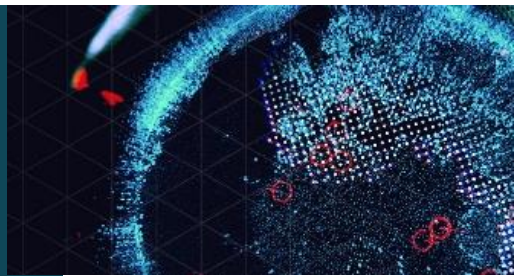
Coronavirus/COVID-19

Checklist for Technology Solutions



March 18, 2020

To assist companies that are developing technology solutions to help predict, mitigate or contain the spread of COVID-19, our cross-practice digital health team has put together a checklist of considerations to keep in mind. For additional guidance, please visit our COVID-19 Legal and Business Toolkit or reach out to us at COVID19@cov.com.

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1 Have you ensured that the technology complies with the applicable regulatory framework?

During a public health emergency like COVID-19, regulators like the U.S. FDA are particularly concerned about companies marketing or making available regulated products that claim to prevent, mitigate, treat, or cure COVID-19, where such products have not been evaluated by the regulatory agency or otherwise assessed for that intended use. To help ensure that your technology helps with the public health response, understand at the outset:

- ☐ What is the "intended use" of the technology and its regulatory positioning in the relevant jurisdiction(s)? For example, will the technology be a regulated medical device and, if so, in which territories?
- ☐ Are there functions that you could perform without triggering regulation as a medical device, if so, do those functions still provide value to the public health response?
- ☐ If the technology ordinarily requires a regulatory approval or pre-market assessment before it may be put onto the market, is there an expedited approval process or other exemption to the regulatory process during the pendency of a public health emergency and, if so, is the proposed technology eligible for such an expedited approval/exemption?
- ☐ If you are partnering or developing a solution on behalf of or in collaboration with someone else, who is responsible for obtaining/maintaining regulatory approval and for communicating with regulatory authorities?

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2 Will the claims about what the technology will do survive advertising review or regulatory scrutiny?

- ☐ How will the software be promoted, and to whom? There may be a different analysis for statements made to the general public compared with those made only to medical professionals.
- ☐ What functionality and/or efficacy will be advertised, and do you have a reasonable and transparent basis for making such claims?
- ☐ If you claim to have certain studies that support your claims, what do those studies show?
- ☐ Have you disclosed and vetted the sources of any external data?

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3 Have you taken steps to mitigate product liability risks through documentation, contract and processes? For example:

- ☐ Accuracy and understandability of information and recommendations
  - ○ Is the information you are providing accurate and understandable?
  - ○ Have you reviewed your user questions and recommendations for understandability?
- ☐ Appropriate warnings and disclaimers
  - ○ Have you included appropriate warnings and disclaimers (e.g., that the software is not a substitute for medical advice or treatment, as applicable)?
  - ○ Have you disclaimed warranties to the extent permissible?
- ☐ Terms of use
  - ○ Do you require users to review and affirmatively consent to the terms of use?
  - ○ Do your terms of use require acknowledgment of disclaimers/warnings and otherwise limit your liability?
- ☐ Monitoring, assessment, and improvement
  - ○ How will you become aware of potential problems with your technology and notify affected users?
  - ○ How are problems prioritized and fixed?

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4 Have privacy and data protection risks appropriately been managed?

- ☐ Will personal data be collected and used by the software? Many jurisdictions and data protection frameworks broadly define personal data to include, for example, device identifiers, coded information, and information linked to them.
- ☐ Will you be processing personal data on behalf of another entity and if so does that impose legal requirements on you?
- ☐ Have you ensured that data subjects are provided an appropriate privacy notice and transparency with respect to the processing of their personal data?
- ☐ Have you ensured that there is an adequate legal basis for the contemplated processing of personal data and that any applicable data subject consent or authorization requirements are satisfied? In some jurisdictions, there may be relevant exemptions or relaxation of consent standards where the processing is necessary for public health or specifically in relation to country or region-level responses to the COVID-19 outbreak.
- ☐ Have you put in place appropriate controls to restrict access to and use of personal information? Data protection regulators may be especially concerned about commercial exploitation of personal data obtained from individuals who were seeking assistance in relation to COVID-19.
- ☐ Do you have appropriate security safeguards in place to prevent unauthorized access to and processing of personal data?
- ☐ Have other data protection requirements been addressed? For example, if there will be international transfers of personal data, are those transfers compliant with applicable law, and have appropriate procedures, such as any required privacy impact assessments and data protection officer consultations, been followed.

