop an initial AI system for RI?

- ○ More than $20M
- ○ $10 - 20M
- ○ $5 - 10M
- ○ $1 - 5M
- ○ None

What level of investment in terms of industry staff time do you believe it will take? How much time in full-time equivalent (FTE) would your company be willing to offer to develop this technology within your company based on a typical 40-hour work week?

- ○ More than 1 FTE
- ○ 0.75 FTE
- ○ 0.5 FTE
- ○ 0.25 FTE
- ○ Less than 0.25 FTE

Thank you for your participation in this survey! If you would like to review your answer before submission, please use the back button. Once you submit your responses, you will not be able to edit them.

Do you have any additional comments about this topic? (ideas, current gaps, barriers)

Appendix D: Informed Consent for Pharmaceutical Companies

KGI Informed Consent Form
PHONE INTERVIEWS

Thank you for your willingness to participate in our research.

STUDY LEADERSHIP. We are graduate students at the Keck Graduate Institute (KGI) in Claremont, CA. We are asking you to participate in a research project for our Team Master's Project, which will conclude May 2018. This project is sponsored by Eli Lilly and Company. Professor Rajesh Parti, a KGI faculty member, is supervising this project.

PURPOSE. The purpose of this study is to research and explore the potential utilization of artificial intelligence and machine learning in the regulatory field. We will interview regulatory professionals of different pharmaceutical companies to identify the best path for the development of this technology. The output of this research will be anonymized and presented in an executive summary which will help articulate the potential of this technology in the regulatory space and promote the creation of a precompetitive consortium which may enable it.

ELIGIBILITY. To take part in this study, you must be over the age of 18 years old.

PARTICIPATION. During the study, you will take a survey asking about your opinions regarding artificial intelligence and machine learning, and their applications in the regulatory intelligence field. This may include questions about your experiences at your company and within the regulatory or technology spaces and questions. Completing this interview will take about 30-45 minutes.

RISKS OF PARTICIPATION. The risks you run by taking part in this study are minimal, and not higher than those faced in everyday life. The risk includes the possibility that you may be offended by some of the questions in the survey. You are free to skip any question that makes you uncomfortable, or stop and exit the survey at any time.

BENEFITS OF PARTICIPATION. Subsequent to your participation in this study, you will receive a comprehensive summary of the anonymized study results. Notably, excerpts of the study results may be shared in future industry settings, but will not be communicated in their entirety in these settings. This study will benefit our team by informing our research and contributing to our education, professional development and Team Master's Project, which is a requirement for the completion of our degrees.

COMPENSATION. There is no compensation for your participation in this survey.

VOLUNTARY PARTICIPATION. Your participation in this study is completely voluntary. You may stop or withdraw from the study at any time, or refuse to answer any particular question for any reason without it being held against you. Your decision whether or not to participate will have no effect on your current or future connection with anyone at KGI.

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I, _____ certify that I have delivered the statement of informed consent to the participant, _____, and have answered any questions they have. Furthermore, I attest that the participant read the informed consent form before participating in research and that she/he appeared to both have knowledge of the research project and understanding of the informed consent form, and has given her/his consent to participate in this research project.

_____ _____

Signature of the Investigator Date

_____

Investigator Printed Name

Appendix E: Informed Consent for Technology Companies

KGI Informed Consent Form
PHONE INTERVIEWS

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PURPOSE. The purpose of this study is to research and explore the utilization of artificial intelligence and machine learning in the current technological environment and in new fields such as biopharmaceutical regulatory field. We are conducting interviews to research the current state of artificial intelligence as a tool to drive decision making. The output of this research will be anonymized and presented in an executive summary which will help articulate the potential of this technology in the regulatory space.

ELIGIBILITY. To take part in this study, you must be over the age of 18 years old.

PARTICIPATION. During the study, we will be asking questions about your opinions regarding artificial intelligence and machine learning, and the current state of their use as a tool for decision making. Completing this interview will take about 30-45 minutes.

RISKS OF PARTICIPATION. The risks you run by taking part in this study are minimal, and not higher than those faced in everyday life. The risk includes the possibility that you may be offended by some of the questions in the interview. You are free to skip any question that makes you uncomfortable, or stop and exit the interview at any time.

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_____ _____

Signature of the Investigator Date

_____

Investigator Printed Name