AAIH

01 June 2020

The Alliance for AI in Healthcare

Additional Considerations for Public Consultation on European Commission Whitepaper: "On Artificial Intelligence - A European approach to excellence and trust"

Dear Reviewer,

We represent the Alliance for Artificial Intelligence in Healthcare, an international coalition of technology developers, pharmaceutical companies, medical practitioners, and research organizations who pursue the common goal of realizing the potential for AI and machine learning in healthcare to significantly improve quality and delivery of care. By convening stakeholders to present a unified voice, we are working to establish responsible, ethical, and reasonable standards for the development and implementation of AI in healthcare. As an organization, the AAIH brings together industry, academia, research institutions, government and NGOs, key opinions leaders, and other international stakeholders to develop appropriate regulatory principles. By engaging with a wide array of participants across the healthcare spectrum, the AAIH works to actualize the promise of artificial intelligence in medicine, thereby improving patients' lives and creating more efficient, sustainable, and accessible healthcare systems.

We are pleased to have the opportunity to read and submit commentary on the European Commission Whitepaper on Artificial Intelligence. While the Whitepaper is a reasonably comprehensive document, during the course of our review we identified several topics, captured below, on which we would like to provide further comment. We appreciate your consideration of the additional commentary.

Additional Subjects for Consideration

1. Our organization applauds the focus on identification of key features that are particularly pertinent to the use and implementation of AI. In addition to types of requirements outlines, we would further emphasize the need for human oversight and intervention into an AI operation. We also would stress the use of a risk-based approach to determine the capacity, robustness, and limitations of such oversight and the definition and establishment of proportional interventions.

2. We applaud the EC for a focus on elevating the standards and expectations for data used in the training and validation of an AI system. We have concerns, however, about the universal roll out of these regulations for the healthcare industry, as there is a real threat that such regulations would be so stringent as to bar the use of any current data sets. For example, it is tremendously difficult to find a biomedical data set that is "…sufficiently broad and [that] cover[s] all relevant scenarios" and "data sets that are sufficiently representative, especially to ensure that all relevant dimensions of gender, ethnicity and other possible grounds of discrimination are appropriately reflected in those data sets" (p. 19). Data collection in healthcare is neither so robust nor so uniform as in other industries, and so this standard will be challenging to meet in the coming years despite a deep commitment to avoiding use of data that create dangerous situations or entrench discrimination.

   We propose that the EC consider alternate routes to enable continued product development while elevating the standards of development in the AI enabled healthcare sector. Some recommendations include:

   - Use of labeling requirements to warn users of the limitations of the data;
   - Facilitation of efforts by AI developers and data scientists to identify and overcome or counter biases that may be present in the data;
   - Use of post-market surveillance to track, identify, and correct biases unaccounted for in development;
   - Definition of a risk/benefit calculation to determine whether the risk of biases in the data is worth the social benefit;
   - A commitment to use of explainable AI when developing a product for commercial marketing, and a parallel embargo on the use of black box algorithms for sensitive applications where the risk of AI-gone-wrong is too great (ex. law enforcement, and insurance claims approvals).

3. We applaud the EC for its commitment to creation of regulatory standardization and the attempt to unify markets for AI products. We further encourage the EC to consider how restrictions, such as those proposed in 5.D, may operate as barriers to commercialization. Further, while creation of single data markets is appealing, the barrier to access and restrictions on use could hinder the biomedical and healthcare industry given the unique use cases and challenges in development of their products. Further, we encourage the EC to expand on its thinking about the role and availability of Real World Evidence as part of this data market, and how such RWE can be integrated into the commitment to increased data access and improved data quality.