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5 Does the technology make use of other data? If so:

- ☐ What are the data sources?
- ☐ If you are using publicly available databases, what are the terms associated with use/extraction of the data in those databases?
- ☐ If you are using third party proprietary databases, then have you got the rights to use the data in those databases for this purpose and what are the usage terms?

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6 Does the technology use machine learning or another form of AI? If so:

- ☐ What impact is the AI having on individuals and organizations?
- ☐ What steps are being taken to make the AI trustworthy (e.g., accurate, safe, free from unintended bias, explainable, secure, reliable and accountable)?

- ☐ How is the training data being procured?
- ☐ Does the commercial agreement appropriately address the AI?

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7 Are you collaborating with others to develop the technology? If you are:

- ☐ What assets, including intellectual property (IP), are you contributing to the collaboration?
- ☐ What assets, including IP, is/are the other party/ies contributing to the collaboration?
- ☐ On what terms are IP and other assets being made available?
- ☐ Who will have what rights in the outputs (for example, algorithms, data, software) of the collaboration?
- ☐ Will you make all outputs available to all to use, e.g., as open source or through publications?
- ☐ What is the governance model between the collaborating parties?
  - How are decisions to be made?

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8 How will the technology be exploited?

- ☐ What will be the exploitation channel for the technology?
  - Will you exploit the technology, or will it be deployed through a partner through public bodies or otherwise?
- ☐ Will the technology be branded, and if so, with what brand(s)?
  - If you are collaborating with others on it, who will own the brand?

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9 Is the technology being developed in response to a governmental "call to action"?

- ☐ If it is, are there any applicable conditions?
- ☐ Are there any government grants or procurement opportunities available (e.g., through public health agencies, or in the U.S., through FEMA)?
- ☐ Are there any government authorities that could be used to support design, production, or distribution of the technology?
- ☐ Are there any restrictions in place that would need to be waived in order to facilitate design, production, or distribution of the technology?

10 What is the insurance position?

- ☐ Have you assessed and quantified the potentially insurable risks that the new technology will create for your business, and checked they are covered by your current policies?
- ☐ If not, do you have all necessary information ready to secure additional insurance coverage?

11 Is the technology to be used in connection with employees and other staff? If so:

- ☐ If the technology will require the collection and use of personal data/PHI, have you considered the application of the points in Section 5 above in relation to staff?
- ☐ Will the intended use of the technology be mandatory or voluntary? If mandatory, for what purpose? Is this a reasonable and proportionate measure to achieve that purpose in the circumstances?
- ☐ What impact will the use of technology have on staff – e.g., could it result in any measures or decisions being taken in relation to them? Could there be a less favorable impact for certain staff who possess characteristics protected under discrimination law? If so, how could this be addressed/mitigated?
- ☐ How will the intended use of the technology be communicated to staff?
- ☐ If the use of technology would involve monitoring the behavior/activities/attributes of staff, have you considered applicable law and guidance relevant to staff monitoring?
- ☐ Have you checked contractual terms, policies, the staff handbook etc. to assess whether any provisions are relevant to the intended use of the technology?
- ☐ Under applicable law, does the use of the technology need to be the subject of prior informal consultation with staff, or formal consultation or even co-determination with appointed staff representatives, such as works councils and trade unions?

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If you have any questions regarding the development and deployment of technology products and services in connection with coronavirus/COVID-19, please contact any of the following members of our digital health team or your usual Covington contacts:

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