BIOMEDICAL IMAGING FOR EQUITABLE DEEP LEARNING, REGULATORY SCIENCE, AND CLINICAL RESEARCH

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Tools, models and statistical methods for signal processing and medical image analysis and training deep learning models to create research prototypes for eventual clinical applications are of special interest to the ISBI biomedical imaging community. But material and optical properties of biological tissues are complex and not easily captured by imaging devices. Added complexity can be introduced by biased datasets with underrepresentation of medical images from races and ethnicities for deep learning, and limited knowledge about regulatory framework needed for commercialization and safety of emerging technologies using image analysis. This abstract describes major topics and opportunities for validating capture devices and medical images of skin (RGB), prostate tissues (digital pathology) and lungs and kidneys (gray scale) for clinical diagnosis. Strategies and methods for training of unbiased, high-performance locked and adaptive deep learning models with uncertainty quantifications. Special emphasis is made on the integration of unbiased imaging data and its positive impact by engendering fairness in deep learning model performance. Additionally, the U.S. Food and Drug Administration (FDA) is working to establish a regulatory framework for software-based medical devices powered by deep learning.

1. BIOMEDICAL IMAGING & CAPTURE FOR UNCERTAINTY-QUANTIFIED DEEP LEARNING

The visually distinct anatomical features (e.g, eye, skin and prostate) require tailored imaging devices and high-fidelity capture of diseased and healthy tissues and their structure at the micro-and-macroscopic level for training deep learning models for clinical assessments. The biological reasons for diverse appearance of humans, such as blood perfusion in skin and pigmentation, cellular structure and tissue anatomy of prostate, and the retinal vasculature in the eyes, etc. provide naturally occurring targets for ionizing and non-ionizing radiation, autofluorescence, and chemical dyes for imaging abnormalities. Recent advances in uncertainty-quantified deep learning architectures and statistical tools can be used for investigating the performance of the image-acquiring medical devices by estimating the pixel-level quality of acquired images prior to segmentation by deep learning models [1].

2. MEDICAL IMAGING FOR DIVERSITY, EQUITY AND INCLUSION

Many deep learning models are trained on datasets that do not contain a diverse range of images, in particular, they lack photos of dark skin and economically and socially marginalized individuals. The dearth of images and data for skin of color is a known problem in dermatology and can have a profound impact on the diagnostic reasoning of clinicians, health outcomes of patients, and biased deep learning models [2]. Expanding the clinical features of medical images to include balanced datasets with different races, ethnicities, and skin tones is a rapidly emerging field to train unbiased deep learning systems. Extrapolations for benchmarking algorithm performance on clinical images from socio-economic labels (income, zip codes, housing) can also be collected by medical imaging researchers for equitable deep learning.

3. REGULATORY PERSPECTIVE: REAL-WORLD PERFORMANCE OF DEEP LEARNING MODELS

The FDA is working to help ensure patients and their caregivers continue to have access to safe and effective products powered by deep learning. Challenges faced by medical devices for computer aided diagnostics and quantitative imaging that incorporate AI/ML technologies are being researched by the Office of Science and Engineering Laboratories (OSEL) within the FDA's Center for Devices and Radiological Health (CDRH). Collaborative efforts with patient groups, healthcare providers, academics, and industry have been launched to help determine thresholds and performance evaluations for the metrics most critical to the real-world performance (RWP) of AI/ML-enabled medical devices. The FDA's Software Precertification (Pre-Cert) Pilot Program and the AI/ML-based Software as a Medical Device (SaMD) Action Plan have suggested an outline for the development of a possible future regulatory model for regulatory oversight of software-based medical devices and their real-world performance [3].

4. REPORTING

The authors report no conflicts or disclosures, and are in compliance with all ethical standards.

5. REFERENCES

[1] S. Ghosal, and P. Shah "A deep-learning toolkit for visualization and interpretation of segmented medical images," *Cell Reports Methods*, vol. 1, no. 7, pp.100107, November, 2021.

[2] Lester, J. C., Jia, J. L., Zhang, L., Okoye, G. A., & Linos, E, "Absence of images of skin of color in publications of COVID-19 skin manifestations," The British journal of dermatology, vol. 183, no. 3, pp. 593–595, May 2020.

[3] U.S. Food and Drug Administration. "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan," https://www.fda.gov/media/145022/download, 2021.

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